

REASONED OPINION

Reasoned opinion on the modification of the existing MRL for trifloxystrobin in beans with pods¹

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ABSTRACT

In accordance with Article 6 of Regulation (EC) No 396/2005, Germany, hereafter referred to as the Evaluating Member State (EMS), received an application from the Landwirtschaftskammer Nordrhein-Westfalen to modify the existing MRL for trifloxystrobin in beans with pods. In order to accommodate for the intended use of trifloxystrobin Germany proposed to raise the existing MRL on beans (with pods) from the value of 0.5 mg/kg to 1 mg/kg. Germany drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005 which was submitted to the European Commission and forwarded to EFSA. According to EFSA the data are sufficient to derive a MRL proposal of 1.0 mg/kg for the intended use on beans with pods. Adequate analytical enforcement methods are available to control the residues of trifloxystrobin in the commodity under consideration. Based on the provisional risk assessment results, EFSA concludes that the intended use of trifloxystrobin on beans with pods will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a consumer health risk.

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KEY WORDS

Trifloxystrobin, beans with pods, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, strobilurin fungicide, CGA 321113.

¹ On request from European Commission, Question No EFSA-Q-2012-00784, approved on 16 April 2013.

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SUMMARY

In accordance with Article 6 of Regulation (EC) No 396/2005, Germany, hereafter referred to as the Evaluating Member State (EMS), received an application from the Landwirtschaftskammer Nordrhein-Westfalen to modify the existing MRL for trifloxystrobin in beans with pods. In order to accommodate for the intended use of trifloxystrobin Germany proposed to raise the existing MRL on beans (with pods) from the value of 0.5 mg/kg to 1 mg/kg. Germany drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005 which was submitted to the European Commission and forwarded to EFSA on 3 September 2012.

EFSA bases its assessment on the evaluation reports, the Draft Assessment Report (DAR) prepared under Council Directive 91/414/EEC, the Commission Review Report on trifloxystrobin, the JMPR Evaluation report as well as the conclusions from previously issued EFSA reasoned opinions on the modification of the existing MRLs for trifloxystrobin.

The toxicological profile of trifloxystrobin was assessed in the framework of the peer review under Council Directive 91/414/EEC and the data were sufficient to derive an ADI of 0.1 mg/kg bw per day. No ARfD was deemed necessary.

The metabolism of trifloxystrobin in primary crops was investigated after foliar applications on apples, cucumbers (fruits and fruiting vegetables) and wheat (cereals) in the framework of the peer review under Council Directive 91/414/EEC and the residue definition for enforcement and risk assessment was set as parent trifloxystrobin. The Joint FAO/WHO Meeting on Pesticide Residues (JMPR), who assessed a metabolism study on peanuts (pulses and oilseeds), concluded that trifloxystrobin shows a similar metabolic behaviour as in wheat. Based on the findings from a metabolism study in sugar beet (roots and tuber vegetables) and the residue trials on leafy and root vegetables, where significant residues of the metabolite CGA 321113 were observed, EFSA has recommended in previously issued reasoned opinions to consider the inclusion of this metabolite in a revised risk assessment residue definition for plant commodities. Since the residue data indicated that metabolite CGA 321113 is not found in beans with pods, EFSA concludes that the residue definitions for enforcement and risk assessment as agreed in the peer review are provisionally applicable. EFSA proposes that the inclusion of the metabolite CGA 321113 in the risk assessment residue definition for plant commodities should be further discussed in the framework of Article 12 of Regulation (EC) No 396/2005.

EFSA concludes that the submitted supervised residue trials are sufficient to derive a MRL proposal of 1.0 mg/kg for the intended use on beans with pods. Adequate analytical enforcement methods are available to control the residues of trifloxystrobin in the commodity under consideration at the validated LOQs of 0.01 to 0.02 mg/kg.

Trifloxystrobin is hydrolytically stable under conditions simulating pasteurisation, but showed minor degradation under baking/brewing/boiling conditions and significant degradation under sterilisation. The main degradation product was the metabolite CGA 321113. Thus, this metabolite should be considered in the risk assessment for processed commodities which have undergone sterilisation process. Specific studies to assess the magnitude of trifloxystrobin residues during the processing of beans with pods are not necessary as the residue levels in raw agricultural commodities (RAC) did not exceed the trigger value of 0.1 mg/kg.

The occurrence of trifloxystrobin and its metabolites in rotational crops was investigated in the framework of the peer review. Based on the available information on the nature of residues in succeeding crops EFSA concludes that significant residue levels are unlikely to occur in rotational crops provided that the compound is used on beans with pods according to the intended GAP (Good Agricultural Practice).

Residues of trifloxystrobin in commodities of animal origin were not assessed in the framework of this application since beans with pods are normally not fed to livestock.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). For the calculation of chronic exposure, EFSA used the median residue value as derived from the residue trials on beans with pods and the median residue value reported for crops that were assessed in previously issued EFSA reasoned opinions. For certain crops these values were multiplied by conversion factors (CF) to cover in the risk assessment the relevant amounts of the metabolite CGA 321113 that were observed in the residue trials. For the remaining commodities of plant and animal origin, the existing MRLs as established in Annexes II and IIIB of Regulation (EC) No 396/2005 were used as input values. No acute consumer exposure was performed due to the low acute toxicity of the active substance.

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake accounted for up to 22.7 % of the ADI (FR all population diet). The contribution of residues in the crop under consideration to the total consumer exposure accounted for a maximum of 0.22 % of the ADI (FR toddler diet).

EFSA concludes that the intended use of trifloxystrobin on beans with pods will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a consumer health risk. The risk assessment has to be regarded as provisional, pending the decision for inclusion of the metabolite CGA 321113 in the residue definition for risk assessment and for CFs from enforcement to risk assessment for all authorised uses of trifloxystrobin.

Thus EFSA proposes to amend the existing MRLs as reported in the summary table.

Summary table

Code number ^(a)	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: Trifloxystrobin (F)				
0260010	Beans with pods	0.5	1.0	The MRL proposal is sufficiently supported by data and no consumer health risk was identified for the intended use.

(a): According to Annex I of Regulation (EC) No 396/2005.

(F): Fat-soluble pesticide.

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BACKGROUND

Regulation (EC) No 396/2005³ establishes the rules governing the setting of pesticide MRLs at European Union level. Article 6 of that Regulation lays down that any party having a legitimate interest or requesting an authorisation for the use of a plant protection product in accordance with Council Directive 91/414/EEC⁴, repealed by Regulation (EC) No 1107/2009⁵, shall submit to a Member State, when appropriate, an application to set or to modify a MRL or to set an import tolerance in accordance with the provisions of Article 7 of that Regulation.

Germany, hereafter referred to as the Evaluating Member State (EMS), received an application from the Landwirtschaftskammer Nordrhein-Westfalen⁶ to modify the existing MRL for the active substance trifloxystrobin in beans with pods. This application was notified to the European Commission and EFSA and was subsequently evaluated by the EMS in accordance with Article 8 of the Regulation.

After completion, the evaluation report was submitted to the European Commission who forwarded the application, the evaluation report and the supporting dossier to EFSA on 3 September 2012.

The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2012-00784 and the following subject:

Trifloxystrobin - Application to modify the existing MRL in beans with pods

The EMS proposed to raise the existing MRL for trifloxystrobin in beans with pods from 0.5 mg/kg to 1 mg/kg.

EFSA proceeded with the assessment of the application and the evaluation report as required by Article 10 of the Regulation.

TERMS OF REFERENCE

In accordance with Article 10 of Regulation (EC) No 396/2005, EFSA shall, based on the evaluation report provided by the evaluating Member State, provide a reasoned opinion on the risks to the consumer associated with the application.

In accordance with Article 11 of that Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within three months (which may be extended to six months where more detailed evaluations need to be carried out) from the date of receipt of the application. Where EFSA requests supplementary information, the time limit laid down shall be suspended until that information has been provided.

In this particular case the deadline for providing the reasoned opinion is 3 December 2012.

³ Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005. OJ L 70, 16.03.2005, p. 1-16.

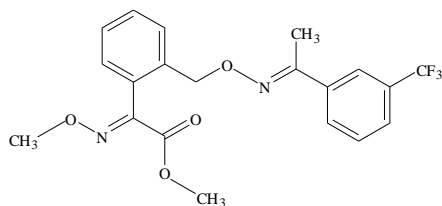
⁴ Council Directive 91/414/EEC of 15 July 1991. OJ L 230, 19.08.1991, p. 1-32.

⁵ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009. OJ L 309, 24.11.2009, p. 1-50.

⁶ Landwirtschaftskammer Nordrhein-Westfalen, Siebengebirgsstraße 200, DE-53229 Bonn, Germany.

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Trifloxystrobin is the ISO common name for methyl (*E*)-methoxyimino-{(*E*)- α -[1-(α,α,α -trifluoro-*m*-tolyl)ethylideneaminoxy]-*o*-tolyl}acetate (IUPAC). The chemical structure of the compound is reported below.



Molecular weight: 408.4 g/mol

Trifloxystrobin is a fungicide belonging to the group of strobilurin chemical compounds. Trifloxystrobin adheres to plants, continuously distributes across the plant surface and small quantities also penetrate gradually into the leaf tissue. The mode of action of trifloxystrobin involves inhibition of mitochondrial respiration in fungi.

Trifloxystrobin was evaluated in the framework of Council Directive 91/414/EEC with the United Kingdom designated as rapporteur Member State (RMS). It was included in Annex I of this Directive by Commission Directive 2003/68/EC⁷ which entered into force on 1 October 2003 for use as a fungicide. In accordance with Commission Implementing Regulation (EU) No 540/2011⁸ trifloxystrobin is approved under Regulation (EC) No 1107/2009, repealing Council Directive 91/414/EEC. The representative uses evaluated during the peer review were foliar applications on grapes, apples, cucumber, wheat, barley and melons. The draft assessment report (DAR) on the active substance trifloxystrobin was not peer reviewed by EFSA and therefore no EFSA conclusion is available.

The EU MRLs for trifloxystrobin are established in Annexes II and IIIB of Regulation (EC) No 396/2005 (Appendix C). EFSA recommendations to modify the existing MRLs on various crops (EFSA, 2008, 2009a, 2009b, 2010, 2011, 2012) have been implemented in five Regulations adopted between 2009 and 2013. The existing EU MRL for trifloxystrobin in beans with pods is set at 0.5 mg/kg. The review of the existing MRLs for that active substance in compliance with Article 12 of the aforementioned Regulation is in progress. The Pesticide Residue Overview File (PROFile) for trifloxystrobin was completed on 12 November 2012. Codex Alimentarius has established CXLs for a wide range of commodities, but no CXL have been set for the crop under consideration.

The details of the intended GAP of trifloxystrobin on beans with pods are given in Appendix A.

⁷ Commission Directive 2003/68/EC of 11 July 2003. OJ L 177, 16.07.2003, p. 12-16.

⁸ Commission Implementing Regulation (EU) No 540/2011 of 23 May 2011. OJ L 153, 11.06.2011, p. 1-186.

ASSESSMENT

EFSA bases its assessment on the evaluation report submitted by the EMS (Germany, 2012), the Draft Assessment Report (DAR) prepared under Council Directive 91/414/EEC (United Kingdom, 2000), the Commission Review Report on trifloxystrobin (EC, 2003), the JMPR Evaluation report (FAO, 2004) as well as the conclusions from previously issued EFSA reasoned opinions on the modification of the existing MRLs for trifloxystrobin (EFSA, 2008, 2009a, 2009b, 2010, 2011, 2012). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011⁹ and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (EC, 1996, 1997a, 1997b, 1997c, 1997d, 1997e, 1997f, 1997g, 2000, 2010a, 2010b, 2011; OECD, 2011).

1. Method of analysis

1.1. Methods for enforcement of residues in food of plant origin

Analytical methods for the determination of trifloxystrobin residues in plant commodities were assessed during the peer review under Council Directive 91/414/EEC and in the previously issued EFSA reasoned opinions on the modification of the existing MRLs for trifloxystrobin (United Kingdom, 2000; EFSA, 2011, 2012). Sufficiently validated analytical methods to determine trifloxystrobin and its metabolite CGA 321113¹⁰ in plant matrices with high water, high acid content and dry commodities at the LOQ of 0.02 mg/kg for each analyte are available.

The multi-residue QuEChERS method described in the European Standard EN 15662:2008 is also applicable. The liquid chromatography coupled with tandem mass spectrometry detection (LC-MS/MS) method analyses trifloxystrobin residues in matrices with high water, high acid and dry content at the LOQ of 0.01 mg/kg (CEN, 2008).

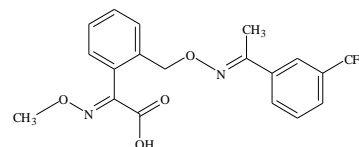
Since the commodity under consideration belongs to the group of high water content commodities, EFSA concludes that sufficiently validated analytical methods for enforcing the proposed MRLs for trifloxystrobin on beans with pods are available.

1.2. Methods for enforcement of residues in food of animal origin

Analytical methods for the determination of residues in food of animal origin were not assessed in the current application since beans with pods are normally not fed to livestock.

⁹ Commission Regulation (EU) No 546/2011 of 10 June 2011. OJ L 155, 11.06.2011, p. 127-175.

¹⁰ CGA 321113: (*E,E*)-trifloxystrobin acid or (*E,E*)-methoxyimino-{2-[1-(3-trifluoromethyl-phenyl)-ethylideneamino-oxymethyl]-phenyl}-acetic acid. Molecular weight: 394.0 g/mol.



2. Mammalian toxicology

The toxicological profile of the active substance was assessed in the framework of the peer review under Council Directive 91/414/EEC (United Kingdom, 2000; EC, 2003). The data were sufficient to derive toxicological reference values for trifloxystrobin which are compiled in Table 2-1.

Table 2-1: Overview of the toxicological reference values

	Source	Year	Value	Study relied upon	Safety factor
Trifloxystrobin					
ADI	EC	2003	0.1 mg/kg bw per day	2-yr toxicity rat study	100
ARfD	EC	2003	Not necessary.		

According to the RMS the toxicity of the metabolite CGA 321113, which is observed in relevant amounts in certain products of plant origin, in the products of animal origin and during product sterilisation, is covered by the toxicological reference value derived for the parent compound (United Kingdom, 2000).

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

The metabolism of trifloxystrobin after foliar applications in primary crops has been investigated in apples, cucumbers, wheat and sugar beet and the details of the metabolism studies are given in the previously issued EFSA reasoned opinion (EFSA, 2011). A metabolism study in peanuts was assessed by the JMPR (FAO, 2004).

The metabolism of trifloxystrobin (*E/E* isomer) in primary crops was complex and mainly proceeded via *cis/trans* isomerisation (*Z/E* isomer, *Z/Z* isomer, *E/Z* isomer) and cleavage of the methyl ester group to form the metabolite (*E,E*)-methoxyimino-{2-[1-(3-trifluoromethyl-phenyl)-ethylideneamino-oxymethyl]-phenyl}-acetic acid (CGA 321113). Trifloxystrobin was the major component of residues in all crops investigated, except peanut kernels¹¹. Metabolites, including CGA 321113, were below the trigger value of 10 % of TRR in all samples of wheat, apples, cucumbers, peanuts and sugar beet leaves and tops, with the exception of sugar beet roots. In sugar beet root two metabolites were at levels exceeding the trigger value: the metabolite II_{19a}¹² accounted for 20 % of the TRR (at 0 DALA) and 15 % of TRR (at 45 DALA); the metabolite CGA 321113 accounted for 11 % of TRR (at 21 and 45 DALA).

The peer review assessed the metabolism on fruits and fruiting vegetables and cereals. The conclusion was that the metabolism proceeded according to a similar pathway and that the residue definition for monitoring and risk assessment should comprise the parent compound only for these crop groups (United Kingdom, 2000). JMPR concluded that the metabolism of trifloxystrobin in peanuts was similar to the metabolism observed in wheat. The metabolism study on sugar beet was submitted in the framework of the MRL application, after the conclusion of the peer review under Council Directive 91/414/EEC (EFSA, 2009a).

¹¹ Trifloxystrobin represented about 2 % of the TRR and an extensive formation of composed triglycerides was observed in the residues (FAO, 2004).

¹² II_{19a}: {2-[1-(2,3-dihydroxy-5-methyl-phenyl)-2-hydroxy-ethylideneamino-oxymethyl]-phenyl}-methoxy-imino acetic acid.

Based on the findings from the metabolism study in root and tuber vegetables and the residue trials on leafy and root vegetables (Brussels sprouts, head cabbage, celery, leek, turnip, swedes, salsify, parsnip, parsley root), where the metabolite CGA 321113 occurred even at higher levels than parent trifloxystrobin, EFSA has recommended in previously issued reasoned opinions to consider the possible inclusion of this metabolite in a revised risk assessment residue definition for plant commodities (EFSA, 2009a, 2009b, 2012).

Since the residue data indicated that the metabolite CGA 321113 is not found in beans with pods, EFSA concludes that the residue definitions for enforcement and risk assessment as agreed in the peer review are provisionally applicable to the crop under consideration. The current residue definition set in Regulation (EC) No 396/2005 is identical to the residue definition for enforcement derived in the peer review. EFSA proposes that the inclusion of the metabolite CGA 321113 in the risk assessment residue definition for plant commodities should be further discussed in the framework of Article 12 of Regulation (EC) No 396/2005.

3.1.1.2. Magnitude of residues

A total of eight trials performed on beans with pods over two seasons in the northern part of France and in Germany were considered as representative of the intended GAP despite minor deficiencies¹³. Four samples¹⁴ were analysed for the metabolite CGA 321113 and the residues at harvest were below the LOQ of 0.02 mg/kg. The residue trials indicate that a MRL of 1.0 mg/kg would be sufficient to support the intended use on trifloxystrobin on beans with pods in Germany.

The results of the residue trials, the related risk assessment input values (highest residue, median residue) and the tentative MRL proposal are summarised in Table 3-1.

The storage stability of trifloxystrobin and the metabolite CGA 321113 in primary crops was investigated in the DAR prepared under Council Directive 91/414/EEC (United Kingdom, 2000). Residues of trifloxystrobin and CGA 321113 were stable in water content matrices for up to 2 years under deep frozen conditions. The supervised residue trial samples were stored within this period of time. EFSA concludes that the residue data are to be considered valid with regard to storage stability.

According to the EMS, the analytical methods used to analyse the supervised residue trial samples have been sufficiently validated and were proven to be fit for the purpose (Germany, 2012).

EFSA concludes that the data are sufficient to derive a MRL of 1.0 mg/kg for the intended use on beans with pods in Germany.

¹³ The 2nd application occurred at the later growth stage of fruit development (BBCH 72 to 77) and a different formulation (water dispersible granule, WG) was applied in two trials.

¹⁴ Samples collected from two GAP-compliant (see Table 3-1) and two non GAP-compliant trials.

Table 3-1: Overview of the available residues trials data

Commodity	Residue region (a)	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) (b)	Highest residue (mg/kg) (c)	MRL proposal (mg/kg)	Media n CF (d)	Comments (e)
			Enforcement (Trifloxystrobin)	Risk assessment (Trifloxystrobin, <i>provisional</i>)					
Enforcement residue definition: Trifloxystrobin									
Beans with pods	NEU	Outdoor	0.06; 0.07; 0.08; 0.16; 0.23; 0.29; 0.50; 0.51 <i>CGA 321113:</i> 2 x <0.02; 6 x n.a.	0.06; 0.07; 0.08; 0.16; 0.23; 0.29; 0.50; 0.51	0.20	0.51	1.0	1.0	R _{ber} = 0.90 R _{max} = 0.82 MRL _{OECD} = 0.97/1.0

(a): NEU (Northern and Central Europe), SEU (Southern Europe and Mediterranean), EU (*i.e.* indoor use) or Import (country code) (EC, 2011).

(b): Median value of the individual trial results according to the enforcement residue definition.

(c): Highest value of the individual trial results according to the enforcement residue definition.

(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residue trial.

(e): Statistical estimation of MRLs according to the EU methodology (R_{ber}, R_{max}; EC, 1997g) and unrounded/rounded values according to the OECD methodology (OECD, 2011).

n.a.= not analysed.

3.1.1.3. Effect of industrial processing and/or household preparation

The effect of processing on the nature of trifloxystrobin was evaluated in the DAR under a range of pH (1-13) at temperatures of 25-60 °C. The compound was hydrolytically stable at pH 5 regardless of the temperature, whereas in neutral and alkaline conditions, CGA 321113 was the major metabolite (United Kingdom, 2000). A hydrolysis study performed at three test conditions (20 minutes at 90°C, pH 4; 60 minutes at 100°C pH 5; 20 minutes at 120°C, pH 6) was assessed by JMPR (FAO, 2004). Trifloxystrobin was hydrolytically stable under conditions simulating pasteurisation, showed minor degradation under baking/brewing/boiling conditions (2.6 % of TRR) and significant degradation under sterilisation (22.5 % of TRR). The main degradation product observed was the metabolite CGA 321113 (2 % at pH 5; 21% at pH 6). Thus, the metabolite CGA 321113 would have to be considered in the risk assessment for processed commodities which have undergone sterilisation processes. However, since the toxicity of metabolite CGA 321113 is covered by that of the parent compound no separate risk assessment is required.

Specific studies to assess the magnitude of trifloxystrobin residues during the processing of beans with pods were not submitted. Such studies are not necessary as the residue levels in raw agricultural commodities (RAC) did not exceed the trigger value of 0.1 mg/kg (EC, 1997d).

3.1.2. Rotational crops

Beans can be grown in crop rotation. The rate of degradation of trifloxystrobin in soil does not exceed the trigger value of 100 days (DT_{90f} of 41 days). Two trifloxystrobin metabolites are more persistent in the soil: CGA 321113 with the DT_{90f} value of more than 500 days and CGA 373466¹⁵ with the maximum DT_{90f} value of 290 days (United Kingdom, 2000). Consequently, the nature and magnitude of the compound and its metabolites uptake in rotational crops should be investigated.

The nature of trifloxystrobin in rotational crops was assessed in the DAR prepared under Council Directive 91/414/EEC (United Kingdom, 2000) and the details of the metabolism studies are given in a previously issued EFSA reasoned opinion (EFSA, 2011). The data on metabolism and distribution of trifloxystrobin in succeeding crops demonstrate that the metabolism of the active substance in rotational crops is similar to the pathway observed in primary crops. Thus, the same residue definition applies.

Based on the results from the metabolism studies in rotational crops, which were performed with a higher application rate (0.5 kg a.s./ha) than the intended seasonal application rate on the crop under consideration (0.4 kg a.s./ha), EFSA concludes that relevant residue levels are unlikely to occur in rotational crops provided that the compound is used on beans with pods according to the intended GAP.

3.2. Nature and magnitude of residues in livestock

Since beans with pods or their by-products are not normally fed to livestock, the nature and magnitude of trifloxystrobin residues in livestock was not assessed in the framework of this application.

¹⁵ CGA 373466: (Z,E)-methoxyimino-{2-[1-(3-trifluoro methyl-phenyl)-ethylideneaminooxymethyl]-phenyl}-acetic acid.

4. Consumer risk assessment

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residue Intake Model (PRIMo). This exposure assessment model contains the relevant European food consumption data for different sub-groups of the EU population¹⁶ (EFSA, 2007).

For the calculation of chronic exposure, EFSA used the median residue value as derived from the residue trials on beans with pods (see Table 3-1) and the median residue value reported for crops that were assessed in previously issued EFSA reasoned opinions (EFSA, 2008, 2009a, 2009b, 2010, 2011, 2012). For certain crops these values were multiplied by conversion factors (CF) to cover in the risk assessment the relevant amounts of the metabolite CGA 321113 that were observed in the residue trial (EFSA, 2009a, 2009b, 2012). For the remaining commodities of plant and animal origin, the existing MRLs as established in Annexes II and IIIB of Regulation (EC) No 396/2005 were used as input values.

The model assumptions for the long-term exposure assessment are considered to be sufficiently conservative for a first tier exposure assessment, assuming that all food items consumed have been treated with the active substance under consideration. In reality, it is not likely that all food consumed will contain residues at the MRL or at levels of the median residue values identified in supervised field trials. However, if this first tier exposure assessment does not exceed the toxicological reference value for long-term exposure (*i.e.* the ADI), a consumer health risk can be excluded with a high probability.

No acute consumer exposure was performed due to the low acute toxicity of the active substance.

The input values used for the dietary exposure calculation are summarised in Table 4-1.

Table 4-1: Input values for the consumer dietary exposure assessment

Commodity	Chronic exposure assessment		Acute exposure assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Residue definition for risk assessment for commodities of plant origin: trifloxystrobin (<i>provisional</i>) Residue definition for risk assessment for commodities of animal origin: sum of trifloxystrobin and its metabolite CGA 321113, expressed as trifloxystrobin				
Beans with pods	0.20	Median residue (see Table 3-1)	Acute risk assessment was not undertaken due to the low acute toxicity of the active substance.	
Globe artichokes	0.07	Median residue (EFSA, 2012)		
Spring onions	0.04 (0.015*2.6)	Median residue*CF ^(a) (EFSA, 2012)		
Aubergines	0.08	Median residue (EFSA, 2011)		
Leafy brassica	0.66	Median residue (EFSA, 2010)		
Blueberry	0.78	Median residue (EFSA, 2009a)		
Lettuce, scarole, herbs	5.5	Median residue (EFSA, 2009a)		
Celery	0.10 (0.08*1.3)	Median residue*CF ^(a) (EFSA, 2009a)		

¹⁶ The calculation of the long-term exposure (chronic exposure) is based on the mean consumption data representative for 22 national diets collected from MS surveys plus 1 regional and 4 cluster diets from the WHO GEMS Food database; for the acute exposure assessment the most critical large portion consumption data from 19 national diets collected from MS surveys is used. The complete list of diets incorporated in EFSA PRIMo is given in its reference section (EFSA, 2007).

Commodity	Chronic exposure assessment		Acute exposure assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Brussels sprouts	0.13 (0.1*1.3)	Median residue *CF ^(a) (EFSA, 2009a)		
Head cabbage	0.05 (0.03*1.7)	Median residue*CF ^(a) (EFSA, 2009a)		
Swedes, turnip, salsify, parsnips, parsley root	0.02 (0.1*2)	Median residue *CF ^(a) (EFSA, 2009b)		
Passion fruit	0.72	Median residue (EFSA, 2008)		
Other commodities of plant and animal origin	MRL	See Appendix C		

(a): The risk assessment is taking into account the residues of the metabolite CGA 321113 for the crops where the available field trials indicated the presence of this metabolite and CFs were established (EFSA, 2009a, 2009b, 2012).

The estimated chronic exposure was then compared with the toxicological reference value derived for trifloxystrobin (see Table 2-1). The results of the intake calculation are presented in Appendix B to this reasoned opinion.

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake values accounted for up to 22.7 % of the ADI (FR all population diet). The contribution of residues in the crop under consideration to the total consumer exposure accounted for a maximum of 0.22 % of the ADI (FR toddler diet).

EFSA concludes that the intended use of trifloxystrobin on beans with pods will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a public health concern. The risk assessment has to be regarded as provisional, pending the decision on the inclusion of the metabolite CGA 321113 in the residue definition for risk assessment and for CFs from enforcement to risk assessment for all authorised uses of trifloxystrobin.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The toxicological profile of trifloxystrobin was assessed in the framework of the peer review under Council Directive 91/414/EEC and the data were sufficient to derive an ADI of 0.1 mg/kg bw per day. No ARfD was deemed necessary.

The metabolism of trifloxystrobin in primary crops was investigated after foliar applications on apples, cucumbers (fruits and fruiting vegetables) and wheat (cereals) in the framework of the peer review under Council Directive 91/414/EEC and the residue definition for enforcement and risk assessment was set as parent trifloxystrobin. The Joint FAO/WHO Meeting on Pesticide Residues (JMPR), who assessed a metabolism study on peanuts (pulses and oilseeds), concluded that trifloxystrobin shows a similar metabolic behaviour as in wheat. Based on the findings from a metabolism study in sugar beet (roots and tuber vegetables) and the residue trials on leafy and root vegetables, where significant residues of the metabolite CGA 321113 were observed, EFSA has recommended in previously issued reasoned opinions to consider the inclusion of this metabolite in a revised risk assessment residue definition for plant commodities. Since the residue data indicated that metabolite CGA 321113 is not found in beans with pods, EFSA concludes that the residue definitions for enforcement and risk assessment as agreed in the peer review are provisionally applicable. EFSA proposes that the inclusion of the metabolite CGA 321113 in the risk assessment residue definition for plant commodities should be further discussed in the framework of Article 12 of Regulation (EC) No 396/2005.

EFSA concludes that the submitted supervised residue trials are sufficient to derive a MRL proposal of 1.0 mg/kg for the intended use on beans with pods. Adequate analytical enforcement methods are available to control the residues of trifloxystrobin in the commodity under consideration at the validated LOQs of 0.01 to 0.02 mg/kg.

Trifloxystrobin is hydrolytically stable under conditions simulating pasteurisation, but showed minor degradation under baking/brewing/boiling conditions and significant degradation under sterilisation. The main degradation product was the metabolite CGA 321113. Thus, this metabolite should be considered in the risk assessment for processed commodities which have undergone sterilisation process. Specific studies to assess the magnitude of trifloxystrobin residues during the processing of beans with pods are not necessary as the residue levels in raw agricultural commodities (RAC) did not exceed the trigger value of 0.1 mg/kg.

The occurrence of trifloxystrobin and its metabolites in rotational crops was investigated in the framework of the peer review. Based on the available information on the nature of residues in succeeding crops EFSA concludes that significant residue levels are unlikely to occur in rotational crops provided that the compound is used on beans with pods according to the intended GAP (Good Agricultural Practice).

Residues of trifloxystrobin in commodities of animal origin were not assessed in the framework of this application since beans with pods are normally not fed to livestock.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). For the calculation of chronic exposure, EFSA used the median residue value as derived from the residue trials on beans with pods and the median residue value reported for crops that were assessed in previously issued EFSA reasoned opinions. For certain crops these values were multiplied by conversion factors (CF) to cover in the risk assessment the relevant amounts of the metabolite CGA 321113 that were observed in the residue trials. For the remaining commodities of plant and animal origin, the existing MRLs as established in Annexes II and IIIB of Regulation (EC) No 396/2005 were used as input values. No acute consumer exposure was performed due to the low acute toxicity of the active substance.

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake accounted for up to 22.7 % of the ADI (FR all

population diet). The contribution of residues in the crop under consideration to the total consumer exposure accounted for a maximum of 0.22 % of the ADI (FR toddler diet).

EFSA concludes that the intended use of trifloxystrobin on beans with pods will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a consumer health risk. The risk assessment has to be regarded as provisional, pending the decision for inclusion of the metabolite CGA 321113 in the residue definition for risk assessment and for CFs from enforcement to risk assessment for all authorised uses of trifloxystrobin.

RECOMMENDATIONS

Code number ^(a)	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: Trifloxystrobin (F)				
0260010	Beans with pods	0.5	1.0	The MRL proposal is sufficiently supported by data and no consumer health risk was identified for the intended use.

(a): According to Annex I of Regulation (EC) No 396/2005.

(F): Fat-soluble pesticide.

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APPENDICES

A GOOD AGRICULTURAL PRACTICE (GAPs)

Crop and/or situation (a)	Member State or Country	F G or I (b)	Pest or group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
				type (d - f)	conc. of a.s. (i)	method kind (f - h)	growth stage & season (j)	number min max (k)	interval min max	kg as/hL min max	water L/ha min max	kg a.s./ha min max		
Beans with pods	DE	F	<i>Sclerotinia sclerotiorum</i> , <i>Uromyces appendiculatus</i>	SC	250 g/L	Spray	BBCH 59-69	2	7-14 d		400-600	0.2	7	Maximum total rate per crop/season: 0.4 kg a.s./ha

- Remarks:
- (a) For crops, EU or other classifications, e.g. Codex, 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 sucking insects, soil born insects, foliar fungi, weeds
 - (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
 - (e) GCPF Technical Monograph No 2, 4th Ed., 1999 or other codes, e.g. OECD/CIPAC, should be used
 - (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 plants - type of equipment used must be indicated
 - (i) g/kg or g/l
 - (j) Growth stage at last treatment (Growth stages of mono- and dicotyledonous plants. BBCH Monograph, 2nd Ed., 2001), 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
 - (m) Remarks may include: Extent of use/economic importance/restrictions (*i.e.* feeding, grazing)

B PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

<div> <div>Trifloxystrobin</div> <div> <div>Status of the active substance: included</div> <div>Code no.</div> </div> <div> <div>LOQ (mg/kg bw): 0.02</div> <div>proposed LOQ:</div> </div> <div>Toxicological end points</div> <div> <div>ADI (mg/kg bw/day): 0.1</div> <div>ARfD (mg/kg bw): n.n.</div> </div> <div> <div>Source of ADI: EC</div> <div>Source of ARfD: EC</div> </div> <div> <div>Year of evaluation: 2003</div> <div>Year of evaluation: 2003</div> </div> </div>									
Chronic risk assessment - refined calculations									
				TMDI (range) in % of ADI					
				minimum - maximum					
				2 23					
				No of diets exceeding ADI:		---			
	Highest calculated TMDI values in % of ADI	MS Diet		Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	pTMRs at LOQ (in % of ADI)
	22.7	FR all population		20.0	Wine grapes	0.5	Table grapes	0.5	Lettuce 0.0
	19.0	WHO Cluster diet B		9.0	Wine grapes	2.0	Lettuce	1.7	Table grapes 0.2
	17.7	DE child		6.3	Table grapes	6.0	Apples	1.1	Oranges 0.1
	16.3	PT General population		12.4	Wine grapes	1.4	Table grapes	0.5	Apples 0.2
	12.9	IE adult		6.3	Wine grapes	1.3	Table grapes	0.6	Peaches 0.3
	12.5	WHO cluster diet E		8.0	Wine grapes	0.8	Table grapes	0.5	Lettuce 0.2
	12.3	NL child		3.8	Table grapes	3.2	Apples	1.1	Scarole (broad-leaf endive) 0.2
	8.6	DK adult		7.0	Wine grapes	0.4	Apples	0.4	Table grapes 0.0
	7.9	NL general		3.1	Wine grapes	1.1	Table grapes	0.7	Lettuce 0.1
	7.7	UK Adult		5.4	Wine grapes	0.6	Lettuce	0.3	Table grapes 0.1
	7.7	ES adult		2.9	Lettuce	2.1	Wine grapes	0.4	Tomatoes 0.0
	7.4	WHO Cluster diet F		3.0	Wine grapes	1.7	Lettuce	0.6	Table grapes 0.1
	6.9	UK vegetarian		4.1	Wine grapes	0.8	Lettuce	0.4	Table grapes 0.1
	6.9	WHO regional European diet		2.1	Lettuce	1.2	Wine grapes	0.8	Table grapes 0.1
	5.8	WHO cluster diet D		1.8	Wine grapes	0.9	Table grapes	0.5	Tomatoes 0.1
	5.7	ES child		2.3	Lettuce	0.7	Oranges	0.6	Apples 0.1
	5.4	UK Toddler		1.2	Table grapes	1.1	Sugar beet (root)	0.9	Apples 0.1
	5.3	IT adult		2.1	Lettuce	0.7	Table grapes	0.6	Tomatoes 0.1
	5.2	FR toddler		1.3	Apples	1.0	Table grapes	0.6	Oranges 0.1
	5.1	IT kids/toddler		1.6	Lettuce	0.7	Tomatoes	0.5	Table grapes 0.1
	4.9	DK child		1.2	Apples	0.9	Table grapes	0.8	Lettuce 0.1
	3.8	PL general population		1.6	Table grapes	1.0	Apples	0.4	Tomatoes 0.1
	3.2	FI adult		1.5	Wine grapes	0.4	Lettuce	0.3	Oranges 0.0
	3.2	FR infant		1.3	Apples	0.4	Table grapes	0.3	Oranges 0.1
	3.1	UK Infant		0.8	Apples	0.5	Sugar beet (root)	0.4	Oranges 0.1
	2.8	SE general population 90th percentile		0.5	Apples	0.4	Tomatoes	0.2	Oranges 0.1
	2.2	LT adult		0.9	Apples	0.3	Lettuce	0.3	Tomatoes 0.1
Conclusion: The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRs were below the ADI. A long-term intake of residues of Trifloxystrobin is unlikely to present a public health concern.									

C EXISTING EU MAXIMUM RESIDUE LEVELS (MRLs)

(Pesticides - Web Version - EU MRLs (File created on 20/03/2013 16:56))

Code number	Groups and examples of individual products to which the MRLs apply	Trifloxystrobin (F)
100000	1. FRUIT FRESH OR FROZEN; NUTS	
110000	(i) Citrus fruit	0,3
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids)	0,3
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0,3
110030	Lemons (Citron, lemon)	0,3
110040	Limes	0,3
110050	Mandarins (Clementine, tangerine and other hybrids)	0,3
110990	Others	0,3
120000	(ii) Tree nuts (shelled or unshelled)	0,02*
120010	Almonds	0,02*
120020	Brazil nuts	0,02*
120030	Cashew nuts	0,02*
120040	Chestnuts	0,02*
120050	Coconuts	0,02*
120060	Hazelnuts (Filbert)	0,02*
120070	Macadamia	0,02*
120080	Pecans	0,02*
120090	Pine nuts	0,02*
120100	Pistachios	0,02*
120110	Walnuts	0,02*
120990	Others	0,02*
130000	(iii) Pome fruit	0,5
130010	Apples (Crab apple)	0,5
130020	Pears (Oriental pear)	0,5
130030	Quinces	0,5
130040	Medlar	0,5
130050	Loquat	0,5
130990	Others	0,5
140000	(iv) Stone fruit	
140010	Apricots	1
140020	Cherries (sweet cherries, sour cherries)	1
140030	Peaches (Nectarines and similar hybrids)	1
140040	Plums (Damson, greengage, mirabelle)	0,2
140990	Others	0,02*
150000	(v) Berries & small fruit	

Code number	Groups and examples of individual products to which the MRLs apply	Trifloxystrobin (F)
151000	(a) Table and wine grapes	5
151010	Table grapes	5
151020	Wine grapes	5
152000	(b) Strawberries	0,5
153000	(c) Cane fruit	0,02*
153010	Blackberries	0,02*
153020	Dewberries (Loganberries, Boysenberries, and cloudberrries)	0,02*
153030	Raspberries (Wineberries)	0,02*
153990	Others	0,02*
154000	(d) Other small fruit & berries	
154010	Blueberries (Bilberries cowberries (red bilberries))	2
154020	Cranberries	0,02*
154030	Currants (red, black and white)	1
154040	Gooseberries (Including hybrids with other ribes species)	1
154050	Rose hips	0,02*
154060	Mulberries (arbutus berry)	0,02*
154070	Azarole (mediteranean medlar)	0,02*
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea sawlowthorn), hawthorn, service berries, and other treeberries)	2
154990	Others	0,02*
160000	(vi) Miscellaneous fruit	
161000	(a) Edible peel	
161010	Dates	0,02*
161020	Figs	0,02*
161030	Table olives	0,3
161040	Kumquats (Marumi kumquats, nagami kumquats)	0,02*
161050	Carambola (Bilimbi)	0,02*
161060	Persimmon	0,02*
161070	Jambolan (java plum) (Java apple (water apple), pomarac, rose apple,	0,02*

Code number	Groups and examples of individual products to which the MRLs apply	Trifloxystrobin (F)
	Brazilian cherry (grumichama), Surinam cherry)	
161990	Others	0,02*
162000	(b) Inedible peel, small	
162010	Kiwi	0,02*
162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	0,02*
162030	Passion fruit	4
162040	Prickly pear (cactus fruit)	0,02*
162050	Star apple	0,02*
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammeey sapote)	0,02*
162990	Others	0,02*
163000	(c) Inedible peel, large	
163010	Avocados	0,02*
163020	Bananas (Dwarf banana, plantain, apple banana)	0,05
163030	Mangoes	0,5
163040	Papaya	1
163050	Pomegranate	0,02*
163060	Chirimoya (Custard apple, sugar apple (sweetsop), llama and other medium sized Annonaceae)	0,02*
163070	Guava	0,02*
163080	Pineapples	0,02*
163090	Bread fruit (Jackfruit)	0,02*
163100	Durian	0,02*
163110	Soursop (guanabana)	0,02*
163990	Others	0,02*
200000	2. VEGETABLES FRESH OR FROZEN	
210000	(i) Root and tuber vegetables	
211000	(a) Potatoes	0,02*
212000	(b) Tropical root and tuber vegetables	0,02*
212010	Cassava (Dasheen, eddoe (Japanese taro), tannia)	0,02*
212020	Sweet potatoes	0,02*

Code number	Groups and examples of individual products to which the MRLs apply	Trifloxystrobin (F)
212030	Yams (Potato bean (yam bean), Mexican yam bean)	0,02*
212040	Arrowroot	0,02*
212990	Others	0,02*
213000	(c) Other root and tuber vegetables except sugar beet	
213010	Beetroot	0,02*
213020	Carrots	0,05
213030	Celeriac	0,02*
213040	Horseradish	0,02*
213050	Jerusalem artichokes	0,02*
213060	Parsnips	0,04
213070	Parsley root	0,04
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	0,02*
213090	Salsify (Scorzoneria, Spanish salsify (Spanish oysterplant))	0,04
213100	Swedes	0,04
213110	Tumips	0,04
213990	Others	0,02*
220000	(ii) Bulb vegetables	
220010	Garlic	0,02*
220020	Onions (Silverskin onions)	0,02*
220030	Shallots	0,02*
220040	Spring onions (Welsh onion and similar varieties)	0,1
220990	Others	0,02*
230000	(iii) Fruiting vegetables	
231000	(a) Solanacea	
231010	Tomatoes (Cherry tomatoes,)	0,5
231020	Peppers (Chilli peppers)	0,3
231030	Aubergines (egg plants) (Pepino)	0,3
231040	Okra, lady's fingers	0,02*
231990	Others	0,02*
232000	(b) Cucurbits - edible peel	0,2
232010	Cucumbers	0,2
232020	Gherkins	0,2
232030	Courgettes (Summer squash, marrow (patisson))	0,2
232990	Others	0,2
233000	(c) Cucurbits-inedible peel	

Code number	Groups and examples of individual products to which the MRLs apply	Trifloxystrobin (F)
233010	Melons (Kiwano)	0,3
233020	Pumpkins (Winter squash)	0,2
233030	Watermelons	0,2
233990	Others	0,02*
234000	(d) Sweet corn	0,02*
239000	(e) Other fruiting vegetables	0,02*
240000	(iv) Brassica vegetables	
241000	(a) Flowering brassica	
241010	Broccoli (Calabrese, Chinese broccoli, Broccoli rabe)	0,05
241020	Cauliflower	0,05
241990	Others	0,02*
242000	(b) Head brassica	
242010	Brussels sprouts	0,5
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0,3
242990	Others	0,02*
243000	(c) Leafy brassica	3
243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	3
243020	Kale (Borecole (curly kale), collards)	3
243990	Others	3
244000	(d) Kohlrabi	0,5
250000	(v) Leaf vegetables & fresh herbs	
251000	(a) Lettuce and other salad plants including Brassicaceae	
251010	Lamb's lettuce (Italian cornsalad)	0,02*
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	10
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curd leaf endive, sugar loaf)	10
251040	Cress	0,02*
251050	Land cress	0,02*
251060	Rocket, Rucola (Wild rocket)	0,02*
251070	Red mustard	0,02*

Code number	Groups and examples of individual products to which the MRLs apply	Trifloxystrobin (F)
251080	Leaves and sprouts of Brassica spp (Mizuna)	0,02*
251990	Others	0,02*
252000	(b) Spinach & similar (leaves)	0,02*
252010	Spinach (New Zealand spinach, turnip greens (turnip tops))	0,02*
252020	Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glasswort)	0,02*
252030	Beet leaves (chard) (Leaves of beetroot)	0,02*
252990	Others	0,02*
253000	(c) Vine leaves (grape leaves)	0,02*
254000	(d) Water cress	0,02*
255000	(e) Witloof	0,02*
256000	(f) Herbs	10
256010	Chervil	10
256020	Chives	10
256030	Celery leaves (fennel leaves , Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cicely and other Apiacea)	10
256040	Parsley	10
256050	Sage (Winter savory, summer savory,)	10
256060	Rosemary	10
256070	Thyme (marjoram, oregano)	10
256080	Basil (Balm leaves, mint, peppermint)	10
256090	Bay leaves (laurel)	10
256100	Tamagron (Hyssop)	10
256990	Others	10
260000	(vi) Legume vegetables (fresh)	
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	0,5
260020	Beans (without pods) (Broad beans, Flageolet, jack bean, lima bean, cowpea)	0,02*
260030	Peas (with pods) (Mangetout (sugar peas))	0,02*

Code number	Groups and examples of individual products to which the MRLs apply	Trifloxystrobin (F)
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0,02*
260050	Lentils	0,02*
260990	Others	0,02*
270000	(vii) Stem vegetables (fresh)	
270010	Asparagus	0,02*
270020	Cardoons	0,02*
270030	Celery	1
270040	Fennel	0,02*
270050	Globe artichokes	0,2
270060	Leek	0,2
270070	Rhubarb	0,02*
270080	Bamboo shoots	0,02*
270090	Palm hearts	0,02*
270990	Others	0,02*
280000	(viii) Fungi	0,02*
280010	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	0,02*
280020	Wild (Chanterelle, Truffle, Morel)	0,02*
280990	Others	0,02*
290000	(ix) Sea weeds	0,02*
300000	3. PULSES, DRY	0,02*
300010	Beans (Broad beans, navy beans, flageolet, jack beans, lima beans, field beans, cowpeas)	0,02*
300020	Lentils	0,02*
300030	Peas (Chickpeas, field peas, chickling vetch)	0,02*
300040	Lupins	0,02*
300990	Others	0,02*
400000	4. OILSEEDS AND OILFRUITS	
401000	(i) Oilseeds	0,05*
401010	Linseed	0,05*
401020	Peanuts	0,05*
401030	Poppy seed	0,05*
401040	Sesame seed	0,05*
401050	Sunflower seed	0,05*
401060	Rape seed (Bird rapeseed, turnip rape)	0,05*
401070	Soya bean	0,05*
401080	Mustard seed	0,05*
401090	Cotton seed	0,05*
401100	Pumpkin seeds	0,05*
401110	Safflower	0,05*
401120	Borage	0,05*

Code number	Groups and examples of individual products to which the MRLs apply	Trifloxystrobin (F)
401130	Gold of pleasure	0,05*
401140	Hempseed	0,05*
401150	Castor bean	0,05*
401990	Others	0,05*
402000	(ii) Oilfruits	
402010	Olives for oil production	0,3
402020	Palm nuts (palm oil kernels)	0,05*
402030	Palmfruit	0,05*
402040	Kapok	0,05*
402990	Others	0,05*
500000	5. CEREALS	
500010	Barley	0,3
500020	Buckwheat	0,02*
500030	Maize	0,02*
500040	Millet (Foxtail millet, teff)	0,02*
500050	Oats	0,02*
500060	Rice	0,02*
500070	Rye	0,05
500080	Sorghum	0,02*
500090	Wheat (Spelt Triticale)	0,05
500990	Others	0,02*
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	0,05*
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	0,05*
620000	(ii) Coffee beans	0,05*
630000	(iii) Herbal infusions (dried)	0,05*
631000	(a) Flowers	0,05*
631010	Camomille flowers	0,05*
631020	Hybiscus flowers	0,05*
631030	Rose petals	0,05*
631040	Jasmine flowers	0,05*
631050	Lime (linden)	0,05*
631990	Others	0,05*
632000	(b) Leaves	0,05*
632010	Strawberry leaves	0,05*
632020	Rooibos leaves	0,05*
632030	Maté	0,05*
632990	Others	0,05*
633000	(c) Roots	0,05*
633010	Valerian root	0,05*
633020	Ginseng root	0,05*
633990	Others	0,05*
639000	(d) Other herbal infusions	0,05*
640000	(iv) Cocoa (fermented beans)	0,05*
650000	(v) Carob (st johns bread)	0,05*

Code number	Groups and examples of individual products to which the MRLs apply	Trifloxystrobin (F)
700000	7. HOPS (dried), including hop pellets and unconcentrated powder	30
800000	8. SPICES	0,05*
810000	(i) Seeds	0,05*
810010	Anise	0,05*
810020	Black caraway	0,05*
810030	Celery seed (Lovage seed)	0,05*
810040	Coriander seed	0,05*
810050	Cumin seed	0,05*
810060	Dill seed	0,05*
810070	Fennel seed	0,05*
810080	Fenugreek	0,05*
810090	Nutmeg	0,05*
810990	Others	0,05*
820000	(ii) Fruits and berries	0,05*
820010	Allspice	0,05*
820020	Anise pepper (Japan pepper)	0,05*
820030	Caraway	0,05*
820040	Cardamom	0,05*
820050	Juniper berries	0,05*
820060	Pepper, black and white (Long pepper, pink pepper)	0,05*
820070	Vanilla pods	0,05*
820080	Tamarind	0,05*
820990	Others	0,05*
830000	(iii) Bark	0,05*
830010	Cinnamon (Cassia)	0,05*
830990	Others	0,05*
840000	(iv) Roots or rhizome	0,05*
840010	Liquorice	0,05*
840020	Ginger	0,05*
840030	Turmeric (Curcuma)	0,05*
840040	Horseradish	0,05*
840990	Others	0,05*
850000	(v) Buds	0,05*
850010	Cloves	0,05*
850020	Capers	0,05*
850990	Others	0,05*

Code number	Groups and examples of individual products to which the MRLs apply	Trifloxystrobin (F)
860000	(vi) Flower stigma	0,05*
860010	Saffron	0,05*
860990	Others	0,05*
870000	(vii) Aril	0,05*
870010	Mace	0,05*
870990	Others	0,05*
900000	9. SUGAR PLANTS	
900010	Sugar beet (root)	0,05
900020	Sugar cane	0,02*
900030	Chicory roots	0,02*
900990	Others	0,02*
1000000	10. PRODUCTS OF ANIMAL ORIGIN-TERRESTRIAL ANIMALS	
1010000	(i) Meat, preparations of meat, offals, blood, animal fats fresh chilled or frozen, salted, in brine, dried or smoked or processed as flours or meals other processed products such as sausages and food preparations based on these	0,04*
1011000	(a) Swine	0,04*
1011010	Meat	0,04*
1011020	Fat free of lean meat	0,04*
1011030	Liver	0,04*
1011040	Kidney	0,04*
1011050	Edible offal	0,04*
1011990	Others	0,04*
1012000	(b) Bovine	0,04*
1012010	Meat	0,04*
1012020	Fat	0,04*
1012030	Liver	0,04*
1012040	Kidney	0,04*
1012050	Edible offal	0,04*
1012990	Others	0,04*
1013000	(c) Sheep	0,04*
1013010	Meat	0,04*
1013020	Fat	0,04*

Code number	Groups and examples of individual products to which the MRLs apply	Trifloxystrobin (F)
1013030	Liver	0,04*
1013040	Kidney	0,04*
1013050	Edible offal	0,04*
1013990	Others	0,04*
1014000	(d) Goat	0,04*
1014010	Meat	0,04*
1014020	Fat	0,04*
1014030	Liver	0,04*
1014040	Kidney	0,04*
1014050	Edible offal	0,04*
1014990	Others	0,04*
1015000	(e) Horses, asses, mules or hinnies	0,04*
1015010	Meat	0,04*
1015020	Fat	0,04*
1015030	Liver	0,04*
1015040	Kidney	0,04*
1015050	Edible offal	0,04*
1015990	Others	0,04*
1016000	(f) Poultry -chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	0,04*
1016010	Meat	0,04*
1016020	Fat	0,04*
1016030	Liver	0,04*
1016040	Kidney	0,04*
1016050	Edible offal	0,04*
1016990	Others	0,04*
1017000	(g) Other farm animals (Rabbit, Kangaroo)	0,04*
1017010	Meat	0,04*
1017020	Fat	0,04*
1017030	Liver	0,04*
1017040	Kidney	0,04*
1017050	Edible offal	0,04*
1017990	Others	0,04*
1020000	(ii) Milk and cream, not concentrated, nor containing added sugar or sweetening matter, butter and other fats	0,02*

Code number	Groups and examples of individual products to which the MRLs apply	Trifloxystrobin (F)
	derived from milk, cheese and curd	
1020010	Cattle	0,02*
1020020	Sheep	0,02*
1020030	Goat	0,02*
1020040	Horse	0,02*
1020990	Others	0,02*
1030000	(iii) Birds' eggs, fresh preserved or cooked Shelled eggs and egg yolks fresh, dried, cooked by steaming or boiling in water, moulded, frozen or otherwise preserved whether or not containing added sugar or sweetening matter	0,04*
1030010	Chicken	0,04*
1030020	Duck	0,04*
1030030	Goose	0,04*
1030040	Quail	0,04*
1030990	Others	0,04*
1040000	(iv) Honey (Royal jelly, pollen)	0,04*
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	0,04*
1060000	(vi) Snails	0,04*
1070000	(vii) Other terrestrial animal products	0,04*

(*) Indicates lower limit of analytical determination

(F): Code 1000000: the sum of trifloxystrobin and its metabolite (*E,E*)-methoxyimino- {2-[1-(3-trifluoromethyl-phenyl)-ethylideneamino-oxymethyl]-phenyl}-acetic acid (CGA 321113)

ABBREVIATIONS

ADI	acceptable daily intake
ARfD	acute reference dose
a.s.	active substance
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CEN	European Committee for Standardisation (Comité Européen de Normalisation, <i>French</i>)
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CXL	Codex Maximum Residue Limit (Codex MRL)
d	day
DALA	days after last application
DAR	Draft Assessment Report
DE	Germany
DT ₉₀	period required for 90 % dissipation (define method of estimation)
EC	European Community
EFSA	European Food Safety Authority
EMS	evaluating Member State
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
GAP	good agricultural practice
GCPF	Global Crop Protection Federation (former GIFAP)
ha	hectare
hL	hectolitre
<i>i.e.</i>	that is (id est, <i>Latin</i>)
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
kg	kilogram
L	litre
LC	liquid chromatography
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
MS/MS	tandem mass spectrometry

NEU	northern European Union
OECD	Organisation for Economic Co-operation and Development
PHI	pre-harvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
PROFile	Pesticide Residue Overview File
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (method)
R _{ber}	statistical calculation of the MRL by using a non-parametric method
R _{max}	statistical calculation of the MRL by using a parametric method
RMS	rapporteur Member State
SC	suspension concentrate
WG	dispersible granule
WHO	World Health Organisation
wk	week
yr	year