EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Food and feed safety, innovation
Pesticides and biocides

Trifloxystrobin

SANTE/10107/2018
25 May 2018

Final Renewal report for the active substance trifloxystrobin
finalised in the Standing Committee on Plants, Animals, Food and Feed
at its meeting on 25 May 2018
in view of the renewal of the approval of trifloxystrobin as active substance
in accordance with Regulation (EC) No 1107/2009[1]

1. Procedure followed for the re-evaluation process

This renewal report has been established as a result of the evaluation of trifloxystrobin, in accordance with Regulation (EC) No 1107/2009[2] and Commission Implementing Regulation (EU) No 844/2012[3] following the submission of an application to renew the approval of this active substance expiring in July 2018.

Trifloxystrobin is a substance that was included in Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market, by Commission Directive 2003/68/EC[4]. Trifloxystrobin is deemed to have been approved under Regulation (EC) No 1107/2009 and is listed in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011[5].

An application for renewal of the approval of trifloxystrobin was submitted by Bayer CropScience AG in accordance with Article 1 of Regulation (EU) No 844/2012.

Commission Implementing Regulation (EU) 2017/841[6] extended until 31 July 2018 the period of approval of trifloxystrobin to allow the completion of its review.

Commission Implementing Regulation (EU) No 686/2012[7] designated the rapporteur Member State and the co-rapporteur Member State which had to submit the relevant renewal assessment reports and recommendations to the European Food Safety Authority (EFSA).

For trifloxystrobin the rapporteur Member State was United Kingdom and the co-rapporteur Member State was Greece.

1 Renewal Report established in accordance with Art. 14 of Regulation (EU) No 844/2012; does not necessarily represent the views of the European Commission.
2 OJ L 309, 24.11.2009, p. 1.
3 OJ L 252, 19.9.2012, p. 26.
4 OJ L 177, 16.7.2003, p. 12.
5 OJ L 16, 20.1.2018, p. 8.
6 OJ L 125, 18.5.2017, p. 12.
7 OJ L 200, 27.7.2012, p. 5.

The United Kingdom finalised in September 2016 its examination, in the form of a renewal assessment report. This Report was sent to the Commission and the European Food Safety Authority on 29 September 2016 and included a recommendation concerning the decision to be taken with regard to the renewal of the approval of trifloxystrobin for the supported uses.

In accordance with Article 13 of Implementing Regulation (EU) No 844/2012, the EFSA organised an intensive consultation of technical experts from Member States, to review the renewal assessment report and the comments received thereon (peer review).

The EFSA sent to the Commission its conclusion on the risk assessment (Conclusions regarding the peer review of the pesticide risk assessment of the active substance)[8] on 19 September 2017.

This conclusion refers to background document A (final revised version of the renewal assessment report) and background document B (EFSA peer review report).

According to the provisions of Article 14 of Implementing Regulation (EU) No 844/2012, the Commission referred a draft renewal report on the renewal of approval to the Standing Committee on Plants, Animals, Food and Feed, for examination on 22 March 2018. The draft renewal report was finalized in the meeting of the Standing Committee on 25 May 2018.

The present renewal report contains the conclusions of the final examination by the Standing Committee. Given the importance of the conclusion of the EFSA, and the comments and clarifications submitted after the conclusion of the EFSA, these documents are also considered to be part of this renewal report.

2. Purposes of this renewal report

This renewal report, including the background documents and appendices hereto, has been developed and finalised in support of **Commission Implementing Regulation (EU) 2018/1060**[9] concerning the renewal of approval of trifloxystrobin as active substance under Regulation (EC) No 1107/2009, and to assist the Member States in decisions on individual plant protection products containing trifloxystrobin they have to take in accordance with the provisions of that Regulation, and in particular the provisions of Article 29(1) of Regulation (EC) No 1107/2009 and the uniform principles laid down in Regulation (EU) No 546/2011[10].

This renewal report provides also for the evaluation required under part I, Section A.2(b) of the above mentioned uniform principles, as well as under several specific sections of chapter B of these principles. In these sections it is provided that Member States, in evaluating applications and granting authorisations, shall take into account the information concerning the requirements of Regulation (EU) No 283/2013[11], submitted for the purpose of renewal of approval of the active substances, as well as the result of the evaluation of those data.

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8 EFSA (European Food Safety Authority), 2017. Conclusion on the peer review of the pesticide risk assessment of the active substance trifloxystrobin EFSA Journal 2017;15(10):4989

9 OJ L 190, 27.7.2018, p. 3.

10 OJ L 155, 11.6.2011, p. 127.

11 Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market Text with EEA relevance (OJ L 93, 3.4.2013, p. 1).

This renewal report will be made available to the public.

The information in this renewal report is, at least partly, based on information which is confidential and/or protected under the provisions of Regulation (EC) No 1107/2009. It is therefore recommended that this renewal report would not be accepted to support any registration outside the context of that Regulation, e.g. in third countries, for which the applicant has not demonstrated to have regulatory access to the information on which this renewal report is based.

3. Overall conclusion in the context of Regulation (EC) No 1107/2009

The overall conclusion from the evaluation is that it may be expected that plant protection products containing trifloxystrobin will still fulfil the safety requirements laid down in Article 4(1) to (3) of Regulation (EC) No 1107/2009. This conclusion is however subject to compliance with the particular requirements in sections 4, 5, 6 and 7 of this report, as well as to the implementation of the provisions of Article 29(1) of Regulation (EC) No 1107/2009 and the uniform principles laid down in Regulation (EU) No 546/2011, for each trifloxystrobin containing plant protection product for which Member States will grant or review the authorisation.

Furthermore, these conclusions were reached within the framework of the uses as a fungicide on grapes and strawberry, which were proposed and supported by the applicant and mentioned in the list of uses supported by available data (attached as Appendix II to this review report).

The following reference values have been finalised as part of this evaluation:

ADI: 0.1 mg/kg bw per day,
ARfD: 0.5 mg/kg bw,
AOEL: 0.06 mg/kg bw per day,
AAOEL: 0.3 mg/kg bw.

EFSA considered for the time being the consumer risk assessment as provisional in view of the (potential) toxicological properties of the three isomers of trifloxystrobin and CGA 321113 and the outstanding data in plant and livestock exposure. However, following an indicative consumer exposure based on the proposed risk assessment residue definition, no acute and chronic intake concerns were identified for grapes, apples and strawberries. In particular, using the EFSA PRIMO Model rev.2, the highest International Estimated Short-Term Intake (IESTI) is 9 % of the Acute Reference Dose (ARfD) for table grapes and the maximum international estimated daily intake (IEDI) is 3.6 % of the Acceptable Daily Intake (ADI) for the DE child. These estimations were made: considering the exposure to the sum of trifloxystrobin, its isomers (CGA 357262, CGA 357261, CGA 331409) and CGA 321113; assuming the same toxicity for isomers and CGA 321113 as for the parent trifloxystrobin; using the highest residue (HR) and supervised trials median residue (STMR) derived from the residue trials for grapes, apples and strawberries.

Extension of the use pattern beyond those described above will require an evaluation at Member State level in order to establish whether the proposed extensions of use can satisfy the requirements of Article 29(1) of Regulation (EC) No 1107/2009 and of the uniform principles laid down in Regulation (EU) No 546/2011.

The review has identified several acceptable exposure scenarios for operators, workers and bystanders, which require however to be confirmed for each plant protection product in accordance with the relevant sections of the above mentioned uniform principles.

Exposure estimates for operators and workers are below the Acceptable Operator Exposure Level (AOEL) and the Acute Acceptable Operator Exposure Level (AAOEL) without the use of personal protective equipment (PPE), except for two exposure scenarios for operators, where using the UK POEM model the calculated exposures were 121% and 163% of the AOEL without PPE (using gloves m/l & app the calculated exposures were 78% and 80%, respectively). In all cases a Tier 1 assessment is sufficient, except for workers harvesting grapes for which a refinement is necessary and a higher tier assessment indicates exposure levels below the AOEL. Exposure estimates for bystander and residents are also below the AOEL (German and EFSA model).

The following points were considered as a critical area of concern as reported in the EFSA Conclusions (2017) for trifloxystrobin:

1. *Trifloxystrobin is proposed by the pesticide peer review to be classified as toxic for reproduction category 2, in accordance with the provisions of Regulation (EC) No 1272/2008 and toxic effects on the endocrine organs have been observed in the available data; therefore the conditions of the interim provisions of Annex II, Point 3.6.5 of Regulation (EC) No 1107/2009 concerning human health for the consideration of endocrine disrupting properties may be met (see Section 2). However, following a scientific assessment trifloxystrobin is considered unlikely to be an endocrine disruptor in mammals.*

   It is acknowledged that EFSA, on the basis of the effects observed on endocrine organs comes to the conclusion that for the parent substance a potential toxicity for reproduction cannot be ruled out. EFSA therefore suggests classifying the substance as a toxic for reproduction category 2. To date, no such classification exists.

   Considering the proposal for classification as toxic for reproduction category 2 and the fact that toxic effects on endocrine organs were observed, trifloxystrobin may be considered to meet the interim criteria for identification of an endocrine disruptor. However, the proposal for classification as toxic for reproduction category 2 came late during the peer review, since the applicant became aware of it only in the EFSA conclusions. Furthermore, such proposal for classification is not agreed by the Rapporteur Member State, who has committed in the available ECHA CLH Registry of Intentions (RoI) to submit a CLH report by 30/04/2018, where such classification is not proposed. Finally, based on the available data (effects on endocrine organs observed only at cytotoxic levels or at doses exceeding the maximum tolerated dose and lack of *in vitro* oestrogen, androgen, thyroid and aromatase activity), the experts agreed that trifloxystrobin is unlikely to be an endocrine disruptor.

2. *CGA 321113, NOA 413161 and NOA 413163 are considered relevant metabolites in groundwater according to Sanco/221/2000 guidance since it cannot be excluded that they will share the potential of trifloxystrobin for reproductive toxicity. The available groundwater exposure assessment indicated that 80th percentile annual average recharge concentrations moving below the top 1m soil layer for these three metabolites would be above the parametric drinking water limit of 0.1 µg/L (that applies to groundwater relevant metabolites) in geoclimatic situations that are represented by all 9 FOCUS groundwater scenarios considering all the representative uses (see Sections 2 and 4).*

   It is acknowledged that EFSA, on the basis of the effects observed on endocrine organs comes to the conclusion that for the parent substance a potential toxicity for reproduction

cannot be ruled out. EFSA therefore suggests classifying the substance as a toxic for reproduction category 2. To date, no such classification exists.

The current practice for the consideration of the relevance of metabolites in groundwater is laid down in the Guidance Document on the assessment of the relevance of metabolites in groundwater of substances regulated under Council Directive 91/414/EEC.

That guidance document does indeed consider that metabolites for classified substances must be considered a priori relevant, unless a toxicological assessment would come to the opposite conclusion. However, that guidance does not consider proposals for classification, which indeed, may be at the end of the day be agreed or not by ECHA.

It is therefore appropriate that the applicant will be requested to submit confirmatory information in relation to the relevance of metabolites in groundwater within a period of one year after the adoption of a definitive classification by the Risk Assessment Committee of ECHA (see below sub point 7).

The following point could not be finalised as reported in the EFSA Conclusions (2017) for trifloxystrobin:

1. *The consumer risk assessment from the consumption of drinking water could not be finalised, while satisfactory information was not available to address the effect of water treatment processes on the nature of the residues that might be present in surface water or groundwater, when surface water or groundwater are abstracted for drinking water and the consumer risk assessment has to be regarded as provisional pending upon the toxicological assessment of CGA 357262, CGA 357261, CGA 331409 and CGA 321113 that have been included in the residue definition for risk assessment for plants with CGA 321113 also having been included in residue definition for risk assessment for animal commodities (see Sections 3 and 4).*

   The indicative consumer risk assessment is favourable and demonstrates that there is a large margin of safety (see section 3 above). Nonetheless, confirmatory information as regards the effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water or groundwater is abstracted for drinking water, are requested two years after adoption of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater.

   The metabolites CGA 357262, CGA 357261 and CGA 331409 are isomers of trifloxystrobin and they are not likely to pose any significantly higher risk than the parent compound. The three metabolites/isomers were investigated in residue studies and they were not found at levels higher than 10 % (sum of the three isomers) of the total radioactive residues (TRR) in any crop investigated. For CGA 357262, the RMS highlighted that the genotoxicity data are available and negative from the original first review of trifloxystrobin (see evaluation table). For CGA 357261 and CGA 331409, the DEREK computational test did not show any additional alert compared to trifloxystrobin and the Ames Test and in vitro micronucleus tests with human lymphocytes were performed and resulted negative for both CGA 357261 and CGA 331409.

4. Identity and Physical/chemical properties

The main identity of trifloxystrobin is given in Appendix I.

The active substance shall have a minimum purity of 975 g/kg. The relevant impurity AE 1344136 shall not exceed 4 g/kg.

5. Endpoints and related information

In order to facilitate Member States, in granting or reviewing authorisations, to apply adequately the provisions of Article 29(1) of Regulation (EC) No 1107/2009 and the uniform principles laid down in Regulation (EU) No 546/2011, the most important endpoints were identified during the re-evaluation process. These endpoints are listed in the conclusion of the EFSA.

6. Particular conditions to be taken into account on short term basis by Member States in relation to the granting of authorisations of plant protection products containing trifloxystrobin

On the basis of the proposed and supported uses (as listed in Appendix II), the following issues have been identified as requiring particular and short term attention from all Member States, in the framework of any authorisations to be granted, varied or withdrawn, as appropriate:

- the protection of groundwater when the substance is applied in regions with vulnerable soil and/or climate conditions;
- the protection of aquatic organisms, of bees, and of fish-eating birds and mammals.

Conditions of use shall include risk mitigation measures, where appropriate.

7. List of studies to be generated

Further studies were identified which were at this stage considered necessary in relation to the approval of trifloxystrobin under the current approval conditions.

The applicant shall submit to the Commission, the Member States and the Authority the information as regards:

(1) the relevance of metabolites that may occur in groundwater, taking into account any relevant classification for trifloxystrobin in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council , in particular as toxic for reproduction category 2;

(2) the effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water or groundwater is abstracted for drinking water.

The applicant shall submit the information mentioned in point (1) within one year after the publication on the website of the European Chemicals Agency of the opinion adopted by the Committee for Risk Assessment of the European Chemicals Agency in accordance with Article 37(4) of Regulation (EC) No 1272/2008 with respect to trifloxystrobin.

The applicant shall submit the information requested under point (2) within two years of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater being made public by the Commission.

Some endpoints however may require the generation or submission of additional studies to be submitted to the Member States in order to ensure authorisations for use under certain conditions.
A complete list of studies to be generated, still ongoing or available but not peer reviewed can be found in the relevant part of the EFSA Conclusion (page 17).

8. Information on studies with claimed data protection

For information of any interested parties, the rapporteur Member State will keep available a document which gives information about the studies for which the applicant has claimed data protection and which during the re-evaluation process were considered as essential with a view to approval under Regulation (EC) No 1107/2009. This information is only given to facilitate the operation of the provisions of Article 62 of Regulation (EC) No 1107/2009 in the Member States. It is based on the best information available but it does not prejudice any rights or obligations of Member States or operators with regard to its uses in the implementation of the provisions of Article 62 of Regulation (EC) No 1107/2009 and neither does it commit the Commission.

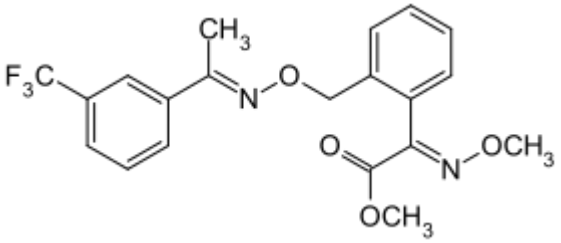
9. Updating of this renewal report

The information in this report may require to be updated from time to time in order to take account of technical and scientific developments as well as of the results of the examination of any information referred to the Commission in the framework of Articles 13, 21, 38, 44, 56 of Regulation (EC) No 1107/2009. Any such adaptation will be finalised in the Standing Committee on Plants, Animals, Food and Feed, in connection with any amendment of the approval conditions for trifloxystrobin.

APPENDIX I

Main identity

TRIFLOXYSTROBIN

Common name (ISO)	Trifloxystrobin
Chemical name (IUPAC)	methyl (E)-methoxyimino-{(E)-α-[1-(α,α,α-trifluoro-m-tolyl)ethylideneaminooxyl]-o-tolyl}acetate
Chemical name (CA)	methyl (αE)-α-(methoxyimino)-2-[[[[(1E)-1-[3-(trifluoromethyl)phenyl]ethylidene]amino]oxy]methyl]benzeneacetate
CIPAC No	617
CAS No	141517-21-7
EC No (EINECS or ELINCS)	Not allocated
FAO SPECIFICATION	Not yet been established
Minimum purity	975 g/kg
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	AE 1344136 (max. 4 g/kg).
Molecular formula	$C_{20}H_{19}F_3N_2O_4$
Molecular mass	408.38 g/mol
Structural formula	

APPENDIX II
List of uses supported by available data
TRIFLOXYSTROBIN

Central Europe: Critical GAPs for Representative crops

Crop and/or situation (a)	Member State	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc. a.s. g/kg (i)	method kind (f-h)	range of growth stage & season (j)	number min-max (k)	Interval between application (min)	kg a.s /hL min-max (l)	Water L/ha min-max	kg a.s./ha min-max (l)		
Grape	Nether lands	Trifloxystrobin WG 50	F	PLASVI	WG	50 %	Tractor mounted/trailed broadcast air assisted sprayer	BBCH 12-89	1 - 3	10	0.0104-0.0312	400-1200	0.125	14	Application timing: april to October
Grape	Slovakia	Trifloxystrobin WG 50	F	BOTRCI, CONLDI, PLASVI, UNCINE	WG	50 %	Tractor mounted/trailed broadcast air assisted sprayer	BBCH 14-89	1 - 3	10	0.0125-0.0625	200-1000	0.125	14	-
Grape	Germany	Trifloxystrobin WG 50	F	UNCINE, PHOPVI, GUIGBI, PSPZTR	WG	50 %	Tractor mounted/trailed broadcast air assisted sprayer	BBCH 13-83	1 - 3	10 -14	0.0075	400 - 1600	0.03 – 0.12	35	-
Strawberry	Germany	Trifloxystrobin WG 50	F G	DIPCEA, MYCOFR, SPHRMA	WG	50 %	Tractor mounted/ trailed equipment: boom sprayer	BBCH 55 - 89	1 - 2	7 -10	0.0075 – 0.015	1000 - 2000	0.150	1	-
-Strawberry	Poland	Trifloxystrobin WG 50	F	MYCOFR, SPHRMA	WG	50 %	Tractor mounted/ trailed equipment: boom sprayer	BBCH 10	1 - 2	7	0.0104-0.0208	600-1200	0.125	1	BBCH 99 treatments of plants after harvest complete

Remarks:

(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)

(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)

(c) *e.g.* biting and sucking insects, soil born insects, foliar fungi, weeds

(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)

(e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide formulation types and international coding system

(f) All abbreviations used must be explained

(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench

(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated

(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). **In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).**

(j) Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application

(k) Indicate the minimum and maximum number of applications possible under practical conditions of use

(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha

(m) PHI - minimum pre-harvest interval

Southern Europe: Critical GAPs for Representative crops

Crop and/or situation (a)	Member State	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc. a.s. g/kg (i)	method kind (f-h)	range of growth stage & season (j)	number min-max (k)	Interval between application (min)	kg a.s /hL min-max (l)	Water L/ha min-max	kg a.s./ha min-max (l)		
Grape	Italy	Trifloxystrobin WG 50	F	UNCINE, GUIGBI	WG	50 %	Tractor mounted/trailed broadcast air assisted sprayer	BBCH 61 - 79	1 - 3	10 - 14	0.0075-0.0125	1000	0.075-0.125	14	Application timing: May to June
Grape	Spain	FLINT	F	UNCINE	WG	50 %	Tractor mounted/trailed broadcast air assisted sprayer	BBCH 69 - 85	1 - 3	10 – 14	0.00625-0.0075	200-1500	0.0125-0.1125	14	
Strawberry	Spain	FLINT	F	DIPCEA, MYCOFR, SPHRMA	WG	50 %	Tractor mounted/ trailed equipment: boom sprayer	BBCH 19 - 89	1 - 2	7	0.0125	500 - 1200	0.0625-0.150	1	

Remarks:

(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)

(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)

(c) *e.g.* biting and sucking insects, soil born insects, foliar fungi, weeds

(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)

(e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide formulation types and international coding system

(f) All abbreviations used must be explained

(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench

(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated

(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). **In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).**

(j) Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application

(k) Indicate the minimum and maximum number of applications possible under practical conditions of use

(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha

(m) PHI - minimum pre-harvest interval

EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate E – Food Safety: plant health, animal health and welfare, international questions
E1 - Plant health

Trifloxystrobin

SANCO/4339/2000-Final

7 April 2003

COMMISSION WORKING DOCUMENT - DOES NOT NECESSARILY REPRESENT THE VIEWS OF THE COMMISSION SERVICES

Review report for the active substance trifloxystrobin

Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 15 April 2003 in view of the inclusion of trifloxystrobin in Annex I of Directive 91/414/EEC.

1. Procedure followed for the evaluation process

This review report has been established as a result of the evaluation of the new active substance trifloxystrobin, made in the context of the work provided for in Articles 5 and 6 of Directive 91/414/EEC concerning the placing of plant protection products on the market, with a view to the possible inclusion of this substance in Annex I to the Directive.

In accordance with the provisions of Article 6(2) of Directive 91/414/EEC, the United Kingdom authorities received on 28 January 1998 an application from Novartis Crop Protection UK Ltd., (the substance was subsequently transferred to Bayer CropScience) hereafter referred to as the applicant, for the inclusion of the active substance trifloxystrobin in Annex I to the Directive. The United Kingdom authorities indicated to the Commission on 04 September 1998 the results of a first examination of the completeness of the dossier, with regard to the data and information requirements provided for in Annex II and, for at least one plant protection product containing the active substance concerned, in Annex III to the Directive. Subsequently, and in accordance with the requirements of Article 6(2), a dossier on trifloxystrobin was distributed to the Member States and the Commission.

The Commission referred the dossier to the Standing Committee on the Food Chain and Animal Health in the meeting of the working group 'legislation' thereof on 15 October 1998, during which the Member States confirmed the receipt of the dossier.

In accordance with the provisions of Article 6(3), which requires the confirmation at Community level that the dossier is to be considered as satisfying, in principle, the data and information requirements provided for in Annex II and, for at least one plant protection product containing the active substance concerned, in Annex III to the Directive and in accordance with

the procedure laid down in Article 20 of the Directive, the Commission confirmed in its Decision 1999/43/EC[1] of 22.12.1998 that these requirements were satisfied.

Within the framework of that decision and with a view to the further organisation of the works related to the detailed examination of the dossier provided for in Article 6(2) and (4) of Directive 91/414/EEC, it was agreed between the Member States and the Commission that the United Kingdom would, as rapporteur Member State, carry out the detailed examination of the dossier and report the conclusions of its examination accompanied by any recommendations on the inclusion or non-inclusion and any conditions relating thereto, to the Commission as soon as possible and at the latest within a period of one year.

The United Kingdom submitted to the Commission on 19.04.2000 the report of its detailed scientific examination, hereafter referred to as the draft assessment report, including, as required, a recommendation concerning the possible inclusion of trifloxystrobin in Annex I to the Directive.

On receipt of the draft assessment report, the Commission forwarded it for consultation to all the Member States on 19.09.2000 as well as to the applicant on 19.01.2001.

The Commission organised further an intensive consultation of specialised scientific experts from a representative number of Member States, to review the draft assessment report and the comments received thereon (peer review), in particular on each of the following disciplines :

- identity and physical /chemical properties ;
- fate and behaviour in the environment ;
- ecotoxicology ;
- mammalian toxicology ;
- residues and analytical methods ;
- regulatory questions.

The meetings for this consultation were organised on behalf of the Commission by the Biologische Bundesanstalt für Land und Forstwirtschaft (BBA) in Braunschweig, Germany, from March to September 2001.

The report of the peer review (i.e. full report) was circulated, for further consultation, to Member States and the sole applicant on 16 November 2001**.**

The dossier, draft assessment report and the peer review report (i.e. full report) including in particular an outline resumé of the remaining technical questions, were referred to the Standing Committee on the Food Chain and Animal Health, and specialised working groups of this Committee, for final examination, with participation of experts from the 15 Member States. This final examination took place from June 2002 to April 2003, and was finalised in the meeting of the Standing Committee on 15 April 2003.

The present review report contains the conclusions of this final examination; given the importance of the draft assessment report, the peer review report (i.e. full report) and the comments and clarifications submitted after the peer review as basic information for the final

[1] OJ No L 14, 19.01.1999, p. 30.

examination process, these documents are considered respectively as background documents A, B and C to this review report and are part of it.

The review did not reveal any open questions or concerns, which would have required a consultation of the Scientific Committee on Plants.

2. Purposes of this review report

This review report, including the background documents and appendices thereto, have been developed and finalised in support of the Directive 2003/68/EC[2] concerning the inclusion of trifloxystrobin in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing trifloxystrobin they have to take in accordance with the provisions of that Directive, and in particular the provisions of article 4(1) and the uniform principles laid down in Annex VI.

This review report provides also for the evaluation required under Section A.2.(b) of the above mentioned uniform principles, as well as under several specific sections of part B of these principles. In these sections it is provided that Member States, in evaluating applications and granting authorisations, shall take into account the information concerning the active substance in Annex II of the directive, submitted for the purpose of inclusion of the active substance in Annex I, as well as the result of the evaluation of those data.

In parallel with the provisions of Article 7(6) of Regulation 3600/92 for existing active substances, the Commission and the Member States will keep available or make available this review report for consultation by any interested parties or will make it available to them on their specific request. Moreover the Commission will send a copy of this review report (not including the background documents) to the applicant.

The information in this review report is, at least partly, based on information which is confidential and/or protected under the provisions of Directive 91/414/EEC. It is therefore recommended that this review report would not be accepted to support any registration outside the context of Directive 91/414/EEC, e.g. in third countries, for which the applicant has not demonstrated possession of regulatory access to the information on which this review report is based.

3. Overall conclusion in the context of Directive 91/414/EEC

The overall conclusion from the evaluation is that it may be expected that plant protection products containing trifloxystrobin will fulfil the safety requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC. This conclusion is however subject to compliance with the particular requirements in sections 4, 5, 6 and 7 of this report, as well as to the implementation of the provisions of Article 4(1) and the uniform principles laid down in Annex VI of Directive 91/414/EEC, for each trifloxystrobin containing plant protection product for which Member States will grant or review the authorisation.

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[2] OJ No L 177, 16.07.2003, p. 12.

Furthermore, these conclusions were reached within the framework of the following uses which were proposed and supported by the sole submitter, and which are outlined in Appendix IV to this report:

- *fungicide against foliar diseases in cereals, fruit and vegetables with a maximum applicatioon rate of 0.25 kg a.s. / ha.*

Extension of the use pattern beyond those described above will require an evaluation at Member State level in order to establish whether the proposed extensions of use can satisfy the requirements of Article 4(1) and of the uniform principles laid down in Annex VI of Directive 91/414/EEC.

4. Specific conclusions which are highlighted in this evaluation

4.1 Residues of trifloxystrobin in foodstuffs

The review has established that the residues arising from the proposed uses, consequent on application consistent with good plant protection practice, have no harmful effects on human or animal health. The Theoretical Maximum Daily Intake (TMDI) for a 60 kg adult is 5.3 % of the Acceptable Daily Intake (ADI), based on the FAO/WHO European Diet (August 1994). This low intake value reflects the current limited use pattern for this active substance. The allocation of an Acute Reference Dose was not warranted.

4.2 Exposure of operators, workers and bystanders

The review has identified acceptable exposure scenarios for operators, workers and bystanders, which require, however, confirmation for each plant protection product in accordance with the relevant sections of the above mentioned uniform principles.

4.3 Ecotoxicology

The review has also concluded that under the proposed and supported conditions of use there are no unacceptable effects on the environment, as provided for in Article 4 (1) (b) (iv) and (v) of Directive 91/414/EEC, provided that certain conditions are taken into account as detailed in section 7 of this report.

5. Identity and Physical/chemical properties

The main identity and the physical/chemical properties of trifloxystrobin are given in Appendix I.

The active substance shall have a minimum purity of 960 g/kg technical product.

The review has established that for the active substance notified by the applicant (now Bayer CropScience), none of the manufacturing impurities considered are, on the basis of information currently available, of toxicological or environmental concern.

6. Endpoints and related information

In order to facilitate Member States, in granting or reviewing authorisations, to apply adequately the provisions of Article 4(1) of Directive 91/414/EEC and the uniform principles laid down in Annex VI of that Directive, the most important endpoints as identified during the evaluation process are listed in Appendix II.

7. Particular conditions to be taken into account on short term basis by Member States in relation to the granting of authorisations of plant protection products containing trifloxystrobin

On the basis of the proposed and supported uses, the following particular issues have been identified as requiring particular and short term attention from the Member States, in the framework of any authorisations to be granted, varied or withdrawn, as appropriate:

Member States should pay particular attention to the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climate conditions. Risk mitigation measures should be applied and/or monitoring programs may be initiated where appropriate.

8. List of studies to be generated

No further studies were identified which were considered at this stage, and under the current inclusion conditions necessary in relation to the inclusion of trifloxystrobin in Annex I.

When granting authorisations Member States may require additional information or monitoring studies in critical regions to ensure adequate protection of ground water resources.

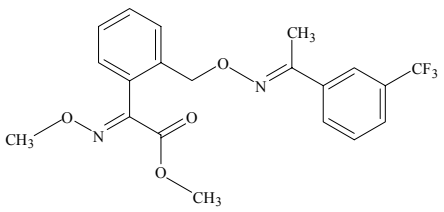
9. Updating of this review report

The technical information in this report may require periodic updating to take account of technical and scientific developments as well as of the results of the examination of any information referred to the Commission in the framework of Articles 7, 10 or 11 of Directive 91/414/EEC. Such adaptations will be examined and finalised in the Standing Committee on the Food Chain and Animal Health, in connection with any amendment of the inclusion conditions for trifloxystrobin in Annex I of the Directive.

APPENDIX I

Identity, physical and chemical properties

TRIFLOXYSTROBIN

Common name (ISO)	TRIFLOXYSTROBIN
Development Code (for new actives only)	CGA 279202
Chemical name (IUPAC)	Methyl (E)-methoxyimino-{(E)-a-[1-a-(a,a,a-trifluoro-m-tolyl)ethylideneaminooxyl]-o-tolyl}acetate
Chemical name (CA)	Methyl (E,E)-a-(methoxyimino)-2-[[[[1-[3-(trifluoromethyl)phenyl]ethylidene]amino]oxy]methyl] benzeneacetate
CIPAC No	617
CAS No	141517-21-7
EEC No	not allocated
FAO SPECIFICATION	an FAO Specification does not yet exist
Minimum purity	960 g / kg
Molecular formula	$C_{20}H_{19}F_3N_2O_4$
Molecular mass	408.4
Structural formula	

Melting point	72.9°C
Boiling point	approx. 312°C at 101.325 kPa (thermal decomposition starts at about 285°C)
Appearance	Pure: white powder Technical material (974 g/kg) off-white powder
Relative density	1.36
Vapour pressure	$3.4 \cdot 10^{-6}$ Pa at 25°C Essentially non-volatile.
Henry's law constant	2.3×10^{-3} Pa m³ mol^{-1} at 25°C
Solubility in water	0.61 mg / l at 25°C, without pH dependence (CGA 279202 has no dissociation constant in an accessible pH range)
Solubility in organic solvents	all results at 25°C acetone >500 g / l dichloromethane >500 g / l ethyl acetate >500 g / l hexane 11 g / l methanol 76 g / l octanol 18 g / l toluene 500 g / l
Partition co-efficient (log P_{ow})	log P_{ow} at 25°C : 4.5 ± (0.0094). no pH dependence
Hydrolytic stability (DT_{50})	pH 5 at 20°C: 8.6 years pH 7 at 20°C: 11.4 weeks pH 9 at 20°C : 27.1 hours
Dissociation constant	CGA 279202 does not have a dissociation constant within the range 2 to 12
Quantum yield of direct photo-transformation in water at ε >290 nm	Φ = 0.0639 (decay of CGA 279202 plus isomers) Φ = 0.2272 (disappearance of CGA 279202)
Flammability	CGA 279202 is not considered highly flammable
Explosive properties	CGA 279202 is not considered an explosive
UV/VIS absorption (max.)	For the absorption maximum at 250.7 nm the molar extinction coefficient was determined to be 17500 l / mol · cm No absorption maximum between 340 nm and 750 nm was observed.
Photostability in water (DT_{50})	1.1 and 1.7 days at pH 5 and pH 7, respectively (natural summer sunlight at geographical latitude of 40°N). Photolytically unstable.

APPENDIX II

END POINTS AND RELATED INFORMATION

TRIFLOXYSTROBIN

1 Toxicology and metabolism

Absorption, distribution, excretion and metabolism in mammals

Rate and extent of absorption:	60% oral absorption based on urinary and biliary excretion and tissue residues after 48 hours.
Distribution:	Widely distributed.
Potential for accumulation:	No potential for accumulation.
Rate and extent of excretion:	Within 48 hours 72-96% of the administered dose eliminated in the urine and faeces.
Toxicologically significant compounds:	Parent compound and metabolites.
Metabolism in animals:	Extensive: hydrolysis, O-demethylation, oxidation and conjugation.

Acute toxicity

Rat LD_{50} oral:	>5000 mg/kg
Rat LD_{50} dermal:	>2000 mg/kg
Rat LC_{50} inhalation:	>4.6 mg/litre
Skin irritation:	Not irritant.
Eye irritation:	Not irritant.
Skin sensitization (test method used and result):	Sensitiser (M&K) (R43).

Short term toxicity

Target / critical effect:	Decreased bodyweight & food consumption. Liver: increased weight, hepatocellular hypertrophy and necrosis. Kidney: increased weight and acute tubular lesions. Pancreas: atrophy.
Lowest relevant oral NOAEL / NOEL:	90-day rat: 100 ppm (6.4 mg/kg bw/day)
Lowest relevant dermal NOAEL / NOEL:	28-day rat: 100 mg/kg bw/day
Lowest relevant inhalation NOAEL / NOEL:	No study - not required

Genotoxicity

No genotoxic potential

Long term toxicity and carcinogenicity

Target / critical effect:	Decreased bodyweight & food consumption. Liver: increased weight, hepatocellular hypertrophy, fatty change and necrosis. Kidney: increased weight.
Lowest relevant NOAEL:	2-yr rat: 250 ppm (9.8 mg/kg bw/day)
Carcinogenicity:	No carcinogenic potential

Reproductive toxicity

Target / critical effect - Reproduction:	Decreased bodyweight gain of pups and delayed eye opening at parental toxic doses.
Lowest relevant reproductive NOAEL / NOEL:	50 ppm(2.3 mg/kg bw/day).
Target / critical effect - Developmental toxicity:	Enlarged thymus (rat) and skeletal effects (rabbit) at maternally toxic dose levels.
Lowest relevant developmental NOAEL / NOEL:	50 mg/kg bw/day (rabbit)

Neurotoxicity

Acute and 90-day neurotoxicity study, rat: No evidence of neurotoxicity

Other toxicological studies

Investigations into replicative DNA synthesis:
No evidence of replicative DNA synthesis in rat or mouse heptocytes following 3-months administration in diet.

Investigations into mitochondrial function:
In vitro studies in isolated rat liver mitochondria indicated trifloxystrobin caused a significant concentration dependant inhibition of mitochondrial respiration.

Studies performed with metabolites:
CGA 373466, NOA 413161, NOA 413163, CGA 357261 and NOA 414412 were of low acute oral toxicity (LD50 values >2000 mg/kg bw) and there was no evidence of genotoxic activity (each tested in 1-3 in vitro assays, including Ames test).

Medical data

New active substance. Limited data. Some evidence of skin and eye irritation in 3 people during field trials (but 120 people without effects).

Summary

	Value	Study	Safety factor
ADI:	0.1 mg/kg bw/day	2-year rat study	100
AOEL	0.06 mg/kg bw/day	2-year rat study (adjusted for 60% oral absorption)	100

ARfD (acute reference dose):	Not allocated - not necessary due to low acute toxicity of trifloxystrobin.

Dermal absorption

In-vivo and in-vitro data submitted. In vivo rat: 38% (low dose, 48 h), 16% (high dose, 48 h) In vitro rat/human: human epidermis was shown to be at least 10-fold less permeable than rat epidermis. Therefore dermal absorption for risk assessment will be 1.6% for the concentrate and 3.8% for the in-use dilutions. Individual Members to decide on precise dermal absorption value to use.

2 Fate and behaviour in the environment

2.1 Fate and behaviour in soil

Route of degradation

Aerobic:

Mineralization after 100 days:	4-64% after 105-365d [^{14}C-GP]-label (n=8), 57% after 365 days [^{14}C-TP]-label (n=1) sterile conditions - negligible after 365 d (n=1)
Non-extractable residues after 100 days:	9-27% after 105-365d [^{14}C-GP]-label (n=8), 27% after 365 days [^{14}C-TP]-label (n=1) sterile conditions - negligible after 365d (n=1)
Major metabolites above 10 % of applied active substance: name and/or code % of applied rate (range and maximum)	CGA321113 85-97% at 7-28d (n=9) [^{14}C-GP & TP]-labels

Supplemental studies

Anaerobic:	Mineralisation negligible Non-extractable residues 7% after 365d Metabolites CGA321113 97% after 90 d (n=1, [^{14}C-GP]-label)
Soil photolysis:	Mineralisation 2-5% after 30d Non-extractable residues 25% after 30d Metabolites CGA321113 36-44% after 2-10d CGA373466 42% after 18-22d (n=2, [^{14}C-GP & TP]-label)
Remarks:	none

Rate of degradation

Laboratory studies

DT_{50}lab (20 °C, aerobic):	Method of calculation 1st, 2 compartment 1st , √ 1st and 1.5st order decline 0.3-3.6d (n=10, 19-25°C, 40-75%WHC, r^2= 0.98-1.0) mean first order normalised to 20°C,–10kPa, 0.67d (from 11 experiments where n= 5) CGA321113: 35->500d (n=10, 19-25°C, 40-75%WHC) CGA321113 mean first order normalised 20°C,–10kPa, 116d (from 11 experiments where n= 5) NOA413161:253 d (n=1, 20°C, 40% WHC) DT_{50lab} (22°C, photolytic):0.7 days of 50°N summer sunlight

	CGA321113: 50 days of 50°N summer sunlight CGA373446: 50 days of 50°N summer sunlight
DT_{90}lab (20 °C, aerobic):	ca. 39 days.
DT_{50}lab (10 °C, aerobic):	1.2d (n=1, 75%WHC, r^2= 1.0 CGA321113: 380 d (n=1, 75%WHC)
DT_{50}lab (20 °C, anaerobic):	0.4d (n=1, r^2= 0.98) CGA321113: >1000d (n=1)

Field studies (country or region)

DT_{50f} from soil dissipation studies:	Northern France (pre-emergence): 9d (n=1, r^2=1.0, 1st order) Southern France (pre-emergence):5d (n=1, r^2=0.96, 1st order) Switzerland (pre-emergence): 2-9d (n=5, r^2=0.95-1.0, 1st, 1.5st & √1st order) Germany (cropping details not provided): 8-12d Italy (pre-emergence): 5d (n=1, r^2=0.98, 1st order) Geometric mean 1st order value used as groundwater modelling input 6.7 d (n=6, 3 Swiss, German, French & Italian trials)
DT_{90f} from soil dissipation studies:	Northern France (pre-emergence): 28d (n=1, r^2=1.0, 1st order) Southern France (pre-emergence):16d (n=1, r^2=0.96, 1st order) Switzerland (pre-emergence): 17-31d (n=5, r^2=0.95-1.0, 1st, 1.5st & √1st order) Germany (cropping details not provided): 26-41d Italy (pre-emergence): 15d (n=1, r^2=0.98, 1st order)
	DT_{50f} and DT_{90f} for metabolites: CGA321113 Northern France: 0.16 mg/kg max (91d), DT50 120d, DT90 400d (r^2=0.99, 1st order, n=1) Southern France:0.12 mg/kg max (28d), DT50 88d, DT90 460d (r^2=0.89, 1.5st order, n=1) Switzerland: 0.17-0.4 mg/kg max (0-31d), DT50 8-110d, DT90 83->500d (r^2=0.87-0.99, 1st, √1st order, n=5) Germany: DT50 58d, DT90 190d (n=1) Italy: DT50 25d, DT90 280d (r^2=0.99, √1st order, n=1) Geometric mean 1st order DT_{50} value used as groundwater modelling input 59.9 d (n=6, 3 Swiss, German, French & Italian trials) normalised to 20°C 41.9d CGA373466 Switzerland: 0.1-0.24 mg/kg max (2-28d), DT50 8.3-86d, DT90 92-290d (r^2=0.92-0.95, 1st, √1st order, n=2) Italy: DT50 40d, DT90 210d (r^2=0.94, 1.5 order, n=1) Geometric mean 1st order DT_{50} value used as groundwater modelling input 52.1 d (n=3, 2 Swiss & Italian trials)) normalised to 20°C 36.1d NOA 413161 Swiss lysimeter study, single Borstel soil 1st order DT50 97.3 d (normalised to 20°C, -10kPa) NOA 413163 Swiss lysimeter study, single Borstel soil 1st order DT50 43.8 d (normalised to 20°C, -10kPa)
Soil accumulation studies:	CGA321113 could accumulate. A plateau concentration is calculated at 0.052mg/kg assuming a DT50 of 120 days, 50% crop interception, 50% formation and 1125g a.s/ha (total annual dose to grapes) is applied a year. An accumulation factor of ca. 1.14 is calculated.

Soil residue studies:	None. Not required
Remarks: e.g. effect of soil pH on degradation rate	none

Adsorption/desorption

K_f / K_{oc}:	K_{oc} trifloxystobin: 1642-3745 (6 soils) mean 2377 CGA321113: 84-194 (6 soils) mean 121 CGA373466: 30-166 (5 soils) mean 88 NOA413161: 4.2 (1 soil) NOA 413163: 4.2 (extrapolated from NOA 413161) K_f trifloxystobin: 11.2-325 (6 soils) CGA321113: 0.58-18.6 (6 soils) CGA373466: 0.17-3.07 (5 soils)
K_d:	K_d NOA413161: 0.042 (1 soil) 1/n trifloxystrobin 0.92-1.0 (6 soils) mean 0.96 CGA321113: 0.95-1.1 (6 soils) mean 1.0 CGA373466: 1.01-1.26 (5 soils) mean 0.89
pH dependence:	No

Mobility

Laboratory studies:

Column leaching:	SETAC/EPA Guideline. 251ml (percolation period 1-144 hours depending on soil type), 5 soil columns. Leachate 0.2-1.2% radioactivity in leachate 86-102% radioactivity in top 6cm soil
Aged residue leaching:	Dutch Guideline. Aged for 2d, 200ml over 2-6d (2 soil columns). [^{14}C-GP]-label Leachate 0.1-0.4% radioactivity in leachate 21-44% radioactivity in top 6cm soil. [^{14}C-TP]-label Leachate 3.3-4.1% radioactivity in leachate 20-35% radioactivity in top 6cm soil. EPA Guideline. Aged for 1-45d, 490ml over <1-84d (7 soil columns). [^{14}C-GP]-label Results after 1 day aging Leachate: <0.1-30.1% radioactivity in leachate. Mainly CGA321113, trifloxystrobin not detected. 10-57% radioactivity in top 6cm of soil

Field studies:

Lysimeter/Field leaching studies:	US:3 months, 1 application of 3.4 kg/ha to 90cm deep soil columns, rainfall 403mm over period. Leachate volume 4806ml, <0.04% radioactivity detected in leachate which was not identified. Switzerland:3 years, BBA guideline study on Borstel soil, 120cm soil monoliths, cropped with wheat. Up to 4

applications over 2 years, 0.5kg a.s. / ha /year, annual rainfall+irrigation 935-1032mm over period. Leachate volumes 404-635ml (43-66% of precipitation, very high).

	Annual average leachate concentrations
Trifloxystrobin	Not detected
CGA373466	up to 0.24 µg/l
CGA321113	up to 1.22 µg/l
NOA413163	up to 2.76 µg/l
NOA413161	up to 6.69 µg/l

All resolved radioactivity representing annual average leacha concentrations > 0.1µg/l was identified.

Remarks:

Residue relevant for environmental monitoring in soil:
trifloxystrobin

2.2 Fate and behaviour in water

Abiotic degradation

Hydrolytic degradation:	pH5: [^{14}C-GP]-label 25°C - DT50 480d (1st order, r^2= 0.54) [^{14}C-TP]-label 25°C - DT50 >1000d (1st order, r^2= 0.02) pH7: [^{14}C-GP]-label 25°C - DT50 39-41d (1st order, r^2= 0.96) CGA321113 32-46%AR at study end [^{14}C-TP]-label 25°C - DT50 40d (1st order, r^2= 0.99) CGA321113 60%AR at study end CGA321113 stable to hydrolysis at 25°C pH9: [^{14}C-GP]-label 25°C - DT50 1.2d (1st order, r^2= 0.98) CGA321113 102%AR [^{14}C-TP]-label 25°C - DT50 2.3d (1st order, r^2= 0.9) CGA321113 93.4%AR CGA321113 stable to hydrolysis at 25°C
Major metabolites:	CGA321113, See above
Photolytic degradation:	[^{14}C-GP]trifloxystrobin Xenon arc lamp (>290nm, 22.2 W/m^2) pH 7.2 DT50 2.7d, CGA 357262 10.2%, CGA357261 40%, M50[isomer of CGA321113] 16.9% Xenon arc lamp (>290nm, 23-40.65 W/m^2) [^{14}C-TP]trifloxystrobin pH5 DT50 2.6d, CGA107170 52%, CGA 357261 41.6%. [^{14}C-TP]trifloxystrobin pH7 DT50 5.8-9.5d, CGA 357261 35%, CGA373466 44.1%, CGA321113 23%, CGA107170 21.4% Photolysis of CGA321113 Xenon-arc lamp (>290nm, 35-44.6 W/m^2) DT50 1.7d Estimated DT50 at 50°N by quantum yield Trifloxystrobin + isomers 42.2d Trifloxystobin alone 3.1d CGA321113 + isomers 42.2d CGA321113 alone 3.4d
Major metabolites:	See above

Biological degradation

Readily biodegradable:	no
Water/sediment study:	
DT_{50} water:	1.1-1.2d
DT_{90} water:	3-4d (1st order, r^2= 0.99-1.0, n=4)
DT_{50} whole system:	1.2-3.5d
DT_{90} whole system:	4-11d (1st order, r^2= 0.98-1.0, n=4)
Distribution in water / sediment systems (active substance)	Max in sediment of 10-42.3% after 1 day. DT50 in sediment 1.5-4.2d (DT90 5-14d, 1st order, r^2=0.99-1.0, n=4)
Distribution in water / sediment systems (metabolites)	CGA321113 Water: max of 41.3-76.9%AR (4-28 days, n=4 [DT_{50} 170-320d, 1st order, r^2=0.75-0.94], n=4) Sediment: max of 42.7-51.1% (21-102 days, n=4 [DT_{50} 460-2940 days, 1st/√2nd order, r^2=0.74-0.88, n=2])
Accumulation in water and/or sediment:	Trifloxystrobin will not accumulate. CGA 321113 may accumulate in sediment (see DT_{50} above).

Degradation in the saturated zone

not submitted not required.

Remarks:

Residue relevant for environmental monitoring in water:

Surface water – trifloxystrobin

Groundwater – trifloxystrobin. Member states may wish to monitor for NOA 413161 in vulnerable groundwater situations as it could approach the 10µg/l drinking water limit for chlorinated aliphatic compounds compounds even though it is considered not relevant.

2.3 Fate and behaviour in air

Volatility

Vapour pressure:	$3.4 \cdot 10^{-6}$ Pa at 25°C Essentially non-volatile.
Henry's law constant:	2.3×10^{-3} Pa m³ mol^{-1} at 25°C

Photolytic degradation

Direct photolysis in air:	not submitted
Photochemical oxidative degradation in air DT_{50}:	DT_{50} 1.5-2 days (Atkinson Method)
Volatilisation:	from plant surfaces (BBA Guideline): 10-15% of applied radioactivity lost after 24hrs from soil: not submitted, not required

Remarks:	Relevant residue for environmental monitoring of air: trifloxystrobin

3 Ecotoxicology

Terrestrial Vertebrates

Acute toxicity to mammals:	LD50 >5000 mg a.s./kg bw (rat) 2 gen. Repro. NOEC >1500 ppm (rat)
Acute toxicity to birds:	LD50 >2000 mg a.s./kg bw (*C virginianus*)
Dietary toxicity to birds:	LC50 >5200 ppm (*C virginianus/A platyrhynchos*)
Reproductive toxicity to birds:	NOEC 320 ppm (*C virginianus*)
Short term oral toxicity to mammals:	90-day rat: 100 ppm (6.4 mg/kg bw/day)

Aquatic Organisms

Acute toxicity fish:	a.s.:	LC_{50}: 0.022 mg/l (96 h, O. mykiss) LC_{50}: 0.015 mg/l (96 h, O. mykiss) LC_{50}: 0.097 mg/l (96 h, L. macrochirus) LC_{50}: 0.033 mg/l (96 h, P. promelas) LC_{50}: 0.16 mg/l (96 h, B. reiro) LC_{50}: 0.039 mg/l (96 h, C. carpio) LC_{50}: 0.067 mg/l (96 h, L. idus) LC_{50}: 0.52 mg/l (96 h, P. reticulata)
	‚Twist‘:	LC_{50}: 0.14 form mg/l (96 h, O. mykiss)
	‚Flint‘:	LC_{50}: 0.036 form mg/l (96 h, O. mykiss)
	CGA 357261:	LC_{50}: 0.9 mg/l (96 h, O. mykiss)
	CGA 107170:	LC_{50}: 13.6 mg/l (96 h, O. mykiss)
	CGA 321113:	LC_{50}: > 106 mg/l (96 h, O. mykiss)
	CGA 373466:	LC_{50}: > 200 mg/l (96 h, O. mykiss)
	NOA 413161:	LC_{50}: > 100 mg/l (96 h, O. mykiss)
	NOA 413163:	LC_{50}: > 100 mg/l (96 h, O. mykiss)
Long term toxicity fish:	a.s.:	NOEC: 0.0077 mg/l (95 d ELS, O. mykiss)
Bioaccumulation fish:	BCF 431 (worst case value, whole body fish)	
Acute toxicity invertebrate:	a.s.:	EC_{50}: 0.011 mg/l (48 h, D. magna) EC_{50}: 0.016 mg/l (48 h, D. magna) EC_{50}: 0.032 mg/l (24 h, D. pulex) EC_{50}: 0.26 mg/l (24 h, B. calyciflorus) EC_{50}: 0.026 mg/l (24 h, T. platyurus) EC_{50}: 0.013 mg/l (48 h, D. longispina) EC_{50}: 0.13 mg/l (48 h, Chydorus sp) EC_{50}: 0.11 mg/l (48 h, Cyclopidae) EC_{50}: 0.20 mg/l (48 h, Chaoborus sp larva) EC_{50}: 0.07 mg/l (48 h, Baetis sp larva) EC_{50}: > 0.31 mg/l (96 h, P acutus acutus) EC_{50}: 0.09 mg/l (48 h, Gammarus sp) ‚Twist‘:EC_{50}: 0.16 form mg/l (48 h, D. magna)
	‚Flint‘:	EC_{50}: 0.010 form mg/l (48 h, D. magna)

	CGA 357261:	EC_{50}: 1.4 mg/l (48 h, D. magna)
	CGA 107170:	EC_{50}: >22.7 mg/l (48 h, D. magna)
	CGA 321113:	EC_{50}: > 100 mg/l (48 h, D. magna)
	CGA 373466:	EC_{50}: > 100 mg/l (48 h, D. magna)
	NOA 413161:	EC_{50}: > 100 mg/l (48 h, D. magna)
	NOA 413163:	EC_{50}: > 100 mg/l (48 h, D. magna)
Chronic toxicity invertebrate:	a.s.:	EC_{50}: 0.0098 mg/l (21 d, D. magna) NOEC: 0.0027 mg/l (21 d, D. magna)
	CGA 321113:	EC_{50}: > 10 mg/l (21 d, D. magna) NOEC: 3.2 mg/l (21 d, D. magna)
Acute toxicity algae:	a.s.:	EbC_{50}: 0.0053 mg/l (72 h, S. subspicatus)
	‚Twist‘:	EbC_{50}: 0.076 form mg/l (72 h, P. subcapitata)
	‚Flint‘:	EbC_{50}: 0.015 form mg/l (72 h, P. subcapitata)
	CGA 357261:	EbC_{50}: 1.4 mg/l (72 h, S. subspicatus)
	CGA 107170:	EbC_{50}: > 30.9 mg/l (72 h, S. subspicatus)
	CGA 321113:	EbC_{50}: > 100 mg/l (72 h, P. subcapitata)
	CGA 373466:	EbC_{50}: > 100 mg/l (72 h, S. subspicatus)
	NOA 413161:	EbC_{50}: > 100 mg/l 72 h, P. subcapitata)
	NOA 413163:	EbC_{50}: > 100 mg/l (72 h, P. subcapitata)
Chronic toxicity sediment dwelling organism:	a.s.:	EC_{50}: 0.45 mg/l (28 d, C. riparius) NOEC: 0.2 mg/l (28 d, C. riparius)
	CGA 321113:	EC_{50}: 49.2 mg/l (28 d, C. riparius) NOEC: 25.0 mg/l (28 d, C. riparius)

Honeybees

Acute oral toxicity:	Active substance: >200 µg a.s./bee ‘Flint’: >187 µg form/bee ‘Twist’: > 142 µg form/bee
Acute contact toxicity:	Active substance: >200 µg a.s./bee ‘Flint’ >200 µg form/bee ‘Twist’: > 100 µg form/bee

Other arthropod species

Test species	**% Effect**
A. colemani (adults)	< 30% mortality/beneficial capacity (250 + 500 g as/ha; 'Flint')
T. pyri (nymphs)	< 30% mortality/beneficial capacity (250 + 500 g as/ha; 'Flint')
C. septempunctata (II instar lavae)	30.4 % mortality (250 g as/ha; 'Flint') 50.4 % beneficial capacity (250 g as/ha; 'Flint') < 30 % mortality/beneficial capacity (500 g as/ha; 'Flint')
C. septempunctata (II instar lavae)	< 30 % mortality/beneficial capacity (250 + 500 g as/ha; 'Flint')
O. insidiosus (nymphs)	100 % mortality (250 + 500 g as/ha; 'Flint')
P. cupreus (adults)	mortality/beneficial capacity - no adverse effects observed (250 + 500 g as/ha; 'Flint')
A. colemani (adults)	100 % mortality (250 + 500 g as/ha; 'Twist')
A. rhopalosiphi (adults)	< 30 % mortality/beneficial capacity (10 g as/ha; 'Twist') 100 % mortality after 48 h (250 + 500 g as/ha; 'Twist')
T. pyri (nymphs)	74 and 93 % mortality at 250 + 500 g as/ha; 'Twist'
C. septempunctata (II instar larve)	39.1 % mortality (500 g as/ha; 'Twist')
A. bileneata (adults)	< 30 % mortality/beneficial capacity (250 + 500 g as/ha; 'Twist')
P. cupreus (adults)	mortality/beneficial capacity - no adverse effects observed (250 + 500 g as/ha; 'Twist')

Field or semi-field tests

The effects of aged residues of 'Flint' on the survival of *O. laevigatus* was examined in a semi-field study on potted grapevine. Mortality and reproductive capacity were assessed. Study indicates 14-day old residues may be toxic, no adverse effects from 30-day old residues. This higher tier study-indicates that population recovery may be possible. Risk management at MS level should be considered.
In a semi-field study, no significant effect on the activity or parasitization potential of *A rhopalosiphi* was reported following 2 applications at the maximum proposed dose of 'Twist'(i.e. 2.0 l/ha). The use of 'Twist' does not pose an unacceptable risk to non-target arthropods. Risk management is not required.

Earthworms

Acute toxicity:	LC50 14-day >1000 mg a.s./kg soil LC50 14-day >1000 mg 'Flint'/kg soil LC50 14-day >1000 mg 'Twist'/kg soil LC50 14-day >1000 mg CGA 321113/kg soil LC50 14-day >1000 mg CGA 373466/kg soil LC50 14-day >1000 mg NOA 413161/kg soil LC50 14-day >1000 mg NOA 413163/kg soil
Reproductive toxicity:	NOEC 56-day 5.0 l 'Stratego'/ha[#] NOEC 56-day 750 g CGA 321113/ha[#] [#] The highest concentration tested. 'Stratego' contains 186 g/l trifloxystrobin and 126 g/l propiconazole.

Soil micro-organisms

Nitrogen mineralization:	<25 % after 24 days at 10000 g a.s./ha
Carbon mineralization:	<25 % after 24 days at 10000 g a.s./ha

APPENDIX III

TRIFLOXYSTROBIN

List of studies which were submitted during the evaluation process and were not cited in the draft assessment report:

B.1 Identity, B.2 Physical and chemical properties, B.3 Data on application and further information, B.4 Proposals for classification and labelling, B.5 Methods of analysis

Annex point/ reference number	**Author(s)**	**Year**	**Title** **Source (where different from company)** **Company, Report No.** **GLP or GEP status (where relevant)** **Published or not**
IIA, 2.3.2	Burkhard, N.	1997a	CGA 321113 – Henry's law constant Source: Novartis Services AG, Basel, Switzerland; Bayer AG, Report No. CGA321113/0010 Date: 1997-11-05 GLP: no not published
IIA, 2.3.2	Burkhard, N.	1997b	CGA 373466 – Henry's law constant Source: Novartis Services AG, Basel, Switzerland; Bayer AG, Report No. CGA373466/0011 Date: 1997-12-01 GLP: no not published
IIA, 2.3.2	Burkhard, N.	1998	NOA 413161 – Henry's law constant Source: Novartis Services AG, Basel, Switzerland; Bayer AG, Report No. NOA413161/0008 Date: 1998-11-16 GLP: no not published
IIA, 2.3.2	Burkhard, N.	1999	NOA 413163 – Henry's law constant B Source: Novartis Services AG, Basel, Switzerland; ayer AG, Report No. NOA413163/0011 Date: 1997-04-21 GLP: no not published

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIA, 2.9.4	Jäkel, K.	1997a	Report on dissociation constant in water – CGA 321113 Source: Novartis Services AG, Basel, Switzerland; Bayer AG, Report No. PP-97/22P.DCW Date: 1997-08-25 GLP: yes not published
IIA, 2.9.4	Jäkel, K.	1997b	Report on dissociation constant in water – CGA 373466 Source: Novartis Services AG, Basel, Switzerland; Bayer AG, Report No. PP-97/17P.DCW Date: 1997-08-25 GLP: yes not published
IIA, 2.9.4	Jäkel, K.	1998a	Report on dissociation constant in water – NOA 413161 Source: Novartis Services AG, Basel, Switzerland; Bayer AG, Report No. PP-98/74P.DCW Date: 1998-09-07 GLP: yes not published
IIA, 2.9.4	Jäkel, K.	1998b	Report on dissociation constant in water – NOA 413163 Source: Novartis Services AG, Basel, Switzerland; Bayer AG, Report No. PP-98/79P.DCW Date: 1998-11-11 GLP: yes not published
IIA, 3.5	Ebbert, M.	2001	Measurement of electron transport through complexes II/ III of isolated *Pyricularia oryzae* (*Magnaporthe grisea)* mitochondria Bayer AG, Report no.: EBO 2001-01 (MO-01-012215) Date: 2001-05-14 unpublished
IIA, 3.5	Neuenschwander, U.	2000a	Report on the biological results obtained with CGA 413161 Source: Novartis Crop Protection AG, Switzerland Bayer AG, report No.: MO-01-017125 Date: 2000-09-26 revised report No. REG02-0004 Date of 2nd Revision: 26.11.2001 unpublished

Annex point/ reference number	**Author(s)**	**Year**	**Title** **Source (where different from company)** **Company, Report No.** **GLP or GEP status (where relevant)** **Published or not**
AII, 3.5	Neuenschwander, U.	2000b	Report on the biological results obtained with CGA 413163 Source: Novartis Crop Protection AG, Switzerland Bayer AG, report No. MO-01-017126 Date: 2000-09-26, revised report No. REG02-0005 Date of 2nd Revision: 26.11.2001 unpublished
IIA, 3.5	Neuenschwander, U.	2000a	Report on the biological results obtained with CGA 413161 Source: Novartis Crop Protection AG, Switzerland Bayer report No.: MO-01-017125 Date: 2000-09-26 unpublished
IIA, 3.5	Neuenschwander, U.	2000b	Report on the biological results obtained with CGA 413163 Source: Novartis Crop Protection AG, Switzerland Bayer report No. MO-01-017126 Date: 2000-09-26 unpublished
IIA, 2.5	Oggenfuss, P.	1999	Spectra of CGA 321113. 2.11.99. Study No. 78597
IIA, 1.9/10	Ohs, P.	2001	Data Sheet. Purity and by-products of techn. a.i. trifloxystrobin (ISO draft proposal). 21.01.2001. CONFIDENTIAL INFORMATION
IIA 4.2.1	Pelz, S., Weber, H.	2002	Enforcement method 00086/M040 for the determination of the residues of trifloxystrobin in cucumber (fruit), citrus (fruit), wheat (grain), almond (seed), hop and leek – validation of DFG method S19 (extended revision). Report: BAY-0118V Date 2002-02-26
IIA, 1.8	Scheider, H. Stulz, J.	2001	Manufacturing Process CGA 279202 Syngenta Crop Protection AG, Basel, Switzerland Process Description, not GLP, not published CONFIDENTIAL INFORMATION

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIA, 3.5	Steinemann, A.	1996	Fungitoxic activity of CGA 279202 isomers and metabolites in vitro Source: Ciba Crop Protection, Basel, Switzerland Bayer AG, Report No.: MO-01-017144 Date: 2001-02-18 revised report No. 96001PO Date of Revision: 21.11.2001 unpublished
IIA, 3.5	Steinemann, A.	1996	Fungitoxic activity of CGA 279202 isomers and metabolites in vitro Source: Ciba Crop Protection, Basel, Switzerland Bayer AG, Report no.: MO-01-017144 Date: 2001-02-18 unpublished
IIA, 2.6	Stulz, J.	1997a	Report on water solubility – CGA 321113 Source: Novartis Services AG, Basel, Switzerland; Bayer AG, Report No. 53237 Date: 1997-09-30 GLP: yes not published
IIA, 2.8	Stulz, J.	1997c	Report on octanol / water partition coefficient – CGA 321113 Source: Novartis Services AG, Basel, Switzerland; Bayer AG, Report No. 53236 Date: 1997-09-17 GLP: yes not published
IIA, 2.6	Stulz, J.	1997b	Report on water solubility – CGA 373466 Source: Novartis Services AG, Basel, Switzerland; Bayer AG, Report No. 52618 Date: 1997-10-20 GLP: yes not published
IIA, 2.8	Stulz, J.	1997d	Report on octanol / water partition coefficient – CGA 373466 Source: Novartis Services AG, Basel, Switzerland; Bayer AG, Report No. 52617 Date: 1997-09-30 GLP: yes not published

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIA, 2.6	Stulz, J.	1998a	Report on water solubility – NOA 413161 Source: Novartis Services AG, Basel, Switzerland; Bayer AG, Report No. 64135 Date: 1998-10-08 GLP: yes not published
IIA, 2.8	Stulz, J.	1998c	Report on octanol / water partition coefficient – NOA 413161 Source: Novartis Services AG, Basel, Switzerland; Bayer AG, Report No. 64134 Date: 1998-10-08 GLP: yes not published
IIA, 2.6	Stulz, J.	1998b	Report on water solubility – NOA 413163 Source: Novartis Services AG, Basel, Switzerland; Bayer AG, Report No. 65680 Date: 1998-10-08 GLP: yes not published
IIA, 2.8	Stulz, J.	1998d	Report on octanol / water partition coefficient – NOA 413163 Source: Novartis Services AG, Basel, Switzerland; Bayer AG, Report No. 65679 Date: 1998-10-08 GLP: yes not published
IIA 4.2.1	Walser, M.	1997	Applicability of multiresidue method DFG S19 for the determination of CGA 279202 (parent) and CGA 321113 (metabolite) in plant materials (apple, grains, and straw of wheat, dried and green cones of hop). Report: Ref 104/97 Date: 1997 –10 -09
IIA, 2.3.1	Widmer, H.	1997a	Vapour pressure of CGA 321113 Source: Novartis Services AG, Basel, Switzerland; Bayer AG, Report No. 97WI30 Date: 1997-09-18 GLP: yes not published

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIA, 2.3.1	Widmer, H.	1997b	Vapour pressure of CGA 373466 Source: Novartis Services AG, Basel, Switzerland; Bayer AG, Report No. 97WI26 Date: 1997-09-18 GLP: yes not published
IIA, 2.3.1	Widmer, H.	1998a	Vapour pressure of NOA 413161 Source: Novartis Services AG, Basel, Switzerland; Bayer AG, Report No. 98WI21 Date: 1998-09-28 GLP: yes not published
IIA, 2.3.1	Widmer, H.	1998b	Vapour pressure of NOA 413163 Source: Novartis Services AG, Basel, Switzerland; Bayer AG, Report No. 98WI23 Date: 1998-10-15 GLP: yes not published
IIA 4.2.3	Williams, R. W.	1998	Analytical method AG-688 for the determination of CGA-279202 and its metabolites CGA-373466, CGA-321113, CGA-357261, CGA-357262 and CGA-331409 in water and sediment by liquid chromatography with mass spectrometric detection, including validation data. Method No. AG-688 Date: 1998-10-09

Plant Protection Product: 'Twist'

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
AIII 2.7.3	Kundel, P.	1999a	Report on product stability (A 9604 A). MO-01 009354 Date: 1999-07-19
AIII 2	Kundel, P.	1999b	Sprayerbility study with A 9604 A. MO-01-015844

Plant Protection Product: 'Flint'

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
AIII 2.7.3	Kundel, P.	1999	Report on product stability (A 9360 B). MO-01009381 Date: 1999-07-23

B.6 Toxicology and metabolism

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIA, 5.8.1	Altmann, A.	2000	NOA 413161 tech. (metabolite of CGA 279202 tech.) - 28-day subacute oral toxicity study in rats (gavage) Novartis Crop Protection AG, Stein, Switzerland Bayer AG, Rep. No. 993090, Date: 30.03.2000 GLP, unpublished
AII 5.3.1	Bachmann M	1999	28 Days Subacute, Oral Toxicity Study in Rats (Gavage). Report CA 2446/0014. 30.6.99 GLP: yes not published
AII 5.2.3	Biedermann K and Decker U	1998	4-hour acute inhalation toxicity study in rats. Report CA 2446/0006. 10.9.98 GLP: yes not published
AII 5.2.4	Cantoreggi S	1998	Acute dermal irritation/corrosion in the rabbit. Report CA 2446/0001. 1.7.98 GLP: yes not published
AII 5.2.5	Cantoreggi S	1998	Acute eye irritation/corrosion in the rabbit. Report CA 2446/0002. 3.7.98 GLP: yes not published
AII 5.2.1	Cantoreggi S	1998	Acute oral toxicity in the rat (limit test). Report CA 2446/0003. 9.7.98 GLP: yes not published
AII 5.2.2	Cantoreggi S	1998	Acute dermal toxicity in the rat (limit test). Report CA 2446/0004. 20.8.98 GLP: yes not published

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
AII 5.2.6	Cantoreggi S	1998	Skin sensitization in the guinea pig (maximization test). Report CA 2446/0005. 18.8.98 GLP: yes not published
AII 5.4.1	Deparade E	1998	Salmonella and Escherichia/mammalian-microsome mutagenicity test. Report CA 2446/0007. 16.9.98 GLP: yes not published
AII 5.4.1	Deparade E	2000	Salmonella and escherichia/mammalian-microsome mutagenicity test. Report CGA 289998/0002. 13.4.00 GLP: yes not published
IIA, 5.3 /01	Freyberger, A.	2002	Effects of trifloxystrobin (CGA 279202) and its metabolites CGA 321113, CGA 373466, NOA 413161 and NOA 413163 on succinate-supported rat liver mitochondrial respiration. Bayer AG, Report No. 31746 Date: 2002-02-06 non-GLP, unpublished
5.3 /03	Herbold, B.	2002c	CGA 279202 - CGA 373466 - V79/HPRT-test in vitro for the detection of induced forward mutations. Bayer AG, Report No. 31962 Date: 2002-04-14 GLP, unpublished
IIA, 5.3 /04	Herbold, B.	2002a	CGA 279202-NOA 413161/413163 - V79/HPRT-test in vitro for the detection of induced forward mutations. Bayer AG, Report No. 32150 Date: 2002-07-02 GLP, unpublished
IIA, 5.3 /05	Herbold, B.	2002d	CGA 279202-CGA 373466 - In vitro chromosome aberration test with chinese hamster V79 cells Bayer AG; Report No. 31961 Date: 2002-04-17 GLP, unpublished
IIA, 5.3 /06	Herbold, B.	2002b	CGA 279202-NOA 413161/413163 - In vitro chromosome aberration test with chinese hamster V79 cells Bayer AG, Report No. 32151 Date: 2002-07-02 GLP, unpublished

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIA, 5.4 /01	Heimann, K.G.	2001	Refined threshold approach for metabolites of Trifloxystrobin Bayer AG, Report No. MO-01-022159 Date: 2001-12-14 non-GLP, unpublished
AII 5.4.1	Ogorek B	1998	Cytogenetic test on chinese hamster cells in vitro. Report CA 2446/0013. 2.12.98 GLP: yes not published
IIA, 5.8.1	Ogorek, B.	1999	Cytogenetic Test on Chinese Hamster Cells in Vitro Novartis Crop Protection AG Bayer AG, Test Number: 993094, 1 Date: 3.12.1999 GLP, unpublished
IIA, 5.8.1	Ogorek, B.	2000	Gene Mutation Test with Chinese Hamster Cells V79 Novartis Crop Protection AG Bayer AG, Rep. No.: 993095, Date: 25.04.2000 GLP, unpublished
AII 5.2.1	Sommer E	2000	Acute Oral Toxicity in the Rat (Limit Test). Report CGA 289999/0001. 30.3.00 GLP: yes not published
IIA, 5.3 /02	Wasinska-Kempka, G.	2002	Investigation of the hepatotoxic potential of trifloxystrobin and its metabolites on primary rat hepatocytes in an in vitro model. Bayer AG, Report No. 31822 Date: 2002-03-01 non-GLP, unpublished

B.7 Residues

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIA 6	Grunenwald, M. C.	1999a	Stability of CGA-279202 and CGA-321113 in crops and processed fractions under freezer storage conditions. Report:160-97 Date: 1999-01-21
IIA 6	Grunenwald, M. C.	1999b	Stability of CGA-279202 and CGA-321113 in meat, milk, and eggs under freezer storage conditions. Report: 301-97 Date: 1999-01-21

IIA 6	Kissling, M.	1999	Stability of residues of CGA-279202 and its metabolite CGA-321113 in deep freeze stored analytical specimens of grapes, cucumber, potatoes and wheat (whole plant, grains and straw). Report: 154/96 Date: 1999-01-06

B.8 Environmental fate and behaviour

Annex point/ reference number	**Author(s)**	**Year**	**Title** **Source (where different from company)** **Company, Report No.** **GLP or GEP status (where relevant)** **Published or not**
IIA, 7.1.2	Adam, D.	2000	Adsorption / desorption of NOA 413161 in Borstel soil Syngenta Crop Protection, Basel, Switzerland Bayer AG, Report No. 00DA09 Date: 2000-12-13 GLP, unpublished
IIA, 7.1.2	Glänzel, A.	2000a	Adsorption / Desorption of CGA 321113 in Borstel soil Source: Novartis crop protection AG, Basel, Switzerland Bayer AG, Report No. 00AG06 Date: 2000-12-12 GLP, unpublished
IIA, 7.1.2	Glänzel, A.	2000b	Adsorption/desorption of CGA 279202 in Borstel soil. Syngenta Crop Protection, Basel, Switzerland Bayer AG, Report No. 00AG05 Date: 2000-12-12 GLP, unpublished
IIA, 7.1.2	Heim, L.G.; Velagaleti, R.	1997	Adsorption-desorption of [phenyl (B)-U-^{14}C]-CGA-373466 in soil Source: Novartis Crop Protection, Switzerland Bayer AG, Report No. 397-96 Date: 1997-11-22 GLP, unpublished
IIA, 7.1.1.1	Mamouni, A.	2001a	Degradation and metabolism of [glyoxyl-phenyl-U-^{14}C]-labelled CGA 321113 in soil Borstel incubated under aerobic conditions at 20 °C Source: Novartis crop protection AG, Basel, Switzerland Bayer AG, Report No. 792606 Date: 2001-08-20 GLP, unpublished
IIA, 7.1.1.1	Mamouni, A.	2001b	Degradation and metabolism of CGA 279202 in one soil incubated under aerobic conditions RCC Ltd., Switzerland Bayer AG, Report No. 777914 Date: 2001-08-20 GLP, unpublished

Annex point/ reference number	**Author(s)**	**Year**	**Title** **Source (where different from company)** **Company, Report No.** **GLP or GEP status (where relevant)** **Published or not**
IIA, 7.1.3	Nicollier, G	2001	[Glyoxyl-phenyl-(U)-^{14}C]-CGA 279202: Mobility and degradation in soil in outdoor lysimeters Source: Syngenta crop protection, Basel, Switzerland; Bayer AG, Report No. 97GN01 Date: 2001-07-13 GLP, unpublished
IIA, 7.1.1.1	Reischmann, F.-J.	2001	Degradation of [glyoxyl-phenyl-U-^{14}C]-labelled NOA 413161 in soil Borstel under aerobic conditions at 20 °C. Syngenta Crop Protection, Basel, Switzerland Bayer AG, Report No. 00MO09 Date: 2001-07-19 GLP, unpublished
IIA, 7.1.1.2	Schäfer, H	2001a	Calculation of DT50 values of CGA 279202 and its metabolites CGA 321113 and CGA 373466 in soil Bayer AG, Report No. MR-329/01 Date: 2001-07-31 unpublished
AII, 7.1.3.3	Schäfer, H.	2001b	Predicted environmental concentration of trifloxystrobin (CGA 279202) and its metabolites CGA 321113 and CGA 373466 in ground water recharge based on PELMO – use in different crops in Northern and Southern Europe. Bayer AG, Report No. MR-365/01 Date: 2001-07-31 unpublished
AII, 7.1.3.3	Schäfer, H.	2001c	Extrapolation of results of a lysimeter study conducted with trifloxystrobin to Dutch environmental conditions using PEARL Bayer AG, Report No. MR-456/01 Date: 2001-09-17 unpublished
AIII, 7.1.3.3	Schäfer, H.	2001d	Estimation of potential amounts of trifloxystrobin metabolites entering fields via irrigation water; Bayer AG, Report No. MR-520/01, Date: October 26, 2001 Unpublished
AII, 7.1.3.3	Schaefer, H.	2002a	Characterisation of the environmental behaviour of metabolites of trifloxystrobin (CGA279202) based on results of a lysimeter study Bayer AG, report No. MR-384/02 Date: 2002-09-23 non-GLP, unpublished
AII, 7.1.3.3	Schaefer, H.	2002b	Predicted environmental concentrations of trifloxystrobin (CGA279202) and its metabolites in ground water recharge based on PEARL Bayer AG, report No. MR-399/02 Date: 2002-09-24 non-GLP, unpublished

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
AII, 7.1.3.3	Schaefer, H.	2002c	Predicted environmental concentrations of trifloxystrobin (CGA279202) and its metabolites in ground water recharge based on PEARL (new use pattern) Bayer AG, report No. MR-398/02 Date: 2002-09-24 non-GLP, unpublished
IIA, 7.1.1.2.2	Tribolet, R.	1999	Residue study with CGA 279202 in soil in Italy Source: Novartis crop protection AG, Basel, Switzerland Bayer AG, Report No. 2046/97 Date: 1999-01-29 GLP, unpublished

B.9 Ecotoxicology

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
AII; 8.6	Anderson, J.P.E.	2001a	Influence of Trifloxistrobin – CGA 321113 on Growth of Pure Cultures of a Soil Fungus, *Mucor circinelloides* (Order Zygomycetes), on Nutrient Medium, Bayer AG, Report No. AJO/221901, Date: July 04, 2001 GLP, unpublished
AII; 8.6	Anderson, J.P.E.	2001b	Influence of Trifloxistrobin – CGA 321113 on Growth of Pure Cultures of a Soil Fungus, *Penicillium janthinellum* (Order Ascomycetes), on Nutrient Medium, Bayer AG, Report No. AJO/222001, Date: July 04, 2001 GLP, unpublished
AII; 8.6	Anderson, J.P.E.	2001c	Influence of Trifloxistrobin – CGA 321113 on Growth of Pure Cultures of a Soil Fungus, *Cladorrhinum foecundissimum* (Order Deuteromycetes), on Nutrient Medium, Bayer AG, Report No. AJO/222101, Date: July 04, 2001 GLP, unpublished
AII; 8.6	Anderson, J.P.E.	2001d	Influence of Trifloxistrobin – CGA 321113 on Growth of Pure Cultures of a Soil Fungus, *Suillus granulatus* (Order Basidiomycetes), on Nutrient Medium, Bayer AG, Report No. AJO/222201, Date: July 04, 2001 GLP, unpublished
AII; 8.6	Anderson, J.P.E.	2001e	Influence of Trifloxistrobin – CGA 321113 on Growth of Pure Cultures of a Soil Fungus, *Phytophthora nicotianae* (Order Oomycetes), on Nutrient Medium, Bayer AG, Report No. AJO/222301, Date: July 04, 2001 GLP, unpublished
IIA, 8.6	Anderson, J.P.E.	2001f	Influence of Trifloxystrobin-NOA 413161 on Growth of Pure Cultures of a Soil Fungus, *Mucor circinelloides* (Order Zygomycetes), on Nutrient Medium, Bayer AG, Report No. AJO/222401, Date: August 15, 2001 GLP, unpublished
IIA, 8.6	Anderson, J.P.E.	2001g	Influence of Trifloxystrobin-NOA 413161 on Growth of Pure Cultures of a Soil Fungus, *Cladorrhinum foecundissimum* (Order Deuteromycetes), on Nutrient Medium, Bayer AG, Report No. AJO/222601, Date: August 15, 2001 GLP, unpublished

Annex point/ reference number	**Author(s)**	**Year**	**Title** **Source (where different from company)** **Company, Report No.** **GLP or GEP status (where relevant)** **Published or not**
IIA, 8.6	Anderson, J.P.E.	2001h	Influence of Trifloxystrobin-NOA 413161 on Growth of Pure Cultures of a Soil Fungus, *Suillus granulatus* (Order Basidiomycetes), on Nutrient Medium, Bayer AG, Report No. AJO/222701, Date: August 15, 2001 GLP, unpublished
IIA, 8.6	Anderson, J.P.E.	2001i	Influence of Trifloxystrobin-NOA 413161 on Growth of Pure Cultures of a Soil Fungus, *Phytophthora nicotianae* (Order Oomycetes), on Nutrient Medium, Bayer AG, Report No. AJO/222801, Date: August 15, 2001 GLP, unpublished
AII, 8.2.1	Knauer, K	1999	Acute toxicity of leachate from lysimeter (No. 5 and 6, Project 95GN01) treated with CGA279202 to Zebra fish *Brachydanio rerio* in a static system. Source: Novartis Services AG, Basel, Switzerland; Bayer AG, Report No. 993532 Date: 1999-09-28 non-GLP, unpublished
AII, 8.2.4	Knauer, K	2000	Acute toxicity of leachate from lysimeter (No. 5 and 6, Project 95GN01) treated with CGA279202 to Cladoceran *Daphnia magna* STRAUSS in a static system. Source: Novartis Services AG, Basel, Switzerland; Bayer AG, Report No. 993531 Date: 2000-01-25 non-GLP, unpublished

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
AII, 8.4.1	Meisner, P.	2001a	Acute Toxicity of Trifloxystrobin - CGA 321113 to Earthworms (*Eisenia fetida*). Bayer AG, report No.: MPE/Rg 384/01, Date: September 18, 2001 GLP, unpublished
AII, 8.4.1	Meisner, P.	2001b	Acute Toxicity of Trifloxystrobin - CGA 373466 to Earthworms (*Eisenia fetida*). Bayer AG, report No.: MPE/Rg 381/01, Date: September 10, 2001 GLP, unpublished
IIA, 8.4.1	Meisner, P.	2001c	Acute Toxicity of Trifloxystrobin - NOA 413161 to Earthworms (*Eisenia fetida*). Bayer AG, report No.: MPE/Rg 382/01, Date: September 13, 2001 GLP, unpublished
IIA, 8.4.1	Meisner, P.	2001d	Acute Toxicity of Trifloxystrobin - NOA 413163 to Earthworms (*Eisenia fetida*). Bayer AG, report No.: MPE/Rg 383/01, Date: September 13, 2001 GLP, unpublished
AII, 8	Moser, Th., Scheffczyk, A.	2002	Acute and reproduction toxicity of CGA 321113 to the collembolan species *Folsomia candida* according to the ISO guideline 11267 “Soil quality - inhibition of reproduction of Collembola (*Folsomia candida*) by soil pollutants” (1999) Source: ECT, Flörsheim, D Bayer AG, Report No.: P25CR Date: January 10, 2002; GLP, unpublished
AII, 8	Moser, Th., Scheffczyk, A.	2002	Acute and reproduction toxicity of NOA 413161 to the collembolan species *Folsomia candida* according to the ISO guideline 11267 “Soil quality - inhibition of reproduction of Collembola (*Folsomia candida*) by soil pollutants” (1999) Source: ECT, Flörsheim, D Bayer AG, Report No.: P26CR Date: January 10, 2002; GLP, unpublished
AII, 8.6	Nienstedt, K.M.	2002	CGA 279202-NOA 413161: Seedling emergence test with *Avena sativa* (oat), *Allium cepa* (common onion), *Brassica napus* (oilseed rape), *Gylcine max* (soybean), *Lactuca sativa* (lettuce), and *Beta vulgaris* (sugar beet); Source: Springborn Europe AG, Horn, CH Bayer AG, Report No.: 1022.022.600 Date: January 28, 2002; GLP, unpublished

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
AII, 8.6	Spatz, B.	2001	Effects of CGA 279202-CGA 321113 on terrestrial (non-target) plants: Seedling emergence and seedling growth test; Source: IBACON, Rossdorf, D Bayer AG, Report No.: 11111086 Date: December 13, 2001; GLP, unpublished
AII, 8.6	Wälder, L.	2000	Herbicide profiling test to evaluate the phytotoxicity of CGA 279202 125 EC (A-9604 A) to terrestrial non-target higher plants; Source: Novartis Crop Protection AG, Stein, CH; Bayer AG, report No. 25; Date: February 28, 2000 non-GLP, unpublished

APPENDIX IV

List of uses supported by available data

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hl min max	water l/ha min max	kg as/ha min max		
Wheat	EU-N/S	A-9604	F	Foliar diseases	EC	125 g/l	foliar	BBCH 71	min. 1 max. 2	3 - 4 weeks	0.005 0.0025	100 - 500	0.25	35	
Barley	EU-N/S	A-9604	F	Foliar diseases	EC	125 g/l	foliar	BBCH 71	min. 1 max. 2	3 - 4 weeks	0.005 0.0025	100 - 500	0.25	35	
Grapes	EU-N/S	FLINTA-9360	F	Foliar diseases	WG	500 g/kg	foliar	BBCH 85	max. 4	7 - 14 days	0.0125	300 - 1500	0.1875	35	
Apples/ Pears	EU-N/S	FLINTA-9360	F	Foliar diseases	WG	500 g/kg	foliar	BBCH 85	max. 6	7 - 14 days	0.005 0.0375 - 0.0075	1500 200 - 1000	0.075 0.075	14 14	
Cucumber/ Zucchini	EU-N/S	FLINTA-9360	F	Foliar diseases	WG	500 g/kg	foliar	BBCH 89	min. 3 max. 5	7 - 14 days	0.00625 - 0.0125	500 - 1500	0.1875	3	
Melon	EU-N/S	FLINTA-9360	F	Foliar diseases	WG	500 g/kg	foliar	BBCH 89	min. 3 max. 5	7 - 14 days	0.00625 - 0.0125	500 - 1000	0.125	3	

Remarks:
(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(i) g/kg or g/l
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) The minimum and maximum number of application possible under practical conditions of use must be provided
(l) PHI - minimum pre-harvest interval

(g) Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench

(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated

(m) Remarks may include: Extent of use/economic importance/restrictions