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REASONED OPINION

Reasoned opinion on the modification of the existing MRLs for trifloxystrobin in horseradish, parsley root and purslane[1]

European Food Safety Authority[2]

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ABSTRACT

In accordance with Article 6 of Regulation (EC) No 396/2005, Belgium, hereafter referred to as the evaluating Member State (EMS Belgium), compiled an application to modify the existing MRLs for trifloxystrobin in horseradish, parsley root and purslane. In order to accommodate for the intended uses of trifloxystrobin, Belgium proposed to raise the existing MRLs from the limit of quantification of 0.02* mg/kg to 0.08 mg/kg for horseradish, from 0.04 mg/kg to 0.08 mg/kg for parsley root and from 0.02* mg/kg to 10 mg/kg for purslane. The EMS 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 MRL proposals for the NEU intended uses on horseradish and parsley root, while for purslane the data were found to be insufficient to derive a robust MRL proposal. Adequate analytical enforcement methods are available to control the residues of trifloxystrobin in the commodities under consideration. Based on the risk assessment results, EFSA concludes that the proposed use of trifloxystrobin on horseradish and parsley root will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a consumer health risk.

KEY WORDS

trifloxystrobin, root and leafy vegetables, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, strobilurin fungicide, CGA 321113

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SUMMARY

In accordance with Article 6 of Regulation (EC) No 396/2005, Belgium, hereafter referred to as the evaluating Member State (EMS Belgium), compiled an application to modify the existing MRLs for trifloxystrobin in horseradish, parsley root and purslane. In order to accommodate for the intended uses of trifloxystrobin, Belgium proposed to raise the existing MRLs from the limit of quantification of 0.02* mg/kg to 0.08 mg/kg for horseradish, from 0.04 mg/kg to 0.08 mg/kg for parsley root and from 0.02* mg/kg to 10 mg/kg for purslane. The EMS 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 2 May 2013.

EFSA bases its assessment on the evaluation report submitted by the EMS, 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 opinions on trifloxystrobin.

The toxicological profile of trifloxystrobin was assessed by the RMS and the data were sufficient to derive an ADI of 0.1 mg/kg bw per day. No ARfD was deemed necessary due to the low toxicity profile of the active substance. According to the RMS United Kingdom, the toxicity of the metabolite CGA 321113 is covered by the toxicological reference value derived for the parent compound.

The metabolism of trifloxystrobin in primary crops was investigated in apples, cucumbers, wheat, sugar beet and peanuts following foliar applications where trifloxystrobin was found as the major residue. The metabolism study in sugar beets and the results of residue trials on several crops (Brussels sprouts, head cabbage, celery) indicated that the metabolite CGA 321113[3] may be present in significant concentrations. Based on these findings 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. EFSA concludes that the metabolism of trifloxystrobin is sufficiently addressed and the residue definition for enforcement established in Regulation (EC) 396/2005 and confirmed by the peer review is trifloxystrobin. For risk assessment, EFSA uses on a provisional basis the residue definition which comprises trifloxystrobin and the metabolite CGA 321113. Validated analytical methods for enforcement of this residue definition are available with an LOQ of 0.02 mg/kg.

EFSA concludes that the submitted data are sufficient to extrapolate residue data from carrots to parsley root and horseradish and to derive MRL proposals in support of the NEU intended uses. For purslane the submitted residue trials on lettuce were found to be insufficient to derive a robust MRL proposal since only few residue trials were performed on varieties which are considered as representative for purslane (limited number of trials on open leaf varieties of lettuce). Adequate analytical enforcement methods are available to control the residues of trifloxystrobin in the commodities under consideration.

Trifloxystrobin is hydrolytically stable under conditions simulating pasteurisation, but showed degradation under baking/brewing/boiling conditions and during sterilisation. The main degradation product observed was the metabolite CGA 321113. However, the toxicity of metabolite CGA 321113 is covered by the parent compound. Specific studies investigating the effects of processing on the magnitude of trifloxystrobin residues in the processed crops under consideration have not been submitted. Considering the insignificant contribution of the crops under consideration to the dietary intake no specific processing studies are required.

The occurrence of trifloxystrobin residues in rotational crops was investigated in lettuce, radish and wheat in the framework of the peer review. Based on the available information on the nature and magnitude of residues in succeeding crops, EFSA concludes that significant residue levels of parent

[3] 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.

trifloxystrobin are unlikely to occur provided that trifloxystrobin is applied on horseradish and parsley root according to the intended GAP. In order to avoid the occurance of trifluoroacetic acid, a substance that was found in low concentrations in rotational crops, Member States should consider specific restrictions.

Residues of trifloxystrobin in commodities of animal origin were not assessed in the framework of this application, since the crops under consideration are not potential feed items for chicken, ruminants and pigs.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). The risk assessment was performed reflecting the risk assessment residue definition as trifloxystrobin, including metabolite CGA 321113 for some crops where the available data indicated the presence of this metabolite. For the calculation of chronic exposure, EFSA used the median residue value derived from the residue trials on carrot as input value for horseradish and parsley root. For several crops the risk assessment values were available to refine the consumer exposure calculations. 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.

EFSA concludes that the proposed use of trifloxystrobin on horseradish and parsley root will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a consumer health risk.

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)				
213040	Horseradish	0.02*	0.08	The MRL proposals are sufficiently supported by data and no consumer health risk was identified for the intended uses on theses crops. The MRL is derived by extrapolation data from carrots.
213070	Parsley root	0.04	0.08	
252020	Purslane	0.02*	No proposal	The number of trials on open leaf varieties was not sufficient to derive a robust MRL proposal.
840040	Horseradish (spice)	0.05*	See comment	The MRL proposal for horseradish (213040) should be applied also for the horseradish listed in the group of spices, taking into account an increase of the concentration resulting from drying.

(a):-According to Annex I of Regulation (EC) No 396/2005.
(*):-Indicates that the MRL is set at the limit of analytical quantification.
(F):-fat soluble pesticide

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BACKGROUND

Regulation (EC) No 396/2005[4] 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/EEC[5], repealed by Regulation (EC) No 1107/2009[6], shall submit to a Member State, when appropriate, an application to modify a MRL in accordance with the provisions of Article 7 of that Regulation.

Belgium, hereafter referred to as the evaluating Member State (EMS), compiled an application to modify the existing MRLs for the trifloxystrobin in horseradish, parsley root and purslane. This application was notified to the European Commission and EFSA, and was subsequently evaluated 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 2 May 2013

The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2013-00369 and the following subject:

Trifloxystrobin – Application to modify the existing MRLs in horseradish, parsley root and purslane

Belgium proposed to raise the existing MRLs of trifloxystrobin from the limit of quantification of 0.02* mg/kg to 0.08 mg/kg for horseradish and to 10 mg/kg for purslane and from 0.04 mg/kg to 0.08 mg/kg for parsley root.

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.

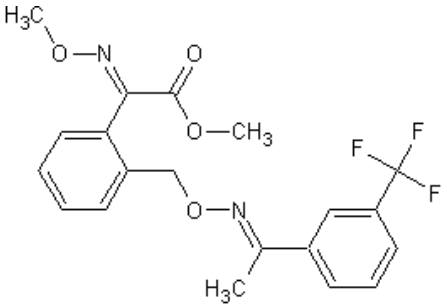
In accordance with Article 11 of that Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within three months (which may be extended to six months where more detailed evaluations need to be carried out) from the date of receipt of the application. Where EFSA requests 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 2 August 2013.

[4] 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.
[5] Council Directive 91/414/EEC of 15 July 1991. OJ L 230, 19.08.1991, p. 1-32.
[6] 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.

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)ethylideneaminooxy]-*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 (EFSA, 2013). The mode of action of trifloxystrobin involves inhibition of mitochondrial respiration in fungi.

Trifloxystrobin is an active substance which was evaluated according to 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/EC[7] which entered into force on 1 October 2003 for use as a fungicide only. In accordance with Commission Implementing Regulation (EU) No 540/2011[8] trifloxystrobin is approved under Regulation (EC) No 1107/2009, repealing Council Directive 91/414/EEC. The representative uses evaluated for the Annex I inclusion were foliar applications on grapes, apples, cucumber, wheat, barley and melons. The draft assessment report (DAR) on the active substance trifloxystrobin prepared by the RMS was not peer reviewed by EFSA and therefore an EFSA conclusion is not 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. Recently, EFSA recommended the modification of the existing MRLs for beans with pods (EFSA 2013). The SCFCAH gave a positive opinion on the proposal (SANCO/11114/2013 rev.1) but the Regulation is not yet published. The review of the existing MRLs for that active substance in compliance with Article 12 of the aforementioned Regulation is in progress. CXLs have been established by Codex Alimentarius for a wide range of crops, but not for the crops under consideration in this assessment.

The details of the intended GAP for trifloxystrobin on the horseradish, parsley root and purslane in Belgium 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 (Belgium, 2013), 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 opinions on trifloxystrobin (EFSA, 2008, 2009a, 2009b, 2010, 2011, 2012, 2013). 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 546/2011[9] 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 (United Kingdom, 2000) and have been also discussed in detail in the previously issued EFSA reasoned opinions (EFSA, 2010, 2011). Adequate multi-residue methods, based on HPLC-UV, GC-ECD and GC-NPD analyses are available for determination of trifloxystrobin in plant matrices with high water content (apples, bananas, cucumbers, melons, potatoes), high acid content (grapes) and dry commodities (wheat, barley) at the LOQ of 0.02 mg/kg (EFSA, 2011).

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). The method can be also applied to quantify the metabolite CGA 321113[10] which was proposed to be included in the risk assessment residue definition.

Since the commodities under consideration belong to the group of high water content commodities, EFSA concludes that sufficiently validated methods for enforcing the proposed MRLs 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 are not assessed in the current application, since the crops under consideration are normally not fed to livestock.

2. Mammalian toxicology

Toxicological reference values for trifloxystrobin were derived at Community level during the peer review of Directive 91/414/EEC (European Commission, 2003). It was concluded that trifloxystrobin does not possess acute toxicological properties; therefore an ARfD value was not established. An overview of the toxicological reference values is provided 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	0.1mg/kg bw per day	2-yr toxicity rat study	100
ARfD	EC	2003	Not necessary		

[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.

According to the RMS the toxicity of the metabolite CGA 321113, which is observed in significant amounts in certain products of plant origin, in products of animal origin and which is formed during the sterilisation process, 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 in primary crops after foliar applications has been investigated in apples, cucumbers, wheat and sugar beet, the details of the metabolism studies are given in the previously issued EFSA reasoned opinion (EFSA, 2012). In addition a metabolism study in peanuts is available which 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 acid metabolite CGA 321113. Trifloxystrobin was the major component of residues in all crops investigated. 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: metabolite II_{19a11} accounted for 20% (at 0 DALA) and 15% of TRR (at 45 DALA) and the metabolite CGA 321113 accounted for 11% of TRR (at 21 and 45 DALA).

Based on the findings of the metabolism studies in root and tuber vegetables and the residue trials on Brussels sprouts, head cabbage and celery, submitted in the framework of the MRL application (EFSA 2009b), where the metabolite CGA 321113 occurred at higher levels than parent trifloxystrobin, EFSA recommended in a previous assessment to consider the possible inclusion of this metabolite in the risk assessment residue definition for plant commodities (EFSA, 2012). A final decision regarding the inclusion should be taken in the framework of the MRL review under Article 12 of Regulation (EC) No 396/2005.

EFSA concludes that the available studies on the metabolism of trifloxystrobin are sufficient; they demonstrate that the current enforcement residue definition (parent trifloxystrobin) is appropriate for the crops under consideration. For risk assessment, on a provisional basis, EFSA will include the metabolite CGA 321113 in the residue definition, pending a final decision on the need to modify the risk assessment residue definition.

3.1.1.2. Magnitude of residues

a. Parsley root & horseradish *(Outdoor GAP:3x250g a.s/ha, PHI 7 days)*

The applicant proposed to derive MRLs for parsley root and horseradish by extrapolation from trials performed on carrots. In total, 8 NEU residue trials on carrots were reported in a previous evaluation report prepared by Belgium in 2009 (Belgium, 2009), two trials were disregarded because the number of application and the PHI were not matching with the intended GAP. The remaining 6 trials were performed in accordance with the GAP proposed for parsley roots and horseradish, deviating not more than 25% from the intended application rate. The samples were analysed for parent trifloxystrobin and its metabolite CGA 321113. The results for both analytes were in the range of <0.02 - 0.04 mg/kg in all trials. The number of submitted residue trials is considered sufficient for extrapolation since the crops under consideration are classified as very minor crops according to the EU Guidance document (EC, 2011). Based on the residue values from the supervised trials, EFSA derives an MRL proposal of 0.08 mg/kg for the intended use of trifloxystrobin on parsley root and fresh horseradish. The MRL is

also applicable to horseradish classified in the group of spices/roots or rhizome (code 840040) using an appropriate dehydration factor.

b. Purslane *(NEU outdoor and indoor GAP:3x250 g a.s./ha, PHI 14 days)*

The EMS did not provide residue trials reflecting the intended GAP of purslane, but referred to residue trials on lettuce which should be used to derive MRL proposals by extrapolation. A number of 8 indoor trials and 6 NEU outdoor trials on lettuce are available which were compliant with the intended GAPs (±25% deviation of the application rate is acceptable). All trials were designed as residue decline studies with sampling at various PHI intervals (0, 3, 7 and 14 days). Samples were analysed for the parent compound and for the metabolite CGA 321113. Only 2 outdoor trials were performed on open leaf varieties (endive and cos lettuce). In the remaining trials, head forming lettuce varieties (Sensai, Garuda, Romaserra, Alexandria, Angie, Ardeola, Robinson and Nadine) were tested or varieties for which EFSA was not able to retrieve details on the morphology to decide whether they should be considered as open leave or head forming varieties (Histor, Roderick and Rosella).

According to the EU guidance document (EC, 2011) a minimum of 8 trials on lettuce, 4 of them on open leaf varieties, are required for deriving a MRL for spinach group. Since purslane is a very minor crop, a reduced data set might be sufficient. However, considering that only 2 outdoor trials and not indoor trials were demonstrably performed on open leaf varieties, EFSA is of the opinion that the database is too weak to derive a robust MRL proposal. In case, further information on the lettuce varieties used in the residue trials confirms that a sufficient number of trials was performed on open leave variety, a MRL proposal could be derived.

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

The storage stability of trifloxystrobin and metabolite CGA 321113 in treated crops has been evaluated under the peer review of Directive 91/414/EEC (The United Kingdom, 2000). Studies demonstrated that residues of trifloxystrobin and CGA-321113 are stable in grapes, cucumbers, potatoes and wheat (grain, straw and whole plant), stored in deep frozen condition, at least for 12 months. For apples, wet pomace and grape juice stored in the freezer condition (approximately -20^{0}C), the stability was demonstrated for at least 6 months. No information was provided regarding the storage period of the carrot samples used to derive the MRL proposal for parsley roots and horseradish. Considering that trifloxystrobin did not show any significant decline in the available storage stability studies, the lack of information on the storage period of carrot samples is considered as a minor deficiency. However, it would be desirable to get the lacking information in the framework of the MRL review under Article 12 of Regulation (EC) No 396/2005 to verify the validity of the studies in carrots.

According to the EMS, the analytical method used to analyse the supervised residue trial samples has been sufficiently validated and was proven to be fit for the purpose (Belgium, 2013).

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)	Median CF (d)	Comments (e)
			Enforcement RD	Risk assessment RD					
Enforcement residue definition: Trifloxystrobin **Risk assessement residue definition**: Sum of trifloxystrobin and its metabolite CGA 321113, expressed as trifloxystrobin (provisional)									
Carrot → horseradish and parsley root	NEU	Outdoor	<0.02; 0.02 (2x); 0.03 (2x); 0.04	<0.04 (2x); <0.03; 0.04; 0.05; 0.08	0.03	0.04	0.08	1.6	R_{ber}= 0.07 R_{max}= 0.06 MRL_{OECD}= 0.08
Lettuce → purslane	EU	Indoor	2.4^{Garuda}; 2.5^{Rodrick}; 2.7$^{Alex.}$; 5.4^{Angie}; 5.6^{Sansai}; 5.7^{Rossela}; 6.6^{Romasera}; 7.2 ^{Histor}	2.4^{Garuda}; 2.7^{Rodrick}; 2.7^{Alex}; 5.4^{Angie}; 5.65^{Sansai}; 5.8^{Rossela}; 6.7^{Romasera}; 7.2^{Histor}			-		The number of trials on open leaf varieties of lettuce was not sufficient to derive an MRL proposal.
Lettuce → purslane	NEU	Outdoor	**0.43**^{Cos}; 0.063**^{Nadine}; **0.79**^{Endive}; 1.65**^{Robinson}; 1.2^{Ardeola}; 1.3^{Ardeola}	0.46^{Cos}; 0.65**^{Nadine}; 0.85^{Endive}; 1.67**^{Robinson}; 1.2^{Ardeola}; 1.3 ^{Ardeola}			-		

(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).
(*): Indicates that the MRL is set at the limit of analytical quantification.
(**) Represents the mean of two trials resulted from the same study
Sensai, Garuda, Romaserra, Alexandria, Angie, Ardeola, Robinson and Nadine are head forming varieties of lettuce.
Cos and Endive are open leaf varieties of lettuce.
Hristor, Rodrick and Rosella- no information found about the varieties (head forming or open leaf lettuce).

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 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 is of relevance for risk assessment for processed commodities which have undergone sterilisation processes. However, the toxicity of metabolite CGA 321113 is covered by that of the parent compound (see section 2).

Specific studies to assess the magnitude of trifloxystrobin residues during the processing of horseradish, parsley root and purslane were not submitted. Considering the insignificant contribution of the crops under consideration to the dietary intake no specific processing studies are required.

3.1.2. Rotational crops

3.1.2.1. Preliminary considerations

Horseradish, parsley root and purslane are grown in rotation with other crops. According to the soil degradation studies performed in the framework of the peer review the DT_{90} value of trifloxystrobin based on the field and laboratory studies is less than 100 days. For the metabolite CGA 321113, the DT_{90} value is more than 500 days and for CGA 373466[11], a relevant soil metabolite, DT_{90} value is up to 290 days (United Kingdom, 2000). According to the European guidelines on rotational crops (EC, 1997b), further investigation of residues in rotational crops is relevant.

3.1.2.2. Nature of residues

The metabolism of trifloxystrobin was investigated in rotational crops in lettuce, radish and wheat in the framework of the peer review (The United Kingdom, 2000). The mentioned crops were planted at different intervals of 30, 120, 174 and 365 days after the bare soil treatment application, using either trifluoro-phenyl-^{14}C-labelled trifloxystrobin or glyoxyl-phenyl-^{14}C-labelled trifloxystrobin, at a rate of 0.5 kg a.s/ha. The total residues measured (expressed as trifloxystrobin) in the 31st day of harvesting were in lettuce (0.025 mg/kg), radish tops and roots (0.041 and 0.031 mg/kg), spring wheat at 50% maturity (0.06mg/kg), grain (0.059 mg/kg) and straw (0.075 mg/kg). In the upper soil layer (0-10cm), the TRR decreased from the 0.375 mg/kg to 0.262 mg/kg over 31 days, corresponding to a half-life of 81 days for TRR. Trifloxystrobin decreased from 86.7% to 3.6% TRR while the metabolites CGA 321113 plus CGA 373465 increased from 2.5% to 46.2%. The corresponding half-life for the mentioned metabolites is approximately 72 days.

The major metabolite detected in all plants studied after one year was trifluoroacetic acid accounted for up to 65.7% of the total radioactive residue (0.016 mg/kg) in radish tops and circa 23% of the radioactive residue (0.014-0.015 mg/kg) in wheat grain.

Based on the above findings, metabolisms in primary and rottional crops were found to be comparable. It is noted however, that the formation of trifluoroacetic acid was not observed in the metabolism in primary crops. Since trifluoroacetic acid is a common metabolite of different active substances (e.g. bifenthrin, flurtamone) a specific residue definition for rotational crops treated with trifloxystrobin is not appropriate. However, it should be noted that recently EFSA received a mandate for a comprehensive dietary exposure assessment as regards trifluoroacetic acid (EFSA-Q-2013-00432).

[11] (Z, E)-methoxyimino-{2-[1-(3-trifluoro methyl-phenyl)-ethylideneaminooxymethyl]-phenyl}-acetic acid

Considering that the application rate used in these studies (0.5 kg a.s./ha) was in the range of the intended seasonal application rate on the crops under consideration (0.6 kg a.s./ha), it can be concluded that residues of parent trifloxystrobin above the LOQ in rotations/succeeding crops are unlikely to occur provided that trifloxystrobin is applied on horseradish and parsley root in compliance with the intended GAP. To avoid measurable residues of the soil metabolite trfluoroacetic acid in rotational crops, Member States may consider specific restrictions when authorising pesticides containing trifloxystrobin.

3.2. Nature and magnitude of residues in livestock

The crops under consideration are not potential feed items for chicken, ruminants and pigs.

4. Consumer risk assessment

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). This exposure assessment model contains the relevant European food consumption data for different sub-groups of the EU population [12] (EFSA, 2007).

For the chronic exposure calculations EFSA used the median residue value derived from the trials on carrots which were extrapolated to horseradish and parsley root, multiplied by conversion factor from enforcement to risk assessment. For certain crops assessed in previously issued EFSA reasoned opinions (EFSA, 2008, 2009a, 2009b, 2010, 2011, 2012, 2013) the median residue values and the respective conversion factors were used. For the remaining commodities the exposure is calculated on the basis of the existing MRLs. Also for purslane, the existing MRL was used as input value since the data were found to be not sufficient to derive a MRL proposal (see table 4-1). No acute exposure calculations were carried out because an ARfD was not deemed necessary for this active substance.

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 assessment 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.

[12] 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).

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**
Risk assessment residue definition for plant products: Sum of trifloxystrobin and its metabolite CGA 321113, expressed as trifloxystrobin (provisional)[(a)] **Risk assessment residue definition for animal products:** Sum of trifloxystrobin and its metabolite CGA321113 expressed as trifloxystrobin				
Horseradish	**0.04**	Median residue*CF(1.6)[(b)] (NEU, outdoor, carrots) (Table 3-1)	Acute risk assessment was not performed since no ARfD is necessary for trifloxystrobin	
Parsley root	**0.04**	Median residue*CF (1.6)[(b)] (NEU, outdoor, carrots) (Table 3-1)		
Purslane	0.02*	Existing MRL		
Beans with pods	0.2	Median residue (EFSA 2013)		
Spring onion	0.04	Median residue * CF(2.6) (EFSA, 2012)		
Globe artichokes	0.07	Median residue (EFSA, 2012)		
Aubergines	0.08	Median residue (EFSA, 2011)		
Blueberries	0.78	Median residue (EFSA, 2009a)		
Brussels sprouts	0.05	Median residue*CF (1.3) (EFSA, 2009a)		
Lettuce, scarole, herbs	5.5	Median residue (EFSA, 2009a)		
Celery	10	Median residue*CF (1.3) (EFSA, 2009a)		
Swedes, turnip, salsify	0.02	Median residue * CF(2.0) (EFSA, 2009b)		
Passion fruit	0.72	Median residue (EFSA, 2008)		
Other commodities of plan and animal origin	MRL	See Appendix C		

(a): Residue definition proposed by EFSA on a provisional basis, see section 3.1.1.1
(b): Median conversion conversion factor for enforcement to risk assessment of 1.6 is obtained by calculating the median of the individual conversion factors for each residue trial on carrots (Belgium 2013)

The calculated 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 up to 22.9 % of the ADI (all FR population diet). The exposure to trifloxystrobin via horseradish and parsley root is expected to be insignificant (less than 0.1 % of the ADI for the DE child diet).

EFSA concludes that the intended use of trifloxystrobin on crops under consideration will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a public health concern.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The toxicological profile of trifloxystrobin was assessed by the RMS and the data were sufficient to derive an ADI of 0.1 mg/kg bw per day. No ARfD was deemed necessary due to the low toxicity profile of the active substance. According to the RMS United Kingdom, the toxicity of the metabolite CGA 321113 is covered by the toxicological reference value derived for the parent compound.

The metabolism of trifloxystrobin in primary crops was investigated in apples, cucumbers, wheat, sugar beet and peanuts following foliar applications where trifloxystrobin was found as the major residue. The metabolism study in sugar beets and the results of residue trials on several crops (Brussels sprouts, head cabbage, celery) indicated that the metabolite CGA 321113 may be present in significant concentrations. Based on these findings 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. EFSA concludes that the metabolism of trifloxystrobin is sufficiently addressed and the residue definition for enforcement established in Regulation (EC) 396/2005 and confirmed by the peer review is trifloxystrobin. For risk assessment, EFSA uses on a provisional basis the residue definition which comprises trifloxystrobin and the metabolite CGA 321113. Validated analytical methods for enforcement of this residue definition are available with an LOQ of 0.02 mg/kg.

EFSA concludes that the submitted data are sufficient to extrapolate residue data from carrots to parsley root and horseradish and to derive MRL proposals in support of the NEU intended uses. For purslane the submitted residue trials on lettuce were found to be insufficient to derive a robust MRL proposal since only few residue trials were performed on varieties which are considered as representative for purslane (limited number of trials on open leaf varieties of lettuce). Adequate analytical enforcement methods are available to control the residues of trifloxystrobin in the commodities under consideration.

Trifloxystrobin is hydrolytically stable under conditions simulating pasteurisation, but showed degradation under baking/brewing/boiling conditions and during sterilisation. The main degradation product observed was the metabolite CGA 321113. However, the toxicity of metabolite CGA 321113 is covered by the parent compound. Specific studies investigating the effects of processing on the magnitude of trifloxystrobin residues in the processed crops under consideration have not been submitted. Considering the insignificant contribution of the crops under consideration to the dietary intake no specific processing studies are required.

The occurrence of trifloxystrobin residues in rotational crops was investigated in lettuce, radish and wheat in the framework of the peer review. Based on the available information on the nature and magnitude of residues in succeeding crops, EFSA concludes that significant residue levels of parent trifloxystrobin are unlikely to occur provided that trifloxystrobin is applied on horseradish and parsley root according to the intended GAP. In order to avoid the occurance of trifluoroacetic acid, a substance that was found in low concentrations in rotational crops, Member States should consider specific restrictions.

Residues of trifloxystrobin in commodities of animal origin were not assessed in the framework of this application, since the crops under consideration are not potential feed items for chicken, ruminants and pigs.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). The risk assessment was performed reflecting the risk assessment residue definition as trifloxystrobin, including metabolite CGA 321113 for some crops where the available data indicated the presence of this metabolite. For the calculation of chronic exposure, EFSA used the median residue value derived from the residue trials on carrot as input value for horseradish and parsley root. For several crops the risk assessment values were available to refine the consumer

exposure calculations. 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.

EFSA concludes that the proposed use of trifloxystrobin on horseradish and parsley root will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a consumer health risk.

RECOMMENDATIONS

Code number[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: Trifloxystrobin (F)				
213040	Horseradish	0.02*	0.08	The MRL proposals are sufficiently supported by data and no consumer health risk was identified for the intended uses on theses crops. The MRL is derived by extrapolation data from carrots.
213070	Parsley root	0.04	0.08	
252020	Purslane	0.02*	No proposal	The number of trials on open leaf varieties was not sufficient to derive a robust MRL proposal.
840040	Horseradish (spice)	0.05*	See comment	The MRL proposal for horseradish (213040) should be applied also for the horseradish listed in the group of spices, taking into account an increase of the concentration resulting from drying.

(a):-According to Annex I of Regulation (EC) No 396/2005.
(*):-Indicates that the MRL is set at the limit of analytical quantification.
(F):-fat soluble pesticide

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APPENDICES

Appendix 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		
Parsley root horseradish	Belgium (NEU)	F	Powdery mildew	WG	50%	Spraying		1-3	7 days			0.2	7	
Purslane (including sorrel and glassworth)	Belgium (NEU)	F	Powdery mildew	WG	50%	Spraying		1-3	7 days			0.2	7	

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)

Pesticide Residue Intake Model (PRIMo)

Trifloxystrobin			
Status of the active substance:	included	Code no.	
LOQ (mg/kg bw):	0.02	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	0.1	ARfD (mg/kg bw):	n.n.
Source of ADI:	EU	Source of ARfD:	EU
Year of evaluation:	2003	Year of evaluation:	2003

Prepare workbook for refined calculations

Undo refined calculations

The risk assessment has been performed on the basis of the MRLs collected from Member States in April 2006. For each pesticide/commodity the highest national MRL was identified (proposed temporary MRL = pTMRL).
The pTMRLs have been submitted to EFSA in September 2006.

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)	Commodity / group of commodities	pTMRLs at LOQ (in % of ADI)
22.9	FR all population	20.0	Wine grapes	0.5	Table grapes	0.5	Lettuce	0.1
19.8	WHO Cluster diet B	9.0	Wine grapes	2.0	Lettuce	1.7	Table grapes	0.3
18.6	DE child	6.3	Table grapes	6.0	Apples	1.1	Oranges	0.4
16.4	PT General population	12.4	Wine grapes	1.4	Table grapes	0.5	Apples	0.2
13.6	IE adult	6.3	Wine grapes	1.3	Table grapes	0.6	Peaches	0.3
13.3	WHO cluster diet E	8.0	Wine grapes	0.8	Table grapes	0.5	Lettuce	0.2
13.1	NL child	3.8	Table grapes	3.2	Apples	1.1	Scarole (broad-leaf endive)	0.8
8.8	DK adult	7.0	Wine grapes	0.4	Apples	0.4	Table grapes	0.1
8.1	NL general	3.1	Wine grapes	1.1	Table grapes	0.7	Lettuce	0.2
7.9	ES adult	2.9	Lettuce	2.1	Wine grapes	0.4	Tomatoes	0.1
7.8	UK Adult	5.4	Wine grapes	0.6	Lettuce	0.3	Table grapes	0.1
7.6	WHO Cluster diet F	3.0	Wine grapes	1.7	Lettuce	0.6	Table grapes	0.2
7.5	WHO regional European diet	2.1	Lettuce	1.2	Wine grapes	0.8	Table grapes	0.2
7.1	UK vegetarian	4.1	Wine grapes	0.8	Lettuce	0.4	Table grapes	0.1
6.7	WHO cluster diet D	1.8	Wine grapes	0.9	Table grapes	0.7	Herbs	0.2
6.2	FR toddler	1.3	Apples	1.0	Table grapes	0.8	Milk and cream,	0.9
6.2	ES child	2.3	Lettuce	0.7	Oranges	0.6	Apples	0.3
5.9	UK Toddler	1.2	Table grapes	1.1	Sugar beet (root)	0.9	Apples	0.5
5.6	IT adult	2.1	Lettuce	0.7	Table grapes	0.6	Tomatoes	0.1
5.4	DK child	1.2	Apples	0.9	Table grapes	0.8	Lettuce	0.3
5.3	IT kids/toddler	1.6	Lettuce	0.7	Tomatoes	0.5	Table grapes	0.1
4.0	UK Infant	0.8	Apples	0.8	Milk and cream,	0.5	Sugar beet (root)	0.9
3.9	PL general population	1.6	Table grapes	1.0	Apples	0.4	Tomatoes	0.1
3.8	FR infant	1.3	Apples	0.5	Milk and cream,	0.4	Table grapes	0.6
3.4	FI adult	1.5	Wine grapes	0.4	Lettuce	0.3	Oranges	0.2
3.3	SE general population 90th percentile	0.5	Apples	0.4	Tomatoes	0.2	Milk and cream,	0.4
2.3	LT adult	0.9	Apples	0.3	Lettuce	0.3	Tomatoes	0.2

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Trifloxystrobin is unlikely to present a public health concern.

Appendix B. Existing EU maximum residue levels (MRLs)

(Pesticides - Web Version - EU MRLs (File created on 23/07/2013 10:43)

Code number	Groups and examples of individual products to which the MRLs apply	Trifloxystrobin (F)(R)
100000	1. FRUIT FRESH OR FROZEN NUTS	0,3
110000	(i) Citrus fruit	0,3
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo (except mineola), ugli and other hybrids)	0,3
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0,3
110030	Lemons (Citron, lemon, Buddha's hand (Citrus medica var. sarcodactylis))	0,3
110040	Limes	0,3
110050	Mandarins (Clementine, tangerine, mineola and other hybrids tangor (Citrus reticulata x sinensis))	0,3
110990	Others	0,02*
120000	(ii) Tree nuts	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	0,5
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	
140000	(iv) Stone fruit	1
140010	Apricots	1
140020	Cherries (Sweet cherries, sour cherries)	1
140030	Peaches (Nectarines and similar hybrids)	0,2
140040	Plums (Damson, greengage, mirabelle, sloe, red date/Chinese date/Chinese jujube (Ziziphus zizyphus))	0,02*
140990	Others	
150000	(v) Berries & small fruit	5
151000	(a) Table and wine grapes	5
151010	Table grapes	5
151020	Wine grapes	0,5
152000	(b) Strawberries	0,02*
153000	(c) Cane fruit	0,02*
153010	Blackberries	0,02*
153020	Dewberries (Loganberries, tayberries, boysenberries, cloudberries and other Rubus hybrids)	0,02*
153030	Raspberries (Wineberries, arctic bramble/raspberry, (Rubus arcticus), nectar raspberries (Rubus arcticus x Rubus idaeus))	0,02*
153990	Others	
154000	(d) Other small fruit & berries	2
154010	Blueberries (Bilberries)	0,02*
154020	Cranberries (Cowberries/red bilberries (V. vitis-idaea))	1
154030	Currants (red, black and white)	1
154040	Gooseberries (Including hybrids with other Ribes species)	0,02*
154050	Rose hips	0,02*
154060	Mulberries (Arbutus berry)	0,02*
154070	Azarole (mediteranean medlar) (Kiwiberry (Actinidia arguta))	2
154080	Elderberries (Black chokeberry/appleberry, mountain ash, buckthorn/sea sallowthorn, hawthorn, serviceberries, and other treeberries)	0,02*
154990	Others	
160000	(vi) Miscellaneous fruit	
161000	(a) Edible peel	0,02*
161010	Dates	0,02*
161020	Figs	0,3
161030	Table olives	0,02*
161040	Kumquats (Marumi kumquats, nagami kumquats, limequats (Citrus aurantifolia x Fortunella spp.))	0,02*
161050	Carambola (Bilimbi)	0,02*
161060	Persimmon	0,02*
161070	Jambolan (java plum) (Java apple/water apple, pomerac, rose apple, Brazilean cherry, Surinam cherry/grumichama (Eugenia uniflora))	0,02*
161990	Others	0,02*
162000	(b) Inedible peel, small	
162010	Kiwi	0,02*
162020	Lychee (Litchi) (Pulasan, rambutan/hairy litchi, longan, mangosteen, langsat, salak)	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, mammey 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	Cherimoya (Custard apple, sugar apple/sweetsop, ilama (Annona diversifolia) and other medium sized Annonaceae fruits)	0,02*
163070	Guava (Red pitaya/dragon fruit (Hylocereus undatus))	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*
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 (Angelica roots, lovage roots, gentiana roots)	0,02*
213050	Jerusalem artichokes (Crosne)	0,02*
213060	Parsnips	0,04
213070	Parsley root	0,04
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties, tiger nut (Cyperus esculentus))	0,02*
213090	Salsify (Scorzonera, Spanish salsify/Spanish oysterplant, edible burdock)	0,04
213100	Swedes	0,04
213110	Turnips	0,04
213990	Others	0,02*
220000	(ii) Bulb vegetables	
220010	Garlic	0,02*
220020	Onions (Other bulb onions, silverskin onions)	0,02*
220030	Shallots	0,02*
220040	Spring onions and welsh onions (Other green onions and similar varieties)	0,1
220990	Others	0,02*
230000	(iii) Fruiting vegetables	

Code number	Groups and examples of individual products to which the MRLs apply	Trifloxystrobin (F)(R)
231000	(a) Solanacea	
231010	Tomatoes (Cherry tomatoes, Physalis spp., gojiberry, wolfberry (Lycium barbarum and L. chinense), tree tomato)	0,5
231020	Peppers (Chilli peppers)	0,3
231030	Aubergines (egg plants) (Pepino, antroewa/white eggplant (S. macrocarpon))	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), lauki (Lagenaria siceraria), chayote, sopropo/bitter melon, snake gourd, angled luffa/teroi)	0,2
232990	Others	0,2
233000	(c) Cucurbits-inedible peel	
233010	Melons (Kiwano)	0,3
233020	Pumpkins (Winter squash, marrow (late variety))	0,2
233030	Watermelons	0,2
233990	Others	0,02*
234000	(d) Sweet corn (Baby corn)	0,02*
239000	(e) Other fruiting vegetables	0,02*
240000	(iv) Brassica vegetables	
241000	(a) Flowering brassica	
241010	Broccoli (Calabrese, Broccoli raab, Chinese broccoli)	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 or Chinese) mustard, pak choi, Chinese flat cabbage/ai goo choi), choi sum, Peking cabbage/pe-tsai)	3
243020	Kale (Borecole/curly kale, collards, Portuguese Kale, Portuguese cabbage, cow cabbage)	3
243990	Others	3
244000	(d) Kohlrabi	0,5
250000	(v) Leaf vegetables & fresh herbs	
251000	(a) Lettuce and other salad plants including Brassicacea	
251010	Lamb's lettuce (Italian corn salad)	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, curly leaf endive, sugar loaf (C. endivia var. crispum/C. intybus var. foliosum), dandelion greens)	10
251040	Cress (Mung bean sprouts, alfalfa sprouts)	0,02*
251050	Land cress	0,02*
251060	Rocket, Rucola (Wild rocket (Diplotaxis spp.))	0,02*
251070	Red mustard	0,02*
251080	Leaves and sprouts of Brassica spp, including turnip greens (Mizuna, leaves of peas and radish and other babyleaf crops, including brassica crops (crops harvested up to 8 true leaf stage), kohlrabi leaves)	0,02*
251990	Others	0,02*
252000	(b) Spinach & similar (leaves)	0,02*
252010	Spinach (New Zealand spinach, amaranthus spinach (pak-khom, tampara), tajer leaves, bitterblad/bitawiri)	0,02*
252020	Purslane (Winter purslane/miner's lettuce, garden purslane, common purslane, sorrel, glassworth, agretti (Salsola soda))	0,02*
252030	Beet leaves (chard) (Leaves of beetroot)	0,02*
252990	Others	0,02*
253000	(c) Vine leaves (grape leaves) (Malabar nightshade, banana leaves, climbing wattle (Acacia pennata))	0,02*
254000	(d) Water cress (Morning glory/Chinese convolvulus/water convolvulus/water spinach/kangkung (Ipomea aquatica), water clover, water mimosa)	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 cisely and other Apiacea leaves, culantro/stinking/long coriander/stink weed (Eryngium foetidum))	10
256040	Parsley (leaves of root parsley)	10
256050	Sage (Winter savory, summer savory, Borago officinalis leaves)	10
256060	Rosemary	10
256070	Thyme (Marjoram, oregano)	10
256080	Basil (Balm leaves, mint, peppermint, holy basil, sweet basil, hairy basil, edible flowers (marigold flower and others), pennywort, wild betel leaf, curry leaves)	10
256090	Bay leaves (laurel) (Lemon grass)	10
256100	Tarragon (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, yard long beans, guar beans, soya beans)	0,5
260020	Beans (without pods) (Broad beans, flageolets, jack bean, lima bean, cowpea)	0,02*
260030	Peas (with pods) (Mangetout/sugar peas/snow peas)	0,02*
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 (Borago officinalis stems)	0,02*
270030	Celery	1
270040	Fennel	0,02*
270050	Globe artichokes (Banana flower)	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 fungi (Common mushroom, oyster mushroom, shiitake, fungus mycelium (vegetative parts))	0,02*
280020	Wild fungi (Chanterelle, truffle, morel, cep)	0,02*
280990	Others	0,02*
290000	(ix) Sea weeds	0,02*
300000	3. PULSES, DRY	0,02*
300010	Beans (Broad beans, navy beans, flageolets, 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 (Other seeds of Cucurbitaceae)	0,05*
401110	Safflower	0,05*
401120	Borage (Purple viper's bugloss/Canary flower (Echium plantagineum), Corn Gromwell (Buglossoides arvensis))	0,05*

Code number	Groups and examples of individual products to which the MRLs apply	Trifloxystrobin (F)(R)
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 (palmoil kernels)	0,05*
402030	Palmfruit	0,05*
402040	Kapok	0,05*
402990	Others	0,05*
500000	5. CEREALS	
500010	Barley	0,3
500020	Buckwheat (Amaranthus, quinoa)	0,02*
500030	Maize	0,02*
500040	Millet (Foxtail millet, teff, finger millet, pearl millet)	0,02*
500050	Oats	0,02*
500060	Rice (Indian/wild rice (Zizania aquatica))	0,02*
500070	Rye	0,05
500080	Sorghum	0,02*
500090	Wheat (Spelt, triticale)	0,05
500990	Others (Canary grass seeds (Phalaris canariensis))	0,02*
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	0,05*
610000	(i) Tea	0,05*
620000	(ii) Coffee beans	
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 (Elderflowers (Sambucus nigra))	0,05*
631050	Lime (linden)	0,05*
631990	Others	0,05*
632000	b) Leaves	0,05*
632010	Strawberry leaves	0,05*
632020	Rooibos leaves (Ginkgo 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) Cocoabeans (fermented or dried)	0,05*
650000	(v) Carob (st johns bread)	0,05*
700000	7. HOPS (dried)	0,05*
800000	8. SPICES	30
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	Sichuan pepper (Anise pepper, Japan pepper)	0,05*
820030	Caraway	0,05*
820040	Cardamom	0,05*
820050	Juniper berries	0,05*
820060	Pepper, black, green 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*
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	0,05*
900010	Sugar beet (root)	
900020	Sugar cane	0,05
900030	Chicory roots	0,02*
900990	Others	0,02*
1000000	10. PRODUCTS OF ANIMAL ORIGIN- TERRESTRIAL ANIMALS	0,02*
1010000	(i) Tissue	
1011000	(a) Swine	0,04*
1011010	Muscle	0,04*
1011020	Fat	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	Muscle	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	Muscle	0,04*
1013020	Fat	0,04*
1013030	Liver	0,04*
1013040	Kidney	0,04*
1013050	Edible offal	0,04*
1013990	Others	0,04*
1014000	(d) Goat	0,04*
1014010	Muscle	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	Muscle	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	Muscle	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, deer)	0,04*
1017010	Muscle	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	0,02*
1020010	Cattle	0,02*
1020020	Sheep	0,02*
1020030	Goat	0,02*
1020040	Horse	0,02*
1020990	Others	0,02*
1030000	(iii) Bird eggs	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, honey comb with honey (comb honey))	0,04*
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	0,04*
1060000	(vi) Snails	0,04*
1070000	(vii) Other terrestrial animal products (Wild game)	0,04*

(*) Indicates lower limit of analytical determination

R - The residue definition differs for the following combination pesticide-code number Trifloxystrobin- code 1000000: the sum of trifloxystrobin and its metabolite (E, E)-methoxyimino- {2-[1-(3-trifluoromethyl-phenyl)-ethylideneamino-oxymethyl]-phenyl}-acetic acid (CGA 321113)

F-fat soluble

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, *French*)
CF	conversion factor for enforcement to risk assessment residue definition
CXL	Codex Maximum Residue Limit (Codex MRL)
d	day
DALA	days after last application
DAR	Draft Assessment Report
DAT	days after treatment
DT_{90}	period required for 90 % dissipation (define method of estimation)
EC	European Community
ECD	electrod capture detection
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
GC	gas chromatography
GCPF	Global Crop Protection Federation (former GIFAP)
ha	hectare
hL	hectolitre
HPLC	High Performance Liquid Chromatography
HR	highest residue
i.e.	that is (id est, *Latin*)
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
LOQ	limit of quantification
LC	liquid chromatography
MRL	maximum residue level
MS/MS	tandem mass spectrometry
NEU	northern European Union
NPD	Nitrogen Phosphorus Detection
OECD	Organisation for Economic Co-operation and Development
PHI	pre-harvest interval

PRIMo	(EFSA) Pesticide Residues Intake Model
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
SANCO	Directorate-General for Health and Consumers
SCFCAH	Standing Committee on the Food Chain and Animal Health
SEU	southern European Union
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
UV	ultra-violet (detector)
WG	water dispersible granule
WHO	World Health Organisation
yr	year