REASONED OPINION

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Modification of the existing maximum residue levels for deltamethrin in celery, Florence fennel and rhubarb

European Food Safety Authority (EFSA)

Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant AHDB Horticulture submitted a request to the competent authority in the United Kingdom (evaluating Member State) to modify the existing maximum residue levels (MRLs) for the active substance deltamethrin in celery, Florence fennel and rhubarb. To accommodate for the intended uses of deltamethrin in these crops, it was considered necessary to raise existing MRLs. Based on the evaluation report prepared by the EMS in accordance with Article 8 of Regulation (EC) No 396/2005, EFSA concludes that the applicant provided sufficient data to derive MRL proposals of 0.3 mg/kg for the proposed uses in celeries, Florence fennels and rhubarbs. Adequate analytical enforcement methods are available to control compliance with the proposed MRLs for deltamethrin in the commodities under consideration. Taking into account the available information, EFSA concludes that residues of deltamethrin at the level expected following the treatment according to the envisaged agricultural practices will not result in a consumer exposure exceeding the toxicological reference values and therefore are unlikely to pose a consumer health risk.

Keywords: deltamethrin, celery, Florence fennel, rhubarb, MRL application, consumer risk assessment

Requestor: European Commission

Question number: EFSA-Q-2016-00492

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, AHDB Horticulture submitted a request to the competent authority of the United Kingdom (evaluating member state (EMS)) to modify the existing maximum residue levels (MRLs) for the active substance deltamethrin in celery, Florence fennel and rhubarb. To accommodate for the intended uses of deltamethrin in these crops, it was considered necessary to raise existing MRLs. The United Kingdom 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 the European Food Safety Authority (EFSA) on 2 August 2016.

EFSA based 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 deltamethrin as well as the conclusion from the previous EFSA opinions on deltamethrin including the review of the existing MRLs under Article 12 of Regulation (EC) No 396/2005.

The toxicological profile of deltamethrin was evaluated in the framework of Directive 91/414/EEC and the data were sufficient to derive an acceptable daily intake (ADI) of 0.01 mg/kg body weight (bw) per day and acute reference dose (ARfD) of 0.01 mg/kg bw.

The metabolism of deltamethrin in primary crops belonging to the group of fruits and fruiting vegetables (apples and tomatoes), pulses, oilseeds (cotton seed) and cereals (maize) was investigated in the framework of the peer review and the MRL review. The metabolism studies showed that the metabolic pathway is similar in all crop groups investigated.

EFSA concluded that for the crops under consideration sufficient information on the metabolic behaviour in primary corps is available; the residue definitions derived in the framework of the MRL review are equally applicable for celery, Florence fennel and rhubarb.

Analytical methods for enforcement of the proposed residue definition are available; these methods are sufficiently validated to demonstrate that they are appropriate for MRL enforcement in the crops under consideration.

In support of the application, four good agricultural practices (GAP)-compliant residue trials on celery have been submitted. Although the celery samples of the supervised field trials were analysed only for the parent compound and not for the two additional metabolites included in the risk assessment residue definition (i.e. alpha-*R*-isomer and *trans*-isomer of deltamethrin), these trials are considered sufficient to derive an MRL proposal for celery; the results can be extrapolated to fennel and rhubarb. To estimate the residue concentration for the metabolites, it is proposed to use the conversion factor derived in the framework of the MRL review for vegetables. This approach is acceptable, taking into account that the new residue definition was established recently, after the residue trials were performed. However, it would be desirable to verify the appropriateness of the conversion factor with residue trials where the samples are analysed for the full residue definition for risk assessment. It is noted that the EMS proposed to set the MRL for Florence fennel on a provisional basis, pending the submission of two additional trials. However, EFSA does not share this view since according to the EU guidance document (European Commission, 2015) four trials on a minor crop are sufficient to derive MRL proposals by extrapolation for other minor crops.

Residues of deltamethrin in commodities of animal origin were not assessed since the crops under consideration in this MRL application are normally not fed to livestock.

The chronic exposure calculations performed in the framework of the MRL review under Article 12 of Regulation (EC) No 396/2005 (EFSA, 2015) was updated, taking into account the safe uses identified in the MRL review and the expected residues in the crops for which MRL proposals were derived. EFSA also performed an acute risk assessment for the commodities under consideration using the highest residue found in the residue trials. EFSA used the tentative conversion factor derived in the framework of the MRL review for vegetables to accommodate for lack of information on the metabolites included in the risk assessment residue definition. The use of the tentative conversion factor introduces an additional element of uncertainty in the risk assessment.

The result of the chronic exposure assessment was below the ADI with the highest international estimated daily intake (IEDI) being 93.6% of ADI (WHO cluster diet B). The contribution of the crops under consideration (expressed as percentage of the ADI) was 0.18% for rhubarb, and below 0.1% for celery and Florence fennel.

The estimated short-term intake for deltamethrin residues expected in celery accounted for 91.8% of the ARfD; for Florence fennel and rhubarb, the short-term intake was estimated to be 40.7% and 74.4% of the ARfD.

Thus, it is concluded that the long-term and short-term intake of residues of deltamethrin resulting from the envisaged uses in celery, Florence fennel and rhubarb is unlikely to present a public health concern.

EFSA proposes to amend the existing MRL as reported in the summary table below.

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Deltamethrin				
270030	Celeries	0.05*	0.30	The MRLs proposed are sufficiently supported by Northern European residue trials on celery which were extrapolated to Florence fennel and rhubarb. No consumer health risk was identified for these commodities containing residues of deltamethrin resulting from the use of the active substance in accordance with the envisaged use
270040	Florence fennels	0.05*	0.30	
270070	Rhubarbs	0.05*	0.30	

MRL: maximum residue level.
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).

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Background

Commission Regulation (EC) No 396/2005[1] establishes the rules governing the setting of pesticide maximum residue levels (MRLs) at the European Union (EU) level. Article 6 of this 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[2], repealed by Regulation (EC) No 1107/2009[3], shall submit to a Member State an application to modify a MRL in accordance with the provisions of Article 7 of the Regulation.

The competent authority in the United Kingdom, hereafter referred to as the evaluating Member State (EMS), received an application from the company AHDB Horticulture[4] to modify the existing MRLs for the active substance deltamethrin in celery, Florence fennel and rhubarb. This application was notified to the European Commission and the European Food Safety Authority (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 and to EFSA on 2 August 2016.

The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2016-00492 and the following subject:

Deltamethrin: MRLs in celeries, Florence fennels and rhubarbs.

The EMS proposed to raise the existing MRL of deltamethrin in the crops under consideration from the limit of quantification (LOQ) set at the level of 0.05 mg/kg to 0.30 mg/kg. For Florence fennel, the EMS suggested to set the MRL only provisionally since four trials were considered insufficient to be used for setting MRLs in two additional minor crops by extrapolation.

Terms of Reference

In accordance with Article 10 of Regulation (EC) No 396/2005, EFSA shall assess the application and the evaluation report and give a reasoned opinion on the risks to the consumer and where relevant to animals associated with the setting of the requested MRLs. The opinion shall include:

- an assessment of whether the analytical method for routine monitoring proposed in the application is appropriate for the intended control purposes;
- the anticipated LOQ for the pesticide/product combination;
- an assessment of the risks of the acceptable daily intake (ADI) and acute reference dose (ARfD) being exceeded as a result of the modification of the MRL;
- the contribution to the intake due to the residues in the products for which the MRLs were requested;
- any other element relevant to the risk assessment.

In accordance with Article 11 of the Regulation, the reasoned opinion shall be provided as soon as possible, at the latest within 3 months from the date of receipt of the application.

The evaluation report submitted by the EMS on 2 August 2016 (United Kingdom, 2016) and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available.

The active substance and its use pattern

The intended uses of a plant protection product containing the active substance deltamethrin on celery, Florence fennel and rhubarb, which are the basis for the current MRL application, are reported in Appendix A.

Deltamethrin is the ISO common name for (*S*)-α-cyano-3-phenoxybenzyl (1*R*,3*R*)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropanecarboxylate (IUPAC). Deltamethrin contains three chiral carbons in different positions and may have seven other potential stereoisomers. For this reason, deltamethrin ([1*R*, *cis*, alpha-*S*]-isomer) is often referred to as *cis*-deltamethrin. In the framework of this assessment, deltamethrin refers to the specific isomer unless specified otherwise.

[1] 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, 16.3.2005, p. 1–16.
[2] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1–32.
[3] 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.
[4] AHDB Horticulture UK, C/O STC, Cawood, Selby, North Yorkshire, YO8 3TZ, UK.

Deltamethrin is a non-systemic insecticide belonging to the chemical class of pyrethroids. It prevents the transmission of nervous impulses in harmful organisms thereby disrupting their nervous system. It is used to control many species of insects, in particular Lepidoptera, Coleoptera and Homoptera in a wide range of crops. Deltamethrin is also used topically for the control of ectoparasites in cattle and sheep.

Deltamethrin is considered as fat-soluble (log P_{ow} = 4.6). The chemical structure of the active substance and its main metabolites are reported in Appendix D.

Deltamethrin was evaluated in the framework of Directive 91/414/EEC with Sweden designated as rapporteur Member State (RMS). The representative uses supported for the peer review process were foliar applications as an insecticide on a large number of crops (including roots and tuber vegetables, fruits and fruiting vegetables, leafy vegetables and oilseeds) and post-harvest uses on pulses, potatoes and cereals. Deltamethrin was included in Annex I of Directive 91/414/EEC by means of Commission Directive 2003/5/EC, which entered into force on 1 November 2003. According to Regulation (EU) No 540/2011, deltamethrin is approved under Regulation (EC) No 1107/2009. This approval is restricted to uses as an insecticide only. As EFSA was not yet involved in the peer review of deltamethrin, an EFSA Conclusion on this active substance is not available.

The review of existing MRLs in the framework of Article 12 of Commission Regulation (EC) No 396/2005 has been finalised (EFSA, 2015); based on the MRLs proposed by EFSA, Annexes II and IIIB of Regulation (EC) No 396/2005 have been recently amended by Regulation (EU) 2016/53[5] and recently by Regulation 2016/1822.[6]

Assessment

EFSA has based its assessment on the evaluation report submitted by the EMS (United Kingdom, 2016), the draft assessment report (DAR) and its addendum prepared under Directive 91/414/EEC (Sweden, 1998, 2002), the review report on deltamethrin (European Commission, 2002), as well as the conclusion from the EFSA reasoned opinions including the review of the existing MRLs for deltamethrin according to Article 12 of Regulation (EC) No 396/2005 (EFSA, 2010, 2015). 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[7] and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (European Commission, 1997a–g, 2000, 2010a, b, 2015; OECD, 2011, 2013).

The list of end points of the studies assessed by EFSA in the framework of the MRL review[8] relevant for the current application, including the end points of studies submitted in support of the current application, are presented in Appendix B.

1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

The metabolism of deltamethrin in primary crops belonging to the group of fruits and fruiting vegetables (apples and tomatoes), pulses, oilseeds (cotton seed) and cereals (maize) was investigated in the framework of the MRL review (EFSA, 2015). The metabolism studies showed that the metabolic pathway is similar in all crop groups investigated.

While for enforcement purposes the parent compound was found to be an appropriate marker substance, EFSA proposed that two additional metabolites (i.e. alpha-*R* isomer and *trans*-isomer)

[5] Commission Regulation (EU) 2016/53 of 19 January 2016 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for deltamethrin, mesotrione, metosulam and pirimiphos-methyl in or on certain products. OJ L 13, 20.1.2016, p. 12–39.

[6] Commission Regulation (EU) 2016/1822 of 13 October 2016 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for aclonifen, deltamethrin, fluazinam, methomyl, sulcotrione and thiodicarb in or on certain products. OJ L 281, 18.10.2016, p. 1–44.

[7] 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, 11.6.2011, p. 127–175.

[8] The updated list of endpoints reflects the decisions on implementing MRL recommendations taken in Commission Regulation (EU) 2016/53.

should be included in the residue definition for risk assessment based on the following considerations (EFSA, 2015): alpha-*R* isomer and *trans*-isomer represent approximately 30–40% of the total residue and information on the toxicity of isomers is not available.

1.1.2. Nature of residues in rotational crops

The crops under consideration (celery, rhubarb and fennel) may be grown in crop rotation. The metabolism of deltamethrin in rotational crops – carrots, lettuce, and barley – has been previously evaluated. In the framework of the MRL review (EFSA, 2015), EFSA concluded that the metabolism in rotational crops appears to be comparable to that in primary crops.

1.1.3. Nature of residues in processed commodities

The effect of processing on the nature of deltamethrin has been investigated in the framework of the peer review (Sweden, 2002) and during previous EFSA assessment (EFSA 2015). No additional information is needed for the current MRL application.

1.1.4. Methods of analysis in plants

In previous assessments, EFSA assessed analytical method to be used for enforcement purpose. Methods for quantifying deltamethrin in plant matrices with high water content, high fat content, acidic and dry commodities using gas chromatography with electron capture detector (GC-ECD) were provided; the LOQ for these matrices was 0.02 mg/kg (EFSA, 2015).

EFSA concludes that adequate analytical methods are available for monitoring of residues in celery, rhubarb and fennel which are crops with high water content.

1.1.5. Stability of residues in plants

Storage stability of deltamethrin was demonstrated at −20°C for a period of 24 months in high water content commodities (cabbage and tomatoes) (FAO, 2002) and at −12°C for 30 months in high oil content commodities (cotton seed) and for 9 months in dry commodities (cereals grain) (Sweden, 1998). The available data were considered sufficient to conclude on the storage stability of deltamethrin in acidic matrices as well (EFSA, 2015).

1.1.6. Proposed residue definitions

EFSA concludes that for the crops under consideration sufficient information on the metabolic behaviour in primary corps is available; the residue definitions derived in the framework of the MRL review are equally applicable for celery, Florence fennel and rhubarb.

Analytical methods for enforcement of the proposed residue definition are available; these methods are sufficiently validated to demonstrate that they are appropriate for MRL enforcement in the crops under consideration.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

In support of the application, four Good Agricultural Practice (GAP)-compliant residue trials on celery have been submitted. The trials were conducted in the United Kingdom and Northern France (see Appendix B, Section B.1.2.1). The samples of these residue trials were analysed for parent deltamethrin only. Since no data were available for the residue definition for risk assessment, the tentative conversion factor derived in the framework of the MRL review for vegetables was used. To estimate the residue concentration for the metabolites, it is proposed to use the conversion factor derived in the framework of the MRL review for vegetables. This approach is acceptable, taking into account that the new residue definition was established recently, after the residue trials were performed.

The storage period of the samples was within the period for which integrity of the samples has been demonstrated. These trials are considered valid and sufficient to derive an MRL proposal for celery. In accordance with the EU guidance document (European Commission, 2015), the MRL proposal can be extrapolated to fennel and rhubarb. It would be desirable to receive results on the concentration of the two metabolites included in the risk assessment residue definition to verify that the tentative conversion factor is appropriate.

It is noted that the EMS proposed to set the MRL for Florence fennel on a provisional basis, pending the submission of two additional trials. However, EFSA does not share this view since according to the EU guidance document (European Commission, 2015) four trials on a minor crop are sufficient to derive MRL proposals by extrapolation for other minor crops.

1.2.2. Magnitude of residues in rotational crops

The possible transfer of deltamethrin residues to crops that are grown in crop rotation has been assessed in previous assessments of EFSA (EFSA, 2010, 2015). The available studies demonstrated that no significant residues (residues below 0.01 mg/kg) are expected in succeeding crops (spinach, carrots and radishes) planted in soil treated once at 0.12 kg a.s./ha. Since the maximum annual application rate for the crops under consideration (0.03 kg a.s./ha) is significantly lower than the application rate tested in the rotational crop study, the previous conclusion is still valid; provided that the active substance is applied according to the proposed GAP, no significant residues are expected in rotational crops.

1.2.3. Magnitude of residues in processed commodities

For celery, rhubarb and fennel, the main processing procedure will be boiling. No specific processing studies for the three crops are available. Processing studies in pulses and potatoes investigated the impact of boiling on the terminal deltamethrin residues. These studies showed that cooking leads to a reduction of the residues (EFSA, 2015). A certain reduction of deltamethrin may be also expected in boiled celery, rhubarb and fennel. However, since the boiling duration for the vegetables under considerations would be significantly shorter than for pulses and potatoes, the results of these studies cannot be directly extrapolated.

1.2.4. Proposed MRLs

Based on the available data, a MRL proposal of 0.30 mg/kg was derived for celery, Florence fennel and rhubarb.

2. Residues in livestock

Animal metabolism has not been considered as animal intake of celery, fennel and rhubarb is not expected as they are not animal feedstuffs.

3. Consumer risk assessment

The chronic exposure calculations performed in the framework of the MRL review under Article 12 of Regulation (EC) No 396/2005 (EFSA, 2015) was updated, taking into account the safe uses identified in the MRL review and the expected residues in the crops for which MRL proposals were derived.

EFSA also performed an acute risk assessment for the commodities under consideration using the highest residue found in the residue trials. Since no information on the residues of the two additional metabolites included in the risk assessment residue definition was available, the risk assessment values (supervised trials median residue ($STMR_{MO}$) and highest residue (HR_{MO})) were multiplied with the tentative conversion factor (CF) derived in the framework of the MRL review for vegetables. The use of the tentative conversion factor introduces an additional element of uncertainty in the risk assessment. The detailed input values for the chronic and acute risk assessment are listed in Appendix C.

The exposure calculations were performed using revision 2 of the EFSA PRIMo (EFSA, 2007). The Excel spreadsheet providing the risk assessment calculations are published together with this reasoned opinion.

The result of the chronic exposure assessment did not exceed the ADI; the highest international estimated daily intake (IEDI) being 93.6% of ADI (WHO cluster diet B). The contribution of the crops under consideration (expressed as percentage of the ADI) was 0.18% for rhubarb, and below 0.1% for celery and Florence fennel.

The estimated short-term intake for deltamethrin residues expected in celery accounted for 91.8% of the ARfD; for Florence fennel and rhubarb, the short-term intake was estimated to be 40.7% and 74.4% of the ARfD.

Thus, it is concluded that the long-term and short-term intake of residues of deltamethrin resulting from the envisaged uses in celery, Florence fennel and rhubarb is unlikely to present a public health concern.

Conclusions and recommendations

Based on the detailed assessment, EFSA derives the MRL proposal summarised in the summary table below (Table 1).

Table 1: Summary table

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Deltamethrin				
0270030	Celeries	0.05*	0.30	The MRLs proposed are sufficiently supported by Northern European residue trials on celery which were extrapolated to Florence fennel and rhubarb. No consumer health risk was identified for these commodities containing residues of deltamethrin resulting from the use of the active substance in accordance with the envisaged use
0270040	Florence fennels	0.05*	0.30	
0270070	Rhubarbs	0.05*	0.30	

MRL: maximum residue level.
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
*Indicates that the MRL is set at the limit of quantification.

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Abbreviations

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CF	conversion factor for enforcement to risk assessment residue definition
CXL	Codex maximum residue limit
DAR	draft assessment report
DAT	days after treatment
EMS	evaluating Member State
GAP	Good Agricultural Practice
GC-ECD	gas chromatography with electron capture detector
HR	highest residue
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
log P_{ow}	logarithm of partition coefficient between *n*-octanol and water
LOQ	limit of quantification
Mo	monitoring
MRL	maximum residue level
MS	Member States
OECD	Organisation for Economic Co-operation and Development
PBI	plant back interval
PF	processing factor
PHI	preharvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
RA	risk assessment
RAC	raw agricultural commodity
RD	residue definition
RMS	rapporteur Member State
SMILES	simplified molecular-input line-entry system
STMR	supervised trials median residue
WHO	World Health Organization

Appendix A – Summary of GAP triggering the amendment of existing EU MRLs

Crop	Region/ MS	Outdoor/ indoor	Member state or country	Pest controlled	Formulation			Application										PHI[c] or waiting period (days)	Comments (max. 250 characters)
Common name					Type[a]	Content		Method	Growth stage[b]		Number		Interval (days)		Rate				
						Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.	Min.	Max.	Unit		
Celery	NEU	Outdoor	UK	Biting and sucking insects	EC	25.0	g/L	Foliar treatment – spraying	12	45–49		4		7		7.50	g a.i./ha	7	–
Florence fennel	NEU	Outdoor	UK	Biting and sucking insects	EC	25.0	g/L	Foliar treatment – spraying	12	45–49		4		7		7.50	g a.i./ha	7	–
Rhubarb	NEU	Outdoor	UK	Biting and sucking insects	EC	25.0	g/L	Foliar treatment – spraying	12	45–49		4		7		7.50	g a.i./ha	7	–

NEU: northern European Union; MS; Member State; EC: emulsion concentrate.
(a): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide.
(b): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.
(c): PHI: minimum preharvest interval.

Appendix B – Selected list of end points

B.1. Residues in plants

B.1.1. Nature of residues and methods of analysis in plants

B.1.1.1. Metabolism studies, methods of analysis and residue definitions in plants

Primary crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**Sampling (DAT)**
	Fruit crops	Apples	Foliar, 1 × 60 g a.s./ha	28
		Tomatoes	Foliar, 2 × 50 g a.s./ha	4, 14, 28
			Local, 14 ug/tomato	
	Cereals	Maize	Foliar, 2 x 110 g a.s./ha	0, 14, 42
	Pulses/Oilseed	Cotton (I)	Local, 3–15 mg/kg leaf	14. 42
		Cotton (II)	Foliar, 0.009 mg/plant	1, 3, 7
			Soil, 0.18 mg/plant	
			Hydroponic, 6.7 mg/plant	
		Cotton (III)	Foliar, 2 × 224 g a.s./ha	4, 10, 28
	Studies I and II on cotton cover the metabolism in leafy vegetables. Study on cotton (I) performed in open field and in glasshouse. Study on cotton (II) investigated translocation. Study on tomatoes performed in glasshouse Sources: Sweden, 1998, 2002; FAO, 2002			
Rotational crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**PBI (DAT)**
	Root/tuber crops	Carrots (I)	Bare soil, 10 × 45 g a.s./ha	30, 120
		Carrots (II)	Bare soil, 1 × 118 g a.s./ha	0
		Radishes	Bare soil, 1 × 118 g a.s./ha	0
	Leafy crops	Lettuce	Bare soil, 10 × 45 g a.s./ha	30, 120
		Spinach	Bare soil, 1 × 118 g a.s./ha	0
	Cereal (small grain)	Barley	Bare soil, 10 × 45 g a.s./ha	30, 120
	In the study on carrots (II), radishes and spinach the crops were cultivated immediately after soil treatment			
	Source: Sweden, 1998			
Processed commodities (hydrolysis study)	**Conditions**			**Investigated?**
	Pasteurisation (20 min, 90°C, pH 4)			Yes
	Baking, brewing and boiling (60 min, 100°C, pH 5)			Yes
	Sterilisation (20 min, 120°C, pH 6)			Yes
	Source: Sweden, 1998, 2002			

PBI: plant back interval; DAT: days after treatment; a.s.: active substance.

Can a general residue definition be proposed for primary crops?	yes
Rotational crop and primary crop metabolism similar?	yes
Residue pattern in processed commodities similar to residue pattern in raw commodities?	yes
Plant residue definition for monitoring (RD-Mo)	Deltamethrin
Plant residue definition for risk assessment (RD-RA)	Sum of deltamethrin and its alpha-R isomer and trans-isomer
Conversion factor (monitoring to risk assessment)	1.25
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)	GC-ECD, high water, high acid, high oil, dry commodities, 0.02 mg/kg (Sweden, 2002; European Commission, 2002).

B.1.1.2. Stability of residues in plants

Plant products (available studies)	Category	Commodity	T (°C)	Stability (months/years)
	High water content	Lettuce	−20	16 months
		Cabbage	−20	24 months
		Tomato	−20	24 months
	High oil content	Cotton seed	−12	30 months
	Dry/high starch	Cereals grain	−12	9 months
	High acid content	–	−20	24 months
	Studies cover also the stability of the isomers included in the residue definition. Result from the storage stability study on tomatoes (borderline between high water and acidic commodity) are extrapolated to the acidic commodities Sources: Sweden, 1998, 2002; FAO, 2002			

B.1.2. Magnitude of residues in plants

B.1.2.1. Summary of residues data from the supervised residue trials

Crop	Region/ indoor[a]	Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg)	Recommendations/ comments (OECD calculations)	MRL proposals (mg/kg)	HR_{Mo} (mg/kg)[b]	$STMR_{Mo}$ (mg/kg)[c]	CF
Celery	NEU	RD_{Mo}: < 0.05; < 0.05; < 0.07; 0.16 RD_{RA}: no results	MRL_{OECD} = 0.293/0.3 MRL proposal can be extrapolated to fennel and rhubarb	0.30	0.16	0.06	1.25[d]

NEU: northern Europe; MRL: maximum residue level; HR: highest residue; STMR: supervised trials median residue; Mo: monitoring; CF: conversion factor.
(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Indoor: indoor EU trials or Country code: if non-EU trials.
(b): Highest residue according to the residue definition for monitoring.
(c): Supervised trials median residue according to the residue definition for monitoring.
(d): Since no data were available for the residue definition for risk assessment, the tentative CF derived in the framework of the MRL review for vegetables was used (EFSA, 2015).

B.1.2.2. Residues in succeeding crops

Confined rotational crop study (quantitative aspect)	No significant residues are expected in the succeeding crops provided that deltamethrin is used according to the GAP assessed in this review. Source: Sweden, 1998.
Field rotational crop study	The field study confirmed the results of the confined rotational crop study. Source: Sweden, 2009.

B.1.2.3. Processing factors

Processed commodity	Number of studies[a]	Processing factor (PF)		CF_P[b]
		Individual values	Median PF	
Indicative processing factors relevant for the crops under consideration (limited data set and residues not analysed according to the proposed residue definitions)[c]				
Potatoes, unpeeled and boiled	4	0.22; 0.27; 0.19; 0.34	0.26	1.25

Processed commodity	Number of studies[a]	Processing factor (PF)		CF_P[b]
		Individual values	Median PF	
Dry pulses, cooked	1	0.10	0.10	1.25

PF: processing factor.
(a): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur).
(b): Tentative conversion factor for risk assessment in the processed commodity is the same as derived from the raw commodities.
(c): Additional processing factors for other crops are reported in a previous EFSA assessment (EFSA, 2015).

B.2. Residues in livestock

Since the crops under assessment are not fed to livestock, the lists of endpoints derived in the MRL review (EFSA, 2015) are valid.

B.3. Consumer risk assessment

B.3.1. Consumer risk assessment without consideration of the existing CXLs

ADI	0.01 mg/kg bw per day (European Commission, 2002)
Highest IEDI, according to EFSA PRIMo	93.6% of ADI (WHO, cluster diet B) Contribution of crops under assessment: Celery: < 0.1% of ADI Rhubarb: 0.18% of ADI Florence fennel: < 0.1% of ADI
Assumptions made for the calculations	The calculation is based on the median residue levels of deltamethrin derived from supervised field trials, multiplied by the conversion factor for risk assessment, in the raw agricultural commodities, except for potatoes where the processing factor for cooking was also applied (see Appendix C, Table C.1). Commodities where no uses were reported or where the MRLs in were lowered to the LOQ although MRLs above the LOQ were proposed by EFSA in the framework of the MRL review, were not taken into account in the risk assessment calculation.
ARfD	0.01 mg/kg bw (European Commission, 2002)
Highest IESTI, according to EFSA PRIMo	Celery: 91.8 % ARfD Rhubarb: 74.4 % ARfD Florence fennel: 40.7 % ARfD
Assumptions made for the calculations	The calculation is based on the highest residue levels of deltamethrin observed in supervised field trials on celery, multiplied by the conversion factor for risk assessment, No processing factors were taken into account.

Appendix C – Input values for the exposure calculations

C.1. Consumer risk assessment

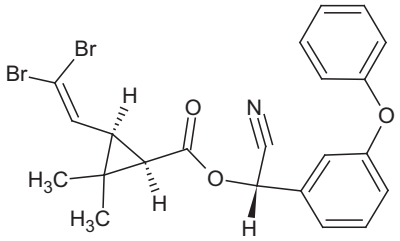
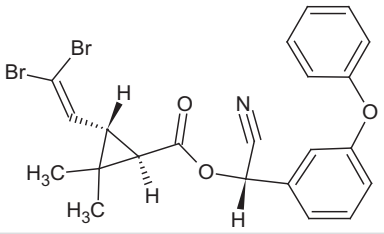
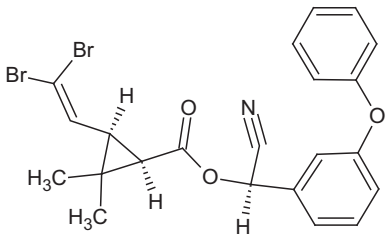
Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Citrus fruits	0.01	$STMR_{Mo}$ × CF (tentative)		
Tree nuts	0.03	$STMR_{Mo}$ × CF (tentative)		
Pome fruits	0.04	$STMR_{Mo}$ × CF (tentative)		
Apricots	0.13	EU MRL (tentative) x CF		
Cherries	0.04	$STMR_{Mo}$ × CF (tentative)		
Peaches	0.03	$STMR_{Mo}$ × CF (tentative)		
Plums	0.01	$STMR_{Mo}$ × CF (tentative)		
Table and wine grapes	0.08	$STMR_{Mo}$ × CF (tentative)		
Strawberries	0.03	$STMR_{Mo}$ × CF (tentative)		
Cane fruit	0.03	$STMR_{Mo}$ × CF (tentative)		
Other small fruits and berries	0.10	$STMR_{Mo}$ × CF (tentative)		
Table olives	0.26	$STMR_{Mo}$ × CF (tentative)		
Kiwi	0.03	$STMR_{Mo}$ × CF (tentative)		
Potatoes	0.02	$STMR_{Mo}$ × CF (tentative)		
Other root and tuber vegetables	0.03	$STMR_{Mo}$ × CF (tentative)		
Garlic	0.03	$STMR_{Mo}$ × CF (tentative)		
Onions	0.03	$STMR_{Mo}$ × CF (tentative)		
Shallots	0.03	$STMR_{Mo}$ × CF (tentative)		
Spring onions	0.07	$STMR_{Mo}$ × CF (tentative)		
Tomatoes	0.03	$STMR_{Mo}$ × CF (tentative)		
Peppers	0.04	$STMR_{Mo}$ × CF (tentative)		
Aubergines (egg plants)	0.07	$STMR_{Mo}$ × CF (tentative)		
Cucurbits edible peel	0.03	$STMR_{Mo}$ × CF (tentative)		
Cucurbits inedible peel	0.03	$STMR_{Mo}$ × CF (tentative)		
Sweet corn	0.03	$STMR_{Mo}$ × CF (tentative)		
Flowering brassica	0.03	$STMR_{Mo}$ × CF (tentative)		
Head cabbage	0.03	$STMR_{Mo}$ × CF (tentative)		
Chinese cabbage	0.02	$STMR_{Mo}$ × CF (tentative)		
Kale	0.40	$STMR_{Mo}$ × CF (tentative)		
Kohlrabi	0.01	MRL × CF (tentative)		
Lamb's lettuce	0.43	$STMR_{Mo}$ × CF (tentative)		
Lettuce	0.19	$STMR_{Mo}$ × CF (tentative)		
Scarole (broad-leaf endive)	0.04	$STMR_{Mo}$ × CF (tentative)		
Cress	0.43	$STMR_{Mo}$ × CF (tentative)		
Land cress	0.43	$STMR_{Mo}$ × CF (tentative)		
Rocket, Rucola	0.43	$STMR_{Mo}$ × CF (tentative)		
Red mustard	0.43	$STMR_{Mo}$ × CF (tentative)		
Leaves and sprouts of Brassica spp	0.16	$STMR_{Mo}$ × CF (tentative)		
Vine leaves	0.16	$STMR_{Mo}$ × CF (tentative)		
Water cress	0.16	$STMR_{Mo}$ × CF (tentative)		
Witloof	0.03	$STMR_{Mo}$ × CF (tentative)		
Herbs	0.43	$STMR_{Mo}$ × CF (tentative)		
Beans (fresh, with pods)	0.01	$STMR_{Mo}$ × CF (tentative)		
Beans (fresh, without pods)	0.01	$STMR_{Mo}$ × CF (tentative)		

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Peas (fresh, with pods)	0.01	$STMR_{Mo}$ × CF (tentative)		
Peas (fresh, without pods)	0.01	$STMR_{Mo}$ × CF (tentative)		
Lentils (fresh)	0.01	$STMR_{Mo}$ × CF (tentative)		
Asparagus	0.02	$STMR_{Mo}$ × CF (tentative)		
Celery	0.08	$STMR_{Mo}$ × CF (tentative)	0.20	HR_{Mo} × CF (2016)
Florence fennel	0.08	$STMR_{Mo}$ × CF (tentative)	0.20	HR_{Mo} × CF (2016)
Rhubarb	0.08	$STMR_{Mo}$ × CF (tentative)	0.20	HR_{Mo} × CF (2016)
Globe artichokes	0.07	$STMR_{Mo}$ × CF (tentative)		
Leek	0.07	$STMR_{Mo}$ × CF (tentative)		
Cultivated fungi	0.03	$STMR_{Mo}$ × CF (tentative)		
Pulses	0.66	$STMR_{Mo}$ × CF (tentative)		
Linseed	0.03	$STMR_{Mo}$ × CF (tentative)		
Poppy seed	0.06	$STMR_{Mo}$ × CF (tentative)		
Sesame seed	0.01	$STMR_{Mo}$ × CF (tentative)		
Sunflower seed	0.06	$STMR_{Mo}$ × CF (tentative)		
Rape seed	0.06	$STMR_{Mo}$ × CF (tentative)		
Mustard seed	0.06	$STMR_{Mo}$ × CF (tentative)		
Cotton seed	0.01	$STMR_{Mo}$ × CF (tentative)		
Pumpkin seeds	0.01	$STMR_{Mo}$ × CF (tentative)		
Safflower	0.01	$STMR_{Mo}$ × CF (tentative)		
Borage	0.06	$STMR_{Mo}$ × CF (tentative)		
Gold of pleasure	0.06	$STMR_{Mo}$ × CF (tentative)		
Hempseed	0.06	$STMR_{Mo}$ × CF (tentative)		
Castor bean	0.06	$STMR_{Mo}$ × CF (tentative)		
Olives for oil production	0.26	$STMR_{Mo}$ × CF (tentative)		
Barley grain	0.88	$STMR_{Mo}$ × CF (tentative)		
Buckwheat grain	0.63	$STMR_{Mo}$ × CF (tentative)		
Maize grain	0.88	$STMR_{Mo}$ × CF (tentative)		
Millet grain	0.63	$STMR_{Mo}$ × CF (tentative)		
Oats grain	0.63	$STMR_{Mo}$ × CF (tentative)		
Rice grain	0.56	$STMR_{Mo}$ × CF (tentative)		
Rye grain	0.88	$STMR_{Mo}$ × CF (tentative)		
Sorghum grain	0.63	$STMR_{Mo}$ × CF (tentative)		
Wheat grain	0.56	$STMR_{Mo}$ × CF (tentative)		
Tea	2.75	$STMR_{Mo}$ × CF (tentative)		
Herbal infusions (dried, flowers)	1.31	$STMR_{Mo}$ × CF (tentative)		
Herbal infusions (dried, leaves)	1.31	$STMR_{Mo}$ × CF (tentative)		
Herbal infusions (dried, roots)	0.09	$STMR_{Mo}$ × CF (tentative)		
Spices (seeds)	0.06	EU MRL × CF		
Spices (fruits and berries)	1.31	$STMR_{Mo}$ × CF (tentative)		
Spices (roots and rhizome)	0.09	$STMR_{Mo}$ × CF (tentative)		
Spices (buds)	1.31	$STMR_{Mo}$ × CF (tentative)		
Spices (flower stigma)	1.31	$STMR_{Mo}$ × CF (tentative)		
Sugar beet (root)	0.03	$STMR_{Mo}$ × CF (tentative)		
Chicory roots	0.01	$STMR_{Mo}$ × CF (tentative)		

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Swine meat	0.03	0.8 × $STMR_{Mo}$ muscle + 0.2 × $STMR_{Mo}$ fat (tentative)		
Swine fat (free of lean meat)	0.06	$STMR_{Mo}$ (tentative)		
Swine liver	0.02	$STMR_{Mo}$ (tentative)		
Swine kidney	0.03	EU MRL		
Ruminant meat	0.03	0.8 × $STMR_{Mo}$ muscle + 0.2 × $STMR_{Mo}$ fat (tentative)		
Ruminant fat	0.08	$STMR_{Mo}$ (tentative)		
Ruminant liver	0.02	$STMR_{Mo}$ (tentative)		
Ruminant kidney	0.03	EU MRL		
Poultry meat	0.02	0.9 × $STMR_{Mo}$ muscle + 0.1 × $STMR_{Mo}$ fat (tentative)		
Poultry fat	0.04	$STMR_{Mo}$ (tentative)		
Poultry liver	0.02	$STMR_{Mo}$ (tentative)		
Ruminant milk	0.02	$STMR_{Mo}$ (tentative)		
Birds' eggs	0.02	$STMR_{Mo}$ (tentative)		

STMR: supervised trials median residue; Mo: monitoring; CF: conversion factor.

Appendix D – Used compound/metabolite codes

Code/trivial name	Chemical name/SMILES notation[(a)]	Structural formula[(a)]
Deltamethrin	(*S*)-α-Cyano-3-phenoxybenzyl (1*R*,3*R*)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropanecarboxylate or (*S*)-α-cyano-3-phenoxybenzyl (1*R*)-*cis*-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropanecarboxylate Br\C(Br)=C/[C@H]3[C@@H](C(=O)O[C@H](C#N)c2cccc(Oc1ccccc1)c2)C3(C)C	
Trans-isomer	(*S*)-Cyano(3-phenoxyphenyl)methyl (1*R*,3*S*)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropanecarboxylate Br\C(Br)=C/[C@@H]3[C@@H](C(=O)O[C@H](C#N)c2cccc(Oc1ccccc1)c2)C3(C)C	
Alpha-R-isomer	(*R*)-Cyano(3-phenoxyphenyl)methyl (1*R*,3*R*)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropanecarboxylate Br\C(Br)=C/[C@H]3[C@@H](C(=O)O[C@@H](C#N)c2cccc(Oc1ccccc1)c2)C3(C)C	

SMILES: simplified molecular-input line-entry system.

(a): ACD/ChemSketch, Advanced Chemistry Development, Inc., ACD/Labs Release: 12.00 Product version: 12.00 (Build 29305, 25 Nov 2008).