

# **Pesticide residues in food – 2004**

FAO  
PLANT  
PRODUCTION  
AND PROTECTION  
PAPER

# **178**

# **REPORT 2004**



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PLANT  
PRODUCTION  
AND PROTECTION  
PAPER**

**178**

Report of the Joint Meeting of the FAO Panel of Experts on  
Pesticide Residues in Food and the Environment and the  
WHO Core Assessment Group on Pesticide Residues  
Rome, Italy, 20–29 September 2004

**WORLD HEALTH ORGANIZATION**

**and**

**FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS**

**Rome, 2004**

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## ABBREVIATIONS

(Well-known abbreviations in general use and SI units are not included.)

|                  |                                                                                                                                       |
|------------------|---------------------------------------------------------------------------------------------------------------------------------------|
| *                | at or about the limit of quantification                                                                                               |
| ADI              | acceptable daily intake                                                                                                               |
| ai               | active ingredient                                                                                                                     |
| AMPA             | ammonethylphosphonic acid                                                                                                             |
| ARfD             | acute reference dose                                                                                                                  |
| bw               | body weight                                                                                                                           |
| CCN              | Codex classification number (for compounds or commodities)                                                                            |
| CCPR             | Codex Committee on Pesticide Residues                                                                                                 |
| CSAF             | chemical-specific adjustment factor                                                                                                   |
| CXL              | Codex level                                                                                                                           |
| DT <sub>50</sub> | time to 50% decomposition                                                                                                             |
| DT <sub>90</sub> | time to 90% decomposition                                                                                                             |
| F <sub>1</sub>   | first filial generation                                                                                                               |
| F <sub>2</sub>   | second filial generation                                                                                                              |
| FAO              | Food and Agricultural Organization of the United Nations                                                                              |
| FOB              | functional observational battery                                                                                                      |
| GAP              | good agricultural practice                                                                                                            |
| GEMS/Food        | Global Environment Monitoring System–Food Contamination Monitoring and Assessment Programme                                           |
| GLP              | good laboratory practice                                                                                                              |
| HPLC             | high-performance liquid chromatography                                                                                                |
| HR               | highest level of residue in the edible portion of a commodity found in trials to estimate a maximum residue limit in the commodity    |
| HR-P             | highest residue in a processed commodity calculated by multiplying the HR of the raw commodity by the corresponding processing factor |
| IEDI             | international estimated daily intake                                                                                                  |
| IENTI            | international estimated short-term dietary intake                                                                                     |
| ILO              | International Labour Organisation                                                                                                     |
| IUPAC            | International Union of Pure and Applied Chemists                                                                                      |
| JECFA            | Joint Expert Committee on Food Additives                                                                                              |
| ISO              | International Standards Organization                                                                                                  |
| JMPR             | Joint Meeting on Pesticide Residues                                                                                                   |
| LC <sub>50</sub> | median lethal concentration                                                                                                           |
| LD <sub>50</sub> | median lethal dose                                                                                                                    |
| LOAEL            | lowest-observed-adverse-effect level                                                                                                  |
| LOQ              | limit of quantification                                                                                                               |
| MRL              | maximum residue limit                                                                                                                 |
| NOAEC            | no-observed-adverse-effect concentration                                                                                              |
| NOAEL            | no-observed-adverse-effect level                                                                                                      |
| OECD             | Organisation for Economic Co-operation and Development                                                                                |
| PHI              | post-harvest interval                                                                                                                 |
| Po               | the recommendation accommodates post-harvest treatment of the food commodity                                                          |
| PoP              | the recommendation accommodates post-harvest treatment of the primary food commodity                                                  |

|                 |                                                                                                                                                          |
|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|
| P <sub>ow</sub> | octanol–water partition coefficient                                                                                                                      |
| ppm             | parts per million                                                                                                                                        |
| RAC             | raw agricultural commodity                                                                                                                               |
| STMR            | supervised trials median residue                                                                                                                         |
| STMR-P          | supervised trials median residue in a processed commodity calculated by multiplying the STMR of the raw commodity by the corresponding processing factor |
| THPI            | 1,2,3,6-tetrahydrophthalimide                                                                                                                            |
| TMDI            | theoretical maximum daily intake                                                                                                                         |
| TRR             | total radiolabelled residue                                                                                                                              |
| UNEP            | United Nations Environment Programme                                                                                                                     |
| US              | United States of America                                                                                                                                 |
| W               | The previous recommendation is withdrawn.                                                                                                                |
| WHO             | World Health Organization                                                                                                                                |

### **Use of JMPR reports and evaluations by registration authorities**

Most of the summaries and evaluations contained in this report are based on unpublished proprietary data submitted for use by JMPR in making its assessments. A registration authority should not grant a registration on the basis of an evaluation unless it has first received authorization for such use from the owner of the data submitted for the JMPR review or has received the data on which the summaries are based, either from the owner of the data or from a second party that has obtained permission from the owner of the data for this purpose.

**PESTICIDE RESIDUES IN FOOD**  
**REPORT OF THE 2004 JOINT FAO/WHO MEETING OF EXPERTS**

**1. INTRODUCTION**

A Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group (JMPR) was held at FAO Headquarters, Rome (Italy), from 20 to 29 September 2004. The Panel Members of FAO and WHO met in preparatory sessions on 15–19 September.

The Meeting was opened by Dr Mahmoud Solh, Director, Plant Production and Protection Division, Department of Agriculture, FAO. On behalf of FAO and WHO, Dr Solh welcomed and thanked the participants for providing their expertise and for the significant time and effort put into this important activity. He noted that on the Meeting agenda there were a number of important issues for consideration, that would result in recommendations to the Codex Committee on Pesticide Residues (CCPR), as well as to Member States. He emphasized the importance of the JMPR and the commitment of FAO/WHO to its continuous support to this very important statutory body which gives scientific advice to FAO, WHO, their member countries and Codex.

Dr Solh noted that the CCPR had once again referred to the JMPR in order to speed up the establishment of maximum residue limits (MRLs) and to refine dietary intake as a result of a critical review by the JMPR, evaluation of the Codex process and the work of the OECD Working Group on Pesticides. He highlighted some of the important activities: the pilot project on work-sharing on the basis of national and regional evaluations; refinements of dietary risk assessment to approximate a more realistic situation at national and international levels; implementation of the recommendations on the York and zoning meetings to conserve resources; establishment of templates for estimating long- and short-term dietary intake; and development of a probabilistic approach to intake assessment.

The Meeting was held in pursuance of recommendations made by previous Meetings and accepted by the governing bodies of FAO and WHO that studies should be undertaken jointly by experts to evaluate possible hazards to humans arising from the occurrence of residues of pesticides in foods. The reports of previous Joint Meetings (see Annex 6) contain information on acceptable daily intakes (ADIs), acute reference doses (ARfDs), MRLs and the general principles that have been used for evaluating pesticides. The supporting documents (residue and toxicological evaluations) contain detailed monographs on these pesticides and include evaluations of analytical methods.

During the Meeting, the FAO Panel of Experts was responsible for reviewing residue and analytical aspects of the pesticides under consideration, including data on their metabolism, fate in the environment and use patterns, and for estimating the maximum levels of residues that might occur as a result of use of the pesticides according to good agricultural practice (GAP). Maximum residue levels and supervised trials median residue (STMR) values were estimated for commodities of animal origin. The WHO Core Assessment Group was responsible for reviewing toxicological and related data and for estimating ADIs and, if necessary, ARfDs, when possible.

The Meeting evaluated 31 pesticides, including two new compounds and 12 compounds that were re-evaluated within the periodic review programme of the CCPR, for toxicity or residues, or both.

The Meeting allocated ADIs and ARfDs, estimated MRLs and recommended them for use by the CCPR, and estimated STMR and highest residue levels as a basis for estimating dietary intake.

The Meeting devoted particular attention to estimating the dietary intakes (both short-term and long-term) of the pesticides reviewed in relation to their ADIs or ARfDs. In particular, for compounds undergoing a complete evaluation or re-evaluation, it distinguished between those for which the estimated intake is below the ADI and those for which the intake might exceed the ADI. Footnotes are used to indicate those pesticides for which the available information indicates that the ADI might be exceeded, and to denote specific commodities in which the available information indicates that the ARfD of the pesticide might be exceeded. A proposal to make this distinction and its rationale are described in detail in the reports of the 1997 JMPR (Annex 6, reference 80, section 2.3) and the 1999 JMPR (Annex 6,

reference 86, section 2.2). Additional considerations are described in the report of the 2000 JMPR (Annex 6, reference 89, sections 2.1–2.3).

## 2. GENERAL CONSIDERATIONS

### 2.1 Guidance on the establishment of acute reference doses

This item summarizes a document drafted by a Working Group of the JMPR WHO Core Assessment Group<sup>1</sup>, and the reader is referred to that document for a more detailed consideration of the issues outlined below. The document provides guidance on the issues to be considered when determining whether it is necessary to establish an acute reference dose (ARfD) on the basis of the hazard profile of a chemical as well on particular end-points that may be particularly relevant to acute effects. Note that it is intended that the detailed document be updated on a regular basis as further experience in establishing ARfDs is gained.

#### *Introduction*

In 1998, the JMPR WHO Core Assessment Group published brief guidance on procedures for setting ARfDs<sup>1</sup>. At its meeting in 2001, the JMPR established an international Working Group to compile a table of all available ARfDs and to collate information from different national agencies about their approaches to setting ARfDs. On the basis of an analysis of this inventory and a comparison of the technical policy approaches to setting ARfDs in different countries, further guidance was drafted by the Working Group and published by the 2002 JMPR<sup>2</sup>. At the request of the 2003 JMPR, the Working Group elaborated further guidance, including: (1) detailed advice on interpretation of certain toxicological end-points (haematotoxicity, immunotoxicity, neurotoxicity, kidney toxicity, liver effects, endocrine effects and developmental toxicity) that might be particularly relevant to acute exposure to pesticides; and (2) recommendations about the design and conduct of a suitable single-dose study that might be useful in identifying a more appropriate no-observed-adverse-effect level (NOAEL) for an acute end-point. This guidance is summarized below.

In 2002, the JMPR recognized that databases on consumption are available for daily intakes but that this information generally cannot be further divided into individual meals. Thus, the original definition of the ARfD was reworded from ‘over a short period of time, usually during one meal or one day’ to ‘the amount that can be ingested in a period of 24 h or less’ (see definition below).

The necessity for setting an ARfD should be considered for other chemicals to which the population may be exposed, such as non-agricultural pesticides, veterinary compounds and contaminants. If it is considered that an ARfD is necessary for such a compound, the guidance provided in this and the more detailed document should be of value. It is hoped that a harmonized approach will be followed in establishing acute health values for these other types of compounds.

#### *Analysis of the inventory of ARfDs set by different agencies (1995–2002)*

An analysis of the ARfDs set for pesticides by several regulatory agencies between 1995 and 2002 was summarized in a working paper used by the Working Group in developing the guidance document published by the 2002 JMPR. The purpose of this inventory was to identify any obvious differences in the derivation of toxicology threshold values, to identify different approaches to the selection of safety or uncertainty factors, and to give more detailed guidance on harmonization of acute risk assessments. This analysis indicated significant variations in decisions about the need to set an ARfD for a particular chemical, in the selected NOAELs and in safety factors, and hence ARfDs, for the same pesticide among different agencies. Most agencies have based some ARfDs on studies in humans, particularly for inhibitors of

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<sup>1</sup> Annex 6, reference 83

<sup>2</sup> Annex 6, reference 95

acetylcholinesterase activity<sup>3</sup>. The database also indicated that the practice employed by the Meeting, of using safety factors of less than 100 (or 10) for carbamate insecticides, had not been followed by any other agency in 1995–2002. It was apparent from the analysis of the database that the current data package of toxicological studies generated for the active ingredients of pesticides is poorly suited to the establishment of ARfDs.

### ***Acute dietary risk assessment***

At the international level, only limited data on acute consumption are available. Adults and children aged 1–6 years are the only population groups for which acute dietary intakes can be estimated. Therefore, during the Meeting, the models for calculating acute dietary intake of pesticide residues were based on these two populations. Since it is generally not possible to model separately the intake of women of childbearing age, the establishment of separate ARfDs is not particularly useful. Therefore, the ARfD used for modelling the dietary intake of the general population should protect this subgroup adequately.

Except for those chemicals that would be very unlikely to leave residues in foodstuffs, it was concluded that the trigger for performing an acute dietary intake assessment should be toxicity concern.

If it is considered unnecessary to establish an ARfD, it can be concluded that short-term intake is unlikely to present a public health concern. Therefore, it is not necessary to estimate the short-term intake of such substances.

### ***General guidance on the derivation of ARfDs***

Most of the scientific concepts applying to the establishment of acceptable dietary intakes (ADIs) apply equally to the establishment of ARfDs. This section is mainly based on the recommendations of the 2002 JMPR but expands on that guidance in a number of areas. The following key issues are highlighted:

#### ***Definition of the ARfD***

The following definition of the ARfD was adopted by the 2002 JMPR: “The ARfD of a chemical is an estimate of the amount of a substance in food and/or drinking-water, normally expressed on a body-weight basis, that can be ingested in a period of 24 h or less, without appreciable health risk to the consumer, on the basis of all the known facts at the time of the evaluation”.

#### ***General considerations in setting an ARfD***

The establishment of an ARfD should be considered for all pesticides whose uses may lead to residues in food and drinking-water. The suggested numerical cut-off for setting ARfDs for pesticides was about 5 mg/kg bw; i.e. if calculations indicated that an ARfD would be greater than this value, then it would not be necessary on practical grounds to set an ARfD, as residue levels necessary to achieve this intake would be highly unlikely to occur in practice.

#### ***Biological and toxicological considerations***

The appropriateness or otherwise of using doses and end-points from short- and long-term studies to establish ARfDs, needs to be carefully considered. The pertinent biology of the system affected should be considered in order to determine whether an acute exposure might compromise the ability of the organ to compensate and maintain homeostasis. Particular weight should be given to observations and investigations at the beginning of studies of repeated doses. Isolated findings showing no specificity or clear pattern are not necessarily indications of toxicity. In the absence of information to the contrary, all toxic effects seen in repeat-dose studies should be evaluated for their relevance in establishing an ARfD. In studies on compounds showing acute toxicity after repeated doses, the adequacy of investigations (including the duration of the

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<sup>3</sup> Until 2002, the United States Environmental Protection Agency had based only one value in their database on a study in humans, but there has been a policy change since that date.



follow-up of the animals to see if there are any delayed effects) must be shown to be adequate before it can be concluded that the compound does not have any acute toxic potential. The NOAEL from the most sensitive species should be used, unless there is evidence to demonstrate it is not appropriate for a human risk assessment.

#### *Stepwise process in setting an ARfD*

The first step is to consider whether, on the basis of the acute toxicity profile and potency of effects, an acute health value is really necessary. The following process for setting ARfDs is suggested:

1. Evaluate the total database on the substance and establish a toxicological profile for the active substance.
2. Consider the principles for not setting an ARfD:
  - No findings indicative of effects elicited by an acute exposure are seen at doses up to about 500 mg/kg bw per day; and/or
  - No substance-related mortalities are observed at doses of up to 1000 mg/kg bw in single-dose studies after oral administration.
  - If mortality is the only trigger, the cause of death should be confirmed as being relevant to human exposures.
  - If the above criteria do not exclude the setting of an ARfD, then further consideration should be given to setting a value, using the most appropriate end-point.
3. Select appropriate end-points for setting an ARfD
  - Select the toxicological end-points that are most relevant for a single (day) exposure.
  - Select the most relevant or adequate study in which these end-points have been adequately determined.
  - Identify the NOAELs for these end-points.
  - Select the most relevant end-point providing the lowest NOAEL.
  - Use an end-point from a repeat-dose study of toxicity if the critical effect of the compound has not been adequately evaluated in a single-dose study. This is likely to be a more conservative approach and should be stated. This does not mean that a safety factor other than the default value should be applied. A refinement of such a NOAEL (e.g. in a special single-dose study) may be necessary, if the acute intake estimation exceeds such a conservatively-established ARfD.
  - If after consideration of all the end-points, an ARfD is not set, justify and explain the reasons.
4. Select appropriate safety factors for setting an ARfD.

Derive the ARfD using an appropriate safety factor(s).

#### *Safety factors*

The process of deriving ARfDs involves the determination of the most appropriate NOAEL and a safety factor (also called an uncertainty or assessment factor). These factors are used to extrapolate from data in animals to the average human and to allow for interindividual variation within the human population.

In determining the appropriate safety factor, a stepwise approach is proposed:

- Determine whether the database is adequate to support the derivation of a chemical-specific adjustment factor (CSAF)<sup>4</sup>.
- If a specific factor cannot be derived, consider if there is any information to indicate reduced or increased uncertainty. If not, the 100-fold (or 10-fold) default should be used.

Whenever a safety factor other than a default is used, a clear explanation of the derivation of the factor must be provided.

#### *Different ARfDs for different population subgroups*

It is preferable to set a single ARfD to cover the whole population. It is important to ensure that any ARfDs established are adequate to protect the embryo and fetus from possible effects in utero. While an ARfD based on developmental effects (on the embryo or fetus) would necessarily apply to women of childbearing age, it is recognized that such an ARfD may be conservative and not relevant to other population subgroups. This is the case for children aged 1–6 years, for whom specific data on acute consumption are available (and thus can be modelled separately with respect to acute dietary intake of residues); the use of such a conservative ARfD for children who generally have a higher intake of food commodities per unit body weight compared with adults could lead to an unreasonably conservative acute dietary risk assessment. Thus, in those situations in which a developmental end-point drives a very conservative ARfD, it may be necessary to set a second value based on another non-developmental end-point.

Alternatively, if the prenatal developmental end-point is the only acute effect of concern, there may be no need to perform an acute dietary intake risk assessment for children. The single ARfD based on a developmental end-point (in the embryo or fetus) would only be used to model the acute dietary intake of the adult population, which includes women of childbearing age.

#### *Use of human data*

Human data from accidental or deliberate poisonings, biomarker monitoring studies, epidemiology studies, volunteer studies, and clinical trials on the same or structurally similar compounds can provide useful data to help establish ARfDs. The use of data from human volunteers in chemical risk assessment is a controversial issue, with a range of views held by different countries and individuals. However, it is recognized that the use of such data can reduce the level of uncertainty inherent in extrapolating from animal models. There needs to be adequate consideration of both scientific and ethical issues. The JMPR has considered human data at many of its meetings. The 2002 JMPR reaffirmed the principle that end-points from studies in human volunteers could be used to set intake standards if they had been conducted in accordance with relevant ethical guidelines. The study should be assessed for the quality and integrity of the data and the adequacy of the documentation of methods (including statistics and control values) and results. A poorly designed or conducted study in humans should not be used for risk assessment. Additionally, because the designs of studies in humans have some limitations in comparison with those in experimental animals, their use should always be considered in the context of the overall toxicological database.

ARfDs based on studies in humans should provide a sufficient margin of safety for toxicological end-points that cannot readily be addressed by such studies (e.g. developmental toxicity).

#### *When an initial estimate of the ARfD is less than the established ADI*

If an ARfD derived using the principles outlined in this guidance document has a numerical value that is lower than the existing ADI, then the ADI should be reconsidered.

### ***Specific guidance on the derivation of ARfDs***

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<sup>4</sup> Draft guidance document for the use of chemical-specific adjustment factors (CSAFs) for interspecies differences and human variability in dose/concentration–response assessment. WHO/UNEP/ILO International Programme on Chemical Safety, July 2001 (WHO/PCS01.4) (<http://www.who.int/ipcs/methods/harmonization/areas/uncertainty/en/print.html>, accessed 15 October 2004)

Particular toxicology end-points that are relevant to the establishment of ARfDs are considered below. Note that this summary is not intended to comprehensively cover all potentially relevant end-points, but focuses on the interpretation of those that have proved to be problematic in reaching a decision as to whether an effect is relevant to an acute exposure.

#### *Haematotoxicity*

The induction of methaemoglobinaemia is considered to be a critical effect in acute responses to chemical exposure. For acute exposure to methaemoglobin-inducing xenobiotics, a level of 4% methaemoglobin (or higher) above the background level in dogs, or a statistically significant increase relative to the background level in rodents is considered to be relevant in setting an ARfD. Haemolytic anaemias induced by mechanical damage, immune mediated anaemia, oxidative injury to erythrocytes and non-oxidative damage are considered to be less relevant for the derivation of ARfDs since the severity of such effects appears generally to depend on prolonged exposure. If changes in haematological parameters are observed early in a repeat-dose study and do not appear to progress during the course of the study, then such effects can be considered to relate to acute exposure to the substance. In assessing whether effects observed in repeat-dose studies should be used for setting an ARfD, the mechanism of action must be evaluated. If known, this could provide arguments for selecting, or not selecting, the end-point for setting an ARfD.

#### *Immunotoxicity*

Data on immunotoxicity derived from short-term studies are not likely to be appropriate for setting a reference dose for limits on acute exposure. It is unlikely that an acute exposure will produce persistent effects on immune function because the cells of the immune system are constantly replaced and because of the inherent redundancy in the system (e.g. alternative mechanisms exist to resist infection).

#### *Neurotoxicity*

The nervous system has a limited capacity for repair and regeneration. Therefore, any neurotoxicity seen in repeat-dose studies could be the result of a single exposure and may not be repairable, i.e. any evidence of neurotoxicity should be considered relevant to an ARfD assessment, unless it can be demonstrated that the effects are produced only after repeated exposures. In addition to long-term or irreversible effects associated with acute exposure, attention should be paid to transient effects, as these could be considered to be adverse under some circumstances.

Delayed neurotoxicity after single chemical exposures can occur, and thus any acute exposure study should have an adequate period of investigation.

In functional observation batteries (FOBs), a large amount of data is produced; interpretation of such studies should include a consideration not only of the statistical significance of results, but also of the nature, severity, persistence, dose–response relationship and pattern of the effects. Isolated findings showing no specificity or clear pattern do not necessarily indicate neurotoxicity.

The most common neurotoxic end-point used to date in the derivation of ARfDs for pesticides is inhibition of acetylcholinesterase activity. The Meeting has previously defined criteria for the assessment of cholinesterase inhibition<sup>5</sup>; these apply equally to the setting of ADIs and ARfDs. For inhibition of acetylcholinesterase activity, a specific cut-off (20%) is used routinely to differentiate between adverse and non-adverse effects.

#### *Effects on the kidney and liver*

If effects on these organs cannot be discounted as being either adaptive or the result of prolonged exposure, an ARfD can be derived on the basis of these effects. Such an ARfD is likely to be conservative and it may be possible to subsequently refine it using the results of an appropriately designed single-dose study. When interpreting data on liver and kidney toxicity in repeat-dose studies, one has to consider two important

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<sup>5</sup> Annex 6, reference 83

aspects; firstly, the type of effect observed and secondly, any information on correlations between exposure duration and effect.

For liver toxicity, it is considered that findings of increased serum cholesterol, cirrhosis, induced activity of metabolizing enzymes, regenerative hyperplasia, hepatocyte hypertrophy, fibrosis, or sclerosis in repeat-dose studies are, in isolation, either adaptive or the result of prolonged exposure and are therefore not applicable for deriving an ARfD.

For kidney toxicity, it is considered that the following findings of toxicity targeted to the kidney in repeat-dose studies are, in isolation, the result of prolonged exposure and are not applicable for deriving an ARfD: increased organ weight; regenerative hyperplasia; altered serum calcium and phosphate concentrations.

All other findings of liver and kidney toxicity should be considered to be potentially relevant to the derivation of an ARfD.

#### *Endocrine effects*

In general, effects on the endocrine system, other than those affecting female reproduction, are considered to be unlikely to arise as a consequence of acute exposure. However, because the process of evaluating endocrine toxicity and mechanisms is an evolving one, the guidance on endocrine disruptor chemicals is considered to be interim.

#### *Developmental effects*

Any treatment-related adverse effect on fetuses or offspring that has resulted from exposure during any phase of development should be considered to be potentially appropriate to use in acute dietary risk assessment, despite the fact that the period of treatment typically consists of repeated dosing. ARfDs based on reductions in fetal body-weight gain may be conservative and should be evaluated in the context of all pertinent data, including other developmental effects. Consideration should be given to the degree of maternal toxicity when considering whether fetal effects may be occurring as a direct effect of the chemical; the presence of severe maternal toxicity means that a direct effect is less likely.

#### ***Single-dose study protocol***

ARfDs established using existing databases of repeat-dose studies may be overly conservative and it may be possible to refine the ARfD by conducting an appropriately-designed single-dose study. The protocol for a proposed single-dose study of toxicity is outlined in the detailed document. Unlike a classical median lethal dose (LD<sub>50</sub>) study, this protocol is not intended to investigate mortality and significant morbidity. On the contrary, it is aimed at investigating a range of more subtle end-points which may arise after a single exposure, or during 1 day of dietary exposure to a test substance. In particular, it is tailored to see whether toxic effects observed in the standard package of repeat-dose studies may occur after single doses, and if so, at what level of exposure.

It is important to note that a specific study designed to enable an accurate ARfD to be set should only be undertaken after the toxicology profile of an active substance has been reasonably well documented and understood, and it is apparent that the available database is not adequate to allow the establishment of a reasonable ARfD. Furthermore, it is not intended that this test guideline should become a routine data requirement. It can, however, be utilized for those chemicals with limited databases that do not allow a clear determination of an appropriate reference dose.

The draft test protocol for the single oral dose study of toxicity will be submitted to the Organization for Economic Co-operation and Development (OECD) Working Group of National Co-ordinators to the Test Guidelines Programme. If it is considered appropriate to incorporate into the OECD test guidelines, it will be useful in directing the conduct of studies directly relevant to the establishment of ARfDs for those chemicals which, because of their use pattern, have the potential to lead to residues in food and drinking-water.

### ***Future considerations***

It is intended that the detailed document drafted by the Working Group of the JMPR WHO Core Assessment Group be updated on a regular basis as further experience in establishing ARfDs is gained. For example, further more detailed guidance on specific end-points (e.g. emesis and diarrhoea in dogs) will be added as these issues are researched and assessed.

The introduction of a specific test protocol for a single-dose study of oral toxicity will aid the process of establishing ARfDs. Once introduced, the utility of such a test guideline will be evaluated by the Meeting. The detailed guidance document will be available from the JMPR Secretariat.

### **2.2 Definition of ‘overall NOAEL’**

During the toxicological evaluation of a compound, the Meeting often has available more than one study in which the same end-points have been addressed. In such situations, the dose spacing may be different, resulting in different NOAELs and lowest-observed-adverse-effect levels (LOAELs). The Meeting agreed that in such circumstances it might be appropriate to consider the studies together. When they are comparable, including consideration of study design, end-points addressed, and strain of animal, the ‘overall NOAEL’ should be the highest value identified in the available studies that provides a reasonable margin ( $\geq 2$ ) over the lowest LOAEL, provided that due consideration is given to the shape of the dose–response curve.

### **2.3 Interim acute reference dose**

The WHO Core Assessment Group is occasionally asked by the FAO Panel of Experts to establish an ARfD for compounds that were not scheduled for toxicological evaluation. In such cases, the ARfD is based on data available from previous evaluations and is used to perform an acute dietary risk assessment. The Meeting decided to call these values ‘interim ARfDs’ (in order to distinguish them from the ARfDs established for compounds that were scheduled for toxicological evaluation) and to publish the derivation of the interim ARfDs under general considerations. These interim ARfDs can be used in dietary risk assessments until they are replaced by a full evaluation, if this is considered necessary.

### ***Setting an ARfD for propineb***

At the present Meeting, the FAO Panel of Experts asked the WHO Core Assessment Group if an ARfD for propineb could be established on the basis of the data available to the 1993 JMPR. Propineb is metabolized to propylenethiourea, which forms part of the residue, and then to carbon disulfide. Propineb is of low acute toxicity (oral LD<sub>50</sub>s in rats and mice are about 5 g/kg bw). The main effects of propineb are on the thyroid and on the nervous system.

The effects of propineb on the thyroid are mediated by propylenethiourea, which is similar to ethylenethiourea; these compounds block the accumulation of iodine by the thyroid gland. The 1993 JMPR took the view that those thyroid changes that were thought to be reversible, e.g. those observed in a study in rat could be considered adaptive. Furthermore, this effect is not appropriate for establishing an ARfD because of the buffering of thyroid hormone levels by homeostatic mechanisms. The existing ADI established by the JMPR (0–0.007 mg/kg bw per day) is based on the NOAEL (10 ppm, equal to 0.74 mg/kg bw per day) for decreased thyroxin and changes in thyroid weights in a short-term study of thyroid function in rats, with a 100-fold safety factor.

*Propylenethiourea:* The limited database on propylenethiourea was reviewed by the Meeting in 1993 when a temporary ADI of 0–0.0002 mg/kg bw was established. At this Meeting in 1993, no information was available on the metabolism of propylenethiourea. The temporary ADI was based on the LOAEL for liver tumours in a 2-year study in mice, with the application of a 1000-fold safety factor because of the inadequate database. The lowest dose in that study was considered to be a marginal effect level.

*Carbon disulfide:* Exposure to carbon disulfide is associated with cardiovascular disease, and carbon disulfide is also neurotoxic, producing demyelination, cerebellar atrophy and peripheral nerve abnormalities. Some or all of these effects are secondary to angiopathy. The effects on long axons might be caused by protein cross-linking. There is evidence from the clinical toxicology literature that carbon disulfide produces effects in humans after single, high-level exposures

*Critical NOAELs for propineb:* The neurotoxicity observed after repeated doses of propineb is considered to be potentially relevant to the establishment of an ARfD. The lowest NOAEL for neurotoxicity was identified in the multigeneration study in rats; the NOAEL in this study was 60 ppm, equivalent to 3 mg/kg bw per day on the basis of hind limb paralysis, and the LOAEL was 200 ppm, equivalent to 10 mg/kg bw per day. In the study of developmental toxicity in rats, the NOAEL for maternal toxicity was 10 mg/kg bw per day. Mild central neurotoxic effects were seen at 30 mg/kg bw per day in the dams. At the highest dose (100 mg/kg bw day), more serious central neurotoxicity was observed in the dams. Because of the shorter duration of dosing, the study of developmental toxicity in rats was considered to be more appropriate for the establishment of an ARfD than the multigeneration study in rats. Therefore the Meeting established an ARfD of 0.1 mg/kg bw, based on the NOAEL of 10 mg/kg bw per day from the study of developmental toxicity in rats, with a safety factor of 100. This should be considered to be an interim ARfD, until a full evaluation of the toxicological database has been conducted. Furthermore, this ARfD is probably conservative and could be refined using the results of an appropriate single-dose study.

## **2.4 Progress report on the JMPR work-sharing pilot project on trifloxystrobin**

A FAO/WHO/OECD pilot project on work-sharing was conducted to test whether national and regional evaluations of pesticide residues and toxicology could be used as a basis for JMPR evaluations. The 2003 CCPR selected trifloxystrobin as the first compound for the project because it had been evaluated in Australia, Canada and the USA and by the European Commission and was scheduled for evaluation by the JMPR in 2004. Unfortunately, a Japanese evaluation was not available for the pilot project. Original data were also provided by the manufacturer.

The objective of work-sharing is to facilitate and expedite reviews by using national and regional evaluations, while maintaining independence and incorporating global perspectives. The pilot project was intended to promote, facilitate and formalize this practice, although it was not expected to save cost or time. Those would be the main goals in the future, with greater efficiency and more transparent evaluations.

Differences in the global applicability of evaluations of toxicological and residue data were noted: Studies on residues are often specific to particular registered uses, which differ from one country to another, while toxicological studies are generally globally relevant.

The data on the toxicology and residues of trifloxystrobin were evaluated by the 2004 JMPR, and experiences in work-sharing were assessed.

### ***Experience in work-sharing on toxicological evaluations***

The Australian monograph served as the ‘master’ evaluation and thus as the main basis for the JMPR monograph, because a preliminary review indicated that it was closest to the JMPR format. The sections on toxicokinetics, human data and metabolites were derived from the European Commission monograph, which was prepared by the United Kingdom.

In the first step, it was found that the manufacturer had submitted the same key toxicological studies on trifloxystrobin to all four agencies and to JMPR. In general, the national and regional reports described the methods and results of the studies in a reasonable level of detail.

The formats of the monographs and the amount of detail given in the study reviews differed substantially. The differences in the formats of the national evaluations made comparisons difficult, obviating

importation of tables into the JMPR monograph. Tables in which the toxicological data from individual studies were summarized and the statistical analyses that supported the conclusions varied significantly in layout and detail, creating a great deal of work for the WHO temporary advisor.

In the next step, the study descriptions and selection of end-points in the Australian monograph were compared with those in the Canadian, US and European Commission monographs. This comparison revealed both similarities and differences in interpretations. When differences were found, JMPR experts made an independent evaluation of the original data and presented it to the JMPR. In only a few instances was it necessary to review the original data.

The process facilitated preparation of a transparent JMPR monograph, as the WHO evaluator could judge the results independently, usually without having to refer to the original studies. The evaluator could thus concentrate on areas of disagreement, helping to focus the JMPR deliberations. The evaluator also benefitted from others' insights into the significance of the effects seen in a study.

As trifloxystrobin represents relatively little hazard and has minimal toxicity, the national evaluations tended to differ on interpretation of the adversity of minor effects, such as changes in body weight and increases in liver weight.

The evaluations agreed reasonably well with regard to the selection and evaluation of key studies. Three studies with similar NOAELs were selected as pivotal for setting three ADI values, ranging from 0.038 to 0.1 mg/kg bw. Derivation of an ARfD was considered unnecessary in all the evaluations except for that of the US Environmental Protection Agency, which has a common practice of setting a separate ARfD for women of child-bearing age.

### ***Experience in work-sharing on residue evaluations***

The generic studies for residue reviews are: pesticide identity, physical and chemical properties, metabolism, environmental fate in soil and water–sediment systems, analytical methods, freezer storage stability, and fate of residues in processing and in feeding to farm animals. National and regional summaries and assessments of data on these subjects were taken into account. Supervised trials, which constitute the major part of a residue evaluation, were not included in this pilot project.

No one national or regional monograph could be used as the 'master' because of differences in the studies on trifloxystrobin. Furthermore, the studies in the dossier provided to JMPR were not all the same as those assessed at national and regional levels. The set of studies provided to the four national and regional authorities and to JMPR was identical only for metabolism in farm animals.

In the first step, a JMPR evaluation and an appraisal were prepared on the basis of the original studies provided by the company. In the second step, the evaluations of the studies in the national and regional reviews were compared with each other and with the JMPR evaluation. A 129-page report on the comparisons was prepared, which will be available on the FAO website.

The assessments of trifloxystrobin submitted by Australia and the European Commission were prepared in monograph format. In this format, excerpts from the applicant's dossier can be used (e.g. tables, metabolism schemes, some text), although the monograph does not include the applicant's proposals or recommendations. Independent, complete, final evaluations of a compound are made without considering registration purposes.

The assessments of trifloxystrobin submitted by Canada and the USA were presented in review format. In this approach, the scientific results are summarized and then the applicant's dossier is subjected to a critical review which includes discussions of the applicant's proposals and recommendations with regard to registration of specific plant protection products.

The trifloxystrobin example showed some similarities and some differences in the procedures and approaches used by national and regional agencies for evaluating residues. These resulted in some divergence

on conclusions, such as those for residue definitions and processing factors. As JMPR considers the worldwide use of pesticides when recommending MRLs for food commodities in international trade, its approach is not necessarily the same as those of national and regional organizations, which operate within registration systems.

### ***Conclusions and recommendations***

#### *Issues relevant for both toxicological and residue evaluations*

- The availability of several national and regional evaluations was useful for both the WHO and the FAO evaluators, despite the problems encountered. FAO, WHO and OECD should thus consider means to facilitate the provision of national or regional evaluations to JMPR evaluators.
- Consideration of multiple national and regional evaluations should aid progress towards international harmonization of dossiers and evaluations.
- The evaluation process, including standardization of formats and guidelines, should be harmonized further internationally. Good progress has been attained in the toxicological evaluations, while more work is necessary to improve work-sharing for residue evaluations.
- A further JMPR pilot work-sharing project should have more flexible procedures, which should be reviewed when the formats and evaluation procedures have been harmonized in guidance documents.

#### *Issues more closely relevant to toxicological evaluations*

- The national and regional evaluations differed considerably in their level of detail in describing toxicological studies, and more guidance and harmonization in this area could improve work-sharing.
- More guidance is needed on the interpretation of specific toxicological data, such as on changes in body and organ weights, and on interpretation of effects on the liver as adaptive or adverse.
- The key advantage of considering multiple national and regional evaluations in the JMPR process is the rapid identification of agreements and disagreements in data interpretation, thus focusing resources on areas of disagreement.

#### *Issues more closely relevant to residue evaluations*

- The project requires further work, incorporating changes based on the experience with trifloxystrobin, before work-sharing, with its anticipated benefits, can be implemented routinely. The experience with trifloxystrobin indicates that JMPR cannot comprehensively accept national or regional conclusions or recommendations for the residue topics included in the pilot project.
- Further progress in international work-sharing could be made by separating the summaries of key data from the conclusions in the submitted studies in the national or regional evaluations for risk assessment and management. This could facilitate mutual exchange and acceptance of study summaries.
- Work-sharing should focus on mutual use of summaries of data validated at national, regional and international level, covering all aspects of the residue evaluation, including data from supervised trials. This would allow exchange of a valid database, thus saving time and potentially reducing the workload.
- Specific assessment results, such as the definition of residue, could be used on a case-by-case basis.
- The current workload of the JMPR precludes additional work by FAO Panel Members on this project, as it would be at the expense of normal residue evaluation commitments, which are regarded by Panel Members as the priority.



## 2.5 Comparison of JMPR recommendations and interim MRL recommendations from the CCPR pilot project

The 2004 CCPR agreed on the main steps of the procedure for establishing interim maximum residue limits (MRLs)<sup>6</sup>. These included a request to JMPR to compare its recommendations with the suggested interim MRLs for trifloxystrobin and fludioxonil and to comment on discrepancies, for the purposes of the pilot project; this would not be considered part of any normal procedure that might eventually evolve. The US Delegation to the CCPR, as Chair of the Pilot Project Working Group, provided FAO with detailed information on the chemicals nominated for interim MRLs. These included summaries of the proposed interim MRLs for fludioxonil and trifloxystrobin, as well as information on toxicology, residue chemistry and dietary risk assessment.

The table shows the proposed interim MRL and the corresponding JMPR recommended MRLs.

| Commodity, CCN                                                                                                                                                                                                                                                                                                                                                             | Interim MRL recommendation (mg/kg) | JMPR MRL recommendation (mg/kg)          | Comment on difference                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <i>Trifloxystrobin</i><br>Interim definition: Plant and animal, trifloxystrobin + CGA321113 or (E,E)-methoxyimino{2-[1-(3-trifluoromethylphenyl)-ethylideneaminoxymethyl]phenyl}acetic acid<br>JMPR definition: Plant, trifloxystrobin; animal, trifloxystrobin + CGA321113 or (E,E)-methoxyimino{2-[1-(3-trifluoromethylphenyl)ethylideneaminoxymethyl]phenyl}acetic acid |                                    |                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Barley, GC640                                                                                                                                                                                                                                                                                                                                                              | 0.3                                | 0.5                                      | High value from European Commission, 0.19 mg/kg. European Commission established 0.3 mg/kg (Tables B.7.49 and B.7.50)<br><br>High value from JMPR, 0.40 mg/kg, based on trial in Germany, 1999                                                                                                                                                                                                                                                                            |
| Grapes, FB269                                                                                                                                                                                                                                                                                                                                                              | 3                                  | 3                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Grapes, dried, DF269                                                                                                                                                                                                                                                                                                                                                       | 5                                  | 5                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Pome fruit, FP9                                                                                                                                                                                                                                                                                                                                                            | 1                                  | 0.7                                      | High value from European Commission, 0.44 mg/kg                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Edible offal (mammalian), MO105                                                                                                                                                                                                                                                                                                                                            | 0.05                               | Kidney, MO98, 0.04*<br>Liver, MO99, 0.05 | Interim, wide scope<br>JMPR, narrow scope                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Eggs, PE112                                                                                                                                                                                                                                                                                                                                                                | 0.04*                              | 0.04*                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Meat (mammalian), MM95                                                                                                                                                                                                                                                                                                                                                     | 0.04*                              | 0.05 (fat)                               | Interpretation of feeding study: JMPR determined a maximum residue in fat of 0.038 mg/kg; 0.04 mg/kg is the LOQ (0.02 trifloxystrobin + 0.02 metabolite). Trifloxystrobin present in fat (0.05 mg/kg) at a feeding level of 20 ppm is approximately twice the US and JMPR calculated dietary intake of cattle. The 0.04 value is based on one feed item, barley, as compared with the much greater intake of the total treated commodities considered by the US and JMPR. |
| Milks, ML106                                                                                                                                                                                                                                                                                                                                                               | 0.02*                              | 0.02*                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Poultry, edible offal of                                                                                                                                                                                                                                                                                                                                                   | 0.04*                              | 0.04*                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Poultry meat                                                                                                                                                                                                                                                                                                                                                               | 0.04*                              | 0.04* (fat)                              | Interpretation of feeding study                                                                                                                                                                                                                                                                                                                                                                                                                                           |

<sup>6</sup> ALINORM 04/27/24, paragraphs 220–234

| Commodity, CCN                                                                                                                                                     | Interim MRL recommendation (mg/kg) | JMPR MRL recommendation (mg/kg)                 | Comment on difference                                                                                                                                                                            |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|-------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <i>Fludioxonil</i>                                                                                                                                                 |                                    |                                                 |                                                                                                                                                                                                  |
| Interim definition: Plant, fludioxonil. Animal, fludioxonil + metabolites determined as 2,2-difluorobenzo[1,1]dioxole-4-carboxylic acid, calculated as fludioxonil |                                    |                                                 |                                                                                                                                                                                                  |
| JMPR definition: Same                                                                                                                                              |                                    |                                                 |                                                                                                                                                                                                  |
| Herbs (fresh), HH726                                                                                                                                               | 10                                 | Basil, HH722, 10<br>Chives, HH727, 10           | JMPR restricted MRLs to specific herbs and did not extend them to all herbs.                                                                                                                     |
| Herbs (dry), HH726                                                                                                                                                 | 65                                 | Basil, dry, DH722, 50<br>Chives, dry, HH727, 50 | JMPR considered two trials and a drying factor of 8, yielding 15 and 24 mg/kg. The interim approach considered one trial each on dried basil and dried chives, with residues of 23 and 31 mg/kg. |
| Blackberry, FB264                                                                                                                                                  | 5                                  | 5                                               | Same data set. US interim value based on US brassica head and stem subgroup 5A (with higher residues for cabbage).                                                                               |
| Blueberry, FB20                                                                                                                                                    | 2                                  | 2                                               |                                                                                                                                                                                                  |
| Broccoli, VB400                                                                                                                                                    | 2                                  | 0.7                                             |                                                                                                                                                                                                  |
| Cabbage, head, VB41                                                                                                                                                | 2                                  | 2                                               | Same data set. Interim MRL based on US tolerance of 0.75 mg/kg rounded up under JMPR rules; highest residue value, 0.46 mg/kg. JMPR reported highest residue of 0.42 mg./kg from same data set.  |
| Carrot, VR577                                                                                                                                                      | 1                                  | 0.7                                             |                                                                                                                                                                                                  |
| Wheat, GC643                                                                                                                                                       | 0.02*                              | Cereal grains GC80, 0.05*                       | Interim based on seed treatments in the USA, with an LOQ of 0.02 mg/kg. JMPR based on 71 trials in Europe and the USA, with LOQs ranging from 0.01 to 0.05 mg/kg.                                |
| Rye, GC650                                                                                                                                                         | 0.02*                              |                                                 |                                                                                                                                                                                                  |
| Spelt, GC4673                                                                                                                                                      | 0.02*                              |                                                 |                                                                                                                                                                                                  |
| Triticale, GC653                                                                                                                                                   | 0.02*                              |                                                 |                                                                                                                                                                                                  |
| Barley, GC640                                                                                                                                                      | 0.02*                              |                                                 |                                                                                                                                                                                                  |
| Oats, GC647                                                                                                                                                        | 0.02*                              |                                                 |                                                                                                                                                                                                  |
| Maize, GC645                                                                                                                                                       | 0.02*                              |                                                 |                                                                                                                                                                                                  |
| Popcorn, GC656                                                                                                                                                     | 0.02*                              |                                                 |                                                                                                                                                                                                  |
| Sorghum, GC651                                                                                                                                                     | 0.02*                              |                                                 |                                                                                                                                                                                                  |
| Cotton-seed, SO691                                                                                                                                                 | 0.05*                              |                                                 |                                                                                                                                                                                                  |
| Currants, FB21                                                                                                                                                     | 2                                  |                                                 | Interim based on translation of blueberry field trials (< 0.05–1.4 mg/kg) to the US bushberry subgroup 13B. JMPR did not make this translation.                                                  |
| Grapes, FB269                                                                                                                                                      | 2                                  | 2                                               | Based on lychee                                                                                                                                                                                  |
| Longan, FI342                                                                                                                                                      | 1                                  | None                                            |                                                                                                                                                                                                  |
| Lychee, FI343                                                                                                                                                      | 1                                  | None                                            |                                                                                                                                                                                                  |
| Mustard greens, VL485                                                                                                                                              | 20                                 | 10                                              | Same data set. Interim maximum residue value, 7.7 mg/kg; JMPR maximum residue, 7.1 mg/kg                                                                                                         |
| Onion, VA385                                                                                                                                                       | 0.2                                | 0.5                                             | Interim based on US data only, with maximum value of 0.11 mg/kg (0.06 mg/kg average for high field trial). Interim included European data, with maximum value of 0.34 mg/kg                      |
| Pistachio, TN675                                                                                                                                                   | 0.1                                | 0.2                                             | Same data set (US). Although highest residue was 0.08 mg/kg, JMPR estimated 0.2 mg/kg on basis of small size of set (n = 3).                                                                     |
| Potato, VR589                                                                                                                                                      | 0.02*                              | 0.02                                            |                                                                                                                                                                                                  |

| Commodity, CCN                              | Interim MRL recommendation (mg/kg) | JMPR MRL recommendation (mg/kg) | Comment on difference                                                                                                                                             |
|---------------------------------------------|------------------------------------|---------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Pulasan, FI357                              | 1                                  | None                            | Based on lychee                                                                                                                                                   |
| Rambutan, FI358                             | 1                                  | None                            | Based on lychee                                                                                                                                                   |
| Rape-seed, SO495                            | 0.01*                              | 0.02*                           | Interim based on translation of data on treatment of other seed (wheat), with an LOQ of 0.01 mg/kg. JMPR based on 15 trials in Europe, with an LOQ of 0.02 mg/kg. |
| Raspberry, FB272                            | 5                                  | 5                               |                                                                                                                                                                   |
| Soya, SO4723                                | 0.01*                              | None                            | JMPR received no data. Interim based on seed treatment use and translation of data for wheat, lettuce, pea, cucumber and radish (all below LOQ)                   |
| Spanish lime, FI366                         | 1                                  | None                            | Based on lychee                                                                                                                                                   |
| Stone fruit, FS12                           | 5                                  | 5                               |                                                                                                                                                                   |
| Strawberry, FB275                           | 2                                  | 3                               | Interim based on US data only, with maximum value of 1.3 mg/kg. JMPR included European data, with maximum of 1.9 mg/kg.                                           |
| Sunflower seed, SO702                       | 0.01*                              | None                            | JMPR received no data. Interim based on seed treatment use and translation of data for wheat, lettuce, pea, cucumber and radish (all < LOQ)                       |
| Sweet corn (corn-on-the-cob), VO447         | 0.02*                              | 0.01*                           | Interim based on LOQ for cereal grain group. Codex does not consider sweet corn in the cereal grain group and evaluated data separately.                          |
| Watercress, VL473                           | 10                                 | 10                              |                                                                                                                                                                   |
| Meat (from mammals other than marine), MM95 | 0.01*                              | 0.01*                           |                                                                                                                                                                   |
| Edible offal (mammalian), MO105             | 0.05*                              | 0.05                            |                                                                                                                                                                   |
| Milks, ML106                                | 0.01*                              | 0.01                            |                                                                                                                                                                   |
| Poultry meat, PM110                         | 0.01*                              | 0.01*                           |                                                                                                                                                                   |
| Poultry, edible offal of, PO111             | 0.05*                              | 0.05*                           |                                                                                                                                                                   |
| Eggs, PE112                                 | 0.05*                              | 0.05*                           |                                                                                                                                                                   |

LOQ, limit of quantification; GAP, good agricultural practice

### ***Trifloxystrobin***

The interim MRL recommendations are based on information and data compiled by the USA from both the European Union and the USA. The maximum residue levels recommended by the JMPR are based on an independent review of studies supplied by the manufacturer and include field trial data from more diverse sources: Australia, Brazil, Canada, Colombia, Costa Rica, Ecuador, Europe (Belgium, Denmark, France, Germany, Italy, The Netherlands, Spain, Switzerland, United Kingdom), Guatemala, Honduras, Mexico, South Africa, and the USA.

The interim MRLs are based on the residue definition in the USA, which is parent plus an acid metabolite. This differs fundamentally from the JMPR definition for enforcement for plant commodities, which is trifloxystrobin only. The residue definitions for dietary intake and for animal commodities are identical.

The manufacturer proposed, via the Pilot Project Working Group on the Interim MRL, only three commodities for this test exercise: grapes, barley and pome fruit, while the JMPR evaluation included an extensive array of plant commodities. Thus, only a limited comparison is possible.

The recommended interim MRLs and JMPR MRLs are similar for some commodities. The exceptions are mammalian meat (interim, 0.04 mg/kg; JMPR, 0.05 mg/kg), pome fruit (interim, 1 mg/kg; JMPR, 0.7 mg/kg) and barley (interim, 0.3 mg/kg; JMPR, 0.5 mg/kg). The discrepancy in the values for meat may be due to the fact that only barley was considered in the animal diet, as this was the only feed commodity suggested by the manufacturer for an interim MRL. The value of 0.04 mg/kg represents the limit of detection of the analytical method. JMPR estimated the intake of cattle at 6.3 ppm, and the USA estimated it at 12 mg/kg. The USA maintains a tolerance of 0.5 mg/kg on the basis of a long list of trifloxystrobin-treated commodities. The value was reduced to 0.04 mg/kg because barley was the only feed item being considered for an interim MRL. The reviews of both the USA and the JMPR considered the maximum residue level in beef fat to be 0.05 mg/kg, derived from a 20 ppm dietary burden of trifloxystrobin. Thus, the difference can be attributed to the limited interim MRL list; the values would both be 0.05 mg/kg with the longer list of animal feed commodities. The value of 0.05 mg/kg is appropriate on the basis of the animal feed items for which JMPR is proposing MRLs.

The interim MRL value of 1 mg/kg for pome fruit is based on the highest residue value of 0.44 mg/kg reported from Europe. The US tolerance is 0.5 mg/kg, based on a maximum residue value of 0.23 mg/kg. Under the JMPR system, the MRL would be either 0.7 mg/kg or 1 mg/kg. The Meeting selected 0.7 mg/kg in view of the large number of trials available (74) and the median of 0.11 mg/kg. These factors suggest that the MRL may be set near the maximum residue value, i.e. 0.7 mg/kg and not 1 mg/kg.

The interim MRL for barley is based on data from field trials considered by the European Commission in establishing a European Union MRL of 0.03 mg/kg. The JMPR considered additional data from field trials. A trial in Germany yielded a maximum residue value of 0.40 mg/kg. The 0.5 mg/kg value is appropriate when this additional information is considered.

The dietary risk assessments for the interim MRLs and for the JMPR MRLs indicated no concern. Using supervised trials median residue (STMR) values and an ADI of 0.04 mg/kg bw per day, the JMPR estimated the intake to be 1–2% of the ADI in regional diets. Using MRL values (for the limited list of commodities) and a reference dose of 0.038 mg/kg bw per day for long-term exposure (USA), the Interim Pilot Project estimated the intake in regional diets to be 0–6% of the ADI.

A calculation of dietary intake during short-term exposure similar to that of JMPR was performed within the Pilot Project, taking the proposed interim MRLs as residue levels and the ARfD determined in the USA (2.5 mg/kg bw per day). It should be noted that the end-point applies only to the subpopulation of females aged 13–49 years and is based on developmental toxicity. The calculation was performed for the general population, because the Codex system does not have data on the consumption of this subpopulation. The ARfD was not exceeded for any commodity. The maximum exposure of the general population (used as a surrogate for women of child-bearing age) was 1% of the ARfD, from apples. The JMPR determined that an ARfD need not be established.

### ***Fludioxonil***

The interim MRLs recommended for fludioxonil are based solely on data from the USA, as the European Commission has not completed its evaluation of fludioxonil. The JMPR made an independent evaluation of studies provided by the manufacturer, which included field trials from Chile, Europe (Denmark, France, Greece, Hungary, Italy, Spain, Sweden, Switzerland), South Africa and the USA.

The residue definitions in the interim proposal and the JMPR recommendation are identical for plants and animals for both enforcement and dietary intake. The interim and the JMPR MRL recommendations

differed for currants, lychee, longan, pulasan, rambutan, Spanish lime, strawberry, sweet corn, broccoli, carrot, mustard greens, bulb onion, basil (dry), chives (dry), pistachio and cereal grains.

The interim MRL for *currants* is based on a translation of data from US blueberry field trials, in which the residue values ranged from < 0.05 to 1.4 mg/kg. Blueberries are the representative commodity for the US bushberry subgroup 13B. The JMPR had no data from trials conducted under GAP and did not consider a translation of data on blueberries to currants.

The interim MRLs for *lychee*, *longan*, *pulasan*, *rambutan* and *Spanish lime* are based on three US field trials with lychee. The JMPR received the same data set but considered that the three trials were conducted substantially in excess of US GAP. US GAP specifies a maximum of four applications, each at 0.25 kg ai/ha, with a 0 day PHI; however, in the trials, five or seven applications were made at the maximum rate, with an approximate 7-day re-treatment interval. On the basis of the results of decline studies conducted with other fruit crops, JMPR concluded that the extra applications might make a significant (25%) contribution to the residue.

The interim MRL proposal for *strawberry* is based on US data only, with a maximum value of 1.3 mg/kg. The JMPR considered both European and US data; the maximum value in the former was 1.9 mg/kg.

The interim MRL proposal for *sweet corn* is based on US data for cereal grains, with an LOQ of 0.01 mg/kg. The Codex System does not place sweet corn in the cereal grains group, and the JMPR evaluated data for sweet corn and field corn, with an LOQ of 0.02 mg/kg.

The same US data were used to derive the interim and the JMPR MRL recommendations for *broccoli*. The interim MRL is based on a high residue value of 0.53 mg/kg, found on one of two samples in one field trial. The value is also based on a US tolerance for the brassica head and stem subgroup 5A, which allows higher residue values for cabbage. The JMPR MRL was based on a high residue value of 0.36 mg/kg, which is the average for the two samples in the same field trial  $([0.53 \text{ mg/kg} + 0.19 \text{ mg/kg}]/2)$ . Under JMPR procedures, 0.5 mg/kg is an appropriate MRL.

The same US data were used to derive the interim and the JMPR MRL recommendations for *carrot*. The interim MRL is based on the US tolerance of 0.75 mg/kg, rounded under JMPR rules to 1 mg/kg. Residue values ranged from 0.04 to 0.42 mg/kg in the nine trials. JMPR considered 0.7 mg/kg to be an appropriate MRL estimate.

The same US data were used to derive the interim and the JMPR MRL recommendations for *mustard greens*. The residue values ranged from 0.06 to 7.1 mg/kg in seven trials. JMPR considered 10 mg/kg to be an appropriate MRL estimate. The proposed interim MRL value of 20 mg/kg does not seem appropriate, given the number of trials and the range of residue values.

The same US data were used to derive the interim and the JMPR MRL recommendations for *dried chives* and *dried basil*. The interim MRL of 65 mg/kg for dried herbs is based on the results of one trial each with basil and chives, with residues of 23 and 31 mg/kg, respectively. The recommended JMPR maximum residue level of 50 mg/kg for dried basil is based on two trials and a drying factor of 8 (from one trial), yielding values of 15 and 24 mg/kg. For dried chives, the recommended JMPR maximum residue level is based on two trials and a drying factor of 8 (from one trial), yielding values of 14 and 31 mg/kg. The recommended JMPR maximum residue level of 50 mg/kg is appropriate for both dried basil and dried chives. The JMPR considered that the limited data available on basil (two trials, one including drying) and chives (two trials, one including drying) were inadequate to recommend an MRL for the general category of dried herbs.

The same US data were used to derive the interim and the JMPR MRL recommendations for *pistachio* nuts. Three trials were conducted in the USA, with the highest residue being 0.08 mg/kg. The interim MRL recommendation is based on the US tolerance of 0.1 mg/kg. The JMPR considered that the number of data points was minimal and therefore estimated an MRL of 0.2 mg/kg.

The interim MRL recommendation for soya (oil seed) of 0.01 mg/kg is based on a translation of data from treatment of seeds for wheat, lettuce, pea, cucumber and radish. JMPR did not receive any data on soya seed treatment and did not translate data on rape or cereal grain.

The interim MRL for rape-seed is based on a translation of data from various seed treatments, with an LOQ of 0.01 mg/kg. The JMPR value is based on the results of trials on the treatment of rape-seed, with an LOQ of 0.02 mg/kg.

The various interim MRLs for cereal grains are based on field trials of seed treatment for wheat, maize and other crops in the USA and are set at the LOQ of 0.02 mg/kg. The JMPR recommendation for the maximum residue level for *cereal grain* is based on 71 seed treatment trials in Europe and the USA, with LOQs ranging from 0.01 to 0.05 mg/kg. The highest value was selected by the JMPR.

The dietary risk assessments with the interim and the JMPR MRLs found no dietary concern. Using STMR values and an ADI of 0.4 mg/kg bw per day, the JMPR estimated the intake at 0–1% of the ADI for regional diets. Using MRL values and a reference dose of 0.03 mg/kg bw per day for long-term exposure (US), the Interim Pilot Project estimated the intake to be 0–13% of the ADI for regional diets. Neither calculation indicates concern associated with long-term dietary intake by the general populations in the five regions of the Global Environment Monitoring System–Food Contamination Monitoring and Assessment Programme (GEMS/Food).

A calculation of dietary intake for short-term exposure similar to that of JMPR was performed in the USA, using the proposed interim MRLs as residue values and the ARfD as determined in the USA (1.0 mg/kg bw per day). It should be noted that the end-point applies only to the subpopulation of females aged 13–49 years. The calculation was performed for the general population, because the Codex system does not have data on the consumption of this subpopulation. The maximum exposure of the general population (used as a surrogate for women of child-bearing age) was 10% of the ARfD, from stone fruits. The JMPR considered that an ARfD need not be established. Both the Pilot Group for the Interim MRL and the JMPR concluded that there was no concern associated with short-term dietary intake from the uses considered.

### **General comments**

Several significant differences in the approaches used by the Pilot Group for the Interim MRL and the JMPR become apparent during consideration of the maximum residue levels, because the JMPR uses the average for replicate samples or from replicate analyses, whereas the interim proposals are based on maximum values. This difference usually has only a minimal effect. The JMPR has access to a larger database of field trials and can thus make recommendations on the basis of wider use. The larger database might give rise to different estimates, even when the residue values are below the LOQ. Consideration of full studies from the manufacturer allows inclusion of results that might be considered ‘outliers’ by the European Commission, thereby giving rise to significantly different estimates of maximum residue levels. As crop groupings and extrapolations differ among classification systems, an interim proposal for a maximum residue level in a commodity that is based on a national crop group might be significantly different from that based on a single commodity by the JMPR.

The JMPR agrees with the goals of the project, namely to accelerate the process for establishing MRLs within the Codex system and the introduction of standards for pesticides that are safer alternatives for use on food and feed. The Meeting expressed concern over the meaning of the word ‘safer’, which could mean either less toxic (hazard) or a lower residue level (exposure), and the extent of the ‘safer’ designation, which could be either for human health (dietary intake) or for environmental effects. The CCPR has included a number of safeguards in the process, the most important being analyses of long-term and short-term dietary intake based on JMPR methods and consideration by the Codex Alimentarius Commission.

The JMPR considers that extensive use of the interim MRL process might create a serious problem. As the interim MRLs are limited to a period of 4 years, pesticides nominated in this process must be

scheduled for and reviewed by the JMPR within this period. If there are many nominations for interim MRLs for pesticides, the currently limited resources of the JMPR might mean that the evaluations of some of the pesticides might not be completed within the 4 years or that other priorities, such as periodic reviews and evaluations, might have to be severely curtailed.

## **2.6 Estimation of maximum residue levels of pesticides in or on spices on the basis of monitoring results**

The setting of MRLs for spices on the basis of monitoring results was discussed by the CCPR on several occasions. The 2002 JMPR prepared guidelines for the submission of monitoring data for evaluation (xx). The CCPR at its Thirty-sixth Session proposed that commodity group A028 be subdivided into groups on the basis of the parts of plants from which they are obtained—seeds, fruits or berries, roots or rhizomes, bark, buds, arils and flower stigmas—and that MRLs for pesticides that had been evaluated within the Codex system should be set for these sub-groups rather than for each of the pesticide–spice combinations.<sup>7</sup>

The CCPR proposed that the MRL should cover at least 95% of the residue population at the 99% confidence level.<sup>8</sup>

The Meeting evaluated the data on residues provided but emphasized that estimating maximum, high and median residue values does not necessarily mean that the use of those compounds for use on spices is approved by the JMPR.

The Meeting considered the nature of monitoring results and identified the following principal differences from residue data derived from supervised field trials:

- The origin and treatment of the lots sampled are not known.
- The sampled commodity might be composed of the produce of several small fields.
- The residues in spice samples were determined by multi-residue procedures, and their contents were usually screened for organochlorine and organophosphorous compounds, which have relatively high LOQs.
- When residue values are reported as being below the LOQ, it is not necessarily true that the sampled commodity was not treated with or exposed to the pesticide.

Consequently, estimation of maximum residue levels for pesticides on the basis of monitoring results requires a different approach from that used for the evaluating the results of supervised field trials.

### ***Basic principles for evaluating monitoring data***

The Meeting assumed that the laboratories reported only valid results. Therefore, all residue data were taken into account as there was no scientific ground for excluding any value as an outlier due to the fact that no information was available on registered or approved uses or application conditions of the pesticides.

It is unlikely that all the sampled commodities were treated with the pesticides in the multi-residue screening procedure; therefore, the proportion of commodities treated with or exposed to a given pesticide was calculated from the ratio of samples containing detectable residues and the total number of samples analysed.

The distributions of residues were scattered or skewed upwards, and no distribution fitting appeared to be appropriate. Consequently, distribution-free statistics was used in estimating the maximum residue level, covering the 95th percentile of the population at the 95% confidence level. Thus, the estimated maximum

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<sup>7</sup> ALINORM 04/24, para 236

<sup>8</sup> CX/PR 04/13

residue level encompasses at least 95% of the residues with 95% probability (in 95% of cases). To satisfy this requirement, a minimum of 58–59 samples is required.

STMR and the highest residue values can be calculated only from supervised trials. The corresponding values from the monitoring data are indicated as median and high residue values, and these can be used like the STMR and highest residue values for estimating short-term and long-term intake of residues.

In accordance with the recommendation of the CCPR, maximum, high and median residue values were estimated for pesticide residues in the spice subgroups shown in Table 1 if at least 58 samples belonging to one subgroup were analysed for the given pesticide. The minimum sample size of 58 provides 95% assurance of finding at least one residue value above the 95th percentile of the residue population in the sampled object. It is not, however, known how many of the measured values are above the 95th percentile and what percentile (95.1th, 99th or 99.9th) the highest residue represents. The 95th percentile of the sample does not necessarily represent the 95th percentile of the residue population in the sampled commodity, especially when the sample size is small.

The procedure used depended on the number of samples containing detectable residues.

- When no sample contained detectable residues, the highest reported LOQ value was used as the maximum residue level and the high residue value. The median residue value was calculated from the reported LOQ values.
- When a large number of samples ( $> 120$ ) contained detectable residues, the sample size was sufficiently large to calculate the upper 95% one-tailed confidence limit of the population of residues, on the basis of binominal (distribution free) probability calculation.<sup>9</sup>

The confidence limits calculated for pirimicarb residues in anise seeds (number of positive samples, 129) are illustrated in Figure 1. The data set contained 129 residue values with maximum and 95th percentile values of 1.4 and 0.68 mg/kg, respectively. The upper confidence limit of the 95th percentile is between 0.93 and 1.2 mg/kg. This would require an MRL of 1.2 mg/kg, but it is rounded up to 2 mg/kg according the general practice of the JMPR.

When more detectable residue values are available ( $n = 343$ ; max 10 values: 11, 9.4, 7, 6.9, 6.8, 6.8, 6.7, 6, 5.9, 4.4, mg/kg; 95th percentile of sample, 3.2 mg/kg; median, 0.5 mg/kg), the upper 95% confidence limit is lower than the maximum of residues observed, and the residue values above the upper confidence limit need not be considered for the maximum residue level. The situation is illustrated in Figure 2.

As the upper 95% confidence limit is between 5.9 and 6 mg/kg, an MRL of 7 mg/kg would be appropriate. The highest three residue values (7, 9.4 and 11 mg/kg) were above the upper 95% confidence limit and did not influence the estimated limit.

3. A few samples ( $\leq 120$ ) contained detectable residues. In such cases, the upper 95% confidence limit cannot be calculated from the 95th percentile value of the residues. Sufficient allowance should be given when the maximum residue level is estimated to be above the highest residue value observed. The situation is illustrated in Figure 3 by the example of dimethoate residues in anise ( $n = 61$ ; maximum, 3 mg/kg; 95th percentile for all samples, 0.9 mg/kg). For the given residue population, the Meeting estimated a maximum residue level of 5 mg/kg.

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<sup>9</sup> Hamilton DJ, Ambrus Á, Dieterle RM, Felsot Á, Harris C, Petersen B, Racke K, Wong SS, Gonzalez R, Tanaka K. Pesticide residues in food—Acute dietary intake. *Pest Manag Sci* 2004;60:311–39.



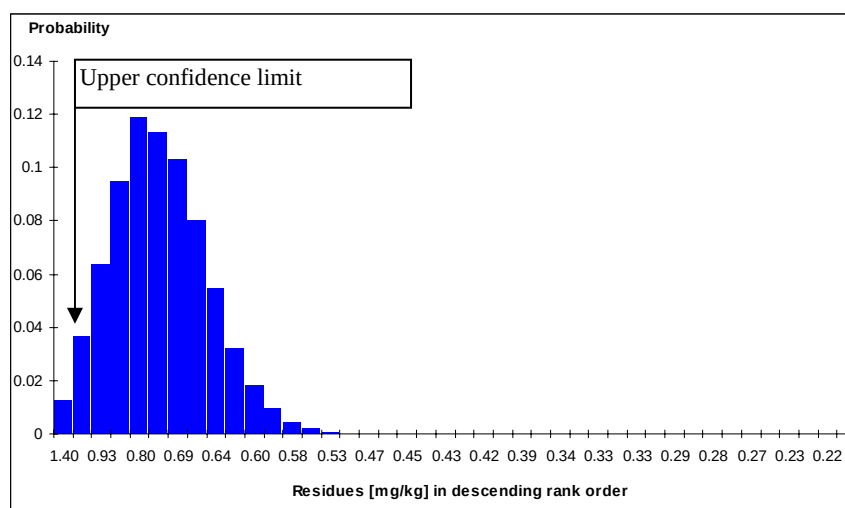


Figure 1. Upper 95% confidence limits for the 95th percentile of pirimicarb residues in anise seed ( $n = 129$ )

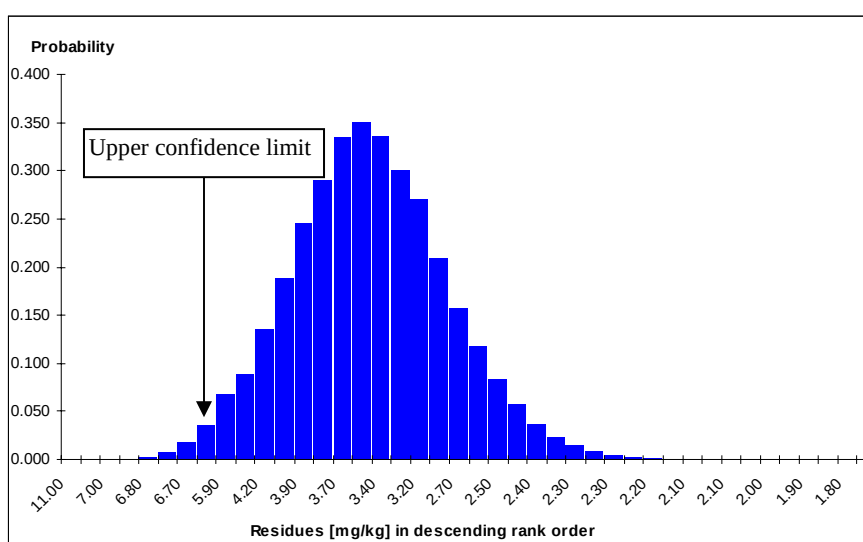


Figure 2. Upper 95% confidence limits for the 95th percentile of chlorpyrifos residues in cumin seed ( $n = 343$ )

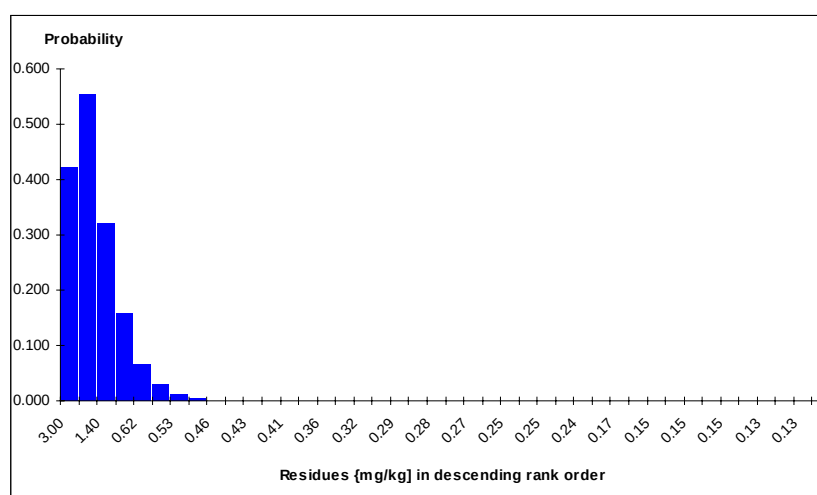


Figure 3. Distribution of estimated 95th percentile estimates of dimethoate residues in anise seed ( $n = 61$ )

***Calculation of international estimated short-term dietary intake (IESTI) and international estimated daily intake (IEDI)***

The revised subgroups of spices in group A28 do not all correspond to the consumption figures used for intake calculations. Therefore, the calculations were made with the combined amounts listed for spices in the GEMS/Food tables, in grams per day.

The calculations of short-term intake were based on the highest value of residues of the given pesticide measured in any spice sample.

The IEDI was calculated only from the residue levels detected in the pesticide–spice commodity combination that made the highest contribution to intake of any of the subgroups. A factor for the proportion of treated commodities was calculated from the ratio of the number of samples containing detectable residues and that containing undetectable residues. Adjustment of the median residue value by this factor was one of the recommended procedures for refining intake calculations.<sup>10</sup>

***Recommendations***

The Meeting recommended that the CCPR accept the principle of setting MRLs on the basis of monitoring results covering the 95th percentile of the residue population at the 95% confidence level. This decision would facilitate use of the statistical procedures for estimating maximum residue levels and acceptance of recommended limits. It should be noted, however, that when MRLs are set at the 95th percentile with 95% confidence, the residue levels might exceed the MRLs in 5% of cases.

Monitoring results should not be used for estimating maximum residue levels that reflect post-harvest use, which results in much higher residue values than foliar application or exposure to spray drift.

***Definition of spices***

Spices (Group 028) are dried aromatic seeds, buds, roots, bark, pods, berries or other fruits from a variety of plants, rhizomes and flowers, or parts thereof, which are used in relatively small quantities for seasoning, flavouring or imparting aroma to foods. They are consumed in dried form after being added to or sprinkled on foods. The portion of the commodity to which the MRL applies (and which is analysed) is only the dried commodity as it moves in international trade.

***Spices of interest and proposed subgroups***

The Committee agreed that spices should be collected into smaller groups to facilitate the setting of group MRLs. On the basis of the above definition and after consultation with the spice trade industry, the spices of interest, grouped on the basis of the parts of plants from which they are obtained, are as shown in the table below.

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<sup>10</sup> Hamilton D, Murray B, Ambrus Á, Baptista G, Ohlin B, Kovacicova J. Optimum use of available residue data in the estimation of dietary intake of pesticides. *Pure Appl Chem* 1997;69:1373–410.

**Group 028—Spices (as modified by the CCPR at its Thirty-sixth Session, 2004; CX PR 04/13)**

| CCN <sup>a</sup>          | Common name                      | Botanical name                                    | Industry associations consulted   |
|---------------------------|----------------------------------|---------------------------------------------------|-----------------------------------|
| <i>Seeds</i>              |                                  |                                                   |                                   |
|                           | Ajowan                           | <i>Carum ajowan</i>                               | ESA                               |
|                           | Bishop's weed                    | <i>Trachyspermum ammi</i>                         | ISO , India                       |
| HS 771                    | Anise                            | <i>Pimpinella anisum</i>                          | ESA, ASTA (fruit in ISO, India)   |
|                           | Black caraway                    | <i>Nigella satia</i>                              | ASTA                              |
| HS 624                    | Celery seed                      | <i>Apium graveolens</i>                           | ASTA, ESA, (fruit in India, ISO)  |
| HS 779                    | Coriander                        | <i>Coriandrum sativum</i>                         | ASTA, India (fruit in ESA)        |
| HS 780                    | Cumin                            | <i>Cuminum cyminum</i>                            | ESA, ASTA (fruit in ISO, India)   |
| HS 730                    | Dill                             | <i>Anethum graveolens</i>                         | ESA, ASTA, India (fruit in ISO)   |
| HS 731                    | Fennel                           | <i>Foeniculum vulgare</i>                         | ESA, ASTA (fruit in India)        |
| HS 782                    | Fenugreek                        | <i>Trigonella foenum graecum</i>                  | ESA, ASTA, India, ISO             |
| HS 789                    | Nutmeg                           | <i>Myristica fragrans</i>                         | ESA, ASTA , India (kernel in ISO) |
| HS 4783                   | Poppy seed                       | <i>Papaver somniferum</i>                         | India                             |
| HS 4785                   | Sesame seed                      | <i>Sesamum indicum</i> or <i>orientale</i>        | India                             |
|                           | Mustard seed                     |                                                   | Proposed addition                 |
| <i>Fruits and berries</i> |                                  |                                                   |                                   |
| HS 4769                   | Allspice                         | <i>Pimenta dioica</i>                             | ESA, ASTA, ISO, India             |
|                           | Anise pepper; Japan pepper       | <i>Zanthoxylum piperitum</i> DC                   | ESA                               |
|                           | Candlenut                        | <i>Aleyrites moluccana</i>                        | Indonesia                         |
| HS 774                    | Caraway                          | <i>Carum carvi</i>                                | ESA, India, ISO (seed in ASTA)    |
| HS 775                    | Cardamom                         | <i>Elettaria cardamomum</i>                       | ESA, ASTA, India, ISO             |
| HS 786                    | Juniper                          | <i>Juniperus communis</i>                         | ASTA, ESA, India, ISO             |
| HS 735                    | Lovage                           | <i>Levisticum officinale</i> Koch                 | ISO, India (root in ESA)          |
| HS 790                    | Pepper (black, white, green)     | <i>Piper nigrum</i>                               | ESA, ASTA, India, ISO             |
| HS 791                    | Pepper, long                     | <i>Piper longum</i>                               | India, ISO                        |
| HS 792                    | Pimento                          | <i>Pimenta officinalis</i>                        | ESA, ASTA                         |
|                           | Pink pepper                      | <i>Schinus terebinthifolius</i> , <i>S. molle</i> | ASTA, ESA                         |
|                           | Sichuan pepper                   | <i>Zanthoxylum bungei</i> Planch                  | ESA                               |
|                           | Star anise                       | <i>Illicium verum</i>                             | ASTA, ESA, ISO, India             |
| HS 795                    | Vanilla bean                     | <i>Vanilla planifolia</i> ; or <i>tahitensis</i>  | ESA, ASTA, ISO, India             |
| <i>Barks</i>              |                                  |                                                   |                                   |
| HS 4775                   | Cassia bark                      | <i>Cinnamomum aromaticum</i>                      | ASTA, ESA, India, ISO             |
| HS 777                    | Cinnamon                         | <i>Cinnamomum zeylanicum</i> , <i>C. verum</i>    | ESA, ASTA, India                  |
|                           | Tejpat                           | <i>Cinnamomum tamala</i>                          | India                             |
| <i>Roots and rhizomes</i> |                                  |                                                   |                                   |
|                           | Asafoetida                       | <i>Ferula assafoetida</i>                         | ESA, India, ISO                   |
| HS 781                    | Elecampane                       | <i>Inula helenium</i>                             | ESA                               |
| HS 784                    | Ginger                           | <i>Zingiber officinale</i>                        | ESA, ASTA, India, ISO             |
|                           | Greater galangal; Siamese ginger | <i>Alpinia galanga</i> Willd                      | ESA, India, ISO                   |

| CCN <sup>a</sup>      | Common name     | Botanical name                                                 | Industry associations consulted     |
|-----------------------|-----------------|----------------------------------------------------------------|-------------------------------------|
|                       | Lesser galangal | <i>Apinia officinarum</i> Hance                                | ESA, ISO                            |
|                       | Galangal        | <i>Kaempferia galanga</i>                                      | ESA, ISO                            |
| HS 772                | Sweet flag      | <i>Acorus calamus</i>                                          | India, ISO                          |
| HS 794                | Turmeric        | <i>Curcuma longa</i>                                           | ESA, ASTA, India, ISO               |
| <i>Buds</i>           |                 |                                                                |                                     |
| HS 7743               | Capers          | <i>Capparis spinosa</i>                                        | ESA, India, ISO                     |
| HS 778                | Cloves          | <i>Syzygium aromaticum</i> ;<br><i>Caryophyllus aromaticus</i> | ESA; ASTA, India, ISO               |
| <i>Flower stigmas</i> |                 |                                                                |                                     |
|                       | Saffron         | <i>Crocus sativus</i>                                          | ESA, India, ISO, ASTA, Spain, Malta |
| <i>Arils</i>          |                 |                                                                |                                     |
| HS 788                | Mace            | <i>Myristica fragrans</i> .                                    | ISO, India, ASTA, ESA               |

CCN, Codex classification number; ASTA, American Spice Trade Association; ESA, European Spice Association; India, Indian Spices Board; ISO, International Standards Organization (specifically, ISO 676 Standard for Spices and Condiments)

<sup>a</sup> Those with a CCN are currently in the list of spices; others are additions to the list.

## 2.7 Revisited: MRLs for fat-soluble pesticides in milk and milk products

The 2003 JMPR reiterated its explanation of the rationale behind the expression of MRLs for fat-soluble pesticides in milk and milk products.<sup>11</sup> Nevertheless, the 2004 CCPR indicated that the procedure is still complex and considered that it was bound to introduce errors. For instance, the JMPR assumes that adding the suffix ‘F’ to an MRL for milk clearly implies that analysis for compliance testing must be conducted on the milk fat. The 2004 CCPR noted that the suffix ‘F’ means only that the specific rule for application of the MRL to the fat in milk products applies. It stated that the MRL applies to the milk as such and might therefore be determined for whole milk.

Currently, the JMPR follows the Codex convention of expressing the MRL for fat-soluble compounds in milk on the basis of the calculated whole product, assuming that all milks contain 4% fat.<sup>12</sup> The residue concentration is calculated for the whole product from the concentration measured in fat, and the MRL would be 1/25th of the residue concentration estimated for the milk fat. Many pesticides are, however, have intermediate solubility in fat; even if they are regarded as fat-soluble, they can be distributed equally between the fat and non-fat portions of milk. For example, if the ratio of residue concentrations between the fat and aqueous phases is 15:1 in milk with 4% fat, the ratio of residue mass distribution is about 2:3, meaning that most of the residue remains in the aqueous phase.

The Meeting decided that, for fat-soluble pesticides, two maximum residue levels will be estimated, if the data permit: one for whole milk and one for milk fat. For enforcement purposes, a comparison can be made either of the residue in milk fat with the MRL for milk (fat) or of the residue in whole milk with the MRL for milk. When needed, maximum residue levels for milk products can then be calculated from the two values, by taking into account the fat content of the milk product and the contribution from the non-fat fraction.

<sup>11</sup> Annex 6, reference 98

<sup>12</sup> FAO/WHO 2000: Codex Alimentarius Volume 2B, Pesticide Residues in Food—Maximum residue limits. Joint FAO/WHO Food Standards Programme, p. 4. Rome, 2000.

Analytical methods should be made available for both milk and milk fat (both with a practical LOQ). The fat should preferably be separated from the milk by physical means, not by chemical solvent extraction, because in solvent extraction residues are extracted from both the aqueous and the lipid phase. As in this way cream (containing 40–60% fat) and not 100% milk fat is obtained, the lipid content of the cream should also be reported. The Meeting requested the CCPR ad-hoc Working Group on Methods of Analysis to give further guidance on analytical methods for measuring residues of fat-soluble pesticide in milk. Estimation of maximum residue levels for spinosad in milk is given here as an example (see also this report).

The 2001 JMPR reported that residues were measured in 119 samples of milk and cream after direct treatment of dairy cows with spinosad, and that the mean quotient of the concentration in cream divided by the concentration in milk was 4.2. A plot of residue levels in whole milk versus residue levels in cream (Figure 4) showed that the residue level in milk was approximately 24% of that in cream (line of best fit through the origin). Data on spinosad residues in milk and cream from a study of feeding to dairy cows are summarised in Table 79 of the JMPR Residue Evaluations of 2001<sup>13</sup>. The mean quotient of the concentration in cream divided by the concentration in milk after feeding at levels of 1, 3 and 10 ppm was 4.0, in good agreement with the results of direct treatment.

The 2001 JMPR estimated a maximum residue level of spinosad in cattle milk of 1 mg/kg on the basis of the highest value in milk, 0.65 mg/kg, after direct treatment. The calculated concentration in cream would be  $0.65 \times 4.2 = 2.7$  mg/kg. On the assumption that the cream in the feeding study was approximately 50% fat, the concentration in fat would be about 5 mg/kg.

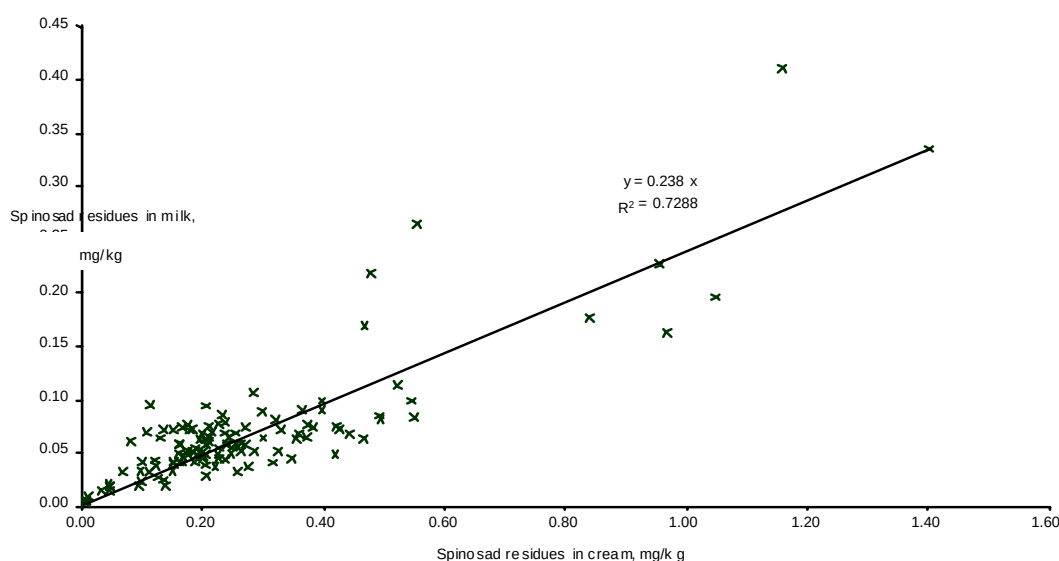


**Figure 4. Residues of spinosad in milk and cream after direct treatment of dairy cows**

The Meeting estimated a maximum residue level for spinosad residues in cattle milk fat of 5 mg/kg. The Meeting noted that the residue of this pesticide of intermediate fat solubility was estimated to be 8.4 times higher in milk fat than in milk, while the default factor would have been 25 when milk MRLs for fat-soluble pesticides are expressed as previously.

<sup>13</sup> Annex 6, reference 93

## 2.8 Revisited: Dietary burden of animals for estimation of MRLs for animal commodities

The 1997 JMPR developed guidance for estimating maximum residue and STMR levels for products of animal origin when residues are transferred from feed items. As a result of experience gained since that time, the Meeting agreed that animals could be exposed for extended periods to certain commodities such as fodder, grain and feeds treated post-harvest which contain residues at the highest level. The Meeting was informed that this situation pertains in Australia and probably in other regions of the world.

For example, on a farm on which 20 ha of an animal feed (forage, fodder or grain) were grown per year with a yield of 10 t/ha on a dry weight basis, enough would be produced to feed 333 head of cattle for 1 month. If the feed constituted less than 100% of the diet, more head of cattle could be fed for 1 month, or the duration of feeding might be longer.

In addition, in the experience of the Meeting, the residue levels of many pesticides on animal feed commodities decrease to only a limited extent during storage.

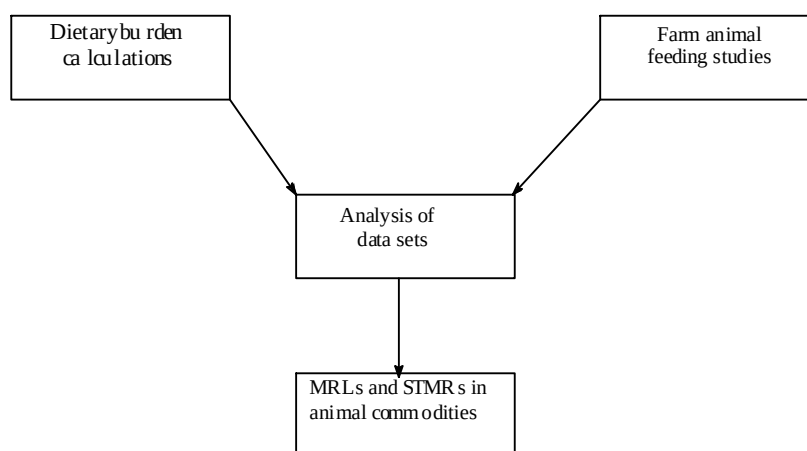
The Meeting agreed that the assumption of the 1986 JMPR, which was used in developing guidance in this area, that “it was unrealistic to assume that the theoretical maximum residue level would be achieved and maintained in the rations of food-producing animals receiving feeds produced on the farm” should no longer apply. Hence, the concept of the time required for residue levels to reach a plateau is also no longer required, thus simplifying estimation of dietary burden. It is recognized that it is unlikely that the individual ingredients of mixed feeds produced from commercially available ingredients would all contain residues at the theoretical maximum level; in these cases, the STMR should be applied to each of the components.

A revision of the relevant text in the *FAO Manual*, taking the above into account, will appear on the FAO website.

### *Residues arising from consumption of feed items*

The 1986 JMPR explained its use of feeding studies with farm animals in estimating MRLs for foods of animal origin. It made the point that a sensible judgement must be made about the expected level of ingestion. The 2004 JMPR noted that it is realistic to assume that the theoretical maximum residue level would be achieved and maintained in the rations of food-producing animals receiving feeds grown on the farm for extended periods.

The estimation of residues that will arise in animal commodities is a two-pronged process, involving feeding studies with farm animals and calculations of dietary burden. These two sets of information are combined to estimate the residue levels that will be found in animal commodities in practice:



The following decision matrix is recommended for use in estimating maximum residue levels and STMR values:

| Maximum residue level                                                      | STMR                                                                 |
|----------------------------------------------------------------------------|----------------------------------------------------------------------|
| Choose:                                                                    | Choose:                                                              |
| feed commodity, highest residue or STMR-P (for dietary burden calculation) | feed commodity STMR or STMR-P (for dietary burden calculation)       |
| highest residue level <sup>1</sup> (from feeding study in farm animals)    | mean residue level <sup>1</sup> (from feeding study in farm animals) |

STMR-P, supervised trials median residue in a processed commodity calculated by multiplying the STMR of the raw commodity by the corresponding processing factor

<sup>1</sup> Residue levels in tissues and eggs of the relevant group of animals in the feeding study. For milk, choose the mean residue in milk from the relevant group of animals in all cases.

The residue contribution of a feed commodity for estimating maximum residue levels is calculated from the percentage of the total diet and the highest residue level in raw agricultural commodity feed items. For processed commodities that are likely to originate from a number of farms, e.g. apple pomace, the STMR-P of the processed commodity is chosen as the likely highest residue value that will occur in practice.

Maximum residue levels in animal commodities are derived from the highest residue values in feed commodities, and STMRs for animal commodities are derived from the STMRs for feed commodities. Separate tables are made for each MRL and STMR estimate, in which all feed items, their Codex commodity group and the residue levels found in crop residue trials are listed. The basis of the residue level is provided; i.e. the basis of the maximum residue level estimate is the highest level for raw agricultural commodities and the STMR-P for processed commodities. The percentage dry matter in the feeds is derived from Appendix IX of the *FAO Manual*, 'Maximum proportion of agricultural commodities in animal feed', except when the data stipulate 100% dry matter. The residue of each feed commodity on a dry weight basis is then calculated.

Starting with the feed item with the highest residue level, the percentage of each feed in the livestock diet is allocated from Appendix IX. Usually, only one feed commodity from each Codex commodity group is used; if more than one is used, it is only up to the full percentage feed allocation for that group. Feeds are allocated a percentage of the diet for each animal until no more than 100% of the diet is used.

The residue contribution (mg/kg) of each feed is then calculated from the dry weight of the residue and the corresponding percentage of the diet. All residue contributions for each animal are then added to determine the total dietary burden.

The procedure illustrated in the diagram and described above is demonstrated in the following worked example for spinosad.

#### *Maximum dietary burden of farm animals estimated for spinosad*

| Commodity         | Codex commodity group | Residue (mg/kg) | Basis of residue value | Dry matter (%) | Residue dry weight (mg/kg) | Feed allocation in total diet (%) |              |         | Residue contribution of feeds (mg/kg) |              |         |
|-------------------|-----------------------|-----------------|------------------------|----------------|----------------------------|-----------------------------------|--------------|---------|---------------------------------------|--------------|---------|
|                   |                       |                 |                        |                |                            | Beef cattle                       | Dairy cattle | Poultry | Beef cattle                           | Dairy cattle | Poultry |
| Apple pomace, wet | AB                    | 0.064           | STMR-P                 | 40             | 0.16                       | 10                                |              |         | 0.016                                 |              |         |
| Citrus pulp       | AB                    | 0.12            | STMR-P                 | 91             | 0.13                       |                                   |              |         |                                       |              |         |
| Maize forage      | AF                    | 3.1             | Highest                | 100            | 3.1                        | 40                                | 50           |         | 1.24                                  | 1.55         |         |
| Maize fodder      | AS                    | 2.1             | Highest                | 100            | 2.1                        |                                   |              |         |                                       |              |         |

| Commodity                   | Codex commodity group | Residue (mg/kg) | Basis of residue value | Dry matter (%) | Residue dry weight (mg/kg) | Feed allocation in total diet (%) |              |         | Residue contribution of feeds (mg/kg) |              |         |
|-----------------------------|-----------------------|-----------------|------------------------|----------------|----------------------------|-----------------------------------|--------------|---------|---------------------------------------|--------------|---------|
|                             |                       |                 |                        |                |                            | Beef cattle                       | Dairy cattle | Poultry | Beef cattle                           | Dairy cattle | Poultry |
| Wheat straw and fodder, dry | AS                    | 0.83            | Highest                | 100            | 0.83                       |                                   |              |         |                                       |              |         |
| Sorghum                     | GC                    | 0.68            | Highest                | 86             | 1.2                        | 40                                | 40           | 80      | 0.27                                  | 0.27         | 0.544   |
| Almond hulls                | AM                    | 1.1             | Highest                | 90             | 2.2                        | 10                                | 10           |         | 0.11                                  | 0.11         |         |
| Cotton-seed hulls           |                       | 0.0020          | STMR-P                 | 90             | 0.0022                     |                                   |              |         |                                       |              |         |
| Cotton-seed meal            |                       | 0.0017          | STMR-P                 | 88             | 0.0019                     |                                   |              | 20      |                                       |              | 0.0004  |
| Total                       |                       |                 |                        |                |                            | 100                               | 100          | 100     |                                       |              |         |
|                             |                       |                 |                        |                |                            | Maximum dietary burden            |              |         | 1.64                                  | 1.93         | 0.54    |

*STMR dietary burden of farm animals estimated for spinosad*

| Commodity                   | Codex commodity group | Residue (mg/kg) | Basis of residue value | Dry matter (%) | Residue dry weight (mg/kg) | Feed allocation in total diet (%) |              |         | Residue contribution of feeds (mg/kg) |              |         |
|-----------------------------|-----------------------|-----------------|------------------------|----------------|----------------------------|-----------------------------------|--------------|---------|---------------------------------------|--------------|---------|
|                             |                       |                 |                        |                |                            | Beef cattle                       | Dairy cattle | Poultry | Beef cattle                           | Dairy cattle | Poultry |
| Apple pomace wet            | AB                    | 0.064           | STMR-P                 | 40             | 0.16                       | 10                                |              |         | 0.016                                 |              |         |
| Citrus pulp                 | AB                    | 0.12            | STMR-P                 | 91             | 0.13                       |                                   |              |         |                                       |              |         |
| Maize forage                | AF                    | 0.70            | STMR                   | 100            | 0.70                       | 40                                | 50           |         | 0.28                                  | 0.35         |         |
| Maize fodder                | AS                    | 0.46            | STMR                   | 100            | 0.46                       |                                   |              |         |                                       |              |         |
| Wheat straw and fodder, dry | AS                    | 0.215           | STMR                   | 100            | 0.22                       |                                   |              |         |                                       |              |         |
| Sorghum                     | GC                    | 0.165           | STMR                   | 86             | 0.19                       | 40                                | 40           | 80      | 0.08                                  | 0.08         | 0.15    |
| Almond hulls                | AM                    | 0.56            | STMR                   | 90             | 0.62                       | 10                                | 10           |         | 0.062                                 | 0.062        |         |
| Cotton seed hulls           | SO                    | 0.0020          | STMR-P                 | 90             | 0.0022                     |                                   |              |         |                                       |              |         |
| Cotton seed meal            | SO                    | 0.0017          | STMR-P                 | 88             | 0.0019                     |                                   |              | 20      |                                       |              | 0.00039 |
| Total                       |                       |                 |                        |                |                            | 100                               | 100          | 100     |                                       |              |         |
|                             |                       |                 |                        |                |                            | STMR dietary burden               |              |         | 0.43                                  | 0.49         | 0.15    |

The poultry dietary burdens are not discussed further in this example.

*Use of the results of farm animal feeding studies and dietary burdens to estimate maximum residue levels and STMR values for commodities of animal origin*

The calculations of dietary burden are compared with the feeding levels in studies of farm animals to estimate maximum residue levels and STMR values on the basis of the following guidelines.

- When a feeding level in a feeding study matches the dietary burden, the residue levels reported in the study can be used directly as estimates of residue levels in tissues, milk and eggs resulting from the dietary burden.
- When a feeding levels in a feeding study differs from the dietary burden, the resulting residues in tissues, milk and eggs can be estimated by interpolation between the closest feeding levels.



- When the dietary burden is below the lowest feeding level in the study, the resulting residues in tissues, milk and eggs can be estimated by applying the transfer factor (residue level in milk or tissue ÷ residue level in diet) at the lowest feeding level to the dietary burden.
- When the dietary burdens of beef and dairy cattle are different, the higher value should be used for calculating the residues in muscle, fat, liver and kidney.
- For estimating maximum and highest residue levels in meat, fat, liver, kidney and eggs, the highest residue level found in an animal in the relevant feeding group of the study should be used.
- For estimating STMR values in meat, fat, liver, kidney and eggs, the mean residue levels in animals in the relevant feeding group of the study are used.
- For estimating maximum residue levels and STMRs in milk, the mean residue levels in the animals in the relevant feeding group of the study are used.
- No more than about 30% above the highest feeding level can be extrapolated to a dietary burden.

The feeding levels in the farm animal feeding studies are entered into a table with the calculations of dietary burden and analysed on the basis of the above guidelines.

In the example of spinosad, the maximum dietary burdens of beef and dairy cattle are 1.6 and 1.9 mg/kg, respectively. Therefore, the levels of residues in tissues and milk are taken by interpolation from the 1 and 3 ppm feeding levels in the study.

The STMR dietary burdens (0.43 and 0.49 mg/kg) are below the lowest feeding level, 1 ppm. Therefore, the resulting residues in tissues and milk are calculated by applying the transfer factors at the lowest feeding level to the STMR dietary burdens.

The highest residue level in an individual tissue from an animal in the relevant feeding group is used with the highest dietary burden of residue to calculate the probable highest residue level in animal commodities. The mean tissue residue in the animals in the relevant feeding group is used with the STMR dietary burden to estimate the STMR values for animal commodities. For milk, the mean plateau residue level in milk from the relevant feeding group was used to estimate both the maximum residue level and the STMR.

The estimated dietary burden of spinosad was 1.6 mg/kg for beef cattle and 1.9 mg/kg for an actual feeding level of 3 ppm in the transfer study. The STMR value was 0.43 mg/kg for beef cattle and 0.49 mg/kg for dairy cattle for an actual feeding level of 1 ppm. The mean spinosad residue level in milk from dairy cattle was 0.13 mg/kg, while the value interpolated from the dietary burden and the feeding levels and the residue levels found in the transfer study was 0.087. The highest tissue residue levels in individual dairy cattle in the relevant feeding group were 1.7 mg/kg in fat (interpolated value, 1.1 mg/kg), 0.069 mg/kg in muscle (0.044 mg/kg), 0.44 mg/kg in liver (0.28 mg/kg) and 0.26 mg/kg in kidney (0.16 mg/kg). The mean residues in dairy cattle tissue (or milk) in the relevant feeding group were 0.044 mg/kg in milk (interpolated value, 0.022 mg/kg), 0.65 mg/kg in fat (0.32 mg/kg), 0.020 mg/kg in muscle (0.010 mg/kg), 0.13 mg/kg in liver (0.064 mg/kg) and 0.065 mg/kg in kidney (0.032 mg/kg).

As the STMR burden of dairy cattle exceeds that of beef cattle, it is used as the maximum residue level and the estimated STMR for fat, muscle, liver and kidney.

The highest residue levels expected in tissues and milk are: 1.1 mg/kg in fat, 0.16 mg/kg in kidney, 0.28 mg/kg in liver and 0.087 mg/kg in milk. The proposed STMR values are: 0.010 mg/kg in cattle meat, 0.032 mg/kg in cattle kidney, 0.064 mg/kg in cattle liver and 0.022 mg/kg in milk.

## 2.9 Statistical methods for estimating MRLs

The Meeting was informed of developments in the use of statistics to estimate the maximum residue level. A group of experts was formed in the USA, consisting of persons involved in MRL setting in the countries of the North American Free Trade Association and the European Food Safety Authority. They investigated the available procedures, primarily those used in the European Union, and decided to pursue a procedure in which a log normal distribution of data is assumed and the lower 95% upper confidence limit on the 95th percentile or the point estimate of the 99th percentile from normal Q–Q plots is used as an approximation of the maximum residue level. The plots give visual evidence of the degree of log normal behaviour of particular residue values. Some comparisons were made of the results obtained from application of this procedure and of the procedure used currently by the JMPR for data sets on fludioxonil. In most cases, there was good agreement. Small data sets often result in estimates of maximum residue levels that are considerably above the maximum. Statistically, this results from the uncertainty associated with few data points.

It was emphasized that any statistical system must be easy to use (spreadsheet) and be based on accepted statistical principles. Such systems might assist evaluators but could never replace professional judgement.

The method is still being developed. The Meeting expressed interest in receiving spreadsheets and documentation for evaluation, when available, and will await further developments.

## 2.10 Application of the recommendations of the OECD project on minimum data requirements to the work of the JMPR

The 2003 JMPR noted that some of the recommendations of the OECD York Workshop<sup>14</sup> and the FAO/OECD Zoning Steering Group were used routinely. The JMPR first considered the activities of the York Workshop at its 1999 Meeting, and subsequent Meetings have incorporated the Workshop recommendation into their work where practical. For example, as a result of the York Workshop, the JMPR has considered glasshouse trials conducted worldwide at the same GAP equivalent. Likewise, post-harvest trials conducted throughout the world at the same GAP are considered equivalent. The York Workshop also provided limited recommendations on crop translations, and the JMPR has been using that guidance routinely. It is noted, however, that the Zoning Steering Group addressed only foliar uses and that the York workshops considered primarily foliar and post-harvest uses. There is no guidance on soil treatment, seed treatment or use of herbicides. It was agreed that a pilot study would be conducted for the 2004 JMPR, in which the effect of full implementation of the recommendations would be considered for a new compound evaluation. Fludioxonil was selected.

The York Workshop and the follow-up Zoning Steering Group offered guidance that is potentially useful in two areas. First, they assigned the minimum number of trials required for evaluating a given pesticide–commodity combination for a maximum residue level, on the basis of three criteria: (1) the significance of the item in the diet of the general population; (2) the significance of the item in trade; and (3) the number of zones in which the commodity is grown. Unfortunately, the Workshop failed to define two of the three criteria adequately. It suggested that an item is ‘significant’ if its consumption represents  $\geq 0.5\%$  of the total diet in any region. Importance in trade and the criteria for designating zones were not defined, and the subsequent Zoning Steering Group did not find a correlation between climatic growing regions and crop residue levels. The Zoning Steering Group suggested that a definition of zones based on climate, e.g. temperate–wet, temperate–dry, cold and tropical, was not relevant.

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<sup>14</sup> *Minimum data requirements for establishing Maximum Residue Limits (MRLs) and import tolerances*, Doc. 2734/SANCO/99

In view of the undefined criteria, the Meeting found it difficult to implement the scheme in determining the minimum number of trials required for a given pesticide–commodity combination. In the absence of guidance, the Meeting based the required number of trial on one or several zones where the likelihood of the crop being grown in substantial quantity in very different geographic and agricultural practice areas was considered. Likewise, the Meeting used its best collective opinion in deciding on the significance of the commodity in trade. The Meeting considered significance relative to international trade and not local or regional trade; thus, a commodity might be of substantial economic importance to a nation or region but not significant on the global scale.

The second area of assistance was in defining representative commodities for crop groups and listing some acceptable translations of data. For example, the York Workshop decided that field trial data for orange or grapefruit and mandarin or lemon could be used to represent all citrus fruit and that data for tomato and pepper could be extrapolated to okra and eggplant. This aspect was not, however, completed; for example, no recommendations were made for leafy vegetables. The Meeting noted that the Codex classification system for food and feed items is currently undergoing a limited revision, and this may be of assistance.

The Meeting compiled a list of commodities for which the following information was available: recommendations on maximum residue levels for fludioxonil, the number of trials available at GAP, the decision of the JMPR, the apparent requirements under the York Workshop criteria, and the result of application of the York Workshop criteria. The list is shown below.

*Maximum residue level recommendations for fludioxonil*

| Commodity               | No. of trials at GAP | JMPR MRL recommendation           | OECD minimum database |                                    |               |                   |
|-------------------------|----------------------|-----------------------------------|-----------------------|------------------------------------|---------------|-------------------|
|                         |                      |                                   | Assumptions           |                                    |               | Recommendation    |
|                         |                      |                                   | No. of zones          | Significant in trade (T), diet (D) | No. of trials |                   |
| Pears                   | 7                    | Yes                               | 2–3                   | D                                  | 8             | No                |
| Stone fruit             | 11                   | Yes (Po)                          | Po                    | T, D                               | 8             | Yes               |
| Grapes                  | 18                   | Yes                               | 2–3                   | T, D                               | 12            | Yes               |
| Strawberry              | 25                   | Yes                               | 2–3                   | D                                  | 8             | Yes               |
| Raspberry               | 4                    | Yes                               | 2–3                   |                                    | 4             | Yes               |
| Blackberry              | 0                    | Yes, translation of raspberry     |                       |                                    |               | Yes (translation) |
| Dewberry                | 0                    | Yes, translation of raspberry     |                       |                                    |               | Yes (translation) |
| Blueberry               | 8                    | Yes                               | 2–3                   |                                    | 4             | Yes               |
| Spring onions           | 3                    | Yes                               | 2–3                   |                                    | 4             | No                |
| Bulb onions             | 13                   | Yes                               | 2–3                   | D                                  | 8             | Yes               |
| Broccoli                | 7                    | Yes                               | 2–3                   | D                                  | 8             | No                |
| Cabbage                 | 6                    | Yes                               | 2–3                   | D                                  | 8             | No                |
| Cucumber                | 13                   | Yes                               | 2–3                   | D                                  | 8             | Yes               |
| Summer squash           | 2                    | Yes (support from cucumber)       | 2–3                   |                                    | 4             | No                |
| Tomato                  | 16                   | Yes                               | 2–3                   | T, D                               | 12            | Yes               |
| Bell pepper             | 10                   | Yes                               | 2–3                   | T, D                               | 12            | Yes               |
| Eggplant                | 4                    | Yes                               | 2–3                   |                                    | 3             | Yes               |
| Sweet corn (on-the-cob) | 8                    | Yes                               | 2–3                   | D                                  | 8             | Yes               |
| Lettuce, head           | 17                   | Yes                               | 2–3                   | T, D                               | 12            | Yes               |
| Watercress              | 2                    | Yes (support from mustard greens) | 2–3                   |                                    | 3             | No                |

| Commodity                         | No. of trials at GAP | JMPR MRL recommendation                  | OECD minimum database |                                    |               |                   |
|-----------------------------------|----------------------|------------------------------------------|-----------------------|------------------------------------|---------------|-------------------|
|                                   |                      |                                          | Assumptions           |                                    |               | Recommendation    |
|                                   |                      |                                          | No. of zones          | Significant in trade (T), diet (D) | No. of trials |                   |
| Mustard greens                    | 7                    | Yes (support form watercress)            | 2–3                   |                                    | 3             | Yes               |
| Bean pod with seed                | 22                   | Yes                                      | 2–3                   | T, D                               | 12            | Yes               |
| Pea with pod                      | 0                    | Translation from bean with pod           |                       |                                    |               | Yes (translation) |
| Peas (succulent)                  | 6                    | Yes                                      | 2–3                   | T, D                               | 12            | No                |
| Pea and bean (dry)                | 5                    | Yes                                      | 2–3                   | D                                  | 8             | No                |
| Potato                            | 17                   | Yes                                      | 2–3                   | T, D                               | 12            | Yes               |
| Carrot                            | 7                    | Yes                                      | 2–3                   | D                                  | 8             | No                |
| Asparagus                         | 2                    | No                                       | 2–3                   |                                    | 3             | No                |
| Cereal grains                     | 71                   | Yes (wheat, rye, barley, maize, sorghum) | > 3                   | T, D                               | 16            | Yes               |
| Pistachio nuts                    | 3                    | Yes                                      | 1                     |                                    | 3             | Yes               |
| Rape-seed                         | 15                   | Yes                                      | 2–3                   | T                                  | 8             | Yes               |
| Cotton-seed                       | 8                    | Yes                                      | 2–3                   | T, D                               | 12            | No                |
| Chives                            | 2                    | Yes                                      | 1                     |                                    | 3             | No                |
| Basil                             | 2                    | Yes                                      | 1                     |                                    | 3             | No                |
| Maize forage                      | 7                    | Yes                                      | > 3                   | N/A                                | 10            | No                |
| Fodder and straw of cereal grains | 50                   | Yes                                      | > 3                   | N/A                                | 10            | Yes               |

Po, the recommendation accommodates post-harvest treatment of the food commodity; N/A, not applicable

<sup>1</sup> Crops with no trials at GAP are not listed.

The Meeting noted that it had extended estimates of maximum residue levels to commodities for which use of the OECD guidance would not have so indicated (cotton-seed, basil, chives, peas, peas and beans (dry), watercress, summer squash, broccoli, cabbage, green onions, pears). These assignments were based, however, on application of criteria that are not defined or only partially described. For example, if one zone were assumed (rather than two or three), use of the OECD guidance would have led to maximum residue level recommendations for all commodities except the herbs, summer squash and watercress.

These evaluations of additional commodities for maximum residue levels are the result of independent scientific judgement by the JMPR. For example, the Meeting considered six or seven trials (in cabbage, pear, broccoli) conducted under GAP and properly documented to be acceptable.

Although the Meeting usually requires a minimum of three or four trials for a minor commodity, it considered two fully documented trials under GAP adequate for the herbs chives and basil. As these commodities are herbs, their consumption is extremely low and pesticide residues on them would not usually pose a hazard. Because the maximum residue level was based on only two trials, the Meeting estimated a considerably higher level than the highest residue level: The high residue level for chives was 3.9 mg/kg, and the Meeting estimated a maximum residue level of 10 mg/kg.

The Meeting considered five trials to be adequate for establishing maximum residue levels for dry beans and dry peas, as the residues were below the LOQ. The OECD recommendations suggest eight trials.

A similar situation existed for cotton-seed. The GAP is for seed treatment use, and all the residue levels were below the LOQ. Metabolism studies after seed treatment and other seed treatment trials predict residues below the LOQ. Thus, the Meeting considered five trials to be acceptable, although the York Workshop would have required eight.

The Meeting also noted that, while the York Workshop provided some information on the translation of residue values for one commodity to another, it did not provide for the mutual support of other commodities with similar use patterns. In the present example, the Meeting agreed to use data on cucumber to support the MRL for summer squash (zucchini) and to use data on mustard greens to support the value for watercress. This is common practice by many national governments and is based on similarities in crop morphology. The York Workshop did provide for the translation of data on raspberry to blackberry and dewberry and the translation of data on bean with pod to pea with pod.

The Meeting recalled the conclusion of the Zoning Steering Group, that trials on a given commodity conducted at the same GAP with similar residues on day 0 be considered equivalent regardless of geographic location. The Group suggested that application method, crop type and local agricultural practices are major contributors to differences in residue levels among trials conducted under the same GAP. Climate has only a minor direct effect. The JMPR suggested, therefore, that hypothetical zones (not geographical zones) be developed on the basis of crop type and variations in agricultural practice. For example, wheat is grown in a relatively uniform manner worldwide (one zone), while grapes are grown under a variety of conditions (of crop height, leaf numbers and plant density; multiple zones).

The Meeting concluded that some of the recommendations of the York Workshop and Zoning Steering Group used by the JMPR will continue to be considered as auxiliary advice but that substantial additional work is required to make the recommendations generally applicable as guidance. Areas in which additional effort is needed include: (1) defining significance in trade, perhaps with a table of commodities and their classifications; (2) determining the criteria for zones and the number of zones for each commodity; (3) extending the list of commodity translations for the purpose of recommending a maximum residue level for one commodity on the basis of available field trial data for another commodity; and (4) completing the list of representative crops for the purpose of recommending group maximum residue levels.

## **2.11 Alignment within one year of toxicological and residue evaluations for new and periodically reviewed compounds**

When a new compound or one undergoing periodic review is evaluated, it is generally preferable to conduct the toxicological and residue reviews in the same year. Practical problems may, however, arise; e.g. when the residue definition is uncertain, the residue evaluation cannot proceed satisfactorily or efficiently. In such cases, it is preferable that the toxicological evaluation precede the residue evaluation.

The Meeting recommended that the toxicological and residue evaluations of new compounds or those undergoing periodic review be scheduled for the same year, when practical. When the residue definition is problematic (e.g. different residue definitions in different national and regional registration systems), the toxicological evaluation should be scheduled 1 year ahead of the residue evaluation.

### 3. DIETARY RISK ASSESSMENT FOR PESTICIDE RESIDUES IN FOOD

#### Assessment of risk from long-term dietary intake

Risks associated with long-term dietary intake were assessed for compounds for which MRLs were recommended and STMRs estimated at the present and previous Meetings. Dietary intakes were calculated by multiplying the concentrations of residues (STMR or STMR-P values or recommended MRLs) by the average daily per capita consumption estimated for each commodity on the basis of the GEMS/Food diet<sup>1,2</sup>. International estimated daily intakes (IEDIs) were derived when STMR or STMR-P values were available, and theoretical maximum daily intakes (TMDIs) were calculated when only existing or recommended MRLs were available. Codex MRLs that have been recommended by the JMPR for withdrawal were not included in the estimates.

Long-term dietary intakes are expressed as a percentage of the ADI for a 60-kg person, with the exception of the intake calculated for the Far Eastern diet, in which a body weight of 55 kg is used. The estimates are summarized in Table 1. Percentages are rounded to one whole number up to 9 and to the nearest 10 above that. Percentages above 100 should not necessarily be interpreted as giving rise to a health concern because of some conservative assumptions used in the assessments. The detailed calculations of long-term dietary intake are given in Annex 3.

The Meeting drew attention to the use of residue levels in muscle tissue for estimating dietary intake of residues in meat of fat-soluble compounds. Previously, residue levels in trimmable fat, with adjustment by a default factor, were used to estimate dietary intake from meat.

Assessments of long-term risk for betazone, captan, carbofuran, fenpropimorph, fenpyroximate, folpet, dimethipin, methamidophos and pirimiphos-methyl were considered by previous meetings. For these compounds, the recommendations made at this Meeting will not significantly affect the previous assessments.

Calculations of dietary intake can be further refined at the national level by taking into account more detailed information, as described in the guidelines for predicting intake of pesticide residues.<sup>1</sup>

**Table 1. Summary of risk assessments of long-term dietary intake conducted by the 2001 JMPR**

| Compound                   | ADI         | Intake range (% of | Type of assessment |
|----------------------------|-------------|--------------------|--------------------|
| Codex code Name            | (mg/ kg bw) | maximum ADI)       |                    |
| 017 Chlorpyrifos           | 0–0.01      | 3–30               | IEDI               |
| 149 Ethoprophos            | 0–0.0004    | 5–10               | IEDI               |
| 037 Fenitrothion           | 0–0.05      | 110–330            | IEDI               |
| 211 Fludioxonil            | 0–0.4       | 0–1                | IEDI               |
| 158 Glyphosate             | 0–1         | 1                  | TMDI               |
| 049 Malathion              | 0–0.3       | 0                  | IEDI               |
| 212 Metalaxyl/ Metalaxyl M | 0–0.08      | 2–10               | TMDI               |
| 094 Methomyl               | 0–0.02      | 1–20               | IEDI               |
| 166 Oxydemeton methyl      | 0–0.0003    | 3–30               | IEDI               |
| 057 Paraquat               | 0–0.005     | 2–5                | IEDI               |
| 112 Phorate                | 0–0.0007    | 40–200             | TMDI               |
| 101 Pirimicarb             | 0–0.02      | 3–20               | TMDI               |

<sup>1</sup> WHO (1997) *Guidelines for predicting dietary intake of pesticide residues*. 2nd revised edition, GEMS/Food Document WHO/FSF/FOS/97.7, Geneva

<sup>2</sup> WHO (1997) *Food consumption and exposure assessment of chemicals*. Report of a FAO/WHO Consultation. Geneva, Switzerland, 10–14 February 1997, Geneva

| Compound        |                       | ADI     | Intake range (% of | Type of assessment |
|-----------------|-----------------------|---------|--------------------|--------------------|
| Codex code Name |                       | (mg/kg) | maximum ADI        |                    |
| 142             | Prochloraz            | 0–0.01  | 7–10               | IEDI               |
| 160             | Propiconazole         | 0–0.07  | 0–1                | TMDI               |
| 105             | Propineb <sup>1</sup> | 0–0.007 | 4–30               | IEDI               |
| 210             | Pyraclostrobin        | 0–0.03  | 0–3                | IEDI               |
| 203             | Spinosad              | 0–0.02  | 9–30               | IEDI               |
| 133             | Triadimefon           | 0–0.03  | 1–6                | TMDI               |
| 168             | Triadimenol           | 0–0.03  | 1–20               | TMDI               |
| 213             | Trifloxystrobin       | 0–0.04  | 1–2                | IEDI               |

### ***Spices and dried chili peppers***

Long-term dietary intake (IEDI) from the consumption of spices was calculated for 28 pesticides for which recommendations were made at the present Meeting on the basis of monitoring data (General item 2.6; Annex 5). For these compounds, the additional contributions to the IEDI from the consumption of spices were < 1% of the respective ADIs for all GEMS/Food regional diets.

The Meeting also calculated TMDIs from the consumption of dried chili peppers using maximum residue levels estimated at this Meeting for 46 pesticides, on the basis of MRLs for peppers (Annex 5). The TMDIs for carbaryl and dimethoate were > 100 % of the respective ADIs in at least one regional diet.

The TMDIs were > 5–100% of the respective ADIs in at least one regional diet for acephate, azinphos-methyl, carbendazim, chlorothalonil, chlorpyrifos, chlorpyrifos-methyl, cyhexatin, cyromazine, dicofol, ethephon, ethoprophos, fenarimol, methamidophos, methomyl, monocrotophos, oxamyl, phosphamidon, procymidone, profenofos, tebufenozide and vinclozolin. For these compounds, a long-term intake calculation based on all uses should be performed before the risk assessment can be finalized.

The TMDIs were ≤ 5% of the respective ADIs in all regional diets for abamectin, benalaxyl, cyfluthrin, cypermethrin, diazinon, dichlofluanid, dinocap, dithiocarbamates, fenpropathrin, fenvalerate, imidacloprid, metalaxyl, methoxyfenozide, permethrin, piperonyl butoxide, propamocarb, pyrethrins, quintozone, spinosad, tebuconazole, tolylfluanid, triadimefon and triadimenol. The Meeting agreed that the intake of these compounds through consumption of dried chili peppers would not significantly affect the risk assessment based on all other uses of the compounds.

### **Assessment of risk from short-term dietary exposure**

Risks associated with short-term dietary intake were assessed for compounds for which STMR and highest residue values were estimated at the present and previous Meetings and for which acute reference doses (ARfDs) has been established, in commodities for which data on consumption were available. The procedures used for calculating the short-term intake are described in detail in sections 2.10 and 3 of the report of the 2003 JMPR.<sup>3</sup>

A risk assessment for short-term dietary intake was conducted for each commodity–compound combination by assessing the IESTI as a percentage of the ARfD. When the maximum residue level was estimated for a Codex commodity group (e.g. citrus fruits), intakes were calculated for individual commodities within the group.

On the basis of data received by the present or previous Meetings, the establishment of an ARfD for bentazone, metalaxyl M, fludioxinil, glyphosate, spinosad, trifloxystrobin was considered unnecessary. The intake of these compounds was therefore not estimated.

An ARfD might be necessary for pirimiphos-methyl but has not yet been established. Therefore, the short-term risk assessment could not be finalized. The Meeting recommended that this compound be evaluated for the establishment of ARfDs in the near future.

<sup>3</sup> Annex 6, reference 98

ARfDs were established for phorate, pirimicarb, propiconazole, triadimefon and triadimenol, but short-term intakes were not calculated as STMR and highest residue values were not available for these compounds.

On the basis of data received by the present Meeting, the establishment of ARfDs for captan and folpet was considered necessary only for women of child-bearing age. The corresponding IESTI could, however, be calculated only from the consumption data available for the general population.

The recommendation made for methamidophos at the present Meeting does not affect the previous assessment for this compound.

The short-term intakes, as percentages of the ARfDs, of the general population and of children are summarized in Table 2. The percentages are rounded to one whole number up to 9 and to the nearest 10 above that. Percentages above 100 should not necessarily be interpreted as giving rise to a health concern because of some conservative assumptions used in the assessments. The detailed calculations of short-term dietary intakes are given in Annex 4.

**Table 2. Summary of risk assessments of short-term dietary intake conducted by the 2004 JMPR**

| Compound   |                   | ARfD (mg/kg bw)  | Commodity               | Percentage of ARfD |                    |
|------------|-------------------|------------------|-------------------------|--------------------|--------------------|
| Codex code | Name              |                  |                         | General population | Children ≤ 6 years |
|            |                   |                  | Grape                   | 150                | –                  |
| 007        | Captan            | 0.3 <sup>1</sup> | Other 19 commodities    | 0–100              | –                  |
| 096        | Carbofuran        | 0.009            | All 20 commodities      | 1–50               | 0–100              |
| 017        | Chlorpyrifos      | 0.1              | All 7 commodities       | 0–10               | 0–40               |
| 151        | Dimethipin        | 0.2              | All 12 commodities      | 0                  | 0–1                |
| 149        | Ethoprophos       | 0.05             | All 11 commodities      | 0–1                | 0–3                |
| 037        | Fenitrothion      | 0.04             | Maize                   | 80                 | 160                |
|            |                   |                  | Wheat bran, unprocessed | 90                 | 150                |
|            |                   |                  | Wholemeal bread         | 50                 | 120                |
|            |                   |                  | Other 22 commodities    | 0–100              | 0–80               |
| 188        | Fenpropimorph     | 0.2              | All 15 commodities      | 0–7                | 0–10               |
| 193        | Fenpyroximate     | 0.01             | Apple                   | 50                 | 130                |
|            |                   |                  | Grape                   | 120                | 310                |
|            |                   |                  | Other 7 commodities     | 0–10               | 0–30               |
| 041        | Folpet            | 0.2 <sup>1</sup> | Lettuce, head           | 190                | –                  |
|            |                   |                  | Other 9 commodities     | 1–100              | –                  |
| 049        | Malathion         | 2                | 6 commodities           | 0–4                | 0–10               |
| 094        | Methomyl          | 0.02             | Pepper                  | 20                 | 20                 |
| 166        | Oxydemeton methyl | 0.002            | Apple                   | 50                 | 130                |
|            |                   |                  | Cabbage, head           | 50                 | 120                |
|            |                   |                  | Grape                   | 80                 | 220                |
|            |                   |                  | Orange                  | 30                 | 120                |
|            |                   |                  | Other 16 commodities    | 0–30               | 0–90               |
| 057        | Paraquat          | 0.006            | All 44 commodities      | 0–20               | 0–50               |
| 142        | Prochloraz        | 0.1              | Mushroom                | 130                | 150                |
|            |                   |                  | Other 46 commodities    | 0–30               | 0–70               |
| 105        | Propineb          | 0.1 <sup>2</sup> | Pepper                  | 110                | 120                |
|            |                   |                  | Other 12 commodities    | 0–30               | 0–90               |
| 210        | Pyraclostrobin    | 0.05             | All 37 commodities      | 0–30               | 0–90               |

<sup>1</sup> Applies only to women of child-bearing age

<sup>2</sup> Interim ARfD



***Spices and dried chili peppers***

Short-term dietary risk assessments from the consumption of spices were performed for 12 pesticides for which recommendations were made at the present Meeting on the basis of monitoring data (item 2.6, Annex 5), when ARfD values were available. The IESTI ranged from 0 to 30 % of the ARfD for both the general population and children for azinphos-methyl, chlorpyrifos, diazinon, dimethoate, disulfoton, endosulfan, fenitrothion, malathion, methamidophos, parathion-methyl and phosalone. The intake of mevinphos represented 170% of the ARfD for the general population and 160% for children.

Short-term dietary risk assessments from the consumption of dried chilli peppers were performed for 14 pesticides for which ARfD values were established, using the maximum residue level estimated by the present Meeting. The intakes ranged from 0 to 100% of the respective ARfDs for the general population and children for acephate, carbaryl, chlorpyrifos, diazinon, ethephon, ethoprophos, imidacloprid, methamidophos, methoxyfenozide, pyrethrins and tolyfluanid. The intakes were 120% of the ARfD for both populations for dimethoate. They were 260% of the ARfD for the general population and 270% for children for oxamyl.

## 4. EVALUATION OF DATA FOR ESTABLISHING VALUES FOR ACCEPTABLE DAILY INTAKES AND ACUTE REFERENCE DOSES FOR HUMANS, MAXIMUM RESIDUE LIMITS AND SUPERVISED TRIAL MEDIAN RESIDUE LEVELS

### 4.1 BENTAZONE (172)

#### TOXICOLOGY

##### *Evaluation for an acute reference dose*

Bentazone is a herbicide that was first evaluated by the JMPR in 1991, when an ADI of 0–0.1 mg/kg bw was allocated on the basis of the NOAEL of 9 mg/kg bw per day in a long-term study in rats and a safety factor of 100. Further data were made available to the 1998 JMPR, including observations in humans and a 90-day study in rats fed with 6-hydroxybentazone, a metabolite of bentazone. Data from studies of genotoxicity with 6-hydroxybentazone were also supplied. It was concluded that 6-hydroxybentazone was less toxic than bentazone, and the ADI of 0–0.1 mg/kg bw was maintained. Data were not evaluated to establish an ARfD. The present Meeting re-evaluated some of the previously evaluated data in order to establish an ARfD, and two cases of acute human poisoning were described.

The oral median lethal dose (LD<sub>50</sub>) for bentazone was 1200–2500 mg/kg bw in rats. In 13-week studies in mice, rats and dogs, interference with blood clotting was a consistently observed effect. There was prolongation of the prothrombin and partial thromboplastin times in mice and rats, and prolongation of the prothrombin and bleeding time in dogs. Additionally, extramedullary haematopoiesis, haemorrhage and haemosiderosis were found in mice at autopsy. Toxicological effects in rats were less dramatic, the NOAEL being identified on the basis of clinical chemistry changes. In dogs, clinical effects, such as hyperactivity, ataxia, prostration and tremor, were seen. At the highest dose in dogs, at histopathological examination of tissues post mortem there was congestion and necrosis in the liver, together with fatty change and, in the spleen, evidence of extramedullary haematopoiesis. Fatty change in the myocardium and cloudy swelling of the renal tubular cells were also observed. The NOAEL for the study in mice was 400 ppm (equal to 90 mg/kg bw per day) on the basis of prolonged prothrombin and partial thromboplastin times at higher dietary concentrations. The NOAEL for the study in rats was 400 ppm (equal to 25.3 mg/kg bw per day) on the basis of clinical chemistry changes observed at the next highest dietary concentration. In the study in dogs, the NOAEL was 300 ppm (equal to 12.0 mg/kg bw per day) on the basis of clinical effects observed at higher dietary concentrations. Three deaths were observed at the highest dose in weeks 11 and 12 of the study. In a 1-year study in dogs, clinical signs (emaciation, dehydration, hyperaemia, alopecia and diarrhoea, which was occasionally bloody) were seen at the highest dietary concentration. The NOAEL for the study was 400 ppm (equal to 13.1 mg/kg bw per day) on the basis of clinical signs, weight loss and anaemia at the highest dietary concentration. It was not considered appropriate to set an ARfD on the clinical signs, reduced body weight or haematological changes occurring in dogs, since significant clinical effects were not seen early in these two studies.

Three studies of developmental toxicity in rats treated by gavage (two studies) or by dietary administration (one study) were evaluated by the Meeting. In the earlier study of rats treated by gavage, neither maternal nor fetal toxicity was seen at any dose; the NOAEL for both maternal and fetal toxicity was thus 200 mg/kg bw per day, the highest dose tested. In the later study in rats treated by gavage, in which higher doses were administered, the NOAEL was 100 mg/kg bw per day on the basis of maternal toxicity (decreased food consumption) and fetal toxicity (postimplantation loss, reduced fetal weight and incompletely ossified fetal skeletons). In the study of developmental toxicity in rats given diets containing bentazone, the NOAEL for maternal toxicity was 4000 ppm (equal to 324 mg/kg per day) on the basis of decreased weight gain and food consumption at 8000 ppm. The NOAEL for fetal toxicity was also 4000 ppm

(equal to 324 mg/kg bw per day) on the basis of decreased fetal weights and fetal liver petechiae at 8000 ppm. Bentazone was not teratogenic in any of the studies of developmental toxicity in rats. The Meeting assessed two studies of developmental toxicity in rabbits. In one study, the NOAEL for maternal and fetal toxicity was 150 mg/kg bw per day, the highest dose tested; neither maternal nor fetal toxicity was observed at any dose. In the second study, which was conducted using higher doses than the earlier study, the NOAEL for maternal toxicity was 150 mg/kg bw per day on the basis of reduction in maternal food consumption at 375 mg/kg bw per day. Postimplantation loss was increased at 375 mg/kg bw per day and there was total implantation loss in one dam. Bentazone was not teratogenic in either study of developmental toxicity in rabbits.

Two case reports of fatal self-poisoning in humans were characterized by vomiting, diarrhea, drowsiness and death from cardiac arrest.

### ***Toxicological evaluation***

The Meeting concluded that the establishment of an ARfD was unnecessary. An addendum to the toxicological monograph was prepared

#### ***Estimate of acute reference dose***

Unnecessary

#### ***Studies that would provide information useful for continued evaluation of the compound***

Further observations in humans

## **DIETARY RISK ASSESSMENT**

### ***Short-term intake***

The 2004 JMPR decided that it was not necessary to establish an ARfD for bentazone. The Meeting therefore concluded that the short-term dietary intake of bentazone residues is unlikely to present a public health concern.

## **4.2 CAPTAN (007)**

### **TOXICOLOGY**

#### ***Evaluation for an acute reference dose***

Captan is a fungicide used for the control of fungal diseases in crops. The JMPR evaluated captan in 1963, 1965, 1969, 1973, 1978, 1982, 1984, 1990 and 1995. Toxicological monographs were prepared in 1963, 1965 and 1969 and addenda to the monographs were prepared in 1973, 1977, 1978, 1982, 1984, 1990 and 1995. In 1984, an ADI of 0–0.1 mg/kg bw was established on the basis of a NOAEL of 12.5 mg/kg bw per day in studies of reproductive toxicity in rats and monkeys. The present Meeting considered the requirement for an ARfD, based on data from the previous evaluations for JMPR and from new studies.

In mice treated orally with captan, the captan molecule is largely degraded to 1,2,3,6-tetrahydrophthalimide (THPI) and thiophosgene (via thiocarbonyl chloride) in the stomach before reaching the duodenum. No captan was detected in blood or urine. Studies of metabolism in vitro with human blood

revealed that captan is rapidly degraded to THPI, with a calculated half-life of 1–4 s. Thiophosgene is detoxified by reaction with, e.g. cysteine or glutathione and is ultimately rapidly excreted.

The acute oral toxicity of captan in rats is low ( $LD_{50}$ , > 5000 mg/kg bw). Mice fed diets containing captan at a concentration of 3000 ppm, equal to 440 mg/kg bw per day, for 28 days showed an initial reduction in food consumption of about 37%. Food consumption gradually recovered over the first week of treatment, although it remained lower than that of controls throughout the 4-week treatment period. After 1 day, no treatment-related macroscopic and microscopic changes were observed in the duodenum or any other tissue examined. From day 3 onwards, the duodenum showed crypt cell hyperplasia, shortening of villi and a general disorganization of the villus enterocytes. From day 7 onward, immature cells were seen at the villus tips.

In a 28-day range-finding study in which dogs were given captan at doses of 30 to 1000 mg/kg bw per day, dose-related emesis, reduced body-weight gain and food consumption were observed in all treatment groups. No other clinical signs were observed. Haematological parameters and histopathology of the duodenum were within normal limits.

In a study from the published literature, the teratogenic effects of a number of phthalimide derivatives, including captan, were tested in pregnant golden hamsters. The Meeting noted that this study had major limitations (e.g. small number of animals per dose, limited reporting of the data) and is therefore of limited value. It does, however, suggest that developmental effects may occur after a single exposure to captan, albeit at maternally toxic doses.

In a study of developmental toxicity in rats treated by gavage, captan was not teratogenic. The NOAEL for maternal toxicity was 18 mg/kg bw per day on the basis of a reduction in body weight and food consumption. The NOAEL for offspring toxicity was 90 mg/kg bw per day on the basis of the reduction in fetal body weight and an increased incidence of skeletal variations.

In a study in rabbits treated by gavage, the NOAEL for maternal toxicity was 10 mg/kg bw per day on the basis of a markedly reduced body-weight gain and reduced food consumption at 30 mg/kg bw per day. The NOAEL for embryo- and fetotoxicity was 10 mg/kg bw per day on the basis of increases in skeletal variations at 30 and 100 mg/kg bw per day. At 100 mg/kg bw per day, increased incidences of early and late intra-uterine deaths were observed, as were increased incidences of several malformations. The NOAEL for these effects was 30 mg/kg bw per day. Multiple malformations observed in two fetuses in the group receiving the intermediate dose were considered to be incidental. In another study in rabbits treated by gavage, the NOAEL for maternal toxicity was 10 mg/kg bw per day on the basis of reduced body-weight gain and food consumption at 40 mg/kg bw per day. On the basis of the increase in postimplantation losses and the increase in incidence of minor skeletal variations at 160 mg/kg bw per day, the NOAEL for embryo- and fetotoxicity was 40 mg/kg bw per day. In a third study in rabbits treated by gavage, the NOAEL for maternal toxicity was 12 mg/kg bw per day on the basis of reductions in body-weight gain during the initial phase of treatment. The NOAEL for embryo- and fetotoxicity was 25 mg/kg bw per day on the basis of a reduction in fetal body weight at 60 mg/kg bw per day. The Meeting considered that maternal toxicity and the associated increases in skeletal variations and fetal body-weight reductions observed were likely to be caused by high local concentrations of captan produced by administration by gavage and are not considered to be relevant to dietary exposure.

While few data on humans are available, captan is known to have caused allergic dermatitis and eye irritation in humans. After ingesting 7.5 g of Captan 50 WP, which is a suspension of captan mixed with water (ratio, 50%), a 17-year-old woman (body weight not reported) experienced some clinical signs, which started 3 h after ingestion and recovered within 72 h. Assuming a body weight of 50–60 kg, this intake equates to a dose of 62.5–75 mg/kg bw.

***Toxicological evaluation***

Other than developmental effects, captan produced no toxicological effects that might be considered to be a consequence of acute exposure. The Meeting concluded that it was not necessary to establish an ARfD for the general population, including children aged 1–6 years for whom separate data on dietary intake are available. The Meeting concluded that it might be necessary to establish an ARfD to protect the embryo or fetus from possible effects in utero. Such an ARfD would apply to women of childbearing age.

The maternal toxicity and associated increases in skeletal variations and fetal body-weight reductions observed in studies of developmental toxicity in rabbits are likely to be caused by high local concentrations of captan and are not considered to be relevant to dietary exposure. However, the observed intra-uterine deaths and fetal malformations could not, with confidence, be attributed to maternal toxicity.

The Meeting concluded that the database was insufficient (in particular, with regard to the absence of studies on the developmental effects of THPI) to establish the mode of action by which the increased incidences of intra-uterine deaths and of fetuses with malformations, observed at 100 mg/kg bw per day (NOAEL, 30 mg/kg bw per day) in rabbits, were induced. As a consequence, their relevance for deriving an ARfD could not be dismissed. Therefore the Meeting established an ARfD of 0.3 mg/kg bw, based on a NOAEL of 30 mg/kg bw per day for increased incidences of intra-uterine deaths and malformations at 100 mg/kg bw per day in the study in rabbits and a safety factor of 100. The use of a safety factor of 100 was considered to be conservative; although the mode of action by which the developmental effects were induced is uncertain, they are possibly secondary to maternal toxicity. The ARfD also covers the effects observed in the case report in humans. The Meeting noted that it might be possible to refine the ARfD using the results of an appropriately designed study.

An addendum to the toxicological monograph was prepared.

***Estimate of acute reference dose***

0.3 mg/kg bw for women of childbearing age

Unnecessary for the general population

**DIETARY RISK ASSESSMENT*****Short-term intake***

The Meeting established an ARfD (0.3 mg/kg bw) for captan for women of childbearing age and decided that an ARfD was unnecessary for the general population including children aged 1–6 years. Women of childbearing age are also part of the general population.

In the absence of relevant studies on the developmental effects of THPI, the Meeting was unable to determine whether or not THPI should be excluded from the residue for dietary risk assessment. The Meeting was not able to finalize the risk assessment before an evaluation of the residue definition for risk assessment and associated residue values for dietary intake estimation had been completed.

**4.3 CARBOFURAN (096)/ CARBOSULFAN (145)****RESIDUE AND ANALYTICAL ASPECTS**

Carbofuran, resulting from use of carbosulfan, was reviewed for residue levels within the periodic review programme in 1997. When the compound was re-evaluated by the JMPR in 2002 and 2003, short-term

risks were assessed for commodities for which recommendations had been made at those Meetings: rice, sweet corn, maize and potato. The CCPR at its Thirty-fifth Session, taking into account concerns expressed by the Delegation of Australia and the Observer from the European Commission, requested GEMS/Food to perform a full short-term intake assessment of carbofuran, to include all the commodities not evaluated previously for which recommendations existed. The assessment was presented to the CCPR at its Thirty-sixth Session (CX/PR 03/4). Except for the consumption of oranges (sweet and sour) by children, none of the IESTI value exceeded the ARfD of 0.009 mg/kg bw. The assessment was conducted with the highest residue (HR) level in the edible portion of 0.5 mg/kg, recommended by the 1997 JMPR for oranges, sweet, sour, from a residue data set in whole orange derived from 53 supervised trials conducted with carbosulfan according to GAP. A maximum residue level of 0.5 mg/kg and a STMR of 0.1 mg/kg were also recommended.

At its Thirty-sixth Session, the Committee noted (ALINORM 04/27/24) that the European Commission had established an ARfD 10 times lower than that established by JMPR. The Committee decided to return to Step 6 the draft MRLs for cantaloupe; cucumber; mandarin; oranges, sweet, sour; squash, summer; and sweet corn (corn-on-the-cob) to address concern about short-term intake.

For the purposes of dietary intake, the residue definition for carbofuran arising from use of carbosulfan and carbofuran is carbofuran + free and conjugated 3-OH carbofuran, expressed as carbofuran. The analytical methods include an acid hydrolysis step to release the conjugate.

At the present Meeting, data on residues in orange pulp in supervised trials conducted with carbosulfan and submitted to the 1997 JMPR were evaluated.

### ***Results of supervised trials on crops***

Six trials in Spain conducted according to GAP with carbosulfan in orange, evaluated by the 1997 JMPR, showed residue levels of carbamates (carbosulfan, carbofuran or 3-OH carbofuran) of < 0.05 mg/kg at 0 days (four trials), 45 days (six trials) and 105 days (four trials). The post-harvest interval (PHI) is 110 days. The residue levels in peel ranged from 0.21 to 0.84 mg/kg 45 days after the last application (two trials) and from < 0.05 to 0.25 mg/kg within 110 days' PHI (four trials).

The Meeting agreed that it is unlikely that residues of carbamates arising from the use of carbosulfan will be present in orange pulp at levels higher than the LOQ (0.05 mg/kg). The Meeting estimated an STMR and a highest residue level of 0.05 mg/kg for carbofuran in orange, sweet, sour.

This estimate is supported by a study on metabolism evaluated by the 1997 JMPR, in which the pulp of oranges treated with <sup>14</sup>C-carbosulfan contained no more than 0.3% of the total radioactive residues 30 days after treatment.

## **DIETARY RISK ASSESSMENT**

### ***Long-term intake***

The Meeting agreed that the STMR in the edible portion of orange estimated by the present Meeting would result in a lower IEDI than that calculated by the 2002 JMPR. The Meeting confirmed the previous conclusion that the long-term intake of carbofuran residues arising from use of carbosulfan and/or carbofuran on the commodities considered by the JMPR is unlikely to present a public health concern.

### ***Short-term intake***

The IESTI of carbofuran, was calculated for all the commodities not evaluated previously, including citrus. The IESTI represented 1–50% of the ARfD for the general population and 1–100% of that for

children. The Meeting concluded that the short-term intake of carbofuran residues in the commodities evaluated at this Meeting is unlikely to present a public health concern.

#### **4.4 CHLORPYRIFOS (017)**

##### **RESIDUE AND ANALYTICAL ASPECTS**

At its Twenty-fifth Session in 1993 (ALINORM 93/24A para. 251), the CCPR identified chlorpyrifos as a candidate for periodic review. At its Twenty-ninth Session in 1997, it scheduled periodic reviews for toxicology in 1999 and for residue chemistry in 2000. The 1999 toxicology review confirmed the ADI of 0.01 mg/kg bw and also established an ARfD of 0.1 mg/kg bw. In the 2000 residue chemistry review, information was supplied on the identity and physical properties of the active ingredient and technical material, metabolism in plants and animals, environmental fate, storage stability, animal feeding studies, field trials, GAP (national labels) and fate of residues in processing.

Chlorpyrifos was scheduled for re-evaluation in 2004 for consideration of maximum residue levels in cotton, potato, rice and soya bean. No MRLs were recommended by the 2000 JMPR on these commodities because of lack of relevant GAP labels or insufficient residue data. Relevant GAP labels and additional residue data to support proposed Codex MRLs in these commodities were submitted to the Meeting for evaluation. The CCPR at its Thirty-sixth Session in 2004 agreed that JMPR would review data from India to support establishment of a maximum residue level on tea. Information was submitted by the Government of India for this purpose.

##### ***Methods of analysis***

Methods for enforcement, data collection and monitoring of chlorpyrifos in different matrices were submitted and evaluated by JMPR in 2000. Additional methods were submitted to the present Meeting for the analysis of cotton-seed, potato, rice and soya bean. Various extraction and clean-up methods are followed by gas chromatography with flame photometric detection. The LOQ for chlorpyrifos is 0.01 mg/kg in all matrices.

The method of analysis for chlorpyrifos in tea was submitted by the Government of India. Residues in the cleaned extract were quantified by gas chromatography with flame-photometric or electron-capture detection. The LOQ is 0.02 mg/kg tea.

##### ***Results of supervised trials on crops***

###### ***Cotton-seed***

Supervised field trials on cotton were conducted at three sites in Australia in 2000 to provide additional residue data for consideration of MRLs for this crop. Bridging studies were conducted with a water-dispersible granule containing 750 g ai/kg and with an emulsifiable concentrate containing 300 g ai/l. Three foliar broadcast applications of each formulation were made at a rate of 1.5 kg ai/ha per application at a 5–8-day interval. A twofold rate of 3.0 kg ai/ha per application was also included. The applications were made at growth stages from late flowering to 15% of the bolls opened, with the last application 17 or 28 days before harvest. Although two sites in Australia have an early PHI (17 days), the residue levels in cotton-seed in these trials were included for MRL consideration because they were within the range of those in all trials. The trials conformed with Australian GAP (0.15–1.5 kg ai/ha in three applications and a 28-day PHI with either formulation). The highest residue level in replicate plots was chosen for estimating the STMR as a worst-case scenario.

Two supervised field trials on cotton were conducted at two sites in Brazil in 1992. Data on residues from the trials were submitted to JMPR in 2000 and accepted as meeting GAP. Briefly, the trials were conducted with an emulsifiable concentrate containing 480 g ai/l at a rate of either 0.96 or 1.92 kg ai/ha (twofold rate) per application. Foliar broadcast applications were made twice in one trial and three times in the other. In 2000, three additional supervised field trials on cotton were conducted at three sites in Brazil, with three foliar broadcast applications of the same emulsifiable concentrate at a rate of 0.96 or 1.92 kg ai/ha per application. The applications were made at growth stages from plant emergence to 30% of the bolls opened. Two replicate plots were used per treatment in each field site. Samples were hand-harvested from control and treated plots at 0, 7 (or 5), 14 (or 15), 21 (or 22) and 28 days after the last application and ginned to generate the cotton-seed (undelinted) samples. The trials conformed with Brazilian GAP (0.14–0.96 kg ai/ha in one to three applications and a 21-day PHI).

Supervised field trials on cotton were conducted in the USA in 1973, 1974 and 1986. Data on residue levels from these trials were submitted to JMPR 2000, and three of the trials were accepted as meeting GAP. Briefly, the trials were conducted with an emulsifiable concentrate containing 480 g ai/l applied as foliar broadcast applications. At a site in Mississippi in 1973, nine applications were made at a rate of either 1.12 or 2.24 kg ai/ha per application. Samples were hand-harvested 0, 3, 7 and 14 days after the last application and ginned to generate undelinted cotton-seed. At another site in Mississippi in 1974, two applications were made at a rate of 0.28 kg ai/ha per application, followed by 12 applications each at 1.12 kg ai/ha. Undelinted cotton-seed samples were generated similarly 15 days after the last application. At a site in California in 1986, five applications were made at 1.12 kg ai/ha, and undelinted cotton-seed samples were generated 14 days after the last application.

On the basis of the trials that conformed to GAP, the chlorpyrifos residue levels, in ranked order (median underlined), was: 0.01 (two), 0.02, 0.03 (two), 0.05, 0.07 (four), 0.11, 0.12, 0.16 and 0.18 mg/kg. The Meeting estimated a maximum residue level of 0.3 mg/kg for cotton-seed, an STMR of 0.07 mg/kg and a highest residue level of 0.18 mg/kg from the supervised trial in the USA in 1986.

### *Potato*

The 2000 JMPR considered data on residues from supervised trials on potatoes, but did not establish MRLs because there were insufficient trials at GAP to estimate the STMR or maximum residue level. Additional data from supervised trials after at-plant application (soil in-furrow) on potatoes were generated in Brazil and submitted to the present Meeting. The proposed MRL from the data on residues after at-plant application would also cover residue levels after foliar application. The data previously summarized for at-plant application were provided again to allow evaluation of residue levels in all supervised trials conducted in Brazil. Four supervised field trials on potatoes were conducted in 1993–94 in Brazil. The data from these trials were submitted to the JMPR in 2000 and accepted as meeting GAP. The trials were conducted with either a granular formulation containing 100 g ai/kg or an emulsifiable concentrate containing 450 g ai/l. A single application was made to soil in-furrow at planting, at a rate of 1.5, 3.0 or 6.0 kg ai/ha for the granular formulation and 2.9 or 5.9 kg ai/ha for the emulsifiable concentrate.

In 1999–2000, seven supervised field trials on potatoes were conducted in Brazil to provide additional data on residue levels for MRLs. Four trials were conducted with the granular formulation at a rate of 3 or 6 kg ai/ha, and three trials were conducted with the emulsifiable concentrate at a rate of 2.7 or 5.4 kg ai/ha. Three replicate plots were maintained for each treatment. A single application of each formulation was made to soil in-furrow at planting. Three samples of potatoes were collected manually at normal harvest from the control and treated plots 100–124 days after application. The highest residue level in replicate plots was chosen for estimating the STMR as a worst-case scenario.

On the basis of at-plant treatment in trials conforming to GAP, the chlorpyrifos residue levels, in ranked order, were: 0.02, 0.03, 0.10, 0.13, 0.29, 0.51, 0.57, 0.58, 0.65, 0.69 and 0.87 mg/kg. The Meeting estimated a maximum residue level of 2 mg/kg for potato, an STMR of 0.51 mg/kg and a highest residue level of 0.87 mg/kg.



*Rice*

The 2000 JMPR considered data on residues from supervised trials on rice, but did not establish MRLs because no trials were conducted at the relevant GAP. Relevant GAP in Colombia, the Philippines and Viet Nam was made available to support the results of the supervised trials submitted to the JMPR in 2000. Some additional data from supervised trials on rice, generated in India and Thailand since 2000, were submitted to the present Meeting. Supervised trials were thus conducted in Colombia, India, the Philippines, Thailand and Viet Nam.

In Colombia, two supervised field trials on rice were conducted in 1998 at two sites. Data on residue levels from these two trials were submitted to the JMPR in 2000. Briefly, the trials were conducted with an emulsifiable concentrate containing 480 g ai/l, applied three times to upland rice. The first application was made at a rate of 0.96 kg ai/ha after germination, followed by a second application at 0.72 kg ai/ha when the plants were at tillering crop growth stage; the final application was made at a rate of 0.34 kg ai/ha 20–21 days before harvest, when 100% of pinnacles were present. Three replicate plots were maintained for each trial. Rice samples from the control and treated plots were hand-harvested 20–21 days after the last application. The supervised trials conformed to Colombian GAP (0.34–0.96 kg ai/ha in a maximum of three applications and 20-day PHI).

In the Philippines, two supervised field trials on rice were conducted in 1998 at two sites. An emulsifiable concentrate containing 300 g ai/l was applied three times at a rate of 0.3 kg ai/ha per application. Data on residue levels in these two trials were submitted to JMPR 2000. The first two applications were made 25 and 40 days after transplantation, and the last application was made 25 days before harvest. Rice grain and straw samples from the control and treated plots were harvested 25 days after the last application. The supervised trials conformed to GAP in the Philippines, which is 0.30 kg ai/ha in a maximum of three applications and 25 days' PHI.

In Viet Nam, two supervised field trials on rice were conducted in 1998 at two sites. Data on residue levels in these two trials were submitted to the JMPR in 2000. Briefly, the trials were conducted with an emulsifiable concentrate containing 300 g ai/l, applied at a rate of 0.42 kg ai/ha. Rice grain and straw samples from the control and treated plots were harvested 10 days after the last application. The supervised trials conformed to GAP in Viet Nam, which is 0.3–0.42 kg ai/ha in one application and 28 days' PHI.

In Thailand, three supervised field trials on rice were conducted in 2002. An emulsifiable concentrate of chlorpyrifos containing 400 g ai/l was applied three times as a foliar application at a rate of 400 g ai/ha per application. The first application was made at mid-booting, and the final one at seed formation. Samples of rice grain and straw from the control and treated plots were hand-harvested 7, 14 and 21 days after the last application. The GAP in Thailand is 0.40 kg ai/ha, with an unspecified number of applications and 7–14 days' PHI.

In India, three supervised field trials on rice were conducted at three sites in 2002. An emulsifiable concentrate of chlorpyrifos containing 200 g ai/l was applied as a foliar application at a single rate of 375 g ai/ha. Samples of grain and straw from the control and treated plots were taken 14 (or 15), 21 and 30 days after application. As the labels were not available in English, the Meeting did not evaluate the data from India.

On the basis of trials on rice conforming to GAP, the chlorpyrifos residue levels, in ranked order, were: 0.02 (two), 0.08 (two), 0.09, 0.15, 0.16, 0.19 and 0.28 mg/kg. The Meeting estimated a maximum residue level of 0.5 mg/kg for rice, an STMR of 0.12 mg/kg and a highest residue level of 0.28 mg/kg.

*Soya bean*

The 2000 JMPR considered data from supervised trials on soya beans, but did not establish MRLs because the data from accepted GAP trials were insufficient for estimating the STMR or maximum residue level. Additional data from supervised trials conducted in 1994–96 on soya beans in Brazil were submitted to

the Meeting. The data from the five trials conducted in the USA according to GAP were provided again to the Meeting.

In Brazil, two field trials were conducted in 1992–93 with an emulsifiable concentrate containing 480 g ai/l, applied three times at either 0.48 or 0.96 kg ai/ha (twofold label rate) per application. Soya beans from the control and treated plots were hand-harvested 20–21 days after the last application. In 1992–93, an additional supervised field trial was conducted with the emulsifiable concentrate applied three times at 0.48 or 0.96 kg ai/ha per application. Soya beans from the control and treated plots were hand-harvested 21 days after application. In 1995, one supervised field trial was conducted in Brazil with the emulsifiable concentrate applied at either 0.34 or 0.77 kg ai/ha. Soya beans from the control and treated plots were harvested 21 days after application. Brazilian GAP is 0.12–0.48 kg ai/ha with one to two applications and 21 days' PHI. The supervised trials represent the worst-case scenario. The residue levels were below the LOQ (< 0.01 mg/kg) in all trials conducted at either the maximum or twice the maximum label rate or in single or triple applications.

In the USA, supervised field trials on soya beans were conducted in 1975–76. Data on residue levels from these trials were submitted to the JMPR in 2000, and five trials were accepted as meeting GAP. Briefly, the trials were conducted with an emulsifiable concentrate containing 480 g ai/l applied once as a directed broadcast spray at crop emergence, followed by three to four foliar broadcast applications during the growing season. The application rates were 0.56–2.2 kg ai/ha at emergence and 0.56–1.1 kg ai/ha at each foliar application. Soya beans were collected from the control and treated plots at normal harvest, 28–31 days after the last application. For replicate plots, the highest residue level was chosen for consideration of the MRL, as a worst-case scenario.

On the basis of trials conforming to GAP, the chlorpyrifos residue levels, in ranked order, were: ≤ 0.01 (six), 0.01 (two) and 0.05 mg/kg. The Meeting estimated a maximum residue level of 0.1 mg/kg for soya bean, an STMR of 0.01 mg/kg and a highest residue level of 0.05 mg/kg.

#### *Tea*

Six supervised field trials were conducted in 1995, 1996, 1998 and 1999 at various sites in India. A chlorpyrifos emulsifiable concentrate containing 200 g/l was applied once at a rate of 0.20 kg ai/ha (0.05 kg ai/hl, 400 l/ha water), which complied with GAP for chlorpyrifos on tea as submitted by the Government.

On the basis of trials conforming to GAP in India, the chlorpyrifos residue levels in tea, in ranked order, were: 0.03, 0.15, 0.19, 0.57, 0.77 and 1.13 mg/kg. The Meeting estimated a maximum residue level of 2.0 mg/kg for tea, an STMR of 0.34 mg/kg and a highest residue level of 1.13 mg/kg.

#### ***Fate of residues during processing***

Studies on processing of cotton-seed, rice and soya beans were submitted but not evaluated by the JMPR in 2000 because no MRLs were established for the raw agricultural commodities of these crops. The processing studies were resubmitted to the present Meeting for evaluation of residue levels in processed products of these raw agricultural commodities. The processing factors and estimated STMR-Ps for cotton-seed, rice and soya bean are summarized below:

| Processed commodity      | Processing factor | STMR (mg/kg) (RAC) | STMR-P (mg/kg) |
|--------------------------|-------------------|--------------------|----------------|
| Cotton hulls             | 0.7               | 0.07               | 0.05           |
| Cotton-seed meal         | 0.1               | 0.07               | < 0.01         |
| Cotton-seed oil, crude   | 1.4               | 0.07               | 0.10           |
| Cotton-seed oil, refined | 0.2               | 0.07               | 0.01           |
| Rice hulls               | 2.44              | 0.12               | 0.29           |
| Rice bran                | 1.80              | 0.12               | 0.22           |
| Rice husked              | 0.13              | 0.12               | 0.016          |

| Processed commodity   | Processing factor | STMR (mg/kg) (RAC) | STMR-P (mg/kg) |
|-----------------------|-------------------|--------------------|----------------|
| Polished rice         | 0.07              | 0.12               | 0.008          |
| Soya bean meal        | < 0.2             | 0.01               | < 0.002        |
| Soya bean crude oil   | 0.4               | 0.01               | 0.004          |
| Soya bean refined oil | 0.4               | 0.01               | 0.004          |
| Soya bean refined     | 0.5               | 0.01               | 0.005          |

STMR-P, STMR of raw agricultural commodity × processing factor of processed product

### ***Residues in animal commodities***

The 2000 JMPR estimated the dietary burden of chlorpyrifos in farm animals and poultry in cases in which calculations from the MRLs yielded maximum theoretical dietary intakes, and calculations from STMR values for feed allowed estimation of STMR values for animal commodities. The present Meeting concluded that the contribution of residues to feed, calculated for the uses considered this year, would not increase the dietary burden assessed by the 2000 JMPR. The Meeting maintained the recommendations of the 2000 JMPR.

## **DIETARY RISK ASSESSMENT**

### ***Long-term intake***

IEDIs for chlorpyrifos were calculated for the five GEMS/Food regional diets from the STMRs and STMR-Ps estimated by this Meeting, in addition to those for 61 commodities from the JMPR 2000 evaluation. The IEDIs were 3–30% of the maximum ADI (0–0.01 mg/kg bw), as shown in Annex 3. The Meeting concluded that the intake of residues of chlorpyrifos resulting from uses that have been considered by the JMPR is unlikely to present a public health concern.

### ***Short-term intake***

The IESTI for chlorpyrifos was calculated for the commodities for which MRLs, STMR values and highest residue values were estimated and for which data on consumption (large portion and unit weight) were available. The results are shown in Annex 4.

The ARfD for chlorpyrifos is 0.1 mg/kg bw. The short-term intakes were calculated for commodities for which highest residues or HR-Ps were estimated by the present Meeting. The calculated short-term intakes were < 100% of the ARfDs for children (0–40%) and for the general population (0–10%). The Meeting concluded that the intake of residues of chlorpyrifos resulting from uses that have been considered by the JMPR is unlikely to present a public health concern for consumers.

## **4.5 DIMETHIPIN (151)**

### **TOXICOLOGY**

#### ***Evaluation for an acute reference dose***

The 1999 JMPR established an ARfD for dimethipin of 0.02 mg/kg bw on the basis of a NOAEL of 20 mg/kg bw per day and a LOAEL of 40 mg/kg bw per day for skeletal malformations (increased incidence of fetuses and of litters containing fetuses with scoliosis and 27 presacral vertebrae) in a study of developmental toxicity in rabbits, and using a safety factor of 1000 in consideration of the nature of the

effects caused. The 2002 JMPR concluded that the 1000-fold safety factor might be excessive and that the ARfD of dimethipin should be reconsidered on the basis of appropriate data.

The present Meeting reconsidered the ARfD for dimethipin. The study of developmental toxicity in rabbits was re-evaluated in the light of a larger set of historical control data for Dutch belted rabbits, provided by the sponsor.

In a study of developmental toxicity in rabbits, does treated with dimethipin at a dose of 40 mg/kg bw per day showed body-weight loss on days 6–12 of gestation and decreased body-weight gain on days 6–28 of gestation. Fetal and litter incidences of scoliosis were 0% and 0% in the controls and 4.0% and 23.1% at 40 mg/kg bw per day, respectively. The observed incidence of scoliosis at 40 mg/kg bw per day was at the upper bound of that for historical controls (i.e. fetal and litter incidences of 4.1 and 20%, respectively). The NOAEL for both maternal and developmental toxicity was 20 mg/kg bw per day.

### ***Toxicological evaluation***

The Meeting established an ARfD of 0.2 mg/kg bw on the basis of the NOAEL of 20 mg/kg bw per day in the study of developmental toxicity in rabbits and a safety factor of 100. The Meeting considered that a safety factor of 100 was adequate, since the observed developmental toxicity was at the upper range of the historical control incidence and was possibly secondary to maternal toxicity.

An addendum to the toxicological monograph was prepared.

*Estimate of acute reference dose*

0.2 mg/kg bw

## **DIETARY RISK ASSESSMENT**

### ***Short-term intake***

The Meeting established an ARfD (0.2 mg/kg bw) for dimethipin. The 2001 JMPR had calculated the IESTI for dimethipin for 12 food commodities (and their processed fractions) for which MRLs were estimated and for which consumption data were available, using the previous ARfD of 0.02 mg/kg bw. The IESTI represented 0% of the ARfD for the general population and 0–1% of the ARfD for children. The Meeting concluded that the short-term intake of residues of dimethipin from uses that have been considered by the JMPR is unlikely to present a public health concern.

## **4.6 DITHIOCARBAMATES (105)**

### **RESIDUE AND ANALYTICAL ASPECTS**

Propineb was evaluated by the present Meeting within the CCPR periodic review programme, and the recommendations for MRLs, STMRs and highest residue levels are discussed in the appraisal of that compound. Recommended MRLs for dithiocarbamates arising from use of propineb are consolidated here.

The 1996 JMPR recommended MRLs for dithiocarbamates in almond hulls, almond, pecan, pome fruits and stone fruits which were based on residue data for ziram. The 1996 JMPR also recommended that estimates of maximum residue levels for dithiocarbamates, which relied primarily on data for ziram, should be temporary until the relevant data on environmental fate had been evaluated.

In view of the decision of the 2003 JMPR that data on environmental fate need be reviewed only when they directly affect estimation of maximum residue levels, the Meeting decided to withdraw its requirement for information on the environmental fate of ziram in soil and in water–sediment systems.

#### 4.7 ETHOPROPHOS (149)

##### RESIDUE AND ANALYTICAL ASPECTS

Ethoprophos, a nematicide and soil-insecticide, was evaluated for residues in 1984 and 1987. The toxicology of ethoprophos was reviewed within the periodic review programme by the 1999 JMPR. Ethoprophos was listed as a priority by the the CCPR at its Thirtieth Session (Alinorm 99/24 App VII) for for periodic review of residues by the 2001 JMPR. The manufacturer requested postponement of the residue evaluation.

The Meeting received information on identity; metabolism and environmental fate; analysis of residues; use pattern; residues resulting from supervised trials on strawberry, banana, cucumber, melon, pepper, tomato, potato, sweet potato and sugar-cane; fate of residues during storage and in processing; residues in food in commerce or at consumption; and national maximum residue limits.

##### *Metabolism*

##### *Animals*

The Meeting received information on the fate of [1-ethyl-<sup>14</sup>C]ethoprophos rats, lactating goats and laying hens dosed orally.

Studies on metabolism in laboratory animal (rats) were evaluated by the WHO Expert Group of the 1999 JMPR, which concluded that <sup>14</sup>C-ethoprophos is rapidly and virtually completely absorbed, metabolized and excreted after oral administration to rats. The main route of excretion was urine (51–56%), but significant proportions were excreted in expired air (about 15%) and faeces (10–14%). Little radiolabel was found in tissues at 168 h, representing less than 2.5% of the dose, and the highest concentrations were found in excretory organs (liver, kidneys and lungs). There was no evidence that bioaccumulation would occur after repeated doses. Ethoprophos was metabolized by dealkylation of one or both S-propyl groups, followed by conjugation.

Lactating goats given feed containing <sup>14</sup>C-ethoprophos at a concentration of 32 ppm excreted 78% of the administered radiolabel in urine (including cage rinse), 3.6% in faeces (including the gastrointestinal tract and contents) and 1.7% in milk; 3.9% of the administered dose was found in tissues. During the 7-day dosing period, 2% of the applied radiolabel was found in expired air. The highest concentration of radioactive residues was found in liver (8.8 mg/kg), while kidney contained 0.93 mg/kg, milk 0.49 mg/kg, muscle 0.095 mg/kg and fat 0.051 mg/kg. The total recovery of the administered dose was 88%.

The majority of the radiolabel in liver and kidney remained in the post-extraction solids, and enzyme and acid digests of these solids co-chromatographed with amino acid standards. Radiolabelled amino acids can be formed by hydrolysis of ethoprophos to ethanol and subsequently to acetaldehyde, acetate, acetyl coenzyme A and amino acids (tricarboxylic acid cycle). Thin-layer chromatography of the polar liver extract showed three radioactive spots, representing 1.1%, 1.4% and 0.45 % of the total radioactive residues (TRR). The first spot co-chromatographed with O-ethyl-S-propyl phosphorothioate and ethyl phosphate, while the other two spots did not co-chromatograph with any of the reference markers used. The parent compound was not found. Radioactivity in the kidney extract was not characterized.

Most of the radioactivity in muscle was released from the post-extracted solids by acid or base treatment, while that in fat was distributed approximately equally between the extracted and unextracted fractions. The radiolabel in the post-extracted solids could be released by enzyme digestion. No further characterization of muscle or fat fractions was attempted owing to the low levels of radioactivity.

The residue levels in milk reached a plateau on the first day of treatment, with an average level over days 0–7 of 0.49 mg/kg (maximum, 0.68 mg/kg). The radioactivity in the chloroform extract of milk (55% TRR) co-chromatographed with standards of the fatty acids palmitic acid, oleic acid and stearic acid, which were poorly resolved. Radiolabelled fatty acids can be formed by hydrolysis of ethoprophos to ethanol. No parent compound was found.

When laying hens were given feed containing  $^{14}\text{C}$ -ethoprophos at a concentration of 2.1 ppm for 7 days, 48% of the total administered radioactivity was recovered in excreta (including the gastrointestinal tract and contents), 1.0% in egg whites, 9.3% in egg yolks, 3.6% in expired volatiles and 3.2% in tissues and blood. The total recovery of the administered radioactivity was 64%. The highest concentration of radioactive residues was found in liver, at 1.2 mg/kg, followed by kidney at 0.42 mg/kg; 0.069 mg/kg radioactive residue was found in fat and 0.010 mg/kg in muscle. A maximum residue level of 0.64 mg/kg was found in egg yolk and 0.029 mg/kg in egg white.

As in goats, most of the radioactivity in liver and kidney remained in the post-extracted solids. Enzyme and acid digests of these solids co-chromatographed with amino acid standards. Thin-layer chromatography of the polar extract of liver contained three radioactive zones, representing 1.9%, 0.95% and 2.0% TRR. The first zone contained *O*-ethyl-*S*-propyl phosphorothioate or ethyl phosphate, the second zone did not co-chromatograph with any of the reference markers used, and the third zone co-chromatographed with *O*-ethyl-*O*-methyl-*S*-propyl phosphorothioate or *O*-ethyl-*S*-methyl-*S*-propyl phosphorodithioate. No parent compound was found.

Most of the radioactivity in muscle was released from the post-extracted solids by acid or base treatment, while that in fat was present mainly in the organic extract. The radiolabel could be released from the post-extracted solids by enzyme digestion. No further characterization of muscle or fat fractions was attempted owing to the low levels of radioactivity.

The radioactive residue level reached a plateau in egg whites on the third day of treatment, but no plateau was reached in egg yolks during the 7-day treatment. The average concentrations found were 0.021 mg/kg in egg whites (average over days 3–7; maximum, 0.029 mg/kg) and 0.30 mg/kg in egg yolks (average over days 0–7; maximum, 0.64 mg/kg). In egg yolks, 84% was extractable in hexane and 11% in chloroform. The hexane fraction of egg yolks co-chromatographed with the fatty acids palmitic, myristic, oleic and stearic acid, which were poorly resolved. No parent compound was found.

The metabolism of ethoprophos in laboratory animals was similar to that in farm animals.

### Plants

The Meeting received information on the fate of ethoprophos labelled with  $^{14}\text{C}$  in the ethyl or the propyl group after soil treatment before planting of pulses or oil seeds (French beans), cereals (maize), root and tuber vegetables (potatoes) and leafy crops (cabbage).

In a greenhouse, *French bean* bedding plants (variety Contender) were planted in clay pots filled with steam-sterilized soil treated with [ $\alpha$ - $^{14}\text{C}$ -ethyl]- or [ $\alpha$ - $^{14}\text{C}$ -propyl]ethoprophos. The compound was applied as a granule formulation at 14.3 mg ai/kg soil. The plants were grown for 63 days and were sampled at weekly intervals from day 7 onwards. The residue levels in soil extracts decreased with time, while the total residues in the bean plants increased with time, from 2.2% of the total applied radioactivity to 13% with the ethyl label and from 0.58% to 8.3% with the propyl label between days 7 and 63. Mainly extractable residues were found early in the study, while unextracted residues predominated (> 57%) from day 21 onwards. In methanol:water extracts of the bean plants, the main compounds were *O*-ethyl-*S*-propyl phosphorothioate and ethyl phosphate. In dichloromethane extracts, the main compounds were the parent (maximum, 13%) and

ethyl propyl sulfide (maximum, 9.2%). The amount of parent compound decreased with time after application and contributed < 10% from day 28 onwards. Minor amounts of propyl disulfide, ethyl propyl sulfoxide (plus methyl propyl sulfoxide) and ethyl propyl sulfone (plus methyl propyl sulfone) were present at some sampling times.

In a greenhouse, *maize seeds* were planted in clay pots filled with steam-sterilized soil treated with [ $\alpha$ - $^{14}\text{C}$ -ethyl]- or [ $\beta$ - $^{14}\text{C}$ -propyl]ethoprophos. Ethoprophos was applied as a granule formulation at 14.3 mg ai/kg soil. Maize plants were grown for 100 days and were sampled at 10-day intervals from day 18 onwards. The residue levels in soil extracts were constant, while those in maize plants increased from 0.96% of the applied radiolabel to 74% for the ethyl label and from 0.26% to 34% with the propyl label between days 18 and 100. Most of the extractable residues in the maize plants were found early in the study, while unextracted residues predominated (> 67%) from day 38 onwards. In methanol:water extracts of the maize plants, the main compounds were *O*-ethyl-*S*-propyl phosphorothioate and ethyl phosphate. In dichloromethane extracts, the main compounds were the parent (maximum, 40% TRR) and ethyl propyl sulfide (maximum, 7.6% TRR). The amount of parent compound decreased over time and contributed < 10% from day 48 onwards. Small amounts of propyl disulfide, ethyl propyl sulfoxide (plus methyl propyl sulfoxide) and ethyl propyl sulfone (plus methyl propyl sulfone) were present at some sampling times. The ethyl label was found mainly on ethyl phosphate.

In a second study on *maize*, silt loam was treated with [1-ethyl- $^{14}\text{C}$ ]ethoprophos (emulsifiable concentrate formulation) at a rate of 13 kg ai/ha in plastic-lined wooden boxes placed in the field. The actual concentration in the soil was 10 mg ai/kg. The application mixture was incorporated to a depth of 10 cm. Sweet maize seeds (variety Early extra sweet) were planted 3 days after soil treatment and were sampled at the green forage stage (soil, whole plant), at maturity (shanks, husks, silks, grain, empty cobs) and at the fodder stage (soil, senescent stalks without cobs). The TRR was 2.2 mg/kg in maize forage, 0.27 mg/kg in maize cobs, 0.25 mg/kg in grain, 0.79 mg/kg in husks and 1.4 mg/kg in fodder. Most of the TRR in these matrices was solvent-extractable. Acid or base hydrolysis released a further 6–14% TRR from forage, grain, cobs and fodder; however, 13% TRR in forage and 40% TRR in grain, cobs and fodder remained unextracted. Ethyl phosphate was the main metabolite detected in green forage, grain and fodder (10%, 35% and 8.9%, respectively). Parent ethoprophos and its metabolite *O*-ethyl-*S*-propyl phosphorothioate were also present in small amounts in forage and fodder. The extracts of forage and fodder further tentatively contained < 1% each of *O*-ethyl-*O*-methyl-*S*-propyl phosphorothioate and *O*-ethyl-*S*-methyl-*S*-propyl phosphorodithioate.

Silt loam was treated with [1-ethyl- $^{14}\text{C}$ ]ethoprophos (emulsifiable concentrate formulation) at a rate of 13 kg ai/ha in plastic-lined wooden boxes placed in the field. The actual concentration in the soil was 15 mg ai/kg. The mixture was incorporated to a depth of 10 cm. *Potatoes* (variety Kennebec) were planted 3 days after soil treatment, and soil and plants were sampled at the 'new potato' stage and at maturity. The TRR was 0.24–0.54 mg/kg in tubers and 1.1–3.8 mg/kg in vines. Most of the TRR was extracted with aqueous methanol. Acid or base hydrolysis solubilized a further 17% of the radioactivity in the vines, while 31% TRR in vines and 23% TRR in tubers remained unextracted. In both vines and the tubers, the main metabolite was ethylphosphate (12% and 38% TRR, respectively). Parent ethoprophos, *O*-ethyl-*S*-propyl phosphorothioate and *O*-ethyl-*O*-methyl-*S*-propyl phosphorothioate (the latter tentatively) were present in small amounts in the vines but were not detected in tubers.

To determine the nature of the unextracted residues in potatoes, sandy loam was treated with [1-ethyl- $^{14}\text{C}$ ]ethoprophos (emulsifiable concentrate formulation) at a dose rate of 13 kg ai/ha in plastic-lined wooden boxes placed in the field. The mixture was incorporated to a depth of 10 cm; the actual concentration in the soil was 5.9 mg ai/kg. Potatoes (minituber variety Kennebec) were planted 3 days after soil treatment and were harvested 118 days (new potato tubers) or 167 days after treatment (mature potatoes). The TRR and extractability were comparable with those in the first study. A sequential extraction scheme showed that 41% TRR in new potato tubers consisted of solvent-extractable residues, 11% TRR was present in starch, 8.5% TRR in protein, 4.4% TRR in pectin, 3.7% TRR in lignin, 8.2% in hemicellulose and 8.8% TRR in cellulose. The unextracted radioactive residue associated with starch was shown to be  $^{14}\text{C}$ -glucose.

Silt loam was treated with [1-ethyl-<sup>14</sup>C]ethoprophos (emulsifiable concentrate) at a rate of 11 kg ai/ha in plastic-lined wooden boxes placed in the field. The actual concentration in the soil was 7.6 mg ai/kg. The mixture was incorporated to a depth of 7.6 cm. *Cabbage* bedding plants (variety Stonehead) were planted 2 days after soil treatment, and soil and plants were sampled at the leafy stage and at maturity. The TRR was 16 mg/kg in leafy cabbage and 3.1 mg/kg in head cabbage. Most of the TRR was extractable, and ethylphosphate was the main metabolite found in both leafy and head cabbage extracts (21% and 24%, respectively). Ethoprophos and *O*-ethyl-*S*-propyl phosphorothioate were present at 0.3–4% in both types of cabbage, and *O*-ethyl-*O*-methyl-*S*-propyl phosphorothioate and *O*-ethyl-*S*-methyl-*S*-propyl phosphorodithioate were tentatively identified at 0.4–1.7%. A supplementary characterization study showed that most of the unextractable radioactive residues in cabbage were incorporated into plant structural components, mainly in lignin (38%).

The metabolism of ethoprophos in plants appears to be qualitatively similar to that in animals; however, the toxicologically significant metabolites *O*-ethyl-*O*-methyl-*S*-propyl phosphorothioate and *O*-ethyl-*S*-methyl-*S*-propyl phosphorodithioate were tentatively identified in hen liver, maize green forage and fodder, potato vines and cabbage heads, but not in rats or goats.

### **Environmental fate**

#### **Soil**

The Meeting received information on aerobic degradation in soil and studies on rotational crops (confined and field).

The route and rate of degradation of [1-<sup>14</sup>C-propyl]ethoprophos was investigated in three studies in different soils under aerobic conditions in the dark at 10 °C and 20–25 °C. On the basis of an application rate of 10.5 kg ai/ha in the field, the test substance was applied at a nominal concentration of 10–14 mg ai/kg dry weight of soil. The main degradation product in soil under aerobic conditions was <sup>14</sup>CO<sub>2</sub>, which accounted for 54–60% of the applied radioactivity after 90 days at 22–25 °C and 43–50% after 110 days at 10 °C. Most of the radioactivity in the extracts was associated with unchanged ethoprophos, representing 90–94% on day 0 and 7.2–9.4% on day 90 at 22 °C. One major metabolite was identified as *O*-ethyl-*S*-propyl phosphorothioate (maximum, 3.6–7.9% of the applied radioactivity); two minor metabolites were *O*-ethyl-*O*-methyl-*S*-propyl phosphorothioate (maximum, 0.7%) and *O*-ethyl-*S*-methyl-*S*-propyl phosphorodithioate (maximum, 0.3%). The half-life of ethoprophos at ambient temperature was 10–25 days, while that at 10 °C was two to three times longer.

In a study of a confined rotational crop, a sandy loam soil was sprayed with [1-ethyl-<sup>14</sup>C]ethoprophos as an emulsifiable concentrate at a rate equivalent to 13.4 kg ai/ha and thus incorporated into the top 10 cm of soil. The soil was placed in boxes inside a screened enclosure, which was heated and covered with plastic during the winter months. The soil was left fallow for 30–365 days after treatment. *Wheat* (variety Anza), *spinach* (variety Polka) and *radish* (variety Cherry Belle) were each planted 30, 120 and 365 days after treatment, and immature and mature crops were harvested at each planting interval. Soil samples were collected at application, at each planting and at each harvest. The TRR in rotational crops was generally much lower after a plant-back interval of 365 days than that after a plant-back interval of 30 days; e.g. mature wheat straw contained a radioactive residue level of 47 mg/kg after a plant-back interval of 30 days and 0.65 mg/kg after a plant-back interval of 365 days. Crops harvested when immature showed similar extractability, while the total extractability from mature wheat was generally lower than that from mature spinach or radish. Some of the remaining solids could be hydrolysed by acid or alkaline treatment; however, 1.9–42% TRR remained unextractable, with the highest portion in wheat chaff 365 days after treatment.

Parent ethoprophos was present in extracts of immature and early maturing crops (radish) at both the 120-day and the 30-day plant-back interval. The parent compound was not found in mature wheat or spinach at the 120-day plant-back interval or in any crop at the 365-day plant-back interval. The main component in each crop matrix was ethyl phosphate, but *O*-ethyl-*S*-propyl phosphorothioate was also found. Many



unidentified compounds were found, some at levels > 10% TRR or 0.05 mg/kg. After hydrolysis of immature spinach extracts from the 120-day plant-back interval, two of the unknown compounds (12% and 8.5% TRR) were found to be conjugates of ethyl phosphate. The levels of the remaining unknown compounds were not sufficient for structural identification. The main component in acid and base hydrolysates of the crops was the parent compound (0.13 mg/kg in mature wheat straw at the 120 day plant-back interval). Most of the remaining radiocarbon was associated with *O*-ethyl-*O*-methyl-*S*-propyl phosphorothioate (0.02 mg/kg). Unextractable residues were characterized in mature wheat straw. General incorporation into cellular components was 40% TRR in extractable residues, 7.7% TRR in starch, 1.5% TRR in protein, 1.9% TRR in pectin, 11% TRR in lignin, 14% TRR in hemi-cellulose, 10% TRR in cellulose and 22% TRR in insoluble residue; the overall recovery was 105%.

In a field study of rotational crops, unlabelled ethoprophos was applied once as an emulsifiable concentrate to sandy loam before planting at an actual rate of 13.5 kg ai/ha. The rotational crops were root vegetables (radish roots), leafy crops (radish leaves, red leaf lettuce, collards), cereals (forage, grain and straw from winter wheat, spring wheat and sorghum) and pulses or oil seeds (forage, grain and straw from cow peas, wando peas, green peas and soya beans and mustard forage). The crops were planted 1, 4, 8 and 12 months after application at two sites. Sample extracts were analysed for ethoprophos and *O*-ethyl-*S*-propyl phosphorothioate by gas chromatography with flame photometry detection. The residue levels were below the LOQ of 0.01 mg/kg in all treated samples from both test sites, except in radish root and radish leaves. The highest level of parent compound found in radish root was in samples taken at the plant-back interval of 31 days with harvest 32 days after planting, at 0.023 mg/kg; in the same samples, the highest level of *O*-ethyl-*S*-propyl phosphorothioate was 0.039 mg/kg. The presence of ethoprophos and *O*-ethyl-*S*-propyl phosphorothioate in radish root and tops was confirmed by gas chromatography–mass spectrometry but at levels at least an order of magnitude lower than those measured by gas chromatography with flame photometry detection.

### **Methods of analysis**

The Meeting received information on enforcement and monitoring methods for the determination of ethoprophos in foodstuffs of plant and animal origin and on the analytical methods used in studies of rotational crops, supervised trials and studies of storage stability, processing and monitoring for determination of ethoprophos and the metabolite *O*-ethyl-*S*-propyl phosphorothioate in foodstuffs of plant origin.

Five enforcement methods were submitted. Ethoprophos can be determined by the Dutch multi-residue method MRM-1 (validated for non-fatty matrices, quantification by gas chromatography with nitrogen–phosphorus or mass spectrometry detection; LOQ, 0.01–0.05 mg/kg) and with the German multi-residue methods DFG-S8 (validated for fruits and vegetables, quantification by gas chromatography with electron capture or alkali flame ionization detection; LOQ, 0.02 mg/kg) and DFG-S19 (validated for foodstuffs of plant and animal origin, quantification with gas chromatography with flame photometry, mass spectrometry or PFP detection, depending on the module used; LOQ, 0.01 mg/kg). Ethoprophos could not be determined by the multi-residue protocols of the US Food and Drug Administration. Method AR 271-01 was proposed as an enforcement method for determination of ethoprophos in milk, egg, meat, fat and liver and is considered valid in the range 0.01–0.1 mg/kg (quantification by gas chromatography with flame photometric detection).

All the methods used in the various studies were based on extraction with hexane, methanol, acetone, ethyl acetate, acetonitrile or petroleum ether:acetone, followed by a clean-up and determination by gas chromatography with MC, flame photometry, nitrogen–phosphorus, flame photometric, mass spectrometry, electron capture or tandem mass spectrometry detection. The LOQs ranged from 0.005 mg/kg to 0.05 mg/kg, 0.01 mg/kg being the most common.

### ***Stability of residues in stored analytical samples***

The Meeting received data on the stability of residues in crops with a high water content (pineapple, broccoli, cabbage, potato, sweet potato, tomato), in dry crops with starch and protein (maize), in dry crops with fat or oil, starch and protein (peanut), in special cases (sugar-cane, tobacco (green, cured)), in processed commodities (pineapple juice, peanut crude oil, peanut refined oil, maize crude oil, maize refined oil, maize starch, refined cane sugar) and in feed remains (pineapple bran, pineapple feed pulp, peanut hulls, peanut meal, peanut vine, dry peanut hay, maize meal, maize forage, maize fodder, maize grain dust, sugar-cane molasses) stored frozen. Crops with a high water and a high acid content (citrus fruits) were not investigated.

The freezer storage stability of ethoprophos depends on the matrix. Parent ethoprophos was found to be stable at  $-20^{\circ}\text{C}$  for a maximum of 9 months in broccoli and pineapple fruit, but for at least 9–12 months in other crops with a high water content (cabbage, sweet potato, potato, peanut vine, maize forage). In another study, the parent compound was stable for at least 19 months in tomato and potato. It was stable for at least 12 months in dry crops with starch and protein (maize grain) and for a maximum of 12 months in tobacco and peanut nutmeat. Ethoprophos was not stable in peanut hay. Ethoprophos and *O*-ethyl-*S*-propyl phosphorothioate were stable at  $-20^{\circ}\text{C}$  for at least 15 months in sugar-cane and its processed commodities. No general conclusions can be drawn for processed commodities and remains.

The results showed that, in general, *O*-ethyl-*S*-propyl phosphorothioate is not stable at  $-20^{\circ}\text{C}$  for  $< 1$  month, although longer storage times are possible for some crops.

### ***Definition of the residue***

Ethoprophos is metabolized rapidly in rats and livestock and was not found in edible tissues. In metabolism studies with labelled compounds, most of the radioactivity was found to be incorporated into natural components, such as fatty acids and amino acids. Low levels of *O*-ethyl-*S*-propyl phosphorothioate or ethyl phosphate were identified in goat and hen liver, and *O*-ethyl-*O*-methyl-*S*-propyl phosphorothioate and *O*-ethyl-*S*-methyl-*S*-propyl phosphorodithioate were tentatively identified in hen liver at low levels. The main route of metabolism in livestock is hydrolysis of the P–S bond, yielding *O*-ethyl-*S*-propyl phosphorothioate and propyl sulfide, with hydrolysis of *O*-ethyl-*S*-propyl phosphorothioate to ethyl phosphate; the ethyl moiety can be split off and become incorporated into natural components like amino acids and fatty acids.

Although ethoprophos is not found in edible tissues, the Meeting agreed that, in the absence of a better indicator, the parent should be considered the compound of interest in animal commodities, both for enforcement and for dietary risk assessment. The log octanol–water partition coefficient ( $P_{ow}$ ) of 2.99 indicates that the residue is not fat-soluble.

The main route of metabolism is similar in plant and animals, although other routes differ. Propylsulfide in plants can react with a parent molecule to yield ethylpropyl sulfide and propyl disulfide, while propylsulfide is methylated in rats.

In edible plant parts (mature maize grain, potato and cabbage), the major residue is ethyl phosphate, which is considered not to be toxicologically relevant and is thus not included in the residue definition for dietary risk assessment. Furthermore, ethyl phosphate is formed by several other organophosphate pesticides (e.g. parathion) and can therefore not be used for enforcement purposes. Ethylpropyl sulfide, which was found in amounts similar to the parent compound in French beans, was not found in rats; however, it behaves similarly to methylpropyl sulfide, which was detected in rats. It is not expected that this metabolite will be toxicologically significant.

Possible candidates for the residue definition are the parent, *O*-ethyl-*S*-propyl phosphorothioate, *O*-ethyl-*O*-methyl-*S*-propyl phosphorothioate and *O*-ethyl-*S*-methyl-*S*-propyl phosphorodithioate.

As reported by the 1999 JMPR, *O*-ethyl-*S*-propyl phosphorothioate, *O*-ethyl-*O*-methyl-*S*-propyl phosphorothioate and *O*-ethyl-*S*-methyl-*S*-propyl phosphorodithioate were tested for toxicity and for their ability to inhibit cholinesterase activity in female rats given single oral doses. The last two metabolites had approximately the same cholinergic toxicity as the parent compound, while the first was less toxic than the parent. As *O*-ethyl-*S*-propyl phosphorothioate is less toxic than the parent compound in rats, is rapidly converted to ethyl phosphate and is not found in mature maize grain, potato tubers or mature cabbage heads, the Meeting decided not to include this metabolite in either residue definition. The two remaining metabolites were not detected in mature maize grain or potato tubers but were tentatively identified in mature cabbage heads. These metabolites were also tentatively identified in animal feedstuffs (maize forage and fodder), although they were not identified in rats. It is possible that the molecules are artefacts formed during extraction with methanol. In view of the low levels found in the metabolism studies, the Meeting decided not to include *O*-ethyl-*O*-methyl-*S*-propyl phosphorothioate or *O*-ethyl-*S*-methyl-*S*-propyl phosphorodithioate in either residue definition.

Definition of the residue for compliance with MRLs and for estimating dietary intake: ethoprophos, for both plant and animal commodities.

### ***Results of supervised residue trials on crops***

Supervised trials were available for stawberry, banana, cucumber, melon, pepper, tomato, potato and sugar-cane, but none were provided for the remaining commodities that currently have a Codex level (CXL). Therefore, the Meeting decided to withdraw the current recommendations for beetroot, cabbage head, gherkin, grape, lettuce head, maize, maize fodder, onion bulb, peanut, peanut fodder, pea (pods and succulent or immature seeds), pineapple, pineapple fodder, pineapple forage, soya bean and soya bean fodder.

#### ***Berries and other small fruit***

##### ***Strawberry***

Ethoprophos is registered in Austria and Spain for use on strawberry with granule and emulsifiable concentrate formulations at the pre-planting or planting stages. Four trials on strawberry were conducted in Italy in 1996–98 at two sites. Application was by drip irrigation with emulsifiable concentrates throughout the growing season but before the fruits had formed. Although drip irrigation is usually the critical GAP and no residues were detected in the trials, the application rate stated on the available labels was 6 kg ai/ha, while that used in the trials was only 1.8–3.5 kg ai/ha. None of the trials was conducted according to GAP.

The Meeting agreed that the available data were insufficient to estimate a maximum residue level for ethoprophos in strawberry.

#### ***Assorted tropical and sub-tropical fruits minus inedible peel***

##### ***Banana***

Trials on bananas were reported to the Meeting from Brazil (GAP: 3.0 g ai/tree, two applications, 3-day PHI), Costa Rica (GAP for Central America: 2.9–3.0 g ai/tree, one application, 30-day PHI), Côte d'Ivoire (GAP: 4.0–8.0 g ai/tree, two to three applications, PHI not specified) and the Phillipines (GAP: 4.0–5.0 g ai/tree, two applications, PHI not specified).

In one trial in the Côte d'Ivoire, the residue levels in banana were below the LOQ (< 0.02 mg/kg).

None of the 20 Costa Rican trials was conducted according to GAP in Central America, as 15 involved overdosing, 14 involved more than one treatment or residues were measured at a PHI of < 30 days. As residue levels above the LOQ were not measured in any of the trials, the Meeting decided that the six trials with a PHI of ≤ 30 days could be considered for estimating the MRL. The residue levels in banana were < 0.02 mg/kg in all six trials.

The two trials in Brazil did not comply to GAP (overdosing, with only one application), and no residues were found. The five trials in the Philippines were also not conducted according to GAP (underdosing). In two of the trials, residue levels of 0.0065 mg/kg and 0.013 mg/kg were found in pulp.

The Meeting decided to combine the results of the trial in the Côte d'Ivoire and of the six trials in Costa Rica to estimate the maximum residue level for banana. The levels in all seven trials were < 0.02 mg/kg. The Meeting agreed to withdraw the previously recommended maximum residue level for banana of 0.02\* mg/kg and to replace it by a recommendation of 0.02 mg/kg. The Meeting estimated an STMR and a highest residue level for ethoprophos in banana of 0.02 mg/kg.

#### *Fruiting vegetables, cucurbits*

##### *Cucumber*

Indoor trials on cucumber in which soil received overall treatment before planting or at transplanting with a granule formulation were reported from Canada and The Netherlands. No GAP was reported for either country. In the five Canadian trials, conducted according to US GAP (12–15 kg ai/ha), the residue levels were < 0.01 mg/kg. In four of the six Dutch trials conducted according to Italian, Portuguese or Spanish GAP (3–10 kg ai/ha, 30–60-day PHI), the residue levels in cucumber were < 0.01 mg/kg.

Seventeen outdoor trials on cucumber, with overall soil treatment with a granule formulation before planting or at transplanting, were reported from the USA. In the five conducted according to US GAP, the residue levels were < 0.005 and < 0.02 (four) mg/kg.

Nine indoor trials on cucumber in which soil received spray treatment with emulsifiable concentrate formulations pre- and post-planting were reported from southern Europe (France, Greece, Italy, Portugal and Spain). The trials were evaluated against Spanish GAP (6.0 kg ai/ha, one application, 60-day PHI). All the trials involved overdosing. In one trial in which ethoprophos was applied after planting, an actual residue level of 0.0090 mg/kg was found at 21 days PHI; however, all trials at the correct PHI showed residue levels of < 0.005 mg/kg.

Ten outdoor trials on cucumber in which soil received spray treatment with emulsifiable concentrate formulations before or at planting were reported from the USA. All the trials were conducted according to US GAP, but the results of one trial was excluded from evaluation as the samples were purportedly mislabelled. The residue levels were < 0.01 (nine) mg/kg.

Eight indoor trials on cucumber in which soil was treated with emulsifiable concentrate formulations by drip irrigation after planting or transplanting were reported from southern Europe (France, Italy and Spain). The trials complied with Spanish GAP (0.6 kg ai/ha, 1–10 applications, maximum total of 6 kg ai/ha, 60-day PHI), except that the latest PHI for which residue levels were reported was 14–15 days. On these days, the residue levels were < 0.005 (six), < 0.01 and 0.012 mg/kg.

The Meeting concluded that, irrespective of the method of application and the site (indoors or outdoors), the residue levels would not be expected to exceed the enforcement LOQ of 0.01 mg/kg. The Meeting agreed to withdraw the previously recommended maximum residue level for cucumber of 0.02\* mg/kg and to replace it by a recommendation of 0.01 mg/kg. The Meeting estimated an STMR and a highest residue level for ethoprophos in cucumber of 0.01 mg/kg.

##### *Melon*

Nine outdoor trials on melon involving overall soil treatment with granule formulations before, at and after planting were reported from southern Europe (France, Italy and Spain). The trials were compared with Portuguese GAP (8 kg ai/ha, 56-day PHI). The residue levels were < 0.005 (seven), 0.0055 and 0.010 mg/kg. The levels in melon pulp (edible portion) were < 0.005 (eight) and 0.012 mg/kg.

Eight outdoor trials on melon involving post-transplanting drip irrigation with emulsifiable concentrate formulations were reported from southern Europe (France, Italy and Spain); however, there is no GAP for drip irrigation on melon in southern Europe.

On the basis of the trials of overall soil treatment, the Meeting agreed to withdraw the previously recommended maximum residue level for melon, except watermelon, of 0.02\* mg/kg and to replace it by a recommendation of 0.02 mg/kg. The Meeting estimated an STMR of 0.005 mg/kg and a highest residue level of 0.012 mg/kg for ethoprophos in the edible portion of melon.

#### *Fruiting vegetables other than cucurbits*

##### *Pepper*

Eleven indoor trials on sweet pepper involving overall soil treatment with granule formulations before or at planting were reported from southern Europe (France, Greece, Italy and Spain). The trials were evaluated against Spanish GAP (6.0–8.0 kg ai/ha, one application, 60-day PHI). The residue levels were: < 0.005 (nine), 0.007 and 0.027 mg/kg.

A further 12 trials from southern Europe on green and sweet pepper involved application of ethoprophos as an emulsifiable concentrate formulation by post-planting drip irrigation. Ten could be evaluated against Italian GAP (1.7–3.5 kg ai/ha, three to four applications, 30-day PHI). The residue levels were: < 0.005 (four), < 0.01 (two), 0.006, 0.0068, 0.007 and 0.044 mg/kg. Two trials on green pepper yielded higher residue levels, but the latest sampling was at a PHI of 14–15 days.

The Meeting decided to combine the results of all the trials, yielding residue levels, in ranked order, of: ≤ 0.005 (13), < 0.01 (two), 0.006, 0.0068, 0.007 (two), 0.027 and 0.044 mg/kg.

The Meeting agreed to withdraw the previously recommended maximum residue level for pepper of 0.02\* mg/kg and to replace it by a recommendation of 0.05 mg/kg for sweet pepper. The Meeting estimated an STMR of 0.005 and a highest residue level of 0.044 mg/kg for ethoprophos on sweet peppers.

##### *Tomato*

Six trials on tomato fruit involving overall soil treatment with granule formulations before or after planting were reported from Brazil (two, no GAP), The Netherlands (indoors) and the USA (three, no GAP). The dose used in the Dutch trial was twice that of Spanish GAP, but no residue level above the LOQ was found (< 0.01 mg/kg).

In 20 trials in southern Europe on tomato fruit, ethoprophos was applied as an emulsifiable concentrate formulation by post-planting drip irrigation or band spraying. The 13 trials conducted according to Italian GAP (1.7–3.5 kg ai/ha, three to four applications, total maximum of 8.6 kg ai/ha, 30-day PHI) or Spanish GAP (0.8–2.0 kg ai/ha, several applications, total maximum of 6 kg ai/ha, 60-day PHI) yielded residue levels of < 0.005 (four) and < 0.01 (nine) mg/kg.

On the basis of the trials conducted in southern Europe, the Meeting estimated a maximum residue level of 0.01\* mg/kg, an STMR of 0.005 mg/kg and a highest residue level of 0.01 mg/kg for ethoprophos on tomato.

#### *Root and tuber vegetables*

##### *Potato*

The results of 62 trials were available in which ethoprophos was applied to potatoes after overall soil treatment or band application with granule formulations before or at planting. Ware potatoes are normally harvested within 90–120 days after application at or a few days before planting. Early maturing potatoes can be harvested before 90 days, while late maturing ones (such as Russet Burbank or Maris Piper varieties) are usually harvested after 120 days. The PHI therefore depends on the crop variety. On most labels, no PHI is indicated, as treatment is made before or at planting, and the potatoes are harvested when they are ready. In

trials in which the time of maturity of the potatoes was not indicated, the residue level measured at the shortest PHI was used for evaluation.

Three Dutch trials were evaluated against Dutch GAP (overall application, pre-planting: 4–10 kg ai/ha; band application at planting, 2.5 kg ai/ha), all yielding < 0.02 mg/kg. In 19 German trials evaluated against Dutch GAP, the residue levels were: < 0.01 (10), 0.0076, 0.012 (two), 0.014, 0.016, 0.017 (two), 0.02 and 0.03 mg/kg.

Three of four trials in the United Kingdom in 1995 suffered from abnormal weather conditions, resulting in retarded growth of the tubers. As residues were found in control samples (up to 0.096 mg/kg in one trial), these trials were excluded from evaluation. The remaining 14 trials in the United Kingdom could not be evaluated against that country's GAP (overall application, pre-planting: 6.6–11 kg ai/ha; band application pre-planting, 4.0–6.0 kg ai/ha; 56-day PHI) because the PHI was longer. Eleven of the trials could be evaluated against Dutch GAP, yielding residue levels of: < 0.005 (seven), 0.005 and < 0.01 (three) mg/kg.

Five French trials could be compared to French GAP (overall application, pre-planting: 6–10 kg ai/ha), yielding residue levels of: < 0.005 (two), < 0.01 (two) and 0.011 mg/kg.

One Spanish trial was evaluated against Spanish GAP (overall application, pre-planting: 6–8 kg ai/ha), yielding a residue level of < 0.01 mg/kg.

Two Greek trials could not be compared with Greek GAP (overall application, pre- or at planting: 8–10 kg ai/ha; 60-day PHI) because of the specified PHI. When they were evaluated against Spanish GAP, the residue levels were < 0.02 mg/kg in both.

Fourteen trials in the USA with a granule formulation were compared with US GAP (pre-planting until prior to crop emergence: overall application, 4.5–13 kg ai/ha; band application, 10 kg ai/treated ha = 3.4 kg ai/ha). In the 12 that complied with GAP, the residue levels were: < 0.01 and < 0.02 (11) mg/kg. In three trials in the USA with an emulsifiable concentrate formulation, which complied with US GAP, the residue levels were < 0.01 (two) and < 0.02 mg/kg.

The Meeting decided to combine the residue levels from all the studies, yielding, in ranked order: < 0.005 (nine), 0.005, < 0.01 (19), < 0.02 (17), 0.0076, 0.011, 0.012 (two), 0.014, 0.016, 0.017 (two), 0.02 and 0.03 mg/kg. The Meeting estimated a maximum residue level of 0.05 mg/kg, an STMR of 0.01 mg/kg and a highest residue level of 0.03 mg/kg.

For assessing the risk to consumers of short-term intake, the possible residue level in single units is more important than the average residue level in a lot, which is the residue level in a representative composite sample. The concept of a variability factor was introduced to describe the relationship between the level in a high-residue unit and the typical or average level in the whole batch. The concept was refined to a more precise definition: the residue level in the 97.5th percentile unit divided by the mean residue level for the lot. There is a relation between the number of data from field trials, the proportion (percentile) of the population covered and the confidence level. The 2003 Meeting determined a method for calculating the variability factor on the basis of probabilities of random sampling from a population, making no assumptions as to the type of distribution.

In four of the trials on potato, residue levels were measured in individual units. Two were among the trials conducted in the United Kingdom in 1995 that were considered unreliable (see above). In a trial in France in 2001, 48 of 50 samples had undetectable residues, making the result unsuitable for calculation of a variability factor. In the fourth trial, conducted in the United Kingdom in 1999, 88 of 100 samples contained finite residue levels, so that a variability factor could be calculated. Applying the method referred to above to the 100 individual values available and using the 97.5th percentile in the calculation, the best estimate of the variability factor is 4.1 when the 12 data points below the LOQ are assumed to be at the LOQ, and 4.2 when those values are assumed to be 0. The 95% confidence limits on these estimates are 2.63 – > 5.6 and 2.75 – > 5.6, respectively. The Meeting decided to use the default variability factor of 3 in calculating the short-term

intake of ethoprophos, as this value was within the confidence interval of the calculated factor, and the default factor was based on a much larger database.

#### *Sweet potato*

The Meeting received the results of four trials on sweet potato in the USA, three of which complied to US GAP (3.3–4.4 kg ai/ha). The residue levels were < 0.01 (two) and 0.014 mg/kg. Three trials is insufficient for recommending a maximum residue level, but the Meeting decided to extrapolate the data on potato to sweet potato, because GAP is similar for the two crops.

On the basis of the trials on potato, the Meeting estimated a maximum residue level of 0.05 mg/kg, an STMR of 0.01 mg/kg and a highest residue level of 0.03 mg/kg for sweet potato.

#### *Grasses for sugar or syrup production*

##### *Sugar-cane*

Fourteen trials were available in which ethoprophos in granule formulations was applied to sugar-cane in the open furrow at planting. Of these, nine trials from the USA complied to US GAP (band application: 2.2–4.6 kg ai/ha; 10–27 kg ai/treated ha). In all cases, the residue level was below the LOQ (< 0.02 mg/kg). Three trials in India were evaluated against Indonesian GAP (band application, pre-planting: 1.0–2.0 kg ai/ha), yielding residue levels of < 0.01 mg/kg. The two trials in Brazil with application after planting had no matching GAP.

The Meeting decided to combine the results of the trials in India and the USA, yielding residue levels, in ranked order, of: < 0.01 (three) and < 0.02 (nine) mg/kg. The Meeting estimated a maximum residue level of 0.02 mg/kg, an STMR of 0.02 mg/kg and a highest residue level of 0.02 mg/kg for ethoprophos on sugar-cane.

#### *Miscellaneous fodder and forage crops (group 052)*

##### *Sugar-cane leaves*

In the three trials on sugar-cane in India, the residue levels in leaves were < 0.01 mg/kg. In three of the trials in the USA, the residue levels in leaves were < 0.02 mg/kg.

The Meeting estimated an STMR and a highest residue level of 0.02 mg/kg for ethoprophos on sugar-cane forage.

#### ***Fate of residues during processing***

The Meeting received information on the fate of residues during commercial storage of bananas. After successive storage at 10 °C and 20 °C for fruit ripening, the residue level remained within 80–130% of the original level.

The Meeting received information on the fate of incurred residues of ethoprophos during the processing of potatoes and sugar-cane.

In the first study on potato, the raw agricultural commodity and the processed fractions (washed tubers, wash water, peeled tuber, wet peel, dry peel, flakes, chips) did not contain residues (< 0.01 mg/kg ethoprophos and < 0.01 mg/kg O-ethyl-S-propyl phosphorothioate). In the second study, no residues were found (< 0.005 mg/kg ethoprophos) in the raw agricultural commodity or in processed fractions (peeled and baked potato). Nevertheless, residues were found in potato peel, at 0.022 and 0.062 mg/kg (average, 0.042 mg/kg) in variety Maris Peer and 0.009 and 0.011 mg/kg (average, 0.010 mg/kg) in variety Desiree. As

the raw agricultural commodity did not contain residues, no processing factors for potato could be calculated; however, it can be concluded tentatively that the residue concentrates in peel and not in potato pulp.

After treatment with ethoprophos at planting, a 2-t batch of sugar-cane was processed into bagasse, mixed juice, clarified juice, mud, syrup, raw sugar and molasses according to commercial practices in a pilot plant. No quantifiable residues ( $< 0.02$  mg/kg) were found in the raw agricultural commodity or its processed fractions. In a second study, in which ethoprophos was applied at planting, no residues ( $< 0.01$  mg/kg) were detected in sugar-cane stalks or juice. Even when an exaggerated dose rate was used, in a third study, no residues ( $< 0.01$  mg/kg) were found in stalks, bagasse, mixed juice, clarified juice, clarifier mud, syrup, molasses or sugar. Therefore, no processing factors for sugar-cane could be calculated.

The Meeting also received information on the distribution of residues in peel and pulp fractions of banana and melon. The results of two trials on banana in which residues were found at harvest indicate that ethoprophos tends to concentrate in the pulp fraction of banana. The results of six trials on melon in which residues were found at harvest indicate that ethoprophos is present in both peel and pulp fractions. Generally, the peel fractions contained slightly higher residue levels.

### ***Residues in animal commodities***

#### ***Dietary burden of farm animals***

The Meeting estimated the dietary burden of ethoprophos residues in farm animals from the diets listed in Appendix IX of the *FAO Manual*. Only one feed commodity from each Codex Commodity Group was used, in this case potato culls (group VR). Calculation from highest residue values provides the concentrations in feed suitable for estimating MRLs for animal commodities, while calculation from the STMR values for feed is suitable for estimating STMR values for animal commodities. In the case of processed commodities, the STMR-P value is used for both intake calculations.

On the basis of a highest residue value of 0.03 mg/kg and 20% dry matter in potato culls, the maximum contribution of residue to the dietary burden would be 0.11 mg/kg for beef cattle given feed containing 75% potato culls and 0.06 mg/kg for dairy cattle given feed containing 40% potato culls.

On the basis of an STMR of 0.01 mg/kg and 20% dry matter, the mean dietary burden of beef cattle given feed containing 75% potato culls would be 0.038 mg/kg, and that of dairy cattle given feed containing 40% culls would be 0.02 mg/kg.

#### ***Maximum residue levels***

The results of the metabolism study in lactating goats given feed containing 32 ppm ethoprophos indicate that no residues are to be expected in mammalian commodities at a maximum dietary burden of 0.11 mg/kg. As laying hens are not exposed to ethoprophos, no maximum residue levels for poultry commodities are required.

The Meeting estimated a maximum residue level of 0.01\* mg/kg in mammalian meat, offal and milks, and STMR and highest residue values of 0.

## **DIETARY RISK ASSESSMENT**

### ***Long-term intake***

The IEDIs of ethoprophos, on the basis of the STMRs estimated for 11 commodities, for the five GEMS/Food regional diets represented 5–10% of the maximum ADI (0–0.0004 mg/kg bw), see Annex 3. The Meeting concluded that the long-term intake of residues of ethoprophos resulting from uses that have been considered by JMPR is unlikely to present a public health concern.



### ***Short-term intake***

The IESTIs for ethoprophos were calculated for 11 food commodities for which maximum residue levels had been estimated and for which consumption data were available. The results are shown in Annex 4.

The IESTI represented 0–1% of the ARfD (0.05 mg/kg bw) for the general population and 0–3% of the ARfD for children. The Meeting concluded that the short-term intake of residues of ethoprophos resulting from uses that have been considered by the JMPR is unlikely to present a public health concern.

## **4.8 FENITROTHION (037)**

### **RESIDUE AND ANALYTICAL ASPECTS**

Fenitrothion was evaluated for residues within the periodic review programme of the CCPR by the 2003 JMPR, which recommended an MRL of 10 mg/kg (accommodating post-harvest treatment, Po) for cereals. The Meeting indicated that additional information on metabolism in cereals (including rice) after pre-harvest treatment, a validated analytical method for the determination of fenitrothion in animal commodities, freezer storage stability of residues in animal commodities, farm animal transfer studies and a processing study on rice were desirable. At the present Meeting, an undertaking was given to submit additional data to support uses on apple, pear and soya bean (dried seed), as these are important traded commodities.

The CCPR at its Thirty-sixth Session agreed to retain the existing MRLs for meat (0.05\* mg/kg, fat), milks (0.002\* mg/kg), unprocessed rice bran (20 mg/kg), polished rice (1 mg/kg), processed wheat bran (2 mg/kg), unprocessed wheat bran (20 mg/kg), wheat flour (2 mg/kg) and wheat wholemeal (5 mg/kg).

The data submitted to address the outstanding points are summarized below.

### ***Metabolism***

#### ***Animals***

No additional data were submitted.

#### ***Plants***

The 2003 JMPR evaluated the fate of fenitrothion after spray application to grapes and tomato (crop category fruits) and the fate of fenitrothion in stored rice. The Meeting received two additional studies on the fate of fenitrothion after pre-harvest spray application to rice under simulated paddy growing conditions.

In the first study, rice plants (variety Hatsushimo) were transplanted to a paddy field which had been prepared in a vinyl tent. The rice plants were sprayed once at 0.375 kg ai/ha with a <sup>32</sup>P-fenitrothion emulsifiable concentrate formulation. At various intervals after application, rice plants were sampled at random by cutting down at the base and separating the leaf sheath and leaf blade. At normal harvest, mature grains were harvested and separated into bran and polished rice.

In mature rice grain, the main metabolite was phosphoric acid, while phosphorothionic acid, dimethylphosphorothioic acid and parent were also found. The residue levels were 7–33 times higher in rice bran than in polished rice. Fenitrooxon, desmethylfenitrothion, desmethylfenitrooxon, dimethylphosphoric acid, monomethylphosphorothioic acid and monomethylphosphoric acid were not detected. In rice grains from plants (varieties Kin-nampu, Ginga, Aichi-asahi) treated with unlabelled fenitrothion, the parent compound could not be detected in rice bran or in polished rice (< 0.1 mg/kg), but 3-methyl-4-nitrophenol was found in rice bran of the varieties Kin-nampu and Aichi-asahi.

In a second study, rice (variety Nihonbare) was grown in a glasshouse under conditions simulating growth in a rice paddy. Rice seedlings were planted in pots filled with soil and flooded with 3–5 cm water throughout the study. The rice was treated with four spray applications of an emulsifiable concentrate formulation containing [phenyl-<sup>14</sup>C]fenitrothion at a nominal dose rate of 0.75 kg ai/ha per application 81 (2 months after planting), 28, 21 and 14 days before mature harvest. Twelve days before harvest, water was withheld from the plants. Rice plants, soil and root samples were collected, and the plants were separated into unhulled whole grain and straw (leaf and stem). The unhulled whole grain was further processed to brown rice and chaff (hulls). The brown rice was further processed to give 90% (w/w) polished rice and 11% (w/w) bran.

A high proportion of the radioactivity was extractable (65–89% TRR). Fenitrothion was detectable in all rice fractions, at 0.003–0.3 mg/kg. The major metabolite in unhulled whole grain, brown rice, polished rice, chaff, bran and straw was 3-methyl-4-nitrophenol, at 0.09–3.9 mg/kg fenitrothion equivalents, and this compound was present in a mixture of free and conjugated forms. The conjugates were hydrolysed to the free form by enzymatic ( $\beta$ -glucosidase) and acid hydrolyses. Fenitrothion was present at levels of 0.30 mg/kg in unhulled whole grain rice, 0.027 mg/kg in brown rice and 0.003 mg/kg in polished rice.

The percentage transference would be equivalent to 8.9% for brown rice and 1.0% for polished rice. Fenitrooxon was present at levels of 0.14 mg/kg in unhulled whole grain rice and 0.009 mg/kg in brown rice; it was not detected in polished rice. Fenitrooxon was also found in bran at 0.042 mg/kg, chaff at 0.84 mg/kg and straw at 0.27 mg/kg. Most of the radioactivity in the post-extracted solids was released by acid or base hydrolysis. 3-Methyl-4-nitrophenol was detected in all the hydrolysates except that of polished rice. Minor amounts (< 2.5% TRR) of aminofenitrothion, fenitrooxon, fenitrothion S-isomer and fenitrothion were also released on hydrolysis. In polished rice, only fenitrothion S-isomer was found.

### ***Environmental fate***

No additional data were submitted.

### ***Methods of analysis***

The 2003 JMPR evaluated enforcement and monitoring methods for plant commodities. The Meeting received two additional analytical methods intended for enforcement and monitoring for animal commodities (RRC 78-32 and RRC 78-32A).

Method RRC 78-32 is used for the determination of fenitrothion (parent), fenitrooxon, aminofenitrothion and 3-methyl-4-nitrophenol in milk, cream and cattle tissues. Method RRC 78-32A is a modification for eggs and poultry tissues. In this appraisal, the focus is on parent compound. Cattle milk, cream and tissue, and eggs and poultry tissues were extracted with acetone or acetonitrile:methanol:water and cleaned, and fenitrothion was determined by gas chromatography–flame photometry detection. The reported LOQ was 0.01 mg/kg for cattle milk and cream and 0.05 mg/kg for eggs and cattle and poultry tissues. The method is considered to be outdated because of the use of glass gas chromatography columns.

The Meeting received information on analytical methods for the determination of parent in foodstuffs of plant, animal or environmental origin as used in various additionally submitted study reports (residue trials, storage stability of analytical samples, processing studies, feeding studies). Fenitrothion was determined by gas chromatography with flame photometry, nitrogen–phosphorus or FT detection. The reported LOQs ranged from 0.001 mg/kg to 0.1 mg/kg.

### ***Stability of residues in stored analytical samples***

The 2003 JMPR evaluated the stability in storage of residues in dry crops with starch and protein (grain of wheat, barley, rice) and in rice straw. The Meeting received additional data on the stability of

residues in crops with a high water content (apple, green soya bean, green broad bean) and dry crops with starch and protein (dry seeds of soya bean, kidney bean, pea).

The Meeting concluded that fenitrothion residues are stable at  $-20^{\circ}\text{C}$  for at least 192 days in apples, for at least 155 days in legumes, for at least 149 days in cereals and for at least 98 days in pulses. In several trials, however, samples were stored at  $-15^{\circ}\text{C}$ ,  $-10^{\circ}\text{C}$ ,  $+5^{\circ}\text{C}$  or  $+10^{\circ}\text{C}$ . Information on the stability of the samples under these conditions was not available.

### ***Definition of the residue***

The 2003 JMPR proposed fenitrothion as the residue definition for compliance with MRLs and for dietary intake, for both plant and animal commodities. The residue is not fat-soluble.

The supported uses of fenitrothion at that time were pre-harvest application on cereals and post-harvest application on stored cereal grains. The 2003 Meeting concluded that the available studies were adequate only for post-harvest uses on stored cereal grains; to support pre-harvest uses on cereals, relevant metabolism studies were required.

The manufacturer now wishes to support use on pome fruit and soya bean. The 2003 JMPR evaluated studies of metabolism in grape and tomato after pre-harvest use. The main metabolites were 3-methyl-4-nitrophenol and its conjugates. Two studies on metabolism in rice after pre-harvest use of fenitrothion were made available to the present Meeting.

The studies confirm that the main metabolite is 3-methyl-4-nitrophenol (free and conjugated). The parent compound was found in the raw agricultural commodity and in all processed fractions (unhulled whole rice grain, brown rice, polished rice, bran, hulls and rice straw). In addition, fenitrooxon was found in unhulled whole rice grain (0.14 mg/kg), brown rice (0.009 mg/kg), bran (0.042 mg/kg), hulls (0.84 mg/kg) and straw (0.27 mg/kg). Fenitrooxon should be considered for inclusion in the residue definition for dietary intake, as the 2000 JMPR concluded that it is the most important metabolite with respect to toxicity. As it is found in small amounts in brown rice and not at all in polished rice (the edible portions for humans), however, the Meeting decided not to include fenitrooxon in the residue definition for dietary intake.

Fenitrothion S-isomer and aminofenitrothion, metabolites that were found but not discussed previously, were present in such small amounts that the Meeting concluded that their inclusion in the residue definition was unnecessary.

Therefore, the Meeting concluded that the residue definition as proposed by the 2003 JMPR do not require alteration.

*Definition of the residue for compliance with MRLs and for estimating dietary intake:* fenitrothion, for both plant and animal commodities.

### ***Results of supervised trials on crops***

The Meeting received information on supervised trials on apple, pear, green broad bean, green soya bean, dry soya bean, dry beans and dry peas.

In 2003, the Meeting summarized the results of supervised trials of pre-harvest treatment on cereal grains (rice, wheat, barley, triticale) in Japan and Australia. In some trials, pre-harvest treatment was combined with seed treatment before planting. The trials were not evaluated at that time, because information on metabolism after pre-harvest treatment was lacking.

#### ***Pome fruit***

Nineteen trials on apple and two trials on pear were conducted in Canada in 1972–73. As there is no GAP in Canada or in the USA, the trials could not be evaluated.

In six of 24 trials on apple conducted in Japan in 1989–95, the analytical samples excluded hulls, pedicels, styler scars and cores. As the Codex commodity for which the maximum residue level is estimated is the whole fruit, the trials could not be evaluated. In the remaining 18 trials, only pedicels, styler scars and cores were removed. The Meeting decided that this deviation from the Codex commodity definition was acceptable, and it evaluated the trials. GAP in Japan is three applications of 0.025–0.050 kg ai/ha, with a PHI of 30 days. In two trials, residues were found in control samples, and those trials could not be evaluated.

The residue levels in trials meeting GAP were, in ranked order: < 0.01, 0.01 (three), 0.02 (two), 0.04, 0.08, 0.10 (two), 0.11, 0.12 and 0.41 mg/kg. The Meeting decided to withdraw the currently recommended maximum residue level for apple and replace it by 0.5 mg/kg, with an STMR of 0.04 mg/kg and a highest residue value of 0.41 mg/kg.

There were only two trials on pear, and neither complied with GAP. Furthermore, Japanese GAP allows six applications on pear and only three on apple. The Meeting decided to maintain withdrawal of the recommendation for pear.

#### *Legume vegetables*

Three trials on green broad beans (seeds only) and seven trials on green soya beans (seeds or beans with pods) were conducted in 1971–95 in Japan. There is no Japanese GAP for broad beans. Japanese GAP for soya beans (dry and green) is foliar spray treatment at 0.025–0.050 kg ai/ha, four applications, 21-day PHI. Two trials in which the portion analysed was green soya bean in the pod and which were conducted according to GAP yielded residue levels of 0.12 mg/kg and 0.18 mg/kg. Two trials is insufficient to estimate a MRL for soya bean, immature seeds.

#### *Pulses*

Nineteen trials on dry harvested soya beans, four trials on beans and two indoor trials on peas were carried out in 1971–90 in Japan. Japanese GAP is described above, except that when fenitrothion is applied by foliar spray from an unmanned helicopter, the dose is 0.50 kg ai/ha. In all but four trials, the PHI exceeded that specified for GAP. In the four trials, the residue levels were: 0.004 (two) and < 0.01 (two) mg/kg. The Meeting decided that four trials is insufficient to estimate a MRL for soya bean, dry.

#### *Cereal grains*

The 2003 Meeting received information from supervised trials on pre-harvest treatment of cereal grains (rice, wheat, barley, triticale) in Australia and Japan. Because of lack of data on metabolism in cereal grains after pre-harvest treatment, the trials could not be evaluated at that time. As the present Meeting received the requested data, the trials can now be evaluated.

Sixteen trials on rice were conducted in Japan in 1993–96 (see 2003 JMPR). In the trials conducted in 1993–95, seeds were soaked in a fenitrothion solution for 24 h before planting and then given four applications of fenitrothion from a knapsack sprayer during the growing season. In the trials performed in 1996, fenitrothion was applied four times from an unmanned helicopter, without prior soaking of the seeds. Fenitrothion is registered in Japan for pre-harvest use on rice at a maximum of four foliar spray applications of 0.375–0.90 kg ai/ha and a PHI of 21 days. The residue levels in the trials complying with Japanese GAP were: < 0.01 (four), 0.01 (two), 0.02, 0.03, 0.04, 0.05, 0.06, 0.07, 0.08, 0.09, 0.10 and 0.12 mg/kg.

Four trials on *winter wheat* were conducted in Australia in 2001 and in Japan in 1993. In these trials, fenitrothion was applied three times from a knapsack sprayer or a boom sprayer. Fenitrothion is registered in Australia for pre-harvest use on cereals with a maximum of three applications of 0.27–0.55 kg ai/ha (interval ≥ 14 days) and a PHI of 14 days; in Japan, it is registered for pre-harvest use on wheat with a single application of 0.45–0.60 kg ai/ha and a PHI of 7 days. The Australian trials were at Australian GAP and yielded residue levels of 0.10 and 0.21 mg/kg. The trials in Japan did not comply completely with Japanese GAP (three applications instead of one), but the results were evaluated. The residue levels were < 0.01 and 0.30 mg/kg.

Three trials on *winter barley* were conducted in Australia in 2001 and in Japan in 1993. Fenitrothion was applied three times from a knapsack sprayer or a hand-held boom sprayer. In Australia, fenitrothion is registered for pre-harvest use on cereals with a maximum of three applications of 0.27–0.55 kg ai/ha (interval  $\geq 14$  days) and a PHI of 14 days. In Japan, fenitrothion is not registered for use on barley. The Australian trial was at Australian GAP and yielded a residue level of  $< 0.06$  mg/kg.

One trial on *winter triticale* was conducted in Australia in 2001, in which fenitrothion was applied three times from a hand-held boom sprayer. The trial was at the Australian GAP for cereal and yielded a residue level of 0.08 mg/kg.

The Meeting decided to combine the results of all the trials on cereals residue, to yield residue levels, in ranked order, of:  $< 0.01$  (five),  $< 0.06$ , 0.01 (two), 0.02, 0.03, 0.04, 0.05, 0.06, 0.07, 0.08 (two), 0.09, 0.10 (two), 0.12, 0.21 and 0.30 mg/kg. As the residue levels resulting from pre-harvest treatment were lower than those after post-harvest treatment, the Meeting decided to maintain the current recommendations for cereal grain of 10 mg/kg (Po), an STMR of 5 mg/kg and a highest residue of 7.6 mg/kg.

#### *Straw, fodder and forage of cereal grains and grasses*

Two trials on *rice* were conducted in Japan in 1993 according to Japanese GAP. The residue levels in straw were 0.31 and 0.44 mg/kg.

Two trials on *winter wheat* were conducted in Australia in 2001 according to Australian GAP. The residue levels in straw were 1.2 and 4.1 mg/kg.

One trial on *winter barley* was conducted in Australia in 2001 according to Australian GAP. The residue level in straw was 0.41 mg/kg.

One trial on *winter triticale* was conducted in Australia in 2001 according to Australian GAP. The residue level in straw was 2.0 mg/kg.

The Meeting decided that there were insufficient data to estimate a maximum residue level in cereal straw.

#### ***Fate of residues during processing***

The 2003 JMPR evaluated the fate of fenitrothion during simulated processing, in stored rice during polishing and cooking and in stored wheat during milling and baking. The Meeting received three additional studies on the fate of fenitrothion after post-harvest treatment of rice during polishing and cooking and in barley during malting.

Rice stored for up to 12 months after post-harvest treatment with fenitrothion at 2–15 g ai/t was separated into polished rice and bran. The polished rice was washed and cooked for 10–15 min at normal to 2.5 atm pressure. Parent compound was analysed in all processed products. The calculated processing factors were 0.11–0.15 for polished rice (mean, 0.14), 6.6–7.2 for bran (mean, 6.9), 0.041–0.049 for washed polished rice (mean, 0.046) and 0.0060–0.033 for cooked washed polished rice (mean, 0.020).

Paddy rice stored for up to 6 months after post-harvest treatment with fenitrothion at 15 g ai/t was processed into husked rice, polished rice and bran. Husked and polished rice were cooked for 25 min. Parent compound was analysed in all processed products. The calculated processing factors were 0.18 for husked rice, 0.08 for polished rice, 0.11 for cooked husked rice and 0.04 for cooked polished rice.

Paddy rice was processed into husked rice, polished rice, hulls and bran. Parent compound was analysed in all processed products. The calculated processing factors were 0.031–0.64 for husked rice (mean, 0.17),  $< 0.002$ –0.087 for polished rice (mean, 0.018), 0.12–10 for hulls (mean, 4.3) and 0.018–2.0 for bran (mean, 0.61).

Barley stored for up to 6 months after post-harvest treatment with 15 g ai/t fenitrothion was processed into malt and was analysed for parent. The calculated processing factors were 0.16-0.24 for malt (mean 0.20).

The table below summarizes the processing factors for wheat, barley and rice commodities. The information on wheat was discussed by the 2003 JMPR. Three studies were available on the processing of rice, yielding different results. As details of the growing conditions, treatments, storage and processing were absent or partial, the Meeting could not judge which study was the most representative of household processing. Therefore, maximum processing factors were used. Processing factors used for the calculation of maximum residue levels and STMR-Ps are underlined.

| Commodity                     | Processing factor (range) | No. of trials | Processing factor (mean) | STMR-P (mg/kg)   | HR-P (mg/kg) |
|-------------------------------|---------------------------|---------------|--------------------------|------------------|--------------|
| Wheat bran                    | 3.9–4.0                   | 2             | <u>3.95</u>              | 19.75            | 30.02        |
| Wheat flour                   | 0.21–0.26                 | 2             | <u>0.235</u>             | 1.175            | 1.786        |
| White bread                   | 0.089–0.11                | 2             | <u>0.10</u>              | 0.5 <sup>a</sup> | 0.76         |
| Wholemeal bread               | 0.33–0.43                 | 2             | <u>0.38</u>              | 1.9              | 2.888        |
| Barley malt                   | 0.16–0.24                 | 2             | <u>0.20</u>              | 1                | 1.52         |
| Husked rice                   | 0.031– <u>0.64</u>        | 22            | 0.17                     | 3.2              | 4.864        |
| Polished rice                 | < 0.002– <u>0.15</u>      | 26            | 0.039                    | 0.75             | 1.14         |
| Rice hulls                    | 0.12– <u>10</u>           | 21            | 4.3                      | 50               | 76           |
| Rice bran                     | 0.018– <u>7.2</u>         | 23            | 1.7                      | 36               | 54.72        |
| Cooked husked rice            | <u>0.11</u>               | 1             |                          | 0.55             | 0.836        |
| Cooked polished rice          | <u>0.04</u>               | 1             |                          | 0.2              | 0.304        |
| Washed polished rice          | 0.041–0.049               | 4             | <u>0.046</u>             | 0.23             | 0.3496       |
| Cooked, washed, polished rice | 0.0060–0.033              | 13            | <u>0.020</u>             | 0.1              | 0.152        |

<sup>a</sup> The Meeting noted that the 2003 Report incorrectly reported an STMR-P of 0.05 mg/kg in white bread.

Using the highest residue level for cereal grains (7.6 mg/kg) and the processing factors indicated above, the Meeting estimated maximum residue levels of 30 mg/kg in wheat bran and 60 mg/kg in rice bran. The Meeting decided to withdraw the current recommendations for 1 mg/kg in polished rice, 2 mg/kg in wheat flour, 1 mg/kg in white bread and 3 mg/kg in wholemeal bread (accommodating post-harvest treatment, PoP), because the MRL would be lower than that of the raw agricultural commodity.

Using the STMR for cereal grains (5 mg/kg), the Meeting estimated STMR-Ps for wheat bran, wheat flour, white bread, wholemeal bread, barley malt, husked rice, polished rice, rice hulls, rice bran, cooked husked rice, cooked polished rice, washed polished rice and cooked washed polished rice, as shown in the table above.

Furthermore, using the highest residue level for cereal grains (7.6 mg/kg), the Meeting estimated HR-Ps for wheat bran, wheat flour, white bread, wholemeal bread, barley malt, husked rice, polished rice, rice hulls, rice bran, cooked husked rice, cooked polished rice, washed polished rice and cooked washed polished rice, as shown in the table above.

The Meeting decided to use the STMR-P and HR-P values for cooked husked rice and cooked polished rice in calculating the dietary intake of fenitrothion from rice.

### Residues in animal commodities

#### Dietary burden of farm animals

The Meeting estimated the dietary burden of fenitrothion residues in farm animals from the diets listed in Appendix IX of the *FAO Manual*. Only one feed commodity from each Codex Commodity Group is used; therefore, the calculation includes wheat grain, but no other cereals, and rice bran, but not rice hulls. Calculation from the highest residue values provides the concentrations in feed suitable for estimating MRLs for animal commodities, while calculation from the STMR values for feed is suitable for estimating STMR values for animal commodities. In the case of processed commodities, the STMR-P value is used for both intake calculations.

#### Estimated maximum dietary burden of farm animals

| Commodity                             | Codex code | Residue (mg/kg) | Basis           | Dry matter (%) | Residue, dry wt (mg/kg) | Dietary content (%) |              |         | Residue contribution of feeds (mg/kg) |              |         |
|---------------------------------------|------------|-----------------|-----------------|----------------|-------------------------|---------------------|--------------|---------|---------------------------------------|--------------|---------|
|                                       |            |                 |                 |                |                         | Beef cattle         | Dairy cattle | Poultry | Beef cattle                           | Dairy cattle | Poultry |
| Rice bran                             | CM         | 36              | STMR-P          | 90             | 40                      |                     |              |         |                                       |              |         |
| Rice hulls                            | CM         | 50              | STMR-P          | 90             | 55.6                    |                     |              |         |                                       |              |         |
| Wheat milled by-products <sup>a</sup> | CF         | 19.75           | STMR-P          | 88             | 22.44                   | 40                  | 50           | 50      | 8.98                                  | 11.22        | 11.22   |
| Wheat grain                           | GC         | 7.6             | Highest residue | 89             | 8.54                    |                     |              |         |                                       |              |         |
| Total                                 |            |                 |                 |                |                         | 40                  | 50           | 50      | 8.98                                  | 11.22        | 11.22   |

<sup>a</sup> Use of wheat bran

#### Estimated mean dietary burden of farm animals

| Commodity                             | Codex code | Residue (mg/kg) | Basis  | Dry matter (%) | Residue, dry wt (mg/kg) | Dietary content (%) |              |         | Residue contribution of feeds (mg/kg) |              |         |
|---------------------------------------|------------|-----------------|--------|----------------|-------------------------|---------------------|--------------|---------|---------------------------------------|--------------|---------|
|                                       |            |                 |        |                |                         | Beef cattle         | Dairy cattle | Poultry | Beef cattle                           | Dairy cattle | Poultry |
| Rice bran                             | CM         | 36              | STMR-P | 90             | 40                      |                     |              |         |                                       |              |         |
| Rice hulls                            | CM         | 50              | STMR-P | 90             | 55.6                    |                     |              |         |                                       |              |         |
| Wheat milled by-products <sup>a</sup> | CF         | 19.75           | STMR-P | 88             | 22.44                   | 40                  | 50           | 50      | 8.98                                  | 11.22        | 11.22   |
| Wheat grain                           | GC         | 5               | STMR   | 89             | 5.62                    |                     |              |         |                                       |              |         |
| Total                                 |            |                 |        |                |                         | 40                  | 50           | 50      | 8.98                                  | 11.22        | 11.22   |

<sup>a</sup> Use of wheat bran

#### Residues in grazing animals and feeding studies

The 2003 JMPR evaluated the fate of fenitrothion residues in cattle grazing on fenitrothion-treated grass and in cattle fed fenitrothion-treated corn. The Meeting received an additional study on cattle grazing on pasture treated with fenitrothion, a feeding study in lactating dairy cattle and a feeding study in laying hens.

Fenitrothion as technical material was applied by air to a 120-ha paddock by the ultra-low volume technique at the rate of 0.508 kg ai/ha. There were 28 *cattle* on the pastures when the application was made, and 38 were brought to the treated pastures immediately after spraying. Four cattle were maintained as controls, with no exposure to fenitrothion. The cattle were allowed to graze on the sprayed pasture for varying periods and were slaughtered within 1 day after removal from the paddock, 2, 4, 7, 14 or 21 days after treatment. Samples of subcutaneous and perirenal fat, meat (neck muscle) and liver were taken for analysis. Some cattle were removed from the treated pasture and were grazed on clean pasture for 2, 4 or 7 days before slaughter to determine the effect on the residue levels of this procedure. Soil and pasture were sampled on days -3, 0, 1, 2, 4, 7, 10, 14 and 21 and analysed for fenitrothion residues. The worst-case estimate of total exposure (pasture + soil + deposition) of the cattle on the day of spraying was 800–900 mg of fenitrothion per animal. As the total intake of dry matter from the pasture was assumed to be 10 kg/day, the exposure corresponds to a fenitrothion content of approximately 90 ppm.

Data on residues found in the pasture indicate a half-life for fenitrothion of 1–2 days, which declined with time; the decay during the first period appeared to be faster than that during later periods on a per hour basis. About 50% of the fenitrothion was gone within 1 day, 75% within 3 days and 90% within 6 days. Data on residues in the soil indicated a half-life for fenitrothion of 2–3 days. The residue levels in all animal commodities were below the LOQ (< 0.2 mg/kg for fat, < 0.02 mg/kg for muscle and liver).

Groups of three *lactating cows* received feed containing fenitrothion at a concentration of 0, 10, 30 or 100 ppm for 28 days. All animals were milked twice daily, and composite milk samples from the morning and afternoon milkings on days -1, 0, 3, 7, 14, 21 and 28 were analysed for residues. Cream was analysed separately; the cream content of the milk was 5–8% and the butterfat content was 3–5%. The levels of residues of fenitrothion in milk were below the LOQ of 0.01 mg/kg for all groups. Residues were measured in cream at some times (scattered among groups), but the levels were never higher than 0.01 mg/kg. Samples of liver, kidney, muscle (cardiac, hind-quarter and front-quarter) and fat (omental and perirenal) were taken. Residue levels above the LOQ of 0.05 mg/kg were not found in any sample at any feed level.

Layer and broiler *hens* received feed containing fenitrothion at 0, 10, 30 or 100 ppm for 28 days. Egg samples were collected twice a week from each group and frozen until ready for analysis. Eggs from birds in the same dose group were combined. Half of the hens at each dietary concentration were killed on day 14, and the remaining hens were killed on day 28 of the study. Samples of red muscle, white muscle, liver and fat were taken at both times. The residue levels in all tissue samples taken on days 14 and 28 were below the limit of determination of 0.05 mg/kg. No residues of fenitrothion were found in eggs taken over the 28-day period.

#### *Maximum residue levels*

The calculated dietary burden of dairy cattle is 11.22 mg/kg, and that of beef cattle is 8.98 mg/kg. In the feeding study with cattle described above, no residues were found at levels above the LOQ (0.05 mg/kg) in muscle, fat, liver or kidney at dietary concentrations of 10, 30 and 100 mg/kg. Therefore, no residues at levels above the LOQ are to be expected at the calculated dietary burden. The levels of residues of fenitrothion in milk were below the LOQ of 0.01 mg/kg.

The calculated dietary burden of poultry is 11.22 mg/kg. In the feeding study in poultry, no residues were detected in muscle, liver, fat or eggs (< 0.05 mg/kg) at dietary concentrations of 10, 30 and 100 mg/kg.

The Meeting recommended maximum residue levels of 0.05\* mg/kg in meat (from mammals other than marine mammals), in edible offal (mammalian), in poultry meat and in eggs. The Meeting also recommended a maximum residue level of 0.01 mg/kg in milks. The STMR and the highest residue values for muscle, fat, liver, kidney, poultry meat and fat are estimated to be 0 mg/kg.



## DIETARY RISK ASSESSMENT

### *Long-term intake*

The IEDIs of fenitrothion, on the basis of the STMRs estimated for 12 commodities, for the five GEMS/Food regional diets represented 110–330% of the maximum ADI (0–0.005 mg/kg bw), see Annex 3. The information provided to the JMPR precludes an estimate that the dietary intake would be below the ADI.

The Meeting noted that the calculations of long-term intake were conservative, as they did not take into account the reduction in residue levels obtained by processing cereal grains, except for processing of wheat, barley and rice. The Meeting extrapolated processing data on wheat to rye. Information on processing of barley (uses besides beer), maize, millet and sorghum would be particularly useful for refining the intake calculations.

### *Short-term intake*

The IESTIs for fenitrothion were calculated for 25 food commodities for which maximum residue levels had been estimated and for which consumption data were available. The results are shown in Annex 4.

The IESTI represented 0–100% of the ARfD (0.04 mg/kg bw) for the general population and 0–160% of the ARfD for children. The values 120%, 150% and 160% represent the estimated short-term intake of wholemeal bread, wheat bran (unprocessed) and maize (fresh, flour), respectively, by children. The Meeting concluded that the short-term intake of residues of fenitrothion from uses other than on these three commodities that have been considered by the JMPR is unlikely to present a public health concern.

The Meeting noted that the intake calculations were conservative, as they did not take into account the reduction in residue levels obtained by processing cereal grains, except for processing of wheat, barley and rice. Information on processing of maize would be particularly useful for refining the intake calculations. Nevertheless, the exceedences found for children in the consumption of wheat bran and wholemeal bread cannot be further refined.

The Meeting noted that the ADI and the ARfD for fenitrothion were established by the 2000 JMPR. At that time, the concepts of overall NOAEL (see item 2.3) and of compound-specific adjustment factors (see item 2.1) had not been fully developed. In addition, the process of establishing ARfDs was at an early stage of development. In view of these considerations, the Meeting concluded that a review of the toxicological database of fenitrothion, taking into account the new concepts, could lead to a refinement of the ADI and the ARfD.

## 4.9 FENPROPIMORPH (188)

### TOXICOLOGY

#### *Evaluation for an acute reference dose*

Fenpropimorph is a morpholine fungicide with systemic activity, interfering with sterol biosynthesis. It was first evaluated by the 1994 JMPR, which established an ADI of 0–0.003 mg/kg bw on the basis of a NOAEL of 10 ppm, equal to 0.3 mg/kg bw per day, in a 2-year study of toxicity and carcinogenicity in rats. At the 2001 JMPR, an ARfD of 1 mg/kg bw was established on the basis of a NOAEL of 100 mg/kg bw per day in an acute neurotoxicity study in rats. In 2002, the Government of Germany asked the Meeting to reconsider the ARfD established for fenpropimorph by the 2001 JMPR, because this Government considered the NOAEL of 15 mg/kg bw per day for teratogenicity in the rabbit to be a more appropriate basis for the ARfD. The present review was undertaken to determine the appropriate end-point and NOAEL for

establishing an ARfD and to evaluate a new screening study of pre- and postnatal developmental toxicity in rats, which was submitted to the present Meeting.

Fenpropimorph is of low acute toxicity; in rats, the oral LD<sub>50</sub> was 1500–3500 mg/kg bw, the dermal LD<sub>50</sub> was 4300 mg/kg bw, and the inhalation LC<sub>50</sub> was 2.9 mg/l of air.

In a study of acute neurotoxicity in rats, the NOAEL was 100 mg/kg bw per day on the basis of clinical and behavioural signs observed at doses of 500 and 1500 mg/kg bw per day.

In a screening study of pre- and postnatal developmental toxicity in rats, the NOAEL for maternal toxicity was < 5 mg/kg bw per day on the basis of decreased food consumption during pregnancy and lactation and reduced body-weight gain during pregnancy, at all doses. The NOAEL for developmental toxicity was < 5 mg/kg bw per day on the basis of reduced body weight or body-weight gain in pups at all doses during lactation.

In a study of prenatal developmental toxicity in rats, an increased incidence of cleft palate (14 fetuses from seven litters) was observed at the highest dose of 160 mg/kg bw per day. At this dose, severe maternal toxicity, including mortality, was found. The NOAEL for developmental toxicity was 40 mg/kg bw per day, while the NOAEL for maternal toxicity was 10 mg/kg bw per day.

In a study of prenatal developmental toxicity in Himalayan rabbits, severe maternal toxicity, including mortality, was found at 60 mg/kg bw per day, the highest dose tested. The number of early resorptions and dead fetuses was increased such that only one fetus survived. This fetus had several abnormalities, including syndactyly of the forelimbs, an anomalous position of the hindlimbs and micromelia, fusion of individual sternebrae and reduced weight and length. At 36 mg/kg bw per day, the clinical signs in dams (diarrhoea, salivation) were less severe and occurred at a lower incidence than at the highest dose. Two animals aborted and three were killed *in extremis*. The number of postimplantation losses was slightly increased at this dose. Six fetuses from two litters had pseudoankylosis, a skeletal variation. The NOAEL was 12 mg/kg bw per day for both maternal toxicity and developmental toxicity.

In a study of prenatal developmental toxicity in Russian rabbits, maternal toxicity (swelling of the anus, reduction of food consumption and of body weight or body-weight gain, weight loss) was observed only at the highest dose tested, 30 mg/kg bw per day. There were no effects on pre- or postimplantation loss, number of live or dead fetuses per litter and sex ratio. Mean gravid uterus weight and weights of male fetuses were significantly reduced at the highest dose. There was an increase in the total number of malformations (21 fetuses from four litters) and in findings described as 'anomalies' (36 fetuses from 13 litters). The malformations occurred mainly in the litters of three dams that showed marked signs of toxicity during treatment. Twenty fetuses from three litters had shortened fore- and hindlimbs, and four fetuses from two litters had a cleft palate. Furthermore, position anomalies were observed in the forelimbs in twenty-five fetuses from seven litters and in the hindlimbs in eight fetuses from three litters. The NOAEL was 15 mg/kg bw per day for both maternal toxicity and developmental toxicity.

### ***Toxicological evaluation***

The Meeting established an ARfD of 0.2 mg/kg bw on the basis of an overall NOAEL of 15 mg/kg bw per day for embryo- and fetotoxicity and teratogenicity in two studies of prenatal developmental toxicity in rabbits and using a safety factor of 100. The LOAEL of 5 mg/kg bw per day for decreased body-weight gain in pups in the screening study of pre- and postnatal developmental toxicity in rats is related to repeated pre- and postnatal exposure and is therefore not considered to be an appropriate basis for establishing an ARfD.

*Levels relevant to risk assessment*

| Species | Study                                                   | Effect                 | NOAEL                             | LOAEL                           |
|---------|---------------------------------------------------------|------------------------|-----------------------------------|---------------------------------|
| Rat     | Acute neurotoxicity                                     | Neurotoxicity          | 100 mg/kg bw per day              | 500 mg/kg bw per day            |
|         | Screening for pre- and postnatal developmental toxicity | Maternal toxicity      | < 5 mg/kg bw per day              | 5 mg/kg bw per day              |
|         |                                                         | Developmental toxicity | < 5 mg/kg bw per day <sup>a</sup> | 5 mg/kg bw per day <sup>a</sup> |
|         | Prenatal toxicity                                       | developmental          | Maternal toxicity                 | 10 mg/kg bw per day             |
| Rabbit  | Prenatal toxicity                                       | developmental          | Developmental toxicity            | 40 mg/kg bw per day             |
|         |                                                         |                        |                                   | 160 mg/kg bw per day            |
|         | Prenatal toxicity                                       | developmental          | Maternal toxicity                 | 12 mg/kg bw per day             |
|         |                                                         |                        | Developmental toxicity            | 12 mg/kg bw per day             |
|         | Prenatal toxicity                                       | developmental          | Maternal toxicity                 | 15 mg/kg bw per day             |
|         |                                                         |                        | Developmental toxicity            | 15 mg/kg bw per day             |

<sup>a</sup> Effect considered not relevant for a single exposure

*Estimate of acute reference dose*

0.2 mg/kg bw

**DIETARY RISK ASSESSMENT*****Short-term intake***

The Meeting estimated an ARfD of 0.2 mg/kg bw for fenpropimorph. The 2001 JMPR had calculated the IESTI for fenpropimorph for 16 food commodities (and their processed fractions) for which MRLs were estimated and for which consumption data were available using the previous ARfD of 1 mg/kg bw.

The IESTI represented 0–7% of the ARfD for the general population and 0–10% of the ARfD for children.

The Meeting concluded that the short-term intake of residues of fenpropimorph from uses that have been considered by the JMPR is unlikely to present a public health concern.

**4.10 FENPYROXIMATE (193)****TOXICOLOGY*****Evaluation for an acute reference dose***

Fenpyroximate is a phenoxy pyrazole acaricide. Fenpyroximate was evaluated by the 1995 JMPR, when an ADI of 0–0.01 mg/kg bw was established on the basis of a NOAEL of 1 mg/kg bw per day in a 104-week study in rats and a safety factor of 100. The critical effect in that study was a reduction in body-weight gain. Fenpyroximate was re-evaluated by the present Meeting in order to determine an ARfD.

The acute oral LD<sub>50</sub> of fenpyroximate was 245 and 480 mg/kg bw in male and female rats, respectively. The toxic effects of fenpyroximate include diarrhoea, failure to gain weight and haematological and clinical chemistry changes. In short-term (range-finding) dietary studies in mice, the effects of fenpyroximate were mainly limited to decreases in food consumption and reduced body-weight gain. The

NOAELs for the two studies were 20 ppm (equal to 2.58 and 3.07 mg/kg bw per day in males and females, respectively) and 80 ppm (equal to 10.8 mg/kg bw per day in males and 11.7 mg/kg bw per day in females). In a 13-week dietary study in rats, effects were seen on body-weight gain, food consumption and haematological and clinical chemistry parameters. The NOAEL for the study was 20 ppm, equal to 1.30 mg/kg bw per day in males and 1.65 mg/kg bw per day in females. In a 13-week study in dogs given capsules containing fenpyroximate, weight loss or decreased weight gain, decreased food consumption and diarrhoea were seen. No NOAEL was identified in this study and the LOAEL was 2 mg/kg bw per day, on the basis of diarrhoea occurring at all doses. This was considered to be a minimal effect level and occurred from the beginning of the study. In a dietary study of reproductive toxicity in rats, parental toxicity comprised reduced body-weight gain and food consumption in both sexes and increased testicular and epididymal weights in males. Offspring toxicity consisted of reduced body-weight gain. A reduction in conception rate and fertility index was observed in one generation only. The NOAELs for parental, offspring and reproductive toxicity were all 30 ppm (equal to 1.99 mg/kg bw per day in parental males, 2.44 mg/kg bw per day in parental females, 2.33 mg/kg bw per day in F<sub>1</sub> males and 2.82 mg/kg bw per day in F<sub>1</sub> females). In a study of developmental toxicity in rats treated by gavage, effects were seen on maternal body weight, while increases in thoracic ribs were found in fetuses. The NOAEL for both effects was 5 mg/kg bw per day. In preliminary and substantive studies of the developmental toxicity of fenpyroximate in rabbits treated by gavage, reduced maternal body weight and food consumption was seen at the higher doses. These effects were not considered relevant for establishing an ARfD. The NOAEL for maternal toxicity was 1 mg/kg bw per day. Significant elevations in the frequency of unilateral and bilateral slightly folded retinas were observed in the fetuses at 5 mg/kg bw per day. No other evidence of fetotoxicity was observed and the biological significance of this finding is unclear.

### ***Toxicological evaluation***

The Meeting established an ARfD of 0.01 mg/kg bw on the basis of the a minimal LOAEL of 2 mg/kg bw per day for the induction of diarrhoea at the beginning of a 13-week study of toxicity in dogs. It was unclear whether the diarrhoea was the result of a direct irritant or pharmacological effect of fenpyroximate. A safety factor of 200 was used since no NOAEL was identified. This ARfD is probably conservative and could be refined using the results of an appropriately designed study.

An addendum to the toxicological monograph was prepared

#### *Estimate of acute reference dose*

0.01 mg/kg bw

#### *Studies that would provide information useful for continued evaluation of the compound*

Appropriately designed single-dose study

## **DIETARY RISK ASSESSMENT**

### ***Short-term intake***

The Meeting established an ARfD of 0.01 mg/kg bw for fenpyroximate. The 1999 JMPR had calculated the IESTI for fenpyroximate for 10 food commodities (and their processed fractions) for which MRLs were estimated and for which consumption data were available, but was not able to finalize the risk assessment because an ARfD was not available.

The IESTI represented 0–120% of the ARfD for the general population and 0–310% of the ARfD for children. The value 120% represents the estimated short-term intake of grapes by the general population. The values 130% and 310% represent the estimated short-term intakes of apples and grapes by children.

The Meeting concluded that the short-term intake of residues of fenpyroximate from uses, other than on apple and grape, that have been considered by the JMPR is unlikely to present a public health concern.

## 4.11 FLUDIOXONIL (211)

### TOXICOLOGY

Fludioxonil is the ISO approved name for a new phenylpyrrole fungicide, 4-(2,2-difluoro-1,3-benzodioxol-4-yl)pyrrole-3-carbonitrile (IUPAC), that interferes with glucose transport across fungal membranes. Fludioxonil has not been evaluated previously by the JMPR.

After oral administration of radiolabelled fludioxonil, the radiolabel is rapidly and extensively (approximately 80% of the administered dose) absorbed, widely distributed, extensively metabolized and rapidly excreted, primarily in the faeces (approximately 80%) via the bile (approximately 70%), with a small amount being excreted in the urine (approximately 20%). The maximum blood concentration is reached within 1 h after administration. Elimination is biphasic, with half-lives of between 2 and 5 h for the first phase and between 30 and 60 h for the second phase. Fludioxonil is rapidly cleared from the blood and tissues, and there is consequently negligible potential for accumulation. The metabolism of fludioxonil proceeds primarily through oxidation of the pyrrole ring, leading to one major (57% of the administered dose) and one minor (4% of the administered dose) oxo-pyrrole metabolite. Hydroxylation of the phenyl ring yields the corresponding phenol metabolite, which represents 2% of the administered dose. These phase I metabolites are subsequently excreted as glucuronyl and sulfate conjugates and, together with unabsorbed and unchanged fludioxonil excreted in faeces, account for approximately 75% of the administered dose. The dimerization of the hydroxy pyrrole metabolite produces a metabolite of an intense blue colour.

The dermal absorption of fludioxonil, excluding material bound to the skin, is low in rats in vivo (< 5%) and in human skin in vitro (< 0.5%). In a study of dermal penetration in rats in vitro, values for dermal absorption at low levels of application were comparable to those obtained in a study performed in vivo (< 2%), but at higher levels significantly overestimated absorption in vivo (38%).

Fludioxonil has low acute toxicity in rats when administered by oral, dermal or inhalation routes, producing no deaths at 5000 and 2000 mg/kg bw and 2.6 mg/l of air, respectively, the highest doses tested. There were also no deaths in mice given fludioxonil at 5000 mg/kg bw by gavage. Fludioxonil is a slight eye irritant in rabbits, but is neither a skin irritant in rabbits nor a skin sensitizer in guinea-pigs (Magnusson & Kligman maximization assay).

In studies with repeated doses in mice and rats, the liver (necrosis, centrilobular hypertrophy, increased serum cholesterol and 5' nucleotidase), the kidneys (nephropathy, inflammation, cysts) and haematopoietic system (mild anaemia) were the principal targets. Such effects often set the LOAELs for these studies, together with reduced body-weight gains. In mice, these effects were observed after 90 days of treatment at 450 mg/kg bw per day and at 590 mg/kg bw per day in one 18-month study, but not at 360 mg/kg bw per day in another such study. In rats, effects were seen at doses of  $\geq 400$  mg/kg bw per day in short-term studies and at 110 mg/kg bw per day in a 2-year study; lower body-weight gains were also observed at these doses. Liver toxicity was generally manifested by increased concentrations of serum cholesterol and bilirubin and centrilobular hypertrophy and/or necrosis. Anaemia in mice (at  $> 590$  mg/kg bw per day for 18 months) and rats (at 1300 mg/kg bw per day for 3 months) was seen at doses greater than the LOAEL. In dogs, anaemia was observed at the LOAEL (at 290 mg/kg bw per day for 3 months, but only after 4 weeks of treatment; and at a dose of 300 mg/kg bw per day for 12 months). No haematological effects were observed in shorter studies in mice (at  $\leq 1050$  mg/kg bw per day for 90 days) or rats (at  $\leq 2500$  mg/kg bw per day for 20 days and at  $\leq 1000$  mg/kg bw per day for 28 days).

Blue discolouration of the urine, perineal fur, kidneys and gastrointestinal tract were common observations in all species. These effects were secondary to the formation of the blue metabolite in quantities that were sufficient, at high doses, to stain the various tissues. The effect is not toxicologically significant and was disregarded in identifying NOAELs from studies in which it was observed.

Fludioxonil gave negative results in assays for reverse mutation in *S. typhimurium* and *E. coli*, gene mutation in Chinese hamster V79 cells, unscheduled DNA synthesis in rat hepatocytes, micronucleus formation in bone marrow of rats and mice in vivo and chromosome aberration in Chinese hamsters in vivo. Fludioxonil was clastogenic in Chinese hamster ovary cells (CCL61) in vitro at non-cytotoxic concentrations. There was no evidence of heritable genetic damage in an assay for dominant lethal mutations in mice.

The Meeting concluded that fludioxonil is unlikely to be genotoxic in vivo.

The carcinogenicity potential of fludioxonil was examined in a study in rats and in two studies in mice. While the incidence of lymphomas was slightly increased in females in one study in mice receiving diets containing fludioxonil at a concentration of 3000 ppm (equal to 360 mg/kg bw per day), no increase was observed in a concurrent life-time study in mice given diets containing fludioxonil at dietary concentrations of up to 7000 ppm (1000 mg/kg bw per day). Lymphoma is a common finding in ageing female CD-1 mice, and the historical incidence at the laboratory conducting these studies was 13–32%, which encompasses the incidence noted in females at 3000 ppm (30%). Given the high background rate of this finding and the lack of any increase in the other study by the same authors using higher doses, the Meeting concluded that the apparent increase in lymphomas observed in one study in mice was incidental. There was no evidence of carcinogenic potential with fludioxonil in the study in rats. The overall NOAELs in the long-term studies were 112 and 37 mg/kg bw per day in mice and rats respectively.

On the basis of the above consideration and on the lack of genotoxic potential in vivo, the Meeting concluded that fludioxonil is unlikely to pose a carcinogenic risk to humans.

In a two-generation study of reproductive toxicity in rats, at a dose of 210 mg/kg bw per day, adult males had reduced body-weight gains and food consumption and pups had lower body-weight gains. The NOAEL for parental and pup toxicity was 21 mg/kg bw per day. The NOAEL for effects on reproductive performance was 21 mg/kg bw per day on the basis of reduced pup weights. As no effects on body-weight gain, or any other parameter, were seen in adult rats at 37 mg/kg bw per day in a 2-year study, the NOAEL for parental animals in the study of reproductive toxicity can also be considered to be > 37 mg/kg bw per day. The NOAEL of 21 mg/kg bw per day for pup toxicity was based on effects observed at 210 mg/kg bw per day. These effects were relatively mild and the dose–response relationship appears to be shallow (12% decrease in body-weight gain over the dose range of 190 mg/kg bw per day, or a 1%, or less, decrease in body-weight gain per dose increment of 16 mg/kg bw per day). Assuming a linear dose–response relationship between 21 and 210 mg/kg bw per day, then at the proposed overall NOAEL for rats of 37 mg/kg bw per day, a decrease in body-weight gain of  $\leq 1\%$  would be predicted in pups; this would not be interpreted as being an adverse effect. Consequently, the use of an overall NOAEL of 37 mg/kg bw per day is also appropriate for pup toxicity. In a study of developmental toxicity in rabbits and another in rats, fludioxonil was neither teratogenic nor fetotoxic and fetal weights were unaffected at doses of up to 1000 and 300 mg/kg bw per day, respectively. Maternal toxicity in these studies was limited to reduced body-weight gain at 1000 and 300 mg/kg bw per day in rats and rabbits, respectively.

The Meeting concluded that the existing database on fludioxonil was adequate to characterize the potential hazards to fetuses, infants and children.

Studies of acute oral toxicity and genotoxicity with a range of plant metabolites of fludioxonil showed that these metabolites are of low acute oral toxicity and are not genotoxic. The NOAEL in a 90-day study in rats given diets containing a photolytic/hydrolytic degradation product of fludioxonil found in soil and water was 800 ppm (equal to 58 mg/kg bw per day), on the basis of increased relative kidney weight and tubular casts at  $\geq 2500$  ppm (in males) and minimal to slight atrophy of the olfactory epithelium at  $\geq 2500$  ppm.

### Toxicological evaluation

The Meeting established an ADI of 0–0.4 mg/kg bw based on a NOAEL of 37 mg/kg bw per day in a 2-year dietary study in rats and a 100-fold safety factor.

Although effects on the kidneys occurred after relatively short periods of exposure, the Meeting concluded that such effects were unlikely to result from a single exposure. Consequently, the Meeting concluded that an ARfD for fludioxonil was unnecessary.

A toxicological monograph was prepared.

#### Levels relevant to risk assessment

| Species | Study                                                       | Effect                   | NOAEL                                                | LOAEL                                   |
|---------|-------------------------------------------------------------|--------------------------|------------------------------------------------------|-----------------------------------------|
| Mouse   | 18 month study of toxicity and carcinogenicity <sup>a</sup> | Toxicity                 | 1000 ppm, equal to 112 mg/kg bw per day              | 3000 ppm, equal to 360 mg/kg bw per day |
|         |                                                             | Carcinogenicity          | 3000 ppm equal to 360 mg/kg bw per day <sup>b</sup>  | —                                       |
| Rat     | 2-year study of toxicity and carcinogenicity <sup>a</sup>   | Toxicity                 | 1000 ppm, equal to 37 mg/kg bw per day               | 3000 ppm, equal to 110 mg/kg bw per day |
|         |                                                             | Carcinogenicity          | 3000 ppm, equal to 110 mg/kg bw per day <sup>b</sup> | —                                       |
|         | Two-generation study of reproductive toxicity <sup>a</sup>  | Parental toxicity        | 300 ppm, equal to 21 mg/kg bw per day <sup>d</sup>   | 3000 ppm, equal to 210 mg/kg bw per day |
|         |                                                             | Embryo- and fetotoxicity | 300 ppm, equal to 21 mg/kg bw per day <sup>d</sup>   | 3000 ppm, equal to 210 mg/kg bw per day |
|         | Developmental toxicity <sup>c</sup>                         | Maternal toxicity        | 100 mg/kg bw per day                                 | 1000 mg/kg bw per day                   |
|         |                                                             | Embryo- and fetotoxicity | 1000 mg/kg bw per day <sup>b</sup>                   | —                                       |
| Rabbit  | Developmental toxicity <sup>c</sup>                         | Maternal toxicity        | 100 mg/kg bw per day                                 | 300 mg/kg bw per day                    |
|         |                                                             | Embryo- and fetotoxicity | 300 mg/kg bw per day <sup>b</sup>                    | —                                       |
| Dog     | 12-month study of toxicity <sup>a,e</sup>                   | Toxicity                 | 1000 ppm, equal to 33 mg/kg bw per day               | 8000 ppm, equal to 300 mg/kg bw per day |

<sup>a</sup> Diet

<sup>b</sup> Highest dose tested

<sup>c</sup> Gavage

<sup>d</sup> The NOAEL of 21 mg/kg bw per day in this study was adjusted upwards to 37 mg/kg bw per day on the basis of an absence of effects in 90-day and 2-year studies in rats at 64 and 37 mg/kg bw per day, respectively. Additionally, interpolation of the reduced weight gain in pups in the study of reproductive toxicity indicated a probably non-adverse, reduction in weight gain of 1% or less at the higher NOAEL of 37 mg/kg bw per day.

<sup>e</sup> The LOAEL for this study was 300 mg/kg bw per day. Owing to the wide dose spacing used for this study, the NOAEL is conservative; hence the slightly higher NOAEL obtained in the 2-year study in rats was selected for establishment of the ADI.

#### Estimate of acceptable daily intake for humans

0–0.4 mg/kg bw

#### Estimate of acute reference dose

Unnecessary

#### Studies that would provide information useful for continued evaluation of the compound

Further observations in humans

***Critical end-points for setting guidance values for exposure to fludioxonil***

|                                                                             |                |                                                                                                                                                                                                                                                |                      |
|-----------------------------------------------------------------------------|----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|
| <i>Absorption, distribution, excretion and metabolism in animals</i>        |                |                                                                                                                                                                                                                                                |                      |
| Rate and extent of oral absorption                                          |                | Rapid, approximately 80%                                                                                                                                                                                                                       |                      |
| Dermal absorption                                                           |                | Poor, < 10% in the rat in vivo; 1% or less in human skin in vitro                                                                                                                                                                              |                      |
| Distribution                                                                |                | Extensive                                                                                                                                                                                                                                      |                      |
| Rate and extent of excretion                                                |                | Largely complete within 24 h; approximately 10% in urine and 80% in the faeces; 70% of the administered dose was excreted in the bile                                                                                                          |                      |
| Potential for accumulation                                                  |                | Low, no evidence of accumulation                                                                                                                                                                                                               |                      |
| Metabolism in mammals                                                       |                | Extensively metabolized, involving primarily oxidation of the pyrrole ring leading to a major (57% of the administered dose) and a minor (4% of the administered dose) oxo-pyrrole metabolite, followed by glucuronyl- and sulfate conjugation |                      |
| Toxicologically significant compounds (animals, plants and the environment) |                | Parent compound and metabolites                                                                                                                                                                                                                |                      |
| <i>Acute toxicity</i>                                                       |                |                                                                                                                                                                                                                                                |                      |
| Rat, LD <sub>50</sub> , oral                                                |                | > 5000 mg/kg bw (no deaths)                                                                                                                                                                                                                    |                      |
| Rat, LD <sub>50</sub> , dermal                                              |                | > 2000 mg/kg bw (no deaths)                                                                                                                                                                                                                    |                      |
| Rat, LC <sub>50</sub> , inhalation                                          |                | > 2.6 mg/l (no deaths)                                                                                                                                                                                                                         |                      |
| Rabbit, dermal irritation                                                   |                | Not irritating                                                                                                                                                                                                                                 |                      |
| Rabbit, eye irritation                                                      |                | Slight irritant                                                                                                                                                                                                                                |                      |
| Skin sensitization                                                          |                | Not sensitizing (Magnusson & Kligman test)                                                                                                                                                                                                     |                      |
| <i>Short-term studies of toxicity</i>                                       |                |                                                                                                                                                                                                                                                |                      |
| Target/critical effect                                                      |                | Damage to liver (rats and dogs) and kidney (mice and rats)                                                                                                                                                                                     |                      |
| Lowest relevant oral NOAEL                                                  |                | 1000 ppm, equal to 33 mg/kg bw per day (12-month study in dogs)                                                                                                                                                                                |                      |
| Lowest relevant dermal NOAEL                                                |                | 200 mg/kg bw per day (rats)                                                                                                                                                                                                                    |                      |
| Lowest relevant inhalation NOAEC                                            |                | —                                                                                                                                                                                                                                              |                      |
| Genotoxicity                                                                |                | Unlikely to pose a genotoxic risk in vivo                                                                                                                                                                                                      |                      |
| <i>Long-term studies of toxicity and carcinogenicity</i>                    |                |                                                                                                                                                                                                                                                |                      |
| Target/critical effect                                                      |                | Reduced body-weight gains and liver necrosis in rats, liver and kidney damage in mice                                                                                                                                                          |                      |
| Lowest relevant NOAEL                                                       |                | 1000 ppm, equal to 37 mg/kg bw per day, in rats                                                                                                                                                                                                |                      |
| Carcinogenicity                                                             |                | Not carcinogenic in rats or mice; unlikely to pose a carcinogenic risk to humans                                                                                                                                                               |                      |
| <i>Reproductive toxicity</i>                                                |                |                                                                                                                                                                                                                                                |                      |
| Reproductive target/critical effect                                         |                | Reduced pup weight gains in rats at parentally toxic doses                                                                                                                                                                                     |                      |
| Lowest relevant reproductive NOAEL                                          |                | 300 ppm, equal to 21 mg/kg bw per day                                                                                                                                                                                                          |                      |
| Developmental target/critical effect                                        |                | None                                                                                                                                                                                                                                           |                      |
| Lowest relevant developmental NOAEL                                         |                | 300 mg/kg bw per day (the highest dose tested in rabbits)                                                                                                                                                                                      |                      |
| Neurotoxicity/delayed neurotoxicity                                         |                | No evidence of neurotoxicity in any study conducted                                                                                                                                                                                            |                      |
| Other toxicological studies                                                 |                | Studies on plant metabolites and a photolytic/hydrolytic degradation product of fludioxonil indicated that these were of no greater toxicity than the parent compound                                                                          |                      |
| Medical data                                                                |                | Medical monitoring since 1992 of employees engaged in the manufacture of fludioxonil, or its formulation, into products has not revealed any adverse health effects                                                                            |                      |
| <b>Summary</b>                                                              | <b>Value</b>   | <b>Study</b>                                                                                                                                                                                                                                   | <b>Safety factor</b> |
| ADI                                                                         | 0–0.4 mg/kg bw | 2-year study in rats (liver effects and reduced body-weight gains)                                                                                                                                                                             | 100                  |
| ARfD                                                                        | Unnecessary    | —                                                                                                                                                                                                                                              | —                    |



## RESIDUE AND ANALYTICAL ASPECTS

Fludioxonil, or 4-(2,2-difluorobenzo[1,3]dioxol-4-yl)-1*H*-pyrrole-3-carbonitrile, is a fungicide that belongs to the chemical class phenylpyrroles. It functions by blocking the protein kinase which catalyses the phosphorylation of a regulatory enzyme of glycerol synthesis. It is specific for a limited number of fungi. It was evaluated for the first time by the 2004 Joint Meeting.

### *Metabolism*

#### *Animals*

The metabolism of <sup>14</sup>C-pyrrole-labelled fludioxonil was studied in goats and laying hens. Two goats were given radiolabelled fludioxonil orally at a level equivalent to 100 ppm in the feed for 4 consecutive days. The levels of radioactive residue, calculated as fludioxonil, were: 0.07 mg/kg in tenderloin muscle, 0.19 mg/kg in fat, 5.8 mg/kg in liver, 2.9 mg/kg in kidney and 2.2 mg/kg in milk on day 4. Organic solvents released 35% of the TRR in liver, 76% in muscle, 50% in kidney, 35% in liver, 87% in fat and 90% in milk. Protease treatment of the solid residues from solvent extraction of liver, kidney and muscle released 75–91% of the remaining activity. Less than half of this released activity was characterized as proteins by derivatization with 2,4-dinitrofluorobenzene.

The main component identified in muscle was fludioxonil, representing 24% and 43% of the TRR in the two goats. Likewise, fludioxonil was the main component of the residue in omental fat, representing 83% TRR. The main identified metabolite in muscle was the sulfate conjugate of the 2-hydroxy or 5-hydroxy derivative of fludioxonil (22% or 2% TRR). Minor metabolites identified in muscle (< 10% TRR) included the 2-*O*-glucuronide derivative of fludioxonil and the 5-*O*-glucuronide derivative of fludioxonil. (The position numbers refer to the pyrrole ring.) About 50% of the residue in muscle and 83% of the residue in fat were identified.

Multiple components were found in kidney and liver. The following were identified in kidney: 2-*O*-glucuronide derivative of fludioxonil (23% TRR); 7'-*O*-glucuronide derivative (8% TRR); 5-*O*-glucuronide derivative (15% TRR); fludioxonil (2% TRR); and 2- or 5-*O*-sulfate ester (0.7% TRR), for a total identification of 48%. In liver, only fludioxonil was identified (14% TRR). Two labile compounds (24% TRR) were also encountered. No compounds without the pyrrole–phenyl linkage were identified.

On the basis of the identified and characterized residues, the Meeting concluded that the metabolism of fludioxonil via the oral route in goats involves oxidation of the pyrrole ring at the 2 and 5 positions, followed by rapid conversion to sulfate and glucuronide conjugates. A minor route involves oxidation of the benzodioxol ring at the 7' position and conversion to the glucuronide conjugate. Evidence was also found for substantial incorporation into natural products, including proteins, in kidney and liver.

Five laying hens were given gelatin capsules containing [<sup>14</sup>C-pyrrole]fludioxonil for 8 consecutive days at a rate equivalent to about 89 ppm in the feed. The vast majority of the radiolabelled residue was eliminated in the excreta (88–102% of the total administered dose). The levels of radioactive residues, calculated as fludioxonil, in the tissues and eggs were as follows: liver, 8.9 mg/kg; muscle, 0.12 mg/kg; skin with fat, 0.25 mg/kg; peritoneal fat, 0.17 mg/kg; egg yolk, 1.8 mg/kg (day 7); egg white, 0.054 mg/kg (day 7).

A series of organic solvent extractions released 61% TRR in liver, 33% in kidney, 62% in muscle, 42% in skin with fat, 74% in egg white and 83% in egg yolk. The solids remaining after solvent extraction of liver (33% TRR), kidney (54%) and muscle (34%) were solubilized with protease and characterized by treatment with 2,4-dinitrofluorobenzene. Protease solubilized 54% of the unextracted activity in liver, 63% of that in kidney and 67% of that in muscle. About 25% of the released radioactivity (< 10% TRR) was derivatized by 2,4-dinitrofluorobenzene at pH 2, indicating the terminal amino group of amino acids.

Alkaline hydrolysis (15% KOH, 95 °C) released all the remaining radioactivity from the solvent-extracted liver (33% TRR), but it could be characterized only as acidic, polar compounds.

About 69% of the TRR in eggs, 24% in liver, 14% in kidney, 44% in muscle and 29% in skin with fat were identified. The main metabolites identified in eggs were the sulfate conjugate of the 1-hydroxy derivative of fludioxonil (40% TRR), the succinamic acid derivative (10% TRR) and the sulfate conjugate of the 2-hydroxy or 5-hydroxy derivative (13% TRR). Fludioxonil was a minor component (2.1% TRR) in eggs. The succinamic acid derivative was the only significant metabolite identified in liver, at about 6% TRR. The metabolites identified in kidney were the glucuronide conjugate of the 2-hydroxy or 5-hydroxy derivative (4.7% TRR), fludioxonil (2.6% TRR) and the 7'-hydroxy derivative (2.8% TRR). The main components identified in breast muscle were fludioxonil (29% TRR) and the sulfate conjugate of the 1-hydroxy derivative. A similar situation existed for skin with attached fat, which contained fludioxonil (9.8%) and the sulfate conjugate of the 1-hydroxy derivative (14%).

On the basis of the characterizations and identifications made in the study of metabolism in hens, the Meeting concluded that metabolism in poultry involves oxidation at the C-2, C-5 and N-1 positions in the pyrrole ring and at the C-7' of the benzodioxol ring. This is followed by the formation of sulfate or glucuronide conjugates. The C-2 hydroxypyrrole further oxidizes to the 2,5-dioxo-2,5-dihydro pyrrole and succinamic acid derivatives. The last two compounds are unique to poultry. The remaining metabolites found in the hen and all the metabolites in ruminants were also found in rats. The studies of metabolism in rats were reviewed by the WHO Expert Group of the 2004 JMPR.

### *Plants*

The metabolism of radiolabelled fludioxonil resulting from its foliar application has been studied in grape, tomato, peach, green onion and head lettuce. Grape vines were sprayed three times at 3-week intervals with [pyrrole-4- $^{14}$ C] fludioxonil at a rate of 500 g ai/ha per application. Samples of grapes and leaves were taken at intervals, immediately after the first application, up to grape maturity 35 days after the final application. Grapes at maturity contained 2.5–2.8 mg/kg of radiolabelled residue, calculated as fludioxonil. About 57% of the TRR was a surface residue, released by a methanol–water rinse; another 32% of the TRR was released by solvent extraction. The leaves at maturity contained 5.2 mg/kg of radiolabelled residue, 52% as a surface residue and 44% solvent extracted.

The residues in grapes and leaves were extensively identified. In grapes at maturity, seven compounds were identified, but only fludioxonil at 70% TRR exceeded 2% TRR. The metabolites included the succinamic acid derivative (< 1% TRR), the 3-hydroxy succinamic acid derivative (< 1% TRR), the glucose conjugate of 2-hydroxyacetamide benzodioxol (< 1% TRR), 2-hydroxyacetamide benodioxol (< 1% TRR), the 2-hydroxy-5-oxo derivative (2% TRR), the 2,5-dioxo derivative (< 1% TRR) and the 1-hydroxy-2,5-dioxo derivative (< 1% TRR). Similar metabolites were identified in leaves, fludioxonil representing 69% of the TRR; no other metabolite exceeded 6% TRR.

The metabolism of [pyrrole-4- $^{14}$ C]fludioxonil was studied in greenhouse tomato plants that were sprayed three times at 2-week intervals with a wettable powder formulation at a single application rate of 750 g ai/ha. Forty days after the last application, leaves and tomatoes were sampled. The leaves contained a fludioxonil-equivalent radiolabelled residue level of 7.0 mg/kg, and the tomatoes contained 0.28 mg/kg. Of the residue on tomatoes, 41% was on the surface. Rinsing and solvent extraction released 95% of the residues in tomatoes and 95% of those in leaves. About 73% of the tomato residue and 69% of the leaf residue was fludioxonil. Five metabolites, representing 3.6% of the TRR in tomato, were identified. These were the same metabolites as in grapes, except that the 2,5-dioxopyrrole derivative was not found and the benzodioxole-4-carboxylic acid derivative was present but at below the LOQ (< 0.001 mg/kg).

The metabolism of [phenyl-U- $^{14}$ C]fludioxonil was studied in peaches. Three foliar applications at 30-day intervals were made at 130 and 1300 g ai/ha, starting at petal fall. Mature fruit was collected 28 days after the second treatment. In a second trial, two applications, 950 and 2860 g ai/ha, were made at a 35-day interval, starting at petal fall. Samples of immature and mature fruits were taken 30 and 114 days after the second application. The radiolabelled residue level, calculated as fludioxonil, was 0.083 mg/kg and

0.98 mg/kg in the first trial after application at 130 and 1300 g ai/ha, respectively. The residue level on mature peaches in the second trial was 0.26 mg/kg (114-day PHI).

Extraction with acetonitrile:water:acetic acid (80:20:1, v/v) released  $\geq 88\%$  TRR in all cases. Analyses were conducted on extracts from 28-day peaches treated at 130 and 1300 g ai/ha in the first trial and on 114-day peaches from the second trial. Fludioxonil was the main component in all cases, ranging from 22% TRR to 62% TRR. Eight metabolites were identified in the 114-day PHI peaches, of which four are also grape or tomato metabolites (succinamic acid derivative, 3% TRR; 2-hydroxy-5-oxo derivative, 1.4% TRR; 2-hydroxy-5-oxo derivative, 1% TRR; benzodioxole-4-carboxylic, 1% TRR). The other metabolites included oxidized fludioxonil glucose conjugates at 7% TRR and an oxirane-2-carboxylic acid derivative at 3% TRR. About 54% of the TRR in peach was identified.

The metabolism of [phenyl- $U$ - $^{14}C$ ]fludioxonil on green onions was studied after radiolabelled fludioxonil was applied twice at a 14-day interval at a rate of 560 or 680 g ai/ha and at 2800 or 3380 g ai/ha. Samples were taken at maturity (14-day PHI) and at other intervals. TRR as fludioxonil represented 1.6 mg/kg on the onions given the 560 or 680 kg ai/ha treatment and 10 mg/kg on those given the 2800 or 3380 g ai/ha treatment. After the 2800 or 3380 g ai/ha treatment, 51% of the TRR was soluble in organic solvents and 21% in water.

The metabolitic profiles were qualitatively similar at the two treatment levels and at the various sampling intervals. In the onions treated at 2800 or 3380 g ai/ha at mature harvest (14-day PHI), fludioxonil comprised 49% of the TRR. Six metabolites were identified, but none represented  $> 2\%$  TRR. These were the same metabolites identified in the studies of grape, tomato and peach metabolism.

The metabolism of [pyrrole-4- $^{14}C$ ]fludioxonil on head lettuce was studied after three foliar treatments at 10-day intervals at 200 g ai/ha. A second experiment was conducted at 600 g ai/ha per application. With a 6-day PHI, the TRR calculated as fludioxonil was 1.3 mg/kg after treatment at 200 g ai/ha and 5.8 mg/kg at 600 g ai/ha treated. Almost 100% of the radioactivity was extracted with methanol:water. Fludioxonil was the main component (68% TRR after the 200 g ai/ha treatment, 80% after the 600 g ai/ha treatment).

Six metabolites, four of which corresponded to metabolites in the studies of tomato, grape and peach, were identified. No metabolite exceeded 3% TRR. Metabolites unique to head lettuce were lactic acid conjugates of fludioxonil (1–2% TRR).

Several studies were also conducted on metabolism after seed treatment. Seed potatoes were treated with [pyrrole-4- $^{14}C$ ]fludioxonil at a rate of 2.5 g ai/100 kg seed. The pieces were planted, and mature potatoes were harvested after 95 days. The tuber contained 0.006 mg/kg radiolabelled residue, calculated as fludioxonil. Fludioxonil represented 21% of the TRR.

Rice seeds were soaked in a [pyrrole-4- $^{14}C$ ]fludioxonil solution equivalent to 6.5 kg ai/100 kg seed. Rice plants were grown in a glasshouse and harvested at maturity, 152 days after treatment. Stalks, hulls and seeds contained  $\leq 0.002$  mg/kg radiolabelled residue as fludioxonil equivalents.

The metabolism of [pyrrole-4- $^{14}C$ ]fludioxonil was studied in field-grown spring wheat plants treated at 7.4 g ai/100 kg seed. Plants were harvested 48 days (ear emergence), 83 days (milky stage) and 106 days (maturity) after treatment. At 48 days, stalks contained 0.005 mg/kg of radioactive residue (calculated as fludioxonil). At 83 days, stalks contained 0.004 mg/kg and ears contained 0.002 mg/kg. At maturity, stalks contained 0.015 mg/kg, husks contained 0.005 mg/kg, and grain contained 0.003 mg/kg.

Cotton-seed was treated at a rate of 2.5 or 5.0 g ai/100 kg seeds with [pyrrole-4- $^{14}C$ ]fludioxonil and then planted in sandy loam soil in pots. Plants were sampled at maturity, 186 days after treatment. Cotton-seed treated at 5.0 g ai/100 kg seed contained 0.003 mg/kg TRR, and those treated at 2.5 g ai/100 kg contained 0.012 mg/kg. Only 20–30% of the radioactivity could be extracted.

Soya bean seeds were treated with [pyrrole-4- $^{14}C$ ]fludioxonil at a rate of 5.0 g ai/100 kg seed and grown to mature plants in a greenhouse. The plants were sampled at intervals of 28 days after planting (sixth

node stage), 38 days (mid- to full bloom stage) and 133 days (maturity). Soya bean forage (sixth node) contained 0.096 mg/kg TRR, calculated as fludioxonil. Soya bean hay (mid-flowering) contained 0.041 mg/kg. At maturity, stalks contained 0.005 mg/kg, dry beans contained 0.015 mg/kg, and dry hulls contained 0.012 mg/kg. The main tentatively identified component in forage and hay was 6-hydroxy-2*H*-chromeno[3,4-*c*]pyrrol-4-one, representing 2% TRR.

The metabolism of fludioxonil in and on plants after foliar and seed treatment is adequately understood. Generally, the residue concentrations resulting from seed treatment were too low to permit extraction and identification. The numerous studies of foliar application indicate a similar metabolic pathway, showing fludioxonil as the main component of the residue.

The pathway is characterized by the generation of a large number of metabolites and proceeds mainly through oxidation. Each metabolite represents < 10% TRR. With the exception of oxidation at the 7'-C of the benzodioxol ring, the oxidations and conjugations occur at the C-2, C-5 and N-1 positions of the pyrrole ring. Ultimately, cleavage of the pyrrole ring, probably via the formation of succinamic acid derivatives, results in formation of 2,2-difluorobenzo[1,3]dioxole metabolites. In studies with pyrrole- or phenyl-labelled <sup>14</sup>C-fludioxonil, no metabolites were found, indicating cleavage of the bond between the phenyl and pyrrole ring.

No information was provided on the degradation of fludioxonil when applied post-harvest. Nevertheless, the use of both short and long PHIs in the trial on metabolism in peaches after foliar application provides some indication of the fate of fludioxonil when applied to fruit post-harvest. The study of metabolism in peach shows that the main constituent in the residue is fludioxonil.

### Soil

The degradation of fludioxonil on soil exposed to light is rapid, with a half-life of < 1 day for the component of fludioxonil on the surface. On the basis of isolated and identified degradates in studies of radiolabelled compound, it would appear that fludioxonil degrades to 4-(2,2-difluorobenzo[1,3]dioxol-4-yl)-2,5-dioxo-2,5-dihydro-1*H*-pyrrole-3-carbonitrile or the 2,5-dioxo derivative of fludioxonil. This metabolite undergoes epoxidation at the C-3 to C-4 position and pyrrole ring opening to give 3-carbamoyl-2-cyano-3-(2,2-difluorobenzo[1,3]dioxol-4-yl)oxirane-2-carboxylic acid. The latter degrades to 2,2-difluoro-benzo[1,3]-dioxole-4-carboxylic acid, a compound found in the studies of rotational crops (see below).

The breakdown of fludioxonil in soil under aerobic conditions with no exposure to light is slow. Mineralization to carbon dioxide is the main route of breakdown (4–45% of applied radioactivity). Some unextractable residues (8–27%) also form. The half-life in sandy loam soil is approximately 250 days.

Four studies of confined rotational crops were conducted with [pyrrole-4-<sup>14</sup>C]fludioxonil. In the first study, soil was sprayed with [pyrrole-4-<sup>14</sup>C]fludioxonil at a rate of 750 g ai/ha, and lettuce, winter wheat, sugar beets and maize were planted after intervals of 90, 140, 320 and 345 days, respectively. Lettuce at maturity (152 days post-treatment) contained 0.006 mg/kg radiolabelled residue, winter wheat stems and grain contained 0.008 and 0.002 mg/kg 429 days post-treatment, sugar beet roots and tops contained 0.001 and < 0.001 mg/kg, respectively, and maize stalks and grain contained 0.005 and < 0.001 mg/kg, respectively, at maturity (519 days after treatment). The concentrations of residue were too low to pursue isolation and identification.

In a follow-up study, spring wheat, mustard and turnips were planted 33 days after application of [pyrrole-4-<sup>14</sup>C]fludioxonil to bare ground at a rate of 120 g ai/ha. At maturity, the residue levels were < 0.01 mg/kg (TRR) in the turnips and mustard greens and 0.006 mg/kg in wheat grain. In 25% mature wheat forage (109 days post-treatment) and in wheat straw (175 days post-treatment), however, the residue levels were 0.058 and 0.12 mg/kg, respectively. The following components were identified in immature wheat forage: fludioxonil (2.4% TRR, 0.001 mg/kg), 6-hydroxy-2*H*-chromeno[3,4-*c*]pyrrol-4-one (11% TRR, 0.006 mg/kg, tentative identification), 4-hydroxy-2,5-dione derivative (4.2% TRR, 0.002 mg/kg), 2,5-dioxo derivative (< 0.001 mg/kg, tentative identification), 2,2-difluoro-benzo[1,3]dioxole-4-carboxylic acid (2.3%

TRR, 0.001 mg/kg, tentative identification) and 2-(2,2-difluorobenzo[1,3]dioxol-4-yl)-2-hydroxyacetamide (< 0.001 mg/kg, tentative identification). Fludioxonil (< 0.001 mg/kg) and similar metabolites at similar concentrations were detected in wheat straw. This work was confirmed by another experiment conducted at 60 g ai/ha.

In a final trial, [phenyl-U-<sup>14</sup>C]fludioxonil was sprayed onto bare ground at a rate of 1120 g ai/ha. Rotational crops of spring wheat, mustard and radishes were planted 30, 90 and 210 days after treatment and grown to normal maturity. Radish tubers contained 0.14, 0.019 and 0.019 mg/kg of radiolabelled residue at plant-back intervals of 30, 90 and 210 days, about 50% of which could be extracted with organic solvents and water. Mustard greens contained 0.033, 0.044 and 0.050 mg/kg at 30, 90 and 120 days after treatment. Mature wheat straw contained 0.36, 0.14 and 0.11 mg/kg radiolabelled residues, and grain contained 0.058, 0.021 and 0.019 at 30, 90 and 120 days plant-back, of which about 40% from straw and 20% from grain was extractable.

The main metabolite identified in the various commodities was 2,2-difluorobenzo[1,3]dioxole-4-carboxylic acid, at levels ranging from 4.4% TRR in mature wheat straw (30-day plant-back) to 38% TRR (radish tuber, 90-day plant-back). Fludioxonil generally represented < 4% TRR ( $\leq 0.001$  mg/kg) in all matrices except mature radish tuber (30-day plant-back), in which it represented 12% TRR or 0.016 mg/kg.

Field rotational crop studies were conducted in which fludioxonil was applied four times to bare soil at 280 g ai/ha per application, followed at plant-back intervals of 30, 90, 150 and 210 days by sowing of wheat, turnips and leaf lettuce. The mature crops contained no detectable residues of fludioxonil at any plant-back interval, with a LOQ of 0.01 mg/kg.

The nature and extent of the residue in rotational crops after use of fludioxonil on the primary crop is adequately delineated. Similar patterns were observed with pyrrole- and phenyl-labelled <sup>14</sup>C-fludioxonil, although somewhat greater concentrations of residue were encountered with the phenyl label. In these trials, fludioxonil was not taken up into rotational crops at plant-back intervals as short as 30 days. The metabolism of fludioxonil in the crops was apparently the same as that seen in target crop studies, but this conclusion is speculative as little or no residue was generally found. Primarily on the basis of the confined study with [phenyl-U-<sup>14</sup>C]fludioxonil, the metabolism and degradation of this compound is characterized by oxidation and cleavage of the pyrrole ring. No metabolites of cleavage of the bond between the phenyl and the pyrrole ring were observed. The proposed metabolic and degradation pathway is that suggested for foliar application of fludioxonil.

The Meeting concluded that the presence of fludioxonil residues in succeeding (rotational) crops from foliar applications is unlikely.

### ***Methods of analysis***

The Committee concluded that adequate analytical methods exist for both monitoring and enforcing MRLs and for gathering data in supervised field trials and processing studies. Methods REM-133/AG631A and AG-597 are suitable for the determination of fludioxonil in samples of plant origin. The methods are fully validated for a range of crops and crop types. In addition, fludioxonil residues can be determined in samples of plant origin by European multi-residue method DG S17.

Method REM-133 involves high-performance liquid chromatography (HPLC) with ultraviolet detection (268 nm). Only fludioxonil is determined. Samples are extracted and then placed on a phenyl solid-phase extraction cartridge and eluted with the appropriate solvent. The samples are analysed by HPLC with column switching (C-18 and phenyl). The validated LOQ is 0.01–0.04 mg/kg. In some European field trials, method REM 133 was modified by the use of only one HPLC column (amino) with a fluorescence detector (excitation, 265 nm; emission, 312 nm). The method was radiovalidated. In this method, 89% of the total radioactivity was solubilized, and 66% of the fludioxonil determined in the metabolism study was identified.

Method AG-597 is another HPLC method with ultraviolet detection (268 nm). Only fludioxonil is determined. Samples are extracted and then cleaned-up by silica solid-phase extraction. Analysis is usually conducted on an amino or a C18 column. The method was validated with a wide array of commodities, with limits of determination of 0.01–0.02 mg/kg, except for sorghum grain, for which the limit was 0.05 mg/kg. The method was validated by the US Environmental Protection Agency. Liquid chromatography with mass spectrometry can be used for confirmation, with quantification on ion 247.

A European multi-residue method based on DFG S19 was developed for an array of plant commodities. Extracts are separated by gel permeation chromatography and analysed by capillary gas chromatography with a mass selective detector, monitoring ions 248, 154 and 127. The method was validated for fludioxonil only at 0.02 mg/kg for tomato, orange, wheat and rape and at 0.01 mg/kg for grape wine.

The Meeting concluded that an adequate method exists for the determination of fludioxonil and certain metabolites in livestock commodities (meat, milk, poultry, eggs). In the HPLC method, fludioxonil and metabolites are converted to 2,2-difluoro-1,3-benzodioxole-4-carboxylic acid. The resulting residue is quantified by external calibration against standards of this conversion product, with HPLC and a ultraviolet detector (230 nm). Column switching is used, and alternate columns are specified as a confirmatory procedure. The method was validated at 0.01 mg/kg for muscle and milk and at 0.05 mg/kg for eggs, fat, liver and kidney.

### ***Stability of residues in stored analytical samples***

The Meeting concluded that fludioxonil is stable in an array of stored frozen commodities. No degradation of fludioxonil was observed in any frozen commodity throughout the duration of the studies. Fludioxonil is stable for at least 24 months in frozen samples of the following commodities: cereal grains, cereal straw, apple, tomato, grape, pea, rape-seed, maize grain, maize meal, sorghum hay, potato tuber and potato flake. Fludioxonil is stable for at least 12 months in frozen broccoli, cabbage and carrots and for 9 months in frozen chives. Fludioxonil is also stable for at least 3 months in frozen peach, plum, cherry and blueberry.

The Meeting also concluded that fludioxonil and metabolites, determined as 2,2-difluoro-1,3-benzodioxole-4-carboxylic acid, are stable for at least 12 months in frozen muscle and for at least 18 months in frozen liver, milk and eggs.

### ***Definition of the residue***

The results of the studies of metabolism after both seed treatment and foliar treatment show that the main identified component of the radiolabelled residue is fludioxonil. The identified metabolites generally represent < 10% of the TRR. The toxicological evaluation did not reveal any metabolites of special concern relative to the parent. The Meeting concluded that the residue definition for plant commodities for compliance with MRLs and for estimation of dietary intake is fludioxonil.

In the analytical methods for plant commodities, HPLC with ultraviolet detection or gas chromatography with mass spectrometry detection, only fludioxonil is determined.

The results of the studies of metabolism in goats and hens were similar. In goats, the main identified metabolite in meat, fat and liver was fludioxonil, representing 33%, 83% and 14% TRR, respectively. The main metabolite in milk and kidney was the pyrrole carbonitrile-*O*-glucuronide, representing 65% and 31% TRR, respectively, and the parent was absent. In hens, fludioxonil was present in muscle (7.9–28.8% TRR) and skin plus attached fat (9.8%). It accounted for 1.2% of the TRR in liver, 2.6% in kidney and 2.2% in egg yolk (equivalent to 2.1% egg TRR). The main identified component of the radioactive residue in eggs and fat was the sulfate conjugate of 4-(2,2-difluorobenzo[1,3]dioxol-4-yl)-1-hydroxy-1*H*-pyrrole-3-carbonitrile. The benzene–pyrrole linkage was intact in all the identified metabolites. The toxicological evaluation did not reveal any metabolites of particular concern relative to the parent.

The  $P_{ow}$  for fludioxonil is 4.1, suggesting that fludioxonil is fat-soluble. In goats, the radioactive residue represented 0.07 mg/kg TRR in muscle and 0.26 mg/kg in fat. The main component in muscle and fat was fludioxonil (24–43% TRR in muscle and 83% in fat). The Meeting concluded that the fludioxonil residue is fat-soluble, but it also noted the lack of information on milk fat from both the metabolism and the feeding study.

In the validated analytical method for fludioxonil, fludioxonil and pyrrole-derivative metabolites are converted to 2,2-difluorobenzo[1,3]dioxole-4-carboxylic acid.

The Meeting concluded that the residue definition of the residue for livestock commodities (for compliance with MRLs and for estimation of dietary intake) is the sum of fludioxonil and its benzopyrrole metabolites, determined as 2,2-difluoro-benzo[1,3]dioxole-4-carboxylic acid and expressed as fludioxonil.

### ***Results of supervised trials on crops***

Supervised trials were conducted with foliar treatment, seed treatment and post-harvest treatment of a variety of crops worldwide.

#### ***Citrus fruit***

Citrus (orange, lemon, grapefruit) was treated by post-harvest dip (120 g ai/hl) or spray (1000 g ai/250 000 kg fruit) in 28 trials conducted in the USA. GAP specifies a maximum of two treatments, one on entering storage and a second on exit of storage for market distribution, at a single application rate of 500 g ai/250 000 kg fruit (2 mg/kg; 0.85 kg ai/hl for droplet-type applications with a low-volume concentrate, 0.24 kg ai/hl for high-volume jet-type sprays) and 0.06 kg ai/hl for 30-s dip treatments. All trials were conducted at twice GAP in a single-application dip or high-volume spray, and nine of the trials included a second application at twice GAP with a re-treatment interval of 0 days. In the absence of data on residue level decline during storage of citrus, the Meeting considered application at twice GAP an approximation of the practical situation of two treatments at GAP with a variable interval between applications.

The residue levels on orange (six trials; one treatment at twice GAP), in ranked order, were: 0.48, 0.90, 1, 1.4, 2.2 and 2.8 mg/kg. The levels on lemon (seven trials; one treatment at twice GAP) were: 0.46, 0.54, 1., 1.1 (two), 2.9 and 3.2 mg/kg, and those on grapefruit (six trials; one treatment at twice GAP) were: 0.51, 0.94, 0.95, 1.4, 3.8 and 5.2 mg/kg. The nine trials consisting of two sequential applications, each at twice the GAP application rate, were considered exaggerations and were not used; the residue levels ranged from 0.52 mg/kg to 6.0 mg/kg.

The Meeting decided to combine the data; the residue levels on citrus (19 trials; one treatment at twice GAP single rate), in ranked order, were: 0.46, 0.48, 0.51, 0.54, 0.90, 0.94, 0.95, 1 (two), 1.1 (two), 1.4 (two), 2.2, 2.8, 2.9, 3.2, 3.8 and 5.2 mg/kg. Data on residues in pulp were available from only one trial on oranges, in which flesh and peel contained approximately equal concentrations of fludioxonil. The Meeting estimated a maximum residue level for whole citrus of 7 mg/kg and an STMR of 1.1 mg/kg.

#### ***Pome fruit***

*Apples* were treated by post-harvest dip or spray in the USA with a 50% wettable powder formulation. GAP specifies a maximum of two treatments, one on entering storage and a second on exit from storage for market distribution, at a single application rate of 500 g ai/250 000 kg fruit (2 mg/kg; 0.85 kg ai/hl for droplet-type applications with a low-volume concentrate, 0.24 kg ai/hl for high-volume jet-type sprays) and 0.06 kg ai/hl for dip treatments of approximately 30 s. Seven trials were conducted at approximately the GAP rate (single application), and two trials were conducted at the GAP rate with two sequential applications: dip at 0.06 kg ai/hl, followed by packing-line spray at 2.5 mg/kg (125% GAP). As GAP specifies two treatments, the Meeting regarded the two trials conducted with two applications as an approximation of GAP. The residue levels were 2.0 and 2.2 mg/kg. The Meeting considered two trials inadequate for estimating a maximum residue level.

*Pears* were treated by post-harvest dip or spray treatment in the USA with a 50% wettable powder formulation. GAP is identical to that for apples. Twelve trials were conducted, but only two were conducted with two applications: 0.048 kg ai/hl drench (80% dip GAP), followed by a packing-line spray at 0.2–0.6 kg ai/hl or 2.2–6.6 mg/kg fruit (110–300% GAP). As GAP specifies two treatments, the Meeting regarded the two trials conducted with two applications as an approximation of GAP. The residue levels (with an exaggerated rate for the second application) were 1.6 and 2.8 mg/kg. The Meeting considered two trials insufficient for estimating a maximum residue level.

The Meeting considered combining the post-harvest trials on pear and apple (same GAP) for mutual support, but considered four trials insufficient for these commodities.

Pears received foliar treatment with a 25% water-dispersible granule formulation in seven trials conducted at GAP (three in Italy, three in Spain and one in France). The GAPs are as follows: Italy, 0.02 kg ai/hl, 0.25 kg ai/ha, three applications, 14-day PHI; Spain, 0.025 kg ai/ha, 0.25 kg ai/ha, three applications, 7-day PHI. No GAP was available for France, and the GAP of Spain was applied to all trials (7-day PHI). The residue levels, in ranked order, were: 0.14, 0.15, 0.18, 0.21, 0.28, 0.32 and 0.36 mg/kg. The Meeting estimated a maximum residue level of 0.7 mg/kg and an STMR of 0.21 mg/kg.

#### *Stone fruit*

In seven post-harvest treatment trials (spray or dip), *peaches* were treated at the GAP of 0.06 kg ai/hl with a 50% wettable powder formulation. The residue levels on peaches after treatment (no storage interval), in ranked order, were: 0.37, 0.42, 1.6, 2.2, 2.8, 3.4 and 3.6 mg/kg.

Trials of foliar application of fludioxonil (62.5% water-dispersible granules, 25% fludioxonil) were conducted in France, Italy and Spain. The relevant GAPs are: France, 0.015 kg ai/hl, 14-day PHI; Italy, 0.015 kg ai/hl, 0.25 kg ai/ha, two applications, 14-day PHI. No GAP was available for Spain, and the GAP of Italy was applied. The residue levels in 11 trials at GAP, in ranked order, were: 0.02, 0.04 (two), 0.08 (two), 0.11, 0.23 (two), 0.29 and 0.33 mg/kg. The data set on post-harvest treatment contained the highest residue values and was used to estimate the maximum residue level and the STMR.

Post-harvest treatment of *plums* was investigated in two trials in the USA. GAP is spray application at 0.06 kg ai/hl of a 50% wettable powder formulation. The results were 0.10 and 0.92 mg/kg. As the results for post-harvest treatment of plums were not statistically significantly different from those for peaches with the same GAP, the populations can be combined for mutual support.

Trials of foliar application of fludioxonil (22.5% water-dispersible granules, 25% fludioxonil) to plums were conducted in France, Italy, Germany and Switzerland. The relevant GAPs are: France, 0.012 kg ai/hl, 0.12 kg ai/ha, three applications, 14-day PHI; Italy, 0.025 kg ai/hl, 0.25 kg ai/ha, two applications, 14-day PHI; Switzerland, 0.3 kg ai/ha, two applications, PHI not specified. GAP in Germany was not available, and the GAP of Italy was applied. In 12 trials at GAP, the residue levels, in ranked order, were: < 0.02, 0.03, 0.04, 0.05, 0.06 (two), 0.065, 0.07, 0.09, 0.10, 0.11 and 0.17 mg/kg. The data set on post-harvest treatment contained the highest residue values and was used to estimate the maximum residue level and the STMR.

Post-harvest treatment of *cherries* was investigated in two trials in the USA. GAP is spray application at 0.06 kg ai/hl of a 50% wettable powder formulation. The residue levels were 0.19 and 0.68 mg/kg. As the results for post-harvest treatment of cherries were not statistically significantly different from those for peaches, with the same GAP, the populations can be combined for mutual support.

A 25% water-dispersible granule formulation of fludioxonil was applied as a foliar spray to cherries in Europe. In six trials, the residue levels ranged from 0.16 to 0.43 mg/kg after a treatment rate of 0.019 kg ai/hl and a PHI of 7 days. No GAP was provided for any country in Europe.

The results for post-harvest treatment (GAP, dip or spray at 0.06 kg ai/hl) of peaches, plums and cherries were combined. The residue levels in the 11 trials, in ranked order, were: 0.10, 0.19, 0.37, 0.42, 0.68,



0.92, 1.6, 2.2, 2.8, 3.4 and 3.6 mg/kg. The Meeting estimated a maximum residue level of 5 mg/kg and an STMR of 0.80 mg/kg for stone fruit.

#### *Berries and other small fruit*

##### *Grape*

Trials on foliar treatment of grape vines were available from Chile, France, Germany, Greece, Italy, South Africa, Spain and Switzerland. The relevant GAPs (25% water-dispersible granules) are: Chile, 0.25 kg ai/ha, two applications, 7-day PHI; France, 0.3 kg ai/ha, two applications, 60-day PHI; Germany, 0.015 kg ai/hl, 0.24 kg ai/ha, two applications, 35-day PHI; Italy, 0.02 kg ai/hl, 0.2 kg ai/ha, two applications, 21-day PHI; Spain, 0.25 kg ai/ha, two applications, 21-day PHI; Switzerland, 0.3 kg ai/ha, one application, early season. The residue values at the GAP of Chile, in ranked order, were: 0.18, 0.24 and 0.28 (two) mg/kg. The trials in France (northern), Germany and Switzerland were evaluated against the GAP of Germany, resulting in six trials in Germany (0.17, 0.20, 0.21, 0.24, 0.28, 0.31 mg/kg) and five trials in Switzerland (0.90, 0.99, 1.4, 1.6 (two) mg/kg) at GAP and combined: 0.17, 0.20, 0.21, 0.24, 0.28, 0.31, 0.90, 0.99, 1.4 and 1.6 (two) mg/kg. The GAP of Spain was used to evaluate the trials in Greece, Italy and Spain. The residue levels in two trials in Spain and one in Italy at this GAP were 0.22, 0.41 and 0.43 mg/kg. The Meeting combined the 18 values for Chile, Germany and Switzerland, Spain and Italy (same population) and found a ranked order of: 0.17, 0.18, 0.20, 0.21, 0.22, 0.24 (two), 0.28 (three), 0.31, 0.41, 0.43, 0.90, 0.99, 1.4 and 1.6 (two) mg/kg. The Meeting estimated a maximum residue level of 2 mg/kg and an STMR of 0.28 mg/kg.

##### *Strawberry*

Foliar applications of a 50% wettable powder formulation were made to strawberries in the USA, and of a 25% water-dispersible granule formulation in Europe (glasshouse and outdoor). The relevant GAPs are: France, 0.25 kg ai/ha, one application, 3-day PHI; Germany, 0.125 kg ai/hl, 0.25 kg ai/ha, three applications, 7-day PHI; Italy, 0.02 kg ai/hl, 0.2 kg ai/ha, three applications, 7-day PHI; Spain, 0.25 kg ai/ha, three applications, 7-day PHI; Switzerland, 0.025 kg ai/hl, 0.3 kg ai/ha, two applications, 14-day PHI; USA, 0.25 kg ai/ha, four applications, 0-day PHI. The values from the eight trials in the USA in ranked order were: 0.22, 0.43, 0.54, 0.62, 1.0, 1.2 (two) and 1.3 mg/kg. At GAP of Spain and Germany (0.25 kg ai/ha, three applications, 7-day PHI), the values from outdoor trials in Germany were 0.04 and 0.05 (two) mg/kg; those in Switzerland were 0.13 (two) mg/kg; those in France were 0.09, 0.25, 0.61 and 0.77 mg/kg; that in Italy was 0.14 mg/kg; those in Spain were 0.64 and 0.83 mg/kg; and that in the United Kingdom was 0.11 mg/kg. These 13 values may be combined: 0.04, 0.05 (two), 0.09, 0.11, 0.13 (two), 0.14, 0.25, 0.61, 0.64, 0.77 and 0.83 mg/kg. When the European and US populations were combined, the residue levels, in ranked order, were: 0.04, 0.05 (two), 0.09, 0.11, 0.13 (two), 0.14, 0.22, 0.25, 0.43, 0.54, 0.61, 0.62, 0.64, 0.77, 0.83, 1.0, 1.2 (two) and 1.3 mg/kg.

Indoor trials were also conducted in France, Italy, Spain and Switzerland. The ranked order of residue values evaluated against the GAP of Italy was: 0.11, 0.21, 0.27 and 1.9 mg/kg.

When the results of the indoor and outdoor trials were combined, the residue levels in the 25 trials, in ranked order, were: 0.04, 0.05 (two), 0.09, 0.11 (two), 0.13 (two), 0.14, 0.21, 0.22, 0.25, 0.27, 0.43, 0.54, 0.61, 0.62, 0.64, 0.77, 0.83, 1.0, 1.2 (two), 1.3 and 1.9 mg/kg. The Meeting estimated a maximum residue level of 3 mg/kg and an STMR of 0.27 mg/kg.

##### *Raspberry*

Foliar applications of a 25% water-dispersible granule formulation of fludioxonil were made to raspberries in Germany and the USA. The relevant GAPs are: Switzerland, 0.025 kg ai/hl, 0.32 kg ai/ha, two applications, 14-day PHI; and USA, 0.25 kg ai/ha, four applications, 0-day PHI. The residue levels, in ranked order, were: 0.19, 0.24 (two) and 0.30 mg/kg in Germany and 0.96, 1.0 (three) and 3.6 mg/kg in the USA.

The Meeting estimated a maximum residue level of 5 mg/kg and an STMR of 1.0 mg/kg for raspberries and extrapolated the values to blackberry and dewberry on the basis of the trials in the USA, which had the highest values.

#### *Blueberry*

Foliar applications of a 25% water-dispersible granule formulation of fludioxonil were made to blueberries in Germany and the USA. The relevant GAP is: USA, 0.25 kg ai/ha, four applications, 0-day PHI. No GAP was available for Germany or other European countries. The residue levels in ranked order at GAP in the USA were: < 0.05, 0.14, 0.26, 0.52, 0.68, 0.84, 0.90 and 1.4 mg/kg. The Meeting estimated a maximum residue level of 2 mg/kg and an STMR of 0.60 mg/kg.

#### *Black and red currant*

Foliar application of a 25% water-dispersible granule formulation of fludioxonil was made to black currants in four trials and to red currants in one trial in Germany. As no GAP is available for Germany or other European countries, the Meeting could not estimate an STMR or maximum residue level.

#### *Assorted tropical and subtropical fruits*

##### *Lychee*

Fludioxonil (25% water-dispersible granules) was applied as a foliar spray to lychee in the USA, where GAP is: 0.25 kg ai/ha, four applications, 0-day PHI. The residue levels in ranked order were: 0.81, 0.92 and 1.4 mg/kg. The Meeting noted that five or seven applications were made at about 7-day intervals and that the extra one or three applications would have been made  $\leq$  21 days before harvest. On the basis of studies of decline in other fruit crops, they might have made a significant contribution (about 25%) to the final residue level. Therefore, the Meeting did not estimate a maximum residue level or an STMR.

##### *Kiwi*

Kiwi fruit in the USA were treated post-harvest at 0.06 kg ai/hl with a wettable powder formulation. GAP specifies application of a 50% wettable powder formulation as a dip at 0.06 kg ai/hl for 30 s or as a low-volume application with a control droplet-type application at 0.24 kg ai/hl or 2.5 mg/kg fruit. Trials were conducted, with two methods (dip, spray) at two locations and a single method (dip) at a third. The ranked order of residue levels in the five trials was: 1.6, 5.2, 7.2, 8.6 and 9.0 mg/kg. The Meeting estimated mg/kg a maximum residue level of 15 mg/kg and an STMR of 7.2 mg/kg for kiwi fruit.

##### *Pomegranate*

Pomegranate in the USA were treated post-harvest at 0.06 kg ai/hl with a wettable powder formulation. The residue levels were 0.65 and 0.95 mg/kg; however, there is no GAP, and the Meeting could not estimate a maximum residue level or an STMR.

#### *Bulb vegetables*

##### *Green (spring) onions*

Fludioxonil was applied as a foliar spray of a wettable powder formulation to green onions in the USA. The relevant GAP is 0.25 kg ai/ha, four applications, 7-day PHI. The residue levels in ranked order were 0.14, 0.59 and 3.0 mg/kg. The Meeting estimated a maximum residue level of 5 mg/kg and an STMR of 0.59 mg/kg.

##### *Bulb onion*

Fludioxonil (wettable powder formulation) was applied as a foliar spray to onions in France, Italy, Germany and Switzerland and in the USA. The relevant GAPs are: Austria, 0.25 kg ai/ha, three applications, 7-day PHI; Switzerland, 0.25 kg ai/ha, two applications, unspecified PHI; and USA, 0.25 kg ai/ha, four applications, 7-day PHI. GAP in Switzerland (assumed 0-day PHI) was applied to the other European

countries in the absence of a GAP for southern Europe. The residue levels in trials on bulb onions (fresh) at the Swiss GAP were: France, < 0.02, 0.05 and 0.06 mg/kg; and Italy, < 0.02, 0.04, 0.07 and 0.34 mg/kg. The levels in three trials on bulb onions (dry) in the USA at US GAP were: < 0.02 (three), 0.04 (two) and 0.06 mg/kg. The Meeting combined the data sets for Europe and the USA and found a ranked order of residue levels of: < 0.02 (five), 0.04 (three), 0.05, 0.06 (two), 0.07 and 0.34 mg/kg. The Meeting estimated a maximum residue level of 0.5 mg/kg and an STMR of 0.04 mg/kg.

### *Brassica vegetables*

#### *Broccoli*

Fludioxonil (water-dispersible granule formulation) was applied as a foliar spray to broccoli in Canada and the USA. The relevant GAP is: 0.25 kg ai/ha, four applications, 7-day PHI. The residue levels in seven trials at US GAP, in ranked order, were: 0.07, 0.10, 0.18, 0.23, 0.26, 0.34 and 0.36 mg/kg. The Meeting estimated a maximum residue level of 0.7 mg/kg and an STMR of 0.23 mg/kg.

#### *Cabbage*

Fludioxonil (water-dispersible granule formulation) was applied as a foliar spray to cabbage in the USA. The relevant GAP is: 0.25 kg ai/ha, four applications, 7-day PHI. The residue levels in ranked order on cabbage with wrapper leaves in six trials at GAP were: 0.17, 0.17, 0.21, 0.27, 0.5 and 1.2 mg/kg. The Meeting estimated a maximum residue level of 2 mg/kg and an STMR of 0.24 mg/kg.

### *Fruiting vegetables*

#### *Cucumber*

A 25% water-dispersible granule formulation of fludioxonil was applied as a foliar spray (glasshouse and field) to cucumbers in Greece, Spain and Switzerland. The relevant GAPs are: Italy, 0.02 kg ai/hl, 0.20 kg ai/ha, three applications, 7-day PHI; Spain, 0.025 kg ai/hl, three applications, 7-day PHI; Switzerland, 0.025 kg ai/hl, 3-day PHI. GAP for Greece was not available, and that of Italy and Spain was used. The results from the 10 glasshouse trials (seven in Spain, one in Greece, two in Switzerland) in ranked order were: < 0.02, 0.02 (two), 0.06 (two), 0.07, 0.08 (two), 0.11 and 0.14 mg/kg. The results from the field trials (one in Greece, two in Spain) were: < 0.02, 0.02 and 0.03 mg/kg. The populations are not statistically significantly different, and the combined results are: < 0.02 (two), 0.02 (three), 0.03, 0.06 (two), 0.07, 0.08 (two), 0.11 and 0.14 mg/kg. The Meeting estimated a maximum residue level of 0.3 mg/kg and an STMR of 0.06 mg/kg.

#### *Summer squash (zucchini)*

Two indoor trials were conducted on zucchini in Italy. The relevant GAP is: 25% water-dispersible granule, 0.02 kg ai/hl, 0.20 kg ai/ha, three applications, 7-day PHI. The residue levels were 0.05 and 0.06 mg/kg. The Meeting agreed to use the results for cucumber as support for summer squash. The residue levels in ranked order were: < 0.02 (two), 0.02 (three), 0.03, 0.05, 0.06 (three), 0.07, 0.08 (two), 0.11 and 0.14 mg/kg. The Meeting estimated a maximum residue level of 0.3 mg/kg and an STMR of 0.06 mg/kg.

#### *Cantaloupe*

A 50% wettable powder formulation was applied to cantaloupe vines (three times 0.28 kg ai/ha, 0.84 kg ai/ha total, 14-day PHI) in the USA by drip irrigation. GAP specifies drip irrigation application of a 50% wettable powder formulation at a rate of 0.28 kg ai/ha. The total seasonal application is limited to 0.84 kg ai/ha, and the PHI is 14 days. The residue levels in ranked order were: < 0.02 (two) and 0.02 (two) mg/kg. The Meeting estimated a maximum residue level of 0.03 mg/kg and an STMR of 0.02 mg/kg for whole melon. No information was available on the residue in pulp.

#### *Tomato*

Fludioxonil (25% water-dispersible granules) was applied as a foliar spray in glasshouses (11 trials) and in the field (two trials) in Greece, Spain, Switzerland and the United Kingdom. The relevant GAPs are:

Italy, 0.02 kg ai/hl, 0.2 kg ai/ha, three applications, 7-day PHI; Spain, 0.025 kg ai/hl, three applications, 7-day PHI; Switzerland, 0.25 kg ai/ha, two applications, 3-day PHI. GAPs were not available for Greece or the United Kingdom. As three applications were used in all trials, the GAPs of Italy and Spain were used (7-day PHI). The residue levels in the 14 glasshouse trials at this GAP in ranked order were: 0.05, 0.08, 0.09 (two), 0.10 (two), 0.13 (two), 0.14 (two), 0.16, 0.21, 0.28 and 0.32 mg/kg. The levels in the outside trials in Switzerland were: 0.04 and 0.07 mg/kg. The two groups were statistically the same population, and the combined levels from the 16 trials were: 0.04, 0.05, 0.07, 0.08, 0.09 (two), 0.10 (two), 0.13 (two), 0.14 (two), 0.16, 0.21, 0.28 and 0.32 mg/kg. The Meeting estimated a maximum residue level of 0.5 mg/kg and an STMR of 0.12 mg/kg.

#### *Bell pepper*

Fludioxonil (25% water-dispersible granules) was applied as a foliar spray to bell (sweet) peppers in eight glasshouse trials and two field trials in Spain and Switzerland. The relevant GAPs are: Austria, 0.025 kg ai/hl, 0.25 kg ai/ha, three applications, 7-day PHI; Italy, 0.02 kg ai/hl, 0.2 kg ai/ha, three applications, 7-day PHI; Spain, 0.25 kg ai/ha, three applications, 7-day PHI. The GAP of Austria and Italy was used. The ranked order of residue levels in the eight glasshouse trials ( six in Spain, two in Switzerland) at GAP was: 0.08, 0.10, 0.14, 0.22, 0.29, 0.46, 0.56 and 0.60 mg/kg. The ranked order in field trials at GAP (one in Italy, one in Spain) was: 0.06 and 0.13 mg/kg. As the two groups are from the same population, they were combined to give levels of: 0.06, 0.08, 0.10, 0.13, 0.14, 0.22, 0.29, 0.46, 0.56 and 0.60 mg/kg. The Meeting estimated a maximum residue level of 1 mg/kg and an STMR of 0.18 mg/kg.

#### *Eggplant*

Fludioxonil formulated as 25% water-dispersible granule was applied to eggplant as a foliar spray three times in glasshouse trials in Italy and Spain. The relevant GAPs are: Italy, 0.02 kg ai/hl, 0.2 kg ai/ha, three applications, 7-day PHI; Spain, 0.025 kg ai/hl, three applications, 7-day PHI. The results at GAP in ranked order were: 0.03, 0.06, 0.06 and 0.08 mg/kg. The Meeting estimated a maximum residue level of 0.3 mg/kg and an STMR of 0.06 mg/kg.

#### *Sweet corn (corn-on-the-cob)*

Fludioxonil (flowable concentrate) was applied to sweet corn seed in the USA before planting. The relevant GAP is 5 g ai/1000 kg seed. The residue levels were < 0.01 in three trials at three to five times GAP. The Meeting recognized the similarity of sweet corn and maize (see below) and decided to translate the field trial data for seed treatment of maize (same GAP as sweet corn) to sweet corn seed treatment. The residue levels in the eight trials were all < 0.01 mg/kg. The Meeting estimated a maximum residue level of 0.01 (\*) mg/kg and an STMR 0.01 mg/kg.

#### *Leafy vegetables*

##### *Lettuce, head*

Fludioxonil (25% water-dispersible granules) was applied as a foliar spray to lettuce in 11 glasshouse and 17 field trials in France, Germany, Italy, Spain and Switzerland. The relevant GAPs are: France, 0.15 kg ai/ha, four applications, 14-day PHI; Italy, 0.018 kg ai/hl, 0.18 kg ai/ha, three applications, 14-day PHI; Spain, 0.15 kg ai/ha, three applications, 14-day PHI; Switzerland, 0.12 kg ai/ha, two applications, early season. No GAP was available for Germany. The GAP of Italy was used to evaluate the trials. The ranked order of residue levels in the glasshouse trials was: 0.72, 0.98, 1.1, 2.4, 2.5, 2.7 (two), 3.4 (two), 4.7 and 6.0 mg/kg. The ranked order of residue levels in the field trials was: < 0.02 (six), 0.02 (two), 0.04 (three), 0.07, 0.11, 0.17, 0.29, 1.2 and 1.2 mg/kg. The two sets are not from the same population. In the basis of the indoor trials, the Meeting estimated a maximum residue level of 10 mg/kg and an STMR of 2.7 mg/kg.

##### *Watercress*

Watercress was treated with fludioxonil (25% water-dispersible granules) as a foliar spray in the USA. The relevant GAP is: 0.25 kg ai/ha, four applications, 0-day PHI. In the two trials at GAP, the residue

levels were 4.2 and 4.5 mg/kg. The OECD York Workshop recommended a minimum of three trials for commodities that are not significant in trade or in the diet. (See mustard greens.)

#### *Mustard greens*

Supervised trials were conducted on mustard greens in the USA. The relevant GAP is: 0.24 kg ai/ha, water-dispersible granules, four applications, 7-day PHI. The ranked order of residue levels in the seven trials at GAP was: 0.06, 0.49, 0.54, 0.76, 1.2, 6.6 and 7.1 mg/kg. The Meeting decided to combine the results of the trials on watercress and mustard greens (same GAP) for mutual support. The ranked order of levels in the nine trials was 0.06, 0.49, 0.54, 0.76, 1.2, 4.2, 4.5, 6.6 and 7.1 mg/kg. The Meeting estimated a maximum residue level of 10 mg/kg and an STMR of 1.2 mg/kg for both watercress and mustard greens.

#### *Legume vegetables and pulses*

##### *Bean pod with seed (common bean, French bean, edible podded bean)*

Fludioxonil (water-dispersible granules) was applied as a foliar spray to beans in pod in 22 field and glasshouse trials in France, Spain and Switzerland. The relevant GAPs are: France, 0.083 kg ai/hl, 0.25 kg ai/ha, number of applications not specified, 14-day PHI; Spain, 0.025 kg ai/hl, three applications, 14-day PHI. No GAP was available for Switzerland, and the GAP of France was applied. The ranked order of residue levels from the 15 field trials was: < 0.02, 0.02 (two), 0.03 (five), 0.04 (two), 0.06 (three), 0.09 and 0.13 mg/kg. The ranked order in the seven glasshouse trials was: 0.03, 0.04 (two), 0.06, 0.09, 0.17 and 0.20 mg/kg. The two groups are not from different populations and were therefore combined to give residue levels of: < 0.02, 0.02 (two), 0.03 (six), 0.04 (four), 0.06 (four), 0.09 (two), 0.13, 0.17 and 0.20 mg/kg. The Meeting estimated a maximum residue level of 0.3 mg/kg and an STMR of 0.04 mg/kg for beans (pods and/or immature seeds). This maximum residue level and STMR are extended to peas with pod.

Trials were also conducted on the seed treatment of broad bean and French bean seeds (flowable concentrate) at 5 g ai/100 kg seed in Denmark and Germany. The residue levels were < 0.02 mg/kg on bean seed in all six trials, but no GAP was available.

##### *Peas (succulent)*

Fludioxonil (25% water-dispersible granules) was applied as a foliar spray to pea vines in France and Switzerland. The relevant GAP is that of France for legume vegetables: 0.083 kg ai/hl, 0.25 kg ai/ha, number of applications not specified, 14-day PHI. No GAP was available for Switzerland, and the GAP of France was applied. The ranked order of residue levels in the trials at GAP was: ≤ 0.02 (10) and 0.02 mg/kg.

Trials were also conducted of seed treatment of peas with a flowable concentrate or water-dispersible granule formulation in France and the United Kingdom. The residue levels were < 0.02 mg/kg in the six trials conducted at the GAP of the United Kingdom (5% water-dispersible granules, 10 g ai/100 kg seed).

The Meeting estimated a maximum residue level of 0.03 mg/kg and an STMR of 0.02 mg/kg for peas, shelled (succulent seeds) on the basis of the trials with foliar application. Nevertheless, the maximum residue level and STMR also accommodate seed treatment use and are extended to succulent beans without pod.

##### *Pulses (dry bean and dry pea)*

A water-dispersible granule formulation of fludioxonil was applied as a foliar spray to pea and bean (kidney) vines in France. The relevant GAP is: Austria and Spain, water-dispersible granules, 0.25 kg ai/ha, two applications, 14-day PHI. No GAP was available for France, and the GAP of Spain was applied. The ranked order of residue levels in dry pea and bean was: < 0.02 (two), 0.04 (two) and 0.05 mg/kg.

Supervised trials on the seed treatment of pea seed in France were also considered. GAP in the United Kingdom is application of a 5% water-dispersible granule formulation of fludioxonil (w/w) at a rate of 10 g

ai/100 kg pea seed. The residue levels in the seven trials at this GAP were < 0.02 mg/kg in dry seed at harvest.

The Meeting estimated a maximum residue level of 0.07 mg/kg and an STMR of 0.02 mg/kg for dry peas and for dry beans after foliar application of fludioxonil. The Meeting noted that this also accommodates use of fludioxonil for seed treatment.

#### *Root and tuber vegetables*

##### *Potato*

Fludioxonil (flowable concentrate, dustable powder) was applied to potato pieces as seed treatment in six trials in Australia, three in South Africa and 13 in the USA. The available GAPs are: Australia, flowable concentrate, 10%, 2.5 g ai/100 kg seed; USA, flowable concentrate, 2.5 g ai/100 kg seed. The ranked order of residue levels on mature potatoes in trials at GAP in Australia and the USA was: < 0.01 (16) and 0.01 (17) mg/kg. The Meeting estimated a maximum residue level of 0.02 mg/kg and an STMR of 0.01 mg/kg.

##### *Yam*

A 50% wettable powder formulation of fludioxonil was applied as post-harvest treatment to yams at 0.06 kg ai/hl in the USA. GAP specifies application of a 50% wettable powder formulation as a single dip application at a rate of 0.06 kg ai/hl for about 30 s. Two trials were conducted at GAP, and in each trial both whole tubers and tuber pieces (cut yams) were tested. The ranked order of residue levels was: 4.6 and 5.0 mg/kg. The Meeting regarded two independent trials as insufficient for estimating a maximum residue level or an STMR.

##### *Carrot*

Nine trials were conducted in the USA in which carrot plots were given four foliar applications of fludioxonil at 0.24 kg ai/ha. The relevant GAP is: water-dispersible granules, 0.25 kg ai/ha, four applications, 7-day PHI. The residue levels in seven trials at GAP were: 0.04, 0.16, 0.18, 0.20, 0.20, 0.25 and 0.42 mg/kg. The Meeting estimated a maximum residue level of 0.7 mg/kg and an STMR of 0.20 mg/kg.

##### *Asparagus*

In two trials in Germany, asparagus plants were treated with a water-dispersible granule formulation after harvest. This gives a PHI of about 240 days. No GAP was available for Germany. GAP for Austria specifies use of a 25% water-dispersible granule formulation three times with a 14–21-day interval at 0.042 kg ai/hl or 0.25 kg ai/ha per application. No PHI is specified, but treatments are to be made at transplantation from the glasshouse to the field. The residue levels in the two German trials were < 0.02 mg/kg. The Meeting considered two trials insufficient for estimating a maximum residue level or an STMR.

#### *Cereal grains*

Fludioxonil formulations were applied to wheat in France, Germany and Switzerland as seed treatment. The relevant GAPs are: Austria, Belgium, United Kingdom, flowable concentrate formulation, 5 g ai/100 kg seed, one application. In the 48 trials conducted at or above GAP, the residue levels in ranked order were: < 0.02 (36) and < 0.04 (12) mg/kg.

One trial was reported from Denmark in which rye seed was treated. The relevant GAP is: Austria, flowable concentrate, 5 g ai/100 kg seed. No GAP is available for Denmark. The residue level was < 0.02 mg/kg.

Fludioxonil was applied as seed treatment to barley in 30 trials in France, Germany and Switzerland. The relevant GAPs are: Austria, Belgium, United Kingdom, flowable concentrate formulation, 5 g ai/100 kg seed. No GAP was available for France, Germany or Switzerland. The residue levels in six trials conducted at or above GAP were < 0.02 mg/kg.

Fludioxonil was applied as a seed treatment to maize (field corn) in 27 trials in France, Germany, Greece, Hungary, Italy and Spain, three trials in South Africa and five trials in the USA. The relevant GAP is: USA, flowable concentrate formulation, 5 g ai/100 kg seed. No GAPs were available for Europe or South Africa, and the GAP of the USA was applied. The ranked order of residue values in trials conducted at GAP and at three and five times the GAP rate were < 0.01 (five) and < 0.02 (seven) mg/kg.

Fludioxonil was applied as seed treatment to sorghum in four trials in the USA. The relevant GAP is flowable concentrate formulation, 5 g ai/100 kg seed. The residue level at three to five times the GAP rate was < 0.05 mg/kg.

All residue levels resulting from seed treatment of the five different cereal grains were below the LOQ. The combined results from all the trials, in ranked order, were: < 0.01 (five), < 0.02 (50), < 0.04 (12) and < 0.05 (four) mg/kg. The Meeting estimated a maximum residue level of 0.05 (\*) mg/kg and an STMR of 0.02 mg/kg for cereal grains.

#### *Pistachio nut*

Fludioxonil was applied as a water-dispersible granule formulation to pistachio trees in the USA. The relevant GAP is: 0.25 kg ai/ha, four applications, 7-day PHI. The residue levels, in ranked order, were: 0.04, 0.05 and 0.08 mg/kg. The Meeting estimated a maximum residue level of 0.2 mg/kg and an STMR 0.05 mg/kg.

#### *Rape-seed*

Fludioxonil was applied to rape as seed treatment in trials in France, Germany, Sweden and the United Kingdom. GAP in Germany is treatment of seed with a flowable concentrate formulation at 12 g fludioxonil per 100 kg seed. The residue levels in the 15 trials at this GAP were < 0.02 mg/kg. The Meeting estimated a maximum residue level of 0.02 (\*) mg/kg and an STMR of 0.02 mg/kg.

#### *Cotton-seed*

Fludioxonil was applied as seed treatment (flowable concentrate and emulsion formulations) to cotton in Greece and the USA. The relevant GAP is: USA, flowable concentrate, 5 g ai/100 kg seed. No GAP was available for Greece (or any other European country), and the GAP of the USA was applied. The ranked order of residue levels in the trials was: < 0.02 (two) and < 0.05 (six) mg/kg. The Meeting estimated a maximum residue level of 0.05 (\*) mg/kg and an STMR of 0.05 mg/kg for cotton-seed.

#### *Herbs*

Fludioxonil was applied as a foliar spray (water-dispersible granules) to chives and basil in the USA. The relevant GAP is 0.25 kg ai/ha, four applications, 7-day PHI. The residue levels were: 1.8 and 3.9 mg/kg on chives and 1.9 and 3.0 mg/kg on basil. The Meeting estimated a maximum residue level of 10 mg/kg and an STMR of 2.4 mg/kg for fresh basil and a maximum residue level of 10 mg/kg and an STMR of 2.8 mg/kg for fresh chives.

For each herb, one trial included drying. The drying factor for chives is 8 (31/3.9), and that for basil is also 8 (23/3). Application of this factor to the data from field trials with chives yielded a revised ranked order of residue levels: 14 and 31 mg/kg. Therefore, the Meeting estimated a maximum residue level of 50 mg/kg and an STMR of 22 mg/kg for dried chives. Application of the drying factor for basil yield a revised ranked order of 15 and 24 mg/kg. Therefore, the Meeting estimated a maximum residue level of 50 mg/kg and an STMR of 20 mg/kg for dried basil.

#### *Animal feedstuffs*

##### *Straw, fodder and forage of cereal grains and grasses*

Trials of residue levels in forage, fodder and straw after application of fludioxonil as seed treatment were conducted with wheat, rye, barley, maize, sweet corn and sorghum. Trials on wheat were conducted in

Europe according to the following relevant GAP: Austria, Belgium, United Kingdom, flowable concentrate formulation, 5 g ai/100 kg seed, one application. In the 45 trials conducted at or above GAP, the ranked order of residue levels in straw was: < 0.02 (eight), < 0.04 (14) and < 0.05 (23) mg/kg. The ranked order of residue levels in forage was: < 0.02 (seven) and < 0.04 (11) mg/kg.

A trial on rye was conducted in Denmark according to the GAP for Austria: flowable concentrate, 5 g ai/100 kg seed. The residue level was < 0.05 mg/kg in straw and < 0.05 mg/kg in forage.

Trials on barley were conducted in Europe according to the GAP for Austria, Belgium and the United Kingdom: flowable concentrate formulation, 5 g ai/100 kg seed. In five trials conducted at or above GAP, the ranked order of residue levels were: < 0.02 and < 0.05 (four) mg/kg in straw and < 0.05 (three) mg/kg in forage.

Trials on maize and sweet corn were conducted Europe (maize only) and in the USA. The relevant GAP was: USA, flowable concentrate formulation, 5 g ai/100 kg seed, as no GAP was available for any country in Europe. There were no detectable residues in fodder (< 0.01 (five) mg/kg) or forage (< 0.01 (seven) mg/kg). Using the default moisture content value of 40% for maize forage (*FAO Manual*, Appendix IX), the Meeting estimated a maximum residue level of 0.03 (\*) mg/kg (0.01/0.40) and an STMR of 0 mg/kg (0.00/0.40) for maize forage (dry).

Field trials were conducted on sorghum in the USA, the relevant GAP being flowable concentrate formulation, 5 g ai/100 kg seed. The residue levels after exaggerated application rates were < 0.01 (four) mg/kg on fodder and < 0.01 (four) mg/kg on forage.

The combined values for fodder and straw in ranked order were: < 0.01 (nine), < 0.02 (nine), < 0.04 (four) and < 0.05 (28). As no data were available on the moisture content, the default value of 83% for maize fodder was used (*FAO Manual*, Appendix IX). The Meeting estimated an STMR of 0 mg/kg (0.00/0.83) and a maximum residue level of 0.06 (\*) mg/kg (0.05/0.83) for fodder (dry) and straw of cereal grains.

#### *Rape forage and straw*

Fludioxonil was applied to rape as seed treatment in trials in France, Germany, Sweden and the United Kingdom. The GAP in Germany is treatment of seed with an flowable concentrate formulation at 12 g fludioxonil per 100 kg seed. The residue levels were < 0.05 mg/kg in forage (12) and straw (six).

### ***Fate of residues during processing***

A study of hydrolysis with [pyrrole-4-<sup>14</sup>C]fludioxonil showed that fludioxonil is stable under the typical conditions of pasteurization, baking, brewing, boiling and sterilization.

The processing (transfer) factors through commercial-type processes for plums, strawberries, grapes, citrus and tomato are summarized in the table below. Factors could not be calculated for cereal grains, cotton-seed or potatoes because there were no quantifiable residues in the raw agricultural commodities, even in trials with exaggerated treatment rates.

#### *Processing factors and STMR-P values for various commodities*

| Raw agricultural commodity |             |              |            | Processed commodity  |                   |                |              |
|----------------------------|-------------|--------------|------------|----------------------|-------------------|----------------|--------------|
| Commodity                  | MRL (mg/kg) | STMR (mg/kg) | HR (mg/kg) | Commodity            | Processing factor | STMR-P (mg/kg) | HR-P (mg/kg) |
| Plum <sup>1</sup>          | 5           | 0.80         | 3.6        | Prunes (dried plums) | 1.91 <sup>2</sup> | 0.96           | 4.3          |
|                            |             |              |            | Juice                | 0.10              | 0.080          |              |
|                            |             |              |            | Preserves            | 0.50              | 0.40           |              |



| Raw agricultural commodity |             |              |            | Processed commodity    |                    |                |              |
|----------------------------|-------------|--------------|------------|------------------------|--------------------|----------------|--------------|
| Commodity                  | MRL (mg/kg) | STMR (mg/kg) | HR (mg/kg) | Commodity              | Processing factor  | STMR-P (mg/kg) | HR-P (mg/kg) |
|                            |             |              |            | Puree                  | 0.80               | 0.64           |              |
| Strawberry                 | 3           | 0.38         | 2.2        | Juice                  | 0.16               | 0.061          |              |
|                            |             |              |            | Preserves              | 0.62               | 0.24           |              |
|                            |             |              |            | Jam                    | 0.34               | 0.13           |              |
| Grapes                     | 2           | 0.28         | 1.6        | Raisins (dried grapes) | 1.1 <sup>3</sup>   | 0.31           | 1.8          |
|                            |             |              |            | Juice                  | 0.92 <sup>4</sup>  | 0.26           |              |
|                            |             |              |            | Wine                   | 0.30 <sup>5</sup>  | 0.08           |              |
|                            |             |              |            | (< 100 days)           |                    |                |              |
|                            |             |              |            | Wine                   | 0.036 <sup>6</sup> | 0.010          |              |
|                            |             |              |            | (>100 days)            |                    |                |              |
| Lemons                     |             |              |            | Juice                  | 0.031              |                |              |
|                            |             |              |            | Oil                    | 61                 |                |              |
|                            |             |              |            | Pulp                   | 2.1                |                |              |
| Tomato                     | 0.5         | 0.12         | 0.32       | Juice                  | 0.22 <sup>7</sup>  | 0.026          |              |
|                            |             |              |            | Paste                  | 1.4 <sup>8</sup>   | 0.17           |              |
|                            |             |              |            | Pomace (wet)           | 3.3 <sup>9</sup>   |                |              |

<sup>1</sup> Stone fruit, includes field trial data for cherries and peaches

<sup>2</sup> Four trials, range 1.8–2.7, mean 1.91, median 1.6

<sup>3</sup> 15 trials, range 0.58–1.7, mean 1.1, median 1.1

<sup>4</sup> 12 trials, range 0.58–1.0, mean 0.92, median 0.86

<sup>5</sup> 17 trials, range 0.012–0.86, mean 0.30, median 0.24

<sup>6</sup> 11 trials, range 0.0086–0.11, mean 0.036, median 0.029

<sup>7</sup> Four trials for pasteurized juice, range 0.20–0.24, average 0.22, median 0.22

<sup>8</sup> Four trials for pasteurized paste, range 1.1–1.6, average 1.4, median 1.35

<sup>9</sup> Two trials for wet pomace, 3.0 and 3.6

### Residues in animal commodities

A feeding study was conducted in which three groups of three dairy cows received 0.55 ppm, 1.6 ppm or 5.5 ppm fludioxonil in the diet for 28–30 days. Residues of fludioxonil and metabolites, determined as CGA-192155 (2,2-difluorobenzo[1,1]dioxole-4-carboxylic acid), were quantifiable only at the highest feeding level (5.5 ppm). Residues were found in the milk of two of three cows, with maximum values of 0.019 mg/kg and 0.014 mg/kg on days 14 and 21, respectively. At the lowest feeding level, residues were detected in milk on days 3–21 at levels of 0.001–0.004 mg/kg, with maximum detection on day 3.

Only tissue samples from cows fed the 5.5 ppm diet were analysed. No residues of fludioxonil or metabolites were found. The LOQ was 0.01 mg/kg in muscle and 0.05 mg/kg in liver, kidney and fat (perirenal and omental).

The dietary intake of ruminants and poultry can be calculated from the recommended STMRs or HRs and consideration of possible animal feed items. The table below shows the bases for the dietary intake calculation.

| Commodity          | Group | Maximum or highest residue level (mg/kg) | STMR or STMR-P (mg/kg) | Dry matter (%) | Dietary content (%) |            |            | Residue contribution (mg/kg) |             |             |
|--------------------|-------|------------------------------------------|------------------------|----------------|---------------------|------------|------------|------------------------------|-------------|-------------|
|                    |       |                                          |                        |                | Beef cattle         | Dairy cows | Poultry    | Beef cattle                  | Dairy cows  | Poultry     |
| Barley grain       | GC    | 0.05                                     |                        | 88             | 50                  | 40         | 75         |                              |             |             |
| Barley straw (dry) | AS    | 0.06                                     |                        |                | 10                  | 60         |            |                              |             |             |
| Cotton-seed        | SO    | 0.05                                     |                        | 88             | 25                  | 25         |            |                              |             |             |
| Cotton-seed meal   |       | 0.05                                     |                        | 89             | 15                  | 15         | 20         |                              |             |             |
| Maize grain        | GC    | 0.05                                     |                        | 88             | 80                  | 40         | <b>80</b>  | 0.02                         | 0.03        | 0.05        |
|                    |       |                                          |                        |                | <b>25</b>           | <b>40</b>  |            |                              |             |             |
| Maize forage (dry) | AF    | 0.03                                     |                        |                | 40                  | 50         |            |                              |             |             |
| Maize fodder (dry) | AS    | 0.06                                     |                        |                | 25                  | 15         |            |                              |             |             |
| Oat grain          | GC    | 0.05                                     |                        | 89             | 50                  | 40         | 80         |                              |             |             |
| Oat straw (dry)    | AS    | 0.06                                     |                        | 90             | 10                  | 10         |            |                              |             |             |
| Potato waste       | AB    |                                          | 0.01                   | 15             | <b>75</b>           | <b>40</b>  |            | 0.05                         | 0.03        |             |
| Rape meal          |       | 0.02                                     |                        | 88             | 15                  | 15         | 15         |                              |             |             |
| Rape forage        | AM    | 0.05                                     |                        | 30             | 30                  | 30         |            |                              |             |             |
|                    |       |                                          |                        |                | <b>20</b>           |            |            |                              |             |             |
| Rye grain          | GC    | 0.05                                     |                        |                | 40                  | 40         | 50         |                              |             |             |
| Rye straw (dry)    | AS    | 0.06                                     |                        | 88             | 10                  | 10         |            |                              |             |             |
| Wheat grain        | GC    | 0.05                                     |                        | 89             | 50                  | 40         | 80         |                              |             |             |
| Wheat forage       | AF    | 0.05                                     |                        | 25             |                     |            |            |                              |             |             |
| Wheat straw (dry)  | AS    | 0.06                                     |                        | 88             | 10                  | 10         |            |                              |             |             |
| Pea seed           | VD    | 0.07                                     |                        | 90             | 20                  | 20         | <b>20</b>  |                              |             | 0.02        |
| <b>Total</b>       |       |                                          |                        |                | <b>100</b>          | <b>100</b> | <b>100</b> | <b>0.07</b>                  | <b>0.06</b> | <b>0.07</b> |

The calculated dietary intakes of beef cattle, dairy cows and poultry are 0.07, 0.06 and 0.07 mg/kg, respectively.

No quantifiable residue was found in the tissues of ruminants at levels 60 times (cows) and 80 times (beef cattle) the calculated dietary burden. Fludioxonil and metabolites were detected in liver and kidney at concentrations of 0.014–0.017 mg/kg and 0.022–0.025 mg/kg, respectively, at the 5.5 ppm feeding level. None was detected in fat or muscle. The Meeting concluded that the maximum residue level is the LOQ, 0.05 (\*) mg/kg, for offal and 0.01 (\*) mg/kg for muscle and that the STMR values for edible offal and muscle are both 0 mg/kg.

In milk, the highest residue level found was 0.019 mg/kg with the 5.5 ppm diet (60 times). The Meeting concluded that the maximum residue level is the LOQ, 0.01 (\*) mg/kg, and that the STMR value for milk is 0 mg/kg.

No feeding study was available with poultry. The dietary intake calculation shows a possible burden of 0.07 ppm. The study of the nature of the residue in poultry was conducted at 89 ppm (1300 times) for 8 consecutive days. While short of the normal 30-day feeding study, the extreme exaggeration provides some idea of the likelihood of residues of fludioxonil and metabolites occurring in poultry commodities. The identified residue levels in eggs, liver, kidney, muscle and skin with fat were 0.26, 0.046, 0.020, 0.036 and 0.036 mg/kg, respectively. This strongly suggests that residues will not be quantifiable in these commodities at a feeding level of 0.07 mg/kg. Therefore, the Meeting estimated MRLs at the LOQ of 0.05 (\*) mg/kg for eggs, 0.01 (\*) mg/kg for poultry meat and 0.05 (\*) mg/kg for poultry offal and STMRs of 0 mg/kg for eggs, poultry meat and poultry offal.

## DIETARY RISK ASSESSMENT

### *Long-term intake*

The IEDIs of fludioxonil based on the STMRs estimated for 45 commodities for the five GEMS/Food regional diets were 0–1% of the ADI (Annex 3). The Meeting concluded that the long-term dietary intake of residues of fludioxonil is unlikely to present a public health concern.

### *Short-term intake*

The 2004 JMPR decided that an ARfD for fludioxinil is unnecessary. The Meeting therefore concluded that the short-term dietary intake of fludioxonil residues is unlikely to present a public health concern.

## 4.12 FOLPET (041)

### TOXICOLOGY

#### *Evaluation for an acute reference dose*

Folpet is a fungicide used for the control of fungal diseases in crops. The Meeting prepared toxicological monographs on folpet in 1969 and 1995, and addenda to the monographs were prepared in 1973, 1984, 1986 and 1990. In 1995, an ADI of 0–0.1 mg/kg bw was established on the basis of a NOAEL of 10 mg/kg bw per day in a 2-year study of toxicity and carcinogenicity in rats, a 1-year study of toxicity in dogs, and studies of reproductive toxicity in rats and rabbits, and using a safety factor of 100. The present Meeting considered the requirement for an ARfD for folpet, based on data from the previous evaluations for JMPR and from new studies.

In rodents treated orally, folpet is rapidly degraded to phthalimide and thiophosgene (via thiocarbonyl chloride). Studies of metabolism in vitro with human blood revealed that folpet is rapidly degraded to phthalimide, with a calculated half-life of 4.9 s. Thiophosgene is rapidly detoxified by reaction with cysteine or glutathione, for example, and is ultimately rapidly excreted.

The acute oral toxicity of folpet in rats is low (LD<sub>50</sub>, > 2000 mg/kg bw). In a study in pregnant hamsters, mortality occurred after a single dose of 400 mg/kg bw. In groups of pregnant New Zealand white rabbits treated for 3 days with folpet at a dose of 60 mg/kg bw per day, mortality was observed that may have been related to treatment.

Mice fed diets containing folpet at 5000 ppm, equal to 845 or 1060 mg/kg bw, for 24 h showed a reduction in food consumption of 10–20%. Immediately after the 24 h of treatment, minimal to moderate epithelial erosions and degeneration of the proximal duodenum were observed in some of these animals. Microscopy revealed moderate loss of villi and slight mucosal congestion in some animals. Microscopy was not performed at later time-points.

Studies of developmental toxicity with folpet have been carried out in hamsters, rats and rabbits.

In a study from the published literature, the teratogenic effects of a number of phthalimide derivatives, including folpet, were tested in pregnant golden hamsters. The Meeting noted that this study has major limitations (e.g. small number of animals per dose, limited reporting of the data) and is therefore of limited value. It does, however, suggest that developmental effects may occur after a single exposure to folpet, albeit at maternally toxic doses.

Folpet has been tested in a number of studies of developmental toxicity in rats. In a study in Sprague-Dawley rats treated by gavage, the NOAEL for maternal toxicity was 60 mg/kg bw per day on the basis of reduced body-weight gain and food consumption and increased incidence of clinical signs at 360 mg/kg bw per day. The NOAEL for embryo- and fetotoxicity was 360 mg/kg bw per day, the highest dose tested. In another study in Sprague-Dawley rats treated by gavage, pregnant females received folpet at a dose of 0, 150, 550, or 2000 mg/kg bw on days 6–15 of gestation. On the basis of effects on body weight and food consumption, the NOAEL for maternal toxicity was 150 mg/kg bw per day. There was a slightly increased incidence of angulated ribs and the reduction in ossification of the interparietal bone at 150 mg/kg bw per day. The maternal toxicity and the associated fetal effects are likely to be caused by high local concentrations of folpet and are not considered to be relevant to dietary exposure. In a third study in Sprague-Dawley rats treated by gavage, the NOAEL for maternal toxicity was 100 mg/kg bw per day on the basis of a reduced body-weight gain in the group receiving the highest dose. As treatment had no effect on fetal growth and development, the NOAEL for developmental toxicity was 800 mg/kg bw per day, the highest dose tested. Therefore, in these three studies of developmental toxicity in rats, the overall NOAEL for maternal toxicity was 150 mg/kg bw per day on the basis of reduction of body-weight gain and food consumption. In two out of three studies, no fetal developmental anomalies were found at doses of up to 800 mg/kg bw per day. In one study, however, a possible slight increase in developmental anomalies was reported at 150 mg/kg bw per day.

Folpet has been tested in a number of studies of developmental toxicity in rabbits treated by gavage. In a study in which New Zealand white rabbits were given folpet at a dose of 0, 10, 20, or 60 mg/kg bw per day on days 6–28 of gestation, the NOAEL for maternal toxicity was 10 mg/kg bw per day on the basis of reduced body-weight gain and food consumption. The NOAEL for fetal toxicity was 10 mg/kg bw per day on the basis of reduced fetal body weights. The maternal toxicity and the associated reduction in fetal body weight are likely to be caused by high local concentrations of folpet and are not considered to be relevant to dietary exposure. At 60 mg/kg bw per day, there was a significant increase in the incidence of hydrocephaly in four fetuses out of three litters. In these same fetuses, skull, gastric, and pulmonary abnormalities were also observed. As the observation of hydrocephaly and cleft palate in one fetus at the intermediate dose was considered to be within the historical control range, the NOAEL for these effects was 20 mg/kg bw per day.

In a second study, HY/CR New Zealand white rabbits were given folpet at a dose of 0, 10, 40, or 160 mg/kg bw per day on days 7–19 of gestation. The NOAEL for maternal toxicity was 10 mg/kg bw per day on the basis of reductions in body-weight gain and in gravid uterine weight. The NOAEL for fetal toxicity was 10 mg/kg bw per day on the basis of an increased incidence of bilateral lumbar ribs and delayed skeletal maturation.

In a pulse-dose study, pregnant D1A Hra: (New Zealand white) rabbits were given folpet at a dose of 60 mg/kg bw per day by gavage on days 7–9, 10–12, 13–15, or 16–18 of gestation. There were occasional occurrences of abortion, but it was not clear whether these abortions were related to treatment with folpet. Maternal body weight and food consumption were significantly reduced in all treated animals. Two fetuses with hydrocephalus were observed, one in the group treated on days 10–12 of gestation and one in the group treated on days 16–18 of gestation. These incidences were considered to be within the historical control range. A significantly increased incidence (12.1%) of fetuses with an irregularly shaped fontanelle was observed in the group treated on days 13–15 of gestation; the incidence in controls was 4.5%. The significance of these effects was not clear.

### ***Toxicological evaluation***

Other than developmental effects, folpet produced no toxicological effects that might be considered to be a consequence of acute exposure. The Meeting concluded that it was not necessary to establish an ARfD for the general population, including children aged 1–6 years for whom separate data on dietary intake are available. The Meeting concluded that it might be necessary to establish an ARfD to protect the embryo or fetus from possible effects in utero. Such an ARfD would apply to women of childbearing age.

The maternal toxicity and the associated reductions in fetal body weight, delayed ossification and increased incidences in skeletal variations observed in studies of developmental toxicity in rabbits are likely to be caused by high local concentrations of folpet and are not considered to be relevant to dietary exposure. However, the increased incidence of hydrocephalus observed could not be attributed with confidence to maternal toxicity.

The Meeting concluded that the database was insufficient (in particular, with regard to the absence of studies on the developmental effects of phthalimide) to establish the mode of action by which the increased incidence of hydrocephalus, observed in rabbits at 60 mg/kg bw per day (NOAEL, 20 mg/kg bw per day) was induced, and as a consequence, their relevance for deriving an ARfD could not be dismissed. Therefore the Meeting established an ARfD of 0.2 mg/kg bw based on a NOAEL of 20 mg/kg bw per day for the increased incidence of hydrocephalus at 60 mg/kg bw per day in rabbits and a safety factor of 100. The use of a safety factor of 100 was considered to be conservative; although the mode of action by which the developmental effects are induced was uncertain, they are possibly secondary to maternal toxicity. The Meeting noted that it might be possible to refine this ARfD using the results of an appropriately designed study.

An addendum to the toxicological monograph was prepared.

*Estimate of acute reference dose*

0.2 mg/kg bw for women of childbearing age

Unnecessary for the general population

## DIETARY RISK ASSESSMENT

### *Short-term intake*

The Meeting set an ARfD of 0.2 mg/kg bw for folpet for women of childbearing age and decided that an ARfD was unnecessary for the general population, including children aged 1–6 years. Women of childbearing age are also part of the general population.

In the absence of relevant studies on the developmental effects of phthalimide (metabolite of folpet), the Meeting was unable to determine whether phthalimide should be excluded from the residue definition for dietary risk assessment. The Meeting was not able to finalize the risk assessment before an evaluation of the residue definition for risk assessment and associated residue values for dietary intake estimation had been completed.

## 4.13 GLYPHOSATE (158)

### TOXICOLOGY

Glyphosate (*N*-(phosphonomethyl)glycine) is a non-selective systemic herbicide that was last evaluated by the JMPR in 1986, when an ADI of 0–0.3 mg/kg bw was established on the basis of a NOAEL of 31 mg/kg bw per day, the highest dose tested in a 26-month study of toxicity in rats. In 1997, JMPR evaluated aminomethylphosphonic acid (AMPA), the main metabolite of glyphosate, and concluded that AMPA was of no greater toxicological concern than its parent compound. A group ADI of 0–0.3 mg/kg bw was established for AMPA alone or in combination with glyphosate. Glyphosate was re-evaluated by the present Meeting within the periodic review programme of the CCPR. The Meeting reviewed new data on glyphosate that had not been reviewed previously and relevant data from the previous evaluations.

After oral administration to rats, [ $^{14}\text{C}$ ]glyphosate was only partially absorbed (about 30–36%) from the gastrointestinal tract. Absorption was not significantly dose-dependent over the range of 10 to 1000 mg/kg bw. Peak plasma concentrations of radiolabel were observed at 0.5–1 h after dosing in rats and hens, respectively, and at 6–8 h after dosing in goats. The highest tissue concentrations were found in bone, with lower concentrations being found in bone marrow, kidney and liver. After oral administration, about 60–70% was eliminated in the faeces. Of the glyphosate that was absorbed, most was excreted in the urine and < 0.2% in expired air. After intravenous application, faecal excretion via bile was only about 2–8% of the administered dose. Whole body clearance (about 99% of an orally administered dose) occurred within approximately 168 h. The estimated half-life for whole-body elimination of the radiolabel was 2.1–7.5 h for the alpha phase and 69–337 h for the beta phase. Repeated dosing did not alter absorption, distribution and excretion. There was very little biotransformation of glyphosate; the only metabolite, AMPA, accounted for  $\leq 0.7\%$  of the administered dose in excreta; the rest was unchanged glyphosate.

Glyphosate has low acute oral toxicity in mice ( $\text{LD}_{50}$ , > 2000 mg/kg bw; no deaths at this dose) and rats ( $\text{LD}_{50}$ , > 5000 mg/kg bw), low acute dermal toxicity in rats ( $\text{LD}_{50}$ , > 2000 mg/kg bw) and rabbits ( $\text{LD}_{50}$ , > 5000 mg/kg bw), and low acute inhalation toxicity in rats ( $\text{LC}_{50}$ , > 4.43 mg/l of air). Clinical signs after acute oral exposure included reduced activity, ataxia and convulsions.

Glyphosate was not irritating to the skin, but produced moderate to severe eye irritation with irreversible corneal opacity in one study. Glyphosate salts were slightly irritating to the eye, with minimal to moderate conjunctival irritation and slight iritis that usually disappeared within 48 h after exposure. Glyphosate was not a skin sensitizer in guinea-pigs.

In short-term studies of toxicity in different species, the most important effects were clinical signs related to gastrointestinal irritation, salivary gland changes (hypertrophy and increase in basophilia of cytoplasm of acinar cells) and hepatotoxicity. In mice, reduced body-weight gain was seen at dietary concentrations of 25 000 ppm. Alterations of the salivary glands were present in mice in one of two short-term studies at dietary concentrations of  $\geq 6250$  ppm; the NOAEL for this finding was 3125 ppm (equal to 507 mg/kg bw per day). In rats, findings included soft faeces, diarrhoea, reduced body-weight gain, decreased food utilization and slightly increased plasma enzyme activities (alkaline phosphatase, alanine aminotransferase) at dietary concentrations of  $\geq 20\,000$  ppm. Additionally, in two out of four 90-day studies in rats, increased incidences of alterations of the salivary glands were observed. At the lower doses, the severity and incidence of these changes were only minimal. The overall NOAEL was 300 mg/kg bw per day.

In dogs, the NOAEL in a 90-day feeding study was 10 000 ppm (equal to 323 mg/kg bw per day) on the basis of reduced body-weight gain, marginal reductions in albumin and calcium concentrations, and increased plasma alkaline phosphatase activities at 50 000 ppm. In a 1-year study in dogs given capsules containing glyphosate, the NOAEL was 30 mg/kg bw per day, on the basis of clinical signs (soft faeces, diarrhoea) and reduced body-weight gain at  $\geq 300$  mg/kg bw per day. In a 1-year feeding study, the NOAEL was 15 000 ppm (equal to 440 mg/kg bw per day) on the basis of reduced body-weight gain at 30 000 ppm.

Long-term studies of toxicity and carcinogenicity were conducted in mice and rats. In the study of carcinogenicity in mice, no toxic effects were observed at up to the highest dose tested (1000 mg/kg bw per day), and there was no evidence of carcinogenicity.

In a 1-year study of toxicity in rats, the NOAEL was 2000 ppm (equal to 141 mg/kg bw per day) on the basis of a reduction in body weight and clinical chemistry findings at 8000 ppm. Three new long-term studies in rats were evaluated. In the first study, the NOAEL was 8000 ppm (equal to 362 mg/kg bw per day) on the basis of a reduction in body weight in females and an increased incidence of cataracts and lens abnormalities in males at 20 000 ppm. In the second study, the NOAEL was 100 mg/kg bw per day on the basis of more pronounced alterations of the parotid and submaxillary salivary glands at  $\geq 300$  mg/kg bw per day. In the most recent 2-year study in rats, the NOAEL was 6000 ppm (equal to 361 mg/kg bw per day) on the basis of a reduction in body weight and food consumption and indications of kidney, prostate and liver toxicity at 20 000 ppm. There was no evidence of a carcinogenic response to treatment in rats.

The genotoxic potential of glyphosate has been extensively tested in a wide range of assays both in vitro and in vivo, including end-points for gene mutation, chromosomal damage and DNA repair. Negative results were obtained in studies performed in compliance with current test guidelines. The Meeting concluded that glyphosate is unlikely to be genotoxic.

In view of the absence of a carcinogenic potential in animals and the lack of genotoxicity in standard tests, the Meeting concluded that glyphosate is unlikely to pose a carcinogenic risk to humans.

Glyphosate had no effect on fertility in either two-generation study of reproductive toxicity in rats. The overall NOAEL for parental and offspring toxicity was 3000 ppm (equal to 197 mg/kg bw per day) on the basis of increased food and water consumption and reduced body-weight gain in F<sub>1</sub> animals, and increased incidences of alterations of parotid and submaxillary salivary glands in parental and F<sub>1</sub> animals at 10 000 ppm.

In studies of developmental toxicity in rats, the NOAEL for maternal and developmental toxicity was 300 mg/kg bw per day, on the basis of clinical signs and reduced body-weight gain in the dams and increased incidences of fetuses with delayed ossification and skeletal anomalies.

In studies of developmental toxicity in rabbits, the NOAEL for maternal toxicity was 100 mg/kg bw per day on the basis of clinical signs and reduced food consumption and body-weight gain. The NOAEL for developmental toxicity was 175 mg/kg bw per day on the basis of reduced fetal weight and delayed ossification and an increased incidence of postimplantation loss. The Meeting concluded that glyphosate is not teratogenic. The Meeting concluded that the existing database on glyphosate was adequate to characterize the potential hazard to fetuses, infants and children.

Hypertrophy and cytoplasmic alterations of the salivary glands (parotid and/or mandibular) was a common and sensitive end-point in six studies: in three 90-day studies (one in mice, two in rats), a 1-year study in rats, a 2-year study in rats and a two-generation study of reproductive toxicity in rats. Mechanistic studies available to the Meeting hypothesized that the mechanism was adrenergic. However, the inability of a  $\beta$ -blocker to significantly inhibit these effects indicates that glyphosate does not act as a  $\beta$ -agonist. Other proposed mechanisms for the salivary gland alterations include oral irritation caused by dietary administration of glyphosate, a strong organic acid. Although the mechanism of the cytoplasmic alterations in the salivary glands was unclear, the Meeting concluded that this treatment-related effect is of unknown toxicological significance.

In a study of acute neurotoxicity in rats, the NOAEL for neurotoxicity was 2000 mg/kg bw, the highest dose tested. In a short-term study of neurotoxicity in rats, the NOAEL for neurotoxicity was 20 000 ppm, equal to 1547 mg/kg bw per day, the highest dose tested. In a study of acute delayed peripheral neuropathy in hens, clinical and histopathological examination found no evidence for acute delayed peripheral neuropathy at a dose of 2000 mg/kg bw.

New toxicological data on AMPA (the primary degradation product of glyphosate in plants, soil and water, and the only metabolite of glyphosate found in animals) was submitted to the present Meeting for evaluation. AMPA was of low acute oral and dermal toxicity in rats (LD<sub>50</sub>, > 5000 and > 2000 mg/kg bw, respectively), and was not a skin sensitizer in guinea-pigs. In a 90-day study of toxicity in rats, the NOAEL was 1000 mg/kg bw per day, the highest dose tested. AMPA had no genotoxic potential in vitro or in vivo. In a study of developmental toxicity in rats, no evidence for embryo- or fetotoxicity was found and the NOAEL for maternal and developmental toxicity was 1000 mg/kg bw per day, the highest dose tested.

On the basis of the new toxicological data, the present Meeting concluded that AMPA is of no greater toxicological concern than its parent compound, thus confirming the conclusion of the 1997 JMPR.

Routine medical surveillance of workers in production and formulation plants revealed no adverse health effects attributable to glyphosate. In operators applying glyphosate products, cases of eye, skin and/or respiratory tract irritation have been reported. Acute intoxication was reported in humans after accidental or intentional ingestion of concentrated glyphosate formulations, resulting in gastrointestinal, cardiovascular,

pulmonary and renal effects and occasionally death. The acute toxicity of glyphosate formulations was likely to be caused by the surfactant in these products.

### ***Toxicological evaluation***

The Meeting established a group ADI for glyphosate and AMPA of 0–1.0 mg/kg bw on the basis of the NOAEL of 100 mg/kg bw per day for salivary gland alterations in a long-term study of toxicity and carcinogenicity in rats and a safety factor of 100. The ADI is supported by NOAELs of 141 and 197 mg/kg bw per day from the 1-year study and the two-generation study of reproductive toxicity in rats, respectively.

The Meeting concluded that it was not necessary to establish an ARfD for glyphosate in view of its low acute toxicity, the absence of relevant developmental toxicity in rats or rabbits as a consequence of acute exposure and the absence of any other toxicological effect that would be elicited by a single dose.

The NOAEL of 30 mg/kg bw per day in a 1-year study in dogs was not considered relevant for establishing either the ADI or ARfD, since the gastrointestinal effects seen in this study at 300 and 1000 mg/kg bw per day were related to high local concentrations of test substance resulting from the administration of glyphosate in capsules.

An addendum to the toxicological monograph was prepared.

### ***Levels relevant to risk assessment***

| Species | Study                                                          | Effect                       | NOAEL                                                      | LOAEL                                         |
|---------|----------------------------------------------------------------|------------------------------|------------------------------------------------------------|-----------------------------------------------|
| Mouse   | 3-month study of toxicity <sup>a,e</sup>                       | Toxicity                     | 3125 ppm, equal to<br>507 mg/kg bw per day                 | 6250 ppm, equal to<br>1065 mg/kg bw per day   |
|         | 2-year study of carcinogenicity <sup>a</sup>                   | Toxicity                     | 1000 mg/kg bw per day <sup>d</sup>                         | —                                             |
|         |                                                                | Carcinogenicity              | 1000 mg/kg bw per day <sup>d</sup>                         | —                                             |
| Rat     | 3-month study of toxicity <sup>a,e</sup>                       | Toxicity                     | 300 mg/kg bw per day                                       | 12 500 ppm, equal to<br>811 mg/kg bw per day  |
|         | 1-year study of toxicity <sup>a</sup>                          | Toxicity                     | 2000 ppm, equal to<br>141 mg/kg bw per day                 | 8000 ppm, equal to<br>560 mg/kg bw per day    |
|         | 2-year study of toxicity and<br>carcinogenicity <sup>a,e</sup> | Toxicity                     | 100 mg/kg bw per day                                       | 300 mg/kg bw per day                          |
|         |                                                                | Carcinogenicity <sup>d</sup> | 20 000 ppm, equal to<br>1214 mg/kg bw per day <sup>d</sup> | —                                             |
|         | Multigeneration reproductive<br>toxicity <sup>a,e</sup>        | Parental toxicity            | 3000 ppm, equal to<br>197 mg/kg bw per day                 | 10 000 ppm, equal to<br>668 mg/kg bw per day  |
|         |                                                                | Offspring toxicity           | 3000 ppm, equal to<br>197 mg/kg bw per day                 | 10 000 ppm, equal to<br>668 mg/kg bw per day  |
|         | Developmental toxicity <sup>b,e</sup>                          | Maternal toxicity            | 300 mg/kg bw per day                                       | 1000 mg/kg bw per day                         |
|         |                                                                | Embryo- and<br>fetotoxicity  | 300 mg/kg bw per day                                       | 1000 mg/kg bw per day                         |
| Rabbit  | Developmental toxicity <sup>b,e</sup>                          | Maternal toxicity            | 100 mg/kg bw per day                                       | 150 mg/kg bw per day                          |
|         |                                                                | Embryo- and<br>fetotoxicity  | 175 mg/kg bw per day                                       | 300 mg/kg bw per day                          |
| Dog     | 3-month study of toxicity <sup>a</sup>                         | Toxicity                     | 10 000 ppm, equal to<br>323 mg/kg bw per day               | 50 000 ppm, equal to<br>1680 mg/kg bw per day |
|         | 1-year study of toxicity <sup>a,c,e</sup>                      | Toxicity                     | 30 mg/kg bw per day <sup>c,f</sup>                         | 300 mg/kg bw per day <sup>c</sup>             |

<sup>a</sup> Diet

<sup>b</sup> Gavage

<sup>c</sup> Capsules

<sup>d</sup> Highest dose tested

<sup>e</sup> Two or more studies combined

<sup>f</sup> Not used for establishing the ADI (or ARfD) since the NOAEL is based on an effect induced by high local concentrations



*Estimate of acceptable daily intake for humans*

0–1.0 mg/kg bw

*Estimate of acute reference dose*

Unnecessary

*Studies that would provide information useful for continued evaluation of the compound*

- Additional information on the mechanism of the changes in the salivary glands
- Further observations in humans

***Critical end-points for setting guidance values for exposure to glyphosate****Absorption, distribution, excretion and metabolism in animals*


---

|                                                                             |                                                                            |
|-----------------------------------------------------------------------------|----------------------------------------------------------------------------|
| Rate and extent of oral absorption                                          | Rapid, approximately 30–36%                                                |
| Dermal absorption                                                           | No information                                                             |
| Distribution                                                                | Widely distributed                                                         |
| Rate and extent of excretion                                                | Largely complete within 48 h; approximately 30% in urine and 70% in faeces |
| Potential for accumulation                                                  | No evidence of accumulation (< 1% after 7 days)                            |
| Metabolism in mammals                                                       | Very limited (< 0.7%), hydrolysis leading to AMPA                          |
| Toxicologically significant compounds (animals, plants and the environment) | Parent compound, AMPA                                                      |

*Acute toxicity*

|                                    |                                                            |
|------------------------------------|------------------------------------------------------------|
| Rat, LD <sub>50</sub> , oral       | > 5000 mg/kg bw                                            |
| Rat, LD <sub>50</sub> , dermal     | > 2000 mg/kg bw                                            |
| Rat, LC <sub>50</sub> , inhalation | > 4.43 mg/l (4-h, nose-only exposure)                      |
| Rabbit, dermal irritation          | Non-irritant                                               |
| Rabbit, eye irritation             | Moderately to severely irritant                            |
| Skin sensitization                 | Not sensitizing (Magnusson and Kligman test, Buehler test) |

*Short-term toxicity*

|                                  |                                                                                                                    |
|----------------------------------|--------------------------------------------------------------------------------------------------------------------|
| Target/critical effect           | Clinical signs (soft faeces, diarrhoea), reduced body-weight gain; liver (toxicity), salivary glands (hypertrophy) |
| Lowest relevant oral NOAEL       | 300 mg/kg bw per day (90-day study in rats)                                                                        |
| Lowest relevant dermal NOAEL     | —                                                                                                                  |
| Lowest relevant inhalation NOAEC | —                                                                                                                  |

*Genotoxicity*

No genotoxic potential

*Long-term studies of toxicity and carcinogenicity*

|                        |                                                                                                                    |
|------------------------|--------------------------------------------------------------------------------------------------------------------|
| Target/critical effect | Reduced body-weight gain; liver (toxicity), salivary glands (hypertrophy), eye (cataract, lens fibre degeneration) |
| Lowest relevant NOAEL  | 100 mg/kg bw per day (2-year study in rats)                                                                        |

|                                            |                                                                                                                                                                                                                                                                                                                                                                       |
|--------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Carcinogenicity                            | No evidence of carcinogenicity in rats or mice                                                                                                                                                                                                                                                                                                                        |
| <i>Reproductive toxicity</i>               |                                                                                                                                                                                                                                                                                                                                                                       |
| Reproductive target/critical effect        | Reduced pup weight at parentally toxic doses                                                                                                                                                                                                                                                                                                                          |
| Lowest relevant reproductive NOAEL         | 197 mg/kg bw per day (two-generation study in rats)                                                                                                                                                                                                                                                                                                                   |
| Developmental target/critical effect       | Embryo- and fetotoxicity at maternally toxic doses (rat, rabbit)                                                                                                                                                                                                                                                                                                      |
| Lowest relevant developmental NOAEL        | 175 mg/kg bw per day (rabbit)                                                                                                                                                                                                                                                                                                                                         |
| <i>Neurotoxicity/delayed neurotoxicity</i> | No evidence of neurotoxicity in any study conducted                                                                                                                                                                                                                                                                                                                   |
| <i>Medical data</i>                        | Medical surveillance of workers in plants producing and formulating glyphosate plants did not reveal any adverse health effects. In operators applying glyphosate products, cases of eye, skin and/or respiratory irritation have been reported. Cases of acute intoxication have been observed after accidental or intentional ingestion of glyphosate formulations. |

| <i>Summary</i>   | <i>Value</i>   | <i>Study</i>                                  | <i>Safety factor</i> |
|------------------|----------------|-----------------------------------------------|----------------------|
| ADI <sup>a</sup> | 0–1.0 mg/kg bw | 2-year study in rats (salivary gland effects) | 100                  |
| ARfD             | Unnecessary    | —                                             | —                    |

<sup>a</sup> For the sum of glyphosate and AMPA

## DIETARY RISK ASSESSMENT

### *Long-term intake*

Estimated theoretical maximum daily intakes for the five GEMS/Food regional diets, based on recommended MRLs, were 1% of the ADI (Annex 3). The Meeting concluded that the long-term intake of residues of glyphosate resulting from uses that have been considered by the JMPR is unlikely to present a public health concern.

### *Short-term intake*

The 2004 JMPR decided that an ARfD for glyphosate is unnecessary. The Meeting therefore concluded that the short-term intake of glyphosate residues is unlikely to present a public health concern.

## 4.14 MALATHION (049)

### RESIDUE AND ANALYTICAL ASPECTS

Malathion has been evaluated many times since 1965. The company asked the CCPR at its Thirty-third Session in 2001 to reconsider withdrawal of the existing Codex MRLs recommended during the periodic review of the compound by the 1999 JMPR. The CCPR at its Thirty-sixth Session decided to retain the current CXL for apple, broccoli, cabbage (head), cereal grains, citrus fruit and grape, awaiting the review of the new residue data by the 2004 JMPR. The company submitted data on mandarin, orange, apple, peach, grape, strawberry, tomato, alfalfa fodder and forage (green) to the present Meeting.

**Results of supervised trials on crops***Citrus fruit*

Sixteen trials were conducted with mandarin and orange in Greece (GAP for citrus, 0.044–0.088 kg ai/hl, 7-day PHI), Italy (GAP, 0.053 kg ai/hl, 20-day PHI) and Spain (GAP for foliar application, 0.11–0.15 kg ai/hl, 7-day PHI) between 2000 and 2002. Malaoxon was analysed in all trials, and the maximum residue level found in fruit was 0.09 mg/kg on the day of the last application.

Ten trials conducted at 0.18 kg ai/hl and five trials performed at 0.30 kg ai/hl were evaluated against Spanish and Portuguese GAP for citrus (0.05–0.30 kg ai/hl, 7-day PHI), respectively. Decline studies conducted in both crops indicated that residue levels decreased slowly within 3 days of the last application, and samples harvested from 7 up to 10–11 days could be considered at GAP.

The residue levels in *mandarin* fruit were, in ranked order: 0.75, 1.8 (three), 2.4 (two), 2.9, 3.1 and 4.7 mg/kg. In mandarin pulp, the levels were: < 0.01, 0.01, 0.02, 0.03, 0.12, 0.15, 0.21 and 0.22 mg/kg.

The residue levels in *orange* fruit were, in ranked order: 0.58, 0.75, 0.89, 1.1, 1.4, 1.6, 1.7 and 2.1 mg/kg. The levels in orange pulp were: < 0.01 (three), 0.01 (two), 0.03 and 0.07 (two) mg/kg. One trial conducted at 0.4 kg ai/hl gave residue levels within the same range.

The Meeting agreed that the levels of residues of malathion in mandarin and orange from trials conducted at GAP could be combined to represent a residue population for citrus. In fruit, the levels were, in ranked order: 0.58, 0.75 (two), 0.89, 1.1, 1.4, 1.6, 1.7, 1.8 (three), 2.1, 2.4 (two), 2.9, 3.1 and 4.7 mg/kg. In citrus pulp, the levels were: < 0.01 (four), 0.01 (three), 0.02, 0.03, 0.07 (two), 0.12, 0.15, 0.21 and 0.22 mg/kg.

The Meeting recommended a maximum residue level of 7 mg/kg, a STMR of 0.02 mg/kg and a highest residue level of 0.22 mg/kg for malathion in citrus.

*Apple*

Twelve trials were conducted on apples in northern France in 2000 and 2001, with three applications at 0.18 kg ai/hl. There is no GAP for malathion in France; however, the results can be evaluated against Spanish or Italian GAP (up to 0.16 kg ai/hl). The PHI is 7 days in Spain and 20 days in Italy. The residue levels in apple fruit at the most critical PHI (7 days) were, in ranked order: 0.02, 0.05 (two), 0.07, 0.08, 0.09, 0.13, 0.14, 0.19, 0.24, 0.25 and 0.37 mg/kg. The levels of malaoxon were < 0.01–0.02 mg/kg.

The Meeting recommended a maximum residue level of 0.5 mg/kg, an STMR of 0.11 mg/kg and an HR of 0.37 mg/kg for malathion in apple.

*Peach*

Four trials were conducted in Italy in 1997 on peaches, with three applications of 0.16 kg ai/hl, corresponding to GAP. The residue levels of malathion in the fruit at 20 days' PHI were < 0.01 (three) and 0.01 mg/kg. No malaoxon was found in the fruit after the last application (0–20 days).

The Meeting agreed that four trials is not enough to recommend a maximum residue level for malathion in peaches. The Meeting confirmed the previous recommendation of 1999 JMPR to withdraw the CXs for malathion in peaches

*Grape*

Six trials were conducted in grapes in southern and northern France (no GAP) in 2000–01, with three applications at 0.27 kg ai/hl. The residue levels of malathion 7 days after the last application were 0.26–1.3 mg/kg.

In four trials conducted in northern Spain in 2000–01 within maximum GAP (0.11–0.15 kg ai/hl, 7-day PHI), the residue levels of malathion at 7 days' PHI were: 1.1, 1.5 (two) and 2.6 mg/kg. The levels of

malaoxon were 0.02–0.13 mg/kg. Four trials conducted in Italy at GAP (0.05–0.16 kg ai/hl, 20-day PHI), evaluated against Spanish GAP, showed levels of 0.01, 0.03 and 0.21 (two) mg/kg.

The residue levels in trials conducted in Italy and Spain according to GAP were 0.01, 0.03, 0.21 (two), 1.1, 1.5 (two) and 2.6 mg/kg.

The Meeting recommended a maximum residue level of 5 mg/kg, a STMR of 0.16 mg/kg and a highest residue level of 2.6 mg/kg for malathion grapes.

#### *Strawberry*

GAPs for malathion on strawberry in Europe are: Denmark, three times 1.1 kg ai/ha, 7-day PHI; Italy, up to 0.16 kg ai/hl, 20-day PHI; Portugal, 0.10 kg ai/hl, 1-day PHI; and Spain, up to 0.15 kg ai/hl, 7-day PHI. In three trials conducted in France, two in Italy and three in Spain with four or six applications at 0.15–0.18 kg ai/hl, the residue levels at 7 days' PHI were < 0.01–0.14 mg/kg.

The Meeting confirmed the currently recommended maximum residue level of 1 mg/kg of malathion in strawberry, which was set by the 1999 JMPR on the basis of trials conducted in the USA according to GAP with a 1-day PHI.

#### *Tomato*

GAP for malathion in tomato is up to 0.088 kg ai/hl with a 7-day PHI in Greece, up to 0.16 kg ai/hl with a 20-day PHI in Italy and up to 0.10 kg ai/hl with a 1-day PHI in Portugal. In five trials conducted in Italy and one in Spain in 1997–2001 according to Greek GAP, the residue levels were < 0.01 (three), 0.01 and 0.02 (two) mg/kg. Four other trials were conducted in these countries at higher or lower rates than GAP.

The Meeting confirmed the currently recommended maximum residue level of 0.5 mg/kg for malathion in tomato, which was set by the 1999 JMPR on the basis of trials conducted in the USA according to GAP with a 1-day PHI.

#### *Alfalfa*

Two trials were conducted in Italy in 2000–01 (no GAP) and two in Spain (GAP, 0.12–0.25 kg ai/hl or 1.5–2.8 kg ai/ha) with one application at 0.15 kg ai/hl (1.5 kg ai/ha). The Italian trials, evaluated against Spanish GAP, gave residue levels of malathion of 0.67 and 0.41 mg/kg on a dry weight basis in alfalfa forage (green) at 7 days' PHI, and 0.12 mg/kg in hay harvested at 7 days' PHI and allowed to dry on the field for 3 days. In the Spanish trials, the residue levels were 1.2 and 3.5 mg/kg in forage and 3.3 mg/kg in hay.

The Meeting confirmed the currently recommended maximum residue levels for malathion on alfalfa forage (green) and alfalfa hay of 500 and 200 mg/kg, respectively, which were set by the 1999 JMPR on the basis of trials conducted in USA according to GAP at 1 day PHI.

## **DIETARY RISK ASSESSMENT**

### ***Long-term intake***

The current ADI for malathion is 0.3 mg/kg bw. IEDIs were calculated for commodities for human consumption for which STMRs were estimated by the 1999 JMPR and by the present Meeting (Annex 3). The IEDI for the five GEMS/Food regional diets was 0% of the maximum ADI. The Meeting concluded that long-term intake of residues of malathion resulting from uses considered by the JMPR is unlikely to present a public health concern.

### ***Short-term intake***

An ARfD for malathion of 2 mg/kg bw was established by the 2003 JMPR. The IESTIs of malathion by the general population and by children were calculated for commodities for which STMR and highest

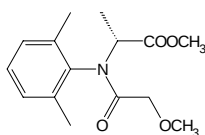
residue values were estimated by the current Meeting (Annex 4). The IESTI was 0–4% of the ARfD for the general population and 0–10% of the ARfD for children. The Meeting concluded that short-term intake of residues of malathion from its use in citrus, apples and grapes is unlikely to present a public health concern.

#### 4.15 METALAXYL M (212)

##### RESIDUE AND ANALYTICAL ASPECTS

The toxicology of metalaxyl-M was evaluated by the 2002 JMPR, which established a group ADI of 0–0.08 mg/kg bw for metalaxyl and metalaxyl-M. Residue and analytical aspects were considered for the first time by the present Meeting. Metalaxyl-M is the biologically active enantiomer (R-enantiomer) of the racemic compound metalaxyl. Metalaxyl was first evaluated by the JMPR in 1982, and Codex MRLs for metalaxyl were established.

Metalaxyl-M is registered for use on fruit, nut and vegetable crops for the control of various fungal diseases such as those caused by *Phytophthora* and *Pythium* spp. It is applied to foliage, soil or seed and also as a post-harvest fruit treatment.



|                         |                                                                              |
|-------------------------|------------------------------------------------------------------------------|
| IUPAC name              | (R)-2-[(2,6-dimethylphenyl)-methoxyacetyl]amino]-propionic acid methyl ester |
| Chemical Abstracts name | N-(2,6-dimethylphenyl)-N-(methoxyacetyl)-D-alanine methyl ester              |

The Meeting received information on the metabolism and environmental fate of metalaxyl-M and on methods of residue analysis, stability in freezer storage, national registered use patterns, the results of supervised trials and farm animal feeding studies, the fate of residues in processing and national MRLs.

As metalaxyl-M constitutes 50% of metalaxyl, investigations into the metabolism and fate of metalaxyl can legitimately be accepted as supporting the metabolism and fate of metalaxyl-M. When the metabolism of metalaxyl and metalaxyl-M was compared directly, it was found to be similar.

In the studies of animal and plant metabolism and environmental fate, metalaxyl or metalaxyl-M uniformly <sup>14</sup>C labelled in the aromatic ring was used.

##### Metabolism

In the list below, the numbering is preserved from the 2002 JMPR toxicology evaluation.

Metabolite 1: N-(2,6-dimethylphenyl)-N-(methoxyacetyl)alanine

Metabolite 3: N-(2,6-dimethylphenyl)-N-(hydroxyacetyl)alanine methyl ester

Metabolite 6: N-(2,6-dimethylphenyl)-N-(hydroxyacetyl)alanine

Metabolite 7: N-(2,6-dimethyl-5-hydroxyphenyl)-N-(methoxyacetyl)alanine methyl ester

Metabolite 8: N-(2-hydroxymethyl-6-methylphenyl)-N-(methoxyacetyl)alanine methyl ester (occurs as two isomers)

Metabolite P: N-[(2-hydroxymethyl)-6-methylphenyl]-N-(hydroxyacetyl)alanine (occurs as two isomers)

### Animals

The Meeting received the results of studies on metabolism in rats, lactating goats and laying hens. When animals were dosed orally with radiolabelled metalaxyl, most of the radiolabel was excreted in the urine within a short time, with a small amount in the faeces. Numerous metabolites resulting from hydrolysis, oxidation and demethylation of metalaxyl and subsequent conjugate formation were identified. In a study in goats, metalaxyl itself was not detected as a component of the residue in tissues or milk. In a study in laying hens, low levels of metalaxyl were present in liver and eggs. The metabolic pathway for metalaxyl was similar in rats, goats and hens.

The absorption, distribution, metabolism and excretion of radiolabel were similar in *rats* dosed orally with  $^{14}\text{C}$ -metalaxyl or  $^{14}\text{C}$ -metalaxyl-M. Detailed information on metabolism in this species is reported in the 2002 JMPR toxicological evaluations.

Very little radiolabel was found in milk (0.003 mg/kg) or tissues (0.057 mg/kg in liver) from a *goat* dosed with  $^{14}\text{C}$ -metalaxyl at the equivalent of 7 ppm in the feed for 10 days.

When two lactating dairy goats were dosed orally once daily for 4 consecutive days by gelatin capsule with  $^{14}\text{C}$ -metalaxyl, equivalent to 77 ppm in the diet, the radiolabel was excreted rapidly: within 24 h of administration, 67% of the daily dose appeared in urine, 9% in faeces and 0.1% in milk. Metalaxyl was not detected as a component of the residue. Metabolite 6 was the main component of the residue in liver (0.19 mg/kg), leg muscle (0.014 mg/kg) and perirenal fat (0.065 mg/kg); metabolite 8 was the main residue component in kidney. The main metabolites in milk were C-10 and C-8 fatty acid conjugates of metabolite 3 (0.058 mg/kg). These fatty acids are conjugated through the hydroxyacetyl group of metabolite 3.

When five laying *hens* were dosed orally once daily for 4 consecutive days by gelatin capsule with  $^{14}\text{C}$ -metalaxyl, equivalent to approximately 100 ppm metalaxyl in the diet, radiolabel recovered in edible tissues and eggs represented 0.97% of the administered dose; the remainder was recovered in excreta. Metabolite P (consisting of P1 and P2, steric isomers) was the main metabolite in egg white (0.056 mg/kg), egg yolk (0.072 mg/kg) and thigh muscle (0.31 mg/kg). Metalaxyl parent was identified in egg white (0.013 mg/kg), egg yolk (0.010 mg/kg) and liver (0.018 mg/kg), but not in thigh muscle or fat (< 0.001 mg/kg).

### Plants

The Meeting received the results of studies on the metabolism of metalaxyl in grape, lettuce and potato and of metalaxyl-M in lettuce. No metabolites were identified in plants which had not already been identified in animals. Parent metalaxyl was the main component of the residue in grapes and in juice produced from the grapes when metalaxyl was used on grape vines. In treated lettuce, parent metalaxyl and metabolite 8 were each present at approximately 20% of the total residue. Metabolite 8 was the main residue component in lettuce in both cases in which metalaxyl and metalaxyl-M were compared. When metalaxyl was used on potato plants, some residue reached the tubers, where parent metalaxyl was the main residue component.

Grapevines in Switzerland were sprayed to runoff seven times at 14-day intervals with a  $^{14}\text{C}$ -metalaxyl spray at a concentration of 0.050 kg ai/hl and were harvested 52 days after the final application. Parent metalaxyl (2.0 mg/kg) constituted 64% of the total residues in *grapes*.

When two grapevines in Switzerland were sprayed to runoff six times at approximately 14-day intervals with a  $^{14}\text{C}$ -metalaxyl spray at a concentration of 0.030 kg ai/hl and harvested 68 days after the final application, parent metalaxyl (0.83 mg/kg) comprised 64% of total residues in the grapes. Metabolite 8 accounted for 20% of the residue, and metabolites 1, 6 and 7 were minor components (1.8–4.3%). When the grapes were separated into juice and presscake, metalaxyl was still the main part of the residue (62% and 57%, respectively).

Metalaxyl was the main identified component of the residue in *lettuce* (18.6% of the total  $^{14}\text{C}$  residue) after seedlings in a greenhouse were sprayed twice, 2 weeks apart, with  $^{14}\text{C}$ -metalaxyl at a rate equivalent to 0.25 kg ai/ha and harvested 2 weeks later. The identified metabolites (including glucose conjugates) were metabolite 8 (22% of the total  $^{14}\text{C}$  residue), metabolite 6 (10%), metabolite 3 (8.9%), metabolite 7 (6.2%) and metabolite 1 (6.0%).

The metabolic pathways of metalaxyl-M and metalaxyl were compared in lettuce in a field in Switzerland treated three times at 10-day intervals with labelled compounds. The levels of total applied residue and parent compounds in the residue were generally comparable. Metabolite 8 (free and conjugated) was the main identified component of the residue in samples taken 14 and 21 days after treatment. Enantiomeric ratio measurements suggested similar disappearance rates for the two enantiomers and little interconversion.

*Potato* plants in the field in Switzerland received five foliar treatments of  $^{14}\text{C}$ -metalaxyl at 0.2 kg ai/ha at 10-day intervals and were harvested at maturity 5 weeks after the final treatment. Little residue reached the tubers (0.02 mg/kg  $^{14}\text{C}$  as metalaxyl). No parent metalaxyl was detected in tubers. In a second experiment, the level of  $^{14}\text{C}$  as metalaxyl in tubers was  $< 0.0001$  mg/kg after  $^{14}\text{C}$ -metalaxyl was applied to the soil (residues in soil, approximately 0.5 mg/kg), indicating that metalaxyl is not taken up by the tubers directly from the soil.

Potato plants in the field in the USA received six foliar treatments, about 2 weeks apart, of  $^{14}\text{C}$ -metalaxyl at 1.3 kg ai/ha. Tubers harvested at maturity, 1 week after the final treatment, contained 0.5 mg/kg  $^{14}\text{C}$  as metalaxyl, of which 50–60% was parent metalaxyl. A number of metabolites were identified, but only the concentration of metabolite 8 exceeded 5% of the residue.

### ***Environmental fate***

#### ***Soil***

The Meeting received information on the behaviour and fate of metalaxyl and metalaxyl-M during aerobic metabolism in a number of soils. The rate of degradation is strongly influenced by the properties of the soil, including its biological activity and the conditions of temperature, moisture and concentration of the residue, with recorded half-lives in the range of 5–180 days. In direct comparisons of metalaxyl and metalaxyl-M under aerobic conditions, metalaxyl-M was the more persistent in one case and less persistent in two others. The main soil metabolite is metabolite 1 or, in the case of metalaxyl-M, the specific enantiomer of metabolite 1.

Field dissipation studies for metalaxyl-M were provided from France, Italy, Spain and Switzerland. Metalaxyl-M residues disappeared from the soil with half-lives ranging from 5 to 35 days. The residues occurred mostly in the top 10 cm of soil, but some reached lower levels. The enantiomer of metabolite 1 was produced in all cases, and its level sometimes exceeded that of the parent metalaxyl-M. A comparison of enantiomeric ratios in metalaxyl residues in soil suggested that the R-enantiomer (i.e. the metalaxyl-M enantiomer) disappeared more quickly than the S-enantiomer. This resulted in a preponderance of S-enantiomer in the metalaxyl residue and a preponderance of R-enantiomer in metabolite 1.

The studies of dissipation in the field suggest that, after use of metalaxyl-M for seed treatment or at the time of sowing, little or none will remain as a soil residue when the crop is harvested.

#### ***Rotational crops***

Information on the fate of radiolabelled metalaxyl in confined crop rotational studies and of unlabelled metalaxyl-M in field rotational crops was made available to the Meeting. The studies with radiolabel showed that parent metalaxyl was usually a minor part of the residue that reached the rotational crop. The identifiable metabolites were also usually minor, but metabolite 8 as glucose conjugates was detected in spring wheat stalks at 2.3 mg/kg. Metalaxyl-M residues were not detected in unconfined field

rotational crops in Switzerland or the United Kingdom, but levels of 0.11 mg/kg were present in broccoli and 0.03 mg/kg in lettuce leaves from crops sown 29 days after treatment of the first crop in a study in Italy. The short interval was used in order to simulate the ploughing-in of a failed crop and the sowing of a new one.

### ***Methods of analysis***

The Meeting received descriptions and validation data for analytical methods for residues of metalaxyl in plant material, animal tissues, milk and eggs.

Common moiety methods rely on the 2,6-dimethylaniline moiety of metalaxyl and many of its metabolites, and these methods have been used to identify metalaxyl residues in animal commodities. The typical LOQs are 0.05 mg/kg for tissues and 0.01 mg/kg for milk. Metabolite 8, containing the 2-hydroxymethyl-6-methylaniline moiety, is apparently partially converted to 2,6-dimethylaniline, resulting in low and variable recoveries.

With gas-liquid chromatography and nitrogen-phosphorus detection and HPLC with mass spectrometry detection procedures for identifying metalaxyl or metalaxyl-M after a simple extraction and limited clean-up, the LOQs are 0.02–0.04 mg/kg for many crop substrates. A modification to the method (method REM 181.06), with the introduction of an HPLC chiral separation step before determination, allows for the analysis of specific enantiomers.

A multi-residue regulatory method (DFG S19) is available for metalaxyl.

Method REM 181.06 (gas-liquid chromatography with mass spectrometry detection) is not a multi-residue method, but it is enantioselective and suitable as a regulatory method for metalaxyl-M.

### ***Stability of residues in stored analytical samples***

The Meeting received information on the stability of residues of metalaxyl-M in crops (orange, potato, rape-seed, tomato, wheat) and animal commodities (beef muscle, beef liver, milk, eggs) during storage of analytical samples. Metalaxyl-M residues were stable in these substrates and under the conditions and intervals of storage (2 years). There was no evidence of epimerization during freezer storage. As a common moiety method was used for the animal commodity samples, storage stability refers to the total residue rather than to parent metalaxyl-M. As the common moiety method, which relies on the 2,6-dimethylaniline moiety, is less suitable for metabolite 8, the freezer stability of this metabolite during storage is not demonstrated.

### ***Definition of the residue***

Parent metalaxyl is the main identifiable component of the residue in crops resulting from use of metalaxyl, although metabolite 8 can occur at approximately the same levels. Metabolite 8 was not considered to be toxicologically significant.

The current residue definition of metalaxyl is metalaxyl. As metalaxyl-M is one enantiomer of metalaxyl, it is covered by the current residue definition. Non-enantioselective methods cannot distinguish metalaxyl-M from metalaxyl, but an enantioselective method is available. While metalaxyl-M and metalaxyl are both registered for crop uses, it is preferable, for enforcement purposes, to maintain a single residue definition. As the 2002 JMPR recommended a group ADI for metalaxyl and metalaxyl-M, the inclusive residue definition is also suitable for risk assessment purposes. The Meeting recommended that metalaxyl-M be contained within the metalaxyl residue definition and recommended amendment of the metalaxyl residue definition to provide definitions for enforcement and risk assessment purposes.



*For plant commodities:* Metalaxyl, including metalaxyl-M. Definition of the residue (for compliance with MRL and for estimation of dietary intake): metalaxyl. Note: Metalaxyl is a racemic mixture of an R-enantiomer and an S-enantiomer. Metalaxyl-M is the R-enantiomer.

In animals dosed with metalaxyl, parent metalaxyl was either a minor part of the residue or was not detected. Analytical methods for metalaxyl are based on a common moiety method, and residues in the farm animal feeding studies were measured by this method. Common moiety residues are acceptable for estimation of dietary intake when the parent compound is a minor part of the residue. The log  $P_{OW}$  for metalaxyl-M is 1.7, and the studies of animal metabolism confirm that metalaxyl is not fat-soluble.

*For animal commodities:* Metalaxyl including metalaxyl-M. Definition of the residue (for compliance with MRL and for estimation of dietary intake): metalaxyl and metabolites containing the 2,6-dimethylaniline moiety, expressed as metalaxyl.

### ***Results of supervised trials on crops***

The Meeting received data from supervised trials with metalaxyl-M used on citrus fruit, apple, grape, onion, tomato, pepper, lettuce, spinach, potato, sunflower and cacao. In some trials, residues were measured on samples taken just before and just after ('zero-day' residue) the final application. The residue level measured just before the final application, expressed as a percentage of zero-day residue, provides a measure of the contribution of previous applications to the final residue in the use pattern used in the trial. For grapes, the average carryover of residue was 32% in 12 trials in Australia, 57% in three trials in Germany and 46% in three trials in Italy. In lettuce, the average carryover was 1.7% in six trials in France, Germany and Italy. In spinach, the average carryover was 1.1% in eight trials in France.

Residue data were evaluated only when labels (or translations of labels) describing the relevant GAP were available to the Meeting.

#### ***Citrus fruit***

Metalaxyl-M is registered for use as a post-harvest treatment on citrus in Israel. It is applied as a 0.1 kg ai/hl spray.

In the trials, the formulation of metalaxyl-M was mixed with a commercial wax to produce a spray solution, which was applied at a rate of 200 l /90 t of fruit (theoretical concentration of residue, 2.1 g/t). The residue levels in three trials on *oranges* were 1.2, 1.3 and 1.6 mg/kg in whole fruit and < 0.02 mg/kg in pulp. This method of post-harvest application includes control of the application rate in terms of the amount of metalaxyl-M per unit weight of fruit. The residue levels agreed substantially with expectations.

The Meeting noted that three supervised trials is generally an insufficient number for a major commodity such as oranges.

The residue levels of metalaxyl-M in the trials conducted in line with Israeli GAP did not exceed the current metalaxyl MRL of 5 mg/kg for citrus fruit.

#### ***Apple***

Metalaxyl-M is registered in Spain for soil treatment around apple trees at 0.5–1.0 g ai/tree and in Italy at 0.5–4 g ai/tree. In two trials each in France, Italy and Spain at application rates of 0.78–10 kg ai/ha, no residues were detected in apples (< 0.02 mg/kg). For an assumed 500–1000 trees per ha, the rate of 10 kg ai/ha appears to be exaggerated.

The Meeting estimated a maximum residue level for metalaxyl-M in apples of 0.02\* and an STMR value of 0 mg/kg.

Metalaxyl-M residue levels complying with the estimated maximum residue level of 0.02\* mg/kg would not exceed the current metalaxyl MRL of 1 mg/kg for pome fruits.

### *Grape*

In Australia, metalaxyl-M is registered for a maximum four applications on grapes at 0.11 kg ai/ha, with a PHI of 7 days. The residue levels in grapes in five Australian trials matching GAP, but with six applications instead of four, were: < 0.02, 0.03, 0.06, 0.14 and 0.52 mg/kg. As the final residue level should not be influenced by earlier applications, residue levels after six applications are acceptable as equivalent to residues levels in GAP trials.

No GAP was available to evaluate the data for grapes treated in Germany and Switzerland.

In Greece, grapes may be treated four times with metalaxyl-M at 0.1 kg ai/ha, with harvest 15 days after the final application. The residue levels in grapes in six trials in Italy and Portugal, conducted substantially according to Greek GAP, were: 0.04, 0.06, 0.18, 0.19, 0.21 and 0.55 mg/kg.

The residue levels in the Australian and European trials appear to be similar and can be combined. In summary, the residue levels in the 11 trials, in ranked order, were: < 0.02, 0.03, 0.04, 0.06, 0.06, 0.14, 0.18, 0.19, 0.21, 0.52 and 0.55 mg/kg

The Meeting estimated a maximum residue level for metalaxyl-M in grapes of 1 mg/kg and an STMR value of 0.14 mg/kg.

Metalaxyl-M residue levels complying with the estimated maximum residue level of 1 mg/kg would not exceed the current metalaxyl MRL of 1 mg/kg for grapes.

### *Onion*

In Ecuador and Uruguay, metalaxyl-M is registered for a maximum of three applications on onions at 0.1 and 0.12 kg ai/ha, with a PHI of 7 days. Metalaxyl-M residue levels in bulb onions in three Brazilian trials matching Uruguayan GAP, but with four applications instead of three, were < 0.02 (two) and 0.02 mg/kg.

Metalaxyl-M is registered in Germany for a maximum of three applications on onions at 0.097 kg ai/ha, with a PHI of 21 days. In four trials in Switzerland with conditions matching German GAP, the residue levels were all below the LOQ (0.02 mg/kg).

Data on residues in trials in onions in Italy and Spain could not be evaluated because no relevant GAP was available.

In summary, the residue levels in the seven trials, in ranked order, were ≤ 0.02 (six) and 0.02 mg/kg.

The Meeting estimated a maximum residue level for metalaxyl-M in onions of 0.03 mg/kg and an STMR value of 0.02 mg/kg.

Metalaxyl-M residue levels complying with the estimated maximum residue level of 0.02 mg/kg would not exceed the current metalaxyl MRL of 2 mg/kg for bulb onions.

### *Tomato*

Metalaxyl-M is registered for foliar application on tomatoes in Algeria, Chile, Ecuador, Greece, Israel and Morocco at 0.10–0.14 kg ai/ha, with a PHI of 3 days and a maximum of three or four treatments.

Residue levels in tomatoes in six greenhouse trials in France, two in Spain and four in Switzerland at 0.15 kg ai/ha, with harvest 3 days after treatment (equivalent to the stated GAP) were: 0.02 (two), 0.02, 0.03, 0.04, 0.04, 0.05, 0.05, 0.08, 0.09, 0.12 and 0.18 mg/kg.

The Meeting estimated a maximum residue level for metalaxyl-M in tomatoes of 0.2 mg/kg and an STMR value of 0.045 mg/kg.

Metalaxyl-M residue levels complying with the estimated maximum residue level of 0.2 mg/kg would not exceed the current metalaxyl MRL of 0.5 mg/kg for tomatoes.

*Pepper*

GAP for use of metalaxyl-M in Italy allows three soil applications of 1 kg ai/ha with a 15-day PHI. Data on residues from Italian and Spanish trials approximating Italian GAP were provided. In some of the trials, residues were measured 10 and 20 days after the final application instead of 15 days, but these trials were considered valid because the residue levels were relatively unchanged. The residue levels in the seven greenhouse trials were: < 0.02 (two), 0.02, 0.03, 0.08, 0.10 and 0.36 mg/kg; and those in the three outdoor trials in Italy were: < 0.02 (two) and 0.02 mg/kg.

The Meeting decided to use the data from the greenhouse trials: < 0.02 (two), 0.02, 0.03, 0.08, 0.10 and 0.36 mg/kg.

The Meeting estimated a maximum residue level for metalaxyl-M in sweet peppers of 0.5 mg/kg and an STMR value of 0.03 mg/kg.

Metalaxyl-M residue levels complying with the estimated maximum residue level of 0.5 mg/kg would not exceed the current metalaxyl MRL of 1 mg/kg for peppers.

*Lettuce*

Metalaxyl-M is registered in Spain for use on lettuce at 0.10 kg ai/ha with a PHI of 14 days. The residue levels in lettuce were < 0.02 mg/kg in an Italian trial matching Spanish GAP. The residue levels in lettuce in four French trials matching Spanish GAP were: < 0.02 (two), 0.02 and 0.03 mg/kg.

Metalaxyl-M is registered in Germany for a maximum of two applications on lettuce at 0.097 kg ai/ha, with a PHI of 21 days. In six trials on head lettuce in Germany under conditions matching GAP, but with three applications instead of two, the residue levels were: < 0.02 (four), 0.02 and 0.03 mg/kg. In two German greenhouse trials at 0.10 kg ai/ha with harvest 21 days after the second application, the residue levels were < 0.02 and 0.41 mg/kg.

In two trials in The Netherlands matching German GAP, the residue levels were < 0.02 mg/kg.

Trials in Spain and Switzerland could not be evaluated because there was no matching GAP.

In summary, the residue levels in lettuce in the 15 trials, in ranked order, were: < 0.02 (10), 0.02 (two), 0.03 (two) and 0.41 mg/kg.

The Meeting estimated a maximum residue level for metalaxyl-M in head lettuce of 0.5 mg/kg and an STMR value of 0.02 mg/kg.

Metalaxyl-M residue levels complying with the estimated maximum residue level of 0.5 mg/kg would not exceed the current metalaxyl MRL of 2 mg/kg for head lettuce.

*Spinach*

Metalaxyl-M is registered in Switzerland for a maximum of six applications on spinach at 0.10 kg ai/ha with a PHI of 14 days. In three trials on spinach in Switzerland at 0.10 kg ai/ha and three at 0.14 kg ai/ha, with intervals before harvest of 10 or 14 days, the residue levels were all < 0.02 kg/ha. The levels were also < 0.02 mg/kg in two trials in Germany matching the conditions of GAP in Switzerland.

In a number of trials in France in which the application rate was 0.10 or 0.14 kg ai/ha, spinach was sampled for analysis 10 and 20 days after treatment. The Meeting noted that the residue levels generally changed slowly between 10 and 20 days post-treatment and decided to accept the residue levels at 10 days as sufficiently close to those expected at 14 days. The residue levels in the 10 French trials were: < 0.02 (two), 0.02 (four), 0.03, 0.04 (two) and 0.05 mg/kg.

In summary, metalaxyl-M residue levels in the 18 trials were < 0.02 (10), 0.02 (four), 0.03, 0.04 (two) and 0.05 mg/kg.

The Meeting estimated a maximum residue level for metalaxyl-M in spinach of 0.1 mg/kg and an STMR value of 0.02 mg/kg.

Metalaxyl-M residue levels complying with the estimated maximum residue level of 0.1 mg/kg would not exceed the current metalaxyl MRL of 2 mg/kg for spinach.

#### *Potato*

Labels were available from Algeria, Australia, Austria, Chile, Ecuador, Greece, Israel and Morocco from formulations for foliar application of metalaxyl-M to potatoes at 0.1–0.12 kg ai/ha. The information on GAP suggests that the recommended foliar application rate on potatoes is 0.1 kg ai/ha in many situations.

The results of supervised trials were available from Brazil (three at 0.1 kg ai/ha and three at 0.2 kg ai/ha), Germany (six at 0.1 kg ai/ha), Switzerland (three at 0.075 kg ai/ha) and the United Kingdom (four at 0.1 kg ai/ha). The residue levels in all 19 trials, measured at intervals of 0–28 days after the final treatment, were below the LOQ (0.02 mg/kg).

As residues were found in potato tubers in the metabolism studies after high application rates, the median residue values cannot be assumed to be nil. The Meeting estimated a maximum residue level for metalaxyl-M in potato of 0.02\* mg/kg and an STMR value of 0.02 mg/kg. Metalaxyl-M residue levels complying with the estimated maximum residue level of 0.02\* mg/kg would not exceed the current metalaxyl MRL of 0.05\* mg/kg for potato.

#### *Sunflower seed*

Metalaxyl-M is registered in China and Serbia and Montenegro for use as a seed treatment at 0.105 kg ai/100 kg sunflower seed. The Meeting agreed that the results of trials from other countries could be evaluated with respect to this seed treatment GAP.

In six trials in France and two in Spain, metalaxyl-M was used as seed treatment at a nominal rate of 105 g ai/100 kg seed (measured, 61–80 g ai/100 kg seed). The residue levels in harvested sunflower seed 125–151 days after sowing were all below the LOQ (0.01 and 0.02 mg/kg). Because of the long interval between sowing and harvest and the solubility of metalaxyl-M, residues would not be expected in harvested sunflower seed.

The Meeting estimated a maximum residue level for metalaxyl-M in sunflower seed of 0.02\* mg/kg and an STMR value of 0 mg/kg. Metalaxyl-M residue levels complying with the estimated maximum residue level of 0.02\* mg/kg would not exceed the current metalaxyl MRL of 0.05\* mg/kg for sunflower seed.

#### *Cacao beans*

Metalaxyl-M is registered in Côte d'Ivoire for use on cacao at 0.012 kg ai/ha. In eight trials in Côte d'Ivoire in which metalaxyl-M was applied as foliar treatment four times at 0.09 kg ai/ha (an exaggerated rate), with harvest 29–30 days after the final treatment, the residue levels in the cacao beans were: < 0.02 (four) and 0.02 (four) mg/kg. The cacao beans were fermented and dried before analysis. The Meeting agreed that the residue levels after application at the label rate would not exceed 0.02 mg/kg.

The Meeting estimated a maximum residue level for metalaxyl-M in cacao beans of 0.02 mg/kg and an STMR value of 0.02 mg/kg.

Metalaxyl-M residue levels complying with the estimated maximum residue level of 0.02 mg/kg would not exceed the current metalaxyl MRL of 0.2 mg/kg for cacao beans.

#### ***Fate of residues during processing***

The Meeting received information on the fate of metalaxyl-M residues during the production of fruit juices and vinification. The Meeting also received information that metalaxyl-M is hydrolytically stable under hydrolysis conditions that simulate those occurring during food processing.

The following processing factors were calculated from the data from the trials. The factors are mean values, excluding those calculated in cases of undetectable residues.

| Commodity | Processed product  | Processing factor | No. of trials |
|-----------|--------------------|-------------------|---------------|
| Orange    | Washed fruit       | 0.97              | 2             |
|           | Juice, pasteurized | 0.060             | 4             |
|           | Oil                | 9.0               | 4             |
|           | Pomace, wet        | 1.1               | 4             |
|           | Pomace, dry        | 4.1               | 4             |
|           | Peel               | 2.5               | 3             |
|           | Pulp               | 0.091             | 1             |
|           | Marmalade          | 0.39              | 4             |
| Grapes    | Juice              | 0.36              | 6             |
|           | Young wine         | 0.87              | 8             |
|           | Wine               | 0.66              | 13            |

The Meeting used the processing factors to estimate STMR-Ps for processed commodities. The processing factor for wine (0.66) was applied to the grape STMR (0.14 mg/kg) to calculate an STMR-P of 0.092 mg/kg for wine. The processing factor for grape juice (0.36) was applied to the grape STMR (0.14 mg/kg) to calculate an STMR-P of 0.050 mg/kg for grape juice.

### ***Residues in animal commodities***

#### ***Feeding studies***

The Meeting received the results of studies of feeding metalaxyl to lactating dairy cows and laying hens, which provided information on probable residue levels in tissues, milk and eggs from residues in animal feeds.

A group of three lactating dairy cows were dosed daily with metalaxyl, equivalent to 75 ppm in their diet, and were slaughtered for tissue collection on days 14, 21 and 28. Liver, kidney, fat and muscle were analysed by a dimethylaniline common moiety method. The residues were transitory and did not accumulate, and the interval between final dose and slaughter (4 and 23.5 h) influenced the residue levels more than the duration of dosing. The level of residue in milk was 0.02 mg/kg. The residue levels in the tissues collected on day 28 from the animal slaughtered 23.5 h after the final dose were 0.11 mg/kg in kidney, 0.12 mg/kg in liver, < 0.05 mg/kg in fat and 0.06–0.08 mg/kg in muscle.

Groups of 15 laying hens were dosed daily for 28 days with metalaxyl at levels equivalent to 10, 30 and 100 ppm in the feed. Tissue and egg samples were analysed by a dimethylaniline common moiety method. No residues appeared in the eggs (< 0.05 mg/kg) at any dose. The residue levels in the tissues of hens fed 10 ppm were generally below the LOQ (< 0.05 mg/kg) or, in a few cases, just above the LOQ.

#### ***Maximum residue levels***

The farm animal feeding studies suggest that residues would generally be undetected or transitory in meat, milk and eggs if metalaxyl was present in animal feeds.

Farm animals are therefore not exposed to residues in their feed from commodities in this evaluation, and no MRLs have been established for metalaxyl in animal commodities. Consequently, the Meeting agreed not to recommend animal commodity maximum residue levels.

## DIETARY RISK ASSESSMENT

### *Long-term intake*

Estimated Theoretical Maximum Daily Intakes for the five GEMS/Food regional diets, based on recommended MRLs for metalaxyl, were in the range of 2-10% of the ADI (Annex 3). The Meeting concluded that the long-term intake of residues of metalaxyl and metalaxyl-M resulting from their uses that have been considered by JMPR is unlikely to present a public health concern.

### *Short-term intake*

The 2002 JMPR decided that an ARfD is unnecessary. The Meeting therefore concluded that the short-term intake of metalaxyl and metalaxyl-M residues is unlikely to present a public health concern.

## 4.16 METHAMIDOPHOS

### RESIDUE AND ANALYTICAL ASPECTS

The 2003 JMPR evaluated supporting information on cucumbers and concluded that the residue data were insufficient to estimate maximum residue limits for acephate or for methamidophos arising from use of acephate. The Meeting noted that the report of the 2003 JMPR, while stating that the number of trials was inadequate for the purposes of estimating a maximum residue level for acephate on cucumber, made no recommendation with respect to the existing recommended maximum residue level for methamidophos arising from the use of acephate.

### *Recommendation*

The Meeting recommended that the MRL of 1 mg/kg for cucumber (CCN: VC0424) be withdrawn.

## 4.17 METHOMYL (094)

### RESIDUE AND ANALYTICAL ASPECTS

Data on methomyl residues were reviewed in 1975, and data from supervised field trials with various crops and related data were considered in 1976, 1978, 1986, 1991 and 2001. At its Thirty-sixth Session, the CCPR noted that new data on mint hay and pepper had been reported and decided to maintain the CXLs for these commodities for 4 years under the periodic review procedure. The evaluation was scheduled for 2004 (ALINORM 04/27/24, para. 124, p 15).

The 2004 Meeting received data on residues from supervised field trials on pepper and mint hay from the manufacturer. Information on labels and current GAP was also provided.

### *Methods of analysis*

The gas chromatographic method for measuring residues of methomyl in many plant commodities, evaluated by the 2001 JMPR, was validated for pepper and mint hay. This method consists of extraction with an organic solvent, liquid-liquid partition and hydrolysis with sodium hydroxide. The latter converts methomyl to methomyl oxime. The final extract is analysed by gas chromatography, usually with a flame photometric detector in the sulfur mode.

A more recent method is based on HPLC. The plant matrix is extracted with solvent, cleaned up on a Florisil column and analysed by HPLC with post-column reaction to convert methomyl to methylamine. Methylamine is derivatized (on-line) and detected by fluorescence.

The gas chromatographic method has been validated for numerous plant commodities at an LOQ of 0.02 mg/kg. The HPLC method and its modifications have been validated at an LOQ of 0.02 mg/kg for methomyl.

The Meeting concluded that adequate methods exist for the determination of methomyl in pepper and mint hay.

### ***Stability of residues in stored analytical samples***

As described by the 2001 JMPR, the stability of methomyl under frozen conditions has been demonstrated in a number crop samples, including broccoli, orange, apple and grape, for up to 24 months.

Data were presented on the stability of methomyl under frozen storage (–10 °C) in mint hay. Adequate stability (> 90% remaining) was demonstrated after 6 months' storage.

The Meeting concluded that methomyl is stable under frozen conditions on mint hay and pepper.

### ***Results of supervised trials on crops***

#### *Peppers*

Supervised trials were conducted on peppers in Canada (no GAP) and the USA (GAP: 1.0 kg ai/ha, 3-day PHI). Fifteen trials (one in Canada, 14 in the USA) were conducted at US GAP, with residue concentrations of 0.02, 0.03, 0.04 (two), 0.08 (two), 0.10 (two), 0.11 (two), 0.12, 0.18, 0.24, 0.26, 0.39 and 0.44 mg/kg.

Supervised trials on peppers were conducted in France (no GAP), Greece (GAP: 0.45 kg ai/ha, 15-day PHI), Italy (GAP: 0.04 kg ai/ha, 10-day PHI), Portugal (no GAP) and Spain (no GAP). In nine trials (two in France, three in Italy, one in Portugal and three in Spain) conducted at about Italian GAP, the ranked order of concentrations was: < 0.02 (five), 0.02 (two), 0.03 and 0.04 mg/kg. The data from southern Europe and the USA were considered to represent different populations. Using only the data from the USA (higher values), the Meeting estimated an STMR value of 0.105 mg/kg, a highest residue of 0.44 mg/kg and a maximum residue level of 0.7 mg/kg, which replaces the previous estimate (1 mg/kg).

#### *Mint hay*

Supervised trials were conducted on fresh mint hay in the USA (GAP: 1.0 kg ai/ha, 14-day PHI, maximum of four applications). In the six trials conducted at GAP, the ranked order of concentrations of residues in fresh and spent mint hay was: 0.02 (three), 0.07 (two), 0.13, 0.16, 0.17, and 0.28 mg/kg. The dry matter in fresh and spent mint is 88%. The Meeting estimated an STMR value of 0.08 mg/kg, a highest residue value of 0.32 mg/kg and a maximum residue level of 0.5 mg/kg for mint hay on a dry weight basis. The Meeting agreed to withdraw the previous recommendation (2 mg/kg) and to replace it with the recommendation for mint hay (0.5 mg/kg, dry weight).

### ***Residues in animal commodities***

As mint hay is not considered to be a significant feed item, establishment of an MRL for mint hay would not significantly change the dietary exposure of animals. The Meeting therefore decided not to revise the previous MRL recommendations for animal commodities (edible offal, meat, milk) on the basis of the addition of mint hay (fresh and spent).

## 4.18 OXYDEMETON METHYL (166)

### RESIDUE AND ANALYTICAL ASPECTS

Oxydemeton methyl was evaluated for residues by the 1998 JMPR within the CCPR periodic review programme and then for residues and toxicology by the JMPR in 1999 and 2002, respectively.

At its Thirty-first Session, the CCPR asked the JMPR to clarify whether demeton-S-methyl and demeton-S-methylsulfon should remain in the residue definition of oxydemeton methyl, as it was believed that registration of these compounds would not be retained. At its Thirty-second Session, the CCPR withdrew the draft MRLs for several commodities, as there was no existing GAP for them. The Committee advanced the proposed draft MRLs to Step 5 and returned the draft MRLs to Step 6 because of intake concerns, which would be considered at its next session. The Committee requested detailed information on oxydemeton methyl. The Committee discussed the residue definition that had been confirmed by the 1999 JMPR. It stated that, as demeton-S-methyl was no longer supported and there was no GAP, its use should be prevented by removing this compound from the residue definition. It was pointed out, however, that demeton-S-methyl could not be distinguished from oxydemeton methyl in analysis and that it could be generated from oxydemeton methyl during analysis. As no agreement was reached, the Committee agreed as a compromise to maintain the present residue definition but to specify that the residue definition and MRLs apply only to residues resulting from use of oxydemeton methyl. Those conditions would be met by adding a note to the residue definition, reading: "The residue definition and MRLs are based on the use of oxydemeton methyl only."

At its Thirty-third Session, the CCPR noted a written comment from the European Commission stating a general reservation (lack of an acute RfD) and a specific reservation on the MRLs for grape, lemon and oranges, sweet, sour (acute risk) and decided to return the draft MRLs to Step 6. The CCPR decided to return all the MRLs to Step 6 until calculations of short-term intake had been obtained from the JMPR. The Committee was informed by the manufacturer that data would be submitted to the 2004 JMPR for a review of the residue definition.

The Meeting received new data on physical and chemical properties (partially updated), analytical methods, fate of residues in processing, plant metabolism (apple), residue data (apples, pears, grapes, cabbage, Brussels sprouts, cauliflower, field peas, potatoes, sugar-beet, fodder beet, wheat, barley, rape and sunflower), GAP and national MRLs.

### **Metabolism**

#### *Plants*

The metabolism of [ethylene-1-<sup>14</sup>C]oxydemeton methyl in *apple* was investigated in the field. Apple trees were sprayed on two separate occasions about 4 months before harvest (pink bud stage, BBCH 57) and then about 3 months before harvest (flowers fading, BBCH 67). The formulated material was prepared at a nominal concentration of 1.4 g ai/l and applied at a nominal rate of 350 g ai/ha. Samples of fruit and leaves were taken for analysis 2 h after the first application (leaves only), 2 h after the second application (leaves only), about 60 days before harvest (first intermediate sample; fruit and leaves), about 30 days before harvest (second intermediate sample; fruit and leaves) and at harvest (fruit and leaves).

Analysis of fruit samples (flesh and peel) from the two intermediate samples showed the presence of oxydemeton methyl, but none was found at harvest. The two intermediate samples did, however, contain desmethyl-oxydemeton methyl sulfone (metabolite 7) and two polar materials (P2 and P3). In the first intermediate sample, polar radioactivity in the flesh accounted for 17% of the radioactivity in the fruit (0.2 mg/kg). In the second intermediate sample, polar radioactivity in the flesh had decreased to 10% of that in fruit (0.05 mg/kg), and by harvest no components were detected.



In the peel extracts, polar metabolites accounted for 3% of the radioactivity in the fruit (0.023 mg/kg) at the first intermediate sampling, and this had increased to 4% (0.026 mg/kg) by the second intermediate sampling. No components were detected at harvest.

The main metabolites detected at the first intermediate sampling time in both flesh and peel were oxydemeton methyl (26.6% fruit radioactivity, 0.245 mg/kg) and demeton-S-methylsulfone (2.9% fruit radioactivity, 0.026 mg/kg). In the second intermediate sample, oxydemeton methyl (1.7% fruit radioactivity, 0.012 mg/kg) and demeton-S-methylsulfone (0.2% fruit radioactivity, 0.001 mg/kg) were detected only in peel extracts. The main component detected in flesh extracts was an unidentified polar compound (14.1% radioactivity, 0.072 mg/kg). No components were detected at harvest in either flesh or peel extracts owing to the low levels of radioactivity in the extract samples ( $< 0.001$  mg/kg). The results of this study do not change the conclusions reached in the 1998 evaluation.

### ***Environmental fate***

#### ***Soil***

The aerobic degradation of oxydemeton methyl was studied in three soils for a maximum of 11 days under aerobic conditions in the dark at 20 °C. [ethylene-1- $^{14}\text{C}$ ]Oxydemeton methyl was applied at a nominal rate of 0.67 mg/kg dry soil, equivalent to the proposed single maximum annual use rate of 250 g ai/ha calculated for 2.5 cm depth of soil.

During the study, the total recovery of radioactivity in individual test vessels ranged from 90.8% to 100%, and the times to 50% and 90% decomposition ( $\text{DT}_{50}$  and  $\text{DT}_{90}$ ) in the three soils ranged from 0.17 to 0.22 and from 0.58 to 0.74 days, respectively. The results also indicate that the main metabolites were continuously degraded, that no metabolite accumulated towards the end of the study and that the bound residues participated in the natural carbon cycle of soil.

Analysis of soil extracts showed two major and one semi-major degradation product, representing 10% or more of the applied radioactivity at any time during the study. The concentration of the 2-ethylsulfinyl ethane sulfonic acid metabolite reached a maximum on day 1 and then declined gradually until day 11. Its concentration was below the LOQ towards the end of the study in soils with higher microbial activity. The 2-ethylsulfonyl ethane sulfonic acid metabolite is an oxidation product of 2-ethylsulfinyl ethane sulfonic acid, and its concentration reached a maximum on day 3 in all soils; it ranked highest, at 16.8% of the applied radioactivity. The level declined towards the end of the study in all soils, and in the most active soil to below the LOQ by day 11. Significant formation of bound residues occurred during overall metabolism of parent compound. The concentration of bound residues reached a maximum on day 11 at about 50% of the applied radioactivity. Soils showed high mineralization capacity, yielding values for  $^{14}\text{CO}_2$  of  $> 30\%$  by day 11. The results of study demonstrate that oxydemeton methyl is quickly degraded in aerobic soils.

#### ***Water–sediment systems***

The hydrolysis of oxydemeton methyl was studied in sterile 0.01 mol/l buffer solutions, which were adjusted to pH 4, 7 or 9, for a maximum of 31 days in the dark at two temperatures. The experiment was carried out in compliance with good laboratory practice (GLP) and in accordance with guidelines of the US Environmental Protection Agency, the Society of Environmental Toxicology and Chemistry, the OECD and the European Commission. The test solutions were prepared with [ethylene-1- $^{14}\text{C}$ ]oxydemeton methyl at a concentration of about 5 mg/l. The pre-test solutions were incubated for 7 days under sterile conditions in the dark at 50 °C. The solutions at pH 4 and pH 7 in the main test were incubated for a maximum of 31 days under sterile conditions in the dark at 25 °C.

In the pre-test at 50 °C and in the main test at 25 °C, oxydemeton methyl was not stable at pH 4, 7 or 9, and considerable degradation occurred. Especially at higher pH values, the compound was thoroughly hydrolysed to desmethyl-oxydemeton methyl and 2-ethylsulfinyl-ethyl mercaptan by cleavage of the P–S

bound. Furthermore, 2-ethylsulfonyl ethane sulfonic acid was observed as an oxidized P–S cleavage product at low percentages (maximum of 2.2% of the applied radioactivity), although it was identified only tentatively.

By calculation from the data obtained at 50 °C, orienting  $DT_{50}$  values (first order) for the hydrolysis of oxydemeton methyl were estimated to be 4.9, 3.5 and 0.2 days at pH 4, 7 and 9, respectively. Using the data obtained at 25 °C, the  $DT_{50}$  values (first order) were estimated to be 91, 42 and 2.5 days at pH 4, 7 and 9, respectively. At 20 °C, the  $DT_{50}$  values calculated from Arrhenius plots ( $1/T$  versus  $\ln(k)$ ) were 174, 73 and 4.5 days at pH 4, 7 and 9, respectively. The results indicate that hydrolytic processes contribute to the degradation of oxydemeton methyl in the environment.

The quantum yield from direct photodegradation of oxydemeton methyl in water was determined according to the European Centre for Ecotoxicology and Toxicology of Chemicals method in polychromatic light. The quantum yield calculated from the ultraviolet absorption data and the kinetics of photodegradation was 0.00078. The resulting quantum yield and data on ultraviolet absorption in aqueous solution were used to estimate the environmental half-life of oxydemeton methyl after direct photodegradation in water in two simulation models. The calculated half-lives were 112 days in summer and 274 days in winter at 30° latitude and 200 days in May) and 790 days in October at 50° latitude.

### ***Methods of analysis***

A number of methods have been developed for the analysis of residues of oxydemeton methyl in various matrices, many of which were reviewed by the 1998 Meeting as part of the periodic review of this compound. The Meeting was provided with additional methods based on the same principle as those evaluated earlier, i.e. use of the oxidation process to produce demeton-S-methylsulfone as the analyte. The LOQs were 0.005 mg/kg for potato; 0.005–0.01 mg/kg for apples and grapes; 0.01 mg/kg for pear, Brussels sprouts, cauliflower, cabbage, corn, sunflower, rape-seed and rape (green plant material); 0.02 mg/kg for wheat grain and 0.05 mg/kg for wheat straw.

### ***Stability of residues in stored analytical samples***

The stability of oxydemeton methyl in stored cabbage, maize, lettuce and papaya was evaluated by the 1998 JMPR, which concluded that data on the stability of stored analytical samples of raw agricultural commodities containing quantifiable residues of oxydemeton methyl were highly desirable. The available information was not representative of the various crop groups, did not cover extended storage intervals and suggested variable storage stability. The manufacture submitted new study data on the storage stability of oxydemeton methyl in several crops.

A study was conducted to determine the stability of oxydemeton methyl in spiked samples of stored apple, dried peas, potato and oil-seed rape (meal and oil at – 20 °C). Samples for the study were obtained from a commercial source. The samples of apple and potato were prepared for use by fine chopping in an industrial food processor; the preparation of samples of dried peas was not recorded in the report. For each crop, 20 g of prepared sample were spiked with formulated oxydemeton methyl at a nominal concentration of 0.1, 1.0 or 10 mg/kg and placed in storage at – 20 °C. Two samples of each were removed for analysis after 0, 3, 6, 12 and 24 months of storage. The analytical method was validated for each crop at each sampling time.

There was no substantial loss of residue during 24 months' storage from apple, potato or oil; however, the residues in dried peas and rape meal apparently decreased to half the initial values after 3 or 6 months of storage. The control samples (un-spiked samples) also showed residues of oxydemeton methyl, with < 0.005–0.022 mg/kg in apple, < 0.005–0.016 mg/kg in dried peas, < 0.01–0.016 mg/kg in potatoes, 0.013–0.03 mg/kg in rape meal and < 0.005–0.011 mg/kg in rape oil. The Meeting concluded that the data submitted on storage stability were insufficient or inadequate, and the former requirement was maintained.

***Definition of the residue***

The Meeting received the results of new studies of plant metabolism and supplementary information on the analytical method. The new data did not, however, provide a basis for changing the current residue definition. The Meeting confirmed its previous recommendation.

***Results of supervised trials on crops***

The results of supervised field trials on apples, pears, grapes, cabbage, Brussels sprouts, cauliflower, field peas, potatoes, sugar-beet, fodder beet, wheat, barley, rape and sunflower were submitted to the Meeting. The new data were evaluated against current GAPs, and highest residue levels were estimated for commodities evaluated by the 1998 JMPR, as the 1998 JMPR did not do so. When no residues were found in any sample in older trials in which the analytical methods used had higher LOQs than current methods, the Meeting decided to use only data from the newly submitted trials in order to avoid unnecessarily high maximum residue levels.

***Citrus fruit***

No data from new supervised trials were submitted. From 11 trials on *orange* and *lemon*, the 1998 JMPR estimated a maximum residue level of 0.2 mg/kg and an STMR of 0.01 mg/kg.

In the 1998 evaluations, the reported residues in pulp, in ranked order, were < 0.01 (seven), 0.01, 0.02 (two) and 0.04 mg/kg. The Meeting estimated a highest residue level of 0.04 mg/kg for orange and lemon.

***Pome fruit***

The results of 15 new supervised trials on apples and two on pears were submitted to the Meeting

One supervised trial on *apples* in northern France in 1998 involved higher doses than used in German GAP (0.13 kg ai/ha once, immediately after flowering). Nevertheless, the residue data could be used, since the residue levels were below the LOQ. Three supervised trials on apples in southern France in 1997 and 1998, three on apples in Italy in 1997 and 1998 and four on apples in Spain in 1997 and 1998 were conducted according to Italian GAP (0.023–0.028 kg ai/hl, 90-day PHI). As two of the four Spanish trials (conducted in 1997) were carried out in the same location under almost identical trial conditions, one residue level was taken from each. The residue levels of oxydemeton methyl in apples were < 0.01 (nine) and 0.01 mg/kg.

One supervised trial on *pears* in southern France in 1998 was conducted according to Italian GAP (0.023–0.028 kg ai/hl, 90-day PHI), and one trial on pears in Germany in 1998 was conducted according to Austrian GAP (0.024 kg ai/hl once, up to 2 weeks after flowering). The residue level of oxydemeton methyl in pears was < 0.01 (two) mg/kg.

The 1998 JMPR evaluated 10 supervised trials on apples and pears and estimated a maximum residue level of 0.05 mg/kg and an STMR of 0.01 mg/kg for apple and pear, based on residue levels, in ranked order, of < 0.01 (seven), 0.03 and < 0.04 (two) mg/kg.

The Meeting confirmed that the residue levels found in the newly submitted trials did not exceed the formerly estimated maximum and highest residue values of 0.04 mg/kg for apple and pear in the 1998 JMPR evaluations.

***Grape***

Three new supervised trials from Germany were conducted within German GAP (0.027 kg ai/hl, up to fully developed inflorescence). The residue levels were < 0.01 (three).

The 1998 JMPR evaluated the results of five supervised trials and estimated a maximum residue level of 0.1 mg/kg and an STMR of 0.04 mg/kg.

The Meeting confirmed that the residue levels found in the newly submitted trials did not exceed the formerly estimated maximum and highest residue values of 0.06 mg/kg for grapes in the 1998 JMPR evaluations. The residue levels, in ranked order, were < 0.04 (four) and 0.06 mg/kg.

#### *Brassica vegetables*

##### *Cabbage (head)*

The results of four new supervised trials were submitted to the Meeting.

Two supervised trials on red and white cabbage in northern France in 1996 and two supervised trials on Savoy cabbage in Germany were conducted according to German GAP (0.16 kg ai/ha (< 50 cm) once, 21-day PHI). The residue levels were < 0.01 (four) mg/kg.

The 1998 JMPR evaluated 16 supervised trials and estimated a maximum residue level of 0.05\* mg/kg and an STMR of 0.03 mg/kg. The highest value of < 0.06 mg/kg was disregarded because of the high LOQ in the older trials (1976).

The Meeting confirmed that the residue levels in the submitted trials did not exceed the formerly estimated maximum and highest residue values of 0.05 mg/kg in the 1998 JMPR evaluations. The residue levels, in ranked order, were < 0.01 (six), 0.02, < 0.03 (three), < 0.04 and < 0.05 (four) mg/kg.

##### *Kale*

No data from new supervised trials were submitted to the Meeting. Four supervised trials were evaluated by the 1998 JMPR, which estimated a maximum residue level of 0.01\* mg/kg and an STMR of 0.01 mg/kg.

On the basis of the reported residue level, < 0.01 (four) mg/kg, the Meeting estimated a highest residue level of 0.01 mg/kg.

##### *Kohlrabi*

No data from new supervised trials were submitted to the Meeting. Four supervised trials were evaluated by the 1998 JMPR, which recommended a maximum residue level of 0.05 mg/kg and an STMR of 0.02 mg/kg. The reported residue levels, in ranked order, were < 0.01 (two), 0.03 and < 0.06 mg/kg. The highest value was disregarded because of the high LOQ associated with the older trials (1979).

The Meeting estimated a highest residue level of 0.05 mg/kg, at the same level as the maximum residue level recommended by the 1998 JMPR.

##### *Brussels sprouts*

Five supervised trials conducted in Germany in 1997 and 1998, two conducted in Belgium in 1997 and 1998, one conducted in the United Kingdom in 1998 and one conducted in northern France in 1998 were submitted to the Meeting; however, no comparable GAP was submitted. The Meeting could not therefore estimate a maximum residue level, an STMR or a highest residue level.

##### *Cauliflower*

The results of eight new supervised trials were submitted to the Meeting. Two trials in Germany in 1996 were conducted according to German GAP (0.16 kg ai/ha (< 50 cm) once, 21-day PHI) and also according to Belgian GAP (0.15 kg ai/ha once, 28-day PHI).

Four supervised trials in southern France in 1996 and 1997 and one in the United Kingdom in 1996 were conducted according to German GAP. One of the trials in France in 1996 involved higher doses than in German GAP, but the residue data could be used for evaluation as the level was below the LOQ.

In all the trials the residue level was  $\leq 0.01$  (eight) mg/kg. The Meeting estimated a maximum residue level of 0.01\* mg/kg and STMR and highest residue values of 0.01 mg/kg for cauliflower.

*Field peas (dry)*

Data from two supervised trials on field peas were submitted to the Meeting, but no information on GAP was provided. The Meeting could therefore not estimate a maximum residue level, an STMR or a highest residue level.

*Potatoes*

The results of 20 supervised trials were submitted to the Meeting.

Two supervised trials in Germany in 1996 and one in the United Kingdom in 1996 were not matched by comparable GAP. Nine supervised trials in France in 1996 and 1998, one in Greece in 1998, three in Italy in 1997 and 1998 and four in Spain in 1997 and 1998 were conducted according to Greek GAP (0.05kg ai/hl three times, 28-day PHI). As two of four Spanish trials conducted in 1997 were carried out in the same location under similar trial conditions, one residue level was taken from each. The residue levels, in ranked order, were < 0.005 (five) and  $\leq 0.01$  (11) mg/kg.

The 1998 JMPR evaluated the results of 16 supervised trials and estimated a maximum residue level of 0.05\* mg/kg and an STMR of 0.02 mg/kg. The reported residue levels, in ranked order, were < 0.01 (seven), < 0.02 (nine) and < 0.05 (two) mg/kg.

The Meeting decided to use the data from the newly submitted trials and estimated a maximum residue level of 0.01\*mg/kg and STMR and highest residue values of 0.01 mg/kg to replace the former recommendations.

*Sugar-beet (root)*

The results of seven supervised trials on sugar-beet and two on fodder beet were submitted to the Meeting.

Three supervised trials on sugar-beet in Spain in 1997 and 1998 and four in Italy in 1997 and 1998 involved higher doses than in Spanish GAP (0.025 kg ai/hl, 30-day PHI) or Italian GAP (0.023–0.028 kg ai/hl, 30-day PHI); however, the residue data could be used for evaluation as all the levels in leaf and root were below the LOQ. As two of the three Spanish trials were conducted at the same location under the same trial conditions, one residue level was taken from each.

Two supervised trials on fodder beet in southern France in 1998 involved higher doses than in Spanish GAP (0.025 kg ai/hl, 30-day PHI), but the residue data could be used for evaluation as all the levels in leaf and root were below the LOQ. Six trials on sugar-beet and two on fodder beet could be evaluated together, as all the residue levels were  $\leq 0.01$  (eight) mg/kg.

The 1998 JMPR evaluated seven supervised trials on sugar-beet and two on fodder beet in Germany, and estimated a maximum residue level of 0.05\* mg/kg and an STMR of 0.04 mg/kg. The reported residue levels, in ranked order, were < 0.01 (four) and < 0.04 (five) mg/kg.

The Meeting decided to use the data from the newly submitted trials and estimated a maximum residue level of 0.01\*mg/kg and an STMR of 0.01 mg/kg, to replace the former recommendations.

*Wheat, barley and rye*

Eleven supervised trials on wheat and two on barley were submitted to the Meeting.

Four supervised trials on wheat in Italy in 1997 and 1998, six in southern France in 1997 and 1998 and one in Spain in 1998 involved higher doses than in Italian GAP (0.023–0.028 kg ai/hl, 30-day PHI), but the data on residues on wheat grain could be used for evaluation as all the levels were below the LOQ. The residue levels, in ranked order, were < 0.01 (six) and < 0.02 (five) mg/kg.

Two supervised trials on barley in southern France in 1997 and 1998 involved slightly higher doses than in the Italian GAP for wheat. The Meeting concluded that this GAP could be applied to trials on barley, as the two crops are cultivated similarly. The residue levels were < 0.01 (two) mg/kg.

The 1998 JMPR evaluated seven supervised trials on wheat and three on barley and estimated a maximum residue level of 0.05\* mg/kg and an STMR of 0.04 mg/kg. The reported residue levels, in ranked order, were < 0.04 (seven) and < 0.05 (three) mg/kg.

The Meeting decided to use the data from the newly submitted trials to estimate the maximum residue level. The combined residue levels, in ranked order, were ≤ 0.01 (eight) and < 0.02 (five) mg/kg. The Meeting estimated a maximum residue level of 0.02\*mg/kg and an STMR of 0.01 mg/kg, to replace the former recommendations.

#### *Rape-seed*

One supervised trial on rape was submitted to the Meeting; however, no information on GAP was provided. The Meeting could therefore not estimate a maximum residue level, an STMR or a highest residue level.

#### *Sunflower seed*

Six supervised trial data on sunflower were submitted to the Meeting; however, no information on GAP was provided. The Meeting could therefore not estimate a maximum residue level, an STMR or a highest residue level.

#### *Sugar-beet (tops)*

The residue levels in the leaves of sugar-beets and fodder beets treated according to GAP, in ranked order, were ≤ 0.01 (five) and < 0.04 (three) mg/kg. The Meeting estimated a maximum residue level of 0.05 mg/kg, an STMR of 0.01 mg/kg and a highest residue level of 0.04 mg/kg, to replace the former recommendations.

#### *Wheat, barley and rye straw and fodder*

The residue levels in straw and fodder from wheat and barley, in ranked order, were ≤ 0.04 (eight), < 0.05 (three) and 0.06 mg/kg. The Meeting estimated a maximum residue level of 0.1 mg/kg, an STMR of 0.04 mg/kg and a highest residue level of 0.06 mg/kg, to replace the former recommendations.

### ***Fate of residues during processing***

The results of studies on residues in processed peas were provided to the Meeting. The samples were fortified with diluted oxydemeton methyl formulation by soaking because the levels of residue in samples produced under GAP conditions were expected to be too low. The reported processing factors were 0.034 for processed marrowfat peas (canning), 0.024 for vining peas (canning), 0.43 for vining peas (freezing) and 0.43 for vining peas (freezing and domestic cooking).

### ***Residues in animal commodities***

The 1998 JMPR, estimated the dietary burden of farm animals and concluded that quantifiable residues of demeton-S-methyl, oxydemeton methyl or demeton-S-methylsulfone are unlikely to occur in commodities of animal origin (meat, milk, poultry and egg). Therefore, MRLs could be set at the practical LOQ of 0.05\* mg/kg for all commodities except milk and at 0.01\* mg/kg for milk. The current Meeting did not recommend the addition of further feed items or an increase in the recommended residue levels. It therefore confirmed the previous maximum residue levels and STMRs for commodities of animal origin and

estimated a highest residue level of 0 mg/kg for cattle fat, eggs, meat of cattle, pigs and sheep, pig fat, poultry fats, poultry meat and sheep fat.

### ***Further work or information***

#### ***Desirable***

Data on the stability of stored analytical samples of raw agricultural commodities containing quantifiable residues of oxydemeton methyl are highly desirable, as the information provided was not representative of the various crop groups, did not cover extended storage and suggested variable storage stability.

## **DIETARY RISK ASSESSMENT**

### ***Long-term intake***

STMR or STMR-P values were estimated by the 1998 JMPR and by the present Meeting for 27 commodities. When data on consumption were available, these values were used in the estimates of dietary intake.

The dietary intake from the five GEMS/Food regional diets, on the basis of the STMR values, represented 3–30% of ADI (Annex 3). The Meeting concluded that the intake of residues of oxydemeton methyl resulting from uses that have been considered by the JMPR is unlikely to present a public health concern.

### ***Short-term intake***

The IESTI for oxydemeton methyl was calculated for the commodities for which maximum residue levels, STMR values and highest residue levels were established and for which data on consumption (of large portions and unit weight) were available. The results are shown in Annex 4.

The ARfD for oxydemeton methyl is 0.002 mg/kg bw. The IESTI represented 0–220% of the ARfD for children and 0–90% of that for the general population. For children, 100% of the ARfD was exceeded in apple (130%), cabbage (120%), grape (220%) and orange (120%).

The Meeting concluded that the short-term intake of residues of oxydemeton methyl from uses on commodities other than apples, cabbages, grapes and oranges that have been considered by the JMPR is unlikely to present a public health concern.

## **4.19 PARAQUAT (057)**

### **RESIDUE AND ANALYTICAL ASPECTS**

Paraquat, a non-selective contact herbicide, was first evaluated by the JMPR for toxicology and residues in 1970. Subsequently, it was reviewed for toxicology in 1972, 1976, 1982, 1985 and 1986 and for residues in 1972, 1976, 1978 and 1981. The Meeting reviewed paraquat toxicologically within the periodic review programme in 2003 and established an ADI of 0–0.005 mg/kg bw and an ARfD of 0.006 mg/kg bw as

paraquat cation. Currently, there are 22 Codex MRLs for plant commodities, their derived products and animal commodities.

The CCPR at its Thirty-second Session identified paraquat as a priority for periodic review by the 2002 JMPR, but residue evaluation was postponed to the present Meeting.

Paraquat is usually available in the form of paraquat dichloride or paraquat bis(methylsulfate). The Meeting received data on metabolism, environmental fate, analytical methods, storage stability, supervised field trials, processing and use patterns.

## **Metabolism**

### *Animals*

The WHO Expert Group of the 2003 JMPR reviewed studies on the excretion balance of paraquat in *rats* given a single dose of 1 or 50 mg/kg bw [1,1'-<sup>14</sup>C-dimethyl]paraquat dichloride or 14 daily doses of 1 mg/kg bw unlabelled paraquat dichloride followed by 1 mg/kg bw of the labelled compound. They also evaluated studies of the biotransformation of paraquat in *rats* given the same doses of radiolabelled paraquat and other studies of metabolism and toxicity in *rats*. They concluded that orally administered paraquat is not well absorbed. Excretion was rapid, with 60–70% in faeces and 10–20% in urine; 90% was excreted within 72 h. Paraquat was eliminated largely unchanged: 90–95% of radiolabelled paraquat in urine was identified as the parent compound.

When 23 mg/kg [1,1'-<sup>14</sup>C-dimethyl]paraquat dichloride were administered through a rumen fistula to one *sheep*, all the administered radiolabel was excreted within 10 days in urine (4%) and faeces (96%), indicating that residues of orally administered paraquat would not remain or accumulate in *sheep* tissues. Most of the radiolabel in urine and faeces was attributed to unchanged paraquat and 2–3% to paraquat monopyridone. Less than 1% 4-carboxy-1-methylpyridinium ion, paraquat dipyridone and monoquat were found.

When 0.92 mg/kg [1,1'-<sup>14</sup>C-dimethyl]paraquat dichloride was administered subcutaneously to a *sheep*, paraquat was again excreted rapidly. Over 80% of the administered radioactivity was excreted in urine, 69% 1 day after treatment. Unchanged paraquat accounted for most of the radiolabel. The monopyridone was present at 2–3% and monoquat as a trace metabolite. The excretion patterns in the two *sheep* were virtually identical, regardless of the route of administration.

A *pig* weighing about 40 kg was fed twice daily with a diet containing [1,1'-<sup>14</sup>C-dimethyl]paraquat ion at a rate equivalent to 50 mg/kg for 7 days. At sacrifice, 69% of the administered radiolabel had been excreted in faeces and 3.4% in urine; 13% was present in the stomach contents and viscera. All the radiolabel found in tissues, except in liver, was attributed to paraquat. About 70% of the radiolabel in the liver was identified as paraquat, with 7% as monoquat ion and about 0.6% as monopyridone ion. This result indicates that there is no significant metabolism of paraquat in *pigs*.

In a similar study, a *pig* was fed a diet containing [2,2',6,6'-<sup>14</sup>C]paraquat ion at a rate equivalent to 50 mg/kg for 7 days. At sacrifice, 72.5% of the administered radiolabel had been excreted in faeces and 2.8% in urine. In the liver, about 70% of the radiolabel was identified as paraquat and 4% as monoquat ion.

A *Fresian cow* weighing 475 kg given a single dose of about 8 mg/kg [1,1'-<sup>14</sup>C-dimethyl]paraquat dichloride from a balling gun excreted 95.6% of the administered radioactivity in faeces within 9 days; 89% was excreted within the first 3 days. Analysis indicated that 97–99% of the radioactivity in 1–4-day faeces and 100% of that in 5–6-day faeces co-chromatographed with paraquat. A total of 0.7% of the administered dose was excreted in urine, 80% of which was excreted within the first 2 days. Paraquat accounted for 90% of the radiolabel in urine on day 1, 70% on day 3 and 62% on day 5. The remaining activity was attributed to paraquat monopyridone and monoquat. Only 0.0032% of the administered radiolabel was recovered from milk within 9 days. The traces of radioactivity in milk (a maximum of 0.005 mg/l as paraquat ion equivalent



milk taken in the morning of day 2) were attributed mainly to paraquat and its monopyridone and to a naturally occurring compound which appeared to be lactose. The residue level of any one compound in milk was  $\leq 0.002$  mg/kg.

When a lactating *goat* was dosed with  $[2,2',6,6'-^{14}\text{C}]$ paraquat dichloride twice daily at each milking for 7 days at a total daily rate equivalent to approximately 100 mg/kg in the diet, 50.3% of the administered radioactivity was excreted in faeces, 2.4% in urine and 33.2% in stomach contents by the time of sacrifice. The total radioactivity, expressed in paraquat ion equivalents, in milk increased during the experimental period, reaching a maximum of 0.0092 mg/kg (equivalent to 0.003% of the daily dose) 4 h before slaughter. Of this radioactivity, 75.7% was attributed to paraquat, and 15.8% did not show a cationic character. There appeared to be no significant metabolism of paraquat in any tissue, except liver and peritoneal fat, where about half the radiolabel was attributed to paraquat, < 5% as monopyridone ion and 5% as monoquat ion.

Warren laying *hens* given  $[2,2',6,6'-^{14}\text{C}]$ paraquat ion in gelatin capsules at a rate equivalent to 30 mg/kg normal diet for 10 days had excreted 99% of the administered radiolabel in faeces at the time of sacrifice; 96.6% of the radiolabel was attributed to unchanged paraquat. The amount of radiolabel in egg albumen did not exceed 0.0014 mg/kg in paraquat ion equivalents throughout the experimental period, while that in the yolk was < 0.001 mg/kg on day 1 and increased gradually to 0.18 mg/kg (in one bird) on day 8. All the radiolabel in yolk was identified as paraquat.

The studies on the fate of orally administered paraquat show that most is excreted unchanged, mainly in faeces and to a much smaller extent in urine. Excretion of paraquat was rapid in all the species studied, hens showing the most efficient excretion. Little paraquat was absorbed from the gastrointestinal tract, and the small amount absorbed was not significantly metabolized. Less than 0.05 mg/kg of paraquat was found in muscle, milk and eggs, even at the high dose rates used in these studies. These findings indicate that no significant bioaccumulation of paraquat is expected to occur in these species.

The metabolism of paraquat in these species was similar. Four metabolites were identified: monoquat, paraquat monopyridone, 4-carboxy-1-methylpyridinium ion and paraquat dipyridone. In all tissues except liver of all the species tested and in goat peritoneal fat, 80–100% of the total radiolabel was attributable to the parent compound, paraquat. In liver and goat peritoneal fat, 50–80% of the radiolabel was associated with paraquat, and absorbed paraquat was metabolized to monoquat and paraquat monopyridone and to a much smaller extent to 4-carboxy-1-methylpyridinium ion. The metabolism of paraquat involves oxygenation of one pyridine ring to form paraquat monopyridone and desmethylation of one pyridine ring to form monoquat. Cleavage of the pyridine–pyridine linkage produces 4-carboxy-1-methylpyridinium ion. The other *N*-methylpyridine moiety would produce carbon dioxide and methylamine.

### Plants

When paraquat is used as a directed spray before sowing, before planting, before emergence and after emergence, it is present in soil as residues, but no direct contact occurs with crops. Sandy loam soil in pots in which *lettuce* and *carrots* were sown was sprayed with  $[\text{U-}^{14}\text{C-bipyridyl}]$ paraquat ion immediately after sowing at rates equivalent to 14.3 kg ai/ha for lettuce and 14.7 kg ai/ha for carrots, which are 13 times the highest current application rates for those crops, and maintained in a greenhouse. The radiolabel in mature lettuce and carrots harvested 65 and 96 days after treatment represented 0.0034 and 0.0048 mg/kg in paraquat ion equivalents, respectively. This result confirms the lack of significant translocation of residues of paraquat from treated soil to lettuce leaves or carrot roots.

Paraquat is also used as a crop desiccant and harvest aid, when it is in direct contact with crops. The foliage of *potatoes* and *soya beans* growing in pots in a greenhouse was treated with  $^{14}\text{C}$ -paraquat at rates equivalent to 8.7 or 8.8 kg ai/ha (potato) and 8.2 kg ai/ha (soya beans), 14–16 times the highest current use for desiccation on potato and soya beans. The average TRR, expressed in paraquat ion equivalents, in soya and potato plants harvested 4 days after treatment were 638 mg/kg in soya foliage, 0.747 mg/kg in soya beans and 0.082 mg/kg in potato tuber. In all the samples, 89–94% of the TRR was identified as paraquat. The rest of the radioactive residue consisted of two or three fractions, none of which exceeded 10% of the respective

TRR. In soya foliage extracts, small amounts of 4-carboxy-1-methylpyridinium ion (0.3% TRR) and monoquat (0.3 % TRR) were found. The latter is a known photodegradation product of paraquat.

As paraquat is strongly adsorbed by soil (see above), its uptake by plants after pre-emergence or post-emergence directed use is insignificant, even at exaggerated application rates. When paraquat was applied as a desiccant to potato and soya bean at a rate > 10 times the highest recommended application rate, with a 4-day PHI, the main component in potato tuber, soya beans and soya foliage was paraquat. In soya foliage, monoquat and 4-carboxy-1-methylpyridinium ion were also found. Although the latter is a known photodegradation product and was not found in soya beans or potato tuber, biotransformation cannot be excluded because the TRR was too low for reliable identification. As the fate of paraquat in soya foliage appears to involve photodegradation, its fate is considered to be common among plants.

The metabolism of paraquat involves desmethylation of one pyridine ring to form monoquat. 4-Carboxy-1-methylpyridinium ion appears to be produced by photolysis of monoquat, with breakdown of the pyridine–pyridine linkage, but involvement of biotransformation cannot be excluded. Paraquat monopyridone and dipyridone, which are found in animals, were not found in plants even at much higher than normal application rates. The transformation of paraquat in plants is similar to its metabolism in animals.

### **Environmental fate**

#### *Soil*

Paraquat was applied to slurries of loam, loamy sand, silty clay loam or coarse sand in 0.01 mol/l aqueous calcium chloride at rates higher than normal, to give 0.01 mg/l in the equilibrium solution after a 16-h equilibration. The calculated adsorption coefficients ranged from 480 in the coarse sand to 50 000 in the loam. At normal application rates, the concentration of paraquat in the equilibrium solution could not be determined (< 0.0075 mg/l). No significant desorption was observed.

A field survey of 242 agricultural soils in Denmark, Germany, Greece, Italy, The Netherlands and the United Kingdom showed that paraquat was strongly adsorbed to all the soil types studied. The adsorption coefficients calculated at application rates much higher than normal ranged from 980 to 400 000, and those adjusted for the organic carbon content of soil were 8400–40 000 000. Adsorption coefficients could not be calculated at normal application rates because the concentration in equilibrium solution was below the limit of determination (0.01 mg/l). On the McCall scale, paraquat was classified as ‘immobile’ in all these soils, without leaching.

[2,6-<sup>14</sup>C]Paraquat was applied to sandy loam soil in pots at a nominal rate of 1.05 kg/ha and incubated in the dark at 20 ± 2 °C under aerobic conditions in order to study the aerobic degradation of paraquat. After 180 days of incubation, paraquat accounted for > 93% of the applied radiocarbon, with no detected degradation products. Less than 0.1% of the applied radioactivity evolved as <sup>14</sup>CO<sub>2</sub> over the 180-day incubation period. The half-life of paraquat in soil under aerobic conditions could not be estimated, although a long half-life in soil was implied by the results of the study.

In long-term field dissipation studies conducted on cropped plots in Australia, Malaysia, The Netherlands, Thailand, the United Kingdom and the USA, the location had no major effect on the field dissipation rate. Generally, paraquat residue levels had declined to about 50% 10–20 years after the start of the studies. This implies a DT<sub>50</sub> of 10–20 years after application of single, large doses of paraquat to soil. The DT<sub>90</sub> could not be estimated in these studies, however, as the experimental periods were too short.

Conventional laboratory studies could not provide useful information on the route or rate of degradation of paraquat in soil because of its strong adsorption to soil minerals and organic matter. In order to obtain information, microbiological degradation studies were conducted with microorganisms isolated from soil. The most effective soil organism for decomposing paraquat was a yeast species, *Lipomyces starkeyi*. When incubated with radiolabelled paraquat, the yeast culture or cultures originating from two sandy loam soils decomposed most of the paraquat, released CO<sub>2</sub> and formed oxalic acid at 24–25 °C.

An unidentified bacterium isolated from soil metabolized [1,1'-<sup>14</sup>C]paraquat to monoquat and 4-carboxy-1-methylpyridinium ion. Extracts of *Achromobacter* D were found to produce CO<sub>2</sub>, methylamine, succinate and formate as metabolites of 4-carboxy-1-methylpyridinium ion. The results showed that the CO<sub>2</sub> originated from a carboxyl group, methylamine from the *N*-methyl group and the carbon skeletons of formate and succinate from the C-2 and C-3–C-6 atoms of the pyridine ring, respectively. These results indicate that the pyridine ring is split between C-2 and C-3.

The degradation rate of paraquat in soil was determined by cultivating 10 mg/kg [U-<sup>14</sup>C-dipyridyl]paraquat with *Lipomyces* and mixed cultures derived from two soils. The degradation of paraquat was rapid, with a DT<sub>50</sub> between 0.02 and 1.3 days after a lag phase of about 2 days, accompanied by rapid mineralization to CO<sub>2</sub> and the formation of several unidentified minor polar metabolites.

The photolysis of [2,2',6,6'-<sup>14</sup>C]-paraquat was studied by applying it to the surface of a highly sandy soil which was exposed to natural sunlight. The proportion of paraquat in samples declined during 85 weeks, at which time paraquat represented 86.6–89.5% of the total radiolabel found in unmixed and mixed soil samples. Thin-layer chromatographic analysis of the 6 mol/l HCl extracts of mixed and unmixed soils contained monoquat ion, paraquat monopyridone ion and an uncharacterized compound, which accounted for 1.4–2.4%, 1.2–1.3% and 1.8–2.4%, respectively, of the total radioactivity after 85 weeks. Photodegradation on the soil surface is not considered to be a major environmental degradation process for paraquat.

#### *Water–sediment systems*

Aqueous photolysis of paraquat was examined by maintaining ring-labelled paraquat in sterilized 0.01 mol/l phosphate buffer solution (28 mg/l) at 25 °C under light. After 36 days of irradiation simulating summer sunlight in Florida (USA), most of the recovered radioactivity was attributed to paraquat, with 0.13% as CO<sub>2</sub> and no photodegradation products. When solutions of radiolabelled paraquat were exposed to unfiltered ultraviolet light, no paraquat remained after 3 days, with formation of CO<sub>2</sub>, methylamine and 4-carboxy-1-methylpyridinium ion; the last metabolite further degraded to CO<sub>2</sub> and methylamine. These results indicate that, while paraquat appears to be stable to photolysis at pH 7, it readily degrades into CO<sub>2</sub> and methylamine when exposed to unfiltered ultraviolet light.

[U-<sup>14</sup>C-dipyridyl]Paraquat in deionized water was applied to the water surface of two continuously aerated sediment–water systems at a rate equivalent to 1.1 kg ai/ha. Paraquat was strongly adsorbed to the sediment in both systems, even immediately after treatment. After 100 days of incubation, 0.1–0.2% of the applied radioactivity was found in the aqueous phase, 92.9–94.9% in extracts from sediment fractions and 4.2–4.5% in unextracted sediment fractions. Most of the radiolabel recovered from the aqueous phase and sediment extract was attributed to paraquat, while no degradation products were detected. The DT<sub>50</sub> or the DT<sub>90</sub> could not be estimated as no significant degradation of paraquat was observed during the experimental period.

#### *Residues in succeeding crops*

Seeds of wheat, lettuce and carrot were sown into individual pots containing a sandy loam soil 0, 30, 120 and 360 days after treatment of the soil with [2,2',6,6'-<sup>14</sup>C]paraquat at an application rate equivalent to 1.05 kg ai/ha, and were maintained in a glasshouse until maturity. Over the course of the study, the TRR in soil represented an average of 99.2% of the applied radioactivity. <sup>14</sup>C-Paraquat accounted for 72.7–99.3% of the TRR in soil extracts and no other radioactive compounds were detected in any soil sample. Radioactive residues, expressed in paraquat ion equivalents per kilogram, were below the LOQ in most crop samples sown 0, 30 and 120 days after treatment. The highest radioactive residue level, 0.009 mg/kg in paraquat ion equivalents, was found in wheat straw sown 30 days after treatment.

Seeds of lettuce and carrot were sown in pots containing sandy loam soil, and the soil was treated immediately afterwards with [U-<sup>14</sup>C-dipyridyl]paraquat at exaggerated rates of 14.3 and 14.7 kg/ha respectively, corresponding to approximately 13 times the highest current application rate. The lettuce was harvested 65 days after treatment and the carrots 96 days after treatment. The levels of radioactive residues in

lettuce leaf and carrot root at harvest were 0.0034 and 0.0048 mg/kg in paraquat ion equivalents, respectively. There is therefore no significant uptake of paraquat into rotational crops, even when the soil is treated at exaggerated rates.

### ***Methods of analysis***

With the long history of registration of paraquat in many countries, many analytical methods have been developed and used for measuring residues in plant and animal commodities. All the methods provided to the Meeting were for analysis of paraquat only. Some analytical methods allow separate determination of paraquat and diquat in a sample.

#### ***Samples of plant origin***

Six analytical methods for the determination of paraquat in plant commodities and oil and oil cake were submitted.

Three of the methods involve extraction of paraquat by refluxing homogenized or comminuted samples in 0.5 mol/l sulfuric acid for 5 h; filtration, cation-exchange chromatography from which paraquat is eluted with saturated ammonium chloride, conversion of paraquat to its coloured free radical with 0.2% (w/v) sodium dithionite in 0.3 mol/l NaOH and spectrophotometric measurement. The methods differ only in the spectrophotometric measures used: absorption of the free radical in the range 360–430 nm measured against a control solution or absorption in the range of 380–430 nm measured in second derivative mode against a paraquat standard.

In the most recent method, the eluate from cation-exchange chromatography is further cleaned up on a C18 SepPak solid phase extraction cartridge, and the second 5-ml eluate is analysed by reverse-phase ion-pair HPLC with ultraviolet detection at 258 nm.

Two other methods developed for the determination of paraquat in liquid samples, such as oil, also involve second derivative spectrophotometry (360–430 nm), but they do not involve extraction with sulfuric acid. Reverse-phase ion-pair HPLC is also used as the confirmatory method.

All these methods were validated in one or several laboratories for vegetables and fruits, cereal grains and seed, grass and straw, sugar-cane juice, oil seeds, oil and oil cake. The LOQ of these methods ranged from 0.01 to 0.05 mg/kg, except for oil cake, for which the LOQ was 0.5 mg/kg. The mean procedural recoveries were 61–107% at fortification rates reflecting both the LOQ and the actual levels of incurred residues. In general, lower recoveries were made from oil and oil cake. The mean recovery from rape-seed oil cake and olive oil was 67% and that from coffee beans was 61%; those from other commodities were > 70%. The relative standard deviation of recoveries ranged from 2% to 19%.

#### ***Samples of animal origin***

Three analytical methods for the determination of paraquat in animal products were submitted.

Two methods, including the most recent, for determining paraquat in milk, eggs and animal tissues involve extraction of paraquat by homogenizing samples in 10% trichloroacetic acid, centrifugation, dilution with water, application to a cation-exchange column, sequential washing, elution of paraquat with saturated ammonium chloride, determination by reverse-phase ion-pair HPLC with ultraviolet detection at 258 nm. Fat in milk, skin with subcutaneous fat and fat samples must be removed by hexane extraction before cation exchange.

A method for analysing liquid samples, including milk, does not involve acid extraction or defatting, and milk is mixed directly with cation exchange resin before packing. Otherwise, this method is the same as those described above.

The LOQs were reported to be 0.005 mg/kg for milk, eggs and bovine, ovine and chicken tissues. The mean procedural recoveries were 75–105%, with a relative standard deviation of 2–13%.

The currently used methods for plant and animal samples were found to be suitable for quantification of paraquat in plant and animal commodities for enforcement purposes. The methods are fully validated and include confirmatory techniques. The earlier methods for quantification of paraquat in plant and animal samples were also found to be suitable in validation; however, a mean recovery < 70% was seen for rape-seed cake, olive oil and coffee beans analysed by one of the methods.

### ***Stability of residues in stored analytical samples***

Investigations were reported of the stability of residues in ground samples of prunes, banana, cabbage, potato, carrot, tomato, maize (grain, forage, fodder and silage), wheat grain, coffee beans, birdsfoot trefoil (forage and hay), meat, milk and eggs stored in a deep freezer at a temperature < -15 °C for 1–4 years.

No decrease in residue levels of paraquat, whether fortified or incurred, was observed in any of the crop matrices during the test period, the longest being 46 months. The exception was a slight decrease in birdsfoot trefoil forage that had been treated at a rate equivalent to 0.54 kg ai/ha and contained incurred residues at 57 mg/kg.

No decrease in the levels of residues of paraquat in animal commodity matrices over time was observed under storage for up to 28 months. The test matrices represented a diverse selection of animal tissues, and the studies demonstrate the stability of paraquat under various storage conditions.

### ***Definition of the residue***

Paraquat is usually available as the dichloride salt or the bis(methylsulfate) salt but is determined as paraquat ion in analysis. Paraquat is known to adsorb strongly to soil, and most of the small amount incorporated into plant remains as paraquat (90%). Its metabolites were not found when paraquat was applied at normal rates. When it was applied post-emergence, most of the applied compound remained, with minimal amounts of photodegradation products, indicating the involvement of photolysis in the transformation of paraquat. The residue of concern in plants is paraquat ion.

In studies of metabolism in rats, cattle, goats, pigs and hens, the metabolic pathway was similar, producing minor levels of oxidized metabolites. The metabolic pathways in animals and plants are similar. In animals, the residue of concern is also paraquat ion.

The definition of the residue in all countries that provided national MRLs to the Meeting was paraquat ion.

All the identified metabolites have been covered by toxicological evaluations, owing either to their occurrence in rats or in independent studies. The ADI recommended by the JMPR is for paraquat cation.

The Meeting therefore agreed that the definition of residues for plant and animal commodities should be: Paraquat cation (for both compliance with MRLs and estimation of dietary intake).

### ***Results of supervised trials on crops***

When used for weed control, paraquat is not sprayed directly onto crops and is strongly adsorbed to soil. Therefore, little paraquat is expected to be found in harvested crops. After pre-emergence application, no residues were expected to be detected in the harvested crops, although some samples contained residues. After use as a harvest aid desiccant, however, paraquat is in direct contact with crops, and the residue levels tend to be much higher than when it is used for weed control.

The Meeting agreed that data from trials of pre-plant and pre-emergence application should be evaluated against any GAP available to the Meeting, regardless of the country or region; while data on trials of post-emergence application and harvest aid desiccation should be evaluated against GAP of the country in which the trials were conducted or of a neighbouring country.

As degradation of paraquat on the surface of crops appears to involve photolysis, residue levels are expected to be similar in all crops, justifying estimation of group MRLs for paraquat.

For estimating STMR from the results of two or more sets of trials with different LOQs in which no residues exceeding the LOQs are reported, the lowest LOQ should be used, as stated in the 2002 *FAO Manual*, unless the residue level can be assumed to be essentially zero. The size of the trial database supporting the lowest LOQ was taken into account in making decisions in these cases.

Since maximum residue levels were estimated for a number of vegetable groups in which the levels were below the LOQ, the Meeting decided to withdraw the previous recommendation for vegetables (except as otherwise listed) of 0.05 \* mg/kg.

In Germany, information is required on the possible contamination of fruits that have fallen onto ground treated with pesticides. Therefore, tests were carried out on apples, stone fruits, grapes and olives to simulate the residue situation in fruit used for juice and other processed products. Nevertheless, direct consumption of fruit picked up from the ground is regarded as inappropriate.

#### *Citrus fruit*

Numerous supervised residue trials have been carried out over several seasons and in several locations on orange in Italy and in California and Florida, USA, and on lime, lemon and grapefruit in Florida.

Paraquat is registered for the control of weeds around the base of citrus fruit trees at a maximum rate of 1 kg ai/ha as an inter-row spray, with no PHI, in Italy and at a maximum rate of 1.14 kg ai/ha as a directed spray, with no PHI, in the USA. The residue levels of paraquat in whole mature *oranges* in trials in Italy and the USA were below the LOQs of 0.01, 0.02 or 0.05 mg/kg, even when paraquat was applied at twice or 30 times the maximum application rate, except in two trials. In one trial with an application rate of 2.44 kg ai/ha, mature fruit from one plot contained paraquat residues at a level of 0.01 mg/kg. In a trial with an application rate of 1.12 kg ai/ha, residue levels of 0.06 and 0.08 mg/kg were found in whole fruit. In this trial, however, the lower fruit-bearing branches were deliberately sprayed, the fruit fell onto sprayed weeds, and they were picked up from the ground within 3 days of spraying for analysis. Even though this represents the worst-case scenario, it does not reflect GAP in any country and is therefore inappropriate for use in estimating a maximum residue level. The residue levels in whole mature oranges in valid trials were, in ranked order: < 0.01 (15), 0.01, < 0.02 (two) and < 0.05 mg/kg (one).

In one trial in the USA, both juice and pulp were analysed for paraquat residues. Although the levels were below the LOQ of 0.01 mg/kg, the procedural recovery was too low for the results to be regarded as reliable.

In trials in the USA on *grapefruit*, *lemon* and *lime* in 1970 and 1972, with application rates reflecting GAP in the USA, the paraquat residue levels were < 0.01 (one) and < 0.05 mg/kg (three).

As the residue situation in oranges and other citrus fruits is similar and GAP is recommended for citrus fruits as a group in Italy and the USA, the Meeting considered it appropriate to establish a group maximum residue level for citrus fruits. The combined residue levels, in ranked order, were: < 0.01 (16), 0.01, < 0.02 (two) and < 0.05 (four) mg/kg. The Meeting estimated a maximum residue level of 0.02 mg/kg, an STMR of 0.01 mg/kg and a highest residue level of 0.02 mg/kg for paraquat in citrus fruits. The value of 0.02 mg/kg covers only the finite residue level found at 0.01 mg/kg.

#### *Pome fruit*

Trials were carried out on apples in Canada, Germany and the United Kingdom and on pears in Canada and Germany.

Paraquat is registered for use to control weeds around the base of pome fruit trees at a maximum rate of 0.66 kg ai/ha with one application and no PHI in the United Kingdom and at a maximum rate of 1.14 kg ai/ha with no PHI in the USA. No information on GAP was available for Canada or Germany, but the results

of trials conducted in those countries were reviewed against the GAP of the USA and United Kingdom, respectively.

Trials on *apple* were conducted at rates of 1.12–4.48 kg ai/ha, and in one trial in the United Kingdom at a highly exaggerated rate of 12.3 kg ai/ha, about 20 times the maximum rate permitted in that country. In the latter trial, paraquat was applied directly to the bark of the trees to simulate worst-case conditions. In some cases, two applications were made, in the same or subsequent years. Apples were harvested 0–780 days after the last application. In trials on *pear*, paraquat was applied at rates of 1.0–4.48 kg ai/ha once or twice, and pears were harvested 0–77 days after the last application. Paraquat residue levels were below the LOQ of 0.01 mg/kg in all apples and pears taken from trees, even after treatment at rates as high as 20 times the maximum GAP rate.

In the trials in Germany, apples and pears taken from the trees were placed on the ground 6–7 days after application and collected about 7 days later for analysis. Residue levels of paraquat of 0.02–0.19 mg/kg were found in the apples, which could be attributed to the transfer of paraquat from the sprayed weed. The Meeting concluded that these data are not appropriate for use in estimating a maximum residue level.

As the residue situations in apples and pears are similar, and GAP is recommended for pome fruits or orchard fruits as a whole in all the countries that provided information on GAP, the Meeting considered it appropriate to establish a group maximum residue level for pome fruits. As the paraquat residue levels in all the valid trials were below the LOQ, even after application at exaggerated rates, the Meeting estimated a maximum residue level for pome fruits of 0.01\* mg/kg, an STMR of 0 mg/kg and a highest residue level of 0 mg/kg.

#### *Stone fruit*

Trials were carried out on peaches, plums, apricots and cherries in Canada, Germany, the United Kingdom and the USA.

Paraquat is registered for use to control weeds around the base of stone fruit trees at a maximum rate of 0.66 kg ai/ha, with one application and no PHI for stone fruits in the United Kingdom and at a maximum rate of 1.14 kg ai/ha, with three applications and a 28-day PHI for stone fruits other than peaches in the USA; the PHI for use on peach trees in the USA is 14 days. No information on GAP was available from Canada or Germany, and the results of trials conducted in those countries were reviewed against the GAP of the USA and the United Kingdom, respectively.

The application rates in the supervised trials ranged from 0.22 to 4.48 kg ai/ha, applied to the base of the fruit trees up to three times in a season; the fruit was harvested from the trees 0–103 days after the last application. No residues of paraquat above the LOQ of 0.01 or 0.05 mg/kg were found in fruit harvested directly from the trees in any trial, even after spraying three times at a rate four times the maximum permitted rate. In most of the US trials, paraquat was applied one or two times instead of the maximum of three, but because of the higher application rates, the total amount applied was higher than the maximum allowed by GAP.

In trials on plums in the United Kingdom, paraquat was applied directly to suckers at rates of 0.22–1.34 kg ai/ha. No residues were found above the LOQ of 0.01 mg/kg in fruit harvested 21 or 55 days later.

In the trials in Germany, fruit were placed on sprayed weeds and collected for analysis about 1 week later. Small amounts of paraquat residues were found (0.02 and 0.04 mg/kg on peach, < 0.01 mg/kg on plum and 0.07 mg/kg on cherry) in the fruit samples, due to transfer from the sprayed weeds. As stone fruit intended for juice production is usually grown in orchards in which herbicides are rarely used, these data were not used for estimating a maximum residue level.

As the residue situations in stone fruits are similar and GAP is recommended for stone fruits or similar GAPs are established for peach and stone fruits excluding peach, the Meeting considered it appropriate to establish a group maximum residue level for stone fruits. As the paraquat residue levels were

below the LOQ, even when applied at exaggerated rates and the methods of analysis in most of the trials had a LOQ of 0.01 mg/kg, the Meeting estimated a maximum residue level for stone fruits of 0.01\* mg/kg and STMR and highest residue values of 0 mg/kg.

#### *Berries and small fruit*

##### *Grape*

Trials on residues in grapes have been conducted in Canada, Japan, Switzerland and the USA at rates of 0.3–4.4 kg ai/ha applied one to five times. Grapes were harvested from the vines at maturity 0–196 days after the last application. Four trials were conducted in Germany in which paraquat was applied between the rows of established vines at a rate of 1.0 kg ai/ha and grapes were sampled from the vines 0–14 days after application.

Paraquat is registered for weed control around grape vines at a maximum rate of 0.72 kg ai/ha, with five applications and a 30-day PHI in Japan and a maximum rate of 1.14 kg ai/ha, with the number of applications and the PHI unspecified in the USA. No information on GAP was available from Canada, Germany or Switzerland, but the results of trials in Canada were reviewed against US GAP.

In all trials in Canada, Japan and the USA reviewed against respective GAP, grapes obtained directly from the vine did not contain paraquat residues at levels above the LOQ of 0.01 or 0.02 mg/kg, even when applied at five times the recommended rate or with a shorter PHI.

In the German trials, bunches of grapes were also placed on the sprayed weed a few days after application and collected 7 days later for analysis. Small amounts of paraquat residues (0.04, 0.07, 0.09, 0.10, 0.13 and 0.17 mg/kg) were found in the grapes due to transfer from the sprayed weeds. When the fruits were sampled directly from the vine, the levels of residues were always below the LOQ of 0.01 mg/kg (six trials), which supports the results of the trials conducted in Canada, Japan and the USA.

The residue levels of paraquat in grapes in the trials that met the respective GAP or were conducted at higher rates were: < 0.01 (16), < 0.02 (three) and < 0.05 (two) mg/kg.

##### *Cane fruit*

Trials on residues were conducted in Canada on red and blackcurrants, blueberries, loganberries, gooseberries and raspberries at rates of application of paraquat of 0.56–2.24 kg ai/ha. Paraquat was applied once and the fruit was harvested 20–111 days after application.

GAP for cane fruit in the USA is a maximum rate of 1.14 kg ai/ha, with the number of applications and PHI unspecified.

Even at double the application rate, cane fruit did not contain paraquat residues at levels above the LOQ of 0.01 mg/kg. The residue levels in 25 trials following GAP or conducted at higher rates were < 0.01 mg/kg.

##### *Strawberry*

Supervised trials were conducted in France, Germany and the United Kingdom in which paraquat was used to control runners of strawberry plants at rates of 0.42–1.32 kg ai/ha once or twice. Berries were harvested 47–226 days after the last application. Three trials in Germany were conducted in plastic greenhouses.

GAP in the United Kingdom for strawberries is a maximum rate of 0.66 kg ai/ha, with one application and PHI unspecified.

The residue levels of paraquat in strawberries in trials following GAP or conducted at higher application rates were < 0.01 (six) and < 0.05 mg/kg.



As the samples analysed in all the trials except that in which grapes were kept and taken from the ground did not contain paraquat residues at levels above the LOQs and the application rate in the respective GAP is similar, the Meeting decided to propose a group maximum residue level for small fruits and berries. The residue levels in these fruits, in ranked order, were:  $\leq 0.01$  (47),  $< 0.02$  (three) and  $< 0.05$  mg/kg (three). The Meeting, considering that use of modern analytical methods would enable lower LOQs, agreed to disregard residue levels of  $< 0.05$  mg/kg and  $< 0.02$  mg/kg and estimated a maximum residue level of  $0.01^*$  mg/kg and STMR and highest residue values of 0 mg/kg.

### *Olive*

Trials on residues in olives have been carried out in Greece, Italy, Spain and the USA (California).

Paraquat is registered for controlling weeds around the base of olive trees at a maximum rate of 1 kg ai/ha, with the number of applications unspecified and a 40-day PHI in Italy and at a maximum rate of 1.14 kg ai/ha, with four applications and a 13-day PHI in the USA. The results of trials conducted in Greece and Spain were reviewed against GAP in Italy.

In trials in Italy, paraquat was applied at rates of 0.54–1.8 kg ai/ha to the base of trees, and olives were harvested from the ground or trees 7–21 days after application. Although the delay was shorter than the recommended PHI of 40 days, the residue levels in the olives were  $< 0.05$  and  $< 0.1$  (two) mg/kg, indicating that at a PHI of 40 days the levels are likely to be  $< 0.1$  mg/kg. No residues ( $< 0.05$  mg/kg) of paraquat were detected in the oil from these fruits.

In one trial in the USA, paraquat was applied four times at an exaggerated rate (5.6 kg ai/ha; 22.4 kg/ha total) and the fruit was harvested from the trees 13 days later for analysis. The residue levels of paraquat were below the LOQ of 0.05 mg/kg, as were the levels in oil and cake prepared from the olives.

In six trials in Spain, olives were harvested from the ground 0, 1 and 7 days after application of paraquat at 0.60 kg ai/ha, simulating the worse-case scenario of collecting olives intended for oil production. In these trials, the application rate was 60% of the maximum allowed in Italy, but the olive fruit were harvested much earlier than the PHI of 40 days. The residue levels in whole fruit were 0.64–10 mg/kg, indicating that there had been transfer of paraquat from the sprayed weeds to the olives. In all the oil produced from these samples, however, the maximum residue levels of paraquat were 0.06 mg/kg, indicating that paraquat is not extracted into oil, as might be expected from its chemical nature.

In other trials in Spain, mature olives were sprayed directly on the ground with paraquat at rates of 0.36–1.3 kg/ha, and the fruit was analysed 3–17 days after application. The residue levels of paraquat in the olives were 0.08–4.4 mg/kg. Residues of paraquat did not transfer to extracted oil, and washing appeared to reduce the levels on the fruit.

In one trial in Greece, mature olives were sprayed directly with paraquat at a rate of 1.0 kg ai/ha to simulate direct spraying on fallen fruit in collection nets during weed control. No residues were found at levels above the LOQ (0.05 mg/kg) in oil extracted from treated fruit harvested 5 days after application.

Olives for oil production are often harvested from the ground and paraquat used for weed control may occasionally be applied directly to the fallen fruit on the ground. The whole fruit will contain some paraquat residue, either through transfer from treated vegetation or through direct spraying. Although the olives may contain relatively high levels of paraquat, no transfer of paraquat to oil occurs. This practice is not in compliance with GAP for olives.

The residue levels in olives taken directly from trees were:  $< 0.05$  and  $< 0.10$  mg/kg (two). In another trial, the level was  $< 0.05$  mg/kg in olives taken from ground that had not been directly sprayed. The residue levels in one US trial conducted at five times the usual rate were below the LOQ of 0.05 mg/kg, indicating that when paraquat is applied in accordance with GAP no residues are expected to occur in olive fruit. The Meeting estimated a maximum residue level of 0.1 mg/kg to replace the previous recommendation

for olive at 1 mg/kg. The Meeting also estimated an STMR of 0.05 mg/kg and a highest residue level of 0.1 mg/kg.

*Assorted tropical fruits minus inedible peel*

Trials on residues were carried out on *passion fruit* in Hawaii, USA, at an application rate of 1.12–4.48 kg ai/ha, to control weeds. Fruit was harvested 1–28 days after application. GAP in the USA for use on passion fruit is a maximum rate of 1.05 kg ai/ha, with an unspecified number of applications and PHI. The residue level in whole fruit in a trial complying with the maximum GAP was 0.13 mg/kg. After application at a rate higher than the maximum GAP, residue levels of up to 0.19 mg/kg were found in whole fruit. The levels in the edible pulp of all passion fruits analysed in the trials, regardless of PHI, ranged from < 0.01 to 0.02 mg/kg at 1.12 kg ai/ha and from < 0.01 to 0.06 mg/kg at higher rates. Higher levels were found in peel than in the edible portion.

Trials on residues were carried out on *kiwifruit* in California, USA, at an application rate of 0.56–2.24 kg ai/ha, three times, to control weeds. Fruit was harvested 7–14 days after the last application. The US GAP for kiwifruit is a maximum rate of 1.14 kg ai/ha, with the number of applications unspecified and a 14-day PHI. The residue level in kiwifruit in one trial conducted in accordance with the maximum US GAP was < 0.01 mg/kg. Even at a higher application rate or a shorter PHI, the levels were below the LOQ of 0.01 mg/kg.

Trials on *guava* were carried out in two locations in Hawaii, USA, with three different application rates of 1.12–4.48 kg ai/ha at each location. Fruit was harvested 1–28 days after application. The US GAP for guava is identical to that for passion fruit. The residue levels of paraquat in all edible pulp and peel analysed were below the LOQ of 0.01 mg/kg at the maximum GAP rate and at rates up to four times the maximum GAP. No residue was found at levels above the LOQ of 0.01 or 0.02 mg/kg in juice, discarded skin or seed obtained from guava treated at 1.12 or 4.48 kg/ha with a 6-day PHI. Although no information was available on residues in whole fruit, levels above the LOQ were not expected in whole fruit in view of the residue situation in pulp, peel and other fractions.

Trials were carried out on *banana* in Honduras, with three applications of paraquat at 1.4 kg ai/ha or a single application at double this rate, to control weeds in established plantations. Fruit was harvested 0–90 days after the last application. As no information was available on GAP in Honduras, the data were reviewed against GAP of the USA (maximum rate of 1.14 kg ai/ha). The residue levels of paraquat in flesh (0- and 3-day PHI) and whole fruit ( $\geq$  7-day PHI) were below the LOQ (0.01 mg/kg) in three trials, except in skin from fruit harvested immediately after application.

Except in the trials on passion fruit, the residue levels in tropical fruits in 10 trials conducted according to the respective GAP were all below the LOQ (< 0.01 mg/kg). The Meeting estimated a maximum residue level for paraquat in assorted tropical fruits with inedible peel, excluding passion fruit, of 0.01\* mg/kg. The Meeting decided to withdraw the previous recommendation for passion fruit.

The residue levels in edible portions of these fruit were below the LOQ:  $\leq 0.01$  (11) mg/kg. The Meeting estimated STMR and highest residue values for paraquat in assorted tropical fruits minus inedible peel, excluding passion fruit, of 0.01mg/kg.

*Bulb vegetables*

Trials on residues were conducted on *onion* in Canada, Germany and the United Kingdom in the 1960s. Paraquat is registered in the USA for pre-plant or pre-emergence application to onion in a limited number of states at a maximum rate of 1.14 kg ai/ha, with one application and a 60-day PHI (200 days in California). Uses on bulb vegetables are not included in the label in the United Kingdom.

In one Canadian trial at twice the GAP rate and with a shorter PHI (36 days), the residue levels were below the LOQ of 0.01 mg/kg. In another Canadian trial at an application rate of 1.12 mg/kg, the levels were also < 0.01 mg/kg, but the PHI was 143 days.

Trials were conducted in Germany for post-emergence directed application and for harvest aid uses, but there was no related GAP.

In one trial conducted in the United Kingdom of pre-emergence application on spring onion, the residue level was 0.02 mg/kg, but the application rate was > 30% higher than the maximum rate allowed in the USA. A further trial on spring onion involved directed post-emergence application, for which no information on GAP was available.

The Meeting concluded that there were insufficient data to recommend a maximum residue level for paraquat in onion bulb or bulb vegetables.

#### *Brassica vegetables*

Residue trials were carried out on *broccoli* in Canada; *Brussels sprouts* in The Netherlands (harvest aid); *cabbage* in Canada, Japan, Spain and the USA; and *cauliflower* in Canada. Paraquat was applied once or twice at 0.67–2.2 kg ai/ha for inter-row weed control, and the crop was harvested 5–52 days after the last application.

Paraquat is registered for use in the cultivation of *Brassica* vegetables during seed-bed preparation as a pre-plant or pre-emergence treatment, or applied as a post-emergence directed or guarded spray for inter-row weed control. GAP in Japan is a maximum rate of 0.36 kg ai/ha, with three applications and a 30-day PHI, for broccoli, cabbage, cauliflower and Chinese cabbage as pre-plant inter-row applications. GAP in the USA is a maximum rate of 1.14 kg ai/ha, with the number of applications and PHI unspecified, for *Brassica* vegetables as pre-plant, pre-emergence treatment.

In trials conducted on broccoli, cabbage and cauliflower in Canada, the residue levels were below the LOQ of 0.01 mg/kg, even when applied at double the rate. The exception was one trial in Canada in which cabbage harvested 51 days after treatment at twice the rate contained a residue level of 0.06 mg/kg. The residue levels were < 0.01 (two) and 0.06 mg/kg.

In two trials conducted on cabbage in Japan, the residue levels were below the LOQ of 0.03 mg/kg even after application at a higher rate of 0.96 kg ai/ha and a shorter PHI of 5 days. At a highly exaggerated rate of 19.2 kg ai/ha but with only one application and a longer PHI of 52 days, the residue levels were also < 0.03 mg/kg.

No information was available on GAP that would allow evaluation of trials conducted in Spain.

Trials on Chinese cabbage were conducted in the USA in which paraquat was applied once as pre-emergence treatment at 1.05 kg ai/ha, followed by three post-emergence directed applications at 0.56 kg ai/ha. The residue levels were < 0.05 and 0.07 mg/kg. The US label allows only pre-plant and pre-emergence applications.

Trials on Brussels sprouts in The Netherlands involved a direct harvest aid application to the vegetable. In these trials, the unwashed vegetable contained a residue level of 7.3 mg/kg after 31 days, while washed vegetable had a reduced level of 1.6 after 31 days. Harvest aid desiccation was not, however, included in the labels provided to the Meeting.

The residue levels in these crops in trials that followed GAP and in trials that showed residue levels below the LOQ were, in ranked order: < 0.01 (two), ≤ 0.03 (two) and 0.06 mg/kg. The Meeting concluded that there were insufficient data for estimating a maximum residue level for *Brassica* vegetables.

#### *Fruiting vegetables*

Numerous residue trials were carried out on tomatoes in Canada and the USA, on cucumbers, melons and summer squash in the USA and on peppers in Canada and the USA.

Paraquat is registered in the USA for use on tomatoes for pre-plant or pre-emergence application at a maximum rate of 1.14 kg ai/ha, with an unspecified number of applications and a 30-day PHI; on tomatoes

for post-emergence directed spray at a maximum rate of 0.55 kg ai/ha, with an unspecified number of applications and a 30-day PHI; on peppers by directed spray application at a maximum rate of 0.55 kg ai/ha, with three applications and no PHI; and on other fruiting vegetables for pre-plant or pre-emergence application at a maximum rate of 1.14 kg ai/ha, with unspecified number of applications and PHI.

The trials in Canada on *tomatoes* were for pre-emergence or pre-planting weed control, in which paraquat was used at a low rate of 0.11 kg ai/ha. Trials on tomatoes in the USA involved post-emergence directed application at 0.56–2.24 kg/ha and an exaggerated single high pre-emergence application at a rate of 11.2 kg ai/ha or pre-emergence application of 1.12 kg ai/ha followed by three inter-row directed applications at 2.8 kg ai/ha. Although samples were harvested 21 days after treatment, 30% shorter than the PHI in US GAP of 30 days, the residue levels in tomatoes were below the LOQ of 0.01 mg/kg after application at 0.56 kg ai/ha for post-emergence directed application, except in one trial in which levels up to 0.04 mg/kg were found. After application at exaggerated rates, the residue levels were still below the LOQ of 0.005 or 0.01 mg/kg or at a maximum of 0.02 mg/kg.

The residue levels in trials following GAP or conducted at higher application rates were, in ranked order: < 0.005 (two), < 0.01 (seven) and 0.04 mg/kg.

The trials on *sweet peppers* were for use of paraquat in inter-row weed control at 0.56–2.2 kg ai/ha. The residue levels in trials at maximum GAP were < 0.01 and 0.01 mg/kg. The levels after exaggerated application rates were either below the LOQ of 0.01 mg/kg, 0.03 mg/kg (once at 1.12 kg ai/ha pre-emergence and four times at 1.12 or 2.24 kg ai/ha post-emergence applications) or 0.02 mg/kg (one trial).

The Meeting considered it appropriate to evaluate residues in tomato and peppers together for estimating the maximum residue level for fruiting vegetables, other than cucurbits. The combined levels were: < 0.005 (two), < 0.01 (eight), 0.01 and 0.04 mg/kg. The Meeting estimated a maximum residue level for fruiting vegetables, other than cucurbits, of 0.05 mg/kg, an STMR of 0.01 mg/kg and a highest residue level of 0.04 mg/kg.

In trials on *cucumbers*, *melons* and *summer squash* in California (USA), paraquat was applied at 1.12 kg ai/ha pre-emergence, followed by three inter-row applications at 0.56 kg ai/ha. While US GAP allows pre-emergence application at a maximum of 1.12 kg ai/ha, the residue levels of paraquat in all 12 trials were below the LOQ of 0.025 mg/kg. The Meeting estimated a maximum residue level for cucurbits of 0.02 mg/kg and STMR and highest residue values of 0 mg/kg.

#### *Leafy vegetables*

Trials for residues were conducted on lettuce in Canada, Germany, Spain, the United Kingdom and the USA, on kale in France, Italy and the United Kingdom and on turnip greens in the USA.

Paraquat is registered for pre-emergence application on collard and lettuce in the USA at a maximum rate of 1.14 kg ai/ha, with the number of applications and PHI unspecified. Uses on leafy vegetables are not included on labels in Italy or the United Kingdom.

Trials on residues on *lettuce* were conducted in Canada, Germany, Spain, the United Kingdom and the USA at application rates of 0.42–2.24 kg/ha; lettuce was sampled 0–147 days after application. In trials conducted in Canada and the USA following US GAP, the residue levels in untrimmed head or bunch were 0.01, 0.04 and 0.05 mg/kg.

The results of trials in the United Kingdom were evaluated against US GAP, as the uses were similar in trials in the two countries. The residue levels in unwashed lettuce head in trials following US GAP were < 0.01, 0.01 and 0.02 mg/kg.

Residue levels up to 1.4 mg/kg were found in German trials on lettuce harvested immediately after one or two applications of paraquat for post-emergence inter-row weed control. The residues were believed to have derived from spray drift onto the outer leaves. In most of these trials, the whole lettuce head was analysed without removal of outer wrapper leaves that were yellow and withered. The residue levels had

declined to close to the LOQ (< 0.01 mg/kg) by 21 days after harvest. The results of trials in Germany and Spain could not be evaluated as no information on GAP in Europe was available.

Residue trials on *kale* were carried out in France, Italy and the United Kingdom at rates of 1.0–2.24 kg/ha, and kale was sampled 0–147 days after application. As no information was available on GAP in Europe, these data were not evaluated.

Six trials on *turnip greens* were carried out in the USA at a rate of 1.12 kg/ha, with sampling 55–128 days after application. The levels of paraquat residue were < 0.025 (three), 0.03, 0.04 and 0.05 mg/kg.

As the US GAPs for collard and lettuce are identical and the residue situations for these crops were similar, the Meeting considered it appropriate to combine the results for estimating a maximum residue level for leafy vegetables. The combined residue results, in ranked order were: < 0.01, 0.01 (two), 0.02, < 0.025 (three), 0.03, 0.04 (two) and 0.05 (two) mg/kg. The Meeting estimated a maximum residue level for paraquat in leafy vegetables of 0.07 mg/kg, an STMR of 0.025 mg/kg and a highest residue level of 0.05 mg/kg.

#### *Legume vegetables and pulses*

Residue trials were conducted on beans (with pod and dry) in Canada, Germany, Italy, The Netherlands and Spain, on broad beans in Spain, on peas in Australia, Canada and the USA, and on soya beans in Brazil and the USA.

Paraquat is registered for weed control and harvest aid on legume vegetables and pulses in Australia, Brazil and the USA as follows:

| Country   | Maximum rate<br>(kg ai/ha) | No. of<br>applications | PHI (days) | Crop               | Type of application                                    |
|-----------|----------------------------|------------------------|------------|--------------------|--------------------------------------------------------|
| Australia | 0.2                        |                        | 14         | Chickpea           | Over-the-top spray                                     |
|           | 0.2                        |                        | 14         | Field pea          | Over-the-top spray                                     |
|           | 0.43                       |                        |            | Soya bean          | Pre-plant                                              |
| Brazil    | 0.6                        | 1                      | 7          | Soya bean          | Pre-plant                                              |
|           | 0.5                        | 1                      | 7          | Soya bean          | Desiccation                                            |
| USA       | 1.14                       |                        | –          | Beans (lima, snap) | Pre-plant, pre-emergence                               |
|           | 1.14                       |                        | –          | Pea                | Pre-plant, pre-emergence                               |
|           | 0.55                       | 2                      | 7          | Pulses             | Harvest aid                                            |
|           | 1.14                       |                        | –          | Soya bean          | Pre-plant or pre-emergence                             |
|           |                            |                        |            |                    | Should not exceed 1.9 l per season                     |
|           | 0.14                       | 2                      | –          | Soya bean          | Post-emergence directed spray                          |
|           |                            |                        |            |                    | Second and final application 7–14 days later if needed |
|           | 0.28                       |                        | 15         | Soya bean          | Harvest aid                                            |

Uses on legumes and pulses were not included in the European labels provided to the current Meeting.

Residue trials were carried out on *dry beans* (genus *Phaseolus*) in Germany, Italy, The Netherlands and Spain, in which paraquat was used for pre-emergence weed control at single application of 0.56 or 2.24 kg ai/ha or post-emergence directed inter-row weeding at rates of 0.28–1.12 kg ai/ha. In trials in Europe, young pods were harvested 0–7 days after treatment and analysed. The residue levels in beans in pods were < 0.05–0.10 mg/kg (five trials). As no related GAP was available, these results were not used in estimating a

maximum residue level. The Meeting concluded that there were insufficient data to estimate a maximum residue level for legume vegetables.

The residue levels of paraquat in dry beans in Canadian trials after pre-emergence application following GAP were < 0.01 (two), < 0.05 and 0.07 mg/kg.

Residue trials were conducted on *broad beans* in Spain after post-emergence directed spray. The residue levels in seeds harvested on the day of application were < 0.05 mg/kg (two); however, no information was available on related GAP.

Residue trials were carried out on *peas* in Canada and the United Kingdom with paraquat used for pre-emergence weed control at single applications or post-emergence directed inter-row weeding at rates of 0.14–1.68 kg ai/ha and harvesting 55–152 days after application. The residue levels of paraquat in seeds were below the LOQ of 0.01 or 0.05 mg/kg in trials with post-emergence application; however, no GAP was available for post-emergence application on peas.

Paraquat was applied at 0.20 or 1.12 kg ai/ha to field peas and chick peas as a harvest aid desiccant in Australia and the USA, with samples taken 1–38 days after application. The resulting residues of paraquat in seed in trials following GAP were found at levels of: 0.05, 0.15, 0.23, 0.25, 0.31 and 0.41 mg/kg.

A number of trials were conducted on *soya beans* in Brazil between 1981 and 1983 with a harvest aid desiccation application of paraquat at 0.25–0.80 kg/ha and sampling 2–21 days after application. The residue levels of paraquat in seed in trials following GAP in Brazil were: < 0.02, 0.03 (two), < 0.05 (two), 0.07, 0.08, 0.09, 0.10, 0.11 (two), 0.13, 0.16 (two) and 0.28 (three) mg/kg.

In trials conducted in the USA with pre-emergence application with or without a post-emergence directed application at 0.14–1.4 kg/ha, the residue levels of paraquat in soya beans harvested 3–147 days after the last application in trials following GAP were < 0.025 (nine) and 0.03 mg/kg.

Other trials were conducted in the USA on harvest aid desiccation application at 0.28 or 0.56 kg/ha and sampling 6–36 days after application. The residue levels of paraquat in seeds in trials following GAP were: < 0.01, 0.02 (four), 0.03 (two), 0.04 (two), 0.05, 0.06, 0.07, 0.08 (two), 0.09, 0.12 and 0.13 mg/kg. The hulls of treated soya beans contained higher residues than seeds.

The results of these trials clearly indicate that the levels of residues arising from harvest desiccant uses are higher than those from pre-emergence or post-emergence application.

The Meeting considered it appropriate to combine the results of trials on field peas and chick peas in Australia and on soya beans in Brazil and the USA in which paraquat was used as a harvest aid desiccant to estimate a group maximum residue level for pulses. The combined residue levels in seeds were, in ranked order: < 0.01 (two), < 0.02, 0.02 (four), 0.03 (four), 0.04 (two), < 0.05 (two), 0.05 (two), 0.06, 0.07 (two), 0.08 (three), 0.09 (two), 0.10, 0.11 (two), 0.12, 0.13 (two), 0.15, 0.16 (two), 0.23, 0.25, 0.28 (three), 0.31 and 0.41 mg/kg. The Meeting estimated a maximum residue level of 0.5 mg/kg to replace the previous recommendation for soya bean and an STMR of 0.08 mg/kg and a highest residue level for pulses of 0.41 mg/kg.

#### *Root and tuber vegetables*

Paraquat is registered for use at a maximum rate of 0.36 kg ai/ha with three applications and a 30-day PHI in Japan for pre-plant, inter-row application on carrot and in the USA at a maximum rate of 1.14 kg ai/ha for pre-emergence treatment of root and tuber vegetables excluding potatoes.

Two residue trials carried out on *beetroot* in Canada and the United Kingdom for pre-emergence application in compliance with US GAP resulted in residue levels of < 0.01 and 0.03 mg/kg.

Residue trials were conducted in the United Kingdom on beetroot and *sugar-beet* in which paraquat was used pre-sowing or pre-emergence at 1.68 kg ai/ha, followed by two directed inter-row applications at

2.24 kg ai/ha after crop emergence. No information was available, however, on GAP for post-emergence application from Europe.

In trials conducted in four states of the USA with pre-emergence application at 1.12 kg ai/ha, the residue levels in sugar-beet roots harvested 136–178 days after application were < 0.05 mg/kg (six) after a single pre-emergence application at 1.12 kg ai/ha. After application at an exaggerated rate of 5.6 kg ai/ha, the residue levels in unwashed root were < 0.05 mg/kg.

Residue trials on *carrots* with use of paraquat for pre-emergence or inter-row weed control have been carried out in Canada, Japan, Germany and the United Kingdom. The residue levels of paraquat in carrot in the Japanese trials after both pre-emergence and inter-row applications were all below the LOQ of 0.03 mg/kg, despite a shorter PHI or use of a highly exaggerated rate of 19.2 kg ai/ha. The residue levels in carrot in four trials following GAP or conducted at higher rates or shorter PHI were < 0.03 mg/kg. In Canadian trials, the residue levels were below the LOQ of 0.01 mg/kg, even in one trial in which the rate was doubled and the PHI shorter.

As no information was available on GAP in Europe, the data from German trials with post-emergence application were not considered in estimating the maximum residue level.

Residue trials were carried out on *parsnips* and *swedes* in the United Kingdom and on *turnips* in Canada and United Kingdom with use of paraquat for pre-emergence weed control (Canada) or pre-emergence followed by inter-row weed control (United Kingdom). The rates of application were 0.56–2.24 kg ai/ha. Turnip, swede and parsnip roots were harvested 49–122 days after application. The residue levels of paraquat in turnips in two Canadian trials that followed US GAP were < 0.01 mg/kg. No information on GAP was available for post-emergence application in Europe.

One trial was conducted in France on *black salsify*, in which paraquat was applied as an inter-row treatment at 0.5 and 0.8 kg ai/ha. There were no residues (< 0.02 mg/kg) in salsify roots harvested 8 and 80 days after treatment; however, no information on GAP was available.

The combined residue levels in beetroot, sugar-beet, carrots and turnips were, in ranked order: < 0.01 (four), < 0.03 (four), 0.03 (two) and < 0.05 (six) mg/kg.

### Potato

Trials were carried out on potatoes in Canada, Germany, the United Kingdom and the USA for pre-emergence, post-emergence and harvest aid applications of paraquat.

Paraquat is registered in the United Kingdom for pre-emergence use at a maximum rate of 0.66 kg ai/ha with one application. It is registered in the USA for pre-plant and pre-emergence broadcast application at a maximum rate of 0.55 kg ai/ha and for broadcast application for pre-harvest vine killing and weed dessication at a maximum rate of 0.42 kg ai/ha with a 3-day PHI. The latter application is restricted to fresh market produce, with a restriction of 2.3 l/ha per season; split applications must be applied a minimum of 5 days apart.

Trials were carried out in Germany with post-emergence directed application. The residue levels were below the LOQ of 0.01 mg/kg.

Several residue trials were carried out in Canada and the USA in which paraquat was applied for weed control by pre-emergence or post-crop emergence application at a rate of 0.20–1.12 kg ai/ha. The residue levels in the tubers in trials following US GAP were < 0.01 (eight) and 0.02 mg/kg. At double the application rate, the residue levels were below the LOQ of 0.01 mg/kg.

Trials were also carried out on harvest aid desiccant use in Canada, the United Kingdom and the USA. The US label allows use of paraquat for vine killing and weed desiccation at a maximum of 0.42 kg ai/ha, with a PHI of 3 days, but in these trials rates equivalent to or higher than twice the maximum rate or a much longer PHI were used. Harvest aid use is not included in the United Kingdom label.

The residue levels in trials of pre- and post-emergence application were < 0.01 (eight) and 0.02 mg/kg. The levels in trials with double the application rate in the USA and in trials conducted in Germany were all below the LOQ.

The Meeting decided to combine the results from trials on beetroot, sugar-beet, carrot, turnip and potato. The combined residue levels, in ranked order, were: < 0.01 (12), 0.02, < 0.03 (four), 0.03 (two) and < 0.05 (six) mg/kg. The Meeting estimated a maximum residue level of 0.05 mg/kg, an STMR of 0.02 mg/kg and a highest residue level of 0.05 mg/kg for root and tuber vegetables. The maximum residue level replaces the previous recommendation for potato.

#### *Stem vegetables*

Residue trials have been carried out on asparagus, celery and globe artichokes in Canada and the USA with use of paraquat for post-emergence directed inter-row weeding at rates of 1.12–3.25 kg ai/ha in a single application. Three applications of 1.12 or 1.35 kg/ha on artichokes were also tested.

Paraquat is registered in the USA for *asparagus* at a maximum rate of 1.14 kg ai/ha for pre-plant and pre-emergence broadcast or banded over-row application and at the same maximum rate with a 6-day PHI for asparagus more than 2 years old by broadcast or banded over-row application. The residue levels were < 0.02 (two) and < 0.05 mg/kg.

Although trials were conducted on *celery* in Canada and on *artichoke* in the USA, no information on GAP for these crops was available. The Meeting concluded that the data were insufficient for estimating a maximum residue level for asparagus.

#### *Cereal grains*

##### *Maize*

Residue trials were conducted on maize in Canada, Italy, the United Kingdom and the USA with pre- and post-emergence applications and harvest aid uses.

Paraquat is registered for use in the USA at a maximum rate of 1.14 kg ai/ha for pre-plant or pre-emergence broadcast or banded over-row applications and at a maximum rate of 0.55 kg ai/ha for post-emergence directed spray. Residue trials were conducted with use of paraquat for pre-emergence weed control or for post-emergence directed spray in Canada and the USA at rates of 0.28–1.12 kg ai/ha.

In a series of trials in the USA in 1987, one pre-emergence application at 1.12 kg ai/ha and two post-emergence applications at 0.31 kg ai/ha were made. Although the post-emergence application rate was not as high as the maximum rate, the pre-emergence application rate was the maximum allowed for pre-emergence application. The Meeting considered that these trials were conducted in accordance with US GAP. The residue levels in trials in Canada and the USA conducted in accordance with US GAP were: < 0.01 (eight) and < 0.025 mg/kg (16). In trials with higher application rates (up to four times), the residue levels were below the LOQ. The levels in maize cobs were also below the LOQ of 0.01 mg/kg (two trials).

In two residue trials in Italy, paraquat was applied pre-emergence at 0.92 kg ai/ha. The residue levels in cob were < 0.05 mg/kg; however, no analysis of kernels or grain was reported.

Trials were conducted in South Africa and the United Kingdom with post-emergence application; however, owing to the lack of relevant GAP for South Africa and the fact that post-emergence application is not included on the label in the United Kingdom, the results of these trials could not be evaluated by the Meeting.

Several trials were conducted in the USA on use of paraquat as a harvest aid desiccator at rates of 0.56–1.12 kg/ha. This use is not included in US GAP, although it is allowed in Argentina, Brazil and Uruguay.



On the basis of the residue levels in maize grain in trials with paraquat applied pre- or post-emergence in Canada and the USA, < 0.01 (eight) and < 0.025 mg/kg (16), the Meeting estimated a maximum residue level of 0.03 mg/kg to replace the previous recommendation for maize and STMR and highest residue values of 0.025 mg/kg.

#### *Sorghum*

A number of residue trials were conducted in the USA, where paraquat is registered for use on sorghum at a maximum rate of 1.14 kg ai/ha, with a PHI of 48 days for grain and 20 days for forage, for pre-plant or pre-emergence broadcast application, and at a maximum rate of 0.55 kg ai/ha in two applications with the same PHIs for post-emergence directed spray. In the latter application, the applications must not exceed 2.5 l per season.

Several residue trials were carried out in the USA in several years and locations, in which paraquat was applied for weed control, either pre-emergence, post-crop emergence directed or as a harvest aid, at rates of 0.21–7.8 kg ai/ha. Samples were taken 20–131 days after pre-emergence or post-emergence directed application. The residue levels in grain in 12 trials conducted in accordance with maximum GAP for pre-emergence or post-emergence applications were all < 0.025 mg/kg. When both pre- and post-emergence applications were made, if the post-application rate was in compliance with GAP, the residue results were taken into consideration in estimating the maximum residue level. In one trial with one pre-emergence application at 0.56 kg ai/ha followed by a post-emergence application at 0.56 kg ai/ha, a residue level of 0.01 mg/kg was found.

In harvest aid desiccation applications, paraquat was applied at a rate of 0.21–2.8 kg/ha, and sorghum was sampled 7–49 days after application. Harvest aid desiccant use is not included on the US label.

The Meeting estimated a maximum residue level of 0.03 mg/kg to replace the previous recommendation and STMR and highest residue values of 0.025 mg/kg for sorghum.

#### *Rice*

Trials on residues of paraquat on rice were conducted in Guatemala, Italy and the USA. Paraquat is registered for use on rice in the USA by pre-plant or pre-emergence broadcast at a maximum rate of 1.14 kg ai/ha, with no PHI specified.

Two trials were conducted in Italy in 1993, in which paraquat was applied at a rate of 0.92 kg ai/ha to the seed bed 5 days before rice was sown. Rice grain and straw samples taken at harvest did not contain residues of paraquat at levels above the LOQ of 0.05 mg/kg.

Three residue trials were conducted in Guatemala in 1983 in which paraquat was applied as a pre-emergence treatment at rates of 0.30 and 1.0 kg ai/ha to rice. Rice grain and straw samples were taken at harvest. The residues in de-husked rice in one trial conducted in compliance with the maximum rate in US GAP were < 0.05 mg/kg, but residues in rice grain were not analysed.

Residue trials were conducted in the USA in 1978 and 1982 in which paraquat was applied as a pre-emergence treatment at rates of 0.56 and 1.12 kg ai/ha to rice. In trials conducted at the maximum GAP, the residue levels in rice grain were below the LOQ of 0.01 (two) or 0.02 mg/kg. No trials were conducted at rates higher than the maximum allowed in US GAP for rice.

The Meeting concluded that there were insufficient data to estimate a maximum residue level and withdrew the previous recommendation for rice and rice, polished.

#### *Tree nuts*

It is common practice to harvest nuts from the ground, and this may result in residues of paraquat in the nuts.

Supervised residue trials were carried out over a number of years in Italy on *hazelnuts* and in the USA on *almonds* (California), *macadamia nuts* (Hawaii), *pecans* (Alabama and Texas), *pistachio nuts* (California) and *walnuts* (California).

Paraquat is registered for use on hazelnuts in Italy at a maximum rate of 1 kg ai/ha with a 40-day PHI and on walnuts at the same maximum rate but with no PHI specified. In the USA, paraquat is registered for use on pistachio nuts at a maximum rate of 1.14 kg ai/ha with a 7-day PHI, with the proviso that no more than two applications should be made after the nuts have split. It is registered for use in the USA on other tree nuts at the same maximum rate with no specification of the number of applications or PHI.

Two trials were conducted in Italy in which hazelnuts were harvested from the ground 1–10 days after treatment around the base of the trees at rates of 0.54–1.8 kg ai/ha. Although the PHI was shorter than 40 days, the residue levels in shelled nuts were below the LOQ of 0.05 mg/kg in one trial. At almost twice the maximum application rate and with a shorter PHI of 10 days, the levels were still below the LOQ.

In a trial in the USA, paraquat was applied at rates of 0.56–4.5 kg ai/ha one to eight times, to control weeds under mature nut trees. In some cases, applications were made over 2 years. Nuts were harvested, in some cases immature, 1–171 days after the last application. The residue levels in shelled nuts in trials following GAP were: < 0.01 (seven), 0.01, 0.02 and < 0.05 (three) mg/kg.

The combined results of all the trials, in ranked order, were: < 0.01 (seven), 0.01, 0.02 and < 0.05 (four) mg/kg. The Meeting estimated a maximum residue level for paraquat in tree nuts of 0.05 mg/kg, an STMR of 0.01 mg/kg and a highest residue level of 0.05 mg/kg.

#### *Oil seeds*

##### *Cotton-seed*

Paraquat is registered for use on cotton in the USA at a maximum rate of 1.14 kg ai/ha, with no specification of the number of applications or PHI, for pre-plant or pre-emergence treatment, and at a maximum rate of 0.55 kg ai/ha, with repeated application if necessary and a 3-day PHI as a harvest aid, with the proviso that a total of 1.5 l should not be exceeded in this use.

Residue trials were conducted in the USA over several years and locations, involving pre-emergence applications at 1.12 kg/ha and harvesting 4–176 days after application. The residue levels in fuzzy seed in trials at the maximum GAP were < 0.01 (four) and 0.04 mg/kg.

In numerous trials with pre-emergence application followed by harvest aid desiccation application or a single application as harvest aid desiccant, the residue levels of paraquat in fuzzy seed in trials following maximum GAP were: 0.07, 0.09, 0.15, 0.16 (two), 0.18, 0.21, 0.23, 0.30, 0.34, 0.35, 0.38, 0.44, 0.46, 0.49, 0.50, 0.58 and 2.0 mg/kg. On the basis of residue levels arising from harvest aid uses, the Meeting estimated a maximum residue level for cotton-seed of 2 mg/kg, to replace the previous recommendation, an STMR of 0.34 mg/kg and a highest residue level of 2 mg/kg.

##### *Sunflower seed*

In the USA, paraquat is registered for use on sunflower at a maximum rate of 1.14 kg ai/ha with no PHI specified for pre-plant or pre-emergence broadcast or banded over-row application and at a maximum rate of 0.55 kg ai/ha with a 7-day PHI for desiccation use.

Trials were conducted with pre-emergence application to sunflowers at 1.12 or 5.6 kg/ha and sampling 41–131 days after application. The residue levels in seeds in four trials conducted in compliance with maximum GAP were < 0.05 mg/kg. When paraquat was applied at five times the maximum recommended rate, the levels were still below the LOQ of 0.05 mg/kg.

In further trials, paraquat was applied as a harvest aid desiccator at 0.28–1.12 kg/ha, and sunflower seeds were harvested 7–21 days after application. The residue levels of paraquat in seeds in trials conducted at maximum GAP were: 0.09, 0.14, 0.15, 0.16 (three), 0.19, 0.22, 0.24, 0.32, 0.35, 0.51, 0.60, 0.74, 0.81

(two) and 0.93 mg/kg. The Meeting used the residue levels arising from harvest aid uses to estimate a maximum residue level for sunflower seed of 2 mg/kg, an STMR of 0.22 mg/kg and a highest residue level of 0.81 mg/kg.

### *Hops*

Residue trials were conducted in Canada and the USA. Paraquat was registered in the USA for use as a directed spray or for suckering and stripping on hops at a maximum rate of 0.55 kg ai/ha in three applications with a 14-day PHI; no more than two applications or applications at no more than 1.5 l/ha were recommended.

In a trial in Canada, a single post-emergence directed application of 1.12 kg ai/ha, which is double the maximum recommended dose, resulted in residue levels of < 0.01 mg/kg in green hops harvested 53 days after application.

In the USA, trials were conducted in the states of Idaho, Oregon and Washington with three post-emergence directed applications of paraquat at 2.8 kg ai/ha. The residue levels of paraquat in dried hops prepared from hops harvested 14 days after the last of three directed application at the maximum GAP rate were 0.05 mg/kg in two trials. At double this rate, the levels in dried hops prepared from green hops harvested 13 or 14 days after the last treatment were below the LOQ of 0.1 mg/kg (0.01 and 0.07 mg/kg). Two applications at higher rates than that of maximum GAP resulted in 0.02 and 0.03 mg/kg in dried hops.

The residue levels in dried hops were 0.05 mg/kg (two). In view of the low levels of residues in the other trials, the Meeting estimated a maximum residue level of 0.1 mg/kg, to replace the previous recommendation, and STMR and highest residue values of 0.05 mg/kg for hops, dry.

### *Tea, green, black*

Residue trials on tea were conducted in India, where paraquat is registered for use for pre-emergence or post-emergence directed application between rows at a maximum rate of 0.75 kg ai/ha in one application, with no PHI specified.

Six trials were conducted at a total application rate of 0.57–2.0 kg ai/ha over 5–6 months. Green tea leaves were harvested 7 or 21 days after blanket application (after the first or last spot application) and processed into black tea, which was analysed. The residue levels of paraquat in black tea from tea plants treated in accordance with GAP in India or at higher rates were almost always below the LOQ of 0.05 mg/kg. In trials conducted in accordance with GAP, the levels in black tea were: ≤ 0.05 (three), 0.07, 0.09 and 0.12 mg/kg.

In other trials in India, with application rates of 0.05–0.06 kg ai/ha, black tea samples from green tea leaves harvested 5 or 7 days after application contained 0.05 mg/kg (one) or < 0.05 mg/kg. As the application rate was much lower than the maximum, these results were not considered in estimating the maximum residue level.

The Meeting estimated a maximum residue level for teas, green, black of 0.2 mg/kg and an STMR of 0.06 mg/kg.

### *Animal feedstuffs*

#### *Soya forage and hay or fodder*

Paraquat is registered for use in Australia, Brazil and the USA for weed control and as a harvest aid on soya beans. In the USA, it is registered for use at a maximum rate of 1.14 kg ai/ha for pre-plant or pre-emergence treatment, not to exceed 1.9 l per season, at a maximum rate of 0.14 kg ai/ha as a post-emergence directed spray with a second and final application 7–14 days later; it can also be used at a maximum rate of 0.28 kg ai/ha with a 15-day PHI as a harvest aid.

The residue levels in forage in trials conducted in the USA in accordance with US GAP were: < 0.025 (12), ≤ 0.05 (13), 0.05, 0.06 (four), 0.07, 0.08, 0.15, 0.28 and 1.8 mg/kg, expressed on a dry weight basis.

The Meeting estimated a maximum residue level for soya bean forage (green) of 2 mg/kg, an STMR of 0.05 mg/kg and a highest residue level of 1.8 mg/kg.

The residue levels in hay or fodder in trials conducted in accordance with US GAP were: < 0.025 (five), 0.04, ≤ 0.05 (four), 0.05, 0.1, 0.2 and 0.3 mg/kg, on a dry weight basis. The Meeting estimated a maximum residue level for soya bean fodder of 0.5 mg/kg, an STMR of 0.05 mg/kg and a highest residue level of 0.3 mg/kg.

#### *Sugar-beet tops*

Trials were conducted on beet and sugar-beet in the United Kingdom and the USA. The residue levels in sugar-beet tops in six trials conducted in accordance with US GAP were < 0.025 mg/kg, on a fresh weight basis. The Meeting estimated a maximum residue level of 0.2 mg/kg and an STMR of 0.11 mg/kg. On the basis of 23% dry matter and a highest residue level on a fresh weight basis of 0.025 mg/kg, the Meeting calculated the highest residue level on a dry weight basis to be 0.11 mg/kg. As there is no code for sugar-beet tops, the maximum residue level was recommended for fodder beet leaves and tops.

#### *Maize forage and fodder*

Trials were conducted in Italy and the USA. The residue levels in maize forage in trials in the USA conducted in accordance with US GAP were ≤ 0.025 (eight), 0.09, 0.6, 2 (two) and 3 (two) mg/kg on a dry weight basis. The Meeting estimated a maximum residue level for maize forage of 5 mg/kg, an STMR of 0.025 mg/kg and a highest residue level of 3 mg/kg.

The levels of residues in silage were mostly below the LOQ of 0.025 or 0.05 mg/kg, except in one trial in which levels up to 0.04 mg/kg were found.

The residue levels in maize fodder in trials in the USA conducted in accordance with US GAP were: ≤ 0.025 (eight), 0.03, 0.05, 0.06, 0.2, 1, 2 and 6 mg/kg on a dry weight basis. The Meeting estimated a maximum residue level for maize fodder of 10 mg/kg, an STMR of 0.025 mg/kg and a highest residue level of 6 mg/kg.

#### *Sorghum forage (green) and straw and fodder, dry*

In trials conducted in the USA in accordance with GAP, the residue levels in sorghum forage were: ≤ 0.025 (six), 0.025 (three), 0.04, 0.06 and 0.2 mg/kg. The Meeting estimated a maximum residue level for sorghum forage (green) of 0.3 mg/kg, an STMR of 0.025 mg/kg and a highest residue level of 0.2 mg/kg.

The residue levels in sorghum fodder or hay (whichever gave higher levels) in trials conducted in accordance with GAP were: < 0.025 (four), 0.03, 0.04, 0.05, 0.06 (two), 0.09, 0.1 and 0.2 mg/kg. The Meeting estimated a maximum residue level for sorghum straw and fodder, dry, of 0.3 mg/kg, an STMR of 0.035 mg/kg and a highest residue level of 0.2 mg/kg.

#### *Rice straw and fodder, dry*

The Meeting concluded that there were insufficient data for estimating a maximum residue level for rice straw and fodder, dry.

#### *Almond hulls*

In three trials conducted in the USA in accordance with GAP, the residue levels in almond hulls were < 0.01 mg/kg. The Meeting estimated maximum residue, STMR and highest residue values of 0.01 mg/kg.

#### *Cotton fodder*

The Meeting concluded that there were insufficient data for estimating a maximum residue level for cotton fodder.

### *Fate of residues during processing*

Numerous studies of residue levels after processing conducted in conjunction with supervised trials were submitted. Residue levels found after processing of raw agricultural commodities into animal feedstuffs are described in the section above. Some processed commodities for which maximum residue levels and STMR-Ps were estimated are also described in that section.

In this section, processing factors from raw commodities to processed food products and by-products are discussed. Information on processing was provided for orange, plum, grape, olive, tomato, sugar-beet, maize, sorghum, cotton-seed, sunflower seed and hop. Processing factors could not be reliably calculated for the processing of orange, plum, grape, tomato and sugar-beet because the paraquat residue levels in both raw commodities and processed products were all below the respective LOQs.

Processing factors were calculated for olive (oil), potato (crisps and granules), maize (milling fractions and oil), sorghum (milling fractions), cotton-seed (trash, gin products and oil), sunflower seed (oil) and hop (dried hop and beer) and are shown below.

| Commodity                         | Processing factor     | STMR-P (mg/kg) |
|-----------------------------------|-----------------------|----------------|
| Olive                             |                       | 0.05           |
| Unwashed olives before processing | 0.57                  |                |
| Washed olives before processing   | < 0.43                |                |
| Virgin oil                        | < 0.35                | 0.018          |
| Refined oil                       | < 0.35                | 0.018          |
| Potato                            |                       | 0.02           |
| Wet peel                          | > 1.9                 | 0.04           |
| Dry peel                          | > 11                  | 0.22           |
| Peeled potato                     | 0.27 <sup>a</sup>     | 0.01           |
| Crisps                            | > 0.95                | 0.02           |
| Granules                          | > 2.7                 | 0.05           |
| Maize                             |                       | 0.025          |
| Wet milling                       |                       |                |
| Coarse starch                     | < 0.25 <sup>a</sup>   | 0.006          |
| Starch                            | < 0.25 <sup>a</sup>   | 0.006          |
| Crude oil                         | < 0.25 <sup>a</sup>   | 0.006          |
| Refined oil                       | < 0.25 <sup>a</sup>   | 0.006          |
| Dry milling                       |                       |                |
| Germ                              | 0.3 <sup>a</sup>      | 0.0075         |
| Grits                             | 0.25–0.5 <sup>a</sup> | 0.0006–0.013   |
| Coarse meal                       | 1 <sup>a</sup>        | 0.025          |
| Meal                              | 0.5 <sup>a</sup>      | 0.013          |
| Flour                             | 1.5 <sup>a</sup>      | 0.038          |
| Crude oil                         | < 0.25 <sup>a</sup>   | 0.006          |
| Refined oil                       | < 0.05 <sup>a</sup>   | 0.001          |
| Sorghum                           |                       | 0.025          |

| Commodity                                      | Processing factor   | STMR-P (mg/kg)      |
|------------------------------------------------|---------------------|---------------------|
| Hulled grain                                   | 0.07 <sup>a</sup>   | 0.002               |
| Dry milled bran                                | 3.9                 | 0.097               |
| Coarse grits                                   | 0.17                | 0.004               |
| Flour                                          | 0.14                | 0.004               |
| Wet milled bran                                | 2.3                 | 0.058               |
| Starch                                         | 0.07                | 0.002               |
| Shorts                                         | 2.6                 | 0.065               |
| Germ                                           | 0.52 <sup>a</sup>   | 0.013               |
| Cotton (from cotton including trash and bolls) |                     |                     |
| Fuzzy seed                                     | 0.08                | 0.34                |
| Crude oil                                      | < 0.006             | 0.01 <sup>b</sup>   |
| Meal                                           | < 0.009             | 0.04                |
| Sunflower seed                                 |                     | 0.3                 |
| Hulls                                          | 2.8 <sup>a</sup>    | 0.64                |
| Meal                                           | 0.05 <sup>a</sup>   | 0.01                |
| Oil                                            | < 0.05 <sup>a</sup> | 0 <sup>b</sup>      |
| Hop                                            |                     |                     |
| Dry cones                                      | 1.2                 | 0.05 <sup>b</sup>   |
| Beer                                           | < 0.28              | 0.0001 <sup>c</sup> |

<sup>a</sup> Based on only one trial.

<sup>b</sup> Estimated from supervised trials

<sup>c</sup> Calculated from a factor of 0.0001

The STMR values for processed products from raw commodities with no residues or for which the results of many supervised trials were available were estimated on the basis of supervised trials.

In four trials in the USA, orange fruit was processed into juice, and the paraquat residues were measured; in all cases, the levels were below the LOQ of 0.01 mg/kg. The residue levels in *orange juice*, including those in trials conducted at rates higher than the maximum application rate, were all below the LOQ of 0.01 mg/kg. The Meeting estimated an STMR-P for orange juice of 0 mg/kg.

No residues of paraquat were found at levels above the LOQ of 0.05 mg/kg in *dried prunes* prepared from plums in two trials. The STMR-P for dried prunes was estimated to be 0 mg/kg.

In a number of trials, olives were processed into oil for analysis of residues. *Olive oil* prepared from olive fruits harvested directly from trees did not contain levels above the LOQ of 0.05 mg/kg. Most samples of olive oil prepared from olive fruits picked up from ground or sprayed directly did not contain paraquat residues at levels above the LOQ; however, in some samples, paraquat residues were found at levels up to 0.06 mg/kg, and fruit harvested at the same time contained 6.8 mg/kg of paraquat residues. As paraquat is unlikely to be transferred into oil owing to its chemical and physical characteristics, its STMR-P is calculated from the processing factor to be 0.018 mg/kg.

*Tomato juice* and *ketchup* prepared from tomato in trials conducted at an exaggerated rate did not contain paraquat residues at levels above the respective LOQ (0.005 mg/kg for juice and 0.025 mg/kg for ketchup). The STMR values for these products were estimated to be 0 mg/kg.

The residue levels in oil prepared from soya bean treated with paraquat as a harvest aid desiccant in accordance with GAP were below the LOQ of 0.01 mg/kg in five trials. The Meeting estimated an STMR-P for *soya bean oil* of 0.01 mg/kg.

The residue levels in cotton-seed oil, crude, were below the LOQ of 0.01 mg/kg in two trials. The Meeting estimated an STMR-P for *cotton-seed oil* of 0.01 mg/kg and decided to withdraw the previous recommendation for cotton-seed oil, edible.

The residue levels in *sunflower seed oil* obtained from sunflower seed in eight trials conducted at the maximum GAP were < 0.01 mg/kg. Oil obtained from sunflower seed in a trial at double the rate did not contain residues at levels above the LOQ of 0.01 mg/kg. The Meeting estimated an STMR-P for sunflower seed oil of 0 mg/kg and decided to withdraw the previous recommendation for sunflower seed oil, crude and edible.

The residue levels of paraquat in *cotton gin by-product* in trials for harvest aid uses were (including results for cotton harvested 13–17 days after treatment): 5.2, 5.3, 5.9, 6.2, 7.3, 8.0, 9.4, 11, 12 (two), 18, 23, 32, 34 and 69 mg/kg. The Meeting estimated an STMR-P of 10.2 mg/kg for cotton gin by-products.

As *maize flour* contained a higher concentration of paraquat residues than maize grain in one trial, the Meeting estimated a maximum residue level of 0.05 mg/kg.

### **Residues in animal commodities**

#### *Dietary burden of farm animals*

The Meeting estimated the dietary burden of paraquat residues for farm animals on the basis of the diets described in Appendix IX to the *FAO Manual* (FAO, 2002), by summing the contribution of each feed to the residue.

#### *Estimated maximum dietary burden of farm animals*

| Crop                  | Residue<br>(mg/kg) | Basis  | Group | Dry<br>matter<br>(%) | Residue/<br>Dry<br>matter<br>(mg/kg) | Dietary content<br>(mg/kg) |               |         | Residue contribution<br>(mg/kg) |               |         |
|-----------------------|--------------------|--------|-------|----------------------|--------------------------------------|----------------------------|---------------|---------|---------------------------------|---------------|---------|
|                       |                    |        |       |                      |                                      | Beef<br>cattle             | Dairy<br>cows | Poultry | Beef<br>cattle                  | Dairy<br>cows | Poultry |
| Sugar-beet tops       | 0.025              | HR     | AV    | 23                   | 0.11                                 |                            |               |         |                                 |               |         |
| Cotton-seed           | 2                  | HR     | SO    | 88                   | 2.27                                 | 25                         | 25            |         | 0.57                            | 0.57          |         |
| Cotton gin by-product | 10.2               | STMR-P |       | 90                   | 11.3                                 | 20                         | 20            |         | 2.27                            | 2.27          |         |
| Maize grain           | 0.025              | HR     | GC    | 88                   | 0.03                                 |                            |               | 80      |                                 |               | 0.023   |
| Maize forage          | 3                  | HR     | AF    |                      | 3                                    | 40                         | 50            |         | 1.2                             | 1.5           | –       |
| Potato, wet peel      | 0.04               | STMR-P | VR    | 15                   | 0.27                                 |                            |               |         |                                 |               |         |
| Sorghum grain         | 0.025              | HR     | GC    | 86                   | 0.03                                 |                            |               |         | –                               |               | –       |
| Sorghum forage        | 0.2                | HR     | AF    | –                    | 0.20                                 |                            |               |         | –                               |               | –       |
| Soya bean             | 0.41               | HR     | VD    | 89                   | 0.46                                 |                            |               | 20      |                                 |               | 0.092   |
| Soya bean, forage     | 1.8                | HR     | AL    | –                    | 1.8                                  | 15                         | 5             |         | 0.27                            | 0.09          | –       |
| Soya bean, hay        | 0.3                | HR     | AL    | –                    | 0.3                                  |                            |               |         | –                               |               | –       |
| Sunflower meal        | 0.011              | STMR-P | AL    | 92                   | 0.01                                 | –                          | –             | –       | –                               | –             | –       |
| Turnip tops           | 0.05               | HR     | VL    | 30                   | 0.17                                 |                            |               |         |                                 |               |         |
| Total                 |                    |        |       |                      |                                      |                            |               |         | 4.30                            | 4.43          | 0.11    |

*Estimated maximum dietary burden of farm animals*

| Crop                  | Residue<br>(mg/kg) | Basis  | Group | Dry<br>matter<br>(%) | Residue/<br>Dry<br>matter<br>(mg/kg) | Dietary content<br>(mg/kg) |               |         | Residue contribution<br>(mg/kg) |               |         |
|-----------------------|--------------------|--------|-------|----------------------|--------------------------------------|----------------------------|---------------|---------|---------------------------------|---------------|---------|
|                       |                    |        |       |                      |                                      | Beef<br>cattle             | Dairy<br>cows | Poultry | Beef<br>cattle                  | Dairy<br>cows | Poultry |
| Sugar-beet tops       | 0.025              | STMR   | AV    | 23                   | 0.11                                 |                            |               |         |                                 |               | –       |
| Cotton-seed           | 0.34               | STMR   | SO    | 88                   | 0.39                                 | 25                         | 25            |         | 0.098                           | 0.098         |         |
| Cotton gin by-product | 10.2               | STMR-P |       | 90                   | 11.3                                 | 20                         | 20            |         | 2.27                            | 2.27          |         |
| Maize grain           | 0.025              | STMR   | GC    | 88                   | 0.028                                |                            |               | 80      |                                 |               | 0.02    |
| Maize forage          | 0.025              | STMR   | AF    |                      | 0.03                                 | 40                         | 50            |         | 0.010                           | 0.013         | –       |
| Potato wet peel       | 0.55               | STMR-P | VR    | 15                   | 0.27                                 |                            |               |         |                                 |               |         |
| Sorghum grain         | 0.025              | STMR   | GC    | 86                   | 0.03                                 |                            |               |         | –                               |               | –       |
| Sorghum forage        | 0.025              | STMR   | AF    |                      | 0.03                                 |                            |               |         | –                               |               | –       |
| Soya bean             | 0.08               | STMR   | VD    | 89                   | 0.09                                 |                            |               | 20      |                                 |               | 0.02    |
| Soya bean, forage     | 0.05               | STMR   | AL    |                      | 0.05                                 | 15                         | 5             |         | 0.008                           | 0.003         | –       |
| Soya bean, hay        | 0.05               | STMR   | AL    |                      | 0.05                                 |                            |               |         | –                               |               | –       |
| Sunflower meal        | 0.011              | STMR-P | AL    | 92                   | 0.01                                 | –                          | –             | –       | –                               |               | –       |
| Turnip tops           | 0.025              | STMR   | VL    | 30                   | 0.08                                 |                            |               |         |                                 |               |         |
| Total                 |                    |        |       |                      |                                      |                            |               |         | 2.39                            | 2.38          | 0.04    |

The dietary burdens of paraquat for estimation of MRL and STMR values for animal commodities are: beef cattle, 4.30 and 2.39 ppm; dairy cattle, 4.43 and 2.38 ppm; and poultry, 0.11 and 0.04 ppm.

*Feeding studies*

In a study of metabolism in goats (see above), one goat was dosed at a rate equivalent to 100 mg/kg of total diet. This is considerably higher than the estimated maximum dietary burden for cattle of 4.30 or 4.43 mg/kg. At 100 mg/kg of diet, the maximum TRRs, expressed in paraquat ion equivalents, found in milk and edible goat tissues were 0.009 mg/kg in milk, 0.12 mg/kg in meat, 0.03 mg/kg in fat, 0.56 mg/kg in liver and 0.74 mg/kg in kidney. In milk, 75.9% of the radiolabel was identified with paraquat.

At the estimated maximum animal burden of 4.30 or 4.43 mg/kg, the levels of paraquat residues were calculated to be < 0.005 mg/kg in milk, 0.005 mg/kg in meat, 0.025 mg/kg in liver and 0.033 mg/kg in kidney. The Meeting estimated maximum residue levels of 0.005\* mg/kg for milks, 0.005 mg/kg for mammalian meat and 0.05 mg/kg for edible mammalian offal. These levels replace the previous recommendations for related animal commodities. The STMR values were estimated to be 0.00002 mg/kg for milk, 0.0003 mg/kg for meat and 0.0018 mg/kg for edible offal; and the highest residue level values were estimated to be 0.005 mg/kg for meat and 0.033 mg/kg for edible offal.

In the study of metabolism in hens (see above), birds were dosed at a rate equivalent to 30 mg/kg of total diet, which is considerably higher than the estimated maximum dietary burden for poultry of 0.11 mg/kg. At 30 mg/kg diet, the maximum TRRs, expressed in paraquat ion equivalents, found in eggs and edible chicken tissues were 0.18 mg/kg in egg yolk, 0.001 mg/kg in egg albumen, 0.05 mg/kg in meat, 0.05 mg/kg in fat and 0.09 mg/kg in liver.

At the estimated maximum animal burden of 0.11 mg/kg, the maximum residue levels were calculated to be far below the LOQ of 0.005 mg/kg in eggs and other tissues. The Meeting estimated the maximum residue levels to be 0.005\* mg/kg for eggs, poultry meat and edible poultry offal. The STMR and highest residue level values were estimated to be 0 for these commodities.



## DIETARY RISK ASSESSMENT

### *Long-term intake*

The IEDIs were calculated for the five GEMS/Food regional diets from the STMR values for fruit, vegetables, maize, sorghum, cotton-seed, sunflower, hops, tea and animal commodities and the STMR-P values for their processed products, as estimated by the current Meeting (Annex 3). The ADI is 0–0.005 mg/kg bw, and the calculated IEDIs were 2–5% of the ADI. The Meeting concluded that the intake of residues of paraquat resulting from uses considered by the current JMPR was unlikely to present a public health concern.

### *Short-term intake*

The IESTIs of paraquat by the general population and by children were calculated for commodities for which STMR or STMR-P values had been estimated by the current Meeting when information on consumption was available (Annex 4). The ARfD is 0.006 mg/kg; the calculated IESTIs for children up to 6 years range from 0 to 50% and those for the general population from 0 to 20% of the ARfD. The Meeting concluded that the short-term intake of residues of paraquat from uses considered by the current Meeting was unlikely to present a public health concern.

## 4.20 PHORATE (112)

### TOXICOLOGY

Phorate is the ISO approved name for phosphorothioic acid, *O*-diethyl *S*-(ethyl thio)methyl ester, which is an organophosphate insecticide that inhibits acetylcholinesterase activity and is a systemic and contact insecticide and acaricide. Phorate was first evaluated by the JMPR in 1977. In 1985, an ADI of 0–0.0002 mg/kg bw was established. Phorate was re-evaluated in 1994 when an ADI of 0–0.0005 mg/kg bw was established. In 1994, because it was reported in a limited study of metabolism in rats that < 40% of the administered dose was excreted, the Meeting requested adequate studies on absorption, for review in 1996. Such studies were received and the ADI established previously was confirmed.

Since the 1994 JMPR, a study of acute neurotoxicity and a 13-week study of neurotoxicity in rats have been submitted. The present Meeting re-evaluated phorate within the periodic review programme of the CCPR, using new data that had not been reviewed previously and relevant data from previous evaluations.

After oral administration of radiolabelled phorate to rats, 77% of the administered dose was recovered in the urine within 24 h after dosing. Faecal excretion accounted for approximately 12% of the administered dose. Over the total duration of the study (192 h), essentially the entire administered dose was eliminated by excretion.

Phorate was highly toxic when administered orally, dermally or by inhalation. The oral LD<sub>50</sub> values for rats were 3.7 mg/kg bw in males and 1.4 mg/kg bw in females. The dermal LD<sub>50</sub> values for rats were 9.3 mg/kg bw in males and 3.9 mg/kg bw in females. The LC<sub>50</sub>s for rats after exposure for 1 h were 0.06 and 0.011 mg/l of air in males and females respectively. Studies of dermal and eye irritation and of dermal sensitization were not performed owing to the high acute toxicity of phorate by skin contact.

The toxicological effects of phorate are associated with inhibition of acetylcholinesterase activity. Inhibition of acetylcholinesterase activity and clinical signs occurred at similar doses in rats, rabbits and dogs, while mice appeared to be somewhat less sensitive. The NOAELs for toxicologically significant inhibition of brain acetylcholinesterase activity were 0.05–0.07 mg/kg bw per day in 13-week and 2-year studies in rats and in 1-year studies in dogs. The NOAELs for clinical signs were generally higher. The Meeting noted that the dose–response curve for acetylcholinesterase inhibition is steep.

In an 18-month study in mice and in a 24-month study in rats, phorate did not increase the incidence of tumours or cause any non-neoplastic effects other than clinical signs secondary to inhibition of acetylcholinesterase activity.

Phorate was tested for genotoxicity in vitro and in vivo in an adequate battery of assays. In view of the lack of genotoxicity in vitro and in vivo and on the basis of the results of studies of carcinogenicity in rodents, the Meeting concluded that phorate is not likely to pose a carcinogenic risk to humans.

In a multigeneration study of reproductive toxicity in mice, the NOAEL was 1.5 ppm (equal to 0.30 mg/kg bw per day) on the basis of slightly reduced lactation indices in four out of the six litters at 3 ppm (equal to 0.60 mg/kg bw per day).

In a two-generation study of reproductive toxicity in rats, phorate showed effects on pup growth and mortality at maternally toxic doses. The NOAEL was 2 ppm (equal to 0.17 mg/kg bw per day) on the basis of decreased brain acetylcholinesterase activity, decreased parental and pup body weights and decreased pup survival at 4 ppm (equal to 0.35 mg/kg bw per day).

In a study of developmental toxicity in rats, the NOAELs for maternal and developmental toxicity with phorate were 0.3 mg/kg bw per day on the basis of mortality, cholinergic signs of toxicity, significantly decreased body weights and food consumption in the dams, decreased fetal body weights and delays in skeletal ossification at 0.4 mg/kg bw per day. No fetal malformations were produced, even at the lethal dose (0.4 mg/kg bw per day), the highest dose tested. The Meeting concluded that phorate is not teratogenic in rats.

Phorate was not embryotoxic, fetotoxic or teratogenic in rabbits at doses of up to and including 1.2 mg/kg bw per day, a dose that produced severe maternal toxicity. The NOAEL for maternal toxicity with phorate was 0.15 mg/kg bw per day on the basis of mortality observed at 0.5 mg/kg bw per day. The NOAEL for developmental toxicity was 1.2 mg/kg bw per day, the highest dose tested.

The Meeting concluded that the existing database on phorate was adequate to characterize the potential hazards to fetuses, infants and children.

In a study of acute neurotoxicity in rats treated by gavage, phorate at a dose of 1 mg/kg bw caused miosis in 2 out of 20 males and 5 out of 20 females, tremors in 2 out of 20 females, fasciculations, slightly impaired locomotion and splayed or dragging hindlimbs in one female and significant inhibition of brain and erythrocyte acetylcholinesterase activity in females (65%), but not in males (14–21%). No histopathological signs were observed. At 0.5 mg/kg bw, miosis was observed in 2 out of 20 males and 2 out of 20 females. Although miosis was observed in a small number of animals (and in 1 out of 20 controls) in the absence of inhibition of erythrocyte and brain acetylcholinesterase activity, it could not be dismissed as a compound-related effect. The NOAEL was 0.25 mg/kg bw on the basis of miosis.

Phorate did not cause acute delayed neurotoxicity in hens. Although measurements of neuropathy target esterase were not carried out, the Meeting noted that the dose used (approximately equal to the LD<sub>50</sub>) was sufficiently high to indicate that dietary exposure to phorate would not cause delayed polyneuropathy.

The mammalian and plant metabolites of phorate, phorate sulfone and phorate sulfoxide, had similar toxicity to the parent compound. In rats, the oral LD<sub>50</sub> values for these metabolites were 1.2–3.5 and 2.2–2.6 mg/kg bw, respectively. The NOAELs for inhibition of brain acetylcholinesterase activity were 0.80 ppm (equal to 0.08 and 0.06 mg/kg bw per day) for phorate sulfone and sulfoxide, respectively, in 90-day studies in rats.

Several cases of occupational and non-occupational poisoning in humans have been reported. The subjects showed typical cholinergic symptoms, including gastrointestinal effects, bradycardia and neurological effects (headache, giddiness, fatigue). Skin and eye irritation were also observed.

### Toxicological evaluation

An ADI of 0–0.0007 mg/kg bw was established on the basis of a overall NOAEL of 0.07 mg/kg bw per day for inhibition of brain acetylcholinesterase activity in rats and dogs and a safety factor of 100. This ADI includes the phorate metabolites, phorate sulfone and phorate sulfoxide.

An ARfD of 0.003 mg/kg bw was also established based on the NOAEL of 0.25 mg/kg bw for miosis in the study with single doses in rats. Although inhibition of acetylcholinesterase activity is a  $C_{\max}$ -dependent phenomenon, a safety factor of 100 was used in view of the steep dose–response curve and the slow recovery of brain acetylcholinesterase activity because of irreversibility of its inhibition. This ARfD includes the metabolites of phorate, phorate sulfone and phorate sulfoxide.

A toxicological monograph was prepared.

### Levels relevant to risk assessment

| Species | Study                                                       | Effect                                         | NOAEL                                                 | LOAEL                                      |
|---------|-------------------------------------------------------------|------------------------------------------------|-------------------------------------------------------|--------------------------------------------|
| Mouse   | 18-month study of toxicity and carcinogenicity <sup>a</sup> | Toxicity                                       | 3 ppm, equivalent to 0.45 mg/kg bw per day            | 6 ppm, equivalent to 0.90 mg/kg bw per day |
|         |                                                             | Carcinogenicity                                | 6 ppm, equal to 0.90 mg/kg bw per day <sup>d</sup>    | —                                          |
| Rat     | Multigeneration study of reproductive toxicity <sup>a</sup> | Parental and offspring toxicity                | 1.5 ppm, equal to 0.30 mg/kg bw per day               | 3 ppm, equal to 0.60 mg/kg bw per day      |
|         | 2-year study of toxicity and carcinogenicity <sup>a</sup>   | Toxicity                                       | 1 ppm, equal to 0.05 mg/kg bw per day                 | 3 ppm, equal to 0.16 mg/kg bw per day      |
|         |                                                             | Carcinogenicity                                | 6 ppm, equal to 0.32 mg/kg bw per day <sup>c, d</sup> | —                                          |
|         | Multigeneration reproductive toxicity <sup>a</sup>          | Parental and offspring toxicity                | 2 ppm, equal to 0.17 mg/kg bw per day                 | 4 ppm, equal to 0.35 mg/kg bw per day      |
|         | Developmental toxicity <sup>a</sup>                         | Embryo- and fetotoxicity and maternal toxicity | 0.3 mg/kg bw per day                                  | 0.40 mg/kg bw per day                      |
|         | Single-dose study <sup>c</sup>                              | Miosis                                         | 0.25 mg/kg bw                                         | 0.50 mg/kg bw per day                      |
| Rabbit  | 13-week study of neurotoxicity <sup>a</sup>                 | Neurotoxicity                                  | 0.07 mg/kg bw per day                                 | 0.3 mg/kg bw per day                       |
|         |                                                             |                                                |                                                       |                                            |
|         | Developmental toxicity <sup>a</sup>                         | Maternal toxicity                              | 0.15 mg/kg bw per day                                 | 0.50 mg/kg bw per day                      |
| Dog     | 1-year study of toxicity <sup>b</sup>                       | Embryo- and fetotoxicity <sup>a</sup>          | 1.2 mg/kg bw per day <sup>d</sup>                     | —                                          |
|         |                                                             | Toxicity                                       | 0.05 mg/kg bw per day                                 | 0.25 mg/kg bw per day                      |

<sup>a</sup> Diet

<sup>b</sup> Capsules

<sup>c</sup> Gavage

<sup>d</sup> Highest dose tested

### Estimate of acceptable daily intake for humans

0–0.0007 mg/kg bw

### Estimate of acute reference dose

0.003 mg/kg bw

### Studies that would provide information useful for the continued evaluation of the compound

Further observation in humans

***Critical end-points for setting guidance values for exposure to phorate****Absorption, distribution, excretion and metabolism in animals*

|                                                                             |                                                                                                                                                                         |
|-----------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Rate and extent of oral absorption                                          | Rapid, approximately 90% within 24 h                                                                                                                                    |
| Dermal absorption                                                           | Extensive based on acute toxicity                                                                                                                                       |
| Distribution                                                                | Rapid and extensive                                                                                                                                                     |
| Potential for accumulation                                                  | None                                                                                                                                                                    |
| Rate and extent of excretion                                                | 89% within 24 h; urinary excretion predominated (77%); faecal excretion (12%)                                                                                           |
| Metabolism in animals                                                       | Major pathway: cleavage of phosphorus–sulfur bond, methylation of the liberated thiol group and oxidation of the resulting divalent moiety to the sulfoxide and sulfone |
| Toxicologically significant compounds (plants, animals and the environment) | Parent, phorate sulfoxide and phorate sulfone                                                                                                                           |

*Acute toxicity*

|                                    |                                                                     |
|------------------------------------|---------------------------------------------------------------------|
| Rat, LD <sub>50</sub> , oral       | 3.7 mg/kg bw in males, 1.4 mg/kg bw in females                      |
| Rat, LD <sub>50</sub> , dermal     | 9.3 mg/kg bw in males, 3.9 mg/kg bw in females                      |
| Rat, LC <sub>50</sub> , inhalation | 0.06 mg/l of air in males (1-h), 0.011 mg/l of air (1-h) in females |
| Rabbit, skin irritation            | Highly toxic by skin contact — could not be tested                  |
| Rabbit, eye irritation             | Highly toxic by eye contact — could not be tested                   |
| Skin sensitization                 | Highly toxic by skin contact — could not be tested                  |

*Short-term studies of toxicity*

|                                  |                                                                       |
|----------------------------------|-----------------------------------------------------------------------|
| Target/critical effect           | Brain and erythrocyte acetylcholinesterase activity and miosis (rats) |
| Lowest relevant oral NOAEL       | 0.07 mg/kg bw per day                                                 |
| Lowest relevant dermal NOAEL     | No data                                                               |
| Lowest relevant inhalation NOAEC | No data                                                               |

*Genotoxicity*

Negative results in vivo and in vitro

*Long-term studies of toxicity and carcinogenicity*

|                        |                                                             |
|------------------------|-------------------------------------------------------------|
| Target/critical effect | Inhibition of erythrocyte and brain cholinesterase activity |
| Lowest relevant NOAEL  | 0.07 mg/kg per day (rat)                                    |
| Carcinogenicity        | Not carcinogenic in mice and rats                           |

*Reproductive toxicity*

|                                      |                                                                                 |
|--------------------------------------|---------------------------------------------------------------------------------|
| Reproduction target/critical effect  | Reduced pup growth at maternally toxic dose                                     |
| Lowest relevant reproductive NOAEL   | 2 ppm, equivalent to 0.17 mg/kg bw per day                                      |
| Developmental target/critical effect | Decreased pup weights and delayed ossification at maternally toxic doses (rats) |
| Lowest relevant developmental NOAEL  | 0.3 mg/kg bw per day (rats)                                                     |

*Neurotoxicity/delayed neurotoxicity*

|                                    |                                                                                     |
|------------------------------------|-------------------------------------------------------------------------------------|
| Single dose study of neurotoxicity |                                                                                     |
| Target/critical effect             | Signs consistent with acetylcholinesterase inhibition; no neuropathological effects |
| Relevant NOAEL                     | 0.25 mg/kg bw                                                                       |
| Delayed neuropathy                 | No delayed neurotoxicity in hens                                                    |

*Medical data*

Findings consistent with inhibition of acetylcholinesterase activity; no record of permanent sequelae

| <i>Summary</i> | <i>Value</i>      | <i>Study</i>                                                                                   | <i>Safety factor</i> |
|----------------|-------------------|------------------------------------------------------------------------------------------------|----------------------|
| ADI            | 0–0.0007 mg/kg bw | Rats and dogs, short- and long-term studies, inhibition of brain acetylcholinesterase activity | 100                  |
| ARfD           | 0–0.003 mg/kg bw  | Rats, single-dose study, miosis                                                                | 100                  |

## DIETARY RISK ASSESSMENT

### *Long-term intake*

The estimated theoretical maximum daily intakes in the five GEMS/Food regional diets, based on recommended MRLs, were in the range of 40–200% of the ADI (Annex 3). Further refinements of dietary intake estimates will be undertaken during the periodic review of phorate residues scheduled for 2005.

### *Short-term intake*

The Meeting established an ARfD for phorate of 0.003 mg/kg bw but was unable to finalize the risk assessment before the residue evaluation, scheduled for 2005, had been completed.

## 4.21 PIRIMICARB (101)

### TOXICOLOGY

Pirimicarb is the ISO approved common name for 2-dimethylamino-5,6-dimethylpyrimidin-4-yl dimethylcarbamate. It is a selective aphicide that is used extensively on a broad range of crops, including vegetable, cereal and orchard crops. The mode of action of pirimicarb is by inhibition of acetylcholinesterase activity.

Pirimicarb was evaluated by the JMPR in 1976, 1978 and 1982; an ADI of 0–0.02 mg/kg bw was established in 1983. Pirimicarb was reviewed by the present Meeting within the periodic review programme of CCPR, using new data not previously reviewed and relevant data from previous evaluations.

Kinetic studies in rats have demonstrated that pirimicarb administered orally to male and female rats is rapidly and extensively absorbed (> 70% of the administered dose) and widely distributed. Radioactivity from [<sup>14</sup>C]pyrimidinyl-labelled pirimicarb was excreted predominantly in the urine, while radioactivity from [<sup>14</sup>C]carbamoyl-labelled pirimicarb was excreted predominantly in expired air. Tissue retention of radioactivity was low. There were no pronounced sex differences in the routes or rates of excretion. Pirimicarb was extensively metabolized, giving rise to 24 metabolites, 17 of which were identified. The main metabolic pathway involves the loss of the carbamate moiety to produce a range of substituted hydroxypyrimidines, some of which are glucuronide conjugates.

The acute oral median LD<sub>50</sub> for pirimicarb was 152 mg/kg bw in male rats and 142 mg/kg bw in female rats, while the acute dermal median LD<sub>50</sub> of pirimicarb was > 2000 mg/kg in both male and female rats. The 4-h inhalation median LC<sub>50</sub> of pirimicarb in rats was 0.948 and 0.858 mg/l of air in males and females respectively. Pirimicarb is not irritating to the rabbit eye or skin. It does, however, have skin sensitizing potential under the conditions of the Magnusson & Kligman maximization test.

In a 21-day study of dermal toxicity in rats, there were no signs of irritation and no clinical signs of systemic toxicity, but there was a reduction in brain cholinesterase activity at 1000 mg/kg bw per day. The NOAEL was 200 mg/kg bw per day.

Acetylcholinesterase that has been inhibited by pirimicarb is rapidly reactivated (both in vivo and in vitro). This property hampers the reliable determination of acetylcholinesterase inhibition in erythrocytes and brain in treated animals, and special attention must be given to crucial methodological features (e.g. time between sampling and measurement, sample temperature and dilution). Consequently, the most reliable indicators of an effect are clinical signs, which usually occur when acetylcholinesterase inhibition is > 50% at nerve terminals.

In experiments with multiple doses, common toxicological targets are blood and acetylcholinesterase.

Three dietary studies of up to 90 days in duration have been conducted in rats. In the first study (in which animals were given diets containing pirimicarb at a concentration of 250 or 750 ppm for 90 days) there were no adverse clinical, haematological or other pathological effects. A reduction in plasma cholinesterase activity was seen at 750 ppm, providing evidence for the absorption of the compound from the intestinal tract. In the second study (in which animals were given diets containing pirimicarb at a concentration of 250 or 750 ppm for 8 weeks) a clear reduction in body-weight gain was seen at 750 ppm, with a slight reduction at 250 ppm. These growth reductions were completely reversible after an 8-week recovery period. In the final study (in which animals were given diets containing pirimicarb at a concentration of 100, 175, 250 or 750 ppm for 8 weeks) there were no adverse clinical effects. A reduction in body-weight gain and food consumption was seen at 750 ppm. Owing to the effect on body-weight gain in the second study at 250 ppm, the Meeting concluded that the overall NOAEL in short-term studies in rats was 175 ppm, equivalent to 17.5 mg/kg bw per day.

Reports of three studies of 13–16 weeks in duration in dogs were available. In the first study, beagle dogs were given diets delivering pirimicarb at a dose of 0, 4, 10 or 25 mg/kg bw per day for at least 90 days. Body weight was reduced at the highest dose and plasma cholinesterase activity was reduced at 10 and 25 mg/kg bw per day. Bone-marrow changes, indicative of increased erythropoiesis, were observed in the terminal blood films in all treatment groups. Three out of 32 animals (two receiving 25 mg/kg bw per day and one receiving 10 mg/kg bw per day) developed anaemia. Two dogs of each sex per group were killed after 90 days (one male only in the group receiving 25 mg/kg bw per day, as one had been killed after 10–11 weeks) and the remainder were allowed to recover untreated for 28 days. Partial recovery from the bone-marrow changes was evident at 28 days after cessation of treatment. A NOAEL for this study was not identified, therefore a second study with diets delivering pirimicarb at a dose of 0.4, 1.8 and 4 mg/kg bw per day for at least 90 days was conducted. An additional group received pirimicarb at 4 mg/kg bw per day for 180 days. There were no adverse clinical or pathological effects, but dogs at 4 mg/kg bw per day showed evidence of increased erythropoietic activity in the bone marrow. The NOAEL was 1.8 mg/kg bw per day. In the third study, foxhounds were given diets delivering pirimicarb at a dose of 0, 2 or 25/50 mg/kg bw per day for 16 weeks, followed by a 7-week recovery period. The dose of 25 mg/kg bw per day was increased to 50 mg/kg bw per day from week 8. Anaemia and reticulocytosis developed in dogs receiving a dose of 50 mg/kg bw per day and bone-marrow changes, characterized by an increase in normoblasts and hypoplasia, were observed. Both the anaemia and bone-marrow changes were reversible when the dose was reduced to 25 mg/kg bw per day, or upon cessation of treatment. The NOAEL in this study in dogs was 2 mg/kg bw per day.

In addition, there were two 2-year dietary studies in dogs and a more recent, guideline-compliant, 1-year study in which pirimicarb was administered in capsules. In the first 2-year dietary study, designed to reproduce and characterize the anaemia, two out of four unrelated beagles had an immune haemolytic anaemia when exposed to pirimicarb at a dose of 25 or 50 mg/kg bw per day for at least 3 months. Dogs at  $\leq 2$  mg/kg bw per day did not show such effects. The anaemia was completely reversible after withdrawal of the compound. Other dogs in the same study showed no haematological changes when exposed to pirimicarb at a dose of up to 50 mg/kg bw per day for 2 years. In the second dietary study, pirimicarb was administered

at a dose of 0.4, 1.8 or 4 mg/kg bw per day for 2 years. There were no adverse changes in growth rate, blood and urine clinical chemistry, organ weights or histopathology. At 4 mg/kg bw per day, there were reductions in haemoglobin concentration and erythrocyte volume fraction in males and a slight increase in the erythroid to myeloid ratio in two females. No adverse changes were detected in the bone marrow. None of the dogs developed overt anaemia. In the most recent study, groups of beagles were dosed orally with gelatine capsules containing pirimicarb delivering a dose of 0, 3.5, 10 or 25/35 mg/kg bw per day for 1 year. The highest dose of 35 mg/kg bw per day could not be sustained owing to adverse clinical signs in week 1, so from week 4 onwards, the dose was reduced to 25 mg/kg bw per day. One female dog receiving 25 mg/kg bw per day was killed humanely in week 36 after significant body-weight loss and the development of anaemia. The haematological changes in this dog were characterized by increased erythropoietic activity in the bone marrow and by histological changes consistent with increased erythrocyte breakdown. No other dog showed any treatment-related haematological changes; however, increased haemosiderin deposition was observed in the liver and spleen of dogs at 25 mg/kg bw per day. The NOAEL in this study was 3.5 mg/kg bw per day; this value is very close to the LOAEL of 4 mg/kg bw identified in three other experiments. The overall NOAEL was 2 mg/kg bw per day in dogs.

The carcinogenic potential of pirimicarb has been assessed in feeding studies of 80 and 96 weeks' duration in mice and 104 weeks in rats. In both species, the highest dose tested induced moderate levels of toxicity. Two studies of carcinogenicity were conducted in Alderley Park Swiss-derived mice and one in C57 black Alderley Park mice; however, one of the studies in Swiss-derived mice, a study that pre-dated the establishment of good laboratory practice (GLP), was not considered adequate for assessing the carcinogenic potential of pirimicarb, owing to a high incidence of respiratory disease. Similarly, three pre-GLP studies in rats were not adequate for carcinogenicity assessment owing to high incidences of respiratory disease.

In Alderley Park Swiss-derived mice given diets containing pirimicarb at a concentration of 0, 0, 200, 400 or 1600 ppm for up to 96 weeks, there was a significant increase in the incidence of liver tumours [classified as type A (hyperplastic nodules and benign neoplasms) and type B nodules (which showed characteristics of malignancy)] at the highest dose (equivalent to approximately 240 mg/kg bw per day), with no evidence of nodule induction at lower doses. The incidence of liver nodules was above the historical control range for the test laboratory. This finding was not confirmed in C57 black Alderley Park mice given diets containing pirimicarb at a concentration of 0, 50, 200 or 700 ppm for at least 80 weeks, where there was no evidence that liver tumours induced by pirimicarb at doses of up to 700 ppm (equal to approximately 94 and 130 mg/kg bw per day in males and females, respectively). Thus, the significant response was only seen at a very high dose and after a prolonged exposure time in a mouse strain with a high and variable background incidence of liver tumours.

Also in Alderley Park Swiss-derived mice, the incidence of pulmonary adenoma was significantly increased in both sexes at the highest dose, but with no significant response at lower doses. Concurrent and historical control data indicate a high and variable spontaneous background incidence of pulmonary adenomas in this strain of mouse. Given the overall variability in the incidence of pulmonary adenoma in these mice, the observation of an increased tumour incidence at the highest dose does not give cause for concern in terms of cancer risk. A small, statistically significant, increase in the incidence of pulmonary adenoma was also observed in female (but not male) C57 black Alderley Park mice at the highest dose tested, with no evidence of pulmonary adenoma induction at lower doses. In contrast to Swiss-derived mice, C57 black mice have a low spontaneous background incidence of pulmonary adenoma. Therefore, the occurrence of these tumours is considered to be treatment-related. The absence of a significant response in male mice could be a chance difference in the incidence of an uncommon tumour type. The Meeting concluded that oral administration of pirimicarb at a dose of up to 700 ppm, equal to 94 and 130 mg/kg bw per day for males and females, respectively, for at least 80 weeks produced a small increase in the incidence of benign lung tumours in females, but not in males. The NOAEL for non-neoplastic effects was 50 ppm, equal to 6.7 mg/kg bw per day, on the basis of slight haematological changes at 200 ppm, equal to 26.6 mg/kg bw per day in the 80-week study.

A 2-year study in rats showed that dietary administration of pirimicarb at 0, 75, 250 or 750 ppm resulted in reduced body-weight gains and food consumption in both sexes at 750 ppm, indicating that a maximum tolerated dose had been achieved. There was also a slight reduction in body-weight gain at 250 ppm in females. There were increases in plasma cholesterol at all observation times at 750 ppm, at weeks 13 and 26 at 250 ppm and (in females only) at week 13 at 75 ppm. Plasma concentrations of triglycerides were increased at 750 ppm in males at weeks 52 and 78 and in females at weeks 13 and 26. Males fed diets containing pirimicarb at 750 ppm showed a small increase in incidence and severity of necrosis in the brain. The significance of this is equivocal, but could not be dismissed as being incidental to treatment with pirimicarb. Females fed diets containing pirimicarb at 750 ppm showed an increased severity of sciatic nerve demyelination and an increased severity and incidence of voluntary muscle degeneration that were considered to be an exacerbation of a spontaneous age-related change. Overall, the findings in the brain, sciatic nerve and voluntary muscle were minor, confined to the highest dose and did not elicit any clinical signs of increased neurological dysfunction. Plasma cholinesterase activity was slightly reduced in females at 250 and 750 ppm, demonstrating the absorption of the test substance, but brain and erythrocyte cholinesterase activities were not affected at any dose. The NOAEL for non-neoplastic effects was 75 ppm, equal to 3.7 mg/kg bw per day, on the basis of reductions in body weights and increases in plasma cholesterol and triglycerides at 250 ppm, equal to 12.3 mg/kg bw per day. There was an overall higher, but non-significant incidence in the number of male rats with tumours at 250 and 750 ppm. This reflected an increased incidence of males with multiple tumours at 250 ppm and of males with single tumours at 750 ppm. There were also small increased incidences of astrocytoma of the brain in all treated groups and in females at 750 ppm, but these were not statistically significant and no dose-response relationship was evident. As there was a decreased incidence of males with multiple tumours at 750 ppm and there were no consistent effects across doses, the Meeting concluded that pirimicarb did not induce a carcinogenic response in any tissue.

The Meeting concluded that pirimicarb had no clear carcinogenic potential in mice or rats. Liver tumours were not consistently found in the two studies in mice, while the benign lung tumours were found only at the highest dose and with clear evidence for a threshold. There were no compound-related increases in the incidences of any tumour type in rats.

Pirimicarb was tested for genotoxicity in an adequate range of studies, both in vitro and in vivo. The results observed were largely negative. A small increase in mutant frequency in the assay for mutation in L5178Y mammalian cells, in the presence of metabolic activation, was considered not to be a significant alert for genotoxicity. Pirimicarb has shown no evidence of genotoxic potential in several test systems in vivo. The Meeting concluded that pirimicarb is unlikely to pose a genotoxic risk to humans.

Because the results of the studies of carcinogenicity in rodents were judged not to provide evidence of carcinogenic potential, an evaluation supported by the lack of genotoxic potential, the Meeting concluded that pirimicarb is unlikely to pose a carcinogenic risk to humans.

In a two-generation study of reproductive toxicity in rats, the NOAEL for adult rats and for their offspring was 200 ppm, equal to 23 mg/kg bw per day in adults, on the basis of systemic toxicity in the parental rats and reduced body-weight gain in the parental rats and the offspring at a dose of 750 ppm, equal to 88 mg/kg bw per day; no other signs of reproductive toxicity were observed at this dose, the highest tested. In studies of developmental toxicity in rats, the NOAEL for foetal toxicity and maternal toxicity was 25 mg/kg bw per day on the basis of reduced fetal weight and maternal body-weight gains at 75 mg/kg bw per day. In studies of developmental toxicity in rabbits, the NOAEL for fetal and developmental toxicity was 60 mg/kg bw per day, the highest dose tested, and the NOAEL for maternal toxicity for 10 mg/kg bw per day, on the basis of reduced food consumption and body-weight gains at 60 mg/kg bw per day. The results from the two studies of developmental toxicity and the study of reproductive toxicity demonstrated that fetuses and pups were not more susceptible than adults to toxicity caused by pirimicarb.

In a study of acute neurotoxicity in rats, a single oral administration of pirimicarb at 110 mg/kg bw per day by gavage resulted in early mortalities, adverse clinical signs and reductions in brain, erythrocyte and plasma cholinesterase activities. These clinical and enzyme activity changes were transient and were not



associated with histopathological changes in the nervous system. At a dose of 40 mg/kg bw, there was evidence of toxicity seen as a single mortality, transient adverse clinical signs in a few rats and reduced motor activity on day 1. Plasma cholinesterase activity was reduced, but this observation was not accompanied by biologically significant reductions in brain or erythrocyte cholinesterase activity at this dose. The Meeting concluded that the NOAEL for acute neurotoxic potential was 10 mg/kg bw per day and this value formed the basis for the ARfD. The acute toxic effects of pirimicarb are due to inhibition of acetylcholinesterase activity at nerve terminals. Inhibition of acetylcholinesterase by carbamates (such as pirimicarb) and organophosphates involves the carbamoylation or phosphorylation of the active site on the enzyme. Plasma cholinesterase is inhibited by a similar mechanism; therefore, although this is a toxicologically irrelevant target, its inhibition serves as an indicator of exposure and a surrogate for the response of acetylcholinesterase. The degree of enzyme inhibition is dependent on the concentration of inhibitor, a property that is particularly significant for carbamates because of the short occupation half-life at the active site of the enzyme (a few minutes, both in vitro and in vivo). Consequently, plasma cholinesterase activity was inhibited after a single dose of pirimicarb at 25 mg/kg bw by gavage, but not after dietary exposure corresponding to a daily dose of about 40 mg/kg bw, when the  $C_{max}$  would have been lower.

In a 90-day study of neurotoxicity, rats fed diets containing pirimicarb at a concentration of 250 or 1000 ppm resulted in toxicity evident as reduced growth and food consumption or utilization. There were no treatment-related effects on the functional observational battery, motor activity, cholinesterase and neurotoxic esterase activities or neuropathology. The NOAEL for neurotoxicity in this study was 1000 ppm, equal to 77 mg/kg bw per day, the highest dose tested.

Studies of toxicity have been conducted on a number of metabolites of pirimicarb: three carbamate metabolites, three hydroxypyrimidine metabolites and three guanidine metabolites. The acute toxicities of two carbamates (the desmethyl pirimicarb and the desmethylformamido pirimicarb metabolites) were of the same order as that of pirimicarb itself, whereas the  $LD_{50}$  values of all the other seven metabolites were less or considerably less than that of pirimicarb itself. In addition, some of these metabolites tested in studies of toxicity with repeated doses and some to assays for genotoxicity. Desmethyl pirimicarb and desmethylformamido pirimicarb had effects on cholinesterase that were similar to those caused by pirimicarb itself and are included in the residue definition, since they occur in plants. In 28- and 90-day studies of toxicity in rats, the hydroxypyrimidine metabolite, 2-dimethylamino-5,6-dimethylpyrimidin-4-ol (and, by implication, its mammalian metabolite, 5,6-dimethyl-2-(methylamino)pyrimidin-4-ol) was of low toxicity; the NOAEL was 240 ppm, equal to 19.5 mg/kg bw per day, on the basis of blood chemistry changes at 800 ppm, equal to 65.6 mg/kg bw per day. NOAELs could not be identified because testing was restricted to single doses in the cases of desmethyl pirimicarb (100 mg/kg bw per day for 2 weeks) and desmethylformamido pirimicarb (25 mg/kg bw per day for 2 weeks). Each of these metabolites caused slight hypochromia (reduced haemoglobin concentrations per cell). Genotoxicity tests were conducted with the hydroxypyrimidines, 2-dimethylamino-5,6-dimethylpyrimidin-4-ol and 5,6-dimethyl-2-(methylamino)pyrimidin-4-ol. Both metabolites, like pirimicarb itself, produced some weak evidence of mutagenic effects in the assay in mouse lymphoma cells, but not in other assays. The Meeting concluded that, within the limitations of studies conducted (short-term and only in rats), desmethyl pirimicarb and desmethylformamido pirimicarb have toxicological profiles similar to that of pirimicarb itself.

The Meeting concluded that the existing database on pirimicarb was adequate to characterize the potential hazards to fetuses, infants and children.

Production workers have been reported to show inhibition of plasma and erythrocyte cholinesterase activity of sufficient severity to result in their movement to other work areas.

### ***Toxicological evaluation***

An ADI of 0–0.02 mg/kg bw was established for pirimicarb and its dimethyl carbamate metabolites on the basis of the overall NOAEL of 2 mg/kg bw per day in 90-day and 2-year studies in dogs treated by dietary administration and with a safety factor of 100.

The Meeting established an ARfD of 0.1 mg/kg bw for pirimicarb on the basis of a NOAEL of 10 mg/kg bw in a study of acute neurotoxicity in rats. Although a reduced safety factor would be supported by the reversibility of clinical signs and the  $C_{\max}$ -dependency of the effects, a safety factor of 100 was used in consideration of the steep dose–response curve (indicated by a mortality at the LOAEL) and the lack of reliable measurement of acetylcholinesterase inhibition. Haematotoxicity in dogs was also considered as a possible end-point for an ARfD; however, in one study in dogs haematological parameters were measured during treatment before the onset of anaemia, indicating that this condition did not occur after a single dose.

A toxicological monograph was prepared

#### *Levels relevant to risk assessment*

| Species | Study                                                                      | Effect                     | NOAEL                                              | LOAEL                                   |
|---------|----------------------------------------------------------------------------|----------------------------|----------------------------------------------------|-----------------------------------------|
| Mouse   | 18-month and 21-month studies of toxicity and carcinogenicity <sup>a</sup> | Toxicity                   | 50 ppm, equal to 6.7 mg/kg bw per day              | 200 ppm, equal to 27 mg/kg bw per day   |
|         |                                                                            | Carcinogenicity            | 200 ppm, equal to 37 mg/kg bw per day              | 700 ppm, equal to 94 mg/kg bw per day   |
| Rat     | 24-month study of toxicity and carcinogenicity <sup>a</sup>                | Toxicity                   | 75 ppm, equal to 3.7 mg/kg bw per day              | 250 ppm, equal to 12.3 mg/kg bw per day |
|         |                                                                            | Carcinogenicity            | 750 ppm, equal to 37 mg/kg bw per day <sup>c</sup> | —                                       |
|         | Two-generation study of reproductive toxicity <sup>a</sup>                 | Parental toxicity          | 200 ppm, equal to 22 mg/kg bw per day              | 750 ppm, equal to 88 mg/kg bw per day   |
|         |                                                                            | Offspring toxicity         | 200 ppm, equal to 23 mg/kg bw per day              | 750 ppm, equal to 88 mg/kg bw per day   |
|         | Developmental toxicity <sup>b</sup>                                        | Maternal toxicity          | 25 mg/kg bw per day                                | 75 mg/kg bw per day                     |
|         |                                                                            | Embryo- and fetotoxicity   | 25 mg/kg bw per day                                | 75 mg/kg bw per day                     |
|         | Single-dose neurotoxicity <sup>b</sup>                                     | Neurotoxicity              | 10 mg/kg bw                                        | 40 mg/kg bw per day                     |
| Rabbit  | 3-month study of neurotoxicity <sup>a</sup>                                | Neurotoxicity              | 1000 ppm, equal to 81 mg/kg per day <sup>c</sup>   | —                                       |
|         |                                                                            | Neurotoxicity              | 1000 ppm, equal to 81 mg/kg per day <sup>c</sup>   | —                                       |
|         | Developmental toxicity <sup>b</sup>                                        | Maternal toxicity          | 10 mg/kg bw per day                                | 60 mg/kg bw per day                     |
| Dog     | 90-day and 2-year studies of toxicity <sup>a</sup>                         | Embryo and foetal toxicity | 60 mg/kg bw per day <sup>c</sup>                   | —                                       |
|         |                                                                            | Toxicity                   | 2 mg/kg bw per day                                 | 4 mg/kg bw per day                      |

<sup>a</sup> Dietary administration

<sup>b</sup> Gavage administration

<sup>c</sup> Highest dose tested

#### *Estimate of acceptable daily intake for humans*

0–0.02 mg/kg bw

#### *Estimate of acute reference dose*

0.1 mg/kg bw

#### *Studies that would provide information useful to the continued evaluation of the compound*

## Further observations in humans

***Critical end-points for setting guidance values for exposure to pirimicarb****Absorption, distribution, excretion and metabolism in animals*

|                                                                         |                                                                                                                                                                                  |
|-------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Rate and extent of oral absorption                                      | Rapid; > 80% absorbed                                                                                                                                                            |
| Dermal absorption                                                       | No study of direct dermal absorption available, but brain cholinesterase activity was inhibited after application of pirimicarb to rat skin, indicating absorption by this route |
| Distribution                                                            | Distributed throughout the body; highest concentrations in liver and fat                                                                                                         |
| Potential for accumulation                                              | Low, owing to rapid excretion                                                                                                                                                    |
| Rate and extent of excretion                                            | Rapid, > 80 % excretion within 24 h                                                                                                                                              |
| Metabolism in animals                                                   | Extensive                                                                                                                                                                        |
| Toxicologically significant compounds (animals, plants and environment) | Parent and the metabolites desmethyl pirimicarb and desmethylformamido pirimicarb                                                                                                |

*Acute toxicity*

|                                    |                                          |
|------------------------------------|------------------------------------------|
| Rat, LD <sub>50</sub> , oral       | 142 mg/kg bw                             |
| Rat, LC <sub>50</sub> , inhalation | 0.858 mg/l (4 h)                         |
| Rabbit, LD <sub>50</sub> , dermal  | > 2000 mg/kg bw                          |
| Rabbit, skin irritation            | Not irritating                           |
| Rabbit, eye irritation             | Not irritating                           |
| Skin sensitization                 | Sensitizing (Magnusson and Kligman test) |

*Short-term studies of toxicity*

|                                  |                                                                             |
|----------------------------------|-----------------------------------------------------------------------------|
| Target/critical effect           | Body-weight gain decrement, haemolytic anaemia or cholinesterase inhibition |
| Lowest relevant oral NOAEL       | 1.8 mg/kg bw per day: (3-month study in dogs)                               |
| Lowest relevant dermal NOAEL     | 2000 mg/kg bw per day (21-day study in rats)                                |
| Lowest relevant inhalation NOAEC | No data available                                                           |

|                     |                                                                                  |
|---------------------|----------------------------------------------------------------------------------|
| <i>Genotoxicity</i> | No genotoxic potential: negative in vivo, positive results in one study in vitro |
|---------------------|----------------------------------------------------------------------------------|

*Long-term studies of toxicity and carcinogenicity*

|                        |                                                                                              |
|------------------------|----------------------------------------------------------------------------------------------|
| Target/critical effect | Blood/anaemia, increased plasma lipids                                                       |
| Lowest relevant NOAEL  | 2 mg/kg bw per day (24-month study in dogs)<br>3.7 mg/kg bw per day (24-month study in rats) |

|                        |                                                                                                                                                                             |
|------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <i>Carcinogenicity</i> | Benign lung tumours in mice induced by a non-genotoxic mode of action; a clear NOAEL was identified; therefore pirimicarb is unlikely to pose a carcinogenic risk to humans |
|------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

*Reproductive toxicity*

|                                      |                                                                      |
|--------------------------------------|----------------------------------------------------------------------|
| Reproductive target/critical effect  | Reduced parental and offspring body weight, clinical signs           |
| Lowest relevant reproductive NOAEL   | 23 mg/kg bw per day                                                  |
| Developmental target/critical effect | Not teratogenic; reduced fetal body weight at maternally toxic doses |
| Lowest relevant developmental NOAEL  | 25 mg/kg bw per day (rat)                                            |

*Neurotoxicity/delayed neurotoxicity*

|                                    |                                                                                                                             |
|------------------------------------|-----------------------------------------------------------------------------------------------------------------------------|
| Target/critical effect             | Nervous system/cholinergic signs                                                                                            |
| Lowest relevant NOAEL              | 10 mg/kg bw                                                                                                                 |
| <i>90-day neurotoxicity</i>        |                                                                                                                             |
| Target/critical effect             | Nervous system/cholinergic signs                                                                                            |
| Lowest relevant NOAEL              | 77 mg/kg bw per day                                                                                                         |
| <i>Other toxicological studies</i> | Desmethyl pirimicarb and desmethylformamido pirimicarb inhibited acetylcholinesterase activity in rats (no studies in dogs) |
| <i>Medical data</i>                | There have been a few reports of cholinesterase inhibition in workers exposed during manufacture.                           |

| <i>Summary</i> | <i>Value</i>    | <i>Study</i>                                                                         | <i>Safety factor</i> |
|----------------|-----------------|--------------------------------------------------------------------------------------|----------------------|
| ADI            | 0–0.02 mg/kg bw | Dog; haematological changes in short- and long-term studies                          | 100                  |
| ARfD           | 0.1 mg/kg bw    | Rat; mortality and clinical signs of neurotoxicity in a study of acute neurotoxicity | 100                  |

## DIETARY RISK ASSESSMENT

### *Long-term intake*

The estimated theoretical maximum daily intakes in the five GEMS/Food regional diets, based on recommended MRLs, were in the range of 3–20% of the ADI (Annex 3). The Meeting concluded that the long-term intake of residues of pirimicarb resulting from uses that have been considered by the JMPR is unlikely to present a public health concern.

### *Short-term intake*

The Meeting established an ARfD of 0.1 mg/kg bw for pirimicarb but was unable to finalize the risk assessment before the residue evaluation, scheduled for 2006, had been completed.

## 4.22 PIRIMIPHOS-METHYL (086)

### RESIDUE AND ANALYTICAL ASPECTS

Pirimiphos-methyl was evaluated for residues by the 2003 JMPR within the CCPR periodic review programme. As no data were reported on the storage stability in animal tissues or eggs, the JMPR recommended withdrawal of the CXLs for eggs and meat (from mammals other than marine mammals). Data on the storage stability of pirimiphos-methyl in animal tissues, milk and eggs were provided to the present Meeting.

### *Stability of residues in stored analytical samples*

Pirimiphos-methyl residues at 0.5 mg/kg were shown to be stable for up to 12 months in beef muscle, liver, kidney, fat and milk and hens' eggs stored below – 18 °C.

***Residues in animal commodities***

The 2003 JMPR calculated the dietary burden of pirimiphos-methyl for estimated MRLs and STMR values for animal commodities as 6.4 and 2.1 mg/kg for beef cattle, 5.6 and 2.9 mg/kg for dairy cattle and 6.3 and 2.1 mg/kg for poultry, respectively. In one study submitted to the 2003 Meeting, the residue levels were below the LOQ (0.01 mg/kg) in heart, liver, kidney, fat and pectoral muscle from cows fed diets containing 0, 5, 15 or 50 ppm (dry weight basis) of pirimiphos-methyl for 30 days. Adductor muscle from one of three cows at the highest feeding level contained detectable residues (0.02 mg/kg). In another study submitted to the previous Meeting, eggs from hens receiving 32 ppm pirimiphos-methyl for 7 days contained residues at a maximum of 0.01 mg/kg. No detectable residues were found in leg or breast muscle.

***Maximum residue levels***

The Meeting agreed that it is unlikely that pirimiphos-methyl residues would remain in tissues of cows fed commodities treated with the insecticide, and recommended a maximum residue level of 0.01\* mg/kg and STMR and highest residue values of 0 mg/kg for pirimiphos-methyl in edible offal (mammalian) and meat (fat) from mammals, other than marine mammals. For calculating dietary intake, the Meeting also recommended an STMR and a highest residue level of 0 mg/kg for pirimiphos-methyl in muscle and fat from mammals other than marine mammals.

The Meeting agreed that it is unlikely that pirimiphos-methyl residues would remain in poultry tissues after birds have been fed commodities treated with the insecticide, and recommended a maximum residue level of 0.01\* mg/kg and STMR and highest residue values of 0 mg/kg for pirimiphos-methyl in poultry meat and poultry edible offal. For estimating dietary intake, the Meeting also recommended STMR and highest residue values of 0 for pirimiphos-methyl in poultry muscle and fat.

Pirimiphos-methyl was detected in eggs of hens at the highest feeding level, which corresponded to five times the dietary burden of poultry for MRL estimation. The Meeting recommended maximum and highest residue levels of 0.01 mg/kg for pirimiphos-methyl in eggs. As the dietary burden for STMR corresponds to 15 times the feeding level, the Meeting agreed to recommend an STMR of 0 mg/kg for eggs.

**DIETARY RISK ASSESSMENT*****Long-term intake***

The Meeting agreed that the STMR of 0 mg/kg estimated by the present Meeting for pirimiphos methyl in animal commodities will not affect the IEDIs calculated by the 2003 JMPR, which concluded that the long-term intake of residues of pirimiphos methyl is unlikely to present a public health concern.

***Short-term intake***

The IESTIs of pirimiphos-methyl by the general population and by children were calculated for commodities for which highest residue levels were estimated by the current Meeting (Annex 4). For all the commodities, the IESTI was 0–0.08 µg/kg bw. Although it might be necessary, no ARfD has yet been established for pirimiphos methyl, and the short-term risk assessment could not be finalized.

## 4.23 PROCHLORAZ (142)

### RESIDUE AND ANALYTICAL ASPECTS

Prochloraz is a broad-spectrum imidazole fungicide that is active against a range of diseases in field crops, fruit and vegetables and is also used on mushrooms, as a post-harvest treatment of fruit and as a seed treatment on cereals. It was evaluated initially in 1983 for residues and toxicology; six additional reviews of residues were carried out between 1985 and 1992, and a periodic toxicological review in 2001. The CCPR at its Twenty-ninth Session scheduled prochloraz for periodic review with respect to residues, and it was included on the 2004 JMPR agenda. The Meeting received information on the metabolism and environmental fate of prochloraz, methods of residue analysis, freezer storage stability, national registered use patterns, the results of supervised residue trials, farm animal feeding studies, fate of residues in processing and national MRLs. Information on GAP and national MRLs was submitted by Australia and Japan.

The formulations that are available include emulsifiable concentrates, suspo-emulsions and wettable powders. A number of formulations with other fungicides are also available, mainly for use on cereal crops. Wettable powder formulations of a 4:1 complex of prochloraz and manganese chloride are available for use on crops susceptible to phytotoxicity.

In this evaluation, the term 'total prochloraz' refers to the parent compound and metabolites containing the common 2,4,6-trichlorophenol moiety, expressed as prochloraz equivalents (using a correction factor of 1.9). The term 'free prochloraz' refers to the parent compound only.

The following abbreviations are used for the metabolites:

|           |                                                                                      |
|-----------|--------------------------------------------------------------------------------------|
| BTS 44595 | <i>N</i> -propyl- <i>N</i> '-2-(2,4,6-trichlorophenoxy)ethylurea                     |
| BTS 44596 | <i>N</i> '-formyl- <i>N</i> -propyl- <i>N</i> -[2-(2,4,6-trichlorophenoxy)ethyl]urea |
| BTS 44770 | <i>N</i> -2-(2,4,6-trichlorophenoxy)ethylurea                                        |
| BTS 9608  | 2,4,6-trichlorophenoxyacetic acid                                                    |
| BTS 45186 | 2,4,6-trichlorophenol                                                                |
| BTS 54906 | 2-(2,4,6-trichloro-3-hydroxyphenoxy)ethanol                                          |
| BTS 54908 | <i>N</i> -2-(2,4,6-trichloro-3-hydroxyphenoxy)ethyl- <i>N</i> -propylurea            |

### Metabolism

#### Animals

The Meeting received information on the metabolism of prochloraz in rats, lactating goats lactating cows and laying hens.

Prochloraz was extensively metabolized in rats, no unchanged parent compound being detected in urine; it was, however, detected in faeces and was the most abundant component on day 1. Faeces contained significant quantities of the plant metabolites BTS 44595 and BTS 44596, formed by opening of the imidazole ring. The most abundant metabolite in urine was BTS 9608, comprising around 35% of the excreted radioactivity. A more recent study in rats (2003) generally confirmed the results of the earlier studies, although a more complex pattern of metabolism was reported, additional metabolites being detected in urine and faeces. The metabolism of prochloraz in the rat proceeds via cleavage of the imidazole ring, oxidation of the side-chain, phenyl-ring hydroxylation and substitution of chlorine by a hydroxyl group. Other processes were revealed in the latest study in rats, including *N*-dealkylation, *N*-deacetylation and sulfate conjugation of hydroxy groups.

Straw from field plots treated 11 weeks before harvest with <sup>14</sup>C-prochloraz and containing the equivalent of 19 mg/kg was fed to a lactating goat daily for 4 days. Milk and blood samples were taken twice daily, and the animal was killed on the fifth day. The highest residue levels were found in liver (0.05 mg/kg),

kidney fat and rumen wall (0.04 mg/kg), expressed as equivalents. All other tissues contained  $\leq 0.03$  mg/kg, milk contained  $\leq 0.006$  mg/l; the maximum level in plasma was 0.08 mg/l.

A lactating cow was given gelatin capsules containing  $^{14}\text{C}$ -prochloraz at a rate providing 1.5 mg/kg bw per day twice a day for 3 days, equivalent to 37.5 mg/kg of diet. The radioactivity in plasma reached a plateau at 72 h, and the levels in milk rose to a plateau of 0.14 mg/l after 24 h. Most of the radioactivity was found in the liver (10 mg/kg) and kidney (1.7 mg/kg), with lower levels in other tissues. Parent prochloraz was not found in the gut contents, plasma, milk or tissues. Analysis of the gut contents indicated that prochloraz was rapidly degraded to the imidazole ring-opened metabolites BTS 44596, BTS 44595 and BTS 44770, and these metabolites were also detected in tissues and in early plasma samples. The phenolic metabolites BTS 54906 and BTS 54908 were prevalent in milk, in addition to BTS 4496 (23% TRR).

In laying hens given  $^{14}\text{C}$ -prochloraz in gelatin capsules daily at a rate of 1.5 mg/day for 14 days, equivalent to 10 mg/kg of diet, 85% of the TRR had been excreted within 24 h, and the levels of radioactivity in eggs, mostly in the yolk, reached a plateau of 1.7 mg/kg by day 8. The highest residue levels were found in the liver (0.9 mg/kg) and gastrointestinal tract (0.8 mg/kg), and levels  $\leq 0.19$  mg/kg were found in skin,  $\leq 0.09$  mg/kg in fat, 0.05 mg/kg in breast muscle and 0.07 mg/kg in thigh muscle. Parent prochloraz was not found in excreta, eggs or tissues; BTS 9608 and BTS 44596 were the main metabolites in liver, muscle, fat and eggs.

Generally, prochloraz is rapidly absorbed, metabolized and excreted, and it is not detected in milk, eggs or tissues. BTS 44596, the formyl urea metabolite, is the residue component found predominantly in egg yolk, and BTS 54906 and BTS 44596 are the main components in milk. Except in liver and to a lesser extent in kidney, the residue levels in tissues are generally low and consist mainly of BTS 44596, BTS 44595 and BTS 44770.

### *Plants*

The Meeting received the results of studies of the metabolism of prochloraz in wheat and oil-seed rape after foliar application, in mushrooms after treatment of the casing and in wheat after seed treatment.

In two studies in which young wheat plants received foliar treatment with radiolabelled prochloraz at 0.25–0.39 kg ai/ha, the residue levels of parent compound were 0.6–1% TRR after 19–20 days. The main metabolites detected were BTS 44596 (32–38%), free and conjugated BTS 44595 (31%) and BTS 45186 (8%). In one of the studies, mature grain harvested 14 weeks after treatment contained  $< 0.05$  mg/kg, representing  $< 0.2\%$  of the TRR present in straw; the residues in grain were mostly bound in fibre, while the residues in straw consisted mainly of BTS 44596 (26% TRR) and BTS 44595 (8% TRR), with less than 0.1% parent compound.

In two studies on mature wheat harvested 13 weeks after foliar treatment with radiolabelled prochloraz at 1 kg ai/ha, the residues in grain represented 3–8% TRR as free BTS 45186 and 40–54% TRR as stable polar conjugates containing the 2,4,6-trichlorophenol moiety. Of the residues in straw, about 5% TRR was free BTS 45186 and 38–58% was conjugates containing the 2,4,6-trichlorophenol moiety.

In wheat plants grown from seed treated with radiolabelled prochloraz (0.4 g ai/kg of seed), 5.6% TRR was measured in aerial plant portions during the first 6 weeks of growth; no further translocation was seen. At maturity, 58% of the applied radiolabel was found in soil and 15% in the root system; no radioactivity was observed in grain.

The metabolism of prochloraz in oil-seed rape was studied after foliar treatment of young plants. Leaves sampled 19 days after treatment contained  $< 3\%$  of the TRR, and the main metabolites were BTS 44596 (20%), BTS 44595 (29%) and material of polar origin (30%). A similar distribution was reported in mature plants; about 3% of the TRR was detected in plant parts that had not been treated directly, and the residues in mature seeds accounted for about 0.1% TRR.

In mushrooms treated with the prochloraz–manganese chloride complex at 3 g ai/m<sup>2</sup> and analysed 8 and 30 days later, unchanged parent compound accounted for 75% and 83% of the extracted radioactivity, respectively, and BTS 9608 accounted for a further 9–10%.

In summary, prochloraz is metabolized to BTS 44596 via cleavage of the imidazole ring, followed by ‘deformylation’ to generate BTS 44595. Low levels of conjugates of both these metabolites are formed, which are resistant to the initial extraction solvents, being released only under more exhaustive conditions (e.g. microwave acetonitrile:water extraction). The fact that polar materials could be converted to BTS 45186 by pyridinium hydrochloride hydrolysis indicates that the trichlorophenol moiety is present in this material. The metabolic fate of prochloraz in oil-seed rape is similar to that in wheat. In mushrooms, prochloraz–manganese complex underwent dissociation to free prochloraz and subsequent metabolism to BTS 9608 and conjugates containing the BTS 45186 moiety.

### *Rotational crops*

The Meeting received information on the behaviour and fate of prochloraz in soil and in rotational crops.

Under normal agricultural conditions, prochloraz is moderately persistent in soil, with a DT<sub>50</sub> of < 40 days. The products of biotic and photolytic degradation, BTS 44596 and BTS 44595, have been detected occasionally in soil samples collected in the field but at levels close to the LOQ.

When prochloraz is applied to bare soil, it is metabolized in rotational crops to BTS 44596, BTS 44595, BTS 45186 and BTS 9608. The levels of total residues declined sharply between 30- and 120-day crops and declined further with soil ageing. The metabolites in rotational crops were essentially the same as those reported in the studies of plant metabolism, except that the levels of BTS 9608 were lower. The concentrations of metabolites were low in all crops (< 0.01 mg/kg), exceeding 0.05 mg/kg only in wheat forage and straw.

### *Methods of analysis*

The Meeting received information on methods for analysis for free prochloraz and for total prochloraz (prochloraz plus metabolites containing the common 2,4,6-trichlorophenol moiety), in plant material, animal tissues and soils. Analytical methods for specific metabolites in plant and animal tissues were also provided.

The ‘common moiety’ method, involving hydrolysis of prochloraz and its metabolites to 2,4,6-trichlorophenol, was used in most of the supervised residue trials and for enforcement purposes. In this method (RESID/88/72) and in an earlier, related method (RESID/82/88), samples are Soxhlet-extracted with acetone, concentrated and hydrolysed with pyridine hydrochloride to break down all components to 2,4,6-trichlorophenol. This hydrolysate is then extracted into petroleum ether by steam distillation, with further clean-up by extraction into the aqueous layer with alkali and re-extraction into toluene after acidification. Total 2,4,6-trichlorophenol residues are determined by gas chromatography (with electron capture detection for plant material and soil and MS detection or mass spectrometry for milk and animal tissues), and the results are expressed as prochloraz equivalents, with a correction factor of 1.9.

Methods for measuring free prochloraz in plant materials are based on acetone extraction, acidification with hydrochloric acid, evaporation and extraction under acid conditions with petroleum ether. The aqueous extract is neutralized, further extracted with petroleum ether and evaporated, and the residue is dissolved in ethyl acetate before analysis by gas chromatography with electron capture detection.

An HPLC method for measuring prochloraz and the major metabolites BTS 44596 and BTS 44595 and the hydroxyamide metabolite BTS 54908 has also been reported for milk (liquid chromatography with tandem mass spectrometry), with an LOQ of 0.01 mg/kg for prochloraz and 0.005 mg/kg for each metabolite.



The LOQs of 'common moiety' methods for prochloraz equivalent in most substrates are 0.01–0.05 mg/kg, although a higher LOQ of 0.1 mg/kg may be required for some materials (immature cereal plants and straw, sub-tropical citrus fruit peel) in which there are high background levels of residues. Recovery efficiencies of about 90% are common, usually ranging from 75% to 110%.

### ***Stability of residues in stored analytical samples***

The Meeting received information on the stability of prochloraz in various commodities under freezer storage (–18 to –20 °C). Less than 30% of the residues had degraded during storage in wheat stored for 24 months, in barley at 23 months, in sugar-beet roots and tops at 14 months, in maize plants at 24 months, in rape-seed at 36 months, in muscle at 12 months, in milk at 12 months and in eggs at 12 months.

### ***Definition of the residue***

Studies of metabolism in lactating goats and cows and in hens indicate that the parent compound is not found in tissues, milk or eggs; however, a number of metabolites containing the 2,4,6-trichlorophenol moiety occur, BTS 44596, BTS 44595, BTS 44770, BTS 54906, BTS 54908 and BTS 9608 being found in one or more of the above substrates.

In plants, the metabolic pathway is consistent, involving cleavage of the imidazole ring to form the aldehyde BTS 44596, oxidation of the side-chain to form the urea (BTS 44595) and the carboxylic acid (BTS 9608, generally only in conjugated form), with eventual formation of the phenol BTS 45186 and its polar conjugates.

The Meeting therefore considered that the residues of toxicological concern would be those of unchanged parent compound, the non-polar metabolites BTS 44595 and BTS 44596 and low levels of free BTS 45186, which are readily extracted from plant material with acetone. The Meeting noted that these compounds are also found in rats and are therefore covered by the toxicological assessment.

The Meeting confirmed the current prochloraz residue definition, 'Sum of prochloraz and its metabolites containing the 2,4,6-trichlorophenol moiety, expressed as prochloraz', for compliance with MRLs and for estimation of dietary intake from both animal and plant commodities.

Taking into account the log  $P_{ow}$  of prochloraz of 3.5 and the results of the animal feeding studies, the Meeting decided that residues of prochloraz should be classified as fat-soluble.

### ***Results of supervised trials on crops***

The results of supervised trials were available for use of prochloraz on citrus fruit (lemon, mandarin, orange), avocado, banana, mango, papaya, pineapple, onion, melon, mushroom, tomato, lettuce, bean, pea, sugar-beet, rape-seed, sunflower seed, linseed, soya bean, barley, oat, rice, rye, wheat and pepper, black.

The results of trials or relevant GAP were not submitted for coffee beans or stone fruits, for which maximum residue levels are currently recommended. The Meeting agreed to withdraw the previously recommended maximum residue levels for these commodities.

The Meeting noted that a post-treatment interval has not been defined for most approved uses on citrus and sub-tropical fruit (inedible peel), and that in the relevant studies on orange, mandarin, avocado and banana, the residue levels, although variable, were often high in fruit sampled after day 0. As the residues in post-harvest-treated fruit did not appear to degrade appreciably during storage, the Meeting agreed to use the results of analyses up to 21 days after treatment to reflect the residue levels expected in fruit immediately after treatment.

*Citrus fruit*

The results of trials of post-harvest dipping and spraying on lemon, mandarin and orange were available from Argentina, Australia, Greece, Italy, Morocco, Spain and the United Kingdom, and the results of post-harvest brushing trials on oranges were available from South Africa.

*Lemon*

GAP in Argentina for citrus includes a post-harvest spray application of 0.2–0.29 kg ai/hl (no post-treatment interval specified). In trials in Spain reflecting this GAP, the residue levels in lemons sampled 12–16 days after treatment were 3.8 and 4.5 mg/kg. The corresponding residue levels in lemon pulp were 0.16 mg/kg and 0.23 mg/kg.

*Orange*

GAP for citrus in Argentina includes a post-harvest spray application of 0.2–0.29 kg ai/hl (no post-treatment interval specified). While no trials in Argentina matched this GAP, one trial in Spain that did showed a residue level of 1.7 mg/kg in oranges (0.07, 0.1, 0.13, 0.14 and 0.17 mg/kg in pulp) sampled 14 days after treatment.

In South Africa, GAP is for a post-harvest brush treatment with 0.15 kg ai/hl (no post-treatment interval specified). In one trial in Argentina reflecting this GAP ( $\pm 25$ –30%), the residue level was 5.3 mg/kg in oranges (0.02 mg/kg in pulp).

In Greece, GAP is for use of prochloraz as a post-harvest dip or spray at up to 0.09 kg ai/hl. Trials in Australia, Morocco and Spain were evaluated against the GAP of Greece. The residue levels in oranges were: 1.3, 1.4, 1.5, 1.7, 2.0, 3.7, 5.9 and 6.8 mg/kg, and those in pulp (edible portion) were: 0.02, 0.06 (two), < 0.1 (two), 0.26, 0.33, 0.56 and 0.92 mg/kg.

The residue levels in oranges, in ranked order, were: 1.3, 1.4, 1.5, 1.7 (two), 2.0, 3.7, 5.3, 5.9 and 6.8 mg/kg, and those in pulp were: 0.02 (two), 0.06 (two), 0.07, < 0.1 (two), 0.1, 0.13, 0.14, 0.17, 0.26, 0.33, 0.56 and 0.92 mg/kg.

*Mandarin*

Two post-harvest trials in Spain matching GAP in Argentina (up to 0.29 kg ai/hl) showed residue levels of 2.1 and 3.5 mg/kg, with corresponding levels of 0.1 and 0.35 mg/kg in pulp.

In Greece, GAP is for use of prochloraz as a dip or spray at up to 0.09 kg ai/hl, while in Spain GAP is for use at up to 0.08 kg ai/hl. The trials in Australia (no GAP), Morocco (no GAP) and Spain were evaluated against the GAP of Greece. The residue levels in mandarins were 2.0, 2.1 (three), 2.3, 3.2, 3.4, 3.5, 3.9, 4.3, 4.6, 5.4 and 5.9 mg/kg, and the corresponding levels in pulp (edible portion) were: 0.07 (two), 0.09 (three), 0.1, 0.12, 0.26 and 0.31 mg/kg.

The residue levels in mandarins, in ranked order, were: 2.0, 2.1 (four), 2.3, 3.2, 3.4, 3.5 (two), 3.9, 4.3, 4.6, 5.4 and 5.9 mg/kg, and the corresponding levels in pulp (edible portion) were: 0.07 (two), 0.09 (three), 0.1 (two), 0.12, 0.26, 0.31 and 0.35 mg/kg.

The Meeting agreed to combine the data for lemon, orange and mandarin, to give a data set for citrus from 27 trials of: 1.3, 1.4, 1.5, 1.7 (two), 2.0 (two), 2.1 (four), 2.3, 3.2, 3.4, 3.5 (two), 3.7, 3.8, 3.9, 4.3, 4.5, 4.6, 5.3, 5.4, 5.9 (two) and 6.8 mg/kg, and residue levels in pulp of: 0.02 (two), 0.06 (two), 0.07 (three), 0.09 (three), < 0.1 (two), 0.1 (three), 0.12, 0.13, 0.14, 0.16, 0.17, 0.23, 0.26 (two), 0.31, 0.33, 0.35, 0.56 and 0.92 mg/kg.

The Meeting estimated a maximum residue level of 10 mg/kg for prochloraz in citrus, replacing the previous recommendation of 5 mg/kg for oranges, sweet and sour. The Meeting also estimated an STMR of 0.1 mg/kg and a highest residue level of 0.92 mg/kg for prochloraz in the edible portion.

*Assorted tropical and sub-tropical fruits minus inedible peel**Avocado*

The results of trials on post-harvest dipping and spraying on avocado were made available to the Meeting from Australia, Colombia (no GAP) and South Africa.

GAP in South Africa is for post-harvest spray at 0.05 kg ai/hl (no post-treatment interval specified). The residue levels in trials in Australia and South Africa matching this GAP were: 0.42, 1, 1, 1.3, 2.3 and 3.5 mg/kg in whole fruit with stone and < 0.1 and 0.11 mg/kg in pulp.

The residue levels in post-harvest trials in Australia and South Africa matching Australian GAP (0.025 kg ai/hl, no post-treatment interval specified) were: 0.39, 0.83, 0.87, 0.92, 1, 1.2 (two) and 2.4 mg/kg in whole fruit with stone and < 0.1 (four) and 0.12 mg/kg in the edible portion.

The residue levels in 14 trials in avocados, in ranked order, were: 0.39, 0.42, 0.83, 0.87, 0.92, 1 (three), 1.2 (two), 1.3, 2.3, 2.4 and 3.5 mg/kg in whole fruit with stone and ≤ 0.1 (five), 0.11 and 0.12 mg/kg in the edible portion.

The Meeting noted that, while data for pre-harvest foliar application were available, no matching GAP was provided.

*Banana*

The results of trials of post-harvest dipping on banana were available from Australia, South Africa and the West Indies, and trials of spray or drench application were reported from the Canary Islands and the Philippines.

GAP in the Philippines is for a spray application at 0.09 kg ai/hl, but no trials matched this GAP. In China, GAP is for use of prochloraz as a dip at up to 0.05 kg ai/hl (no post-treatment interval specified). The residue levels in trials of dipping in Australia, the Canary Islands, South Africa and the West Indies matching this GAP were: 1.8, 2.5, 2.6, 2.7, 3.0, 3.3, 3.5 and 5.1 mg/kg in whole fruit and: 0.04, < 0.1, 0.1, 0.11, 0.12 and 0.17 (two) mg/kg in pulp.

In Australia, GAP (0.025 kg ai/hl) is for use of prochloraz as a dip. The residue levels in dipping trials in Australia, the Canary Islands, the Philippines, South Africa and the West Indies matching this GAP were: < 0.1, 0.69, 1.1, 1.3, 1.6, 1.7 (two), 2.3, 2.4, 2.9, 3.0 and 3.4 mg/kg in whole fruit and: 0.03, 0.06, 0.07, 0.08, < 0.1, 0.1 (two), 0.12 (two), 0.13 and 0.21 (two) mg/kg in pulp.

The residue levels in banana, in ranked order, were: < 0.1, 0.69, 1.1, 1.3, 1.6, 1.7, 1.8, 2.3, 2.4, 2.5, 2.6, 2.7, 2.9, 3.0 (two), 3.4, 3.5 and 5.1 mg/kg in whole fruit, and the residue levels in pulp were: 0.03, 0.04, 0.06, 0.07, 0.08, < 0.1 (two), 0.1 (three), 0.11, 0.12 (three), 0.13, 0.17 (two) and 0.21 (two) mg/kg.

The Meeting noted that, while data for pre-harvest foliar applications were available, no matching GAP was provided.

*Mango*

The Meeting was provided with the results of trials on pre-harvest foliar spray in Israel (no GAP), Malaysia (GAP: 0.056 kg ai/hl, 15-day PHI), South Africa (no GAP) and Taiwan (no GAP), and of trials on post-harvest dipping in Australia (post-harvest spray at 0.025 kg ai/hl, no post-treatment interval specified), Colombia (0.025 kg ai/hl, no post-treatment interval specified), Israel (no GAP) and South Africa (maximum of 0.08 kg ai/hl, no post-treatment interval specified).

None of the pre-harvest trials from Malaysia matched Malaysian GAP.

None of the post-harvest treatment trials matched GAP in China (0.1 kg ai/hl) or South Africa (maximum of 0.08 kg ai/hl), but four trials in Australia, Colombia, Israel and South Africa matched GAP in

Brazil (0.05 kg ai/hl) and Peru (0.045 kg ai/hl). In these trials, the residue levels in total fruit were: 1, 1.2, 1.3 and 1.4 mg/kg, while those in the edible portion were: 0.18 and 0.44 mg/kg.

In three trials in Australia and South Africa that matched GAP in Australia and Colombia (0.025 kg ai/hl), the residue levels were 0.48, 0.68 and 1.8 mg/kg in whole fruit without stone and 0.1 and 0.47 mg/kg in pulp.

The residue levels in the post-harvest trials on mango, in ranked order, were: 0.48, 0.68, 1, 1.2, 1.3 and 1.4 (two) mg/kg, and those in pulp were: 0.1, 0.18, 0.44 and 0.47 mg/kg.

#### *Papaya*

The results of post-harvest dipping trials were provided from Australia (GAP: 0.025 kg ai/hl, no post-treatment interval specified), Brazil (GAP: 0.034 kg ai/hl, 3-day post-treatment interval) and South Africa (no GAP).

In three post-harvest dipping trials in Australia and South Africa that matched the GAP of Australia (0.025 kg ai/hl), the residue levels were: 0.41, 0.61 and 1.4 mg/kg in whole fruit (including pips) and < 0.1 and 0.7 mg/kg in the edible portion.

#### *Pineapple*

The results of post-harvest dipping trials were made available from Australia (GAP: 0.025 kg ai/hl, no post-treatment interval specified) and Kenya (no GAP). In the one trial matching Australian GAP, the residue level was 1.1 mg/kg in whole fruit and 0.18 mg/kg in the edible portion.

The Meeting considered that the available data on residue levels in avocado, banana, mango, papaya and pineapple were sufficient to mutually support a group maximum residue level for assorted tropical and sub-tropical fruits minus inedible peel. The residue levels, in ranked order, were: < 0.1, 0.39, 0.41, 0.42, 0.48, 0.61, 0.68, 0.69, 0.83, 0.87, 0.92, 1 (four), 1.1 (two), 1.2 (three), 1.3 (three), 1.4 (three), 1.6, 1.7, 1.8, 2.3 (two), 2.4 (two), 2.5, 2.6, 2.7, 2.9, 3.0 (two), 3.4, 3.5 (two) and 5.1 mg/kg in whole fruit in 43 trials, and: 0.03, 0.04, 0.06, 0.07, 0.08, < 0.1 (eight), 0.1 (four), 0.11 (two), 0.12 (four), 0.13, 0.17 (two), 0.18 (two), 0.21 (two), 0.44, 0.47 and 0.7 mg/kg in the edible portion in 33 trials.

The Meeting estimated a maximum residue level of 7 mg/kg for prochloraz in assorted tropical and sub-tropical fruits minus inedible peel, replacing the previous recommendations of 5 mg/kg for avocado and banana, 2 mg/kg for mango and 1 mg/kg for papaya. The Meeting also estimated an STMR of 0.1 mg/kg and a highest residue level of 0.7 mg/kg for prochloraz in the edible portion.

#### *Onion*

The results of field trials on onions were made available to the Meeting from The Netherlands (no GAP) and from Thailand (no GAP). The results of post-harvest dipping trials were provided from Australia (no GAP).

#### *Melon*

The results of field trials on melons involving foliar drenching and flood irrigation were made available to the Meeting from Spain. None of the trials matched Spanish GAP (up to four applications at 0.9 kg ai/ha, 15-day PHI). The results of post-harvest dipping trials were provided from Australia and Colombia, but no matching GAP was available.

#### *Mushroom*

The Meeting noted two distinct patterns of use of prochloraz on mushrooms: one established in the United Kingdom, involving two to three casing sprays of 0.3–0.6 g ai/m<sup>2</sup>, with a PHI of 2 days, and the other common in a number of other European countries, Australia and New Zealand, involving one or more treatments at 1.5 g ai/m<sup>2</sup> and a PHI of 10–14 days.

In seven trials in The Netherlands, Switzerland and the United Kingdom matching GAP in Denmark, Italy, The Netherlands, New Zealand and Poland (one or two treatments at 1.5 g ai/m<sup>2</sup>, 10-day PHI), the residue levels were: 0.21, 0.25, 0.48, 0.71 and 0.74 mg/kg.

The maximum GAP of two sprays of 0.6 g ai/m<sup>2</sup> (2-day PHI) in the United Kingdom is supported by the results of trials in Germany and the United Kingdom, with residue levels of: 0.81, 3.6, 6.2 and 37 mg/kg.

The Meeting noted that these two residue populations are different and, on the basis of the data supporting the United Kingdom GAP, estimated a maximum residue level of 40 mg/kg for prochloraz in mushrooms, an STMR of 4.9 mg/kg and a highest residue level of 37 mg/kg. The recommended maximum residue level of 40 mg/kg for mushrooms replaces the previous recommendation of 2.0 mg/kg.

#### *Tomato*

The results of field trials of both foliar application and soil drenching on tomatoes were made available to the Meeting from Israel (no GAP) and the USA (no GAP).

#### *Lettuce*

The results of field trials on lettuce, head, were made available to the Meeting from Australia (GAP: 0.18 kg ai/ha, 0.023 kg ai/hl, 7-day PHI) and from the United Kingdom (no GAP). Trials on protected lettuce crops were also provided by the United Kingdom (no GAP). Four trials in Australia matching Australian GAP showed residue levels of: 0.06, 0.16, 0.41 and 0.59 mg/kg.

The Meeting agreed that the available data were insufficient to estimate a maximum residue level for lettuce.

#### *Beans, dry*

The results of field trials on beans were made available to the Meeting from Germany, and two trials of seed treatment were provided from Brazil. No matching GAP was available for either use pattern.

#### *Peas, dry*

The results of field trials on peas were made available to the Meeting from Germany and the United Kingdom; however, no matching GAP was available.

#### *Sugar-beet*

The results of field trials on sugar-beet were made available to the Meeting from Italy (GAP: one or two applications at 0.48–0.8 kg ai/ha, 20-day PHI). Three of the trials matched Italian GAP ( $\pm$  30%); however, because the control samples apparently contained high residue levels, the Meeting agreed that the available data were insufficient to estimate a maximum residue level for sugar-beet.

#### *Oil seeds*

##### *Rape-seed*

The results of field trials from Canada (no GAP), Denmark (GAP: 0.45–0.7 kg ai/ha, 28-day PHI), France (GAP: 0.45–0.6 kg ai/ha), Germany (GAP: 0.6 kg ai/ha, 56-day PHI), Sweden (no GAP) and the United Kingdom (GAP: 0.2–0.5 kg ai/ha, 42-day PHI, maximum of 1 kg ai/ha per season) were made available to the Meeting.

In trials in Denmark, France and Germany that matched German GAP (0.6 kg ai/ha, 56-day PHI), the residue levels in mature seed were: 0.05, 0.07, 0.08, 0.09 (two), < 0.1 (four), 0.11, 0.12 and 0.15 mg/kg.

In field trials from the United Kingdom matching the corresponding GAP (up to 0.5 kg ai/ha, 42-day PHI), the residue levels in mature rape-seed were < 0.1 (five), 0.1 (three), 0.12, 0.14, 0.17, 0.18, 0.19, < 0.2 (two), 0.22, 0.24, 0.36, 0.39, 0.46 and 0.48 mg/kg.

The residue levels in rape-seed, in ranked order, were: 0.05, 0.07, 0.08, 0.09 (two), < 0.1 (nine), 0.1 (three), 0.11, 0.12 (two), 0.14, 0.15, 0.17, 0.18, 0.19, < 0.2 (two), 0.22, 0.24, 0.36, 0.39, 0.46 and 0.48 mg/kg in 33 trials.

The Meeting estimated a maximum residue level of 0.7 mg/kg for prochloraz in rape-seed, replacing the previous recommendation of 0.5 mg/kg. The Meeting also established an STMR of 0.1 mg/kg and a highest residue level of 0.48 mg/kg.

#### *Sunflower seed*

The results of field trials in France (GAP: one or two applications at 0.32–0.6 kg ai/ha, no PHI specified) were made available to the Meeting. In view of the similarity between GAP in France and that in Croatia (GAP: up to two applications at 0.6 kg ai/ha, 63-day PHI), the Meeting evaluated the trials in France against GAP in Croatia.

In the 11 trials, the residue levels were: ≤ 0.1 (eight), 0.14, 0.27 and 0.32 mg/kg,

One trial on seed treatment was reported from France, but no matching GAP was available

The Meeting estimated a maximum residue level of 0.5 mg/kg, an STMR of 0.1 mg/kg and a highest residue level of 0.32 mg/kg for sunflower seed.

#### *Linseed*

The results of six trials of seed treatment were reported from the United Kingdom (GAP: 0.4 g ai/kg seed) in which seed treated with prochloraz according to GAP was grown to maturity and the daughter seeds analysed for residues 149–178 days after planting. In all the trials, the residue levels of total prochloraz were below the LOQ of 0.05 mg/kg. As a residue level of 0.04 mg/kg was reported in the control samples in one trial, the Meeting decided to evaluate the remaining five trials, with residue levels < 0.05 mg/kg.

The Meeting estimated a maximum residue level of 0.05\* mg/kg, an STMR of 0.05 mg/kg and a highest residue level of 0.05 mg/kg for linseed.

#### *Soya beans*

The results of two field trials by foliar application on soya beans were made available to the Meeting from France, but no GAP was available.

#### *Cereal grains*

##### *Barley*

The results of field trials on barley were made available to the Meeting from Austria (GAP: one application at 0.45 kg ai/ha, 35-day PHI), Brazil (GAP: 0.45 kg ai/ha, 32-day PHI), Canada (no GAP), Denmark (maximum GAP: one application at 0.45 kg ai/ha, PHI up to Zadoks 39), France (maximum GAP: 0.6 kg ai/ha, PHI up to stem elongation), Germany (maximum GAP: one application at 0.48 kg ai/ha, 35-day PHI), Greece (maximum GAP: 0.19 kg ai/ha, 56-day PHI), The Netherlands (GAP: 0.45 kg ai/ha, 42-day PHI), Italy (maximum: GAP: 0.8 kg ai/ha, 40-day PHI), Portugal (GAP: 0.45 kg ai/ha, 35-day PHI), Spain (maximum GAP: one application at 0.72 kg ai/ha, 60-day PHI), Sweden (one application at 0.45 kg ai/ha, PHI not specified) and the United Kingdom (maximum GAP: 0.45 kg ai/ha, 42-day PHI).

In five trials in Denmark, The Netherlands and the United Kingdom, involving a single application of prochloraz, which matched German GAP (0.48 kg ai/ha, 35-day PHI), the residue levels in grain were: < 0.05, 0.06, 0.08, 0.13 and 0.21 mg/kg.

The residue levels in 34 trials in Belgium, Denmark, France, Germany, Sweden and the United Kingdom with two applications and matching GAP in the United Kingdom (0.45 kg ai/ha, 42-day PHI) were: < 0.02 (two), 0.03, 0.07, 0.08 (three), 0.1 (three), 0.11 (two), 0.12 (two), 0.14, 0.16 (three), 0.23 (two), 0.24, 0.26 (two), 0.3, 0.31, 0.35, 0.38, 0.45, 0.48, 0.5, 0.53, 0.59, 0.65 and 0.68 mg/kg.

In 15 trials in France, Greece, Italy, Portugal and Spain involving two applications of prochloraz according to GAP in Portugal (0.45 kg ai/ha, 35-day PHI), the residue levels were: 0.13, 0.21, 0.22, 0.23, 0.26, 0.3, 0.35, 0.36, 0.41, 0.43, 0.46, 0.47, 0.51, 0.87 and 0.88 mg/kg.

The residue levels in 54 trials in barley, in ranked order, were: < 0.02 (two), 0.03, < 0.05, 0.06, 0.07, 0.08 (four), 0.1 (three), 0.11 (two), 0.12 (two), 0.13 (two), 0.14, 0.16 (three), 0.21 (two), 0.22, 0.23 (three), 0.24, 0.26 (three), 0.3 (two), 0.31, 0.35 (two), 0.36, 0.38, 0.41, 0.43, 0.45, 0.46, 0.47, 0.48, 0.5, 0.51, 0.53, 0.59, 0.65, 0.68, 0.87 and 0.88 mg/kg.

The Meeting also received data from field trials in Denmark (GAP: 20 g ai/100 kg seed) and Germany (no GAP) on barley grown from seed treated with prochloraz. In the 17 trials matching GAP in Denmark, the residue levels of total prochloraz were < 0.01 (two) and < 0.05 (15) mg/kg.

#### *Oats*

Prochloraz is registered for use on cereals in Austria, Belgium, Croatia, Denmark and Germany, with a common GAP of one or two foliar applications at 0.45 kg ai/ha, and a 35-day PHI. None of the four trials provided from Denmark matched this GAP.

The Meeting was also provided with the results of trials of seed treatment in Germany (GAP: 20 g ai/kg seed), in which the residue levels in oats grown from seed treated with prochloraz were: < 0.05 (eight) and < 0.1 (two) mg/kg.

#### *Rice*

Field trials of foliar application on rice were made reported to the Meeting from Japan (no GAP), Spain (GAP: 0.45 kg ai/ha, 15-day PHI) and Taiwan China (no GAP). None of the trials in Spain matched Spanish GAP.

#### *Rye*

Field trials of foliar application on rye were reported to the Meeting from Denmark (maximum GAP: one application at 0.45 kg ai/ha, 28-day PHI) and Germany (maximum GAP: one to two applications at 0.48 kg ai/ha, 35-day PHI). In three trials in Germany that matched German GAP, the residue levels were: 0.06, 0.09 and < 0.1 mg/kg. The Meeting noted that GAP for rye in the United Kingdom is similar to that in Germany but with a PHI of 42 days. It therefore considered that the trials in Germany supported the United Kingdom GAP. The residue levels in trials matching GAP in the United Kingdom were: < 0.05, 0.05, 0.06 (three), 0.09 and < 0.1 mg/kg.

The Meeting also received the results of field trials of seed treatment in Germany (GAP: 20 g ai/100 kg seed) with regard to residues in rye grown from seed treated with prochloraz. In five trials matching German GAP, the residue levels of total prochloraz were < 0.02 (two) and < 0.05 (three) mg/kg.

#### *Wheat*

The results of field trials on wheat were made available to the Meeting from Austria (GAP: one application at 0.45 kg ai/ha, 35-day PHI), Brazil (GAP: 0.45 kg ai/ha, 40-day PHI), the former Czechoslovakia (no GAP), Denmark (maximum GAP: one application at 0.45 kg ai/ha, 28-day PHI), France (maximum GAP: 0.6 kg ai/ha, PHI up to stem elongation), Germany (maximum GAP: one application at 0.48 kg ai/ha, 35-day PHI) Italy (GAP: 0.45 kg ai/ha, 42-day PHI), The Netherlands (GAP: 0.45 kg ai/ha, 42-day PHI), Portugal (no GAP), Spain (maximum GAP: one application at 0.72 kg ai/ha, 60-day PHI), Sweden (one application at 0.45 kg ai/ha, PHI not specified), the United Kingdom (maximum GAP: 0.45 kg ai/ha, 42-day PHI) and the USA (no GAP).

None of the trials in Spain trials matched Spanish GAP. One trial in Italy matching Italian GAP (maximum GAP: 0.8 kg ai/ha, 40-day PHI) showed a residue level of 0.12 mg/kg. In six trials in the former Czechoslovakia, The Netherlands and the United Kingdom involving a single application of prochloraz, which matched German GAP (maximum GAP: one application at 0.48 kg ai/ha, 35-day PHI), the residue levels in grain were: < 0.05, 0.09, 0.12, 0.21, 0.23 and 0.24 mg/kg.

The residue levels in trials in southern France, Greece, Italy, Portugal and Spain involving two applications of prochloraz according to GAP in Portugal (0.45 kg ai/ha, 35-day PHI) were: < 0.05 (six), 0.07 (two), 0.09, 0.13, 0.14, 0.15, 0.52 and 1.2 mg/kg. The residue levels in trials involving two applications of prochloraz to wheat in northern France, Germany and the United Kingdom and matching GAP in Belgium and the United Kingdom (maximum GAP: 0.45 kg ai/ha, 42-day PHI) were: 0.03, < 0.05 (10), 0.05 (two), 0.06 (two), 0.07 (two), 0.08, 0.09, < 0.1 (four), 0.11, 0.12 (two), 0.13, 0.15, 0.16, 0.17, 0.2 and 0.31 (two) mg/kg.

The residue levels in 54 trials in wheat, in ranked order, were: 0.03, < 0.05 (17), 0.05 (two), 0.06 (two), 0.07 (four), 0.08, 0.09 (three), < 0.1 (four), 0.11, 0.12 (four), 0.13 (two), 0.14, 0.15 (two), 0.16, 0.17, 0.2, 0.21, 0.23, 0.24, 0.31 (two), 0.52 and 1.2 mg/kg.

The Meeting also received the results of field trials on residues in wheat grown from seed treated with prochloraz in Denmark (no GAP), Germany (GAP: 20 g ai/100 kg seed), Greece (no GAP) and the United Kingdom (GAP: 14 g ai/100 kg seed). In the 26 trials matching GAP in Germany, the residue levels of total prochloraz were: < 0.01 (three), < 0.02 (nine) and < 0.05 (14) mg/kg..

The Meeting considered that the available data on barley, rye and wheat treated by foliar application were sufficient to mutually support a group maximum residue level for cereal grains. The residue levels, in ranked order, in 118 trials were: < 0.02 (two), 0.03 (two), < 0.05 (19), 0.05 (three), 0.06 (seven), 0.07 (five), 0.08 (five), 0.09 (five), < 0.1 (six), 0.1 (three), 0.11 (three), 0.12 (six), 0.13 (four), 0.14 (two), 0.15 (two), 0.16 (four), 0.17, 0.2, 0.21 (three), 0.22, 0.23 (four), 0.24 (two), 0.26 (three), 0.3 (two), 0.31 (three), 0.35 (two), 0.36, 0.38, 0.41, 0.43, 0.45, 0.46, 0.47, 0.48, 0.5, 0.51, 0.52, 0.53, 0.59, 0.65, 0.68, 0.87, 0.88 and 1.2 mg/kg.

The Meeting estimated a maximum residue level of 2 mg/kg for prochloraz in cereal grains, replacing the previous recommendations of 0.5 mg/kg for barley, oats, rye and wheat. The Meeting also estimated an STMR of 0.11 mg/kg and a highest residue level of 1.2 mg/kg.

The Meeting agreed that the proposed maximum residue level, the STMR and the highest residue level for cereal grains based on foliar application would also accommodate seed treatment use of prochloraz.

#### *Pepper, black*

The results of trials on foliar application on black pepper were made available to the Meeting from Malaysia (GAP: 0.05 kg ai/hl, 30-day PHI). In trials matching this GAP, the residue levels were 5.0 and 5.1 mg/kg.

The Meeting estimated a maximum residue level of 10 mg/kg, an STMR of 5.1 mg/kg and a highest residue level of 5.1 mg/kg for prochloraz in pepper, black.

#### *Animal feed commodities*

##### *Barley straw and fodder, dry*

In four trials on barley in Denmark and The Netherlands involving a single application of prochloraz and which matched the GAP of Germany, the residue levels in barley straw were: 5.0, 6.8, 7.0 and 17 mg/kg.

The residue levels in straw in 34 trials in Belgium, Denmark, France, Germany, Sweden and the United Kingdom with two applications and matching GAP in the United Kingdom were: 0.68, 0.7, 1.1 (two), 1.4, 1.6, 2.1, 2.3, 2.4, 3.3, 3.5, 3.6, 3.7, 4.1 (two), 4.5, 4.8, 5.4, 5.7, 6.0, 6.5, 6.7, 7.6, 9.7 (two), 9.8, 12, 13 (two), 14 (two), 21, 24 and 30 mg/kg.



In 15 trials in France, Greece, Portugal and Spain, involving two applications of prochloraz according to GAP in Portugal, the residue levels in straw were: 4.0, 4.1, 4.6, 5.0, 6.4, 7.0, 7.1, 8.2, 8.4 (two), 8.8, 12 (two), 13 and 20 mg/kg.

The residue levels in barley straw in the 53 trials, in ranked order, were: 0.68, 0.7, 1.1 (two), 1.4, 1.6, 2.1, 2.3, 2.4, 3.3, 3.5, 3.6, 3.7, 4.0, 4.1 (three), 4.5, 4.6, 4.8, 5.0 (two), 5.4, 5.7, 6.0, 6.4, 6.5, 6.7, 6.8, 7.0 (two), 7.1, 7.6, 8.2, 8.4 (two), 8.8, 9.7 (two), 9.8, 12 (three), 13 (three), 14 (two), 17, 20, 21, 24 and 30 mg/kg.

In field trials in Denmark (GAP: 20 g ai/100 kg seed) and Germany (no GAP) on residues in barley grown from seed treated with prochloraz, the residue levels of total prochloraz in straw in 17 trials matching Danish GAP were: < 0.05 (three), < 0.1 (13) and < 0.2 mg/kg.

*Oat straw and fodder, dry*

In 10 field trials of seed treatment in Germany that matched German GAP (20 g ai/kg seed), the residue levels of total prochloraz in oat straw grown from seed treated with prochloraz were: < 0.05 (two), < 0.1 (seven) and < 0.2 mg/kg.

*Rye straw and fodder, dry*

In three trials in Germany matching German GAP, the residue levels in straw were: 1.1, 1.5 and 1.7 mg/kg. The residue levels in additional trials in Germany matching GAP in the United Kingdom were: 0.09, 3.1, 3.4 and 4.7 mg/kg. The residue levels in rye straw, in ranked order, were: 0.09, 1.1, 1.5, 1.7, 3.1, 3.4 and 4.7 mg/kg.

In five trials in Germany matching German GAP on residues in straw from rye grown from seed treated with prochloraz, the residue levels of total prochloraz were: < 0.1 (four) and < 0.2 mg/kg.

*Wheat straw and fodder, dry*

In six trials on wheat conducted in the former Czechoslovakia, The Netherlands and the United Kingdom involving a single application of prochloraz and matching German GAP, the residue levels in straw were: 1.5, 4.6, 5.2, 6.4, 6.8 and 11 mg/kg.

The residue levels in straw in 14 trials on wheat in southern France, Greece, Italy, Portugal and Spain involving two applications of prochloraz according to GAP in Portugal (0.45 kg ai/ha, 35-day PHI), the residue levels were: 3.5, 4.3, 8.0, 8.2 (two), 8.3, 9.6 (two), 10 (two), 11, 13 (two) and 22 mg/kg.

The residue levels in 32 trials involving two applications of prochloraz to wheat in northern France, Germany and the United Kingdom matching GAP in Belgium and the United Kingdom were: 1.7, 1.8, 2.3, 2.4, 2.5, 2.6, 2.7 (two), 2.8, 3.0, 3.7, 4.3, 5.1, 5.2, 5.3, 5.6, 5.8, 6.5, 6.6, 6.9, 8.0, 8.8, 10, 11 (three), 13, 15, 16, 19, 20 and 22 mg/kg.

The residue levels in wheat straw in all 52 trials, in ranked order, were: 1.5, 1.7, 1.8, 2.3, 2.4, 2.5, 2.6, 2.7 (two), 2.8, 3.0, 3.5, 3.7, 4.3 (two), 4.6, 5.1, 5.2 (two), 5.3, 5.6, 5.8, 6.4, 6.5, 6.6, 6.8, 6.9, 8.0 (two), 8.2 (two), 8.3, 8.8, 9.6 (two), 10 (three), 11 (five), 13 (three), 15, 16, 19, 20 and 22 (two) mg/kg.

In 24 trials of seed treatment matching German GAP, the residue levels of total prochloraz in wheat straw were: < 0.05 (four), < 0.06, < 0.1 (17) and < 0.2 (two) mg/kg.

The Meeting considered that the available data on barley, rye and wheat straw and fodder treated by foliar application were sufficient to mutually support a group maximum residue level for straw and fodder, dry, of cereal grains. The residue levels in the 112 trials, in ranked order, were: 0.09, 0.68, 0.7, 1.1 (three), 1.4, 1.5 (two), 1.7 (two), 1.6, 1.8, 2.1, 2.3 (two), 2.4 (two), 2.5, 2.6, 2.7 (two), 2.8, 3.0, 3.1, 3.3, 3.4, 3.5 (two), 3.6, 3.7 (two), 4.0, 4.1 (three), 4.3 (two), 4.5, 4.6 (two), 4.7, 4.8, 5.0 (two), 5.1, 5.2 (two), 5.3, 5.4, 5.6, 5.7, 5.8, 6.0, 6.4 (two), 6.5 (two), 6.6, 6.7, 6.8 (two), 6.9, 7.0 (two), 7.1, 7.6, 8.0 (two), 8.2 (three), 8.3, 8.4 (two), 8.8 (two), 9.6 (two), 9.7 (two), 9.8, 10 (three), 11 (five), 12 (three), 13 (five), 14 (two), 15, 16, 17, 19, 20 (two), 21, 22 (two), 24 and 30 mg/kg.

Allowing for a dry matter content of 90% (*FAO Manual*), the Meeting estimated a maximum residue level of 40 mg/kg for prochloraz in straw and fodder, dry, of cereal grains, replacing the previous recommendations of 15 mg/kg for barley straw and fodder, dry; oats straw and fodder, dry; rye straw and fodder, dry, and wheat straw and fodder, dry. The Meeting also estimated an STMR of 7.2 mg/kg and a highest residue level of 33 mg/kg.

The Meeting agreed that the available data indicated that the proposed maximum residue level, STMR and highest residue level for straw and fodder, dry, after foliar application would also accommodate seed treatment use of prochloraz.

### ***Fate of residues during storage***

The Meeting received the results of a study on the fate of prochloraz residues in oranges. Fruit dipped in prochloraz at 0.1–0.2 kg ai/hl and shipped under refrigeration for 44 days were stored at 4 °C or 20 °C for a further 7, 14 or 21 days. No significant degradation of residue was observed during the post-shipping 21-day storage period, as > 87% of the residue remained in the stored fruit. The median retention value was 99% for ambient-stored fruit and 117% for cool-stored fruit.

### ***Fate of residues during processing***

The effect of processing on levels of residues of prochloraz was studied in barley, rape-seed and wheat, and the residue levels in oil and press cake were reported in several field trials on sunflower seed; residue levels in green black pepper and in processed white pepper were reported in one trial on pepper. A study on residues in dehydrated and preserved mushrooms was also provided to the Meeting. The processing factors of relevance to estimation of maximum residue levels, the dietary burden of farm animals and dietary risk assessment, shown below, were derived from these studies.

| Raw agricultural commodity | Processed product   | No. of samples | Mean processing factor |
|----------------------------|---------------------|----------------|------------------------|
| Barley                     | Beer                | 4              | 0.09                   |
| Wheat                      | Bran (total)        | 1              | 4.3                    |
|                            | Flour (unspecified) | 3              | 0.23                   |
|                            | Bread (whole grain) | 1              | 1.3                    |
| Rape-seed                  | Seed cake (meal)    | 18             | 0.79                   |
|                            | Refined oil         | 4              | < 0.6                  |
| Sunflower seed             | Seed cake (meal)    | 6              | 0.49                   |
| Pepper                     | Black peppercorns   | 4              | 0.96                   |
|                            | White peppercorns   | 4              | 0.35                   |
| Mushrooms                  | Dehydrated          | 3              | 3.7                    |
|                            | Preserved           | 2              | 0.4                    |
|                            | Preservation liquor | 2              | 0.65                   |

*Wheat* was processed into milled by-products (bran), flour and whole-grain bread, with processing factors of 4.3, 0.23 and 1.3, respectively. On the basis of the STMR value of 0.11 mg/kg for cereal grains, the STMR-Ps were 0.025 mg/kg for wheat flour and 0.14 mg/kg for wholemeal bread.

Wheat milled by-products (bran) is listed as animal feed in the *FAO Manual* (Appendix IX). Allowing for the standard 88% dry matter, the Meeting estimated an STMR-P of 0.54 mg/kg for wheat bran (dry weight).

On the basis of the highest residue level of 1.2 mg/kg, the processing factor of 4.3 and the standard dry matter content of 88%, the Meeting recommended a maximum residue level of 7 mg/kg for wheat bran, unprocessed (dry weight basis).

*Barley* was processed into beer, with a processing factor of 0.09. On the basis of the STMR value of 0.11 mg/kg for cereal grains, the STMR-P for beer was 0.01 mg/kg.

The residue levels in seed cake in trials on *rape* in Denmark and Germany, matching the GAP of the United Kingdom and Germany, respectively, and used in estimating the maximum residue levels, were: < 0.05, 0.05 (three), 0.07, 0.08 (two) and 0.1 mg/kg. The Meeting established an STMR-P of 0.06 mg/kg for rape-seed meal.

In four processing studies, the residue levels in refined oil from rape-seed containing 0.07–0.12 mg/kg were below the LOQ (< 0.05 mg/kg). Using a processing factor of < 0.6 and an STMR of 0.1 mg/kg for rape-seed, the Meeting established an STMR-P of 0.06 mg/kg for rape-seed oil, edible.

The residue levels in seed cake in three trials on *sunflower seed* in France that were used in estimating the maximum residue level were ≤ 0.1 (two) and 0.15 mg/kg. Taking into account the STMR for sunflower seed (0.1 mg/kg) and the processing factor of 0.49, the Meeting established an STMR-P of 0.05 mg/kg for sunflower seed meal.

The Meeting agreed to use the STMR of 0.1 mg/kg for sunflower seed and the processing factor of < 0.6 derived for refined rape-seed oil to estimate an STMR-P of 0.06 mg/kg for sunflower seed oil (refined).

In a field study in Malaysia on green (fresh) *peppercorns*, the residues were not concentrated during the sun-drying process used to produce black peppercorns (mean processing factor, 0.96), and the residue levels decreased during husking to produce white peppercorns (mean processing factor, 0.35).

## Residues in animal commodities

### Dietary burden of farm animals

The Meeting estimated the dietary burden of total prochloraz in cows and poultry on the basis of the diets listed in Appendix IX of the *FAO Manua*. Calculations from MRLs and highest residue levels provide the levels in feed suitable for estimating MRLs for animal commodities, while calculations from STMR values for feed are suitable for estimating STMR values for animal commodities. The percentage of dry matter is taken as 100% when MRLs and STMR values are already expressed as dry weight.

### Estimated maximum dietary burden of farm animals

| Commodity                | Group | Residue<br>(mg/kg) | Basis  | Dry matter<br>(%) | Residue/Dry<br>matter (mg/kg) | Dietary content (%) |                 |           | Residue contribution<br>(mg/kg) |                 |         |
|--------------------------|-------|--------------------|--------|-------------------|-------------------------------|---------------------|-----------------|-----------|---------------------------------|-----------------|---------|
|                          |       |                    |        |                   |                               | Beef<br>cattle      | Dairy<br>cattle | Poultry   | Beef<br>cattle                  | Dairy<br>cattle | Poultry |
| Rape meal                | –     | 0.06               | STMR-P | 88                | 0.07                          |                     |                 |           |                                 |                 |         |
| Sunflower meal           | –     | 0.05               | STMR-P | 92                | 0.05                          |                     |                 |           |                                 |                 |         |
| Barley straw             | AS    | 33                 | HR     | 100               | 33                            | <b>10</b>           | <b>60</b>       |           | 3.3                             | 19.8            |         |
| Wheat straw              | AS    | 33                 | HR     | 100               | 33                            |                     |                 |           |                                 |                 |         |
| Rye straw                | AS    | 33                 | HR     | 100               | 33                            |                     |                 |           |                                 |                 |         |
| Oat straw                | AS    | 33                 | HR     | 100               | 33                            |                     |                 |           |                                 |                 |         |
| Wheat milled by-products | CF    | 0.54               | STMR-P | 100               | 0.54                          | <b>10</b>           |                 | <b>20</b> | 0.05                            |                 | 0.11    |
| Barley grain             | GC    | 1.2                | HR     | 88                | 1.36                          |                     |                 |           |                                 |                 |         |

| Commodity   | Group | Residue<br>(mg/kg) | Basis | Dry matter<br>(%) | Residue/Dry<br>matter (mg/kg) | Dietary content (%) |                 |           | Residue contribution<br>(mg/kg) |                 |            |
|-------------|-------|--------------------|-------|-------------------|-------------------------------|---------------------|-----------------|-----------|---------------------------------|-----------------|------------|
|             |       |                    |       |                   |                               | Beef<br>cattle      | Dairy<br>cattle | Poultry   | Beef<br>cattle                  | Dairy<br>cattle | Poultry    |
| Corn grain  | GC    | 1.2                | HR    | 88                | 1.36                          | <b>80</b>           | <b>40</b>       | <b>80</b> | 1.09                            | 0.55            | 1.09       |
| Rye grain   | GC    | 1.2                | HR    | 88                | 1.36                          |                     |                 |           |                                 |                 |            |
| Wheat grain | GC    | 1.2                | HR    | 89                | 1.35                          |                     |                 |           |                                 |                 |            |
| Oat grain   | GC    | 1.2                | HR    | 89                | 1.35                          |                     |                 |           |                                 |                 |            |
| Total       |       |                    |       |                   |                               | 100                 | 100             | 100       | <b>4.4</b>                      | <b>20</b>       | <b>1.2</b> |

*Estimated median dietary burden of farm animals*

| Commodity                | Group | Residue<br>(mg/kg) | Basis  | Dry matter<br>(%) | Residue/Dry<br>matter (mg/kg) | Dietary content (%) |                 |           | Residue contribution<br>(mg/kg) |                 |             |
|--------------------------|-------|--------------------|--------|-------------------|-------------------------------|---------------------|-----------------|-----------|---------------------------------|-----------------|-------------|
|                          |       |                    |        |                   |                               | Beef<br>cattle      | Dairy<br>cattle | Poultry   | Beef<br>cattle                  | Dairy<br>cattle | Poultry     |
| Rape meal                | –     | 0.06               | STMR-P | 88                | 0.07                          |                     |                 |           |                                 |                 |             |
| Sunflower meal           | –     | 0.05               | STMR-P | 92                | 0.05                          |                     |                 |           |                                 |                 |             |
| Barley straw             | AS    | 7.2                | STMR   | 100               | 7.2                           | <b>10</b>           | <b>60</b>       |           | 0.72                            | 4.32            |             |
| Wheat straw              | AS    | 7.2                | STMR   | 100               | 7.2                           |                     |                 |           |                                 |                 |             |
| Rye straw                | AS    | 7.2                | STMR   | 100               | 7.2                           |                     |                 |           |                                 |                 |             |
| Oat straw                | AS    | 7.2                | STMR   | 100               | 7.2                           |                     |                 |           |                                 |                 |             |
| Wheat milled by-products | CF    | 0.54               | STMR-P | 100               | 0.54                          | <b>10</b>           |                 | <b>20</b> | 0.05                            |                 | 0.11        |
| Barley grain             | GC    | 0.11               | STMR   | 88                | 0.13                          |                     |                 |           |                                 |                 |             |
| Corn grain               |       | 0.11               | STMR   | 88                | 0.13                          | <b>80</b>           | <b>40</b>       | <b>80</b> | 0.1                             | 0.05            | 0.1         |
| Rye grain                | GC    | 0.11               | STMR   | 88                | 0.13                          |                     |                 |           |                                 |                 |             |
| Wheat grain              | GC    | 0.11               | STMR   | 89                | 0.12                          |                     |                 |           |                                 |                 |             |
| Oat grain                | GC    | 0.11               | STMR   | 89                | 0.12                          |                     |                 |           |                                 |                 |             |
| Total                    |       |                    |        |                   |                               | 100                 | 100             | 100       | <b>0.87</b>                     | <b>4.4</b>      | <b>0.21</b> |

The total dietary burdens of prochloraz for estimating MRLs for animal commodities (residue levels in animal feeds expressed as dry weight) are 4.4 ppm for beef cattle, 20 ppm for dairy cattle and 1.2 ppm for poultry. The associated median dietary burdens for estimating STMR are 0.87 ppm for beef cattle, 4.4 ppm for dairy cattle and 0.21 ppm for poultry.

*Feeding studies*

The Meeting received information from two studies on the residue levels in tissues and milk from dairy cows dosed with prochloraz for 28 days at an equivalent of 10, 30 and 100 ppm in the diet and from a feeding study in which calves were fed a diet containing prochloraz twice daily, resulting in a rate of 0.263 mg/kg bw (dietary concentration could not be estimated).

In one of the studies in dairy cows, tissues were analysed for total prochloraz residues by gas chromatography with mass spectrometry detection after conversion of the metabolites to 2,4,6-trichlorophenol. The mean recovery efficiency was 89%, and the LOQ was 0.05 mg/kg. At the end of the 28-day treatment period, the mean residue levels in muscle ranged from < 0.05 mg/kg to 0.37 mg/kg in cows at the highest dose. In subcutaneous fat, the mean residue levels ranged from 0.09 mg/kg at the lowest dose to 1.2 mg/kg at the highest dose, and those in peritoneal fat ranged from 0.16 mg/kg to 1 mg/kg for the three groups. The

mean residue levels in kidney were 0.52 mg/kg at the lowest dose to 3.2 mg/kg at the highest, and those in liver were 2.8 mg/kg at the lowest dose, 6.4 mg/kg at 30 ppm and 23 mg/kg at 100 ppm.

The results of the study in which calves were dosed at 0.26 mg/kg bw for 28 days were similar to those for cows receiving the lowest dose, with mean residue levels of 2.2 mg/kg in liver, 0.55 mg/kg in kidney, 0.09 mg/kg in fat and 0.06–0.09 mg/kg in muscle.

Residues of free prochloraz and three metabolites were measured in milk from cows dosed twice daily after milking with prochloraz for 28 days at an equivalent of 10, 30 and 100 ppm in the diet. Traces of prochloraz were detected in the group at 100 ppm from day 4 and in the group at 30 ppm after day 28, but all the residue levels were below the reported LOQ of 0.01 mg/kg. No residues of the metabolites BTS 54906 and BTS 54908 were detected in milk from cows at any dose. Trace levels (< 0.01 mg/kg) of BTS 44596 were reported in milk from cows at 30 ppm from day 22, and the average levels in milk from cows at 100 ppm reached a plateau of  $0.01 \pm 0.003$  mg/kg from day 4. Milk sampled and separated on day 24 contained average levels of BTS 44596 of 0.005 mg/kg in skim milk and 0.032 mg/kg in cream, suggesting preferential partitioning (six times) into milk fat.

#### Maximum residue levels

As the total dietary burdens of *beef and dairy cattle* are 4.4 and 20 ppm, respectively, the maximum residue levels to be expected in tissues can be obtained by interpolating the results of feeding at a level of 10 or 30 ppm. The maximum residue levels reported were 3.3 mg/kg and 9 mg/kg in liver, 0.24 mg/kg and 0.51 mg/kg in fat, 0.05 mg/kg and 0.14 mg/kg in muscle and 0.59 mg/kg and 1.8 mg/kg in kidney.

The median dietary burdens were 0.87 ppm for beef cattle and 4.4 ppm for dairy cattle. STMR values can be extrapolated from the mean residue levels in tissues of animals at 10 ppm, i.e. 2.8 mg/kg in liver, 0.13 mg/kg in fat, < 0.05 mg/kg in muscle and 0.52 mg/kg in kidney. The mean residue level in milk at both feeding levels was < 0.01 mg/kg,

| Dietary burden (mg/kg) <sup>a</sup><br>Feeding level [ppm] <sup>b</sup> |                 | Prochloraz residue level (mg/kg) <sup>c</sup> |  |                     |        |                     |       |                |        |                   |      |
|-------------------------------------------------------------------------|-----------------|-----------------------------------------------|--|---------------------|--------|---------------------|-------|----------------|--------|-------------------|------|
|                                                                         |                 | Milk (mean)                                   |  | Fat                 | Muscle |                     | Liver |                | Kidney |                   |      |
|                                                                         |                 |                                               |  | High                | Mean   | High                | Mean  | High           | Mean   | High              | Mean |
| MRL beef cattle                                                         | (20)<br>[10:30] |                                               |  | (0.38)<br>0.24:0.51 |        | (0.1)<br>0.05:0.14  |       | (6.2)<br>3.3:9 |        | (1.2)<br>0.59:1.8 |      |
| MRL dairy cattle                                                        | (20)<br>[10:30] | (< 0.01)<br>< 0.01:< 0.01                     |  |                     |        |                     |       |                |        |                   |      |
| STMR beef cattle                                                        | (4.4)<br>[5]    |                                               |  | (0.057)<br>0.13     |        | (< 0.022)<br>< 0.05 |       | (1.23)<br>2.8  |        | (0.229)<br>0.52   |      |
| STMR dairy cattle                                                       | (4.4)<br>[5]    | (< 0.0044)<br>< 0.01                          |  |                     |        |                     |       |                |        |                   |      |

<sup>a</sup> In parentheses, estimated dietary burden

<sup>b</sup> In square brackets, actual feeding levels in transfer studies

<sup>c</sup> Values in parentheses in italics are derived from the dietary burden, feeding levels and residue levels found in the transfer studies. 'High' is the highest residue level in an individual tissue in the relevant feeding group. 'Mean' is the mean residue level in tissue (or milk) in the relevant feeding group.

On the basis of the above considerations, the Meeting estimated highest residue levels of 0.1 mg/kg in meat (muscle), 0.38 mg/kg in meat (fat), 6.2 mg/kg in edible offal (mammalian) and 0 mg/kg in milks.

The Meeting estimated maximum residue levels of 0.5 mg/kg (fat) in meat (from mammals other than marine mammals); 10 mg/kg in edible offal, mammalian and 0.05 (\*) mg/kg in milks. These recommendations replace the previous recommendations of 0.5 mg/kg for cattle fat, 0.1 (\*) mg/kg for cattle meat, 5.0 mg/kg for cattle, edible offal of, and 0.1 (\*) mg/kg for milks. The Meeting estimated STMRs of 0.02 mg/kg for meat (muscle), 0.06 mg/kg for meat (fat), 1.2 mg/kg for edible offal (mammalian) and 0 mg/kg for milks.

For poultry, the information provided by the study of metabolism in hens at feeding rates of 5 and 10 ppm in hens was considered by the Meeting to be sufficient for use in estimating maximum residue levels in eggs and poultry tissues. In tissues from birds at 5 ppm, the maximum residue levels were 0.41 mg/kg in liver, 0.029 mg/kg in fat and 0.02 mg/kg in muscle. The average residue level in eggs after a plateau had been reached at day 8 was 0.28 mg/kg. The average residue levels in hens at 5 ppm were 0.34 mg/kg in liver, 0.028 mg/kg in fat, 0.019 mg/kg in muscle and 0.28 mg/kg in eggs (after day 8).

The total dietary burden of poultry is 1.2 mg/kg, and the median dietary burden is 0.21 mg/kg. The Meeting agreed that extrapolation from the results for hens at the 5 ppm feeding level in the metabolism study was appropriate for estimating maximum residue levels, STMRs and highest residue levels

| Dietary burden (mg/kg) <sup>a</sup><br>Feeding level [ppm] <sup>b</sup> |               | Prochloraz residue levels (mg/kg) <sup>c</sup> |                   |      |                   |      |                  |      |
|-------------------------------------------------------------------------|---------------|------------------------------------------------|-------------------|------|-------------------|------|------------------|------|
|                                                                         |               | Eggs (mean)                                    | Fat               |      | Muscle            |      | Liver            |      |
|                                                                         |               |                                                | High              | Mean | High              | Mean | High             | Mean |
| MRL poultry                                                             | (1.2)<br>[5]  | (0.0672)<br>0.28                               | (0.007)<br>0.029  |      | (0.0048)<br>0.02  |      | (0.0984)<br>0.41 |      |
| STMR poultry                                                            | (0.21)<br>[5] | (0.0118)<br>0.28                               | (0.0012)<br>0.028 |      | (0.0008)<br>0.019 |      | (0.0143)<br>0.34 |      |

<sup>a</sup> In parentheses, estimated dietary burden

<sup>b</sup> In square brackets, actual feeding levels in transfer studies

<sup>c</sup> Values in parentheses in italics are derived from the dietary burden, feeding levels and residue levels found in the transfer studies. 'High' is the highest residue level in an individual tissue in the relevant feeding group. 'Mean' is the mean residue level in tissue in the relevant feeding group.

On the basis of this extrapolation, the Meeting estimated highest residue levels of 0.005 mg/kg for poultry meat, 0.007 mg/kg for poultry fats, 0.1 mg/kg for poultry, edible offal of, and 0.07 mg/kg for eggs.

The Meeting estimated maximum residue levels of 0.05 (\*) mg/kg for poultry meat, 0.2 mg/kg for poultry, edible offal of, and 0.1 mg/kg for eggs; it also estimated STMRs of 0.001 mg/kg in poultry meat (muscle), 0.001 mg/kg in poultry meat (fat), 0.015 mg/kg in poultry, edible offal of, and 0.012 mg/kg in eggs.

## DIETARY RISK ASSESSMENT

### Long-term intake

The evaluation of prochloraz resulted in recommendations for MRLs and STMRs for raw and processed commodities. Data were available on the consumption of 35 food commodities, and these were used in calculating dietary intake. The results are shown in Annex 3.

The IEDIs in the five GEMS/Food regional diets, on the basis of the estimated STMRs, represented 7–10% of the ADI of 0–0.01 mg/kg bw (Annex 3). The Meeting concluded that the long-term intake of residues of prochloraz from uses that have been considered by the JMPR is unlikely to present a public health concern.

### Short-term intake

The IESTI of prochloraz was calculated for the food commodities (and their processing fractions) for which maximum and highest residue levels had been estimated and for which data on consumption were available. The results are shown in Annex 4.

The IESTI varied from 0 to 130% of the ARfD (0.1 mg/kg bw) for the general population and from 0 to 150% of the ARfD for children ≤ 6 years. The short-term intake of mushrooms, for which the calculation

was made, represented 150% of the ARfD for children  $\leq 6$  years and 130% of the ARfD for the general population. The information provided to the Meeting precluded a conclusion that the short-term dietary intake of mushrooms would result in residue levels below the ARfD.

## 4.24 PROPICONAZOLE (160)

### TOXICOLOGY

Propiconazole is the ISO approved name for 1-[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl-methyl]-1*H*-1,2,4-triazole, a systemic fungicide that acts by inhibition of ergosterol biosynthesis. Propiconazole was evaluated toxicologically by the JMPR in 1987, when an ADI of 0–0.04 mg/kg bw was established on the basis of the NOAEL of 4 mg/kg bw per day for effects on body weight, clinical chemistry and haematology in a 2-year study in rats, and this was supported by the NOAEL of 7 mg/kg bw per day in a 1-year study in dogs. Propiconazole was considered by the present Meeting within the periodic review programme of the CCPR. The Meeting reviewed new data on propiconazole that had not been reviewed previously and relevant data from the previous evaluation.

After oral administration of radiolabelled propiconazole to rats and mice, the radiolabel is rapidly ( $C_{\max}$  at 1 h) and extensively (> 80% of the administered dose) absorbed and widely distributed, with the highest concentrations being found in the liver and kidney. Excretion of the radiolabel is rapid (80% in 24 h) with significant amounts being found in the urine (39–81%) and the faeces (20–50%), the proportions varying with dose, species and sex. There is a significant degree of biliary excretion and subsequent enterohepatic recirculation. There was no evidence for bioaccumulation with tissue or carcass residues being typically < 1% of the administered dose 6 days after dosing. Propiconazole is extensively metabolized and < 5% of the dose remains as parent compound; however, many metabolites have not been identified. The primary metabolic steps involve oxidation of the propyl side-chain on the dioxolane ring to give hydroxy or carboxylic acid derivatives. Hydroxylation of the chlorophenyl and triazole rings followed by conjugation with sulfate or glucuronide was also detected. There is evidence for only limited cleavage between the triazole and chlorophenyl rings. The extent of cleavage of the dioxolane ring was significantly different according to species and sex, representing about 60% of urinary radioactivity in male mice, 30% in female mice and 10–30% in male rats. In rats, about 30% propiconazole is absorbed within 10 h of dermal application.

Propiconazole has moderate acute oral toxicity in rats and mice ( $LD_{50}$  values, about 1500 mg/kg bw) and low acute dermal ( $LD_{50}$  values, > 4000 mg/kg bw) and inhalation toxicity ( $LC_{50}$ , > 5 mg/l of air). Propiconazole is not an eye irritant in rabbits, but is irritating to rabbit skin and is a skin sensitizer in guinea-pigs in the Magnusson and Kligman test.

Decreased body-weight gain was seen in short- and long-term studies of toxicity and studies of developmental and reproductive toxicity and was often linked with reduced food consumption. In studies of repeated doses, liver was the primary target organ for toxicity attributable to propiconazole. In rats, erythrocyte parameters were reduced and a range of clinical chemistry changes were seen, however, with the exception of reduced chloride and cholesterol concentrations, there was no consistent pattern between sexes and studies, and results were generally within the physiological range.

In two studies, mice given diets containing propiconazole at  $\geq 850$  ppm for up to 17 weeks had increases in liver weight, reduced concentrations of serum cholesterol and increased hepatocyte hypertrophy, vacuolation and necrosis. The findings were present after 4 weeks and did not progress with increased duration of dosing. The NOAEL was 500 ppm (equal to 65–85 mg/kg bw per day) in both studies.

Rats given propiconazole at 450 mg/kg bw per day for 28 days by gavage exhibited a range of effects. Males had reductions in body-weight gain, while females had clinical signs of toxicity and reductions

in erythrocyte parameters. Both sexes had increased liver weights and hepatocyte hypertrophy, with hepatocyte necrosis also being seen in females. Increases in liver weight with hepatocyte hypertrophy were seen at 150 mg/kg bw per day, but these effects were not considered to be adverse and the NOAEL was this dose. In a 13-week dietary study in rats, reductions in body-weight gain, increased relative liver weight and increased  $\gamma$ -glutamyltranspeptidase activity was seen in both sexes at 6000 ppm. In females, erythrocyte parameters were reduced at this dose. The NOAEL was 1200 ppm (equal to 76 mg/kg bw per day).

Dogs appeared to be sensitive to the local effects of propiconazole as manifested by gastrointestinal tract irritation at  $\geq 8.4$  mg/kg bw per day; the NOAELs were 250 ppm (equal to 6.9 mg/kg bw per day) after 90 days and 1.9 mg/kg bw per day after 1 year. No systemic effects were seen in dogs receiving 8.4 mg/kg bw per day for 1 year or 1250 ppm (equal to 35 mg/kg bw per day) for 90 days, the highest doses tested.

In a 3-week (five applications per week) study of dermal toxicity in rabbits, tremors, dyspnoea and ataxia were increased at  $\geq 1000$  mg/kg bw per day. The NOAEL was 200 mg/kg bw per day. In a 13-week (5 days per week; 6 h per day) study in rats treated by inhalation, reduced body-weight gain was seen in females at 0.19 mg/l of air; the NOAEC was 0.085 mg/l of air.

The carcinogenic potential of propiconazole was studied in one study in rats and in two studies in mice. In a 2-year dietary study in male and female mice and an 18-month dietary study in male mice, the liver was the only target organ. At  $\geq 500$  ppm, there were decreases in body-weight gain and serum concentration of cholesterol and increases in liver weight, hepatocellular hypertrophy and hepatocellular vacuolation. The NOAEL for non-neoplastic effects in both studies was 100 ppm (equal to 11 mg/kg bw per day). Propiconazole was a hepatocarcinogen only in male mice, on the basis of significant increases in the incidence of liver tumours at  $\geq 850$  ppm (equal to 108 mg/kg bw per day), with a NOAEL of 500 ppm (equal to 59 mg/kg bw per day). Assays for hepatocyte proliferation (measured by bromodeoxyuridine incorporation) in mice showed qualitative similarities between propiconazole and phenobarbital. The doses that produced increases in tumour incidences ( $\geq 850$  ppm) also produced cell proliferation, increased liver weight and hepatocyte hypertrophy. Studies of liver enzyme induction in mice showed that propiconazole increased the activity of a number of cytochrome P450s, particularly Cyp2b and exhibited similar characteristics to a phenobarbital-type inducer of xenobiotic metabolizing enzymes. The progression from cytochrome P450 (Cyp2b) induction, initial mitogenic response, hepatocyte hypertrophy and increased liver weight to tumours is consistent with a mode of action similar to that of phenobarbital.

At 2500 ppm (96 mg/kg bw per day) in a 2-year dietary study in rats, there were reductions in body-weight gain in both sexes. Increased incidences of enlarged hepatocytes were present in males and increases in atrophy of the exocrine pancreas and dilatation of the uterine lumen in females. Slight ( $< 10\%$ ), transient reductions in body-weight gain, variations in clinical chemistry and haematology parameters that fell within physiological ranges at 500 ppm (equal to 18 mg/kg bw per day) were not considered to be adverse. Propiconazole was not carcinogenic in rats at doses of up to 2500 ppm (equal to 96 mg/kg bw per day). The NOAEL in the 2-year study in rats was 500 ppm (equal to 18 mg/kg bw per day).

Propiconazole gave negative results in an adequate battery of studies of genotoxicity in vitro and in vivo.

The Meeting concluded that propiconazole was unlikely to be genotoxic.

On the basis of the above consideration of the male mouse liver tumours, the high doses required to induce tumours, the likely mechanism of action, the absence of tumorigenicity in rats and the negative results in studies of genotoxicity, the Meeting concluded that propiconazole was unlikely to pose a carcinogenic risk to humans.

In a two-generation study of reproductive toxicity in rats, reproductive parameters were not affected by treatment with propiconazole. At 500 ppm (equivalent to 35 mg/kg bw per day) dams had reduced body-weight gains ( $p < 0.01$ ) and both sexes exhibited hepatotoxicity, thus the NOAEL for parental toxicity was 100 ppm (equivalent to 7 mg/kg bw per day). The NOAEL for offspring toxicity was 100 ppm (equivalent to



7 mg/kg bw per day) on the basis of decreased pup body weights in the F<sub>2b</sub> litters ( $p < 0.01$ ). The NOAEL for reproductive effects was 500 ppm (equivalent to 35 mg/kg bw per day) on the basis of reduced pup survival at 2500 ppm (equivalent to 175 mg/kg bw per day).

Three studies of developmental toxicity were conducted in rats and one in rabbits. In the first study in rats, at the highest dose of 300 mg/kg bw per day there was evidence of maternal toxicity and retarded development, but no malformations. In the second study, propiconazole caused developmental delay (incomplete ossification of sternebrae and rudimentary cervical ribs) at a dose of 90 mg/kg bw per day, which also produced a slight, transient reduction in food consumption and body-weight gain at the initiation of dosing. The NOAEL was 90 mg/kg bw per day for maternal effects and 30 mg/kg bw per day for developmental effects. A low incidence of cleft palate was observed at 90 mg/kg bw per day (one fetus, 0.3%) and at 360/300 mg/kg bw per day (two fetuses, 0.7%) in the presence of severe maternal toxicity. The maternal toxicity included lethargy, ataxia, salivation and reductions in food consumption and body-weight gain at the start of the dosing period. The cleft palate finding was also seen at a low incidence in rats in an extensive study that specifically investigated the palate and jaw at a single dose of 300 mg/kg bw per day. Cleft palates were detected in two out of 2064 fetuses of treated animals versus none in the 2122 fetuses of controls, in the presence of severe maternal toxicity. Marked maternal toxicity was observed throughout the treatment period, included reductions in food consumption and body-weight gain, ataxia, coma, lethargy and prostration and three treatment-related deaths among 189 dams. Cleft palate is a very rare but occasional finding in control rats and there were published data that indicated testing compounds at maternally toxic doses is associated in some way with the induction of a number of malformations, including cleft palate.

Propiconazole was not teratogenic in rabbits. The NOAEL for fetal effects was 250 mg/kg bw per day on the basis of an increased incidence of the formation of thirteenth ribs at 400 mg/kg bw per day in the presence of maternal body-weight loss, signs of toxicity and abortions. The NOAEL for maternal toxicity was 100 mg/kg bw per day on the basis of reduced food consumption and body-weight loss at 250 mg/kg bw per day.

No studies of neurotoxicity with propiconazole were available; however, no evidence of neurotoxicity was apparent in any of the available studies.

Humans exposed to formulated products containing propiconazole have shown local irritant reactions. No evidence of sensitization was seen in an epicutaneous test in 20 volunteers.

The Meeting concluded that the existing database on propiconazole was adequate to characterize the potential hazards to fetuses, infants and children.

### ***Toxicological evaluation***

The Meeting established an ADI of 0–0.07 mg/kg bw based on the NOAEL of 7 mg/kg bw per day in a multigeneration study of reproductive toxicity in rats and a 100-fold safety factor. This value covers all other end-points and is supported by NOAELs of 11 mg/kg bw per day in a 24-month study in mice and 18 mg/kg bw per day in a 2-year study in rats. This ADI is protective against the local effects seen in the gastrointestinal tract in dogs (NOAEL, 1.9 mg/kg bw per day), which were considered to be concentration-dependent and hence would merit a safety factor of 25.

An ARfD of 0.3 mg/kg bw was established based on the NOAEL of 30 mg/kg bw per day in the study of developmental toxicity in rats and a 100-fold safety factor. The NOAEL was identified on the basis of slight increases in rudimentary ribs and unossified sternebrae at 90 mg/kg bw per day, which could not be discounted. This provides an adequate margin over the maternal toxicity and cleft palate seen at 300 mg/kg bw per day. The Meeting noted that the highest dose tested in dogs was 35 mg/kg bw per day and that the proposed ARfD would be protective for any potentially acute effects observed in dogs.

A toxicological monograph was prepared.

*Levels relevant to risk assessment*

| Species | Study                                                          | Effect                                  | NOAEL                                               | LOAEL                                               |
|---------|----------------------------------------------------------------|-----------------------------------------|-----------------------------------------------------|-----------------------------------------------------|
| Mouse   | 24-month study of toxicity and carcinogenicity <sup>a, e</sup> | Toxicity                                | 100 ppm, equal to 11 mg/kg bw per day               | 500 ppm, equal to 59 mg/kg bw per day               |
|         |                                                                | Carcinogenicity                         | 500 ppm, equal to 59 mg/kg bw per day               | 850 ppm, equal to 108 mg/kg bw per day              |
| Rat     | 2-year study of toxicity and carcinogenicity <sup>a</sup>      | Toxicity                                | 500 ppm, equal to 18 mg/kg bw per day               | 2500 ppm, equal to 96 mg/kg bw per day              |
|         |                                                                | Carcinogenicity                         | 2500 ppm, equal to 96 mg/kg bw per day <sup>c</sup> | —                                                   |
|         | Two-generation study of reproductive toxicity <sup>a</sup>     | Parental toxicity                       | 100 ppm, equivalent to 7 mg/kg bw per day           | 500 ppm, equivalent to 35 mg/kg bw per day          |
|         |                                                                | Offspring toxicity                      | 100 ppm, equivalent to 7 mg/kg bw per day           | 500 ppm, equivalent to 35 mg/kg bw per day          |
|         |                                                                | Developmental toxicity <sup>b</sup>     | 90 mg/kg bw per day                                 | 300 mg/kg bw per day                                |
| Rabbit  | Developmental toxicity <sup>b</sup>                            | Embryo- or fetotoxicity                 | 30 mg/kg bw per day                                 | 90 mg/kg bw per day                                 |
|         |                                                                | Maternal toxicity                       | 100 mg/kg bw per day                                | 250 mg/kg bw per day                                |
|         |                                                                | Embryo- or fetotoxicity                 | 250 mg/kg bw per day                                | 400 mg/kg bw per day                                |
| Dog     | 3-month study of toxicity <sup>a</sup>                         | Systemic effects                        | 1250 ppm, equal to 35 mg/kg bw per day <sup>c</sup> | —                                                   |
|         |                                                                | Local effects on gastrointestinal tract | 250 ppm, equal to 6.9 mg/kg bw per day              | 1250 ppm, equal to 35 mg/kg bw per day <sup>c</sup> |
|         | 12-month study of toxicity <sup>d</sup>                        | Systemic effects                        | 8.4 mg/kg bw per day <sup>c</sup>                   | —                                                   |
|         |                                                                | Local effects on gastrointestinal tract | 1.9 mg/kg bw per day                                | 8.4 mg/kg bw per day <sup>c</sup>                   |

<sup>a</sup> Diet<sup>b</sup> Gavage<sup>c</sup> Highest dose tested<sup>d</sup> Capsules<sup>e</sup> Two studies*Estimate of acceptable daily intake for humans*

0–0.07 mg/kg bw

*Estimate acute reference dose*

0.3 mg/kg bw

*Studies that would provide information useful for continued evaluation of the compound*

Further observations in humans

***Critical end-points for setting guidance values for exposure to propiconazole****Absorption, distribution, excretion and metabolism in animals*

|                                     |                                                                                                                 |
|-------------------------------------|-----------------------------------------------------------------------------------------------------------------|
| Rate and extent of oral absorption: | > 80% in 48 h                                                                                                   |
| Dermal absorption                   | About 30% in 10 h (rat)                                                                                         |
| Distribution:                       | Widely distributed; highest concentrations in the liver and kidney                                              |
| Potential for accumulation:         | Limited                                                                                                         |
| Rate and extent of excretion:       | > 95% in the faeces and urine in 48 h; extensive enterohepatic recirculation (68% of administered dose in bile) |

|                                                                             |                                                                                                                                                                                                                             |
|-----------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Metabolism in animals                                                       | Extensive; oxidation of propyl side-chain; hydroxylation of phenyl and triazole rings, plus conjugation; cleavage of dioxolane ring                                                                                         |
| Toxicologically significant compounds (animals, plants and the environment) | Propiconazole; triazolyl alanine and triazolyl acetic acid are produced in plants but not animals                                                                                                                           |
| <i>Acute toxicity</i>                                                       |                                                                                                                                                                                                                             |
| Rat, LD <sub>50</sub> , oral                                                | 1517 mg/kg bw                                                                                                                                                                                                               |
| Rat, LD <sub>50</sub> , dermal                                              | > 4000 mg/kg bw                                                                                                                                                                                                             |
| Rat, LC <sub>50</sub> , inhalation                                          | > 5 mg/l of air (4-h; nose only)                                                                                                                                                                                            |
| Rabbit, dermal irritation                                                   | Irritating                                                                                                                                                                                                                  |
| Rabbit, eye irritation                                                      | Not irritating                                                                                                                                                                                                              |
| Skin sensitization                                                          | Sensitizing (Magnusson and Kligman test)                                                                                                                                                                                    |
| <i>Short-term studies of toxicity</i>                                       |                                                                                                                                                                                                                             |
| Target/critical effect                                                      | Body weight, liver (mice, rats); erythrocytes (rat); stomach (dog)                                                                                                                                                          |
| Lowest relevant oral NOAEL                                                  | 50 ppm, equal to 1.9 mg/kg bw per day (1-year study in dogs)                                                                                                                                                                |
| Lowest relevant dermal NOAEL                                                | 200 mg/kg bw per day (5 days/week)                                                                                                                                                                                          |
| Lowest relevant inhalation NOAEL                                            | 0.085 mg/l (6 h/day; 5 days/week)                                                                                                                                                                                           |
| <i>Genotoxicity</i>                                                         | Not genotoxic in vitro or in vivo                                                                                                                                                                                           |
| <i>Long-term studies of toxicity and carcinogenicity</i>                    |                                                                                                                                                                                                                             |
| Target/critical effect                                                      | Liver hypertrophy and tumours (mice)<br>Liver, body weight, uterine lumen dilatation (rats)                                                                                                                                 |
| Lowest relevant NOAEL                                                       | 100 ppm, equal to 11 mg/kg bw per day (mice)                                                                                                                                                                                |
| Carcinogenicity                                                             | Hepatocellular tumours in male mice ( $\geq$ 850 ppm, equal to 108 mg/kg bw per day). Phenobarbital-type mechanism. The NOAEL was 500 ppm (equal to 59 mg/kg bw per day).<br>Unlikely to pose a carcinogenic risk to humans |
| <i>Reproductive toxicity</i>                                                |                                                                                                                                                                                                                             |
| Reproduction target/critical effect                                         | Reduced pup weight at parentally toxic dose                                                                                                                                                                                 |
| Lowest relevant reproductive NOAEL                                          | 100 ppm, equivalent to 7 mg/kg bw per day (rat)                                                                                                                                                                             |
| Developmental target/critical effect                                        | Skeletal variations                                                                                                                                                                                                         |
| Lowest relevant developmental NOAEL                                         | 30 mg/kg bw per day (rat)                                                                                                                                                                                                   |
| <i>Neurotoxicity/delayed neurotoxicity</i>                                  | No specific studies; no findings in other studies                                                                                                                                                                           |
| <i>Other toxicological studies</i>                                          |                                                                                                                                                                                                                             |
| Mechanism of induction of liver tumours                                     | Phenobarbital-type mode of action indicated by cell proliferation, liver weight and microsomal enzyme induction patterns                                                                                                    |
| <i>Medical data</i>                                                         | Local irritation associated with exposure to the formulated product                                                                                                                                                         |

| <i>Summary</i> | <i>Value</i>    | <i>Study</i>                                                | <i>Safety factor</i> |
|----------------|-----------------|-------------------------------------------------------------|----------------------|
| ADI            | 0–0.07 mg/kg bw | Reproductive toxicity in rats: pup and parental body weight | 100                  |
| ARfD           | 0.3 mg/kg bw    | Developmental toxicity in rats: embryo- or fetotoxicity     | 100                  |

## DIETARY RISK ASSESSMENT

### *Long-term intake*

Theoretical maximum daily intake were estimated for the commodities of human consumption for which Codex (CX) MRLs existed (Annex 3). The intakes in the five GEMS/Food regional diets ranged from 0 to 1% of the maximum ADI. The Meeting concluded that the long-term intake of residues of propiconazole resulting from uses considered by the JMPR is unlikely to present a public health concern.

### *Short-term intake*

An ARfD of 0.3 mg/kg bw was established for propiconazole at this Meeting, but IESTIs could not be calculated, as the residues of the compound were evaluated before procedures for estimating STMRs and highest residue levels in the edible portion of a commodity found in trials used to estimate an MRL had been established. Propiconazole was scheduled for periodic evaluation of residues in 2007, when the risk assessment would be finalized.

## 4.25 PROPINEB (105)

### TOXICOLOGY

At the present Meeting, the FAO Panel of Experts asked the WHO Core Assessment Group to establish an ARfD for propineb on the basis of the data available to the 1993 JMPR. The results of this evaluation are given in section 2.3.1.

### RESIDUE AND ANALYTICAL ASPECTS

Propineb is a broad-spectrum dithiocarbamate fungicide used on many crops. It has been evaluated several times, the initial evaluation being in 1977 and the latest in 1993. It was listed in the periodic review programme of the CCPR at its Thirty-third Session for residue review by the 2003 JMPR (ALINORM 99/24) but was re-scheduled for evaluation in 2004. The Meeting received information on the metabolism and environmental fate of propineb, methods of residue analysis, freezer storage stability, national registered use patterns, the results of supervised residue trials and national MRLs. Information on GAP, national MRLs and residue data were submitted by Australia and Japan.

The 1993 JMPR established an ADI for propineb of 0–0.007 mg/kg bw, and the 1999 JMPR established an ADI of 0–0.0003 and an ARfD of 0.003 mg/kg bw for the metabolite propylenethiourea.

### *Metabolism*

#### *Animals*

The Meeting received the results of studies of the metabolism of propineb in rats and a lactating goat. The biotransformation and degradation pathways in the goat were similar to those established in studies of rat metabolism. The metabolism of <sup>14</sup>C-propineb proceeds mainly via propylenethiourea and propylene diamine.

Once formed, propylenethiourea undergoes further reactions, leading to propylene urea, which can in turn be transformed by methylation to 2-methoxy-4-methylimidazoline. Other metabolites of propylenethiourea include 2-methylthio-4-methylimidazoline and 2-sulfonyl-4-methylimidazoline; the latter can undergo further metabolism to 4-methylimidazoline and *N*-formylpropylene diamine. In the lactating goat, the main metabolites detected were 2-methylthio-4-methylimidazoline in milk (48% TRR), kidney (25% TRR) and muscle (17% TRR), a sulfonyl conjugate of propylenethiourea in liver (23% TRR) and kidney (18% TRR) and propylenethiourea in fat and muscle (23% TRR).

### *Plants*

The Meeting received the results of studies on the metabolism of propineb in apples, grapes, potato vines and tomato. The metabolism of  $^{14}\text{C}$ -propineb was similar. It proceeds mainly via propylenethiourea (apple, 15% TRR; grape, 5.3% TRR; tomato, 30% TRR; potato vine, 3.5% TRR), which is itself further metabolized to propylene urea (apple, 5% TRR; tomato, 6.7% TRR; potato vine, 9.7% TRR). Propylenethiourea is also transformed to 4-methylimidazoline (apple, 10% TRR; tomato, 5% TRR; potato vine, 9.4% TRR), which on ring opening and oxidation gives *N*-formyl-propylene diamine (tomato, 6.7% TRR). The main metabolites identified in potato tubers after foliar spray were propylene urea (21% TRR) and a conjugate of its oxidation product 5-methylhydantoin (11% TRR). In a study on grapes harvested 0, 21 and 43 days after the last of one or three foliar applications of [1-propane- $^{14}\text{C}$ ]propineb, 83% of the  $^{14}\text{C}$  was located on the surface of the fruit 43 days after three foliar sprays. Propineb was the main component of the radiolabelled residue at all times sampled (about 42% TRR at 43 days), metabolites each accounting for < 6% of the residues.

In contrast, when two applications of  $^{14}\text{C}$ -propineb were made at the pre-blossom growth stage and grapes harvested about 100 days after the last application, most of the  $^{14}\text{C}$  was associated with small molecules arising from incorporation of  $^{14}\text{C}$  into natural plant products. Only low levels of propineb, propylene urea and *N*-formylpropylene diamine were detected, all at < 2% TRR.

After one or three applications of  $^{14}\text{C}$ -propineb to individual fruit on an apple tree, most (55–59%) of the  $^{14}\text{C}$  residue 14 days after application was located on the surface of the fruit. After 14 days, propineb accounted for 15–22% of the TRR, and no individual metabolite was present at > 10% TRR.

The metabolism of  $^{14}\text{C}$ -propylenethiourea was also studied after application to apples. Propylenethiourea (metabolite 1) undergoes rapid degradation on apples, only 0.7% of the applied  $^{14}\text{C}$  remaining on or in the peel 3 days after application. The main metabolite of propylenethiourea is the main metabolite of propineb, 4-methyl-imidazoline.

In greenhouse tomatoes harvested 7 days after four foliar applications of  $^{14}\text{C}$ -propineb, most of the TRR was located on the surface of the fruit (about 70%), propineb accounting for 11% of the TRR. With the exception of propylenethiourea, which accounted for 30% of the TRR, all other metabolites were present at < 10% of the TRR.

In potato tubers and vines harvested 14 days after four foliar applications of  $^{14}\text{C}$ -propineb, the  $^{14}\text{C}$  residues in vines were mainly propineb (29%), with smaller amounts of propylene urea (10%) and 4-methylimidazoline (6.4%). Propylenethiourea was only a minor metabolite (3.5% TRR). In contrast, propineb and propylenethiourea were not detected in tubers. Propylene urea was the main metabolite (21%), with smaller amounts of a derivative of 5-methylhydantoin (11%). Most of the  $^{14}\text{C}$  in tubers was incorporated into natural products (33%).

### *Environmental fate*

The Meeting received information on the behaviour and fate of propineb during solution photolysis in aerobic soil metabolism. Information was also provided on the soil adsorption properties of propineb and on its behaviour and fate during anaerobic soil metabolism and column leaching of aged residues. Consistent

with the policy outlined by the 2003 JMPR, only data on environmental fate relevant to residues of propineb in crops were evaluated.

Crop rotation studies were not provided; however, the aerobic soil metabolism of propineb was rapid, with inferred degradation half-lives of < 1 day. The main degradate formed was propylene urea. In aqueous solution, propineb is readily hydrolysed, the rate of hydrolysis increasing with pH; the DT<sub>50</sub> values were 1–5 days. The rate of degradation in the field and in aquatic environments is fast, and propineb is not expected to persist in the environment.

### ***Methods of analysis***

Propineb residues are measured as CS<sub>2</sub> or propylene diamine formed by a common acid hydrolysis step. Samples in the field trials were analysed for propineb as CS<sub>2</sub> (spectrophotometry) or propylene diamine (gas chromatography with electron capture or mass spectrometry detection) and for propylenethiourea (HPLC with ultraviolet detection, gas chromatography with flame photometric detection). LOQs of 0.05–0.1 mg/kg for propineb and 0.01 mg/kg for propylenethiourea were reported to be achievable in numerous commodities.

### ***Stability of residues in stored analytical samples***

The Meeting received information on the stability of propineb residues during storage of analytical samples at freezer temperatures. The available data indicate that the combined residues of propineb and propylenethiourea are stable under frozen storage conditions (–20 °C) in and on the following commodities (storage interval in parentheses): tomatoes (2 years); tomato juice (2 years); tomato marc (2 years) and potatoes (2 years for propineb, 2 weeks for propylenethiourea).

### ***Definition of the residue***

The studies of metabolism in grapes, apples and tomatoes after spraying with propineb demonstrated rapid degradation of the residues on the surface of plant parts. The patterns of metabolites found were similar in different species of plants. The main metabolites found in plants—propylenethiourea, propylene urea, 4-methylimidazoline, 2-sulfonyl-4-methylimidazoline and *N*-formylpropylene diamine—were also detected in animals. The Meeting agreed that propineb and propylenethiourea should be regarded as the residues of toxicological concern.

For estimating dietary intake and to enable comparison of the calculated intakes with the ADI, the residues should be expressed in terms of propineb (propineb = 1.9 × CS<sub>2</sub>).

Currently, the residue definition for dithiocarbamates including propineb is ‘total dithiocarbamates, determined as CS<sub>2</sub>, evolved during acid digestion and expressed as mg CS<sub>2</sub>/kg’. Propineb can be determined by a specific method that measures both CS<sub>2</sub> and the amine (propylene diamine) released on acid hydrolysis. Therefore, separate MRLs could be established for propineb. Until specific methods are developed for all dithiocarbamates, however, the listing of one compound under two different residue definitions would be confusing for analysts and enforcement agencies. The *FAO Manual* (page 51) states that no compound, metabolite or analyte should be listed in more than one residue definition. In national systems, the residue definition for propineb is generally in terms of CS<sub>2</sub>.

The Meeting agreed that the residue definition applicable to propineb should continue to be that for dithiocarbamates in general. For estimation of dietary intake and for the risk assessment component relating to exposure, the metabolite propylenethiourea is considered to be toxicologically relevant and must be accounted for. For an overall risk assessment of ‘thyroid-active’ dithiocarbamates such as propineb, the 1997 JMPR “agreed that it is necessary to combine not only the intake of different parent pesticides but also the intake of [ethylene thiourea] or propylenethiourea” and recommended that an ADI adjustment approach be used. Therefore, in estimating dietary intake, residues of both propineb and propylenethiourea must be accounted

for and their relative toxicity taken into account. A conservative approach is to sum the residues after scaling the propylenethiourea residues for 'potency' on the basis of the ratio of the ADIs for propineb and propylenethiourea (2.3), in order to estimate STMRS, and the ratio to ARfDs (3.3) for estimating the highest residue levels. This approach has been used for dimethoate–omethoate and acephate–methamidophos. The ratios are based on mass and do not require correction for relative molecular mass.

For estimation of the STMR for propineb, residue = propineb +  $(2.3 \times \text{propylenethiourea})$

For estimation of the highest residue level for propineb, residue = propineb +  $(3.3 \times \text{propylenethiourea})$

*Definition of propineb residue for compliance with MRLs:* Total dithiocarbamates, determined as CS<sub>2</sub>, evolved during acid digestion and expressed as mg CS<sub>2</sub>/kg

*Definition of propineb residue for estimation of dietary intake:* propineb and propylenethiourea

These definitions apply to plant and animal commodities.

### **Results of supervised trials on crops**

The results of supervised trials were available on the use of propineb on apple, asparagus, cabbage, cherry, Chinese cabbage, celery, citrus (orange), cucumber, garlic, grape, leek, lettuce, melon, onion, olive, pear, pepper, potato, tomato and watermelon.

The Meeting decided to use only data from trials in which propineb was determined as CS<sub>2</sub> for estimation of maximum residue, STMR and highest residue levels. In some cases, untreated control samples also contained residues of CS<sub>2</sub>. Trials were considered acceptable if the residue levels in untreated control samples were < 10% of the residue in the treated crop or, when propineb was also determined as propylene diamine, there was satisfactory agreement between the results for propineb determined as CS<sub>2</sub> and propylene diamine.

The following relation is useful when considering the data: CS<sub>2</sub> residue (mg/kg) =  $0.52 \times \text{propineb residues (mg/kg)}$ .

#### *Citrus fruit*

Trials on citrus were conducted in Brazil and Japan but were provided only in summary form, which was unsuitable for the purpose of estimating maximum residue levels.

#### *Pome fruit*

Trials on apple and pear were conducted in Belgium (GAP, 0.49–0.71 kg ai/ha fruit tree leaf wall, equivalent to 0.84–1.6 kg ai/ha for a standard orchard, applied just after flowering), Germany (GAP, 1.58 kg ai/ha, 0.105 kg ai/hl, 28-day PHI), Italy (GAP, 0.105–0.14 kg ai/hl, 28-day PHI) and Spain (GAP for pome fruit, 0.14–0.21 kg ai/hl, 28-day PHI). The trials conducted in Germany, Italy and Spain did not match GAP in the respective countries and were evaluated against the GAP of Belgium.

In two trials in Belgium and one in Germany on *apple*, the residue levels of propineb (measured as CS<sub>2</sub>) in untreated controls were unacceptable. One trial in Belgium approximated Belgian GAP, with levels of propineb residues < 0.10 mg/kg (propylenethiourea, < 0.01 mg/kg). In a further trial in Germany and one in Spain that approximated Belgian GAP, the residue levels were < 0.10 and < 0.10 mg/kg (propylenethiourea, < 0.01 (two) mg/kg).

Trials on *pear* were conducted in Belgium (GAP, 0.49–0.71 kg ai/ha fruit tree leaf wall, equivalent to 0.84–1.6 kg ai/ha for a standard orchard, applied just after flowering), Germany (GAP, 1.58 kg ai/ha, 0.105 kg ai/hl, 28-day PHI) and Italy (GAP, 0.105–0.14 kg ai/hl, 28-day PHI). One trial in Belgium and one

in Germany matched GAP in Belgium, with levels of propineb residues of < 0.10 and 0.10 mg/kg, respectively. The levels of propylenethiourea residues were: < 0.01 mg/kg.

The Meeting considered that the number of trials on apples and pears was inadequate for the purpose of estimating maximum residue levels and agreed to withdraw its previous recommendation for propineb of 2 mg/kg as CS<sub>2</sub> for apples and pears.

#### *Cherry*

Six trials on cherry were conducted in Germany (GAP, 0.105 kg ai/hl, 28-day PHI) which approximated German GAP. Two trials were conducted at two locations, which differed only in the formulation used; one trial at each location was selected for estimating maximum residue levels. The residue levels in the six trials were < 0.05 (two), 0.05, 0.06, 0.13 and 0.15 mg/kg for CS<sub>2</sub> and < 0.01 (four) and 0.02 (two) mg/kg for propylenethiourea.

The residue levels of propineb ( $1.9 \times \text{CS}_2$ ) and propylenethiourea, combined as explained above (residue = propineb +  $2.3 \times \text{propylenethiourea}$ ), used for estimating the STMR were < 0.12 (three), 0.14, 0.29 and 0.33 mg/kg. The highest residue level for dietary intake was estimated to be 0.35 mg/kg (residue = propineb +  $3.3 \times \text{propylenethiourea}$ ). The Meeting estimated a maximum residue level for propineb in cherries of 0.2 mg/kg as CS<sub>2</sub>, an STMR of 0.13 mg/kg as propineb and a highest residue level of 0.35 mg/kg as propineb.

#### *Grape*

Trials on wine grapes were conducted in France (GAP, 0.68 kg ai/ha, 21-day PHI) and Germany (GAP, 2.8 kg ai/ha, 0.14 kg ai/hl, 56-day PHI) after pre-blossom application. None of the trials approximated GAP in the respective countries. Trials were also conducted on table and wine grapes after pre- and post-blossom applications in France (GAP, 0.68 kg ai/ha, 21-day PHI), Greece (GAP, 0.14 kg ai/hl, 7-day PHI for table grapes, 21-day PHI for wine grapes), Italy (GAP, 0.14 kg ai/hl, 28-day PHI) and Spain (GAP, 0.28 kg ai/hl, 15-day PHI). None of the trials matched GAP. The Meeting agreed to withdraw the previous recommendations for propineb in grapes of 2 mg/kg as CS<sub>2</sub>.

#### *Olive*

Trials on olives were conducted in Spain (GAP, 0.21 kg ai/hl, 15-day PHI), but none matched GAP.

#### *Onion*

Trials on onion were conducted in Australia (GAP, 1.4 kg ai/ha, 0.14 kg ai/hl, 14-day PHI) and Brazil (GAP 2.1 kg ai/ha, 7-day PHI), but the latter was available only in the form of a summary. The residue levels of propineb (measured as propylene diamine and not CS<sub>2</sub>) in the Australian trials approximating GAP were < 0.2 and 1.2 mg/kg. The number of trials was considered by the Meeting to be inadequate for estimating a maximum residue level, and the Meeting agreed to withdraw its previous recommendation for propineb in onion, bulb, of 0.2 (\*) mg/kg as CS<sub>2</sub>.

#### *Garlic*

Trials on garlic were conducted in Brazil; however, the data were supplied only in summary form and were therefore not suitable for estimating a maximum residue level.

#### *Lettuce*

Trials on lettuce were conducted in Australia (GAP, 1.4 kg ai/ha, 0.14 kg ai/hl, 3-day PHI) and Brazil (no information on GAP). The latter was available only in the form of a summary. The residue levels of propineb (measured as propylene diamine and not CS<sub>2</sub>) in the Australian trials approximating GAP were 0.3 and 2.5 mg/kg. The number of trials was considered by the Meeting to be inadequate for the purposes of estimating a maximum residue level.



*Brassica vegetables*

Trials on head cabbage were available from Brazil (no GAP) and on Chinese cabbage from Thailand (no GAP). As no relevant GAP was available and as the data were provided only in summary form, the Meeting was unable to estimate a maximum residue level for these vegetables.

*Cucumber*

Trials on cucumbers grown in greenhouses in Greece (GAP for vegetables, 0.18 kg ai/ha, 3-day PHI), Italy (no GAP) and Spain (GAP, 0.21 kg ai/ha, 3-day PHI) were made available to the Meeting. The trials in Italy and Spain did not match GAP for those countries and were assessed against the GAP of Greece. The levels of propineb residues (measured as CS<sub>2</sub>) in three trials in Greece approximating GAP in Greece were 0.60, 0.90 and 1.1 mg/kg (propylenethiourea, 0.01, < 0.01 and 0.02 mg/kg). The levels of propineb residues in one trial in Italy and three in Spain matching GAP  $\pm$  25% in Greece were 0.20, 0.20, 0.43 and 0.47 mg/kg (propylenethiourea, < 0.01 (four) mg/kg). Conversion of the residue levels expressed in terms of propineb to CS<sub>2</sub> gives values of 0.10 (two), 0.22, 0.24, 0.31, 0.47 and 0.57 mg/kg. The Meeting estimated a maximum residue level for propineb in cucumbers of 1 mg/kg as CS<sub>2</sub>.

The appropriately scaled and totalled residue levels of propineb and propylenethiourea for estimating the STMR were: 0.22 (two), 0.45, 0.49, 0.62, 0.92 and 1.1 mg/kg. The highest residue level was estimated to be 1.1 mg/kg. For estimation of dietary intake, the Meeting estimated STMR and highest residue levels for propineb in cucumbers of 0.49 and 1.1 mg/kg, respectively.

*Melon (except watermelon)*

Trials on melons (except watermelon) were reported from Greece (GAP for vegetables, 0.18 kg ai/ha, 3-day PHI) and Spain (GAP, 0.21 kg ai/hl, 15-day PHI; GAP for cucurbits, 0.21 kg ai/hl, 3-day PHI). The levels of propineb residues (measured as propylene diamine) in two trials in Spain matching Spanish GAP  $\pm$  25% were 0.52 and 1.5 mg/kg (propylenethiourea, 0.05 and 0.06 mg/kg). One field trial in Greece, in which 0.43 mg/kg were found (propylenethiourea, < 0.01 mg/kg) also matched GAP in that country. Data were not available for propineb measured as CS<sub>2</sub> in any of the trials at the relevant PHI. The Meeting considered three trials inadequate for the purposes of estimating a maximum residue level for melon (except watermelon) and agreed to withdraw its previous recommendation of 0.1 (\*) mg/kg as CS<sub>2</sub>.

*Watermelon*

Trials on watermelon were reported from Greece (GAP for vegetables, 0.18 kg ai/hl, 3-day PHI) and Italy (no GAP). The levels of propineb residues in two trials in Greece matching Greek GAP  $\pm$  25% were 0.17 and 0.31 mg/kg (propylenethiourea, < 0.01 and 0.02 mg/kg). Two field trials in Italy approximating GAP in Greece showed residue levels of 0.17 and 0.29 mg/kg (propylenethiourea, 0.01 and 0.02 mg/kg). Data were not available for propineb determined as CS<sub>2</sub> at the relevant PHI in any of the trials. The Meeting considered the number of trials inadequate for the purposes of estimating a maximum residue level for watermelon.

*Tomato*

Trials on field tomatoes were reported from France (GAP, 0.21 kg ai/hl, 7-day PHI), Germany (GAP, 0.84 kg ai/ha at crop height < 0.5 m; 1.26 kg ai/ha at crop height 0.5–1.25 m; 1.68 kg ai/ha at crop height > 1.25 m; 7-day PHI) and Spain (GAP, 0.21 kg ai/hl, 3-day PHI). The CS<sub>2</sub> residue levels in four trials in Germany matching GAP were 0.11, 0.14, 0.40 and 0.55 mg/kg, equivalent to 0.21, 0.27, 0.76 and 1.0 mg/kg as propineb (propylenethiourea, < 0.02 (three) and 0.02 mg/kg).

Four trials were available from France and four from Spain which were conducted according to GAP in the respective countries. As GAP in France and Spain differs only with respect to the PHI, the Meeting decided to evaluate the French and Spanish trials against the GAP of Spain to obtain a representative data set. The residue levels of propineb in these trials were 0.14, 0.22, 0.26, 0.35, 0.49, 0.94, 1.0 and 1.1 mg/kg (propylenethiourea, < 0.01, 0.02 (two), 0.04, 0.05 (two) and 0.06 (two) mg/kg).

Additional trials on tomatoes grown under protected cover (greenhouse) were reported from France, Germany and Spain and evaluated against the GAP of Spain, which is the same for tomatoes grown in the field and protected under cover. The residue levels of CS<sub>2</sub> reported in terms of propineb  $\geq 3$  days after the last application were 0.82, 1.1, 1.3, 1.5, 2.3 and 2.4 mg/kg. The levels of propylenethiourea residues were 0.04, 0.05, 0.06, 0.08, 0.09 and 0.16 mg/kg.

The Meeting considered that the residue levels in field trials conducted in Germany according to German GAP and the trials under cover and in the field conducted according to GAP in Spain represent similar residue populations and could be combined for the purposes of estimating a maximum residue level. The residue levels expressed in terms of CS<sub>2</sub>, were: 0.07, 0.11 (two), 0.14 (two), 0.18, 0.25, 0.40, 0.42, 0.49, 0.52, 0.54, 0.57 (two), 0.68, 0.78 and 1.2 (two) mg/kg.

The Meeting estimated a maximum residue level for propineb in tomatoes of 2 mg/kg as CS<sub>2</sub> to replace the previous recommendation for tomatoes of 1 mg/kg as CS<sub>2</sub>.

The appropriately scaled and totalled residue levels of propineb and propylenethiourea in the 18 trials used for estimating the STMR were: 0.16, 0.26, 0.27, 0.31 (two), 0.44, 0.61, 0.81, 0.89, 1.1 (three), 1.2 (two), 1.3, 1.7, 2.5 and 2.8 mg/kg. The Meeting estimated the STMR for propineb in tomatoes at 1.0 mg/kg and the highest residue level at 2.9 mg/kg.

#### *Peppers (sweet)*

Trials on field-grown peppers in France (no GAP) and Spain (GAP, 0.21 kg ai/hl, 3-day PHI) were made available to the Meeting. The French trials were evaluated against GAP of Spain. In two trials in France matching GAP in Spain, the residue levels of propineb were 0.22 and 0.83 mg/kg (propylenethiourea, 0.02 and 0.07 mg/kg). Four trials in Spain that matched GAP for peppers showed propineb residue levels of 0.60, 1.4 (two) and 1.7 mg/kg (propylenethiourea, 0.09, 0.12, 0.17 and 0.18 mg/kg). The levels of propineb residues in field-grown peppers were thus: 0.22, 0.60, 0.83, 1.4 (two) and 1.7 mg/kg. The corresponding levels of propylenethiourea residues were: 0.02, 0.07, 0.09, 0.12, 0.17 and 0.18 mg/kg.

Trials on peppers grown in greenhouses in France (no GAP), Germany (no GAP) and Spain (GAP, 0.21 kg ai/hl, 3-day PHI) were made available to the Meeting. The trials in France and Germany were evaluated against GAP in Spain. Residues of propineb in sweet peppers grown indoors were 1.3, 2.1 and 11 mg/kg (propylenethiourea, 0.05, 0.23 and 0.71 mg/kg) in three trials in Spain; and 0.75, 1.4, 1.5 and 1.7 mg/kg (propylenethiourea, 0.06, 0.07, 0.10 and 0.11 mg/kg) in four trials in France. Thus, the levels of propineb in sweet peppers grown in greenhouses were: 0.75, 1.3, 1.4, 1.5, 1.7, 2.1 and 11 mg/kg (propylenethiourea: 0.05, 0.06, 0.07, 0.10, 0.11, 0.23 and 0.71 mg/kg). Conversion of the levels of CS<sub>2</sub> residues reported in terms of propineb back to CS<sub>2</sub> gave levels of 0.11, 0.31, 0.39, 0.43, 0.68, 0.73 (three), 0.78, 0.88 (two), 1.1 and 5.7 mg/kg. The Meeting estimated a maximum residue level for propineb in peppers, sweet, of 7 mg/kg as CS<sub>2</sub>.

The appropriately scaled and totalled residue levels of propineb and propylenethiourea in the 13 trials used for estimating the STMR were: 0.27, 0.89, 0.99, 1.0, 1.4, 1.6 (two), 1.7 (two), 2.0, 2.1, 2.6 and 13 mg/kg as propineb. The STMR was 1.6 mg/kg and the highest residue level was estimated to be 13 mg/kg.

#### *Potato*

Field trials on potatoes were made available to the Meeting from France (GAP, 0.21 kg ai/hl, PHI not specified), Germany (GAP, 1.3 kg ai/ha, 7-day PHI), Spain (GAP, 0.21 kg ai/hl, 15-day PHI) and the United Kingdom (no GAP). The trials in Germany and the United Kingdom did not comply with the relevant GAP. The trials in France were evaluated against GAP in Spain.

In three trials in France approximating Spanish GAP, the levels of propineb residues on potatoes were <0.10 (two) and 0.14 mg/kg (propylenethiourea, <0.01 (three) mg/kg). Three trials in Spain approximating GAP in that country showed propineb residue levels of <0.10 (three) mg/kg (propylenethiourea, <0.01 (three) mg/kg). Conversion of the residue levels determined as CS<sub>2</sub> but reported in terms of propineb to CS<sub>2</sub> gave levels of <0.05 (five) and 0.073 mg/kg. The Meeting estimated a maximum

residue level for propineb in potatoes of 0.1 mg/kg as CS<sub>2</sub>, which replaces the previous recommendation of 0.1 (\*) mg/kg.

The appropriately scaled and totalled residue levels of propineb and propylenethiourea in six trials used for estimating the STMR were: 0.12 (five) and 0.16 mg/kg. The Meeting estimated an STMR for propineb in potatoes of < 0.12 mg/kg and a highest residue level of 0.16 mg/kg.

#### *Celery*

Two trials on celery were reported from Australia (GAP, 1.4 kg ai/ha, 0.14 kg ai/hl, 7-day PHI), which showed propineb residue levels of < 0.2 and 0.4 mg/kg (propylenethiourea not analysed). The Meeting considered the number of trials inadequate for the purpose of estimating a maximum residue level for celery.

#### *Asparagus*

In a single trial on asparagus in Peru (GAP, 2.1 kg ai/ha, 0.21 kg ai/hl, 30-day PHI) that matched GAP in that country, the residue levels of propineb were < 0.01 mg/kg (propylenethiourea not measured).

The Meeting considered the number of trials inadequate for the purpose of estimating a maximum residue level for asparagus.

#### ***Fate of residues during processing***

The Meeting received the results of studies on incurred residues of propineb and propylenethiourea in apples, pears, cherries, tomatoes, grapes and olives after washing and further processing in a range of fractions. Only the studies relevant to commodities for which maximum residue levels have been estimated are reported below.

It would not usually be appropriate to derive processing factors for propylenethiourea, as these would reflect both the effect of processing and also the formation of propylenethiourea from propineb, especially after boiling steps. In the present case, the use of processing factors would result in overestimates of the residue levels of propylenethiourea in processed commodities, and the Meeting decided to continue to use this approach. Nevertheless, if concern about dietary intake were identified, the Meeting would consider refining the approach to estimate propylenethiourea residues in processed commodities.

In trials in Germany, cherries were processed according to simulated household and commercial practices into washed fruit, juice, jam and preserves. The processing factors for juice and jam prepared by household procedures in two trials each were 0.5–0.6 (mean, 0.55) for juice and 0.3–0.4 (mean, 0.35) for jam. Propylenethiourea residues did not concentrate in juice or jam, with mean processing factors of < 0.68 for juice and < 0.78 for jam. After simulated commercial preparation, the mean processing factors for propineb in three trials each were 0.63 (range, 0.6–0.7) for washed fruit and 0.15 (range, 0.13–0.16) for preserves. The corresponding mean values for propylenethiourea were 1 for washed fruit and < 0.5 for preserves.

The Meeting considered that it would be appropriate to use the mean processing factors from the various studies, to reflect different commercial practices. For cherries, it estimated processing factors for propineb of 0.63 in washed fruit, 0.55 in juice, 0.15 in preserves and 0.35 in jam. The processing factors for propylenethiourea were 1 in washed fruit, < 0.68 in juice, < 0.5 in preserves and < 0.78 in jam.

Processing studies for tomatoes with respect to washed fruit, juice, ketchup, paste and preserves were reported. For washed fruit, the mean processing factors in four studies were 0.45 (range, 0.3–0.6) for propineb and 0.4 (range, 0.3–0.5) for propylenethiourea. In the case of juice, the mean processing factor for propineb in 10 studies was < 0.12 (range, < 0.06–0.2), while that for propylenethiourea in nine studies was 0.91 (range, 0.3–2.3). The levels of residues of propineb were significantly reduced during the preparation of preserves and ketchup, with mean processing factors of 0.15 in four studies on preserves (range, 0.1–0.2) and < 0.12 in six studies on ketchup (range, < 0.06–< 0.25). Residues were concentrated during preparation of paste, with a mean processing factor in four studies of 1.1 (range, 0.4–2.0). The mean processing factors for

propylenethiourea were 0.75 ( $n = 4$ ; range, 0.5–1) for preserves, 0.54 ( $n = 5$ ; range, 0.3–0.7) for ketchup and 11 ( $n = 4$ ; range, 6.8–17) for paste.

The Meeting considered that it would be appropriate to use the mean processing factors from the various studies to reflect different commercial practices. For tomato, it estimated processing factors for propineb of 0.45 in washed fruit, < 0.12 in juice, 0.15 in preserves, < 0.12 in ketchup and 1.1 in paste. For propylenethiourea, processing factors of 0.4 in washed fruit, 0.91 in tomato juice, 0.75 in preserves, 0.54 in ketchup and 11 in paste were established.

| Commodity | Processing factor <sub>propineb</sub> | Propineb residues (mg/kg) |              | Processing factor <sub>propylenethiourea</sub> | Propylenethiourea residues (mg/kg) |              | Adjusted values (mg/kg) |                 |
|-----------|---------------------------------------|---------------------------|--------------|------------------------------------------------|------------------------------------|--------------|-------------------------|-----------------|
|           |                                       | For STMR/ STMR-P          | For HR/ HR-P |                                                | For STMR/ STMR-P                   | For HR/ HR-P | STMR <sup>1</sup>       | HR <sup>2</sup> |
| Cherry    |                                       | 0.128                     | 0.351        |                                                | 0.01                               | 0.02         |                         |                 |
| Washed    | 0.63                                  | 0.0803                    | 0.221        | 1                                              | 0.01                               | 0.02         | 0.103                   | 0.287           |
| Juice     | 0.55                                  | 0.0701                    |              | 0.68                                           | 0.0068                             |              | 0.0858                  |                 |
| Preserves | 0.15                                  | 0.0191                    |              | 0.5                                            | 0.005                              |              | 0.0306                  |                 |
| Jam       | 0.35                                  | 0.0446                    |              | 0.78                                           | 0.0078                             |              | 0.0626                  |                 |
| Tomato    |                                       | 1.0                       | 2.93         |                                                | 0.03                               | 0.16         |                         |                 |
| Washed    | 0.45                                  | 0.45                      | 1.32         | 0.4                                            | 0.012                              | 0.064        | 0.478                   | 1.53            |
| Juice     | 0.12                                  | 0.12                      |              | 0.91                                           | 0.0273                             |              | 0.183                   |                 |
| Preserves | 0.15                                  | 0.15                      |              | 0.75                                           | 0.0225                             |              | 0.202                   |                 |
| Ketchup   | 0.12                                  | 0.12                      |              | 0.54                                           | 0.0162                             |              | 0.157                   |                 |
| Paste     | 1.1                                   | 1.1                       |              | 11                                             | 0.33                               |              | 1.86                    |                 |

<sup>1</sup> Adjusted STMR-P = STMR-P<sub>propineb</sub> + 2.3 × STMR-P<sub>propylenethiourea</sub>

<sup>2</sup> adjusted HR-P = HR-P<sub>propineb</sub> + 3.3 × HR-P<sub>propylenethiourea</sub>

## Residues in animals commodities

### Dietary burden of farm animals

The Meeting estimated the dietary burden of propineb residues of farm animals on the basis of the diets described in Appendix IX of the *FAO Manual*. As no relevant items were identified, the dietary burdens for estimating MRLs and STMRs for animal commodities (residue levels in animal feeds expressed in dry weight) are zero for all the relevant animal diets.

### Maximum residue levels

The Meeting estimated maximum residue levels of 0.05 (\*) mg/kg for meat (from mammals other than marine mammals), 0.05 (\*) mg/kg for edible offal (mammalian) and 0.01 (\*) mg/kg for milks.

The Meeting estimated maximum residue levels of 0.05 (\*) mg/kg for poultry meat, 0.05 (\*) for poultry offal and 0.01 (\*) mg/kg for eggs. The STMRs for animal commodities are zero.

## DIETARY RISK ASSESSMENT

The Meeting considered how best to approach the dietary risk assessment of mixed residues of propineb and propylenethiourea and decided that an appropriately conservative approach would be to calculate the sum of the residues after scaling the propylenethiourea residues to account for the difference in toxicity. The relevant factors for long-term and short-term intake were derived from the ratios of the ADI and ARfD values for propineb and propylenethiourea, which are 2.3 and 3.3, respectively. Dietary intake

estimates for the residues, adjusted for potency and combined, were compared with the ADI and interim ARfD for propineb (See general item 2.2, Interim acute reference dose).

#### **Long-term intake**

The evaluation of propineb resulted in recommendations for MRLs and STMRs for raw and processed commodities. Data were available on the consumption of 15 food commodities and were used in the dietary intake calculation. The results are shown in Annex 3.

The IEDIs in the five GEMS/Food regional diets, based on estimated STMRs, were 4–30% of the ADI of 0–0.007 mg/kg bw for propineb (Annex 3). The Meeting concluded that the long-term intake of residues of propineb and propylenethiourea from uses that have been considered by the JMPR is unlikely to present a public health concern.

#### **Short-term intake**

The IESTI for propineb was calculated for the food commodities (and their processing fractions) for which maximum and highest residue levels had been estimated and for which data on consumption were available. The results are shown in Annex 4.

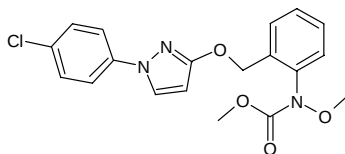
The IESTI was 0–110 % of the interim ARfD (0.1 mg/kg bw) for the general population and 0–120% of the interim ARfD for children  $\leq 6$  years. The values 110% and 120% represent the estimated short-term intake of sweet peppers by the general population and children, respectively.

The Meeting concluded that the short-term intake of residues of propineb from uses other than on sweet peppers that have been considered by the JMPR is unlikely to present a public health concern.

## **4.26 PYRACLOSTROBIN (210)**

### **RESIDUE AND ANALYTICAL ASPECTS**

Residue and analytical aspects of pyraclostrobin were considered for the first time by the present Meeting.



Pyraclostrobin, chemical name (IUPAC) methyl *N*-(2-{{[1-(4-chlorophenyl)-1*H*-pyrazol-3-yl]-oxymethyl}phenyl)-*N*-methoxycarbamate, is a new fungicidal active ingredient. It represents a modification of the structural pattern of natural fungicides called strobilurins.

The Meeting received information on the metabolism and environmental fate of pyraclostrobin, methods of residue analysis, freezer storage stability, national registered use patterns, the results of supervised residue trials, farm animal feeding studies, fate of residues in processing and national MRLs.

#### **Metabolism**

##### **Animals**

The Meeting received the results of metabolism studies in rats, lactating goats and laying hens. The metabolism and distribution of pyraclostrobin in plants and livestock was investigated with [chlorophenyl-<sup>14</sup>C]pyraclostrobin and [tolyl-<sup>14</sup>C]pyraclostrobin

The main metabolite are methyl-*N*-(2{[1-(4-chlorophenyl)-1*H*-pyrazol-3-yl]oxymethyl}phenyl) carbamate (500M07) and 1-(4-chlorophenyl)-1*H*-pyrazol-3-yl hydrogen sulfate.

Metabolism in laboratory rats was evaluated by the WHO panel of the 2003 JMPR, which concluded that the metabolism proceeds through three main pathways. The methoxy group on the tolyl-methoxycarbamate moiety is readily lost, with few main metabolites retaining this group. Hydroxylation of the benzene or pyrazole ring is followed by conjugation with glucuronide. Many metabolites are derived from the chlorophenol pyrazole or tolyl-methoxycarbamate moieties of pyraclostrobin. The metabolites were similar in both sexes and at all doses. No unchanged parent compound was found in bile or urine, and only small amounts were found in faeces.

Studies of the metabolism of pyraclostrobin in *goats* showed that residues in products of animal origin derive from the parent compound as well as from its *N*-desmethoxylation product. The metabolism and distribution of pyraclostrobin were investigated in lactating goats given material labelled in the chlorophenyl or in the tolyl ring. After five consecutive daily oral administrations of <sup>14</sup>C-pyraclostrobin at a nominal dosage of 12 or 50 mg/kg of feed, there was rapid absorption from the gastrointestinal tract. Radioactivity was excreted mainly via the faeces. The radiolabel in milk accounted for only 0.1–0.5% of the total applied radioactivity. There was no indication of accumulation of <sup>14</sup>C-pyraclostrobin in tissues. The parent compound was found in fat, muscle and, at lower amounts, in liver. Metabolites are formed in liver and kidney by hydroxylation of the chlorophenyl and tolyl rings and by cleavage of the molecule. Little extraction was seen in liver.

<sup>14</sup>C-Pyraclostrobin is thus metabolized in goats by three key steps: (1) desmethoxylation at the oxime ether bond, (2) hydroxylation of the chlorophenyl, the pyrazole or the tolyl ring system and (3) cleavage of the two ring systems with subsequent oxidation of the two resulting molecules.

Pyraclostrobin was present in all tissues and in milk and was the main residue component in muscle and in fat (log  $P_{ow}$  = 3.99).

Tissues and eggs from *hens* that received an exaggerated dose of 12 mg/kg feed of [chlorophenyl-<sup>14</sup>C]pyraclostrobin or 13 mg/kg [tolyl-<sup>14</sup>C]pyraclostrobin contained low residue levels consisting of three main metabolites. The parent compound was found in fat and eggs but not in liver. The main metabolite in liver was the glucuronic acid conjugate, which was bound to the tolyl ring of the demethoxylated parent structure. The desmethoxy metabolite 500M07 was also present in fat and eggs,

Five routes of biotransformation were detected. The predominant transformation was the demethoxylation step. Second, the demethoxylated metabolite was oxygenated at the tolyl ring, followed by conjugation with glucuronic acid. Third, the demethoxylated metabolite was hydroxylated at the chlorophenyl or the pyrazole ring, again followed by a conjugation reaction with glucuronic acid. Fourth, the parent compound was hydroxylated at the chlorophenyl ring in the *para* position, whereby the C-1 was shifted to the *meta* position (NIH shift). Fifth, the parent compound was cleaved at the methylene ether bridge. A specific variation was substitution of C-1 by glucuronic acid.

The main metabolite in fat and eggs was 500M07, and that in liver was the glucuronic acid conjugate. The metabolism in rats, goats and hens were comparable.

#### Plants

The Meeting received the results of studies of the metabolism of pyraclostrobin in grapes, potatoes and wheat.

The metabolism of pyraclostrobin in *grapes* was investigated with material labelled in the tolyl or the chlorophenyl ring. Applications were made six times at a rate of 0.25 kg ai/ha, and the grapes were harvested

40 days after the last application. The relevant residue in grapes consists of the parent compound and its desmethoxy metabolite 500M07. Some other compounds were identified as products formed by cleavage of the molecule. *O*-Glucosylation and methoxylation were of minor importance, representing much less than 10% of the TRR.

Studies of metabolism in *potato* were conducted with material labelled in the tolyl or the chlorophenyl ring. Six post-emergence applications were made at the intended use rate of 300 g/ha. The relevant residue in potato green matter and tuber consisted of the parent compound (65% and 2.5% of the TRR, respectively) and its desmethoxy metabolite 500M07 (6.2% and 0.6% of the TRR, respectively) at growth stage 70.

Some other compounds were identified as products formed by cleavage of the molecule. *O*-Glucosylation and methoxylation were of minor importance, representing far less than 10% of the TRR. The total residue levels in the edible portion (potato tubers) were low. One derivative found in larger amounts in tubers was identified as the naturally occurring amino acid L-tryptophan. This compound represented 10% of the TRR in tuber at growth stage 70, but its contribution increased to 29.2% of the TRR at growth stage 85–89. It should not therefore be regarded as a relevant residue that must be covered by the analytical method.

*Wheat* received two application at 0.3 kg ai/ha, and samples were collected 0, 31 and 41 days after the last treatment. The relevant residue of  $^{14}\text{C}$ -pyraclostrobin in wheat consists of unchanged parent compound and its desmethoxy metabolite 500M07. Tryptophan, which is formed in considerable amounts from pyraclostrobin in grain, is a natural ingredient and is therefore of no toxicological concern. All the other metabolites identified represented < 10% TRR and are thus of minor importance. The low levels of unextractable residues in forage and straw indicate that pyraclostrobin and its metabolites are not firmly associated with cell wall polymers. Somewhat larger amounts of unextractable were found in grain, as some of the radioactivity was incorporated into or associated with grain protein and starch.

The metabolic pathways in grapes, potatoes and wheat were qualitatively similar. Pyraclostrobin and its desmethoxy metabolite 500M07 constituted the main part of the residue. In addition, hydroxylation in the tolyl and the chlorophenyl rings and cleavage reactions between the two ring systems were observed. The hydroxylation reaction is followed by glucosylation or methylation, whereas the intermediates of the cleavage reaction are further transformed by conjugation or the shikimate pathway. Transformation via the shikimate pathway resulted in the formation of the natural amino acid L-tryptophan in potato tubers and wheat grain.

## Environmental fate

### Soil

The Meeting received the results of studies on the fate and behaviour in soil of [tolyl- $^{14}\text{C}$ ]pyraclostrobin and [chlorophenyl- $^{14}\text{C}$ ]pyraclostrobin.

Pyraclostrobin was investigated for aerobic metabolism in a number of soils. The degradation of pyraclostrobin in aerobic soil studies is characterized by a relatively low mineralization rate (about 5% of the total applied radioactivity within 100 days) and formation of large amounts of bound residues (about 55% of the total). The same metabolites, the *trans*-azooxy and the *trans*-azo dimers (or *N,N'*-bis-[2-(1*H*-pyrazol-3-ylloxymethyl)phenyl]diazene) of pyraclostrobin, were found in all soil types. The amount of the *trans*-azooxy dimer generally exceeded 10% the total applied radioactivity (maximum, 31%), whereas that of the *trans*-azo dimer slightly exceeded 10% of the total applied in only one of the investigated soils. The amount of bound residue increased with time, and the most of the radiolabel was associated with insoluble humins and high-molecular-mass humic acids. No release of pyraclostrobin or its metabolites was observed, even with harsh extraction methods (NaOH) or with intensive activity of soil-eating animals (earthworms). Photolytic degradation leads to the same degradation products; however, all the metabolites were formed in amounts less than 10% of the total applied radioactivity.

Pyraclostrobin is degraded in soil under laboratory conditions, with DT<sub>50</sub> values ranging from 12 to 101 days in five microbially active soils. Higher soil moisture contents generally accelerated the degradation. Photolysis did not significantly influence the degradation rate; however, it reduced the amounts of the *trans*-azooxy and the *trans*-azo dimers of pyraclostrobin. In field studies, the DT<sub>50</sub> values of pyraclostrobin were much lower, ranging from 2 to 37 days. The DT<sub>90</sub> values in the field were 83–230 days. The DT<sub>50</sub> values of the soil metabolites in the laboratory were 60–166 days for the *trans*-azooxy dimer and 38–159 days for the *trans*-azo dimer. (The high values for the latter were calculated for soils in which the metabolite was formed in amounts < 10% total applied radioactivity.) Under field conditions, however, the metabolites 500M07 and *trans*-azo dimer were not detected. Only the *trans*-azooxy dimer was found sporadically in trace amounts close to the LOQ.

With regard to mobility, no radiolabel was found in leaching studies, and pyraclostrobin remained in the first layer of soil (< 12 cm). Thus, pyraclostrobin and its metabolites are not mobile in soil.

The results indicate that pyraclostrobin and its metabolites are not stable in soil. They were degraded quickly and were not mobile.

#### *Succeeding crops*

The residue levels and the nature of the residues of pyraclostrobin were investigated in three succeeding crops, radish, lettuce and wheat, after application at a rate of 900 g ai/ha. The total residues in the edible parts of the succeeding crops were low at all plant-back intervals. There was no accumulation of pyraclostrobin or its degradation products in the parts of plants used for human or animal consumption.

#### **Methods of analysis**

Methods for the determination of pyraclostrobin in plant and animal matrices are based on HPLC with ultraviolet, mass spectrometry or tandem mass spectrometry detection. The LOQ is 0.02 mg/kg in plant matrices, 0.01 mg/kg in milk and 0.05 mg/kg in others animal matrices.

Plant matrices are extracted with methanol:water and purified on a micro-C<sub>18</sub> column with a micro silica gel column step. Independent laboratory validation showed good performance of the methods.

Animal matrices can be extracted with acetone or acetonitrile and purified by liquid–liquid partition. Further clean-up is necessary before determination.

For enforcement, HPLC with ultraviolet detection was used, but some difficulties were found for crops like hops and oilseed crops.

#### **Stability of residues in stored analytical samples**

The stability of pyraclostrobin in plant matrices was shown to be 19 months. Untreated samples were fortified with 1.0 mg/kg pyraclostrobin and its metabolite 500M07. The residues in peanut meat, peanut oil, wheat grain, wheat straw, sugar beet tops, sugar beet roots, tomatoes and grape juice were stable during storage (range, 88–106% for the parent and 84–120% for the metabolite 500 M07).

Untreated samples of muscle, liver and milk from a cow were fortified with pyraclostrobin at 0.5 mg/kg (0.1 mg/kg in milk) or a mixture of 0.5 mg/kg (0.1 mg/kg for milk) pyraclostrobin and the same amount of a hydroxylated metabolite. Other potential metabolites also form these analytes on cleavage of the methylene ether bridge. After about 0, 30, 60, 90, 120 and 240 days, samples were analysed by BASF methods Nos 439 and 446. The results used to calculate stability were corrected for individual procedural recoveries. The average results of analysis for the parent compound with method 446 show degradation in muscle and milk. The model hydroxylated metabolite appeared to be less stable after 240 days' storage (68–86% in liver, milk and muscle). Nevertheless, this result does not affect the validity of the cow feeding study,



as milk samples, in which degradation of the metabolite was fastest, were analysed within 91 days of sampling.

### ***Definition of the residue***

Three studies were performed on metabolism in three crop categories: grape for fruits, potato for root and tuber vegetables and wheat for cereals. Pyraclostrobin (grape fruits, potato green matter, wheat forage, wheat straw) and the desmethoxy metabolite 500M07 (grape fruits, potato green matter, wheat forage, wheat straw) accounted for most of the residue in most plant samples investigated. As the desmethoxy metabolite occurred in much smaller amounts than parent pyraclostrobin, the metabolite was not included in the definition of the relevant residue.

Studies of metabolism in goats and hens showed that the residues in products of animal origin derive from the parent compound and from its *N*-desmethoxylation product. Oxidation of the aromatic rings to several hydroxylated compounds and cleavage of the molecule led to further metabolites. As these transformations occur in matrices with small amounts of parent or little extractability, residue data obtained by this method represent reasonable worst-case estimates for risk assessment in all matrices. Furthermore, a method for parent only was developed to monitor residues of pyraclostrobin.

The Meeting agreed that the parent compound is suitable for enforcement in plant and animal commodities and is also the compound of interest for dietary risk assessment.

*Definition of the residue for compliance with MRL and for estimation of dietary intake:* pyraclostrobin.

The residue is fat-soluble.

### ***Results of supervised trials on crops***

The Meeting received data from supervised trials on citrus, nuts, apple, stone fruit, grape, strawberry, raspberry, blueberry, banana, mango, papaya, carrot, radish, sugar beet, garlic, onion, tomato, red pepper, summer squash, cucumber, lettuce, bean, lentil, pea dry, peanut, soya bean, oat, wheat, barley, maize and coffee. Most of the trials were carried out in the USA. All of the information from Europe and the USA was acceptable. The trials were conducted according to GLP.

#### *Citrus fruit*

GAP trials was reported from the Republic of Korea (citrus), South Africa (grapefruit and orange) and the USA (grapefruit, lemon, lime, orange, tangelo and tangerine).

#### *Orange*

Trials were conducted in Argentina (one) at 0.075 kg ai/ha, with four applications, including a study on the decline of residues, and in the USA (13) at GAP (0.274 kg ai/ha, four applications, 14-day PHI). The residue levels in orange were: 0.12, 0.13, 0.17 (two), 0.18, 0.19, 0.23, 0.24, 0.25, 0.26, 0.34, 0.35, 0.37 and 0.51 mg/kg. The Meeting estimated a maximum residue level of 1 mg/kg, an STMR of 0.24 mg/kg and a highest residue level of 0.51 mg/kg for orange.

No residue was detected in pulp in five trials (< 0.02 mg/kg).

#### *Grapefruit*

Six trials were carried out in the USA at GAP (0.27 kg ai/ha, four applications, 14-day PHI). The pyraclostrobin residue levels were: 0.07, 0.08, 0.11, 0.12, 0.19 and 0.24 mg/kg. The Meeting estimated a maximum residue level of 0.5 mg/kg, an STMR of 0.12 mg/kg and a highest residue level of 0.24 mg/kg for grapefruit.

The residue in pulp was below the LOQ in one trial.

*Lemon*

Trials were conducted in Argentina (two trials at 0.075 kg ai/ha, four applications with two decay curves), Brazil (four trials with one decay curve) and the USA (five trials at GAP: 0.27 kg ai/ha, four applications, 14-day PHI). The trials in Brazil could not be evaluated (no GAP), and no results were available from the trial in Argentina at 14 days.

Pyraclostrobin residue levels in lemons in the five US trials were 0.15, 0.19, 0.20, 0.28 and 0.32 mg/kg. The Meeting estimated a maximum residue level of 0.5 mg/kg, an STMR of 0.20 mg/kg and a highest residue level of 0.32 mg/kg for lemon.

The Meeting agreed to combine the above results in order to estimate a maximum residue level for citrus fruit. The combined results from the trials in Argentina and the USA, in ranked order, were: 0.07, 0.08, 0.11, 0.12 (two), 0.13, 0.15, 0.17 (two), 0.18, 0.19 (three), 0.20, 0.23, 0.24 (two), 0.25, 0.26, 0.28, 0.32, 0.34, 0.35, 0.37 and 0.51 mg/kg.

The Meeting estimated a maximum residue level of 1 mg/kg, with an STMR of 0.19 mg/kg and a highest residue level of 0.51 mg/kg for citrus.

*Apple*

GAP in Brazil was reported to be a rate of 0.1 kg ai/ha, with four applications and a 14-day PHI. Eight trials were conducted in Brazil at 0.15 kg ai/ha with two decay curves and six trials at 0.3 kg ai/ha. The Meeting agreed that no maximum residue level for apple could be established.

*Stone fruit*

GAP was reported from Canada (stone fruit) and the USA (peach, nectarine, apricot, plum, prune and cherry). The rate of application in the two countries is the same, 0.13 kg ai/ha with five applications. The waiting period is 10 days in Canada and 0 day in the USA.

*Peach*

Eighteen trials were carried out in the USA according to GAP. Two trials with decay curves were available. Pyraclostrobin residue levels in peaches were 0.07, 0.08 (two), 0.10 (two), 0.11, 0.13, 0.14, 0.15 (two), 0.16 (two), 0.20, 0.21, 0.23, 0.26, 0.28 and 0.31 mg/kg. The Meeting estimated a maximum residue level of 0.5 mg/kg, an STMR of 0.15 mg/kg and a highest residue level of 0.31 mg/kg for peaches.

*Cherry*

Twelve trials on sour cherries were conducted in the USA according to GAP. Pyraclostrobin residue levels were 0.25 (two), 0.27, 0.34, 0.38, 0.42, 0.43, 0.48, 0.50 (two), 0.51 and 0.63 mg/kg. The Meeting estimated a maximum residue level of 1 mg/kg, an STMR of 0.43 mg/kg and a highest residue level of 0.63 mg/kg for cherry.

*Plum:* Twelve trials were carried out in the USA according to GAP, including two with decay curves. Pyraclostrobin residue levels were 0.02 (two), 0.03, 0.04 (two), 0.05, 0.06 (three), 0.12, 0.13 and 0.19 mg/kg. The Meeting estimated a maximum residue level of 0.3 mg/kg, an STMR of 0.06 mg/kg and a highest residue level of 0.19 mg/kg for plums.

*Berries and small fruit*

*Grape*

A total of 48 trials were performed in representative growing areas in Brazil, Europe and the USA. GAP was 0.1 kg ai/ha with two applications and a 7-day PHI in Brazil (four trials), 0.16 kg ai/ha with eight and three applications and a 35-day PHI in Europe (30 trials) and 0.168 kg ai/ha with three applications and a 14-day PHI in the USA (14 trials).

The pyraclostrobin residue levels in grapes in trials conducted according to GAP in Brazil were 0.36, 0.79, 1.1 and 1.4. The levels in trials conducted according to GAP in Europe (France, Germany, Italy and Spain) were 0.13, 0.16, 0.17 (two), 0.20, 0.23, 0.25, 0.26, 0.36, 0.40, 0.44 (two), 0.47, 0.56, 0.59 (two), 0.64, 0.67, 0.74, 0.75, 0.76, 0.78 (two), 1.2 and 1.3 mg/kg. The levels in trials conducted according to GAP in the USA were 0.09, 0.10 (two), 0.12 (two), 0.22, 0.24, 0.35, 0.43, 0.49 (two), 0.55, 0.67 and 1.2 mg/kg.

The Meeting agreed to combine the results in order to estimate a maximum residue level for grapes. The levels, in ranked order, were: 0.09, 0.10 (two), 0.12 (two), 0.13, 0.16, 0.17 (two), 0.20, 0.22, 0.23, 0.24, 0.25, 0.26, 0.35, 0.36 (two), 0.40, 0.43, 0.44 (two), 0.47, 0.49 (two), 0.55, 0.56, 0.59 (two), 0.64, 0.67 (two), 0.74, 0.75, 0.76, 0.78 (two), 0.79, 1.1, 1.2 (two), 1.3 and 1.4. The Meeting estimated a maximum residue level of 2 mg/kg, an STMR of 0.44 mg/kg and a highest residue level of 1.4 mg/kg for grapes.

#### *Strawberry*

GAP was reported for Canada and the USA. Eight trials were carried out in the USA at GAP (0.2 kg ai/ha, five applications, 0-day PHI), one with a decay curve.

The levels of pyraclostrobin residues in strawberries in trials conducted according to GAP in the USA were: 0.06, 0.10, 0.13, 0.15, 0.16, 0.19, 0.24 and 0.26 mg/kg. The Meeting estimated a maximum residue level of 0.5 mg/kg, an STMR of 0.16 mg/kg and a highest residue level of 0.26 mg/kg for strawberry on the basis outdoor uses of pyraclostrobin.

#### *Raspberry*

GAP is reported for the USA only, with four applications at 0.2 kg ai/ha and 0-day PHI. The results of three trials were provided.

The Meeting agreed that no maximum residue level for raspberries could be established.

#### *Blueberry*

GAP was available in Canada and the USA. The rate of application (0.2 kg ai/ha) and the number of applications (four) were the same, but the PHI in the USA is 0 days. Six trials were performed in the USA, but one included 50% ripe fruit.

The levels of pyraclostrobin residues in blueberries in trials conducted according to GAP in the USA were, in ranked order: 0.19, 0.30, 0.33, 0.35, 0.48 and 0.57 mg/kg. The Meeting estimated a maximum residue level of 1 mg/kg, an STMR of 0.34 mg/kg and a highest residue level of 0.57 mg/kg for blueberry.

#### *Assorted tropical fruit minus inedible peel*

##### *Banana*

Twelve trials were conducted in the main banana-growing regions of Central and South America. In all the trials, the formulation BAS 500 00F was applied eight times at a rate of 0.1 kg ai/ha. According to regional agricultural practice, the bananas were treated both bagged and unbagged and collected separately. Samples of whole bananas with peel were taken directly after the last application. No levels > 0.02 mg/kg were found in any sample.

The levels of pyraclostrobin residues in bananas in trials conducted according to GAP in Colombia (two), Costa Rica (three), Ecuador (three), France, Guatemala and Mexico were < 0.02 mg/kg. The Meeting estimated a maximum residue level of 0.02\* mg/kg, an STMR of 0.02 mg/kg and a highest residue level of 0.02 mg/kg for bananas.

##### *Mango*

GAP in Brazil requires a maximum rate of 0.1 kg ai/ha, with two applications and a 7-day PHI. Four trials were conducted in Brazil at a rate of 0.225 kg ai/ha with three applications, and three trials were conducted at a rate of 0.45 kg ai/ha. No residues were detected at 0 or 7 days (< 0.05 mg/kg).

The Meeting agreed to propose a maximum residue level of 0.05\* mg/kg and STMR and highest residue values of 0.05 mg/kg.

*Papaya*

GAP in Brazil requires a maximum rate of 0.1 kg ai/ha, four applications and a 7-day PHI. Four trials were reported from Brazil at a rate of 0.125 kg ai/ha and three trials at 0.25 kg ai/ha. No residues were detected at 7 days (< 0.05 mg/kg)

The Meeting estimated a maximum residue level of 0.05\* mg/kg and STMR and highest residue values of 0.05 mg/kg for papaya.

*Bulb vegetables*

GAP was reported for Brazil (onions), Canada (bulb vegetable) and the USA (garlic and onions). The maximum rate of application is 0.1 kg ai/ha in Brazil and 0.17 kg ai/ha in Canada and the USA. The PHI is 3 days for onions and 7 days for garlic in Brazil and 7 days in Canada and the USA.

Seven trials were conducted on garlic in Brazil, but only four in accordance with GAP, and seven trials were conducted on onions, none of which conformed to GAP. Nine trials on onions were conducted in the USA.

*Garlic*

In the four trials in Brazil conforming to GAP, all the residue levels were < 0.05 mg/kg.

The Meeting estimated a maximum residue level of 0.05\* mg/kg and STMR and highest residue values of 0.05 mg/kg for garlic.

*Onion*

Four trials in Brazil conducted at a rate of 0.15 kg ai/ha and a PHI of 7 days and three trials at a rate of 0.30 kg ai/ha and 7-day PHI could not be used to evaluate the residue levels.

*Bulb onion*

In six trials carried out in the USA according to GAP, the levels of pyraclostrobin residues in dry onions were: 0.02 (five) and 0.09 mg/kg. The Meeting estimated a maximum residue level of 0.20 mg/kg, an STMR of 0.02 mg/kg and a highest residue level of 0.09 mg/kg for onions, dry.

*Spring onion*

In three trials conducted according to GAP in the USA, the levels of pyraclostrobin residues in spring onions were 0.05, 0.42 and 0.53 mg/kg.

The Meeting agreed that no maximum residue level for spring onions could be established

*Fruiting vegetables*

*Tomato*

GAP was reported for Brazil, Canada (fruiting vegetables), Chile and the USA. The critical GAP was a maximum rate of 0.224 kg ai/ha, six applications and a 0-day PHI. Three outdoor trials were conducted in Brazil and 21 in the USA, which included two with decay curves.

The levels of pyraclostrobin residues in tomatoes in trials conducted according to GAP in Brazil were, in ranked order: 0.02, 0.03 and 0.12 mg/kg. The levels in the trials in the USA were, in ranked order: 0.06, 0.07 (two), 0.08, 0.10, 0.11 (four), 0.12 (three), 0.13 (two), 0.15, 0.16, 0.17 (three), 0.19 and 0.21 mg/kg.

The Meeting combined the data from Brazil and the USA, giving levels, in ranked order, of: 0.02, 0.03, 0.06, 0.07 (two), 0.08, 0.10, 0.11 (four), 0.12 (four), 0.13 (two), 0.15, 0.16, 0.17 (three), 0.19 and 0.21 mg/kg.

The Meeting estimated a maximum residue level of 0.3 mg/kg, an STMR of 0.12 mg/kg and a highest residue level of 0.21 mg/kg for tomato.

#### *Chili pepper*

GAP was reported for Brazil (maximum rate of 0.1 kg ai/ha and 3-day PHI), Canada (fruiting vegetable), the Republic of Korea and the USA (maximum rate of 0.224 kg ai/ha, six applications and 0-day GAP).

Four trials were reported from Brazil at 0.15 kg ai/ha and three at 0.3 kg ai/ha, which did not correspond to GAP.

The levels of pyraclostrobin residues in chili peppers in trials conforming to GAP in the USA were 0.14, 0.22 and 0.82 mg/kg.

The Meeting agreed that no maximum residue level for chili pepper could be established.

#### *Fruiting vegetables*

GAP was reported for Canada (fruiting vegetable, cucurbits) and the USA (squash summer), at a rate of application of 0.22 kg ai/ha, four applications and a 0-day PHI.

##### *Summer squash*

In six trials conducted according to GAP on summer squash in the USA, the levels of residues, in ranked order, were: 0.03, 0.07, 0.14, 0.17 and 0.18 mg/kg.

The Meeting estimated a maximum residue level of 0.3 mg/kg, an STMR of 0.15 mg/kg and a highest residue level of 0.18 mg/kg for summer squash.

##### *Cucumber*

Four trials were carried out on cucumber in Brazil at 0.1 kg ai/ha and three trials at 0.2 kg ai/ha, in accordance with GAP in Brazil (0.1 kg ai/ha, 3-day PHI). The pyraclostrobin residue levels were < 0.02 mg/kg.

The Meeting agreed that the data were insufficient, and no maximum residue level could be recommended.

#### *Lettuce*

No GAP was provided. Five trials in the USA were conducted at 0.22 kg ai/ha. The Meeting agreed that no maximum residue level for lettuce could be recommended.

#### *Legume vegetables and pulses*

##### *Beans*

GAP for beans in Brazil is a maximum rate of 0.075 kg ai/ha, three applications and a 14-day PHI; that in Canada is a maximum rate of 0.1 kg ai/ha, two applications and a 30-day PHI; and that in the USA is a maximum rate of 0.2 kg ai/ha, two applications and a 30-day PHI.

In 10 trials conducted at 0.224 kg ai/ha, the residue levels 21 days after application were < 0.02 (eight), 0.04 and 0.10 mg/kg.

The Meeting estimated a maximum residue level of 0.2 mg/kg, an STMR of 0.02 mg/kg and a highest residue level of 0.10 mg/kg for dry beans.

The results of nine trials on snap beans were presented, but no GAP was available. The Meeting agreed that no maximum residue level for snap beans could be established.

*Lentils*

GAP was reported for Canada at a maximum rate of 0.1 kg ai/ha, two applications and a 30-day PHI. GAP in the USA is a maximum rate of 0.22 kg ai/ha with two applications.

Three trials were carried out in Canada, and three were conducted in the USA at a rate of 0.224 kg ai/ha. Pyraclostrobin residue levels in lentils in trials conforming to GAP in the USA were, in ranked order: 0.03, 0.08, 0.11, 0.15, 0.17 and 0.39 mg/kg.

The Meeting estimated a maximum residue level of 0.5 mg/kg, an STMR of 0.13 mg/kg and a highest residue level of 0.39 mg/kg for lentils.

*Peas, dry*

GAP in Canada for dry field peas is a maximum rate of 0.1 kg ai/ha, two applications and a 30-day PHI. That in the USA is a maximum rate of application of 0.224 kg ai/ha and a 30-day PHI. Six trials were conducted in Canada and two in the USA at the rate of 0.224 kg ai/ha.

The levels of pyraclostrobin residues in peas (dry) in trials conducted according to GAP in the USA, in ranked order, were: < 0.02 (two), 0.04, 0.05, 0.09, 0.13, 0.14, and 0.20 mg/kg.

The Meeting estimated a maximum residue level for peas, dry, of 0.3 mg/kg, an STMR of 0.07 mg/kg and a highest residue level of 0.20 mg/kg.

*Peanut*

GAP was reported for Argentina, Brazil and the USA. The critical GAP was that of the USA, which requires a maximum rate of 0.274 kg ai/ha, five applications and a 14-day PHI.

In four trials conducted in Brazil and 12 in the USA, no residues were detected in nutmeat (< 0.02 mg/kg).

The pyraclostrobin residue levels in peanut in trials conforming to GAP in Brazil and the USA were < 0.02 mg/kg or < 0.025 mg/kg (one). The Meeting estimated a maximum residue level of 0.05\* mg/kg, an STMR of 0.02 mg/kg and a highest residue level of 0.025 mg/kg for peanut.

*Soya bean*

GAP was reported for Argentina, Brazil and Paraguay. GAP in Brazil is a maximum rate of 0.08 kg ai/ha with two applications and a 14-day PHI. One trial was conducted in Argentina and eight in Brazil (only four at GAP). In Argentina, the residue level was 0.03 mg/kg. In Brazil, results were presented only for grain. No residues were detected (< 0.02 mg/kg), even after application at 0.1 kg ai/ha.

The Meeting agreed that no maximum residue level for soya bean could be established.

*Root and tuber vegetables*

*Carrot*

GAP was reported for Brazil, Canada and the USA. The rate and number of applications are the same in Canada and the USA (0.22 kg ai/ha, three applications), but the PHI is 3 days in Canada and 0 days in the USA. In Brazil, the rate of application is lower (0.1 kg ai/ha) and the PHI is 7 days. One trial was conducted in Brazil and eight in the USA, only six of which were at GAP.

The levels of pyraclostrobin residues in carrots in trials conducted according to GAP in Brazil and the USA, in ranked order, were: 0.03 (two), 0.04, 0.12 (two), 0.15 and 0.24 mg/kg. The Meeting estimated a maximum residue level of 0.50 mg/kg, an STMR of 0.12 mg/kg and a highest residue level of 0.24 mg/kg for carrots.

*Radish*

GAP in the USA is a maximum application rate of 0.224 kg ai/ha, three applications and a 0-day PHI). The same GAP is applicable to horseradish. Five trials were carried out in the USA, and the values for radish tops and root were reported.

The levels of pyraclostrobin residues in radishes were 0.05, 0.07, 0.08, 0.23 and 0.30 mg/kg. The Meeting estimated a maximum residue level of 0.50 mg/kg, an STMR of 0.08 mg/kg and a highest residue level of 0.30 mg/kg for radish.

The residue levels in radish tops were 7.5, 9.6, 9.9, 12 and 15 mg/kg. The Meeting estimated a maximum residue level of 20 mg/kg, an STMR of 9.9 mg/kg and a highest residue level of 15 mg/kg for radish tops.

*Sugar beet*

GAP in Canada and the USA is the same, with a maximum rate of 0.22 kg ai/ha, four applications and a 7-day PHI. In 12 trials conducted in USA according to GAP, the pyraclostrobin residue levels in sugar beet were: < 0.02 (two), 0.02, 0.03 (two), 0.04 (two), 0.06, 0.08 (two), 0.11 and 0.13 mg/kg. The Meeting estimated a maximum residue level of 0.2 mg/kg, an STMR of 0.04 mg/kg and a highest residue level of 0.13 mg/kg for sugar beet.

*Potato*

GAP was reported for Brazil, Canada and the USA. GAP in Brazil is a maximum rate of 0.1 kg ai/ha with five applications and a 3-day PHI, and GAP in the USA is a maximum rate of application of 0.219 kg ai/ha with six applications and a 3-day PHI.

In trials conducted according to GAP in Brazil, Canada and the USA, no residues were detected (< 0.02 mg/kg).

The Meeting estimated a maximum residue level for potatoes of 0.02\* mg/kg and STMR and highest residue values of 0.02 mg/kg.

*Cereal grains**Oats*

GAP was reported for Brazil, Denmark, Estonia, France, Ireland, Latvia, Lithuania and the United Kingdom. The maximum rate of application was around 0.2 kg ai/ha with one to two applications and a PHI of 30 days.

Eight trials were conducted according to GAP in Brazil at 0.166, 0.2, 0.333 or 0.4 kg ai/ha. The levels of pyraclostrobin residues in oat grain were, in ranked order: 0.04, 0.05, 0.06, 0.14, 0.20, 0.23, 0.25 and 0.42 mg/kg. The Meeting estimated a maximum residue level of 0.5 mg/kg, an STMR of 0.17 mg/kg and a highest residue level of 0.42 mg/kg for oat grain.

*Wheat*

GAP was reported from Argentina, Belgium, Brazil, Canada, Denmark, Estonia, France, Germany, Ireland, Latvia, Lithuania, The Netherlands, Switzerland and the United Kingdom. The rate of application was 0.20–0.25 kg ai/ha with two applications and a 35-day PHI. GAP in the USA is a maximum of 0.22 kg ai/ha and a 40-day PHI.

In Brazil, eight trials were conducted according to GAP, four at 0.167 kg ai/ha and four at 0.2 kg ai/ha; 13 trials exceeded GAP: four at 0.3 kg ai/ha, three at 0.335 kg ai/ha, three at 0.4 kg ai/ha and three at 0.6 kg ai/ha. Thirty trials were conducted in Europe: one in Denmark, eight in France, five in Germany, two in The Netherlands, nine in Spain, one in Sweden and four in the United Kingdom. In North America, 11 trials were conducted in Canada and 23 in the USA according to US GAP.

The levels of pyraclostrobin residues in wheat grain in the trials conducted according to GAP in Brazil were: 0.02, 0.03 and 0.04 (two) mg/kg.

In all the European trials, samples of whole plant without roots were taken directly after the last application. On the third sampling day, at the proposed PHI of 35 days, various samples were taken, depending on ripening, with ears taken in 30 trials and grain in 27 trials. The pyraclostrobin residue levels in wheat grain in trials that conformed to GAP were: < 0.02 (22), 0.03, 0.04 (two), 0.05 and 0.09 mg/kg.

The residue levels in wheat grain in 11 trials in Canada and 23 trials in the USA that conformed to GAP were < 0.02 mg/kg.

The levels of pyraclostrobin residues in wheat grain in GAP trials in Brazil, Europe, Canada and the USA were of the same order of magnitude, and the Meeting decided that the data could be pooled. The residue levels, in ranked order, were: < 0.02 (56), 0.02, 0.03 (two), 0.04 (four), 0.05 and 0.09 mg/kg. The Meeting estimated a maximum residue level for wheat grain of 0.2 mg/kg, an STMR of 0.02 mg/kg and a highest residue level of 0.09 mg/kg.

### *Barley*

GAP was reported for Belgium, Brazil, Canada, Denmark, Estonia, France, Germany, Ireland, Latvia, Luxembourg, Macedonia, Switzerland, the United Kingdom and the USA. GAP in Europe is a rate of application of 0.20–0.25 kg ai/ha, two applications and a 30–35-day PHI. Two trials were conducted according to GAP in Belgium, seven in France, four in Germany, three in Spain, five in Sweden and four in the United Kingdom, for a total of 25 trials.

The pyraclostrobin residue levels in barley grain in trials corresponding to GAP in Europe were, in ranked order: < 0.02 (six), 0.02 (two), 0.03 (six), 0.04 (four), 0.05 (two), 0.06, 0.07, 0.08, 0.09, 0.10, 0.29 and 0.32 mg/kg.

A total of 14 trials were carried out in Brazil, but only eight conformed to GAP. The residue levels in barley grain in the latter trials were, in ranked order: 0.04, 0.05, 0.06, 0.07, 0.08 (three) and 0.09 mg/kg.

In the 26 trials conducted in the USA on barley grain according to GAP (0.22 kg ai/ha), the pyraclostrobin residue levels, in ranked order, were: < 0.02 (19), 0.03 (three), 0.05 (two), 0.07 and 0.14 mg/kg.

As GAP in Brazil, Europe and the USA is similar and the residue levels were in the same range, the results were combined. The levels, in ranked order, were: < 0.02 (25), 0.02 (two), 0.03 (nine), 0.04 (five), 0.05 (five), 0.06 (two), 0.07 (three), 0.08 (four), 0.09 (two), 0.10, 0.14, 0.29 and 0.32 mg/kg.

The Meeting estimated a maximum residue level for barley grain of 0.5 mg/kg, an STMR of 0.03 mg/kg and a highest residue level of 0.32 mg/kg.

### *Maize*

GAP in Brazil allows two applications of 0.15 kg ai/ha or 0.1 kg ai/ha with a 45-day PHI on maize.

Four trials were conducted at 0.2 kg ai/ha and four at 0.133 kg ai/ha. The residue levels in trials conforming to GAP were < 0.02 mg/kg.

The Meeting estimated a maximum residue level for maize of 0.02\* mg/kg and STMR and highest residue values of 0.02 mg/kg.

### *Rye*

GAP in the USA allows two applications of 0.22 kg ai/ha with a 40-day PHI on rye. In five trials conducted at 0.22 kg ai/ha but with a PHI of about 60 days, the pyraclostrobin residue levels in rye were < 0.02 mg/kg at 60 days.

The Meeting agreed that no maximum residue level for rye could be estimated.



*Tree nuts*

GAP was reported from the USA for beechnut, Brazil nut, butter nut, cashew, macadamia nut, pecan, walnut and pistachio. The rate of application was 0.13 kg ai/ha, with four applications and a waiting period of 14 days (pecan and pistachio). For almond, the new GAP was 0.13 kg ai/ha, with four applications and a waiting period of > 100 days.

*Almond:* Ten trials were carried out in the USA with a 120-day PHI. The results for nutmeat were < 0.02 mg/kg. The Meeting estimated a maximum residue level of 0.02\*mg/kg, an STMR of 0.02 mg/kg and a highest residue level of 0.02 mg/kg.

*Pecan:* Ten trials were conducted in the USA according to GAP. Pyraclostrobin residue levels in pecan were < 0.02 mg/kg. The Meeting estimated a maximum residue level of 0.02\*mg/kg, an STMR of 0.02 mg/kg and a highest residue level of 0.02 mg/kg for pecan.

*Pistachio:* Six trials were carried out in the USA according to GAP. The pyraclostrobin residue levels were: 0.02 (two), 0.16, 0.27, 0.44 and 0.45 mg/kg. The Meeting estimated a maximum residue level of 1 mg/kg, an STMR of 0.22 mg/kg and a highest residue level of 0.45 mg/kg for pistachio.

*Coffee*

GAP in Brazil is a maximum rate of 0.2 kg ai/ha with two applications and a 45-day PHI. Four trials were conducted at 0.175 kg ai/ha and three at 0.35 kg ai/ha. The pyraclostrobin residue levels were < 0.02 (two), 0.03 and 0.15 mg/kg.

**The Meeting agreed that no maximum residue level for coffee could be estimated***Animal feedstuffs**Fodder beet leaves and tops*

GAP is the same for Canada and the USA, with a maximum rate of 0.22 kg ai/ha, four applications and a 7-day PHI. In 12 trials conducted in the USA according to GAP, the levels of pyraclostrobin residues, in ranked order, were: 0.28, 1.3, 1.4, 1.5 (two), 1.6, 1.7, 2.0, 2.6, 2.8, 3.9 and 5.3 mg/kg.

Eight trials were conducted in Europe and reported, but the registration is pending.

The Meeting estimated a maximum residue level of 10 mg/kg, an STMR of 1.64 mg/kg and a highest residue level of 5.3 mg/kg for sugar beet tops. On a dry basis, the maximum residue level was 50 mg/kg, the STMR was 7.1 mg/kg and the highest residue level was 23 mg/kg.

*Peanut hay*

GAP was reported for Argentina, Brazil and the USA. The critical GAP is 0.274 kg ai/ha with five applications and a 14-day PHI. In 12 trials conducted according to GAP in the USA, the pyraclostrobin residue levels in peanut hay, in ranked order, were: 1.5, 3.3, 4.0, 4.8, 4.9, 9.0, 15, 18, 19 (two) and 24 mg/kg.

The Meeting estimated a maximum residue level of 50 mg/kg, an STMR of 9.0 mg/kg and a highest residue level of 24 mg/kg for peanut hay.

On the basis of the dry matter, which is listed as 85% in the *FAO Manual*, the STMR is equivalent to 11 mg/kg and the highest residue level to 29 mg/kg. These values were used to calculate the animal burden.

*Pea hays and vines*

GAP was reported for Canada (dried field peas, 0.1 kg ai/ha with two applications and a 30-day PHI) and the USA (0.22 kg ai/ha and a 30-day PHI). Six trials were conducted in Canada and two in the USA at an application rate of 0.224 kg ai/ha.

The levels of pyraclostrobin residues in pea vines in trials conforming to GAP in the USA were: 3.3, 3.8, 4.2, 5.0, 5.1, 5.5 (two) and 7.0 mg/kg.

The Meeting estimated a maximum residue level for pea vines of 10 mg/kg, an STMR of 5.1 mg/kg and a highest residue level of 7.0 mg/kg.

On the basis of the dry matter, which is listed as 25% in the *FAO Manual*, the maximum residue level was estimated at 40 mg/kg, the STMR at 20 mg/kg and the highest residue level at 28 mg/kg in pea vine. These values were used to calculate the animal burden.

The levels of pyraclostrobin residues in pea hay in trials conforming to GAP in the USA were: 4.9, 5.3, 6.4, 7.2, 7.5, 9.2, 12 and 18 mg/kg.

The Meeting estimated a maximum residue level for pea hay of 20 mg/kg, an STMR of 6.8 mg/kg and a highest residue level of 18 mg/kg.

On the basis of the dry matter, which is listed as 88% in the *FAO Manual*, the maximum residue level was estimated at 30 mg/kg, the STMR at 7.8 mg/kg and the highest residue level at 20 mg/kg in pea hay.

*Barley straw, hay (fodder) and haulms*

GAP was reported for Belgium, Brazil, Canada, Denmark, Estonia, France, Germany, Ireland, Latvia, Luxembourg, Macedonia, Switzerland, the United Kingdom and the USA. The maximum rate of application is 0.2–0.25 kg ai/ha with two applications and a 30–35-day PHI. In Europe, 25 trials were conducted, with two in Belgium, seven in France, four in Germany, three in Spain, five in Sweden and four in the United Kingdom.

The levels of pyraclostrobin residues in barley straw in trials that complied with GAP in Europe were: 0.48, 0.66, 0.78 (two), 0.72, 0.84, 0.99, 1.0, 1.7 (two), 1.8, 2.0, 2.6 (two), 2.8 (three), 3.9, 4.4 (two), 4.8, 4.9, 5.7, 5.8 and 6.9 mg/kg.

The levels of pyraclostrobin residues in barley straw in trials that complied with GAP in Canada and the USA were: 0.09, 0.12 (two), 0.26, 0.30 (two), 0.31, 0.32 (two), 0.39, 0.45, 0.52, 0.57, 0.82, 1.1, 1.3, 1.4, 1.5 (two), 1.9, 2.4, 2.8 and 4.0 mg/kg.

The Meeting agreed to combine the above results for estimating a maximum residue level for barley straw. The residue levels, in ranked order, were: 0.09, 0.12 (two), 0.26, 0.30 (two), 0.31, 0.32 (two), 0.39, 0.45, 0.48, 0.52, 0.57, 0.66, 0.72, 0.78 (two), 0.82, 0.84, 0.99, 1.0, 1.1, 1.3, 1.4, 1.5 (two), 1.7 (two), 1.8, 1.9, 2.0, 2.4, 2.6 (two), 2.8 (four), 3.9, 4.0, 4.4 (two), 4.8, 4.9, 5.7, 5.8 and 6.9 mg/kg.

The levels of pyraclostrobin residues in barley haulms in trials that complied with GAP in Europe were: 0.41, 0.53, 0.54, 0.58, 0.72, 0.73, 0.74, 0.87, 0.88, 0.98, 1.2, 1.3, 1.4 (two), 1.5, 1.6, 1.7, 1.8, 2.5, 3.2, 3.4, 4.1, 4.3, 6.6 and 7.6 mg/kg.

The levels of pyraclostrobin residues in barley hay in trials that complied with GAP in Canada and the USA were: 0.93, 0.96, 1.0 (two), 1.1, 1.2, 1.3, 1.5, 1.6 (three), 1.9, 2.1, 2.2 (two), 2.5, 2.8, 3.2 (two), 3.6, 3.7, 12 (two), 17 and 19 mg/kg.

*Wheat straw, hay (fodder) and haulms*

GAP was reported for Argentina, Belgium, Brazil, Canada, Denmark, Estonia, France, Germany, Ireland, Latvia, Lithuania, The Netherlands, Switzerland, the United Kingdom and the USA. The rate of application is 0.20–0.25 kg ai/ha with two applications and a 35-day PHI.

In 27 trials in Europe, samples of whole plant without roots were taken directly after the last application, and samples of haulms and straw were taken about 3 weeks after the last application. On the third sampling day, which was at the proposed 35-day PHI, various samples were taken, depending on ripening; in 27 trials, haulms and straw were taken.

The levels of pyraclostrobin residues in wheat straw in trials that conformed to GAP in Europe were: 0.67, 0.75, 0.87, 1.2, 1.4, 1.5, 1.6, 1.7, 1.7 (two), 1.8, 1.9 (two), 2.0 (two), 2.1, 2.2, (five), 2.3, 2.5, 3.2, 5.0, 5.5 and 5.7 mg/kg.

The levels of pyraclostrobin residues in wheat straw in trials that conformed to GAP in Canada and the USA were: 0.03, 0.06, 0.07, 0.09, 0.10 (two), 0.11, 0.12, 0.13 (two), 0.15, 0.20, 0.21, 0.23, 0.24, 0.32, 0.34, 0.37, 0.52, 0.56, 0.74, 0.85, 0.90, 0.95, 1.1, 1.6, 1.7, 2.2, 3.5, 3.8 and 4.1 mg/kg.

The Meeting agreed to combine the above results for estimating a maximum residue level for wheat straw. The residue levels, in ranked order, were: 0.03, 0.06, 0.07, 0.09, 0.10 (two), 0.11, 0.12, 0.13 (two), 0.15, 0.20, 0.21, 0.23, 0.24, 0.32, 0.34, 0.37, 0.52, 0.56, 0.67, 0.74, 0.75, 0.85, 0.87, 0.90, 0.95, 1.1, 1.2, 1.4, 1.5, 1.6 (two), 1.7 (four), 1.9 (three), 2.0 (two), 2.1, 2.2 (six), 2.3, 2.5, 3.1, 3.5, 3.8, 4.1, 5.0, 5.5 and 5.7 mg/kg.

The levels of pyraclostrobin residues in wheat haulms in trials that conformed to GAP in Europe were: 0.50, 0.52, 0.56, 0.62, 0.74, 0.75, 0.79, 0.81, 0.84, 0.85, 0.89, 0.92, 0.94, 0.96, 0.98, 0.99, 1.0 (two), 1.1, 1.2, 1.3 (two), 1.4 (two), 1.5, 1.6, 1.9, 2.7 (two) and 3.2 mg/kg.

The levels of pyraclostrobin residues in wheat hay in trials that conformed to GAP in Canada and the USA were: 0.21, 0.24, 0.27, 0.43, 0.46, 0.49, 0.54, 0.72, 0.75, 0.83, 0.89, 0.91, 0.93, 0.95, 1.0 (two), 1.1, 1.2, 1.4 (two), 1.5 (two), 1.6, 1.8 (two), 1.9, 2.0, 2.2 (two), 2.3, 3.0, 3.1 and 4.6 mg/kg.

#### *Rye straw*

GAP was reported from the USA at a rate of application of 0.2–0.25 kg ai/ha with two applications and a 40-day PHI. Five trials were conducted but with a longer PHI. The levels of pyraclostrobin residues were 0.11, 0.14, 0.17, 0.27 and 0.30 mg/kg.

The Meeting agreed that no maximum residue level for rye straw could be estimated.

The Meeting agreed to combine the results for barley and wheat straw (106 trials) in estimating a maximum residue level for cereal straw. The residue levels, in ranked order, were: 0.03, 0.06, 0.07, 0.09 (two), 0.10 (two), 0.11, 0.12 (three), 0.13 (two), 0.15, 0.20, 0.21, 0.23, 0.24, 0.26, 0.30 (two), 0.31, 0.32 (three), 0.34, 0.37, 0.39, 0.45, 0.48, 0.52 (two), 0.56, 0.57, 0.66, 0.67, 0.72, 0.74, 0.75, 0.78 (two), 0.82, 0.84, 0.85, 0.87, 0.90, 0.95, 0.99, 1.03, 1.1 (two), 1.2, 1.3, 1.4 (two), 1.5 (three), 1.6 (two), 1.7 (six), 1.8 (two), 1.9 (three), 2.0 (two), 2.1 (two), 2.2 (six), 2.3, 2.4, 2.5, 2.6 (two), 2.8 (four), 3.1, 3.5, 3.8, 3.9, 4.0, 4.10, 4.4 (two), 4.8, 4.9, 5.0, 5.5, 5.7 (two), 5.8 and 6.9 mg/kg.

The Meeting agreed to combine the results for barley and wheat fodder (59 trials) in estimating a maximum residue level for cereal fodder. The residue levels, in ranked order, were: 0.21, 0.24, 0.27, 0.43, 0.46, 0.49, 0.54, 0.72, 0.75, 0.83, 0.89, 0.91, 0.93 (two), 0.95, 0.96, 1.0 (four), 1.1 (two), 1.2 (two), 1.3, 1.4 (two), 1.5 (three), 1.6 (four), 1.8 (two), 1.9 (two), 2.0, 2.1, 2.2 (four), 2.3, 2.5, 2.8, 3.0, 3.1, 3.2 (two), 3.6, 3.7, 4.6, 11, 12, 17 and 19 mg/kg.

Allowing for the standard 88% dry matter for cereal straw and fodder (*FAO Manual* p. 49), the Meeting estimated a maximum residue level of 30 mg/kg, an STMR of 1.69 mg/kg and a highest residue level of 21.7 mg/kg. The highest residue level was taken into account in calculating the animal dietary burden.

#### *Almond hulls*

GAP was reported from the USA with 10 trials conducted according to GAP. The levels of pyraclostrobin residues in almond hulls were: < 0.02 (two), 0.11, 0.16, 0.19, 0.21, 0.47, 0.55, 0.87 and 1.3 mg/kg.

The Meeting estimated a maximum residue level of 2 mg/kg, an STMR of 0.20 mg/kg and a highest residue level of 1.34 mg/kg for almond hulls. The highest residue level was taken into account in calculating the animal dietary burden.

### ***Fate of residues during processing***

Studies were conducted on grapes, barley and wheat, and the respective intermediate end- and waste products were analysed. For grapes, the data covered whole grapes, cold must, heated must, wet pomace, wine from cold must, wine from heated must, juice and raisins. For barley, the data covered pearling dust, pot barley, malt, malt germs, spent grain, trub (flocks), beer yeast and beer. For wheat, flour, bran, middlings, shorts and germ were analysed.

The processing factors for total residues in the transformation from *grape* to must, wine and juice were  $< 1$  (0.08–0.013), indicating that the residues did not concentrate. Concentration factors of 2.4–5.6 were calculated for residues in processing from whole grape to pomace; the concentration factor for total residues in processing from whole grapes to raisins was 3.1, which may be due to loss of water during processing.

In the processed fractions obtained for pot *barley* and beer production, such as pearling dust, malt, malt germs, spent grain, trub (flocks) and beer yeast, none of which are meant for consumption, the residues of pyraclostrobin showed some concentration, with factors ranging from 1.29 to 7.86. In the final products to be consumed, such as pot barley and beer, however, no concentration of pyraclostrobin residues was observed, as expressed by processing factors of  $< 1$  ( $< 0.6$ ). The processing factor from barley to beer cannot be calculated owing to the low contamination of barley, but the transfer factor can be assumed to be low.

The processing factors for total residues in the transformation from *wheat* grain to all processed fractions were  $< 1$  ( $< 0.6$ ), indicating that the residues did not concentrate. The transfer factor for wheat germ was 0.8. The processing factors and STMR-P values for all the commodities investigated were:

| Commodity   | Processing factor | STMR-P (mg/kg) |
|-------------|-------------------|----------------|
| Grape juice | 0.013             | 0.005          |
| Wine        | $< 0.1$           | $< 0.044$      |
| Must        | 0.15              | 0.07           |
| Wet pomace  | 2.4–5.6           | 2.46           |
| Raisin      | 3.1               | 1.36           |
| Malt        | 1                 | 0.03           |
| Beer        | $< 0.6$           | $< 0.025$      |
| Wheat flour | $< 0.6$           | $< 0.01$       |
| Wheat bran  | $< 0.6$           | $< 0.01$       |
| Wheat germ  | 0.8               | 0.016          |

### ***Residues in animals commodities***

#### ***Dietary burden of farm animals***

The Meeting estimated the dietary burden of pyraclostrobin residues in farm animals on the basis of the diets listed in Appendix IX of the *FAO Manual*. The percentage of dry matter is taken as 100% when MRLs and STMR values are expressed as dry weight.

*Estimated maximum dietary burden of farm animals*

| Commodity          | Group | Residue (mg/kg highest residue) | Residue (mg/kg on dry matter basis) <sup>a</sup> | Dietary content (%) |              |         | Residue contribution (mg/kg) |              |         |
|--------------------|-------|---------------------------------|--------------------------------------------------|---------------------|--------------|---------|------------------------------|--------------|---------|
|                    |       |                                 |                                                  | Beef cattle         | Dairy cattle | Poultry | Beef cattle                  | Dairy cattle | Poultry |
| Almond hulls       | AM    | 1.34                            | 1.34                                             |                     |              |         |                              |              |         |
| Barley grain       | GC    | 0.36                            | 0.36                                             | 50                  | 40           | 75      | 0.18                         |              | 0.27    |
| Cereal fodder      | AS    | 21.7                            | 21.7                                             | 25                  | 60/50        |         | 5.4                          | 10.8         |         |
| Sugar beet         | AB    | 0.15                            | 0.15                                             |                     |              |         |                              |              |         |
| Peanut hay         | AL    | 28.8                            | 28.8                                             | 25                  | 50           |         | 7.28                         | 14.4         |         |
| Pea hay            | AL    | 20.5                            | 20.5                                             |                     |              |         |                              |              |         |
| Pea vines          | AL    | 28                              | 28                                               | 25                  | 50           |         |                              |              |         |
| Fodder beet leaves | AV    | 23                              | 23                                               |                     |              |         |                              |              |         |
| Total              |       |                                 |                                                  | 100                 | 100          | 75      | 12.9                         | 25.2         | 0.27    |

<sup>a</sup> 100% dry matter for all commodities

*Estimated median dietary burden of farm animals*

| Commodity        | Group | Residue (mg/kg on STMR basis) | Residue (mg/kg on dry matter basis) <sup>a</sup> | Dietary content (%) |              |         | Residue contribution (mg/kg) |              |         |
|------------------|-------|-------------------------------|--------------------------------------------------|---------------------|--------------|---------|------------------------------|--------------|---------|
|                  |       |                               |                                                  | Beef cattle         | Dairy cattle | Poultry | Beef cattle                  | Dairy cattle | Poultry |
| Almonds hulls    | AM    | 0.2                           | 0.22                                             | 10                  | 10           |         |                              |              |         |
| Barley grain     | GC    | 0.034                         | 0.034                                            | 50                  | 40           | 75      | 0.017                        | 0.014        | 0.025   |
| Cereal fodder    | AS    | 1.69                          | 1.69                                             | 10                  | 60           |         |                              |              |         |
| Fodder beet tops | AV    | 7.1                           | 7.1                                              | 20                  | 10           |         | 1.42                         | 0.71         |         |
| Sugar beet       | AB    | 0.045                         | 0.045                                            | 20                  | 20           |         |                              |              |         |
| Peanut hay       | AL    | 10.6                          | 10.6                                             | 25                  | 50           |         |                              |              |         |
| Pea hay          | AL    | 7.75                          | 7.75                                             | 25                  | 50           |         |                              |              |         |
| Pea vines        | AL    | 20.2                          | 20.2                                             | 25                  | 50           |         | 5.06                         | 10.1         |         |
| Total            |       |                               |                                                  | 95                  | 100          | 75      | 6.5                          | 10.8         | 0.025   |

<sup>a</sup> 100% dry matter for all commodities

The dietary burdens of pyraclostrobin for estimates of STMR and highest residue level values in animal commodities (residue levels in animal feeds expressed as dry weight) are, respectively, 6.5 mg/kg and 12.9 mg/kg for beef cattle, 10.8 mg/kg and 25.2 mg/kg for dairy cattle and 0.025 mg/kg and 0.27 mg/kg for poultry.

*Feeding studies*

In one feeding study, dairy cows were given feed containing pyraclostrobin at 0, 8.8, 27.2 or 89.6 mg/kg for 28 days. No residues of pyraclostrobin were detected in milk, meat, fat, kidney or tissues from the group given the concentration relevant to normal agricultural conditions (27.2 mg/kg) or at the other two concentrations. Low levels of pyraclostrobin metabolites might occur in liver.

The Meeting decided not consider these studies, as pyraclostrobin is fat-soluble and no residues were detected. The study of metabolism in goats, summarized below, was used to estimate residues in animal products.

| Tissue            | Residue (mg/kg)    |                    |                    |                    | Value taken into account | Dietary burden estimate (ppm) |       |
|-------------------|--------------------|--------------------|--------------------|--------------------|--------------------------|-------------------------------|-------|
|                   | At 12 ppm          |                    | At 50 ppm          |                    |                          | 25.2                          | 10.8  |
|                   | Chlorophenyl label | Tolyl label        | Chlorophenyl label | Tolyl label        |                          |                               |       |
| Milk <sup>a</sup> | 0.012              | 0.01               | 0.067              | 0.027              | 0.047                    | 0.0236                        | 0.01  |
| Muscle            | 0.01               | 0.01               | 0.089              | 0.048              | 0.089                    | 0.044                         | 0.009 |
| Fat               | 0.069              | 0.061              | 0.82               | 0.32               | 0.82                     | 0.41                          | 0.063 |
| Liver             | 0.008 <sup>b</sup> | 0.006 <sup>b</sup> | 0.021              | 0.07               | 0.07                     | 0.035                         | 0.007 |
| Kidney            | 0.01 <sup>b</sup>  | 0.007 <sup>b</sup> | 0.074 <sup>b</sup> | 0.073 <sup>b</sup> | 0.074                    | 0.037                         | 0.009 |

<sup>a</sup> Mean values; comprises pyraclostrobin and metabolite 500M07

<sup>b</sup> Comprises pyraclostrobin and metabolite 500M07 at the lower dose for liver and at both doses for kidney

### Maximum residue levels

On the basis of the estimated residue levels at the calculated dietary burdens, the Meeting recommended a maximum residue level of 0.03 mg/kg and an STMR of 0.01 mg/kg for milk.

The Meeting recommended a maximum residue level of 0.5 mg/kg for meat (fat) of mammals other than marine mammals and for edible offal, an STMR of 0.008 mg/kg and a highest residue level of 0.037 mg/kg for edible offal, an STMR of 0.009 mg/kg and a highest residue level of 0.044 mg/kg for muscle, and an STMR of 0.063 mg/kg and a highest residue level of 0.41 mg/kg for fat.

No feeding study was performed in chickens. The Meeting noted that in the study of metabolism in laying hens, pyraclostrobin was not detected in tissues (< 0.002 mg/kg) or eggs (< 0.002 mg/kg) at a feeding level of 12 mg/kg, which was 30 times higher than the calculated dietary burden (0.27 ppm).

The Meeting agreed that it is unlikely that pyraclostrobin residues will be detected in the products of poultry fed commodities treated with this compound. The Meeting estimated a maximum residue level of 0.05\* mg/kg and STMR and highest residue level values of 0 for pyraclostrobin in eggs, meat (fat) and edible offal of poultry.

## DIETARY RISK ASSESSMENT

### Long-term intake

The IEDI of pyraclostrobin calculated on the basis of the recommendations made at the present Meeting for the five GEMS/Food regional diets represented 0–3% of the ADI (0–0.03 mg/kg per day in a 2-year study in rats).

The Meeting concluded that the long-term intake of residues of pyraclostrobin resulting from uses that have been considered by the JMPR is unlikely to present a public health concern.

***Short-term intake***

The IESTI of pyraclostrobin calculated on the basis of the recommendations made at the present Meeting represented 0–90% of the ARfD (0–0.05 mg/kg per day in a study on developmental toxicity in rabbits) for children and 0–40% of the ARfD for the general population.

The Meeting concluded that the short-term intake of residues of pyraclostrobin resulting from uses that have been considered by the JMPR is unlikely to present a public health concern.

**4.27 SPICES****RESIDUE AND ANALYTICAL ASPECTS**

The issue of setting maximum residue levels for spices on the basis of the results of monitoring was discussed by the CCPR on several occasions. The 2002 JMPR prepared guidelines for the format of submission of monitoring data for evaluation (ALINORM 02/24). At its Thirty-sixth Session, the CCPR proposed to divide the commodity group 028 into subgroups on the basis of the part of the plant from which they are obtained (seeds, fruits or berries, roots or rhizomes, bark, buds, arils and flower stigmas) and proposed that maximum residue levels for pesticides that had been evaluated within the Codex system should be set for the subgroups instead of for each pesticide–spice combination (ALINORM 04/24, para 236). Furthermore, the maximum residue levels for dry chili peppers should be set on the basis of the existing maximum residue levels for peppers, taking into account the processing and dehydration factors as appropriate (ALINORM 04/24, para 242).

The Government of India, through the Indian Spice Board, the American Spice Trade Association, the European Spice Association and the Government of Egypt provided data resulting from pesticide monitoring programmes on spices during the period 1996–2003. The Delegation of South Africa coordinated the compilation of data for submission to the JMPR.

The JMPR reviewed the residue monitoring data provided and estimated maximum residue levels for the spice subgroups. The residue data on cumin from Egypt indicated that several pesticides might be applied post-harvest. Similarly, the residue levels of malathion and profenofos on anise seed were much higher than those of other pesticides, indicating possible post-harvest use of malathion and profenofos. The Meeting concluded that post-harvest use of pesticides on spices should be regulated by national governments, and monitoring data should not be used for estimating maximum residue levels reflecting post-harvest use. Consequently, the results of residue trials that suggested post-harvest use were not included in the 2004 evaluation.

The Meeting emphasized that the fact that it has estimated maximum, median and high residue values does not mean that it has approved use of the compounds on spices and chili peppers.

The Meeting noted that poppy seed (SO 698), mustard seed (SO 90) and sesame seed (SO700) are used as major food ingredients in several countries. It therefore considered it more appropriate to keep them in the oil seeds group (A023) and to remove them from group A028. The recommended maximum residue levels for the seed subgroup of spices does not include these seeds.

The large number of residue values for some pesticide–commodity combination allowed proper statistical treatment of the monitoring data. The principles applied are discussed in detail under section 2.6 of the General Considerations.

In addition, the following major principles were followed in evaluating the residue data for estimation of maximum, median and high residue values:

- All the residue data were considered; no data point was excluded as an outlier.
- Residue values reported as '0' were replaced by 'below the limit of quantification' (LOQ).
- Maximum, median and high residue levels were recommended when the database allowed estimation of > 95th percentile of the residue population at a 95% confidence (probability) level. That required a minimum of 58–59 samples. Use of the 95% confidence interval is recommended, as it is used for estimating the variability factor in short-term exposure assessment and is generally applied in biometry.
- As very few data were available for commodities derived from bark, buds, arils and flower stigmas, these spices are summarized together in the tables. Maximum residue levels could be estimated in only a few cases
- When residues were detectable, estimation of the maximum residue level for the subgroup also took into account the number of residue data and residue levels for the particular pesticide–commodity combination.
- A maximum residue level was proposed at the limit of determination when no residues were detectable, even if the minimum sample requirements (59) was not met for satisfying the specified probability (> 95th percentile) and confidence (95%) interval for any subgroup.
- When residues were undetectable and different LOQ values were reported for a particular pesticide from the different data sources, the maximum residue level was proposed at the highest LOQ provided for the pesticide. As there was no evidence for nil residues, the median was calculated from the values corresponding to the reported LOQs. The high residue level was considered to be equal to the highest reported LOQ. Addition of \* after a residue value does not necessarily indicate that residues will not occur in detectable amounts if a more sensitive method is used.
- The estimated median and high residue values can be used in the same way as the STMR and highest residue values obtained from supervised trials for estimating long-term and short-term intake of residues.
- A substantial proportion of random samples did not contain detectable residues, indicating that the sampled lots had probably not been treated with or exposed to the given pesticide. Therefore, the median residue values were derived from the detected residue levels. Long-term intake was calculated from the residue data for that commodity that made the largest contribution to intake and the percentage of the treated proportion of that crop.
- When no residues were detected, the median level of residues was taken as equivalent to the median LOQ, as a conservative estimate.
- The short-term intake calculations were performed with the highest residue value for the pesticide measured in any spice sample, after the necessary adjustments for consumption figures described in the evaluation.

### ***Sampling and analytical methods***

The samples were taken from randomly selected lots either before export or upon arrival in the importing country. No information was provided on the sampling procedures, the size or the mass of samples.

The samples were analysed by multi-residue procedures, resulting in average recoveries of 70–120%, with the exception of ethion, with a recovery of 150%. The LOQs ranged from 0.01 mg/kg to 0.5 mg/kg. The difference in the LOQ values reported by different laboratories was sometimes 10-fold. Data on the reproducibility of methods and other performance parameters were provided in only a few cases.



**Results of monitoring studies***Acephate*

The 225 samples analysed comprised seeds (79), fruits or berries (77), roots or rhizomes (42) and bark, buds and arils (27). All the results were below the LOQ: 0.2 mg/kg for data from the American Spice Trade Association and India and 0.02 mg/kg for data from the European Spice Association, regardless of the subgroup in which the spices were classified.

The Meeting estimated a maximum residue limit of 0.2 (\*) mg/kg and median and high residue values of 0.2 mg/kg for spices.

As none of the samples contained detectable residues, no factor can be introduced into calculations of long-term intake to take into account the proportion of samples containing detectable residues.

*Azinphos-methyl*

The 260 samples analysed comprised seeds (86), fruits or berries (92), roots or rhizomes (46) and bark, buds and arils (36).

All the results were below the limit of determination: 0.5 mg/kg for data from the American Spice Trade Association and India and 0.1 mg/kg for data from the European Spice Association.

The Meeting estimated a maximum residue level of 0.5 (\*) mg/kg, a median residue level of 0.1 mg/kg and a high residue level of 0.5 mg/kg for spices.

As none of the samples contained detectable residues, no factor can be introduced into calculations of long-term intake to take into account the proportion of samples containing detectable residues.

*Chlorpyrifos*

The 2632 samples analysed comprised seeds (2165), fruits or berries (155), roots or rhizomes (270) and bark, buds and arils (42). The LOQ was 0.05 mg/kg in all data sources.

Detectable residues were found in celery seed, coriander and cumin. The levels, in ranked order, were: 0.12, 0.15, 0.16, 0.18, 0.25, 0.26, 0.41, 0.44, 0.54 and 0.54 mg/kg. Detectable residues were found in one of 18 samples of anise seeds in Canada and 78 of 744 samples in Egypt. The levels found were, in ranked order: 0.01 (two), 0.05 (12), 0.06 (seven), 0.07 (eight), 0.08 (nine), 0.09 (four), 0.1 (two), 0.11 (three), 0.13 (six), 0.14 (six), 0.15, 0.17 (two), 0.18, 0.21 (three), 0.22, 0.23, 0.32, 0.33, 0.36, 0.5 (two), 0.54, 0.9, 1.8, 2, 3 and 3.6 mg/kg. For fennel, 1228 samples were analysed, and 18 contained detectable residues. The levels, in ranked order, were: 0.05 (two), 0.06, 0.07, 0.08, 0.1 (two), 0.11 (five), 0.13, 0.14, 0.15, 0.22 (two) and 1.4 mg/kg.

The Meeting concluded that the levels of residues in seeds are comparable and estimated a maximum residue level of 5 mg/kg, a median residue level of 0.09 mg/kg and a high residue level of 3.6 mg/kg (based on residue data for anise seed) for the seed subgroup of spices.

Detectable residues were measured in cardamom and pepper in the fruit subgroup, at levels, in ranked order, of: 0.05 (two), 0.06, 0.07, 0.08, 0.11, 0.20, 0.54 and 0.71 mg/kg.

The Meeting estimated a maximum residue level of 1 mg/kg, a median residue level of 0.05 mg/kg and a high residue level of 0.71 mg/kg for the fruit subgroup.

Detectable residues were found in ginger and turmeric in the roots subgroup, at levels, in ranked order, of: 0.05, 0.13, 0.24, 0.28, 0.31, 0.37 and 0.72 mg/kg.

The Meeting estimated a maximum residue level of 1 mg/kg, a median residue level of 0.05 mg/kg and a high residue level of 0.72 mg/kg for the roots subgroup.

Detectable residues were found ( $> 0.05$  mg/kg) in the subgroups of bark, buds and arils in three studies. As only 42 measurements were available, however, maximum residue levels could not be estimated for these subgroups.

The Meeting recommended use of a high residue level of 3.6 mg/kg for calculation of short-term intake, and a median residue level of 0.09 mg/kg and a factor of 0.1 to take into account the proportion of samples containing detectable residues for calculating long-term intake.

#### *Chlorpyrifos-methyl*

The 1822 samples analysed comprised seeds (1432), fruits or berries (80), roots or rhizomes (142) and bark, buds and arils (25). The LOQ was 0.05 mg/kg in all data sources.

Detectable levels of residues were found in 68 of 983 samples of anise seed, one of 49 samples of celery seed (0.01 mg/kg), one of 19 samples of coriander (0.01 mg/kg) and four of 345 samples of fennel (0.07, 0.08, 0.12 and 0.16 mg/kg). The combined residue levels were, in ranked order: 0.02 (two), 0.05 (two), 0.06 (four), 0.07 (three), 0.08 (seven), 0.09 (eight), 0.1 (five), 0.11, 0.12 (three), 0.13 (three), 0.14, 0.15 (two), 0.16 (five), 0.17, 0.18 (two), 0.19, 0.2 (two), 0.22 (three), 0.24 (two), 0.25, 0.28, 0.3, 0.31, 0.32, 0.38 and 0.39 mg/kg.

The Meeting estimated a maximum residue level of 1 mg/kg, a high residue level of 0.39 mg/kg and a median residue level of 0.05 mg/kg for the seed subgroup of spices.

Three of 156 samples of caraway contained detectable residues, at: 0.06, 0.1 and 0.12 mg/kg.

The Meeting estimated a maximum residue level of 0.3 mg/kg, a high residue level of 0.12 mg/kg and a median residue level of 0.1 mg/kg for the fruits subgroup of spices.

Detectable residues were found in ginger and turmeric in the roots subgroup, at levels, in ranked order, of: 0.013 (12), 0.017, 0.03 (two), 0.031, 0.034 (two), 0.037, 0.038, 0.05, 0.06, 0.07, 0.071, 0.073, 0.082, 0.089, 0.091, 0.098, 0.14 (three), 0.16, 0.29, 0.39 and 2.9 mg/kg.

The Meeting estimated a maximum residue level of 5 mg/kg, a high residue level of 2.9 mg/kg and a median residue level (on the basis of data for ginger) of 0.77 mg/kg for the roots subgroup.

Lack of sufficient data prevented estimation of maximum residue levels for the bark, buds and arils subgroups.

The Meeting recommended use of a high residue level of 2.9 mg/kg for calculating short-term intake, and a median residue level of 0.77 mg/kg and a factor of 1 to take into account the proportion of samples containing detectable residues for calculating long-term intake.

#### *Cypermethrin*

The 174 samples analysed comprised seeds (38), fruits or berries (65), roots or rhizomes (58) and bark, buds and arils (13). The LOQ was 0.05 mg/kg in all data sources.

Commodities in the seed subgroup contained detectable residues at levels of 0.076–0.93 mg/kg.

One of 57 samples of pepper contained detectable residues (0.065 mg/kg), but none were found in eight samples of other commodities in the fruits subgroup. The Meeting estimated a maximum residue level of 0.1 mg/kg, a high residue level of 0.05 mg/kg and a median residue level of 0.05 mg/kg for the fruits or berries subgroup of spices.

Three of 58 samples of commodities in the subgroup of roots or rhizomes contained detectable residues, at levels of: 0.05, 0.11 and 0.12 mg/kg.

The Meeting estimated a maximum residue level of 0.2 mg/kg, a high residue level of 0.12 mg/kg and a median residue level of 0.11 mg/kg for roots or rhizomes.

The limited database was considered insufficient for estimating maximum residue levels for the other subgroups.

The Meeting recommended use of a high residue level of 0.12 mg/kg for calculating short-term intake, and a median residue level of 0.11 mg/kg and a factor of 0.04 to take into account the proportion of samples containing detectable residues in calculating long-term intake.

#### *Diazinon*

The 1948 samples analysed comprised seeds (1559), fruits or berries (115), roots or rhizomes (234) and bark, buds and arils (40). The LOQ was 0.1 mg/kg for the data from the American Spice Trade Association and India and 0.05 mg/kg for those from Egypt and Europe.

The residue levels in spices from fruits and from bark, buds and arils were below the LOQ (0.1 mg/kg).

Detectable residues were found in 69 of 667 samples of anise, at levels, in ranked order, of: 0.05, 0.06 (four), 0.07, 0.08 (two), 0.09 (three), 0.1 (two), 0.11, 0.12 (two), 0.13, 0.14 (four), 0.15 (three), 0.16 (two), 0.17 (four), 0.18 (two), 0.19 (three), 0.21, 0.22, 0.24, 0.28, 0.3, 0.32 (two), 0.33 (two), 0.35, 0.37, 0.39, 0.41, 0.42 (two), 0.47, 0.473, 0.48, 0.51, 0.59, 0.6, 0.82, 0.88, 0.9, 1.1 (two), 1.2, 1.3, 1.8 (two), 2.1, 2.7, 3.5 and 3.6 mg/kg. Detectable residues were found in 31 of 734 samples of fennel seed, at levels, in ranked order, of: 0.05 (two), 0.06 (three), 0.07 (three), 0.08 (two), 0.1 (three), 0.12, 0.17 (two), 0.19, 0.2, 0.21, 0.23, 0.24 (two), 0.26, 0.45, 0.59, 0.65, 0.72, 0.76, 0.77, 1.2 and 1.7 mg/kg. Detectable residues were measured in celery and cumin seeds at levels of 0.1 (two), 0.14 and 0.29 mg/kg.

The Meeting estimated a maximum residue level of 5 mg/kg, a high residue level of 3.6 mg/kg and a median residue level (on the basis of data on anise seed) of 0.19 mg/kg for the seed subgroup.

Detectable residues were measured in two samples of turmeric, at levels of 0.23 and 0.26 mg/kg. No residues were measured in fruit and rhizome spices.

The Meeting estimated a maximum residue level of 0.5 mg/kg, a high residue level of 0.26 mg/kg and a median residue level of 0.05 mg/kg for the roots or rhizomes subgroup of spices, and a maximum residue level of 0.1 (\*) mg/kg, a high residue level of 0.1 mg/kg and a median residue level of 0.05 mg/kg for fruits. No recommendation could be made for the bark, buds and arils subgroups.

The Meeting recommended use of a high residue level of 3.6 mg/kg for calculating short-term intake, and a median residue level of 0.19 mg/kg and a factor of 0.1 to take into account the proportion of samples containing detectable residues in calculating long-term intake.

#### *Dichlorvos*

The 277 samples analysed comprised seeds (100), fruits or berries (93), roots or rhizomes (48) and bark, buds and arils (36).

The residue levels in all samples were below the LOQ (0.1 mg/kg). The Meeting estimated a maximum residue level of 0.1 (\*) mg/kg and high and median residue levels of 0.1 mg/kg for residues of dichlorvos on all spices.

As none of the samples contained detectable residues, no factor can be used in long-term intake calculations to take into account the proportion of samples containing detectable residues.

*Dicofol*

The 416 samples analysed comprised seeds (67), fruits or berries (85), roots or rhizomes (230) and bark, buds and arils (34). The LOQ was 0.05 mg/kg for all data sources.

No residues were detected in the seeds subgroup. One of 42 pepper samples contained residue at the LOQ.

Detectable residues were found in ginger and turmeric in the roots subgroup, at levels, in ranked order, of: 0.02, 0.035, 0.036 and 0.05 mg/kg.

The Meeting estimated a maximum residue level of 0.05 (\*) mg/kg and high and median residue levels of 0.05 mg/kg for the seed subgroup, and a maximum residue level of 0.1 mg/kg and high and median residue levels of 0.05 mg/kg for the fruit, rhizomes and roots subgroups.

Four samples of spices in the bark, buds and arils subgroups contained residues at the LOQ (0.05 mg/kg). The data did not allow estimation of maximum residue levels for these subgroups.

The Meeting recommended use of a high residue level of 0.05 mg/kg for calculating short-term intake, and a median residue level of 0.05 mg/kg and a factor of 0.03 to take into account the proportion of samples containing detectable residues in calculating long-term intake.

*Dimethoate*

The 2613 samples analysed comprised seeds (2121), fruits or berries (381), roots or rhizomes (75) and bark, buds and arils (36).

Detectable residues were found in 61 of 744 samples of anise seeds at levels, in ranked order, of: 0.05 (three), 0.06 (five), 0.07 (three), 0.08 (two), 0.09 (two), 0.1 (two), 0.12 (three), 0.13 (three), 0.14, 0.15 (five), 0.17 (two), 0.18, 0.24 (two), 0.25 (four), 0.27 (two), 0.28 (two), 0.29, 0.29, 0.32, 0.35, 0.36, 0.39, 0.41, 0.42, 0.43, 0.44, 0.46, 0.53 (two), 0.57, 0.62, 0.9, 1.4, 2.5 and 3 mg/kg.

Detectable residues were found in 69 of 1284 samples of fennel at levels, in ranked order, of: 0.03, 0.05 (four), 0.06 (four), 0.07 (six), 0.08 (four), 0.09 (four), 0.1 (three), 0.11, 0.12, 0.13, 0.14 (three), 0.15 (four), 0.16, 0.18 (two), 0.2 (two), 0.21, 0.25 (two), 0.3, 0.32 (three), 0.33 (two), 0.34, 0.35, 0.37, 0.38 (two), 0.43 (two), 0.51 (four), 0.53 (two), 0.54, 0.94, 1.1 and 1.4 (two) mg/kg. Residues were not detected in the other seed samples (0.05–0.1 mg/kg).

The Meeting estimated a maximum residue level of 5 mg/kg, a high residue level of 3 mg/kg and a median residue level of 0.17 mg/kg (on the basis of data on anise seed) for the seeds subgroup.

Five of 277 samples of caraway samples from Egypt contained residues, at levels of: 0.08, 0.17 (two) and 0.22 (two) mg/kg.

The Meeting estimated a maximum residue level of 0.5 mg/kg, a high residue level of 0.22 mg/kg and a median residue level of 0.05 mg/kg for the fruits subgroup.

No residue was detected in 75 samples of root and rhizome spices. The Meeting estimated a maximum residue level of 0.1 (\*) mg/kg and high and median residue levels of 0.1 mg/kg for the roots and rhizomes subgroup.

No limits could be estimated for the bark, buds and arils subgroups.

The Meeting recommended use of a high residue level of 3 mg/kg for calculating short-term intake, and a median residue level of 0.17 mg/kg and a factor of 0.08 to take into account the proportion of samples containing detectable residues in calculating long-term intake.

*Disulfoton*

The 223 samples analysed comprised seeds (67), fruits or berries (66), roots or rhizomes (69) and bark, buds and arils (21).

As all the residue levels were below the LOQ (0.05 mg/kg), the Meeting estimated a maximum residue level of 0.05 (\*) mg/kg and high and median residue levels of 0.05 mg/kg for disulfoton on spices. As none of the samples contained detectable residues, no factor could be used in calculating long-term intake to take into account the proportion of samples containing detectable residues.

*Endosulfan*

The 981 samples analysed comprised seeds (331), fruits or berries (208), roots or rhizomes (401) and bark, buds and arils (41). The LOQ was 0.03 mg/kg for the trials reported by the American Spice Trade Association and India and 0.1 mg/kg for data from Europe.

Data were provided for  $\alpha$ -endosulfan,  $\beta$ -endosulfan, endosulfan sulfate, as well as for total endosulfan residues. The maximum residue levels were estimated on the basis of the results of monitoring for total endosulfan residues.

In the seeds subgroup, detectable residues were measured in celery seed, coriander and dill seed, at levels in ranked order of: 0.035 (two), 0.04, 0.1 (11), 0.12, 0.14, 0.20, 0.34, 0.45 and 0.63 mg/kg.

The Meeting estimated a maximum residue level of 1 mg/kg, a high residue level of 0.63 mg/kg and a median residue level of 0.03 mg/kg for the seeds subgroup of spices.

In the fruits subgroup, detectable residues were measured in cardamom and pepper, at levels in ranked order of: 0.03, 0.04, 0.075, 0.08, 0.09 (four), 0.10, 0.11, 0.12 (three), 3.1 and 3.2 mg/kg.

The Meeting estimated a maximum residue level of 5 mg/kg, a high residue level of 3.2 mg/kg and a median residue level of 0.12 mg/kg (on the basis of data for pepper) for the fruits subgroup of spices.

In the subgroup of roots or rhizomes, detectable residues were measured in ginger and turmeric at levels, in ranked order, of: 0.04 (two), 0.06, 0.08, 0.1 and 0.24 mg/kg.

The Meeting estimated a maximum residue level of 0.5 mg/kg, a high residue level of 0.24 mg/kg and a median residue level of 0.1 mg/kg for the subgroup roots or rhizomes.

The 41 samples in the bark, buds and arils subgroups did not contain detectable residues (< 0.1 mg/kg).

The Meeting recommended use of a high residue level of 3.2 mg/kg for calculating short-term intake, and a median residue level of 0.12 mg/kg and a factor of 0.05 to take into account the proportion of samples containing detectable residues in calculating long-term intake.

*Ethion*

The 754 analysed comprised seeds (190), fruits or berries (155), roots or rhizomes (367) and bark, buds and arils (42). The LOQ was 0.1 mg/kg for data from the American Spice Trade Association and India and 0.05 mg/kg for data from the European Spice Association.

In the seeds subgroup, detectable residues were measured in anise, coriander and cumin at levels, in ranked order, of 0.11, 0.13, 0.21 and 1.8 mg/kg.

The Meeting estimated a maximum residue level of 3 mg/kg, a high residue level of 1.8 mg/kg and a median residue level of 0.1 mg/kg for the seeds subgroup of spices.

In the fruits subgroup, detectable residues were measured in cardamom and pepper (black, white and pink) at levels, in ranked order, of 0.12, 0.33 and 3.1 mg/kg.

The Meeting estimated a maximum residue level of 5 mg/kg, a high residue level of 3.1 mg/kg and a median residue level of 1.7 mg/kg (on the basis of data on pepper) for the fruits subgroup of spices.

In the subgroup of roots or rhizomes, detectable residues were measured in ginger, at levels of 0.11 and 0.15 mg/kg.

The Meeting estimated a maximum residue level of 0.3 mg/kg, a high residue level of 0.15 mg/kg and a median residue level of 0.05 mg/kg for the roots or rhizomes subgroup of spices.

The 42 samples in the bark, buds and arils subgroups did not contain detectable residues ( $< 0.05$ – $< 0.1$  mg/kg)

The Meeting recommended use of a high residue level of 3.1 mg/kg for calculating short-term intake, and a median residue level of 1.7 mg/kg and a factor of 0.02 to take into account the proportion of samples containing detectable residues in calculating long-term intake.

### *Fenitrothion*

The 2424 samples analysed comprised seeds (1920), fruits or berries (230), roots or rhizomes (234) and bark, buds and arils (40). The limit of determination was 0.1 mg/kg for data from the American Spice Trade Association and India, and 0.05 mg/kg for data from Egypt and the European Spice Association.

Detectable residues were found in 22 of 756 samples of anise seeds in Egypt, at levels of: 0.05, 0.08 (two), 0.1, 0.12 (two), 0.13, 0.15, 0.25, 0.4 (two), 0.41 (two), 0.87, 0.88, 1 (three), 1.4 (two), 2 and 5.4 mg/kg. No residues were detected in 18 samples from other sources ( $< 0.1$  mg/kg). Detectable residues were measured in celery seed, cumin and coriander at levels of 0.17, 0.19 and 1.5 mg/kg, respectively.

The Meeting estimated a maximum residue level of 7 mg/kg, a high residue level of 5.4 mg/kg and a median residue level of 0.4 mg/kg (on the basis of data for anise seed) for the seed subgroup of spices.

Detectable residues were measured in caraway in the fruit subgroup, at levels of: 0.05, 0.1, 0.12, 0.22 and 0.4 mg/kg.

The Meeting estimated a maximum residue level of 1 mg/kg, a high residue level of 0.4 mg/kg and a median residue level of 0.05 mg/kg for the fruit subgroup of spices.

All the samples in the root subgroup of spices contained residues at levels below the LOQ. The Meeting estimated a maximum residue level of 0.1 (\*) mg/kg, a high residue level of 0.1 mg/kg and a median residue level of 0.05 mg/kg for the root subgroup of spices.

All samples in the bark, buds and arils subgroups contained residues at levels below the LOQ. The database did not allow estimation of a maximum residue level.

The Meeting recommended use of a high residue level of 5.4 mg/kg for calculating short-term intake, and a median residue level of 0.4 mg/kg and a factor of 0.03 to take into account the proportion of samples containing detectable residues in calculating long-term intake.

### *Iprodion*

The 339 samples analysed comprised seeds (93), fruits or berries (38), roots or rhizomes (192) and bark, buds and arils (16). The LOQ was 0.05 mg/kg in all the data sources.

No residues were detectable in seeds. The Meeting estimated a maximum residue level of 0.05 (\*) mg/kg and high and median residue levels of 0.05 mg/kg for the seed subgroup of spices.

One of 92 samples of ginger contained residue at the LOQ level (0.05 mg/kg). The Meeting estimated a maximum residue level of 0.1 mg/kg and high and median residue levels of 0.05 mg/kg for the root subgroup of spices.

Detectable residues were also found in the other subgroups, but the database was insufficient for estimating maximum residue levels.

The Meeting recommended use of a high residue level of 0.05 mg/kg for calculating short-term intake, and a median residue level of 0.05 mg/kg and a factor of 0.01 to take into account the proportion of samples containing detectable residues in calculating long-term intake.

### *Malathion*

The total number of samples analysed (581) included seeds (185), fruits or berries (115), roots or rhizomes (234) and bark, buds and arils (47). The limit of determination was 0.1 mg/kg for data from American Spice Trade Association and India, and 0.05 mg/kg for data from Egypt and the European Spice Association.

In the seed subgroup, detectable residues were measured in anise, celery seed, cumin, fennel seed and nutmeg. The levels, in ranked order, were: 0.16 (four), 0.18, 0.22, 0.32, 0.38, 0.48, 0.58 and 0.86 mg/kg. As the data from Egypt indicated post-harvest use, they were not taken into consideration.

The Meeting estimated a maximum residue level of 2 mg/kg, a high residue level of 0.86 mg/kg and a median residue level of 0.48 mg/kg (on the basis of data on celery seed) for the seed subgroup of spices.

In the fruit subgroup, detectable residues were measured in three of 66 samples of pepper, at levels of 0.1, 0.42 and 0.48 mg/kg, and in 17 of 307 samples of caraway at levels of: 0.1, 0.3, 0.05 (two), 0.06 (two), 0.07 (four), 0.09 (two), 0.19, 0.26, 0.31, 0.33 and 0.46 mg/kg. The combined residue levels, in ranked order, were: 0.1, 0.3, 0.05 (two), 0.06 (two), 0.07 (four), 0.09 (two), 0.1, 0.19, 0.26, 0.31, 0.33, 0.42, 0.46 and 0.48 mg/kg.

The Meeting estimated a maximum residue level of 1 mg/kg, a high residue level of 0.48 mg/kg and a median residue level of 0.05 mg/kg for the fruit subgroup of spices.

In the subgroup of roots or rhizomes, detectable residues were measured in ginger and turmeric, at levels of 0.1, 0.12 and 0.16 mg/kg.

The Meeting estimated a maximum residue level of 0.5 mg/kg, a high residue level of 0.16 mg/kg and a median residue level of 0.05 mg/kg for the root or rhizome subgroup of spices.

The ranked order of the detectable residue levels in 47 samples from the bark, buds and arils subgroups was: 0.1 (four), 0.12, 0.14, 0.3, 0.48, 0.96, 1.02, 1.04, 1.88, 1.96 and 2 mg/kg.

The Meeting considered that the database was insufficient for estimating maximum residue levels.

The Meeting recommended use of a high residue level of 0.86 mg/kg for calculating short-term intake, and a median residue level of 0.48 mg/kg and a factor of 0.06 to take into account the proportion of samples containing detectable residues in calculating long-term intake.

### *Metalaxyl*

The 1306 samples analysed in Egypt comprised anise seeds (411) and fennel seeds (895). The LOQ was 0.05 mg/kg.

Six of 411 samples of anise seeds contained detectable residues, at levels of: 0.2, 0.22, 0.4, 0.47, 0.64 and 0.65 mg/kg. Four of 895 samples of fennel contained detectable residues, at levels of: 0.17, 0.29, 0.4 and

3.2 mg/kg. The combined residue levels, in ranked order, were: 0.17, 0.2, 0.22, 0.29, 0.4 (two), 0.47, 0.64, 0.65 and 3.2 mg/kg.

The Meeting estimated a maximum residue level of 5 mg/kg, a high residue level of 3.2 mg/kg and a median residue level of 0.43 mg/kg for the seed subgroup of spices.

For calculation of long-term intake, the Meeting recommended use of a correction factor of 0.015 to take into account the proportion of samples containing detectable residues.

#### *Methamidophos*

The 260 samples analysed comprised seeds (96), fruits or berries (92), roots or rhizomes (46) and bark, buds and arils (36). All the residue levels were below the limit of determination (0.1mg/kg for data from the American Spice Trade Association and India and 0.01 mg/kg for data from the European Spice Association). The data on cumin from Egypt, which indicated post-harvest use, were not taken into consideration.

The Meeting estimated a maximum residue level of 0.1 (\*) mg/kg, a high residue level of 0.1 mg/kg and a median residue level of 0.01 mg/kg for spices.

#### *Mevinphos*

The 554 samples analysed comprised seeds (158), fruits or berries (114), roots or rhizomes (232) and bark, buds and arils (40). The LOQ was 0.2 mg/kg for data from the American Spice Trade Association and India, and 0.05 mg/kg for data from the European Spice Association.

In the seed subgroup, detectable residues were measured in celery seed at 2.9 mg/kg. The Meeting estimated a maximum residue level of 5 mg/kg, a high residue level of 2.9 mg/kg and a median residue level of 0.05 mg/kg (on the basis of data on celery seed) for the seed subgroup of spices.

In the fruit subgroup, no detectable residues were measured. The Meeting estimated a maximum residue level of 0.2 (\*) mg/kg, a high residue level of 0.2 mg/kg and a median residue level of 0.05 mg/kg for the fruit subgroup of spices.

In the subgroup of roots or rhizomes, detectable residues were measured in ginger and turmeric. The levels, in ranked order, were: 0.2, 0.21, 0.22, 0.24, 0.27, 0.3, 0.31, 0.34, 0.37, 0.39, 0.4, 0.41 and 0.47 mg/kg. The Meeting estimated a maximum residue level of 1 mg/kg, a high residue level of 0.47 mg/kg and a median residue level of 0.31 mg/kg for the root or rhizome subgroup of spices.

The 40 samples from bark, buds and arils did not contain detectable residues (< 0.2 mg/kg). The database did not allow estimation of maximum residue levels.

The Meeting recommended use of a high residue level of 2.9 mg/kg for calculating short-term intake, and a median residue level of 0.05 mg/kg and a factor of 0.02 to take into account the proportion of samples containing detectable residues in calculating long-term intake.

#### *Parathion*

The 329 samples analysed comprised seeds (114), fruits or berries (105), roots or rhizomes (74) and bark, buds and arils (36). The LOQ was 0.1 mg/kg for all data sources.

Seed spices did not contain detectable residues. The Meeting estimated a maximum residue level of 0.1 (\*) mg/kg and high and median residue levels of 0.1 mg/kg for the seed subgroup of spices.



One sample of pepper and one sample in the root and rhizome subgroup contained residues at the LOQ. The Meeting estimated a maximum residue level of 0.2 mg/kg and high and median residue levels of 0.1 mg/kg for the fruit and the root and rhizome subgroups of spices.

Three samples in the bark subgroup contained residues at the LOQ, indicating that detectable residues might occur in these commodities. The database was insufficient for estimating maximum residue levels.

The Meeting recommended use of a high residue level of 0.1 mg/kg for calculating short-term intake, and a median residue level of 0.1 mg/kg and a factor of 1 to take into account the proportion of samples containing detectable residues in calculating long-term intake.

#### *Parathion-methyl*

The 821 samples analysed comprised seeds (359), fruits or berries (155), roots or rhizomes (265) and bark, buds and arils (42). The LOQ was 0.1 mg/kg for data from the American Spice Trade Association and India and 0.05 mg/kg for data from Egypt and the European Spice Association.

In the seed subgroup, detectable residues were measured in anise, celery seed, coriander, cumin and fennel seed. The levels, in ranked order, were: 0.1, 0.13, 0.14, 0.16, 0.2, 0.21, 0.23, 0.24 (two), 0.31, 0.33, 0.36, 0.37, 0.38, 0.43, 0.51, 0.86, 0.97, 1.1, 1.2 and 2.4 (two) mg/kg.

The Meeting estimated a maximum residue level of 5 mg/kg, a high residue level of 2.4 mg/kg and a median residue levels of 0.43 mg/kg (on the basis of data on cumin seed) for the seed subgroup of spices.

In the fruit subgroup, detectable residues were measured in pepper at levels of 0.1 and 3.4 mg/kg.

The Meeting estimated a maximum residue level of 5 mg/kg, a high residue level of 3.4 mg/kg and a median residue level of 0.1 mg/kg for the fruit subgroup of spices.

In the subgroup of roots or rhizomes, detectable residues were measured in ginger and turmeric. The levels, in ranked order, were: 0.1, 0.13, 0.14 (two), 0.17, 0.24, 0.3, 1.2 (two), 1.5 and 1.7 mg/kg.

The Meeting estimated a maximum residue level of 3 mg/kg, a high residue level of 1.7 mg/kg and a median residue level of 0.24 mg/kg for the root or rhizome subgroup of spices.

Three of the 42 samples from the bark, buds and arils subgroups contain detectable residues at the LOQ (< 0.1 mg/kg). The database did not allow estimation of maximum residue levels.

The Meeting recommended use of a high residue level of 3.4 mg/kg for calculating short-term intake, and a median residue level of 0.43 mg/kg and a factor of 0.25 to take into account the proportion of samples containing detectable residues in calculating long-term intake.

#### *Permethrin*

A total of 160 samples of various spices, including 68 seeds, were analysed for residues of permethrin. No residues were detected. The Meeting estimated a maximum residue level of 0.05 (\*) mg/kg and high and median residue levels of 0.05 mg/kg.

As none of the samples contained detectable residues, no factor can be used in calculating long-term intake to take into account the proportion of samples containing detectable residues.

#### *Phenthoate*

Ten of 415 samples of anise seed contained detectable residues, at levels of: 0.05, 0.19, 0.49, 1.1 (two), 1.3, 1.4 (two), 5 and 5.2. The LOQ was 0.05 mg/kg.

The Meeting estimated a maximum residue level of 7 mg/kg, a high residue level of 5.2 mg/kg and a median residue level of 1.2 mg/kg for the seed subgroup of spices.

For the calculation of long-term intake, the Meeting recommended use of a correction factor of 0.024 to take into account the proportion of samples containing detectable residues.

#### *Phorate*

The 336 samples analysed comprised seeds (115), fruits or berries (117), roots or rhizomes (75) and bark, buds and arils (29). The LOQ was 0.1 mg/kg for data from the American Spice Trade Association and India, and 0.05 mg/kg for data from the European Spice Association.

Of the samples analysed, only two of cumin showed detectable residues of phorate, at 0.12 and 0.3 mg/kg.

The Meeting estimated a maximum residue level of 0.5 mg/kg, a high residue level of 0.3 mg/kg and a median residue level of 0.21 mg/kg for the seed subgroup of spices, and a maximum residue level of 0.1 (\*) mg/kg and high and median residue levels of 0.1 mg/kg for the fruit and the root and rhizome subgroups. The data were insufficient for estimating maximum residue levels for the other subgroups.

The Meeting recommended use of a high residue level of 0.3 mg/kg for calculating short-term intake, and a median residue level of 0.21 mg/kg and a factor of 0.06 to take into account the proportion of samples containing detectable residues in calculating long-term intake.

#### *Phosalone*

The 607 samples analysed comprised seeds (176), fruits or berries (80), roots or rhizomes (226) and bark, buds and arils (25). The origin of the samples was not given in several cases. The LOQ was 0.05 mg/kg for all data sources.

Samples of anise, celery and cumin contained detectable residues at levels of 0.1, 0.95 and 0.25 mg/kg, respectively.

The Meeting estimated a maximum residue level of 2 mg/kg, a high residue level of 0.95 mg/kg and a median residue level of 0.25 mg/kg for the seed subgroup of spices.

Three of 44 samples of pepper contained detectable residues, at levels of 0.05, 0.85 and 0.89 mg/kg.

The Meeting estimated a maximum residue level of 2 mg/kg, a high residue level of 0.89 mg/kg and a median residue level of 0.85 mg/kg for the fruit subgroup of spices.

Detectable residues were found in ginger and turmeric in the root subgroup. The levels, in ranked order, were: 0.05, 0.14, 0.22, 0.27, 0.31, 0.4, 0.49, 0.5 and 1.49 mg/kg.

The Meeting estimated a maximum residue level of 3 mg/kg, a high residue level of 1.49 mg/kg and a median residue level of 0.31 mg/kg for the root and rhizome subgroup.

Residues were also detected in spices in the bark, buds and arils subgroups. The data available were, however, insufficient to allow estimation of maximum residue levels.

The Meeting recommended use of a high residue level of 1.5 mg/kg for calculating short-term intake, and a median residue level of 0.85 mg/kg and a factor of 0.07 to take into account the proportion of samples containing detectable residues in calculating long-term intake.

*Pirimicarb*

In Egypt, 129 of 484 samples of anise seed and 54 of 824 samples of fennel seed contained detectable residues, at levels of: 0.05 (11), 0.06 (22), 0.07 (nine), 0.08 (nine), 0.09 (14), 0.1 (11), 0.12 (six), 0.13 (seven), 0.14 (eight), 0.15 (seven), 0.16 (six), 0.17 (four), 0.18 (three), 0.19 (two), 0.2 (three), 0.22 (five), 0.23, 0.24, 0.26, 0.27 (three), 0.28 (four), 0.29 (two), 0.31, 0.33 (three), 0.34 (two), 0.35, 0.37 (two), 0.38, 0.39, 0.41, 0.42 (two), 0.43, 0.44, 0.45, 0.47 (two), 0.53 (two), 0.54 (two), 0.58 (two), 0.59 (two), 0.6 (two), 0.64, 0.67, 0.69, 0.7 (two), 0.8, 0.84, 0.93, 0.94, 1.2, 1.4 (two), 1.5 and 3 mg/kg. The LOQ was 0.05 mg/kg.

The Meeting estimated a maximum residue level of 5 mg/kg, a high residue level of 3 mg/kg and a median residue level of 0.14 mg/kg for the seed subgroup of spices.

For the calculation of long-term intake, the Meeting recommended use of a correction factor of 0.27 to take into account the proportion of samples containing detectable residues.

*Pirimiphos-methyl*

The 1314 samples analysed comprised seeds (1137), fruits or berries (94), roots or rhizomes (47) and bark, buds and arils (36). The LOQ was 0.1 mg/kg for data from the American Spice Trade Association and India and 0.05 mg/kg for those from Egypt and Europe.

In the seed subgroup, detectable residues were measured in 16 of 492 samples of anise, at levels of: 0.05, 0.06, 0.07, 0.08, 0.12, 0.17, 0.18, 0.19, 0.27, 0.32, 0.47, 0.58, 0.6, 0.61, 0.63 and 1.8 mg/kg; in five of 556 samples of fennel, at levels of: 0.05, 0.07, 0.08, 0.1 and 0.11 mg/kg) and in one sample of nutmeg at 0.1 mg/kg.

The Meeting estimated a maximum residue level of 3 mg/kg, a high residue level of 1.8 mg/kg and a median residue level of 0.23 mg/kg (on the basis of data for anise) for the seed subgroup of spices.

In the fruit subgroup, detectable residues were measured at the LOQ in cardamon (0.18 mg/kg) and pepper (0.1 mg/kg, two samples).

The Meeting estimated a maximum residue level of 0.5 mg/kg and high and median residue levels of 0.1 mg/kg for the fruit subgroup of spices.

Residues were also detected at the LOQ in one sample in the root subgroup and in the bark, buds and arils subgroups. The data were insufficient for estimation of maximum residue levels.

The Meeting recommended use of a high residue level of 1.8 mg/kg for calculating short-term intake, and a median residue level of 0.23 mg/kg and a factor of 0.03 to take into account the proportion of samples containing detectable residues in calculating long-term intake.

*Quintozene*

The 550 samples analysed comprised seeds (163), fruits or berries (111), roots or rhizomes (236) and bark, buds and arils (40). The LOQ was 0.01 mg/kg for all data sources.

In the seed subgroup, detectable residues were measured in coriander, cumin, and fennel seed. The levels, in ranked order, were: 0.01 (two), 0.02 (two) and 0.05 mg/kg.

The Meeting estimated a maximum residue level of 0.1 mg/kg, a high residue level of 0.05 mg/kg and a median residue level of 0.01 mg/kg for the seed subgroup of spices.

In the fruit subgroup, detectable residues were measured at the LOQ in one sample of pepper and one of vanilla.

The Meeting estimated a maximum residue level of 0.02 mg/kg and high and median residue levels of 0.01 mg/kg for the fruit subgroup of spices.

In the subgroup of roots or rhizomes, detectable residues were measured in ginger and turmeric. The levels, in ranked order, were: 0.01, 0.04, 0.05 (two), 0.08 and 1.2 mg/kg.

The Meeting estimated a maximum residue level of 2 mg/kg, a high residue level of 1.2 mg/kg and a median residue level of 0.05 mg/kg (on the basis of data on turmeric) for the root and rhizome subgroup of spices.

In the subgroup of bark, buds and arils, detectable residues were measured at the LOQ in cloves, cassia and cinnamon.

The database was insufficient for estimation of maximum residue levels.

The Meeting recommended use of a high residue level of 1.2 mg/kg for calculating short-term intake, and a median residue level of 0.05 mg/kg and a factor of 0.035 to take into account the proportion of samples containing detectable residues in calculating long-term intake.

### *Vinclozolin*

The 442 samples analysed comprised seeds (110), fruits or berries (80), roots or rhizomes (227) and bark, buds and arils (25). The LOQ was 0.05 mg/kg for all data sources.

None of the sample contained detectable residues.

The Meeting estimated a maximum residue level of 0.05 (\*) mg/kg and high and median residue levels of 0.05 mg/kg for spices.

As none of the samples contained detectable residues, no factor can be used in calculating long-term intakes to take into account the proportion of samples containing detectable residues.

### *Other pesticides*

The results of monitoring were submitted for aldicarb, amitraz, bendiocarb, bifenthrin, captan, carbaryl, carbofuran, chlorothalonil, chlorpropham, cyfluthrin, demeton, dicloran, dicrotophos, diphenylamine, esfenvalerate, ethoprop, ethoxyquin, fenamiphos, fenarimol, fenpropathrin, fenthion, fenvalerate, folpet, imazalil, isophenphos, methoicarb, methomyl, myclobutanil, monocrotophos, *ortho*-phenylphenol, oxamyl, phosmet, phosphamidon, propiconazole, propoxur, pyrethrins, terbufos, thiabendazole, triadimefon, trichlorfon and triforin. The amount of data on residues did not, however, meet the minimum requirements for estimating maximum residue levels.

### ***Estimation of maximum residue levels for pesticide residues in and on dry chili peppers***

The database of the US Department of Agriculture indicates that the water content of various fresh peppers ranges from 88% to 94%. The average dehydration factor, derived on the basis of the assumption of complete loss of water, is 11.6. A similar approximate value (11.3) can be obtained by taking into account the water content of dried peppers. As dried peppers always contain 5–10% water, the rounded value of 10 used by the spice trade industry can be considered realistic for estimating the concentration of pesticide residues when it is assumed that all the residues present in fresh peppers remain in the dried peppers. As no processing studies were available, in accord with the request of the CCPR, the Meeting used the default value of 10 for estimating maximum residue levels for pesticide residues in dried chili peppers.

***Further work or information***

Before maximum residue levels can be estimated, additional data are required on residues in subgroups of spices for which insufficient data were available for evaluation by the present Meeting.

**DIETARY RISK ASSESSMENT**

The Meeting evaluated data on residues of 28 pesticides based on monitoring and estimated maximum residue levels for 47 pesticides in or on dried chili peppers on the basis of MRLs established for fresh sweet and chili peppers. The intakes of the pesticides from spices and chili were compared to existing ADI and ARfD values only; intakes arising from other uses of the compounds were not considered.

Details of the intake estimations are given in Annex 5 to this report.

**4.28 SPINOSAD (203)****RESIDUE AND ANALYTICAL ASPECTS**

Spinosad was first evaluated by the 2001 JMPR, which established an ADI of 0–0.02 mg/kg bw. An ARfD was judged to be unnecessary. MRLs were recommended for fruits, vegetables, nuts, oil seeds, cereal grains, animal feeds and animal commodities. Questions about the MRL for milk were raised by the CCPR at its Thirty-fifth and Thirty-sixth Sessions, and the JMPR was requested to consider further how MRLs for milk and milk fat should be expressed.

The Meeting received information on registered uses and data from supervised residue trials on grapes and stored grain. Information on direct uses of spinosad on sheep for control of blowfly and lice and supporting residue data were also received.

***Methods of analysis***

An immunoassay method previously evaluated by the 2001 JMPR was used in the supervised trials on grapes.

The analytical method used for analysis of spinosad residues in cereal grains and processed products was based on previously evaluated methods. Samples were extracted with acetonitrile and water and the extracts cleaned up on a strong cation-exchange column. Spinosyns A, D, K, B and *N*-demethyl D were eluted with dilute ammonium acetate in acetonitrile and methanol, ready for analysis by HPLC with mass selective detection. The LOQ was 0.01 mg/kg.

The analytical methods used for fat, muscle, liver, kidney and bovine milk were similar in principle to the above method, but with variations in clean-up depending on the substrate. The LOQ for milk was 0.005 mg/kg, and that for the other substrates was 0.01 mg/kg.

***Results of supervised trials on crops******Grape***

The Meeting received the results of supervised trials for use of spinosad on grapes in the USA. The samples were analysed by immunoassay method GRM 96.11, which was evaluated by the JMPR previously.

In the USA, spinosad may be applied to grapes at 0.14 kg ai/ha with a maximum seasonal application of 0.49 kg ai/ha and harvesting 7 days after the final application. In 12 trials in the USA that conformed

substantially to the registered use, the residue levels were: < 0.01, 0.02, 0.03, 0.05, 0.077, 0.082, 0.086, 0.13, 0.17, 0.22, 0.23 and 0.39 mg/kg.

The residue levels of spinosad in grapes in supervised trials in France, Italy and Spain are recorded in Table 39 (p. 761) of the JMPR Residue Evaluations for 2001. Spinosad may be used on grapes in Cyprus at 0.072 kg ai/ha with a PHI of 7 days. The conditions used in trials in France, Italy and Spain, where the application rate was 0.060 kg with a PHI of 5 days, were considered sufficiently similar to those of Cyprus GAP. The residue levels, determined by an HPLC method, in grapes in two trials in France (0.01 and 0.03 mg/kg), one trial in Italy (0.09 mg/kg) and one trial in Spain (0.19 mg/kg) were, in ranked order: 0.01, 0.03, 0.09 and 0.19 mg/kg. The levels in the same samples determined by the immunoassay method were: 0.02, 0.04, 0.15 and 0.24 mg/kg.

The Meeting combined the data from Europe and the USA obtained by the immunoassay method. The residue levels in the 16 trials, in ranked order, median underlined, were: < 0.01, 0.02 (two), 0.03, 0.04, 0.05, 0.077, 0.082, 0.086, 0.13, 0.15, 0.17, 0.22, 0.23, 0.24 and 0.39 mg/kg.

The Meeting estimated a maximum residue level of 0.5 mg/kg and an STMR value for spinosad in grapes of 0.084 mg/kg.

### ***Fate of residues during storage***

In a series of trials with cereal grain (barley, maize, oats, rice and wheat) in the USA, spinosad was applied to grain at a target rate of 1 g ai/t. Most of the trials were small-scale, only 18–23 kg grain being treated; in two larger trials, 9.9 t of maize and 30.9 t of wheat were treated. The duration of storage was 3–11 months at ambient temperatures. Samples were analysed by HPLC with mass spectrometry detection.

The residue levels in grain immediately after treatment represented 43–91% of the target application rate, reflecting the efficiency of application in the experiments. In the two larger trials, the initial residue levels were 77% and 87% of the target rates. The residue levels declined very slowly, if at all. The highest residue level in each trial was taken, whether at day 0 or after 11 months' storage. The trial in which a dose rate of 1.6 g ai/t was used was excluded as being outside GAP. The residue levels in the 20 trials were: 0.43, 0.45, 0.47, 0.58, 0.59, 0.63, 0.67, 0.69 (three), 0.70, 0.75, 0.79, 0.81, 0.86, 0.90, 0.91 (two), 0.93 and 0.95 mg/kg.

In three further trials in the USA in which wheat in storage batches of 135–225 t was treated at 1 g ai/t for storage and processing, the spinosad residue levels after 6 months' storage were 0.52, 0.73 and 0.79 mg/kg.

The residue levels in the 23 trials, in ranked order, were: 0.43, 0.45, 0.47, 0.52, 0.58, 0.59, 0.63, 0.67, 0.69 (three), 0.70, 0.73, 0.75, 0.79 (two), 0.81, 0.86, 0.90, 0.91 (two), 0.93 and 0.95 mg/kg.

The Meeting estimated a maximum residue level of 1 mg/kg and an STMR for spinosad on cereal grains of 0.70 mg/kg on the basis of post-harvest use. The Meeting withdrew its previous recommendations for maize (0.01\* mg/kg) and sorghum (1 mg/kg), to be replaced by the recommendation for cereal grains.

### ***Fate of residues during processing***

Three trials in France and one in Italy on processing of grapes to pomace and wine are summarized on pp. 823–824 of the JMPR Residue Evaluations of 2001.

In these trials, the levels of spinosad residues were below the LOQ (0.01 mg/kg) in all wine samples. As the residue levels in grapes were low (< 0.01–0.03 mg/kg), the best estimate of the processing factor for wine is < 0.33. Processing factors of 3.3 and 1.4 for juice and 1.6 for raisins produced from grapes were calculated in two trials in the USA. Juice was produced on a very small scale, with manual crushing, pressing and straining of about 1 kg of grapes, and this was not considered representative of a commercial process.

Processing studies on cereals were provided from the USA, comprising milling of maize (two trials), rice (two trials) and wheat (one trial) and three trials of wheat milling and baking. Spinosad residues were found essentially on the outside of the grain and were strongly concentrated in the aspirated grain fraction from the milling of maize and wheat. The residue levels in grits and flour were much lower than those in the grain. Most of the residues on rice remained with the husk and bran, with little occurring on white rice.

The following processing factors were calculated from the results of the trials. The factors are mean values, excluding those calculated from undetectable results, except for wine in which no residues were detected.

| Commodity | Product          | Processing factor | No. of trials |
|-----------|------------------|-------------------|---------------|
| Grapes    | Wine             | < 0.33            | 4             |
|           | Raisins          | 1.6               | 1             |
| Maize     | Grits            | 0.082             | 2             |
|           | Flour            | 0.19              | 2             |
|           | Oil, dry milling | 0.28              | 2             |
|           | Oil, wet milling | 1.1               | 2             |
|           |                  |                   |               |
| Rice      | Hulls            | 2.8               | 2             |
|           | Bran             | 0.79              | 2             |
|           | Brown rice       | 0.11              | 2             |
|           | White rice       | 0.022             | 2             |
| Wheat     | Bran             | 2.0               | 4             |
|           | Shorts           | 1.2               | 4             |
|           | Flour            | 0.26              | 4             |
|           | Baked bread      | 0.14              | 3             |

The Meeting used the processing factors for wine, raisins and cereals to estimate STMR-Ps for processed commodities.

The processing factor for wine (< 0.33) was applied to the STMR for grape (0.084 mg/kg) to calculate an STMR-P of 0.028 mg/kg for wine.

The processing factor for raisins (1.6) was applied to the highest residue level in grapes (0.39 mg/kg) and the STMR for grape (0.084 mg/kg) to calculate a highest residue level of 0.62 mg/kg and an STMR-P of 0.13 mg/kg for raisins.

The Meeting estimated a maximum residue level of 1 mg/kg and an STMR-P value of 0.13 mg/kg for spinosad on dried grapes (currants, raisins and sultanas).

The processing factors for processed cereal fractions were applied to the STMR for cereal grains (0.70 mg/kg) to calculate the following STMR-P values: grits, 0.057 mg/kg; maize flour, 0.13 mg/kg; maize oil, 0.77 mg/kg; rice hulls, 2.0 mg/kg; rice bran, 0.55 mg/kg; brown rice, 0.077 mg/kg; white rice, 0.015 mg/kg; wheat bran, 1.4 mg/kg; wheat flour, 0.18 mg/kg; and white bread, 0.098 mg/kg.

The processing factor for wheat bran (2.0) was applied to the highest residue level in cereals grain (0.95 mg/kg) to calculate a highest residue level of 1.9 mg/kg for wheat bran.

The Meeting estimated a maximum residue level for spinosad on wheat bran of 2 mg/kg.

## ***Residues in animal commodities***

### *Direct treatment of animals*

The Meeting received information on residue levels occurring in the tissues of sheep treated with spinosad in a plunge dip, by application of a pour-on formulation and by application of an aerosol to fly-strike wounds.

Sheep (25) were treated in a plunge dip containing 20 mg ai/l spinosad prepared from a 25 g/l suspension concentrate in a supervised trial in line with Australian guidelines and registered uses in Australia in 2000. Groups of animals were slaughtered for tissue collection on days 5, 15, 35, 49 and 63 after treatment. Samples were analysed by HPLC-MS after a conventional extraction and clean-up procedure evaluated by the 2001 JMPR. The highest levels of residues of spinosad in tissues 5 or 15 days after treatment were: 0.014 mg/kg in liver, 0.011 mg/kg in kidney, 0.011 mg/kg in muscle, 0.032 mg/kg in back fat and 0.094 mg/kg in peri-renal fat.

Two plunge dip trials on sheep in Australia were reported by the 2001 JMPR (Residue Evaluations, Table 73, pp. 813–814). The dip concentration was 10 mg ai/l. The highest tissue concentrations of spinosad residues were: < 0.01 mg/kg in liver, 0.014 mg/kg in kidney, < 0.01 mg/kg in muscle, 0.033 mg/kg in back fat and 0.042 mg/kg in peri-renal fat.

The data on residues from pour-on trials on sheep could not be evaluated because spinosad pour-on uses on sheep are not registered.

A spinosad aerosol spray is registered in Australia for treating fly-strike wounds on sheep. A typical wound of 200 cm<sup>2</sup> should take 6 s to treat. In a trial of the aerosol formulation in Australia in 2002, 14 sheep with fly-strike lesions measuring 108–1600 cm<sup>2</sup> were treated with spinosad according to the proposed label instructions and were slaughtered 2 and 7 days after treatment for tissue collection. The aerosol product contained 4 mg/g spinosad and 0.8 mg/g chlorhexidine digluconate (The registered product has 2.8 mg/g spinosad and 0.39 mg/g chlorhexidine digluconate.) and was delivered at a rate of 1.54 g of formulation per second. The animals were clipped around the fly-strike area, the area was measured and the dose was calculated at a rate of 1 s of aerosol spray per 40 cm<sup>2</sup> of affected area. The highest residue levels were: 0.04 mg/kg in liver, 0.03 mg/kg in kidney, 0.03 mg/kg in muscle, 0.14 mg/kg in back fat and 0.20 mg/kg in peri-renal fat.

The Meeting noted that the aerosol treatment resulted in higher residue levels in tissues than the plunge dip or the previously evaluated jetting treatment.

The Meeting estimated maximum residue levels for spinosad of 0.3 (fat) mg/kg in sheep meat and 0.1 mg/kg in edible offal of sheep.

### *Maximum residue levels*

Spinosad residues can occur in meat and milk after direct use on animals or from residues in animal feeds.

The 2001 JMPR evaluated a feeding study with dairy cows, compiled a dietary burden for farm animals and estimated maximum residue levels of 2 mg/kg in cattle meat (fat), 0.5 mg/kg in cattle kidney and 0.5 mg/kg in cattle liver. It estimated STMRS of 0.32 mg/kg in cattle fat, 0.010 mg/kg in cattle meat, 0.032 mg/kg in cattle kidney and 0.064 mg/kg in cattle liver. These estimates for cattle commodities were superseded by estimates derived from direct treatment of cattle, which resulted in higher residue levels. The MRL recommendations associated with direct treatment of cattle were: 3 mg/kg (fat) in cattle meat, 1 mg/kg in cattle kidney and 2 mg/kg in cattle liver.



The 2002 JMPR<sup>1</sup> introduced a policy of recommending maximum residue levels for mammalian meat and offal rather than MRLs for cattle meat and offal when residues occurred in feed and a suitable study of cattle feeding was available. In the light of this policy, the Meeting recommended that the 2001 recommendations be reviewed.

The current Meeting proposed maximum residue levels for mammalian meat and offal based on the results of the feeding study in dairy cows and the corresponding dietary burden. None of the recommendations for MRLs by the current Meeting change the previously estimated dietary burden of spinosad residue in cattle. The MRLs for cattle meat, liver and kidney were retained because they are related to direct treatment, which produces higher residue levels than occur from feed. Therefore, the MRLs for mammalian meat and offal should have the qualification 'except cattle'.

The Meeting estimated a maximum residue level of 2 (fat) mg/kg for 'Meat (from mammals other than marine mammals) [except cattle]' and associated STMRs of 0.01 mg/kg for meat and 0.32 mg/kg for fat.

The Meeting estimated a maximum residue level of 0.5 mg/kg for 'Edible offal (mammalian) [except cattle]' and associated STMRs of 0.064 mg/kg for liver and 0.032 mg/kg for kidney.

The Meeting withdrew the current recommendations for sheep meat (0.01\* (fat) mg/kg) and edible offal of sheep (0.01\* mg/kg), which are superseded by the recommendations for mammalian meat and offal. The Meeting also noted that residue levels resulting from direct treatment of sheep by jetting, plunge dipping and aerosol treatment of wounds did not exceed the maximum residue levels resulting from feed residues. There is no separate MRL recommendation for sheep related to these direct uses.

The CCPR expressed concern about the MRL for spinosad in milk, the levels of spinosad in milk fat and how MRLs might best be expressed for partially fat-soluble compounds in milk. (See also general report item 2.7 on fat-soluble pesticide residues in milk.)

The 2001 JMPR reported that, after direct treatment of dairy cows with spinosad, residues were measured in 119 samples of milk and cream and that the mean quotient of the concentration in cream divided by the concentration in milk was 4.2. A plot of the same residue levels in whole milk against those in cream showed that the residue level in milk was approximately 24% of that in cream (line of best fit through the origin). (See figure in section 2.7.)

The levels of spinosad residues in milk and cream from a feeding study in dairy cows are summarized in Table 79 of the JMPR Residue Evaluations of 2001. The mean quotient of the concentration in cream divided by the concentration in milk from cows at feeding levels of 1, 3 and 10 ppm was 4.0, in good agreement with the results for direct treatment.

The MRL for milk (1 mg/kg) was estimated on the basis of the highest residue level in milk, 0.65 mg/kg, after direct treatment. The calculated concentration in cream would then be  $0.65 \times 4.2 = 2.7$  mg/kg. On the assumption that cream is approximately 50% fat, the concentration in fat would be about 5 mg/kg.

The Meeting estimated a maximum residue level for spinosad residues in cattle milk fat of 5 mg/kg.

## DIETARY RISK ASSESSMENT

### *Long-term intake*

The evaluation of spinosad resulted in recommendations for new MRLs and STMR values for raw and processed commodities. Data on consumption were available for 42 food commodities from this and previous evaluations and were used to calculate dietary intake. The results are shown in Annex 3.

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<sup>1</sup> JMPR Report. 2002. 2.11. Maximum residue levels for animal commodities—group MRLs.

The IEDIs in the five GEMS/Food regional diets, based on estimated STMRS were 9-30% of the ADI (0-0.02 mg/kg bw). The Meeting concluded that long-term intake of residues of spinosad from uses that have been considered by the JMPR is unlikely to present a public health concern.

#### *Short-term intake*

The 2001 JMPR concluded that it was unnecessary to establish an ARfD for spinosad. The Meeting therefore concluded that short-term dietary intake of spinosad residues is unlikely to present a risk to consumers.

## **4.29 TRIADIMENOL (168) AND TRIADIMEFON (133)**

### **TOXICOLOGY**

The toxicity of triadimenol ((1RS,2RS;1RS,2SR)-1-(4-chlorophenoxy)-3,3-dimethyl-1-(1*H*-1,2,4-triazol-1-yl)butan-2-ol), a triazole fungicide, was evaluated by the 1989 JMPR, when an ADI of 0–0.05 mg/kg bw was established based on a NOAEL of 5 mg/kg bw per day in a two-generation study in rats. As currently manufactured, triadimenol is an 80:20 mixture of the diastereoisomers A (1RS,2SR) and B (1RS,2RS). Older studies of toxicity in the database were performed with 60:40 mixtures.

Triadimefon is closely chemically related to triadimenol, with which it shares some similar metabolic pathways in animals. The toxicity of triadimefon ((RS)-1-(4-chlorophenoxy)-3,3-dimethyl-1-(1*H*-1,2,4-triazol-1-yl)butan-2-one) was evaluated by the JMPR in 1981, 1983 and 1985. An ADI of 0–0.03 mg/kg bw was established based on a NOAEL of 50 ppm, equivalent to 2.5 mg/kg bw per day, in a 2-year study in rats.

Although triadimenol and triadimefon are independent active ingredients, on the basis of their close chemical and toxicological relationship they were re-evaluated together by the present Meeting within the periodic review programme of the CCPR. Triadimenol and triadimefon act as fungicides by blocking fungal ergosterol biosynthesis. The mechanism of action of these fungicides is inhibition of demethylation.

#### ***Triadimenol***

In rats, radiolabelled triadimenol is rapidly absorbed from the gastrointestinal tract, with radioactivity reaching peak concentrations in most tissues between 1 and 4 h after dosing. Up to 90% of the administered dose was excreted, with an elimination half-life for the radiolabel of between 6 and 15 h. Excretion was essentially complete within 96 h. After 5–6 days, radioactivity in most organs was below the limits of quantification.

Renal excretion accounted for up to 21% of the orally administered dose in males and up to 48% in females. The remainder was found in the faeces. In bile-duct cannulated males 93% of the administered dose was recovered in the bile and only 6% in the urine. Thus a substantial amount of the administered dose undergoes enterohepatic recycling. Radioactivity in expired air was negligible.

Triadimenol was extensively metabolized, predominantly by oxidation of one of the *t*-butyl methyl groups to give hydroxy or carboxy derivatives. The putative intermediate triadimefon has not been isolated. Cleavage of the chloro-phenyl and the triazole group was of minor significance. In the urine and faeces most of the metabolites were not conjugated, but in bile the metabolites were found to be extensively glucuronidated.

Triadimenol has low to moderate acute toxicity. The acute oral LD<sub>50</sub> both in mice and rats was in the range of 700 to 1500 mg/kg bw, with increasing toxicity for increasing isomer ratios A (1RS,2SR):B (1RS,2RS). This finding was supported by an oral LD<sub>50</sub> of 579 mg/kg bw for isomer A and 5000 mg/kg bw for isomer B tested separately. In rats, the dermal LD<sub>50</sub> was > 5000 mg/kg bw and the LC<sub>50</sub> upon inhalation was > 0.954 mg/l of air (after an exposure of 4 h).

Triadimenol is not an eye or skin irritant in rabbits and is not a sensitizer in the maximization test in guinea-pigs.

In short-term studies in mice, rats and dogs, the main effect of triadimenol was on the liver.

In a study comparing the 80:20 and 60:40 isomer mixtures, rats were treated for 28 days by gavage. Both isomer compositions slightly increased motor activity at  $\geq 45$  mg/kg bw per day and induced mixed function oxidase activity and reversibly increased liver weight at 100 mg/kg bw per day. In mice fed diets containing triadimenol at a concentration of 160 to 4500 ppm for 13 weeks, one out of ten males at 4500 ppm died. In both sexes at  $\geq 1500$  ppm, there were increased liver weights accompanied by increased alanine aminotransferase and aspartate aminotransferase activities. Reduced erythrocyte volume fraction and increased mean corpuscular haemoglobin concentration were observed in females at the highest dose. The NOAEL was 500 ppm, equal to 76.8 mg/kg bw per day.

In two 3-month feeding studies in rats, liver weights were increased at  $\geq 600$  ppm ( $< 10\%$  at 600 ppm), with cellular hypertrophy at 3000 ppm. Liver enzyme activities in serum were not increased. In one study, at the highest dose of 2400 ppm, kidney and ovary weights were also increased. At the highest doses in both studies, there were slight changes in some haematology parameters. The lowest NOAEL after oral administration in the short-term studies in rats was 600 ppm, equal to 39.6 mg/kg bw per day. In a 3-week study in rats treated by inhalation, no effects were observed at up to the highest dose of 2.2 mg/l of air.

In a 3-week study in rabbits, dermal application of triadimenol did not cause any dermal or systemic reactions at the highest dose tested, 250 mg/kg bw per day.

In a 3-month, a 6-month and a 2-year study, dogs were given diets containing triadimenol at concentrations of up to 2400 ppm. The only significant findings were decreased body-weight gain at 2400 ppm, liver and kidney weight increases at the highest doses and increased P450 levels. The overall NOAEL was 600 ppm, equal to 21.1 mg/kg bw per day.

In two long-term studies, mice were given diets containing triadimenol at a concentration of up to 2000 ppm. In one study, Crl:CD-1(ICR)BR mice were kept for 80 weeks and in the other study CF<sub>1</sub>/WF 74 mice were kept for 2 years. At 2000 ppm, reduced body-weight gains were recorded and liver weights were increased, as were testes weights in one study. Additionally, liver enzyme activity was higher. In one study, histopathological examination of the liver showed more basophilic foci at  $\geq 80$  ppm, predominantly in males, but there was a poor dose-response relationship and similar values have been reported in control groups in other studies. Hepatocellular hypertrophy and single cell necrosis were found at  $\geq 400$  ppm. At 2000 ppm, additional histopathological changes to the liver were reported. At the intermediate dose, 400 ppm, but not at the highest dose, males had slightly more liver adenomas and carcinomas. There was no clear dose-response relationship, and values were within the historical control range of 6–17%. In females at the highest dose, two out of 50 animals had luteomas; this was within the range for historical controls of 0.9–10%. In the other study, females at the intermediate and highest dose had more liver adenomas and in both sexes at the highest dose, the incidences of liver hyperplastic nodules and thyroid cystic alterations were increased. The increase in liver adenomas is a common finding in mice, which is considered to be of questionable relevance for humans. The overall NOAEL was 500 ppm, equal to 140 mg/kg bw per day.

In a long-term feeding study in rats, at the highest concentration of 2000 ppm reduced body-weight gain was found in both sexes, as were changes in the weights of a number of organs, including spleen, lung and testes. However, there was a poor relationship with dose. In females, kidney, liver and ovarian weights were higher at the highest dose. In both sexes at 2000 ppm, the activities of liver enzymes (alanine aminotransferase and aspartate aminotransferase in both sexes and glutamate dehydrogenase in males) were slightly increased. At the highest dose, minor changes in haematology parameters were at the borderline of the physiological range at some time-points. There was no histopathological evidence for any non-neoplastic or neoplastic changes. The NOAEL was 500 ppm, equal to 25 mg/kg bw per day.

In a series of studies of genotoxicity in vitro and in vivo, triadimenol consistently gave negative results. The Meeting concluded that triadimenol is unlikely to be genotoxic.

In view of the lack of genotoxicity observed and the finding of liver tumours only in female mice and only at concentrations at which liver toxicity was observed, the Meeting concluded that triadimenol is not likely to pose a carcinogenic risk to humans.

To study reproductive performance during exposure to triadimenol, two- and three-generation feeding studies were performed in rats given diets containing triadimenol at concentrations of up to 500 ppm and up to 2000 ppm, respectively. In the study in which the higher doses were administered, matings in all three generations consistently showed reduced fertility at  $\geq 500$  ppm; in  $F_0$  matings, this finding was observed at 125 ppm. Reduced viability was observed in  $F_1$  pups of both matings at 2000 ppm,  $F_2$  pups from the first mating at  $\geq 500$  ppm and  $F_2$  pups of the second mating at 2000 ppm. All  $F_3$  pups from the first mating died at  $\geq 500$  ppm, but not those from the second mating. At 500 ppm, increased testicular and ovarian weights were observed in  $F_{1b}$  parents in the study in which lower doses were administered and increased testicular weights in the  $F_{2b}$  parents at 2000 ppm. The lowest NOAEL in these studies was 100 ppm, equal to 8.6 mg/kg bw per day

Several studies of developmental toxicity were performed in rats, over a dose range of 5 to 120 mg/kg bw per day. In one study, an increase in supernumerary lumbar ribs was found at  $\geq 25$  mg/kg bw per day, and in another study there was an increase in postimplantation losses at 120 mg/kg bw per day. In three out of the four studies, increased placental weights were noted at doses of 30 to 100 mg/kg bw per day. Such effects have been reported with other azoles. Triadimenol did not induce malformations in studies of developmental toxicity and clear NOAELs for developmental toxicity could be established; the lowest NOAEL was 15 mg/kg bw per day.

The NOAEL for offspring toxicity in rabbits was 4 mg/kg bw per day, on the basis of slightly increased postimplantation losses at the maternally toxic dose of 200 mg/kg bw per day.

Clinical signs (general restlessness, alternating phases of increased and reduced motility, aggressivity) observed during tests for acute toxicity suggested possible effects on the central nervous system.

The Meeting concluded that the existing database on triadimenol was adequate to characterize the potential hazards to fetuses, infants and children.

A medical survey of personnel working in the production of triadimenol gave no indication of any substance-related effects.

#### *Toxicological evaluation*

Although a series of tests for acute neurotoxicity in mice were available, a NOAEL for triadimenol for neurotoxicity could not be identified because of technical shortcomings in these studies. As triadimenol is closely related to triadimefon in terms of chemical structure and toxicological effects, and in the view of the lack of sound studies of neurotoxicity with triadimenol, the Meeting concluded that studies of neurotoxicity performed with triadimefon could serve as a basis for deriving an ADI and an ARfD for triadimenol. This was supported by evidence for similar neurotoxic potential in a published study of acute toxicity with triadimenol and triadimefon.

The Meeting established an ADI of 0–0.03 mg/kg based on the NOAEL of 3.4 mg/kg bw per day for hyperactivity in a study of neurotoxicity with triadimefon in a 13-week feeding study in rats, and with a safety factor of 100.

The Meeting established an ARfD of 0.08 mg/kg bw on the basis of the NOAEL of 2 mg/kg bw for hyperactivity in a study of acute neurotoxicity in rats treated with triadimefon by gavage. A safety factor of 25 was applied because the effects were  $C_{\max}$ -dependent and reversible (see comments on triadimefon).

A toxicological monograph was prepared for triadimenol and triadimefon.

### ***Triadimefon***

In a study on the absorption, distribution, metabolism and excretion of triadimefon in rats, the dose given and pretreatment with non-labelled triadimefon did not significantly affect excretion and metabolism patterns. In males about one-third and in females about two-thirds of the administered dose was excreted in the urine and vice versa in the faeces. After 96 h, 2% of the radioactivity remained in females and 9% in males, with the highest residue levels found in liver and kidneys.

The metabolism of triadimefon starts either by direct oxidation of a *t*-butyl methyl group to the hydroxy or the carboxy compound with subsequent glucuronidation, or these steps are preceded by reduction of the keto group of triadimefon to the putative intermediate, triadimenol. Therefore, many of the metabolites found in triadimenol metabolism studies are also found with triadimefon. Nevertheless, the metabolism of triadimefon in rats provides a pathway for demethylation of the *t*-butyl group, which is not seen with triadimenol. This might be owing to very low biotransformation of triadimenol via triadimefon as intermediate.

The acute oral LD<sub>50</sub> in mice and rats was in the range of 363 to 1855 mg/kg bw. The dermal LD<sub>50</sub> was > 5000 mg/kg bw and the LC<sub>50</sub> on inhalation was > 3.27 mg/l of air.

In rabbits, a few treatment-related effects including skin and eye irritation were recorded, but the irritation potential of triadimefon was very low. In guinea-pigs, technical-grade triadimefon of low purity was a sensitizer in the Büehler test for skin sensitization. However, purified triadimefon did not have any sensitizing potential in guinea-pigs in the Magnusson & Kligman maximization test, even after induction with technical-grade triadimefon of low purity.

In short-term studies in rats and dogs, the main effects of triadimefon were on the liver.

In three short-term studies in rats (treated by gavage at doses of up to 30 mg/kg bw per day for 30 days, by gavage at doses of up to 25 mg/kg bw per day for 4 weeks and given diets containing triadimefon at concentrations of up to 2000 ppm for 12 weeks) the overall NOAEL was 150 mg/kg bw per day, the highest dose tested.

In two studies in dogs fed diets containing triadimefon for 13 weeks and 2 years, the highest concentrations administered were 2400 ppm and 2000 ppm, respectively. Body-weight decreases, relative liver weight increases and liver enzyme induction were observed predominantly in the group receiving the highest dose, and, in the short-term study only, there were also effects on haematology parameters. The overall NOAEL in these studies was 600 ppm, equal to 17.3 mg/kg bw per day, in the 2-year study.

The dermal application of triadimefon at 1000 mg/kg bw per day to rats for 3 weeks (6 h per day for 5 days per week) caused diffuse acanthosis at the application site and increased activity and reactivity. The NOAEL was 300 mg/kg bw per day. The dermal application of triadimefon at 50 and 250 mg/kg bw per day to rabbits for 4 weeks (5 days per week) caused mild erythema at the application sites. Rats exposed by inhalation to triadimefon at 0.3 mg/l of air had reduced body-weight gain and increased liver weights.

In two 2-year feeding studies in mice, severely decreased body-weight gains, changes in several haematology parameters and increased liver weights and increased enzyme activity were observed at the highest dietary concentration of 1800 ppm. Starting at 300 ppm, histopathological changes, including nodular changes, hypertrophy and single cell necrosis, were found in the liver. These effects were more pronounced at the highest dose, and in one study an increase in hepatocellular adenomas was also reported. In the other study, a re-examination of histopathology slides led to re-classification of findings for adenomas and carcinomas. Owing to incomplete re-examination, a final conclusion on whether the incidences were increased or not was not possible. However, liver adenomas in the presence of liver toxicity in mice are generally not believed to be of toxicological concern for humans.

The lowest NOAEL was 50 ppm in the feed, equal to 13.5 mg/kg bw per day, on the basis of nodular changes and single cell necrosis in the liver at 300 ppm.

With the exception of behavioural changes and severe histopathological lesions in several organs observed in one study at the highest dose of 5000 ppm, the toxicological profile in two 2-year feeding studies in rats was very similar to that of the studies in mice. After 23 weeks of exposure to the highest dose at 5000 ppm, animals showed violent activity and refused the feed and became moribund. The surviving animals in this group were terminated at week 39. They showed haemorrhagic lesions in the stomach mucosa, blood-filled and dilated alveolar vessels, degenerative processes in proximal kidney tubules of females, atrophied spleens with signs of decreased haematopoiesis, some giant spermatids in testes and decreased haematopoiesis in the bone marrow of males. At the lower dietary concentrations of 1800 and 500 ppm, reduced body-weight gains, increased liver weights and mildly increased liver enzyme activities were recorded. In one study, ovary weights were higher and adrenal weights lower. Mild effects on haematology were found in both studies. In one study at the highest dietary concentration of 1800 ppm, a marginal increase in thyroid cystic hyperplasias and more thyroid follicular adenomas (five versus zero for both sexes taken together) were found. When compared with historical controls, this effect was not significant. The overall NOAEL was 300 ppm, equal to 16.4 mg/kg bw per day.

In a series of studies of genotoxicity *in vitro* and *in vivo*, all results were consistently negative. The Meeting concluded that triadimefon is unlikely to be genotoxic.

In view of the lack of genotoxicity and the finding only of liver adenomas in mice and equivocal changes in thyroid follicular adenomas in rats at concentrations at which organ toxicity was observed, the Meeting concluded that triadimefon is not likely to pose a carcinogenic risk to humans.

In two related multigeneration studies, rats received diets containing triadimefon at concentrations of up to 1800 ppm. Maternal and pup weight development was reduced at doses of  $\geq 300$  ppm and, in the first generation at the highest dose, the viability of the pups was reduced. At the highest dose, two matings of the F<sub>1</sub> animals to give F<sub>2</sub> generation pups resulted in one female becoming pregnant in the first mating and none in the second. In the second study, again at 1800 ppm, the fertility of the F<sub>0</sub> generation was not affected, but that of the F<sub>1</sub> generation was, albeit not to the same extent as in the first study. Viability and pup weights were reduced. In a cross mating in which only one sex was exposed to triadimefon, only the matings with exposed males gave significantly reduced fertility, correlating with reduced insemination indices. Therefore, reduced fertility seemed to have resulted mainly from impaired mounting willingness of exposed males. In males at the highest dose, the concentration of testosterone was double that in control males, and testes weights were increased. However, no correlation between individual testosterone levels and spermograms and mating willingness was observed, although reduced mating willingness did appear to correlate with reduced body weight. It appears that prenatal, but not postnatal, exposure of males affected mating willingness. The lowest NOAEL was 50 ppm, equivalent to 3.75 mg/kg bw per day, based on a LOAEL of 1800 ppm for reproductive effects.

In studies of developmental toxicity in rats treated by inhalation (one study) and by gavage (two studies), inhalation exposure at air concentrations of up to 0.114 mg/l of air on days 6–15 of gestation did not result in any findings indicative of developmental toxicity. In the studies of rats treated by gavage, however, supernumerary ribs in one study at 90 mg/kg bw per day, increased placental weights at 100 mg/kg bw per day, and cleft palates at doses of  $\geq 75$  mg/kg bw per day were found. These doses also reduced the body-weight gains of dams by up to 50% over the exposure period, but not when averaged over the whole gestation period. In four studies in rabbits, body-weight loss in dams was observed at a dose of  $\geq 30$  mg/kg bw per day. Over the dose range of 60 to 120 mg/kg bw per day, increased litter losses, and caudal vertebrae malformations and cleft palates were found either in one or the other study and delayed ossification and scapula malformations were observed in both studies. Additionally, in one study, the uncommon finding of umbilical hernia was recorded in pups at 60 and 80 mg/kg bw per day. Scapula deformations were also found

at 40 mg/kg bw per day, the lowest dose tested in the study. Overall, the lowest NOAEL for offspring toxicity was 20 mg/kg bw on the basis of scapula deformations at 40 mg/kg bw in rabbits.

Several studies provide evidence that triadimefon has neurotoxic potential. In a study in which single doses of triadimefon were administered by gavage and in a 13-week feeding study, several signs of hyperactivity, increased motility and stereotypic behaviour were found. The NOAEL in the former study was 2 mg/kg bw on the basis of reversible neurotoxic effects at 35 mg/kg bw. These were considered to be  $C_{\max}$ -dependent effects in view of the fact that a dose of 54.6 mg/kg bw per day in the short-term feeding study caused similar effects only after several days. The NOAEL for this study was 50 ppm, equivalent to 3.4 mg/kg bw. In a comparative study of acute neurotoxicity in Long Evans rats treated by gavage with a group of 14 triazoles or structurally related compounds, hyperactivity at 100 mg/kg bw, but not at 50 mg/kg bw, was recorded for both triadimenol and triadimefon. In this study, the dose-response curves for triadimenol and triadimefon were very similar, suggesting a common mechanism of neurotoxicity.

The Meeting concluded that the existing database on triadimefon was adequate to characterize the potential hazards to fetuses, infants and children.

A medical survey of the personnel working in the production of triadimefon gave no indication of any substance-related effects.

#### *Toxicological evaluation*

The Meeting established an ADI of 0–0.03 mg/kg bw on the basis of the NOAEL of 3.4 mg/kg bw per day for hyperactivity in a study of neurotoxicity in rats fed with triadimefon and a safety factor of 100.

The Meeting established an ARfD of 0.08 mg/kg bw based on the NOAEL of 2 mg/kg bw for hyperactivity in a study of acute neurotoxicity in rats given triadimefon by gavage. A safety factor of 25 was used since the effects were  $C_{\max}$ -dependent and reversible.

A toxicological monograph was prepared for triadimenol and triadimefon.

#### ***Plant metabolites of triadimefon, triadimenol and other triazole fungicides***

Triazole, triazolyllalanine and triazole acetic acid are plant metabolites of several triazole fungicides, including triadimenol and triadimefon.

After oral administration of triazole, triazolyllalanine and triazole acetic acid to rats, these compounds are rapidly and completely absorbed. Urinary excretion is the main excretion pathway for 90% or more of the administered dose, and only a few percent are found in the faeces. Except for triazolyllalanine, which is metabolized to a minor extent to *N*-acetyltriazolyllalanine, these compounds are virtually not metabolized and are excreted unchanged. Owing to rapid and complete excretion, there is no potential for accumulation in the body for any of these plant metabolites.

The acute oral toxicity of all three compounds is low, with  $LD_{50}$ s of > 5000 mg/kg bw, except for triazole, with an  $LD_{50}$  of 1649 mg/kg bw.

Only a few tests for genotoxicity have been performed on triazole and triazole acetic acid and all gave negative results. Triazolyllalanine was more extensively tested; only one test for cell transformation in vitro gave a positive result, while the results of another similar test and all other tests were negative.

In a 3-month feeding study in rats, triazole induced fat deposition in the liver and changes in haematological parameters at the highest dose of 2500 ppm. In 3-month feeding studies in rats and, the only effect of triazolyllalanine was to reduce body-weight gain at the highest dose of 20 000 ppm. No effects were recorded in a 2-week study in rats fed with triazole acetic acid at the highest dose of 8000 ppm.

In a study of developmental toxicity with triazole in rats, at  $\geq 100$  mg/kg bw per day fetuses showed increased incidence of undescended testicles and at 200 mg/kg bw per day malformations of the hind legs were found. In studies of reproductive and developmental toxicity with triazolylalanine in rats, only very minor effects on pups, indicative of general toxicity, such as reduced birth weights and retarded ossification processes were found at high doses. There were no studies of reproductive and developmental toxicity with triazole acetic acid.

Since triazolylalanine and triazole acetic acid were of low systemic toxicity and developmental effects with triazole occur at doses of  $\geq 100$  mg/kg bw per day, these metabolites were judged not to pose an additional risk to humans.

*Levels relevant to risk assessment of triadimenol\**

| Species | Study                                                      | Effect                   | NOAEL                                                | LOAEL                                   |
|---------|------------------------------------------------------------|--------------------------|------------------------------------------------------|-----------------------------------------|
| Mouse   | 80-week study of toxicity and carcinogenicity <sup>a</sup> | Toxicity                 | 500 ppm, equal to 140 mg/kg bw per day               | 2000 ppm, equal to 620 mg/kg bw per day |
|         |                                                            | Carcinogenicity          | 500 ppm, equal to 140 mg/kg bw per day               | 2000 ppm, equal to 620 mg/kg bw per day |
| Rat     | 2-year study of toxicity and carcinogenicity <sup>a</sup>  | Toxicity                 | 500 ppm, equal to 25 mg/kg bw per day                | 2000 ppm, equal to 105 mg/kg bw per day |
|         |                                                            | Carcinogenicity          | 2000 ppm, equal to 105 mg/kg bw per day <sup>c</sup> | —                                       |
|         | Two-generation study of reproductive toxicity <sup>a</sup> | Parental toxicity        | 100 ppm, equal to 8.6 mg/kg bw per day               | 500 ppm, equal to 43.0 mg/kg bw per day |
|         |                                                            | Pup toxicity             | 100 ppm, equal to 8.6 mg/kg bw per day               | 500 ppm, equal to 43.0 mg/kg bw per day |
|         | Developmental toxicity <sup>b</sup>                        | Maternal toxicity        | 25 mg/kg bw per day                                  | 60 mg/kg bw per day                     |
|         |                                                            | Embryo- and fetotoxicity | 15 mg/kg bw per day                                  | 25 mg/kg bw per day                     |
| Rabbit  | Developmental toxicity <sup>b</sup>                        | Maternal toxicity        | 40 mg/kg bw per day                                  | 200 mg/kg bw per day                    |
|         |                                                            | Embryo- and fetotoxicity | 40 mg/kg bw per day                                  | 200 mg/kg bw per day                    |
| Dog     | 13-week study of toxicity <sup>a</sup>                     | Toxicity                 | 600 ppm equal to 21.1 mg/kg bw per day               | 2400 ppm equal to 85.9 mg/kg bw per day |

\* See comments on triadimefon

<sup>a</sup> Diet

<sup>b</sup> Gavage

<sup>c</sup> Highest dose tested

*Estimate of acceptable daily intake for humans*

0–0.03 mg/kg bw

*Estimate of acute reference dose*

0.08 mg/kg bw

*Studies that would provide information useful for the continued evaluation of the compound*

Further observations in humans



***Critical end-points for establishing guidance values for exposure to triadimenol****Absorption, distribution, metabolism and excretion in animals*


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|                                                                                |                                                                         |
|--------------------------------------------------------------------------------|-------------------------------------------------------------------------|
| Rate and extent of oral absorption                                             | Rapid (peak within 1.5 h); > 90%                                        |
| Distribution                                                                   | Widely distributed                                                      |
| Potential for accumulation                                                     | Low, half lives of 6–15 h                                               |
| Rate and extent of excretion                                                   | 79–90% within 24 h                                                      |
| Metabolism                                                                     | Very extensive; predominantly oxidation of <i>t</i> -butyl methyl group |
| Toxicologically significant compounds<br>(animals, plants and the environment) | Triadimenol, triadimefon, triazole                                      |

*Acute toxicity*

|                                    |                                                         |
|------------------------------------|---------------------------------------------------------|
| Rat, LD <sub>50</sub> , oral       | 579–5000 mg/kg bw (varies with isomer composition)      |
| Rat, LD <sub>50</sub> , dermal     | > 5000 mg/kg bw                                         |
| Rat, LC <sub>50</sub> , inhalation | > 0.95 mg/l                                             |
| Rabbit, dermal irritation          | Not irritating                                          |
| Rabbit, eye irritation             | Not irritating                                          |
| Skin sensitization                 | Not sensitizing (Magnusson & Kligman maximization test) |

*Short-term studies of toxicity*

|                  |                                       |
|------------------|---------------------------------------|
| Critical effects | Liver toxicity (2-year study in dogs) |
| Lowest NOAEL     | 21.1 mg/kg bw                         |

*Genotoxicity*

Negative results in vitro and in vivo

*Long-term studies of toxicity and carcinogenicity*

|                  |                                                                               |
|------------------|-------------------------------------------------------------------------------|
| Critical effects | Body and organ weight changes (2-year study in rats)                          |
| Lowest NOAEL     | 25 mg/kg bw                                                                   |
| Carcinogenicity  | Liver adenomas in female mice; unlikely to pose a carcinogenic risk to humans |

*Reproductive toxicity*

|                            |                                                            |
|----------------------------|------------------------------------------------------------|
| Critical effects           | Increased ovary and testes weights (rat)                   |
| Lowest reproductive NOAEL  | 8.6 mg/kg bw                                               |
| Critical effects           | Increased supernumerary lumbar ribs; not teratogenic (rat) |
| Lowest developmental NOAEL | 15 mg/kg bw                                                |

*Neurotoxicity/delayed neurotoxicity*

|                           |                 |
|---------------------------|-----------------|
| Critical effects at LOAEL | See triadimefon |
| Lowest NOAEL              | See triadimefon |

*Other toxicological studies*

Metabolites are of no greater toxicological concern than the parent

*Medical data*

No effects on health in manufacturing personnel

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| Summary | Value           | Study                                                                     | Safety factor |
|---------|-----------------|---------------------------------------------------------------------------|---------------|
| ADI     | 0–0.03 mg/kg bw | Rat, short-term study of neurotoxicity with triadimefon (see triadimefon) | 100           |
| ARfD    | 0.08 mg/kg bw   | Rat, study of acute neurotoxicity with triadimefon (see triadimefon)      | 25            |

*Levels relevant to risk assessment of triadimefon*

| Species | Study                                                       | Effect                   | NOAEL                                                | LOAEL                                        |
|---------|-------------------------------------------------------------|--------------------------|------------------------------------------------------|----------------------------------------------|
| Mouse   | 21-month study of toxicity and carcinogenicity <sup>a</sup> | Toxicity                 | 50 ppm, equal to 13.5 mg/kg bw per day               | 300 ppm, equal to 76 mg/kg bw per day        |
|         |                                                             | Carcinogenicity          | 300 ppm, equal to 76 mg/kg bw per day                | 1800 ppm, equal to 550 mg/kg bw per day      |
| Rat     | 105-week study of toxicity and carcinogenicity <sup>a</sup> | Toxicity                 | 300 ppm, equal to 16.4 mg/kg bw per day              | 1800 ppm, equal to 114 mg/kg bw per day      |
|         |                                                             | Carcinogenicity          | 1800 ppm, equal to 114 mg/kg bw per day <sup>c</sup> | —                                            |
|         | Two-generation study of reproductive toxicity <sup>a</sup>  | Parental toxicity        | 300 ppm, equal to 22.8 mg/kg bw per day              | 1800 ppm, equal to 136.8 mg/kg bw per day    |
|         |                                                             | Pup toxicity             | 300 ppm, equal to 22.8 mg/kg bw per day              | 1800 ppm, equal to 136.8 mg/kg bw per day    |
|         | Developmental toxicity <sup>b</sup>                         | Maternal toxicity        | 10 mg/kg bw per day                                  | 30 mg/kg bw per day                          |
|         |                                                             | Embryo- and fetotoxicity | 30 mg/kg bw per day                                  | 90 mg/kg bw per day                          |
|         | Acute neurotoxicity <sup>b</sup>                            | Neurotoxicity            | 2 mg/kg bw                                           | 35 mg/kg bw                                  |
| Rabbit  | 13-week study of neurotoxicity <sup>a</sup>                 | Neurotoxicity            | 50 ppm, equivalent to 3.4 mg/kg bw per day           | 800 ppm, equivalent to 54.6 mg/kg bw per day |
|         |                                                             | Maternal toxicity        | 10 mg/kg bw per day                                  | 30 mg/kg bw per day                          |
|         |                                                             | Embryo- and fetotoxicity | 20 mg/kg bw per day                                  | 50 mg/kg bw per day                          |
| Dog     | 2-year study of toxicity <sup>a</sup>                       | Toxicity                 | 300 ppm equal to 11.7 mg/kg bw per day               | 200 ppm equal to 48.8 mg/kg bw per day       |

<sup>a</sup> Diet

<sup>b</sup> Gavage

<sup>c</sup> Highest dose tested

*Estimate of acceptable daily intake for humans*

0–0.03 mg/kg bw

*Estimate of acute reference dose*

0.08 mg/kg bw

*Studies that would provide information useful for the continued evaluation of the compound*

Further observations in humans

***Critical end-points for setting guidance values for exposure to triadimenol***

|                                                                             |              |                                                                                                                                           |               |
|-----------------------------------------------------------------------------|--------------|-------------------------------------------------------------------------------------------------------------------------------------------|---------------|
| Absorption, distribution, metabolism and excretion in animals               |              |                                                                                                                                           |               |
| Rate and extent of oral absorption                                          |              | ≥ 28% in females, ≥ 67% in males as urinary excretion                                                                                     |               |
| Distribution                                                                |              | Widely distributed in kidneys and liver                                                                                                   |               |
| Potential for accumulation                                                  |              | Low                                                                                                                                       |               |
| Rate and extent of excretion                                                |              | 90–98% excretion within 96 h                                                                                                              |               |
| Metabolism                                                                  |              | Very extensive; predominantly oxidation of tert-butyl methyl group                                                                        |               |
| Toxicologically significant compounds (plants, animals and the environment) |              | Triadimenol, triadimefon, triazole                                                                                                        |               |
| Acute toxicity                                                              |              |                                                                                                                                           |               |
| Rat, LD <sub>50</sub> , oral                                                |              | 363–1855 mg/kg bw                                                                                                                         |               |
| Rat, LD <sub>50</sub> , dermal                                              |              | > 5000 mg/kg bw                                                                                                                           |               |
| Rat, LC <sub>50</sub> , inhalation                                          |              | > 3.27 mg/l                                                                                                                               |               |
| Rabbit, dermal irritation                                                   |              | Not irritating                                                                                                                            |               |
| Rabbit, eye irritation                                                      |              | Not irritating                                                                                                                            |               |
| Skin sensitization                                                          |              | Technical-grade triadimefon is sensitizing, purified triadimefon is not sensitizing (Büehler, and Magnusson & Kligman maximization tests) |               |
| Short-term studies of toxicity                                              |              |                                                                                                                                           |               |
| Critical effects                                                            |              | Liver effects (dog)                                                                                                                       |               |
| Lowest NOAEL                                                                |              | 17.3 mg/kg bw                                                                                                                             |               |
| Genotoxicity                                                                |              | Negative in vitro and in vivo                                                                                                             |               |
| Long-term studies of toxicity and carcinogenicity                           |              |                                                                                                                                           |               |
| Critical effects                                                            |              | Liver nodular changes, hypertrophy and single cell necrosis                                                                               |               |
| Lowest NOAEL                                                                |              | 13.5 mg/kg bw per day                                                                                                                     |               |
| Carcinogenicity                                                             |              | Liver adenomas in mice; unlikely to pose a carcinogenic risk to humans                                                                    |               |
| Reproductive toxicity                                                       |              |                                                                                                                                           |               |
| Critical effects                                                            |              | Impaired reproductive performance (rat)                                                                                                   |               |
| Lowest reproductive NOAEL                                                   |              | 22.8 mg/kg bw per day                                                                                                                     |               |
| Critical effects                                                            |              | Scapula malformations at maternal toxic doses (rabbit)                                                                                    |               |
| Lowest developmental NOAEL                                                  |              | 20 mg/kg bw per day                                                                                                                       |               |
| Neurotoxicity/delayed neurotoxicity                                         |              |                                                                                                                                           |               |
| Critical effects                                                            |              | Increased activity in study of acute neurotoxicity after gavage administration (rat)                                                      |               |
| Lowest NOAEL                                                                |              | 2 mg/kg bw                                                                                                                                |               |
| Critical effects                                                            |              | Increased activity in short-term feeding study (rat)                                                                                      |               |
| Lowest NOAEL                                                                |              | 3.4 mg/kg bw                                                                                                                              |               |
| Other toxicological studies                                                 |              | Metabolites are of no greater toxicological concern than the parent                                                                       |               |
| Medical data                                                                |              | No effects on health in manufacturing personnel                                                                                           |               |
| Summary                                                                     | Value        | Study                                                                                                                                     | Safety factor |
| ADI                                                                         | 0–0.03 mg/kg | Rat, short-term study of neurotoxicity                                                                                                    | 100           |
| ARfD                                                                        | 0.08 mg/kg   | Rat, study of acute neurotoxicity                                                                                                         | 25            |

**DIETARY RISK ASSESSMENT*****Triadimenol******Long-term intake***

Theoretical maximum daily intakes were calculated for the commodities of human consumption for which Codex MRLs existed (Annex 3). The theoretical maximum daily intakes in the five GEMS/Food regional diets represented 1–20% of the maximum ADI (0.03 mg/kg bw per day). The Meeting concluded

that the long-term intake of residues of triadimenol resulting from uses of triadimenol and triadimefon considered by the JMPR is unlikely to present a public health concern.

#### *Short-term intake*

An ARfD of 0.08 mg/kg bw was established for triadimenol by the present Meeting. IESTIs could not, however, be calculated, as the residues of the compound were evaluated by the Meeting before the procedures for estimation of STMR and highest residue values were established. Triadimenol was scheduled for periodic evaluation of residues in 2006, when the risk assessment would be finalized.

### ***Triadimefon***

#### *Long-term intake*

Theoretical maximum daily intakes were calculated for the commodities of human consumption for which Codex MRLs existed (Annex 3). The theoretical maximum daily intakes in the five GEMS/Food regional diets represented 1–6% of the maximum ADI (0.03 mg/kg bw per day). The Meeting concluded that the long-term intake of residues of triadimefon considered by the JMPR is unlikely to present a public health concern.

#### *Short-term intake*

An ARfD of 0.08 mg/kg bw was established for triadimefon by the present Meeting. IESTIs could not, however, be calculated, as the residues of the compound were evaluated by the Meeting before the procedures for estimation of STMR and highest residue values were established. Triadimefon was scheduled for periodic evaluation of residues in 2006, when the risk assessment would be finalized.

## **4.30 TRIFLOXYSTROBIN (213)**

### **TOXICOLOGY**

Trifloxystrobin (methyl(*E*)-methoxyimino-{(*E*)- $\alpha$ -[1-( $\alpha,\alpha,\alpha$ -trifluoro-*meta*-tolyl)ethylideneamino-oxy]-*ortho*-tolyl}acetate) is a new broad-spectrum foliar fungicide, which is a synthetic analogue of the naturally occurring strobilurins. Trifloxystrobin has not been evaluated previously by the JMPR.

After oral administration, radiolabelled trifloxystrobin was rapidly and appreciably absorbed (66% of the administered dose) in rats of both sexes. The main route of elimination (63–84%) was in the faeces; some of the fecal elimination was via bile (30–45%) while only one-third or less of the administered dose was excreted in the urine, and none through expired air. There was almost complete degradation of trifloxystrobin after single low dose, at 0.5 mg/kg bw, but up to 45% was eliminated unchanged in the faeces after a high dose, at 100 mg/kg bw. The metabolite pattern in rats is very complex; about 35 metabolites were identified in the urine, faeces and bile. The main steps in the metabolic pathway include hydrolysis of the methyl ester to the corresponding acid, *O*-demethylation of the methoxyimino group yielding a hydroxyimino compound and oxidation of the ethylideneamino methyl group to a primary alcohol and then to the corresponding carboxylic acid. These steps are followed by a complex pattern of further, minor reactions. Cleavage between the glyoxylphenyl and trifluormethylphenyl moieties accounted for about 10% of the administered dose.

The metabolism of trifloxystrobin in plants is similar to that in animals and occurs primarily via cleavage of the methyl ester group to form CGA 321113 (*E,E*)-methoxyimino-{2-[1-(3-trifluoro methyl-phenyl)-ethylideneaminooxymethyl]-phenyl}-acetic acid. In the rat, this metabolite undergoes further hydroxylation and conjugation (glucuronide and sulfate) at the trifluoromethyl phenyl ring. In goat liver, taurine and glycine conjugates of CGA 321113 were the principal residue components (up to 28% of the total

radioactive residues). Conjugated metabolites are generally less toxic and more rapidly excreted than an unconjugated parent compound. Being biotransformation products in the rat, CGA 321113 and its metabolites are assumed to have been adequately tested and accounted for in rats given trifloxystrobin. Also, CGA 321113 is not likely to be more toxic than trifloxystrobin.

Dermal absorption of trifloxystrobin in rats was low and slightly decreased with increasing dose. Compared with human epidermis, rat epidermis was 9 and 19 times more permeable in a test *in vitro* at a dose of 0.24 and 10.27 mg/cm<sup>2</sup>, respectively. In a study of absorption *in vivo*, in which a low or a high dose of radiolabelled trifloxystrobin was applied to the shaved backs of male rats, the amount of recovered radioactivity in the blood was low, but the overall absorption was moderate, ranging from 5 to 10% in 24 h and increasing to 16% at 48 h.

Trifloxystrobin has low acute oral toxicity in rats and mice (LD<sub>50</sub>, > 5000 mg/kg), low acute dermal toxicity in rats and rabbits (LD<sub>50</sub>, > 2000 mg/kg), low acute inhalation toxicity in rats (LC<sub>50</sub>, > 4.65 mg/l), is not a skin irritant in rabbits, is a moderate eye irritant in unwashed rabbit eyes but is not irritating in washed rabbit eyes. It is a skin sensitizer in guinea-pigs, according to the Magnusson & Kligman maximization test, but is not a skin sensitizer in guinea-pigs according to the Buehler test.

In studies of toxicity with repeated doses, slight decreases (5–10%) in body weight and/or body-weight gain were regarded as non-adverse in the absence of other effects.

In studies of repeated doses in mice, the liver and spleen were the principal target organs at the same or higher doses than those affecting body weight and food efficiency. In the 90-day study in male and female mice, liver weight was increased and there were findings on microscopy, including hepatocyte hypertrophy and focal or single cell necrosis. There were also increased incidences of extramedullary haematopoiesis in the spleen at doses of  $\geq 315$  mg/kg bw per day. The NOAEL for these effects was 77 mg/kg bw per day.

In a 90-day dietary study in rats, the NOAEL was 31 mg/kg bw per day on the basis of statistically significantly decreased body-weight gain of 20% and 40% in males and females, respectively, increased relative liver weights, changes in clinical chemistry and liver histopathology findings (mainly hepatocellular hypertrophy), in addition to atrophy of the pancreas at the next higher dose of 127 mg/kg bw per day.

At or above a daily dose of trifloxystrobin at 150 mg/kg bw per day for 3 months or 50 mg/kg bw per day for 1 year, dogs had episodes of diarrhoea, vomiting, reduced food intake, increased relative liver weight and hepatocyte hypertrophy, in addition to changes in clinical chemistry parameters indicative of liver toxicity and/or perturbed metabolism, dehydration, poor nutrition and possible starvation. Body weights were also affected. In the 3-month study, animals of both sexes had body-weight loss of about 0.4 kg and 2.8 kg at 150 and 500 mg/kg bw per day, respectively. In the 1-year study, body-weight gain in females at 50 and 200 mg/kg bw per day were decreased throughout the study, and at week 52 body-weight gain was about 20% below control values. The NOAELs were 30 and 5 mg/kg bw per day in the 3-month and 1-year studies, respectively.

The long-term study of toxicity and carcinogenicity with trifloxystrobin was evaluated in bioassays in mice and rats. In the 18-month dietary feeding study in mice, the NOAEL was 36 mg/kg bw per day on the basis of liver effects, including increased liver weight (both sexes) and increased single cell necrosis (males), in addition to impaired body-weight gain (females). There was no evidence of carcinogenicity in mice tested at adequate doses.

In the 2-year study in rats, the NOAEL was 30 mg/kg bw per day on the basis of statistically significantly retarded body-weight gain in males (11–17%) and females (17–27%) and decreased food consumption (by 4% and 8%, respectively) and increased relative weights of heart, liver and kidneys (each by about 20%) in females at the highest dose of 62 mg/kg bw per day. The overall incidence of tumours was lower in the treated animals. Benign adrenal medullary tumours (10% versus 0% in controls) and haemangioma in the mesenteric lymph nodes (10.2% versus 0% in controls) were increased in male rats at the highest dose tested. Incidences of the adrenal medullary tumours were within the range of incidences for historical controls. The incidence of haemangioma in the mesenteric lymph nodes in males of the high dose

group was outside the range of historical control incidences. There was markedly reduced mortality in the group receiving the highest dose tested, and this may have contributed to the higher incidence of tumours in this group compared to controls. In ageing male rats of this strain, degenerative lesions associated with the mesenteric lymph nodes are common and are hard to distinguish from neoplastic lesions (haemangiomas). Some age-associated non-neoplastic findings, such as angiomatous hyperplasia of the mesenteric lymph nodes, were increased in males at the highest dose and the increases were correlated with decreased food intake and a lower body-weight development.

The Meeting concluded that there was no treatment-related carcinogenicity of any toxicological concern.

A wide range of assays for genotoxic potential with trifloxystrobin were conducted in vitro and in vivo, including testing for gene mutation, chromosomal damage and DNA repair. At or near cytotoxic doses and in the presence of metabolic activation, trifloxystrobin was weakly mutagenic at cytotoxic doses in the test for forward gene mutation in Chinese hamster V79 cells. Results were equivocal in the absence of metabolic activation. Metabolites of trifloxystrobin [CGA 357261 (Z, E-isomer), CGA 373466 and NOA 414412] were not mutagenic in the Ames test. The Meeting concluded that trifloxystrobin and its metabolites are not genotoxic.

Because of the absence of findings indicative of genotoxicity or carcinogenicity, the Meeting concluded that trifloxystrobin is unlikely to pose a carcinogenic risk to humans.

In the two-generation study in rats given trifloxystrobin at a dose of 55 or 111 mg/kg bw per day, pups in the F<sub>1</sub> and F<sub>2</sub> litters had retarded body-weight development during lactation. The NOAEL for parental toxicity was 3.8 mg/kg bw per day on the basis of findings at 55 mg/kg bw per day, i.e. reduced body weight and food consumption, in addition to histopathology findings in the liver and kidneys. The NOAEL for offspring toxicity was 3.8 mg/kg bw per day on the basis of retarded body-weight development during lactation. The NOAEL for reproductive toxicity was 111 mg/kg bw per day.

Trifloxystrobin was not teratogenic in rats and rabbits when tested at doses of up to 1000 and 500 mg/kg bw per day, respectively. In rats, the NOAEL for developmental toxicity was 100 mg/kg bw per day on the basis of increased incidences of enlarged thymus. In rabbits, the NOAEL for developmental toxicity was 250 mg/kg bw per day on the basis of increased incidences of skeletal anomalies in the form of fused sternbrae 3 and 4. Maternal toxicity in rats and rabbits was limited to reduced food consumption and body-weight loss at 100 and 250 mg/kg bw per day with NOAELs of 10 and 50 mg/kg bw per day, respectively. The developmental effects were considered to be a consequence of overall maternal toxicity.

The Meeting concluded that the existing database on trifloxystrobin was adequate to characterize the potential hazards to fetuses, infants and children.

In a study of acute oral neurotoxicity in rats given a single dose of trifloxystrobin at 2000 mg/kg bw, the functional observational battery revealed no indications for potential neurological or behavioural effects.

### ***Toxicological evaluation***

The Meeting established an ADI of 0–0.04 mg/kg bw based on the parental NOAEL of 3.8 mg/kg bw per day in a multigeneration study of reproductive toxicity in rats and a 100-fold safety factor. The LOAEL was 55 mg/kg bw per day on the basis of effects on body weight and food consumption, in addition to liver and kidney histopathology findings. This value is supported by the NOAEL of 5 mg/kg bw per day in the 1-year study in dogs.

The Meeting concluded that it was unnecessary to establish an ARfD for trifloxystrobin on the basis of its low acute toxicity and the fact that developmental effects were considered to be a result of severe

maternal toxicity, which is related to decreased food intake rather than systemic toxicity. Also, the vomiting and diarrhoea observed in dogs were clearly related to local irritation, rather than systemic acute toxicity.

A toxicological monograph was prepared.

#### Levels relevant to risk assessment

| Species | Study                                                       | Effect                   | NOAEL                                                | LOAEL                                               |
|---------|-------------------------------------------------------------|--------------------------|------------------------------------------------------|-----------------------------------------------------|
| Mouse   | 18-month study of toxicity and carcinogenicity <sup>a</sup> | Toxicity                 | 300 ppm, equal to 36 mg/kg bw per day                | 1000 ppm, equal to 124 mg/kg bw per day             |
|         |                                                             | Carcinogenicity          | 2000 ppm, equal to 246 mg/kg bw per day <sup>b</sup> | —                                                   |
| Rat     | 2-year studies of toxicity and carcinogenicity <sup>a</sup> | Toxicity                 | 750 ppm, equal to 30 mg/kg bw per day                | 1500 ppm, equal to 62 mg/kg bw per day <sup>b</sup> |
|         |                                                             | Carcinogenicity          | 1500 ppm, equal to 62 mg/kg bw per day <sup>b</sup>  | —                                                   |
|         | Two-generation reproductive toxicity <sup>a</sup>           | Parental toxicity        | 50 ppm, equal to 3.8 mg/kg bw per day                | 750 ppm, equal to 55 mg/kg bw per day               |
|         |                                                             | Offspring toxicity       | 50 ppm, equal to 3.8 mg/kg bw per day                | 750 ppm, equal to 55 mg/kg bw per day               |
|         | Developmental toxicity <sup>c</sup>                         | Maternal toxicity        | 10 mg/kg bw per day                                  | 100 mg/kg bw per day                                |
|         |                                                             | Embryo- and fetotoxicity | 100 mg/kg bw per day                                 | 1000 mg/kg bw per day                               |
| Rabbit  | Developmental toxicity <sup>c</sup>                         | Maternal toxicity        | 50 mg/kg bw per day                                  | 250 mg/kg bw per day                                |
|         |                                                             | Embryo- and fetotoxicity | 250 mg/kg bw per day                                 | 500 mg/kg bw per day                                |
| Dog     | 3-month study of toxicity <sup>d,e</sup>                    | Toxicity                 | 30 mg/kg bw per day                                  | 150 mg/kg bw per day                                |
|         | 12-month study of toxicity <sup>d</sup>                     | Toxicity                 | 5 mg/kg bw per day                                   | 50 mg/kg bw per day                                 |

<sup>a</sup> Diet

<sup>b</sup> Highest dose tested

<sup>c</sup> Gavage

<sup>d</sup> Gelatine capsule

<sup>e</sup> Two or more studies combined

#### Estimate of acceptable daily intake for humans

0–0.04 mg/kg bw

#### Estimate of acute reference dose

Unnecessary

#### Studies that would provide information useful for continued evaluation of the compound

Further observations in humans

#### Critical end-points for setting guidance values for exposure to trifloxystrobin

##### Absorption, distribution, excretion and metabolism in animals

|                                                                             |                                                                                                                                                  |
|-----------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------|
| Rate and extent of absorption                                               | 66% in 48 h                                                                                                                                      |
| Distribution                                                                | Widely distributed; highest concentrations in blood, liver and kidneys                                                                           |
| Potential for accumulation                                                  | No potential for accumulation.                                                                                                                   |
| Rate and extent of excretion                                                | Within 48 h, 72–96% of the administered dose is eliminated in the urine and faeces                                                               |
| Metabolism in animals                                                       | Extensive: hydrolysis, O-demethylation, oxidation, conjugation, chain shortening and cleavage between glyoxylphenyl and trifluoromethyl moieties |
| Toxicologically significant compounds (plants, animals and the environment) | Parent compound, main acid metabolite is CGA 321113                                                                                              |

*Acute toxicity*

|                                     |                                       |
|-------------------------------------|---------------------------------------|
| Rat, LD <sub>50</sub> , oral        | > 5000 mg/kg bw                       |
| Rat, LD <sub>50</sub> , dermal      | > 2000 mg/kg bw                       |
| Rat, LC <sub>50</sub> , inhalation: | > 4.6 mg/l                            |
| Rabbit, skin irritation:            | Not irritating                        |
| Rabbit, eye irritation:             | Not irritating                        |
| Skin sensitization                  | Sensitizer (Magnusson & Kligman test) |

*Short-term studies of toxicity*

|                                  |                                                                                                                                      |
|----------------------------------|--------------------------------------------------------------------------------------------------------------------------------------|
| Target/critical effect           | Body weight, food consumption, clinical signs, liver (pathology), kidney (weight), pancreas (atrophy), spleen (weight and pathology) |
| Lowest relevant oral NOAEL       | 5 mg/kg bw per day (1-year study in dogs)                                                                                            |
| Lowest relevant dermal NOAEL     | ≥ 1000 mg/kg bw per day (28-day study in rats)                                                                                       |
| Lowest relevant inhalation NOAEC | No relevant study                                                                                                                    |

*Genotoxicity*

No genotoxic potential, negative results in vivo, one positive result in study in vitro at cytotoxic doses.

*Long-term studies of toxicity and carcinogenicity*

|                        |                                                                      |
|------------------------|----------------------------------------------------------------------|
| Target/critical effect | Body weight (mouse, rat), food consumption (rat), liver (mouse, rat) |
| Lowest relevant NOAEL  | 30 mg/kg bw per day (2-year study in rats)                           |
| Carcinogenicity        | Unlikely to pose a carcinogenic risk to humans                       |

*Reproductive toxicity*

|                                      |                                                                                               |
|--------------------------------------|-----------------------------------------------------------------------------------------------|
| Target/critical effect               | Decreased body-weight gain of pups accompanied by delayed eye opening at parental toxic doses |
| Lowest relevant reproductive NOAEL   | 50 ppm (3.8 mg/kg bw per day)s                                                                |
| Developmental target/critical effect | Enlarged thymus (rat) and skeletal effects (rabbit) at maternally toxic doses                 |
| Lowest relevant developmental NOAEL  | 100 mg/kg bw per day (rat)                                                                    |

*Neurotoxicity*

No evidence of acute neurotoxicity in rats

*Other toxicological studies*

No evidence of replicative DNA synthesis in rat or mouse hepatocytes after 3-months administration in diet

A range of metabolites had low acute oral toxicity and there was no evidence of genotoxic activity

*Medical data*

New active substance; limited data; some evidence of skin and eye irritation in three people during field trials (but 120 people without effects)

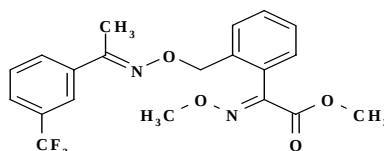
| <b>Summary</b> | <b>Value</b>    | <b>Study</b>                                                           | <b>Safety factor</b> |
|----------------|-----------------|------------------------------------------------------------------------|----------------------|
| ADI            | 0–0.04 mg/kg bw | Rat, reproduction study, reduced body weight, liver and kidney effects | 100                  |
| ARfD           | Unnecessary     | —                                                                      | —                    |



## RESIDUE AND ANALYTICAL ASPECTS

The residue and analytical aspects of trifloxystrobin were considered for the first time by the present Meeting.

Trifloxystrobin, a member of the strobilurin group, is a broad-spectrum contact fungicide for foliar use; it has mesosystemic properties. The mode of action of strobilurins involves inhibition of mitochondrial respiration by blockage of the electron transfer chain. The fungicidal properties of trifloxystrobin are derived from the parent ester, and the acid (the main metabolite) is essentially inactive. Trifloxystrobin has registered uses on horticultural crops, vegetables and cereals in many countries.



|                          |                                                                                                                                                                        |
|--------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| IUPAC name:              | methyl ( <i>E</i> )-methoxyimino-[( <i>E</i> )- $\alpha$ -[1-( $\alpha,\alpha,\alpha$ -trifluoro- <i>meta</i> -tolyl)ethylideneamino]oxy]- <i>ortho</i> -tolyl}acetate |
| Chemical Abstracts name: | methyl ( $\alpha E$ )- $\alpha$ -(methoxyimino)-2-[[[( <i>E</i> )-[1-[3-(trifluoromethyl)phenyl]ethylidene]amino]oxy]methyl]benzeneacetate                             |

The Meeting received information on the metabolism and environmental fate of trifloxystrobin, methods of residue analysis, stability in freezer storage, national registered use patterns, the results of supervised residue trials, the results of farm animal feeding studies, fate of residues in processing and national MRLs.

Trifloxystrobin is a white powder which melts at 73 °C. It is not highly volatile (vapour pressure,  $3 \times 10^{-6}$  Pa). It does not dissociate and is only slightly water-soluble (0.6 mg/l). The log  $P_{ow}$  is 4.5, suggesting that bioaccumulation may occur. Trifloxystrobin is hydrolytically stable at environmental pHs, but photochemical degradation was shown to occur. The active technical substance is not considered to be explosive or inflammable.

### Metabolism

#### Animals

The metabolism of trifloxystrobin was investigated in rats, goats and poultry, and the metabolic pathways were comparable in the three species. The studies were performed with  $^{14}\text{C}$ -trifloxystrobin labelled uniformly in one of the two phenyl rings, [glyoxylphenyl- $\text{U}^{14}\text{C}$ ]trifloxystrobin and [trifluoromethylphenyl- $\text{U}^{14}\text{C}$ ]trifloxystrobin, each compound being administered separately. The name [glyoxylphenyl- $\text{U}^{14}\text{C}$ ]trifloxystrobin was introduced during the development of trifloxystrobin to reflect the route of synthesis of radiolabelled material.

After oral administration to rats of each sex, radiolabelled trifloxystrobin was rapidly and appreciably absorbed (35–65% of dose). Faeces was the main route of elimination (63–84%), some of which was through bile (30–45%) while only one-third or less of the administered dose was excreted in urine and none in expired air. There was near-complete degradation of trifloxystrobin after a single low dose of 0.5 mg/kg bw;

however, after a dose of 100 mg/kg bw, up to 45% was eliminated unchanged in faeces. The pattern of metabolites in rats is complex: about 35 metabolites were isolated from urine, faeces and bile and identified. The main steps in the metabolic pathway include hydrolysis of the methyl ester to the corresponding acid, O-demethylation of the methoxyimino group, yielding a hydroxyimino compound, and oxidation of the ethylideneamino methyl group to a primary alcohol and then to the corresponding carboxylic acid. These steps are followed by a complex pattern of further, minor reactions. Cleavage between the two phenyl rings accounted for about 10% of the dose.

Lactating *goats* were given diets containing [glyoxylphenyl- $U^{14}C$ ]trifloxystrobin or [trifluoromethylphenyl- $U^{14}C$ ]trifloxystrobin at an equivalent of 100 ppm for 4 days and were slaughtered 6 h after the last dose. Up to 20% of the applied dose was excreted in urine and 45% in faeces, while 0.05–0.08% of the total dose was eliminated in milk, corresponding to about 0.1 mg/kg trifloxystrobin equivalents, and a plateau was reached after 48 h.

Most tissue residues were found in liver, bile and kidney, accounting for 0.28–0.57%, 0.07–0.24% and 0.026–0.052% of the applied dose, respectively. These values correspond to 2.6–5.2 mg/kg, 29–77 mg/kg and 1.7–2.9 mg/kg as trifloxystrobin equivalents. Lower levels were found in fat, muscle and blood. The main components of the residue were the parent compound, its carboxylic acid, CGA 321113 (chemical name: (*E,E*)-methoxyimino-{2-[1-(3-trifluoromethyl-phenyl)ethylideneaminooxymethyl]phenyl}acetic acid) and taurine and glycine conjugates of CGA 321113. The amino acid conjugates were the main residue components in the liver (up to 28% TRR). These metabolites were not considered to be of toxicological concern. CGA 321113 was the main radioactive residue in muscle (up to 57% TRR) and kidney (up to 74% TRR), and trifloxystrobin was the principal component in milk (up to 74% TRR) and fat (up to 82% TRR).

*Hens* were given diets containing trifloxystrobin at an equivalent of 100 ppm in the diet for 4 days and were killed 6 h after the last dose. Up to 0.16% and 87% of the applied dose were eliminated in eggs and excreta, respectively. A plateau was not reached in egg yolk. The residue levels appeared to be increasing rapidly at the end of the study.

Eggs contained 0.1–0.2% of the applied dose. The maximum concentration in egg white was 0.56 mg/kg, and that in egg yolk was 2.3 mg/kg as trifloxystrobin equivalents. Lean meat contained 0.11–0.22% of the dose (0.13–0.35 mg/kg trifloxystrobin equivalents); skin and attached fat 0.14–0.39% (0.8–1.8 mg/kg); peritoneal fat, 0.07–0.21% (1.9–2.7 mg/kg); kidney, 0.11–0.25% (6–13 mg/kg); and liver, 0.28–0.68% (3.8–8.6 mg/kg). The TRR (including that in intestine and gizzard) was 78–91%.

Characterization of the radioactive tissue residues revealed that parent trifloxystrobin was a major residue in muscle (up to 28% TRR), fat and skin (up to 55% TRR) and egg yolk (up to 9% TRR) of laying hens. The carboxylic acid derivative (CGA 321113) was the main residue in egg white (up to 26% TRR) and liver (up to 5.1% TRR).

### Plants

The metabolism of trifloxystrobin in plants was investigated in wheat, apples, cucumbers, sugar beet and peanuts with  $^{14}C$ -trifloxystrobin applied by spray. Although the number of metabolite fractions differed in the different plants, the metabolic pathways in these the crops were comparable.

In mature *wheat*, the highest TRRs were found in straw (3.85 mg/kg trifloxystrobin equivalents), followed by husks (0.14 mg/kg) and grain (0.02 mg/kg). The composition of the TRRs was complex; trifloxystrobin and its isomers constituted less than 5%.

Studies on wheat showed that the absorption of trifloxystrobin by plants was relatively rapid, with about 15% of the TRR appearing within the first 24 h, 29% within 3 days and 44% within 14 days. Characterization of the surface radioactivity in wheat revealed that trifloxystrobin is relatively stable to photodegradation, accounting for up to about 80% of the surface radioactivity after 14 days. In contrast, absorbed residue appeared to undergo rapid degradation: the trifloxystrobin concentration declined

exponentially, with an apparent half-life of 12 h. Up to 35 metabolite fractions were found in wheat, most of which constituted less than 1% TRR.

In *apple*, 14 days after treatment, the main residue component was the parent compound trifloxystrobin (*E,E* isomer), which, together with its *Z,Z*, *Z,E* and *E,Z* isomers, constituted about 92% of the residue.

In the leaves and fruits of *cucumber*, the residue consisted of trifloxystrobin (80–93% TRR), isomers of trifloxystrobin (2.3–3.8% TRR) and CGA 321113 (0.9–4.2% TRR).

In *sugar-beet*, the main compounds found, with both labels, in the tops and roots were trifloxystrobin and its *E,Z* and *Z,Z* isomers. They accounted for up to 69% TRR in tops (1.1 mg/kg trifloxystrobin) and 52% in roots (0.02 mg/kg trifloxystrobin). CGA 321113 represented up to 5.2% (0.073 mg/kg) and up to 11% (0.012 mg/kg) of the TRR in tops and roots, respectively.

In *peanut*, many metabolite fractions containing only one moiety of the parent molecule were detected, generally similar to those found in wheat. Extensive formation of sugar and malonyl sugar conjugates was found in most metabolite fractions. In vines, the percentage of extractable radioactive residues (acetonitrile:water) amounted to 91% TRR. Extractable residues represented up to 74% in mature hay and up to 53% in nutmeat. The unextracted residues were solubilized by hot extraction and sequential hydrolyses with cellulase, protease, HCl and NaOH. The radioactive residues that remained unextracted under these exhaustive conditions represented < 10% TRR.

In general, the metabolism of trifloxystrobin in crops is complex, owing to isomerization of the parent compound and its metabolites. Overall, the metabolism of trifloxystrobin is similar in all crops and involves the following steps:

- *cis*–*trans* isomerization of trifloxystrobin (*E,E*- isomer) to its *E,Z*-, *Z,Z* and *Z,E*- isomers
- hydrolysis of the methyl esters of the parent and its isomers to carboxylic acids
- *cis*–*trans* isomerization of the *E,E*-carboxylic acid CGA 321113
- hydroxylation of the trifluoromethylphenyl ring, followed by sugar conjugation
- oxidation of the methyl of the 2-ethylideneamino group with subsequent sugar conjugation
- cleavage of the N–O bridge, followed by oxidation of the trifluoromethylphenyl moiety to form the acetophenone derivative, with subsequent sugar conjugation
- cleavage of the N–O bridge, followed by oxidation of the glyoxylphenyl moiety, with eventual formation of phthalic acid
- formation of unextracted residues.

### ***Environmental fate***

#### ***Water–sediment systems***

Because trifloxystrobin is used for foliar spray treatment and on paddy rice, only studies of hydrolysis and degradation in water–sediment systems were considered.

Trifloxystrobin is relatively stable hydrolytically under sterile neutral and weakly acid conditions, whereas under alkaline conditions hydrolytic degradation increases with increasing pH. The acid CGA 321113 formed under alkaline conditions is not degraded hydrolytically. No ring cleavage is observed at pH  $\geq 5$ .

In biologically active aquatic systems such as a paddy rice plot, trifloxystrobin was rapidly degraded in both flooding water and paddy soil, with a maximum half-life of 2–5 days. As in sterile hydrolysis, the main product in a paddy rice field was the acid CGA 321113. While this metabolite is stable to sterile

hydrolysis, it was rapidly degraded in the rice plot, with degradation half-lives of 7–8 days in flooding water and paddy soil. Besides CGA 321113, formed by biotic hydrolysis, isomerization of the parent compound and CGA 321113 occurred, resulting in formation of the parent *Z,E*- isomer CGA 357261 in small amounts and the acid *Z,E*- isomer CGA 373466 in large amounts. CGA 373466 degraded rapidly in the water layer, with a half-life of 4.2 days. A half-life with reasonable significance could not be estimated for CGA 357261 owing to the very low concentrations in the range of the LOQ.

The photolytic half-lives of trifloxystrobin in sterile aqueous buffered solutions at 25 °C under a xenon arc light (12 h light–12 h dark cycle) were 20.4 h at pH 5 and 31.5 h at pH 7. The corresponding predicted environmental half-lives in summer sunlight at a geographical latitude of 40° N were 1.1 and 1.7 days at pH 5 and pH 7, respectively.

#### *Rotational crops*

The Meeting received the results of confined crop rotation studies with <sup>14</sup>C-trifloxystrobin with both labels and from crop rotation trials with unlabelled trifloxystrobin. In some trials, a first crop was treated with trifloxystrobin, while in others bare ground was treated directly with trifloxystrobin as an extreme case for residues in soil from the first crop. The normal rotation was a first crop followed in rotation by a root crop (radish, turnip), a vegetable (lettuce, spinach) and a cereal (wheat). The rotation crops were sown or planted from 30 days to 1 year after the final treatment of the first crop or bare ground.

In a study with an exaggerated application rate of 2.2 kg ai/ha to bare soil, turnips, spinach and wheat were planted and components of each were analysed 30 and 120 days after application. The residue levels of trifloxystrobin equivalent were higher with the trifluoromethylphenyl label than the glyoxylphenyl label. The levels of trifluoromethylphenyl label (as trifloxystrobin equivalents) after 30/120 days were: 0.06/0.04 mg/kg in turnip leaves, 0.02/0.02 mg/kg in turnip roots, 0.25/0.26 mg/kg in spinach, 0.28/0.19 mg/kg in 25% mature wheat fodder, 0.14/0.10 mg/kg in mature wheat fodder, 0.17/0.20 mg/kg in wheat straw and 0.07/0.06 mg/kg in wheat grain. With the other label, only a small proportion of the TRR were usually identified or characterized; trifloxystrobin represented < 2%. CGA 321113 represented up to 8.5% of the TRR in turnip leaves and 17.5% in turnip roots (0.003 mg/kg). With the trifluoromethyl-<sup>14</sup>C label, 37–100% of the TRR was identified or characterized. Trifloxystrobin, its conformational isomers and the acid CGA 321113 and its isomers were reported, all at < 0.01 mg/kg. Trifluoroacetic acid was found as a major degradation product in all crops, especially in wheat (up to 0.23 mg/kg in immature fodder and 0.12 mg/kg in straw), indicating breakdown of the trifluoromethylphenyl ring. As trifluoroacetic acid was observed only rarely as a plant metabolite in target crops after foliar application, it is likely that its precursor is formed in the soil or rhizosphere of the plants.

In unconfined rotational studies with unlabelled trifloxystrobin, no residues of trifloxystrobin (< 0.02 mg/kg) or CGA 321113 (< 0.02 mg/kg) were detected in any of the rotational crops at 30-day plant-back intervals, except in wheat straw and grain in one trial.

The rotational crop studies suggest that trifloxystrobin itself and the acid CGA 321113 do not occur in rotational crops at levels ≥ 0.01 mg/kg.

#### **Methods of analysis**

The Meeting received descriptions and validation data for analytical methods for residues of trifloxystrobin and the metabolite CGA 321113 in crops and animal commodities. The methods rely on gas–liquid chromatography, HPLC and liquid chromatography with tandem mass spectrometry detection and generally achieve LOQs of 0.01–0.02 mg/kg in crop and animal matrices, except dry matrices such as hay, straw (LOQ, 0.05 mg/kg) and hops (LOQ, 0.1 mg/kg). The recoveries were in the range of 70–120% for both analytes.

In most of the field studies, the determination of trifloxystrobin and CGA 321113 in plant and animal commodities was based on extraction of the samples with acetonitrile and water (80:20, v/v), filtration,

liquid–liquid partitioning with a three-solvent system (sodium chloride-saturated water, toluene and hexane), clean-up on a C18 solid extraction column, partitioning into methyl *tert*-butyl ether:hexane, concentration to dryness and dissolution in 0.1% polyethylene glycol in acetone for gas chromatographic analysis with nitrogen–phosphorus detection. The LOQ was 0.02 mg/kg in all matrices except peanut hay and cereal straw (0.05 mg/kg) and milk (0.01 mg/kg). This method (or with electron capture detection) was used in the rotational crop, storage stability and field trial studies. The nitrogen–phosphorus detection method is proposed as a monitoring method.

The standard multi-method DFG S 19 can be used for enforcement purposes for the determination of trifloxystrobin in all plant materials except hops.

Data on the extraction efficiency of the methods with weathered radiolabelled samples from the studies of metabolism in apples, cucumbers, peanuts, wheat grain and straw, and matrices from the animal metabolism studies were submitted. The amount of residue extracted was similar to that in the metabolism studies.

### ***Stability of residues in stored analytical samples***

The Meeting received information on the stability of trifloxystrobin and CGA 321113 in crops, farm animal commodities and processed commodities at freezer temperatures for 1–2 years. Trifloxystrobin and CGA 321113 were generally stable for the duration of testing, i.e. a decline in residue levels was not evident or was < 30%.

### ***Definition of the residue***

The metabolism of trifloxystrobin in animals is similar to that in plants and occurs primarily via cleavage of the methyl ester group to form CGA 321113. In plants, the main component of the residue is trifloxystrobin. CGA 321113 is the principal residue component in animal tissues (except fat). Trifloxystrobin is the principal residue in milk and fat.

The metabolite CGA 321113 accounts for about 30% of the terminal residue in some raw plant commodities (strawberries, leeks, Brussels sprouts, flowerhead brassicas, carrots, barley, wheat, maize, rice, hops, peanut fodder, barley straw, maize fodder and rice straw). Furthermore, trifloxystrobin can be hydrolysed to CGA 321113 during processing. In these cases, the nature of the residue in the processed product may differ somewhat from that in the raw agricultural commodity. Therefore, CGA 321113 should be included in the residue definition for risk assessment for plant commodities.

The Meeting agreed that the residue definition for enforcement purposes for plant commodities should be trifloxystrobin *per se*, and that for animal commodities should be the parent compound plus CGA 321113 (expressed as trifloxystrobin equivalents).

The Meeting agreed that the residue definition for consideration of dietary intake should consist of the parent compound plus CGA 321113 (expressed as trifloxystrobin equivalents), to cover the occurrence of residues in both plant and animal commodities as well as in processed products.

The log  $P_{ow}$  for trifloxystrobin is 4.5, which suggests that the compound is fat-soluble. As the levels of trifloxystrobin were higher in fat than in muscle, residues in fat are appropriate for controlling residues in meat. The Meeting agreed that the residues of trifloxystrobin are fat-soluble.

*Definition of the residue in plant commodities for compliance with MRLs:* trifloxystrobin.

*Definition of the residue in plant commodities for estimation of dietary intake:* sum of trifloxystrobin and CGA 321113, expressed as trifloxystrobin.

*Definition of the residue in animal commodities for compliance with MRLs and estimation of dietary intake:* sum of trifloxystrobin and CGA 321113, expressed as trifloxystrobin.

The residue is fat-soluble.

### ***Results of supervised trials on crops***

The Meeting received the results of supervised trials on citrus fruit, pome fruit, stone fruit, grapes, strawberries, bananas, leeks, head cabbage, Brussels sprouts, cauliflower and broccoli, cucumbers, melons, summer squash, tomatoes, peppers, Chinese cabbage, beans, soya beans, carrots, celeriac, potatoes, sugar-beet, celery, chicory, cereals (wheat, barley, maize, rice), almonds, tree nuts, cotton-seed, peanuts, coffee beans and hops; and on animal feed items such as almond hulls, cereal straws, peanut hay and sugar-beet tops. In most cases, the acid metabolite CGA 321113 was determined as well as the parent compound.

The sum of trifloxystrobin and CGA 321113 was calculated and expressed as trifloxystrobin on the basis of the relative molecular masses. A conversion factor of 1.036 is required to express CGA 321113 as trifloxystrobin. As CGA 321113 does not generally constitute a significant proportion of the residue in crops, when the levels of trifloxystrobin or CGA 321113 were below the LOQ, their sum was calculated as in the examples below.

| Trifloxystrobin (mg/kg) | CGA 321113 (mg/kg) | Total (expressed as trifloxystrobin) (mg/kg) |
|-------------------------|--------------------|----------------------------------------------|
| < 0.02                  | < 0.02             | < 0.02                                       |
| < 0.02                  | 0.03               | 0.05                                         |
| 0.10                    | < 0.02             | 0.10                                         |
| 0.92                    | 0.16               | 1.1                                          |

Two sets of data are reported: trifloxystrobin *per se* for estimation of maximum residue levels and the sum of trifloxystrobin and CGA 321113 expressed as trifloxystrobin for estimation of STMRS.

Treatment with trifloxystrobin is limited to up to four applications per season, but in some trials on fruits (pome fruit, grapes, banana) and vegetables (cucurbits, sweet pepper, tomato) up to 10 treatments were made. To investigate the influence of the number of applications on the residue levels, two trials were conducted in apples. Trifloxystrobin was applied four times to apple trees at a rate of 0.12 or 0.15 kg ai/ha with spray intervals of 12–17 days. Samples of fruit were taken before and after each application. The average carry-over of residue (ratio of residue concentration before and after pesticide application) was approximately 40% and at the same level, suggesting that two applications are likely to result in higher residue levels than one application, but three or more applications should not produce residue levels significantly different from those resulting from two. The Meeting agreed that the residue at harvest is influenced only by the final three or four applications, and trials with more than four treatments were used to estimate maximum residue levels and STMRS.

### ***Citrus fruit***

The results of supervised trials for residues in orange, grapefruit and lemon were received from South Africa and the USA.

Use of trifloxystrobin as a foliar spray is registered in South Africa with two applications of 0.005 kg ai/hl and a PHI of 76 days. The six trials on orange that were submitted did not reflect GAP.

In the USA, trifloxystrobin may be used as a foliar spray on citrus fruit at three to four applications of 0.07–0.14 kg ai/ha with a 30-day PHI. As the level of CGA 321113 was below the LOQ in all samples, the data populations for enforcement and risk assessment purposes are identical. The levels of trifloxystrobin residues in whole fruit in trials approximating these conditions at the highest rate were: 0.05, 0.07, 0.08, 0.09, 0.10, 0.11, 0.12, 0.15 (two), 0.16, 0.17, 0.19, 0.21 and 0.23 mg/kg in orange; < 0.02, 0.03 (two), 0.04, 0.06, 0.08 (two) and 0.10 mg/kg in grapefruit; and < 0.02, 0.02, 0.09, 0.11, 0.13 and 0.22 mg/kg in lemon.

The Meeting agreed to combine these results in estimating a maximum residue level for citrus fruit. As no data were available on residues in the edible portion, the STMR was also estimated from the data for whole fruit. The combined concentrations in the 28 trials in the USA, in ranked order, were: < 0.02 (two), 0.02, 0.03 (two), 0.04, 0.05, 0.06, 0.07, 0.08 (three), 0.09 (two), 0.10 (two), 0.11 (two), 0.12, 0.13, 0.15 (two), 0.16, 0.17, 0.19, 0.21, 0.22 and 0.23 mg/kg for trifloxystrobin as well as for the sum of trifloxystrobin and CGA 321113 expressed as trifloxystrobin.

The Meeting estimated a maximum residue level of 0.5 mg/kg and an STMR value of 0.095 mg/kg for residues of trifloxystrobin in whole citrus fruits.

#### *Pome fruit*

Trials were conducted on apple and pear in Australia, Canada, Europe, South Africa and the USA.

In Australia, trifloxystrobin may be applied to *apples* in three applications of 0.005 kg ai/hl with a 35-day PHI. Because the number of treatments had little influence on the residue concentration, two trials with six applications of 0.0038 kg ai/hl were considered close enough to GAP to allow evaluation. The trifloxystrobin residue level in apples was < 0.04 mg/kg, and the level for the sum of trifloxystrobin and CGA 321113 (< 0.04 mg/kg) expressed as trifloxystrobin was 0.08 mg/kg.

GAP for use of trifloxystrobin on apples and pears is similar in many countries in Europe. In France and Italy, trifloxystrobin is registered for use on apples and pears up to a total of three applications at 0.0075 kg ai/hl with a PHI of 14 days. The trifloxystrobin residue levels in apples in four trials in France, one in Germany, one in Greece, six in Italy, three in Spain and nine in Switzerland, conducted according to appropriate GAP, were: 0.04 (two), 0.05 (four), 0.06, 0.07 (two), 0.08, 0.09 (two), 0.10 (two), 0.12, 0.13, 0.15, 0.17, 0.19 (two), 0.20, 0.21, 0.30 and 0.44 mg/kg. The residue levels of CGA 321113 were all below the LOQ.

One trial in Greece, one in Italy and two in Spain on *pears* were reported. The residue concentrations of both trifloxystrobin and the sum of trifloxystrobin and CGA 321113 expressed as trifloxystrobin were 0.06, 0.07, 0.11 and 0.12 mg/kg.

In Spain, four treatments at 0.0075–0.015 kg ai/hl with a PHI of 14 days are allowed on apples and pears. The residue concentration of both trifloxystrobin and the sum of trifloxystrobin and CGA 321113 expressed as trifloxystrobin in one Spanish trial on apples was 0.19 mg/kg.

In Germany, four treatments at 0.025 kg ai/ha per metre height of crown (0.075 kg ai/ha for a tree with a 3-m crown) and 0.005 kg ai/hl with a PHI of 14 days on apples and pears are allowed. The residue levels of trifloxystrobin and of the sum of trifloxystrobin and CGA 321113 expressed as trifloxystrobin in one trial on apples were both 0.11 mg/kg. The residue level of trifloxystrobin in one trial on pears was 0.17 mg/kg, and the level of the sum of trifloxystrobin and CGA 321113 expressed as trifloxystrobin was 0.19 mg/kg.

In Belgium and Luxembourg, four treatments with 0.085 kg ai/ha and a PHI of 14 days are allowed on apples and pears. The trifloxystrobin residue levels in apples in five trials in France, two in Germany and three in The Netherlands were: 0.03, 0.04, 0.05, 0.07 (four), 0.13 (two), 0.14 and 0.37 mg/kg. The levels of

the sum of trifloxystrobin and CGA 321113 expressed as trifloxystrobin were 0.03, 0.04, 0.05, 0.07 (four), 0.13, 0.14, 0.15 and 0.41 mg/kg.

In South Africa, trifloxystrobin is registered for use on apples at up to three applications of 0.0038–0.005 kg ai/hl with a PHI of 7 days, and it is registered for use on pears at three applications of 0.0038 kg ai/hl with a PHI of 14 days. In two trials each on apples and pears, the residue levels of trifloxystrobin were 0.03, 0.04, 0.05 and 0.06 mg/kg, and the levels of the sum of trifloxystrobin and CGA 321113 expressed as trifloxystrobin were 0.03, 0.04 and 0.06 (two) mg/kg.

The use pattern in the USA allows spraying of trifloxystrobin in four applications of 0.105 kg ai/ha on apples and pears with a PHI of 14 days. The concentrations of trifloxystrobin residues in trials in Canada and the USA in apples were: 0.04, 0.09, 0.10, 0.12, 0.13, 0.14, 0.16 (two), 0.18 (three), 0.21, 0.24, 0.26, 0.31 and 0.37 mg/kg, and those in pears were: 0.07, 0.08, 0.09, 0.10 (two), 0.14, 0.15, 0.17, 0.22 and 0.23 mg/kg. The residue levels of the sum of trifloxystrobin and CGA 321113 expressed as trifloxystrobin in apples were: 0.04, 0.09, 0.10, 0.12, 0.13, 0.14, 0.16 (two), 0.18 (two), 0.21 (two), 0.24, 0.26, 0.31 and 0.37 mg/kg, and those in pears were: 0.07, 0.08, 0.09, 0.10, 0.14, 0.15, 0.17, 0.20, 0.22 and 0.23 mg/kg.

The Meeting agreed to combine the data sets on apples and pears from two trials in Australia 42 trials in Europe, four trials in South Africa and 26 trials in Canada and the USA. The residue concentrations of trifloxystrobin *per se*, in ranked order, were: 0.03 (two), < 0.04, 0.04 (five), 0.05 (six), 0.06 (three), 0.07 (eight), 0.08 (three), 0.09 (four), 0.10 (five), 0.11 (two), 0.12 (three), 0.13 (four), 0.14 (three), 0.15 (two), 0.16 (two), 0.17 (three), 0.18 (three), 0.19 (three), 0.20, 0.21 (two), 0.22, 0.23, 0.24, 0.26, 0.30, 0.31, 0.37 (two) and 0.44 mg/kg. The residue concentrations of the sum of trifloxystrobin and CGA 321113 expressed as trifloxystrobin, in ranked order, were: 0.03 (two), < 0.04, 0.04 (five), 0.05 (five), 0.06 (four), 0.07 (eight), 0.08 (three), 0.09 (four), 0.10 (four), 0.11 (two), 0.12 (three), 0.13 (three), 0.14 (three), 0.15 (three), 0.16 (two), 0.17 (two), 0.18 (two), 0.19 (four), 0.20 (two), 0.21 (three), 0.22, 0.23, 0.24, 0.26, 0.30, 0.31, 0.37, 0.41 and 0.44 mg/kg.

The Meeting estimated a maximum residue level of 0.7 mg/kg and an STMR value of 0.11 mg/kg for residues of trifloxystrobin in pome fruit.

#### Stone fruit

The results of supervised trials on residues of trifloxystrobin in apricots, cherries, peaches and plums were received from Europe and the USA. Trifloxystrobin is registered for use on apricots, nectarines, peaches, cherries and plums in Switzerland (three applications of 0.2 kg ai/ha, 0.013 kg ai/hl, 21-day PHI) and the USA (four applications of 0.14 kg ai/ha, 1-day PHI). In Spain, trifloxystrobin may be used on peaches and nectarines four times at 0.015 kg ai/hl with a 7-day PHI.

In 14 trials on *cherry* in six states of the USA in 1998, with four applications of 0.14 kg ai/ha and harvesting after 1 day, the concentrations of trifloxystrobin residues were: 0.26, 0.33, 0.34, 0.37, 0.38, 0.39, 0.53, 0.54, 0.55, 0.56, 0.58, 0.63, 0.66 and 0.84 mg/kg. The residue concentrations of the sum of trifloxystrobin and CGA 321113 expressed as trifloxystrobin were: 0.28, 0.37, 0.38 (two), 0.41, 0.42, 0.58, 0.59 (two), 0.61, 0.62, 0.69, 0.73 and 0.90 mg/kg.

In two trials on *apricot* in Switzerland, which matched GAP, the trifloxystrobin residue levels were 0.14 and 0.28 mg/kg, and the total residue levels were 0.14 and 0.30 mg/kg.

Three trials conducted in southern Europe (France, Italy and Spain) on *peach* were evaluated against Spanish GAP. The trifloxystrobin residue levels were 0.14, 0.18 and 0.48 mg/kg, and the total residue levels were 0.15, 0.18 and 0.52 mg/kg. In 14 trials on peach in six states of the USA in 1998, with four applications of 0.14 kg ai/ha and harvesting after 1 day, the concentrations of trifloxystrobin residues were: 0.06, 0.18, 0.21, 0.25, 0.32, 0.34, 0.39, 0.41, 0.65, 0.82 (two), 0.89, 1.8 and 1.9 mg/kg. The residue concentrations of the sum of trifloxystrobin and CGA 321113 expressed as trifloxystrobin were: 0.06, 0.21 (two), 0.25, 0.32, 0.34, 0.39, 0.41, 0.70, 0.86, 0.88, 0.94, 1.9 and 2.0 mg/kg.



In nine trials on *plum* in four states of the USA in 1998, with four applications of 0.14 kg ai/ha and harvesting after 1 day, the concentrations of trifloxystrobin residues and of total residues were: 0.02, 0.06 (two), 0.09, 0.15, 0.19, 0.21 (two) and 0.53 mg/kg.

The Meeting agreed to combine the data from all the trials on residues in stone fruit. The combined results for trifloxystrobin were: 0.02, 0.06 (three), 0.09, 0.14 (two), 0.15, 0.18 (two), 0.19, 0.21 (three), 0.25, 0.26, 0.28, 0.32, 0.33, 0.34 (two), 0.37, 0.38, 0.39 (two), 0.41, 0.48, 0.53 (two), 0.54, 0.55, 0.56, 0.58, 0.63, 0.65, 0.66, 0.82 (two), 0.84, 0.89, 1.8 and 1.9 mg/kg. The residue concentrations of the sum of trifloxystrobin and CGA 321113 expressed as trifloxystrobin were: 0.02, 0.06 (three), 0.09, 0.14, 0.15 (two), 0.18, 0.19, 0.21 (four), 0.25, 0.28, 0.30, 0.32, 0.34, 0.37, 0.38 (two), 0.39, 0.41 (two), 0.42, 0.52, 0.53, 0.58, 0.59 (two), 0.61, 0.62, 0.69, 0.70, 0.73, 0.86, 0.88, 0.90, 0.94, 1.9 and 2.0 mg/kg.

The Meeting estimated a maximum residue level of 3 mg/kg and an STMR of 0.38 mg/kg for residues in stone fruit.

#### *Berries and small fruit*

Trials on *grape* were conducted in Australia, Canada, France, Germany, Greece, Italy, South Africa, Spain, Switzerland and the USA.

In Australia, trifloxystrobin may be used on grapes at 0.0075 kg ai/hl with a 35-day PHI after three applications. In trials in Australia matching GAP conditions, the trifloxystrobin residue levels were: < 0.02, 0.04, 0.08 and 0.09 (two) mg/kg. The residue concentrations of the sum of trifloxystrobin and CGA 321113 expressed as trifloxystrobin were: < 0.02, 0.04, 0.09 (two) and 0.11 mg/kg.

In Canada, trifloxystrobin may be used up to four times at 0.07 kg ai/ha and in the USA up to 0.14 kg ai/ha with a 14-day PHI. In two Canadian and 12 US trials matching GAP conditions, the trifloxystrobin residue levels were: 0.04, 0.06, 0.09, 0.16, 0.17, 0.21, 0.26, 0.28, 0.29, 0.33, 0.61, 0.62, 1.1 and 2.2 mg/kg. The residue concentrations of the sum of trifloxystrobin and CGA 321113 expressed as trifloxystrobin were: 0.04, 0.06, 0.09, 0.16, 0.17, 0.21, 0.26, 0.28, 0.33, 0.36, 0.63, 0.64, 1.2 and 2.2 mg/kg.

In Germany, registered use is three applications of 0.12 kg ai/ha with harvesting 35 days after the last treatment. Two trials in France, four in Germany and four in Switzerland with three applications of 0.13 kg ai/ha and a 35–36-day PHI matched this GAP. The trifloxystrobin residue levels were 0.03, 0.04 (three), 0.06 (two), 0.13, 0.14, 0.27 and 0.29 mg/kg. The residue concentrations of the sum of trifloxystrobin and CGA 321113 expressed as trifloxystrobin were: 0.04 (two), 0.05 (two), 0.06, 0.07, 0.16 (two), 0.29 and 0.30 mg/kg.

Trifloxystrobin is registered for use in South Africa at up to 0.011 kg ai/hl with a 14-day PHI. Residues in grapes in three trials with this use pattern were 0.11, 0.18 and 0.24 mg/kg for trifloxystrobin and 0.15, 0.22 and 0.38 mg/kg for total residues.

Trifloxystrobin is registered for use in Spain at four applications of 0.075 kg ai/ha with a 30-day PHI. In one trial in Greece, two in Italy and four in Spain approximating these conditions, the trifloxystrobin residue levels were 0.05, 0.08, 0.11, 0.13, 0.14, 0.28 and 0.36 mg/kg. The total residue levels were 0.05, 0.08, 0.11, 0.13, 0.14, 0.28 and 0.38 mg/kg.

In summary, the residue levels of trifloxystrobin *per se* in 39 trials in Australia, Europe, South Africa, Canada and the USA, in ranked order, were: < 0.02, 0.03, 0.04 (five), 0.05, 0.06 (three), 0.08 (two), 0.09 (three), 0.11 (two), 0.13 (two), 0.14 (two), 0.16, 0.17, 0.18, 0.21, 0.24, 0.26, 0.27, 0.28 (two), 0.29 (two), 0.33, 0.36, 0.61, 0.62, 1.1 and 2.2 mg/kg. The residue concentrations of the sum of trifloxystrobin and CGA 321113 expressed as trifloxystrobin were: < 0.02, 0.04 (four), 0.05 (three), 0.06 (two), 0.07, 0.08, 0.09 (three), 0.11 (two), 0.13, 0.14, 0.15, 0.16 (three), 0.17, 0.21, 0.22, 0.26, 0.28 (two), 0.29, 0.30, 0.33, 0.36, 0.38 (two), 0.63, 0.64, 1.2 and 2.2 mg/kg.

The Meeting estimated a maximum residue level of 3 mg/kg and an STMR of 0.15 mg/kg for residues in grapes.

The Swiss pattern of use of trifloxystrobin on *strawberry* allows three spray applications at 0.25 kg ai/ha with a PHI of 14 days. In five trials matching GAP conditions, the residue levels of trifloxystrobin *per se* were: 0.04, 0.05, 0.06, 0.10 and 0.13 mg/kg. The residue concentrations of the sum of trifloxystrobin and CGA 321113 expressed as trifloxystrobin were 0.08, 0.09, 0.10, 0.14 and 0.18 mg/kg.

The Meeting estimated a maximum residue level of 0.2 mg/kg and an STMR of 0.10 mg/kg for residues in strawberries.

#### *Banana*

Trifloxystrobin may be used in Latin America on bananas at four applications of 0.09 kg ai/ha with a 0-day PHI. The results of supervised trials on residues in bagged and unbagged banana after up to 11 treatments at 0.01–0.16 kg ai/ha by aerial application were received from Colombia (four), Costa Rica (six), Ecuador (six), Guatemala (four), Honduras (two) and Mexico (two). The treatment was typical of that performed by commercial aerial sprayers from a fixed-winged airplane or a helicopter. In four trials in Martinique, bananas were treated six times at 0.09 kg ai/ha by a foliar backpack sprayer with aerial boom. In two trials in Puerto Rico, plants were treated 10 times at 0.1–0.13 kg ai/ha by spraying over the top, simulating aerial application. Although the actual treatment rate in some trials exceeded GAP by more than 30%, these trials were included in the evaluation because of the very low residue levels ( $\leq$  LOQ). In whole bagged and unbagged fruit, the trifloxystrobin residue concentrations for estimation of the maximum residue level were: < 0.01 (four), < 0.02 (23), 0.02 and 0.03 (two) mg/kg. In the edible portion, the residue concentrations of the sum of trifloxystrobin and CGA 321113 expressed as trifloxystrobin were: < 0.01 (four) and < 0.02 (26) mg/kg.

The Meeting estimated a maximum residue level of 0.05 mg/kg and an STMR of 0.02 mg/kg for residues in bananas.

#### *Leek*

The Swiss pattern of use of trifloxystrobin on leeks allows three spray applications at 0.19 kg ai/ha with a PHI of 7 days. The levels of trifloxystrobin residues in leek in one trial in France, one in Germany, one in The Netherlands and two in Switzerland that met these conditions were: 0.08, 0.14, 0.15 and 0.40 (two) mg/kg. The corresponding total residues were: 0.13, 0.26, 0.31, 0.47 and 0.49 mg/kg.

The Meeting estimated a maximum residue level of 0.7 mg/kg and an STMR of 0.31 mg/kg for residues in leeks.

#### *Brassica vegetables*

The Swiss pattern of use of trifloxystrobin on broccoli, cauliflower, Brussels sprouts and head cabbage allows three spray applications at 0.13–0.25 kg ai/ha with a PHI of 7 days. The trials on head cabbage, Brussels sprouts, broccoli and cauliflower were evaluated together for mutual support.

One trial on *head cabbage* in Germany, one in The Netherlands and two in Switzerland matching maximum GAP, with a rate of 0.25 kg ai/ha, were submitted. The residue levels of trifloxystrobin *per se* were: 0.02 (two), 0.03 and 0.07 mg/kg, and those of total residues were 0.03, 0.04 (two) and 0.11 mg/kg.

Two trials on *Brussels sprouts* in France, one in Germany, two in Switzerland and one in the United Kingdom matching maximum GAP, with a rate of 0.25 kg ai/ha, were submitted. The residue levels of trifloxystrobin *per se* were: 0.10, 0.16, 0.18, 0.19, 0.20 and 0.35 mg/kg, and those of total residues were: 0.18, 0.22, 0.26, 0.27, 0.28 and 0.39 mg/kg.

One trial on *cauliflower* in Germany and two in Switzerland and two trials on broccoli in Germany and one in the United Kingdom, which matched GAP with a rate of 0.2–0.25 kg ai/ha, were submitted. The residue levels of trifloxystrobin *per se* were: < 0.01, < 0.02, 0.09, 0.13 (two) and 0.26 mg/kg, and those of total residues were: < 0.02, 0.04, 0.13, 0.16, 0.23 and 0.26 mg/kg.

The combined levels of trifloxystrobin residues in broccoli, cauliflower, Brussels sprouts and head cabbage were, in ranked order: < 0.01, < 0.02, 0.02 (two), 0.03, 0.07, 0.09, 0.10, 0.13 (two), 0.16, 0.18, 0.19, 0.20, 0.26 and 0.35 mg/kg. Those of total residues were: < 0.02, 0.03, 0.04 (three), 0.11, 0.13, 0.16, 0.18, 0.22, 0.23, 0.26 (two), 0.27, 0.28 and 0.39 mg/kg.

The Meeting estimated a maximum residue level of 0.5 mg/kg and an STMR of 0.17 mg/kg for residues in flowerhead brassica, Brussels sprouts and head cabbage.

#### *Chinese cabbage*

Trifloxystrobin is registered in Switzerland for use on Chinese cabbage up to three times at 0.25 kg ai/ha with a 7-day PHI. The concentrations of trifloxystrobin residues in Chinese cabbage in two Swiss trials were 0.01 and 0.33 mg/kg. The corresponding total residue levels were 0.01 and 0.35 mg/kg.

The Meeting concluded that there were insufficient data to estimate a maximum residue level and an STMR for residues in Chinese cabbage.

#### *Fruiting vegetables*

##### *Cucurbits*

Trifloxystrobin is registered in Switzerland for use on *cucumber* up to three times at 0.25 kg ai/ha and a 3-day PHI for indoor use. Eight trials conducted in glasshouses in Italy (one), The Netherlands (two), Spain (four) and Switzerland (one) approximated Swiss GAP. The trifloxystrobin residue levels were: 0.02, 0.03 (two), 0.04, 0.06, 0.07 and 0.14 (two) mg/kg. The total residue levels were 0.02, 0.03 (two), 0.04, 0.10, 0.12 and 0.17 (two) mg/kg.

Trifloxystrobin is registered in the USA for use on cucurbit vegetables such as chayote, Chinese waxgourd, citron melon, cucumber, gherkin, edible gourds, muskmelon, pumpkin, summer squash, winter squash and watermelon, as up to four applications of 0.14 kg ai/ha and a 0-day PHI for outdoor use. Eight outdoor trials on *cucumber* in seven states in accord with GAP conditions were reported. The trifloxystrobin residue levels were: 0.03, 0.04 (three), 0.05, 0.06, 0.17 and 0.22 mg/kg. The total residue levels were 0.03, 0.04 (three), 0.05, 0.06, 0.17 and 0.24 mg/kg.

The data from the indoor and outdoor trials on cucumbers could be combined as they were apparently for similar data populations. The residue levels of trifloxystrobin *per se* in the European and North American trials were, in ranked order: 0.02, 0.03 (three), 0.04 (four), 0.05, 0.06 (two), 0.07, 0.14 (two), 0.17 and 0.22 mg/kg. The corresponding total residue levels were 0.02, 0.03 (three), 0.04 (four), 0.05, 0.06, 0.10, 0.12, 0.17 (three) and 0.24 mg/kg.

In Italy, trifloxystrobin may be used on *melon* up to three times at 0.13 kg ai/ha with a 3-day PHI. Three trials in Italy and four in Spain complied with this use pattern. Both the trifloxystrobin and the total residue levels were: < 0.02 (two), 0.04, 0.07, 0.10, 0.11 and 0.19 mg/kg. Six trials in the USA on melons matching GAP for cucurbits resulted in trifloxystrobin and total residue levels of: 0.07, 0.10 (two), 0.11, 0.18 and 0.24 mg/kg.

In five trials in the USA on *summer squash* matching GAP for cucurbits, the trifloxystrobin and the total residue levels were: < 0.02, 0.09, 0.11, 0.15 and 0.23 mg/kg.

The Meeting decided to pool the data on cucumbers (16 trials), melons (13 trials) and summer squash (five trials) to estimate a maximum residue level for cucurbits. The trifloxystrobin residue levels were < 0.02 (three), 0.02, 0.03 (three), 0.04 (five), 0.05, 0.06 (two), 0.07 (three), 0.09, 0.10 (three), 0.11 (three), 0.14 (two), 0.15, 0.17, 0.18, 0.19, 0.22, 0.23 and 0.24 mg/kg. The corresponding total residue levels, in ranked order, were: < 0.02 (three), 0.02, 0.03 (three), 0.04 (five), 0.05, 0.06, 0.07 (two), 0.09, 0.10 (four), 0.11 (three), 0.12, 0.15, 0.17 (three), 0.18, 0.19, 0.23 and 0.24 (two) mg/kg.

The Meeting estimated a maximum residue level of 0.3 mg/kg and an STMR of 0.095 mg/kg for residues in cucurbits.

*Sweet peppers*

In the USA, trifloxystrobin may be used on sweet peppers four times at 0.14 kg ai/ha with a 3-day PHI. The levels of both trifloxystrobin and total residues in 12 outdoor trials in five states conducted according to GAP were: 0.03, 0.04 (two), 0.05 (two), 0.08, 0.12 (three), 0.14 and 0.16 (two) mg/kg.

The Meeting estimated a maximum residue level of 0.3 mg/kg, and an STMR of 0.1 mg/kg.

*Tomato*

In the USA, trifloxystrobin may be used on tomatoes four times at 0.14 kg ai/ha with a 3-day PHI. The trifloxystrobin and the total residue levels in 18 outdoor trials in five states conducted according to GAP were: < 0.02 (two), 0.03, 0.06, 0.07 (five), 0.09 (three), 0.10, 0.13, 0.20, 0.29, 0.43 and 0.49 mg/kg.

The Meeting estimated a maximum residue level of 0.7 mg/kg and an STMR of 0.08 mg/kg for residues in tomatoes.

*Legume vegetables and pulses**Beans (dry)*

Trifloxystrobin may be used on beans in Brazil three times at 0.1–0.13 kg ai/ha with a 15-day PHI. Five trials with four applications at 0.15 kg ai/ha and a further five trials with three to four applications of 0.094 kg ai/ha and a 15-day PHI in Brazil approximately matched GAP. The trifloxystrobin residue levels were < 0.02 (four) and ≤0.05 (six) mg/kg. As CGA 321113 was not determined, the trials were not considered for evaluation.

The Meeting concluded that there were insufficient data to estimate a maximum residue level and an STMR for residues in beans (dry).

*Soya beans (dry)*

Trifloxystrobin may be used on soya beans in Brazil twice at 0.056–0.075 kg ai/ha with a 30-day PHI and once at 0.056 kg ai/ha with a 20-day PHI in Argentina. Three trials with two applications at 0.063 kg ai/ha, three trials with two applications at 0.094 kg ai/ha and a further three trials with two applications at 0.13 kg ai/ha and a 21–30-day PHI in Brazil were reported. The trifloxystrobin residue levels were all < 0.05 mg/kg. As CGA 321113 was not determined, the trials were not considered for evaluation.

The Meeting concluded that there were insufficient data to estimate a maximum residue level and an STMR for residues in soya bean (dry).

*Root and tuber vegetables**Carrot*

Trifloxystrobin is registered in Switzerland for use on carrots up to three times at 0.25 kg ai/ha with a 7-day PHI. The concentrations of trifloxystrobin residues in carrots in one trial in Belgium, one in Germany, two in The Netherlands and two in Switzerland conducted according to the Swiss use pattern were: < 0.02, 0.02 (two), 0.03 (two) and 0.04 mg/kg. The corresponding total residue levels were < 0.02, 0.02, 0.03, 0.04 (two) and 0.08 mg/kg.

The Meeting estimated a maximum residue level of 0.1 mg/kg and an STMR of 0.035 mg/kg for residues in carrot.

*Celeriac*

Trifloxystrobin is registered in Switzerland for use on celeriac up to three times at 0.25 kg ai/ha with a 14-day PHI. The concentrations of trifloxystrobin residues in celeriac in two Swiss trials were 0.02 and 0.03 mg/kg. The corresponding total residue levels were 0.03 and 0.04 mg/kg.

The Meeting concluded that there were insufficient data to estimate a maximum residue level and STMR for residues in celeriac.

*Potato*

In the USA, trifloxystrobin may be used on potatoes six times at 0.14 kg ai/ha with a 7-day PHI. In 15 trials in 13 states conducted according to GAP, all the levels of trifloxystrobin and CGA 321113 residues in tubers were below the LOQ (0.02 mg/kg).

The Meeting estimated a maximum residue level of 0.02\* mg/kg and an STMR of 0.02 mg/kg for residues in potato.

*Sugar-beet*

Italian GAP allows three treatments with an emulsifiable concentrate at rates of 0.11–0.15 kg ai/ha, and Swiss GAP allows one application at 0.15 kg ai/ha, both with a PHI of 21 days, for sugar-beet. In nine trials in France, two in Italy, two in Spain and one in Switzerland that matched GAP, the residue levels of trifloxystrobin *per se* and of total residues in the roots were: < 0.02 (13) and 0.02 mg/kg.

Trifloxystrobin is registered in the USA for use on sugar-beet up to three times at 0.12 kg ai/ha with a 21-day PHI. The trifloxystrobin residue levels in sugar-beet roots in 19 trials in seven states conducted in line with these conditions were: < 0.02 (11), 0.02 (three), 0.03 (three) and 0.04 (two) mg/kg. The corresponding total residue levels were < 0.02 (11), 0.02 (three), 0.03 (two), 0.04 (two) and 0.06 mg/kg.

In summary, the trifloxystrobin residue levels in the 14 trials in Europe and 19 in the USA were: < 0.02 (24), 0.02 (four), 0.03 (three) and 0.04 (two) mg/kg. The corresponding total residue levels were < 0.02 (24), 0.02 (four), 0.03 (two), 0.04 (two) and 0.06 mg/kg.

The Meeting estimated a maximum residue level of 0.05 mg/kg and an STMR of 0.02 mg/kg for residues in sugar-beet.

*Celery*

Trifloxystrobin is registered in Switzerland for use on celery up to three times at 0.25 kg ai/ha with a 7-day PHI. The concentrations of trifloxystrobin and total residues in whole celery plants without roots in three Swiss trials conducted according to GAP were: 0.12, 0.18 and 0.21 mg/kg.

The Meeting concluded that there were sufficient data and estimated a maximum residue level of 1 mg/kg and an STMR of 0.18 mg/kg for residues in celery as a minor crop.

*Witloof chicory*

Trifloxystrobin is registered in Switzerland for use on chicory up to three times at 0.25 kg ai/ha with a 21-day PHI. The concentrations of trifloxystrobin residues in chicory leaves in two Swiss trials were 0.34 and 0.86 mg/kg. The corresponding total residue levels were 0.37 and 0.94 mg/kg. The trifloxystrobin and the total residue levels in the roots were both 0.02 mg/kg.

The Meeting concluded that there were insufficient data to estimate a maximum residue level and STMR for residues in witloof chicory.

*Cereal grains**Barley*

In some countries of Europe, trifloxystrobin is used twice at 0.25 kg ai/ha (France, Germany, United Kingdom) or 0.19 kg ai/ha (Belgium) or once at 0.15 kg ai/ha (Austria). The PHI is 35 days in Austria, Germany and the United Kingdom and 42 days in Belgium and France. In one trial in Denmark, 30 in France, six in Germany and two in the United Kingdom matching the appropriate European GAP, the trifloxystrobin residue levels in barley grain were < 0.02 (10), 0.02 (four), 0.03 (five), 0.04 (two), 0.05 (four), 0.06, 0.07 (three), 0.11 (four), 0.12 (two), 0.13 (two), 0.18 and 0.40 mg/kg. The corresponding total residue levels were < 0.02 (10), 0.02 (four), 0.03 (four), 0.04 (three), 0.05 (two), 0.07 (four), 0.09 (two), 0.11 (three), 0.13, 0.14, 0.15, 0.16, 0.17, 0.18 and 0.46 mg/kg.

The Meeting estimated a maximum residue level of 0.5 mg/kg and an STMR of 0.04 mg/kg for residues in barley. A highest residue level of 0.46 mg/kg was estimated for calculating the dietary burden of farm animals.

*Wheat*

Brazilian GAP allows two treatments at 0.075 kg ai/ha with a 30-day PHI. Six Brazilian trials were conducted with three applications at 0.15 kg ai/ha. In all these trials, the trifloxystrobin residue levels were below the LOQ of 0.05 mg/kg. As CGA 321113 was not determined, the trials were not considered for evaluation.

Trifloxystrobin may be used twice at 0.25 kg ai/ha in France Germany, Ireland and the United Kingdom; at 0.19 kg ai/ha in Austria, Belgium, Hungary, Italy, Luxembourg, Poland and Switzerland; and at 0.13 kg ai/ha in Slovakia, with PHIs of 35–45 days. In 26 trials in France, 10 in Germany, one in Sweden and two in Switzerland matching the appropriate European GAP, the trifloxystrobin residue levels in wheat grain were: < 0.02 (32), 0.02 (three), 0.03 (two), 0.05 and 0.14 mg/kg. The corresponding total residue levels were: < 0.02 (32), 0.02 (three), 0.03 (two), 0.07 and 0.20 mg/kg.

Trifloxystrobin is registered in the USA for use on wheat up to two times at 0.09 kg ai/ha with a 35-day PHI. In 33 trials in 11 states where these conditions were approximated, the trifloxystrobin and the total residue levels in wheat grain were: < 0.02 (30), 0.02 and 0.03 (two) mg/kg.

In summary, the trifloxystrobin residue levels in the 39 European and the 33 US trials were: < 0.02 (62), 0.02 (four), 0.03 (four), 0.05 and 0.14 mg/kg. The corresponding total residue levels were: < 0.02 (62), 0.02 (four), 0.03 (four), 0.07 and 0.20 mg/kg.

The Meeting estimated a maximum residue level of 0.2 mg/kg and an STMR of 0.02 mg/kg for residues in wheat. A highest residue level of 0.2 mg/kg was estimated for calculating the dietary burden of farm animals.

*Maize*

Brazilian GAP allows two treatments at 0.075–0.1 kg ai/ha with a 30-day PHI. Three Brazilian trials at three times 0.1 kg ai/ha were conducted. In all the trials, the trifloxystrobin residue levels were below the LOQ of 0.05 mg/kg. As CGA 321113 was not determined, the trials were not considered for evaluation.

Trifloxystrobin is registered in the USA for use on maize up to three times at 0.11 kg ai/ha. The PHI for maize grain is not specified, but the product should not be applied after silking. In 24 field trials in 14 states where these conditions were approximated, the levels of trifloxystrobin residues in maize grain were < 0.02 (24) mg/kg, and the total residue levels were < 0.02 (23) and 0.05 mg/kg.

The Meeting estimated a maximum residue level and an STMR of 0.02 mg/kg for residues in maize. A highest residue level of 0.05 mg/kg was estimated for calculating the dietary burden of farm animals.

*Rice*

Brazilian GAP allows two foliar treatments at 0.10–0.13 kg ai/ha with a 15-day PHI. Five Brazilian trials with three applications at 0.15 kg ai/ha and a 14–18-day PHI were conducted. The levels of trifloxystrobin residues in rice grain with husk were: < 0.05, 0.05, 0.10, 0.13 and 0.22 mg/kg. As CGA 321113 was not determined, these trials were not included in the evaluation.

Trifloxystrobin is registered in the USA for use on rice up to two times at 0.17 kg ai/ha with a 35-day PHI. In 19 trials in five states where these conditions were approximated, the trifloxystrobin residue levels in rice grain with husk before processing were: < 0.02 (five), 0.03, 0.04 (two), 0.10, 0.11 (two), 0.12, 0.25, 0.30, 0.34, 0.56, 0.68, 2.4 and 3.4 mg/kg. The corresponding total residue levels were < 0.02 (five), 0.04, 0.06, 0.07, 0.13, 0.16, 0.20, 0.21, 0.33, 0.41, 0.46, 0.63, 0.75, 2.5 and 3.4 mg/kg.

The Meeting estimated a maximum residue level of 5 mg/kg and an STMR of 0.16 mg/kg for residues in rice. A highest residue level of 3.4 mg/kg was estimated for calculating the dietary burden of farm animals.

*Tree nuts*

Trifloxystrobin is registered in the USA for use on beechnuts, brazil nuts, butternuts, cashew nuts, chestnuts, chinquapins, filberts, macadamia nuts and walnuts up to four times, and almonds up to three times at 0.14 kg ai/ha with a 60-day PHI. Three treatments at 0.091 kg ai/ha with a PHI of 30 days may be used on pecans.

In six trials on *almonds* in California in which these conditions were approximated, the trifloxystrobin and the total residue levels in almond nuts without shells were < 0.02 mg/kg.

In 11 trials on *pecans* in five states, with eight treatments at 0.14 kg ai/ha and a 30-day PHI, the trifloxystrobin and the total residue levels in pecan nuts without shells were < 0.02 mg/kg.

The Meeting estimated a maximum residue level of 0.02\* mg/kg and an STMR of 0 mg/kg for residues in tree nuts.

*Cotton-seed*

Brazilian GAP allows up to three foliar treatments at 0.063–0.075 kg ai/ha with a 21-day PHI. Three Brazilian trials with three applications at 0.1 kg ai/ha and a 21-day PHI were conducted. The samples were not analysed for CGA 321113. In all three trials, the trifloxystrobin residue levels were below the LOQ of 0.05 mg/kg.

The Meeting concluded that there were insufficient data to estimate a maximum residue level and an STMR for cotton-seed.

*Peanuts*

Brazilian GAP allows three foliar treatments at 0.075 kg ai/ha with a 15-day PHI for peanuts. Three Brazilian trials with three applications at 0.10 kg ai/ha and a 15-day PHI were conducted. The trifloxystrobin residue levels in peanuts without shells were < 0.05 mg/kg. As CGA 321113 was not determined, these trials were not included in the evaluation.

Trifloxystrobin is registered in the USA for use on peanuts twice at an application rate of 0.13 kg ai/ha or six times at 0.064 kg ai/ha with a PHI of 14 days. In 22 trials with eight applications at 0.07 kg ai/ha and 12 trials with eight applications at 0.14 kg ai/ha were in seven states in 1996–98, the trifloxystrobin and total residue levels in kernels were all < 0.02 mg/kg.

The Meeting estimated a maximum residue level of 0.02\* mg/kg and an STMR of 0 mg/kg for residues in peanuts.

*Coffee beans*

Brazilian GAP allows three treatments at 0.075–0.11 kg ai/ha with a 30-day PHI. Four Brazilian trials with three applications at 0.11 kg ai/ha were conducted. In all four trials, the trifloxystrobin residue levels were below the LOQ of 0.05 mg/kg. As CGA 321113 was not determined, these trials were not included in the evaluation.

The Meeting concluded that there were insufficient data to estimate a maximum residue level or an STMR for coffee beans.

*Hops*

German and Austrian GAP allows two treatments of hops at a spray concentration of 0.013 kg ai/hl and a PHI of 14 days. Five German trials with four to six applications of trifloxystrobin at a spray concentration of 0.013 kg ai/ha were reported. In cones harvested 14 days after the last treatment and dried, the trifloxystrobin residue levels were: 4.7, 5.4, 8.8, 16 and 26 mg/kg. The corresponding total residue levels were: 6.2, 6.7, 10, 18 and 29 mg/kg.

In the USA, trifloxystrobin may be used on hops four times at 0.14 kg ai/ha with a 14-day PHI. In three trials in two states with six treatments at 0.14 kg ai/ha and a 13–14-day PHI, the trifloxystrobin residue levels in dried cones were 4.5, 9.3 and 10 mg/kg. The corresponding total residue levels were 4.9, 9.9 and 11 mg/kg.

In summary, the trifloxystrobin residue levels in the three trials in Germany and the three in the USA were: 4.5, 4.7, 5.4, 8.8, 9.3, 10, 16 and 26 mg/kg, and the corresponding total residue levels were: 4.9, 6.2, 6.7, 9.9, 10, 11, 18 and 29 mg/kg.

The Meeting estimated a maximum residue level of 40 mg/kg and an STMR of 9.95 mg/kg for residues in hops, dry.

*Animal feedstuffs**Almond hulls*

Trifloxystrobin is registered in the USA for use on almonds up to three times at 0.14 kg ai/ha and a 60-day PHI. Six trials on almonds in California approximating these conditions were reported. The trifloxystrobin residue levels in hulls were: 0.25, 0.42, 0.72, 1.2, 1.6 and 1.8 mg/kg, and the total residue levels were: 0.25, 0.42, 0.75, 1.2, 1.6 and 1.9 mg/kg (fresh weight).

Allowing for the standard 90% dry matter for almond hulls (*FAO Manual*, p. 147), the Meeting estimated a maximum residue level of 3 mg/kg and an STMR of 1.08 mg/kg for almond hulls (dry weight). A highest residue level of 2.1 mg/kg was estimated for calculating the dietary burden of farm animals.

*Peanut fodder*

Trifloxystrobin is registered in the USA for use on peanuts with a maximum GAP of two applications at 0.13 kg ai/ha and a PHI of 14 days. In 12 trials with eight applications at 0.14 kg ai/ha in six states in 1996, the trifloxystrobin residue levels in peanut hay were: 0.19 (two), 0.25, 0.27, 0.29, 0.34, 0.46, 0.71, 0.84, 1.4, 3.4 and 3.7 mg/kg. The corresponding total residue levels were: 0.37, 0.40, 0.42, 0.47, 0.50, 0.63, 0.82, 1.1, 1.4, 2.1, 4.1 and 4.2 mg/kg (fresh weight).



Allowing for the standard 85% dry matter for peanut hay (*FAO Manual*, p. 148), the Meeting estimated a maximum residue level of 5 mg/kg and an STMR (dry weight) of 0.85 mg/kg for residues in peanut fodder. A highest residue level of 4.94 mg/kg was estimated for calculating the dietary burden of farm animals.

*Barley straw and fodder, dry*

Trifloxystrobin may be used twice at 0.25 kg ai/ha in France, Germany and the United Kingdom; twice at 0.19 kg ai/ha in Belgium; and once at 0.15 kg ai/ha in Austria. The PHI is 35 days in Austria, Germany and the United Kingdom and 42 days in Belgium and France. The trifloxystrobin residue levels in barley straw in one trial in Denmark, 23 in France, six in Germany and two in the United Kingdom, matching appropriate European GAP were: 0.09, 0.15, 0.23, 0.31, 0.32, 0.33, 0.38 (two), 0.43, 0.49, 0.50, 0.53, 0.61, 0.64, 0.66, 0.68, 0.69, 0.72, 0.78, 0.81 (two), 0.91 (two), 0.93, 1.0, 1.1, 1.3, 1.5, 1.6, 1.8, 2.4 and 4.2 mg/kg. The corresponding total residue levels were: 0.09, 0.15, 0.30, 0.33, 0.38 (three), 0.48, 0.58, 0.64, 0.67, 0.68, 0.75, 0.77, 0.79, 0.80 (two), 0.86, 0.93, 0.94 (two), 1.1 (four), 1.5 (two), 1.7, 1.8, 1.9, 2.6 and 4.4 mg/kg (fresh weight).

Allowing for the standard 89% dry matter for barley straw (*FAO Manual*, p. 147), the Meeting estimated a maximum residue level of 7 mg/kg and an STMR value (dry weight) of 0.9 mg/kg for residues in barley straw and fodder, dry. A highest residue level of 4.9 mg/kg was estimated for calculating the dietary burden of farm animals.

*Wheat straw and fodder, dry*

Trifloxystrobin may be used on wheat at 0.25 kg ai/ha in France, Germany, Ireland and the United Kingdom; at 0.19 kg ai/ha in Austria, Belgium, Hungary, Italy, Luxembourg, Poland and Switzerland; and at 0.13 kg ai/ha in Slovakia. The PHIs are 35–45 days. In 26 trials in France, 10 in Germany, one in Sweden and two in Switzerland that matched appropriate European GAP, the trifloxystrobin residue levels in wheat straw were: < 0.05, 0.07, 0.09 (two), 0.13, 0.16 (two), 0.17, 0.19 (two), 0.30, 0.31, 0.33, 0.34, 0.35, 0.38, 0.40, 0.50, 0.57, 0.59, 0.62, 0.70, 0.73, 0.76, 0.77, 0.81, 0.83, 0.85, 0.94, 0.99, 1.1, 1.3 (two), 1.4, 1.6, 1.8, 1.9, 2.3 and 2.5 mg/kg. The corresponding total residue levels were < 0.05, 0.07, 0.09, 0.13, 0.15, 0.16 (two), 0.24, 0.25, 0.26, 0.38 (three), 0.41, 0.42, 0.43, 0.51, 0.57, 0.77, 0.78 (two), 0.87, 0.89, 0.94, 0.95 (two), 1.0, 1.1, 1.2 (two), 1.3, 1.5, 1.6, 1.7, 1.8, 2.1, 2.6 (two) and 2.7 mg/kg (fresh weight).

Trifloxystrobin is registered in the USA for use on wheat up to two times at 0.09 kg ai/ha with a 35-day PHI. In 23 trials in eight states where these conditions were approximated, the trifloxystrobin residue levels in wheat straw were: 0.08 (two), 0.11 (two), 0.12 (two), 0.13, 0.14, 0.15, 0.17, 0.19 (two), 0.26, 0.27, 0.29, 0.31, 0.34, 0.51, 0.61, 0.96, 0.97, 1.4 and 1.9 mg/kg. The corresponding total residue levels were 0.08, 0.11 (three), 0.12 (two), 0.14, 0.15 (two), 0.19, 0.21, 0.22, 0.26, 0.29, 0.31, 0.36, 0.44, 0.51, 0.64, 1.0, 1.1, 1.6 and 2.4 mg/kg (fresh weight).

In summary, the trifloxystrobin residue levels in the 39 European and the 23 US trials, in ranked order, were: < 0.05, 0.07, 0.08 (two), 0.09 (two), 0.11 (two), 0.12 (two), 0.13 (two), 0.14, 0.15, 0.16 (two), 0.17 (two), 0.19 (four), 0.26, 0.27, 0.29, 0.30, 0.31 (two), 0.33, 0.34 (two), 0.35, 0.38, 0.40, 0.50, 0.51, 0.57, 0.59, 0.61, 0.62, 0.70, 0.73, 0.76, 0.77, 0.81, 0.83, 0.85, 0.94, 0.96, 0.97, 0.99, 1.1, 1.3 (two), 1.4 (two), 1.6, 1.8, 1.9 (two), 2.3 and 2.5 mg/kg. The total residue levels were: < 0.05, 0.07, 0.08, 0.09, 0.11 (three), 0.12 (two), 0.13, 0.14, 0.15 (three), 0.16 (two), 0.19, 0.21, 0.22, 0.24, 0.25, 0.26 (two), 0.29, 0.31, 0.36, 0.38 (two), 0.38, 0.41, 0.42, 0.43, 0.44, 0.51 (two), 0.57, 0.64, 0.77, 0.78 (two), 0.87, 0.89, 0.94, 0.95 (two), 1.0 (two), 1.1 (two), 1.2 (two), 1.3, 1.5, 1.6 (two), 1.7, 1.8, 2.1, 2.4, 2.6 (two) and 2.7 mg/kg (fresh weight).

Allowing for the standard 88% dry matter for wheat straw (*FAO Manual*, p. 149), the Meeting estimated a maximum residue level of 5 mg/kg and an STMR (dry weight) of 0.48 mg/kg for residues in wheat straw and fodder, dry. A highest residue level of 3.07 mg/kg was estimated for calculating the dietary burden of farm animals.

*Maize fodder*

Trifloxystrobin is registered in the USA for use on maize up to three times at 0.11 kg ai/ha. In 24 field trials in 14 states where these conditions were approximated and with a PHI of 30 days, the trifloxystrobin residue levels in maize stover were: 0.04, 0.32, 0.37, 0.42, 0.43, 0.53, 0.56, 0.64, 0.88, 0.96 (two), 1.0, 1.2, 1.5, 2.0, 2.1, 2.2 (two), 2.7, 2.9, 3.2, 3.9, 4.0 and 5.4 mg/kg. The corresponding total residue levels were 0.09, 0.37, 0.41, 0.47, 0.56, 0.65, 0.74, 0.80, 1.3, 1.4 (three), 1.5, 1.9, 2.4, 2.5, 2.6, 2.8, 3.5, 3.9, 4.4 (two), 4.5 and 7.1 mg/kg.

Allowing for the standard 83% dry matter for maize stover (*FAO Manual*, p. 147), the Meeting estimated a maximum residue level of 10 mg/kg and an STMR (dry weight) of 1.75 mg/kg for residues in maize fodder. A highest residue level of 8.55 mg/kg was estimated for calculating the dietary burden of farm animals.

*Rice straw and fodder, dry*

Trifloxystrobin is registered in the USA for use on rice up to two times at 0.17 kg ai/ha with a 35-day PHI. In 19 trials in five states where these conditions were approximated, the trifloxystrobin residue levels in rice straw were: 0.07, 0.25, 0.37, 0.42, 0.44, 0.50, 0.54, 0.57, 0.78, 1.0, 1.1, 1.3, 2.0, 2.4, 2.5, 2.6 (two), 5.3 and 6.1 mg/kg. The corresponding total residue levels were 0.07, 0.32, 0.45, 0.54, 0.60, 0.74, 0.83, 0.84, 1.0, 1.3, 1.6, 2.1, 2.6, 3.2 (three), 3.7, 5.5 and 7.3 mg/kg (fresh weight).

Allowing for the standard 90% dry matter for rice straw (*FAO Manual*, p. 149), the Meeting estimated a maximum residue level of 10 mg/kg and an STMR (dry weight) of 1.4 mg/kg for residues in rice straw and fodder, dry. A highest residue level of 8.1 mg/kg was estimated for calculating the dietary burden of farm animals.

*Sugar-beet leaves or tops*

Italian GAP allows three treatments at rates of 0.11–0.15 kg ai/ha, and Swiss GAP allows once at 0.15 kg ai/ha, both with a PHI of 21 days, for sugar-beets. The residue levels of trifloxystrobin *per se* in sugar-beet tops in nine trials in France, two in Italy, two in Spain and one in Switzerland matching GAP were: < 0.02 (three), < 0.05 (five), 0.05, 0.07, 0.09, 0.14, 0.33 and 0.44 mg/kg. The corresponding total residue levels were: < 0.02 (three), < 0.05 (five), 0.05, 0.09 (two), 0.17, 0.41 and 0.44 mg/kg (fresh weight).

Trifloxystrobin is registered in the USA for use on sugar-beet up to three times at 0.12 kg ai/ha with a 21-day PHI. In 19 trials in seven states where these conditions were matched, the trifloxystrobin residues in sugar-beet tops were 0.08 (two), 0.14, 0.17, 0.21, 0.23, 0.24, 0.26, 0.35, 0.54, 0.56, 0.61, 0.64, 0.72, 0.98, 1.6, 2.3 and 2.4 (two) mg/kg. The corresponding total residue levels were 0.08 (two), 0.14, 0.17, 0.23 (two), 0.24, 0.26, 0.39, 0.54, 0.61 (two), 0.66, 0.72, 0.98, 1.6, 2.4 and 2.5 (two) mg/kg (fresh weight).

The data sets from Europe and the USA appeared to be from different populations and were not combined. The Meeting agreed to estimate a maximum residue level and an STMR on the basis of the results of the trials in the USA.

Allowing for the standard 23% dry matter for sugar beet tops (*FAO Manual*, p. 147), the Meeting estimated a maximum residue level of 15 mg/kg and an STMR (dry weight) of 2.3 mg/kg for residues in sugar-beet leaves or tops. A highest residue level of 10.9 mg/kg was estimated for calculating the dietary burden of farm animals.

***Fate of residues during processing***

The Meeting received information on the fate and nature of trifloxystrobin residues under various conditions of hydrolysis. Trifloxystrobin is partially hydrolysed to CGA 321113 under conditions representative of baking, brewing and boiling (2.6%) and sterilization (22.5%). It was stable under conditions representative of pasteurization. Any possible effects of hydrolysis on the nature of the residue during

processing are covered by the fact that the only relevant metabolite (CGA 321113) was determined in all the residue and processing trials.

The effect of processing on the level of residues of trifloxystrobin has been studied for barley, cabbage, cotton, grapes, hops, maize, oranges, peanuts, pome fruit, potatoes, rice, stone fruit, strawberries, sugar-beet, tomatoes and wheat. The processing factors shown below were calculated from the total residue levels (sum of trifloxystrobin and CGA 321113, expressed as trifloxystrobin).

| Raw agricultural commodity | Processed product  | No. of samples | Mean processing factor |
|----------------------------|--------------------|----------------|------------------------|
| Orange                     | Juice              | 5              | < 0.19                 |
|                            | Oil                | 5              | 130                    |
|                            | Pulp, dry          | 5              | 3.4                    |
| Apple, pear                | Juice              | 7              | 0.16                   |
|                            | Sauce and preserve | 4              | 0.48                   |
|                            | Fruit, dried       | 2              | 0.39                   |
|                            | Pomace, wet        | 6              | 9.4                    |
|                            | Pomace, dried      | 1              | 25.6                   |
| Plum                       | Dried prune        | 4              | 1.5                    |
| Peach                      | Preserve           | 1              | < 0.05                 |
| Grapes                     | Juice              | 14             | 0.24                   |
|                            | Must               | 27             | 0.46                   |
|                            | Wine               | 35             | 0.15                   |
|                            | Fruit, dried       | 4              | 2.3                    |
|                            | Pomace, wet        | 1              | 2.25                   |
| Strawberry                 | Preserve           | 2              | 0.29                   |
|                            | Jam                | 2              | 0.62                   |
| Tomato                     | Paste              | 5              | 1.6                    |
|                            | Puree              | 5              | 0.56                   |
| Potato                     | Flakes             | 2              | < 0.42                 |
|                            | Chips              | 2              | < 0.42                 |
|                            | Wet peel           | 2              | 2.3                    |
| Sugar-beet                 | White sugar        | 2              | < 0.18                 |
|                            | Dried pulp         | 2              | 3.4                    |
|                            | Molasses           | 2              | 1.5                    |
| Barley                     | Beer               | 1              | 0.04                   |
| Wheat                      | Bran               | 2              | 2.7                    |
|                            | Germ               | 1              | < 0.67                 |
|                            | Meal and flour     | 2              | 0.4                    |
|                            | Wholemeal          | 1              | 0.5                    |
|                            | Wholemeal bread    | 1              | 0.25                   |
| Rice                       | Polished grain     | 4              | 0.18                   |
|                            | Hull               | 4              | 3.2                    |
|                            | Bran               | 4              | 1.4                    |
| Hops                       | Spent hops         | 1              | 0.04                   |
|                            | Yeast              | 1              | 0.007                  |

| Raw agricultural commodity | Processed product | No. of samples | Mean processing factor |
|----------------------------|-------------------|----------------|------------------------|
|                            | Beer              | 1              | < 0.001                |

*Oranges* were processed into juice, oil and dried pulp with processing factors of < 0.19, 130 and 3.4, respectively. On the basis of the STMR value of 0.095 mg/kg for whole citrus fruits, the STMR-Ps were 0.018 mg/kg for citrus juice and 12 mg/kg for oil. Allowing for the standard 91% dry matter, the Meeting estimated a maximum residue level of 1 mg/kg and an STMR-P of 0.35 mg/kg ( $0.095 \times 3.4 \times 1.0989$ ) for residues in dried citrus pulp (dry weight).

*Apples* and *pears* were processed into juice, sauce or preserve, wet pomace, dry pomace and dried fruit, with processing factors of 0.16, 0.48, 9.4, 25.6 and 0.39, respectively. On the basis of the STMR value of 0.11 mg/kg for pome fruit, the STMR-P was 0.018 mg/kg for juice, 0.053 mg/kg for sauce, 0.053 mg/kg for preserve and 0.043 mg/kg for dried fruit of apple and pear. In the *FAO Manual* (Appendix IX), wet apple pomace is listed as animal feed. Allowing for the standard 40% dry matter, the Meeting estimated an STMR-P of 2.6 mg/kg ( $0.11 \times 9.4 \times 2.5$ ) for residues in wet apple pomace (dry weight).

*Peaches* were processed into preserve (canned fruits) with a processing factor of 0.05. On the basis of the STMR value of 0.38 mg/kg for stone fruit, the STMR-P was 0.019 mg/kg for residues in canned fruits of peaches, nectarines and apricots.

*Plums* were processed into dried prunes with a processing factor of 1.5. On the basis of the STMR value of 0.38 mg/kg for stone fruit, the STMR-P was 0.57 mg/kg for dried prunes.

*Grapes* were processed into juice, must, wine and dried fruit (raisins) with processing factors of 0.24, 0.46, 0.15 and 2.3, respectively. On the basis of the STMR value of 0.15 mg/kg for grapes, the STMR-P was 0.036 mg/kg for juice, 0.07 mg/kg for must, 0.023 mg/kg for wine and 0.345 mg/kg for raisins (dried grapes). On the basis of the highest trifloxystrobin residue level of 2.2 mg/kg, the Meeting estimated a maximum residue level of 5 mg/kg for residues in raisins (dried grapes).

*Strawberries* were processed into preserve (canned fruits) and jam with processing factors of 0.29 and 0.62, respectively. On the basis of the STMR value of 0.10 mg/kg for strawberries, the STMR-P values were 0.029 mg/kg for residues in canned strawberries and 0.062 mg/kg for those in jam.

*Head cabbage* was cooked. Because residues were not detected in the raw commodity, a processing factor could not be calculated and the levels of residues in the processed commodity could not be estimated.

*Tomatoes* were processed into paste and puree with processing factors of 1.6 and 0.56, respectively. On the basis of the STMR value of 0.08 mg/kg for tomato, the STMR-Ps were 0.13 mg/kg for residues in tomato paste and 0.045 mg/kg for residues in puree.

*Potatoes* were processed into flakes, chips and wet peel with processing factors of 0.42, 0.42 and 2.3, respectively. On the basis of the STMR value of 0.02 mg/kg for residues in potatoes, the STMR-Ps were 0.008 mg/kg for residues in potato flakes and chips. In the *FAO Manual* (Appendix IX), wet peel (processed potato waste) is listed as animal feed. Allowing for the standard 15% dry matter, an STMR-P of 0.307 mg/kg ( $0.02 \times 2.3 \times 6.67$ ) was estimated for potato wet peel (dry weight).

*Sugar-beet* was processed into white sugar, dried pulp and molasses with processing factors of 0.18, 3.4 and 1.5, respectively. On the basis of the STMR value of 0.02 mg/kg, the STMR-P for white sugar was 0.0036 mg/kg. In the *FAO Manual* (Appendix IX), sugar-beet dried pulp (88% dry matter) and molasses (75% dry matter) are listed as animal feeds. On the basis of the highest trifloxystrobin residue level of 0.04 mg/kg, the Meeting estimated maximum residue levels of 0.2 mg/kg ( $0.04 \times 3.4 \times 1.14$ ) for sugar-beet dried pulp and 0.1 mg/kg ( $0.04 \times 1.5 \times 1.33$ ) for sugar-beet molasses (dry weight). The estimated STMR-P values were 0.077 mg/kg ( $0.02 \times 3.4 \times 1.14$ ) for sugar-beet dried pulp and 0.04 mg/kg ( $0.02 \times 1.5 \times 1.33$ ) for sugar beet molasses (dry weight).

*Wheat* was processed into the milled by-products bran, flour, wholemeal, wholemeal bread and germ, with processing factors of 2.7, 0.4, 0.67, 0.33 and 0.67, respectively. On the basis of the STMR value of 0.02 mg/kg for wheat grain, the STMR-Ps were 0.008 for wheat flour, 0.01 for wholemeal, 0.005 for wholemeal bread and 0.013 for germ. In the *FAO Manual* (Appendix IX), bran is listed as an animal feed. Allowing for the standard 88% dry matter for wheat milled by-products, the Meeting estimated an STMR-P of 0.062 mg/kg ( $0.02 \times 2.7 \times 1.14$ ) for wheat bran, unprocessed (dry weight). On the basis of the highest trifloxystrobin residue level of 0.14 mg/kg, the Meeting estimated a maximum residue level of 0.5 mg/kg ( $0.14 \times 2.7 \times 1.14 = 0.43$ ) for wheat bran, unprocessed (dry weight).

*Maize* was processed to meal, grits, flour and oil. Because residues were not detected in the raw commodity, processing factors could not be calculated and the residue levels in the processed commodities could not be estimated.

*Rice* with husk was processed into polished rice, bran and hulls with processing factors of 0.18, 1.4 and 3.2, respectively. On the basis of the STMR of 0.16 mg/kg for rice with husks, an STMR-P of 0.029 mg/kg was calculated for polished rice. In the *FAO Manual* (Appendix IX), rice bran and hulls are listed as animal feed. Allowing for the standard 90% dry matter, the Meeting estimated STMR-P values of 0.57 mg/kg ( $0.16 \times 3.2 \times 1.1$ ) for rice hulls and 0.25 mg/kg ( $0.16 \times 1.4 \times 1.1$ ) for rice bran, unprocessed (dry weight). On the basis of the highest trifloxystrobin residue level of 3.4 mg/kg in rice with husks, the Meeting estimated a maximum residue level of 7 mg/kg for residues in rice bran, unprocessed (dry weight).

*Cotton* was processed to refined oil. Because residues were not detected in the raw commodity, a processing factor could not be calculated and the residue levels in the processed commodities could not be estimated.

*Peanuts* were processed to meal and refined oil. Because residues were not detected in the raw commodity, a processing factor could not be calculated and the residue levels in the processed commodities could not be estimated.

*Hops* were processed for use in beer, with a processing factor of 0.001. On the basis of the STMR value of 9.95 mg/kg for dry hops, an STMR-P of 0.01 mg/kg was calculated for beer. *Barley* was processed into beer with a processing factor of 0.04. On the basis of the STMR value of 0.04 mg/kg, the STMR-P for beer was 0.0016 mg/kg. Because the STMR-P arising from residues in barley was lower, the Meeting estimated an STMR-P of 0.01 mg/kg for residues in beer, on the basis of residues in hops.

## Residues in animal commodities

### Dietary burden of farm animals

The Meeting estimated the dietary burden of trifloxystrobin residues in farm animals on the basis of the diets listed in Appendix IX of the *FAO Manual*. Calculation from highest residue and STMR-P values provides the levels in feed suitable for estimating MRLs, while calculation from STMR and STMR-P values for feed is suitable for estimating STMR values for animal commodities. The percentage dry matter is taken as 100% when the highest residue levels and STMRs are already expressed as dry weight.

### Estimated maximum dietary burden of farm animals

| Commodity         | CC | Residue<br>(mg/kg) | Basis  | Dry<br>matter<br>(%) | Residue,<br>dry weight<br>(mg/kg) | Diet content (%) |                 |         | Residue contribution<br>(mg/kg) |                 |         |
|-------------------|----|--------------------|--------|----------------------|-----------------------------------|------------------|-----------------|---------|---------------------------------|-----------------|---------|
|                   |    |                    |        |                      |                                   | Beef<br>cattle   | Dairy<br>cattle | Poultry | Beef<br>cattle                  | Dairy<br>cattle | Poultry |
| Almond hulls      | AM | 2.1                | HR     | 100                  | 2.1                               |                  |                 |         |                                 |                 |         |
| Apple pomace, wet | AB | 2.6                | STMR-P | 100                  | 2.6                               | 15               |                 |         | 0.39                            |                 |         |

| Commodity                           | CC | Residue<br>(mg/kg) | Basis  | Dry<br>matter<br>(%) | Residue,<br>dry weight<br>(mg/kg) | Diet content (%) |                 |         | Residue contribution<br>(mg/kg) |                 |         |
|-------------------------------------|----|--------------------|--------|----------------------|-----------------------------------|------------------|-----------------|---------|---------------------------------|-----------------|---------|
|                                     |    |                    |        |                      |                                   | Beef<br>cattle   | Dairy<br>cattle | Poultry | Beef<br>cattle                  | Dairy<br>cattle | Poultry |
| Barley grain                        | GC | 0.46               | HR     | 88                   | 0.528                             |                  |                 | 40      |                                 |                 | 0.211   |
| Barley straw                        | AS | 4.9                | HR     | 100                  | 4.9                               |                  | 60              |         |                                 | 2.94            |         |
| Citrus pulp, dried                  | AB | 0.35               | STMR-P | 100                  | 0.35                              |                  |                 |         |                                 |                 |         |
| Maize grain                         | GC | 0.05               | HR     | 88                   | 0.057                             |                  |                 |         |                                 |                 |         |
| Maize fodder                        | AS | 8.55               | HR     | 100                  | 8.55                              | 25               |                 |         | 2.14                            |                 |         |
| Peanut fodder (hay)                 | AL | 4.94               | HR     | 100                  | 4.94                              |                  |                 |         |                                 |                 |         |
| Potato wet peel                     | AB | 0.307              | STMR-P | 100                  | 0.307                             |                  |                 |         |                                 |                 |         |
| Rice                                | GC | 3.4                | HR     | 88                   | 3.86                              | 40               | 30              | 60      | 1.54                            | 1.16            | 2.32    |
| Rice bran                           | CM | 0.25               | STMR-P | 100                  | 0.25                              |                  |                 |         |                                 |                 |         |
| Rice hulls                          | CM | 0.57               | STMR-P | 100                  | 0.57                              |                  |                 |         |                                 |                 |         |
| Rice straw and fodder,<br>dry       | AS | 8.1                | HR     | 100                  | 8.1                               |                  |                 |         |                                 |                 |         |
| Sugar-beet leaves and<br>tops       | AV | 10.9               | HR     | 100                  | 10.9                              | 20               | 10              |         | 2.18                            | 1.09            |         |
| Sugar-beet, dried pulp              | AB | 0.077              | STMR-P | 100                  | 0.077                             |                  |                 |         |                                 |                 |         |
| Sugar-beet molasses                 | DM | 0.04               | STMR-P | 100                  | 0.04                              |                  |                 |         |                                 |                 |         |
| Wheat grain                         | GC | 0.2                | HR     | 89                   | 0.225                             |                  |                 |         |                                 |                 |         |
| Wheat straw                         | AS | 3.07               | HR     | 100                  | 3.07                              |                  |                 |         |                                 |                 |         |
| Wheat milled by-<br>products (bran) | CM | 0.062              | STMR-P | 100                  | 0.062                             |                  |                 |         |                                 |                 |         |
| Total                               |    |                    |        |                      |                                   | 100              | 100             | 100     | 6.3                             | 5.2             | 2.5     |

*Estimated mean dietary burden of farm animals*

| Commodity                     | CC | Residue<br>(mg/kg) | Basis  | Dry<br>matter<br>(%) | Residue/<br>dry weight<br>(mg/kg) | Diet content (%) |                 |         | Residue contribution<br>(mg/kg) |                 |         |
|-------------------------------|----|--------------------|--------|----------------------|-----------------------------------|------------------|-----------------|---------|---------------------------------|-----------------|---------|
|                               |    |                    |        |                      |                                   | Beef<br>cattle   | Dairy<br>cattle | Poultry | Beef<br>cattle                  | Dairy<br>cattle | Poultry |
| Almond hulls                  | AM | 1.08               | STMR   | 100                  | 1.08                              |                  | 10              |         |                                 | 0.108           |         |
| Apple pomace, wet             | AB | 2.6                | STMR-P | 100                  | 2.6                               | 40               | 20              |         | 1.04                            | 0.52            |         |
| Barley grain                  | GC | 0.04               | STMR   | 88                   | 0.045                             |                  |                 |         |                                 |                 |         |
| Barley straw                  | AS | 0.9                | STMR   | 100                  | 0.9                               |                  | 60              |         |                                 | 0.54            |         |
| Citrus pulp, dried            | AB | 0.35               | STMR-P | 100                  | 0.35                              |                  |                 |         |                                 |                 |         |
| Maize grain                   | GC | 0.02               | STMR   | 88                   | 0.023                             |                  |                 |         |                                 |                 |         |
| Maize fodder                  | AS | 1.75               | STMR   | 100                  | 1.75                              | 25               |                 |         | 0.4375                          |                 |         |
| Peanut fodder (hay)           | AL | 0.85               | STMR   | 100                  | 0.85                              | 15               |                 |         | 0.1275                          |                 |         |
| Potato, wet peel              | AB | 0.307              | STMR-P | 100                  | 0.307                             |                  |                 |         |                                 |                 |         |
| Rice                          | GC | 0.16               | STMR   | 88                   | 0.182                             |                  |                 | 60      |                                 |                 | 0.1092  |
| Rice bran                     | CM | 0.25               | STMR-P | 100                  | 0.25                              |                  |                 | 25      |                                 |                 | 0.0625  |
| Rice hulls                    | CM | 0.57               | STMR-P | 100                  | 0.57                              |                  |                 | 15      |                                 |                 | 0.086   |
| Rice straw and fodder,<br>dry | AS | 1.4                | STMR   | 100                  | 1.4                               |                  |                 |         |                                 |                 |         |
| Sugar-beet leaves and         | AV | 2.3                | STMR   | 100                  | 2.3                               | 20               | 10              |         | 0.46                            | 0.23            |         |

| Commodity                           | CC | Residue<br>(mg/kg) | Basis  | Dry<br>matter<br>(%) | Residue/<br>dry weight<br>(mg/kg) | Diet content (%) |                 |         | Residue contribution<br>(mg/kg) |                 |         |
|-------------------------------------|----|--------------------|--------|----------------------|-----------------------------------|------------------|-----------------|---------|---------------------------------|-----------------|---------|
|                                     |    |                    |        |                      |                                   | Beef<br>cattle   | Dairy<br>cattle | Poultry | Beef<br>cattle                  | Dairy<br>cattle | Poultry |
| tops                                |    |                    |        |                      |                                   |                  |                 |         |                                 |                 |         |
| Sugar-beet dried pulp               | AB | 0.077              | STMR-P | 100                  | 0.077                             |                  |                 |         |                                 |                 |         |
| Sugar-beet molasses                 | DM | 0.04               | STMR-P | 100                  | 0.04                              |                  |                 |         |                                 |                 |         |
| Wheat grain                         | GC | 0.02               | STMR   | 89                   | 0.0225                            |                  |                 |         |                                 |                 |         |
| Wheat straw                         | AS | 0.48               | STMR   | 100                  | 0.48                              |                  |                 |         |                                 |                 |         |
| Wheat milled by-<br>products (bran) | CM | 0.062              | STMR-P | 100                  | 0.062                             |                  |                 |         |                                 |                 |         |
| Total                               |    |                    |        |                      |                                   | 100              | 100             | 100     | 2.1                             | 1.4             | 0.26    |

The dietary burdens of trifloxystrobin for estimating maximum residue levels and STMRs for animal commodities (residue concentrations in animal feeds expressed as dry weight) are 6.3 and 2.1 mg/kg for beef cattle, 5.2 and 1.4 mg/kg for dairy cattle, 2.5 and 0.26 mg/kg for poultry.

#### Feeding studies

The Meeting received information on residues arising in tissues and milk of *dairy cows* dosed with trifloxystrobin in capsules at the equivalent of 2, 5.9 or 21 ppm in the diet for 28–30 days.

The sum of trifloxystrobin and CGA 321113 was calculated and expressed as trifloxystrobin on the basis of relative molecular masses. A conversion factor of 1.036 is required to express the CGA 321113 residues as trifloxystrobin equivalents. As this metabolite constitutes a significant proportion of the residue in animal products, when the level of trifloxystrobin or CGA 321113 was below its LOQ, the sum of trifloxystrobin and CGA 321113 was calculated, as in the examples below, and expressed as trifloxystrobin.

| Trifloxystrobin (mg/kg) | CGA 321113 (mg/kg) | Total expressed as trifloxystrobin (mg/kg) |
|-------------------------|--------------------|--------------------------------------------|
| < 0.02                  | < 0.02             | < 0.04                                     |
| < 0.02                  | 0.03               | 0.05                                       |
| 0.09                    | < 0.02             | 0.11                                       |

No residues (sum of trifloxystrobin and CGA 321113) were detectable in milk (< 0.02 mg/kg), round muscle (< 0.04 mg/kg) or tenderloin (< 0.04 mg/kg) from cattle given the highly exaggerated feeding level of 21 ppm. No residues of either parent or metabolite were found in liver, kidney or fat samples from animals at 2 or 5.9 ppm (total residue, < 0.04 mg/kg). Maximum residue levels of 0.09 mg/kg (total residue, 0.11 mg/kg) and 0.02 mg/kg (total residue, 0.04 mg/kg), detected as the metabolite CGA 321113 and expressed as trifloxystrobin, were found in liver and kidney, respectively, from cattle at 21 ppm; and maximum residue levels of 0.06 mg/kg (total residue, 0.08 mg/kg) and 0.05 mg/kg (total residue, 0.07 mg/kg), detected as intact trifloxystrobin, were found in perirenal fat and omental fat, respectively, from these animals.

The Meeting received information on the concentrations of residues in tissues and eggs from *laying hens* dosed with trifloxystrobin at the equivalent of 1.5, 4.5 or 15 ppm in the diet for 28 days. The hens were killed on day 29, and composite tissue samples of breast plus thigh, skin plus attached fat, peritoneal fat, and liver were taken. Eggs and tissues were analysed for trifloxystrobin and CGA 321113. No residues (total residues, < 0.04 mg/kg) were detected in any of the eggs, tissues or organs taken from hens at the highest dietary level of 15 ppm.

*Maximum residue levels*

The Meeting noted that no trifloxystrobin or CGA 321113 residues were detected in milk (total, < 0.02 mg/kg), muscle (< 0.04 mg/kg), kidney (< 0.04 mg/kg), liver (< 0.04 mg/kg) or fat (< 0.04 mg/kg) from animals dosed for 28 days at 5.9 ppm, which was close to the maximum dietary burdens of beef and dairy cattle (8.2 and 7.4 ppm). The highest residue level of trifloxystrobin was found in perirenal fat at 0.06 mg/kg (total residue, 0.08 mg/kg), and the highest level of CGA 321113 was found in liver at 0.09 mg/kg (total residue, 0.11 mg/kg) from animals given 21 ppm.

| Dietary burden (ppm)               | Trifloxystrobin total residue (mg/kg) |                     |                     |                 |                 |                 |                 |                 |                 |
|------------------------------------|---------------------------------------|---------------------|---------------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| Feeding level [ppm]                | Milk                                  | Muscle              |                     | Liver           |                 | Kidney          |                 | Fat             |                 |
|                                    | (mean)                                | Highest             | Mean                | Highest         | Mean            | Highest         | Mean            | Highest         | Mean            |
| MRL beef cattle<br>(6.3)<br>[21]   |                                       | (< 0.012)<br>< 0.04 |                     | (0.033)<br>0.11 |                 | (0.012)<br>0.04 |                 | (0.024)<br>0.08 |                 |
| MRL dairy cattle<br>(5.2)<br>[21]  | (< 0.005)<br>< 0.02                   |                     |                     |                 |                 |                 |                 |                 |                 |
| STMR beef cattle<br>(2.1)<br>[21]  |                                       |                     | (< 0.004)<br>< 0.04 |                 | (0.008)<br>0.08 |                 | (0.004)<br>0.04 |                 | (0.006)<br>0.06 |
| STMR dairy cattle<br>(1.4)<br>[21] | (< 0.001)<br>< 0.02                   |                     |                     |                 |                 |                 |                 |                 |                 |

The maximum concentrations of residues expected in tissues are < 0.012 mg/kg in muscle, 0.033 mg/kg in liver, 0.012 mg/kg in kidney, 0.024 mg/kg in fat and < 0.005 mg/kg in milk. The mean extrapolated concentrations are < 0.004 mg/kg in muscle, 0.008 mg/kg in liver, 0.004 mg/kg in kidney, 0.006 mg/kg in fat and < 0.001 mg/kg in milk.

Taking into account the fat solubility of trifloxystrobin (the acid metabolite CGA 321113 is poorly soluble in fat), the Meeting estimated a maximum residue level of 0.05 mg/kg for the sum of trifloxystrobin and CGA 321113 in meat (fat) from mammals other than marine mammals on the basis of residue levels in trimmable fat, and a maximum residue level of 0.02\* mg/kg for residues in milks. The estimated maximum residue levels are 0.05 mg/kg for liver and 0.04\* mg/kg for kidney of cattle, goats, pigs and sheep.

The estimated STMR values are 0.006 mg/kg in fat, 0 mg/kg in muscle, 0.008 mg/kg in liver, 0.004 mg/kg in kidney and 0 in milks.

The Meeting noted that in the feeding study in laying hens, no trifloxystrobin or CGA 321113 residues (total residue, < 0.04 mg/kg) were detected in eggs, tissues or organs from hens at the highest feeding level of 15 ppm. As the maximum dietary burden of 2.5 mg/kg was much lower, the Meeting agreed that the expected level of trifloxystrobin and CGA 321113 residues in poultry tissues and eggs would be essentially 0.

The Meeting estimated maximum residue levels of 0.04\* mg/kg for residues in eggs, poultry meat (fat) and edible offal. The Meeting recommended that the STMR values should be 0 in eggs, poultry meat, edible offal and fat.

**DIETARY RISK ASSESSMENT***Long-term intake*

The IEDIs of trifloxystrobin, on the basis of the STMRs estimated for 37 commodities, for the five GEMS/Food regional diets represented 1–2% of the ADI (Annex 3). The Meeting concluded that the long-



term intake of residues of trifloxystrobin resulting from uses that have been considered by the JMPR is unlikely to present a public health concern.

***Short-term intake***

The 2004 JMPR decided that it was unnecessary to establish an ArfD. The present Meeting therefore concluded that the short-term intake of trifloxystrobin residues is unlikely to present a public health concern.

## 5. RECOMMENDATIONS

- 5.1 The Meeting developed a guidance document for deriving acute reference doses (ARfDs) (section 2.1). This document includes general considerations, summarizing all previous considerations of the Meeting on this topic, including a stepwise process for setting ARfDs and for selecting appropriate end-points and safety factors, as well as specific guidance for assessing particular toxicologic end-points of relevance for setting ARfDs. This document should be updated regularly, as further experience in establishing ARfDs is gained. The introduction of a specific test protocol for single-dose, oral toxicity studies will aid in establishing ARfDs when relevant.
- 5.2 The WHO Core Assessment Group occasionally establishes ARfDs for compounds that were not scheduled for toxicological evaluation, on the basis of data from previous evaluations, to facilitate acute dietary risk assessment. The Meeting decided to call these values 'interim ARfDs'. These interim ARfDs can be used in dietary risk assessments until they are replaced by a full evaluation, if this is considered necessary.
- 5.3 The pilot work-sharing project concluded and recommended the following:
  - The availability of several national or regional evaluations was found to be useful by the WHO and FAO evaluators. Although problems were encountered, consideration of national or regional evaluations in the development of JMPR monographs had several benefits. FAO, WHO and OECD should consider means to facilitate the provision of national and regional evaluations for JMPR evaluators.
  - Consideration of multiple national and regional evaluations should promote international harmonization of dossiers and evaluations.
  - The evaluation process, including standardization of formats and development of guidelines, should be further harmonized at the international level. Good progress has been reached in toxicological evaluations, and more basic work is necessary to improve work-sharing for residue evaluations.
  - A further JMPR pilot work-sharing project should have a more flexible procedure, which should be reviewed when there is greater harmonization of formats and evaluation procedures (harmonization of guidance documents).
- 5.4 The JMPR considered that extensive use of the interim MRL process might create a serious problem. As interim MRLs are limited to a period of four years, pesticides nominated under the process must be scheduled for and reviewed by the JMPR within this period. If there are many interim MRL pesticide nominations, evaluations might not be completed for some within the four-year period or other priorities, such as periodic review of pesticides and evaluations, might have to be severely curtailed, owing to the current limited resources of the JMPR.
- 5.5 For spices, the Meeting recommended that CCPR accept the principle of setting MRLs on the basis of monitoring data covering the 95th percentile of the residue population with 95% confidence. That decision would facilitate use of statistically based procedures for estimating maximum residue levels and acceptance of recommended limits. It should be noted, however, that when MRLs are set at the 95th percentile with 95% confidence, the residue levels might exceed the MRL in 5% of cases.  
  
Monitoring data should not be used for estimating maximum residue levels reflecting post-harvest use, which results in significantly higher residue levels than foliar application or exposure to spray drift.

- 5.6 The Meeting decided that two maximum residue levels will be estimated for fat-soluble pesticides from now on, if the data permit: one for whole milk and one for milk fat. For enforcement purposes, the residue level in milk fat can be compared with the MRL for milk (fat), or the residue level in whole milk can be compared with the MRL for milk. When needed, maximum residue levels in milk products can be calculated from these two numbers, by taking into account both the fat content of the milk product and the contribution from the non-fat fraction.
- 5.7 For animal feed commodities, the Meeting agreed that the assumption of the 1986 JMPR used in developing guidance in this area, that “it was unrealistic to assume that the theoretical maximum residue level would be achieved and maintained in the rations of food-producing animals receiving feeds produced on the farm”, should no longer apply. Hence, the concept of time for residues to reach a plateau level, rapid or slow, is also no longer required, and the process of estimating dietary burdens is simplified. The Meeting recognized that it is unlikely that the individual ingredients in mixed feeds produced from commercially available ingredients would all contain residues at the theoretical maximum level; in these cases, the STMR should be applied for each component.
- A revision of the relevant text in the *FAO Manual*, taking into account the above, will appear on the FAO website.
- 5.8 The Meeting expressed interest in receiving spreadsheets and documentation for evaluating the statistical method for MRL estimation. Such systems might aid the evaluators but could never replace professional judgement, when available. Further developments are awaited.
- 5.9 Some of the recommendations of the York workshop on minimum data requirements and the global zoning report have been used by the JMPR and will continue to be considered as auxiliary advice. The Meeting concluded, however, that substantial additional work is required to make the recommendations generally applicable as guidance. Areas that require additional effort include: (1) defining significance in trade, perhaps with a table of commodities and their classification; (2) determining the criteria for zones and the number of zones for each commodity; (3) extending the list of commodity translations, for the purpose of recommending maximum residue levels for one commodity on the basis of data from field trials for another commodity; and (4) completing the list of representative crops for the purpose of recommending maximum residue levels for crop groups.

## 6. FUTURE WORK

The items listed below should be considered by the Meeting in 2006 and 2007. The compounds listed include those recommended as priorities by the CCPR at its Thirty-sixth and earlier sessions and compounds scheduled for re-evaluation within the CCPR periodic review programme.

### 2006 JMPR

#### Toxicological evaluations

##### *New compounds*

Bifenazate  
Dimethomorph  
Quinoxifen

##### *Periodic re-evaluations*

Cyfluthrin and  $\beta$ -cyfluthrin (157)  
Cyromazine (169)  
 $\alpha$ - and  $\zeta$ -Cypermethrin  
Flusilazole (165)  
Procymidone (136)  
Profenofos (171)

##### *Evaluations*

Haloxyfop (194)  
Pirimiphos-methyl (086): acute toxicity  
Thiabendazole (065): acute toxicity  
Thiophanate-methyl (077): acute toxicity

#### Residue evaluations

##### *New compounds*

Bifenazate  
Dimethomorph  
Quinoxifen

##### *Periodic re-evaluations*

$\alpha$ - and  $\zeta$ -Cypermethrin  
Cypermethrin (118)  
Pirimicarb (101)  
Propamocarb (148)  
Propiconazole (160)  
Triadimefon (133) To be evaluated  
Triadimenol (168) together

##### *Evaluations*

Propargite (113)

## 2007 JMPR

**Toxicological evaluations*****New compounds***

Pyrimethanil  
Zoxamide

***Periodic re-evaluations***

Azinphos-methyl (002)  
 $\lambda$ -Cyhalothrin  
Fentin (040)  
Vinclozolin (159)

**Residue evaluations*****New compounds***

Pyrimethanil  
Zoxamide

***Periodic re-evaluations***

Clofentezine (156)  
Permethrin (120)  
Triazophos (143)  
Triforine (116)

## ANNEX 1

### ACCEPTABLE DAILY INTAKES, SHORT-TERM DIETARY INTAKES, ACUTE REFERENCE DOSES, RECOMMENDED MAXIMUM RESIDUE LIMITS AND SUPERVISED TRIALS MEDIAN RESIDUE VALUES RECORDED BY THE 2004 MEETING

The following extracts of the results of the annual Joint FAO/WHO Meeting on Pesticide Residues (JMPR) are provided to make them accessible to interested parties at an early date.

The Meeting evaluated 31 pesticides. Three were new compounds, and 11 were re-evaluated within the periodic review programme of the Codex Committee on Pesticide Residues (CCPR). The Meeting allocated acceptable daily intakes (ADIs), acute reference doses (ARfDs) and, for the first time, interim ARfDs. Interim ARfDs were allocated for use in short-term dietary risk assessment of compounds that were not scheduled for toxicological evaluation. These values are derived ad hoc from data used at previous meetings. They can be used in dietary risk assessments until they are replaced by a full evaluation, if this is considered necessary.

The Meeting estimated maximum residue levels, which it recommended for use as maximum residue limits (MRLs) by the CCPR. It also estimated supervised trials median residue (STMR) and highest residue (HR) levels as a basis for estimation of the dietary intake of residues of the pesticides reviewed. Application of HR levels is explained in the report of the 1999 Meeting (section 2.4). The allocations and estimates are shown in the Table 1.

The Meeting also estimated, for the first time, maximum residue levels of various pesticides in spice subgroups specified by the CCPR from monitoring data, and in dried chilli peppers taking into account the MRLs for fresh chilli peppers and peppers. The recommended values are listed separately in Tables 2 and 3.

Pesticides for which the estimated dietary intakes might, on the basis of the available information, exceed their ADIs are marked with footnotes, as explained in detail in the report of the 1999 Meeting (section 2.2). Footnotes are also applied to specific commodities when the available information indicated that the ARfD of a pesticide might be exceeded when the commodity was consumed. It should be noted that these distinctions apply only to new compounds and those re-evaluated within the CCPR periodic review programme.

Table 1 includes the Codex reference numbers of the compounds and the Codex classification numbers (CCNs) of the commodities, to facilitate reference to the Codex maximum limits for pesticide residues (*Codex Alimentarius*, Vol. 2B) and other documents and working documents of the Codex Alimentarius Commission. Both compounds and commodities are listed in alphabetical order.

Apart from the abbreviations indicated above, the following qualifications are used in the Table.

|                                                                                                 |                                                                                                                                                                           |
|-------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| * (following name of pesticide)                                                                 | New compound                                                                                                                                                              |
| ** (following name of pesticide)                                                                | Compound reviewed within CCPR periodic review programme                                                                                                                   |
| * (following recommended MRL)                                                                   | At or about the limit of quantification                                                                                                                                   |
| HR-P                                                                                            | Highest residue in a processed commodity, in mg/kg, calculated by multiplying the HR in the raw commodity by the processing factor                                        |
| Po                                                                                              | The recommendation accommodates post-harvest treatment of the commodity.                                                                                                  |
| PoP (following recommendation for processed foods (classes D and E in the Codex classification) | The recommendation accommodates post-harvest treatment of the primary food commodity.                                                                                     |
| STMR-P                                                                                          | An STMR for a processed commodity calculated by applying the concentration or reduction factor for the process to the STMR calculated for the raw agricultural commodity. |
| V (following recommendations for commodities of animal origin)                                  | The recommendation accommodates veterinary uses.                                                                                                                          |
| W (in place of a recommended MRL)                                                               | The previous recommendation is withdrawn, or withdrawal of the recommended MRL or existing Codex or draft MRL is recommended.                                             |

**Table 1. Recommended maximum residue levels, STMR and HR values and allocated ADI and ARfD values**

| Pesticide (Codex reference number)                                                                                                                                                  | CCN     | Commodity                                      | Recommended MRL |              | STMR or STMR-P, mg/kg | HR or HR-P mg/kg |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|------------------------------------------------|-----------------|--------------|-----------------------|------------------|
|                                                                                                                                                                                     |         |                                                | New             | Previous     |                       |                  |
| <b>Bentazone (172)</b>                                                                                                                                                              |         |                                                |                 |              |                       |                  |
| ADI: 0–0.1 mg/kg bw                                                                                                                                                                 |         |                                                |                 |              |                       |                  |
| ARfD: unnecessary                                                                                                                                                                   |         |                                                |                 |              |                       |                  |
| <b>Captan (007)</b>                                                                                                                                                                 |         |                                                |                 |              |                       |                  |
| ADI: 0–0.1 mg/kg bw                                                                                                                                                                 |         |                                                |                 |              |                       |                  |
| ARfD: 0.3 mg/kg bw (for women of child-bearing age)                                                                                                                                 |         |                                                |                 |              |                       |                  |
| <b>Carbofuran (096)</b>                                                                                                                                                             | FC 0004 | Orange, sweet, sour                            |                 |              | 0.1                   | 0.05             |
| ADI: 0–0.002 mg/kg bw                                                                                                                                                               |         |                                                |                 |              |                       |                  |
| ARfD: 0.009 mg/kg bw                                                                                                                                                                |         |                                                |                 |              |                       |                  |
| <i>Residue for estimation of dietary intake in plant and animal commodities: sum of carbofuran, 3-hydroxycarbofuran and conjugated 3-hydroxycarbofuran, expressed as carbofuran</i> |         |                                                |                 |              |                       |                  |
| <b>Chlorpyrifos (017)</b>                                                                                                                                                           | SO 0691 | Cotton-seed                                    | 0.3             |              | 0.07                  |                  |
| ADI: 0–0.01 mg/kg bw                                                                                                                                                                |         | Cotton-seed meal                               |                 | < 0.01       |                       |                  |
| ARfD: 0.1 mg/kg bw                                                                                                                                                                  |         | Cotton-seed hulls                              |                 |              | 0.05                  |                  |
|                                                                                                                                                                                     | OC 0691 | Cotton-seed oil, crude                         |                 |              | 0.10                  |                  |
|                                                                                                                                                                                     | OR 0691 | Cotton-seed oil, refined                       | 0.05            |              | 0.01                  |                  |
|                                                                                                                                                                                     | VR 0589 | Potato                                         | 2               |              | 0.51                  | 0.87             |
|                                                                                                                                                                                     | GC 0649 | Rice                                           | 0.5             |              | 0.12                  |                  |
|                                                                                                                                                                                     | CM 1205 | Rice, polished                                 |                 |              | 0.008                 |                  |
|                                                                                                                                                                                     | CM 0649 | Rice, husked                                   |                 |              | 0.016                 |                  |
|                                                                                                                                                                                     |         | Rice hulls                                     |                 |              | 0.29                  |                  |
|                                                                                                                                                                                     | CM 1206 | Rice bran, unprocessed                         |                 |              | 0.22                  |                  |
|                                                                                                                                                                                     | VD 0541 | Soya bean (dry)                                | 0.1             |              | 0.01                  |                  |
|                                                                                                                                                                                     |         | Soya bean meal                                 |                 |              | < 0.002               |                  |
|                                                                                                                                                                                     | OC 0541 | Soya bean oil, crude                           |                 |              | 0.004                 |                  |
|                                                                                                                                                                                     | OR 0541 | Soya bean oil, refined                         | 0.03            |              | 0.004                 |                  |
|                                                                                                                                                                                     | DT 1114 | Tea, green, black (black, fermented and dried) | 2               |              | 0.34                  |                  |
| <i>Residue for compliance with MRLs and estimation of dietary intake in plant and animal commodities: chlorpyrifos</i>                                                              |         |                                                |                 |              |                       |                  |
| The residue is fat-soluble                                                                                                                                                          |         |                                                |                 |              |                       |                  |
| <b>Dimethipin (151)</b>                                                                                                                                                             |         |                                                |                 |              |                       |                  |
| ADI: 0–0.02 mg/kg bw                                                                                                                                                                |         |                                                |                 |              |                       |                  |
| ARfD: 0.2 mg/kg bw                                                                                                                                                                  |         |                                                |                 |              |                       |                  |
| <b>Dithiocarbamates</b>                                                                                                                                                             | VC 0424 | Cucumber                                       | 2 c, N, p       | 2 c, N       |                       |                  |
| Ferbam                                                                                                                                                                              | MO 0105 | Edible offal (mammalian)                       | 0.1 C, m, p     | 0.1 C, m     |                       |                  |
| ADI: 0–0.003 mg/kg bw                                                                                                                                                               | PE 0112 | Eggs                                           | 0.05(*) C, p    | 0.05(*) C    |                       |                  |
| Propineb                                                                                                                                                                            | FB 0269 | Grapes                                         | 5 C, m, n       | 5 C, m, n, p |                       |                  |

| Pesticide (Codex reference number) | CCN     | Commodity                                     | Recommended MRL mg/kg |                 | STMR or STMR-P, mg/kg | HR or HR-P mg/kg |
|------------------------------------|---------|-----------------------------------------------|-----------------------|-----------------|-----------------------|------------------|
|                                    |         |                                               | New                   | Previous        |                       |                  |
| ADI: 0–0.007 mg/kg bw              | MM 0095 | Meat (from mammals other than marine mammals) | 0.05(*)<br>c, m, p    | 0.05(*) c, m    |                       |                  |
| Thiram                             | VC 0046 | Melon (except watermelon)                     | 0.5 C                 | 0.5 C, p        |                       |                  |
| ADI: 0–0.01 mg/kg bw               | ML 0106 | Milks                                         | 0.05(*) c, m, p       | 0.05(*) c, m    |                       |                  |
| Ziram                              | VA 0385 | Onion, bulb                                   | 0.5 C                 | 0.5 C, p        |                       |                  |
| ADI: 0–0.003 mg/kg bw              | TN 0672 | Pecan                                         | 0.1(*) Z              | 0.1(*) T Z      |                       |                  |
|                                    | VO 0445 | Peppers, sweet                                | 7 c, m, P             | 1 c, m,         |                       |                  |
|                                    | FP 0009 | Pome fruits                                   | 5 C, M, H, Z          | 5 C, M, p, H, Z |                       |                  |
|                                    | VR 0587 | Potato                                        | 0.2 c, m, n, p        | 0.2 c, m, n     |                       |                  |
|                                    | PM 0110 | Poultry meat                                  | 0.1 c, p              | 0.1 C           |                       |                  |
|                                    | PO 0111 | Poultry, edible offal of                      | 0.1 c, p              | 0.1 C           |                       |                  |
|                                    | FS 0012 | Stone fruit                                   | 7 h, p, Z             | 7 T h, Z        |                       |                  |

*Residue for compliance with MRLs and estimation of dietary intake in plant and animal commodities:* total dithiocarbamates, determined as CS<sub>2</sub>, evolved during acid digestion and expressed as mg CS<sub>2</sub>/kg.

*Notes:*

1. Recommended MRLs refer to the total residues from the use of any or each of the dithiocarbamates.
2. Recommendations are based on trials with; n, maneb; m, metiram; c, mancozeb; p, propineb; h, thiram; z, ziram. Compounds shown in upper case as those on which the estimates of maximum residue levels are mainly based.
3. The information provided to the JMPR precludes an estimate that the dietary intake would be below the interim ARfD for propineb.

T: the 1996 JMPR recommended that the MRL should be designated as temporary pending review of data on environmental fate.

|                            |         |                                               |         |         |                     |                     |
|----------------------------|---------|-----------------------------------------------|---------|---------|---------------------|---------------------|
| <b>Ethoprophos** (149)</b> | FI 0327 | Banana                                        | 0.02    | 0.02(*) | 0.02                | 0.02                |
| ADI: 0–0.0004 mg/kg bw     | VR 0574 | Beetroot                                      | W       | 0.02(*) |                     |                     |
| ARfD: 0.05 mg/kg bw        | VB 0041 | Cabbage, head                                 | W       | 0.02(*) |                     |                     |
|                            | VC 0424 | Cucumber                                      | 0.01    | 0.02(*) | 0.01                | 0.01                |
|                            | MO 0105 | Edible offal (mammalian)                      | 0.01(*) |         | Liver 0<br>Kidney 0 | Liver 0<br>Kidney 0 |
|                            | VC 0425 | Gherkin                                       | W       | 0.02*   |                     |                     |
|                            | FB 0269 | Grape                                         | W       | 0.02*   |                     |                     |
|                            | VL 0482 | Lettuce, head                                 | W       | 0.02(*) |                     |                     |
|                            | GC 0645 | Maize                                         | W       | 0.02(*) |                     |                     |
|                            | AS 0645 | Maize fodder                                  | W       | 0.02(*) |                     |                     |
|                            | AF 0645 | Maize forage                                  | W       | 0.02(*) |                     |                     |
|                            | MM 0095 | Meat (from mammals other than marine mammals) | 0.01(*) |         | Muscle 0<br>Fat 0   | Muscle 0<br>Fat 0   |
|                            | VC 0046 | Melons, except watermelon                     | 0.02    | 0.02(*) | 0.005               | 0.012               |
|                            | ML 0106 | Milks                                         | 0.01(*) |         | 0                   |                     |
|                            | VA 0385 | Onion, bulb                                   | W       | 0.02(*) |                     |                     |
|                            | SO 0697 | Peanut                                        | W       | 0.02(*) |                     |                     |
|                            | AL 0697 | Peanut fodder                                 | W       | 0.02(*) |                     |                     |
|                            | VP 0063 | Peas (pods and succulent = immature seeds)    | W       | 0.02(*) |                     |                     |
|                            | VO 0051 | Peppers                                       | W       | 0.02(*) |                     |                     |
|                            | VO 0445 | Peppers, sweet                                | 0.05    |         | 0.005               | 0.044               |



| Pesticide (Codex reference number) | CCN     | Commodity        | Recommended MRL mg/kg |          | STMR or STMR-P, mg/kg | HR or HR-P mg/kg |
|------------------------------------|---------|------------------|-----------------------|----------|-----------------------|------------------|
|                                    |         |                  | New                   | Previous |                       |                  |
|                                    | FI 0353 | Pineapple        | W                     | 0.02(*)  |                       |                  |
|                                    | AM 0353 | Pineapple fodder | W                     | 0.02(*)  |                       |                  |
|                                    | AV 0353 | Pineapple forage | W                     | 0.02(*)  |                       |                  |
|                                    | VR 0589 | Potato           | 0.05                  | 0.02(*)  | 0.01                  | 0.03             |
|                                    | VD 0541 | Soya bean (dry)  | W                     | 0.02(*)  |                       |                  |
|                                    | AL 0541 | Soya bean fodder | W                     | 0.02(*)  |                       |                  |
|                                    | GS 0659 | Sugar cane       | 0.02                  | –        | 0.02                  | 0.02             |
|                                    | VR 0508 | Sweet potato     | 0.05                  | –        | 0.01                  | 0.03             |
|                                    | VO 0448 | Tomato           | 0.01(*)               | –        | 0.005                 | 0.01             |

*Residue for compliance with MRLs and estimation of dietary intake in plant and animal commodities: ethoprophos*

|                                        |         |                                               |                         |          |          |          |
|----------------------------------------|---------|-----------------------------------------------|-------------------------|----------|----------|----------|
| <b>Fenitrothion</b> (037) <sup>1</sup> | FP 0226 | Apple                                         | 0.5                     | W        | 0.04     | 0.41     |
| ADI: 0–0.005 mg/kg bw                  | GC 0080 | Cereal grain                                  | 10 (Po) <sup>2, 3</sup> | 10 (Po)  | 5        | 7.6      |
| ARfD: 0.04 mg/kg bw                    | MO 0105 | Edible offal (mammalian)                      | 0.05(*)                 | –        | Liver 0  | Liver 0  |
|                                        |         |                                               |                         |          | Kidney 0 | Kidney 0 |
|                                        | PE 0112 | Egg                                           | 0.05(*)                 | –        | 0        | 0        |
|                                        | MM 0095 | Meat (from mammals other than marine mammals) | 0.05(*)                 | W        | Muscle 0 | Muscle 0 |
|                                        |         |                                               |                         |          | Fat 0    | Fat 0    |
|                                        | ML 0106 | Milks                                         | 0.01                    | W        | 0        |          |
|                                        | FP 0230 | Pear                                          | W                       | W        |          |          |
|                                        | PM 0110 | Poultry meat                                  | 0.05(*)                 | –        | Muscle 0 | Muscle 0 |
|                                        |         |                                               |                         |          | Fat 0    | Fat 0    |
|                                        | CM 1206 | Rice bran, unprocessed                        | 60                      | W        | 36       | 55       |
|                                        | CM 0649 | Rice, husked                                  |                         |          | 3.2      | 4.9      |
|                                        | CM 1205 | Rice, polished                                | W                       | W        | 0.44     | 1.1      |
|                                        |         | Cooked husked rice                            |                         |          | 0.55     | 0.84     |
|                                        |         | Cooked polished rice                          |                         |          | 0.2      | 0.30     |
|                                        |         | Washed polished rice                          |                         |          | 0.23     | 0.35     |
|                                        |         | Cooked washed polished rice                   |                         |          | 0.1      | 0.15     |
|                                        | CM 0654 | Wheat bran, unprocessed                       | 30 (PoP) <sup>1</sup>   | 20 (PoP) | 20       | 30       |
|                                        | CF 1211 | Wheat flour                                   | W                       | W        | 1.2      | 1.8      |
|                                        | CP 1211 | White bread                                   | W                       | W        | 0.5      | 0.76     |
|                                        | CP 1212 | Wholemeal bread                               | W                       |          | 1.9      | 2.9      |

*Residue for compliance with MRLs and estimation of dietary intake in plant and animal commodities: Fenitrothion*

<sup>1</sup> The information provided to the JMPR precludes an estimate that the dietary intake would be below the ADI.

<sup>2</sup> Proposal by 2003 JMPR, the recommendation is now considered to also cover pre-harvest use of fenitrothion.

<sup>3</sup> The information provided to the JMPR precludes an estimate that the dietary intake would be below the ARfD.

#### **Fenpropimorph** (188)

ADI: 0–0.003 mg/kg bw

ARfD: 0.2 mg/kg bw

#### **Fenpyroximate** (193)

ADI: 0–0.01 mg/kg bw

ARfD: 0.01mg/kg bw

| Pesticide (Codex reference number)                                    | CCN     | Commodity                                                             | Recommended MRL<br>mg/kg |          | STMR or<br>STMR-P,<br>mg/kg | HR or<br>HR-P<br>mg/kg |
|-----------------------------------------------------------------------|---------|-----------------------------------------------------------------------|--------------------------|----------|-----------------------------|------------------------|
|                                                                       |         |                                                                       | New                      | Previous |                             |                        |
| <b>Fludioxonil*</b> (211)<br>ADI: 0–0.4 mg/kg bw<br>ARfD: unnecessary | HH 0722 | Basil                                                                 | 10                       |          | 2.4                         |                        |
|                                                                       | DH 0722 | Basil, dry                                                            | 50                       |          | 20                          |                        |
|                                                                       | VD 0071 | Bean (dry)                                                            | 0.07                     |          | 0.02                        |                        |
|                                                                       | VP 0061 | Bean, except broad bean and soya bean (green pods and immature seeds) | 0.3                      |          | 0.04                        |                        |
|                                                                       | VP 0062 | Beans, shelled (succulent = immature seeds)                           | 0.03                     |          | 0.02                        |                        |
|                                                                       | FB 0264 | Blackberry                                                            | 5                        |          | 1.0                         |                        |
|                                                                       | FB 0020 | Blueberry                                                             | 2                        |          | 0.60                        |                        |
|                                                                       | VB 0400 | Broccoli                                                              | 0.7                      |          | 0.23                        |                        |
|                                                                       | VB 0041 | Cabbage, head                                                         | 2                        |          | 0.24                        |                        |
|                                                                       | VR 0577 | Carrot                                                                | 0.7                      |          | 0.20                        |                        |
|                                                                       | GC 0080 | Cereal grain                                                          | 0.05(*)                  |          | 0.02                        |                        |
|                                                                       | HH 0727 | Chive                                                                 | 10                       |          | 2.8                         |                        |
|                                                                       |         | Chive (dried)                                                         | 50                       |          | 22                          |                        |
|                                                                       | FC 0001 | Citrus fruit                                                          | 7 (Po)                   |          | 1.1                         |                        |
|                                                                       | SO 0691 | Cotton-seed                                                           | 0.05(*)                  |          | 0.05                        |                        |
|                                                                       | VC 0424 | Cucumber                                                              | 0.3                      |          | 0.06                        |                        |
|                                                                       | FB 0266 | Dewberry (including boysenberry and loganberry)                       | 5                        |          | 1.0                         |                        |
|                                                                       | DF 0269 | Dried grape (= currant, raisin and sultana)                           |                          |          | 0.31                        |                        |
|                                                                       | MO 0105 | Edible offal (mammalian)                                              | 0.05(*)                  |          | 0                           |                        |
|                                                                       | VO 0440 | Egg plant (aubergine)                                                 | 0.3                      |          | 0.06                        |                        |
|                                                                       | PE 0112 | Egg                                                                   | 0.05(*)                  |          | 0                           |                        |
|                                                                       | FB 0269 | Grape                                                                 | 2                        |          | 0.28                        |                        |
|                                                                       | JF 0269 | Grape juice                                                           |                          |          | 0.26                        |                        |
|                                                                       | FI 0341 | Kiwifruit                                                             | 15 (Po)                  |          | 7.2                         |                        |
|                                                                       | VL 0482 | Lettuce, head                                                         | 10                       |          | 2.7                         |                        |
|                                                                       | AF 0645 | Maize forage (dry)                                                    | 0.03(*)                  |          | 0                           |                        |
|                                                                       | MM 0095 | Meat (from mammals other than marine mammals)                         | 0.01(*)                  |          | 0                           |                        |
|                                                                       | VC 0046 | Melon, except watermelon                                              | 0.03                     |          | 0.02                        |                        |
|                                                                       | ML 0106 | Milks                                                                 | 0.01                     |          | 0                           |                        |
|                                                                       | VL 0485 | Mustard greens                                                        | 10                       |          | 1.2                         |                        |
|                                                                       | VA 0385 | Onion, bulb                                                           | 0.5                      |          | 0.04                        |                        |
|                                                                       | VA 0389 | Onion, spring                                                         | 5                        |          | 0.59                        |                        |
|                                                                       | FP 0230 | Pear                                                                  | 0.7                      |          | 0.21                        |                        |
|                                                                       | VD 0072 | Pea (dry)                                                             | 0.07                     |          | 0.02                        |                        |
|                                                                       | VP 0063 | Pea (pods and succulent = immature seeds)                             | 0.3                      |          | 0.04                        |                        |
|                                                                       | VP 0064 | Pea, shelled (succulent seeds)                                        | 0.03                     |          | 0.02                        |                        |
|                                                                       | VO 0455 | Peppers, sweet                                                        | 1                        |          | 0.18                        |                        |
|                                                                       | TN 0675 | Pistachio nut                                                         | 0.2                      |          | 0.05                        |                        |
|                                                                       |         | Plum juice                                                            |                          |          | 0.08                        |                        |

| Pesticide (Codex reference number) | CCN     | Commodity                              | Recommended MRL<br>mg/kg |          | STMR or<br>STMR-P,<br>mg/kg | HR or<br>HR-P<br>mg/kg |
|------------------------------------|---------|----------------------------------------|--------------------------|----------|-----------------------------|------------------------|
|                                    |         |                                        | New                      | Previous |                             |                        |
|                                    |         | Plum preserve                          |                          |          | 0.40                        |                        |
|                                    |         | Plum puree                             |                          |          | 0.64                        |                        |
|                                    | VR 0589 | Potato                                 | 0.02                     |          | 0.01                        |                        |
|                                    | PM 0110 | Poultry meat                           | 0.01(*)                  |          | 0                           |                        |
|                                    | PO 0111 | Poultry, edible offal of               | 0.05(*)                  |          | 0                           |                        |
|                                    | DF 0014 | Prune (dried plum)                     |                          |          | 0.96                        |                        |
|                                    | SO 0495 | Rape seed                              | 0.02(*)                  |          | 0.02                        |                        |
|                                    | FB 0272 | Raspberry, red, black                  | 5                        |          | 1.0                         |                        |
|                                    | FS 0012 | Stone fruit                            | 5 (Po)                   |          | 0.80                        |                        |
|                                    | AS 0081 | Straw and fodder (dry) of cereal grain | 0.06(*)                  |          | 0                           |                        |
|                                    | FB 0275 | Strawberry                             | 3                        |          | 0.27                        |                        |
|                                    |         | Strawberry juice                       |                          |          | 0.06                        |                        |
|                                    |         | Strawberry preserve                    |                          |          | 0.24                        |                        |
|                                    |         | Strawberry jam                         |                          |          | 0.13                        |                        |
|                                    | VC 0431 | Squash, summer                         | 0.3                      |          | 0.06                        |                        |
|                                    | VO 0447 | Sweet corn (corn-on-the-cob)           | 0.01(*)                  |          | 0.01                        |                        |
|                                    | VO 0448 | Tomato                                 | 0.5                      |          | 0.12                        |                        |
|                                    | JF 0448 | Tomato juice                           |                          |          | 0.026                       |                        |
|                                    |         | Tomato paste                           |                          |          | 0.17                        |                        |
|                                    | VL 0473 | Watercress                             | 10                       |          | 1.2                         |                        |
|                                    |         | Wine (grape)                           |                          |          | 0.01                        |                        |

*Residue for compliance with MRLs and estimation of dietary intake in plant commodities: fludioxonil*

*Residue for compliance with MRLs and estimation of dietary intake in animal commodities: sum of fludioxonil and metabolites determined as 2,2-difluorobenzo[1,1]dioxole-4-carboxylic acid, expressed as fludioxonil*

Fludioxonil is fat-soluble

#### **Folpet (041)**

ADI: 0–0.1 mg/kg bw

ARfD: 0.2 mg/kg bw (for women of childbearing age)

#### **Glyphosate\*\* (158)**

ADI: 0–1 mg/kg bw

ARfD: unnecessary

|                        |         |              |     |   |      |      |
|------------------------|---------|--------------|-----|---|------|------|
| <b>Malathion (049)</b> | FP 0226 | Apple        | 0.5 | W | 0.11 | 0.37 |
| ADI: 0–0.3 mg/kg bw    | FC 0001 | Citrus fruit | 7   | W | 0.02 | 0.22 |
| ARfD: 2 mg/kg bw       | FB 0269 | Grape        | 5   | W | 0.16 | 2.6  |
|                        | FS 0247 | Peach        | W   | W |      |      |

*Residue for compliance with MRLs and estimation of dietary intake in plant and animal commodities: malathion*

|                                                  |         |               |         |              |      |  |
|--------------------------------------------------|---------|---------------|---------|--------------|------|--|
| <b>Metalaxyl-M* (212)</b>                        | FP 0009 | Apple         | 0.02(*) | (Metalaxyl)  |      |  |
|                                                  |         |               |         | Pome fruit 1 | 0    |  |
| ADI: 0–0.08 mg/kg bw for metalaxyl-M + metalaxyl | FB 0269 | Grape         | 1       | 1            | 0.14 |  |
| ARfD: unnecessary                                | VL 0482 | Lettuce, head | 0.5     | 2            | 0.02 |  |

| Pesticide (Codex reference number) | CCN     | Commodity      | Recommended MRL mg/kg |           | STMR or STMR-P, mg/kg | HR or HR-P mg/kg |
|------------------------------------|---------|----------------|-----------------------|-----------|-----------------------|------------------|
|                                    |         |                | New                   | Previous  |                       |                  |
|                                    | VA 0385 | Onion, bulb    | 0.03                  | 2         | 0.02                  |                  |
|                                    | VO 0445 | Peppers, sweet | 0.5                   | Peppers 1 | 0.03                  |                  |
|                                    | VO 0448 | Tomato         | 0.2                   | 0.5       | 0.045                 |                  |
|                                    | VR 0589 | Potato         | 0.02(*)               | 0.05(*)   | 0.02                  |                  |
|                                    | VL 0502 | Spinach        | 0.1                   | 2         | 0.02                  |                  |
|                                    | SO 0702 | Sunflower seed | 0.02(*)               | 0.05(*)   | 0                     |                  |
|                                    | SB 0715 | Cacao bean     | 0.02                  | 0.2       | 0.02                  |                  |
|                                    |         | Grape juice    |                       |           | 0.050                 |                  |
|                                    |         | Wine           |                       |           | 0.092                 |                  |

*Residue (of metalaxyl including metalaxyl-M) for compliance with MRLs and estimation of dietary intake in plant commodities: metalaxyl*

*Residue (of metalaxyl including metalaxyl-M) for compliance with MRLs and estimation of dietary intake in animal commodities: sum of metalaxyl and metabolites containing the 2,6-dimethylaniline moiety, expressed as metalaxyl.*

#### Notes

No new MRLs are recommended because all MRLs required for metalaxyl-M are covered by existing MRLs for metalaxyl. The values listed in the 'New' column are the estimated maximum residue levels for metalaxyl-M and, because they do not exceed the existing metalaxyl MRLs, are not intended to replace them.

Metalaxyl is a racemic mixture of (R) and (S) enantiomers. Metalaxyl-M is the (R) enantiomer.

No MRLs are currently recommended for animal commodities.

|                            |         |          |     |   |       |      |
|----------------------------|---------|----------|-----|---|-------|------|
| <b>Methamidophos</b> (100) | VC 0424 | Cucumber | W   | 1 |       |      |
| ADI: 0–0.004 mg/kg bw      |         |          |     |   |       |      |
| ARfD: 0.01 mg/kg bw        |         |          |     |   |       |      |
| <b>Methomyl</b> (094)      | VO 0051 | Peppers  | 0.7 | 1 | 0.105 | 0.44 |
| ADI: 0–0.02 mg/kg bw       | AM 0738 | Mint hay | 0.5 | 2 | 0.08  | 0.32 |
| ARfD: 0.02 mg/kg bw        |         |          |     |   |       |      |

*Residue for compliance with MRLs and estimation of dietary intake in plant and animal commodities: sum of methomyl and thiodicarb, expressed as methomyl*

|                                     |         |                                             |         |         |       |      |
|-------------------------------------|---------|---------------------------------------------|---------|---------|-------|------|
| <b>Oxydemeton methyl</b> (166)      | FP 0226 | Apple <sup>2</sup>                          |         | 0.05    | 0.01  | 0.04 |
| ADI: 0–0.0003 <sup>1</sup> mg/kg bw | JF 0226 | Apple juice                                 |         |         | 0.01  |      |
| ARfD: 0.002 mg/kg bw                |         | Apple sauce                                 |         |         | 0.005 |      |
|                                     | GC 0640 | Barley <sup>4</sup>                         | 0.02(*) | 0.05(*) | 0.01  |      |
|                                     | AS 0640 | Barley straw and fodder, dry <sup>4</sup>   | 0.1     | 2       |       |      |
|                                     | VB 0041 | Cabbage, head <sup>2,3</sup>                |         | 0.05(*) | 0.03  | 0.05 |
|                                     | MF 0812 | Cattle fat <sup>3</sup>                     |         | 0.05(*) | 0     | 0    |
|                                     | VB 0404 | Cauliflower <sup>4</sup>                    | 0.01(*) | W       | 0.01  | 0.01 |
|                                     | VD 0526 | Common bean (dry) <sup>5</sup>              |         | 0.1     | 0.01  |      |
|                                     | SO 0691 | Cotton-seed <sup>5</sup>                    |         | 0.05    | 0.01  |      |
|                                     | OR 0691 | Cotton-seed oil, edible <sup>5</sup>        |         |         | 0.002 |      |
|                                     | PE 0112 | Egg <sup>3</sup>                            |         | 0.05(*) | 0     | 0    |
|                                     | FB 0269 | Grape <sup>2</sup>                          |         | 0.1     | 0.04  | 0.06 |
|                                     | VL 0480 | Kale <sup>3</sup>                           |         | 0.01(*) | 0.01  | 0.01 |
|                                     | VB 0405 | Kohlrabi <sup>3</sup>                       |         | 0.05    | 0.02  | 0.05 |
|                                     | FC 0204 | Lemon <sup>3</sup>                          |         | 0.2     | 0.01  | 0.04 |
|                                     | MM 0097 | Meat of cattle, pigs and sheep <sup>3</sup> |         | 0.05(*) | 0     | 0    |

| Pesticide (Codex reference number) | CCN     | Commodity                                | Recommended MRL mg/kg |          | STMR or STMR-P, mg/kg | HR or HR-P mg/kg |
|------------------------------------|---------|------------------------------------------|-----------------------|----------|-----------------------|------------------|
|                                    |         |                                          | New                   | Previous |                       |                  |
|                                    | ML 0106 | Milks <sup>3</sup>                       |                       | 0.01(*)  | 0                     |                  |
|                                    | FC 0004 | Orange, sweet, sour <sup>2,3</sup>       |                       | 0.2      | 0.01                  | 0.04             |
|                                    | FP 0230 | Pear <sup>3</sup>                        |                       | 0.05     | 0.01                  | 0.04             |
|                                    | MF 0818 | Pig fat <sup>3</sup>                     |                       | 0.05(*)  | 0                     | 0                |
|                                    | VR 0589 | Potato <sup>4</sup>                      | 0.01(*)               | 0.05(*)  | 0.01                  | 0.01             |
|                                    | PF 0111 | Poultry fat <sup>3</sup>                 |                       | 0.05(*)  | 0                     | 0                |
|                                    | PM 0110 | Poultry meat <sup>3</sup>                |                       | 0.05(*)  | 0                     | 0                |
|                                    | GC 0650 | Rye <sup>4</sup>                         | 0.02(*)               | 0.05(*)  | 0.01                  |                  |
|                                    | AS 0650 | Rye straw and fodder, dry <sup>4</sup>   | 0.1                   | 2        |                       |                  |
|                                    | MF 0822 | Sheep fat <sup>3</sup>                   |                       | 0.05(*)  | 0                     | 0                |
|                                    | VR 0596 | Sugar beet <sup>4</sup>                  | 0.01(*)               | 0.05(*)  | 0.01                  |                  |
|                                    | AV 0596 | Sugar-beet leaf or top <sup>4</sup>      | 0.05                  | 0.05(*)  |                       |                  |
|                                    | GC 0654 | Wheat <sup>4</sup>                       | 0.02(*)               | 0.05(*)  | 0.01                  |                  |
|                                    | AS 0654 | Wheat straw and fodder, dry <sup>4</sup> | 0.1                   | 2        |                       |                  |

*Residue for compliance with MRLs and estimation of dietary intake in plant and animal commodities:* sum of oxydemeton methyl, demeton-S-methyl and demeton-S-methylsulphon, expressed as oxydemeton methyl

*Notes* The definition of the residue and recommendations for MRLs are based only on use of oxydemeton methyl.

<sup>1</sup> Group ADI for demeton-S-methyl and related compounds

<sup>2</sup> The information provided precluded an estimate that the dietary would be below the ARfD for children aged  $\leq 6$  years

<sup>3</sup> STMRs/STMRPs or HRs/HRPs were estimated on the basis of the 1998 evaluation.

<sup>4</sup> STMRs/STMRPs or HRs/HRPs were estimated on the basis of new data submitted to the 2004 JMPR.

<sup>5</sup> Case 3 commodities do not require estimation of the HR for short-term intake assessment.

|                         |         |                                                                                     |              |          |        |       |
|-------------------------|---------|-------------------------------------------------------------------------------------|--------------|----------|--------|-------|
| <b>Paraquat**</b> (057) | AM 0660 | Almond hulls                                                                        | 0.01 (*)     |          |        |       |
| ADI: 0–0.005 mg/kg bw   | FI 0030 | Assorted tropical and subtropical fruits minus inedible peel (except passion fruit) | 0.01 (*)     |          | 0.01   | 0.01  |
| ARfD: 0.006 mg/kg bw    | FB 0018 | Berries and other small fruit                                                       | 0.01 (*)     |          | 0      | 0     |
|                         | MO 1280 | Cattle kidney                                                                       | W            | 0.5      |        |       |
|                         | FC 0001 | Citrus fruit                                                                        | 0.02         | –        | 0.01   | 0.02  |
|                         | JF 0004 | Orange juice                                                                        |              |          | 0      |       |
|                         | SO 0691 | Cotton-seed                                                                         | 2            | 0.2      | 0.21   |       |
|                         | OC 0691 | Cotton-seed oil, crude                                                              |              |          | 0.01   |       |
|                         | OR 0691 | Cotton-seed oil, edible                                                             | W            | 0.05 (*) |        |       |
|                         | MO 0105 | Edible offal (mammalian)                                                            | 0.05         |          | 0.0007 | 0.033 |
|                         | MO 0097 | Edible offal of cattle, pigs and sheep                                              | W            | 0.05 (*) |        |       |
|                         | PE 0112 | Egg                                                                                 | 0.005 (*)    | 0.01 (*) | 0      | 0     |
|                         | AV 1051 | Fodder beet leaves or tops                                                          | 0.2 (dry wt) |          |        |       |
|                         | VC 0045 | Fruiting vegetables, cucurbits                                                      | 0.02         |          | 0      | 0     |
|                         | VO 0050 | Fruiting vegetables, other than cucurbits                                           | 0.05         |          | 0.01   | 0.04  |
|                         | JF 0448 | Tomato juice                                                                        |              |          | 0      |       |
|                         |         | Tomato ketchup                                                                      |              |          | 0      |       |
|                         | DH 1100 | Hops, dry                                                                           | 0.1          | 0.2      | 0.05   | 0.05  |
|                         |         | Beer                                                                                |              |          | 0.0001 |       |

| Pesticide (Codex reference number) | CCN      | Commodity                                      | Recommended MRL<br>mg/kg |          | STMR or<br>STMR-P,<br>mg/kg | HR or<br>HR-P<br>mg/kg |
|------------------------------------|----------|------------------------------------------------|--------------------------|----------|-----------------------------|------------------------|
|                                    |          |                                                | New                      | Previous |                             |                        |
|                                    | VL 0053  | Leafy vegetables                               | 0.07                     |          | 0.025                       | 0.05                   |
|                                    | GC 0645  | Maize                                          | 0.03                     | 0.1      | 0.025                       |                        |
|                                    | CF 1255  | Maize flour                                    | 0.05                     |          | 0.038                       |                        |
|                                    |          | Maize germ                                     |                          |          | 0.0075                      |                        |
|                                    |          | Maize grits and meal                           |                          |          | 0.013                       |                        |
|                                    | OC 0645  | Maize oil, crude                               |                          |          | 0.006                       |                        |
|                                    |          | Corn starch                                    |                          |          | 0.006                       |                        |
|                                    | AS 0645  | Maize fodder                                   | 10 (dry wt.)             |          |                             |                        |
|                                    | AF 0645  | Maize forage                                   | 5 (dry wt.)              |          |                             |                        |
|                                    | MM 0095  | Meat (from mammals other than marine mammals)  | 0.005                    |          | 0.0001                      | 0.005                  |
|                                    | MM 0097  | Meat of cattle, pigs and sheep                 | W                        | 0.05 (*) |                             |                        |
|                                    | ML 0106  | Milks                                          | 0.005(*)                 | 0.01 (*) | 0.00008                     |                        |
|                                    | FT 0305  | Olive                                          | 0.1                      | 1        | 0.05                        | 0.1                    |
|                                    | OC 0305  | Olive oil, virgin                              |                          |          | 0.018                       |                        |
|                                    | FI 0351  | Passion fruit                                  | W                        | 0.2      |                             |                        |
|                                    | MO 1284  | Pig kidney                                     | W                        | 0.5      |                             |                        |
|                                    | FP 0009  | Pome fruits                                    | 0.01 (*)                 | —        | 0                           | 0                      |
|                                    | VR 0589  | Potato                                         | W                        | 0.2      |                             |                        |
|                                    |          | Potato crisps                                  |                          |          | 0.02                        |                        |
|                                    |          | Potato granules                                |                          |          | 0.05                        |                        |
|                                    | PO 0111  | Poultry, edible offal of                       | 0.005 (*)                |          | 0                           | 0                      |
|                                    | PM 0110  | Poultry meat                                   | 0.005 (*)                |          | 0                           | 0                      |
|                                    | VD 0070  | Pulses                                         | 0.5                      |          | 0.1                         |                        |
|                                    | GC 0649  | Rice                                           | W                        | 10       |                             |                        |
|                                    | CM 1205  | Rice, polished                                 | W                        | 0.5      |                             |                        |
|                                    | VR 0075  | Root and tuber vegetables                      | 0.05                     |          | 0.02                        | 0.05                   |
|                                    | MO 1288  | Sheep kidney                                   | W                        | 0.5      |                             |                        |
|                                    | GC 0651  | Sorghum                                        | 0.03                     | 0.5      | 0.025                       |                        |
|                                    |          | Sorghum flour                                  |                          |          | 0.004                       |                        |
|                                    |          | Sorghum germ                                   |                          |          | 0.013                       |                        |
|                                    | AF 0651  | Sorghum forage (green)                         | 0.3 (dry wt)             |          |                             |                        |
|                                    | AS 0651  | Sorghum straw and fodder, dry                  | 0.3 (dry wt)             |          |                             |                        |
|                                    | VD 0541  | Soya bean (dry)                                | W                        | 0.1      |                             |                        |
|                                    | AL 0541  | Soya bean fodder                               | 0.5 (dry wt)             |          |                             |                        |
|                                    | AL 1265  | Soya bean forage (green)                       | 2 (dry wt)               |          |                             |                        |
|                                    | OC 0541  | Soya bean oil, crude                           |                          |          | 0.01                        |                        |
|                                    | FS 0012  | Stone fruit                                    | 0.01 (*)                 |          | 0                           | 0                      |
|                                    | DF 0014  | Prune                                          |                          |          | 0                           |                        |
|                                    | SO 0702  | Sunflower seed                                 | 2                        | 2        | 0.22                        |                        |
|                                    | OC 0702  | Sunflower seed oil, crude                      | W                        | 0.05 (*) | 0                           |                        |
|                                    | OR 0702  | Sunflower seed oil, edible                     | W                        | 0.05 (*) |                             |                        |
|                                    | DT 1114  | Tea, green, black (black, fermented and dried) | 0.2                      |          | 0.06                        |                        |
|                                    | TN 0085  | Tree nuts                                      | 0.05                     |          | 0.01                        | 0.05                   |
|                                    | AO1 0002 | Vegetables (except those listed)               | W                        | 0.05 (*) |                             |                        |

| Pesticide (Codex reference number)                                                                                            | CCN                  | Commodity                | Recommended MRL<br>mg/kg                                     |                               | STMR or<br>STMR-P,<br>mg/kg | HR or<br>HR-P<br>mg/kg         |                               |
|-------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------------|--------------------------------------------------------------|-------------------------------|-----------------------------|--------------------------------|-------------------------------|
|                                                                                                                               |                      |                          | New                                                          | Previous                      |                             |                                |                               |
| Residue for compliance with MRLs and estimation of dietary intake in plant and animal commodities: paraquat cation            |                      |                          |                                                              |                               |                             |                                |                               |
| Phorate** (112)                                                                                                               |                      |                          |                                                              |                               |                             |                                |                               |
| ADI: 0–0.0007 mg/kg bw                                                                                                        |                      |                          |                                                              |                               |                             |                                |                               |
| ARfD: 0.003 mg/kg bw                                                                                                          |                      |                          |                                                              |                               |                             |                                |                               |
| Pirimicarb** (101)                                                                                                            |                      |                          |                                                              |                               |                             |                                |                               |
| ADI: 0–0.02 mg/kg bw                                                                                                          |                      |                          |                                                              |                               |                             |                                |                               |
| ARfD: 0.1 mg/kg bw                                                                                                            |                      |                          |                                                              |                               |                             |                                |                               |
| Pirimiphos-methyl (086)                                                                                                       | MO 0105              | Edible offal (mammalian) | 0.01(*) <sup>1</sup>                                         |                               | 0                           | 0                              |                               |
|                                                                                                                               | ADI: 0–0.03 mg/kg bw | PE 0112                  | Egg                                                          | 0.01                          | 0.05                        | 0                              | 0.01                          |
|                                                                                                                               |                      | MM 0095                  | Meat (from mammals other than marine mammals)                | 0.01(*) <sup>1</sup><br>(fat) | 0.05(*)                     | Muscle: 0<br>Fat: 0            | Muscle: 0<br>Fat: 0           |
|                                                                                                                               |                      | PM 0110                  | Poultry meat                                                 | 0.01(*) <sup>1</sup>          |                             | Muscle: 0<br>Fat: 0            | Muscle: 0<br>Fat: 0           |
|                                                                                                                               |                      | PM 0111                  | Poultry, edible offal of                                     | 0.01(*) <sup>1</sup>          |                             | 0                              | 0                             |
| <sup>1</sup> No residues expected from consumption of feed commodities with pirimiphos-methyl residues, as evaluated by JMPR. |                      |                          |                                                              |                               |                             |                                |                               |
| Residue for compliance with MRLs and estimation of dietary intake in plant and animal commodities: pirimiphos-methyl.         |                      |                          |                                                              |                               |                             |                                |                               |
| The residue is fat-soluble.                                                                                                   |                      |                          |                                                              |                               |                             |                                |                               |
| Prochloraz** (142)                                                                                                            | FI 0326              | Avocado                  | W <sup>1</sup>                                               | 5 (Po)                        |                             |                                |                               |
|                                                                                                                               | ADI: 0–0.01 mg/kg bw | FI 0030                  | Assorted tropical and subtropical fruits minus inedible peel | 7 (Po)                        | 0.1                         | 0.7                            |                               |
|                                                                                                                               | ARfD: 0.1 mg/kg bw   | FI 0327                  | Banana                                                       | W <sup>1</sup>                | 5 (Po)                      |                                |                               |
|                                                                                                                               |                      | GC 0640                  | Barley                                                       | W <sup>1</sup>                | 0.5                         |                                |                               |
|                                                                                                                               |                      | AS 0640                  | Barley straw and fodder, dry                                 | W <sup>1</sup>                | 15                          |                                |                               |
|                                                                                                                               |                      |                          | Beer                                                         |                               |                             | 0.01                           |                               |
|                                                                                                                               |                      | MF 0812                  | Cattle fat                                                   | W <sup>1</sup>                | 0.5                         |                                |                               |
|                                                                                                                               |                      | MM 0812                  | Cattle meat                                                  | W <sup>1</sup>                | 0.1 (*)                     |                                |                               |
|                                                                                                                               |                      | MO 0812                  | Cattle, edible offal of                                      | W <sup>1</sup>                | 5                           |                                |                               |
|                                                                                                                               |                      | GC 0080                  | Cereal grains                                                | 2                             |                             | 0.11                           | 1.2                           |
|                                                                                                                               |                      | FC 0001                  | Citrus fruits                                                | 10 (Po)                       |                             | 0.1                            | 0.92                          |
|                                                                                                                               |                      | SB 0716                  | Coffee beans                                                 | W                             | 0.2                         |                                |                               |
|                                                                                                                               |                      | MO 0105                  | Edible offal (mammalian)                                     | 10                            |                             | 1.2                            | 6.2                           |
|                                                                                                                               |                      | PE 0112                  | Eggs                                                         | 0.1                           |                             | 0.012                          | 0.07                          |
|                                                                                                                               |                      | SO 0693                  | Linseed                                                      | 0.05 (*)                      |                             | 0.05                           | 0.05                          |
|                                                                                                                               |                      | FI 0345                  | Mango                                                        | W <sup>1</sup>                | 2 (Po)                      |                                |                               |
|                                                                                                                               |                      | MM 0095                  | Meat (from mammals other than marine mammals)                | 0.5 (fat)                     |                             | 0.02<br>(muscle)<br>0.06 (fat) | 0.1<br>(muscle)<br>0.38 (fat) |
|                                                                                                                               |                      | ML 0106                  | Milks                                                        | 0.05 *                        | 0.1*                        | 0                              | 0                             |
|                                                                                                                               |                      | VO 0450                  | Mushroom                                                     | 40                            | 2                           | 4.9                            | 37                            |
|                                                                                                                               |                      | GC 0647                  | Oat                                                          | W <sup>1</sup>                | 0.5                         |                                |                               |
|                                                                                                                               |                      | AS 0647                  | Oat straw and fodder, dry                                    | W <sup>1</sup>                | 15                          |                                |                               |
|                                                                                                                               | FC 0004              | Orange, sweet, sour      | W <sup>1</sup>                                               | 5 Po                          |                             |                                |                               |

| Pesticide (Codex reference number) | CCN     | Commodity                              | Recommended MRL mg/kg |          | STMR or STMR-P, mg/kg         | HR or HR-P mg/kg              |
|------------------------------------|---------|----------------------------------------|-----------------------|----------|-------------------------------|-------------------------------|
|                                    |         |                                        | New                   | Previous |                               |                               |
|                                    | FI 0350 | Papaya                                 | W <sup>1</sup>        | 1 Po     |                               |                               |
|                                    | HS 0790 | Pepper, black, white                   | 10                    |          | 5.1                           | 5.1                           |
|                                    | PM 0110 | Poultry meat                           | 0.05*                 |          | 0.001 (muscle)<br>0.001 (fat) | 0.005 (muscle)<br>0.007 (fat) |
|                                    | PO 0111 | Poultry, edible offal of               | 0.2                   |          | 0.015                         | 0.1                           |
|                                    | SO 0495 | Rape seed                              | 0.7                   | 0.5      | 0.1                           | 0.48                          |
|                                    |         | Rape-seed meal                         |                       |          | 0.06                          |                               |
|                                    | OR 0495 | Rape-seed oil, edible                  |                       |          | 0.06                          |                               |
|                                    | GC 0650 | Rye                                    | W <sup>1</sup>        | 0.5      |                               |                               |
|                                    | AS 0650 | Rye straw and fodder, dry              | W <sup>1</sup>        | 15       |                               |                               |
|                                    | FS 0012 | Stone fruit                            | W                     | 0.05     |                               |                               |
|                                    | AS 0081 | Straw and fodder (dry) of cereal grain | 40                    |          |                               |                               |
|                                    | SO 0702 | Sunflower seed                         | 0.5                   |          | 0.1                           | 0.32                          |
|                                    |         | Sunflower seed meal                    |                       |          | 0.05                          |                               |
|                                    | OR 0702 | Sunflower seed oil, edible             | 1                     |          | 0.06                          |                               |
|                                    | GC 0654 | Wheat                                  | W <sup>1</sup>        | 0.5      |                               |                               |
|                                    | CM 0654 | Wheat bran, unprocessed                | 7                     |          | 0.54                          |                               |
|                                    | AS 0654 | Wheat straw and fodder, dry            | W <sup>1</sup>        | 15       |                               |                               |
|                                    | CF 1211 | Wheat flour                            |                       |          | 0.025                         |                               |
|                                    | CP 1212 | Wholemeal bread                        |                       |          | 0.14                          |                               |

<sup>1</sup> Replaced by recommendation for wider group of commodities

*Residue for compliance with MRLs and estimation of dietary intake in plant and animal commodities:* sum of prochloraz and its metabolites containing the 2,4,6-trichlorophenol moiety, expressed as prochloraz.

The residue is fat-soluble

#### **Propiconazole\*\* (160)**

ADI: 0–0.07 mg/kg bw

ARfD: 0.3 mg/kg bw

|                                         |         |                                               |          |         |      |      |
|-----------------------------------------|---------|-----------------------------------------------|----------|---------|------|------|
| <b>Propineb**</b>                       | FP 0226 | Apple                                         | W        | 2       |      |      |
| ADI: 0–0.007mg/kg bw                    | FS 0013 | Cherry                                        | 0.2      | –       | 0.13 | 0.35 |
| Interim <sup>1</sup> ARfD: 0.1 mg/kg bw | VC 0424 | Cucumber                                      | 1        | –       | 0.49 | 1.1  |
|                                         | MO 0105 | Edible offal (mammalian)                      | 0.05 (*) | –       | 0    | 0    |
|                                         | PE 0112 | Egg                                           | 0.01 (*) | –       | 0    | 0    |
|                                         | FB 0269 | Grape                                         | W        | 2       |      |      |
|                                         | MM 0095 | Meat (from mammals other than marine mammals) | 0.05 (*) | –       | 0    | 0    |
|                                         | VC 0046 | Melon (except watermelon)                     | W        | 0.1 (*) |      |      |
|                                         | VA 0385 | Onion, bulb                                   | W        | 0.2 (*) |      |      |
|                                         | FP 0230 | Pear                                          | W        | 2       |      |      |
|                                         | VO 0445 | Peppers, sweet                                | 7        | –       | 1.6  | 13   |
|                                         | VR 0587 | Potato                                        | 0.1      | 0.1 (*) | 0.12 | 0.16 |
|                                         | PM 0110 | Poultry meat                                  | 0.05 (*) | –       | 0    | 0    |
|                                         | PO 0111 | Poultry, edible offal of                      | 0.05 (*) | –       | 0    | 0    |



| Pesticide (Codex reference number)                                                                                                                                                                                                                                                                                                                                                                                                                              | CCN     | Commodity                                     | Recommended MRL<br>mg/kg |          | STMR or<br>STMR-P,<br>mg/kg | HR or<br>HR-P<br>mg/kg     |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|-----------------------------------------------|--------------------------|----------|-----------------------------|----------------------------|
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |         |                                               | New                      | Previous |                             |                            |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | VO 0448 | Tomato                                        | 2                        | 1        | 1                           | 2.9                        |
| <i>Residue for compliance with MRLs in plant and animal commodities: total dithiocarbamates, determined as CS<sub>2</sub>, evolved during acid digestion and expressed as mg CS<sub>2</sub>/kg</i>                                                                                                                                                                                                                                                              |         |                                               |                          |          |                             |                            |
| <i>Residue for estimation of dietary intake in plant and animal commodities: sum of propineb and propylenethiourea</i>                                                                                                                                                                                                                                                                                                                                          |         |                                               |                          |          |                             |                            |
| <i>Notes All recommended MRLs are covered by the existing or recommended MRLs for dithiocarbamates.</i>                                                                                                                                                                                                                                                                                                                                                         |         |                                               |                          |          |                             |                            |
| <sup>1</sup> The WHO Core Assessment Group is occasionally asked by the FAO Panel of Experts to establish an ARfD for compounds that were not scheduled for toxicological evaluation, for use in acute dietary risk assessment. This value is derived ad hoc from data from previous meetings and is therefore called an interim ARfD. It can be used in dietary risk assessments until they are replaced by full evaluations, if this is considered necessary. |         |                                               |                          |          |                             |                            |
| <b>Pyraclostrobin*</b> (210)                                                                                                                                                                                                                                                                                                                                                                                                                                    | AM 0660 | Almond hull                                   | 2                        |          | 0.20                        |                            |
| ADI: 0–0.03 mg/kg bw                                                                                                                                                                                                                                                                                                                                                                                                                                            | TN 0660 | Almond                                        | 0.02(*)                  |          | 0.02                        | 0.02                       |
| ARfD: 0.05 mg/kg bw                                                                                                                                                                                                                                                                                                                                                                                                                                             | FI 0327 | Banana                                        | 0.02(*)                  |          | 0.02                        | 0.02                       |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | GC 0640 | Barley                                        | 0.5                      |          | 0.03                        |                            |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |         | Malt                                          |                          |          | 0.03                        |                            |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | VD 0071 | Bean (dry)                                    | 0.2                      |          | 0.02                        | 0.10                       |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | FB 0020 | Blueberry                                     | 1                        |          | 0.34                        | 0.57                       |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | VR 0577 | Carrot                                        | 0.5                      |          | 0.12                        | 0.24                       |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | FS 0013 | Cherry                                        | 1                        |          | 0.43                        | 0.63                       |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | FC 0001 | Citrus fruit                                  | 1                        |          | 0.19                        | 0.51                       |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | DF 0269 | Dried grape (currant, raisin, sultana)        | 5                        |          | 1.36                        | 4.27                       |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | MO 0095 | Edible offal, mammalian                       | 0.05(*)                  |          | 0.008                       | 0.037                      |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | PE 0112 | Egg                                           | 0.05(*)                  |          | 0                           | 0                          |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | AV 1051 | Fodder beet leaf or top                       | 50                       |          |                             |                            |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | VA 0381 | Garlic                                        | 0.05(*)                  |          | 0.05                        | 0.05                       |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | FB 0269 | Grape                                         | 2                        |          | 0.44                        | 1.38                       |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | JF 0269 | Grape juice                                   |                          |          | 0.005                       |                            |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |         | Wine                                          |                          |          | 0.04                        |                            |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | VD 0533 | Lentil (dry)                                  | 0.5                      |          | 0.13                        |                            |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | GC 0645 | Maize                                         | 0.02(*)                  |          | 0.02                        |                            |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | FI 0345 | Mango                                         | 0.05(*)                  |          | 0.05                        | 0.05                       |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | MM 0095 | Meat (from mammals other than marine mammals) | 0.5 (fat)                |          | Muscle: 0.009<br>Fat: 0.063 | Muscle: 0.044<br>Fat: 0.41 |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | ML 0106 | Milks                                         | 0.03                     |          | 0.01                        |                            |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | GC 0647 | Oat                                           | 0.5                      |          | 0.17                        |                            |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | VA 0385 | Onion, bulb                                   | 0.2                      |          | 0.02                        | 0.09                       |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | FI 0350 | Papaya                                        | 0.05(*)                  |          | 0.05                        | 0.05                       |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | FS 0247 | Peach                                         | 0.5                      |          | 0.15                        | 0.31                       |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | SO 0703 | Peanut                                        | 0.02(*)                  |          | 0.02                        | 0.02                       |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | AL 0697 | Peanut fodder                                 | 50                       |          |                             |                            |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | VD 0072 | Pea (dry)                                     | 0.3                      |          | 0.07                        |                            |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |         | Pea vines                                     | 40                       |          |                             |                            |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |         | Pea hay                                       | 30                       |          |                             |                            |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | TN 0672 | Pecan                                         | 0.02(*)                  |          | 0.02                        | 0.02                       |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | TN 0678 | Pistachio nut                                 | 1                        |          | 0.22                        | 0.45                       |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | FS 0014 | Plum (including prune)                        | 0.3                      |          | 0.06                        | 0.19                       |

| Pesticide (Codex reference number)                                                                                        | CCN     | Commodity                                                                  | Recommended MRL mg/kg |                  | STMR or STMR-P, mg/kg                        | HR or HR-P mg/kg  |
|---------------------------------------------------------------------------------------------------------------------------|---------|----------------------------------------------------------------------------|-----------------------|------------------|----------------------------------------------|-------------------|
|                                                                                                                           |         |                                                                            | New                   | Previous         |                                              |                   |
|                                                                                                                           | VR 0589 | Potato                                                                     | 0.02(*)               |                  | 0.02                                         | 0.02              |
|                                                                                                                           | PM 0110 | Poultry meat                                                               | 0.05(*)<br>(fat)      |                  | Muscle 0<br>fat 0                            | Muscle 0<br>fat 0 |
|                                                                                                                           | PO 0111 | Poultry, edible offal of                                                   | 0.05(*)               |                  | 0                                            | 0                 |
|                                                                                                                           | VR 0494 | Radish                                                                     | 0.5                   |                  | 0.08                                         | 0.3               |
|                                                                                                                           | VL 0494 | Radish leaf (including radish top)                                         | 20                    |                  | 9.9                                          | 15                |
|                                                                                                                           | VC 0431 | Squash, summer                                                             | 0.3                   |                  | 0.15                                         | 0.18              |
|                                                                                                                           | AS 0081 | Straw and fodder (dry) of cereal grain                                     | 30                    |                  | 1.69                                         |                   |
|                                                                                                                           | FB 0275 | Strawberry                                                                 | 0.5                   |                  | 0.16                                         | 0.26              |
|                                                                                                                           | VR 0596 | Sugar beet                                                                 | 0.2                   |                  | 0.04                                         |                   |
|                                                                                                                           | VO 0448 | Tomato                                                                     | 0.3                   |                  | 0.12                                         | 0.21              |
|                                                                                                                           | GC 0654 | Wheat                                                                      | 0.2                   |                  | 0.02                                         |                   |
|                                                                                                                           | CF 1211 | Wheat flour                                                                |                       |                  | 0.012                                        |                   |
|                                                                                                                           | CF 1210 | Wheat germ                                                                 |                       |                  | 0.016                                        |                   |
| <i>Residue for compliance with MRLs and estimation of dietary intake in plant and animal commodities: pyraclostrobin.</i> |         |                                                                            |                       |                  |                                              |                   |
| The residue is fat-soluble.                                                                                               |         |                                                                            |                       |                  |                                              |                   |
| <b>Spinosad</b> (203)                                                                                                     | FM 0812 | Cattle milk fat                                                            | 5                     |                  |                                              |                   |
| ADI: 0–0.02 mg/kg bw                                                                                                      | GC 0080 | Cereal grain                                                               | 1 (Po)                |                  | 0.70                                         |                   |
| ARfD: unnecessary                                                                                                         | DF 0269 | Dried grape (currant, raisin and sultana)                                  | 1                     |                  | 0.13                                         |                   |
|                                                                                                                           | MO 0105 | Edible offal (mammalian) [except cattle] <sup>2</sup>                      | 0.5                   |                  | Liver:<br>0.064<br>Kidney:<br>0.032<br>0.084 |                   |
|                                                                                                                           | FB 0269 | Grape                                                                      | 0.5                   |                  |                                              |                   |
|                                                                                                                           | GC 0645 | Maize                                                                      | W <sup>1</sup>        | 0.01(*)          |                                              |                   |
|                                                                                                                           | MM 0095 | Meat (from mammals other than marine mammals) [except cattle] <sup>2</sup> | 2 (fat)               |                  | Meat 0.01<br>Fat: 0.32                       |                   |
|                                                                                                                           | MM 0822 | Sheep meat                                                                 | W <sup>1</sup>        | 0.01(*)<br>(fat) |                                              |                   |
|                                                                                                                           | MO 0822 | Sheep, edible offal of                                                     | W <sup>1</sup>        | 0.01(*)          |                                              |                   |
|                                                                                                                           | GC 0651 | Sorghum                                                                    | W <sup>1</sup>        | 1                |                                              |                   |
|                                                                                                                           | CM 0654 | Wheat bran, unprocessed                                                    | 2                     |                  | 1.4                                          |                   |
|                                                                                                                           |         | Grits                                                                      |                       |                  | 0.057                                        |                   |
|                                                                                                                           | CF 1255 | Maize flour                                                                |                       |                  | 0.13                                         |                   |
|                                                                                                                           | OC 0645 | Maize oil, crude                                                           |                       |                  | 0.77                                         |                   |
|                                                                                                                           | CM 1206 | Rice bran, unprocessed                                                     |                       |                  | 0.55                                         |                   |
|                                                                                                                           |         | Rice hull                                                                  |                       |                  | 2.0                                          |                   |
|                                                                                                                           | CM 0649 | Rice, husked (brown rice)                                                  |                       |                  | 0.077                                        |                   |
|                                                                                                                           | CM 1205 | Rice, polished (white rice)                                                |                       |                  | 0.015                                        |                   |
|                                                                                                                           | CF 1211 | Wheat flour                                                                |                       |                  | 0.18                                         |                   |
|                                                                                                                           | CP 1211 | White bread                                                                |                       |                  | 0.098                                        |                   |
|                                                                                                                           |         | Wine                                                                       |                       |                  | 0.027                                        |                   |

*Residue for compliance with MRLs and estimation of dietary intake in plant and animal commodities: sum of spinosyn A and spinosyn D*

The residue is fat-soluble, but residues in milk should be determined in whole milk.

<sup>1</sup> Replaced by recommendation for wider group of commodities.

| Pesticide (Codex reference number)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | CCN     | Commodity                                  | Recommended MRL |          | STMR or STMR-P, mg/kg | HR or HR-P mg/kg |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|--------------------------------------------|-----------------|----------|-----------------------|------------------|
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |         |                                            | mg/kg           |          |                       |                  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |         |                                            | New             | Previous |                       |                  |
| <sup>2</sup> The recommendations are derived from a dairy cow feeding study and the corresponding animal dietary burden. They are extended to ‘Edible offal (mammalian) [except cattle]’ and ‘Meat (from mammals other than marine mammals) [except cattle]’ following the policy of the 2002 JMPR. The proposed MRLs for cattle meat (3 mg/kg, fat), cattle kidney (1 mg/kg) and cattle liver (2mg/kg), arising from the direct use of spinosad on cattle, should remain. They exceed the recommendations for mammalian meat and offal, and so require the restriction ‘except cattle’ to the general commodity descriptions. |         |                                            |                 |          |                       |                  |
| <b>Triadimefon** (133)</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |         |                                            |                 |          |                       |                  |
| ADI: 0–0.03 mg/kg bw                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |         |                                            |                 |          |                       |                  |
| ARfD: 0.08 mg/kg bw                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |         |                                            |                 |          |                       |                  |
| <b>Triadimenol** (168)</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |         |                                            |                 |          |                       |                  |
| ADI: 0–0.03 mg/kg bw                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |         |                                            |                 |          |                       |                  |
| ARfD: 0.08 mg/kg bw                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |         |                                            |                 |          |                       |                  |
| <b>Trifloxystrobin* (213)</b><br>ADI: 0–0.04 mg/kg bw<br>ARfD: unnecessary                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | AM 0660 | Almond hulls <sup>1</sup>                  | 3               |          |                       |                  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | DF 0226 | Apple, dried                               |                 |          | 0.043                 |                  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | JF 0226 | Apple juice                                |                 |          | 0.018                 |                  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |         | Apple sauce                                |                 |          | 0.053                 |                  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |         | Apple preserve                             |                 |          | 0.053                 |                  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |         | Apricot, canned                            |                 |          | 0.019                 |                  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | FI 0327 | Banana                                     | 0.05            |          | 0.02                  |                  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | GC 0640 | Barley                                     | 0.5             |          | 0.04                  |                  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | AS 0640 | Barley straw and fodder (dry) <sup>1</sup> | 7               |          |                       |                  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |         | Beer (residue arising from hops)           |                 |          | 0.01                  |                  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | VB 0402 | Brussels sprout                            | 0.5             |          | 0.17                  |                  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | VR 0577 | Carrot                                     | 0.1             |          | 0.035                 |                  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | VB 0041 | Cabbage, head                              | 0.5             |          | 0.17                  |                  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | VS 0624 | Celery                                     | 1               |          | 0.18                  |                  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | FC 0001 | Citrus fruit <sup>2</sup>                  | 0.5             |          | 0.095                 |                  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | JF 0001 | Citrus juice <sup>2</sup>                  |                 |          | 0.018                 |                  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | AB 0001 | Citrus pulp, dry <sup>1</sup>              | 1               |          |                       |                  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |         | Citrus oil (orange)                        |                 |          | 12                    |                  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | DF 0269 | Dried grape (raisin)                       | 5               |          | 0.345                 |                  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | PE 0112 | Egg                                        | 0.04(*)         |          | 0                     |                  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | VB 0042 | Flowerhead brassica                        | 0.5             |          | 0.17                  |                  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | VC 0045 | Fruiting vegetables, cucurbits             | 0.3             |          | 0.095                 |                  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | FB 0269 | Grape                                      | 3               |          | 0.15                  |                  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | JF 0269 | Grape juice                                |                 |          | 0.036                 |                  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |         | Must                                       |                 |          | 0.07                  |                  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |         | Wine                                       |                 |          | 0.023                 |                  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | DH 1100 | Hops, dry                                  | 40              |          | 9.95                  |                  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | MO 0098 | Kidney of cattle, goats, pigs and sheep    | 0.04(*)         |          | 0.004                 |                  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | VA 0384 | Leek                                       | 0.7             |          | 0.31                  |                  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | MO 0099 | Liver of cattle, goats, pigs and sheep     | 0.05            |          | 0.008                 |                  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | GC 0645 | Maize                                      | 0.02            |          | 0.02                  |                  |

| Pesticide (Codex reference number) | CCN     | Commodity                                     | Recommended MRL<br>mg/kg |          | STMR or<br>STMR-P,<br>mg/kg | HR or<br>HR-P<br>mg/kg |
|------------------------------------|---------|-----------------------------------------------|--------------------------|----------|-----------------------------|------------------------|
|                                    |         |                                               | New                      | Previous |                             |                        |
|                                    | AS 0645 | Maize fodder <sup>1</sup>                     | 10                       |          |                             |                        |
|                                    | MM 0095 | Meat (from mammals other than marine mammals) | 0.05 (fat)               |          | Fat: 0.006<br>Muscle: 0     |                        |
|                                    | ML0106  | Milks                                         | 0.02(*)                  |          | 0                           |                        |
|                                    |         | Nectarine, canned                             |                          |          | 0.019                       |                        |
|                                    |         | Peach, canned                                 |                          |          | 0.019                       |                        |
|                                    | SO 0697 | Peanut                                        | 0.02(*)                  |          | 0                           |                        |
|                                    | AL 0697 | Peanut fodder <sup>1</sup>                    | 5                        |          |                             |                        |
|                                    |         | Pear, dried                                   |                          |          | 0.043                       |                        |
|                                    |         | Pear juice                                    |                          |          | 0.018                       |                        |
|                                    |         | Pear preserve                                 |                          |          | 0.053                       |                        |
|                                    | VO 0445 | Peppers, sweet                                | 0.3                      |          | 0.1                         |                        |
|                                    | FP 0009 | Pome fruit                                    | 0.7                      |          | 0.11                        |                        |
|                                    | VR 0589 | Potato                                        | 0.02(*)                  |          | 0.02                        |                        |
|                                    |         | Potato chips                                  |                          |          | 0.008                       |                        |
|                                    |         | Potato flakes                                 |                          |          | 0.008                       |                        |
|                                    | PO 0111 | Poultry, edible offal of                      | 0.04(*)                  |          | 0                           |                        |
|                                    | PM 0110 | Poultry meat                                  | 0.04(*)<br>(fat)         |          | Fat: 0<br>Muscle: 0         |                        |
|                                    |         | Prune, dried                                  |                          |          | 0.57                        |                        |
|                                    | GC 0649 | Rice                                          | 5                        |          | 0.16                        |                        |
|                                    | CM 1205 | Rice, polished                                |                          |          | 0.029                       |                        |
|                                    | CM 1206 | Rice bran, unprocessed <sup>1</sup>           | 7                        |          | 0.25                        |                        |
|                                    | AS 0649 | Rice straw and fodder, dry <sup>1</sup>       | 10                       |          |                             |                        |
|                                    | FS 0012 | Stone fruit                                   | 3                        |          | 0.38                        |                        |
|                                    | FB 0275 | Strawberry                                    | 0.2                      |          | 0.1                         |                        |
|                                    |         | Strawberry, canned                            |                          |          | 0.029                       |                        |
|                                    |         | Strawberry jam                                |                          |          | 0.062                       |                        |
|                                    | VR 0596 | Sugar beet                                    | 0.05                     |          | 0.02                        |                        |
|                                    |         | White sugar                                   |                          |          | 0.0036                      |                        |
|                                    | AB 0596 | Sugar beet pulp, dry <sup>1</sup>             | 0.2                      |          |                             |                        |
|                                    | DM 0596 | Sugar beet molasses <sup>1</sup>              | 0.1                      |          |                             |                        |
|                                    | AM 0596 | Sugar beet leaves or tops <sup>1</sup>        | 15                       |          |                             |                        |
|                                    | VO 0448 | Tomato                                        | 0.7                      |          | 0.08                        |                        |
|                                    |         | Tomato paste                                  |                          |          | 0.13                        |                        |
|                                    |         | Tomato puree                                  |                          |          | 0.045                       |                        |
|                                    | TN 0085 | Tree nuts                                     | 0.02(*)                  |          | 0                           |                        |
|                                    | GC 0654 | Wheat                                         | 0.2                      |          | 0.02                        |                        |
|                                    | CM 0654 | Wheat bran, unprocessed <sup>1</sup>          | 0.5                      |          | 0.062                       |                        |
|                                    | CF 1211 | Wheat flour                                   |                          |          | 0.008                       |                        |
|                                    | CF 1210 | Wheat germ                                    |                          |          | 0.013                       |                        |
|                                    | CF 1212 | Wheat wholemeal                               |                          |          | 0.01                        |                        |
|                                    | CP 1212 | Wheat wholemeal bread                         |                          |          | 0.005                       |                        |
|                                    | AS 0654 | Wheat straw and fodder, dry <sup>1</sup>      | 5                        |          |                             |                        |

| Pesticide (Codex reference number)                                                                                                                                                                       | CCN | Commodity | Recommended MRL<br>mg/kg |          | STMR or<br>STMR-P,<br>mg/kg | HR or<br>HR-P<br>mg/kg |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----|-----------|--------------------------|----------|-----------------------------|------------------------|
|                                                                                                                                                                                                          |     |           | New                      | Previous |                             |                        |
| <i>Residue in plant commodities</i>                                                                                                                                                                      |     |           |                          |          |                             |                        |
| for compliance with MRLs: trifloxystrobin                                                                                                                                                                |     |           |                          |          |                             |                        |
| for estimation of dietary intake: sum of trifloxystrobin and [(E,E)-methoxyimino-{2-[1-(3-trifluoromethylphenyl)ethylideneaminooxymethyl]phenyl}acetic acid] (CGA 321113), expressed as trifloxystrobin. |     |           |                          |          |                             |                        |
| <i>Residue in animal commodities</i>                                                                                                                                                                     |     |           |                          |          |                             |                        |
| For compliance with MRLs and estimation of dietary intake:                                                                                                                                               |     |           |                          |          |                             |                        |
| sum of trifloxystrobin and [(E,E)-methoxyimino-{2-[1-(3-trifluoromethylphenyl)ethylideneamino-oxymethyl]phenyl}acetic acid] (CGA 321113), expressed as trifloxystrobin.                                  |     |           |                          |          |                             |                        |
| The residue is fat-soluble.                                                                                                                                                                              |     |           |                          |          |                             |                        |
| <sup>1</sup> Expressed on dry weight                                                                                                                                                                     |     |           |                          |          |                             |                        |
| <sup>2</sup> STMR, STMR-P based on whole fruit residue data                                                                                                                                              |     |           |                          |          |                             |                        |

**Table 2. Recommended MRLs, STMR and HR values for spices**

| Pesticide           | Group or subgroup of spices   | Proposed MRL<br>(mg/kg) | Median <sup>2</sup><br>(mg/kg) | High residue <sup>2</sup><br>(mg/kg) |
|---------------------|-------------------------------|-------------------------|--------------------------------|--------------------------------------|
| Acephate            | Entire group 028 <sup>3</sup> | 0.2(*)                  | 0.2                            | 0.2                                  |
| Azinphos-methyl     | Entire group 028 <sup>3</sup> | 0.5(*)                  | 0.1                            | < 0.5                                |
|                     | Seeds                         | 5                       |                                |                                      |
| Chlorpyrifos        | Fruits or berries             | 1                       | 0.09                           | 3.6                                  |
|                     | Roots or rhizomes             | 1                       |                                |                                      |
| Chlorpyrifos-methyl | Seeds                         | 1                       |                                |                                      |
|                     | Fruits                        | 0.3                     | 0.77                           | 2.9                                  |
|                     | Roots or rhizomes             | 5                       |                                |                                      |
| Cypermethrin        | Fruits or berries             | 0.1                     | 0.11                           | 0.12                                 |
|                     | Roots or rhizomes             | 0.2                     |                                |                                      |
|                     | Seeds                         | 5                       |                                |                                      |
| Diazinon            | Fruits                        | 0.1 (*)                 | 0.19                           | 3.6                                  |
|                     | Roots or rhizomes             | 0.5                     |                                |                                      |
| Dichlorvos          | Entire group 028 <sup>3</sup> | 0.1(*)                  | 0.1                            | 0.1                                  |
|                     | Seeds                         | 0.05(*)                 |                                |                                      |
| Dicofol             | Fruits or berries             | 0.1                     | 0.05                           | 0.05                                 |
|                     | Roots or rhizomes             | 0.1                     |                                |                                      |
|                     | Seeds                         | 5                       |                                |                                      |
| Dimethoate          | Fruits or berries             | 0.5                     | 0.17                           | 3                                    |
|                     | Roots or rhizomes             | 0.1(*)                  |                                |                                      |
| Disulfoton          | Entire group 028 <sup>3</sup> | 0.05(*)                 | 0.05                           | 0.05                                 |
|                     | Seeds                         | 1                       |                                |                                      |
| Endosulfan (total)  | Fruits or berries             | 5                       | 0.12                           | 3.2                                  |
|                     | Roots or rhizomes             | 0.5                     |                                |                                      |
|                     | Seeds                         | 3                       |                                |                                      |
| Ethion              | Fruits or berries             | 5                       | 1.7                            | 3.1                                  |
|                     | Roots or rhizomes             | 0.3                     |                                |                                      |
|                     | Seeds                         | 7                       | 0.4                            | 5.4                                  |
| Fenitrothion        | Fruits or berries             | 1                       |                                |                                      |
|                     | Roots or rhizomes             | 0.1(*)                  |                                |                                      |

| Pesticide         | Group or subgroup of spices     | Proposed MRL<br>(mg/kg) | Median <sup>2</sup><br>(mg/kg) | High residue <sup>2</sup><br>(mg/kg) |
|-------------------|---------------------------------|-------------------------|--------------------------------|--------------------------------------|
| Iprodion          | Seeds                           | 0.05(*)                 |                                |                                      |
|                   | Roots or rhizomes               | 0.1                     | 0.05                           | 0.05                                 |
|                   | Seeds                           | 2                       | 0.48                           | 0.86                                 |
| Malathion         | Fruits or berries               | 1                       |                                |                                      |
|                   | Roots or rhizomes               | 0.5                     |                                |                                      |
| Metalaxyl         | Seeds                           | 5                       | 0.43                           | 3.2                                  |
| Methamidophos     | Entire group 028 <sup>3</sup>   | 0.1(*)                  | 0.01                           | 0.1                                  |
|                   | Seeds                           | 5                       |                                |                                      |
| Mevinphos         | Fruits or berries               | 0.2(*)                  | 0.05                           | 2.9                                  |
|                   | Roots or rhizomes               | 1                       |                                |                                      |
|                   | Seeds                           | 0.1 (*)                 |                                |                                      |
| Parathion         | Fruits or berries               | 0.2                     | 0.1                            | 0.1                                  |
|                   | Roots or rhizomes               | 0.2                     |                                |                                      |
|                   | Seeds                           | 5                       |                                |                                      |
| Parathion-methyl  | Fruits or berries               | 5                       | 0.43                           | 3.4                                  |
|                   | Roots or rhizomes               | 3                       |                                |                                      |
| Permethrin        | Entire group 028 <sup>3</sup>   | 0.05 (*)                | 0.05                           | 0.05                                 |
| Phenthoate        | Seeds                           | 7 <sup>c</sup>          | 1.2                            | 5.2                                  |
|                   | Seeds sub-group                 | 0.5                     | 0.21                           | 0.3                                  |
| Phorate           | Fruits or berries               | 0.1(*)                  |                                |                                      |
|                   | Roots or rhizomes               | 0.1(*)                  |                                |                                      |
| Phosalone         | Seeds                           | 2                       |                                |                                      |
|                   | Fruits                          | 2                       | 0.85                           |                                      |
|                   | Roots or rhizomes               | 3                       |                                | 1.5                                  |
| Pirimicarb        | Seeds                           | 5                       | 0.14                           | 3                                    |
| Pirimiphos-methyl | Seeds subgroup                  | 3                       |                                |                                      |
|                   | Fruits subgroup                 | 0.5                     | 0.23                           | 1.8                                  |
|                   | Seeds subgroup                  | 0.1                     |                                |                                      |
| Quintozene        | Fruits or berries               | 0.02                    | 0.05                           | 1.2                                  |
|                   | Roots or rhizomes               | 2                       |                                |                                      |
| Vinclozoline      | Entire spice group <sup>3</sup> | 0.05 (*)                | 0.05                           | 0.05                                 |

<sup>1</sup> The residue definitions remain the same as those recommended for the given pesticide in other plant commodities.

<sup>2</sup> Values recommended for calculation of short term and chronic intakes are indicated.

<sup>3</sup> The Group of A28 as modified by the 36<sup>th</sup> Session of CCPR

**Table 3. Recommended maximum residue levels of residues in/on dried chili peppers<sup>1</sup>**

| Pesticide                              | Recommended MRL for dried chili<br>pepper (mg/kg) | Notes |
|----------------------------------------|---------------------------------------------------|-------|
| 177 Abamectin                          | 0.2                                               |       |
| 95 Acephate                            | 50                                                |       |
| 2 Azinphos-methyl                      | 10                                                |       |
| 155 Benalaxyl                          | 0.5                                               |       |
| 47 Bromide ion                         | 200                                               |       |
| 8 Carbaryl                             | 50                                                |       |
| 72 Carbendazim (based on chilli peper) | 20                                                |       |

| Pesticide |                     | Recommended MRL for dried chili pepper (mg/kg) | Notes |
|-----------|---------------------|------------------------------------------------|-------|
| 81        | Chlorothalonil      | 70                                             |       |
| 17        | Chlorpyrifos        | 20                                             |       |
| 90        | Chlorpyrifos-methyl | 5                                              |       |
| 157       | Cyfluthrin          | 2                                              |       |
| 67        | Cyhexatin           | 5                                              |       |
| 118       | Cypermethrin        | 5                                              |       |
| 169       | Cyromazine          | 10                                             |       |
| 22        | Diazinon            | 0.5                                            |       |
| 82        | Dichlofluanid       | 20                                             |       |
| 26        | Dicofol             | 10                                             |       |
| 27        | Dimethoate          | 50                                             |       |
| 87        | Dinocap             | 2                                              |       |
| 105       | Dithiocarbamates    | 10                                             |       |
| 106       | Ethephon            | 50                                             |       |
| 149       | Ethoprophos         | 0.2                                            | (a)   |
| 192       | Fenarimol           | 5                                              |       |
| 185       | Fenpropathrin       | 10                                             |       |
| 119       | Fenvalerate         | 5                                              |       |
| 206       | Imidacloprid        | 1                                              |       |
| 49        | Malathion           | 1                                              |       |
| 138       | Metalaxyl           | 10                                             |       |
| 100       | Methamidophos       | 20                                             |       |
| 94        | Methomyl            | 10                                             | (b)   |
| 209       | Methoxyfenozide     | 20                                             |       |
| 54        | Monocrotophos       | 2                                              |       |
| 126       | Oxamyl              | 50                                             |       |
| 120       | Permethrin          | 10                                             |       |
| 61        | Phosphamidon        | 2                                              |       |
| 62        | Piperonyl butoxide  | 20                                             |       |
| 101       | Pirimicarb          | 20                                             |       |
| 86        | Pirimiphos-methyl   | 10                                             | (c)   |
| 136       | Procymidone         | 50                                             |       |
| 171       | Profenofos          | 50                                             |       |
| 148       | Propamocarb         | 10                                             |       |
| 63        | Pyrethrins          | 0.5                                            |       |
| 64        | Quintozene          | 0.1                                            |       |
| 203       | Spinosad            | 3                                              |       |
| 189       | Tebuconazole        | 5                                              |       |
| 196       | Tebufenozide        | 10                                             |       |
| 162       | Tolylfluanid        | 20                                             |       |
| 133       | Triadimefon         | 1                                              |       |
| 168       | Triadimenol         | 1                                              |       |
| 159       | Vinclozolin         | 30                                             |       |

The residue definitions remain the same as those recommended for the given pesticide in other plant commodities.

(a) The 2004 JMPR recommended a new maximum residue level of 0.05 mg/kg for sweet pepper

(b) Withdrawn by the 2001 JMPR. The 2004 JMPR recommended a new maximum residue level of 0.7 mg/kg.

(c) Withdrawn by the 2003 JMPR

## ANNEX 2

### INDEX OF REPORTS AND EVALUATIONS OF PESTICIDES BY THE JMPR

Numbers in parentheses after the names of pesticides are Codex classification numbers. The abbreviations used are:

T, evaluation of toxicology

R, evaluation of residue and analytical aspects

E, evaluation of effects on the environment

|                                        |                                                                                                                                                                                              |
|----------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Abamectin (177)                        | 1992 (T,R), 1994 (T,R), 1995 (T), 1997 (T,R), 2000 (R)                                                                                                                                       |
| Acephate (095)                         | 1976 (T,R), 1979 (R), 1981 (R), 1982 (T), 1984 (T,R), 1987 (T), 1988 (T), 1990 (T,R), 1991 (corr. to 1990 R evaluation), 1994 (R), 1996 (R), 2002 (T), 2003 (R), 2004 (corr. to 2003 report) |
| Acrylonitrile                          | 1965 (T,R)                                                                                                                                                                                   |
| Aldicarb (117)                         | 1979 (T,R), 1982 (T,R), 1985 (R), 1988 (R), 1990 (R), 1991 (corr. to 1990 evaluation), 1992 (T), 1993 (R), 1994 (R), 1996 (R), 2001 (R), 2002 (R)                                            |
| Aldrin (001)                           | 1965 (T), 1966 (T,R), 1967 (R), 1974 (R), 1975 (R), 1977 (T), 1990 (R), 1992 (R)                                                                                                             |
| Allethrin                              | 1965 (T,R)                                                                                                                                                                                   |
| Aminocarb (134)                        | 1978 (T,R), 1979 (T,R)                                                                                                                                                                       |
| Aminomethylphosphonic acid (AMPA, 198) | 1997 (T,R)                                                                                                                                                                                   |
| Amitraz (122)                          | 1980 (T,R), 1983 (R), 1984 (T,R), 1985 (R), 1986 (R), 1989 (R), 1990 (T,R), 1991 (R & corr. to 1990 R evaluation), 1998 (T)                                                                  |
| Amitrole (079)                         | 1974 (T,R), 1977 (T), 1993 (T,R), 1997 (T), 1998 (R)                                                                                                                                         |
| Anilazine (163)                        | 1989 (T,R), 1992 (R)                                                                                                                                                                         |
| Azinphos-ethyl (068)                   | 1973 (T,R), 1983 (R)                                                                                                                                                                         |
| Azinphos-methyl (002)                  | 1965 (T), 1968 (T,R), 1972 (R), 1973 (T), 1974 (R), 1991 (T,R), 1992 (corr. to 1991 report), 1993 (R), 1995 (R)                                                                              |
| Azocyclotin (129)                      | 1979 (R), 1981 (T), 1982 (R), 1983 (R), 1985 (R), 1989 (T,R), 1991 (R), 1994 (T)                                                                                                             |
| Benalaxyl (155)                        | 1986 (R), 1987 (T), 1988 (R), 1992 (R), 1993 (R)                                                                                                                                             |
| Bendiocarb (137)                       | 1982 (T,R), 1984 (T,R), 1989 (R), 1990 (R)                                                                                                                                                   |
| Benomyl (069)                          | 1973 (T,R), 1975 (T,R), 1978 (T,R), 1983 (T,R), 1988 (R), 1990 (R), 1994 (R), 1995 (T,E), 1998 (R)                                                                                           |
| Bentazone (172)                        | 1991 (T,R), 1992 (corr. to 1991 report, Annex I), 1994 (R), 1995 (R), 1998 (T,R), 1999 (corr. to 1998 report), 2004(T)                                                                       |
| BHC (technical-grade)                  | 1965 (T), 1968 (T,R), 1973 (T,R) (see also Lindane)                                                                                                                                          |
| Bifenthrin (178)                       | 1992 (T,R), 1995 (R), 1996 (R), 1997 (R)                                                                                                                                                     |
| Binapacryl (003)                       | 1969 (T,R), 1974 (R), 1982 (T), 1984 (R), 1985 (T,R)                                                                                                                                         |
| Bioresmethrin (093)                    | 1975 (R), 1976 (T,R), 1991 (T,R)                                                                                                                                                             |
| Biphenyl                               | See Diphenyl                                                                                                                                                                                 |
| Bitertanol (144)                       | 1983 (T), 1984 (R), 1986 (R), 1987 (T), 1988 (R), 1989 (R), 1991 (R), 1998 (T), 1999 (R), 2002 (R)                                                                                           |
| Bromide ion (047)                      | 1968 (R), 1969 (T,R), 1971 (R), 1979 (R), 1981 (R), 1983 (R), 1988 (T,R), 1989 (R), 1992 (R)                                                                                                 |



|                            |                                                                                                                                                                                                                                                      |
|----------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Bromomethane (052)         | 1965 (T,R), 1966 (T,R), 1967 (R), 1968 (T,R), 1971 (R), 1979 (R), 1985 (R), 1992 (R)                                                                                                                                                                 |
| Bromophos (004)            | 1972 (T,R), 1975 (R), 1977 (T,R), 1982 (R), 1984 (R), 1985 (R)                                                                                                                                                                                       |
| Bromophos-ethyl (005)      | 1972 (T,R), 1975 (T,R), 1977 (R)                                                                                                                                                                                                                     |
| Bromopropylate (070)       | 1973 (T,R), 1993 (T,R)                                                                                                                                                                                                                               |
| Butocarboxim (139)         | 1983 (R), 1984 (T), 1985 (T), 1986 (R)                                                                                                                                                                                                               |
| Buprofezin (173)           | 1991 (T,R), 1995 (R), 1996 (corr. to 1995 report.), 1999 (R)                                                                                                                                                                                         |
| sec-Butylamine (089)       | 1975 (T,R), 1977 (R), 1978 (T,R), 1979 (R), 1980 (R), 1981 (T), 1984 (T,R: withdrawal of temporary ADI, but no evaluation)                                                                                                                           |
| Cadusafos (174)            | 1991 (T,R), 1992 (R), 1992 (R)                                                                                                                                                                                                                       |
| Camphoclor (071)           | 1968 (T,R), 1973 (T,R)                                                                                                                                                                                                                               |
| Captafol (006)             | 1969 (T,R), 1973 (T,R), 1974 (R), 1976 (R), 1977 (T,R), 1982 (T), 1985 (T,R), 1986 (corr. to 1985 report), 1990 (R), 1999 (acute Rf D)                                                                                                               |
| Captan (007)               | 1965 (T), 1969 (T,R), 1973 (T), 1974 (R), 1977 (T,R), 1978 (T,R), 1980 (R), 1982 (T), 1984 (T,R), 1986 (R), 1987 (R and corr. to 1986 R evaluation), 1990 (T,R), 1991 (corr. to 1990 R evaluation), 1994 (R), 1995 (T), 1997 (R), 2000 (R), 2004 (T) |
| Carbaryl (008)             | 1965 (T), 1966 (T,R), 1967 (T,R), 1968 (R), 1969 (T,R), 1970 (R), 1973 (T,R), 1975 (R), 1976 (R), 1977 (R), 1979 (R), 1984 (R), 1996 (T), 2001 (T), 2002 (R)                                                                                         |
| Carbendazim (072)          | 1973 (T,R), 1976 (R), 1977 (T), 1978 (R), 1983 (T,R), 1985 (T,R), 1987 (R), 1988 (R), 1990 (R), 1994 (R), 1995 (T,E), 1998 (T,R), 2003 (R)                                                                                                           |
| Carbofuran (096)           | 1976 (T,R), 1979 (T,R), 1980 (T), 1982 (T), 1991 (R), 1993 (R), 1996 (T), 1997 (R), 1999 (corr. to 1997 report), 2002 (T, R), 2003 (R) (See also carbosulfan), 2004 (R)                                                                              |
| Carbon disulfide (009)     | 1965 (T,R), 1967 (R), 1968 (R), 1971 (R), 1985 (R)                                                                                                                                                                                                   |
| Carbon tetrachloride (010) | 1965 (T,R), 1967 (R), 1968 (T,R), 1971 (R), 1979 (R), 1985 (R)                                                                                                                                                                                       |
| Carbophenothion (011)      | 1972 (T,R), 1976 (T,R), 1977 (T,R), 1979 (T,R), 1980 (T,R), 1983 (R)                                                                                                                                                                                 |
| Carbosulfan (145)          | 1984 (T,R), 1986 (T), 1991 (R), 1992 (corr. to 1991 report), 1993 (R), 1997 (R), 1999 (R), 2002 (R), 2003 (T, R), 2004 (R, corr. to 2003 report)                                                                                                     |
| Cartap (097)               | 1976 (T,R), 1978 (T,R), 1995 (T,R)                                                                                                                                                                                                                   |
| Chinomethionat (080)       | 1968 (T,R) (as oxythioquinox), 1974 (T,R), 1977 (T,R), 1981 (T,R), 1983 (R), 1984 (T,R), 1987 (T)                                                                                                                                                    |
| Chlorbenside               | 1965 (T)                                                                                                                                                                                                                                             |
| Chlordane (012)            | 1965 (T), 1967 (T,R), 1969 (R), 1970 (T,R), 1972 (R), 1974 (R), 1977 (T,R), 1982 (T), 1984 (T,R), 1986 (T)                                                                                                                                           |
| Chlordimeform (013)        | 1971 (T,R), 1975 (T,R), 1977 (T), 1978 (T,R), 1979(T), 1980(T), 1985(T), 1986 (R), 1987 (T)                                                                                                                                                          |
| Chlorfenson                | 1965 (T)                                                                                                                                                                                                                                             |
| Chlorfenvinphos (014)      | 1971 (T,R), 1984 (R), 1994 (T), 1996 (R)                                                                                                                                                                                                             |
| Chlormequat (015)          | 1970 (T,R), 1972 (T,R), 1976 (R), 1985 (R), 1994 (T,R), 1997 (T), 1999 (acute Rf D), 2000 (R)                                                                                                                                                        |
| Chlorobenzilate (016)      | 1965 (T), 1968 (T,R), 1972 (R), 1975 (R), 1977 (R), 1980 (T)                                                                                                                                                                                         |
| Chloropicrin               | 1965 (T,R)                                                                                                                                                                                                                                           |

|                                              |                                                                                                                                                                                                                               |
|----------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Chloropropylate                              | 1968 (T,R), 1972 (R)                                                                                                                                                                                                          |
| Chlorothalonil (081)                         | 1974 (T,R), 1977 (T,R), 1978 (R), 1979 (T,R), 1981 (T,R), 1983 (T,R), 1984 (corr. to 1983 report and T evaluation), 1985 (T,R), 1987 (T), 1988 (R), 1990 (T,R), 1991 (corr. to 1990 evaluation), 1992 (T), 1993 (R), 1997 (R) |
| Chlorpropham                                 | 1965 (T), 2000 (T), 2001 (R)                                                                                                                                                                                                  |
| Chlorpyrifos (017)                           | 1972 (T,R), 1974 (R), 1975 (R), 1977 (T,R), 1981 (R), 1982 (T,R), 1983 (R), 1989 (R), 1995 (R), 1999 (T), 2000 (R), 2004 (R)                                                                                                  |
| Chlorpyrifos-methyl (090)                    | 1975 (T,R), 1976 (R, Annex I only), 1979 (R), 1990 (R), 1991 (T,R), 1992 (T and corr. to 1991 report), 1993 (R), 1994 (R), 2001 (T)                                                                                           |
| Chlorthion                                   | 1965 (T)                                                                                                                                                                                                                      |
| Clethodim (187)                              | 1994 (T,R), 1997 (R), 1999 (R), 2002 (R)                                                                                                                                                                                      |
| Clofentezine (156)                           | 1986 (T,R), 1987 (R), 1989 (R), 1990 (R), 1992 (R)                                                                                                                                                                            |
| Coumaphos (018)                              | 1968 (T,R), 1972 (R), 1975 (R), 1978 (R), 1980 (T,R), 1983 (R), 1987 (T), 1990 (T,R)                                                                                                                                          |
| Crufomate (019)                              | 1968 (T,R), 1972 (R)                                                                                                                                                                                                          |
| Cyanophenfos (091)                           | 1975 (T,R), 1978 (T: ADI extended, but no evaluation), 1980, (T), 1982 (R), 1983 (T)                                                                                                                                          |
| Cycloxydim (179)                             | 1992 (T,R), 1993 (R)                                                                                                                                                                                                          |
| Cyfluthrin (157)                             | 1986 (R), 1987 (T and corr. to 1986 report), 1989 (R), 1990 (R), 1992 (R)                                                                                                                                                     |
| Cyhalothrin (146)                            | 1984 (T,R), 1986 (R), 1988 (R)                                                                                                                                                                                                |
| Cyhexatin (tricyclohexyltin hydroxide) (067) | 1970 (T,R), 1973 (T,R), 1974 (R), 1975 (R), 1977 (T), 1978 (T,R), 1980 (T), 1981 (T), 1982 (R), 1983 (R), 1985 (R), 1988 (T), 1989 (T), 1991 (T,R), 1992 (R), 1994 (T)                                                        |
| Cypermethrin (118)                           | 1979 (T,R), 1981 (T,R), 1982 (R), 1983 (R), 1984 (R), 1985 (R), 1986 (R), 1987 (corr. to 1986 evaluation), 1988 (R), 1990 (R)                                                                                                 |
| Cyprodinil (207)                             | 2003 (T,R), 2004 (corr. to 2003 report)                                                                                                                                                                                       |
| Cyromazine (169)                             | 1990 (T,R), 1991 (corr. to 1990 R evaluation), 1992 (R)                                                                                                                                                                       |
| 2,4-D (020)                                  | 1970 (T,R), 1971 (T,R), 1974 (T,R), 1975 (T,R), 1980 (R), 1985, (R), 1986 (R), 1987 (corr. to 1986 report, Annex I), 1996 (T), 1997 (E), 1998 (R), 2001 (R)                                                                   |
| Daminozide (104)                             | 1977 (T,R), 1983 (T), 1989 (T,R), 1991 (T)                                                                                                                                                                                    |
| DDT (021)                                    | 1965 (T), 1966 (T,R), 1967 (T,R), 1968 (T,R), 1969 (T,R), 1978 (R), 1979 (T), 1980 (T), 1983 (T), 1984 (T), 1993 (R), 1994 (R), 1996 (R)                                                                                      |
| Deltamethrin (135)                           | 1980 (T,R), 1981 (T,R), 1982 (T,R), 1984 (R), 1985 (R), 1986 (R), 1987 (R), 1988 (R), 1990 (R), 1992 (R), 2000 (T), 2002 (R)                                                                                                  |
| Demeton (092)                                | 1965 (T), 1967 (R), 1975 (R), 1982 (T)                                                                                                                                                                                        |
| Demeton-S-methyl (073)                       | 1973 (T,R), 1979 (R), 1982 (T), 1984 (T,R), 1989 (T,R), 1992 (R), 1998 (R)                                                                                                                                                    |
| Demeton-S-methylsulphon (164)                | 1973 (T,R), 1982 (T), 1984 (T,R), 1989 (T,R), 1992 (R)                                                                                                                                                                        |
| Dialifos (098)                               | 1976 (T,R), 1982 (T), 1985 (R)                                                                                                                                                                                                |

|                                          |                                                                                                                                                                                                                                                                          |
|------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Diazinon (022)                           | 1965 (T), 1966 (T), 1967 (R), 1968 (T,R), 1970 (T,R), 1975 (R), 1979 (R), 1993 (T,R), 1994 (R), 1996 (R), 1999 (R), 2001 (T)                                                                                                                                             |
| 1,2-Dibromoethane (023)                  | 1965 (T,R), 1966 (T,R), 1967 (R), 1968 (R), 1971 (R), 1979 (R), 1985 (R)                                                                                                                                                                                                 |
| Dicloran (083)                           | 2003 (R)                                                                                                                                                                                                                                                                 |
| Dichlorfluanid (082)                     | 1969 (T,R), 1974 (T,R), 1977 (T,R), 1979 (T,R), 1981 (R), 1982 (R), 1983 (T,R), 1985 (R)                                                                                                                                                                                 |
| 1,2-Dichloroethane (024)                 | 1965 (T,R), 1967 (R), 1971 (R), 1979 (R), 1985 (R)                                                                                                                                                                                                                       |
| Dichlorvos (025)                         | 1965 (T,R), 1966 (T,R), 1967 (T,R), 1969 (R), 1970 (T,R), 1974 (R), 1977 (T), 1993 (T,R)                                                                                                                                                                                 |
| Dicloran (083)                           | 1974 (T,R), 1977 (T,R), 1998 (T,R)                                                                                                                                                                                                                                       |
| Dicofol (026)                            | 1968 (T,R), 1970 (R), 1974 (R), 1992 (T,R), 1994 (R)                                                                                                                                                                                                                     |
| Dieldrin (001)                           | 1965 (T), 1966 (T,R), 1967 (T,R), 1968 (R), 1969 (R), 1970, (T,R), 1974 (R), 1975 (R), 1977 (T), 1990 (R), 1992 (R)                                                                                                                                                      |
| Diffubenzuron (130)                      | 1981 (T,R), 1983 (R), 1984 (T,R), 1985 (T,R), 1988 (R), 2001 (T), 2002 (R)                                                                                                                                                                                               |
| Dimethipin (151)                         | 1985 (T,R), 1987 (T,R), 1988 (T,R), 1999 (T), 2001 (R), 2004 (T)                                                                                                                                                                                                         |
| Dimethoate (027)                         | 1965 (T), 1966 (T), 1967 (T,R), 1970 (R), 1973 (R in evaluation of formothion), 1977 (R), 1978 (R), 1983 (R) 1984 (T,R) 1986 (R), 1987 (T,R), 1988 (R), 1990 (R), 1991 (corr. to 1990 evaluation), 1994 (R), 1996 (T), 1998 (R), 2003 (T,R), 2004 (corr. to 2003 report) |
| Dimethrin                                | 1965 (T)                                                                                                                                                                                                                                                                 |
| Dinocap (087)                            | 1969 (T,R), 1974 (T,R), 1989 (T,R), 1992 (R), 1998 (R), 1999 (R), 2000 (T), 2001 (R)                                                                                                                                                                                     |
| Dioxathion (028)                         | 1968 (T,R), 1972 (R)                                                                                                                                                                                                                                                     |
| Diphenyl (029)                           | 1966 (T,R), 1967 (T)                                                                                                                                                                                                                                                     |
| Diphenylamine (030)                      | 1969 (T,R), 1976 (T,R), 1979 (R), 1982 (T), 1984 (T,R), 1998 (T), 2001 (R), 2003 (R)                                                                                                                                                                                     |
| Diquat (031)                             | 1970 (T,R), 1972 (T,R), 1976 (R), 1977 (T,R), 1978 (R), 1994 (R)                                                                                                                                                                                                         |
| Disulfoton (074)                         | 1973 (T,R), 1975 (T,R), 1979 (R), 1981 (R), 1984 (R), 1991 (T,R), 1992 (corr. to 1991 report, Annex I), 1994 (R), 1996 (T), 1998 (R)                                                                                                                                     |
| Dithianon (180)                          | 1992 (T,R), 1995 (R), 1996 (corr. to 1995 report)                                                                                                                                                                                                                        |
| Dithiocarbamates (105)                   | 1965 (T), 1967 (T,R), 1970 (T,R), 1983 (R propineb, thiram), 1984 (R propineb), 1985 (R), 1987 (T thiram), 1988 (R thiram), 1990 (R), 1991 (corr. to 1990 evaluation), 1992 (T thiram), 1993 (T,R), 1995 (R), 1996 (T,R ferbam, ziram; R thiram), 2004 (R)               |
| 4,6-Dinitro- <i>ortho</i> -cresol (DNOC) | 1965 (T)                                                                                                                                                                                                                                                                 |
| Dodine (084)                             | 1974 (T,R), 1976 (T,R), 1977 (R), 2000 (T), 2003 (R) 2004 (corr. to 2003 report)                                                                                                                                                                                         |
| Edifenphos (099)                         | 1976 (T,R), 1979 (T,R), 1981 (T,R)                                                                                                                                                                                                                                       |
| Endosulfan (032)                         | 1965 (T), 1967 (T,R), 1968 (T,R), 1971 (R), 1974 (R), 1975 (R), 1982 (T), 1985 (T,R), 1989 (T,R), 1993 (R), 1998 (T)                                                                                                                                                     |
| Endrin (033)                             | 1965 (T), 1970 (T,R), 1974 (R), 1975 (R), 1990 (R), 1992 (R)                                                                                                                                                                                                             |
| Esfenvalerate (204)                      | 2002 (T, R)                                                                                                                                                                                                                                                              |
| Ethephon (106)                           | 1977 (T,R), 1978 (T,R), 1983 (R), 1985 (R), 1993 (T), 1994 (R), 1995 (T), 1997 (T), 2002 (T)                                                                                                                                                                             |

|                              |                                                                                                                                                                                                                              |
|------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Ethiofencarb (107)           | 1977 (T,R), 1978 (R), 1981 (R), 1982 (T,R), 1983 (R)                                                                                                                                                                         |
| Ethion (034)                 | 1968 (T,R), 1969 (R), 1970 (R), 1972 (T,R), 1975 (R),<br>1982 (T), 1983 (R), 1985 (T), 1986 (T), 1989 (T),<br>1990 (T), 1994 (R)                                                                                             |
| Ethoprophos (149)            | 1983 (T), 1984 (R), 1987 (T), 1999 (T), 2004 (R)                                                                                                                                                                             |
| Ethoxyquin (035)             | 1969 (T,R), 1998 (T), 1999 (R)                                                                                                                                                                                               |
| Ethylene dibromide           | See 1,2-Dibromoethane                                                                                                                                                                                                        |
| Ethylene dichloride          | See 1,2-Dichloroethane                                                                                                                                                                                                       |
| Ethylene oxide               | 1965 (T,R), 1968 (T,R), 1971 (R)                                                                                                                                                                                             |
| Ethylenethiourea (ETU) (108) | 1974 (R), 1977 (T,R), 1986 (T,R), 1987 (R), 1988<br>(T,R), 1990 (R), 1993 (T,R)                                                                                                                                              |
| Etofenprox (184)             | 1993 (T,R)                                                                                                                                                                                                                   |
| Etrifos (123)                | 1980 (T,R), 1982 (T,R <sup>1</sup> ), 1986 (T,R), 1987 (R), 1988<br>(R), 1989 (R), 1990 (R)                                                                                                                                  |
| Famoxadone ( 208)            | 2003 (T,R)                                                                                                                                                                                                                   |
| Fenamiphos (085)             | 1974 (T,R), 1977 (R), 1978 (R), 1980 (R), 1985 (T),<br>1987 (T), 1997 (T), 1999 (R), 2002 (T)                                                                                                                                |
| Fenarimol (192)              | 1995 (T,R,E), 1996 (R and corr. to 1995 report)                                                                                                                                                                              |
| Fenbuconazole (197)          | 1997 (T,R)                                                                                                                                                                                                                   |
| Fenbutatin oxide (109)       | 1977 (T,R), 1979 (R), 1992 (T), 1993 (R)                                                                                                                                                                                     |
| Fenchlorfos (036)            | 1968 (T,R), 1972 (R), 1983 (R)                                                                                                                                                                                               |
| Fenitrothion (037)           | 1969 (T,R), 1974 (T,R), 1976 (R), 1977 (T,R), 1979<br>(R), 1982 (T), 1983 (R), 1984 (T,R), 1986 (T,R), 1987<br>(R and corr. to 1986 R evaluation), 1988 (T), 1989<br>(R), 2000 (T), 2003 (R), 2004 (R, corr. to 2003 report) |
| Fenpropathrin (185)          | 1993 (T,R)                                                                                                                                                                                                                   |
| Fenpropimorph (188)          | 1994 (T), 1995 (R), 1999 (R), 2001 (T), 2004 (T)                                                                                                                                                                             |
| Fenpyroximate (193)          | 1995 (T,R), 1996 (corr. to 1995 report.), 1999 (R),<br>2004 (T)                                                                                                                                                              |
| Fensulfothion (038)          | 1972 (T,R), 1982 (T), 1983 (R)                                                                                                                                                                                               |
| Fenthion (039)               | 1971 (T,R), 1975 (T,R), 1977 (R), 1978 (T,R), 1979<br>(T), 1980 (T), 1983 (R), 1989 (R), 1995 (T,R,E), 1996<br>(corr. to 1995 report), 1997 (T), 2000 (R)                                                                    |
| Fentin compounds (040)       | 1965 (T), 1970 (T,R), 1972 (R), 1986 (R), 1991 (T,R),<br>1993 (R), 1994 (R)                                                                                                                                                  |
| Fenvalerate (119)            | 1979 (T,R), 1981 (T,R), 1982 (T), 1984 (T,R), 1985<br>(R), 1986 (T,R), 1987 (R and corr. to 1986 report),<br>1988 (R), 1990 (R), 1991 (corr. to 1990 R evaluation)                                                           |
| Ferbam                       | See Dithiocarbamates, 1965 (T), 1967 (T,R), 1996<br>(T,R)                                                                                                                                                                    |
| Fipronil                     | 1997 (T), 2000 (T), 2001 (R)                                                                                                                                                                                                 |
| Fipronil-desulfinyl          | 1997 (T)                                                                                                                                                                                                                     |
| Flucythrinate (152)          | 1985 (T,R), 1987 (R), 1988 (R), 1989 (R), 1990 (R),<br>1993 (R)                                                                                                                                                              |
| Fludioxinil ( )              | 2004 (T,R)                                                                                                                                                                                                                   |
| Flumethrin (195)             | 1996 (T,R)                                                                                                                                                                                                                   |
| Flusilazole (165)            | 1989 (T,R), 1990 (R), 1991 (R), 1993 (R), 1995 (T)                                                                                                                                                                           |
| Flutolanil (205)             | 2002 (T, R)                                                                                                                                                                                                                  |
| Folpet (041)                 | 1969 (T,R), 1973 (T), 1974 (R), 1982 (T), 1984 (T,R),<br>1986 (T), 1987 (R), 1990 (T,R), 1991 (corr. to 1990 R<br>evaluation), 1993 (T,R), 1994 (R), 1995 (T), 1997 (R),<br>1998 (R), 1999(R) , 2002 (T), 2004 (T)           |
| Formothion (042)             | 1969 (T,R), 1972 (R), 1973 (T,R), 1978 (R), 1998 (R)                                                                                                                                                                         |

|                            |                                                                                                                                                                                                                                                  |
|----------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Glufosinate-ammonium (175) | 1991 (T,R), 1992 (corr. to 1991 report, Annex I), 1994 (R), 1998 (R), 1999 (T,R)                                                                                                                                                                 |
| Glyphosate (158)           | 1986 (T,R), 1987 (R and corr. to 1986 report), 1988 (R), 1994 (R), 1997 (T,R), 2004 (T)                                                                                                                                                          |
| Guazatine (114)            | 1978 (T,R), 1980 (R), 1997 (T,R)                                                                                                                                                                                                                 |
| Haloxypop (194)            | 1995 (T,R), 1996 (R and corr. to 1995 report), 2001 (R)                                                                                                                                                                                          |
| Heptachlor (043)           | 1965 (T), 1966 (T,R), 1967 (R), 1968 (R), 1969 (R), 1970 (T,R), 1974 (R), 1975 (R), 1977 (R), 1987 (R), 1991 (T,R), 1992 (corr. to 1991 report, Annex I), 1993 (R), 1994 (R)                                                                     |
| Hexachlorobenzene (044)    | 1969 (T,R), 1973 (T,R), 1974 (T,R), 1978(T), 1985 (R)                                                                                                                                                                                            |
| Hexaconazole (170)         | 1990 (T,R), 1991 (R and corr. to 1990 R evaluation), 1993 (R)                                                                                                                                                                                    |
| Hexythiazox (176)          | 1991 (T,R), 1994 (R), 1998 (R)                                                                                                                                                                                                                   |
| Hydrogen cyanide (045)     | 1965 (T,R)                                                                                                                                                                                                                                       |
| Hydrogen phosphide (046)   | 1965 (T,R), 1966 (T,R), 1967 (R), 1969 (R), 1971 (R)                                                                                                                                                                                             |
| Imazalil (110)             | 1977 (T,R), 1980 (T,R), 1984 (T,R), 1985 (T,R), 1986 (T), 1988 (R), 1989 (R), 1991 (T), 1994 (R), 2000 (T), 2001 (T)                                                                                                                             |
| Imidacloprid               | 2001 (T), 2002 (R)                                                                                                                                                                                                                               |
| Iprodione (111)            | 1977 (T,R), 1980 (R), 1992 (T), 1994 (R), 1995 (T), 2001 (R)                                                                                                                                                                                     |
| Isofenphos (131)           | 1981 (T,R), 1982 (T,R), 1984 (R), 1985 (R), 1986 (T,R), 1988 (R), 1992 (R)                                                                                                                                                                       |
| Kresoxim-methyl (199)      | 1998 (T,R), 2001 (R)                                                                                                                                                                                                                             |
| Lead arsenate              | 1965 (T), 1968 (T,R)                                                                                                                                                                                                                             |
| Leptophos (088)            | 1974 (T,R), 1975 (T,R), 1978 (T,R)                                                                                                                                                                                                               |
| Lindane (048)              | 1965 (T), 1966 (T,R), 1967 (R), 1968 (R), 1969 (R), 1970 (T,R, published as Annex VI to 1971 evaluations), 1973 (T,R), 1974 (R), 1975 (R), 1977 (T,R), 1978 (R), 1979 (R), 1989 (T,R), 1997 (T), 2002 (T), 2003 (R), 2004 (corr. to 2003 report) |
| Malathion (049)            | 1965 (T), 1966 (T,R), 1967 (corr. to 1966 R evaluation), 1968 (R), 1969 (R), 1970 (R), 1973 (R), 1975 (R), 1977 (R), 1984 (R), 1997 (T), 1999 (R), 2000 (R), 2003 (T), 2004 (R)                                                                  |
| Maleic hydrazide (102)     | 1976 (T,R), 1977 (T,R), 1980 (T), 1984 (T,R), 1996 (T), 1998 (R)                                                                                                                                                                                 |
| Mancozeb (050)             | 1967 (T,R), 1970 (T,R), 1974 (R), 1977 (R), 1980 (T,R), 1993 (T,R)                                                                                                                                                                               |
| Maneb                      | See Dithiocarbamates, 1965 (T), 1967 (T,R), 1987 (T), 1993 (T,R)                                                                                                                                                                                 |
| Mecarbam (124)             | 1980 (T,R), 1983 (T,R), 1985 (T,R), 1986 (T,R), 1987 (R)                                                                                                                                                                                         |
| Metalaxyl (138)            | 1982 (T,R), 1984 (R), 1985 (R), 1986 (R), 1987 (R), 1989 (R), 1990 (R), 1992 (R), 1995 (R)                                                                                                                                                       |
| Metalaxyl –M (212)         | 2002 (T), 2004 (R)                                                                                                                                                                                                                               |

|                         |                                                                                                                                                                                |
|-------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Methacrifos (125)       | 1980 (T,R), 1982 (T), 1986 (T), 1988 (T), 1990 (T,R), 1992 (R)                                                                                                                 |
| Methamidophos (100)     | 1976 (T,R), 1979 (R), 1981 (R), 1982 (T,R), 1984 (R), 1985 (T), 1989 (R), 1990 (T,R), 1994 (R), 1996 (R), 1997 (R), 2002 (T), 2003 (R), 2004 (R, corr. to 2003 report)         |
| Methidathion (051)      | 1972 (T,R), 1975 (T,R), 1979 (R), 1992 (T,R), 1994 (R), 1997 (T)                                                                                                               |
| Methiocarb (132)        | 1981 (T,R), 1983 (T,R), 1984 (T), 1985 (T), 1986 (R), 1987 (T,R), 1988 (R), 1998 (T), 1999 (R)                                                                                 |
| Methomyl (094)          | 1975 (R), 1976 (R), 1977 (R), 1978 (R), 1986 (T,R), 1987 (R), 1988 (R), 1989 (T,R), 1990 (R), 1991 (R), 2001 (T,R), 2004 (R)                                                   |
| Methoprene (147)        | 1984 (T,R), 1986 (R), 1987 (T and corr. to 1986 report), 1988 (R), 1989 (R), 2001 (T)                                                                                          |
| Methoxychlor            | 1965 (T), 1977 (T)                                                                                                                                                             |
| Methoxyfenozide (209)   | 2003 (T,R), 2004 (corr. to 2003 report)                                                                                                                                        |
| Methyl bromide (052)    | See Bromomethane                                                                                                                                                               |
| Metiram (186)           | 1993 (T), 1995 (R)                                                                                                                                                             |
| Mevinphos (053)         | 1965 (T), 1972 (T,R), 1996 (T), 1997 (E,R), 2000 (R)                                                                                                                           |
| MGK 264                 | 1967 (T,R)                                                                                                                                                                     |
| Monocrotophos (054)     | 1972 (T,R), 1975 (T,R), 1991 (T,R), 1993 (T), 1994 (R)                                                                                                                         |
| Myclobutanil (181)      | 1992 (T,R), 1997 (R), 1998 (R)                                                                                                                                                 |
| Nabam                   | See Dithiocarbamates, 1965 (T), 1976 (T,R)                                                                                                                                     |
| Nitrofen (140)          | 1983 (T,R)                                                                                                                                                                     |
| Omethoate (055)         | 1971 (T,R), 1975 (T,R), 1978 (T,R), 1979 (T), 1981 (T,R), 1984 (R), 1985 (T), 1986 (R), 1987 (R), 1988 (R), 1990 (R), 1998 (R)                                                 |
| Organomercury compounds | 1965 (T), 1966 (T,R), 1967 (T,R)                                                                                                                                               |
| Oxamyl (126)            | 1980 (T,R), 1983 (R), 1984 (T), 1985 (T,R), 1986 (R), 2002 (T,R)                                                                                                               |
| Oxydemeton-methyl (166) | 1965 (T, as demeton-S-methyl sulfoxide), 1967 (T), 1968 (R), 1973 (T,R), 1982 (T), 1984 (T,R), 1989 (T,R), 1992 (R), 1998 (R), 1999 (corr. to 1992 report), 2002 (T), 2004 (R) |
| Oxythioquinox           | See Chinomethionat                                                                                                                                                             |
| Paclobutrazol (161)     | 1988 (T,R), 1989 (R)                                                                                                                                                           |
| Paraquat (057)          | 1970 (T,R), 1972 (T,R), 1976 (T,R), 1978 (R), 1981 (R), 1982 (T), 1985 (T), 1986 (T), 2003 (T), 2004 (R)                                                                       |
| Parathion (058)         | 1965 (T), 1967 (T,R), 1969 (R), 1970 (R), 1984 (R), 1991 (R), 1995 (T,R), 1997 (R), 2000 (R)                                                                                   |
| Parathion-methyl (059)  | 1965 (T), 1968 (T,R), 1972 (R), 1975 (T,R), 1978 (T,R), 1979 (T), 1980 (T), 1982 (T), 1984 (T,R), 1991 (R), 1992 (R), 1994 (R), 1995 (T), 2000 (R), 2003 (R)                   |
| Penconazole (182)       | 1992 (T,R), 1995 (R)                                                                                                                                                           |
| Permethrin (120)        | 1979 (T,R), 1980 (R), 1981 (T,R), 1982 (R), 1983 (R), 1984 (R), 1985 (R), 1986 (T,R), 1987 (T), 1988 (R), 1989 (R), 1991 (R), 1992 (corr. to 1991 report), 1999 (T)            |
| 2-Phenylphenol (056)    | 1969 (T,R), 1975 (R), 1983 (T), 1985 (T,R), 1989 (T), 1990 (T,R), 1999 (T,R), 2002 (R)                                                                                         |
| Phenothrin (127)        | 1979 (R), 1980 (T,R), 1982 (T), 1984 (T), 1987 (R), 1988 (T,R)                                                                                                                 |
| Phenthoate (128)        | 1980 (T,R), 1981 (R), 1984 (T)                                                                                                                                                 |

|                              |                                                                                                                                                                                                                 |
|------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Phorate (112)                | 1977 (T,R), 1982 (T), 1983 (T), 1984 (R), 1985 (T), 1990 (R), 1991 (R), 1992 (R), 1993 (T), 1994 (T), 1996 (T), 2004 (T)                                                                                        |
| Phosalone (060)              | 1972 (T,R), 1975 (R), 1976 (R), 1993 (T), 1994 (R), 1997 (T), 1999 (R), 2001 (T)                                                                                                                                |
| Phosmet (103)                | 1976 (R), 1977 (corr. to 1976 R evaluation), 1978 (T,R), 1979 (T,R), 1981 (R), 1984 (R), 1985 (R), 1986 (R), 1987 (R and corr. to 1986 R evaluation), 1988 (R), 1994 (T), 1997 (R), 1998 (T), 2002 (R), 2003(R) |
| Phosphine                    | See Hydrogen phosphide                                                                                                                                                                                          |
| Phosphamidon (061)           | 1965 (T), 1966 (T), 1968 (T,R), 1969 (R), 1972 (R), 1974 (R), 1982 (T), 1985 (T), 1986 (T)                                                                                                                      |
| Phoxim (141)                 | 1982 (T), 1983 (R), 1984 (T,R), 1986 (R), 1987 (R), 1988 (R)                                                                                                                                                    |
| Piperonyl butoxide (062)     | 1965 (T,R), 1966 (T,R), 1967 (R), 1969 (R), 1972 (T,R), 1992 (T,R), 1995 (T), 2001 (R), 2002 (R)                                                                                                                |
| Pirimicarb (101)             | 1976 (T,R), 1978 (T,R), 1979 (R), 1981 (T,R), 1982 (T), 1985 (R), 2004 (T)                                                                                                                                      |
| Pirimiphos-methyl (086)      | 1974 (T,R), 1976 (T,R), 1977 (R), 1979 (R), 1983 (R), 1985 (R), 1992 (T), 1994 (R), 2003 (R), 2004 (R, corr. to 2003 report)                                                                                    |
| Prochloraz (142)             | 1983 (T,R), 1985 (R), 1987 (R), 1988 (R), 1989 (R), 1990 (R), 1991 (corr. to 1990 report, Annex I, and R evaluation), 1992 (R), 2001 (T), 2004 (R)                                                              |
| Procymidone(136)             | 1981 (R), 1982 (T), 1989 (T,R), 1990 (R), 1991 (corr. to 1990 Annex I), 1993 (R), 1998 (R)                                                                                                                      |
| Profenofos (171)             | 1990 (T,R), 1992 (R), 1994 (R), 1995 (R)                                                                                                                                                                        |
| Propamocarb (148)            | 1984 (T,R), 1986 (T,R), 1987 (R)                                                                                                                                                                                |
| Propargite (113)             | 1977 (T,R), 1978 (R), 1979 (R), 1980 (T,R), 1982 (T,R), 1999 (T), 2002 (R)                                                                                                                                      |
| Propham (183)                | 1965 (T), 1992 (T,R)                                                                                                                                                                                            |
| Propiconazole (160)          | 1987 (T,R), 1991 (R), 1994 (R), 2004 (T)                                                                                                                                                                        |
| Propineb                     | 1977 (T,R), 1980 (T), 1983 (T), 1984 (R), 1985 (T,R), 1993 (T,R), 2004 2004 (R)                                                                                                                                 |
| Propoxur (075)               | 1973 (T,R), 1977 (R), 1981 (R), 1983 (R), 1989 (T), 1991 (R), 1996 (R)                                                                                                                                          |
| Propylenethiourea (PTU, 150) | 1993 (T,R), 1994 (R), 1999 (T)                                                                                                                                                                                  |
| Pyraclostrobin (210)         | 2003 (T), 2004 (R)                                                                                                                                                                                              |
| Pyrazophos (153)             | 1985 (T,R), 1987 (R), 1992 (T,R), 1993 (R)                                                                                                                                                                      |
| Pyrethrins (063)             | 1965 (T), 1966 (T,R), 1967 (R), 1968 (R), 1969 (R), 1970 (T), 1972 (T,R), 1974 (R), 1999 (T), 2000 (R), 2003 (T,R)                                                                                              |
| Pyriproxyfen (200)           | 1999 (R,T), 2000 (R), 2001 (T)                                                                                                                                                                                  |
| Quintozene (064)             | 1969 (T,R) 1973 (T,R), 1974 (R), 1975 (T,R), 1976 (Annex I, corr. to 1975 R evaluation), 1977 (T,R), 1995 (T,R), 1998 (R)                                                                                       |
| Spinosad (203)               | 2001 (T,R), 2004 (R)                                                                                                                                                                                            |
| 2,4,5-T (121)                | 1970 (T,R), 1979 (T,R), 1981 (T)                                                                                                                                                                                |
| Tebuconazole (189)           | 1994 (T,R), 1996 (corr. to Annex II of 1995 report), 1997 (R)                                                                                                                                                   |
| Tebufenozide (196)           | 1996 (T,R), 1997 (R), 1999 (R), 2001 (T,R), 2003(T)                                                                                                                                                             |
| Tecnazine (115)              | 1974 (T,R), 1978 (T,R), 1981 (R), 1983 (T), 1987 (R), 1989 (R), 1994 (T,R)                                                                                                                                      |
| Teflubenzuron (190)          | 1994 (T), 1996 (R)                                                                                                                                                                                              |

|                            |                                                                                                                                                                                                            |
|----------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Terbufos (167)             | 1989 (T,R), 1990 (T,R), 2003 (T)                                                                                                                                                                           |
| Thiabendazole (065)        | 1970 (T,R), 1971 (R), 1972 (R), 1975 (R), 1977 (T,R), 1979 (R), 1981 (R), 1997 (R), 2000 (R)                                                                                                               |
| Thiodicarb (154)           | 1985 (T,R), 1986 (T), 1987 (R), 1988 (R), 2000 (T), 2001 (R)                                                                                                                                               |
| Thiometon (076)            | 1969 (T,R), 1973 (T,R), 1976 (R), 1979 (T,R), 1988 (R)                                                                                                                                                     |
| Thiophanate-methyl (077)   | 1973 (T,R), 1975 (T,R), 1977 (T), 1978 (R), 1988 (R), 2002 (R)                                                                                                                                             |
| Thiram (105)               | 1990 (R), 1994 (R), 1995 (T,E), 1998 (T,R)<br>See Dithiocarbamates, 1965 (T), 1967 (T,R), 1970 (T,R), 1974 (T), 1977 (T), 1983 (R), 1984 (R), 1985 (T,R), 1987 (T), 1988 (R), 1989 (R), 1992 (T), 1996 (R) |
| Tolclofos-methyl (191)     | 1994 (T,R) 1996 (corr. to Annex II of 1995 report)                                                                                                                                                         |
| Tolyfluanid (162)          | 1988 (T,R), 1990 (R), 1991 (corr. to 1990 report), 2002 (T,R), 2003 (R)                                                                                                                                    |
| Toxaphene                  | See Camphechlor                                                                                                                                                                                            |
| Triadimefon (133)          | 1979 (R), 1981 (T,R), 1983 (T,R), 1984 (R), 1985 (T,R), 1986 (R), 1987 (R and corr. to 1986 R evaluation), 1988 (R), 1989 (R), 1992 (R), 1995 (R), 2004 (T)                                                |
| Triadimenol (168)          | 1989 (T,R), 1992 (R), 1995 (R), 2004 (T)                                                                                                                                                                   |
| Triazolylalanine           | 1989 (T,R)                                                                                                                                                                                                 |
| Triazophos (143)           | 1982 (T), 1983 (R), 1984 (corr. to 1983 report, Annex I), 1986 (T,R), 1990 (R), 1991 (T and corr. to 1990 R evaluation), 1992 (R), 1993 (T,R), 2002 (T)                                                    |
| Trichlorfon (066)          | 1971 (T,R), 1975 (T,R), 1978 (T,R), 1987 (R)                                                                                                                                                               |
| Trichloronat               | 1971 (T,R)                                                                                                                                                                                                 |
| Trichloroethylene          | 1968 (R)                                                                                                                                                                                                   |
| Tricyclohexyltin hydroxide | See Cyhexatin                                                                                                                                                                                              |
| Trifloxystrobin (213)      | 2004 (T, R)                                                                                                                                                                                                |
| Triforine (116)            | 1977 (T), 1978 (T, R), 1997 (T)                                                                                                                                                                            |
| Triphenyltin compounds     | See Fentin compounds                                                                                                                                                                                       |
| Vamidothion (078)          | 1973 (T,R), 1982 (T), 1985 (T,R), 1987 (R), 1988 (T), 1990 (R), 1992 (R)                                                                                                                                   |
| Vinclozolin (159)          | 1986 (T,R), 1987 (R and corr. to 1986 report and R evaluation), 1988 (T,R), 1989 (R), 1990 (R), 1992 (R), 1995 (T)                                                                                         |
| Zineb (105)                | See Dithiocarbamates, 1965 (T), 1967 (T,R), 1993 (T)                                                                                                                                                       |
| Ziram (105)                | See Dithiocarbamates, 1965 (T), 1967 (T,R), 1996 (T,R)                                                                                                                                                     |



## ANNEX 3

### INTERNATIONAL ESTIMATED DAILY INTAKES OF PESTICIDE RESIDUES

The following tables give details of the international estimated daily intakes of the pesticides evaluated by the Meeting for the five GEMS/ Food diets and show the ratios of the estimated intakes to the corresponding ADIs.

(\*) at or about the LOQ

The ranges of the ratios of intake:ADI for all the compounds evaluated are tabulated in Section 3.

Diet: g/person per day; intake: daily intake: µg/person

#### CHLORPYRIFOS ( 017 )

#### International estimated daily intake

ADI = 0–0.01 mg/kg bw

| Codex code | Commodity                                  | STMR or STMR-P (mg/kg) | Mid-East |        | Far-East |        | African |        | Latin American |        | European |        |
|------------|--------------------------------------------|------------------------|----------|--------|----------|--------|---------|--------|----------------|--------|----------|--------|
|            |                                            |                        | Diet     | Intake | Diet     | Intake | Diet    | Intake | Diet           | Intake | Diet     | Intake |
| TN 0660    | Almond                                     | 0.05                   | 0.5      | 0.0    | 0.0      | 0.0    | 0.0     | 0.0    | 0.1            | 0.0    | 1.8      | 0.1    |
| JF 0226    | Apple juice                                | 0.027                  | 4.5      | 0.1    | 0        | 0.0    | 0       | 0.0    | 0.3            | 0.0    | 3.8      | 0.1    |
| FI 0327    | Banana                                     | 0.01                   | 8.3      | 0.1    | 26.2     | 0.3    | 21.0    | 0.2    | 102.3          | 1.0    | 22.8     | 0.2    |
| VB 0400    | Broccoli                                   | 0.02                   | 0.5      | 0.0    | 1.0      | 0.0    | 0.0     | 0.0    | 1.1            | 0.0    | 2.7      | 0.1    |
| VB 0403    | Cabbage, Savoy                             | 0.15                   | 0.1      | 0.0    | 0.1      | 0.0    | 0.1     | 0.0    | 0.1            | 0.0    | 0.1      | 0.0    |
| VR 0577    | Carrot                                     | 0.025                  | 2.8      | 0.1    | 2.5      | 0.1    | 0.0     | 0.0    | 6.3            | 0.2    | 22.0     | 0.6    |
| MM 0812    | Cattle meat                                | 0.02                   | 14.6     | 0.3    | 2.7      | 0.1    | 10.4    | 0.2    | 30.0           | 0.6    | 63.3     | 1.3    |
| MO 1280    | Cattle, kidney                             | 0.01                   | 0.1      | 0.0    | 0.0      | 0.0    | 0.1     | 0.0    | 0.2            | 0.0    | 0.2      | 0.0    |
| MO 1281    | Cattle, liver                              | 0.01                   | 0.2      | 0.0    | 0        | 0.0    | 0.1     | 0.0    | 0.3            | 0.0    | 0.4      | 0.0    |
| VB 0404    | Cauliflower                                | 0.01                   | 1.3      | 0.0    | 1.5      | 0.0    | 0       | 0.0    | 0.3            | 0.0    | 13       | 0.1    |
| VL 0467    | Chinese cabbage, type pe-tsai              | 0.18                   | ND       | –      | ND       | –      | ND      | –      | ND             | –      | ND       | –      |
| FC 0001    | Citrus fruit                               | 0.08                   | 47.1     | 3.8    | 6.3      | 0.5    | 5.1     | 0.4    | 54.6           | 4.4    | 44.6     | 3.6    |
| SB 0716    | Coffee beans                               | 0.01                   | 5.3      | 0.1    | 0.4      | 0.0    | 0.0     | 0.0    | 3.6            | 0.0    | 7.9      | 0.1    |
| VP 0526    | Common bean (green pods or immature seeds) | 0.01                   | 3.5      | 0.0    | 0.8      | 0.0    | 0.0     | 0.0    | 4.0            | 0.0    | 12.0     | 0.1    |
| OR 0691    | Cotton-seed oil, edible                    | 0.01                   | 3.8      | 0.0    | 0.5      | 0.0    | 0.5     | 0.0    | 0.5            | 0.0    | 0.0      | 0.0    |
| PE 0112    | Eggs                                       | 0.001                  | 14.6     | 0.0    | 13.1     | 0.0    | 3.7     | 0.0    | 11.9           | 0.0    | 37.6     | 0.0    |
| FB 0269    | Grapes (fresh, wine, dried)                | 0.085                  | 16.1     | 1.4    | 1.0      | 0.1    | 0.0     | 0.0    | 1.6            | 0.1    | 16.1     | 1.4    |
| GC 0645    | Maize (fresh, flour)                       | 0.015                  | 48.3     | 0.7    | 31.2     | 0.5    | 106.2   | 1.6    | 41.8           | 0.6    | 8.8      | 0.1    |
| OR 0645    | Maize oil, edible                          | 0.03                   | 1.8      | 0.1    | 0.0      | 0.0    | 0.3     | 0.0    | 0.5            | 0.0    | 1.3      | 0.0    |
| ML 0107    | Milk of cattle, goats and sheep            | 0.005                  | 110.3    | 0.6    | 23.9     | 0.1    | 41.3    | 0.2    | 160.1          | 0.8    | 289.3    | 1.4    |
| VA 0385    | Onion, bulb                                | 0.04                   | 23.0     | 0.9    | 11.5     | 0.5    | 7.3     | 0.3    | 13.8           | 0.6    | 27.8     | 1.1    |
| JF 0004    | Orange juice                               | 0.007                  | 7.3      | 0.1    | 0.0      | 0.0    | 0.0     | 0.0    | 0.3            | 0.0    | 4.5      | 0.0    |
| FS 0247    | Peach                                      | 0.042                  | 1.3      | 0.1    | 0.3      | 0.0    | 0.0     | 0.0    | 0.4            | 0.0    | 6.3      | 0.3    |

### Annex 3

304

| Codex code | Commodity                                      | STMR or STMR-P (mg/kg) | Mid-East |      | Far-East |     | African |      | Latin American |      | European |       |
|------------|------------------------------------------------|------------------------|----------|------|----------|-----|---------|------|----------------|------|----------|-------|
| VP 0063    | Peas (green pods and immature seeds)           | 0.01                   | 5.5      | 0.1  | 2.0      | 0.0 | 0.0     | 0.0  | 0.8            | 0.0  | 14.0     | 0.1   |
| TN 0672    | Pecan                                          | 0.05                   | 0.0      | 0.0  | 0.0      | 0.0 | 0.0     | 0.0  | 0.0            | 0.0  | 0.3      | 0.0   |
| VO 0445    | Peppers, sweet (including pim(i)ento)          | 0.38                   | 3.3      | 1.3  | 2.0      | 0.8 | 5.3     | 2.0  | 2.3            | 0.9  | 10.3     | 3.9   |
| MO 0818    | Pig, edible offal of                           | 0                      | 0.0      | 0.0  | 1.0      | 0.0 | 0.0     | 0.0  | 1.0            | 0.0  | 5.0      | 0.0   |
| MM 0818    | Pig meat                                       | 0.001                  | 0.0      | 0.0  | 27.2     | 0.0 | 2.6     | 0.0  | 10.5           | 0.0  | 75.8     | 0.1   |
| FS 0014    | Plum (fresh, prunes)                           | 0.04                   | 1.8      | 0.1  | 0.5      | 0.0 | 0.0     | 0.0  | 0.0            | 0.0  | 4.3      | 0.2   |
| FP 0009    | Pome fruits                                    | 0.17                   | 10.8     | 1.8  | 7.5      | 1.3 | 0.3     | 0.1  | 6.5            | 1.1  | 51.3     | 8.7   |
| VR 0589    | Potato                                         | 0.51                   | 59.0     | 30.1 | 19.2     | 9.8 | 20.6    | 10.5 | 40.8           | 20.8 | 240.8    | 122.8 |
| PM 0110    | Poultry meat                                   | 0.001                  | 31.0     | 0.0  | 13.2     | 0.0 | 5.5     | 0.0  | 25.3           | 0.0  | 53.0     | 0.1   |
| PO 0111    | Poultry, edible offal of                       | 0                      | 0.1      | 0.0  | 0.1      | 0.0 | 0.1     | 0.0  | 0.4            | 0.0  | 0.4      | 0.0   |
| CM 1206    | Rice bran, unprocessed                         | 0.22                   | ND       | –    | ND       | –   | ND      | –    | ND             | –    | ND       | –     |
| CM 0649    | Rice, husked                                   | 0.016                  | 0.0      | 0.0  | 1.8      | 0.0 | 34.7    | 0.6  | 21.0           | 0.3  | 2.5      | 0.0   |
| CM 1205    | Rice, polished                                 | 0.008                  | 48.8     | 0.4  | 277.5    | 2.2 | 68.8    | 0.6  | 65.5           | 0.5  | 9.3      | 0.1   |
| MM 0822    | Sheep meat                                     | 0.02                   | 13.5     | 0.3  | 0.7      | 0.0 | 2       | 0.0  | 3              | 0.1  | 10.3     | 0.2   |
| MO 0822    | Sheep, edible offal of                         | 0.01                   | 1.3      | 0.0  | 0.0      | 0.0 | 0.5     | 0.0  | 0.0            | 0.0  | 1.3      | 0.0   |
| GC 0651    | Sorghum                                        | 0.04                   | 2.0      | 0.1  | 9.7      | 0.4 | 26.6    | 1.1  | 0.0            | 0.0  | 0.0      | 0.0   |
| OR 0541    | Soya bean oil, refined                         | 0.004                  | 1.3      | 0.0  | 1.7      | 0.0 | 3.0     | 0.0  | 14.5           | 0.1  | 4.3      | 0.0   |
| FB 0275    | Strawberry                                     | 0.09                   | 0.0      | 0.0  | 0.0      | 0.0 | 0.0     | 0.0  | 0.0            | 0.0  | 5.3      | 0.5   |
| VR 0596    | Sugar-beet                                     | 0.015                  | 0.5      | 0.0  | 0.0      | 0.0 | 0.0     | 0.0  | 0.3            | 0.0  | 2.0      | 0.0   |
| VO 0447    | Sweet corn (corn-on-the-cob)                   | 0.01                   | 0.0      | 0.0  | 0.0      | 0.0 | 4.4     | 0.0  | 0.0            | 0.0  | 8.3      | 0.1   |
| DT 1114    | Tea, green, black (black, fermented and dried) | 0.34                   | 2.3      | 0.8  | 1.2      | 0.4 | 0.5     | 0.2  | 0.5            | 0.2  | 2.3      | 0.8   |
| VO 0448    | Tomato (fresh)                                 | 0.13                   | 44.1     | 5.7  | 5.7      | 0.7 | 14.6    | 1.9  | 25.5           | 3.3  | 34.9     | 4.5   |
| JF 0448    | Tomato juice                                   | 0.026                  | 0.3      | 0.0  | 0.0      | 0.0 | 0.0     | 0.0  | 0.0            | 0.0  | 2.0      | 0.1   |
|            | Tomato paste                                   | 0.026                  | 5.8      | 0.2  | 0.2      | 0.0 | 0.3     | 0.0  | 0.0            | 0.0  | 4.0      | 0.1   |
| TN 0678    | Walnuts                                        | 0.05                   | 0.0      | 0.0  | 0.0      | 0.0 | 0.0     | 0.0  | 0.0            | 0.0  | 0.5      | 0.0   |
| CM 0654    | Wheat bran, unprocessed                        | 0.03                   | ND       | –    | ND       | –   | ND      | –    | ND             | –    | ND       | –     |
| CF 1211    | Wheat flour                                    | 0.002                  | 323.0    | 0.6  | 114.0    | 0.2 | 28.3    | 0.1  | 112.0          | 0.2  | 175.8    | 0.4   |
|            | Total intake (µg/person)                       |                        | 49.7     |      | 18.1     |     | 19.9    |      | 36.0           |      | 153.3    |       |
|            | Body weight per region (kg bw)                 |                        | 60       |      | 55       |     | 60      |      | 60             |      | 60       |       |
|            | ADI (µg/person)                                |                        | 600      |      | 550      |     | 600     |      | 600            |      | 600      |       |
|            | % ADI                                          |                        | 8.3%     |      | 3.3%     |     | 3.3%    |      | 6.0%           |      | 25.6%    |       |
|            | Rounded % ADI                                  |                        | 8%       |      | 3%       |     | 3%      |      | 6%             |      | 30%      |       |

### Annex 3

#### ETHOPROPHOS (149)

International estimated daily intake

ADI = 0–0.0004 mg/kg bw

| Codex Code                     | Commodity                                                  | STMR or STMR-P (mg/kg) | Mid-East |        | Far-East |        | African |        | Latin American |        | European |        |
|--------------------------------|------------------------------------------------------------|------------------------|----------|--------|----------|--------|---------|--------|----------------|--------|----------|--------|
|                                |                                                            |                        | Diet     | Intake | Diet     | Intake | Diet    | Intake | Diet           | Intake | Diet     | Intake |
| FI 0327                        | Banana                                                     | 0.02                   | 8.3      | 0.2    | 26.2     | 0.5    | 21.0    | 0.4    | 102.3          | 2.0    | 22.8     | 0.5    |
| VC 0424                        | Cucumber                                                   | 0.01                   | 2.4      | 0.0    | 2.3      | 0.0    | 0.0     | 0.0    | 4.2            | 0.0    | 4.5      | 0.0    |
| MO 0105                        | Edible offal (mammalian)                                   | 0                      | 4.2      | 0.0    | 1.4      | 0.0    | 2.8     | 0.0    | 6.1            | 0.0    | 12.4     | 0.0    |
| MM 0095                        | Meat from mammals other than marine mammals: 20% as fat    | 0                      | 7.4      | 0.0    | 6.6      | 0.0    | 4.8     | 0.0    | 9.4            | 0.0    | 31.1     | 0.0    |
| MM 0095                        | Meat from mammals other than marine mammals: 80% as muscle | 0                      | 29.6     | 0.0    | 26.2     | 0.0    | 19.0    | 0.0    | 37.6           | 0.0    | 124.4    | 0.0    |
| VC 0046                        | Melon, except watermelon                                   | 0.005                  | 16.0     | 0.1    | 2.0      | 0.0    | 0.0     | 0.0    | 2.8            | 0.0    | 18.3     | 0.1    |
| ML 0106                        | Milks                                                      | 0                      | 116.9    | 0.0    | 32.1     | 0.0    | 41.8    | 0.0    | 160.1          | 0.0    | 289.3    | 0.0    |
| VO 0445                        | Peppers, sweet (including pim(i)ento)                      | 0.005                  | 3.3      | 0.0    | 2.0      | 0.0    | 5.3     | 0.0    | 2.3            | 0.0    | 10.3     | 0.1    |
| VR 0589                        | Potato                                                     | 0.01                   | 59.0     | 0.6    | 19.2     | 0.2    | 20.6    | 0.2    | 40.8           | 0.4    | 240.8    | 2.4    |
| GS 0659                        | Sugar cane                                                 | 0.02                   | 18.5     | 0.4    | 7.3      | 0.1    | 15.9    | 0.3    | 3.5            | 0.1    | 0.0      | 0.0    |
| VR 0508                        | Sweet potato                                               | 0.01                   | 1.5      | 0.0    | 81.3     | 0.8    | 14.3    | 0.1    | 13.8           | 0.1    | 1.3      | 0.0    |
| VO 0448                        | Tomato (fresh, juice, paste, peeled)                       | 0.005                  | 81.5     | 0.4    | 7.0      | 0.0    | 16.5    | 0.1    | 25.5           | 0.1    | 66.6     | 0.3    |
| Total intake (µg/person)       |                                                            |                        | 1.7      |        | 1.8      |        | 1.2     |        | 2.9            |        | 3.4      |        |
| Body weight per region (kg bw) |                                                            |                        | 60       |        | 55       |        | 60      |        | 60             |        | 60       |        |
| ADI (µg/person)                |                                                            |                        | 24       |        | 22       |        | 24      |        | 24             |        | 24       |        |
| % ADI                          |                                                            |                        | 7.0%     |        | 8.0%     |        | 5.0%    |        | 11.9%          |        | 14.2%    |        |
| Rounded % ADI                  |                                                            |                        | 7%       |        | 8%       |        | 5%      |        | 10%            |        | 10%      |        |

**FENITROTHION (37)**

International estimated daily intake

ADI = 0–0.005 mg/kg bw

| Codex code                     | Commodity                                                     | STMR or<br>STMR-P<br>(mg/kg) | Mid-East |        | Far-East |        | African |        | Latin American |        | European |        |
|--------------------------------|---------------------------------------------------------------|------------------------------|----------|--------|----------|--------|---------|--------|----------------|--------|----------|--------|
|                                |                                                               |                              | Diet     | Intake | Diet     | Intake | Diet    | Intake | Diet           | Intake | Diet     | Intake |
| FP 0226                        | Apple                                                         | 0.04                         | 7.5      | 0.3    | 4.7      | 0.2    | 0.3     | 0.0    | 5.5            | 0.2    | 40.0     | 1.6    |
| GC 0640                        | Barley (beer only)                                            | 1                            | ND       | –      | ND       | –      | ND      | –      | ND             | –      | ND       | –      |
| GC 0640                        | Barley (fresh)                                                | 5                            | 1.0      | 5.0    | 3.5      | 17.5   | 1.8     | 9.0    | 6.5            | 32.5   | 19.8     | 99.0   |
| GC 0641                        | Buckwheat                                                     | 5                            | 0.0      | 0.0    | 1.0      | 5.0    | 0.0     | 0.0    | 0.0            | 0.0    | 0.0      | 0.0    |
| MO 0105                        | Edible offal (mammalian)                                      | 0                            | 4.2      | 0.0    | 1.4      | 0.0    | 2.8     | 0.0    | 6.1            | 0.0    | 12.4     | 0.0    |
| PE 0112                        | Eggs                                                          | 0                            | 14.6     | 0.0    | 13.1     | 0.0    | 3.7     | 0.0    | 11.9           | 0.0    | 37.6     | 0.0    |
| GC 0645                        | Maize (fresh, flour)                                          | 5                            | 48.3     | 241.5  | 31.2     | 156.0  | 106.2   | 531.0  | 41.8           | 209.0  | 8.8      | 44.0   |
| MM 0095                        | Meat from mammals other than<br>marine mammals: 20% as fat    | 0                            | 7.4      | 0.0    | 6.6      | 0.0    | 4.8     | 0.0    | 9.4            | 0.0    | 31.1     | 0.0    |
| MM 0095                        | Meat from mammals other than<br>marine mammals: 80% as muscle | 0                            | 29.6     | 0.0    | 26.2     | 0.0    | 19.0    | 0.0    | 37.6           | 0.0    | 124.4    | 0.0    |
| ML 0106                        | Milks                                                         | 0                            | 116.9    | 0.0    | 32.1     | 0.0    | 41.8    | 0.0    | 160.1          | 0.0    | 289.3    | 0.0    |
| GC 0646                        | Millet                                                        | 5                            | 2.5      | 12.5   | 9.3      | 46.5   | 51.8    | 259.0  | 0.0            | 0.0    | 0.0      | 0.0    |
| GC 0647                        | Oats                                                          | 5                            | 0.0      | 0.0    | 0.0      | 0.0    | 0.2     | 1.0    | 0.8            | 4.0    | 2.0      | 10.0   |
| PM 0110                        | Poultry meat: 10% as fat                                      | 0                            | 3.1      | 0.0    | 1.3      | 0.0    | 0.6     | 0.0    | 2.5            | 0.0    | 5.3      | 0.0    |
| PM 0110                        | Poultry meat: 90% as muscle                                   | 0                            | 27.9     | 0.0    | 11.9     | 0.0    | 5.0     | 0.0    | 22.8           | 0.0    | 47.7     | 0.0    |
| CM 1206                        | Rice bran, unprocessed                                        | 36                           | ND       | –      | ND       | –      | ND      | –      | ND             | –      | ND       | –      |
| CM 0649                        | Rice, husked and cooked                                       | 0.55                         | 0.0      | 0.0    | 1.8      | 1.0    | 34.7    | 19.1   | 21.0           | 11.6   | 2.5      | 1.4    |
| CM 1205                        | Rice, polished and cooked                                     | 0.2                          | 48.8     | 9.8    | 277.5    | 55.5   | 68.8    | 13.8   | 65.5           | 13.1   | 9.3      | 1.9    |
| CF 1250                        | Rye flour                                                     | 1.175                        | 0.0      | 0.0    | 1.0      | 1.2    | 0.0     | 0.0    | 0.0            | 0.0    | 1.5      | 1.8    |
| GC 0651                        | Sorghum                                                       | 5                            | 2.0      | 10.0   | 9.7      | 48.5   | 26.6    | 133.0  | 0.0            | 0.0    | 0.0      | 0.0    |
| GC 0653                        | Triticale                                                     | 5                            | 0.0      | 0.0    | 1.0      | 5.0    | 0.0     | 0.0    | 0.0            | 0.0    | 0.0      | 0.0    |
| CM 0654                        | Wheat bran, unprocessed                                       | 19.75                        | ND       | –      | ND       | –      | ND      | –      | ND             | –      | ND       | –      |
|                                | Wheat bulgur wholemeal                                        | 1.175                        | 0.3      | 0.4    | 0.0      | 0.0    | 0.0     | 0.0    | 0.0            | 0.0    | 0.0      | 0.0    |
|                                | Wheat macaroni                                                | 1.175                        | 1.0      | 1.2    | 0.3      | 0.4    | 0.0     | 0.0    | 2.8            | 3.3    | 1.3      | 1.5    |
|                                | Wheat pastry                                                  | 1.175                        | 3.0      | 3.5    | 0.5      | 0.6    | 0.0     | 0.0    | 2.0            | 2.4    | 1.0      | 1.2    |
| CP 1211                        | White bread                                                   | 0.5                          | 215.3    | 107.7  | 76.0     | 38.0   | 18.9    | 9.5    | 37.3           | 18.7   | 117.2    | 58.6   |
| CP 1212                        | Wholemeal bread                                               | 1.9                          | 107.7    | 204.6  | 38.0     | 72.2   | 9.4     | 17.9   | 74.7           | 141.9  | 58.6     | 111.3  |
| Total intake (µg/person)       |                                                               |                              | 596.4    |        | 447.5    |        | 993.2   |        | 436.6          |        | 332.2    |        |
| Body weight per region (kg bw) |                                                               |                              | 60       |        | 55       |        | 60      |        | 60             |        | 60       |        |
| ADI (µg/person)                |                                                               |                              | 300      |        | 275      |        | 300     |        | 300            |        | 300      |        |
| % ADI                          |                                                               |                              | 198.8%   |        | 162.7%   |        | 331.1%  |        | 145.5%         |        | 110.7%   |        |
| Rounded % ADI                  |                                                               |                              | 200%     |        | 160%     |        | 330%    |        | 150%           |        | 110%     |        |

### Annex 3

#### FLUDIOXONIL (211)

International estimated daily intake

ADI = 0–0.4 mg/kg bw

| Codex code | Commodity                                                         | STMR or STMR-P (mg/kg) | Mid-East |        | Far-East |        | African |        | Latin American |        | European |        |
|------------|-------------------------------------------------------------------|------------------------|----------|--------|----------|--------|---------|--------|----------------|--------|----------|--------|
|            |                                                                   |                        | Diet     | Intake | Diet     | Intake | Diet    | Intake | Diet           | Intake | Diet     | Intake |
| FC 0001    | Citrus fruit                                                      | 1.1                    | 47.1     | 51.8   | 6.3      | 6.9    | 5.1     | 5.6    | 54.6           | 60.1   | 44.6     | 49.1   |
| VD 0071    | Beans (dry)                                                       | 0.02                   | 2.3      | 0.0    | 4.8      | 0.1    | 0.0     | 0.0    | 13.0           | 0.3    | 3.5      | 0.1    |
| VP 0061    | Beans except broad and soya beans (green pods and immature seeds) | 0.04                   | 3.9      | 0.2    | 0.9      | 0.0    | 0.0     | 0.0    | 4.4            | 0.2    | 13.2     | 0.5    |
| VP 0062    | Beans, shelled (immature seeds)                                   | 0.02                   | 0.1      | 0.0    | 0.1      | 0.0    | 0.1     | 0.0    | 0.1            | 0.0    | 0.1      | 0.0    |
| FB 0264    | Blackberry                                                        | 1                      | 0.0      | 0.0    | 0.0      | 0.0    | 0.0     | 0.0    | 0.0            | 0.0    | 0.0      | 0.0    |
| FB 0020    | Blueberry                                                         | 0.6                    | 0.0      | 0.0    | 0.0      | 0.0    | 0.0     | 0.0    | 0.0            | 0.0    | 0.5      | 0.3    |
| VB 0400    | Broccoli                                                          | 0.23                   | 0.5      | 0.1    | 1.0      | 0.2    | 0.0     | 0.0    | 1.1            | 0.3    | 2.7      | 0.6    |
|            | Cabbages (head and leafy Brassicas, kohlrabi)                     | 0.24                   | 5.0      | 1.2    | 9.7      | 2.3    | 0.0     | 0.0    | 10.5           | 2.5    | 26.8     | 6.4    |
| VR 0577    | Carrot                                                            | 0.2                    | 2.8      | 0.6    | 2.5      | 0.5    | 0.0     | 0.0    | 6.3            | 1.3    | 22.0     | 4.4    |
| GC 0080    | Cereal grains                                                     | 0.02                   | 429.9    | 8.6    | 450.8    | 9.0    | 318.3   | 6.4    | 252.4          | 5.0    | 221.9    | 4.4    |
| OR 0691    | Cotton-seed oil, edible                                           | 0.05                   | 3.8      | 0.2    | 0.5      | 0.0    | 0.5     | 0.0    | 0.5            | 0.0    | 0.0      | 0.0    |
| VC 0424    | Cucumber                                                          | 0.06                   | 2.4      | 0.1    | 2.3      | 0.1    | 0.0     | 0.0    | 4.2            | 0.2    | 4.5      | 0.3    |
| FB 0266    | Dewberry, including boysenberry and loganberry                    | 1                      | 0.0      | 0.0    | 0.0      | 0.0    | 0.0     | 0.0    | 0.0            | 0.0    | 0.0      | 0.0    |
| DH 0170    | Dried herbs                                                       | 22                     | ND       | –      | ND       | –      | ND      | –      | ND             | –      | ND       | –      |
| MO 0105    | Edible offal (mammalian)                                          | 0                      | 4.2      | 0.0    | 1.4      | 0.0    | 2.8     | 0.0    | 6.1            | 0.0    | 12.4     | 0.0    |
| VO 0440    | Egg plant                                                         | 0.06                   | 6.3      | 0.4    | 3.0      | 0.2    | 0.7     | 0.0    | 6.0            | 0.4    | 2.3      | 0.1    |
| PE 0112    | Eggs                                                              | 0                      | 14.6     | 0.0    | 13.1     | 0.0    | 3.7     | 0.0    | 11.9           | 0.0    | 37.6     | 0.0    |
| FB 0269    | Grapes (fresh, wine, excluding dried grapes)                      | 0.28                   | 15.8     | 4.4    | 1.0      | 0.3    | 0.0     | 0.0    | 1.3            | 0.4    | 13.8     | 3.9    |
| DF 0269    | Grapes, dried (currants, raisins and sultanas)                    | 0.31                   | 0.3      | 0.1    | 0.0      | 0.0    | 0.0     | 0.0    | 0.3            | 0.1    | 2.3      | 0.7    |
| HH 0720    | Herbs                                                             |                        | ND       | –      | ND       | –      | ND      | –      | ND             | –      | ND       | –      |
| FI 0341    | Kiwi fruit                                                        | 7.2                    | 0.0      | 0.0    | 0.0      | 0.0    | 1.9     | 13.7   | 0.1            | 0.7    | 1.5      | 10.8   |
| VL 0482    | Lettuce, head                                                     | 2.7                    | 2.3      | 6.2    | 0.0      | 0.0    | 0.0     | 0.0    | 5.8            | 15.7   | 22.5     | 60.8   |
| MM 0095    | Meat from mammals other than marine mammals                       | 0                      | 37.0     | 0.0    | 32.8     | 0.0    | 23.8    | 0.0    | 47.0           | 0.0    | 155.5    | 0.0    |
| VC 0046    | Melon, except watermelon                                          | 0.02                   | 16.0     | 0.3    | 2.0      | 0.0    | 0.0     | 0.0    | 2.8            | 0.1    | 18.3     | 0.4    |
| ML 0106    | Milks                                                             | 0                      | 116.9    | 0.0    | 32.1     | 0.0    | 41.8    | 0.0    | 160.1          | 0.0    | 289.3    | 0.0    |
| VL 0485    | Mustard greens                                                    | 1.2                    | 0.1      | 0.1    | 0.1      | 0.1    | 0.1     | 0.1    | 0.1            | 0.1    | 0.1      | 0.1    |
| VA 0385    | Onion, bulb                                                       | 0.04                   | 23.0     | 0.9    | 11.5     | 0.5    | 7.3     | 0.3    | 13.8           | 0.6    | 27.8     | 1.1    |
| FP 0230    | Pear                                                              | 0.21                   | 3.3      | 0.7    | 2.8      | 0.6    | 0.0     | 0.0    | 1.0            | 0.2    | 11.3     | 2.4    |
| VD 0072    | Peas (dry)                                                        | 0.02                   | 0.5      | 0.0    | 1.7      | 0.0    | 5.1     | 0.1    | 1.3            | 0.0    | 1.8      | 0.0    |
| VP 0063    | Peas (green pods and immature seeds)                              | 0.04                   | 5.5      | 0.2    | 2.0      | 0.1    | 0.0     | 0.0    | 0.8            | 0.0    | 14.0     | 0.6    |
| VP 0064    | Peas, shelled (immature seeds)                                    | 0.02                   | 4.0      | 0.1    | 0.5      | 0.0    | 0.0     | 0.0    | 0.2            | 0.0    | 10.1     | 0.2    |
| VO 0445    | Peppers, sweet (including pim(i)ento)                             | 0.18                   | 3.3      | 0.6    | 2.0      | 0.4    | 5.3     | 1.0    | 2.3            | 0.4    | 10.3     | 1.9    |
| TN 0675    | Pistachio nut                                                     | 0.05                   | 0.3      | 0.0    | 0.0      | 0.0    | 0.0     | 0.0    | 0.0            | 0.0    | 0.0      | 0.0    |

### Annex 3

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| Codex code | Commodity                      | STMR or STMR-P (mg/kg) | Mid-East |        | Far-East |        | African |        | Latin American |        | European |        |
|------------|--------------------------------|------------------------|----------|--------|----------|--------|---------|--------|----------------|--------|----------|--------|
|            |                                |                        | Diet     | Intake | Diet     | Intake | Diet    | Intake | Diet           | Intake | Diet     | Intake |
| VR 0589    | Potato                         | 0.01                   | 59.0     | 0.6    | 19.2     | 0.2    | 20.6    | 0.2    | 40.8           | 0.4    | 240.8    | 2.4    |
| PM 0110    | Poultry meat                   | 0                      | 31.0     | 0.0    | 13.2     | 0.0    | 5.5     | 0.0    | 25.3           | 0.0    | 53.0     | 0.0    |
| PO 0111    | Poultry, edible offal of       | 0                      | 0.1      | 0.0    | 0.1      | 0.0    | 0.1     | 0.0    | 0.4            | 0.0    | 0.4      | 0.0    |
| DF 0014    | Prunes                         | 0.96                   | 0.0      | 0.0    | 0.0      | 0.0    | 0.0     | 0.0    | 0.0            | 0.0    | 0.5      | 0.5    |
| OR 0495    | Rape-seed oil, edible          | 0.02                   | 4.5      | 0.1    | 2.7      | 0.1    | 0.0     | 0.0    | 0.3            | 0.0    | 7.3      | 0.1    |
| FB 0272    | Raspberry, red, black          | 1                      | 0.0      | 0.0    | 0.0      | 0.0    | 0.0     | 0.0    | 0.0            | 0.0    | 0.5      | 0.5    |
| VA 0389    | Spring onion                   | 0.59                   | 0.0      | 0.0    | 2.0      | 1.2    | 1.5     | 0.9    | 4.0            | 2.4    | 1.0      | 0.6    |
| VC 0431    | Squash, summer                 | 0.06                   | 10.5     | 0.6    | 2.2      | 0.1    | 0.0     | 0.0    | 14.0           | 0.8    | 3.5      | 0.2    |
| FS 0012    | Stone fruit                    | 0.8                    | 7.3      | 5.8    | 1.0      | 0.8    | 0.0     | 0.0    | 0.8            | 0.6    | 23.3     | 18.6   |
| FB 0275    | Strawberry                     | 0.27                   | 0.0      | 0.0    | 0.0      | 0.0    | 0.0     | 0.0    | 0.0            | 0.0    | 5.3      | 1.4    |
| VO 0447    | Sweet corn (corn-on-the-cob)   | 0.01                   | 0.0      | 0.0    | 0.0      | 0.0    | 4.4     | 0.0    | 0.0            | 0.0    | 8.3      | 0.1    |
| VO 0448    | Tomato (fresh)                 | 0.12                   | 44.1     | 5.3    | 5.7      | 0.7    | 14.6    | 1.8    | 25.5           | 3.1    | 34.9     | 4.2    |
| JF 0448    | Tomato juice                   | 0.026                  | 0.3      | 0.0    | 0.0      | 0.0    | 0.0     | 0.0    | 0.0            | 0.0    | 2.0      | 0.1    |
|            | Tomato paste                   | 0.17                   | 5.8      | 1.0    | 0.2      | 0.0    | 0.3     | 0.1    | 0.0            | 0.0    | 4.0      | 0.7    |
| VL 0473    | Watercress                     | 1.2                    | 0.1      | 0.1    | 0.1      | 0.1    | 0.1     | 0.1    | 0.1            | 0.1    | 0.1      | 0.1    |
|            | Wine only                      | 0.01                   | 0.5      | 0.0    | 0.0      | 0.0    | 0.8     | 0.0    | 19.8           | 0.2    | 97.8     | 1.0    |
|            | Total intake (µg/person)       |                        |          | 90.5   |          | 24.6   |         | 30.3   |                | 96.1   |          | 179.5  |
|            | Body weight per region (kg bw) |                        |          | 60     |          | 55     |         | 60     |                | 60     |          | 60     |
|            | ADI (µg/person)                |                        |          | 24 000 |          | 22 000 |         | 24 000 |                | 24 000 |          | 24 000 |
|            | % AD                           |                        |          | 0.4%   |          | 0.1%   |         | 0.1%   |                | 0.4%   |          | 0.7%   |
|            | Rounded % ADI                  |                        |          | 0%     |          | 0%     |         | 0%     |                | 0%     |          | 1%     |

### Annex 3

#### GLYPHOSATE (158)

ADI = 0–1 mg/kg bw

| Codex code                     | Commodity                    | MRL (mg/kg) | Mid-East |        | Far-East |        | African |        | Latin American |        | European |        |
|--------------------------------|------------------------------|-------------|----------|--------|----------|--------|---------|--------|----------------|--------|----------|--------|
|                                |                              |             | Diet     | Intake | Diet     | Intake | Diet    | Intake | Diet           | Intake | Diet     | Intake |
| GC 0640                        | Barley (fresh)               | 20          | 1.0      | 20.0   | 3.5      | 70.0   | 1.8     | 36.0   | 6.5            | 130.0  | 19.8     | 396.0  |
| VD 0071                        | Beans (dry)                  | 2           | 2.3      | 4.6    | 4.8      | 9.6    | 0.0     | 0.0    | 13.0           | 26.0   | 3.5      | 7.0    |
| MM 0812                        | Cattle meat                  | 0.1         | 14.6     | 1.5    | 2.7      | 0.3    | 10.4    | 1.0    | 30.0           | 3.0    | 63.3     | 6.3    |
| ML 0812                        | Cattle milk                  | 0.1         | 79.5     | 8.0    | 23.2     | 2.3    | 35.8    | 3.6    | 159.3          | 15.9   | 287.0    | 28.7   |
| MO 0812                        | Cattle, edible offal of      | 2           | 2.5      | 5.0    | 0.3      | 0.6    | 1.8     | 3.6    | 5.0            | 10.0   | 6.0      | 12.0   |
| SO 0691                        | Cotton-seed                  | 10          | 0.0      | 0.0    | 0.0      | 0.0    | 0.0     | 0.0    | 0.0            | 0.0    | 0.0      | 0.0    |
| OC 0691                        | Cotton-seed oil, crude       | 0.05        | 3.8      | 0.2    | 0.5      | 0.0    | 0.5     | 0.0    | 0.5            | 0.0    | 0.0      | 0.0    |
| OR 0691                        | Cotton-seed oil, edible      | 0.05        | 3.8      | 0.2    | 0.5      | 0.0    | 0.5     | 0.0    | 0.5            | 0.0    | 0.0      | 0.0    |
| PE 0112                        | Eggs                         | 0.1         | 14.6     | 1.5    | 13.1     | 1.3    | 3.7     | 0.4    | 11.9           | 1.2    | 37.6     | 3.8    |
| FI 0341                        | Kiwi fruit                   | 0.1         | 0.0      | 0.0    | 0.0      | 0.0    | 1.9     | 0.2    | 0.1            | 0.0    | 1.5      | 0.2    |
| GC 0645                        | Maize (fresh, flour)         | 1           | 48.3     | 48.3   | 31.2     | 31.2   | 106.2   | 106.2  | 41.8           | 41.8   | 8.8      | 8.8    |
| GC 0647                        | Oats                         | 20          | 0.0      | 0.0    | 0.0      | 0.0    | 0.2     | 4.0    | 0.8            | 16.0   | 2.0      | 40.0   |
| VD 0072                        | Peas (dry)                   | 5           | 0.5      | 2.5    | 1.7      | 8.5    | 5.1     | 25.5   | 1.3            | 6.5    | 1.8      | 9.0    |
| MO 0818                        | Pig, edible offal of         | 1           | 0.0      | 0.0    | 1.0      | 1.0    | 0.0     | 0.0    | 1.0            | 1.0    | 5.0      | 5.0    |
| MM 0818                        | Pigmeat                      | 0.1         | 0.0      | 0.0    | 27.2     | 2.7    | 2.6     | 0.3    | 10.5           | 1.1    | 75.8     | 7.6    |
| PM 0110                        | Poultry meat                 | 0.1         | 31.0     | 3.1    | 13.2     | 1.3    | 5.5     | 0.6    | 25.3           | 2.5    | 53.0     | 5.3    |
| SO 0495                        | Rape-seed                    | 10          | 0.0      | 0.0    | 0.0      | 0.0    | 0.0     | 0.0    | 0.0            | 0.0    | 0.0      | 0.0    |
| GC 0649                        | Rice                         | 0.1         | 48.8     | 4.9    | 279.3    | 27.9   | 103.4   | 10.3   | 86.5           | 8.7    | 11.8     | 1.2    |
| GC 0651                        | Sorghum                      | 20          | 2.0      | 40.0   | 9.7      | 194.0  | 26.6    | 532.0  | 0.0            | 0.0    | 0.0      | 0.0    |
| VD 0541                        | Soya bean (dry)              | 20          | 4.5      | 90.0   | 2.0      | 40.0   | 0.5     | 10.0   | 0.0            | 0.0    | 0.0      | 0.0    |
| VP 0541                        | Soya bean (immature seeds)   | 0.2         | 0.1      | 0.0    | 0.1      | 0.0    | 0.1     | 0.0    | 0.0            | 0.0    | 0.0      | 0.0    |
| VO 0447                        | Sweet corn (corn-on-the-cob) | 0.1         | 0.0      | 0.0    | 0.0      | 0.0    | 4.4     | 0.4    | 0.0            | 0.0    | 8.3      | 0.8    |
| GC 0654                        | Wheat                        | 5           | 4.3      | 21.5   | 0.8      | 4.0    | 0.0     | 0.0    | 4.8            | 24.0   | 2.2      | 11.0   |
| CM 0654                        | Wheat bran, unprocessed      | 20          | ND       | –      | ND       | –      | ND      | –      | ND             | –      | ND       | –      |
| CF 1211                        | Wheat flour                  | 0.5         | 323.0    | 161.5  | 114.0    | 57.0   | 28.3    | 14.2   | 112.0          | 56.0   | 175.8    | 87.9   |
| CF 1212                        | Wheat wholemeal              | 5           | ND       | –      | ND       | –      | ND      | –      | ND             | –      | ND       | –      |
| Total intake (µg/person)       |                              |             | 412.7    |        | 451.8    |        | 748.3   |        | 343.7          |        | 630.5    |        |
| Body weight per region (kg bw) |                              |             | 60       |        | 55       |        | 60      |        | 60             |        | 60       |        |
| ADI (µg/person)                |                              |             | 60 000   |        | 55 000   |        | 60 000  |        | 60 000         |        | 60 000   |        |
| % ADI                          |                              |             | 0.7%     |        | 0.8%     |        | 1.2%    |        | 0.6%           |        | 1.1%     |        |
| Rounded % ADI                  |                              |             | 1%       |        | 1%       |        | 1%      |        | 1%             |        | 1%       |        |

## International estimated daily intake

ADI = 0–0.3 mg/kg bw

| Codex code | Commodity                                                        | STMR or STMR-P (mg/kg) | Mid-East |        | Far-East |        | African |        | Latin American |        | European |        |
|------------|------------------------------------------------------------------|------------------------|----------|--------|----------|--------|---------|--------|----------------|--------|----------|--------|
|            |                                                                  |                        | Diet     | Intake | Diet     | Intake | Diet    | Intake | Diet           | Intake | Diet     | Intake |
| FP 0226    | Apple                                                            | 0.11                   | 7.5      | 0.8    | 4.7      | 0.5    | 0.3     | 0.0    | 5.5            | 0.6    | 40.0     | 4.4    |
| VS 0621    | Asparagus                                                        | 0.305                  | 0.0      | 0.0    | 0.0      | 0.0    | 0.0     | 0.0    | 0.0            | 0.0    | 1.5      | 0.5    |
| VD 0071    | Beans (dry)                                                      | 0.36                   | 2.3      | 0.8    | 4.8      | 1.7    | 0.0     | 0.0    | 13.0           | 4.7    | 3.5      | 1.3    |
| VP 0061    | Beans except broad and soya bean (green pods and immature seeds) | 0.31                   | 3.9      | 1.2    | 0.9      | 0.3    | 0.0     | 0.0    | 4.4            | 1.4    | 13.2     | 4.1    |
| FB 0020    | Blueberry                                                        | 2.27                   | 0.0      | 0.0    | 0.0      | 0.0    | 0.0     | 0.0    | 0.0            | 0.0    | 0.5      | 1.1    |
| FC 0001    | Citrus fruit                                                     | 0.02                   | 47.1     | 0.9    | 6.3      | 0.1    | 5.1     | 0.1    | 54.6           | 1.1    | 44.6     | 0.9    |
| OR 0691    | Cotton-seed oil, edible                                          | 3.06                   | 3.8      | 11.6   | 0.5      | 1.5    | 0.5     | 1.5    | 0.5            | 1.5    | 0.0      | 0.0    |
| VC 0424    | Cucumber                                                         | 0.02                   | 2.4      | 0.0    | 2.3      | 0.0    | 0.0     | 0.0    | 4.2            | 0.1    | 4.5      | 0.1    |
| FB 0269    | Grapes (fresh, wine, dried)                                      | 0.16                   | 16.1     | 2.6    | 1.0      | 0.2    | 0.0     | 0.0    | 1.6            | 0.3    | 16.1     | 2.6    |
| GC 0645    | Maize (fresh, flour)                                             | 0.01                   | 48.3     | 0.5    | 31.2     | 0.3    | 106.2   | 1.1    | 41.8           | 0.4    | 8.8      | 0.1    |
| VL 0485    | Mustard greens                                                   | 0.07                   | 0.1      | 0.0    | 0.1      | 0.0    | 0.1     | 0.0    | 0.1            | 0.0    | 0.1      | 0.0    |
| VA 0385    | Onion, bulb                                                      | 0.23                   | 23.0     | 5.3    | 11.5     | 2.6    | 7.3     | 1.7    | 13.8           | 3.2    | 27.8     | 6.4    |
| VO 0051    | Peppers                                                          | 0.01                   | 3.4      | 0.0    | 2.1      | 0.0    | 5.4     | 0.1    | 2.4            | 0.0    | 10.4     | 0.1    |
| VL 0502    | Spinach                                                          | 0.35                   | 0.5      | 0.2    | 0.0      | 0.0    | 0.0     | 0.0    | 0.3            | 0.1    | 2.0      | 0.7    |
| VA 0389    | Spring onion                                                     | 0.52                   | 0.0      | 0.0    | 2.0      | 1.0    | 1.5     | 0.8    | 4.0            | 2.1    | 1.0      | 0.5    |
| FB 0275    | Strawberry                                                       | 0.25                   | 0.0      | 0.0    | 0.0      | 0.0    | 0.0     | 0.0    | 0.0            | 0.0    | 5.3      | 1.3    |
| VO 0447    | Sweet corn (corn-on-the-cob)                                     | 0.01                   | 0.0      | 0.0    | 0.0      | 0.0    | 4.4     | 0.0    | 0.0            | 0.0    | 8.3      | 0.1    |
| VO 0448    | Tomato (fresh)                                                   | 0.25                   | 44.1     | 11.0   | 5.7      | 1.4    | 14.6    | 3.7    | 25.5           | 6.4    | 34.9     | 8.7    |
| JF 0448    | Tomato juice                                                     | 0                      | 0.3      | 0.0    | 0.0      | 0.0    | 0.0     | 0.0    | 0.0            | 0.0    | 2.0      | 0.0    |
| VR 0506    | Turnip, garden                                                   | 0.05                   | 0.5      | 0.0    | 0.0      | 0.0    | 0.0     | 0.0    | 0.3            | 0.0    | 2.0      | 0.1    |
| GC 0654    | Wheat                                                            | 0.04                   | 327.3    | 13.1   | 114.8    | 4.6    | 28.3    | 1.1    | 116.8          | 4.7    | 178.0    | 7.1    |
|            | Total intake (µg/person)                                         |                        |          | 48.2   |          | 14.4   |         | 10.1   |                | 26.5   |          | 40.1   |
|            | Body weight per region (kg bw)                                   |                        |          | 60     |          | 55     |         | 60     |                | 60     |          | 60     |
|            | ADI (µg/person)                                                  |                        |          | 18 000 |          | 16 500 |         | 18 000 |                | 18 000 |          | 18 000 |
|            | % ADI                                                            |                        |          | 0.3%   |          | 0.1%   |         | 0.1%   |                | 0.1%   |          | 0.2%   |
|            | Rounded % ADI                                                    |                        |          | 0%     |          | 0%     |         | 0%     |                | 0%     |          | 0%     |



### Annex 3

#### METALAXYL (138) and METALAXYL-M (212)

Theoretical maximum daily intake

ADI = 0–0.08 mg/kg bw

| Codex code | Commodity                            | MRL<br>(mg/kg) | Mid-East |        | Far-East |        | African |        | Latin American |        | European |        |
|------------|--------------------------------------|----------------|----------|--------|----------|--------|---------|--------|----------------|--------|----------|--------|
|            |                                      |                | Diet     | Intake | Diet     | Intake | Diet    | Intake | Diet           | Intake | Diet     | Intake |
| VS 0621    | Asparagus                            | 0.05           | 0.0      | 0.0    | 0.0      | 0.0    | 0.0     | 0.0    | 0.0            | 0.0    | 1.5      | 0.1    |
| FI 0326    | Avocado                              | 0.2            | 0.0      | 0.0    | 0.0      | 0.0    | 0.2     | 0.0    | 3.3            | 0.7    | 1.0      | 0.2    |
| VB 0400    | Broccoli                             | 0.5            | 0.5      | 0.3    | 1.0      | 0.5    | 0.0     | 0.0    | 1.1            | 0.6    | 2.7      | 1.4    |
| VB 0402    | Brussels sprouts                     | 0.2            | 0.5      | 0.1    | 1.0      | 0.2    | 0.0     | 0.0    | 1.1            | 0.2    | 2.7      | 0.5    |
| VB 0403    | Cabbage, Savoy                       | 0.5            | 0.1      | 0.1    | 0.1      | 0.1    | 0.1     | 0.1    | 0.1            | 0.1    | 0.1      | 0.1    |
| VB 0041    | Cabbages, head (see Savoy cabbage)   |                | ND       | –      | ND       | –      | ND      | –      | ND             | –      | ND       | –      |
| SB 0715    | Cacao bean                           | 0.2            | 0.5      | 0.1    | 0.0      | 0.0    | 0.0     | 0.0    | 1.3            | 0.3    | 3.1      | 0.6    |
| VR 0577    | Carrot                               | 0.05           | 2.8      | 0.1    | 2.5      | 0.1    | 0.0     | 0.0    | 6.3            | 0.3    | 22.0     | 1.1    |
| VB 0404    | Cauliflower                          | 0.5            | 1.3      | 0.7    | 1.5      | 0.8    | 0       | 0.0    | 0.3            | 0.2    | 13       | 6.5    |
| GC 0080    | Cereal grain                         | 0.05           | 429.9    | 21.5   | 450.8    | 22.5   | 318.3   | 15.9   | 252.4          | 12.6   | 221.9    | 11.1   |
| FC 0001    | Citrus fruit                         | 5              | 47.1     | 235.5  | 6.3      | 31.5   | 5.1     | 25.5   | 54.6           | 273.0  | 44.6     | 223.0  |
| SO 0691    | Cotton-seed                          | 0.05           | 0.0      | 0.0    | 0.0      | 0.0    | 0.0     | 0.0    | 0.0            | 0.0    | 0.0      | 0.0    |
| VC 0424    | Cucumber                             | 0.5            | 2.4      | 1.2    | 2.3      | 1.1    | 0.0     | 0.0    | 4.2            | 2.1    | 4.5      | 2.3    |
| VC 0425    | Gherkin                              | 0.5            | 2.4      | 1.2    | 2.3      | 1.1    | 0.0     | 0.0    | 4.2            | 2.1    | 4.5      | 2.3    |
| FB 0269    | Grapes (fresh, wine, dried)          | 1              | 16.1     | 16.1   | 1.0      | 1.0    | 0.0     | 0.0    | 1.6            | 1.6    | 16.1     | 16.1   |
| DH 1100    | Hops, dry                            | 10             | 0.1      | 1.0    | 0.1      | 1.0    | 0.1     | 1.0    | 0.1            | 1.0    | 0.1      | 1.0    |
| VL 0482    | Lettuce, head                        | 2              | 2.3      | 4.6    | 0.0      | 0.0    | 0.0     | 0.0    | 5.8            | 11.6   | 22.5     | 45.0   |
| VC 0046    | Melon, except watermelon             | 0.2            | 16.0     | 3.2    | 2.0      | 0.4    | 0.0     | 0.0    | 2.8            | 0.6    | 18.3     | 3.7    |
| VA 0385    | Onion, bulb                          | 2              | 23.0     | 46.0   | 11.5     | 23.0   | 7.3     | 14.6   | 13.8           | 27.6   | 27.8     | 55.6   |
| SO 0697    | Peanut                               | 0.1            | 0.3      | 0.0    | 0.2      | 0.0    | 2.3     | 0.2    | 0.3            | 0.0    | 3.0      | 0.3    |
| VP 0064    | Peas, shelled (immature seeds)       | 0.05           | 4.0      | 0.2    | 0.5      | 0.0    | 0.0     | 0.0    | 0.2            | 0.0    | 10.1     | 0.5    |
| VO 0051    | Peppers                              | 1              | 3.4      | 3.4    | 2.1      | 2.1    | 5.4     | 5.4    | 2.4            | 2.4    | 10.4     | 10.4   |
| FP 0009    | Pome fruits                          | 1              | 10.8     | 10.8   | 7.5      | 7.5    | 0.3     | 0.3    | 6.5            | 6.5    | 51.3     | 51.3   |
| VR 0589    | Potato                               | 0.05           | 59.0     | 3.0    | 19.2     | 1.0    | 20.6    | 1.0    | 40.8           | 2.0    | 240.8    | 12.0   |
| FB 0272    | Raspberry, red, black                | 0.2            | 0.0      | 0.0    | 0.0      | 0.0    | 0.0     | 0.0    | 0.0            | 0.0    | 0.5      | 0.1    |
| VD 0541    | Soya bean (dry)                      | 0.05           | 4.5      | 0.2    | 2.0      | 0.1    | 0.5     | 0.0    | 0.0            | 0.0    | 0.0      | 0.0    |
| VL 0502    | Spinach                              | 2              | 0.5      | 1.0    | 0.0      | 0.0    | 0.0     | 0.0    | 0.3            | 0.6    | 2.0      | 4.0    |
| VC 0431    | Squash, summer                       | 0.2            | 10.5     | 2.1    | 2.2      | 0.4    | 0.0     | 0.0    | 14.0           | 2.8    | 3.5      | 0.7    |
| VR 0596    | Sugar-beet                           | 0.05           | 0.5      | 0.0    | 0.0      | 0.0    | 0.0     | 0.0    | 0.3            | 0.0    | 2.0      | 0.1    |
| OC 0702    | Sunflower seed oil, crude            | 0.05           | 9.3      | 0.5    | 0.5      | 0.0    | 0.3     | 0.0    | 0.8            | 0.0    | 8.5      | 0.4    |
| SO 0702    | Sunflower seed, consumed fresh       | 0.05           | 1.0      | 0.1    | 0.0      | 0.0    | 0.6     | 0.0    | 0.0            | 0.0    | 0.0      | 0.0    |
| VO 0448    | Tomato (fresh, juice, paste, peeled) | 0.5            | 81.5     | 40.8   | 7.0      | 3.5    | 16.5    | 8.3    | 25.5           | 12.8   | 66.6     | 33.3   |
| VC 0432    | Watermelon                           | 0.2            | 49.3     | 9.9    | 9.5      | 1.9    | 0.0     | 0.0    | 5.5            | 1.1    | 7.8      | 1.6    |

### Annex 3

312

| Codex code | Commodity                      | MRL<br>(mg/kg) | Mid-East |        | Far-East |        | African |        | Latin American |        | European |        |
|------------|--------------------------------|----------------|----------|--------|----------|--------|---------|--------|----------------|--------|----------|--------|
|            |                                |                | Diet     | Intake | Diet     | Intake | Diet    | Intake | Diet           | Intake | Diet     | Intake |
| VC 0433    | Winter squash                  | 0.2            | 1.5      | 0.3    | 0.3      | 0.1    | 0.0     | 0.0    | 2.0            | 0.4    | 0.5      | 0.1    |
|            | Total intake (µg/person)       |                |          | 403.8  |          | 99.9   |         | 72.4   |                | 363.0  |          | 485.2  |
|            | Body weight per region (kg bw) |                |          | 60     |          | 55     |         | 60     |                | 60     |          | 60     |
|            | ADI (µg/person)                |                |          | 4800   |          | 4400   |         | 4800   |                | 4800   |          | 4800   |
|            | % ADI                          |                |          | 8.4%   |          | 2.3%   |         | 1.5%   |                | 7.6%   |          | 10.1%  |
|            | Rounded % ADI                  |                |          | 8%     |          | 2%     |         | 2%     |                | 8%     |          | 10%    |

### METHOMYL (94)

International estimated daily intake

ADI = 0–0.02 mg/kg bw

| Codex code | Commodity                                                                | STMR or STMR-P<br>(mg/kg) | Mid-East |        | Far-East |        | African |        | Latin American |        | European |        |
|------------|--------------------------------------------------------------------------|---------------------------|----------|--------|----------|--------|---------|--------|----------------|--------|----------|--------|
|            |                                                                          |                           | Diet     | Intake | Diet     | Intake | Diet    | Intake | Diet           | Intake | Diet     | Intake |
| FP 0226    | Apple                                                                    | 0.41                      | 7.5      | 3.1    | 4.7      | 1.9    | 0.3     | 0.1    | 5.5            | 2.3    | 40.0     | 16.4   |
| VS 0621    | Asparagus                                                                | 0.33                      | 0.0      | 0.0    | 0.0      | 0.0    | 0.0     | 0.0    | 0.0            | 0.0    | 1.5      | 0.5    |
| GC 0640    | Barley (fresh)                                                           | 2 <sup>a</sup>            | 1.0      | 2.0    | 3.5      | 7.0    | 1.8     | 3.6    | 6.5            | 13.0   | 19.8     | 39.6   |
| -          | Beans (dry), including broad beans                                       | 0.02                      | 6.8      | 0.1    | 6.8      | 0.1    | 0.0     | 0.0    | 13.5           | 0.3    | 4.3      | 0.1    |
| VP 0061    | Beans except broad bean and soya bean<br>(green pods and immature seeds) | 0.055                     | 3.9      | 0.2    | 0.9      | 0.0    | 0.0     | 0.0    | 4.4            | 0.2    | 13.2     | 0.7    |
| VB 0040    | Brassica vegetables (flowerhead, head<br>and leafy Brassicas, kohlrabi)  | 1.3                       | 6.3      | 8.2    | 11.2     | 14.6   | 0.0     | 0.0    | 10.8           | 14.0   | 39.8     | 51.7   |
| VS 0624    | Celery                                                                   | 0.66                      | 0.5      | 0.3    | 0.0      | 0.0    | 0.0     | 0.0    | 0.3            | 0.2    | 2.0      | 1.3    |
| FC 0001    | Citrus fruit                                                             | 0.034                     | 47.1     | 1.6    | 6.3      | 0.2    | 5.1     | 0.2    | 54.6           | 1.9    | 44.6     | 1.5    |
| OR 0691    | Cotton-seed oil, edible                                                  | 0.006                     | 3.8      | 0.0    | 0.5      | 0.0    | 0.5     | 0.0    | 0.5            | 0.0    | 0.0      | 0.0    |
| MO 0105    | Edible offal (mammalian)                                                 | 0                         | 4.2      | 0.0    | 1.4      | 0.0    | 2.8     | 0.0    | 6.1            | 0.0    | 12.4     | 0.0    |
| PE 0840    | Chicken eggs                                                             | 0                         | 14.5     | 0.0    | 13.0     | 0.0    | 3.6     | 0.0    | 11.8           | 0.0    | 37.5     | 0.0    |
| VC 0045    | Fruiting vegetables, cucurbits                                           | 0.02                      | 80.5     | 1.6    | 18.2     | 0.4    | 0.0     | 0.0    | 30.5           | 0.6    | 38.5     | 0.8    |
| FB 0269    | Grapes (fresh, wine, excluding dried<br>grapes)                          | 0.86                      | 15.8     | 13.6   | 1.0      | 0.9    | 0.0     | 0.0    | 1.3            | 1.1    | 13.8     | 11.9   |
| VL 0053    | Leafy vegetables                                                         | 1.4                       | 7.8      | 10.9   | 9.7      | 13.6   | 0.7     | 1.0    | 16.5           | 23.1   | 51.7     | 72.4   |
| GC 0645    | Maize (fresh, flour)                                                     | 0.02                      | 48.3     | 1.0    | 31.2     | 0.6    | 106.2   | 2.1    | 41.8           | 0.8    | 8.8      | 0.2    |
| OR 0645    | Maize oil, edible                                                        | 0.004                     | 1.8      | 0.0    | 0.0      | 0.0    | 0.3     | 0.0    | 0.5            | 0.0    | 1.3      | 0.0    |
| MM 0095    | Meat from mammals other than marine<br>mammals                           | 0                         | 37.0     | 0.0    | 32.8     | 0.0    | 23.8    | 0.0    | 47.0           | 0.0    | 155.5    | 0.0    |
| ML 0106    | Milks                                                                    | 0                         | 116.9    | 0.0    | 32.1     | 0.0    | 41.8    | 0.0    | 160.1          | 0.0    | 289.3    | 0.0    |
| FS 0245    | Nectarine                                                                | 0.05                      | 1.3      | 0.1    | 0.3      | 0.0    | 0.0     | 0.0    | 0.4            | 0.0    | 6.3      | 0.3    |
| GC 0647    | Oats                                                                     | 0.02 <sup>a</sup>         | 0.0      | 0.0    | 0.0      | 0.0    | 0.2     | 0.0    | 0.8            | 0.0    | 2.0      | 0.0    |
| VA 0385    | Onion, bulb                                                              | 0.068                     | 23.0     | 1.6    | 11.5     | 0.8    | 7.3     | 0.5    | 13.8           | 0.9    | 27.8     | 1.9    |
| JF 0004    | Orange juice                                                             | 0.004                     | 7.3      | 0.0    | 0.0      | 0.0    | 0.0     | 0.0    | 0.3            | 0.0    | 4.5      | 0.0    |

### Annex 3

| Codex code                     | Commodity                            | STMR or STMR-P (mg/kg) | Mid-East |        | Far-East |        | African |        | Latin American |        | European |        |
|--------------------------------|--------------------------------------|------------------------|----------|--------|----------|--------|---------|--------|----------------|--------|----------|--------|
|                                |                                      |                        | Diet     | Intake | Diet     | Intake | Diet    | Intake | Diet           | Intake | Diet     | Intake |
| FS 0247                        | Peach                                | 0.05                   | 1.3      | 0.1    | 0.3      | 0.0    | 0.0     | 0.0    | 0.4            | 0.0    | 6.3      | 0.3    |
| FP 0230                        | Pear                                 | 0.09                   | 3.3      | 0.3    | 2.8      | 0.3    | 0.0     | 0.0    | 1.0            | 0.1    | 11.3     | 1.0    |
| VP 0063                        | Peas (green pods and immature seeds) | 0.46                   | 5.5      | 2.5    | 2.0      | 0.9    | 0.0     | 0.0    | 0.8            | 0.4    | 14.0     | 6.4    |
| VO 0051                        | Peppers                              | 0.105                  | 3.4      | 0.4    | 2.1      | 0.2    | 5.4     | 0.6    | 2.4            | 0.3    | 10.4     | 1.1    |
| FS 0014                        | Plum (fresh, prune)                  | 0.08                   | 1.8      | 0.1    | 0.5      | 0.0    | 0.0     | 0.0    | 0.0            | 0.0    | 4.3      | 0.3    |
| VR 0589                        | Potato                               | 0                      | 59.0     | 0.0    | 19.2     | 0.0    | 20.6    | 0.0    | 40.8           | 0.0    | 240.8    | 0.0    |
| PO 0111                        | Poultry, edible offal of             | 0                      | 0.1      | 0.0    | 0.1      | 0.0    | 0.1     | 0.0    | 0.4            | 0.0    | 0.4      | 0.0    |
| PM 0110                        | Poultry meat                         | 0                      | 31.0     | 0.0    | 13.2     | 0.0    | 5.5     | 0.0    | 25.3           | 0.0    | 53.0     | 0.0    |
| VD 0541                        | Soya bean (dry)                      | 0.04                   | 4.5      | 0.2    | 2.0      | 0.1    | 0.5     | 0.0    | 0.0            | 0.0    | 0.0      | 0.0    |
| OR 0541                        | Soya bean oil, refined               | 0.04                   | 1.3      | 0.1    | 1.7      | 0.1    | 3.0     | 0.1    | 14.5           | 0.6    | 4.3      | 0.2    |
| VO 0447                        | Sweet corn (corn-on-the-cob)         | 0.065                  | 0.0      | 0.0    | 0.0      | 0.0    | 4.4     | 0.3    | 0.0            | 0.0    | 8.3      | 0.5    |
| VO 0448                        | Tomato (fresh)                       | 0.16                   | 44.1     | 7.1    | 5.7      | 0.9    | 14.6    | 2.3    | 25.5           | 4.1    | 34.9     | 5.6    |
|                                | Tomato paste                         | 0.007                  | 5.8      | 0.0    | 0.2      | 0.0    | 0.3     | 0.0    | 0.0            | 0.0    | 4.0      | 0.0    |
| CM 0654                        | Wheat bran, unprocessed              | 0.27                   | ND       | -      | ND       | -      | ND      | -      | ND             | -      | ND       | -      |
| CF 1211                        | Wheat flour                          | 0.003                  | 323.0    | 1.0    | 114.0    | 0.3    | 28.3    | 0.1    | 112.0          | 0.3    | 175.8    | 0.5    |
| CF 1210                        | Wheat germ                           | 0.13                   | 0.1      | 0.0    | 0.1      | 0.0    | 0.0     | 0.0    | 0.1            | 0.0    | 0.1      | 0.0    |
| Total intake (µg/person)       |                                      |                        | 56.0     |        | 43.0     |        | 10.9    |        | 64.2           |        | 215.4    |        |
| Body weight per region (kg bw) |                                      |                        | 60       |        | 55       |        | 60      |        | 60             |        | 60       |        |
| ADI (µg/person)                |                                      |                        | 1200     |        | 1100     |        | 1200    |        | 1200           |        | 1200     |        |
| % ADI                          |                                      |                        | 4.7%     |        | 3.9%     |        | 0.9%    |        | 5.4%           |        | 18.0%    |        |
| Rounded % ADI                  |                                      |                        | 5%       |        | 4%       |        | 1%      |        | 5%             |        | 20%      |        |

# Annex 3

314

## OXYDEMETON METHYL

International estimated daily intake

ADI = 0–0.02 mg/kg bw

| Codex code                     | Commodity                                           | STMR or<br>STMR-P<br>(mg/kg) | Mid-East |        | Far East |        | African |        | Latin American |        | European |        |
|--------------------------------|-----------------------------------------------------|------------------------------|----------|--------|----------|--------|---------|--------|----------------|--------|----------|--------|
|                                |                                                     |                              | Diet     | Intake | Diet     | Intake | Diet    | Intake | Diet           | Intake | Diet     | Intake |
| FC 0204                        | Lemon                                               | 0.01                         | 1.9      | 0.0    | 0.2      | 0.0    | 0.0     | 0.0    | 5.4            | 0.1    | 2.4      | 0.0    |
| FC 0004                        | Orange, sweet, sour (including orange-like hybrids) | 0.01                         | 31.5     | 0.3    | 4.0      | 0.0    | 4.8     | 0.0    | 31.0           | 0.3    | 29.8     | 0.3    |
| FP 0226                        | Apple                                               | 0.01                         | 7.5      | 0.1    | 4.7      | 0.0    | 0.3     | 0.0    | 5.5            | 0.1    | 40.0     | 0.4    |
| JF 0226                        | Apple juice                                         | 0.01                         | 4.5      | 0.0    | 0        | 0.0    | 0       | 0.0    | 0.3            | 0.0    | 3.8      | 0.0    |
| FP 0230                        | Pear                                                | 0.01                         | 3.3      | 0.0    | 2.8      | 0.0    | 0.0     | 0.0    | 1.0            | 0.0    | 11.3     | 0.1    |
| FB 0269                        | Grapes (fresh, wine, dried)                         | 0.04                         | 16.1     | 0.6    | 1.0      | 0.0    | 0.0     | 0.0    | 1.6            | 0.1    | 16.1     | 0.6    |
| VR 0589                        | Potato                                              | 0.01                         | 59.0     | 0.6    | 19.2     | 0.2    | 20.6    | 0.2    | 40.8           | 0.4    | 240.8    | 2.4    |
| VR 0596                        | Sugar-beet                                          | 0.01                         | 0.5      | 0.0    | 0.0      | 0.0    | 0.0     | 0.0    | 0.3            | 0.0    | 2.0      | 0.0    |
| VB 0403                        | Cabbage, Savoy                                      | 0.03                         | 0.1      | 0.0    | 0.1      | 0.0    | 0.1     | 0.0    | 0.1            | 0.0    | 0.1      | 0.0    |
| VB 0404                        | Cauliflower                                         | 0.01                         | 1.3      | 0.0    | 1.5      | 0.0    | 0       | 0.0    | 0.3            | 0.0    | 13       | 0.1    |
| VB 0405                        | Kohlrabi                                            | 0.02                         | 0.1      | 0.0    | 0.1      | 0.0    | 0.1     | 0.0    | 0.1            | 0.0    | 0.1      | 0.0    |
| VL 0480                        | Kale                                                | 0.01                         | 0.5      | 0.0    | 0.0      | 0.0    | 0.0     | 0.0    | 0.3            | 0.0    | 2.0      | 0.0    |
| VD 0526                        | Common bean (dry)                                   | 0.01                         | 0.1      | 0.0    | 0.1      | 0.0    | 0.1     | 0.0    | 0.1            | 0.0    | 0.1      | 0.0    |
| SO 0691                        | Cotton-seed                                         | 0.01                         | 0.0      | 0.0    | 0.0      | 0.0    | 0.0     | 0.0    | 0.0            | 0.0    | 0.0      | 0.0    |
| OR 0691                        | Cotton-seed oil, edible                             | 0.002                        | 3.8      | 0.0    | 0.5      | 0.0    | 0.5     | 0.0    | 0.5            | 0.0    | 0.0      | 0.0    |
| GC 0640                        | Barley (fresh)                                      | 0.01                         | 1.0      | 0.0    | 3.5      | 0.0    | 1.8     | 0.0    | 6.5            | 0.1    | 19.8     | 0.2    |
| GC 0650                        | Rye                                                 | 0.01                         | 0.0      | 0.0    | 1.0      | 0.0    | 0.0     | 0.0    | 0.0            | 0.0    | 1.5      | 0.0    |
| GC 0654                        | Wheat                                               | 0.01                         | 327.3    | 3.3    | 114.8    | 1.1    | 28.3    | 0.3    | 116.8          | 1.2    | 178.0    | 1.8    |
| MM 0097                        | Meat of cattle, pigs and sheep                      | 0                            | 28.1     | 0.0    | 30.6     | 0.0    | 15.0    | 0.0    | 43.5           | 0.0    | 149.4    | 0.0    |
| MF 0812                        | Cattle fat                                          | 0                            | 0.3      | 0.0    | 0.3      | 0.0    | 0.3     | 0.0    | 1.5            | 0.0    | 0.0      | 0.0    |
| MF 0818                        | Pig fat                                             | 0                            | ND       | –      | ND       | –      | ND      | –      | ND             | –      | ND       | –      |
| MF 0822                        | Sheep fat                                           | 0                            | 0.1      | 0.0    | 0.1      | 0.0    | 0.1     | 0.0    | 0.1            | 0.0    | 0.1      | 0.0    |
| PM 0110                        | Poultry meat                                        | 0                            | 31.0     | 0.0    | 13.2     | 0.0    | 5.5     | 0.0    | 25.3           | 0.0    | 53.0     | 0.0    |
| PF 0111                        | Poultry, fat                                        | 0                            | 3.1      | 0.0    | 1.3      | 0.0    | 0.6     | 0.0    | 2.5            | 0.0    | 5.3      | 0.0    |
| ML 0106                        | Milks                                               | 0                            | 116.9    | 0.0    | 32.1     | 0.0    | 41.8    | 0.0    | 160.1          | 0.0    | 289.3    | 0.0    |
| PE 0112                        | Eggs                                                | 0                            | 14.6     | 0.0    | 13.1     | 0.0    | 3.7     | 0.0    | 11.9           | 0.0    | 37.6     | 0.0    |
| Total intake (µg/person)       |                                                     |                              | 5.0      |        | 1.6      |        | 0.6     |        | 2.2            |        | 6.1      |        |
| Body weight per region (kg bw) |                                                     |                              | 60       |        | 55       |        | 60      |        | 60             |        | 60       |        |
| ADI (µg/person)                |                                                     |                              | 18       |        | 16.5     |        | 18      |        | 18             |        | 18       |        |
| % ADI                          |                                                     |                              | 28.0%    |        | 9.5%     |        | 3.1%    |        | 11.9%          |        | 33.8%    |        |
| Rounded % ADI                  |                                                     |                              | 30%      |        | 9%       |        | 3%      |        | 10%            |        | 30%      |        |

### Annex 3

#### PARAQUAT (057)

International estimated daily intake

ADI = 0–0.005 mg/kg bw

| Codex code | Commodity                                   | STMR or STMR-P (mg/kg) | Mid-East |        | Far-East |        | African |        | Latin American |        | European |        |
|------------|---------------------------------------------|------------------------|----------|--------|----------|--------|---------|--------|----------------|--------|----------|--------|
|            |                                             |                        | Diet     | Intake | Diet     | Intake | Diet    | Intake | Diet           | Intake | Diet     | Intake |
| FI 0326    | Avocado                                     | 0.01                   | 0.0      | 0.0    | 0.0      | 0.0    | 0.2     | 0.0    | 3.3            | 0.0    | 1.0      | 0.0    |
| FI 0327    | Banana                                      | 0.01                   | 8.3      | 0.1    | 26.2     | 0.3    | 21.0    | 0.2    | 102.3          | 1.0    | 22.8     | 0.2    |
| FB 0018    | Berry and other small fruits                | 0                      | 16.0     | 0.0    | 1.0      | 0.0    | 0.0     | 0.0    | 1.6            | 0.0    | 23.5     | 0.0    |
| FC 0001    | Citrus fruit                                | 0.01                   | 47.1     | 0.5    | 6.3      | 0.1    | 5.1     | 0.1    | 54.6           | 0.5    | 44.6     | 0.4    |
| OC 0691    | Cotton-seed oil, crude                      | 0.01                   | 3.8      | 0.0    | 0.5      | 0.0    | 0.5     | 0.0    | 0.5            | 0.0    | 0.0      | 0.0    |
| MO 0105    | Edible offal (mammalian)                    | 0.0007                 | 4.2      | 0.0    | 1.4      | 0.0    | 2.8     | 0.0    | 6.1            | 0.0    | 12.4     | 0.0    |
| PE 0112    | Eggs                                        | 0                      | 14.6     | 0.0    | 13.1     | 0.0    | 3.7     | 0.0    | 11.9           | 0.0    | 37.6     | 0.0    |
| VO 0050    | Fruiting vegetables other than cucurbits    | 0.01                   | 92.3     | 0.9    | 12.6     | 0.1    | 27.0    | 0.3    | 33.9           | 0.3    | 91.6     | 0.9    |
| VC 0045    | Fruiting vegetables, cucurbits              | 0                      | 80.5     | 0.0    | 18.2     | 0.0    | 0.0     | 0.0    | 30.5           | 0.0    | 38.5     | 0.0    |
| DH 1100    | Hops, dry                                   | 0.05                   | 0.1      | 0.0    | 0.1      | 0.0    | 0.1     | 0.0    | 0.1            | 0.0    | 0.1      | 0.0    |
| FI 0341    | Kiwi fruit                                  | 0.01                   | 0.0      | 0.0    | 0.0      | 0.0    | 1.9     | 0.0    | 0.1            | 0.0    | 1.5      | 0.0    |
| VL 0053    | Leafy vegetables                            | 0.025                  | 7.8      | 0.2    | 9.7      | 0.2    | 0.7     | 0.0    | 16.5           | 0.4    | 51.7     | 1.3    |
| CF 1255    | Maize flour                                 | 0.038                  | 31.8     | 1.2    | 31.2     | 1.2    | 106.2   | 4.0    | 40.3           | 1.5    | 8.8      | 0.3    |
| GC 0645    | Maize (fresh)                               | 0.025                  | 16.5     | 0.4    | 0.0      | 0.0    | 0.0     | 0.0    | 1.5            | 0.0    | 0.0      | 0.0    |
| OC 0645    | Maize oil, crude                            | 0.006                  | 1.8      | 0.0    | 0.0      | 0.0    | 0.3     | 0.0    | 0.5            | 0.0    | 1.3      | 0.0    |
| FI 0345    | Mango                                       | 0.01                   | 2.3      | 0.0    | 5.3      | 0.1    | 3.4     | 0.0    | 6.3            | 0.1    | 0.0      | 0.0    |
| MM 0095    | Meat from mammals other than marine mammals | 0.0001                 | 37.0     | 0.0    | 32.8     | 0.0    | 23.8    | 0.0    | 47.0           | 0.0    | 155.5    | 0.0    |
| ML 0106    | Milks                                       | 0.00008                | 116.9    | 0.0    | 32.1     | 0.0    | 41.8    | 0.0    | 160.1          | 0.0    | 289.3    | 0.0    |
| OC 0305    | Olive oil, crude                            | 0.018                  | 1.5      | 0.0    | 0.0      | 0.0    | 0.0     | 0.0    | 0.0            | 0.0    | 7.8      | 0.1    |
| FT 0305    | Olives                                      | 0.05                   | 1.3      | 0.1    | 0.0      | 0.0    | 0.0     | 0.0    | 0.3            | 0.0    | 2.8      | 0.1    |
| FI 0350    | Papaya                                      | 0.01                   | 0.0      | 0.0    | 0.2      | 0.0    | 0.0     | 0.0    | 5.3            | 0.1    | 0.0      | 0.0    |
| FI 0351    | Passion fruit                               | 0.01                   | 0.0      | 0.0    | 0.0      | 0.0    | 1.9     | 0.0    | 0.1            | 0.0    | 1.5      | 0.0    |
| FI 0353    | Pineapple (fresh, canned)                   | 0.01                   | 0.8      | 0.0    | 10.2     | 0.1    | 3.1     | 0.0    | 15.8           | 0.2    | 3.3      | 0.0    |
| FI 0354    | Plantain                                    | 0.01                   | 0.0      | 0.0    | 0.0      | 0.0    | 41.3    | 0.4    | 56.5           | 0.6    | 0.0      | 0.0    |
| FP 0009    | Pome fruits                                 | 0                      | 10.8     | 0.0    | 7.5      | 0.0    | 0.3     | 0.0    | 6.5            | 0.0    | 51.3     | 0.0    |
| PM 0110    | Poultry meat                                | 0                      | 31.0     | 0.0    | 13.2     | 0.0    | 5.5     | 0.0    | 25.3           | 0.0    | 53.0     | 0.0    |
| PO 0111    | Poultry, edible offal of                    | 0                      | 0.1      | 0.0    | 0.1      | 0.0    | 0.1     | 0.0    | 0.4            | 0.0    | 0.4      | 0.0    |
| VD 0070    | Pulses                                      | 0.1                    | 18.9     | 1.9    | 14.5     | 1.5    | 17.5    | 1.8    | 20.3           | 2.0    | 9.4      | 0.9    |
| VR 0075    | Roots and tubers                            | 0.02                   | 61.8     | 1.2    | 108.5    | 2.2    | 321.3   | 6.4    | 159.3          | 3.2    | 242.0    | 4.8    |
| GC 0651    | Sorghum                                     | 0.025                  | 2.0      | 0.1    | 9.7      | 0.2    | 26.6    | 0.7    | 0.0            | 0.0    | 0.0      | 0.0    |
| OC 0541    | Soya bean oil, crude                        | 0.01                   | 1.3      | 0.0    | 1.7      | 0.0    | 3.0     | 0.0    | 14.5           | 0.1    | 4.3      | 0.0    |
| FS 0012    | Stone fruits                                | 0                      | 7.3      | 0.0    | 1.0      | 0.0    | 0.0     | 0.0    | 0.8            | 0.0    | 23.3     | 0.0    |
| OC 0702    | Sunflower seed oil, crude                   | 0                      | 9.3      | 0.0    | 0.5      | 0.0    | 0.3     | 0.0    | 0.8            | 0.0    | 8.5      | 0.0    |
| SO 0702    | Sunflower seed, consumed fresh              | 0.22                   | 1.0      | 0.2    | 0.0      | 0.0    | 0.6     | 0.1    | 0.0            | 0.0    | 0.0      | 0.0    |

### Annex 3

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| Codex code | Commodity                                      | STMR or STMR-P (mg/kg) | Mid-East |        | Far-East |        | African |        | Latin American |        | European |        |
|------------|------------------------------------------------|------------------------|----------|--------|----------|--------|---------|--------|----------------|--------|----------|--------|
|            |                                                |                        | Diet     | Intake | Diet     | Intake | Diet    | Intake | Diet           | Intake | Diet     | Intake |
| DT 1114    | Tea, green, black (black, fermented and dried) | 0.06                   | 2.3      | 0.1    | 1.2      | 0.1    | 0.5     | 0.0    | 0.5            | 0.0    | 2.3      | 0.1    |
| TN 0085    | Tree nuts                                      | 0.01                   | 1.1      | 0.0    | 13.5     | 0.1    | 4.5     | 0.0    | 17.8           | 0.2    | 4.6      | 0.0    |
|            | Total intake (µg/person)                       |                        |          | 7.0    |          | 6.1    |         | 14.2   |                | 10.4   |          | 9.6    |
|            | Body weight per region (kg bw)                 |                        |          | 60     |          | 55     |         | 60     |                | 60     |          | 60     |
|            | ADI (µg/person)                                |                        |          | 300    |          | 275    |         | 300    |                | 300    |          | 300    |
|            | % ADI                                          |                        |          | 2.3%   |          | 2.2%   |         | 4.7%   |                | 3.5%   |          | 3.2%   |
|            | Rounded % ADI                                  |                        |          | 2%     |          | 2%     |         | 5%     |                | 3%     |          | 3%     |

### PHORATE (112)

International estimated daily intake

ADI = 0–0.0007 mg/kg bw

| Codex code | Commodity                                   | MRL (mg/kg) | Mid-East |        | Far-East |        | African |        | Latin American |        | European |        |
|------------|---------------------------------------------|-------------|----------|--------|----------|--------|---------|--------|----------------|--------|----------|--------|
|            |                                             |             | Diet     | Intake | Diet     | Intake | Diet    | Intake | Diet           | Intake | Diet     | Intake |
| VP 0526    | Common bean (green pods or immature seeds)  | 0.1         | 3.5      | 0.4    | 0.8      | 0.1    | 0.0     | 0.0    | 4.0            | 0.4    | 12.0     | 1.2    |
| SO 0691    | Cotton-seed                                 | 0.05        | 0.0      | 0.0    | 0.0      | 0.0    | 0.0     | 0.0    | 0.0            | 0.0    | 0.0      | 0.0    |
| PE 0112    | Eggs                                        | 0.05        | 14.6     | 0.7    | 13.1     | 0.7    | 3.7     | 0.2    | 11.9           | 0.6    | 37.6     | 1.9    |
| GC 0645    | Maize (fresh, flour)                        | 0.05        | 48.3     | 2.4    | 31.2     | 1.6    | 106.2   | 5.3    | 41.8           | 2.1    | 8.8      | 0.4    |
| MM 0095    | Meat from mammals other than marine mammals | 0.05        | 37.0     | 1.9    | 32.8     | 1.6    | 23.8    | 1.2    | 47.0           | 2.4    | 155.5    | 7.8    |
| ML 0106    | Milks                                       | 0.05        | 116.9    | 5.8    | 32.1     | 1.6    | 41.8    | 2.1    | 160.1          | 8.0    | 289.3    | 14.5   |
| SO 0697    | Peanut                                      | 0.1         | 0.3      | 0.0    | 0.2      | 0.0    | 2.3     | 0.2    | 0.3            | 0.0    | 3.0      | 0.3    |
| OC 0697    | Peanut oil, crude                           | 0.05        | 0.0      | 0.0    | 1.8      | 0.1    | 3.5     | 0.2    | 0.5            | 0.0    | 1.8      | 0.1    |
| OR 0697    | Peanut oil, edible                          | 0.05        | 0.0      | 0.0    | 1.8      | 0.1    | 3.5     | 0.2    | 0.5            | 0.0    | 1.8      | 0.1    |
| VR 0589    | Potato                                      | 0.2         | 59.0     | 11.8   | 19.2     | 3.8    | 20.6    | 4.1    | 40.8           | 8.2    | 240.8    | 48.2   |
| GC 0651    | Sorghum                                     | 0.05        | 2.0      | 0.1    | 9.7      | 0.5    | 26.6    | 1.3    | 0.0            | 0.0    | 0.0      | 0.0    |
| VP 0541    | Soya bean (immature seeds)                  | 0.05        | 0.1      | 0.0    | 0.1      | 0.0    | 0.1     | 0.0    | 0.0            | 0.0    | 0.0      | 0.0    |
| VR 0596    | Sugar-beet                                  | 0.05        | 0.5      | 0.0    | 0.0      | 0.0    | 0.0     | 0.0    | 0.3            | 0.0    | 2.0      | 0.1    |
| VO 0447    | Sweet corn (corn-on-the-cob)                | 0.05        | 0.0      | 0.0    | 0.0      | 0.0    | 4.4     | 0.2    | 0.0            | 0.0    | 8.3      | 0.4    |
| GC 0654    | Wheat                                       | 0.05        | 327.3    | 16.4   | 114.8    | 5.7    | 28.3    | 1.4    | 116.8          | 5.8    | 178.0    | 8.9    |
|            | Total intake (µg/person)                    |             |          | 39.5   |          | 15.8   |         | 16.4   |                | 27.5   |          | 83.8   |
|            | Body weight per region (kg bw)              |             |          | 60     |          | 55     |         | 60     |                | 60     |          | 60     |
|            | ADI (µg/person)                             |             |          | 42     |          | 38.5   |         | 42     |                | 42     |          | 42     |
|            | % ADI                                       |             |          | 94.1%  |          | 41.1%  |         | 39.2%  |                | 65.6%  |          | 199.6% |
|            | Rounded % ADI                               |             |          | 90%    |          | 40%    |         | 40%    |                | 70%    |          | 200%   |

### Annex 3

#### PIRIMICARB (101)

Theoretical maximum daily intake

ADI = 0–0.02 mg/kg bw

| Codex code | Commodity                                           | MRL (mg/kg) | Mid-East |        | Far-East |        | African |        | Latin American |        | European |        |
|------------|-----------------------------------------------------|-------------|----------|--------|----------|--------|---------|--------|----------------|--------|----------|--------|
|            |                                                     |             | Diet     | Intake | Diet     | Intake | Diet    | Intake | Diet           | Intake | Diet     | Intake |
| FC 0001    | Citrus fruit                                        | 0.05        | 47.1     | 2.4    | 6.3      | 0.3    | 5.1     | 0.3    | 54.6           | 2.7    | 44.6     | 2.2    |
| GC 0640    | Barley (fresh)                                      | 0.05        | 1.0      | 0.1    | 3.5      | 0.2    | 1.8     | 0.1    | 6.5            | 0.3    | 19.8     | 1.0    |
| VP 0062    | Beans, shelled (immature seeds)                     | 0.1         | 0.1      | 0.0    | 0.1      | 0.0    | 0.1     | 0.0    | 0.1            | 0.0    | 0.1      | 0.0    |
| VR 0574    | Beetroot                                            | 0.05        | 0.5      | 0.0    | 0.0      | 0.0    | 0.0     | 0.0    | 0.3            | 0.0    | 2.0      | 0.1    |
| VB 0400    | Broccoli                                            | 1           | 0.5      | 0.5    | 1.0      | 1.0    | 0.0     | 0.0    | 1.1            | 1.1    | 2.7      | 2.7    |
| VB 0402    | Brussels sprouts                                    | 1           | 0.5      | 0.5    | 1.0      | 1.0    | 0.0     | 0.0    | 1.1            | 1.1    | 2.7      | 2.7    |
| VB 0403    | Cabbage, Savoy                                      | 1           | 0.1      | 0.1    | 0.1      | 0.1    | 0.1     | 0.1    | 0.1            | 0.1    | 0.1      | 0.1    |
| VB 0041    | Cabbage, head (see Savoy cabbage)                   | ND          | –        | –      | ND       | –      | ND      | –      | ND             | –      | ND       | –      |
| VB 0404    | Cauliflower                                         | 1           | 1.3      | 1.3    | 1.5      | 1.5    | 0       | 0.0    | 0.3            | 0.3    | 13       | 13.0   |
| VS 0624    | Celery                                              | 1           | 0.5      | 0.5    | 0.0      | 0.0    | 0.0     | 0.0    | 0.3            | 0.3    | 2.0      | 2.0    |
| VP 0526    | Common bean (green pods or immature seeds)          | 1           | 3.5      | 3.5    | 0.8      | 0.8    | 0.0     | 0.0    | 4.0            | 4.0    | 12.0     | 12.0   |
| SO 0691    | Cotton-seed                                         | 0.05        | 0.0      | 0.0    | 0.0      | 0.0    | 0.0     | 0.0    | 0.0            | 0.0    | 0.0      | 0.0    |
| VC 0424    | Cucumber                                            | 1           | 2.4      | 2.4    | 2.3      | 2.3    | 0.0     | 0.0    | 4.2            | 4.2    | 4.5      | 4.5    |
| FB 0278    | Currant, black                                      | 0.5         | 0.0      | 0.0    | 0.0      | 0.0    | 0.0     | 0.0    | 0.0            | 0.0    | 0.0      | 0.0    |
| VO 0440    | Eggplant                                            | 1           | 6.3      | 6.3    | 3.0      | 3.0    | 0.7     | 0.7    | 6.0            | 6.0    | 2.3      | 2.3    |
| PE 0112    | Eggs                                                | 0.05        | 14.6     | 0.7    | 13.1     | 0.7    | 3.7     | 0.2    | 11.9           | 0.6    | 37.6     | 1.9    |
| VL 0476    | Endive                                              | 1           | 0.5      | 0.5    | 0.0      | 0.0    | 0.0     | 0.0    | 0.3            | 0.3    | 2.0      | 2.0    |
| VC 0425    | Gherkin                                             | 1           | 2.4      | 2.4    | 2.3      | 2.3    | 0.0     | 0.0    | 4.2            | 4.2    | 4.5      | 4.5    |
| VB 0405    | Kohlrabi                                            | 0.5         | 0.1      | 0.1    | 0.1      | 0.1    | 0.1     | 0.1    | 0.1            | 0.1    | 0.1      | 0.1    |
| VA 0384    | Leek                                                | 0.5         | 0.5      | 0.3    | 0.0      | 0.0    | 0.0     | 0.0    | 0.3            | 0.2    | 2.0      | 1.0    |
| VL 0482    | Lettuce, head                                       | 1           | 2.3      | 2.3    | 0.0      | 0.0    | 0.0     | 0.0    | 5.8            | 5.8    | 22.5     | 22.5   |
| MM 0095    | Meat from mammals other than marine mammals         | 0.05        | 37.0     | 1.9    | 32.8     | 1.6    | 23.8    | 1.2    | 47.0           | 2.4    | 155.5    | 7.8    |
| ML 0106    | Milks                                               | 0.05        | 116.9    | 5.8    | 32.1     | 1.6    | 41.8    | 2.1    | 160.1          | 8.0    | 289.3    | 14.5   |
| GC 0647    | Oats                                                | 0.05        | 0.0      | 0.0    | 0.0      | 0.0    | 0.2     | 0.0    | 0.8            | 0.0    | 2.0      | 0.1    |
| VA 0385    | Onion, bulb                                         | 0.5         | 23.0     | 11.5   | 11.5     | 5.8    | 7.3     | 3.7    | 13.8           | 6.9    | 27.8     | 13.9   |
| FC 0004    | Orange, sweet, sour (including orange-like hybrids) | 0.5         | 31.5     | 15.8   | 4.0      | 2.0    | 4.8     | 2.4    | 31.0           | 15.5   | 29.8     | 14.9   |
| HH 0740    | Parsley                                             | 1           | 0.1      | 0.1    | 0.1      | 0.1    | 0.1     | 0.1    | 0.1            | 0.1    | 0.1      | 0.1    |
| VR 0588    | Parsnip                                             | 0.05        | 0.5      | 0.0    | 0.0      | 0.0    | 0.0     | 0.0    | 0.3            | 0.0    | 2.0      | 0.1    |
| FS 0247    | Peach                                               | 0.5         | 1.3      | 0.6    | 0.3      | 0.1    | 0.0     | 0.0    | 0.4            | 0.2    | 6.3      | 3.1    |
| VP 0063    | Peas (green pods and immature seeds)                | 0.2         | 5.5      | 1.1    | 2.0      | 0.4    | 0.0     | 0.0    | 0.8            | 0.2    | 14.0     | 2.8    |
| TN 0672    | Pecan                                               | 0.05        | 0.0      | 0.0    | 0.0      | 0.0    | 0.0     | 0.0    | 0.0            | 0.0    | 0.3      | 0.0    |
| VO 0444    | Peppers, chili                                      | 2           | 0.1      | 0.2    | 0.1      | 0.2    | 0.1     | 0.2    | 0.1            | 0.2    | 0.1      | 0.2    |
| VO 0445    | Peppers, sweet (including pim(i)ento)               | 1           | 3.3      | 3.3    | 2.0      | 2.0    | 5.3     | 5.3    | 2.3            | 2.3    | 10.3     | 10.3   |
| FS 0014    | Plum (fresh, prunes)                                | 0.5         | 1.8      | 0.9    | 0.5      | 0.3    | 0.0     | 0.0    | 0.0            | 0.0    | 4.3      | 2.2    |
| FP 0009    | Pome fruit                                          | 1           | 10.8     | 10.8   | 7.5      | 7.5    | 0.3     | 0.3    | 6.5            | 6.5    | 51.3     | 51.3   |
| VR 0589    | Potato                                              | 0.05        | 59.0     | 3.0    | 19.2     | 1.0    | 20.6    | 1.0    | 40.8           | 2.0    | 240.8    | 12.0   |
| VR 0494    | Radish                                              | 0.05        | 0.5      | 0.0    | 0.0      | 0.0    | 0.0     | 0.0    | 0.3            | 0.0    | 2.0      | 0.1    |
| SO 0495    | Rape-seed                                           | 0.2         | 0.0      | 0.0    | 0.0      | 0.0    | 0.0     | 0.0    | 0.0            | 0.0    | 0.0      | 0.0    |

### Annex 3

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|                                |                                      |      |       |       |       |      |      |      |       |       |       |       |
|--------------------------------|--------------------------------------|------|-------|-------|-------|------|------|------|-------|-------|-------|-------|
| FB 0272                        | Raspberry, red, black                | 0.5  | 0.0   | 0.0   | 0.0   | 0.0  | 0.0  | 0.0  | 0.0   | 0.0   | 0.5   | 0.3   |
| VL 0502                        | Spinach                              | 1    | 0.5   | 0.5   | 0.0   | 0.0  | 0.0  | 0.0  | 0.3   | 0.3   | 2.0   | 2.0   |
| FB 0275                        | Strawberry                           | 0.5  | 0.0   | 0.0   | 0.0   | 0.0  | 0.0  | 0.0  | 0.0   | 0.0   | 5.3   | 2.7   |
| VR 0596                        | Sugar-beet                           | 0.05 | 0.5   | 0.0   | 0.0   | 0.0  | 0.0  | 0.0  | 0.3   | 0.0   | 2.0   | 0.1   |
| VO 0447                        | Sweet corn (corn-on-the-cob)         | 0.05 | 0.0   | 0.0   | 0.0   | 0.0  | 4.4  | 0.2  | 0.0   | 0.0   | 8.3   | 0.4   |
| VO 0448                        | Tomato (fresh, juice, paste, peeled) | 1    | 81.5  | 81.5  | 7.0   | 7.0  | 16.5 | 16.5 | 25.5  | 25.5  | 66.6  | 66.6  |
| VR 0506                        | Turnip, garden                       | 0.05 | 0.5   | 0.0   | 0.0   | 0.0  | 0.0  | 0.0  | 0.3   | 0.0   | 2.0   | 0.1   |
| VL 0473                        | Watercress                           | 1    | 0.1   | 0.1   | 0.1   | 0.1  | 0.1  | 0.1  | 0.1   | 0.1   | 0.1   | 0.1   |
| GC 0654                        | Wheat                                | 0.05 | 327.3 | 16.4  | 114.8 | 5.7  | 28.3 | 1.4  | 116.8 | 5.8   | 178.0 | 8.9   |
| Total intake (µg/person)       |                                      |      |       | 177.3 |       | 48.5 |      | 35.9 |       | 107.3 |       | 289.1 |
| Body weight per region (kg bw) |                                      |      |       | 60    |       | 55   |      | 60   |       | 60    |       | 60    |
| ADI (µg/person)                |                                      |      |       | 1200  |       | 1100 |      | 1200 |       | 1200  |       | 1200  |
| % ADI                          |                                      |      |       | 14.8% |       | 4.4% |      | 3.0% |       | 8.9%  |       | 24.1% |
| Rounded % ADI                  |                                      |      |       | 10%   |       | 4%   |      | 3%   |       | 9%    |       | 20%   |



### Annex 3

#### PROCHLORAZ (142)

International estimated daily intake

ADI = 0–0.01 mg/kg bw

| Codex code | Commodity                                               | STMR or STMR-P (mg/kg) | Mid-East |        | Far-East |        | African |        | Latin American |        | European |        |
|------------|---------------------------------------------------------|------------------------|----------|--------|----------|--------|---------|--------|----------------|--------|----------|--------|
|            |                                                         |                        | Diet     | Intake | Diet     | Intake | Diet    | Intake | Diet           | Intake | Diet     | Intake |
| FC 0001    | Citrus fruit                                            | 0.1                    | 47.1     | 4.7    | 6.3      | 0.6    | 5.1     | 0.5    | 54.6           | 5.5    | 44.6     | 4.5    |
| FI 0326    | Avocado                                                 | 0.1                    | 0.0      | 0.0    | 0.0      | 0.0    | 0.2     | 0.0    | 3.3            | 0.3    | 1.0      | 0.1    |
| FI 0327    | Banana                                                  | 0.1                    | 8.3      | 0.8    | 26.2     | 2.6    | 21.0    | 2.1    | 102.3          | 10.2   | 22.8     | 2.3    |
| GC 0640    | Barley (beer only)                                      | 0.01                   | ND       | –      | ND       | –      | ND      | –      | ND             | –      | ND       | –      |
| GC 0080    | Cereal grain                                            | 0.11                   | 0.0      | 0.0    | 298.8    | 32.9   | 280.6   | 30.9   | 65.7           | 7.2    | 0.0      | 0.0    |
| FI 0332    | Custard apple                                           | 0.1                    | ND       | –      | ND       | –      | ND      | –      | ND             | –      | ND       | –      |
| MO 0105    | Edible offal (mammalian)                                | 1.2                    | 4.2      | 5.0    | 1.4      | 1.7    | 2.8     | 3.4    | 6.1            | 7.3    | 12.4     | 14.9   |
| PE 0112    | Eggs                                                    | 0.012                  | 14.6     | 0.2    | 13.1     | 0.2    | 3.7     | 0.0    | 11.9           | 0.1    | 37.6     | 0.5    |
| FI 0335    | Feijoa                                                  | 0.1                    | ND       | –      | ND       | –      | ND      | –      | ND             | –      | ND       | –      |
| FI 0336    | Guava                                                   | 0.1                    | ND       | –      | ND       | –      | ND      | –      | ND             | –      | ND       | –      |
| FI 0338    | Jackfruit                                               | 0.1                    | ND       | –      | ND       | –      | ND      | –      | ND             | –      | ND       | –      |
| FI 0341    | Kiwi fruit                                              | 0.1                    | 0.0      | 0.0    | 0.0      | 0.0    | 1.9     | 0.2    | 0.1            | 0.0    | 1.5      | 0.2    |
| SO 0693    | Linseed                                                 | 0.05                   | 0.0      | 0.0    | 0.0      | 0.0    | 0.0     | 0.0    | 0.0            | 0.0    | 0.0      | 0.0    |
| FI 0345    | Mango                                                   | 0.1                    | 2.3      | 0.2    | 5.3      | 0.5    | 3.4     | 0.3    | 6.3            | 0.6    | 0.0      | 0.0    |
| MM 0095    | Meat from mammals other than marine mammals: 20% as fat | 0.06                   | 7.4      | 0.4    | 6.6      | 0.4    | 4.8     | 0.3    | 9.4            | 0.6    | 31.1     | 1.9    |
|            |                                                         | 0.02                   | 29.6     | 0.6    | 26.2     | 0.5    | 19.0    | 0.4    | 37.6           | 0.8    | 124.4    | 2.5    |
| ML 0106    | Milks                                                   | 0                      | 116.9    | 0.0    | 32.1     | 0.0    | 41.8    | 0.0    | 160.1          | 0.0    | 289.3    | 0.0    |
| VO 0450    | Mushroom                                                | 4.9                    | 0.3      | 1.5    | 0.5      | 2.5    | 0.0     | 0.0    | 0.0            | 0.0    | 4.0      | 19.6   |
| FI 0350    | Papaya                                                  | 0.1                    | 0.0      | 0.0    | 0.2      | 0.0    | 0.0     | 0.0    | 5.3            | 0.5    | 0.0      | 0.0    |
| FI 0351    | Passion fruit                                           | 0.1                    | 0.0      | 0.0    | 0.0      | 0.0    | 1.9     | 0.2    | 0.1            | 0.0    | 1.5      | 0.2    |
| HS 0790    | Pepper (black, white)                                   | 5.1                    | 0.3      | 1.5    | 0.0      | 0.0    | 0.0     | 0.0    | 0.0            | 0.0    | 0.0      | 0.0    |
| FI 0352    | Persimmon, American                                     | 0.1                    | ND       | –      | ND       | –      | ND      | –      | ND             | –      | ND       | –      |
| FI 0353    | Pineapple (fresh, canned)                               | 0.1                    | 0.8      | 0.1    | 10.2     | 1.0    | 3.1     | 0.3    | 15.8           | 1.6    | 3.3      | 0.3    |
| FI 0354    | Plantain                                                | 0.1                    | 0.0      | 0.0    | 0.0      | 0.0    | 41.3    | 4.1    | 56.5           | 5.7    | 0.0      | 0.0    |
| PM 0110    | Poultry meat: 10% as fat                                | 0.001                  | 3.1      | 0.0    | 1.3      | 0.0    | 0.6     | 0.0    | 2.5            | 0.0    | 5.3      | 0.0    |
| PM 0110    | Poultry meat: 90% as muscle                             | 0.001                  | 27.9     | 0.0    | 11.9     | 0.0    | 5.0     | 0.0    | 22.8           | 0.0    | 47.7     | 0.0    |
| PO 0111    | Poultry, edible offal of                                | 0.015                  | 0.1      | 0.0    | 0.1      | 0.0    | 0.1     | 0.0    | 0.4            | 0.0    | 0.4      | 0.0    |
| FI 0358    | Rambutan                                                | 0.1                    | ND       | –      | ND       | –      | ND      | –      | ND             | –      | ND       | –      |
| SO 0495    | Rape-seed                                               | 0.1                    | 0.0      | 0.0    | 0.0      | 0.0    | 0.0     | 0.0    | 0.0            | 0.0    | 0.0      | 0.0    |
| OR 0495    | Rape-seed oil, edible                                   | 0.06                   | 4.5      | 0.3    | 2.7      | 0.2    | 0.0     | 0.0    | 0.3            | 0.0    | 7.3      | 0.4    |
| OR 0702    | Sunflower seed oil, edible                              | 0.06                   | 9.3      | 0.6    | 0.5      | 0.0    | 0.3     | 0.0    | 0.8            | 0.0    | 8.5      | 0.5    |
| SO 0702    | Sunflower seed, consumed fresh                          | 0.1                    | 1.0      | 0.1    | 0.0      | 0.0    | 0.6     | 0.1    | 0.0            | 0.0    | 0.0      | 0.0    |
| CM 0654    | Wheat bran, unprocessed                                 | 0.54                   | ND       | –      | ND       | –      | ND      | –      | ND             | –      | ND       | –      |
| CF 1211    | Wheat flour                                             | 0.025                  | 323.0    | 8.1    | 114.0    | 2.9    | 28.3    | 0.7    | 112.0          | 2.8    | 175.8    | 4.4    |

### Annex 3

320

| Codex<br>code | Commodity                      | STMR or<br>STMR-P<br>(mg/kg) | Mid-East |        | Far-East |        | African |        | Latin American |        | European |        |
|---------------|--------------------------------|------------------------------|----------|--------|----------|--------|---------|--------|----------------|--------|----------|--------|
|               |                                |                              | Diet     | Intake | Diet     | Intake | Diet    | Intake | Diet           | Intake | Diet     | Intake |
| CP 1212       | Wholemeal bread                | 0.14                         | 107.7    | 15.1   | 38.0     | 5.3    | 9.4     | 1.3    | 74.7           | 10.5   | 58.6     | 8.2    |
|               | Total intake (µg/person)       |                              |          | 39.2   |          | 51.3   |         | 44.8   |                | 53.8   |          | 60.4   |
|               | Body weight per region (kg bw) |                              |          | 60     |          | 55     |         | 60     |                | 60     |          | 60     |
|               | ADI (µg/person)                |                              |          | 600    |          | 550    |         | 600    |                | 600    |          | 600    |
|               | % ADI                          |                              |          | 6.5%   |          | 9.3%   |         | 7.5%   |                | 9.0%   |          | 10.1%  |
|               | Rounded % ADI                  |                              |          | 7%     |          | 9%     |         | 7%     |                | 9%     |          | 10%    |

### Annex 3

#### PROPICONAZOLE (160)

#### International estimated daily intake

ADI = 0–0.0700 mg/kg bw

| Codex code                     | Commodity                                   | STMR or STMR- P (mg/kg) | Mid-East |        | Far-East |        | African |        | Latin American |        | European |        |
|--------------------------------|---------------------------------------------|-------------------------|----------|--------|----------|--------|---------|--------|----------------|--------|----------|--------|
|                                |                                             |                         | Diet     | Intake | Diet     | Intake | Diet    | Intake | Diet           | Intake | Diet     | Intake |
| TN 0660                        | Almond                                      | 0.05                    | 0.5      | 0.0    | 0.0      | 0.0    | 0.0     | 0.0    | 0.1            | 0.0    | 1.8      | 0.1    |
| FI 0327                        | Banana                                      | 0.1                     | 8.3      | 0.8    | 26.2     | 2.6    | 21.0    | 2.1    | 102.3          | 10.2   | 22.8     | 2.3    |
| GC 0640                        | Barley (fresh)                              | 0.05                    | 1.0      | 0.1    | 3.5      | 0.2    | 1.8     | 0.1    | 6.5            | 0.3    | 19.8     | 1.0    |
| SB 0716                        | Coffee bean                                 | 0.1                     | 5.3      | 0.5    | 0.4      | 0.0    | 0.0     | 0.0    | 3.6            | 0.4    | 7.9      | 0.8    |
| MO 0105                        | Edible offal (mammalian)                    | 0.05                    | 4.2      | 0.2    | 1.4      | 0.1    | 2.8     | 0.1    | 6.1            | 0.3    | 12.4     | 0.6    |
| PE 0112                        | Eggs                                        | 0.05                    | 14.6     | 0.7    | 13.1     | 0.7    | 3.7     | 0.2    | 11.9           | 0.6    | 37.6     | 1.9    |
| FB 0269                        | Grapes (fresh, wine, dried)                 | 0.5                     | 16.1     | 8.1    | 1.0      | 0.5    | 0.0     | 0.0    | 1.6            | 0.8    | 16.1     | 8.1    |
| FI 0345                        | Mango                                       | 0.05                    | 2.3      | 0.1    | 5.3      | 0.3    | 3.4     | 0.2    | 6.3            | 0.3    | 0.0      | 0.0    |
| MM 0095                        | Meat from mammals other than marine mammals | 0.05                    | 37.0     | 1.9    | 32.8     | 1.6    | 23.8    | 1.2    | 47.0           | 2.4    | 155.5    | 7.8    |
| ML 0106                        | Milks                                       | 0.01                    | 116.9    | 1.2    | 32.1     | 0.3    | 41.8    | 0.4    | 160.1          | 1.6    | 289.3    | 2.9    |
| GC 0647                        | Oats                                        | 0.05                    | 0.0      | 0.0    | 0.0      | 0.0    | 0.2     | 0.0    | 0.8            | 0.0    | 2.0      | 0.1    |
| SO 0703                        | Peanut, whole                               | 0.1                     | 0.0      | 0.0    | 4.0      | 0.4    | 5.5     | 0.6    | 1.3            | 0.1    | 0.3      | 0.0    |
| TN 0672                        | Pecan                                       | 0.05                    | 0.0      | 0.0    | 0.0      | 0.0    | 0.0     | 0.0    | 0.0            | 0.0    | 0.3      | 0.0    |
| PM 0110                        | Poultry meat                                | 0.05                    | 31.0     | 1.6    | 13.2     | 0.7    | 5.5     | 0.3    | 25.3           | 1.3    | 53.0     | 2.7    |
| SO 0495                        | Rape-seed                                   | 0.05                    | 0.0      | 0.0    | 0.0      | 0.0    | 0.0     | 0.0    | 0.0            | 0.0    | 0.0      | 0.0    |
| GC 0650                        | Rye                                         | 0.05                    | 0.0      | 0.0    | 1.0      | 0.1    | 0.0     | 0.0    | 0.0            | 0.0    | 1.5      | 0.1    |
| FS 0012                        | Stone fruits                                | 1                       | 7.3      | 7.3    | 1.0      | 1.0    | 0.0     | 0.0    | 0.8            | 0.8    | 23.3     | 23.3   |
| VR 0596                        | Sugar-beet                                  | 0.05                    | 0.5      | 0.0    | 0.0      | 0.0    | 0.0     | 0.0    | 0.3            | 0.0    | 2.0      | 0.1    |
| GS 0659                        | Sugar-cane                                  | 0.05                    | 18.5     | 0.9    | 7.3      | 0.4    | 15.9    | 0.8    | 3.5            | 0.2    | 0.0      | 0.0    |
| GC 0654                        | Wheat                                       | 0.05                    | 327.3    | 16.4   | 114.8    | 5.7    | 28.3    | 1.4    | 116.8          | 5.8    | 178.0    | 8.9    |
| Total intake (µg/person)       |                                             |                         | 39.7     |        | 14.5     |        | 7.3     |        | 25.2           |        | 60.5     |        |
| Body weight per region (kg bw) |                                             |                         | 60       |        | 55       |        | 60      |        | 60             |        | 60       |        |
| ADI (µg/person)                |                                             |                         | 4200     |        | 3850     |        | 4200    |        | 4200           |        | 4200     |        |
| % ADI                          |                                             |                         | 0.9%     |        | 0.4%     |        | 0.2%    |        | 0.6%           |        | 1.4%     |        |
| Rounded % ADI                  |                                             |                         | 1%       |        | 0%       |        | 0%      |        | 1%             |        | 1%       |        |

### Annex 3

322

#### PROPINEB

#### International estimated daily intake

ADI = 0–0.007 mg/kg bw

| Codex code                     | Commodity                                                  | STMR or STMR-P (mg/kg) | Mid-East |        | Far-East |        | African |        | Latin American |        | European |        |
|--------------------------------|------------------------------------------------------------|------------------------|----------|--------|----------|--------|---------|--------|----------------|--------|----------|--------|
|                                |                                                            |                        | Diet     | Intake | Diet     | Intake | Diet    | Intake | Diet           | Intake | Diet     | Intake |
| FS 0013                        | Cherry                                                     | 0.13                   | 0.0      | 0.0    | 0.0      | 0.0    | 0.0     | 0.0    | 0.0            | 0.0    | 3.0      | 0.4    |
| VC 0424                        | Cucumber                                                   | 0.49                   | 2.4      | 1.2    | 2.3      | 1.1    | 0.0     | 0.0    | 4.2            | 2.0    | 4.5      | 2.2    |
| MO 0105                        | Edible offal (mammalian)                                   | 0                      | 4.2      | 0.0    | 1.4      | 0.0    | 2.8     | 0.0    | 6.1            | 0.0    | 12.4     | 0.0    |
| PE 0112                        | Eggs                                                       | 0                      | 14.6     | 0.0    | 13.1     | 0.0    | 3.7     | 0.0    | 11.9           | 0.0    | 37.6     | 0.0    |
| MM 0095                        | Meat from mammals other than marine mammals: 20% as fat    | 0                      | 7.4      | 0.0    | 6.6      | 0.0    | 4.8     | 0.0    | 9.4            | 0.0    | 31.1     | 0.0    |
| MM 0095                        | Meat from mammals other than marine mammals: 80% as muscle | 0                      | 29.6     | 0.0    | 26.2     | 0.0    | 19.0    | 0.0    | 37.6           | 0.0    | 124.4    | 0.0    |
| ML 0106                        | Milks                                                      | 0                      | 116.9    | 0.0    | 32.1     | 0.0    | 41.8    | 0.0    | 160.1          | 0.0    | 289.3    | 0.0    |
| VO 0445                        | Peppers, sweet (including pim(i)ento)                      | 1.6                    | 3.3      | 5.3    | 2.0      | 3.2    | 5.3     | 8.5    | 2.3            | 3.7    | 10.3     | 16.5   |
| VR 0589                        | Potato                                                     | 0.12                   | 59.0     | 7.1    | 19.2     | 2.3    | 20.6    | 2.5    | 40.8           | 4.9    | 240.8    | 28.9   |
| PM 0110                        | Poultry meat: 10% as fat                                   | 0                      | 3.1      | 0.0    | 1.3      | 0.0    | 0.6     | 0.0    | 2.5            | 0.0    | 5.3      | 0.0    |
| PM 0110                        | Poultry meat: 90% as muscle                                | 0                      | 27.9     | 0.0    | 11.9     | 0.0    | 5.0     | 0.0    | 22.8           | 0.0    | 47.7     | 0.0    |
| PO 0111                        | Poultry, edible offal of                                   | 0                      | 0.1      | 0.0    | 0.1      | 0.0    | 0.1     | 0.0    | 0.4            | 0.0    | 0.4      | 0.0    |
| VO 0448                        | Tomato (fresh, juice, paste, peeled)                       | 1                      | 81.5     | 81.5   | 7.0      | 7.0    | 16.5    | 16.5   | 25.5           | 25.5   | 66.6     | 66.6   |
| JF 0448                        | Tomato juice                                               | 0.182                  | 0.3      | 0.1    | 0.0      | 0.0    | 0.0     | 0.0    | 0.0            | 0.0    | 2.0      | 0.4    |
|                                | Tomato paste                                               | 1.86                   | 5.8      | 10.8   | 0.2      | 0.4    | 0.3     | 0.6    | 0.0            | 0.0    | 4.0      | 7.4    |
| Total intake (µg/person)       |                                                            |                        | 105.9    |        | 14.0     |        | 28.0    |        | 36.1           |        | 122.4    |        |
| Body weight per region (kg bw) |                                                            |                        | 60       |        | 55       |        | 60      |        | 60             |        | 60       |        |
| ADI (µg/person)                |                                                            |                        | 420      |        | 385      |        | 420     |        | 420            |        | 420      |        |
| % ADI                          |                                                            |                        | 25.2%    |        | 3.6%     |        | 6.7%    |        | 8.6%           |        | 29.1%    |        |
| Rounded % ADI                  |                                                            |                        | 30%      |        | 4%       |        | 7%      |        | 9%             |        | 30%      |        |

### Annex 3

#### PYRACLOSTROBIN (210)

International estimated daily intake

ADI = 0–0.03 mg/kg bw

| Codex code | Commodity                                                  | STMR or STMR-P (mg/kg) | Mid-East |        | Far-East |        | African |        | Latin American |        | European |        |
|------------|------------------------------------------------------------|------------------------|----------|--------|----------|--------|---------|--------|----------------|--------|----------|--------|
|            |                                                            |                        | Diet     | Intake | Diet     | Intake | Diet    | Intake | Diet           | Intake | Diet     | Intake |
| FC 0001    | Citrus fruit                                               | 0.19                   | 47.1     | 8.9    | 6.3      | 1.2    | 5.1     | 1.0    | 54.6           | 10.4   | 44.6     | 8.5    |
| TN 0660    | Almond                                                     | 0.02                   | 0.5      | 0.0    | 0.0      | 0.0    | 0.0     | 0.0    | 0.1            | 0.0    | 1.8      | 0.0    |
| FI 0327    | Banana                                                     | 0.02                   | 8.3      | 0.2    | 26.2     | 0.5    | 21.0    | 0.4    | 102.3          | 2.0    | 22.8     | 0.5    |
| GC 0640    | Barley (fresh)                                             | 0.03                   | 1.0      | 0.0    | 3.5      | 0.1    | 1.8     | 0.1    | 6.5            | 0.2    | 19.8     | 0.6    |
| VD 0071    | Beans (dry)                                                | 0.02                   | 2.3      | 0.0    | 4.8      | 0.1    | 0.0     | 0.0    | 13.0           | 0.3    | 3.5      | 0.1    |
| FB 0020    | Blueberry                                                  | 0.34                   | 0.0      | 0.0    | 0.0      | 0.0    | 0.0     | 0.0    | 0.0            | 0.0    | 0.5      | 0.2    |
| VR 0577    | Carrot                                                     | 0.12                   | 2.8      | 0.3    | 2.5      | 0.3    | 0.0     | 0.0    | 6.3            | 0.8    | 22.0     | 2.6    |
| FS 0013    | Cherry                                                     | 0.43                   | 0.0      | 0.0    | 0.0      | 0.0    | 0.0     | 0.0    | 0.0            | 0.0    | 3.0      | 1.3    |
| MO 0105    | Edible offal (mammalian)                                   | 0.008                  | 4.2      | 0.0    | 1.4      | 0.0    | 2.8     | 0.0    | 6.1            | 0.0    | 12.4     | 0.1    |
| PE 0112    | Eggs                                                       | 0                      | 14.6     | 0.0    | 13.1     | 0.0    | 3.7     | 0.0    | 11.9           | 0.0    | 37.6     | 0.0    |
| VA 0381    | Garlic                                                     | 0.05                   | 2.0      | 0.1    | 2.2      | 0.1    | 0.0     | 0.0    | 0.5            | 0.0    | 3.0      | 0.2    |
| FB 0269    | Grapes (fresh, wine, excluding dried grapes)               | 0.44                   | 15.8     | 7.0    | 1.0      | 0.4    | 0.0     | 0.0    | 1.3            | 0.6    | 13.8     | 6.1    |
| DF 0269    | Grapes, dried (currants, raisins and sultanas)             | 1.36                   | 0.3      | 0.4    | 0.0      | 0.0    | 0.0     | 0.0    | 0.3            | 0.4    | 2.3      | 3.1    |
| VD 0533    | Lentil (dry)                                               | 0.13                   | 2.8      | 0.4    | 0.7      | 0.1    | 0.0     | 0.0    | 0.0            | 0.0    | 2.3      | 0.3    |
| GC 0645    | Maize (fresh)                                              | 0.02                   | 16.5     | 0.3    | 0.0      | 0.0    | 0.0     | 0.0    | 1.5            | 0.0    | 0.0      | 0.0    |
| FI 0345    | Mango                                                      | 0.05                   | 2.3      | 0.1    | 5.3      | 0.3    | 3.4     | 0.2    | 6.3            | 0.3    | 0.0      | 0.0    |
| MM 0095    | Meat from mammals other than marine mammals: 20% as fat    | 0.063                  | 7.4      | 0.5    | 6.6      | 0.4    | 4.8     | 0.3    | 9.4            | 0.6    | 31.1     | 2.0    |
| MM 0095    | Meat from mammals other than marine mammals: 80% as muscle | 0.009                  | 29.6     | 0.3    | 26.2     | 0.2    | 19.0    | 0.2    | 37.6           | 0.3    | 124.4    | 1.1    |
| ML 0106    | Milks                                                      | 0.01                   | 116.9    | 1.2    | 32.1     | 0.3    | 41.8    | 0.4    | 160.1          | 1.6    | 289.3    | 2.9    |
| GC 0647    | Oats                                                       | 0.17                   | 0.0      | 0.0    | 0.0      | 0.0    | 0.2     | 0.0    | 0.8            | 0.1    | 2.0      | 0.3    |
|            | Onion, dry                                                 | 0.02                   | 23.0     | 0.5    | 9.5      | 0.2    | 5.8     | 0.1    | 9.8            | 0.2    | 26.8     | 0.5    |
| FI 0350    | Papaya                                                     | 0.05                   | 0.0      | 0.0    | 0.2      | 0.0    | 0.0     | 0.0    | 5.3            | 0.3    | 0.0      | 0.0    |
|            | Peach and nectarine                                        | 0.15                   | 2.5      | 0.4    | 0.5      | 0.1    | 0.0     | 0.0    | 0.8            | 0.1    | 12.5     | 1.9    |
| SO 0697    | Peanut                                                     | 0.02                   | 0.3      | 0.0    | 0.2      | 0.0    | 2.3     | 0.0    | 0.3            | 0.0    | 3.0      | 0.1    |
| VD 0072    | Peas (dry)                                                 | 0.07                   | 0.5      | 0.0    | 1.7      | 0.1    | 5.1     | 0.4    | 1.3            | 0.1    | 1.8      | 0.1    |
| TN 0672    | Pecan                                                      | 0.02                   | 0.0      | 0.0    | 0.0      | 0.0    | 0.0     | 0.0    | 0.0            | 0.0    | 0.3      | 0.0    |
| TN 0675    | Pistachio nut                                              | 0.22                   | 0.3      | 0.1    | 0.0      | 0.0    | 0.0     | 0.0    | 0.0            | 0.0    | 0.0      | 0.0    |
| FS 0014    | Plum (fresh)                                               | 0.06                   | 1.8      | 0.1    | 0.5      | 0.0    | 0.0     | 0.0    | 0.0            | 0.0    | 3.8      | 0.2    |
| VR 0589    | Potato                                                     | 0.02                   | 59.0     | 1.2    | 19.2     | 0.4    | 20.6    | 0.4    | 40.8           | 0.8    | 240.8    | 4.8    |
| PM 0110    | Poultry meat                                               | 0                      | 31.0     | 0.0    | 13.2     | 0.0    | 5.5     | 0.0    | 25.3           | 0.0    | 53.0     | 0.0    |
| PO 0111    | Poultry, edible offal of                                   | 0                      | 0.1      | 0.0    | 0.1      | 0.0    | 0.1     | 0.0    | 0.4            | 0.0    | 0.4      | 0.0    |
| PF 0111    | Poultry, fats                                              | 0                      | 3.1      | 0.0    | 1.3      | 0.0    | 0.6     | 0.0    | 2.5            | 0.0    | 5.3      | 0.0    |
| VR 0494    | Radish                                                     | 0.08                   | 0.5      | 0.0    | 0.0      | 0.0    | 0.0     | 0.0    | 0.3            | 0.0    | 2.0      | 0.2    |
| VC 0431    | Squash, summer                                             | 0.15                   | 10.5     | 1.6    | 2.2      | 0.3    | 0.0     | 0.0    | 14.0           | 2.1    | 3.5      | 0.5    |
| FB 0275    | Strawberry                                                 | 0.16                   | 0.0      | 0.0    | 0.0      | 0.0    | 0.0     | 0.0    | 0.0            | 0.0    | 5.3      | 0.8    |
| VO 0448    | Tomato (fresh)                                             | 0.12                   | 44.1     | 5.3    | 5.7      | 0.7    | 14.6    | 1.8    | 25.5           | 3.1    | 34.9     | 4.2    |

### Annex 3

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| Codex code | Commodity                      | STMR or STMR-P (mg/kg) | Mid-East |        | Far-East |        | African |        | Latin American |        | European |        |
|------------|--------------------------------|------------------------|----------|--------|----------|--------|---------|--------|----------------|--------|----------|--------|
|            |                                |                        | Diet     | Intake | Diet     | Intake | Diet    | Intake | Diet           | Intake | Diet     | Intake |
|            | Total intake (µg/person)       |                        |          | 33.0   |          | 7.3    |         | 5.6    |                | 26.7   |          | 49.5   |
| GC 0654    | Wheat                          | 0.02                   | 4.3      | 0.1    | 0.8      | 0.0    | 0.0     | 0.0    | 4.8            | 0.1    | 2.2      | 0.0    |
| CM 0654    | Wheat bran. unprocessed        | 0.012                  | ND       | –      | ND       | –      | ND      | –      | ND             | –      | ND       | –      |
| CF 1211    | Wheat flour                    | 0.012                  | 323.0    | 3.9    | 114.0    | 1.4    | 28.3    | 0.3    | 112.0          | 1.3    | 175.8    | 2.1    |
| CF 1210    | Wheat germ                     | 0.016                  | 0.1      | 0.0    | 0.1      | 0.0    | 0.0     | 0.0    | 0.1            | 0.0    | 0.1      | 0.0    |
|            | Wine only                      | 0.04                   | 0.5      | 0.0    | 0.0      | 0.0    | 0.8     | 0.0    | 19.8           | 0.8    | 97.8     | 3.9    |
|            | Body weight per region (kg bw) |                        |          | 60     |          | 55     |         | 60     |                | 60     |          | 60     |
|            | ADI (µg/person)                |                        |          | 1800   |          | 1650   |         | 1800   |                | 1800   |          | 1800   |
|            | % ADI                          |                        |          | 1.8%   |          | 0.4%   |         | 0.3%   |                | 1.5%   |          | 2.7%   |
|            | Rounded % ADI                  |                        |          | 2%     |          | 0%     |         | 0%     |                | 1%     |          | 3%     |

### Annex 3

#### SPINOSAD (203)

#### International estimated daily intake

ADI = 0–0.02 mg/kg bw

| Codex code | Commodity                                                                    | STMR or STMR-P (mg/kg) | Mid-East |        | Far-East |        | African |        | Latin American |        | European |        |
|------------|------------------------------------------------------------------------------|------------------------|----------|--------|----------|--------|---------|--------|----------------|--------|----------|--------|
|            |                                                                              |                        | Diet     | Intake | Diet     | Intake | Diet    | Intake | Diet           | Intake | Diet     | Intake |
| TN 0660    | Almond                                                                       | 0.01                   | 0.5      | 0.0    | 0.0      | 0.0    | 0.0     | 0.0    | 0.1            | 0.0    | 1.8      | 0.0    |
| FP 0226    | Apple                                                                        | 0.0165                 | 7.5      | 0.1    | 4.7      | 0.1    | 0.3     | 0.0    | 5.5            | 0.1    | 40.0     | 0.7    |
| JF 0226    | Apple juice                                                                  | 0.0013                 | 4.5      | 0.0    | 0        | 0.0    | 0       | 0.0    | 0.3            | 0.0    | 3.8      | 0.0    |
|            | Brassica vegetables (flowerhead, head and leafy Brassicas, kohlrabi)         | 0.27                   | 6.3      | 1.7    | 11.2     | 3.0    | 0.0     | 0.0    | 10.8           | 2.9    | 39.8     | 10.7   |
| MM 0812    | Cattle meat                                                                  | 0.078                  | 14.6     | 1.1    | 2.7      | 0.2    | 10.4    | 0.8    | 30.0           | 2.3    | 63.3     | 4.9    |
| ML 0812    | Cattle milk                                                                  | 0.65                   | 79.5     | 51.7   | 23.2     | 15.1   | 35.8    | 23.3   | 159.3          | 103.5  | 287.0    | 186.6  |
| MO 1280    | Cattle kidney                                                                | 0.31                   | 0.1      | 0.0    | 0.0      | 0.0    | 0.1     | 0.0    | 0.2            | 0.1    | 0.2      | 0.1    |
| MO 1281    | Cattle liver                                                                 | 0.66                   | 0.2      | 0.1    | 0        | 0.0    | 0.1     | 0.1    | 0.3            | 0.2    | 0.4      | 0.3    |
| VS 0624    | Celery                                                                       | 0.97                   | 0.5      | 0.5    | 0.0      | 0.0    | 0.0     | 0.0    | 0.3            | 0.3    | 2.0      | 1.9    |
| GC 0080    | Cereal grains, excluding maize flour, polished rice, wheat flour             | 0.7                    | 26.3     | 18.4   | 28.1     | 19.7   | 115.0   | 80.5   | 34.6           | 24.2   | 28.0     | 19.6   |
| FC 0001    | Citrus fruit                                                                 | 0.01                   | 47.1     | 0.5    | 6.3      | 0.1    | 5.1     | 0.1    | 54.6           | 0.5    | 44.6     | 0.4    |
| OC 0691    | Cotton-seed oil, crude                                                       | 0.0018                 | 3.8      | 0.0    | 0.5      | 0.0    | 0.5     | 0.0    | 0.5            | 0.0    | 0.0      | 0.0    |
| OR 0691    | Cotton-seed oil, edible                                                      | 0.002                  | 3.8      | 0.0    | 0.5      | 0.0    | 0.5     | 0.0    | 0.5            | 0.0    | 0.0      | 0.0    |
| MO 0105    | Edible offal (mammalian), excluding cattle                                   | 0.064                  | 1.7      | 0.1    | 1.1      | 0.1    | 1.0     | 0.1    | 1.1            | 0.1    | 6.4      | 0.4    |
| PE 0112    | Eggs                                                                         | 0.01                   | 14.6     | 0.1    | 13.1     | 0.1    | 3.7     | 0.0    | 11.9           | 0.1    | 37.6     | 0.4    |
| VC 0045    | Fruiting vegetables. cucurbits                                               | 0.046                  | 80.5     | 3.7    | 18.2     | 0.8    | 0.0     | 0.0    | 30.5           | 1.4    | 38.5     | 1.8    |
| FB 0269    | Grapes (fresh, wine, excluding dried grapes)                                 | 0.084                  | 15.8     | 1.3    | 1.0      | 0.1    | 0.0     | 0.0    | 1.3            | 0.1    | 13.8     | 1.1    |
| DF 0269    | Grapes, dried (currants, raisins and sultanas)                               | 0.13                   | 0.3      | 0.0    | 0.0      | 0.0    | 0.0     | 0.0    | 0.3            | 0.0    | 2.3      | 0.3    |
| FI 0341    | Kiwi fruit                                                                   | 0.02                   | 0.0      | 0.0    | 0.0      | 0.0    | 1.9     | 0.0    | 0.1            | 0.0    | 1.5      | 0.0    |
| VL 0053    | Leafy vegetables                                                             | 1.9                    | 7.8      | 14.8   | 9.7      | 18.4   | 0.7     | 1.3    | 16.5           | 31.4   | 51.7     | 98.2   |
| VP 0060    | Legume vegetables                                                            | 0.041                  | 9.9      | 0.4    | 3.1      | 0.1    | 0.1     | 0.0    | 5.6            | 0.2    | 28.4     | 1.2    |
| CF 1255    | Maize flour                                                                  | 0.13                   | 31.8     | 4.1    | 31.2     | 4.1    | 106.2   | 13.8   | 40.3           | 5.2    | 8.8      | 1.1    |
| OC 0645    | Maize oil, crude                                                             | 0.77                   | 1.8      | 1.4    | 0.0      | 0.0    | 0.3     | 0.2    | 0.5            | 0.4    | 1.3      | 1.0    |
| MM 0095    | Meat from mammals other than marine mammals: 20% as fat, excluding cattle    | 0.32                   | 4.5      | 1.4    | 6.0      | 1.9    | 2.7     | 0.9    | 3.4            | 1.1    | 18.4     | 5.9    |
| MM 0095    | Meat from mammals other than marine mammals: 80% as muscle, excluding cattle | 0.01                   | 17.9     | 0.2    | 24.1     | 0.2    | 10.7    | 0.1    | 13.6           | 0.1    | 73.8     | 0.7    |
| JF 0004    | Orange juice                                                                 | 0.0072                 | 7.3      | 0.1    | 0.0      | 0.0    | 0.0     | 0.0    | 0.3            | 0.0    | 4.5      | 0.0    |
| VO 0051    | Peppers                                                                      | 0.056                  | 3.4      | 0.2    | 2.1      | 0.1    | 5.4     | 0.3    | 2.4            | 0.1    | 10.4     | 0.6    |
| VR 0589    | Potato                                                                       | 0                      | 59.0     | 0.0    | 19.2     | 0.0    | 20.6    | 0.0    | 40.8           | 0.0    | 240.8    | 0.0    |
| PM 0110    | Poultry meat                                                                 | 0.01                   | 31.0     | 0.3    | 13.2     | 0.1    | 5.5     | 0.1    | 25.3           | 0.3    | 53.0     | 0.5    |
| CM 1206    | Rice bran. unprocessed                                                       | 0.55                   | ND       | –      | ND       | –      | ND      | –      | ND             | –      | ND       | –      |
| CM 0649    | Rice, husked                                                                 | 0.077                  | 0.0      | 0.0    | 1.8      | 0.1    | 34.7    | 2.7    | 21.0           | 1.6    | 2.5      | 0.2    |
| CM 1205    | Rice, polished                                                               | 0.015                  | 48.8     | 0.7    | 277.5    | 4.2    | 68.8    | 1.0    | 65.5           | 1.0    | 9.3      | 0.1    |
| VD 0541    | Soya bean (dry)                                                              | 0                      | 4.5      | 0.0    | 2.0      | 0.0    | 0.5     | 0.0    | 0.0            | 0.0    | 0.0      | 0.0    |

### Annex 3

326

| Codex code                     | Commodity                    | STMR or STMR-P (mg/kg) | Mid-East |        | Far-East |        | African |        | Latin American |        | European |        |
|--------------------------------|------------------------------|------------------------|----------|--------|----------|--------|---------|--------|----------------|--------|----------|--------|
|                                |                              |                        | Diet     | Intake | Diet     | Intake | Diet    | Intake | Diet           | Intake | Diet     | Intake |
| FS 0012                        | Stone fruits                 | 0.0265                 | 7.3      | 0.2    | 1.0      | 0.0    | 0.0     | 0.0    | 0.8            | 0.0    | 23.3     | 0.6    |
| VO 0447                        | Sweet corn (corn-on-the-cob) | 0.01                   | 0.0      | 0.0    | 0.0      | 0.0    | 4.4     | 0.0    | 0.0            | 0.0    | 8.3      | 0.1    |
| VO 0448                        | Tomato (fresh)               | 0.03                   | 44.1     | 1.3    | 5.7      | 0.2    | 14.6    | 0.4    | 25.5           | 0.8    | 34.9     | 1.0    |
| JF 0448                        | Tomato juice                 | 0.0075                 | 0.3      | 0.0    | 0.0      | 0.0    | 0.0     | 0.0    | 0.0            | 0.0    | 2.0      | 0.0    |
|                                | Tomato paste                 | 0.059                  | 5.8      | 0.3    | 0.2      | 0.0    | 0.3     | 0.0    | 0.0            | 0.0    | 4.0      | 0.2    |
| CM 0654                        | Wheat bran. unprocessed      | 1.4                    | ND       | -      | ND       | -      | ND      | -      | ND             | -      | ND       | -      |
| CF 1211                        | Wheat flour                  | 0.18                   | 323.0    | 58.1   | 114.0    | 20.5   | 28.3    | 5.1    | 112.0          | 20.2   | 175.8    | 31.6   |
| CP 1211                        | White bread                  | 0.098                  | 215.3    | 21.1   | 76.0     | 7.4    | 18.9    | 1.9    | 37.3           | 3.7    | 117.2    | 11.5   |
|                                | Wine only                    | 0.027                  | 0.5      | 0.0    | 0.0      | 0.0    | 0.8     | 0.0    | 19.8           | 0.5    | 97.8     | 2.6    |
| Total intake (µg/person)       |                              |                        | 184.2    |        | 96.8     |        | 132.7   |        | 202.5          |        | 386.7    |        |
| Body weight per region (kg bw) |                              |                        | 60       |        | 55       |        | 60      |        | 60             |        | 60       |        |
| ADI (µg/person)                |                              |                        | 1200     |        | 1100     |        | 1200    |        | 1200           |        | 1200     |        |
| % ADI                          |                              |                        | 15.4%    |        | 8.8%     |        | 11.1%   |        | 16.9%          |        | 32.2%    |        |
| Rounded % ADI                  |                              |                        | 20%      |        | 9%       |        | 10%     |        | 20%            |        | 30%      |        |



### Annex 3

#### TRIADIMEFON (133)

Estimated theoretical maximum daily intake

ADI = 0–0.03 mg/kg bw

| Codex code                     | Commodity                                   | MRL (mg/kg) | Mid-East |        | Far-East |        | African |        | Latin American |        | European |        |
|--------------------------------|---------------------------------------------|-------------|----------|--------|----------|--------|---------|--------|----------------|--------|----------|--------|
|                                |                                             |             | Diet     | Intake | Diet     | Intake | Diet    | Intake | Diet           | Intake | Diet     | Intake |
| FP 0009                        | Pome fruit                                  | 0.5         | 10.8     | 5.4    | 7.5      | 3.8    | 0.3     | 0.2    | 6.5            | 3.3    | 51.3     | 25.7   |
| GC 0640                        | Barley (fresh)                              | 0.5         | 1.0      | 0.5    | 3.5      | 1.8    | 1.8     | 0.9    | 6.5            | 3.3    | 19.8     | 9.9    |
| VD 0524                        | Chick-pea (dry)                             | 0.05        | 3.3      | 0.2    | 2.5      | 0.1    | 0.0     | 0.0    | 0.0            | 0.0    | 1.0      | 0.1    |
| SB 0716                        | Coffee bean                                 | 0.05        | 5.3      | 0.3    | 0.4      | 0.0    | 0.0     | 0.0    | 3.6            | 0.2    | 7.9      | 0.4    |
| FB 0021                        | Currant, red, black, white                  | 0.2         | 0.0      | 0.0    | 0.0      | 0.0    | 0.0     | 0.0    | 0.0            | 0.0    | 0.3      | 0.1    |
| PE 0112                        | Eggs                                        | 0.05        | 14.6     | 0.7    | 13.1     | 0.7    | 3.7     | 0.2    | 11.9           | 0.6    | 37.6     | 1.9    |
| VC 0045                        | Fruiting vegetables, cucurbits              | 0.1         | 80.5     | 8.1    | 18.2     | 1.8    | 0.0     | 0.0    | 30.5           | 3.1    | 38.5     | 3.9    |
| FB 0269                        | Grapes (fresh. Wine, dried)                 | 0.5         | 16.1     | 8.1    | 1.0      | 0.5    | 0.0     | 0.0    | 1.6            | 0.8    | 16.1     | 8.1    |
| DH 1100                        | Hops, dry                                   | 10          | 0.1      | 1.0    | 0.1      | 1.0    | 0.1     | 1.0    | 0.1            | 1.0    | 0.1      | 1.0    |
| FI 0345                        | Mango                                       | 0.05        | 2.3      | 0.1    | 5.3      | 0.3    | 3.4     | 0.2    | 6.3            | 0.3    | 0.0      | 0.0    |
| MM 0095                        | Meat from mammals other than marine mammals | 0.05        | 37.0     | 1.9    | 32.8     | 1.6    | 23.8    | 1.2    | 47.0           | 2.4    | 155.5    | 7.8    |
| ML 0106                        | Milks                                       | 0.05        | 116.9    | 5.8    | 32.1     | 1.6    | 41.8    | 2.1    | 160.1          | 8.0    | 289.3    | 14.5   |
| GC 0647                        | Oats                                        | 0.1         | 0.0      | 0.0    | 0.0      | 0.0    | 0.2     | 0.0    | 0.8            | 0.1    | 2.0      | 0.2    |
| VA 0387                        | Onion, Welsh                                | 0.05        | ND       | –      | ND       | –      | ND      | –      | ND             | –      | ND       | –      |
| VP 0063                        | Peas (green pods and immature seeds)        | 0.1         | 5.5      | 0.6    | 2.0      | 0.2    | 0.0     | 0.0    | 0.8            | 0.1    | 14.0     | 1.4    |
| VO 0445                        | Peppers. sweet (including pim(i)ento)       | 0.1         | 3.3      | 0.3    | 2.0      | 0.2    | 5.3     | 0.5    | 2.3            | 0.2    | 10.3     | 1.0    |
| FI 0353                        | Pineapple (fresh)                           | 2           | 0.0      | 0.0    | 9.3      | 18.6   | 2.6     | 5.2    | 15.5           | 31.0   | 1.3      | 2.6    |
| PM 0110                        | Poultry meat                                | 0.05        | 31.0     | 1.6    | 13.2     | 0.7    | 5.5     | 0.3    | 25.3           | 1.3    | 53.0     | 2.7    |
| FB 0272                        | Raspberry, red, black                       | 1           | 0.0      | 0.0    | 0.0      | 0.0    | 0.0     | 0.0    | 0.0            | 0.0    | 0.5      | 0.5    |
| GC 0650                        | Rye                                         | 0.1         | 0.0      | 0.0    | 1.0      | 0.1    | 0.0     | 0.0    | 0.0            | 0.0    | 1.5      | 0.2    |
| VA 0389                        | Spring onion                                | 0.05        | 0.0      | 0.0    | 2.0      | 0.1    | 1.5     | 0.1    | 4.0            | 0.2    | 1.0      | 0.1    |
| FB 0275                        | Strawberry                                  | 0.1         | 0.0      | 0.0    | 0.0      | 0.0    | 0.0     | 0.0    | 0.0            | 0.0    | 5.3      | 0.5    |
| VR 0596                        | Sugar-beet                                  | 0.1         | 0.5      | 0.1    | 0.0      | 0.0    | 0.0     | 0.0    | 0.3            | 0.0    | 2.0      | 0.2    |
| VO 0448                        | Tomato (fresh. juice. paste. peeled)        | 0.2         | 81.5     | 16.3   | 7.0      | 1.4    | 16.5    | 3.3    | 25.5           | 5.1    | 66.6     | 13.3   |
| GC 0654                        | Wheat                                       | 0.1         | 327.3    | 32.7   | 114.8    | 11.5   | 28.3    | 2.8    | 116.8          | 11.7   | 178.0    | 17.8   |
| Total intake (µg/person)       |                                             |             | 83.5     |        | 45.9     |        | 17.9    |        | 72.5           |        | 113.5    |        |
| Body weight per region (kg bw) |                                             |             | 60       |        | 55       |        | 60      |        | 60             |        | 60       |        |
| ADI (µg/person)                |                                             |             | 1800     |        | 1650     |        | 1800    |        | 1800           |        | 1800     |        |
| % ADI                          |                                             |             | 4.6%     |        | 2.8%     |        | 1.0%    |        | 4.0%           |        | 6.3%     |        |
| Rounded % ADI                  |                                             |             | 5%       |        | 3%       |        | 1%      |        | 4%             |        | 6%       |        |

**TRIADIMENOL (168)**

## Theoretical maximum daily intake

ADI = 0–0.03 mg/kg bw

| Codex code                     | Commodity                                   | MRL (mg/kg) | Mid-East |        | Far-East |        | African |        | Latin American |        | European |        |
|--------------------------------|---------------------------------------------|-------------|----------|--------|----------|--------|---------|--------|----------------|--------|----------|--------|
|                                |                                             |             | Diet     | Intake | Diet     | Intake | Diet    | Intake | Diet           | Intake | Diet     | Intake |
| FP 0009                        | Pome fruit                                  | 0.5         | 10.8     | 5.4    | 7.5      | 3.8    | 0.3     | 0.2    | 6.5            | 3.3    | 51.3     | 25.7   |
| VS 0620                        | Artichoke, globe                            | 1           | 2.3      | 2.3    | 0.0      | 0.0    | 0.0     | 0.0    | 0.0            | 0.0    | 5.5      | 5.5    |
| FI 0327                        | Banana                                      | 0.2         | 8.3      | 1.7    | 26.2     | 5.2    | 21.0    | 4.2    | 102.3          | 20.5   | 22.8     | 4.6    |
| GC 0640                        | Barley (fresh)                              | 0.5         | 1.0      | 0.5    | 3.5      | 1.8    | 1.8     | 0.9    | 6.5            | 3.3    | 19.8     | 9.9    |
| VD 0524                        | Chick-pea (dry)                             | 0.05        | 3.3      | 0.2    | 2.5      | 0.1    | 0.0     | 0.0    | 0.0            | 0.0    | 1.0      | 0.1    |
| SB 0716                        | Coffee bean                                 | 0.1         | 5.3      | 0.5    | 0.4      | 0.0    | 0.0     | 0.0    | 3.6            | 0.4    | 7.9      | 0.8    |
| FB 0021                        | Currants, red, black, white                 | 0.5         | 0.0      | 0.0    | 0.0      | 0.0    | 0.0     | 0.0    | 0.0            | 0.0    | 0.3      | 0.2    |
| PE 0112                        | Eggs                                        | 0.05        | 14.6     | 0.7    | 13.1     | 0.7    | 3.7     | 0.2    | 11.9           | 0.6    | 37.6     | 1.9    |
| VC 0045                        | Fruiting vegetables. cucurbits              | 2           | 80.5     | 161.0  | 18.2     | 36.4   | 0.0     | 0.0    | 30.5           | 61.0   | 38.5     | 77.0   |
| FB 0269                        | Grapes (fresh, wine, dried)                 | 2           | 16.1     | 32.2   | 1.0      | 2.0    | 0.0     | 0.0    | 1.6            | 3.2    | 16.1     | 32.2   |
| FI 0345                        | Mango                                       | 0.05        | 2.3      | 0.1    | 5.3      | 0.3    | 3.4     | 0.2    | 6.3            | 0.3    | 0.0      | 0.0    |
| MM 0095                        | Meat from mammals other than marine mammals | 0.05        | 37.0     | 1.9    | 32.8     | 1.6    | 23.8    | 1.2    | 47.0           | 2.4    | 155.5    | 7.8    |
| ML 0106                        | Milks                                       | 0.01        | 116.9    | 1.2    | 32.1     | 0.3    | 41.8    | 0.4    | 160.1          | 1.6    | 289.3    | 2.9    |
| GC 0647                        | Oats                                        | 0.2         | 0.0      | 0.0    | 0.0      | 0.0    | 0.2     | 0.0    | 0.8            | 0.2    | 2.0      | 0.4    |
| VA 0387                        | Onion, Welsh                                | 0.05        | ND       | -      | ND       | -      | ND      | -      | ND             | -      | ND       | -      |
| VP 0063                        | Peas (green pods and immature seeds)        | 0.1         | 5.5      | 0.6    | 2.0      | 0.2    | 0.0     | 0.0    | 0.8            | 0.1    | 14.0     | 1.4    |
| VO 0445                        | Peppers, sweet (including pim(i)ento)       | 0.1         | 3.3      | 0.3    | 2.0      | 0.2    | 5.3     | 0.5    | 2.3            | 0.2    | 10.3     | 1.0    |
| FI 0353                        | Pineapple (fresh, canned, juice, dried)     | 1           | ND       | –      | ND       | –      | ND      | –      | ND             | –      | ND       | –      |
| PM 0110                        | Poultry meat                                | 0.05        | 31.0     | 1.6    | 13.2     | 0.7    | 5.5     | 0.3    | 25.3           | 1.3    | 53.0     | 2.7    |
| FB 0272                        | Raspberry, red.,black                       | 0.5         | 0.0      | 0.0    | 0.0      | 0.0    | 0.0     | 0.0    | 0.0            | 0.0    | 0.5      | 0.3    |
| GC 0650                        | Rye                                         | 0.2         | 0.0      | 0.0    | 1.0      | 0.2    | 0.0     | 0.0    | 0.0            | 0.0    | 1.5      | 0.3    |
| VA 0389                        | Spring onion                                | 0.05        | 0.0      | 0.0    | 2.0      | 0.1    | 1.5     | 0.1    | 4.0            | 0.2    | 1.0      | 0.1    |
| FB 0275                        | Strawberry                                  | 0.1         | 0.0      | 0.0    | 0.0      | 0.0    | 0.0     | 0.0    | 0.0            | 0.0    | 5.3      | 0.5    |
| VR 0596                        | Sugar-beet                                  | 0.1         | 0.5      | 0.1    | 0.0      | 0.0    | 0.0     | 0.0    | 0.3            | 0.0    | 2.0      | 0.2    |
| VO 0448                        | Tomato (fresh, juice, paste, peeled)        | 0.5         | 81.5     | 40.8   | 7.0      | 3.5    | 16.5    | 8.3    | 25.5           | 12.8   | 66.6     | 33.3   |
| GC 0654                        | Wheat                                       | 0.2         | 327.3    | 65.5   | 114.8    | 23.0   | 28.3    | 5.7    | 116.8          | 23.4   | 178.0    | 35.6   |
| Total intake (µg/person)       |                                             |             | 316.3    |        | 80.0     |        | 22.1    |        | 134.5          |        | 244.1    |        |
| Body weight per region (kg bw) |                                             |             | 60       |        | 55       |        | 60      |        | 60             |        | 60       |        |
| ADI (µg/person)                |                                             |             | 1800     |        | 1650     |        | 1800    |        | 1800           |        | 1800     |        |
| % ADI                          |                                             |             | 17.6%    |        | 4.8%     |        | 1.2%    |        | 7.5%           |        | 13.6%    |        |
| Rounded % ADI                  |                                             |             | 20%      |        | 5%       |        | 1%      |        | 7%             |        | 10%      |        |

### Annex 3

#### TRIFLOXYSTROBIN (213)

International estimated daily intake

ADI = 0–0.04 mg/kg bw

| Codex code | Commodity                                                  | STMR or STMR-P (mg/kg) | Mid-East |        | Far-East |        | African |        | Latin American |        | European |        |
|------------|------------------------------------------------------------|------------------------|----------|--------|----------|--------|---------|--------|----------------|--------|----------|--------|
|            |                                                            |                        | Diet     | Intake | Diet     | Intake | Diet    | Intake | Diet           | Intake | Diet     | Intake |
| FI 0327    | Banana                                                     | 0.02                   | 8.3      | 0.2    | 26.2     | 0.5    | 21.0    | 0.4    | 102.3          | 2.0    | 22.8     | 0.5    |
| GC 0640    | Barley (fresh)                                             | 0.04                   | 1.0      | 0.0    | 3.5      | 0.1    | 1.8     | 0.1    | 6.5            | 0.3    | 19.8     | 0.8    |
| VB 0400    | Broccoli                                                   | 0.17                   | 0.5      | 0.1    | 1.0      | 0.2    | 0.0     | 0.0    | 1.1            | 0.2    | 2.7      | 0.5    |
| VB 0402    | Brussels sprouts                                           | 0.17                   | 0.5      | 0.1    | 1.0      | 0.2    | 0.0     | 0.0    | 1.1            | 0.2    | 2.7      | 0.5    |
| VB 0403    | Cabbage, Savoy                                             | 0.17                   | 0.1      | 0.0    | 0.1      | 0.0    | 0.1     | 0.0    | 0.1            | 0.0    | 0.1      | 0.0    |
| VR 0577    | Carrot                                                     | 0.035                  | 2.8      | 0.1    | 2.5      | 0.1    | 0.0     | 0.0    | 6.3            | 0.2    | 22.0     | 0.8    |
| VB 0404    | Cauliflower                                                | 0.17                   | 1.3      | 0.2    | 1.5      | 0.3    | 0       | 0.0    | 0.3            | 0.1    | 13       | 2.2    |
| VS 0624    | Celery                                                     | 0.18                   | 0.5      | 0.1    | 0.0      | 0.0    | 0.0     | 0.0    | 0.3            | 0.1    | 2.0      | 0.4    |
| FC 0001    | Citrus fruit                                               | 0.095                  | 47.1     | 4.5    | 6.3      | 0.6    | 5.1     | 0.5    | 54.6           | 5.2    | 44.6     | 4.2    |
| MO 0097    | Edible offal of cattle, pigs and sheep                     | 0.008                  | 3.8      | 0.0    | 1.3      | 0.0    | 2.3     | 0.0    | 6.0            | 0.0    | 12.3     | 0.1    |
| PE 0112    | Eggs                                                       | 0                      | 14.6     | 0.0    | 13.1     | 0.0    | 3.7     | 0.0    | 11.9           | 0.0    | 37.6     | 0.0    |
| VC 0045    | Fruiting vegetables. cucurbits                             | 0.095                  | 80.5     | 7.6    | 18.2     | 1.7    | 0.0     | 0.0    | 30.5           | 2.9    | 38.5     | 3.7    |
| FB 0269    | Grapes (fresh, wine, excluding dried grapes)               | 0.15                   | 15.8     | 2.4    | 1.0      | 0.2    | 0.0     | 0.0    | 1.3            | 0.2    | 13.8     | 2.1    |
| DF 0269    | Grapes, dried (currants, raisins and sultanas)             | 0.345                  | 0.3      | 0.1    | 0.0      | 0.0    | 0.0     | 0.0    | 0.3            | 0.1    | 2.3      | 0.8    |
| DH 1100    | Hops, dry                                                  | 9.95                   | 0.1      | 1.0    | 0.1      | 1.0    | 0.1     | 1.0    | 0.1            | 1.0    | 0.1      | 1.0    |
| VA 0384    | Leek                                                       | 0.31                   | 0.5      | 0.2    | 0.0      | 0.0    | 0.0     | 0.0    | 0.3            | 0.1    | 2.0      | 0.6    |
| GC 0645    | Maize (fresh. flour)                                       | 0.02                   | 48.3     | 1.0    | 31.2     | 0.6    | 106.2   | 2.1    | 41.8           | 0.8    | 8.8      | 0.2    |
| MM 0095    | Meat from mammals other than marine mammals: 20% as fat    | 0.006                  | 7.4      | 0.0    | 6.6      | 0.0    | 4.8     | 0.0    | 9.4            | 0.0    | 31.1     | 0.0    |
| MM 0095    | Meat from mammals other than marine mammals: 80% as muscle | 0                      | 29.6     | 0.0    | 26.2     | 0.0    | 19.0    | 0.0    | 37.6           | 0.0    | 124.4    | 0.0    |
| ML 0106    | Milks                                                      | 0                      | 116.9    | 0.0    | 32.1     | 0.0    | 41.8    | 0.0    | 160.1          | 0.0    | 289.3    | 0.0    |
| JF 0004    | Orange juice                                               | 0.018                  | 7.3      | 0.1    | 0.0      | 0.0    | 0.0     | 0.0    | 0.3            | 0.0    | 4.5      | 0.1    |
| SO 0697    | Peanut                                                     | 0                      | 0.3      | 0.0    | 0.2      | 0.0    | 2.3     | 0.0    | 0.3            | 0.0    | 3.0      | 0.0    |
| VO 0445    | Peppers, sweet (including pim(i)ento)                      | 0.1                    | 3.3      | 0.3    | 2.0      | 0.2    | 5.3     | 0.5    | 2.3            | 0.2    | 10.3     | 1.0    |
| FP 0009    | Pome fruit                                                 | 0.11                   | 10.8     | 1.2    | 7.5      | 0.8    | 0.3     | 0.0    | 6.5            | 0.7    | 51.3     | 5.6    |
| VR 0589    | Potato                                                     | 0.02                   | 59.0     | 1.2    | 19.2     | 0.4    | 20.6    | 0.4    | 40.8           | 0.8    | 240.8    | 4.8    |
| PM 0110    | Poultry meat: 10% as fat                                   | 0                      | 3.1      | 0.0    | 1.3      | 0.0    | 0.6     | 0.0    | 2.5            | 0.0    | 5.3      | 0.0    |
| PM 0110    | Poultry meat: 90% as muscle                                | 0                      | 27.9     | 0.0    | 11.9     | 0.0    | 5.0     | 0.0    | 22.8           | 0.0    | 47.7     | 0.0    |
| PO 0111    | Poultry, edible offal of                                   | 0                      | 0.1      | 0.0    | 0.1      | 0.0    | 0.1     | 0.0    | 0.4            | 0.0    | 0.4      | 0.0    |
| GC 0649    | Rice                                                       | 0.16                   | 48.8     | 7.8    | 279.3    | 44.7   | 103.4   | 16.5   | 86.5           | 13.8   | 11.8     | 1.9    |
| FS 0012    | Stone fruit                                                | 0.38                   | 7.3      | 2.8    | 1.0      | 0.4    | 0.0     | 0.0    | 0.8            | 0.3    | 23.3     | 8.9    |
| FB 0275    | Strawberry                                                 | 0.1                    | 0.0      | 0.0    | 0.0      | 0.0    | 0.0     | 0.0    | 0.0            | 0.0    | 5.3      | 0.5    |
| VR 0596    | Sugar-beet                                                 | 0.02                   | 0.5      | 0.0    | 0.0      | 0.0    | 0.0     | 0.0    | 0.3            | 0.0    | 2.0      | 0.0    |
| VO 0448    | Tomato (fresh)                                             | 0.08                   | 44.1     | 3.5    | 5.7      | 0.5    | 14.6    | 1.2    | 25.5           | 2.0    | 34.9     | 2.8    |
|            | Tomato paste                                               | 0.13                   | 5.8      | 0.8    | 0.2      | 0.0    | 0.3     | 0.0    | 0.0            | 0.0    | 4.0      | 0.5    |
| TN 0085    | Tree nuts                                                  | 0                      | 1.1      | 0.0    | 13.5     | 0.0    | 4.5     | 0.0    | 17.8           | 0.0    | 4.6      | 0.0    |

### Annex 3

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| Codex code | Commodity                      | STMR or STMR-P (mg/kg) | Mid-East |        | Far-East |        | African |        | Latin American |        | European |        |
|------------|--------------------------------|------------------------|----------|--------|----------|--------|---------|--------|----------------|--------|----------|--------|
|            |                                |                        | Diet     | Intake | Diet     | Intake | Diet    | Intake | Diet           | Intake | Diet     | Intake |
| GC 0654    | Wheat                          | 0.02                   | 327.3    | 6.5    | 114.8    | 2.3    | 28.3    | 0.6    | 116.8          | 2.3    | 178.0    | 3.6    |
| CF 1210    | Wheat germ                     | 0.013                  | 0.1      | 0.0    | 0.1      | 0.0    | 0.0     | 0.0    | 0.1            | 0.0    | 0.1      | 0.0    |
|            | Total intake (µg/person)       |                        |          | 41.8   |          | 54.7   |         | 23.4   |                | 33.7   |          | 48.0   |
|            | Body weight per region (kg bw) |                        |          | 60     |          | 55     |         | 60     |                | 60     |          | 60     |
|            | ADI (µg/person)                |                        |          | 2400   |          | 2200   |         | 2400   |                | 2400   |          | 2400   |
|            | % ADI                          |                        |          | 1.7%   |          | 2.5%   |         | 1.0%   |                | 1.4%   |          | 2.0%   |
|            | Rounded % ADI                  |                        |          | 2%     |          | 2%     |         | 1%     |                | 1%     |          | 2%     |

# ANNEX 4

## INTERNATIONAL ESTIMATES OF SHORT-TERM DIETARY INTAKES OF PESTICIDE RESIDUES

### CARBOFURAN (96)

International estimate of short-term intake for

ARfD = 0.009 mg/kg bw (9 µg/kg bw)

Maximum

% ARfD: 50%

### General population

| Codex code | Commodity                                              | STMR or STMR-P (mg/kg) | HR or HR-P (mg/kg) | Large portion diet |                  |                          | Unit weight     |         |                                 | Variability factor | Case | IESTI (µg/kg bw/day) | % ARfD rounded |
|------------|--------------------------------------------------------|------------------------|--------------------|--------------------|------------------|--------------------------|-----------------|---------|---------------------------------|--------------------|------|----------------------|----------------|
|            |                                                        |                        |                    | Country            | Body weight (kg) | Large portion (g/person) | Unit weight (g) | Country | Unit weight, edible portion (g) |                    |      |                      |                |
| FC 0001    | Citrus fruits                                          | –                      | 0.05               |                    |                  |                          |                 |         |                                 |                    |      |                      | –              |
| FI 0327    | Banana                                                 | –                      | 0.1                | SAF                | 55.7             | 613                      | 708             | USA     | 481                             | 3                  | 2a   | 2.83                 | 30%            |
| VC 4199    | Cantaloupe                                             | –                      | 0.13               | USA                | 65.0             | 606                      | 552             | USA     | 276                             | 3                  | 2a   | 2.32                 | 30%            |
| MF 0812    | Cattle fat                                             | –                      | 0.05               | USA                | 65.0             | 60                       | –               | –       | ND                              |                    | 1    | 0.05                 | 1%             |
| SB 0716    | Coffee beans                                           | 0.1                    | –                  | NLD                | 63.0             | 66                       | –               | –       | ND                              |                    | 3    | 0.10                 | 1%             |
| VC 0424    | Cucumber                                               | –                      | 0.29               | NLD                | 63.0             | 313                      | 301             | USA     | 286                             | 3                  | 2a   | 4.07                 | 50%            |
| MO 0096    | Edible offal of cattle goats, horses, pigs and sheep   | –                      | 0.05               | FRA                | 62.3             | 277                      | –               | –       | ND                              |                    | 1    | 0.22                 | 2%             |
| MF 0814    | Goat fat                                               | –                      | 0.05               | USA                | 65.0             | 18                       | –               | –       | ND                              |                    | 1    | 0.01                 | 0%             |
| FC 0203    | Grapefruit                                             | –                      | 0.05               | JPN                | 52.6             | 947                      | 340             | SWE     | 167                             | 3                  | 2a   | 1.22                 | 10%            |
| FC 0204    | Lemon                                                  | –                      | 0.05               | FRA                | 62.3             | 115                      | 173             | SWE     | 92                              | 3                  | 2a   | 0.24                 | 3%             |
| FC 0206    | Mandarin                                               | –                      | 0.05               | JPN                | 52.6             | 409                      | 168             | USA     | 124                             | 3                  | 2a   | 0.62                 | 7%             |
| MM 0096    | Meat of cattle goats, horses, pigs and sheep           | –                      | 0.05               | AUS                | 67.0             | 520                      | –               | –       | ND                              |                    | 1    | 0.39                 | 4%             |
| ML 0106    | Milks                                                  | 0.05                   | –                  | USA                | 65.0             | 2466                     | –               | –       | ND                              |                    | 3    | 1.90                 | 20%            |
| FC 0004    | Orange, sweet, sour (including orange-like hybrids)    | –                      | 0.05               | USA                | 65.0             | 564                      | 251             | SWE     | 178                             | 3                  | 2a   | 0.71                 | 8%             |
| MF 0818    | Pig fat                                                | –                      | 0.05               | AUS                | 67.0             | 144                      | –               | –       | ND                              |                    | 1    | 0.11                 | 1%             |
| VR 0589    | Potato                                                 | –                      | 0.05               | NLD                | 63.0             | 687                      | 216             | UNK     | 216                             | 3                  | 2a   | 0.89                 | 10%            |
| SO 0699    | Safflower seed                                         | 0.1                    | –                  | –                  | –                | ND                       | –               | –       | ND                              |                    | 3    | ND                   | –              |
| FC 0005    | Shaddocks or pomelos (including Shaddock-like hybrids) | –                      | 0.05               | USA                | 65.0             | 448                      | 210             | FRA     | 126                             | 3                  | 2a   | 0.54                 | 6%             |
| VC 0431    | Squash, summer                                         | –                      | 0.26               | FRA                | 62.3             | 343                      | 300             | FRA     | 270                             | 3                  | 2a   | 3.68                 | 40%            |
| GS 0659    | Sugar-cane                                             | 0.1                    | –                  | SAF                | 55.7             | 89                       | –               | –       | ND                              |                    |      |                      | –              |
| VO 0447    | Sweet corn (corn-on-the-cob)                           | –                      | 0.08               | USA                | 65.0             | 367                      | 215             | UNK     | 125                             | 3                  | 2a   | 0.76                 | 8%             |

## Annex 4

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**CARBOFURAN (96)**

International estimate of short-term intake for  
**Children up to 6 years**

Acute RfD= 0.009 mg/kg bw; 9 µg/kg bw  
 Maximum % ARfD: 100%

| Codex code | Commodity                                              | STM or STM-P (mg/kg) | HR or HR-P (mg/kg) | Large portion diet |                  |                          | Unit weight     |         | Variability factor | Case | IESTI (µg/kg bw/day) | % ARfD rounded |                                 |
|------------|--------------------------------------------------------|----------------------|--------------------|--------------------|------------------|--------------------------|-----------------|---------|--------------------|------|----------------------|----------------|---------------------------------|
|            |                                                        |                      |                    | Country            | Body weight (kg) | Large portion (g/person) | Unit weight (g) | Country |                    |      |                      |                | Unit weight, edible portion (g) |
| FC 0001    | Citrus fruit                                           | –                    | 0.05               |                    |                  |                          |                 |         |                    |      |                      |                |                                 |
| FI 0327    | Banana                                                 | –                    | 0.1                | JPN                | 15.9             | 312                      | 708             | USA     | 481                | 3    | 2b                   | 5.88           | 70%                             |
| VC 4199    | Cantaloupe                                             | –                    | 0.13               | USA                | 15.0             | 270                      | 552             | USA     | 276                | 3    | 2b                   | 7.01           | 80%                             |
| MF 0812    | Cattle fat                                             | –                    | 0.05               | USA                | 15.0             | 27                       | –               | –       | ND                 |      | 1                    | 0.09           | 1%                              |
| SB 0716    | Coffee bean                                            | 0.1                  | –                  | NLD                | 17.0             | 19                       | –               | –       | ND                 |      | 3                    | 0.11           | 1%                              |
| VC 0424    | Cucumber                                               | –                    | 0.29               | NLD                | 17.0             | 162                      | 301             | USA     | 286                | 3    | 2b                   | 8.29           | 90%                             |
| MO 0096    | Edible offal of cattle goats, horses, pigs and sheep   | –                    | 0.05               | FRA                | 17.8             | 203                      | –               | –       | ND                 |      | 1                    | 0.57           | 6%                              |
| MF 0814    | Goat fat                                               | –                    | 0.05               | USA                | 15.0             | 3                        | –               | –       | ND                 |      | 1                    | 0.01           | 0%                              |
| FC 0203    | Grapefruit                                             | –                    | 0.05               | FRA                | 17.8             | 381                      | 340             | SWE     | 167                | 3    | 2a                   | 2.01           | 20%                             |
| FC 0204    | Lemon                                                  | –                    | 0.05               | JPN                | 15.9             | 88                       | 173             | SWE     | 92                 | 3    | 2b                   | 0.83           | 9%                              |
| FC 0206    | Mandarin                                               | –                    | 0.05               | JPN                | 15.9             | 353                      | 168             | USA     | 124                | 3    | 2a                   | 1.89           | 20%                             |
| MM 0096    | Meat of cattle goats, horses, pigs and sheep           | –                    | 0.05               | AUS                | 19.0             | 261                      | –               | –       | ND                 |      | 1                    | 0.69           | 8%                              |
| ML 0106    | Milks                                                  | 0.05                 | –                  | USA                | 15.0             | 1286                     | –               | –       | ND                 |      | 3                    | 4.29           | 50%                             |
| FC 0004    | Orange, sweet, sour (including orange-like hybrids)    | –                    | 0.05               | UNK                | 14.5             | 495                      | 251             | SWE     | 178                | 3    | 2a                   | 2.94           | 30%                             |
| MF 0818    | Pig fat                                                | –                    | 0.05               | FRA                | 17.8             | 85                       | –               | –       | ND                 |      | 1                    | 0.24           | 3%                              |
| VR 0589    | Potato                                                 | –                    | 0.05               | SAF                | 14.2             | 300                      | 216             | UNK     | 216                | 3    | 2a                   | 2.58           | 30%                             |
| SO 0699    | Safflower seed                                         | 0.1                  | –                  | –                  | –                | ND                       | –               | –       | ND                 |      | 3                    | ND             | –                               |
| FC 0005    | Shaddocks or pomelos (including Shaddock-like hybrids) | –                    | 0.05               | FRA                | 17.8             | 381                      | 210             | FRA     | 126                | 3    | 2a                   | 1.78           | 20%                             |
| VC 0431    | Squash, summer                                         | –                    | 0.26               | AUS                | 19.0             | 219                      | 300             | FRA     | 270                | 3    | 2b                   | 8.99           | 100%                            |
| GS 0659    | Sugar-cane                                             | 0.1                  | –                  | SAF                | 14.2             | 60                       | –               | –       | ND                 | ND   | ND                   | ND             | –                               |
| VO 0447    | Sweet corn (corn-on-the-cob)                           | –                    | 0.08               | UNK                | 14.5             | 161                      | 215             | UNK     | 125                | 3    | 2a                   | 2.26           | 30%                             |

## Annex 4

### CHLORPYRIFOS (17)

International estimate of short-term intake for  
**General population**

Acute RfD= 0.1 mg/kg bw; 100 µg/kg bw  
Maximum % ARfD: 10%

| Codex code | Commodity                | STMR or STMR-P (mg/kg) | HR or HR-P (mg/kg) | Large portion diet |                  |                          | Unit weight     |         | Variability factor | Case | IESTI (µg/kg bw/day) | % ARfD rounded |                                 |
|------------|--------------------------|------------------------|--------------------|--------------------|------------------|--------------------------|-----------------|---------|--------------------|------|----------------------|----------------|---------------------------------|
|            |                          |                        |                    | Country            | Body weight (kg) | Large portion (g/person) | Unit weight (g) | Country |                    |      |                      |                | Unit weight, edible portion (g) |
| VR 0589    | Potato                   | –                      | 0.86               | NLD                | 63.0             | 687                      | 200             | FRA     | 160                | 3    | 2a                   | 13.74          | 10%                             |
| OR 0691    | Cotton-seed oil, edible  | 0.01                   | –                  | USA                | 65.0             | 9                        | –               | –       | ND                 | ND   | 3                    | 0.00           | 0%                              |
| CM 1206    | Rice bran, unprocessed   | 0.22                   | –                  | AUS                | 67.0             | 50                       | –               | –       | ND                 | ND   | 3                    | 0.16           | 0%                              |
| CM 0649    | Rice, husked             | 0.016                  | –                  | JPN                | 52.6             | 319                      | –               | –       | ND                 | ND   | 3                    | 0.10           | 0%                              |
| CM 1205    | Rice, polished           | 0.008                  | –                  | JPN                | 52.6             | 402                      | –               | –       | ND                 | ND   | 3                    | 0.06           | 0%                              |
| OR 0541    | Soya bean oil, refined   | 0.004                  | –                  | USA                | 65.0             | 98                       | –               | –       | ND                 | ND   | 3                    | 0.01           | 0%                              |
| DT 0171    | Teas (tea and herb teas) | 0.34                   | –                  | –                  | –                | ND                       | –               | –       | ND                 | ND   | 3                    | ND             | –                               |

### CHLORPYRIFOS (17)

International estimate of short-term intake for  
**Children up to 6 years**

Acute RfD= 0.1 mg/kg bw; 100 µg/kg bw  
Maximum % ARfD: 40%

| Codex code | Commodity                | STMR or STMR-P (mg/kg) | HR or HR-P (mg/kg) | Large portion diet |                  |                          |                 | Unit weight |                                 | Variability factor | Case | IESTI (µg/kg bw/day) | % ARfD rounded |
|------------|--------------------------|------------------------|--------------------|--------------------|------------------|--------------------------|-----------------|-------------|---------------------------------|--------------------|------|----------------------|----------------|
|            |                          |                        |                    | Country            | Body weight (kg) | Large portion (g/person) | Unit weight (g) | Country     | Unit weight, edible portion (g) |                    |      |                      |                |
| VR 0589    | Potato                   | –                      | 0.86               | SAF                | 14.2             | 300                      | 200             | FRA         | 160                             | 3                  | 2a   | 37.53                | 40%            |
| OR 0691    | Cotton-seed oil, edible  | 0.01                   | –                  | USA                | 15.0             | 6                        | –               | –           | ND                              | ND                 | 3    | 0.00                 | 0%             |
| CM 1206    | Rice bran, unprocessed   | 0.22                   | –                  | USA                | 15.0             | 3                        | –               | –           | ND                              | ND                 | 3    | 0.05                 | 0%             |
| CM 0649    | Rice, husked             | 0.016                  | –                  | FRA                | 17.8             | 223                      | –               | –           | ND                              | ND                 | 3    | 0.20                 | 0%             |
| CM 1205    | Rice, polished           | 0.008                  | –                  | JPN                | 15.9             | 199                      | –               | –           | ND                              | ND                 | 3    | 0.10                 | 0%             |
| OR 0541    | Soya bean oil, refined   | 0.004                  | –                  | USA                | 15.0             | 35                       | –               | –           | ND                              | ND                 | 3    | 0.01                 | 0%             |
| DT 0171    | Teas (tea and herb teas) | 0.34                   | –                  | –                  | –                | ND                       | –               | –           | ND                              | ND                 | 3    | ND                   | –              |

**DIMETHIPIN (151)**

International estimate of short-term intake for  
**General population**

Acute RfD: 0.2 mg/kg bw; 200 µg/kg bw  
Maximum ArfD: % : 0%

| Codex Code | Commodity                                                  | STMR or STMR-P (mg/kg) | HR or HR-P (mg/kg) | Large portion diet |                  |                          | Unit weight     |         | Variability factor | Case | IESTI (µg/kg bw/day) | % ARfD rounded |                                 |
|------------|------------------------------------------------------------|------------------------|--------------------|--------------------|------------------|--------------------------|-----------------|---------|--------------------|------|----------------------|----------------|---------------------------------|
|            |                                                            |                        |                    | Country            | Body weight (kg) | Large portion (g/person) | Unit weight (g) | Country |                    |      |                      |                | Unit weight, edible portion (g) |
| VR 0589    | Potato                                                     | –                      | 0.02               | NLD                | 63.0             | 687                      | 216             | UNK     | 216                | 3    | 2a                   | 0.36           | 0%                              |
| PE 0840    | Chicken egg                                                | –                      | 0                  | FRA                | 62.3             | 219                      | –               | –       | ND                 | ND   | 1                    | 0.00           | 0%                              |
| OR 0691    | Cotton-seed oil, edible                                    | 0.02                   | –                  | USA                | 65.0             | 9                        | –               | –       | ND                 | ND   | 3                    | 0.00           | 0%                              |
| MO 0105    | Edible offal (mammalian)                                   | –                      | 0                  | FRA                | 62.3             | 277                      | –               | –       | ND                 | ND   | 1                    | 0.00           | 0%                              |
| MM 0095    | Meat from mammals other than marine mammals: 20% as fat    | –                      | 0                  | AUS                | 67.0             | 104                      | –               | –       | ND                 | ND   | 1                    | 0.00           | 0%                              |
| MM 0095    | Meat from mammals other than marine mammals: 80% as muscle | –                      | 0                  | AUS                | 67.0             | 417                      | –               | –       | ND                 | ND   | 1                    | 0.00           | 0%                              |
| ML 0106    | Milks                                                      | 0                      | –                  | USA                | 65.0             | 2466                     | –               | –       | ND                 | ND   | 3                    | 0.00           | 0%                              |
| PM 0110    | Poultry meat: 10% as fat                                   | –                      | 0                  | AUS                | 67.0             | 43                       | –               | –       | ND                 | ND   | 1                    | 0.00           | 0%                              |
| PM 0110    | Poultry meat: 90% as muscle                                | –                      | 0                  | AUS                | 67.0             | 388                      | –               | –       | ND                 | ND   | 1                    | 0.00           | 0%                              |
| PO 0111    | Poultry, edible offal of                                   | –                      | 0                  | USA                | 65.0             | 248                      | –               | –       | ND                 | ND   | 1                    | 0.00           | 0%                              |
| OR 0495    | Rape-seed oil, edible                                      | 0.1                    | –                  | AUS                | 67.0             | 65                       | –               | –       | ND                 | ND   | 3                    | 0.10           | 0%                              |
| SO 0702    | Sunflower seed                                             | 0.01                   | –                  | USA                | 65.0             | 193                      | –               | –       | ND                 | ND   | 3                    | 0.03           | 0%                              |

**DIMETHIPIN (151)**

International estimate of short-term intake for  
**Children up to 6 years**

Acute RfD: 0.2 mg/kg bw; 200 µg/kg bw  
Maximum % ARfD: 1%

| Codex Code | Commodity                                               | STMR or STMR-P (mg/kg) | HR or HR-P (mg/kg) | Large portion diet |                  |                          | Unit weight     |         | Variability factor | Case | IESTI (µg/kg bw/day) | % ARfD rounded |                                 |
|------------|---------------------------------------------------------|------------------------|--------------------|--------------------|------------------|--------------------------|-----------------|---------|--------------------|------|----------------------|----------------|---------------------------------|
|            |                                                         |                        |                    | Country            | Body weight (kg) | Large portion (g/person) | Unit weight (g) | Country |                    |      |                      |                | Unit weight, edible portion (g) |
| VR 0589    | Potato                                                  | –                      | 0.02               | SAF                | 14.2             | 300                      | 216             | UNK     | 216                | 3    | 2a                   | 1.03           | 1%                              |
| PE 0840    | Chicken eggs                                            | –                      | 0                  | FRA                | 17.8             | 134                      | –               | –       | ND                 | ND   | 1                    | 0.00           | 0%                              |
| OR 0691    | Cotton-seed oil, edible                                 | 0.02                   | –                  | USA                | 15.0             | 6                        | –               | –       | ND                 | ND   | 3                    | 0.01           | 0%                              |
| MO 0105    | Edible offal (mammalian)                                | –                      | 0                  | FRA                | 17.8             | 203                      | –               | –       | ND                 | ND   | 1                    | 0.00           | 0%                              |
| MM 0095    | Meat from mammals other than marine mammals: 20% as fat | –                      | 0                  | AUS                | 19.0             | 52                       | –               | –       | ND                 | ND   | 1                    | 0.00           | 0%                              |



## Annex 4

|         |                                                            |      |   |     |      |      |   |   |    |    |   |      |    |
|---------|------------------------------------------------------------|------|---|-----|------|------|---|---|----|----|---|------|----|
| MM 0095 | Meat from mammals other than marine mammals: 80% as muscle | –    | 0 | AUS | 19.0 | 208  | – | – | ND | ND | 1 | 0.00 | 0% |
| ML 0106 | Milks                                                      | 0    | – | USA | 15.0 | 1286 | – | – | ND | ND | 3 | 0.00 | 0% |
| PM 0110 | Poultry meat: 10% as fat                                   | –    | 0 | AUS | 19.0 | 22   | – | – | ND | ND | 1 | 0.00 | 0% |
| PM 0110 | Poultry meat: 90% as muscle                                | –    | 0 | AUS | 19.0 | 201  | – | – | ND | ND | 1 | 0.00 | 0% |
| PO 0111 | Poultry, edible offal of                                   | –    | 0 | USA | 15.0 | 37   | – | – | ND | ND | 1 | 0.00 | 0% |
| OR 0495 | Rape-seed oil, edible                                      | 0.1  | – | AUS | 19.0 | 18   | – | – | ND | ND | 3 | 0.10 | 0% |
| SO 0702 | Sunflower seed                                             | 0.01 | – | USA | 15.0 | 24   | – | – | ND | ND | 3 | 0.02 | 0% |

### ETHOPROPHOS (149)

International estimate of short-term intake for  
General population

Acute RfD= 0.05 mg/kg bw; 50 µg/kg bw  
Maximum % ARfD: 1%

| Codex code | Commodity                                                  | STMR or STMR-P (mg/kg) | HR or HR-P (mg/kg) | Large portion diet |                  |                          |                 | Unit weight |                                 | Variability factor | Case | IESTI (µg/kg bw/day) | % ARfD rounded |
|------------|------------------------------------------------------------|------------------------|--------------------|--------------------|------------------|--------------------------|-----------------|-------------|---------------------------------|--------------------|------|----------------------|----------------|
|            |                                                            |                        |                    | Country            | Body weight (kg) | Large portion (g/person) | Unit weight (g) | Country     | Unit weight, edible portion (g) |                    |      |                      |                |
| FI 0327    | Banana                                                     | –                      | 0.02               | SAF                | 55.7             | 613                      | 900             | FRA         | 612                             | 3                  | 2a   | 0.66                 | 1%             |
| VC 0424    | Cucumber                                                   | –                      | 0.01               | NLD                | 63.0             | 313                      | 400             | FRA         | 360                             | 3                  | 2b   | 0.15                 | 0%             |
| MO 0105    | Edible offal (mammalian)                                   | –                      | 0                  | FRA                | 62.3             | 277                      | –               | –           | ND                              | ND                 | 1    | 0.00                 | 0%             |
| MM 0095    | Meat from mammals other than marine mammals: 20% as fat    | –                      | 0                  | AUS                | 67.0             | 104                      | –               | –           | ND                              | ND                 | 1    | 0.00                 | 0%             |
| MM 0095    | Meat from mammals other than marine mammals: 80% as muscle | –                      | 0                  | AUS                | 67.0             | 417                      | –               | –           | ND                              | ND                 | 1    | 0.00                 | 0%             |
| VC 0046    | Melon, except watermelon                                   | –                      | 0.012              | USA                | 65.0             | 655                      | 700             | JPN         | 700                             | 3                  | 2b   | 0.36                 | 1%             |
| ML 0106    | Milks                                                      | 0                      | –                  | USA                | 65.0             | 2466                     | –               | –           | ND                              | ND                 | 3    | 0.00                 | 0%             |
| VO 0445    | Peppers, sweet (including pim(i)ento)                      | –                      | 0.044              | FRA                | 62.3             | 207                      | 172             | UNK         | 160                             | 3                  | 2a   | 0.37                 | 1%             |
| VR 0589    | Potato                                                     | –                      | 0.03               | NLD                | 63.0             | 687                      | 216             | UNK         | 216                             | 3                  | 2a   | 0.53                 | 1%             |
| GS 0659    | Sugar-cane                                                 | –                      | 0.02               | SAF                | 55.7             | 89                       | –               | –           | ND                              | ND                 | ND   | ND                   | –              |
| VR 0508    | Sweet potato                                               | –                      | 0.03               | USA                | 65.0             | 536                      | 130             | USA         | 105                             | 3                  | 2a   | 0.34                 | 1%             |
| VO 0448    | Tomato (fresh, juice, paste, peeled)                       | –                      | 0.01               | USA                | 65.0             | 391                      | 150             | JPN         | 150                             | 3                  | 2a   | 0.11                 | 0%             |

**ETHOPROPHOS (149)**

International estimate of short-term intake for  
**Children up to 6 years**

Acute RfD= 0.050 mg/kg bw; 50 µg/kg bw  
Maximum % ARfD: 3%

| Codex code | Commodity                                                  | STMR or STMR-P (mg/kg) | HR or HR-P (mg/kg) | Large portion diet |                  |                          | Unit weight     |         | Variability factor | Case | IESTI (µg/kg bw/day) | % ARfD rounded |                                 |
|------------|------------------------------------------------------------|------------------------|--------------------|--------------------|------------------|--------------------------|-----------------|---------|--------------------|------|----------------------|----------------|---------------------------------|
|            |                                                            |                        |                    | Country            | Body weight (kg) | Large portion (g/person) | Unit weight (g) | Country |                    |      |                      |                | Unit weight, edible portion (g) |
| FI 0327    | Banana                                                     | –                      | 0.02               | JPN                | 15.9             | 312                      | 900             | FRA     | 612                | 3    | 2b                   | 1.18           | 2%                              |
| VC 0424    | Cucumber                                                   | –                      | 0.01               | NLD                | 17.0             | 162                      | 400             | FRA     | 360                | 3    | 2b                   | 0.29           | 1%                              |
| MO 0105    | Edible offal (mammalian)                                   | –                      | 0                  | FRA                | 17.8             | 203                      | –               | –       | ND                 | ND   | 1                    | 0.00           | 0%                              |
| MM 0095    | Meat from mammals other than marine mammals: 20% as fat    | –                      | 0                  | AUS                | 19.0             | 52                       | –               | –       | ND                 | ND   | 1                    | 0.00           | 0%                              |
| MM 0095    | Meat from mammals other than marine mammals: 80% as muscle | –                      | 0                  | AUS                | 19.0             | 208                      | –               | –       | ND                 | ND   | 1                    | 0.00           | 0%                              |
| VC 0046    | Melon, except watermelon                                   | –                      | 0.012              | AUS                | 19.0             | 413                      | 700             | FRA     | 420                | 3    | 2b                   | 0.78           | 2%                              |
| ML 0106    | Milks                                                      | 0                      | –                  | USA                | 15.0             | 1286                     | –               | –       | ND                 | ND   | 3                    | 0.00           | 0%                              |
| VO 0445    | Peppers, sweet (including pim(i)ento)                      | –                      | 0.044              | AUS                | 19.0             | 60                       | 172             | UNK     | 160                | 3    | 2b                   | 0.42           | 1%                              |
| VR 0589    | Potato                                                     | –                      | 0.03               | SAF                | 14.2             | 300                      | 216             | UNK     | 216                | 3    | 2a                   | 1.55           | 3%                              |
| GS 0659    | Sugar-cane                                                 | –                      | 0.02               | SAF                | 14.2             | 60                       | –               | –       | ND                 | ND   | ND                   | ND             | –                               |
| VR 0508    | Sweet potato                                               | –                      | 0.03               | USA                | 15.0             | 166                      | 130             | USA     | 105                | 3    | 2a                   | 0.75           | 2%                              |
| VO 0448    | Tomato (fresh, juice, paste, peeled)                       | –                      | 0.01               | USA                | 15.0             | 159                      | 150             | JPN     | 150                | 3    | 2a                   | 0.31           | 1%                              |

## Annex 4

### FENITROTHION (37)

International estimate of short-term intake for  
**General population**

Acute RfD= 0.04 mg/kg bw (40 µg/kg bw)  
Maximum % ARfD: 100%

| Codex code | Commodity                                                  | STMR or STMR-P (mg/kg) | HR or HR-P (mg/kg) | Large portion diet |                  |                          | Unit weight     |         | Variability factor | Case | IESTI (µg/kg bw/day) | % ARfD rounded |                                 |
|------------|------------------------------------------------------------|------------------------|--------------------|--------------------|------------------|--------------------------|-----------------|---------|--------------------|------|----------------------|----------------|---------------------------------|
|            |                                                            |                        |                    | Country            | Body weight (kg) | Large portion (g/person) | Unit weight (g) | Country |                    |      |                      |                | Unit weight, edible portion (g) |
| FP 0226    | Apple                                                      | –                      | 0.41               | USA                | 65.0             | 1348                     | 200             | JPN     | 200                | 3    | 2a                   | 11.03          | 30%                             |
| GC 0640    | Barley (beer only)                                         | –                      | 1.52               | AUS                | 67.0             | 528                      | –               | –       | ND                 | ND   | 1                    | 11.98          | 30%                             |
| GC 0640    | Barley (fresh)                                             | –                      | 7.6                | –                  | –                | ND                       | –               | –       | ND                 | ND   | 1                    | ND             | –                               |
| GC 0641    | Buckwheat                                                  | –                      | 7.6                | NLD                | 63.0             | 117                      | –               | –       | ND                 | ND   | 1                    | 14.14          | 40%                             |
| PE 0840    | Chicken eggs                                               | –                      | 0                  | FRA                | 62.3             | 219                      | –               | –       | ND                 | ND   | 1                    | 0.00           | 0%                              |
| MO 0105    | Edible offal (mammalian)                                   | –                      | 0                  | FRA                | 62.3             | 277                      | –               | –       | ND                 | ND   | 1                    | 0.00           | 0%                              |
| GC 0645    | Maize (fresh, flour, oil)                                  | –                      | 7.6                | FRA                | 62.3             | 260                      | –               | –       | ND                 | ND   | 1                    | 31.69          | 80%                             |
| MM 0095    | Meat from mammals other than marine mammals: 20% as fat    | –                      | 0                  | AUS                | 67.0             | 104                      | –               | –       | ND                 | ND   | 1                    | 0.00           | 0%                              |
| MM 0095    | Meat from mammals other than marine mammals: 80% as muscle | –                      | 0                  | AUS                | 67.0             | 417                      | –               | –       | ND                 | ND   | 1                    | 0.00           | 0%                              |
| ML 0106    | Milks                                                      | 0                      | –                  | USA                | 65.0             | 2466                     | –               | –       | ND                 | ND   | 3                    | 0.00           | 0%                              |
| GC 0646    | Millet                                                     | –                      | 7.6                | AUS                | 67.0             | 101                      | –               | –       | ND                 | ND   | 1                    | 11.40          | 30%                             |
| GC 0647    | Oats                                                       | –                      | 7.6                | FRA                | 62.3             | 305                      | –               | –       | ND                 | ND   | 1                    | 37.24          | 90%                             |
| PM 0110    | Poultry meat: 10% as fat                                   | –                      | 0                  | AUS                | 67.0             | 43                       | –               | –       | ND                 | ND   | 1                    | 0.00           | 0%                              |
| PM 0110    | Poultry meat: 90% as muscle                                | –                      | 0                  | AUS                | 67.0             | 388                      | –               | –       | ND                 | ND   | 1                    | 0.00           | 0%                              |
| CM 1206    | Rice bran, unprocessed                                     | –                      | 54.72              | AUS                | 67.0             | 50                       | –               | –       | ND                 | ND   | 1                    | 40.82          | 100%                            |
| CM 0649    | Rice, husked and cooked                                    | –                      | 0.836              | JPN                | 52.6             | 319                      | –               | –       | ND                 | ND   | 1                    | 5.07           | 10%                             |
| CM 1205    | Rice, polished and cooked                                  | –                      | 0.304              | JPN                | 52.6             | 402                      | –               | –       | ND                 | ND   | 1                    | 2.32           | 6%                              |
| CF 1250    | Rye flour                                                  | –                      | 1.786              | FRA                | 62.3             | 115                      | –               | –       | ND                 | ND   | 1                    | 3.29           | 8%                              |
| GC 0651    | Sorghum                                                    | –                      | 7.6                | USA                | 65.0             | 18                       | –               | –       | ND                 | ND   | 1                    | 2.05           | 5%                              |
| GC 0653    | Triticale                                                  | –                      | 7.6                | –                  | –                | ND                       | –               | –       | ND                 | ND   | 1                    | ND             | –                               |
| CM 0654    | Wheat bran, unprocessed                                    | –                      | 30.02              | USA                | 65.0             | 80                       | –               | –       | ND                 | ND   | 1                    | 36.92          | 90%                             |
|            | Wheat bulgur wholemeal                                     | –                      | 1.786              | –                  | –                | ND                       | –               | –       | ND                 | ND   | 1                    | ND             | –                               |
| CF 1211    | Wheat flour                                                | –                      | 1.786              | USA                | 65.0             | 365                      | –               | –       | ND                 | ND   | 1                    | 10.04          | 30%                             |
|            | Wheat macaroni                                             | –                      | 1.786              | –                  | –                | ND                       | –               | –       | ND                 | ND   | 1                    | ND             | –                               |
|            | Wheat pastry                                               | –                      | 1.786              | –                  | –                | ND                       | –               | –       | ND                 | ND   | 1                    | ND             | –                               |
| CP 1211    | White bread                                                | –                      | 0.76               | SAF                | 55.7             | 479                      | –               | –       | ND                 | ND   | 1                    | 6.54           | 20%                             |
| CP 1212    | Wholemeal bread                                            | –                      | 2.888              | SAF                | 55.7             | 395                      | –               | –       | ND                 | ND   | 1                    | 20.50          | 50%                             |

**FENITROTHION (37)**

International estimate of short-term intake for

Acute RfD= 0.04 mg/kg bw; 40 µg/kg bw

**Children up to 6 years**

Maximum % ARfD:

160%

| Codex code | Commodity                                                  | STMR or STMR-P (mg/kg) | HR or HR-P (mg/kg) | Large portion diet |                  |                          | Unit weight     |         |                                 | Variability factor | Case | IESTI (µg/kg bw/day) | % ARfD rounded |
|------------|------------------------------------------------------------|------------------------|--------------------|--------------------|------------------|--------------------------|-----------------|---------|---------------------------------|--------------------|------|----------------------|----------------|
|            |                                                            |                        |                    | Country            | Body weight (kg) | Large portion (g/person) | Unit weight (g) | Country | Unit weight, edible portion (g) |                    |      |                      |                |
| FP 0226    | Apple                                                      | –                      | 0.41               | USA                | 15.0             | 679                      | 200             | JPN     | 200                             | 3                  | 2a   | 29.49                | 70%            |
| GC 0640    | Barley (beer only)                                         | –                      | 1.52               | AUS                | 19.0             | 12                       | –               | –       | ND                              | ND                 | 1    | 0.94                 | 2%             |
| GC 0640    | Barley (fresh)                                             | –                      | 7.6                | –                  | –                | ND                       | –               | –       | ND                              | ND                 | 1    | ND                   | –              |
| GC 0641    | Buckwheat                                                  | –                      | 7.6                | NLD                | 17.0             | 59                       | –               | –       | ND                              | ND                 | 1    | 26.30                | 70%            |
| PE 0840    | Chicken eggs                                               | –                      | 0                  | FRA                | 17.8             | 134                      | –               | –       | ND                              | ND                 | 1    | 0.00                 | 0%             |
| MO 0105    | Edible offal (mammalian)                                   | –                      | 0                  | FRA                | 17.8             | 203                      | –               | –       | ND                              | ND                 | 1    | 0.00                 | 0%             |
| GC 0645    | Maize (fresh, flour, oil)                                  | –                      | 7.6                | FRA                | 17.8             | 148                      | –               | –       | ND                              | ND                 | 1    | 63.31                | 160%           |
| MM 0095    | Meat from mammals other than marine mammals: 20% as fat    | –                      | 0                  | AUS                | 19.0             | 52                       | –               | –       | ND                              | ND                 | 1    | 0.00                 | 0%             |
| MM 0095    | Meat from mammals other than marine mammals: 80% as muscle | –                      | 0                  | AUS                | 19.0             | 208                      | –               | –       | ND                              | ND                 | 1    | 0.00                 | 0%             |
| ML 0106    | Milks                                                      | 0                      | –                  | USA                | 15.0             | 1286                     | –               | –       | ND                              | ND                 | 3    | 0.00                 | 0%             |
| GC 0646    | Millet                                                     | –                      | 7.6                | –                  | –                | ND                       | –               | –       | ND                              | ND                 | 1    | ND                   | –              |
| GC 0647    | Oats                                                       | –                      | 7.6                | USA                | 15.0             | 62                       | –               | –       | ND                              | ND                 | 1    | 31.54                | 80%            |
| PM 0110    | Poultry meat: 10% as fat                                   | –                      | 0                  | AUS                | 19.0             | 22                       | –               | –       | ND                              | ND                 | 1    | 0.00                 | 0%             |
| PM 0110    | Poultry meat: 90% as muscle                                | –                      | 0                  | AUS                | 19.0             | 201                      | –               | –       | ND                              | ND                 | 1    | 0.00                 | 0%             |
| CM 1206    | Rice bran, unprocessed                                     | –                      | 54.72              | USA                | 15.0             | 3                        | –               | –       | ND                              | ND                 | 1    | 11.49                | 30%            |
| CM 0649    | Rice, husked                                               | –                      | 0.836              | FRA                | 17.8             | 223                      | –               | –       | ND                              | ND                 | 1    | 10.45                | 30%            |
| CM 1205    | Rice, polished                                             | –                      | 0.304              | JPN                | 15.9             | 199                      | –               | –       | ND                              | ND                 | 1    | 3.80                 | 9%             |
| CF 1250    | Rye flour                                                  | –                      | 1.786              | USA                | 15.0             | 18                       | –               | –       | ND                              | ND                 | 1    | 2.11                 | 5%             |
| GC 0651    | Sorghum                                                    | –                      | 7.6                | –                  | –                | ND                       | –               | –       | ND                              | ND                 | 1    | ND                   | –              |
| GC 0653    | Triticale                                                  | –                      | 7.6                | –                  | –                | ND                       | –               | –       | ND                              | ND                 | 1    | ND                   | –              |
| CM 0654    | Wheat bran, unprocessed                                    | –                      | 30.02              | USA                | 15.0             | 30                       | –               | –       | ND                              | ND                 | 1    | 59.44                | 150%           |
|            | Wheat bulgur wholemeal                                     | –                      | 1.786              | –                  | –                | ND                       | –               | –       | ND                              | ND                 | 1    | ND                   | –              |
| CF 1211    | Wheat flour                                                | –                      | 1.786              | AUS                | 19.0             | 194                      | –               | –       | ND                              | ND                 | 1    | 18.27                | 50%            |
|            | Wheat macaroni                                             | –                      | 1.786              | –                  | –                | ND                       | –               | –       | ND                              | ND                 | 1    | ND                   | –              |
|            | Wheat pastry                                               | –                      | 1.786              | –                  | –                | ND                       | –               | –       | ND                              | ND                 | 1    | ND                   | –              |
| CP 1211    | White bread                                                | –                      | 0.76               | SAF                | 14.2             | 270                      | –               | –       | ND                              | ND                 | 1    | 14.44                | 40%            |
| CP 1212    | Wholemeal bread                                            | –                      | 2.888              | SAF                | 14.2             | 240                      | –               | –       | ND                              | ND                 | 1    | 48.81                | 120%           |

## Annex 4

### FENPROPIMORPH (188)

International estimate of short-term intake for  
**General population**

Acute RfD= 0.2 mg/kg bw; 200 µg/kg bw  
Maximum % ARfD: 7%

| Codex code | Commodity                                                  | STMR or STMR-P (mg/kg) | HR or HR-P (mg/kg) | Large portion diet |                  |                          | Unit weight     |         | Variability factor | Case | IESTI (µg/kg bw/day) | % ARfD rounded |                                 |
|------------|------------------------------------------------------------|------------------------|--------------------|--------------------|------------------|--------------------------|-----------------|---------|--------------------|------|----------------------|----------------|---------------------------------|
|            |                                                            |                        |                    | Country            | Body weight (kg) | Large portion (g/person) | Unit weight (g) | Country |                    |      |                      |                | Unit weight, edible portion (g) |
| FI 0327    | Banana                                                     | –                      | 0.43               | SAF                | 55.7             | 613                      | 900             | FRA     | 612                | 3    | 2a                   | 14.18          | 7%                              |
| GC 0640    | Barley (beer only)                                         | 0.05                   | –                  | AUS                | 67.0             | 528                      | –               | –       | ND                 | ND   | 3                    | 0.39           | 0%                              |
| GC 0640    | Barley (fresh)                                             | 0.05                   | –                  | –                  | –                | ND                       | –               | –       | ND                 | ND   | 3                    | ND             | –                               |
| GC 0640    | Barley (fresh, flour, beer)                                | 0.05                   | –                  | NLD                | 63.0             | 378                      | –               | –       | ND                 | ND   | 3                    | 0.30           | 0%                              |
| PE 0840    | Chicken eggs                                               | –                      | 0                  | FRA                | 62.3             | 219                      | –               | –       | ND                 | ND   | 1                    | 0.00           | 0%                              |
| MO 0098    | Kidney of cattle (g)oats, pigs and sheep                   | –                      | 0.026              | USA                | 65.0             | 788                      | –               | –       | ND                 | ND   | 1                    | 0.32           | 0%                              |
| MO 0099    | Liver of cattle (g)oats, pigs and sheep                    | –                      | 0.22               | USA                | 65.0             | 380                      | –               | –       | ND                 | ND   | 1                    | 1.28           | 1%                              |
| MM 0095    | Meat from mammals other than marine mammals: 20% as fat    | –                      | 0.006              | AUS                | 67.0             | 104                      | –               | –       | ND                 | ND   | 1                    | 0.01           | 0%                              |
| MM 0095    | Meat from mammals other than marine mammals: 80% as muscle | –                      | 0.009              | AUS                | 67.0             | 417                      | –               | –       | ND                 | ND   | 1                    | 0.06           | 0%                              |
| ML 0106    | Milks                                                      | 0.004                  | –                  | USA                | 65.0             | 2466                     | –               | –       | ND                 | ND   | 3                    | 0.15           | 0%                              |
| GC 0647    | Oats                                                       | 0.05                   | –                  | FRA                | 62.3             | 305                      | –               | –       | ND                 | ND   | 3                    | 0.25           | 0%                              |
| PM 0110    | Poultry meat: 10% as fat                                   | –                      | 0                  | AUS                | 67.0             | 43                       | –               | –       | ND                 | ND   | 1                    | 0.00           | 0%                              |
| PM 0110    | Poultry meat: 90% as muscle                                | –                      | 0                  | AUS                | 67.0             | 388                      | –               | –       | ND                 | ND   | 1                    | 0.00           | 0%                              |
| PO 0111    | Poultry, edible offal of                                   | –                      | 0                  | USA                | 65.0             | 248                      | –               | –       | ND                 | ND   | 1                    | 0.00           | 0%                              |
| GC 0650    | Rye                                                        | 0.05                   | –                  | NLD                | 63.0             | 77                       | –               | –       | ND                 | ND   | 3                    | 0.06           | 0%                              |
| VR 0596    | Sugar beet                                                 | 0.05                   | –                  | –                  | –                | ND                       | –               | –       | ND                 | ND   | ND                   | ND             | –                               |
| GC 0654    | Wheat                                                      | 0.05                   | –                  | USA                | 65.0             | 383                      | –               | –       | ND                 | ND   | 3                    | 0.29           | 0%                              |

**FENPROPIMORPH (188)**

International estimate of short-term intake for  
**Children up to 6 years**

Acute RfD= 0.2 mg/kg bw; 200 µg/kg bw  
Maximum % ARfD: 10%

| Codex code | Commodity                                                  | STMR or STMR-P (mg/kg) | HR or HR-P (mg/kg) | Large portion diet |                  |                          | Unit weight     |         |                                 | Variability factor | Case | IESTI (µg/kg bw/day) | % ARfD rounded |
|------------|------------------------------------------------------------|------------------------|--------------------|--------------------|------------------|--------------------------|-----------------|---------|---------------------------------|--------------------|------|----------------------|----------------|
|            |                                                            |                        |                    | Country            | Body weight (kg) | Large portion (g/person) | Unit weight (g) | Country | Unit weight, edible portion (g) |                    |      |                      |                |
| FI 0327    | Banana                                                     | –                      | 0.43               | JPN                | 15.9             | 312                      | 900             | FRA     | 612                             | 3                  | 2b   | 25.30                | 10%            |
| GC 0640    | Barley (beer only)                                         | 0.05                   | –                  | AUS                | 19.0             | 12                       | –               | –       | ND                              | ND                 | 3    | 0.03                 | 0%             |
| GC 0640    | Barley (fresh)                                             | 0.05                   | –                  | –                  | –                | ND                       | –               | –       | ND                              | ND                 | 3    | ND                   | –              |
| GC 0640    | Barley (fresh, flour, beer)                                | 0.05                   | –                  | AUS                | 19.0             | 14                       | –               | –       | ND                              | ND                 | 3    | 0.04                 | 0%             |
| PE 0840    | Chicken eggs                                               | –                      | 0                  | FRA                | 17.8             | 134                      | –               | –       | ND                              | ND                 | 1    | 0.00                 | 0%             |
| MO 0098    | Kidney of cattle (g)oats, pigs and sheep                   | –                      | 0.026              | USA                | 15.0             | 187                      | –               | –       | ND                              | ND                 | 1    | 0.32                 | 0%             |
| MO 0099    | Liver of cattle (g)oats, pigs and sheep                    | –                      | 0.22               | FRA                | 17.8             | 203                      | –               | –       | ND                              | ND                 | 1    | 2.51                 | 1%             |
| MM 0095    | Meat from mammals other than marine mammals: 20% as fat    | –                      | 0.006              | AUS                | 19.0             | 52                       | –               | –       | ND                              | ND                 | 1    | 0.02                 | 0%             |
| MM 0095    | Meat from mammals other than marine mammals: 80% as muscle | –                      | 0.009              | AUS                | 19.0             | 208                      | –               | –       | ND                              | ND                 | 1    | 0.10                 | 0%             |
| ML 0106    | Milks                                                      | 0.004                  | –                  | USA                | 15.0             | 1286                     | –               | –       | ND                              | ND                 | 3    | 0.34                 | 0%             |
| GC 0647    | Oats                                                       | 0.05                   | –                  | USA                | 15.0             | 62                       | –               | –       | ND                              | ND                 | 3    | 0.21                 | 0%             |
| PM 0110    | Poultry meat: 10% as fat                                   | –                      | 0                  | AUS                | 19.0             | 22                       | –               | –       | ND                              | ND                 | 1    | 0.00                 | 0%             |
| PM 0110    | Poultry meat: 90% as muscle                                | –                      | 0                  | AUS                | 19.0             | 201                      | –               | –       | ND                              | ND                 | 1    | 0.00                 | 0%             |
| PO 0111    | Poultry, edible offal of                                   | –                      | 0                  | USA                | 15.0             | 37                       | –               | –       | ND                              | ND                 | 1    | 0.00                 | 0%             |
| GC 0650    | Rye                                                        | 0.05                   | –                  | NLD                | 17.0             | 37                       | –               | –       | ND                              | ND                 | 3    | 0.11                 | 0%             |
| VR 0596    | Sugar beet                                                 | 0.05                   | –                  | –                  | –                | ND                       | –               | –       | ND                              | ND                 | ND   | ND                   | –              |
| GC 0654    | Wheat                                                      | 0.05                   | –                  | USA                | 15.0             | 151                      | –               | –       | ND                              | ND                 | 3    | 0.50                 | 0%             |

## Annex 4

### FENPYROXIMATE (193)

International estimate of short-term intake for  
**General population**

Acute RfD= 0.01 mg/kg bw; 10 µg/kg bw  
Maximum % ARfD 120 %

| Codex code | Commodity                                           | STMR or STMR-P (mg/kg) | HR or HR-P (mg/kg) | Large portion diet |                  |                          | Unit weight     |         | Variability factor | Case | IESTI (µg/kg bw/day) | % ARfD rounded |                                 |
|------------|-----------------------------------------------------|------------------------|--------------------|--------------------|------------------|--------------------------|-----------------|---------|--------------------|------|----------------------|----------------|---------------------------------|
|            |                                                     |                        |                    | Country            | Body weight (kg) | Large portion (g/person) | Unit weight (g) | Country |                    |      |                      |                | Unit weight, edible portion (g) |
| FP 0226    | Apple                                               | –                      | 0.18               | USA                | 65.0             | 1348                     | 200             | JPN     | 200                | 3    | 2a                   | 4.84           | 50%                             |
| JF 0226    | Apple juice                                         | 0.04                   | –                  | –                  | –                | ND                       | –               | –       | ND                 | ND   | ND                   | ND             | –                               |
| MM 0812    | Cattle meat: 20% as fat                             | –                      | 0                  | AUS                | 67.0             | 93                       | –               | –       | ND                 | ND   | 1                    | 0.00           | 0%                              |
| MM 0812    | Cattle meat: 80% as muscle                          | –                      | 0                  | AUS                | 67.0             | 374                      | –               | –       | ND                 | ND   | 1                    | 0.00           | 0%                              |
| MO 0812    | Cattle, edible offal of                             | –                      | 0                  | SAF                | 55.7             | 524                      | –               | –       | ND                 | ND   | 1                    | 0.00           | 0%                              |
| FB 0269    | Grapes (fresh, dried, excluding wine)               | –                      | 0.57               | AUS                | 67.0             | 513                      | 456             | SWE     | 438                | 3    | 2a                   | 11.81          | 120%                            |
| DH 1100    | Hops, dry                                           | 4.4                    | –                  | USA                | 65.0             | 6                        | –               | –       | ND                 | ND   | 3                    | 0.40           | 4%                              |
| ML 0106    | Milks                                               | 0.002                  | –                  | USA                | 65.0             | 2466                     | –               | –       | ND                 | ND   | 3                    | 0.08           | 1%                              |
| FC 0004    | Orange, sweet, sour (including orange-like hybrids) | –                      | 0.09               | USA                | 65.0             | 564                      | 200             | JPN     | 200                | 3    | 2a                   | 1.34           | 10%                             |
|            | Wine only                                           | 0.005                  | –                  | AUS                | 67.0             | 1131                     | –               | –       | ND                 | ND   | 3                    | 0.08           | 1%                              |

### FENPYROXIMATE (193)

International estimate of short-term intake for  
**Children up to 6 years**

Acute RfD= 0.01 mg/kg bw; 10 µg/kg bw  
Maximum %ArfD: 310%

| Codex code | Commodity                                           | STMR or STMR-P (mg/kg) | HR or HR-P (mg/kg) | Large portion diet |                  |                          | Unit weight     |         | Variability factor | Case | IESTI (µg/kg bw/day) | % ARfD rounded |                                 |
|------------|-----------------------------------------------------|------------------------|--------------------|--------------------|------------------|--------------------------|-----------------|---------|--------------------|------|----------------------|----------------|---------------------------------|
|            |                                                     |                        |                    | Country            | Body weight (kg) | Large portion (g/person) | Unit weight (g) | Country |                    |      |                      |                | Unit weight, edible portion (g) |
| FP 0226    | Apple                                               | –                      | 0.18               | USA                | 15.0             | 679                      | 200             | JPN     | 200                | 3    | 2a                   | 12.95          | 130%                            |
| JF 0226    | Apple juice                                         | 0.04                   | –                  | –                  | –                | ND                       | –               | –       | ND                 | ND   | ND                   | ND             | –                               |
| MM 0812    | Cattle meat: 20% as fat                             | –                      | 0                  | AUS                | 19.0             | 48                       | –               | –       | ND                 | ND   | 1                    | 0.00           | 0%                              |
| MM 0812    | Cattle meat: 80% as muscle                          | –                      | 0                  | AUS                | 19.0             | 190                      | –               | –       | ND                 | ND   | 1                    | 0.00           | 0%                              |
| MO 0812    | Cattle, edible offal of                             | –                      | 0                  | FRA                | 17.8             | 203                      | –               | –       | ND                 | ND   | 1                    | 0.00           | 0%                              |
| FB 0269    | Grapes (fresh, dried, excluding wine)               | –                      | 0.57               | AUS                | 19.0             | 342                      | 456             | SWE     | 438                | 3    | 2b                   | 30.78          | 310%                            |
| DH 1100    | Hops, dry                                           | 4.4                    | –                  | JPN                | 15.9             | 0                        | –               | –       | ND                 | ND   | 3                    | 0.13           | 1%                              |
| ML 0106    | Milks                                               | 0.002                  | –                  | USA                | 15.0             | 1286                     | –               | –       | ND                 | ND   | 3                    | 0.17           | 2%                              |
| FC 0004    | Orange, sweet, sour (including orange-like hybrids) | –                      | 0.09               | UNK                | 14.5             | 495                      | 200             | JPN     | 200                | 3    | 2a                   | 5.56           | 60%                             |
|            | Wine only                                           | 0.005                  | –                  | AUS                | 19.0             | 4                        | –               | –       | ND                 | ND   | 3                    | 0.00           | 0%                              |

**MALATHION (49)**

International estimate of short-term intake for  
**General population**

Acute RfD= 2. mg/kg bw; 2000 µg/kg bw  
Maximum % ARfD: 4%

| Codex code | Commodity                                           | STMR or STMR-P (mg/kg) | HR or HR-P (mg/kg) | Large portion diet |                  |                          | Unit weight     |         | Variability factor | Case | IESTI (µg/kg bw/day) | % ARfD rounded |                                 |
|------------|-----------------------------------------------------|------------------------|--------------------|--------------------|------------------|--------------------------|-----------------|---------|--------------------|------|----------------------|----------------|---------------------------------|
|            |                                                     |                        |                    | Country            | Body weight (kg) | Large portion (g/person) | Unit weight (g) | Country |                    |      |                      |                | Unit weight, edible portion (g) |
| FP 0226    | Apple                                               | –                      | 0.37               | USA                | 65.0             | 1348                     | 162             | SWE     | 149                | 3    | 2a                   | 9.37           | 0%                              |
| FC 0203    | Grapefruit                                          | –                      | 0.22               | JPN                | 52.6             | 947                      | 340             | SWE     | 167                | 3    | 2a                   | 5.35           | 0%                              |
| FB 0269    | Grapes (fresh, wine, dried)                         | –                      | 2.6                | AUS                | 67.0             | 1004                     | 456             | SWE     | 438                | 3    | 2a                   | 72.95          | 4%                              |
| FC 0204    | Lemon                                               | –                      | 0.22               | FRA                | 62.3             | 115                      | 173             | SWE     | 92                 | 3    | 2a                   | 1.05           | 0%                              |
| FC 0206    | Mandarin                                            | –                      | 0.22               | JPN                | 52.6             | 409                      | 133             | UNK     | 100                | 3    | 2a                   | 2.54           | 0%                              |
| FC 0004    | Orange, sweet, sour (including orange-like hybrids) | –                      | 0.22               | USA                | 65.0             | 564                      | 251             | SWE     | 178                | 3    | 2a                   | 3.12           | 0%                              |

**MALATHION (49)**

International estimate of short-term intake for  
**Children up to 6 years**

ARfD = 2.0 mg/kg bw (2000 µg/kg bw)  
Maximum % ARfD: 10%

| Codex code | Commodity                                            | STMR or STMR-P (mg/kg) | HR or HR-P (mg/kg) | Large portion diet |                  |                          | Unit weight     |         | Variability factor | Case | IESTI (µg/kg bw/day) | % ARfD rounded |                                 |
|------------|------------------------------------------------------|------------------------|--------------------|--------------------|------------------|--------------------------|-----------------|---------|--------------------|------|----------------------|----------------|---------------------------------|
|            |                                                      |                        |                    | Country            | Body weight (kg) | Large portion (g/person) | Unit weight (g) | Country |                    |      |                      |                | Unit weight, edible portion (g) |
| FP 0226    | Apple                                                | –                      | 0.37               | USA                | 15.0             | 679                      | 162             | SWE     | 149                | 3    | 2a                   | 24.10          | 1%                              |
| FC 0203    | Grapefruit                                           | –                      | 0.22               | FRA                | 17.8             | 381                      | 340             | SWE     | <b>167</b>         | 3    | 2a                   | 8.83           | 0%                              |
| FB 0269    | Grapes (fresh, wine, dried)                          | –                      | 2.6                | JPN                | 15.9             | 388                      | 456             | SWE     | 438                | 3    | 2b                   | 190.24         | 10%                             |
| FC 0204    | Lemon                                                | –                      | 0.22               | JPN                | 15.9             | 88                       | 173             | SWE     | 92                 | 3    | 2b                   | 3.67           | 0%                              |
| FC 0206    | Mandarin                                             | –                      | 0.22               | JPN                | 15.9             | 353                      | 133             | UNK     | 100                | 3    | 2a                   | 7.65           | 0%                              |
| FC 0004    | Oranges, sweet, sour (including orange-like hybrids) | –                      | 0.22               | UNK                | 14.5             | 495                      | 251             | SWE     | 178                | 3    | 2a                   | 12.92          | 1%                              |



## Annex 4

### METHOMYL (94)

International estimate of short-term intake for  
**General population**

ARfD = 0.02 mg/kg bw; 20 µg/kg bw  
Maximum % ARfD: 20%

| Codex code | Commodity | STMR or STMR-P (mg/kg) | HR or HR-P (mg/kg) | Country | Large portion diet |                          | Unit weight (g) | Unit weight Country | Unit weight, edible portion (g) | Variability factor | Case | IESTI (µg/kg bw/day) | % ARfD rounded |
|------------|-----------|------------------------|--------------------|---------|--------------------|--------------------------|-----------------|---------------------|---------------------------------|--------------------|------|----------------------|----------------|
| VO 0051    | Peppers   | 0.10                   | 0.44               | FRA     | Body weight (kg)   | Large portion (g/person) | 172             | UNK                 | 160                             | 3                  | 2a   | 3.72                 | 20%            |

### METHOMYL (94)

International estimate of short-term intake for  
**Children up to 6 years**

ARfD = 0.02 mg/kg bw; 20µg/kg bw  
Maximum % ARfD 20%

| Codex code | Commodity | STMR or STMR-P (mg/kg) | HR or HR-P (mg/kg) | Country | Large portion diet |                          | Unit weight (g) | Unit weight Country | Unit weight, edible portion (g) | Variability factor | Case | IESTI (µg/kg bw/day) | % ARfD rounded |
|------------|-----------|------------------------|--------------------|---------|--------------------|--------------------------|-----------------|---------------------|---------------------------------|--------------------|------|----------------------|----------------|
| VO 0051    | Peppers   | 0.10                   | 0.44               | AUS     | Body weight (kg)   | Large portion (g/person) | 172             | UNK                 | 160                             | 3                  | 2b   | 4.17                 | 20%            |

### OXYDEMETON METHYL (166)

International estimate of short-term intake for  
**General population**

ARfD = 0.002 mg/kg bw (2 µg/kg bw)  
Maximum % ARfD: 80%

| Codex code | Commodity                   | STMR or STMR-P (mg/kg) | HR or HR-P (mg/kg) | Country | Large portion diet |                          | Unit weight (g) | Unit weight Country | Unit weight, edible portion (g) | Variability factor | Case | IESTI (µg/kg bw/day) | % ARfD rounded |
|------------|-----------------------------|------------------------|--------------------|---------|--------------------|--------------------------|-----------------|---------------------|---------------------------------|--------------------|------|----------------------|----------------|
| FP 0226    | Apple                       | –                      | 0.04               | USA     | Body weight (kg)   | Large portion (g/person) | 162             | SWE                 | 149                             | 3                  | 2a   | 1.01                 | 50%            |
| JF 0226    | Apple juice                 | 0.01                   | –                  | –       | –                  | ND                       | –               | –                   | ND                              | ND                 | ND   | ND                   | –              |
| GC 0640    | Barley (fresh, flour, beer) | 0.01                   | –                  | NLD     | 63.0               | 378                      | –               | –                   | ND                              | ND                 | 3    | 0.06                 | 3%             |
| VB 0041    | Cabbages, head              | –                      | 0.05               | SAF     | 55.7               | 362                      | 771             | UNK                 | 540                             | 3                  | 2b   | 0.98                 | 50%            |

| Codex code | Commodity                                           | STM or STM-P (mg/kg) | HR or HR-P (mg/kg) | Large portion diet |                  |                          | Unit weight     |         |                                 | Variability factor | Case | IESTI (µg/kg bw/day) | % ARfD rounded |
|------------|-----------------------------------------------------|----------------------|--------------------|--------------------|------------------|--------------------------|-----------------|---------|---------------------------------|--------------------|------|----------------------|----------------|
|            |                                                     |                      |                    | Country            | Body weight (kg) | Large portion (g/person) | Unit weight (g) | Country | Unit weight, edible portion (g) |                    |      |                      |                |
| MF 0812    | Cattle fat                                          | –                    | 0                  | USA                | 65.0             | 60                       | –               | –       | ND                              | ND                 | 1    | 0.00                 | 0%             |
| VB 0404    | Cauliflower (head)                                  | –                    | 0.01               | UNK                | 70.1             | 579                      | 1733            | UNK     | 780                             | 3                  | 2b   | 0.25                 | 10%            |
| VD 0526    | Common bean (dry)                                   | 0.01                 | –                  | FRA                | 62.3             | 283                      | –               | –       | ND                              | ND                 | 3    | 0.05                 | 2%             |
| PE 0112    | Eggs                                                | –                    | 0                  | –                  | –                | ND                       | –               | –       | ND                              | ND                 | 1    | ND                   | –              |
| FB 0269    | Grapes (fresh, wine, dried)                         | –                    | 0.06               | AUS                | 67.0             | 1004                     | 456             | SWE     | 438                             | 3                  | 2a   | 1.68                 | 80%            |
| VL 0480    | Kale                                                | –                    | 0.01               | NLD                | 63.0             | 337                      | –               | –       | ND                              | ND                 | ND   | ND                   | –              |
| VB 0405    | Kohlrabi                                            | –                    | 0.05               | NLD                | 63.0             | 283                      | 135             | USA     | 99                              | 3                  | 2a   | 0.38                 | 20%            |
| FC 0204    | Lemon                                               | –                    | 0.04               | FRA                | 62.3             | 115                      | 173             | SWE     | 92                              | 3                  | 2a   | 0.19                 | 10%            |
| MM 0097    | Meat of cattle, pigs and sheep                      | –                    | 0                  | AUS                | 67.0             | 520                      | –               | –       | ND                              | ND                 | 1    | 0.00                 | 0%             |
| ML 0106    | Milks                                               | 0                    | –                  | USA                | 65.0             | 2466                     | –               | –       | ND                              | ND                 | 3    | 0.00                 | 0%             |
| FC 0004    | Orange, sweet, sour (including orange-like hybrids) | –                    | 0.04               | USA                | 65.0             | 564                      | 251             | SWE     | 178                             | 3                  | 2a   | 0.57                 | 30%            |
| FP 0230    | Pear                                                | –                    | 0.04               | USA                | 65.0             | 693                      | 187             | UNK     | 170                             | 3                  | 2a   | 0.64                 | 30%            |
| MF 0818    | Pig fat                                             | –                    | 0                  | AUS                | 67.0             | 144                      | –               | –       | ND                              | ND                 | 1    | 0.00                 | 0%             |
| VR 0589    | Potato                                              | –                    | 0.01               | NLD                | 63.0             | 687                      | 216             | UNK     | 216                             | 3                  | 2a   | 0.18                 | 9%             |
| PM 0110    | Poultry meat                                        | –                    | 0                  | AUS                | 67.0             | 431                      | –               | –       | ND                              | ND                 | 1    | 0.00                 | 0%             |
| PF 0111    | Poultry, fat                                        | –                    | 0                  | FRA                | 62.3             | 46                       | –               | –       | ND                              | ND                 | 1    | 0.00                 | 0%             |
| GC 0650    | Rye                                                 | 0.01                 | –                  | NLD                | 63.0             | 77                       | –               | –       | ND                              | ND                 | 3    | 0.01                 | 1%             |
| MF 0822    | Sheep fat                                           | –                    | 0                  | USA                | 65.0             | 54                       | –               | –       | ND                              | ND                 | 1    | 0.00                 | 0%             |
| VR 0596    | Sugar beet                                          | 0.01                 | –                  | –                  | –                | ND                       | –               | –       | ND                              | ND                 | ND   | ND                   | –              |
| GC 0654    | Wheat                                               | 0.01                 | –                  | USA                | 65.0             | 383                      | –               | –       | ND                              | ND                 | 3    | 0.06                 | 3%             |

## Annex 4

### OXYDEMETON-METHYL (166)

International estimate of short-term intake for  
Children up to 6 years

ARfD = 0.002 mg/kg bw; 2 µg/kg bw  
Maximum % ARfD: 220%

| Codex code | Commodity                                           | STMR or STMR-P (mg/kg) | HR or HR-P (mg/kg) | Large portion diet |                  |                          | Unit weight     |         |                                 | Variability factor | Case | IESTI (µg/kg bw/day) | % ARfD rounded |
|------------|-----------------------------------------------------|------------------------|--------------------|--------------------|------------------|--------------------------|-----------------|---------|---------------------------------|--------------------|------|----------------------|----------------|
|            |                                                     |                        |                    | Country            | Body weight (kg) | Large portion (g/person) | Unit weight (g) | Country | Unit weight, edible portion (g) |                    |      |                      |                |
| FP 0226    | Apple                                               | –                      | 0.04               | USA                | 15.0             | 679                      | 162             | SWE     | 149                             | 3                  | 2a   | 2.60                 | 130%           |
| JF 0226    | Apple juice                                         | 0.01                   | –                  | –                  | –                | ND                       | –               | –       | ND                              | ND                 | ND   | ND                   | –              |
| GC 0640    | Barley (fresh, flour, beer)                         | 0.01                   | –                  | AUS                | 19.0             | 14                       | –               | –       | ND                              | ND                 | 3    | 0.01                 | 0%             |
| VB 0041    | Cabbage, head                                       | –                      | 0.05               | SAF                | 14.2             | 220                      | 771             | UNK     | 540                             | 3                  | 2b   | 2.33                 | 120%           |
| MF 0812    | Cattle fat                                          | –                      | 0                  | USA                | 15.0             | 27                       | –               | –       | ND                              | ND                 | 1    | 0.00                 | 0%             |
| VB 0404    | Cauliflower (head)                                  | –                      | 0.01               | NLD                | 17.0             | 209                      | 1733            | UNK     | 780                             | 3                  | 2b   | 0.37                 | 20%            |
| VD 0526    | Common bean (dry)                                   | 0.01                   | –                  | FRA                | 17.8             | 209                      | –               | –       | ND                              | ND                 | 3    | 0.12                 | 6%             |
| PE 0112    | Eggs                                                | –                      | 0                  | –                  | –                | ND                       | –               | –       | ND                              | ND                 | 1    | ND                   | –              |
| FB 0269    | Grapes (fresh, wine, dried)                         | –                      | 0.06               | JPN                | 15.9             | 388                      | 456             | SWE     | 438                             | 3                  | 2b   | 4.39                 | 220%           |
| VL 0480    | Kale                                                | –                      | 0.01               | NLD                | 17.0             | 149                      | –               | –       | ND                              | ND                 | ND   | ND                   | –              |
| VB 0405    | Kohlrabi                                            | –                      | 0.05               | –                  | –                | ND                       | 135             | USA     | 99                              | 3                  | ND   | ND                   | –              |
| FC 0204    | Lemon                                               | –                      | 0.04               | JPN                | 15.9             | 88                       | 173             | SWE     | 92                              | 3                  | 2b   | 0.67                 | 30%            |
| MM 0097    | Meat of cattle, pigs and sheep                      | –                      | 0                  | AUS                | 19.0             | 261                      | –               | –       | ND                              | ND                 | 1    | 0.00                 | 0%             |
| ML 0106    | Milks                                               | 0                      | –                  | USA                | 15.0             | 1286                     | –               | –       | ND                              | ND                 | 3    | 0.00                 | 0%             |
| FC 0004    | Orange, sweet, sour (including orange-like hybrids) | –                      | 0.04               | UNK                | 14.5             | 495                      | 251             | SWE     | 178                             | 3                  | 2a   | 2.35                 | 120%           |
| FP 0230    | Pear                                                | –                      | 0.04               | UNK                | 14.5             | 279                      | 187             | UNK     | 170                             | 3                  | 2a   | 1.71                 | 90%            |
| MF 0818    | Pig fat                                             | –                      | 0                  | FRA                | 17.8             | 85                       | –               | –       | ND                              | ND                 | 1    | 0.00                 | 0%             |
| VR 0589    | Potato                                              | –                      | 0.01               | SAF                | 14.2             | 300                      | 216             | UNK     | 216                             | 3                  | 2a   | 0.52                 | 30%            |
| PM 0110    | Poultry meat                                        | –                      | 0                  | AUS                | 19.0             | 224                      | –               | –       | ND                              | ND                 | 1    | 0.00                 | 0%             |
| PF 0111    | Poultry, fat                                        | –                      | 0                  | FRA                | 17.8             | 20                       | –               | –       | ND                              | ND                 | 1    | 0.00                 | 0%             |
| GC 0650    | Rye                                                 | 0.01                   | –                  | NLD                | 17.0             | 37                       | –               | –       | ND                              | ND                 | 3    | 0.02                 | 1%             |
| MF 0822    | Sheep fat                                           | –                      | 0                  | USA                | 15.0             | 28                       | –               | –       | ND                              | ND                 | 1    | 0.00                 | 0%             |
| VR 0596    | Sugar-beet                                          | 0.01                   | –                  | –                  | –                | ND                       | –               | –       | ND                              | ND                 | ND   | ND                   | –              |

**PARAQUAT (057) :**

International estimate of short-term intake for  
**General population**

ARfD = 0.006 mg/kg bw/day (6 µg/kg bw/day)  
Maximum % ARfD: 20%

| Codex code | Commodity                                   | STMR or STMR-P (mg/kg) | HR or HR-P (mg/kg) | Large portion diet |                  |                          | Unit weight     |         |                                 | Variability factor | Case | IESTI (µg/kg bw/day) | % ARfD rounded |
|------------|---------------------------------------------|------------------------|--------------------|--------------------|------------------|--------------------------|-----------------|---------|---------------------------------|--------------------|------|----------------------|----------------|
|            |                                             |                        |                    | Country            | Body weight (kg) | Large portion (g/person) | Unit weight (g) | Country | Unit weight, edible portion (g) |                    |      |                      |                |
| TN 0660    | Almond                                      | –                      | 0.05               | JPN                | 52.6             | 74                       | –               | –       | ND                              | ND                 | 1    | 0.07                 | 1%             |
| FP 0226    | Apple                                       | –                      | 0                  | USA                | 65.0             | 1348                     | 138             | USA     | 127                             | 3                  | 2a   | 0.00                 | 0%             |
| FI 0327    | Banana                                      | –                      | 0.01               | SAF                | 55.7             | 613                      | 708             | USA     | 481                             | 3                  | 2a   | 0.28                 | 5%             |
| VR 0577    | Carrot                                      | –                      | 0.05               | NLD                | 63.0             | 335                      | 250             | JPN     | 250                             | 3                  | 2a   | 0.66                 | 10%            |
| ML 0812    | Cattle milk                                 | 0.00008                | –                  | NLD                | 63.0             | 2515                     | –               | –       | ND                              | ND                 | 3    | 0.00                 | 0%             |
| PE 0840    | Chicken eggs                                | –                      | 0                  | FRA                | 62.3             | 219                      | –               | –       | ND                              | ND                 | 1    | 0.00                 | 0%             |
| VD 0524    | Chick-pea (dry)                             | 0.1                    | –                  | FRA                | 62.3             | 203                      | –               | –       | ND                              | ND                 | 3    | 0.33                 | 5%             |
| VD 0526    | Common bean (dry)                           | 0.1                    | –                  | FRA                | 62.3             | 283                      | –               | –       | ND                              | ND                 | 3    | 0.45                 | 8%             |
| SO 0691    | Cotton-seed                                 | 0.21                   | –                  | USA                | 65.0             | 3                        | –               | –       | ND                              | ND                 | 3    | 0.01                 | 0%             |
| OC 0691    | Cotton-seed oil, crude†                     | 0.01                   | –                  | USA                | 65.0             | 9                        | –               | –       | ND                              | ND                 | 3    | 0.00                 | 0%             |
| MO 0105    | Edible offal (mammalian)                    | –                      | 0.033              | FRA                | 62.3             | 277                      | –               | –       | ND                              | ND                 | 1    | 0.15                 | 2%             |
| FB 0269    | Grapes (fresh, wine, dried)                 | –                      | 0                  | AUS                | 67.0             | 1004                     | 125             | FRA     | 118                             | 3                  | 2a   | 0.00                 | 0%             |
| FC 0203    | Grapefruit                                  | –                      | 0.02               | JPN                | 52.6             | 947                      | 256             | USA     | 125                             | 3                  | 2a   | 0.46                 | 8%             |
| FI 0336    | Guava                                       | –                      | 0.01               | AUS                | 67.0             | 450                      | 90              | USA     | 87                              | 3                  | 2a   | 0.09                 | 2%             |
| TN 0666    | Hazelnut                                    | –                      | 0.05               | AUS                | 67.0             | 70                       | –               | –       | ND                              | ND                 | 1    | 0.05                 | 1%             |
| DH 1100    | Hops, dry                                   | 0.05                   | –                  | USA                | 65.0             | 6                        | –               | –       | ND                              | ND                 | 3    | 0.00                 | 0%             |
| FI 0341    | Kiwi fruit                                  | –                      | 0.01               | NLD                | 63.0             | 355                      | 76              | USA     | 74                              | 3                  | 2a   | 0.08                 | 1%             |
| FC 0204    | Lemon                                       | –                      | 0.02               | FRA                | 62.3             | 115                      | 108             | USA     | 72                              | 3                  | 2a   | 0.08                 | 1%             |
| VL 0482    | Lettuce, head                               | –                      | 0.05               | USA                | 65.0             | 213                      | 539             | USA     | 512                             | 3                  | 2b   | 0.49                 | 8%             |
| VL 0483    | Lettuce, leaf                               | –                      | 0.05               | NLD                | 63.0             | 152                      | 10              | USA     | 10                              | 1                  | 1    | 0.12                 | 2%             |
| TN 0669    | Macadamia nuts                              | –                      | 0.05               | USA                | 65.0             | 107                      | –               | –       | ND                              | ND                 | 1    | 0.08                 | 1%             |
| CF 1255    | Maize flour                                 | 0.038                  | –                  | AUS                | 67.0             | 90                       | –               | –       | ND                              | ND                 | 3    | 0.05                 | 1%             |
| GC 0645    | Maize (fresh, flour, oil)                   | 0.025                  | –                  | FRA                | 62.3             | 260                      | –               | –       | ND                              | ND                 | 3    | 0.10                 | 2%             |
| OC 0645    | Maize oil, crude†                           | 0.006                  | –                  | NLD                | 63.0             | 43                       | –               | –       | ND                              | ND                 | 3    | 0.00                 | 0%             |
| MM 0095    | Meat from mammals other than marine mammals | –                      | 0.005              | AUS                | 67.0             | 521                      | –               | –       | ND                              | ND                 | 1    | 0.04                 | 1%             |
| FS 0245    | Nectarine                                   | –                      | 0                  | USA                | 65.0             | 590                      | 136             | USA     | 125                             | 3                  | 2a   | 0.00                 | 0%             |
| FT 0305    | Olive                                       | –                      | 0.1                | NLD                | 63.0             | 63                       | –               | –       | ND                              | ND                 | ND   | ND                   | –              |
| OC 0305    | Olive oil, virgin                           | 0.018                  | –                  | –                  | –                | ND                       | –               | –       | ND                              | ND                 | 3    | ND                   | –              |

## Annex 4

| Codex code | Commodity                                           | STMR or STMR-P (mg/kg) | HR or HR-P (mg/kg) | Large portion diet |                  |                          | Unit weight     |         | Variability factor | Case | IESTI (µg/kg bw/day) | % ARfD rounded |                                 |
|------------|-----------------------------------------------------|------------------------|--------------------|--------------------|------------------|--------------------------|-----------------|---------|--------------------|------|----------------------|----------------|---------------------------------|
|            |                                                     |                        |                    | Country            | Body weight (kg) | Large portion (g/person) | Unit weight (g) | Country |                    |      |                      |                | Unit weight, edible portion (g) |
| FC 0004    | Orange, sweet, sour (including orange-like hybrids) | –                      | 0.02               | USA                | 65.0             | 564                      | 131             | USA     | 96                 | 3    | 2a                   | 0.23           | 4%                              |
| FS 0247    | Peach                                               | –                      | 0                  | SAF                | 55.7             | 685                      | 98              | USA     | 85                 | 3    | 2a                   | 0.00           | 0%                              |
| FP 0230    | Pear                                                | –                      | 0                  | USA                | 65.0             | 693                      | 166             | USA     | 151                | 3    | 2a                   | 0.00           | 0%                              |
| VD 0072    | Peas (dry)                                          | 0.1                    | –                  | FRA                | 62.3             | 445                      | –               | –       | ND                 | ND   | 3                    | 0.71           | 10%                             |
| VO 0445    | Peppers, sweet (including pim(i)ento)               | –                      | 0.04               | FRA                | 62.3             | 207                      | 119             | USA     | 98                 | 3    | 2a                   | 0.26           | 4%                              |
| VR 0589    | Potato                                              | –                      | 0.05               | NLD                | 63.0             | 687                      | 122             | USA     | 99                 | 3    | 2a                   | 0.70           | 10%                             |
| PM 0110    | Poultry meat                                        | –                      | 0                  | AUS                | 67.0             | 431                      | –               | –       | ND                 | ND   | 1                    | 0.00           | 0%                              |
| FB 0275    | Strawberry                                          | –                      | 0                  | FRA                | 62.3             | 346                      | 14              | FRA     | 13                 | 1    | 1                    | 0.00           | 0%                              |
| GC 0651    | Sorghum                                             | 0.025                  | –                  | USA                | 65.0             | 18                       | –               | –       | ND                 | ND   | 3                    | 0.01           | 0%                              |
| VD 0541    | Soya bean (dry)                                     | 0.1                    | –                  | JPN                | 52.6             | 159                      | –               | –       | ND                 | ND   | 3                    | 0.30           | 5%                              |
| OC 0541    | Soya bean oil, crude†                               | 0.01                   | –                  | USA                | 65.0             | 98                       | –               | –       | ND                 | ND   | 3                    | 0.02           | 0%                              |
| VL 0502    | Spinach (bunch)                                     | –                      | 0.05               | NLD                | 63.0             | 820                      | 340             | USA     | 245                | 3    | 2a                   | 1.04           | 20%                             |
| SO 0702    | Sunflower seed                                      | 0.22                   | –                  | USA                | 65.0             | 193                      | –               | –       | ND                 | ND   | 3                    | 0.65           | 10%                             |
| OC 0702    | Sunflower seed oil, crude†                          | 0                      | –                  | FRA                | 62.3             | 61                       | –               | –       | ND                 | ND   | 3                    | 0.00           | 0%                              |
| DT 1114    | Tea, green, black (black, fermented and dried)      | 0.01                   | –                  | JPN                | 52.6             | 16                       | –               | –       | ND                 | ND   | 3                    | 0.00           | 0%                              |
| VO 0448    | Tomato (fresh, juice, paste, peeled)                | –                      | 0.04               | USA                | 65.0             | 391                      | 123             | USA     | 123                | 3    | 2a                   | 0.39           | 7%                              |
| TN 0085    | Tree nuts                                           | –                      | 0.05               | JPN                | 52.6             | 107                      | –               | –       | ND                 | ND   | 1                    | 0.10           | 2%                              |
| VL 0506    | Turnip greens                                       | –                      | 0.05               | USA                | 65.0             | 353                      | 800             | JPN     | 800                | 3    | 2b                   | 0.81           | 10%                             |

†, calculated from information on consumption of edible oils

**PARAQUAT (057) :**

International estimate of short-term intake for  
**Children up to 6 years**

ARfD = 0.006 mg/kg bw; 6 µg/kg bw

Maximum % ARfD: 50%

| Codex code | Commodity                                   | STMR or STMR-P (mg/kg) | HR or HR-P (mg/kg) | Large portion diet |                  |                          | Unit weight     |         |                                 | Variability factor | Case | IESTI (µg/kg bw/day) | % ARfD rounded |
|------------|---------------------------------------------|------------------------|--------------------|--------------------|------------------|--------------------------|-----------------|---------|---------------------------------|--------------------|------|----------------------|----------------|
|            |                                             |                        |                    | Country            | Body weight (kg) | Large portion (g/person) | Unit weight (g) | Country | Unit weight, edible portion (g) |                    |      |                      |                |
| TN 0660    | Almond                                      | –                      | 0.05               | FRA                | 17.8             | 31                       | –               | –       | ND                              | ND                 | 1    | 0.09                 | 1%             |
| FP 0226    | Apple                                       | –                      | 0                  | USA                | 15.0             | 679                      | 138             | USA     | 127                             | 3                  | 2a   | 0.00                 | 0%             |
| FI 0327    | Banana                                      | –                      | 0.01               | JPN                | 15.9             | 312                      | 708             | USA     | 481                             | 3                  | 2b   | 0.59                 | 10%            |
| VR 0577    | Carrot                                      | –                      | 0.05               | FRA                | 17.8             | 205                      | 250             | JPN     | 250                             | 3                  | 2b   | 1.73                 | 30%            |
| ML 0812    | Cattle milk                                 | 0.00008                | –                  | AUS                | 19.0             | 1450                     | –               | –       | ND                              | ND                 | 3    | 0.01                 | 0%             |
| PE 0840    | Chicken eggs                                | –                      | 0                  | FRA                | 17.8             | 134                      | –               | –       | ND                              | ND                 | 1    | 0.00                 | 0%             |
| VD 0524    | Chick-pea (dry)                             | 0.1                    | –                  | USA                | 15.0             | 34                       | –               | –       | ND                              | ND                 | 3    | 0.23                 | 4%             |
| VD 0526    | Common bean (dry)                           | 0.1                    | –                  | FRA                | 17.8             | 209                      | –               | –       | ND                              | ND                 | 3    | 1.18                 | 20%            |
| SO 0691    | Cotton-seed                                 | 0.21                   | –                  | USA                | 15.0             | 1                        | –               | –       | ND                              | ND                 | 3    | 0.01                 | 0%             |
| OC 0691    | Cotton-seed oil, crude†                     | 0.01                   | –                  | USA                | 15.0             | 6                        | –               | –       | ND                              | ND                 | 3    | 0.00                 | 0%             |
| MO 0105    | Edible offal (mammalian)                    | –                      | 0.033              | FRA                | 17.8             | 203                      | –               | –       | ND                              | ND                 | 1    | 0.38                 | 6%             |
| FB 0269    | Grapes (fresh, wine, dried)                 | –                      | 0                  | JPN                | 15.9             | 388                      | 125             | FRA     | 118                             | 3                  | 2a   | 0.00                 | 0%             |
| FC 0203    | Grapefruit                                  | –                      | 0.02               | FRA                | 17.8             | 381                      | 256             | USA     | 125                             | 3                  | 2a   | 0.71                 | 10%            |
| FI 0336    | Guava                                       | –                      | 0.01               | AUS                | 19.0             | 34                       | 90              | USA     | 87                              | 3                  | 2b   | 0.05                 | 1%             |
| TN 0666    | Hazelnuts                                   | –                      | 0.05               | NLD                | 17.0             | 11                       | –               | –       | ND                              | ND                 | 1    | 0.03                 | 1%             |
| DH 1100    | Hops, dry                                   | 0.05                   | –                  | JPN                | 15.9             | 0                        | –               | –       | ND                              | ND                 | 3    | 0.00                 | 0%             |
| FI 0341    | Kiwi fruit                                  | –                      | 0.01               | JPN                | 15.9             | 162                      | 76              | USA     | 74                              | 3                  | 2a   | 0.19                 | 3%             |
| FC 0204    | Lemon                                       | –                      | 0.02               | JPN                | 15.9             | 88                       | 108             | USA     | 72                              | 3                  | 2a   | 0.29                 | 5%             |
| VL 0482    | Lettuce, head                               | –                      | 0.05               | NLD                | 17.0             | 84                       | 539             | USA     | 512                             | 3                  | 2b   | 0.74                 | 10%            |
| VL 0483    | Lettuce, leaf                               | –                      | 0.05               | NLD                | 17.0             | 102                      | 10              | USA     | 10                              | 1                  | 1    | 0.30                 | 5%             |
| TN 0669    | Macadamia nuts                              | –                      | 0.05               | –                  | –                | ND                       | –               | –       | ND                              | ND                 | 1    | ND                   | –              |
| CF 1255    | Maize flour                                 | 0.038                  | –                  | AUS                | 19.0             | 60                       | –               | –       | ND                              | ND                 | 3    | 0.12                 | 2%             |
| GC 0645    | Maize (fresh, flour, oil)                   | 0.025                  | –                  | FRA                | 17.8             | 148                      | –               | –       | ND                              | ND                 | 3    | 0.21                 | 3%             |
| OC 0645    | Maize oil, crude†                           | 0.006                  | –                  | FRA                | 17.8             | 21                       | –               | –       | ND                              | ND                 | 3    | 0.01                 | 0%             |
| MM 0095    | Meat from mammals other than marine mammals | –                      | 0.005              | AUS                | 19.0             | 261                      | –               | –       | ND                              | ND                 | 1    | 0.07                 | 1%             |
| FS 0245    | Nectarine                                   | –                      | 0                  | AUS                | 19.0             | 302                      | 136             | USA     | 125                             | 3                  | 2a   | 0.00                 | 0%             |
| FT 0305    | Olive                                       | –                      | 0.1                | FRA                | 17.8             | 49                       | –               | –       | ND                              | ND                 | ND   | ND                   | –              |
| OC 0305    | Olive oil, virgin                           | 0.018                  | –                  | –                  | –                | ND                       | –               | –       | ND                              | ND                 | 3    | ND                   | –              |

#### Annex 4

|         |                                                     |       |      |     |      |     |     |     |     |    |    |      |     |
|---------|-----------------------------------------------------|-------|------|-----|------|-----|-----|-----|-----|----|----|------|-----|
| FC 0004 | Orange, sweet, sour (including orange-like hybrids) | –     | 0.02 | UNK | 14.5 | 495 | 131 | USA | 96  | 3  | 2a | 0.95 | 20% |
| FS 0247 | Peach                                               | –     | 0    | AUS | 19.0 | 315 | 98  | USA | 85  | 3  | 2a | 0.00 | 0%  |
| FP 0230 | Pear                                                | –     | 0    | UNK | 14.5 | 279 | 166 | USA | 151 | 3  | 2a | 0.00 | 0%  |
| VD 0072 | Peas (dry)                                          | 0.1   | –    | FRA | 17.8 | 107 | –   | –   | ND  | ND | 3  | 0.60 | 10% |
| VO 0445 | Peppers, sweet (including pim(i)ento)               | –     | 0.04 | AUS | 19.0 | 60  | 119 | USA | 98  | 3  | 2b | 0.38 | 6%  |
| VR 0589 | Potato                                              | –     | 0.05 | SAF | 14.2 | 300 | 122 | USA | 99  | 3  | 2a | 1.75 | 30% |
| PM 0110 | Poultry meat                                        | –     | 0    | AUS | 19.0 | 224 | –   | –   | ND  | ND | 1  | 0.00 | 0%  |
| GC 0651 | Sorghum                                             | 0.025 | –    | –   | –    | ND  | –   | –   | ND  | ND | 3  | ND   | –   |
| VD 0541 | Soya bean (dry)                                     | 0.1   | –    | JPN | 15.9 | 88  | –   | –   | ND  | ND | 3  | 0.56 | 9%  |
| OC 0541 | Soya bean oil, crude†                               | 0.01  | –    | USA | 15.0 | 35  | –   | –   | ND  | ND | 3  | 0.02 | 0%  |
| VL 0502 | Spinach (bunch)                                     | –     | 0.05 | SAF | 14.2 | 420 | 340 | USA | 245 | 3  | 2a | 3.20 | 50% |
| FB 0275 | Strawberry                                          | –     | 0    | AUS | 19.0 | 176 | 14  | FRA | 13  | 1  | 1  | 0.00 | 0%  |
| SO 0702 | Sunflower seed                                      | 0.22  | –    | USA | 15.0 | 24  | –   | –   | ND  | ND | 3  | 0.35 | 6%  |
| OC 0702 | Sunflower seed oil, crude†                          | 0     | –    | FRA | 17.8 | 37  | –   | –   | ND  | ND | 3  | 0.00 | 0%  |
| DT 1114 | Tea, green, black (black, fermented and dried)      | 0.01  | –    | JPN | 15.9 | 10  | –   | –   | ND  | ND | 3  | 0.01 | 0%  |
| VO 0448 | Tomato (fresh, juice, paste, peeled)                | –     | 0.04 | USA | 15.0 | 159 | 123 | USA | 123 | 3  | 2a | 1.08 | 20% |
| TN 0085 | Tree nuts                                           | –     | 0.05 | AUS | 19.0 | 28  | –   | –   | ND  | ND | 1  | 0.07 | 1%  |
| VL 0506 | Turnip greens                                       | –     | 0.05 | USA | 15.0 | 90  | 800 | JPN | 800 | 3  | 2b | 0.90 | 10% |

†, calculated from information on consumption of edible oils

International estimate of short-term intake for  
**General population**

ARfD = 0.1 mg/kg bw; 100 µg/kg bw  
Maximum % ARfD:

130%

| Codex code | Commodity                                                             | STMR or STMR-P (mg/kg) | HR or HR-P (mg/kg) | Large portion diet |                  |                          | Unit weight     |         |                                 | Variability factor | Case | IESTI (µg/kg bw/day) | % ARfD rounded |
|------------|-----------------------------------------------------------------------|------------------------|--------------------|--------------------|------------------|--------------------------|-----------------|---------|---------------------------------|--------------------|------|----------------------|----------------|
|            |                                                                       |                        |                    | Country            | Body weight (kg) | Large portion (g/person) | Unit weight (g) | Country | Unit weight, edible portion (g) |                    |      |                      |                |
| FI 0326    | Avocado                                                               | –                      | 0.7                | FRA                | 62.3             | 260                      | 300             | FRA     | 180                             | 3                  | 2a   | 6.96                 | 7%             |
| FI 0327    | Banana                                                                | –                      | 0.7                | SAF                | 55.7             | 613                      | 720             | JPN     | 720                             | 3                  | 2b   | 23.10                | 20%            |
| GC 0640    | Barley (fresh, flour, beer)                                           | 0.11                   | –                  | NLD                | 63.0             | 378                      | –               | –       | ND                              | ND                 | 3    | 0.66                 | 1%             |
| CM 0081    | Bran, unprocessed of cereal grain (except buckwheat, canihua, quinoa) | 0.54                   | –                  | AUS                | 67.0             | 37                       | –               | –       | ND                              | ND                 | 3    | 0.30                 | 0%             |
| PE 0840    | Chicken eggs                                                          | –                      | 0.07               | FRA                | 62.3             | 219                      | –               | –       | ND                              | ND                 | 1    | 0.25                 | 0%             |
| FI 0332    | Custard apple                                                         | –                      | 0.7                | AUS                | 67.0             | 654                      | –               | –       | ND                              | ND                 | 1    | 6.83                 | 7%             |
| MO 0105    | Edible offal (mammalian)                                              | –                      | 6.2                | FRA                | 62.3             | 277                      | –               | –       | ND                              | ND                 | 1    | 27.53                | 30%            |
| FI 0335    | Feijoa                                                                | –                      | 0.7                | AUS                | 67.0             | 120                      | –               | –       | ND                              | ND                 | 1    | 1.25                 | 1%             |
| FC 0203    | Grapefruit                                                            | –                      | 0.92               | JPN                | 52.6             | 947                      | 400             | JPN     | 400                             | 3                  | 2a   | 30.55                | 30%            |
| FI 0336    | Guava                                                                 | –                      | 0.7                | AUS                | 67.0             | 450                      | 90              | USA     | 87                              | 3                  | 2a   | 6.53                 | 7%             |
| FI 0338    | Jackfruit                                                             | –                      | 0.7                | AUS                | 67.0             | 348                      | –               | –       | ND                              | ND                 | 1    | 3.63                 | 4%             |
| FI 0341    | Kiwi fruit                                                            | –                      | 0.7                | NLD                | 63.0             | 355                      | 120             | JPN     | 120                             | 3                  | 2a   | 6.61                 | 7%             |
| FC 0204    | Lemon                                                                 | –                      | 0.92               | FRA                | 62.3             | 115                      | 173             | SWE     | 92                              | 3                  | 2a   | 4.41                 | 4%             |
| FC 0205    | Lime                                                                  | –                      | 0.92               | AUS                | 67.0             | 590                      | 67              | USA     | 56                              | 3                  | 2a   | 9.64                 | 10%            |
| SO 0693    | Linseed                                                               | 0.05                   | –                  | NLD                | 63.0             | 21                       | –               | –       | ND                              | ND                 | 3    | 0.02                 | 0%             |
| GC 0645    | Maize (fresh, flour, oil)                                             | 0.11                   | –                  | FRA                | 62.3             | 260                      | –               | –       | ND                              | ND                 | 3    | 0.46                 | 0%             |
| FC 0206    | Mandarin                                                              | –                      | 0.92               | JPN                | 52.6             | 409                      | 168             | USA     | 124                             | 3                  | 2a   | 11.50                | 10%            |
| FC 0003    | Mandarins (including Mandarin-like hybrids)                           | –                      | 0.92               | USA                | 65.0             | 394                      | –               | –       | ND                              | ND                 | 1    | 5.58                 | 6%             |
| MM 0095    | Meat from mammals other than marine mammals: 20% as fat               | –                      | 0.38               | AUS                | 67.0             | 104                      | –               | –       | ND                              | ND                 | 1    | 0.59                 | 1%             |
| ML 0106    | Milks                                                                 | 0                      | –                  | USA                | 65.0             | 2466                     | –               | –       | ND                              | ND                 | 3    | 0.00                 | 0%             |
| GC 0646    | Millet                                                                | 0.11                   | –                  | AUS                | 67.0             | 101                      | –               | –       | ND                              | ND                 | 3    | 0.17                 | 0%             |
| VO 0450    | Mushroom                                                              | –                      | 37                 | FRA                | 62.3             | 219                      | 21              | UNK     | 20                              | 1                  | 1    | 129.87               | 130%           |
| GC 0647    | Oats                                                                  | 0.11                   | –                  | FRA                | 62.3             | 305                      | –               | –       | ND                              | ND                 | 3    | 0.54                 | 1%             |
| FC 0004    | Orange, sweet, sour (including orange-like hybrids)                   | –                      | 0.92               | USA                | 65.0             | 564                      | 200             | JPN     | 200                             | 3                  | 2a   | 13.65                | 10%            |



## Annex 4

| Codex code | Commodity                                              | STMTR or STMTR-P (mg/kg) | HR or HR-P (mg/kg) | Large portion diet |                  |                          | Unit weight     |         | Variability factor | Case | IESTI (µg/kg bw/day) | % ARfD rounded |                                 |
|------------|--------------------------------------------------------|--------------------------|--------------------|--------------------|------------------|--------------------------|-----------------|---------|--------------------|------|----------------------|----------------|---------------------------------|
|            |                                                        |                          |                    | Country            | Body weight (kg) | Large portion (g/person) | Unit weight (g) | Country |                    |      |                      |                | Unit weight, edible portion (g) |
| FI 0350    | Papaya                                                 | –                        | 0.7                | USA                | 65.0             | 567                      | 250             | JPN     | 250                | 3    | 2a                   | 11.49          | 10%                             |
| FI 0351    | Passion fruit                                          | –                        | 0.7                | JPN                | 52.6             | 554                      | –               | –       | ND                 | ND   | 1                    | 7.37           | 7%                              |
| HS 0790    | Pepper (black, white)                                  | 5.1                      | –                  | –                  | –                | ND                       | –               | –       | ND                 | ND   | 3                    | ND             | –                               |
| FI 0352    | Persimmon, American                                    | –                        | 0.7                | AUS                | 67.0             | 672                      | 122             | SWE     | 102                | 3    | 2a                   | 9.16           | 9%                              |
| FI 0353    | Pineapple (fresh, canned, juice, dried)                | –                        | 0.7                | JPN                | 52.6             | 371                      | 700             | FRA     | 420                | 3    | 2b                   | 14.83          | 10%                             |
| FI 0354    | Plantain                                               | –                        | 0.7                | AUS                | 67.0             | 160                      | –               | –       | ND                 | ND   | 1                    | 1.67           | 2%                              |
| PM 0110    | Poultry meat: 10% as fat                               | –                        | 0.007              | AUS                | 67.0             | 43                       | –               | –       | ND                 | ND   | 1                    | 0.00           | 0%                              |
| PM 0110    | Poultry meat: 90% as muscle                            | –                        | 0.005              | AUS                | 67.0             | 388                      | –               | –       | ND                 | ND   | 1                    | 0.03           | 0%                              |
| PO 0111    | Poultry, edible offal of                               | –                        | 0.1                | USA                | 65.0             | 248                      | –               | –       | ND                 | ND   | 1                    | 0.38           | 0%                              |
| FI 0358    | Rambutan                                               | –                        | 0.7                | AUS                | 67.0             | 562                      | –               | –       | ND                 | ND   | 1                    | 5.87           | 6%                              |
| OR 0495    | Rape-seed oil, edible                                  | 0.06                     | –                  | AUS                | 67.0             | 65                       | –               | –       | ND                 | ND   | 3                    | 0.06           | 0%                              |
| GC 0649    | Rice                                                   | 0.11                     | –                  | FRA                | 62.3             | 312                      | –               | –       | ND                 | ND   | 3                    | 0.55           | 1%                              |
| GC 0650    | Rye                                                    | 0.11                     | –                  | NLD                | 63.0             | 77                       | –               | –       | ND                 | ND   | 3                    | 0.13           | 0%                              |
| FC 0005    | Shaddocks or pomelos (including Shaddock-like hybrids) | –                        | 0.92               | USA                | 65.0             | 448                      | 210             | FRA     | 126                | 3    | 2a                   | 9.91           | 10%                             |
| GC 0651    | Sorghum                                                | 0.11                     | –                  | USA                | 65.0             | 18                       | –               | –       | ND                 | ND   | 3                    | 0.03           | 0%                              |
| SO 0702    | Sunflower seed                                         | 0.1                      | –                  | USA                | 65.0             | 193                      | –               | –       | ND                 | ND   | 3                    | 0.30           | 0%                              |
| OR 0702    | Sunflower seed oil, edible                             | 0.06                     | –                  | FRA                | 62.3             | 61                       | –               | –       | ND                 | ND   | 3                    | 0.06           | 0%                              |
| FC 4031    | Tangelo                                                | –                        | 0.92               | AUS                | 67.0             | 114                      | –               | –       | ND                 | ND   | ND                   | ND             | –                               |
| GC 0653    | Triticale                                              | 0.11                     | –                  | –                  | –                | ND                       | –               | –       | ND                 | ND   | 3                    | ND             | –                               |
| GC 0654    | Wheat                                                  | 0.11                     | –                  | USA                | 65.0             | 383                      | –               | –       | ND                 | ND   | 3                    | 0.65           | 1%                              |
| CM 0654    | Wheat bran, unprocessed                                | 0.54                     | –                  | USA                | 65.0             | 80                       | –               | –       | ND                 | ND   | 3                    | 0.66           | 1%                              |
| CF 1211    | Wheat flour                                            | 0.025                    | –                  | USA                | 65.0             | 365                      | –               | –       | ND                 | ND   | 3                    | 0.14           | 0%                              |
| CP 1212    | Wholemeal bread                                        | 0.14                     | –                  | SAF                | 55.7             | 395                      | –               | –       | ND                 | ND   | 3                    | 0.99           | 1%                              |

**PROCHLORAZ (142)**

International estimate of short-term intake for  
**Children up to 6 years**

ARfD = 0.1 mg/kg bw ; 100 µg/kg bw  
 Maximum % ARfD:

150%

| Codex code | Commodity                                                             | STMTR or STMTR-P (mg/kg) | HR or HR-P (mg/kg) | Large portion diet |                  |                          | Unit weight     |         |                                 | Variability factor | Case | IESTI (µg/kg bw/day) | % ARfD rounded |
|------------|-----------------------------------------------------------------------|--------------------------|--------------------|--------------------|------------------|--------------------------|-----------------|---------|---------------------------------|--------------------|------|----------------------|----------------|
|            |                                                                       |                          |                    | Country            | Body weight (kg) | Large portion (g/person) | Unit weight (g) | Country | Unit weight, edible portion (g) |                    |      |                      |                |
| FI 0326    | Avocado                                                               | –                        | 0.7                | USA                | 15.0             | 131                      | 300             | FRA     | 180                             | 3                  | 2b   | 18.27                | 20%            |
| FI 0327    | Banana                                                                | –                        | 0.7                | JPN                | 15.9             | 312                      | 900             | FRA     | 612                             | 3                  | 2b   | 41.18                | 40%            |
| GC 0640    | Barley (fresh, flour, beer)                                           | 0.11                     | –                  | AUS                | 19.0             | 14                       | –               | –       | ND                              | ND                 | 3    | 0.08                 | 0%             |
| CM 0081    | Bran, unprocessed of cereal grain (except buckwheat, canihua, quinoa) | 0.54                     | –                  | AUS                | 19.0             | 13                       | –               | –       | ND                              | ND                 | 3    | 0.36                 | 0%             |
| PE 0840    | Chicken eggs                                                          | –                        | 0.07               | FRA                | 17.8             | 134                      | –               | –       | ND                              | ND                 | 1    | 0.53                 | 1%             |
| FI 0332    | Custard apple                                                         | –                        | 0.7                | –                  | –                | ND                       | –               | –       | ND                              | ND                 | 1    | ND                   | –              |
| MO 0105    | Edible offal (mammalian)                                              | –                        | 6.2                | FRA                | 17.8             | 203                      | –               | –       | ND                              | ND                 | 1    | 70.62                | 70%            |
| FI 0335    | Feijoa                                                                | –                        | 0.7                | –                  | –                | ND                       | –               | –       | ND                              | ND                 | 1    | ND                   | –              |
| FC 0203    | Grapefruit                                                            | –                        | 0.92               | FRA                | 17.8             | 381                      | 400             | JPN     | 400                             | 3                  | 2b   | 59.15                | 60%            |
| FI 0336    | Guava                                                                 | –                        | 0.7                | AUS                | 19.0             | 34                       | 90              | USA     | 87                              | 3                  | 2b   | 3.80                 | 4%             |
| FI 0338    | Jackfruit                                                             | –                        | 0.7                | –                  | –                | ND                       | –               | –       | ND                              | ND                 | 1    | ND                   | –              |
| FI 0341    | Kiwi fruit                                                            | –                        | 0.7                | JPN                | 15.9             | 162                      | 76              | USA     | 74                              | 3                  | 2a   | 13.63                | 10%            |
| FC 0204    | Lemon                                                                 | –                        | 0.92               | JPN                | 15.9             | 88                       | 173             | SWE     | 92                              | 3                  | 2b   | 15.35                | 20%            |
| FC 0205    | Lime                                                                  | –                        | 0.92               | AUS                | 19.0             | 26                       | 67              | USA     | 56                              | 3                  | 2b   | 3.75                 | 4%             |
| SO 0693    | Linseed                                                               | 0.05                     | –                  | –                  | –                | ND                       | –               | –       | ND                              | ND                 | 3    | ND                   | –              |
| GC 0645    | Maize (fresh, flour, oil)                                             | 0.11                     | –                  | FRA                | 17.8             | 148                      | –               | –       | ND                              | ND                 | 3    | 0.92                 | 1%             |
| FC 0206    | Mandarin                                                              | –                        | 0.92               | JPN                | 15.9             | 353                      | 168             | USA     | 124                             | 3                  | 2a   | 34.83                | 30%            |
| FC 0003    | Mandarin (including mandarin-like hybrids)                            | –                        | 0.92               | USA                | 15.0             | 205                      | –               | –       | ND                              | ND                 | 1    | 12.56                | 10%            |
| FI 0345    | Mango                                                                 | –                        | 0.7                | AUS                | 19.0             | 207                      | 339             | SWE     | 234                             | 3                  | 2b   | 22.89                | 20%            |
| MM 0095    | Meat from mammals other than marine mammals: 20% as fat               | –                        | 0.38               | AUS                | 19.0             | 52                       | –               | –       | ND                              | ND                 | 1    | 1.04                 | 1%             |
| MM 0095    | Meat from mammals other than marine mammals: 80% as muscle            | –                        | 0.1                | AUS                | 19.0             | 208                      | –               | –       | ND                              | ND                 | 1    | 1.10                 | 1%             |
| ML 0106    | Milks                                                                 | 0                        | –                  | USA                | 15.0             | 1286                     | –               | –       | ND                              | ND                 | 3    | 0.00                 | 0%             |
| GC 0646    | Millet                                                                | 0.11                     | –                  | –                  | –                | ND                       | –               | –       | ND                              | ND                 | 3    | ND                   | –              |
| VO 0450    | Mushroom                                                              | –                        | 37                 | FRA                | 17.8             | 71                       | 21              | UNK     | 20                              | 1                  | 1    | 148.00               | 150%           |
| GC 0647    | Oats                                                                  | 0.11                     | –                  | USA                | 15.0             | 62                       | –               | –       | ND                              | ND                 | 3    | 0.46                 | 0%             |
| FC 0004    | Orange, sweet, sour (including orange-like hybrids)                   | –                        | 0.92               | UNK                | 14.5             | 495                      | 200             | JPN     | 200                             | 3                  | 2a   | 56.79                | 60%            |

## Annex 4

| Codex code | Commodity                                              | STMTR or STMTR-P (mg/kg) | HR or HR-P (mg/kg) | Large portion diet |                  |                          | Unit weight     |         | Variability factor | Case | IESTI (µg/kg bw/day) | % ARfD rounded |                                 |
|------------|--------------------------------------------------------|--------------------------|--------------------|--------------------|------------------|--------------------------|-----------------|---------|--------------------|------|----------------------|----------------|---------------------------------|
|            |                                                        |                          |                    | Country            | Body weight (kg) | Large portion (g/person) | Unit weight (g) | Country |                    |      |                      |                | Unit weight, edible portion (g) |
| FI 0350    | Papaya                                                 | –                        | 0.7                | USA                | 15.0             | 240                      | 346             | SWE     | 232                | 3    | 2a                   | 32.84          | 30%                             |
| FI 0351    | Passion fruit                                          | –                        | 0.7                | JPN                | 15.9             | 167                      | –               | –       | ND                 | ND   | 1                    | 7.37           | 7%                              |
| HS 0790    | Pepper (black, white)                                  | 5.1                      | –                  | –                  | –                | ND                       | –               | –       | ND                 | ND   | 3                    | ND             | –                               |
| FI 0352    | Persimmon, American                                    | –                        | 0.7                | –                  | –                | ND                       | 122             | SWE     | 102                | 3    | ND                   | ND             | –                               |
| FI 0353    | Pineapple (fresh, canned, juice, dried)                | –                        | 0.7                | JPN                | 15.9             | 216                      | 700             | FRA     | 420                | 3    | 2b                   | 28.58          | 30%                             |
| FI 0354    | Plantain                                               | –                        | 0.7                | –                  | –                | ND                       | –               | –       | ND                 | ND   | 1                    | ND             | –                               |
| PM 0110    | Poultry meat: 10% as fat                               | –                        | 0.007              | AUS                | 19.0             | 22                       | –               | –       | ND                 | ND   | 1                    | 0.01           | 0%                              |
| PM 0110    | Poultry meat: 90% as muscle                            | –                        | 0.005              | AUS                | 19.0             | 201                      | –               | –       | ND                 | ND   | 1                    | 0.05           | 0%                              |
| PO 0111    | Poultry, edible offal of                               | –                        | 0.1                | USA                | 15.0             | 37                       | –               | –       | ND                 | ND   | 1                    | 0.25           | 0%                              |
| FI 0358    | Rambutan                                               | –                        | 0.7                | AUS                | 19.0             | 20                       | –               | –       | ND                 | ND   | 1                    | 0.74           | 1%                              |
| OR 0495    | Rape-seed oil, edible                                  | 0.06                     | –                  | AUS                | 19.0             | 18                       | –               | –       | ND                 | ND   | 3                    | 0.06           | 0%                              |
| GC 0649    | Rice                                                   | 0.11                     | –                  | FRA                | 17.8             | 223                      | –               | –       | ND                 | ND   | 3                    | 1.38           | 1%                              |
| GC 0650    | Rye                                                    | 0.11                     | –                  | NLD                | 17.0             | 37                       | –               | –       | ND                 | ND   | 3                    | 0.24           | 0%                              |
| FC 0005    | Shaddocks or pomelos (including Shaddock-like hybrids) | –                        | 0.92               | FRA                | 17.8             | 381                      | 210             | FRA     | 126                | 3    | 2a                   | 32.74          | 30%                             |
| GC 0651    | Sorghum                                                | 0.11                     | –                  | –                  | –                | ND                       | –               | –       | ND                 | ND   | 3                    | ND             | –                               |
| SO 0702    | Sunflower seed                                         | 0.1                      | –                  | USA                | 15.0             | 24                       | –               | –       | ND                 | ND   | 3                    | 0.16           | 0%                              |
| OR 0702    | Sunflower seed oil, edible                             | 0.06                     | –                  | FRA                | 17.8             | 37                       | –               | –       | ND                 | ND   | 3                    | 0.12           | 0%                              |
| FC 4031    | Tangelo                                                | –                        | 0.92               | –                  | –                | ND                       | –               | –       | ND                 | ND   | ND                   | ND             | –                               |
| GC 0653    | Triticale                                              | 0.11                     | –                  | –                  | –                | ND                       | –               | –       | ND                 | ND   | 3                    | ND             | –                               |
| GC 0654    | Wheat                                                  | 0.11                     | –                  | USA                | 15.0             | 151                      | –               | –       | ND                 | ND   | 3                    | 1.11           | 1%                              |
| CM 0654    | Wheat bran, unprocessed                                | 0.54                     | –                  | USA                | 15.0             | 30                       | –               | –       | ND                 | ND   | 3                    | 1.07           | 1%                              |
| CF 1211    | Wheat flour                                            | 0.025                    | –                  | AUS                | 19.0             | 194                      | –               | –       | ND                 | ND   | 3                    | 0.26           | 0%                              |
| CP 1212    | Wholemeal bread                                        | 0.14                     | –                  | SAF                | 14.2             | 240                      | –               | –       | ND                 | ND   | 3                    | 2.37           | 2%                              |

**PROPINEB**

International estimate of short-term intake for  
**General population**

ARfD = 0.1 mg/kg bw ; 100 µg/kg bw  
Maximum % ARfD: 110%

| Codex code | Commodity                                                  | STMR or STMR-P (mg/kg) | HR or HR-P (mg/kg) | Large portion diet |                  |                          | Unit weight     |         | Variability factor | Case | IESTI (µg/kg bw/day) | % ARfD rounded |                                 |
|------------|------------------------------------------------------------|------------------------|--------------------|--------------------|------------------|--------------------------|-----------------|---------|--------------------|------|----------------------|----------------|---------------------------------|
|            |                                                            |                        |                    | Country            | Body weight (kg) | Large portion (g/person) | Unit weight (g) | Country |                    |      |                      |                | Unit weight, edible portion (g) |
| FS 0013    | Cherry                                                     | –                      | 0.35               | FRA                | 62.3             | 375                      | 12              | UNK     | 10                 | 1    | 1                    | 2.11           | 2%                              |
| PE 0840    | Chicken eggs                                               | –                      | 0                  | FRA                | 62.3             | 219                      | –               | –       | ND                 | ND   | 1                    | 0.00           | 0%                              |
| VC 0424    | Cucumber                                                   | –                      | 1.1                | NLD                | 63.0             | 313                      | 400             | FRA     | 360                | 3    | 2b                   | 16.40          | 20%                             |
| MO 0105    | Edible offal (mammalian)                                   | –                      | 0                  | FRA                | 62.3             | 277                      | –               | –       | ND                 | ND   | 1                    | 0.00           | 0%                              |
| MM 0095    | Meat from mammals other than marine mammals: 20% as fat    | –                      | 0                  | AUS                | 67.0             | 104                      | –               | –       | ND                 | ND   | 1                    | 0.00           | 0%                              |
| MM 0095    | Meat from mammals other than marine mammals: 80% as muscle | –                      | 0                  | AUS                | 67.0             | 417                      | –               | –       | ND                 | ND   | 1                    | 0.00           | 0%                              |
| ML 0106    | Milks                                                      | 0                      | –                  | USA                | 65.0             | 2466                     | –               | –       | ND                 | ND   | 3                    | 0.00           | 0%                              |
| VO 0445    | Peppers, sweet (including pim(i)ento)                      | –                      | 13                 | FRA                | 62.3             | 207                      | 172             | UNK     | 160                | 3    | 2a                   | 110.05         | 110%                            |
| VR 0589    | Potato                                                     | –                      | 0.16               | NLD                | 63.0             | 687                      | 216             | UNK     | 216                | 3    | 2a                   | 2.84           | 3%                              |
| PM 0110    | Poultry meat: 10% as fat                                   | –                      | 0                  | AUS                | 67.0             | 43                       | –               | –       | ND                 | ND   | 1                    | 0.00           | 0%                              |
| PM 0110    | Poultry meat: 90% as muscle                                | –                      | 0                  | AUS                | 67.0             | 388                      | –               | –       | ND                 | ND   | 1                    | 0.00           | 0%                              |
| PO 0111    | Poultry, edible offal of                                   | –                      | 0                  | USA                | 65.0             | 248                      | –               | –       | ND                 | ND   | 1                    | 0.00           | 0%                              |
| VO 0448    | Tomato (fresh, juice, paste, peeled)                       | –                      | 2.9                | USA                | 65.0             | 391                      | 150             | JPN     | 150                | 3    | 2a                   | 30.81          | 30%                             |
| JF 0448    | Tomato juice                                               | 0.18                   | –                  | –                  | –                | ND                       | –               | –       | ND                 | ND   | 3                    | ND             | –                               |
|            | Tomato paste                                               | 1.86                   | –                  | –                  | –                | ND                       | –               | –       | ND                 | ND   | ND                   | ND             | –                               |

## Annex 4

### PROPINEB

International estimate of short-term intake for  
Children up to 6 years

ARfD = 0.1 mg/kg bw ; 100 µg/kg bw  
Maximum % ARfD: 120%

| Codex code | Commodity                                                  | STMR or STMR-P (mg/kg) | HR or HR-P (mg/kg) | Large portion diet |                  |                          | Unit weight     |         | Variability factor | Case | IESTI (µg/kg bw/day) | % ARfD rounded |                                 |
|------------|------------------------------------------------------------|------------------------|--------------------|--------------------|------------------|--------------------------|-----------------|---------|--------------------|------|----------------------|----------------|---------------------------------|
|            |                                                            |                        |                    | Country            | Body weight (kg) | Large portion (g/person) | Unit weight (g) | Country |                    |      |                      |                |                                 |
|            |                                                            |                        |                    |                    |                  |                          |                 |         |                    |      |                      |                | Unit weight, edible portion (g) |
| FS 0013    | Cherry                                                     | –                      | 0.35               | FRA                | 17.8             | 297                      | 12              | UNK     | 10                 | 1    | 1                    | 5.83           | 6%                              |
| PE 0840    | Chicken eggs                                               | –                      | 0                  | FRA                | 17.8             | 134                      | –               | –       | ND                 | ND   | 1                    | 0.00           | 0%                              |
| VC 0424    | Cucumber                                                   | –                      | 1.1                | NLD                | 17.0             | 162                      | 400             | FRA     | 360                | 3    | 2b                   | 31.45          | 30%                             |
| MO 0105    | Edible offal (mammalian)                                   | –                      | 0                  | FRA                | 17.8             | 203                      | –               | –       | ND                 | ND   | 1                    | 0.00           | 0%                              |
| MM 0095    | Meat from mammals other than marine mammals: 20% as fat    | –                      | 0                  | AUS                | 19.0             | 52                       | –               | –       | ND                 | ND   | 1                    | 0.00           | 0%                              |
| MM 0095    | Meat from mammals other than marine mammals: 80% as muscle | –                      | 0                  | AUS                | 19.0             | 208                      | –               | –       | ND                 | ND   | 1                    | 0.00           | 0%                              |
| ML 0106    | Milks                                                      | 0                      | –                  | USA                | 15.0             | 1286                     | –               | –       | ND                 | ND   | 3                    | 0.00           | 0%                              |
| VO 0445    | Peppers, sweet (including pim(i)ento)                      | –                      | 13                 | AUS                | 19.0             | 60                       | 172             | UNK     | 160                | 3    | 2b                   | 123.24         | 120%                            |
| VR 0589    | Potato                                                     | –                      | 0.16               | SAF                | 14.2             | 300                      | 216             | UNK     | 216                | 3    | 2a                   | 8.24           | 8%                              |
| PM 0110    | Poultry meat: 10% as fat                                   | –                      | 0                  | AUS                | 19.0             | 22                       | –               | –       | ND                 | ND   | 1                    | 0.00           | 0%                              |
| PM 0110    | Poultry meat: 90% as muscle                                | –                      | 0                  | AUS                | 19.0             | 201                      | –               | –       | ND                 | ND   | 1                    | 0.00           | 0%                              |
| PO 0111    | Poultry, edible offal of                                   | –                      | 0                  | USA                | 15.0             | 37                       | –               | –       | ND                 | ND   | 1                    | 0.00           | 0%                              |
| VO 0448    | Tomato (fresh, juice, paste, peeled)                       | –                      | 2.9                | USA                | 15.0             | 159                      | 150             | JPN     | 150                | 3    | 2a                   | 88.74          | 90%                             |
| FJ 0448    | Tomato juice                                               | 0.18                   | –                  | –                  | –                | ND                       | –               | –       | ND                 | ND   | 3                    | ND             | –                               |
|            | Tomato paste                                               | 1.86                   | –                  | –                  | –                | ND                       | –               | –       | ND                 | ND   | ND                   | ND             | –                               |

**PYRACLOSTROBIN (210)**

International estimate of short-term intake for  
**General population**

Acute RfD= 0.05 mg/kg bw; 50µg/kg bw  
Maximum % of ArfD 30%

| Codex code | Commodity                                              | STMR or STMR-P (mg/kg) | HR or HR-P (mg/kg) | Large portion diet |                  |                          | Unit weight     |         |                                 | Variability factor | Case | IESTI (µg/kg bw/day) | % ArfD rounded |
|------------|--------------------------------------------------------|------------------------|--------------------|--------------------|------------------|--------------------------|-----------------|---------|---------------------------------|--------------------|------|----------------------|----------------|
|            |                                                        |                        |                    | Country            | Body weight (kg) | Large portion (g/person) | Unit weight (g) | Country | Unit weight, edible portion (g) |                    |      |                      |                |
| TN 0660    | Almond                                                 | –                      | 0.02               | JPN                | 52.6             | 74                       | –               | –       | ND                              | ND                 | 1    | 0.03                 | 0%             |
| FI 0327    | Banana                                                 | –                      | 0.02               | SAF                | 55.7             | 613                      | 900             | FRA     | 612                             | 3                  | 2a   | 0.66                 | 1%             |
| GC 0640    | Barley (fresh, flour, beer)                            | 0.04                   | –                  | NLD                | 63.0             | 378                      | –               | –       | ND                              | ND                 | 3    | 0.24                 | 0%             |
| VD 0071    | Beans (dry)                                            | 0.02                   | –                  | FRA                | 62.3             | 255                      | –               | –       | ND                              | ND                 | 3    | 0.08                 | 0%             |
| FB 0020    | Blueberry                                              | –                      | 0.57               | AUS                | 67.0             | 158                      | –               | –       | ND                              | ND                 | ND   | ND                   | –              |
| VR 0577    | Carrot                                                 | –                      | 0.24               | NLD                | 63.0             | 335                      | 100             | FRA     | 89                              | 3                  | 2a   | 1.95                 | 4%             |
| FS 0013    | Cherry                                                 | –                      | 0.63               | FRA                | 62.3             | 375                      | 5               | FRA     | 4                               | 1                  | 1    | 3.79                 | 8%             |
| SB 0716    | Coffee bean                                            | 0.03                   | –                  | NLD                | 63.0             | 66                       | –               | –       | ND                              | ND                 | 3    | 0.03                 | 0%             |
| MO 0105    | Edible offal (mammalian)                               | –                      | 0.037              | FRA                | 62.3             | 277                      | –               | –       | ND                              | ND                 | 1    | 0.16                 | 0%             |
| PE 0112    | Eggs                                                   | –                      | 0                  | –                  | –                | ND                       | –               | –       | ND                              | ND                 | 1    | ND                   | –              |
| VA 0381    | Garlic                                                 | –                      | 0.05               | FRA                | 62.3             | 22                       | –               | –       | ND                              | ND                 | ND   | ND                   | –              |
| FB 0269    | Grapes (fresh, dried, excluding wine)                  | –                      | 1.38               | AUS                | 67.0             | 513                      | 150             | JPN     | 150                             | 3                  | 2a   | 16.75                | 30%            |
| DF 0269    | Grapes, dried (currants, raisins and sultanas)         | –                      | 4.27               | FRA                | 62.3             | 135                      | –               | –       | ND                              | ND                 | 1    | 9.27                 | 20%            |
| VR 0583    | Horseradish                                            | –                      | 0.3                | FRA                | 62.3             | 493                      | –               | –       | ND                              | ND                 | ND   | ND                   | –              |
| VD 0533    | Lentil (dry)                                           | 0.13                   | –                  | FRA                | 62.3             | 435                      | –               | –       | ND                              | ND                 | 3    | 0.91                 | 2%             |
| GC 0645    | Maize (fresh)                                          | 0.02                   | –                  | –                  | –                | ND                       | –               | –       | ND                              | ND                 | 3    | ND                   | –              |
| GC 0645    | Maize (fresh, flour, oil)                              | 0.02                   | –                  | FRA                | 62.3             | 260                      | –               | –       | ND                              | ND                 | 3    | 0.08                 | 0%             |
| FI 0345    | Mango                                                  | –                      | 0.05               | FRA                | 62.3             | 567                      | 207             | USA     | 139                             | 3                  | 2a   | 0.68                 | 1%             |
| MM 0095    | Meat from mammals other than marine mammals 20% as fat | –                      | 0.41               | AUS                | 67.0             | 104                      | –               | –       | ND                              | ND                 | 1    | 0.64                 | 1%             |
| MM 0095    | Meat from mammals other than marine mammals 80% as fat | –                      | 0.044              | AUS                | 67.0             | 417                      | –               | –       | ND                              | ND                 | 1    | 0.27                 | 1%             |
| ML0106     | Milks                                                  | 0.01                   | –                  | USA                | 65.0             | 2466                     | –               | –       | ND                              | ND                 | 3    | 0.38                 | 1%             |
| GC 0647    | Oats                                                   | 0.17                   | –                  | FRA                | 62.3             | 305                      | –               | –       | ND                              | ND                 | 3    | 0.83                 | 2%             |
| VA 0385    | Onion, bulb                                            | –                      | 0.09               | FRA                | 62.3             | 306                      | 165             | UNK     | 150                             | 3                  | 2a   | 0.88                 | 2%             |
| FC 0004    | Orange, sweet, sour (including orange-like hybrids)    | –                      | 0.51               | USA                | 65.0             | 564                      | 190             | FRA     | 137                             | 3                  | 2a   | 6.57                 | 10%            |
| FI 0350    | Papaya                                                 | –                      | 0.05               | USA                | 65.0             | 567                      | 250             | JPN     | 250                             | 3                  | 2a   | 0.82                 | 2%             |

## Annex 4

| Codex code | Commodity                            | STMR or STMR-P (mg/kg) | HR or HR-P (mg/kg) | Large portion diet |                  |                          | Unit weight     |         |                                 | Variability factor | Case | IESTI (µg/kg bw/day) | % ArfD rounded |
|------------|--------------------------------------|------------------------|--------------------|--------------------|------------------|--------------------------|-----------------|---------|---------------------------------|--------------------|------|----------------------|----------------|
|            |                                      |                        |                    | Country            | Body weight (kg) | Large portion (g/person) | Unit weight (g) | Country | Unit weight, edible portion (g) |                    |      |                      |                |
| VD 4511    | Pea (dry) = field pea (dry)          | 0.17                   | –                  | NLD                | 63.0             | 252                      | –               | –       | ND                              | ND                 | 3    | 0.68                 | 1%             |
| FS 0247    | Peach                                | –                      | 0.31               | SAF                | 55.7             | 685                      | 150             | JPN     | 150                             | 3                  | 2a   | 5.48                 | 10%            |
| SO 0697    | Peanut                               | 0.02                   | –                  | FRA                | 62.3             | 161                      | –               | –       | ND                              | ND                 | 3    | 0.05                 | 0%             |
| TN 0672    | Pecan                                | –                      | 0.02               | AUS                | 67.0             | 23                       | –               | –       | ND                              | ND                 | 1    | 0.01                 | 0%             |
| TN 0675    | Pistachio nut                        | –                      | 0.45               | AUS                | 67.0             | 300                      | –               | –       | ND                              | ND                 | 1    | 2.02                 | 4%             |
| FS 0014    | Plums (fresh, prunes)                | –                      | 0.19               | USA                | 65.0             | 413                      | 59              | UNK     | 55                              | 3                  | 2a   | 1.53                 | 3%             |
| VR 0589    | Potato                               | 0.02                   | 0.02               | NLD                | 63.0             | 687                      | 200             | FRA     | 160                             | 3                  | 2a   | 0.32                 | 1%             |
| PM 0110    | Poultry meat                         | –                      | 0                  | AUS                | 67.0             | 431                      | –               | –       | ND                              | ND                 | 1    | 0.00                 | 0%             |
| PO 0111    | Poultry, edible offal of             | –                      | 0                  | USA                | 65.0             | 248                      | –               | –       | ND                              | ND                 | 1    | 0.00                 | 0%             |
| PF 0111    | Poultry, fats                        | –                      | 0                  | FRA                | 62.3             | 46                       | –               | –       | ND                              | ND                 | 1    | 0.00                 | 0%             |
| VC 0431    | Squash, summer                       | –                      | 0.18               | FRA                | 62.3             | 343                      | 196             | USA     | 186                             | 3                  | 2a   | 2.07                 | 4%             |
| FB 0275    | Strawberry                           | –                      | 0.26               | FRA                | 62.3             | 346                      | 14              | FRA     | 13                              | 1                  | 1    | 1.44                 | 3%             |
| VO 0448    | Tomato (fresh, juice, paste, peeled) | –                      | 0.21               | USA                | 65.0             | 391                      | 85              | UNK     | 85                              | 3                  | 2a   | 1.81                 | 4%             |
| GC 0654    | Wheat                                | 0.02                   | –                  | USA                | 65.0             | 383                      | –               | –       | ND                              | ND                 | 3    | 0.12                 | 0%             |
| CM 0654    | Wheat bran, unprocessed              | 0.012                  | –                  | USA                | 65.0             | 80                       | –               | –       | ND                              | ND                 | 3    | 0.01                 | 0%             |
| CF 1211    | Wheat flour                          | 0.012                  | –                  | USA                | 65.0             | 365                      | –               | –       | ND                              | ND                 | 3    | 0.07                 | 0%             |
| CF 1210    | Wheat germ                           | 0.016                  | –                  | FRA                | 62.3             | 207                      | –               | –       | ND                              | ND                 | 3    | 0.05                 | 0%             |
|            | Wine only                            | 0.04                   | –                  | AUS                | 67.0             | 1131                     | –               | –       | ND                              | ND                 | 3    | 0.68                 | 1%             |

For citrus, it was noted that no residues occurred in pulp, so the acute exposure was 0.

For grapes, it was noted that the consumption took in account dried grapes.

| PYRACLOSTROBIN (210) |                                                        | International estimate of short-term intake for<br>Children up to 6 years |                    |                    |                  |                          |                 |         |                                 | Acute RfD=0.05 mg/kg bw; 50µg/kg bw<br>Maximum Acute RfD% 90% |      |                      |                |
|----------------------|--------------------------------------------------------|---------------------------------------------------------------------------|--------------------|--------------------|------------------|--------------------------|-----------------|---------|---------------------------------|---------------------------------------------------------------|------|----------------------|----------------|
| Codex code           | Commodity                                              | STMR or STMR-P (mg/kg)                                                    | HR or HR-P (mg/kg) | Large portion diet |                  |                          | Unit weight     |         |                                 | Variability factor                                            | Case | IESTI (µg/kg bw/day) | % ARfD rounded |
|                      |                                                        |                                                                           |                    | Country            | Body weight (kg) | Large portion (g/person) | Unit weight (g) | Country | Unit weight, edible portion (g) |                                                               |      |                      |                |
| TN 0660              | Almond                                                 | –                                                                         | 0.02               | FRA                | 17.8             | 31                       | –               | –       | ND                              | ND                                                            | 1    | 0.04                 | 0%             |
| FI 0327              | Banana                                                 | –                                                                         | 0.02               | JPN                | 15.9             | 312                      | 900             | FRA     | 612                             | 3                                                             | 2b   | 1.18                 | 2%             |
| GC 0640              | Barley (fresh, flour, beer)                            | 0.04                                                                      | –                  | AUS                | 19.0             | 14                       | –               | –       | ND                              | ND                                                            | 3    | 0.03                 | 0%             |
| VD 0071              | Beans (dry)                                            | 0.02                                                                      | –                  | FRA                | 17.8             | 209                      | –               | –       | ND                              | ND                                                            | 3    | 0.24                 | 0%             |
| FB 0020              | Blueberry                                              | –                                                                         | 0.57               | FRA                | 17.8             | 138                      | –               | –       | ND                              | ND                                                            | ND   | ND                   | –              |
| VR 0577              | Carrot                                                 | –                                                                         | 0.24               | FRA                | 17.8             | 205                      | 100             | FRA     | 89                              | 3                                                             | 2a   | 5.16                 | 10%            |
| FS 0013              | Cherry                                                 | –                                                                         | 0.63               | FRA                | 17.8             | 297                      | 5               | FRA     | 4                               | 1                                                             | 1    | 10.50                | 20%            |
| SB 0716              | Coffee bean                                            | 0.03                                                                      | –                  | NLD                | 17.0             | 19                       | –               | –       | ND                              | ND                                                            | 3    | 0.03                 | 0%             |
| MO 0105              | Edible offal (mammalian)                               | –                                                                         | 0.037              | FRA                | 17.8             | 203                      | –               | –       | ND                              | ND                                                            | 1    | 0.57                 | 1%             |
| PE 0112              | Eggs                                                   | –                                                                         | 0                  | –                  | –                | ND                       | –               | –       | ND                              | ND                                                            | 1    | ND                   | –              |
| VA 0381              | Garlic                                                 | –                                                                         | 0.05               | FRA                | 17.8             | 30                       | –               | –       | ND                              | ND                                                            | ND   | ND                   | –              |
| FB 0269              | Grapes (fresh, dried, excluding wine)                  | –                                                                         | 1.38               | AUS                | 19.0             | 342                      | 150             | JPN     | 150                             | 3                                                             | 2a   | 46.63                | 90%            |
| DF 0269              | Grapes, dried (currants, raisins and sultanas)         | –                                                                         | 4.27               | USA                | 15.0             | 59                       | –               | –       | ND                              | ND                                                            | 1    | 16.87                | 30%            |
| VR 0583              | Horseradish                                            | –                                                                         | 0.3                | USA                | 15.0             | 127                      | –               | –       | ND                              | ND                                                            | ND   | ND                   | –              |
| VD 0533              | Lentil (dry)                                           | 0.13                                                                      | –                  | FRA                | 17.8             | 127                      | –               | –       | ND                              | ND                                                            | 3    | 0.93                 | 2%             |
| GC 0645              | Maize (fresh)                                          | 0.02                                                                      | –                  | –                  | –                | ND                       | –               | –       | ND                              | ND                                                            | 3    | ND                   | –              |
| GC 0645              | Maize (fresh, flour, oil)                              | 0.02                                                                      | –                  | FRA                | 17.8             | 148                      | –               | –       | ND                              | ND                                                            | 3    | 0.17                 | 0%             |
| FI 0345              | Mango                                                  | –                                                                         | 0.05               | AUS                | 19.0             | 207                      | 207             | USA     | 139                             | 3                                                             | 2a   | 1.27                 | 3%             |
| MM 0095              | Meat from mammals other than marine mammals 20% as fat | –                                                                         | 0.41               | AUS                | 19.0             | 52                       | –               | –       | ND                              | ND                                                            | 1    | 1.12                 | 2%             |
| MM 0095              | Meat from mammals other than marine mammals 80% as fat | –                                                                         | 0.044              | AUS                | 19.0             | 208                      | –               | –       | ND                              | ND                                                            | 1    | 0.48                 | 1%             |
| ML 0106              | Milks                                                  | 0.01                                                                      | –                  | USA                | 15.0             | 1286                     | –               | –       | ND                              | ND                                                            | 3    | 0.86                 | 2%             |
| GC 0647              | Oats                                                   | 0.17                                                                      | –                  | USA                | 15.0             | 62                       | –               | –       | ND                              | ND                                                            | 3    | 0.71                 | 1%             |
| VA 0385              | Onion, bulb                                            | –                                                                         | 0.09               | FRA                | 17.8             | 127                      | 165             | UNK     | 150                             | 3                                                             | 2b   | 1.93                 | 4%             |
| FC 0004              | Orange, sweet, sour (including orange-like hybrids)    | –                                                                         | 0.51               | UNK                | 14.5             | 495                      | 190             | FRA     | 137                             | 3                                                             | 2a   | 27.03                | 50%            |
| FI 0350              | Papaya                                                 | –                                                                         | 0.05               | USA                | 15.0             | 240                      | 250             | JPN     | 250                             | 3                                                             | 2b   | 2.40                 | 5%             |
| VD 4511              | Pea (dry) = field pea (dry)                            | 0.17                                                                      | –                  | –                  | –                | ND                       | –               | –       | ND                              | ND                                                            | 3    | ND                   | –              |
| FS 0247              | Peach                                                  | –                                                                         | 0.31               | AUS                | 19.0             | 315                      | 150             | JPN     | 150                             | 3                                                             | 2a   | 10.04                | 20%            |



## Annex 4

| Codex code | Commodity                            | STMR or STMR-P (mg/kg) | HR or HR-P (mg/kg) | Large portion diet |                  |                          | Unit weight     |         | Variability factor | Case | IESTI (µg/kg bw/day) | % ARfD rounded |                                 |
|------------|--------------------------------------|------------------------|--------------------|--------------------|------------------|--------------------------|-----------------|---------|--------------------|------|----------------------|----------------|---------------------------------|
|            |                                      |                        |                    | Country            | Body weight (kg) | Large portion (g/person) | Unit weight (g) | Country |                    |      |                      |                | Unit weight, edible portion (g) |
| SO 0697    | Peanut                               | 0.02                   | –                  | USA                | 15.0             | 78                       | –               | –       | ND                 | ND   | 3                    | 0.10           | 0%                              |
| TN 0672    | Pecan                                | –                      | 0.02               | AUS                | 19.0             | 22                       | –               | –       | ND                 | ND   | 1                    | 0.02           | 0%                              |
| TN 0675    | Pistachio nut                        | –                      | 0.45               | AUS                | 19.0             | 63                       | –               | –       | ND                 | ND   | 1                    | 1.48           | 3%                              |
| FS 0014    | Plums (fresh, prunes)                | –                      | 0.19               | FRA                | 17.8             | 254                      | 59              | UNK     | 55                 | 3    | 2a                   | 3.90           | 8%                              |
| VR 0589    | Potato                               | 0.02                   | 0.02               | SAF                | 14.2             | 300                      | 200             | FRA     | 160                | 3    | 2a                   | 0.87           | 2%                              |
| PM 0110    | Poultry meat                         | –                      | 0                  | AUS                | 19.0             | 224                      | –               | –       | ND                 | ND   | 1                    | 0.00           | 0%                              |
| PO 0111    | Poultry, edible offal of             | –                      | 0                  | USA                | 15.0             | 37                       | –               | –       | ND                 | ND   | 1                    | 0.00           | 0%                              |
| PF 0111    | Poultry, fat                         | –                      | 0                  | FRA                | 17.8             | 20                       | –               | –       | ND                 | ND   | 1                    | 0.00           | 0%                              |
| VC 0431    | Squash, summer                       | –                      | 0.18               | AUS                | 19.0             | 219                      | 196             | USA     | 186                | 3    | 2a                   | 5.60           | 10%                             |
| FB 0275    | Strawberry                           | –                      | 0.26               | AUS                | 19.0             | 176                      | 14              | FRA     | 13                 | 1    | 1                    | 2.41           | 5%                              |
| VO 0448    | Tomato (fresh, juice, paste, peeled) | –                      | 0.21               | USA                | 15.0             | 159                      | 85              | UNK     | 85                 | 3    | 2a                   | 4.61           | 9%                              |
| GC 0654    | Wheat                                | 0.02                   | –                  | USA                | 15.0             | 151                      | –               | –       | ND                 | ND   | 3                    | 0.20           | 0%                              |
| CM 0654    | Wheat bran, unprocessed              | 0.012                  | –                  | USA                | 15.0             | 30                       | –               | –       | ND                 | ND   | 3                    | 0.02           | 0%                              |
| CF 1211    | Wheat flour                          | 0.012                  | –                  | AUS                | 19.0             | 194                      | –               | –       | ND                 | ND   | 3                    | 0.12           | 0%                              |
| CF 1210    | Wheat germ                           | 0.016                  | –                  | USA                | 15.0             | 8                        | –               | –       | ND                 | ND   | 3                    | 0.01           | 0%                              |
|            | Wine only                            | 0.04                   | –                  | AUS                | 19.0             | 4                        | –               | –       | ND                 | ND   | 3                    | 0.01           | 0%                              |

For citrus, it was noted that no residues were found in pulp.  
Raisin included dried grapes.

## ANNEX 5

### ESTIMATION OF DAILY INTAKE OF PESTICIDES IN AND ON SPICES

In view of the nature of data derived from monitoring and the lack of detailed information on spice consumption, several assumptions and approximations had to be made for calculating the daily intake of residues of pesticides in or on spices:

- As the subgroups of spices used in the GEM/Food diets did not coincide with those agreed upon by the CCPR at its Thirty-sixth session, consumption of the entire spices group was used in calculating long- and short-term intake.
- The ratio of the number of samples containing detectable residues and all samples taken from a given commodity–pesticide combination was used to reflect the proportion of commodities that were treated with or exposed to the pesticide. The factor derived was used in calculating the IEDI.
- The IEDI was calculated only from the residue levels detected in a particular spice commodity–pesticide combination that made the greatest contribution to intake of any of the subgroups.
- The IESTI was calculated when an ARfD value was available.
- The consumption of ‘dried chili peppers’ was estimated to be about 10% of the combined consumption of fresh sweet and chili peppers (VO 0051, VO 0444, VO 0445).
- For dried chili peppers, only TMDIs could be calculated, as the only residue value available was one derived by extrapolation from the MRLs of fresh peppers. The IESTI was also calculated from estimated maximum residue levels.
- The residue level in a composite sample taken from a spice shipment containing several lots represents the average level in the mixed commodity. This value provides information similar to that of the median residue level from supervised trials. Therefore, the highest residue levels observed in composite samples were used to calculate short-term intake, instead of the median value which would have been used for results derived from supervised trials.
- Estimates were made for spices and chili pepper independently.

The Meeting evaluated residues of 28 pesticides from monitoring data and estimated maximum residue levels for 47 pesticides in dried chili peppers on the basis of MRLs established for fresh sweet and chili peppers. The intakes from spices and chili were compared with the existing ADI and ARfD values only; intakes arising from other uses of the compounds were not considered.

#### *Long-term intake*

##### *Spices*

The results of intake calculations showed that the IEDI for spices was less than 1% in all diets. The Meeting concluded that spice consumption would not change the risk assessment based on all other uses of the compounds.

##### *Chilli peppers*

The calculated TMDIs for dried chilli peppers were less than 5% of the ADI in any GEMS/Food diet for abamectin, benalaxyl, cyluthrin, cypermethrin, diazinon, dichlofulanid, dinocap, dithiocarbamates, fenpropathrin, fenvalerate, imidacoprid, metalaxyl, methoxyfenozide, permethrin, piperonyl butoxide, propamocarb, pyrethrins, quintozone, spinosad, tebuconazole, tolylfluanid, triadimefon and triadimenol. The Meeting concluded that consumption of dried chilli pepper would not change the risk assessment based on all other uses of the compounds.

The residues of acephate, azinphos-methyl, carbaryl, carbendazim, chlorothalonil, chlorpyrifos, chlorpyrifos-methyl, cyhexatin, cyromazine, dicofol, dimethoate, dithiocarbamates, ethephon, ethoprophos, fenarimol, fenpropathrin, methamidophos, methomyl, monocrotophos, oxamyl, phosphamidon, procymidone, profenofos, tebufenozide and vinclozolin in dried chili pepper contribute more than 5% of the ADI. The Meeting concluded that a complete assessment of the long-term intake of these compounds should be carried out, taking into account the residues derived from all other uses.

Use of dimethoate on peppers exceeded the ADI (430%) on chili pepper alone. The Meeting could not conclude that its use would not present a health public concern.

### Short-term intake

The IESTI values for spices ranged from < 1% to 170% (mevinphos).

For chili peppers, intake values at or above the ARfD were calculated for dimethoate (120%), methamidophos (100%) and oxamyl (270%).

The intakes of both spices and chili pepper (expressed in mg/kg bw per day) were similar for children and for the general population.

The Meeting concluded that short-term intake of pesticide residues, other than those listed above, deriving from consumption of spices and dried chili pepper is unlikely to present a public health concern.

### Summary of results of IEDI and IESTI calculations for spices

| Compound            | Long-term intake (% ADI) <sup>a</sup> |                                    |                                   |                                          |                                    | Short-term intake (% ArfD) <sup>a</sup> |                                   |
|---------------------|---------------------------------------|------------------------------------|-----------------------------------|------------------------------------------|------------------------------------|-----------------------------------------|-----------------------------------|
|                     | Mid-East<br>(0.043 g/kg<br>bw/day)    | Far-East<br>(0.055 g/kg<br>bw/day) | African<br>(0.030 g/kg<br>bw/day) | Latin American<br>(0.008 g/kg<br>bw/day) | European<br>(0.008 g/kg<br>bw/day) | Adult<br>(1.75 g/kg<br>bw/day)          | Children<br>(1.67 g/kg<br>bw/day) |
| Acephate            | 0                                     | 0                                  | 0                                 | 0                                        | 0                                  | 0                                       | 0                                 |
| Azinphos-methyl     | 0                                     | 0                                  | 0                                 | 0                                        | 0                                  |                                         |                                   |
| Chlorpyrifos        | 0                                     | 0                                  | 0                                 | 0                                        | 0                                  | 5                                       | 5                                 |
| Chlorpyrifos-methyl | 0                                     | 0                                  | 0                                 | 0                                        | 0                                  |                                         |                                   |
| Cypermethrin        | 0                                     | 0                                  | 0                                 | 0                                        | 0                                  |                                         |                                   |
| Diazinon            | 0                                     | 0                                  | 0                                 | 0                                        | 0                                  | 20                                      | 20                                |
| Dichlorvos          | 0                                     | 0                                  | 0                                 | 0                                        | 0                                  |                                         |                                   |
| Dicofol             | 0                                     | 0                                  | 0                                 | 0                                        | 0                                  |                                         |                                   |
| Dimethoate          | 0                                     | 0                                  | 0                                 | 0                                        | 0                                  | 25                                      | 25                                |
| Disulfoton          | 0                                     | 0                                  | 0                                 | 0                                        | 0                                  | 5                                       | 5                                 |
| Endosulfan          | 0                                     | 0                                  | 0                                 | 0                                        | 0                                  | 30                                      | 25                                |
| Ethion              | 0                                     | 0                                  | 0                                 | 0                                        | 0                                  |                                         |                                   |
| Fenitrothion        | 0                                     | 0                                  | 0                                 | 0                                        | 0                                  | 25                                      | 25                                |
| Iprodion            | 0                                     | 0                                  | 0                                 | 0                                        | 0                                  |                                         |                                   |
| Malathion           | 0                                     | 0                                  | 0                                 | 0                                        | 0                                  | 0                                       | 0                                 |
| Metalaxyl           | 0                                     | 0                                  | 0                                 | 0                                        | 0                                  |                                         |                                   |
| Methamidophos       | 0                                     | 0                                  | 0                                 | 0                                        | 0                                  | 0                                       | 0                                 |
| Mevinphos           | 0                                     | 0                                  | 0                                 | 0                                        | 0                                  | 170                                     | 160                               |
| Parathion           | 0                                     | 0                                  | 0                                 | 0                                        | 0                                  |                                         |                                   |
| Parathion-methyl    | 0                                     | 0                                  | 0                                 | 0                                        | 0                                  | 20                                      | 20                                |
| Permethrin          | 0                                     | 0                                  | 0                                 | 0                                        | 0                                  |                                         |                                   |
| Phenthoate          | 0                                     | 0                                  | 0                                 | 0                                        | 0                                  |                                         |                                   |
| Phorate             | 0                                     | 0                                  | 0                                 | 0                                        | 0                                  |                                         |                                   |

| Compound          | Long-term intake (% ADI) <sup>a</sup> |                                    |                                   |                                          |                                    | Short-term intake (% ArfD) <sup>a</sup> |                                   |
|-------------------|---------------------------------------|------------------------------------|-----------------------------------|------------------------------------------|------------------------------------|-----------------------------------------|-----------------------------------|
|                   | Mid-East<br>(0.043 g/kg<br>bw/day)    | Far-East<br>(0.055 g/kg<br>bw/day) | African<br>(0.030 g/kg<br>bw/day) | Latin American<br>(0.008 g/kg<br>bw/day) | European<br>(0.008 g/kg<br>bw/day) | Adult<br>(1.75 g/kg<br>bw/day)          | Children<br>(1.67 g/kg<br>bw/day) |
| Phosalone         | 0                                     | 0                                  | 0                                 | 0                                        | 0                                  | 0                                       | 0                                 |
| Pirimicarb        | 0                                     | 0                                  | 0                                 | 0                                        | 0                                  |                                         |                                   |
| Pirimiphos-methyl | 0                                     | 0                                  | 0                                 | 0                                        | 0                                  |                                         |                                   |
| Quintozene        | 0                                     | 0                                  | 0                                 | 0                                        | 0                                  |                                         |                                   |
| Vinclozolin       | 0                                     | 0                                  | 0                                 | 0                                        | 0                                  |                                         |                                   |

<sup>a</sup> Rounded figures

### Summary of results of calculations of TMDI (% ADI) and IESTI (% ARfD) from MRLs proposed for dried chili peppers

| Compound            | Long-term intake (% ADI) <sup>a</sup> |                                    |                                   |                                          |                                    | Short-term intake (% ArfD) <sup>a</sup> |                                    |
|---------------------|---------------------------------------|------------------------------------|-----------------------------------|------------------------------------------|------------------------------------|-----------------------------------------|------------------------------------|
|                     | Mid-East<br>(0.057 g/kg<br>bw/day)    | Far-East<br>(0.038 g/kg<br>bw/day) | African<br>(0.090 g/kg<br>bw/day) | Latin American<br>(0.040 g/kg<br>bw/day) | European<br>(0.173 g/kg<br>bw/day) | Adults<br>(0.472 g/kg<br>bw/day)        | Children<br>(0.477 g/kg<br>bw/day) |
| Abamectin           | 1                                     | 0                                  | 1                                 | 0                                        | 2                                  |                                         |                                    |
| Acephate            | 30                                    | 20                                 | 45                                | 20                                       | 90                                 | 50                                      | 50                                 |
| Azinphos-methyl     | 10                                    | 10                                 | 20                                | 10                                       | 35                                 |                                         |                                    |
| Benalaxyl           | 0                                     | 0                                  | 0                                 | 0                                        | 0                                  |                                         |                                    |
| Carbaryl            | 35                                    | 20                                 | 60                                | 25                                       | 110                                | 10                                      | 10                                 |
| Carbendazim         | 5                                     | 5                                  | 5                                 | 5                                        | 10                                 |                                         |                                    |
| Chlorothalonil      | 10                                    | 10                                 | 20                                | 10                                       | 40                                 |                                         |                                    |
| Chlorpyrifos        | 10                                    | 10                                 | 20                                | 10                                       | 35                                 | 10                                      | 10                                 |
| Chlorpyrifos-methyl | 5                                     | 0                                  | 5                                 | 0                                        | 10                                 |                                         |                                    |
| Cyfluthrin          | 0                                     | 0                                  | 0                                 | 0                                        | 0                                  |                                         |                                    |
| Cyhexatin           | 0                                     | 5                                  | 5                                 | 5                                        | 10                                 |                                         |                                    |
| Cypermethrin        | 0                                     | 0                                  | 0                                 | 0                                        | 0                                  |                                         |                                    |
| Cyromazine          | 5                                     | 0                                  | 5                                 | 0                                        | 10                                 |                                         |                                    |
| Diazinon            | 0                                     | 0                                  | 0                                 | 0                                        | 0                                  | 0                                       | 0                                  |
| Dichlofluanid       | 0                                     | 0                                  | 0                                 | 0                                        | 1                                  |                                         |                                    |
| Dicofol             | 30                                    | 20                                 | 45                                | 20                                       | 90                                 |                                         |                                    |
| Dimethoate          | 140                                   | 90                                 | 230                               | 100                                      | 430                                | 120                                     | 120                                |
| Dinocap             | 0                                     | 0                                  | 0                                 | 0                                        | 0                                  |                                         |                                    |
| Dithiocarbamates    | 0                                     | 0                                  | 5                                 | 0                                        | 5                                  |                                         |                                    |
| Ethephon            | 5                                     | 5                                  | 10                                | 5                                        | 20                                 | 50                                      | 50                                 |
| Ethoprophos         | 5                                     | 0                                  | 5                                 | 0                                        | 10                                 | 0                                       | 0                                  |
| Fenarimol           | 5                                     | 0                                  | 5                                 | 0                                        | 10                                 |                                         |                                    |
| Fenpropathrin       | 5                                     | 0                                  | 5                                 | 0                                        | 5                                  |                                         |                                    |
| Fenvalerate         | 0                                     | 0                                  | 0                                 | 0                                        | 5                                  |                                         |                                    |
| Imidacloprid        | 0                                     | 0                                  | 0                                 | 0                                        | 0                                  | 0                                       | 0                                  |
| Metalaxyl           | 0                                     | 0                                  | 0                                 | 0                                        | 0                                  |                                         |                                    |
| Methamidophos       | 30                                    | 20                                 | 50                                | 20                                       | 90                                 | 90                                      | 100                                |

| Compound           | Long-term intake (% ADI) <sup>a</sup> |                                    |                                   |                                          |                                    | Short-term intake (% ArfD) <sup>a</sup> |                                    |
|--------------------|---------------------------------------|------------------------------------|-----------------------------------|------------------------------------------|------------------------------------|-----------------------------------------|------------------------------------|
|                    | Mid-East<br>(0.057 g/kg<br>bw/day)    | Far-East<br>(0.038 g/kg<br>bw/day) | African<br>(0.090 g/kg<br>bw/day) | Latin American<br>(0.040 g/kg<br>bw/day) | European<br>(0.173 g/kg<br>bw/day) | Adults<br>(0.472 g/kg<br>bw/day)        | Children<br>(0.477 g/kg<br>bw/day) |
| Methomyl           | 5                                     | 0                                  | 5                                 | 0                                        | 10                                 | 20                                      | 20                                 |
| Methoxyfenozide    | 0                                     | 0                                  | 0                                 | 5                                        | 0                                  | 0                                       | 0                                  |
| Monocrotophos      | 20                                    | 10                                 | 30                                | 10                                       | 60                                 |                                         |                                    |
| Oxamyl             | 30                                    | 20                                 | 50                                | 20                                       | 100                                | 260                                     | 270                                |
| Permethrin         | 0                                     | 0                                  | 0                                 | 0                                        | 5                                  |                                         |                                    |
| Phosphamidon       | 20                                    | 20                                 | 40                                | 20                                       | 70                                 |                                         |                                    |
| Piperonyl butoxide | 0                                     | 0                                  | 0                                 | 0                                        | 0                                  |                                         |                                    |
| Procymidone        | 0                                     | 0                                  | 5                                 | 0                                        | 10                                 |                                         |                                    |
| Profenofos         | 30                                    | 20                                 | 50                                | 20                                       | 90                                 |                                         |                                    |
| Propamocarb        | 0                                     | 0                                  | 0                                 | 0                                        | 2                                  |                                         |                                    |
| Pyrethrins         | 0                                     | 0                                  | 0                                 | 0                                        | 0                                  | 0                                       | 0                                  |
| Quintozene         | 0                                     | 0                                  | 0                                 | 0                                        | 0                                  |                                         |                                    |
| Spinosad           | 0                                     | 0                                  | 0                                 | 0                                        | 5                                  |                                         |                                    |
| Tebuconazole       | 0                                     | 0                                  | 0                                 | 0                                        | 5                                  |                                         |                                    |
| Tebufenozide       | 5                                     | 0                                  | 5                                 | 0                                        | 10                                 |                                         |                                    |
| Tolylfluanid       | 0                                     | 0                                  | 0                                 | 0                                        | 5                                  | 0                                       | 0                                  |
| Triadimefon        | 0                                     | 0                                  | 0                                 | 0                                        | 0                                  |                                         |                                    |
| Triadimenol        | 0                                     | 0                                  | 0                                 | 0                                        | 0                                  |                                         |                                    |
| Vinclozolin        | 20                                    | 10                                 | 30                                | 10                                       | 50                                 |                                         |                                    |

<sup>a</sup> Rounded figures

## ANNEX 6

### REPORTS AND OTHER DOCUMENTS RESULTING FROM PREVIOUS JOINT MEETINGS OF THE FAO PANEL OF EXPERTS ON PESTICIDE RESIDUES IN FOOD AND THE ENVIRONMENT AND WHO EXPERT GROUPS ON PESTICIDE RESIDUES

1. Principles governing consumer safety in relation to pesticide residues. Report of a meeting of a WHO Expert Committee on Pesticide Residues held jointly with the FAO Panel of Experts on the Use of Pesticides in Agriculture. FAO Plant Production and Protection Division Report, No. PL/1961/11; WHO Technical Report Series, No. 240, 1962.
2. Evaluation of the toxicity of pesticide residues in food. Report of a Joint Meeting of the FAO Committee on Pesticides in Agriculture and the WHO Expert Committee on Pesticide Residues. FAO Meeting Report, No. PL/1963/13; WHO/Food Add./23, 1964.
3. Evaluation of the toxicity of pesticide residues in food. Report of the Second Joint Meeting of the FAO Committee on Pesticides in Agriculture and the WHO Expert Committee on Pesticide Residues. FAO Meeting Report, No. PL/1965/10; WHO/Food Add./26.65, 1965.
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5. Evaluation of the hazards to consumers resulting from the use of fumigants in the protection of food. FAO Meeting Report, No. PL/1965/10/2; WHO/Food Add./28.65, 1965.
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## ANNEX 7

## CORRECTIONS TO THE REPORT OF THE 2003 MEETING

Changes are shown in bold. Only significant factual errors and omissions are listed.

*Table of contents*

p. iii **4.3 Dimethoate (027) (T,R)**

**Section 3**

p. 17 Table 1, Dodine, **change** ADI 0–0.2 to **ADI 0–0.1** mg/kg bw

p. 20 Table 2 Acephate, **change** ArfD 0.003 to **ARfD 0.05** mg/kg bw

**Section 4**

p. 36 para 3, line 5, **change** 190–630% to **110–630%**

p. 40 Maximum burden table, footnote 4, **change** 2 mg/kg to **13** mg/kg as benomyl

*4.3 Carbosulfan/carbofuran*

p. 47 para 2, last sentence, **change** Carbosulfan was less than 0.02 mg/kg to **0.002** mg/kg

p. 48 Potatoes, para 6, **insert:** The only measurable value of 0.02 mg/kg was taken as the HR.

p. 51 lines 1–2. **change** ‘... an STMR of 0.217 mg/kg for carbofuran in sugar beet leaves or tops.’ to ‘... an STMR of 0.217 mg/kg (**dry wt**) for carbofuran in sugar beet leaves or tops.’

pp. 51–52, Maximum burden table, column , row 3: **change** Sugar beet to Sugar beet **leaves or tops**

row 4: **change** Dry citrus to Dry citrus **pulp**

p.52 STMR burden table, column 1, row 3: **change** Sugar beet to Sugar beet **leaves or tops**  
Penultimate para, **change to** The **ruminant dietary burden of carbofuran** established by the **1997 JMPR (Report, p. 50)** was based on a diet containing 80% of alfalfa fodder; there **were** few animal feed items.

*4.4 Cyprodinil*

p. 61 lines 2–3, **change** 2-anilino-4-(2-hydroxypropyl)-6-methylpyrimidinamin-5-ol to **2-anilino-4-(2-hydroxypropyl)-6-methylpyrimidin-5-ol**

*4.6 Dimethoate*

p. 79 Plant metabolism: last para. **change** The plant metabolites of omethoate to **The plant metabolites of III, XI, XII, and XX**

p. 81 para 3, lines 1–2, **change** Residues in whole lemon fruit at a 21-day PHI were 0.76 and 1.10 mg/kg dimethoate and 0.07 and 0.11 mg/kg omethoate. to **Residues in whole lemon fruit at a 21- or 28-day PHI were 0.76 and 1.10 mg/kg dimethoate and 0.10 and 0.11 mg/kg omethoate.**

para 6, lines 3–4, **change** The dimethoate residues ... are in rank order 0.15, 0.2, 0.29, 0.35, 0.37 (2), 0.41, 0.48, 0.52, 0.65, 0.76, 0.77, 0.83, 0.85, 1.04, 1.1, 1.17, 1.34, 1.48, 1.50 and 3.1 mg/kg. to **The dimethoate residues ... are in rank order 0.02, 0.06, 0.11, 0.15, 0.2, 0.21, 0.29, 0.35, 0.37 (2), 0.41, 0.48, 0.52, 0.65, 0.76, 0.77 (2), 0.83, 0.85, 0.97, 1.04, 1.1, 1.17, 1.33, 1.34, 1.48, 1.50 and 3.1 mg/kg.**

para 8, lines 3–4, **change** For the purpose of estimating STMR-Ps for processed commodities, the STMRs are 0.76 mg/kg for dimethoate and 0.035 mg/kg for omethoate. to **For the purpose of estimating STMR-Ps for processed commodities, the STMRs are 0.71 mg/kg for dimethoate and 0.08 mg/kg for omethoate.**

p. 82 Olives, line 6., **change** In Italy the rate is 0.028–0.56 kg ai/hl .... to **In Italy the rate is 0.028–0.056 kg ai/hl ....**

p. 86 last para, **change** The residues in wheat straw from northern Europe at PHI 28 days (or at earliest commercial harvest) in ranked order were <0.002 (3), <0.01 (2), 0.02, 0.05 and 0.07 mg/kg of dimethoate, and <0.002 (5), <0.01 (3) mg/kg of omethoate. to **The residues in**

wheat straw from northern Europe at PHI 28 days (or at earliest commercial harvest) in ranked order were <0.01 (3), 0.01, 0.02, 0.05 and 0.07 mg/kg of dimethoate, and <0.002, <0.01 (6) mg/kg of omethoate.

- p. 87 para 6, line 3 and following table, **change** ... STMRs for citrus fruits (dimethoate 0.76, Omethoate 0.08 mg/kg) ... to ... **STMRs for citrus fruits (dimethoate 0.71, Omethoate 0.08 mg/kg) ...**

The estimated processing factors and STMR-Ps for orange juice, dry orange pulp, processed olive products and wheat products are summarized below. **Replace the following entries.**

| Processed commodity | Processing factor |                   | STMR of RAC, mg/kg |             | STMR-P <sup>1</sup> , mg/kg |
|---------------------|-------------------|-------------------|--------------------|-------------|-----------------------------|
|                     | Dimethoate        | Omethoate         | Dimethoate         | Omethoate   |                             |
| Orange juice        | 0.14 <sup>2</sup> | 0.21 <sup>2</sup> | <b>0.71</b>        | <b>0.08</b> | <b>0.27</b>                 |
| Orange pulp, dry    | 2.1 <sup>2</sup>  | 1.7 <sup>2</sup>  | <b>0.71</b>        | <b>0.08</b> | <b>1.6<sup>3</sup></b>      |
| Olive, processed    | 0.21              | 0.12              | 0.04               | 0.22        | <b>0.272</b>                |

#### 4.8 Dodine

- p. 94 Table, Farm animal dietary burden. **Replace the following entries.**

| Commodity         | STMR-P (mg/kg) | Group | Dry matter % | Residue on dry basis mg/kg | Percent of diet |              | Residue contribution, mg/kg |              |
|-------------------|----------------|-------|--------------|----------------------------|-----------------|--------------|-----------------------------|--------------|
|                   |                |       |              |                            | Beef cattle     | Dairy cattle | Beef cattle                 | Dairy cattle |
| Apple pomace, wet | 8.69           | AB    | 40           | 21.7                       | 40              | 20           | 8.7                         | 4.4          |

#### 4.10 Fenitrothion

- p. 117 para 4, lines 5–6. **Change** ...0.089 and 0.11 for white bread (mean 0.010) ...to...**0.089 and 0.11 for white bread (mean 0.10) ...**  
 para 5, lines 3–4. **Change...** and STMR-Ps of ... 0.05 mg/kg in white bread ... to ... **and STMR-Ps of ... 0.50 mg/kg in white bread ...**
- p. 118 last 2 lines.  
 ... (Transfer factor = residue level in egg or tissue ÷ feeding level in diet metabolism study) at this feeding level **the level of the dietary burden.**

#### 4.12 Lindane

- p. 128 Mean farm animal dietary burden. **Replace the following entries.**

| Commodity           | Group | Residue mg/kg | Basis | % dry matter | Residue on dry wt mg/kg | Chosen diets, % |              |         | Residue contribution, mg/kg |              |         |
|---------------------|-------|---------------|-------|--------------|-------------------------|-----------------|--------------|---------|-----------------------------|--------------|---------|
|                     |       |               |       |              |                         | Beef cattle     | Dairy cattle | Poultry | Beef cattle                 | Dairy cattle | Poultry |
| Wheat hay           | AS    | <b>0.01</b>   | STMR  | 88           | <b>0.011</b>            | 25              |              |         | <b>0.003</b>                |              |         |
| Mean dietary burden |       |               |       |              |                         |                 |              |         | 0.011                       | 0.014        | 0.005   |

#### 4.13 Methamidophos

- p. 141 para 3, last sentence. **Change** ... the existing CXLs of 0.01 (\*) mg/kg for cattle fat, cattle meat, goat meat, goat fat, sheep meat, sheep fat and milks. to ... **the existing CXLs of 0.01 (\*) mg/kg for cattle fat, cattle meat, goat meat, goat fat, pig meat, pig fat, sheep meat, sheep fat and milks.**  
 para 5, last line. **Change** ... with the exception of cabbage (head) and tomatoes. to ... **with the exception of broccoli, cauliflower, apples, sweet peppers, cabbage (head) and tomatoes.**

#### 4.14 Methoxyfenozide

p. 165 second para. **Change** ... the acute RfD varied from 0% to 100% for the general population ... to ... **the acute RfD varied from 0% to 10% for the general population ...**

#### 4.18 Pirimiphos-methyl

p. 181 para 3, lines 1–2. **Change** Since no data were reported on the storage stability of pirimiphos-methyl or its metabolites in animal tissues, milk or eggs, the Meeting concluded...to **Since no data were reported on the storage stability of pirimiphos-methyl or its metabolites in animal tissues or eggs, Meeting concluded...**

#### Annex 1

**Replace the following entries.**

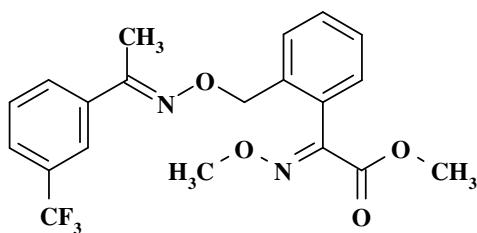
| Pesticide<br>(Codex reference<br>no.) | ADI,<br>mg/kg bw | CCN            | Commodity                  | Recommended MRL,<br>mg/kg |          | STMR or<br>STMR-P,<br>mg/kg | HR or HR-P<br>mg/kg  |
|---------------------------------------|------------------|----------------|----------------------------|---------------------------|----------|-----------------------------|----------------------|
|                                       |                  |                |                            | New                       | Previous |                             |                      |
| Carbofuran <sup>1</sup> (096)         | 0–0.002          | AF 0645        | Maize forage               | <b>0.5 (dry wt)</b>       |          | <b>0.13 (dry wt)</b>        |                      |
|                                       |                  | AV 0596        | Sugar beet leaves or tops  | <b>0.05* (dry wt)</b>     |          |                             |                      |
| Dimethoate <sup>1</sup> (027)         |                  | <b>VO 0448</b> | <b>Tomato</b>              | <b>W</b>                  | <b>2</b> |                             |                      |
| Fenitrothion**(037) <sup>1</sup>      |                  | CP 1211        | White bread                | W                         | 0.2 PoP  | <b>0.50</b>                 |                      |
| Methamidophos*<br>(100)               | 0–0.004          | AM1051         | Fodder beet leaves or tops | <b>30 (dry wt)</b>        |          | <b>9.1 (dry wt)</b>         | <b>26.5 (dry wt)</b> |
|                                       |                  | AV 0596        | Sugar beet leaves or tops  | <b>30 (dry wt)</b>        | 1        | <b>9.1 (dry wt)</b>         | <b>26.5 (dry wt)</b> |
| Methoxyfenozide*<br>(209)             | 0–0.1            | AM 0660        | Almond hulls               | <b>50 (dry wt)</b>        |          | <b>13 (fresh wt)</b>        |                      |
|                                       |                  | SO 0691        | Cotton seed                | 7                         |          | <b>0.39</b>                 |                      |
|                                       |                  | AS 0645        | Maize fodder               | 60 (dry wt)               |          | <b>8.2 (fresh wt)</b>       |                      |
|                                       |                  | AF 0645        | Maize forage               | 50 (dry wt)               |          | <b>4.5 (fresh wt)</b>       |                      |
|                                       |                  | TN 0085        | Tree nuts                  | 0.1                       |          | <b>0.021</b>                | 0.074                |
| Pyraclostrobin *                      |                  |                |                            |                           |          |                             |                      |
| (210)                                 |                  |                |                            |                           |          |                             |                      |

**TRIFLOXYSTROBIN (213)**

*First draft prepared by Dr Ursula Banasiak, Federal Institute for Risk Assessment, Berlin,  
Germany*

**IDENTITY**

Common name: trifloxystrobin  
 Chemical name:  
     IUPAC: methyl (*E*)-methoxyimino-[(*E*)- $\alpha$ -[1-( $\alpha,\alpha,\alpha$ -trifluoro-*m*-tolyl)ethylideneaminoxy]-*o*-tolyl] acetate  
     CA: methyl ( $\alpha E$ )-( $\alpha$ -(methoxyimino)-2-[[[*E*]-[1-[3-(trifluoromethyl)phenyl]ethylidene]amino]oxy]methyl] benzeneacetate  
 Manufacturer's code number: CGA279202  
 CAS number: 141517-21-7  
 CIPAC number: 617  
 Molecular formula: C<sub>20</sub>H<sub>19</sub>F<sub>3</sub>N<sub>2</sub>O<sub>4</sub>  
                                     Structural formula:



Molecular mass: 408.4 g/mol

Formulations:

| Formulation     | Content of active ingredients                      | Trade names                   |
|-----------------|----------------------------------------------------|-------------------------------|
| WG 50 (500 WG)  | 500 g/kg trifloxystrobin                           | Flint, Zato, Consist, Natchez |
| WG 25 (250 WG)  | 250 g/kg trifloxystrobin                           | Gem                           |
| EC 125          | 125 g/l trifloxystrobin                            | Twist, Aprix, Bonus, Scarfax  |
| DC 125          | 125 g/l trifloxystrobin                            | Twist                         |
| EC 075 (7.5 EC) | 75 g/l trifloxystrobin                             | Tega                          |
| SC 250          | 250 g/l trifloxystrobin                            | Flint                         |
| SC 500          | 500 g/l trifloxystrobin                            | Twist                         |
| EC 267.5        | 187.5 g/l trifloxystrobin<br>80 g/l cyproconazole  | Sphere, Sfera, Agora, Dexter  |
| SC 535          | 375 g/l trifloxystrobin<br>160 g/l cyproconazole   | (Sphere)                      |
| EC 250          | 125 g/l trifloxystrobin<br>125 g/l propiconazole   | Stratego, Rombus              |
| EC 312.5        | 187.5 g/l trifloxystrobin<br>125 g/l propiconazole | Stratego                      |
| WG 49 (490 WG)  | 25% trifloxystrobin                                | Eclair                        |



## 24% cymoxanil

**Physical and chemical properties**

A detailed chemical and physical characterisation of the pure and technical active ingredients is given in Table 1.

References to test materials used:

- 1 Trifloxystrobin (batch AMS 759/101, purity 99.7%)
- 2 Trifloxystrobin (batch P.706029, purity 97.4%)
- 3 Trifloxystrobin (batch AMS 759/3, purity 99.9%)
- 4 [(U)-<sup>14</sup>C-Phenyl-glyoxylate]trifloxystrobin, radiochemical purity > 99%, specific radioactivity 4.03 MBq/mg
- 5 [Trifluoromethyl-phenyl-(U)-<sup>14</sup>C]trifloxystrobin, radiochemical purity > 97%, specific radioactivity 3.4 MBq/mg
- 6 CGA321113 (batch BPS 885/1, purity 99%)

Table 1. Physical and chemical properties of trifloxystrobin.

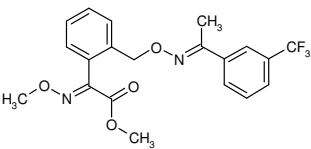
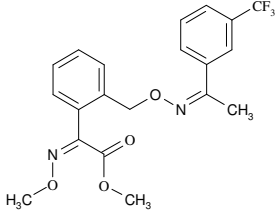
| Property                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Test Material, Method                      | Report No.           |                         |  |   |                           |      |             |   |                           |      |              |   |                           |     |              |                      |                  |
|----------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|----------------------|-------------------------|--|---|---------------------------|------|-------------|---|---------------------------|------|--------------|---|---------------------------|-----|--------------|----------------------|------------------|
| Physical state, colour                 | Active substance, pure: white powder<br>Active substance as manufactured: off-white powder                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Material 1<br>Material 2                   | 46887<br>53274       |                         |  |   |                           |      |             |   |                           |      |              |   |                           |     |              |                      |                  |
| Odour                                  | Active substance, pure: odourless<br>Active substance as manufactured: slightly sweet odour                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Material 1<br>Material 2                   | 46887<br>53274       |                         |  |   |                           |      |             |   |                           |      |              |   |                           |     |              |                      |                  |
| Melting point                          | 72.9°C                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Material 1, OECD 102                       | 46880                |                         |  |   |                           |      |             |   |                           |      |              |   |                           |     |              |                      |                  |
| Density                                | 1.36 g/cm <sup>3</sup> at 20°C                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Material 1, OECD 109                       | PP-96/63P.DES        |                         |  |   |                           |      |             |   |                           |      |              |   |                           |     |              |                      |                  |
| Vapour pressure                        | 3.4 · 10 <sup>-6</sup> Pa at 25°C (extrapolated from fit of measurements between 40 and 65°C)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Material 1, OECD 104                       | 96WI29               |                         |  |   |                           |      |             |   |                           |      |              |   |                           |     |              |                      |                  |
| Volatility                             | Henry's law constant at 25°C (calculated):<br>2.3 · 10 <sup>-3</sup> Pa · m <sup>3</sup> /mol                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                            | MO-01-003756         |                         |  |   |                           |      |             |   |                           |      |              |   |                           |     |              |                      |                  |
| Solubility in water                    | 0.61 mg/l at 25°C<br>Because trifloxystrobin has no dissociation constant in an accessible pH range, the pH has no effect on the water-solubility in the pH range 4 to 10.                                                                                                                                                                                                                                                                                                                                                                                                                  | Material 1, OECD 105                       | 46885                |                         |  |   |                           |      |             |   |                           |      |              |   |                           |     |              |                      |                  |
| Solubility in organic solvents         | n-hexane 11 g/l at 25°C<br>1-octanol 18 g/l at 25°C<br>methanol 76 g/l at 25°C<br>toluene 500 g/l at 25°C<br>ethyl acetate > 500 g/l at 25°C<br>acetone > 500 g/l at 25°C<br>dichloromethane > 500 g/l at 25°C                                                                                                                                                                                                                                                                                                                                                                              | Material 2, SOP 209/5 about CIPAC MT 157.3 | 53276                |                         |  |   |                           |      |             |   |                           |      |              |   |                           |     |              |                      |                  |
| Dissociation constant                  | Trifloxystrobin does not show any acidic or basic properties in the range pH 2 - pH 12.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Material 1, OECD 112                       | 46883                |                         |  |   |                           |      |             |   |                           |      |              |   |                           |     |              |                      |                  |
| Partition coefficient n-octanol/ water | P <sub>OW</sub> = 32000 ± 680 at 25°C<br>log P <sub>OW</sub> = 4.5 ± 0.0094 at 25°C<br>The effect of pH (4-9) was not investigated because trifloxystrobin has neither acidic nor basic properties in water.                                                                                                                                                                                                                                                                                                                                                                                | Material 1, OECD 107                       | 46884                |                         |  |   |                           |      |             |   |                           |      |              |   |                           |     |              |                      |                  |
| Hydrolysis rate                        | Hydrolysis half-lives of trifloxystrobin at 20°C were determined to be:<br><table border="1"> <thead> <tr> <th>pH</th> <th>k [s<sup>-1</sup>]</th> <th>DT<sub>50</sub> [days]</th> <th></th> </tr> </thead> <tbody> <tr> <td>5</td> <td>2.5557 · 10<sup>-9</sup></td> <td>3139</td> <td>(8.6 years)</td> </tr> <tr> <td>7</td> <td>1.0012 · 10<sup>-7</sup></td> <td>80.1</td> <td>(11.4 weeks)</td> </tr> <tr> <td>9</td> <td>7.1108 · 10<sup>-6</sup></td> <td>1.1</td> <td>(27.1 hours)</td> </tr> </tbody> </table> <p>The main degradation product at and above pH 5 was CGA321113</p> | pH                                         | k [s <sup>-1</sup> ] | DT <sub>50</sub> [days] |  | 5 | 2.5557 · 10 <sup>-9</sup> | 3139 | (8.6 years) | 7 | 1.0012 · 10 <sup>-7</sup> | 80.1 | (11.4 weeks) | 9 | 7.1108 · 10 <sup>-6</sup> | 1.1 | (27.1 hours) | Material 4, OECD 111 | 94PK01<br>94UL04 |
| pH                                     | k [s <sup>-1</sup> ]                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | DT <sub>50</sub> [days]                    |                      |                         |  |   |                           |      |             |   |                           |      |              |   |                           |     |              |                      |                  |
| 5                                      | 2.5557 · 10 <sup>-9</sup>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 3139                                       | (8.6 years)          |                         |  |   |                           |      |             |   |                           |      |              |   |                           |     |              |                      |                  |
| 7                                      | 1.0012 · 10 <sup>-7</sup>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 80.1                                       | (11.4 weeks)         |                         |  |   |                           |      |             |   |                           |      |              |   |                           |     |              |                      |                  |
| 9                                      | 7.1108 · 10 <sup>-6</sup>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 1.1                                        | (27.1 hours)         |                         |  |   |                           |      |             |   |                           |      |              |   |                           |     |              |                      |                  |

| Property                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Test Material, Method | Report No. |        |            |       |       |            |       |        |            |       |       |            |       |            |            |       |             |                       |        |
|---------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|------------|--------|------------|-------|-------|------------|-------|--------|------------|-------|-------|------------|-------|------------|------------|-------|-------------|-----------------------|--------|
| Photochemical degradation | <p>The experimental photolytic half-lives of trifloxystrobin in sterile aqueous buffered solutions (pH 5 and pH 7) under a Xenon arc light (12 hours light followed by 12 hours dark intervals) were found to be</p> <p>20.4 hours at pH 5 and 25°C and</p> <p>31.5 hours at pH 7 and 25°C</p> <p>corresponding to predicted environmental half-lives under natural summer sunlight at geographical latitude of 40°N of 1.1 and 1.7 days at pH 5 and pH 7 respectively</p> <p>Dark controls at 25°C showed a half-life of 3.1 years at pH 5 and 27.4 days at pH 7.</p> <p>Isomerisation of the active substance is the main consequence of irradiation. After 380 hours of irradiation the following concentrations of the four isomers were found :</p> <table><tr><td>trifloxystrobin</td><td>(E,E)</td><td>10.4 %</td></tr><tr><td>CGA331 409</td><td>(E,Z)</td><td>1.5 %</td></tr><tr><td>CGA357 261</td><td>(Z,E)</td><td>12.4 %</td></tr><tr><td>CGA357 262</td><td>(Z,Z)</td><td>3.5 %</td></tr></table> <p>Degradation of the parent compound isomers led to the following acid isomers :</p> <table><tr><td>CGA373 466</td><td>(Z,E)</td><td>up to 13 %</td></tr><tr><td>CGA321 113</td><td>(E,E)</td><td>up to 5.3 %</td></tr></table> <p>Further degradation led to cleavage of the molecule between the two ring systems. After 360 hours irradiation at pH 5 54.8 % of the applied radioactivity of the used trifluoromethyl-(U)-phenyl-labelled trifloxystrobin were trapped in toluene and identified as CGA107170.</p> <p>The recoveries at pH 5 were between 90.8 % and 104.2 % of the applied radioactivity.</p> | trifloxystrobin       | (E,E)      | 10.4 % | CGA331 409 | (E,Z) | 1.5 % | CGA357 261 | (Z,E) | 12.4 % | CGA357 262 | (Z,Z) | 3.5 % | CGA373 466 | (Z,E) | up to 13 % | CGA321 113 | (E,E) | up to 5.3 % | Material 5, EPA 161-2 | 94PK02 |
| trifloxystrobin           | (E,E)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 10.4 %                |            |        |            |       |       |            |       |        |            |       |       |            |       |            |            |       |             |                       |        |
| CGA331 409                | (E,Z)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 1.5 %                 |            |        |            |       |       |            |       |        |            |       |       |            |       |            |            |       |             |                       |        |
| CGA357 261                | (Z,E)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 12.4 %                |            |        |            |       |       |            |       |        |            |       |       |            |       |            |            |       |             |                       |        |
| CGA357 262                | (Z,Z)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 3.5 %                 |            |        |            |       |       |            |       |        |            |       |       |            |       |            |            |       |             |                       |        |
| CGA373 466                | (Z,E)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | up to 13 %            |            |        |            |       |       |            |       |        |            |       |       |            |       |            |            |       |             |                       |        |
| CGA321 113                | (E,E)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | up to 5.3 %           |            |        |            |       |       |            |       |        |            |       |       |            |       |            |            |       |             |                       |        |

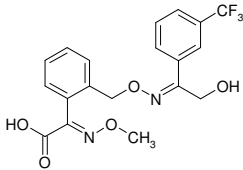
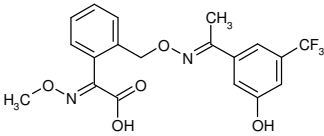
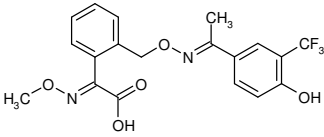
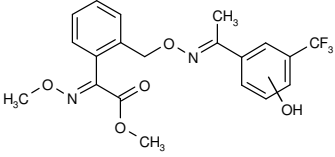
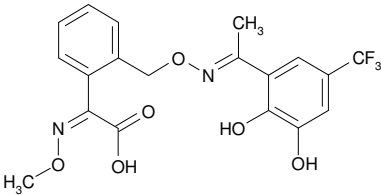
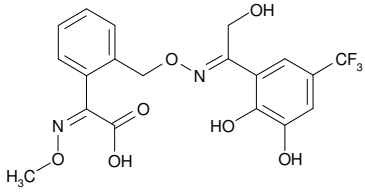
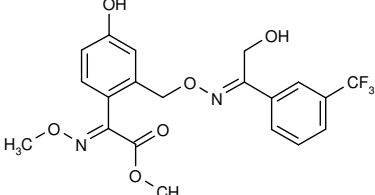
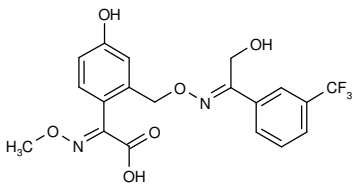
## METABOLISM AND ENVIRONMENTAL FATE

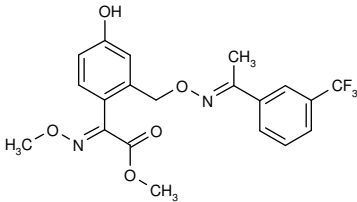
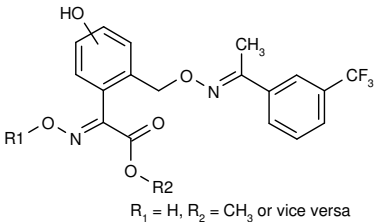
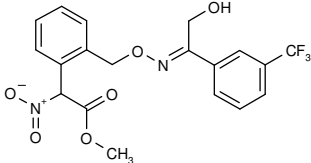
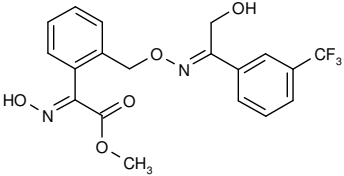
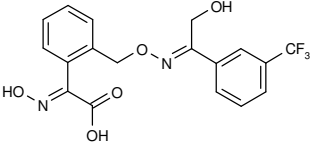
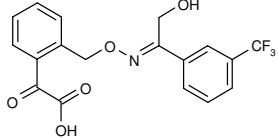
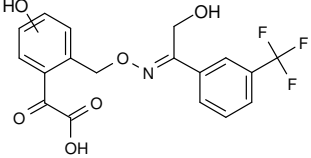
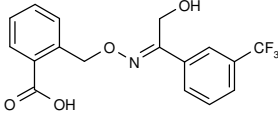
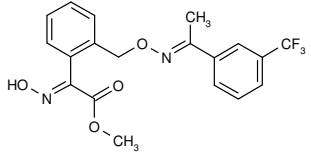
Chemical names, structures and code names of metabolites and degradation products of trifloxystrobin are shown below. The chemical names are those provided by the manufacturer without modification and do not necessarily reflect IUPAC or CAS practice.

List of Metabolites – sorted by chemical structures

| Structure                                                                           | Name                                                                                                                                                                                                  | Occurrence                                                                                                              |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------|
|  | <p><u>CGA279202</u>, Trifloxystrobin, Met 1F, Met 8G (Parent) (EE-isomer)</p> <p>(E,E)-Methoxyimino-{2-[1-(3-trifluoro methyl-phenyl)-ethylideneamino-oxymethyl]-phenyl}-acetic acid methyl ester</p> | <p>Wheat, Apple, Cucumber, Sugar beet, Rotational crops</p> <p>Hen, Goat, Rat, Soil, Water, Fish</p>                    |
|  | <p><u>CGA357262</u> (ZZ-isomer)</p> <p>(Z,Z)-Methoxyimino-{2-[1-(3-trifluoro methyl-phenyl)-ethylideneamino-oxymethyl]-phenyl}-acetic acid methyl ester</p>                                           | <p>Wheat, Apple, Cucumber, Sugar beet</p> <p>Soil (minor, bare ground, photolysis)</p> <p>Water (minor, photolysis)</p> |

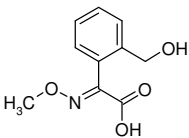
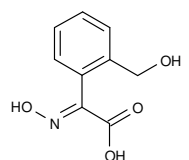
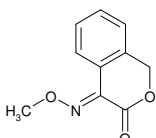
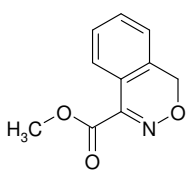
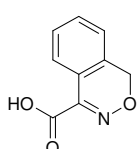
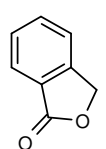
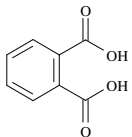
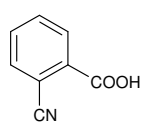
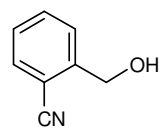
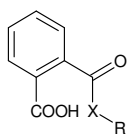
| Structure | Name                                                                                                                                                                                                                  | Occurrence                                                                                                           |
|-----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------|
|           | <u>CGA357261</u> (ZE-isomer)<br>(Z,E)-Methoxyimino-{2-[1-(3-trifluoro methyl-phenyl)-ethylideneaminooxymethyl]-phenyl}-acetic acid methyl ester                                                                       | Wheat, Apple, Cucumber<br>Soil (bare ground, photolysis)<br>Water (photolysis)                                       |
|           | <u>CGA331409</u> (EZ-isomer)<br>(E,Z)-Methoxyimino-{2-[1-(3-trifluoro methyl-phenyl)-ethylideneamino-oxymethyl]-phenyl}-acetic acid methyl ester                                                                      | Wheat, Apple, Cucumber,<br>Sugar beet<br>Soil, Water (traces, by<br>photolysis)<br>Fish                              |
|           | <u>CGA321113</u><br>Met 4F, 2G, L7a*, L7b**, I <sub>15</sub> , I <sub>24</sub><br>(E,E)-Methoxyimino-{2-[1-(3-trifluoro methyl-phenyl)-ethylideneaminooxymethyl]-phenyl}-acetic acid (*taurine-, **glycine conjugate) | Wheat, Apple, Cucumber,<br>Sugar beet, Rotational crops<br>Goat, Hen, Rat<br>Soil (hydrolysis pH >5),<br>Water, Fish |
|           | <u>CGA373466</u><br>I <sub>24b</sub><br>(Z,E)-Methoxyimino-{2-[1-(3-trifluoro methyl-phenyl)-ethylideneaminooxymethyl]-phenyl}-acetic acid                                                                            | Wheat, Apple, Sugar beet,<br>Soil (Rotational crops)<br>Soil (bare ground), Water<br>(photolysis)<br>Fish            |
|           | <u>CGA373465</u><br>(E,Z)-Methoxyimino-{2-[1-(3-trifluoro methyl-phenyl)-ethylideneaminooxymethyl]-phenyl}-acetic acid                                                                                                | Soil (Rotational crops)<br>Water (minor, photolysis)                                                                 |
|           | <u>NOA413161</u> (EZ-isomer)<br>I <sub>5</sub><br>(E,Z)-{2-[carboxy-(3-trifluoromethyl-phenyl)-methyleneaminoxy-methyl]-phenyl}-methoxyiminoacetic acid                                                               | Wheat, Rotational crops<br>Soil                                                                                      |
|           | <u>NOA413163</u> (EE-isomer)<br>I <sub>6</sub><br>(E,E)-{2-[carboxy-(3-trifluoromethyl-phenyl)-methyleneaminoxy-methyl]-phenyl}-methoxyiminoacetic acid                                                               | Wheat, Rotational crops<br>Soil                                                                                      |
|           | <u>NOA443152; Met.2U/I</u><br>Met 2U, Met 20U (glucuronide), Met 5F, I <sub>10</sub><br>2-[2-hydroxy-1-(3-trifluoromethyl-phenyl)-ethylideneaminoxy-methyl]-phenyl-methoxyimino-acetic acid                           | Wheat, Cucumber, Sugar beet,<br>Rotational crops<br>Goat<br>Hen<br>Rat                                               |

| Structure                                                                           | Name                                                                                                                                                             | Occurrence                                              |
|-------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------|
|    | <b>BO 172741</b> (E,E isomer)<br>isomer of NOA443152<br>(2-[2-hydroxy-1-(3-trifluoromethyl-phenyl)-ethyldeneaminooxy-methyl]-phenyl)-methoxyimino-acetic acid    | Wheat                                                   |
|    | <b>NOA414412</b><br>I <sub>14</sub> , I <sub>12</sub><br>2-[1-(3-hydroxy-5-trifluoromethyl-phenyl)-ethyldeneaminooxymethyl]-phenyl}-methoxyimino-acetic acid     | Wheat, Cucumber, Sugar beet,<br>Rotational crops<br>Rat |
|    | <b>NOA417076</b><br>(E,E)-2-[1-(4-Hydroxy-3-trifluoromethyl-phenyl)-ethyldeneaminooxymethyl]-phenyl}-methoxyimino-acetic acid                                    | Apple, Cucumber<br>Rat, Hen                             |
|    | <b>Met L13b</b><br>{2-[1-(hydroxy-5-trifluoromethyl-phenyl)-ethyldeneaminooxymethyl]-phenyl}-methoxyimino-acetic acid methyl ester                               | Hen                                                     |
|   | <b>II<sub>21a</sub></b><br>benzeneacetic acid, 2-[[[(1E)-1-[2,3-dihydroxy-5-(trifluoromethyl)phenyl]ethyldene]amino]oxy]-methyl]-a-(methoxyimino)-<br>(CAS name) | Sugar beet                                              |
|  | <b>II 19a</b><br>benzeneacetic acid, 2-[[[(1Z)-1-[2,3-dihydroxy-5-(trifluoromethyl)phenyl]-2-hydroxyethyldene]amino]oxy]methyl]-a-(methoxyimino)-<br>(CAS name)  | Sugar beet                                              |
|  | <b>Met 8F</b><br>{4-hydroxy-2-[2-hydroxy-1-(3-trifluoro methyl-phenyl)-ethyldeneaminooxymethyl]-phenyl}-methoxyimino-acetic acid methyl ester                    | Rat                                                     |
|  | <b>Met 19U</b><br>{4-hydroxy-2-[2-hydroxy-1-(3-trifluoro methyl-phenyl)-ethyldeneaminooxymethyl]-phenyl}-methoxyimino-acetic acid                                | Rat                                                     |

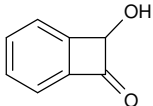
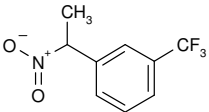
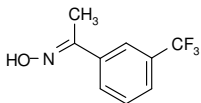
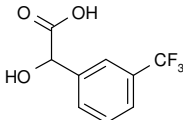
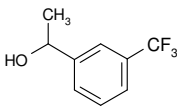
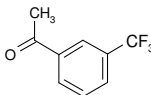
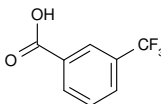
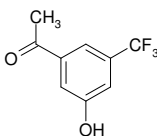
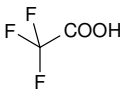
| Structure                                                                                                                                                | Name                                                                                                                                                                                   | Occurrence                                             |
|----------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------|
|                                                                         | <u>Met 7F</u><br>{4-hydroxy-2-[1-(3-trifluoromethyl-phenyl)-ethylideneaminoxymethyl]-phenyl}-methoxyimino-acetic acid methyl ester                                                     | Goat<br>Rat                                            |
|  <p>R<sub>1</sub> = H, R<sub>2</sub> = CH<sub>3</sub> or vice versa</p> | <u>Met 9F</u><br>Chemical name is not available                                                                                                                                        | Rat                                                    |
|                                                                         | <u>Met 3U</u><br>{2-[2-hydroxy-1-(3-trifluoromethyl-phenyl)-ethylideneaminoxymethyl]-phenyl}-nitro-acetic acid methyl ester                                                            | Hen<br>Rat                                             |
|                                                                        | <u>Met 3F</u><br>Met 4aG is the glucuronide<br>hydroxyimino-{2-[2-hydroxy-1-(3-trifluoromethyl-phenyl)-ethylideneaminoxymethyl]-phenyl}-acetic acid methyl ester                       | Goat<br>Hen<br>Rat                                     |
|                                                                       | <u>Met 6U</u><br>Met 5G is the sulfate<br>hydroxyimino-{2-[2-hydroxy-1-(3-trifluoromethyl-phenyl)-ethylideneaminoxymethyl]-phenyl}-acetic acid                                         | Goat<br>Hen<br>Rat                                     |
|                                                                       | <u>Met 5U</u><br>{2-[2-hydroxy-1-(3-trifluoromethyl-phenyl)-ethylideneaminoxymethyl]-phenyl}-oxo-acetic acid                                                                           | Hen<br>Rat                                             |
|                                                                       | <u>EGR1</u><br>{hydroxy-2-[2-hydroxy-1-(3-trifluoromethyl-phenyl)-ethylideneaminoxymethyl]-phenyl}-oxo-acetic acid                                                                     | Hen (from unextractables of egg yolk, workup artefact) |
|                                                                       | <u>Met 4U</u><br>EGR9<br>2-[2-hydroxy-1-(3-trifluoromethyl-phenyl)-ethylideneaminoxymethyl]-benzoic acid                                                                               | Hen<br>Rat                                             |
|                                                                       | <u>NOA405637</u><br>Met 2F<br>The glucuronide conjugate is Met 2F, Met L13a<br>hydroxyimino-{2-[1-(3-trifluoromethyl-phenyl)-ethylideneaminoxymethyl]-phenyl}-acetic acid methyl ester | Goat<br>Hen<br>Rat<br>Fish (cysteine and G-conjugate)  |

| Structure | Name                                                                                                                                            | Occurrence                             |
|-----------|-------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------|
|           | <u>Met 6bG</u><br>(excreted as glucuronide)<br>6-({1-[2-(carboxy-methoxyimino-methyl)-benzyloxyimino]-ethyl}-5-trifluoromethyl-phenoxy)         | Rat                                    |
|           | <u>Met 1U</u><br>Met 6F (Met 6a is the sulfate),<br>hydroxyimino-{2-[1-(3-trifluoromethyl-phenyl)-ethylideneaminooxymethyl]-phenyl}-acetic acid | Goat<br>Hen<br>Rat<br>Fish (conjugate) |
|           | <u>Met EW11</u><br>2-[1-(3-trifluoromethyl-phenyl)-ethylideneaminooxymethyl]-benzaldehyde oxime                                                 | Hen                                    |
|           | <u>EGR10b</u><br>{hydroxy-2-[1-(3-trifluoromethyl-phenyl)-ethylideneaminooxymethyl]-phenyl}-oxo-acetic acid methyl ester                        | Hen (from unextractables of egg yolk)  |
|           | <u>EGR10c</u><br>{hydroxy-2-[1-(3-trifluoromethyl-phenyl)-ethylideneaminooxymethyl]-phenyl}-oxo-acetic acid                                     | Hen (from unextractables of egg yolk)  |
|           | <u>EGR10a</u><br>2-[1-(3-trifluoromethyl-phenyl)-ethylideneaminooxymethyl]-benzoic acid                                                         | Hen (from unextractables of egg yolk)  |
|           | <u>Met L24</u><br>2-[1-(3-trifluoromethyl-phenyl)-ethylideneaminooxymethyl]-benzaldehyde                                                        | Hen                                    |
|           | <u>EGR8</u><br>hydroxy-2-[1-(3-trifluoromethyl-phenyl)-ethylideneaminooxymethyl]-benzoic acid                                                   | Hen (from unextractables of egg yolk)  |
|           | <u>Met 10U</u><br>[2-(hydroxyimino-methoxycarbonyl-methyl)-benzyloxyimino]-(3-trifluoromethyl-phenyl)-acetic acid                               | Rat                                    |
|           | <u>Met 13U</u><br>(2-carbamoyl-benzyloxyimino)-(3-trifluoromethyl-phenyl)-acetic acid<br>(as taurine conjugate)                                 | Rat                                    |

| Structure | Name                                                                                                                                                                 | Occurrence                             |
|-----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------|
|           | <u>Met 14U</u><br>2-[carboxy-(3-trifluoromethyl-phenyl)-methyleneaminoxymethyl]-benzoic acid                                                                         | Rat                                    |
|           | <u>BO 172323</u><br>isomer of BO 172631<br>2-[2-hydroxy-1-(3-trifluoromethyl-phenyl)-ethylideneaminoxymethyl]-benzonitrile                                           | Wheat                                  |
|           | <u>BO 172631</u><br>Met III <sub>5</sub> , L14<br>2-[2-hydroxy-1-(3-trifluoromethyl-phenyl)-ethylideneaminoxymethyl]-benzonitrile                                    | Wheat<br>Hen (artefact)                |
|           | <u>Met EW1b</u><br>hydroxy-2-[2-hydroxy-1-(3-trifluoromethyl-phenyl)-ethylideneaminoxymethyl]-benzonitrile                                                           | Hen                                    |
|           | <u>CGA357276 (E)</u><br>2-[1-(3-trifluoromethyl-phenyl)-ethylideneaminoxymethyl]-benzonitrile                                                                        | Hen (artefact)<br>soil (artefact)      |
|           | <u>NOA409480 (Z)</u><br>2-[1-(3-trifluoromethyl-phenyl)-ethylideneaminoxymethyl]-benzonitrile                                                                        | Soil photolysis<br>(probably artefact) |
|           | <u>CGA373463</u><br>2-(carboxy-methoxyimino-methyl)- benzoic acid                                                                                                    | Rat                                    |
|           | <u>EX5</u><br>(hydroxy-2-hydroxymethyl-phenyl)-methoxyimino-acetic acid                                                                                              | Hen                                    |
|           | <u>F2b2-3a&amp;b (A2)</u><br>methyl ester of CGA373463<br>2-(carboxymethyl-methoxyimino-methyl)-benzoic acid<br>2-[(1E)-N,2-dimethoxy-2-oxoethanimidoyl]benzoic acid | Peanuts                                |

| Structure                                                                           | Name                                                                                                    | Occurrence                                        |
|-------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------|---------------------------------------------------|
|    | <u>CGA347242</u><br>F2b2-3a&b (A1)<br>(2-hydroxyethyl-phenyl)-methoxyimino-acetic acid                  | Apple (intermediate postulated)<br>Peanuts<br>Rat |
|    | <u>Met 18U</u> (as sulfate)<br>hydroxyimino-(2-hydroxymethyl-phenyl)-acetic acid]-ester                 | Rat                                               |
|    | <u>CGA320299</u><br>4-(O-methyloxime)1H-2-benzopyran-3,4-dione, Isochroman-3,4-dione 4-(O-methyl-oxime) | Apple<br>Fish                                     |
|    | <u>CGA289565</u><br>methyl-1-H-2,3-benzoxazine-4-carboxylate                                            | water (hydrolysis at pH 1)                        |
|   | <u>WFX-IX-86</u><br>1H-2,3-benzoxazine-4-carboxylic acid                                                | Peanuts                                           |
|  | <u>CGA166988</u><br>3-H-isobensofuran-1-one                                                             | Hen                                               |
|  | <u>CGA367619</u><br>Met 16U, FHW0115D<br>phthalic acid<br>benzene-1,2-dicarboxylic acid                 | Wheat, Peanut<br>Rat,                             |
|  | <u>FHW0115C</u><br>2-cyanobenzoic acid                                                                  | Wheat                                             |
|  | <u>OHBN</u><br>2-hydroxymethyl benzonitrile                                                             | Water (photolysis)                                |
|  | <u>SA 04275</u><br>unstable conjugate of phthalic acid<br>(CGA367619)                                   | Wheat                                             |

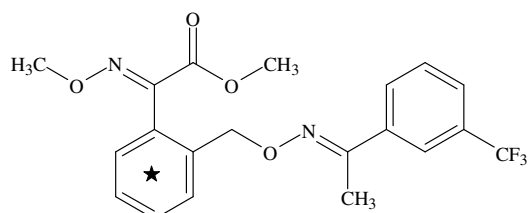


| Structure                                                                           | Name                                                                                    | Occurrence                                          |
|-------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|-----------------------------------------------------|
|    | <u>SA 04271</u><br>8-hydroxybicyclo[4.2.0]octa-1,3,5-trien-7-one                        | Wheat                                               |
|    | <u>Met 8U</u><br>1-(1-nitro-ethyl)-3-trifluoromethyl-benzene                            | Rat                                                 |
|    | <u>CGA300624</u> , Met 11U (S-Conjugate)<br>1-(3-trifluoromethyl-phenyl)-ethanone oxime | Goat<br>Hen<br>Rat                                  |
|    | <u>CGA354870</u> , Met 12U<br>hydroxy-(3-trifluoromethyl-phenyl)-acetic acid            | Goat<br>Hen<br>Rat                                  |
|    | <u>CGA328265</u><br>1-[3-(trifluoromethyl)phenyl]ethanol                                | Peanuts<br>Soil                                     |
|   | <u>CGA107170</u><br>3-trifluoromethyl-acetophenon                                       | Soil and water (photolysis,<br>volatile to the air) |
|  | <u>CGA55641</u> , Met 7U<br>3-trifluoromethyl-benzoic acid                              | Rat                                                 |
|  | <u>BO 17372</u><br>5-hydroxy-3trifluoromethyl-acetophenon                               | Wheat                                               |
|  | <u>TFMB</u><br>Trifluoromethyl benzene                                                  | Soil (photolysis)                                   |
|  | <u>TFA</u><br>Trifluoroacetic acid                                                      | Rotational crops                                    |

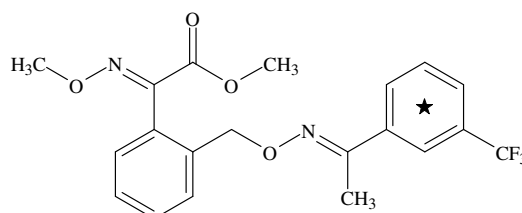
Studies of metabolism and degradation were carried out with [ $^{14}\text{C}$ ]-trifloxystrobin labelled in the *o*-substituted ring or the *m*-substituted ring as shown below.

Note: Trifloxystrobin does not contain a glyoxyl group, but a glyoxyl group is present in an intermediate in its synthesis. As the name Glyoxyl-phenyl- $^{14}\text{C}$ -trifloxystrobin has been used extensively in the manufacturers' references and elsewhere it is retained here.

[Glyoxyl-phenyl- $^{14}\text{C}$ ]-trifloxystrobin



[Trifluoromethyl-phenyl- $^{14}\text{C}$ ]-trifloxystrobin



★ = position of label

### Animal metabolism

The metabolism of trifloxystrobin has been studied in laboratory rats, goats and hens according to GLP. Rat metabolism studies were evaluated by the WHO Core Assessment Group of the 2004 JMPR. A short summary of the rat metabolism in comparison with the goat and hen metabolism is given at the end of this section.

#### *Lactating goat*

Report No. 09/97 (Ruembeli, 1997). Two lactating goats (Gemsfarbige Gebirgsziege strain; 51.7 and 35.1 kg bodyweight) were dosed intraruminally for four consecutive days with [trifluoromethyl-Phenyl- $^{14}\text{C}$ ] trifloxystrobin (purity >99%) by gelatin capsule. The mean dose/day was 170.4 mg trifloxystrobin, equivalent to 107.3 and 100.2 ppm in the feed (mean 103.8 ppm) or 3.48 and 5.0 mg/kg body weight (mean 4.24 mg/kg). Average feed consumptions were 1.6 and 1.7 kg/goat per day (for days 1 to 3).

Urine and faeces were collected separately at 24-hour intervals over the acclimatisation and dosing periods. Milk samples were collected twice daily before and during the treatment period. Morning and evening milks were not mixed and the last milking took place just before the goats were slaughtered. The animals were killed 6 hours after the last dose. At that time, blood, samples of the GI tract, leg muscle, tenderloin, omental fat, perirenal fat, kidney, liver, and bile were taken for analysis.

Radioactivity in all specimens was determined by LSC. Radioactivity in solid samples was determined after combustion or tissue solubilization. TLC and HPLC were used in metabolite identification and characterisation. The goats excreted approximately 65 and 60% of the total dose (milk 0.08 and 0.07%, faeces 45 and 44%, and urine 20 and 15%). Cage wash and cage debris made up 0.3 and 0.7% of the total doses.

The maximum concentration of radioactivity reported in the milk of goat 1 was 0.12 mg/kg trifloxystrobin equivalents, present in milk taken 48-55 hours after the start of dosing. At 24-31 hours, the concentration was 0.119 mg/kg trifloxystrobin equivalents. In goat 2, the highest radioactivity reported was 0.121 mg/kg trifloxystrobin equivalents. This also occurred at the 48-55 hour interval. In the total milk sampled over 78 hours, the average concentrations of trifloxystrobin were 0.084 mg/kg equivalents in goat 1 and 0.086 mg/kg equivalents in goat 2. Total radioactivities in a.m. and p.m.

milk were not determined separately. The distribution of radioactivity in tissues, blood and bile is shown in Table 2.

Table 2. Distribution of the TRR in goat tissues after dosing at the equivalent of 100 ppm in the feed (Report no. 09/97).

| Sample           | % of dose administered |        | mg/kg trifloxystrobin equivalents |        |
|------------------|------------------------|--------|-----------------------------------|--------|
|                  | Goat 1                 | Goat 2 | Goat 1                            | Goat 2 |
| Leg muscle       | 0.036                  | 0.036  | 0.044                             | 0.085  |
| Tenderloin       | 0.002                  | 0.002  | 0.048                             | 0.081  |
| Omental fat      | 0.072                  | 0.028  | 0.148                             | 0.442  |
| Perirenal fat    | 0.035                  | 0.023  | 0.153                             | 0.475  |
| Kidney           | 0.036                  | 0.026  | 1.86                              | 1.79   |
| Liver            | 0.566                  | 0.512  | 4.67                              | 4.99   |
| Blood            | 0.06                   | 0.066  | 0.22                              | 0.28   |
| Bile             | 0.242                  | 0.098  | 69.3                              | 76.8   |
| GIT/rumen        | 21.3                   | 28.2   |                                   |        |
| Total eliminated | 65.2                   | 59.7   |                                   |        |
| Total recovery   | 87.5                   | 88.8   |                                   |        |

GIT: gastrointestinal tract

The storage stability of metabolites present in liver was investigated by comparison of the metabolite distribution in an extract of fresh liver with the metabolite distribution in the same extract stored for 7 months at  $-20^{\circ}\text{C}$ . In addition, liver stored for 4 and 23 months was extracted and compared with the fresh liver. There was no significant difference in extractability, and the composition of the metabolites did not change significantly during storage of the whole liver or of the liver extract.

Investigations with fresh milk extract and milk stored at  $-20^{\circ}\text{C}$  and extracted after 4 and 23 months showed similar results. Residues of trifloxystrobin in liver were between 36 and 191% of the starting concentration over the storage period, and in milk between 80 and 86%.

The quantitative distribution of metabolites in tissues taken at slaughter and in the milk sampled over the dosing period is shown in Table 3.

Table 3. Distribution of metabolites in tissues at slaughter and in milk sampled over the study period (Report no. 09/97).

| Metabolite fraction    | Percentage of radioactivity in sample and ( $\mu\text{g/kg}$ trifloxystrobin equivalents) |          |           |                    |          |         |       |        |
|------------------------|-------------------------------------------------------------------------------------------|----------|-----------|--------------------|----------|---------|-------|--------|
|                        | Muscle                                                                                    | Fat      | Liver     | Liver <sup>1</sup> | Kidneys  | Milk    | Urine | Faeces |
| trifloxystrobin        | 21 (12)                                                                                   | 79 (151) | 2.8 (136) | 2.8 (136)          | 1.8 (34) | 52 (44) |       | 22     |
| CGA321113              | 57 (33)                                                                                   | 10 (20)  | 13 (626)  | 13 (626)           | 54 (993) | 3.6 (3) | 70    | 36     |
| L7a <sup>2</sup>       | 1.2 (0.7)                                                                                 |          | 28 (1337) | 28 (1337)          | 13 (233) | 13 (11) |       |        |
| L7b <sup>3</sup>       | 1.2 (0.7)                                                                                 |          | 9 (435)   | 11 (515)           | 5.2 (95) |         |       | 2.9    |
| Others                 | 8.2                                                                                       | 1.6      | 11        | 24                 | 8.8      | 24      | 24    | 29     |
| No. of other fractions | 7                                                                                         | 3        | 3         | 5                  | 5        | 6       | 5     | 5      |
| Total                  | 88                                                                                        | 91       | 64        | 78                 | 83       | 92      | 94    | 90     |
| Polar                  | 1.3                                                                                       | 0.3      | 2.1       | 16                 | 11       | 2.3     | 6     |        |
| Non-polar              | 0.7                                                                                       | 2.2      | 0.7       | 0.7                | 0.4      | 1.3     |       |        |
| Unextractable          | 9.7                                                                                       | 6.6      | 34        | 5                  | 6.2      | 4.5     |       | 11     |

<sup>1</sup> after microwave-assisted extraction

<sup>2</sup> L7a identified as the taurine conjugate of CGA321113

<sup>3</sup> L7b identified as the glycine conjugate of CGA321113

Report no. 14/97 (Ruembeli, 1997). Two other lactating goats of the same strain (40.1 and 47.5 kg bodyweight) were dosed in the same way for four consecutive days with [Glyoxyl-Phenyl-(U)- $^{14}\text{C}$ ] trifloxystrobin (purity >98%). The mean dose/day was 170.8 mg trifloxystrobin, equivalent to 100.4

ppm in the feed for both goats (4.52 and 3.74 mg/kg body weight/day; average feed consumptions were 1.7 kg/goat per day). The animals were slaughtered about 6 hours after the last dose and samples were taken as before. Sampling of milk, urine and faeces was also as in the previous experiment, and similar analytical procedures were used. At the time of slaughter, the animals weighed 37.8 and 45.7 kg.

Approximately 59 and 58% of the total administered dose was excreted (milk 0.08 and 0.05%; faeces 37 and 35%; urine 18 and 20%). Cage wash and cage debris made up 4 and 3% of the total dose.

The maximum concentration of radioactivity reported in the milk of goat 1 was 0.153 mg/kg as trifloxystrobin equivalents, recorded in milk taken 24-31 hours after commencement of dosing. In goat 2, the maximum concentration was 0.11 mg/kg trifloxystrobin equivalents, at the 55-72 hours interval. In the total milk sampled over 78 hours the average concentrations of trifloxystrobin were 0.097 mg/kg in goat 1 and 0.08 mg/kg in goat 2. The radioactivity in tissues, blood and bile at slaughter was distributed as shown in Table 4.

Table 4. Distribution of the TRR in goat tissues after dosing at the equivalent of 100 ppm in the feed (Report no. 14/97).

| Sample           | % of dose administered |        | mg/kg trifloxystrobin equivalents |        |
|------------------|------------------------|--------|-----------------------------------|--------|
|                  | Goat 1                 | Goat 2 | Goat 1                            | Goat 2 |
| Leg muscle       | 0.11                   | 0.078  | 0.095                             | 0.061  |
| Tenderloin       | 0.003                  | 0.003  | 0.082                             | 0.067  |
| Omental fat      | 0.045                  | 0.06   | 0.52                              | 0.3    |
| Perirenal fat    | 0.014                  | 0.049  | 0.52                              | 0.31   |
| Kidney           | 0.052                  | 0.032  | 2.9                               | 1.7    |
| Liver            | 0.54                   | 0.28   | 5.2                               | 2.6    |
| Blood            | 0.12                   | 0.08   | 0.43                              | 0.24   |
| Bile             | 0.093                  | 0.07   | 58                                | 29     |
| GIT/rumen        | 27                     | 16     |                                   |        |
| Total eliminated | 59                     | 58     |                                   |        |
| Total recovery   | 87                     | 75     |                                   |        |

GIT: gastrointestinal tract

The storage stability of metabolites present in liver was investigated by comparison of the quantitative metabolite pattern of fresh liver extract with the metabolite pattern in the same extract stored at  $-20^{\circ}\text{C}$  and with extracts from whole liver stored frozen and extracted after about 10 and 20 months. There was no significant difference in extractability and the metabolic profile did not change significantly during storage of the whole liver or storage of the liver extracts. Investigations with fresh milk extracts and whole milk stored at  $-20^{\circ}\text{C}$  and extracted after about 10 and 20 months showed similar results. Residues of trifloxystrobin in liver during the storage period were between 92 and 125% of the initial levels. In milk, total residues were virtually unchanged over the storage periods.

The quantitative distribution of metabolites in the tissues taken at slaughter and in the milk sampled over the dosing period is shown in Table 5.

Table 5. Distribution of compounds in tissues at slaughter and in milk sampled over the study period (Report no. 14/97).

| Fraction        | % of radioactivity in sample and ( $\mu\text{g/kg}$ trifloxystrobin equivalents) |          |           |                    |           |           |       |        |
|-----------------|----------------------------------------------------------------------------------|----------|-----------|--------------------|-----------|-----------|-------|--------|
|                 | Muscle                                                                           | Fat      | Liver     | Liver <sup>1</sup> | Kidney    | Milk      | Urine | Faeces |
| Trifloxystrobin | 26 (20)                                                                          | 82 (292) | 1 (40)    | 2.5 (97)           | 1.8 (42)  | 74 (66)   |       | 48     |
| CGA321113       | 51 (39)                                                                          | 11 (40)  | 38 (1493) | 40 (1549)          | 74 (1714) | 4.8 (4.3) | 72    | 13     |
| L7a             | 0.3 (0.2)                                                                        |          | 5.2 (205) | 5.2 (205)          | 1.4 (32)  | 3.3 (2.9) | 1.6   | 0.3    |
| L7b             | 2.0 (1.6)                                                                        |          | 7.9 (310) | 12 (461)           | 4.9 (114) | 1 (0.9)   | 7.3   | 5.3    |
| Others          | 4.6                                                                              |          | 11        | 24                 | 12        | 12        | 11    | 14     |

| Fraction               | % of radioactivity in sample and ( $\mu\text{g/kg}$ trifloxystrobin equivalents) |     |       |                    |        |      |       |        |
|------------------------|----------------------------------------------------------------------------------|-----|-------|--------------------|--------|------|-------|--------|
|                        | Muscle                                                                           | Fat | Liver | Liver <sup>1</sup> | Kidney | Milk | Urine | Faeces |
| No. of other fractions | 2                                                                                | 0   | 6     | 7                  | 4      | 5    | 3     | 5      |
| Total                  | 84                                                                               | 93  | 63    | 84                 | 94     | 95   | 92    | 81     |
| Polar                  | 1.7                                                                              | 1   | 2.7   | 9.9                |        |      | 8.1   | 1.9    |
| Non-polar              | 2.7                                                                              | 4   | 3.1   | 4.4                | 1.3    | 2.5  |       | 2.8    |
| Unextractable          | 11                                                                               | 1.7 | 31    | 2.1                | 5.2    | 2.8  |       | 14     |

<sup>1</sup> after microwave-assisted extraction.

The two studies show that the principal route of elimination in goats is via the faeces and to a lesser extent urine. Comparison of the metabolic profiles in the faeces and urine leads to the conclusion that the metabolism of trifloxystrobin in goats follows the same pathways as in rats. Trifloxystrobin was the major residue in the fat and milk and there was evidence that radioactive residues reached plateau concentrations in the milk. The parent compound is not the major component of the residue in muscle, liver or kidney.

#### *Laying hens*

Report nos. 10/97 and 22/97 (Ruembeli, 1997, 1988). Groups of five laying hens (Leghorn, LSL blanches, 22 weeks old) were dosed orally with trifluoromethyl-phenyl- $^{14}\text{C}$ -trifloxystrobin or glyoxyl-phenyl- $^{14}\text{C}$ -trifloxystrobin by gelatin capsule for four consecutive days. The daily dose was 11.6 or 11.9 mg per bird, equivalent to 91-107.3 or 92-108.3 ppm in the feed (mean for each group 100.7 or 98.9 ppm) corresponding to 7.4-8.1 or 6.2-7.1 mg/kg body weight (mean for groups was 7.7 or 6.7 mg/kg body weight). Daily feed consumption in the two groups during days 1 to 3 of dosing was 107-137 and 105-130 g/day/bird, with means of 116 and 121 g feed/day.

Feed and water were available *ad libitum* (feed intake was measured). Egg production did not appear to be affected by the dosing regime. Excreta and eggs were collected throughout the studies and the birds were killed about 6 hours after the last dose. Blood, thigh and breast muscle, skin with attached fat, peritoneal fat, liver, kidneys, and gastrointestinal tract contents were sampled at the time of slaughter.

Approximately 73 to 83% of the dose in study 10/97 and 74-87% in 22/97 was eliminated in the excreta over the 0-78 hour period.

Study 10/97. In egg whites, the total radioactivity peaked between 24 and 72 hours of dosing. Maximum egg white levels (as trifloxystrobin equivalents over the 0-72 hour dosing period) in each bird were 0.19, 0.14, 0.15, 0.56, and 0.15 mg/kg. Total radioactive residues in the egg yolks increased over time and did not appear to have reached maximum values at the end of the dosing period. Total egg yolk values during 0-78 hours were between 0.71 and 1.24 mg/kg trifloxystrobin equivalents. The radioactivity in egg whites and yolks made up 0.13-0.16% of the total recovered radioactivity.

Lean meat contained 0.11-0.22% of the dose (0.13-0.35 mg/kg trifloxystrobin equivalents), skin and attached fat 0.14-0.39% (0.8-1.8 mg/kg trifloxystrobin equivalents), peritoneal fat 0.07-0.21% (1.9-2.7 mg/kg trifloxystrobin equivalents), kidney 0.11-0.25% (6-13 mg/kg trifloxystrobin equivalents), and liver 0.28-0.62% (3.8-8.6 mg/kg trifloxystrobin equivalents). The total recovered radioactivity (including intestinal and gizzard) was between 78 and 91%.

TLC analysis of liver homogenate and egg white homogenate after approximately 6 and 23 months frozen storage at  $-20^{\circ}\text{C}$  indicated that the extractability and metabolite composition did not change significantly in either case. The stability of trifloxystrobin residues in poultry meat and eggs was not further considered.

The parent compound was the major identified component of the radioactive residue in lean meat, skin with fat, egg yolk and excreta. In egg white and liver, CGA321113 was the major component with little or no parent present. Table 6 summarises the quantitative distribution of major metabolites in tissues, eggs, and excreta, as µg/kg trifloxystrobin equivalents and as% of the sample radioactivity.

Table 6. Distribution of radioactivity in tissues, eggs and excreta (Report no. 10/97).

| Sample                        | Total µg/kg | mg/kg as trifloxystrobin and (% of TRR in sample) |                 |                  |               |
|-------------------------------|-------------|---------------------------------------------------|-----------------|------------------|---------------|
|                               |             | CGA321113                                         | Trifloxystrobin | Total identified | Unextractable |
| Lean meat <sup>1</sup>        | 210         |                                                   | 58 (28%)        | 158 (75%)        | 30 (14%)      |
| Fat and skin <sup>2</sup>     | 1482        | 20 (1.3%)                                         | 820 (55%)       | 1382 (93%)       | 47 (3.2%)     |
| Liver <sup>3</sup>            | 6316        | 321 (5.1%)                                        | 64 (1%)         | 3996 (63%)       | 1825 (29%)    |
| Egg white <sup>4</sup>        | 125         | 32 (26%)                                          |                 | 123 (99%)        | 1.6 (1.3%)    |
| Egg yolk <sup>5</sup>         | 1016        |                                                   | 38 (3.7%)       | 171 (17%)        | 804 (79%)     |
| Excreta (% only) <sup>6</sup> |             | 4.4%                                              | 28%             | 89%              | 11%           |

<sup>1</sup> 8 other fractions isolated (0.7-24.3 µg/kg trifloxystrobin equivalents)

<sup>2</sup> 9 other fractions isolated (10-180 µg/kg trifloxystrobin equivalents)

<sup>3</sup> 13 other fractions isolated (77-798 µg/kg trifloxystrobin equivalents)

<sup>4</sup> 6 other fractions isolated (4.6-48 µg/kg trifloxystrobin equivalents)

<sup>5</sup> 5 other fractions isolated (5.7-48 µg/kg trifloxystrobin equivalents)

<sup>6</sup> 10 other fractions isolated (approximately 57% of the identified radioactivity)

The unextractable fractions from liver were subjected to microwave treatment with 2-propanol/water at 100-180°C and most of the unextractable material was released. At least 13 metabolites or degradation products were present. Each contributed less than 5% of the total radioactive residues in the liver. Microwave-assisted extraction (up to 150°C) of the unextractables in the egg yolk released an additional 78% of the yolk radioactivity. Seven minor metabolites (each less than 5% of the total yolk radioactivity) and three major metabolites or degradation products at levels of 9-35% were released. An additional 4.2% (43 µg/kg) of trifloxystrobin was recovered by microwave extraction.

Trifloxystrobin was the major residue in lean meat and fat plus skin. Comparison of the metabolic profiles in the excreta with those in goat urine and rat faeces lead to the conclusion that metabolism of trifloxystrobin in hens follows the same pathways as in goats and rats. A plateau effect was not clearly demonstrated in egg yolks. Trifloxystrobin was quantifiable (0.038 mg/kg) but not a major constituent of the radioactivity in egg yolk (1.016 mg/kg trifloxystrobin equivalents).

Study 22/97. In the egg yolk the total radioactivity continued to increase over the dosing period. Concentrations of radioactivity (mg/kg trifloxystrobin equivalents) in the yolks were 0-0.003 (0-24 hours), 0.06-0.44 (24-48 hours), 1.2-2 (48-72 hours), and 2.2-2.3 (72-78 hours). In egg whites the total radioactivity gave indications of having reached plateau levels between 24 and 78 hours from the start of dosing; mg/kg trifloxystrobin equivalents over the 0-78 hour period were 0-0.004 (0-24 hours), 0.03-0.18 (24-48 hours), 0.03-0.15 (48-72 hours), and 0.06-0.26 (72-78 hours) with mean concentrations of 0.002, 0.107, 0.067 and 0.14 mg/kg.

Over the 0-78 hour dosing period, 0.005-0.04% of the dose was present in the egg whites and 0.07-0.16% in the egg yolks. Total concentrations of radioactivity in the egg whites were 0.079 and in the egg yolks 0.96 mg/kg trifloxystrobin equivalents (0-78 hours).

After 78 hours, lean meat contained 0.12-0.15% of the dose (0.13-0.20 mg/kg trifloxystrobin equivalents), skin and attached fat 0.18-0.27% (0.66-0.84 mg/kg), peritoneal fat 0.1-0.13% (0.84-1.3 mg/kg), kidney 0.16-0.22% (5.9-9.4 mg/kg), and liver 0.38-0.68% (4.6-8.1 mg/kg). The total recovered radioactivity (including intestinal and gizzard radioactivity) was between 82 and 90%.

TLC analysis of liver and egg white homogenates after approximately 10 and 20 months frozen storage at  $-20^{\circ}\text{C}$  indicated that the extractability and metabolite composition did not change significantly in either case.

In lean meat, skin with fat, and excreta, the parent was a major component. In egg white, CGA321113 was one of the major components, with no parent present. Table 7 summarises the quantitative distribution of the main compounds in tissues, eggs, and excreta as  $\mu\text{g/kg}$  trifloxystrobin equivalents and as % of the sample radioactivity.

Table 7. Distribution of radioactivity in tissues, eggs and excreta (Report no. 22/97).

| Sample              | Total $\mu\text{g/kg}$ | mg/kg as trifloxystrobin and (% of TRR in sample) |        |                 |        |                  |       |
|---------------------|------------------------|---------------------------------------------------|--------|-----------------|--------|------------------|-------|
|                     |                        | CGA321113                                         |        | Trifloxystrobin |        | Total identified |       |
| Lean meat           | 172                    | 8.5                                               | (5%)   | 10              | (6%)   | 64               | (37%) |
| Fat and skin        | 829                    |                                                   |        | 302             | (36%)  | 708              | (85%) |
| Liver               | 5814                   | 183                                               | (3%)   | 22              | (0.4%) | 2930             | (50%) |
| Egg white           | 79                     | 10                                                | (12%)  |                 |        | 59               | (75%) |
| Egg yolk            | 963                    | 5                                                 | (0.5%) | 9               | (1%)   | 77               | (8%)  |
| Excreta<br>(% only) |                        |                                                   | 5.5%   |                 | 20%    |                  | 83%   |
|                     |                        |                                                   |        |                 |        |                  | 12%   |

In the lean meat, 7 other metabolites were identified, ranging in concentration from 3 to 13  $\mu\text{g/kg}$ . In fat and skin, 6 other metabolites were reported (30-170  $\mu\text{g/kg}$ ). Liver contained another 10 metabolites (117-498  $\mu\text{g/kg}$ ), egg white 7 (3-21  $\mu\text{g/kg}$ ) and egg yolk 6 (6-24  $\mu\text{g/kg}$ ).

Most of the unextractables in the liver were released by microwave treatment with 2-propanol/water at  $100-180^{\circ}\text{C}$ . 2-D TLC showed a complex pattern with 14 fractions identified. Each of these contributed less than 5% of the total radioactive residues in the liver. Microwave-assisted extraction (up to  $150^{\circ}\text{C}$ ) of the unextractables in the egg yolk released an additional 79% of the total yolk radioactivity. In the major fraction extracted, several minor metabolites (each less than 5% of the total yolk radioactivity) and three major metabolites or degradation products were released at levels of 4-26% of the total radioactivity.

The results from the two hen studies were comparable and showed that trifloxystrobin residues could be expected in fat and eggs when hens were exposed to levels of 100 ppm trifloxystrobin in the diet. Trifloxystrobin was a major residue in lean meat, and skin with fat. The parent was the major compound found in the excreta.

Comparison of metabolites found in the hen excreta with those in rat faeces and goat urine indicated that the metabolism followed the same principal pathways in the three species. A plateau was not clearly demonstrated in egg yolks. Trifloxystrobin was quantifiable (0.01 mg/kg) but not a major constituent of the total yolk residues (0.96 mg/kg trifloxystrobin equivalents).

#### *Summary – animal metabolism*

In rat metabolism studies evaluated by the WHO Core Assessment Group at the present Meeting the fate of trifloxystrobin was investigated after single oral administrations of the  $^{14}\text{C}$ -labelled compound. Doses of 0.5 mg/kg bw and 100 mg/kg bw were absorbed from the gastro-intestinal tract to the extent of about 60% and about 27 to 41% respectively. Biliary excretion was the major route of elimination. The metabolite pattern in rats is very complex. About 35 metabolites were isolated from urine, faeces and bile and identified. The major steps in the metabolic pathway include hydrolysis of the methyl ester to the corresponding acid, *O*-demethylation of the methoxyimino group yielding a hydroxyimino compound and oxidation of the ethylideneamino methyl group to a primary alcohol, followed by partial oxidation to the corresponding carboxylic acid. These are followed by a complex pattern of

further, minor reactions. Cleavage between the two phenyl moieties accounted for about 10% of the dose.

In goats dosed at the equivalent of 100 ppm the dominant elimination was in the faeces. 0.05 – 0.08% of the total dose was eliminated in the milk which corresponds to about 0.1 mg/kg trifloxystrobin equivalents. Major tissue residues were found in the liver, bile and kidneys accounting for 0.28-0.57%, 0.07-0.24% and 0.026-0.052% of the applied dose respectively. These values correspond to 2.6-5.2, 29-77 and 1.7-2.9 mg/kg as trifloxystrobin equivalents. Minor amounts were found in fat, muscle and blood. The major compounds were the parent trifloxystrobin, its carboxylic acid CGA321113 and conjugates thereof. Demethylation of the methoxyimino group of trifloxystrobin and CGA321113 and hydroxylation of the ethylidene group and the *o*-tolyl ring was found in minor fractions. Cleavage between the two phenyl rings was a minor reaction detected in the study with the trifluoromethyl-phenyl label but was not observed in animals treated with the *o*-tolyl-labelled compound.

In hens dosed at the equivalent of 100 ppm up to 0.16% and 87% of the applied dose was eliminated in the eggs and excreta respectively. Tissue residues (TRR as trifloxystrobin equivalents) 6 h after the last dose were: 0.13-0.35 mg/kg in lean meat, 0.84-2.7 mg/kg in peritoneal fat, 0.66-1.8 mg/kg in skin with attached fat, 3.8-8.6 mg/kg in liver and 5.9-13 mg/kg in kidneys. The maximum concentration in egg white was 0.56 mg/kg and in egg yolk 2.3 mg/kg. Unchanged trifloxystrobin was the major residue in lean meat and skin with fat, and was the major compound eliminated in the excreta. The major metabolite in liver was formed by hydroxylation of the trifluoromethyl-phenyl ring. All the other major metabolites were formed by hydrolysis of the parent molecule to form its carboxylic acid CGA321113 and/or demethylation of the methoxyimino group, followed by decarboxylation, hydrolysis and hydroxylation reactions. Minor reactions were cleavage of the molecule between the two phenyl rings and sulfate conjugation.

The metabolism of trifloxystrobin proceeds in the goat and hen by the same major pathways as in the rat. Overall pathways in goats, hens and rat are shown in Figure 1.

On the basis of the livestock metabolism studies, the sum of the parent compound trifloxystrobin and its metabolite CGA321113 is considered to be the residue of concern in food commodities of animal origin.



Figure 1. Proposed metabolic pathways in goats, hens and rats (part 1).

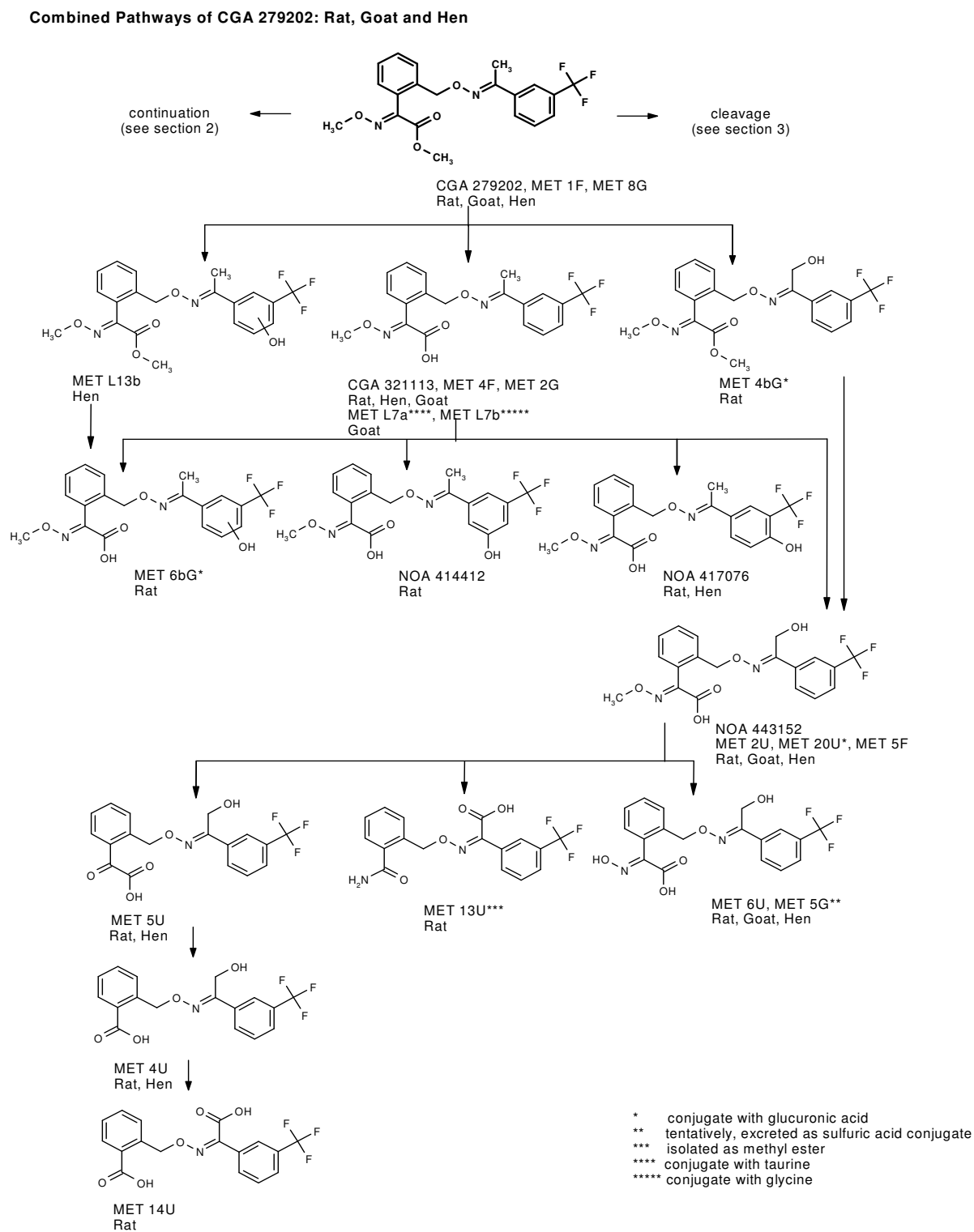


Figure 1 continued. Proposed metabolic pathways in goats, hens and rats (part 2).

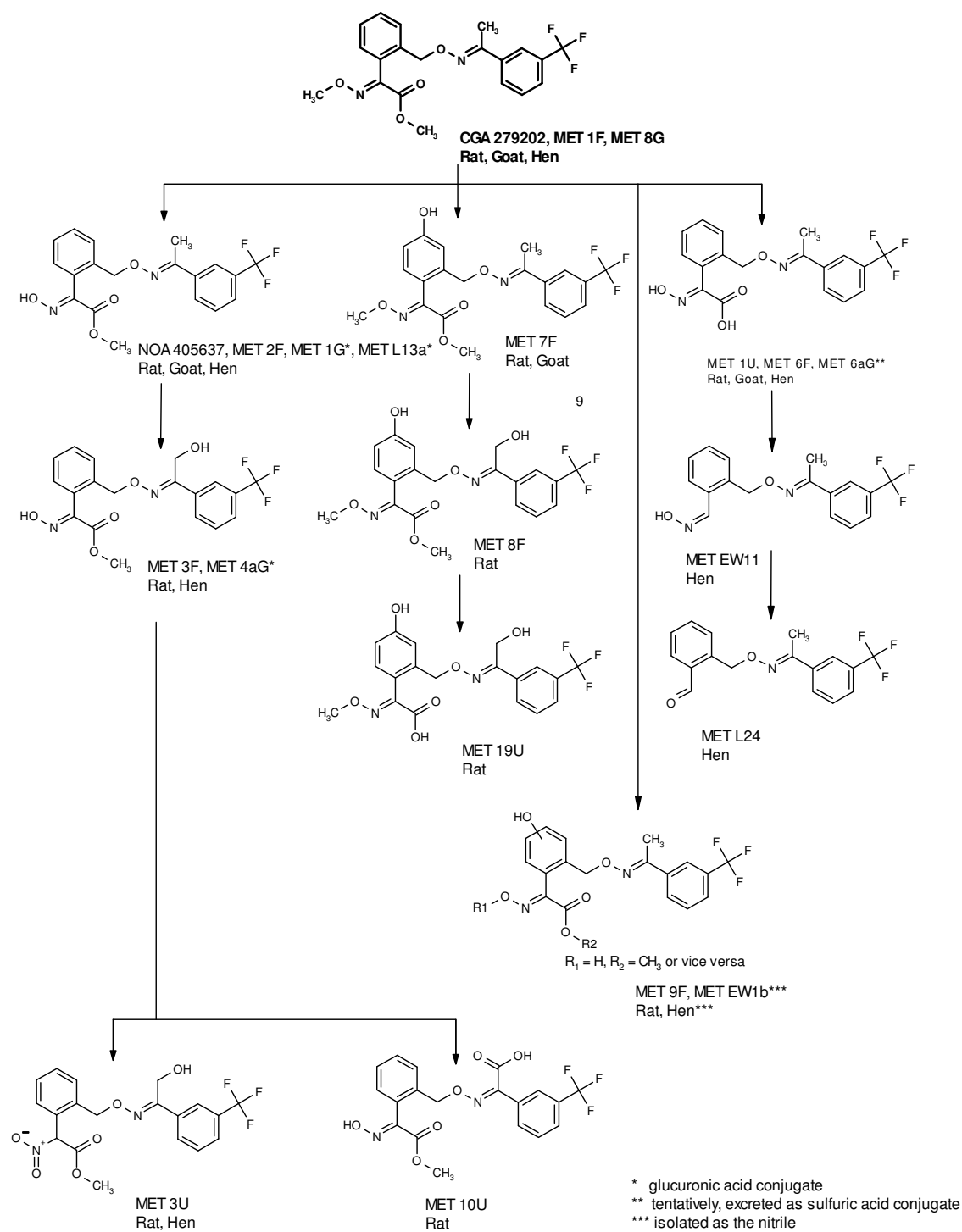
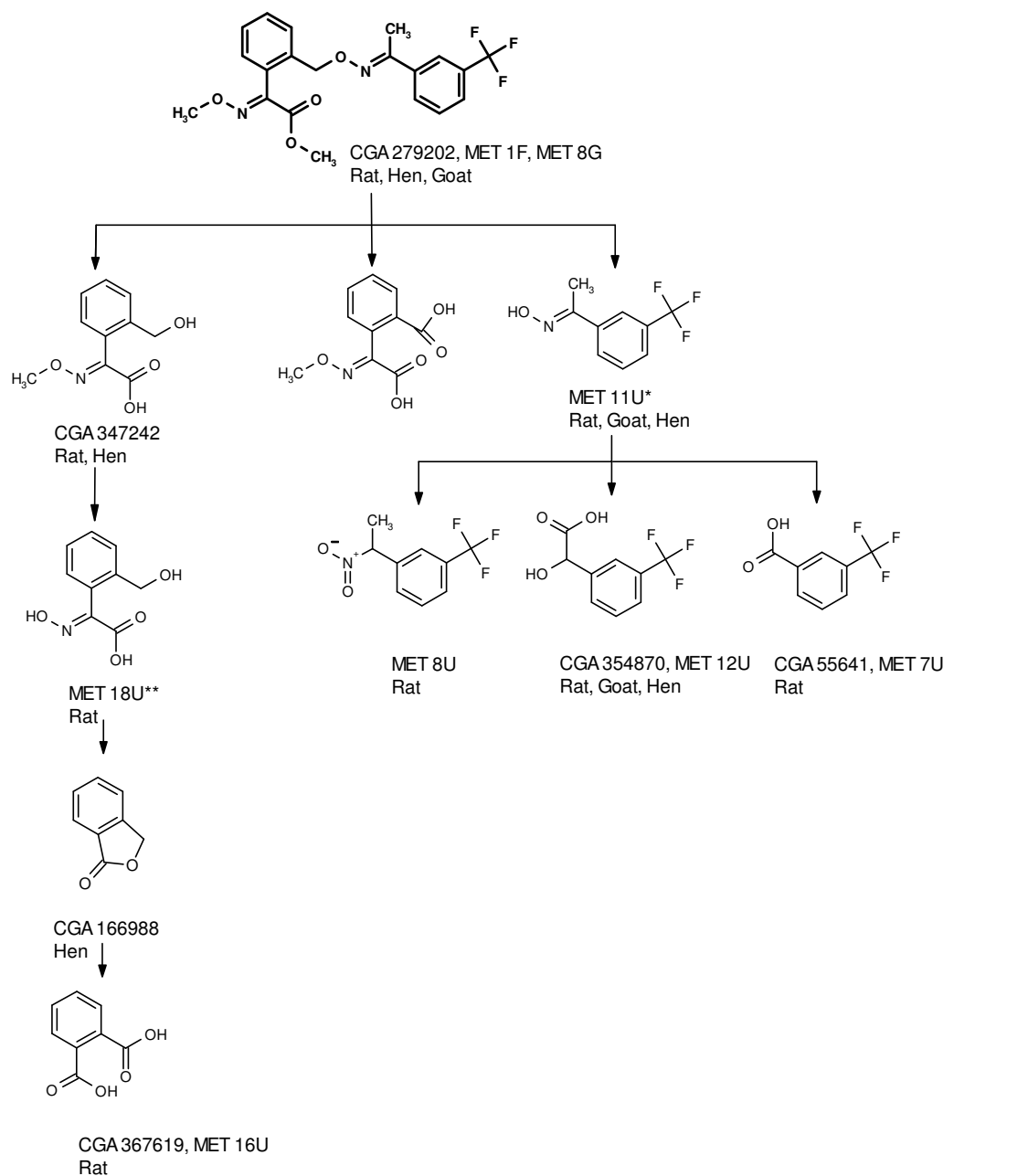


Figure 1 continued. Proposed metabolic pathways in goats, hens and rats (part 3).



\* sulfuric acid conjugate

\*\* tentatively, excreted as sulfuric acid conjugate

### Plant metabolism

The metabolism of trifloxystrobin has been studied after spray application in apples, cucumbers, wheat, sugar beets and peanuts according to GLP.

#### Apples

Report no. CMR 12/97 (Kiffe, 1997). Three apple trees (var. *Golden Delicious*), approximately 4 years old and grown in a greenhouse, were treated with four applications of a WG 50 formulation of

[trifluoromethyl-phenyl-(U)-<sup>14</sup>C] trifloxystrobin at a concentration of 10 g ai/100L. The sprays were applied at 4-week intervals and the total amount applied was equivalent to the recommended 40 g ai/100L (6 x 6.7 g ai/100L) or 400 g ai/ha (1000 trees/ha). The treatments started after flowering. Apples and samples of foliage were taken 1 hour and 2 weeks (harvest) after the fourth application. Apples were washed with acetonitrile/water to determine surface radioactivity and the washed apples were then used for flesh and peel analysis. Radioactivity was determined by liquid scintillation counting (LSC) and metabolites were identified by TLC and HPLC.

At harvest the TRR in the whole fruit was 0.83 mg/kg trifloxystrobin equivalents, with 0.75 mg/kg equivalents in the peel (0.29 mg/kg parent and its isomers) and 0.012 mg/kg equivalents in the pulp (0.002 mg/kg parent and its isomers). In the foliage, the TRR was 46 mg/kg parent equivalents, of which the majority was identified as the parent and its isomers. The quantification of metabolites in different plant fractions is shown below.

Table 8. Quantification of residue fractions in apples after treatment with [CF<sub>3</sub>-phenyl-(U)-<sup>14</sup>C]-trifloxystrobin (Report no. 12/97).

| Sample  | TRR mg/kg <sup>1</sup> | %TRR <sup>2</sup> | Metabolite fractions present at harvest (mg/kg as trifloxystrobin <sup>3</sup> ) |                   |                   |                   |                                |                               |                               |                 |
|---------|------------------------|-------------------|----------------------------------------------------------------------------------|-------------------|-------------------|-------------------|--------------------------------|-------------------------------|-------------------------------|-----------------|
|         |                        |                   | II <sub>8a</sub>                                                                 | II <sub>10a</sub> | II <sub>11a</sub> | II <sub>22a</sub> | II <sub>24b</sub> <sup>4</sup> | II <sub>24</sub> <sup>5</sup> | II <sub>25</sub> <sup>6</sup> | UR <sup>7</sup> |
| Surface |                        | 82                |                                                                                  |                   |                   |                   |                                |                               |                               |                 |
| Peel    | 0.75                   | 17                | 0.012                                                                            | 0.011             | 0.017             | n.d. <sup>8</sup> | 0.009                          |                               | 0.51                          | 0.09            |
| Pulp    | 0.01                   | 1.2               | 0.001                                                                            | 0.001             | <0.001            | 0.001             | 0.001                          |                               | 0.003                         | 0.002           |
| Fruit   | 0.83                   | 100               | 0.003                                                                            | 0.002             | 0.003             | 0.001             | 0.005                          |                               | 0.76                          | 0.04            |
| Foliage | 46                     | 100               | 0.56                                                                             | 1.8               | 0.32              | n.d. <sup>8</sup> | 0.46                           |                               | 36                            | 3.2             |

<sup>1</sup> Trifloxystrobin equivalents.

<sup>2</sup> Sum of radioactivity found on surface, peel, and flesh defined as 100% (whole fruit).

<sup>3</sup> Quantified by 2-D TLC.

<sup>4</sup> CGA373466.

<sup>5</sup> CGA321113.

<sup>6</sup> Consists of trifloxystrobin and its isomers, CGA331409, CGA357262, and CGA357261.

<sup>7</sup> Unresolved.

<sup>8</sup> not detected; limit of detection 0.001 mg/kg.

Trifloxystrobin was the major component of the radioactive residue in all samples (foliage, surface, peel, and flesh). At harvest there was a TRR of 0.83 mg/kg trifloxystrobin equivalents in the whole fruit, of which 0.67 mg/kg was identified as trifloxystrobin, 0.043 mg/kg as CGA357261 (the *Z,E* isomer), 0.018 mg/kg as CGA357262 (the *Z,Z* isomer) and 0.028 mg/kg as, CGA331409 (the *E,Z* isomer). In foliage, the TRR was 46 mg/kg parent equivalents, with 33 mg/kg parent, 2.6 mg/kg CGA357261 1.2 mg/kg CGA357262 and 1.5 mg/kg CGA331409.

Storage stability investigations of peel and flesh samples stored at -18°C for about 8 months indicated no significant change in the metabolite profile either quantitatively or qualitatively. Specific information on the storage stability of trifloxystrobin in apple matrices was not provided.

Report no. CMR13/97 (Kiffe, 1997). Three similar apple trees were treated as above, but with glyoxyl-phenyl-(U)-<sup>14</sup>C-labelled trifloxystrobin.

Foliage was sampled 2 weeks after the last (fourth) application, at harvest. Apples were sampled 1 hour and 2 weeks after the fourth application. The apples were washed (CH<sub>3</sub>CN/water) to determine surface radioactivity and the peel and pulp then analysed separately. Radioactivity was determined by liquid scintillation counting and metabolites were identified by TLC and HPLC.

At harvest the TRR in the whole fruit was 1.3 mg/kg trifloxystrobin equivalents, with 0.7 mg/kg of the TRR in the peel (0.31 mg/kg parent and its isomers), and 0.032 mg/kg in the flesh (0.004 mg/kg parent and its isomers). In the foliage, the TRR was 72 mg/kg equivalents, of which the majority was identified as the parent and its isomers. Extractable radioactivity from the foliage, peel,

and fruit accounted for between 86 and 99.5% of the radioactivity found in the plant parts. Quantification of metabolite fractions in the apples at harvest is shown in Table 9.

Table 9. Quantification of metabolite fractions in apples after treatment with [glyoxyl-phenyl-(U)-<sup>14</sup>C]-trifloxystrobin (Report no. CMR13/97).

| Sample  | TRR mg/kg <sup>1</sup> | % of TRR <sup>2</sup> | Metabolite fractions present at harvest (mg/kg as trifloxystrobin <sup>3</sup> ) |                   |                   |                   |                                |                               |                               |                 |
|---------|------------------------|-----------------------|----------------------------------------------------------------------------------|-------------------|-------------------|-------------------|--------------------------------|-------------------------------|-------------------------------|-----------------|
|         |                        |                       | II <sub>8a</sub>                                                                 | II <sub>10a</sub> | II <sub>11a</sub> | II <sub>22a</sub> | II <sub>24b</sub> <sup>4</sup> | II <sub>24</sub> <sup>5</sup> | II <sub>25</sub> <sup>6</sup> | UR <sup>7</sup> |
| Surface |                        | 87                    |                                                                                  |                   |                   |                   |                                |                               |                               |                 |
| Peel    | 0.70                   | 11                    | 0.061                                                                            |                   |                   | 0.015             | 0.009                          | 0.013                         | 0.45                          | 0.028           |
| Pulp    | 0.032                  | 1.9                   | 0.008                                                                            |                   |                   | 0.002             | 0.001                          |                               | 0.002                         | 0.002           |
| Fruit   | 1.3                    | 100                   | 0.019                                                                            |                   |                   | 0.004             | 0.005                          |                               | 1.2                           | 0.043           |
| Foliage | 72                     | 100                   | 1.1                                                                              | 2.7               | 0.79              | n.d. <sup>8</sup> | n.d. <sup>8</sup>              |                               | 58                            | 6.2             |

<sup>1</sup> Trifloxystrobin equivalents.

<sup>2</sup> Sum of radioactivity found on surface, peel, and pulp defined as 100% (whole fruit).

<sup>3</sup> Quantified by 2-D TLC.

<sup>4</sup> CGA373466.

<sup>5</sup> CGA321113.

<sup>6</sup> Consists of trifloxystrobin and its isomers, CGA331409, CGA357262, and CGA357261.

<sup>7</sup> Unresolved.

<sup>8</sup> not detected; limit of detection 0.001 mg/kg.

Trifloxystrobin was the major component of the radioactivity in the foliage, surface, peel, and pulp. Total radioactive residues of 1.3 mg/kg equivalents in the whole fruit at harvest included 1.1 mg/kg trifloxystrobin, 0.042 mg/kg CGA357261 (the *Z,E* isomer), 0.018 mg/kg CGA357262 (the *Z,Z* isomer) and 0.028 mg/kg CGA331409 (the *E,Z* isomer). In foliage, the total radioactive residues were 72 mg/kg equivalents, with 54 mg/kg parent, 2.8 mg/kg CGA357261, 1.3 mg/kg CGA357262 and 1.9 mg/kg CGA331409.

Stability studies of fruit washings stored at 4°C and peel and pulp samples stored at -18°C for about 7 months indicated no significant changes in the metabolite profile either quantitatively or qualitatively. Specific information on the storage stability of trifloxystrobin in apple matrices was not provided.

The two apple studies showed no significant differences with respect to TRR or the distribution of metabolites in the various fractions analysed. Trifloxystrobin was identified as the major compound associated with harvested apples.

### *Cucumber*

Report nos. CMR22/97 and CMR23/97 (Stingelin, 1997). Cucumber plants (about 7 weeks old) were treated with three applications of [CF<sub>3</sub>-phenyl-(U)-<sup>14</sup>C]trifloxystrobin (CMR23/97) or glyoxyl-phenyl-(U)-<sup>14</sup>C]trifloxystrobin (CMR, 22/97) formulated as 50 WG products. Sprays at concentrations of 20.8 g ai/100l were applied at 7 day intervals, the first application being made shortly after the first flowering. The total amount of active material applied was 940 g ai/ha/season.

Samples of foliage and fruit were collected 0, 1 and 7 days after the final spray. Total radioactivity was determined by combustion analysis and/or scintillation counting. Characterisation of the radioactivity was by TLC.

The distribution of radioactivity in the cucumber foliage and fruit is shown in Tables 10 and 11.

Table 10. Quantification of residue fractions in cucumber plants after treatment with [CF<sub>3</sub>-phenyl-(U)-<sup>14</sup>C]-trifloxystrobin (Report no. CMR23/97).

| Sample/DAT         | TRR<br>(mg/kg equiv.) | Extractable residues, mg/kg and (%TRR) |             |                 |             |             |  |
|--------------------|-----------------------|----------------------------------------|-------------|-----------------|-------------|-------------|--|
|                    |                       | CGA321113                              | CGA357261   | trifloxystrobin | CGA357262   | CGA331409   |  |
| Foliage 0 days     | 34.7                  | 0.38 (1.1)                             | 0.31 (0.9)  | 29 (83.6)       | <0.001 (0)  | 0.6 (1.7)   |  |
| Foliage 7 days     | 16.6                  | 0.23 (1.4)                             | 0.18 (1)    | 13.6 (81)       | <0.001 (0)  | 0.25 (1.5)  |  |
| Small fruit 0 days | 0.9                   | 0.01 (1.1)                             | 0.005 (0.6) | 0.81 (93)       | 0.009 (1.1) | 0.006 (0.7) |  |
| Small fruit 7 days | 0.59                  | 0.017 (2.9)                            | 0.003 (0.5) | 0.51 (86.4)     | 0.012 (2)   | 0.007 (1.2) |  |
| Large fruit 1 day  | 0.4                   | 0.006 (1.5)                            | 0.002 (0.5) | 0.37 (92)       | 0.008 (2)   | 0.005 (1.2) |  |
| Large fruit 7 days | 0.19                  | 0.008 (4.2)                            | 0.002 (1.1) | 0.17 (89.5)     | 0.003 (1.6) | 0.002 (1.1) |  |

DAT: days after treatment

Table 11. Quantification of residue fractions in cucumber plants after treatment with [glyoxyl-phenyl-(U)-<sup>14</sup>C]-trifloxystrobin (Report no. CMR22/97).

| Sample/DAT         | TRR<br>(mg/kg equiv.) | Extractable residues, mg/kg and (%TRR) |             |                 |              |             |  |
|--------------------|-----------------------|----------------------------------------|-------------|-----------------|--------------|-------------|--|
|                    |                       | CGA321113                              | CGA357261   | trifloxystrobin | CGA357262    | CGA331409   |  |
| Foliage 0 days     | 32.7                  | 0.29 (0.9)                             | 0.36 (1.1)  | 28.2 (86.2)     | <0.001 (0)   | 0.72 (2.2)  |  |
| Foliage 7 days     | 24.9                  | 0.32 (1.3)                             | 0.30 (1.2)  | 20.3 (81.5)     | <0.001 (0)   | 0.35 (1.4)  |  |
| Small fruit 0 days | 1.19                  | 0.02 (1.7)                             | 0.01 (0.8)  | 1.0 (86.6)      | 0.015 (1.3)  | 0.013 (1.1) |  |
| Small fruit 7 days | 2.29                  | 0.053 (2.3)                            | 0.021 (0.9) | 2 (87.3)        | <0.001 (0)   | 0.046 (2)   |  |
| Large fruit 1 day  | 0.53                  | 0.007 (1.3)                            | 0.006 (1.1) | 0.46 (86.8)     | <0.001 (0.2) | 0.007 (1.3) |  |
| Large fruit 7 days | 0.3                   | 0.01 (3.3)                             | 0.004 (1.3) | 0.24 (80)       | 0.003 (1)    | 0.003 (1)   |  |

The highest levels of radioactivity (33-35 mg/kg equivalents) occurred in the foliage immediately after application, and these levels fell by approximately 25-50% within 7 days. TLC analysis of the TRRs showed that the main component of the radioactivity in all samples was trifloxystrobin, which constituted 80 to 93% of the TRR. The *cis/trans* isomers of trifloxystrobin were detected at low levels in all samples (CGA357261 0.5 to 1.3% of the TRR; CGA357262 0 to 2%, and CGA331409 0.7 to 2.2%. The free acid of trifloxystrobin (CGA321113) constituted 0.9 to 4.2%.

### Wheat

Report no. CMR15/97 (Gross, 1997). Plots of spring wheat (about 1.5 m<sup>2</sup>) were treated twice with [CF<sub>3</sub>-phenyl-(U)-<sup>14</sup>C]-trifloxystrobin; the first application of 250 g ai/ha was made 41 days after sowing (BBCH 30-31; beginning of shooting/elongation phase), and the second, at the same application rate, 17 days later (BBCH 49-51; late shooting/beginning of ear emergence phase).

Samples of wheat shoots and stalks were collected immediately after the first and second applications (i.e. days 0 and 17). Samples of wheat ears and stalks were collected 24 days after the second application (day 41; 50% crop maturity), and samples of grain, husks and straw were collected 52 days after the second application (day 69; mature wheat). Total radioactive residues were determined by combustion and scintillation counting. Characterisation of the radioactivity was by a series of techniques including solid-phase extraction, microwave extraction, enzyme cleavage and TLC. The distribution of <sup>14</sup>C in the samples is tabulated below (Table 12).

Table 12. Quantification of residue fractions in wheat after treatment with [CF<sub>3</sub>-phenyl-(U)-<sup>14</sup>C]-trifloxystrobin (Report no. CMR15/97).

| Sampling                              | Sample | TRR<br>(mg/kg) | Extract-<br>able<br>(%) | Un-<br>extractable<br>(%) | Characterisation of the extractable residues, mg/kg and (% of the TRR) |                      |               |               |
|---------------------------------------|--------|----------------|-------------------------|---------------------------|------------------------------------------------------------------------|----------------------|---------------|---------------|
|                                       |        |                |                         |                           | CGA<br>357261                                                          | Trifloxy-<br>strobin | CGA<br>357262 | CGA<br>331409 |
| Immediately<br>after 1st<br>treatment | shoots | 14.37          | 98.0                    | 2.0                       | ND                                                                     | 12.89 (89.7%)        | ND            | ND            |

| Sampling                              | Sample | TRR<br>(mg/kg) | Extract-<br>able<br>(%) | Un-<br>extractable<br>(%) | Characterisation of the extractable residues, mg/kg and (% of the TRR) |                      |               |                |
|---------------------------------------|--------|----------------|-------------------------|---------------------------|------------------------------------------------------------------------|----------------------|---------------|----------------|
|                                       |        |                |                         |                           | CGA<br>357261                                                          | Trifloxy-<br>strobin | CGA<br>357262 | CGA<br>331409  |
| Immediately<br>after 2nd<br>treatment | shoots | 10.99          | 95.9                    | 4.1                       | ND                                                                     | 9.28 (84.4%)         | ND            | ND             |
| 24 days after<br>2nd treatment        | ears   | 0.081          | 91.1                    | 11.7                      | -                                                                      | 0.003 (3.7%)         | -             | -              |
|                                       | stalks | 5.473          | 90.0                    | 8.9                       | 0.016 (0.3%)                                                           | 0.038 (0.7%)         | 0.011 (0.2%)  | 0.016 (0.3%)   |
| 52 days after<br>2nd treatment        | grain  | 0.020          | 71.5                    | 33.3                      | -                                                                      | <0.001               | -             | -              |
|                                       | husks  | 0.142          | 70.8                    | 33.8                      | <0.001<br>(<0.7%)                                                      | 0.003 (2.1%)         | 0.001 (0.7%)  | <0.001 (<0.7%) |
|                                       | straw  | 3.851          | 69.2                    | 27.2                      | 0.028 (0.7%)                                                           | 0.033 (0.9%)         | 0.017 (0.4%)  | 0.024 (0.6%)   |

ND: not determined

In mature wheat the highest levels of radioactivity were found in the straw (3.85 mg/kg equivalents), with 0.14 mg/kg equivalents in the husks and 0.02 mg/kg in the grain. The composition of the residue was complex, and trifloxystrobin and its isomers constituted less than 5% of the TRR. The overall metabolic profile in wheat straw and husk showed at least 30 metabolites (unidentified), none of which accounted for more than 7% of the TRR. Comparison of the crude extracts of straw showed that the metabolic profiles in non-polar and polar fractions were qualitatively similar, indicating that metabolism in wheat produces essentially metabolites containing both ring systems.

Report no. CMR18/97 (Gross, 1997). This was a continuation of the study described above, with the aim of identifying the metabolites present in the straw and husk of the treated wheat.

Characterisation of the radioactive compounds now included HPLC, and metabolites were identified by NMR, APCI-MS, GC-MS, and LC-MS, and co-chromatography with reference compounds.

*Cell culture experiment.* Stock cultures of wheat (*Heines Koga II*) were grown as a cell suspension. The cells were allowed to reach the exponential growth phase (5 days) before the addition of <sup>14</sup>C-labelled trifloxystrobin. Cells were harvested 14 days after treatment, homogenized, and subjected to a range of extraction procedures to isolate and identify the radiolabelled metabolites.

The metabolite pattern of CF<sub>2</sub>-phenyl-labelled trifloxystrobin is complex, with up to 35 metabolite fractions found, but most of the metabolites constituted less than 1% of the TRR. The structures identified showed that the metabolism of trifloxystrobin occurred mainly via:

- cleavage of the methyl ester group to form CGA321113;
- hydroxylation of the CF<sub>3</sub>-phenyl ring to form NOA414412;
- oxidation of the ethylidene methyl group to give the isomeric carboxylic acids NOA413161 (EZ) and NOA413163 (EE);
- sugar conjugation of metabolites I<sub>10</sub>, I<sub>12</sub> and I<sub>14</sub> to give the water-soluble metabolites II<sub>8</sub>, II<sub>10</sub> and II<sub>11</sub>, which represent the major part of the radioactivity in immature wheat forage.

The following minor metabolic pathways were identified:

- cis/trans isomerisation of the parent trifloxystrobin and its free acid;
- loss of methoxy from methoxyimino side chain in combination with methyl oxidation of the ethylideneaminoxy group to form metabolite fraction III<sub>5</sub> (i.e. 2-[2-hydroxy-1-(3-trifluoromethylphenyl)ethylideneaminoxymethyl]benzonitrile).

Analysis of the unextractable residues showed that the radioactivity in grain was mostly incorporated into starch. In contrast, the unextractable residues in straw consisted mainly of additional metabolites that were not completely extracted from the matrix (i.e. only a small proportion of the unextractable radioactivity in straw was associated with cell wall fractions such as pectin, cellulose and lignin).

Stingelin, 1997 (Reports CMR04/97 and CMR25/97) carried out identical experiments to those described by Gross (1977; reports CMR15/97 and CMR18/97) except that [glyoxyl-phenyl-(U-; ettt. was used..

Report no. CMR04/97 (Stingelin, 1997). The objectives of this experiment were to determine the rate at which  $^{14}\text{C}$ -labelled trifloxystrobin penetrates the surface of treated wheat plants and to examine the distribution and nature of trifloxystrobin residues in field-grown spring wheat by characterising the extractable radioactivity in shoots, stalks, ears, straw, husks and grain.

Plots of spring wheat (about 2 x 2 m) were treated twice at 250 g ai/ha with [glyoxy]phenyl-(U)- $^{14}\text{C}$ ]-trifloxystrobin 41 and 58 days after sowing, as before.

Plant samples for the penetration study were collected 1 hour, 2 hours, 3 hours, 1 day, 3 days, 7 days and 14 days after the first application. The distribution of the surface and penetrated radioactivite residues is shown in Tables 13 and 14.

Table 13. Surface radioactivity in wheat (Report no. CMR04/97).

| Sampling time after application | TRR (mg/kg equiv.) | Surface radio-activity (%) | Characterisation of the surface radioactivity |                     |                           |                     |                     |                       |
|---------------------------------|--------------------|----------------------------|-----------------------------------------------|---------------------|---------------------------|---------------------|---------------------|-----------------------|
|                                 |                    |                            | CGA 331409 (EZ) (%)                           | CGA 357262 (ZZ) (%) | trifloxy-strobin (EE) (%) | CGA 357261 (ZE) (%) | CGA 321113 (EE) (%) | Polar metabolites (%) |
| 1 hour                          | 11.70              | 96.9                       | 3.7                                           | ND                  | 89.0                      | 3.1                 | ND                  | 2.4                   |
| 3 hours                         | 10.57              | 96.3                       | 4.4                                           | ND                  | 85.0                      | 6.5                 | ND                  | 2.2                   |
| 24 hours                        | 12.47              | 106.5                      | 3.8                                           | 2.1                 | 80.0                      | 8.4                 | ND                  | 4.2                   |
| 3 days                          | 7.28               | 86.4                       | 2.5                                           | 1.4                 | 83.6                      | 5.7                 | ND                  | 5.5                   |
| 7 days                          | 6.09               | 88.3                       | 1.9                                           | 1.0                 | 84.7                      | 4.7                 | ND                  | 5.0                   |
| 14 days                         | 2.29               | 41.9                       | 2.4                                           | 3.3                 | 76.5                      | 8.5                 | ND                  | 7.6                   |

ND: not determined

Table 14. Penetrated radioactivity in wheat (Report no. CMR04/97).

| Sampling time after application | TRRs (mg/kg equiv.) | Penetrated radio-activity (%) | Characterisation of the penetrated radioactivity |                     |                           |                     |                     |                       |
|---------------------------------|---------------------|-------------------------------|--------------------------------------------------|---------------------|---------------------------|---------------------|---------------------|-----------------------|
|                                 |                     |                               | CGA 331409 (EZ) (%)                              | CGA 357262 (ZZ) (%) | trifloxy-strobin (EE) (%) | CGA 357261 (ZE) (%) | CGA 321113 (EE) (%) | Polar metabolites (%) |
| 1 hour                          | 11.70               | 3.1                           | 4.4                                              | ND                  | 73.5                      | 3.2                 | 2.9                 | 12.5                  |
| 3 hours                         | 10.57               | 5.6                           | 5.8                                              | 2.0                 | 64.0                      | 5.6                 | 7.2                 | 17.5                  |
| 24 hours                        | 12.47               | 15.1                          | 8.1                                              | 2.6                 | 37.3                      | 8.2                 | 2.9                 | 39.2                  |
| 3 days                          | 7.28                | 28.9                          | 4.4                                              | 2.8                 | 17.5                      | 2.8                 | 0.5                 | 66.8                  |
| 7 days                          | 6.09                | 30.9                          | 2.8                                              | 2.5                 | 13.6                      | 2.6                 | 0.9                 | 69.5                  |
| 14 days                         | 2.29                | 43.8                          | 1.4                                              | 1.3                 | 9.1                       | 1.6                 | 0.7                 | 80.2                  |

ND: not determined

The results show that penetration of the wheat plant by trifloxystrobin is quite rapid, reaching about 15% within 24 hours and about 30% within 3 days. Characterisation of the surface residue revealed that trifloxystrobin is relatively stable photolytically as the level of the parent compound on the plant surface fell only from 89% after 1 hour to 76.5% after 14 days. In contrast, the penetrated trifloxystrobin appeared to undergo exponential decay, resulting in an apparent half-life of about 12 hours. The decrease in penetrated trifloxystrobin levels was correlated with an increase in the levels of polar metabolites.

In the associated *metabolism study* shoots were collected immediately after the first and second applications of  $^{14}\text{C}$ -labelled trifloxystrobin (i.e. days 0 and 17 of the experiment), ears and



stalks 24 days after the second application (day 41 of the experiment; 50% crop maturity), and grain, husks and straw 52 days after the second application (day 69; mature wheat).

Total radioactive residues were determined by combustion analysis and scintillation counting, and the products characterised by autoradiography, TLC, HPLC, enzyme cleavage and acid hydrolysis.

The distribution of  $^{14}\text{C}$  is shown in Table 15.

Table 15. Distribution of residues in wheat (Report no. CMR04/97).

| Sampling time                     | Sample | TRR (mg/kg equiv.) | Extractable (%) | Unextractable (%) | Characterisation of extractable residues, mg/kg and (% of the TRR) |                      |                |                |
|-----------------------------------|--------|--------------------|-----------------|-------------------|--------------------------------------------------------------------|----------------------|----------------|----------------|
|                                   |        |                    |                 |                   | CGA357261 (ZE)                                                     | trifloxystrobin (EE) | CGA357262 (ZZ) | CGA331409 (EZ) |
| Immediately after first treatment | shoots | 10.24              | --              | --                | ND                                                                 | ND                   | ND             | ND             |
| Immediately after 2nd treatment   | shoots | 7.255              | 98.1            | 1.9               | ND                                                                 | ND                   | ND             | ND             |
| 24 days after 2nd treatment       | ears   | 0.411              | 97.3            | 2.8               | 0.001 (0.3%)                                                       | 0.002 (0.6%)         | <0.001 (0.1%)  | <0.001 (0.1%)  |
|                                   | stalks | 4.650              | 101.3           | 2.6               | 0.040 (0.9%)                                                       | 0.180 (3.9%)         | 0.018 (0.4%)   | 0.022 (0.5%)   |
| 52 days after 2nd treatment       | grain  | 0.099              | 76.9            | 29.0              | 0.001 (1.2 %)                                                      | 0.001 (1.3 %)        | --             | --             |
|                                   | husks  | 0.780              | 71.7            | 24.1              | 0.011 (1.4%)                                                       | 0.007 (0.8%)         | --             | --             |
|                                   | straw  | 5.482              | 75.7            | 15.8              | 0.057 (1.0%)                                                       | 0.123 (2.2%)         | 0.023 (0.4%)   | 0.037 (0.7%)   |

ND: not determined

The overall metabolic profile in wheat straw and husk showed at least 30 fractions, none of which accounted for more than 5% of the TRR. Hydrolysis of grain, husk and straw samples with hydrochloric acid at 100°C for 16-18 hours resulted in the release of two main products, 3*H*-isobenzofuran-1-one (phthalide) and benzene-1,2-dicarboxylic acid (phthalic acid). The results indicate that the glyoxylphenyl ring played only a minor role in the transformation of trifloxystrobin. The phthalide is believed to originate from metabolites with an intact bridge between the two phenyl ring systems, while the precursors of the phthalic acid derivative contained only the glyoxylphenyl part of the original molecule with an oxidised side chain. It was concluded that the phthalide/phthalic acid products of acid hydrolysis could not be used as a common moiety for residues analysis, since the phthalide may be released as a natural compound from wheat grain at levels of 0.05 mg/kg, and the phthalic acid may potentially be present in samples as a result of contact with packaging material.

Report no. CMR25/97 Stingelin, 1997). Plots of spring wheat (about 1.5 m) were treated twice with [glyoxyl-phenyl-(U)- $^{14}\text{C}$ ]-trifloxystrobin. The details of treatment, sample collection and metabolite identification were as in the studies by Gross (1997).

The metabolite pattern of [glyoxyl-phenyl-(U)-trifloxystrobin is complex and virtually identical to that of the CF<sub>3</sub>-phenyl-labelled compound identified by Gross (1997), although the author also detected the formation of the minor products CGA166988 (3*H*-isobenzofuran-1-one), quoted above, and 2-[1-(3-trifluoromethylphenyl) ethylideneamino-oxymethyl]-benzonitrile, which may be artefacts of the decarboxylation/acid hydrolysis of genuine metabolites. Again, most of the metabolites constituted less than 1% of the TRR.

Analysis of the unextracted residues again showed that the radioactivity in grain was mostly incorporated into starch whereas those in straw consisted mainly of additional metabolites that were not completely extracted from the matrix.

Report no. MR-027/02 (Reiner and Bongartz, 2002). The metabolism of trifloxystrobin in the straw and grain of spring wheat was investigated after two spray applications of 250 g/ha [trifluoromethyl-

phenyl-UL-14C]trifloxystrobin giving the seasonal maximum rate of 500 g ai/ha. The first application was at growth stage 33 of the BBCH code and the second at growth stage 69, 42 days after the first.

Immature hay samples were collected 3 days after the second application, and grain and straw were harvested at maturity, 32 days later. Samples were first homogenized at room temperature with acetonitrile/water 8:2, then treated by microwave extraction at 150°C using acetonitrile/water. Remaining solids were treated with the starch-cleaving enzyme diastase.

Radioactivity was measured in solid samples by LSC after combustion, and in extracts after separation in various TLC and HPLC systems. Characterisation, identification and structure elucidation of metabolites was by co-chromatography with reference standard compounds, LC/MS/MS and <sup>1</sup>H-NMR spectrometry.

The total radioactive residue in hay amounted to 5.2 mg/kg expressed as the parent compound. 92.3% of the TRR was extracted with acetonitrile/water at room temperature and was partitioned into a dichloromethane phase and an aqueous phase. A further 5.6% of the TRR was in the microwave extract.

The TRR in straw amounted to 6.13 mg/kg and the extraction procedure was the same as with hay. Only 71.9% of the TRR was in the initial acetonitrile/water extract whereas that in the microwave extract increased to 19.1% of the TRR.

The TRR in grain was only 0.12 mg/kg and 66.9% of it was extracted with acetonitrile/water. The remaining solids (solids 1, 33.1%, 0.040 mg/kg) were treated with diastase which released an additional 21.4%. After diastase treatment, only 0.014 mg/kg of the TRR remained unextracted.

The results are given in Table 16.

Table 16. Total residues in spring wheat after two applications of [CF<sub>3</sub>-phenyl-UL-<sup>14</sup>C]-trifloxystrobin (Report no. MR-027/02).

| Fraction (50 g of sample extracted)   | hay   |        | straw  |        | grain  |         |
|---------------------------------------|-------|--------|--------|--------|--------|---------|
|                                       | %     | mg/kg  | %      | mg/kg  | %      | mg/kg   |
| dichloromethane phase                 | 53.0  | 2.75   | 47.8   | 2.93   | 26.2   | 0.032   |
| aqueous phase (1)                     | 39.3  | 2.04   | 24.1   | 1.48   | 40.7   | 0.049   |
| (solids 1, further extracted)         | (7.7) | (0.40) | (28.1) | (1.72) | (33.1) | (0.04)  |
| microwave extract                     | 5.6   | 0.29   | 19.1   | 1.17   | n.a.   | n.a.    |
| diastase extract (further hydrolysed) | n.a.  | n.a.   | n.a.   | n.a.   | (21.4) | (0.026) |
| toluene phase                         | n.a.  | n.a.   | n.a.   | n.a.   | 10.5   | 0.013   |
| aqueous phase 2                       | n.a.  | n.a.   | n.a.   | n.a.   | 10.9   | 0.013   |
| solids 2 (unextracted residue)        | 2.1   | 0.11   | 9.0    | 0.55   | 11.7   | 0.014   |
| Total radioactive residue (TRR)       | 100   | 5.2    | 100    | 6.13   | 100    | 0.12    |

n.a. not analysed

The identified extracted radioactive residues were grouped as parent compound plus isomers, other metabolites and aglycones. The sum of the parent isomers accounted for 43.5% (2.26 mg/kg) of the TRR in hay, 25.5% (1.56 mg/kg) in straw and 39.7% (0.048 mg/kg) in grain. In total, 80.7% (4.19 mg/kg) of the TRR was identified in hay, 67.1% (4.11 mg/kg) in straw and 61.4% (0.074 mg/kg) in grain. The remaining extracted radioactivity was characterised as fractionated by the extraction procedure, partitioning in aqueous and dichloromethane phases and HPLC or TLC analysis. Details are given in Tables 17 for hay, 18 for straw and 19 for grain.

Table 17. Characterisation and identification of radioactive residues in hay after treatment of wheat plants with [trifluoromethyl-phenyl-UL-<sup>14</sup>C]-trifloxystrobin (Report no. MR-027/02).

| Compound or fraction                                                   | Description                              | Occurrence | %      | mg/kg  |
|------------------------------------------------------------------------|------------------------------------------|------------|--------|--------|
| Total identified (parent isomers, metabolites and aglycones)           |                                          |            | (80.7) | (4.19) |
| Total trifloxystrobin isomers                                          |                                          |            | (43.5) | (2.26) |
| CGA357261                                                              | Z,E-isomer                               | D, M       | 6.7    | 0.35   |
| trifloxystrobin                                                        | E,E-isomer                               | D, M       | 31.1   | 1.61   |
| CGA357262                                                              | Z,Z-isomer                               | D          | 2.0    | 0.11   |
| CGA331409                                                              | E,Z-isomer                               | D          | 3.8    | 0.20   |
| Other identified metabolites                                           |                                          |            | (10.3) | (0.54) |
| CGA321113                                                              | carboxylic acid                          | D          | 1.6    | 0.08   |
| CGA373466                                                              | carboxylic acid                          | D          | 0.3    | 0.02   |
| NOA414412                                                              | CF <sub>3</sub> -ring-OH-carboxylic acid | D          | 2.1    | 0.11   |
| NOA443152                                                              | hydroxycarboxylic acid                   | D          | 1.8    | 0.09   |
| BO172741                                                               | hydroxycarboxylic acid                   | D          | 0.9    | 0.04   |
| (isomer of NOA443152)                                                  |                                          |            |        |        |
| NOA413163                                                              | dicarboxylic acid                        | A          | 3.7    | 0.19   |
| NOA413161                                                              | dicarboxylic acid                        | A          | n.d.   | n.d.   |
| Identified aglycones of the following conjugates                       |                                          |            | (26.8) | (1.39) |
| conjugate 1 of NOA414412                                               | CF <sub>3</sub> -ring-OH-carboxylic acid | A          | 3.5    | 0.18   |
| conjugate 2 of NOA414412                                               | CF <sub>3</sub> -ring-OH-carboxylic acid | A          | 5.3    | 0.28   |
| conjugate 1 of NOA443152                                               | hydroxycarboxylic acid                   | A          | 8.1    | 0.42   |
| conjugate 2 of NOA443152                                               | hydroxycarboxylic acid                   | A          | 0.9    | 0.05   |
| conjugate 1 of BO172741                                                | hydroxycarboxylic acid                   | A          | 4.5    | 0.23   |
| conjugate 2 of BO172741                                                | hydroxycarboxylic acid                   | A          | 3.7    | 0.19   |
| conjugate of BO172631                                                  | hydroxynitrile                           | M          | 0.3    | 0.02   |
| conjugate of BO172323                                                  | hydroxynitrile                           | M          | 0.6    | 0.03   |
| Subtotals characterised by extraction procedure, partitioning and HPLC |                                          |            | (17.2) | (0.89) |
| regions 1, 2, 4, 6 and 10 (each ≤0.07 mg/kg)                           |                                          | D          | 4.3    | 0.22   |
| regions 1-5, 7, 12, 14 and 15 (each ≤0.09 mg/kg)                       |                                          | A          | 9.7    | 0.50   |
| regions 3-6 (each ≤0.09 mg/kg)                                         |                                          | M          | 3.2    | 0.17   |
| Total extracted                                                        |                                          |            | 97.9   | 5.09   |
| Solids 2 (unextracted residue)                                         |                                          |            | 2.1    | 0.11   |
| Total residue                                                          |                                          |            | 100.0  | 5.20   |

A: aqueous phase

D: dichloromethane phase

M: microwave extract

Table 18. Characterisation and identification of radioactive residues in straw after treatment of wheat plants with [trifluoromethyl-phenyl-UL-<sup>14</sup>C]-trifloxystrobin (Report no. MR-027/02).

| Compound or fraction                                         | Description | Occurrence | %      | mg/kg  |
|--------------------------------------------------------------|-------------|------------|--------|--------|
| Total identified (parent isomers, metabolites and aglycones) |             |            | (67.1) | (4.11) |
| Total trifloxystrobin isomers                                |             |            | (25.5) | (1.56) |
| CGA357261                                                    | Z,E-isomer  | D, M       | 5.3    | 0.32   |
| trifloxystrobin                                              | E,E-isomer  | D, M       | 14.3   | 0.88   |
| CGA357262                                                    | Z,Z-isomer  | D          | 2.4    | 0.14   |

| Compound or fraction                                                   | Description                              | Occurrence | %      | mg/kg  |
|------------------------------------------------------------------------|------------------------------------------|------------|--------|--------|
| CGA331409                                                              | E,Z-isomer                               | D          | 3.6    | 0.22   |
| Other identified metabolites                                           |                                          |            | (34.1) | (2.09) |
| CGA321113                                                              | carboxylic acid                          | D          | 4.2    | 0.26   |
| CGA373466                                                              | carboxylic acid                          | D          | 1.8    | 0.11   |
| NOA414412                                                              | CF <sub>3</sub> -ring-OH-carboxylic acid | D, A       | 7.0    | 0.43   |
| NOA443152                                                              | hydroxycarboxylic acid                   | D, A       | 6.5    | 0.40   |
| BO172741<br>(isomer of NOA443152)                                      | hydroxycarboxylic acid                   | D, A       | 4.1    | 0.25   |
| BO172631                                                               | hydroxycyano compound                    | D          | 1.0    | 0.06   |
| BO172323                                                               | hydroxycyano compound                    | D          | 0.9    | 0.05   |
| BO17372                                                                | CF <sub>3</sub> -ring-OH                 | A          | 0.9    | 0.06   |
| NOA413163                                                              | dicarboxylic acid                        | A          | 5.8    | 0.35   |
| NOA413161                                                              | dicarboxylic acid                        | A          | 1.8    | 0.11   |
| Identified aglycones of the following conjugates                       |                                          |            | (7.6)  | (0.46) |
| conjugate 1 of NOA414412                                               | CF <sub>3</sub> -ring-OH-carboxylic acid | A          | 0.5    | 0.03   |
| conjugate 2 of NOA414412                                               | CF <sub>3</sub> -ring-OH-carboxylic acid | A          | 0.7    | 0.04   |
| conjugate 1 of NOA443152                                               | hydroxycarboxylic acid                   | A          | 2.2    | 0.14   |
| conjugate 2 of NOA443152                                               | hydroxycarboxylic acid                   | A          | 0.7    | 0.04   |
| conjugate 1 of BO172741                                                | hydroxycarboxylic acid                   | A          | 1.1    | 0.07   |
| conjugate of BO172631                                                  | hydroxycyano compound                    | M          | 1.3    | 0.08   |
| conjugate of BO172323                                                  | hydroxycyano compound                    | M          | 1.1    | 0.07   |
| Subtotals characterised by extraction procedure, partitioning and HPLC |                                          |            | (23.9) | (1.46) |
| regions 1-8, 10, 11, 14, 18, 20, 21 (each ≤0.04 mg/kg)                 |                                          | D          | 4.3    | 0.26   |
| regions 1-10, 13, 15, 21 and 23 (each ≤0.07 mg/kg)                     |                                          | A          | 6.0    | 0.37   |
| regions 1-3, 5, 7-12 (each ≤0.23 mg/kg)                                |                                          | M          | 13.5   | 0.83   |
| Total extracted                                                        |                                          |            | 91     | 5.58   |
| Solids 2 (unextracted residue)                                         |                                          |            | 9.0    | 0.55   |
| Total residue                                                          |                                          |            | 100    | 6.13   |

A: aqueous phase

D: dichloromethane phase

M: microwave extract

Table 19. Characterisation and identification of radioactive residues in grain after treatment of wheat plants with [trifluoromethyl-phenyl-UL-<sup>14</sup>C]-trifloxystrobin (Report no. MR-027/02).

| Compound or fraction                                         | Description                              | Occurrence | %      | mg/kg   |
|--------------------------------------------------------------|------------------------------------------|------------|--------|---------|
| Total identified (parent isomers, metabolites and aglycones) |                                          |            | (61.4) | (0.074) |
| Total trifloxystrobin isomers                                |                                          |            | (39.7) | (0.048) |
| CGA357261                                                    | Z,E-isomer                               | D, A1      | 8.0    | 0.010   |
| Trifloxystrobin                                              | E,E-isomer                               | D, A1      | 19.6   | 0.024   |
| CGA357262                                                    | Z,Z-isomer                               | D, A1      | 6.3    | 0.008   |
| CGA331409                                                    | E,Z-isomer                               | D, A1      | 5.8    | 0.007   |
| Other identified metabolites                                 |                                          |            | (21.7) | (0.026) |
| CGA321113                                                    | carboxylic acid                          | D          | 2.6    | 0.003   |
| CGA373466                                                    | carboxylic acid                          | D          | 1.2    | 0.001   |
| NOA414412                                                    | CF <sub>3</sub> -ring-OH-carboxylic acid | D          | 5.2    | 0.006   |
| NOA443152                                                    | hydroxycarboxylic acid                   | D          | 4.6    | 0.006   |

| Compound or fraction                                                                                                   | Description            | Occurrence | %      | mg/kg   |
|------------------------------------------------------------------------------------------------------------------------|------------------------|------------|--------|---------|
| BO172741<br>(isomer of NOA443152)                                                                                      | hydroxycarboxylic acid | D          | 1.5    | 0.002   |
| NOA413163                                                                                                              | dicarboxylic acid      | A1         | 2.9    | 0.004   |
| NOA413161                                                                                                              | dicarboxylic acid      | A1         | 0.3    | <0.001  |
| glucoside of NOA443152                                                                                                 | hydroxycarboxylic acid | A1         | 3.4    | 0.004   |
| Subtotals characterised by extraction procedure, enzymatic hydrolysis, acidic hydrolysis, partitioning and HPLC or TLC |                        |            | (26.9) | (0.032) |
| regions 1-3 (each $\leq 0.003$ mg/kg)                                                                                  |                        | A1         | 5.5    | 0.007   |
| regions 1-4 (each $\leq 0.007$ mg/kg)                                                                                  |                        | T          | 10.5   | 0.013   |
| aqueous phase 2, polar radioactivity                                                                                   |                        | A2         | 10.9   | 0.013   |
| Total extracted                                                                                                        |                        |            | 88.3   | 0.106   |
| Solids 2 (unextracted residue)                                                                                         |                        |            | 11.7   | 0.014   |
| Total residue                                                                                                          |                        |            | 100    | 0.12    |

A1, A2: aqueous phase

D: dichloromethane phase

T: toluene phase

Significant amounts of the parent compound (E,E-isomer) were isomerized. A main metabolic reaction in spring wheat was the hydrolysis of the parent methyl ester. Hydroxylation of the ethylidene methyl group and the 1,3-disubstituted trifluoromethyl ring at the meta-position was also important. Significant amounts of the hydroxylated metabolites were also detected as sugar conjugates. The methyl group was partly oxidised to carboxy. A hydroxylated iminomethyl group was also present in two minor metabolites (isomers) in hay and straw.

Report no. MR-028/02 (Reiner and Bongartz, 2002). This was identical to the previous study, except that [glyoxyl-phenyl-UL- $^{14}$ C]-trifloxystrobin was used.

The TRR in hay amounted to 5.98 mg/kg expressed as parent compound; 94.1% of the TRR was extracted with acetonitrile/water and partitioned into dichloromethane and aqueous phases, and a further 4.5% was in the microwave extract.

The TRR in straw amounted to 6.12 mg/kg, of which 76.3% was extracted with acetonitrile/water and 16.9% by microwave extraction.

The TRR in grain was 0.262 mg/kg and 76.5% was extracted with acetonitrile/water. Solids 1 (23.5%, 0.061 mg/kg) when treated with diastase yielded 17.0% of soluble residue, with only 0.017 mg/kg of the TRR remaining unextracted in solids 2. The results are summarized in Table 20.

Table 20. Total residues in plant parts of spring wheat at various time intervals after two applications of [glyoxyl-phenyl-UL- $^{14}$ C]-trifloxystrobin (Report no. MR-028/02).

| Fraction (50 g of sample extracted)   | hay   |        | straw  |        | grain  |         |
|---------------------------------------|-------|--------|--------|--------|--------|---------|
|                                       | %     | mg/kg  | %      | mg/kg  | %      | mg/kg   |
| dichloromethane phase                 | 54.1  | 3.24   | 50.0   | 3.06   | 16.3   | 0.043   |
| aqueous phase (1)                     | 40.0  | 2.39   | 26.3   | 1.61   | 60.2   | 0.158   |
| (solids 1, further extracted)         | (5.9) | (0.35) | (23.7) | (1.45) | (23.5) | (0.061) |
| microwave extract                     | 4.5   | 0.27   | 16.9   | 1.03   | n.a.   | n.a.    |
| diastase extract (further hydrolysed) | n.a.  | n.a.   | n.a.   | n.a.   | (17.0) | (0.044) |
| ethyl acetate phase                   | n.a.  | n.a.   | n.a.   | n.a.   | 14.0   | 0.037   |
| aqueous phase 2                       | n.a.  | n.a.   | n.a.   | n.a.   | 3.0    | 0.008   |
| solids 2 (unextracted residue)        | 1.4   | 0.08   | 6.8    | 0.42   | 6.5    | 0.017   |
| Total radioactive residue (TRR)       | 100   | 5.98   | 100    | 6.12   | 100    | 0.262   |

n.a. not analysed

The four parent isomers accounted for 53.1% (3.18 mg/kg) of the TRR in hay, 29.3% (1.79 mg/kg) in straw and 17.9% (0.047 mg/kg) in grain. In total, 85.9% (5.13 mg/kg) of the TRR was identified in hay, 70.4% (4.31 mg/kg) in straw and 48.2% (0.126 mg/kg) in grain. The remaining extracted radioactivity was characterised as above. Details are given in Tables 21, 22 and 23.

The metabolites found in the experiment with CF<sub>3</sub>-phenyl-labelled material were also identified in this study. It was also seen that, after cleavage between the rings, the glyoxylphenyl moiety was intensively degraded and the oxidation product phthalic acid was formed in significant amounts. The anticipated precursor (*o*-cyanobenzoic acid) was also identified. A derivative of phthalic acid was tentatively identified as a cyclic keto-alcohol.

Table 21. Characterisation and identification of radioactive residues in hay after treatment of wheat plants with [glyoxyl-phenyl-UL-<sup>14</sup>C]-trifloxystrobin (Report no. MR-028/02).

| Compound or fraction                                                            | Description                              | Occurrence | %      | mg/kg  |
|---------------------------------------------------------------------------------|------------------------------------------|------------|--------|--------|
| Totals identified (parent isomers, metabolites and aglycones)                   |                                          |            | (85.9) | (5.13) |
| Total trifloxystrobin isomers                                                   |                                          |            | (53.1) | (3.18) |
| CGA357261                                                                       | Z,E-isomer                               | D, M       | 7.1    | 0.42   |
| CGA279202                                                                       | E,E-isomer                               | D, M       | 40.3   | 2.41   |
| CGA357262                                                                       | Z,Z-isomer                               | D, M       | 2.2    | 0.13   |
| CGA331409                                                                       | E,Z-isomer                               | D, M       | 3.6    | 0.21   |
| Other identified metabolites                                                    |                                          |            | (8.9)  | (0.53) |
| CGA321113                                                                       | carboxylic acid                          | D          | 1.3    | 0.08   |
| CGA373466                                                                       | carboxylic acid                          | D          | 0.2    | 0.01   |
| NOA414412                                                                       | CF <sub>3</sub> -ring-OH-carboxylic acid | D          | 0.7    | 0.04   |
| NOA443152                                                                       | hydroxycarboxylic acid                   | D          | 0.5    | 0.03   |
| NOA413163                                                                       | dicarboxylic acid                        | A          | 4.0    | 0.24   |
| FHW0115C                                                                        | cyanobenzoic acid                        | A, M       | 1.4    | 0.09   |
| FHW0115D (CGA367619)                                                            | phthalic acid                            | A          | 0.7    | 0.04   |
| Tentatively identified metabolite                                               |                                          |            | (0.1)  | (0.01) |
| SA04271                                                                         | cyclic keto-alcohol                      | M          | 0.1    | 0.01   |
| Identified aglycones of the following conjugates                                |                                          |            | (23.7) | (1.42) |
| conjugate 1 of NOA414412                                                        | CF <sub>3</sub> -ring-OH-carboxylic acid | A          | 2.1    | 0.13   |
| conjugate 2 of NOA414412                                                        | CF <sub>3</sub> -ring-OH-carboxylic acid | A          | 6.8    | 0.40   |
| conjugate 1 of NOA443152                                                        | hydroxycarboxylic acid                   | A          | 7.2    | 0.43   |
| conjugate 2 of NOA443152                                                        | hydroxycarboxylic acid                   | A          | 1.2    | 0.07   |
| conjugate 1 of BO172741                                                         | hydroxycarboxylic acid                   | A          | 3.7    | 0.22   |
| conjugate 2 of BO172741                                                         | hydroxycarboxylic acid                   | A          | 2.5    | 0.15   |
| conjugate of BO172631                                                           | hydroxycyano compound                    | M          | 0.1    | 0.00   |
| conjugate of BO172323                                                           | hydroxycyano compound                    | M          | 0.2    | 0.01   |
| Subtotals characterised (by extraction procedure, partitioning, LC-MS and HPLC) |                                          |            | (12.7) | (0.76) |
| SA04273                                                                         | metabolite of polar group                | A          | 1.6    | 0.10   |
| regions 1 and 6 (each ≤0.02 mg/kg)                                              |                                          | D          | 0.5    | 0.03   |
| regions 1, 2, 4, 6, 8-13, 15, 21 and 22 (each ≤0.09 mg/kg)                      |                                          | A          | 9.1    | 0.54   |
| regions 2-5, 7 and 10-13 (each ≤0.02 mg/kg)                                     |                                          | M          | 1.5    | 0.09   |
| Total extracted                                                                 |                                          |            | 98.6   | 5.89   |
| Solids 2 (unextracted residue)                                                  |                                          |            | 1.4    | 0.08   |
| Total residue                                                                   |                                          |            | 100    | 5.98   |

A: aqueous phase

D: dichloromethane phase

M: microwave extract

Table 22. Characterisation and identification of radioactive residues in straw after treatment of wheat plants with [glyoxyl-phenyl-UL-<sup>14</sup>C]-trifloxystrobin (Report no. MR-028/02).

| Compound or fraction                                                   | Description                              | Occurrence | %      | mg/kg  |
|------------------------------------------------------------------------|------------------------------------------|------------|--------|--------|
| Totals identified (parent isomers, metabolites and aglycones)          |                                          |            | (70.4) | (4.31) |
| Total trifloxystrobin isomers                                          |                                          |            | (29.3) | (1.79) |
| CGA357261                                                              | Z,E-isomer                               | D, M       | 5.3    | 0.33   |
| CGA279202                                                              | E,E-isomer                               | D, M       | 18.6   | 1.14   |
| CGA357262                                                              | Z,Z-isomer                               | D          | 2.3    | 0.14   |
| CGA331409                                                              | E,Z-isomer                               | D          | 3.1    | 0.19   |
| Other identified metabolites                                           |                                          |            | (33.5) | (2.05) |
| CGA321113                                                              | carboxylic acid                          | D          | 3.8    | 0.23   |
| CGA373466                                                              | carboxylic acid                          | D          | 2.0    | 0.12   |
| NOA414412                                                              | CF <sub>3</sub> -ring-OH-carboxylic acid | D, A       | 6.5    | 0.40   |
| NOA443152                                                              | hydroxycarboxylic acid                   | D, A       | 5.9    | 0.36   |
| BO172741 (isomer of NOA443152)                                         | hydroxycarboxylic acid                   | D, A       | 3.5    | 0.21   |
| BO172631                                                               | hydroxycyano compound                    | D          | 0.7    | 0.04   |
| BO172323                                                               | hydroxycyano compound                    | D          | 0.5    | 0.03   |
| NOA413163                                                              | dicarboxylic acid                        | A          | 5.0    | 0.31   |
| NOA413161                                                              | dicarboxylic acid                        | A          | 1.4    | 0.08   |
| FHW0115C                                                               | cyanobenzoic acid                        | A, M       | 3.0    | 0.18   |
| FHW0115D (CGA367619)                                                   | phthalic acid                            | A, M       | 1.2    | 0.07   |
| Tentatively identified metabolite                                      |                                          |            | (1.5)  | (0.09) |
| SA04271                                                                | cyclic keto alcohol                      | A, M       | 1.5    | 0.09   |
| Identified aglycones of the following conjugates                       |                                          |            | (6.1)  | (0.37) |
| conjugate 1 of NOA414412                                               | CF <sub>3</sub> -ring-OH-carboxylic acid | A          | 0.3    | 0.02   |
| conjugate 2 of NOA414412                                               | CF <sub>3</sub> -ring-OH-carboxylic acid | A          | 0.5    | 0.03   |
| conjugate 1 of NOA443152                                               | hydroxycarboxylic acid                   | A          | 2.0    | 0.12   |
| conjugate 2 of NOA443152                                               | hydroxycarboxylic acid                   | A          | 0.3    | 0.02   |
| conjugate 1 of BO172741                                                | hydroxycarboxylic acid                   | A          | 1.2    | 0.07   |
| conjugate of BO172631                                                  | hydroxycyano compound                    | M          | 0.9    | 0.06   |
| conjugate of BO172323                                                  | hydroxycyano compound                    | M          | 0.9    | 0.05   |
| Subtotals characterised by extraction procedure, partitioning and HPLC |                                          |            | (22.8) | (1.39) |
| SA04273                                                                | metabolite of polar group                | A, M       | 3.8    | 0.23   |
| regions 1-3, 5, 8, 12, 14 and 15 (each ≤0.04 mg/kg)                    |                                          | D          | 2.7    | 0.16   |
| regions 1-3, 5, 8, 9, 13, 14, 20, 21, 23 (each ≤0.13 mg/kg)            |                                          | A          | 7.6    | 0.46   |
| regions 4, 5, 9-13 (each ≤0.16 mg/kg)                                  |                                          | M          | 8.7    | 0.53   |
| Total extracted                                                        |                                          |            | 93.2   | 5.70   |
| Solids 2 (unextracted residue)                                         |                                          |            | 6.8    | 0.42   |
| Total residue                                                          |                                          |            | 100    | 6.12   |

A1, A2: aqueous phases

D: dichloromethane phase

M: microwave extract

Table 23. Characterisation and identification of radioactive residues in grain after treatment of wheat plants with [glyoxyl-phenyl-UL-<sup>14</sup>C]-trifloxystrobin (Report no. MR-028/02).

| Compound or fraction                                                                                                     | Description                              | Occurrence | %      | mg/kg   |
|--------------------------------------------------------------------------------------------------------------------------|------------------------------------------|------------|--------|---------|
| Total identified (parent isomers, metabolites and aglycones)                                                             |                                          |            | (48.2) | (0.126) |
| Total trifloxystrobin isomers                                                                                            |                                          |            | (17.9) | (0.047) |
| CGA357261                                                                                                                | Z,E-isomer                               | D, A1      | 2.9    | 0.008   |
| CGA279202                                                                                                                | E,E-isomer                               | D, A1      | 11.1   | 0.029   |
| CGA357262                                                                                                                | Z,Z-isomer                               | D, A1      | 1.8    | 0.005   |
| CGA331409                                                                                                                | E,Z-isomer                               | D, A1      | 2.1    | 0.005   |
| Other identified metabolites                                                                                             |                                          |            | (19.2) | (0.05)  |
| CGA321113                                                                                                                | carboxylic acid                          | D          | 1.7    | 0.005   |
| CGA373466                                                                                                                | carboxylic acid                          | D          | 0.9    | 0.002   |
| NOA414412                                                                                                                | CF <sub>3</sub> -ring-OH-carboxylic acid | D          | 2.4    | 0.006   |
| NOA443152                                                                                                                | hydroxycarboxylic acid                   | D          | 1.9    | 0.005   |
| NOA413163                                                                                                                | dicarboxylic acid                        | A1         | 1.8    | 0.005   |
| NOA413161                                                                                                                | dicarboxylic acid                        | A1         | 0.3    | 0.001   |
| glucoside of NOA443152                                                                                                   | hydroxycarboxylic acid                   | A1         | 3.4    | 0.009   |
| FHW0115C                                                                                                                 | cyanobenzoic acid                        | A1         | 3.6    | 0.009   |
| FHW0115D (CGA367619)                                                                                                     | phthalic acid                            | A1         | 3.1    | 0.008   |
| Tentatively identified metabolites                                                                                       |                                          |            | (11.1) | (0.029) |
| SA04271                                                                                                                  | cyclic keto-alcohol                      | A1         | 9.6    | 0.025   |
| SA04273                                                                                                                  | metabolite of polar group                | A1         | 5.0    | 0.013   |
| SA04275                                                                                                                  | instable phthalic acid conjugate         | A1         | 1.5    | 0.004   |
| Subtotals characterised (by extraction procedure, enzymatic hydrolysis, acidic hydrolysis, partitioning and HPLC or TLC) |                                          |            | (45.3) | (0.119) |
| regions 1 and 6 (each ≤0.005 mg/kg)                                                                                      |                                          | D          | 2.4    | 0.006   |
| regions 1-5, 7, 10, 11 and 12 (each ≤0.019 mg/kg)                                                                        |                                          | A1         | 21.0   | 0.055   |
| regions 1 and 2 (each ≤0.019 mg/kg)                                                                                      |                                          | EA         | 14.0   | 0.037   |
| aqueous phase 2, polar radioactivity                                                                                     |                                          | A2         | 3.0    | 0.008   |
| Total extracted                                                                                                          |                                          |            | 93.5   | 0.245   |
| Solids 2 (unextracted residue)                                                                                           |                                          |            | 6.5    | 0.017   |
| Total residue                                                                                                            |                                          |            | 100.0  | 0.262   |

A: aqueous phase

D: dichloromethane phase

EA: ethyl acetate phase

### *Sugar beet*

Report nos. 99MK09 and 99MK10 (Kiffe, 2000). Sugar beets were treated three times at three-week intervals with trifluoromethylphenyl- or glyoxylphenyl-labelled trifloxystrobin formulated as EC 125 at a rate of 130 or 141 g ai/ha for the first, 137 or 132 g ai/ha for the second and 128 or 127 g ai/ha for the third application (in total 395 or 400 g ai/ha, the recommended rate). Applications were started at growth stage BBCH 39 (crop cover complete: leaves cover 90% of ground).

Whole plants were collected 1 hour after the first application, 1 hour after the second application, and 1 hour, 21 and 45 days after the last application. Soil samples were also collected at these times.



To generate higher plant residues for characterization and identification, beets were treated three times with the two labelled formulations at a rate of 692 or 830 g ai/ha for the first, 693 or 691 g ai/ha for the second and 768 or 683 g ai/ha for the third application (in total 2153 or 2204 g ai/ha, approximately a 5.5-fold rate) at three-week intervals again starting at growth stage BBCH 39. Whole plants were collected 21 and 45 days after the last application. Soil samples were also collected at the last sampling.

Collected samples were separated into tops and roots, homogenized and extracted first at room temperature five times with acetonitrile/water (8:2), and then in a microwave extractor with n-propanol/water at 120-150°C. Solid samples before and after extraction were combusted to determine the total and unextractable radioactivity by LSC.

Combined extracts were analyzed by three different TLC systems and HPLC. Characterisation and identification of metabolites was based on mass and <sup>1</sup>H-NMR spectrometry as well as co-chromatography with reference compounds.

At the low application rates, total radioactive residues 21 days after the last application were 1.52 and 1.4 mg/kg in tops, 0.038 and 0.113 mg/kg in roots and 0.106 and 0.098 mg/kg in the top soil layer (0-10 cm). At harvest 45 days after the last application, total radioactive residues accounted for 0.453 and 0.73 mg/kg in tops, 0.021 and 0.025 mg/kg in roots and 0.162 and 0.13 mg/kg in the 0-10 cm soil layer.

Trifloxystrobin could be detected in all plant parts as well as in soil. Unextractable radioactivity from the trifluoromethylphenyl label after cold and microwave extraction accounted for 3.7% and 2.2% of the total radioactive residues in tops, 11.6% and 10.6% in roots and 9.2% and 14.3% in soil 21 days and 45 days after the last application respectively. The corresponding figures from the glyoxyphenyl label were 3.9 and 4.7% in tops, 12.2 and 3.5% in roots, and 13.7 and 16.6% in soil.

The results of the overdose experiments reflected the higher application rates. Total radioactive residues 21 days after the last application were 10.1 and 7.13 mg/kg in tops and 0.55 and 0.34 mg/kg in roots. At harvest 45 days after the last application, the TRRs were 4.16 and 7.76 mg/kg in tops, 0.48 and 0.49 mg/kg in roots and 0.92 and 0.46 mg/kg in the 0-10 cm soil layer. Unchanged trifloxystrobin was detected in plant parts and in soil.

The metabolic patterns from the trifluoromethylphenyl label in tops and roots were identical at both application rates. Metabolite fraction II<sub>25</sub> was identified as trifloxystrobin and its isomer CGA331409. The minor metabolites II<sub>24</sub>, II<sub>24b</sub>, II<sub>23a</sub> and II<sub>22</sub> were identified as CGA321113, CGA373466, NOA443152 and NOA414412 respectively, by silica gel TLC and/or reversed-phase HPLC co-chromatography with reference standards. NOA443152 and NOA414412 were also found as glucose conjugates (metabolites II<sub>11</sub> is the glucose conjugate of NOA443152, metabolite II<sub>10</sub> is the glucose conjugate of NOA414412). Metabolite II<sub>9b</sub> was identified as the glucose conjugate of II<sub>21a</sub>.

The main compounds found in the tops and roots were trifloxystrobin and its *E,Z*- and *Z,Z*-isomers. They accounted for up to 68.9% (1.045 mg/kg) in tops and 51.5% (0.02 mg/kg) of the TRR in roots. CGA321113 was found to a lower extent in the roots and tops (up to 8.7% of the TRR, equivalent to 0.003 mg/kg, and up to 2.7% equivalent to 0.041 mg/kg respectively).

On the basis of the structures identified, the metabolism of trifloxystrobin in sugar beets appears to proceed via several routes:

- Cis/trans isomerization of the parent compound.
- Ester hydrolysis to CGA321113 followed by cis/trans isomerization to CGA373466.
- Hydroxylation of the trifluoromethylphenyl ring to NOA414412 or its isomer with subsequent sugar conjugation to form metabolite II<sub>10</sub> or II<sub>9b</sub>.
- Oxidation at the ethylidene methyl group to NOA443152 with subsequent sugar conjugation.

- Formation of unextracted residues.

### *Peanuts*

Report No. ABR-97084 (Rezaaiyan, 1997). The metabolism of trifloxystrobin in peanuts was investigated following four spray applications at four-week intervals of 560 g ai/ha labelled trifloxystrobin giving a seasonal maximum rate of 2240 g ai/ha. Two plots were treated, one with [trifluoromethyl-UL-<sup>14</sup>C]-trifloxystrobin, and one with [glyoxyl-phenyl-UL-<sup>14</sup>C]-trifloxystrobin.

Immature vines were collected on day 0 after the 1st application and 14 days after the 2nd application. Mature plants were harvested 14 days after 4th application. Soil samples were taken before and directly after the 1st application and at harvest, 14 days after the 4th application.

Mature plants were separated into hay, hulls (shells) and kernels (peanuts) and homogenised frozen. Samples were extracted at room temperature with hexane followed by acetonitrile/water (8:2). ACN/H<sub>2</sub>O extracts were further separated by partitioning with water and dichloromethane.

Radioactivity was measured in solid samples by LSC after combustion, and in extracts after separation by various TLC and HPLC systems. Characterisation, identification and structure elucidation of metabolites was by co-chromatography with reference standards LC/MS/MS and 1H-NMR spectrometry. Unextracted residues were characterised by hydrolysis with NaOH or HCl and enzymatic cleavage with lipase, protease or cellulase.

The total radioactive residues after the 1st application were 20.7 mg/kg and 24.9 mg/kg in glyoxyl-phenyl- and CF<sub>3</sub>-phenyl-treated vines respectively. Residue levels decreased rapidly with plant growth and were only 7.7 mg/kg and 9.1 mg/kg 14 days after the 2nd application. Radioactive residues in mature hay amounted to 26.3 mg/kg and 27.9 mg/kg 14 days after the 4th application. In mature hulls residue levels were 1.08 mg/kg and 1.15 mg/kg from the glyoxyl-phenyl and CF<sub>3</sub>-phenyl labels, and in mature peanuts 0.305 mg/kg and 0.18 mg/kg.

In the 0-10 cm soil layer total radioactive residues directly after the 1st application amounted to 0.22 mg/kg and 0.24 mg/kg. Residues increased only slightly with the number of applications and accounted for 0.34 and 0.37 mg/kg 14 days after the 4th treatment. Most of the radioactive residues in soil samples collected 14 days after the last application could be extracted (60.5% and 70.7% of the TRR). The main component of the extractable residues was the mono-acid CGA321113. CGA373466 and CGA357276 and the parent compound were also identified.

In the immature vines the extractable radioactive residues amounted to 86.3 and 90.9% of the TRR for the glyoxyl-phenyl and CF<sub>3</sub>-phenyl labels respectively, in mature hay 67.7 and 74.1% respectively, and in mature kernels 52.6 and 51.6%. Unextractable radioactivity after extraction with acetonitrile/water amounted to 9.9 and 10.7% of the TRR in immature vines, 30.4 and 24.3% in mature hay and 55.4 and 53.2% in mature kernels (Table 24).

Table 24. Distribution of radioactivity in peanuts after treatment with [trifluoromethyl-phenyl-(U)-<sup>14</sup>C]- and [glyoxyl-phenyl-(U)-<sup>14</sup>C]-trifloxystrobin (Report no. ABR-97084).

| Fraction                                 | Radio-label | Vines (day 0) <sup>1</sup> | Vines (immature) <sup>2</sup> |                    | Hay (mature) <sup>3</sup> |                    | Hull (mature) <sup>3</sup> | Kernels (mature) <sup>3</sup> |                    |
|------------------------------------------|-------------|----------------------------|-------------------------------|--------------------|---------------------------|--------------------|----------------------------|-------------------------------|--------------------|
|                                          |             | mg/kg <sup>4</sup>         | % of TRR                      | mg/kg <sup>4</sup> | % of TRR                  | mg/kg <sup>4</sup> | mg/kg <sup>4</sup>         | % of TRR                      | mg/kg <sup>4</sup> |
| acetonitrile/<br>water extract           | A           | n.a.                       | 90.89                         | 7.030              | 67.68                     | 17.827             | n.a.                       | 26.99                         | 0.074              |
|                                          | B           |                            | 86.25                         | 7.860              | 74.09                     | 20.686             |                            | 20.66                         | 0.034              |
| organosoluble<br>of ACN/H <sub>2</sub> O | A           | n.a.                       | 56.45                         | 4.366              | 42.42                     | 11.174             | n.a.                       | 4.70                          | 0.013              |
|                                          | B           |                            | 66.89                         | 6.097              | 55.35                     | 15.455             |                            | 12.53                         | 0.021              |

| Fraction                              | Radio-label | Vines (day 0) <sup>1</sup> | Vines (immature) <sup>2</sup> |                    | Hay (mature) <sup>3</sup> |                    | Hull (mature) <sup>3</sup> | Kernels (mature) <sup>3</sup> |                    |
|---------------------------------------|-------------|----------------------------|-------------------------------|--------------------|---------------------------|--------------------|----------------------------|-------------------------------|--------------------|
|                                       |             | mg/kg <sup>4</sup>         | % of TRR                      | mg/kg <sup>4</sup> | % of TRR                  | mg/kg <sup>4</sup> | mg/kg <sup>4</sup>         | % of TRR                      | mg/kg <sup>4</sup> |
| water-soluble of ACN/H <sub>2</sub> O | A           | n.a.                       | 26.05                         | 2.014              | 21.01                     | 5.534              | n.a.                       | 22.35                         | 0.061              |
|                                       | B           | n.a.                       | 17.89                         | 1.630              | 16.84                     | 4.701              | n.a.                       | 7.45                          | 0.012              |
| hexane extract                        | A           | n.a.                       | n.a.                          | n.a.               | n.a.                      | n.a.               | n.a.                       | 25.63                         | 0.070              |
|                                       | B           | n.a.                       | n.a.                          | n.a.               | n.a.                      | n.a.               | n.a.                       | 30.89                         | 0.051              |
| unextracted residue                   | A           | n.a.                       | 10.65                         | 0.823              | 30.40                     | 8.007              | n.a.                       | 55.36                         | 0.152              |
|                                       | B           | n.a.                       | 9.91                          | 0.903              | 24.32                     | 6.790              | n.a.                       | 53.17                         | 0.098              |
| Total (TRR)                           | A           | 20.742                     | 101.54                        | 7.734              | 98.08                     | 26.340             | 1.148                      | 107.98                        | 0.305              |
|                                       | B           | 24.899                     | 96.16                         | 9.114              | 98.41                     | 24.899             | 1.081                      | 104.72                        | 0.184              |

A: glyoxyl-phenyl

B: trifluoromethyl-phenyl

n.a. not analysed

<sup>1</sup> directly after 1st application

<sup>2</sup> 14 days after 2nd application

<sup>3</sup> 14 days after 4th application

<sup>4</sup> <sup>14</sup>C expressed as trifloxystrobin

Metabolite patterns in the organosoluble fractions of the acetonitrile/water extracts from immature vines and mature hay were very similar for both labels. No metabolites resulting from the cleavage of the N-O bridge between the rings were detected in reasonable amounts. The major compounds were identified as parent trifloxystrobin, its isomers CGA357261, CGA357262 and CGA331409, and the mono-acid metabolites CGA321113 and CGA373466.

Metabolic profiles in the water-soluble fraction were similar for immature vines, mature hay and mature kernels. However, significant differences between the radiolabels were observed, indicating a cleavage of the N-O bond between the aromatic ring systems and the formation of label-specific metabolites. The major water-soluble metabolites in mature hay and immature vines were present mainly as malonyl sugar and sugar conjugates. They were identified as conjugates of CGA321113, CGA300624 (oxime of CF<sub>3</sub>-methylphenyl moiety), CGA347242 (acid of glyoxyl phenyl moiety), CGA107170 (trifluoromethylacetophenone), CGA328365 (1-[3-(trifluoromethyl)phenyl]ethanol) and CGA55641 (trifluoromethylbenzoic acid).

In kernels only trifloxystrobin, CGA321113 and CGA373466 were identified in the organosoluble fraction. In the aqueous phase label-specific metabolites of the glyoxyl moiety were identified in the organosoluble fraction, resulting from cleavage between the rings. They were phthalic acid (CGA367619), a sugar conjugate of CGA347242 which is the glyoxyl moiety of the acid CGA321113, and F2b2-3a&b(A2), the methyl ester of CGA373463. The residue in the hexane fraction from mature kernels was shown to be composed of radiolabelled triglycerides.

Unextracted residues were solubilised by hot extraction and sequential hydrolyses with cellulase, protease, HCl and NaOH. Residues released by these procedures were identified as trifloxystrobin and its isomers CGA357261, CGA357262 and CGA331409, and the carboxylic acid metabolites CGA321113 and CGA373466. Radioactive residues remaining unextractable even under exhaustive conditions were <10% of the TRR in all samples. Detailed metabolic profiles from both radiolabels in immature vines (14 days after 2nd application), mature hay (harvested 14 days after 4th application) and mature kernels are shown in Tables 25, 26 and 27.

Table 25. Characterisation and identification of radioactive residues in immature vines after treatment of peanut plants with [trifluoromethyl-phenyl-UL-<sup>14</sup>C]- and [glyoxyl-phenyl-UL-<sup>14</sup>C]trifloxystrobin (Report no. ABR-97084).

| Compound or fraction                                                                        | glyoxyl-phenyl |       | CF <sub>3</sub> -phenyl |       |
|---------------------------------------------------------------------------------------------|----------------|-------|-------------------------|-------|
|                                                                                             | % of TRR       | mg/kg | % of TRR                | mg/kg |
| Extractable radioactive residues                                                            | 90.89          | 7.030 | 86.25                   | 7.860 |
| Total trifloxystrobin isomers                                                               | 41.04          | 3.174 | 47.29                   | 4.31  |
| CGA279202 ( <i>E,E</i> - isomer)                                                            | 32.40          | 2.506 | 38.60                   | 3.518 |
| CGA357261 ( <i>Z,E</i> - isomer)                                                            | 2.94           | 0.227 | 2.94                    | 0.268 |
| CGA357262 ( <i>Z,Z</i> - isomer)                                                            | 2.48           | 0.192 | 2.41                    | 0.219 |
| CGA331409 ( <i>E,Z</i> - isomer)                                                            | 3.22           | 0.249 | 3.34                    | 0.305 |
| CGA321113 ( <i>E,E</i> carboxylic acid)                                                     | 1.35           | 0.105 | 2.04                    | 0.185 |
| CGA373466 ( <i>Z,E</i> carboxylic acid)                                                     | n.d.           | n.d.  | 0.33                    | 0.030 |
| hydroxy CGA321113 (hydroxylated on CF <sub>3</sub> -phenyl ring or ethylidene methyl group) | n.d.           | n.d.  | 1.49                    | 0.135 |
| CGA321113 malonyl glucose conjugate                                                         | 11.63          | 0.899 | 15.19                   | 1.384 |
| CGA321113 sugar conjugate                                                                   | 1.52           | 0.117 | 0.15                    | 0.014 |
| CGA328365 malonyl glucose conjugate                                                         |                |       | 1.25                    | 0.114 |
| CGA300624 malonyl glucose conjugate                                                         |                |       | 0.40                    | 0.036 |
| CGA367619 (phthalic acid, Fb2-4b)                                                           | 1.42           | 0.110 |                         |       |
| F2b2-3a&b(A2) (methyl ester of CGA373463)                                                   | 1.14           | 0.088 |                         |       |
| CGA347242 glucose conjugate (carboxylic acid of glyoxyl moiety)                             | 6.36           | 0.492 |                         |       |
| WFX-IX-86 (1,2-benzisoxazole-3-carboxylic acid)                                             | 1.54           | 0.119 |                         |       |
| TFA (trifluoroacetic acid)                                                                  |                |       | 0.28                    | 0.025 |
| CGA107170-glucose conjugate                                                                 |                |       | 0.95                    | 0.087 |
| CGA55641-glucose conjugate                                                                  |                |       | 1.47                    | 0.135 |
| Unextracted <sup>a</sup> radioactive residues                                               | 10.65          | 0.823 | 9.91                    | 0.903 |
| CGA279202 ( <i>E,E</i> -isomer)                                                             | 0.81           | 0.062 | 0.90                    | 0.082 |
| CGA357261 ( <i>Z,E</i> -isomer)                                                             | 0.24           | 0.018 | 0.21                    | 0.020 |
| CGA357262 ( <i>Z,Z</i> -isomer)                                                             | 0.22           | 0.017 | 0.25                    | 0.022 |
| CGA331409 ( <i>E,Z</i> -isomer)                                                             | 0.27           | 0.021 | 0.27                    | 0.024 |
| CGA321113 (carboxylic acid)                                                                 | 0.42           | 0.033 | 0.41                    | 0.037 |
| CGA373466 (carboxylic acid)                                                                 | 0.24           | 0.019 | 0.17                    | 0.015 |
| CGA373465 (carboxylic acid)                                                                 | 0.07           | 0.005 | 0.06                    | 0.005 |
| CGA367619 (phthalic acid, Fb2-4b)                                                           | 0.14           | 0.011 |                         |       |
| F2b2-3a&b(A2) (methyl ester of CGA373463)                                                   | 0.14           | 0.011 |                         |       |
| CGA300624 malonyl glucose conjugate                                                         | 0.40           | 0.031 |                         |       |
| Total identified residues (extractable)                                                     | 66.22          | 5.104 | 70.84                   | 6.455 |
| Total identified residues (unextracted)                                                     | 2.95           | 0.228 | 2.27                    | 0.205 |
| Total identified                                                                            | 68.94          | 5.332 | 73.11                   | 6.66  |

n.d.: not detected

<sup>a</sup> residues released by hydrolysis and/or enzymatic cleavage

Table 26. Characterisation and identification of radioactive residues in mature hay after treatment of peanut plants with [trifluoromethyl-phenyl-UL-<sup>14</sup>C]- and [glyoxyl-phenyl-UL-<sup>14</sup>C]trifloxystrobin (Report no. ABR-97084).

| Compound or fraction             | glyoxyl-phenyl |        | CF <sub>3</sub> -phenyl |        |
|----------------------------------|----------------|--------|-------------------------|--------|
|                                  | % of TRR       | mg/kg  | % of TRR                | mg/kg  |
| Extractable radioactive residues | 67.68          | 17.827 | 74.09                   | 20.686 |
| Total trifloxystrobin isomers    | 35.18          | 9.263  | 51.48                   | 14.374 |

| Compound or fraction                                                                        | glyoxyl-phenyl |        | CF <sub>3</sub> -phenyl |        |
|---------------------------------------------------------------------------------------------|----------------|--------|-------------------------|--------|
|                                                                                             | % of TRR       | mg/kg  | % of TRR                | mg/kg  |
| CGA279202 ( <i>E,E</i> -isomer)                                                             | 29.02          | 7.643  | 43.51                   | 12.148 |
| CGA357261 ( <i>Z,E</i> isomer)                                                              | 2.21           | 0.581  | 2.66                    | 0.742  |
| CGA357262 ( <i>Z,Z</i> isomer)                                                              | 1.32           | 0.346  | 1.77                    | 0.495  |
| CGA331409 ( <i>E,Z</i> isomer)                                                              | 2.63           | 0.693  | 3.54                    | 0.989  |
| CGA321113 ( <i>E,E</i> carboxylic acid)                                                     | 3.14           | 0.827  | 3.87                    | 1.082  |
| CGA373466 ( <i>Z,E</i> carboxylic acid)                                                     | 1.65           | 0.436  | 0.55                    | 0.155  |
| hydroxy CGA321113 (hydroxylated on CF <sub>3</sub> -phenyl ring or ethylidene methyl group) | 0.47           | 0.123  | 1.82                    | 0.510  |
| CGA321113 malonyl glucose conjugate                                                         | 4.86           | 1.279  | 1.62                    | 0.453  |
| CGA321113 sugar conjugate                                                                   | 0.07           | 0.019  | n.d.                    | n.d.   |
| CGA328365 malonyl glucose conjugate                                                         |                |        | 2.48                    | 0.692  |
| CGA300624 malonyl glucose conjugate                                                         |                |        | n.d.                    | n.d.   |
| CGA367619 (phthalic acid, Fb2-4b)                                                           | 1.17           | 0.307  |                         |        |
| F2b2-3a&b(A2) (methyl ester of CGA373463)                                                   | 1.20           | 0.315  |                         |        |
| CGA347242 glucose conjugate (carboxylic acid of glyoxyl moiety)                             | 3.72           | 0.980  |                         |        |
| WFX-IX-86 (1,2-benzisoxazole-3-carboxylic acid)                                             | 2.48           | 0.653  |                         |        |
| TFA (trifluoroacetic acid)                                                                  |                |        | 0.78                    | 0.217  |
| CGA107170-glucose conjugate                                                                 |                |        | 1.87                    | 0.522  |
| CGA55641-glucose conjugate                                                                  |                |        | 3.00                    | 0.838  |
| Unextracted <sup>a</sup> radioactive residues                                               | 30.40          | 8.007  | 24.32                   | 6.790  |
| CGA279202 ( <i>E,E</i> isomer)                                                              | 0.30           | 0.079  | 3.00                    | 0.837  |
| CGA357261 ( <i>Z,E</i> isomer)                                                              | n.d.           | n.d.   | 0.50                    | 0.139  |
| CGA357262 ( <i>Z,Z</i> isomer)                                                              | n.d.           | n.d.   | 0.41                    | 0.115  |
| CGA331409 ( <i>E,Z</i> isomer)                                                              | n.d.           | n.d.   | 0.54                    | 0.151  |
| CGA321113 ( <i>E,E</i> carboxylic acid)                                                     | 0.09           | 0.024  | 1.22                    | 0.341  |
| CGA373466 ( <i>Z,E</i> carboxylic acid)                                                     | n.d.           | n.d.   | 0.20                    | 0.057  |
| CGA373465 ( <i>E,E</i> carboxylic acid)                                                     | n.d.           | n.d.   | n.d.                    | n.d.   |
| CGA367619 (phthalic acid, Fb2-4b)                                                           | 1.51           | 0.398  |                         |        |
| F2b2-3a&b(A2) (methyl ester of CGA373463)                                                   | n.d.           | n.d.   |                         |        |
| CGA347242 glucose conjugate                                                                 | 4.21           | 1.11   |                         |        |
| Total identified residues (extractable)                                                     | 53.94          | 14.202 | 67.47                   | 18.843 |
| Total identified residues (unextracted)                                                     | 6.11           | 1.611  | 5.87                    | 1.64   |
| Total identified                                                                            | 60.05          | 15.813 | 73.34                   | 20.483 |

n.d.: not detected

<sup>a</sup> residues released by hydrolysis and/or enzymatic cleavage

Table 27. Characterisation and identification of radioactive residues in mature kernels after treatment of peanut plants with [trifluoromethyl-phenyl-UL-<sup>14</sup>C]- and [glyoxyl-phenyl-UL-<sup>14</sup>C]-trifloxystrobin (Report no. ABR-97084).

| Fraction                         | Identity               | glyoxyl-phenyl |            | trifluoromethyl-phenyl |            |
|----------------------------------|------------------------|----------------|------------|------------------------|------------|
|                                  |                        | % of TRR       | mg/kg      | % of TRR               | mg/kg      |
| Extractable radioactive residues |                        | 52.63          | 0.144      | 51.55                  | 0.085      |
| hexane extract                   |                        | 25.63          | 0.070      | 30.89                  | 0.051      |
|                                  | CGA357261 (Z,E isomer) | sum: 1.98      | sum: 0.005 | sum: 1.61              | sum: 0.003 |
|                                  | CGA279202 (parent)     |                |            |                        |            |
|                                  | CGA357262 (Z,Z isomer) |                |            |                        |            |
|                                  | CGA331409 (E,Z isomer) |                |            |                        |            |

| Fraction                                           | Identity                                | glyoxyl-phenyl |            | trifluoromethyl-phenyl |            |
|----------------------------------------------------|-----------------------------------------|----------------|------------|------------------------|------------|
|                                                    |                                         | % of TRR       | mg/kg      | % of TRR               | mg/kg      |
|                                                    | CGA321113 ( <i>E,E</i> carboxylic acid) |                |            |                        |            |
|                                                    | CGA373466 ( <i>E,E</i> carboxylic acid) |                |            |                        |            |
|                                                    | <sup>14</sup> C-triglycerides           | 23.65          | 0.065      | 29.28                  | 0.048      |
| dichloromethane soluble phase of ACN/water extract |                                         | 4.70           | 0.013      | 12.53                  | 0.021      |
|                                                    | CGA357261 ( <i>Z,E</i> isomer)          | n.d.           | n.d.       | sum: 2.31              | sum: 0.004 |
|                                                    | CGA279202 (parent)                      |                |            |                        |            |
|                                                    | CGA321113 ( <i>E,E</i> carboxylic acid) | sum: 1.11      | sum: 0.003 | sum: 2.04              | sum: 0.003 |
|                                                    | CGA373466 ( <i>Z,E</i> carboxylic acid) |                |            |                        |            |
| water-soluble phase of ACN/water extract           |                                         | 22.35          | 0.061      | 7.45                   | 0.012      |
|                                                    | F2b2-4b (phthalic acid)                 | 5.97           | 0.016      |                        |            |
|                                                    | F2b2-3a&b(A2)                           | 3.35           | 0.009      |                        |            |
|                                                    | CGA347242, gluc. conj.                  | 8.80           | 0.024      |                        |            |
| Total identified                                   |                                         | 44.87          | 0.123      | 35.24                  | 0.058      |

n.d.: not detected

### Summary - metabolism in plants

In wheat, the total radioactive residues (TRR) at harvest after CF<sub>3</sub>-phenyl label treatment were 0.02-0.12 mg/kg parent equivalents for grain, 0.14 mg/kg for husk and 3.85-6.13 mg/kg for straw. Concentrations of the parent compound (EE-isomer) accounted for <0.001-0.024 mg/kg in grain, 0.001 mg/kg in husk and 0.050-0.88 mg/kg in straw. The TRR at harvest after glyoxyl-phenyl label treatment reached 0.099-0.262 mg/kg parent equivalents in grain, 0.78 mg/kg in husk and 5.48-6.12 mg/kg in straw. Parent (EE-isomer) concentrations in grain, husk and straw amounted to 0.001-0.029 mg/kg, 0.006 mg/kg and 0.121-1.14 mg/kg respectively. Differences between the TRR from the two labels were due to the timing of application and not owing to the label differences. In wheat the metabolite pattern was rather complex, owing to isomerization of the parent compound and its metabolites, and cleavage of the N-O bond between the two aromatic ring systems. In straw, up to 35 metabolite fractions were found, most of them at levels below 1% of the total radioactive residues. All major fractions were characterized or identified, the content and nature of the bound residues in grain and straw were also elucidated.

In apples and cucumbers metabolism was less significant and the parent EE isomer of trifloxystrobin accounted for more than 80% of the total radioactivity. In sugar beet the main compounds found, with both labels, in the tops and roots were trifloxystrobin and its isomers (CGA331409 and CGA357262). They accounted for up to 68.9% of the TRR in tops and 51.5% in roots. CGA321113 was found to a lower extent in the roots and tops (respectively up to 10.8% of the TRR, equivalent to 0.012 mg/kg, and up to 5.2% equivalent to 0.073 mg/kg). In peanuts, many metabolite fractions containing only one moiety of the parent molecule were detected, generally similar to those found in wheat. Extensive formation of sugar and malonyl sugar conjugates was found with all metabolite fractions.

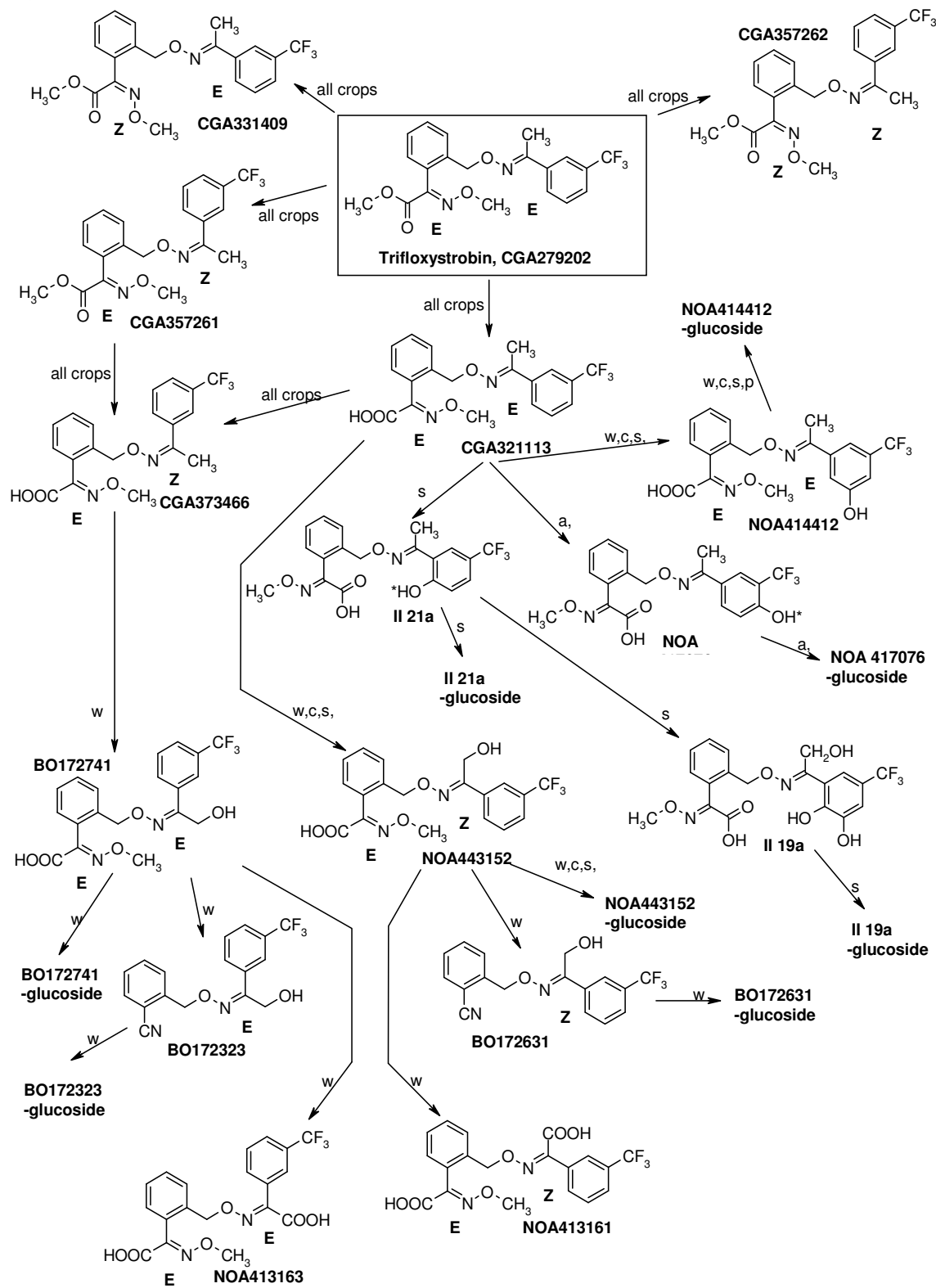
In general, the metabolism of trifloxystrobin in crops is complex owing to isomerization of the parent compound and its metabolites. Broadly, the metabolism of trifloxystrobin is similar in all crops examined:

- Cis/trans isomerization of the *E,E* isomer
- Hydrolysis of the methyl esters of the parent compound and its isomer CGA357261 to carboxylic acids CGA321113 and CGA373466
- Cis/trans isomerization of carboxylic acid CGA321113 to CGA373466
- Hydroxylation of the trifluoromethylphenyl ring, followed by sugar conjugation
- Methyl oxidation of the ethylideneaminoxy group with subsequent sugar conjugation

- Cleavage of the N-O bridge, followed by oxidation of the trifluoromethylphenyl moiety to form the acetophenone derivative and subsequent sugar conjugation
- Cleavage of the N-O bridge, followed by oxidation of the glyoxyl-phenyl moiety, eventually forming phthalic acid by alternative routes
- Formation of bound residues.

The proposed metabolic pathways for trifloxystrobin in plants are given in Figure 2.

Figure 2. Proposed metabolic pathways of trifloxystrobin in plants (Part 1).



a: apple; w: wheat; c: cucumber; s: sugar beet; p: peanuts



[illegible]

a: apple; w: wheat; c: cucumber; s: sugar beet; p: peanuts

## Environmental fate

Because trifloxystrobin is used for foliar spray treatment and on paddy rice, only studies on hydrolysis and residue degradation in water-sediment systems and rotational crops were considered.

### Hydrolysis

Report no. 94PK01 (Kitschmann, 1996). The hydrolysis of glyoxyl-phenyl-labelled trifloxystrobin was investigated in the dark at pH 1, 5, 7, 9 and 13 and temperatures of 25, 40 and 60°C at a concentration of 0.3 mg ai/l, which is half of the reported water-solubility. The test duration was variable depending on pH and temperature. At pH 5, 7 and 9 at 25°C it was 30 days. Aliquots of the test solutions were radioassayed by liquid scintillation counting. The <sup>14</sup>C balances at the different pH values were in the range of 95.3-104.0%. Determination of trifloxystrobin and its hydrolysis products was by TLC and HPLC. Mass spectrometry was used to confirm the identity of trifloxystrobin and major hydrolysis products.

Hydrolysis at pH 1, 5, 7 and 9 was described by pseudo first order reaction kinetics. Best-fit evaluation of the data was obtained by solving the 1st order kinetics equation  $\ln(C) = \ln(C_0) - kt$  with a non-linear procedure. The half-lives of hydrolysis of trifloxystrobin at environmentally relevant temperatures are given in Table 28.

The main degradation product above pH 5 was identified as the acid CGA321113. Hydrolysis at pH 1 showed only one major degradation product, which was generated by cleavage of the bridge between the two aromatic rings. This was identified as CGA289565.

The half-lives of CGA321113 at pH 9 and 13 at 60°C were determined to be 742 and 452 days respectively. At environmentally relevant pH values CGA321113 would not be degraded by hydrolysis.

Table 28. Hydrolytic half-lives (first order kinetics) of glyoxyl-phenyl-labelled trifloxystrobin (Report no. 94PK01).

| pH | non-linear evaluation (best fit): |                     | linear evaluation:  |
|----|-----------------------------------|---------------------|---------------------|
|    | 20°C (calculated)                 | 25°C (experimental) | 25°C (experimental) |
| 1  | 3.9 days                          | 2.2 days            |                     |
| 5  | 8.6 years                         | 4.7 years           | 480 days            |
| 7  | 11.4 weeks                        | 41.5 days           | 39-41 days          |
| 9  | 27.1 hours                        | 15.0 hours          | 28.8 hours          |
| 13 | <5 min (estimated)                | <5 minutes          |                     |

Report no. 94UL04 (Ulbrich, 1997). In this study the hydrolysis of trifloxystrobin was investigated under identical conditions to Kitschmann, 1996, but using the CF<sub>3</sub>-phenyl-labelled test substance.

Half-lives at environmentally relevant temperatures (Table 29) were comparable to those in the previous study. At pH >5 CGA321113 was again the major product. The half-lives of CGA321113 were determined by a pseudo first order kinetic model based on consecutive reactions at 60°C as 72.3 days, 85.7 days and 155.2 days at pH 7, 9 and 13 respectively. The values confirm that under environmental conditions CGA321113 will only be degraded very slowly by hydrolysis.

Hydrolysis at pH 1 showed one major degradation product, generated by cleavage of the bridge between the two aromatic rings and identified as CGA107170 (3-trifluoromethylacetophenone). The nitrile CGA357276 found at pH 9 and pH 13 at 60°C was formed by thermal elimination of CO<sub>2</sub> and methanol from CGA321113.

Table 29. Hydrolytic half-lives (first-order kinetics) of CF<sub>3</sub>-phenyl-<sup>14</sup>C trifloxystrobin (Report no. 94UL04).

| pH | non-linear evaluation (best fit): |                     | linear evaluation:  |
|----|-----------------------------------|---------------------|---------------------|
|    | 20°C (calculated)                 | 25°C (experimental) | 25°C (experimental) |
| 1  | 4.6 days                          | 2.6 days            | >1000 days          |
| 5  | 4.7 years                         | 2.7 years           |                     |
| 7  | 10.7 weeks                        | 40.0 days           | 40 days             |
| 9  | 26.4 hours                        | 15.0 hours          | 55.2 days           |
| 13 | est. <5 minutes                   | <5 minutes          |                     |

Report no. 97WI40 (Widmer, 1997). Measurements of vapour pressure were carried out with the trifloxystrobin acid metabolites CGA321113 (EE) and CGA373466 (ZE) by the gas-saturation method, in which a stream of nitrogen is passed over glass pearls covered with the test substance.

In all experiments at elevated temperatures (>50°C) the vapour pressure of the compounds could not be determined owing to thermal decomposition to nitriles which were identified in the cooling traps by HPLC co-chromatography with reference material CGA357276. It can therefore be concluded that the formation of the nitrile CGA357276 in hydrolysis experiments at 60°C was an artefact caused by thermal decomposition. CGA357276 would not be a hydrolysis product of CGA321113 under realistic environmental conditions.

The proposed degradation pathways of trifloxystrobin in water involving hydrolytic and biotic degradation are shown in Figure 3.

#### *Degradation in water/sediment systems*

Report no. 242.40 (Manuli and Jacobson, 2000). A study was conducted to evaluate the mobility and degradation of trifloxystrobin in water and soil when applied under field conditions to a paddy rice crop in Arkansas. Unlabelled trifloxystrobin was applied twice, with a 14-day interval, to a flooded rice crop at 190 g ai/ha per treatment.

Rice plants were 3-4 months old and the canopy covered about 60% of the soil/water surface. The soil at the test site was poorly drained and was characterised as a silty clay in the upper, clay in the middle and clay loam in the deeper soil layers. Soil characteristics are given in detail in Table 30. The water level in the treated plots was maintained at a depth of about 10-18 cm.

Water samples were taken one day before the first application and at intervals of a few days up to 30 days after the second application, when the rice crops were drained. Soil cores were collected on several days, before and after applications, up to 364 days. Soil was taken to a depth of 15 cm in the flooded field and up to 90 cm in the drained field.

Trifloxystrobin and the five degradation products CGA373466, CGA321113, CGA357261, CGA357262 and CGA331409 were determined in soil and water by LC-MS. The limit of quantification for all analytes was 0.1 µg/kg in water and 2 µg/kg in soil.

Table 30. Aquatic field dissipation study with trifloxystrobin: soil characterisation for soil depth 0-90 cm (Report no. 242.40).

| Characteristics based on dry matter   | Soil depth, cm |       |       |           |
|---------------------------------------|----------------|-------|-------|-----------|
|                                       | 0-15           | 15-30 | 30-60 | 60-90     |
| pH (KCl)                              | 6.7            | 6.3   | 6.3   | 6.5       |
| Organic matter (%)                    | 1.9            | 1.2   | 1.2   | 0.4       |
| CEC potl. (mmol/z/100g soil)          | 26.5           | 32.5  | 29.8  | 24.5      |
| Clay (0-0.002 mm) (%)                 | 42             | 56    | 54    | 40        |
| Silt (0.002 - 0.05 mm) (%)            | 44             | 30    | 28    | 36        |
| Sand (0.05 - 2.0 mm) (%)              | 14             | 14    | 18    | 24        |
| Soil Texture (USDA)                   | silty clay     | clay  | clay  | clay loam |
| Water holding capacity at 1/3 bar (%) | 36.9           | 42.1  | 40.9  | 37.2      |
| Water holding capacity at 15 bar (%)  | 22.7           | 28.8  | 27.8  | 21.9      |

Initial concentrations of trifloxystrobin in water samples collected immediately after the 1st and 2nd applications were 69.4 µg ai/l and 51.9 µg ai/l respectively. Taking into account the depth of the water layer (12.5 cm at the 1st application, 17.5 cm at the 2nd application) these values represent 51% and 54% of the theoretical concentration. In view of the canopy of about 60% it can be assumed that a similar quantity of the initially applied test substance remained on the rice foliage, so the initial recovery of test substance in the paddy water was considered adequate.

Water samples were analysed for the parent compound and its major degradation products found in soil degradation and hydrolysis studies which are the parent isomers CGA357261, CGA357262 and CGA331409, the mono-acid CGA321113, and its isomer CGA373466. Concentrations measured at different sampling dates after the 2nd application are given in Table 31.

Concentrations of trifloxystrobin in water decreased rapidly. Two days after the 2nd application only 2.84 µg/l, 5% of the initial concentration, and from day 5 only concentrations between 0.6 µg/l and the LOQ of 0.1 µg/l were found. Trifloxystrobin was predominantly degraded to CGA357261, CGA321113 and CGA373466. CGA321113 and CGA373466 were formed in major amounts. Maximum concentrations of both were reached 3 days after the last applications, with 56.1 µg/l CGA321113 and 13.9 µg/l CGA373466. CGA357261 was the only parent isomer which could be detected in the water layer, at concentrations ranging between the LOQ (0.10 µg/l) and 0.604 µg/l throughout the sampling period.

In soil in the upper layer (0-15 cm), concentrations of the parent compound decreased relatively slowly during the flooding period, from 13.6 µg/kg at day 0 to 4.57 µg/kg at day 30, but rapidly immediately after drainage at day 30 to <2.0 µg/kg. As in water CGA321113 and CGA373466 were the main products, with up to 21.3 and 6.39 µg/kg respectively, while parent isomers were only sporadically detected (Table 32).

Table 31. Aquatic field dissipation study. Residues ( $\mu\text{g/l}$ ) of trifloxystrobin and degradation products in paddy water after application of 2 x 190 g ai/ha (Report no. 242.40).

| sampling  | DALA | parent* | CGA357261* | CGA357262* | CGA331409* | CGA321113* | CGA373466* |
|-----------|------|---------|------------|------------|------------|------------|------------|
| 01.Sep.98 | 0    | 51.9    | 0.271      | <0.1       | <0.1       | 8.0        | 1.16       |
| 02.Sep.98 | 1    | 10.6    | 0.604      | <0.1       | <0.1       | 22.6       | 5.83       |
| 03.Sep.98 | 2    | 2.84    | 0.325      | <0.1       | <0.1       | 36.5       | 8.11       |
| 04.Sep.98 | 3    | 3.80    | 0.414      | <0.1       | 0.1        | 56.1       | 13.9       |
| 06.Sep.98 | 5    | 0.327   | 0.118      | <0.1       | <0.1       | 32.7       | 8.97       |
| 08.Sep.98 | 7    | 0.618   | <0.1       | <0.1       | <0.1       | 13.2       | 2.38       |
| 11.Sep.98 | 10   | 0.236   | 0.165      | <0.1       | <0.1       | 19.7       | 7.28       |
| 15.Sep.98 | 14   | 0.548   | 0.221      | <0.1       | <0.1       | 23.9       | 11.0       |
| 18.Sep.98 | 17   | <0.1    | <0.1       | <0.1       | <0.1       | 16.4       | 7.54       |
| 22.Sep.98 | 21   | 0.174   | <0.1       | <0.1       | <0.1       | 8.66       | 4.36       |
| 26.Sep.98 | 25   | <0.1    | <0.1       | <0.1       | <0.1       | 3.79       | 1.46       |
| 01.Oct.98 | 30   | 0.268   | 0.127      | <0.1       | <0.1       | 1.83       | 0.921      |

\* Results represents an average of all analyses with no correction for procedural recovery  
DALA: days after last application

Table 32. Aquatic field dissipation study. Residues ( $\mu\text{g/kg}$ ) of trifloxystrobin and degradation products in soil after application of 2 x 190 g ai/ha (Report no. 242.40).

| sampling  | DALA | parent   | CGA<br>357261 | CGA<br>357262 | CGA<br>331409 | CGA<br>321113 | CGA<br>321113 | CGA<br>321113 | CGA<br>373466 |
|-----------|------|----------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|
|           |      | 0-15 cm* | 0-15 cm*      | 0-15 cm*      | 0-15 cm*      | 0-15 cm       | 15-30 cm      | 30-45 cm      | 0-15 cm**     |
| 01.Sep.98 | 0    | 13.6     | <2.0          | <2.0          | <2.0          | 11.7          | -             | -             | 4.35          |
| 02.Sep.98 | 1    | 11.7     | <2.0          | <2.0          | <2.0          | 17.1          | -             | -             | 5.18          |
| 04.Sep.98 | 3    | 10.4     | <2.0          | <2.0          | <2.0          | 16.9          | -             | -             | 5.21          |
| 08.Sep.98 | 7    | 6.44     | <2.0          | <2.0          | <2.0          | 19.0          | -             | -             | 5.25          |
| 15.Sep.98 | 14   | 9.69     | <2.0          | <2.0          | <2.0          | 17.9          | -             | -             | 6.39          |
| 22.Sep.98 | 21   | 6.85     | <2.0          | <2.0          | <2.0          | 19.7          | -             | -             | 6.32          |
| 01.Oct.98 | 30   | 4.57     | <2.0          | <2.0          | <2.0          | 18.4          | -             | -             | 6.22          |
| 16.Oct.98 | 45   | <2.0     | <2.0          | <2.0          | <2.0          | 14.1          | 2.56          | <2.0          | 4.04          |
| 31.Oct.98 | 60   | <2.0     | <2.0          | <2.0          | <2.0          | 16.9          | 2.43          | <2.0          | 5.14          |
| 30.Nov.98 | 90   | 4.07     | 2.71          | <2.0          | 4.66          | 19.7          | 2.59          | <2.0          | 5.40          |
| 31.Dec.98 | 121  | <2.0     | <2.0          | 4.48          | <2.0          | 21.3          | 2.23          | <2.0          | 6.25          |
| 04.Mar.99 | 184  | <2.0     | <2.0          | <2.0          | <2.0          | 13.8          | <2.0          | 2.21          | 4.23          |
| 29.May.99 | 270  | <2.0     | <2.0          | <2.0          | <2.0          | 10.4          | <2.0          | <2.0          | 2.35          |
| 31.Aug.99 | 364  | <2.0     | <2.0          | <2.0          | <2.0          | 2.68          | <2.0          | <2.0          | <2.0          |

\* No residues in the 15-30 cm layer and below

\*\* No samples above the LOD ( $2 \mu\text{g/kg}$ ) at 15-30 cm. One sample with  $2.34 \mu\text{g/kg}$  at 184 DALA in 30-45 cm

DALA: days after last application

Dissipation kinetics of trifloxystrobin, CGA321113, CGA373466 and CGA357261 were calculated for the water phase by linear regression analysis on the basis of the concentration curve of each compound, starting with the maximum concentration. Half-lives were 5 days for trifloxystrobin, 4.2 days for CGA373466, 6.6 days for CGA321113 and 18 days for CGA357261.

#### Summary - degradation in water

Trifloxystrobin is relatively stable hydrolytically under sterile neutral and weakly acid conditions but under alkaline conditions degradation increases with increasing pH.

The acid CGA321113 formed under alkaline conditions is not degraded hydrolytically. At elevated temperatures CGA321113 eliminates CO<sub>2</sub> and methanol to form the nitrile CGA357276.

Hydrolysis at pH 1 showed two major degradation products which were generated by cleavage of the bridge between the two aromatic rings, CGA289565 and CGA107170. No ring cleavage is observed at pH  $\geq 5$ .

Photolytic degradation of trifloxystrobin occurs as described in Table 1. The experimental photolytic half-lives of trifloxystrobin in sterile aqueous buffered solutions at 25°C under xenon arc light (12 hours light / 12 hours dark cycle) were found to be 20.4 hours at pH 5 and 31.5 hours at pH 7. The predicted environmental half-lives under natural summer sunlight at a latitude of 40° N were 1.1 and 1.7 days at pH 5 and 7 respectively.

Irradiation of trifloxystrobin in aqueous buffered solution at pH 5 and 7 led to isomerization of the active substance and the hydrolytic product CGA321113. After 380 hours of irradiation the four isomers of the parent compound were found in following concentrations: trifloxystrobin (E,E) 10.4%; CGA331409 (E,Z) 1.5%; CGA357261 (Z,E) 12.4%; CGA357262 (Z,Z) 3.5%. In addition, two isomers of the mono-acid degradation product were found: CGA373466 (Z,E) up to 13% and CGA321113 (E,E) up to 5.3%. Further degradation led to cleavage of the molecule between the two ring systems. After 360 hours irradiation at pH 5 of trifluoromethylphenyl-labelled trifloxystrobin 54.8% of the applied radioactivity was trapped in toluene and identified as CGA107170.

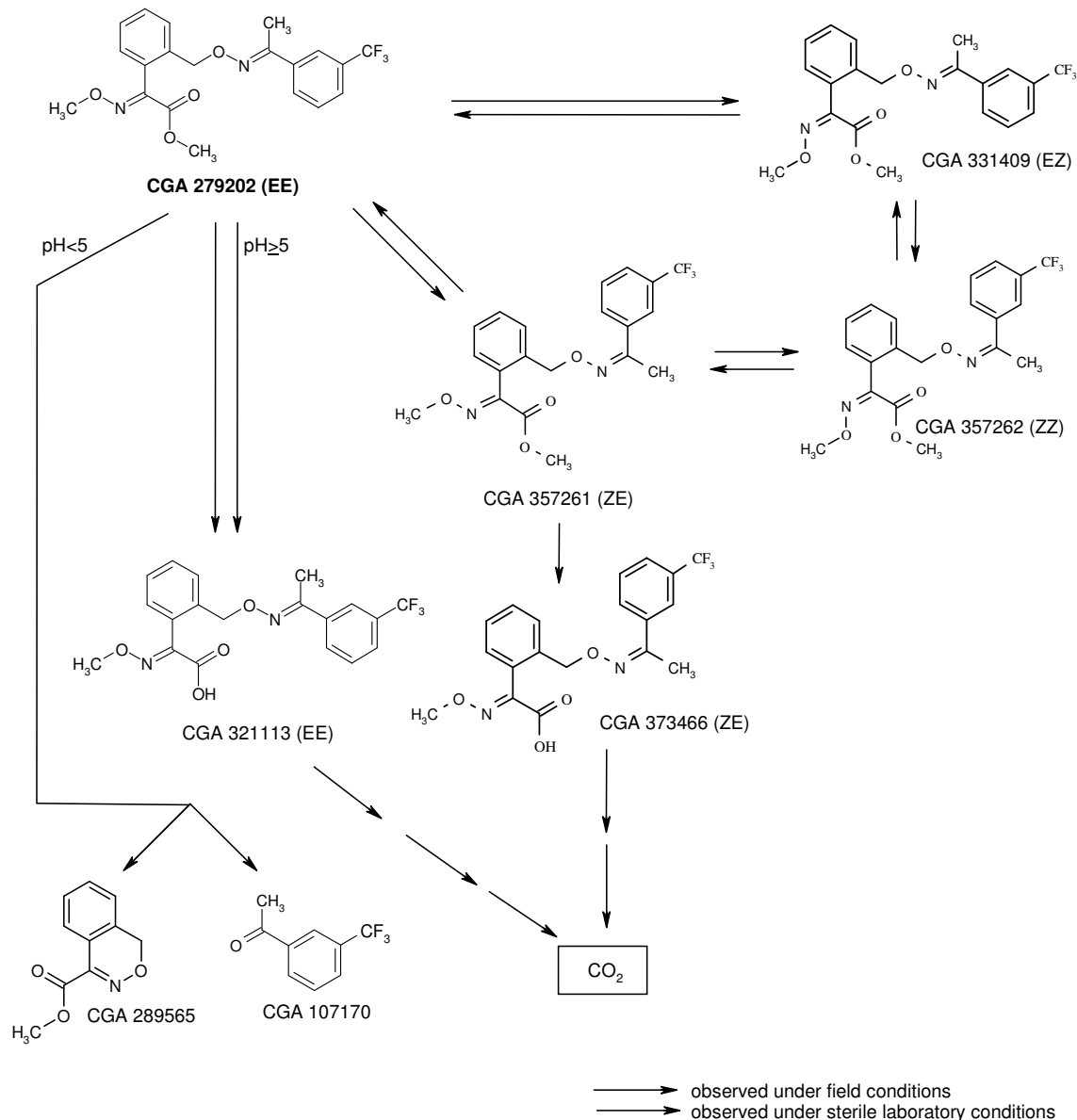
In the biologically active aquatic system of a paddy rice plot trifloxystrobin was rapidly degraded in both flooding water and soil, with a maximum half-life of about 2-5 days. As in sterile hydrolysis the principal product in a paddy rice field was the acid CGA321113. Although stable to sterile hydrolysis, CGA321113 was rapidly degraded in the rice plot with half-lives of 7-8 days in flooding water and paddy soil. Isomerization of both the parent compound and CGA321113 was observed, resulting in the formation of the parent isomer CGA357261 in minor amounts and the mono acid isomer CGA373466 in major amounts. Degradation of CGA373466 in the water layer was rapid with a half-life of 4.2 days. Concentrations of CGA357261 in the range of the LOQ were too low to estimate a half-life with reasonable significance.

Table 33. Half-lives of trifloxystrobin and degradation products in a paddy rice field.

| Compound        | DT <sub>50</sub> , days<br>(dissipation from water) | DT <sub>50</sub> , days<br>(degradation in water and paddy soil) |            |
|-----------------|-----------------------------------------------------|------------------------------------------------------------------|------------|
|                 | water                                               | water                                                            | paddy soil |
| trifloxystrobin | 5                                                   | 0.4                                                              | 2.1        |
| CGA321113       | 6.6                                                 | 7.7                                                              | 7.4        |
| CGA373466       | 4.2                                                 | -                                                                | -          |

The pathways of abiotic and biotic degradation of trifloxystrobin in aquatic systems are shown in Figure 3.

Figure 3. Proposed degradation pathways of trifloxystrobin in aquatic systems.



### Residues in rotational crops

Two confined rotational crop studies in Europe (Gross, 1997, Stingelin, 1997, Kennedy, 1997) with labelled trifloxystrobin, and a field study using unlabelled trifloxystrobin in the USA (Hayworth, 1999) were reported.

Report no. CMR26/97 (Gross, 1997). The uptake, distribution, and degradation of [CF<sub>3</sub>-phenyl-(U)<sup>14</sup>C]-trifloxystrobin after application at a rate of 500 g ai/ha to bare ground were investigated in the following rotational crops.

|          |                             |                                         |
|----------|-----------------------------|-----------------------------------------|
| Planting | 31 days after application:  | lettuce 1, radish 1, and spring wheat 1 |
|          | 120 days after application: | lettuce 2, radish 2                     |
|          | 174 days after application: | winter wheat                            |
|          | 365 days after application: | lettuce 3, radish 3, and spring wheat 2 |

Plant samples and soil cores (0-10 cm, 10-20 cm and 20-30 cm layers) were collected. All harvested samples were kept frozen at or below -18°C. The homogenized plant material (30-200 g) was extracted with acetonitrile/water 8:2 in approximately 4 ml solvent per g plant material. The suspensions were shaken for at least four hours in a mechanical shaker and then centrifuged. This extraction procedure was repeated five times or until the radioactivity in the last of the extracts was less than 5% of the radioactivity of the first one. Soil samples (50-200 g) were extracted with 80% aqueous acetonitrile (0.5-1 g/ml) as described for plant samples.

The unextractable radioactivity was determined by combustion of dry aliquots of the extracted plant material. The combined extracts were radio-assayed by liquid scintillation counting and characterized by TLC.

The total radioactive residues in the rotational crops were found to be

- 0.025 mg/kg, 0.01 mg/kg and 0.005 mg/kg in lettuce at plant-back intervals of 31, 120 and 365 days
- 0.041 mg/kg, 0.016 mg/kg and 0.009 mg/kg in radish tops and 0.031 mg/kg, 0.003 mg/kg and 0.002 mg/kg in radish roots at plant-back intervals of 31, 120 and 365 days
- 0.046 mg/kg, 0.059 mg/kg, 0.075 mg/kg, and 0.125 mg/kg in the 50% mature sample (whole tops), in grain, husks, and straw of spring wheat 1 planted at a plant-back interval of 301 days
- 0.005 mg/kg, 0.005 mg/kg, 0.021 mg/kg, and 0.023 mg/kg in the 50% mature sample (whole tops), in grain, husks, and straw of spring wheat 2 planted at a plant-back interval of 365 days
- 0.011 mg/kg, 0.005 mg/kg, 0.005 mg/kg, 0.012 mg/kg, and 0.015 mg/kg in the fall cutting sample, the 50% mature sample (whole tops), in grain, husks, and straw of winter wheat planted at a plant-back interval of 174 days.

Characterization of the radioactivity in various plant parts showed that trifluoroacetic acid (TFA) was the major degradation product in all crops, especially in spring wheat and radish (up to 16 µg/kg), demonstrating breakdown of the trifluoromethylphenyl ring. As trifluoroacetic acid was not observed as a plant metabolite in most target crops after foliar application (except very low amounts in peanuts), it is likely that its precursor is formed in the soil or rhizosphere of the plants.

The qualitative metabolite pattern in spring wheat rotational crops was similar to the pattern found in spring wheat after two spray treatments with [CF<sub>3</sub>-phenyl-(U)-<sup>14</sup>C]trifloxystrobin with the exception of the metabolite mentioned above.

Measurable amounts of trifloxystrobin and its acid CGA321113 could be detected in the tops and roots of radish only at the 31 days plant-back interval (5 and 6 µg/kg). I<sub>5</sub> (NOA413161), I<sub>6</sub> (NOA413163), I<sub>10</sub> (NOA443152) and its isomer I<sub>12</sub>, and I<sub>14</sub> (NOA414412) could be characterized in spring wheat straw.

Report no. CMR24/97 (Stingelin, 1997). In a similar experiment with [glyoxyl-phenyl-(U)-<sup>14</sup>C] trifloxystrobin applied at the same rate, planting was as follows.

|                             |                                         |
|-----------------------------|-----------------------------------------|
| 31 days after application:  | lettuce 1, radish 1, and spring wheat 1 |
| 120 days after application: | lettuce 2, radish 2                     |
| 174 days after application: | winter wheat                            |
| 365 days after application: | spring wheat 2                          |

Plant samples and soil cores (0-10 cm, 10-20 cm and 20-30 cm layers) were collected and extracted as before, but unextracted plant residues were subjected to a microwave extraction using 80% aqueous 1-propanol at 30 bar and 100-150°C.



The plant and soil samples after extraction were air dried, homogenized in a disk mill, and aliquots combusted to determine the unextractable radioactivity. The combined extracts were radio-assayed by liquid scintillation counting and characterized by TLC.

All harvested samples were kept frozen at or below -18°C. As a representative sample *whole tops-1* from *spring wheat 1* were tested for storage stability by comparison of analyses at the beginning and end of the experimental period. Qualitatively, no significant changes were found but quantitatively some changes could be observed.

The total radioactive residues were

- 0.023 mg/kg and 0.007 mg/kg in lettuce at plant-back intervals of 31 and 120 days
- 0.028 mg/kg and 0.005 mg/kg in radish tops and 0.018 mg/kg and 0.002 mg/kg in radish roots at plant-back intervals of 31 and 120 days
- 0.06 mg/kg, 0.037 mg/kg, 0.058 mg/kg, and 0.121 mg/kg in the 50% mature sample (whole tops), in grain, husks, and straw of spring wheat 1 planted at plant-back intervals of 30 days
- 0.002 mg/kg, 0.004 mg/kg, 0.004 mg/kg, and 0.007 mg/kg in the 50% mature sample (whole tops) in grain, husks, and straw of spring wheat 2 planted at a plant-back interval of 365 days
- 0.008 mg/kg, 0.002 mg/kg, 0.003 mg/kg, 0.002 mg/kg, and 0.004 mg/kg in the autumn cutting sample, the 50% mature sample (whole tops), in grain, husks, and straw of winter wheat planted at a plant-back interval of 174 days.

Characterization of the radioactivity in the plants showed that

- The qualitative metabolite pattern in rotational crops was similar to the pattern found in spring wheat after two spray treatments with [glyoxyl-phenyl-(U)-<sup>14</sup>C]trifloxystrobin
- No single metabolite fraction accounted for more than 10 µg/kg in any of the rotational crops at any plant-back interval
- Minor amounts of trifloxystrobin and its isomers (0.3-1.4 µg/kg) could be detected in all rotational crops except in the straw of spring wheat
- I<sub>5</sub> (NOA413161), I<sub>6</sub> (NOA413163), I<sub>12</sub> (isomer of NOA443152) and I<sub>15</sub> (CGA321113) were identified.

The total radioactive residues in the 0-10 cm soil layer disappeared with a half-life of about 81 days and the major fraction, consisting of CGA321113 and CGA373465, disappeared with a half-life of about 72 days.

Report no. ABR-97087 (Kennedy, 1997). The uptake, distribution, and degradation of [trifluoromethyl-phenyl-(U)-<sup>14</sup>C]- and [glyoxyl-phenyl-(U)-<sup>14</sup>C] trifloxystrobin after bare ground application in early or late summer at a rate of 2.2 kg ai/ha were investigated in the following rotational crops.

#### Planting

|                             |                                               |                                                                                                   |
|-----------------------------|-----------------------------------------------|---------------------------------------------------------------------------------------------------|
| 30 days after application:  | [trifluoromethyl-phenyl-(U)- <sup>14</sup> C] | spinach 1 [CF <sub>3</sub> ]<br>turnips 1 [CF <sub>3</sub> ]<br>winter wheat 1 [CF <sub>3</sub> ] |
|                             | [glyoxyl-phenyl-(U)- <sup>14</sup> C]         | spinach 1 [gly]<br>turnips 1 [gly]<br>winter wheat 1 [gly]                                        |
| 120 days after application: | [trifluoromethyl-phenyl-(U)- <sup>14</sup> C] | spinach 2 [CF <sub>3</sub> ]<br>turnips 2 [CF <sub>3</sub> ]<br>winter wheat 2 [CF <sub>3</sub> ] |
|                             | [glyoxyl-phenyl-(U)- <sup>14</sup> C]         | spinach 2 [gly]<br>turnips 2 [gly]<br>winter wheat 2 [gly]                                        |

For each plant-back interval, leafy vegetables (spinach) and root vegetables (turnips) were harvested at maturity, and cereals were harvested at 25%, 50% and 100% maturity. Soil samples were collected before application, directly after application and at last harvest.

Mature turnips were separated into leaves and roots, and mature wheat into fodder (straw and husks) and grain. Collected plant samples were homogenised, and 100-200 g batches were extracted with twice the volume of a mixture of acetonitrile and water (80:20). Extracts were pooled and assayed by LSC to determine the amount of extractable radioactivity. The acetonitrile/water extracts were individually concentrated by rotary evaporation until the acetonitrile stopped condensing. The aqueous solution was then partitioned twice with dichloromethane. The organic fractions were combined and the radioactivities in both the aqueous and organic fractions were determined by LSC. Finally, the unextractable radioactivity was determined by combustion of dry aliquots of the extracted plant material.

Soil samples were also extracted with 80% aqueous acetonitrile.

Sample extracts were also analysed by TLC and HPLC. Identification of metabolites was by co-chromatography with reference standard compounds.

The average total radioactive residues in rotational crops following soil application of [CF<sub>3</sub>-phenyl-(U)-<sup>14</sup>C]- and [glyoxyl-phenyl-(U)-<sup>14</sup>C]trifloxystrobin respectively at a rate of 2.2 kg ai/ha were

- 0.254 mg/kg and 0.016 mg/kg in spinach leaves at a plant-back interval of 30 days, and 0.264 mg/kg and 0.058 mg/kg at a plant-back interval of 120 days
- 0.064 mg/kg and 0.011 mg/kg in turnip leaves at a plant-back interval of 30 days, and 0.037 mg/kg and 0.021 mg/kg at a plant-back interval of 120 days
- 0.017 mg/kg and 0.005 mg/kg in turnip roots at a plant-back interval of 30 days, and 0.018 mg/kg and 0.015 mg/kg at a plant-back interval of 120 days
- 0.282 mg/kg and 0.021 mg/kg in (25% mature) wheat fodder at a plant-back interval of 30 days, and 0.190 mg/kg and 0.058 mg/kg at a plant-back interval of 120 days
- 0.138 mg/kg and 0.021 mg/kg in (50% mature) wheat fodder at a plant-back interval of 30 days, and 0.101 mg/kg and 0.082 mg/kg at a plant-back interval of 120 days
- 0.165 mg/kg and 0.042 mg/kg in mature wheat straw at a plant-back interval of 30 days, and 0.200 mg/kg and 0.127 mg/kg at a plant-back interval of 120 days
- 0.069 mg/kg and 0.029 mg/kg in mature wheat grain at a plant-back interval of 30 days, and 0.061 mg/kg and 0.057 mg/kg at a plant-back interval of 120 days.
- 

In soil residues ranged from 0.876 to 1.342 mg/kg directly after application. They decreased to 0.212 to 0.603 mg/kg at planting, and to 0.206-0.294 mg/kg at harvest.

In general, radioactive residues in crops treated with the CF<sub>3</sub>-label were higher than those treated with the glyoxyl-label.

After application of [trifluoromethyl-phenyl-(U)-<sup>14</sup>C]trifloxystrobin, trifluoroacetic acid was found as a major degradation product in all crops, especially in spring wheat (up to 0.23 mg/kg in 25% mature fodder and 0.12 mg/kg in mature straw), demonstrating breakdown of the trifluoromethylphenyl ring. As trifluoroacetic acid was practically absent in target crops after foliar application, it is likely that its precursor is formed in the soil or rhizosphere of the plants.

In samples treated with [glyoxyl-phenyl-(U)-<sup>14</sup>C]trifloxystrobin the products containing only the labelled moiety of the parent molecule were the hydroxy acid CGA347242, the corresponding lactone CGA320299 and phthalic acid (CGA367619).

Minor amounts of trifloxystrobin and its isomers (up to 1 µg/kg) could be detected in nearly all rotational crops. Exceptions were spinach leaves planted 30 days after application, and most immature wheat and wheat straw samples.

The carboxylic acid CGA321113 was detected in all rotational crops at low levels up to 3 µg/kg. In many samples the isomer CGA373466 was found at similarly low levels.

In soil, the main components detected were the parent compound and its isomers CGA357262 and CGA331409, and the mono-acids CGA321113, CGA373466 and CGA373465.

Report no. 109-97 (Hayworth, 1999). The uptake of trifloxystrobin and CGA321113 in rotational crops planted 30 and 120 days after 4 applications of trifloxystrobin to bare ground or primary (target) crops was investigated in 7 field trials in the USA.

At six locations, fields cropped with cucumber or squash plants were treated 4 times with trifloxystrobin at 282 g ai/ha by foliar spray application, at intervals of 7 days. At one location bare ground instead of cropped soil was treated. At plant-back intervals of 30 and 120 days, representative crops (lettuce as a leafy vegetable, turnip as a root vegetable, and wheat as a cereal crop) were planted. The crops were grown under normal agricultural conditions and plant samples were collected at harvest.

Samples were stored frozen until extraction, when they were homogenised and extracted twice with acetonitrile/water (8:2). Further preparation included liquid-liquid extraction and clean-up steps. Samples were chromatographed by GC with an NPD and GC-MS (as a confirmatory method). Only trifloxystrobin and CGA321113 were determined.

No residues of trifloxystrobin (<0.02 mg/kg) or CGA321113 (<0.02 mg/kg) were detected in any of the rotational crops at the 30 days plant-back intervals except in wheat straw and grain from one trial. Samples with plant-back intervals of 120 days were therefore not analysed.

## RESIDUE ANALYSIS

### Analytical methods

#### *Enforcement method*

Report no. 00086/M040 (Weber and Pelz, 2002). A standard multi-residue method, DFG S19, can be used for monitoring purposes for the determination of trifloxystrobin in plant materials (Bayer method no. 00086/M040). Typical watery, acidic, dry, and oily samples (cucumber, citrus, wheat grain, and almond), as well as hops and leeks were chosen as representative crops to test the method for its applicability as an enforcement method.

In the revision of DFG S19, cucumbers, oranges, wheat, leeks and hops are extracted with acetone. Water is added, taking the natural water content of the sample into account, so that the acetone:water ratio is 2:1. Sodium chloride is added and the extract partitioned against ethyl acetate/cyclohexane, after which the organic phase is purified by GPC on BioBeads S-X3, using ethyl acetate/cyclohexane as the eluent. Almonds are extracted with acetone and acetonitrile with calcium silicate, and the organic phase is cleaned up by GPC. The final ethyl acetate/cyclohexane eluates are concentrated and reconstituted in ethyl acetate.

Hops are subjected to an additional clean-up on a silica gel mini-column (1 g deactivated silica gel and 5-10 mm of sodium sulfate). After preconditioning the column with hexane, isooctane is added to the concentrated eluate from the previous GPC step. The column is rinsed and eluted with

toluene and then with toluene/acetone. The last eluate is then concentrated on an evaporator and reconstituted in ethyl acetate.

The samples were analysed by GC-MSD. Recoveries from samples spiked at 0.02 mg/kg (LOQ) and 0.2 mg/kg ranged from 81 to 110% in all crops tested except hops, with relative standard deviations (RSD) of 1.6-16%. Accuracy, precision and linearity were all well within guideline specifications. With regard to specificity, no significant interferences were observed except in the case of oranges, where a background level of about 25% of the LOQ was found. Method S19 was successfully validated for representative oily, acidic, dry and watery crops, as well as for leeks.

Hops were fortified at 0.05 and 0.5 mg/kg, but recoveries were unsatisfactory, so DFG method S19 is not appropriate for the determination of trifloxystrobin in hops.

### *Specialised methods*

Report no. REM177.02 (Kissling, 1996). In method REM 177.02, used for the determination of trifloxystrobin in plant materials, homogenised samples are extracted with acetonitrile/water (8 + 2). An aliquot of the extract is diluted with 0.002 M hydrochloric acid and saturated sodium chloride solution, and partitioned twice with *tert*-butyl methyl ether. Liquid samples are directly partitioned with *ter*.-butyl methyl ether. The solvent is evaporated in a gentle stream of air at about 40°C and the residue is redissolved in n-hexane and passed through a conditioned amino-modified silica gel column. The column is washed with hexane and the analyte is eluted with *tert*-butyl methyl ether. The organic phase is evaporated as before and the residue redissolved in acetonitrile/water (35 + 65). Final quantification of trifloxystrobin is by HPLC with UV detection.

The LOQ for the method was 0.02 mg/kg for solid samples (apples, potatoes, pumpkins) and 0.01 mg/l for liquids (wine, juice). Mean recoveries from the samples tested at the LOQ and 10 times the LOQ ranged from 76 to 109%, with relative standard deviations (RSD) between 0.6% and 13.2%. Accuracy, precision, and repeatability were all tested and within guideline specifications. A confirmatory technique was also developed and reported, which involves dissolving the final residue in isooctane with determination by GC/ECD.

Report no. REM177.03 (Kissling, 1996). Method REM 177.03 is used for the determination of trifloxystrobin and CGA321113 in plant samples such as cereal grain and straw and bananas. Homogenised samples are extracted with acetonitrile/water (8 + 2) by heating under reflux (cereal grain and straw) or by maceration with a high-speed homogeniser. After filtration of the extract, an aliquot is taken for clean-up by a 3-layer liquid-liquid partition by adding saturated sodium chloride solution, toluene and hexane. The middle layer is collected and partitioned with hexane. The hexane phase is discarded, and the remaining organic phase evaporated. After reconstitution in a mixture of 0.085% aqueous phosphoric acid and acetone (95 + 5), a solid-phase extraction clean-up follows on a C<sub>18</sub> modified silica gel column. After elution with 0.085% aqueous phosphoric acid/acetone (3 + 7), the solution is evaporated to the aqueous remainder, and the sample is partitioned with hexane/*tert*-butyl methyl ether (1 + 1). The organic phase is evaporated and the residue redissolved in 0.1% polyethylene glycol in acetone. Final determination is by GC with electron capture detection.

Report no. 141/96 (Kissling, 1996). The method REM 177.03 was validated in a separate study. The LOQ for the method was 0.02 mg/kg for all tested samples except cereal straw (0.05 mg/kg). The overall recoveries were 90% and 91% for trifloxystrobin and CGA321113 respectively, with RSDs of 10% and 9%. Accuracy, precision, and repeatability were all tested and within guideline specifications.

The efficiency of extraction of method REM 177.03 tested by comparing the amount of radioactivity extracted with the TRR in a specimen treated with <sup>14</sup>C-labelled trifloxystrobin was 62% for wheat grain (total radioactivity 6055 dpm/g) and 65% for wheat straw (total radioactivity 156887 dpm/g).

Report no. REM 177.04 (Kissling, 1997). Method REM 177.04 is used for the determination of trifloxystrobin and CGA321113 in green and dry hop cones. Homogenised samples are extracted with acetonitrile/water (8 + 2) by heating under reflux. After filtration of the extract, clean-up is by a 3 layer liquid-liquid partition, additional partition with hexane and solid-phase extraction on a C<sub>18</sub> column as above. After the addition of a 0.2% ammonia solution, the two analytes are separated by liquid-liquid partition under alkaline conditions with hexane.

The hexane phase containing trifloxystrobin is evaporated, and the residue redissolved in hexane, transferred to an amino-modified silica gel cartridge and the analyte eluted with *tert*-butyl methyl ether. After evaporation, the residue is redissolved in 0.1% polyethylene glycol in acetone for final determination of trifloxystrobin by GC with electron capture detection as before.

The aqueous layer containing CGA321113 is mixed with 0.1 M HCl and *tert*-butyl methyl ether for liquid-liquid partition. The partition is repeated and the combined organic phases are evaporated. After clean-up on a conditioned amino-modified silica gel cartridge the analyte is eluted with acetonitrile/0.2% ammonia solution, saturated NaCl solution is added and the analyte is partitioned into hexane-*tert*-butyl methyl ether. The organic phase is evaporated and the residue dissolved in acetonitrile-water. Final determination of CGA321113 is by HPLC with UV detection. For both analytes, the limit of quantification was 0.1 mg/kg in green cones and 0.5 mg/kg in dry cones.

Report no. 161/97 (Kissling, 1997). Method REM 177.04 was validated in a separate study. For both analytes, the limit of quantification was 0.1 mg/kg in green cones and 0.5 mg/kg in dry cones. The overall recoveries for the method were 86% and 81% for trifloxystrobin and CGA321113 respectively, with RSDs of 7% and 9%. Repeatability, reproducibility and recovery were all tested and within guideline specifications.

Report no. AG-659 (Campell, 1997). Method AG-659 is suitable for the determination of trifloxystrobin and CGA321113 in plant materials and animal tissues and products. The same clean-up procedure is used as in REM 177.03, except that the organic phase for the last partition step is a mixture of hexane and *tert*-butyl methyl ether (1 + 1). Quantification of the analytes is by GC with NP detection.

Report no. AG-659A (Campell, 1998). AG-659A is a supplement to method AG-659, which it supersedes. The protocol of the method was extended to include the analysis of animal tissue samples from goats and poultry. All significant aspects of extraction, purification and residue determination remain unchanged.

Extraction efficiency data for GC/NPD method AG-659A using weathered radiolabelled samples from the plant metabolism studies for apples, cucumbers, and peanuts, and from the animal metabolism studies were submitted. The results (% extracted during validation of method AG-659A v. % extracted during metabolism studies) were apples 99% v. 100%, peanut kernels 52% v. 45%, peanut hay 82% v. 70%, cucumbers 120% v. 100%, goat meat 66% v. 88%, goat milk 90% v. 92% and poultry meat 80% v. 75%.

Report no. 756-99 (Eudy and Ediger, 1999). Validation data for AG-659 and AG-659A were presented. The mean recovery rates of trifloxystrobin over all fortification levels from animal tissues and products ranged from 84% for breast and thigh of chicken (fortification levels 0.02 to 0.05 mg/kg) with a relative standard deviation (RSD) of 8.1%, to 116% for cattle kidney (fortification levels 0.02 to 1.0 mg/kg, RSD of 18.2%). For crops, the lowest mean recovery rate was 78% from peanut meal (fortification levels 0.02 to 0.2 mg/kg), and the highest rate was 99% for potato granules (RSD 11%; fortification levels 0.02 to 0.5 mg/kg). The method can also be used for the determination of trifloxystrobin in hops, a sample that is difficult to analyse. The overall recovery from dried cones

(fortification levels varying between 0.1 and 20 mg/kg) was 82.7% for the parent compound (RSD 19.5%), and 91.0% for CGA321113 (RSD 23.8%).

In animal tissues and products, the mean recovery rates of CGA321113 over all fortification levels ranged from 71% from breast and thigh of chicken (RSD 3.3%; fortification levels 0.02 to 0.05 mg/kg) to 115% from chicken liver (RSD 12.6%; fortification levels 0.02 to 0.1 mg/kg). Recovery levels from crops were between 78% for cucumber (RSD 19%; fortification levels 0.02 to 1 mg/kg) and 94% for grapes (RSD 9.1%; fortification levels 0.02 to 10 mg/kg).

The LOQ was 0.02 mg/kg for both trifloxystrobin and CGA321113 in all samples except milk, peanut hay, and hops. The LOQ for milk was 0.01 mg/kg, for peanut hay 0.05 mg/kg, and for hops 0.1 mg/kg. Accuracy and precision were reported as satisfactory.

A confirmatory technique was also reported in which the residues are determined by GC-MS. For both trifloxystrobin and CGA321113, the mean recoveries from peanut hay were 73% (fortification levels 0.05 to 10 mg/kg), with relative standard deviations of 8.9% for trifloxystrobin and 15.1% for CGA321113. Validation of method AG-659A also included the extractability and recovery results from the <sup>14</sup>C- trifloxystrobin animal sample validation.

Report no. 279202/564 (Bandong, 1998); Report no. ABR-98013 (Hamilton, 1998). The two equivalent methods AG-659 and AG-659A (Campbell 1997, 1998) were validated in two independent laboratories (ILV) for the determination of trifloxystrobin and CGA321113 in the representative crops apples, bananas, raisins and peanut hay, as well as the animal samples liver, eggs, and milk. In each study, duplicates of control samples and 4 fortified samples (2 each at the LOQ and at 2-40 times the LOQ) were extracted and analysed. The method was validated successfully for all samples, with overall average recoveries of 95% and 97% for trifloxystrobin and CGA321113 in the first study (Bandong, 1998), and 103% and 89% in the second (Hamilton, 1998); the respective overall relative standard deviations were 18.3% and 13.6% in the first study, and 17% and 16% in the second.

When both reports are considered together, four recoveries were obtained for each substrate and approximate spike level. The pooled recovery data yielded mean values of 74.5-95.8% for trifloxystrobin at or about the LOQ in plant materials (RSD range 5.4-20.6%), and 86.5-105% at higher fortification levels (RSD 7.2-21.7%). In animal substrates, the mean values at the LOQ were 82-104.5% for trifloxystrobin (RSD range 13.3-28%) and 88-105% for CGA321113 (RSD range 18.3-28.1%). After fortification at levels 2-3 times the LOQs, the recovery levels were 82.8-102.3% and 101.8-108.3% for the two compounds respectively. The RSD ranged from 3.5 to 19.2% in the latter experiments.

Report no. 99/5/1647 (Peterson, 1999). Method 265A.00 is used for the determination of trifloxystrobin and CGA321113 in fresh and processed plant material. Apples, grapes, grape juice and wine are extracted with aqueous acetonitrile. The extract is diluted with hydrochloric acid and extracted with *tert*-butyl methyl ether. The organic phase is dried with anhydrous sodium sulfate, evaporated to dryness and reconstituted in mobile phase before injection on the HPLC column.

Fortification levels were 0.02 mg/kg (for grapes only), 0.04 mg/kg (for apples only), 0.05, 0.1, 0.2 and 0.5 mg/kg (for grapes and apples), and 0.02 and 0.1mg/l (for juice and wine). The mean recoveries of trifloxystrobin and CGA321113 were in the range 70-110% (except that the recovery of CGA321113 from grapes was slightly below 70% at 0.02 mg/kg).

For both analytes, the LOQ was 0.02 mg/kg in grapes, 0.02 mg/l in grape juice and wine, and 0.04 mg/kg in apples.

Report no. 99/5/1647 (Peterson, 1999). The method was validated in a separate study. The LOQ for trifloxystrobin and CGA321113 was 0.02 mg/kg for grapes, 0.02 mg/l for grape juice and wine and

0.04 mg/kg for apples. Recoveries ranged from 66 to 124% for trifloxystrobin and 58-130% for CGA321113.

Report no. 200177 (Haan, 2002). Method 200177 is suitable for trifloxystrobin and CGA321113 in plant materials. The residues are extracted from homogenised plant samples with acetonitrile/water (4 + 1) in a blender. The suspension is vacuum-filtered through a paper filter. The remaining solids are blended a second time with fresh solvent and filtered. The filtrates are combined and internal standard is added. The total volume is adjusted to 50 ml with acetonitrile / water (4 + 1). After solid-phase extraction on an SPE column under slight vacuum, the column is rinsed with acetonitrile/water (4 + 1) and the analytes are eluted with acetonitrile. The solution is evaporated to dryness and the dry residue dissolved in acetonitrile/water (4 + 1). The final determination is with LC/MS/MS in the positive ion mode. The LOQ was 0.01 mg/kg for both analytes.

Report no. 06742 (MR-078/02) (Nuesslein, 2002). Method 06742 was developed for the determination of residues of trifloxystrobin and CGA321113 in plant materials (carrots, Brussels sprouts, cabbages, tomatoes, red peppers, lettuce). Both analytes are extracted with acetonitrile/water. After filtration and concentration to the aqueous remainder, the acidified crude extract is purified by liquid-liquid partition in a mixture of cyclohexane and ethyl acetate and separation on a ChemElut cartridge. The residues are quantified by reverse-phase HPLC with Turbo-Ionspray MS/MS detection. The LOQ was 0.02 mg/kg in all samples.

Recoveries of trifloxystrobin ranged from 72 to 99% with mean values at each level between 81 and 93% and relative standard deviations between 0.7 and 10.4%. Recoveries of CGA321113 were between 71 and 103% with mean values at each level between 83 and 100% and relative standard deviations between 0.6 and 8.1%. The linearity of the detector response was demonstrated over the appropriate range of concentrations. The repeatability was shown successfully with carrots and tomatoes.

Report no. 00742 (MR-052/03) (Nuesslein, 2003). This supplement was developed for validating analytical method 00742 for the determination of trifloxystrobin and CGA321113 in additional plant materials. Recoveries were determined at fortification levels of 0.02 mg/kg, 0.2 mg/kg and 2 mg/kg with beans (bean with pod), broccoli (head), cauliflower (head), cherries, cucumbers, currants, leeks (shoots), melon fruit and peel, plums and strawberry fruit, jam and preserve. The LOQ was 0.02 mg/kg in all samples. Individual recovery rates ranged from 68 to 103% with overall RSDs between 1.1 and 9.3%. In the case of CGA321113, recoveries were between 81 and 101% with overall standard deviations (RSD) between 1.4 and 5.4%. The repeatability was shown to be satisfactory for cauliflower and strawberry.

Report no. REM177.05 (Kissling, 1997). In method REM 177.05, used for the determination of trifloxystrobin in body fluids, samples are extracted with acetonitrile/water (8 + 2) by shaking and extracts are centrifuged. An aliquot of the extract is taken for a 3-layer liquid-liquid partition by adding saturated sodium chloride solution, toluene and hexane. The middle layer is collected and an additional partition with hexane follows. The hexane phase is discarded and the organic phase evaporated. Reconstitution in a mixture of 0.085% aqueous phosphoric acid and acetone (95 + 5) is followed by a solid-phase extraction clean-up on a C<sub>18</sub> modified silica gel column. After elution with a mixture of 0.085% aqueous phosphoric acid/acetone (3 + 7), the solution is evaporated to the aqueous remainder, and the analytes partitioned into *tert*-butyl methyl ether/hexane (1 + 1). After evaporation, the analytes are redissolved in 0.1% polyethylene glycol in acetone. Final quantification is by GC with electron capture detection.

Report no. 164/97 (Kissling, 1997). The method was validated in a separate study. The LOQ for the method was 0.01 mg/kg for the tested substrates. The overall recoveries for the method were 95% and 86% for trifloxystrobin and CGA321113 respectively, with RSDs of 6% and 11%. Mean recoveries at the LOQ and 10 times the LOQ ranged from 90 to 100% for the parent compound and 78 to 94% for CGA321113, with relative standard deviations of 4-5% and 1-11% respectively. Accuracy, precision,

and repeatability were all tested and within guideline specifications. A confirmatory technique was also reported, based on determination by GC with MS detection.

### Stability of residues in stored analytical samples

Storage stability data from trials with apples, cucumbers, potatoes, wheat, grapes, peanuts and their corresponding processed products were reported.

Report no. 160-97 (Grunenwald, 1999); Report no. 154/96 (Kissling, 1999). In the study by Grunenwald samples of apple, apple wet pomace, peanut kernels, peanut oil and grape juice were fortified with 0.5 to 1 mg/kg of trifloxystrobin or CGA321113. Immediately after fortification, a sample was taken to determine the initial residue (fortification level). The remaining fortified samples were deep-frozen at about -20°C and analysed after nominal storage periods of 2, 6, 12 and 18 months.

In the study by Kissling samples of grapes, cucumbers, potatoes and wheat (whole plant, grain and straw) were homogenised and fortified with 0.5 mg/kg trifloxystrobin or CGA321113 (wheat straw: 1 mg/kg). Immediately after fortification, a sample was taken to determine the initial residue (fortification level). The remaining fortified specimens were deep frozen below -18°C and analysed after 2, 4, 8, 12, 18 and 24 months.

No significant decrease of residues was observed after the tested period of 18 or 24 months. Thus the residues of trifloxystrobin and CGA321113 are stable under freezer storage conditions for at least 24 months in grapes, cucumbers, potatoes and wheat and 18 months in apple, apple wet pomace, peanut kernels, peanut oil and grape juice. Hence, the results of the storage stability studies validate the results from the residue trials with respect to the stability of trifloxystrobin and CGA321113 in frozen samples. The results are shown in Tables 34-37.

Table 34. Storage stability of trifloxystrobin in plant samples (Report no. 154/96, Kissling, 1999).

| Sample              | Average % remaining after storage (months) |     |     |     |     |     |     |
|---------------------|--------------------------------------------|-----|-----|-----|-----|-----|-----|
|                     | 0                                          | 2   | 4   | 8   | 12  | 18  | 24  |
| Grape               | 100                                        | 103 | 93  | 109 | 114 | 103 | 99  |
| Cucumber            | 100                                        | 96  | 100 | 89  | 93  | 95  | 89  |
| Potato              | 100                                        | 96  | 93  | 95  | 107 | 91  | 97  |
| Wheat (straw)       | 100                                        | 107 | 99  | 106 | 94  | 113 | 115 |
| Wheat (grain)       | 100                                        | 99  | 87  | 104 | 81  | 95  | 103 |
| Wheat (whole plant) | 100                                        | 100 | 101 | 99  | 98  | 108 | 100 |

Table 35. Storage stability of CGA321113 in plant samples (Report no. 154/96, Kissling, 1999).

| Sample              | Average % remaining after storage (months) |     |     |     |     |     |     |
|---------------------|--------------------------------------------|-----|-----|-----|-----|-----|-----|
|                     | 0                                          | 2   | 4   | 8   | 12  | 18  | 24  |
| Grape               | 100                                        | 104 | 95  | 105 | 112 | 102 | 96  |
| Cucumber            | 100                                        | 132 | 102 | 86  | 93  | 92  | 85  |
| Potato              | 100                                        | 99  | 95  | 97  | 108 | 98  | 103 |
| Wheat (straw)       | 100                                        | 102 | 97  | 98  | 92  | 107 | 111 |
| Wheat (grain)       | 100                                        | 93  | 104 | 109 | 78  | 90  | 96  |
| Wheat (whole plant) | 100                                        | 98  | 99  | 91  | 93  | 106 | 102 |

Table 36. Storage stability of trifloxystrobin in plant samples (Report no. 160-97, Grunenwald, 1999).

| Sample           | Average % remaining after storage (months) |     |    |    |    |
|------------------|--------------------------------------------|-----|----|----|----|
|                  | 0                                          | 2   | 6  | 12 | 18 |
| Apple (fruit)    | 117                                        | 80  | 92 | 95 | 82 |
| Apple (pomace)   | 108                                        | 103 | 94 | 91 | 81 |
| Peanut (kernels) | 110                                        | 70  | 90 | 87 | 86 |



| Sample            | Average % remaining after storage (months) |     |     |     |     |
|-------------------|--------------------------------------------|-----|-----|-----|-----|
|                   | 0                                          | 2   | 6   | 12  | 18  |
| Peanut (hay)      | 107                                        | 108 | 75  | 119 | 99  |
| Peanut (oil)      | 92                                         | 102 | 117 | 94  | 102 |
| Potato (granules) | 102                                        | 99  | 75  | 70  | 84  |
| Grape (juice)     | 99                                         | 93  | 92  | 106 | 108 |

Table 37. Storage stability of CGA321113 in plant samples (Report no. 160-97, Grunenwald, 1999).

| Sample            | Average % remaining after storage (months) |     |     |     |     |
|-------------------|--------------------------------------------|-----|-----|-----|-----|
|                   | 0                                          | 2   | 6   | 12  | 18  |
| Apple (fruit)     | 89                                         | 75  | 112 | 78  | 75  |
| Apple (pomace)    | 108                                        | 82  | 104 | 87  | 68  |
| Peanut (kernels)  | 111                                        | 71  | 78  | 87  | 72  |
| Peanut (hay)      | 101                                        | 95  | 99  | 93  | 96  |
| Peanut (oil)      | 84                                         | 111 | 110 | 109 | 107 |
| Potato (granules) | 97                                         | 109 | 102 | 100 | 86  |
| Grape (juice)     | 116                                        | 114 | 85  | 107 | 96  |

Report no. 301-97 (Grunenwald, 1999). Samples of muscle, liver, milk and eggs were homogenised and fortified with 1 mg/kg trifloxystrobin or CGA321113. Immediately after fortification, a sample was taken to determine the initial residues (fortification level). The remaining fortified specimens were deep-frozen below -20°C and analysed after nominal intervals of 3, 6 and 12 months.

No significant decrease of residues was observed after the tested period of 12 months. The results validate the results from the feeding trials with respect to the stability of trifloxystrobin and CGA321113 in frozen samples. The results are shown Tables 38 and 39.

Table 38. Storage stability of trifloxystrobin in animal samples (Report no. 301-97, Grunenwald, 1999).

| Sample      | Average % remaining after storage (months) |     |     |     |
|-------------|--------------------------------------------|-----|-----|-----|
|             | 0                                          | 3   | 6   | 12  |
| Beef muscle | 97                                         | 115 | 103 | 120 |
| Beef liver  | 104                                        | 106 | 81  | 73  |
| Milk        | 105                                        | 110 | 107 | 71  |
| Eggs        | 111                                        | 98  | 95  | 79  |

Table 39. Storage stability of CGA321113 in animal samples (Report no. 301-97, Grunenwald, 1999).

| Sample      | Average % remaining after storage (months) |     |     |     |
|-------------|--------------------------------------------|-----|-----|-----|
|             | 0                                          | 3   | 6   | 12  |
| Beef muscle | 105                                        | 100 | 124 | 101 |
| Beef liver  | 115                                        | 119 | 72  | 111 |
| Milk        | 105                                        | 101 | 87  | 102 |
| Eggs        | 113                                        | 94  | 79  | 91  |

## USE PATTERN

Trifloxystrobin is a broad-spectrum contact fungicide for foliar use with mesostemic properties. The active substance is not translocated in the vascular system. Trifloxystrobin is active against fungi from all four classes: *Ascomycetes*, *Deuteromycetes*, *Basidiomycetes* and *Oomycetes*. It is used on a wide range of agricultural and horticultural crops grown in open fields or protected under glass or plastic in temperate, sub tropical and tropical climates. It is mainly used on grapes, pome fruits, citrus fruits,

bananas and cereals, but it is also used commercially on stone fruits, strawberries, vegetables of all kinds, pulses, tree nuts, oilseeds, coffee and hops.

The use of trifloxystrobin is supported by supervised residue trials in the following crops or crop groups: citrus, pome fruit, stone fruit, grapes, strawberry, banana, cereals, leek, head cabbage, Chinese cabbage, Brussels sprouts, cauliflower and broccoli, cucumber, melon, summer squash, tomato, pepper, beans, soya beans, carrot, celeriac, potato, sugar beet, celery, chicory, cereals (wheat, barley, maize, rice), almonds, tree nuts, cotton, peanut, coffee and hops. Certified labels with English translations were submitted by the manufacturer. Information on GAP reflects the registration status as of February 2004. Use patterns which are supported by residue data are summarised in Table 40.

Products containing the active substance trifloxystrobin are sold under different trade names depending on mixing partner, the type of formulation, the country and market section. The most common trade names for straight (solo) formulations are Flint®, Twist® and Tega®. Co-formulations with other fungicides are Stratego®/Rombus® (trifloxystrobin and propiconazole), Sphere®/Sfera® (trifloxystrobin and cyproconazole) and Eclair® (trifloxystrobin and cymoxanil).

Table 40. Use patterns of trifloxystrobin in foliar spray applications.

| Crop                          | Country      | Formulation<br>conc. of ai | Application              |                        |                    | PHI<br>(days)       |
|-------------------------------|--------------|----------------------------|--------------------------|------------------------|--------------------|---------------------|
|                               |              |                            | Rate (kg ai/ha)          | Spray conc. (kg ai/hl) | No.                |                     |
| Almond                        | USA          | WG 500 g/kg                | 0.07-0.14                |                        | max 3              | 60                  |
| Apple                         | Australia    | WG 500 g/kg                |                          | 0.005                  | max 3              | 35, 70 <sup>1</sup> |
| Apple                         | Austria      | WG 500 g/kg                |                          | 0.005                  | 3                  | 14                  |
| Apple                         | Belgium      | WG 500 g/kg                | 0.05 <sup>2</sup> /0.085 |                        | 4                  | 14                  |
| Apple                         | Canada       | WG 500 g/kg                | 0.07-0.11                |                        | 4 (2) <sup>3</sup> | n. s.               |
| Apple                         | Croatia      | WG 500 g/kg                |                          | 0.005-0.0075           | max 5              | 21                  |
| Apple (excl.<br>cider apples) | France       | WG 500 g/kg                |                          | 0.0075                 | max 3              | 14                  |
| Apple                         | Germany      | WG 500 g/kg                | 0.025 <sup>2</sup>       | 0.005                  | 3 (4)              | 14                  |
| Apple                         | Hungary      | WG 500 g/kg                | 0.075                    |                        | max 3-4            | 14                  |
| Apple                         | Italy        | WG 500 g/kg                | 0.075-0.11               | 0.005-0.0075           | max 3              | 14                  |
| Apple                         | Japan        | SC 250 g/kg                |                          | 0.0083-0.0167          | 1 - 4              | 1                   |
| Apple                         | Luxembourg   | WG 500 g/kg                | 0.05 <sup>2</sup> /0.085 |                        | 4                  | 14                  |
| Apple                         | Mexico       | WG 500 g/kg                | 0.075-0.1                |                        | 4 (2) <sup>4</sup> | 14                  |
| Apple                         | New Zealand  | WG 500 g/kg                |                          | 0.005                  | max 3              | 70                  |
| Apple                         | Poland       | WG 500 g/kg                | 0.075                    |                        | 3 (4) <sup>5</sup> | 14                  |
| Apple                         | Poland       | WG 500 g/kg                | 0.1                      |                        | 2                  | 14                  |
| Apple                         | Romania      | WG 500 g/kg                |                          | 0.005                  | 4 - 6              | 14                  |
| Apple                         | South Africa | WG 500 g/kg                |                          | 0.0038-0.005           | 3                  | 7                   |
| Apple                         | Slovakia     | WG 500 g/kg                | 0.075                    | 0.0075                 | 2 - 3              | 14                  |
| Apple                         | Spain        | WG 500 g/kg                |                          | 0.0075-0.015           | max 4              | 14                  |
| Apple                         | Switzerland  | WG 500 g/kg                | 0.12                     | 0.0075                 | max 4              | 21                  |
| Apple                         | Turkey       | WG 500 g/kg                |                          | 0.0075                 | 2 - 3              | 14                  |
| Apple                         | Ukraine      | WG 500 g/kg                | 0.075                    |                        | 3                  | 20                  |
| Apple                         | USA          | WG 500 g/kg                | 0.0530.105               |                        | 3 (4) <sup>5</sup> | 14                  |
| Apricot                       | Switzerland  | WG 500 g/kg                | 0.2                      | 0.013                  | max 3              | 21                  |
| Apricot                       | USA          | WG 500 g/kg                | 0.07-0.14                |                        | max 4              | 1                   |
| Banana                        | Colombia     | EC 75 g/l                  | 0.075-0.09               |                        | max 4              | 0                   |
| Banana                        | Costa Rica   | EC 75 g/l                  | 0.075-0.09               |                        | 3 - 4              | n. r.               |
| Banana                        | Ecuador      | EC 75 g/l                  | 0.075                    |                        | max 4              | 0                   |
| Banana                        | Guatemala    | EC 75 g/l                  | 0.075-0.09               |                        | 3 - 4              | n. r.               |
| Banana                        | Honduras     | EC 75 g/l                  | 0.075-0.09               |                        | 3 - 4              | n. r.               |
| Banana                        | Nicaragua    | EC 75 g/l                  | 0.075-0.09               |                        | 3 - 4              | n. r.               |

| Crop                    | Country       | Formulation<br>conc. of ai | Application     |                        |                    | PHI<br>(days)           |
|-------------------------|---------------|----------------------------|-----------------|------------------------|--------------------|-------------------------|
|                         |               |                            | Rate (kg ai/ha) | Spray conc. (kg ai/hl) | No.                |                         |
| Banana                  | Panama        | EC 75 g/l                  | 0.075-0.09      |                        | 3 - 4              | n. r.                   |
| Barley                  | Austria       | EC 187.5 g/l               | 0.15            |                        | 1                  | 35                      |
| Barley                  | Belgium       | DC 125 g/l                 | 0.19            |                        | max 2              | 42                      |
| Barley                  | France        | EC 125 g/l                 | 0.25            |                        | max 2              | 42                      |
| Barley                  | Germany       | SC 500 g/l                 | 0.25            |                        | max 2              | 35                      |
| Barley                  | Great Britain | SC 500 g/l                 | 0.25            |                        | max 2              | 35                      |
| Barley                  | Great Britain | EC 125 g/l                 | 0.25            |                        | max 2              | 35                      |
| Barley, spring          | Hungary       | EC 187.5 g/l               | 0.15-0.19       |                        | 1 - 2              | n. s.                   |
| Barley                  | Ireland       | EC 125 g/l                 | 0.25            |                        | max 2              | usable up to<br>BBCH 71 |
| Barley                  | Italy         | EC 187.5 g/l               | 0.11-0.19       |                        | max 3              | 42                      |
| Barley                  | Luxembourg    | DC 125 g/l                 | 0.19            |                        | max 2              | 42                      |
| Barley                  | Poland        | EC 187.5 g/l               | 0.15-0.19       |                        | n. s.              | 45                      |
| Barley                  | Poland        | EC 125 g/l                 | 0.125           |                        | n. s.              | 35                      |
| Barley, spring          | Slovakia      | EC 125 g/l                 | 0.125           |                        | n. s.              | 35                      |
| Barley                  | Switzerland   | EC 187.5 g/l               | 0.19            |                        | 1                  | appl. latest<br>BBCH 51 |
| Bean                    | Brazil        | WG 500 g/kg                | 0.1-0.13        |                        | 3                  | 15                      |
| Bean                    | Brazil        | EC 125 g/l                 | 0.075           |                        | 1 - 2              | 15                      |
| Beechnut                | USA           | WG 500 g/kg                | 0.07-0.14       |                        | max 4              | 60                      |
| Brazil Nut              | USA           | WG 500 g/kg                | 0.07-0.14       |                        | max 4              | 60                      |
| Broccoli                | Switzerland   | WG 500 g/kg                | 0.13-0.25       |                        | max 3              | 7                       |
| Brussels<br>sprouts     | Switzerland   | WG 500 g/kg                | 0.13-0.25       |                        | max 3              | 7                       |
| Butternut               | USA           | WG 500 g/kg                | 0.07-0.14       |                        | max 4              | 60                      |
| Cabbage,<br>Chinese     | Switzerland   | WG 500 g/kg                | 0.13-0.25       |                        | max 3              | 7                       |
| Cabbage, Head           | Switzerland   | WG 500 g/kg                | 0.13-0.25       |                        | max 3              | 7                       |
| Carrots                 | Switzerland   | WG 500 g/kg                | 0.13-0.25       |                        | max 3              | 7                       |
| Cashew                  | USA           | WG 500 g/kg                | 0.07-0.14       |                        | max 4              | 60                      |
| Cauliflower             | Switzerland   | WG 500 g/kg                | 0.13-0.25       |                        | max 3              | 7                       |
| Celeriac                | Switzerland   | WG 500 g/kg                | 0.13-0.25       |                        | max 3              | 14                      |
| Celery                  | Switzerland   | WG 500 g/kg                | 0.13-0.25       |                        | max 3              | 7                       |
| Cherry                  | Switzerland   | WG 500 g/kg                | 0.2             | 0.013                  | max 3              | 21                      |
| Cherry                  | USA           | WG 500 g/kg                | 0.07-0.14       |                        | max 4              | 1                       |
| Chestnuts               | USA           | WG 500 g/kg                | 0.07-0.14       |                        | max 4              | 60                      |
| Chicory                 | Switzerland   | WG 500 g/kg                | 0.13-0.25       |                        | max 3              | 21                      |
| Chinquapins             | USA           | WG 500 g/kg                | 0.07-0.14       |                        | max 4              | 60                      |
| Citrus<br>(excl. lemon) | South Africa  | WG 500 g/kg                |                 | 0.005                  | 2                  | 76                      |
| Citrus                  | USA           | WG 250 g/kg                | 0.07-0.14       |                        | 3 (4) <sup>5</sup> | 30                      |
| Coffee                  | Brazil        | EC 187.5 g/l               | 0.075-0.11      |                        | 3                  | 30                      |
| Cotton                  | Brazil        | EC 125 g/l                 | 0.063-0.075     |                        | 2 - 3              | 21                      |
| Cucumber                | Japan         | SC 250 g/kg                |                 | 0.01                   | 1 - 3              | 1                       |
| Cucumber                | Mexico        | WG 500 g/kg                | 0.06-0.09       | 0.013-0.019            | 4 (2) <sup>4</sup> | 0                       |
| Cucumber                | Switzerland   | WG 500 g/kg                | indoor0.25      | 0.025                  | max 3              | 3                       |
| Cucumber                | USA           | WG 500 g/kg                | 0.053-0.14      |                        | max 4              | 0                       |
| Cucurbits               | South Africa  | WG 500 g/kg                | min. 0.03       | 0.0063                 | 3                  | 7                       |
| Filberts                | USA           | WG 500 g/kg                | 0.07-0.14       |                        | max 4              | 60                      |
| Grapes                  | Australia     | WG 500 g/kg                |                 | 0.0075                 | max 3              | 35, 70 <sup>1</sup>     |
| Grapes                  | Austria       | WG 500 g/kg                | 0.06-0.12       | 0.0038-0.0075          | max 3              | 35                      |

| Crop                     | Country      | Formulation<br>conc. of ai | Application              |                        |                     | PHI<br>(days)         |
|--------------------------|--------------|----------------------------|--------------------------|------------------------|---------------------|-----------------------|
|                          |              |                            | Rate (kg ai/ha)          | Spray conc. (kg ai/hl) | No.                 |                       |
| Grapes                   | Canada       | WG 500 g/kg                | 0.053-0.07               |                        | max 4 <sup>6</sup>  | n. s.                 |
| Grapes, wine             | France       | WG 500 g/kg                |                          | 0.0063                 | max 3               | 35                    |
| Grapes, wine             | Germany      | WG 500 g/kg                | 0.0450.12 <sup>7</sup>   | 0.008                  | max 3               | 35                    |
| Grapes, table            | Germany      | WG 500 g/kg                | 0.06 <sup>7</sup>        | 0.008                  | max 3               | 35                    |
| Grapes                   | Hungary      | WG 250 g/kg                | 0.13                     |                        | max 3-4             | 21                    |
| Grapes                   | Italy        | WG 500 g/kg                | 0.063-0.13               | 0.0063-0.013           | max 3               | 35                    |
| Grapes                   | Mexico       | WG 500 g/kg                | 0.05-0.1                 |                        | 4 (2) <sup>4</sup>  | 14                    |
| Grapes                   | Portugal     | WG 500 g/kg                | 0.063-0.075              | 0.0063-0.0075          | 3                   | 35                    |
| Grapes                   | Romania      | WG 250 g/kg                | 0.13                     | 0.013                  | 1 - 4               | 14                    |
| Grapes                   | Slovenia     | WG 250 g/kg                | 0.063-0.13               |                        | max 4               | n. s.                 |
| Grapes, table            | South Africa | WG 500 g/kg                | 0.038-0.075              | 0.0075                 | 3                   | 28-42                 |
| Grapes, wine             | South Africa | WG 500 g/kg                | 0.023-0.11               | 0.0075 <sup>8</sup>    | 3                   | 14                    |
| Grapes, wine             | South Africa | WG 500 g/kg                | 0.034-0.17               | 0.011 <sup>9</sup>     | 2                   | 14                    |
| Grapes                   | Spain        | WG 500 g/kg                | 0.075                    | 0.013-0.015            | max 4               | 30                    |
| Grapes                   | Switzerland  | WG 500 g/kg                | 0.05-0.12                | 0.015                  | max 3               | last appl. mid August |
| Grapes                   | Switzerland  | WG 250 g/kg                | 0.1-0.2                  |                        | max 3               | last appl. mid August |
| Grape                    | Turkey       | WG 500 g/kg                |                          | 0.005                  | 2 - 3               | 35                    |
| Grapes excl. Concord Gr. | USA          | WG 500 g/kg                | 0.053-0.14               |                        | max 4               | 14                    |
| Hops                     | Austria      | WG 500 g/kg                | 0.075-0.38               | 0.013                  | max 2               | 14                    |
| Hops                     | Germany      | WG 500 g/kg                | 0.38-0.63                | 0.013                  | max 2               | 14                    |
| Hops                     | USA          | WG 500 g/kg                | 0.0380.14                |                        | 3 (4) <sup>5</sup>  | 14                    |
| Leek                     | Switzerland  | EC 187.5 g/l               | 0.19                     |                        | max 3               | 7                     |
| Macadamia                | USA          | WG 500 g/kg                | 0.07-0.14                |                        | max 4               | 60                    |
| Maize                    | Brazil       | EC 125 g/l                 | 0.075-0.1                |                        | 1 - 2               | 30                    |
| Maize                    | USA          | EC 125 g/l                 | 0.064-0.11               |                        | max 2-3             | 30 <sup>10</sup>      |
| Melon                    | Italy        | WG 500 g/kg                | 0.075-0.13               | 0.0075-0.013           | max 3               | 3                     |
| Melon                    | Mexico       | WG 500 g/kg                | 0.06-0.09                | 0.013-0.019            | 4 (2) <sup>4</sup>  | 0                     |
| Melon                    | Turkey       | WG 500 g/kg                |                          | 0.0075                 | 2-3                 | 5                     |
| Melon, musk              | USA          | WG 500 g/kg                | 0.053-0.14               |                        | max 4               | 0                     |
| Nectarine                | Spain        | WG 500 g/kg                |                          | 0.015                  | max 4               | 7                     |
| Nectarine                | Switzerland  | WG 500 g/kg                | 0.2                      | 0.013                  | max 3               | 21                    |
| Nectarine                | USA          | WG 500 g/kg                | 0.07-0.14                |                        | max 4               | 1                     |
| Peach                    | Spain        | WG 500 g/kg                |                          | 0.015                  | max 4               | 7                     |
| Peach                    | Switzerland  | WG 500 g/kg                | 0.2                      | 0.013                  | max 3               | 21                    |
| Peach                    | USA          | WG 500 g/kg                | 0.07-0.14                |                        | max 4               | 1                     |
| Peanut                   | Argentina    | EC 187.5 g/l               | 0.084                    |                        | max 3               | 15                    |
| Peanut                   | Brazil       | EC 125 g/l                 | 0.075                    |                        | 3                   | 15                    |
| Peanut                   | USA          | EC 125 g/l                 | 0.064                    |                        | 6 (2) <sup>11</sup> | 14                    |
| Peanut                   | USA          | EC 125 g/l                 | 0.13                     |                        | 2                   | 14                    |
| Pear                     | Australia    | WG 500 g/kg                |                          | 0.005                  | max 3               | 35, 70 <sup>1</sup>   |
| Pear                     | Austria      | WG 500 g/kg                |                          | 0.005                  | 3                   | 14                    |
| Pear                     | Belgium      | WG 500 g/kg                | 0.05 <sup>2</sup> /0.085 |                        | 4                   | 14                    |
| Pear                     | Canada       | WG 500 g/kg                | 0.07-0.11                |                        | 4 (2) <sup>3</sup>  | n. s.                 |
| Pear                     | France       | WG 500 g/kg                |                          | 0.0075                 | max 3               | 14                    |
| Pear                     | Germany      | WG 500 g/kg                | 0.025 <sup>2</sup>       | 0.005                  | 3 (4)               | 14                    |
| Pear                     | Hungary      | WG 500 g/kg                | 0.05-0.075               |                        | n. s.               | 14                    |
| Pear                     | Italy        | WG 500 g/kg                | 0.075-0.11               | 0.005-0.0075           | max 3               | 14                    |
| Pear                     | Luxembourg   | WG 500 g/kg                | 0.05 <sup>2</sup> /0.085 |                        | 4                   | 14                    |

| Crop              | Country       | Formulation<br>conc. of ai | Application     |                        |                     | PHI<br>(days)           |
|-------------------|---------------|----------------------------|-----------------|------------------------|---------------------|-------------------------|
|                   |               |                            | Rate (kg ai/ha) | Spray conc. (kg ai/hl) | No.                 |                         |
| Pear              | Mexico        | WG 500 g/kg                | 0.075-0.1       |                        | 4 (2) <sup>4</sup>  | 14                      |
| Pear              | New Zealand   | WG 500 g/kg                |                 | 0.005                  | max 3               | 70                      |
| Pear              | Poland        | WG 500 g/kg                | 0.075           |                        | 3 (4) <sup>5</sup>  | 14                      |
| Pear              | Romania       | WG 500 g/kg                |                 | 0.005                  | 4 - 6               | 14                      |
| Pear              | South Africa  | WG 500 g/kg                |                 | 0.0038                 | 3                   | 14                      |
| Pear              | Slovakia      | WG 500 g/kg                | 0.075           | 0.0075                 | 2 - 3               | 14                      |
| Pear              | Spain         | WG 500 g/kg                |                 | 0.0075-0.015           | max 4               | 14                      |
| Pear              | Switzerland   | WG 500 g/kg                | 0.12            | 0.0075                 | max 4               | 21                      |
| Pear              | Ukraine       | WG 500 g/kg                | 0.075           |                        | 3                   | 20                      |
| Pear              | USA           | WG 500 g/kg                | 0.0530.105      |                        | 3 (4) <sup>5</sup>  | 14                      |
| Pecans            | USA           | EC 125 g/l                 | 0.091           |                        | max 3               | 30                      |
| Pepper            | USA           | WG 500 g/kg                | 0.053-0.14      |                        | max 4               | 3                       |
| Plum              | Switzerland   | WG 500 g/kg                | 0.2             | 0.013                  | max 3               | 21                      |
| Plum              | USA           | WG 500 g/kg                | 0.07-0.14       |                        | max 4               | 1                       |
| Pome fruit        | Slovenia      | WG 500 g/kg                | 0.05-0.075      |                        | 4                   | 21                      |
| Potato            | USA           | WG 250 g/kg                | 0.11-0.14       |                        | 6 (2) <sup>11</sup> | 7                       |
| Rice              | Brazil        | WG 500 g/kg                | 0.10-0.13       |                        | 2                   | 15                      |
| Rice              | USA           | WG 250 g/kg                | 0.11-0.17       |                        | max 2               | 35                      |
| Rice              | USA           | EC 125 g/l                 | 0.13-0.15       |                        | max 2               | 35                      |
| Soya bean         | Argentina     | EC 187.5 g/l               | 0.056           |                        | 1                   | 20                      |
| Soya bean         | Brazil        | EC 125 g/l                 | 0.05            |                        | 2                   | 30                      |
| Soya bean         | Brazil        | EC 187.5 g/l               | 0.056-0.075     |                        | 2                   | 30                      |
| Soya bean         | Brazil        | EC 187.5 g/l               | 0.056           |                        | n. s.               | 30                      |
| Squash,<br>Summer | USA           | WG 500 g/kg                | 0.053-0.14      |                        | max 4               | 0                       |
| Strawberry        | Switzerland   | WG 500 g/kg                | 0.25            | 0.025                  | max 3               | 14                      |
| Sugar beet        | Italy         | EC 187.5 g/l               | 0.11-0.15       |                        | 2 - 3               | 21                      |
| Sugar beet        | Switzerland   | EC 187.5 g/l               | 0.15            |                        | 1                   | 21                      |
| Sugar beet        | USA           | WG 250 g/kg                | 0.11-0.12       |                        | max 3 <sup>12</sup> | 21                      |
| Tea plant         | Japan         | SC 250 g/kg                |                 | 0.0083- 0.0167         | 1 - 2               | 14                      |
| Tomato            | USA           | WG 500 g/kg                | 0.07-0.14       |                        | max 4               | 3                       |
| Walnut            | USA           | WG 500 g/kg                | 0.07-0.14       |                        | max 4               | 60                      |
| Wheat             | Argentina     | EC 187.5 g/l               | 0.11-0.15       |                        | max 3               | 35                      |
| Wheat             | Austria       | EC 187.5 g/l               | 0.19            |                        | 1                   | 35                      |
| Wheat             | Belgium       | DC 125 g/l                 | 0.19            |                        | max 2               | 42                      |
| Wheat             | Brazil        | EC 125 g/l                 | 0.075           |                        | 1 - 2               | 30                      |
| Wheat *           | Canada        | EC 125 g/l                 | 0.13            |                        | max 2               | 45                      |
| Wheat *           | Canada        | WG 500 g/kg                | 0.12            |                        | max 2               | 45                      |
| Wheat             | France        | EC 125 g/l                 | 0.25            |                        | max 2               | 42                      |
| Wheat             | Germany       | SC 500 g/l                 | 0.25            |                        | max 2               | 35                      |
| Wheat, Winter     | Great Britain | SC 500 g/l                 | 0.25            |                        | max 2               | 35                      |
| Wheat, Winter     | Great Britain | EC 125 g/l                 | 0.25            |                        | max 2               | 35                      |
| Wheat, Winter     | Hungary       | EC 187.5 g/l               | 0.15-0.19       |                        | 1 or 2              | n. s.                   |
| Wheat             | Ireland       | EC 125 g/l                 | 0.25            |                        | max 2               | usable up to<br>BBCH 71 |
| Wheat             | Italy         | EC 187.5 g/l               | 0.11-0.19       |                        | max 3               | 42                      |
| Wheat             | Luxembourg    | DC 125 g/l                 | 0.19            |                        | max 2               | 42                      |
| Wheat             | Poland        | EC 187.5 g/l               | 0.15-0.19       |                        | n. s.               | 45                      |
| Wheat             | Poland        | EC 125 g/l                 | 0.13            |                        | n. s.               | 35                      |
| Wheat, Winter     | Slovakia      | EC 125 g/l                 | 0.13            |                        | n. s.               | 35                      |

| Crop  | Country     | Formulation<br>conc. of ai | Application     |                        |       | PHI<br>(days)           |
|-------|-------------|----------------------------|-----------------|------------------------|-------|-------------------------|
|       |             |                            | Rate (kg ai/ha) | Spray conc. (kg ai/hl) | No.   |                         |
| Wheat | Switzerland | EC 187.5 g/l               | 0.19            |                        | 1     | appl. latest<br>BBCH 61 |
| Wheat | USA         | EC 125 g/l                 | 0.09            |                        | max 2 | 35                      |

n. r. no restrictions

n. s. not specified on label

\* includes winter, spring, hard red, durum, Canada prairie and soft white wheat

<sup>1</sup> apple, pear, grape (Australia): 70 days PHI for export

<sup>2</sup> kg/ha vertical fruit leaf wall

<sup>3</sup> max. 4 applications of strobilurins per season. Do not apply more than 2 sequential applications of strobilurin fungicides before alternating to a non-strobilurin fungicide for at least 2 applications

<sup>4</sup> applications in blocks of two

<sup>5</sup> 3-4 applications per season, max. 3 subsequent applications

<sup>6</sup> max. applications per year: table and wine grapes 4; other grapes 3. Max 2 sequential applications of strobilurin fungicides before applying a non-strobilurin fungicide

<sup>7</sup> base application rate 0.03 kg ai/ha

<sup>8</sup> 10-14 day programme

<sup>9</sup> 18-21 day programme

<sup>10</sup> PHI for forage

<sup>11</sup> 2-6 applications; not more than 2 sequential applications

<sup>12</sup> not more than 1 application before using a fungicide with a different mode of action

## RESIDUES RESULTING FROM SUPERVISED TRIALS ON CROPS

The Meeting received information on trifloxystrobin supervised field trials for

|            |                  |                |                      |
|------------|------------------|----------------|----------------------|
| Fruits     | citrus           | Tables 41 – 42 | oranges              |
|            |                  | Table 43       | grapefruit           |
|            |                  | Table 44       | lemon                |
|            | pome<br>stone    | Tables 45 – 49 | apple and pear       |
|            |                  | Table 50       | apricot              |
|            |                  | Table 51       | cherries             |
|            |                  | Table 52       | peach                |
|            |                  | Table 53       | plum                 |
|            | berries          | Table 54 – 57  | grapes               |
|            |                  | Table 58       | strawberry           |
| Vegetables | tropical<br>bulb | Table 59       | banana               |
|            |                  | Table 60       | leek                 |
|            | brassica         | Table 61       | head cabbage         |
|            |                  | Table 62       | Brussels sprouts     |
|            |                  | Table 63       | flowerhead brassicas |
|            | fruiting         | Tables 64 – 65 | cucumber             |
|            |                  | Table 66       | melons               |
|            |                  | Table 67       | summer squash        |
|            |                  | Table 68       | sweet pepper         |
|            |                  | Table 69       | tomato               |
|            | leafy            | Table 70       | Chinese cabbage      |
|            | pulses           | Table 71       | beans                |
|            |                  | Table 72       | soya beans           |
|            | root and tuber   | Table 73       | carrot               |
|            |                  | Table 74       | celeriac             |
|            |                  | Table 75       | potato               |
|            | stalk and stem   | Tables 76 – 77 | sugar beet           |
|            |                  | Table 78       | celery               |
|            |                  | Table 79       | witloof chicory      |

|                     |                |                            |
|---------------------|----------------|----------------------------|
| Cereal grains       | Table 80       | barley                     |
|                     | Tables 81 – 83 | wheat                      |
|                     | Table 84       | maize                      |
|                     | Table 85       | rice                       |
| Tree nuts           | Table 86       | almonds                    |
|                     | Table 87       | pecan                      |
| Oil seeds           | Table 88       | cotton seed                |
|                     | Table 89       | peanut                     |
| Further commodities | Table 90       | coffee beans               |
|                     | Table 91       | hops                       |
| Animal feed         | Table 92       | almond hulls               |
|                     | Table 93       | peanut fodder              |
|                     | Table 94       | barley straw               |
|                     | Table 95       | maize stover               |
|                     | Table 96       | rice straw                 |
|                     | Tables 97 – 98 | wheat straw                |
|                     | Tables 99 –100 | sugar beet leaves and tops |

The trials were well documented with laboratory and field reports including method validation, procedural recoveries with spiking at residue levels similar to those occurring in samples from the supervised trials, and dates of analyses or duration of sample storage. Although control plots were included in the trials no results are shown in the Tables except where the residues in the control samples exceeded the LOQ. Residue data are unadjusted for recoveries. Results from replicate field plots are presented as individual values, and from replicate field samples as individual values followed by the mean. Results from replicate laboratory samples are presented as the means. When no residues were detected they are shown as below the LOQ. Residues, application rates and spray concentrations have generally been rounded to two significant figures or, for residues near the LOQ, to one significant figure. Residues values from the trials conducted according to maximum GAP have been used for the estimation of maximum residue levels and STMRS. These results are double underlined.

The corresponding data on the parent compound and CGA321113 expressed as trifloxystrobin conversion (factor 408/394) are given in the Tables.

#### *Citrus fruits*

In supervised trials on oranges, grapefruit and lemons reported to the Meeting from South Africa and the USA, the leaves of the crops were sprayed with 25WG and 50 WG formulations.

Table 41. Results of residue trials with trifloxystrobin on oranges in South Africa

| Year | Application |    |             |          | Residues (mg/kg)           |                |                      |                | Report No.;<br>Study No. |
|------|-------------|----|-------------|----------|----------------------------|----------------|----------------------|----------------|--------------------------|
|      | Form        | No | kg ai/ha    | kg ai/hl | Sample                     | PHI<br>(days)  | trifloxy-<br>strobin | CGA-<br>321113 |                          |
| 1997 | 50<br>WG    | 2  | 0.89 - 0.91 | 0.03     | fruit                      | 0 <sup>1</sup> | 0.18                 | 0.05           | 2411/97<br>SAF-2411-97   |
|      |             |    |             |          |                            | 0              | 1.6                  | 0.05           |                          |
|      |             |    |             |          |                            | 3              | 1.6                  | 0.05           |                          |
|      |             |    |             |          |                            | 7              | 1.2                  | 0.06           |                          |
|      |             |    |             |          |                            | 14             | 0.94                 | 0.05           |                          |
|      |             |    |             |          |                            | 21             | 0.74                 | 0.05           |                          |
|      |             |    |             |          |                            | 28             | 0.52                 | 0.06           |                          |
|      |             |    |             |          | peel                       | 76             | 0.58                 | 0.11           |                          |
|      |             |    |             |          | pulp                       | 76             | <0.02                | <0.02          |                          |
|      |             |    |             |          | whole fruit,<br>calculated | 76             | 0.20                 | 0.04           |                          |

| Year | Application |    |             |          | Residues (mg/kg)           |                |                      |                | Report No.;<br>Study No. |
|------|-------------|----|-------------|----------|----------------------------|----------------|----------------------|----------------|--------------------------|
|      | Form        | No | kg ai/ha    | kg ai/hl | Sample                     | PHI<br>(days)  | trifloxy-<br>strobin | CGA-<br>321113 |                          |
| 1997 | 50<br>WG    | 2  | 0.46        | 0.015    | fruit                      | 0 <sup>1</sup> | 0.08                 | 0.02           | 2410/97<br>SAF-2410-97   |
|      |             |    |             |          |                            | 0              | 0.74                 | 0.02           |                          |
|      |             |    |             |          |                            | 3              | 0.76                 | 0.03           |                          |
|      |             |    |             |          |                            | 7              | 0.72                 | 0.03           |                          |
|      |             |    |             |          |                            | 14             | 0.50                 | 0.04           |                          |
|      |             |    |             |          |                            | 21             | 0.35                 | 0.04           |                          |
|      |             |    |             |          |                            | 28             | 0.26                 | 0.04           |                          |
|      |             |    |             |          | peel                       | 76             | 0.20                 | 0.07           |                          |
|      |             |    |             |          | pulp                       | 76             | <0.02                | <0.02          |                          |
|      |             |    |             |          | whole fruit,<br>calculated | 76             | 0.07                 | 0.03           |                          |
| 1997 | 50<br>WG    | 2  | 0.56 - 0.59 | 0.015    | fruit                      | 0 <sup>1</sup> | 0.05                 | 0.02           | 2409/97<br>SAF-2409-97   |
|      |             |    |             |          |                            | 0              | 0.72                 | 0.02           |                          |
|      |             |    |             |          |                            | 3              | 0.49                 | 0.02           |                          |
|      |             |    |             |          |                            | 7              | 0.39                 | 0.02           |                          |
|      |             |    |             |          |                            | 14             | 0.29                 | 0.02           |                          |
|      |             |    |             |          |                            | 21             | 0.20                 | 0.02           |                          |
|      |             |    |             |          |                            | 28             | 0.13                 | 0.02           |                          |
|      |             |    |             |          | peel                       | 76             | 0.12                 | 0.04           |                          |
|      |             |    |             |          | pulp                       | 76             | <0.02                | <0.02          |                          |
|      |             |    |             |          | whole fruit,<br>calculated | 76             | 0.06                 | 0.02           |                          |
| 1999 | 50<br>WG    | 2  | 0.34        | 0.01     | fruit                      | 0              | 0.42                 | <0.01          | 2179/99<br>SAF-2179-99   |
|      |             |    |             |          |                            | 7              | 0.33                 | <0.01          |                          |
|      |             |    |             |          |                            | 14             | 0.26                 | <0.01          |                          |
|      |             |    |             |          |                            | 28             | 0.19                 | <0.01          |                          |
|      |             |    |             |          |                            | 56             | 0.12                 | <0.01          |                          |
|      |             |    |             |          | peel                       | 104            | 0.31                 | <0.01          |                          |
|      |             |    |             |          |                            | 104            | 0.24                 | <0.01          |                          |
|      |             |    |             |          | pulp                       | 104            | <0.01                | <0.01          |                          |
|      |             |    |             |          |                            | 104            | <0.01                | <0.01          |                          |
|      |             |    |             |          | whole fruit,<br>calculated | 104            | 0.12                 | <0.01          |                          |
| 1999 | 50<br>WG    | 2  | 0.17        | 0.005    | fruit                      | 0              | 0.28                 | <0.01          | 2178/99<br>SAF-2178-99   |
|      |             |    |             |          |                            | 7              | 0.14                 | <0.01          |                          |
|      |             |    |             |          |                            | 14             | 0.12                 | <0.01          |                          |
|      |             |    |             |          |                            | 28             | 0.07                 | <0.01          |                          |
|      |             |    |             |          |                            | 56             | 0.04                 | <0.01          |                          |
|      |             |    |             |          | peel                       | 104            | 0.07                 | <0.01          |                          |
|      |             |    |             |          |                            | 104            | 0.12                 | <0.01          |                          |
|      |             |    |             |          | pulp                       | 104            | <0.01                | <0.01          |                          |
|      |             |    |             |          |                            | 104            | <0.01                | <0.01          |                          |
|      |             |    |             |          | whole fruit,<br>calculated | 104            | 0.03                 | <0.01          |                          |
| 1999 | 50<br>WG    | 2  | 0.17        | 0.005    | fruit                      | 0              | 0.24                 | <0.01          | 2177/99<br>SAF-2177-99   |
|      |             |    |             |          |                            | 7              | 0.18                 | <0.01          |                          |
|      |             |    |             |          |                            | 14             | 0.17                 | <0.01          |                          |
|      |             |    |             |          |                            | 28             | 0.07                 | <0.01          |                          |
|      |             |    |             |          |                            | 56             | 0.05                 | <0.01          |                          |
|      |             |    |             |          | peel                       | 104            | 0.08                 | <0.01          |                          |
|      |             |    |             |          |                            | 104            | 0.09                 | <0.01          |                          |
|      |             |    |             |          | pulp                       | 104            | <0.01                | <0.01          |                          |
|      |             |    |             |          |                            | 104            | <0.01                | <0.01          |                          |
|      |             |    |             |          | whole fruit,<br>calculated | 104            | 0.03                 | <0.01          |                          |

<sup>1</sup> before last treatment



Table 42. Results of residue trials with trifloxystrobin on oranges in the USA.

| Location,<br>year         | Application |    |          |                    | Residues (mg/kg) |               |                      |                 | Report No.;<br>Study No.   |
|---------------------------|-------------|----|----------|--------------------|------------------|---------------|----------------------|-----------------|----------------------------|
|                           | Form        | No | kg ai/ha | kg ai/hl           | Sample           | PHI<br>(days) | trifloxy-<br>strobin | CGA321113       |                            |
| CA, 1998                  | 50<br>WG    | 4  | 0.17     | 0.025              | fruit            | 0             | 0.30                 | <0.02           | SAM 4474<br>02-FR-002-98-A |
|                           |             |    |          |                    |                  | 0             | 0.30                 | <0.02           |                            |
|                           |             |    |          |                    |                  | 8             | 0.36                 | <0.02           |                            |
|                           |             |    |          |                    |                  | 8             | 0.35                 | <0.02           |                            |
|                           |             |    |          |                    |                  | 18            | 0.27                 | <0.02           |                            |
|                           |             |    |          |                    |                  | 18            | 0.30                 | <0.02           |                            |
|                           |             |    |          |                    |                  | 25            | 0.23                 | <0.02           |                            |
|                           |             |    |          |                    |                  | 25            | 0.22                 | <0.02           |                            |
|                           |             |    |          |                    |                  | 32            | 0.16                 | <0.02           |                            |
|                           |             |    |          |                    |                  | 32            | <u>0.19</u>          | <u>&lt;0.02</u> |                            |
|                           |             |    |          |                    |                  | 39            | 0.21                 | <0.02           |                            |
|                           |             |    |          |                    |                  | 39            | 0.21                 | <0.02           |                            |
| CA, 1998                  | 50<br>WG    | 4  | 0.17     | 0.012              | fruit            | 0             | 0.43                 | <0.02           | SAM 4474<br>02-FR-002-98-B |
|                           |             |    |          |                    |                  | 0             | 0.41                 | <0.02           |                            |
|                           |             |    |          |                    |                  | 32            | <u>0.23</u>          | <u>&lt;0.02</u> |                            |
|                           |             |    |          |                    |                  | 32            | 0.20                 | <0.02           |                            |
| FL, 1998                  | 50<br>WG    | 4  | 0.17     | 0.023 -<br>0.025   | fruit            | 30            | <u>0.11</u>          | <u>&lt;0.02</u> | SAM 4474<br>OS-FR-402-98   |
|                           |             |    |          |                    |                  | 30            | 0.07                 | <0.02           |                            |
| FL, 1998                  | 50<br>WG    | 4  | 0.17     | 0.023 -<br>0.025   | fruit            | 30            | <u>0.21</u>          | <u>&lt;0.02</u> | SAM 4474<br>OS-FR-403-98   |
|                           |             |    |          |                    |                  | 30            | 0.18                 | <0.02           |                            |
| FL, 1998                  | 50<br>WG    | 4  | 0.17     | 0.024 -<br>0.025   | fruit            | 30            | <u>0.10</u>          | <u>&lt;0.02</u> | SAM 4474<br>OS-FR-405-98   |
|                           |             |    |          |                    |                  | 30            | 0.10                 | <0.02           |                            |
| FL, 1998                  | 50<br>WG    | 4  | 0.17     | 0.01               | fruit            | 26            | <u>0.08</u>          | <u>&lt;0.02</u> | SAM 4474<br>OS-FR-406-98   |
|                           |             |    |          |                    |                  | 26            | 0.07                 | <0.02           |                            |
| FL, 1998                  | 50<br>WG    | 4  | 0.17     | 0.023 -<br>0.025   | fruit            | 30            | 0.12                 | <0.02           | SAM 4474<br>OS-FR-407-98   |
|                           |             |    |          |                    |                  | 30            | <u>0.15</u>          | <u>&lt;0.02</u> |                            |
| FL, 1998                  | 50<br>WG    | 4  | 0.17     | 0.009              | fruit            | 26            | <u>0.09</u>          | <u>&lt;0.02</u> | SAM 4474<br>OS-FR-408-98   |
|                           |             |    |          |                    |                  | 26            | 0.08                 | <0.02           |                            |
| TX, 1998                  | 50<br>WG    | 4  | 0.17     | 0.023 -<br>0.024   | fruit            | 30            | <u>0.15</u>          | <u>&lt;0.02</u> | SAM 4474<br>OS-FR-310-98-A |
|                           |             |    |          |                    |                  | 30            | 0.14                 | <0.02           |                            |
| TX, 1998                  | 50<br>WG    | 4  | 0.17     | 0.0064 -<br>0.0071 | fruit            | 30            | 0.11                 | <0.02           | SAM 4474<br>OS-FR-310-98-B |
|                           |             |    |          |                    |                  | 30            | <u>0.12</u>          | <u>&lt;0.02</u> |                            |
| AZ, 1998                  | 50<br>WG    | 4  | 0.17     | 0.025              | fruit            | 29            | <u>0.17</u>          | <u>&lt;0.02</u> | SAM 4474<br>OW-FR-517-98   |
|                           |             |    |          |                    |                  | 29            | 0.15                 | <0.02           |                            |
| FL, 1998                  | 50<br>WG    | 4  | 0.17     | 0.0074             | fruit            | 0             | 0.17                 | <0.02           | SAM 4474<br>07-FR-003-98   |
|                           |             |    |          |                    |                  | 0             | 0.16                 | <0.02           |                            |
|                           |             |    |          |                    |                  | 8             | 0.06                 | <0.02           |                            |
|                           |             |    |          |                    |                  | 8             | 0.07                 | <0.02           |                            |
|                           |             |    |          |                    |                  | 15            | 0.05                 | <0.02           |                            |
|                           |             |    |          |                    |                  | 15            | 0.05                 | <0.02           |                            |
|                           |             |    |          |                    |                  | 22            | 0.05                 | <0.02           |                            |
|                           |             |    |          |                    |                  | 22            | 0.05                 | <0.02           |                            |
|                           |             |    |          |                    |                  | 30            | <u>0.05</u>          | <u>&lt;0.02</u> |                            |
|                           |             |    |          |                    |                  | 30            | 0.04                 | <0.02           |                            |
|                           |             |    |          |                    |                  | 36            | 0.04                 | <0.02           |                            |
|                           |             |    |          |                    |                  | 36            | 0.04                 | <0.02           |                            |
| Orange<br>FL, USA<br>1998 | 50<br>WG    | 4  | 0.17     | 0.011              | fruit            | 26            | <u>0.16</u>          | <u>&lt;0.02</u> | SAM 4474<br>OS-FR-404-98-A |
|                           |             |    |          |                    |                  | 26            | 0.13                 | <0.02           |                            |
| CA, 1998                  | 50<br>WG    | 4  | 0.17     | 0.0076             | fruit            | 30            | <u>0.07</u>          | <u>&lt;0.02</u> | SAM 4474<br>OW-FR-516-98-A |
|                           |             |    |          |                    |                  | 30            | 0.05                 | <0.02           |                            |

Table 43. Results of residue trials with trifloxystrobin on grapefruit in the USA.

| Location,<br>year | Application |    |          |                  | Residues (mg/kg) |                                                                  |                                                                                                     |                                                                                                                    | Report No.,<br>Study No.       |
|-------------------|-------------|----|----------|------------------|------------------|------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------|--------------------------------|
|                   | Form        | No | kg ai/ha | kg ai/hl         | Sample           | PHI<br>(days)                                                    | trifloxy-<br>strobin                                                                                | CGA321113                                                                                                          |                                |
| FL, 1998          | 50<br>WG    | 4  | 0.17     | 0.0074           | fruit            | 30<br>30                                                         | <u>0.03</u><br>0.03                                                                                 | <u>&lt;0.02</u><br><0.02                                                                                           | SAM 4474<br>07-FR-004-98-B     |
| FL, 1998          | 50<br>WG    | 4  | 0.17     | 0.025            | fruit            | 30<br>30                                                         | <u>0.03</u><br>0.03                                                                                 | <u>&lt;0.02</u><br><0.02                                                                                           | SAM 4474<br>07-FR-004-98-A     |
| CA, 1998          | 50<br>WG    | 4  | 0.17     | 0.012            | fruit            | 32<br>32                                                         | <u>0.10</u><br>0.09                                                                                 | <u>&lt;0.02</u><br><0.02                                                                                           | SAM 4474<br>02-FR-003-98       |
| FL, 1998          | 50<br>WG    | 4  | 0.17     | 0.0075-<br>0.008 | fruit            | 0<br>0<br>9<br>9<br>16<br>16<br>22<br>22<br>29<br>29<br>36<br>36 | 0.17<br>0.20<br>0.12<br>0.13<br>0.07<br>0.08<br>0.08<br>0.08<br><u>0.08</u><br>0.08<br>0.07<br>0.07 | <0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><u>&lt;0.02</u><br><0.02<br><0.02<br><0.02 | SAM 4474<br>OS-FR-409-98       |
| FL, 1998          | 50<br>WG    | 4  | 0.17     | 0.024-<br>0.025  | fruit            | 30<br>30                                                         | <u>0.04</u><br>0.04                                                                                 | <u>&lt;0.02</u><br><0.02                                                                                           | SAM 4474<br>OS-FR-410-98       |
| TX, 1998          | 50<br>WG    | 4  | 0.17     | 0.023-<br>0.024  | fruit            | 30<br>30                                                         | <u>0.06</u><br>0.03                                                                                 | <u>&lt;0.02</u><br><0.02                                                                                           | SAM 4474<br>OS-FR-311-98-<br>A |
| TX, 1998          | 50<br>WG    | 4  | 0.17     | 0.007            | fruit            | 30<br>30                                                         | 0.05<br><u>0.08</u>                                                                                 | <0.02<br><u>&lt;0.02</u>                                                                                           | SAM 4474<br>OS-FR-311-98-<br>B |
| AZ, 1998          | 50<br>WG    | 4  | 0.17     | 0.025            | fruit            | 30<br>30                                                         | <u>&lt;0.02</u><br><0.02                                                                            | <u>&lt;0.02</u><br><0.02                                                                                           | SAM 4474<br>OW-FR-518-98       |

Table 44. Results of residue trials with trifloxystrobin on lemon in the USA.

| Location,<br>Year | Application |    |          |                  | Residues (mg/kg) |                                                                  |                                                                                                     |                                                                                                                    | Report No.,<br>Study No.   |
|-------------------|-------------|----|----------|------------------|------------------|------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------|----------------------------|
|                   | Form        | No | kg ai/ha | kg ai/hl         | Sample           | PHI<br>(days)                                                    | trifloxy-<br>strobin                                                                                | CGA-<br>321113                                                                                                     |                            |
| FL, 1998          | 50<br>WG    | 4  | 0.17     | 0.024 -<br>0.025 | fruit            | 28<br>28                                                         | 0.02<br><u>0.02</u>                                                                                 | <0.02<br><u>&lt;0.02</u>                                                                                           | SAM 4474<br>OS-FR-411-98-A |
| FL, 1998          | 50<br>WG    | 4  | 0.17     | 0.008            | fruit            | 28<br>28                                                         | <0.02<br><u>&lt;0.02</u>                                                                            | <0.02<br><u>&lt;0.02</u>                                                                                           | SAM 4474<br>OS-FR-411-98-B |
| AZ, 1998          | 50<br>WG    | 4  | 0.17     | 0.015            | fruit            | 31<br>31                                                         | 0.09<br><u>0.11</u>                                                                                 | <0.02<br><u>&lt;0.02</u>                                                                                           | SAM 4474<br>OW-FR-521-98   |
| CA, 1998          | 50<br>WG    | 4  | 0.17     | 0.021            | fruit            | 30<br>30                                                         | <u>0.13</u><br>0.12                                                                                 | <u>&lt;0.02</u><br><0.02                                                                                           | SAM 4474<br>OW-FR-108-98   |
| CA, 1998          | 50<br>WG    | 4  | 0.17     | 0.008            | fruit            | 0<br>0<br>9<br>9<br>16<br>16<br>23<br>23<br>30<br>30<br>37<br>37 | 0.16<br>0.20<br>0.23<br>0.22<br>0.21<br>0.19<br>0.20<br>0.14<br>0.16<br><u>0.22</u><br>0.12<br>0.15 | <0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><u>&lt;0.02</u><br><0.02<br><0.02 | SAM 4474<br>OW-FR-519-98   |
| CA, 1998          | 50<br>WG    | 4  | 0.17     | 0.025            | fruit            | 29□29                                                            | <u>0.09</u> □0.0<br>6                                                                               | <u>&lt;0.02</u><br><0.02                                                                                           | SAM 4474<br>OW-FR-520-98   |

*Pome fruits*

The results of supervised trials on apples and pears conducted using foliar spray applications of 50 WG formulations were reported from Australia, Canada, Northern and Southern European countries, South Africa and the USA.

In two trials on apples (Kissling, 1998; report no. 511/98) trifloxystrobin was applied four times to the trees at a rate of 0.12 or 0.15 kg ai/ha at intervals of 12 to 17 days. Samples of fruit were taken before and after each application (Table 45).

Table 45. Residues of trifloxystrobin in apples before and after each of four applications in trials in Switzerland.

| Sampling                      | Residues (mg/kg) |        | Report No. |
|-------------------------------|------------------|--------|------------|
|                               | Plot 1           | Plot 2 |            |
| after 1st application         | 0.42             | 0.45   | 511/98     |
| before 2nd application        | 0.15             | 0.14   |            |
| after 2nd application         | 0.43             | 0.31   |            |
| before 3rd application        | 0.17             | 0.09   |            |
| after 3rd application         | 0.54             | 0.28   |            |
| before 4th application        | 0.21             | 0.12   |            |
| after 4th application         | 0.34             | 0.29   |            |
| 43 days after 4th application | 0.11             | 0.11   |            |
| 51 days after 4th application | 0.11             | 0.08   |            |

Table 46. Results of residue trials with trifloxystrobin on pome fruits in South Africa.

| Crop year  | Application |    |             |          | Residues (mg/kg) |            |                  |                 | Report No.; Study No.  |
|------------|-------------|----|-------------|----------|------------------|------------|------------------|-----------------|------------------------|
|            | Form        | No | kg ai/ha    | kg ai/hl | Sample           | PHI (days) | trifloxy-strobin | CGA321113       |                        |
| Apple 1995 | 50 WG       | 7  | 0.026-0.044 | 0.0038   | fruit            | 0          | 0.09             | <0.02           | 2215/95<br>SAF-2215-95 |
|            |             |    |             |          |                  | 3          | 0.03             | <0.02           |                        |
|            |             |    |             |          |                  | 7          | <u>0.03</u>      | <u>&lt;0.02</u> |                        |
|            |             |    |             |          |                  | 14         | <0.02            | <0.02           |                        |
|            |             |    |             |          |                  | 21         | <0.02            | <0.02           |                        |
|            |             |    |             |          |                  | 27         | <0.02            | <0.02           |                        |
|            |             |    |             |          |                  | 48         | <0.02            | <0.02           |                        |
|            |             |    |             |          |                  |            |                  |                 |                        |
| Apple 1995 | 50 WG       | 7  | 0.026-0.044 | 0.0038   | fruit            | 0          | 0.11             | <0.02           | 2216/95<br>SAF-2216-95 |
|            |             |    |             |          |                  | 3          | 0.06             | <0.02           |                        |
|            |             |    |             |          |                  | 7          | <u>0.04</u>      | <u>&lt;0.02</u> |                        |
|            |             |    |             |          |                  | 14         | <0.02            | <0.02           |                        |
|            |             |    |             |          |                  | 21         | 0.03             | <0.02           |                        |
|            |             |    |             |          |                  | 27         | <0.02            | <0.02           |                        |
|            |             |    |             |          |                  | 66         | <0.02            | <0.02           |                        |
|            |             |    |             |          |                  |            |                  |                 |                        |
| Pear 1999  | 50 WG       | 3  | 0.0642      | 0.0037   | fruit            | 0          | 0.25             | 0.01            | 2163/99<br>SAF-2163-99 |
|            |             |    |             |          |                  | 3          | 0.16             | 0.01            |                        |
|            |             |    |             |          |                  | 7          | 0.13             | 0.01            |                        |
|            |             |    |             |          |                  | 14         | <u>0.06</u>      | <u>&lt;0.01</u> |                        |
|            |             |    |             |          |                  | 21         | 0.03             | <0.01           |                        |
|            |             |    |             |          |                  | 28         | 0.03             | <0.01           |                        |
|            |             |    |             |          |                  | 74         | <0.01            | <0.01           |                        |
|            |             |    |             |          |                  | 74         | <0.01            | <0.01           |                        |

| Crop year | Application |    |          |          | Residues (mg/kg) |            |                  |             | Report No.; Study No.  |
|-----------|-------------|----|----------|----------|------------------|------------|------------------|-------------|------------------------|
|           | Form        | No | kg ai/ha | kg ai/hl | Sample           | PHI (days) | trifloxy-strobin | CGA321113   |                        |
| Pear 1999 | 50 WG       | 3  | 0.062    | 0.0037   | fruit            | 0          | 0.18             | <0.01       | 2165/99<br>SAF-2165-99 |
|           |             |    |          |          |                  | 3          | 0.15             | 0.01        |                        |
|           |             |    |          |          |                  | 7          | 0.11             | 0.01        |                        |
|           |             |    |          |          |                  | 14         | <u>0.05</u>      | <u>0.01</u> |                        |
|           |             |    |          |          |                  | 21         | 0.04             | <0.01       |                        |
|           |             |    |          |          |                  | 28         | 0.02             | <0.01       |                        |
|           |             |    |          |          |                  | 66         | <0.01            | <0.01       |                        |
|           |             |    |          |          |                  | 66         | <0.01            | <0.01       |                        |

Table 47. Results of residue trials with trifloxystrobin on apple in Australia.

| Year                 | Application |    |          |          | Residues (mg/kg) |                |                  |                 | Report No.; Study No.         |
|----------------------|-------------|----|----------|----------|------------------|----------------|------------------|-----------------|-------------------------------|
|                      | Form        | No | kg ai/ha | kg ai/hl | Sample           | PHI (days)     | trifloxy-strobin | CGA321113       |                               |
| 1998                 | 50 WG       | 6  | 0.075    | 0.0038   | fruit            | 0 <sup>1</sup> | <0.04            | <0.04           | 99/5/1646<br>AUS-99-5-1646-A1 |
|                      |             |    |          |          |                  | 0 <sup>1</sup> | 0.05             | <0.04           |                               |
|                      |             |    |          |          |                  | 0              | 0.04             | <0.04           |                               |
|                      |             |    |          |          |                  | 0              | 0.06             | <0.04           |                               |
|                      |             |    |          |          |                  | 7              | 0.05             | <0.04           |                               |
|                      |             |    |          |          |                  | 7              | <0.04            | <0.04           |                               |
|                      |             |    |          |          |                  | 14             | <0.04            | <0.04           |                               |
|                      |             |    |          |          |                  | 14             | <0.04            | <0.04           |                               |
|                      |             |    |          |          |                  | 21             | <0.04            | <0.04           |                               |
|                      |             |    |          |          |                  | 21             | <0.04            | <0.04           |                               |
|                      |             |    |          |          |                  | 28             | <0.04            | <0.04           |                               |
|                      |             |    |          |          |                  | 28             | <0.04            | <0.04           |                               |
|                      |             |    |          |          |                  | 35             | <u>&lt;0.04</u>  | <u>&lt;0.04</u> |                               |
|                      |             |    |          |          |                  | 35             | <0.04            | <0.04           |                               |
|                      |             |    |          |          |                  | 42             | <0.04            | <0.04           |                               |
| 1998                 | 50 WG       | 6  | 0.15     | 0.0075   | fruit            | 0 <sup>1</sup> | 0.10             | <0.04           | 99/5/1646<br>AUS-99-5-1646-A2 |
|                      |             |    |          |          |                  | 0 <sup>1</sup> | 0.11             | <0.04           |                               |
|                      |             |    |          |          |                  | 0              | 0.17             | <0.04           |                               |
|                      |             |    |          |          |                  | 0              | 0.16             | <0.04           |                               |
|                      |             |    |          |          |                  | 7              | 0.14             | <0.04           |                               |
|                      |             |    |          |          |                  | 7              | 0.12             | <0.04           |                               |
|                      |             |    |          |          |                  | 14             | 0.07             | <0.04           |                               |
|                      |             |    |          |          |                  | 14             | 0.07             | <0.04           |                               |
|                      |             |    |          |          |                  | 21             | 0.06             | <0.04           |                               |
|                      |             |    |          |          |                  | 21             | 0.05             | <0.04           |                               |
|                      |             |    |          |          |                  | 28             | 0.04             | <0.04           |                               |
|                      |             |    |          |          |                  | 28             | 0.04             | <0.04           |                               |
|                      |             |    |          |          |                  | 35             | <0.04            | <0.04           |                               |
|                      |             |    |          |          |                  | 35             | <0.04            | <0.04           |                               |
|                      |             |    |          |          |                  | 42             | <0.04            | <0.04           |                               |
| Apple Australia 1998 | 50 WG       | 6  | 0.075    | 0.0038   | fruit            | 0 <sup>1</sup> | 0.05             | <0.04           | 99/5/1646<br>AUS-99-5-1646-B1 |
|                      |             |    |          |          |                  | 0 <sup>1</sup> | 0.14             | <0.04           |                               |
|                      |             |    |          |          |                  | 0              | 0.06             | <0.04           |                               |
|                      |             |    |          |          |                  | 0              | 0.21             | <0.04           |                               |
|                      |             |    |          |          |                  | 7              | 0.14             | <0.04           |                               |
|                      |             |    |          |          |                  | 7              | 0.12             | <0.04           |                               |
|                      |             |    |          |          |                  | 13             | 0.12             | <0.04           |                               |
|                      |             |    |          |          |                  | 13             | 0.12             | <0.04           |                               |
|                      |             |    |          |          |                  | 21             | 0.27             | <0.04           |                               |
|                      |             |    |          |          |                  | 21             | 0.13             | <0.04           |                               |
|                      |             |    |          |          |                  | 28             | 0.13             | <0.04           |                               |
|                      |             |    |          |          |                  | 28             | 0.06             | <0.04           |                               |
|                      |             |    |          |          |                  | 35             | 0.04             | <0.04           |                               |
|                      |             |    |          |          |                  | 35             | <u>0.08</u>      | <u>&lt;0.04</u> |                               |
|                      |             |    |          |          |                  | 42             | 0.05             | <0.04           |                               |
|                      |             |    |          |          |                  | 42             | <0.04            | <0.04           |                               |

| Year                       | Application |    |          |          | Residues (mg/kg) |                |                      |           | Report No.;<br>Study No.          |
|----------------------------|-------------|----|----------|----------|------------------|----------------|----------------------|-----------|-----------------------------------|
|                            | Form        | No | kg ai/ha | kg ai/hl | Sample           | PHI<br>(days)  | trifloxy-<br>strobin | CGA321113 |                                   |
| Apple<br>Australia<br>1998 | 50<br>WG    | 6  | 0.15     | 0.0075   | fruit            | 0 <sup>1</sup> | 0.18                 | <0.04     | 99/5/1646<br>AUS-99-5-<br>1646-B2 |
|                            |             |    |          |          |                  | 0 <sup>1</sup> | 0.06                 | <0.04     |                                   |
|                            |             |    |          |          |                  | 0              | 0.27                 | <0.04     |                                   |
|                            |             |    |          |          |                  | 0              | 0.36                 | <0.04     |                                   |
|                            |             |    |          |          |                  | 7              | 0.21                 | <0.04     |                                   |
|                            |             |    |          |          |                  | 7              | 0.14                 | <0.04     |                                   |
|                            |             |    |          |          |                  | 13             | 0.12                 | <0.04     |                                   |
|                            |             |    |          |          |                  | 13             | 0.11                 | <0.04     |                                   |
|                            |             |    |          |          |                  | 21             | 0.10                 | <0.04     |                                   |
|                            |             |    |          |          |                  | 21             | 0.27                 | <0.04     |                                   |
|                            |             |    |          |          |                  | 28             | 0.08                 | <0.04     |                                   |
|                            |             |    |          |          |                  | 28             | 0.27                 | <0.04     |                                   |
|                            |             |    |          |          |                  | 35             | 0.15                 | <0.04     |                                   |
|                            |             |    |          |          |                  | 35             | 0.07                 | <0.04     |                                   |
|                            |             |    |          |          |                  | 42             | 0.08                 | <0.04     |                                   |
|                            |             |    |          |          |                  | 42             | 0.10                 | <0.04     |                                   |

<sup>1</sup> before last treatment

Table 48. Results of residue trials with trifloxystrobin on pome fruits in the USA and Canada.

| Crop<br>Location,<br>Year | Application |    |          |          | Residues (mg/kg) |                |                             |                                  | Report No.;<br>Study No.     |
|---------------------------|-------------|----|----------|----------|------------------|----------------|-----------------------------|----------------------------------|------------------------------|
|                           | Form        | No | kg ai/ha | kg ai/hl | Sample           | PHI<br>(days)  | trifloxy-<br>strobin        | CGA-<br>321113                   |                              |
| Apple<br>CO, USA<br>1996  | 50<br>WG    | 4  | 0.1      | 0.011    | fruit            | 14<br>14       | 0.15<br><u>0.18</u>         | 0.03<br><u>0.03</u>              | 110433<br>USA-MW-FR-315-96-B |
| Apple<br>OH, USA<br>1996  | 50<br>WG    | 4  | 0.1      | 0.008    | fruit            | 14<br>14       | 0.18<br><u>0.26</u>         | <0.02<br><u>&lt;0.02</u>         | 110433<br>USA-NE-FR-210-96-B |
| Apple<br>MI, USA<br>1996  | 50<br>WG    | 4  | 0.1      | 0.011    | fruit            | 14<br>14       | 0.13<br><u>0.16</u>         | <0.02<br><u>&lt;0.02</u>         | 110433<br>USA-NE-FR-725-96-B |
| Apple<br>NY, USA<br>1996  | 50<br>WG    | 4  | 0.1      | 0.011    | fruit            | 14<br>14       | 0.15<br><u>0.31</u>         | <0.02<br><u>&lt;0.02</u>         | 110433<br>USA-NE-FR-820-96-B |
| Apple<br>PN, USA<br>1996  | 50<br>WG    | 4  | 0.1      | 0.01     | fruit            | 15<br>15       | 0.14<br><u>0.14</u>         | <0.02<br><u>&lt;0.02</u>         | 110433<br>USA-NE-FR-821-96-B |
| Apple<br>CA, USA<br>1996  | 50<br>WG    | 4  | 0.1      | 0.011    | fruit            | 14<br>14       | 0.09<br><u>0.18</u>         | <0.02<br><u>&lt;0.02</u>         | 110433<br>USA-OW-FR-409-96-B |
| Apple<br>CA, USA<br>1996  | 50<br>WG    | 4  | 0.1      | 0.011    | fruit            | 0              | 0.13                        | <0.02                            | 110433<br>USA-OW-FR-410-96-B |
|                           |             |    |          |          |                  | 0              | 0.12                        | <0.02                            |                              |
|                           |             |    |          |          |                  | 1              | 0.11                        | <0.02                            |                              |
|                           |             |    |          |          |                  | 1              | 0.15                        | <0.02                            |                              |
|                           |             |    |          |          |                  | 3              | 0.12                        | <0.02                            |                              |
|                           |             |    |          |          |                  | 3              | 0.10                        | <0.02                            |                              |
|                           |             |    |          |          |                  | 7              | 0.14                        | <0.02                            |                              |
|                           |             |    |          |          |                  | 7              | 0.12                        | <0.02                            |                              |
|                           |             |    |          |          |                  | 14             | <u>0.10</u>                 | <u>&lt;0.02</u>                  |                              |
|                           |             |    |          |          |                  | 14             | 0.09                        | <0.02                            |                              |
|                           |             |    |          |          |                  | 21             | 0.06                        | <0.02                            |                              |
|                           |             |    |          |          |                  | 21             | 0.03                        | <0.02                            |                              |
| Apple<br>WA, USA<br>1996  | 50<br>WG    | 4  | 0.1      | 0.011    | fruit            | 14<br>14<br>14 | 0.13<br><u>0.24</u><br>0.14 | <0.02<br><u>&lt;0.02</u><br>0.03 | 110433<br>USA-OW-FR-634-96-B |
| Apple<br>WA, USA<br>1996  | 50<br>WG    | 4  | 0.1      | 0.11     | fruit            | 13<br>13       | 0.11<br><u>0.12</u>         | <0.02<br><u>&lt;0.02</u>         | 110433<br>USA-OW-FR-635-96-B |

| Crop<br>Location,<br>Year | Application |    |          |                 | Residues (mg/kg) |                                                                    |                                                                                                             |                                                                                                                                      | Report No.;<br>Study No.           |
|---------------------------|-------------|----|----------|-----------------|------------------|--------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|
|                           | Form        | No | kg ai/ha | kg ai/hl        | Sample           | PHI<br>(days)                                                      | trifloxy-<br>strobin                                                                                        | CGA-<br>321113                                                                                                                       |                                    |
| Apple<br>OR, USA<br>1996  | 50<br>WG    | 4  | 0.1      | 0.009           | fruit            | 14<br>14                                                           | 0.13<br><u>0.21</u>                                                                                         | <0.02<br><u>&lt;0.02</u>                                                                                                             | 110433<br>USA-OW-FR-636-96-B       |
| Apple<br>ID, USA<br>1996  | 50<br>WG    | 4  | 0.1      | 0.011           | fruit            | 14<br>14                                                           | 0.23<br><u>0.37</u>                                                                                         | <0.02<br><u>&lt;0.02</u>                                                                                                             | 110433<br>USA-OW-FR-637-96-B       |
| Apple<br>NC, USA<br>1996  | 50<br>WG    | 4  | 0.1      | 0.01            | fruit            | 14<br>14                                                           | 0.10<br><u>0.13</u>                                                                                         | <0.02<br><u>&lt;0.02</u>                                                                                                             | 110433<br>USA-OS-FR-605-96-B       |
| Apple<br>Canada<br>1999   | 50<br>WG    | 4  | 0.1      | 0.011           | fruit            | 14<br>14                                                           | <u>0.04</u><br>0.03                                                                                         | <u>&lt;0.02</u><br><0.02                                                                                                             | CER 04412/99<br>CND-CER04412/99-A  |
| Apple<br>Canada<br>1999   | 50<br>WG    | 4  | 0.1      | 0.012           | fruit            | 14<br>14                                                           | <u>0.16</u><br>0.09                                                                                         | <u>&lt;0.02</u><br><0.02                                                                                                             | CER 04412/99<br>CND-CER04412-99-B  |
| Apple<br>Canada<br>1999   | 50<br>WG    | 4  | 0.1      | 0.011-<br>0.012 | fruit            | 14<br>14                                                           | 0.07<br><u>0.09</u>                                                                                         | <0.02<br><u>&lt;0.02</u>                                                                                                             | CER 04412/99<br>CND-CER04412-99-C  |
| Apple<br>WA, USA<br>1996  | 50<br>WG    | 4  | 0.1      | 0.01            | fruit            | 0<br>0<br>1<br>1<br>3<br>3<br>7<br>7<br>14<br>14<br>14<br>21<br>21 | 0.32<br>0.22<br>0.33<br>0.28<br>0.10<br>0.24<br>0.11<br>0.08<br><u>0.18</u><br>0.09<br>0.07<br>0.08<br>0.08 | <0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><u>&lt;0.02</u><br><0.02<br><0.02<br><0.02<br><0.02<br><0.02 | 110433<br>USA-05-FR-005-96-B       |
| Pear<br>USA<br>1996       | 50<br>WG    | 4  | 0.1      | 0.012           | fruit            | 13<br>13                                                           | 0.09<br><u>0.15</u>                                                                                         | <0.02<br><u>&lt;0.02</u>                                                                                                             | 110433<br>USA-NE-FR-822-96-B       |
| Pear<br>USA<br>1996       | 50<br>WG    | 4  | 0.1      | 0.008           | fruit            | 14<br>14                                                           | <u>0.10</u><br>0.05                                                                                         | <u>0.04</u><br><0.02                                                                                                                 | 110433<br>USA-OW-FR-414-96-B       |
| Pear<br>USA<br>1996       | 50<br>WG    | 4  | 0.1      | 0.11            | fruit            | 14<br>14                                                           | <u>0.23</u><br>0.17                                                                                         | <u>&lt;0.02</u><br><0.02                                                                                                             | 110433<br>USA-OW-FR-638-96-B       |
| Pear<br>USA<br>1996       | 50<br>WG    | 4  | 0.1      | 0.011           | fruit            | 14<br>14                                                           | <u>0.14</u><br>0.13                                                                                         | <u>0.03</u><br>0.03                                                                                                                  | 110433<br>USA-OW-FR-639-96-B       |
| Pear<br>USA<br>1996       | 50<br>WG    | 4  | 0.1      | 0.011-<br>0.013 | fruit            | 14<br>14                                                           | <u>0.22</u><br>0.14                                                                                         | <u>&lt;0.02</u><br><0.02                                                                                                             | 110433<br>USA-OW-FR-640-96-B       |
| Pear<br>USA<br>1996       | 50<br>WG    | 4  | 0.1      | 0.007           | fruit            | 0<br>0<br>1<br>1<br>3<br>3<br>7<br>7<br>14<br>14<br>21<br>21       | 0.54<br>0.43<br>0.38<br>0.44<br>0.43<br>0.74<br>0.20<br>0.44<br>0.13<br><u>0.17</u><br>0.13<br>0.15         | 0.02<br>0.02<br>0.03<br>0.03<br>0.03<br>0.04<br>0.03<br>0.02<br>0.03<br><u>0.03</u><br>0.03<br>0.03                                  | 110433<br>USA-02-FR-023-96-B       |
| Pear<br>Canada<br>1999    | 50<br>WG    | 4  | 0.1-0.11 |                 | fruit            | 14<br>14                                                           | <u>0.09</u><br>0.07                                                                                         | <u>&lt;0.02</u><br><0.02                                                                                                             | CER 04413/99<br>CND- CER04413-99-A |

| Crop<br>Location,<br>Year | Application |    |          |          | Residues (mg/kg) |               |                      |                       | Report No.;<br>Study No.           |
|---------------------------|-------------|----|----------|----------|------------------|---------------|----------------------|-----------------------|------------------------------------|
|                           | Form        | No | kg ai/ha | kg ai/hl | Sample           | PHI<br>(days) | trifloxy-<br>strobin | CGA-<br>321113        |                                    |
| Pear<br>Canada<br>1999    | 50<br>WG    | 4  | 0.1-0.11 |          | fruit            | 15<br>15      | <u>0.10</u><br>0.07  | <u>≤0.02</u><br><0.02 | CER 04413/99<br>CND-CER04413-99-B  |
| Pear<br>Canada<br>1999    | 50<br>WG    | 4  | 0.1-0.11 |          | fruit            | 14            | <u>0.07</u>          | <u>≤0.02</u>          | CER 04413/99<br>CND-CER04413-99-C1 |
| Pear<br>Canada<br>1999    | 50<br>WG    | 4  | 0.1-0.11 |          | fruit            | 14            | <u>0.08</u>          | <u>≤0.02</u>          | CER 04413/99<br>CND-CER04413-99-C2 |

Table 49. Results of residue trials with trifloxystrobin on pome fruit in Europe.

| Crop<br>Country,<br>Year     | Application |    |          |          | Residues (mg/kg) |                                            |                                                     |                                                      | Report No.;<br>Study No.     |
|------------------------------|-------------|----|----------|----------|------------------|--------------------------------------------|-----------------------------------------------------|------------------------------------------------------|------------------------------|
|                              | Form        | No | kg ai/ha | kg ai/hl | Sample           | PHI<br>(days)                              | trifloxy-<br>strobin                                | CGA-<br>321113                                       |                              |
| Apple<br>Germany<br>1995     | 50<br>WG    | 10 | 0.08     | 0.01     | fruit            | 0<br>7<br>10<br>14<br>21                   | 0.10<br>0.06<br>0.05<br><u>0.05</u><br>0.05         | <0.02<br><0.02<br><0.02<br><u>≤0.02</u><br><0.02     | FR10/95/31<br>BRD-FR10-95-31 |
| Apple<br>Germany<br>1995     | 50<br>WG    | 10 | 0.075    | 0.005    | fruit            | 0<br>7<br>10<br>14<br>21                   | 0.19<br>0.19<br>0.18<br><u>0.11</u><br>0.09         | <0.02<br><0.02<br><0.02<br><u>≤0.02</u><br><0.02     | FR10/95/42<br>BRD-FR10-95-42 |
| Apple<br>France<br>1995      | 50<br>WG    | 10 | 0.075    | 0.015    | fruit            | 0 <sup>1</sup><br>0<br>7<br>14<br>21<br>28 | 0.21<br>0.34<br>0.14<br><u>0.13</u><br>0.12<br>0.10 | 0.02<br>0.03<br><0.02<br><u>0.02</u><br>0.02<br>0.02 | OF95134/KJ11<br>FRA-KJ11     |
| Apple<br>Switzerland<br>1995 | 50<br>WG    | 10 | 0.075    | 0.0075   | fruit            | 0<br>7<br>11<br>14<br>21                   | 0.26<br>0.10<br>0.07<br><u>0.08</u><br>0.05         | <0.02<br><0.02<br><0.02<br><u>≤0.02</u><br><0.02     | 2034/95<br>SWZ-2034-95       |
| Apple<br>Germany<br>1996     | 50<br>WG    | 10 | 0.075    | 0.01     | fruit            | 0<br>7<br>10<br>14<br>21                   | 0.35<br>0.21<br>0.18<br><u>0.13</u><br>0.09         | <0.02<br><0.02<br><0.02<br><u>≤0.02</u><br><0.02     | gr00996<br>BRD-gr00996       |
| Apple<br>France<br>1996      | 50<br>WG    | 10 | 0.075    | 0.0075   | fruit            | 13                                         | <u>0.10</u>                                         | <u>≤0.02</u>                                         | OF96122/KJ72<br>FRA-KJ72     |
| Apple<br>France<br>1996      | 50<br>WG    | 10 | 0.075    | 0.0075   | fruit            | 14                                         | <u>0.30</u>                                         | <u>≤0.02</u>                                         | OF96122/SJ26<br>FRA-SJ26     |
| Apple<br>Switzerland<br>1996 | 50<br>WG    | 6  | 0.075    | 0.0075   | fruit            | 14<br>14                                   | <u>0.12</u><br>0.09                                 | <u>≤0.02</u><br><0.02                                | 2014/96<br>SWZ-2014-96       |
| Apple<br>Switzerland<br>1996 | 50<br>WG    | 6  | 0.075    | 0.0075   | fruit            | 14<br>14                                   | 0.04<br><u>0.06</u>                                 | <0.02<br><u>≤0.02</u>                                | 2015/96<br>SWZ-2015-96       |
| Apple<br>Switzerland<br>1996 | 50<br>WG    | 10 | 0.075    | 0.0075   | fruit            | 14<br>14                                   | <u>0.19</u><br>0.10                                 | <u>≤0.02</u><br><0.02                                | 2016/96<br>SWZ-2016-96       |
| Apple<br>Switzerland<br>1996 | 50<br>WG    | 10 | 0.075    | 0.0075   | fruit            | 14<br>14                                   | <u>0.05</u><br>0.05                                 | <u>≤0.02</u><br><0.02                                | 2017/96<br>SWZ-2017-96       |

| Crop<br>Country,<br>Year     | Application |    |                 |                 | Residues (mg/kg) |                                            |                                                     |                                                     | Report No.;<br>Study No. |
|------------------------------|-------------|----|-----------------|-----------------|------------------|--------------------------------------------|-----------------------------------------------------|-----------------------------------------------------|--------------------------|
|                              | Form        | No | kg ai/ha        | kg ai/hl        | Sample           | PHI<br>(days)                              | trifloxy-<br>strobin                                | CGA-<br>321113                                      |                          |
| Apple<br>Germany<br>1998     | 50<br>WG    | 6  | 0.075-<br>0.086 | 0.0075          | fruit            | 0<br>6<br>13                               | 0.18<br>0.12<br><u>0.05</u>                         | <0.02<br><0.02<br><u>&lt;0.02</u>                   | gr50598<br>BRD-gr50598   |
| Apple<br>France<br>1998      | 50<br>WG    | 5  | 0.08            | 0.01            | fruit            | 0<br>7<br>14                               | 0.09<br>0.05<br><u>0.07</u>                         | <0.02<br><0.02<br><u>&lt;0.02</u>                   | 9811001<br>FRA-9811001   |
| Apple<br>Netherlands<br>1998 | 50<br>WG    | 5  | 0.06-0.08       | 0.03            | fruit            | 0<br>0<br>14<br>14                         | 0.13<br>0.09<br><u>0.07</u><br>0.07                 | <0.02<br><0.02<br><u>&lt;0.02</u><br><0.02          | 2158/98<br>NIE-2158-98   |
| Apple<br>Netherlands<br>1998 | 50<br>WG    | 5  | 0.06-0.07       | 0.03            | fruit            | 0<br>0<br>14<br>14                         | 0.05<br>0.06<br>0.04<br><u>0.07</u>                 | <0.02<br><0.02<br><0.02<br><u>&lt;0.02</u>          | 2159/98<br>NIE-2159-98   |
| Apple<br>Netherlands<br>1998 | 50<br>WG    | 5  | 0.07-0.08       | 0.033-<br>0.033 | fruit            | 0<br>0<br>14<br>14                         | 0.08<br>0.07<br><u>0.07</u><br>0.04                 | <0.02<br><0.02<br><u>&lt;0.02</u><br><0.02          | 2160/98<br>NIE-2160-98   |
| Apple<br>Switzerland<br>1998 | 50<br>WG    | 6  | 0.075           | 0.0075          | fruit            | 0<br>3<br>7<br>14                          | 0.19<br>0.18<br>0.11<br><u>0.09</u>                 | <0.02<br><0.02<br><0.02<br><u>&lt;0.02</u>          | 2060/98<br>SWZ-2060-98   |
| Apple<br>Switzerland<br>1998 | 50<br>WG    | 6  | 0.075           | 0.0075          | fruit            | 0<br>3<br>7<br>14                          | 0.16<br>0.12<br>0.14<br><u>0.10</u>                 | <0.02<br><0.02<br><0.02<br><u>&lt;0.02</u>          | 2061/98<br>SWZ-2061-98   |
| Apple<br>France<br>1999      | 50<br>WG    | 3  | 0.075           | 0.015           | fruit            | 0<br>7<br>14<br>14                         | 0.10<br>0.03<br><u>0.03</u><br>0.02                 | <0.02<br><0.02<br><u>&lt;0.02</u><br><0.02          | 2007/99<br>FRA-2007-99   |
| Apple<br>Netherlands<br>1999 | 50<br>WG    | 3  | 0.06-0.08       | 0.03            | fruit            | 0<br>7<br>14<br>14                         | 0.08<br>0.04<br>0.03<br><u>0.04</u>                 | <0.02<br><0.02<br><0.02<br><u>&lt;0.02</u>          | 2109/99<br>NIE-2109-99   |
| Apple<br>Switzerland<br>1999 | 50<br>WG    | 3  | 0.075           | 0.0075          | fruit            | 0<br>7<br>14<br>14                         | 0.19<br>0.08<br>0.03<br><u>0.04</u>                 | <0.02<br><0.02<br><0.02<br><u>&lt;0.02</u>          | 2124/99<br>SWZ-2124-99   |
| Apple<br>Switzerland<br>1999 | 50<br>WG    | 3  | 0.075           | 0.008           | fruit            | 0<br>7<br>14<br>14                         | 0.08<br>0.06<br><u>0.05</u><br>0.03                 | <0.01<br><0.01<br><u>&lt;0.01</u><br><0.01          | 2125/99<br>SWZ-2125-99-A |
| Apple<br>France<br>1995      | 50<br>WG    | 10 | 0.075           | 0.015           | fruit            | 0 <sup>1</sup><br>0<br>7<br>14<br>21<br>28 | 0.53<br>0.53<br>0.43<br><u>0.37</u><br>0.32<br>0.22 | 0.05<br>0.05<br>0.04<br><u>0.04</u><br>0.04<br>0.04 | OF95134/FP97<br>FRA-FP97 |
| Apple<br>France<br>1995      | 50<br>WG    | 10 | 0.075           | 0.011           | fruit            | 7<br>14<br>21<br>28                        | 0.27<br><u>0.14</u><br>0.12<br>0.09                 | <0.02<br><u>&lt;0.02</u><br><0.02<br><0.02          | OF95135/LD05<br>FRA-LD05 |
| Apple<br>Italy<br>1995       | 50<br>WG    | 6  | 0.075           | 0.006           | fruit            | 0<br>14<br>28<br>35<br>42                  | 0.12<br><u>0.07</u><br>0.05<br>0.02<br>0.02         | <0.02<br><u>&lt;0.02</u><br><0.02<br><0.02<br><0.02 | 2115/95<br>ITA-2115-95   |



| Crop<br>Country,<br>Year | Application |    |          |                  | Residues (mg/kg) |                          |                                             |                                                     | Report No.;<br>Study No. |
|--------------------------|-------------|----|----------|------------------|------------------|--------------------------|---------------------------------------------|-----------------------------------------------------|--------------------------|
|                          | Form        | No | kg ai/ha | kg ai/hl         | Sample           | PHI<br>(days)            | trifloxy-<br>strobin                        | CGA-<br>321113                                      |                          |
| Apple<br>Italy<br>1995   | 50<br>WG    | 10 | 0.075    | 0.0075           | fruit            | 0<br>6<br>13<br>20<br>27 | 0.10<br>0.04<br>0.03<br>0.03<br><u>0.04</u> | <0.02<br><0.02<br><0.02<br><0.02<br><u>&lt;0.02</u> | 2116/95<br>ITA-2116-95   |
| Apple<br>France<br>1996  | 50<br>WG    | 10 | 0.075    | 0.0075           | fruit            | 14                       | <u>0.44</u>                                 | <u>&lt;0.02</u>                                     | OF96122/FP13<br>FRA-FP13 |
| Apple<br>France<br>1996  | 50<br>WG    | 10 | 0.075    | 0.0075           | fruit            | 14                       | <u>0.17</u>                                 | <u>&lt;0.02</u>                                     | OF96122/LD69<br>FRA-LD69 |
| Apple<br>Italy<br>1996   | 50<br>WG    | 10 | 0.075    | 0.005            | fruit            | 14<br>14                 | 0.04<br><u>0.05</u>                         | <0.02<br><u>&lt;0.02</u>                            | 2082/96<br>ITA-2082-96   |
| Apple<br>Italy<br>1996   | 50<br>WG    | 10 | 0.075    | 0.005            | fruit            | 10<br>10                 | 0.07<br>0.04                                | <0.02<br><0.02                                      | 2083/96<br>ITA-2083-96   |
| Apple<br>Italy<br>1997   | 50<br>WG    | 6  | 0.11     | 0.0075           | fruit            | 14<br>14                 | 0.07<br><u>0.09</u>                         | <0.02<br><u>&lt;0.02</u>                            | 2075/97<br>ITA-2075-97   |
| Apple<br>Italy<br>1997   | 50<br>WG    | 6  | 0.11     | 0.0075           | fruit            | 14<br>14                 | 0.12<br><u>0.13</u>                         | <0.02<br><u>&lt;0.02</u>                            | 2076/97<br>ITA-2076-97   |
| Apple<br>Spain<br>1997   | 50<br>WG    | 6  | 0.11     | 0.005-<br>0.012  | fruit            | 14<br>14                 | <u>0.19</u><br>0.18                         | <u>&lt;0.02</u><br><0.02                            | 2048/97<br>SPA-2048-97   |
| Apple<br>Spain<br>1997   | 50<br>WG    | 6  | 0.11     | 0.006-<br>0.007  | fruit            | 14<br>14                 | 0.12<br><u>0.15</u>                         | <0.02<br><u>&lt;0.02</u>                            | 2049/97<br>SPA-2049-97   |
| Apple<br>Greece<br>1998  | 50<br>WG    | 6  | 0.11     | 0.007-<br>0.0075 | fruit            | 14<br>14                 | 0.17<br><u>0.20</u>                         | <0.02<br><u>&lt;0.02</u>                            | 2135/98<br>GRI-2135-98   |
| Apple<br>Italy<br>1998   | 50<br>WG    | 6  | 0.11     | 0.007-<br>0.0075 | fruit            | 0<br>3<br>7<br>14        | 0.14<br>0.15<br>0.12<br><u>0.07</u>         | <0.02<br><0.02<br><0.02<br><u>&lt;0.02</u>          | 2034/98<br>ITA-2034-98   |
| Apple<br>Spain<br>1998   | 50<br>WG    | 6  | 0.11     | 0.007-<br>0.008  | fruit            | 0<br>3<br>7<br>14        | 0.36<br>0.30<br>0.26<br><u>0.21</u>         | <0.02<br><0.02<br><0.02<br><u>&lt;0.02</u>          | 2030/98<br>SPA-2030-98   |
| Apple<br>Spain<br>1998   | 50<br>WG    | 6  | 0.12     | 0.0085           | fruit            | 0<br>3<br>7<br>14        | 0.27<br>0.29<br>0.29<br><u>0.19</u>         | <0.02<br><0.02<br><0.02<br><u>&lt;0.02</u>          | 2055/98<br>SPA-2055-98   |
| Pear<br>Germany<br>1996  | 50<br>WG    | 10 | 0.075    | 0.005            | fruit            | 0<br>6<br>10<br>14<br>21 | 0.27<br>0.21<br>0.24<br>0.13<br><u>0.17</u> | 0.02<br>0.02<br>0.02<br><0.02<br><u>0.02</u>        | gr01096<br>BRD-2180-96   |
| Pear<br>Greece<br>1998   | 50<br>WG    | 6  | 0.07     | 0.005            | fruit            | 14<br>14                 | <u>0.12</u><br>0.11                         | <u>&lt;0.02</u><br><0.02                            | 2136/98<br>GRI-2136-98   |
| Pear<br>Italy<br>1998    | 50<br>WG    | 6  | 0.075    | 0.005            | fruit            | 0<br>3<br>7<br>14        | 0.14<br>0.10<br>0.09<br><u>0.06</u>         | <0.02<br><0.02<br><0.02<br><u>&lt;0.02</u>          | 2035/98<br>ITA-2035-98   |
| Pear<br>Spain<br>1998    | 50<br>WG    | 6  | 0.08     | 0.006            | fruit            | 0<br>3<br>7<br>14        | 0.13<br>0.11<br>0.08<br><u>0.07</u>         | <0.02<br><0.02<br><0.02<br><u>&lt;0.02</u>          | 2058/98<br>SPA-2058-98   |

| Crop<br>Country,<br>Year | Application |    |                |          | Residues (mg/kg) |               |                      |                | Report No.;<br>Study No. |
|--------------------------|-------------|----|----------------|----------|------------------|---------------|----------------------|----------------|--------------------------|
|                          | Form        | No | kg ai/ha       | kg ai/hl | Sample           | PHI<br>(days) | trifloxy-<br>strobin | CGA-<br>321113 |                          |
| Pear<br>Spain<br>1998    | 50<br>WG    | 6  | 0.07-<br>0.075 | 0.006    | fruit            | 0             | 0.17                 | <0.02          | 2059/98<br>SPA-2059-98   |
|                          |             |    |                |          |                  | 3             | 0.17                 | <0.02          |                          |
|                          |             |    |                |          |                  | 10            | 0.10                 | <0.02          |                          |
|                          |             |    |                |          |                  | 17            | 0.11                 | <0.02          |                          |

<sup>1</sup> before last treatment

### Stone fruits

The results of supervised trials on apricots, cherries, peaches and plums carried out in Europe and the USA using foliar sprays with 50 WG formulations were reported to the Meeting.

Table 50. Results of residue trials with trifloxystrobin on apricots in Switzerland in 2000.

| Application |    |          |          | Residues (mg/kg)           |               |                      |                 | Report No.;<br>Study No. |
|-------------|----|----------|----------|----------------------------|---------------|----------------------|-----------------|--------------------------|
| Form        | No | kg ai/ha | kg ai/hl | Sample                     | PHI<br>(days) | trifloxy-<br>strobin | CGA321113       |                          |
| 50<br>WG    | 3  | 0.25     | 0.013    | pulp                       | 0             | 0.63                 | 0.01            | 2062/00<br>SWZ-2062-00   |
|             |    |          |          |                            | 7             | 0.45                 | <0.01           |                          |
|             |    |          |          |                            | 14            | 0.15                 | 0.01            |                          |
|             |    |          |          |                            | 21            | 0.07                 | 0.01            |                          |
|             |    |          |          |                            | 21            | 0.15                 | <0.01           |                          |
|             |    |          |          | whole fruit,<br>calculated | 14            | 0.14                 | 0.01            |                          |
| 50<br>WG    | 3  | 0.25     | 0.019    | pulp                       | 21            | 0.07                 | 0.01            | 2063/00<br>SWZ-2063-00   |
|             |    |          |          |                            | 21            | <u>0.14</u>          | <u>&lt;0.01</u> |                          |
|             |    |          |          |                            | 14            | 0.29                 | 0.02            |                          |
|             |    |          |          |                            | 21            | <u>0.28</u>          | <u>0.02</u>     |                          |
|             |    |          |          |                            | 21            | 0.20                 | 0.02            |                          |
|             |    |          |          | whole fruit,<br>calculated | 14            | 0.29                 | 0.02            |                          |
|             |    |          |          | whole fruit,<br>calculated | 21            | <u>0.28</u>          | <u>0.02</u>     |                          |
|             |    |          |          |                            | 21            | 0.20                 | 0.02            |                          |

Table 51. Results of residue trials with trifloxystrobin on cherries in the USA and Switzerland.

| Crop<br>Country,<br>Year        | Application |    |          |          | Residues (mg/kg) |               |                      |             | Report No.;<br>Study No.         |
|---------------------------------|-------------|----|----------|----------|------------------|---------------|----------------------|-------------|----------------------------------|
|                                 | Form        | No | kg ai/ha | kg ai/hl | Sample           | PHI<br>(days) | trifloxy-<br>strobin | CGA321113   |                                  |
| Cherry, sour<br>UT, USA<br>1998 | 50<br>WG    | 4  | 0.14     | 0.01     | fruit            | 1             | <u>0.55</u>          | <u>0.04</u> | 149-98<br>USA-MW-FR-<br>710-98   |
|                                 |             |    |          |          |                  | 1             | 0.48                 | 0.04        |                                  |
| Cherry, sour<br>MI, USA<br>1998 | 50<br>WG    | 4  | 0.14     | 0.006    | fruit            | 0             | 0.67                 | 0.07        | 149-98<br>USA-NE-FR-<br>716-98   |
|                                 |             |    |          |          |                  | 0             | 0.63                 | 0.06        |                                  |
|                                 |             |    |          |          |                  | 1             | 0.29                 | 0.04        |                                  |
|                                 |             |    |          |          |                  | 1             | <u>0.53</u>          | <u>0.06</u> |                                  |
|                                 |             |    |          |          |                  | 2             | 0.20                 | 0.03        |                                  |
|                                 |             |    |          |          |                  | 2             | 0.31                 | 0.06        |                                  |
| Cherry, sour<br>MI, USA<br>1998 | 50<br>WG    | 4  | 0.14     | 0.15     | fruit            | 1             | <u>0.58</u>          | <u>0.04</u> | 149-98<br>USA-NE-FR-<br>717-98   |
|                                 |             |    |          |          |                  | 1             | 0.42                 | 0.03        |                                  |
| Cherry, sour<br>NY, USA<br>1998 | 50<br>WG    | 4  | 0.14     | 0.03     | fruit            | 1             | <u>0.34</u>          | <u>0.04</u> | 149-98<br>USA-NE-FR-<br>804-98-A |
|                                 |             |    |          |          |                  | 1             | 0.32                 | 0.04        |                                  |
| Cherry, sour<br>NY, USA<br>1998 | 50<br>WG    | 4  | 0.14     | 0.008    | fruit            | 1             | <u>0.66</u>          | <u>0.07</u> | 149-98<br>USA-NE-FR-<br>804-98-B |
|                                 |             |    |          |          |                  | 1             | 0.47                 | 0.05        |                                  |

| Crop<br>Country,<br>Year            | Application |    |          |                 | Residues (mg/kg)              |                            |                                                     |                                                            | Report No.;<br>Study No.         |
|-------------------------------------|-------------|----|----------|-----------------|-------------------------------|----------------------------|-----------------------------------------------------|------------------------------------------------------------|----------------------------------|
|                                     | Form        | No | kg ai/ha | kg ai/hl        | Sample                        | PHI<br>(days)              | trifloxy-<br>strobin                                | CGA321113                                                  |                                  |
| Cherry, sour<br>UT, USA<br>1998     | 50<br>WG    | 4  | 0.14     | 0.025-<br>0.028 | fruit                         | 1<br>1                     | <u>0.38</u><br>0.30                                 | <u>0.03</u><br><0.02                                       | 149-98<br>USA-OW-FR-<br>702-98-A |
| Cherry, sour<br>UT, USA<br>1998     | 50<br>WG    | 4  | 0.14     | 0.008-<br>0.009 | fruit                         | 1<br>1                     | 0.53<br><u>0.54</u>                                 | 0.04<br><u>0.04</u>                                        | 149-98<br>USA-OW-FR-<br>702-98-B |
| Cherry,<br>sweet<br>MI, USA<br>1998 | 50<br>WG    | 4  | 0.14     | 0.15            | fruit                         | 1<br>1                     | 0.33<br><u>0.33</u>                                 | 0.04<br><u>0.05</u>                                        | 149-98<br>USA-NE-FR-<br>714-98   |
| Cherry,<br>sweet<br>MI, USA<br>1998 | 50<br>WG    | 4  | 0.14     | 0.02            | fruit                         | 1<br>1                     | 0.63<br><u>0.84</u>                                 | 0.05<br><u>0.06</u>                                        | 149-98<br>USA-NE-FR-<br>715-98-A |
| Cherry,<br>sweet<br>MI, USA<br>1998 | 50<br>WG    | 4  | 0.14     | 0.006-<br>0.007 | fruit                         | 1<br>1                     | 0.54<br><u>0.63</u>                                 | 0.06<br><u>0.06</u>                                        | 149-98<br>USA-NE-FR-<br>715-98-B |
| Cherry,<br>sweet<br>CA, USA<br>1998 | 50<br>WG    | 4  | 0.14     | 0.027           | fruit                         | 1<br>1                     | <u>0.56</u><br>0.38                                 | <u>0.05</u><br>0.04                                        | 149-98<br>USA-OW-FR-<br>406-98   |
| Cherry,<br>sweet<br>WA, USA<br>1998 | 50<br>WG    | 4  | 0.14     | 0.022           | fruit                         | 1<br>1                     | 0.25<br><u>0.26</u>                                 | 0.03<br><u>0.02</u>                                        | 149-98<br>USA-OW-FR-<br>610-98   |
| Cherry,<br>sweet<br>CA, USA<br>1998 | 50<br>WG    | 4  | 0.14     | 0.01            | fruit                         | 0<br>0<br>1<br>1<br>2<br>2 | 0.45<br>0.63<br>0.34<br><u>0.37</u><br>0.24<br>0.27 | <0.02<br>0.03<br><0.02<br><u>&lt;0.02</u><br><0.02<br>0.02 | 149-98<br>USA-02-FR-<br>007-98   |
| Cherry,<br>sweet<br>OR, USA<br>1999 | 50<br>WG    | 4  | 0.14     | 0.007           | fruit                         | 1<br>1                     | 0.25<br><u>0.39</u>                                 | 0.03<br><u>0.03</u>                                        | 149-98<br>USA-OW-FR-<br>612-99   |
| Cherry<br>Switzerland<br>2000       | 50<br>WG    | 3  | 0.25     | 0.024-<br>0.028 | fruit                         | 0<br>7<br>14               | 0.58<br>0.31<br>0.14                                | 0.02<br>0.02<br>0.02                                       | 2060/00<br>SWZ-2060-00           |
|                                     |             |    |          |                 | whole<br>fruit,<br>calculated | 21<br>21                   | 0.05<br>0.07                                        | 0.01<br>0.01                                               |                                  |
|                                     |             |    |          |                 | pulp                          | 21<br>21                   | 0.07<br>0.09                                        | 0.02<br>0.02                                               |                                  |
|                                     |             |    |          |                 | fruit                         | 0                          | 0.54                                                | 0.01                                                       |                                  |
|                                     |             |    |          |                 | pulp                          | 7<br>14<br>21<br>21        | 0.18<br>0.09<br>0.09<br>0.06                        | 0.01<br>0.02<br>0.02<br>0.01                               |                                  |
| Cherry<br>Switzerland<br>2000       | 50<br>WG    | 3  | 0.25     | 0.024-<br>0.028 | whole<br>fruit,<br>calculated | 7<br>14<br>21<br>21        | 0.14<br>0.07<br>0.08<br>0.05                        | 0.01<br>0.01<br>0.01<br>0.01                               | 2061/00<br>SWZ-2061-00           |
|                                     |             |    |          |                 | fruit                         | 0                          | 0.54                                                | 0.01                                                       |                                  |
|                                     |             |    |          |                 | pulp                          | 7<br>14<br>21<br>21        | 0.18<br>0.09<br>0.09<br>0.06                        | 0.01<br>0.02<br>0.02<br>0.01                               |                                  |
|                                     |             |    |          |                 | fruit                         | 0                          | 0.54                                                | 0.01                                                       |                                  |
|                                     |             |    |          |                 | pulp                          | 7<br>14<br>21<br>21        | 0.18<br>0.09<br>0.09<br>0.06                        | 0.01<br>0.02<br>0.02<br>0.01                               |                                  |

Table 52. Results of residue trials with trifloxystrobin on peach.

| Country,<br>Year         | Application |    |          |                 | Residues (mg/kg)           |                            |                                                                |                                                                                                                | Report No.;<br>Study No.         |
|--------------------------|-------------|----|----------|-----------------|----------------------------|----------------------------|----------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------|----------------------------------|
|                          | Form        | No | kg ai/ha | kg ai/hl        | Sample                     | PHI<br>(days)              | trifloxy-<br>strobin                                           | CGA321113                                                                                                      |                                  |
| Peach<br>PA, USA<br>1998 | 50<br>WG    | 4  | 0.14     | 0.02            | fruit                      | 1<br>1                     | <u>0.82</u><br>0.63                                            | <u>0.04</u><br>0.04                                                                                            | 149-98<br>USA-NE-FR-<br>603-98-A |
| Peach<br>PA, USA<br>1998 | 50<br>WG    | 4  | 0.14     | 0.004           | fruit                      | 1<br>1                     | 0.85<br><u>0.89</u>                                            | 0.06<br><u>0.05</u>                                                                                            | 149-98<br>USA-NE-FR-<br>603-98-B |
| Peach<br>MI, USA<br>1998 | 50<br>WG    | 4  | 0.14     | 0.15            | fruit                      | 1<br>1                     | <u>0.21</u><br>0.18                                            | <u>&lt;0.02</u><br><u>&lt;0.02</u>                                                                             | 149-98<br>USA-NE-FR-<br>712-98-A |
| Peach<br>MI, USA<br>1998 | 50<br>WG    | 4  | 0.14     | 0.009           | fruit                      | 1<br>1                     | <u>0.39</u><br>0.34                                            | <u>&lt;0.02</u><br><u>&lt;0.02</u>                                                                             | 149-98<br>USA-NE-FR-<br>712-98-B |
| Peach<br>TX, USA<br>1998 | 50<br>WG    | 4  | 0.14     | 0.023-<br>0.024 | fruit                      | 1<br>1                     | <u>1.9</u><br>1.6                                              | <u>0.06</u><br>0.05                                                                                            | 149-98<br>USA-OS-FR-<br>203-98-A |
| Peach<br>TX, USA<br>1998 | 50<br>WG    | 4  | 0.14     | 0.008           | fruit                      | 1<br>1                     | 1.7<br><u>1.8</u>                                              | 0.08<br><u>0.08</u>                                                                                            | 149-98<br>USA-OS-FR-<br>203-98-B |
| Peach<br>NC, USA<br>1998 | 50<br>WG    | 4  | 0.14     | 0.01            | fruit                      | 1<br>1                     | 0.28<br><u>0.32</u>                                            | <u>&lt;0.02</u><br><u>&lt;0.02</u>                                                                             | 149-98<br>USA-OS-FR-<br>611-98   |
| Peach<br>CA, USA<br>1998 | 50<br>WG    | 4  | 0.14     | 0.028           | fruit                      | 1<br>1                     | 0.61<br><u>0.65</u>                                            | 0.05<br><u>0.05</u>                                                                                            | 149-98<br>USA-OS-FR-<br>617-98-A |
| Peach<br>CA, USA<br>1998 | 50<br>WG    | 4  | 0.14     | 0.007           | fruit                      | 1<br>1                     | <u>0.82</u><br>0.79                                            | <u>0.06</u><br>0.06                                                                                            | 149-98<br>USA-OS-FR-<br>617-98-B |
| Peach<br>GA, USA<br>1998 | 50<br>WG    | 4  | 0.14     | 0.018           | fruit                      | 1<br>1                     | <u>0.41</u><br>0.40                                            | <u>&lt;0.02</u><br><u>&lt;0.02</u>                                                                             | 149-98<br>USA-OS-FR-<br>834-98   |
| Peach<br>CA, USA<br>1998 | 50<br>WG    | 4  | 0.14     | 0.02            | fruit                      | 1<br>1                     | <u>0.06</u><br>0.05                                            | <u>&lt;0.02</u><br><u>&lt;0.02</u>                                                                             | 149-98<br>USA-OW-FR-<br>109-98   |
| Peach<br>CA, USA<br>1998 | 50<br>WG    | 4  | 0.14     | 0.027-<br>0.028 | fruit                      | 1<br>1                     | <u>0.25</u><br>0.18                                            | <u>&lt;0.02</u><br><u>&lt;0.02</u>                                                                             | 149-98<br>USA-OW-FR-<br>403-98-A |
| Peach<br>CA, USA<br>1998 | 50<br>WG    | 4  | 0.14     | 0.01            | fruit                      | 1<br>1                     | 0.32<br><u>0.34</u>                                            | <u>&lt;0.02</u><br><u>&lt;0.02</u>                                                                             | 149-98<br>USA-OW-FR-<br>403-98-B |
| Peach<br>CA, USA<br>1998 | 50<br>WG    | 4  | 0.14     | 0.01            | fruit                      | 0<br>0<br>1<br>1<br>2<br>2 | 0.24<br>0.50<br><u>&lt;0.02</u><br><u>0.21</u><br>0.20<br>0.19 | <u>&lt;0.02</u><br><u>&lt;0.02</u><br><u>&lt;0.02</u><br><u>&lt;0.02</u><br><u>&lt;0.02</u><br><u>&lt;0.02</u> | 149-98<br>USA-02-FR-<br>004-98   |
| Peach<br>Spain<br>1999   | 50<br>WG    | 3  | 0.11     | 0.008           | pulp                       | 0<br>0<br>7<br>7           | 0.33<br>0.29<br>0.18<br>0.14                                   | 0.02<br>0.02<br>0.02<br><u>&lt;0.02</u>                                                                        | 2016/99<br>SPA-2016-99           |
|                          |             |    |          |                 |                            | 0<br>0<br>7<br>7           | 0.28<br>0.25<br>0.16<br>0.12                                   | 0.02<br>0.02<br>0.02<br><u>&lt;0.02</u>                                                                        |                                  |
|                          |             |    |          |                 | whole fruit,<br>calculated | 0<br>0<br>7<br>7           | 0.28<br>0.25<br>0.16<br>0.12                                   | 0.02<br>0.02<br>0.02<br><u>&lt;0.02</u>                                                                        |                                  |
|                          |             |    |          |                 |                            | 0<br>0<br>7<br>7           | 0.43<br>0.24<br>0.22<br>0.39                                   | 0.01<br>0.02<br>0.02<br>0.01                                                                                   |                                  |
|                          |             |    |          |                 | pulp                       | 0<br>7<br>7<br>7           | 0.43<br>0.24<br>0.22<br>0.39                                   | 0.01<br>0.02<br>0.02<br>0.01                                                                                   |                                  |
|                          |             |    |          |                 |                            | 0<br>7<br>7<br>7           | 0.24<br>0.22<br>0.22<br>0.20                                   | 0.02<br>0.02<br>0.02<br>0.02                                                                                   |                                  |
|                          |             |    |          |                 | whole fruit,<br>calculated | 0<br>7<br>7<br>7           | 0.39<br>0.22<br>0.22<br>0.20                                   | 0.01<br>0.02<br>0.02<br>0.02                                                                                   |                                  |
|                          |             |    |          |                 |                            | 0<br>7<br>7<br>7           | 0.24<br>0.22<br>0.22<br>0.20                                   | 0.02<br>0.02<br>0.02<br>0.02                                                                                   |                                  |
| Peach<br>Spain<br>2000   | 50<br>WG    | 3  | 0.11     | 0.0075          | pulp                       | 0<br>7<br>7<br>7           | 0.43<br>0.24<br>0.22<br>0.39                                   | 0.01<br>0.02<br>0.02<br>0.01                                                                                   | 2029/00<br>SPA-2029-00           |
|                          |             |    |          |                 | whole fruit,<br>calculated | 0<br>7<br>7<br>7           | 0.39<br>0.22<br>0.22<br>0.20                                   | 0.01<br>0.02<br>0.02<br>0.02                                                                                   |                                  |

| Country,<br>Year        | Application |    |          |          | Residues (mg/kg)           |               |                      |                 | Report No.;<br>Study No. |
|-------------------------|-------------|----|----------|----------|----------------------------|---------------|----------------------|-----------------|--------------------------|
|                         | Form        | No | kg ai/ha | kg ai/hl | Sample                     | PHI<br>(days) | trifloxy-<br>strobin | CGA321113       |                          |
| Peach<br>Spain<br>1999  | 50<br>WG    | 3  | 0.11     | 0.011    | pulp                       | 0             | 1.4                  | 0.05            | 2015/99<br>SPA-2015-99   |
|                         |             |    |          |          |                            | 0             | 1.5                  | 0.06            |                          |
|                         |             |    |          |          |                            | 7             | 0.54                 | 0.04            |                          |
|                         |             |    |          |          |                            | 7             | 0.40                 | 0.04            |                          |
|                         |             |    |          |          | whole fruit,<br>calculated | 0             | 1.1                  | 0.04            |                          |
|                         |             |    |          |          |                            | 0             | 1.2                  | 0.05            |                          |
|                         |             |    |          |          |                            | 7             | <u>0.48</u>          | <u>0.04</u>     |                          |
|                         |             |    |          |          |                            | 7             | <u>0.35</u>          | <u>0.04</u>     |                          |
| Peach<br>Italy<br>2000  | 50<br>WG    | 3  | 0.11     | 0.011    | pulp                       | 7             | 0.19                 | <0.01           | 2095/00<br>ITA-2095-00   |
|                         |             |    |          |          |                            | 7             | 0.15                 | <0.01           |                          |
|                         |             |    |          |          | whole fruit,<br>calculated | 7             | <u>0.18</u>          | <u>&lt;0.01</u> |                          |
|                         |             |    |          |          |                            | 7             | 0.14                 | <0.01           |                          |
| Peach<br>Italy<br>1999  | 50<br>WG    | 3  | 0.11     | 0.0075   | pulp                       | 0             | 0.26                 | <0.01           | 2111/99<br>ITA-2111-99   |
|                         |             |    |          |          |                            | 3             | 0.28                 | <0.01           |                          |
|                         |             |    |          |          |                            | 7             | 0.20                 | <0.01           |                          |
|                         |             |    |          |          |                            | 7             | 0.23                 | <0.01           |                          |
|                         |             |    |          |          |                            | 14            | 0.18                 | 0.01            |                          |
|                         |             |    |          |          |                            | 19            | 0.22                 | 0.01            |                          |
|                         |             |    |          |          | whole fruit,<br>calculated | 14            | 0.16                 | <0.01           |                          |
|                         |             |    |          |          |                            | 19            | 0.18                 | <0.01           |                          |
| Peach<br>France<br>1999 | 50<br>WG    | 3  | 0.12     | 0.016    | pulp                       | 0             | 0.14                 | 0.01            | 2017/99<br>FRA-2017-99   |
|                         |             |    |          |          |                            | 3             | 0.10                 | <0.01           |                          |
|                         |             |    |          |          |                            | 7             | 0.08                 | <0.01           |                          |
|                         |             |    |          |          |                            | 7             | <u>0.14</u>          | <u>0.01</u>     |                          |
|                         |             |    |          |          |                            | 14            | 0.07                 | 0.01            |                          |
|                         |             |    |          |          |                            | 19            | 0.04                 | <0.01           |                          |
|                         |             |    |          |          | whole fruit,<br>calculated | 19            | 0.04                 | <0.01           |                          |
|                         |             |    |          |          |                            |               |                      |                 |                          |

Table 53. Results of residue trials with trifloxystrobin on plum in the USA and Switzerland.

| Country,<br>Year | Application |    |          |                 | Residues (mg/kg) |               |                      |                 | Report No.;<br>Study No. |
|------------------|-------------|----|----------|-----------------|------------------|---------------|----------------------|-----------------|--------------------------|
|                  | Form        | No | kg ai/ha | kg ai/hl        | Sample           | PHI<br>(days) | trifloxy-<br>strobin | CGA-<br>321113  |                          |
| MI, USA<br>1998  | 50<br>WG    | 4  | 0.14     | 0.15            | fruit            | 1             | 0.10                 | <0.02           | 149-98                   |
|                  |             |    |          |                 |                  | 1             | <u>0.15</u>          | <u>&lt;0.02</u> | USA-NE-FR-713-98-A       |
| MI, USA<br>1998  | 50<br>WG    | 4  | 0.14     | 0.007-<br>0.008 | fruit            | 1             | 0.17                 | <0.02           | 149-98                   |
|                  |             |    |          |                 |                  | 1             | <u>0.21</u>          | <u>&lt;0.02</u> | USA-NE-FR-713-98-B       |
| CA, USA<br>1998  | 50<br>WG    | 4  | 0.14     | 0.022           | fruit            | 1             | <u>0.19</u>          | <u>&lt;0.02</u> | 149-98                   |
|                  |             |    |          |                 |                  | 1             | 0.17                 | <0.02           | USA-OW-FR-404-98         |
| CA, USA<br>1998  | 50<br>WG    | 4  | 0.14     | 0.009-<br>0.01  | fruit            | 1             | <u>0.09</u>          | <u>&lt;0.02</u> | 149-98                   |
|                  |             |    |          |                 |                  | 1             | 0.08                 | <0.02           | USA-OW-FR-405-98-A       |
|                  |             |    |          |                 |                  | 1             | 0.07                 | <0.02           |                          |
| OR, USA<br>1998  | 50<br>WG    | 4  | 0.14     | 0.02            | fruit            | 1             | <u>0.06</u>          | <u>&lt;0.02</u> | 149-98                   |
|                  |             |    |          |                 |                  | 1             | 0.04                 | <0.02           | USA-OW-FR-609-98-A       |
| OR, USA<br>1998  | 50<br>WG    | 4  | 0.14     | 0.006           | fruit            | 1             | <u>0.06</u>          | <u>&lt;0.02</u> | 149-98                   |
|                  |             |    |          |                 |                  | 1             | 0.04                 | <0.02           | USA-OW-FR-609-98-B       |
| CA, USA<br>1998  | 50<br>WG    | 4  | 0.14     | 0.01            | fruit            | 0             | <0.02                | <0.02           | 149-98                   |
|                  |             |    |          |                 |                  | 0             | 0.03                 | <0.02           | USA-02-FR-005-98         |
|                  |             |    |          |                 |                  | 1             | <0.02                | <0.02           |                          |
|                  |             |    |          |                 |                  | 1             | <u>0.02</u>          | <u>&lt;0.02</u> |                          |
|                  |             |    |          |                 |                  | 2             | 0.02                 | <0.02           |                          |
|                  |             |    |          |                 |                  | 2             | 0.05                 | <0.02           |                          |
| CA, USA<br>1998  | 50<br>WG    | 4  | 0.14     | 0.02            | fruit            | 1             | <u>0.21</u>          | <u>&lt;0.02</u> | 149-98                   |
|                  |             |    |          |                 |                  | 1             | 0.19                 | <0.02           | USA-02-FR-006-98-A       |

### *Berries and other small fruits*

Table 54. Results of residue trials with trifloxystrobin on grapes in Australia.

| Country,<br>Year | Application |    |          |          | Residues (mg/kg) |                |                      |                 | Report No.;<br>Study No.      |
|------------------|-------------|----|----------|----------|------------------|----------------|----------------------|-----------------|-------------------------------|
|                  | FL          | No | kg ai/ha | kg ai/hl | Sample           | PHI<br>(days)  | trifloxy-<br>strobil | CGA<br>321113   |                               |
| 1997             | 50<br>WG    | 6  | 0.075    | 0.008    | berry            | 0 <sup>1</sup> | 0.10                 | <0.02           | 99/5/1645<br>AUS-99-5-1645-C1 |
|                  |             |    |          |          |                  | 0 <sup>1</sup> | 0.16                 | <0.02           |                               |
|                  |             |    |          |          |                  | 0              | 0.22                 | <0.02           |                               |
|                  |             |    |          |          |                  | 7              | 0.17                 | <0.02           |                               |
|                  |             |    |          |          |                  | 7              | 0.20                 | <0.02           |                               |
|                  |             |    |          |          |                  | 13             | 0.13                 | <0.02           |                               |
|                  |             |    |          |          |                  | 13             | 0.11                 | <0.02           |                               |
|                  |             |    |          |          |                  | 21             | 0.09                 | <0.02           |                               |
|                  |             |    |          |          |                  | 21             | 0.08                 | <0.02           |                               |
|                  |             |    |          |          |                  | 28             | 0.03                 | <0.02           |                               |
|                  |             |    |          |          |                  | 36             | 0.08                 | <0.02           |                               |
|                  |             |    |          |          |                  | 36             | <u>0.09</u>          | <u>&lt;0.02</u> |                               |
| 1997             | 50<br>WG    | 6  | 0.075    | 0.009    | berry            | 0 <sup>1</sup> | <0.02                | <0.02           | 99/5/1645<br>AUS-99-5-1645-D1 |
|                  |             |    |          |          |                  | 0              | 0.09                 | <0.02           |                               |
|                  |             |    |          |          |                  | 8              | 0.09                 | 0.02            |                               |
|                  |             |    |          |          |                  | 8              | 0.06                 | <0.02           |                               |
|                  |             |    |          |          |                  | 15             | 0.08                 | 0.02            |                               |
|                  |             |    |          |          |                  | 15             | 0.12                 | 0.03            |                               |
|                  |             |    |          |          |                  | 23             | 0.07                 | 0.03            |                               |
|                  |             |    |          |          |                  | 23             | 0.08                 | 0.04            |                               |
|                  |             |    |          |          |                  | 29             | 0.06                 | 0.03            |                               |
|                  |             |    |          |          |                  | 29             | 0.07                 | 0.03            |                               |
|                  |             |    |          |          |                  | 36             | <u>0.04</u>          | <u>&lt;0.02</u> |                               |
|                  |             |    |          |          |                  | 36             | 0.03                 | <0.02           |                               |

| Country,<br>Year | Application |    |          |          | Residues (mg/kg) |                                                                                                                  |                                                                                                                                       |                                                                                                                                     | Report No.;<br>Study No.          |
|------------------|-------------|----|----------|----------|------------------|------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|
|                  | FL          | No | kg ai/ha | kg ai/hl | Sample           | PHI<br>(days)                                                                                                    | trifloxy-<br>strobin                                                                                                                  | CGA<br>321113                                                                                                                       |                                   |
| 1998             | 50<br>WG    | 6  | 0.075    | 0.008    | berry            | 0 <sup>1</sup><br>0 <sup>1</sup><br>0<br>0<br>7<br>7<br>14<br>14<br>21<br>21<br>28<br>28<br>35                   | 0.12<br>0.09<br>0.14<br>0.10<br>0.13<br>0.14<br>0.10<br>0.12<br>0.06<br>0.11<br>0.10<br>0.07<br><u>0.08</u>                           | <0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><0.02<br>0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><u>0.03</u>     | P98/42<br>AUS-P98-42-A1           |
| 1998             | 50<br>WG    | 6  | 0.075    | 0.0075   | berry            | 0 <sup>1</sup><br>0 <sup>1</sup><br>0<br>0<br>7<br>7<br>14<br>14<br>21<br>21<br>28<br>28<br>35<br>35<br>42<br>42 | 0.26<br>0.10<br>1.9<br>3.0<br><0.02<br>0.03<br><0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><0.02 | <0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><0.02 | P98/42<br>AUS-P98-42-B1           |
| 1998             | 50<br>WG    | 6  | 0.075    | 0.008    | berry            | 0 <sup>1</sup><br>0 <sup>1</sup><br>0<br>0<br>7<br>7<br>14<br>14<br>21<br>21<br>28<br>28<br>35<br>35             | 0.14<br>0.06<br>0.05<br>0.20<br>0.12<br>0.16<br>0.12<br>0.10<br>0.08<br>0.18<br>0.09<br>0.08<br><u>0.09</u><br>0.08                   | 0.02<br><0.02<br><0.02<br><0.02<br>0.03<br>0.03<br><0.02<br><0.02<br><0.02<br>0.04<br>0.03<br>0.03<br><u>&lt;0.02</u><br><0.02      | P98/42<br>AUS-P98-42-C1           |
| 1998             | 50<br>WG    | 6  | 0.075    | 0.0075   | berry            | 0 <sup>1</sup><br>0 <sup>1</sup><br>0<br>0<br>7<br>7<br>13<br>13                                                 | 0.10<br>0.13<br>0.26<br>0.29<br>0.12<br>0.12<br>0.13<br>0.13                                                                          | <0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><0.02                                                                | 99/5/1645<br>AUS-99-5-1645-<br>A2 |
| 1999             | 50<br>WG    | 3  | 0.075    | 0.0075   | berry            | 61<br>61                                                                                                         | <0.02<br><0.02                                                                                                                        | <0.02<br><0.02                                                                                                                      | P99/40<br>AUS-P99-40-A1           |
| 1999             | 50<br>WG    | 3  | 0.075    | 0.0075   | berry            | 53<br>53                                                                                                         | <0.02<br><0.02                                                                                                                        | <0.02<br><0.02                                                                                                                      | P99/40<br>AUS-P99-40-B1           |
| 1999             | 50<br>WG    | 3  | 0.075    | 0.0074   | berry            | 75<br>75                                                                                                         | <0.02<br><0.02                                                                                                                        | <0.02<br><0.02                                                                                                                      | P99/40<br>AUS-P99-40-C1           |
| 1999             | 50<br>WG    | 3  | 0.075    | 0.0075   | berry            | 106<br>106                                                                                                       | <0.02<br><0.02                                                                                                                        | <0.02<br><0.02                                                                                                                      | P99/40<br>AUS-P99-40-D1           |
| 1999             | 50          | 3  | 0.075    | 0.007    | berry            | 75                                                                                                               | <0.02                                                                                                                                 | <0.02                                                                                                                               | P99/49                            |

| Country,<br>Year | Application |    |          |          | Residues (mg/kg) |               |                      |               | Report No.;<br>Study No. |
|------------------|-------------|----|----------|----------|------------------|---------------|----------------------|---------------|--------------------------|
|                  | FL          | No | kg ai/ha | kg ai/hl | Sample           | PHI<br>(days) | trifloxy-<br>strobin | CGA<br>321113 |                          |
|                  | WG          |    |          |          |                  | 75            | <0.02                | <0.02         | AUS-P99-49-C3            |

<sup>1</sup> before last treatment

Table 55. Results of residue trials with trifloxystrobin on grapes in South Africa in 1995.

| Application |    |           |          | Residues (mg/kg) |                |                      |             | Report No.;<br>Study No. |
|-------------|----|-----------|----------|------------------|----------------|----------------------|-------------|--------------------------|
| Form        | No | kg ai/ha  | kg ai/hl | Sample           | PHI<br>(days)  | trifloxy-<br>strobin | CGA321113   |                          |
| 125<br>EC   | 9  | 0.05-0.13 | 0.013    | berry            | 0              | 0.36                 | 0.05        | 2204/95<br>SAF-2204-95   |
|             |    |           |          |                  | 3              | 0.21                 | 0.06        |                          |
|             |    |           |          |                  | 7              | 0.12                 | 0.04        |                          |
|             |    |           |          |                  | 14             | <u>0.18</u>          | <u>0.04</u> |                          |
|             |    |           |          |                  | 21             | 0.17                 | 0.03        |                          |
|             |    |           |          |                  | 28             | 0.13                 | 0.03        |                          |
|             |    |           |          |                  | 47             | 0.06                 | 0.03        |                          |
| 125<br>EC   | 7  | 0.06-0.19 | 0.013    | berry            | 0 <sup>1</sup> | 0.17                 | 0.09        | 2211/95<br>SAF-2211-95   |
|             |    |           |          |                  | 0              | 1.14                 | 0.12        |                          |
|             |    |           |          |                  | 3              | 0.65                 | 0.15        |                          |
|             |    |           |          |                  | 7              | 0.47                 | 0.18        |                          |
|             |    |           |          |                  | 14             | <u>0.24</u>          | <u>0.14</u> |                          |
|             |    |           |          |                  | 21             | 0.12                 | 0.11        |                          |
|             |    |           |          |                  | 28             | 0.10                 | 0.10        |                          |
| 50<br>WG    | 7  | 0.06-0.19 | 0.013    | berry            | 0 <sup>1</sup> | 0.12                 | 0.02        | 2214/95<br>SAF-2214-95   |
|             |    |           |          |                  | 0              | 0.50                 | 0.05        |                          |
|             |    |           |          |                  | 3              | 0.35                 | 0.05        |                          |
|             |    |           |          |                  | 7              | 0.19                 | 0.03        |                          |
|             |    |           |          |                  | 14             | <u>0.11</u>          | <u>0.04</u> |                          |
|             |    |           |          |                  | 21             | 0.05                 | 0.03        |                          |
|             |    |           |          |                  | 28             | 0.04                 | 0.03        |                          |
|             |    |           |          |                  | 42             | 0.06                 | 0.03        |                          |

<sup>1</sup> before last treatment

Table 56. Results of residue trials with trifloxystrobin on grapes in Europe.

| Country,<br>Year | Application |    |          |                 | Residues (mg/kg) |               |                      |                 | Report No.;<br>Study No. |
|------------------|-------------|----|----------|-----------------|------------------|---------------|----------------------|-----------------|--------------------------|
|                  | Form        | No | kg ai/ha | kg ai/hl        | Sample           | PHI<br>(days) | trifloxy-<br>strobin | CGA<br>321113   |                          |
| Germany<br>1997  | 50<br>WG    | 8  | 0.19     | 0.023-<br>0.047 | berry            | 0             | 1.3                  | 0.13            | gr45597<br>BRD-gr45597   |
|                  |             |    |          |                 |                  | 13            | 0.99                 | 0.09            |                          |
|                  |             |    |          |                 |                  | 28            | 0.69                 | 0.06            |                          |
|                  |             |    |          |                 |                  | 36            | 0.65                 | 0.06            |                          |
|                  |             |    |          |                 |                  | 43            | 0.65                 | 0.06            |                          |
| Germany<br>1997  | 50<br>WG    | 8  | 0.19     | 0.023-<br>0.047 | berry            | 0             | 2.0                  | 0.12            | gr46597<br>BRD-gr46597   |
|                  |             |    |          |                 |                  | 13            | 1.2                  | 0.10            |                          |
|                  |             |    |          |                 |                  | 28            | 0.54                 | 0.07            |                          |
|                  |             |    |          |                 |                  | 36            | 0.59                 | 0.07            |                          |
|                  |             |    |          |                 |                  | 43            | 0.46                 | 0.06            |                          |
| France<br>1999   | 50<br>WG    | 3  | 0.13     | 0.09-0.11       | berry            | 0             | 0.18                 | <0.02           | 2114/99<br>FRA-2114-99   |
|                  |             |    |          |                 |                  | 14            | 0.12                 | 0.02            |                          |
|                  |             |    |          |                 |                  | 35            | <u>0.04</u>          | <u>&lt;0.02</u> |                          |
|                  |             |    |          |                 |                  | 35            | 0.04                 | <0.02           |                          |
| France<br>1999   | 50<br>WG    | 3  | 0.13     | 0.13            | berry            | 0             | 0.37                 | 0.02            | 2115/99<br>FRA-2115-99   |
|                  |             |    |          |                 |                  | 14            | 0.28                 | 0.02            |                          |
|                  |             |    |          |                 |                  | 35            | <u>0.13</u>          | <u>0.03</u>     |                          |
|                  |             |    |          |                 |                  | 35            | 0.13                 | 0.03            |                          |
| Germany<br>2000  | 50<br>WG    | 3  | 0.13     | 0.016           | berry            | 0             | 0.72                 | <0.01           | gr43500<br>BRD-gr43500   |
|                  |             |    |          |                 |                  | 35            | <u>0.27</u>          | <u>0.02</u>     |                          |



| Country,<br>Year    | Application |    |           |                 | Residues (mg/kg) |                           |                                      |                                      | Report No.;<br>Study No.        |
|---------------------|-------------|----|-----------|-----------------|------------------|---------------------------|--------------------------------------|--------------------------------------|---------------------------------|
|                     | Form        | No | kg ai/ha  | kg ai/hl        | Sample           | PHI<br>(days)             | trifloxy-<br>strobin                 | CGA<br>321113                        |                                 |
| Germany<br>2000     | 50<br>WG    | 3  | 0.13      | 0.016           | berry            | 0<br>35                   | 0.62<br><u>0.29</u>                  | <0.01<br><u>0.01</u>                 | gr44500<br>BRD-gr44500          |
| Germany<br>2000     | 50<br>WG    | 3  | 0.13      | 0.006           | berry            | 0<br>35                   | 0.16<br><u>0.06</u>                  | 0.01<br><u>&lt;0.01</u>              | gr45800<br>BRD-gr45800          |
| Germany<br>2000     | 50<br>WG    | 3  | 0.13      | 0.006           | berry            | 0<br>35                   | 0.16<br><u>0.14</u>                  | <0.01<br><u>0.02</u>                 | gr46900<br>BRD-gr46900          |
| Switzerland<br>2000 | 50<br>WG    | 3  | 0.13      | 0.012           | berry            | 35<br>35                  | <u>0.06</u><br>0.06                  | <u>0.01</u><br>0.01                  | 2008/00<br>SWZ-2008-00          |
| Switzerland<br>2000 | 50<br>WG    | 3  | 0.13      | 0.009           | berry            | 35<br>35<br>36<br>36      | 0.04<br>0.04<br><u>0.04</u><br>0.03  | 0.01<br>0.01<br><u>0.01</u><br>0.01  | 2147/00<br>SWZ-2147-A           |
| Switzerland<br>2000 | 50<br>WG    | 3  | 0.13      | 0.009           | berry            | 36                        | <u>0.04</u>                          | <u>0.01</u>                          | 2147/00<br>SWZ-2147-B1          |
| Switzerland<br>2000 | 50<br>WG    | 3  | 0.13      | 0.009           | berry            | 36                        | <u>0.03</u>                          | <u>0.01</u>                          | 2147/00<br>SWZ-2147-B2          |
| Germany<br>1995     | 49<br>WG    | 8  | 0.19-0.22 | 0.02-0.05       | berry            | 0<br>21<br>35<br>41<br>48 | 1.1<br>0.52<br>0.34<br>0.32<br>0.29  | 0.19<br>0.12<br>0.11<br>0.12<br>0.11 | CGD03<br>BRD-CGD03              |
| Switzerland<br>1995 | 49<br>WG    | 8  | 0.19      | 0.013           | berry            | 0<br>28<br>35<br>42<br>49 | 1.6<br>0.25<br>0.24<br>0.15<br>0.15  | 0.11<br>0.09<br>0.09<br>0.07<br>0.08 | 2035/95<br>SWZ-2035-95          |
| Switzerland<br>1995 | 49<br>WG    | 8  | 0.19      | 0.013           | berry            | 0<br>28<br>35<br>42<br>49 | 1.7<br>0.64<br>0.58<br>0.52<br>0.18  | 0.09<br>0.06<br>0.05<br>0.06<br>0.03 | 2036/95<br>SWZ-2036-95          |
| Germany<br>1995     | 49<br>WG    | 8  | 0.19-0.20 | 0.019-<br>0.020 | berry            | 0<br>21<br>35<br>41<br>48 | 3.4<br>1.8<br>1.1<br>0.94<br>1.4     | 0.18<br>0.11<br>0.07<br>0.07<br>0.15 | 951047008<br>BRD-FR08-95-<br>43 |
| Germany<br>1996     | 49<br>WG    | 8  | 0.18-0.19 | 0.024-<br>0.047 | berry            | 0<br>14<br>28<br>35<br>42 | 1.5<br>1.2<br>1.2<br>1.2<br>1.0      | 0.04<br>0.03<br>0.03<br>0.03<br>0.03 | gr01196<br>BRD-gr01196          |
| Germany<br>1996     | 49<br>WG    | 8  | 0.15-0.21 | 0.022-<br>0.038 | berry            | 0<br>14<br>28<br>35<br>42 | 0.73<br>0.47<br>0.29<br>0.31<br>0.24 | 0.06<br>0.04<br>0.05<br>0.04<br>0.04 | gr01296<br>BRD-gr01296          |
| France<br>1996      | 49<br>WG    | 8  | 0.19      | 0.17-0.19       | berry            | 35                        | 0.52                                 | 0.12                                 | OF96125/DE17<br>FRA-DE17        |
| France<br>1996      | 49<br>WG    | 8  | 0.19      | 0.09            | berry            | 36                        | 0.83                                 | 0.11                                 | OF96126/KJ58<br>FRA-KJ58        |

| Country,<br>Year    | Application |    |                 |                  | Residues (mg/kg) |                           |                                      |                                            | Report No.;<br>Study No.       |
|---------------------|-------------|----|-----------------|------------------|------------------|---------------------------|--------------------------------------|--------------------------------------------|--------------------------------|
|                     | Form        | No | kg ai/ha        | kg ai/hl         | Sample           | PHI<br>(days)             | trifloxy-<br>strobin                 | CGA<br>321113                              |                                |
| Switzerland<br>1998 | 49<br>WG    | 4  | 0.20            | 0.05             | berry            | -1<br>0<br>15<br>28<br>46 | 0.34<br>0.79<br>0.33<br>0.21<br>0.18 | 0.06<br>0.06<br>0.04<br>0.03<br>0.04       | 526/98<br>SWZ-98-<br>3.211.051 |
| Switzerland<br>1998 | 49<br>WG    | 4  | 0.20            | 0.05             | berry            | -1<br>0<br>15<br>28<br>46 | 0.27<br>0.57<br>0.25<br>0.12<br>0.11 | 0.09<br>0.08<br>0.05<br>0.04<br>0.04       | 526/98<br>SWZ-98-3-<br>211.052 |
| Switzerland<br>1998 | 49<br>WG    | 4  | 0.20            | 0.02             | berry            | -2<br>1<br>29<br>42       | 0.32<br>0.65<br>0.16<br>0.11         | 0.04<br>0.04<br>0.03<br>0.02               | 526/98<br>SWZ-98-3-<br>211.060 |
| Switzerland<br>1998 | 49<br>WG    | 4  | 0.20            | 0.03             | berry            | -1<br>1<br>15<br>29<br>50 | 0.40<br>0.74<br>0.34<br>0.18<br>0.20 | 0.06<br>0.06<br>0.06<br>0.04<br>0.05       | 526/98<br>SWZ-98-<br>3.211.061 |
| Spain<br>1997       | 50<br>WG    | 6  | 0.075           | 0.015-<br>0.04   | berry            | 31<br>31                  | 0.11<br><u>0.28</u>                  | <0.02<br><u>&lt;0.02</u>                   | 2050/97<br>SPA-2050-97         |
| Spain<br>1997       | 50<br>WG    | 6  | 0.074-<br>0.076 | 0.009-<br>0.011  | berry            | 30<br>30                  | 0.07<br><u>0.08</u>                  | <0.02<br><u>&lt;0.02</u>                   | 2051/97<br>SPA-2051-97         |
| Greece<br>1998      | 50<br>WG    | 6  | 0.075           | 0.0075           | berry            | 21<br>21<br>28<br>28      | 0.19<br>0.20<br><u>0.14</u><br>0.13  | 0.02<br>0.02<br><u>&lt;0.02</u><br><0.02   | 2134/98<br>GRI-2134-98         |
| Italy<br>1998       | 50<br>WG    | 6  | 0.10            | 0.010            | berry            | 0<br>14<br>21<br>28       | 0.31<br>0.17<br>0.16<br><u>0.13</u>  | <0.02<br><0.02<br><0.02<br><u>&lt;0.02</u> | 2042/98<br>ITA-2042-98         |
| Italy<br>1998       | 50<br>WG    | 6  | 0.10            | 0.010-<br>0.013  | berry            | 0<br>14<br>21<br>28       | 0.18<br>0.10<br>0.05<br><u>0.05</u>  | 0.02<br><0.02<br><0.02<br><u>&lt;0.02</u>  | 2043/98<br>ITA-2043-98         |
| Spain<br>1998       | 50<br>WG    | 6  | 0.075           | 0.014            | berry            | 21<br>29                  | 0.26<br><u>0.36</u>                  | 0.02<br><u>0.02</u>                        | 2056/98<br>SPA-2056-98         |
| Spain<br>1998       | 50<br>WG    | 6  | 0.076           | 0.0075-<br>0.009 | berry            | 21<br>21<br>31<br>31      | 0.16<br>0.16<br>0.10<br><u>0.11</u>  | <0.02<br><0.02<br><0.02<br><u>&lt;0.02</u> | 2057/98<br>SPA-2057-98         |

Table 57. Results of residue trials with trifloxystrobin on grapes in Canada and the USA.

| Country,<br>Year | Application |    |          |                 | Residues (mg/kg)   |               |                      |                          | Report No.;<br>Study No.          |
|------------------|-------------|----|----------|-----------------|--------------------|---------------|----------------------|--------------------------|-----------------------------------|
|                  | Form        | No | kg ai/ha | kg ai/hl        | Sample             | PHI<br>(days) | trifloxy-<br>strobin | CGA<br>321113            |                                   |
| Canada<br>1999   | 50<br>WG    | 6  | 0.07     | 0.007           | bunch of<br>grapes | 13<br>13      | 0.04<br><u>0.06</u>  | <0.02<br><u>&lt;0.02</u> | CER 04414/99<br>CND-CER04414-99-A |
| Canada<br>1999   | 50<br>WG    | 5  | 0.07     | 0.007           | bunch of<br>grapes | 14            | <u>2.2</u>           | <u>0.02</u>              | CER 04414/99<br>CND-CER04414-99-B |
| NY, USA<br>1996  | 50<br>WG    | 6  | 0.14     | 0.015           | berry              | 14<br>14      | <u>0.09</u><br>0.08  | <u>&lt;0.02</u><br><0.02 | 110440<br>USA-NE-FR-825-96        |
| PA, USA<br>1996  | 50<br>WG    | 6  | 0.14     | 0.015-<br>0.016 | berry              | 14<br>14      | <u>0.62</u><br>0.55  | <u>0.02</u><br>0.02      | 110440<br>USA-NE-FR-826-96        |

| Country,<br>Year | Application |    |          |                 | Residues (mg/kg) |               |                      |                 | Report No.;<br>Study No.     |
|------------------|-------------|----|----------|-----------------|------------------|---------------|----------------------|-----------------|------------------------------|
|                  | Form        | No | kg ai/ha | kg ai/hl        | Sample           | PHI<br>(days) | trifloxy-<br>strobin | CGA-<br>321113  |                              |
| CA, USA<br>1996  | 50<br>WG    | 6  | 0.14     | 0.025           | berry            | 0             | 0.20                 | <0.02           | 110440<br>USA-OW-FR-415-96-A |
|                  |             |    |          |                 |                  | 0             | 0.43                 | <0.02           |                              |
|                  |             |    |          |                 |                  | 1             | 0.73                 | <0.02           |                              |
|                  |             |    |          |                 |                  | 1             | 0.45                 | <0.02           |                              |
|                  |             |    |          |                 |                  | 3             | 0.47                 | <0.02           |                              |
|                  |             |    |          |                 |                  | 3             | 0.45                 | <0.02           |                              |
|                  |             |    |          |                 |                  | 7             | 0.34                 | <0.02           |                              |
|                  |             |    |          |                 |                  | 7             | 0.31                 | <0.02           |                              |
|                  |             |    |          |                 |                  | 14            | 0.25                 | <0.02           |                              |
|                  |             |    |          |                 |                  | 14            | <u>0.33</u>          | <u>&lt;0.02</u> |                              |
|                  |             |    |          |                 |                  | 22            | 0.09                 | <0.02           |                              |
|                  |             |    |          |                 |                  | 22            | 0.15                 | <0.02           |                              |
| CA, USA<br>1996  | 50<br>WG    | 6  | 0.14     | 0.03            | berry            | 0             | 0.96                 | 0.04            | 110440<br>USA-02-FR-025-96-A |
|                  |             |    |          |                 |                  | 0             | 0.81                 | 0.05            |                              |
|                  |             |    |          |                 |                  | 1             | 0.57                 | 0.04            |                              |
|                  |             |    |          |                 |                  | 1             | 0.87                 | 0.06            |                              |
|                  |             |    |          |                 |                  | 4             | 0.59                 | 0.04            |                              |
|                  |             |    |          |                 |                  | 4             | 0.96                 | 0.04            |                              |
|                  |             |    |          |                 |                  | 7             | 0.57                 | 0.03            |                              |
|                  |             |    |          |                 |                  | 7             | 0.66                 | 0.04            |                              |
|                  |             |    |          |                 |                  | 14            | <u>1.1</u>           | <u>0.05</u>     |                              |
|                  |             |    |          |                 |                  | 14            | 1.0                  | 0.05            |                              |
|                  |             |    |          |                 |                  | 21            | 0.38                 | 0.03            |                              |
|                  |             |    |          |                 |                  | 21            | 0.53                 | 0.045           |                              |
| CA, USA<br>1996  | 50<br>WG    | 6  | 0.14     | 0.025           | berry            | 14            | 0.22                 | <0.02           | 110440                       |
|                  |             |    |          |                 |                  | 14            | <u>0.26</u>          | <u>&lt;0.02</u> | USA-OW-FR-416-96             |
| CA, USA<br>1996  | 50<br>WG    | 6  | 0.14     | 0.03            | berry            | 14            | 0.03                 | <0.02           | 110440                       |
|                  |             |    |          |                 |                  | 14            | <u>0.04</u>          | <u>&lt;0.02</u> | USA-OW-FR-417-96             |
| CA, USA<br>1996  | 50<br>WG    | 6  | 0.14     | 0.03            | berry            | 14            | <u>0.17</u>          | <u>&lt;0.02</u> | 110440                       |
|                  |             |    |          |                 |                  | 14            | 0.16                 | <0.02           | USA-OW-FR-418-96             |
| CA, USA<br>1996  | 50<br>WG    | 6  | 0.14     | 0.03            | berry            | 14            | <u>0.16</u>          | <u>&lt;0.02</u> | 110440                       |
|                  |             |    |          |                 |                  | 14            | 0.15                 | <0.02           | USA-OW-FR-419-96             |
| CA, USA<br>1996  | 50<br>WG    | 6  | 0.14     | 0.03            | berry            | 14            | 0.26                 | <0.02           | 110440                       |
|                  |             |    |          |                 |                  | 14            | <u>0.28</u>          | <u>&lt;0.02</u> | USA-OW-FR-531-96             |
| CA, USA<br>1996  | 50<br>WG    | 6  | 0.14     | 0.009           | berry            | 14            | <u>0.29</u>          | <u>0.07</u>     | 110440                       |
|                  |             |    |          |                 |                  | 14            | 0.26                 | 0.06            | USA-OW-FR-532-96             |
| WA, USA<br>1996  | 50<br>WG    | 6  | 0.14     | 0.015           | berry            | 13            | 0.15                 | <0.02           | 110440                       |
|                  |             |    |          |                 |                  | 13            | <u>0.21</u>          | <u>&lt;0.02</u> | USA-OW-FR-647-96             |
| OR, USA<br>1996  | 50<br>WG    | 6  | 0.14     | 0.015-<br>0.017 | berry            | 14            | <u>0.61</u>          | <u>0.02</u>     | 110440                       |
|                  |             |    |          |                 |                  | 14            | 0.51                 | 0.02            | USA-OW-FR-648-96             |

Table 58. Results of residue trials with trifloxystrobin on strawberry in Europe.

| Country,<br>Year    | Application |    |          |          | Residues (mg/kg) |               |                      |                            | Report No.;<br>Study No. |
|---------------------|-------------|----|----------|----------|------------------|---------------|----------------------|----------------------------|--------------------------|
|                     | Form        | No | kg ai/ha | kg ai/hl | Sample           | PHI<br>(days) | trifloxy-<br>strobin | CGA3211<br>13 <sup>1</sup> |                          |
| Switzerland<br>1999 | 50<br>WG    | 3  | 0.25     | 0.025    | berry            | 0             | 1.2                  | 0.05                       | 2080/99<br>SWZ-2080-99   |
|                     |             |    |          |          |                  | 3             | 0.30                 | 0.05                       |                          |
|                     |             |    |          |          |                  | 7             | 0.20                 | 0.06                       |                          |
|                     |             |    |          |          |                  | 14            | <u>0.10</u>          | <u>0.04</u>                |                          |
|                     |             |    |          |          |                  | 14            | 0.10                 | 0.04                       |                          |
| Switzerland<br>2000 | 50<br>WG    | 3  | 0.25     | 0.03     | berry            | 0             | 0.38                 | 0.03                       | 2045/00<br>SWZ-2045-00   |
|                     |             |    |          |          |                  | 3             | 0.29                 | 0.03                       |                          |
|                     |             |    |          |          |                  | 7             | 0.17                 | 0.04                       |                          |
|                     |             |    |          |          |                  | 10            | 0.12                 | 0.04                       |                          |
|                     |             |    |          |          |                  | 14            | 0.09                 | 0.04                       |                          |
|                     |             |    |          |          |                  | 14            | <u>0.13</u>          | <u>0.05</u>                |                          |

| Country,<br>Year | Application |    |          |          | Residues (mg/kg) |                |                      |                            | Report No.;<br>Study No. |
|------------------|-------------|----|----------|----------|------------------|----------------|----------------------|----------------------------|--------------------------|
|                  | Form        | No | kg ai/ha | kg ai/hl | Sample           | PHI<br>(days)  | trifloxy-<br>strobin | CGA3211<br>13 <sup>1</sup> |                          |
| France<br>2002   | 50<br>WG    | 3  | 0.25     | 0.04     | fruit            | 0 <sup>1</sup> | 0.06                 | 0.03                       | RA-2038/02<br>0080-02    |
|                  |             |    |          |          |                  | 0              | 0.14                 | 0.03                       |                          |
|                  |             |    |          |          |                  | 1              | 0.11                 | 0.03                       |                          |
|                  |             |    |          |          |                  | 3              | 0.15                 | 0.03                       |                          |
|                  |             |    |          |          |                  | 7              | 0.08                 | 0.03                       |                          |
|                  |             |    |          |          |                  | 14             | <u>0.06</u>          | <u>0.04</u>                |                          |
| Germany<br>2002  | 50<br>WG    | 3  | 0.25     | 0.04     | fruit            | 0 <sup>1</sup> | 0.14                 | 0.04                       | RA-2038/02<br>0187-02    |
|                  |             |    |          |          |                  | 0              | 0.32                 | 0.05                       |                          |
|                  |             |    |          |          |                  | 1              | 0.28                 | 0.04                       |                          |
|                  |             |    |          |          |                  | 3              | 0.27                 | 0.05                       |                          |
|                  |             |    |          |          |                  | 7              | 0.12                 | 0.06                       |                          |
|                  |             |    |          |          |                  | 14             | <u>0.04</u>          | <u>0.05</u>                |                          |
| Germany<br>2002  | 50<br>WG    | 3  | 0.25     | 0.04     | fruit            | 0 <sup>1</sup> | 0.08                 | 0.02                       | RA-2038/02<br>0188-02    |
|                  |             |    |          |          |                  | 0              | 0.22                 | 0.02                       |                          |
|                  |             |    |          |          |                  | 1              | 0.20                 | 0.03                       |                          |
|                  |             |    |          |          |                  | 3              | 0.15                 | 0.03                       |                          |
|                  |             |    |          |          |                  | 7              | 0.07                 | 0.04                       |                          |
|                  |             |    |          |          |                  | 14             | <u>0.05</u>          | <u>0.03</u>                |                          |

*Assorted tropical and subtropical fruits – inedible peel*

*Banana*

The results of supervised trials carried on bananas using foliar sprays of 75 EC formulations were reported from Costa Rica, Columbia, Ecuador, Guatemala, Honduras, Mexico, Puerto Rico and Martinique. Except for the trials in Martinique, six individual field samples were taken at each sampling date.

Table 59. Results of residue trials with trifloxystrobin on bagged and unbagged bananas.

| Country,<br>Year                        | Application |    |              |          | Residues (mg/kg)           |               |                      |                     | Report No.;<br>Study No. |
|-----------------------------------------|-------------|----|--------------|----------|----------------------------|---------------|----------------------|---------------------|--------------------------|
|                                         | Form        | No | kg ai/ha     | kg ai/hl | Sample                     | PHI<br>(days) | trifloxy-<br>strobin | CGA-<br>321113      |                          |
| Banana,<br>bagged Costa<br>Rica<br>1996 | 75 EC<br>✈  | 10 | 0.1-<br>0.13 | 0.5      | pulp                       | 0             | <0.02 (6)            | <0.02 (6)           | 128/96<br>COR-2144-96-A  |
|                                         |             |    |              |          |                            | 2             | <0.02 (6)            | <0.02 (6)           |                          |
|                                         |             |    |              |          |                            | 7             | <0.02 (6)            | <0.02 (6)           |                          |
|                                         |             |    |              |          |                            | 10            | <0.02 (6)            | <0.02 (6)           |                          |
|                                         |             |    |              |          | peel                       | 0             | <0.02 (6)            | <0.02 (6)           |                          |
|                                         |             |    |              |          |                            | 2             | <0.02 (6)            | <0.02 (6)           |                          |
|                                         |             |    |              |          |                            | 7             | <0.02 (6)            | <0.02 (6)           |                          |
|                                         |             |    |              |          |                            | 10            | <0.02 (6)            | <0.02 (6)           |                          |
|                                         |             |    |              |          | whole fruit,<br>calculated | 0             | <u>&lt;0.02 (6)</u>  | <u>&lt;0.02 (6)</u> |                          |
|                                         |             |    |              |          |                            | 2             | <0.02 (6)            | <0.02 (6)           |                          |
|                                         |             |    |              |          |                            | 7             | <0.02 (6)            | <0.02 (6)           |                          |
|                                         |             |    |              |          |                            | 10            | <0.02 (6)            | <0.02 (6)           |                          |

| Country,<br>Year                          | Application |    |               |               | Residues (mg/kg)           |               |                      |                     | Report No.;<br>Study No. |
|-------------------------------------------|-------------|----|---------------|---------------|----------------------------|---------------|----------------------|---------------------|--------------------------|
|                                           | Form        | No | kg ai/ha      | kg ai/hl      | Sample                     | PHI<br>(days) | trifloxy-<br>strobin | CGA-<br>321113      |                          |
| Banana,<br>unbagged<br>Costa Rica<br>1996 | 75 EC<br>→  | 10 | 0.1-<br>0.13  | 0.5           | pulp                       | 0             | <0.02 (5)            | <0.02 (5)           | 128/96<br>COR-2144-96-B  |
|                                           |             |    |               |               |                            | 0             | <0.02                | 0.02                |                          |
|                                           |             |    |               |               |                            | 2             | <0.02 (6)            | <0.02 (6)           |                          |
|                                           |             |    |               |               |                            | 7             | <0.02 (6)            | <0.02 (6)           |                          |
|                                           |             |    |               |               |                            | 10            | <0.02 (6)            | <0.02 (6)           |                          |
|                                           |             |    |               |               | peel                       | 0             | <0.02 (5)            | <0.02 (5)           |                          |
|                                           |             |    |               |               |                            | 0             | 0.05                 | 0.02                |                          |
|                                           |             |    |               |               |                            | 2             | 0.10                 | 0.04                |                          |
|                                           |             |    |               |               |                            | 2             | 0.03                 | 0.02                |                          |
|                                           |             |    |               |               |                            | 2             | 0.02                 | <0.02               |                          |
|                                           |             |    |               |               |                            | 2             | 0.02                 | <0.02               |                          |
|                                           |             |    |               |               |                            | 2             | 0.05                 | 0.02                |                          |
|                                           |             |    |               |               |                            | 2             | <0.02                | <0.02               |                          |
|                                           |             |    |               |               |                            | 7             | <0.02 (5)            | <0.02 (5)           |                          |
|                                           |             |    |               |               |                            | 7             | 0.03                 | 0.02                |                          |
|                                           |             |    |               |               |                            | 10            | <0.02 (5)            | <0.02 (5)           |                          |
|                                           |             |    |               |               |                            | 10            | 0.02                 | <0.02               |                          |
|                                           |             |    |               |               | whole fruit,<br>calculated | 0             | <0.02 (5)            | <0.02 (5)           |                          |
|                                           |             |    |               |               |                            | 0             | 0.03                 | 0.02                |                          |
|                                           |             |    |               |               |                            | 2             | 0.05                 | 0.02                |                          |
|                                           |             |    |               |               |                            | 2             | <0.02 (4)            | <0.02 (4)           |                          |
|                                           |             |    |               |               |                            | 2             | 0.03                 | <0.02               |                          |
|                                           |             |    |               |               |                            | 2             | mean <u>0.03</u>     | <u>&lt;0.02</u>     |                          |
|                                           |             |    |               |               |                            | 7             | <0.02 (6)            | <0.02 (6)           |                          |
|                                           |             |    |               |               |                            | 10            | <0.02 (6)            | <0.02 (6)           |                          |
| Banana,<br>bagged<br>Costa Rica<br>1996   | 75 EC<br>→  | 10 | 0.11-<br>0.13 | 0.37-<br>0.51 | pulp                       | 0             | <0.02 (6)            | <0.02 (6)           | 128/96<br>COR-2146-96-A  |
|                                           |             |    |               |               |                            | 7             | <0.02 (6)            | <0.02 (6)           |                          |
|                                           |             |    |               |               | peel                       | 0             | <0.02 (6)            | <0.02 (6)           |                          |
|                                           |             |    |               |               |                            | 7             | <0.02 (6)            | <0.02 (6)           |                          |
|                                           |             |    |               |               | whole fruit,<br>calculated | 0             | <u>&lt;0.02 (6)</u>  | <u>&lt;0.02 (6)</u> |                          |
|                                           |             |    |               |               |                            | 7             | <0.02 (6)            | <0.02 (6)           |                          |
| Banana,<br>unbagged<br>Costa Rica<br>1996 | 75 EC<br>→  | 10 | 0.11-<br>0.13 | 0.37-<br>0.51 | pulp                       | 0             | <0.02 (6)            | <0.02 (6)           | 128/96<br>COR-2146-96-B  |
|                                           |             |    |               |               |                            | 7             | <0.02 (6)            | <0.02 (6)           |                          |
|                                           |             |    |               |               | peel                       | 0             | <0.02 (4)            | <0.02 (4)           |                          |
|                                           |             |    |               |               |                            | 0             | 0.02 (2)             | <0.02 (2)           |                          |
|                                           |             |    |               |               |                            | 7             | <0.02 (5)            | <0.02 (5)           |                          |
|                                           |             |    |               |               |                            | 7             | 0.02                 | <0.02               |                          |
|                                           |             |    |               |               | whole fruit,<br>calculated | 0             | <0.02 (5)            | <0.02 (5)           |                          |
|                                           |             |    |               |               |                            | 0             | <u>0.02</u>          | <u>&lt;0.02</u>     |                          |
|                                           |             |    |               |               |                            | 7             | <0.02 (6)            | <0.02 (6)           |                          |
| Banana,<br>bagged Costa<br>Rica<br>1996   | 75 EC<br>→  | 10 | 0.08-<br>0.13 | 0.51-<br>0.57 | pulp                       | 0             | <0.02 (6)            | <0.02 (6)           | 128/96<br>COR-2147-96-A  |
|                                           |             |    |               |               |                            | 7             | <0.02 (6)            | <0.02 (6)           |                          |
|                                           |             |    |               |               | peel                       | 0             | <0.02 (6)            | <0.02 (6)           |                          |
|                                           |             |    |               |               |                            | 7             | <0.02 (6)            | <0.02 (6)           |                          |
|                                           |             |    |               |               | whole fruit,<br>calculated | 0             | <u>&lt;0.02 (6)</u>  | <u>&lt;0.02 (6)</u> |                          |
|                                           |             |    |               |               |                            | 7             | <0.02 (6)            | <0.02 (6)           |                          |
| Banana,<br>unbagged<br>Costa Rica<br>1996 | 75 EC<br>→  | 10 | 0.08-<br>0.13 | 0.51-<br>0.57 | pulp                       | 0             | <0.02 (6)            | <0.02 (6)           | 128/96<br>COR-2147-96-B  |
|                                           |             |    |               |               |                            | 7             | <0.02 (6)            | <0.02 (6)           |                          |
|                                           |             |    |               |               | peel                       | 0             | <0.02 (3)            | <0.02 (3)           |                          |
|                                           |             |    |               |               |                            | 0             | 0.02(2)              | <0.02 (2)           |                          |
|                                           |             |    |               |               |                            | 0             | 0.03                 | <0.02               |                          |
|                                           |             |    |               |               |                            | 7             | <0.02 (6)            | <0.02 (6)           |                          |
|                                           |             |    |               |               | whole fruit,<br>calculated | 0             | <u>&lt;0.02 (6)</u>  | <u>&lt;0.02 (6)</u> |                          |
|                                           |             |    |               |               |                            | 7             | <0.02 (6)            | <0.02 (6)           |                          |

| Country,<br>Year                       | Application |    |               |               | Residues (mg/kg)           |               |                      |                     | Report No.;<br>Study No. |
|----------------------------------------|-------------|----|---------------|---------------|----------------------------|---------------|----------------------|---------------------|--------------------------|
|                                        | Form        | No | kg ai/ha      | kg ai/hl      | Sample                     | PHI<br>(days) | trifloxy-<br>strobin | CGA-<br>321113      |                          |
| Banana,<br>bagged<br>Ecuador<br>1996   | 75 EC<br>➔  | 10 | 0.10-<br>0.14 | 0.45-<br>0.54 | pulp                       | 0             | <0.02 (6)            | <0.02 (6)           | 129/96<br>ECU-2148-96-A  |
|                                        |             |    |               |               |                            | 2             | <0.02 (6)            | <0.02 (6)           |                          |
|                                        |             |    |               |               |                            | 7             | <0.02 (6)            | <0.02 (6)           |                          |
|                                        |             |    |               |               |                            | 10            | <0.02 (6)            | <0.02 (6)           |                          |
|                                        |             |    |               |               | peel                       | 0             | <0.02 (6)            | <0.02 (6)           |                          |
|                                        |             |    |               |               |                            | 2             | <0.02 (6)            | <0.02 (6)           |                          |
|                                        |             |    |               |               |                            | 7             | <0.02 (6)            | <0.02 (6)           |                          |
|                                        |             |    |               |               |                            | 10            | <0.02 (6)            | <0.02 (6)           |                          |
|                                        |             |    |               |               | whole fruit,<br>calculated | 0             | <u>&lt;0.02 (6)</u>  | <u>&lt;0.02 (6)</u> |                          |
|                                        |             |    |               |               |                            | 2             | <0.02 (6)            | <0.02 (6)           |                          |
|                                        |             |    |               |               |                            | 7             | <0.02 (6)            | <0.02 (6)           |                          |
|                                        |             |    |               |               |                            | 10            | <0.02 (6)            | <0.02 (6)           |                          |
| Banana,<br>unbagged<br>Ecuador<br>1996 | 75 EC<br>➔  | 10 | 0.10-<br>0.14 | 0.45-<br>0.54 | pulp                       | 0             | <0.02 (6)            | <0.02 (6)           | 129/96<br>ECU-2148-96-B  |
|                                        |             |    |               |               |                            | 2             | <0.02 (6)            | <0.02 (6)           |                          |
|                                        |             |    |               |               |                            | 7             | <0.02 (6)            | <0.02 (6)           |                          |
|                                        |             |    |               |               |                            | 10            | <0.02 (6)            | <0.02 (6)           |                          |
|                                        |             |    |               |               | peel                       | 0             | <0.02 (6)            | <0.02 (6)           |                          |
|                                        |             |    |               |               |                            | 2             | <0.02 (6)            | <0.02 (6)           |                          |
|                                        |             |    |               |               |                            | 7             | <0.02 (6)            | <0.02 (6)           |                          |
|                                        |             |    |               |               |                            | 10            | <0.02 (6)            | <0.02 (6)           |                          |
|                                        |             |    |               |               | whole fruit,<br>calculated | 0             | <u>&lt;0.02 (6)</u>  | <u>&lt;0.02 (6)</u> |                          |
|                                        |             |    |               |               |                            | 2             | <0.02 (6)            | <0.02 (6)           |                          |
|                                        |             |    |               |               |                            | 7             | <0.02 (6)            | <0.02 (6)           |                          |
|                                        |             |    |               |               |                            | 10            | <0.02 (6)            | <0.02 (6)           |                          |
| Banana,<br>bagged<br>Ecuador<br>1996   | 75 EC<br>➔  | 10 | 0.11-<br>0.12 | 0.56          | pulp                       | 0             | <0.02 (6)            | <0.02 (6)           | 129/96<br>ECU-2151-96-A  |
|                                        |             |    |               |               |                            | 7             | <0.02 (6)            | <0.02 (6)           |                          |
|                                        |             |    |               |               | peel                       | 0             | <0.02 (6)            | <0.02 (6)           |                          |
|                                        |             |    |               |               |                            | 7             | <0.02 (6)            | <0.02 (6)           |                          |
|                                        |             |    |               |               | whole fruit,<br>calculated | 0             | <u>&lt;0.02 (6)</u>  | <u>&lt;0.02 (6)</u> |                          |
|                                        |             |    |               |               |                            | 7             | <0.02 (6)            | <0.02 (6)           |                          |
| Banana,<br>unbagged<br>Ecuador<br>1996 | 75 EC<br>➔  | 10 | 0.11-<br>0.12 | 0.56          | pulp                       | 0             | <0.02 (6)            | <0.02 (6)           | 129/96<br>ECU-2151-96-B  |
|                                        |             |    |               |               |                            | 7             | <0.02 (6)            | <0.02 (6)           |                          |
|                                        |             |    |               |               | peel                       | 0             | <0.02 (6)            | <0.02 (6)           |                          |
|                                        |             |    |               |               |                            | 7             | <0.02 (6)            | <0.02 (6)           |                          |
|                                        |             |    |               |               | whole fruit,<br>calculated | 0             | <u>&lt;0.02 (6)</u>  | <u>&lt;0.02 (6)</u> |                          |
|                                        |             |    |               |               |                            | 7             | <0.02 (6)            | <0.02 (6)           |                          |
| Banana,<br>bagged<br>Ecuador<br>1996   | 75 EC<br>➔  | 10 | 0.10-<br>0.16 | 0.56          | pulp                       | 0             | <0.02 (6)            | <0.02 (6)           | 129/96<br>ECU-2150-96-A  |
|                                        |             |    |               |               |                            | 7             | <0.02 (6)            | <0.02 (6)           |                          |
|                                        |             |    |               |               | peel                       | 0             | <0.02 (6)            | <0.02 (6)           |                          |
|                                        |             |    |               |               |                            | 7             | <0.02 (6)            | <0.02 (6)           |                          |
|                                        |             |    |               |               | whole fruit,<br>calculated | 0             | <u>&lt;0.02 (6)</u>  | <u>&lt;0.02 (6)</u> |                          |
|                                        |             |    |               |               |                            | 7             | <0.02 (6)            | <0.02 (6)           |                          |
| Banana,<br>unbagged<br>Ecuador<br>1996 | 75 EC<br>➔  | 10 | 0.10-<br>0.16 | 0.56          | pulp                       | 0             | <0.02 (6)            | <0.02 (6)           | 129/96<br>ECU-2150-96-B  |
|                                        |             |    |               |               |                            | 7             | <0.02 (6)            | <0.02 (6)           |                          |
|                                        |             |    |               |               | peel                       | 0             | <0.02 (6)            | <0.02 (6)           |                          |
|                                        |             |    |               |               |                            | 7             | <0.02 (6)            | <0.02 (6)           |                          |
|                                        |             |    |               |               | whole fruit,<br>calculated | 0             | <u>&lt;0.02 (6)</u>  | <u>&lt;0.02 (6)</u> |                          |
|                                        |             |    |               |               |                            | 7             | <0.02 (6)            | <0.02 (6)           |                          |

| Country,<br>Year                        | Application |    |               |               | Residues (mg/kg)           |               |                      |                     | Report No.;<br>Study No. |
|-----------------------------------------|-------------|----|---------------|---------------|----------------------------|---------------|----------------------|---------------------|--------------------------|
|                                         | Form        | No | kg ai/ha      | kg ai/hl      | Sample                     | PHI<br>(days) | trifloxy-<br>strobin | CGA-<br>321113      |                          |
| Banana,<br>bagged<br>Colombia<br>1996   | 75 EC<br>✈  | 11 | 0.09-<br>0.13 | 0.56-<br>0.57 | pulp                       | 0             | <0.02 (6)            | <0.02 (6)           | 130/96<br>COL-2152-96-A  |
|                                         |             |    |               |               |                            | 2             | <0.02 (6)            | <0.02 (6)           |                          |
|                                         |             |    |               |               |                            | 7             | <0.02 (6)            | <0.02 (6)           |                          |
|                                         |             |    |               |               |                            | 10            | <0.02 (6)            | <0.02 (6)           |                          |
|                                         |             |    |               |               | peel                       | 0             | <0.02 (6)            | <0.02 (6)           |                          |
|                                         |             |    |               |               |                            | 2             | <0.02 (6)            | <0.02 (6)           |                          |
|                                         |             |    |               |               |                            | 7             | <0.02 (6)            | <0.02 (6)           |                          |
|                                         |             |    |               |               |                            | 10            | <0.02 (6)            | <0.02 (6)           |                          |
|                                         |             |    |               |               | whole fruit,<br>calculated | 0             | <u>&lt;0.02 (6)</u>  | <u>&lt;0.02 (6)</u> |                          |
|                                         |             |    |               |               |                            | 2             | <0.02 (6)            | <0.02 (6)           |                          |
|                                         |             |    |               |               |                            | 7             | <0.02 (6)            | <0.02 (6)           |                          |
|                                         |             |    |               |               |                            | 10            | <0.02 (6)            | <0.02 (6)           |                          |
| Banana,<br>unbagged<br>Colombia<br>1996 | 75 EC<br>✈  | 11 | 0.09-<br>0.13 | 0.56-<br>0.57 | pulp                       | 0             | <0.02 (6)            | <0.02 (6)           | 130/96<br>COL-2152-96-B  |
|                                         |             |    |               |               |                            | 2             | <0.02 (6)            | <0.02 (6)           |                          |
|                                         |             |    |               |               |                            | 7             | <0.02 (6)            | <0.02 (6)           |                          |
|                                         |             |    |               |               |                            | 10            | <0.02 (6)            | <0.02 (6)           |                          |
|                                         |             |    |               |               | peel                       | 0             | <0.02 (6)            | <0.02 (6)           |                          |
|                                         |             |    |               |               |                            | 2             | <0.02 (6)            | <0.02 (6)           |                          |
|                                         |             |    |               |               |                            | 7             | <0.02 (6)            | <0.02 (6)           |                          |
|                                         |             |    |               |               |                            | 10            | <0.02 (6)            | <0.02 (6)           |                          |
|                                         |             |    |               |               | whole fruit,<br>calculated | 0             | <u>&lt;0.02 (6)</u>  | <u>&lt;0.02 (6)</u> |                          |
|                                         |             |    |               |               |                            | 2             | <0.02 (6)            | <0.02 (6)           |                          |
|                                         |             |    |               |               |                            | 7             | <0.02 (6)            | <0.02 (6)           |                          |
|                                         |             |    |               |               |                            | 10            | <0.02 (6)            | <0.02 (6)           |                          |
| Banana,<br>bagged<br>Colombia<br>1996   | 75 EC<br>✈  | 11 | 0.10-<br>0.12 | 0.56          | pulp                       | 0             | <0.02 (6)            | <0.02 (6)           | 130/96<br>COL-2154-96-A  |
|                                         |             |    |               |               |                            | 7             | <0.02 (6)            | <0.02 (6)           |                          |
|                                         |             |    |               |               | peel                       | 0             | <0.02 (6)            | <0.02 (6)           |                          |
|                                         |             |    |               |               |                            | 7             | <0.02 (6)            | <0.02 (6)           |                          |
|                                         |             |    |               |               | whole fruit,<br>calculated | 0             | <u>&lt;0.02 (6)</u>  | <u>&lt;0.02 (6)</u> |                          |
|                                         |             |    |               |               |                            | 7             | <0.02 (6)            | <0.02 (6)           |                          |
| Banana,<br>unbagged<br>Colombia<br>1996 | 75 EC<br>✈  | 11 | 0.10-<br>0.12 | 0.56          | pulp                       | 0             | <0.02 (6)            | <0.02 (6)           | 130/96<br>COL-2154-96-B  |
|                                         |             |    |               |               |                            | 7             | <0.02 (6)            | <0.02 (6)           |                          |
|                                         |             |    |               |               | peel                       | 0             | <0.02 (6)            | <0.02 (6)           |                          |
|                                         |             |    |               |               |                            | 7             | <0.02 (6)            | <0.02 (6)           |                          |
|                                         |             |    |               |               | whole fruit,<br>calculated | 0             | <u>&lt;0.02 (6)</u>  | <u>&lt;0.02 (6)</u> |                          |
|                                         |             |    |               |               |                            | 7             | <0.02 (6)            | <0.02 (6)           |                          |
| Banana,<br>bagged<br>Guatemala<br>1996  | 75 EC<br>✈  | 10 | 0.11-<br>0.16 | 0.51-<br>0.61 | pulp                       | 0             | <0.02 (6)            | <0.02 (6)           | 131/96<br>GUA-2155-96-A  |
|                                         |             |    |               |               |                            | 2             | <0.02 (6)            | <0.02 (6)           |                          |
|                                         |             |    |               |               |                            | 7             | <0.02 (6)            | <0.02 (6)           |                          |
|                                         |             |    |               |               |                            | 10            | <0.02 (6)            | <0.02 (6)           |                          |
|                                         |             |    |               |               | peel                       | 0             | <0.02 (6)            | <0.02 (6)           |                          |
|                                         |             |    |               |               |                            | 2             | <0.02 (6)            | <0.02 (6)           |                          |
|                                         |             |    |               |               |                            | 7             | <0.02 (6)            | <0.02 (6)           |                          |
|                                         |             |    |               |               |                            | 10            | <0.02 (6)            | <0.02 (6)           |                          |
|                                         |             |    |               |               | whole fruit,<br>calculated | 0             | <u>&lt;0.02 (6)</u>  | <u>&lt;0.02 (6)</u> |                          |
|                                         |             |    |               |               |                            | 2             | <0.02 (6)            | <0.02 (6)           |                          |
|                                         |             |    |               |               |                            | 7             | <0.02 (6)            | <0.02 (6)           |                          |
|                                         |             |    |               |               |                            | 10            | <0.02 (6)            | <0.02 (6)           |                          |

| Country,<br>Year                         | Application |    |               |               | Residues (mg/kg)           |               |                      |                | Report No.;<br>Study No. |
|------------------------------------------|-------------|----|---------------|---------------|----------------------------|---------------|----------------------|----------------|--------------------------|
|                                          | Form        | No | kg ai/ha      | kg ai/hl      | Sample                     | PHI<br>(days) | trifloxy-<br>strobin | CGA-<br>321113 |                          |
| Banana,<br>unbagged<br>Guatemala<br>1996 | 75 EC<br>→  | 10 | 0.11-<br>0.16 | 0.51-<br>0.61 | pulp                       | 0             | <0.02 (6)            | <0.02 (6)      | 131/96<br>GUA-2155-96-B  |
|                                          |             |    |               |               |                            | 2             | <0.02 (6)            | <0.02 (6)      |                          |
|                                          |             |    |               |               |                            | 7             | <0.02 (6)            | <0.02 (6)      |                          |
|                                          |             |    |               |               |                            | 10            | <0.02 (6)            | <0.02 (6)      |                          |
|                                          |             |    |               |               | peel                       | 0             | 0.02                 | <0.02          |                          |
|                                          |             |    |               |               |                            | 0             | <0.02 (5)            | <0.02 (5)      |                          |
|                                          |             |    |               |               |                            | 2             | <0.02 (5)            | <0.02 (5)      |                          |
|                                          |             |    |               |               |                            | 2             | 0.02                 | <0.02          |                          |
|                                          |             |    |               |               |                            | 7             | <0.02 (5)            | <0.02 (5)      |                          |
|                                          |             |    |               |               | whole fruit,<br>calculated | 7             | 0.02                 | <0.02          |                          |
|                                          |             |    |               |               |                            | 10            | <0.02 (6)            | <0.02 (6)      |                          |
|                                          |             |    |               |               |                            | 0             | <0.02 (6)            | <0.02 (6)      |                          |
|                                          |             |    |               |               |                            | 2             | <0.02 (6)            | <0.02 (6)      |                          |
|                                          |             |    |               |               |                            | 7             | <0.02 (6)            | <0.02 (6)      |                          |
|                                          |             |    |               |               |                            | 10            | <0.02 (6)            | <0.02 (6)      |                          |
| Banana,<br>bagged<br>Guatemala<br>1996   | 75 EC<br>→  | 10 | 0.10-<br>0.13 | 0.23-<br>0.57 | pulp                       | 0             | <0.02 (6)            | <0.02 (6)      | 131/96<br>GUA-2157-96-A  |
|                                          |             |    |               |               |                            | 7             | <0.02 (6)            | <0.02 (6)      |                          |
|                                          |             |    |               |               | peel                       | 0             | <0.02 (6)            | <0.02 (6)      |                          |
|                                          |             |    |               |               |                            | 7             | <0.02 (6)            | <0.02 (6)      |                          |
| Banana,<br>unbagged<br>Guatemala<br>1996 | 75 EC<br>→  | 10 | 0.10-<br>0.13 | 0.23-<br>0.57 | whole fruit,<br>calculated | 0             | <0.02 (6)            | <0.02 (6)      |                          |
|                                          |             |    |               |               |                            | 7             | <0.02 (6)            | <0.02 (6)      |                          |
|                                          |             |    |               |               | pulp                       | 0             | <0.02 (6)            | <0.02 (6)      | 131/96<br>GUA-2157-96-B  |
|                                          |             |    |               |               |                            | 7             | <0.02 (6)            | <0.02 (6)      |                          |
| Banana,<br>bagged<br>Mexico<br>1996      | 75 EC<br>→  | 10 | 0.10-<br>0.13 | 0.57-<br>0.68 | peel                       | 0             | 0.03                 | <0.02          |                          |
|                                          |             |    |               |               |                            | 0             | <0.02 (5)            | <0.02 (5)      |                          |
|                                          |             |    |               |               | whole fruit,<br>calculated | 7             | <0.02 (6)            | <0.02 (6)      |                          |
|                                          |             |    |               |               |                            | 0             | <0.02 (6)            | <0.02 (6)      |                          |
| Banana,<br>unbagged<br>Mexico<br>1996    | 75 EC<br>→  | 10 | 0.10-<br>0.13 | 0.57-<br>0.68 | pulp                       | 0             | <0.02 (6)            | <0.02 (6)      | 132/96<br>MEX-2158-96-A  |
|                                          |             |    |               |               |                            | 7             | <0.02 (6)            | <0.02 (6)      |                          |
|                                          |             |    |               |               | peel                       | 0             | <0.02 (6)            | <0.02 (6)      |                          |
|                                          |             |    |               |               |                            | 7             | <0.02 (6)            | <0.02 (6)      |                          |
| Banana,<br>bagged<br>Honduras<br>1996    | 75 EC<br>→  | 10 | 0.12          | 0.51-<br>0.57 | whole fruit,<br>calculated | 0             | <0.02 (5)            | <0.02 (5)      | 132/96<br>MEX-2158-96-B  |
|                                          |             |    |               |               |                            | 0             | 0.02                 | <0.02          |                          |
|                                          |             |    |               |               | pulp                       | 7             | <0.02 (6)            | <0.02 (6)      |                          |
|                                          |             |    |               |               |                            | 0             | <0.02 (6)            | <0.02 (6)      |                          |
| Banana,<br>unbagged<br>Honduras<br>1996  | 75 EC<br>→  | 10 | 0.12          | 0.51-<br>0.57 | peel                       | 0             | <0.02 (6)            | <0.02 (6)      | 133/96<br>HON-2159-96-A  |
|                                          |             |    |               |               |                            | 7             | <0.02 (6)            | <0.02 (6)      |                          |
|                                          |             |    |               |               | whole fruit,<br>calculated | 0             | <0.02 (6)            | <0.02 (6)      |                          |
|                                          |             |    |               |               |                            | 7             | <0.02 (6)            | <0.02 (6)      |                          |
| Banana,<br>unbagged<br>Honduras<br>1996  | 75 EC<br>→  | 10 | 0.12          | 0.51-<br>0.57 | pulp                       | 0             | <0.02 (6)            | <0.02 (6)      | 133/96<br>HON-2159-96-B  |
|                                          |             |    |               |               |                            | 7             | <0.02 (6)            | <0.02 (6)      |                          |
|                                          |             |    |               |               | peel                       | 0             | <0.02 (6)            | <0.02 (6)      |                          |
|                                          |             |    |               |               |                            | 7             | <0.02 (6)            | <0.02 (6)      |                          |
| Banana,<br>unbagged<br>Honduras<br>1996  | 75 EC<br>→  | 10 | 0.12          | 0.51-<br>0.57 | whole fruit,<br>calculated | 0             | <0.02 (6)            | <0.02 (6)      |                          |
|                                          |             |    |               |               |                            | 7             | <0.02 (6)            | <0.02 (6)      |                          |
|                                          |             |    |               |               | pulp                       | 0             | <0.02 (6)            | <0.02 (6)      |                          |
|                                          |             |    |               |               |                            | 7             | <0.02 (6)            | <0.02 (6)      |                          |



| Country,<br>Year                           | Application |    |               |               | Residues (mg/kg)           |                                 |                                                                        |                                                                         | Report No.;<br>Study No.                                                        |
|--------------------------------------------|-------------|----|---------------|---------------|----------------------------|---------------------------------|------------------------------------------------------------------------|-------------------------------------------------------------------------|---------------------------------------------------------------------------------|
|                                            | Form        | No | kg ai/ha      | kg ai/hl      | Sample                     | PHI<br>(days)                   | trifloxy-<br>strobin                                                   | CGA-<br>321113                                                          |                                                                                 |
| Banana,<br>bagged<br>Puerto Rico<br>1997   | 75 EC       | 10 | 0.10-<br>0.13 | 0.53-<br>0.54 | pulp                       | 0<br>7                          | <0.02 (6)<br><0.02 (6)                                                 | <0.02 (6)<br><0.02 (6)                                                  | 134/96<br>PUR-2160-96-A                                                         |
|                                            |             |    |               |               | peel                       | 0<br>0<br>0<br>0<br>7<br>7<br>7 | 0.04<br>0.04<br><0.02 (3)<br>0.14<br><0.02 (4)<br>0.02<br>0.05         | 0.02<br>0.02<br><0.02 (3)<br>0.04<br><0.02 (4)<br><0.02<br><0.02        | ground treatment,<br>spraying over the<br>top, simulating<br>aerial application |
|                                            |             |    |               |               | whole fruit,<br>calculated | 0<br>0<br>0<br>0<br>7<br>7      | 0.02 (2)<br><0.02 (3)<br>0.06<br>mean <u>0.03</u><br><0.02 (5)<br>0.02 | <0.02 (2)<br><0.02 (3)<br>0.02<br><u>&lt;0.02</u><br><0.02 (5)<br><0.02 |                                                                                 |
|                                            |             |    |               |               |                            |                                 |                                                                        |                                                                         |                                                                                 |
|                                            |             |    |               |               |                            |                                 |                                                                        |                                                                         |                                                                                 |
|                                            |             |    |               |               |                            |                                 |                                                                        |                                                                         |                                                                                 |
|                                            |             |    |               |               |                            |                                 |                                                                        |                                                                         |                                                                                 |
|                                            |             |    |               |               |                            |                                 |                                                                        |                                                                         |                                                                                 |
|                                            |             |    |               |               |                            |                                 |                                                                        |                                                                         |                                                                                 |
|                                            |             |    |               |               |                            |                                 |                                                                        |                                                                         |                                                                                 |
|                                            |             |    |               |               |                            |                                 |                                                                        |                                                                         |                                                                                 |
| Banana,<br>unbagged<br>Puerto Rico<br>1997 | 75 EC       | 10 | 0.10-<br>0.13 | 0.53-<br>0.54 | pulp                       | 0<br>7                          | <0.02 (6)<br><0.02 (6)                                                 | <0.02 (6)<br><0.02 (6)                                                  | 134/96<br>PUR-2160-96-B                                                         |
|                                            |             |    |               |               | peel                       | 0<br>0<br>7<br>7                | 0.03<br><0.02 (5)<br>0.04<br><0.02 (5)                                 | <0.02<br><0.02 (5)<br><0.02<br><0.02 (5)                                | ground treatment,<br>spraying over top,<br>simulating aerial<br>application     |
|                                            |             |    |               |               | whole fruit,<br>calculated | 0<br>7<br>7                     | <u>&lt;0.02 (6)</u><br>0.02<br><0.02 (5)                               | <u>&lt;0.02 (6)</u><br><u>&lt;0.02</u><br><0.02 (5)                     |                                                                                 |
|                                            |             |    |               |               |                            |                                 |                                                                        |                                                                         |                                                                                 |
|                                            |             |    |               |               |                            |                                 |                                                                        |                                                                         |                                                                                 |
|                                            |             |    |               |               |                            |                                 |                                                                        |                                                                         |                                                                                 |
| Banana,<br>bagged<br>Martinique<br>2000    | 75 EC       | 6  | 0.094         | 0.30-<br>0.36 | pulp                       | 0<br>3<br>7                     | <0.01<br><0.01<br><0.01                                                | <0.01<br><0.01<br><0.01                                                 | 2154/00<br>MAR-2154-00-A                                                        |
|                                            |             |    |               |               | peel                       | 0<br>3<br>7                     | <0.01<br><0.01<br><0.01                                                | <0.01<br><0.01<br><0.01                                                 | foliar backpack<br>sprayer with aerial<br>boom                                  |
|                                            |             |    |               |               | whole fruit,<br>calculated | 0<br>3<br>7                     | <u>&lt;0.01</u><br><0.01<br><0.01                                      | <u>&lt;0.01</u><br><0.01<br><0.01                                       |                                                                                 |
|                                            |             |    |               |               |                            |                                 |                                                                        |                                                                         |                                                                                 |
|                                            |             |    |               |               |                            |                                 |                                                                        |                                                                         |                                                                                 |
|                                            |             |    |               |               |                            |                                 |                                                                        |                                                                         |                                                                                 |
| Banana,<br>unbagged<br>Martinique<br>2000  | 75 EC       | 6  | 0.094         | 0.30-<br>0.36 | pulp                       | 0<br>3<br>7                     | <0.01<br><0.01<br><0.01                                                | <0.01<br><0.01<br><0.01                                                 | 2154/00<br>MAR-2154-00-B                                                        |
|                                            |             |    |               |               | peel                       | 0<br>3<br>7                     | <0.01<br><0.01<br><0.01                                                | <0.01<br><0.01<br><0.01                                                 | foliar backpack<br>sprayer with aerial<br>boom                                  |
|                                            |             |    |               |               | whole fruit,<br>calculated | 0<br>3<br>7                     | <u>&lt;0.01</u><br><0.01<br><0.01                                      | <u>&lt;0.01</u><br><0.01<br><0.01                                       |                                                                                 |
|                                            |             |    |               |               |                            |                                 |                                                                        |                                                                         |                                                                                 |
|                                            |             |    |               |               |                            |                                 |                                                                        |                                                                         |                                                                                 |
|                                            |             |    |               |               |                            |                                 |                                                                        |                                                                         |                                                                                 |
| Banana,<br>bagged<br>Martinique<br>2000    | 75 EC       | 6  | 0.09          | 0.30-<br>0.36 | pulp                       | 0<br>3<br>7                     | <0.01<br><0.01<br><0.01                                                | <0.01<br><0.01<br><0.01                                                 | 2155/00<br>MAR-2155-00-A                                                        |
|                                            |             |    |               |               | peel                       | 0<br>3<br>7                     | <0.01<br><0.01<br><0.01                                                | <0.01<br><0.01<br><0.01                                                 | foliar backpack<br>sprayer with aerial<br>boom                                  |
|                                            |             |    |               |               | whole fruit,<br>calculated | 0<br>3<br>7                     | <u>&lt;0.01</u><br><0.01<br><0.01                                      | <u>&lt;0.01</u><br><0.01<br><0.01                                       |                                                                                 |
|                                            |             |    |               |               |                            |                                 |                                                                        |                                                                         |                                                                                 |
|                                            |             |    |               |               |                            |                                 |                                                                        |                                                                         |                                                                                 |
|                                            |             |    |               |               |                            |                                 |                                                                        |                                                                         |                                                                                 |
| Banana,<br>unbagged<br>Martinique<br>2000  | 75 EC       | 6  | 0.09          | 0.30-<br>0.36 | pulp                       | 0<br>3<br>7                     | <0.01<br><0.01<br><0.01                                                | <0.01<br><0.01<br><0.01                                                 | 2155/00<br>MAR-2155-00-B                                                        |
|                                            |             |    |               |               | peel                       | 0<br>3<br>7                     | 0.01<br><0.01<br>0.01                                                  | <0.01<br><0.01<br><0.01                                                 | foliar backpack<br>sprayer with aerial<br>boom                                  |
|                                            |             |    |               |               |                            |                                 |                                                                        |                                                                         |                                                                                 |

| Country,<br>Year | Application |    |          |          | Residues (mg/kg)           |               |                                   |                                   | Report No.;<br>Study No. |
|------------------|-------------|----|----------|----------|----------------------------|---------------|-----------------------------------|-----------------------------------|--------------------------|
|                  | Form        | No | kg ai/ha | kg ai/hl | Sample                     | PHI<br>(days) | trifloxy-<br>strobin              | CGA-<br>321113                    |                          |
|                  |             |    |          |          | whole fruit,<br>calculated | 0<br>3<br>7   | <u>&lt;0.01</u><br><0.01<br><0.01 | <u>&lt;0.01</u><br><0.01<br><0.01 |                          |

➔ aerial application by helicopter or fixed-winged airplane

### *Bulb vegetables*

#### *Leek*

Table 60. Results of residue trials with trifloxystrobin on leek.

| Country,<br>Year    | Application |    |           |          | Residues (mg/kg)                           |                |                      |               | Report No.;<br>Study No. |
|---------------------|-------------|----|-----------|----------|--------------------------------------------|----------------|----------------------|---------------|--------------------------|
|                     | Form        | No | kg ai/ha  | kg ai/hl | Sample                                     | PHI<br>(days)  | trifloxy-<br>strobin | CGA<br>321113 |                          |
| France<br>2002      | 50<br>WG    | 3  | 0.2       | 0.034    | shoot                                      | 0 <sup>1</sup> | 0.83                 | 0.07          | RA-2031/02<br>0085-02    |
|                     |             |    |           |          |                                            | 0              | 1.8                  | 0.07          |                          |
|                     |             |    |           |          |                                            | 3              | 0.95                 | 0.07          |                          |
|                     |             |    |           |          |                                            | 7              | <u>0.40</u>          | <u>0.07</u>   |                          |
|                     |             |    |           |          |                                            | 14             | 0.14                 | 0.07          |                          |
|                     |             |    |           |          |                                            | 20             | 0.13                 | 0.09          |                          |
| Netherlands<br>2002 | 50<br>WG    | 3  | 0.20-0.21 | 0.034    | shoot                                      | 0 <sup>1</sup> | <0.02                | 0.05          | RA-2031/02<br>0134-02    |
|                     |             |    |           |          |                                            | 0              | 0.86                 | 0.07          |                          |
|                     |             |    |           |          |                                            | 3              | 0.61                 | 0.07          |                          |
|                     |             |    |           |          |                                            | 7              | <u>0.40</u>          | <u>0.09</u>   |                          |
|                     |             |    |           |          |                                            | 14             | 0.08                 | 0.07          |                          |
|                     |             |    |           |          |                                            | 21             | 0.04                 | 0.05          |                          |
| Germany<br>2002     | 50<br>WG    | 3  | 0.2       | 0.034    | shoot                                      | 0 <sup>1</sup> | 0.11                 | 0.03          | RA-2031/02<br>0135-02    |
|                     |             |    |           |          |                                            | 0              | 0.68                 | 0.04          |                          |
|                     |             |    |           |          |                                            | 3              | 0.17                 | 0.06          |                          |
|                     |             |    |           |          |                                            | 7              | <u>0.08</u>          | <u>0.05</u>   |                          |
|                     |             |    |           |          |                                            | 14             | 0.06                 | 0.04          |                          |
|                     |             |    |           |          |                                            | 21             | 0.03                 | 0.03          |                          |
| Switzerland<br>2000 | 267.5<br>EC | 3  | 0.15      | 0.03     | whole plant<br>without<br>roots<br>(shoot) | 0              | 1.5                  | 0.14          | 2067/00<br>SWZ-2067-00   |
|                     |             |    |           |          |                                            | 7              | <u>0.14</u>          | <u>0.17</u>   |                          |
|                     |             |    |           |          |                                            | 14             | 0.04                 | 0.09          |                          |
|                     |             |    |           |          |                                            | 21             | 0.01                 | 0.04          |                          |
|                     |             |    |           |          |                                            | 21             | 0.02                 | 0.06          |                          |
| Switzerland<br>2000 | 267.5<br>EC | 3  | 0.15      | 0.03     | whole plant<br>without<br>roots<br>(shoot) | 0              | 1.3                  | 0.10          | 2068/00<br>SWZ-2068-00   |
|                     |             |    |           |          |                                            | 7              | <u>0.15</u>          | <u>0.11</u>   |                          |
|                     |             |    |           |          |                                            | 14             | 0.08                 | 0.07          |                          |
|                     |             |    |           |          |                                            | 21             | 0.03                 | 0.04          |                          |
|                     |             |    |           |          |                                            | 21             | 0.04                 | 0.05          |                          |

*Brassica vegetables**Head cabbage*

Table 61. Results of residue trials with trifloxystrobin on head cabbage.

| Country,<br>Year                         | Application |    |          |          | Residues (mg/kg) |                |                      |                 | Report No.;<br>Study No. |
|------------------------------------------|-------------|----|----------|----------|------------------|----------------|----------------------|-----------------|--------------------------|
|                                          | Form        | No | kg ai/ha | kg ai/hl | Sample           | PHI<br>(days)  | trifloxy-<br>strobin | CGA321113       |                          |
| Cabbage<br>Switzerland<br>2000           | 50<br>WG    | 3  | 0.25     | 0.05     | head             | 0              | 0.19                 | 0.01            | 2056/00<br>SWZ-2056-00   |
|                                          |             |    |          |          |                  | 3              | 0.10                 | 0.02            |                          |
|                                          |             |    |          |          |                  | 7              | <u>0.02</u>          | <u>0.02</u>     |                          |
|                                          |             |    |          |          |                  | 14             | <0.01                | 0.01            |                          |
|                                          |             |    |          |          |                  | 14             | 0.01                 | 0.01            |                          |
| Cabbage<br>Switzerland<br>2000           | 50<br>WG    | 3  | 0.25     | 0.05     | head             | 0              | 0.93                 | 0.02            | 2057/00<br>SWZ-2057-00   |
|                                          |             |    |          |          |                  | 3              | 0.06                 | 0.02            |                          |
|                                          |             |    |          |          |                  | 7              | <u>0.02</u>          | <u>0.02</u>     |                          |
|                                          |             |    |          |          |                  | 14             | <0.01                | 0.02            |                          |
|                                          |             |    |          |          |                  | 14             | <0.01                | 0.01            |                          |
| Cabbage,<br>red Belgium<br>2001          | 50<br>WG    | 3  | 0.13     | 0.021    | head             | 0 <sup>1</sup> | 0.03                 | 0.03            | RA-2198/01<br>0641-01    |
|                                          |             |    |          |          |                  | 0              | 0.47                 | 0.03            |                          |
|                                          |             |    |          |          |                  | 7              | 0.02                 | 0.04            |                          |
|                                          |             |    |          |          |                  | 14             | <0.02                | 0.02            |                          |
|                                          |             |    |          |          |                  | 21             | <0.02                | <0.02           |                          |
| Cabbage,<br>red<br>Netherlands<br>2001   | 50<br>WG    | 3  | 0.13     | 0.021    | head             | 0 <sup>1</sup> | <0.02                | <0.02           | RA-2198/01<br>0642-01    |
|                                          |             |    |          |          |                  | 0              | 0.07                 | <0.02           |                          |
|                                          |             |    |          |          |                  | 7              | <0.02                | <0.02           |                          |
|                                          |             |    |          |          |                  | 14             | <0.02                | <0.02           |                          |
|                                          |             |    |          |          |                  | 21             | <0.02                | <0.02           |                          |
| Cabbage,<br>white<br>Germany<br>2001     | 50<br>WG    | 3  | 0.13     | 0.021    | head             | 0 <sup>1</sup> | <0.02                | <0.02           | RA-2198/01<br>0640-01    |
|                                          |             |    |          |          |                  | 0              | 0.18                 | <0.02           |                          |
|                                          |             |    |          |          |                  | 7              | <0.02                | <0.02           |                          |
|                                          |             |    |          |          |                  | 14             | <0.02                | <0.02           |                          |
|                                          |             |    |          |          |                  | 14             | <0.02                | <0.02           |                          |
| Cabbage,<br>white<br>Germany<br>2001     | 50<br>WG    | 3  | 0.13     | 0.021    | head             | 0 <sup>1</sup> | <0.02                | <0.02           | RA-2198/01<br>0643-01    |
|                                          |             |    |          |          |                  | 0              | 0.03                 | <0.02           |                          |
|                                          |             |    |          |          |                  | 7              | <0.02                | <0.02           |                          |
|                                          |             |    |          |          |                  | 14             | <0.02                | <0.02           |                          |
|                                          |             |    |          |          |                  | 14             | <0.02                | <0.02           |                          |
| Cabbage,<br>red<br>Germany<br>2002       | 50<br>WG    | 3  | 0.25     | 0.042    | head             | 0 <sup>1</sup> | 0.04                 | <0.02           | RA-2052/02<br>0233-02    |
|                                          |             |    |          |          |                  | 0              | 0.33                 | <0.02           |                          |
|                                          |             |    |          |          |                  | 7              | 0.02                 | <0.02           |                          |
|                                          |             |    |          |          |                  | 14             | <u>0.03</u>          | <u>&lt;0.02</u> |                          |
|                                          |             |    |          |          |                  | 21             | <0.02                | <0.02           |                          |
| Cabbage,<br>white<br>Netherlands<br>2002 | 50<br>WG    | 3  | 0.25     | 0.042    | head             | 0 <sup>1</sup> | <0.02                | <0.02           | RA-2052/02<br>0232-02    |
|                                          |             |    |          |          |                  | 0              | 0.11                 | 0.02            |                          |
|                                          |             |    |          |          |                  | 7              | <u>0.07</u>          | <u>0.04</u>     |                          |
|                                          |             |    |          |          |                  | 14             | 0.03                 | 0.02            |                          |
|                                          |             |    |          |          |                  | 21             | <0.02                | 0.02            |                          |
| Cabbage,<br>white<br>Netherlands<br>2002 | 50<br>WG    | 3  | 0.25     | 0.042    | head             | 0 <sup>1</sup> | <0.02                | <0.02           | RA-2052/02<br>0232-02    |
|                                          |             |    |          |          |                  | 0              | 0.11                 | 0.02            |                          |
|                                          |             |    |          |          |                  | 7              | <u>0.07</u>          | <u>0.04</u>     |                          |
|                                          |             |    |          |          |                  | 14             | 0.03                 | 0.02            |                          |
|                                          |             |    |          |          |                  | 21             | <0.02                | 0.02            |                          |
| Cabbage,<br>white<br>Netherlands<br>2002 | 50<br>WG    | 3  | 0.25     | 0.042    | head             | 0 <sup>1</sup> | <0.02                | <0.02           | RA-2052/02<br>0232-02    |
|                                          |             |    |          |          |                  | 0              | 0.11                 | 0.02            |                          |
|                                          |             |    |          |          |                  | 7              | <u>0.07</u>          | <u>0.04</u>     |                          |
|                                          |             |    |          |          |                  | 14             | 0.03                 | 0.02            |                          |
|                                          |             |    |          |          |                  | 21             | <0.02                | 0.02            |                          |
| Cabbage,<br>white<br>Netherlands<br>2002 | 50<br>WG    | 3  | 0.25     | 0.042    | head             | 0 <sup>1</sup> | <0.02                | <0.02           | RA-2052/02<br>0232-02    |
|                                          |             |    |          |          |                  | 0              | 0.11                 | 0.02            |                          |
|                                          |             |    |          |          |                  | 7              | <u>0.07</u>          | <u>0.04</u>     |                          |
|                                          |             |    |          |          |                  | 14             | 0.03                 | 0.02            |                          |
|                                          |             |    |          |          |                  | 21             | <0.02                | 0.02            |                          |
| Cabbage,<br>white<br>Netherlands<br>2002 | 50<br>WG    | 3  | 0.25     | 0.042    | head             | 0 <sup>1</sup> | <0.02                | <0.02           | RA-2052/02<br>0232-02    |
|                                          |             |    |          |          |                  | 0              | 0.11                 | 0.02            |                          |
|                                          |             |    |          |          |                  | 7              | <u>0.07</u>          | <u>0.04</u>     |                          |
|                                          |             |    |          |          |                  | 14             | 0.03                 | 0.02            |                          |
|                                          |             |    |          |          |                  | 21             | <0.02                | 0.02            |                          |
| Cabbage,<br>white<br>Netherlands<br>2002 | 50<br>WG    | 3  | 0.25     | 0.042    | head             | 0 <sup>1</sup> | <0.02                | <0.02           | RA-2052/02<br>0232-02    |
|                                          |             |    |          |          |                  | 0              | 0.11                 | 0.02            |                          |
|                                          |             |    |          |          |                  | 7              | <u>0.07</u>          | <u>0.04</u>     |                          |
|                                          |             |    |          |          |                  | 14             | 0.03                 | 0.02            |                          |
|                                          |             |    |          |          |                  | 21             | <0.02                | 0.02            |                          |

| Country,<br>Year                              | Application |    |          |          | Residues (mg/kg) |                                            |                                                    |                                                    | Report No.;<br>Study No.                                |
|-----------------------------------------------|-------------|----|----------|----------|------------------|--------------------------------------------|----------------------------------------------------|----------------------------------------------------|---------------------------------------------------------|
|                                               | Form        | No | kg ai/ha | kg ai/hl | Sample           | PHI<br>(days)                              | trifloxy-<br>strobin                               | CGA321113                                          |                                                         |
| Cabbage,<br>red<br>Germany<br>2002            | 50<br>WG    | 3  | 0.25     | 0.042    | head             | 0 <sup>1</sup><br>0<br>7<br>14<br>21<br>28 | <0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><0.02 | <0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><0.02 | RA-2052/02<br>0231-02<br><br>trial invalid <sup>2</sup> |
| Cabbage,<br>white<br>Great<br>Britain<br>2002 | 50<br>WG    | 3  | 0.25     | 0.042    | head             | 0 <sup>1</sup><br>0<br>7<br>14<br>21<br>28 | 0.33<br>3.3<br>3.3<br>0.16<br>0.13<br>0.07         | 0.04<br>0.05<br>0.08<br>0.05<br>0.03<br>0.02       | RA-2052/02<br>0234-02<br><br>trial invalid <sup>3</sup> |

<sup>1</sup> before last treatment<sup>2</sup> trial invalid, heavy rainfall after last treatment<sup>3</sup> trial invalid, last application (BBCH 43) and sampling (BBCH 45) at an early growth stage*Brussels sprouts*

Table 62. Results of residue trials with trifloxystrobin on Brussels sprouts.

| Country,<br>Year    | Form     | No | Application |          | Sample | Residues (mg/kg)                           |                                                   |                                                    | Report No.;<br>Study No. |
|---------------------|----------|----|-------------|----------|--------|--------------------------------------------|---------------------------------------------------|----------------------------------------------------|--------------------------|
|                     |          |    | kg ai/ha    | kg ai/hl |        | PHI<br>(days)                              | trifloxy-<br>strobin                              | CGA321113                                          |                          |
| Switzerland<br>2000 | 50<br>WG | 3  | 0.25        | 0.05     | sprout | 0<br>4<br>7<br>14<br>14                    | 0.32<br>0.49<br><u>0.16</u><br>0.05<br>0.09       | 0.05<br>0.09<br><u>0.06</u><br>0.02<br>0.03        | 2054/00<br>SWZ-2054-00   |
| Switzerland<br>2000 | 50<br>WG | 3  | 0.25        | 0.05     | sprout | 0<br>3<br>7<br>14<br>14                    | 0.57<br>0.35<br><u>0.20</u><br>0.15<br>0.14       | 0.10<br>0.10<br><u>0.08</u><br>0.05<br>0.05        | 2055/00<br>SWZ-2055-00   |
| Germany<br>2001     | 50<br>WG | 3  | 0.13        | 0.021    | sprout | 0 <sup>1</sup><br>0<br>8<br>14<br>21<br>29 | <0.02<br>0.11<br><0.02<br><0.02<br><0.02<br><0.02 | <0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><0.02 | RA-2197/01<br>0633-01    |
| France<br>2001      | 50<br>WG | 3  | 0.13        | 0.021    | sprout | 0 <sup>1</sup><br>0<br>7<br>14<br>21<br>28 | <0.02<br>0.03<br>0.02<br><0.02<br><0.02<br><0.02  | <0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><0.02 | RA-2197/01<br>0634-01    |
| Netherlands<br>2001 | 50<br>WG | 3  | 0.13        | 0.021    | sprout | 0 <sup>1</sup><br>0<br>7<br>14<br>21<br>28 | 0.02<br>0.12<br>0.11<br>0.04<br><0.02<br><0.02    | <0.02<br><0.02<br>0.03<br>0.03<br>0.02<br>0.02     | RA-2197/01<br>0635-01    |

| Country,<br>Year         | Application |    |           |          | Sample | Residues (mg/kg) |                      |                 | Report No.;<br>Study No. |
|--------------------------|-------------|----|-----------|----------|--------|------------------|----------------------|-----------------|--------------------------|
|                          | Form        | No | kg ai/ha  | kg ai/hl |        | PHI<br>(days)    | trifloxy-<br>strobin | CGA321113       |                          |
| Belgium<br>2001          | 50<br>WG    | 3  | 0.13-0.14 | 0.021    | sprout | 0 <sup>1</sup>   | <0.02                | <0.02           | RA-2197/01<br>0637-01    |
|                          |             |    |           |          |        | 0                | 0.04                 | <0.02           |                          |
|                          |             |    |           |          |        | 7                | 0.03                 | <0.02           |                          |
|                          |             |    |           |          |        | 14               | <0.02                | <0.02           |                          |
|                          |             |    |           |          |        | 21               | <0.02                | <0.02           |                          |
|                          |             |    |           |          |        | 28               | <0.02                | <0.02           |                          |
| France<br>2002           | 50<br>WG    | 3  | 0.25      | 0.042    | sprout | 0 <sup>1</sup>   | <0.02                | 0.05            | RA-2051/02<br>0222-02    |
|                          |             |    |           |          |        | 0                | 0.23                 | 0.05            |                          |
|                          |             |    |           |          |        | 7                | <u>0.19</u>          | <u>0.07</u>     |                          |
|                          |             |    |           |          |        | 14               | 0.06                 | 0.09            |                          |
|                          |             |    |           |          |        | 21               | 0.04                 | 0.09            |                          |
|                          |             |    |           |          |        | 28               | 0.03                 | 0.07            |                          |
| France<br>2002           | 50<br>WG    | 3  | 0.25      | 0.042    | sprout | 0 <sup>1</sup>   | 0.32                 | 0.06            | RA-2051/02<br>0224-02    |
|                          |             |    |           |          |        | 0                | 0.56                 | 0.06            |                          |
|                          |             |    |           |          |        | 7                | <u>0.35</u>          | <u>0.04</u>     |                          |
|                          |             |    |           |          |        | 14               | 0.02                 | <0.02           |                          |
|                          |             |    |           |          |        | 21               | 0.02                 | <0.02           |                          |
|                          |             |    |           |          |        | 28               | <0.02                | <0.02           |                          |
| Germany<br>2002          | 50<br>WG    | 3  | 0.25      | 0.042    | sprout | 0 <sup>1</sup>   | 0.15                 | <0.02           | RA-2051/02<br>0225-02    |
|                          |             |    |           |          |        | 0                | 0.45                 | 0.02            |                          |
|                          |             |    |           |          |        | 7                | <u>0.18</u>          | <u>&lt;0.02</u> |                          |
|                          |             |    |           |          |        | 14               | 0.13                 | <0.02           |                          |
|                          |             |    |           |          |        | 21               | 0.06                 | <0.02           |                          |
|                          |             |    |           |          |        | 28               | 0.03                 | <0.02           |                          |
| Great<br>Britain<br>2002 | 50<br>WG    | 3  | 0.25      | 0.042    | sprout | 0 <sup>1</sup>   | 0.08                 | 0.16            | RA-2051/02<br>0226-02    |
|                          |             |    |           |          |        | 0                | 0.44                 | 0.17            |                          |
|                          |             |    |           |          |        | 7                | <u>0.10</u>          | <u>0.17</u>     |                          |
|                          |             |    |           |          |        | 14               | 0.06                 | 0.15            |                          |
|                          |             |    |           |          |        | 21               | 0.04                 | 0.13            |                          |
|                          |             |    |           |          |        | 28               | 0.02                 | 0.09            |                          |

<sup>1</sup> before last treatment

### Flowerhead brassicas

Table 63. Results of residue trials with trifloxystrobin on cauliflower and broccoli.

| Country,<br>Year                   | Application |    |          |          | Sample                          | Residues (mg/kg) |                      |                 | Report No.;<br>Study No. |
|------------------------------------|-------------|----|----------|----------|---------------------------------|------------------|----------------------|-----------------|--------------------------|
|                                    | Form        | No | kg ai/ha | kg ai/hl |                                 | PHI<br>(days)    | trifloxy-<br>strobin | CGA321113       |                          |
| Cauliflower<br>Switzerland<br>2000 | 50<br>WG    | 3  | 0.25     | 0.05     | head                            | 0                | 0.33                 | 0.03            | 2058/00<br>SWZ-2058-00   |
|                                    |             |    |          |          |                                 | 3                | 0.19                 | 0.09            |                          |
|                                    |             |    |          |          |                                 | 7                | <u>0.13</u>          | <u>0.10</u>     |                          |
|                                    |             |    |          |          |                                 | 14               | 0.03                 | 0.06            |                          |
|                                    |             |    |          |          |                                 | 14               | 0.02                 | 0.06            |                          |
|                                    |             |    |          |          |                                 |                  |                      |                 |                          |
| Cauliflower<br>Switzerland<br>2000 | 50<br>WG    | 3  | 0.25     | 0.05     | head                            | 0                | 0.07                 | 0.03            | 2059/00<br>SWZ-2059-00   |
|                                    |             |    |          |          |                                 | 3                | 0.01                 | 0.04            |                          |
|                                    |             |    |          |          |                                 | 7                | <u>&lt;0.01</u>      | <u>0.03</u>     |                          |
|                                    |             |    |          |          |                                 | 14               | <0.01                | 0.03            |                          |
|                                    |             |    |          |          |                                 | 14               | <0.01                | 0.03            |                          |
|                                    |             |    |          |          |                                 |                  |                      |                 |                          |
| Cauliflower<br>Germany<br>2002     | 50<br>WG    | 3  | 0.20     | 0.034    | whole plant<br>without<br>roots | 0 <sup>1</sup>   | <0.02                | <0.02           | RA-2032/02<br>0074-02    |
|                                    |             |    |          |          |                                 | 0                | 1.5                  | <0.02           |                          |
|                                    |             |    |          |          | curd                            | 7                | <u>&lt;0.02</u>      | <u>&lt;0.02</u> |                          |
|                                    |             |    |          |          |                                 | 14               | <0.02                | <0.02           |                          |
|                                    |             |    |          |          |                                 | 21               | <0.02                | 0.02            |                          |
|                                    |             |    |          |          |                                 |                  |                      |                 |                          |

| Country,<br>Year                  | Application |    |          |          | Residues (mg/kg)                |                     |                               |                                   | Report No.;<br>Study No. |
|-----------------------------------|-------------|----|----------|----------|---------------------------------|---------------------|-------------------------------|-----------------------------------|--------------------------|
|                                   | Form        | No | kg ai/ha | kg ai/hl | Sample                          | PHI<br>(days)       | trifloxy-<br>strobin          | CGA321113                         |                          |
| Broccoli<br>Germany<br>2002       | 50<br>WG    | 3  | 0.20     | 0.034    | whole plant<br>without<br>roots | 0 <sup>1</sup><br>0 | <0.02<br>1.8                  | <0.02<br><0.02                    | RA-2032/02<br>0136-02    |
|                                   |             |    |          |          | curd                            | 7<br>14<br>20       | <u>0.09</u><br><0.02<br><0.02 | <u>0.04</u><br><0.02<br><0.02     |                          |
|                                   |             |    |          |          |                                 |                     |                               |                                   |                          |
| Broccoli<br>Great Britain<br>2002 | 50<br>WG    | 3  | 0.20     | 0.034    | whole plant<br>without<br>roots | 0 <sup>1</sup><br>0 | 0.94<br>2.6                   | <0.02<br>0.03                     | RA-2032/02<br>0137-02    |
|                                   |             |    |          |          | curd                            | 7<br>14<br>21       | <u>0.13</u><br>0.03<br><0.02  | <u>0.03</u><br>0.02<br><0.02      |                          |
|                                   |             |    |          |          |                                 |                     |                               |                                   |                          |
| Broccoli<br>Germany<br>2002       | 50<br>WG    | 3  | 0.20     | 0.034    | whole plant<br>without<br>roots | 0 <sup>1</sup><br>0 | <0.02<br>1.5                  | <0.02<br><0.02                    | RA-2032/02<br>0138-02    |
|                                   |             |    |          |          | curd                            | 7<br>14<br>21       | <u>0.26</u><br>0.02<br><0.02  | <u>&lt;0.02</u><br><0.02<br><0.02 |                          |
|                                   |             |    |          |          |                                 |                     |                               |                                   |                          |

*Fruiting vegetables, cucurbits*

*Cucumber*

In the USA eight field trials, and in Europe eight greenhouse were conducted.

Table 64. Results of residue field trials with trifloxystrobin on cucumber in the USA.

| Location<br>Year | Application |    |          |                 | Residues (mg/kg) |                  |                                     |                                            | Report No.;<br>Study No.        |
|------------------|-------------|----|----------|-----------------|------------------|------------------|-------------------------------------|--------------------------------------------|---------------------------------|
|                  | Form        | No | kg ai/ha | kg ai/hl        | Sample           | PHI<br>(days)    | trifloxy-<br>strobin                | CGA321113                                  |                                 |
| CA,<br>1996      | 50 WG       | 8  | 0.14     | 0.075           | fruit            | 0<br>0           | 0.13<br><u>0.22</u>                 | <0.02<br><u>0.02</u>                       | ABR-97120<br>USA-OW-FR-420-96   |
| CA,<br>1996      | 50 WG       | 8  | 0.14     | 0.06            | fruit            | 0<br>0<br>3<br>3 | 0.11<br><u>0.17</u><br>0.07<br>0.10 | <0.02<br><u>&lt;0.02</u><br><0.02<br><0.02 | ABR-97120<br>USA-02-FR-073-96-A |
| WI,<br>1997      | 50 WG       | 8  | 0.14     | 0.055-<br>0.086 | fruit            | 0<br>0           | 0.03<br><u>0.03</u>                 | <0.02<br><u>&lt;0.02</u>                   | ABR-97120<br>USA-MW-FR-701-97A  |
| MI,<br>1997      | 50 WG       | 8  | 0.14     | 0.049-<br>0.051 | fruit            | 0<br>0           | 0.04<br><u>0.04</u>                 | <0.02<br><u>&lt;0.02</u>                   | ABR-97120<br>USA-NE-FR-701-97-A |
| TX,<br>1997      | 50 WG       | 8  | 0.14     | 0.072-<br>0.076 | fruit            | 0<br>0           | 0.03<br><u>0.04</u>                 | <0.02<br><u>&lt;0.02</u>                   | ABR-97120<br>USA-OS-FR-301-97-A |
| NC,<br>1997      | 50 WG       | 8  | 0.14     | 0.10            | fruit            | 0<br>0           | <u>0.05</u><br>0.03                 | <u>&lt;0.02</u><br><0.02                   | ABR-97120<br>USA-OS-FR-601-97-A |
| SC,<br>1997      | 50 WG       | 8  | 0.14     | 0.072-<br>0.074 | fruit            | 0<br>0           | 0.02<br><u>0.04</u>                 | <0.02<br><u>&lt;0.02</u>                   | ABR-97120<br>USA-OS-FR-602-97-A |

| Location<br>Year | Application |    |          |          | Residues (mg/kg) |               |                      |                 | Report No.;<br>Study No.        |
|------------------|-------------|----|----------|----------|------------------|---------------|----------------------|-----------------|---------------------------------|
|                  | Form        | No | kg ai/ha | kg ai/hl | Sample           | PHI<br>(days) | trifloxy-<br>strobin | CGA321113       |                                 |
| FL, 1997         | 50 WG       | 8  | 0.14     | 0.30     | fruit            | 0             | 0.05                 | <0.02           | ABR-97120<br>USA-07-FR-011-97-A |
|                  |             |    |          |          |                  | 0             | <u>0.06</u>          | <u>&lt;0.02</u> |                                 |
|                  |             |    |          |          |                  | 1             | 0.06                 | <0.02           |                                 |
|                  |             |    |          |          |                  | 1             | 0.04                 | <0.02           |                                 |
|                  |             |    |          |          |                  | 3             | <0.02                | <0.02           |                                 |
|                  |             |    |          |          |                  | 3             | <0.02                | <0.02           |                                 |
|                  |             |    |          |          |                  | 5             | <0.02                | <0.02           |                                 |
|                  |             |    |          |          |                  | 5             | <0.02                | <0.02           |                                 |

Table 65. Results of residue trials in a greenhouse with trifloxystrobin on cucumber in Europe.

| Country,<br>Year    | Application |    |           |                 | Residues (mg/kg) |                |                      |                 | Report No.;<br>Study No. |
|---------------------|-------------|----|-----------|-----------------|------------------|----------------|----------------------|-----------------|--------------------------|
|                     | Form        | No | kg ai/ha  | kg ai/hl        | Sample           | PHI<br>(days)  | trifloxy-<br>strobin | CGA321113       |                          |
| Italy<br>1996       | 50 WG       | 5  | 0.18-0.19 | 0.019-<br>0.027 | fruit            | 0 <sup>1</sup> | <0.02                | <0.02           | 2079/96<br>ITA-2079-96   |
|                     |             |    |           |                 |                  | 0              | 0.13                 | 0.04            |                          |
|                     |             |    |           |                 |                  | 3              | <u>0.02</u>          | <u>&lt;0.02</u> |                          |
|                     |             |    |           |                 |                  | 5              | <0.02                | <0.02           |                          |
|                     |             |    |           |                 |                  | 7              | <0.02                | <0.02           |                          |
| Switzerland<br>1996 | 50 WG       | 5  | 0.19      | 0.013           | fruit            | 0 <sup>1</sup> | 0.02                 | <0.02           | 2020/96<br>SWZ-2020-96   |
|                     |             |    |           |                 |                  | 0              | 0.05                 | <0.02           |                          |
|                     |             |    |           |                 |                  | 1              | 0.05                 | <0.02           |                          |
|                     |             |    |           |                 |                  | 3              | <u>0.04</u>          | <u>&lt;0.02</u> |                          |
|                     |             |    |           |                 |                  | 5              | 0.04                 | <0.02           |                          |
| Spain<br>1996       | 50 WG       | 5  | 0.19      | 0.019           | fruit            | 0 <sup>1</sup> | 0.02                 | 0.02            | 2053/96<br>SPA-2053-96   |
|                     |             |    |           |                 |                  | 0              | 0.16                 | 0.03            |                          |
|                     |             |    |           |                 |                  | 1              | 0.13                 | 0.05            |                          |
|                     |             |    |           |                 |                  | 3              | <u>0.06</u>          | <u>0.04</u>     |                          |
|                     |             |    |           |                 |                  | 7              | <0.02                | 0.02            |                          |
| Spain<br>1996       | 50 WG       | 5  | 0.19      | 0.019           | fruit            | 0 <sup>1</sup> | 0.02                 | 0.02            | 2054/96<br>SPA-2054-96   |
|                     |             |    |           |                 |                  | 0              | 0.12                 | 0.03            |                          |
|                     |             |    |           |                 |                  | 1              | 0.11                 | 0.05            |                          |
|                     |             |    |           |                 |                  | 3              | <u>0.07</u>          | <u>0.05</u>     |                          |
|                     |             |    |           |                 |                  | 7              | <0.02                | 0.02            |                          |
| Spain<br>1996       | 50 WG       | 5  | 0.19      | 0.017-<br>0.027 | fruit            | 0 <sup>1</sup> | 0.06                 | 0.02            | 2164/96<br>SPA-2164-96   |
|                     |             |    |           |                 |                  | 0              | 0.13                 | 0.02            |                          |
|                     |             |    |           |                 |                  | 1              | 0.17                 | 0.03            |                          |
|                     |             |    |           |                 |                  | 3              | <u>0.14</u>          | <u>0.03</u>     |                          |
|                     |             |    |           |                 |                  | 7              | 0.09                 | 0.02            |                          |
| Spain<br>1996       | 50 WG       | 5  | 0.19      | 0.017-<br>0.019 | fruit            | 0 <sup>1</sup> | 0.04                 | <0.02           | 2165/96<br>SPA-2165-96   |
|                     |             |    |           |                 |                  | 0              | 0.17                 | <0.02           |                          |
|                     |             |    |           |                 |                  | 1              | 0.16                 | 0.02            |                          |
|                     |             |    |           |                 |                  | 3              | <u>0.14</u>          | <u>0.03</u>     |                          |
|                     |             |    |           |                 |                  | 7              | 0.10                 | 0.02            |                          |
| Netherlands<br>1996 | 50 WG       | 5  | 0.19      | 0.011-<br>0.017 | fruit            | 0 <sup>1</sup> | <0.02                | <0.02           | 2102/96<br>NIE-2102-96   |
|                     |             |    |           |                 |                  | 0              | 0.06                 | <0.02           |                          |
|                     |             |    |           |                 |                  | 1              | 0.07                 | <0.02           |                          |
|                     |             |    |           |                 |                  | 3              | <u>0.03</u>          | <u>&lt;0.02</u> |                          |
|                     |             |    |           |                 |                  | 5              | 0.02                 | <0.02           |                          |
|                     |             |    |           |                 |                  | 7              | <0.02                | <0.02           |                          |
|                     |             |    |           |                 |                  | 14             | <0.02                | <0.02           |                          |

| Country,<br>Year    | Application |    |           |                 | Residues (mg/kg) |                |                      |                 | Report No.;<br>Study No. |
|---------------------|-------------|----|-----------|-----------------|------------------|----------------|----------------------|-----------------|--------------------------|
|                     | Form        | No | kg ai/ha  | kg ai/hl        | Sample           | PHI<br>(days)  | trifloxy-<br>strobin | CGA321113       |                          |
| Netherlands<br>1996 | 50 WG       | 5  | 0.18-0.19 | 0.011-<br>0.015 | fruit            | 0 <sup>1</sup> | <0.02                | <0.02           | 2103/96<br>NIE-2103-96   |
|                     |             |    |           |                 |                  | 0              | 0.05                 | <0.02           |                          |
|                     |             |    |           |                 |                  | 1              | 0.04                 | <0.02           |                          |
|                     |             |    |           |                 |                  | 3              | <u>0.03</u>          | <u>&lt;0.02</u> |                          |
|                     |             |    |           |                 |                  | 5              | 0.03                 | <0.02           |                          |
|                     |             |    |           |                 |                  | 7              | <0.02                | <0.02           |                          |
|                     |             |    |           |                 |                  | 14             | <0.02                | <0.02           |                          |

*Melons, except watermelon*

Table 66. Results of residue trials with trifloxystrobin on melons.

| Location,<br>Year | Application |    |          |                 | Sample | Residues (mg/kg) |                      |                 | Report No.;<br>Study No.            |
|-------------------|-------------|----|----------|-----------------|--------|------------------|----------------------|-----------------|-------------------------------------|
|                   | Form        | No | kg ai/ha | kg ai/hl        |        | PHI<br>(days)    | trifloxy-<br>strobin | CGA321113       |                                     |
| AZ, USA<br>1996   | 50 WG       | 8  | 0.14     | 0.06            | fruit  | 0                | 0.22                 | <0.02           | ABR-97120<br>USA-02-FR-074-<br>96-A |
|                   |             |    |          |                 |        | 0                | <u>0.24</u>          | <u>&lt;0.02</u> |                                     |
|                   |             |    |          |                 |        | 1                | 0.18                 | <0.02           |                                     |
|                   |             |    |          |                 |        | 1                | 0.17                 | <0.02           |                                     |
|                   |             |    |          |                 |        | 3                | 0.08                 | <0.02           |                                     |
|                   |             |    |          |                 |        | 3                | 0.19                 | <0.02           |                                     |
|                   |             |    |          |                 |        | 5                | 0.19                 | <0.02           |                                     |
| TX, USA<br>1997   | 50 WG       | 8  | 0.14     | 0.27-0.30       | fruit  | 0                | 0.10                 | <0.02           | ABR-97120<br>USA-OS-FR-<br>302-97-A |
|                   |             |    |          |                 |        | 0                | <u>0.10</u>          | <u>&lt;0.02</u> |                                     |
| GA, USA<br>1997   | 50 WG       | 8  | 0.14     | 0.075           | fruit  | 0                | <u>0.07</u>          | <u>&lt;0.02</u> | ABR-97120<br>USA-OS-FR-<br>830-97-A |
|                   |             |    |          |                 |        | 0                | 0.03                 | <0.02           |                                     |
| CA, USA<br>1997   | 50 WG       | 8  | 0.14     | 0.03            | fruit  | 0                | <u>0.18</u>          | <u>&lt;0.02</u> | ABR-97120<br>USA-OW-FR-<br>527-97-A |
|                   |             |    |          |                 |        | 0                | 0.11                 | <0.02           |                                     |
| AZ, USA<br>1997   | 50 WG       | 8  | 0.14     | 0.075           | fruit  | 0                | 0.07                 | <0.02           | ABR-97120<br>USA-OW-FR-<br>528-97-A |
|                   |             |    |          |                 |        | 0                | <u>0.10</u>          | <u>&lt;0.02</u> |                                     |
| IN, USA<br>1998   | 50 WG       | 8  | 0.14     | 0.08-0.10       | fruit  | 0                | <u>0.11</u>          | <u>&lt;0.02</u> | 146-98<br>USA-NE-FR-<br>102-98-A    |
|                   |             |    |          |                 |        | 0                | 0.04                 | <0.02           |                                     |
|                   |             |    |          |                 |        | 3                | 0.03                 | <0.02           |                                     |
|                   |             |    |          |                 |        | 3                | 0.08                 | <0.02           |                                     |
| Spain<br>1996     | 50 WG       | 5  | 0.13     | 0.006           | fruit  | 0 <sup>1</sup>   | <0.02                | <0.02           | 2051/96<br>SPA-2051-96              |
|                   |             |    |          |                 |        | 0                | 0.02                 | <0.02           |                                     |
|                   |             |    |          |                 |        | 1                | <0.02                | <0.02           |                                     |
|                   |             |    |          |                 |        | 3                | <u>&lt;0.02</u>      | <u>&lt;0.02</u> |                                     |
|                   |             |    |          |                 |        | 7                | <0.02                | <0.02           |                                     |
| Spain<br>1996     | 50 WG       | 5  | 0.13     | 0.006           | fruit  | 0 <sup>1</sup>   | <0.02                | <0.02           | 2052/96<br>SPA-2052-96              |
|                   |             |    |          |                 |        | 0                | 0.02                 | <0.02           |                                     |
|                   |             |    |          |                 |        | 1                | <0.02                | <0.02           |                                     |
|                   |             |    |          |                 |        | 3                | <u>&lt;0.02</u>      | <u>&lt;0.02</u> |                                     |
|                   |             |    |          |                 |        | 7                | <0.02                | <0.02           |                                     |
| Italy<br>1996     | 50 WG       | 5  | 0.13     | 0.021           | fruit  | 0 <sup>1</sup>   | <0.02                | <0.02           | 2080/96<br>ITA-2080-96              |
|                   |             |    |          |                 |        | 0                | 0.14                 | <0.02           |                                     |
|                   |             |    |          |                 |        | 3                | <u>0.07</u>          | <u>&lt;0.02</u> |                                     |
|                   |             |    |          |                 |        | 5                | 0.02                 | <0.02           |                                     |
|                   |             |    |          |                 |        | 7                | 0.02                 | <0.02           |                                     |
| Italy<br>1996     | 50 WG       | 5  | 0.13     | 0.013-<br>0.014 | fruit  | 7                | 0.06                 | <0.02           | 2081/96<br>ITA-2081-96              |
|                   |             |    |          |                 |        | 7                | 0.06                 | <0.02           |                                     |



| Location,<br>Year | Form  | Application |          |                 | Sample | Residues (mg/kg) |                      |                          | Report No.;<br>Study No. |
|-------------------|-------|-------------|----------|-----------------|--------|------------------|----------------------|--------------------------|--------------------------|
|                   |       | No          | kg ai/ha | kg ai/hl        |        | PHI<br>(days)    | trifloxy-<br>strobin | CGA321113                |                          |
| Spain<br>1997     | 50 WG | 5           | 0.13     | 0.016           | fruit  | 3<br>3           | <u>0.19</u><br>0.12  | <u>&lt;0.02</u><br><0.02 | 2052/97<br>SPA-2052-97   |
| Spain<br>1997     | 50 WG | 5           | 0.13     | 0.013           | fruit  | 3<br>3           | 0.02<br><u>0.04</u>  | <0.02<br><u>&lt;0.02</u> | 2053/97<br>SPA-2053-97   |
| Italy<br>1997     | 50 WG | 5           | 0.13     | 0.013-<br>0.014 | fruit  | 3<br>3           | 0.08<br><u>0.11</u>  | <0.02<br><u>&lt;0.02</u> | 2388/97<br>ITA-2388-97   |
| Italy<br>1997     | 50 WG | 5           | 0.13     | 0.021           | fruit  | 3<br>3           | <u>0.10</u><br>0.09  | <u>&lt;0.02</u><br><0.02 | 2389/97<br>ITA-2389-97   |

### Summer squash

Table 67. Results of residue trials with trifloxystrobin on summer squash.

| Location,<br>Year    | Application |    |                 |                  | Sample | Residues (mg/kg)                     |                                                                     |                                                                                | Report No.;<br>Study No.            |
|----------------------|-------------|----|-----------------|------------------|--------|--------------------------------------|---------------------------------------------------------------------|--------------------------------------------------------------------------------|-------------------------------------|
|                      | Form        | No | kg ai/ha        | kg ai/hl         |        | PHI<br>(days)                        | trifloxy-<br>strobin                                                | CGA321113                                                                      |                                     |
| FL, USA<br>1996      | 50 WG       | 8  | 0.14            | 0.30             | fruit  | 0<br>0<br>3<br>3                     | 0.06<br>0.10<br>0.04<br><u>0.15</u>                                 | <0.02<br><0.02<br><0.02<br><u>&lt;0.02</u>                                     | ABR-97120<br>USA-07-FR-010-<br>96-A |
| MI, USA<br>1997      | 50 WG       | 8  | 0.14            | 0.05             | fruit  | 0<br>0                               | 0.06<br><u>0.11</u>                                                 | <0.02<br><u>&lt;0.02</u>                                                       | ABR-97120<br>USA-NE-FR-<br>702-97-A |
| NY, USA<br>1997      | 50 WG       | 8  | 0.14            | 0.075            | fruit  | 0<br>0                               | 0.06<br><u>0.09</u>                                                 | <0.02<br><u>&lt;0.02</u>                                                       | ABR-97120<br>USA-NE-FR-<br>810-97-A |
| GA, USA<br>1997      | 50 WG       | 8  | 0.14            | 0.075-<br>0.076  | fruit  | 0<br>0                               | <0.02<br><u>&lt;0.02</u>                                            | <0.02<br><u>&lt;0.02</u>                                                       | ABR-97120<br>USA-OS-FR-<br>831-97-A |
| CA, USA<br>1997      | 50 WG       | 8  | 0.14            | 0.06             | fruit  | 0<br>0<br>1<br>1<br>3<br>3<br>5<br>5 | <u>0.23</u><br>0.18<br>0.14<br>0.13<br>0.07<br>0.10<br>0.08<br>0.13 | <u>&lt;0.02</u><br><0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><0.02 | ABR-97120<br>USA-02-FR-001-<br>97-A |
| South Africa<br>1998 | 50 WG       | 5  | 0.031-<br>0.047 | 0.006-<br>0.0065 | fruit  | 0<br>3<br>7<br>14<br>21              | <0.02<br><0.02<br><0.02<br><0.02<br><0.02                           | <0.02<br><0.02<br><0.02<br><0.02<br><0.02                                      | 2255/98<br>SAF-2255-98              |
| South Africa<br>1998 | 50 WG       | 5  | 0.033-<br>0.047 | 0.006            | fruit  | 0<br>3<br>7<br>14<br>21              | <0.02<br><0.02<br><0.02<br><0.02<br><0.02                           | <0.02<br><0.02<br><0.02<br><0.02<br><0.02                                      | 2256/98<br>SAF-2256-98              |
| South Africa<br>1998 | 50 WG       | 5  | 0.064-<br>0.094 | 0.013            | fruit  | 0<br>3<br>7<br>14<br>21              | 0.02<br><0.02<br><0.02<br><0.02<br><0.02                            | <0.02<br><0.02<br><0.02<br><0.02<br><0.02                                      | 2257/98<br>SAF-2256-98              |

*Fruiting vegetables, other than cucurbits**Sweet pepper*

Table 68. Results of residue field trials with trifloxystrobin on sweet pepper in the USA.

| Location,<br>Year | Application |    |           |           | Residues (mg/kg) |                                                                          |                                                                                                                     |                                                                                                                                      | Report No.;<br>Study No.  |
|-------------------|-------------|----|-----------|-----------|------------------|--------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
|                   | Form        | No | kg ai/ha  | kg ai/hl  | Sample           | PHI<br>(days)                                                            | trifloxy-<br>strobin                                                                                                | CGA-<br>321113                                                                                                                       |                           |
| MI, 1997          | 50<br>WG    | 8  | 0.14-0.17 | 0.05-0.07 | fruit            | 3<br>3                                                                   | <u>0.03</u><br>0.03                                                                                                 | <u>&lt;0.02</u><br><0.02                                                                                                             | 40-97<br>USA-NE-FR-733-97 |
| TX, 1997          | 50<br>WG    | 8  | 0.14      | 0.05      | fruit            | 3<br>3                                                                   | 0.11<br><u>0.12</u>                                                                                                 | <0.02<br><u>&lt;0.02</u>                                                                                                             | 40-97<br>USA-OS-FR-322-97 |
| NC, 1997          | 50<br>WG    | 8  | 0.14      | 0.30      | fruit            | 3<br>3                                                                   | <u>0.05</u><br>0.04                                                                                                 | <u>&lt;0.02</u><br><0.02                                                                                                             | 40-97<br>USA-OS-FR-608-97 |
| CA, 1997          | 50<br>WG    | 8  | 0.14      | 0.06      | fruit            | 3<br>3                                                                   | <u>0.14</u><br>0.12                                                                                                 | <u>&lt;0.02</u><br><0.02                                                                                                             | 40-97<br>USA-OW-FR-531-97 |
| CA, 1997          | 50<br>WG    | 8  | 0.14      | 0.30      | fruit            | 3<br>3                                                                   | 0.11<br><u>0.12</u>                                                                                                 | <0.02<br><u>&lt;0.02</u>                                                                                                             | 40-97<br>USA-02-FR-008-97 |
| FL, 1997          | 50<br>WG    | 8  | 0.14      | 0.03      | fruit            | 0<br>0<br>1<br>1<br>3<br>3<br>5<br>5                                     | 0.12<br>0.12<br>0.08<br>0.06<br>0.03<br><u>0.04</u><br><0.02<br><0.02                                               | <0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><u>&lt;0.02</u><br><0.02<br><0.02                                                       | 40-97<br>USA-07-FR-006-97 |
| CA, 2001          | 50<br>WG    | 4  | 0.14      | 0.21-0.22 | fruit            | 0<br>0<br>3<br>3<br>5<br>5<br>7<br>7<br>10<br>10<br>13<br>13<br>15<br>15 | 0.11<br>0.07<br>0.10<br>0.11<br>0.12<br>0.09<br><u>0.16</u><br>0.10<br>0.08<br>0.09<br>0.11<br>0.07<br>0.08<br>0.08 | <0.01<br><0.01<br><0.01<br><0.01<br><0.01<br><0.01<br><u>&lt;0.01</u><br><0.01<br><0.01<br><0.01<br><0.01<br><0.01<br><0.01<br><0.01 | 200169<br>BAY-FL004-01D-A |
| CA, 2001          | 50<br>WG    | 8  | 0.14      | 0.21-0.22 | fruit            | 0<br>0<br>3<br>3<br>5<br>5<br>7<br>7<br>10<br>10<br>13<br>13<br>15<br>15 | 0.07<br>0.11<br>0.06<br><u>0.08</u><br>0.08<br>0.07<br>0.05<br>0.03<br>0.06<br>0.05<br>0.04<br>0.06<br>0.04<br>0.07 | <0.01<br><0.01<br><0.01<br><u>&lt;0.01</u><br><0.01<br><0.01<br><0.01<br><0.01<br><0.01<br><0.01<br><0.01<br><0.01<br><0.01<br><0.01 | 200169<br>BAY-FL004-01D-B |

| Location,<br>Year | Application |    |           |           | Residues (mg/kg) |               |                      |                 | Report No.;<br>Study No.  |
|-------------------|-------------|----|-----------|-----------|------------------|---------------|----------------------|-----------------|---------------------------|
|                   | Form        | No | kg ai/ha  | kg ai/hl  | Sample           | PHI<br>(days) | trifloxy-<br>strobin | CGA-<br>321113  |                           |
| TX, 2001          | 50<br>WG    | 4  | 0.14-0.15 | 0.24-0.25 | fruit            | 0             | 0.03                 | <0.01           | 200169<br>BAY-FL005-01D-A |
|                   |             |    |           |           |                  | 0             | 0.04                 | <0.01           |                           |
|                   |             |    |           |           |                  | 3             | <u>0.04</u>          | <u>&lt;0.01</u> |                           |
|                   |             |    |           |           |                  | 3             | 0.03                 | <0.01           |                           |
|                   |             |    |           |           |                  | 5             | 0.03                 | <0.01           |                           |
|                   |             |    |           |           |                  | 7             | 0.03                 | <0.01           |                           |
|                   |             |    |           |           |                  | 10            | 0.03                 | <0.01           |                           |
|                   |             |    |           |           |                  | 13            | 0.02                 | <0.01           |                           |
|                   |             |    |           |           |                  | 13            | 0.03                 | <0.01           |                           |
|                   |             |    |           |           |                  | 16            | 0.02                 | <0.01           |                           |
| TX, 2001          | 50<br>WG    | 8  | 0.14      | 0.21-0.25 | fruit            | 0             | 0.05                 | <0.01           | 200169<br>BAY-FL005-01D-B |
|                   |             |    |           |           |                  | 0             | 0.05                 | <0.01           |                           |
|                   |             |    |           |           |                  | 3             | 0.04                 | <0.01           |                           |
|                   |             |    |           |           |                  | 3             | <u>0.05</u>          | <u>&lt;0.01</u> |                           |
|                   |             |    |           |           |                  | 5             | 0.04                 | <0.01           |                           |
|                   |             |    |           |           |                  | 5             | 0.02                 | <0.01           |                           |
|                   |             |    |           |           |                  | 7             | 0.04                 | <0.01           |                           |
|                   |             |    |           |           |                  | 7             | 0.03                 | <0.01           |                           |
|                   |             |    |           |           |                  | 10            | 0.02                 | <0.01           |                           |
|                   |             |    |           |           |                  | 10            | 0.05                 | <0.01           |                           |
|                   |             |    |           |           |                  | 13            | 0.03                 | <0.01           |                           |
|                   |             |    |           |           |                  | 13            | 0.01                 | <0.01           |                           |
|                   |             |    |           |           |                  | 16            | 0.01                 | <0.01           |                           |
|                   |             |    |           |           |                  | 16            | 0.03                 | <0.01           |                           |
| CA, 2001          | 50<br>WG    | 4  | 0.14      | 0.19-0.20 | fruit            | 0             | 0.16                 | <0.01           | 200169<br>BAY-FL006-01D-A |
|                   |             |    |           |           |                  | 0             | 0.18                 | <0.01           |                           |
|                   |             |    |           |           |                  | 3             | 0.13                 | <0.01           |                           |
|                   |             |    |           |           |                  | 3             | 0.14                 | <0.01           |                           |
|                   |             |    |           |           |                  | 5             | 0.13                 | <0.01           |                           |
|                   |             |    |           |           |                  | 5             | <u>0.16</u>          | <u>&lt;0.01</u> |                           |
|                   |             |    |           |           |                  | 7             | 0.10                 | <0.01           |                           |
|                   |             |    |           |           |                  | 7             | 0.06                 | <0.01           |                           |
|                   |             |    |           |           |                  | 10            | 0.07                 | <0.01           |                           |
|                   |             |    |           |           |                  | 10            | 0.04                 | <0.01           |                           |
|                   |             |    |           |           |                  | 13            | 0.04                 | <0.01           |                           |
|                   |             |    |           |           |                  | 13            | 0.09                 | <0.01           |                           |
|                   |             |    |           |           |                  | 16            | 0.03                 | <0.01           |                           |
|                   |             |    |           |           |                  | 16            | 0.06                 | <0.01           |                           |
| CA, 2001          | 50<br>WG    | 8  | 0.14      | 0.20      | fruit            | 0             | 0.10                 | <0.01           | 200169<br>BAY-FL006-01D-B |
|                   |             |    |           |           |                  | 0             | 0.13                 | <0.01           |                           |
|                   |             |    |           |           |                  | 3             | <u>0.12</u>          | <u>&lt;0.01</u> |                           |
|                   |             |    |           |           |                  | 5             | 0.10                 | <0.01           |                           |
|                   |             |    |           |           |                  | 5             | 0.08                 | <0.01           |                           |
|                   |             |    |           |           |                  | 7             | 0.08                 | <0.01           |                           |
|                   |             |    |           |           |                  | 10            | 0.09                 | <0.01           |                           |
|                   |             |    |           |           |                  | 10            | 0.07                 | <0.01           |                           |
|                   |             |    |           |           |                  | 13            | 0.07                 | <0.01           |                           |
|                   |             |    |           |           |                  | 13            | 0.08                 | <0.01           |                           |
|                   |             |    |           |           |                  | 16            | 0.05                 | <0.01           |                           |

### Tomato

Table 69. Results of residue field trials with trifloxystrobin on tomato in the USA.

| Location,<br>Year | Application |    |          |          | Residues (mg/kg) |               |                      |                 | Report No.;<br>Study No.  |
|-------------------|-------------|----|----------|----------|------------------|---------------|----------------------|-----------------|---------------------------|
|                   | Form        | No | kg ai/ha | kg ai/hl | Sample           | PHI<br>(days) | trifloxy-<br>strobin | CGA-<br>321113  |                           |
| FL, 1997          | 50<br>WG    | 8  | 0.14     | 0.05     | fruit            | 3             | <u>&lt;0.02</u>      | <u>&lt;0.02</u> | 40-97<br>USA-FL-FR-405-97 |
|                   |             |    |          |          |                  | 3             | <0.02                | <0.02           |                           |

| Location,<br>Year | Application |    |          |          | Residues (mg/kg) |                                                                          |                                                                                                                     |                                                                                                                                      | Report No.;<br>Study No.    |
|-------------------|-------------|----|----------|----------|------------------|--------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|
|                   | Form        | No | kg ai/ha | kg ai/hl | Sample           | PHI<br>(days)                                                            | trifloxy-<br>strobin                                                                                                | CGA-<br>321113                                                                                                                       |                             |
| OH, 1997          | 50<br>WG    | 8  | 0.14     | 0.06     | fruit            | 3<br>3                                                                   | 0.09<br><u>0.13</u>                                                                                                 | <0.02<br><u>&lt;0.02</u>                                                                                                             | 40-97<br>USA-NE-FR-202-97   |
| PA, 1997          | 50<br>WG    | 8  | 0.14     | 0.05     | fruit            | 3<br>3                                                                   | 0.02<br><u>0.03</u>                                                                                                 | <0.02<br><u>&lt;0.02</u>                                                                                                             | 40-97<br>USA-NE-FR-306-97   |
| SC, 1997          | 50<br>WG    | 8  | 0.14     | 0.30     | fruit            | 3<br>3                                                                   | 0.05<br><u>0.07</u>                                                                                                 | <0.02<br><u>&lt;0.02</u>                                                                                                             | 40-97<br>USA-OS-FR-607-97   |
| CA, 1997          | 50<br>WG    | 8  | 0.14     | 0.05     | fruit            | 3<br>3                                                                   | 0.13<br><u>0.20</u>                                                                                                 | <0.02<br><u>&lt;0.02</u>                                                                                                             | 40-97<br>USA-OW-FR-410-97   |
| CA, 1997          | 50<br>WG    | 8  | 0.14     | 0.05     | fruit            | 3<br>3<br>3                                                              | <u>0.49</u><br>0.34<br>0.18                                                                                         | <u>&lt;0.02</u><br><0.02<br><0.02                                                                                                    | 40-97<br>USA-OW-FR-411-97-A |
| CA, 1997          | 50<br>WG    | 8  | 0.14     | 0.04     | fruit            | 3<br>3                                                                   | <u>0.07</u><br>0.05                                                                                                 | <u>&lt;0.02</u><br><0.02                                                                                                             | 40-97<br>USA-OW-FR-412-97   |
| CA, 1997          | 50<br>WG    | 8  | 0.14     | 0.05     | fruit            | 3<br>3                                                                   | <u>0.06</u><br>0.06                                                                                                 | <u>&lt;0.02</u><br><0.02                                                                                                             | 40-97<br>USA-OW-FR-529-97   |
| CA, 1997          | 50<br>WG    | 8  | 0.14     | 0.30     | fruit            | 3<br>3                                                                   | 0.08<br><u>0.09</u>                                                                                                 | <0.02<br><u>&lt;0.02</u>                                                                                                             | 40-97<br>USA-02-FR-006-97   |
| FL, 1997          | 50<br>WG    | 8  | 0.14     | 0.026    | fruit            | 0<br>0<br>1<br>1<br>3<br>3<br>5<br>5                                     | 0.15<br>0.11<br><0.02<br><0.02<br><u>&lt;0.02</u><br><0.02<br><0.02<br><0.02                                        | <0.02<br><0.02<br><0.02<br><0.02<br><u>&lt;0.02</u><br><0.02<br><0.02<br><0.02                                                       | 40-97<br>USA-07-FR-004-97   |
| CA, 1998          | 50<br>WG    | 8  | 0.14     | 0.06     | fruit            | 3<br>3                                                                   | <u>0.07</u><br>0.05                                                                                                 | <u>&lt;0.02</u><br><0.02                                                                                                             | 40-97<br>USA-OW-FR-555-98   |
| CA, 1998          | 50<br>WG    | 8  | 0.14     | 0.06     | fruit            | 0<br>0<br>1<br>1<br>3<br>3<br>3<br>5<br>5                                | 0.10<br>0.24<br>0.36<br>0.29<br>0.19<br><u>0.29</u><br>0.12<br>0.11<br>0.16                                         | <0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><u>&lt;0.02</u><br><0.02<br><0.02<br><0.02                                              | 40-97<br>USA-02-FR-007-97-A |
| CA, 2001          | 50<br>WG    | 4  | 0.14     | 0.15     | fruit            | 0<br>0<br>3<br>3<br>5<br>5<br>7<br>7<br>10<br>10<br>12<br>12<br>16<br>16 | 0.32<br>0.30<br>0.34<br>0.15<br>0.21<br>0.20<br>0.23<br>0.20<br>0.19<br>0.15<br>0.13<br>0.18<br><u>0.09</u><br>0.11 | <0.01<br><0.01<br><0.01<br><0.01<br><0.01<br><0.01<br><0.01<br><0.01<br><0.01<br><0.01<br><0.01<br><0.01<br><u>&lt;0.01</u><br><0.01 | 200169<br>BAY-FL001-01D-A   |



| Location,<br>Year | Application |    |          |           | Residues (mg/kg) |               |                      |                 | Report No.;<br>Study No.  |
|-------------------|-------------|----|----------|-----------|------------------|---------------|----------------------|-----------------|---------------------------|
|                   | Form        | No | kg ai/ha | kg ai/hl  | Sample           | PHI<br>(days) | trifloxy-<br>strobin | CGA-<br>321113  |                           |
| CA, 2001          | 50<br>WG    | 8  | 0.14     | 0.21-0.22 | fruit            | 0             | 0.08                 | <0.01           | 200169<br>BAY-FL003-01D-B |
|                   |             |    |          |           |                  | 0             | 0.08                 | <0.01           |                           |
|                   |             |    |          |           |                  | 3             | <u>0.10</u>          | <u>&lt;0.01</u> |                           |
|                   |             |    |          |           |                  | 3             | 0.06                 | <0.01           |                           |
|                   |             |    |          |           |                  | 5             | 0.07                 | <0.01           |                           |
|                   |             |    |          |           |                  | 5             | 0.06                 | <0.01           |                           |
|                   |             |    |          |           |                  | 7             | 0.05                 | <0.01           |                           |
|                   |             |    |          |           |                  | 7             | 0.06                 | <0.01           |                           |
|                   |             |    |          |           |                  | 10            | 0.08                 | <0.01           |                           |
|                   |             |    |          |           |                  | 10            | 0.06                 | <0.01           |                           |
|                   |             |    |          |           |                  | 13            | 0.07                 | <0.01           |                           |
|                   |             |    |          |           |                  | 13            | 0.05                 | <0.01           |                           |
|                   |             |    |          |           |                  | 15            | 0.04                 | <0.01           |                           |
|                   |             |    |          |           |                  | 15            | 0.03                 | <0.01           |                           |

*Leafy vegetables (including Brassica leafy vegetables)*

*Chinese cabbage*

Table 70. Results of residue field trials with trifloxystrobin on Chinese cabbage in Switzerland in 2000.

| Application |    |          |          | Residues (mg/kg) |               |                      |                 | Report No.;<br>Study No. |
|-------------|----|----------|----------|------------------|---------------|----------------------|-----------------|--------------------------|
| Form        | No | kg ai/ha | kg ai/hl | Sample           | PHI<br>(days) | trifloxy-<br>strobin | CGA321113       |                          |
| 50<br>WG    | 3  | 0.25     | 0.05     | head             | 0             | 1.6                  | 0.05            | 2052/00<br>SWZ-2052-00   |
|             |    |          |          |                  | 3             | 0.14                 | 0.02            |                          |
|             |    |          |          |                  | 7             | <u>0.01</u>          | <u>&lt;0.01</u> |                          |
|             |    |          |          |                  | 14            | <0.01                | <0.01           |                          |
|             |    |          |          |                  | 14            | <0.01                | <0.01           |                          |
| 50<br>WG    | 3  | 0.25     | 0.05     | head             | 0             | 1.0                  | 0.02            | 2053/00<br>SWZ-2053-00   |
|             |    |          |          |                  | 3             | 0.81                 | 0.03            |                          |
|             |    |          |          |                  | 7             | <u>0.33</u>          | <u>0.02</u>     |                          |
|             |    |          |          |                  | 14            | 0.03                 | 0.01            |                          |
|             |    |          |          |                  | 14            | 0.01                 | 0.01            |                          |

*Pulses*

*Beans (dry)*

Table 71. Results of residue field trials with trifloxystrobin on beans in Brazil.

| Year | Application |    |          |          | Residues (mg/kg)     |               |                      |                | Report No.;<br>Study No.       |
|------|-------------|----|----------|----------|----------------------|---------------|----------------------|----------------|--------------------------------|
|      | Form        | No | kg ai/ha | kg ai/hl | Sample               | PHI<br>(days) | trifloxy-<br>strobin | CGA-<br>321113 |                                |
| 1998 | 50<br>WG    | 4  | 0.15     | 0.05     | seed                 | 0             | <0.02                | n.a.           | FR001/99<br>BRA-FR001-99-A     |
|      |             |    |          |          |                      | 7             | <0.02                |                |                                |
|      |             |    |          |          |                      | 15            | <0.02                |                |                                |
| 1999 | 50<br>WG    | 4  | 0.15     |          | seed                 | 0             | <0.02                | n.a.           | FR002/99<br>BRA-FR002-99-A     |
|      |             |    |          |          |                      | 7             | <0.02                |                |                                |
|      |             |    |          |          |                      | 15            | <0.02                |                |                                |
| 2000 | 50<br>WG    | 4  | 0.15     | 0.05     | bean, without<br>pod | 15            | <0.05                | n.a.           | M00140-JJB<br>BRA-M00140-JJB-A |
| 2001 | 50<br>WG    | 4  | 0.15     | 0.06     | bean, without<br>pod | 15            | <0.05                | n.a.           | M00140-JSA<br>BRA-M00140-JSA-A |

| Year | Application |    |          |          | Residues (mg/kg)     |               |                      |                | Report No.;<br>Study No.       |
|------|-------------|----|----------|----------|----------------------|---------------|----------------------|----------------|--------------------------------|
|      | Form        | No | kg ai/ha | kg ai/hl | Sample               | PHI<br>(days) | trifloxy-<br>strobin | CGA-<br>321113 |                                |
| 2001 | 50<br>WG    | 4  | 0.15     | 0.075    | bean, without<br>pod | 15            | <0.05                | n.a.           | M00140-RPK<br>BRA-M00140-RPK-A |
| 1999 | 250<br>EC   | 3  | 0.094    | 0.02     | seed                 | 15<br>15      | <0.02<br><0.02       | n.a.           | FR029/99<br>BRA-FR029-99-A     |
| 1999 | 250<br>EC   | 4  | 0.094    |          | seed                 | 15<br>15      | <0.02<br><0.02       | n.a.           | FR030/99<br>BRA-FR030-99-A     |
| 2000 | 250<br>EC   | 3  | 0.094    | 0.03     | bean, without<br>pod | 15            | <0.05                | n.a.           | M00146-JJB<br>BRA-M00146-JJB-A |
| 2001 | 250<br>EC   | 3  | 0.094    | 0.04     | bean, without<br>pod | 15            | <0.05                | n.a.           | M00146-JSA<br>BRA-M00146-JSA-A |
| 2001 | 250<br>EC   | 3  | 0.094    | 0.05     | bean, without<br>pod | 15            | <0.05                | n.a.           | M00146-RPK<br>BRA-M00146-RPK-A |

n.a. not analysed

*Soya bean (dry)*

Table 72. Results of residue field trials with trifloxystrobin on soya bean in Brazil.

| Year | Application |    |          |          | Residues (mg/kg) |               |                      |                | Report No.;<br>Study No.                 |
|------|-------------|----|----------|----------|------------------|---------------|----------------------|----------------|------------------------------------------|
|      | Form        | No | kg ai/ha | kg ai/hl | Sample           | PHI<br>(days) | trifloxy-<br>strobin | CGA-<br>321113 |                                          |
| 2002 | 250 EC      | 2  | 0.063    | 0.031    | seed             | 21            | <0.05                | n.a.           | BRA S-P-677/02-S1<br>BRA-S-P-677/02-S1-A |
| 2002 | 250 EC      | 2  | 0.13     | 0.063    | seed             | 21            | <0.05                | n.a.           | BRA S-P-677/02-S1<br>BRA-S-P-677/02-S1-B |
| 2002 | 250 EC      | 2  | 0.063    | 0.031    | seed             | 21            | <0.05                | n.a.           | BRA S-P-677/02-S2<br>BRA-S-P-677/02-S2-A |
| 2002 | 250 EC      | 2  | 0.13     | 0.063    | seed             | 21            | <0.05                | n.a.           | BRA S-P-677/02-S2<br>BRA-S-P-677/02-S2-B |
| 2002 | 250 EC      | 2  | 0.063    | 0.031    | seed             | 21            | <0.05                | n.a.           | BRA S-P-677/02-S3<br>BRA-S-P-677/02-S3-A |
| 2002 | 250 EC      | 2  | 0.13     | 0.063    | seed             | 21            | <0.05                | n.a.           | BRA S-P-677/02-S3<br>BRA-S-P-677/02-S3-B |
| 2003 | 267.5<br>EC | 2  | 0.094    | 0.031    | seed             | 30            | <0.05                | n.a.           | FR03BRA012-P1<br>BRA-FR03BRA012-P1-A     |
| 2003 | 267.5<br>EC | 2  | 0.094    | 0.031    | seed             | 30            | <0.05                | n.a.           | FR03BRA012-P2<br>BRA-FR03BRA012-P2-A     |
| 2003 | 267.5<br>EC | 2  | 0.094    | 0.031    | seed             | 30            | <0.05                | n.a.           | FR03BRA012-P3<br>BRA-FR03BRA012-P3-A     |

n.a. not analysed

*Root and tuber vegetables**Carrot*

Table 73. Results of residue trials with trifloxystrobin on carrot.

| Country,<br>Year    | Application |    |           |          | Residues (mg/kg) |                |                      |                 | Report No.;<br>Study No. |
|---------------------|-------------|----|-----------|----------|------------------|----------------|----------------------|-----------------|--------------------------|
|                     | Form        | No | kg ai/ha  | kg ai/hl | Sample           | PHI<br>(days)  | trifloxy-<br>strobin | CGA321113       |                          |
| Switzerland<br>1999 | 50<br>WG    | 3  | 0.25      | 0.03     | root, washed     | 0              | 0.02                 | 0.03            | 2081/99<br>SWZ-2081-99   |
|                     |             |    |           |          |                  | 7              | <u>0.04</u>          | <u>0.04</u>     |                          |
|                     |             |    |           |          |                  | 14             | 0.02                 | 0.03            |                          |
|                     |             |    |           |          |                  | 21             | <0.02                | 0.03            |                          |
|                     |             |    |           |          |                  | 21             | <0.02                | 0.02            |                          |
| Switzerland<br>2000 | 50<br>WG    | 3  | 0.25      | 0.05     | root, washed     | 0              | 0.01                 | <0.01           | 2047/00<br>SWZ-2047-00   |
|                     |             |    |           |          |                  | 3              | 0.03                 | 0.01            |                          |
|                     |             |    |           |          |                  | 7              | <u>0.03</u>          | <u>0.01</u>     |                          |
|                     |             |    |           |          |                  | 14             | 0.02                 | 0.01            |                          |
|                     |             |    |           |          |                  | 14             | 0.02                 | 0.01            |                          |
| Germany<br>2001     | 50<br>WG    | 3  | 0.25      | 0.04     | root             | 0 <sup>1</sup> | 0.02                 | <0.02           | RA-2196/01<br>0627-01    |
|                     |             |    |           |          |                  | 0              | 0.02                 | <0.02           |                          |
|                     |             |    |           |          |                  | 7              | <u>0.02</u>          | <u>0.02</u>     |                          |
|                     |             |    |           |          |                  | 14             | 0.02                 | 0.02            |                          |
|                     |             |    |           |          |                  | 21             | 0.02                 | 0.02            |                          |
| Belgium<br>2001     | 50<br>WG    | 3  | 0.22-0.26 | 0.04     | root             | 0 <sup>1</sup> | 0.02                 | <0.02           | RA-2196/01<br>0628-01    |
|                     |             |    |           |          |                  | 0              | 0.02                 | <0.02           |                          |
|                     |             |    |           |          |                  | 7              | <u>&lt;0.02</u>      | <u>&lt;0.02</u> |                          |
|                     |             |    |           |          |                  | 14             | <0.02                | <0.02           |                          |
|                     |             |    |           |          |                  | 21             | <0.02                | <0.02           |                          |
| Netherlands<br>2001 | 50<br>WG    | 3  | 0.25      | 0.04     | root             | 0 <sup>1</sup> | <0.02                | <0.02           | RA-2196/01<br>0629-01    |
|                     |             |    |           |          |                  | 0              | <0.02                | <0.02           |                          |
|                     |             |    |           |          |                  | 7              | <u>0.02</u>          | <u>&lt;0.02</u> |                          |
|                     |             |    |           |          |                  | 14             | <0.02                | <0.02           |                          |
|                     |             |    |           |          |                  | 21             | <0.02                | <0.02           |                          |
| Netherlands<br>2001 | 50<br>WG    | 3  | 0.25      | 0.04     | root             | 0 <sup>1</sup> | <0.02                | <0.02           | RA-2196/01<br>0630-01    |
|                     |             |    |           |          |                  | 0              | <0.02                | <0.02           |                          |
|                     |             |    |           |          |                  | 7              | <u>0.03</u>          | <u>&lt;0.02</u> |                          |
|                     |             |    |           |          |                  | 14             | <0.02                | <0.02           |                          |
|                     |             |    |           |          |                  | 21             | <0.02                | <0.02           |                          |

*Celeriac*

Table 74. Results of residue trials with trifloxystrobin on celeriac in Switzerland in 2000.

| Application |    |          |          | Residues (mg/kg) |               |                      |             | Report No.;<br>Study No. |
|-------------|----|----------|----------|------------------|---------------|----------------------|-------------|--------------------------|
| Form        | No | kg ai/ha | kg ai/hl | Sample           | PHI<br>(days) | trifloxy-<br>strobin | CGA321113   |                          |
| 50<br>WG    | 3  | 0.25     | 0.05     | root, washed     | 0             | 0.02                 | <0.01       | 2048/00<br>SWZ-2048-00   |
|             |    |          |          |                  | 7             | 0.02                 | 0.01        |                          |
|             |    |          |          |                  | 14            | <u>0.02</u>          | <u>0.01</u> |                          |
|             |    |          |          |                  | 21            | 0.01                 | <0.01       |                          |
|             |    |          |          |                  | 21            | <0.01                | <0.01       |                          |



| Application |    |          |          | Residues (mg/kg) |                          |                                             |                                              | Report No.;<br>Study No. |
|-------------|----|----------|----------|------------------|--------------------------|---------------------------------------------|----------------------------------------------|--------------------------|
| Form        | No | kg ai/ha | kg ai/hl | Sample           | PHI<br>(days)            | trifloxy-<br>strobin                        | CGA321113                                    |                          |
| 50<br>WG    | 3  | 0.25     | 0.05     | root, washed     | 0<br>7<br>14<br>21<br>21 | 0.03<br>0.03<br><u>0.03</u><br>0.03<br>0.04 | 0.01<br><0.01<br><u>0.01</u><br>0.01<br>0.01 | 2049/00<br>SWZ-2049-00   |

*Potato*

Table 75. Results of residue trials with trifloxystrobin on potato in the USA.

| Location,<br>Year | Application |    |          |                 | Residues (mg/kg) |                  |                                            |                                            | Report No.;<br>Study No.        |
|-------------------|-------------|----|----------|-----------------|------------------|------------------|--------------------------------------------|--------------------------------------------|---------------------------------|
|                   | Form        | No | kg ai/ha | kg ai/hl        | Sample           | PHI<br>(days)    | trifloxy-<br>strobin                       | CGA-<br>321113                             |                                 |
| CO, 1996          | 50<br>WG    | 6  | 0.14     | 0.08-0.10       | tuber            | 7<br>7           | <u>&lt;0.02</u><br><0.02                   | <u>&lt;0.02</u><br><0.02                   | 55-96<br>USA-MW-FR-316-96       |
| ND, 1996          | 50<br>WG    | 6  | 0.14     | 0.05            | tuber            | 0<br>0<br>7<br>7 | <0.02<br><0.02<br><u>&lt;0.02</u><br><0.02 | <0.02<br><0.02<br><u>&lt;0.02</u><br><0.02 | 55-96<br>USA-MW-FR-511-96-<br>A |
| MN, 1996          | 50<br>WG    | 6  | 0.14     | 0.10            | tuber            | 7<br>7           | <u>&lt;0.02</u><br><0.02                   | <u>&lt;0.02</u><br><0.02                   | 55-96<br>USA-MW-FR-512-96       |
| WI, 1996          | 50<br>WG    | 6  | 0.14     | 0.075           | tuber            | 7<br>7           | <u>&lt;0.02</u><br><0.02                   | <u>&lt;0.02</u><br><0.02                   | 55-96<br>USA-MW-FR-706-96       |
| MI, 1996          | 50<br>WG    | 6  | 0.14     | 0.065           | tuber            | 7<br>7           | <u>&lt;0.02</u><br><0.02                   | <u>&lt;0.02</u><br><0.02                   | 55-96<br>USA-NE-FR-726-96       |
| ME, 1996          | 50<br>WG    | 6  | 0.14     | 0.075           | tuber            | 7<br>7           | <u>&lt;0.02</u><br><0.02                   | <u>&lt;0.02</u><br><0.02                   | 55-96<br>USA-NE-FR-823-96       |
| NY, 1996          | 50<br>WG    | 6  | 0.14     | 0.06            | tuber            | 7<br>7           | <u>&lt;0.02</u><br><0.02                   | <u>&lt;0.02</u><br><0.02                   | 55-96<br>USA-NE-FR-824-96       |
| NC, 1996          | 50<br>WG    | 6  | 0.14     | 0.10            | tuber            | 7<br>7           | <u>&lt;0.02</u><br><0.02                   | <u>&lt;0.02</u><br><0.02                   | 55-96<br>USA-OS-FR-606-96       |
| ID, 1996          | 50<br>WG    | 6  | 0.14     | 0.30            | tuber            | 7<br>7           | <u>&lt;0.02</u><br><0.02                   | <u>&lt;0.02</u><br><0.02                   | 55-96<br>USA-OW-FR-642-96       |
| ID, 1996          | 50<br>WG    | 6  | 0.14     | 0.04            | tuber            | 7<br>7           | <u>&lt;0.02</u><br><0.02                   | <u>&lt;0.02</u><br><0.02                   | 55-96<br>USA-OW-FR-643-96       |
| WA, 1996          | 50<br>WG    | 6  | 0.14     | 0.056-<br>0.058 | tuber            | 7<br>7           | <u>&lt;0.02</u><br><0.02                   | <u>&lt;0.02</u><br><0.02                   | 55-96<br>USA-OW-FR-644-96       |
| WA, 1996          | 50<br>WG    | 6  | 0.14     | 0.056-<br>0.058 | tuber            | 7<br>7           | <u>&lt;0.02</u><br><0.02                   | <u>&lt;0.02</u><br><0.02                   | 55-96<br>USA-OW-FR-645-96       |
| OR, 1996          | 50<br>WG    | 6  | 0.14     | 0.075           | tuber            | 7<br>7           | <u>&lt;0.02</u><br><0.02                   | <u>&lt;0.02</u><br><0.02                   | 55-96<br>USA-OW-FR-646-96       |
| CA, 1996          | 50<br>WG    | 6  | 0.14     | 0.30            | tuber            | 7<br>7           | <u>&lt;0.02</u><br><0.02                   | <u>&lt;0.02</u><br><0.02                   | 55-96<br>USA-02-FR-024-96       |
| FL, 1996          | 50<br>WG    | 6  | 0.14     | 0.025           | tuber            | 7<br>7           | <u>&lt;0.02</u><br><0.02                   | <u>&lt;0.02</u><br><0.02                   | 55-96<br>USA-07-FR-004-96       |

*Sugar beet*

Table 76. Results of residue trials with trifloxystrobin on sugar beet in the USA.

| Location<br>Year | Application |    |          |                 | Residues (mg/kg) |                                                      |                                                                                              |                                                                                                  | Report No.;<br>Study No.     |
|------------------|-------------|----|----------|-----------------|------------------|------------------------------------------------------|----------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------|------------------------------|
|                  | Form        | No | kg ai/ha | kg ai/hl        | Sample           | PHI<br>(days)                                        | trifloxy-<br>strobin                                                                         | CGA321113                                                                                        |                              |
| ID, 1997         | 50<br>WG    | 3  | 0.12     | 0.26            | root             | 21<br>21                                             | <u>&lt;0.02</u><br><0.02                                                                     | <u>&lt;0.02</u><br><0.02                                                                         | 35-97<br>USA-OW-FR-626-97    |
| ID, 1997         | 50<br>WG    | 3  | 0.12     | 0.041           | root             | 21<br>21                                             | <u>&lt;0.02</u><br><0.02                                                                     | <u>&lt;0.02</u><br><0.02                                                                         | 35-97<br>USA-OW-FR-627-97    |
| CO, 1997         | 50<br>WG    | 3  | 0.12     | 0.083           | root             | 21<br>21                                             | <0.02<br><u>0.04</u>                                                                         | <0.02<br><u>&lt;0.02</u>                                                                         | 35-97<br>USA-MW-FR-312-97    |
| WI, 1997         | 50<br>WG    | 3  | 0.12     | 0.083           | root             | 21<br>21                                             | <0.02<br><u>0.02</u>                                                                         | <0.02<br><u>&lt;0.02</u>                                                                         | 35-97<br>USA-MW-FR-313-97    |
| NE, 1997         | 50<br>WG    | 3  | 0.12     | 0.066           | root             | 21<br>21                                             | <u>&lt;0.02</u><br><0.02                                                                     | <u>&lt;0.02</u><br><0.02                                                                         | 35-97<br>USA-MW-FR-622-97    |
| MI, 1997         | 50<br>WG    | 3  | 0.12     | 0.26            | root             | 21<br>21                                             | <u>&lt;0.02</u><br><0.02                                                                     | <u>&lt;0.02</u><br><0.02                                                                         | 35-97<br>USA-NE-FR-731-97    |
| MN, 1997         | 50<br>WG    | 3  | 0.12     | 0.066           | root             | 23<br>23<br>23                                       | <u>&lt;0.02</u><br><0.02<br><0.02                                                            | <u>&lt;0.02</u><br><0.02<br><0.02                                                                | 35-97<br>USA-OW-FR-223-97-A  |
| MN,<br>1997      | 50<br>WG    | 3  | 0.12     | 0.066           | root             | 0<br>0<br>7<br>7<br>14<br>14<br>21<br>21<br>28<br>28 | 0.06<br>0.06<br><0.02<br><0.02<br>0.04<br>0.05<br>0.02<br><u>0.04</u><br><0.02<br><0.02      | <0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><u>&lt;0.02</u><br><0.02<br><0.02 | 35-97<br>USA-OW-FR-224-97    |
| CA, 1997         | 50<br>WG    | 3  | 0.12     | 0.053           | root             | 0<br>0<br>7<br>7<br>14<br>14<br>21<br>21<br>28<br>28 | 0.08<br>0.07<br><0.02<br><0.02<br>0.03<br>0.03<br><u>&lt;0.02</u><br><0.02<br><0.02<br><0.02 | <0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><u>&lt;0.02</u><br><0.02<br><0.02<br><0.02 | 35-97<br>USA-OW-FR-402-97    |
| ID, 1997         | 50<br>WG    | 3  | 0.12     | 0.26            | root             | 21<br>21                                             | <u>&lt;0.02</u><br><0.02                                                                     | <u>&lt;0.02</u><br><0.02                                                                         | 35-97<br>USA-OW-FR-626-97    |
| ID, 1997         | 50<br>WG    | 3  | 0.12     | 0.041           | root             | 21<br>21                                             | <u>&lt;0.02</u><br><0.02                                                                     | <u>&lt;0.02</u><br><0.02                                                                         | 35-97<br>USA-OW-FR-627-97    |
| NE, 1998         | 50<br>WG    | 3  | 0.12     | 0.066           | root             | 21<br>21                                             | <u>0.03</u><br><0.02                                                                         | <u>&lt;0.02</u><br><0.02                                                                         | 152-98<br>USA-MW-FR-615-98-A |
| MN,<br>1998      | 50<br>WG    | 3  | 0.12     | 0.066           | root             | 21<br>21                                             | <0.02<br><u>0.03</u>                                                                         | 0.02<br><u>0.03</u>                                                                              | 152-98<br>USA-OW-FR-216-98-A |
| ID, 1998         | 50<br>WG    | 3  | 0.12     | 0.044-<br>0.046 | root             | 21<br>21                                             | <0.02<br><u>0.03</u>                                                                         | <0.02<br><u>&lt;0.02</u>                                                                         | 152-98<br>USA-OW-FR-312-98-A |
| CA, 1998         | 50<br>WG    | 3  | 0.12     | 0.044-<br>0.046 | root             | 21<br>21                                             | <u>&lt;0.02</u><br><0.02                                                                     | <u>&lt;0.02</u><br><0.02                                                                         | 152-98<br>USA-OW-FR-522-98-A |
| NE, 1998         | 250<br>EC   | 3  | 0.12     | 0.066           | root             | 21<br>21                                             | <u>&lt;0.02</u><br><0.02                                                                     | <u>&lt;0.02</u><br><0.02                                                                         | 152-98<br>USA-MW-FR-615-98-B |
| MN, 1998         | 250<br>EC   | 3  | 0.12     | 0.066           | root             | 21<br>21                                             | <u>0.02</u><br><0.02                                                                         | <u>&lt;0.02</u><br><0.02                                                                         | 152-98<br>USA-OW-FR-216-98-B |
| ID, 1998         | 250<br>EC   | 3  | 0.12     | 0.044-<br>0.046 | root             | 21<br>21                                             | <u>&lt;0.02</u><br><0.02                                                                     | <u>&lt;0.02</u><br><0.02                                                                         | 152-98<br>USA-OW-FR-312-98-B |
| CA, 1998         | 250<br>EC   | 3  | 0.12     | 0.044           | root             | 21<br>21                                             | <u>0.02</u><br>0.02                                                                          | <u>&lt;0.02</u><br><0.02                                                                         | 152-98<br>USA-OW-FR-522-98-B |

Table 77. Results of residue trials with trifloxystrobin on sugar beet in Europe.

| Country,<br>Year       | Application |    |          |                 | Residues (mg/kg) |                                |                                                              |                                                              | Report No.;<br>Study No.               |
|------------------------|-------------|----|----------|-----------------|------------------|--------------------------------|--------------------------------------------------------------|--------------------------------------------------------------|----------------------------------------|
|                        | Form        | No | kg ai/ha | kg ai/hl        | Sample           | PHI<br>(days)                  | trifloxy-<br>strobin                                         | CGA3211<br>13                                                |                                        |
| France-<br>North, 1999 | 267.5<br>EC | 2  | 0.13     | 0.04            | root             | 45<br>45                       | <0.02<br><0.02                                               | <0.02<br><0.02                                               | 9911101<br>FRA-9911101                 |
| France-<br>North, 1999 | 267.5<br>EC | 2  | 0.13     | 0.04-0.05       | root             | 45<br>45                       | <0.02<br><0.02                                               | <0.02<br><0.02                                               | 9911102<br>FRA-9911102                 |
| France-<br>North, 1998 | 267.5<br>EC | 2  | 0.13     | 0.05            | root             | 46<br>46                       | <0.02<br><0.02                                               | <0.02<br><0.02                                               | 2163/98<br>FRA-2163-98                 |
| France-<br>North, 1998 | 267.5<br>EC | 2  | 0.13     | 0.03            | root             | 43<br>43                       | <0.02<br><0.02                                               | <0.02<br><0.02                                               | 2164/98<br>FRA-2164-98                 |
| France-<br>North, 1999 | 267.5<br>EC | 2  | 0.13     | 0.05            | root             | 0<br>21<br>30<br>45            | <0.02<br><u>&lt;0.02</u><br><0.02<br><0.02                   | <0.02<br><u>&lt;0.02</u><br><0.02<br><0.02                   | 9910901<br>FRA-9910901                 |
| France-<br>North, 1999 | 267.5<br>EC | 2  | 0.13     | 0.05            | root             | 0<br>21<br>30<br>45            | <0.02<br><u>&lt;0.02</u><br><0.02<br><0.02                   | <0.02<br><u>&lt;0.02</u><br><0.02<br><0.02                   | 9910902<br>FRA-9910902                 |
| France-<br>North, 1999 | 267.5<br>EC | 2  | 0.13     | 0.04            | root             | 0<br>21<br>30<br>45            | <0.02<br><u>&lt;0.02</u><br><0.02<br><0.02                   | <0.02<br><u>&lt;0.02</u><br><0.02<br><0.02                   | 9910903<br>FRA-9910903                 |
| France-<br>South, 1999 | 267.5<br>EC | 2  | 0.13     | 0.03            | root             | 0<br>22<br>30<br>43            | <0.02<br><u>&lt;0.02</u><br><0.02<br><0.02                   | <0.02<br><u>&lt;0.02</u><br><0.02<br><0.02                   | 9911001<br>FRA-9911001-A               |
| France-<br>South, 1999 | 267.5<br>EC | 3  | 0.13     | 0.03            | root             | 0<br>22<br>30<br>43            | <0.02<br><u>&lt;0.02</u><br><0.02<br><0.02                   | <0.02<br><u>&lt;0.02</u><br><0.02<br><0.02                   | 9911001<br>FRA-9911001-B               |
| France-<br>South, 1999 | 267.5<br>EC | 2  | 0.13     | 0.04            | root             | 0<br>21<br>30<br>45            | <0.02<br><u>&lt;0.02</u><br><0.02<br><0.02                   | <0.02<br><u>&lt;0.02</u><br><0.02<br><0.02                   | 9911002<br>FRA-9911002-A               |
| France-<br>South, 1999 | 267.5<br>EC | 3  | 0.13     | 0.04            | root             | 0<br>21<br>30<br>45            | <0.02<br><u>&lt;0.02</u><br><0.02<br><0.02                   | <0.02<br><u>&lt;0.02</u><br><0.02<br><0.02                   | 9911002<br>FRA-9911002-B               |
| France-<br>South, 2000 | 267.5<br>EC | 3  | 0.13     | 0.013           | root             | 0<br>20<br>20                  | 0.08<br><u>0.02</u><br><0.02                                 | 0.02<br><u>&lt;0.02</u><br><0.02                             | NOV/RES/00061<br>FRA-NOV-RES-<br>00061 |
| France-<br>South, 2000 | 267.5<br>EC | 3  | 0.13     | 0.03            | root             | 0<br>20<br>20                  | 0.02<br><u>&lt;0.02</u><br><0.02                             | <0.02<br><u>&lt;0.02</u><br><0.02                            | NOV/RES/00062<br>FRA-NOV-RES-<br>00062 |
| Spain, 1999            | 267.5<br>EC | 3  | 0.13     | 0.013           | root             | 21<br>21                       | <u>&lt;0.02</u><br><0.02                                     | <u>&lt;0.02</u><br><0.02                                     | 2060/99<br>SPA-2060-99                 |
| Spain, 1999            | 267.5<br>EC | 3  | 0.13     | 0.012-<br>0.014 | root             | 0<br>7<br>14<br>21<br>21       | <0.02<br><0.02<br><0.02<br><u>&lt;0.02</u><br><0.02          | <0.02<br><0.02<br><0.02<br><u>&lt;0.02</u><br><0.02          | 2061/99<br>SPA-2061-99                 |
| Italy, 1999            | 267.5<br>EC | 3  | 0.13     | 0.02            | root             | 0<br>7<br>14<br>21<br>21<br>28 | <0.02<br><0.02<br><0.02<br><0.02<br><u>&lt;0.02</u><br><0.02 | <0.02<br><0.02<br><0.02<br><0.02<br><u>&lt;0.02</u><br><0.02 | 2074/99<br>ITA-2074-99                 |
| Italy, 1999            | 267.5<br>EC | 3  | 0.13     | 0.02            | root             | 21<br>21                       | <u>&lt;0.02</u><br><0.02                                     | <u>&lt;0.02</u><br><0.02                                     | 2075/99<br>ITA-2075-99                 |

| Country,<br>Year     | Application |    |          |          | Residues (mg/kg) |               |                      |                 | Report No.;<br>Study No. |
|----------------------|-------------|----|----------|----------|------------------|---------------|----------------------|-----------------|--------------------------|
|                      | Form        | No | kg ai/ha | kg ai/hl | Sample           | PHI<br>(days) | trifloxy-<br>strobin | CGA3211<br>13   |                          |
| Switzerland,<br>1999 | 267.5<br>EC | 2  | 0.13     | 0.02     | root             | 0             | <0.02                | <0.02           | 2086/99<br>SWZ-2086-99   |
|                      |             |    |          |          |                  | 21            | <u>&lt;0.02</u>      | <u>&lt;0.02</u> |                          |
|                      |             |    |          |          |                  | 30            | <0.02                | <0.02           |                          |
|                      |             |    |          |          |                  | 45            | <0.02                | <0.02           |                          |
|                      |             |    |          |          |                  | 45            | <0.02                | <0.02           |                          |

*Stalk and stem vegetables*

*Celery*

Table 78. Results of residue trials with trifloxystrobin on celery in Switzerland in 2000.

| Application |    |          |          | Residues (mg/kg)             |                |                      |                 | Report No.;<br>Study No. |
|-------------|----|----------|----------|------------------------------|----------------|----------------------|-----------------|--------------------------|
| Form        | No | kg ai/ha | kg ai/hl | Sample                       | PHI<br>(days)  | trifloxy-<br>strobin | CGA321113       |                          |
| 50 WG       | 3  | 0.25     | 0.05     | whole plant<br>without roots | 0              | 0.29                 | <0.01           | 2146/00<br>SWZ-2146-00   |
|             |    |          |          |                              | 3              | 0.33                 | <0.01           |                          |
|             |    |          |          |                              | 7              | <u>0.18</u>          | <u>&lt;0.01</u> |                          |
|             |    |          |          |                              | 14             | 0.12                 | <0.01           |                          |
|             |    |          |          |                              | 14             | 0.11                 | <0.01           |                          |
| 50 WG       | 4  | 0.25     | 0.05     | whole plant<br>without roots | 0 <sup>1</sup> | 0.27                 | <0.01           | 2050/00<br>SWZ-2050-00   |
|             |    |          |          |                              | 0              | 0.56                 | <0.01           |                          |
|             |    |          |          |                              | 3              | 0.42                 | 0.01            |                          |
|             |    |          |          |                              | 7              | <u>0.21</u>          | <u>&lt;0.01</u> |                          |
|             |    |          |          |                              | 14             | 0.13                 | <0.01           |                          |
| 50 WG       | 3  | 0.25     | 0.05     | whole plant<br>without roots | 0              | 0.09                 | <0.01           | 2051/00<br>SWZ-2051-00   |
|             |    |          |          |                              | 3              | 0.06                 | <0.01           |                          |
|             |    |          |          |                              | 7              | <u>0.12</u>          | <u>&lt;0.01</u> |                          |
|             |    |          |          |                              | 14             | 0.11                 | <0.01           |                          |
|             |    |          |          |                              | 14             | 0.16                 | <0.01           |                          |

*Witloof chicory (sprouts)*

Table 79. Results of residue field trials with trifloxystrobin on witloof chicory in Switzerland in 2000.

| Application |    |          |          | Residues (mg/kg) |               |                      |                 | Report No.;<br>Study No. |
|-------------|----|----------|----------|------------------|---------------|----------------------|-----------------|--------------------------|
| Form        | No | kg ai/ha | kg ai/hl | Sample           | PHI<br>(days) | trifloxy-<br>strobin | CGA321113       |                          |
| 50 WG       | 3  | 0.25     | 0.05     | leaf             | 0             | 5.4                  | 0.11            | 2069/00<br>SWZ-2069-00   |
|             |    |          |          |                  | 21            | <u>0.34</u>          | <u>0.03</u>     |                          |
|             |    |          |          |                  | 21            | 0.32                 | 0.03            |                          |
|             |    |          |          | root             | 21            | 0.01                 | <0.01           |                          |
|             |    |          |          |                  | 21            | <u>0.02</u>          | <u>&lt;0.01</u> |                          |
| 50 WG       | 3  | 0.25     | 0.05     | leaf             | 0             | 8.0                  | 0.13            | 2070/00<br>SWZ-2070-00   |
|             |    |          |          |                  | 21            | <u>0.86</u>          | <u>0.08</u>     |                          |
|             |    |          |          |                  | 21            | 0.74                 | 0.08            |                          |
|             |    |          |          | root             | 21            | 0.01                 | <0.01           |                          |
|             |    |          |          |                  | 21            | <u>0.02</u>          | <u>&lt;0.01</u> |                          |

*Cereal grains**Barley*

Table 80. Results of residue trials with trifloxystrobin on barley grain.

| Country,<br>Year                        | Application |    |           |          | Residues (mg/kg)     |                                            |                                        | Report No.;<br>Study No. |
|-----------------------------------------|-------------|----|-----------|----------|----------------------|--------------------------------------------|----------------------------------------|--------------------------|
|                                         | Form        | No | kg ai/ha  | kg ai/hl | PHI<br>(days)        | trifloxy-<br>strobin                       | CGA321113                              |                          |
| Barley<br>France- South<br>2000         | 500<br>SC   | 2  | 0.24-0.26 | 0.06     | 42<br>42             | 0.10<br><u>0.13</u>                        | <0.02<br><u>0.03</u>                   | 0011601<br>FRA-0011601   |
| Barley<br>France-South<br>2000          | 500<br>SC   | 2  | 0.25-0.26 | 0.06     | 42<br>42             | <u>0.07</u><br>0.05                        | <u>&lt;0.02</u><br><0.02               | 0011602<br>FRA-0011602   |
| Barley<br>France- South<br>1997         | 125<br>EC   | 2  | 0.25      | 0.06     | 38                   | <u>0.18</u>                                | <u>&lt;0.02</u>                        | 2166/97<br>FRA-2166-97   |
| Barley<br>France- South<br>1997         | 125<br>EC   | 2  | 0.25      | 0.075    | 34                   | <u>0.02</u>                                | <u>&lt;0.02</u>                        | 2167/97<br>FRA-2167-97   |
| Barley<br>France- South<br>1997         | 125<br>EC   | 2  | 0.25      | 0.06     | 34                   | <u>0.05</u>                                | <u>0.02</u>                            | 2168/97<br>FRA-2168-97   |
| Barley<br>France- South<br>1997         | 125<br>EC   | 2  | 0.25      | 0.06     | 34                   | <u>0.11</u>                                | <u>0.04</u>                            | 2169/97<br>FRA-2169-97   |
| Barley, winter<br>France- South<br>1996 | 125<br>EC   | 2  | 0.25      | 0.06     | 41                   | <u>&lt;0.02</u>                            | <u>&lt;0.02</u>                        | OF96118/LD88<br>FRA-LD88 |
| Barley, winter<br>France- South<br>1996 | 125<br>EC   | 2  | 0.25      | 0.06     | 42                   | <u>&lt;0.02</u>                            | <u>&lt;0.02</u>                        | OF96119/BY02<br>FRA-BY02 |
| Barley<br>France- South<br>1997         | 267.5<br>EC | 2  | 0.19      | 0.05     | 43                   | <u>&lt;0.02</u>                            | <u>&lt;0.02</u>                        | 2228/97<br>FRA-2228-97   |
| Barley<br>France- South<br>1997         | 267.5<br>EC | 2  | 0.19      | 0.05     | 45                   | <u>&lt;0.02</u>                            | <u>&lt;0.02</u>                        | 2229/97<br>FRA-2229-97   |
| Barley<br>France- South<br>1997         | 267.5<br>EC | 2  | 0.19      | 0.06     | 45                   | <u>0.02</u>                                | <u>&lt;0.02</u>                        | 2230/97<br>FRA-2230-97   |
| Barley<br>France- South<br>1997         | 267.5<br>EC | 2  | 0.19      | 0.05     | 42                   | <u>0.12</u>                                | <u>0.02</u>                            | 2231/97<br>FRA-2231-97   |
| Barley, winter<br>France- South<br>1998 | 267.5<br>EC | 2  | 0.17-0.18 | 0.05     | 33<br>33<br>45<br>45 | 0.05<br>0.05<br><u>0.07</u><br><u>0.07</u> | <0.02<br><0.02<br><u>0.02</u><br><0.02 | 9813203<br>FRA-9813203   |
| Barley, winter<br>France- South<br>1998 | 267.5<br>EC | 2  | 0.18      | 0.05     | 33<br>33<br>45<br>45 | 0.09<br>0.08<br><u>0.13</u><br>0.11        | 0.03<br>0.03<br><u>0.04</u><br>0.04    | 9813204<br>FRA-9813204   |
| Barley<br>France- North<br>1997         | 535<br>SC   | 2  | 0.19      | 0.05     | 40                   | <u>0.05</u>                                | <u>&lt;0.02</u>                        | 2224/97<br>FRA-2224-97   |
| Barley<br>France- North<br>1997         | 535<br>SC   | 2  | 0.19      | 0.05     | 44                   | <u>0.04</u>                                | <u>&lt;0.02</u>                        | 2225/97<br>FRA-2225-97   |
| Barley<br>France- North<br>1997         | 535<br>SC   | 2  | 0.19      | 0.05     | 46                   | <u>0.04</u>                                | <u>&lt;0.02</u>                        | 2226/97<br>FRA-2226-97   |

| Country,<br>Year                         | Application |    |           |          | Residues (mg/kg)     |                                            |                                            | Report No.;<br>Study No. |
|------------------------------------------|-------------|----|-----------|----------|----------------------|--------------------------------------------|--------------------------------------------|--------------------------|
|                                          | Form        | No | kg ai/ha  | kg ai/hl | PHI<br>(days)        | trifloxy-<br>strobin                       | CGA321113                                  |                          |
| Barley<br>France- North<br>1997          | 535<br>SC   | 2  | 0.19      | 0.05     | 46                   | <u>0.05</u>                                | <u>&lt;0.02</u>                            | 2227/97<br>FRA-2227-97   |
| Barley, spring<br>France- North<br>1998  | 267.5<br>EC | 2  | 0.18-0.19 | 0.05     | 45<br>45             | <u>&lt;0.02</u><br><0.02                   | <u>&lt;0.02</u><br><0.02                   | 9810602<br>FRA-9810602   |
| Barley, winter<br>France- North<br>1998  | 267.5<br>EC | 2  | 0.19      | 0.05     | 43<br>43             | <u>0.02</u><br>0.02                        | <u>&lt;0.02</u><br><0.02                   | 9810502<br>FRA-9810502   |
| Barley, winter<br>France- North<br>1998  | 267.5<br>EC | 2  | 0.19      | 0.05     | 35<br>35<br>47<br>47 | <u>&lt;0.02</u><br><0.02<br><0.02<br><0.02 | <u>&lt;0.02</u><br><0.02<br><0.02<br><0.02 | 9813201<br>FRA-9813201   |
| Barley, winter<br>France- North<br>1998  | 267.5<br>EC | 2  | 0.18      | 0.05     | 35<br>35<br>47<br>47 | <u>&lt;0.02</u><br><0.02<br><0.02<br><0.02 | <u>&lt;0.02</u><br><0.02<br><0.02<br><0.02 | 9813202<br>FRA-9813202   |
| Barley<br>France- North<br>1997          | 267.5<br>EC | 2  | 0.19      | 0.05     | 40                   | <u>0.03</u>                                | <u>&lt;0.02</u>                            | 2220/97<br>FRA-2220-97   |
| Barley<br>France- North<br>1997          | 267.5<br>EC | 2  | 0.19      | 0.05     | 44                   | <u>&lt;0.02</u>                            | <u>&lt;0.02</u>                            | 2221/97<br>FRA-2221-97   |
| Barley<br>France- North<br>1997          | 267.5<br>EC | 2  | 0.19      | 0.05     | 46                   | <u>0.03</u>                                | <u>&lt;0.02</u>                            | 2222/97<br>FRA-2222-97   |
| Barley<br>France- North<br>1997          | 267.5<br>EC | 2  | 0.19      | 0.05     | 46                   | <u>0.03</u>                                | <u>&lt;0.02</u>                            | 2223/97<br>FRA-2223-97   |
| Barley, winter<br>France –<br>North 1997 | 250<br>EC   | 2  | 0.25      | 0.06     | 45                   | <u>&lt;0.02</u>                            | <u>&lt;0.02</u>                            | 9711601<br>FRA-9711601   |
| Barley, spring<br>France- North<br>1997  | 250<br>EC   | 2  | 0.25      | 0.06     | 45                   | <u>&lt;0.02</u>                            | <u>&lt;0.02</u>                            | 9715102<br>FRA-9715102   |
| Barley, spring<br>France- North<br>1999  | 125<br>EC   | 2  | 0.25      | 0.06     | 46<br>46<br>46       | <u>0.03</u><br>0.03<br>0.02                | <u>0.01</u><br>0.01<br><0.01               | 2021/99<br>FRA-2021-99   |
| Barley, spring<br>France- North<br>1999  | 125<br>EC   | 2  | 0.25-0.26 | 0.06     | 39<br>39<br>39       | 0.04<br><u>0.06</u><br>0.04                | 0.01<br><u>0.01</u><br>0.01                | 2022/99<br>FRA-2022-99   |
| Barley, winter<br>Denmark<br>1996        | 125<br>EC   | 2  | 0.25      | 0.10     | 42<br>58             | 0.10<br><u>0.11</u>                        | <0.02<br><u>&lt;0.02</u>                   | FR0796<br>DAE-FR0796     |
| Barley, winter<br>Germany<br>1996        | 125<br>EC   | 2  | 0.25      | 0.06     | 35<br>42             | <0.02<br><u>0.02</u>                       | <0.02<br><u>&lt;0.02</u>                   | gr37296<br>BRD-2170-96   |
| Barley, winter<br>Germany<br>1999        | 125<br>EC   | 2  | 0.25      | 0.06     | 35<br>42             | <u>0.40</u><br><0.02                       | <u>0.06</u><br><0.02                       | gr37399<br>BRD-2143-99   |
| Barley, winter<br>Germany<br>1995        | 312.5<br>EC | 2  | 0.19      | 0.05     | 35<br>42             | <u>0.03</u><br>0.03                        | <u>&lt;0.02</u><br><0.02                   | gr3295<br>BRD-gr22395    |
| Barley, winter<br>Germany<br>1996        | 312.5<br>EC | 2  | 0.19      | 0.05     | 35<br>42             | <u>0.07</u><br>0.04                        | <u>0.02</u><br>0.02                        | gr33696<br>BRD-gr33696   |
| Barley, winter<br>Germany<br>2000        | 500<br>SC   | 2  | 0.25      | 0.06     | 34                   | <u>0.12</u>                                | <u>0.01</u>                                | gr59100<br>BRD-gr59100   |
| Barley, spring<br>Germany<br>1999        | 125<br>EC   | 2  | 0.25      | 0.06     | 34<br>41             | <u>0.05</u><br>0.04                        | <u>0.02</u><br>0.03                        | gr35199<br>BRD-2141-99   |

| Country,<br>Year                        | Application |    |          |          | Residues (mg/kg) |                      |                 | Report No.;<br>Study No. |
|-----------------------------------------|-------------|----|----------|----------|------------------|----------------------|-----------------|--------------------------|
|                                         | Form        | No | kg ai/ha | kg ai/hl | PHI<br>(days)    | trifloxy-<br>strobin | CGA321113       |                          |
| Barley, winter<br>Great Britain<br>1996 | 125<br>EC   | 2  | 0.25     | 0.13     | 47               | <u>0.11</u>          | <u>&lt;0.02</u> | FR0296<br>ENG-FR0296     |
| Barley, winter<br>Great Britain<br>1996 | 125<br>EC   | 2  | 0.25     | 0.13     | 44               | <u>0.11</u>          | <u>&lt;0.02</u> | FR0396<br>ENG-FR0396     |

### Wheat

Table 81. Results of residue trials with trifloxystrobin in wheat in Brazil in 2002.

| Application |    |          |          | Residues (mg/kg) |                      |           | Report No.;<br>Study No.                   |
|-------------|----|----------|----------|------------------|----------------------|-----------|--------------------------------------------|
| Form        | No | kg ai/ha | kg ai/hl | PHI<br>(days)    | trifloxy-<br>strobin | CGA321113 |                                            |
| 267.5 EC    | 3  | 0.15     | 0.05     | 30               | <0.05                | n.a.      | BRA S-A1-630/02-S1<br>BRA-S-A1-630/02-S1-A |
| 267.5 EC    | 3  | 0.15     | 0.05     | 30               | <0.05                | n.a.      | BRA S-A1-630/02-S2<br>BRA-S-A1-630/02-S2-A |
| 267.5 EC    | 3  | 0.15     | 0.05     | 30               | <0.05                | n.a.      | BRA S-A1-630/02-S3<br>BRA-S-A1-630/02-S3-A |
| 250 EC      | 3  | 0.13     | 0.042    | 30               | <0.05                | n.a.      | BRA S-A1-631/02-S1<br>BRA-S-A1-631/02-S1-A |
| 250 EC      | 3  | 0.13     | 0.063    | 30               | <0.05                | n.a.      | BRA S-A1-631/02-S2<br>BRA-S-A1-631/02-S2-A |
| 250 EC      | 3  | 0.13     | 0.063    | 30               | <0.05                | n.a.      | BRA S-A1-631/02-S3<br>BRA-S-A1-631/02-S3-A |

n.a. not analysed

Table 82. Results of residue trials with trifloxystrobin in wheat in the USA.

| Location,<br>Year  | Application |    |          |               | Residues (mg/kg) |               |                                    |                                    | Report No.;<br>Study No.     |
|--------------------|-------------|----|----------|---------------|------------------|---------------|------------------------------------|------------------------------------|------------------------------|
|                    | Form        | No | kg ai/ha | kg ai/hl      | Sample           | PHI<br>(days) | trifloxy-<br>strobin               | CGA321113                          |                              |
| KS, 1998           | 250<br>EC   | 2  | 0.12     | 0.10          | grain            | 35<br>35      | <u>&lt;0.02</u><br><u>&lt;0.02</u> | <u>&lt;0.02</u><br><u>&lt;0.02</u> | 153-98<br>USA-MW-FR-313-98-D |
| OK, 1998           | 250<br>EC   | 2  | 0.12     | 0.09          | grain            | 30<br>30      | <u>&lt;0.02</u><br><u>&lt;0.02</u> | <u>&lt;0.02</u><br><u>&lt;0.02</u> | 153-98<br>USA-OS-FR-732-98-D |
| TX, 1998           | 250<br>EC   | 2  | 0.12     | 0.10          | grain            | 37<br>37      | <u>&lt;0.02</u><br><u>&lt;0.02</u> | <u>&lt;0.02</u><br><u>&lt;0.02</u> | 153-98<br>USA-OS-FR-733-98-D |
| ND, 1998           | 250<br>EC   | 2  | 0.12     | 0.09          | grain            | 37<br>37      | <0.02<br><u>0.02</u>               | <u>&lt;0.02</u><br><u>&lt;0.02</u> | 153-98<br>USA-OW-FR-217-98-D |
| NC, 1998           | 250<br>EC   | 2  | 0.12     | 0.13          | grain            | 45<br>45      | <u>&lt;0.02</u><br><u>&lt;0.02</u> | <u>&lt;0.02</u><br><u>&lt;0.02</u> | 153-98<br>USA-OS-FR-613-98-D |
| KS, 1998           | 50<br>WG    | 2  | 0.12     | 0.10          | grain            | 35<br>35      | <u>&lt;0.02</u><br><u>&lt;0.02</u> | <u>&lt;0.02</u><br><u>&lt;0.02</u> | 153-98<br>USA-MW-FR-313-98-C |
| NC, 1998           | 50<br>WG    | 2  | 0.12     | 0.13          | grain            | 45<br>45      | <u>&lt;0.02</u><br><u>&lt;0.02</u> | <u>&lt;0.02</u><br><u>&lt;0.02</u> | 153-98<br>USA-OS-FR-613-98-C |
| TX, 1998           | 50<br>WG    | 2  | 0.12     | 0.10          | grain            | 37<br>37      | <u>&lt;0.02</u><br><u>&lt;0.02</u> | <u>&lt;0.02</u><br><u>&lt;0.02</u> | 153-98<br>USA-OS-FR-733-98-C |
| ND, 1998           | 50<br>WG    | 2  | 0.12     | 0.09          | grain            | 37<br>37      | <u>&lt;0.02</u><br><u>&lt;0.02</u> | <u>&lt;0.02</u><br><u>&lt;0.02</u> | 153-98<br>USA-OW-FR-217-98-C |
| spring<br>MT, 1997 | 50<br>WG    | 1  | 0.12     | 0.08          | grain            | 36<br>36      | <u>&lt;0.02</u><br><u>&lt;0.02</u> | <u>&lt;0.02</u><br><u>&lt;0.02</u> | 43-97<br>USA-OW-FR-204-97-B  |
| spring<br>MT, 1997 | 50<br>WG    | 2  | 0.12     | 0.07-<br>0.08 | grain            | 36<br>36      | <u>&lt;0.02</u><br><u>&lt;0.02</u> | <u>&lt;0.02</u><br><u>&lt;0.02</u> | 43-97<br>USA-OW-FR-204-97-C  |

| Location,<br>Year  | Application |    |           |               | Residues (mg/kg) |                                              |                                                                             |                                                                             | Report No.;<br>Study No.    |
|--------------------|-------------|----|-----------|---------------|------------------|----------------------------------------------|-----------------------------------------------------------------------------|-----------------------------------------------------------------------------|-----------------------------|
|                    | Form        | No | kg ai/ha  | kg ai/hl      | Sample           | PHI<br>(days)                                | trifloxy-<br>strobin                                                        | CGA321113                                                                   |                             |
| spring<br>MT, 1997 | 50<br>WG    | 1  | 0.12      | 0.07          | grain            | 43<br>43                                     | <u>≤0.02</u><br><0.02                                                       | <u>≤0.02</u><br><0.02                                                       | 43-97<br>USA-OW-FR-205-97-B |
| spring<br>MT, 1997 | 50<br>WG    | 2  | 0.12      | 0.07-<br>0.08 | grain            | 43<br>43                                     | <0.02<br><u>0.03</u>                                                        | <0.02<br><u>≤0.02</u>                                                       | 43-97<br>USA-OW-FR-205-97-C |
| spring<br>MN, 1997 | 50<br>WG    | 1  | 0.12      | 0.05          | grain            | 44<br>44                                     | <u>≤0.02</u><br><0.02                                                       | <u>≤0.02</u><br><0.02                                                       | 43-97<br>USA-OW-FR-220-97-B |
| spring<br>MN, 1997 | 50<br>WG    | 2  | 0.12      | 0.05          | grain            | 44<br>44                                     | <u>≤0.02</u><br><0.02                                                       | <u>≤0.02</u><br><0.02                                                       | 43-97<br>USA-OW-FR-220-97-C |
| winter<br>MO, 1997 | 50<br>WG    | 1  | 0.12      | 0.07          | grain            | 43<br>43                                     | <u>≤0.02</u><br><0.02                                                       | <u>≤0.02</u><br><0.02                                                       | 43-97<br>USA-MW-FR-201-97-B |
| winter<br>MO, 1997 | 50<br>WG    | 2  | 0.12      | 0.07          | grain            | 43<br>43                                     | <u>≤0.02</u><br><0.02                                                       | <u>≤0.02</u><br><0.02                                                       | 43-97<br>USA-MW-FR-201-97-C |
| winter<br>KS, 1997 | 50<br>WG    | 1  | 0.14      | 0.07          | grain            | 36<br>36<br>36                               | <u>≤0.02</u><br><0.02<br><0.02                                              | <u>≤0.02</u><br><0.02<br><0.02                                              | 43-97<br>USA-MW-FR-309-97-B |
| winter<br>KS, 1997 | 50<br>WG    | 2  | 0.12-0.14 | 0.07          | grain            | 36<br>36<br>36                               | <u>≤0.02</u><br><0.02<br><0.02                                              | <u>≤0.02</u><br><0.02<br><0.02                                              | 43-97<br>USA-MW-FR-309-97-C |
| winter<br>KS, 1997 | 50<br>WG    | 1  | 0.12      | 0.13          | grain            | 35<br>35                                     | <u>≤0.02</u><br><0.02                                                       | <u>≤0.02</u><br><0.02                                                       | 43-97<br>USA-MW-FR-310-97-B |
| winter<br>KS, 1997 | 50<br>WG    | 2  | 0.12      | 0.13          | grain            | 35<br>35                                     | <u>≤0.02</u><br><0.02                                                       | <u>≤0.02</u><br><0.02                                                       | 43-97<br>USA-MW-FR-310-97-C |
| winter<br>CO, 1997 | 50<br>WG    | 1  | 0.12      | 0.09          | grain            | 38<br>38                                     | <u>≤0.02</u><br><0.02                                                       | <u>≤0.02</u><br><0.02                                                       | 43-97<br>USA-MW-FR-311-97-B |
| winter<br>CO, 1997 | 50<br>WG    | 2  | 0.12      | 0.09          | grain            | 38<br>38                                     | <u>≤0.02</u><br><0.02                                                       | <u>≤0.02</u><br><0.02                                                       | 43-97<br>USA-MW-FR-311-97-C |
| winter<br>NE, 1997 | 50<br>WG    | 1  | 0.12      | 0.07          | grain            | 33<br>33                                     | <u>≤0.02</u><br><0.02                                                       | <u>≤0.02</u><br><0.02                                                       | 43-97<br>USA-MW-FR-621-97-B |
| winter<br>NE, 1997 | 50<br>WG    | 2  | 0.12      | 0.07          | grain            | 33<br>33                                     | <u>≤0.02</u><br><0.02                                                       | <u>≤0.02</u><br><0.02                                                       | 43-97<br>USA-MW-FR-621-97-C |
| winter<br>AR, 1997 | 50<br>WG    | 1  | 0.12      | 0.09          | grain            | 43<br>43                                     | <u>≤0.02</u><br><0.02                                                       | <u>≤0.02</u><br><0.02                                                       | 43-97<br>USA-OS-FR-103-97-B |
| winter<br>AR, 1997 | 50<br>WG    | 2  | 0.12      | 0.09          | grain            | 43<br>43                                     | <u>0.03</u><br>0.02                                                         | <u>≤0.02</u><br><0.02                                                       | 43-97<br>USA-OS-FR-103-97-C |
| winter<br>NC, 1997 | 50<br>WG    | 1  | 0.12      | 0.09          | grain            | 34<br>34                                     | <u>≤0.02</u><br><0.02                                                       | <u>≤0.02</u><br><0.02                                                       | 43-97<br>USA-OS-FR-603-97-B |
| winter<br>NC, 1997 | 50<br>WG    | 2  | 0.12      | 0.09          | grain            | 34<br>34                                     | <u>≤0.02</u><br><0.02                                                       | <u>≤0.02</u><br><0.02                                                       | 43-97<br>USA-OS-FR-603-97-C |
| winter<br>OK, 1997 | 50<br>WG    | 1  | 0.12      | 0.09          | grain            | 34<br>34<br>38<br>38<br>44<br>44<br>51<br>51 | <u>≤0.02</u><br><0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><0.02 | <u>≤0.02</u><br><0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><0.02 | 43-97<br>USA-OS-FR-730-97-B |
| winter<br>OK, 1997 | 50<br>WG    | 2  | 0.12      | 0.09          | grain            | 34<br>34<br>38<br>38<br>44<br>44<br>51<br>51 | <u>≤0.02</u><br><0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><0.02 | <u>≤0.02</u><br><0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><0.02 | 43-97<br>USA-OS-FR-730-97-C |
| winter<br>OK, 1997 | 50<br>WG    | 1  | 0.12      | 0.07          | grain            | 47<br>47<br>47                               | <0.02<br><0.02<br><0.02                                                     | <0.02<br><0.02<br><0.02                                                     | 43-97<br>USA-OS-FR-731-97-B |



| Location,<br>Year  | Application |    |          |          | Residues (mg/kg) |                |                                    |                                    | Report No.;<br>Study No.    |
|--------------------|-------------|----|----------|----------|------------------|----------------|------------------------------------|------------------------------------|-----------------------------|
|                    | Form        | No | kg ai/ha | kg ai/hl | Sample           | PHI<br>(days)  | trifloxy-<br>strobin               | CGA321113                          |                             |
| winter<br>OK, 1997 | 50<br>WG    | 2  | 0.12     | 0.07     | grain            | 47<br>47<br>47 | <0.02<br><0.02<br><0.02            | <0.02<br><0.02<br><0.02            | 43-97<br>USA-OS-FR-731-97-C |
| winter<br>TX, 1997 | 50<br>WG    | 1  | 0.12     | 0.08     | grain            | 32<br>32       | <u>&lt;0.02</u><br><u>&lt;0.02</u> | <u>&lt;0.02</u><br><u>&lt;0.02</u> | 43-97<br>USA-OS-FR-735-97-B |
| winter<br>TX, 1997 | 50<br>WG    | 2  | 0.12     | 0.08     | grain            | 32<br>32       | <u>&lt;0.02</u><br><0.02           | <u>&lt;0.02</u><br><0.02           | 43-97<br>USA-OS-FR-735-97-C |

Table 83. Results of residue trials with trifloxystrobin in wheat in Europe.

| Country,<br>Year                        | Application |    |          |          | Residues (mg/kg) |                |                                   |                                   | Report No.;<br>Study No. |
|-----------------------------------------|-------------|----|----------|----------|------------------|----------------|-----------------------------------|-----------------------------------|--------------------------|
|                                         | Form        | No | kg ai/ha | kg ai/hl | Sample           | PHI<br>(days)  | trifloxy-<br>strobin              | CGA321<br>113                     |                          |
| Wheat, winter<br>Germany 2000           | 500<br>SC   | 2  | 0.25     | 0.06     | grain            | 35             | <u>0.14</u>                       | <u>0.06</u>                       | gr57100<br>BRD-gr57100   |
| Wheat, winter<br>Germany 2000           | 500<br>SC   | 2  | 0.25     | 0.06     | grain            | 36             | <u>0.02</u>                       | <u>&lt;0.01</u>                   | gr58200<br>BRD-gr58200   |
| Wheat, winter<br>Germany 1995           | 312.5<br>EC | 2  | 0.19     | 0.047    | grain            | 36<br>42       | <u>&lt;0.02</u><br><0.02          | <u>&lt;0.02</u><br><0.02          | gr3195<br>BRD-gr12395    |
| Wheat, winter<br>Germany 1995           | 312.5<br>EC | 2  | 0.19     | 0.047    | grain            | 35<br>42       | <u>&lt;0.02</u><br><0.02          | <u>&lt;0.02</u><br><0.02          | gr3195<br>BRD-gr42395    |
| Wheat, winter<br>France-North,<br>1995  | 312.5<br>EC | 2  | 0.19     | 0.047    | grain            | 41             | <u>&lt;0.02</u>                   | <u>&lt;0.02</u>                   | OF95137/KJ19<br>FRA-KJ19 |
| Wheat, winter<br>Germany 1996           | 312.5<br>EC | 2  | 0.19     | 0.047    | grain            | 34<br>41       | <u>&lt;0.02</u><br><0.02          | <u>&lt;0.02</u><br><0.02          | gr31196<br>BRD-gr31196   |
| Wheat, winter<br>Germany 1996           | 312.5<br>EC | 2  | 0.19     | 0.047    | grain            | 40<br>42       | <0.02<br><u>&lt;0.02</u>          | <0.02<br><u>&lt;0.02</u>          | gr32296<br>BRD-gr32296   |
| Wheat, winter<br>Sweden<br>1998         | 312.5<br>EC | 2  | 0.18     | 0.09     | grain            | 35<br>42<br>48 | <u>&lt;0.02</u><br><0.02<br><0.02 | <u>&lt;0.02</u><br><0.02<br><0.02 | gr97098<br>SWD-gr97098   |
| Wheat, winter<br>Switzerland<br>1997    | 125<br>EC   | 2  | 0.25     | 0.05     | grain            | 47             | <u>&lt;0.02</u>                   | <u>&lt;0.02</u>                   | 2272/97<br>SWZ-2272-97   |
| Wheat<br>Switzerland<br>1997            | 125<br>EC   | 2  | 0.25     | 0.05     | grain            | 42             | <u>&lt;0.02</u>                   | <u>&lt;0.02</u>                   | 2013/96<br>SWZ-2013-96   |
| Wheat, spring<br>Germany 1999           | 125<br>EC   | 2  | 0.25     | 0.06     | grain            | 34<br>41       | <u>&lt;0.02</u><br><0.02          | <u>&lt;0.02</u><br><0.02          | gr38499<br>BRD-2144-99   |
| Wheat, winter<br>Germany 1996           | 125<br>EC   | 2  | 0.25     | 0.06     | grain            | 34<br>41       | <u>0.02</u><br><0.02              | <u>&lt;0.02</u><br><0.02          | gr35196<br>BRD-2168-96   |
| Wheat, winter<br>Germany 1996           | 125<br>EC   | 2  | 0.25     | 0.06     | grain            | 40<br>42       | <0.02<br><u>&lt;0.02</u>          | <0.02<br><u>&lt;0.02</u>          | gr36296<br>BRD-2169-96   |
| Wheat, winter<br>France-North,<br>1996  | 125<br>EC   | 2  | 0.25     | 0.06     | grain            | 41             | <u>&lt;0.02</u>                   | <u>&lt;0.02</u>                   | OF96116/SJ14<br>FRA-SJ14 |
| Wheat, winter<br>Germany 1997           | 125<br>EC   | 2  | 0.25     | 0.06     | grain            | 35<br>42       | 0.02<br><u>0.05</u>               | <0.02<br><u>0.02</u>              | gr49197<br>BRD-gr49197   |
| Wheat, winter<br>France-North,<br>1997  | 267.5<br>EC | 2  | 0.19     | 0.047    | grain            | 42             | <u>&lt;0.02</u>                   | <u>&lt;0.02</u>                   | 2236/97<br>FRA-2236-97   |
| Wheat, winter<br>France- North,<br>1997 | 267.5<br>EC | 2  | 0.19     | 0.047    | grain            | 46             | <u>&lt;0.02</u>                   | <u>&lt;0.02</u>                   | 2237/97<br>FRA-2237-97   |
| Wheat, winter<br>France-North,<br>1997  | 267.5<br>EC | 2  | 0.19     | 0.047    | grain            | 44             | <u>&lt;0.02</u>                   | <u>&lt;0.02</u>                   | 2238/97<br>FRA-2238-97   |

| Country,<br>Year                       | Application |    |           |          | Residues (mg/kg) |                      |                                                                          |                                                                          | Report No.;<br>Study No. |
|----------------------------------------|-------------|----|-----------|----------|------------------|----------------------|--------------------------------------------------------------------------|--------------------------------------------------------------------------|--------------------------|
|                                        | Form        | No | kg ai/ha  | kg ai/hl | Sample           | PHI<br>(days)        | trifloxy-<br>strobin                                                     | CGA321<br>113                                                            |                          |
| Wheat, winter<br>France-North,<br>1997 | 267.5<br>EC | 2  | 0.19      | 0.047    | grain            | 46                   | <u>&lt;0.02</u>                                                          | <u>&lt;0.02</u>                                                          | 2239/97<br>FRA-2239-97   |
| Wheat, winter<br>France-North,<br>1998 | 267.5<br>EC | 2  | 0.17-0.18 | 0.047    | grain            | 34<br>34<br>43<br>43 | <u>0.03</u><br>0.03<br><u>&lt;0.02</u><br><u>&lt;0.02</u>                | <u>&lt;0.02</u><br><u>&lt;0.02</u><br><u>&lt;0.02</u><br><u>&lt;0.02</u> | 9813101<br>FRA-9813101   |
| Wheat, winter<br>France-North,<br>1998 | 267.5<br>EC | 2  | 0.19      | 0.047    | grain            | 49<br>49             | <u>&lt;0.02</u><br><u>&lt;0.02</u>                                       | <u>&lt;0.02</u><br><u>&lt;0.02</u>                                       | 9813102<br>FRA-9813102   |
| Wheat<br>France-North,<br>1997         | 535<br>SC   | 2  | 0.19      | 0.047    | grain            | 42                   | <u>&lt;0.02</u>                                                          | <u>&lt;0.02</u>                                                          | 2240/97<br>FRA-2240-97   |
| Wheat<br>France-North,<br>1997         | 535<br>SC   | 2  | 0.19      | 0.047    | grain            | 46                   | <u>&lt;0.02</u>                                                          | <u>&lt;0.02</u>                                                          | 2241/97<br>FRA-2241-97   |
| Wheat<br>France-North,<br>1997         | 535<br>SC   | 2  | 0.19      | 0.047    | grain            | 44                   | <u>&lt;0.02</u>                                                          | <u>&lt;0.02</u>                                                          | 2242/97<br>FRA-2242-97   |
| Wheat<br>France-North,<br>1997         | 535<br>SC   | 2  | 0.19      | 0.047    | grain            | 46                   | <u>&lt;0.02</u>                                                          | <u>&lt;0.02</u>                                                          | 2243/97<br>FRA-2243-97   |
| Wheat<br>France-South,<br>2000         | 500<br>SC   | 2  | 0.25      | 0.06     | grain            | 44<br>44             | <u>&lt;0.02</u><br><u>&lt;0.02</u>                                       | <u>&lt;0.02</u><br><u>&lt;0.02</u>                                       | 0011701<br>FRA-0011701   |
| Wheat<br>France-South,<br>2000         | 500<br>SC   | 2  | 0.25      | 0.08     | grain            | 42<br>42             | <u>0.02</u><br>0.02                                                      | <u>&lt;0.01</u><br><u>&lt;0.01</u>                                       | 2106/00<br>FRA-2106-00-A |
| Wheat<br>France-South,<br>1997         | 125<br>EC   | 2  | 0.25      | 0.06     | grain            | 34                   | <u>0.03</u>                                                              | <u>&lt;0.02</u>                                                          | 2170/97<br>FRA-2170-97   |
| Wheat<br>France-South,<br>1997         | 125<br>EC   | 2  | 0.25      | 0.075    | grain            | 31                   | <u>&lt;0.02</u>                                                          | <u>&lt;0.02</u>                                                          | 2171/97<br>FRA-2171-97   |
| Wheat<br>France-South,<br>1997         | 125<br>EC   | 2  | 0.25      | 0.06     | grain            | 35                   | <u>&lt;0.02</u>                                                          | <u>&lt;0.02</u>                                                          | 2172/97<br>FRA-2172-97   |
| Wheat<br>France-South,<br>1997         | 125<br>EC   | 2  | 0.25      | 0.06     | grain            | 35                   | <u>&lt;0.02</u>                                                          | <u>&lt;0.02</u>                                                          | 2173/97<br>FRA-2173-97   |
| Wheat<br>France-South,<br>1996         | 125<br>EC   | 2  | 0.25      | 0.06     | grain            | 42                   | <u>&lt;0.02</u>                                                          | <u>&lt;0.02</u>                                                          | OF96116/LD87<br>FRA-LD87 |
| Wheat<br>France-South,<br>1996         | 125<br>EC   | 2  | 0.25      | 0.06     | grain            | 42                   | <u>&lt;0.02</u>                                                          | <u>&lt;0.02</u>                                                          | OF96117<br>FRA-OF96117   |
| Wheat<br>France-South,<br>1997         | 267.5<br>EC | 2  | 0.19      | 0.047    | grain            | 45                   | <u>&lt;0.02</u>                                                          | <u>&lt;0.02</u>                                                          | 2244/97<br>FRA-2244-97   |
| Wheat<br>France-South,<br>1997         | 267.5<br>EC | 2  | 0.19      | 0.047    | grain            | 45                   | <u>&lt;0.02</u>                                                          | <u>&lt;0.02</u>                                                          | 2245/97<br>FRA-2245-97   |
| Wheat<br>France-South,<br>1997         | 267.5<br>EC | 2  | 0.19      | 0.056    | grain            | 42                   | <u>&lt;0.02</u>                                                          | <u>&lt;0.02</u>                                                          | 2246/97<br>FRA-2246-97   |
| Wheat<br>France-South,<br>1997         | 267.5<br>EC | 2  | 0.19      | 0.047    | grain            | 46                   | <u>&lt;0.02</u>                                                          | <u>&lt;0.02</u>                                                          | 2247/97<br>FRA-2247-97   |
| Wheat<br>France-South,<br>1998         | 267.5<br>EC | 2  | 0.17-0.2  | 0.047    | grain            | 37<br>37<br>47<br>47 | <u>&lt;0.02</u><br><u>&lt;0.02</u><br><u>&lt;0.02</u><br><u>&lt;0.02</u> | <u>&lt;0.02</u><br><u>&lt;0.02</u><br><u>&lt;0.02</u><br><u>&lt;0.02</u> | 9813103<br>FRA-9813103   |

| Country,<br>Year               | Application |    |          |          | Residues (mg/kg) |               |                      |                 | Report No.;<br>Study No. |
|--------------------------------|-------------|----|----------|----------|------------------|---------------|----------------------|-----------------|--------------------------|
|                                | Form        | No | kg ai/ha | kg ai/hl | Sample           | PHI<br>(days) | trifloxy-<br>strobin | CGA321<br>113   |                          |
| Wheat<br>France-South,<br>1998 | 267.5<br>EC | 2  | 0.19-0.2 | 0.047    | grain            | 36            | <0.02                | <0.02           | 9813104<br>FRA-9813104   |
|                                |             |    |          |          |                  | 36            | <0.02                | <0.02           |                          |
|                                |             |    |          |          |                  | 45            | <u>&lt;0.02</u>      | <u>&lt;0.02</u> |                          |
|                                |             |    |          |          |                  | 45            | <0.02                | <0.02           |                          |

*Maize*

Table 84. Results of residue trials with trifloxystrobin in maize.

| Location,<br>Year | Application |    |          |           | Residues (mg/kg) |                                                        |                                                                                                  |                                                                                                  | Report No.;<br>Study No.                   |
|-------------------|-------------|----|----------|-----------|------------------|--------------------------------------------------------|--------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------|--------------------------------------------|
|                   | Form        | No | kg ai/ha | kg ai/hl  | Sample           | PHI<br>(days)                                          | trifloxy-<br>strobin                                                                             | CGA-<br>321113                                                                                   |                                            |
| Brazil<br>2002    | 250<br>EC   | 2  | 0.10     | 0.05      | kernel           | 30                                                     | <u>&lt;0.05</u>                                                                                  | n.a.                                                                                             | BRA S-A2-676/02-S1<br>BRA-S-A2-676/02-S1-A |
| Brazil<br>2002    | 250<br>EC   | 2  | 0.10     | 0.05      | kernel           | 30                                                     | <u>&lt;0.05</u>                                                                                  | n.a.                                                                                             | BRA S-A2-676/02-S2<br>BRA-S-A2-676/02-S2-A |
| Brazil<br>2002    | 250<br>EC   | 2  | 0.10     | 0.05      | kernel           | 30                                                     | <u>&lt;0.05</u>                                                                                  | n.a.                                                                                             | BRA S-A2-676/02-S3<br>BRA-S-A2-676/02-S3-A |
| IA, USA<br>1998   | 250<br>EC   | 4  | 0.12     | 0.06      | grain            | 29<br>29                                               | <u>&lt;0.02</u><br><0.02                                                                         | <u>0.03</u><br>0.03                                                                              | 144-98<br>USA-MW-FR-150-98-B               |
| IA, USA<br>1998   | 250<br>EC   | 4  | 0.12     | 0.05      | grain            | 30<br>30                                               | <u>&lt;0.02</u><br><0.02                                                                         | <u>&lt;0.02</u><br><0.02                                                                         | 144-98<br>USA-MW-FR-151-98-B               |
| MO, USA<br>1998   | 250<br>EC   | 4  | 0.12     | 0.06      | grain            | 30<br>30                                               | <u>&lt;0.02</u><br><0.02                                                                         | <u>&lt;0.02</u><br><0.02                                                                         | 144-98<br>USA-MW-FR-201-98-B               |
| IL, USA<br>1998   | 250<br>EC   | 4  | 0.12     | 0.05      | grain            | 30<br>30                                               | <u>&lt;0.02</u><br><0.02                                                                         | <u>&lt;0.02</u><br><0.02                                                                         | 144-98<br>USA-MW-FR-405-98-B               |
| IA, USA<br>1998   | 250<br>EC   | 4  | 0.12     | 0.05-0.07 | grain            | 9<br>9<br>16<br>16<br>23<br>23<br>30<br>30<br>36<br>36 | <0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><u>&lt;0.02</u><br><0.02<br><0.02<br><0.02 | <0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><u>&lt;0.02</u><br><0.02<br><0.02<br><0.02 | 144-98<br>USA-MW-FR-501-98-B               |
| SD, USA<br>1998   | 250<br>EC   | 4  | 0.12     | 0.05-0.07 | grain            | 29<br>29                                               | <u>&lt;0.02</u><br><0.02                                                                         | <u>&lt;0.02</u><br><0.02                                                                         | 144-98<br>USA-MW-FR-502-98-B               |
| NE, USA<br>1998   | 250<br>EC   | 4  | 0.12     | 0.05-0.07 | grain            | 30<br>30                                               | <u>&lt;0.02</u><br><0.02                                                                         | <u>&lt;0.02</u><br><0.02                                                                         | 144-98<br>USA-MW-FR-610-98-B               |
| NE, USA<br>1998   | 250<br>EC   | 4  | 0.12     | 0.07      | grain            | 30<br>30                                               | <u>&lt;0.02</u><br><0.02                                                                         | <u>&lt;0.02</u><br><0.02                                                                         | 144-98<br>USA-MW-FR-611-98-B               |
| NE, USA<br>1998   | 250<br>EC   | 4  | 0.12     | 0.05-0.07 | grain            | 30<br>30                                               | <u>&lt;0.02</u><br><0.02                                                                         | <u>&lt;0.02</u><br><0.02                                                                         | 144-98<br>USA-MW-FR-612-98                 |
| WI, USA<br>1998   | 250<br>EC   | 4  | 0.12     | 0.05-0.06 | grain            | 30<br>30                                               | <u>&lt;0.02</u><br><0.02                                                                         | <u>&lt;0.02</u><br><0.02                                                                         | 144-98<br>USA-MW-FR-701-98-B               |
| MN, USA<br>1998   | 250<br>EC   | 4  | 0.12     | 0.06      | grain            | 9<br>9<br>16<br>16<br>23<br>23<br>30<br>30<br>37<br>37 | 0.06<br>0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><u>&lt;0.02</u><br><0.02<br><0.02<br><0.02   | <0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><u>&lt;0.02</u><br><0.02<br><0.02<br><0.02 | 144-98<br>USA-MW-FR-801-98-B               |
| MN, USA<br>1998   | 250<br>EC   | 4  | 0.12     | 0.06      | grain            | 30<br>30                                               | <u>&lt;0.02</u><br><0.02                                                                         | <u>&lt;0.02</u><br><0.02                                                                         | 144-98<br>USA-MW-FR-802-98-B               |

| Location,<br>Year | Application |    |           |           | Residues (mg/kg) |               |                          |                          | Report No.;<br>Study No.     |
|-------------------|-------------|----|-----------|-----------|------------------|---------------|--------------------------|--------------------------|------------------------------|
|                   | Form        | No | kg ai/ha  | kg ai/hl  | Sample           | PHI<br>(days) | trifloxy-<br>strobin     | CGA-<br>321113           |                              |
| IN, USA<br>1998   | 250<br>EC   | 4  | 0.12      | 0.26      | grain            | 30<br>30      | <u>&lt;0.02</u><br><0.02 | <u>&lt;0.02</u><br><0.02 | 144-98<br>USA-NE-FR-103-98-B |
| IN, USA<br>1998   | 250<br>EC   | 4  | 0.12      | 0.066     | grain            | 30<br>30      | <u>&lt;0.02</u><br><0.02 | <u>&lt;0.02</u><br><0.02 | 144-98<br>USA-NE-FR-104-98-B |
| IN, USA<br>1998   | 250<br>EC   | 4  | 0.12      | 0.26      | grain            | 30<br>30      | <u>&lt;0.02</u><br><0.02 | <u>&lt;0.02</u><br><0.02 | 144-98<br>USA-NE-FR-105-98   |
| OH, USA<br>1998   | 250<br>EC   | 4  | 0.06      | 0.033     | grain            | 28<br>28      | <0.02<br><0.02           | <0.02<br><0.02           | 144-98<br>USA-NE-FR-203-98-B |
| MI, USA<br>1998   | 250<br>EC   | 4  | 0.11-0.12 | 0.05      | grain            | 29<br>29      | <u>&lt;0.02</u><br><0.02 | <u>&lt;0.02</u><br><0.02 | 144-98<br>USA-NE-FR-710-98-B |
| NY, USA<br>1998   | 250<br>EC   | 4  | 0.12      | 0.053     | grain            | 30<br>30      | <u>&lt;0.02</u><br><0.02 | <u>&lt;0.02</u><br><0.02 | 144-98<br>USA-NE-FR-802-98-B |
| TX, USA<br>1998   | 250<br>EC   | 4  | 0.12      | 0.26      | grain            | 28<br>28      | <u>&lt;0.02</u><br><0.02 | <u>&lt;0.02</u><br><0.02 | 144-98<br>USA-OS-FR-201-98-B |
| NC, USA<br>1998   | 250<br>EC   | 4  | 0.12      | 0.07      | grain            | 34<br>34      | <u>&lt;0.02</u><br><0.02 | <u>&lt;0.02</u><br><0.02 | 144-98<br>USA-OS-FR-609-98-B |
| CA, USA<br>1998   | 250<br>EC   | 4  | 0.12      | 0.05      | grain            | 35<br>35      | <u>&lt;0.02</u><br><0.02 | <u>&lt;0.02</u><br><0.02 | 144-98<br>USA-OW-FR-107-98-B |
| IL, USA<br>1998   | 250<br>EC   | 4  | 0.12-0.15 | 0.06-0.08 | grain            | 29<br>29      | <u>&lt;0.02</u><br><0.02 | <u>&lt;0.02</u><br><0.02 | 144-98<br>USA-04-FR-004-98-B |
| KS, USA<br>1999   | 250<br>EC   | 4  | 0.12      | 0.07      | grain            | 29<br>29      | <u>&lt;0.02</u><br><0.02 | <u>&lt;0.02</u><br><0.02 | 751-99<br>USA-MW-FR-317-99-A |
| KS, USA<br>1999   | 250<br>EC   | 4  | 0.12      | 0.06-0.07 | grain            | 29<br>29      | <u>&lt;0.02</u><br><0.02 | <u>&lt;0.02</u><br><0.02 | 751-99<br>USA-MW-FR-318-99   |
| OH, USA<br>1999   | 250<br>EC   | 4  | 0.12      | 0.06-0.07 | grain            | 30<br>30      | <u>&lt;0.02</u><br><0.02 | <u>&lt;0.02</u><br><0.02 | 751-99<br>USA-NE-FR-203-99   |

n.a. not analysed

*Rice*

Table 85. Results of residue trials with trifloxystrobin in rice.

| Country,<br>Year | Application |    |          |          | Residues (mg/kg) |                |                                           |                                           | Report No.;<br>Study No.       |
|------------------|-------------|----|----------|----------|------------------|----------------|-------------------------------------------|-------------------------------------------|--------------------------------|
|                  | Form        | No | kg ai/ha | kg ai/hl | Sample           | PHI<br>(days)  | trifloxy-<br>strobin                      | CGA-<br>321113                            |                                |
| Brazil<br>1999   | 50<br>WG    | 3  | 0.15     | 0.05     | grain            | 15<br>15       | <u>0.13</u><br>0.12                       | n.a.                                      | FR007/99<br>BRA-FR007-99-A     |
| Brazil<br>1999   | 50<br>WG    | 3  | 0.15     |          | grain            | 18<br>18       | <u>0.22</u><br>0.20                       | n.a.                                      | FR008/99<br>BRA-FR008-99-A     |
| Brazil<br>2000   | 50<br>WG    | 3  | 0.15     | 0.075    | grain            | 15             | <u>0.05</u>                               | n.a.                                      | M00139-RPK<br>BRA-M00139-RPK-A |
| Brazil<br>2001   | 50<br>WG    | 3  | 0.15     | 0.06     | grain            | 15             | <u>0.10</u>                               | n.a.                                      | M00139-JJB<br>BRA-M00139-JJB-A |
| Brazil<br>2001   | 50<br>WG    | 3  | 0.15     | 0.05     | grain            | 14             | <u>&lt;0.05</u>                           | n.a.                                      | M00139-LZF<br>BRA-M00139-LZF-A |
| Brazil<br>1999   | 250<br>EC   | 2  | 0.13     |          | grain            | 27<br>27       | 0.03<br>0.03                              | n.a.                                      | FR027/99<br>BRA-FR027-99-A     |
| Brazil<br>1999   | 250<br>EC   | 3  | 0.13     |          | grain            | 27<br>27       | 0.11<br>0.10                              | n.a.                                      | FR028/99<br>BRA-FR028-99-A     |
| AR, USA<br>1998  | 50<br>WG    | 2  | 0.17     | 0.15     | grain            | 36<br>36       | <u>0.34</u><br>0.33                       | <u>0.07</u><br>0.06                       | 150-98<br>USA-OS-FR-104-98-B   |
| AR, USA<br>1998  | 50<br>WG    | 2  | 0.17     | 0.09     | grain            | 35<br>35<br>35 | <u>0.10</u><br><u>0.12</u><br><u>0.06</u> | <u>0.07</u><br><u>0.08</u><br><u>0.04</u> | 150-98<br>USA-OS-FR-105-98-A   |

| Country,<br>Year | Application |    |          |           | Residues (mg/kg) |               |                      |                 | Report No.;<br>Study No.     |
|------------------|-------------|----|----------|-----------|------------------|---------------|----------------------|-----------------|------------------------------|
|                  | Form        | No | kg ai/ha | kg ai/hl  | Sample           | PHI<br>(days) | trifloxy-<br>strobin | CGA-<br>321113  |                              |
| AR, USA<br>1998  | 50<br>WG    | 2  | 0.17     | 0.09      | grain            | 14            | 0.18                 | 0.03            | 150-98<br>USA-OS-FR-106-98   |
|                  |             |    |          |           |                  | 14            | 0.17                 | 0.03            |                              |
|                  |             |    |          |           |                  | 21            | 0.06                 | 0.02            |                              |
|                  |             |    |          |           |                  | 21            | 0.09                 | 0.02            |                              |
|                  |             |    |          |           |                  | 28            | 0.04                 | <0.02           |                              |
|                  |             |    |          |           |                  | 28            | 0.06                 | <0.02           |                              |
|                  |             |    |          |           |                  | 35            | 0.03                 | <0.02           |                              |
|                  |             |    |          |           |                  | 35            | 0.04                 | <0.02           |                              |
|                  |             |    |          |           |                  | 45            | 0.03                 | 0.02            |                              |
|                  |             |    |          |           |                  | 45            | 0.04                 | 0.02            |                              |
| AR, USA<br>1998  | 50<br>WG    | 2  | 0.17     | 0.37      | grain            | 35            | <u>0.11</u>          | <u>0.05</u>     | 150-98<br>USA-OS-FR-107-98   |
|                  |             |    |          |           |                  | 35            | 0.07                 | 0.03            |                              |
| AR, USA<br>1998  | 50<br>WG    | 2  | 0.17     | 0.17-0.18 | grain            | 34            | <u>0.11</u>          | <u>0.10</u>     | 150-98<br>USA-OS-FR-108-98   |
|                  |             |    |          |           |                  | 34            | 0.09                 | 0.09            |                              |
| MO, USA<br>1998  | 50<br>WG    | 2  | 0.17     | 0.14-0.15 | grain            | 35            | 0.54                 | 0.06            | 150-98<br>USA-OS-FR-109-98   |
|                  |             |    |          |           |                  | 35            | <u>0.68</u>          | <u>0.07</u>     |                              |
| TX, USA<br>1998  | 50<br>WG    | 2  | 0.17     | 0.14-0.15 | grain            | 40            | <u>&lt;0.02</u>      | <u>&lt;0.02</u> | 150-98<br>USA-OS-FR-204-98-B |
|                  |             |    |          |           |                  | 40            | <0.02                | <0.02           |                              |
| TX, USA<br>1998  | 50<br>WG    | 2  | 0.17     | 0.15      | grain            | 37            | <u>&lt;0.02</u>      | <u>&lt;0.02</u> | 150-98<br>USA-OS-FR-206-98   |
|                  |             |    |          |           |                  | 37            | <0.02                | <0.02           |                              |
| LA, USA<br>1998  | 50<br>WG    | 2  | 0.17     | 0.09-0.12 | grain            | 35            | <0.02                | <0.02           | 150-98<br>USA-OS-FR-901-98-A |
|                  |             |    |          |           |                  | 35            | <u>0.03</u>          | <u>0.04</u>     |                              |
|                  |             |    |          |           |                  | 35            | 0.04                 | 0.02            |                              |
| LA, USA<br>1998  | 50<br>WG    | 2  | 0.17     | 0.37      | grain            | 35            | <u>0.04</u>          | <u>&lt;0.02</u> | 150-98<br>USA-OS-FR-902-98   |
|                  |             |    |          |           |                  | 35            | 0.04                 | <0.02           |                              |
| LA, USA<br>1998  | 50<br>WG    | 2  | 0.17     | 0.17-0.18 | grain            | 35            | <u>&lt;0.02</u>      | <u>&lt;0.02</u> | 150-98<br>USA-OS-FR-903-98   |
|                  |             |    |          |           |                  | 35            | <0.02                | <0.02           |                              |
| MS, USA<br>1998  | 50<br>WG    | 2  | 0.17     | 0.15-0.17 | grain            | 35            | <u>0.10</u>          | <u>0.03</u>     | 150-98<br>USA-OS-FR-904-98   |
|                  |             |    |          |           |                  | 35            | 0.09                 | 0.03            |                              |
| CA, USA<br>1998  | 50<br>WG    | 2  | 0.17     | 0.074     | grain            | 35            | <u>3.4</u>           | <u>0.03</u>     | 150-98<br>USA-OW-FR-407-98   |
|                  |             |    |          |           |                  | 35            | 2.5                  | 0.08            |                              |
| CA, USA<br>1998  | 50<br>WG    | 2  | 0.17     | 0.13      | grain            | 35            | <u>2.4</u>           | <u>0.10</u>     | 150-98<br>USA-OW-FR-408-98-B |
|                  |             |    |          |           |                  | 35            | 2.2                  | 0.10            |                              |
| MS, USA<br>1998  | 50<br>WG    | 2  | 0.17     | 0.13      | grain            | 14            | 0.16                 | 0.10            | 150-98<br>USA-03-FR-001-98   |
|                  |             |    |          |           |                  | 14            | 0.25                 | 0.11            |                              |
|                  |             |    |          |           |                  | 21            | 0.15                 | 0.06            |                              |
|                  |             |    |          |           |                  | 21            | 0.13                 | 0.04            |                              |
|                  |             |    |          |           |                  | 27            | 0.16                 | 0.06            |                              |
|                  |             |    |          |           |                  | 27            | 0.20                 | 0.07            |                              |
|                  |             |    |          |           |                  | 34            | 0.23                 | 0.12            |                              |
|                  |             |    |          |           |                  | 34            | 0.25                 | 0.12            |                              |
|                  |             |    |          |           |                  | 42            | 0.19                 | 0.09            |                              |
|                  |             |    |          |           |                  | 42            | <u>0.30</u>          | <u>0.16</u>     |                              |
| AR, USA<br>1998  | 250<br>EC   | 2  | 0.17     | 0.15      | grain            | 36            | <u>0.25</u>          | <u>0.08</u>     | 150-98<br>USA-OS-FR-104-98-A |
|                  |             |    |          |           |                  | 36            | 0.24                 | 0.07            |                              |
| CA, USA<br>1998  | 250<br>EC   | 2  | 0.17     | 0.13      | grain            | 35            | <u>0.56</u>          | <u>0.07</u>     | 150-98<br>USA-OW-FR-408-98-A |
|                  |             |    |          |           |                  | 35            | 0.52                 | 0.08            |                              |
| MO, USA<br>1998  | 250<br>EC   | 2  | 0.17     | 0.15      | grain            | 35            | <u>&lt;0.02</u>      | <u>&lt;0.02</u> | 150-98<br>USA-OS-FR-110-98-A |
|                  |             |    |          |           |                  | 35            | <0.02                | <0.02           |                              |
| TX, USA<br>199   | 250<br>EC   | 2  | 0.17     | 0.14-0.15 | grain            | 40            | <u>&lt;0.02</u>      | <u>&lt;0.02</u> | 150-98<br>USA-OS-FR-204-98-A |
|                  |             |    |          |           |                  | 40            | <0.02                | <0.02           |                              |

n.a. not analysed

*Nuts and seeds**Almonds*

Table 86. Results of residue trials with trifloxystrobin in almonds.

| Country,<br>Year | Application |    |          |          | Residues (mg/kg)     |                                                          |                                                                                                            |                                                                                                            | Report No.;<br>Study No.     |
|------------------|-------------|----|----------|----------|----------------------|----------------------------------------------------------|------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------|------------------------------|
|                  | Form        | No | kg ai/ha | kg ai/hl | Sample               | PHI<br>(days)                                            | trifloxy-<br>strobin                                                                                       | CGA321<br>113                                                                                              |                              |
| CA, USA<br>1998  | 50<br>WG    | 4  | 0.14     | 0.15     | nut without<br>shell | 62<br>62                                                 | <u>&lt;0.02</u><br><0.02                                                                                   | <u>&lt;0.02</u><br><0.02                                                                                   | 143-98<br>USA-OW-FR-402-98   |
| CA, USA<br>1998  | 50<br>WG    | 4  | 0.14     | 0.007    | nut without<br>shell | 63<br>63                                                 | <u>&lt;0.02</u><br><0.02                                                                                   | <u>&lt;0.02</u><br><0.02                                                                                   | 143-98<br>USA-OW-FR-514-98   |
| CA, USA<br>1998  | 50<br>WG    | 4  | 0.14     | 0.15     | nut without<br>shell | 62<br>62                                                 | <u>&lt;0.02</u><br><0.02                                                                                   | <u>&lt;0.02</u><br><0.02                                                                                   | 143-98<br>USA-OW-FR-515-98   |
| CA, USA<br>1998  | 50<br>WG    | 4  | 0.14     | 0.02     | nut without<br>shell | 63<br>63                                                 | <u>&lt;0.02</u><br><0.02                                                                                   | <u>&lt;0.02</u><br><0.02                                                                                   | 143-98<br>USA-02-FR-001-98-A |
| CA, USA<br>1998  | 50<br>WG    | 4  | 0.14     | 0.01     | nut without<br>shell | 40<br>40<br>49<br>49<br>55<br>55<br>63<br>63<br>68<br>68 | <0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><u>&lt;0.02</u><br><u>&lt;0.02</u><br><0.02<br><0.02 | <0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><u>&lt;0.02</u><br><u>&lt;0.02</u><br><0.02<br><0.02 | 143-98<br>USA-02-FR-001-98-B |
| CA, USA<br>1999  | 50<br>WG    | 4  | 0.14     | 0.009    | nut without<br>shell | 53<br>53                                                 | <u>&lt;0.02</u><br><0.02                                                                                   | <u>&lt;0.02</u><br><0.02                                                                                   | 110852<br>USA-OW-FR-404-99   |

Table 87. Results of residue trials with trifloxystrobin on pecan in the USA.

| Location,<br>Year | Application |    |          |          | Residues (mg/kg)     |                                                                  |                                                                                                                    |                                                                                                                    | Report No.;<br>Study No.     |
|-------------------|-------------|----|----------|----------|----------------------|------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------|------------------------------|
|                   | Form        | No | kg ai/ha | kg ai/hl | Sample               | PHI<br>(days)                                                    | trifloxy-<br>strobin                                                                                               | CGA321<br>113                                                                                                      |                              |
| GA, 1998          | 50<br>WG    | 8  | 0.14     | 0.01     | nut without<br>shell | 0<br>0<br>8<br>8<br>15<br>15<br>22<br>22<br>29<br>29<br>36<br>36 | <0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><u>&lt;0.02</u><br><0.02<br><0.02<br><0.02 | <0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><0.02<br><u>&lt;0.02</u><br><0.02<br><0.02<br><0.02 | 155-98<br>USA-OS-FR-838-98-B |
| TX, 1998          | 50<br>WG    | 8  | 0.14     | 0.02     | nut without<br>shell | 30<br>30                                                         | <u>&lt;0.02</u><br><0.02                                                                                           | <u>&lt;0.02</u><br><0.02                                                                                           | 155-98<br>USA-OS-FR-205-98-C |
| TX, 1998          | 50<br>WG    | 8  | 0.14     | 0.01     | nut without<br>shell | 30<br>30                                                         | <u>&lt;0.02</u><br><0.02                                                                                           | <u>&lt;0.02</u><br><0.02                                                                                           | 155-98<br>USA-OS-FR-205-98-D |
| TX, 1998          | 250<br>EC   | 8  | 0.14     | 0.02     | nut without<br>shell | 30<br>30                                                         | <u>&lt;0.02</u><br><0.02                                                                                           | <u>&lt;0.02</u><br><0.02                                                                                           | 155-98<br>USA-OS-FR-205-98-A |
| TX, 1998          | 250<br>EC   | 8  | 0.14     | 0.01     | nut without<br>shell | 30<br>30                                                         | <u>&lt;0.02</u><br><0.02                                                                                           | <u>&lt;0.02</u><br><0.02                                                                                           | 155-98<br>USA-OS-FR-205-98-B |
| NM, 1998          | 250<br>EC   | 8  | 0.14     | 0.02     | nut without<br>shell | 28<br>28                                                         | <u>&lt;0.02</u><br><0.02                                                                                           | <u>&lt;0.02</u><br><0.02                                                                                           | 155-98<br>USA-OS-FR-734-98-A |
| NM, 1998          | 250<br>EC   | 8  | 0.14     | 0.01     | nut without<br>shell | 28<br>28                                                         | <u>&lt;0.02</u><br><0.02                                                                                           | <u>&lt;0.02</u><br><0.02                                                                                           | 155-98<br>USA-OS-FR-734-98-B |

| Location,<br>Year | Application |    |          |                 | Residues (mg/kg)     |               |                      |               | Report No.;<br>Study No.     |
|-------------------|-------------|----|----------|-----------------|----------------------|---------------|----------------------|---------------|------------------------------|
|                   | Form        | No | kg ai/ha | kg ai/hl        | Sample               | PHI<br>(days) | trifloxy-<br>strobin | CGA321<br>113 |                              |
| GA, 1998          | 250<br>EC   | 8  | 0.14     | 0.01            | nut without<br>shell | 0             | <0.02                | <0.02         | 155-98<br>USA-OS-FR-838-98-A |
|                   |             |    |          |                 |                      | 0             | <0.02                | <0.02         |                              |
|                   |             |    |          |                 |                      | 8             | <0.02                | <0.02         |                              |
|                   |             |    |          |                 |                      | 8             | <0.02                | <0.02         |                              |
|                   |             |    |          |                 |                      | 15            | <0.02                | <0.02         |                              |
|                   |             |    |          |                 |                      | 15            | <0.02                | <0.02         |                              |
|                   |             |    |          |                 |                      | 22            | <0.02                | <0.02         |                              |
|                   |             |    |          |                 |                      | 22            | <0.02                | <0.02         |                              |
|                   |             |    |          |                 |                      | 29            | ≤0.02                | ≤0.02         |                              |
|                   |             |    |          |                 |                      | 29            | <0.02                | <0.02         |                              |
|                   |             |    |          |                 |                      | 36            | <0.02                | <0.02         |                              |
|                   |             |    |          |                 |                      | 36            | <0.02                | <0.02         |                              |
| AL, 1998          | 250<br>EC   | 8  | 0.14     | 0.14-0.15       | nut without<br>shell | 34            | ≤0.02                | ≤0.02         | 155-98<br>USA-OS-FR-839-98   |
|                   |             |    |          |                 |                      | 34            | <0.02                | <0.02         |                              |
| LA, 1998          | 250<br>EC   | 8  | 0.14     | 0.13-0.14       | nut without<br>shell | 30            | ≤0.02                | ≤0.02         | 155-98<br>USA-OS-FR-905-98-A |
|                   |             |    |          |                 |                      | 30            | <0.02                | <0.02         |                              |
| LA, 1998          | 250<br>EC   | 8  | 0.14     | 0.008-<br>0.009 | nut without<br>shell | 30            | ≤0.02                | ≤0.02         | 155-98<br>USA-OS-FR-905-98-B |
|                   |             |    |          |                 |                      | 30            | <0.02                | <0.02         |                              |

*Oilseed**Cotton seed*

Table 88. Results of residue trials with trifloxystrobin on cotton seed.

| Country,<br>Year | Application |    |          |          | Residues (mg/kg) |               |                      |                | Report No.;<br>Study No.                   |
|------------------|-------------|----|----------|----------|------------------|---------------|----------------------|----------------|--------------------------------------------|
|                  | Form        | No | kg ai/ha | kg ai/hl | Sample           | PHI<br>(days) | trifloxy-<br>strobin | CGA-<br>321113 |                                            |
| Brazil<br>2002   | 250<br>EC   | 3  | 0.1      | 0.033    | seed             | 21            | ≤0.05                | n.a.           | BRA S-K1-672/02-S1<br>BRA-S-K1-672/02-S1-A |
| Brazil<br>2002   | 250<br>EC   | 3  | 0.1      | 0.033    | seed             | 21            | ≤0.05                | n.a.           | BRA S-K1-672/02-S2<br>BRA-S-K1-672/02-S2-A |
| Brazil<br>2002   | 250<br>EC   | 3  | 0.1      | 0.033    | seed             | 21            | ≤0.05                | n.a.           | BRA S-K1-672/02-S3<br>BRA-S-K1-672/02-S3-A |

n.a. not analysed

*Peanut*

Table 89. Results of residue trials with trifloxystrobin on peanut.

| Country,<br>Year | Application |    |          |          | Residues (mg/kg)     |               |                      |               | Report No.;<br>Study No.                   |
|------------------|-------------|----|----------|----------|----------------------|---------------|----------------------|---------------|--------------------------------------------|
|                  | Form        | No | kg ai/ha | kg ai/hl | Sample               | PHI<br>(days) | trifloxy-<br>strobin | CGA321<br>113 |                                            |
| Brazil<br>2002   | 250<br>EC   | 4  | 0.10     | 0.033    | Nut without<br>shell | 15            | ≤0.05                | n.a.          | BRA S-G4-674/02-S1<br>BRA-S-G4-674/02-S1-A |
| Brazil<br>2002   | 250<br>EC   | 4  | 0.10     | 0.033    | Nut without<br>shell | 15            | ≤0.05                | n.a.          | BRA S-G4-674/02-S2<br>BRA-S-G4-674/02-S2-A |
| Brazil<br>2002   | 250<br>EC   | 4  | 0.10     | 0.033    | Nut without<br>shell | 15            | ≤0.05                | n.a.          | BRA S-G4-674/02-S3<br>BRA-S-G4-674/02-S3-A |
| VA, USA<br>1996  | 50<br>WG    | 8  | 0.07     | 0.05     | kernel               | 14            | ≤0.02                | ≤0.02         | 53-96<br>USA-NE-FR-303-96-A                |
| VA, USA<br>1996  | 50<br>WG    | 8  | 0.14     | 0.10     | kernel               | 14            | ≤0.02                | ≤0.02         | 53-96<br>USA-NE-FR-303-96-B                |

| Country,<br>Year | Form     | Application |          |               | Sample | Residues (mg/kg) |                      |               | Report No.,<br>Study No.     |
|------------------|----------|-------------|----------|---------------|--------|------------------|----------------------|---------------|------------------------------|
|                  |          | No          | kg ai/ha | kg ai/hl      |        | PHI<br>(days)    | trifloxy-<br>strobin | CGA321<br>113 |                              |
| TX, USA<br>1996  | 50<br>WG | 8           | 0.07     | 0.04          | kernel | 15               | ≤0.02                | ≤0.02         | 53-96<br>USA-OS-FR-202-96-A  |
|                  |          |             |          |               |        | 15               | <0.02                | <0.02         |                              |
| TX, USA<br>1996  | 50<br>WG | 8           | 0.14     | 0.08          | kernel | 0                | <0.02                | <0.02         | 53-96<br>USA-OS-FR-202-96-B  |
|                  |          |             |          |               |        | 0                | <0.02                | <0.02         |                              |
|                  |          |             |          |               |        | 3                | <0.02                | <0.02         |                              |
|                  |          |             |          |               |        | 3                | <0.02                | <0.02         |                              |
|                  |          |             |          |               |        | 8                | <0.02                | <0.02         |                              |
|                  |          |             |          |               |        | 8                | <0.02                | <0.02         |                              |
|                  |          |             |          |               |        | 15               | ≤0.02                | ≤0.02         |                              |
|                  |          |             |          |               |        | 15               | <0.02                | <0.02         |                              |
|                  |          |             |          |               |        | 22               | <0.02                | <0.02         |                              |
|                  |          |             |          |               |        | 22               | <0.02                | <0.02         |                              |
| TX, USA<br>1996  | 50<br>WG | 8           | 0.07     | 0.04          | kernel | 14               | ≤0.02                | ≤0.02         | 53-96<br>USA-OS-FR-314-96-A  |
|                  |          |             |          |               |        | 14               | <0.02                | <0.02         |                              |
| TX, USA<br>1996  | 50<br>WG | 8           | 0.14     | 0.075         | kernel | 14               | ≤0.02                | ≤0.02         | 53-96<br>USA-OS-FR-314-96-B  |
|                  |          |             |          |               |        | 14               | <0.02                | <0.02         |                              |
| SC, USA<br>1996  | 50<br>WG | 8           | 0.07     | 0.04          | kernel | 14               | ≤0.02                | ≤0.02         | 53-96<br>USA-OS-FR-604-96-A  |
|                  |          |             |          |               |        | 14               | <0.02                | <0.02         |                              |
| SC, USA<br>1996  | 50<br>WG | 8           | 0.14     | 0.075         | kernel | 14               | ≤0.02                | ≤0.02         | 53-96<br>USA-OS-FR-604-96-B  |
|                  |          |             |          |               |        | 14               | <0.02                | <0.02         |                              |
| OK, USA<br>1996  | 50<br>WG | 8           | 0.07     | 0.04-<br>0.05 | kernel | 16               | ≤0.02                | ≤0.02         | 53-96<br>USA-OS-FR-753-96-A  |
|                  |          |             |          |               |        | 16               | <0.02                | <0.02         |                              |
| OK, USA<br>1996  | 50<br>WG | 8           | 0.14     | 0.075-<br>0.1 | kernel | 16               | ≤0.02                | ≤0.02         | 53-96<br>USA-OS-FR-753-96-B  |
|                  |          |             |          |               |        | 16               | <0.02                | <0.02         |                              |
| GA, USA<br>1996  | 50<br>WG | 8           | 0.07     | 0.04          | kernel | 14               | ≤0.02                | ≤0.02         | 53-96<br>USA-OS-FR-841-96-A  |
|                  |          |             |          |               |        | 14               | <0.02                | <0.02         |                              |
| GA, USA<br>1996  | 50<br>WG | 8           | 0.14     | 0.08          | kernel | 0                | <0.02                | <0.02         | 53-96<br>USA-OS-FR-841-96-B  |
|                  |          |             |          |               |        | 0                | <0.02                | <0.02         |                              |
|                  |          |             |          |               |        | 3                | <0.02                | <0.02         |                              |
|                  |          |             |          |               |        | 3                | <0.02                | <0.02         |                              |
|                  |          |             |          |               |        | 7                | <0.02                | <0.02         |                              |
|                  |          |             |          |               |        | 7                | <0.02                | <0.02         |                              |
|                  |          |             |          |               |        | 14               | ≤0.02                | ≤0.02         |                              |
|                  |          |             |          |               |        | 14               | <0.02                | <0.02         |                              |
|                  |          |             |          |               |        | 21               | <0.02                | <0.02         |                              |
|                  |          |             |          |               |        | 21               | <0.02                | <0.02         |                              |
| GA, USA<br>1996  | 50<br>WG | 8           | 0.07     | 0.04          | kernel | 14               | ≤0.02                | ≤0.02         | 53-96<br>USA-OS-FR-842-96-A  |
|                  |          |             |          |               |        | 14               | <0.02                | <0.02         |                              |
| GA, USA<br>1996  | 50<br>WG | 8           | 0.14     | 0.08          | kernel | 14               | ≤0.02                | ≤0.02         | 53-96<br>USA-OS-FR-842-96-B  |
|                  |          |             |          |               |        | 14               | <0.02                | <0.02         |                              |
| GA, USA<br>1996  | 50<br>WG | 8           | 0.07     | 0.04          | kernel | 14               | ≤0.02                | ≤0.02         | 53-96<br>USA-OS-FR-843-96-A  |
|                  |          |             |          |               |        | 14               | <0.02                | <0.02         |                              |
| GA, USA<br>1996  | 50<br>WG | 8           | 0.14     | 0.07-<br>0.08 | kernel | 14               | ≤0.02                | ≤0.02         | 53-96<br>USA-OS-FR-843-96-B  |
|                  |          |             |          |               |        | 14               | <0.02                | <0.02         |                              |
| GA, USA<br>1996  | 50<br>WG | 8           | 0.07     | 0.14-<br>0.15 | kernel | 14               | ≤0.02                | ≤0.02         | 53-96<br>USA-OS-FR-844-96-A  |
|                  |          |             |          |               |        | 14               | <0.02                | <0.02         |                              |
| GA, USA<br>1996  | 50<br>WG | 8           | 0.14     | 0.29-<br>0.30 | kernel | 14               | ≤0.02                | ≤0.02         | 53-96<br>USA-OS-FR-844-96-B  |
|                  |          |             |          |               |        | 14               | <0.02                | <0.02         |                              |
| GA, USA<br>1996  | 50<br>WG | 8           | 0.07     | 0.04          | kernel | 14               | ≤0.02                | ≤0.02         | 53-96<br>USA-OS-FR-845-96-A  |
|                  |          |             |          |               |        | 14               | <0.02                | <0.02         |                              |
| GA, USA<br>1996  | 50<br>WG | 8           | 0.14     | 0.07          | kernel | 14               | ≤0.02                | ≤0.02         | 53-96<br>USA-OS-FR-845-96-B  |
|                  |          |             |          |               |        | 14               | <0.02                | <0.02         |                              |
| FL, USA<br>1996  | 50<br>WG | 8           | 0.07     | 0.012         | kernel | 17               | ≤0.02                | ≤0.02         | 53-96<br>USA-07-FR-003-96-A  |
|                  |          |             |          |               |        | 17               | <0.02                | <0.02         |                              |
| FL, USA<br>1996  | 50<br>WG | 8           | 0.14     | 0.025         | kernel | 17               | ≤0.02                | ≤0.02         | 53-96<br>USA-07-FR-003-96-B  |
|                  |          |             |          |               |        | 17               | <0.02                | <0.02         |                              |
| NC, USA<br>1997  | 50<br>WG | 8           | 0.07     | 0.049         | kernel | 14               | ≤0.02                | ≤0.02         | 53-96<br>USA-OS-FR-609-97-A  |
|                  |          |             |          |               |        | 14               | <0.02                | <0.02         |                              |
| NC, USA<br>1997  | 50<br>WG | 8           | 0.14     | 0.10          | kernel | 14               | ≤0.02                | ≤0.02         | 53-96<br>USA-OS-FR-609-97-B  |
|                  |          |             |          |               |        | 14               | <0.02                | <0.02         |                              |
| TX, USA<br>1998  | 50<br>WG | 8           | 0.07     | 0.04          | kernel | 14               | ≤0.02                | ≤0.02         | 151-98<br>USA-OS-FR-312-98-A |
|                  |          |             |          |               |        | 14               | <0.02                | <0.02         |                              |



| Country,<br>Year | Form      | No | Application |               | Sample | Residues (mg/kg) |                          |                          | Report No.;<br>Study No.     |
|------------------|-----------|----|-------------|---------------|--------|------------------|--------------------------|--------------------------|------------------------------|
|                  |           |    | kg ai/ha    | kg ai/hl      |        | PHI<br>(days)    | trifloxy-<br>strobin     | CGA321<br>113            |                              |
| TX, USA<br>1998  | 250<br>EC | 8  | 0.07        | 0.04          | kernel | 14<br>14         | <u>&lt;0.02</u><br><0.02 | <u>&lt;0.02</u><br><0.02 | 151-98<br>USA-OS-FR-312-98-B |
| NC, USA<br>1998  | 50<br>WG  | 8  | 0.07        | 0.075         | kernel | 14<br>14         | <u>&lt;0.02</u><br><0.02 | <u>&lt;0.02</u><br><0.02 | 151-98<br>USA-OS-FR-612-98-A |
| NC, USA<br>1998  | 250<br>EC | 8  | 0.07        | 0.075         | kernel | 14<br>14         | <u>&lt;0.02</u><br><0.02 | <u>&lt;0.02</u><br><0.02 | 151-98<br>USA-OS-FR-612-98-B |
| OK, USA<br>1998  | 50<br>WG  | 8  | 0.07        | 0.05-<br>0.06 | kernel | 14               | <u>&lt;0.02</u>          | <u>&lt;0.02</u>          | 151-98<br>USA-OS-FR-731-98-A |
| OK, USA<br>1998  | 250<br>EC | 8  | 0.07        | 0.05-<br>0.06 | kernel | 14<br>14         | <u>&lt;0.02</u><br><0.02 | <u>&lt;0.02</u><br><0.02 | 151-98<br>USA-OS-FR-731-98-B |
| GA, USA<br>1998  | 50<br>WG  | 8  | 0.07        | 0.037         | kernel | 13<br>13         | <u>&lt;0.02</u><br><0.02 | <u>&lt;0.02</u><br><0.02 | 151-98<br>USA-OS-FR-837-98-A |
| GA, USA<br>1998  | 250<br>EC | 8  | 0.07        | 0.037         | kernel | 13<br>13         | <u>&lt;0.02</u><br><0.02 | <u>&lt;0.02</u><br><0.02 | 151-98<br>USA-OS-FR-837-98-B |
| FL, USA<br>1998  | 50<br>WG  | 8  | 0.07        | 0.025         | kernel | 14<br>14         | <u>&lt;0.02</u><br><0.02 | <u>&lt;0.02</u><br><0.02 | 151-98<br>USA-07-FR-001-98-A |
| FL, USA<br>1998  | 250<br>EC | 8  | 0.07        | 0.025         | kernel | 14<br>14         | <u>&lt;0.02</u><br><0.02 | <u>&lt;0.02</u><br><0.02 | 151-98<br>USA-07-FR-001-98-B |

n.a. not analysed

*Seed for beverages and sweets**Coffee beans*

Table 90. Results of residue trials with trifloxystrobin on coffee beans in Brazil.

| Year | Application |    |          |          | Sample    | Residues (mg/kg) |                      |                | Report No.;<br>Study No.                   |
|------|-------------|----|----------|----------|-----------|------------------|----------------------|----------------|--------------------------------------------|
|      | Form        | No | kg ai/ha | kg ai/hl |           | PHI<br>(days)    | trifloxy-<br>strobin | CGA-<br>321113 |                                            |
| 2002 | 267.5<br>EC | 3  | 0.11     | 0.023    | bean, dry | 30               | <u>&lt;0.05</u>      | n.a.           | BRA S-E1-671/02-S1<br>BRA-S-E1-671/02-S1-A |
| 2002 | 267.5<br>EC | 3  | 0.11     | 0.023    | bean, dry | 30               | <u>&lt;0.05</u>      | n.a.           | BRA S-E1-671/02-S2<br>BRA-S-E1-671/02-S2-A |
| 2002 | 267.5<br>EC | 3  | 0.11     | 0.023    | bean, dry | 30               | <u>&lt;0.05</u>      | n.a.           | BRA S-E1-671/02-S3<br>BRA-S-E1-671/02-S3-A |
| 2003 | 267.5<br>EC | 3  | 0.11     | 0.023    | bean, dry | 30               | <u>&lt;0.05</u>      | n.a.           | BRA S-E1-671/02-S4<br>BRA-S-E1-671/02-S4-A |

n.a. not analysed

*Hops*

Table 91. Results of residue trials with trifloxystrobin on hops.

| Country,<br>Year | Application |    |           |          | Residues (mg/kg) |                 |                       |                     | Report No.;<br>Study No.     |
|------------------|-------------|----|-----------|----------|------------------|-----------------|-----------------------|---------------------|------------------------------|
|                  | Form        | No | kg ai/ha  | kg ai/hl | Sample           | PHI<br>(days)   | trifloxy-<br>strobins | CGA-<br>321113      |                              |
| WA, USA<br>1998  | 50<br>WG    | 6  | 0.14      | 0.015    | cone, dried      | 0               | 19                    | 1.7                 | 148-98<br>USA-OW-FR-606-98-A |
|                  |             |    |           |          |                  | 0               | 19                    | 1.5                 |                              |
|                  |             |    |           |          |                  | 3               | 10                    | 0.65                |                              |
|                  |             |    |           |          |                  | 3               | 17                    | 0.59                |                              |
|                  |             |    |           |          |                  | 6               | 12                    | 0.71                |                              |
|                  |             |    |           |          |                  | 6               | 17                    | 1.2                 |                              |
|                  |             |    |           |          |                  | 10              | 14                    | 1.4                 |                              |
|                  |             |    |           |          |                  | 10              | 18                    | 1.9                 |                              |
|                  |             |    |           |          |                  | 13              | <u>9.3</u>            | <u>0.57</u>         |                              |
|                  |             |    |           |          |                  | 13              | 8.7                   | 0.33                |                              |
|                  |             |    |           |          |                  | 18              | 5.4                   | 0.68                |                              |
|                  |             |    |           |          |                  | 18              | 8.7                   | 0.88                |                              |
|                  |             |    |           |          |                  | WA, USA<br>1998 | 50<br>WG              | 6                   |                              |
| OR, USA<br>1998  | 50<br>WG    | 6  | 0.14      | 0.01     | cone, dried      | 14<br>14        | <u>4.5</u><br>4.4     | <u>0.41</u><br>0.38 | 148-98<br>USA-OW-FR-608-98-A |
| Germany<br>1996  | 50<br>WG    | 4  | 0.38-0.50 | 0.013    | cone, green      | 0               | 10                    | 0.38                | gr01796<br>BRD-gr01796       |
|                  |             |    |           |          |                  | 7               | 9.1                   | 0.43                |                              |
|                  |             |    |           |          |                  | 9               | 7.3                   | 0.48                |                              |
|                  |             |    |           |          |                  | 14              | 7.5                   | 0.43                |                              |
|                  |             |    |           |          |                  | 21              | 6.1                   | 0.3                 |                              |
|                  |             |    |           |          | cone, dried      | 14              | <u>16</u>             | <u>2.0</u>          |                              |
| Germany<br>1996  | 50<br>WG    | 4  | 0.38-0.50 | 0.013    | cone, green      | 0               | 7.1                   | 0.68                | RF0296<br>BRD-RF0296         |
|                  |             |    |           |          |                  | 6               | 6.1                   | 0.65                |                              |
|                  |             |    |           |          |                  | 9               | 4.8                   | 0.73                |                              |
|                  |             |    |           |          |                  | 14              | 3.0                   | 0.55                |                              |
|                  |             |    |           |          |                  | 21              | 2.7                   | 0.48                |                              |
|                  |             |    |           |          | cone, dried      | 14              | <u>4.7</u>            | <u>1.48</u>         |                              |
| Germany<br>1996  | 50<br>WG    | 4  | 0.38-0.50 | 0.013    | cone, green      | 0               | 4.3                   | 0.45                | RF0396<br>BRD-RF0396         |
|                  |             |    |           |          |                  | 6               | 4.6                   | 0.64                |                              |
|                  |             |    |           |          |                  | 9               | 3.8                   | 0.52                |                              |
|                  |             |    |           |          |                  | 14              | 2.6                   | 0.44                |                              |
|                  |             |    |           |          |                  | 21              | 4.5                   | 0.51                |                              |
|                  |             |    |           |          | cone, dried      | 14              | <u>8.8</u>            | <u>1.4</u>          |                              |
| Germany<br>1996  | 50<br>WG    | 4  | 0.38-0.50 | 0.013    | cone, green      | 0               | 6.0                   | 0.45                | RF0496<br>BRD-RF0496         |
|                  |             |    |           |          |                  | 6               | 2.8                   | 0.30                |                              |
|                  |             |    |           |          |                  | 9               | 3.8                   | 0.35                |                              |
|                  |             |    |           |          |                  | 14              | 3.1                   | 0.45                |                              |
|                  |             |    |           |          |                  | 21              | 1.8                   | 0.33                |                              |
|                  |             |    |           |          | cone, dried      | 14              | <u>5.4</u>            | <u>1.3</u>          |                              |
| Germany<br>1997  | 49<br>WG    | 6  | 0.12-0.51 | 0.019    | cone, green      | 0               | 6.0                   | 0.45                | 2162/97<br>BRD-2162-97       |
|                  |             |    |           |          |                  | 7               | 3.7                   | 0.43                |                              |
|                  |             |    |           |          |                  | 9               | 2.0                   | 0.40                |                              |
|                  |             |    |           |          |                  | 14              | 2.9                   | 0.44                |                              |
|                  |             |    |           |          |                  | 21              | 3.1                   | 0.50                |                              |
|                  |             |    |           |          | cone, dried      | 14              | 9.5                   | 2.3                 |                              |
| Germany<br>1997  | 49<br>WG    | 6  | 0.13-0.52 | 0.019    | cone, green      | 0               | 4.2                   | 0.35                | 2163/97<br>BRD-2163-97       |
|                  |             |    |           |          |                  | 7               | 4.5                   | 0.43                |                              |
|                  |             |    |           |          |                  | 9               | 2.5                   | 0.26                |                              |
|                  |             |    |           |          |                  | 14              | 3.6                   | <0.1                |                              |
|                  |             |    |           |          |                  | 21              | 2.8                   | <0.1                |                              |
|                  |             |    |           |          | cone, dried      | 14              | 11                    | 1.7                 |                              |

| Country,<br>Year | Application |    |           |          | Residues (mg/kg) |               |                      |                | Report No.;<br>Study No. |
|------------------|-------------|----|-----------|----------|------------------|---------------|----------------------|----------------|--------------------------|
|                  | Form        | No | kg ai/ha  | kg ai/hl | Sample           | PHI<br>(days) | trifloxy-<br>strobin | CGA-<br>321113 |                          |
| Germany<br>1997  | 49<br>WG    | 6  | 0.13-0.53 | 0.019    | cone, green      | 0             | 4.8                  | 0.47           | 2164/97<br>BRD-2164-97   |
|                  |             |    |           |          |                  | 7             | 3.5                  | 0.52           |                          |
|                  |             |    |           |          |                  | 9             | 3.4                  | 0.40           |                          |
|                  |             |    |           |          |                  | 14            | 2.9                  | 0.47           |                          |
|                  |             |    |           |          |                  | 21            | 1.9                  | 0.47           |                          |
|                  |             |    |           |          | cone, dried      | 14            | 11                   | 1.42           |                          |
| Germany<br>1997  | 49<br>WG    | 6  | 0.13-0.50 | 0.013    | cone, green      | 0             | 14                   | 0.39           | 2165/97<br>BRD-2165-97   |
|                  |             |    |           |          |                  | 7             | 11                   | 0.16           |                          |
|                  |             |    |           |          |                  | 11            | 8.1                  | 0.28           |                          |
|                  |             |    |           |          |                  | 14            | 7.5                  | 0.66           |                          |
|                  |             |    |           |          |                  | 11            | <u>26</u>            | <u>2.5</u>     |                          |
|                  |             |    |           |          | cone, dried      | 11            | <u>26</u>            | <u>2.5</u>     |                          |

### Animal feed commodities

#### Almond hulls

Table 92. Results of residue trials with trifloxystrobin in almond hulls in the USA.

| Location,<br>Year | Application |    |          |          | Residues (mg/kg) |               |                      |                 | Report No.;<br>Study No.     |
|-------------------|-------------|----|----------|----------|------------------|---------------|----------------------|-----------------|------------------------------|
|                   | Form        | No | kg ai/ha | kg ai/hl | Sample           | PHI<br>(days) | trifloxy-<br>strobin | CGA321<br>113   |                              |
| CA, 1998          | 50 WG       | 4  | 0.14     | 0.15     | hull             | 62            | <u>1.2</u>           | <u>&lt;0.02</u> | 143-98<br>USA-OW-FR-402-98   |
|                   |             |    |          |          |                  | 62            | 0.98                 | <0.02           |                              |
| CA, 1998          | 50 WG       | 4  | 0.14     | 0.007    | hull             | 63            | 0.39                 | <0.02           | 143-98<br>USA-OW-FR-514-98   |
|                   |             |    |          |          |                  | 63            | <u>0.42</u>          | <u>&lt;0.02</u> |                              |
| CA, 1998          | 50 WG       | 4  | 0.14     | 0.15     | hull             | 62            | 0.22                 | <0.02           | 143-98<br>USA-OW-FR-515-98   |
|                   |             |    |          |          |                  | 62            | <u>0.25</u>          | <u>&lt;0.02</u> |                              |
| CA, 1998          | 50 WG       | 4  | 0.14     | 0.02     | hull             | 63            | 0.72                 | 0.02            | 143-98<br>USA-02-FR-001-98-A |
|                   |             |    |          |          |                  | 63            | <u>0.72</u>          | <u>0.03</u>     |                              |
| CA, 1998          | 50 WG       | 4  | 0.14     | 0.01     | hull             | 40            | 0.39                 | <0.02           | 143-98<br>USA-02-FR-001-98-B |
|                   |             |    |          |          |                  | 40            | 0.51                 | <0.02           |                              |
|                   |             |    |          |          |                  | 49            | 0.74                 | <0.02           |                              |
|                   |             |    |          |          |                  | 49            | 0.82                 | <0.02           |                              |
|                   |             |    |          |          |                  | 55            | 0.62                 | <0.02           |                              |
|                   |             |    |          |          |                  | 55            | 0.61                 | <0.02           |                              |
|                   |             |    |          |          |                  | 63            | 1.1                  | 0.03            |                              |
|                   |             |    |          |          |                  | 63            | 1.2                  | 0.03            |                              |
|                   |             |    |          |          |                  | 68            | <u>1.8</u>           | <u>0.06</u>     |                              |
|                   |             |    |          |          |                  | 68            | 1.8                  | 0.06            |                              |
| CA, 1999          | 50 WG       | 4  | 0.14     | 0.009    | hull             | 53            | <u>1.6</u>           | <u>0.04</u>     | 110852<br>USA-OW-FR-404-99   |
|                   |             |    |          |          |                  | 53            | 1.4                  | 0.03            |                              |

#### Peanut fodder

Table 93. Results of residue trials with trifloxystrobin on peanut hay in the USA.

| Location,<br>Year | Application |    |          |          | Residues (mg/kg) |               |                      |                | Report No.;<br>Study No.    |
|-------------------|-------------|----|----------|----------|------------------|---------------|----------------------|----------------|-----------------------------|
|                   | Form        | No | kg ai/ha | kg ai/hl | Sample           | PHI<br>(days) | trifloxy-<br>strobin | CGA-<br>321113 |                             |
| VA, 1996          | 50<br>WG    | 8  | 0.07     | 0.05     | hay              | 14            | 0.26                 | 0.20           | 53-96<br>USA-NE-FR-303-96-A |
|                   |             |    |          |          |                  | 14            | 0.26                 | 0.21           |                             |
| VA, 1996          | 50<br>WG    | 8  | 0.14     | 0.10     | hay              | 14            | 0.82                 | 0.59           | 53-96<br>USA-NE-FR-303-96-B |
|                   |             |    |          |          |                  | 14            | <u>1.4</u>           | <u>0.67</u>    |                             |
| TX, 1996          | 50<br>WG    | 8  | 0.07     | 0.04     | hay              | 15            | 0.27                 | 0.18           | 53-96<br>USA-OS-FR-202-96-A |
|                   |             |    |          |          |                  | 15            | 0.50                 | 0.33           |                             |

| Location,<br>Year | Application |    |          |           | Residues (mg/kg) |               |                      |                | Report No.;<br>Study No.    |
|-------------------|-------------|----|----------|-----------|------------------|---------------|----------------------|----------------|-----------------------------|
|                   | Form        | No | kg ai/ha | kg ai/hl  | Sample           | PHI<br>(days) | trifloxy-<br>strobin | CGA-<br>321113 |                             |
| TX, 1996          | 50<br>WG    | 8  | 0.14     | 0.08      | hay              | 0             | 2.1                  | 0.48           | 53-96<br>USA-OS-FR-202-96-B |
|                   |             |    |          |           |                  | 0             | 7.4                  | 0.74           |                             |
|                   |             |    |          |           |                  | 3             | 3.0                  | 0.60           |                             |
|                   |             |    |          |           |                  | 3             | 2.9                  | 0.85           |                             |
|                   |             |    |          |           |                  | 8             | 0.93                 | 0.47           |                             |
|                   |             |    |          |           |                  | 8             | 1.3                  | 0.72           |                             |
|                   |             |    |          |           |                  | 15            | 0.26                 | 0.20           |                             |
|                   |             |    |          |           |                  | 15            | <u>0.46</u>          | <u>0.36</u>    |                             |
|                   |             |    |          |           |                  | 22            | 0.27                 | 0.20           |                             |
|                   |             |    |          |           |                  | 22            | 0.27                 | 0.25           |                             |
| TX, 1996          | 50<br>WG    | 8  | 0.07     | 0.04      | hay              | 14            | 0.09                 | 0.12           | 53-96                       |
|                   |             |    |          |           |                  | 14            | 0.09                 | 0.12           | USA-OS-FR-314-96-A          |
| TX, 1996          | 50<br>WG    | 8  | 0.14     | 0.075     | hay              | 14            | 0.15                 | 0.17           | 53-96                       |
|                   |             |    |          |           |                  | 14            | <u>0.19</u>          | <u>0.23</u>    | USA-OS-FR-314-96-B          |
| SC, 1996          | 50<br>WG    | 8  | 0.07     | 0.04      | hay              | 14            | 0.36                 | 0.21           | 53-96                       |
|                   |             |    |          |           |                  | 14            | 0.43                 | 0.24           | USA-OS-FR-604-96-A          |
| SC, 1996          | 50<br>WG    | 8  | 0.14     | 0.075     | hay              | 14            | <u>0.71</u>          | <u>0.42</u>    | 53-96                       |
|                   |             |    |          |           |                  | 14            | 0.73                 | 0.39           | USA-OS-FR-604-96-B          |
| OK, 1996          | 50<br>WG    | 8  | 0.07     | 0.04-0.05 | hay              | 16            | 1.3                  | 0.34           | 53-96                       |
|                   |             |    |          |           |                  | 16            | 0.95                 | 0.32           | USA-OS-FR-753-96-A          |
| OK, 1996          | 50<br>WG    | 8  | 0.14     | 0.075-0.1 | hay              | 16            | <u>1.6</u>           | <u>0.39</u>    | 53-96                       |
|                   |             |    |          |           |                  | 16            | <u>3.4</u>           | <u>0.67</u>    | USA-OS-FR-753-96-B          |
| GA, 1996          | 50<br>WG    | 8  | 0.07     | 0.04      | hay              | 14            | 0.23                 | 0.22           | 53-96                       |
|                   |             |    |          |           |                  | 14            | 0.21                 | 0.16           | USA-OS-FR-841-96-A          |
| GA, 1996          | 50<br>WG    | 8  | 0.14     | 0.08      | hay              | 0             | 6.6                  | 0.70           | 53-96<br>USA-OS-FR-841-96-B |
|                   |             |    |          |           |                  | 0             | 5.6                  | 1.1            |                             |
|                   |             |    |          |           |                  | 3             | 6.6                  | 1.2            |                             |
|                   |             |    |          |           |                  | 3             | 7.5                  | 1.0            |                             |
|                   |             |    |          |           |                  | 7             | 1.5                  | 1.2            |                             |
|                   |             |    |          |           |                  | 7             | 1.4                  | 1.2            |                             |
|                   |             |    |          |           |                  | 14            | <u>0.34</u>          | <u>0.29</u>    |                             |
|                   |             |    |          |           |                  | 14            | 0.28                 | 0.22           |                             |
|                   |             |    |          |           |                  | 21            | 0.18                 | 0.15           |                             |
|                   |             |    |          |           |                  | 21            | 0.22                 | 0.20           |                             |
| GA, 1996          | 50<br>WG    | 8  | 0.07     | 0.04      | hay              | 14            | 0.18                 | 0.18           | 53-96                       |
|                   |             |    |          |           |                  | 14            | 0.18                 | 0.15           | USA-OS-FR-842-96-A          |
| GA, 1996          | 50<br>WG    | 8  | 0.14     | 0.08      | hay              | 14            | 0.16                 | 0.15           | 53-96                       |
|                   |             |    |          |           |                  | 14            | <u>0.19</u>          | <u>0.18</u>    | USA-OS-FR-842-96-B          |
| GA, 1996          | 50<br>WG    | 8  | 0.07     | 0.04      | hay              | 14            | 0.28                 | 0.21           | 53-96                       |
|                   |             |    |          |           |                  | 14            | 0.38                 | 0.26           | USA-OS-FR-843-96-A          |
| GA, 1996          | 50<br>WG    | 8  | 0.14     | 0.07-0.08 | hay              | 14            | <u>0.29</u>          | <u>0.21</u>    | 53-96                       |
|                   |             |    |          |           |                  | 14            | 0.29                 | 0.20           | USA-OS-FR-843-96-B          |
| GA, 1996          | 50<br>WG    | 8  | 0.07     | 0.14-0.15 | hay              | 14            | <0.05                | <0.05          | 53-96                       |
|                   |             |    |          |           |                  | 14            | 0.06                 | 0.06           | USA-OS-FR-844-96-A          |
| GA, 1996          | 50<br>WG    | 8  | 0.14     | 0.29-0.30 | hay              | 14            | 0.15                 | 0.09           | 53-96                       |
|                   |             |    |          |           |                  | 14            | <u>0.25</u>          | <u>0.15</u>    | USA-OS-FR-844-96-B          |
| GA, 1996          | 50<br>WG    | 8  | 0.07     | 0.04      | hay              | 14            | 0.19                 | 0.17           | 53-96                       |
|                   |             |    |          |           |                  | 14            | 0.25                 | 0.23           | USA-OS-FR-845-96-A          |
| GA, 1996          | 50<br>WG    | 8  | 0.14     | 0.07      | hay              | 14            | <u>0.84</u>          | <u>0.58</u>    | 53-96                       |
|                   |             |    |          |           |                  | 14            | 0.77                 | 0.55           | USA-OS-FR-845-96-B          |
| FL, 1996          | 50<br>WG    | 8  | 0.07     | 0.012     | hay              | 17            | 0.16                 | 0.08           | 53-96                       |
|                   |             |    |          |           |                  | 17            | 0.19                 | 0.14           | USA-07-FR-003-96-A          |
| FL, 1996          | 50<br>WG    | 8  | 0.14     | 0.025     | hay              | 17            | 0.29                 | 0.15           | 53-96                       |
|                   |             |    |          |           |                  | 17            | <u>0.27</u>          | <u>0.20</u>    | USA-07-FR-003-96-B          |
| NC, 1997          | 50<br>WG    | 8  | 0.07     | 0.049     | hay              | 14            | 1.2                  | 0.18           | 53-96                       |
|                   |             |    |          |           |                  | 14            | 1.3                  | 0.20           | USA-OS-FR-609-97-A          |
| NC, 1997          | 50<br>WG    | 8  | 0.14     | 0.10      | hay              | 14            | 2.6                  | 0.51           | 53-96                       |
|                   |             |    |          |           |                  | 14            | <u>3.7</u>           | <u>0.47</u>    | USA-OS-FR-609-97-B          |
| TX, 1998          | 50<br>WG    | 8  | 0.07     | 0.04      | hay              | 14            | <0.05                | 0.07           | 151-98                      |
|                   |             |    |          |           |                  | 14            | <0.05                | 0.06           | USA-OS-FR-312-98-A          |

| Location,<br>Year | Application |    |          |           | Residues (mg/kg) |               |                      |                | Report No.;<br>Study No.     |
|-------------------|-------------|----|----------|-----------|------------------|---------------|----------------------|----------------|------------------------------|
|                   | Form        | No | kg ai/ha | kg ai/hl  | Sample           | PHI<br>(days) | trifloxy-<br>strobin | CGA-<br>321113 |                              |
| TX, 1998          | 250<br>EC   | 8  | 0.07     | 0.04      | hay              | 14<br>14      | <0.05<br><0.05       | 0.06<br>0.07   | 151-98<br>USA-OS-FR-312-98-B |
| NC, 1998          | 50<br>WG    | 8  | 0.07     | 0.075     | hay              | 14<br>14      | 0.83<br>0.52         | 0.61<br>0.43   | 151-98<br>USA-OS-FR-612-98-A |
| NC, 1998          | 250<br>EC   | 8  | 0.07     | 0.075     | hay              | 14<br>14      | 0.43<br>0.34         | 0.71<br>0.42   | 151-98<br>USA-OS-FR-612-98-B |
| OK, 1998          | 50<br>WG    | 8  | 0.07     | 0.05-0.06 | hay              | 14<br>14      | n.a.<br><0.05        | n.a.<br><0.05  | 151-98<br>USA-OS-FR-731-98-A |
| OK, 1998          | 250<br>EC   | 8  | 0.07     | 0.05-0.06 | hay              | 14<br>14      | 0.12<br><0.05        | 0.20<br><0.05  | 151-98<br>USA-OS-FR-731-98-B |
| GA, 1998          | 50<br>WG    | 8  | 0.07     | 0.037     | hay              | 13<br>13      | 0.16<br>0.35         | 0.22<br>0.41   | 151-98<br>USA-OS-FR-837-98-A |
| GA, 1998          | 250<br>EC   | 8  | 0.07     | 0.037     | hay              | 13<br>13      | 0.30<br>0.37         | 0.47<br>0.60   | 151-98<br>USA-OS-FR-837-98-B |
| FL, 1998          | 50<br>WG    | 8  | 0.07     | 0.025     | hay              | 14<br>14      | 0.13<br><0.05        | 0.18<br><0.05  | 151-98<br>USA-07-FR-001-98-A |
| FL, 1998          | 250<br>EC   | 8  | 0.07     | 0.025     | hay              | 14<br>14      | <0.05<br><0.05       | <0.05<br>0.09  | 151-98<br>USA-07-FR-001-98-B |

n.a. not analysed

*Straw, fodder and forage of cereal grains and grasses**Barley straw and fodder, dry*

Table 94. Results of residue trials with trifloxystrobin on barley straw.

| Country,<br>Year                        | Application |    |           |          | Residues (mg/kg) |               |                      |                     | Report No.;<br>Study No. |
|-----------------------------------------|-------------|----|-----------|----------|------------------|---------------|----------------------|---------------------|--------------------------|
|                                         | Form        | No | kg ai/ha  | kg ai/hl | Sample           | PHI<br>(days) | trifloxy-<br>strobin | CGA-<br>321113      |                          |
| Barley<br>France- South<br>2000         | 500<br>SC   | 2  | 0.24-0.26 | 0.06     | straw            | 42<br>42      | <u>0.81</u><br>0.58  | <u>0.24</u><br>0.16 | 0011601<br>FRA-0011601   |
| Barley<br>France-South<br>2000          | 500<br>SC   | 2  | 0.25-0.26 | 0.06     | straw            | 42<br>42      | <u>1.0</u><br>0.96   | <u>0.09</u><br>0.08 | 0011602<br>FRA-0011602   |
| Barley<br>France- South<br>1997         | 125<br>EC   | 2  | 0.25      | 0.06     | straw            | 38            | <u>2.4</u>           | <u>0.16</u>         | 2166/97<br>FRA-2166-97   |
| Barley<br>France- South<br>1997         | 125<br>EC   | 2  | 0.25      | 0.075    | straw            | 34            | <u>0.91</u>          | <u>0.20</u>         | 2167/97<br>FRA-2167-97   |
| Barley<br>France- South<br>1997         | 125<br>EC   | 2  | 0.25      | 0.06     | straw            | 34            | <u>0.81</u>          | <u>0.13</u>         | 2168/97<br>FRA-2168-97   |
| Barley<br>France- South<br>1997         | 125<br>EC   | 2  | 0.25      | 0.06     | straw            | 34            | <u>1.5</u>           | <u>0.16</u>         | 2169/97<br>FRA-2169-97   |
| Barley, winter<br>France- South<br>1996 | 125<br>EC   | 2  | 0.25      | 0.06     | straw            | 41            | <u>0.15</u>          | <u>&lt;0.05</u>     | OF96118/LD88<br>FRA-LD88 |
| Barley<br>France- South<br>1997         | 267.5<br>EC | 2  | 0.19      | 0.05     | straw            | 43            | <u>0.31</u>          | <u>0.07</u>         | 2228/97<br>FRA-2228-97   |
| Barley<br>France- South<br>1997         | 267.5<br>EC | 2  | 0.19      | 0.05     | straw            | 45            | <u>0.69</u>          | <u>0.06</u>         | 2229/97<br>FRA-2229-97   |
| Barley<br>France- South<br>1997         | 267.5<br>EC | 2  | 0.19      | 0.06     | straw            | 45            | <u>0.72</u>          | <u>0.14</u>         | 2230/97<br>FRA-2230-97   |

| Country,<br>Year                        | Application |    |           |          | Residues (mg/kg) |                      |                                            |                                                                          | Report No.;<br>Study No. |
|-----------------------------------------|-------------|----|-----------|----------|------------------|----------------------|--------------------------------------------|--------------------------------------------------------------------------|--------------------------|
|                                         | Form        | No | kg ai/ha  | kg ai/hl | Sample           | PHI<br>(days)        | trifloxy-<br>strobin                       | CGA-<br>321113                                                           |                          |
| Barley<br>France- South<br>1997         | 267.5<br>EC | 2  | 0.19      | 0.05     | straw            | 42<br>42             | 0.80<br><u>1.3</u>                         | 0.17<br><u>0.21</u>                                                      | 2231/97<br>FRA-2231-97   |
| Barley, winter<br>France- South<br>1998 | 267.5<br>EC | 2  | 0.17-0.18 | 0.05     | straw            | 33<br>33<br>45<br>45 | 1.12<br>1.08<br><u>0.91</u><br>0.90        | 0.20<br>0.20<br><u>0.16</u><br>0.17                                      | 9813203<br>FRA-9813203   |
| Barley, winter<br>France- South<br>1998 | 267.5<br>EC | 2  | 0.18      | 0.05     | straw            | 33<br>33<br>45<br>45 | 0.81<br>0.61<br>0.54<br><u>0.64</u>        | 0.14<br>0.10<br>0.12<br><u>0.15</u>                                      | 9813204<br>FRA-9813204   |
| Barley<br>France- North<br>1997         | 535<br>SC   | 2  | 0.19      | 0.05     | straw            | 40                   | <u>0.61</u>                                | <u>0.19</u>                                                              | 2224/97<br>FRA-2224-97   |
| Barley<br>France- North<br>1997         | 535<br>SC   | 2  | 0.19      | 0.05     | straw            | 44                   | <u>0.38</u>                                | <u>&lt;0.05</u>                                                          | 2225/97<br>FRA-2225-97   |
| Barley<br>France- North<br>1997         | 535<br>SC   | 2  | 0.19      | 0.05     | straw            | 46                   | <u>0.66</u>                                | <u>0.11</u>                                                              | 2226/97<br>FRA-2226-97   |
| Barley<br>France- North<br>1997         | 535<br>SC   | 2  | 0.19      | 0.05     | straw            | 46                   | <u>0.78</u>                                | <u>0.16</u>                                                              | 2227/97<br>FRA-2227-97   |
| Barley, winter<br>France- North<br>1998 | 267.5<br>EC | 2  | 0.19      | 0.05     | straw            | 35<br>47             | <0.05<br><u>0.09</u>                       | <0.05<br><u>&lt;0.05</u>                                                 | 9813201<br>FRA-9813201   |
| Barley, winter<br>France- North<br>1998 | 267.5<br>EC | 2  | 0.18      | 0.05     | straw            | 35<br>35<br>47<br>47 | <u>0.32</u><br><u>0.38</u><br>0.30<br>0.29 | <u>&lt;0.05</u><br><u>&lt;0.05</u><br><u>&lt;0.05</u><br><u>&lt;0.05</u> | 9813202<br>FRA-9813202   |
| Barley<br>France- North<br>1997         | 267.5<br>EC | 2  | 0.19      | 0.05     | straw            | 40                   | <u>0.53</u>                                | <u>0.11</u>                                                              | 2220/97<br>FRA-2220-97   |
| Barley<br>France- North<br>1997         | 267.5<br>EC | 2  | 0.19      | 0.05     | straw            | 44                   | <u>0.33</u>                                | <u>&lt;0.05</u>                                                          | 2221/97<br>FRA-2221-97   |
| Barley<br>France- North<br>1997         | 267.5<br>EC | 2  | 0.19      | 0.05     | straw            | 46                   | <u>0.50</u>                                | <u>0.08</u>                                                              | 2222/97<br>FRA-2222-97   |
| Barley<br>France- North<br>1997         | 267.5<br>EC | 2  | 0.19      | 0.05     | straw            | 46                   | <u>0.43</u>                                | <u>0.05</u>                                                              | 2223/97<br>FRA-2223-97   |
| Barley, winter<br>Denmark<br>1996       | 125<br>EC   | 2  | 0.25      | 0.10     | straw            | 42<br>58             | 3.1<br><u>4.2</u>                          | 0.06<br><u>0.19</u>                                                      | FR0796<br>DAE-FR0796     |
| Barley, winter<br>Germany<br>1996       | 125<br>EC   | 2  | 0.25      | 0.06     | straw            | 35<br>42             | <u>0.68</u><br>0.32                        | <u>0.12</u><br>0.11                                                      | gr37296<br>BRD-2170-96   |
| Barley, winter<br>Germany<br>1999       | 125<br>EC   | 2  | 0.25      | 0.06     | straw            | 35<br>42             | <u>1.6</u><br><0.05                        | <u>0.29</u><br><0.05                                                     | gr37399<br>BRD-2143-99   |
| Barley, winter<br>Germany<br>1995       | 312.5<br>EC | 2  | 0.19      | 0.05     | straw            | 35<br>42             | 0.17<br><u>0.23</u>                        | 0.05<br><u>0.07</u>                                                      | gr3295<br>BRD-gr22395    |
| Barley, winter<br>Germany<br>1996       | 312.5<br>EC | 2  | 0.19      | 0.05     | straw            | 35<br>42             | <u>0.32</u><br>0.22                        | <u>0.36</u><br>0.38                                                      | gr33696<br>BRD-gr33696   |
| Barley, winter<br>Germany<br>2000       | 500<br>SC   | 2  | 0.25      | 0.06     | straw            | 34                   | <u>1.1</u>                                 | <u>0.42</u>                                                              | gr59100<br>BRD-gr59100   |

| Country,<br>Year                        | Application |    |          |          | Residues (mg/kg) |               |                      |                     | Report No.;<br>Study No. |
|-----------------------------------------|-------------|----|----------|----------|------------------|---------------|----------------------|---------------------|--------------------------|
|                                         | Form        | No | kg ai/ha | kg ai/hl | Sample           | PHI<br>(days) | trifloxy-<br>strobin | CGA-<br>321113      |                          |
| Barley, spring<br>Germany<br>1999       | 125<br>EC   | 2  | 0.25     | 0.06     | straw            | 34<br>41      | 0.35<br><u>0.49</u>  | 0.18<br><u>0.18</u> | gr35199<br>BRD-2141-99   |
| Barley, winter<br>Great Britain<br>1996 | 125<br>EC   | 2  | 0.25     | 0.13     | straw            | 47            | <u>1.8</u>           | <u>≤0.05</u>        | FR0296<br>ENG-FR029      |
| Barley, winter<br>Great Britain<br>1996 | 125<br>EC   | 2  | 0.25     | 0.13     | straw            | 44            | <u>0.93</u>          | <u>≤0.05</u>        | FR0396<br>ENG-FR0396     |

*Maize fodder*

Table 95. Results of residue trials with trifloxystrobin on maize stover in the USA.

| Location,<br>Year | Application |    |          |           | Residues (mg/kg) |                                                                  |                                                                                                 |                                                                                                     | Report No.;<br>Study No.     |
|-------------------|-------------|----|----------|-----------|------------------|------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|------------------------------|
|                   | Form        | No | kg ai/ha | kg ai/hl  | Sample           | PHI<br>(days)                                                    | trifloxy-<br>strobin                                                                            | CGA321<br>113                                                                                       |                              |
| IA, 1998          | 250<br>EC   | 4  | 0.12     | 0.06      | stover           | 29<br>29                                                         | <u>0.53</u><br>0.44                                                                             | <u>0.12</u><br>0.14                                                                                 | 144-98<br>USA-MW-FR-150-98-B |
| IA, 1998          | 250<br>EC   | 4  | 0.12     | 0.05      | stover           | 30<br>30                                                         | <u>1.0</u><br>1.0                                                                               | <u>0.38</u><br>0.33                                                                                 | 144-98<br>USA-MW-FR-151-98-B |
| MO, 1998          | 250<br>EC   | 4  | 0.12     | 0.06      | stover           | 30<br>30                                                         | 0.35<br><u>0.43</u>                                                                             | 0.13<br><u>0.13</u>                                                                                 | 144-98<br>USA-MW-FR-201-98-B |
| IL, 1998          | 250<br>EC   | 4  | 0.12     | 0.05      | stover           | 30<br>30                                                         | 0.71<br><u>0.96</u>                                                                             | 0.44<br><u>0.46</u>                                                                                 | 144-98<br>USA-MW-FR-405-98-B |
| IA, 1998          | 250<br>EC   | 4  | 0.12     | 0.05-0.07 | stover           | 0<br>0<br>9<br>9<br>16<br>16<br>23<br>23<br>30<br>30<br>36<br>36 | 4.6<br>6.9<br>2.9<br>3.6<br>0.93<br>1.4<br>1.3<br>0.80<br>0.67<br><u>1.2</u><br>0.78<br>0.99    | 0.41<br>0.34<br>0.44<br>0.66<br>0.22<br>0.37<br>0.41<br>0.21<br>0.18<br><u>0.24</u><br>0.24<br>0.31 | 144-98<br>USA-MW-FR-501-98-B |
| SD, 1998          | 250<br>EC   | 4  | 0.12     | 0.05-0.07 | stover           | 29<br>29                                                         | 3.2<br><u>3.9</u>                                                                               | 0.42<br><u>0.51</u>                                                                                 | 144-98<br>USA-MW-FR-502-98-B |
| NE, 1998          | 250<br>EC   | 4  | 0.12     | 0.05-0.07 | stover           | 30<br>30                                                         | <u>2.9</u><br>2.8                                                                               | <u>1.0</u><br>1.1                                                                                   | 144-98<br>USA-MW-FR-610-98-B |
| NE, 1998          | 250<br>EC   | 4  | 0.12     | 0.07      | stover           | 30<br>30                                                         | <u>0.64</u><br>0.60                                                                             | <u>0.17</u><br>0.12                                                                                 | 144-98<br>USA-MW-FR-611-98-B |
| NE, 1998          | 250<br>EC   | 4  | 0.12     | 0.05-0.07 | stover           | 30<br>30                                                         | 1.2<br><u>2.7</u>                                                                               | 0.9<br><u>1.8</u>                                                                                   | 144-98<br>USA-MW-FR-612-98   |
| WI, 1998          | 250<br>EC   | 4  | 0.12     | 0.05-0.06 | stover           | 30<br>30                                                         | <u>2.1</u><br>1.2                                                                               | <u>0.51</u><br>0.38                                                                                 | 144-98<br>USA-MW-FR-701-98-B |
| MN, 1998          | 250<br>EC   | 4  | 0.12     | 0.06      | stover           | 0<br>0<br>9<br>9<br>16<br>16<br>23<br>23<br>30<br>30<br>37<br>37 | 1.7<br>0.86<br>5.1<br>4.1<br>0.39<br>0.68<br>1.1<br>0.52<br>0.80<br><u>0.88</u><br>0.61<br>0.63 | 0.19<br>0.29<br>0.64<br>0.61<br>0.30<br>0.34<br>0.54<br>0.27<br>0.36<br><u>0.37</u><br>0.27<br>0.28 | 144-98<br>USA-MW-FR-801-98-B |

| Location,<br>Year | Application |    |           |           | Residues (mg/kg) |               |                      |                      | Report No.;<br>Study No.     |
|-------------------|-------------|----|-----------|-----------|------------------|---------------|----------------------|----------------------|------------------------------|
|                   | Form        | No | kg ai/ha  | kg ai/hl  | Sample           | PHI<br>(days) | trifloxy-<br>strobin | CGA321<br>113        |                              |
| MN, 1998          | 250<br>EC   | 4  | 0.12      | 0.06      | stover           | 30<br>30      | <u>0.96</u><br>0.86  | <u>0.49</u><br>0.37  | 144-98<br>USA-MW-FR-802-98-B |
| IN, 1998          | 250<br>EC   | 4  | 0.12      | 0.26      | stover           | 30<br>30      | 2.6<br><u>3.2</u>    | 0.25<br><u>0.27</u>  | 144-98<br>USA-NE-FR-103-98-B |
| IN, 1998          | 250<br>EC   | 4  | 0.12      | 0.07      | stover           | 30<br>30      | <u>2.2</u><br>1.2    | <u>0.24</u><br>0.17  | 144-98<br>USA-NE-FR-104-98-B |
| IN, 1998          | 250<br>EC   | 4  | 0.12      | 0.26      | stover           | 30<br>30      | 3.0<br><u>4.0</u>    | 0.57<br><u>0.43</u>  | 144-98<br>USA-NE-FR-105-98   |
| OH, 1998          | 250<br>EC   | 4  | 0.06      | 0.033     | stover           | 28<br>28      | 0.72<br>0.59         | 0.45<br>0.41         | 144-98<br>USA-NE-FR-203-98-B |
| MI, 1998          | 250<br>EC   | 4  | 0.11-0.12 | 0.05      | stover           | 29<br>29      | <u>2.0</u><br>1.8    | <u>0.79</u><br>0.70  | 144-98<br>USA-NE-FR-710-98-B |
| NY, 1998          | 250<br>EC   | 4  | 0.12      | 0.053     | stover           | 30<br>30      | <u>0.56</u><br>0.58  | <u>0.18</u><br>0.11  | 144-98<br>USA-NE-FR-802-98-B |
| TX, 1998          | 250<br>EC   | 4  | 0.12      | 0.26      | stover           | 28<br>28      | 0.67<br><u>2.2</u>   | 0.11<br><u>0.26</u>  | 144-98<br>USA-OS-FR-201-98-B |
| NC, 1998          | 250<br>EC   | 4  | 0.12      | 0.07      | stover           | 34<br>34      | <u>0.04</u><br>0.04  | <u>0.05</u><br>0.04  | 144-98<br>USA-OS-FR-609-98-B |
| CA, 1998          | 250<br>EC   | 4  | 0.12      | 0.05      | stover           | 35<br>35      | <u>0.37</u><br>0.19  | <u>0.04</u><br>0.03  | 144-98<br>USA-OW-FR-107-98-B |
| IL, 1998          | 250<br>EC   | 4  | 0.12-0.15 | 0.06-0.08 | stover           | 29<br>29      | <u>5.4</u><br>3.0    | <u>1.7</u><br>1.6    | 144-98<br>USA-04-FR-004-98-B |
| KS, 1999          | 250<br>EC   | 4  | 0.12      | 0.07      | stover           | 29<br>29      | 0.28<br><u>0.42</u>  | 0.03<br><u>0.05</u>  | 751-99<br>USA-MW-FR-317-99-A |
| KS, 1999          | 250<br>EC   | 4  | 0.12      | 0.06-0.07 | stover           | 29<br>29      | 0.20<br><u>0.32</u>  | <0.02<br><u>0.05</u> | 751-99<br>USA-MW-FR-318-99   |
| OH, 1999          | 250<br>EC   | 4  | 0.12      | 0.06-0.07 | stover           | 30<br>30      | 1.2<br><u>1.5</u>    | 0.40<br><u>0.41</u>  | 751-99<br>USA-NE-FR-203-99   |

n.a. not analysed

*Rice straw and fodder, dry*

Table 96. Results of residue trials with trifloxystrobin in rice straw in the USA.

| Location,<br>Year | Application |    |          |           | Residues (mg/kg) |                                                          |                                                                                 |                                                                                     | Report No.;<br>Study No.     |
|-------------------|-------------|----|----------|-----------|------------------|----------------------------------------------------------|---------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|------------------------------|
|                   | Form        | No | kg ai/ha | kg ai/hl  | Sample           | PHI<br>(days)                                            | trifloxy-<br>strobin                                                            | CGA-<br>321113                                                                      |                              |
| AR, 1998          | 50<br>WG    | 2  | 0.17     | 0.15      | straw            | 36<br>36                                                 | 5.5<br><u>6.1</u>                                                               | 1.3<br><u>1.2</u>                                                                   | 150-98<br>USA-OS-FR-104-98-B |
| AR, 1998          | 50<br>WG    | 2  | 0.17     | 0.09      | straw            | 35<br>35                                                 | 0.64<br><u>0.78</u>                                                             | 0.17<br><u>0.22</u>                                                                 | 150-98<br>USA-OS-FR-105-98-A |
| AR, 1998          | 50<br>WG    | 2  | 0.17     | 0.09      | straw            | 14<br>14<br>21<br>21<br>28<br>28<br>35<br>35<br>45<br>45 | 1.2<br>1.5<br>0.80<br>1.1<br>0.89<br>0.82<br>0.97<br><u>1.0</u><br>0.58<br>0.50 | 0.18<br>0.24<br>0.17<br>0.29<br>0.40<br>0.30<br>0.29<br><u>0.32</u><br>0.34<br>0.26 | 150-98<br>USA-OS-FR-106-98   |
| AR, 1998          | 50<br>WG    | 2  | 0.17     | 0.37      | straw            | 35<br>35                                                 | 0.84<br><u>2.0</u>                                                              | 0.31<br><u>0.12</u>                                                                 | 150-98<br>USA-OS-FR-107-98   |
| AR, 1998          | 50<br>WG    | 2  | 0.17     | 0.17-0.18 | straw            | 34<br>34                                                 | 0.46<br><u>0.57</u>                                                             | 0.29<br><u>0.27</u>                                                                 | 150-98<br>USA-OS-FR-108-98   |
| MO, 1998          | 50<br>WG    | 2  | 0.17     | 0.14-0.15 | straw            | 35<br>35                                                 | <u>2.4</u><br>1.5                                                               | <u>0.81</u><br>1.1                                                                  | 150-98<br>USA-OS-FR-109-98   |



| Location,<br>Year | Application |    |          |           | Residues (mg/kg) |                                                          |                                                                                  |                                                                                    | Report No.;<br>Study No.     |
|-------------------|-------------|----|----------|-----------|------------------|----------------------------------------------------------|----------------------------------------------------------------------------------|------------------------------------------------------------------------------------|------------------------------|
|                   | Form        | No | kg ai/ha | kg ai/hl  | Sample           | PHI<br>(days)                                            | trifloxy-<br>strobin                                                             | CGA-<br>321113                                                                     |                              |
| TX, 1998          | 50<br>WG    | 2  | 0.17     | 0.14-0.15 | straw            | 40<br>40                                                 | 0.34<br><u>0.44</u>                                                              | 0.07<br><u>0.10</u>                                                                | 150-98<br>USA-OS-FR-204-98-B |
| TX, 1998          | 50<br>WG    | 2  | 0.17     | 0.15      | straw            | 37<br>37                                                 | 0.05<br><u>0.07</u>                                                              | <0.02<br><u>&lt;0.02</u>                                                           | 150-98<br>USA-OS-FR-206-98   |
| LA, 1998          | 50<br>WG    | 2  | 0.17     | 0.09-0.12 | straw            | 35<br>35                                                 | 0.32<br><u>0.42</u>                                                              | 0.12<br><u>0.18</u>                                                                | 150-98<br>USA-OS-FR-901-98-A |
| LA, 1998          | 50<br>WG    | 2  | 0.17     | 0.37      | straw            | 35<br>35                                                 | 1.1<br><u>1.1</u>                                                                | 0.38<br><u>0.47</u>                                                                | 150-98<br>USA-OS-FR-902-98   |
| LA, 1998          | 50<br>WG    | 2  | 0.17     | 0.17-0.18 | straw            | 35<br>35                                                 | 0.32<br><u>0.54</u>                                                              | 0.12<br><u>0.20</u>                                                                | 150-98<br>USA-OS-FR-903-98   |
| MS, 1998          | 50<br>WG    | 2  | 0.17     | 0.15-0.17 | straw            | 35<br>35                                                 | 0.30<br><u>0.50</u>                                                              | 0.24<br><u>0.33</u>                                                                | 150-98<br>USA-OS-FR-904-98   |
| CA, 1998          | 50<br>WG    | 2  | 0.17     | 0.074     | straw            | 35<br>35                                                 | 4.4<br><u>5.3</u>                                                                | 0.17<br><u>0.17</u>                                                                | 150-98<br>USA-OW-FR-407-98   |
| CA, 1998          | 50<br>WG    | 2  | 0.17     | 0.13      | straw            | 35<br>35                                                 | <u>2.6</u><br>2.5                                                                | <u>0.55</u><br>0.64                                                                | 150-98<br>USA-OW-FR-408-98-B |
| MS, 1998          | 50<br>WG    | 2  | 0.17     | 0.13      | straw            | 14<br>14<br>21<br>21<br>27<br>27<br>34<br>34<br>42<br>42 | 0.86<br>1.7<br>0.96<br>1.0<br>0.67<br>0.86<br>0.51<br>0.51<br>0.46<br><u>1.3</u> | 0.41<br>0.62<br>0.69<br>0.77<br>0.64<br>0.84<br>0.42<br>0.41<br>0.56<br><u>1.3</u> | 150-98<br>USA-03-FR-001-98   |
| AR, 1998          | 250<br>EC   | 2  | 0.17     | 0.15      | straw            | 36<br>36                                                 | <u>2.6</u><br>1.7                                                                | <u>1.1</u><br>0.66                                                                 | 150-98<br>USA-OS-FR-104-98-A |
| CA, 1998          | 250<br>EC   | 2  | 0.17     | 0.13      | straw            | 35<br>35                                                 | 1.7<br><u>2.5</u>                                                                | 0.48<br><u>0.70</u>                                                                | 150-98<br>USA-OW-FR-408-98-A |
| MO, 1998          | 250<br>EC   | 2  | 0.17     | 0.15      | straw            | 35<br>35                                                 | 0.20<br><u>0.25</u>                                                              | 0.06<br><u>0.07</u>                                                                | 150-98<br>USA-OS-FR-110-98-A |
| TX, 1998          | 250<br>EC   | 2  | 0.17     | 0.14-0.15 | straw            | 40<br>40                                                 | <u>0.37</u><br>0.19                                                              | <u>0.08</u><br>0.04                                                                | 150-98<br>USA-OS-FR-204-98-A |

*Wheat straw and fodder, dry*

Table 97. Results of residue trials with trifloxystrobin in wheat straw in Europe.

| Country,<br>Year                        | Application |    |          |          | Residues (mg/kg) |               |                      |                          | Report No.;<br>Study No. |
|-----------------------------------------|-------------|----|----------|----------|------------------|---------------|----------------------|--------------------------|--------------------------|
|                                         | Form        | No | kg ai/ha | kg ai/hl | Sample           | PHI<br>(days) | trifloxy-<br>strobin | CGA321113                |                          |
| Wheat, winter<br>Germany 2000           | 500 SC      | 2  | 0.25     | 0.06     | straw            | 35            | <u>1.3</u>           | <u>0.31</u>              | gr57100<br>BRD-gr57100   |
| Wheat, winter<br>Germany 2000           | 500 SC      | 2  | 0.25     | 0.06     | straw            | 36            | <u>1.6</u>           | <u>0.14</u>              | gr58200<br>BRD-gr58200   |
| Wheat, winter<br>Germany 1995           | 312.5<br>EC | 2  | 0.19     | 0.047    | straw            | 36<br>42      | <u>0.35</u><br><0.05 | <u>0.07</u><br><0.05     | gr3195<br>BRD-gr12395    |
| Wheat, winter<br>Germany 1995           | 312.5<br>EC | 2  | 0.19     | 0.047    | straw            | 35<br>42      | <u>0.07</u><br>0.06  | <u>&lt;0.05</u><br><0.05 | gr3195<br>BRD-gr42395    |
| Wheat, winter<br>France- North,<br>1995 | 312.5<br>EC | 2  | 0.19     | 0.047    | straw            | 41            | <u>0.59</u>          | <u>0.18</u>              | OF95137/KJ19<br>FRA-KJ19 |
| Wheat, winter<br>Germany 1996           | 312.5<br>EC | 2  | 0.19     | 0.047    | straw            | 34<br>41      | <u>0.73</u><br>0.24  | <u>0.21</u><br>0.15      | gr31196<br>BRD-gr31196   |
| Wheat, winter<br>Germany 1996           | 312.5<br>EC | 2  | 0.19     | 0.047    | straw            | 40<br>42      | 0.52<br><u>0.81</u>  | 0.26<br><u>0.14</u>      | gr32296<br>BRD-gr32296   |

| Country,<br>Year                        | Application |    |               |          | Residues (mg/kg) |                |                             |                               | Report No.;<br>Study No. |
|-----------------------------------------|-------------|----|---------------|----------|------------------|----------------|-----------------------------|-------------------------------|--------------------------|
|                                         | Form        | No | kg ai/ha      | kg ai/hl | Sample           | PHI<br>(days)  | trifloxy-<br>strobin        | CGA321113                     |                          |
| Wheat, winter<br>Sweden 1998            | 312.5<br>EC | 2  | 0.18          | 0.09     | straw            | 35<br>42<br>48 | 0.08<br>0.09<br><u>0.09</u> | <0.05<br><0.05<br><u>0.06</u> | gr97098<br>SWD-gr97098   |
| Wheat, winter<br>Switzerland 1997       | 125 EC      | 2  | 0.25          | 0.05     | straw            | 47             | <u>0.19</u>                 | <u>0.07</u>                   | 2272/97<br>SWZ-2272-97   |
| Wheat<br>Switzerland<br>1997            | 125 EC      | 2  | 0.25          | 0.05     | straw            | 42             | <u>0.16</u>                 | <u>&lt;0.05</u>               | 2013/96<br>SWZ-2013-96   |
| Wheat, spring<br>Germany 1999           | 125 EC      | 2  | 0.25          | 0.06     | straw            | 34<br>41       | <u>0.31</u><br>0.18         | <u>0.07</u><br><0.05          | gr38499<br>BRD-2144-99   |
| Wheat, winter<br>Germany 1996           | 125 EC      | 2  | 0.25          | 0.06     | straw            | 34<br>41       | <u>0.85</u><br>0.51         | <u>0.43</u><br>0.28           | gr35196<br>BRD-2168-96   |
| Wheat, winter<br>Germany 1996           | 125 EC      | 2  | 0.25          | 0.06     | straw            | 40<br>42       | 1.2<br><u>2.3</u>           | 0.19<br><u>0.33</u>           | gr36296<br>BRD-2169-96   |
| Wheat, winter<br>France- North,<br>1996 | 125 EC      | 2  | 0.25          | 0.06     | straw            | 41             | <u>0.62</u>                 | <u>0.16</u>                   | OF96116/SJ14<br>FRA-SJ14 |
| Wheat, winter<br>Germany 1997           | 125 EC      | 2  | 0.25          | 0.06     | straw            | 35<br>42       | <u>1.8</u><br>1.4           | <u>0.82</u><br>0.88           | gr49197<br>BRD-gr49197   |
| Wheat, winter<br>France- North,<br>1997 | 267.5<br>EC | 2  | 0.19          | 0.047    | straw            | 42             | <u>0.77</u>                 | <u>0.18</u>                   | 2236/97<br>FRA-2236-97   |
| Wheat, winter<br>France- North,<br>1997 | 267.5<br>EC | 2  | 0.19          | 0.047    | straw            | 46             | <u>0.30</u>                 | <u>0.08</u>                   | 2237/97<br>FRA-2237-97   |
| Wheat, winter<br>France- North,<br>1997 | 267.5<br>EC | 2  | 0.19          | 0.047    | straw            | 44             | <u>0.16</u>                 | <u>&lt;0.05</u>               | 2238/97<br>FRA-2238-97   |
| Wheat, winter<br>France- North,<br>1997 | 267.5<br>EC | 2  | 0.19          | 0.047    | straw            | 46             | <u>&lt;0.05</u>             | <u>&lt;0.05</u>               | 2239/97<br>FRA-2239-97   |
| Wheat, winter<br>France- North,<br>1998 | 267.5<br>EC | 2  | 0.17-<br>0.18 | 0.047    | straw            | 34<br>43       | 2.6<br><u>2.5</u>           | 0.14<br><u>0.16</u>           | 9813101<br>FRA-9813101   |
| Wheat, winter<br>France- North,<br>1998 | 267.5<br>EC | 2  | 0.19          | 0.047    | straw            | 34<br>49       | <u>0.09</u><br>0.08         | <u>&lt;0.05</u><br><0.05      | 9813102<br>FRA-9813102   |
| Wheat<br>France- North,<br>1997         | 535 SC      | 2  | 0.19          | 0.047    | straw            | 42             | <u>1.4</u>                  | <u>0.4</u>                    | 2240/97<br>FRA-2240-97   |
| Wheat<br>France- North,<br>1997         | 535 SC      | 2  | 0.19          | 0.047    | straw            | 46             | <u>0.40</u>                 | <u>0.11</u>                   | 2241/97<br>FRA-2241-97   |
| Wheat<br>France- North,<br>1997         | 535 SC      | 2  | 0.19          | 0.047    | straw            | 44             | <u>0.33</u>                 | <u>0.05</u>                   | 2242/97<br>FRA-2242-97   |
| Wheat<br>France- North,<br>1997         | 535 SC      | 2  | 0.19          | 0.047    | straw            | 46             | <u>0.13</u>                 | <u>&lt;0.05</u>               | 2243/97<br>FRA-2243-97   |
| Wheat<br>France- South,<br>2000         | 500 SC      | 2  | 0.25          | 0.06     | straw            | 44<br>44       | <u>0.99</u><br>0.90         | <u>0.17</u><br>0.20           | 0011701<br>FRA-0011701   |
| Wheat<br>France-South,<br>2000          | 500 SC      | 2  | 0.25          | 0.08     | straw            | 42<br>42       | <u>1.9</u><br>1.6           | <u>0.15</u><br>0.12           | 2106/00<br>FRA-2106-00-A |
| Wheat<br>France-South,<br>1997          | 125 EC      | 2  | 0.25          | 0.06     | straw            | 34             | <u>1.3</u>                  | <u>0.16</u>                   | 2170/97<br>FRA-2170-97   |
| Wheat<br>France-South,<br>1997          | 125 EC      | 2  | 0.25          | 0.075    | straw            | 31             | <u>0.70</u>                 | <u>0.17</u>                   | 2171/97<br>FRA-2171-97   |

| Country,<br>Year               | Application |    |          |          | Residues (mg/kg) |               |                      |                     | Report No.;<br>Study No. |
|--------------------------------|-------------|----|----------|----------|------------------|---------------|----------------------|---------------------|--------------------------|
|                                | Form        | No | kg ai/ha | kg ai/hl | Sample           | PHI<br>(days) | trifloxy-<br>strobin | CGA321113           |                          |
| Wheat<br>France-South,<br>1997 | 125 EC      | 2  | 0.25     | 0.06     | straw            | 35            | <u>0.94</u>          | <u>0.13</u>         | 2172/97<br>FRA-2172-97   |
| Wheat<br>France-South,<br>1997 | 125 EC      | 2  | 0.25     | 0.06     | straw            | 35            | <u>0.38</u>          | <u>0.05</u>         | 2173/97<br>FRA-2173-97   |
| Wheat<br>France-South,<br>1996 | 125 EC      | 2  | 0.25     | 0.06     | straw            | 42            | <u>0.17</u>          | <u>0.08</u>         | OF96116/LD87<br>FRA-LD87 |
| Wheat<br>France-South,<br>1996 | 125 EC      | 2  | 0.25     | 0.06     | straw            | 42            | <u>0.83</u>          | <u>0.17</u>         | OF96117<br>FRA-OF96117   |
| Wheat<br>France-South,<br>1997 | 267.5<br>EC | 2  | 0.19     | 0.047    | straw            | 45            | <u>0.76</u>          | <u>0.13</u>         | 2244/97<br>FRA-2244-97   |
| Wheat<br>France-South,<br>1997 | 267.5<br>EC | 2  | 0.19     | 0.047    | straw            | 45            | <u>0.34</u>          | <u>0.07</u>         | 2245/97<br>FRA-2245-97   |
| Wheat<br>France-South,<br>1997 | 267.5<br>EC | 2  | 0.19     | 0.056    | straw            | 42            | <u>0.19</u>          | <u>0.05</u>         | 2246/97<br>FRA-2246-97   |
| Wheat<br>France-South,<br>1997 | 267.5<br>EC | 2  | 0.19     | 0.047    | straw            | 46            | <u>0.50</u>          | <u>0.07</u>         | 2247/97<br>FRA-2247-97   |
| Wheat<br>France-South,<br>1998 | 267.5<br>EC | 2  | 0.17-0.2 | 0.047    | straw            | 37<br>47      | 1.1<br><u>1.1</u>    | 0.08<br><u>0.10</u> | 9813103<br>FRA-9813103   |
| Wheat<br>France-South,<br>1998 | 267.5<br>EC | 2  | 0.19-0.2 | 0.047    | straw            | 36<br>45      | 0.37<br><u>0.57</u>  | 0.15<br><u>0.21</u> | 9813104<br>FRA-9813104   |

Table 98. Results of residue trials with trifloxystrobin on wheat straw in the USA.

| Location,<br>Year            | Application |    |          |          | Residues (mg/kg) |               |                      |                          | Report No.;<br>Study No.     |
|------------------------------|-------------|----|----------|----------|------------------|---------------|----------------------|--------------------------|------------------------------|
|                              | Form        | No | kg ai/ha | kg ai/hl | Sample           | PHI<br>(days) | trifloxy-<br>strobin | CGA-<br>321113           |                              |
| Wheat<br>KS, 1998            | 250<br>EC   | 2  | 0.12     | 0.10     | straw            | 35<br>35      | 0.10<br><u>0.15</u>  | <0.02<br><u>&lt;0.02</u> | 153-98<br>USA-MW-FR-313-98-D |
| Wheat<br>OK, 1998            | 250<br>EC   | 2  | 0.12     | 0.09     | straw            | 30<br>30      | 0.11<br><u>0.13</u>  | <0.02<br><u>0.02</u>     | 153-98<br>USA-OS-FR-732-98-D |
| Wheat<br>TX, 1998            | 250<br>EC   | 2  | 0.12     | 0.10     | straw            | 37<br>37      | <u>0.14</u><br>0.10  | <u>&lt;0.02</u><br><0.02 | 153-98<br>USA-OS-FR-733-98-D |
| Wheat<br>ND, 1998            | 250<br>EC   | 2  | 0.12     | 0.09     | straw            | 37<br>37      | 0.11<br><u>0.17</u>  | 0.04<br><u>0.05</u>      | 153-98<br>USA-OW-FR-217-98-D |
| Wheat<br>NC, 1998            | 250<br>EC   | 2  | 0.12     | 0.13     | straw            | 45<br>45      | 0.05<br><0.03        | 0.04<br><0.03            | 153-98<br>USA-OS-FR-613-98-D |
| Wheat<br>KS, 1998            | 50<br>WG    | 2  | 0.12     | 0.10     | straw            | 35<br>35      | 0.11<br><u>0.19</u>  | <0.02<br><u>&lt;0.02</u> | 153-98<br>USA-MW-FR-313-98-C |
| Wheat<br>NC, 1998            | 50<br>WG    | 2  | 0.12     | 0.13     | straw            | 45<br>45      | 0.07<br>0.12         | 0.05<br>0.08             | 153-98<br>USA-OS-FR-613-98-C |
| Wheat<br>TX, 1998            | 50<br>WG    | 2  | 0.12     | 0.10     | straw            | 37<br>37      | n.a.<br><u>0.51</u>  | <0.02<br><u>&lt;0.02</u> | 153-98<br>USA-OS-FR-733-98-C |
| Wheat<br>ND, 1998            | 50<br>WG    | 2  | 0.12     | 0.09     | straw            | 37<br>37      | 0.04<br><u>0.08</u>  | 0.02<br><u>0.03</u>      | 153-98<br>USA-OW-FR-217-98-C |
| Wheat,<br>spring<br>MT, 1997 | 50<br>WG    | 1  | 0.12     | 0.08     | straw            | 36<br>36      | 0.57<br><u>0.61</u>  | 0.03<br><u>0.03</u>      | 43-97<br>USA-OW-FR-204-97-B  |

| Location,<br>Year            | Application |    |           |           | Residues (mg/kg) |               |                      |                          | Report No.;<br>Study No.    |
|------------------------------|-------------|----|-----------|-----------|------------------|---------------|----------------------|--------------------------|-----------------------------|
|                              | Form        | No | kg ai/ha  | kg ai/hl  | Sample           | PHI<br>(days) | trifloxy-<br>strobin | CGA-<br>321113           |                             |
| Wheat,<br>spring<br>MT, 1997 | 50<br>WG    | 2  | 0.12      | 0.07-0.08 | straw            | 36<br>36      | <u>0.96</u><br>0.80  | <u>0.09</u><br>0.08      | 43-97<br>USA-OW-FR-204-97-C |
| Wheat,<br>spring<br>MT, 1997 | 50<br>WG    | 1  | 0.12      | 0.07      | straw            | 43<br>43      | 0.46<br>0.51         | 0.03<br>0.03             | 43-97<br>USA-OW-FR-205-97-B |
| Wheat,<br>spring<br>MT, 1997 | 50<br>WG    | 2  | 0.12      | 0.07-0.08 | straw            | 43<br>43      | 1.1<br>0.94          | 0.06<br>0.06             | 43-97<br>USA-OW-FR-205-97-C |
| Wheat,<br>spring<br>MN, 1997 | 50<br>WG    | 1  | 0.12      | 0.05      | straw            | 44<br>44      | 0.34<br>0.52         | 0.04<br>0.07             | 43-97<br>USA-OW-FR-220-97-B |
| Wheat,<br>spring<br>MN, 1997 | 50<br>WG    | 2  | 0.12      | 0.05      | straw            | 44<br>44      | 0.31<br>0.40         | 0.04<br>0.07             | 43-97<br>USA-OW-FR-220-97-C |
| Wheat,<br>winter<br>MO, 1997 | 50<br>WG    | 1  | 0.12      | 0.07      | straw            | 43<br>43      | 0.09<br>0.07         | <0.02<br><0.02           | 43-97<br>USA-MW-FR-201-97-B |
| Wheat,<br>winter<br>MO, 1997 | 50<br>WG    | 2  | 0.12      | 0.07      | straw            | 43<br>43      | 0.09<br>0.06         | <0.02<br><0.02           | 43-97<br>USA-MW-FR-201-97-C |
| Wheat,<br>winter<br>KS, 1997 | 50<br>WG    | 1  | 0.14      | 0.07      | straw            | 36<br>36      | <u>0.08</u><br>0.08  | <u>&lt;0.02</u><br><0.02 | 43-97<br>USA-MW-FR-309-97-B |
| Wheat,<br>winter<br>KS, 1997 | 50<br>WG    | 2  | 0.12-0.14 | 0.07      | straw            | 36<br>36      | <u>0.12</u><br>0.12  | <u>&lt;0.02</u><br><0.02 | 43-97<br>USA-MW-FR-309-97-C |
| Wheat,<br>winter<br>KS, 1997 | 50<br>WG    | 1  | 0.12      | 0.13      | straw            | 35<br>35      | 0.11<br><u>0.12</u>  | <0.02<br><u>&lt;0.02</u> | 43-97<br>USA-MW-FR-310-97-B |
| Wheat,<br>winter<br>KS, 1997 | 50<br>WG    | 2  | 0.12      | 0.13      | straw            | 35<br>35      | 0.18<br><u>0.19</u>  | 0.02<br><u>0.02</u>      | 43-97<br>USA-MW-FR-310-97-C |
| Wheat,<br>winter<br>CO, 1997 | 50<br>WG    | 1  | 0.12      | 0.09      | straw            | 38<br>38      | <u>0.26</u><br>0.12  | <u>&lt;0.02</u><br><0.02 | 43-97<br>USA-MW-FR-311-97-B |
| Wheat,<br>winter<br>CO, 1997 | 50<br>WG    | 2  | 0.12      | 0.09      | straw            | 38<br>38      | 0.20<br><u>0.29</u>  | <0.02<br><u>&lt;0.02</u> | 43-97<br>USA-MW-FR-311-97-C |
| Wheat,<br>winter<br>NE, 1997 | 50<br>WG    | 1  | 0.12      | 0.07      | straw            | 33<br>33      | 0.07<br><u>0.11</u>  | <0.02<br><u>&lt;0.02</u> | 43-97<br>USA-MW-FR-621-97-B |
| Wheat,<br>winter<br>NE, 1997 | 50<br>WG    | 2  | 0.12      | 0.07      | straw            | 33<br>33      | <u>0.11</u><br>0.09  | <u>&lt;0.02</u><br><0.02 | 43-97<br>USA-MW-FR-621-97-C |
| Wheat,<br>winter<br>AR, 1997 | 50<br>WG    | 1  | 0.12      | 0.09      | straw            | 43<br>43      | 1.0<br>0.76          | 0.21<br>0.13             | 43-97<br>USA-OS-FR-103-97-B |
| Wheat,<br>winter<br>AR, 1997 | 50<br>WG    | 2  | 0.12      | 0.09      | straw            | 43<br>43      | 1.6<br>2.0           | 0.32<br>0.19             | 43-97<br>USA-OS-FR-103-97-C |
| Wheat,<br>winter<br>NC, 1997 | 50<br>WG    | 1  | 0.12      | 0.09      | straw            | 34<br>34      | 1.3<br><u>1.4</u>    | 0.26<br><u>0.23</u>      | 43-97<br>USA-OS-FR-603-97-B |
| Wheat,<br>winter<br>NC, 1997 | 50<br>WG    | 2  | 0.12      | 0.09      | straw            | 34<br>34      | <u>1.9</u><br>1.7    | <u>0.53</u><br>0.49      | 43-97<br>USA-OS-FR-603-97-C |

| Location,<br>Year            | Application |    |          |          | Residues (mg/kg) |               |                      |                | Report No.;<br>Study No.    |
|------------------------------|-------------|----|----------|----------|------------------|---------------|----------------------|----------------|-----------------------------|
|                              | Form        | No | kg ai/ha | kg ai/hl | Sample           | PHI<br>(days) | trifloxy-<br>strobin | CGA-<br>321113 |                             |
| Wheat,<br>winter<br>OK, 1997 | 50<br>WG    | 1  | 0.12     | 0.09     | straw            | 34            | 0.12                 | 0.02           | 43-97<br>USA-OS-FR-730-97-B |
|                              |             |    |          |          |                  | 34            | <u>0.27</u>          | <u>0.04</u>    |                             |
|                              |             |    |          |          |                  | 38            | 0.12                 | 0.02           |                             |
|                              |             |    |          |          |                  | 38            | 0.18                 | 0.04           |                             |
|                              |             |    |          |          |                  | 44            | 0.13                 | 0.05           |                             |
|                              |             |    |          |          |                  | 44            | 0.21                 | 0.07           |                             |
|                              |             |    |          |          |                  | 51            | 0.23                 | 0.07           |                             |
|                              |             |    |          |          |                  | 51            | 0.23                 | 0.08           |                             |
| Wheat,<br>winter<br>OK, 1997 | 50<br>WG    | 2  | 0.12     | 0.09     | straw            | 34            | 0.18                 | 0.03           | 43-97<br>USA-OS-FR-730-97-C |
|                              |             |    |          |          |                  | 34            | 0.27                 | 0.04           |                             |
|                              |             |    |          |          |                  | 38            | 0.21                 | 0.03           |                             |
|                              |             |    |          |          |                  | 38            | 0.19                 | 0.03           |                             |
|                              |             |    |          |          |                  | 44            | 0.14                 | 0.04           |                             |
|                              |             |    |          |          |                  | 44            | 0.21                 | 0.07           |                             |
|                              |             |    |          |          |                  | 51            | 0.32                 | 0.07           |                             |
|                              |             |    |          |          |                  | 51            | <u>0.31</u>          | <u>0.13</u>    |                             |
| Wheat,<br>winter<br>OK, 1997 | 50<br>WG    | 1  | 0.12     | 0.07     | straw            | 47            | 0.56                 | <0.02          | 43-97<br>USA-OS-FR-731-97-B |
|                              |             |    |          |          |                  | 47            | 0.57                 | <0.02          |                             |
| Wheat,<br>winter<br>OK, 1997 | 50<br>WG    | 2  | 0.12     | 0.07     | straw            | 47            | 0.05                 | <0.02          | 43-97<br>USA-OS-FR-731-97-C |
|                              |             |    |          |          |                  | 47            | 0.04                 | <0.02          |                             |
| Wheat,<br>winter<br>TX, 1997 | 50<br>WG    | 1  | 0.12     | 0.08     | straw            | 32            | 0.29                 | 0.02           | 43-97<br>USA-OS-FR-735-97-B |
|                              |             |    |          |          |                  | 32            | <u>0.34</u>          | <u>0.02</u>    |                             |
| Wheat,<br>winter<br>TX, 1997 | 50<br>WG    | 2  | 0.12     | 0.08     | straw            | 32            | 0.71                 | 0.05           | 43-97<br>USA-OS-FR-735-97-C |
|                              |             |    |          |          |                  | 32            | <u>0.97</u>          | <u>0.05</u>    |                             |

*Sugar beet leaves and tops*

Table 99. Results of residue trials with trifloxystrobin on sugar beet in the USA (tops).

| Location,<br>Year | Application |    |          |          | Residues (mg/kg) |               |                      |                | Report No.;<br>Study No.    |
|-------------------|-------------|----|----------|----------|------------------|---------------|----------------------|----------------|-----------------------------|
|                   | Form        | No | kg ai/ha | kg ai/hl | Sample           | PHI<br>(days) | trifloxy-<br>strobin | CGA-<br>321113 |                             |
| ID, 1997          | 50<br>WG    | 3  | 0.12     | 0.26     | tops             | 21            | <u>0.08</u>          | <u>≤0.02</u>   | 35-97<br>USA-OW-FR-626-97   |
|                   |             |    |          |          |                  | 21            | 0.08                 | <0.02          |                             |
| ID, 1997          | 50<br>WG    | 3  | 0.12     | 0.041    | tops             | 21            | 2.2                  | 0.06           | 35-97<br>USA-OW-FR-627-97   |
|                   |             |    |          |          |                  | 21            | <u>2.4</u>           | <u>0.10</u>    |                             |
| CO, 1997          | 50<br>WG    | 3  | 0.12     | 0.083    | tops             | 21            | 0.50                 | <0.02          | 35-97<br>USA-MW-FR-312-97   |
|                   |             |    |          |          |                  | 21            | <u>0.56</u>          | <u>0.05</u>    |                             |
| WI, 1997          | 50<br>WG    | 3  | 0.12     | 0.083    | tops             | 21            | 1.4                  | 0.03           | 35-97<br>USA-MW-FR-313-97   |
|                   |             |    |          |          |                  | 21            | <u>1.6</u>           | <u>0.04</u>    |                             |
| NE, 1997          | 50<br>WG    | 3  | 0.12     | 0.066    | tops             | 21            | <u>0.35</u>          | <u>0.04</u>    | 35-97<br>USA-MW-FR-622-97   |
|                   |             |    |          |          |                  | 21            | 0.28                 | 0.04           |                             |
| MI, 1997          | 50<br>WG    | 3  | 0.12     | 0.26     | tops             | 21            | <u>0.24</u>          | <u>≤0.02</u>   | 35-97<br>USA-NE-FR-731-97   |
|                   |             |    |          |          |                  | 21            | 0.23                 | <0.02          |                             |
| MN, 1997          | 50<br>WG    | 3  | 0.12     | 0.066    | tops             | 23            | 0.11                 | <0.02          | 35-97<br>USA-OW-FR-223-97-A |
|                   |             |    |          |          |                  | 23            | <u>0.17</u>          | <u>≤0.02</u>   |                             |

| Location,<br>Year | Application |    |          |                 | Residues (mg/kg) |               |                      |                 | Report No.;<br>Study No.  |
|-------------------|-------------|----|----------|-----------------|------------------|---------------|----------------------|-----------------|---------------------------|
|                   | Form        | No | kg ai/ha | kg ai/hl        | Sample           | PHI<br>(days) | trifloxy-<br>strobin | CGA-<br>321113  |                           |
| MN, 1997          | 50<br>WG    | 3  | 0.12     | 0.066           | tops             | 0             | 1.7                  | 0.03            | 35-97<br>USA-OW-FR-224-97 |
|                   |             |    |          |                 |                  | 0             | 1.9                  | 0.03            |                           |
|                   |             |    |          |                 |                  | 7             | 0.82                 | <0.02           |                           |
|                   |             |    |          |                 |                  | 7             | 0.90                 | <0.02           |                           |
|                   |             |    |          |                 |                  | 14            | 0.46                 | <0.02           |                           |
|                   |             |    |          |                 |                  | 14            | 0.44                 | <0.02           |                           |
|                   |             |    |          |                 |                  | 21            | 0.13                 | <0.02           |                           |
|                   |             |    |          |                 |                  | 21            | <u>0.26</u>          | <u>&lt;0.02</u> |                           |
|                   |             |    |          |                 |                  | 28            | 0.10                 | <0.02           |                           |
|                   |             |    |          |                 |                  | 28            | 0.09                 | <0.02           |                           |
| CA, 1997          | 50<br>WG    | 3  | 0.12     | 0.053           | tops             | 0             | 3.4                  | 0.05            | 35-97<br>USA-OW-FR-402-97 |
|                   |             |    |          |                 |                  | 0             | 3.3                  | 0.05            |                           |
|                   |             |    |          |                 |                  | 7             | 2.8                  | 0.03            |                           |
|                   |             |    |          |                 |                  | 7             | 2.8                  | 0.03            |                           |
|                   |             |    |          |                 |                  | 14            | 1.5                  | <0.02           |                           |
|                   |             |    |          |                 |                  | 14            | 1.4                  | <0.02           |                           |
|                   |             |    |          |                 |                  | 21            | <u>0.98</u>          | <u>&lt;0.02</u> |                           |
|                   |             |    |          |                 |                  | 21            | 0.89                 | <0.02           |                           |
|                   |             |    |          |                 |                  | 28            | 0.73                 | <0.02           |                           |
|                   |             |    |          |                 |                  | 28            | 0.54                 | <0.02           |                           |
| ID, 1997          | 50<br>WG    | 3  | 0.12     | 0.26            | tops             | 21            | <u>0.08</u>          | <u>&lt;0.02</u> | 35-97                     |
|                   |             |    |          |                 |                  | 21            | 0.08                 | <0.02           | USA-OW-FR-626-97          |
| ID, 1997          | 50<br>WG    | 3  | 0.12     | 0.041           | tops             | 21            | 2.2                  | 0.06            | 35-97                     |
|                   |             |    |          |                 |                  | 21            | <u>2.4</u>           | <u>0.10</u>     | USA-OW-FR-627-97          |
| NE, 1998          | 50<br>WG    | 3  | 0.12     | 0.066           | tops             | 21            | 0.08                 | <0.02           | 152-98                    |
|                   |             |    |          |                 |                  | 21            | <u>0.23</u>          | <u>&lt;0.02</u> | USA-MW-FR-615-98-A        |
| MN, 1998          | 50<br>WG    | 3  | 0.12     | 0.066           | tops             | 21            | 0.49                 | 0.02            | 152-98                    |
|                   |             |    |          |                 |                  | 21            | <u>0.61</u>          | <u>&lt;0.02</u> | USA-OW-FR-216-98-A        |
| ID, 1998          | 50<br>WG    | 3  | 0.12     | 0.044-<br>0.046 | tops             | 21            | 0.66                 | <0.02           | 152-98                    |
|                   |             |    |          |                 |                  | 21            | <u>0.72</u>          | <u>&lt;0.02</u> | USA-OW-FR-312-98-A        |
| CA, 1998          | 50<br>WG    | 3  | 0.12     | 0.044-<br>0.046 | tops             | 21            | 2.1                  | 0.06            | 152-98                    |
|                   |             |    |          |                 |                  | 21            | <u>2.3</u>           | <u>0.06</u>     | USA-OW-FR-522-98-A        |
| NE, 1998          | 250<br>EC   | 3  | 0.12     | 0.066           | tops             | 21            | <u>0.14</u>          | <u>&lt;0.02</u> | 152-98                    |
|                   |             |    |          |                 |                  | 21            | 0.11                 | <0.02           | USA-MW-FR-615-98-B        |
| MN, 1998          | 250<br>EC   | 3  | 0.12     | 0.066           | tops             | 21            | 0.17                 | <0.02           | 152-98                    |
|                   |             |    |          |                 |                  | 21            | <u>0.21</u>          | <u>0.02</u>     | USA-OW-FR-216-98-B        |
| ID, 1998          | 250<br>EC   | 3  | 0.12     | 0.044-<br>0.046 | tops             | 21            | <u>0.54</u>          | <u>&lt;0.02</u> | 152-98                    |
|                   |             |    |          |                 |                  | 21            | 0.54                 | <0.02           | USA-OW-FR-312-98-B        |
| CA, 1998          | 250<br>EC   | 3  | 0.12     | 0.044           | tops             | 21            | <u>0.64</u>          | <u>0.02</u>     | 152-98                    |
|                   |             |    |          |                 |                  | 21            | 0.52                 | 0.02            | USA-OW-FR-522-98-B        |

Table 100. Results of residue trials with trifloxystrobin on sugar beet in Europe (tops).

| Country,<br>Year       | Application |    |          |           | Residues (mg/kg) |               |                      |                             | Report No.;<br>Study No. |
|------------------------|-------------|----|----------|-----------|------------------|---------------|----------------------|-----------------------------|--------------------------|
|                        | Form        | No | kg ai/ha | kg ai/hl  | Sample           | PHI<br>(days) | trifloxy-<br>strobin | CGA-<br>321113 <sup>1</sup> |                          |
| France-<br>North, 1999 | 267.5<br>EC | 2  | 0.13     | 0.04      | tops             | 45            | <0.05                | <0.05                       | 9911101                  |
|                        |             |    |          |           |                  | 45            | <0.05                | <0.05                       | FRA-9911101              |
| France-<br>North, 1999 | 267.5<br>EC | 2  | 0.13     | 0.04-0.05 | tops             | 45            | <0.05                | <0.05                       | 9911102                  |
|                        |             |    |          |           |                  | 45            | <0.05                | <0.05                       | FRA-9911102              |
| France-<br>North, 1998 | 267.5<br>EC | 2  | 0.13     | 0.05      | leaf             | 46            | 0.04                 | <0.02                       | 2163/98                  |
|                        |             |    |          |           |                  | 46            | <0.02                | <0.02                       | FRA-2163-98              |
|                        |             |    |          |           | tops             | 46            | 0.04                 | <0.02                       |                          |
|                        |             |    |          |           |                  |               |                      |                             |                          |
| France-<br>North, 1998 | 267.5<br>EC | 2  | 0.13     | 0.03      | tops             | 43            | 0.02                 | <0.02                       | 2164/98                  |
|                        |             |    |          |           |                  | 43            | <0.02                | <0.02                       | FRA-2164-98              |
| France-<br>North, 1999 | 267.5<br>EC | 2  | 0.13     | 0.05      | tops             | 0             | 0.94                 | <0.05                       | 9910901                  |
|                        |             |    |          |           |                  | 21            | <u>0.09</u>          | <u>&lt;0.05</u>             | FRA-9910901              |
|                        |             |    |          |           |                  | 30            | 0.10                 | <0.05                       |                          |
|                        |             |    |          |           |                  | 45            | <0.05                | <0.05                       |                          |

| Country,<br>Year        | Application |    |          |                 | Residues (mg/kg) |                                |                                                     |                                                           | Report No.;<br>Study No.               |
|-------------------------|-------------|----|----------|-----------------|------------------|--------------------------------|-----------------------------------------------------|-----------------------------------------------------------|----------------------------------------|
|                         | Form        | No | kg ai/ha | kg ai/hl        | Sample           | PHI<br>(days)                  | trifloxy-<br>strobin                                | CGA-<br>321113 <sup>1</sup>                               |                                        |
| France –<br>North, 1999 | 267.5<br>EC | 2  | 0.13     | 0.05            | tops             | 0<br>21<br>30<br>45            | 3.2<br><u>&lt;0.05</u><br><0.05<br><0.05            | 0.11<br><u>&lt;0.05</u><br><0.05<br><0.05                 | 9910902<br>FRA-9910902                 |
| France-<br>North, 1999  | 267.5<br>EC | 2  | 0.13     | 0.04            | tops             | 0<br>21<br>30<br>45            | 2.4<br><u>0.44</u><br><0.05<br><0.05                | 0.05<br><u>&lt;0.05</u><br><0.05<br><0.05                 | 9910903<br>FRA-9910903                 |
| France-<br>South, 1999  | 267.5<br>EC | 2  | 0.13     | 0.03            | tops             | 0<br>22<br>30<br>43            | 0.35<br><u>&lt;0.05</u><br><0.05<br><0.05           | 0.05<br><u>&lt;0.05</u><br><0.05<br><0.05                 | 9911001<br>FRA-9911001-A               |
| France-<br>South, 1999  | 267.5<br>EC | 3  | 0.13     | 0.03            | tops             | 0<br>22<br>30<br>43            | 0.92<br><u>&lt;0.05</u><br><0.05<br><0.05           | 0.20<br><u>&lt;0.05</u><br><0.05<br><0.05                 | 9911001<br>FRA-9911001-B               |
| France-<br>South, 1999  | 267.5<br>EC | 2  | 0.13     | 0.04            | tops             | 0<br>21<br>30<br>45            | 1.4<br><u>&lt;0.05</u><br><0.05<br><0.05            | 0.07<br><u>&lt;0.05</u><br><0.05<br><0.05                 | 9911002<br>FRA-9911002-A               |
| France-<br>South, 1999  | 267.5<br>EC | 3  | 0.13     | 0.04            | tops             | 0<br>21<br>30<br>45            | 2.3<br><u>&lt;0.05</u><br><0.05<br><0.05            | 0.14<br><u>&lt;0.05</u><br><0.05<br><0.05                 | 9911002<br>FRA-9911002-B               |
| France-<br>South, 2000  | 267.5<br>EC | 3  | 0.13     | 0.013           | tops             | 0<br>20<br>20                  | 2.9<br><u>0.33</u><br>0.19                          | 0.07<br><u>0.08</u><br>0.04                               | NOV/RES/00061<br>FRA-NOV-RES-<br>00061 |
| France-<br>South, 2000  | 267.5<br>EC | 3  | 0.13     | 0.03            | tops             | 0<br>20<br>20                  | 0.84<br><u>&lt;0.02</u><br><0.02                    | 0.06<br><u>&lt;0.02</u><br><0.02                          | NOV/RES/00062<br>FRA-NOV-RES-<br>00062 |
| Spain, 1999             | 267.5<br>EC | 3  | 0.13     | 0.013           | tops             | 21<br>21                       | <u>0.14</u><br>0.12                                 | <u>0.03</u><br>0.03                                       | 2060/99<br>SPA-2060-99                 |
| Spain, 1999             | 267.5<br>EC | 3  | 0.13     | 0.012-<br>0.014 | tops             | 0<br>7<br>14<br>21<br>21       | 0.77<br>0.18<br>0.07<br><u>0.07</u><br>0.05         | 0.11<br>0.04<br>0.03<br><u>0.02</u><br><u>0.02</u>        | 2061/99<br>SPA-2061-99                 |
| Italy, 1999             | 267.5<br>EC | 3  | 0.13     | 0.02            | tops             | 0<br>7<br>14<br>21<br>21<br>28 | 0.50<br>0.13<br>0.06<br>0.02<br><u>0.05</u><br>0.02 | 0.04<br>0.05<br>0.04<br><0.02<br><u>&lt;0.02</u><br><0.02 | 2074/99<br>ITA-2074-99                 |
| Italy, 1999             | 267.5<br>EC | 3  | 0.13     | 0.02            | tops             | 21<br>21                       | <u>&lt;0.02</u><br><0.02                            | <u>&lt;0.02</u><br><0.02                                  | 2075/99<br>ITA-2075-99                 |
| Switzerland,<br>1999    | 267.5<br>EC | 2  | 0.13     | 0.02            | tops             | 0<br>21<br>30<br>45<br>45      | 0.35<br><u>&lt;0.02</u><br><0.02<br><0.02<br><0.02  | 0.04<br><u>&lt;0.02</u><br><0.02<br><0.02<br><0.02        | 2086/99<br>SWZ-2086-99                 |

## FATE OF RESIDUES IN STORAGE AND PROCESSING

### In storage

No data submitted.

### In processing

#### *Nature of residues*

Morgenroth (2000; report No. 00MO02), described the degradation of glyoxyl-phenyl-[U-<sup>14</sup>C]trifloxystrobin in buffered water under laboratory conditions simulating processing methods such as pasteurisation, baking and sterilisation for raw agricultural commodities (RAC). Radiolabelled trifloxystrobin was dissolved in citrate buffers at concentrations of about 0.3 mg/l. The test systems were incubated at 90 °C, pH 4 for 20 min. (pasteurisation); 100 °C, pH 5 for 60 min. (baking, brewing and boiling) and 120 °C, pH 6 for 20 min. (sterilisation), and samples analysed by thin-layer chromatography, with quantification by liquid scintillation counting.

Trifloxystrobin was hydrolytically stable under pasteurisation, showed minor degradation of 2.6% under baking, brewing and boiling conditions, and degradation of 22.5% under sterilisation. The main degradation product observed (2% at pH 5 and 20.8% at pH 6) was CGA321113.

#### *Effect of processing on the level of residues*

Processing studies on barley, cabbage, cotton, grapes, hops, maize, orange, peanuts, pome fruit, potato, rice, stone fruit, strawberry, sugar beet, tomato and wheat are reported in Tables 108–119. The residues in the raw agricultural commodity (RAC) used for the calculation of the processing factor are in bold. In RACs and processed products CGA321113 was determined in parallel with the parent compound. The processing factors were based on the total trifloxystrobin equivalents (sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin; conversion factor 1.036 for CGA321113). If the residues in the RAC were at or below the LOQ, no processing factors were calculated.

#### *Oranges*

In 1998 in five trials in the USA orange trees were sprayed as follows: treatment 1 four foliar spray applications at 14-day intervals at a rate of 0.17 kg ai/ha; treatment 2 four applications at a 3-fold rate (0.52 kg ai/ha) and treatment 3 four applications at a 5-fold rate (0.865 kg ai/ha). Fruit samples were taken on day 26 or 30 after the last application, and residues determined in the raw agricultural commodity and processed products.

Washed oranges were placed in an abrasion peeler to break the oil sacs. Cold water was sprayed into the peeler to trap the highly volatile oil, and the resulting emulsion of oil, water and peel solids was treated with Citropex, an enzyme preparation to increase oil yield. Subsequently, the oil emulsion was passed through a screen separator to separate the peel solids from the emulsion. The peel solids were resuspended with water and again passed through the separator to remove the remaining oil. The oil emulsion was collected and centrifuged to separate water, oil and peel solids, and the oil treated enzymatically and subsequently centrifuged to remove the remaining water and peel solids.

To produce juice, the abraded oranges were extracted with a juice extractor and the resulting juice passed through a screen to remove coarse pulp and pieces of peel. Pulp and peel were combined for further processing.



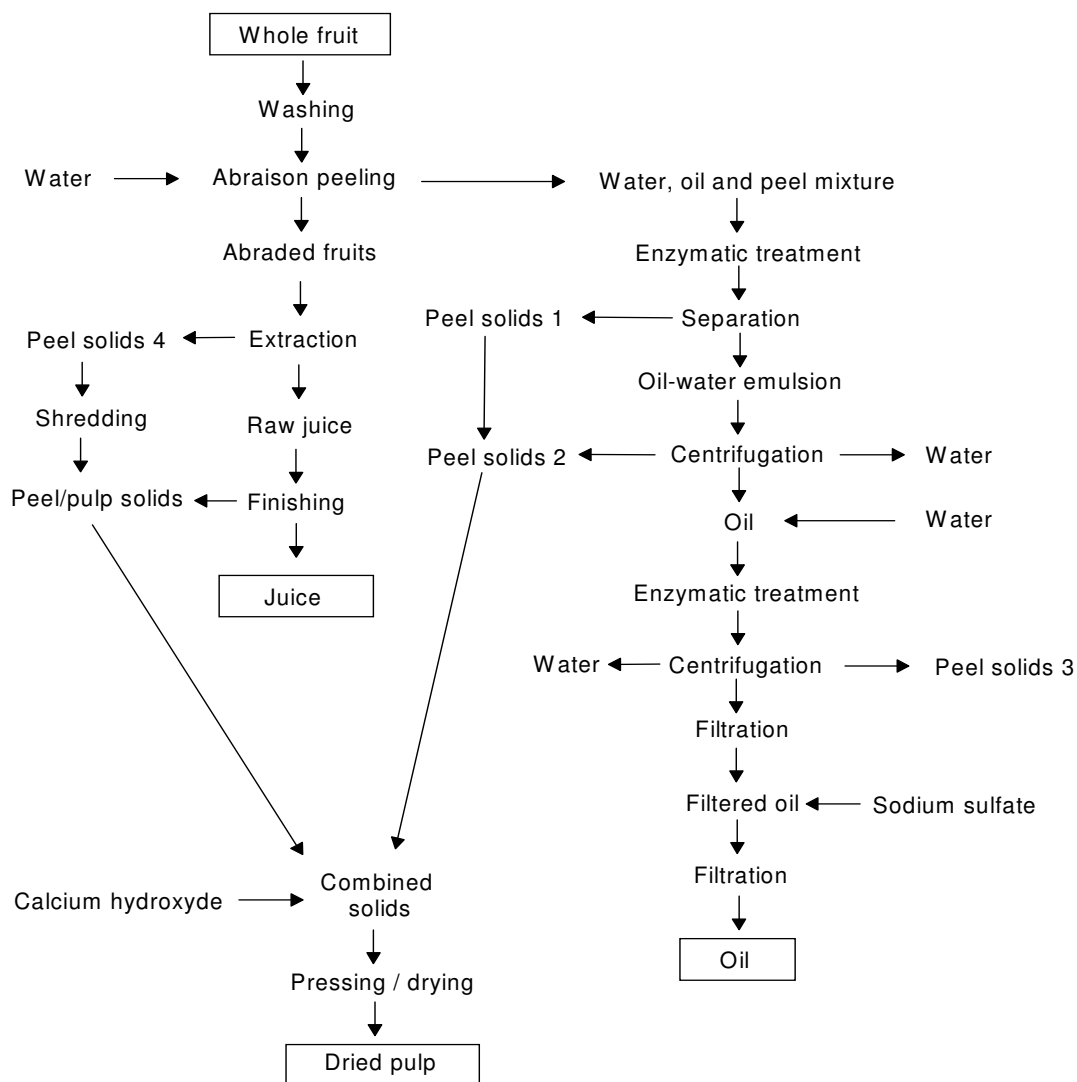
For dried pulp, all of the peel and pulp fractions were combined, ground and neutralised with calcium hydroxide, then pressed to remove water and dried in a dryer to a water content of about 5-10%.

The detailed processing steps are shown in Figure 4. The results of the trials are summarised in Table 101.

Table 101. Trifloxystrobin residues in oranges and their processed products, USA, 1998.

| Report No.;<br>Study No.       | Application |    |             |               | Sample              | PHI<br>(days) | Residues (mg/kg)     |                 |             | Proc.<br>factor      |
|--------------------------------|-------------|----|-------------|---------------|---------------------|---------------|----------------------|-----------------|-------------|----------------------|
|                                | Form        | No | kg<br>ai/ha | kg ai/hl      |                     |               | trifloxy-<br>strobin | CGA-<br>321113  | Total       |                      |
| SAM 4474<br>OW-FR-516-<br>98-A | 50<br>WG    | 4  | 0.17        | 0.008         | whole fruit, washed | <b>30</b>     | <b>0.06</b>          | <b>&lt;0.02</b> | <b>0.06</b> | <0.33<br>113<br>3    |
|                                |             |    |             |               | juice               | 30            | <0.02                | <0.02           | <0.02       |                      |
|                                |             |    |             |               | oil                 | 30            | 6.1                  | 0.70            | 6.8         |                      |
|                                |             |    |             |               | pulp, dry           | 30            | 0.18                 | <0.02           | 0.18        |                      |
| SAM 4474<br>OW-FR-516-<br>98-C | 50<br>WG    | 4  | 0.87        | 0.04          | whole fruit, washed | <b>30</b>     | <b>0.53</b>          | <b>&lt;0.02</b> | <b>0.53</b> | <0.038<br>66<br>1.34 |
|                                |             |    |             |               | juice               | 30            | <0.02                | <0.02           | <0.02       |                      |
|                                |             |    |             |               | oil                 | 30            | 33.1                 | 1.8             | 35          |                      |
|                                |             |    |             |               | pulp, dry           | 30            | 0.67                 | 0.04            | 0.71        |                      |
| SAM 4474<br>OS-FR-404-<br>98-A | 50<br>WG    | 4  | 0.17        | 0.01          | whole fruit, washed | <b>26</b>     | <b>0.05</b>          | <b>&lt;0.02</b> | <b>0.05</b> | <0.4<br>138<br>5.2   |
|                                |             |    |             |               | juice               | 26            | <0.02                | <0.02           | <0.02       |                      |
|                                |             |    |             |               | oil                 | 26            | 6.2                  | 0.69            | 6.9         |                      |
|                                |             |    |             |               | pulp, dry           | 26            | 0.22                 | 0.04            | 0.26        |                      |
| SAM 4474<br>OS-FR-404-<br>98-B | 50<br>WG    | 4  | 0.52        | 0.03          | whole fruit, washed | <b>26</b>     | <b>0.13</b>          | <b>&lt;0.02</b> | <b>0.13</b> | <0.15<br>166<br>5.2  |
|                                |             |    |             |               | juice               | 26            | <0.02                | <0.02           | <0.02       |                      |
|                                |             |    |             |               | oil                 | 26            | 20.4                 | 1.2             | 21.6        |                      |
|                                |             |    |             |               | pulp, dry           | 26            | 0.59                 | 0.09            | 0.68        |                      |
| SAM 4474<br>OS-FR-404-<br>98-C | 50<br>WG    | 4  | 0.87        | 0.05-<br>0.06 | whole fruit, washed | <b>26</b>     | <b>0.43</b>          | <b>0.02</b>     | <b>0.45</b> | <0.04<br>166<br>2.38 |
|                                |             |    |             |               | juice               | 26            | <0.02                | <0.02           | <0.02       |                      |
|                                |             |    |             |               | oil                 | 26            | 73.0                 | 1.7             | 74.7        |                      |
|                                |             |    |             |               | pulp, dry           | 26            | 0.99                 | 0.08            | 1.07        |                      |

Figure 4. Processing of oranges to juice, oil and dried pulp.



### *Pome fruit*

In 1996 and 1999 four residue trials were conducted in Europe with trifloxystrobin on apples, and samples were also collected for processing studies. In two trials, the apple trees were treated three or ten times at an application rate of 0.075 kg ai/ha each. In the other two trials the trees were treated three times at the 5-fold rate (0.38 kg ai/ha). In 1996, in a processing trial in Europe pear trees were treated ten times at a rate of 0.075 kg ai/ha, and in six processing trials in the USA apple trees were sprayed using three different treatment regimes: treatment 1 (1-fold rate) four foliar sprays at a rate of 0.1 kg ai/ha; treatment 2 four applications at the 3-fold rate (0.3 kg ai/ha); and treatment 3 four applications at the 5-fold rate (0.5 kg ai/ha). Residues were determined in the raw agricultural commodity 14 days after the last application and in a variety of processed products. The results of the trials are summarised in Table 102.

Apple sauce was prepared by boiling washed and sliced apples and then passing the fruit through a sieve. In some cases sugar, citric acid and ascorbic acid were added and the sauce pasteurised. By pressing apples, juice and wet pomace were separated. The raw juice was then further prepared to give clear and pasteurised juice. The detailed processing steps are shown in Figure 5.

In the pear trial fruits were washed and peeled, cores removed, then the fruits were boiled with sugar solution, water, citric acid and ascorbic acid. The preserve was sterilised.

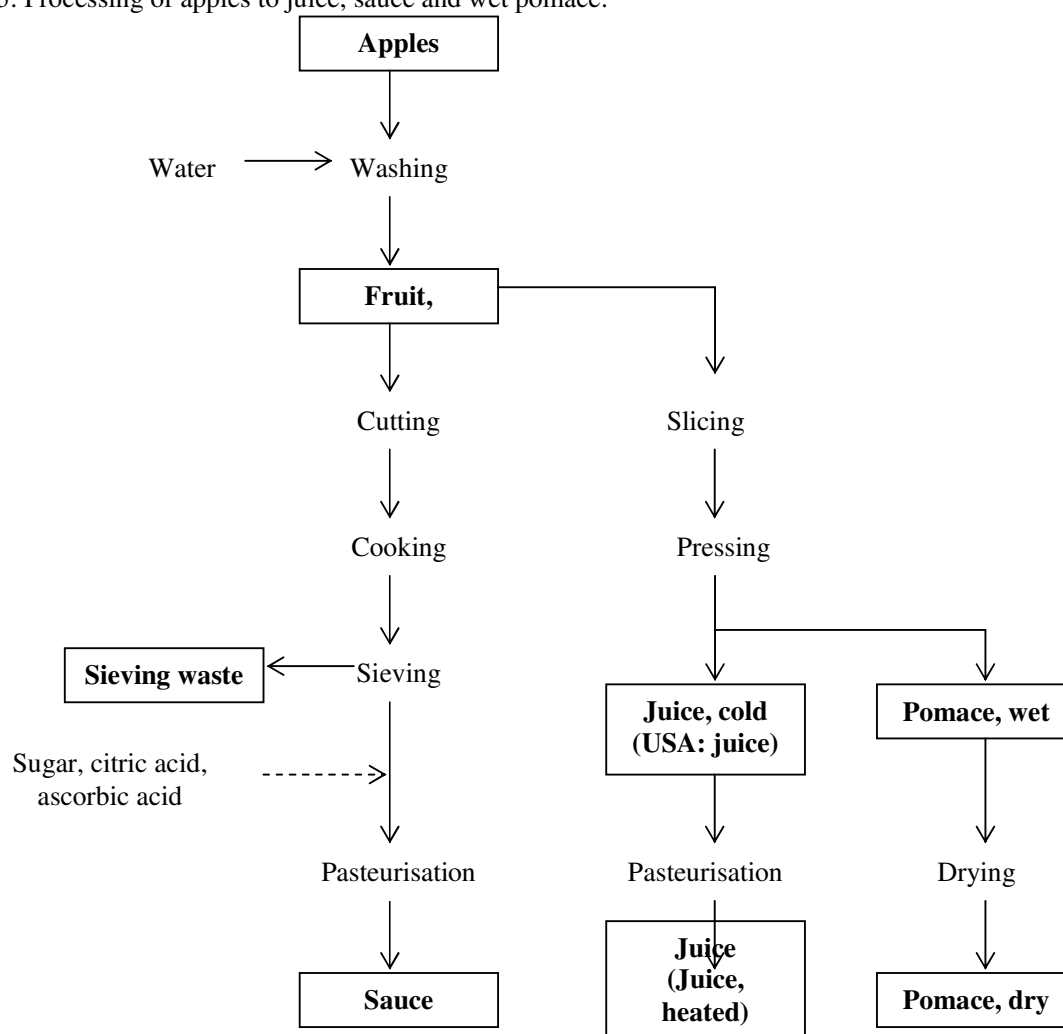
For dried apples and pears the fruits were peeled, cores removed, then cut into discs/rings, sulfured in  $K_2S_2O_5$  solution and dried until a maximum moisture content of 25%.

Table 102. Trifloxystrobin residues in pome fruit and processed products.

| Crop<br>Country,<br>Year           | Application |    |             |          | Sample                       | PHI<br>(days) | Residues (mg/kg)     |                 |             | Proc.<br>factor                   | Report No.;<br>Study No.                          |
|------------------------------------|-------------|----|-------------|----------|------------------------------|---------------|----------------------|-----------------|-------------|-----------------------------------|---------------------------------------------------|
|                                    | Form        | No | kg<br>ai/ha | kg ai/hl |                              |               | trifloxy-<br>strobin | CGA-<br>321113  | Total       |                                   |                                                   |
| Apple,<br>France<br>1999           | 50<br>WG    | 3  | 0.075       | 0.015    | fruit<br>juice               | <b>14</b>     | <b>0.03</b>          | <b>&lt;0.02</b> | <b>0.03</b> | <0.33<br>1.33                     | 2007/99<br>FRA-2007-<br>99                        |
|                                    |             |    |             |          | sauce                        | 14            | <0.01                | <0.01           | <0.01       |                                   |                                                   |
|                                    |             |    |             |          |                              | 14            | 0.04                 | <0.01           | 0.04        |                                   |                                                   |
| Apple,<br>Germany<br>1996          | 50<br>WG    | 10 | 0.075       | 0.01     | fruit<br>whole<br>fruit,     | <b>14</b>     | <b>0.13</b>          | <b>&lt;0.02</b> | <b>0.13</b> | 0.92<br><br>2.69<br>0.31<br><0.15 | gr00996<br>BRD-<br>gr00996                        |
|                                    |             |    |             |          | washed<br>juice              | 14            | 0.12                 | <0.02           | 0.12        |                                   |                                                   |
|                                    |             |    |             |          | pomace,                      | 14            | <0.02                | <0.02           | <0.02       |                                   |                                                   |
|                                    |             |    |             |          | wet<br>sauce                 | 14            | 0.33                 | 0.02            | 0.35        |                                   |                                                   |
|                                    |             |    |             |          | fruit,<br>dried              | 14            | 0.04                 | <0.02           | 0.04        |                                   |                                                   |
|                                    |             |    |             |          |                              | 14            | <0.02                | <0.02           | <0.02       |                                   |                                                   |
| Apple,<br>Switzer-<br>land<br>1999 | 50<br>WG    | 3  | 0.38        | 0.04     | fruit<br>juice,              | <b>14</b>     | <b>0.25</b>          | <b>&lt;0.01</b> | <b>0.25</b> | 0.036<br>0.012<br>5.2<br>25.6     | 2125/99<br>SWZ-2125-<br>99-B2                     |
|                                    |             |    |             |          | cold<br>juice,               | 14            | 0.009                | <0.002          | 0.009       |                                   |                                                   |
|                                    |             |    |             |          | heated<br>pomace,            | 14            | 0.003                | <0.002          | 0.003       |                                   |                                                   |
|                                    |             |    |             |          | wet<br>pomace,<br>dried      | 14            | 1.25                 | 0.05            | 1.3         |                                   |                                                   |
| Apple,<br>Switzer-<br>land<br>1999 | 50<br>WG    | 3  | 0.38        | 0.04     | fruit<br>whole<br>fruit,     | <b>14</b>     | <b>0.35</b>          | <b>&lt;0.01</b> | <b>0.35</b> | 0.83<br>2.8<br>0.13               | 2125/99<br>SWZ-2125-<br>99-B3                     |
|                                    |             |    |             |          | washed<br>waste,             | 14            | 0.29                 | <0.01           | 0.29        |                                   |                                                   |
|                                    |             |    |             |          | sieving<br>sauce             | 14            | 0.98                 | <0.01           | 0.98        |                                   |                                                   |
| Pear,<br>Germany<br>1996           | 50<br>WG    | 10 | 0.075       | 0.005    | fruit<br>whole<br>fruit,     | <b>14</b>     | <b>0.13</b>          | <b>&lt;0.02</b> | <b>0.13</b> | 1.15<br>0.62                      | gr01096<br>BRD-2180-<br>96                        |
|                                    |             |    |             |          | washed<br>sauce/<br>preserve | 14            | 0.13                 | 0.02            | 0.15        |                                   |                                                   |
|                                    |             |    |             |          | fruit,<br>dried              | 14            | <0.02                | <0.02           | <0.02       |                                   |                                                   |
| Apple<br>USA<br>1996               | 50<br>WG    | 4  | 0.1         | 0.01     | fruit<br>whole<br>fruit,     | <b>14</b>     | <b>0.14</b>          | <b>0.03</b>     | <b>0.17</b> | 0.53<br>6.6<br>0.12               | 110433<br>ABR-97074<br>USA-OW-<br>FR-634-96-<br>B |
|                                    |             |    |             |          | washed<br>pomace,            | 14            | 0.09                 | <0.02           | 0.09        |                                   |                                                   |
|                                    |             |    |             |          | wet<br>juice                 | 14            | 1.1                  | 0.03            | 1.13        |                                   |                                                   |
|                                    |             |    |             |          |                              | 14            | <0.02                | <0.02           | <0.02       |                                   |                                                   |
|                                    |             |    |             |          |                              |               |                      |                 |             |                                   |                                                   |
|                                    |             |    |             |          |                              |               |                      |                 |             |                                   |                                                   |

| Crop<br>Country,<br>Year | Application |    |             |          | Sample                  | PHI<br>(days) | Residues (mg/kg)     |                 |             | Proc.<br>factor | Report No.;<br>Study No.                          |
|--------------------------|-------------|----|-------------|----------|-------------------------|---------------|----------------------|-----------------|-------------|-----------------|---------------------------------------------------|
|                          | Form        | No | kg<br>ai/ha | kg ai/hl |                         |               | trifloxy-<br>strobin | CGA-<br>321113  | Total       |                 |                                                   |
| Apple<br>USA<br>1996     | 50<br>WG    | 4  | 0.29        | 0.032    | fruit                   | 14            | <b>0.26</b>          | <b>0.03</b>     | <b>0.29</b> | 1.07            | 110433<br>ABR-97074<br>USA-OW-<br>FR-634-96-<br>C |
|                          |             |    |             |          | whole                   | 14            | 0.31                 | <0.02           | 0.31        |                 |                                                   |
|                          |             |    |             |          | fruit,<br>washed        | 14            | 3.2                  | 0.05            | 3.25        |                 |                                                   |
|                          |             |    |             |          | pomace,<br>wet<br>juice | 14            | 0.03                 | <0.02           | 0.03        |                 |                                                   |
| Apple<br>USA<br>1996     | 50<br>WG    | 4  | 0.49        | 0.053    | fruit                   | 14            | <b>0.53</b>          | <b>0.03</b>     | <b>0.56</b> | 1.14            | 110433<br>ABR-97074<br>USA-OW-<br>FR-634-96-<br>D |
|                          |             |    |             |          | whole                   | 14            | 0.64                 | <0.02           | 0.64        |                 |                                                   |
|                          |             |    |             |          | fruit,<br>washed        | 14            | 6.7                  | 0.10            | 6.8         |                 |                                                   |
|                          |             |    |             |          | pomace,<br>wet<br>juice | 14            | 0.04                 | <0.02           | 0.04        |                 |                                                   |
| Apple<br>USA<br>1996     | 50<br>WG    | 4  | 0.01        | 0.01     | fruit                   | 14            | <b>0.07</b>          | <b>&lt;0.02</b> | <b>0.07</b> | 1.7             | 110433<br>ABR-97074<br>USA-05-<br>FR-005-96-<br>B |
|                          |             |    |             |          | whole                   | 14            | 0.12                 | <0.02           | 0.12        |                 |                                                   |
|                          |             |    |             |          | fruit,<br>washed        | 14            | 1.3                  | <0.02           | 1.3         |                 |                                                   |
|                          |             |    |             |          | pomace,<br>wet<br>juice | 14            | <0.02                | <0.02           | <0.02       |                 |                                                   |

Figure 5. Processing of apples to juice, sauce and wet pomace.



*Stone fruit*

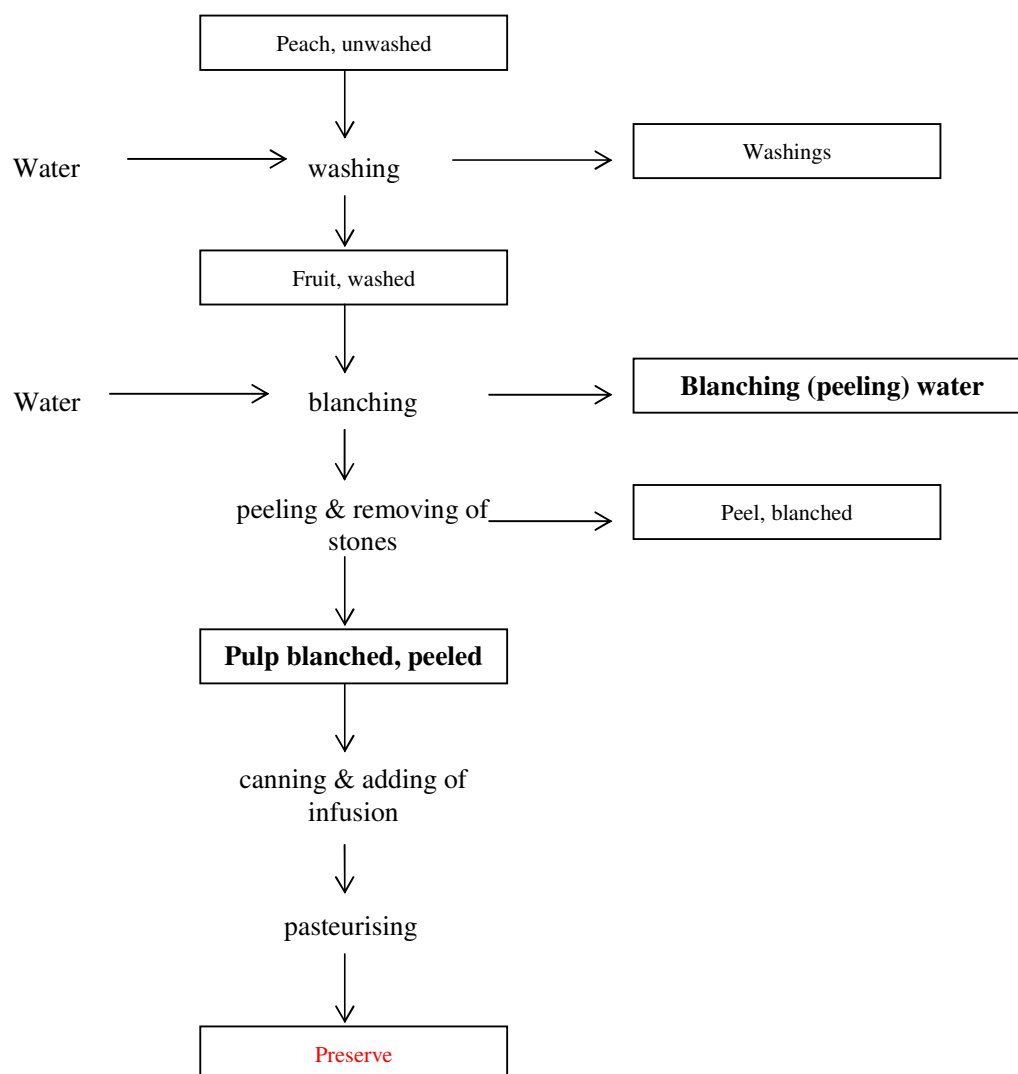
In 1998 in four processing trials in the USA plum trees were treated four times with trifloxystrobin 50 WG using foliar spray applications either at a rate of 0.14 kg ai/ha, or the 5-fold rate (0.7 kg ai/ha). Residues were determined in the raw agricultural commodity (RAC) one day after the last application and in dried prunes.

In 2000 in a trial in Italy on peaches trifloxystrobin was applied three times to the trees at a rate of 0.11 kg ai/ha, and samples taken at the recommended PHI of 7 days. Residues were determined in the fruit, in washed fruits and washings, peeling water, blanched peel and preserve. The detailed processing steps are shown in Figure 6. The results of the trials are summarised in Table 103.

Table 103. Trifloxystrobin residues in stone fruits and their processed products.

| Crop<br>Country<br>Year | Application |    |             |             | Sample            | PHI<br>(days) | Residues (mg/kg)     |                 |             | Proc.<br>factor                       | Report No.;<br>Study No.         |
|-------------------------|-------------|----|-------------|-------------|-------------------|---------------|----------------------|-----------------|-------------|---------------------------------------|----------------------------------|
|                         | Form        | No | kg<br>ai/ha | kg<br>ai/hl |                   |               | trifloxy-<br>strobin | CGA321<br>113   | Total       |                                       |                                  |
| Plum<br>USA<br>1998     | 50<br>WG    | 4  | 0.14        | 0.01        | fruit             | 1             | <b>0.07</b>          | <b>&lt;0.02</b> | <b>0.07</b> | 1.43                                  | 149-98<br>USA-OW-FR-<br>405-98-A |
|                         |             |    |             |             | dried prune       | 1             | 0.10                 | <0.02           | 0.10        |                                       |                                  |
| Plum<br>USA<br>1998     | 50<br>WG    | 4  | 0.70        | 0.05        | fruit             | 1             | <b>0.31</b>          | <b>&lt;0.02</b> | <b>0.31</b> | 1.55                                  | 149-98<br>USA-OW-FR-<br>405-98-B |
|                         |             |    |             |             | dried prune       | 1             | 0.48                 | <0.02           | 0.48        |                                       |                                  |
| Plum<br>USA<br>1998     | 50<br>WG    | 4  | 0.14        | 0.01        | fruit             | 1             | <b>0.15</b>          | <b>&lt;0.02</b> | <b>0.15</b> | 1.73                                  | 149-98<br>USA-02-FR-<br>006-98-B |
|                         |             |    |             |             | dried prune       | 1             | 0.23                 | 0.03            | 0.26        |                                       |                                  |
| Plum<br>USA<br>1998     | 50<br>WG    | 4  | 0.70        | 0.05        | fruit             | 1             | <b>1.1</b>           | <b>&lt;0.05</b> | <b>1.1</b>  | 1.34                                  | 149-98<br>USA-02-FR-<br>006-98-C |
|                         |             |    |             |             | dried prune       | 1             | 1.4                  | 0.07            | 1.47        |                                       |                                  |
| Peach<br>Italy<br>2000  | 50<br>WG    | 3  | 0.11        | 0.01        | fruit             | 7             | <b>0.19</b>          | <b>0.01</b>     | <b>0.20</b> | 0.85<br>0.12<br><0.05<br>3.6<br><0.05 | 2095/00<br>ITA-2095-00           |
|                         |             |    |             |             | pulp              | 7             | 0.17                 | <0.01           | 0.17        |                                       |                                  |
|                         |             |    |             |             | washings          | 7             | 0.024                | <0.01           | 0.024       |                                       |                                  |
|                         |             |    |             |             | pulp,<br>blanched | 7             | <0.01                | <0.01           | <0.01       |                                       |                                  |
|                         |             |    |             |             | peel,<br>blanched | 7             | 0.7                  | 0.02            | 0.72        |                                       |                                  |
|                         |             |    |             |             | preserve          | 7             | <0.01                | <0.01           | <0.01       |                                       |                                  |

Figure 6. Production of processed peaches.



### Grapes

Numerous trials were carried out to determine whether trifloxystrobin-related residues would concentrate in wine (55 trials), must and juice, or dried fruit (12 trials).

A total of 34 processing trials was carried out in Australia on grapes. For processing to dried fruit sultanas were dipped in dipping oil and sodium bicarbonate and then dried according to normal commercial practice. For wine grapes were crushed and destemmed, the must pressed (white wine) and the juice transferred to a fermentation vessel for inoculation with dry yeast. The results are shown in Table 103.

Table 104. Trifloxystrobin residues in grapes and processed products, Australia, 1997–1999.

| Report No.;<br>Study No.          | Application |    |                |           | Sample                | PHI<br>(days) | Residues (mg/kg)         |                          | Total                    | Proc.<br>factor |
|-----------------------------------|-------------|----|----------------|-----------|-----------------------|---------------|--------------------------|--------------------------|--------------------------|-----------------|
|                                   | Form        | No | kg ai/ha       | kg ai/hl  |                       |               | trifloxy-<br>strobin     | CGA-<br>321113           |                          |                 |
| 99/5/1645<br>AUS-99-5-1645-<br>C1 | 50<br>WG    | 6  | 0.075          | 0.008     | berry                 | 36            | <b>0.09</b>              | <b>&lt;0.02</b>          | <b>0.09</b>              | <0.22           |
|                                   |             |    |                |           | juice                 | 36            | <0.02                    | <0.02                    | <0.02                    |                 |
|                                   |             |    |                |           | wine                  | 36            | <0.02                    | <0.02                    | <0.02                    |                 |
| 99/5/1645<br>AUS-99-5-1645-<br>C2 | 50<br>WG    | 6  | 0.15           | 0.016     | berry                 | 36            | <b>0.18</b>              | <b>&lt;0.02</b>          | <b>0.18</b>              | <0.11           |
|                                   |             |    |                |           | juice                 | 36            | <0.02                    | <0.02                    | <0.02                    |                 |
|                                   |             |    |                |           | wine                  | 36            | <0.02                    | <0.02                    | <0.02                    |                 |
| 99/5/1645<br>AUS-99-5-1645-<br>D1 | 50<br>WG    | 6  | 0.075          | 0.009     | berry                 | 36            | <b>0.04</b>              | <b>&lt;0.02</b>          | <b>0.04</b>              | <0.5            |
|                                   |             |    |                |           | juice                 | 36            | <0.02                    | <0.02                    | <0.02                    |                 |
|                                   |             |    |                |           | wine                  | 36            | <0.02                    | <0.02                    | <0.02                    |                 |
| 99/5/1645<br>AUS-99-5-1645-<br>D2 | 50<br>WG    | 6  | 0.15           | 0.018     | berry                 | 36            | <b>0.13</b>              | <b>&lt;0.02</b>          | <b>0.13</b>              | <0.15           |
|                                   |             |    |                |           | juice                 | 36            | <0.02                    | <0.02                    | <0.02                    |                 |
|                                   |             |    |                |           | wine                  | 36            | <0.02                    | <0.02                    | <0.02                    |                 |
| P98/42<br>AUS-P98-42-C3           | 50<br>WG    | 6  | 0.075          | 0.03      | berry                 | 35            | <b>0.13</b>              | <b>0.05</b>              | <b>0.18</b>              | <0.11           |
|                                   |             |    |                |           | juice                 | 35            | <0.02                    | <0.02                    | <0.02                    |                 |
|                                   |             |    |                |           | wine                  | 35            | <0.02                    | <0.02                    | <0.02                    |                 |
| P98/42<br>AUS-P98-42-C4           | 50<br>WG    | 6  | 0.075-<br>0.15 | 0.03-0.06 | berry                 | 35            | <b>0.21</b>              | <b>0.03</b>              | <b>0.24</b>              | <0.08           |
|                                   |             |    |                |           | juice                 | 35            | <0.02                    | <0.02                    | <0.02                    |                 |
|                                   |             |    |                |           | wine                  | 35            | <0.02                    | <0.02                    | <0.02                    |                 |
| P99/40<br>AUS-P99-40-A1           | 50<br>WG    | 3  | 0.075          | 0.0075    | berry                 | 61            | <b>&lt;0.02</b>          | <b>&lt;0.02</b>          | <b>&lt;0.02</b>          |                 |
|                                   |             |    |                |           | juice                 | 61            | <0.02                    | <0.02                    | <0.02                    |                 |
|                                   |             |    |                |           | wine                  | 61            | <0.02                    | <0.02                    | <0.02                    |                 |
| P99/40<br>AUS-P99-40-A2           | 50<br>WG    | 3  | 0.15           | 0.015     | berry                 | 61            | <b>&lt;0.02</b>          | <b>&lt;0.02</b>          | <b>&lt;0.02</b>          |                 |
|                                   |             |    |                |           | juice                 | 61            | <0.02                    | <0.02                    | <0.02                    |                 |
|                                   |             |    |                |           | wine                  | 61            | <0.02                    | <0.02                    | <0.02                    |                 |
| P99/40<br>AUS-P99-40-B1           | 50<br>WG    | 3  | 0.075          | 0.0075    | berry                 | 53            | <b>&lt;0.02</b>          | <b>&lt;0.02</b>          | <b>&lt;0.02</b>          |                 |
|                                   |             |    |                |           | juice                 | 53            | <0.02                    | <0.02                    | <0.02                    |                 |
|                                   |             |    |                |           | wine                  | 53            | <0.02                    | <0.02                    | <0.02                    |                 |
| P99/40<br>AUS-P99-40-B2           | 50<br>WG    | 3  | 0.15           | 0.015     | berry                 | 53            | <b>&lt;0.02</b>          | <b>&lt;0.02</b>          | <b>&lt;0.02</b>          |                 |
|                                   |             |    |                |           | juice                 | 53            | <0.02                    | <0.02                    | <0.02                    |                 |
|                                   |             |    |                |           | wine                  | 53            | <0.02                    | <0.02                    | <0.02                    |                 |
| P99/40<br>AUS-P99-40-B3           | 50<br>WG    | 3  | 0.075          | 0.03      | berry                 | 53            | <b>&lt;0.02</b>          | <b>&lt;0.02</b>          | <b>&lt;0.02</b>          |                 |
|                                   |             |    |                |           | juice                 | 53            | <0.02                    | <0.02                    | <0.02                    |                 |
|                                   |             |    |                |           | wine                  | 53            | <0.02                    | <0.02                    | <0.02                    |                 |
| P99/40<br>AUS-P99-40-B4           | 50<br>WG    | 3  | 0.15           | 0.06      | berry                 | 53            | <b>&lt;0.02</b>          | <b>&lt;0.02</b>          | <b>&lt;0.02</b>          |                 |
|                                   |             |    |                |           | juice                 | 53            | <0.02                    | <0.02                    | <0.02                    |                 |
|                                   |             |    |                |           | wine                  | 53            | <0.02                    | <0.02                    | <0.02                    |                 |
| P99/40<br>AUS-P99-40-C1           | 50<br>WG    | 3  | 0.075          | 0.007     | berry                 | 75            | <b>&lt;0.02</b>          | <b>&lt;0.02</b>          | <b>&lt;0.02</b>          |                 |
|                                   |             |    |                |           | juice                 | 75            | <0.02                    | <0.02                    | <0.02                    |                 |
|                                   |             |    |                |           | wine                  | 75            | <0.02                    | <0.02                    | <0.02                    |                 |
| P99/40<br>AUS-P99-40-C2           | 50<br>WG    | 3  | 0.15           | 0.015     | berry                 | 75            | <b>0.03</b>              | <b>&lt;0.02</b>          | <b>0.03</b>              | <0.67           |
|                                   |             |    |                |           | juice                 | 75            | <0.02                    | <0.02                    | <0.02                    |                 |
|                                   |             |    |                |           | wine                  | 75            | <0.02                    | <0.02                    | <0.02                    |                 |
| P99/40<br>AUS-P99-40-C3           | 50<br>WG    | 3  | 0.075          | 0.03      | berry                 | 75            | <b>0.03</b>              | <b>&lt;0.02</b>          | <b>0.03</b>              | <0.67           |
|                                   |             |    |                |           | juice                 | 75            | <0.02                    | <0.02                    | <0.02                    |                 |
|                                   |             |    |                |           | wine                  | 75            | <0.02                    | <0.02                    | <0.02                    |                 |
| P99/40<br>AUS-P99-40-C4           | 50<br>WG    | 3  | 0.15           | 0.06      | berry                 | 75            | <b>&lt;0.02</b>          | <b>&lt;0.02</b>          | <b>&lt;0.02</b>          |                 |
|                                   |             |    |                |           | juice                 | 75            | <0.02                    | <0.02                    | <0.02                    |                 |
|                                   |             |    |                |           | wine                  | 75            | <0.02                    | <0.02                    | <0.02                    |                 |
| P99/40<br>AUS-P99-40-D1           | 50<br>WG    | 3  | 0.075          | 0.008     | berry                 | 106           | <b>&lt;0.02</b>          | <b>&lt;0.02</b>          | <b>&lt;0.02</b>          |                 |
|                                   |             |    |                |           | juice                 | 106           | <0.02                    | <0.02                    | <0.02                    |                 |
|                                   |             |    |                |           | wine                  | 106           | <0.02                    | <0.02                    | <0.02                    |                 |
| P99/40<br>AUS-P99-40-D2           | 50<br>WG    | 3  | 0.15           | 0.015     | berry                 | 106           | <b>&lt;0.02</b>          | <b>&lt;0.02</b>          | <b>&lt;0.02</b>          |                 |
|                                   |             |    |                |           | juice                 | 106           | <0.02                    | <0.02                    | <0.02                    |                 |
|                                   |             |    |                |           | wine                  | 106           | <0.02                    | <0.02                    | <0.02                    |                 |
| P99/49<br>AUS-P99-49-A1           | 50<br>WG    | 3  | 0.075          | 0.03      | berry<br>fruit, dried | 75<br>75      | <b>&lt;0.02</b><br><0.02 | <b>&lt;0.02</b><br><0.02 | <b>&lt;0.02</b><br><0.02 |                 |
| P99/49<br>AUS-P99-49-A2           | 50<br>WG    | 3  | 0.15           | 0.055     | berry<br>fruit, dried | 75<br>75      | <b>&lt;0.02</b><br><0.02 | <b>&lt;0.02</b><br><0.02 | <b>&lt;0.02</b><br><0.02 |                 |

| Report No.;<br>Study No. | Application |    |          |          | Sample                | PHI<br>(days) | Residues (mg/kg)     |                |                | Proc.<br>factor |
|--------------------------|-------------|----|----------|----------|-----------------------|---------------|----------------------|----------------|----------------|-----------------|
|                          | Form        | No | kg ai/ha | kg ai/hl |                       |               | trifloxy-<br>strobin | CGA-<br>321113 | Total          |                 |
| P99/49<br>AUS-P99-49-B1  | 50<br>WG    | 3  | 0.075    | 0.027    | berry<br>fruit, dried | 60<br>60      | <0.02<br>0.03        | <0.02<br><0.02 | <0.02<br>0.03  |                 |
| P99/49<br>AUS-P99-49-B2  | 50<br>WG    | 3  | 0.15     | 0.05     | berry<br>fruit, dried | 60<br>60      | <0.02<br>0.10        | <0.02<br><0.02 | <0.02<br>0.10  |                 |
| P99/49<br>AUS-P99-49-C1  | 50<br>WG    | 3  | 0.075    | 0.03     | berry<br>fruit, dried | 75<br>75      | <0.02<br><0.02       | <0.02<br><0.02 | <0.02<br><0.02 |                 |
| P99/49<br>AUS-P99-49-C2  | 50<br>WG    | 3  | 0.15     | 0.05     | berry<br>fruit, dried | 75<br>75      | <0.02<br>0.03        | <0.02<br><0.02 | <0.02<br>0.03  |                 |
| P99/49<br>AUS-P99-49-C3  | 50<br>WG    | 3  | 0.075    | 0.007    | berry<br>fruit, dried | 75<br>75      | <0.02<br><0.02       | <0.02<br><0.02 | <0.02<br><0.02 |                 |
| P99/49<br>AUS-P99-49-C4  | 50<br>WG    | 3  | 0.15     | 0.014    | berry<br>fruit, dried | 75<br>75      | <0.02<br>0.02        | <0.02<br><0.02 | <0.02<br>0.02  |                 |

In South Africa in three processing trials wine grapes were treated nine times at rates between 0.05 and 0.19 kg ai/ha. Samples were collected on day 47 or 53 after the last application. Information on the processing of grapes to wine was not reported. The results are shown in Table 104.

Table 105. Trifloxystrobin residues in grapes and processed products, South Africa, 1995.

| Report No.;<br>Study No. | Application |    |                |          | Sample        | PHI<br>(days) | Residues (mg/kg)     |                |               | Proc.<br>factor |
|--------------------------|-------------|----|----------------|----------|---------------|---------------|----------------------|----------------|---------------|-----------------|
|                          | Form        | No | kg ai/ha       | kg ai/hl |               |               | trifloxy-<br>strobin | CGA-<br>321113 | Total         |                 |
| 2204/95<br>SAF-2204-95   | 125<br>EC   | 9  | 0.05-0.13      | 0.013    | berry<br>wine | 47<br>47      | 0.06<br><0.02        | 0.03<br><0.02  | 0.09<br><0.02 | <0.22           |
| 2205/95<br>SAF-2205-95   | 125<br>EC   | 9  | 0.05-0.13      | 0.013    | wine          | 53            | <0.02                | <0.02          | <0.02         |                 |
| 2207/95<br>SAF-2207-95   | 125<br>EC   | 9  | 0.075-<br>0.19 | 0.02     | wine          | 53            | <0.02                | <0.02          | <0.02         |                 |

Eighteen processing trials were carried out on grapes in Northern Europe with trifloxystrobin 50 WG or a mixture of trifloxystrobin with cymoxanil (49 WG) from 1995 to 2000. Grapes were treated three, four or eight times at rates between 0.125 and 0.385 kg ai/ha, and samples for processing taken about 35 and 41 to 50 days after the last application. In Southern Europe ten processing trials was conducted on grapes with trifloxystrobin 50 WG, 1996-1998. Grapes were treated either eight times at a rate of 0.19 kg ai/ha with a PHI of 35 days, or six times at rates between 0.074 and 0.1 kg ai/ha and samplings on day 21 or 29-31. The results are shown in Table 106.

For must, grapes were crushed and pressed and the must sulfured, and for wine the must was mixed with yeast (sugar was added in some cases). After fermentation and deposit of the young wine, it was separated from the yeast and SO<sub>2</sub> and Bentonite were added, followed by further separations and filtering.

For raisins bunches of grapes were dipped either into boiling water ("dipped production") or into NaOH ("golden production"). After washing the bunches were dried and berries picked.

Table 106. Trifloxystrobin residues in grapes and processed products from Europe.

| Country,<br>Year | Application |    |               |                 | Sample | PHI<br>(days) | Residues (mg/kg)     |                |       | Proc.<br>factor | Report No.;<br>Study No.   |
|------------------|-------------|----|---------------|-----------------|--------|---------------|----------------------|----------------|-------|-----------------|----------------------------|
|                  | Form        | No | kg<br>ai/ha   | kg ai/hl        |        |               | trifloxy-<br>strobin | CGA-<br>321113 | Total |                 |                            |
| Germany<br>1996  | 50<br>WG    | 8  | 0.35-<br>0.39 | 0.047-<br>0.094 | berry  | 35            | 0.97                 | 0.04           | 1.01  | 0.079<br><0.02  | gr01396<br>BRD-<br>gr01396 |
|                  |             |    |               |                 | must   | 35            | 0.08                 | <0.02          | 0.08  |                 |                            |
|                  |             |    |               |                 | wine   | 35            | <0.02                | <0.02          | <0.02 |                 |                            |
| Germany<br>1996  | 50<br>WG    | 8  | 0.34-<br>0.38 | 0.044-<br>0.075 | berry  | 35            | 0.34                 | 0.03           | 0.37  | 0.135<br><0.05  | gr01496<br>BRD-<br>gr01496 |
|                  |             |    |               |                 | must   | 35            | 0.05                 | <0.02          | 0.05  |                 |                            |
|                  |             |    |               |                 | wine   | 35            | <0.02                | <0.02          | <0.02 |                 |                            |



| Country,<br>Year         | Application |    |               |                 | Sample                            | PHI<br>(days) | Residues (mg/kg)     |                |               | Proc.<br>factor         | Report No.;<br>Study No.        |
|--------------------------|-------------|----|---------------|-----------------|-----------------------------------|---------------|----------------------|----------------|---------------|-------------------------|---------------------------------|
|                          | Form        | No | kg<br>ai/ha   | kg ai/hl        |                                   |               | trifloxy-<br>strobin | CGA-<br>321113 | Total         |                         |                                 |
| Germany<br>1997          | 50<br>WG    | 8  | 0.19          | 0.023-<br>0.047 | berry<br>must<br>wine             | 36            | <b>0.65</b>          | <b>0.06</b>    | <b>0.71</b>   | 0.085<br><0.028         | gr45597<br>BRD-<br>gr45597      |
|                          |             |    |               |                 |                                   | 37            | 0.06                 | <0.02          | 0.06          |                         |                                 |
|                          |             |    |               |                 |                                   | 37            | <0.02                | <0.02          | <0.02         |                         |                                 |
| Germany<br>1997          | 50<br>WG    | 8  | 0.19          | 0.023-<br>0.047 | berry<br>must<br>wine             | 36            | <b>0.59</b>          | <b>0.07</b>    | <b>0.66</b>   | 0.091<br><0.03          | gr46597<br>BRD-<br>gr46597      |
|                          |             |    |               |                 |                                   | 37            | 0.04                 | 0.02           | 0.06          |                         |                                 |
|                          |             |    |               |                 |                                   | 37            | <0.02                | <0.02          | <0.02         |                         |                                 |
| Germany<br>1995          | 49<br>WG    | 8  | 0.19-<br>0.22 | 0.023-<br>0.047 | berry<br>must<br>wine             | 41            | <b>0.32</b>          | <b>0.12</b>    | <b>0.44</b>   | 0.091<br><0.045         | CGD03<br>BRD-CGD03              |
|                          |             |    |               |                 |                                   | 41            | 0.02                 | 0.02           | 0.04          |                         |                                 |
|                          |             |    |               |                 |                                   | 41            | <0.02                | <0.02          | <0.02         |                         |                                 |
| Switzer-<br>land<br>1995 | 49<br>WG    | 8  | 0.19          | 0.013           | berry                             | 42            | <b>0.15</b>          | <b>0.07</b>    | <b>0.22</b>   | 0.32<br>0.23<br>0.091   | 2035/95<br>SWZ-2035-<br>95      |
|                          |             |    |               |                 | must                              | 42            | 0.07                 | <0.02          | 0.07          |                         |                                 |
|                          |             |    |               |                 | wine, first                       | 42            | 0.05                 | <0.02          | 0.05          |                         |                                 |
|                          |             |    |               |                 | filtrate<br>wine, 2nd<br>filtrate | 42            | <0.02                | <0.02          | <0.02         |                         |                                 |
| Switzer-<br>land<br>1995 | 49<br>WG    | 8  | 0.19          | 0.013           | berry                             | 42            | <b>0.52</b>          | <b>0.06</b>    | <b>0.58</b>   | 0.72<br>0.29<br>0.034   | 2036/95<br>SWZ-2036-<br>95      |
|                          |             |    |               |                 | must                              | 42            | 0.42                 | <0.02          | 0.42          |                         |                                 |
|                          |             |    |               |                 | wine, first                       | 42            | 0.13                 | 0.04           | 0.17          |                         |                                 |
|                          |             |    |               |                 | filtrate<br>wine, 2nd<br>filtrate | 42            | <0.01                | <0.02          | <0.02         |                         |                                 |
| Germany<br>1995          | 49<br>WG    | 8  | 0.19-<br>0.20 | 0.02            | berry                             | 41            | <b>0.94</b>          | <b>0.07</b>    | <b>1.01</b>   | 2.25<br>0.14<br>0.02    | 951047008<br>BRD-FR08-<br>95-43 |
|                          |             |    |               |                 | pomace,                           | 41            | 2.0                  | 0.27           | 2.27          |                         |                                 |
|                          |             |    |               |                 | wet<br>must<br>wine               | 41<br>41      | 0.14<br><0.02        | <0.02<br><0.02 | 0.14<br><0.02 |                         |                                 |
| Germany<br>1996          | 49<br>WG    | 8  | 0.18-<br>0.19 | 0.024-<br>0.047 | berry                             | 35            | <b>1.2</b>           | <b>0.03</b>    | <b>1.23</b>   | 0.057<br><0.016         | gr01196<br>BRDgr01196           |
|                          |             |    |               |                 | must                              | 35            | 0.07                 | <0.02          | 0.07          |                         |                                 |
|                          |             |    |               |                 | wine                              | 35            | <0.02                | <0.02          | <0.02         |                         |                                 |
| Germany<br>1996          | 49<br>WG    | 8  | 0.15-<br>0.21 | 0.022-<br>0.038 | berry                             | 35            | <b>0.31</b>          | <b>0.04</b>    | <b>0.35</b>   | 0.14<br><0.057          | gr01296<br>BRDgr01296           |
|                          |             |    |               |                 | must                              | 34            | 0.05                 | <0.02          | 0.05          |                         |                                 |
|                          |             |    |               |                 | wine                              | 34            | <0.02                | <0.02          | <0.02         |                         |                                 |
| France<br>1996           | 49<br>WG    | 8  | 0.19          | 0.17-<br>0.19   | berry                             | 35            | <b>0.52</b>          | <b>0.12</b>    | <b>0.64</b>   | 1.28<br>0.047           | OF96125/DE<br>17<br>FRA-DE17    |
|                          |             |    |               |                 | must                              | 35            | 0.78                 | 0.04           | 0.82          |                         |                                 |
|                          |             |    |               |                 | wine                              | 35            | 0.02                 | 0.01           | 0.03          |                         |                                 |
| France<br>1996           | 49<br>WG    | 8  | 0.19          | 0.094           | berry                             | 36            | <b>0.83</b>          | <b>0.11</b>    | <b>0.94</b>   | 1.64<br>0.106           | OF96126/KJ<br>58<br>FRA-KJ58    |
|                          |             |    |               |                 | must                              | 36            | 1.5                  | 0.04           | 1.54          |                         |                                 |
|                          |             |    |               |                 | wine                              | 36            | 0.08                 | 0.02           | 0.1           |                         |                                 |
| Switzer-<br>land<br>1998 | 49<br>WG    | 4  | 0.20          | 0.05            | berry                             | 46            | <b>0.18</b>          | <b>0.04</b>    | <b>0.22</b>   | 0.636<br>0.09           | 526/98<br>SWZ-98-<br>3.211.051  |
|                          |             |    |               |                 | must                              | 46            | 0.14                 | <0.02          | 0.14          |                         |                                 |
|                          |             |    |               |                 | wine                              | 46            | <0.02                | <0.02          | <0.02         |                         |                                 |
| Switzer-<br>land<br>1998 | 49<br>WG    | 4  | 0.20          | 0.05            | berry                             | 46            | <b>0.11</b>          | <b>0.04</b>    | <b>0.15</b>   | 0.29<br><0.13           | 526/98<br>SWZ-98-3-<br>211.052  |
|                          |             |    |               |                 | must                              | 46            | 0.044                | <0.02          | 0.044         |                         |                                 |
|                          |             |    |               |                 | wine                              | 46            | <0.02                | <0.02          | <0.02         |                         |                                 |
| Switzer-<br>land<br>1998 | 49<br>WG    | 4  | 0.20          | 0.02            | berry                             | 42            | <b>0.11</b>          | <b>0.02</b>    | <b>0.13</b>   | <0.15<br><0.15          | 526/98<br>SWZ-98-3-<br>211.060  |
|                          |             |    |               |                 | must                              | 42            | <0.02                | <0.02          | <0.02         |                         |                                 |
|                          |             |    |               |                 | wine                              | 42            | <0.02                | <0.02          | <0.02         |                         |                                 |
| Switzer-<br>land<br>1998 | 49<br>WG    | 4  | 0.20          | 0.033           | berry                             | 50            | <b>0.20</b>          | <b>0.05</b>    | <b>0.25</b>   | 0.252<br>0.16           | 526/98<br>SWZ-98-<br>3.211.061  |
|                          |             |    |               |                 | must                              | 50            | 0.063                | <0.02          | 0.063         |                         |                                 |
|                          |             |    |               |                 | wine                              | 50            | <0.02                | 0.02           | 0.04          |                         |                                 |
| Italy<br>1996            | 50<br>WG    | 8  | 0.19          | 0.021           | berry                             | 35            | <b>0.11</b>          | <b>0.05</b>    | <b>0.16</b>   | 0.375<br><0.125         | 2084/96<br>ITA-2084-96          |
|                          |             |    |               |                 | must                              | 35            | 0.06                 | <0.02          | 0.06          |                         |                                 |
|                          |             |    |               |                 | wine                              | 35            | <0.02                | <0.02          | <0.02         |                         |                                 |
| Italy<br>1996            | 50<br>WG    | 8  | 0.19          | 0.027           | berry                             | 35            | <b>1.3</b>           | <b>0.06</b>    | <b>1.36</b>   | 0.485<br>0.074<br>0.015 | 2085/96<br>ITA-2085-96          |
|                          |             |    |               |                 | must                              | 35            | 0.66                 | <0.02          | 0.66          |                         |                                 |
|                          |             |    |               |                 | wine, first                       | 35            | 0.10                 | <0.02          | 0.10          |                         |                                 |
|                          |             |    |               |                 | filtrate<br>wine, 2nd<br>filtrate | 35<br>35      | 0.02<br>0.02         | <0.02<br><0.02 | 0.02<br>0.02  |                         |                                 |

| Country,<br>Year         | Application |    |               |                 | Sample                              | PHI<br>(days) | Residues (mg/kg)     |                 |               | Proc.<br>factor                                                     | Report No.;<br>Study No.   |
|--------------------------|-------------|----|---------------|-----------------|-------------------------------------|---------------|----------------------|-----------------|---------------|---------------------------------------------------------------------|----------------------------|
|                          | Form        | No | kg<br>ai/ha   | kg ai/hl        |                                     |               | trifloxy-<br>strobin | CGA-<br>321113  | Total         |                                                                     |                            |
| Italy<br>1997            | 50<br>WG    | 8  | 0.19          | 0.027           | berry                               | 35            | <b>0.46</b>          | <b>0.03</b>     | <b>0.49</b>   | 0.898<br>0.061<br>0.082                                             | 2077/97<br>ITA-2077-97     |
|                          |             |    |               |                 | must                                | 35            | 0.44                 | <0.02           | 0.44          |                                                                     |                            |
|                          |             |    |               |                 | wine, first<br>filtrate             | 35            | 0.03                 | <0.02           | 0.03          |                                                                     |                            |
|                          |             |    |               |                 | wine, 2nd<br>filtrate               | 35            | 0.04                 | <0.02           | 0.04          |                                                                     |                            |
| Italy<br>1997            | 50<br>WG    | 8  | 0.19          | 0.019-<br>0.021 | berry                               | 35            | <b>0.24</b>          | <b>0.055</b>    | <b>0.295</b>  | 0.576<br>0.068                                                      | 2078/97<br>ITA-2078-97     |
|                          |             |    |               |                 | must<br>wine                        | 35<br>35      | 0.17<br><0.02        | <0.02<br><0.02  | 0.17<br><0.02 |                                                                     |                            |
| Spain<br>1997            | 50<br>WG    | 6  | 0.08          | 0.015-<br>0.04  | berry                               | 31            | <b>0.11</b>          | <b>&lt;0.02</b> | <b>0.11</b>   | 1.18<br>0.43<br>mean<br>0.805<br><0.18<br><0.07<br>mean<br><0.125   | 2050/97<br>SPA-2050-97     |
|                          |             |    |               |                 | must                                | 31            | <b>0.28</b>          | <b>&lt;0.02</b> | <b>0.28</b>   |                                                                     |                            |
|                          |             |    |               |                 |                                     | 31            | 0.13                 | <0.02           | 0.13          |                                                                     |                            |
|                          |             |    |               |                 |                                     | 31            | 0.12                 | <0.02           | 0.12          |                                                                     |                            |
|                          |             |    |               |                 | wine                                | 31            | <0.02                | <0.02           | <0.02         |                                                                     |                            |
|                          |             |    |               |                 |                                     | 31            | <0.02                | <0.02           | <0.02         |                                                                     |                            |
| Spain<br>1997            | 50<br>WG    | 6  | 0.07-<br>0.08 | 0.009-<br>0.011 | berry                               | 30            | <b>0.07</b>          | <b>&lt;0.02</b> | <b>0.07</b>   | 0.43<br>0.625<br>mean<br>0.528<br><0.286<br><0.25<br>mean<br><0.268 | 2051/97<br>SPA-2051-97     |
|                          |             |    |               |                 | must                                | 30            | <b>0.08</b>          | <b>&lt;0.02</b> | <b>0.08</b>   |                                                                     |                            |
|                          |             |    |               |                 |                                     | 30            | 0.03                 | <0.02           | 0.03          |                                                                     |                            |
|                          |             |    |               |                 |                                     | 30            | 0.05                 | <0.02           | 0.05          |                                                                     |                            |
|                          |             |    |               |                 | wine                                | 30            | <0.02                | <0.02           | <0.02         |                                                                     |                            |
|                          |             |    |               |                 |                                     | 30            | <0.02                | <0.02           | <0.02         |                                                                     |                            |
| Italy<br>1998            | 50<br>WG    | 6  | 0.10          | 0.01            | berry                               | 21            | <b>0.16</b>          | <b>&lt;0.02</b> | <b>0.16</b>   | 0.69<br>0.19<br><0.125                                              | 2042/98<br>ITA-2042-98     |
|                          |             |    |               |                 | must                                | 21            | 0.11                 | <0.02           | 0.11          |                                                                     |                            |
|                          |             |    |               |                 | wine, first<br>filtrate             | 21            | 0.03                 | <0.02           | 0.03          |                                                                     |                            |
|                          |             |    |               |                 | wine, 2nd<br>filtrate               | 21            | <0.02                | <0.02           | <0.02         |                                                                     |                            |
| Italy<br>1998            | 50<br>WG    | 6  | 0.10          | 0.01-<br>0.013  | berry                               | 21            | <b>0.05</b>          | <b>&lt;0.02</b> | <b>0.05</b>   | 0.6<br><0.4                                                         | 2043/98<br>ITA-2043-98     |
|                          |             |    |               |                 | must<br>wine                        | 21<br>21      | 0.03<br><0.02        | <0.02<br><0.02  | 0.03<br><0.02 |                                                                     |                            |
| Spain<br>1998            | 50<br>WG    | 6  | 0.08          | 0.014           | berry                               | 29            | <b>0.36</b>          | <b>0.02</b>     | <b>0.38</b>   | 0.47<br>0.16                                                        | 2056/98<br>SPA-2056-98     |
|                          |             |    |               |                 | must<br>wine                        | 29<br>29      | 0.18<br>0.06         | <0.02<br><0.02  | 0.18<br>0.06  |                                                                     |                            |
| Spain<br>1998            | 50<br>WG    | 6  | 0.08          | 0.009           | berry                               | 21            | <b>0.16</b>          | <b>&lt;0.02</b> | <b>0.16</b>   | 0.76<br><0.125                                                      | 2057/98<br>SPA-2057-98     |
|                          |             |    |               |                 | must                                | 21            | 0.12                 | <0.02           | 0.12          |                                                                     |                            |
|                          |             |    |               |                 | wine                                | 21            | <0.02                | <0.02           | <0.02         |                                                                     |                            |
| Switzer-<br>land<br>2000 | 50<br>WG    | 3  | 0.13          | 0.009           | berry                               | 36            | <b>0.04</b>          | <b>0.01</b>     | <b>0.05</b>   | 3                                                                   | 2147/00<br>SWZ-2147-<br>B1 |
|                          |             |    |               |                 | berry after<br>dipping <sup>1</sup> | 36            | 0.02                 | <0.01           | 0.02          |                                                                     |                            |
|                          |             |    |               |                 | berry after<br>dipping,<br>washed   | 36            | 0.03                 | 0.01            | 0.04          |                                                                     |                            |
|                          |             |    |               |                 | raisin                              | 36            | 0.12                 | 0.03            | 0.15          |                                                                     |                            |
|                          |             |    |               |                 | dippings                            | 36            | 0.02                 | <0.01           | 0.02          |                                                                     |                            |
|                          |             |    |               |                 | washings                            | 36            | <0.01                | <0.01           | <0.01         |                                                                     |                            |
| Switzer-<br>land<br>2000 | 50<br>WG    | 3  | 0.13          | 0.009           | berry                               | 36            | <b>0.03</b>          | <b>0.01</b>     | <b>0.04</b>   | 3.25                                                                | 2147/00<br>SWZ-2147-<br>B2 |
|                          |             |    |               |                 | berry after<br>dipping <sup>2</sup> | 36            | 0.03                 | 0.01            | 0.04          |                                                                     |                            |
|                          |             |    |               |                 | berry after<br>dipping,<br>washed   | 36            | 0.02                 | 0.01            | 0.03          |                                                                     |                            |
|                          |             |    |               |                 | raisin                              | 36            | 0.09                 | 0.04            | 0.13          |                                                                     |                            |
|                          |             |    |               |                 | dippings                            | 36            | <0.01                | 0.03            | 0.04          |                                                                     |                            |
|                          |             |    |               |                 | washings                            | 36            | <0.01                | <0.01           | <0.01         |                                                                     |                            |

<sup>1</sup> in boiling water<sup>2</sup> in NaOH

In 1996 in six processing trials in the USA using a 50 WG solution of trifloxystrobin grapes were sprayed six times, either at the 1-fold rate at 0.14 kg ai/ha, the 3-fold rate (0.42 kg ai/ha), or the 5-fold rate (0.70 kg ai/ha). Samples for processing were taken 14 days after the last application. For juice the grapes were crushed, the pulp collected and the stems discarded. The pulp was then heated, filtered and pasteurised. Raisins were processed in the field by air-drying for 17 or 26 days according to normal agricultural practice. Residues were determined in the raw agricultural commodity and in a variety of processed products. The results are shown in Table 107.

Table 107. Trifloxystrobin residues in grapes and processed products, USA, 1996.

| Report No.;<br>Study No.         | Application |    |             |          | Sample          | PHI<br>(days) | Residues (mg/kg)     |                 |             | Proc.<br>factor |
|----------------------------------|-------------|----|-------------|----------|-----------------|---------------|----------------------|-----------------|-------------|-----------------|
|                                  | Form        | No | kg<br>ai/ha | kg ai/hl |                 |               | trifloxy-<br>strobin | CGA-<br>321113  | Total       |                 |
| 110440<br>USA-OW-FR-<br>415-96-A | 50<br>WG    | 6  | 0.14        | 0.025    | bunch of grapes | 14            | <b>0.24</b>          | <b>&lt;0.02</b> | <b>0.24</b> | 0.167           |
|                                  |             |    |             |          | juice           | 14            | 0.04                 | <0.02           | 0.04        |                 |
|                                  |             |    |             |          | raisin          | 14            | 0.14                 | <0.02           | 0.14        |                 |
| 110440<br>USA-OW-FR-<br>415-96-B | 50<br>WG    | 6  | 0.42        | 0.075    | bunch of grapes | 14            | <b>0.87</b>          | <b>0.02</b>     | <b>0.89</b> | 0.18            |
|                                  |             |    |             |          | juice           | 14            | 0.16                 | <0.02           | 0.16        |                 |
| 110440<br>USA-OW-FR-<br>415-96-C | 50<br>WG    | 6  | 0.70        | 0.13     | bunch of grapes | 14            | <b>1.1</b>           | <b>0.02</b>     | <b>1.12</b> | 0.13            |
|                                  |             |    |             |          | juice           | 14            | 0.15                 | <0.02           | 0.15        |                 |
| 110440<br>USA-02-FR-<br>025-96-A | 50<br>WG    | 6  | 0.14        | 0.03     | bunch of grapes | 14            | <b>0.60</b>          | <b>0.07</b>     | <b>0.67</b> | 0.09            |
|                                  |             |    |             |          | juice           | 14            | 0.06                 | <0.02           | 0.06        |                 |
|                                  |             |    |             |          | raisin          | 14            | 1.5                  | 0.16            | 1.66        |                 |
| 110440<br>USA-02-FR-<br>025-96-B | 50<br>WG    | 6  | 0.42        | 0.09     | bunch of grapes | 14            | <b>1.8</b>           | <b>0.08</b>     | <b>1.88</b> | 0.08            |
|                                  |             |    |             |          | juice           | 14            | 0.13                 | 0.02            | 0.15        |                 |
| 110440<br>USA-02-FR-<br>025-96-C | 50<br>WG    | 6  | 0.70        | 0.15     | bunch of grapes | 14            | <b>2.2</b>           | <b>0.08</b>     | <b>2.28</b> | 0.167           |
|                                  |             |    |             |          | juice           | 14            | 0.34                 | 0.04            | 0.38        |                 |

Figure 7. Processing to must and wine.

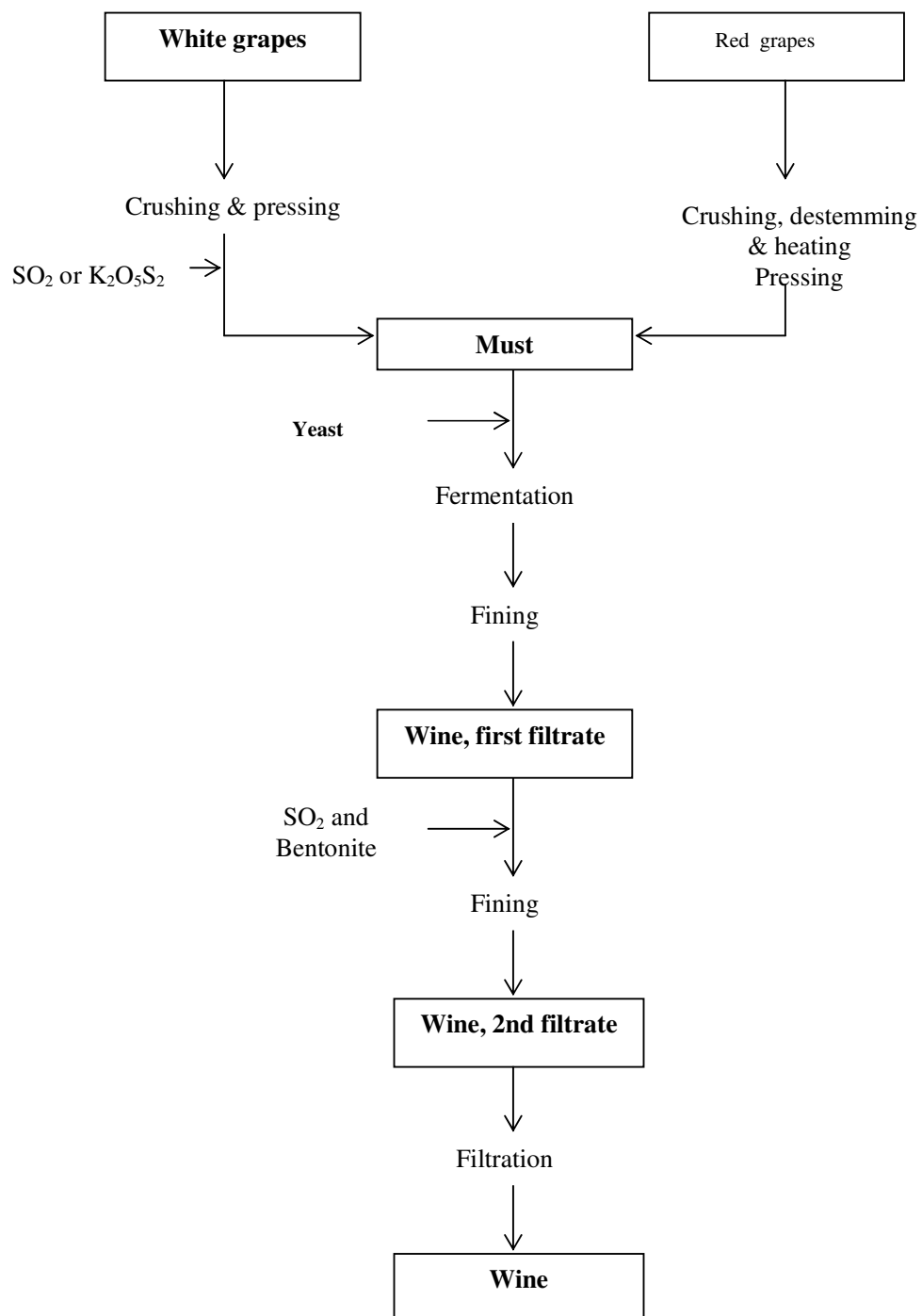


Figure 8. Processing to raisins (Europe).

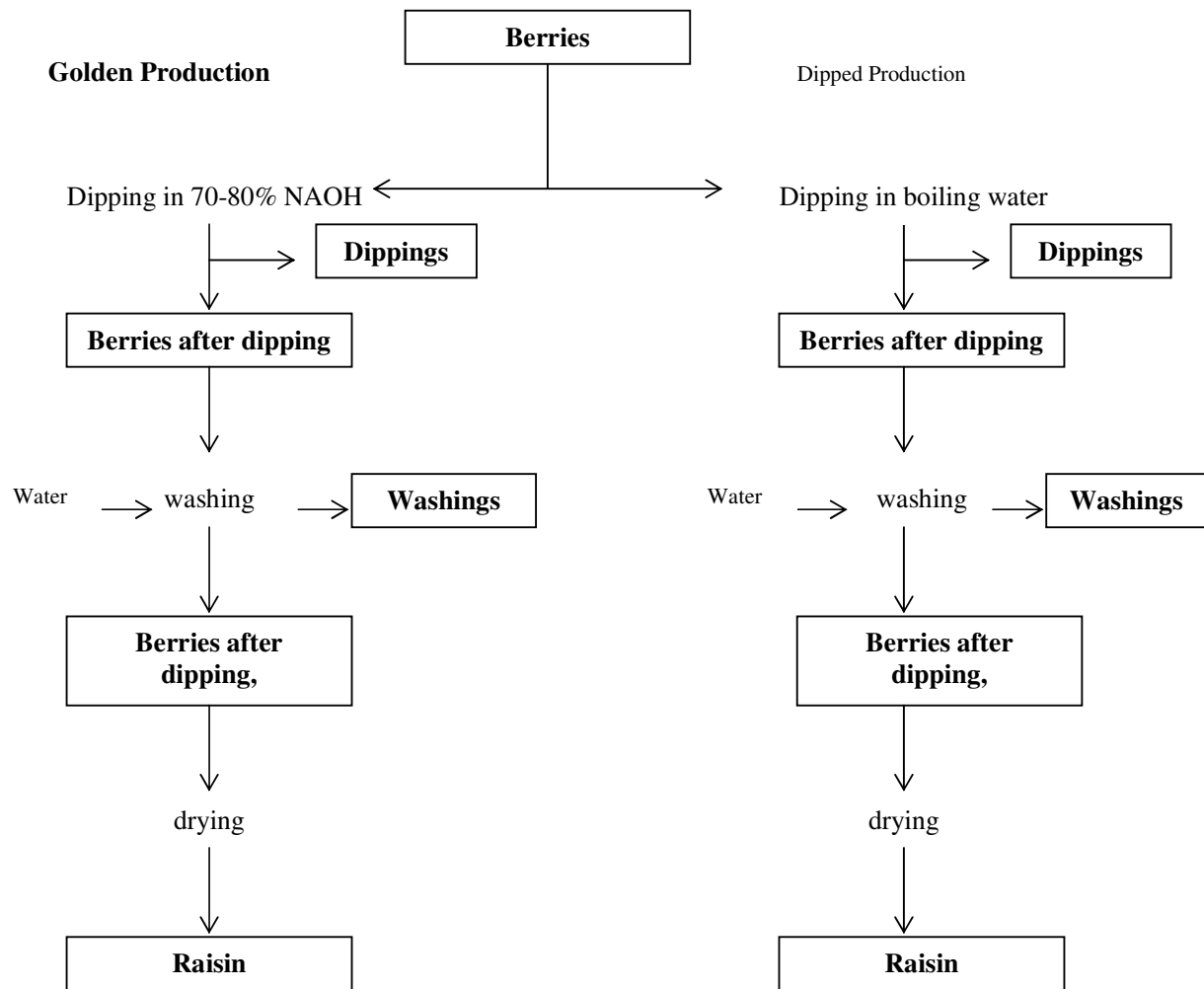
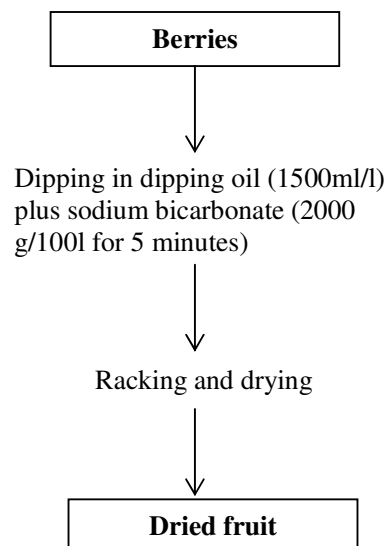


Figure 9. Processing to raisins (Australia).



*Strawberries*

In two processing studies in 2002 in Northern Europe trifloxystrobin 50 WG was applied three times to strawberry plants at a product rate of 0.5 kg/ha and 600 l water per ha, corresponding to a spray concentration of 0.083% and 0.25 kg ai/ha. Samples were taken 3 days after the last treatment. Residues were determined in the raw agricultural commodity (fruit), washed fruit, washings, preserve and jam. The processing in the laboratory of washed fruits, washing water and jam simulated household practice, and that of strawberry preserve industrial practice.

Strawberries were washed in standing water under slow movement, and stalks removed as necessary. For preserves, washed fruits were placed in cans and sugar solution was added, before pasteurisation at about 90°C. For jam processes were the same except some of the fruit was minced with a mixer, and the remainder chopped with a knife into small pieces. Gelling agent was then added and the mixture heated to 98-100°C for about 3 minutes. The processing steps are shown in Figures 10 and 11.

The results of the trials are shown in Table 108.

Table 108. Trifloxystrobin residues in strawberries and processed products, Europe.

| Country,<br>Year | Application |    |             |          | Sample        | PHI<br>(days) | Residues (mg/kg)     |                 |             | Proc.<br>factor | Report No.;<br>Study No.            |
|------------------|-------------|----|-------------|----------|---------------|---------------|----------------------|-----------------|-------------|-----------------|-------------------------------------|
|                  | Form        | No | kg<br>ai/ha | kg ai/hl |               |               | trifloxy-<br>strobin | CGA321<br>113   | Total       |                 |                                     |
| Germany<br>2002  | 50<br>WG    | 3  | 0.25        | 0.042    | fruit         | 3             | <b>0.15</b>          | <b>0.03</b>     | <b>0.18</b> | 0.33            | RA-2038/02<br>RA-3038/02<br>0188-02 |
|                  |             |    |             |          | fruit, washed | 3             | 0.13                 | 0.04            | 0.17        |                 |                                     |
|                  |             |    |             |          | preserve      | 3             | 0.06                 | <0.02           | 0.06        |                 |                                     |
|                  |             |    |             |          | washings      | 3             | 0.03                 | <0.02           | 0.03        |                 |                                     |
|                  |             |    |             |          | jam           | 3             | 0.12                 | 0.02            | 0.12        |                 |                                     |
| France<br>2002   | 50<br>WG    | 3  | 0.25        | 0.042    | fruit         | 3             | <b>0.12</b>          | <b>&lt;0.02</b> | <b>0.12</b> | 0.25            | RA-2038/02<br>RA-3038/02<br>0191-02 |
|                  |             |    |             |          | fruit, washed | 3             | 0.08                 | <0.02           | 0.08        |                 |                                     |
|                  |             |    |             |          | preserve      | 3             | 0.03                 | <0.02           | 0.03        |                 |                                     |
|                  |             |    |             |          | washings      | 3             | 0.05                 | <0.02           | 0.05        |                 |                                     |
|                  |             |    |             |          | jam           | 3             | 0.07                 | <0.02           | 0.07        |                 |                                     |

Figure 10. Processing of strawberries to preserves.

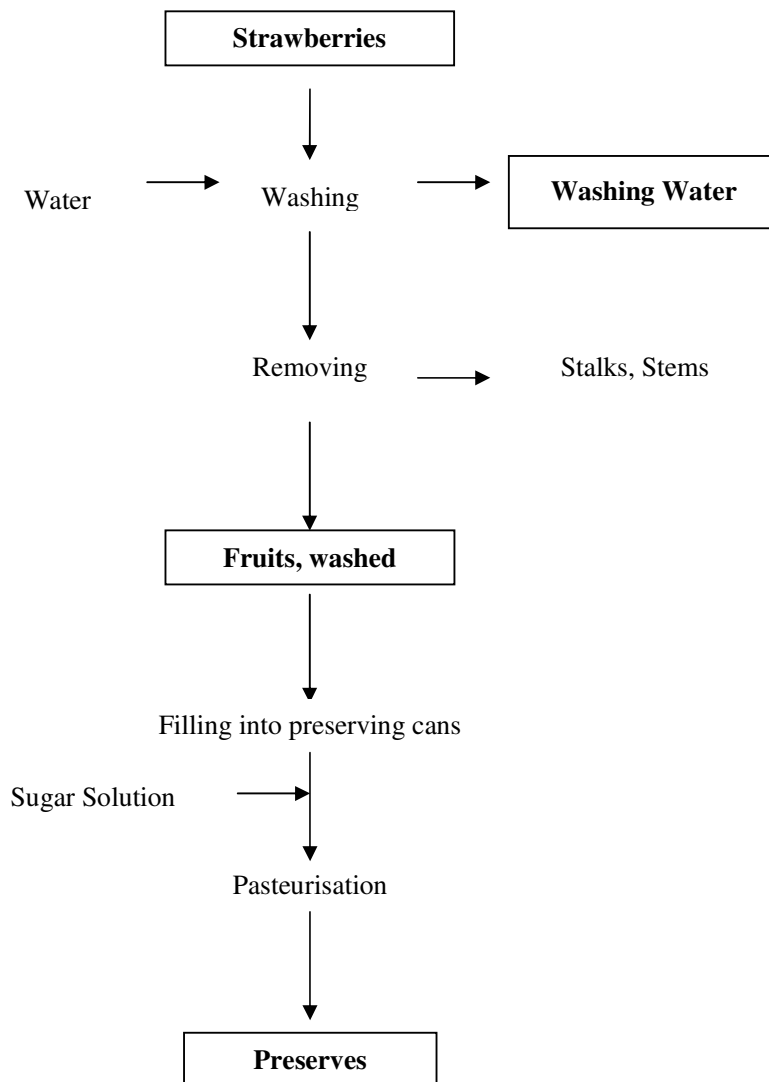
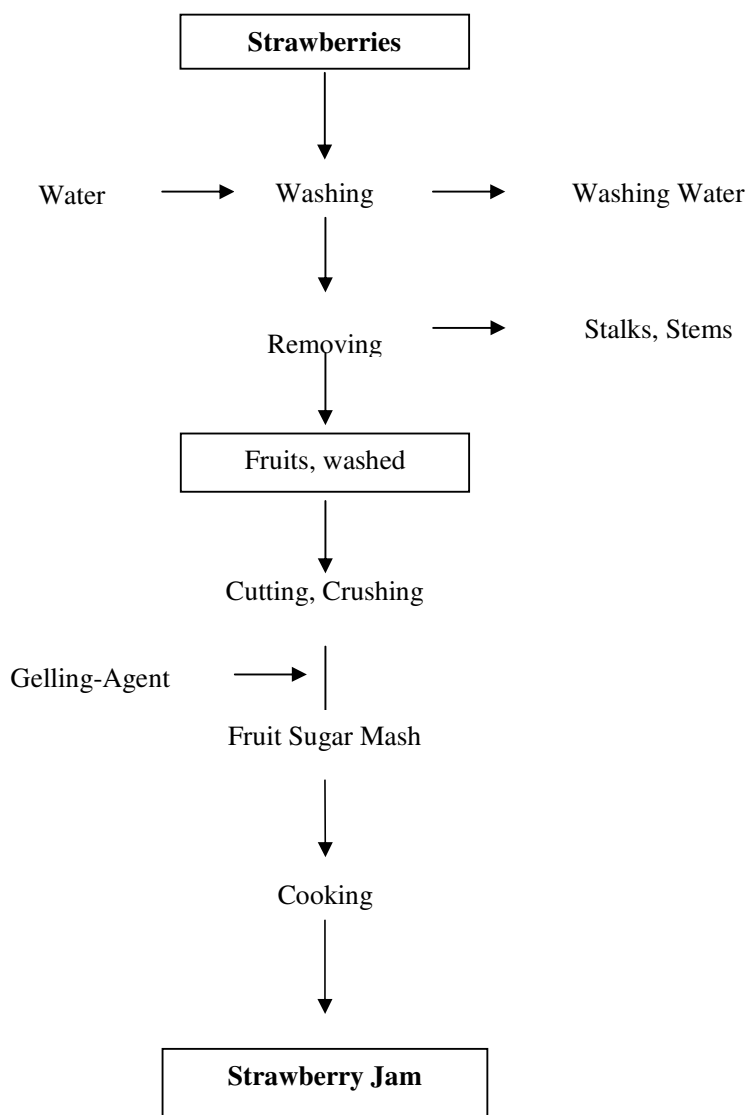


Figure 11. Processing of strawberries to jam.



### Cabbage

Two processing studies were conducted using three applications of trifloxystrobin 50 WG at a rate of 0.125 kg ai/ha. Cabbage samples were cooked. Residues in all samples of the raw agricultural commodity, washed head, washings, cooking water and cooked head were below the LOQ (0.02 mg/kg), so the processing factor cannot be calculated (Table 109). The processing steps are shown in Figure 12.

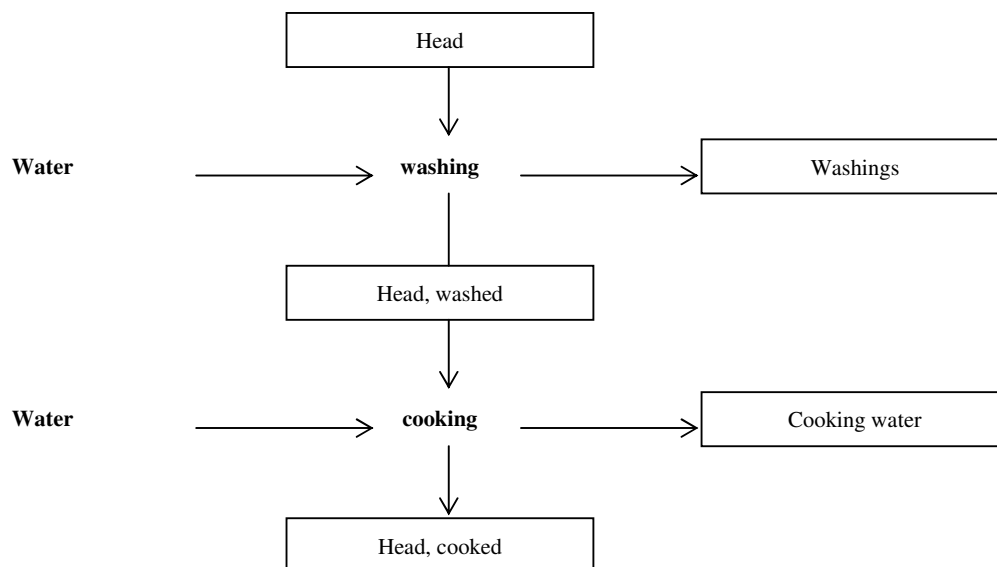
Table 109. Trifloxystrobin residues in white cabbage and its processed products, Germany, 2001.

| Report No.;<br>Study No.            | Application |    |             |          | Sample       | PHI<br>(days) | Residues (mg/kg)     |               |       |
|-------------------------------------|-------------|----|-------------|----------|--------------|---------------|----------------------|---------------|-------|
|                                     | Form        | No | kg<br>ai/ha | kg ai/hl |              |               | trifloxy-<br>strobin | CGA321<br>113 | Total |
| RA-2198/01<br>RA-3198/01<br>0640-01 | 50<br>WG    | 3  | 0.13        | 0.021    | head         | 14            | <0.02                | <0.02         | <0.02 |
|                                     |             |    |             |          | head, washed | 14            | <0.02                | <0.02         | <0.02 |
|                                     |             |    |             |          | washings     | 14            | <0.02                | <0.02         | <0.02 |
|                                     |             |    |             |          | head, cooked | 14            | <0.02                | <0.02         | <0.02 |



| Report No.;<br>Study No.            | Application |    |             |          | Sample        | PHI<br>(days) | Residues (mg/kg)     |               |       |
|-------------------------------------|-------------|----|-------------|----------|---------------|---------------|----------------------|---------------|-------|
|                                     | Form        | No | kg<br>ai/ha | kg ai/hl |               |               | trifloxy-<br>strobin | CGA321<br>113 | Total |
|                                     |             |    |             |          | cooking water | 14            | <0.02                | <0.02         | <0.02 |
| RA-2198/01<br>RA-3198/01<br>0643-01 | 50<br>WG    | 3  | 0.13        | 0.021    | head          | 14            | <0.02                | <0.02         | <0.02 |
|                                     |             |    |             |          | head, washed  | 14            | <0.02                | <0.02         | <0.02 |
|                                     |             |    |             |          | washings      | 14            | <0.02                | <0.02         | <0.02 |
|                                     |             |    |             |          | head, cooked  | 14            | <0.02                | <0.02         | <0.02 |
|                                     |             |    |             |          | cooking water | 14            | <0.02                | <0.02         | <0.02 |

Figure 12. Processing to washed and cooked cabbage.



### Tomato

In 1997 in five processing trials in the USA solutions of trifloxystrobin (50 WG) were sprayed eight times on the leaves of the plants at a volume ranging from 234-283 l/ha either at the 1-fold rate (0.14 kg ai/ha), the 3-fold rate (0.42 kg ai/ha) or the 5-fold rate (0.7 kg ai/ha). Tomato samples were taken on day 3 after the last application. Residues were determined in the RAC, purée and paste.

For juice, the washed tomatoes were placed in a grinder, crushed, disgorged into a tank, then pumped into a hot break system, with water at the required outlet temperature. The tomato crush was heated to about 98°C, and passed through a screen to remove peel and seeds (wet pomace) to produce juice.

For purée, juice was circulated in a vacuum evaporator until condensed. When the natural tomato soluble solids (NTSS) were within the range 8-16%, the purée was collected into a drum, weighed, and thoroughly mixed. A portion was used to produce the canned purée fraction sample. It was transferred into a small steam jacketed kettle, and stirred while being heated to 90-92°C. The NTSS values were then between 7.0 and 7.8%, and the purée was canned.

For paste, another portion was transferred to a vacuum kettle evaporator for condensing. When the NTSS were 24-25%, the paste was transferred into a small steam jacketed kettle, heated to 88°C while being stirred. The NTSS values were then between 25.8 and 27.5% and the paste was canned. The results of the trials are summarised in Table 110.

Table 110. Trifloxystrobin residues in tomatoes and their processed products, USA, 1997-1998.

| Report No.;<br>Study No.        | Application |    |             |          | Sample | PHI<br>(days) | Residues (mg/kg)     |                 |             | Proc.<br>factor |
|---------------------------------|-------------|----|-------------|----------|--------|---------------|----------------------|-----------------|-------------|-----------------|
|                                 | Form        | No | kg<br>ai/ha | kg ai/hl |        |               | trifloxy-<br>strobin | CGA321<br>113   | Total       |                 |
| 40-97<br>USA-OW-FR-<br>411-97-A | 50<br>WG    | 8  | 0.14        | 0.05     | fruit  | 3             | <b>0.18</b>          | <b>&lt;0.02</b> | <b>0.18</b> | 1.39<br>0.33    |
|                                 |             |    |             |          | paste  | 3             | 0.23                 | 0.02            | 0.25        |                 |
|                                 |             |    |             |          | purée  | 3             | 0.06                 | <0.02           | 0.06        |                 |
| 40-97<br>USA-OW-FR-<br>411-97-B | 50<br>WG    | 8  | 0.42        | 0.15     | fruit  | 3             | <b>0.69</b>          | <b>&lt;0.02</b> | <b>0.69</b> | 1.16<br>0.71    |
|                                 |             |    |             |          | paste  | 3             | 0.75                 | 0.05            | 0.80        |                 |
|                                 |             |    |             |          | purée  | 3             | 0.49                 | <0.02           | 0.49        |                 |
| 40-97<br>USA-OW-FR-<br>411-97-C | 50<br>WG    | 8  | 0.70        | 0.25     | fruit  | 3             | <b>0.87</b>          | <b>&lt;0.02</b> | <b>0.87</b> | 1.57<br>1.18    |
|                                 |             |    |             |          | paste  | 3             | 1.3                  | 0.07            | 1.37        |                 |
|                                 |             |    |             |          | purée  | 3             | 1.0                  | 0.03            | 1.03        |                 |
| 40-97<br>USA-02-FR-<br>007-97-A | 50<br>WG    | 8  | 0.14        | 0.06     | fruit  | 3             | <b>0.12</b>          | <b>&lt;0.02</b> | <b>0.12</b> | 1<br><0.17      |
|                                 |             |    |             |          | paste  | 3             | 0.12                 | <0.02           | 0.12        |                 |
|                                 |             |    |             |          | purée  | 3             | <0.02                | <0.02           | <0.02       |                 |
| 40-97<br>USA-02-FR-<br>007-97-B | 50<br>WG    | 8  | 0.70        | 0.30     | fruit  | 3             | <b>0.59</b>          | <b>&lt;0.02</b> | <b>0.59</b> | 2.83<br>0.424   |
|                                 |             |    |             |          | paste  | 3             | 1.6                  | 0.07            | 1.67        |                 |
|                                 |             |    |             |          | purée  | 3             | 0.25                 | <0.02           | 0.25        |                 |

*Potatoes*

In 1996 in six processing trials in the USA using trifloxystrobin 50 WG potato plants were sprayed four times at the 1-fold rate of 0.28 kg ai/ha, the 3-fold rate (0.84 kg ai/ha) or at the 5-fold rate (1.4 kg ai/ha). The spray volume ranged from 281 to 318 l/ha. Tuber samples were taken 7 days after the last application. Residues were determined in the raw agricultural commodity, in washed tubers, peel residues, flakes and chips. The results are summarised in Table 111. Processing factors cannot be calculated because residues were below the LOQ in the RAC.

Having been washed, peeled and trimmed, potatoes were cut into slabs for flakes and sliced for chips, and then washed to remove free starch. The sliced potatoes were fried in hot oil, deoiled and salted to produce chips. For flakes the slabs of potato were cooked, mashed, mixed with additives, dried and milled. The detailed processing steps are shown in Figures 13 and 14.

Table 110. Trifloxystrobin residues in potatoes and their processed products, USA, 1996.

| Report No.;<br>Study No.        | Application |    |             |          | Sample        | PHI<br>(days) | Residues (mg/kg)     |                 |                 | Proc.<br>factor |
|---------------------------------|-------------|----|-------------|----------|---------------|---------------|----------------------|-----------------|-----------------|-----------------|
|                                 | Form        | No | kg<br>ai/ha | kg ai/hl |               |               | trifloxy-<br>strobin | CGA-<br>321113  | Total           |                 |
| 55-96<br>USA-MW-<br>FR-511-96-B | 50<br>WG    | 4  | 0.28        | 0.099    | tuber         | 7             | <b>&lt;0.02</b>      | <b>&lt;0.02</b> | <b>&lt;0.02</b> |                 |
|                                 |             |    |             |          | tuber, washed | 7             | <0.02                | <0.02           | <0.02           |                 |
|                                 |             |    |             |          | peel rest     | 7             | <0.02                | <0.02           | <0.02           |                 |
|                                 |             |    |             |          | flakes        | 7             | <0.02                | <0.02           | <0.02           |                 |
|                                 |             |    |             |          | chips         | 7             | <0.02                | <0.02           | <0.02           |                 |
| 55-96<br>USA-MW-<br>FR-511-96-C |             | 4  | 0.84        | 0.30     | tuber         | 7             | <b>&lt;0.02</b>      | <b>&lt;0.02</b> | <b>&lt;0.02</b> |                 |
|                                 |             |    |             |          | tuber, washed | 7             | <0.02                | <0.02           | <0.02           |                 |
|                                 |             |    |             |          | peel rest     | 7             | <0.02                | <0.02           | <0.02           |                 |
|                                 |             |    |             |          | flakes        | 7             | <0.02                | <0.02           | <0.02           |                 |
|                                 |             |    |             |          | chips         | 7             | <0.02                | <0.02           | <0.02           |                 |
| 55-96<br>USA-MW-<br>FR-511-96-D | 50<br>WG    | 4  | 1.4         | 0.50     | tuber         | 7             | <b>&lt;0.02</b>      | <b>&lt;0.02</b> | <b>&lt;0.02</b> |                 |
|                                 |             |    |             |          | tuber, washed | 7             | <0.02                | <0.02           | <0.02           |                 |
|                                 |             |    |             |          | peel rest     | 7             | 0.03                 | <0.02           | 0.03            |                 |
|                                 |             |    |             |          | flakes        | 7             | <0.02                | <0.02           | <0.02           |                 |
|                                 |             |    |             |          | chips         | 7             | <0.02                | <0.02           | <0.02           |                 |
| 55-96<br>USA-OW-<br>FR-699-96-A | 50<br>WG    | 4  | 0.28        | 0.09     | tuber         | 7             | <b>&lt;0.02</b>      | <b>&lt;0.02</b> | <b>&lt;0.02</b> |                 |
|                                 |             |    |             |          | tuber, washed | 7             | <0.02                | <0.02           | <0.02           |                 |
|                                 |             |    |             |          | peel rest     | 7             | <0.02                | 0.03            | 0.05            |                 |
|                                 |             |    |             |          | flakes        | 7             | <0.02                | <0.02           | <0.02           |                 |
|                                 |             |    |             |          | chips         | 7             | <0.02                | <0.02           | <0.02           |                 |

| Report No.;<br>Study No.        | Application |    |             |          | Sample        | PHI<br>(days) | Residues (mg/kg)     |                |             | Proc.<br>factor                 |
|---------------------------------|-------------|----|-------------|----------|---------------|---------------|----------------------|----------------|-------------|---------------------------------|
|                                 | Form        | No | kg<br>ai/ha | kg ai/hl |               |               | trifloxy-<br>strobin | CGA-<br>321113 | Total       |                                 |
| 55-96<br>USA-OW-<br>FR-699-96-B | 50<br>WG    | 4  | 0.84        | 0.26     | tuber         | 7             | <b>&lt;0.02</b>      | <b>0.02</b>    | <b>0.04</b> | 2<br><br>2<br>2<br>2<br>2       |
|                                 |             |    |             |          | tuber, washed | 7             | <0.02                | 0.02           | 0.04        |                                 |
|                                 |             |    |             |          | peel rest     | 7             | <0.02                | 0.06           | 0.08        |                                 |
|                                 |             |    |             |          | flakes        | 7             | <0.02                | <0.02          | <0.02       |                                 |
|                                 |             |    |             |          | chips         | 7             | <0.02                | <0.02          | <0.02       |                                 |
| 55-96<br>USA-OW-<br>FR-699-96-C | 50<br>WG    | 4  | 1.4         | 0.44     | tuber         | 7             | <b>&lt;0.02</b>      | <b>0.04</b>    | <b>0.06</b> | 2.5<br>2.5<br>2.5<br>2.5<br>2.5 |
|                                 |             |    |             |          | tuber, washed | 7             | <0.02                | 0.03           | 0.05        |                                 |
|                                 |             |    |             |          | peel rest     | 7             | 0.05                 | 0.10           | 0.15        |                                 |
|                                 |             |    |             |          | flakes        | 7             | <0.02                | <0.02          | <0.02       |                                 |
|                                 |             |    |             |          | chips         | 7             | <0.02                | <0.02          | <0.02       |                                 |

Figure 13. Processing of potatoes to flakes.

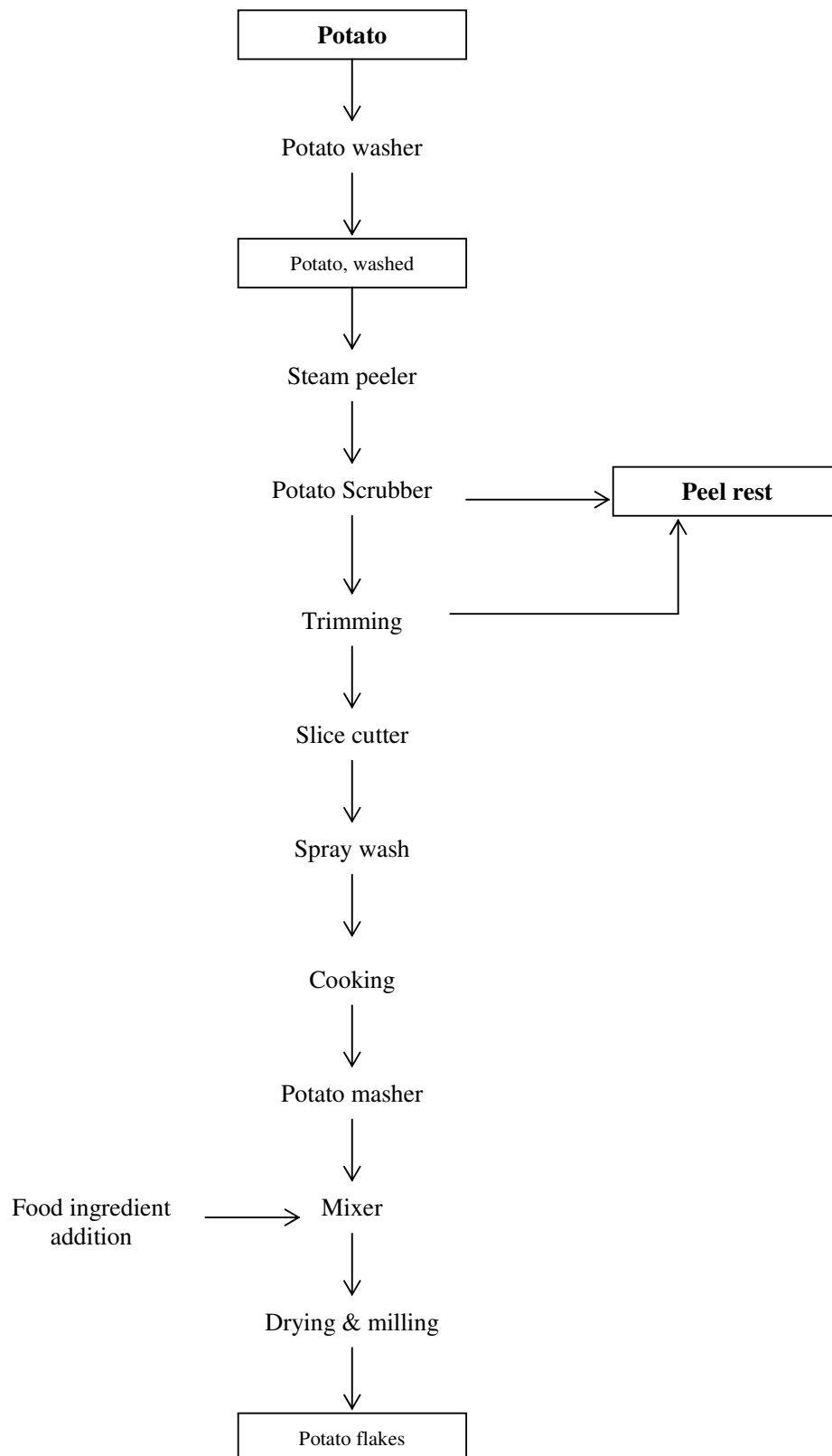
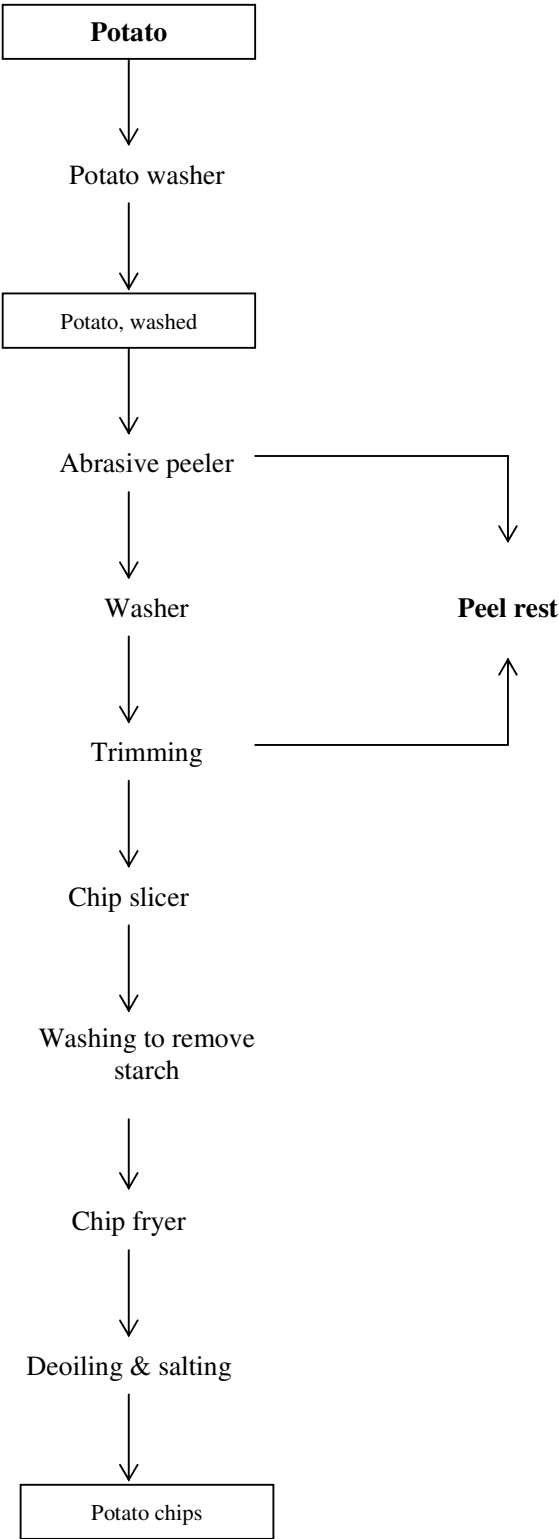


Figure 14. Processing of potatoes to chips.



*Sugar beet*

In 1997 in three processing trials in the USA plants were sprayed three times with solutions of trifloxystrobin 50 WG, either with foliar spray applications at 1-fold rate of 0.12 kg ai/ha, at the 3-fold rate (0.37 kg ai/ha) or at the 5-fold rate (0.62 kg ai/ha). The spray volume was 187 l/ha. Samples were taken on day 23 after the last application. Residues were determined in roots, tops, white sugar, dry pulp and molasses.

Sugar beets were washed with water and sliced. After diffusion of the pieces the pulp was pressed to remove free juice which was then returned to the diffuser. The pressed beet pulp was dried to below 10% moisture (dried pulp). The raw juice was purified, filtered and boiled (sugar crystallisation). The mixture of sugar crystals and syrup was centrifuged to produce molasses and wet sugar. The sugar was dried (dried sugar/white sugar). The results of the trials are summarised in Table 112.

Table 112. Trifloxystrobin residues in sugar beet and processed products, USA, 1997.

| Report No.;<br>Study No.        | Application |    |          |          | Sample      | PHI<br>(days) | Residues (mg/kg)     |                 |                 | Proc.<br>factor |
|---------------------------------|-------------|----|----------|----------|-------------|---------------|----------------------|-----------------|-----------------|-----------------|
|                                 | Form        | No | kg ai/ha | kg ai/hl |             |               | trifloxy-<br>strobin | CGA321<br>113   | Total           |                 |
| 35-97<br>USA-OW-<br>FR-223-97-A | 50<br>WG    | 3  | 0.12     | 0.066    | root        | 23            | <b>&lt;0.02</b>      | <b>&lt;0.02</b> | <b>&lt;0.02</b> |                 |
|                                 |             |    |          |          | white sugar | 23            | <0.02                | <0.02           | <0.02           |                 |
|                                 |             |    |          |          | pulp, dry   | 23            | 0.06                 | <0.02           | 0.06            |                 |
|                                 |             |    |          |          | molasses    | 23            | <0.02                | 0.03            | 0.05            |                 |
| 35-97<br>USA-OW-<br>FR-223-97-B | 50<br>WG    | 3  | 0.37     | 0.20     | root        | 23            | <b>0.11</b>          | <b>&lt;0.02</b> | <b>0.11</b>     | <0.18           |
|                                 |             |    |          |          | white sugar | 23            | <0.02                | <0.02           | <0.02           |                 |
|                                 |             |    |          |          | pulp, dry   | 23            | 0.21                 | <0.02           | 0.21            |                 |
|                                 |             |    |          |          | molasses    | 23            | <0.02                | 0.11            | 0.13            |                 |
| 35-97<br>USA-OW-<br>FR-223-97-C | 50<br>WG    | 3  | 0.62     | 0.33     | root        | 23            | <b>0.12</b>          | <b>&lt;0.02</b> | <b>0.12</b>     | <0.17           |
|                                 |             |    |          |          | white sugar | 23            | <0.02                | <0.02           | <0.02           |                 |
|                                 |             |    |          |          | pulp, dry   | 23            | 0.56                 | 0.03            | 0.59            |                 |
|                                 |             |    |          |          | molasses    | 23            | <0.02                | 0.20            | 0.22            |                 |

*Barley*

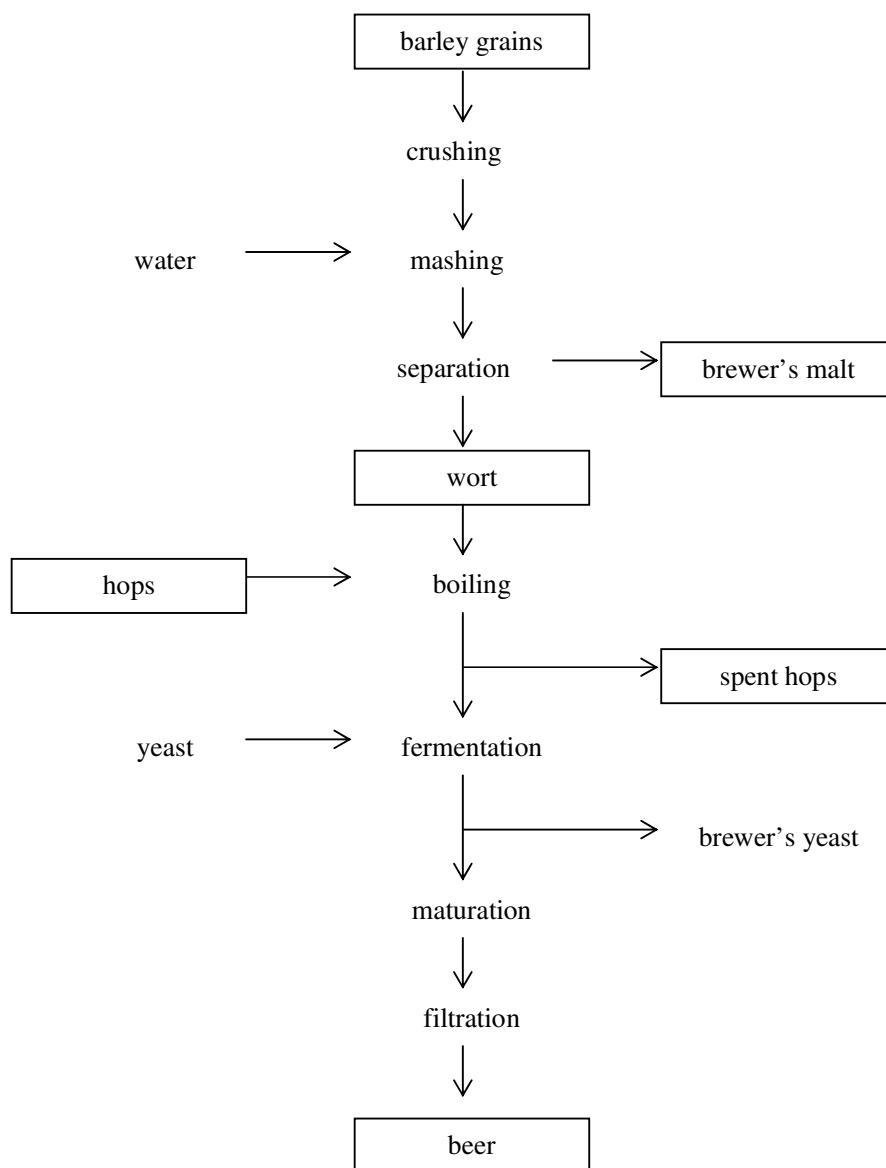
In France six processing trials were carried out in 1997-1999. Crops were sprayed twice with solutions of trifloxystrobin 125 EC, Stratego 250 EC or Sphere 267.5 either at about 0.25 kg/ha or 0.18 to 0.19 kg/ha, with a spray volume ranging between 385 and 423 l/ha. Grain was sampled 39 to 46 days after the last application, and residues determined in the raw agricultural commodity (grain) and the processed products. The processing steps are shown in Figure 15, and results summarised in Table 113.

Table 113. Trifloxystrobin residues in barley and processed products, France, 1997-1998.

| Report No.;<br>Study No. | Application |    |             |                 | Sample        | PHI<br>(days) | Residues (mg/kg)     |                 |                 | Proc.<br>factor |
|--------------------------|-------------|----|-------------|-----------------|---------------|---------------|----------------------|-----------------|-----------------|-----------------|
|                          | Form        | No | kg<br>ai/ha | kg ai/hl        |               |               | trifloxy-<br>strobin | CGA321<br>113   | Total           |                 |
| 9715102<br>FRA-9715102   | 250<br>EC   | 2  | 0.25        | 0.059-<br>0.065 | grain         | 45            | <b>&lt;0.02</b>      | <b>&lt;0.02</b> | <b>&lt;0.02</b> |                 |
|                          |             |    |             |                 | brewer's malt | 45            | <0.02                | <0.02           | <0.02           |                 |
|                          |             |    |             |                 | wort          | 45            | <0.02                | <0.02           | <0.02           |                 |
|                          |             |    |             |                 | beer          | 45            | <0.01                | <0.01           | <0.01           |                 |
| 9711601<br>FRA-9711601   | 250<br>EC   | 2  | 0.25        | 0.061           | grain         | 45            | <b>&lt;0.02</b>      | <b>&lt;0.02</b> | <b>&lt;0.02</b> |                 |
|                          |             |    |             |                 | brewer's malt | 45            | <0.02                | <0.02           | <0.02           |                 |
|                          |             |    |             |                 | wort          | 45            | <0.02                | <0.02           | <0.02           |                 |
|                          |             |    |             |                 | beer          | 45            | <0.01                | <0.01           | <0.01           |                 |

| Report No.;<br>Study No. | Application |    |               |          | Sample         | PHI<br>(days) | Residues (mg/kg)     |                 |                 | Proc.<br>factor |
|--------------------------|-------------|----|---------------|----------|----------------|---------------|----------------------|-----------------|-----------------|-----------------|
|                          | Form        | No | kg<br>ai/ha   | kg ai/hl |                |               | trifloxy-<br>strobin | CGA321<br>113   | Total           |                 |
| 2021/99<br>FRA-2021-99   | 125<br>EC   | 2  | 0.25          | 0.063    | grain          | <b>46</b>     | <b>0.02</b>          | <b>&lt;0.01</b> | <b>0.02</b>     |                 |
|                          |             |    |               |          | brewer's malt  | 46            | 0.01                 | <0.005          | 0.01            |                 |
|                          |             |    |               |          | tepral wort    | 46            | <0.002               | <0.002          | <0.002          |                 |
|                          |             |    |               |          | fermented wort | 46            | <0.002               | <0.002          | <0.002          |                 |
|                          |             |    |               |          | brewing wort   | 46            | <0.002               | <0.002          | <0.002          |                 |
|                          |             |    |               |          | beer           | 46            | <0.002               | <0.002          | <0.002          |                 |
| 2022/99<br>FRA-2022-99   | 125<br>EC   | 2  | 0.25-<br>0.26 | 0.062    | grain          | <b>39</b>     | <b>0.04</b>          | <b>0.01</b>     | <b>0.05</b>     |                 |
|                          |             |    |               |          | brewer's malt  | 39            | 0.01                 | <0.005          | 0.01            |                 |
|                          |             |    |               |          |                | 39            | 0.02                 | <0.005          | 0.02            |                 |
|                          |             |    |               |          | tepral wort    | 39            | <0.002               | <0.002          | <0.002          |                 |
|                          |             |    |               |          | fermented wort | 39            | <0.002               | <0.002          | <0.002          |                 |
|                          |             |    |               |          | brewing wort   | 39            | <0.002               | <0.002          | <0.002          |                 |
| 9810602<br>FRA-9810602   | 267.5<br>EC | 2  | 0.18-<br>0.19 | 0.047    | beer           | 39            | <0.002               | <0.002          | <0.002          | <0.04           |
|                          |             |    |               |          | grain          | <b>45</b>     | <b>&lt;0.02</b>      | <b>&lt;0.02</b> | <b>&lt;0.02</b> |                 |
|                          |             |    |               |          | brewer's malt  | 45            | <0.02                | <0.02           | <0.02           |                 |
|                          |             |    |               |          | wort           | 45            | <0.01                | <0.01           | <0.01           |                 |
|                          |             |    |               |          | beer           | 45            | <0.01                | <0.01           | <0.01           |                 |
| 9810502<br>FRA-9810502   | 267.5<br>EC | 2  | 0.19          | 0.047    | grain          | <b>43</b>     | <b>0.02</b>          | <b>&lt;0.02</b> | <b>0.02</b>     |                 |
|                          |             |    |               |          | brewer's malt  | 43            | <0.02                | <0.02           | <0.02           |                 |
|                          |             |    |               |          | wort           | 43            | <0.01                | <0.01           | <0.01           |                 |
|                          |             |    |               |          | beer           | 43            | <0.01                | <0.01           | <0.01           |                 |

Figure 15. Processing of barley and hops to beer.



### Wheat

In 2000 in one processing trial in France with trifloxystrobin 500 SC wheat was sprayed twice at an application rate of 0.42 kg ai/hl (corresponding to 1.23 and 1.25 kg ai/ha). Grain samples were taken on day 42 after the last application. Residues were determined in the raw agricultural commodity (RAC) and in a variety of processed products.

In 1997 in eight processing trials in the USA wheat was sprayed with trifloxystrobin 50 WG once or twice at 0.12-0.14 kg/ha, or twice at about 0.37 kg ai/ha, or twice at about 0.62 kg ai/ha with spray volumes of 187 (178) l/ha. Grain was sampled 36 or 47 days after the last application. Residues were determined in the raw agricultural commodity (RAC) and in a variety of processed products. The grain samples were dried, cleaned by aspiration and screening, moisture-adjusted and broken in mills. After the bran was separated, the sample was reduced to flour. The results are summarised in Table 114.



Table 114. Trifloxystrobin residues in wheat and processed products.

| Country,<br>Year | Application |    |               |                 | Sample              | PHI<br>(days) | Residues (mg/kg)     |                 |                 | Proc.<br>factor              | Report No.;<br>Study No.        |
|------------------|-------------|----|---------------|-----------------|---------------------|---------------|----------------------|-----------------|-----------------|------------------------------|---------------------------------|
|                  | Form        | No | kg<br>ai/ha   | kg ai/hl        |                     |               | trifloxy-<br>strobin | CGA321<br>113   | Total           |                              |                                 |
| France<br>2000   | 500<br>SC   | 2  | 1.2-<br>1.3   | 0.42            | grain               | 42            | <b>0.04</b>          | <b>&lt;0.01</b> | <b>0.04</b>     | 2.75<br>05<br>0.25           | 2106/00<br>FRA-2106-<br>00-B    |
|                  |             |    |               |                 |                     | 42            | 0.03                 | <0.01           | 0.03            |                              |                                 |
|                  |             |    |               |                 |                     | 42            | 0.02                 | <0.01           | 0.02            |                              |                                 |
|                  |             |    |               |                 | bran                | 42            | 0.10                 | 0.01            | 0.11            |                              |                                 |
|                  |             |    |               |                 | meal                | 42            | <0.005               | <0.005          | <0.005          |                              |                                 |
|                  |             |    |               |                 | whole meal          | 42            | 0.02                 | <0.005          | 0.02            |                              |                                 |
|                  |             |    |               |                 | whole meal<br>bread | 42            | 0.01                 | <0.005          | 0.01            |                              |                                 |
|                  |             |    |               |                 |                     |               |                      |                 |                 |                              |                                 |
| USA<br>1997      | 50<br>WG    | 1  | 0.14          | 0.073           | grain               | 36            | <b>&lt;0.02</b>      | <b>&lt;0.02</b> | <b>&lt;0.02</b> |                              | 43-97<br>USA-MW-<br>FR-309-97-B |
|                  |             |    |               |                 | aspir. grain        | 36            | 0.18                 | 0.03            | 0.21            |                              |                                 |
|                  |             |    |               |                 | fractions           |               |                      |                 |                 |                              |                                 |
|                  |             |    |               |                 | germs               | 36            | <0.02                | <0.02           | <0.02           |                              |                                 |
|                  |             |    |               |                 | bran                | 36            | <0.02                | <0.02           | <0.02           |                              |                                 |
|                  |             |    |               |                 | middlings           | 36            | <0.02                | <0.02           | <0.02           |                              |                                 |
|                  |             |    |               |                 | shorts              | 36            | <0.02                | <0.02           | <0.02           |                              |                                 |
|                  |             |    |               |                 | low grade           | 36            | <0.02                | <0.02           | <0.02           |                              |                                 |
|                  |             |    |               |                 | flour               | 36            | <0.02                | <0.02           | <0.02           |                              |                                 |
|                  |             |    |               |                 | patent flour        |               |                      |                 |                 |                              |                                 |
| USA<br>1997      | 50<br>WG    | 2  | 0.12-<br>0.14 | 0.066-<br>0.074 | grain               | 36            | <b>&lt;0.02</b>      | <b>&lt;0.02</b> | <b>&lt;0.02</b> |                              | 43-97<br>USA-MW-<br>FR-309-97-C |
|                  |             |    |               |                 | aspir. grain        | 36            | 0.26                 | 0.04            | 0.30            |                              |                                 |
|                  |             |    |               |                 | fractions           |               |                      |                 |                 |                              |                                 |
|                  |             |    |               |                 | germs               | 36            | <0.02                | <0.02           | <0.02           |                              |                                 |
|                  |             |    |               |                 | bran                | 36            | <0.02                | <0.02           | <0.02           |                              |                                 |
|                  |             |    |               |                 | middlings           | 36            | <0.02                | <0.02           | <0.02           |                              |                                 |
|                  |             |    |               |                 | shorts              | 36            | <0.02                | <0.02           | <0.02           |                              |                                 |
|                  |             |    |               |                 | low grade           | 36            | <0.02                | <0.02           | <0.02           |                              |                                 |
|                  |             |    |               |                 | flour               |               |                      |                 |                 |                              |                                 |
|                  |             |    |               |                 | patent flour        | 36            | <0.02                | <0.02           | <0.02           |                              |                                 |
| USA<br>1997      | 50<br>WG    | 2  | 0.37-<br>0.42 | 0.20-<br>0.22   | grain               | 36            | <b>&lt;0.02</b>      | <b>&lt;0.02</b> | <b>&lt;0.02</b> |                              | 43-97<br>USA-MW-<br>FR-309-97-D |
|                  |             |    |               |                 | aspir. grain        | 36            | 0.80                 | 0.10            | 0.90            |                              |                                 |
|                  |             |    |               |                 | fractions           |               |                      |                 |                 |                              |                                 |
|                  |             |    |               |                 | germs               | 36            | <0.02                | <0.02           | <0.02           |                              |                                 |
|                  |             |    |               |                 | bran                | 36            | 0.03                 | <0.02           | 0.03            |                              |                                 |
|                  |             |    |               |                 | middlings           | 36            | <0.02                | <0.02           | <0.02           |                              |                                 |
|                  |             |    |               |                 | shorts              | 36            | <0.02                | <0.02           | <0.02           |                              |                                 |
|                  |             |    |               |                 | low grade           | 36            | <0.02                | <0.02           | <0.02           |                              |                                 |
|                  |             |    |               |                 | flour               |               |                      |                 |                 |                              |                                 |
|                  |             |    |               |                 | patent flour        | 36            | <0.02                | <0.02           | <0.02           |                              |                                 |
| USA<br>1997      | 50<br>WG    | 2  | 0.62-<br>0.69 | 0.33-<br>0.37   | grain               | 36            | <b>0.03</b>          | <b>&lt;0.02</b> | <b>0.03</b>     | 0.67<br>2.67<br>0.67<br>0.67 | 43-97<br>USA-MW-<br>FR-309-97-E |
|                  |             |    |               |                 | aspir. grain        | 36            | 2.7                  | 0.34            | 3.04            |                              |                                 |
|                  |             |    |               |                 | fractions           |               |                      |                 |                 |                              |                                 |
|                  |             |    |               |                 | germs               | 36            | <0.02                | <0.02           | <0.02           |                              |                                 |
|                  |             |    |               |                 | bran                | 36            | 0.08                 | <0.02           | 0.08            |                              |                                 |
|                  |             |    |               |                 | middlings           | 36            | <0.02                | <0.02           | <0.02           |                              |                                 |
|                  |             |    |               |                 | shorts              | 36            | 0.02                 | <0.02           | 0.02            |                              |                                 |
|                  |             |    |               |                 | low grade           | 36            | <0.02                | <0.02           | <0.02           |                              |                                 |
|                  |             |    |               |                 | flour               |               |                      |                 |                 |                              |                                 |
|                  |             |    |               |                 | patent flour        | 36            | 0.02                 | <0.02           | 0.02            |                              |                                 |
| USA<br>1997      | 50<br>WG    | 1  | 0.12          | 0.066           | grain               | 47            | <b>&lt;0.02</b>      | <b>&lt;0.02</b> | <b>&lt;0.02</b> |                              | 43-97<br>USA-OS-FR-<br>731-97-B |
|                  |             |    |               |                 | aspir. grain        | 47            | <0.02                | <0.02           | <0.02           |                              |                                 |
|                  |             |    |               |                 | fractions           |               |                      |                 |                 |                              |                                 |
|                  |             |    |               |                 | germs               | 47            | <0.02                | <0.02           | <0.02           |                              |                                 |
|                  |             |    |               |                 | bran                | 47            | <0.02                | <0.02           | <0.02           |                              |                                 |
|                  |             |    |               |                 | middlings           | 47            | <0.02                | <0.02           | <0.02           |                              |                                 |
|                  |             |    |               |                 | shorts              | 47            | <0.02                | <0.02           | <0.02           |                              |                                 |
|                  |             |    |               |                 | low grade           | 47            | <0.02                | <0.02           | <0.02           |                              |                                 |
|                  |             |    |               |                 | flour               |               |                      |                 |                 |                              |                                 |
|                  |             |    |               |                 | patent flour        | 47            | <0.02                | <0.02           | <0.02           |                              |                                 |

| Country,<br>Year | Application |    |             |                 | Sample             | PHI<br>(days) | Residues (mg/kg)     |               |       | Proc.<br>factor | Report No.;<br>Study No.        |
|------------------|-------------|----|-------------|-----------------|--------------------|---------------|----------------------|---------------|-------|-----------------|---------------------------------|
|                  | Form        | No | kg<br>ai/ha | kg ai/hl        |                    |               | trifloxy-<br>strobin | CGA321<br>113 | Total |                 |                                 |
| USA<br>1997      | 50<br>WG    | 2  | 0.12        | 0.066-<br>0.069 | grain              | 47            | <0.02                | <0.02         | <0.02 |                 | 43-97<br>USA-OS-FR-<br>731-97-C |
|                  |             |    |             |                 | aspir. grain       | 47            | <0.02                | <0.02         | <0.02 |                 |                                 |
|                  |             |    |             |                 | fractions          |               |                      |               |       |                 |                                 |
|                  |             |    |             |                 | germs              | 47            | <0.02                | <0.02         | <0.02 |                 |                                 |
|                  |             |    |             |                 | bran               | 47            | <0.02                | <0.02         | <0.02 |                 |                                 |
|                  |             |    |             |                 | middlings          | 47            | <0.02                | <0.02         | <0.02 |                 |                                 |
|                  |             |    |             |                 | shorts             | 47            | <0.02                | <0.02         | <0.02 |                 |                                 |
|                  |             |    |             |                 | low grade<br>flour | 47            | <0.02                | <0.02         | <0.02 |                 |                                 |
| USA<br>1997      | 50<br>WG    | 2  | 0.37        | 0.20-<br>0.21   | patent flour       | 47            | <0.02                | <0.02         | <0.02 |                 | 43-97<br>USA-OS-FR-<br>731-97-D |
|                  |             |    |             |                 | grain              | 47            | <0.02                | <0.02         | <0.02 |                 |                                 |
|                  |             |    |             |                 | aspir. grain       | 47            | 0.04                 | <0.02         | 0.04  |                 |                                 |
|                  |             |    |             |                 | fractions          |               |                      |               |       |                 |                                 |
|                  |             |    |             |                 | germs              | 47            | <0.02                | <0.02         | <0.02 |                 |                                 |
|                  |             |    |             |                 | bran               | 47            | <0.02                | <0.02         | <0.02 |                 |                                 |
|                  |             |    |             |                 | middlings          | 47            | <0.02                | <0.02         | <0.02 |                 |                                 |
|                  |             |    |             |                 | shorts             | 47            | <0.02                | <0.02         | <0.02 |                 |                                 |
| USA<br>1997      | 50<br>WG    | 2  | 0.37        | 0.20-<br>0.21   | low grade<br>flour | 47            | <0.02                | <0.02         | <0.02 |                 | 43-97<br>USA-OS-FR-<br>731-97-E |
|                  |             |    |             |                 | patent flour       | 47            | <0.02                | <0.02         | <0.02 |                 |                                 |
|                  |             |    |             |                 | grain              | 47            | <0.02                | <0.02         | <0.02 |                 |                                 |
|                  |             |    |             |                 | aspir. grain       | 47            | 0.09                 | <0.02         | 0.09  |                 |                                 |
|                  |             |    |             |                 | fractions          |               |                      |               |       |                 |                                 |
|                  |             |    |             |                 | germs              | 47            | <0.02                | <0.02         | <0.02 |                 |                                 |
|                  |             |    |             |                 | bran               | 47            | <0.02                | <0.02         | <0.02 |                 |                                 |
|                  |             |    |             |                 | middlings          | 47            | <0.02                | <0.02         | <0.02 |                 |                                 |
| USA<br>1997      | 50<br>WG    | 2  | 0.37        | 0.20-<br>0.21   | shorts             | 47            | <0.02                | <0.02         | <0.02 |                 | 43-97<br>USA-OS-FR-<br>731-97-E |
|                  |             |    |             |                 | low grade<br>flour | 47            | <0.02                | <0.02         | <0.02 |                 |                                 |
|                  |             |    |             |                 | patent flour       | 47            | <0.02                | <0.02         | <0.02 |                 |                                 |
|                  |             |    |             |                 | grain              | 47            | <0.02                | <0.02         | <0.02 |                 |                                 |
|                  |             |    |             |                 | aspir. grain       | 47            | 0.09                 | <0.02         | 0.09  |                 |                                 |
|                  |             |    |             |                 | fractions          |               |                      |               |       |                 |                                 |
|                  |             |    |             |                 | germs              | 47            | <0.02                | <0.02         | <0.02 |                 |                                 |
|                  |             |    |             |                 | bran               | 47            | <0.02                | <0.02         | <0.02 |                 |                                 |

### Maize

In 1998 in four processing trials in the USA maize was sprayed four times either at about 0.12 kg/ha applied to the leaves, or at the 5-fold rate (0.62 kg/ha), with spray volumes ranging from 196 to 224 l/ha. Grain/kernel samples were taken on day 29 or 30 after the last application. Residues were determined in the raw agricultural commodity and in a variety of processed products.

Samples were dried to a moisture content of 10-13%. Grain dust was removed (aspiration). After screening and tempering whole corn was dry-milled and separated into hulls, germ, grits (large, medium and small), coarse meal, meal, flour, flaked germ and crude oil (after solvent extraction), refined oil, and soapstock. Wet milled corn samples were processed into hulls, germ, gluten, starch, presscake from the expeller, crude oil from the expeller, presscake after solvent extraction, refined oil, and soapstock. The detailed processing steps are shown in Figure 16. The results of the trials are summarised in Table 115.

Table 115. Trifloxystrobin residues in maize and its processed products, USA, 1998.

| Report No.;<br>Study No.         | Application |    |             |          | Sample          | PHI<br>(days) | Residues (mg/kg)     |                |       | Proc.<br>factor |
|----------------------------------|-------------|----|-------------|----------|-----------------|---------------|----------------------|----------------|-------|-----------------|
|                                  | Form        | No | kg<br>ai/ha | kg ai/hl |                 |               | trifloxy-<br>strobin | CGA-<br>321113 | Total |                 |
| 144-98<br>USA-MW-FR-<br>151-98-B | 250<br>EC   | 4  | 0.12        | 0.053    | kernel          | 30            | <0.02                | <0.02          | <0.02 |                 |
|                                  |             |    |             |          | aspirated grain | 30            | 0.05                 | <0.02          | 0.05  |                 |
|                                  |             |    |             |          | fractions       |               |                      |                |       |                 |
|                                  |             |    |             |          | meal            | 30            | <0.02                | <0.02          | <0.02 |                 |
|                                  |             |    |             |          | grits           | 30            | <0.02                | <0.02          | <0.02 |                 |
|                                  |             |    |             |          | flour           | 30            | <0.02                | <0.02          | <0.02 |                 |

| Report No.;<br>Study No.         | Application |    |               |                 | Sample          | PHI<br>(days) | Residues (mg/kg)     |                 |                 | Proc.<br>factor |
|----------------------------------|-------------|----|---------------|-----------------|-----------------|---------------|----------------------|-----------------|-----------------|-----------------|
|                                  | Form        | No | kg<br>ai/ha   | kg ai/hl        |                 |               | trifloxy-<br>strobin | CGA-<br>321113  | Total           |                 |
| 144-98<br>USA-04-FR-<br>004-98-B | 250<br>EC   | 4  | 0.12-<br>0.15 | 0.055-<br>0.078 | oil, dry milled | 30            | <0.02                | <0.02           | <0.02           |                 |
|                                  |             |    |               |                 | starch          | 30            | <0.02                | <0.02           | <0.02           |                 |
|                                  |             |    |               |                 | oil, wet milled | 30            | <0.02                | <0.02           | <0.02           |                 |
|                                  |             |    |               |                 | kernel          | 29            | <b>&lt;0.02</b>      | <b>&lt;0.02</b> | <b>&lt;0.02</b> |                 |
|                                  |             |    |               |                 | aspirated grain | 29            | 0.07                 | <0.02           | 0.07            |                 |
|                                  |             |    |               |                 | fractions       |               |                      |                 |                 |                 |
|                                  |             |    |               |                 | meal            | 29            | <0.02                | <0.02           | <0.02           |                 |
|                                  |             |    |               |                 | grits           | 29            | <0.02                | <0.02           | <0.02           |                 |
|                                  |             |    |               |                 |                 | 29            | <0.02                | <0.02           | <0.02           |                 |
| 144-98<br>USA-MW-FR-<br>151-98-C | 250<br>EC   | 4  | 0.62          | 0.26            | flour           | 29            | <0.02                | <0.02           | <0.02           |                 |
|                                  |             |    |               |                 | oil, dry milled | 29            | <0.02                | <0.02           | <0.02           |                 |
|                                  |             |    |               |                 | starch          | 29            | <0.02                | <0.02           | <0.02           |                 |
|                                  |             |    |               |                 | oil, wet milled | 29            | <0.02                | <0.02           | <0.02           |                 |
|                                  |             |    |               |                 | kernel          | 30            | <b>0.02</b>          | <b>&lt;0.02</b> | <b>0.02</b>     |                 |
|                                  |             |    |               |                 | aspirated grain | 30            | 1.4                  | 0.11            | 1.51            |                 |
|                                  |             |    |               |                 | fractions       |               |                      |                 |                 |                 |
|                                  |             |    |               |                 | meal            | 30            | <0.02                | <0.02           | <0.02           |                 |
|                                  |             |    |               |                 | grits           | 30            | <0.02                | <0.02           | <0.02           |                 |
| 144-98<br>USA-04-FR-<br>004-98-C | 250<br>EC   | 4  | 0.62          | 0.31            | flour           | 30            | 0.02                 | <0.02           | 0.02            |                 |
|                                  |             |    |               |                 | oil, dry milled | 30            | <0.02                | <0.02           | <0.02           |                 |
|                                  |             |    |               |                 | starch          | 30            | <0.02                | <0.02           | <0.02           |                 |
|                                  |             |    |               |                 | oil, wet milled | 30            | 0.07                 | <0.02           | 0.07            |                 |
|                                  |             |    |               |                 | kernel          | 29            | <b>&lt;0.02</b>      | <b>&lt;0.02</b> | <b>&lt;0.02</b> |                 |
|                                  |             |    |               |                 | aspirated grain | 29            | 0.04                 | <0.02           | 0.04            |                 |
|                                  |             |    |               |                 | fractions       |               |                      |                 |                 |                 |
|                                  |             |    |               |                 | meal            | 29            | <0.02                | <0.02           | <0.02           |                 |
|                                  |             |    |               |                 | grits           | 29            | <0.02                | <0.02           | <0.02           |                 |
|                                  |             |    |               |                 | flour           | 29            | <0.02                | <0.02           | <0.02           |                 |
|                                  |             |    |               |                 | oil, dry milled | 29            | <0.02                | <0.02           | <0.02           |                 |
|                                  |             |    |               |                 | starch          | 29            | <0.02                | <0.02           | <0.02           |                 |
|                                  |             |    |               |                 | oil, wet milled | 29            | 0.03                 | <0.02           | 0.03            |                 |
|                                  |             |    |               |                 |                 |               |                      |                 |                 |                 |
|                                  |             |    |               |                 |                 |               |                      |                 |                 |                 |

### Rice

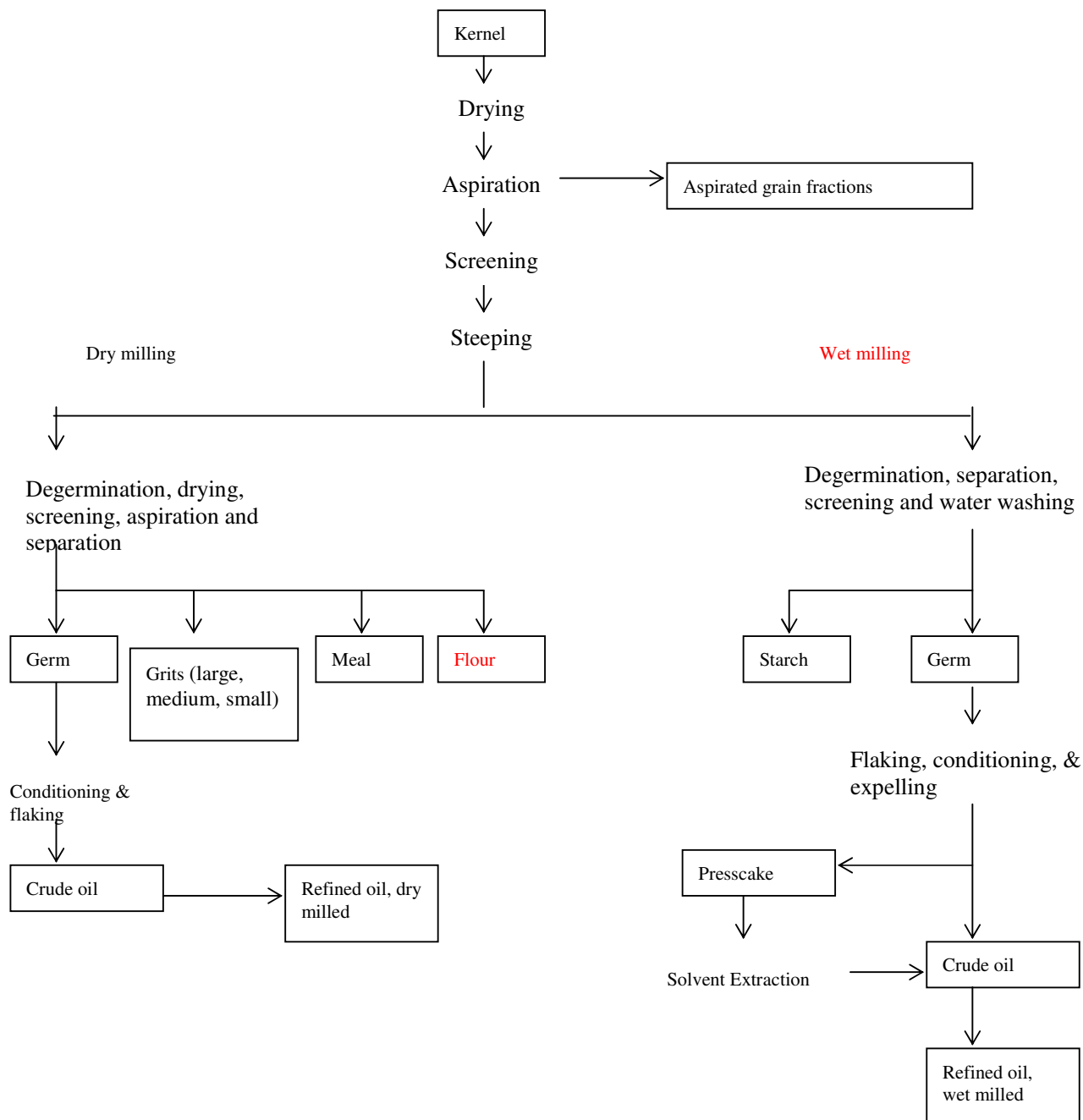
In 1998 in four US processing trials plants were foliar-sprayed twice with trifloxystrobin 50 WG either at a rate of 0.17 kg ai/ha, or at 0.865 kg ai/ha (5-fold rate), at spray volumes ranging from 140 to 196 l/ha. Grain samples were taken 35 days after the last application, and residues determined in the raw agricultural commodity and in the polished grain, hull and bran. Rough rice samples were dried to a moisture content of 11-14%. After aspiration and screening the hulls were separated from the brown rice, and the brown rice was decorticated to give bran and white milled rice (polished grain). The results of the trials are summarised in Table 116.

Table 116. Trifloxystrobin residues in rice and processed products, USA, 1998.

| Report No.;<br>Study No.         | Application |    |             |               | Sample          | PHI<br>(days) | Residues (mg/kg)     |                |             | Proc.<br>factor |
|----------------------------------|-------------|----|-------------|---------------|-----------------|---------------|----------------------|----------------|-------------|-----------------|
|                                  | Form        | No | kg<br>ai/ha | kg ai/hl      |                 |               | trifloxy-<br>strobin | CGA-<br>321113 | Total       |                 |
| 150-98<br>USA-OS-FR-<br>105-98-A | 50<br>WG    | 2  | 0.17        | 0.092         | grain           | 35            | <b>0.06</b>          | <b>0.04</b>    | <b>0.10</b> | <0.2            |
|                                  |             |    |             |               | grain, polished | 35            | <0.02                | <0.02          | <0.02       |                 |
|                                  |             |    |             |               | hull            | 35            | 0.14                 | 0.05           | 0.19        |                 |
|                                  |             |    |             |               | bran            | 35            | 0.09                 | 0.05           | 0.14        |                 |
| 150-98<br>USA-OS-FR-<br>901-98-A | 50<br>WG    | 2  | 0.17        | 0.09-<br>0.12 | grain           | 35            | <b>0.04</b>          | <b>0.02</b>    | <b>0.06</b> | <0.33           |
|                                  |             |    |             |               | grain, polished | 35            | <0.02                | <0.02          | <0.02       |                 |
|                                  |             |    |             |               | hull            | 35            | 0.19                 | 0.04           | 0.23        |                 |
|                                  |             |    |             |               | bran            | 35            | 0.06                 | 0.05           | 0.11        |                 |
| 150-98<br>USA-OS-FR-             | 50<br>WG    | 2  | 0.87        | 0.46          | grain           | 35            | <b>0.50</b>          | <b>0.15</b>    | <b>0.65</b> | 0.125           |
|                                  |             |    |             |               | grain, polished | 35            | <0.02                | 0.06           | 0.08        |                 |

| Report No.;<br>Study No.<br>105-98-B | Application |    |             |               | Sample          | PHI<br>(days) | Residues (mg/kg)     |                |             | Proc.<br>factor |
|--------------------------------------|-------------|----|-------------|---------------|-----------------|---------------|----------------------|----------------|-------------|-----------------|
|                                      | Form        | No | kg<br>ai/ha | kg ai/hl      |                 |               | trifloxy-<br>strobin | CGA-<br>321113 | Total       |                 |
|                                      |             |    |             |               |                 |               |                      |                |             |                 |
| 150-98<br>USA-OS-FR-<br>901-98-B     | 50<br>WG    | 2  | 0.87        | 0.44-<br>0.62 | hull            | 35            | 1.6                  | 0.27           | 1.9         | 2.9             |
|                                      |             |    |             |               | bran            | 35            | 0.48                 | 0.17           | 0.65        | 1               |
|                                      |             |    |             |               | grain           | 35            | <b>0.29</b>          | <b>0.11</b>    | <b>0.40</b> |                 |
|                                      |             |    |             |               | grain, polished | 35            | <0.02                | 0.04           | <0.02       | <0.05           |
|                                      |             |    |             |               | hull            | 35            | 1.4                  | 0.22           | 1.6         | 4               |
|                                      |             |    |             |               | bran            | 35            | 0.34                 | 0.20           | 0.54        | 1.4             |

Figure 16. Processing of maize to meal, flour and oil.



*Cotton*

In two US processing studies cotton was treated once with trifloxystrobin 50 WG either at 0.14 kg ai/ha (1-fold rate) or 5-fold rate (0.7 kg ai/ha). Samples were processed to refined oil. Residues in all samples of the raw agricultural commodity, gin trash and refined oil were below the limit of quantification (0.05 mg/kg), so no processing factors could be calculated. The results of the trials are summarised in Table 117.

Table 117. Trifloxystrobin residues in cotton and processed products, USA, 1999.

| Report No.;<br>Study No.         | Application |    |             |          | Sample       | PHI<br>(days) | Residues (mg/kg)     |                |       |
|----------------------------------|-------------|----|-------------|----------|--------------|---------------|----------------------|----------------|-------|
|                                  | Form        | No | kg<br>ai/ha | kg ai/hl |              |               | trifloxy-<br>strobin | CGA-<br>321113 | Total |
| 110786<br>USA-OS-FR-<br>308-99-A | 50<br>WG    | 1  | 0.14        | 0.15     | seed         | 152           | <0.05                | <0.05          | <0.05 |
|                                  |             |    |             |          | oil, refined | 152           | <0.05                | <0.05          | <0.05 |
| 110786<br>USA-OS-FR-<br>308-99-B | 50<br>WG    | 1  | 0.70        | 0.75     | seed         | 152           | <0.05                | <0.05          | <0.05 |
|                                  |             |    |             |          | oil, refined | 152           | <0.05                | <0.05          | <0.05 |

*Peanut*

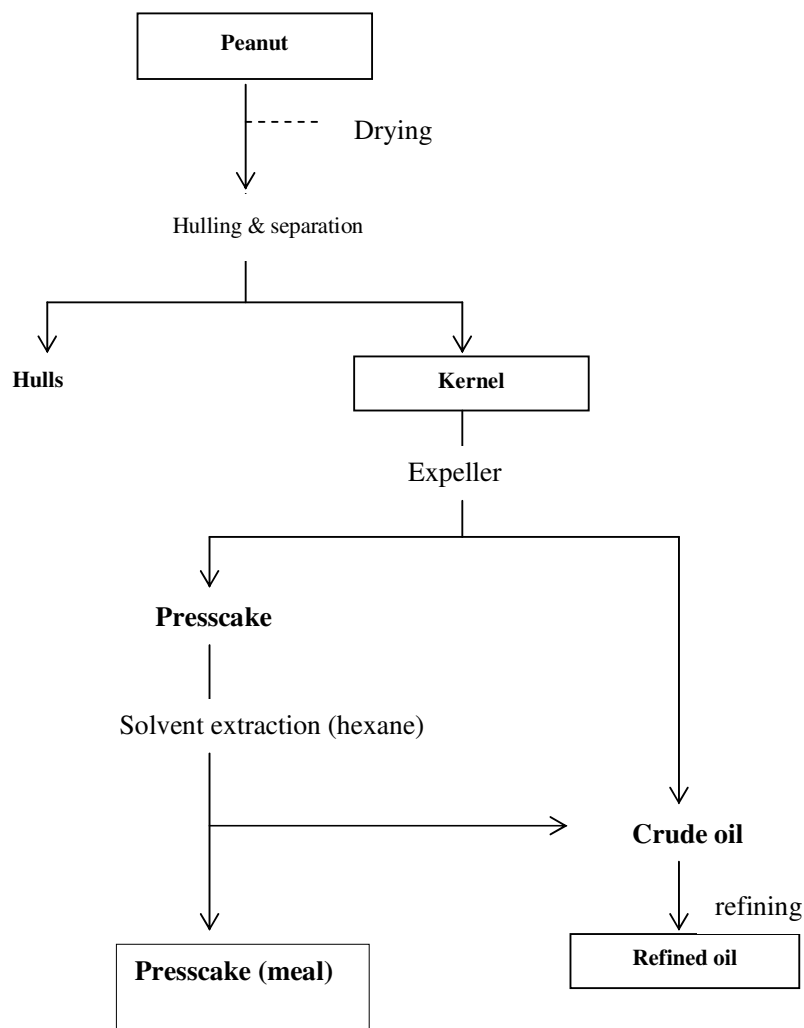
In 1996 in four US processing trials plants were sprayed eight times with trifloxystrobin 50 WG either at a rate of 0.14 kg ai/ha or at 0.42 kg ai/ha (3-fold rate), with spray volumes of about 187 l/ha. Peanut samples were taken 14 days after the last application. Because residues determined in the kernels were below the LOQ, processing factors could not be calculated.

Whole peanuts were dried to a moisture content of 7-12% (hull). After aspiration and screening the nuts were shelled to separate the kernels and the kernels dried to a final moisture of 7-10%, then heated and pressed in an expeller to crude oil and presscake (meal). Oil was refined. The detailed processing steps are shown in Figure 17. The results of the trials are summarised in Table 118.

Table 118. Trifloxystrobin residues in peanuts and their processed products, USA, 1996.

| Report No.;<br>Study No.        | Application |    |             |                 | Sample       | PHI<br>(days) | Residues (mg/kg)     |                |       |
|---------------------------------|-------------|----|-------------|-----------------|--------------|---------------|----------------------|----------------|-------|
|                                 | Form        | No | kg<br>ai/ha | kg ai/hl        |              |               | trifloxy-<br>strobin | CGA-<br>321113 | Total |
| 53-96<br>USA-OS-FR-<br>842-96-B | 50<br>WG    | 8  | 0.14        | 0.075-<br>0.076 | meat         | 14            | <0.02                | <0.02          | <0.02 |
|                                 |             |    |             |                 | meal         | 14            | <0.02                | <0.02          | <0.02 |
|                                 |             |    |             |                 | oil, refined | 14            | <0.02                | <0.02          | <0.02 |
| 53-96<br>USA-OS-FR-<br>842-96-C | 50<br>WG    | 8  | 0.42        | 0.23            | meat         | 14            | <0.02                | <0.02          | <0.02 |
|                                 |             |    |             |                 | meal         | 14            | <0.02                | 0.06           | 0.08  |
|                                 |             |    |             |                 | oil, refined | 14            | <0.02                | <0.02          | <0.02 |
| 53-96<br>USA-OS-FR-<br>314-96-B | 50<br>WG    | 8  | 0.14        | 0.075           | meat         | 14            | <0.02                | <0.02          | <0.02 |
|                                 |             |    |             |                 | meal         | 14            | <0.02                | <0.02          | <0.02 |
|                                 |             |    |             |                 | oil, refined | 14            | <0.02                | <0.02          | <0.02 |
| 53-96<br>USA-OS-FR-<br>314-96-C | 50<br>WG    | 8  | 0.42        | 0.23            | meat         | 14            | <0.02                | <0.02          | <0.02 |
|                                 |             |    |             |                 | meal         | 14            | <0.02                | 0.08           | 0.10  |
|                                 |             |    |             |                 | oil, refined | 14            | <0.02                | <0.02          | <0.02 |

Figure 17. Processing of peanut to (kernels) meal and oil.



### Hops

In 1996 in a trial in Germany to investigate the effects of processing on residue levels in processed hop commodities trifloxystrobin 50 WG was applied four times to plants at a rate of 0.75 to 1.0 kg/ha, equivalent to 0.38 to 0.50 kg ai/ha. The spray rate was adjusted to plant height (max. volume 5000 l/ha). Samples of cones were taken at the recommended PHI of 14 days. The processing steps are the same as those shown in Figure 15 for barley. The results are summarised in Table 119.

Table 119. Trifloxystrobin residues in hops and their processed products, Germany, 1996.

| Report No.;<br>Study No. | Application |    |               |          | Sample        | PHI<br>(days) | Residues (mg/kg)     |                |             | Proc.<br>factor |
|--------------------------|-------------|----|---------------|----------|---------------|---------------|----------------------|----------------|-------------|-----------------|
|                          | Form        | No | kg<br>ai/ha   | kg ai/hl |               |               | trifloxy-<br>strobin | CGA-<br>321113 | Total       |                 |
| gr01796<br>BRD-gr01796   | 50<br>WG    | 4  | 0.38-<br>0.50 | 0.013    | cone, dried   | 14            | <b>15.7</b>          | <b>1.98</b>    | <b>17.7</b> | 0.04            |
|                          |             |    |               |          | brewer's malt | 14            | <0.02                | <0.02          | <0.02       |                 |
|                          |             |    |               |          | spent hops    | 14            | 0.68                 | 0.04           | 0.72        |                 |
|                          |             |    |               |          | wort          | 14            | <0.02                | <0.02          | <0.02       |                 |
|                          |             |    |               |          | beer, young   | 14            | <0.02                | <0.02          | <0.02       | 0.007<br><0.001 |
|                          |             |    |               |          | yeast         | 14            | 0.08                 | 0.04           | 0.12        |                 |
|                          |             |    |               |          | beer          | 14            | <0.02                | <0.02          | <0.02       |                 |

### Summary

The processing factors calculated from the total residues (sum of trifloxystrobin and CGA321113) are shown in Table 120.

Table 120. Summary of processing factors. Data are from trials recorded in Tables 101–119.

| RAC         | Processed product | Processing factors (PF)                                                                                                                                                                                                                                   | No. | Mean proc. factor |
|-------------|-------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----|-------------------|
| Orange      | juice             | <0.038, <0.04, <0.15, <0.33, <0.4                                                                                                                                                                                                                         | 5   | <0.19             |
|             | oil               | 66, 113, 138, 166, 166                                                                                                                                                                                                                                    | 5   | 130               |
|             | pulp, dry         | 1.34, 2.38, 3, 5.2, 5.2                                                                                                                                                                                                                                   | 5   | 3.4               |
| Apple, Pear | juice             | 0.036, 0.07, 0.103, <0.12, <0.15, <0.29, <0.33                                                                                                                                                                                                            | 7   | 0.16              |
|             | sauce/preserve    | 0.13, <0.15, 0.31, 1.33,                                                                                                                                                                                                                                  | 4   | 0.48              |
|             | fruit, dried      | <0.15, 0.62                                                                                                                                                                                                                                               | 2   | 0.39              |
|             | pomace, wet       | 2.69, 5.2, 6.6, 11.2, 12.1, 18.6                                                                                                                                                                                                                          | 6   | 9.4               |
|             | pomace, dried     | 25.6                                                                                                                                                                                                                                                      | 1   | 25.6              |
| Plum        | dried prune       | 1.34, 1.43, 1.55, 1.73                                                                                                                                                                                                                                    | 4   | 1.5               |
| Peach       | preserve          | <0.05                                                                                                                                                                                                                                                     | 1   | <0.05             |
| Grapes      | juice             | <0.08, 0.08, 0.09, <0.11, <0.11, 0.13, <0.15, 0.167, 0.167, 0.18, <0.22, <0.5, <0.67, <0.67                                                                                                                                                               | 14  | 0.24              |
|             | must              | 0.057, 0.079, 0.085, 0.091, 0.091, 0.128, 0.135, 0.14, 0.14, <0.15, 0.252, 0.29, 0.32, 0.375, 0.47, 0.485, 0.528, 0.576, 0.6, 0.636, 0.69, 0.72, 0.76, 0.805, 0.898, 1.28, 1.64                                                                           | 27  | 0.46              |
|             | wine              | 0.015, <0.016, <0.02, <0.02, <0.028, <0.03, <0.034, <0.045, 0.047, <0.05, <0.057, 0.068, <0.08, 0.082, 0.09, <0.091, 0.106, <0.11, <0.11, <0.125, <0.125, <0.125, <0.125, <0.13, <0.15, <0.15, 0.16, 0.16, <0.22, <0.22, <0.268, <0.4, <0.5, <0.67, <0.67 | 35  | 0.15              |
|             | fruit, dried      | 0.58, 2.48, 3, 3.25                                                                                                                                                                                                                                       | 4   | 2.3               |
|             | pomace, wet       | 2.25                                                                                                                                                                                                                                                      | 1   | 2.25              |
|             |                   |                                                                                                                                                                                                                                                           |     |                   |
| Strawberry  | preserve          | 0.25, 0.33                                                                                                                                                                                                                                                | 2   | 0.29              |
|             | jam               | 0.58, 0.667                                                                                                                                                                                                                                               | 2   | 0.62              |
| Tomato      | paste             | 1.0, 1.16, 1.39, 1.57, 2.83                                                                                                                                                                                                                               | 5   | 1.6               |
|             | purée             | <0.17, 0.33, 0.424, 0.71, 1.18                                                                                                                                                                                                                            | 5   | 0.56              |
| Potato      | flakes            | <0.33, <0.5                                                                                                                                                                                                                                               | 2   | <0.42             |
|             | chips             | <0.33, <0.5                                                                                                                                                                                                                                               | 2   | <0.42             |
|             | peel rest         | 2.0, 2.5                                                                                                                                                                                                                                                  | 2   | 2.3               |
| Sugar beet  | white sugar       | <0.17, <0.18                                                                                                                                                                                                                                              | 2   | <0.18             |
|             | dried pulp        | 1.91, 4.92                                                                                                                                                                                                                                                | 2   | 3.4               |
|             | molasses          | 1.18, 1.83                                                                                                                                                                                                                                                | 2   | 1.5               |
| Barley      | beer              | <0.04                                                                                                                                                                                                                                                     | 1   | 0.04              |
| Wheat       | bran              | 2.67, 2.75                                                                                                                                                                                                                                                | 2   | 2.7               |
|             | germ              | <0.67                                                                                                                                                                                                                                                     | 1   | <0.67             |
|             | meal/flour        | <0.125, 0.67                                                                                                                                                                                                                                              | 2   | 0.4               |
|             | whole meal        | 0.5                                                                                                                                                                                                                                                       | 1   | 0.5               |
|             | whole meal bread  | 0.25                                                                                                                                                                                                                                                      | 1   | 0.25              |
| Rice        | polished grain    | <0.05, 0.125, <0.2, <0.33                                                                                                                                                                                                                                 | 4   | 0.18              |
|             | hull              | 1.9, 2.9, 3.8, 4.0                                                                                                                                                                                                                                        | 4   | 3.2               |
|             | bran              | 1.0, 1.4, 1.4, 1.8                                                                                                                                                                                                                                        | 4   | 1.4               |
| Hops        | spent hops        | 0.04                                                                                                                                                                                                                                                      | 1   | 0.04              |
|             | yeast             | 0.007                                                                                                                                                                                                                                                     | 1   | 0.007             |
|             | beer              | <0.001                                                                                                                                                                                                                                                    | 1   | <0.001            |

## RESIDUES IN ANIMAL COMMODITIES

### Direct animal treatment

No study reported.

### Farm animal feeding studies

#### *Dairy cattle*

A feeding study (Campell, 1997; Report No. ABR-97075) was conducted with three groups (each consisting of 3 cows plus a control cow) of lactating Holstein cows were dosed daily for 28 to 30 days with trifloxystrobin in gelatine capsules (random samples analysed to assess conformity and stability) at target rates of 2 ppm (1X), 6 ppm (3X), and 20 ppm (10X) in the diet. Actual rates were very close to the targets at 2 ppm, 5.9 ppm, and 21 ppm respectively. The 1X level ranged from 0.061 to 0.067 mg/kg/bw. Milk was sampled throughout the study and the cows were killed twenty to twenty-four hours after the final dose.

Tissue and milk samples were analysed by method AG 659, which determines trifloxystrobin and its acid metabolite CGA321113 by capillary gas chromatography using nitrogen/phosphorus detection (NPD), after acetonitrile/water extraction and solvent partition plus clean-up on C-18 solid-phase extraction cartridge. The LOQ was 0.01 mg/kg for milk and 0.02 mg/kg for tissues for each analyte.

Analysis of capsules on days 0 and 29 indicated that nominal dosages were achieved and no significant degradation had occurred during the study. Recoveries ranged from 95% to 121% (average 109%). Residues of trifloxystrobin and CGA321113 were undetectable in the milk (<0.02 mg/kg total, expressed as trifloxystrobin), round muscle (<0.04 mg/kg), and tenderloin (<0.04 mg/kg) at all feeding levels. Maximum residues of CGA321113 were 0.09 mg/kg and 0.02 mg/kg in the liver and kidney respectively at the high dose, and total residues of the parent compound and its metabolite were below the LOQ (<0.04 mg/kg) at the other two levels. Maximum residues of 0.06 mg/kg and 0.05 mg/kg, as intact trifloxystrobin, were found in perirenal fat and omental fat respectively at the high dose level. A single perirenal fat sample at the middle level contained a residue equivalent to 0.05 mg/kg; this was anomalous, as it was the only fat sample in which CGA321113 was detected (at the LOQ, 0.02 mg/kg). The corresponding trifloxystrobin residue was 0.03 mg/kg. Since no residues were detected in the samples from the other two animals in this group, and the level of trifloxystrobin was similar to that found at the high dose, this single fat residue is suspect. Residues were undetectable on re-analysis. The maximum residues are shown in Table 121, and individual results at the high feeding level are given in Table 122.

Table 121. Maximum residues detected in dairy cows dosed with trifloxystrobin for 28 to 30 days (Campell, 1997; Report No. ABR-97075).

| Sample | Day   | Maximum trifloxystrobin residues (mg/kg) |        |                    |                   |        |                    |                   |        |                    |
|--------|-------|------------------------------------------|--------|--------------------|-------------------|--------|--------------------|-------------------|--------|--------------------|
|        |       | Dose 2 ppm (1X)                          |        |                    | Dose 5.9 ppm (3X) |        |                    | Dose 21 ppm (10X) |        |                    |
|        |       | parent                                   | 321113 | Total <sup>1</sup> | parent            | 321113 | Total <sup>1</sup> | parent            | 321113 | Total <sup>1</sup> |
| Milk   | 0     | -                                        | -      | -                  | -                 | -      | -                  | <0.01             | <0.01  | <0.02              |
|        | 1     | -                                        | -      | -                  | -                 | -      | -                  | <0.01             | <0.01  | <0.02              |
|        | 3     | -                                        | -      | -                  | -                 | -      | -                  | <0.01             | <0.01  | <0.02              |
|        | 7     | -                                        | -      | -                  | -                 | -      | -                  | <0.01             | <0.01  | <0.02              |
|        | 14    | -                                        | -      | -                  | -                 | -      | -                  | <0.01             | <0.01  | <0.02              |
|        | 21    | -                                        | -      | -                  | -                 | -      | -                  | <0.01             | <0.01  | <0.02              |
|        | 26    | -                                        | -      | -                  | -                 | -      | -                  | <0.01             | <0.01  | <0.02              |
| Liver  | 28-30 | <0.02                                    | <0.02  | <0.04              | <0.02             | <0.02  | <0.04              | <0.02             | 0.09   | <u>0.11</u>        |
| Kidney | 28-30 | <0.02                                    | <0.02  | <0.04              | <0.02             | <0.02  | <0.04              | <0.02             | 0.02   | <u>0.04</u>        |



| Sample        | Day   | Maximum trifloxystrobin residues (mg/kg) |        |                    |                     |                     |                     |                   |        |                    |
|---------------|-------|------------------------------------------|--------|--------------------|---------------------|---------------------|---------------------|-------------------|--------|--------------------|
|               |       | Dose 2 ppm (1X)                          |        |                    | Dose 5.9 ppm (3X)   |                     |                     | Dose 21 ppm (10X) |        |                    |
|               |       | parent                                   | 321113 | Total <sup>1</sup> | parent              | 321113              | Total <sup>1</sup>  | parent            | 321113 | Total <sup>1</sup> |
| Perirenal fat | 28-30 | <0.02                                    | <0.02  | <0.04              | (0.03) <sup>2</sup> | (0.02) <sup>2</sup> | (0.05) <sup>2</sup> | 0.06              | <0.02  | 0.08               |
| Omental fat   | 28-30 | <0.02                                    | <0.02  | <0.04              | <0.02               | <0.02               | <0.04               | 0.05              | <0.02  | 0.07               |
| Round         | 28-30 | -                                        | -      | -                  | -                   | -                   | -                   | <0.02             | <0.02  | <0.04              |
| Tenderloin    | 28-30 | -                                        | -      | -                  | -                   | -                   | -                   | <0.02             | <0.02  | <0.04              |

<sup>1</sup>Total residues expressed as trifloxystrobin equivalents.

<sup>2</sup>Residues found in only one of three animals. Re-analysis of the sample showed no detectable residues.

Table 122. Single residues found in the tissues of dairy cows dosed with 21 ppm trifloxystrobin for 28 to 30 days (Campell, 1997; Report No. ABR-97075).

| Sample            | Cow No./sample | Residues mg/kg |        |       |
|-------------------|----------------|----------------|--------|-------|
|                   |                | parent         | 321113 | Total |
| Round muscle      | 4A             | <0.02          | <0.02  | <0.04 |
|                   | 4B             | <0.02          | <0.02  | <0.04 |
|                   | 4C             | <0.02          | <0.02  | <0.04 |
| Tenderloin muscle | 4A             | <0.02          | <0.02  | <0.04 |
|                   | 4B             | <0.02          | <0.02  | <0.04 |
|                   | 4C             | <0.02          | <0.02  | <0.04 |
| Omental fat       | 4A             | 0.05           | <0.02  | 0.07  |
|                   | 4B             | 0.03           | <0.02  | 0.05  |
|                   | 4C             | 0.04           | <0.02  | 0.06  |
| Perirenal fat     | 4A             | 0.06           | <0.02  | 0.08  |
|                   | 4B             | 0.03           | <0.02  | 0.05  |
|                   | 4C             | 0.04           | <0.02  | 0.04  |
| Liver             | 4A             | <0.02          | 0.04   | 0.06  |
|                   | 4B             | <0.02          | 0.09   | 0.11  |
|                   | 4C             | <0.02          | 0.05   | 0.07  |
| Kidney            | 4A             | 0.02           | <0.02  | 0.04  |
|                   | 4B             | 0.02           | <0.02  | 0.04  |
|                   | 4C             | <0.02          | <0.02  | <0.04 |

### Poultry

A three-level poultry feeding study (1.5 ppm, 4.5 ppm and 15 ppm in the diet) on laying hens was conducted with trifloxystrobin in the USA in 1998 (Hayworth, 1999; Report No. 243-98). Eggs were collected before dosing (day 0), and on dose-days 1, 3, 7, 14, 21, and 28 days, and the hens killed on day 29. Composite tissue samples of breast plus thigh, skin plus attached fat, peritoneal fat, and liver and eggs were analysed according to method AG 659A. No residues (<0.02 mg/kg) were detected in any of the eggs, tissues or organs taken from the hens at the highest treatment level of 15 mg/kg.

## RESIDUES IN FOOD IN COMMERCE OR CONSUMPTION

No data reported.

## NATIONAL MAXIMUM RESIDUE LIMITS

Definition of the residue: trifloxystrobin (otherwise indicated by ☉)

Status February 2004, except European Community Status June 2004.

| Country / Commodity                                                  |             | MRL mg/kg | Comments                                            |           |
|----------------------------------------------------------------------|-------------|-----------|-----------------------------------------------------|-----------|
| <b>Australia</b>                                                     |             |           |                                                     | published |
| Bananas                                                              |             | 0.1 T     | ①                                                   |           |
| Grapes                                                               |             | 0.5       | ①                                                   |           |
| Grapes                                                               | dried       | 2         | ①                                                   |           |
| Edible offal                                                         | (mammalian) | 0.05      | ① Level at or about the LOQ                         |           |
| Meat                                                                 | (mammalian) | 0.05      | ① Level at or about the LOQ                         |           |
| Milks                                                                |             | 0.02      | ① Level at or about the LOQ                         |           |
| Pome fruit                                                           |             | 0.3       | ①                                                   |           |
| Pome fruit pomace                                                    | dry         | 15        | ①                                                   |           |
| <b>Austria</b>                                                       |             |           |                                                     | published |
| Barley                                                               |             | 0.2       |                                                     |           |
| Grape                                                                |             | 2         |                                                     |           |
| Hop                                                                  |             | 50        |                                                     |           |
| Pome fruit                                                           |             | 0.5       |                                                     |           |
| Rye                                                                  |             | 0.5       |                                                     |           |
| Triticale                                                            |             | 0.5       |                                                     |           |
| Wheat                                                                |             | 0.05      |                                                     |           |
| Others                                                               |             | 0.02      | Level at or about the LOQ                           |           |
| <b>Belgium</b>                                                       |             |           |                                                     | published |
| Apple                                                                |             | 0.5       |                                                     |           |
| Banana                                                               |             | 0.05 I    |                                                     |           |
| Barley                                                               |             | 0.2       |                                                     |           |
| Citrus                                                               |             | 0.3 I     |                                                     |           |
| Milk                                                                 |             | 0.00      | Before the LOQ (0.01 mg/kg)                         |           |
| Pear                                                                 |             | 0.5       |                                                     |           |
| Wheat                                                                |             | 0.05      |                                                     |           |
| Other plant commodities                                              |             | 0.00      | Before the LOQ (0.02 mg/kg)                         |           |
| Other food of animal origin except milk                              |             | 0.00      | ① Before the LOQ (0.02 mg/kg)                       |           |
| <b>Brazil</b>                                                        |             |           |                                                     | published |
| Bean                                                                 |             | 0.2       |                                                     |           |
| Coffee                                                               |             | 0.05      |                                                     |           |
| Corn                                                                 |             | 0.05      |                                                     |           |
| Cotton                                                               |             | 0.05      |                                                     |           |
| Peanut                                                               |             | 0.05      |                                                     |           |
| Rice                                                                 |             | 0.2       |                                                     |           |
| Soya                                                                 |             | 0.05      |                                                     |           |
| Wheat                                                                |             | 0.05      |                                                     |           |
| <b>Canada</b>                                                        |             |           |                                                     | published |
| Almond                                                               |             | 0.04      | ①                                                   |           |
| Barley                                                               |             | 0.05      | ①                                                   |           |
| Beet, sugar                                                          |             | 0.1       | ①                                                   |           |
| Vegetables, Cucurbits                                                |             | 0.5       | ①                                                   |           |
| Vegetables, Fruiting                                                 |             | 0.5       | ①                                                   |           |
| Grape                                                                |             | 2         | ①                                                   |           |
| Grape                                                                | raisin      | 5         | ①                                                   |           |
| Meat, meat by-products and fat of cattle, goat, hog, horse and sheep |             | 0.04      | ①                                                   |           |
| Meat, meat by-products and fat of poultry, eggs                      |             | 0.04      | ①                                                   |           |
| Milk                                                                 |             | 0.02      | ①                                                   |           |
| Oat                                                                  |             | 0.05      | ①                                                   |           |
| Pome fruit                                                           |             | 0.5       | ①                                                   |           |
| Potato                                                               | tuber       | 0.04      | ①                                                   |           |
| Wheat                                                                | grain       | 0.05      | ①                                                   |           |
| <b>European Community</b>                                            |             |           |                                                     | published |
| Banana                                                               |             | 0.05      | SANCO/10587/2003rev7                                |           |
| Other miscellaneous fruits                                           |             | 0.02*     | Brussels, 17.06.2004                                |           |
| Citrus fruits                                                        |             | 0.3       | * indicates lower limit of analytical determination |           |
| Tree nuts                                                            |             | 0.02*     |                                                     |           |
| Pome fruit                                                           |             | 0.5       |                                                     |           |
| Apricot                                                              |             | 1         | all EU-MRLs are provisional                         |           |

| Country / Commodity              |  | MRL mg/kg | Comments                                                                                                                                                                                 |           |
|----------------------------------|--|-----------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| Cherries                         |  | 1         | in accordance with Article 4(1)(f) of Directive 91/414/EEC: unless amended, this level will become definitive with effect from [4 years from date of coming into force of the Directive] |           |
| Peach                            |  | 1         |                                                                                                                                                                                          |           |
| Other stone fruits               |  | 0.02*     |                                                                                                                                                                                          |           |
| Table and wine grapes            |  | 5         |                                                                                                                                                                                          |           |
| Strawberries                     |  | 0.02*     |                                                                                                                                                                                          |           |
| Cane fruit                       |  | 0.02*     |                                                                                                                                                                                          |           |
| Currants                         |  | 1         |                                                                                                                                                                                          |           |
| Gooseberries                     |  | 1         |                                                                                                                                                                                          |           |
| Other berries and small fruits   |  | 0.02*     |                                                                                                                                                                                          |           |
| Root and tuber vegetables        |  | 0.02*     |                                                                                                                                                                                          |           |
| Bulb vegetables                  |  | 0.02*     |                                                                                                                                                                                          |           |
| Tomatoes                         |  | 0.5       |                                                                                                                                                                                          |           |
| Other solanacea                  |  | 0.02*     |                                                                                                                                                                                          |           |
| Sweet corn                       |  | 0.02*     |                                                                                                                                                                                          |           |
| Cucurbits edible peel            |  | 0.2       |                                                                                                                                                                                          |           |
| Melons                           |  | 0.3       |                                                                                                                                                                                          |           |
| Other cucurbits inedible peel    |  | 0.02*     |                                                                                                                                                                                          |           |
| Sweet corn                       |  | 0.02*     |                                                                                                                                                                                          |           |
| Brassica vegetables              |  | 0.02*     |                                                                                                                                                                                          |           |
| Leafy vegetables and fresh herbs |  | 0.02*     |                                                                                                                                                                                          |           |
| Legume vegetables                |  | 0.02*     |                                                                                                                                                                                          |           |
| Stem vegetables                  |  | 0.02*     |                                                                                                                                                                                          |           |
| Fungi                            |  | 0.02*     |                                                                                                                                                                                          |           |
| Pulses                           |  | 0.02*     |                                                                                                                                                                                          |           |
| Oil seeds                        |  | 0.05*     |                                                                                                                                                                                          |           |
| Potatoes                         |  | 0.02*     |                                                                                                                                                                                          |           |
| Tea                              |  | 0.05*     |                                                                                                                                                                                          |           |
| Hops                             |  | 30        |                                                                                                                                                                                          |           |
| Cereals                          |  |           |                                                                                                                                                                                          |           |
| Barley                           |  | 0,3       |                                                                                                                                                                                          |           |
| Rye                              |  | 0,05      |                                                                                                                                                                                          |           |
| Triticale                        |  | 0.05      |                                                                                                                                                                                          |           |
| Wheat                            |  | 0.05      |                                                                                                                                                                                          |           |
| Other cereals                    |  | 0.02*     |                                                                                                                                                                                          |           |
| <b>France</b>                    |  |           |                                                                                                                                                                                          | published |
| Barley                           |  | 0.2       | wine                                                                                                                                                                                     |           |
| Cucumber                         |  | 0.2       |                                                                                                                                                                                          |           |
| Grape                            |  | 3         |                                                                                                                                                                                          |           |
| Grape                            |  | 0.3       |                                                                                                                                                                                          |           |
| Pome fruit                       |  | 0.5       |                                                                                                                                                                                          |           |
| Melon                            |  | 0.2       |                                                                                                                                                                                          |           |
| Wheat                            |  | 0.05      |                                                                                                                                                                                          |           |
| <b>Germany</b>                   |  |           |                                                                                                                                                                                          | published |
| Barley                           |  | 0.2       |                                                                                                                                                                                          |           |
| Currant                          |  | 1         |                                                                                                                                                                                          |           |
| Gooseberry                       |  | 1         |                                                                                                                                                                                          |           |
| Grape                            |  | 2         |                                                                                                                                                                                          |           |
| Hop                              |  | 30        |                                                                                                                                                                                          |           |
| Others                           |  | 0.02      |                                                                                                                                                                                          |           |
| Peach                            |  | 0.5 I     |                                                                                                                                                                                          |           |
| Pome fruit                       |  | 0.5       |                                                                                                                                                                                          |           |
| Rye                              |  | 0.05      |                                                                                                                                                                                          |           |
| Tea                              |  | 0.05      |                                                                                                                                                                                          |           |
| Triticale                        |  | 0.05      |                                                                                                                                                                                          |           |
| Wheat                            |  | 0.05      |                                                                                                                                                                                          |           |
| <b>Israel</b>                    |  |           |                                                                                                                                                                                          | published |
| Cucumber                         |  | 0.1       |                                                                                                                                                                                          |           |
| Grape                            |  | 1         |                                                                                                                                                                                          |           |
| Peach                            |  | 0.7       |                                                                                                                                                                                          |           |
| Strawberry                       |  | 0.2       |                                                                                                                                                                                          |           |
| Tomato                           |  | 0.2       |                                                                                                                                                                                          |           |
| <b>Italy</b>                     |  |           |                                                                                                                                                                                          | published |
| Apple                            |  | 0.5       |                                                                                                                                                                                          |           |

| Country / Commodity        |                          | MRL mg/kg | Comments                                                                                     |           |
|----------------------------|--------------------------|-----------|----------------------------------------------------------------------------------------------|-----------|
| Banana                     | wine                     | 0.1 I     |                                                                                              |           |
| Barley                     |                          | 0.2       |                                                                                              |           |
| Beet, sugar                |                          | 0.05      |                                                                                              |           |
| Cucumber                   |                          | 0.2       |                                                                                              |           |
| Courgette                  |                          | 0.2       |                                                                                              |           |
| Grape                      |                          | 3         |                                                                                              |           |
| Grape                      |                          | 0.3       |                                                                                              |           |
| Melon                      |                          | 0.2       |                                                                                              |           |
| Melon, water               |                          | 0.2       |                                                                                              |           |
| Pear                       |                          | 0.5       |                                                                                              |           |
| Wheat                      |                          | 0.05      |                                                                                              |           |
| <b>Luxembourg</b>          |                          |           | Before the LOQ (0.02 mg/kg)<br>Before the LOQ (0.02 mg/kg)<br>Before the LOQ (0.02 mg/kg)    | published |
| Apple                      |                          | 0.5       |                                                                                              |           |
| Barley                     |                          | 0.2       |                                                                                              |           |
| Grape                      |                          | 2         |                                                                                              |           |
| Pear                       |                          | 0.00      |                                                                                              |           |
| Rye                        |                          | 0.00      |                                                                                              |           |
| Triticale                  |                          | 0.00      |                                                                                              |           |
| Wheat                      |                          | 0.2       |                                                                                              |           |
| <b>Netherlands</b>         |                          |           |                                                                                              | published |
| Barley                     |                          | 0.2       |                                                                                              |           |
| Wheat                      |                          | 0.05      |                                                                                              |           |
| Pome fruit                 |                          | 0.5       |                                                                                              |           |
| <b>South Africa</b>        |                          |           |                                                                                              | published |
| Apple                      |                          | 0.1       |                                                                                              |           |
| Citrus fruit               |                          | 0.1       |                                                                                              |           |
| Grape                      |                          | 0.5       |                                                                                              |           |
| Pear                       |                          | 0.1       |                                                                                              |           |
| <b>Spain</b>               | leaves and tops<br>straw |           | Before the LOQ (0.02 mg/kg)<br><br><br><br><br><br><br><br><br><br>Level at or about the LOQ | published |
| Barley                     |                          | 0.2       |                                                                                              |           |
| Beet, sugar                |                          | 0.02      |                                                                                              |           |
| Beet, sugar                |                          | 0.2       |                                                                                              |           |
| Cereal                     |                          | 3         |                                                                                              |           |
| Cucumber                   |                          | 0.2       |                                                                                              |           |
| Courgette                  |                          | 0.2       |                                                                                              |           |
| Grape                      |                          | 5         |                                                                                              |           |
| Melon                      |                          | 0.5       |                                                                                              |           |
| Peach and nectarine        |                          | 0.5       |                                                                                              |           |
| Pome fruit                 |                          | 1         |                                                                                              |           |
| Wheat                      |                          | 0.05      |                                                                                              |           |
| Others                     |                          | 0.02      |                                                                                              |           |
| <b>Switzerland</b>         | wine                     |           |                                                                                              | published |
| Banana                     |                          | 0.02 I    |                                                                                              |           |
| Barley                     |                          | 0.2       |                                                                                              |           |
| Beet, garden               |                          | 0.02      |                                                                                              |           |
| Beet, sugar                |                          | 0.02      |                                                                                              |           |
| Brassica vegetables        |                          | 0.5       |                                                                                              |           |
| Carrot                     |                          | 0.1       |                                                                                              |           |
| Celeriac                   |                          | 0.1       |                                                                                              |           |
| Celery                     |                          | 0.5       |                                                                                              |           |
| Chicory, witloof           |                          | 0.1       |                                                                                              |           |
| Cucumber                   |                          | 0.2       |                                                                                              |           |
| Grape                      |                          | 3         |                                                                                              |           |
| Grape                      |                          | 0.3       |                                                                                              |           |
| Leek                       |                          | 0.5       |                                                                                              |           |
| Melon                      |                          | 0.02      |                                                                                              |           |
| Onion                      |                          | 2         |                                                                                              |           |
| Berry fruit (except grape) |                          | 2         |                                                                                              |           |
| Pome fruit                 |                          | 0.5       |                                                                                              |           |
| Rye                        |                          | 0.05      |                                                                                              |           |
| Stone fruit                |                          | 0.5       |                                                                                              |           |
| Triticale                  |                          | 0.05      |                                                                                              |           |
| Wheat                      |                          | 0.05      |                                                                                              |           |

| Country / Commodity       |                           | MRL mg/kg | Comments                         |           |
|---------------------------|---------------------------|-----------|----------------------------------|-----------|
| <b>Taiwan</b>             |                           |           |                                  | published |
| Pears                     |                           | 0.05      |                                  |           |
| Stone fruit               |                           | 0.05      |                                  |           |
| <b>UK</b>                 |                           |           |                                  | published |
| Apple                     |                           | 0.3       | temporary until EU harmonisation |           |
| Barley                    |                           | 0.5       | temporary until EU harmonisation |           |
| Cherry                    |                           | 2 I       |                                  |           |
| Citrus                    |                           | 0.3 I     |                                  |           |
| Pear                      |                           | 0.3       | temporary until EU harmonisation |           |
| Tomato                    |                           | 1 I       |                                  |           |
| Wheat, winter             |                           | 0.02      |                                  |           |
| <b>USA</b>                |                           |           |                                  | published |
| Almond                    | nut without shell         | 0.04      | ①                                |           |
| Almond                    | hulls                     | 3         | ①                                |           |
| Apple                     | pomace, dried             | 5         | ①                                |           |
| Banana                    |                           | 0.1       | ①                                |           |
| Beet, sugar               | dried pulp                | 0.4       | ①                                |           |
| Beet, sugar               | molasses                  | 0.2       | ①                                |           |
| Beet, sugar               | root                      | 0.1       | ①                                |           |
| Beet, sugar               | tops                      | 4         | ①                                |           |
| Cattle                    | fat                       | 0.05      | ①                                |           |
| Cattle                    | meat                      | 0.05      | ①                                |           |
| Cattle                    | meat by-products          | 0.05      | ①                                |           |
| Citrus                    | fruit (group 10)          | 0.3       | ①                                |           |
| Citrus                    | dried pulp                | 0.8       | ①                                |           |
| Citrus                    | oil                       | 30        | ①                                |           |
| Cereals                   | aspirated grain fractions | 5         | ①                                |           |
| Corn                      | field, forage             | 0.2       | ①                                |           |
| Corn                      | field, grain              | 0.05      | ①                                |           |
| Corn                      | field, refined oil        | 0.1       | ①                                |           |
| Corn                      | field, stover             | 7         | ①                                |           |
| Corn                      | pop, grain                | 0.05      | ①                                |           |
| Corn                      | pop, stover               | 7         | ①                                |           |
| Egg                       |                           | 0.04      | ①                                |           |
| Goat                      | fat                       | 0.05      | ①                                |           |
| Goat                      | meat                      | 0.05      | ①                                |           |
| Goat                      | meat by-products          | 0.05      | ①                                |           |
| Grape                     |                           | 2         | ①                                |           |
| Grape                     | raisin                    | 5         | ①                                |           |
| Hop                       | cone, dried               | 11        | ①                                |           |
| Horse                     | fat                       | 0.05      | ①                                |           |
| Horse                     | meat                      | 0.05      | ①                                |           |
| Horse                     | meat by-products          | 0.05      | ①                                |           |
| Milk                      |                           | 0.02      | ①                                |           |
| Nut, tree                 | (group 14)                | 0.04      | ①                                |           |
| Peanut                    |                           | 0.05      | ①                                |           |
| Peanut                    | hay                       | 4         | ①                                |           |
| Pistachio                 |                           | 0.04      | ①                                |           |
| Pig                       | fat                       | 0.05      | ①                                |           |
| Pig                       | meat                      | 0.05      | ①                                |           |
| Pig                       | meat by-products          | 0.05      | ①                                |           |
| Pome fruit                |                           | 0.5       | ①                                |           |
| Potato                    | tuber                     | 0.04      | ①                                |           |
| Poultry                   | fat                       | 0.04      | ①                                |           |
| Poultry                   | meat                      | 0.04      | ①                                |           |
| Poultry                   | meat by-products          | 0.04      | ①                                |           |
| Stone fruit except cherry | (group 12)                | 2         | ①                                |           |
| Rice                      | grain                     | 3.5       | ①                                |           |
| Rice                      | hulls                     | 8         | ①                                |           |
| Rice                      | straw                     | 7.5       | ①                                |           |

| Country / Commodity |                  | MRL mg/kg | Comments |  |
|---------------------|------------------|-----------|----------|--|
| Sheep               | fat              | 0.05      | ①        |  |
| Sheep               | meat             | 0.05      | ①        |  |
| Sheep               | meat by-products | 0.05      | ①        |  |
| Vegetable, curcubit | (group 9)        | 0.05      | ①        |  |
| Vegetable, fruiting | (group 8)        | 0.05      | ①        |  |
| Wheat               | bran             | 0.15      | ①        |  |
| Wheat               | forage           | 0.3       | ①        |  |
| Wheat               | grain            | 0.05      | ①        |  |
| Wheat               | hay              | 0.2       | ①        |  |
| Wheat               | straw            | 5         | ①        |  |

① Residue definition: sum of trifloxystrobin and CGA321113, calculated as trifloxystrobin

I: Import tolerance

T: Temporary MRL

Cucurbit vegetables (Crop Group 9) includes balsam apple, balsam pear, cantaloupe, chayote, cucumber, cucumber (chinese), gherkin (west indian), gourd (edible), melon, melon (citron), muskmelon, pumpkin, squash, squash (summer, winter), watermelon and waxgourd (chinese))

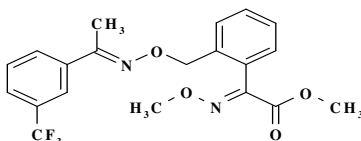
Fruiting vegetables (Crop Group 8) includes chili, eggplant, groundcherry, pepino, pepper, pepper (bell, nonbell, nonbell (sweet)), tomatillo and tomato)

Pome fruits (Crop Group 11) includes apple, crabapples, loquat, mayhaw, pear, pear oriental and quince)

## APPRAISAL

The residue and analytical aspects of trifloxystrobin were considered for the first time by the present Meeting.

Trifloxystrobin, a member of the strobilurin group, is a broad-spectrum contact fungicide for foliar use; it has meso-systemic properties. The mode of action of strobilurins involves inhibition of mitochondrial respiration by blockage of the electron transfer chain. The fungicidal properties of trifloxystrobin are derived from the parent ester, and the acid (the main metabolite) is essentially inactive. Trifloxystrobin has registered uses on horticultural crops, vegetables and cereals in many countries.



IUPAC name: methyl (*E*)-methoxyimino-[(*E*)- $\alpha$ -[1-( $\alpha,\alpha,\alpha$ -trifluoro-*meta*-tolyl)ethylidene-aminooxy]-*ortho*-tolyl]acetate

Chemical Abstracts name: methyl ( $\alpha E$ )- $\alpha$ -(methoxyimino)-2-[[[(*E*)-[1-[3-(trifluoromethyl)phenyl]-ethylidene]amino]oxy]methyl]benzeneacetate

The Meeting received information on the metabolism and environmental fate of trifloxystrobin, methods of residue analysis, stability in freezer storage, national registered use patterns, the results of supervised residue trials, the results of farm animal feeding studies, fate of residues in processing and national MRLs.

Trifloxystrobin is a white powder which melts at 73 °C. It is not highly volatile (vapour pressure,  $3 \times 10^{-6}$  Pa). It does not dissociate and is only slightly water-soluble (0.6 mg/l). The log  $P_{OW}$

is 4.5, suggesting that bioaccumulation may occur. Trifloxystrobin is hydrolytically stable at environmental pHs, but photochemical degradation was shown to occur. The active technical substance is not considered to be explosive or inflammable.

### **Metabolism**

#### *Animals*

The metabolism of trifloxystrobin was investigated in rats, goats and poultry, and the metabolic pathways were comparable in the three species. The studies were performed with  $^{14}\text{C}$ -trifloxystrobin labelled uniformly in one of the two phenyl rings, [glyoxyphenyl- $\text{U}^{14}\text{C}$ ]trifloxystrobin and [trifluoromethylphenyl- $\text{U}^{14}\text{C}$ ]trifloxystrobin, each compound being administered separately. The name [glyoxyphenyl- $\text{U}^{14}\text{C}$ ]trifloxystrobin was introduced during the development of trifloxystrobin to reflect the route of synthesis of radiolabelled material.

After oral administration to *rats* of each sex, radiolabelled trifloxystrobin was rapidly and appreciably absorbed (35–65% of dose). Faeces was the main route of elimination (63–84%), some of which was through bile (30–45%) while only one-third or less of the administered dose was excreted in urine and none in expired air. There was near-complete degradation of trifloxystrobin after a single low dose of 0.5 mg/kg bw; however, after a dose of 100 mg/kg bw, up to 45% was eliminated unchanged in faeces. The pattern of metabolites in rats is complex: about 35 metabolites were isolated from urine, faeces and bile and identified. The main steps in the metabolic pathway include hydrolysis of the methyl ester to the corresponding acid, *O*-demethylation of the methoxyimino group, yielding a hydroxyimino compound, and oxidation of the ethylideneamino methyl group to a primary alcohol and then to the corresponding carboxylic acid. These steps are followed by a complex pattern of further, minor reactions. Cleavage between the two phenyl rings accounted for about 10% of the dose.

Lactating *goats* were given diets containing [glyoxyphenyl- $\text{U}^{14}\text{C}$ ]trifloxystrobin or [trifluoromethylphenyl- $\text{U}^{14}\text{C}$ ]trifloxystrobin at an equivalent of 100 ppm for 4 days and were slaughtered 6 h after the last dose. Up to 20% of the applied dose was excreted in urine and 45% in faeces, while 0.05–0.08% of the total dose was eliminated in milk, corresponding to about 0.1 mg/kg trifloxystrobin equivalents, and a plateau was reached after 48 h.

Most tissue residues were found in liver, bile and kidney, accounting for 0.28–0.57%, 0.07–0.24% and 0.026–0.052% of the applied dose respectively. These values correspond to 2.6–5.2 mg/kg, 29–77 mg/kg and 1.7–2.9 mg/kg as trifloxystrobin equivalents. Lower levels were found in fat, muscle and blood. The main components of the residue were the parent compound, its carboxylic acid, CGA321113 (chemical name: (*E,E*)-methoxyimino-{2-[1-(3-trifluoromethylphenyl)ethylideneamino]oxymethyl}phenyl}acetic acid) and taurine and glycine conjugates of CGA321113. The amino acid conjugates were the main residue components in the liver (up to 28% of the TRR). These metabolites were not considered to be of toxicological concern. CGA321113 was the main radioactive residue in muscle (up to 57% of the TRR) and kidney (up to 74% of the TRR), and trifloxystrobin was the principal component in milk (up to 74% of the TRR) and fat (up to 82% of the TRR).

*Hens* were given diets containing trifloxystrobin at an equivalent of 100 ppm in the diet for 4 days and were killed 6 h after the last dose. Up to 0.16% and 87% of the applied dose were eliminated in eggs and excreta respectively. A plateau was not reached in egg yolk. The residue levels appeared to be increasing rapidly at the end of the study.

Eggs contained 0.1–0.2% of the applied dose. The maximum concentration in egg white was 0.56 mg/kg, and that in egg yolk was 2.3 mg/kg as trifloxystrobin equivalents. Lean meat contained 0.11–0.22% of the dose (0.13–0.35 mg/kg trifloxystrobin equivalents); skin and attached fat 0.14–0.39% (0.8–1.8 mg/kg); peritoneal fat, 0.07–0.21% (1.9–2.7 mg/kg); kidney, 0.11–0.25% (6–13 mg/kg); and liver, 0.28–0.68% (3.8–8.6 mg/kg). The TRR (including that in intestine and gizzard) was 78–91%.

Characterization of the radioactive tissue residues revealed that parent trifloxystrobin was a major residue in muscle (up to 28% of the TRR), fat and skin (up to 55% of the TRR) and egg yolk (up to 9% of the TRR) of laying hens. The carboxylic acid derivative (CGA321113) was the main residue in egg white (up to 26% of the TRR) and liver (up to 5.1% of the TRR).

### Plants

The metabolism of trifloxystrobin in plants was investigated in wheat, apples, cucumbers, sugar beet and peanuts with  $^{14}\text{C}$ -trifloxystrobin applied by spray. Although the number of metabolite fractions differed in the different plants, the metabolic pathways in these the crops were comparable.

In mature *wheat*, the highest TRRs were found in straw (3.85 mg/kg trifloxystrobin equivalents), followed by husks (0.14 mg/kg) and grain (0.02 mg/kg). The composition of the TRRs was complex; trifloxystrobin and its isomers constituted less than 5%.

Studies on wheat showed that the absorption of trifloxystrobin by plants was relatively rapid, with about 15% of the TRR appearing within the first 24 h, 29% within 3 days and 44% within 14 days. Characterization of the surface radioactivity in wheat revealed that trifloxystrobin is relatively stable to photodegradation, accounting for up to about 80% of the surface radioactivity after 14 days. In contrast, absorbed residue appeared to undergo rapid degradation: the trifloxystrobin concentration decreased exponentially, with an apparent half-life of 12 h. Up to 35 metabolite fractions were found in wheat, most of which constituted less than 1% of the TRR.

In *apple*, 14 days after treatment, the main residue component was the parent compound trifloxystrobin (*E,E* isomer), which, together with its *Z,Z*, *Z,E* and *E,Z* isomers, constituted about 92% of the residue.

In the leaves and fruits of *cucumber*, the residue consisted of trifloxystrobin (80–93% of the TRR), isomers of trifloxystrobin (2.3–3.8% of the TRR) and CGA321113 (0.9–4.2% of the TRR).

In *sugar-beet*, the main compounds found, with both labels, in the tops and roots were trifloxystrobin and its *E,Z* and *Z,Z* isomers. They accounted for up to 69% of the TRR in tops (1.1 mg/kg trifloxystrobin) and 52% in roots (0.02 mg/kg trifloxystrobin). CGA321113 represented up to 5.2% (0.073 mg/kg) and up to 11% (0.012 mg/kg) of the TRR in tops and roots respectively.

In *peanut*, many metabolite fractions containing only one moiety of the parent molecule were detected, generally similar to those found in wheat. Extensive formation of sugar and malonyl sugar conjugates was found in most metabolite fractions. In vines, the percentage of extractable radioactive residues (acetonitrile:water) amounted to 91% of the TRR. Extractable residues represented up to 74% in mature hay and up to 53% in kernels. The unextracted residues were solubilized by hot extraction and sequential hydrolyses with cellulase, protease, HCl and NaOH. The radioactive residues that remained unextracted under these exhaustive conditions represented < 10% of the TRR.

In general, the metabolism of trifloxystrobin in crops is complex, owing to isomerization of the parent compound and its metabolites. Overall, the metabolism of trifloxystrobin is similar in all crops and involves the following steps:

- *cis-trans* isomerization of trifloxystrobin (*E,E*- isomer) to its *E,Z*-, *Z,Z* and *Z,E*- isomers
- hydrolysis of the methyl esters of the parent and its isomers to carboxylic acids
- *cis-trans* isomerization of the *E,E*-carboxylic acid CGA321113
- hydroxylation of the trifluoromethylphenyl ring, followed by sugar conjugation
- oxidation of the methyl of the 2-ethylideneamino group with subsequent sugar conjugation
- cleavage of the N–O bridge, followed by oxidation of the trifluoromethylphenyl moiety to form the acetophenone derivative, with subsequent sugar conjugation



- cleavage of the N–O bridge, followed by oxidation of the glyoxylphenyl moiety, with eventual formation of phthalic acid
- formation of unextracted residues.

### *Environmental fate*

#### *Water–sediment systems*

Because trifloxystrobin is used for foliar spray treatment and on paddy rice, only studies of hydrolysis and degradation in water–sediment systems were considered.

Trifloxystrobin is relatively stable hydrolytically under sterile neutral and weakly acid conditions, whereas under alkaline conditions hydrolytic degradation increases with increasing pH. The acid CGA321113 formed under alkaline conditions is not degraded hydrolytically. No ring cleavage is observed at  $\text{pH} \geq 5$ .

In biologically active aquatic systems such as a paddy rice plot, trifloxystrobin was rapidly degraded in both flooding water and paddy soil, with a maximum half-life of 2–5 days. As in sterile hydrolysis, the main product in a paddy rice field was the acid CGA321113. While this metabolite is stable to sterile hydrolysis, it was rapidly degraded in the rice plot, with degradation half-lives of 7–8 days in flooding water and paddy soil. Besides CGA321113, formed by biotic hydrolysis, isomerization of the parent compound and CGA321113 occurred, resulting in formation of the parent *Z,E*- isomer CGA357261 in small amounts and the acid *Z,E*- isomer CGA373466 in large amounts. CGA373466 degraded rapidly in the water layer, with a half-life of 4.2 days. A half-life with reasonable significance could not be estimated for CGA357261 owing to the very low concentrations in the range of the LOQ.

The photolytic half-lives of trifloxystrobin in sterile aqueous buffered solutions at 25 °C under a xenon arc light (12 h light–12 h dark cycle) were 20.4 h at pH 5 and 31.5 h at pH 7. The corresponding predicted environmental half-lives in summer sunlight at a geographical latitude of 40° N were 1.1 and 1.7 days at pH 5 and pH 7 respectively.

#### *Rotational crops*

The Meeting received the results of confined crop rotation studies with  $^{14}\text{C}$ -trifloxystrobin with both labels and from crop rotation trials with unlabelled trifloxystrobin. In some trials, a first crop was treated with trifloxystrobin, while in others bare ground was treated directly with trifloxystrobin as an extreme case for residues in soil from the first crop. The normal rotation was a first crop followed in rotation by a root crop (radish, turnip), a vegetable (lettuce, spinach) and a cereal (wheat). The rotation crops were sown or planted from 30 days to 1 year after the final treatment of the first crop or bare ground.

In a study with an exaggerated application rate of 2.2 kg ai/ha to bare soil, turnips, spinach and wheat were planted and components of each were analysed 30 and 120 days after application. The residue levels of trifloxystrobin equivalent were higher with the trifluoromethylphenyl label than the glyoxylphenyl label. The levels of trifluoromethylphenyl label (as trifloxystrobin equivalents) after 30/120 days were: 0.06/0.04 mg/kg in turnip leaves, 0.02/0.02 mg/kg in turnip roots, 0.25/0.26 mg/kg in spinach, 0.28/0.19 mg/kg in 25% mature wheat fodder, 0.14/0.10 mg/kg in mature wheat fodder, 0.17/0.20 mg/kg in wheat straw and 0.07/0.06 mg/kg in wheat grain. With the other label, only a small proportion of the TRR were usually identified or characterized; trifloxystrobin represented < 2%. CGA321113 represented up to 8.5% of the TRR in turnip leaves and 17.5% in turnip roots (0.003 mg/kg). With the trifluoromethyl- $^{14}\text{C}$  label, 37–100% of the TRR was identified or characterized. Trifloxystrobin, its conformational isomers and the acid CGA321113 and its isomers were reported, all at < 0.01 mg/kg. Trifluoroacetic acid was found as a major degradation product in all crops, especially in wheat (up to 0.23 mg/kg in immature fodder and 0.12 mg/kg in straw), indicating breakdown of the trifluoromethylphenyl ring. As trifluoroacetic acid was observed only rarely as a plant metabolite in target crops after foliar application, it is likely that its precursor is formed in the soil or rhizosphere of the plants.

In unconfined rotational studies with unlabelled trifloxystrobin, no residues of trifloxystrobin ( $< 0.02$  mg/kg) or CGA321113 ( $< 0.02$  mg/kg) were detected in any of the rotational crops at 30-day plant-back intervals, except in wheat straw and grain in one trial.

The rotational crop studies suggest that trifloxystrobin itself and the acid CGA321113 do not occur in rotational crops at levels  $\geq 0.01$  mg/kg.

### ***Methods of analysis***

The Meeting received descriptions and validation data for analytical methods for residues of trifloxystrobin and the metabolite CGA321113 in crops and animal commodities. The methods rely on gas-liquid chromatography, HPLC and liquid chromatography with tandem mass spectrometry detection and generally achieve LOQs of 0.01–0.02 mg/kg in crop and animal samples, except dry samples such as hay, straw (LOQ, 0.05 mg/kg) and hops (LOQ, 0.1 mg/kg). The recoveries were in the range of 70–120% for both analytes.

In most of the field studies, the determination of trifloxystrobin and CGA321113 in plant and animal commodities was based on extraction of the samples with acetonitrile and water (80:20, v/v), filtration, liquid-liquid partitioning with a three-solvent system (sodium chloride-saturated water, toluene and hexane), clean-up on a C18 solid extraction column, partitioning into methyl *tert*-butyl ether:hexane, concentration to dryness and dissolution in 0.1% polyethylene glycol in acetone for gas chromatographic analysis with nitrogen-phosphorus detection. The LOQ was 0.02 mg/kg in all samples except peanut hay and cereal straw (0.05 mg/kg) and milk (0.01 mg/kg). This method (or with electron capture detection) was used in the rotational crop, storage stability and field trial studies. The nitrogen-phosphorus detection method is proposed as a monitoring method.

The standard multi-method DFG S 19 can be used for enforcement purposes for the determination of trifloxystrobin in all plant materials except hops.

Data on the extraction efficiency of the methods with weathered radiolabelled samples from the studies of metabolism in apples, cucumbers, peanuts, wheat grain and straw, and samples from the animal metabolism studies were submitted. The amount of residue extracted was similar to that in the metabolism studies.

### ***Stability of residues in stored analytical samples***

The Meeting received information on the stability of trifloxystrobin and CGA321113 in crops, farm animal commodities and processed commodities at freezer temperatures for 1–2 years. Trifloxystrobin and CGA321113 were generally stable for the duration of testing, i.e. a decrease in residue levels was not evident or was  $< 30\%$ .

### ***Definition of the residue***

The metabolism of trifloxystrobin in animals is similar to that in plants and occurs primarily via cleavage of the methyl ester group to form CGA321113. In plants, the main component of the residue is trifloxystrobin. CGA321113 is the principal residue component in animal tissues (except fat). Trifloxystrobin is the principal residue in milk and fat.

The metabolite CGA321113 accounts for about 30% of the terminal residue in some raw plant commodities (strawberries, leeks, Brussels sprouts, flowerhead brassicas, carrots, barley, wheat, maize, rice, hops, peanut fodder, barley straw, maize fodder and rice straw). Furthermore, trifloxystrobin can be hydrolysed to CGA321113 during processing. In these cases, the nature of the residue in the processed product may differ somewhat from that in the raw agricultural commodity. Therefore, CGA321113 should be included in the residue definition for risk assessment for plant commodities.

The Meeting agreed that the residue definition for enforcement purposes for plant commodities should be trifloxystrobin *per se*, and that for animal commodities should be the parent compound plus CGA321113 (expressed as trifloxystrobin equivalents).

The Meeting agreed that the residue definition for consideration of dietary intake should consist of the parent compound plus CGA321113 (expressed as trifloxystrobin equivalents), to cover the occurrence of residues in both plant and animal commodities as well as in processed products.

The log  $P_{OW}$  for trifloxystrobin is 4.5, which suggests that the compound is fat-soluble. As the levels of trifloxystrobin were higher in fat than in muscle, residues in fat are appropriate for controlling residues in meat. The Meeting agreed that the residues of trifloxystrobin are fat-soluble.

*Definition of the residue in plant commodities for compliance with MRLs:* trifloxystrobin.

*Definition of the residue in plant commodities for estimation of dietary intake:* sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin.

*Definition of the residue in animal commodities for compliance with MRLs and estimation of dietary intake:* sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin.

The residue is fat-soluble.

### ***Results of supervised trials on crops***

The Meeting received the results of supervised trials on citrus fruit, pome fruit, stone fruit, grapes, strawberries, bananas, leeks, head cabbage, Brussels sprouts, cauliflower and broccoli, cucumbers, melons, summer squash, tomatoes, peppers, Chinese cabbage, beans, soya beans, carrots, celeriac, potatoes, sugar-beet, celery, chicory, cereals (wheat, barley, maize, rice), almonds, tree nuts, cottonseed, peanuts, coffee beans and hops; and on animal feed items such as almond hulls, cereal straws, peanut hay and sugar-beet tops. In most cases, the acid metabolite CGA321113 was determined as well as the parent compound.

The sum of trifloxystrobin and CGA321113 was calculated and expressed as trifloxystrobin on the basis of the relative molecular masses. A conversion factor of 1.036 is required to express CGA321113 as trifloxystrobin. As CGA321113 does not generally constitute a significant proportion of the residue in crops, when the levels of trifloxystrobin or CGA321113 were below the LOQ, their sum was calculated as in the examples below.

| Trifloxystrobin (mg/kg) | CGA321113 (mg/kg) | Total (expressed as trifloxystrobin) (mg/kg) |
|-------------------------|-------------------|----------------------------------------------|
| < 0.02                  | < 0.02            | < 0.02                                       |
| < 0.02                  | 0.03              | 0.05                                         |
| 0.10                    | < 0.02            | 0.10                                         |
| 0.92                    | 0.16              | 1.1                                          |

Two sets of data are reported: trifloxystrobin *per se* for estimation of maximum residue levels and the sum of trifloxystrobin and CGA321113 expressed as trifloxystrobin for estimation of STMRs.

Treatment with trifloxystrobin is limited to up to four applications per season, but in some trials on fruits (pome fruit, grapes, banana) and vegetables (cucurbits, sweet pepper, tomato) up to 10 treatments were made. To investigate the influence of the number of applications on the residue levels, two trials were conducted in apples. Trifloxystrobin was applied four times to apple trees at a rate of 0.12 or 0.15 kg ai/ha with spray intervals of 12–17 days. Samples of fruit were taken before and after each application. The average carry-over of residue (ratio of residue concentration before and after pesticide application) was approximately 40% and at the same level, suggesting that two applications are likely to result in higher residue levels than one application, but three or more

applications should not produce residue levels significantly different from those resulting from two. The Meeting agreed that the residue at harvest is influenced only by the final three or four applications, and trials with more than four treatments were used to estimate maximum residue levels and STMRs.

### *Citrus fruit*

The results of supervised trials for residues in orange, grapefruit and lemon were received from South Africa and the USA.

Use of trifloxystrobin as a foliar spray is registered in South Africa with two applications of 0.005 kg ai/hl and a PHI of 76 days. The six trials on orange that were submitted did not reflect GAP.

In the USA, trifloxystrobin may be used as a foliar spray on citrus fruit at three to four applications of 0.07–0.14 kg ai/ha with a 30-day PHI. As the level of CGA321113 was below the LOQ in all samples, the data populations for enforcement and risk assessment purposes are identical. The levels of trifloxystrobin residues in whole fruit in trials approximating these conditions at the highest rate were: 0.05, 0.07, 0.08, 0.09, 0.10, 0.11, 0.12, 0.15 (two), 0.16, 0.17, 0.19, 0.21 and 0.23 mg/kg in orange; < 0.02, 0.03 (two), 0.04, 0.06, 0.08 (two) and 0.10 mg/kg in grapefruit; and < 0.02, 0.02, 0.09, 0.11, 0.13 and 0.22 mg/kg in lemon.

The Meeting agreed to combine these results in estimating a maximum residue level for citrus fruit. As no data were available on residues in the edible portion, the STMR was also estimated from the data for whole fruit. The combined concentrations in the 28 trials in the USA, in ranked order, were: < 0.02 (two), 0.02, 0.03 (two), 0.04, 0.05, 0.06, 0.07, 0.08 (three), 0.09 (two), 0.10 (two), 0.11 (two), 0.12, 0.13, 0.15 (two), 0.16, 0.17, 0.19, 0.21, 0.22 and 0.23 mg/kg for trifloxystrobin as well as for the sum of trifloxystrobin and CGA321113 expressed as trifloxystrobin.

The Meeting estimated a maximum residue level of 0.5 mg/kg and an STMR value of 0.095 mg/kg for residues of trifloxystrobin in whole citrus fruits.

### *Pome fruit*

Trials were conducted on apple and pear in Australia, Canada, Europe, South Africa and the USA.

In Australia, trifloxystrobin may be applied to *apples* in three applications of 0.005 kg ai/hl with a 35-day PHI. Because the number of treatments had little influence on the residue concentration, two trials with six applications of 0.0038 kg ai/hl were considered close enough to GAP to allow evaluation. The trifloxystrobin residue level in apples was < 0.04 mg/kg, and the level for the sum of trifloxystrobin and CGA321113 (< 0.04 mg/kg) expressed as trifloxystrobin was 0.08 mg/kg.

GAP for use of trifloxystrobin on apples and pears is similar in many countries in Europe. In France and Italy, trifloxystrobin is registered for use on apples and pears up to a total of three applications at 0.0075 kg ai/hl with a PHI of 14 days. The trifloxystrobin residue levels in apples in four trials in France, one in Germany, one in Greece, six in Italy, three in Spain and nine in Switzerland, conducted according to appropriate GAP, were: 0.04 (two), 0.05 (four), 0.06, 0.07 (two), 0.08, 0.09 (two), 0.10 (two), 0.12, 0.13, 0.15, 0.17, 0.19 (two), 0.20, 0.21, 0.30 and 0.44 mg/kg. The residue levels of CGA321113 were all below the LOQ.

One trial in Greece, one in Italy and two in Spain on *pears* were reported. The residue concentrations of both trifloxystrobin and the sum of trifloxystrobin and CGA321113 expressed as trifloxystrobin were 0.06, 0.07, 0.11 and 0.12 mg/kg.

In Spain, four treatments at 0.0075–0.015 kg ai/hl with a PHI of 14 days are allowed on apples and pears. The residue concentration of both trifloxystrobin and the sum of trifloxystrobin and CGA321113 expressed as trifloxystrobin in one Spanish trial on apples was 0.19 mg/kg.

In Germany, four treatments at 0.025 kg ai/ha per metre height of crown (0.075 kg ai/ha for a tree with a 3-m crown) and 0.005 kg ai/hl with a PHI of 14 days on apples and pears are allowed. The

residue levels of trifloxystrobin and of the sum of trifloxystrobin and CGA321113 expressed as trifloxystrobin in one trial on apples were both 0.11 mg/kg. The residue level of trifloxystrobin in one trial on pears was 0.17 mg/kg, and the level of the sum of trifloxystrobin and CGA321113 expressed as trifloxystrobin was 0.19 mg/kg.

In Belgium and Luxembourg, four treatments with 0.085 kg ai/ha and a PHI of 14 days are allowed on apples and pears. The trifloxystrobin residue levels in apples in five trials in France, two in Germany and three in The Netherlands were: 0.03, 0.04, 0.05, 0.07 (four), 0.13 (two), 0.14 and 0.37 mg/kg. The levels of the sum of trifloxystrobin and CGA321113 expressed as trifloxystrobin were 0.03, 0.04, 0.05, 0.07 (four), 0.13, 0.14, 0.15 and 0.41 mg/kg.

In South Africa, trifloxystrobin is registered for use on apples at up to three applications of 0.0038–0.005 kg ai/hl with a PHI of 7 days, and it is registered for use on pears at three applications of 0.0038 kg ai/hl with a PHI of 14 days. In two trials each on apples and pears, the residue levels of trifloxystrobin were 0.03, 0.04, 0.05 and 0.06 mg/kg, and the levels of the sum of trifloxystrobin and CGA321113 expressed as trifloxystrobin were 0.03, 0.04 and 0.06 (two) mg/kg.

The use pattern in the USA allows spraying of trifloxystrobin in four applications of 0.105 kg ai/ha on apples and pears with a PHI of 14 days. The concentrations of trifloxystrobin residues in trials in Canada and the USA in apples were: 0.04, 0.09, 0.10, 0.12, 0.13, 0.14, 0.16 (two), 0.18 (three), 0.21, 0.24, 0.26, 0.31 and 0.37 mg/kg, and those in pears were: 0.07, 0.08, 0.09, 0.10 (two), 0.14, 0.15, 0.17, 0.22 and 0.23 mg/kg. The residue levels of the sum of trifloxystrobin and CGA321113 expressed as trifloxystrobin in apples were: 0.04, 0.09, 0.10, 0.12, 0.13, 0.14, 0.16 (two), 0.18 (two), 0.21 (two), 0.24, 0.26, 0.31 and 0.37 mg/kg, and those in pears were: 0.07, 0.08, 0.09, 0.10, 0.14, 0.15, 0.17, 0.20, 0.22 and 0.23 mg/kg.

The Meeting agreed to combine the data sets on apples and pears from two trials in Australia 42 trials in Europe, four trials in South Africa and 26 trials in Canada and the USA. The residue concentrations of trifloxystrobin *per se*, in ranked order, were: 0.03 (two), < 0.04, 0.04 (five), 0.05 (six), 0.06 (three), 0.07 (eight), 0.08 (three), 0.09 (four), 0.10 (five), 0.11 (two), 0.12 (three), 0.13 (four), 0.14 (three), 0.15 (two), 0.16 (two), 0.17 (three), 0.18 (three), 0.19 (three), 0.20, 0.21 (two), 0.22, 0.23, 0.24, 0.26, 0.30, 0.31, 0.37 (two) and 0.44 mg/kg. The residue concentrations of the sum of trifloxystrobin and CGA321113 expressed as trifloxystrobin, in ranked order, were: 0.03 (two), < 0.04, 0.04 (five), 0.05 (five), 0.06 (four), 0.07 (eight), 0.08 (three), 0.09 (four), 0.10 (four), 0.11 (two), 0.12 (three), 0.13 (three), 0.14 (three), 0.15 (three), 0.16 (two), 0.17 (two), 0.18 (two), 0.19 (four), 0.20 (two), 0.21 (three), 0.22, 0.23, 0.24, 0.26, 0.30, 0.31, 0.37, 0.41 and 0.44 mg/kg.

The Meeting estimated a maximum residue level of 0.7 mg/kg and an STMR value of 0.11 mg/kg for residues of trifloxystrobin in pome fruit.

#### *Stone fruit*

The results of supervised trials on residues of trifloxystrobin in apricots, cherries, peaches and plums were received from Europe and the USA. Trifloxystrobin is registered for use on apricots, nectarines, peaches, cherries and plums in Switzerland (three applications of 0.2 kg ai/ha, 0.013 kg ai/hl, 21-day PHI) and the USA (four applications of 0.14 kg ai/ha, 1-day PHI). In Spain, trifloxystrobin may be used on peaches and nectarines four times at 0.015 kg ai/hl with a 7-day PHI.

In 14 trials on *cherry* in six states of the USA in 1998, with four applications of 0.14 kg ai/ha and harvesting after 1 day, the concentrations of trifloxystrobin residues were: 0.26, 0.33, 0.34, 0.37, 0.38, 0.39, 0.53, 0.54, 0.55, 0.56, 0.58, 0.63, 0.66 and 0.84 mg/kg. The residue concentrations of the sum of trifloxystrobin and CGA321113 expressed as trifloxystrobin were: 0.28, 0.37, 0.38 (two), 0.41, 0.42, 0.58, 0.59 (two), 0.61, 0.62, 0.69, 0.73 and 0.90 mg/kg.

In two trials on *apricot* in Switzerland, which matched GAP, the trifloxystrobin residue levels were 0.14 and 0.28 mg/kg, and the total residue levels were 0.14 and 0.30 mg/kg.

Three trials in southern Europe (France, Italy and Spain) on *peach* were evaluated against Spanish GAP. The trifloxystrobin residue levels were 0.14, 0.18 and 0.48 mg/kg, and the total residue levels were 0.15, 0.18 and 0.52 mg/kg. In 14 trials on peach in six states of the USA in 1998, with

four applications of 0.14 kg ai/ha and harvesting after 1 day, the concentrations of trifloxystrobin residues were: 0.06, 0.18, 0.21, 0.25, 0.32, 0.34, 0.39, 0.41, 0.65, 0.82 (two), 0.89, 1.8 and 1.9 mg/kg. The residue concentrations of the sum of trifloxystrobin and CGA321113 expressed as trifloxystrobin were: 0.06, 0.21 (two), 0.25, 0.32, 0.34, 0.39, 0.41, 0.70, 0.86, 0.88, 0.94, 1.9 and 2.0 mg/kg.

In nine trials on *plum* in four states of the USA in 1998, with four applications of 0.14 kg ai/ha and harvesting after 1 day, the concentrations of trifloxystrobin residues and of total residues were: 0.02, 0.06 (two), 0.09, 0.15, 0.19, 0.21 (two) and 0.53 mg/kg.

The Meeting agreed to combine the data from all the trials on residues in stone fruit. The combined results for trifloxystrobin were: 0.02, 0.06 (three), 0.09, 0.14 (two), 0.15, 0.18 (two), 0.19, 0.21 (three), 0.25, 0.26, 0.28, 0.32, 0.33, 0.34 (two), 0.37, 0.38, 0.39 (two), 0.41, 0.48, 0.53 (two), 0.54, 0.55, 0.56, 0.58, 0.63, 0.65, 0.66, 0.82 (two), 0.84, 0.89, 1.8 and 1.9 mg/kg. The residue concentrations of the sum of trifloxystrobin and CGA321113 expressed as trifloxystrobin were: 0.02, 0.06 (three), 0.09, 0.14, 0.15 (two), 0.18, 0.19, 0.21 (four), 0.25, 0.28, 0.30, 0.32, 0.34, 0.37, 0.38 (two), 0.39, 0.41 (two), 0.42, 0.52, 0.53, 0.58, 0.59 (two), 0.61, 0.62, 0.69, 0.70, 0.73, 0.86, 0.88, 0.90, 0.94, 1.9 and 2.0 mg/kg.

The Meeting estimated a maximum residue level of 3 mg/kg and an STMR of 0.38 mg/kg for residues in stone fruit.

#### *Berries and small fruit*

Trials on *grape* were conducted in Australia, Canada, France, Germany, Greece, Italy, South Africa, Spain, Switzerland and the USA.

In Australia, trifloxystrobin may be used on grapes at 0.0075 kg ai/hl with a 35-day PHI after three applications. In trials in Australia matching GAP conditions, the trifloxystrobin residue levels were: <0.02, 0.04, 0.08 and 0.09 (two) mg/kg. The residue concentrations of the sum of trifloxystrobin and CGA321113 expressed as trifloxystrobin were: <0.02, 0.04, 0.09 (two) and 0.11 mg/kg.

In Canada, trifloxystrobin may be used up to four times at 0.07 kg ai/ha and in the USA up to 0.14 kg ai/ha with a 14-day PHI. In two Canadian and 12 US trials matching GAP conditions, the trifloxystrobin residue levels were: 0.04, 0.06, 0.09, 0.16, 0.17, 0.21, 0.26, 0.28, 0.29, 0.33, 0.61, 0.62, 1.1 and 2.2 mg/kg. The residue concentrations of the sum of trifloxystrobin and CGA321113 expressed as trifloxystrobin were: 0.04, 0.06, 0.09, 0.16, 0.17, 0.21, 0.26, 0.28, 0.33, 0.36, 0.63, 0.64, 1.2 and 2.2 mg/kg.

In Germany, registered use is three applications of 0.12 kg ai/ha with harvesting 35 days after the last treatment. Two trials in France, four in Germany and four in Switzerland with three applications of 0.13 kg ai/ha and a 35–36-day PHI matched this GAP. The trifloxystrobin residue levels were 0.03, 0.04 (three), 0.06 (two), 0.13, 0.14, 0.27 and 0.29 mg/kg. The residue concentrations of the sum of trifloxystrobin and CGA321113 expressed as trifloxystrobin were: 0.04 (two), 0.05 (two), 0.06, 0.07, 0.16 (two), 0.29 and 0.30 mg/kg.

Trifloxystrobin is registered for use in South Africa at up to 0.011 kg ai/hl with a 14-day PHI. Residues in grapes in three trials with this use pattern were 0.11, 0.18 and 0.24 mg/kg for trifloxystrobin and 0.15, 0.22 and 0.38 mg/kg for total residues.

Trifloxystrobin is registered for use in Spain at four applications of 0.075 kg ai/ha with a 30-day PHI. In one trial in Greece, two in Italy and four in Spain approximating these conditions, the trifloxystrobin residue levels were 0.05, 0.08, 0.11, 0.13, 0.14, 0.28 and 0.36 mg/kg. The total residue levels were 0.05, 0.08, 0.11, 0.13, 0.14, 0.28 and 0.38 mg/kg.

In summary, the residue levels of trifloxystrobin *per se* in 39 trials in Australia, Europe, South Africa, Canada and the USA, in ranked order, were: <0.02, 0.03, 0.04 (five), 0.05, 0.06 (three), 0.08 (two), 0.09 (three), 0.11 (two), 0.13 (two), 0.14 (two), 0.16, 0.17, 0.18, 0.21, 0.24, 0.26, 0.27, 0.28 (two), 0.29 (two), 0.33, 0.36, 0.61, 0.62, 1.1 and 2.2 mg/kg. The residue concentrations of the sum of trifloxystrobin and CGA321113 expressed as trifloxystrobin were: <0.02, 0.04 (four), 0.05 (three),

0.06 (two), 0.07, 0.08, 0.09 (three), 0.11 (two), 0.13, 0.14, 0.15, 0.16 (three), 0.17, 0.21, 0.22, 0.26, 0.28 (two), 0.29, 0.30, 0.33, 0.36, 0.38 (two), 0.63, 0.64, 1.2 and 2.2 mg/kg.

The Meeting estimated a maximum residue level of 3 mg/kg and an STMR of 0.15 mg/kg for residues in grapes.

The Swiss pattern of use of trifloxystrobin on *strawberry* allows three spray applications at 0.25 kg ai/ha with a PHI of 14 days. In five trials matching GAP conditions, the residue levels of trifloxystrobin *per se* were: 0.04, 0.05, 0.06, 0.10 and 0.13 mg/kg. The residue concentrations of the sum of trifloxystrobin and CGA321113 expressed as trifloxystrobin were 0.08, 0.09, 0.10, 0.14 and 0.18 mg/kg.

The Meeting estimated a maximum residue level of 0.2 mg/kg and an STMR of 0.10 mg/kg for residues in strawberries.

#### *Banana*

Trifloxystrobin may be used in Latin America on bananas at four applications of 0.09 kg ai/ha with a 0-day PHI. The results of supervised trials on residues in bagged and unbagged banana after up to 11 treatments at 0.01–0.16 kg ai/ha by aerial application were received from Colombia (four), Costa Rica (six), Ecuador (six), Guatemala (four), Honduras (two) and Mexico (two). The treatment was typical of that performed by commercial aerial sprayers from a fixed-winged airplane or a helicopter. In four trials in Martinique, bananas were treated six times at 0.09 kg ai/ha by a foliar backpack sprayer with aerial boom. In two trials in Puerto Rico, plants were treated 10 times at 0.1–0.13 kg ai/ha by spraying over the top, simulating aerial application. Although the actual treatment rate in some trials exceeded GAP by more than 30%, these trials were included in the evaluation because of the very low residue levels ( $\leq$  LOQ). In whole bagged and unbagged fruit, the trifloxystrobin residue concentrations for estimation of the maximum residue level were: < 0.01 (four), < 0.02 (23), 0.02 and 0.03 (two) mg/kg. In the edible portion, the residue concentrations of the sum of trifloxystrobin and CGA321113 expressed as trifloxystrobin were: < 0.01 (four) and < 0.02 (26) mg/kg.

The Meeting estimated a maximum residue level of 0.05 mg/kg and an STMR of 0.02 mg/kg for residues in bananas.

#### *Leek*

The Swiss pattern of use of trifloxystrobin on leeks allows three spray applications at 0.19 kg ai/ha with a PHI of 7 days. The levels of trifloxystrobin residues in leek in one trial in France, one in Germany, one in The Netherlands and two in Switzerland that met these conditions were: 0.08, 0.14, 0.15 and 0.40 (two) mg/kg. The corresponding total residues were: 0.13, 0.26, 0.31, 0.47 and 0.49 mg/kg.

The Meeting estimated a maximum residue level of 0.7 mg/kg and an STMR of 0.31 mg/kg for residues in leeks.

#### *Brassica vegetables*

The Swiss pattern of use of trifloxystrobin on broccoli, cauliflower, Brussels sprouts and head cabbage allows three spray applications at 0.13–0.25 kg ai/ha with a PHI of 7 days. The trials on head cabbage, Brussels sprouts, broccoli and cauliflower were evaluated together for mutual support.

One trial on *head cabbage* in Germany, one in The Netherlands and two in Switzerland matching maximum GAP, with a rate of 0.25 kg ai/ha, were submitted. The residue levels of trifloxystrobin *per se* were: 0.02 (two), 0.03 and 0.07 mg/kg, and those of total residues were 0.03, 0.04 (two) and 0.11 mg/kg.

Two trials on *Brussels sprouts* in France, one in Germany, two in Switzerland and one in the UK matching maximum GAP, with a rate of 0.25 kg ai/ha, were submitted. The residue levels of trifloxystrobin *per se* were: 0.10, 0.16, 0.18, 0.19, 0.20 and 0.35 mg/kg, and those of total residues were: 0.18, 0.22, 0.26, 0.27, 0.28 and 0.39 mg/kg.

One trial on *cauliflower* in Germany and two in Switzerland and two trials on *broccoli* in Germany and one in the UK, which matched GAP with a rate of 0.2–0.25 kg ai/ha, were submitted. The residue levels of trifloxystrobin *per se* were: < 0.01, < 0.02, 0.09, 0.13 (two) and 0.26 mg/kg, and those of total residues were: < 0.02, 0.04, 0.13, 0.16, 0.23 and 0.26 mg/kg.

The combined levels of trifloxystrobin residues in broccoli, cauliflower, Brussels sprouts and head cabbage were, in ranked order: < 0.01, < 0.02, 0.02 (two), 0.03, 0.07, 0.09, 0.10, 0.13 (two), 0.16, 0.18, 0.19, 0.20, 0.26 and 0.35 mg/kg. Those of total residues were: < 0.02, 0.03, 0.04 (three), 0.11, 0.13, 0.16, 0.18, 0.22, 0.23, 0.26 (two), 0.27, 0.28 and 0.39 mg/kg.

The Meeting estimated a maximum residue level of 0.5 mg/kg and an STMR of 0.17 mg/kg for residues in flowerhead brassica, Brussels sprouts and head cabbage.

#### *Chinese cabbage*

Trifloxystrobin is registered in Switzerland for use on Chinese cabbage up to three times at 0.25 kg ai/ha with a 7-day PHI. The concentrations of trifloxystrobin residues in Chinese cabbage in two Swiss trials were 0.01 and 0.33 mg/kg. The corresponding total residue levels were 0.01 and 0.35 mg/kg.

The Meeting concluded that there were insufficient data to estimate a maximum residue level and an STMR for residues in Chinese cabbage.

#### *Fruiting vegetables*

##### *Cucurbits*

Trifloxystrobin is registered in Switzerland for use on *cucumber* up to three times at 0.25 kg ai/ha and a 3-day PHI for indoor use. Eight trials conducted in glasshouses in Italy (one), The Netherlands (two), Spain (four) and Switzerland (one) approximated Swiss GAP. The trifloxystrobin residue levels were: 0.02, 0.03 (two), 0.04, 0.06, 0.07 and 0.14 (two) mg/kg. The total residue levels were 0.02, 0.03 (two), 0.04, 0.10, 0.12 and 0.17 (two) mg/kg.

Trifloxystrobin is registered in the USA for use on cucurbit vegetables such as chayote, Chinese waxgourd, citron melon, cucumber, gherkin, edible gourds, muskmelon, pumpkin, summer squash, winter squash and watermelon, as up to four applications of 0.14 kg ai/ha and a 0-day PHI for outdoor use. Eight outdoor trials on *cucumber* in seven states in accord with GAP conditions were reported. The trifloxystrobin residue levels were: 0.03, 0.04 (three), 0.05, 0.06, 0.17 and 0.22 mg/kg. The total residue levels were 0.03, 0.04 (three), 0.05, 0.06, 0.17 and 0.24 mg/kg.

The data from the indoor and outdoor trials on cucumbers could be combined as they were apparently for similar data populations. The residue levels of trifloxystrobin *per se* in the European and North American trials were, in ranked order: 0.02, 0.03 (three), 0.04 (four), 0.05, 0.06 (two), 0.07, 0.14 (two), 0.17 and 0.22 mg/kg. The corresponding total residue levels were 0.02, 0.03 (three), 0.04 (four), 0.05, 0.06, 0.10, 0.12, 0.17 (three) and 0.24 mg/kg.

In Italy, trifloxystrobin may be used on *melon* up to three times at 0.13 kg ai/ha with a 3-day PHI. Three trials in Italy and four in Spain complied with this use pattern. Both the trifloxystrobin and the total residue levels were: < 0.02 (two), 0.04, 0.07, 0.10, 0.11 and 0.19 mg/kg. Six trials in the USA on melons matching GAP for cucurbits resulted in trifloxystrobin and total residue levels of: 0.07, 0.10 (two), 0.11, 0.18 and 0.24 mg/kg.

In five trials in the USA on *summer squash* matching GAP for cucurbits, the trifloxystrobin and the total residue levels were: < 0.02, 0.09, 0.11, 0.15 and 0.23 mg/kg.

The Meeting decided to pool the data on cucumbers (16 trials), melons (13 trials) and summer squash (five trials) to estimate a maximum residue level for cucurbits. The trifloxystrobin residue levels were < 0.02 (three), 0.02, 0.03 (three), 0.04 (five), 0.05, 0.06 (two), 0.07 (three), 0.09, 0.10 (three), 0.11 (three), 0.14 (two), 0.15, 0.17, 0.18, 0.19, 0.22, 0.23 and 0.24 mg/kg. The corresponding total residue levels, in ranked order, were: < 0.02 (three), 0.02, 0.03 (three), 0.04 (five), 0.05, 0.06, 0.07 (two), 0.09, 0.10 (four), 0.11 (three), 0.12, 0.15, 0.17 (three), 0.18, 0.19, 0.23 and 0.24 (two) mg/kg.



The Meeting estimated a maximum residue level of 0.3 mg/kg and an STMR of 0.095 mg/kg for residues in cucurbits.

*Sweet peppers*

In the USA, trifloxystrobin may be used on sweet peppers four times at 0.14 kg ai/ha with a 3-day PHI. The levels of both trifloxystrobin and total residues in 12 outdoor trials in five states conducted according to GAP were: 0.03, 0.04 (two), 0.05 (two), 0.08, 0.12 (three), 0.14 and 0.16 (two) mg/kg.

The Meeting estimated a maximum residue level of 0.3 mg/kg, and an STMR of 0.1 mg/kg.

*Tomato*

In the USA, trifloxystrobin may be used on tomatoes four times at 0.14 kg ai/ha with a 3-day PHI. The trifloxystrobin and the total residue levels in 18 outdoor trials in five states conducted according to GAP were: < 0.02 (two), 0.03, 0.06, 0.07 (five), 0.09 (three), 0.10, 0.13, 0.20, 0.29, 0.43 and 0.49 mg/kg.

The Meeting estimated a maximum residue level of 0.7 mg/kg and an STMR of 0.08 mg/kg for residues in tomatoes.

*Legume vegetables and pulses*

*Beans (dry)*

Trifloxystrobin may be used on beans in Brazil three times at 0.1–0.13 kg ai/ha with a 15-day PHI. Five trials with four applications at 0.15 kg ai/ha and a further five trials with three to four applications of 0.094 kg ai/ha and a 15-day PHI in Brazil approximately matched GAP. The trifloxystrobin residue levels were < 0.02 (four) and < 0.05 (six) mg/kg. As CGA321113 was not determined, the trials were not considered for evaluation.

The Meeting concluded that there were insufficient data to estimate a maximum residue level and an STMR for residues in beans (dry).

*Soya beans (dry)*

Trifloxystrobin may be used on soya beans in Brazil twice at 0.056–0.075 kg ai/ha with a 30-day PHI and once at 0.056 kg ai/ha with a 20-day PHI in Argentina. Three trials with two applications at 0.063 kg ai/ha, three trials with two applications at 0.094 kg ai/ha and a further three trials with two applications at 0.13 kg ai/ha and a 21–30-day PHI in Brazil were reported. The trifloxystrobin residue levels were all < 0.05 mg/kg. As CGA321113 was not determined, the trials were not considered for evaluation.

The Meeting concluded that there were insufficient data to estimate a maximum residue level and an STMR for residues in soya bean (dry).

*Root and tuber vegetables*

*Carrot*

Trifloxystrobin is registered in Switzerland for use on carrots up to three times at 0.25 kg ai/ha with a 7-day PHI. The concentrations of trifloxystrobin residues in carrots in one trial in Belgium, one in Germany, two in The Netherlands and two in Switzerland conducted according to the Swiss use pattern were: < 0.02, 0.02 (two), 0.03 (two) and 0.04 mg/kg. The corresponding total residue levels were < 0.02, 0.02, 0.03, 0.04 (two) and 0.08 mg/kg.

The Meeting estimated a maximum residue level of 0.1 mg/kg and an STMR of 0.035 mg/kg for residues in carrot.

*Celeriac*

Trifloxystrobin is registered in Switzerland for use on celeriac up to three times at 0.25 kg ai/ha with a 14-day PHI. The concentrations of trifloxystrobin residues in celeriac in two Swiss trials were 0.02 and 0.03 mg/kg. The corresponding total residue levels were 0.03 and 0.04 mg/kg.

The Meeting concluded that there were insufficient data to estimate a maximum residue level and STMR for residues in celeriac.

#### *Potato*

In the USA, trifloxystrobin may be used on potatoes six times at 0.14 kg ai/ha with a 7-day PHI. In 15 trials in 13 states conducted according to GAP, all the levels of trifloxystrobin and CGA321113 residues in tubers were below the LOQ (0.02 mg/kg).

The Meeting estimated a maximum residue level of 0.02\* mg/kg and an STMR of 0.02 mg/kg for residues in potato.

#### *Sugar-beet*

Italian GAP allows three treatments with an emulsifiable concentrate at rates of 0.11–0.15 kg ai/ha, and Swiss GAP allows one application at 0.15 kg ai/ha, both with a PHI of 21 days, for sugar-beet. In nine trials in France, two in Italy, two in Spain and one in Switzerland that matched GAP, the residue levels of trifloxystrobin *per se* and of total residues in the roots were: < 0.02 (13) and 0.02 mg/kg.

Trifloxystrobin is registered in the USA for use on sugar-beet up to three times at 0.12 kg ai/ha with a 21-day PHI. The trifloxystrobin residue levels in sugar-beet roots in 19 trials in seven states conducted in line with these conditions were: < 0.02 (11), 0.02 (three), 0.03 (three) and 0.04 (two) mg/kg. The corresponding total residue levels were < 0.02 (11), 0.02 (three), 0.03 (two), 0.04 (two) and 0.06 mg/kg.

In summary, the trifloxystrobin residue levels in the 14 trials in Europe and 19 in the USA were: < 0.02 (24), 0.02 (four), 0.03 (three) and 0.04 (two) mg/kg. The corresponding total residue levels were < 0.02 (24), 0.02 (four), 0.03 (two), 0.04 (two) and 0.06 mg/kg.

The Meeting estimated a maximum residue level of 0.05 mg/kg and an STMR of 0.02 mg/kg for residues in sugar-beet.

#### *Celery*

Trifloxystrobin is registered in Switzerland for use on celery up to three times at 0.25 kg ai/ha with a 7-day PHI. The concentrations of trifloxystrobin and total residues in whole celery plants without roots in three Swiss trials conducted according to GAP were: 0.12, 0.18 and 0.21 mg/kg.

The Meeting concluded that there were sufficient data and estimated a maximum residue level of 1 mg/kg and an STMR of 0.18 mg/kg for residues in celery as a minor crop.

#### *Witloof chicory*

Trifloxystrobin is registered in Switzerland for use on chicory up to three times at 0.25 kg ai/ha with a 21-day PHI. The concentrations of trifloxystrobin residues in chicory leaves in two Swiss trials were 0.34 and 0.86 mg/kg. The corresponding total residue levels were 0.37 and 0.94 mg/kg. The trifloxystrobin and the total residue levels in the roots were both 0.02 mg/kg.

The Meeting concluded that there were insufficient data to estimate a maximum residue level and STMR for residues in witloof chicory.

### *Cereal grains*

#### *Barley*

In some countries of Europe, trifloxystrobin is used twice at 0.25 kg ai/ha (France, Germany, UK) or 0.19 kg ai/ha (Belgium) or once at 0.15 kg ai/ha (Austria). The PHI is 35 days in Austria, Germany and the UK and 42 days in Belgium and France. In one trial in Denmark, 30 in France, six

in Germany and two in the UK matching the appropriate European GAP, the trifloxystrobin residue levels in barley grain were < 0.02 (10), 0.02 (four), 0.03 (five), 0.04 (two), 0.05 (four), 0.06, 0.07 (three), 0.11 (four), 0.12 (two), 0.13 (two), 0.18 and 0.40 mg/kg. The corresponding total residue levels were < 0.02 (10), 0.02 (four), 0.03 (four), 0.04 (three), 0.05 (two), 0.07 (four), 0.09 (two), 0.11 (three), 0.13, 0.14, 0.15, 0.16, 0.17, 0.18 and 0.46 mg/kg.

The Meeting estimated a maximum residue level of 0.5 mg/kg and an STMR of 0.04 mg/kg for residues in barley. A highest residue level of 0.46 mg/kg was estimated for calculating the dietary burden of farm animals.

#### *Wheat*

Brazilian GAP allows two treatments at 0.075 kg ai/ha with a 30-day PHI. Six Brazilian trials were conducted with three applications at 0.15 kg ai/ha. In all these trials, the trifloxystrobin residue levels were below the LOQ of 0.05 mg/kg. As CGA321113 was not determined, the trials were not considered for evaluation.

Trifloxystrobin may be used twice at 0.25 kg ai/ha in France Germany, Ireland and the UK; at 0.19 kg ai/ha in Austria, Belgium, Hungary, Italy, Luxembourg, Poland and Switzerland; and at 0.13 kg ai/ha in Slovakia, with PHIs of 35–45 days. In 26 trials in France, 10 in Germany, one in Sweden and two in Switzerland matching the appropriate European GAP, the trifloxystrobin residue levels in wheat grain were: < 0.02 (32), 0.02 (three), 0.03 (two), 0.05 and 0.14 mg/kg. The corresponding total residue levels were: < 0.02 (32), 0.02 (three), 0.03 (two), 0.07 and 0.20 mg/kg.

Trifloxystrobin is registered in the USA for use on wheat up to twice at 0.09 kg ai/ha with a 35-day PHI. In 33 trials in 11 states where these conditions were approximated, the trifloxystrobin and the total residue levels in wheat grain were: < 0.02 (30), 0.02 and 0.03 (two) mg/kg.

In summary, the trifloxystrobin residue levels in the 39 European and the 33 US trials were: < 0.02 (62), 0.02 (four), 0.03 (four), 0.05 and 0.14 mg/kg. The corresponding total residue levels were: < 0.02 (62), 0.02 (four), 0.03 (four), 0.07 and 0.20 mg/kg.

The Meeting estimated a maximum residue level of 0.2 mg/kg and an STMR of 0.02 mg/kg for residues in wheat. A highest residue level of 0.2 mg/kg was estimated for calculating the dietary burden of farm animals.

#### *Maize*

Brazilian GAP allows two treatments at 0.075–0.1 kg ai/ha with a 30-day PHI. Three Brazilian trials at three times 0.1 kg ai/ha were conducted. In all the trials, the trifloxystrobin residue levels were below the LOQ of 0.05 mg/kg. As CGA321113 was not determined, the trials were not considered for evaluation.

Trifloxystrobin is registered in the USA for use on maize up to three times at 0.11 kg ai/ha. The PHI for maize grain is not specified, but the product should not be applied after silking. In 24 field trials in 14 states where these conditions were approximated, the levels of trifloxystrobin residues in maize grain were < 0.02 (24) mg/kg, and the total residue levels were < 0.02 (23) and 0.05 mg/kg.

The Meeting estimated a maximum residue level and an STMR of 0.02 mg/kg for residues in maize. A highest residue level of 0.05 mg/kg was estimated for calculating the dietary burden of farm animals.

#### *Rice*

Brazilian GAP allows two foliar treatments at 0.10–0.13 kg ai/ha with a 15-day PHI. Five Brazilian trials with three applications at 0.15 kg ai/ha and a 14–18-day PHI were conducted. The levels of trifloxystrobin residues in rice grain with husk were: < 0.05, 0.05, 0.10, 0.13 and 0.22 mg/kg. As CGA321113 was not determined, these trials were not included in the evaluation.

Trifloxystrobin is registered in the USA for use on rice up to twice at 0.17 kg ai/ha with a 35-day PHI. In 19 trials in five states where these conditions were approximated, the trifloxystrobin residue levels in rice grain with husk before processing were: < 0.02 (five), 0.03, 0.04 (two), 0.10, 0.11 (two), 0.12, 0.25, 0.30, 0.34, 0.56, 0.68, 2.4 and 3.4 mg/kg. The corresponding total residue levels were < 0.02 (five), 0.04, 0.06, 0.07, 0.13, 0.16, 0.20, 0.21, 0.33, 0.41, 0.46, 0.63, 0.75, 2.5 and 3.4 mg/kg.

The Meeting estimated a maximum residue level of 5 mg/kg and an STMR of 0.16 mg/kg for residues in rice. A highest residue level of 3.4 mg/kg was estimated for calculating the dietary burden of farm animals.

#### *Tree nuts*

Trifloxystrobin is registered in the USA for use on beechnuts, brazil nuts, butternuts, cashew nuts, chestnuts, chinquapins, filberts, macadamia nuts and walnuts up to four times, and almonds up to three times at 0.14 kg ai/ha with a 60-day PHI. Three treatments at 0.091 kg ai/ha with a PHI of 30 days may be used on pecans.

In six trials on *almonds* in California in which these conditions were approximated, the trifloxystrobin and the total residue levels in almond nuts without shells were < 0.02 mg/kg.

In 11 trials on *pecans* in five states, with eight treatments at 0.14 kg ai/ha and a 30-day PHI, the trifloxystrobin and the total residue levels in pecan nuts without shells were < 0.02 mg/kg.

The Meeting estimated a maximum residue level of 0.02\* mg/kg and an STMR of 0 mg/kg for residues in tree nuts.

#### *Cotton-seed*

Brazilian GAP allows up to three foliar treatments at 0.063–0.075 kg ai/ha with a 21-day PHI. Three Brazilian trials with three applications at 0.1 kg ai/ha and a 21-day PHI were conducted. The samples were not analysed for CGA321113. In all three trials, the trifloxystrobin residue levels were below the LOQ of 0.05 mg/kg.

The Meeting concluded that there were insufficient data to estimate a maximum residue level and an STMR for cotton-seed.

#### *Peanuts*

Brazilian GAP allows three foliar treatments at 0.075 kg ai/ha with a 15-day PHI for peanuts. Three Brazilian trials with three applications at 0.10 kg ai/ha and a 15-day PHI were conducted. The trifloxystrobin residue levels in peanuts without shells were < 0.05 mg/kg. As CGA321113 was not determined, these trials were not included in the evaluation.

Trifloxystrobin is registered in the USA for use on peanuts twice at an application rate of 0.13 kg ai/ha or six times at 0.064 kg ai/ha with a PHI of 14 days. In 22 trials with eight applications at 0.07 kg ai/ha and 12 trials with eight applications at 0.14 kg ai/ha were in seven states in 1996–98, the trifloxystrobin and total residue levels in kernels were all < 0.02 mg/kg.

The Meeting estimated a maximum residue level of 0.02\* mg/kg and an STMR of 0 mg/kg for residues in peanuts.

#### *Coffee beans*

Brazilian GAP allows three treatments at 0.075–0.11 kg ai/ha with a 30-day PHI. Four Brazilian trials with three applications at 0.11 kg ai/ha were conducted. In all four trials, the trifloxystrobin residue levels were below the LOQ of 0.05 mg/kg. As CGA321113 was not determined, these trials were not included in the evaluation.

The Meeting concluded that there were insufficient data to estimate a maximum residue level or an STMR for coffee beans.

### *Hops*

German and Austrian GAP allows two treatments of hops at a spray concentration of 0.013 kg ai/hl and a PHI of 14 days. Five German trials with four to six applications of trifloxystrobin at a spray concentration of 0.013 kg ai/ha were reported. In cones harvested 14 days after the last treatment and dried, the trifloxystrobin residue levels were: 4.7, 5.4, 8.8, 16 and 26 mg/kg. The corresponding total residue levels were: 6.2, 6.7, 10, 18 and 29 mg/kg.

In the USA, trifloxystrobin may be used on hops four times at 0.14 kg ai/ha with a 14-day PHI. In three trials in two states with six treatments at 0.14 kg ai/ha and a 13–14-day PHI, the trifloxystrobin residue levels in dried cones were 4.5, 9.3 and 10 mg/kg. The corresponding total residue levels were 4.9, 9.9 and 11 mg/kg.

In summary, the trifloxystrobin residue levels in the three trials in Germany and the three in the USA were: 4.5, 4.7, 5.4, 8.8, 9.3, 10, 16 and 26 mg/kg, and the corresponding total residue levels were: 4.9, 6.2, 6.7, 9.9, 10, 11, 18 and 29 mg/kg.

The Meeting estimated a maximum residue level of 40 mg/kg and an STMR of 9.95 mg/kg for residues in hops, dry.

### *Animal feedstuffs*

#### *Almond hulls*

Trifloxystrobin is registered in the USA for use on almonds up to three times at 0.14 kg ai/ha and a 60-day PHI. Six trials on almonds in California approximating these conditions were reported. The trifloxystrobin residue levels in hulls were: 0.25, 0.42, 0.72, 1.2, 1.6 and 1.8 mg/kg, and the total residue levels were: 0.25, 0.42, 0.75, 1.2, 1.6 and 1.9 mg/kg (fresh weight).

Allowing for the standard 90% dry matter for almond hulls (*FAO Manual*, p. 147), the Meeting estimated a maximum residue level of 3 mg/kg and an STMR of 1.08 mg/kg for almond hulls (dry weight). A highest residue level of 2.1 mg/kg was estimated for calculating the dietary burden of farm animals.

#### *Peanut fodder*

Trifloxystrobin is registered in the USA for use on peanuts with a maximum GAP of two applications at 0.13 kg ai/ha and a PHI of 14 days. In 12 trials with eight applications at 0.14 kg ai/ha in six states in 1996, the trifloxystrobin residue levels in peanut hay were: 0.19 (two), 0.25, 0.27, 0.29, 0.34, 0.46, 0.71, 0.84, 1.4, 3.4 and 3.7 mg/kg. The corresponding total residue levels were: 0.37, 0.40, 0.42, 0.47, 0.50, 0.63, 0.82, 1.1, 1.4, 2.1, 4.1 and 4.2 mg/kg (fresh weight).

Allowing for the standard 85% dry matter for peanut hay (*FAO Manual*, p. 148), the Meeting estimated a maximum residue level of 5 mg/kg and an STMR (dry weight) of 0.85 mg/kg for residues in peanut fodder. A highest residue level of 4.94 mg/kg was estimated for calculating the dietary burden of farm animals.

#### *Barley straw and fodder, dry*

Trifloxystrobin may be used twice at 0.25 kg ai/ha in France, Germany and the UK; twice at 0.19 kg ai/ha in Belgium; and once at 0.15 kg ai/ha in Austria. The PHI is 35 days in Austria, Germany and the UK and 42 days in Belgium and France. The trifloxystrobin residue levels in barley straw in one trial in Denmark, 23 in France, six in Germany and two in the UK, matching appropriate European GAP were: 0.09, 0.15, 0.23, 0.31, 0.32, 0.33, 0.38 (two), 0.43, 0.49, 0.50, 0.53, 0.61, 0.64, 0.66, 0.68, 0.69, 0.72, 0.78, 0.81 (two), 0.91 (two), 0.93, 1.0, 1.1, 1.3, 1.5, 1.6, 1.8, 2.4 and 4.2 mg/kg. The corresponding total residue levels were: 0.09, 0.15, 0.30, 0.33, 0.38 (three), 0.48, 0.58, 0.64, 0.67, 0.68, 0.75, 0.77, 0.79, 0.80 (two), 0.86, 0.93, 0.94 (two), 1.1 (four), 1.5 (two), 1.7, 1.8, 1.9, 2.6 and 4.4 mg/kg (fresh weight).

Allowing for the standard 89% dry matter for barley straw (*FAO Manual*, p. 147), the Meeting estimated a maximum residue level of 7 mg/kg and an STMR value (dry weight) of

0.9 mg/kg for residues in barley straw and fodder, dry. A highest residue level of 4.9 mg/kg was estimated for calculating the dietary burden of farm animals.

*Wheat straw and fodder, dry*

Trifloxystrobin may be used on wheat at 0.25 kg ai/ha in France, Germany, Ireland and the UK; at 0.19 kg ai/ha in Austria, Belgium, Hungary, Italy, Luxembourg, Poland and Switzerland; and at 0.13 kg ai/ha in Slovakia. The PHIs are 35–45 days. In 26 trials in France, 10 in Germany, one in Sweden and two in Switzerland that matched appropriate European GAP, the trifloxystrobin residue levels in wheat straw were: < 0.05, 0.07, 0.09 (two), 0.13, 0.16 (two), 0.17, 0.19 (two), 0.30, 0.31, 0.33, 0.34, 0.35, 0.38, 0.40, 0.50, 0.57, 0.59, 0.62, 0.70, 0.73, 0.76, 0.77, 0.81, 0.83, 0.85, 0.94, 0.99, 1.1, 1.3 (two), 1.4, 1.6, 1.8, 1.9, 2.3 and 2.5 mg/kg. The corresponding total residue levels were < 0.05, 0.07, 0.09, 0.13, 0.15, 0.16 (two), 0.24, 0.25, 0.26, 0.38 (three), 0.41, 0.42, 0.43, 0.51, 0.57, 0.77, 0.78 (two), 0.87, 0.89, 0.94, 0.95 (two), 1.0, 1.1, 1.2 (two), 1.3, 1.5, 1.6, 1.7, 1.8, 2.1, 2.6 (two) and 2.7 mg/kg (fresh weight).

Trifloxystrobin is registered in the USA for use on wheat up to twice at 0.09 kg ai/ha with a 35-day PHI. In 23 trials in eight states where these conditions were approximated, the trifloxystrobin residue levels in wheat straw were: 0.08 (two), 0.11 (two), 0.12 (two), 0.13, 0.14, 0.15, 0.17, 0.19 (two), 0.26, 0.27, 0.29, 0.31, 0.34, 0.51, 0.61, 0.96, 0.97, 1.4 and 1.9 mg/kg. The corresponding total residue levels were 0.08, 0.11 (three), 0.12 (two), 0.14, 0.15 (two), 0.19, 0.21, 0.22, 0.26, 0.29, 0.31, 0.36, 0.44, 0.51, 0.64, 1.0, 1.1, 1.6 and 2.4 mg/kg (fresh weight).

In summary, the trifloxystrobin residue levels in the 39 European and the 23 US trials, in ranked order, were: < 0.05, 0.07, 0.08 (two), 0.09 (two), 0.11 (two), 0.12 (two), 0.13 (two), 0.14, 0.15, 0.16 (two), 0.17 (two), 0.19 (four), 0.26, 0.27, 0.29, 0.30, 0.31 (two), 0.33, 0.34 (two), 0.35, 0.38, 0.40, 0.50, 0.51, 0.57, 0.59, 0.61, 0.62, 0.70, 0.73, 0.76, 0.77, 0.81, 0.83, 0.85, 0.94, 0.96, 0.97, 0.99, 1.1, 1.3 (two), 1.4 (two), 1.6, 1.8, 1.9 (two), 2.3 and 2.5 mg/kg. The total residue levels were: < 0.05, 0.07, 0.08, 0.09, 0.11 (three), 0.12 (two), 0.13, 0.14, 0.15 (three), 0.16 (two), 0.19, 0.21, 0.22, 0.24, 0.25, 0.26 (two), 0.29, 0.31, 0.36, 0.38 (two), 0.38, 0.41, 0.42, 0.43, 0.44, 0.51 (two), 0.57, 0.64, 0.77, 0.78 (two), 0.87, 0.89, 0.94, 0.95 (two), 1.0 (two), 1.1 (two), 1.2 (two), 1.3, 1.5, 1.6 (two), 1.7, 1.8, 2.1, 2.4, 2.6 (two) and 2.7 mg/kg (fresh weight).

Allowing for the standard 88% dry matter for wheat straw (*FAO Manual*, p. 149), the Meeting estimated a maximum residue level of 5 mg/kg and an STMR (dry weight) of 0.48 mg/kg for residues in wheat straw and fodder, dry. A highest residue level of 3.07 mg/kg was estimated for calculating the dietary burden of farm animals.

*Maize fodder*

Trifloxystrobin is registered in the USA for use on maize up to three times at 0.11 kg ai/ha. In 24 field trials in 14 states where these conditions were approximated and with a PHI of 30 days, the trifloxystrobin residue levels in maize stover were: 0.04, 0.32, 0.37, 0.42, 0.43, 0.53, 0.56, 0.64, 0.88, 0.96 (two), 1.0, 1.2, 1.5, 2.0, 2.1, 2.2 (two), 2.7, 2.9, 3.2, 3.9, 4.0 and 5.4 mg/kg. The corresponding total residue levels were 0.09, 0.37, 0.41, 0.47, 0.56, 0.65, 0.74, 0.80, 1.3, 1.4 (three), 1.5, 1.9, 2.4, 2.5, 2.6, 2.8, 3.5, 3.9, 4.4 (two), 4.5 and 7.1 mg/kg.

Allowing for the standard 83% dry matter for maize stover (*FAO Manual*, p. 147), the Meeting estimated a maximum residue level of 10 mg/kg and an STMR (dry weight) of 1.75 mg/kg for residues in maize fodder. A highest residue level of 8.55 mg/kg was estimated for calculating the dietary burden of farm animals.

*Rice straw and fodder, dry*

Trifloxystrobin is registered in the USA for use on rice up to twice at 0.17 kg ai/ha with a 35-day PHI. In 19 trials in five states where these conditions were approximated, the trifloxystrobin residue levels in rice straw were: 0.07, 0.25, 0.37, 0.42, 0.44, 0.50, 0.54, 0.57, 0.78, 1.0, 1.1, 1.3, 2.0, 2.4, 2.5, 2.6 (two), 5.3 and 6.1 mg/kg. The corresponding total residue levels were 0.07, 0.32, 0.45, 0.54, 0.60, 0.74, 0.83, 0.84, 1.0, 1.3, 1.6, 2.1, 2.6, 3.2 (three), 3.7, 5.5 and 7.3 mg/kg (fresh weight).

Allowing for the standard 90% dry matter for rice straw (*FAO Manual*, p. 149), the Meeting estimated a maximum residue level of 10 mg/kg and an STMR (dry weight) of 1.4 mg/kg for residues in rice straw and fodder, dry. A highest residue level of 8.1 mg/kg was estimated for calculating the dietary burden of farm animals.

*Sugar-beet leaves or tops*

Italian GAP allows three treatments at rates of 0.11–0.15 kg ai/ha, and Swiss GAP allows once at 0.15 kg ai/ha, both with a PHI of 21 days, for sugar-beets. The residue levels of trifloxystrobin *per se* in sugar-beet tops in nine trials in France, two in Italy, two in Spain and one in Switzerland matching GAP were: < 0.02 (three), < 0.05 (five), 0.05, 0.07, 0.09, 0.14, 0.33 and 0.44 mg/kg. The corresponding total residue levels were: < 0.02 (three), < 0.05 (five), 0.05, 0.09 (two), 0.17, 0.41 and 0.44 mg/kg (fresh weight).

Trifloxystrobin is registered in the USA for use on sugar-beet up to three times at 0.12 kg ai/ha with a 21-day PHI. In 19 trials in seven states where these conditions were matched, the trifloxystrobin residues in sugar-beet tops were 0.08 (two), 0.14, 0.17, 0.21, 0.23, 0.24, 0.26, 0.35, 0.54, 0.56, 0.61, 0.64, 0.72, 0.98, 1.6, 2.3 and 2.4 (two) mg/kg. The corresponding total residue levels were 0.08 (two), 0.14, 0.17, 0.23 (two), 0.24, 0.26, 0.39, 0.54, 0.61 (two), 0.66, 0.72, 0.98, 1.6, 2.4 and 2.5 (two) mg/kg (fresh weight).

The data sets from Europe and the USA appeared to be from different populations and were not combined. The Meeting agreed to estimate a maximum residue level and an STMR on the basis of the results of the trials in the USA.

Allowing for the standard 23% dry matter for sugar beet tops (*FAO Manual*, p. 147), the Meeting estimated a maximum residue level of 15 mg/kg and an STMR (dry weight) of 2.3 mg/kg for residues in sugar-beet leaves or tops. A highest residue level of 10.9 mg/kg was estimated for calculating the dietary burden of farm animals.

***Fate of residues during processing***

The Meeting received information on the fate and nature of trifloxystrobin residues under various conditions of hydrolysis. Trifloxystrobin is partially hydrolysed to CGA321113 under conditions representative of baking, brewing and boiling (2.6%) and sterilization (22.5%). It was stable under conditions representative of pasteurization. Any possible effects of hydrolysis on the nature of the residue during processing are covered by the fact that the only relevant metabolite (CGA321113) was determined in all the residue and processing trials.

The effect of processing on the level of residues of trifloxystrobin has been studied for barley, cabbage, cotton, grapes, hops, maize, oranges, peanuts, pome fruit, potatoes, rice, stone fruit, strawberries, sugar-beet, tomatoes and wheat. The processing factors shown below were calculated from the total residue levels (sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin).

| Raw agricultural commodity | Processed product  | No. of samples | Mean processing factor |
|----------------------------|--------------------|----------------|------------------------|
| Orange                     | Juice              | 5              | < 0.19                 |
|                            | Oil                | 5              | 130                    |
|                            | Pulp, dry          | 5              | 3.4                    |
| Apple, pear                | Juice              | 7              | 0.16                   |
|                            | Sauce and preserve | 4              | 0.48                   |
|                            | Fruit, dried       | 2              | 0.39                   |
|                            | Pomace, wet        | 6              | 9.4                    |
|                            | Pomace, dried      | 1              | 25.6                   |
| Plum                       | Dried prune        | 4              | 1.5                    |
| Peach                      | Preserve           | 1              | < 0.05                 |

| Raw agricultural commodity | Processed product | No. of samples | Mean processing factor |
|----------------------------|-------------------|----------------|------------------------|
| Grapes                     | Juice             | 14             | 0.24                   |
|                            | Must              | 27             | 0.46                   |
|                            | Wine              | 35             | 0.15                   |
|                            | Fruit, dried      | 4              | 2.3                    |
|                            | Pomace, wet       | 1              | 2.25                   |
| Strawberry                 | Preserve          | 2              | 0.29                   |
|                            | Jam               | 2              | 0.62                   |
| Tomato                     | Paste             | 5              | 1.6                    |
|                            | Purée             | 5              | 0.56                   |
| Potato                     | Flakes            | 2              | < 0.42                 |
|                            | Chips             | 2              | < 0.42                 |
|                            | Wet peel          | 2              | 2.3                    |
| Sugar-beet                 | White sugar       | 2              | < 0.18                 |
|                            | Dried pulp        | 2              | 3.4                    |
|                            | Molasses          | 2              | 1.5                    |
| Barley                     | Beer              | 1              | 0.04                   |
| Wheat                      | Bran              | 2              | 2.7                    |
|                            | Germ              | 1              | < 0.67                 |
|                            | Meal and flour    | 2              | 0.4                    |
|                            | Wholemeal         | 1              | 0.5                    |
|                            | Wholemeal bread   | 1              | 0.25                   |
| Rice                       | Polished grain    | 4              | 0.18                   |
|                            | Hull              | 4              | 3.2                    |
|                            | Bran              | 4              | 1.4                    |
| Hops                       | Spent hops        | 1              | 0.04                   |
|                            | Yeast             | 1              | 0.007                  |
|                            | Beer              | 1              | < 0.001                |

*Oranges* were processed into juice, oil and dried pulp with processing factors of < 0.19, 130 and 3.4 respectively. On the basis of the STMR value of 0.095 mg/kg for whole citrus fruits, the STMR-Ps were 0.018 mg/kg for citrus juice and 12 mg/kg for oil. Allowing for the standard 91% dry matter, the Meeting estimated a maximum residue level of 1 mg/kg and an STMR-P of 0.35 mg/kg ( $0.095 \times 3.4 \times 1.0989$ ) for residues in dried citrus pulp (dry weight).

*Apples* and *pears* were processed into juice, sauce or preserve, wet pomace, dry pomace and dried fruit, with processing factors of 0.16, 0.48, 9.4, 25.6 and 0.39 respectively. On the basis of the STMR value of 0.11 mg/kg for pome fruit, the STMR-P was 0.018 mg/kg for juice, 0.053 mg/kg for sauce, 0.053 mg/kg for preserve and 0.043 mg/kg for dried fruit of apple and pear. In the *FAO Manual* (Appendix IX), wet apple pomace is listed as animal feed. Allowing for the standard 40% dry matter, the Meeting estimated an STMR-P of 2.6 mg/kg ( $0.11 \times 9.4 \times 2.5$ ) for residues in wet apple pomace (dry weight).

*Peaches* were processed into preserve (canned fruits) with a processing factor of 0.05. On the basis of the STMR value of 0.38 mg/kg for stone fruit, the STMR-P was 0.019 mg/kg for residues in canned fruits of peaches, nectarines and apricots.

*Plums* were processed into dried prunes with a processing factor of 1.5. On the basis of the STMR value of 0.38 mg/kg for stone fruit, the STMR-P was 0.57 mg/kg for dried prunes.



*Grapes* were processed into juice, must, wine and dried fruit (raisins) with processing factors of 0.24, 0.46, 0.15 and 2.3 respectively. On the basis of the STMR value of 0.15 mg/kg for grapes, the STMR-P was 0.036 mg/kg for juice, 0.07 mg/kg for must, 0.023 mg/kg for wine and 0.345 mg/kg for raisins (dried grapes). On the basis of the highest trifloxystrobin residue level of 2.2 mg/kg, the Meeting estimated a maximum residue level of 5 mg/kg for residues in raisins (dried grapes).

*Strawberries* were processed into preserve (canned fruits) and jam with processing factors of 0.29 and 0.62 respectively. On the basis of the STMR value of 0.10 mg/kg for strawberries, the STMR-P values were 0.029 mg/kg for residues in canned strawberries and 0.062 mg/kg for those in jam.

*Head cabbage* was cooked. Because residues were not detected in the raw commodity, a processing factor could not be calculated and the levels of residues in the processed commodity could not be estimated.

*Tomatoes* were processed into paste and purée with processing factors of 1.6 and 0.56 respectively. On the basis of the STMR value of 0.08 mg/kg for tomato, the STMR-Ps were 0.13 mg/kg for residues in tomato paste and 0.045 mg/kg for residues in purée.

*Potatoes* were processed into flakes, chips and wet peel with processing factors of 0.42, 0.42 and 2.3 respectively. On the basis of the STMR value of 0.02 mg/kg for residues in potatoes, the STMR-Ps were 0.008 mg/kg for residues in potato flakes and chips. In the *FAO Manual* (Appendix IX), wet peel (processed potato waste) is listed as animal feed. Allowing for the standard 15% dry matter, an STMR-P of 0.307 mg/kg ( $0.02 \times 2.3 \times 6.67$ ) was estimated for potato wet peel (dry weight).

*Sugar-beet* was processed into white sugar, dried pulp and molasses with processing factors of 0.18, 3.4 and 1.5 respectively. On the basis of the STMR value of 0.02 mg/kg, the STMR-P for white sugar was 0.0036 mg/kg. In the *FAO Manual* (Appendix IX), sugar-beet dried pulp (88% dry matter) and molasses (75% dry matter) are listed as animal feeds. On the basis of the highest trifloxystrobin residue level of 0.04 mg/kg, the Meeting estimated maximum residue levels of 0.2 mg/kg ( $0.04 \times 3.4 \times 1.14$ ) for sugar-beet dried pulp and 0.1 mg/kg ( $0.04 \times 1.5 \times 1.33$ ) for sugar-beet molasses (dry weight). The estimated STMR-P values were 0.077 mg/kg ( $0.02 \times 3.4 \times 1.14$ ) for sugar-beet dried pulp and 0.04 mg/kg ( $0.02 \times 1.5 \times 1.33$ ) for sugar beet molasses (dry weight).

*Wheat* was processed into the milled by-products bran, flour, wholemeal, wholemeal bread and germ, with processing factors of 2.7, 0.4, 0.67, 0.33 and 0.67 respectively. On the basis of the STMR value of 0.02 mg/kg for wheat grain, the STMR-Ps were 0.008 for wheat flour, 0.01 for wholemeal, 0.005 for wholemeal bread and 0.013 for germ. In the *FAO Manual* (Appendix IX), bran is listed as an animal feed. Allowing for the standard 88% dry matter for wheat milled by-products, the Meeting estimated an STMR-P of 0.062 mg/kg ( $0.02 \times 2.7 \times 1.14$ ) for wheat bran, unprocessed (dry weight). On the basis of the highest trifloxystrobin residue level of 0.14 mg/kg, the Meeting estimated a maximum residue level of 0.5 mg/kg ( $0.14 \times 2.7 \times 1.14 = 0.43$ ) for wheat bran, unprocessed (dry weight).

*Maize* was processed to meal, grits, flour and oil. Because residues were not detected in the raw commodity, processing factors could not be calculated and the residue levels in the processed commodities could not be estimated.

*Rice* with husk was processed into polished rice, bran and hulls with processing factors of 0.18, 1.4 and 3.2 respectively. On the basis of the STMR of 0.16 mg/kg for rice with husks, an STMR-P of 0.029 mg/kg was calculated for polished rice. In the *FAO Manual* (Appendix IX), rice bran and hulls are listed as animal feed. Allowing for the standard 90% dry matter, the Meeting estimated STMR-P values of 0.57 mg/kg ( $0.16 \times 3.2 \times 1.1$ ) for rice hulls and 0.25 mg/kg ( $0.16 \times 1.4 \times 1.1$ ) for rice bran, unprocessed (dry weight). On the basis of the highest trifloxystrobin residue level of 3.4 mg/kg in rice with husks, the Meeting estimated a maximum residue level of 7 mg/kg for residues in rice bran, unprocessed (dry weight).

*Cotton* was processed to refined oil. Because residues were not detected in the raw commodity, a processing factor could not be calculated and the residue levels in the processed commodities could not be estimated.

*Peanuts* were processed to meal and refined oil. Because residues were not detected in the raw commodity, a processing factor could not be calculated and the residue levels in the processed commodities could not be estimated.

*Hops* were processed for use in beer, with a processing factor of 0.001. On the basis of the STMR value of 9.95 mg/kg for dry hops, an STMR-P of 0.01 mg/kg was calculated for beer. Barley was processed into beer with a processing factor of 0.04. On the basis of the STMR value of 0.04 mg/kg, the STMR-P for beer was 0.0016 mg/kg. Because the STMR-P arising from residues in barley was lower, the Meeting estimated an STMR-P of 0.01 mg/kg for residues in beer, on the basis of residues in hops.

### ***Residues in animal commodities***

#### *Dietary burden of farm animals*

The Meeting estimated the dietary burden of trifloxystrobin residues in farm animals on the basis of the diets listed in Appendix IX of the *FAO Manual*. Calculation from highest residue and STMR-P values provides the levels in feed suitable for estimating MRLs, while calculation from STMR and STMR-P values for feed is suitable for estimating STMR values for animal commodities. The percentage dry matter is taken as 100% when the highest residue levels and STMRs are already expressed as dry weight.

#### *Estimated maximum dietary burden of farm animals*

| Commodity                     | CC | Residue<br>(mg/kg) | Basis  | Dry<br>matter<br>(%) | Residue,<br>dry<br>weight<br>(mg/kg) | Diet content (%) |                 |         | Residue contribution<br>(mg/kg) |                 |         |
|-------------------------------|----|--------------------|--------|----------------------|--------------------------------------|------------------|-----------------|---------|---------------------------------|-----------------|---------|
|                               |    |                    |        |                      |                                      | Beef<br>cattle   | Dairy<br>cattle | Poultry | Beef<br>cattle                  | Dairy<br>cattle | Poultry |
| Almond hulls                  | AM | 2.1                | HR     | 100                  | 2.1                                  |                  |                 |         |                                 |                 |         |
| Apple pomace, wet             | AB | 2.6                | STMR-P | 100                  | 2.6                                  | 15               |                 |         | 0.39                            |                 |         |
| Barley grain                  | GC | 0.46               | HR     | 88                   | 0.528                                |                  |                 | 40      |                                 |                 | 0.211   |
| Barley straw                  | AS | 4.9                | HR     | 100                  | 4.9                                  |                  | 60              |         |                                 | 2.94            |         |
| Citrus pulp, dried            | AB | 0.35               | STMR-P | 100                  | 0.35                                 |                  |                 |         |                                 |                 |         |
| Maize grain                   | GC | 0.05               | HR     | 88                   | 0.057                                |                  |                 |         |                                 |                 |         |
| Maize fodder                  | AS | 8.55               | HR     | 100                  | 8.55                                 | 25               |                 |         | 2.14                            |                 |         |
| Peanut fodder (hay)           | AL | 4.94               | HR     | 100                  | 4.94                                 |                  |                 |         |                                 |                 |         |
| Potato wet peel               | AB | 0.307              | STMR-P | 100                  | 0.307                                |                  |                 |         |                                 |                 |         |
| Rice                          | GC | 3.4                | HR     | 88                   | 3.86                                 | 40               | 30              | 60      | 1.54                            | 1.16            | 2.32    |
| Rice bran                     | CM | 0.25               | STMR-P | 100                  | 0.25                                 |                  |                 |         |                                 |                 |         |
| Rice hulls                    | CM | 0.57               | STMR-P | 100                  | 0.57                                 |                  |                 |         |                                 |                 |         |
| Rice straw and<br>fodder, dry | AS | 8.1                | HR     | 100                  | 8.1                                  |                  |                 |         |                                 |                 |         |
| Sugar-beet leaves<br>and tops | AV | 10.9               | HR     | 100                  | 10.9                                 | 20               | 10              |         | 2.18                            | 1.09            |         |
| Sugar-beet, dried<br>pulp     | AB | 0.077              | STMR-P | 100                  | 0.077                                |                  |                 |         |                                 |                 |         |
| Sugar-beet molasses           | DM | 0.04               | STMR-P | 100                  | 0.04                                 |                  |                 |         |                                 |                 |         |
| Wheat grain                   | GC | 0.2                | HR     | 89                   | 0.225                                |                  |                 |         |                                 |                 |         |
| Wheat straw                   | AS | 3.07               | HR     | 100                  | 3.07                                 |                  |                 |         |                                 |                 |         |

| Commodity                       | CC | Residue<br>(mg/kg) | Basis  | Dry<br>matter<br>(%) | Residue/<br>dry<br>weight<br>(mg/kg) | Diet content (%) |                 |         | Residue contribution<br>(mg/kg) |                 |         |
|---------------------------------|----|--------------------|--------|----------------------|--------------------------------------|------------------|-----------------|---------|---------------------------------|-----------------|---------|
|                                 |    |                    |        |                      |                                      | Beef<br>cattle   | Dairy<br>cattle | Poultry | Beef<br>cattle                  | Dairy<br>cattle | Poultry |
| Wheat milled by-products (bran) | CM | 0.062              | STMR-P | 100                  | 0.062                                |                  |                 |         |                                 |                 |         |
| Total                           |    |                    |        |                      |                                      | 100              | 100             | 100     | 6.3                             | 5.2             | 2.5     |

*Estimated mean dietary burden of farm animals*

| Commodity                       | CC | Residue<br>(mg/kg) | Basis  | Dry<br>matter<br>(%) | Residue/<br>dry<br>weight<br>(mg/kg) | Diet content (%) |                 |         | Residue contribution<br>(mg/kg) |                 |         |
|---------------------------------|----|--------------------|--------|----------------------|--------------------------------------|------------------|-----------------|---------|---------------------------------|-----------------|---------|
|                                 |    |                    |        |                      |                                      | Beef<br>cattle   | Dairy<br>cattle | Poultry | Beef<br>cattle                  | Dairy<br>cattle | Poultry |
| Almond hulls                    | AM | 1.08               | STMR   | 100                  | 1.08                                 |                  | 10              |         |                                 | 0.108           |         |
| Apple pomace, wet               | AB | 2.6                | STMR-P | 100                  | 2.6                                  | 40               | 20              |         | 1.04                            | 0.52            |         |
| Barley grain                    | GC | 0.04               | STMR   | 88                   | 0.045                                |                  |                 |         |                                 |                 |         |
| Barley straw                    | AS | 0.9                | STMR   | 100                  | 0.9                                  |                  | 60              |         |                                 | 0.54            |         |
| Citrus pulp, dried              | AB | 0.35               | STMR-P | 100                  | 0.35                                 |                  |                 |         |                                 |                 |         |
| Maize grain                     | GC | 0.02               | STMR   | 88                   | 0.023                                |                  |                 |         |                                 |                 |         |
| Maize fodder                    | AS | 1.75               | STMR   | 100                  | 1.75                                 | 25               |                 |         | 0.437<br>5                      |                 |         |
| Peanut fodder (hay)             | AL | 0.85               | STMR   | 100                  | 0.85                                 | 15               |                 |         | 0.127<br>5                      |                 |         |
| Potato, wet peel                | AB | 0.307              | STMR-P | 100                  | 0.307                                |                  |                 |         |                                 |                 |         |
| Rice                            | GC | 0.16               | STMR   | 88                   | 0.182                                |                  |                 | 60      |                                 |                 | 0.1092  |
| Rice bran                       | CM | 0.25               | STMR-P | 100                  | 0.25                                 |                  |                 | 25      |                                 |                 | 0.0625  |
| Rice hulls                      | CM | 0.57               | STMR-P | 100                  | 0.57                                 |                  |                 | 15      |                                 |                 | 0.086   |
| Rice straw and fodder, dry      | AS | 1.4                | STMR   | 100                  | 1.4                                  |                  |                 |         |                                 |                 |         |
| Sugar-beet leaves and tops      | AV | 2.3                | STMR   | 100                  | 2.3                                  | 20               | 10              |         | 0.46                            | 0.23            |         |
| Sugar-beet dried pulp           | AB | 0.077              | STMR-P | 100                  | 0.077                                |                  |                 |         |                                 |                 |         |
| Sugar-beet molasses             | DM | 0.04               | STMR-P | 100                  | 0.04                                 |                  |                 |         |                                 |                 |         |
| Wheat grain                     | GC | 0.02               | STMR   | 89                   | 0.0225                               |                  |                 |         |                                 |                 |         |
| Wheat straw                     | AS | 0.48               | STMR   | 100                  | 0.48                                 |                  |                 |         |                                 |                 |         |
| Wheat milled by-products (bran) | CM | 0.062              | STMR-P | 100                  | 0.062                                |                  |                 |         |                                 |                 |         |
| Total                           |    |                    |        |                      |                                      | 100              | 100             | 100     | 2.1                             | 1.4             | 0.26    |

The dietary burdens of trifloxystrobin for estimating maximum residue levels and STMRs for animal commodities (residue concentrations in animal feeds expressed as dry weight) are 6.3 and 2.1 mg/kg for beef cattle, 5.2 and 1.4 mg/kg for dairy cattle, 2.5 and 0.26 mg/kg for poultry.

**Feeding studies**

The Meeting received information on residues arising in tissues and milk of *dairy cows* dosed with trifloxystrobin in capsules at the equivalent of 2, 5.9 or 21 ppm in the diet for 28–30 days.

The sum of trifloxystrobin and CGA321113 was calculated and expressed as trifloxystrobin on the basis of relative molecular masses. A conversion factor of 1.036 is required to express the CGA321113 residues as trifloxystrobin equivalents. As this metabolite constitutes a significant proportion of the residue in animal products, when the level of trifloxystrobin or CGA321113 was

below its LOQ, the sum of trifloxystrobin and CGA321113 was calculated, as in the examples below, and expressed as trifloxystrobin.

| Trifloxystrobin (mg/kg) | CGA321113 (mg/kg) | Total expressed as trifloxystrobin (mg/kg) |
|-------------------------|-------------------|--------------------------------------------|
| < 0.02                  | < 0.02            | < 0.04                                     |
| < 0.02                  | 0.03              | 0.05                                       |
| 0.09                    | < 0.02            | 0.11                                       |

No residues (sum of trifloxystrobin and CGA321113) were detectable in milk (< 0.02 mg/kg), round muscle (< 0.04 mg/kg) or tenderloin (< 0.04 mg/kg) from cattle given the highly exaggerated feeding level of 21 ppm. No residues of either parent or metabolite were found in liver, kidney or fat samples from animals at 2 or 5.9 ppm (total residue, < 0.04 mg/kg). Maximum residue levels of 0.09 mg/kg (total residue, 0.11 mg/kg) and 0.02 mg/kg (total residue, 0.04 mg/kg), detected as the metabolite CGA321113 and expressed as trifloxystrobin, were found in liver and kidney respectively, from cattle at 21 ppm; and maximum residue levels of 0.06 mg/kg (total residue, 0.08 mg/kg) and 0.05 mg/kg (total residue, 0.07 mg/kg), detected as intact trifloxystrobin, were found in perirenal fat and omental fat respectively, from these animals.

The Meeting received information on the concentrations of residues in tissues and eggs from *laying hens* dosed with trifloxystrobin at the equivalent of 1.5, 4.5 or 15 ppm in the diet for 28 days. The hens were killed on day 29, and composite tissue samples of breast plus thigh, skin plus attached fat, peritoneal fat, and liver were taken. Eggs and tissues were analysed for trifloxystrobin and CGA321113. No residues (total residues, < 0.04 mg/kg) were detected in any of the eggs, tissues or organs taken from hens at the highest dietary level of 15 ppm.

#### *Maximum residue levels*

The Meeting noted that no trifloxystrobin or CGA321113 residues were detected in milk (total, < 0.02 mg/kg), muscle (< 0.04 mg/kg), kidney (< 0.04 mg/kg), liver (< 0.04 mg/kg) or fat (< 0.04 mg/kg) from animals dosed for 28 days at 5.9 ppm, which was close to the maximum dietary burdens of beef and dairy cattle (8.2 and 7.4 ppm). The highest residue level of trifloxystrobin was found in perirenal fat at 0.06 mg/kg (total residue, 0.08 mg/kg), and the highest level of CGA321113 was found in liver at 0.09 mg/kg (total residue, 0.11 mg/kg) from animals given 21 ppm.

| Dietary burden (ppm) | Trifloxystrobin total residue (mg/kg) |           |      |         |      |         |      |         |      |
|----------------------|---------------------------------------|-----------|------|---------|------|---------|------|---------|------|
| Feeding level [ppm]  | Milk                                  | Muscle    |      | Liver   |      | Kidney  |      | Fat     |      |
|                      | (mean)                                | Highest   | Mean | Highest | Mean | Highest | Mean | Highest | Mean |
| MRL beef cattle      |                                       |           |      |         |      |         |      |         |      |
| (6.3)                |                                       | (< 0.012) |      | (0.033) |      | (0.012) |      | (0.024) |      |
| [21]                 |                                       | < 0.04    |      | 0.11    |      | 0.04    |      | 0.08    |      |
| MRL dairy cattle     |                                       |           |      |         |      |         |      |         |      |
| (5.2)                | (< 0.005)                             |           |      |         |      |         |      |         |      |
| [21]                 | < 0.02                                |           |      |         |      |         |      |         |      |
| STMR beef cattle     |                                       |           |      |         |      |         |      |         |      |
| (2.1)                |                                       | (< 0.004) |      | (0.008) |      | (0.004) |      | (0.006) |      |
| [21]                 |                                       | < 0.04    |      | 0.08    |      | 0.04    |      | 0.06    |      |
| STMR dairy cattle    |                                       |           |      |         |      |         |      |         |      |
| (1.4)                | (< 0.001)                             |           |      |         |      |         |      |         |      |
| [21]                 | < 0.02                                |           |      |         |      |         |      |         |      |

The maximum concentrations of residues expected in tissues are < 0.012 mg/kg in muscle, 0.033 mg/kg in liver, 0.012 mg/kg in kidney, 0.024 mg/kg in fat and < 0.005 mg/kg in milk. The mean extrapolated concentrations are < 0.004 mg/kg in muscle, 0.008 mg/kg in liver, 0.004 mg/kg in kidney, 0.006 mg/kg in fat and < 0.001 mg/kg in milk.

Taking into account the fat solubility of trifloxystrobin (the acid metabolite CGA321113 is poorly soluble in fat), the Meeting estimated a maximum residue level of 0.05 mg/kg for the sum of

trifloxystrobin and CGA321113 in meat (fat) from mammals other than marine mammals on the basis of residue levels in trimmable fat, and a maximum residue level of 0.02\* mg/kg for residues in milks. The estimated maximum residue levels are 0.05 mg/kg for liver and 0.04\* mg/kg for kidney of cattle, goats, pigs and sheep.

The estimated STMR values are 0.006 mg/kg in fat, 0 mg/kg in muscle, 0.008 mg/kg in liver, 0.004 mg/kg in kidney and 0 in milks.

The Meeting noted that in the feeding study in laying hens, no trifloxystrobin or CGA321113 residues (total residue, < 0.04 mg/kg) were detected in eggs, tissues or organs from hens at the highest feeding level of 15 ppm. As the maximum dietary burden of 2.5 mg/kg was much lower, the Meeting agreed that the expected level of trifloxystrobin and CGA321113 residues in poultry tissues and eggs would be essentially 0.

The Meeting estimated maximum residue levels of 0.04\* mg/kg for residues in eggs, poultry meat (fat) and edible offal. The Meeting recommended that the STMR values should be 0 in eggs, poultry meat, edible offal and fat.

## RECOMMENDATIONS

The Meeting estimated the maximum residue levels and STMR values shown below. The maximum residue levels are recommended for use as MRLs.

### *Definition of the residue*

#### *Plants*

For compliance with MRLs: trifloxystrobin.

For estimation of dietary intake: sum of trifloxystrobin and [(*E,E*)-methoxy-imino-{2-[1-(3-trifluoromethylphenyl)ethylideneamino]oxymethyl}phenyl]acetic acid] (CGA321113), expressed as trifloxystrobin.

#### *Animals*

For compliance with MRLs and estimation of dietary intake: sum of trifloxystrobin and [(*E,E*)-methoxyimino-{2-[1-(3-trifluoromethylphenyl)ethylideneamino-oxymethyl]phenyl}acetic acid] (CGA321113), expressed as trifloxystrobin.

The residue is fat-soluble.

| CCN     | Commodity Name                             | MRL, mg/kg |          | STMR or STMR-P, mg/kg |
|---------|--------------------------------------------|------------|----------|-----------------------|
|         |                                            | New        | Previous |                       |
| AM 0660 | Almond hulls <sup>1</sup>                  | 3          |          |                       |
| DF 0226 | Apples, dried                              |            |          | 0.043                 |
| JF 0226 | Apple juice                                |            |          | 0.018                 |
|         | Apple sauce                                |            |          | 0.053                 |
|         | Apple preserve                             |            |          | 0.053                 |
|         | Apricot, canned                            |            |          | 0.019                 |
| FI 0327 | Banana                                     | 0.05       |          | 0.02                  |
| GC 0640 | Barley                                     | 0.5        |          | 0.04                  |
| AS 0640 | Barley straw and fodder (dry) <sup>1</sup> | 7          |          |                       |
|         | Beer (residue arising from hops)           |            |          | 0.01                  |
| VB 0402 | Brussels sprouts                           | 0.5        |          | 0.17                  |
| VR 0577 | Carrot                                     | 0.1        |          | 0.035                 |
| VB 0041 | Cabbages, Head                             | 0.5        |          | 0.17                  |
| VS 0624 | Celery                                     | 1          |          | 0.18                  |
| FC 0001 | Citrus fruits <sup>2</sup>                 | 0.5        |          | 0.095                 |

| CCN     | Commodity Name                                | MRL, mg/kg    |          | STMR or STMR-P, mg/kg     |
|---------|-----------------------------------------------|---------------|----------|---------------------------|
|         |                                               | New           | Previous |                           |
| JF 0001 | Citrus juice                                  |               |          | 0.018                     |
| AB 0001 | Citrus pulp, dry <sup>1</sup>                 | 1             |          |                           |
|         | Citrus oil (orange)                           |               |          | 12                        |
| DF 0269 | Dried grapes (Raisins)                        | 5             |          | 0.345                     |
| PE 0112 | Eggs                                          | 0.04(*)       |          | 0                         |
| VB 0042 | Flowerhead brassicas                          | 0.5           |          | 0.17                      |
| VC 0045 | Fruiting vegetables, Cucurbits                | 0.3           |          | 0.095                     |
| FB 0269 | Grapes                                        | 3             |          | 0.15                      |
| JF 0269 | Grape juice                                   |               |          | 0.036                     |
|         | Must                                          |               |          | 0.07                      |
|         | Wine                                          |               |          | 0.023                     |
| DH 1100 | Hops, dry                                     | 40            |          | 9.95                      |
| MO 0098 | Kidney of cattle, goats, pig and sheep        | 0.04(*)       |          | 0.004                     |
| VA 0384 | Leek                                          | 0.7           |          | 0.31                      |
| MO 0099 | Liver of cattle, goats, pig and sheep         | 0.05          |          | 0.008                     |
| GC 0645 | Maize                                         | 0.02          |          | 0.02                      |
| AS 0645 | Maize fodder <sup>1</sup>                     | 10            |          |                           |
| MM 0095 | Meat (from mammals other than marine mammals) | 0.05 (fat)    |          | 0.006 (fat)<br>0 (muscle) |
| ML0106  | Milks                                         | 0.02(*)       |          | 0                         |
|         | Nectarine, canned                             |               |          | 0.019                     |
|         | Peach, canned                                 |               |          | 0.019                     |
| SO 0697 | Peanut                                        | 0.02*         |          | 0                         |
| AL 0697 | Peanut fodder <sup>1</sup>                    | 5             |          |                           |
|         | Pears, dried                                  |               |          | 0.043                     |
|         | Pear juice                                    |               |          | 0.018                     |
|         | Pear preserve                                 |               |          | 0.053                     |
| VO 0445 | Peppers, Sweet                                | 0.3           |          | 0.1                       |
| FP 0009 | Pome fruits                                   | 0.7           |          | 0.11                      |
| VR 0589 | Potato                                        | 0.02(*)       |          | 0.02                      |
|         | Potato chips                                  |               |          | 0.008                     |
|         | Potato flakes                                 |               |          | 0.008                     |
| PM 0110 | Poultry meat                                  | 0.04(*) (fat) |          | 0 (fat) 0 (muscle)        |
| PO 0111 | Poultry, Edible offal of                      | 0.04(*)       |          | 0                         |
|         | Prunes, dried                                 |               |          | 0.57                      |
| GC 0649 | Rice                                          | 5             |          | 0.16                      |
| CM 1205 | Rice, polished                                |               |          | 0.029                     |
| CM 1206 | Rice bran, unprocessed <sup>1</sup>           | 7             |          | 0.25                      |
| AS 0649 | Rice straw and fodder, dry <sup>1</sup>       | 10            |          |                           |
| FS 0012 | Stone fruits                                  | 3             |          | 0.38                      |
| FB 0275 | Strawberry                                    | 0.2           |          | 0.1                       |
|         | Strawberry, canned                            |               |          | 0.029                     |
|         | Strawberry jam                                |               |          | 0.062                     |
| VR 0596 | Sugar beet                                    | 0.05          |          | 0.02                      |
|         | White sugar                                   |               |          | 0.0036                    |
| AB 0596 | Sugar beet pulp, dry <sup>1</sup>             | 0.2           |          |                           |
| DM 0596 | Sugar beet molasses <sup>1</sup>              | 0.1           |          |                           |
| AM 0596 | Sugar beet leaves or tops <sup>1</sup>        | 15            |          |                           |
| VO0448  | Tomato                                        | 0.7           |          | 0.08                      |
|         | Tomato paste                                  |               |          | 0.13                      |
|         | Tomato purée                                  |               |          | 0.045                     |
| TN 0085 | Tree nuts                                     | 0.02(*)       |          | 0                         |
| GC 0654 | Wheat                                         | 0.2           |          | 0.02                      |
| CM 0654 | Wheat bran, unprocessed <sup>1</sup>          | 0.5           |          | 0.062                     |
| CF 1211 | Wheat flour                                   |               |          | 0.008                     |
| CF 1210 | Wheat germ                                    |               |          | 0.013                     |
| CF 1212 | Wheat wholemeal                               |               |          | 0.01                      |
| CP 1212 | Wheat wholemeal bread                         |               |          | 0.005                     |
| AS 0654 | Wheat straw and fodder, dry <sup>1</sup>      | 5             |          |                           |

<sup>1</sup>Expressed on dry weight basis<sup>2</sup>STMR, STMR-P based on whole fruit residue data

## DIETARY RISK ASSESSMENT

### *Long-term intake*

The IEDIs of trifloxystrobin, on the basis of the STMRs estimated for 37 commodities, for the five GEMS/Food regional diets represented 1–2% of the ADI (Annex 3). The Meeting concluded that the long-term intake of residues of trifloxystrobin resulting from uses that have been considered by the JMPR is unlikely to present a public health concern.

### *Short-term intake*

The 2004 JMPR decided that it was unnecessary to establish an ArfD. The present Meeting therefore concluded that the short-term intake of trifloxystrobin residues is unlikely to present a public health concern.

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### 5.31 TRIFLOXYSTROBIN (213)

#### RESIDUE AND ANALYTICAL ASPECTS

Trifloxystrobin was first evaluated for toxicology and residues by the JMPR in 2004. The Meeting derived an ADI of 0.04 mg/kg bw per day and decided that an ARfD is unnecessary. Maximum residue levels, STMRs and STMR-Ps for 73 commodities or commodity groups were estimated.

In 2004 the Meeting agreed that the residue definition for enforcement purposes for plant commodities should be trifloxystrobin *per se*. For enforcement of animal commodities and for consideration of dietary intake of plant or animal commodities the residue definition should be parent compound and (*E,E*)-methoxyimino-2-[1-(3-trifluoromethyl-phenyl) ethylideneaminooxymethyl]-phenyl}acetic acid) (expressed as trifloxystrobin equivalents). The metabolite is also known as CGA 321113.

The compound was listed by the Forty-third Session of the CCPR for the review of additional MRLs. The 2012 JMPR received residue data for strawberries, papaya, olives, tomato, lettuce, radish and asparagus.

#### *Methods of analysis*

The Meeting received information on analytical methods used for the determination of trifloxystrobin residues and its acid metabolite CGA 321113 in samples derived from supervised trials on asparagus, lettuce, olives, papaya, radish, strawberry and tomatoes. The residues were determined by LC-MS/MS or GC-MS/MS with LOQs of 0.01–0.02 mg/kg.

The freezer storage stability studies carried out with asparagus and papaya showed that the trifloxystrobin residues and the metabolite CGA 321113 were stable for the longest period for which the samples were stored at or below -15 °C. The studies reported by the 2004 JMPR cover the other sample materials evaluated by the present Meeting.

#### *Results of supervised residue trials on crops*

The OECD calculator was used as a tool in the estimation of the maximum residue level from the selected residue data set obtained from trials conducted according to GAP. As a first step, the Meeting reviewed all relevant factors related to each data set in arriving at a best estimate of the maximum residue level using expert judgment. Then, the OECD calculator was employed. If the statistical calculation spreadsheet suggested a different value from that recommended by the JMPR, a brief explanation of the deviation was provided.

#### *Strawberry*

Based on the Swiss GAP (3 × 0.25 kg ai/ha, PHI 14 days) and five European supervised trials, the 2004 JMPR estimated a maximum residue level of 0.2 mg/kg and an STMR of 0.1 mg/kg.

The 2012 Meeting received additional residue data from the USA and Australia. The Australian trials were carried out with 3 × 0.2 kg ai/ha and did not match the GAP (3 × 0.15 kg ai/ha, PHI 1 day). The registered GAP in the USA is 6 × 0.11 kg ai/ha and a 0-day PHI. In eight trials matching GAP conditions, the residue levels of trifloxystrobin *per se* were (n=8): 0.10, 0.19, 0.20, 0.28, 0.30, 0.44, 0.47 and 0.50 mg/kg. The residue concentrations of the sum of trifloxystrobin and CGA 321113 were: 0.23, 0.23, 0.27, 0.31, 0.36, 0.47, 0.51 and 0.56 mg/kg.

The Meeting estimated a maximum residue level of 1 mg/kg and an STMR of 0.335 mg/kg for trifloxystrobin in strawberries to replace the former recommendation.

*Olives*

The Spanish GAP is  $2 \times 0.005$  kg ai/hL and a PHI of 14 days. The first application is recommended in spring, the second in autumn. Eight trials conducted in Southern Europe with one treatment of 0.005 kg ai/hL in autumn and a PHI of 14 days showed residues of trifloxystrobin *per se* of 0.04, 0.05, 0.07, 0.07, 0.10, 0.11, 0.12 and 0.13 mg/kg. In four Southern European trials with two applications (one in spring and one in autumn with 0.006 kg ai/hL, spraying interval of 71–99 days between the two treatments), the residue levels of trifloxystrobin *per se* were 0.02, 0.04, 0.10 and 0.13 mg/kg. The Meeting noticed that the first spray treatment did not influence the residue concentration and decided to combine the two datasets. The trifloxystrobin residues (n=12) were: 0.02, 0.04, 0.04, 0.05, 0.07, 0.07, 0.10, 0.10, 0.11, 0.12, 0.13 and 0.13 mg/kg.

Because the residues of CGA 321113 were below the LOQ, for estimation of STMR (sum of parent and CGA 321113), the trifloxystrobin data were used.

The Meeting estimated a maximum residue level of 0.3 mg/kg and an STMR of 0.085 mg/kg for trifloxystrobin in olives.

*Papaya*

The GAP in the USA is maximal four foliar applications of 0.14 kg ai/ha at a maximal seasonal rate of 0.56 kg ai/ha and a PHI of 0 days. Four trials were conducted on papaya in the USA in 2003 with foliar treatment by  $4 \times 0.14$ –0.15 kg ai/ha, PHI 0 days. The trifloxystrobin residues were 0.07, 0.15, 0.22 and 0.27 mg/kg. The residue concentrations of the sum of trifloxystrobin and CGA 321113 were: 0.07, 0.15, 0.25 and 0.31 mg/kg.

The Meeting estimated a maximum residue level of 0.6 mg/kg and an STMR of 0.2 mg/kg for trifloxystrobin in papaya.

*Brussels sprouts*

The 2004 JMPR estimated a maximum residue level of 0.5 mg/kg and a STMR of 0.17 mg/kg for residues of trifloxystrobin in flowerhead brassica, Brussels sprouts and head cabbage but in the CCPR reports, a CXL of 0.1 mg/kg was listed for Brussels sprouts. The company requested a clarification. No new data were submitted.

The current Meeting noted that the value of 0.1 mg/kg as CXL for Brussels sprouts is an administrative error in the Codex System. The MRL recommendation made by the 2004 JMPR was 0.5 mg/kg.

*Tomatoes*

Based on the US GAP ( $4 \times 0.14$  kg ai/ha, PHI 3 days) and 18 supervised trials, the 2004 JMPR estimated a maximum residue level of 0.7 mg/kg and an STMR of 0.08 mg/kg.

The 2012 JMPR received six further US outdoor trials according to US GAP. The residue concentrations of the sum of trifloxystrobin and CGA 321113 were: 0.03, 0.04, 0.06, 0.06, 0.09 and 0.11 mg/kg.

The Meeting agreed that a new recommendation for trifloxystrobin on tomatoes based on the data submitted to the 2012 JMPR was not necessary. Therefore, the previous recommendations for a maximum residue level and STMR were maintained.

*Egg plant*

The US GAP of trifloxystrobin on eggplant is  $5 \times 0.07$ –0.14 kg ai/ha at a maximum of 0.56 kg ai/ha per season and a 3 day PHI, the same GAP is registered for tomatoes.

The Meeting agreed to extrapolate from tomato to eggplant and recommended a maximum residue level of 0.7 mg/kg and an STMR of 0.08 mg/kg for trifloxystrobin in egg plant.

*Lettuce, head*

The GAP for greenhouse grown lettuce is in the Netherlands  $3 \times 0.2$  kg ai/ha and a PHI of 7 days. Eight indoor European trials (France (2), Germany (2), Italy (2), Portugal (1), the Netherlands (1)) treated with  $3 \times 0.25$  kg ai/ha were received.

In eight trials on head lettuce matching the GAP conditions of the Netherlands (application rate +25 %), the residue levels of trifloxystrobin *per se* were: 2.4, 2.5, 2.7, 5.4, 5.6, 5.7, 6.6 and 7.2 mg/kg. The residue concentrations of the sum of trifloxystrobin and CGA 321113 were: 2.4, 2.7, 2.7, 5.4, 5.7, 5.8, 6.7 and 7.2 mg/kg.

The Meeting estimated a maximum residue level of 15 mg/kg and an STMR of 5.55 mg/kg for trifloxystrobin in lettuce, head.

*Radish leaves (including Radish tops)*

The registered GAP on radish in the USA is  $4 \times 0.07$ – $0.14$  kg ai/ha at a maximal rate of 0.28 kg ai/ha per year and a PHI of 7 days. Six field trials were conducted with  $2 \times 0.14$ – $0.15$  kg ai/ha and a PHI of 6–8 days.

In radish tops, the residue levels of trifloxystrobin *per se* were: 0.07, 0.22, 0.26, 2.3, 5.3 and 6.8 mg/kg. The residue concentrations of the sum of trifloxystrobin and CGA 321113 were: 0.13, 0.32, 0.37, 2.4, 5.4 and 7.2 mg/kg.

The Meeting estimated a maximum residue level of 15 mg/kg and an STMR of 1.4 mg/kg for trifloxystrobin in radish leaves.

*Radish*

The registered GAP on radish in the USA is  $4 \times 0.07$ – $0.14$  kg ai/ha at a maximal rate of 0.28 kg ai/ha per year and a PHI of 7 days. Six field trials were conducted with  $2 \times 0.14$ – $0.15$  kg ai/ha and a PHI of 6–8 days.

In radish roots, the residue levels of trifloxystrobin *per se* were: < 0.02 (3), 0.03, 0.04 and 0.05 mg/kg. The residue concentrations of the sum of trifloxystrobin and CGA 321113 were: < 0.02, 0.06, 0.06 and 0.07 (3) mg/kg.

The Meeting estimated a maximum residue level of 0.08 mg/kg and an STMR of 0.065 mg/kg for trifloxystrobin in radish.

*Asparagus*

The GAP in the USA is  $3 \times 0.11$ – $0.14$  kg ai/ha at a maximal seasonal rate of 0.42 kg ai/ha and a PHI of 180 days (California 90 days). Seven trials were conducted on asparagus in the USA in 2002 with foliar treatment by  $3 \times 0.14$ – $0.15$  kg ai/ha and PHIs of 92–188 days. In the sprouts, neither residues of trifloxystrobin (< 0.05 mg/kg) nor the metabolite CGA 321113 (< 0.02 mg/kg) were detected.

The Meeting estimated a maximum residue level of 0.05\* mg/kg and an STMR of 0 for trifloxystrobin in asparagus.

***Fate of residues during processing***

The effect of processing on the level of residues of trifloxystrobin and the metabolite CGA 321113 has been studied for strawberries and olives. The processing factors (PF) were calculated from the total residue levels (sum of trifloxystrobin and CGA 321113). The best estimates of the processing factors are shown below. Processes included in the table are those that lead to STMR-P values useful for dietary intake estimations.

| Raw agricultural commodity (RAC) | Processed commodity  | Best estimate processing factor (PF) | RAC STMR | STMR-P |
|----------------------------------|----------------------|--------------------------------------|----------|--------|
| Strawberry                       | Strawberry jam       | 0.58                                 | 0.335    | 0.194  |
|                                  | Strawberry preserves | 0.29                                 |          | 0.097  |

| Raw agricultural commodity (RAC) | Processed commodity | Best estimate processing factor (PF) | RAC STMR | STMR-P |
|----------------------------------|---------------------|--------------------------------------|----------|--------|
| Olives                           | Olive oil, crude    | 3                                    | 0.085    | 0.255  |
|                                  | Olive oil, refined  | 4.15                                 |          | 0.353  |

The Meeting estimated the following STMR-P values: 0.194 mg/kg for strawberry jam, 0.097 mg/kg for strawberry, canned, 0.255 mg/kg for olive oil, crude and 0.353 for olive oil, refined.

A maximum residue level for the processed commodity will only be recommended if the resulting residue value is higher than the maximum residue level proposed for the corresponding RAC. Because of the fact that the PF is >1 for olive oils and the oils are commodities in trade, maximum residue levels were proposed for olive oil, crude and olive oil, refined.

The Meeting estimated a maximum residue level for olive oil, crude of 0.9 mg/kg and for olive oil, refined of 1.2 mg/kg.

#### ***Residues in animal commodities***

As the commodities evaluated by the 2012 JMPR are not included in the OECD farm animal feeding table, there is no need to re-calculate the farm animal dietary burden.

The Meeting concluded that a re-evaluation of the maximum residue levels for animal commodities was not necessary.

### **DIETARY RISK ASSESSMENT**

#### ***Long-term intake***

The International Estimated Daily Intakes (IEDIs) of trifloxystrobin were calculated for the 13 GEMS/Food cluster diets using STMRs and STMR-Ps estimated by the JMPR in 2004 and 2012. The results are shown in Annex 3.

The ADI is 0–0.04 mg/kg bw and the calculated IEDIs were 1–5 % of the maximum ADI. The Meeting concluded that the long-term intake of residues of trifloxystrobin from the uses considered by the JMPR is unlikely to present a public health concern.

#### ***Short-term intake***

The 2004 JMPR decided that it was unnecessary to establish an ARfD. The present Meeting therefore concluded that the short-term intake of trifloxystrobin residues is unlikely to present a public health concern.



**TRIFLOXYSTROBIN (213)**

*The first draft was prepared by Dr U Banasiak, Federal Institute for Risk Assessment, Berlin, Germany*

**EXPLANATION**

Trifloxystrobin was first evaluated for toxicology and residues by the JMPR in 2004. The Meeting derived an ADI of 0–0.04 mg/kg bw per day and decided that an ARfD is unnecessary. Maximum residue levels, STMRs and STMR-Ps for 73 commodities or commodity groups were estimated.

In 2004 the Meeting agreed that the residue definition for enforcement purposes for plant commodities should be trifloxystrobin per se, and that for animal commodities the residue definition should be parent compound and CGA 321113 (expressed as trifloxystrobin equivalents). The Meeting agreed that the residue definition for consideration of dietary intake should consist of the parent compound and CGA 321113 (expressed as trifloxystrobin equivalents).

The compound was listed by the Forty-third Session of the CCPR for the review of additional MRLs. The 2012 JMPR received residue data for strawberries, papaya, olives, tomato, lettuce, radish and asparagus. A re-consideration of the CXL of Brussels sprouts was requested by the company.

**RESIDUE ANALYSIS*****Analytical methods***

The Meeting received information on analytical methods for trifloxystrobin residues and its acid metabolite CGA 321113 in plant materials. Some of the methods were evaluated by the 2004 JMPR (de Haan, 2002, Report No 200177; Nuesslein, 2002, method No 00742, Report No MR -078/02; Nuesslein, 2003, method No 00742/E001, Report No MR -052/03). New submitted methods are briefly described below. The recoveries are summarised in Table 1.

Method: 00742/M001

Reference: MR-050/04, Edition No M-246806-01-1

Commodity: Olive fruit, oil, pomace

Analyte: Trifloxystrobin, CGA 321113

LOQ: 0.02 mg/kg

Determination: HPLC-MS/MS

Description: Samples are extracted with acetonitrile/water. The extract is purified by liquid-liquid partition on ChemElut cartridge, thereby partitioning the analytes in a mixture of cyclohexane/ethyl acetate. The modification consists of use of stable isotopically labelled internal standard. The residues are quantified by reversed-phase HPLC with Turbo-Ionspray MS/MS-detection.

Method: 01013

Reference: MR-06/138, Edition No M-283439-03-1

Commodity: Citrus fruit, pea green seed, wheat grain, rape seed, maize green material

Analyte: Trifloxystrobin, CGA 321113

LOQ: 0.01 mg/kg

Determination: HPLC-MS/MS

Description: Samples are extracted with acetonitrile/water. After filtration of the extract, the stable isotopically labelled analytes were added. The solution was made up to volume, diluted and subjected to reverse phase HPLC-MS/MS without a further clean-up step.

*Method:* ATM-0001.03/04

*Reference:* ATM-0001.03, ATM-0001.04

*Commodity:* Strawberry

*Analyte:* Trifloxystrobin, CGA 321113

*LOQ:* 0.01 mg/kg, recoveries were not reported

*Determination:* GC-MS/MS

*Description:* Samples are extracted with acetonitrile/water (80:20 v/v). After cleaning with dichloromethane and water and a C18 solid phase extraction column with acetonitrile, the quantitation of residues was performed by GC-MS/MS.

*Method:* Batelle Study No N105501

*Reference:* RATFY012 Analytical Report, Batelle Study No N105501

*Commodity:* Strawberry

*Analyte:* Trifloxystrobin, CGA 321113

*LOQ:* 0.01 mg/kg

*Determination:* LC-MS/MS

*Description:* Samples are extracted with acetonitrile/water (4:1, v/v). After cleaning with 0.1% formic acid in water and a C18 solid phase extraction column with acetonitrile, the quantitation of residues was performed by HPLC-electrospray ionisation/tandem mass spectrometry.

Table 1 Recoveries of trifloxystrobin and CGA 321113

| Analyte         | Matrix               | Fortification (mg/kg) | n | Recovery mean (%) | RSD (%) | Reference                               |
|-----------------|----------------------|-----------------------|---|-------------------|---------|-----------------------------------------|
| Trifloxystrobin | Citrus fruit         | 0.01                  | 5 | 100               | 2.4     | MR-06/138                               |
|                 |                      | 0.1                   | 5 | 97                | 4.3     |                                         |
|                 | Olive fruit          | 0.02                  | 5 | 80                | 7.1     | MR-50/04                                |
|                 |                      | 0.2                   | 5 | 89                | 2.4     |                                         |
|                 |                      | 2.0                   | 3 | 86                | 1.8     |                                         |
|                 | Olive oil            | 0.02                  | 3 | 90                | 7.3     | MR-50/04                                |
|                 |                      | 0.2                   | 3 | 90                | 4.6     |                                         |
|                 | Olive pomace         | 0.02                  | 3 | 87                | 4.3     | MR-50/04                                |
|                 |                      | 0.2                   | 3 | 91                | 1.1     |                                         |
|                 |                      | 2.0                   | 3 | 86                | 2.9     |                                         |
|                 | Peas fruit           | 0.01                  | 5 | 100               | 3.1     | MR-06/138                               |
|                 |                      | 0.1                   | 5 | 100               | 3.4     |                                         |
|                 | Rape seed            | 0.01                  | 5 | 101               | 3.6     | MR-06/138                               |
|                 |                      | 0.1                   | 5 | 98                | 3.5     |                                         |
|                 | Strawberries         | 0.01                  | 8 | 94                | 9.4     | RATFY012<br>Batelle Study No<br>N105501 |
|                 |                      | 0.048                 | 2 | 99                |         |                                         |
|                 |                      | 0.193                 | 2 | 91                |         |                                         |
|                 |                      | 0.579                 | 3 | 81                | 1.3     |                                         |
|                 | Wheat grain          | 0.01                  | 5 | 99                | 4.0     | MR-06/138                               |
|                 |                      | 0.1                   | 5 | 98                | 2.3     |                                         |
|                 | Maize green material | 0.01                  | 5 | 108               | 5.1     | MR-06/138                               |
|                 |                      | 0.1                   | 5 | 101               | 4.4     |                                         |
| CGA 321113      | Citrus fruit         | 0.01                  | 5 | 103               | 12.3    | MR-06/138                               |
|                 |                      | 0.1                   | 5 | 101               | 4.3     |                                         |
|                 | Olive fruit          | 0.02                  | 5 | 84                | 6.0     | MR-50/04                                |
|                 |                      | 0.2                   | 5 | 93                | 2.1     |                                         |
|                 |                      | 2.0                   | 3 | 91                | 1.9     |                                         |
|                 | Olive oil            | 0.02                  | 3 | 85                | 3.6     | MR-50/04                                |
|                 |                      | 0.2                   | 3 | 83                | 5.0     |                                         |
|                 | Olive pomace         | 0.02                  | 3 | 76                | 3.9     | MR-50/04                                |
|                 |                      | 0.2                   | 3 | 85                | 4.8     |                                         |
|                 |                      | 2.0                   | 3 | 79                | 6.3     |                                         |

| Analyte | Matrix               | Fortification (mg/kg) | n | Recovery mean (%) | RSD (%) | Reference                               |
|---------|----------------------|-----------------------|---|-------------------|---------|-----------------------------------------|
|         | Peas fruit           | 0.01                  | 5 | 99                | 5.8     | MR-06/138                               |
|         |                      | 0.1                   | 5 | 102               | 3.7     |                                         |
|         | Rape seed            | 0.01                  | 5 | 102               | 6.6     | MR-06/138                               |
|         |                      | 0.1                   | 5 | 104               | 5.0     |                                         |
|         | Strawberries         | 0.01                  | 8 | 83                | 8.0     | RATFY012<br>Batelle Study No<br>N105501 |
|         |                      | 0.05                  | 2 | 91                |         |                                         |
|         |                      | 0.2                   | 2 | 91                |         |                                         |
|         |                      | 0.6                   | 3 | 81                |         |                                         |
|         | Wheat grain          | 0.01                  | 5 | 77                | 3.3     | MR-06/138                               |
|         |                      | 0.1                   | 5 | 98                | 2.8     |                                         |
|         | Maize green material | 0.01                  | 5 | 104               | 8.4     | MR-06/138                               |
|         |                      | 0.1                   | 5 | 85                | 4.5     |                                         |

### *Stability of residues in stored analytical samples*

Storage stability studies were conducted with trifloxystrobin in various plant materials. Results show that no significant decrease of residues was observed after the tested period of 18 or 24 months. Thus the residues of trifloxystrobin and CGA 321113 are stable under freezer storage conditions for at least 24 months (grape fruit, cucumber fruit, potato, and wheat grain, straw and whole plant) or 18 months (apple fruit, apple wet pomace, peanut nutmeat, peanut oil, and grape juice). Hence, the results of storage stability studies validate the results from the residue trials with respect to the stability of trifloxystrobin and CGA 321113 in frozen samples. Individual data on storage stability and the reports were reported by JMPR in 2004.

New storage stability data at temperatures of -15 to -27 °C were submitted for papaya and asparagus. The data are summarised in Table 2.

Table 2 Storage stability data for papaya and asparagus

| Matrix    | Analyte         | Fortification level (mg/kg) | Residues remaining (mg/kg) (%) |     | Storage (days) | Study No          |
|-----------|-----------------|-----------------------------|--------------------------------|-----|----------------|-------------------|
| Papaya    | Trifloxystrobin | 2.05                        | 2.27                           | 111 | 553            | IR-4-PR No. 07973 |
|           |                 | 2.06                        | 2.00                           | 97  | 553            |                   |
|           |                 | 2.06                        | 2.09                           | 101 | 553            |                   |
|           | CGA 321113      | 2.01                        | 2.33                           | 116 | 553            |                   |
|           |                 | 2.02                        | 1.99                           | 99  | 553            |                   |
|           |                 | 2.02                        | 2.13                           | 106 | 553            |                   |
| Asparagus | Trifloxystrobin | 0.2                         | 0.23                           | 115 | 203            | IR-4 PR No. 08212 |
|           |                 | 0.2                         | 0.24                           | 120 | 203            |                   |
|           |                 | 0.2                         | 0.22                           | 110 | 204            |                   |
|           | CGA 321113      | 0.2                         | 0.20                           | 100 | 203            |                   |
|           |                 | 0.2                         | 0.21                           | 105 | 203            |                   |
|           |                 | 0.2                         | 0.19                           | 95  | 204            |                   |

## USE PATTERN

The information available to the 2012 JMPR on registered uses of trifloxystrobin is summarised in Table 3. Copies of labels were made available to the Meeting.

Table 3 Registered uses of trifloxystrobin.

| Crop      | Country | Form  | Method | F/G | Remarks                                                  | Application |          |           | PHI, days |
|-----------|---------|-------|--------|-----|----------------------------------------------------------|-------------|----------|-----------|-----------|
|           |         |       |        |     |                                                          | No          | kg ai/hL | kg ai/ha  |           |
| Asparagus | USA     | WG 50 | foliar | F   | PHI 90 days for California, max 0.42 kg ai/ha per season | 3           |          | 0.11–0.14 | 90/180    |
| Egg plant | USA     | WG 50 | foliar | F/G | max 0.56 kg ai/ha                                        | 5           |          | 0.07–0.14 | 3         |

| Crop       | Country     | Form  | Method | F/G | Remarks                                                   | Application |          |            | PHI, days |
|------------|-------------|-------|--------|-----|-----------------------------------------------------------|-------------|----------|------------|-----------|
|            |             |       |        |     |                                                           | No          | kg ai/hL | kg ai/ha   |           |
|            |             |       |        |     | per season, e.g. 4 × 0.14 kg ai/ha                        |             |          |            |           |
| Lettuce    | Netherlands | WG 50 | foliar | G   |                                                           | 3           |          | 0.2        | 7         |
|            | Switzerland | WG 50 | foliar | F   |                                                           | 3           |          | 0.125–0.25 | 14        |
|            | Switzerland | WG 50 | foliar | G   |                                                           | 3           |          | 0.125–0.25 | 21        |
| Olives     | Spain       | WG 50 | foliar | F   | 1 <sup>st</sup> app. in spring, 2 <sup>nd</sup> in autumn | 2           | 0.005    |            | 14        |
| Papaya     | USA         | WG 50 | foliar | F   | max. 0.56 kg ai/ha per season                             | 4           |          | 0.14       | 0         |
| Radish     | USA         | WG 50 | foliar | F   | max. 0.28 kg ai/ha per year                               | 4           |          | 0.07–0.14  | 7         |
| Strawberry | Australia   | WG 50 | foliar |     |                                                           | 3           |          | 0.1–0.15   | 1         |
|            | Netherlands | WG 50 | foliar |     |                                                           | 3           |          | 0.0625     | 3         |
|            | Switzerland | WG 50 | foliar |     |                                                           | 3           | 0.025    | 0.25       | 14        |
|            | USA         | WG 50 | foliar |     |                                                           | 6           |          | 0.07–0.112 | 0         |
| Tomato     | USA         | WG 50 | foliar | F/G | max 0.56 kg ai/ha per season, e.g. 4 × 0.14 kg ai/ha      | 5           |          | 0.07–0.14  | 3         |

## RESIDUES RESULTING FROM SUPERVISED TRIALS ON CROPS

The Meeting received information on supervised field trials for trifloxystrobin uses that produced residues in the following commodities.

| Commodity      | Codex No | Group                                                    | Table No |
|----------------|----------|----------------------------------------------------------|----------|
| Strawberry     | FB 0275  | Berries and other small fruits                           | 4        |
| Olives         | FT 0305  | Assorted tropical and sub-tropical fruit – edible peel   | 5        |
| Papaya         | FI 0350  | Assorted tropical and sub-tropical fruit – inedible peel | 6        |
| Tomatoes       | VO 0448  | Fruiting vegetables, other than cucurbits                | 7        |
| Lettuce, head  | VL 0482  | Leafy vegetables                                         | 8        |
| Radish, leaves | VL 0494  |                                                          | 9        |
| Radish         | VR 0494  | Root and tuber vegetables                                | 10       |
| Asparagus      | VS 0621  | Stalk and stem vegetables                                | 11       |

Trials were well documented with laboratory and field reports. Laboratory reports included method validation with procedural recoveries from spiking at residue levels similar to those occurring in samples from the supervised trials. Dates of analysis or duration of residue sample storage were also provided. Undetected residues were generally reported lower than the LOQ.

The corresponding data on the parent compound (molecular mass 408) and the trifloxystrobin acid CGA321113 (molecular mass 394) are reported. The use of a conversion factor (1.036) is not necessary for calculation of total residues. The sum of trifloxystrobin and CGA 321113 was calculated according to the procedure described by 2004 JMPR: As CGA 321113 does not generally constitute a significant portion of the residues in crops, when the levels of trifloxystrobin or CGA 321113 were below the LOQ, their sum was calculated as the examples below.

| <i>Trifloxystrobin (mg/kg)</i> | <i>CGA 321113 (mg/kg)</i> | <i>Total (mg/kg)</i> |
|--------------------------------|---------------------------|----------------------|
| < 0.02                         | < 0.02                    | < 0.02               |
| < 0.02                         | 0.03                      | 0.05                 |
| 0.10                           | < 0.02                    | 0.10                 |
| 0.92                           | 0.16                      | 1.08                 |

Residue values from the trials conducted according to maximum GAP have been used for the estimation of maximum residue levels. Those results included in the evaluation are underlined. If two field samples were taken or results of two replicate plots were submitted, the mean value was calculated for trifloxystrobin and the total residue only for trials according to GAP.

### Strawberry

The use of trifloxystrobin in strawberry is registered in Australia, the USA, Switzerland, the Netherlands, and other countries. The Swiss use pattern and corresponding residue trials were previously submitted in 2004 and resulted in the establishment of a Codex MRL of 0.2 mg/kg. The Australian and the US uses required a revision of that Codex MRL. Residue data are summarised below. The majority of the Australian trials were carried out with two replicated plots per treatment. Additionally, further replicates were conducted with different spray concentrations. In cases of replicates with the same application rate but different spray concentration, the highest residue value was used for the evaluation.

Table 4 Trifloxystrobin residues in strawberries

| Country, year, location, (variety)          | Application |    |          |          | Residues in mg/kg |                 |            |       | Report No. Study No. Remarks                                       |
|---------------------------------------------|-------------|----|----------|----------|-------------------|-----------------|------------|-------|--------------------------------------------------------------------|
|                                             | Form        | No | kg ai/ha | kg ai/hL | PHI (days)        | Trifloxystrobin | CGA 321113 | Total |                                                                    |
| Australia, 2002<br>Bli Bli, QLD (Adina)     | WG          | 3  | 0.2      | 0.044    | 0 <sup>a</sup>    | 0.38            |            |       | BCS-0001<br>AUS-BCS-0001-A1<br><br>No GLP<br><br>2 replicate plots |
|                                             |             |    |          |          | 0                 | 0.90            | 0.08       |       |                                                                    |
|                                             |             |    |          |          | 0                 | 0.73            | 0.07       |       |                                                                    |
|                                             |             |    |          |          | 1                 | 0.67            | 0.10       | 0.77  |                                                                    |
|                                             |             |    |          |          | 1                 | 0.47            | 0.03       | 0.50  |                                                                    |
|                                             |             |    |          |          | 3                 | 0.19            | 0.08       |       |                                                                    |
|                                             |             |    |          |          | 3                 | 0.38            | 0.10       |       |                                                                    |
|                                             |             |    |          |          |                   |                 |            |       |                                                                    |
|                                             | WG          | 3  | 0.21     | 0.02     | 0 <sup>a</sup>    | 0.46            | 0.17       |       | BCS-0001<br>AUS-BCS-0001-B1<br><br>No GLP<br><br>2 replicate plots |
|                                             |             |    |          |          | 0 <sup>a</sup>    | 0.50            | 0.19       |       |                                                                    |
|                                             |             |    |          |          | 0                 | 0.66            | 0.05       |       |                                                                    |
|                                             |             |    |          |          | 0                 | 0.32            | 0.06       |       |                                                                    |
|                                             |             |    |          |          | 1                 | 0.92            | 0.14       |       |                                                                    |
|                                             |             |    |          |          | 1                 | 0.73            | 0.18       | 1.06  |                                                                    |
|                                             |             |    |          |          | 3                 | 0.41            | 0.08       | 0.91  |                                                                    |
|                                             |             |    |          |          | 3                 | 0.40            | 0.17       |       |                                                                    |
| Australia, 2002<br>Bli Bli, QLD (Camarossa) | WG          | 3  | 0.2      | 0.044    | 0 <sup>a</sup>    | 0.16            | 0.02       |       | BCS-0002<br>AUS-BCS-0002-A1<br><br>No GLP<br><br>2 replicate plots |
|                                             |             |    |          |          | 0 <sup>a</sup>    | 0.17            | 0.02       |       |                                                                    |
|                                             |             |    |          |          | 0                 | 0.29            | 0.02       |       |                                                                    |
|                                             |             |    |          |          | 0                 | 0.35            | 0.02       |       |                                                                    |
|                                             |             |    |          |          | 1                 | 0.28            | 0.02       |       |                                                                    |
|                                             |             |    |          |          | 1                 | 0.25            | 0.01       | 0.30  |                                                                    |
|                                             |             |    |          |          | 3                 | 0.06            | 0.01       | 0.26  |                                                                    |
|                                             |             |    |          |          | 3                 | 0.18            | 0.02       |       |                                                                    |
|                                             |             |    |          |          | 5                 | 0.20            | 0.02       |       |                                                                    |
|                                             |             |    |          |          | 5                 | 0.11            | 0.02       |       |                                                                    |
|                                             |             |    |          |          | 7                 | 0.14            | 0.03       |       |                                                                    |
|                                             |             |    |          |          | 7                 | 0.09            | 0.03       |       |                                                                    |
|                                             | WG          | 3  | 0.2–0.23 | 0.02     | 0 <sup>a</sup>    | 0.16            | 0.03       |       | BCS-0002<br>AUS-BCS-0002-B1<br><br>No GLP<br><br>2 replicate plots |
|                                             |             |    |          |          | 0 <sup>a</sup>    | 0.09            | 0.02       |       |                                                                    |
|                                             |             |    |          |          | 0                 | 0.21            | 0.02       |       |                                                                    |
|                                             |             |    |          |          | 0                 | 0.12            | 0.01       |       |                                                                    |
|                                             |             |    |          |          | 1                 | 0.25            | 0.02       |       |                                                                    |
|                                             |             |    |          |          | 1                 | 0.11            | 0.01       | 0.27  |                                                                    |
|                                             |             |    |          |          | 3                 | 0.18            | 0.02       | 0.12  |                                                                    |
|                                             |             |    |          |          | 3                 | 0.13            | 0.02       |       |                                                                    |
|                                             |             |    |          |          | 5                 | 0.19            | 0.03       |       |                                                                    |
|                                             |             |    |          |          | 5                 | 0.18            | 0.02       |       |                                                                    |
|                                             |             |    |          |          | 7                 | 0.19            | 0.04       |       |                                                                    |
|                                             |             |    |          |          | 7                 | 0.15            | 0.03       |       |                                                                    |
| Australia, 2002<br>Wamuran, QLD             | WG          | 3  | 0.2      | 0.033    | 0 <sup>a</sup>    | 0.07            | 0.06       |       | BCS-0003<br>AUS-BCS-0003-A1                                        |
|                                             |             |    |          |          | 0                 | 0.21            | 0.04       |       |                                                                    |
|                                             |             |    |          |          | 1                 | 0.13            | 0.07       | 0.20  |                                                                    |
|                                             |             |    |          |          | 3                 | 0.09            | 0.10       |       |                                                                    |

| Country, year, location, (variety)                 | Application |    |           |            | Residues in mg/kg                       |                                                                     |                                                          |       | Report No. Study No. Remarks                                                               |
|----------------------------------------------------|-------------|----|-----------|------------|-----------------------------------------|---------------------------------------------------------------------|----------------------------------------------------------|-------|--------------------------------------------------------------------------------------------|
|                                                    | Form        | No | kg ai/ha  | kg ai/hL   | PHI (days)                              | Trifloxystrobin                                                     | CGA 321113                                               | Total |                                                                                            |
| (Camarossa)                                        |             |    |           |            | 5<br>7                                  | 0.07<br>0.05                                                        | 0.07<br>0.08                                             |       |                                                                                            |
|                                                    | WG          | 3  | 0.2–0.29  | 0.02–0.029 | 0 <sup>a</sup><br>0<br>1<br>3<br>5<br>7 | 0.19<br>0.49<br>0.48<br>0.36<br>0.24<br>0.16                        | 0.11<br>0.11<br>0.14<br>0.16<br>0.20<br>0.18             | 0.62  | BCS-0003<br>AUS-BCS-0003-B1                                                                |
| Australia, 2002<br>Wamuran, QLD<br>(Sweet Charlie) | WG          | 3  | 0.2       | 0.033      | 0 <sup>a</sup><br>0<br>1<br>3<br>5<br>7 | 0.11<br>0.26<br>0.24<br>0.05<br>0.03<br>0.03                        | 0.10<br>0.08<br>0.10<br>0.08<br>0.08<br>0.07             | 0.34  | BCS-0004<br>AUS-BCS-0004-A1                                                                |
| Australia, 2002<br>Silvan, VIC (Selva)             | WG          | 3  | 0.2       | 0.043      | 0 <sup>a</sup><br>0<br>1<br>3<br>5<br>7 | 0.04<br>0.10<br>0.14<br>0.12<br>0.07<br>0.05                        | < 0.01<br>0.05<br>0.02<br>0.01<br>0.03<br>0.02           | 0.16  | BCS-0005<br>AUS-BCS-0005-V1<br>AUS-BCS-005-V1-A1<br>3.appl. 17-12-02                       |
|                                                    | WG          | 3  | 0.18–0.19 | 0.02       | 0 <sup>a</sup><br>0<br>1<br>3<br>5<br>7 | 0.06<br>0.11<br>0.11<br>0.06<br>0.05<br>0.05                        | < 0.01<br>< 0.01<br>< 0.01<br>< 0.01<br>< 0.01<br>0.01   | 0.11  | BCS-0005<br>AUS-BCS-0005-V1<br>AUS-BCS-005-V1-B1<br>3.appl. 17-12-02                       |
| Australia, 2003<br>Silvan, VIC (Selva)             | WG          | 3  | 0.2       | 0.043      | 0 <sup>a</sup><br>0<br>1<br>3<br>5<br>7 | 0.01<br>0.10<br>0.07<br>0.05<br>0.03<br>0.06                        | < 0.01<br>< 0.01<br>< 0.01<br>< 0.01<br>< 0.01<br>< 0.01 | 0.07  | BCS-0005<br>AUS-BCS-0005-V2<br>AUS-BCS-005-V2-A1<br>3.appl. 26-02-03                       |
|                                                    | WG          | 3  | 0.17–0.19 | 0.02       | 0 <sup>a</sup><br>0<br>1<br>3<br>5<br>7 | 0.02<br>0.08<br>0.09<br>0.07<br>0.03<br>0.03                        | < 0.01<br>< 0.01<br>< 0.01<br>< 0.01<br>< 0.01<br>< 0.01 | 0.09  | BCS-0005<br>AUS-BCS-0005-V2<br>AUS-BCS-005-V2-B1<br>3.appl. 26-02-03                       |
| Australia, 2003<br>Seville, VIC (Selva)            | WG          | 3  | 0.2       | 0.053      | 0 <sup>a</sup><br>0<br>1<br>3<br>5<br>7 | 0.36<br>0.83<br>0.44<br>0.47<br>0.42<br>0.50/<br>0.018 <sup>b</sup> | 0.04<br>0.13<br>0.18<br>0.20<br>0.18<br>0.13             | 0.67  | BCS-0005<br>AUS-BCS-0005-V3<br>AUS-BCS-005-V3-A1<br>3.appl. 01-05-03                       |
|                                                    | WG          | 3  | 0.2       | 0.053      | 0 <sup>a</sup><br>0<br>1<br>3<br>5<br>7 | 0.36<br>0.58<br>0.44<br>0.46<br>0.46<br>0.49                        | 0.02<br>0.06<br>0.10<br>0.07<br>0.06<br>0.07             | 0.56  | BCS-0005<br>AUS-BCS-0005-V4<br>AUS-BCS-005-V4-A1<br>3.appl. 01-05-03<br>Replicate to V3-A1 |
|                                                    |             |    |           |            |                                         | 0.48                                                                |                                                          | 0.615 | Mean of V3-A1, V4-A1                                                                       |
| Australia, 2003<br>Seville, VIC (Selva)            | WG          | 3  | 0.24      | 0.02       | 0 <sup>a</sup><br>0<br>1<br>3<br>5<br>7 | 0.40<br>1.74<br>3.70<br>1.73<br>0.67<br>0.47                        | 0.07<br>0.13<br>0.11<br>0.07<br>0.10<br>0.11             | 3.81  | BCS-0005<br>AUS-BCS-0005-V3<br>AUS-BCS-005-V3-B1<br>3.appl. 01-05-03                       |
|                                                    | WG          | 3  | 0.24      | 0.02       | 0 <sup>a</sup>                          | 0.49                                                                | 0.14                                                     |       | BCS-0005                                                                                   |

| Country, year,<br>location,<br>(variety)      | Application |    |          |          | Residues in mg/kg             |                                                  |                                              |                                | Report No.<br>Study No.<br>Remarks                                                |
|-----------------------------------------------|-------------|----|----------|----------|-------------------------------|--------------------------------------------------|----------------------------------------------|--------------------------------|-----------------------------------------------------------------------------------|
|                                               | Form        | No | kg ai/ha | kg ai/hL | PHI<br>(days)                 | Trifloxystrobin                                  | CGA<br>321113                                | Total                          |                                                                                   |
|                                               |             |    |          |          | 0<br>1<br>3<br>5<br>7         | 2.00<br>0.62<br>0.46<br>1.05<br>0.52             | 0.04<br>0.07<br>0.10<br>0.09<br>0.05         | 1.14                           | AUS-BCS-0005-V4<br>AUS-BCS-005-V4-B1<br>3.appl. 01-05-03<br>Replicate to<br>V3-B1 |
|                                               |             |    |          |          |                               | 2.4                                              |                                              | 2.5                            | Mean of V3-B1,<br>V4-B1                                                           |
| France<br>2002                                | WG          | 3  | 0.25     | 0.04     | 0<br>1<br>3<br>7<br>14        | 0.14<br>0.11<br>0.15<br>0.08<br>0.06             | 0.03<br>0.03<br>0.03<br>0.03<br>0.04         | 0.1                            | RA-2038/02<br>0080-02<br><br>Reported by 2004<br>JMPR                             |
| Germany<br>2002                               | WG          | 3  | 0.25     | 0.04     | 0<br>1<br>3<br>7<br>14        | 0.32<br>0.28<br>0.27<br>0.12<br>0.04             | 0.05<br>0.04<br>0.05<br>0.06<br>0.05         | 0.09                           | RA-2038/02<br>0187-02<br><br>Reported by 2004<br>JMPR                             |
| Germany<br>2002                               | WG          | 3  | 0.25     | 0.04     | 0<br>1<br>3<br>7<br>14        | 0.22<br>0.20<br>0.15<br>0.07<br>0.05             | 0.02<br>0.03<br>0.03<br>0.04<br>0.03         | 0.08                           | RA-2038/02<br>0188-02<br><br>Reported by 2004<br>JMPR                             |
| Switzerland<br>1999                           | WG          | 3  | 0.25     | 0.025    | 0<br>3<br>7<br>14<br>14       | 1.2<br>0.3<br>0.2<br>0.1<br>0.10                 | 0.05<br>0.05<br>0.06<br>0.04<br>0.04         | 0.14                           | 2080/99<br>SWZ-2080-99<br><br>Reported by 2004<br>JMPR                            |
| Switzerland<br>2000                           | WG          | 3  | 0.25     | 0.03     | 0<br>3<br>7<br>10<br>14<br>14 | 0.38<br>0.29<br>0.17<br>0.12<br>0.09<br>0.13     | 0.03<br>0.03<br>0.04<br>0.04<br>0.04<br>0.05 | 0.13<br>0.18<br>Mean<br>0.16   | 2045/00<br>SWZ-2045-00<br><br>Reported by 2004<br>JMPR                            |
| USA, 2005<br>Penn Yan, NY<br>(Honeye)         | WG          | 6  | 0.11     | 0.02     | 0<br>0                        | 0.18<br>0.19<br>Mean<br>0.19                     | 0.084<br>0.086                               | 0.264<br>0.276<br>Mean<br>0.27 | RATFY012<br>TF021-05H<br>Duplicate samples                                        |
| USA, 2006<br>Quitman, GA<br>(Chandler)        | WG          | 6  | 0.11     | 0.02     | 0<br>0                        | 0.40<br>0.47<br>Mean<br>0.44                     | 0.030<br>0.036                               | 0.43<br>0.506<br>Mean<br>0.47  | RATFY012<br>TF022-05H<br>Duplicate samples                                        |
| USA, 2005<br>Oviedo, FL<br>(Sweet<br>Charlie) | WG          | 6  | 0.11     | 0.02     | 0<br>0                        | 0.47<br>0.52<br>Mean<br>0.50                     | 0.065<br>0.073                               | 0.535<br>0.593<br>Mean<br>0.56 | RATFY012<br>TF023-05H<br>Duplicate samples                                        |
| USA, 2005<br>New Era, MI<br>(Allstar)         | WG          | 6  | 0.11     | 0.02     | 0<br>0                        | 0.098<br>0.11<br>Mean<br>0.10                    | 0.013<br>0.011                               | 0.111<br>0.121<br>Mean<br>0.23 | RATFY012<br>TF024-05H<br>Duplicate samples                                        |
| USA, 2005<br>Madera, CA<br>(Quinalt)          | WG          | 6  | 0.11     | 0.02     | 0<br>0<br><br>3<br>3          | 0.24<br>0.32<br>Mean<br>0.28<br><br>0.18<br>0.17 | 0.027<br>0.028<br><br>0.024<br>0.020         | 0.267<br>0.348<br>Mean<br>0.31 | RATFY012<br>TF025-05D<br>Duplicate samples                                        |

| Country, year, location, (variety)          | Application |    |          |                 | Residues in mg/kg            |                                              |                                                    |                                         | Report No. Study No. Remarks               |
|---------------------------------------------|-------------|----|----------|-----------------|------------------------------|----------------------------------------------|----------------------------------------------------|-----------------------------------------|--------------------------------------------|
|                                             | Form        | No | kg ai/ha | kg ai/hL        | PHI (days)                   | Trifloxystrobin                              | CGA 321113                                         | Total                                   |                                            |
|                                             |             |    |          |                 | 5<br>5<br>7<br>7<br>10<br>10 | 0.15<br>0.16<br>0.17<br>0.16<br>0.10<br>0.14 | 0.019<br>0.017<br>0.017<br>0.016<br>0.014<br>0.013 |                                         |                                            |
| USA, 2006<br>Sanger, CA<br>(Camarosa)       | WG          | 6  | 0.11     | 0.017–<br>0.019 | 0<br>0<br>0                  | 0.18<br>0.24<br>0.19<br>Mean<br>0.20         | 0.023<br>0.027<br>0.037                            | 0.203<br>0.267<br>0.227<br>Mean<br>0.23 | RATFY012<br>TF026-05H<br>3 samples         |
| USA, 2006<br>Porterville, CA (Ozark Beauty) | WG          | 6  | 0.11     | 0.019–<br>0.021 | 0<br>0                       | 0.42<br>0.52<br>Mean 0.47                    | 0.045<br>0.042                                     | 0.465<br>0.562<br>Mean<br>0.51          | RATFY012<br>TF027-05H<br>Duplicate samples |
| USA, 2005<br>Covallis, OR<br>(Puget Summer) | WG          | 6  | 0.11     | 0.018–<br>0.02  | 0<br>0                       | 0.33<br>0.27<br>Mean<br>0.30                 | 0.056<br>0.054                                     | 0.386<br>0.324<br>Mean<br>0.36          | RATFY012<br>TF028-05H<br>Duplicate samples |

<sup>a</sup> Residues before last treatment

<sup>b</sup> Residues in untreated control

### Olives

Eight trials on olives were carried out in Southern Europe in 2003/04. Samples were analysed by analytical method 00742/M001 at an LOQ of 0.02 mg/kg. In 2008 and 2009, four trials were conducted in Southern Europe. Residues were quantified by method 01013 with a LOQ of 0.01 mg/kg. The results are shown in Table 5. Due to the fact that residues of CGA 321113 were below the LOQ at the recommended PHI, the trifloxystrobin data were used for the estimation of the STMR (total residues).

Table 5 Trifloxystrobin residues in olives

| Country, year, location, (variety)                 | Application |    |          |          | Residues in mg/kg |                                      |                                        |                                                | Report No, Trial No   |
|----------------------------------------------------|-------------|----|----------|----------|-------------------|--------------------------------------|----------------------------------------|------------------------------------------------|-----------------------|
|                                                    | Form        | No | kg ai/ha | kg ai/hL | Sample            | PHI (days)                           | Trifloxystrobin                        | CGA 321113                                     |                       |
| Spain, 2004, E-43570 St. Barbara (Morrut)          | WG          | 1  | 0.072    | 0.006    | fruit             | 0<br>7<br>14<br>28                   | 0.23<br>0.22<br>0.12<br>0.08           | < 0.02<br>< 0.02<br>< 0.02<br>< 0.02           | RA-2055/03<br>0379-03 |
| Greece, 2003, GR-20008 Kovtalas-Korinthia (Manaki) | WG          | 1  | 0.06     | 0.005    | fruit             | 0 <sup>a</sup><br>0<br>7<br>14<br>28 | < 0.02<br>0.14<br>0.15<br>0.04<br>0.05 | < 0.02<br>< 0.02<br>< 0.02<br>< 0.02<br>< 0.02 | RA-2055/03<br>0380-03 |
| Spain, 2003, E-41640 Osuna (Martena)               | WG          | 1  | 0.06     | 0.005    | fruit             | 0<br>13                              | 0.29<br>0.13                           | < 0.02<br>< 0.02                               | RA-2055/03<br>0381-03 |
| Italy, 2003, I-70031 Andria (Coratina)             | WG          | 1  | 0.06     | 0.005    | fruit             | 0<br>14                              | 0.20<br>0.07                           | < 0.02<br>< 0.02                               | RA-2055/03<br>0382-03 |
| Spain, 2004, E-08292 Esparraguera (Vera)           | WG          | 1  | 0.06     | 0.005    | fruit             | 0<br>15                              | 0.09<br>0.07                           | < 0.02<br>< 0.02                               | RA-2010/04<br>0047-04 |
| Greece, 2004,                                      | WG          | 1  | 0.06     | 0.005    | fruit             | 0                                    | 0.23                                   | < 0.02                                         | RA-2010/04            |



| Country, year, location, (variety)                     | Application |    |          |          | Residues in mg/kg |                                            |                                                |                                                          | Report No, Trial No                                       |
|--------------------------------------------------------|-------------|----|----------|----------|-------------------|--------------------------------------------|------------------------------------------------|----------------------------------------------------------|-----------------------------------------------------------|
|                                                        | Form        | No | kg ai/ha | kg ai/hL | Sample            | PHI (days)                                 | Trifloxystrobin                                | CGA 321113                                               |                                                           |
| GR-35007 Livanates (Kalamon)                           |             |    |          |          |                   | 14                                         | 0.10                                           | < 0.02                                                   | 0048-04                                                   |
| Italy, 2004, I-70031 Andria (Coratina)                 | WG          | 1  | 0.06     | 0.005    | fruit             | 0<br>7<br>14<br>28                         | 0.15<br>0.10<br>0.11<br>0.06                   | < 0.02<br>< 0.02<br>< 0.02<br>< 0.02                     | RA-2010/04<br>0049-04                                     |
| Portugal, 2004, P-2000 Povia de Santarem (Galega)      | WG          | 1  | 0.06     | 0.005    | fruit             | 0<br>7<br>14<br>28                         | 0.09<br>0.07<br>0.04<br>0.04                   | < 0.02<br>< 0.02<br>< 0.02<br>< 0.02                     | RA-2010/04<br>0050-04                                     |
| Spain, 2008, E-43570 St. Barbara (Morrut)              | WG          | 2  | 0.06     | 0.006    | fruit             | 0 <sup>a</sup><br>0<br>7<br>14<br>22<br>28 | 0.02<br>0.37<br>0.24<br>0.13<br>0.10<br>0.07   | < 0.01<br>0.01<br>< 0.01<br>< 0.01<br>< 0.01<br>< 0.01   | 08-2211<br>08-2211-01<br><br>Spraying interval<br>82 days |
| Italy, 2008, I-95100 Catania (Bella die Spagna)        | WG          | 2  | 0.06     | 0.006    | fruit             | 0 <sup>a</sup><br>0<br>7<br>14<br>22<br>28 | < 0.01<br>0.05<br>0.04<br>0.02<br>0.02<br>0.02 | < 0.01<br>< 0.01<br>< 0.01<br>< 0.01<br>< 0.01<br>< 0.01 | 08-2211<br>08-2211-03<br><br>Spraying interval<br>84 days |
| Spain, 2009, E-08791 St.Llorenc d' Hortons (Arbequina) | WG          | 2  | 0.06     | 0.006    | fruit             | 0 <sup>a</sup><br>0<br>7<br>14<br>22<br>28 | < 0.01<br>0.07<br>0.10<br>0.10<br>0.09<br>0.06 | < 0.01<br>< 0.01<br>< 0.01<br>< 0.01<br>0.01<br>0.01     | 09-2015<br>09-2015-01<br><br>Spraying interval<br>99 days |
| Portugal, 2009, P-2000-205 Santarem (Galega)           | WG          | 2  | 0.06     | 0.006    | fruit             | 0 <sup>a</sup><br>0<br>7<br>14<br>22<br>28 | < 0.01<br>0.09<br>0.05<br>0.04<br>0.03<br>0.02 | < 0.01<br>< 0.01<br>< 0.01<br>< 0.01<br>< 0.01<br>< 0.01 | 09-2015<br>09-2015-03<br><br>Spraying interval<br>71 days |

<sup>a</sup> before last treatment

### Papaya

Four trials on papaya located in the USA were submitted (see Table 6). In each trial, four applications of trifloxystrobin 7 to 8 days apart were made. The application rates ranged from 0.14 to 0.15 kg ai/ha per treatment for a total rate range of 0.567 to 0.584 kg ai/ha per season. The samples were harvested on the day of the last application and analysed by method No. AG-659A, as reported by the 2004 JMPR. The storage interval for field-treated samples ranged from 468 days to 504 days. Storage stability data were submitted and show that the residues are stable under the storage conditions.

Table 6 Trifloxystrobin residues in papaya fruits

| Country, year, location, (variety)        | Application |    |                              |          | Residues in mg/kg |                              |                  |                                     | Report No, Field-ID-No, Remarks                                                       |
|-------------------------------------------|-------------|----|------------------------------|----------|-------------------|------------------------------|------------------|-------------------------------------|---------------------------------------------------------------------------------------|
|                                           | Form        | No | kg ai/ha                     | kg ai/hL | PHI (days)        | Trifloxystrobin              | CGA 321113       | Total                               |                                                                                       |
| USA, 2003, Homestead, FL 33031 (Red Lady) | WG          | 4  | 0.14<br>0.15<br>0.15<br>0.14 |          | 0<br>0            | 0.07<br>0.07<br>Mean<br>0.07 | < 0.02<br>< 0.02 | 0.07<br>0.07<br>Mean<br><u>0.07</u> | IR-4-PR<br>No.07973,<br>7973.03-FL37,<br>Last appl.<br>30-05-2003,<br>2 field samples |

| Country, year, location, (variety)         | Application |    |                              |          | Residues in mg/kg |                              |                  |                              | Report No, Field-ID-No, Remarks                                        |
|--------------------------------------------|-------------|----|------------------------------|----------|-------------------|------------------------------|------------------|------------------------------|------------------------------------------------------------------------|
|                                            | Form        | No | kg ai/ha                     | kg ai/hL | PHI (days)        | Trifloxystrobin              | CGA 321113       | Total                        |                                                                        |
| USA, 2003, Homestead, FL 33031, (Red Lady) | WG          | 4  | 0.14<br>0.14<br>0.15<br>0.15 |          | 0<br>0            | 0.15<br>0.15<br>Mean<br>0.15 | < 0.02<br>< 0.02 | 0.15<br>0.15<br>Mean<br>0.15 | IR-4-PR No.07973, 7973.03-FL38, Last appl. 24-06-2003, 2 field samples |
| USA, 2003, Haleiwa, HI 96712, (Gold)       | WG          | 4  | 0.15<br>0.14<br>0.15<br>0.14 |          | 0<br>0            | 0.28<br>0.25<br>Mean<br>0.27 | 0.04<br>0.04     | 0.32<br>0.29<br>Mean<br>0.31 | IR-4-PR No.07973, 7973.03-HI03, Last appl. 05-06-2003, 2 field samples |
| USA, 2003, Keaau, HI 96749, (Kapoho)       | WG          | 4  | 0.14<br>0.14<br>0.15<br>0.14 |          | 0<br>0            | 0.21<br>0.22<br>Mean<br>0.22 | 0.03<br>0.04     | 0.24<br>0.26<br>Mean<br>0.25 | IR-4-PR No.07973 7973.03-HI04 Last appl. 17-07-2003, 2 field samples   |

### Tomatoes

The 2004 JMPR evaluated 18 trials on tomatoes. Six further trials were conducted in the USA in 2008, three each with WG and SC formulation. The residues of trifloxystrobin and CGA 321113 were determined according to method No. 200177 with a LOQ of 0.01 mg/kg (JMPR 2004). The results are shown in Table 7. Due to the fact that residues of CGA 321113 were below the LOQ at the recommended PHI, the trifloxystrobin data were used for the estimation of the STMR (total residues).

Table 7 Trifloxystrobin residues in tomatoes

| Country, Year, Location, (Variety)       | Application |    |           |             | Residues in mg/kg |            |                                |                  | Report No, Trial No, Remarks           |
|------------------------------------------|-------------|----|-----------|-------------|-------------------|------------|--------------------------------|------------------|----------------------------------------|
|                                          | Form        | No | kg ai/ha  | kg ai/hL    | Sample            | PHI (days) | Trifloxystrobin                | CGA 321113       |                                        |
| USA, 2008, San Joaquin, CA, (Heinz)      | WG          | 4  | 0.14      | 0.12        | Fruit             | 3<br>3     | 0.033<br>0.026<br>Mean<br>0.03 | < 0.01<br>< 0.01 | RAGMP126, GM003-08BA 2 replicate plots |
| USA, 2008, San Joaquin, CA, (Heinz)      | SC          | 4  | 0.13–0.14 | 0.12        | Fruit             | 3<br>3     | 0.030<br>0.053<br>Mean<br>0.04 | < 0.01<br>< 0.01 | RAGMP126 GM003-08BA 2 replicate plots  |
| USA, 2008, Kettleman City, CA (CXD-187)  | WG          | 4  | 0.14      | 0.087–0.10  | Fruit             | 3<br>3     | 0.098<br>0.086<br>Mean<br>0.09 | < 0.01<br>< 0.01 | RAGMP126 GM002-08BA 2 replicate plots  |
| USA, 2008, Kettleman City, CA, (CXD-187) | SC          | 4  | 0.14      | 0.087–0.10  | Fruit             | 3<br>3     | 0.115<br>0.106<br>Mean<br>0.11 | < 0.01<br>< 0.01 | RAGMP126 GM002-08BA 2 replicate plots  |
| USA, 2008, Oviedo, FL (Better Boy)       | WG          | 4  | 0.14      | 0.079       | Fruit             | 3<br>3     | 0.07<br>0.05<br>Mean<br>0.06   | < 0.01<br>< 0.01 | RAGMP126 GM001-08BA 2 replicate plots  |
| USA, 2008, Oviedo, FL (Better Boy)       | SC          | 4  | 0.14      | 0.077–0.078 | Fruit             | 3<br>3     | 0.062<br>0.053<br>Mean<br>0.06 | < 0.01<br>< 0.01 | RAGMP126 GM001-08BA 2 replicate plots  |

*Lettuce, Head*

Indoor residue trials on lettuce were carried out in 2002 in European countries. The spray intervals between applications were 7 days. The residues of trifloxystrobin and its metabolite CGA 321113 were determined according to method 00742 with a LOQ of 0.02 mg/kg. The results are summarised in Table 8.

Table 8 Residues of trifloxystrobin in head lettuce, carried out in greenhouse

| Country, Year, Location, (Variety)                  | Application |    |          |              | Residues in mg/kg                   |                                 |                                        |       | Report No, Trial No   |
|-----------------------------------------------------|-------------|----|----------|--------------|-------------------------------------|---------------------------------|----------------------------------------|-------|-----------------------|
|                                                     | Form        | No | kg ai/ha | Growth stage | PHI (days)                          | Trifloxystrobin                 | CGA 321113                             | Total |                       |
| France, 2002, F-31790 St Jory, (Garuda)             | WG          | 3  | 0.25     | 47           | 0 <sup>1</sup><br>0<br>3<br>7<br>14 | 6.3<br>12<br>5.6<br>2.4<br>0.47 | 0.05<br>0.37<br>0.03<br>0.04<br>< 0.02 | 2.4   | RA-2036/02<br>0172-02 |
| France, 2002, F-84140 Montfavet, (Sansai)           | WG          | 3  | 0.25     | 48           | 0 <sup>1</sup><br>0<br>3<br>7<br>14 | 4.8<br>9.0<br>6.4<br>5.6<br>3.2 | 0.04<br>0.09<br>0.03<br>0.05<br>< 0.02 | 5.7   | RA-2036/02<br>0073-02 |
| Germany, 2002, D-40764 Langenfeld, (Roderick)       | WG          | 3  | 0.25     | 47           | 0<br>7<br>15                        | 6.9<br>2.5<br>1.9               | 0.22<br>0.18<br>0.09                   | 2.7   | RA-2036/02<br>0174-02 |
| Germany, 2002, D-42799 Leichlingen, (Histor)        | WG          | 3  | 0.25     | 45           | 0 <sup>1</sup><br>0<br>3<br>7<br>14 | 4.8<br>11<br>8.5<br>7.2<br>2.5  | 0.05<br>0.08<br>0.07<br>0.04<br>0.04   | 7.2   | RA-2036/02<br>0171-02 |
| Italy, 2002, I-71030 Zapponeta, (Rosella)           | WG          | 3  | 0.25     | 45           | 0<br>7<br>14                        | 13<br>5.7<br>2.1                | 0.20<br>0.12<br>0.04                   | 5.8   | RA-2036/02<br>0178-02 |
| Italy, 2002, I-00050 Palidoro-Fumicino, (Romaserra) | WG          | 3  | 0.25     | 48           | 0 <sup>1</sup><br>0<br>3<br>7<br>14 | 4.1<br>8.2<br>6.7<br>6.6<br>4.6 | 0.08<br>0.11<br>0.13<br>0.14<br>0.13   | 6.7   | RA-2036/02<br>0173-02 |
| Netherlands, 2002, NL-1693 Wefershoof, (Alexandria) | WG          | 3  | 0.25     | 42           | 0<br>7<br>14                        | 8.2<br>2.7<br>1.4               | 0.03<br>< 0.02<br>< 0.02               | 2.7   | RA-2036/02<br>0175-02 |
| Portugal, 2002, P-2000-618 Povoa (Angiew)           | WG          | 3  | 0.25     | 43           | 0<br>7<br>14                        | 9.5<br>5.4<br>2.2               | 0.05<br>0.04<br>0.02                   | 5.4   | RA-2036/02<br>0176-02 |

*Radish*

Six trials on radish located in the USA were submitted. At each trial, two foliar directed applications of trifloxystrobin 7 to 8 days apart were made. The application rates ranged from 0.14 to 0.15 kg ai/ha per treatment for a total rate range of 0.28 to 0.3 kg ai/ha per season or from 0.28 to 0.3 kg ai/ha per treatment for a total rate range of 0.55 to 0.59 kg ai/ha per season. Samples were taken for tops (leaves) and roots, the results are shown in tables 9 and 10, respectively.

Table 9 Trifloxystrobin residues in radish tops

| Country, Year, Location, (Variety) | Application |    |              | Residues in mg/kg |                 |                |              | Report No, Trial No, Remarks |
|------------------------------------|-------------|----|--------------|-------------------|-----------------|----------------|--------------|------------------------------|
|                                    | Form        | No | kg ai/ha     | PHI (days)        | Trifloxystrobin | CGA 321113     | Total        |                              |
| USA, 2002, Holtville, CA,          | WDG         | 2  | 0.14<br>0.14 | 7                 | 2.6<br>2.0      | 0.048<br>0.047 | 2.65<br>2.05 | IR-4 PR<br>No. 08363,        |

| Country, Year, Location, (Variety)        | Application |    |              | Residues in mg/kg |                                   |                |                                   | Report No, Trial No, Remarks                   |
|-------------------------------------------|-------------|----|--------------|-------------------|-----------------------------------|----------------|-----------------------------------|------------------------------------------------|
|                                           | Form        | No | kg ai/ha     | PHI (days)        | Trifloxystrobin                   | CGA 321113     | Total                             |                                                |
| (Cherry Belle)                            |             |    |              |                   | Mean <u>2.3</u>                   |                | Mean <u>2.4</u>                   | CA106                                          |
|                                           | WDG         | 2  | 0.3<br>0.3   | 7                 | 7.8<br>6.2                        | 0.089<br>0.066 |                                   | 2 field samples                                |
| USA, 2002, Citra, FL, (Cabernet F1)       | WDG         | 2  | 0.14<br>0.14 | 7                 | 6.0<br>4.6<br>Mean <u>5.3</u>     | 0.24<br>0.24   | 6.24<br>4.64<br>Mean <u>5.4</u>   | IR-4 PR<br>No. 08363,<br>FL48                  |
|                                           | WDG         | 2  | 0.28<br>0.28 | 7                 | 9.2<br>9.8                        | 0.39<br>0.31   |                                   | 2 field samples<br>Last application<br>5/9/02  |
| USA, 2002, Citra, FL, (Cabernet F1)       | WDG         | 2  | 0.14<br>0.14 | 7                 | 6.6<br>7.0<br>Mean <u>6.8</u>     | 0.42<br>0.33   | 7.02<br>7.33<br>Mean <u>7.2</u>   | IR-4 PR<br>No. 08363,<br>FL49                  |
|                                           | WDG         | 2  | 0.28<br>0.29 | 7                 | 17<br>12                          | 0.53<br>0.47   |                                   | 2 field samples<br>Last application<br>5/14/02 |
| USA, 2002, Freeville, NY, (Cherriette F1) | WDG         | 2  | 0.15<br>0.14 | 6                 | 0.08<br>0.068<br>Mean <u>0.07</u> | 0.069<br>0.052 | 0.149<br>0.12<br>Mean <u>0.13</u> | IR-4 PR<br>No. 08363,<br>NY19                  |
|                                           | WDG         | 2  | 0.29<br>0.28 | 6                 | 0.13<br>0.12                      | 0.20<br>0.13   |                                   | 2 field samples                                |
| USA, 2002, Aurora, OR, (Rebel)            | WDG         | 2  | 0.15<br>0.14 | 8                 | 0.18<br>0.34<br>Mean <u>0.26</u>  | 0.10<br>0.12   | 0.28<br>0.46<br>Mean <u>0.37</u>  | IR-4 PR<br>No. 08363,<br>OR22                  |
|                                           | WDG         | 2  | 0.29<br>0.28 | 8                 | 0.57<br>0.86                      | 0.11<br>0.12   |                                   | 2 field samples                                |
| USA, 2002, Arlington, WI, (Cornet)        | WDG         | 2  | 0.15<br>0.15 | 7                 | 0.25<br>0.18<br>Mean <u>0.22</u>  | 0.12<br>0.088  | 0.37<br>0.268<br>Mean <u>0.32</u> | IR-4 PR<br>No. 08363,<br>WI35                  |
|                                           | WDG         | 2  | 0.29<br>0.3  | 7                 | 0.48<br>0.40                      | 0.22<br>0.12   |                                   | 2 field samples                                |

Table 10 Trifloxystrobin residues in radish roots

| Country, Year, Location, (Variety)        | Application |    |              | Residues in mg/kg |                                           |                  |                                           | Report No, Trial No, Remarks                   |
|-------------------------------------------|-------------|----|--------------|-------------------|-------------------------------------------|------------------|-------------------------------------------|------------------------------------------------|
|                                           | Form        | No | kg ai/ha     | PHI (days)        | Trifloxystrobin                           | CGA 321113       | Total                                     |                                                |
| USA, 2002, Holtville, CA, (Cherry Belle)  | WDG         | 2  | 0.14<br>0.14 | 7                 | < 0.02<br>< 0.02<br>Mean <u>&lt; 0.02</u> | < 0.02<br>< 0.02 | < 0.02<br>< 0.02<br>Mean <u>&lt; 0.02</u> | IR-4 PR<br>No. 08363,<br>CA106                 |
|                                           | WDG         | 2  | 0.30<br>0.30 | 7                 | 0.034<br>0.050                            | < 0.02<br>< 0.02 |                                           | 2 field samples                                |
| USA, 2002, Citra, FL, (Cabernet F1)       | WDG         | 2  | 0.14<br>0.14 | 7                 | 0.036<br>< 0.02<br>Mean <u>0.03</u>       | 0.038<br>0.04    | 0.074<br>0.06<br>Mean <u>0.07</u>         | IR-4 PR<br>No. 08363,<br>FL48                  |
|                                           | WDG         | 2  | 0.28<br>0.28 | 7                 | 0.10<br>0.054                             | 0.067<br>0.056   |                                           | 2 field samples<br>Last application<br>5/9/02  |
| USA, 2002, Citra, FL, (Cabernet F1)       | WDG         | 2  | 0.14<br>0.14 | 7                 | 0.038<br>0.058<br>Mean <u>0.05</u>        | < 0.02<br>0.022  | 0.038<br>0.08<br>Mean <u>0.06</u>         | IR-4 PR<br>No. 08363,<br>FL49                  |
|                                           | WDG         | 2  | 0.28<br>0.29 | 7                 | 0.092<br>0.12                             | 0.040<br>0.041   |                                           | 2 field samples<br>Last application<br>5/14/02 |
| USA, 2002, Freeville, NY, (Cherriette F1) | WDG         | 2  | 0.15<br>0.14 | 6                 | < 0.02<br>< 0.02<br>Mean <u>&lt; 0.02</u> | 0.036<br>0.049   | 0.056<br>0.069<br>Mean <u>0.06</u>        | IR-4 PR<br>No. 08363,<br>NY19                  |
|                                           | WDG         | 2  | 0.29<br>0.28 | 6                 | < 0.02<br>< 0.02                          | 0.052<br>0.079   |                                           | 2 field samples                                |
| USA, 2002, Aurora, OR, (Rebel)            | WDG         | 2  | 0.15<br>0.14 | 8                 | 0.041<br>0.038<br>Mean <u>0.04</u>        | 0.035<br>0.030   | 0.076<br>0.068<br>Mean <u>0.07</u>        | IR-4 PR<br>No. 08363,<br>OR22                  |

| Country, Year, Location, (Variety) | Application |    |              | Residues in mg/kg |                                 |                |                             | Report No, Trial No, Remarks               |
|------------------------------------|-------------|----|--------------|-------------------|---------------------------------|----------------|-----------------------------|--------------------------------------------|
|                                    | Form        | No | kg ai/ha     | PHI (days)        | Trifloxystrobin                 | CGA 321113     | Total                       |                                            |
|                                    | WDG         | 2  | 0.29<br>0.28 | 8                 | 0.068<br>0.080                  | 0.032<br>0.028 |                             |                                            |
| USA, 2002, Arlington, WI, (Cornet) | WDG         | 2  | 0.15<br>0.15 | 7                 | < 0.02<br>< 0.02<br>Mean < 0.02 | 0.038<br>0.054 | 0.058<br>0.074<br>Mean 0.07 | IR-4 PR No. 08363, WI35<br>2 field samples |
|                                    | WDG         | 2  | 0.29<br>0.30 | 7                 | 0.030<br>0.024                  | 0.091<br>0.081 |                             |                                            |

### *Asparagus*

Seven trials on asparagus located in the USA were submitted. At each trial, three foliar directed applications of trifloxystrobin 13 to 15 days apart were made. The application rates ranged from 0.14 to 0.15 kg ai/ha per treatment for a total rate range of 0.42 to 0.43 kg ai/ha per season. Samples were analysed by method AG-659A which was reported by the 2004 JMPR.

Table 11 Trifloxystrobin residues in asparagus.

| Country, Year, Location, (Variety)                  | Application |    |          | Residues in mg/kg |        |                 |            | Report No, Trial No, Remarks |
|-----------------------------------------------------|-------------|----|----------|-------------------|--------|-----------------|------------|------------------------------|
|                                                     | Form        | No | kg ai/ha | PHI (days)        | Sample | Trifloxystrobin | CGA 321113 |                              |
| USA, 2002, Stockton, CA, (UC157)                    | WG          | 3  | 0.14     | 92                | Spears | < 0.05          | < 0.02     | IR-4 PR No. 08212, CA107     |
|                                                     |             |    | 0.14     |                   |        | < 0.05          | < 0.02     |                              |
|                                                     |             |    | 0.14     | 98                |        | < 0.05          | < 0.02     |                              |
| USA, 2002, San Ardo, CA, (UC157)                    | WG          | 3  | 0.15     | 100               | Spears | < 0.05          | < 0.02     | IR-4 PR No. 08212, CA108     |
|                                                     |             |    | 0.14     |                   |        | < 0.05          | < 0.02     |                              |
|                                                     |             |    | 0.14     |                   |        |                 |            |                              |
| USA, 2002, Caldwell, ID, (Jersey King)              | WG          | 3  | 0.14     | 167               | Spears | < 0.05          | < 0.02     | IR-4 PR No. 08212, ID11      |
|                                                     |             |    | 0.14     |                   |        | < 0.05          | < 0.02     |                              |
|                                                     |             |    | 0.14     |                   |        |                 |            |                              |
| USA, 2002, Holt, MI, (Jersey Knight)                | WG          | 3  | 0.14     | 181               | Spears | < 0.05          | < 0.02     | IR-4 PR No. 08212, MI25      |
|                                                     |             |    | 0.14     |                   |        | < 0.05          | < 0.02     |                              |
|                                                     |             |    | 0.14     |                   |        |                 |            |                              |
| USA, 2002, East Lansing, MI, (Jersey Gigant)        | WG          | 3  | 0.14     | 176               | Spears | < 0.05          | < 0.02     | IR-4 PR No. 08212, MI26      |
|                                                     |             |    | 0.14     |                   |        | < 0.05          | < 0.02     |                              |
|                                                     |             |    | 0.14     |                   |        |                 |            |                              |
| USA, 2002, Bridgeton, NJ, (New Jersey Male Hybrids) | WG          | 3  | 0.14     | 180               | Spears | < 0.05          | < 0.02     | IR-4 PR No. 08212, NJ29      |
|                                                     |             |    | 0.15     |                   |        | < 0.05          | < 0.02     |                              |
|                                                     |             |    | 0.14     |                   |        |                 |            |                              |
| USA, 2002, Moxee, WA, (Mary Washington)             | WG          | 3  | 0.14     | 176               | Spears | < 0.05          | < 0.02     | IR-4 PR No. 08212, WA35      |
|                                                     |             |    | 0.14     | 188               |        | < 0.05          | < 0.02     |                              |
|                                                     |             |    | 0.14     |                   |        |                 |            |                              |

## FATES OF RESIDUES IN STORAGE AND PROCESSING

### *In processing*

The effect of processing on trifloxystrobin residues was investigated in strawberries and olives.

#### *Strawberries*

One processing study (RA-3038/02, 2 European trials) was reported by the 2004 JMPR. One further study was conducted in 2006 in the USA to determine trifloxystrobin residues in strawberry washed or cooked fruit (jam) following treatment with trifloxystrobin WG 50. Six spray applications at a rate of 0.011 kg ai/ha were made with a 5 to 7-day interval between applications. Strawberry fruits were harvested at the day of the last application (PHI of 0 days). The harvested fruits were washed and cooked with fruit pectin and sugar. The results are shown in Table 12.

Table 12 Residues of trifloxystrobin in strawberry fruit and processed products, report RATFY012

| Country, Year, Location, (Variety) | Application |    |          |              | Residues in mg/kg |            |                 |            |               |
|------------------------------------|-------------|----|----------|--------------|-------------------|------------|-----------------|------------|---------------|
|                                    | Form        | No | kg ai/ha | Growth stage | Sample            | PHI (days) | Trifloxystrobin | CGA 321113 | Total residue |
| USA, 2006, Sanger, CA (Camarosa)   | WG          | 6  | 0.11     | 89           | Fruit             | 0          | 0.19            | 0.037      | 0.23          |
|                                    |             |    |          |              | Fruit, washed     |            | 0.12            | 0.027      | 0.15          |
|                                    |             |    |          |              | Jam               |            | 0.093           | 0.025      | 0.12          |

### Olives

The purpose of the studies submitted was to determine the magnitude of residues of trifloxystrobin in/on olive fruit and processed products as washed fruit, press cake (pomace, wet), crude oil, pre-clarified crude oil, neutralised crude oil and refined oil.

Trifloxystrobin 50 WG was applied once to olive trees at about 0.01% spray concentration (product rate of about 0.12 kg/ha, water rate of 1200L/ha), corresponding to a rate of active substance of about 0.06 kg ai/ha. The application was carried out at 14 days prior to the expected date of harvest (PHI 14 days).

The olives were washed in standing water by moving them around slowly. The washed olives were crushed into olive pulp in a cutter. Salt was added to the olive pulp and then the olive pulp was pressed into press cake and a water/oil emulsion. The wet pomace was sampled. The water/oil emulsion was separated into crude oil and vegetation water in a separating funnel (further cleaning by centrifugation). Crude oil was pre-clarified by heating (15 min at approx. 85–90 °C) in the presence of water and citric acid solution. The remaining part of the pre-clarified oil was transferred into the neutralization apparatus and heated up to 90 °C while stirring. After addition of 60% (w/w) sodium hydroxide, the stirring was stopped. Within a few minutes, the free fatty acids are converted into their sodium soaps and soap stock is formed. After removal of the soap stock the oil was centrifuged in order to remove remaining rests of the soap stock. Neutralised crude oil was transferred into a bleaching flask and heated up to 80–90 °C while stirring. After the addition of 0.5–2.0% (w/w) fuller's earth, the oil was stirred for about 30 minutes. Basically, the following distillation (3.5 h, 130–220 °C) was a steam distillation. The steam is formed in a steam-generating tube which extends into the hot oil. The steam removes the constituents that are volatile in water vapour from the oil. It condenses in a separate flask via a cooler. After cooling, the refined oil was sampled.

The results are shown in Table 13. Because of the fact that the CGA 321113 residues were below or at the LOQ at the recommended PHI, the trifloxystrobin data corresponded to the total residues.

Table 13 Residues of trifloxystrobin in olives and processed products, PHI fruits 14 days

| Country, Year, Location, (Variety)                 | Application |    |          |          | Residues in mg/kg        |                 |            | Report No, Trial No |
|----------------------------------------------------|-------------|----|----------|----------|--------------------------|-----------------|------------|---------------------|
|                                                    | Form        | No | kg ai/ha | kg ai/hL | Sample                   | Trifloxystrobin | CGA 321113 |                     |
| Spain, 2004, E-43570 St. Barbara (Morrut)          | WG          | 1  | 0.07     | 0.006    | Fruit                    | 0.12            | < 0.02     | RA-3055/03 0379-03  |
|                                                    |             |    |          |          | Whole fruit, washed      | 0.12            | < 0.02     |                     |
|                                                    |             |    |          |          | Separation water         | < 0.02          | < 0.02     |                     |
|                                                    |             |    |          |          | Washings                 | 0.02            | < 0.02     |                     |
|                                                    |             |    |          |          | Pomace, wet              | 0.19            | < 0.02     |                     |
|                                                    |             |    |          |          | Oil, crude               | 0.66            | < 0.02     |                     |
|                                                    |             |    |          |          | Crude oil, pre-clarified | 0.70            | < 0.02     |                     |
|                                                    |             |    |          |          | Crude oil, neutralised   | 0.58            | < 0.02     |                     |
| Greece, 2003, GR-20008 Kovtalas-Korinthia (Manaki) | WG          | 1  | 0.06     | 0.005    | Oil, refined             | 0.58            | < 0.02     | RA-3055/03 0380-03  |
|                                                    |             |    |          |          | Fruit                    | 0.04            | < 0.02     |                     |
|                                                    |             |    |          |          | Whole fruit, washed      | 0.05            | < 0.02     |                     |
|                                                    |             |    |          |          | Separation water         | < 0.02          | < 0.02     |                     |
|                                                    |             |    |          |          | Washings                 | < 0.02          | < 0.02     |                     |
|                                                    |             |    |          |          | Pomace, wet              | 0.06            | < 0.02     |                     |
|                                                    |             |    |          |          | Oil, crude               | 0.14            | < 0.02     |                     |
|                                                    |             |    |          |          | Crude oil, pre-clarified | 0.15            | < 0.02     |                     |

| Country,<br>Year, Location,<br>(Variety)                   | Application |    |             |          | Residues in mg/kg        |                 |               | Report No,<br>Trial No |
|------------------------------------------------------------|-------------|----|-------------|----------|--------------------------|-----------------|---------------|------------------------|
|                                                            | Form        | No | kg<br>ai/ha | kg ai/hL | Sample                   | Trifloxystrobin | CGA<br>321113 |                        |
|                                                            |             |    |             |          | Crude oil, neutralised   | 0.14            | < 0.02        |                        |
|                                                            |             |    |             |          | Oil, refined             | 0.14            | < 0.02        |                        |
| Italy, 2004,<br>I-70031 Andria<br>(Coratina)               | WG          | 1  | 0.06        | 0.005    | Fruit                    | 0.11            | < 0.02        | RA 3010/04<br>0049-04  |
|                                                            |             |    |             |          | Whole fruit, washed      | 0.07            | < 0.02        |                        |
|                                                            |             |    |             |          | Separation water         | < 0.02          | < 0.02        |                        |
|                                                            |             |    |             |          | Washings                 | < 0.02          | < 0.02        |                        |
|                                                            |             |    |             |          | Pomace, wet              | 0.11            | < 0.02        |                        |
|                                                            |             |    |             |          | Oil, crude               | 0.12            | < 0.02        |                        |
|                                                            |             |    |             |          | Crude oil, pre-clarified | 0.12            | < 0.02        |                        |
| Portugal, 2004,<br>P-2000 Povia<br>de Santarem<br>(Galega) | WG          | 1  | 0.06        | 0.005    | Fruit                    | 0.04            | < 0.02        | RA 3010/04<br>0050-04  |
|                                                            |             |    |             |          | Whole fruit, washed      | 0.05            | < 0.02        |                        |
|                                                            |             |    |             |          | Separation water         | < 0.02          | < 0.02        |                        |
|                                                            |             |    |             |          | Washings                 | < 0.02          | < 0.02        |                        |
|                                                            |             |    |             |          | Pomace, wet              | 0.09            | < 0.02        |                        |
|                                                            |             |    |             |          | Oil, crude               | 0.08            | 0.02          |                        |
|                                                            |             |    |             |          | Crude oil, pre-clarified | 0.07            | < 0.02        |                        |

The processing factors shown below were calculated from the total residue levels (sum of trifloxystrobin and CGA 321113).

Table 14 Summary of processing factors for trifloxystrobin total residues

| Raw agricultural commodity (RAC) | Processed commodity  | Calculated processing factors                | Best estimate (mean or median) |
|----------------------------------|----------------------|----------------------------------------------|--------------------------------|
| Strawberry                       | Strawberry jam       | 0.52, 0.58 <sup>a</sup> , 0.667 <sup>a</sup> | 0.58                           |
|                                  | Strawberry preserves | 0.25 <sup>a</sup> , 0.33 <sup>a</sup>        | 0.29                           |
| Olives                           | Olive oil, crude     | 1.09, 2.5, 3.5, 5.5                          | 3.0                            |
|                                  | Olive oil, refined   | 3.5, 4.8                                     | 4.15                           |

<sup>a</sup> reported by JMPR in 2004

## APPRAISAL

Trifloxystrobin was first evaluated for toxicology and residues by the JMPR in 2004. The Meeting derived an ADI of 0.04 mg/kg bw per day and decided that an ARfD is unnecessary. Maximum residue levels, STMRs and STMR-Ps for 73 commodities or commodity groups were estimated.

In 2004 the Meeting agreed that the residue definition for enforcement purposes for plant commodities should be trifloxystrobin *per se*. For enforcement of animal commodities and for consideration of dietary intake of plant or animal commodities the residue definition should be parent compound and (*E,E*)-methoxyimino-2-[1-(3-trifluoromethyl-phenyl) ethylideneaminoxy-methyl]-phenyl}acetic acid) (expressed as trifloxystrobin equivalents). The metabolite is also known as CGA 321113.

The compound was listed by the Forty-third Session of the CCPR for the review of additional MRLs. The 2012 JMPR received residue data for strawberries, papaya, olives, tomato, lettuce, radish and asparagus.

### Methods of analysis

The Meeting received information on analytical methods used for the determination of trifloxystrobin residues and its acid metabolite CGA 321113 in samples derived from supervised trials on asparagus, lettuce, olives, papaya, radish, strawberry and tomatoes. The residues were determined by LC-MS/MS or GC-MS/MS with LOQs of 0.01–0.02 mg/kg.

The freezer storage stability studies carried out with asparagus and papaya showed that the trifloxystrobin residues and the metabolite CGA 321113 were stable for the longest period for which

the samples were stored at or below -15 °C. The studies reported by the 2004 JMPR cover the other sample materials evaluated by the present Meeting.

### ***Results of supervised residue trials on crops***

The OECD calculator was used as a tool in the estimation of the maximum residue level from the selected residue data set obtained from trials conducted according to GAP. As a first step, the Meeting reviewed all relevant factors related to each data set in arriving at a best estimate of the maximum residue level using expert judgment. Then, the OECD calculator was employed. If the statistical calculation spreadsheet suggested a different value from that recommended by the JMPR, a brief explanation of the deviation was provided.

#### ***Strawberry***

Based on the Swiss GAP (3 × 0.25 kg ai/ha, PHI 14 days) and five European supervised trials, the 2004 JMPR estimated a maximum residue level of 0.2 mg/kg and an STMR of 0.1 mg/kg.

The 2012 Meeting received additional residue data from the USA and Australia. The Australian trials were carried out with 3 × 0.2 kg ai/ha and did not match the GAP (3 × 0.15 kg ai/ha, PHI 1 day). The registered GAP in the USA is 6 × 0.11 kg ai/ha and a 0-day PHI. In eight trials matching GAP conditions, the residue levels of trifloxystrobin *per se* were (n=8): 0.10, 0.19, 0.20, 0.28, 0.30, 0.44, 0.47 and 0.50 mg/kg. The residue concentrations of the sum of trifloxystrobin and CGA 321113 were: 0.23, 0.23, 0.27, 0.31, 0.36, 0.47, 0.51 and 0.56 mg/kg.

The Meeting estimated a maximum residue level of 1 mg/kg and an STMR of 0.335 mg/kg for trifloxystrobin in strawberries to replace the former recommendation.

#### ***Olives***

The Spanish GAP is 2×0.005 kg ai/hL and a PHI of 14 days. The first application is recommended in spring, the second in autumn. Eight trials conducted in Southern Europe with one treatment of 0.005 kg ai/hL in autumn and a PHI of 14 days showed residues of trifloxystrobin *per se* of 0.04, 0.05, 0.07, 0.07, 0.10, 0.11, 0.12 and 0.13 mg/kg. In four Southern European trials with two applications (one in spring and one in autumn with 0.006 kg ai/hL, spraying interval of 71–99 days between the two treatments), the residue levels of trifloxystrobin *per se* were 0.02, 0.04, 0.10 and 0.13 mg/kg. The Meeting noticed that the first spray treatment did not influence the residue concentration and decided to combine the two datasets. The trifloxystrobin residues (n=12) were: 0.02, 0.04, 0.04, 0.05, 0.07, 0.07, 0.10, 0.10, 0.11, 0.12, 0.13 and 0.13 mg/kg.

Because the residues of CGA 321113 were below the LOQ, for estimation of STMR (sum of parent and CGA 321113), the trifloxystrobin data were used.

The Meeting estimated a maximum residue level of 0.3 mg/kg and an STMR of 0.085 mg/kg for trifloxystrobin in olives.

#### ***Papaya***

The GAP in the USA is maximal four foliar applications of 0.14 kg ai/ha at a maximal seasonal rate of 0.56 kg ai/ha and a PHI of 0 days. Four trials were conducted on papaya in the USA in 2003 with foliar treatment by 4 × 0.14–0.15 kg ai/ha, PHI 0 days. The trifloxystrobin residues were 0.07, 0.15, 0.22 and 0.27 mg/kg. The residue concentrations of the sum of trifloxystrobin and CGA 321113 were: 0.07, 0.15, 0.25 and 0.31 mg/kg.

The Meeting estimated a maximum residue level of 0.6 mg/kg and an STMR of 0.2 mg/kg for trifloxystrobin in papaya.

#### ***Brussels sprouts***

The 2004 JMPR estimated a maximum residue level of 0.5 mg/kg and a STMR of 0.17 mg/kg for residues of trifloxystrobin in flowerhead brassica, Brussels sprouts and head cabbage but in the CCPR



reports, a CXL of 0.1 mg/kg was listed for Brussels sprouts. The company requested a clarification. No new data were submitted.

The current Meeting noted that the value of 0.1 mg/kg as CXL for Brussels sprouts is an administrative error in the Codex System. The MRL recommendation made by the 2004 JMPR was 0.5 mg/kg.

#### *Tomatoes*

Based on the US GAP (4 × 0.14 kg ai/ha, PHI 3 days) and 18 supervised trials, the 2004 JMPR estimated a maximum residue level of 0.7 mg/kg and an STMR of 0.08 mg/kg.

The 2012 JMPR received six further US outdoor trials according to US GAP. The residue concentrations of the sum of trifloxystrobin and CGA 321113 were: 0.03, 0.04, 0.06, 0.06, 0.09 and 0.11 mg/kg.

The Meeting agreed that a new recommendation for trifloxystrobin on tomatoes based on the data submitted to the 2012 JMPR was not necessary. Therefore, the previous recommendations for a maximum residue level and STMR were maintained.

#### *Egg plant*

The US GAP of trifloxystrobin on eggplant is 5 × 0.07–0.14 kg ai/ha at a maximum of 0.56 kg ai/ha per season and a 3 day PHI, the same GAP is registered for tomatoes.

The Meeting agreed to extrapolate from tomato to eggplant and recommended a maximum residue level of 0.7 mg/kg and an STMR of 0.08 mg/kg for trifloxystrobin in egg plant.

#### *Lettuce, Head*

The GAP for greenhouse grown lettuce is in the Netherlands 3 × 0.2 kg ai/ha and a PHI of 7 days. Eight indoor European trials (France (2), Germany (2), Italy (2), Portugal (1), the Netherlands (1)) treated with 3 × 0.25 kg ai/ha were received.

In eight trials on head lettuce matching the GAP conditions of the Netherlands (application rate +25 %), the residue levels of trifloxystrobin *per se* were: 2.4, 2.5, 2.7, 5.4, 5.6, 5.7, 6.6 and 7.2 mg/kg. The residue concentrations of the sum of trifloxystrobin and CGA 321113 were: 2.4, 2.7, 2.7, 5.4, 5.7, 5.8, 6.7 and 7.2 mg/kg.

The Meeting estimated a maximum residue level of 15 mg/kg and an STMR of 5.55 mg/kg for trifloxystrobin in lettuce, head.

#### *Radish leaves (including Radish tops)*

The registered GAP on radish in the USA is 4 × 0.07–0.14 kg ai/ha at a maximal rate of 0.28 kg ai/ha per year and a PHI of 7 days. Six field trials were conducted with 2 × 0.14–0.15 kg ai/ha and a PHI of 6–8 days.

In radish tops, the residue levels of trifloxystrobin *per se* were: 0.07, 0.22, 0.26, 2.3, 5.3 and 6.8 mg/kg. The residue concentrations of the sum of trifloxystrobin and CGA 321113 were: 0.13, 0.32, 0.37, 2.4, 5.4 and 7.2 mg/kg.

The Meeting estimated a maximum residue level of 15 mg/kg and an STMR of 1.4 mg/kg for trifloxystrobin in radish leaves.

#### *Radish*

The registered GAP on radish in the USA is 4 × 0.07–0.14 kg ai/ha at a maximal rate of 0.28 kg ai/ha per year and a PHI of 7 days. Six field trials were conducted with 2 × 0.14–0.15 kg ai/ha and a PHI of 6–8 days.

In radish roots, the residue levels of trifloxystrobin *per se* were: < 0.02 (3), 0.03, 0.04 and 0.05 mg/kg. The residue concentrations of the sum of trifloxystrobin and CGA 321113 were: < 0.02, 0.06, 0.06 and 0.07 (3) mg/kg.

The Meeting estimated a maximum residue level of 0.08 mg/kg and an STMR of 0.065 mg/kg for trifloxystrobin in radish.

### *Asparagus*

The GAP in the USA is 3 × 0.11–0.14 kg ai/ha at a maximal seasonal rate of 0.42 kg ai/ha and a PHI of 180 days (California 90 days). Seven trials were conducted on asparagus in the USA in 2002 with foliar treatment by 3 × 0.14–0.15 kg ai/ha and PHIs of 92–188 days. In the sprouts, neither residues of trifloxystrobin (< 0.05 mg/kg) nor the metabolite CGA 321113 (< 0.02 mg/kg) were detected.

The Meeting estimated a maximum residue level of 0.05\* mg/kg and an STMR of 0 for trifloxystrobin in asparagus.

### ***Fate of residues during processing***

The effect of processing on the level of residues of trifloxystrobin and the metabolite CGA 321113 has been studied for strawberries and olives. The processing factors (PF) were calculated from the total residue levels (sum of trifloxystrobin and CGA 321113). The best estimates of the processing factors are shown below. Processes included in the table are those that lead to STMR-P values useful for dietary intake estimations.

| Raw agricultural commodity (RAC) | Processed commodity  | Best estimate processing factor (PF) | RAC STMR | STMR-P |
|----------------------------------|----------------------|--------------------------------------|----------|--------|
| Strawberry                       | Strawberry jam       | 0.58                                 | 0.335    | 0.194  |
|                                  | Strawberry preserves | 0.29                                 |          | 0.097  |
| Olives                           | Olive oil, crude     | 3                                    | 0.085    | 0.255  |
|                                  | Olive oil, refined   | 4.15                                 |          | 0.353  |

The Meeting estimated the following STMR-P values: 0.194 mg/kg for strawberry jam, 0.097 mg/kg for strawberry, canned, 0.255 mg/kg for olive oil, crude and 0.353 for olive oil, refined.

A maximum residue level for the processed commodity will only be recommended if the resulting residue value is higher than the maximum residue level proposed for the corresponding RAC. Because of the fact that the PF is >1 for olive oils and the oils are commodities in trade, maximum residue levels were proposed for olive oil, crude and olive oil, refined.

The Meeting estimated a maximum residue level for olive oil, crude of 0.9 mg/kg and for olive oil, refined of 1.2 mg/kg.

### ***Residues in animal commodities***

As the commodities evaluated by the 2012 JMPR are not included in the OECD farm animal feeding table, there is no need to re-calculate the farm animal dietary burden.

The Meeting concluded that a re-evaluation of the maximum residue levels for animal commodities was not necessary.

## **RECOMMENDATIONS**

On the basis of the data from supervised trials the Meeting concluded that the residue levels listed below are suitable for establishing maximum residue limits and for IEDI assessment.

Definition of the residue for plant commodities for compliance with the MRL: *Trifloxystrobin*

Definition of the residue for plant commodities for estimation of dietary intake: *Sum of trifloxystrobin and (E,E)-methoxyimino- {2-[1-(3-trifluoromethyl-phenyl) ethylideneaminooxymethyl]-phenyl}acetic acid* (CGA 321113), expressed as *trifloxystrobin*.

Definition of the residue for animal commodities for compliance with the MRL and for dietary intake: *Sum of trifloxystrobin and (E,E)-methoxyimino-2-[1-(3-trifluoromethyl-phenyl) ethylideneaminoxymethyl]-phenyl}acetic acid) (CGA 321113), expressed as trifloxystrobin.*

The residue is fat-soluble.

| CCN     | Commodity Name                        | Recommended MRL, mg/kg |          | STMR or STMR-P mg/kg |
|---------|---------------------------------------|------------------------|----------|----------------------|
|         |                                       | proposed               | previous |                      |
| VS 0621 | Asparagus                             | 0.05*                  |          | 0                    |
| VO 0440 | Egg plant                             | 0.7                    |          | 0.08                 |
| VL 0482 | Lettuce, head                         | 15                     |          | 5.55                 |
| FT 0305 | Olives                                | 0.3                    |          | 0.085                |
| OC 0305 | Olive oil, crude                      | 0.9                    |          | 0.255                |
| OR 0305 | Olive oil, refined                    | 1.2                    |          | 0.353                |
| FI 0350 | Papaya                                | 0.6                    |          | 0.2                  |
| VL 0494 | Radish leaves (including Radish tops) | 15                     |          | 1.4                  |
| VR 0494 | Radish                                | 0.08                   |          | 0.065                |
| FB 0275 | Strawberry                            | 1                      | 0.2      | 0.335                |
|         | Strawberry, canned                    |                        |          | 0.097                |
|         | Strawberry jam                        |                        |          | 0.194                |

## DIETARY RISK ASSESSMENT

### Long-term intake

The International Estimated Daily Intakes (IEDIs) of trifloxystrobin were calculated for the 13 GEMS/Food cluster diets using STMRs and STMR-Ps estimated by the JMPR in 2004 and 2012. The results are shown in Annex 3 of the JMPR 2012 Report.

The ADI is 0–0.04 mg/kg bw and the calculated IEDIs were 1–5 % of the maximum ADI. The Meeting concluded that the long-term intake of residues of trifloxystrobin from the uses considered by the JMPR is unlikely to present a public health concern.

### Short-term intake

The 2004 JMPR decided that it was unnecessary to establish an ARfD. The present Meeting therefore concluded that the short-term intake of trifloxystrobin residues is unlikely to present a public health concern.

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| Code       | Author                 | Year | Title, Institute, Report reference                                                                                                                                                                                   |
|------------|------------------------|------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| RA-3055/03 | Zimmer, D              | 2005 | Determination of the residues of trifloxystrobin in/on olive and processed commodities after spraying of Flint (50 WG) in the field in Spain and Greece. Bayer CropScience AG, Edition No MO-05-004758. Unpublished. |
| RAGMP126   | Netzband, D & Abele, R | 2009 | Gem 500 SC and Flint 50 WG—Magnitude of the residue in/on tomatoes. Bayer CropScience AG, Edition No M-350815-01-1. Unpublished.                                                                                     |
| RATFY012   | Krolski, ME            | 2006 | Flint 50 WG—Magnitude of the residue in/on strawberries. Bayer CropScience AG, Edition No M-281857-01-1. Unpublished.                                                                                                |
|            | Klein, O               | 2012 | Letter by Otto Klein, Bayer CropScience, to Yang, YongZhen, 03 May 2012. CXL for trifloxystrobin on Brussels sprouts.                                                                                                |

## 5.29 TRIFLOXYSTROBIN (213)

### RESIDUE AND ANALYTICAL ASPECTS

Trifloxystrobin was first evaluated by the JMPR in 2004 (T, R) and in 2012 (R). The 2004 Meeting established an ADI of 0–0.04 mg/kg bw and decided that ARfD was not necessary. The Meeting agreed that the residue definition for enforcement purposes for plant commodities should be trifloxystrobin per se, for animal commodities and dietary intake assessment the residue definition should be parent compound and CGA 321113 (expressed as trifloxystrobin equivalents) for plant and animal commodities.

Trifloxystrobin was listed by the Forty-sixth Session of CCPR (2014) for the evaluation by the 2015 JMPR for additional MRLs. Supervised trials data were submitted for evaluation on dry soya bean, lentil, chick pea and pea.

Analytical methods used for supervised trials were also provided.

#### *Analytical methods*

The Meeting received descriptions and validation data for analytical methods for residues of trifloxystrobin, CGA 321113 and several other metabolites in different plant matrices.

The plant materials are generally extracted with a mixture of acetonitrile/water. After filtration and concentration to the aqueous remainder, the acidified crude extract is purified, where necessary, by liquid-liquid partition. The residues are quantified by reverse-phase HPLC with MS/MS-detection. The average recoveries of trifloxystrobin and CGA 321113 and their relative standard deviations from test portions spiked at 0.01–2 mg/kg levels were for peas (100–101%, 3.1–4.7%) and soya beans (86–91%, 6.4, 19%). The limits of quantification ranged between 0.01–0.02 mg/kg.

The DFG method S19, evaluated in 2004, is suitable for enforcement.

#### *Residues resulting from supervised trials on crops*

The sum of trifloxystrobin and CGA 321113 was calculated and expressed as trifloxystrobin on the basis of the relative molecular masses. A conversion factor of 1.036 is required to express CGA 321113 as trifloxystrobin. As CGA 321113 does not generally constitute a significant proportion of the residue in crops, when the levels of trifloxystrobin or CGA 321113 were below the LOQ, their sum was calculated according to the method used by the 2004 JMPR.

| Trifloxystrobin (mg/kg) | CGA 321113 (mg/kg) | Total (expressed as trifloxystrobin) (mg/kg) |
|-------------------------|--------------------|----------------------------------------------|
| < 0.01                  | < 0.01             | < 0.01                                       |
| < 0.01                  | 0.011              | 0.021                                        |
| 0.10                    | < 0.02             | 0.10                                         |
| 0.92                    | 0.16               | 1.1                                          |

In field trials duplicate samples were taken from each treated plot. Of the duplicate results the non-detected residues were disregarded in the calculation of average residue. As a conservative approach, if the residues measured were 0.015 and <0.01, the calculated average was taken as 0.015 mg/kg.

#### *Pulses*

##### *Soya bean*

The GAP in Canada allows maximum 2 times 0.0625 kg/ha treatment with a 20 day PHI. In 4 trials conducted according to GAP the residues in soya bean seeds were < 0.01 mg/kg (4).

The Brazilian GAP permits up to 4 treatments with 0.060 kg/ai/ha or 2 treatments with 0.075 kg ai/ha with a PHI of 20 days. Following treatment according to GAP the trifloxystrobin

residues were below the LOQ ( $< 0.01$  or  $< 0.02$  mg/kg). CGA 321113 residues occurred in seven samples at 0.01–0.02 mg/kg level.

The US GAP permits 3 applications at rates between 0.0913–0.127 kg ai/ha and a PHI of 21 days. In 2003 a total of 20 trials were conducted in the USA applying trifloxystrobin three times at rates of 0.086–0.095 kg ai/ha. In addition, another 20 trials were performed in 2005 with application rates of 0.13 kg ai/ha and samples were taken at 21 days. Duplicate samples were taken from each site.

The US use patterns represent the critical GAP. The nominal application rates in US trials are within  $\pm 25\%$  of the GAP. The residues of parent compound in rank order were:  $< 0.01$  (28), 0.01 (4), 0.012, 0.014, 0.016 (2), 0.021, 0.027, and 0.041 mg/kg.

The sum of residues were in rank order:  $< 0.01$  (24), 0.012 (4), 0.021 (2), 0.023 (2), 0.024, 0.025, 0.026, 0.027, 0.039, 0.043, 0.057 and 0.058 mg/kg.

The Meeting estimated a maximum residue level of 0.05 mg/kg for trifloxystrobin in soya beans, and an STMR residue of 0.01 mg/kg for the sum of trifloxystrobin and CGA 321113.

#### *Beans and peas, dry*

The use of trifloxystrobin in/on dry pea, chickpea and lentil is registered in Canada and the USA.

Nine trials were conducted on dry peas and nine trials on dry beans according the GAP in Canada (1-2 application with 0.132 kg ai/ha, the PHI is 30 days). Duplicate samples were taken at each sampling interval.

In beans, the average residues of trifloxystrobin at about 30 days were  $< 0.01$  mg/kg in all (9) samples.

The sum of trifloxystrobin and CGA 321113 residues expressed as trifloxystrobin were in rank order:  $< 0.01$  (5), 0.021 (2), 0.022, and 0.023 mg/kg.

In peas, the residues of trifloxystrobin at about 30 days were all  $< 0.01$  mg/kg in all (9) samples.

The sum of residues of trifloxystrobin and CGA 321113 expressed as trifloxystrobin (mg/kg) at about 30 days were:  $< 0.01$  (3), 0.021 (2), 0.022, 0.023, 0.027 and 0.033 mg/kg.

The use pattern is the same for beans and peas and the residues are not different. Consequently the residue datasets can be combined for mutual support.

The residues of trifloxystrobin in dry bean and pea seeds were  $< 0.01$  mg/kg.

The sum of residues in beans and peas in rank order were:  $< 0.01$  (8), 0.021 (4), 0.022, 0.023 (2), 0.025, 0.027 and 0.033 mg/kg.

As the use pattern for lentils is the same as for beans and peas, the Meeting decided that the database is sufficient for making recommendation for these three commodities.

The Meeting estimated a maximum residue level of 0.01\* mg/kg and an STMR residue of 0.021 mg/kg for dry beans, lentils, and pea.

#### ***Animal feed***

##### *Soya bean forage and hay*

Altogether 40 trials were conducted in USA in accordance with registered use patterns. Residues in forage and hay were measured and reported. However, grazing animals on soya bean fields or using forage and hay as animal feed are not permitted, therefore the results of trials were not evaluated.

*Pea forage and hay*

The average residues of trifloxystrobin and CGA 321113 measured in pea green materials (pea vine) obtained from trials conducted according to Canadian GAP are listed below.

Trifloxystrobin residues: 0.61, 0.78, 0.91, 0.92, 1.05, 1.10, 1.30, 1.50 and 1.95 mg/kg.

The sum of trifloxystrobin and CGA 321113 residues: 0.64, 0.81, 0.94, 0.95, 1.09, 1.15, 1.35, 1.54 and 1.98 mg/kg.

The Meeting estimated highest residue of 2 mg/kg and median residue of 1.1 mg/kg for the sum of trifloxystrobin and CGA321113 in pea vine for animal burden calculations.

The residues of trifloxystrobin and CGA 321113 (TFSA) measured in pea hay obtained from trials conducted according to Canadian GAP are listed below. Trifloxystrobin residues: 2.1, 3.0, 3.1, 3.3, 4.2, 5.3, 6.0, 6.7 and 6.8 mg/kg.

The sum of residues were in rank order: 2.2, 3.2, 3.3, 3.6, 4.5, 5.6, 6.3, 6.9 and 7.1 mg/kg

The Meeting estimated a maximum residue level of 17 mg/kg (dry weight) for peanut hay.

The Meeting estimated highest residue of 7.1 mg/kg and median residue of 4.5 mg/kg for the sum of trifloxystrobin and CGA321113 in pea hay for animal burden calculation.

***Fate of Residues in Storage and Processing***

Soya bean was treated with reifloxystrobin three times at a rate of 0.446–0.471 kg/ha and harvested 19 days after last application. The average total trifloxystrobin residue was 0.26 mg/kg in soya bean seed (raw agricultural commodity (RAC)), 18.2 mg/kg in soya bean aspirated grain fractions, 0.12 mg/kg in hulls, < 0.01 mg/kg in meal, and 0.03 mg/kg in refined oil. Concentration of the total trifloxystrobin residue was seen only in the soya bean aspirated grain fractions (processing factor about 70). No concentration of the total trifloxystrobin residue was seen in soya bean hulls, meal, or refined oil.

For the purpose of animal burden calculation, the Meeting estimated median residue of 0.7 mg/kg for aspirated grain fraction, 0.01 mg/kg for hull and < 0.0008 mg/kg for meal of soya bean.

***Residues in animal commodities***

Animal feeding studies were evaluated by the 2004 Meeting. Dairy cows were dosed with trifloxystrobin in capsules at the equivalent of 2, 5.9 or 21 ppm in the diet for 28–30 days. The residues measured in various samples are summarised below:

| Sample        | Day   | Maximum trifloxystrobin residues (mg/kg) |        |        |              |        |        |             |        |        |
|---------------|-------|------------------------------------------|--------|--------|--------------|--------|--------|-------------|--------|--------|
|               |       | Dose 2 ppm                               |        |        | Dose 5.9 ppm |        |        | Dose 21 ppm |        |        |
|               |       | Parent                                   | 321113 | Total  | Parent       | 321113 | Total  | Parent      | 321113 | Total  |
| Milk          | 26    | -                                        | -      | -      | -            | -      | -      | < 0.01      | < 0.01 | < 0.02 |
| Liver         | 28-30 | < 0.02                                   | < 0.02 | < 0.04 | < 0.02       | < 0.02 | < 0.04 | < 0.02      | 0.09   | 0.11   |
| Kidney        | 28-30 | < 0.02                                   | < 0.02 | < 0.04 | < 0.02       | < 0.02 | < 0.04 | < 0.02      | 0.02   | 0.04   |
| Perirenal fat | 28-30 | < 0.02                                   | < 0.02 | < 0.04 |              |        |        | 0.06        | < 0.02 | 0.08   |
| Omental fat   | 28-30 | < 0.02                                   | < 0.02 | < 0.04 | < 0.02       | < 0.02 | < 0.04 | 0.05        | < 0.02 | 0.07   |
| Round         | 28-30 | -                                        | -      | -      | -            | -      | -      | < 0.02      | < 0.02 | < 0.04 |
| Tenderloin    | 28-30 | -                                        | -      | -      | -            | -      | -      | < 0.02      | < 0.02 | < 0.04 |

Laying hens were dosed at 1.5, 4.5 and 15 ppm level for 29 days. At the highest treatment level no residues (< 0.02 mg/kg) were detected in composite tissue samples of breast plus thigh, skin plus attached fat, peritoneal fat, liver and eggs.

The Meeting estimated the dietary burden of trifloxystrobin in farm animals on the basis of the diets listed in Annex 6 of the 2009 JMPR Report and using the estimated residues in livestock feed commodities evaluated by the present and previous Meetings.



|                   | Trifloxystrobin animal dietary burden, ppm, of dry matter diet |      |                   |                   |           |      |       |       |
|-------------------|----------------------------------------------------------------|------|-------------------|-------------------|-----------|------|-------|-------|
|                   | US-Canada                                                      |      | EU                |                   | Australia |      | Japan |       |
|                   | Max                                                            | Mean | Max               | Mean              | Max       | Mean | Max   | Mean  |
| Beef cattle       | 2.17                                                           | 1.15 | 26.6 <sup>a</sup> | 6.97 <sup>b</sup> | 8.24      | 5.00 | 4.53  | 0.84  |
| Dairy cattle      | 2.79                                                           | 1.27 | 23.2 <sup>c</sup> | 6.37 <sup>d</sup> | 8.21      | 4.11 | 2.11  | 0.43  |
| Poultry - broiler | 0.11                                                           | 0.11 | 0.069             | 0.069             | 0.15      | 0.15 | 0.03  | 0.03  |
| Poultry – layer   | 0.11                                                           | 0.11 | 1.83 <sup>e</sup> | 0.78 <sup>f</sup> | 0.15      | 0.15 | 0.079 | 0.079 |

<sup>a</sup> Suitable for estimation maximum residue levels in meat

<sup>b</sup> Suitable for estimation of median residues in meat

<sup>c</sup> Suitable for estimation maximum residue levels in milk

<sup>d</sup> Suitable for estimation median residue levels in milk

<sup>e</sup> Suitable for estimation maximum residue levels in poultry meat and edible offal

<sup>f</sup> Suitable for estimation median residue levels in poultry meat and edible offal

The maximum dietary burden of beef cattle and dairy cattle is about 30% higher than the maximum feeding level of 21 ppm. The Meeting concluded that the residues observed at the highest feeding level can still be used as a basis for estimation of maximum residues in meat, offal and milk.

The Meeting concluded that the current Codex limits cover the residues derived from the uses of trifloxystrobin and maintains its previous recommendations.

## RECOMMENDATIONS

On the basis of the data from supervised trials the Meeting concluded that the residue levels listed in Annex 1 are suitable for establishing maximum residue limits and for IEDI assessment.

## DIETARY RISK ASSESSMENT

### *Long-term intake*

The International Estimated Daily Intakes (IEDIs) of trifloxystrobin were calculated for the 17 GEMS/Food cluster diets using STMRs and STMR-Ps estimated by the JMPR in 2004, 2012 and the current meeting. The results are shown in Annex 3.

The ADI is 0–0.04 mg/kg bw and the calculated IEDIs were 1–4% of the maximum ADI. The Meeting concluded that the long-term intake of residues of trifloxystrobin from the uses considered by the JMPR is unlikely to present a public health concern.

### *Short-term intake*

The 2004 JMPR decided that it was unnecessary to establish an ARfD. The present Meeting therefore concluded that the short-term intake of trifloxystrobin residues is unlikely to present a public health

## TRIFLOXYSTROBIN (213)

*The first draft was prepared by Professor Arpad Ambrus, Hungarian Food Chain Safety Office, Budapest Hungary*

### EXPLANATION

Trifloxystrobin is a broad-spectrum contact fungicide for foliar application. It was first evaluated by the JMPR in 2004 (T, R) and 2012 (R). The 2004 Meeting established an ADI of 0–0.04 mg/kg bw and decided that ARfD was not necessary. The Meeting agreed that the residue definition for enforcement purposes for plant commodities should be trifloxystrobin per se, for animal commodities and dietary intake assessment the residue definition should be parent compound and CGA 321113 (expressed as trifloxystrobin equivalents).

Data on identity, formulations, physical and chemical properties, metabolism and environmental fate of trifloxystrobin were submitted to the JMPR in 2004. No new information was made available. Supervised trials data were submitted for a number of commodities for evaluation by the 2004, and 2012 JMPR.

Trifloxystrobin was listed by the 46<sup>th</sup> Session of CCPR (2014) for the evaluation by the 2015 JMPR for additional MRLs. Additional supervised trial data were submitted for evaluation on dry soya beans, lentils, chick peas and peas together with new data, which were not available in the first evaluation in 2004.

### METHODS OF RESIDUE ANALYSIS

#### *Analytical methods*

The Meeting received descriptions and validation data for analytical methods for residues of trifloxystrobin (CGA 321113) and several other metabolites in different plant matrices.

The DFG method S19, evaluated in 2004, is suitable for enforcement. Analytical methods used in residue trials evaluated by the present Meeting are summarized below.

#### *Method 00742 (Nuesslein, F 2002)*

The method was developed and validated for the determination of residues of parent trifloxystrobin and CGA 321113 (metabolite) in/on sample materials of carrots, Brussels sprouts, cabbages, tomatoes, red peppers and lettuce. Both analytes were extracted from plant materials using a mixture of acetonitrile/water. After filtration and concentration to the aqueous remainder, the acidified crude extract was purified by liquid-liquid partition on a ChemElut cartridge, thereby partitioning the analytes in a mixture of cyclohexane / ethyl acetate. The residues were quantified by reverse-phase HPLC with Turbo-Ionspray MS/MS-detection. The limit of quantitation (LOQ) was 0.02 mg/kg in all matrices. Recoveries for trifloxystrobin ranged from 72 to 99% with mean values between 81 and 93% and relative standard deviations between 0.7 and 10.4%. In the case of CGA 321113, recoveries were between 71 and 103% with mean values between 83 and 100% and relative standard deviations between 0.6 and 8.1%. The repeatability was tested with carrots and tomatoes.

#### *Supplement E001 for method 00742 (Nuesslein, F 2003)*

The analytical method 00742 was validated for the determination of trifloxystrobin and CGA 321113 in additional plant materials. Recovery tests were performed at fortification levels of 0.02 mg/kg, 0.20 mg/kg and 2.0 mg/kg with the sample materials beans (beans with pods), broccoli (head), cauliflower (head), cherries (fruit), cucumbers (fruit), currants (fruit), leeks (shoots), melons (fruit, peel), plums (fruit) and strawberries (fruit, jam and preserves). The LOQ was 0.02 mg/kg in all matrices. Individual recovery rates of trifloxystrobin ranged from 68 to 103% with overall standard deviations (RSD) between 1.1 and 9.3%. In the case of CGA 321113, recoveries were between 81 and

101% with overall standard deviations (RSD) between 1.4 and 5.4%. The repeatability was tested successfully with cauliflower and strawberries.

*Method 00765 (Sur, R 2003.)*

The method was developed and validated to determine trifloxystrobin, its metabolite CGA 321113, and cyproconazole in/on cucumbers, green peppers, melons and tomatoes. The active substances and the metabolite were extracted twice from the sample material with an acetonitrile/water mixture. After filtration and dilution the extract solution was subjected to HPLC-MS/MS analysis for quantitation. For all three analytes two transitions are recorded. The LOQ for all analytes was 0.01 mg/kg. The method was validated by spiking control samples with the analytes at fortification levels of 0.01 and 0.1 mg/kg. The overall mean recovery for the quantifier transition was 99% (RSD 3.8%, n=32) for trifloxystrobin and 100% (RSD 2.7%, n=32) for CGA 321113. For the qualifier transition the overall mean recovery was 100% (RSD 4%, n=32) for trifloxystrobin and 96% (RSD 6.2%, n = 32) for CGA 321113. The repeatability was tested with melons and tomatoes.

*Method 01013 (Brumhard, B and Stuke, S 2007.)*

The method was developed for the determination of residues of trifloxystrobin and metabolite CGA 321113, and other active substances and their metabolites in/on plant material (citrus fruit, pea green seed, wheat grain, rape seed, and corn green material). All analytes were extracted from plant materials using a mixture of acetonitrile/water. After filtration of the extract, the stable isotopically labelled analytes were added. The solution was made up to volume, diluted and subjected to reversed phase HPLC-MS/MS without a further clean-up step.

The LOQ for the determination of trifloxystrobin and CGA 321113 was 0.01 mg/kg in all matrices tested. The method was validated by spiking control samples with the analytes at fortification levels of 0.01 and 0.1 mg/kg. Mean recoveries for each fortification level and the overall mean recovery were within the 70–110% range for all matrices. The correlation between the injected amount of substance and the detector response was linear for solvent standards ranging from 0.005 to 50 µg/L. Possible matrix effects were eliminated by the internal standard procedure using isotopically stable labelled standards.

Apparent residues in control samples were below  $0.3 \times \text{LOQ}$ . Two MRM transitions were monitored and calculated for each analyte and each matrix tested. The HPLC-MS/MS method is highly specific and an additional confirmatory method is not necessary. The repeatability was tested successfully with all matrices. Relative standard deviations were below 20% for all analytes and sample materials. The method 01013 allows determination of trifloxystrobin-derived residues in crops with a LOQ of 0.01 mg/kg.

*Method 01313 (Stuke, S 2013.)*

The method was developed for the determination of residues of trifloxystrobin (CGA 279202) and metabolite CGA 321113, and their isomers CGA357262, CGA357261, CGA331409, and CGA373466 in/on corn green material, bean dry seed, wheat grain, rape seed, dried hops and orange fruit. All analytes were extracted from plant materials using a mixture of acetonitrile/water. After filtration by using celite and addition of ammonium acetate solution to adjust the pH, the extract was made up to volume, diluted and subjected to HPLC-MS/MS measurement. The LOQ for the determination of trifloxystrobin and CGA 321113 was 0.01 mg/kg in all matrices tested. The method was validated by spiking control samples with the analytes at fortification levels of 0.01 and 0.1 mg/kg (0.05 and 0.5 mg/kg in hops). Mean recoveries for each fortification level and the overall mean recovery were within the 70–110% range for trifloxystrobin and CGA 321113. The mean and the overall mean relative standard deviations at each fortification level were below 20%.

The results of the method validation were confirmed using a second and a third MRM transition for confirmation. The LOQ was 0.01 mg/kg for trifloxystrobin-derived residues.

*Method 200177 (de Haan, RA 2002.)*

The method was developed for the determination of trifloxystrobin and CGA 321113 in plant materials. The residues of trifloxystrobin and CGA 321113 were extracted from homogenised plant samples with acetonitrile/water (4 vol. + 1 vol.) in a blender. The suspension was vacuum filtered through a paper filter. The remaining solids were blended a second time with fresh solvent and filtered. The filtrates were combined and deuterated internal standard was added. The total volume was adjusted to 50 mL with acetonitrile/water (4 vol. + 1 vol.). A solid phase extraction was performed on a SPE column under slight vacuum. The column was rinsed with acetonitrile/water (4 vol. + 1 vol.) and the analytes were eluted with acetonitrile. The solution was evaporated to dryness, the dry residue was subsequently dissolved in acetonitrile/water (4 vol. + 1 vol.). The final determination was done with LC/MS/MS in the positive ion mode. The LOQ was 0.01 mg/kg.

The recovery values obtained during the validation of the above methods are summarized in Table 1.

Table 1 Recovery of trifloxystrobin and CGA321113 from different plant materials

| Sample /method                                                                          | Analyte         | Spike level<br>[mg/kg] | No of<br>tests | Mean recovery [%] | RSD [%] |
|-----------------------------------------------------------------------------------------|-----------------|------------------------|----------------|-------------------|---------|
| Method 00742 trifloxystrobin 409.2 →186.3 (145.2) amu; CGA 321113: 395.1→186.1 (145.2). |                 |                        |                |                   |         |
| Carrot                                                                                  | Trifloxystrobin | 0.02, 0.2              | 10             | 85                | 5.9     |
|                                                                                         | CGA321113       |                        | 10             | 83                | 5.6     |
| Brussels sprout                                                                         | Trifloxystrobin | 0.02, 0.2, 2.0         | 9              | 86                | 5.2     |
|                                                                                         | CGA321113       |                        |                | 90                | 5.6     |
| Cabbage, head                                                                           | Trifloxystrobin | 0.02, 0.2, 2.0         | 9              | 84                | 5.3     |
|                                                                                         | CGA321113       |                        | 9              | 91                | 2.5     |
| Lettuce, head                                                                           | Trifloxystrobin | 0.02, 0.2, 2.0         | 9              | 88                | 7.5     |
|                                                                                         | CGA321113       |                        | 9              | 95                | 3.0     |
| Pepper                                                                                  | Trifloxystrobin | 0.02, 0.2, 2.0         | 9              | 90                | 4.5     |
|                                                                                         | CGA321113       |                        | 9              | 96                | 3.3     |
| Tomato                                                                                  | Trifloxystrobin | 0.02, 0.2              | 10             | 89                | 9.5     |
|                                                                                         | CGA321113       |                        | 10             | 96                | 5.2     |
| Method 00742/Supplement E001                                                            |                 |                        |                |                   |         |
| Bean                                                                                    | Trifloxystrobin | 0.02, 0.2, 2.0         | 9              | 91                | 5.3     |
|                                                                                         | CGA321113       |                        |                | 91                | 5.1     |
| Broccoli, head                                                                          | Trifloxystrobin | 0.02, 0.2, 2.0         | 9              | 93                | 3.6     |
|                                                                                         | CGA321113       |                        |                | 96                | 4.1     |
| Cauliflower                                                                             | Trifloxystrobin | 0.02, 0.2              | 10             | 92                | 3.6     |
|                                                                                         | CGA321113       |                        |                | 93                | 4.1     |
| Cherry, fruit                                                                           | Trifloxystrobin | 0.02, 0.2, 2.0         | 9              | 95                | 2.7     |
|                                                                                         | CGA321113       |                        |                | 94                | 2.9     |
| Cucumber                                                                                | Trifloxystrobin | 0.02, 0.2, 2.0         | 9              | 94                | 3.5     |
|                                                                                         | CGA321113       |                        |                | 90                | 4.7     |
| Currant                                                                                 | Trifloxystrobin | 0.02, 0.2, 2.0         | 9              | 92                | 4.0     |
|                                                                                         | CGA321113       |                        |                | 95                | 4.3     |
| Leek                                                                                    | Trifloxystrobin | 0.02, 0.2, 2.0         | 9              | 93                | 1.9     |
|                                                                                         | CGA321113       |                        |                | 94                | 1.8     |
| Melon, fruit                                                                            | Trifloxystrobin | 0.02, 0.2, 2.0         | 9              | 94                | 2.3     |
|                                                                                         | CGA321113       |                        |                | 94                | 2.6     |
| Melon, peel                                                                             | Trifloxystrobin | 0.02, 0.2, 2.0         | 9              | 93                | 1.1     |
|                                                                                         | CGA321113       |                        |                | 94                | 1.4     |
| Plum, fruit                                                                             | Trifloxystrobin | 0.02, 0.2, 2.0         | 9              | 94                | 1.3     |
|                                                                                         | CGA321113       |                        |                | 96                | 1.4     |
| Strawberry, fruit                                                                       | Trifloxystrobin | 0.02, 0.2              | 10             | 86                | 9.3     |
|                                                                                         | CGA321113       |                        |                | 89                | 3.8     |
| Strawberry, jam                                                                         | Trifloxystrobin | 0.02, 0.2, 2.0         | 9              | 94                | 5.3     |
|                                                                                         | CGA321113       |                        |                | 95                | 4.7     |
| Strawberry, preserve                                                                    | Trifloxystrobin | 0.02, 0.2, 2.0         | 9              | 95                | 5.4     |
|                                                                                         | CGA321113       |                        |                | 95                | 5.4     |
| Method 00765 trifloxystrobin 409.2 →186.3 (145.2) amu; CGA 321113: 395.1→186.1 (145.2). |                 |                        |                |                   |         |
| Cucumber                                                                                | Trifloxystrobin | 0.01, 0.1              | 6              | 94                | 2.9     |

| Sample /method                                                                                                                                              | Analyte         | Spike level [mg/kg] | No of tests | Mean recovery [%] | RSD [%] |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|---------------------|-------------|-------------------|---------|
|                                                                                                                                                             | CGA321113       |                     |             | 99                | 3.0     |
| Green pepper                                                                                                                                                | Trifloxystrobin | 0.01, 0.1           | 6           | 101               | 3.4     |
|                                                                                                                                                             | CGA321113       |                     |             | 102               | 3.3     |
| Melon                                                                                                                                                       | Trifloxystrobin | 0.01, 0.1           | 10          | 97                | 1.9     |
|                                                                                                                                                             | CGA321113       |                     |             | 98                | 107     |
| Tomato                                                                                                                                                      | Trifloxystrobin | 0.01, 0.1           | 10          | 101               | 1.9     |
|                                                                                                                                                             | CGA321113       |                     |             | 100               | 1.9     |
| Method 01013 trifloxystrobin 409.2 →186.3 (145.2) amu; CGA 321113: 395.1→186.1 (145.2).                                                                     |                 |                     |             |                   |         |
| Citrus fruit                                                                                                                                                | Trifloxystrobin | 0.01, 0.1           | 10          | 99                | 3.7     |
|                                                                                                                                                             | CGA321113       |                     |             | 102               | 8.8     |
| Peas                                                                                                                                                        | Trifloxystrobin | 0.01, 0.1           | 10          | 100               | 3.1     |
|                                                                                                                                                             | CGA321113       |                     |             | 101               | 4.7     |
| Rape seed                                                                                                                                                   | Trifloxystrobin | 0.01, 0.1           | 10          | 99                | 3.6     |
|                                                                                                                                                             | CGA321113       |                     |             | 103               | 5.6     |
| Wheat grain                                                                                                                                                 | Trifloxystrobin | 0.01, 0.1           | 10          | 98                | 3.1     |
|                                                                                                                                                             | CGA321113       |                     |             | 88                | 13.2    |
| Corn green material                                                                                                                                         | Trifloxystrobin | 0.01, 0.1           | 10          | 104               | 5.6     |
|                                                                                                                                                             | CGA321113       |                     |             | 94                | 12.8    |
| Method 200177 trifloxystrobin 409.2 →186.3 (145.2) amu; CGA 321113: 395.1→186.1 (145.2).<br>TFS-d <sub>3</sub> 412 →186; CGA 321113-d <sub>3</sub> 398 →186 |                 |                     |             |                   |         |
| Pepper, tomato                                                                                                                                              | Trifloxystrobin | 0.01                | 16          | 93                | 11.2    |
|                                                                                                                                                             | CGA321113       |                     |             | 91                | 13.6    |
| Soya beans                                                                                                                                                  | Trifloxystrobin | 0.01, 0.05, 0.2     |             | 86                | 6.4     |
|                                                                                                                                                             | CGA321113       |                     |             | 91                | 19      |

### Stability of residues in stored analytical samples

Individual data on storage stability were evaluated by the 2004 JMPR. The results indicated that the residues of trifloxystrobin and CGA 321113 are stable under freezer storage conditions for at least 24 months (grapes, cucumbers, potato, and wheat grain, straw and whole plant) or 18 months (apple fruit, apple wet pomace, peanut nutmeat, peanut oil, and grape juice). No new information was provided.

### USE PATTERNS

Various formulations of trifloxystrobin are registered for application in chickpeas, dry peas, lentils and soya (Table 2) for the control of various fungus diseases of Chickpea (Ch), dry peas (Dp), Lentils (L) and soya (S): *Alternaria* spp. (S), *Ascochyta lentis* (L), *Ascochyta pisi* (Dp), *Ascochyta rabiei* (Ch), *Botrytis cinerea* (CH, L), *Cercospora kikuchii* (S), *Cercospora sojina* (S), *Colletotrichum truncatum* (Ch,L,S), *Corynespora cassiicola* (S), *Diaporthe phaseolorum* (S), *Erysiphe diffusa* (S), *Macrophomina phaseolina* (S), *Microspheera diffusa* (S), *Mycosphaerella pinodes* (Dp), *Phakopsora pachyrhizi* (S), *Phomopsis longicolla* (S), *Rhizoctonia solani* (S), *Sclerotinia sclerotiorum* (Ch, L, S), and *Septoria glycines* (S).

Table 2 Composition of trifloxystrobin formulations

| Formulation | Active ingredient content                        |
|-------------|--------------------------------------------------|
| SC 500      | 375 g/L trifloxystrobin + 125 g/L prothionazole  |
| SC 535      | 375 g/L trifloxystrobin + 160 g/L cyproconazole  |
| EC 267.5    | 187.5 g/L trifloxystrobin + 80 g/L cyproconazole |
| SC 325      | 150 g/L trifloxystrobin + 175 g/L prothionazole  |
| EC 250      | 125 g/L trifloxystrobin + 125 g/L propiconazole  |
| SC 300      | 100 g/L trifloxystrobin + 200 g/L tebuconazole   |

Table 3 Registered uses for foliar application of trifloxystrobin in peas, lentils and soya beans

| Crop     | Country | Formulation | Application      |     | PHI (days)             |
|----------|---------|-------------|------------------|-----|------------------------|
|          |         |             | Rate, [kg ai/ha] | No. |                        |
| Chickpea | Canada  | SC 325      | 0.132            | 1–2 | 30 (seed) <sup>a</sup> |

| Crop      | Country | Formulation | Application      |        |        | PHI<br>(days)          |
|-----------|---------|-------------|------------------|--------|--------|------------------------|
|           |         |             | Rate, [kg ai/ha] |        | No.    |                        |
| Chickpea  | USA     | SC 325      |                  | 0.12   | 1–2    | 30 (seed) <sup>a</sup> |
| Dry peas  | Canada  | SC 325      |                  | 0.132  | 1–2    | 30 (seed) <sup>a</sup> |
| Dry peas  | USA     | SC 325      |                  | 0.12   | 1–2    | 30 (seed) <sup>a</sup> |
| Lentils   | Canada  | SC 325      |                  | 0.132  | 1–2    | 30 (seed) <sup>a</sup> |
| Lentils   | USA     | SC 325      |                  | 0.12   | 1–2    | 30 (seed) <sup>a</sup> |
| Soya bean | Brazil  | EC 267.5    | 0.0563           | 0.075  | 2      | 30                     |
|           |         | SC 325      | 0.045–           | 0.060  | 2      | 30                     |
|           |         | SC 300      | 0.04–            | 0.06   | 1–4    | 30                     |
|           |         | SC 535      | 0.0563–          | 0.075  | 2      | 30                     |
|           |         | EC 250      |                  | 0.05   | 2      | 30                     |
| Soya bean | Canada  | EC 250      |                  | 0.0625 | max. 2 | 20 <sup>b</sup>        |
|           |         | SC 325      |                  | 0.0858 | max. 2 | 20 <sup>b</sup>        |
| Soya bean | USA     | EC 250      |                  | 0.0913 | max. 3 | 21 <sup>b</sup>        |
| Soya bean | USA     | SC 500      | 0.1095           | 0.1271 | max. 3 | 21 <sup>b</sup>        |

<sup>a</sup> Do not apply within 7 days of cutting or swathing of the crop for forage

<sup>b</sup> Do not graze or feed soya bean forage or hay

## RESIDUES RESULTING FROM SUPERVISED TRIALS ON CROPS

Numerous residue trials were performed according to GLP with different mixture formulations of trifloxystrobin.

Trials were generally well documented with laboratory and field reports. Laboratory reports included method validation with procedural recoveries from spiking at residue levels similar to those occurring in samples from the supervised trials. Dates of analyses or duration of residue sample storage were also provided. Although trials included control plots, no control data are recorded in the tables except where residues in control samples exceeded the LOQ. Control samples are indicated in the summary tables with a "c". Unless stated otherwise, residue data are recorded unadjusted for recovery. The averages of detected residues, used for estimation of residue levels, are double underlined.

Residues have generally been rounded to two significant figures or, for residues near the LOQ, to one significant figure. However, the calculations were made with Excel utilising all digits. Residue values from the trials conducted according to GAP have been used for the estimation of maximum residue levels. Those results included in the evaluation are underlined.

### Pulses

#### Soya beans

Four field trials were conducted in Canada (Ardiel, KD 2007.) with application rates of two times 0.0625 kg trifloxystrobin/ha and sampling 19 or 21 days after the last application.

In 2003 a total of twenty residue trials were performed in the USA. Trifloxystrobin was applied three times at application rates of 0.086 to 0.095 kg trifloxystrobin/ha. Samples of soya bean (seed) were taken at days 19 to 24 after the last application. In 2005 an additional twenty residue trials were conducted in the USA. Trifloxystrobin was applied three times at application rates of 0.122 to 0.134 kg ai/ha. Samples of soya bean (seed) were taken at days 19 to 23 after the last application.

The residues of trifloxystrobin and CGA 321113 were determined according to method 200177. The LOQ was 0.01 mg/kg.

Altogether 16 trials were reported from Brazil according to the Brazilian use patterns with two applications up to 0.075 or four applications up to 0.06 kg trifloxystrobin/ha and a PHI of about 30 days. The LOQ was 0.01–0.02 mg/kg (Anon. 2010, Anon. 2012a, 2012b, Resende, G 2011, Santiago, L 2012a, 2012b, Galhiane, MS and de Sousa, SL 2006a, Galhiane, MS and de

Sousa, SL 2006b, Galhiane, MS and de Sousa, SL 2006c, Galhiane, MS and de Sousa, SL 2006d, Galhiane, MS and de Sousa, SL 2006e, Galhiane, MS and de Sousa, SL 2006f.).

The results of the trials are summarized in Tables 4–6.



Table 4 Results of residue trials conducted with 250 EC trifloxystrobin (TFS) in/on soya bean seed in Canada

| Study<br>Trial No.<br>Plot No.<br>Year                    |                        |                                       | Application |               |                   |    |     | Residues [mg/kg] <sup>a</sup> |        |        |  |
|-----------------------------------------------------------|------------------------|---------------------------------------|-------------|---------------|-------------------|----|-----|-------------------------------|--------|--------|--|
|                                                           | Crop<br>Variety        | Country                               | No          | kg/ha<br>(as) | kg/hL<br>(as)     | GS | DAT | TFS                           | CGA    |        |  |
| Canadian GAP: 2 time 0.0625 kg ai/ha with PHI of 30 days. |                        |                                       |             |               |                   |    |     |                               |        |        |  |
| 06BCS-14<br>05BCS06-01-05D<br>CND-05BCS06-01-05D, 2005    | DeKalb,<br>DKBOO-99    | Canada<br>Rock-wood                   | 2           | 0.0625        | 0.0179–<br>0.0182 | 87 | 9   | 0.012                         | < 0.01 | < 0.01 |  |
|                                                           |                        |                                       |             |               |                   |    | 9   | < 0.01                        | < 0.01 |        |  |
|                                                           |                        |                                       |             |               |                   |    | 14  | < 0.01                        | < 0.01 |        |  |
|                                                           |                        |                                       |             |               |                   |    | 14  | < 0.01                        | < 0.01 |        |  |
|                                                           |                        |                                       |             |               |                   |    | 21  | < 0.01                        | < 0.01 |        |  |
|                                                           |                        |                                       |             |               |                   |    | 21  | < 0.01                        | < 0.01 |        |  |
|                                                           |                        |                                       |             |               |                   |    | 24  | < 0.01                        | < 0.01 |        |  |
|                                                           |                        |                                       |             |               |                   |    | 24  | < 0.01                        | < 0.01 |        |  |
|                                                           |                        |                                       |             |               |                   |    | 30  | < 0.01                        | < 0.01 |        |  |
|                                                           |                        |                                       |             |               |                   |    | 30  | < 0.01                        | < 0.01 |        |  |
| 06BCS-14<br>05BCS06-02-05H<br>CND-05BCS06-02-05H, 2005    | Pioneer<br>90B73       | Canada<br>Green-field                 | 2           | 0.0625        | 0.0166–<br>0.0182 | 86 | 19  | < 0.01                        | < 0.01 |        |  |
|                                                           |                        |                                       |             |               |                   |    | 19  | < 0.01                        | < 0.01 |        |  |
| 06BCS-14<br>05BCS06-03-05H<br>CND-05BCS06-03-05H, 2005    | SeCan<br>Raptor        | Canada<br>Breslau                     | 2           | 0.0625        | 0.0168–<br>0.0185 | 85 | 19  | < 0.01                        | < 0.01 |        |  |
|                                                           |                        |                                       |             |               |                   |    | 19  | < 0.01                        | < 0.01 |        |  |
| 06BCS-14<br>05BCS06-04-05H<br>CND-05BCS06-04-05H, 2005    | Herbic.<br>Inc. 26-02R | Canada<br>St-Pie<br>America,<br>North | 2           | 0.0625        | 0.0230–<br>0.0231 | 77 | 21  | < 0.01                        | < 0.01 |        |  |
|                                                           |                        |                                       |             |               |                   |    | 21  | < 0.01                        | < 0.01 |        |  |

FL=Formulation

No=number of applications

GS=growth stage at last application

DAT=days after last treatment

TFS= trifloxystrobin

<sup>a</sup> Residues were measured in dry seeds.

Table 5 Results of residue trials conducted with trifloxystrobin in/on soya bean seed in Brazil

| Study<br>Trial No.<br>Plot No.<br>Year      | Crop<br>Variety                | Country<br>Location         | Application |    |               |                   |    | DDAT           | Residues [mg/kg] <sup>a</sup>        |                               |        |
|---------------------------------------------|--------------------------------|-----------------------------|-------------|----|---------------|-------------------|----|----------------|--------------------------------------|-------------------------------|--------|
|                                             |                                |                             | FL          | No | kg/ha<br>(as) | kg/hL<br>(as)     | GS |                | TFS                                  | CGA<br>321113                 | Sum    |
| Brazil GAP: SC325 max 2×75 g/ha PHI=30 days |                                |                             |             |    |               |                   |    |                |                                      |                               |        |
| F11-035<br>F11-035-01<br>2011               | Soya bean<br>TMG<br>7161 RR    | Brazil<br>Paulinia          | 325<br>SC   | 2  | 0.06000.0650  | 0.0300-<br>0.0325 | 75 | 25<br>30<br>35 | < 0.01<br>< 0.01<br>< 0.01           | 0.01<br>< 0.01<br>< 0.01      | < 0.01 |
| F11-035<br>F11-035-02<br>2012               | Soya bean<br>Monsoy<br>7808 RR | Brazil<br>Ribeirão<br>Preto | 325<br>SC   | 2  | 0.06080.0615  | 0.0304-<br>0.0308 | 71 | 25<br>30<br>35 | < 0.01<br>< 0.01<br>< 0.01           | 0.02<br>0.02<br>0.01          | 0.03   |
| F11-035<br>F11-035-03<br>2012               | Soya bean<br>BRS GO<br>7560    | Brazil<br>Uber-<br>lândia   | 325<br>SC   | 2  | 0.05970.0608  | 0.0298-<br>0.0304 | 79 | 25<br>30<br>35 | < 0.01<br>< 0.01<br>< 0.01           | < 0.01<br>< 0.01<br>< 0.01    | < 0.01 |
| F11-035<br>F11-035-04<br>2012               | Soya bean<br>ANTA 82           | Brazil<br>Trindade          | 325<br>SC   | 2  | 0.0600        | 0.0300            | 75 | 30             | < 0.01                               | 0.01                          | < 0.01 |
| F11-035<br>F11-035-05<br>2011               | Soya bean<br>CD206             | Brazil<br>Castro            | 325<br>SC   | 2  | 0.06000.0653  | 0.0300-<br>0.0327 | 65 | 32             | < 0.01                               | 0.01                          | < 0.01 |
| F11-036<br>F11-036-01<br>2011               | Soya bean<br>TMG<br>7161 RR    | Brazil<br>Paulinia          | 325<br>SC   | 2  | 0.0766        | 0.0383            | 75 | 25<br>30<br>35 | < 0.01<br><u>&lt; 0.01</u><br>< 0.01 | < 0.01<br><u>0.01</u><br>0.01 | 0.02   |



## Trifloxystrobin

| Study Trial No.<br>Plot No.<br>Year                                              | Crop Variety                   | Country Location                 | Application |    |              |                   |    | DDAT           | Residues [mg/kg] <sup>a</sup> |                        |        |
|----------------------------------------------------------------------------------|--------------------------------|----------------------------------|-------------|----|--------------|-------------------|----|----------------|-------------------------------|------------------------|--------|
|                                                                                  |                                |                                  | FL          | No | kg/ha (as)   | kg/hL (as)        | GS |                | TFS                           | CGA 321113             | Sum    |
| F11-036<br>F11-036-02<br>2012                                                    | Soya bean<br>Monsoy<br>7808 RR | Brazil<br>Ribeirão<br>Preto      | 325<br>SC   | 2  | 0.07500.0759 | 0.0375-<br>0.0380 | 71 | 25<br>30<br>35 | < 0.01<br>< 0.01<br>< 0.01    | 0.02<br>0.02<br>0.02   | 0.03   |
| F11-036<br>F11-036-03<br>2012                                                    | Soya bean<br>M 7908<br>RR      | Brazil<br>Uber-<br>lândia        | 325<br>SC   | 2  | 0.07140.0774 | 0.0357-<br>0.0387 | 75 | 25<br>30<br>35 | < 0.01<br>< 0.01<br>< 0.01    | < 0.01<br>0.01<br>0.01 | 0.02   |
| F11-036<br>F11-036-04<br>2012                                                    | Soya bean<br>ANTA 82           | Brazil<br>Trindade               | 325<br>SC   | 2  | 0.07500.0762 | 0.0375-<br>0.0381 | 75 | 30             | < 0.01                        | < 0.01                 | < 0.01 |
| F11-036<br>F11-036-05<br>2011                                                    | Soya bean<br>CD 206            | Brazil<br>Castro                 | 325<br>SC   | 2  | 0.07660.0776 | 0.0383-<br>0.0388 | 65 | 32             | < 0.01                        | 0.01                   |        |
| Brazilian GAP: SC 300: 0.05 kg ai/ha 4 times; 0.06 kg ai/ha 2 times, PHI 30 days |                                |                                  |             |    |              |                   |    |                |                               |                        |        |
| F09-022<br>F09-022-02<br>2010                                                    | Soya bean<br>M7908<br>RR       | Überlan-<br>dia / MG             | 300<br>SC   | 4  | 0.073-0.080  | 0.037-<br>0.040   | 83 | 25             | < 0.01                        | < 0.01                 | < 0.01 |
| F09-022<br>F09-022-03<br>2010                                                    | Soya bean<br>NK 8350           | Ponta<br>Grossa /<br>Parana      | 300<br>SC   | 4  | 0.07250.0849 | 0.0363-<br>0.0425 | 60 | 28             | < 0.01<br>(n.d.)              | < 0.01                 | < 0.01 |
| F09-022<br>F09-022-04<br>2010                                                    | Soya bean<br>Valiosa           | Goiania /<br>GO                  | 300<br>SC   | 4  | 0.075-0.077  | 0.038-<br>0.039   | 85 | 29             | < 0.01                        | < 0.01<br>(n.d.)       | < 0.01 |
| UNESP RA-<br>992/06<br>FR05BRA001<br>BRA-<br>FR05BRA001-<br>P1-A, 2005           | Soya bean<br>CD 205            | EAE-<br>Paulinia/<br>SP          | 75<br>WG    | 4  | 0.050        | 0.025             | 86 | 30             | < 0.02                        | < 0.01<br>(n.d.)       | < 0.02 |
| UNESP RA-<br>993/06<br>FR05BRA001<br>BRA-<br>FR05BRA001-<br>P2-A, 2005           | Soya bean<br>CD 201            | Brazil<br>Londrina -<br>PR       | 75<br>WG    | 4  | 0.050        | 0.025             | 85 | 30             | < 0.02                        | < 0.01<br>(n.d.)       | < 0.02 |
| UNESP RA-<br>994/06<br>FR05BRA001<br>BRA-<br>FR05BRA001-<br>P3-A, 2005           | Soya bean<br>Xingu             | Brazil<br>Rondono-<br>polis - MT | 75<br>WG    | 4  | 0.050        | 0.025             | 83 | 30             | < 0.01<br>(n.d.)              | < 0.01<br>(n.d.)       | < 0.01 |

FL=Formulation

No=number of applications

GS=growth stage at last application

DAT=days after last treatment

TFS: trifloxystrobin

n.d.=residues below limit of detection

<sup>a</sup> Residues were measured in dry seeds,

Table 6. Results of residue trials conducted with trifloxystrobin in/on soya bean in the USA.

| Study<br>Trial No.<br>Plot No.<br>Year                        |                               |                                 | Application |        |                 |                 |    |                                                          |                                                                                                                      | Residues [mg/kg] <sup>a</sup>                                                                                       |         |  |
|---------------------------------------------------------------|-------------------------------|---------------------------------|-------------|--------|-----------------|-----------------|----|----------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------|---------|--|
|                                                               | Variety                       | Country                         | FL          | N<br>o | kg/ha<br>(as)   | kg/hL<br>(as)   | GS | DAT                                                      | TFS                                                                                                                  | CGA<br>321113                                                                                                       | Sum     |  |
| USA GAP 250EC, 0.09125 kg/ha max 3 times with PHI of 21 days  |                               |                                 |             |        |                 |                 |    |                                                          |                                                                                                                      |                                                                                                                     |         |  |
| RCTFY004<br>FL079-03H<br>USA-FL079-<br>03H-B, 2003            | Hartz<br>Seed<br>H6686R<br>R  | USA<br>Tifton,<br>Georgia       | 250<br>EC   | 3      | 0.092           | 0.064           | 86 | 20<br>20                                                 | < 0.01<br>< 0.01                                                                                                     | < 0.01<br>< 0.01                                                                                                    | < 0.01  |  |
| RCTFY004<br>FL080-03H<br>USA-FL080-<br>03H-B, 2003            | NK S73-<br>Z5                 | USA<br>Molino,<br>Florida       | 250<br>EC   | 3      | 0.084–<br>0.092 | 0.043–<br>0.044 | 79 | 24<br>24                                                 | < 0.01<br>< 0.01                                                                                                     | < 0.01<br>< 0.01                                                                                                    | < 0.,01 |  |
| RCTFY004<br>FL081-03H<br>USA-FL081-<br>03H-B, 2003            | Hornbec<br>k<br>5588RR        | USA<br>Proctor,<br>Arkansas     | 250<br>EC   | 3      | 0.091–<br>0.092 | 0.063–<br>0.066 | 91 | 21<br>21                                                 | < 0.01<br>< 0.01                                                                                                     | < 0.01<br>< 0.01                                                                                                    | < 0.01  |  |
| RCTFY004<br>FL082-03H<br>USA-FL082-<br>03H-B, 2003            | Delta<br>King<br>5661 RR      | USA<br>Newport,<br>Arkansas     | 250<br>EC   | 3      | 0.092–<br>0.093 | 0.049–<br>0.049 | 79 | 20<br>20                                                 | < 0.01<br>< 0.01                                                                                                     | < 0.01<br>< 0.01                                                                                                    | < 0.01  |  |
| RCTFY004<br>FL083-03D<br>USA-FL083-<br>03D-B<br>2003          | S56-D7                        | USA<br>Leland,<br>Mississippi   | 250<br>EC   | 3      | 0.087–<br>0.092 | 0.068–<br>0.078 | 77 | 18<br>18<br>21<br>21<br>26<br>26<br>27<br>27<br>32<br>32 | 0.055<br>0.020<br>0.018<br>0.035<br><u>0.265</u><br>0.012<br>< 0.01<br>0.030<br>0.019<br>0.014<br>0.015              | 0.022<br>< 0.01<br>< 0.01<br>< 0.01<br><u>&lt; 0.01</u><br>< 0.01<br>< 0.01<br>< 0.01<br>< 0.01<br>< 0.01<br>< 0.01 | 0.265   |  |
| RCTFY004<br>FL084-03D<br>USA-FL084-<br>03D-B<br>: yes<br>2003 | FS<br>HT322<br>STS            | USA<br>Seymour,<br>Illinois     | 250<br>EC   | 3      | 0.092–<br>0.093 | 0.063–<br>0.068 | 85 | 18<br>18<br>21<br>21<br>24<br>24<br>27<br>27<br>33<br>33 | < 0.01<br>< 0.01<br><u>&lt; 0.01</u><br><u>&lt; 0.01</u><br>< 0.01<br>< 0.01<br>< 0.01<br>< 0.01<br>< 0.01<br>< 0.01 | < 0.01<br>< 0.01<br><u>&lt; 0.01</u><br><u>&lt; 0.01</u><br>< 0.01<br>< 0.01<br>0.017<br>0.014<br>< 0.01<br>< 0.01  |         |  |
| RCTFY004<br>FL085-03H<br>USA-FL085-<br>03H-B, 2003            | NK S26<br>C9                  | USA<br>Springfield,<br>Nebraska | 250<br>EC   | 3      | 0.092           | 0.063–<br>0.064 |    | 21<br>21                                                 | < 0.01<br>< 0.01                                                                                                     | < 0.01<br>< 0.01                                                                                                    | < 0.01  |  |
| RCTFY004<br>FL086-03H<br>USA-FL086-<br>03H-B, 2003            | Patriot<br>Round-<br>up Ready | USA<br>Stilwell,<br>Kansas      | 250<br>EC   | 3      | 0.087–<br>0.095 | 0.060–<br>0.066 | 85 | 22<br>22                                                 | 0.041<br>0.040<br>0.041                                                                                              | 0.016<br>0.016<br>0.016                                                                                             | 0.057   |  |
| RCTFY004<br>FL087-03H<br>USA-FL087-<br>03H-B, 2003            | Becks<br>323RR                | USA<br>Oxford,<br>Indiana       | 250<br>EC   | 3      | 0.091–<br>0.093 | 0.048–<br>0.053 | 79 | 20<br>20                                                 | < 0.01<br>< 0.01                                                                                                     | < 0.01<br>< 0.01                                                                                                    | < 0.01  |  |
| RCTFY004<br>FL088-03H<br>USA-FL088-<br>03H-B, 2003            | 92B94                         | USA<br>Bagley,<br>Iowa          | 250<br>EC   | 3      | 0.090–<br>0.094 | 0.040–<br>0.041 | 77 | 20<br>20                                                 | < 0.01<br>< 0.01                                                                                                     | < 0.01<br>< 0.01                                                                                                    | < 0.01  |  |
| RCTFY004<br>FL089-03H<br>USA-FL089-<br>03H-B, 2003            | BT-402                        | USA<br>Carlyle,<br>Illinois     | 250<br>EC   | 3      | 0.090–<br>0.094 | 0.048–<br>0.061 | 79 | 19<br>19                                                 | 0.010<br>< 0.01<br>0.01                                                                                              | 0.013<br>0.020<br>0.017                                                                                             | 0.027   |  |

## Trifloxystrobin

| Study<br>Trial No.<br>Plot No.<br>Year                | Variety                  | Country                             | Application |        |                 |                   |    |          | Residues [mg/kg] <sup>a</sup> |                                 |        |
|-------------------------------------------------------|--------------------------|-------------------------------------|-------------|--------|-----------------|-------------------|----|----------|-------------------------------|---------------------------------|--------|
|                                                       |                          |                                     | FL          | N<br>o | kg/ha<br>(as)   | kg/hL<br>(as)     | GS | DAT      | TFS                           | CGA<br>321113                   | Sum    |
| RCTFY004<br>FL090-03H<br>USA-FL090-<br>03H-B, 2003    | GL2301<br>RR             | USA<br>Saginaw,<br>Michigan         | 250<br>EC   | 3      | 0.092           | 0.047–<br>0.048   | 81 | 20<br>20 | < 0.01<br>< 0.01<br>< 0.01    | <u>0.013</u><br>< 0.01<br>0.013 | 0.023  |
| RCTFY004<br>FL091-03H<br>USA-FL091-<br>03H-B, 2003    | Mycogen<br>44150         | USA<br>Gardner,<br>North<br>Dakota  | 250<br>EC   | 3      | 0.091–<br>0.093 | 0.031–<br>0.031   | 79 | 20<br>20 | < 0.01<br>< 0.01<br>< 0.01    | 0.013<br>< 0.01<br>0.013        | 0.023  |
| RCTFY004<br>FL092-03H<br>USA-FL092-<br>03H-B, 2003    | SC 9373                  | USA<br>New<br>Holland,<br>Ohio      | 250<br>EC   | 3      | 0.089–<br>0.093 | 0.060–<br>0.061   | 77 | 19<br>19 | < 0.01<br>< 0.01              | < 0.01<br>< 0.01                | < 0.01 |
| RCTFY004<br>FL093-03H<br>USA-FL093-<br>03H-B, 2003    | Dekalb<br>06-51          | USA<br>Campbell,<br>Minnesota       | 250<br>EC   | 3      | 0.091–<br>0.092 | 0.032–<br>0.033   | 93 | 20<br>20 | < 0.01<br>< 0.01              | < 0.01<br>< 0.01                | < 0.01 |
| RCTFY004<br>FL094-03H<br>USA-FL094-<br>03H-B, 2003    | Pioneer9<br>1m50         | USA<br>Geneva,<br>Minnesota         | 250<br>EC   | 3      | 0.091–<br>0.094 | 0.062–<br>0.063   | 95 | 20<br>20 | < 0.01<br>< 0.01              | < 0.01<br>< 0.01                | < 0.01 |
| RCTFY004<br>FL095-03H<br>USA-FL095-<br>03H-B, 2003    | Dekalb<br>3151           | USA<br>Sheridan,<br>Indiana         | 250<br>EC   | 3      | 0.091–<br>0.094 | 0.055–<br>0.061   | 81 | 21<br>21 | < 0.01<br>< 0.01              | < 0.01<br>< 0.01                | < 0.01 |
| RCTFY004<br>FL096-03H<br>USA-FL096-<br>03H-B, 2003    | Rough<br>Rider           | USA<br>Northwood<br>North<br>Dakota | 250<br>EC   | 3      | 0.091–<br>0.094 | 0.033–<br>0.033   | 95 | 21<br>21 | < 0.01<br>< 0.01              | < 0.01<br>< 0.01                | < 0.01 |
| RCTFY004<br>FL097-03H<br>USA-FL097-<br>03H-B, 2003    | Pioneer<br>93B86         | USA<br>Richland,<br>Iowa            | 250<br>EC   | 3      | 0.090–<br>0.092 | 0.043–<br>0.059   | 91 | 19<br>19 | < 0.01<br>< 0.01              | < 0.01<br>< 0.01                | < 0.01 |
| RCTFY004<br>FL098-03H<br>USA-FL098-<br>03H-B, 2003    | Brunner<br>BR-1500<br>RR | USA<br>Arkansas,<br>Wisconsin       | 250<br>EC   | 3      | 0.095           | 0.033–<br>0.033   | 81 | 20<br>20 | < 0.01<br>< 0.01              | < 0.01<br>< 0.01                | < 0.01 |
| US GAP 500 SC: 0.1095–0.1271 max 3 times, PHI 21 days |                          |                                     |             |        |                 |                   |    |          |                               |                                 |        |
| RATFY011<br>TF001-05H<br>USA-TF001-<br>05H-B, 2005    | S73-Z5                   | USA<br>Tifton                       | 500<br>SC   | 3      | 0.128           | 0.0977–<br>0.100  | 87 | 21<br>21 | <u>&lt; 0.01</u><br>< 0.01    | <u>&lt; 0.01</u><br>< 0.01      | < 0.01 |
| RATFY011<br>TF002-05H<br>USA-TF002-<br>05H-B, 2005    | Pioneer<br>95B96         | USA<br>Molino                       | 500<br>SC   | 3      | 0.123–<br>0.129 | 0.107–<br>0.110   | 88 | 19<br>19 | < 0.01<br><u>0.029</u>        | < 0.01<br><u>&lt; 0.01</u>      | 0.02   |
| RATFY011<br>TF003-05H<br>USA-TF003-<br>05H-B, 2005    | AG4403<br>RR             | USA<br>Proctor                      | 500<br>SC   | 3      | 0.128–<br>0.129 | 0.0895–<br>0.0902 | 92 | 20<br>20 | 0.030<br>0.022<br>0.026       | 0.017<br>0.016<br>0.0165        | 0.043  |
| RATFY011<br>TF004-05H<br>USA-TF004-<br>05H-B, 2005    | DPL<br>5806 RR           | USA<br>Cheneyville                  | 500<br>SC   | 3      | 0.128–<br>0.129 | 0.0848–<br>0.0896 | 80 | 21<br>21 | 0.011<br>0.013<br>0.012       | < 0.01<br>< 0.01<br>< 0.01      | 0.012  |

| Study<br>Trial No.<br>Plot No.<br>Year             | Variety                            | Country                 | Application |    |                 |                   |    | DAT                                                      | Residues [mg/kg] <sup>a</sup>                                                                                                    |                                                                                                                                |        |
|----------------------------------------------------|------------------------------------|-------------------------|-------------|----|-----------------|-------------------|----|----------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------|--------|
|                                                    |                                    |                         | FL          | No | kg/ha<br>(as)   | kg/hL<br>(as)     | GS |                                                          | TFS                                                                                                                              | CGA<br>321113                                                                                                                  | Sum    |
| RATFY011<br>TF005-05D<br>USA-TF005-<br>05D-B, 2005 | Soya<br>bean<br>Pioneer<br>9492 RR | USA<br>Leland           | 500<br>SC   | 3  | 0.130–<br>0.132 | 0.0872–<br>0.0898 | 83 | 17<br>17<br>21<br>21<br>23<br>23<br>27<br>27<br>31<br>31 | < 0.01<br>< 0.01<br><u>0.014</u><br><u>&lt; 0.01</u><br><u>0.014</u><br>< 0.01<br>< 0.01<br>< 0.01<br>< 0.01<br>< 0.01<br>< 0.01 | < 0.01<br>< 0.01<br>< 0.01<br><u>&lt; 0.01</u><br><u>&lt; 0.01</u><br>< 0.01<br>< 0.01<br>< 0.01<br>< 0.01<br>< 0.01<br>< 0.01 | 0.012  |
| RATFY011<br>TF006-05D<br>USA-TF006-<br>05D-B, 2005 | RG 200<br>RR                       | USA<br>Sabin            | 500<br>SC   | 3  | 0.128–<br>0.133 | 0.0757–<br>0.0847 | 70 | 16<br>16<br>21<br>21<br>24<br>24<br>27<br>27<br>31<br>31 | < 0.01<br>< 0.01<br>< 0.01<br>< 0.01<br><u>&lt; 0.01</u><br><u>0.014</u><br><u>0.014</u><br>< 0.01<br>< 0.01<br>< 0.01<br>< 0.01 | < 0.01<br>< 0.01<br>< 0.01<br>0.011<br><u>&lt; 0.01</u><br><u>0.010</u><br><u>0.01</u><br>0.010<br>< 0.01<br>< 0.01<br>< 0.01  | 0.021  |
| RATFY011<br>TF007-05H<br>USA-TF007-<br>05H-B, 2005 | Taylor<br>427 RR                   | USA<br>Stilwell         | 500<br>SC   | 3  | 0.128–<br>0.133 | 0.0908–<br>0.0937 | 83 | 20<br>20                                                 | < 0.01<br>< 0.01                                                                                                                 | < 0.01<br>< 0.01                                                                                                               | < 0.01 |
| RATFY011<br>TF008-05H<br>USA-TF008-<br>05H-B, 2005 | Nk 32G5                            | USA<br>Spring-<br>field | 500<br>SC   | 3  | 0.127–<br>0.130 | 0.104–<br>0.106   | 79 | 19<br>19                                                 | 0.013<br>0.015<br>0.014                                                                                                          | 0.010<br>< 0.01<br>0.01                                                                                                        | 0.0244 |
| RATFY011<br>TF009-05H<br>USA-TF009-<br>05H-B, 2005 | HS3236                             | USA<br>Monti-cello      | 500<br>SC   | 3  | 0.127–<br>0.133 | 0.0901–<br>0.0943 | 79 | 20<br>20                                                 | < 0.01<br>< 0.01                                                                                                                 | < 0.01<br>< 0.01                                                                                                               | < 0.01 |
| RATFY011<br>TF010-05H<br>USA-TF010-<br>05H-B, 2005 | Taylor<br>427 RR                   | USA<br>Stilwell         | 500<br>SC   | 3  | 0.126–<br>0.130 | 0.0906–<br>0.0935 | 87 | 20<br>20                                                 | 0.012<br>< 0.01<br>0.012                                                                                                         | < 0.01<br>< 0.01<br>< 0.01                                                                                                     | 0.012  |
| RATFY011<br>TF011-05H<br>USA-TF011-<br>05H-B, 2005 | Asgrow<br>2801                     | USA<br>Earlham          | 500<br>SC   | 3  | 0.128–<br>0.129 | 0.104–<br>0.106   | 79 | 19<br>19                                                 | < 0.01<br>0.018<br>0.014                                                                                                         | 0.010<br>< 0.01<br>0.01                                                                                                        | 0.0254 |
| RATFY011<br>TF012-05H<br>USA-TF012-<br>05H-B, 2005 | 92M70                              | USA<br>Bagley           | 500<br>SC   | 3  | 0.128–<br>0.129 | 0.102–<br>0.105   | 79 | 21<br>21                                                 | < 0.01<br>< 0.01                                                                                                                 | < 0.01<br>< 0.01                                                                                                               | < 0.01 |
| RATFY011<br>TF013-05H<br>USA-TF013-<br>05H-B, 2005 | Mycogen<br>0941731                 | USA<br>Gardner          | 500<br>SC   | 3  | 0.130–<br>0.132 | 0.0788–<br>0.0910 | 81 | 21<br>21                                                 | < 0.01<br>< 0.01<br>< 0.01                                                                                                       | 0.011<br>< 0.01<br>0.011                                                                                                       | 0.021  |
| RATFY011<br>TF014-05H<br>USA-TF014-<br>05H-B, 2005 | SC 9374                            | USA<br>New<br>Holland   | 500<br>SC   | 3  | 0.128–<br>0.133 | 0.0883–<br>0.0899 | 95 | 19<br>19                                                 | < 0.01<br>< 0.01                                                                                                                 | < 0.01<br>< 0.01                                                                                                               | < 0.01 |
| RATFY011<br>TF015-05H<br>USA-TF015-<br>05H-B, 2005 | Pioneer<br>92M80                   | USA<br>York             | 500<br>SC   | 3  | 0.127–<br>0.129 | 0.0686–<br>0.0690 | 77 | 21<br>21                                                 | 0.015<br>0.017<br>0.16                                                                                                           | 0.038<br>0.043<br>0.042                                                                                                        | 0.058  |
| RATFY011<br>TF016-05H<br>USA-TF016-<br>05H-B, 2005 | NK 43-<br>B1                       | USA<br>Carlyle          | 500<br>SC   | 3  | 0.127–<br>0.129 | 0.0696–<br>0.0759 | 79 | 20<br>20                                                 | < 0.01<br>< 0.01                                                                                                                 | < 0.01<br>< 0.01                                                                                                               | < 0.01 |

| Study Trial No.<br>Plot No.<br>Year            | Variety                    | Country         | Application |    |                 |                   |    |          | Residues [mg/kg] <sup>a</sup> |                            |         |
|------------------------------------------------|----------------------------|-----------------|-------------|----|-----------------|-------------------|----|----------|-------------------------------|----------------------------|---------|
|                                                |                            |                 | FL          | No | kg/ha (as)      | kg/hL (as)        | GS | DAT      | TFS                           | CGA 321113                 | Sum     |
| RATFY011<br>TF017-05H<br>USA-TF017-05H-B, 2005 | Asgrow AG1603              | USA<br>Arkansaw | 500<br>SC   | 3  | 0.129–<br>0.130 | 0.0733–<br>0.0734 | 79 | 21<br>21 | < 0.01<br>< 0.01              | < 0.01<br>< 0.01           | < 0.01  |
| RATFY011<br>TF018-05H<br>USA-TF018-05H-B, 2005 | Dairyland 3410             | USA<br>Sheridan | 500<br>SC   | 3  | 0.126–<br>0.127 | 0.0608–<br>0.0692 | 97 | 21<br>21 | < 0.01<br>< 0.01              | < 0.01<br>< 0.01           | < 0.01  |
| RATFY011<br>TF019-05H<br>USA-TF019-05H-B, 2005 | Soya bean<br>Asgrow 3802   | USA<br>Kiowa    | 500<br>SC   | 3  | 0.129–<br>0.131 | 0.0872–<br>0.108  | 95 | 23<br>23 | 0.015<br>< 0.01<br>0.012      | < 0.01<br>< 0.01<br>< 0.01 | < 0.012 |
| RATFY011<br>TF020-05H<br>USA-TF020-05H-B, 2005 | Soya bean<br>Pioneer 93B85 | USA<br>St. John | 500<br>SC   | 3  | 0.126–<br>0.132 | 0.0751–<br>0.0781 | 79 | 19<br>19 | 0.030<br>0.011<br>0.02        | 0.018<br>0.017<br>0.018    | 0.039   |

FL=Formulation

No=number of applications

GS=growth stage at last application

DAT=days after last treatment

TFS=Trifloxystrobin

<sup>a</sup> Residues were measured in dry seeds*Beans and Peas (dry)Green beans*

Nine field trials were conducted in Canada in 2012 with trifloxystrobin in/on dry beans (Milo, J and Harbin, A 2013a.) Two applications at 0.129 to 0.137 kg ai/ha were done with a spray interval of 10 to 14 days and a pre-harvest interval of 28 to 32 days.

Nine field trials were conducted in Canada in 2012 with trifloxystrobin in/on peas (Milo, J and Harbin, A 2013b.). Two applications at 0.108 to 0.135 kg ai/ha were done with a spray interval of 11 to 14 days and a pre-harvest interval of 29 to 31 days.

The residues of trifloxystrobin and CGA 321113 were quantified according to methods 00742, 00742/M001 and 01313 at a LOQ of 0.01 mg/kg.

The results are summarized in Tables 7 and 8.

Table 7 Results of residue trials conducted with 325 SC trifloxystrobin in/on kidney beans in Canada

| Study<br>Trial No.<br>Plot No.<br>Year                    |                                |                         | Application |               |                   |    |          | Residues [mg/kg] <sup>a</sup> |                         |         |
|-----------------------------------------------------------|--------------------------------|-------------------------|-------------|---------------|-------------------|----|----------|-------------------------------|-------------------------|---------|
|                                                           | Crop<br>Variety                | Country                 | No          | kg/ha<br>(as) | kg/hL<br>(as)     | GS | DAT      | TFS                           | CGA<br>321113           | SUM     |
| Canadian GAP SC325> 0.132 kg ai/ha 1–2 times, PHI 30 days |                                |                         |             |               |                   |    |          |                               |                         |         |
| RAJAN003<br>RAJAN003-01-<br>12H, 2012                     | Zorro<br>Black<br>Bean         | Canada<br>Arthur        | 2           | 0.13430.1375  | 0.0959–<br>0.0982 | 77 | 29<br>29 | < 0.01<br>< 0.01<br>< 0.01    | 0.011<br>0.011<br>0.011 | < 0.021 |
| RAJAN003<br>RAJAN003-02-<br>12H, 2012                     | Red<br>Hawk<br>(red<br>Kidney) | Canada<br>Rock-<br>wood | 2           | 0.13570.1362  | 0.0969–<br>0.0973 | 73 | 32<br>32 | < 0.01<br>< 0.01              | < 0.01<br>< 0.01        | < 0.01  |
| RAJAN003<br>RAJAN003-03-<br>12H, 2012                     | Zorro<br>Black<br>Bean         | Canada<br>Breslau       | 2           | 0.1292        | 0.0923            | 75 | 29<br>29 | < 0.01<br>< 0.01<br>< 0.01    | 0.010<br>0.012<br>0.011 | 0.021   |

| Study<br>Trial No.<br>Plot No.<br>Year | Crop<br>Variety           | Country            | Application |                   |                   |    |                                                                | Residues [mg/kg] <sup>a</sup>                                                                                                          |                                                                                                                       |              |
|----------------------------------------|---------------------------|--------------------|-------------|-------------------|-------------------|----|----------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------|--------------|
|                                        |                           |                    | No          | kg/ha<br>(as)     | kg/hL<br>(as)     | GS | DAT                                                            | TFS                                                                                                                                    | CGA<br>321113                                                                                                         | SUM          |
| RAJAN003<br>RAJAN003-04-<br>12H, 2012  | Pinto                     | Canada<br>Whitecap | 2           | 0.13060.1319      | 0.0933–<br>0.0942 | 66 | 28<br>28                                                       | < 0.01<br>< 0.01<br>< 0.01                                                                                                             | 0.012<br>0.013<br>0.012                                                                                               | 0.023        |
| RAJAN003<br>RAJAN003-05-<br>12H, 2012  | Pintos                    | Canada<br>Outlook  | 2           | 0.13060.1315      | 0.0933–<br>0.0939 | 65 | 28<br>28                                                       | < 0.01<br>< 0.01<br>< 0.01                                                                                                             | < 0.01<br>< 0.01<br>< 0.01                                                                                            | < 0.01       |
| RAJAN003<br>RAJAN003-06-<br>12H, 2012  | Pinto                     | Canada<br>Kenaston | 2           | 0.13040.1343      | 0.0931–<br>0.0959 | 66 | 28<br>28                                                       | < 0.01<br>< 0.01<br>< 0.01                                                                                                             | < 0.01<br>< 0.01<br>< 0.01                                                                                            | < 0.01       |
| RAJAN003<br>RAJAN003-07-<br>12H, 2012  | Viva<br>Pink              | Canada<br>Taber    | 2           | 0.12940.135       | 0.0924–<br>0.0964 | 75 | 32<br>32                                                       | < 0.01<br>< 0.01<br>< 0.01                                                                                                             | < 0.01<br>< 0.01<br>< 0.01                                                                                            | < 0.01       |
| RAJAN003<br>RAJAN003-07-<br>12H, 2012  | Viva<br>Pink              | Canada<br>Taber    | 2           | 0.12940.135       | 0.0924–<br>0.0964 | 75 | 32<br>32                                                       | < 0.01<br>< 0.01<br>< 0.01                                                                                                             | < 0.01<br>< 0.01<br>< 0.01                                                                                            |              |
| RAJAN003<br>RAJAN003-08-<br>12D, 2012  | Pinto                     | Canada<br>Rosthern | 2           | 0.12940.1314      | 0.0924–<br>0.0939 | 71 | 21<br>21<br>25<br>25<br>29<br>29<br>29<br>36<br>36<br>40<br>40 | 0.011<br>0.018<br>< 0.01<br>< 0.01<br><u>&lt; 0.01</u><br><u>&lt; 0.01</u><br><u>&lt; 0.01</u><br>< 0.01<br>< 0.01<br>< 0.01<br>< 0.01 | 0.015<br>0.017<br>0.014<br>0.013<br><u>0.012</u><br><u>0.011</u><br><u>0.012</u><br>0.012<br>< 0.01<br>0.011<br>0.011 | <u>0.022</u> |
| RAJAN003<br>RAJAN003-09-<br>12H, 2012  | Bean,<br>Kidney<br>Pintos | Canada<br>Alvena   | 2           | 0.1315-<br>0.1327 | 0.0939–<br>0.0948 | 71 | 31<br>31                                                       | < 0.01<br>< 0.01<br>< 0.01                                                                                                             | < 0.01<br>< 0.01<br>< 0.01                                                                                            | < 0.01       |

FL=Formulation

No=number of applications

GS=growth stage at last application

DAT=days after last treatment

TFS=trifloxystrobin

<sup>a</sup> Residues were measured in dry seeds,

Table 8 Results of residue trials conducted with 325 SC trifloxystrobin in/on pea in 2012

| Study<br>Trial No.<br>Plot No.                                      |                       |                    | Application |                   |                   |    |          |                            | Residues [mg/kg] <sup>a</sup>        |        |  |
|---------------------------------------------------------------------|-----------------------|--------------------|-------------|-------------------|-------------------|----|----------|----------------------------|--------------------------------------|--------|--|
|                                                                     | Crop<br>Variety       | Country            | No          | kg/ha<br>(as)     | kg/hL<br>(as)     | GS | DAT      | TFS                        | CGA<br>321113                        | Sum    |  |
| Canadian GAP: SC325, 0.132 kg ai/ha 1–2 times with PHI of 30 (seed) |                       |                    |             |                   |                   |    |          |                            |                                      |        |  |
| RAJAN004<br>RAJAN004-01-12H                                         | Pea, field<br>Meadow  | Canada<br>Whitecap | 2           | 0.1301–<br>0.1305 | 0.0929–<br>0.0932 | 72 | 31<br>31 | < 0.01<br>< 0.01<br>< 0.01 | 0.021<br>0.023<br><u>0.022</u>       | 0.033  |  |
| RAJAN004<br>RAJAN004-02-12H                                         | Pea, field<br>Meadow  | Canada<br>Outlook  | 2           | 0.1312–<br>0.1314 | 0.0937–<br>0.0939 | 71 | 31<br>31 | < 0.01<br>< 0.01<br>< 0.01 | 0.011<br>0.014<br><u>0.012</u>       | 0.023  |  |
| RAJAN004<br>RAJAN004-03-12H                                         | Pea, field<br>Admiral | USA<br>Carring-ton | 2           | 0.1308–<br>0.1357 | 0.0934–<br>0.0969 | 73 | 30<br>30 | < 0.01<br>< 0.01<br>< 0.01 | 0.016<br>0.016<br>0.016              | 0.027  |  |
| RAJAN004<br>RAJAN004-04-12H                                         | Pea, field<br>Meadow  | Canada<br>Kenaston | 2           | 0.1303–<br>0.1311 | 0.0931–<br>0.0936 | 73 | 29<br>29 | < 0.01<br>< 0.01<br>< 0.01 | < 0.01<br>< 0.01<br>< 0.01           | < 0.01 |  |
| RAJAN004<br>RAJAN004-05-12H                                         | Pea, field<br>Meadow  | Canada<br>Waldheim | 2           | 0.1326–<br>0.133  | 0.0947–<br>0.0950 | 71 | 29<br>29 | < 0.01<br>< 0.01<br>< 0.01 | <u>&lt; 0.01</u><br>< 0.01<br>< 0.01 | < 0.01 |  |

| Study Trial No.<br>Plot No. | Crop Variety            | Country            | Application |                   |                   |    |                                                          | Residues [mg/kg] <sup>a</sup>                                                                                                                            |                                                                                                                                                              |        |
|-----------------------------|-------------------------|--------------------|-------------|-------------------|-------------------|----|----------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|
|                             |                         |                    | No          | kg/ha (as)        | kg/hL (as)        | GS | DAT                                                      | TFS                                                                                                                                                      | CGA 321113                                                                                                                                                   | Sum    |
| RAJAN004<br>RAJAN004-06-12H | Pea, field Meadow       | Canada Alvena      | 2           | 0.1329            | 0.0949            | 72 | 29<br>29                                                 | < 0.01<br>< 0.01                                                                                                                                         | 0.011<br>0.011                                                                                                                                               | 0.021  |
| RAJAN004<br>RAJAN004-07-12H | Pea, field Meadow       | Canada Wakaw       | 2           | 0.1309–<br>0.1339 | 0.0935–<br>0.0956 | 71 | 29<br>29                                                 | < 0.01<br>< 0.01                                                                                                                                         | 0.011<br>0.013                                                                                                                                               | 0.022  |
| RAJAN004<br>RAJAN004-08-12H | Pea, field Thunder-bird | Canada Joseph-burg | 2           | 0.1266–<br>0.1341 | 0.0904–<br>0.0958 | 75 | 30<br>30                                                 | < 0.01<br>< 0.01                                                                                                                                         | 0.010<br>0.011                                                                                                                                               | 0.021  |
| RAJAN004<br>RAJAN004-09-12D | Pea, field Meadow       | Canada Rosthern    | 2           | 0.108–<br>0.1082  | 0.0771–<br>0.0773 | 69 | 20<br>20<br>25<br>25<br>31<br>31<br>34<br>34<br>40<br>40 | 0.012<br>0.012<br>0.016<br>0.019<br><u>&lt; 0.01</u><br><u>&lt; 0.01</u><br><u>&lt; 0.01</u><br><u>&lt; 0.01</u><br><u>&lt; 0.01</u><br><u>&lt; 0.01</u> | < 0.01<br>< 0.01<br>< 0.01<br>< 0.01<br><u>&lt; 0.01</u><br><u>&lt; 0.01</u><br><u>&lt; 0.01</u><br><u>&lt; 0.01</u><br><u>&lt; 0.01</u><br><u>&lt; 0.01</u> | < 0.01 |

FL=Formulation; No=number of applications; GS=growth stage at last application; DAT=days after last treatment; TFS: trifloxystrobin; <sup>1</sup>. Residues were measured in dry seeds,

### Animal feeds

The conditions of supervised trials are described under the respective commodities. Only the residues in relevant animal commodities are summarized.

Table 9 Residues of trifloxystrobin in/on soya bean forage derived from trials conducted in the USA

| Study<br>Trial No.<br>Plot No.<br>Year                                                                        |                       |                                    | Application |    |                 |                 |    |                                                  | Residues [mg/kg] <sup>a</sup>                                                      |                                                                                        |
|---------------------------------------------------------------------------------------------------------------|-----------------------|------------------------------------|-------------|----|-----------------|-----------------|----|--------------------------------------------------|------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------|
|                                                                                                               | Variety               | Country                            | FL          | No | kg/ha<br>(as)   | kg/hL<br>(as)   | GS | DAT                                              | TFS                                                                                | CGA<br>321113                                                                          |
| USA GAP 250EC, 0.09125 kg/ha max 3 times with PHI of 21 days<br>Do not graze or feed soya bean forage or hay. |                       |                                    |             |    |                 |                 |    |                                                  |                                                                                    |                                                                                        |
| RCTFY004<br>FL079-03H<br>USA-FL079-03H-A, 2003                                                                | Hartz Seed<br>H6686RR | USA<br>Tifton,<br>Georgia          | 250<br>EC   | 3  | 0.092           | 0.052–<br>0.064 | 67 | 0                                                | 1.53<br>6.07                                                                       | 0.106<br>0.395                                                                         |
| RCTFY004<br>FL080-03H<br>USA-FL080-03H-A, 2003                                                                | NK S73-Z5             | USA<br>Molino,<br>Florida          | 250<br>EC   | 3  | 0.086–<br>0.094 | 0.043–<br>0.046 | 74 | 0                                                | 0.81<br>1.21                                                                       | 0.075<br>0.096                                                                         |
| RCTFY004<br>FL081-03H<br>USA-FL081-03H-A, 2003                                                                | Horn-beck<br>5588RR   | USA<br>Proctor,<br>Arkansas        | 250<br>EC   | 3  | 0.092           | 0.063–<br>0.066 | 71 | 0                                                | 2.92<br>4.65                                                                       | 0.137<br>0.219                                                                         |
| RCTFY004<br>FL082-03H<br>USA-FL082-03H-A, 2003                                                                | Delta King<br>5661 RR | USA<br>Newport,<br>Arkansas        | 250<br>EC   | 3  | 0.092–<br>0.094 | 0.049–<br>0.049 | 75 | 0                                                | 3.12<br>3.48                                                                       | 0.168<br>0.176                                                                         |
| RCTFY004<br>FL083-03D<br>USA-FL083-03D-A,2003                                                                 | S56-D7                | USA<br>Leland,<br>Mississi-<br>ppi | 250<br>EC   | 3  | 0.091–<br>0.094 | 0.074–<br>0.076 | 70 | 0<br>0<br>3<br>3<br>5<br>5<br>7<br>7<br>10<br>10 | 3.00<br>2.90<br>2.11<br>0.828<br>0.590<br>0.978<br>1.27<br>0.685<br>0.630<br>0.388 | 0.226<br>0.295<br>0.215<br>0.158<br>0.138<br>0.230<br>0.154<br>0.122<br>0.091<br>0.081 |

| Study<br>Trial No.<br>Plot No.<br>Year             | Variety                      | Country                              | Application |    |                 |                 |    | DAT                                              | Residues [mg/kg] <sup>a</sup>                                                      |                                                                                        |
|----------------------------------------------------|------------------------------|--------------------------------------|-------------|----|-----------------|-----------------|----|--------------------------------------------------|------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------|
|                                                    |                              |                                      | FL          | No | kg/ha<br>(as)   | kg/hL<br>(as)   | GS |                                                  | TFS                                                                                | CGA<br>321113                                                                          |
| RCTFY004<br>FL084-03D<br>USA-FL084-<br>03D-A, 2003 | FS HT322<br>STS              | USA<br>Seymour,<br>Illinois          | 250<br>EC   | 3  | 0.093           | 0.061–<br>0.062 | 72 | 0<br>0<br>3<br>3<br>6<br>6<br>8<br>8<br>10<br>10 | 2.80<br>2.72<br>1.30<br>1.25<br>0.822<br>0.895<br>0.752<br>0.902<br>0.705<br>0.728 | 0.121<br>0.135<br>0.186<br>0.195<br>0.160<br>0.166<br>0.151<br>0.160<br>0.131<br>0.133 |
| RCTFY004<br>FL085-03H<br>USA-FL085-<br>03H-A, 2003 | NK S26 C9                    | USA<br>Spring-<br>field,<br>Nebraska | 250<br>EC   | 3  | 0.092–<br>0.183 | 0.061–<br>0.129 | 65 | 0                                                | 2.30<br>1.58                                                                       | 0.095<br>0.083                                                                         |
| RCTFY004<br>FL086-03H<br>USA-FL086-<br>03H-A, 2003 | Patriot<br>Round-up<br>Ready | USA<br>Stilwell,<br>Kansas           | 250<br>EC   | 3  | 0.093–<br>0.187 | 0.063–<br>0.132 | 79 | 0                                                | 4.45<br>6.90                                                                       | 0.178<br>0.225                                                                         |
| RCTFY004<br>FL087-03H<br>USA-FL087-<br>03H-A, 2003 | Becks 323RR                  | USA<br>Oxford,<br>Indiana            | 250<br>EC   | 3  | 0.094–<br>0.095 | 0.051–<br>0.059 | 69 | 0                                                | 3.45<br>3.55                                                                       | 0.208<br>0.196                                                                         |
| RCTFY004<br>FL088-03H<br>USA-FL088-<br>03H-A, 2003 | 92B94                        | USA<br>Bagley,<br>Iowa               | 250<br>EC   | 3  | 0.089–<br>0.092 | 0.036–<br>0.042 | 67 | 0                                                | 3.50<br>5.00                                                                       | 0.164<br>0.240                                                                         |
| RCTFY004<br>FL089-03H<br>USA-FL089-<br>03H-A, 2003 | BT-402                       | USA<br>Carlyle,<br>Illinois          | 250<br>EC   | 3  | 0.089–<br>0.093 | 0.060–<br>0.065 | 69 | 0                                                | 3.18<br>3.75                                                                       | 0.213<br>0.222                                                                         |
| RCTFY004<br>FL090-03H<br>USA-FL090-<br>03H-A, 2003 | GL2301RR                     | USA<br>Saginaw,<br>Michigan          | 250<br>EC   | 3  | 0.091–<br>0.092 | 0.047–<br>0.048 | 69 | 0                                                | 1.54<br>9.87                                                                       | 0.121<br>0.948                                                                         |
| RCTFY004<br>FL091-03H<br>USA-FL091-<br>03H-A, 2003 | Mycogen<br>44150             | USA<br>Gardner,<br>North<br>Dakota   | 250<br>EC   | 3  | 0.092–<br>0.093 | 0.030–<br>0.037 | 81 | 0                                                | 4.85<br>/0.027 <sup>b</sup><br>6.98                                                | 0.485<br>0.508                                                                         |
| RCTFY004<br>FL092-03H<br>USA-FL092-<br>03H-A, 2003 | SC 9373                      | USA<br>New<br>Holland,<br>Ohio       | 250<br>EC   | 3  | 0.091–<br>0.093 | 0.062–<br>0.066 | 69 | 0                                                | 2.48<br>2.32                                                                       | 0.154<br>0.140                                                                         |
| RCTFY004<br>FL093-03H<br>USA-FL093-<br>03H-A, 2003 | Dekalb 06-51                 | USA<br>Campbell,<br>Minnesota        | 250<br>EC   | 3  | 0.091–<br>0.092 | 0.032–<br>0.033 | 70 | 0                                                | 2.75<br>3.15                                                                       | 0.224<br>0.258                                                                         |
| RCTFY004<br>FL094-03H<br>USA-FL094-<br>03H-A, 2003 | Pioneer91m50                 | USA<br>Geneva,<br>Minnesota          | 250<br>EC   | 3  | 0.091–<br>0.092 | 0.058–<br>0.061 | 69 | 0                                                | 5.28<br>4.92                                                                       | 0.365<br>0.338                                                                         |
| RCTFY004<br>FL095-03H<br>USA-FL095-<br>03H-A, 2003 | Dekalb 3151                  | USA<br>Sheridan,<br>Indiana          | 250<br>EC   | 3  | 0.091–<br>0.092 | 0.057–<br>0.058 | 70 | 0                                                | 3.28<br>2.46                                                                       | 0.244<br>0.199                                                                         |
| RCTFY004<br>FL096-03H<br>USA-FL096-<br>03H-A, 2003 | Rough Rider                  | USA<br>Northwood,<br>North<br>Dakota | 250<br>EC   | 3  | 0.089–<br>0.094 | 0.032–<br>0.033 | 69 | 0                                                | 2.70<br>2.95                                                                       | 0.255<br>0.270                                                                         |
| RCTFY004<br>FL097-03H<br>USA-FL097-<br>03H-A, 2003 | Pioneer<br>93B86             | USA<br>Richland,<br>Iowa             | 250<br>EC   | 3  | 0.091–<br>0.094 | 0.050–<br>0.067 | 67 | 0                                                | 3.18<br>3.30                                                                       | 0.115<br>0.117                                                                         |



## Trifloxystrobin

| Study<br>Trial No.<br>Plot No.<br>Year                                                                 | Variety                | Country                       | Application |    |                 |                   |    |                                                  | Residues [mg/kg] <sup>a</sup>                                                          |                                                                                        |
|--------------------------------------------------------------------------------------------------------|------------------------|-------------------------------|-------------|----|-----------------|-------------------|----|--------------------------------------------------|----------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------|
|                                                                                                        |                        |                               | FL          | No | kg/ha<br>(as)   | kg/hL<br>(as)     | GS | DAT                                              | TFS                                                                                    | CGA<br>321113                                                                          |
| RCTFY004<br>FL098-03H<br>USA-FL098-<br>03H-A, 2003                                                     | Brunner BR-<br>1500-RR | USA<br>Arkansas,<br>Wisconsin | 250<br>EC   | 3  | 0.093–<br>0.096 | 0.033–<br>0.033   | 69 | 0                                                | 3.95<br>3.38                                                                           | 0.148<br>0.115                                                                         |
| US GAP 500 SC: 0.1095–0.1271 max 3 times, PHI 21 days<br>Do not graze or feed soya bean forage or hay. |                        |                               |             |    |                 |                   |    |                                                  |                                                                                        |                                                                                        |
| RATFY011<br>TF001-05H<br>USA-TF001-<br>05H-A, 2005                                                     | S73-Z5                 | USA<br>Tifton                 | 500<br>SC   | 3  | 0.128           | 0.0762–<br>0.102  | 67 | 0                                                | 6.065<br>6.843                                                                         | 0.228<br>0.210                                                                         |
| RATFY011<br>TF002-05H<br>USA-TF002-<br>05H-A, 2005                                                     | Pioneer<br>95B96       | USA<br>Molino                 | 500<br>SC   | 3  | 0.123–<br>0.132 | 0.0971–<br>0.110  | 70 | 0                                                | 6.771<br>6.365                                                                         | 0.186<br>0.199                                                                         |
| RATFY011<br>TF003-05H<br>USA-TF003-<br>05H-A, 2005                                                     | AG4403 RR              | USA<br>Proctor                | 500<br>SC   | 3  | 0.128–<br>0.129 | 0.0902–<br>0.0928 | 69 | 0                                                | 21.80<br>23.86                                                                         | 0.262<br>0.257                                                                         |
| RATFY011<br>TF004-05H<br>USA-TF004-<br>05H-A, 2005                                                     | DPL 5806 RR            | USA<br>Cheney-<br>ville       | 500<br>SC   | 3  | 0.122–<br>0.127 | 0.0738–<br>0.0871 | 69 | 0                                                | 10.22<br>9.059                                                                         | 0.171<br>0.150                                                                         |
| RATFY011<br>TF005-05D<br>USA-TF005-<br>05D-A, 2005                                                     | Pioneer 9492<br>RR     | USA<br>Leland                 | 500<br>SC   | 3  | 0.130–<br>0.132 | 0.107–<br>0.112   | 66 | 0<br>0<br>3<br>3<br>5<br>5<br>7<br>7<br>11<br>11 | 9.389<br>10.47<br>7.858<br>8.267<br>5.482<br>5.094<br>3.728<br>3.512<br>2.783<br>2.658 | 0.228<br>0.257<br>0.382<br>0.379<br>0.335<br>0.305<br>0.299<br>0.297<br>0.261<br>0.213 |
| RATFY011<br>TF006-05D<br>USA-TF006-<br>05D-A, 2005                                                     | RG 200 RR              | USA<br>Sabin                  | 500<br>SC   | 3  | 0.125–<br>0.130 | 0.0771–<br>0.0839 |    | 0<br>0<br>3<br>3<br>5<br>5<br>7<br>7<br>10<br>10 | 11.53<br>11.14<br>2.455<br>2.393<br>1.287<br>1.554<br>1.288<br>1.144<br>1.567<br>0.676 | 0.285<br>0.267<br>0.296<br>0.319<br>0.214<br>0.246<br>0.175<br>0.169<br>0.263<br>0.125 |
| RATFY011<br>TF007-05H<br>USA-TF007-<br>05H-A, 2005                                                     | Taylor 427<br>RR       | USA<br>Stilwell               | 500<br>SC   | 3  | 0.128–<br>0.132 | 0.0898–<br>0.0934 | 75 | 0                                                | 13.75<br>17.36                                                                         | 0.243<br>0.316                                                                         |
| RATFY011<br>TF008-05H<br>USA-TF008-<br>05H-A, 2005                                                     | Nk 32G5                | USA<br>Spring-field           | 500<br>SC   | 3  | 0.129           | 0.102–<br>0.106   | 67 | 0                                                | 11.07<br>9.589                                                                         | 0.274<br>0.259                                                                         |
| RATFY011<br>TF009-05H<br>USA-TF009-<br>05H-A, 2005                                                     | HS3236                 | USA<br>Monti-cello            | 500<br>SC   | 3  | 0.124–<br>0.132 | 0.0917–<br>0.0921 | 70 | 0                                                | 14.49<br>14.18                                                                         | 0.254<br>0.230                                                                         |
| RATFY011<br>TF010-05H<br>USA-TF010-<br>05H-A, 2005                                                     | Taylor 427<br>RR       | USA<br>Stilwell               | 500<br>SC   | 3  | 0.128–<br>0.134 | 0.0895–<br>0.0937 | 77 | 0                                                | 5.984<br>6.586                                                                         | 0.138<br>0.147                                                                         |

| Study<br>Trial No.<br>Plot No.<br>Year             | Variety             | Country               | Application |    |                 |                   |    |     | DAT            | Residues [mg/kg] <sup>a</sup> |  |
|----------------------------------------------------|---------------------|-----------------------|-------------|----|-----------------|-------------------|----|-----|----------------|-------------------------------|--|
|                                                    |                     |                       | FL          | No | kg/ha<br>(as)   | kg/hL<br>(as)     | GS | TFS |                | CGA<br>321113                 |  |
| RATFY011<br>TF011-05H<br>USA-TF011-<br>05H-A, 2005 | Asgrow 2801         | USA<br>Earlham        | 500<br>SC   | 3  | 0.128–<br>0.130 | 0.101–<br>0.106   | 67 | 0   | 8.649<br>8.747 | 0.343<br>0.318                |  |
| RATFY011<br>TF012-05H<br>USA-TF012-<br>05H-A, 2005 | 92M70               | USA<br>Bagley         | 500<br>SC   | 3  | 0.124–<br>0.128 | 0.0992–<br>0.102  | 66 | 0   | 9.009<br>5.698 | 0.249<br>0.182                |  |
| RATFY011<br>TF013-05H<br>USA-TF013-<br>05H-A, 2005 | Myco-gen<br>0941731 | USA<br>Gardner        | 500<br>SC   | 3  | 0.131–<br>0.133 | 0.0887–<br>0.0963 | 71 | 0   | 16.11<br>17.30 | 0.307<br>0.297                |  |
| RATFY011<br>TF014–05H<br>USA-TF014-<br>05H-A, 2005 | SC 9374             | USA<br>New<br>Holland | 500<br>SC   | 3  | 0.126–<br>0.131 | 0.0879–<br>0.0894 | 70 | 0   | 11.41<br>10.09 | 0.203<br>0.199                |  |
| RATFY011<br>TF015-05H<br>USA-TF015-<br>05H-A, 2005 | Pioneer<br>92M80    | USA<br>York           | 500<br>SC   | 3  | 0.127–<br>0.129 | 0.0686–<br>0.0690 | 67 | 0   | 12.73<br>8.950 | 0.274<br>0.257                |  |
| RATFY011<br>TF016-05H<br>USA-TF016-<br>05H-A, 2005 | NK 43-B1            | USA<br>Carlyle        | 500<br>SC   | 3  | 0.127–<br>0.128 | 0.0743–<br>0.0934 | 66 | 0   | 13.58<br>12.19 | 0.358<br>0.353                |  |
| RATFY011<br>TF017-05H<br>USA-TF017-<br>05H-A, 2005 | Asgrow<br>AG1603    | USA<br>Arkansaw       | 500<br>SC   | 3  | 0.129           | 0.0729–<br>0.0733 | 69 | 0   | 12.46<br>13.44 | 0.276<br>0.277                |  |
| RATFY011<br>TF018-05H<br>USA-TF018-<br>05H-A, 2005 | Dairy-land<br>3410  | USA<br>Sheridan       | 500<br>SC   | 3  | 0.124–<br>0.130 | 0.0667–<br>0.0723 | 69 | 0   | 6.096<br>5.792 | 0.129<br>0.120                |  |
| RATFY011<br>TF019-05H<br>USA-TF019-<br>05H-A, 2005 | Asgrow 3802         | USA<br>Kiowa          | 500<br>SC   | 3  | 0.127–<br>0.129 | 0.101–<br>0.106   | 69 | 0   | 15.26<br>16.67 | 0.343<br>0.332                |  |
| RATFY011<br>TF020-05H<br>USA-TF020-<br>05H-A, 2005 | Pioneer<br>93B85    | USA<br>St. John       | 500<br>SC   | 3  | 0.126–<br>0.129 | 0.0736–<br>0.0759 | 73 | 0   | 10.43<br>10.66 | 0.369<br>0.418                |  |

FL=Formulation

No=number of applications

GS=growth stage at last application

DAT=days after last treatment

<sup>a</sup> Residues were measured in forage samples<sup>b</sup> residues in control

TFS=trifloxystrobin;

Table 10 Residues of trifloxystrobin in/on soya bean hay derived from trials conducted in the USA

| Study<br>Trial No.<br>Plot No.<br>Year                                                                        |                              |                                    | Application |    |                 |                 |    | Residues <sup>a</sup> [mg/kg]                   |                                      |
|---------------------------------------------------------------------------------------------------------------|------------------------------|------------------------------------|-------------|----|-----------------|-----------------|----|-------------------------------------------------|--------------------------------------|
|                                                                                                               | Variety                      | Country                            | FL          | No | kg/ha<br>(as)   | kg/hL<br>(as)   | GS | TFS                                             | CGA 321113                           |
| USA GAP 250EC, 0.09125 kg/ha max 3 times with PHI of 21 days<br>Do not graze or feed soya bean forage or hay. |                              |                                    |             |    |                 |                 |    |                                                 |                                      |
| RCTFY004<br>FL079-03H<br>USA-FL079-03H-A,2003                                                                 | Hartz Seed<br>H6686RR        | USA<br>Tifton,<br>Georgia          | 250<br>EC   | 3  | 0.092           | 0.052–<br>0.064 | 67 | 9.62<br>8.50                                    | 0.908<br>0.840                       |
| RCTFY004<br>FL080-03H<br>USA-FL080-03H-A, 2003                                                                | NK S73-Z5                    | USA<br>Molino,<br>Florida          | 250<br>EC   | 3  | 0.086–<br>0.094 | 0.043–<br>0.046 | 74 | 4.00<br>3.58                                    | 0.535<br>0.518                       |
| RCTFY004<br>FL081-03H<br>USA-FL081-03H-A, 2003                                                                | Horn-beck<br>5588RR          | USA<br>Proctor,<br>Arkansas        | 250<br>EC   | 3  | 0.092           | 0.063–<br>0.066 | 71 | 5.50<br>5.55                                    | 0.602<br>0.562                       |
| RCTFY004<br>FL082-03H<br>USA-FL082-03H-A, 2003                                                                | Delta King<br>5661 RR        | USA<br>Newport,<br>Arkansas        | 250<br>EC   | 3  | 0.092–<br>0.094 | 0.049–<br>0.049 | 75 | 9.18<br>2.22                                    | 0.540<br>0.129                       |
| RCTFY004<br>FL083-03D<br>USA-FL083-03D-A, 2003                                                                | S56-D7                       | USA<br>Leland,<br>Mississippi      | 250<br>EC   | 3  | 0.091–<br>0.094 | 0.074–<br>0.076 | 70 | 6.30<br>6.55                                    | 0.788<br>0.730                       |
| RCTFY004<br>FL084-03D<br>USA-FL084-03D-A, 2003                                                                | FS HT322<br>STS              | USA<br>Seymour,<br>Illinois        | 250<br>EC   | 3  | 0.093           | 0.061–<br>0.062 | 72 | 10.4<br>9.82                                    | 0.90<br>0.0.88                       |
| RCTFY004<br>FL085-03H<br>USA-FL085-03H-A, 2003                                                                | NK S26 C9                    | USA<br>Springfield,<br>Nebraska    | 250<br>EC   | 3  | 0.092–<br>0.183 | 0.061–<br>0.129 | 65 | 6.25 <sup>c</sup><br>/5.55 <sup>b</sup><br>3.80 | 0.858<br>/1.04 <sup>b</sup><br>0.570 |
| RCTFY004<br>FL086-03H<br>USA-FL086-03H-A, 2003                                                                | Patriot<br>Round-up<br>Ready | USA<br>Stilwell,<br>Kansas         | 250<br>EC   | 3  | 0.093–<br>0.187 | 0.063–<br>0.132 | 79 | 9.98<br>10.4                                    | 0.902<br>0.930                       |
| RCTFY004<br>FL087-03H<br>USA-FL087-03H-A, 2003                                                                | Becks 323RR                  | USA<br>Oxford,<br>Indiana          | 250<br>EC   | 3  | 0.094–<br>0.095 | 0.051–<br>0.059 | 69 | 10.4<br>12.3                                    | 1.20<br>1.36                         |
| RCTFY004<br>FL088-03H<br>USA-FL088-03H-A, 2003                                                                | 92B94                        | USA<br>Bagley,<br>Iowa             | 250<br>EC   | 3  | 0.089–<br>0.092 | 0.036–<br>0.042 | 67 | 8.38<br>10.6                                    | 1.11<br>1.25                         |
| RCTFY004<br>FL089-03H<br>USA-FL089-03H-A, 2003                                                                | BT-402                       | USA<br>Carlyle,<br>Illinois        | 250<br>EC   | 3  | 0.089–<br>0.093 | 0.060–<br>0.065 | 69 | 7.92<br>10.2                                    | 4.12<br>4.45                         |
| RCTFY004<br>FL090-03H<br>USA-FL090-03H-A, 2003                                                                | GL2301RR                     | USA<br>Saginaw,<br>Michigan        | 250<br>EC   | 3  | 0.091–<br>0.092 | 0.047–<br>0.048 | 69 | 14.6<br>12.1                                    | 2.00<br>1.35                         |
| RCTFY004<br>FL091-03H<br>USA-FL091-03H-A, 2003                                                                | Myco-gen<br>44150            | USA<br>Gardner,<br>North<br>Dakota | 250<br>EC   | 3  | 0.092–<br>0.093 | 0.030–<br>0.037 | 81 | 15.4<br>13.2                                    | 2.52<br>2.58                         |
| RCTFY004<br>FL092-03H<br>USA-FL092-03H-A, 2003                                                                | SC 9373                      | USA<br>New<br>Holland,<br>Ohio     | 250<br>EC   | 3  | 0.091–<br>0.093 | 0.062–<br>0.066 | 69 | 4.92<br>7.05                                    | 0.732<br>1.07                        |

| Study<br>Trial No.<br>Plot No.<br>Year                                                                 | Variety                | Country                              | Application |    |                 |                   |    | Residues <sup>a</sup> [mg/kg]           |                                        |
|--------------------------------------------------------------------------------------------------------|------------------------|--------------------------------------|-------------|----|-----------------|-------------------|----|-----------------------------------------|----------------------------------------|
|                                                                                                        |                        |                                      | FL          | No | kg/ha<br>(as)   | kg/hL<br>(as)     | GS | TFS                                     | CGA 321113                             |
| RCTFY004<br>FL093-03H<br>USA-FL093-03H-A, 2003                                                         | Dekalb 06-51           | USA<br>Campbell,<br>Minnesota        | 250<br>EC   | 3  | 0.091–<br>0.092 | 0.032–<br>0.033   | 70 | 8.20<br>7.40                            | 1.04<br>1.02                           |
| RCTFY004<br>FL094-03H<br>USA-FL094-03H-A, 2003                                                         | Pioneer91m50           | USA<br>Geneva,<br>Minnesota          | 250<br>EC   | 3  | 0.091–<br>0.092 | 0.058–<br>0.061   | 69 | 4.28<br>5.00                            | 0.690<br>0.812                         |
| RCTFY004<br>FL095-03H<br>USA-FL095-03H-A, 2003                                                         | Dekalb 3151            | USA<br>Sheridan,<br>Indiana          | 250<br>EC   | 3  | 0.091–<br>0.092 | 0.057–<br>0.058   | 70 | 1.66<br>5.19                            | 0.278<br>0.638                         |
| RCTFY004<br>FL096-03H<br>USA-FL096-03H-A, 2003                                                         | Rough Rider            | USA<br>Northwood,<br>North<br>Dakota | 250<br>EC   | 3  | 0.089–<br>0.094 | 0.032–<br>0.033   | 69 | 10.1<br>7.00                            | 1.96<br>1.46                           |
| RCTFY004<br>FL097-03H<br>USA-FL097-03H-A, 2003                                                         | Pioneer<br>93B86       | USA<br>Richland,<br>Iowa             | 250<br>EC   | 3  | 0.091–<br>0.094 | 0.050–<br>0.067   | 67 | 4.02<br>5.30                            | 0.362<br>0.475                         |
| RCTFY004<br>FL098-03H<br>USA-FL098-03H-A, 2003                                                         | Brunner BR-<br>1500-RR | USA<br>Arkansaw,<br>Wisconsin        | 250<br>EC   | 3  | 0.093–<br>0.096 | 0.033–<br>0.033   | 69 | 11.8<br>9.88                            | 0.638<br>0.515                         |
| US GAP 500 SC: 0.1095–0.1271 max 3 times, PHI 21 days<br>Do not graze or feed soya bean forage or hay. |                        |                                      |             |    |                 |                   |    |                                         |                                        |
| RATFY011<br>TF001-05H<br>USA-TF001-05H-A, 2005                                                         | S73-Z5                 | USA<br>Tifton                        | 500<br>SC   | 3  | 0.128           | 0.0762–<br>0.102  | 67 | 8.374<br>10.37                          | 0.884<br>1.191                         |
| RATFY011<br>TF002-05H<br>USA-TF002-05H-A, 2005                                                         | Pioneer<br>95B96       | USA<br>Molino                        | 500<br>SC   | 3  | 0.123–<br>0.132 | 0.0971–<br>0.110  | 70 | 19.44<br>25.34                          | 0.906<br>1.149                         |
| RATFY011<br>TF003-05H<br>USA-TF003-05H-A, 2005                                                         | AG4403 RR              | USA<br>Proctor                       | 500<br>SC   | 3  | 0.128–<br>0.129 | 0.0902–<br>0.0928 | 69 | 60.81<br>70.90                          | 1.089<br>1.404                         |
| RATFY011<br>TF004-05H<br>USA-TF004-05H-A, 2005                                                         | DPL 5806<br>RR         | USA<br>Cheneyville                   | 500<br>SC   | 3  | 0.122–<br>0.127 | 0.0738–<br>0.0871 | 69 | 38.99<br>30.51                          | 0.793<br>0.883                         |
| RATFY011<br>TF005-05D<br>USA-TF005-05D-A, 2005                                                         | Pioneer 9492<br>RR     | USA<br>Leland                        | 500<br>SC   | 3  | 0.130–<br>0.132 | 0.107–<br>0.112   | 66 | 30.78<br>/ <sup>b</sup> 0.0127<br>28.24 | 1.218<br>1.846<br>0.827                |
| RATFY011<br>TF006-05D<br>USA-TF006-05D-A, 2005                                                         | RG 200 RR              | USA<br>Sabin                         | 500<br>SC   | 3  | 0.125–<br>0.130 | 0.0771–<br>0.0839 | 67 | 31.47<br>30.13                          | 2.026<br>1.675                         |
| RATFY011<br>TF007-05H<br>USA-TF007-05H-A, 2005                                                         | Taylor 427<br>RR       | USA<br>Stilwell                      | 500<br>SC   | 3  | 0.128–<br>0.132 | 0.0898–<br>0.0934 | 75 | 41.21<br>/0.0960 <sup>b</sup><br>44.00  | 0.956<br>/0.0349 <sup>b</sup><br>0.732 |
| RATFY011<br>TF008-05H<br>USA-TF008-05H-A, 2005                                                         | Nk 32G5                | USA<br>Springfield                   | 500<br>SC   | 3  | 0.129           | 0.102–<br>0.106   | 67 | 39.46<br>/0.0295 <sup>b</sup><br>40.51  | 1.293<br>1.559                         |

## Trifloxystrobin

| Study<br>Trial No.<br>Plot No.<br>Year             | Variety             | Country               | Application |    |                 |                   |    | Residues <sup>a</sup> [mg/kg]          |                    |
|----------------------------------------------------|---------------------|-----------------------|-------------|----|-----------------|-------------------|----|----------------------------------------|--------------------|
|                                                    |                     |                       | FL          | No | kg/ha<br>(as)   | kg/hL<br>(as)     | GS | TFS                                    | CGA 321113         |
| RATFY011<br>TF009-05H<br>USA-TF009-05H-<br>A, 2005 | HS3236              | USA<br>Monti-cello    | 500<br>SC   | 3  | 0.124–<br>0.132 | 0.0917–<br>0.0921 | 70 | 47.32<br>/0.0200 <sup>b</sup><br>46.71 | 1.264<br><br>1.543 |
| RATFY011<br>TF010-05H<br>USA-TF010-05H-<br>A, 2005 | Taylor 427<br>RR    | USA<br>Stilwell       | 500<br>SC   | 3  | 0.128–<br>0.134 | 0.0895–<br>0.0937 | 77 | 21.51<br>/0.0205 <sup>b</sup><br>11.16 | 0.639<br><br>0.455 |
| RATFY011<br>TF011-05H<br>USA-TF011-05H-<br>A, 2005 | Asgrow 2801         | USA<br>Earlham        | 500<br>SC   | 3  | 0.128–<br>0.130 | 0.101–<br>0.106   | 67 | 26.98<br>/0.0187 <sup>b</sup><br>33.67 | 0.955<br><br>1.361 |
| RATFY011<br>TF012-05H<br>USA-TF012-05H-<br>A, 2005 | 92M70               | USA<br>Bagley         | 500<br>SC   | 3  | 0.124–<br>0.128 | 0.0992–<br>0.102  | 66 | 21.61<br>/0.0158 <sup>b</sup><br>21.46 | 1.470<br><br>1.373 |
| RATFY011<br>TF013-05H<br>USA-TF013-05H-<br>A, 2005 | Myco-gen<br>0941731 | USA<br>Gardner        | 500<br>SC   | 3  | 0.131–<br>0.133 | 0.0887–<br>0.0963 | 71 | 42.98<br>45.69                         | 1.518<br>1.611     |
| RATFY011<br>TF014-05H<br>USA-TF014-05H-<br>A, 2005 | SC 9374             | USA<br>New<br>Holland | 500<br>SC   | 3  | 0.126–<br>0.131 | 0.0879–<br>0.0894 | 70 | 15.90<br>18.71                         | 1.465<br>1.120     |
| RATFY011<br>TF015-05H<br>USA-TF015-05H-<br>A, 2005 | Pioneer<br>92M80    | USA<br>York           | 500<br>SC   | 3  | 0.127–<br>0.129 | 0.0686–<br>0.0690 | 67 | 22.60<br>27.57                         | 0.821<br>1.175     |
| RATFY011<br>TF016-05H<br>USA-TF016-05H-<br>A, 2005 | NK 43-B1            | USA<br>Carlyle        | 500<br>SC   | 3  | 0.127–<br>0.128 | 0.0743–<br>0.0934 | 66 | 40.04<br>37.37                         | 5.460<br>5.743     |
| RATFY011<br>TF017-05H<br>USA-TF017-05H-<br>A, 2005 | Asgrow<br>AG1603    | USA<br>Arkansaw       | 500<br>SC   | 3  | 0.129           | 0.0729–<br>0.0733 | 69 | 32.68<br>/0.0158 <sup>b</sup><br>31.00 | 1.647<br><br>1.749 |
| RATFY011<br>TF018-05H<br>USA-TF018-05H-<br>A, 2005 | Dairy-land<br>3410  | USA<br>Sheridan       | 500<br>SC   | 3  | 0.124–<br>0.130 | 0.0667–<br>0.0723 | 69 | 8.100<br>8.446                         | 0.337<br>0.346     |
| RATFY011<br>TF019-05H<br>USA-TF019-05H-<br>A, 2005 | Asgrow 3802         | USA<br>Kiowa          | 500<br>SC   | 3  | 0.127–<br>0.129 | 0.101–<br>0.106   | 69 | 30.74<br>36.92                         | 1.202<br>1.372     |
| RATFY011<br>TF020-05H<br>USA-TF020-05H-<br>A, 2005 | Pioneer<br>93B85    | USA<br>St. John       | 500<br>SC   | 3  | 0.126–<br>0.129 | 0.0736–<br>0.0759 | 73 | 32.58<br>/0.0113 <sup>b</sup><br>34.38 | 2.032<br><br>1.878 |

FL=Formulation

No=number of applications

GS=growth stage at last application

DAT=days after last treatment

TFS: trifloxystrobin

<sup>a</sup> Samples were taken 0–3 days after last application<sup>b</sup> Residues in control

Table 11 Residues in green parts of pea derived from trials conducted with 325 SC trifloxystrobin in Canada

| Study<br>Trial No.<br>Plot No.<br>Year | Crop<br>Variety                | Country                   | Application |                   |                   |    | DAT                                    | Residues <sup>a</sup> [mg/kg]                                                       |                                                                                                    |       |
|----------------------------------------|--------------------------------|---------------------------|-------------|-------------------|-------------------|----|----------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|-------|
|                                        |                                |                           | No          | kg/ha<br>(as)     | kg/hL<br>(as)     | GS |                                        | TFS                                                                                 | CGA<br>321113                                                                                      | Sum   |
| RAJAN004<br>RAJAN004-01-<br>12H, 2012  | Pea, field<br>Meadow           | Canada<br>Whitecap        | 2           | 0.1301–<br>0.1305 | 0.0929–<br>0.0932 | 72 | 6<br>6                                 | 0.81<br>1.0<br>0.90                                                                 | 0.039<br>0.038<br>0.038                                                                            | 0.945 |
| RAJAN004<br>RAJAN004-02-<br>12H, 2012  | Pea, field<br>Meadow           | Canada<br>Outlook         | 2           | 0.13120.1314      | 0.0937–<br>0.0939 | 71 | 6<br>6                                 | 1.0<br>1.1<br>1.0                                                                   | 0.039<br>0.040<br>0.04                                                                             | 1.09  |
| RAJAN004<br>RAJAN004-03-<br>12H, 2012  | Pea, field<br>Admiral          | USA<br>Carring-<br>ton    | 2           | 0.13080.1357      | 0.0934–<br>0.0969 | 73 | 7<br>7                                 | 1.3<br>1.3<br>1.3                                                                   | 0.055<br>0.048<br>0.052                                                                            | 1.35  |
| RAJAN004<br>RAJAN004-04-<br>12H, 2012  | Pea, field<br>Meadow           | Canada<br>Kenaston        | 2           | 0.13030.1311      | 0.0931–<br>0.0936 | 73 | 8<br>8                                 | 0.67<br>0.55<br>0.61                                                                | 0.027<br>0.025<br>0.026                                                                            | 0.637 |
| RAJAN004<br>RAJAN004-05-<br>12H, 2012  | Pea, field<br>Meadow           | Canada<br>Waldheim        | 2           | 0.1326–0.133      | 0.0947–<br>0.0950 | 71 | 6<br>6                                 | 0.79<br>0.77<br>0.78                                                                | 0.033<br>0.031<br>0.032                                                                            | 0.813 |
| RAJAN004<br>RAJAN004-06-<br>12H, 2012  | Pea, field<br>Meadow           | Canada<br>Alvena          | 2           | 0.1329            | 0.0949            | 72 | 6<br>6                                 | 1.6<br>1.4<br>1.5                                                                   | 0.039<br>0.038<br>0.385                                                                            | 1.54  |
| RAJAN004<br>RAJAN004-07-<br>12H, 2012  | Pea, field<br>Meadow           | Canada<br>Wakaw           | 2           | 0.13090.1339      | 0.0935–<br>0.0956 | 71 | 6<br>6                                 | 0.73<br>1.1<br>0.915                                                                | 0.035<br>0.038<br>0.037                                                                            | 0.953 |
| RAJAN004<br>RAJAN004-08-<br>12H, 2012  | Pea, field<br>Thunder-<br>bird | Canada<br>Joseph-<br>burg | 2           | 0.12660.1341      | 0.0904–<br>0.0958 | 75 | 7<br>7                                 | 1.2<br>1.0<br>1.1                                                                   | 0.051<br>0.041<br>0.046                                                                            | 1.15  |
| RAJAN004<br>RAJAN004-09-<br>12D, 2012  | Pea, field<br>Meadow           | Canada<br>Rosthern        | 2           | 0.108–0.1082      | 0.0771–<br>0.0773 | 69 | 0<br>0<br>3<br>3<br>7<br>7<br>13<br>13 | 2.4<br>3.1<br>1.7<br>1.6<br><u>2.3</u><br><u>1.6</u><br><u>1.95</u><br>0.67<br>0.73 | 0.013<br>0.011<br>0.030<br>0.032<br><u>0.035</u><br><u>0.023</u><br><u>0.029</u><br>0.032<br>0.030 | 1.98  |

FL=Formulation

No=number of applications

GS=growth stage at last application

DAT=Days after last treatment

TFS: trifloxystrobin

<sup>a</sup>.Residues were measured in green materials.

Table 12 Residue in/on pea hay derived from trials conducted with 325 SC trifloxystrobin in/on pea in Canada

| Study<br>Trial No.<br>Plot No.<br>Year | Crop<br>Variety      | Country            | Application |                   |                   |    | DAT    | Residues <sup>a</sup> [mg/kg] |                       |      |
|----------------------------------------|----------------------|--------------------|-------------|-------------------|-------------------|----|--------|-------------------------------|-----------------------|------|
|                                        |                      |                    | No          | kg/ha<br>(as)     | kg/hL<br>(as)     | GS |        | TFS                           | CGA<br>321113         | Sum  |
| RAJAN004<br>RAJAN004-01-<br>12H, 2012  | Pea, field<br>Meadow | Canada<br>Whitecap | 2           | 0.1301–<br>0.1305 | 0.0929–<br>0.0932 | 72 | 6<br>6 | 2.2<br>6.2<br>4.2             | 0.18<br>0.43<br>0.305 | 4.51 |
| RAJAN004<br>RAJAN004-02-<br>12H, 2012  | Pea, field<br>Meadow | Canada<br>Outlook  | 2           | 0.1312–<br>0.1314 | 0.0937–<br>0.0939 | 71 | 6<br>6 | 5.4<br>6.6<br>6.0             | 0.29<br>0.35<br>0.32  | 6.33 |

| Study<br>Trial No.<br>Plot No.<br>Year | Crop<br>Variety                | Country                   | Application |                   |                   |    |                                        | Residues <sup>a</sup> [mg/kg]                             |                                                                       |             |
|----------------------------------------|--------------------------------|---------------------------|-------------|-------------------|-------------------|----|----------------------------------------|-----------------------------------------------------------|-----------------------------------------------------------------------|-------------|
|                                        |                                |                           | No          | kg/ha<br>(as)     | kg/hL<br>(as)     | GS | DAT                                    | TFS                                                       | CGA<br>321113                                                         | Sum         |
| RAJAN004<br>RAJAN004-03-<br>12H, 2012  | Pea, field<br>Admiral          | USA<br>Carrington         | 2           | 0.1308–<br>0.1357 | 0.0934–<br>0.0969 | 73 | 7<br>7                                 | 2.1<br>2.1<br>2.1                                         | 0.13<br>0.041<br>0.086                                                | 2.19        |
| RAJAN004<br>RAJAN004-04-<br>12H, 2012  | Pea, field<br>Meadow           | Canada<br>Kenaston        | 2           | 0.1303–<br>0.1311 | 0.0931–<br>0.0936 | 73 | 8<br>8                                 | 3.1<br>3.1<br>3.1                                         | 0.15<br>0.18<br>0.165                                                 | 3.27        |
| RAJAN004<br>RAJAN004-05-<br>12H, 2012  | Pea, field<br>Meadow           | Canada<br>Waldheim        | 2           | 0.1326–<br>0.133  | 0.0947–<br>0.0950 | 71 | 6<br>6                                 | 3.5<br>3.1<br>3.3                                         | 0.30<br>0.25<br>0.275                                                 | 3.58        |
| RAJAN004<br>RAJAN004-06-<br>12H, 2012  | Pea, field<br>Meadow           | Canada<br>Alvena          | 2           | 0.1329            | 0.0949            | 72 | 6<br>6                                 | 6.6<br>6.8<br>6.7                                         | 0.31<br>0.49<br>0.40                                                  | 7.11        |
| RAJAN004<br>RAJAN004-07-<br>12H, 2012  | Pea, field<br>Meadow           | Canada<br>Wakaw           | 2           | 0.1309–<br>0.1339 | 0.0935–<br>0.0956 | 71 | 6<br>6                                 | 6.0<br>4.6<br>5.3                                         | 0.24<br>0.26<br>0.25                                                  | 5.56        |
| RAJAN004<br>RAJAN004-08-<br>12H, 2012  | Pea, field<br>Thunder-<br>bird | Canada<br>Joseph-<br>burg | 2           | 0.1266–<br>0.1341 | 0.0904–<br>0.0958 | 75 | 7<br>7                                 | 8.2<br>5.3<br>6.75                                        | 0.23<br>0.15<br>1.19                                                  | 6.95        |
| RAJAN004<br>RAJAN004-09-<br>12D, 2012  | Pea, field<br>Meadow           | Canada<br>Rosthern        | 2           | 0.108–<br>0.1082  | 0.0771–<br>0.0773 | 69 | 0<br>0<br>3<br>3<br>7<br>7<br>13<br>13 | 15<br>13<br>7.2<br>6.6<br>3.1<br>2.9<br>3.0<br>3.0<br>1.6 | 0.37<br>0.35<br>0.21<br>0.22<br>0.17<br>0.16<br>0.165<br>0.25<br>0.33 | <u>3.17</u> |

FL=Formulation

No=number of applications

GS=growth stage at last application

DAT=days after last treatment

TFS: trifloxystrobin

<sup>a</sup> Residues were measured in hay,

### *Fate of residues in storage and processing*

The effect of processing on trifloxystrobin residues was investigated in soya beans in the USA. In one trial, three foliar spray applications at rates of 0.446–0.471 kg trifloxystrobin/ha were made to soya beans with a 8 to 9-day interval between applications. Soya beans were harvested at normal maturity at a 19-day after last application (Beedle, EC and Harbin, AM 2005b.). Subsamples of the soya bean seed were removed for analysis. The remainder of the soya bean seed was used to generate aspirated grain fractions and then processed into hulls, meal, and refined oil. Processing was performed using batch procedures that simulated commercial processing practices. The residues of trifloxystrobin and CGA 321113 were determined according to method 200177. The individual analyte residues were summed to give a total trifloxystrobin residue. The limit of quantitation (LOQ) for total trifloxystrobin residue was 0.01 mg/kg in soya bean seed, hulls, meal, and refined oil, and 0.10 mg/kg in soya bean aspirated grain fractions.

Table 13 Results of processing soya beans treated with trifloxystrobin

| Crop<br>Variety | Application |    |                 | Portion analysed | Residues [mg/kg] |            |        | Pf     |
|-----------------|-------------|----|-----------------|------------------|------------------|------------|--------|--------|
|                 | FL          | No | kg/ha<br>(as)   |                  | TFS              | CGA 321113 | Total  |        |
| S56-D7          | 250<br>EC   | 3  | 0.223-<br>0.235 | seed             | 0.223            | 0.038      | 0.261  | –      |
|                 |             |    |                 | hull             | 0.116            | < 0.01     | 0.124  | 0.48   |
|                 |             |    |                 | meal             | < 0.01           | < 0.01     | < 0.01 | < 0.04 |
|                 |             |    |                 | oil, refined     | 0.034            | < 0.01     | 0.034  | 0.13   |

| Crop Variety | Application |    |            | Portion analysed          | Residues [mg/kg] |            |       | Pf   |
|--------------|-------------|----|------------|---------------------------|------------------|------------|-------|------|
|              | FL          | No | kg/ha (as) |                           | TFS              | CGA 321113 | Total |      |
|              |             |    |            | aspirated grain fractions | 16.1             | 2.08       | 18.2  | 69.7 |

### ***Residues in animal commodities***

Dairy and poultry feeding studies were submitted for the 2004 JMPR review.

## **APPRAISAL**

Trifloxystrobin was first evaluated by the JMPR in 2004 (T, R) and in 2012 (R). The 2004 Meeting established an ADI of 0–0.04 mg/kg bw and decided that ARfD was not necessary. The Meeting agreed that the residue definition for enforcement purposes for plant commodities should be trifloxystrobin per se, for animal commodities and dietary intake assessment the residue definition should be parent compound and CGA 321113 (expressed as trifloxystrobin equivalents) for plant and animal commodities.

Trifloxystrobin was listed by the Forty-sixth Session of CCPR (2014) for the evaluation by the 2015 JMPR for additional MRLs. Supervised trials data were submitted for evaluation on dry soya bean, lentil, chick pea and pea.

Analytical methods used for supervised trials were also provided.

### ***Analytical methods***

The Meeting received descriptions and validation data for analytical methods for residues of trifloxystrobin, CGA 321113 and several other metabolites in different plant matrices.

The plant materials are generally extracted with a mixture of acetonitrile/water. After filtration and concentration to the aqueous remainder, the acidified crude extract is purified, where necessary, by liquid-liquid partition. The residues are quantified by reverse-phase HPLC with MS/MS-detection. The average recoveries of trifloxystrobin and CGA 321113 and their relative standard deviations from test portions spiked at 0.01–2 mg/kg levels were for peas (100–101%, 3.1–4.7%) and soya beans (86–91%, 6.4, 19%). The limits of quantification ranged between 0.01–0.02 mg/kg.

The DFG method S19, evaluated in 2004, is suitable for enforcement.

### ***Residues resulting from supervised trials on crops***

The sum of trifloxystrobin and CGA 321113 was calculated and expressed as trifloxystrobin on the basis of the relative molecular masses. A conversion factor of 1.036 is required to express CGA 321113 as trifloxystrobin. As CGA 321113 does not generally constitute a significant proportion of the residue in crops, when the levels of trifloxystrobin or CGA 321113 were below the LOQ, their sum was calculated according to the method used by the 2004 JMPR.

| Trifloxystrobin (mg/kg) | CGA 321113 (mg/kg) | Total (expressed as trifloxystrobin) (mg/kg) |
|-------------------------|--------------------|----------------------------------------------|
| < 0.01                  | < 0.01             | < 0.01                                       |
| < 0.01                  | 0.011              | 0.021                                        |
| 0.10                    | < 0.02             | 0.10                                         |
| 0.92                    | 0.16               | 1.1                                          |

In field trials duplicate samples were taken from each treated plot. Of the duplicate results the non-detected residues were disregarded in the calculation of average residue. As a conservative



approach, if the residues measured were 0.015 and < 0.01, the calculated average was taken as 0.015 mg/kg.

### *Pulses*

#### *Soya bean*

The GAP in Canada allows maximum 2 times 0.0625 kg/ha treatment with a 20 day PHI. In 4 trials conducted according to GAP the residues in soya bean seeds were < 0.01 mg/kg (4).

The Brazilian GAP permits up to 4 treatments with 0.060 kg/ai/ha or 2 treatments with 0.075 kg ai/ha with a PHI of 20 days. Following treatment according to GAP the trifloxystrobin residues were below the LOQ (< 0.01 or < 0.02 mg/kg). CGA 321113 residues occurred in seven samples at 0.01–0.02 mg/kg level.

The US GAP permits 3 applications at rates between 0.0913–0.127 kg ai/ha and a PHI of 21 days. In 2003 a total of 20 trials were conducted in the USA applying trifloxystrobin three times at rates of 0.086–0.095 kg ai/ha. In addition, another 20 trials were performed in 2005 with application rates of 0.13 kg ai/ha and samples were taken at 21 days. Duplicate samples were taken from each site.

The US use patterns represent the critical GAP. The nominal application rates in US trials are within  $\pm 25\%$  of the GAP. The residues of parent compound in rank order were: < 0.01 (28), 0.01 (4), 0.012, 0.014, 0.016 (2), 0.021, 0.027, and 0.041 mg/kg.

The sum of residues were in rank order: < 0.01 (24), 0.012 (4), 0.021 (2), 0.023 (2), 0.024, 0.025, 0.026, 0.027, 0.039, 0.043, 0.057 and 0.058 mg/kg.

The Meeting estimated a maximum residue level of 0.05 mg/kg for trifloxystrobin in soya beans, and an STMR residue of 0.01 mg/kg for the sum of trifloxystrobin and CGA 321113.

#### *Beans and peas, dry*

The use of trifloxystrobin in/on dry pea, chickpea and lentil is registered in Canada and the USA.

Nine trials were conducted on dry peas and nine trials on dry beans according the GAP in Canada (1-2 application with 0.132 kg ai/ha, the PHI is 30 days). Duplicate samples were taken at each sampling interval.

In beans, the average residues of trifloxystrobin at about 30 days were < 0.01 mg/kg in all (9) samples.

The sum of trifloxystrobin and CGA 321113 residues expressed as trifloxystrobin were in rank order: < 0.01 (5), 0.021 (2), 0.022, and 0.023 mg/kg.

In peas, the residues of trifloxystrobin at about 30 days were all < 0.01 mg/kg in all (9) samples.

The sum of residues of trifloxystrobin and CGA 321113 expressed as trifloxystrobin (mg/kg) at about 30 days were: < 0.01 (3), 0.021 (2), 0.022, 0.023, 0.027 and 0.033 mg/kg.

The use pattern is the same for beans and peas and the residues are not different. Consequently the residue datasets can be combined for mutual support.

The residues of trifloxystrobin in dry bean and pea seeds were < 0.01 mg/kg.

The sum of residues in beans and peas in rank order were: < 0.01 (8), 0.021 (4), 0.022, 0.023 (2), 0.025, 0.027 and 0.033 mg/kg.

As the use pattern for lentils is the same as for beans and peas, the Meeting decided that the database is sufficient for making recommendation for these three commodities.

The Meeting estimated a maximum residue level of 0.01\* mg/kg and an STMR residue of 0.021 mg/kg for dry beans, lentils, and pea.

### ***Animal feed***

#### ***Soya bean forage and hay***

Altogether 40 trials were conducted in USA in accordance with registered use patterns. Residues in forage and hay were measured and reported. However, grazing animals on soya bean fields or using forage and hay as animal feed are not permitted, therefore the results of trials were not evaluated.

#### ***Pea forage and hay***

The average residues of trifloxystrobin and CGA 321113 measured in pea green materials (pea vine) obtained from trials conducted according to Canadian GAP are listed below.

Trifloxystrobin residues: 0.61, 0.78, 0.91, 0.92, 1.05, 1.10, 1.30, 1.50 and 1.95 mg/kg.

The sum of trifloxystrobin and CGA 321113 residues: 0.64, 0.81, 0.94, 0.95, 1.09, 1.15, 1.35, 1.54 and 1.98 mg/kg.

The Meeting estimated highest residue of 2 mg/kg and median residue of 1.1 mg/kg for the sum of trifloxystrobin and CGA321113 in pea vine for animal burden calculations.

The residues of trifloxystrobin and CGA 321113 (TFSA) measured in pea hay obtained from trials conducted according to Canadian GAP are listed below. Trifloxystrobin residues: 2.1, 3.0, 3.1, 3.3, 4.2, 5.3, 6.0, 6.7 and 6.8 mg/kg.

The sum of residues were in rank order: 2.2, 3.2, 3.3, 3.6, 4.5, 5.6, 6.3, 6.9 and 7.1 mg/kg

The Meeting estimated a maximum residue level of 17 mg/kg (dry weight) for peanut hay.

The Meeting estimated highest residue of 7.1 mg/kg and median residue of 4.5 mg/kg for the sum of trifloxystrobin and CGA321113 in pea hay for animal burden calculation.

### ***Fate of Residues in Storage and Processing***

Soya bean was treated with trifloxystrobin three times at a rate of 0.446–0.471 kg/ha and harvested 19 days after last application. The average total trifloxystrobin residue was 0.26 mg/kg in soya bean seed (raw agricultural commodity (RAC)), 18.2 mg/kg in soya bean aspirated grain fractions, 0.12 mg/kg in hulls, < 0.01 mg/kg in meal, and 0.03 mg/kg in refined oil. Concentration of the total trifloxystrobin residue was seen only in the soya bean aspirated grain fractions (processing factor about 70). No concentration of the total trifloxystrobin residue was seen in soya bean hulls, meal, or refined oil.

For the purpose of animal burden calculation, the Meeting estimated median residue of 0.7 mg/kg for aspirated grain fraction, 0.01 mg/kg for hull and < 0.0008 mg/kg for meal of soya bean.

### ***Residues in animal commodities***

Animal feeding studies were evaluated by the 2004 Meeting. Dairy cows were dosed with trifloxystrobin in capsules at the equivalent of 2, 5.9 or 21 ppm in the diet for 28–30 days. The residues measured in various samples are summarized below:

| Sample        | Day   | Maximum trifloxystrobin residues (mg/kg) |        |        |              |        |        |             |        |        |
|---------------|-------|------------------------------------------|--------|--------|--------------|--------|--------|-------------|--------|--------|
|               |       | Dose 2 ppm                               |        |        | Dose 5.9 ppm |        |        | Dose 21 ppm |        |        |
|               |       | Parent                                   | 321113 | Total  | Parent       | 321113 | Total  | Parent      | 321113 | Total  |
| Milk          | 26    | -                                        | -      | -      | -            | -      | -      | < 0.01      | < 0.01 | < 0.02 |
| Liver         | 28-30 | < 0.02                                   | < 0.02 | < 0.04 | < 0.02       | < 0.02 | < 0.04 | < 0.02      | 0.09   | 0.11   |
| Kidney        | 28-30 | < 0.02                                   | < 0.02 | < 0.04 | < 0.02       | < 0.02 | < 0.04 | < 0.02      | 0.02   | 0.04   |
| Perirenal fat | 28-30 | < 0.02                                   | < 0.02 | < 0.04 |              |        |        | 0.06        | < 0.02 | 0.08   |
| Omental fat   | 28-30 | < 0.02                                   | < 0.02 | < 0.04 | < 0.02       | < 0.02 | < 0.04 | 0.05        | < 0.02 | 0.07   |
| Round         | 28-30 | -                                        | -      | -      | -            | -      | -      | < 0.02      | < 0.02 | < 0.04 |
| Tenderloin    | 28-30 | -                                        | -      | -      | -            | -      | -      | < 0.02      | < 0.02 | < 0.04 |

Laying hens were dosed at 1.5, 4.5 and 15 ppm level for 29 days. At the highest treatment level no residues (< 0.02 mg/kg) were detected in composite tissue samples of breast plus thigh, skin plus attached fat, peritoneal fat, liver and eggs.

The Meeting estimated the dietary burden of trifloxystrobin in farm animals on the basis of the diets listed in Annex 6 of the 2009 JMPR Report and using the estimated residues in livestock feed commodities evaluated by the present and previous Meetings.

|                   | Trifloxystrobin animal dietary burden, ppm, of dry matter diet |      |                   |                   |           |      |       |       |
|-------------------|----------------------------------------------------------------|------|-------------------|-------------------|-----------|------|-------|-------|
|                   | US-Canada                                                      |      | EU                |                   | Australia |      | Japan |       |
|                   | Max                                                            | Mean | Max               | Mean              | Max       | Mean | Max   | Mean  |
| Beef cattle       | 2.17                                                           | 1.15 | 26.6 <sup>a</sup> | 6.97 <sup>b</sup> | 8.24      | 5.00 | 4.53  | 0.84  |
| Dairy cattle      | 2.79                                                           | 1.27 | 23.2 <sup>c</sup> | 6.37 <sup>d</sup> | 8.21      | 4.11 | 2.11  | 0.43  |
| Poultry - broiler | 0.11                                                           | 0.11 | 0.069             | 0.069             | 0.15      | 0.15 | 0.03  | 0.03  |
| Poultry – layer   | 0.11                                                           | 0.11 | 1.83 <sup>e</sup> | 0.78 <sup>f</sup> | 0.15      | 0.15 | 0.079 | 0.079 |

<sup>a</sup> Suitable for estimation maximum residue levels in meat

<sup>b</sup> Suitable for estimation of median residues in meat

<sup>c</sup> Suitable for estimation maximum residue levels in milk

<sup>d</sup> Suitable for estimation median residue levels in milk

<sup>e</sup> Suitable for estimation maximum residue levels in poultry meat and edible offal

<sup>f</sup> Suitable for estimation median residue levels in poultry meat and edible offal

The maximum dietary burden of beef cattle and dairy cattle is about 30% higher than the maximum feeding level of 21 ppm. The Meeting concluded that the residues observed at the highest feeding level can still be used as a basis for estimation of maximum residues in meat, offal and milk.

The Meeting concluded that the current Codex limits cover the residues derived from the uses of trifloxystrobin and maintains its previous recommendations.

## RECOMMENDATIONS

On the basis of the data from supervised trials the Meeting concluded that the residue levels listed in Annex 1 to the Report were suitable for establishing maximum residue limits and for IEDI assessment.

| CCN    | Commodity Name | MRL, mg/kg proposed | previous | STMR or STMR-P mg/kg |
|--------|----------------|---------------------|----------|----------------------|
| VD0071 | Beans, dry     | 0.01*               |          | 0.021                |
| VD0533 | Lentils        | 0.01*               |          | 0.021                |
| VD4511 | Pea, dry       | 0.01*               |          | 0.021                |
| VD0541 | Soya bean      | 0.05                |          | 0.01                 |
|        |                |                     |          |                      |

## DIETARY RISK ASSESSMENT

### Long-term intake

The International Estimated Daily Intakes (IEDIs) of trifloxystrobin were calculated for the 17 GEMS/Food cluster diets using STMRs and STMR-Ps estimated by the JMPR in 2004, 2012 and the current meeting. The results are shown in Annex 3 to the 2015 Report.

The ADI is 0–0.04 mg/kg bw and the calculated IEDIs were 1–4% of the maximum ADI. The Meeting concluded that the long-term intake of residues of trifloxystrobin from the uses considered by the JMPR is unlikely to present a public health concern.

**Short-term intake**

The 2004 JMPR decided that it was unnecessary to establish an ARfD. The present Meeting therefore concluded that the short-term intake of trifloxystrobin residues is unlikely to present a public health.

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| F11-036         | Anon                        | 2012b | F11-035-02, F11-035-03, F11-035-04, F11-035-05. Unpublished. Translation of Santiago, L, 2012a. JAU 6476 & CGA 279202; soya bean; SC 325; Brazil; BBA. Bayer S.A., Bayer CropScience, Sao Paulo, Brazil. Bayer CropScience AG, Report No.: F11-036, Edition Number: M-444463-02-1, includes F11-036-01, F11-036-02, F11-036-03, F11-036-04, F11-036-05. Unpublished. Translation of Santiago, L, 2012b. |
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| UNESP RA-993/0  | Galhiane, MS & de Sousa, SL | 2006c | Tebuconazol & Trifloxystrobin; 75 WG; soya; Brazil; BBA. Universidade Estadual Paulista (UNESP), Bauru, Brazil. Bayer CropScience AG, Report No.: UNESP RA-993/06, Edition Number: M-276661-01-2, includes FR05BRA001-P2. Unpublished. Translation of Galhiane, MS & de Sousa, SL, 2006d.                                                                                                               |
| UNESP RA-994/06 | Galhiane, MS & de Sousa, SL | 2006e | Tebuconazol & Trifloxystrobin; 75 WG; soya; Brazil; BBA. Universidade Estadual Paulista (UNESP), Bauru, Brazil. Bayer CropScience AG, Report No.: UNESP RA-994/06, Edition Number: M-276638-01-2, includes FR05BRA001-P3. Unpublished. Translation of Galhiane, MS & de Sousa, SL, 2006f.                                                                                                               |





## TRIFLOXYSTROBIN (213)

*The first draft was prepared by Dr DJ MacLachlan, Department of Agriculture and Water Resources, Canberra, Australia.*

### EXPLANATION

Trifloxystrobin (methyl (E)-methoxyimino-{(E)- $\alpha$ -[1-( $\alpha,\alpha,\alpha$ -trifluoro-meta-tolyl)ethylidene-aminooxy]-ortho-tolyl}acetate) was first evaluated for toxicology and residues by the JMPR in 2004. The Meeting derived an ADI of 0–0.04 mg/kg bw, decided that an ARfD is unnecessary and concluded that the residue definition for plant commodities for compliance with MRL values was trifloxystrobin *per se* and for animal commodities compliance with MRL values as well as for consumer risk assessment was the sum of trifloxystrobin and (E,E)-methoxyimino-{2-[1-(3-trifluoromethyl-phenyl) ethylidene-aminooxymethyl]-phenyl}acetic acid = CGA321113) (expressed as trifloxystrobin equivalents). The residue is fat soluble.

Trifloxystrobin was scheduled at the 48<sup>th</sup> session of the CCPR for the evaluation of additional MRLs for head cabbage, cauliflower, broccoli, spinach, cotton and ginseng by the 2017 JMPR.

### RESIDUE ANALYSIS

#### *Analytical methods*

The method used for the analysis of head cabbage, cauliflower, broccoli, spinach and cotton samples was method 200177, which was evaluated by the 2004, and 2015 JMPR.

The Meeting received summarized information on an analytical method for trifloxystrobin and CGA321113 residues in ginseng. The analytical method used to analyse for trifloxystrobin involves homogenisation of a fresh ginseng and acetone mixture (with dry ice), filtering to remove solids. In the case of dried ginseng and red dried ginseng samples, distilled water was added to wet the samples prior to addition of acetonitrile, homogenisation and filtering to remove solids. Acetonitrile:distilled water:saturated lead acetate (5:2:1 v/v/v) are added to an aliquot of the dried ginseng and red ginseng extracts, the mixture shaken for 30 minutes prior to filtration to remove solids. The filter cake is washed with acetonitrile and the rinsate and filtrate combined.

The extracts obtained for fresh, dried and red ginseng are partitioned with distilled water:saturated NaCl:dichloromethane (6:2:1 v/v/v). The organic layer is separated and dried over anhydrous sodium sulphate and the solvent removed (35 °C, rotary evaporator). The residue is dissolved in *n*-hexane for clean-up on a Florsil column pre-washed with *n*-hexane followed by *n*-hexane:dichloromethane:acetonitrile (49.65:50:0.35 v/v/v) and the trifloxystrobin eluted with *n*-hexane:dichloromethane:acetonitrile (45:50:5 v/v/v) and the collected fraction concentrated to dryness (35 °C rotary evaporator) with the resulting residue dissolved in acetone for quantitation by GC-NPD.

Analysis of samples for CGA321113 involves homogenisation of a fresh ginseng, 0.1% H<sub>3</sub>PO<sub>4</sub>, and acetone mixture, filtering to remove solids. In the case of dried ginseng and red dried ginseng samples, distilled water was added to wet the samples and the mixture allowed to sit for one hour prior to addition of 0.1% H<sub>3</sub>PO<sub>4</sub> and acetone, homogenisation and filtering to remove solids.

The extracts obtained for fresh, dried and red ginseng are partitioned with distilled water:saturated NaCl:*n*-hexane (3:1:1 v/v/v). The organic layer is discarded and the aqueous layer shaken with dichloromethane, which is separated, dried over anhydrous sodium sulphate and evaporated to dryness (35 °C, rotary evaporator). The residue is dissolved in *n*-hexane for clean-up on a Florsil column pre-washed with *n*-hexane followed by *n*-hexane:ethyl acetate (80:20 v/v) and the CGA321113 eluted with acetonitrile:formic acid (100:0.5 v/v) and the collected fraction concentrated to just dryness (35 °C rotary evaporator) with the resulting residue dissolved in acetone for quantitation by GC-NPD.



The detector response was linear for fresh ginseng, dried and red ginseng and water extract of dried ginseng over the concentration range 0.1-6 mg/kg for trifloxystrobin ( $r^2 \geq 0.9987$ ,  $n=7$ ) and 0.05–5 mg/kg for CGA321113 ( $r^2 \geq 0.9991$ ,  $n=7$ ). No interferences were reported.

Mean recoveries were within the range 70–120% for all commodities investigated and supported LOQs of 0.03 to 0.06 mg/kg for ginseng and 0.07 mg/kg for ginseng processed commodities. The method is suitable for the analysis of residues in ginseng and ginseng processed commodities.

Table 1 Summary of concurrent recovery data from trials conducted in 2013 and 2014 (Kyung 2014)

| Commodity                      | trifloxystrobin |   |                   |         | CGA321113     |   |                   |         |
|--------------------------------|-----------------|---|-------------------|---------|---------------|---|-------------------|---------|
|                                | Spike (mg/kg)   | N | Mean recovery (%) | RSD (%) | Spike (mg/kg) | N | Mean recovery (%) | RSD (%) |
| Fresh ginseng                  | 0.03            | 5 | 87                | 5.9     | 0.03          | 5 | 76                | 5.7     |
|                                | 0.06            | 5 | 88                | 3.9     | 0.1           | 5 | 75                | 3.7     |
|                                | 0.1             | 5 | 94                | 2.7     | 0.3           | 5 | 75                | 4.0     |
|                                | 0.3             | 5 | 86                | 3.0     |               |   |                   |         |
|                                | 0.6             | 5 | 92                | 2.2     |               |   |                   |         |
| Dried ginseng                  | 0.07            | 5 | 76                | 5.6     | 0.07          | 5 | 84                | 9.6     |
|                                | 0.13            | 5 | 107               | 6.7     | 0.2           | 5 | 76                | 4.7     |
|                                | 0.2             | 5 | 90                | 8.1     | 0.7           | 5 | 79                | 5.1     |
|                                | 0.7             | 5 | 88                | 4.0     |               |   |                   |         |
|                                | 1.3             | 5 | 85                | 6.4     |               |   |                   |         |
| Red ginseng                    | 0.07            | 5 | 86                | 5.5     | 0.07          | 5 | 82                | 6.1     |
|                                | 0.13            | 5 | 82                | 1.5     | 0.2           | 5 | 81                | 7.6     |
|                                | 0.2             | 5 | 80                | 5.6     | 0.7           | 5 |                   |         |
|                                | 0.7             | 5 | 88                | 4.1     |               |   |                   |         |
|                                | 1.3             | 5 | 90                | 1.8     |               |   | 81                | 8.0     |
| Water extract of dried ginseng | 0.07            | 5 | 100               | 15      | 0.07          | 5 | 88                | 5.4     |
|                                | 0.2             | 5 | 92                | 12      | 0.2           | 5 | 85                | 7.7     |
|                                | 0.7             | 5 | 90                | 17      | 0.7           | 5 | 73                | 5.5     |
| Water extract of red ginseng   | 0.07            | 5 | 90                | 7.5     | 0.07          | 5 | 93                | 7.9     |
|                                | 0.2             | 5 | 83                | 6.8     | 0.2           | 5 | 75                | 4.1     |
|                                | 0.7             | 5 | 81                | 6.5     | 0.7           | 5 | 75                | 5.2     |

### *Stability of residues in stored analytical samples*

The stability of residues in samples on frozen storage was evaluated by the 2004 JMPR for a range of commodities. Residues of trifloxystrobin and CGA321113 were stable under freezer storage conditions for at least 24 months in the case of grapefruit, cucumber, potato and wheat commodities (grain, straw and whole plant) or 18 months for apple (fruit, wet pomace), peanut (nutmeat, oil) and grape juice. The stability data covered commodities that are representative of high water content (apple, cucumber, grape juice), high acid content (grapefruit), high oil content (peanut) and high protein/starch content (potato, wheat) and can be extrapolated to the commodities considered at the current Meeting.

Maximum storage to analysis intervals were: 11.6 months for broccoli, 11.2 months for cauliflower, 10.8 months for cabbage, 11.3 months for spinach, 15 months for cottonseed, 10 months for gin by-products and 9.9 months for ginseng. The periods of demonstrated stability cover the frozen storage intervals used in the residue studies on crops.

Additionally information on spiked samples stored at for the same intervals as samples from residue trials was made available for ginseng. Samples of control ginseng were fortified with trifloxystrobin or CGA321113 at 0.03 to 1.3 mg/kg prior to freezing of the homogenised fresh, dried, red and water extracts. Residues in stored samples were 70–91% (five replicates per sample) of the nominal fortification level at the time of analysis, which occurred after 21 to 296 days of frozen storage.

**USE PATTERN**

The information available to the 2017 JMPR on registered uses of trifloxystrobin relevant to the residue trial data made available is summarised in Table 2.

Table 2 Use of trifloxystrobin

| Crop                          | Country           | No (int)   | Growth stage                | Application rate (g ai/ha)                                                             | Spray concentration (g ai/hL) | Spray volume (L/ha) | PHI (days)                                       |
|-------------------------------|-------------------|------------|-----------------------------|----------------------------------------------------------------------------------------|-------------------------------|---------------------|--------------------------------------------------|
| Brassica leafy greens         | USA               | 2-3 (5-14) |                             | 92-139 g ai/ha, max 281 g ai/ha/yr                                                     |                               | -<br>>18.7→         | 0                                                |
| Brassica, head and stem       | USA               | 2-3 (7-14) |                             | 92-139 g ai/ha, max 281 g ai/ha/yr                                                     |                               | -<br>>18.7→         | 0                                                |
| Cotton (foliar)               | USA               | 3 (14)     |                             | Foliar: 137 g ai/ha, max 411 g ai/ha/y                                                 |                               | >93.5 grd<br>>18.7→ | 30                                               |
| Cotton (in-furrow and banded) | USA               | 1          |                             | In-furrow or banded at planting: 137 g ai/ha or 0.835 g ai/100 m if row spacing 0.91 m |                               | >93.5 grd           | (30)                                             |
| Ginseng                       | Republic of Korea | 3 (10)     | Flowering, Fruiting, Mature | (67)                                                                                   | 3.35                          | 2000 grd            | 21                                               |
| Ginseng                       | USA               | 2 (14)     |                             | 139 g ai/ha, max 281 g ai/ha/y                                                         |                               | -<br>>18.7→         | 7                                                |
| Leaf petioles                 | USA               | 2-4 (14)   |                             | 73-106 g ai/ha, max 281 or 420 g ai/ha/y for all trifloxystrobin sources g ai/ha/year  |                               | -<br>>18.7→         | 7                                                |
| Leafy greens                  | USA               | 2 (5-14)   |                             | 139 g ai/ha, max 281 g ai/ha/y or 420 g ai/ha/y for all trifloxystrobin sources        |                               | -<br>>18.7→         | 0 broadcast<br>Lettuce 0 broadcast,<br>20 d band |

grd = application using ground based equipment

→ = application by aircraft

**RESIDUES STUDIES**

The Meeting received information on supervised field trials on the following crops or crop groups:

| Commodity                                  | Table |
|--------------------------------------------|-------|
| Brassicas (broccoli, cauliflower, cabbage) | 3     |
| Spinach                                    | 4     |
| Cotton                                     | 5     |
| Ginseng                                    | 6     |

Residue values from the trials conducted according to maximum GAP have been used for the estimation of maximum residue levels. Those results included in the evaluation are underlined.

The sum of trifloxystrobin and CGA321113 was calculated and expressed as trifloxystrobin on the basis of the relative molecular masses. A conversion factor of 1.036 is required to express CGA321113 as trifloxystrobin. As CGA321113 does not generally constitute a significant proportion of the residue in crops, when the levels of trifloxystrobin or CGA321113 were below the LOQ, their sum was calculated as in the examples provided by the 2004 JMPR and copied below.

| Trifloxystrobin (mg/kg) | CGA321113 (mg/kg) | Total (expressed as trifloxystrobin)<br>(mg/kg) |
|-------------------------|-------------------|-------------------------------------------------|
| < 0.02                  | < 0.02            | < 0.02                                          |
| < 0.02                  | 0.03              | 0.05                                            |
| 0.10                    | < 0.02            | 0.10                                            |
| 0.92                    | 0.16              | 1.1                                             |

### *Brassica vegetables*

Table 3 Residues of trifloxystrobin and CGA321113 (mg/kg) in brassicas (Fischer and Harbin 2008 M-307503-01-1) (mean of duplicate samples) following applications of trifloxystrobin in an SC-formulation

| Location, year, variety<br>BRASSICAS                    | N<br>(int) | Rate<br>(g ai/ha) | Spray<br>volume<br>(L/ha) | GS<br>BBCH | DALA                        | Sample                                                                       | Trifloxystrobin<br>(mg/kg)                          | CGA321113<br>(mg/kg)                           | Total<br>(mg/kg)                             |
|---------------------------------------------------------|------------|-------------------|---------------------------|------------|-----------------------------|------------------------------------------------------------------------------|-----------------------------------------------------|------------------------------------------------|----------------------------------------------|
| <b>Broccoli</b>                                         |            |                   |                           |            |                             |                                                                              |                                                     |                                                |                                              |
| Raymondville<br>TX USA 2007<br>Green Magic              | 2 (5)      | 148<br>143        | 186<br>180                | 49<br>49   | 0                           | Heads+stalks                                                                 | <u>0.68</u>                                         | 0.02                                           | 0.70                                         |
| Guadalupe CA<br>USA 2007<br>Heritage                    | 2 (5)      | 134<br>141        | 122<br>137                | 48<br>49   | 0                           | Heads+stalks                                                                 | <u>0.67</u>                                         | < 0.01                                         | 0.67                                         |
| Sanger CA USA<br>2007 Marathon                          | 2 (5)      | 141<br>143        | 136<br>163                | 49<br>49   | 0<br>1<br>3<br>7<br>10      | Heads+stalks<br>Heads+stalks<br>Heads+stalks<br>Heads+stalks<br>Heads+stalks | <u>0.44</u><br>0.37<br>0.30<br>0.19<br>0.16         | 0.02<br>0.03<br>0.03<br>0.03<br>0.04           | 0.46<br>0.40<br>0.33<br>0.22<br>0.20         |
| <b>Cauliflower</b>                                      |            |                   |                           |            |                             |                                                                              |                                                     |                                                |                                              |
| King City CA<br>USA 2007<br>Solvang                     | 2 (6)      | 140<br>141        | 140<br>141                | 47<br>49   | 0                           | Heads+stalks                                                                 | <u>&lt; 0.01</u>                                    | < 0.01                                         | < 0.01                                       |
| Sanger CA USA<br>2007 Shasta                            | 2 (5)      | 142<br>150        | 136<br>170                | 46<br>47   | 0                           | Heads+stalks                                                                 | <u>0.32</u>                                         | 0.03                                           | 0.36                                         |
| Corvallis CA<br>USA 2007<br>Minuteman <sup>a</sup>      | 2 (5)      | 147<br>140        | 148<br>141                | 48<br>49   | 0                           | Heads+stalks                                                                 | <u>0.01</u>                                         | < 0.01                                         | 0.01                                         |
| <b>Cabbage</b>                                          |            |                   |                           |            |                             |                                                                              |                                                     |                                                |                                              |
| Germansville PA<br>2007 USA Blue<br>Lagoon <sup>b</sup> | 2 (5)      | 142<br>146        | 182<br>185                | 46<br>49   | 0<br>0<br>1<br>3<br>7<br>10 | H+WL<br>H-WL<br>H+WL<br>H+WL<br>H+WL<br>H+WL                                 | <u>0.37</u><br>0.01<br>0.33<br>0.16<br>0.05<br>0.10 | 0.02<br>< 0.01<br>0.02<br>0.02<br>0.02<br>0.02 | 0.39<br>0.01<br>0.34<br>0.18<br>0.07<br>0.12 |
| Athens GA USA<br>2007 Bonnies<br>Best hybrid            | 2 (5)      | 142<br>139        | 98<br>92                  | 48<br>49   | 0                           | H+WL<br>H-WL                                                                 | <u>0.47</u><br>0.01                                 | 0.01<br>< 0.01                                 | 0.48<br>0.01                                 |
| Belle Glade FL<br>2007 USA<br>Emblem                    | 2 (5)      | 142<br>141        | 177<br>188                | 45<br>49   | 0                           | H+WL<br>H-WL                                                                 | <u>0.58</u><br>0.03                                 | 0.01<br>< 0.01                                 | 0.60<br>0.03                                 |
| Richland IA<br>USA 2007<br>Stonehead <sup>c</sup>       | 2 (5)      | 142<br>142        | 155<br>155                | 49<br>49   | 0                           | H+WL<br>H-WL                                                                 | <u>0.47</u><br>< 0.01                               | 0.01<br>< 0.01                                 | 0.49<br>< 0.01                               |
| Uvalde TX USA<br>2007 Blue<br>Thunder <sup>d</sup>      | 2 (5)      | 140<br>140        | 184<br>180                | 49<br>49   | 0                           | H+WL<br>H-WL                                                                 | <u>0.11</u><br>< 0.01                               | < 0.01<br>< 0.01                               | 0.11<br>< 0.01                               |
| Corning CA<br>USA 2007<br>Copenhagen                    | 2 (5)      | 139<br>142        | 187<br>187                | 48<br>49   | 0                           | H+WL<br>H-WL                                                                 | <u>0.03</u><br>0.01                                 | < 0.01<br>< 0.01                               | 0.03<br>0.01                                 |

H+WL = heads with wrapper leaves

H-WL = heads without wrapper leaves

<sup>a</sup> Corvallis cauliflower: 18 mm rain within 24 hours of spray two

<sup>b</sup> Germansville cabbage: 21 mm rain within 24 hours of spray one

<sup>c</sup> Richland cabbage: 33 mm rain within 24 hours of spray one

<sup>d</sup> Uvalde cabbage: 0.3 mm rain within 24 hours of spray two

### Spinach

Table 4 Residues of trifloxystrobin and CGA321113 (mg/kg) in spinach (Fischer and Harbin 2010 M-307507-02-1) (mean of duplicate samples) following applications of trifloxystrobin in an SC-formulation

| Location, year, variety<br>SPINACH        | N (int) | Rate (g ai/ha) | Spray volume (L/ha) | GS BBCH  | DALA                   | Sample | Trifloxystrobin (mg/kg)                 | CGA321113 (mg/kg)                      | Total (mg/kg)                    |
|-------------------------------------------|---------|----------------|---------------------|----------|------------------------|--------|-----------------------------------------|----------------------------------------|----------------------------------|
| Germansville PA USA 2007 Tyee             | 2 (5)   | 142<br>147     | 183<br>183          | 45<br>47 | 0                      | Leaves | <u>7.6</u>                              | 0.06                                   | 7.6                              |
| Suffolk VA USA 2007 Tyee                  | 2 (5)   | 142<br>142     | 123<br>120          | 45<br>45 | 0                      | Leaves | <u>10</u>                               | 0.05                                   | 10                               |
| Hinton OK USA 2007 Bloomsdale             | 2 (7)   | 145<br>143     | 124<br>121          | 31<br>37 | 0                      | Leaves | <u>9.5</u>                              | 0.05                                   | 9.6                              |
| Jerome ID USA 2007 Unipack 151            | 2 (6)   | 142<br>139     | 174<br>170          | 45<br>47 | 0                      | Leaves | <u>4.8</u>                              | 0.02                                   | 4.8                              |
| King City CA USA 2007 Interceptor/Avenger | 2 (5)   | 140<br>141     | 140<br>135          | 45<br>45 | 0<br>1<br>3<br>7<br>10 | Leaves | <u>5.3</u><br>4.8<br>4.2<br>1.3<br>0.60 | 0.03<br>0.03<br>0.02<br>0.02<br>< 0.01 | 5.4<br>4.8<br>4.3<br>1.3<br>0.60 |
| Fresno CA USA 2007 Shasta                 | 2 (5)   | 139<br>139     | 117<br>117          | 43<br>45 | 0                      | Leaves | <u>7.6</u>                              | 0.04                                   | 7.6                              |

### Oilseed

#### Cotton seed

Table 5 Residues of trifloxystrobin and CGA321113 (mg/kg) in undelinted cotton seed (Netzband and Jerkins 2015 M-524431-01-1) (mean of duplicate samples) following applications of trifloxystrobin in an SC-formulation

| Location, year, variety<br>COTTON SEED                  | N (int)      | Rate (g ai/ha)    | Spray volume (L/ha) | GS BBCH        | DALA                       | Sample <sup>a</sup> | Trifloxystrobin (mg/kg)                                | CGA321113 (mg/kg)                              | Total (mg/kg)                                |
|---------------------------------------------------------|--------------|-------------------|---------------------|----------------|----------------------------|---------------------|--------------------------------------------------------|------------------------------------------------|----------------------------------------------|
| Talasee AL USA 2013 DPL 1050                            | 3 (14<br>14) | 142<br>140<br>139 | 188<br>278<br>183   | 69<br>71<br>80 | 29                         | Undelinted seed     | <u>&lt; 0.01</u>                                       | < 0.01                                         | < 0.01                                       |
| Greenville MS USA 2013 Phytogen 499                     | 3 (13<br>15) | 142<br>140<br>138 | 133<br>140<br>134   | 74<br>76<br>80 | 31                         | Undelinted seed     | <u>&lt; 0.01</u>                                       | < 0.01                                         | < 0.01                                       |
| Proctor AR USA 2013 FM1944 GLB2 10/9 <sup>b</sup>       | 3 (14<br>14) | 137<br>138<br>138 | 103<br>96<br>96     | 75<br>75<br>83 | 30                         | Undelinted seed     | 0.01                                                   | < 0.01                                         | 0.01                                         |
| Proctor AR USA 2013 DynaGro 2570 B2RF 15/9 <sup>b</sup> | 3 (14<br>14) | 139<br>139<br>140 | 106<br>97<br>97     | 75<br>75<br>82 | 25<br>29<br>35<br>40<br>44 | Undelinted seed     | < 0.01<br>< 0.01<br>< 0.01<br><u>0.03</u><br>< 0.01    | < 0.01<br>< 0.01<br>< 0.01<br>< 0.01<br>< 0.01 | < 0.01<br>< 0.01<br>< 0.01<br>0.03<br>< 0.01 |
| Uvalde TX USA 2013 DPL 0912 B2RF <sup>c</sup>           | 3 (14<br>14) | 139<br>140<br>139 | 112<br>113<br>112   | 65<br>80<br>84 | 23<br>29<br>34<br>38<br>44 | Undelinted seed     | 0.01<br><u>&lt; 0.01</u><br>< 0.01<br>< 0.01<br>< 0.01 | < 0.01<br>< 0.01<br>< 0.01<br>< 0.01<br>< 0.01 | 0.01<br>< 0.01<br>< 0.01<br>< 0.01<br>< 0.01 |

| Location, year, variety<br>COTTON SEED        | N<br>(int)   | Rate (g<br>ai/ha) | Spray<br>volume<br>(L/ha) | GS<br>BBCH     | DALA                       | Sample <sup>a</sup> | Trifloxystrobin<br>(mg/kg)                        | CGA321113<br>(mg/kg)                           | Total<br>(mg/kg)                     |
|-----------------------------------------------|--------------|-------------------|---------------------------|----------------|----------------------------|---------------------|---------------------------------------------------|------------------------------------------------|--------------------------------------|
| Tahoka TX USA 2013<br>DP0912 B2RF             | 3 (14<br>12) | 145<br>144<br>146 | 142<br>141<br>143         | 85             | 28                         | Undelinted seed     | <u>0.11</u>                                       | < 0.01                                         | 0.11                                 |
| Levelland TX USA<br>2013 FM1944 GLB2          | 3 (14<br>13) | 144<br>141<br>143 | 141<br>139<br>140         | 69<br>80<br>85 | 28                         | Undelinted seed     | <u>0.10</u> c0.03                                 | < 0.01                                         | 0.10                                 |
| Hinton OK USA 2013<br>FM1960 B2F <sup>d</sup> | 3 (13<br>14) | 139<br>140<br>140 | 150<br>186<br>194         | 73<br>79<br>84 | 26<br>30<br>36<br>40<br>43 | Undelinted seed     | 0.04<br>0.05 c0.03<br>0.04<br>0.03<br><u>0.08</u> | < 0.01<br>< 0.01<br>< 0.01<br>< 0.01<br>< 0.02 | 0.04<br>0.05<br>0.04<br>0.03<br>0.08 |
| Wall TX USA 2013<br>FM1944 GLB2               | 3 (14<br>14) | 141<br>139<br>141 | 138<br>132<br>135         | 77<br>78<br>87 | 27                         | Undelinted seed     | <u>0.03</u>                                       | < 0.01                                         | 0.03                                 |
| Paso Robles CA USA<br>2013 DP 399             | 3 (14<br>14) | 146<br>140<br>139 | 289<br>278<br>275         | 83<br>85<br>88 | 28                         | Undelinted seed     | <u>0.26</u>                                       | < 0.01                                         | 0.26                                 |
| Sanger CA USA 2013<br>FM1944 GLB2             | 3 (14<br>14) | 143<br>145<br>140 | 243<br>268<br>235         | 80<br>85<br>87 | 29                         | Undelinted seed     | <u>0.02</u>                                       | < 0.01                                         | 0.02                                 |
| Porterville CA USA<br>2013 Phytogen 499       | 3 (14<br>13) | 138<br>139<br>138 | 234<br>282<br>277         | 80<br>84<br>89 | 25<br>30                   | Undelinted seed     | 0.08<br><u>0.20</u>                               | 0.03<br>< 0.01                                 | 0.10<br>0.20                         |

All applications were made using ground-based equipment. The adjuvant INDUCE PH (0.1% v/v) was used in all applications.

<sup>a</sup> samples were collected by hand except for three trials, Uvalde, Hinton and Wall where cotton seed was harvested using stripper equipment. Prior to analysis, seed cotton was sent for processing (ginning) into the derived commodity of undelinted cotton seed; in the three trials using stripper cotton, cotton gin by-products (gin trash), were also generated.

<sup>b</sup> the trials were conducted at the same location and with final application within a 5 day interval. These trials are not considered independent for the purposes of estimating maximum residue limits.

<sup>c</sup> Uvalde 15 mm rain within 24 hours of the third spray

<sup>d</sup> Hinton 5 mm rain within 24 hours of spray two

Trifloxystrobin is considered a meso-systemic fungicide, that is residues penetrate the leaf surface but are not significantly translocated to other plant parts. Residues in cotton seed generally increased with increase in growth stage reflecting the increasing proportion of bolls open (BBCH 80 = 1<sup>st</sup> open bolls, BBCH 81 = about 10% bolls open, BBCH 82 = about 20% bolls open, BBCH 83 = about 30% bolls open, BBCH 89 = about 90% bolls open), and therefore seeds potentially exposed to contact with spray liquid (Figure 1).

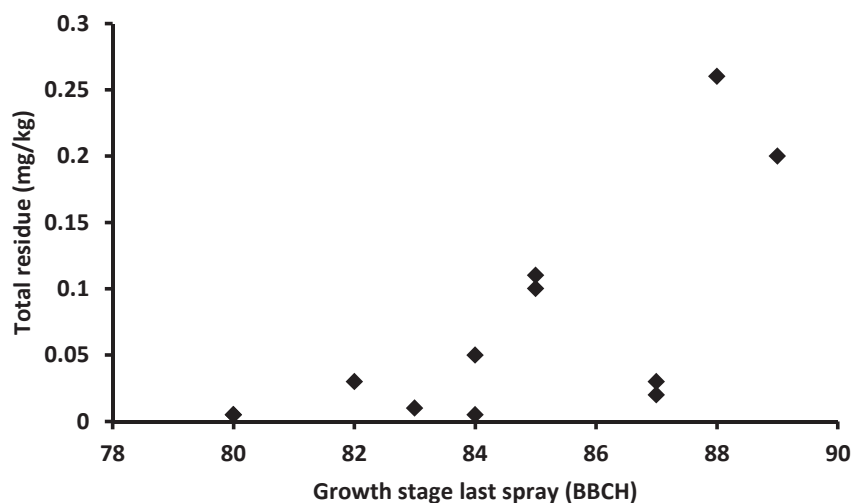


Figure 1 Residues in cotton seed versus BBCH growth stage for the timing of the last application

### Ginseng

Table 6 Residues of trifloxystrobin and CGA321113 (mg/kg, mean of nine replicates) in ginseng (Kyung 2014) following applications of trifloxystrobin in an SC-formulation

| Location, year, variety<br>GINSENG                     | N | Rate (g<br>ai/ha) | Spray<br>Concentration<br>(g ai/hL) | Spray<br>volume<br>(L/ha) | GS     | DALA | Trifloxystrobin<br>(mg/kg) | CGA321113<br>(mg/kg) | Total<br>(mg/kg) |
|--------------------------------------------------------|---|-------------------|-------------------------------------|---------------------------|--------|------|----------------------------|----------------------|------------------|
| Yeongju-si<br>Gyeongsangbuk-do,<br>Korea<br>2013 7/9   | 3 | 65                | 3.33                                | 1950                      | mature | 21   | < 0.06                     | < 0.03               | < 0.06           |
|                                                        |   | 67                | 3.35                                | 2000                      |        |      |                            |                      |                  |
|                                                        |   | 65                | 3.33                                | 1950                      |        |      |                            |                      |                  |
| 2014 26/8 same plot as<br>treated 2013 <sup>a</sup>    | 3 | 64                | 3.32                                | 1925                      | mature | 21   | < 0.03                     | < 0.03               | < 0.03           |
|                                                        |   | 67                | 3.35                                | 2000                      |        |      |                            |                      |                  |
|                                                        |   | 65                | 3.33                                | 1950                      |        |      |                            |                      |                  |
| 2014 26/8 new plot <sup>a</sup>                        | 3 | 64                | 3.32                                | 1925                      | mature | 21   | < 0.03                     | < 0.03               | < 0.03           |
|                                                        |   | 67                | 3.35                                | 2000                      |        |      |                            |                      |                  |
|                                                        |   | 65                | 3.33                                | 1950                      |        |      |                            |                      |                  |
| Geumsan-gun,<br>Chungcheongnam-do<br>Korea<br>2013 8/9 | 3 | 63                | 3.32                                | 1900                      | mature | 21   | < 0.06                     | < 0.03               | < 0.06           |
|                                                        |   | 65                | 3.33                                | 1950                      |        |      |                            |                      |                  |
|                                                        |   | 65                | 3.33                                | 1950                      |        |      |                            |                      |                  |
| 2014 27/8 same plot as<br>treated 2013 <sup>a</sup>    | 3 | 65                | 3.33                                | 1950                      | mature | 21   | < 0.03                     | < 0.03               | < 0.03           |
|                                                        |   | 67                | 3.35                                | 2000                      |        |      |                            |                      |                  |
|                                                        |   | 63                | 3.32                                | 1900                      |        |      |                            |                      |                  |
| 2014 different plot <sup>a</sup>                       | 3 | 65                | 3.33                                | 1950                      | mature | 21   | < 0.03                     | < 0.03               | < 0.03           |
|                                                        |   | 67                | 3.35                                | 2000                      |        |      |                            |                      |                  |
|                                                        |   | 63                | 3.32                                | 1900                      |        |      |                            |                      |                  |
| Jeungpyeong-gun,<br>Chungcheongbuk-do<br>Korea 2013    | 3 | 65                | 3.33                                | 1950                      | Mature | 21   | < 0.06                     | < 0.03               | < 0.06           |
|                                                        |   | 64                | 3.32                                | 1925                      |        |      |                            |                      |                  |
|                                                        |   | 67                | 3.35                                | 2000                      |        |      |                            |                      |                  |
| 2014 same plot as<br>treated 2013 <sup>a</sup>         | 3 | 65                | 3.33                                | 1950                      | mature | 21   | < 0.03                     | < 0.03               | < 0.03           |
|                                                        |   | 65                | 3.33                                | 1950                      |        |      |                            |                      |                  |
|                                                        |   | 67                | 3.35                                | 2000                      |        |      |                            |                      |                  |
| 2014 different plot <sup>a</sup>                       | 3 | 65                | 3.33                                | 1950                      | mature | 21   | < 0.03                     | < 0.03               | < 0.03           |
|                                                        |   | 65                | 3.33                                | 1950                      |        |      |                            |                      |                  |
|                                                        |   | 67                | 3.35                                | 2000                      |        |      |                            |                      |                  |

<sup>a</sup> There is no carry-over of residues from one year to the next. Trials conducted at the same location with the same treatment dates are not considered independent for the purposes of estimating maximum residue limits

**Animal feeds**

Table 7 Residues of trifloxystrobin and CGA321113 (mg/kg) in cotton gin by-products (Netzband and Jerkins 2015 M-524431-01-1) (mean of duplicate samples) following applications of trifloxystrobin in an SC-formulation

| Location, year, variety<br>Gin by-products    | N (int)   | Rate (g ai/ha) | Spray volume (L/ha) | GS | DALA | Sample     | Trifloxystrobin (mg/kg) | CGA321113 (mg/kg) | Total (mg/kg) |
|-----------------------------------------------|-----------|----------------|---------------------|----|------|------------|-------------------------|-------------------|---------------|
| Uvalde TX USA 2013 DPL 0912 B2RF <sup>a</sup> | 3 (14 14) | 139            | 112                 | 65 | 23   | Gin byp82  | 0.36                    | 0.12              | 0.48          |
|                                               |           | 140            | 113                 | 80 | 29   | 88         | 0.24                    | 0.09              | 0.33          |
|                                               |           | 139            | 112                 | 84 | 34   | 89%DM      | 0.23                    | 0.11              | 0.34          |
|                                               |           |                |                     |    | 38   | 82         | 0.20                    | 0.10              | 0.31          |
|                                               |           |                |                     |    | 44   | 87         | 0.18                    | 0.13              | 0.31          |
| Hinton USA 2013 FM1960 B2F <sup>b</sup>       | 3 (13 14) | 139            | 150                 | 73 | 26   | Gin byp 79 | 1.3                     | 0.06              | 1.4           |
|                                               |           | 140            | 186                 | 79 | 30   | 86         | 0.93 c0.04              | 0.06              | 1.0           |
|                                               |           | 140            | 194                 | 84 | 36   | 83%DM      | 0.76                    | 0.06              | 0.82          |
|                                               |           |                |                     |    | 40   | 85         | 0.93                    | 0.07              | 1.0           |
|                                               |           |                |                     |    | 43   | 87         | 0.67                    | 0.05              | 0.72          |
| Wall TX USA 2013 FM1944 GLB2                  | 3 (14 14) | 141            | 138                 | 77 | 27   | Gin byp    | 0.71 c0.02              | 0.18              | 0.89          |
|                                               |           | 139            | 132                 | 78 |      |            |                         |                   |               |
|                                               |           | 141            | 135                 | 87 |      |            |                         |                   |               |

<sup>a</sup> Uvalde 15 mm rain within 24 hours of the third spray

<sup>b</sup> Hinton 5 mm rain within 24 hours of spray two

**Fate of residues in processing****Broccoli**

The effect on residues of the household preparation steps washing and cooking of broccoli was made available to the meeting (Fischer and Harbin 2008 M-307503-01-1).

Washed: Broccoli head and stems were rinsed under a stream of tap water for 30 sec, excess water shaken off and the samples placed on paper towels to dry for 2 minutes.

Cooked: Washed broccoli was cooked in boiling water for 8 minutes, drained and cooled.

Table 8 Residues of trifloxystrobin and CGA321113 (mg/kg) in broccoli after processing (Fischer and Harbin 2008 M-307503-01-1) (mean of duplicate samples)

| Location, year, variety<br>BROCCOLI | N (int) | Rate (g ai/ha) | DALA | Sample       | Trifloxystrobin (mg/kg) | CGA321113 (mg/kg) | Total (mg/kg) | PFtri | PFtot |
|-------------------------------------|---------|----------------|------|--------------|-------------------------|-------------------|---------------|-------|-------|
| Sanger CA USA 2007 Marathon         | 2 (5)   | 141            | 0    | Heads+stalks | 0.41                    | 0.03              | 0.44          |       |       |
|                                     |         | 143            |      | washed       | 0.32                    | 0.03              | 0.35          | 0.78  | 0.80  |
|                                     |         |                |      | Cooked       | 0.36                    | 0.01              | 0.37          | 0.88  | 0.84  |

PFtri = processing factor for trifloxystrobin

PFtot = processing factor for the sum of trifloxystrobin and CGA321113

**Spinach**

The effect on residues of the household preparation steps washing and cooking of spinach was also investigated (Fischer and Harbin 2010 M-307507-02-1).

Washed: Spinach was washed by agitation in a sink of water for 30 seconds. The water was drained and the process repeated three times. After the last wash, excess water shaken off and the samples placed on paper towels to dry for 2 minutes.

Cooked: Washed spinach was cooked in boiling water for 2-3 minutes, drained and cooled.

Table 9 Residues of trifloxystrobin and CGA321113 (mg/kg) in spinach after processing (Fischer and Harbin 2010 M-307507-02-1) (mean of duplicate samples)

| Location, year, variety<br>SPINACH              | N<br>(int) | Rate (g ai/ha) | DALA | Sample | Trifloxystrobin<br>(mg/kg) | CGA321113<br>(mg/kg) | Total<br>(mg/kg) | PFtri | PFtot |
|-------------------------------------------------|------------|----------------|------|--------|----------------------------|----------------------|------------------|-------|-------|
| King City CA USA<br>2007<br>Interceptor/Avenger | 2 (5)      | 140<br>141     | 0    | Fresh  | 5.14                       | 0.04                 | 5.19             |       |       |
|                                                 |            |                |      | Washed | 5.22                       | 0.04                 | 5.26             | 1.0   | 1.0   |
|                                                 |            |                |      | Cooked | 1.83                       | 0.02                 | 1.85             | 0.36  | 0.36  |

PFtri = processing factor for trifloxystrobin

PFtot = processing factor for the sum of trifloxystrobin and CGA321113

### Cotton

A study of the effect of processing cottonseed to oil on residues was made available to the meeting (Veal 2015 M-524279-01-1). Three applications of an SC formulation of trifloxystrobin were made to cotton at an application rate of approximately 700 g ai/ha with harvest about 30 days after the last application.

Undelinted seed was processed into hulls, cottonseed meal, and refined oil. Samples were processed to simulate commercial practice as closely as possible. Prior to ginning, the seed cotton was cleaned with an attached stick extractor to remove gin trash (gin by-products). Seed was saw-ginned to remove most of the lint (ginned cottonseed = undelinted cottonseed). With approximately 11–15% remaining lint, the undelinted cottonseed was saw delinted to produce delinted cottonseed (ca. 3% lint remaining). The delinted seed was mechanically cracked on a roller mill followed by screening to separate the hulls from the kernel. The kernel material was adjusted to 13.5% moisture and processed into meal and crude oil by heating kernels to 79–91 °C for 28–32 minutes, after which the kernel material was flaked (roll gap 0.02–0.03 cm) and the flaked material fed into a continuous processor (extruder). As material moved through the extruder, steam was injected directly on the product. The maximum temperature of the exiting collets was 93–121 °C. Collets were dried in an oven at 66–82 °C for 30–40 minutes and then solvent extracted in batches (hexane 49–60 °C). After 30 minutes the hexane was drained, fresh hexane added and the extraction process repeated, three times in total. After final draining, the spent collets (meal) were heated to 99–104 °C in a steam heated paddle mixer to remove residual hexane and toasted in an electric cooker and the moisture adjusted to 15% and screened. The miscella (crude oil + hexane) was passed through a vacuum evaporator (91–96 °C) to remove the hexane and filtered prior to refining. The crude oil was heated to 70–76 °C, water added (to 3% weight of oil), stirred for 30–60 min and centrifuged to remove gums. The de-gummed oil was treated with 85% phosphoric acid equal to 0.03% the weight of oil and stirred for 29–31 minutes at 40–44 °C, centrifuged and filtered to remove slime. The resulting pre-clarified oil was mixed with NaOH at 20–24 °C for 15 minutes, the temperature increased to 63–67 °C for a further 12 minutes. The neutralised oil was centrifuged to remove the solids (soapstock) and the refined oil decanted and vacuum filtered. Refined oil was heated to 40–50 °C and activated bleaching earth added (1% by weight), the temperature increased to 85–100 °C and held at this temperature for 10–15 minutes, cooled and filtered to produce bleached oil. The bleached oil was held at 220–230 °C under vacuum for 28–32 minutes. After this period the oil was cooled during which time 0.5% citric acid was added and the resulting refined bleached deodorised oil collected (=oil, refined).

The processing factors range from 0.02 to 0.17, indicating that no concentration occurred in processed fractions.



Table 10 Residues of trifloxystrobin and CGA321113 (mg/kg) in cotton seed processed commodities (means of three individual analyses) (Veal 2015 M-524279-01-1)

| Location, year, variety<br>COTTON SEED                          | N | Rate (g<br>ai/ha) | DALA | Sample                     | Trifloxystrobin<br>(mg/kg) | CGA321113<br>(mg/kg) <sup>a</sup> | Total<br>(mg/kg) | PFtri   | PFtot   |
|-----------------------------------------------------------------|---|-------------------|------|----------------------------|----------------------------|-----------------------------------|------------------|---------|---------|
| Cheneyville LA USA<br>2013 Phytogen<br>499 WRF<br>72.7 kg batch | 3 | 730<br>711<br>728 | 29   | Undelinted<br>seed         | 0.178                      | 0.021                             | 0.181            |         |         |
|                                                                 |   |                   |      | Meal                       | < 0.01                     | < 0.01                            | < 0.01           | < 0.06  | < 0.05  |
|                                                                 |   |                   |      | Hulls                      | 0.020                      | 0.013                             | 0.033            | 0.11    | 0.17    |
|                                                                 |   |                   |      | Crude oil,<br>preclarified | 0.014                      | < 0.01                            | 0.014            | 0.08    | 0.12    |
|                                                                 |   |                   |      | Oil, solvent<br>extracted  | 0.014                      | < 0.01                            | 0.014            | 0.08    | 0.12    |
|                                                                 |   |                   |      | Crude oil,<br>neutralised  | < 0.01                     | < 0.01                            | < 0.01           | < 0.06  | < 0.05  |
|                                                                 |   |                   |      | Oil, refined               | < 0.01                     | < 0.01                            | < 0.01           | < 0.06  | < 0.05  |
| Levelland TX USA<br>2013 DP0912 B2RF<br>80.5 kg batch           | 3 | 716<br>699<br>703 | 28   | Undelinted<br>seed         | 3.122                      | < 0.01                            | 3.122            |         |         |
|                                                                 |   |                   |      | Meal                       | < 0.01                     | < 0.01                            | < 0.01           | < 0.003 | < 0.003 |
|                                                                 |   |                   |      | Hulls                      | 0.159                      | < 0.01                            | 0.159            | 0.05    | 0.05    |
|                                                                 |   |                   |      | Crude oil,<br>preclarified | 0.135                      | < 0.01                            | 0.135            | 0.04    | 0.04    |
|                                                                 |   |                   |      | Oil, solvent<br>extracted  | 0.131                      | < 0.01                            | 0.131            | 0.04    | 0.04    |
|                                                                 |   |                   |      | Crude oil,<br>neutralised  | 0.116                      | < 0.01                            | 0.116            | 0.04    | 0.04    |
|                                                                 |   |                   |      | Oil, refined               | 0.060                      | < 0.01                            | 0.060            | 0.02    | 0.02    |

<sup>a</sup> CGA321113 determined as CGA321113 and calculated as trifloxystrobin

PFtri = processing factor for trifloxystrobin

PFtot = processing factor for the sum of trifloxystrobin and CGA321113

### Ginseng

The residue trials on ginseng also contained information on processing (Kyung 2014). Processed products were processed by four different methods (dried ginseng, red ginseng, water extracts of dried ginseng and water extracts of red ginseng). Samples of processed ginseng products were transferred into polyethylene bags and stored at -20 °C until analysis.

Fresh ginseng were harvested and washed with tap water to remove soil particle from the roots. The washed fresh ginseng were blended, packed individually in polyethylene bags and stored at -20 °C until analysis.

Dried ginseng: Fresh washed ginseng were dried in a hot air drying machine set to 60 °C to water content < 14%. The dried ginseng were blended, packed individually in polyethylene bags and stored at -20 °C until analysis.

Red ginseng: Fresh washed ginseng were washed and steamed for 3 hours at 98 °C. The steamed ginsengs were dried in hot air drying machine set to 65 °C to reach a water content of about 50~55%. Small roots were removed and further drying processes were carried out under sunlight to reach a final water content < 14%. The dried ginsengs were blended, packed individually in polyethylene bags and stored at -20 °C until analysis.

Water extracts of dried ginseng and water extracts of red ginseng: Dried ginseng or red ginseng was cut into about 1 cm in size and extracted three times in refluxing extractor with water at 85 °C for about 18 hours. The extracts were evaporated with a vacuum rotary evaporator to reach the 72° Brix. The extracts were packed in polyethylene bottles individually and stored at -20 °C until analysis.

No residues were detected in fresh ginseng or in ginseng processed products. It was not possible to derive processing factors for ginseng.

In summary, trifloxystrobin did not concentrate in any of the processed commodities considered by the current meeting (Table 10).

Table 10 Summary of trifloxystrobin processing factors

| Commodity   | Processing fraction | PFtri          | PFtot          |
|-------------|---------------------|----------------|----------------|
| Broccoli    | Washed broccoli     | 0.78           | 0.80           |
|             | Cooked broccoli     | 0.88           | 0.84           |
| Spinach     | Washed spinach      | 1.0            | 1.0            |
|             | Cooked spinach      | 0.36           | 0.36           |
| Cotton seed | Meal                | < 0.003 < 0.06 | < 0.003 < 0.05 |
|             | Hulls               | 0.05 0.11      | 0.05 0.17      |
|             | Crude oil           | 0.04 < 0.06    | 0.04 < 0.05    |
|             | Refined oil         | 0.02 < 0.06    | 0.02 < 0.05    |

PFtri = processing factor for trifloxystrobin

PFtot = processing factor for the sum of trifloxystrobin and CGA321113

## APPRAISAL

Trifloxystrobin was first evaluated for toxicology and residues by the JMPR in 2004. The Meeting derived an ADI of 0–0.04 mg/kg bw, decided that an ARfD is unnecessary and concluded that the residue definition for plant commodities for compliance with MRL values was trifloxystrobin. For animal commodities for compliance with MRL values as well as for dietary risk assessment for both plant and animal commodities, the residue definition was the sum of trifloxystrobin and (*E,E*)-methoxyimino- $\{2-[1-(3\text{-trifluoromethyl-phenyl})\text{ ethylidene-aminooxymethyl}]\text{-phenyl}\}$ acetic acid = CGA321113) (expressed as trifloxystrobin equivalents). The residue is fat soluble.

Trifloxystrobin was scheduled at the 48<sup>th</sup> session of the CCPR for the evaluation of additional MRLs for head cabbage, cauliflower, broccoli, spinach, cotton and ginseng by the 2017 JMPR.

### Methods of analysis

The method used for the analysis of head cabbage, cauliflower, broccoli, spinach and cotton samples was method 200177 which was evaluated by the 2004 and 2015 JMPR. The Meeting received summarized information on an analytical method for trifloxystrobin and CGA321113 residues in ginseng. Mean recoveries were within the range 70–120% for all commodities investigated and supported LOQs of 0.03 mg/kg (2014 trials) to 0.06 mg/kg (2013 trials) for ginseng and 0.07 mg/kg for ginseng processed commodities. The method is suitable for the analysis of residues in ginseng and ginseng processed commodities.

### Stability of residues in stored analytical samples

The stability of residues in samples on frozen storage was evaluated by the 2004 JMPR for a range of commodities. Residues of trifloxystrobin and CGA321113 were stable under freezer storage conditions for at least 24 months in the case of grapefruit, cucumber, potato and wheat commodities (grain, straw and whole plant) or 18 months for apple (fruit, wet pomace), peanut (nutmeat, oil) and grape juice. The stability data covered commodities that are representative of high water content (apple, cucumber, grape juice), high acid content (grapefruit), high oil content (peanut) and high protein/starch content (potato, wheat) and can be extrapolated to the commodities considered at the current Meeting. Samples in the trials considered by the current Meeting were stored frozen for periods less than the period of stability demonstrated in studies supplied to the 2004 JMPR and are therefore considered unlikely to have been adversely affected by storage.

**Results of supervised residue trials on crops**

The Meeting received information on supervised field trials on brassicas (broccoli, cauliflower and cabbage), spinach, cotton and ginseng.

The sum of trifloxystrobin and CGA321113 was calculated and expressed as trifloxystrobin on the basis of the relative molecular masses. A conversion factor of 1.036 is required to express CGA321113 as trifloxystrobin. As CGA321113 does not generally constitute a significant proportion of the residue in crops, when the levels of trifloxystrobin or CGA321113 were below the LOQ, their sum was calculated as in the examples provided by the 2004 JMPR and copied below.

| Trifloxystrobin (mg/kg) | CGA321113 (mg/kg) | Total (expressed as trifloxystrobin) (mg/kg) |
|-------------------------|-------------------|----------------------------------------------|
| < 0.02                  | < 0.02            | < 0.02                                       |
| < 0.02                  | 0.03              | 0.05                                         |
| 0.10                    | < 0.02            | 0.10                                         |
| 0.92                    | 0.16              | 1.1                                          |

**Brassicas**

The critical GAP in the USA for brassica, head and stem vegetables is for two to three applications at a maximum rate of 139 g ai/ha, at 7–14 day intervals and a PHI of 0 days with a maximum seasonal rate of 281 g ai/ha/yr.

Three trials in broccoli (trifloxystrobin: 0.44, 0.67, 0.68 mg/kg) three trials in cauliflower (< 0.01, 0.01, 0.32 mg/kg) and six trials in head cabbage (with wrapper leaves) (0.03, 0.11, 0.37, 0.47, 0.48, 0.58 mg/kg) matched cGAP in the USA.

Corresponding total residues were:

Broccoli (0.46, 0.67, 0.70 mg/kg)

Cauliflower (< 0.01, 0.01, 0.36 mg/kg)

Head cabbage (without wrapper leaves) (< 0.01, < 0.01, 0.01, 0.01, 0.01, 0.03 mg/kg)

The number of trials on broccoli and cauliflower are too few to estimate a maximum residue level for these crops. The Meeting explored the possibility of estimating a group maximum residue level for subgroup 010A, flowerhead brassicas based on the combined dataset however, the residue data for broccoli and cauliflower were from two different populations and could not be combined. The Meeting concluded there is insufficient data to estimate a new maximum residue levels for both broccoli and cauliflower.

For cabbages, utilising the residues from trials (n=6) approximating cGAP ( $139 \pm 25\%$  g ai/ha) in the USA, the Meeting recommended a maximum residue level of 1.5 mg/kg, and an STMR of 0.01 mg/kg for head cabbage to replace the previous recommendation of 0.5 mg/kg.

**Spinach**

In the USA the critical GAP for leafy greens is for two applications at a maximum rate of 139 g ai/ha, at an interval of 14 days with a PHI of 0 days.

Six trials in spinach approximated critical GAP ( $139 \pm 25\%$  g ai/ha) with trifloxystrobin residues (n=6): 4.8, 5.3, 7.6, 7.6, 9.5 and 10 mg/kg.

The Meeting estimated a maximum residue level of 20 mg/kg for spinach.

Corresponding total residues were: 4.8, 5.4, 7.6, 7.6, 9.6 and 10 mg/kg. The Meeting estimated an STMR of 7.6 mg/kg for spinach.

**Cotton seed**

The critical GAP for cotton is for 3 applications at a maximum rate of 137 g ai/ha, at 14 day intervals and a PHI of 30 days.

In eleven trials approximating critical GAP ( $137 \pm 25\%$  g ai/ha) residues of trifloxystrobin were (n=11): < 0.01, < 0.01, < 0.01, 0.02, 0.03, 0.03, 0.08, 0.10, 0.11, 0.20 and 0.26 mg/kg.

The Meeting estimated a maximum residue level of 0.4 mg/kg for cottonseed.

Residues of CGA311123 were all < 0.01 mg/kg and did not contribute to the total residue. The Meeting estimated an STMR of 0.03 mg/kg.

### *Ginseng*

The critical GAP for ginseng in the Republic of Korea is for 3 applications at a maximum rate of 3.35 g ai/hL, at 10 day intervals and a PHI of 21 days.

In six trials from the Republic of Korea approximating critical GAP ( $3.35 \pm 25\%$  g ai/hL) residues were (n=6): < 0.03 < 0.03 < 0.03, < 0.06, < 0.06, < 0.06 mg/kg.

The Meeting estimated a maximum residue level of 0.03\* mg/kg and STMR of 0.03 mg/kg for ginseng.

### *Animal feedstuffs*

#### *Cotton gin by-products*

The critical GAP for cotton is for 3 applications at a maximum rate of 137 g ai/ha, at 14 day intervals and a PHI of 30 days. In three trials approximating critical GAP residues of trifloxystrobin were (n=3): 0.24, 0.71, 0.93 mg/kg. The Meeting estimated a median residue for cotton gin by-products of 0.71 mg/kg and a highest residue of 0.93 mg/kg.

### *Fate of residues in processing*

No residues were detected in fresh ginseng or in ginseng processed products. Residues in processed ginseng products will be covered by the maximum residue level recommended for fresh ginseng.

Trifloxystrobin did not concentrate in any of the other processed commodities considered by the current meeting.

#### Summary of trifloxystrobin processing factors

| Commodity   | Processing fraction | PF <sub>tri</sub> | PF <sub>tot</sub> (best estimate) | STMR <sub>RAC tot</sub> | STMR-P<br>= STMR <sub>RAC tot</sub> × PF <sub>tot</sub> |
|-------------|---------------------|-------------------|-----------------------------------|-------------------------|---------------------------------------------------------|
| Broccoli    | Washed broccoli     | 0.78              | 0.80                              | 0.03                    |                                                         |
|             | Cooked broccoli     | 0.88              | 0.84                              |                         |                                                         |
| Spinach     | Washed spinach      | 1.0               | 1.0                               |                         |                                                         |
|             | Cooked spinach      | 0.36              | 0.36                              |                         |                                                         |
| Cotton seed | Meal                | < 0.003 < 0.06    | < 0.003 < 0.05 (0.003)            |                         | 0.00009                                                 |
|             | Hulls               | 0.05 0.11         | 0.05 0.17 (0.11)                  |                         | 0.0033                                                  |
|             | Crude oil           | 0.04 < 0.06       | 0.04 < 0.05 (0.04)                |                         | 0.0012                                                  |
|             | Refined oil         | 0.02 < 0.06       | 0.02 < 0.05 (0.02)                |                         | 0.0006                                                  |

PF<sub>tri</sub> = processing factor for trifloxystrobin

PF<sub>tot</sub> = processing factor for the sum of trifloxystrobin and CGA321113

### *Residues in animal commodities*

#### *Estimation of livestock dietary burdens*

The only commodity used as a livestock feed and for which the JMPR has made recommendations are cabbage with wrapper leaves and cotton gin by-products (gin trash). The additional contribution to the dietary burden using the estimated median and highest residue levels is less than 10% of the total. Based on the minor change in livestock dietary burden, the Meeting did not recalculate residues in animal commodities or revise its recommendations for maximum residue levels.

## RECOMMENDATIONS

On the basis of the data obtained from supervised residue trials the Meeting concluded that the residue levels listed below are suitable for establishing maximum residue limits and for IEDI assessment.

### *Residue in plant commodities*

for compliance with MRLs: *trifloxystrobin*

for estimation of dietary exposure: *sum of trifloxystrobin and [(E,E)-methoxyimino-{2-[1-(3-trifluoromethylphenyl)ethylideneaminooxymethyl]phenyl}acetic acid] (CGA 321113), expressed as trifloxystrobin.*

### *Residue in animal commodities*

For compliance with MRLs and estimation of dietary exposure: *sum of trifloxystrobin and [(E,E)-methoxyimino-{2-[1-(3-trifluoromethylphenyl)ethylideneaminooxymethyl]phenyl}acetic acid] (CGA 321113), expressed as trifloxystrobin.*

*The residue is fat soluble.*

Table of recommendations

| Commodity |                | Recommended MRL (mg/kg) |          | STMR or STMR-P (mg/kg) | HR, HR-P, highest residue (mg/kg) |
|-----------|----------------|-------------------------|----------|------------------------|-----------------------------------|
| CCN       | Name           | New                     | Previous |                        |                                   |
| VB 0041   | Cabbages, Head | 1.5                     | 0.5      | 0.01                   |                                   |
| SO 0691   | Cotton seed    | 0.4                     |          | 0.03                   |                                   |
| VR 0604   | Ginseng        | 0.03*                   |          | 0.03                   |                                   |
| VL 0502   | Spinach        | 20                      |          | 7.6                    |                                   |

Table of additional STMR/median and HR/highest residue values for use in dietary intake and livestock dietary burden estimation.

| Commodity |                                 | Recommended MRL (mg/kg) |          | STMR or STMR-P, median residue (mg/kg) | HR, HR-P, highest residue (mg/kg) |
|-----------|---------------------------------|-------------------------|----------|----------------------------------------|-----------------------------------|
| CCN       | Name                            | New                     | Previous |                                        |                                   |
|           | Cotton seed meal                |                         |          | 0.00009                                |                                   |
|           | Cotton seed hulls               |                         |          | 0.0033                                 |                                   |
| OR 0691   | Cotton seed refined oil, edible |                         |          | 0.0006                                 |                                   |
|           | Cotton gin by-products          |                         |          | 0.71                                   | 0.93                              |

## DIETARY RISK ASSESSMENT

### *Long-term dietary exposure*

The International Estimated Daily Intakes (IEDIs) of trifloxystrobin were calculated for the 17 GEMS/Food cluster diets using STMRs and STMR-Ps estimated by the JMPR in 2004, 2015 and current meeting. The results are shown in Annex 3 to the 2017 Report.

The ADI is 0–0.04 mg/kg bw and the calculated IEDIs were 1–7% of the maximum ADI. The Meeting concluded that the long-term dietary exposure to residues of trifloxystrobin from the uses considered by the JMPR is unlikely to present a public health concern.

### *Short-term dietary exposure*

The 2004 JMPR decided that an ARfD for trifloxystrobin was unnecessary. The Meeting therefore concluded that the short-term dietary exposure to residues of trifloxystrobin resulting from uses that have been considered by the JMPR is unlikely to present a public health concern.

## REFERENCES

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### 5.37 TRIFLOXYSTROBIN (213)

#### RESIDUE AND ANALYTICAL ASPECTS

Trifloxystrobin was first evaluated for toxicology and residues by the JMPR in 2004. The Meeting derived an ADI of 0–0.04 mg/kg bw, decided that an ARfD is unnecessary and concluded that the residue definition for plant commodities for compliance with MRL values was trifloxystrobin. For animal commodities for compliance with MRL values as well as for dietary risk assessment for both plant and animal commodities, the residue definition was the sum of trifloxystrobin and (*E,E*)-methoxyimino- $\{2-[1-(3\text{-trifluoromethyl-phenyl})\text{ ethylidene-aminooxymethyl}]\text{-phenyl}\}$ acetic acid = CGA321113) (expressed as trifloxystrobin equivalents). The residue is fat soluble.

Trifloxystrobin was scheduled at the 48<sup>th</sup> session of the CCPR for the evaluation of additional MRLs for head cabbage, cauliflower, broccoli, spinach, cotton and ginseng by the 2017 JMPR.

#### *Methods of analysis*

The method used for the analysis of head cabbage, cauliflower, broccoli, spinach and cotton samples was method 200177 which was evaluated by the 2004 and 2015 JMPR. The Meeting received summarized information on an analytical method for trifloxystrobin and CGA321113 residues in ginseng. Mean recoveries were within the range 70–120% for all commodities investigated and supported LOQs of 0.03 mg/kg (2014 trials) to 0.06 mg/kg (2013 trials) for ginseng and 0.07 mg/kg for ginseng processed commodities. The method is suitable for the analysis of residues in ginseng and ginseng processed commodities.

#### *Stability of residues in stored analytical samples*

The stability of residues in samples on frozen storage was evaluated by the 2004 JMPR for a range of commodities. Residues of trifloxystrobin and CGA321113 were stable under freezer storage conditions for at least 24 months in the case of grapefruit, cucumber, potato and wheat commodities (grain, straw and whole plant) or 18 months for apple (fruit, wet pomace), peanut (nutmeat, oil) and grape juice. The stability data covered commodities that are representative of high water content (apple, cucumber, grape juice), high acid content (grapefruit), high oil content (peanut) and high protein/starch content (potato, wheat) and can be extrapolated to the commodities considered at the current Meeting. Samples in the trials considered by the current Meeting were stored frozen for periods less than the period of stability demonstrated in studies supplied to the 2004 JMPR and are therefore considered unlikely to have been adversely affected by storage.

#### *Results of supervised residue trials on crops*

The Meeting received information on supervised field trials on brassicas (broccoli, cauliflower and cabbage), spinach, cotton and ginseng.

The sum of trifloxystrobin and CGA321113 was calculated and expressed as trifloxystrobin on the basis of the relative molecular masses. A conversion factor of 1.036 is required to express CGA321113 as trifloxystrobin. As CGA321113 does not generally constitute a significant proportion of the residue in crops, when the levels of trifloxystrobin or CGA321113 were below the LOQ, their sum was calculated as in the examples provided by the 2004 JMPR and copied below.

| Trifloxystrobin (mg/kg) | CGA321113 (mg/kg) | Total (expressed as trifloxystrobin) (mg/kg) |
|-------------------------|-------------------|----------------------------------------------|
| < 0.02                  | < 0.02            | < 0.02                                       |
| < 0.02                  | 0.03              | 0.05                                         |
| 0.10                    | < 0.02            | 0.10                                         |
| 0.92                    | 0.16              | 1.1                                          |



*Brassicas*

The critical GAP in the USA for brassica, head and stem vegetables is for two to three applications at a maximum rate of 139 g ai/ha, at 7-14 day intervals and a PHI of 0 days with a maximum seasonal rate of 281 g ai/ha/yr.

Three trials in broccoli (trifloxystrobin: 0.44, 0.67, 0.68 mg/kg) three trials in cauliflower (< 0.01, 0.01, 0.32 mg/kg) and six trials in head cabbage (with wrapper leaves) (0.03, 0.11, 0.37, 0.47, 0.48, 0.58 mg/kg) matched cGAP in the USA.

Corresponding total residues were:

Broccoli (0.46, 0.67, 0.70 mg/kg)

Cauliflower (< 0.01, 0.01, 0.36 mg/kg)

Head cabbage (without wrapper leaves) (< 0.01, < 0.01, 0.01, 0.01, 0.01, 0.03 mg/kg)

The number of trials on broccoli and cauliflower are too few to estimate a maximum residue level for these crops. The Meeting explored the possibility of estimating a group maximum residue level for subgroup 010A, flowerhead brassicas based on the combined dataset however, the residue data for broccoli and cauliflower were from two different populations and could not be combined. The Meeting concluded there is insufficient data to estimate a new maximum residue levels for both broccoli and cauliflower.

For cabbages, utilising the residues from trials (n=6) approximating cGAP (139±25% g ai/ha) in the USA, the Meeting recommended a maximum residue level of 1.5 mg/kg, and an STMR of 0.01 mg/kg for head cabbage to replace the previous recommendation of 0.5 mg/kg.

*Spinach*

In the USA the critical GAP for leafy greens is for two applications at a maximum rate of 139 g ai/ha, at an interval of 14 days with a PHI of 0 days.

Six trials in spinach approximated critical GAP (139±25% g ai/ha) with trifloxystrobin residues (n=6): 4.8, 5.3, 7.6, 7.6, 9.5 and 10 mg/kg.

The Meeting estimated a maximum residue level of 20 mg/kg for spinach.

Corresponding total residues were: 4.8, 5.4, 7.6, 7.6, 9.6 and 10 mg/kg. The Meeting estimated an STMR of 7.6 mg/kg for spinach.

*Cotton seed*

The critical GAP for cotton is for 3 applications at a maximum rate of 137 g ai/ha, at 14 day intervals and a PHI of 30 days.

In eleven trials approximating critical GAP (137±25% g ai/ha) residues of trifloxystrobin were (n=11): < 0.01, < 0.01, < 0.01, 0.02, 0.03, 0.03, 0.08, 0.10, 0.11, 0.20 and 0.26 mg/kg.

The Meeting estimated a maximum residue level of 0.4 mg/kg for cottonseed.

Residues of CGA311123 were all < 0.01 mg/kg and did not contribute to the total residue. The Meeting estimated an STMR of 0.03 mg/kg.

*Ginseng*

The critical GAP for ginseng in the Republic of Korea is for 3 applications at a maximum rate of 3.35 g ai/hL, at 10 day intervals and a PHI of 21 days.

In six trials from the Republic of Korea approximating critical GAP (3.35±25% g ai/hL) residues were (n=6): < 0.03 < 0.03 < 0.03, < 0.06, < 0.06, < 0.06 mg/kg.

The Meeting estimated a maximum residue level of 0.03\* mg/kg and STMR of 0.03 mg/kg for ginseng.

## Animal feedstuffs

### Cotton gin by-products

The critical GAP for cotton is for 3 applications at a maximum rate of 137 g ai/ha, at 14 day intervals and a PHI of 30 days. In three trials approximating critical GAP residues of trifloxystrobin were (n=3): 0.24, 0.71, 0.93 mg/kg. The Meeting estimated a median residue for cotton gin by-products of 0.71 mg/kg and a highest residue of 0.93 mg/kg.

### Fate of residues in processing

No residues were detected in fresh ginseng or in ginseng processed products. Residues in processed ginseng products will be covered by the maximum residue level recommended for fresh ginseng.

Trifloxystrobin did not concentrate in any of the other processed commodities considered by the current meeting.

### Summary of trifloxystrobin processing factors

| Commodity   | Processing fraction | PF <sub>tri</sub> | PF <sub>tot</sub> (best estimate) | STMR <sub>RAC tot</sub> | STMR-P<br>= STMR <sub>RAC tot</sub> × PF <sub>tot</sub> |
|-------------|---------------------|-------------------|-----------------------------------|-------------------------|---------------------------------------------------------|
| Broccoli    | Washed broccoli     | 0.78              | 0.80                              |                         |                                                         |
|             | Cooked broccoli     | 0.88              | 0.84                              |                         |                                                         |
| Spinach     | Washed spinach      | 1.0               | 1.0                               |                         |                                                         |
|             | Cooked spinach      | 0.36              | 0.36                              |                         |                                                         |
| Cotton seed | Meal                | < 0.003 < 0.06    | < 0.003 < 0.05 (0.003)            | 0.03                    | 0.00009                                                 |
|             | Hulls               | 0.05 0.11         | 0.05 0.17 (0.11)                  |                         | 0.0033                                                  |
|             | Crude oil           | 0.04 < 0.06       | 0.04 < 0.05 (0.04)                |                         | 0.0012                                                  |
|             | Refined oil         | 0.02 < 0.06       | 0.02 < 0.05 (0.02)                |                         | 0.0006                                                  |

PF<sub>tri</sub> = processing factor for trifloxystrobin

PF<sub>tot</sub> = processing factor for the sum of trifloxystrobin and CGA321113

## Residues in animal commodities

### Estimation of livestock dietary burdens

The only commodity used as a livestock feed and for which the JMPR has made recommendations are cabbage with wrapper leaves and cotton gin by-products (gin trash). The additional contribution to the dietary burden using the estimated median and highest residue levels is less than 10% of the total. Based on the minor change in livestock dietary burden, the Meeting did not recalculate residues in animal commodities or revise its recommendations for maximum residue levels.

## RECOMMENDATIONS

On the basis of the data obtained from supervised residue trials the Meeting concluded that the residue levels listed in Annex 1 are suitable for establishing maximum residue limits and for IEDI assessment.

### Residue in plant commodities

for compliance with MRLs: *trifloxystrobin*

for estimation of dietary exposure: *sum of trifloxystrobin and [(E,E)-methoxyimino-{2-[1-(3-trifluoromethylphenyl)ethylideneaminoxymethyl]phenyl}acetic acid] (CGA 321113), expressed as trifloxystrobin.*

### Residue in animal commodities

For compliance with MRLs and estimation of dietary exposure:

sum of trifloxystrobin and [(E,E)-methoxyimino-{2-[1-(3-trifluoromethylphenyl)ethylideneaminoxymethyl]phenyl}acetic acid] (CGA 321113), expressed as trifloxystrobin.

*The residue is fat soluble.*

## DIETARY RISK ASSESSMENT

### ***Long-term dietary exposure***

The International Estimated Daily Intakes (IEDIs) of trifloxystrobin were calculated for the 17 GEMS/Food cluster diets using STMRS and STMR-Ps estimated by the JMPR in 2004, 2015 and current meeting. The results are shown in Annex 3.

The ADI is 0–0.04 mg/kg bw and the calculated IEDIs were 1–7% of the maximum ADI. The Meeting concluded that the long-term dietary exposure to residues of trifloxystrobin from the uses considered by the JMPR is unlikely to present a public health concern

### ***Short-term dietary exposure***

The 2004 JMPR decided that an ARfD for trifloxystrobin was unnecessary. The Meeting therefore concluded that the short-term dietary exposure to residues of trifloxystrobin resulting from uses that have been considered by the JMPR is unlikely to present a public health concern.