

REASONED OPINION

Reasoned Opinion on the modification of the existing maximum residue levels for esfenvalerate in peppers, broccoli and lettuce¹

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ABSTRACT

In accordance with Article 6 of Regulation (EC) No 396/2005, Italy, hereafter referred to as the evaluating Member State (EMS), received an application from Agchem Project Consulting on behalf of Esfenvalerate Task Force to modify the existing maximum residue levels (MRLs) for the active substance esfenvalerate in peppers, broccoli and lettuce according to the intended uses. In order to accommodate for the intended uses of esfenvalerate, the EMS proposed to raise the existing MRLs from the limit of quantification (LOQ) 0.02 mg/kg to 0.05 mg/kg for peppers and broccoli and 0.06 mg/kg for lettuce. 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 investigating the magnitude of esfenvalerate residues are sufficient to derive MRL proposals of 0.05 mg/kg for the use on peppers, 0.05 mg/kg for the use on broccoli and 0.2 mg/kg for the use on lettuce. Adequate analytical enforcement methods are available to control the residues of esfenvalerate in these commodities. Based on the risk assessment results, EFSA concludes that the intended uses of esfenvalerate on peppers, broccoli and lettuce will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a consumer health risk.

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KEY WORDS

esfenvalerate, vegetables, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, pyrethroids, fenvalerate

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SUMMARY

In accordance with Article 6 of Regulation (EC) No 396/2005, Italy, hereafter referred to as the evaluating Member State (EMS), received an application from Agchem Project Consulting on behalf of Esfenvalerate Task Force to modify the existing maximum residue levels (MRLs) for the active substance esfenvalerate in peppers, broccoli and lettuce according to the intended uses. In order to accommodate for the intended uses of esfenvalerate, the EMS proposed to raise the existing MRLs from the limit of quantification (LOQ) 0.02 mg/kg to 0.05 mg/kg for peppers and broccoli and 0.06 mg/kg for lettuce. 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 10 October 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 esfenvalerate, the JMPR Evaluation report as well as the conclusion from a previous EFSA opinion on esfenvalerate (Article 12 MRL review).

EFSA proposes MRLs based on a comprehensive assessment of the properties of the active substance and the residue levels resulting from the good agricultural practices (GAP) defined for the treated crops. The assessment includes the toxicological profile and setting of toxicological reference values, the metabolism and magnitude of residues in commodities of plant (i.e. primary crops, processed commodities and rotational crops) and animal origin, as well as the analytical methods used. Consumer exposure estimates taking into account the proposed MRLs are then compared to toxicological reference values to assess the risk of the active substance according to the intended uses.

The toxicological profile of esfenvalerate was assessed in the DAR by the rapporteur Member State Portugal and the data were sufficient to derive the toxicological reference values acceptable daily intake (ADI) of 0.02 mg/kg bw per day and acute reference dose (ARfD) of 0.05 mg/kg bw.

The metabolism of esfenvalerate in primary crops was investigated in three different crop groups following foliar application. Metabolic patterns in the different studies were shown to be similar and the relevant residue for enforcement and risk assessment in all crops supported in the framework of Article 12 MRL review was defined as fenvalerate (any ratio of constituent isomers including esfenvalerate). For the use on peppers, broccoli and lettuce, EFSA concludes that the metabolism of esfenvalerate in primary crops is sufficiently addressed and that the residue definitions derived are applicable.

Submitted supervised residues trials investigating the magnitude of esfenvalerate residues are sufficient to derive MRL proposals of 0.05 mg/kg for the use on peppers, 0.05 mg/kg for the use on broccoli and 0.2 mg/kg for the use on lettuce. Adequate analytical enforcement methods are available to control the residues of esfenvalerate in these commodities at the validated LOQ of 0.01 mg/kg.

Specific studies investigating the magnitude of esfenvalerate residues in processed commodities are not required, as the residues expected in raw agricultural commodities (RAC) are low and the total theoretical maximum daily intake (TMDI) is below the trigger value of 10 % of the ADI (see below).

The occurrence of esfenvalerate residues in rotational crops was investigated 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 are unlikely to occur in rotational crops provided that the compound is used on peppers, broccoli and lettuce according to the proposed GAP.

Residues of esfenvalerate in commodities of animal origin were not assessed in the framework of this application, since peppers, broccoli and lettuce are normally not fed to livestock.

The consumer risk assessment was then performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRiMo). In the framework of Article 12 MRL review a comprehensive short- and long-

term consumer exposure assessment was performed, taking into account the existing uses of esfenvalerate at EU level, those codex maximum residue limit (CXLs) which were sufficiently supported by data and veterinary MRLs. The long-term consumer risk assessment was now updated, including the median residue concentrations observed in peppers, broccoli and lettuce. The acute exposure assessment was performed only with regard to the commodities under consideration. No acute and long-term consumer risk was identified in relation to the MRL proposals for peppers, broccoli and lettuce. The total calculated intake accounted for up to 9 % of the ADI (Netherlands child). The contribution of residues in peppers, broccoli and lettuce to the total consumer exposure accounted for a maximum of 0.03 % of the ADI (French toddler) and 7 % of the ARfD for lettuce (German child).

EFSA concludes that the intended uses of esfenvalerate on peppers, broccoli and lettuce will not result in a consumer exposure exceeding the toxicological reference values 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: fenvalerate: any ratio of constituent isomers including esfenvalerate				
231020	Pepper	0.02*	0.05	The MRL proposals are sufficiently supported by data and no consumer health risk was identified for the intended uses on these crops.
241010	Broccoli	0.02*	0.05	
251020	Lettuce	0.02*	0.2	

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

(*): Indicates that the MRL is set at the limit of analytical quantification.

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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 modify a MRL in accordance with the provisions of Article 7 of that Regulation.

Italy, hereafter referred to as the evaluating Member State (EMS), received an application from the company Agchem Project Consulting on behalf of Esfenvalerate Task Force⁶ to modify the existing MRLs for the active substance esfenvalerate in peppers, broccoli and lettuce. 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 10 October 2013.

The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2013-00818 and the following subject:

Esfenvalerate - Application to set new MRLs in various crops.

Italy proposed to raise the existing MRLs of esfenvalerate in peppers, broccoli and lettuce from the limit of quantification 0.02 mg/kg to 0.05 mg/kg for peppers and broccoli and 0.06 mg/kg for lettuce.

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 10 January 2014.

³ Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.03.2005, p. 1-16.

⁴ Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.08.1991, p. 1-32.

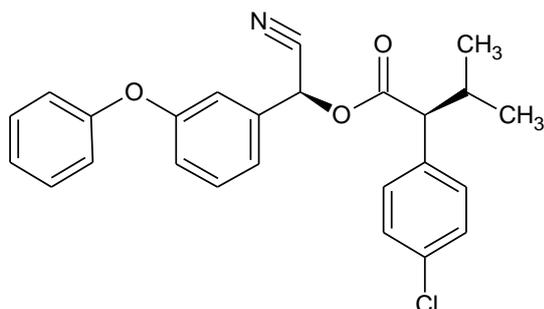
⁵ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1-50.

⁶ Agchem Project Consulting on behalf of Esfenvalerate Task Force, Avenue du Tourail, 290. 845880. Coustellet Oppède. France.

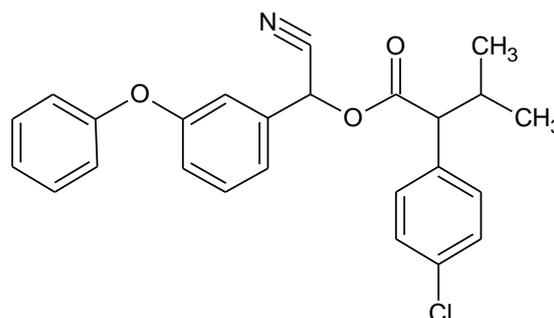
THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Esfenvalerate is the ISO common name for (α S)- α -cyano-3-phenoxybenzyl (2S)-2-(4-chlorophenyl)-3-methylbutyrate (IUPAC). Before esfenvalerate was developed, fenvalerate was used in pesticides as active substance; fenvalerate is composed of four isomers ([2S, α S], [2S, α R], [2R, α S] and [2R, α R]) in approximately equal proportions. Esfenvalerate is the biologically active isomer ([2S, α S]) of fenvalerate. The chemical structure of both compounds is reported below.

Esfenvalerate



Fenvalerate



Molecular weight: 419.91 g/mol

Esfenvalerate and fenvalerate are systemic insecticides belonging to the group of pyrethroid compounds chemical family. They act as a contact and stomachal poison with neurotoxic effects against a wide range of insect pests in a variety of crops.

Esfenvalerate was evaluated in the framework of Council Directive 91/414/EEC with Portugal designated as rapporteur Member State (RMS). It was included in Annex I of this Directive by Directive 2000/67/EC⁷ which entered into force on 8 January 2001 for use as insecticide only. In accordance with Commission Implementing Regulation (EU) No 540/2011⁸ esfenvalerate is approved under Regulation (EC) No 1107/2009, repealing Council Directive 91/414/EEC.

The representative uses evaluated in the peer review were foliar applications on several crops. The peer review is currently in progress for the Annex I renewal (AIR) under Regulation (EC) No 1107/2009. The Renewal Assessment Report (RAR) was submitted to EFSA on 30 July 2013; the EFSA conclusion is not yet available.

The EU MRLs for esfenvalerate are established in Annexes II and IIIB of Regulation (EC) No 396/2005 (Appendix C). In 2011, EFSA reviewed the existing MRLs for all authorized uses in accordance with Article 12 of Regulation (EC) No 396/2005 (EFSA, 2011). The implementation of the proposals derived by EFSA is under preparation (SANCO/10698/2013, voted in SCFCAH on 17 September 2013). A second regulation is in preparation (SANCO/12375/2013, voted in SCFCAH on 19 November 2013) which incorporates the CXLs relevant for esfenvalerate which were adopted in 2013 by CAC. It is noted that according to the Regulations under preparation the residue definition will be amended. The recently voted MRLs were also included in Appendix C.

The existing EU MRLs for esfenvalerate on the crops under consideration (peppers, broccoli and lettuce) are set at the LOQ of 0.02 mg/kg. Codex Alimentarius has established (CXLs) for fenvalerate

⁷ Commission Directive 2000/67/EC of 23 October 2000 including an active substance (esfenvalerate) in Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products in the market. OJ L257, 28.10.2000, p.38-40.

⁸ Commission Implementing Regulation (EU) No 540/2011 of 23 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.06.2011, p. 1-186.

and esfenvalerate on a wide range of commodities. In 2012 JMPR recommended to delete the MRLs for fenvalerate; no CXLs are established for esfenvalerate for peppers, broccoli and lettuce.

The details of the intended GAPs for esfenvalerate are given in Appendix A.

ASSESSMENT

EFSA bases its assessment on the evaluation report submitted by the EMS (Italy, 2013), the Draft Assessment Report (DAR) prepared under Council Directive 91/414/EEC (Portugal, 1996), the Commission Review Report on esfenvalerate (EC, 2005), the JMPR Evaluation report (FAO, 2002a,b) as well as the conclusions from a previous EFSA opinion on esfenvalerate (EFSA, 2011). 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-g, 2000, 2010a,b, 2011; OECD, 2011).

Since the assessment according to Commission Regulation (EU) No 188/2011 is not yet finalised, the conclusions reported in this reasoned opinion might need to be reconsidered in the light of the outcome of the decision on the renewal of the approval.

1. Method of analysis

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

The availability of analytical enforcement methods for the determination of esfenvalerate residues in plant commodities including plant matrices with high water content have been investigated under Article 12 MRL review (EFSA, 2011). Sufficiently validated analytical methods based on gas chromatography with different detectors (mass sensitive detector, ECD) are available. From the validation data in different plant matrices (high water content, high oil content, dry and acidic matrices) it was concluded that an LOQ of 0.02 mg/kg can be achieved for the proposed residue definition fenvalerate (any ratio of constituent isomers including esfenvalerate).

EFSA concludes that sufficiently validated analytical methods for enforcing the proposed MRLs for esfenvalerate on peppers, broccoli and lettuce 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 peppers, broccoli and lettuce are normally not fed to livestock.

2. Mammalian toxicology

The toxicological profile of the active substance esfenvalerate was assessed in the framework of the peer review under Directive 91/414/EEC (EC, 2005). The data were sufficient to derive toxicological reference values for esfenvalerate which are compiled in Table 2-1.

Under Article 12 MRL review EFSA concluded that applying the toxicological reference values of esfenvalerate to a combined residue definition for all fenvalerate isomers is expected to provide sufficient protection for the consumers (EFSA, 2011).

Table 2-1: Overview of the toxicological reference values

	Source	Year	Value	Study relied upon	Safety factor
esfenvalerate					
ADI	EC	2005	0.02 mg/kg bw per day	Reproduction (esfenvalerate), and long term (fenvalerate), in rat	100

⁹ Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.06.2011, p. 127-175.

ARfD	EC	2005	0.05 mg/kg bw	Acute oral rat and mouse and acute neurotoxicity (esfenvalerate)	100
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It is noted that JMPR established an ADI and ARfD of 0.02 mg/kg bw (per day) for esfenvalerate (FAO, 2002). For fenvalerate, JMPR established an ADI of 0.02 mg/kg bw per day and ARfD of 0.2 (FAO, 2012).

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 esfenvalerate in primary crops was evaluated by the RMS (Portugal, 1996) in the framework of the peer review under Directive 91/414/EEC. Under Article 12 Review EFSA reassessed the metabolism of esfenvalerate in primary crops also taking into account an additional metabolism study in wheat assessed by JMPR (EFSA, 2011; FAO, 2002a,b).

The metabolism studies are described in detail in the EFSA reasoned opinion on the MRL Review under Article 12 of Regulation (EC) No 396/2005 (EFSA, 2011).

Under Article 12 review, EFSA proposed to establish a common residue definition for all isomers of fenvalerate and to define the relevant residue both for enforcement and risk assessment as fenvalerate (any ratio of constituent isomers including esfenvalerate). Considering that available metabolism studies are covering four different plant groups and that metabolism patterns were found to be similar in all studies, this residue definition can be applied to all commodities of plant origin.

It is noted that currently; two separate residue definitions for enforcement are established by Regulation (EC) No 396/2005: 1) Fenvalerate and esfenvalerate (sum of RR and SS isomers) and 2) Fenvalerate and esfenvalerate (sum of RS and SR isomers). The amendment of the existing residue definitions as proposed by EFSA (EFSA, 2011) is in preparation (SANCO/10698/2013).

For the uses on peppers, broccoli and lettuce, EFSA concludes that the metabolism of esfenvalerate is sufficiently addressed and the residue definitions for enforcement and risk assessment agreed during Article 12 review are applicable.

3.1.1.2. Magnitude of residues

a. Peppers (sweet)

In support of the intended indoor GAPs the applicant submitted eight residue trials. Two trials were not fully GAP compliant (the trial was performed with a PHI of 2 days instead 3 days). Since they represent a worst case and the residues are below the LOQ both trials are included to derive the MRL. The trials were performed in 2009 and 2013. A sufficient number of trials is available to derive a MRL for peppers grown under indoor conditions (EC, 2001).

In support of the intended southern outdoor GAPs the applicant submitted three residue trials. One trial was not fully GAP compliant but within the acceptable deviation (PHI tested was 4 days instead 3 days). Considering that peppers are a major crop in SEU, the number of three GAP compliant trials is not sufficient to derive a MRL for peppers grown under outdoor conditions (EC, 2011).

b. Broccoli

In support of the intended southern outdoor GAPs the applicant submitted four residue trials. One trial was not fully GAP compliant but within the acceptable deviation (PHI tested was 6 days instead 7 days). The trials were performed in Spain in 2009 and 2010. Sufficient number of trials is available to derive a MRL for broccoli grown under outdoor conditions (EC, 2001).

c. Lettuce

In support of the intended southern outdoor GAPs the applicant submitted 10 residue trials. Six of these trials were performed with open leaf lettuce. In one trial with open leaf variety samples were taken at a PHI of 6 days instead 9 days. The trial is considered as not representative and was therefore not included in the database to derive the MRL. One additional trial was not fully GAP compliant but within the acceptable deviation (PHI tested was 8 days instead 9 days). A sufficient number of trials on lettuce is available to derive a MRL proposal for lettuce (EC, 2001).

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 esfenvalerate in primary crops was investigated in the DAR under Directive 91/414/EEC (Portugal, 1996) and in the JMPR report (FAO, 2002). Residues of esfenvalerate were found to be stable when stored deep frozen for up to 36 months in matrices with high water-, high acid-, and high oil content and for up to 24 months in dry matrices. As the supervised residue trial samples were stored under conditions for which integrity of the samples was demonstrated, it is concluded that the residue data are valid with regard to storage stability.

According to the EMS, the analytical method used to analyse the supervised residue trial samples has been sufficiently validated with a LOQ of 0.01 mg/kg and was proven to be fit for the purpose (Italy, 2013).

EFSA concludes that the data are sufficient to derive a MRL proposal of 0.05 mg/kg for peppers, 0.05 mg/kg for broccoli and 0.2 mg/kg for lettuce.

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 (fenvalerate: any ratio of constituent isomers including esfenvalerate)	Risk assessment (fenvalerate: any ratio of constituent isomers including esfenvalerate)					
Enforcement residue definition: fenvalerate: any ratio of constituent isomers including esfenvalerate									
Peppers (sweet)	SEU	Outdoor	3 x 0.02	3 x 0.02	-	-	-	-	Insufficient number of trials
	EU	Indoor	2x <0.01; 4x 0.01; 0.02; 0.03 ^(f)	2x<0.01; 4x0.01; 0.02; 0.03	0.01	0.03	0.05	1	R _{ber} =0.035 R _{max} =0.037 MRL _{OECD} = 0.04/0.05
Broccoli	SEU	Outdoor	2x 0.01; 2x 0.02	2x 0.01; 2x 0.02	0.02	0.02	0.05	1	R _{ber} =0.04 R _{max} =0.045 MRL _{OECD} = 0.045/0.05
Lettuce	SEU	Outdoor	2x <0.01; 2x 0.01 ^(g) ; 0.01; 2x 0.02 ^(g) ; 0.04 ^(g) ; 0.12 ^(f)	2x <0.01; 2x 0.01 ^(g) ; 0.01; 2x 0.02 ^(g) ; 0.04 ^(g) ; 0.12 ^(f)	0.01	0.12	0.2	1	R _{ber} = 0.06 R _{max} =0.14 MRL _{OECD} = 0.17/0.2

(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).

(f): The trial was identified as outlier (Dixon-test). However, since no rationale could be provided for the result, the trial was not removed from the dataset.

(g): Trials performed with open leaf varieties.

(*): Indicates that the MRL is set at the limit of analytical quantification.

3.1.1.3. Effect of industrial processing and/or household preparation

Specific studies to assess the magnitude of esfenvalerate residues during the processing of peppers or broccoli are not necessary as the residue levels in raw agricultural commodities (RAC) did not exceed the trigger value of 0.1 mg/kg and as the total theoretical maximum daily intake (TMDI) amounts to less than 10 % of the ADI (EC, 1997d). For the third crop under assessment (lettuce) no processing studies are required, since lettuce is normally consumed without processing.

3.1.2. Rotational crops

Peppers, broccoli and lettuce can be grown in rotation with other plants and therefore the possible occurrence of residues in succeeding crops resulting from the use on primary crops has to be assessed. The soil degradation studies demonstrated that the degradation rate of esfenvalerate is moderate was 206-420 days (Portugal, 1996), which is above the trigger value of 100 days. Thus, further studies investigating the metabolism and magnitude of the compound uptake in rotational crops are required (EC, 1997c).

The metabolism of esfenvalerate in rotational crops was assessed in the DAR prepared under Directive 91/414/EEC (Portugal, 1996). More details of the studies are reported in the Article 12 MRL review EFSA reasoned opinion (EFSA, 2011).

Under Article 12 review EFSA concluded that relevant residue levels are unlikely to occur in rotational crops provided that the compound is used according to the proposed GAPs considering application rates between 0.005 – 0.035 kg a.s./ha (EFSA, 2011). Since the maximum application rate for the crops under consideration is 0.03 kg a.s./ha relevant residue levels are unlikely to occur in rotational crops for the supported uses.

3.2. Nature and magnitude of residues in livestock

Since pepper, broccoli and lettuce are not normally fed to livestock, the nature and magnitude of esfenvalerate residues in livestock is not assessed in the framework of this application (EC, 1996).

4. Consumer risk assessment

In the framework of Article 12 MRL review a comprehensive short- and long-term consumer exposure assessment was performed, taking into account the existing uses of esfenvalerate at EU level, those CXLs which were sufficiently supported by data and veterinary MRLs (EFSA, 2011).

The long-term consumer risk assessment is now updated (section 4 of the EFSA reasoned opinion (EFSA, 2011)), including the median residue concentrations observed in peppers, broccoli and lettuce.

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 population¹⁰ (EFSA, 2007).

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.

¹⁰ 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).

The acute exposure assessment was performed only with regard to the commodities under consideration assuming the consumption of a large portion of the food items as reported in the national food surveys and that these items contained residues at the highest level as observed in supervised field trials. A variability factor accounting for the inhomogeneous distribution on the individual items consumed was included in the calculation, when required (EFSA, 2007).

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
Risk assessment residue definition: fenvalerate: any ratio of constituent isomers including esfenvalerate				
Peppers	0.01	Median residue (table 3-1)	0.03	Highest residue (table 3-1)
Broccoli	0.02	Median residue (table 3-1)	0.02	Highest residue (table 3-1)
Lettuce	0.01	Median residue (table 3-1)	0.12	Highest residue (table 3-1)
Other commodities of food and animal origin	See table 4-2 in section 4 of the EFSA reasoned opinion (EFSA, 2011)		Acute risk assessment was undertaken only with regard to the crop under consideration.	

The estimated exposure was then compared with the toxicological reference values derived for esfenvalerate (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 accounted for up to 9 % of the ADI (NL child). The contribution of residues in peppers, broccoli and lettuce to the total consumer exposure accounted for a maximum of 0.03 % of the ADI (FR toddler).

No acute consumer risk was identified in relation to the MRL proposals for peppers, broccoli and lettuce. The calculated maximum exposure in percentage of the ARfD was 7 % for lettuce (DE child).

EFSA concludes that the intended use of esfenvalerate on peppers, broccoli and lettuce will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a public health concern.

CONCLUSIONS AND RECOMMENDATIONS

EFSA proposes MRLs based on a comprehensive assessment of the properties of the active substance and the residue levels resulting from the good agricultural practices (GAP) defined for the treated crops. The assessment includes the toxicological profile and setting of toxicological reference values, the metabolism and magnitude of residues in commodities of plant (i.e. primary crops, processed commodities and rotational crops) and animal origin, as well as the analytical methods used. Consumer exposure estimates taking into account the proposed MRLs are then compared to toxicological reference values to assess the risk of the active substance according to the intended uses.

The toxicological profile of esfenvalerate was assessed in the DAR by the rapporteur Member State Portugal and the data were sufficient to derive the toxicological reference values acceptable daily intake (ADI) of 0.02 mg/kg bw per day and acute reference dose (ARfD) of 0.05 mg/kg bw.

The metabolism of esfenvalerate in primary crops was investigated in three different crop groups following foliar application. Metabolic patterns in the different studies were shown to be similar and the relevant residue for enforcement and risk assessment in all crops supported in the framework of Article 12 MRL review was defined as fenvalerate (any ratio of constituent isomers including esfenvalerate). For the use on peppers, broccoli and lettuce, EFSA concludes that the metabolism of esfenvalerate in primary crops is sufficiently addressed and that the residue definitions derived are applicable.

Submitted supervised residues trials investigating the magnitude of esfenvalerate residues are sufficient to derive MRL proposals of 0.05 mg/kg for the use on peppers, 0.05 mg/kg for the use on broccoli and 0.2 mg/kg for the use on lettuce. Adequate analytical enforcement methods are available to control the residues of esfenvalerate in these commodities at the validated LOQ of 0.01 mg/kg.

Specific studies investigating the magnitude of esfenvalerate residues in processed commodities are not required, as the residues expected in raw agricultural commodities (RAC) are low and the total theoretical maximum daily intake (TMDI) is below the trigger value of 10 % of the ADI (see below).

The occurrence of esfenvalerate residues in rotational crops was investigated 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 are unlikely to occur in rotational crops provided that the compound is used on peppers, broccoli and lettuce according to the proposed GAP.

Residues of esfenvalerate in commodities of animal origin were not assessed in the framework of this application, since peppers, broccoli and lettuce are normally not fed to livestock.

The consumer risk assessment was then performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRiMo). In the framework of Article 12 MRL review a comprehensive short- and long-term consumer exposure assessment was performed, taking into account the existing uses of esfenvalerate at EU level, those codex maximum residue limit (CXLs) which were sufficiently supported by data and veterinary MRLs. The long-term consumer risk assessment was now updated, including the median residue concentrations observed in peppers, broccoli and lettuce. The acute exposure assessment was performed only with regard to the commodities under consideration. No acute and long-term consumer risk was identified in relation to the MRL proposals for peppers, broccoli and lettuce. The total calculated intake accounted for up to 9 % of the ADI (Netherlands child). The contribution of residues in peppers, broccoli and lettuce to the total consumer exposure accounted for a maximum of 0.03 % of the ADI (French toddler) and 7 % of the ARfD for lettuce (German child).

EFSA concludes that the intended uses of esfenvalerate on peppers, broccoli and lettuce will not result in a consumer exposure exceeding the toxicological reference values 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: fenvalerate: any ratio of constituent isomers including esfenvalerate				
231020	Pepper	0.02*	0.05	The MRL proposals are sufficiently supported by data and no consumer health risk was identified for the intended uses on these crops.
241010	Broccoli	0.02*	0.05	
251020	Lettuce	0.02*	0.2	

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

(*): Indicates that the MRL is set at the limit of analytical quantification.

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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. 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		
Peppers	ES, PT, IT, EL	F/G	- Aphids - White fly (<i>Bemisia tabaci</i> , <i>Trialeurodes vaporariorum</i>) -BEMITA TRIAVA - Caterpillar (Plusia spp., Spodoptera exigua)	EC	25 g/L	Foliar pray	Vegetable growing BBCH 21-89 Field: April – September	2	15 days	0.05 / 0.015	300/1000	0.015	3	
Broccoli	ES, PT, IT, EL	F	- Aphids (<i>Aphis gossypii</i> , <i>Myzus persicae</i>) - White fly (<i>Bemisia tabaci</i> , <i>Trialeurodes vaporariorum</i>) -BEMITA TRIAVA Caterpillar (<i>Pieris</i>)	EC	25 g/L	Foliar pray	Vegetable growing BBCH 19-49 September –April	2	15 days	0.045 / 0.015	300 / 1000	0.015	7	
Lettuce	ES, PT, IT, EL	F	- Aphids (<i>Aphis gossypii</i> , <i>Myzus persicae</i>) -White fly (<i>Bemisia tabaci</i> , <i>Trialeurodes vaporariorum</i>) -BEMITA, TRIAVA Caterpillars (<i>Heliothis</i> spp., <i>Spodoptera</i>)	EC	25 g/L		Vegetable growing BBCH 19-49 March-June and September-December	2	15 days	0.045 / 0.015	300 / 900	0.0135	9	

Remarks:

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. 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		

- (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)

Appendix B. Pesticide Residue Intake Model (PRIMO)

esfenvalerate									
Status of the active substance:		Included		Code no.		Prepare workbook for refined calculations			
LOQ (mg/kg bw):				proposed LOQ:					
Toxicological end points									
ADI (mg/kg bw/day):		0.02		ARfD (mg/kg bw):		0.05			
Source of ADI:		COM		Source of ARfD:		COM			
Year of evaluation:		2000		Year of evaluation:		2000			
Undo refined calculations									
Chronic risk assessment - refined calculations									
				TMDI (range) in % of ADI minimum - maximum					
				1 9					
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)	
8.8	NL child	5.9	Milk and milk products: Cattle	1.1	Apples	0.3	Potatoes		
6.6	FR infant	5.1	Milk and milk products: Cattle	0.4	Apples	0.3	Carrots		
6.6	DE child	2.9	Milk and milk products: Cattle	2.1	Apples	0.3	Table grapes		
3.8	ES child	2.5	Milk and milk products: Cattle	0.2	Wheat	0.2	Apples		
3.6	SE general population 90th percentile	2.5	Milk and milk products: Cattle	0.2	Potatoes	0.2	Apples		
3.5	WHO Cluster diet B	0.6	Milk and milk products: Cattle	0.4	Wine grapes	0.4	Wheat		
3.0	IE adult	0.6	Milk and milk products: Cattle	0.4	Barley	0.3	Wine grapes		
2.7	NL general	1.3	Milk and milk products: Cattle	0.2	Apples	0.2	Wine grapes		
2.6	WHO cluster diet E	0.6	Milk and milk products: Cattle	0.4	Wine grapes	0.3	Barley		
2.5	WHO regional European diet	1.0	Milk and milk products: Cattle	0.2	Potatoes	0.1	Wheat		
2.4	WHO cluster diet D	0.9	Milk and milk products: Cattle	0.3	Wheat	0.2	Potatoes		
2.3	WHO Cluster diet F	0.8	Milk and milk products: Cattle	0.2	Barley	0.2	Wheat		
2.3	UK Toddler	1.1	Sugar beet (root)	0.3	Apples	0.2	Wheat		
2.2	FR all population	1.0	Wine grapes	0.5	Milk and milk products: Cattle	0.2	Wheat		
2.2	ES adult	1.0	Milk and milk products: Cattle	0.2	Barley	0.1	Apples		
2.0	FR toddler	0.5	Apples	0.3	Potatoes	0.2	Carrots		
1.9	DK child	0.4	Apples	0.3	Wheat	0.2	Rye		
1.8	PT General population	0.6	Wine grapes	0.3	Potatoes	0.2	Wheat		
1.8	LT adult	0.8	Milk and milk products: Cattle	0.3	Apples	0.2	Potatoes		
1.7	UK Infant	0.5	Sugar beet (root)	0.3	Apples	0.2	Potatoes		
1.1	DK adult	0.3	Wine grapes	0.1	Apples	0.1	Wheat		
1.0	IT kids/toddler	0.3	Wheat	0.2	Apples	0.1	Tomatoes		
1.0	UK vegetarian	0.2	Wine grapes	0.2	Sugar beet (root)	0.1	Apples		
0.9	PL general population	0.4	Apples	0.2	Potatoes	0.1	Tomatoes		
0.9	UK Adult	0.3	Wine grapes	0.2	Sugar beet (root)	0.1	Wheat		
0.8	IT adult	0.2	Wheat	0.1	Apples	0.1	Tomatoes		
0.5	FI adult	0.1	Wine grapes	0.1	Apples	0.1	Potatoes		
<p>Conclusion: The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI. A long-term intake of residues of esfenvalerate is unlikely to present a public health concern.</p>									

Acute risk assessment /children - refined calculations						Acute risk assessment / adults / general population - refined calculations						
The acute risk assessment is based on the ARfD.												
For each commodity the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS an average European unit weight was used for the IESTI calculation.												
In the IESTI 1 calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002), for lettuce a variability factor of 5 was used.												
In the IESTI 2 calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce the calculation was performed with a variability factor of 3.												
Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100 % of the ARfD.												
Unprocessed commodities	No of commodities for which ARfD/ADI is exceeded (IESTI 1):			No of commodities for which ARfD/ADI is exceeded (IESTI 2):			No of commodities for which ARfD/ADI is exceeded (IESTI 1):			No of commodities for which ARfD/ADI is exceeded (IESTI 2):		
	---			---			---			---		
	IESTI 1	*)	**)	IESTI 2	*)	**)	IESTI 1	*)	**)	IESTI 2	*)	**)
	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
	6.5	Lettuce	0.12 / -	3.9	Lettuce	0.12 / -	2.6	Lettuce	0.12 / -	1.6	Lettuce	0.12 / -
3.8	Peppers	0.03 / -	2.7	Peppers	0.03 / -	1.0	Peppers	0.03 / -	0.9	Broccoli	0.02 / -	
2.3	Broccoli	0.02 / -	1.7	Broccoli	0.02 / -	0.9	Broccoli	0.02 / -	0.7	Peppers	0.03 / -	
No of critical MRLs (IESTI 1)			---			No of critical MRLs (IESTI 2)			---			
Processed commodities	No of commodities for which ARfD/ADI is exceeded:			No of commodities for which ARfD/ADI is exceeded:			No of commodities for which ARfD/ADI is exceeded:			No of commodities for which ARfD/ADI is exceeded:		
	---			---			---			---		
	Highest % of ARfD/ADI	Processed commodities	***) pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Processed commodities	***) pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Processed commodities	***) pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Processed commodities	***) pTMRL/ threshold MRL (mg/kg)
*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.												
**) pTMRL: provisional temporary MRL												
***) pTMRL: provisional temporary MRL for unprocessed commodity												
Conclusion:												
For esfenvalerate IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.												
No exceedance of the ARfD/ADI was identified for any unprocessed commodity.												
For processed commodities, no exceedance of the ARfD/ADI was identified.												

Appendix C. Existing EU maximum residue levels (MRLs)

(Pesticides - Web Version - EU MRLs (File created on 31/03/2014 15.08))

Code number	Groups and examples of individual products to which the MRLs apply	Fenvalerate and Esfenvalerate (Sum of RR & SS isomers)	Fenvalerate (any ratio of constituent isomers including esfenvalerate)(F) (R) (SANCO/12375/2013)
100000	1. FRUIT FRESH OR FROZEN NUTS		
110000	(i) Citrus fruit	0.02*	0,02*
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo (except mineola), ugli and other hybrids)	0.02*	0,02*
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0.02*	0,02*
110030	Lemons (Citron, lemon, Buddha's hand (Citrus medica var. sarcodactylis))	0.02*	0,02*
110040	Limes	0.02*	0,02*
110050	Mandarins (Clementine, tangerine, mineola and other hybrids tangor (Citrus reticulata x sinensis))	0.02*	0,02*
110990	Others	0.02*	0,02*
120000	(ii) Tree nuts	0.02*	0,05*
120010	Almonds	0.02*	0,05* (ft)
120020	Brazil nuts	0.02*	0,05*
120030	Cashew nuts	0.02*	0,05*
120040	Chestnuts	0.02*	0,05*
120050	Coconuts	0.02*	0,05*
120060	Hazelnuts (Filbert)	0.02*	0,05*
120070	Macadamia	0.02*	0,05*
120080	Pecans	0.02*	0,05*
120090	Pine nuts	0.02*	0,05*
120100	Pistachios	0.02*	0,05*
120110	Walnuts	0.02*	0,05*
120990	Others	0.02*	0,05*
130000	(iii) Pome fruit	0.05	
130010	Apples (Crab apple)	0.05	0,1 (ft)
130020	Pears (Oriental pear)	0.05	0,1 (ft)
130030	Quinces	0.05	0,02*
130040	Medlar	0.05	0,02*
130050	Loquat	0.05	0,02*
130990	Others	0.05	0,02*
140000	(iv) Stone fruit		
140010	Apricots	0.1	0,2

Code number	Groups and examples of individual products to which the MRLs apply	Fenvalerate and Esfenvalerate (Sum of RR & SS isomers)	Fenvalerate (any ratio of constituent isomers including esfenvalerate)(F) (R) (SANCO/12375/2013)
140020	Cherries (Sweet cherries, sour cherries)	0.02*	0,02* (ft)
140030	Peaches (Nectarines and similar hybrids)	0.1	0,2
140040	Plums (Damson, greengage, mirabelle, sloe, red date/Chinese date/Chinese jujube (Ziziphus zizyphus))	0.02*	0,02* (ft)
140990	Others	0.02*	0,02*
150000	(v) Berries & small fruit		
151000	(a) Table and wine grapes	0.1	0,3
151010	Table grapes	0.1	0,3
151020	Wine grapes	0.1	0,3
152000	(b) Strawberries	0.02*	0,02* (ft)
153000	(c) Cane fruit	0.02*	0,02*
153010	Blackberries	0.02*	0,02*
153020	Dewberries (Loganberries, tayberries, boysenberries, cloudberrys and other Rubus hybrids)	0.02*	0,02*
153030	Raspberries (Wineberries, arctic bramble/raspberry, (Rubus arcticus), nectar raspberries (Rubus arcticus x Rubus idaeus))	0.02*	0,02* (ft)
153990	Others	0.02*	0,02*
154000	(d) Other small fruit & berries	0.02*	0,02*
154010	Blueberries (Bilberries)	0.02*	0,02*
154020	Cranberries (Cowberries/red berries (V. vitis-idaea))	0.02*	0,02*
154030	Currants (red, black and white)	0.02*	0,02*
154040	Gooseberries (Including hybrids with other Ribes species)	0.02*	0,02*
154050	Rose hips	0.02*	0,02*
154060	Mulberries (Arbutus berry)	0.02*	0,02*
154070	Azarole (mediteranean medlar) (Kiwiberry)	0.02*	0,02*

Code number	Groups and examples of individual products to which the MRLs apply	Fenvalerate and Esfenvalerate (Sum of RR & SS isomers)	Fenvalerate (any ratio of constituent isomers including esfenvalerate)(F) (R) (SANCO/12375/2013)
	(Actinidia arguta)		
154080	Elderberries (Black chokeberry/appleberry, mountain ash, buckthorn/sea sawallowthorn, hawthorn, serviceberries, and other treeberries)	0.02*	0,02*
154990	Others	0.02*	0,02*
160000	(vi) Miscellaneous fruit	0.02*	
161000	(a) Edible peel	0.02*	0,02*
161010	Dates	0.02*	0,02*
161020	Figs	0.02*	0,02*
161030	Table olives	0.02*	0,02*
161040	Kumquats (Marumi kumquats, nagami kumquats, limequats (Citrus aurantifolia x Fortunella spp.))	0.02*	0,02*
161050	Carambola (Bilimbi)	0.02*	0,02*
161060	Persimmon	0.02*	0,02*
161070	Jambolan (java plum) (Java apple/water apple, pomeac, rose apple, Brazilian cherry, Surinam cherry/grumichama (Eugenia uniflora))	0.02*	0,02*
161990	Others	0.02*	0,02*
162000	(b) Inedible peel, small	0.02*	0,02*
162010	Kiwi	0.02*	0,02*
162020	Lychee (Litchi) (Pulasan, rambutan/hairy litchi, longan, mangosteen, langsat, salak)	0.02*	0,02*
162030	Passion fruit	0.02*	0,02*
162040	Prickly pear (cactus fruit)	0.02*	0,02*
162050	Star apple	0.02*	0,02*
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel/yellow sapote, mammy sapote)	0.02*	0,02*
162990	Others	0.02*	0,02*

Code number	Groups and examples of individual products to which the MRLs apply	Fenvalerate and Esfenvalerate (Sum of RR & SS isomers)	Fenvalerate (any ratio of constituent isomers including esfenvalerate)(F) (R) (SANCO/12375/2013)
163000	(c) Inedible peel, large	0.02*	
163010	Avocados	0.02*	0,02*
163020	Bananas (Dwarf banana, plantain, apple banana)	0.02*	0,02*
163030	Mangoes	0.02*	1,5
163040	Papaya	0.02*	0,02*
163050	Pomegranate	0.02*	0,02*
163060	Cherimoya (Custard apple, sugar apple/sweetsop, ilama (Annona diversifolia) and other medium sized Annonaceae fruits)	0.02*	0,02*
163070	Guava (Red pitaya/dragon fruit (Hylocereus undatus))	0.02*	0,02*
163080	Pineapples	0.02*	0,02*
163090	Bread fruit (Jackfruit)	0.02*	0,02*
163100	Durian	0.02*	0,02*
163110	Soursop (guanabana)	0.02*	0,02*
163990	Others	0.02*	0,02*
200000	2. VEGETABLES FRESH OR FROZEN		
210000	(i) Root and tuber vegetables	0.02*	0,02*
211000	(a) Potatoes	0.02*	0,02*
212000	(b) Tropical root and tuber vegetables	0.02*	0,02*
212010	Cassava (Dasheen, eddoe/Japanese taro, tannia)	0.02*	0,02*
212020	Sweet potatoes	0.02*	0,02*
212030	Yams (Potato bean/yam bean, Mexican yam bean)	0.02*	0,02*
212040	Arrowroot	0.02*	0,02*
212990	Others	0.02*	0,02*
213000	(c) Other root and tuber vegetables except sugar beet	0.02*	0,02*
213010	Beetroot	0.02*	0,02*
213020	Carrots	0.02*	0,02* (ft)
213030	Celeriac	0.02*	0,02*
213040	Horseradish (Angelica roots, lovage roots, gentiana roots)	0.02*	0,02* (ft)
213050	Jerusalem artichokes (Crosne)	0.02*	0,02*
213060	Parsnips	0.02*	0,02*

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213070	Parsley root	0.02*	0,02* (ft)
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties, tiger nut (Cyperus esculentus))	0.02*	0,02* (ft)
213090	Salsify (Scorzoneria, Spanish salsify/Spanish oysterplant, edible burdock)	0.02*	0,02*
213100	Swedes	0.02*	0,02*
213110	Turnips	0.02*	0,02*
213990	Others	0.02*	0,02*
220000	(ii) Bulb vegetables	0.02*	0,02*
220010	Garlic	0.02*	0,02* (ft)
220020	Onions (Other bulb onions, silverskin onions)	0.02*	0,02* (ft)
220030	Shallots	0.02*	0,02*
220040	Spring onions and welsch onions (Other green onions and similar varieties)	0.02*	0,02*
220990	Others	0.02*	0,02*
230000	(iii) Fruiting vegetables		
231000	(a) Solanacea		
231010	Tomatoes (Cherry tomatoes, Physalis spp., gojiberry, wolfberry (Lycium barbarum and L. chinense), tree tomato)	0.05	0,1
231020	Peppers (Chilli peppers)	0.02*	0,02* (ft)
231030	Aubergines (egg plants) (Pepino, antroewa/white eggplant (S. macrocarpon))	0.02*	0,06
231040	Okra (lady's fingers)	0.02*	0,02*
231990	Others	0.02*	0,02*
232000	(b) Cucurbits — edible peel	0.02*	0,02* (ft)
232010	Cucumbers	0.02*	0,02* (ft)
232020	Gherkins	0.02*	0,02* (ft)
232030	Courgettes (Summer squash, marrow (patisson), lauki (Lagenaria siceraria), chayote, sopropo/bitter melon, snake gourd, angled luffa/teroi)	0.02*	0,02* (ft)

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232990	Others	0.02*	0,02* (ft)
233000	(c) Cucurbits-inedible peel	0.02*	0,02*
233010	Melons (Kiwano)	0.02*	0,02* (ft)
233020	Pumpkins (Winter squash, marrow (late variety))	0.02*	0,02*
233030	Watermelons	0.02*	0,02*
233990	Others	0.02*	0,02*
234000	(d) Sweet corn (Baby corn)	0.02*	0,02* (ft)
239000	(e) Other fruiting vegetables	0.02*	0,02*
240000	(iv) Brassica vegetables		
241000	(a) Flowering brassica	0.02*	0,02* (ft)
241010	Broccoli (Calabrese, Broccoli raab, Chinese broccoli)	0.02*	0,02* (ft)
241020	Cauliflower	0.02*	0,02* (ft)
241990	Others	0.02*	0,02* (ft)
242000	(b) Head brassica		
242010	Brussels sprouts	0.05	0,05 (ft)
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0.1	0,08
242990	Others	0.02*	0,02*
243000	(c) Leafy brassica	0.02*	0,02*
243010	Chinese cabbage (Indian or Chinese) mustard, pak choi, Chinese flat cabbage/ai goo choi, choi sum, Peking cabbage/pe-tsai)	0.02*	0,02*
243020	Kale (Borecole/curly kale, collards, Portuguese Kale, Portuguese cabbage, cow cabbage)	0.02*	0,02*
243990	Others	0.02*	0,02*
244000	(d) Kohlrabi	0.02*	0,02*
250000	(v) Leaf vegetables & fresh herbs	0.02*	
251000	(a) Lettuce and other salad plants including Brassicacea	0.02*	0,02*
251010	Lamb's lettuce (Italian com salad)	0.02*	0,02*
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce),	0.02*	0,02* (ft)

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	iceberg lettuce, romaine (cos) lettuce)		
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)	0.02*	0,02*
251040	Cress (Mung bean sprouts, alfalfa sprouts)	0.02*	0,02*
251050	Land cress	0.02*	0,02*
251060	Rocket, Rucola (Wild rocket (Diplotaxis spp.))	0.02*	0,02*
251070	Red mustard	0.02*	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*	0,02*
251990	Others	0.02*	0,02*
252000	(b) Spinach & similar (leaves)	0.02*	0,02*
252010	Spinach (New Zealand spinach, amaranthus spinach (pak-khom, tampara), tajar leaves, bitterblad/bitawiri)	0.02*	0,02* (ft)
252020	Purslane (Winter purslane/miner's lettuce, garden purslane, common purslane, sorrel, glassworth, agretti (Salsola soda))	0.02*	0,02*
252030	Beet leaves (chard) (Leaves of beetroot)	0.02*	0,02*
252990	Others	0.02*	0,02*
253000	(c) Vine leaves (grape leaves) (Malabar nightshade, banana leaves, climbing wattle (Acacia pennata))	0.02*	0,02*
254000	(d) Water cress (Morning	0.02*	0,02*

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	glory/Chinese convolvulus/water convolvulus/water spinach/kangkung (Ipomea aquatica), water clover, water mimosa)		
255000	(e) Witloof	0.02*	0,02*
256000	(f) Herbs	0.02*	0,05*
256010	Chervil	0.02*	0,05*
256020	Chives	0.02*	0,05*
256030	Celery leaves (Fennel leaves, coriander leaves, dill leaves, caraway leaves, lovage, angelica, sweet cicely and other Apiacea leaves, culantro/stinking/long coriander/stink weed (Eryngium foetidum))	0.02*	0,05*
256040	Parsley (leaves of root parsley)	0.02*	0,05* (ft)
256050	Sage (Winter savory, summer savory, Borago officinalis leaves)	0.02*	0,05*
256060	Rosemary	0.02*	0,05*
256070	Thyme (Marjoram, oregano)	0.02*	0,05*
256080	Basil (Balm leaves, mint, peppermint, holy basil, sweet basil, hairy basil, edible flowers (marigold flower and others), pennywort, wild betel leaf, curry leaves)	0.02*	0,05*
256090	Bay leaves (laurel) (Lemon grass)	0.02*	0,05*
256100	Taragon (Hyssop)	0.02*	0,05*
256990	Others	0.02*	0,05*
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)	0.02*	0,1
260020	Beans (without pods)	0.02*	0,02*

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	(Broad beans, flageolets, jack bean, lima bean, cowpea)		
260030	Peas (with pods) (Mangetout/sugar peas/snow peas)	0.1	0,1
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0.02*	0,02*
260050	Lentils	0.02*	0,02*
260990	Others	0.02*	0,02*
270000	(vii) Stem vegetables (fresh)	0.02*	0,02*
270010	Asparagus	0.02*	0,02*
270020	Cardoons (Borago officinalis stems)	0.02*	0,02*
270030	Celery	0.02*	0,02*
270040	Fennel	0.02*	0,02*
270050	Globe artichokes (Banana flower)	0.02*	0,02*
270060	Leek	0.02*	0,02* (ft)
270070	Rhubarb	0.02*	0,02*
270080	Bamboo shoots	0.02*	0,02*
270090	Palm hearts	0.02*	0,02*
270990	Others	0.02*	0,02*
280000	(viii) Fungi	0.02*	0,02*
280010	Cultivated fungi (Common mushroom, oyster mushroom, shiitake, fungus mycelium (vegetative parts))	0.02*	0,02*
280020	Wild fungi (Chanterelle, truffle, morel, cep)	0.02*	0,02*
280990	Others	0.02*	0,02*
290000	(ix) Sea weeds		0,02*
300000	3. PULSES, DRY	0.02*	0,02*
300010	Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas)	0.02*	0,02*
300020	Lentils	0.02*	0,02* (ft)
300030	Peas (Chickpeas, field peas, chickling vetch)	0.02*	0,02*
300040	Lupins	0.02*	0,02*
300990	Others	0.02*	0,02*
400000	4. OILSEEDS AND OILFRUITS		0,05*

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401000	(i) Oilseeds	0.05*	0,05*
401010	Linseed	0.05*	0,05*
401020	Peanuts	0.05*	0,05*
401030	Poppy seed	0.05*	0,05*
401040	Sesame seed	0.05*	0,05*
401050	Sunflower seed	0.05*	0,05*
401060	Rape seed (Bird rapeseed, turnip rape)	0.05*	0,05*
401070	Soya bean	0.05*	0,05*
401080	Mustard seed	0.05*	0,05*
401090	Cotton seed	0.05*	0,05*
401100	Pumpkin seeds (Other seeds of Cucurbitaceae)	0.05*	0,05*
401110	Safflower	0.05*	0,05*
401120	Borage (Purple viper's bugloss/Canary flower (Echium plantagineum), Corn Gromwell (Buglossoides arvensis))	0.05*	0,05*
401130	Gold of pleasure	0.05*	0,05*
401140	Hempseed	0.05*	0,05*
401150	Castor bean	0.05*	0,05*
401990	Others	0.05*	0,05*
402000	(ii) Oilfruits		0,05*
402010	Olives for oil production	0.02*	0,05*
402020	Palm nuts (palmoil kernels)	0.05	0,05*
402030	Palmfruit	0.05	0,05*
402040	Kapok	0.05	0,05*
402990	Others	0.05	0,05*
500000	5. CEREALS		
500010	Barley	0.2	0,3 (ft)
500020	Buckwheat (Amaranthus, quinoa)	0.02*	0,02*
500030	Maize	0.02*	0,02* (ft)
500040	Millet (Foxtail millet, teff, finger millet, pearl millet)	0.02*	0,02*
500050	Oats	0.2	0,3 (ft)
500060	Rice (Indian/wild rice (Zizania aquatica))	0.02*	0,02*
500070	Rye	0.05	0,2 (ft)
500080	Sorghum	0.02*	0,02* (ft)
500090	Wheat (Spelt, triticale)	0.05	0,2 (ft)
500990	Others (Canary grass seeds (Phalaris canariensis))	0.02*	0,02*
600000	6. TEA, COFFEE,	0.05*	0,1*

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	HERBAL INFUSIONS AND COCOA		
610000	(i) Tea	0.05*	0,1*
620000	(ii) Coffee beans	0.05*	0,1*
630000	(iii) Herbal infusions (dried)	0.05*	0,1*
631000	(a) Flowers	0.05*	0,1*
631010	Camomille flowers	0.05*	0,1*
631020	Hybiscus flowers	0.05*	0,1*
631030	Rose petals	0.05*	0,1*
631040	Jasmine flowers (Elderflowers (Sambucus nigra))	0.05*	0,1*
631050	Lime (linden)	0.05*	0,1*
631990	Others	0.05*	0,1*
632000	b) Leaves	0.05*	0,1*
632010	Strawberry leaves	0.05*	0,1*
632020	Rooibos leaves (Ginkgo leaves)	0.05*	0,1*
632030	Maté	0.05*	0,1*
632990	Others	0.05*	0,1*
633000	(c) Roots	0.05*	0,1*
633010	Valerian root	0.05*	0,1*
633020	Ginseng root	0.05*	0,1*
633990	Others	0.05*	0,1*
639000	(d) Other herbal infusions	0.05*	0,1*
640000	(iv) Cocoa beans (fermented or dried)	0.05*	0,1*
650000	(v) Carob (st johns bread)	0.05*	0,1*
700000	7. HOPS (dried)	0.05*	0,1*
800000	8. SPICES	0.05*	
810000	(i) Seeds	0.05*	0,1* (ft)
810010	Anise	0.05*	0,1* (ft)
810020	Black caraway	0.05*	0,1* (ft)
810030	Celery seed (Lovage seed)	0.05*	0,1* (ft)
810040	Coriander seed	0.05*	0,1* (ft)
810050	Cumin seed	0.05*	0,1* (ft)
810060	Dill seed	0.05*	0,1* (ft)
810070	Fennel seed	0.05*	0,1* (ft)
810080	Fenugreek	0.05*	0,1* (ft)
810090	Nutmeg	0.05*	0,1* (ft)
810990	Others	0.05*	0,1* (ft)
820000	(ii) Fruits and berries	0.05*	0,1*
820010	Allspice	0.05*	0,1*
820020	Sichuan pepper (Anise pepper, Japan pepper)	0.05*	0,1*

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820030	Caraway	0.05*	0,1*
820040	Cardamom	0.05*	0,1*
820050	Juniper berries	0.05*	0,1*
820060	Pepper, black, green and white (Long pepper, pink pepper)	0.05*	0,1*
820070	Vanilla pods	0.05*	0,1*
820080	Tamarind	0.05*	0,1*
820990	Others	0.05*	0,1*
830000	(iii) Bark	0.05*	0,1*
830010	Cinnamon (Cassia)	0.05*	0,1*
830990	Others	0.05*	0,1*
840000	(iv) Roots or rhizome	0.05*	
840010	Liquorice	0.05*	0,1*
840020	Ginger	0.05*	0,1*
840030	Turmeric (Curcuma)	0.05*	0,1*
840040	Horseradish	0.05*	(ft)
840990	Others	0.05*	0,1*
850000	(v) Buds	0.05*	0,1*
850010	Cloves	0.05*	0,1*
850020	Capers	0.05*	0,1*
850990	Others	0.05*	0,1*
860000	(vi) Flower stigma	0.05*	0,1*
860010	Saffron	0.05*	0,1*
860990	Others	0.05*	0,1*
870000	(vii) Aril	0.05*	0,1*
870010	Mace	0.05*	0,1*
870990	Others	0.05*	0,1*
900000	9. SUGAR PLANTS		0,02*
900010	Sugar beet (root)	1	0,02*
900020	Sugar cane	0.02*	0,02*
900030	Chicory roots	0.02*	0,02*
900990	Others	0.02*	0,02*
1000000	10. PRODUCTS OF ANIMAL ORIGIN- TERRESTRIAL ANIMALS		
1010000	(i) Tissue		
1011000	(a) Swine	0.2	(ft)
1011010	Muscle	0.2	0,02* (ft)
1011020	Fat	0.2	0,03 (ft)
1011030	Liver	0.2	0,02* (ft)
1011040	Kidney	0.2	0,02* (ft)
1011050	Edible offal	0.2	0,02* (ft)
1011990	Others	0.2	0,02* (ft)
1012000	(b) Bovine	0.2	(ft)

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1012010	Muscle	0.2	0,025 (ft)
1012020	Fat	0.2	0,25 (ft)
1012030	Liver	0.2	0,07 (ft)
1012040	Kidney	0.2	0,05 (ft)
1012050	Edible offal	0.2	0,02* (ft)
1012990	Others	0.2	0,02* (ft)
1013000	(c) Sheep	0.2	(ft)
1013010	Muscle	0.2	0,02* (ft)
1013020	Fat	0.2	0,2 (ft)
1013030	Liver	0.2	0,07 (ft)
1013040	Kidney	0.2	0,05 (ft)
1013050	Edible offal	0.2	0,02* (ft)
1013990	Others	0.2	0,02* (ft)
1014000	(d) Goat	0.2	(ft)
1014010	Muscle	0.2	0,02* (ft)
1014020	Fat	0.2	0,2 (ft)
1014030	Liver	0.2	0,07 (ft)
1014040	Kidney	0.2	0,05 (ft)
1014050	Edible offal	0.2	0,02* (ft)
1014990	Others	0.2	0,02* (ft)
1015000	(e) Horses, asses, mules or hinnies	0.2	(ft)
1015010	Muscle	0.2	0,02* (ft)
1015020	Fat	0.2	0,2 (ft)
1015030	Liver	0.2	0,07 (ft)
1015040	Kidney	0.2	0,05 (ft)
1015050	Edible offal	0.2	0,02* (ft)
1015990	Others	0.2	0,02* (ft)
1016000	(f) Poultry -chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon		0,02* (ft)
1016010	Muscle	0.02*	0,02* (ft)
1016020	Fat	0.2	0,02* (ft)
1016030	Liver	0.2	0,02* (ft)
1016040	Kidney	0.2	0,02* (ft)
1016050	Edible offal	0.2	0,02* (ft)
1016990	Others	0.2	0,02* (ft)
1017000	(g) Other farm animals (Rabbit, kangaroo, deer)	0.2	(ft)
1017010	Muscle	0.2	0,02* (ft)
1017020	Fat	0.2	0,2 (ft)
1017030	Liver	0.2	0,07 (ft)
1017040	Kidney	0.2	0,05 (ft)
1017050	Edible offal	0.2	0,02* (ft)
1017990	Others	0.2	0,02* (ft)
1020000	(ii) Milk	0.02*	(ft)

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1020010	Cattle	0.02*	0,04 (ft)
1020020	Sheep	0.02*	0,02* (ft)
1020030	Goat	0.02*	0,02* (ft)
1020040	Horse	0.02*	0,02* (ft)
1020990	Others	0.02*	0,02* (ft)
1030000	(iii) Bird eggs	0.02*	0,02* (ft)
1030010	Chicken	0.02*	0,02* (ft)
1030020	Duck	0.02*	0,02* (ft)
1030030	Goose	0.02*	0,02* (ft)
1030040	Quail	0.02*	0,02* (ft)
1030990	Others	0.02*	0,02* (ft)
1040000	(iv) Honey (Royal jelly, pollen, honey comb with honey (comb honey))		0,05*
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)		0,02* (ft)
1060000	(vi) Snails		0,02* (ft)
1070000	(vii) Other terrestrial animal products (Wild game)		0,02* (ft)

(*) Indicates lower limit of analytical determination
(ft) Specific footnotes on confirmatory data to be provided.
(R) = The residue definition differs for the following combinations pesticide-code number:
1011030, 1011040, 1012030, 1012040, 1013030, 1013040, 1014030, 1014040, 1015030, 1015040, 1016030, 1016040, 1017030 and 1017040: sum of fenvalerate (any ratio of constituent isomers including esfenvalerate) and CPIA (chlorophenyl isovaleric acid), expressed as fenvalerate

ABBREVIATIONS

ADI	acceptable daily intake
AIR	Annex I Renewal
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
CF	conversion factor for enforcement to risk assessment residue definition
CIPAC	Collaborative International Pesticide Analytical Council
CXL	Codex Maximum Residue Limit (Codex MRL)
DAR	Draft Assessment Report
DE	Germany
EC	emulsifiable concentrate
EC	European Community
EFSA	European Food Safety Authority
EL	Greece
EMS	evaluating Member State
EU	European Union
ES	Spain
FAO	Food and Agriculture Organisation of the United Nations
FR	France
GAP	good agricultural practice
GCPF	Global Crop Protection Federation (former GIFAP)
ha	hectare
hL	hectolitre
HR	highest residue
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
IT	Italy
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
kg	kilogram
LOQ	limit of quantification
MRL	maximum residue level
NL	Netherlands
OECD	Organisation for Economic Co-operation and Development
PHI	pre-harvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model

PT	Portugal
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
RAC	raw agricultural commodity
RMS	rapporteur Member State
SANCO	Directorate-General for Health and Consumers
SEU	Southern European Union
TMDI	theoretical maximum daily intake