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Modification of the existing maximum residue level for deltamethrin in carobs/Saint John's breads

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Bayer SAS – Crop Science Division submitted a request to the competent national authority in Spain to modify the existing maximum residue level (MRL) for the active substance deltamethrin in carobs/Saint John's breads. The data submitted in support of the request were found to suffice to derive an MRL proposal for carobs. An adequate analytical method for enforcement is available to control the residues of deltamethrin in the commodity under consideration at the validated limit of quantification (LOQ) of 0.01 mg/kg. Based on the risk assessment results using the PRIMo rev. 3.1 model, EFSA concluded that the short-term consumer exposure for the intended post-harvest use on carobs did not exceed the toxicological reference value. The long-term intake of residues of deltamethrin indicated a consumer risk. Although residues in carobs are minor contributors to the overall chronic consumer exposure, a risk management consideration is required to decide whether the MRL proposal for carobs is acceptable. The risk assessment shall be regarded as indicative and affected by non-standard uncertainties.

Keywords: Deltamethrin, carobs, insecticide, MRL, consumer risk assessment

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, Bayer SAS – Crop Science Division submitted an application to the competent national authority in Spain (evaluating Member State, EMS) to modify the existing maximum residue level (MRL) for the active substance deltamethrin in carob (or Saint John's bread). 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 the European Food Safety Authority (EFSA) on 25 September 2018. To accommodate for the intended use of deltamethrin, the EMS proposed to raise the existing MRL from the limit of quantification (LOQ) to 0.7 mg/kg.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified data gaps which needed further clarification, which were requested from the EMS. On 8 April 2020, the EMS submitted the requested information and a revised evaluation report, which replaced the previously submitted evaluation report.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC, the data evaluated under previous MRL assessments and the additional data provided by the EMS in the framework of this application, the following conclusions are derived.

The metabolism of deltamethrin following foliar or local applications was investigated in crops belonging to the groups of fruits (apples and tomatoes), pulses and oilseeds (cotton seed) and cereals (maize). The metabolism studies showed that the metabolic pathway is similar in all crop groups investigated. Specific metabolism studies investigating the nature of deltamethrin after post-harvest treatment are not available. Given the results of the available metabolism studies where parent deltamethrin was the main residue, the MRL review concluded that a more extensive metabolism is unlikely in post-harvest treatment. Studies investigating the effect of processing on the nature of deltamethrin (hydrolysis studies) demonstrated that deltamethrin is stable. EFSA concluded that for the crop assessed in this application, metabolism of deltamethrin in primary crops, and the possible degradation in processed products has been sufficiently addressed.

As the proposed use of deltamethrin is on a permanent crop for post-harvest application, investigations of residues in rotational crops are not required.

Based on the metabolic pattern identified in metabolism studies, hydrolysis studies and the toxicological significance of its isomers, the residue definition for enforcement in plant products was set as deltamethrin (cis-deltamethrin). For risk assessment, the residue definition was proposed as the sum of cis-deltamethrin and its alpha-R-isomer and trans-isomer provisionally, pending further toxicological data on these compounds.

Sufficiently validated analytical methods are available to quantify residues in the crop assessed in this application according to the enforcement residue definition. The method enables quantification of residues at or above 0.01 mg/kg (LOQ).

The available residue trials suffice to derive an MRL proposal of 0.7 mg/kg for carobs/Saint John's breads.

Specific studies investigating the magnitude of deltamethrin residues in processed commodities are not required, as the total theoretical maximum daily intake (TMDI) of the crop under assessment is well below the trigger value of 10% of the acceptable daily intake (ADI). However, processing factors (PF) for carob flour were derived from the supervised residue trials submitted and are recommended to be included in Annex VI of Regulation (EC) No 396/2005 as follows:

- Carob, flour, < 4 mm particle size: 1.9
- Carob, flour, > 4 mm particle size: 0.7

Residues of deltamethrin in commodities of animal origin were not assessed since the crop under consideration in this MRL application is normally not fed to livestock in significant amounts.

The toxicological profile of deltamethrin was assessed in the framework of the EU pesticides peer review under 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 an acute reference dose (ARfD) of 0.01 mg/kg bw.

The consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo). The chronic exposure calculations took into account the expected residue on carobs and in all crops for which the MRL recommendations of EFSA were implemented in the EU Regulation, whereas the acute risk assessment was performed only for the crop under consideration. After post-harvest use, deltamethrin isomers included in the residue definition for risk assessment are not expected to be formed as shown during subsequent post-harvest storage in the dark in trials with

maize grains submitted in this MRL application. Nevertheless, the tentative conversion factor between enforcement and risk assessment derived in the framework of the MRL review was also applied to carob residues.

A long-term consumer intake concern was identified for the European diets incorporated in the EFSA PRIMo rev. 3.1. The total calculated intake accounted for a maximum of 108% of the ADI (NL, toddler diet). The contribution of residues in carobs to the total exposure was low with 0.05% of the ADI. The acute exposure calculation did not identify acute consumer intake concerns related to deltamethrin residues from the intended use on carobs (40% of the ARfD).

Based on these calculations, EFSA concluded that the short-term consumer exposure for the intended post-harvest use on carobs did not exceed the toxicological reference value. The long-term intake of residues of deltamethrin indicated, however, a consumer risk. Although residues in carobs are minor contributors to the overall chronic consumer exposure, a risk management consideration is required to decide whether the MRL proposal for carobs is acceptable. The risk assessment shall be regarded as indicative and affected by non-standard uncertainties.

The renewal assessment of the active substance in accordance with Regulation (EC) No 1107/2009 is ongoing, and therefore, the conclusions reported in this reasoned opinion might need to be reconsidered in the light of the outcome of the peer review.

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

Full details of all endpoints and the consumer risk assessment can be found in Appendices B–D.

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Deltamethrin (cis-deltamethrin)[(F)]				
0650000	Carobs/Saint John's breads	0.01*	Further risk management considerations required	For the post-harvest indoor use, EFSA derived an MRL proposal of 0.7 mg/kg for whole fruits In an indicative risk assessment, no acute consumer concern has been identified for the proposed use on carobs. However, using the PRIMo rev. 3.1 the ADI of NL toddler diet was exceeded (108%). Contribution of carobs was low (0.05% ADI, DE, child diet) Thus, further risk management considerations are required to decide whether the MRL proposal is acceptable. The risk assessment is affected by non-standard uncertainties

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

Table of contents

Assessment

The European Food Safety Authority (EFSA) received an application to modify the existing maximum residue level (MRL) for deltamethrin in carob. The detailed description of the intended use of deltamethrin in carobs/Saint John's breads which is the basis for the current MRL application is reported in Appendix A.

Deltamethrin is the ISO common name for (*S*)-α-cyano-3-phenoxybenzyl (*1R*, *3R*)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropanecarboxylate (IUPAC). The chemical structures of the active substance and its main isomers are reported in Appendix E.

Deltamethrin was evaluated in the framework of Directive 91/414/EEC[1] with Sweden designated as rapporteur Member State (RMS) for the representative uses as a foliar treatment on a large number of crops (including roots and tuber vegetables, fruits and fruiting vegetables, leafy vegetables and oilseeds), and as a post-harvest treatment on pulses, potatoes and cereals. The draft assessment report (DAR) prepared by the RMS was not peer reviewed by EFSA. Therefore, no EFSA conclusion is available. Deltamethrin was approved[2] for the use as insecticide on 1 November 2003.

The process of renewal of the first approval is currently ongoing.

The EU MRLs for deltamethrin are established in Annexes II of Regulation (EC) No 396/2005[3]. The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has been performed (EFSA, 2015) and the proposed modifications have been implemented in the MRL legislation. After completion of the MRL review, EFSA has issued two reasoned opinions on the modification of MRLs for deltamethrin. The proposals from these reasoned opinions have been considered in recent MRL regulation(s).[4] The Codex Alimentarius Commission (CAC) adopted Codex maximum residue limits (CXLs) for deltamethrin under Regulation (EU) No 441/2012[5] and Regulation (EU) No 2018/687[6].

In accordance with Article 6 of Regulation (EC) No 396/2005, Bayer SAS – Crop Science submitted an application to the competent national authority in Spain (EMS) to modify the existing MRL for the active substance deltamethrin in carobs (Saint John's breads). The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to EFSA on 25 September 2018. To accommodate for the intended use of deltamethrin, the EMS proposed to raise the existing MRL from the limit of quantification (LOQ) to 0.7 mg/kg. EFSA assessed the application and the evaluation report as required by Article 10 of the MRL Regulation. EFSA identified data gaps which needed further clarification, which were requested from the EMS. On 8 April 2020, the EMS submitted the requested information and a revised evaluation report, which replaced the previously submitted evaluation report.

EFSA based its assessment on the evaluation report submitted by the EMS (Spain, 2018), the draft assessment report (DAR) and its addendum (Sweden, 1998, 2002) prepared under Directive 91/414/EEC, the Commission review report on deltamethrin (European Commission, 2002), the reasoned opinion on the MRL review of the existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (EFSA, 2015) as well as the conclusions from previous EFSA opinions on deltamethrin (EFSA, 2017a, 2018b).

For this application, the data requirements established in Regulation (EU) No 544/2011[7] and the guidance documents applicable at the date of submission of the application to the EMS are applicable

[1] 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.

[2] Commission Directive 2003/5/EC of 10 January 2003 amending Council Directive 91/414/EEC to include deltamethrin as active substance. OJ L 8, 14.1.2003, p. 7–9.

[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, 16.3.2005, p. 1–16.

[4] For an overview of all MRL Regulations on this active substance, please consult: http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=pesticide.residue.selection&language=EN

[5] Commission Regulation (EU) No 441/2012 of 24 May 2012 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 bifenazate, bifenthrin, boscalid, cadusafos, chlorantraniliprole, chlorothalonil, clothianidin, cyproconazole, deltamethrin, dicamba, difenoconazole, dinocap, etoxazole, fenpyroximate, flubendiamide, fludioxonil, glyphosate, metalaxyl-M, meptyldinocap, novaluron, thiamethoxam, and triazophos in or on certain products. OJ L 135, 25.5.2012, p. 4–56.

[6] Commission Regulation (EU) 2018/687 of 4 May 2018 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 acibenzolar-S-methyl, benzovindiflupyr, bifenthrin, bixafen, chlorantraniliprole, deltamethrin, flonicamid, fluazifop-P, isofetamid, metrafenone, pendimethalin and teflubenzuron in or on certain products. L 121, 16.5.2018, p. 63–104.

[7] Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances. OJ L 155, 11.6.2011, p. 1–66.

(European Commission, 1997a–g, 2000, 2010a,b, 2017; OECD, 2011, 2013). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011[8]

As the EU pesticides peer review of the active substance in accordance with Regulation (EC) No 1107/2009 is not yet finalised, the conclusions reported in this reasoned opinion should be taken as provisional and might need to be recognised in the light of the peer review.

A selected list of end points of the studies assessed by EFSA in the framework of this MRL application including the end points of relevant studies assessed previously is presented in Appendix B.

The evaluation report submitted by the EMS (Spain, 2018) 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 as background documents to this reasoned opinion.

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 (apples and tomatoes), pulses and oilseeds (cotton seed) and cereals (maize) was investigated in the framework of the MRL review. The metabolism studies after foliar and local treatment showed that the metabolic pathway is similar in all crop groups investigated. Deltamethrin was the main component of residues (up to 77% of the total radioactive residue (TRR)) with alpha-R-isomer and trans-isomer accounting for approximately 30–40% of the TRR.

Studies investigating the metabolism of deltamethrin following post-harvest treatment are not available and are not required. The MRL review reasonably assumed that, when applied post-harvest, deltamethrin is not expected to undergo a more extensive metabolism (EFSA, 2015).

For the intended post-harvest use, the metabolic behaviour in primary crops is sufficiently addressed.

1.1.2. Nature of residues in rotational crops

As the proposed use of deltamethrin is for post-harvest application on a permanent crop, investigations of residues in rotational crops are not required. Nevertheless, a rotational crop metabolism study is available. EFSA concluded that the metabolism in rotational crops was comparable to that in primary crops (EFSA, 2015).

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 Directive 91/414/EEC (Sweden, 2002) and in the framework of the MRL review (EFSA, 2015). It was concluded that the deltamethrin is hydrolytically stable under the standard hydrolysis conditions.

1.1.4. Methods of analysis in plants

Analytical methods for the determination of deltamethrin residues in plants were assessed during the MRL review and in previous MRL applications (EFSA, 2015, 2017a, 2018b). A multi-residue method was fully validated for the analysis of cis-deltamethrin residues by gas chromatography with mass selective detection (GS-MSD) in high water content, high acid content, high oil content and dry matrices at the LOQ of 0.01 mg/kg. The method allows separating the isomers of deltamethrin (EFSA, 2018b).

Carobs are not classified in any specific matrix group (European Commission, 2010a). Since the above method was successfully validated in all matrices for which a method is required, EFSA concludes that this analytical method for enforcement is appropriate to analyse residues in carobs as well.

[8] 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.

1.1.5. Storage 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 and at –12°C for 30 months in high oil content commodities and for 9 months in dry commodities (EFSA, 2015). Considering that for this application, the analysis of samples from the submitted residue trials was conducted within 30 days after treatment, storage stability studies are not required (European Commission, 1997f).

1.1.6. Proposed residue definitions

Based on the metabolic pattern identified in metabolism studies, the results of hydrolysis studies, the toxicological significance of deltamethrin relevant isomers and the capabilities of enforcement analytical methods, the following residue definitions were proposed by the MRL review (EFSA, 2015).

- residue definition for enforcement: deltamethrin (cis-deltamethrin);
- residue definition for risk assessment: sum of cis-deltamethrin and its alpha-R isomer and trans-isomer (provisional).

The residue definition for enforcement set in Regulation (EC) No 396/2005 is identical with the above-mentioned residue definition.

The same residue definitions are applicable to rotational crops and processed products (EFSA, 2015).

The risk assessment residue definition should be considered on a provisional basis, pending the assessment of further toxicological data investigating the toxicological properties of the alpha-R isomer and trans-isomer of deltamethrin (EFSA, 2015).

Taking into account of the proposed use assessed in this application, EFSA concluded that these residue definitions are appropriate and no further information is required.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

In support of the MRL application, the applicant submitted four trials performed during the 2016 growing season in four different facilities in representative areas for carob in Spain. All trials were performed according to the intended EU post-harvest use by spraying the test product on stored homogenised chopped carob pods. Following treatment 'homogenised chopped pulp and seed of carobs' samples were dried for 20–60 min before separation into 'chopped pulp < 4 mm', 'chopped pulp > 4 mm' and 'seeds'. Samples of each fraction were subsequently collected within 45–70 min following treatment.

The samples of these residue trials were stored for less than 30 days prior to analysis and therefore integrity of the samples did not need to be demonstrated (see Section 1.1.5). According to the assessment of the EMS, the analytical methods used to measure residues in the samples were sufficiently validated and fit for purpose (Spain, 2018).

Carob is classified as a minor crop in Europe, and therefore, a minimum of four trials are required (European Commission, 2017). The samples were analysed for the parent compound only. In the residue trials conducted post-harvest on carob fruits (chopped), residue values of deltamethrin in carob chopped pulp < 4 mm were higher than in chopped pulp > 4 mm and seeds. Subsequently, residues for whole carob fruits were calculated.

Deltamethrin isomers (trans-deltamethrin and alpha-R-deltamethrin) included in the residue definition for risk assessment were not analysed for. The EMS argued that their analysis can be waived because after post-harvest treatment and storage in the dark, formation of the deltamethrin isomers included in the residue definition for risk assessment is not expected to occur. The assumption was substantiated with the results from four[9] residue trials on maize analysed according to the residue definition for risk assessment during subsequent storage time (0, 7, 23 and 92 days) after post-harvest treatment. The two isomers were found always below the LOQ of 0.01 mg/kg (Spain, 2018). Meanwhile and since the toxicological profile of the deltamethrin isomers is not fully elucidated, further residue data are not required taking also into account the low contribution of carob to the human diet.

[9] In one trial samples were stored for 300 days, exceeding the demonstrated storage stability in dry commodities.

EFSA concludes that the available trials suffice to derive an MRL proposal of 0.7 mg/kg on carobs in support of the intended post-harvest GAP.

1.2.2. Magnitude of residues in rotational crops

As the proposed use of deltamethrin is a post-harvest use on a permanent crop, investigations of residues in rotational crops are not required.

1.2.3. Magnitude of residues in processed commodities

Specific studies investigating the magnitude of carob residues in processed commodities are in principle not required, since the total theoretical maximum daily intake (TMDI) for carobs is well below the trigger value of 10% of the ADI. Nevertheless, processing factors (PF) for flour (of < 4 mm and of > 4 mm) could be derived from the residue trials submitted (see Appendix B.1.2.3). EFSA recommends including these PFs in Annex VI of Regulation (EC) No 396/2005.

1.2.4. Proposed MRLs

The available data are considered sufficient to derive an MRL proposal for the intended post-harvest use on carobs. Although the samples of the supervised field trials were analysed only for the parent compound and not for the two additional compounds included in the risk assessment residue definition (i.e. alpha-R-isomer and trans-isomer of deltamethrin), these trials are considered sufficient to perform a consumer risk assessment (see Section 1.2.1) for the post-harvest use on carobs. In Section 3, EFSA assessed whether residues on these crops resulting from the intended use are likely to pose a consumer health risk.

2. Residues in livestock

Not relevant for this assessment because carob is not usually used for feed purposes in significant amounts and is not expected to impact the dietary burden derived in a previous EFSA assessment (EFSA, 2018b).

3. Consumer risk assessment

EFSA performed a dietary risk assessment using revision 3.1 of the EFSA PRIMo (EFSA, 2018a, 2019). This exposure assessment model contains food consumption data for different subgroups of the EU population and allows the acute and chronic exposure assessment to be performed in accordance with the internationally agreed methodology for pesticide residues (FAO, 2016).

The toxicological reference values for deltamethrin used in the risk assessment (i.e. ADI and ARfD values) were derived in the framework of the EU pesticides peer review (European Commission, 2002). A lack of information on the toxicological profiles of the deltamethrin isomers (trans-deltamethrin and alpha-R-deltamethrin) was identified in previous EFSA assessments (EFSA, 2015, 2017a, 2018b). EFSA therefore reiterated in this assessment the proposal to assess these toxicological data in the framework of the renewal of the approval of the active substance deltamethrin. Further data were not requested for this crop considering the post-harvest use (see Section 1.2.1) and the low contribution of carobs to the human diet.

In the framework of the MRL review, a comprehensive long-term exposure assessment was performed, taking into account the existing uses at EU level and acceptable CXLs (EFSA, 2015). EFSA updated the calculation with the supervised trials median residue (STMR) value derived from the residue trials submitted in support of this MRL application for carob. In addition, STMR values derived in EFSA opinions published after the MRL review (EFSA, 2017a, 2018b) and as derived by Codex for rape seeds (FAO, 2016; EFSA, 2017b) were included.

The tentative conversion factor (CF) of 1.25 between enforcement and risk assessment derived previously (EFSA, 2015) was applied, except for asparagus (where reliably a no-residue situation was established) and for the STMRs derived from the implemented CXLs (because expected to cover all components included in the residue definition for risk assessment). The acute exposure assessment was performed only with regard to the commodity under consideration.

Although residues of trans-deltamethrin and alpha-R-deltamethrin are not expected in post-harvest treated carobs, the input values in carobs were multiplied by the CF of 1.25. Using the CF is in line with the approach of the EMS[10] and the previous EFSA assessment of post-harvest uses in the framework of the MRL review (EFSA, 2015). The input values used in the exposure calculations are summarised in Appendix D.1.

When using the EFSA PRIMo 3.1 model, a long-term consumer intake concern was identified for the Dutch toddler diet. The total calculated intake accounted for a maximum of 108% of the ADI. The contribution of residues in carob to the total exposure was low with 0.05% of the ADI (DE, child). The acute exposure calculation did not identify acute consumer intake concerns related to deltamethrin residues from the intended use on carob (40% of the ARfD, IE child).

During the previous assessments, the consumer risk assessment was considered as indicative because of the following elements:

- Use of conversion factor for risk assessment instead of information on the actual occurrence of residues of trans-deltamethrin and alpha-R-deltamethrin;
- Lack of information on the toxicological profile of trans-deltamethrin and alpha-R-deltamethrin;
- Lack of information on the metabolism of trans-deltamethrin and alpha R-deltamethrin in livestock;
- Adequate livestock feeding studies in cows and hens, investigating all relevant tissues and matrices according to the residue definitions for monitoring and risk assessment simultaneously.

Therefore, the consumer risk assessment shall be regarded as indicative and affected by non-standard uncertainties.

EFSA concluded that the long-term intake of residues of deltamethrin indicated a consumer risk with a diet included in PRIMo rev. 3.1 and would need to be refined. The major contributors are maize (49%), wheat (22%) and milk (12%).

A more realistic consumer risk assessment will be performed in the framework of evaluation of data to confirm MRLs following the review of existing MRLs, when full information on authorised uses of deltamethrin supported by data and additional residue trials analysed according to the residue definition for risk assessment will be available to EFSA. However, the contribution of residues in carobs to the overall actual long-term exposure is low (0.05% of the ADI). No short-term consumer concern was identified for the intended post-harvest use on carobs.

It is noted that the estimated short-term exposure to deltamethrin residues related to the existing uses of deltamethrin exceeded the ARfD for pears (138%) and lettuces (138%), while the exposure calculated in the framework of the MRL review using the PRIMo 2 model was below the ARfD (EFSA, 2015). Further refinements of the acute risk assessment might be possible when the confirmatory data requested by the MRL review (EFSA, 2015) will be available.

For further details on the exposure calculations, a screenshot of the Report sheet of the PRIMo is presented in Appendix C.

4. Conclusion and Recommendations

The data submitted in support of this MRL application were found to be sufficient to derive an MRL proposal for carob; however, further risk management considerations are needed.

Using the PRIMo rev. 3.1 model, the short-term consumer exposure for the intended post-harvest use on carobs did not exceed the toxicological reference value. Although residues in carobs are minor contributors to the overall chronic consumer exposure, the long-term intake of residues of deltamethrin resulting from the existing uses indicated a consumer risk. The risk assessment shall be regarded as indicative and affected by non-standard uncertainties.

The renewal assessment of the active substance in accordance with Regulation (EC) No 1107/2009 is ongoing, and therefore, the conclusions reported in this reasoned opinion might need to be reconsidered in the light of the outcome of the peer review.

The MRL recommendations are summarised in Appendix B.4.

[10] It is noted that the EMS included the CF of 1.25 and used the STMR/HR values derived for the processed fraction pulp < 4 mm of carob in the consumer risk assessment (Spain, 2018). Additionally, the EMS multiplied the STMR values derived for the implemented CXLs assessed during the MRL review by the CF for risk assessment.

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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
CAC	Codex Alimentarius Commission
CAS	Chemical Abstract Service
CCPR	Codex Committee on Pesticide Residues
CF	conversion factor for enforcement to risk assessment residue definition
CIRCA	(EU) Communication & Information Resource Centre Administrator
CS	capsule suspension
CV	coefficient of variation (relative standard deviation)
CXL	Codex maximum residue limit
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
DP	dustable powder
DS	powder for dry seed treatment
EC	emulsifiable concentrate
EMS	evaluating Member State
FAO	Food and Agriculture Organization of the United Nations
FID	flame ionisation detector
GAP	Good Agricultural Practice
GC	gas chromatography
GC-FID	gas chromatography with flame ionisation detector
GC-MS	gas chromatography with mass spectrometry
GC-MS/MS	gas chromatography with tandem mass spectrometry
GPC	Gel Permeation Chromatography
GS	growth stage
HR	highest residue
IESTI	international estimated short-term intake
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LC	liquid chromatography
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
MS	mass spectrometry detector
MS/MS	tandem mass spectrometry detector
MW	molecular weight
NEU	northern Europe
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
SANCO	Directorate-General for Health and Consumers
SEU	southern Europe

STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
UV	ultraviolet (detector)
WHO	World Health Organization

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

Crop and/or situation	NEU, SEU, MS or country	F G or I[a]	Pests or group of pests controlled	Preparation		Application				Application rate per treatment				PHI (days)[d]	Remarks
				Type[b]	Conc. a.s.	Method kind	Range of growth stages & season[c]	Number min–max	Interval between application (min)	g a.s./hL min–max	Water L/ha min–max	Rate	Unit		
Carob	EU (Spain)	I	Storage insects	EC	25 g/L	Spray	Post-harvest	1	–		5 L/tonne	0.5	g a.s./ tonne	n.a.	

MRL: maximum residue level; GAP: Good Agricultural Practice; NEU: northern European Union; SEU: southern European Union; MS: Member State; a.s.: active substance; EC: emulsifiable concentrate; n.a.: not applicable.
(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 7th Edition. Revised March 2017. Catalogue of pesticide formulation types and international coding system.
(c): 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.
(d): PHI – minimum preharvest interval.

Appendix B – 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)**	**Comment/Source**
	Fruit crops	Apple	Foliar, 2 × 60 g a.s./ha	28	EFSA (2015)
		Tomato	Foliar, 1 × 50 g a.s./ha	4, 14, 28	EFSA (2015)
			Local, 14 µg/tomato		EFSA (2015)
	Cereals/ grass	Maize	Foliar, 2 × 110 g a.s./ha	0, 14, 42	EFSA (2015)
	Pulses/ oilseeds	Cotton (I)	Local, 3–15 mg/kg leaf	14, 42	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 (EFSA, 2015)
		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	

Rotational crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**PBI (DAT)**	**Comment/Source**
	Root/tuber crops	Carrot	Bare soil, 10 × 45 g a.s./ha	30, 120	EFSA (2015)
		Carrot	Bare soil, 1 × 118 g a.s./ha	0	
		Radish	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	

Processed commodities (hydrolysis study)	**Conditions**	**Stable?**	**Comment/Source**
	Pasteurisation (20 min, 90°C, pH 4)	Yes	Sweden (2002), EFSA (2015)
	Baking, brewing/boiling (60 min, 100°C, pH 5)	Yes	Sweden (2002), EFSA (2015)
	Sterilisation (20 min, 120°C, pH 6)	Yes	Sweden (2002), EFSA (2015)

Can a general residue definition be proposed for primary crops?	Yes	EFSA (2015)
Rotational crop and primary crop metabolism similar?	Yes	EFSA (2015)
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes	EFSA (2015)
Plant residue definition for monitoring (RD-Mo)	Deltamethrin (*cis*-deltamethrin)	
Plant residue definition for risk assessment (RD-RA)	Sum of cis-deltamethrin and its alpha-*R*-isomer and trans-isomer (provisional, pending the assessment of further toxicological data investigating the toxicological properties of the alpha-*R*-isomer and trans-isomer of deltamethrin (EFSA, 2015)). Tentative CF risk of 1.25 (EFSA, 2015)	
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)	Multi residue method DFG S19; extraction with acetone/water (high water, high acid and dry commodities) or acetonitrile/acetone (high oil), filtered and evaporated to dryness, clean-up with GPC using ethyl acetate/cyclohexane followed by mini silica column, determination by GC-MSD, LOQ: 0.01 mg/kg (EFSA, 2018b).	

a.s.: active substance; DAT: days after treatment; PBI: plant-back interval; CF: conversion factor; GPC: gel permeation chromatography; GC-MSD: gas chromatography with mass selective detection; LOQ: limit of quantification.

B.1.1.2. Stability of residues in plants

Plant products (available studies)	**Category**	**Commodity**	**T (°C)**	**Stability period**		**Compounds covered**	**Comment/ Source**
				Value	**Unit**		
	High water content	Lettuce	–20	16	Months	cis-deltamethrin, its alpha-R-isomer and trans-isomer	EFSA (2015)
		Cabbage	–20	24	Months		EFSA (2015)
		Tomato	–20	24	Months		EFSA (2015)
	High oil content	Cotton seed	–12	30	Months		EFSA (2015)
	Dry/High starch	Cereals grain	–12	9	Months		EFSA (2015)
	High acid content	–	–	–	–	–	–

B.1.2. Magnitude of residues in plants

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

Commodity	Region/Indoor[a]	Residue levels observed in the supervised residue trials (mg/kg)[b]	Comments/ Source	Calculated MRL (mg/kg)	HR[c] (mg/kg)	STMR[d] (mg/kg)	CF[e]
Carobs	Indoor (Po-use)	Mo = 0.405; 0.368; 0.361[f], 0.333 RA = no data	Residue trials on carob compliant with post-harvest (Po) GAP	0.7	Mo: 0.405	Mo: 0.365	1.25 (tentative)

MRL: maximum residue level; GAP: Good Agricultural Practice; Mo: monitoring; RA: risk assessment.
(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): Individual residue levels of each carob fraction (< 4 mm; > 4 mm; seeds) were adjusted by specific yield factors for each of the four warehouses (A-D) [A: 27% (< 4 mm), 63% (> 4 mm), 10% seeds; B: 27% (< 4 mm), 62% (> 4 mm), 10% seeds; C: 30% (< 4 mm), 59% (> 4 mm), 11% seeds; D: 26% (< 4 mm), 63% (> 4 mm), 11% seeds] (Spain, 2018).
(c): Highest residue. The highest residue refers to deltamethrin concentration in the recalculated whole commodity based on data in fractions (< 4 mm, > 4 mm, seeds).
(d): Supervised trials median residue. The median residue for risk assessment refers to deltamethrin concentration in the recalculated whole commodity based on data in fractions (< 4 mm, > 4 mm, seeds).
(e): Conversion factor to recalculate residues from the residue definition for monitoring to the residue definition for risk assessment tentatively applied. Although residues of deltamethrin isomers are not expected to occur after Po-use, the tentative CF applied in the framework of the MRL review for Po-treatment was used (EFSA, 2015).
(f): This residue value is based on a value for pulp (< 4 mm) of 0.679 mg/kg (Tables 3.1.2-1, 3.1.2-2, 3.1.4-1 in Spain (2018).

B.1.2.2. Residues in rotational crops

Residues in rotational and succeeding crops expected based on confined rotational crop study?	Not triggered	Post-harvest use in permanent crop. No significant residues are expected in the succeeding crops provided that the maximum annual application rate of deltamethrin is 0.12 kg/ha (EFSA, 2015)
Residues in rotational and succeeding crops expected based on field rotational crop study?	Not triggered	Post-harvest use in permanent crop. The field study confirmed the results of the confined rotational crop study (EFSA, 2015)

B.1.2.3. Processing factors

Processed commodity	Number of valid studies[a]	Processing (PF)		CF_P[b]	Comment/ Source
		Individual values	Median PF		
Carob, flour, < 4 mm particle size	4	1.5; 2 × 1.9; 2.0	1.9	–	Spain (2018)
Carob, flour, > 4 mm particle size	4	0.6; 2 × 0.7; 0.8	0.7	–	Spain (2018)

(a): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur).
(b): Conversion factor for risk assessment in the processed commodity could not be calculated as flour was analysed only for deltamethrin.

B.2. Residues in livestock

Not relevant.

B.3. Consumer risk assessment

ARfD	0.01 mg/kg bw (European Commission, 2002)
Highest IESTI, according to EFSA PRIMo	Carobs: 40% ARfD (IE child)
Assumptions made for the calculations	The calculation is based on the highest residue level according to the enforcement residue definition as estimated in carobs (whole fruit) from the submitted residue trials. The tentative conversion factor for risk assessment of 1.25 was applied (EFSA, 2015). Calculations were performed with PRIMo revision 3.1
ADI	0.01 mg/kg bw per day (European Commission, 2002)
Highest IEDI, according to EFSA PRIMo	108% ADI (NL, toddler diet) Contribution of crop assessed: Carob: 0.05% of ADI (DE, child)
Assumptions made for the calculations	The calculation is based on the median residue level according to the enforcement residue definition as estimated in carobs (whole fruit) from the submitted residue trials. For the remaining commodities, the STMR values as derived in the previous EFSA assessments were used as input values (EFSA, 2015, 2017a,b, 2018b). The tentative conversion factor (CF) of 1.25 for risk assessment was applied for the EU uses, including the intended post-harvest use on carobs, expect for asparagus. For this crop, no CF was used because a no residue situation could reliably be established (EFSA, 2015). No CF was applied for the STMRs derived from implemented CXLs because expected to cover all components included in the residue definition for risk assessment. For potatoes, the processing factor of 0.26 (unpeeled and boiled) was applied (EFSA, 2015) The contributions of commodities where no GAP or no safe CXLs was reported in the framework of the MRL review and in the EFSA assessments following the MRL review were not included in the calculation Calculations performed with PRIMo revision 3.1

ARfD: acute reference dose; bw: body weight; IESTI: international estimated short-term intake; PRIMo: (EFSA) Pesticide Residues Intake Model; ADI: acceptable daily intake; IEDI: international estimated daily intake; STMR: supervised trials median residue; CXL: codex maximum residue limit; GAP: Good Agricultural Practice; MRL: maximum residue level.

B.4. Recommended MRLs

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Deltamethrin (cis-deltamethrin)[(F)]				
0650000	Carobs/Saint John's breads	0.01*	Further risk management considerations required	For the post-harvest indoor use, EFSA derived an MRL proposal of 0.7 mg/kg for whole fruits In an indicative risk assessment, no acute consumer concern has been identified for the proposed use on carobs. However, using the PRIMo rev. 3.1., the ADI of NL toddler diet was exceeded (108%). Contribution of carobs was low (0.05% ADI, DE, child diet) Thus, further risk management considerations are required to decide whether the MRL proposal is acceptable. The risk assessment is affected by non-standard uncertainties

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

Appendix C – Pesticide Residue Intake Model (PRIMo)

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Deltamethrin (*cis*-deltamethrin) (F)

LOQs (mg/kg) range from: 0.01 to: 0.70

Toxicological reference values

ADI (mg/kg bw per day):	0.01	ARfD (mg/kg bw):	0.01
Source of ADI:	EC	Source of ARfD:	EC
Year of evaluation:	2002	Year of evaluation:	2002

Input values

Details – chronic risk assessment | Supplementary results – chronic risk assessment

Details – acute risk assessment/children | Details – acute risk assessment/adults

Comments:

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : 1

	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	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	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	108%	NL toddler	10.85	49%	Maize/corn	22%	Wheat	12%	Milk: Cattle		108%
	76%	DK child	7.60	39%	Rye	25%	Wheat	3%	Oat		76%
	70%	GEMS/Food G06	6.99	41%	Wheat	9%	Maize/corn	9%	Rice		70%
	51%	GEMS/Food G08	5.11	23%	Wheat	6%	Barley	4%	Rye		51%
	50%	DE child	4.97	24%	Wheat	6%	Rye	4%	Milk: Cattle		50%
	49%	GEMS/Food G10	4.95	22%	Wheat	7%	Rice	5%	Maize/corn		49%
	49%	GEMS/Food G15	4.92	26%	Wheat	5%	Barley	4%	Maize/corn		49%
	46%	RO general	4.60	29%	Wheat	7%	Maize/corn	2%	Milk: Cattle		46%
	46%	FR child 3 15 yr	4.59	26%	Wheat	5%	Milk: Cattle	3%	Maize/corn		46%
	45%	GEMS/Food G07	4.48	24%	Wheat	4%	Barley	2%	Maize/corn		45%
	43%	NL child	4.35	23%	Wheat	5%	Milk: Cattle	2%	Sugar beet roots		43%
	42%	UK infant	4.17	15%	Wheat	8%	Milk: Cattle	7%	Maize/corn		42%
	42%	IT toddler	4.16	37%	Wheat	1%	Rice	0.5%	Lettuces		42%
	42%	ES child	4.16	25%	Wheat	3%	Rice	2%	Milk: Cattle		42%
	40%	GEMS/Food G11	4.02	20%	Wheat	5%	Barley	2%	Rice		40%
	38%	UK toddler	3.76	22%	Wheat	4%	Milk: Cattle	3%	Rice		38%
	38%	PT general	3.75	22%	Wheat	4%	Rice	3%	Maize/corn		38%
	35%	FR toddler 2 3 yr	3.45	17%	Wheat	6%	Milk: Cattle	3%	Rice		35%
	33%	IE adult	3.31	13%	Wheat	3%	Tea (dried leaves of Camellia sinensis)	2%	Buckwheat and other pseudo-cereals		33%
	32%	SE general	3.18	18%	Wheat	3%	Bovine: Muscle/meat	2%	Milk: Cattle		32%
	29%	DE general	2.87	11%	Wheat	4%	Rye	4%	Barley		29%
	27%	DE women 14-50 yr	2.75	12%	Wheat	3%	Rye	2%	Milk: Cattle		27%
	27%	IT adult	2.73	23%	Wheat	1%	Rice	0.7%	Lettuces		27%
	26%	ES adult	2.61	13%	Wheat	3%	Barley	1%	Rice		26%
	24%	FR adult	2.37	13%	Wheat	3%	Tea (dried leaves of Camellia sinensis)	2%	Wine grapes		24%
	23%	NL general	2.32	11%	Wheat	2%	Barley	2%	Milk: Cattle		23%
	23%	FI 3 yr	2.26	7%	Wheat	5%	Rye	4%	Oat		23%
	21%	LT adult	2.11	8%	Rye	6%	Wheat	1%	Buckwheat and other pseudo-cereals		21%
	20%	UK vegetarian	1.99	12%	Wheat	2%	Rice	1%	Tea (dried leaves of Camellia sinens		20%
	18%	FI 6 yr	1.80	5%	Wheat	4%	Rye	2%	Rice		18%
	17%	UK adult	1.71	9%	Wheat	2%	Rice	1%	Tea (dried leaves of Camellia sinens		17%
	16%	DK adult	1.56	6%	Wheat	4%	Rye	1%	Milk: Cattle		16%
	12%	FR infant	1.18	4%	Wheat	3%	Milk: Cattle	0.5%	Apples		12%
	10%	FI adult	1.05	5%	Rye	2%	Wheat	0.9%	Oat		10%
	10%	IE child	1.01	7%	Wheat	2%	Rice	0.7%	Milk: Cattle		10%
	3%	PL general	0.29	0.8%	Potatoes	0.6%	Apples	0.2%	Table grapes		3%

Conclusion:
The estimated TMDI/NEDI/IEDI was in the range of 0 % to 108.5 % of the ADI.
For 1 diet(s), the ADI is exceeded.

Acute risk assessment/children	Acute risk assessment/adults/general population
Details – acute risk assessment/children	Details – acute risk assessment/adults

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): 3

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
138%	Pears	0.1/0.1	14
138%	Lettuces	0.5/0.36	14
100%	Table grapes	0.2/0.14	10
96%	Leeks	0.3/0.16	9.6
95%	Peaches	0.15/0.1	9.5
86%	Apples	0.2/0.08	8.6
81%	Wheat	1/0.56	8.1
75%	Celeries	0.3/0.2	7.5
74%	Rhubarbs	0.3/0.2	7.4
72%	Kales	0.15/0.16	7.2
71%	Rice	1/0.56	7.1
63%	Aubergines/egg plants	0.4/0.25	6.3
60%	Sweet peppers/bell peppers	0.2/0.1	6.0
59%	Cucumbers	0.2/0.09	5.9
55%	Potatoes	0.3/0.04	5.5
54%	Kiwi fruits (green, red,	0.15/0.09	5.4
53%	Vanilla pods	15/8.75	5.3
48%	Lamb's lettuce/corn salads	2/1.73	4.8
47%	Maize/corn	2/0.7	4.7
46%	Roman rocket/rucola	2/1.73	4.6
46%	Beans	0.6/0.25	4.6
44%	Rye	2/0.7	4.4
44%	Chinese cabbages/pe-tsai	0.2/0.14	4.4
42%	Courgettes	0.2/0.09	4.2
40%	Carobs/Saint John's bread	0.7/0.51	4.0
39%	Barley	2/0.7	3.9

Expand/collapse list

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
92%	Red mustards	2/1.73	9.2
68%	Aubergines/egg plants	0.4/0.25	6.8
53%	Chamomille	15/8.75	5.3
53%	Chamomille	15/8.75	5.3
53%	Chamomille	15/8.75	5.3
53%	Chamomille	15/8.75	5.3
53%	Chamomille	15/8.75	5.3
48%	Rice	1/0.56	4.8
47%	Wheat	1/0.56	4.7
47%	Table grapes	0.2/0.14	4.7
44%	Lettuces	0.5/0.36	4.4
37%	Florence fennels	0.3/0.2	3.7
35%	Rooibos	15/8.75	3.5
35%	Rooibos	15/8.75	3.5
35%	Chinese cabbages/pe-tsai	0.2/0.14	3.5
34%	Blueberries	0.6/0.38	3.4
34%	Rye	2/0.7	3.4
34%	Barley	2/0.7	3.4
33%	Wine grapes	0.2/0.14	3.3
32%	Lamb's lettuce/corn salads	2/1.73	3.2
32%	Celeries	0.3/0.2	3.2
32%	Head cabbages	0.1/0.08	3.2
31%	Kales	0.15/0.16	3.1
31%	Lentils	1/0.5	3.1
31%	Pears	0.1/0.1	3.1
26%	Hybiscus/roselle	15/8.75	2.6

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation) 3

Processed commodities

Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI): 1

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
45%	Kales/boiled	0.15/0.16	4.5
44%	Rice/milling (polishing)	1/0.29	4.4
43%	Oat/milling (flakes)	2/1.43	4.3

Expand/collapse list

Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): 2

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
21%	Courgettes/boiled	0.2/0.09	2.1
17%	Cauliflowers/boiled	0.1/0.04	1.7
16%	Wine grapes/juice	0.2/0.08	1.6

Conclusion:
The estimated short-term intake (IESTI) exceeded the toxicological reference value for 3 commodities.

For processed commodities, the toxicological reference value was exceeded in one or several cases.

Appendix D – Input values for the exposure calculations

D.1. Consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Carobs	0.46	$STMR_{Mo} \times CF^{(a)}$	0.51	$HR_{Mo} \times CF^{(a)}$
Citrus fruits	0.01	$STMR_{Mo} \times CF^{(a)}$ (EFSA, 2015)	The acute exposure assessment was performed only for the commodity under consideration	
Tree nuts	0.03	$STMR_{Mo} \times CF^{(a)}$ (EFSA, 2015)		
Apples	0.03	STMR CXL[(b)] (EFSA, 2015)		
Pears	0.04	$STMR_{Mo} \times CF^{(a)}$ (EFSA, 2015)		
Quinces	0.04	$STMR_{Mo} \times CF^{(a)}$ (EFSA, 2015)		
Medlars	0.04	$STMR_{Mo} \times CF^{(a)}$ (EFSA, 2015)		
Loquats	0.04	$STMR_{Mo} \times CF^{(a)}$ (EFSA, 2015)		
Apricots	0.04	$STMR_{Mo} \times CF^{(a)}$ (EFSA, 2015)		
Cherries	0.05	$STMR_{Mo} \times CF^{(a)}$ (EFSA, 2015)		
Peaches	0.04	$STMR_{Mo} \times CF^{(a)}$ (EFSA, 2015)		
Plums	0.01	$STMR_{Mo} \times CF^{(a)}$ (EFSA, 2015)		
Table and wine grapes	0.08	$STMR_{Mo} \times CF^{(a)}$ (EFSA, 2015)		
Strawberries	0.02	STMR CXL[(b)] (EFSA, 2015)		
Cane fruits	0.04	$STMR_{Mo} \times CF^{(a)}$ (EFSA, 2015)		
Other small fruits and berries	0.10	$STMR_{Mo} \times CF^{(a)}$ (EFSA, 2015)		
Table olives	0.21	STMR CXL[(b)] (EFSA, 2015)		
Kiwi fruits	0.03	$STMR_{Mo} \times CF^{(a)}$ (EFSA, 2015)		
Potatoes	0.023	$STMR_{Mo} \times$ PF (0.26) $\times CF^{(a)}$ (EFSA, 2015)		
Other root and tuber vegetables	0.03	$STMR_{Mo} \times CF^{(a)}$ (EFSA, 2015)		
Garlic	0.03	$STMR_{Mo} \times CF^{(a)}$ (EFSA, 2015)		
Onions	0.03	$STMR_{Mo} \times CF^{(a)}$ (EFSA, 2015)		
Shallots	0.03	$STMR_{Mo} \times CF^{(a)}$ (EFSA, 2015)		
Spring onions	0.08	$STMR_{Mo} \times CF^{(a)}$ (EFSA, 2015)		
Tomatoes	0.03	$STMR_{Mo} \times CF^{(a)}$ (EFSA, 2015)		
Peppers	0.04	$STMR_{Mo} \times CF^{(a)}$ (EFSA, 2015)		
Aubergines (egg plants)	0.08	$STMR_{Mo} \times CF^{(a)}$ (EFSA, 2015)		
Cucurbits edible peel	0.02	STMR CXL[(b)] (EFSA, 2015)		
Melons	0.03	$STMR_{Mo} \times CF^{(a)}$ (EFSA, 2015)		
Pumpkins	0.02	STMR CXL[(b)] (EFSA, 2015)		
Watermelons	0.03	$STMR_{Mo} \times CF^{(a)}$ (EFSA, 2015)		
Sweet corn	0.03	$STMR_{Mo} \times CF^{(a)}$ (EFSA, 2015)		
Flowering brassica	0.02	STMR CXL[(b)] (EFSA, 2015)		
Brussels sprouts	0.0125	$STMR_{Mo} \times CF^{(a)}$ (EFSA, 2015)		
Head cabbage	0.03	$STMR_{Mo} \times CF^{(a)}$(EFSA, 2015)		
Chinese cabbage	0.03	$STMR_{Mo} \times CF^{(a)}$ (EFSA, 2015)		
Kale	0.06	$STMR_{Mo} \times CF^{(a)}$ (EFSA, 2018b)		
Kohlrabies	0.0125	$STMR_{Mo} \times \times CF^{(a)}$ (EFSA, 2015)		
Lamb's lettuce	0.43	$STMR_{Mo} \times CF^{(a)}$ (EFSA, 2015)		
Lettuce	0.19	$STMR_{Mo} \times CF^{(a)}$ (EFSA, 2015)		
Escarole (broad-leaf endive)	0.04	$STMR_{Mo} \times CF^{(a)}$ (EFSA, 2015)		

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Cress	0.43	$STMR_{Mo}$ × CF[a] (EFSA, 2015)		
Land cress	0.43	$STMR_{Mo}$ × CF[a] (EFSA, 2015)		
Roman rocket, Rucola	0.43	$STMR_{Mo}$ × CF[a] (EFSA, 2015)		
Red mustards	0.43	$STMR_{Mo}$ × CF[a] (EFSA, 2015)		
Baby leaf crops (including brassica species)	0.43	$STMR_{Mo}$ × CF[a] (EFSA, 2015)		
Grape leaves & similar species	0.43	$STMR_{Mo}$ × CF[a] (EFSA, 2015)		
Watercress	0.43	$STMR_{Mo}$ × CF[a] (EFSA, 2015)		
Witloof	0.03	$STMR_{Mo}$ × CF[a] (EFSA, 2015)		
Herbs and edible flowers	0.43	$STMR_{Mo}$ × × CF[a] (EFSA, 2015)		
Beans (fresh, with pods)	0.01	STMR CXL[b] (EFSA, 2015)		
Beans (fresh, without pods)	0.01	STMR CXL[b] (EFSA, 2015)		
Peas (fresh, with pods)	0.01	STMR CXL[b] (EFSA, 2015)		
Peas (fresh, without pods)	0.01	STMR CXL[b] (EFSA, 2015)		
Lentils (fresh)	0.01	STMR CXL[b] (EFSA, 2015)		
Asparagus	0.01	$STMR_{Mo}$[b] (EFSA, 2015)		
Celery	0.08	$STMR_{Mo}$ × CF[a] (EFSA, 2017a)		
Florence fennel	0.08	$STMR_{Mo}$ × CF[a] (EFSA, 2017a)		
Rhubarb	0.08	$STMR_{Mo}$ × CF[a] (EFSA, 2017a)		
Globe artichokes	0.07	$STMR_{Mo}$ × CF[a] (EFSA, 2015)		
Leek	0.08	$STMR_{Mo}$ × CF[a] (EFSA, 2015)		
Cultivated fungi	0.02	STMR CXL[b] (EFSA, 2015)		
Beans (dry)	0.25	$STMR_{Mo}$ × CF (EFSA, 2015		
Pulses, except dry beans	0.50	STMR CXL[b] (EFSA, 2015)		
Linseed	0.03	$STMR_{Mo}$ × CF[a] (EFSA, 2015)		
Poppy seed	0.06	$STMR_{Mo}$ × CF[a] (EFSA, 2015)		
Sesame seed	0.0125	$STMR_{Mo}$ × CF[a] (EFSA, 2015)		
Sunflower seed	0.05	STMR CXL[b] (EFSA, 2015)		
Rape seed	0.07	STMR CXL[b] (FAO, 2016)		
Mustard seed	0.06	$STMR_{Mo}$ × CF[a] (EFSA, 2015)		
Cotton seed	0.0125	$STMR_{Mo}$ × CF[a] (EFSA, 2015)		
Pumpkin seeds	0.0125	$STMR_{Mo}$ × CF[a] (EFSA, 2015)		
Safflower	0.0125	$STMR_{Mo}$ × CF[a] (EFSA, 2015)		
Borage	0.06	$STMR_{Mo}$ × CF[a] (EFSA, 2015)		
Gold of pleasure	0.06	$STMR_{Mo}$ × CF[a] (EFSA, 2015)		
Hemp seed	0.06	$STMR_{Mo}$ × CF[a] (EFSA, 2015)		
Castor bean	0.06	$STMR_{Mo}$ × CF[a] (EFSA, 2015)		
Olives for oil production	0.26	$STMR_{Mo}$ × CF[a] (EFSA, 2015)		
Barley grain	0.70	STMR CXL[b] (EFSA, 2015)		
Buckwheat grain	0.70	STMR CXL[b] (EFSA, 2015)		
Maize grain	0.70	STMR CXL[b] (EFSA, 2015)		
Millet grain	0.70	STMR CXL[b] (EFSA, 2015)		
Oats grain	0.70	STMR CXL[b] (EFSA, 2015)		

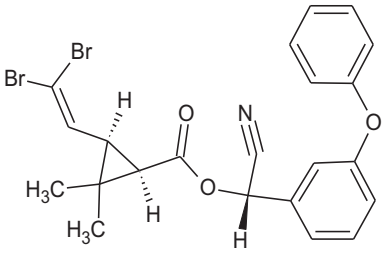
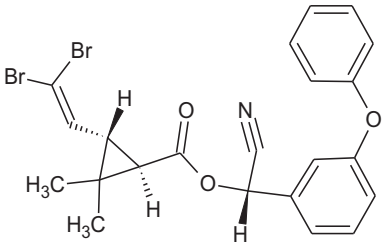
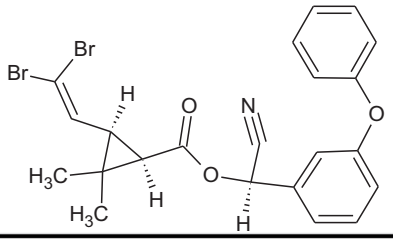
Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Rice grain	0.56	$STMR_{Mo} \times CF$)[a]; (EFSA, 2015)		
Rye grain	0.70	STMR CXL[b] (EFSA, 2015)		
Sorghum grain	0.70	STMR CXL[b] (EFSA, 2015)		
Wheat grain	0.56	$STMR_{Mo} \times CF$[a] (EFSA, 2015)		
Teas	2.20	STMR CXL[b] (EFSA, 2015)		
Herbal infusions (flowers)	1.31	$STMR_{Mo} \times CF$[a] (EFSA, 2015)		
Herbal infusions (leaves, herbs)	1.31	$STMR_{Mo} \times CF$[a] (EFSA, 2015)		
Herbal infusions (roots)	0.09	$STMR_{Mo} \times CF$[a] (EFSA, 2015)		
Spices (fruits and berries)	1.31	$STMR_{Mo} \times CF$ (tentative)[a] (EFSA, 2015)		
Spices (roots and rhizome)	0.05	STMR CXL[b] (EFSA, 2015)		
Spices (buds)	1.31	$STMR_{Mo} \times CF$[a] (EFSA, 2015)		
Spices (flower stigma)	1.31	$STMR_{Mo} \times CF$[a] (EFSA, 2015)		
Sugar beet (root)	0.03	$STMR_{Mo} \times CF$[a] (EFSA, 2015)		
Chicory roots	0.0125	$STMR_{Mo} \times CF$[a] (EFSA, 2015)		
Swine meat	0.06	0.8 × STMR (muscle)+ 0.2 × STMR (fat) (EFSA, 2015)		
Swine fat (free of lean meat)	0.16	STMR CXL[b] (EFSA, 2015)		
Swine liver	0.03	STMR CXL[b] (EFSA, 2015)		
Swine kidney	0.03	STMR CXL[b] (EFSA, 2015)		
Swine edible offal	0.16	STMR CXL[b] (EFSA, 2015)		
Ruminant meat	0.06	0.8 × STMR (muscle) + 0.2 × STMR (fat) (EFSA, 2015)		
Ruminant fat	0.16	STMR CXL[b] (EFSA, 2015)		
Ruminant liver	0.03	STMR CXL[b] (EFSA, 2015)		
Ruminant kidney	0.03	STMR CXL[b] (EFSA, 2015)		
Ruminant edible offal	0.16	STMR CXL[b] (EFSA, 2015)		
Poultry meat	0.02	0.9 × STMR (muscle) + 0.1 × STMR (fat) (EFSA, 2015)		
Poultry fat	0.04	STMR CXL[b] (EFSA, 2015)		
Poultry liver	0.02	STMR CXL[b] (EFSA, 2015)		
Milk	0.02	STMR CXL[b] (EFSA, 2015)		
Birds' eggs	0.02	STMR CXL[b] (EFSA, 2015)		

STMR: supervised trials median residue; HR: highest residue; Mo: monitoring; CF: conversion factor; PF: processing factor; CXL: Codex maximum residue limit.

(a): The tentative conversion factor (CF) of 1.25 for risk assessment was applied. The CF was derived considering that results from 263 residue samples showing that the combined contribution of both the *trans*- and *alpha* R-isomers would not exceed 20% of the residue. Thus, pending the assessment of the toxicological properties of these isomers and the submission of further information to address the data gaps identified in the MRL review (EFSA, 2015).

(b): No conversion factor was applied for the EU use on asparagus because the MRL review could reliably exclude that residues would occur (EFSA, 2015) and for the CXL implemented in the EU Regulation because the risk assessment values derived by JMPR cover all components included in the residue definition for risk assessment.

Appendix E – Used compound codes

Code/trivial name[a]	Chemical name/SMILES notation[b]	Structural formula[c]
Deltamethrin (cis-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]1[C@@H](C(=O)O[C@H](C#N)c2cccc(Oc3ccccc3)c2)C1(C)C OWZREIFADZCYQD-NSHGMRRFSA-N	
trans-isomer	(*S*)-cyano(3-phenoxybenzyl) (1*R*,3*S*)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropanecarboxylate Br/C(Br)=C/[C@@H]1[C@@H](C(=O)O[C@H](C#N)c2cccc(Oc3ccccc3)c2)C1(C)C OWZREIFADZCYQD-GGPKGHCWSA-N	
alpha-R-isomer	(*R*)- α-cyano-3-phenoxybenzyl (1*R*,3*R*)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropanecarboxylate Br/C(Br)=C/[C@H]1[C@@H](C(=O)O[C@@H](C#N)c2cccc(Oc3ccccc3)c2)C1(C)C OWZREIFADZCYQD-BJLQDIEVSA-N	

IUPAC: International Union of Pure and Applied Chemistry; SMILES: simplified molecular-input line-entry system; InChiKey: International Chemical Identifier Key.
(a): The metabolite name in bold is the name used in the conclusion.
(b): ACD/Name 2019.1.3 ACD/Labs 2019 Release (File version N05E41, Build 111418, 3 September 2019).
(c): ACD/ChemSketch 2019.1.3 ACD/Labs 2019 Release (File version C05H41, Build 111302, 27 A 2019).