EFSA Journal

REASONED OPINION

ADOPTED: 18 February 2022

doi: 10.2903/j.efsa.2022.7198

Setting of import tolerances for deltamethrin in mangoes and papayas

EFSA (European Food Safety Authority),
Giulia Bellisai, Giovanni Bernasconi, Alba Brancato, Luis Carrasco Cabrera, Irene Castellan, Lucien Ferreira, German Giner, Luna Greco, Samira Jarrah, Renata Leuschner, Jose Oriol Magrans, Ileana Miron, Stefanie Nave, Ragnor Pedersen, Hermine Reich, Tobin Robinson, Silvia Ruocco, Miguel Santos, Alessia Pia Scarlato, Anne Theobald and Alessia Verani

Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Bayer SAS submitted a request to the competent national authority in Austria to set import tolerances for the active substance deltamethrin in mangoes and papayas. The data submitted in support of the request were found to be sufficient to derive maximum residue level (MRL) proposals for mangoes and papayas. Adequate analytical methods for enforcement are available to control the residues of deltamethrin (*cis*-deltamethrin) in plant matrices under consideration at the validated limit of quantification (LOQ) of 0.01 mg/kg. Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of residues resulting from the use of deltamethrin according to the reported agricultural practices is unlikely to present a risk to consumer health. The risk assessment shall be regarded as indicative and affected by non-standard uncertainties.

Keywords: deltamethrin, mangoes, papayas, import tolerance, pesticide, MRL, consumer risk assessment

Requestor: European Commission

Question number: EFSA-Q-2021-00569

Correspondence: pesticides.mrl@efsa.europa.eu

Declarations of interest: The declarations of interest of all scientific experts active in EFSA's work are available at https://ess.efsa.europa.eu/doi/doiweb/doisearch.

Acknowledgments: EFSA wishes to thank Stathis Anagnos, Laszlo Bura, Aija Kazocina, Andrea Mioč, Marta Szot, Aikaterini Vlachou for the support provided to this scientific output.

Suggested citation: EFSA (European Food Safety Authority), Bellisai G, Bernasconi G, Brancato A, Carrasco Cabrera L, Castellan I, Ferreira L, Giner G, Greco L, Jarrah S, Leuschner R, Magrans JO, Miron I, Nave S, Pedersen R, Reich H, Robinson T, Ruocco S, Santos M, Scarlato AP, Theobald A and Verani A, 2022. Reasoned Opinion on the setting of import tolerances for deltamethrin in mangoes and papayas. EFSA Journal 2022;20(3):7198, 33 pp. https://doi.org/10.2903/j.efsa.2022.7198

ISSN: 1831-4732

The EFSA Journal is a publication of the European Food Safety Authority, a European agency funded by the European Union.

Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, Bayer SAS submitted an application to the competent national authority in Austria (Rapporteur Member State) to set import tolerances for the active substance deltamethrin in mangoes and papayas. The evaluating Member State (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 1 October 2021. The EMS proposed to establish maximum residue levels (MRLs) for mangoes and papayas from the existing default value of 0.01–0.1 mg/kg for papayas and to 0.05 mg/kg for mangoes, both imported from Brazil.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation.

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, pulses and oilseeds and cereals and in rotational crops. The metabolism studies showed that the metabolic pathway in primary crops is similar in all crop groups investigated and comparable to the metabolism observed in the rotational crops. 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 ~ 30–40% of the TRR.

Studies investigating the effect of processing on the nature of deltamethrin (hydrolysis studies) showed that deltamethrin was stable except under sterilisation conditions with the formation of two degradation products which were considered of no toxicological relevance during the peer review of deltamethrin, based on the available data.

Based on the metabolic pattern identified in metabolism studies and in hydrolysis studies, 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. The conclusions reported in this reasoned opinion might need to be reconsidered in the light of the outcome of the ongoing renewal process.

Sufficiently validated analytical methods are available to quantify deltamethrin residues in plants, including difficult matrices, and in animal products according to the enforcement residue definition. The methods enable quantification of deltamethrin residues at or above 0.01 mg/kg (LOQ) in plants and products of animal origin and 0.05 mg/kg in difficult matrices. The method allows separating the isomers of deltamethrin and is therefore able to quantify the *cis*-deltamethrin according to the enforcement residue definition.

EFSA concluded that for the crops assessed in this application, metabolism of deltamethrin in primary crops, and the possible degradation in processed products has been sufficiently addressed and that the derived residue definitions are applicable.

The available residue trials are sufficient to derive MRL proposals of 0.1 mg/kg for papayas and of 0.05 mg/kg in mangoes.

Processing factors (PF) for the crops under assessment were derived from processing studies provided and are recommended to be included in Annex VI of Regulation (EC) No 396/2005 as follows:

- Mango/pulp: < 0.48.
- Papaya/pulp: < 0.36.

Further specific studies investigating the magnitude of deltamethrin residues in processed commodities are not required, as significant residues are not expected in pulp fractions of mangoes and papayas.

Investigations on the magnitude of residues in rotational crops are not required for imported 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 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.

Lacking toxicological information on the *alpha-R* isomer and the *trans*-isomer, the MRL review considered the residue definition for risk assessment as provisional, assuming that the isomers included in the risk assessment residue definition are covered by the toxicological reference values of *cis*-deltamethrin. Pending the assessment of relevant toxicological data in the framework of the ongoing renewal of approval process of deltamethrin under Regulation (EC) No 1107/2009, the consumer risk assessment presented in the current reasoned opinion is based on the same assumption.

The consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo).

The short-term exposure did not exceed the ARfD for mangoes (23.6% ARfD) and papayas (12.7% ARfD).

Regarding the long-term exposure, in the framework of the present assessment, EFSA updated the most conservative scenario calculated in the evaluation of Article 12 confirmatory data. The calculations are based on input values as derived from the authorised uses reported in the framework of the MRL review, the acceptable Codex MRLs and the STMR values derived from the residue trials submitted for the Article 12 confirmatory data and in support of the recent MRL applications for tomatoes and okra. For mangoes and papayas, the input values were the STMR values in pulp fractions (expressed according to the residue definition for risk assessment) as derived from the supervised field trials submitted in support of the present MRL application. Although the margin of safety is very narrow, a long-term consumer intake concern was not identified for the European diets incorporated in the EFSA PRIMo rev. 3.1. The total long-term exposure accounted for a maximum of 99% of the ADI (NL toddler). Nevertheless, for the intended uses on mangoes and papayas, the contribution of residues to the total exposure was very low (individually less than 0.1% the ADI).

The consumer risk assessment should be regarded as indicative and affected by non-standard uncertainties. In addition to the lack of toxicological information on *alpha-R* isomer and the *trans*-isomer of deltamethrin, the chronic risk assessment performed in the framework of the evaluation of confirmatory data following the Article 12 MRL review was affected by additional non-standard uncertainties related to the lack of a full data set of residue trials analysed for the provisional risk assessment residue definition.

The renewal assessment of the active substance in accordance with Regulation (EC) No 1107/2009 is currently ongoing. Considering that the conclusion on the toxicological properties of metabolites of deltamethrin, and consequently, the decision on the definitive residue definitions should be derived, based on discussion with Member State experts, in due course, EFSA did not anticipate these discussions under the current assessment but considered the same assumptions as made in previous peer review and review of MRLs assessments. Hence, the conclusions reported in this reasoned opinion might need to be reconsidered in the light of the outcome of the peer review for renewal of the approval.

The summary table below provides an overview of the recommended MRL modifications to Regulation (EU) No 396/2005.

Full details of all end points 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)]				
0163030	Mangoes	0.01*	0.05	The submitted data are sufficient to derive an import tolerance (BR GAP). Risk for consumers unlikely.
0163040	Papayas	0.01*	0.1	The submitted data are sufficient to derive an import tolerance (BR GAP). Risk for consumers unlikely.

MRL: maximum residue level; GAP: Good Agricultural Practice.
*: 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 set an import tolerance for the active substance deltamethrin in mangoes and papayas. The detailed description of the existing uses of deltamethrin authorised in Brazil in mangoes and papayas, which are 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 metabolites 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 root 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 Annex 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 several reasoned opinions on the modification of MRLs for deltamethrin. The proposals from certain reasoned opinions have been considered in recent MRL regulations.[4] Certain Codex maximum residue limits (CXLs) have been taken over in the EU MRL legislation.[5] Furthermore, EFSA has recently performed an evaluation of the confirmatory data following the Article 12 MRL review in a combined assessment of the Article 10 MRL application on tomatoes and okra/lady's finger (EFSA, 2022); this EFSA reasoned opinion was also taken in consideration in the present assessment.

In accordance with Article 6 of Regulation (EC) No 396/2005, Bayer SAS submitted an application to the competent national authority in Austria (evaluating Member State, EMS) to set import tolerances for the active substance deltamethrin in mangoes and papayas. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to EFSA on 1 October 2021. The EMS proposed to establish maximum residue levels (MRLs) for mangoes and papayas from the existing default value of 0.01–0.1 mg/kg for papayas and to 0.05 mg/kg for mangoes, both imported from Brazil.

EFSA based its assessment on the evaluation report submitted by the EMS (Austria, 2021), 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 according to Article 12 of Regulation No 396/2005 (EFSA, 2015) and its confirmatory data assessment (EFSA, 2022), as well as the conclusions from previous EFSA opinions on deltamethrin (EFSA, 2017a,2018b,2020,2022) and the EFSA scientific report (EFSA, 2017b).

For this application, the data requirements established in Regulation (EU) No 544/2011[6] and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 1997a–g, 2010a,b, 2017, 2020, 2021; OECD, 2011). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011[7].

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

[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, 16.03.2005, p. 1–16.

[4] For an overview of all MRL Regulations on this active substance, please consult: https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/active-substances/?event=search.as

[5] For an overview of all MRL Regulations on this active substance, please consult: ttps://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/active-substances/?event=search.as

[6] 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.

[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.

The EU pesticides peer review for the renewal of approval of deltamethrin in accordance with Regulation (EC) No 1107/2009 is ongoing, and therefore, the conclusions reported in this reasoned opinion may need to be reconsidered in the light of the outcome 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 (Austria, 2021) 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 (cottonseed) and cereals (maize) was investigated in the framework of the MRL review (EFSA, 2015). 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 TRR) with *alpha*-R-isomer and *trans*-isomer accounting for ~ 30–40% of the TRR.

For the intended uses on mangoes and papayas (foliar application), the metabolic behaviour in primary crops is sufficiently addressed.

1.1.2. Nature of residues in rotational crops

Investigations of residues in rotational crops are not required for imported 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 Directive 91/414/EEC (Sweden, 2002) and in the framework of the MRL review (EFSA, 2015). It was concluded that deltamethrin is hydrolytically stable under conditions simulating pasteurisation and brewing, baking and boiling. Under sterilisation conditions, significant degradation of deltamethrin in two main metabolites was observed which were considered during the peer review as well-known plant metabolites with no toxicological relevance, and therefore, this evidence base was accepted during the MRL review (EFSA, 2015).

In the MRL review, it was outlined that in the hydrolysis studies, residues were reported as deltamethrin; however, it was not clear whether the analytical method used analysed for the sum of all isomers.

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).

During the MRL review, an analytical method 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) was evaluated and validated at the limit of quantification (LOQ) of 0.02 mg/kg. However, as this method was not considered highly specific, a confirmatory method was required as Article 12 confirmatory data (EFSA, 2015).

This data gap was addressed in the framework of the assessment of the confirmatory data of the MRL review (EFSA, 2022). EFSA concluded that a full validation of a multiresidue DFG S19 method for the analysis of cis-deltamethrin residues by gas chromatography with mass selective detection (GS-MSD) was provided for high water content, high acid content, high fat content and dry matrices at the LOQ of 0.01 mg/kg. The method allows separating the isomers of deltamethrin.

The same analytical method (DFG S19) was also reported in the evaluation report submitted in the present application (Austria, 2021) and is therefore considered valid.

As mango and papaya belong to the high-water content commodities, EFSA concludes that analytical methods are available for monitoring of deltamethrin residues in these commodities.

1.1.5. Storage stability of residues in plants

For the crops under assessment in the present MRL application (mangoes and papayas), storage stability of deltamethrin was demonstrated at −20°C for a period of 24 months in high water content commodities (EFSA, 2015). This is considered sufficient for these two authorised uses.

Regarding the other matrices, reference is made to the assessment of the confirmatory data of the MRL review (EFSA, 2022) where end points on storage stability in dry/high starch commodities, acidic commodities and other matrices (maize stover) were updated (see Appendix B.1.1.2).

1.1.6. Proposed residue definitions

Based on the metabolic pattern identified in metabolism studies, the results of hydrolysis studies, the toxicological significance of isomers and metabolites, the capabilities of enforcement analytical methods, the following residue definitions were proposed:

- 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 same residue definitions are applicable to rotational crops and, provisionally, in processed products (EFSA, 2015). The residue definition for enforcement set in Regulation (EC) No 396/2005 is identical with the residue definition mentioned above.

The risk assessment residue definition was established 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) (see also Section 3). For the authorised uses 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 residue trials performed in Brazil on mangoes (over 2017 and 2018) and papayas (over 2018 and 2019). The samples were analysed for the parent compound (enforcement residue definition) and the metabolites as included in the provisional residue definitions for risk assessment. According to the assessment of the EMS, the methods used were sufficiently validated and fit for purpose (Austria, 2021).

The samples of these residue trials were stored under conditions for which integrity of the samples has been demonstrated.

A sufficient number of trials is available for mangoes (four trials) and papayas (five trials). Based on these trials, an MRL of 0.05 mg/kg can be derived for mangoes and an MRL of 0.1 mg/kg can be derived for papayas. It is noted that in pulp (the edible part of these commodities), all compounds relevant for the risk assessment residue definition (*cis*-deltamethrin, its *alpha-R* isomer and its *trans*-isomer) were found to remain below the LOQ of 0.01 mg/kg. Therefore, median residue (STMR) and highest residue (HR) values for risk assessment purpose can be derived as the value of 0.03 mg/kg (sum of LOQs of the three compounds).

1.2.2. Magnitude of residues in rotational crops

Investigations of residues in rotational crops are not required for imported crops.

1.2.3. Magnitude of residues in processed commodities

Specific processing studies for the crops under assessment are not available. However, the available residue trials do provide detailed results for mango and papaya pulp. Residue levels for all relevant compounds (*cis*-deltamethrin, its *alpha-R* isomer and its *trans*-isomer) are below the LOQ (0.01 mg/kg for each compound) in pulp fraction.

The results were used to derive peeling factors for the monitoring residue definition. These PFs are based on indicative ratio of deltamethrin residues of 0.01 mg/kg (=LOQ for deltamethrin) in fruit pulp and residues in the whole fruit.

EFSA notes that in the framework on the present application, the EMS has reported processing trials performed on apple and citrus fruits and on maize processed products (Austria, 2021). As these data are not relevant for the crops under assessment (mangoes and papayas), these trials were not considered in this opinion.

1.2.4. Proposed MRLs

The available data are considered sufficient to derive MRL proposals as well as risk assessment values for the commodities under evaluation. In Section 3, EFSA assessed whether residues on these crops resulting from the uses authorised in Brazil are likely to pose a consumer health risk.

2. Residues in livestock

Not relevant as mangoes and papayas are not used for feed purposes.

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, 2020). EFSA therefore reiterates in this assessment the proposal to assess these toxicological data in the framework of the renewal of the approval of the active substance deltamethrin. Meanwhile, the consumer risk assessment is still performed assuming that the toxicity of these isomers is covered by the toxicological reference values set for *cis*-deltamethrin.

The short-term exposure assessment was performed for the commodities assessed in this application (mangoes and papayas). The calculations were based on the highest residues (HR) derived from supervised field trials submitted in support of this MRL application. For both mangoes and papayas, EFSA considered the HR in pulp fractions, expressed according to the residue definition for risk assessment. Considering the sum of LOQs for all compounds relevant for risk assessment, the value of 0.03 mg/kg was retained for the short-term exposure assessment of mangoes and papayas. These input values can be found in Appendix D.1.

The short-term exposure did not exceed the ARfD for mangoes and papayas (see Appendix B.3).

In the framework of the evaluation of confirmatory data following the Article 12 MRL review for deltamethrin, a comprehensive long-term exposure assessment was performed (EFSA, 2022). It considered the authorised uses reported in the framework of the MRL review, the acceptable Codex MRL (CXLs) and the STMR values derived from the residue trials submitted for the Art. 12 confirmatory data and in support of the MRL applications for tomatoes and okra (EFSA, 2022).

The approach which was followed for the consumer exposure assessment is outlined below:

After the submission of the confirmatory data, there were still EU uses for which the data set for the residue definition for risk assessment was incomplete. Therefore, EFSA prepared **two exposure scenarios**. **Scenario 1** did not consider uses not fully supported by a complete data set according to the residue definition for risk assessment. On the contrary, under **scenario 2,** those uses not fully supported by a complete data set according to the residue definition for risk assessment were included, having at hand some evidence that the metabolites comprised in the risk assessment residue definition were unlikely to occur. **Scenario 2** was meant to provide additional information for risk managers to decide whether, despite the data gaps not fully addressed, certain MRLs may be maintained, considering that the residue definition for risk assessment might need to be reviewed in the light of new information on residue trials (EFSA, 2022).

In the framework of the present application, EFSA updated the most conservative scenario calculated in the evaluation of Article 12 confirmatory data, namely **scenario 2**. EFSA updated the calculations with the relevant STMR values (expressed according to the risk assessment residue definition) derived for mango pulp and papaya pulp from the supervised field trials submitted in support of this application. Considering the sum of LOQs for all compounds relevant for risk

assessment, the value of 0.03 mg/kg was retained for the long-term exposure assessment of mangoes and papayas. The input values used in the exposure calculations are summarised in Appendix D.1.

Considering above-mentioned assumptions and uncertainties, the chronic exposure does not exceed the ADI. However, the margin of safety is very narrow with regard to the ADI for Dutch toddler's (99% of the ADI).

Furthermore, the consumer risk assessment should be regarded as indicative and affected by non-standard uncertainties. During the previous assessments, the following elements were highlighted by EFSA (EFSA, 2022):

- Lack of information on the actual occurrence of residues of *trans*-deltamethrin and *alpha*-R-deltamethrin in certain crops;
- 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;
- Absence of adequate livestock feeding studies in cows and hens, investigating residues in all relevant tissues and matrices according to the residue definitions for monitoring and risk assessment simultaneously.

Although a high degree of uncertainty remains due to the points identified above, EFSA concluded that neither the long-term nor short-term intake of residues of deltamethrin indicated a consumer risk with a diet included in PRIMo 3.1. Furthermore, it should be noted that the contribution arising from the crops under assessment (based on residues in mangoes (pulp) and papayas (pulp)) to the overall long-term exposure is very low (individually less than 0.1% of the ADI; see Appendix B.3). The major contributor is maize (49%). It is to be noted that for maize, the values in the European consumption data refer to maize oil, which can be considered to provide an overestimation of a fat-soluble active substance as deltamethrin. It is further to be noted that a default processing factor of 20 is currently included in the calculation (EFSA, 2022).[8]

For further details on the exposure calculations, a screenshot of the Report sheet of the PRIMo 3.1. 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 MRL proposals for mangoes and papayas.

A lack of information on the toxicological profiles of the deltamethrin isomers (*trans*-deltamethrin and *alpha-R*-deltamethrin) was identified in previous EFSA assessments and has not been addressed under the present MRL application. Therefore, the risk assessment residue definition, which currently includes both deltamethrin isomers is still considered provisional. EFSA reiterates its proposal to assess the toxicity of deltamethrin isomers in the framework of the renewal of the approval of deltamethrin, which is currently ongoing. Meanwhile, the consumer risk assessment was still performed assuming that the toxicity of these isomers is covered by the toxicological reference values set for *cis*-deltamethrin.

Pending the assessment of further toxicological data of the *alpha-R*-isomer and *trans*-isomer of deltamethrin included in the provisional risk assessment residue definition, the consumer risk assessment should be regarded as indicative and affected by non-standard uncertainties. In the framework of the present application, EFSA updated the most conservative consumer exposure scenario calculated in the evaluation of Article 12 confirmatory data with the residue data in mangoes and papayas from the authorised uses in Brazil. The results indicate a very narrow margin of safety regarding the chronic exposure (99% of the ADI for Dutch toddlers). However, it should be noted that the contribution of residues in mangoes (pulp) and papayas (pulp) to the overall long-term exposure is very low (individually below 0.1% of the ADI) and that the short-term exposure did not exceed the ARfD for these commodities (mangoes: 23.6% ARfD; papayas: 12.7% ARfD).

[8] EFSA takes note that within the present assessment, the EMS reported the availability of new GAPs on maize and new residue data that may modify the input values for maize and maize-based processed products (Austria, 2021). However, since no intended use on maize was notified by the applicant within the current application, it was not deemed relevant to consider these data in the present assessment. These data could still be used in the future for an update of the risk assessment, in the framework of an appropriate MRL application on maize.

EFSA concluded that the authorised uses of deltamethrin on mangoes and papayas will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers' health.

It should also be noted that the renewal assessment of the active substance in accordance with Regulation (EC) No 1107/2009 is currently ongoing. Considering that the conclusion on the toxicological properties of metabolites of deltamethrin, and consequently, the decision on the definitive residue definitions will be derived in discussion with Member State experts in due course, EFSA did not anticipate these discussions and decisions in the current assessment. Hence, 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.

References

Austria, 2021. Evaluation report on the modification of MRLs for deltamethrin in mango and papaya. September 2021, 154 pp. Available online: www.efsa.europa.eu

EFSA (European Food Safety Authority), 2015. Review of the existing maximum residue levels (MRLs) for deltamethrin according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2015;13 (11):4309, 104 pp. https://doi.org/10.2903/j.efsa.2015.4309

EFSA (European Food Safety Authority), 2017a. Reasoned opinion on the modification of the existing MRLs for deltamethrin in celery. Florence Fennel and Rhubarb. EFSA Journal 2017;15(1):4683, 24 pp. https://doi.org/10.2903/j.efsa.2017.4683

EFSA (European Food Safety Authority), 2017b. Scientific Report of EFSA on scientific support for preparing an EU position in the 49th Session of the Codex Committee on Pesticide Residues (CCPR). EFSA Journal 2017;15 (7):4929, 162 pp. https://doi.org/10.2903/j.efsa.2017.4929

EFSA (European Food Safety Authority), Brancato A, Brocca D, Ferreira L, Greco L, Jarrah S, Leuschner R, Medina P, Miron I, Nougadere A, Pedersen R, Reich H, Santos M, Stanek A, Tarazona J, Theobald A and Villamar-Bouza L, 2018a. Guidance on use of EFSA Pesticide Residue Intake Model (EFSA PRIMo revision 3). EFSA Journal 2018;16(1):5147, 43 pp. https://doi.org/10.2903/j.efsa.2018.5147

EFSA (European Food Safety Authority), Brancato A, Brocca D, De Lentdecker C, Erdos Z, Ferreira L, Greco L, Jarrah S, Kardassi D, Leuschner R, Lythgo C, Medina P, Miron I, Molnar T, Nougadere A, Pedersen R, Reich H, Sacchi A, Santos M, Stanek A, Sturma J, Jose T, Anne T, Vagenende B, Verani A and Villamar-Bouza L, 2018b. Reasoned Opinion on the modification of the existing maximum residue level for deltamethrin in kale. EFSA Journal 2018;16(1):5153, 26 pp. https://doi.org/10.2903/j.efsa.2018.5153

EFSA (European Food Safety Authority), Anastassiadou M, Brancato A, Carrasco Cabrera L, Ferreira L, Greco L, Jarrah S, Kazocina A, Leuschner R, Magrans JO, Miron I, Pedersen R, Raczyk M, Reich H, Ruocco S, Sacchi A, Santos M, Stanek A, Tarazona J, Theobald A and Verani A, 2019. Pesticide Residue Intake Model- EFSA PRIMo revision 3.1 (update of EFSA PRIMo revision 3). EFSA Supporting Publication 2019;EN-1605, 15 pp. https://doi.org/10.2903/sp.efsa.2019.EN-1605

EFSA (European Food Safety Authority), Anastassiadou M, Bernasconi G, Brancato A, Carrasco Cabrera L, Ferreira L, Greco L, Jarrah S, Kazocina A, Leuschner R, Magrans JO, Miron I, Nave S, Pedersen R, Reich H, Rojas A, Sacchi A, Santos M, Theobald A, Vagenende B and Verani A, 2020. Reasoned Opinion on the modification of the existing maximum residue level for deltamethrin in carobs/Saint John's breads. EFSA Journal 2020;18 (10):6271, 26 pp. https://doi.org/10.2903/j.efsa.2020.6271

European Food Safety Authority (EFSA), Bellisai G, Bernasconi G, Brancato A, Cabrera LC, Ferreira L, Giner G, Greco L, Jarrah S, Leuschner R, Magrans JO, Miron I, Nave S, Pedersen R, Reich H, Ruocco S, Santos M, Scarlato AP, Theobald A, Vagenende B and Verani A, 2022. Evaluation of confirmatory data following the Article 12 MRL review and modification of the existing maximum residue levels for deltamethrin in tomatoes and okra/lady's fingers. EFSA Journal 2022;20(1):7107, 152 pp. https://doi.org/10.2903/j.efsa.2022.7107

European Commission, 1997a. Appendix A. Metabolism and distribution in plants. 7028/VI/95-rev.3, 22 July 1997.

European Commission, 1997b. Appendix B. General recommendations for the design, preparation and realization of residue trials. Annex 2. Classification of (minor) crops not listed in the Appendix of Council Directive 90/642/EEC. 7029/VI/95-rev. 6, 22 July 1997.

European Commission, 1997c. Appendix C. Testing of plant protection products in rotational crops. 7524/VI/95-rev. 2, 22 July 1997.

European Commission, 1997d. Appendix E. Processing studies. 7035/VI/95-rev. 5, 22 July 1997.

European Commission, 1997e. Appendix F. Metabolism and distribution in domestic animals. 7030/VI/95-rev. 3, 22 July 1997.

European Commission, 1997f. Appendix H. Storage stability of residue samples. 7032/VI/95-rev. 5, 22 July 1997.

European Commission, 1997g. Appendix I. Calculation of maximum residue level and safety intervals. 7039/VI/95 22 July 1997. As amended by the document: classes to be used for the setting of EU pesticide maximum residue levels (MRLs). SANCO 10634/2010, finalised in the Standing Committee on the Food Chain and Animal Health at its meeting of 23–24 March 2010.

European Commission, 2002. Review report for the active substance deltamethrin. Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 18 October 2002 in view of the inclusion of deltamethrin in Annex I of Council. Directive 91/414/EEC. 6504/VI/99-final, 17 October 2002.
European Commission, 2010a. Classes to be used for the setting of EU pesticide Maximum Residue Levels (MRLs). SANCO 10634/2010-rev. 0, Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting of 23–24 March 2010.
European Commission, 2010b. Residue analytical methods. For post-registration control. SANCO/825/00-rev. 8.1, 16 November 2010.
European Commission, 2017. Technical Guideline on the Evaluation of Extraction Efficiency of Residue Analytical Methods. SANTE 2017/10632, Rev. 3, 22 November 2017.
European Commission, 2020. Technical guidelines on data requirements for setting maximum residue levels, comparability of residue trials and extrapolation on residue data on products from plant and animal origin. SANTE/2019/12752, 23 November 2020.
European Commission, 2021. Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes. SANTE/2020/12830, Rev.1 24. February 2021.
FAO (Food and Agriculture Organization of the United Nations), 2016. Submission and evaluation of pesticide residues data for the estimation of Maximum Residue Levels in food and feed. Pesticide Residues. 3rd Edition. FAO Plant Production and Protection Paper 225, 298 pp.
OECD (Organisation for Economic Co-operation and Development), 2011. OECD MRL calculator: spreadsheet for single data set and spreadsheet for multiple data set, 2 March 2011. In: Pesticide Publications/Publications on Pesticide Residues. Available online: https://www.oecd.org
Sweden, 1998. Draft assessment report on the active substance deltamethrin prepared by the rapporteur Member State Sweden in the framework of Council Directive 91/414/EEC, October 1998.
Sweden, 2002. Addendum to the draft assessment report on the active substance deltamethrin prepared by the rapporteur Member State Sweden in the framework of Council Directive 91/414/EEC, June 2002.

Abbreviations

a.s.	active substance
ADI	acceptable daily intake
AR	applied radioactivity
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CCPR	Codex Committee on Pesticide Residues
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
eq	residue expressed as a.s. equivalent
FAO	Food and Agriculture Organization of the United Nations
GAP	Good Agricultural Practice
GC	gas chromatography
HR	highest residue
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ILV	independent laboratory validation
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
LC	liquid chromatography
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
MS	mass spectrometry detector
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
SC	suspension concentrate
SEU	southern Europe
STMR	supervised trials median residue
TRR	total radioactive residue
WHO	World Health Organization

Appendix A – Summary of authorised uses 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 (max)	Interval between application (min)	g a.s./hL (min–max)	Water L/ha (min–max)	Rate	Unit		
Papayas	Brazil	F	*Ceratitis capitata*	EC	25 g/L (2.5% m/v)	Foliar treatment – broadcast spraying	See remark	3	14	1.25–1.56	800–1,000	max 12.5 per treatment (max 37.5 per season)	g a.s./ha	1	Systematically monitor the orchard and start application when there is an average accumulation of 0.5 flies per trap per day. In areas where a great quantity of flies is detected, the insecticide must be applied combined with hydrolysed protein (5%) or sugar cane syrup (10%) directing the jet to the upper third of plants' crown. Reapply when it reaches such ratio again, at intervals of 14 days between applications.
Mangoes	Brazil	F	*Ceratitis capitata*	EC	25 g/L (2.5% m/v)	Foliar treatment – broadcast spraying	See remark	3	14	1.25–1.56	800–1,000	max 12.5 per treatment (max 37.5 per season)	g a.s./ha	1	

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.

(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	Apples	Foliar, 2 x 60 g a.s./ha	28	EFSA (2015)
		Tomatoes	Foliar, 1 x 50 g a.s./ha	4, 14, 28	Study on tomatoes performed in glasshouse (EFSA, 2015).
			Local, 14 μg/ tomato		EFSA (2015)
	Cereals/grass	Maize	Foliar, 2 x 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) was performed in open field and in glasshouse. Study on cotton (II) investigated translocation.
		Cotton (II)	Foliar, 0.009 mg/ plant	1, 3, 7	
			Soil, 0.18 mg/plant		
			Hydroponic, 6.7 mg/plant		
		Cotton (III)	Foliar, 2 x 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	Carrots (I)	Bare soil, 10 × 45 g a.s./ha	30, 120	In the study on carrots (II), radishes and spinaches, the crops were cultivated immediately after soil treatment (EFSA, 2015).
		Carrots (II)	Bare soil, 1 × 118 g a.s./ha	0	
		Radishes	Bare soil, 1 × 118 g a.s./ha	0	
	Leafy crops	Lettuces	Bare soil, 10 × 45 g a.s./ha	30, 120	
		Spinaches	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	EFSA (2015)
	Baking, brewing/boiling (60 min, 100°C, pH 5)			Yes	EFSA (2015)
	Sterilisation (20 min, 120°C, pH 6)			No	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?	Pasteurisation: yes Baking/brewing/boiling: yes Sterilisation: No	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)).	
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)	High water, high acid, high oil content and dry commodities: Multi residue method DFG S19/GC–MSD, LOQ: 0.01 mg/kg The method allows separating the isomers of deltamethrin (EFSA, 2018b, 2022). Difficult matrices (tea, dried leaves, caraway, black pepper, curcuma) GC–MSD, LOQ of 0.05 mg/kg. Confirmation available. ILV available (EFSA, 2022).	

DAT: days after treatment; a.s.: active substance; GC–MSD: gas chromatography with mass selective detection; LOQ: limit of quantification; ILV: independent laboratory validation.

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	Lettuces	–20	16	Months	*cis*-deltamethrin, its *alpha-R*-isomer and *trans*-isomer	EFSA (2015)
		Cabbages	–20	24	Months	*cis*-deltamethrin, its *alpha-R*-isomer and *trans*-isomer	EFSA (2015)
		Tomatoes	–20	24	Months	*cis*-deltamethrin, its *alpha-R*-isomer and *trans*-isomer	EFSA (2015)
		Maize forage	–23 to –27	13	Months	*cis*-deltamethrin and *trans*-isomer	EFSA (2022)
		Maize forage	–23 to –27	Inconclusive	–	*alpha-R*-isomer[(a)]	EFSA (2022)
	High oil content	Cotton seed	–12	30	Months	*cis*-deltamethrin, its *alpha-R*-isomer and *trans*-isomer	EFSA (2015)
	Dry/High starch	Cereals grain	–12	9	Months	*cis*-deltamethrin, its *alpha-R*-isomer and *trans*-isomer	EFSA (2015)
		Maize grain	–23 to –27	16	Months	*cis*-deltamethrin and trans-deltamethrin	EFSA (2022)
		Maize grain	–23 to –27	23	Months	*alpha-R*-isomer	EFSA (2022)
		Maize flour	–23 to –27	15	Months	*cis*-deltamethrin, its *alpha-R*-isomer and *trans*-isomer	EFSA (2022)
		Maize starch	–23 to –27	16	Months	*cis*-deltamethrin, its *alpha-R*-isomer and *trans*-isomer	EFSA (2022)
	High acid content	Oranges	< –18	25	Months	*cis*-deltamethrin, its *alpha-R*-isomer and *trans*-isomer	EFSA (2022)
	Other matrices	Maize stover	–23 to –27	15	Months	*cis*-deltamethrin, and *trans*-isomer	EFSA (2022)
		Maize stover	–23 to –27	Inconclusive	–	*alpha-R*-isomer[(b)]	EFSA (2022)

(a): The EMS reported a lack of confirmation of the initial fortification at the time point zero (EFSA, 2022).
(b): It is to be noted that at the 23 months' time point, the recovery was 70% in one sample and in the other sample recovery was less leading to an average of 67%, the previous time point tested in the study was the initial day zero where sample mean recovery was low, 78% (EFSA, 2022).

B.1.2. Magnitude of residues in plants

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

Commodity	Region[a]	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR[b] (mg/kg)	STMR[c] (mg/kg)	CF[d]
Papayas	BR	*Whole fruit:* **Mo:** 0.028; 0.028; 0.028[e]; 0.036; 0.046[e] **RA:** 0.048; 0.048; 0.048[e]; 0.056; 0.066[e] *Pulp:* **RA:** 5 × < 0.03	Residue trials on papayas compliant with GAP. The *alpha-R* isomer and the *trans*-isomer of deltamethrin were both found < LOQ in whole fruit and pulp. MRL_{OECD} = 0.10	0.1	*Whole fruit:* **Mo:** 0.046 **RA:** 0.066 *Pulp:* **RA:** < 0.03	*Whole fruit:* **Mo:** 0.028 **RA:** 0.048 *Pulp:* **RA:** < 0.03	1
Mangoes	BR	*Whole fruit (calculated)*[f]*:* **Mo:** < 0.01; 0.017; 0.021; 0.023[e] **RA:** < 0.03; 0.037; 0.041; 0.043[e] *Pulp:* **RA:** 4 × < 0.03	Residue trials on mangoes compliant with GAP. The *alpha-R* isomer and the *trans*-isomer of deltamethrin were both found < LOQ in whole fruit and pulp. MRL_{OECD} = 0.05	0.05	*Whole fruit:* **Mo:** 0.023 **RA:** 0.043 *Pulp:* **RA:** < 0.03	*Whole fruit:* **Mo:** 0.019 **RA:** 0.039 *Pulp:* **RA:** < 0.03	1

MRL: maximum residue level; GAP: Good Agricultural Practice; Mo: monitoring; RA: risk assessment; LOQ: limit of quantification.
(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, EU: indoor EU trials or Country code: if non-EU trials.
(b): Highest residue. The highest residue for risk assessment refers to the whole commodity and not to the edible portion.
(c): Supervised trials median residue. The median residue for risk assessment refers to the whole commodity and not to the edible portion.
(d): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment. As residues of the compounds included in the residue definition for risk assessment only (*alpha-R*-isomer and *trans*-isomer) were all ≤ LOQ, the CF was derived as 1.
(e): Residues levels were found to be higher at a PHI longer than 1 day (defined in GAP).
(f): Residue values for 'whole fruit, calculated' were calculated based on results of fruit (pit removed) using a relation factor calculated based on sample weights (Austria, 2021).

B.1.2.2. Residues in rotational crops

Residues in rotational and succeeding crops expected based on confined rotational crop study?	No	Investigations of residues in rotational crops are not required for imported crops. It is noted that 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?	No	The results of the confined rotational crop study are confirmed by a field rotational crop study (EFSA, 2015).

B.1.2.3. Processing factors

Processed commodity	Number of valid studies[a]	Processing Factor (PF)		CF_P[b]	Comment/Source
		Individual values	Median PF		
Papayas, peeled	5	< 0.22; < 0.28; < 0.36; < 0.36; < 0.36	< 0.36	n.c.	Peeling factor based on RD for monitoring, noting that in pulp, residue levels for all compounds (*cis*-deltamethrin, its *alpha-R* isomer and its *trans*-isomer) are below the LOQ (0.01 mg/kg for each compound). (Austria, 2021)
Mangoes, peeled	3	< 0.43; < 0.48; < 0.59	< 0.48	n.c.	
Potatoes, unpeeled and boiled	4	0.22; 0.27; 0.19; 0.34	0.26	n.c.	EFSA (2015) Tentative[c]
Potatoes, fried	4	0.03; 0.03; 0.04; 0.04	0.04	n.c.	EFSA (2015) Tentative[c]
Apples, juice	1	0.01	0.01	n.c.	EFSA (2015) Tentative[c]
Apples, wet pomace	1	5.70	5.70	n.c.	
Strawberries, canned	1	0.65	0.65	n.c.	
Tomatoes, paste	1	0.40	0.40	n.c.	
Tomatoes, ketchup	1	1.00	1.00	n.c.	
Tomatoes, juice	1	1.00	1.00	n.c.	
Dry pulses, cooked	1	0.10	0.10	n.c.	
Sunflower seed, crude oil	1	10	10	n.c.	
Rape seed, crude oil	1	10	10	n.c.	
Cotton seed, crude oil	1	0.02	0.02	n.c.	
Olives, crude oil after warm press	1	1.60	1.60	n.c.	
Barley, beer	1	0.02	0.02	n.c.	
Maize, crude oil	1	20	20	n.c.	
Rice, polished	1	0.20	0.20	n.c.	

PF: processing factor; n.c.: not calculated (for the use assessed in the MRL review, information on the residues according to the risk assessment residue definition was not available and a conversion factor (CF) for risk assessment could not be calculated and therefore a tentative CF of 1.25 was applied); RD: residue definition.
(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; median of the individual conversion factors for each processing residues trial. CFs cannot be calculated (n.c.) as it is not clear if an analytical method covering all the isomers has been used to analyse residues in the processing studies (EFSA, 2015).
(c): A tentative PF is derived based on a limited data set and/or residues not analysed according to the proposed residue definitions (EFSA, 2015).

B.2. Residues in livestock

Not relevant as mangoes and papayas are not used for feed purposes.

B.3. Consumer risk assessment

ARfD	0.01 mg/kg bw (European Commission, 2002)
Highest IESTI, according to EFSA PRIMo	Authorized uses: Mangoes: 23.6% of ARfD Papayas: 12.7% of ARfD
Assumptions made for the calculations	The calculation is based on the highest residues (HR) derived from supervised field trials submitted in support of this MRL application. For both mangoes and papayas, EFSA considered the HR in pulp fractions, expressed according to the residue definition for risk assessment. Considering the sum of LOQs for all compounds relevant for risk assessment, the value of 0.03 mg/kg was retained for mangoes and papayas. Calculations performed with PRIMo revision 3.1.

ADI	0.01 mg/kg bw per day (European Commission, 2002)
Highest IEDI, according to EFSA PRIMo	99% of ADI (NL toddler) Contribution of crops assessed: Mangoes: 0.08% of ADI (IE adult) Papayas: 0.01% of ADI (SE general)
Assumptions made for the calculations	For mangoes and papayas, the calculation is based on the median residue (STMR) derived from supervised field trials submitted in support of this MRL application. For both mangoes and papayas, EFSA considered the STMR in pulp fractions, expressed according to the residue definition for risk assessment. Considering the sum of LOQs for all compounds relevant for risk assessment, the value of 0.03 mg/kg was retained for mangoes and papayas. For all other commodities, the input values were as used in the EFSA assessment of confirmatory data of the Article 12 MRL review (EFSA, 2022). Full description on how those input values were derived is available in the EFSA opinion on the evaluation of the confirmatory data of the article 12 MRL review (EFSA, 2022). For the present assessment, EFSA updated the most conservative consumer exposure scenario, namely **scenario 2** as described in EFSA, 2022. Pending the assessment of further toxicological data of the *alpha-R*-isomer and *trans*-isomer of deltamethrin included in the provisional risk assessment residue definition, the consumer risk assessment should be regarded as indicative and affected by non-standard uncertainties (EFSA, 2022). 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; MRL: maximum residue level; LOQ: limit of quantification; ADI: acceptable daily intake; IEDI: international estimated daily intake.

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)]				
0163030	Mangoes	0.01*	0.05	The submitted data are sufficient to derive an import tolerance (BR GAP). Risk for consumers unlikely.
0163040	Papayas	0.01*	0.1	The submitted data are sufficient to derive an import tolerance (BR GAP). Risk for consumers unlikely.

MRL: maximum residue level; GAP: Good Agricultural Practice.
*: 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)

Scenario 2

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

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 : ---

	Calculated exposure (% of ADI)	MS Diet	Expsoure (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)	99%	NL toddler	9.88	49%	Maize/corn	18%	Wheat	10%	Milk: Cattle		99%
	69%	DK child	6.91	39%	Rye	20%	Wheat	3%	Oat		69%
	58%	GEMS/Food G06	5.84	33%	Wheat	9%	Maize/corn	7%	Rice		58%
	43%	GEMS/Food G08	4.33	18%	Wheat	6%	Barley	4%	Rye		43%
	42%	GEMS/Food G15	4.17	20%	Wheat	5%	Barley	4%	Maize/corn		42%
	41%	GEMS/Food G10	4.14	18%	Wheat	6%	Rice	5%	Maize/corn		41%
	40%	DE child	4.05	19%	Wheat	6%	Rye	4%	Apples		40%
	39%	FR child 3 15 yr	3.87	21%	Wheat	4%	Milk: Cattle	3%	Maize/corn		39%
	38%	RO general	3.82	23%	Wheat	7%	Maize/corn	2%	Milk: Cattle		38%
	37%	UK infant	3.72	12%	Wheat	7%	Maize/corn	7%	Milk: Cattle		37%
	37%	GEMS/Food G07	3.71	19%	Wheat	4%	Barley	2%	Maize/corn		37%
	36%	NL child	3.59	19%	Wheat	4%	Milk: Cattle	2%	Maize/corn		36%
	34%	ES child	3.44	20%	Wheat	2%	Rice	2%	Milk: Cattle		34%
	33%	IT toddler	3.32	30%	Wheat	0.9%	Rice	0.4%	Tomatoes		33%
	33%	UK toddler	3.28	18%	Wheat	4%	Beans	4%	Milk: Cattle		33%
	33%	GEMS/Food G11	3.26	16%	Wheat	5%	Barley	1%	Milk: Cattle		33%
	31%	PT general	3.05	18%	Wheat	4%	Rice	3%	Maize/corn		31%
	29%	FR toddler 2 3 yr	2.87	14%	Wheat	5%	Milk: Cattle	3%	Rice		29%
	29%	IE adult	2.85	10%	Wheat	3%	Tea (dried leaves of Camellia sinensis)	2%	Buckwheat and other pseudo-cereals		29%
	25%	SE general	2.53	14%	Wheat	2%	Bovine: Muscle/meat	2%	Milk: Cattle		25%
	25%	DE general	2.48	8%	Wheat	4%	Rye	4%	Barley		25%
	23%	DE women 14-50 yr	2.32	10%	Wheat	3%	Rye	2%	Milk: Cattle		23%
	21%	IT adult	2.15	19%	Wheat	0.8%	Rice	0.3%	Tomatoes		21%
	21%	ES adult	2.15	11%	Wheat	3%	Barley	1%	Rice		21%
	20%	FR adult	1.98	10%	Wheat	3%	Tea (dried leaves of Camellia sinensis)	0.9%	Wine grapes		20%
	20%	FI 3 yr	1.97	5%	Wheat	5%	Rye	4%	Oat		20%
	19%	NL general	1.94	9%	Wheat	2%	Barley	1%	Milk: Cattle		19%
	19%	LT adult	1.89	8%	Rye	5%	Wheat	1%	Buckwheat and other pseudo-cereals		19%
	17%	UK vegetarian	1.70	9%	Wheat	2%	Beans	2%	Rice		17%
	16%	FI 6 yr	1.58	4%	Wheat	4%	Rye	2%	Oat		16%
	14%	UK adult	1.43	8%	Wheat	2%	Rice	1%	Tea (dried leaves of Camellia sinensis)		14%
	13%	DK adult	1.31	5%	Wheat	4%	Rye	0.9%	Milk: Cattle		13%
	10%	FR infant	0.96	4%	Wheat	3%	Milk: Cattle	0.5%	Apples		10%
	9%	FI adult	0.93	5%	Rye	1%	Wheat	0.9%	Oat		9%
	8%	IE child	0.82	5%	Wheat	1%	Rice	0.6%	Milk: Cattle		8%
	2%	PL general	0.22	0.6%	Apples	0.3%	Potatoes	0.3%	Tomatoes		2%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Deltamethrin (cis-deltamethrin) (F) is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

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. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

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):	---	**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)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
97%	Pears	0.09 / 0.07	9.7	55%	Chamomille	9 / 9.1	5.5
91%	Beans	1 / 0.5	9.1	55%	Chamomille	9 / 9.1	5.5
86%	Apples	0.2 / 0.08	8.6	55%	Chamomille	9 / 9.1	5.5
77%	Leeks	0.3 / 0.13	7.7	55%	Chamomille	9 / 9.1	5.5
76%	Peaches	0.15 / 0.08	7.6	55%	Chamomille	9 / 9.1	5.5
75%	Celeries	0.3 / 0.2	7.5	54%	Aubergines/egg plants	0.4 / 0.2	5.4
74%	Rhubarbs	0.3 / 0.2	7.4	53%	Red mustards	2 / 1	5.3
72%	Kales	0.15 / 0.16	7.2	38%	Rice	1 / 0.45	3.8
66%	Table grapes	0.2 / 0.09	6.6	38%	Wheat	1 / 0.45	3.8
65%	Wheat	1 / 0.45	6.5	37%	Florence fennels	0.3 / 0.2	3.7
59%	Cucumbers	0.2 / 0.09	5.9	36%	Rooibos	9 / 9.1	3.6
57%	Rice	1 / 0.45	5.7	36%	Rooibos	9 / 9.1	3.6
50%	Aubergines/egg plants	0.4 / 0.2	5.0	34%	Rye	2 / 0.7	3.4
47%	Maize/corn	2 / 0.7	4.7	34%	Barley	2 / 0.7	3.4
44%	Rye	2 / 0.7	4.4	33%	Beans	1 / 0.5	3.3

Expand/collapse list

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

Processed commodities

Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI):	1	**Results for adults** 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)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
256%	Maize / oil	2 / 27.5	26	140%	Maize / oil	2 / 27.5	14
91%	Florence fennels / boiled	0.3 / 0.2	9.1	79%	Barley / beer	2 / 0.22	7.9
80%	Pumpkins / boiled	0.2 / 0.09	8.0	68%	Celeries / boiled	0.3 / 0.2	6.8
75%	Rhubarbs / sauce/puree	0.3 / 0.2	7.5	61%	Beans / canned	1 / 0.85	6.1
74%	Leeks / boiled	0.3 / 0.13	7.4	50%	Pumpkins / boiled	0.2 / 0.09	5.0
70%	Wheat / milling (flour)	1 / 0.58	7.0	39%	Florence fennels / boiled	0.3 / 0.2	3.9
69%	Lentils / boiled	1 / 0.85	6.9	29%	Rhubarbs / sauce/puree	0.3 / 0.2	2.9
61%	Peas / canned	1 / 0.34	6.1	25%	Wheat / bread/pizza	1 / 0.58	2.5
60%	Millet / boiled	2 / 0.44	6.0	25%	Millet / boiled	2 / 0.44	2.5
59%	Buckwheat / bulgur and grits	2 / 1.1	5.9	23%	Leeks / boiled	0.3 / 0.13	2.3
45%	Kales / boiled	0.15 / 0.16	4.5	23%	Peas / canned	1 / 0.34	2.3
40%	Rye / boiled	2 / 1.1	4.0	22%	Rice / milling (polishing)	1 / 0.23	2.2
40%	Oat / boiled	2 / 1.1	4.0	22%	Wheat / pasta	1 / 0.58	2.2
40%	Buckwheat / boiled	2 / 1.1	4.0	21%	Courgettes / boiled	0.2 / 0.09	2.1
40%	Barley / cooked	2 / 1.1	4.0	20%	Wheat / bread (wholemeal)	1 / 0.58	2.0

Expand/collapse list

Conclusion:

No exceedance of the toxicological reference value was identified for any unprocessed commodity.

A short-term intake of residues of Deltamethrin (cis-deltamethrin) (F) is unlikely to present a public health risk.

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

Code	Commodity	Existing/ proposed MRL	Source/ type of MRL	Chronic risk assessment		Acute risk assessment	
				Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: Sum of *cis*-deltamethrin and its *alpha-R*-isomer and *trans*-isomer							
163030	**Mangoes**	**0.05**	**Proposed**	**0.03**	**STMR-pulp**	**0.03**	**HR-pulp**
163040	**Papayas**	**0.1**	**Proposed**	**0.03**	**STMR-pulp**	**0.03**	**HR-pulp**
110010	Grapefruits	0.02	CXL (2004)	0.01	STMR-RAC	0.01	HR-RAC
110020	Oranges	0.02	CXL (2004)	0.01	STMR-RAC	0.01	HR-RAC
110030	Lemons	0.02	CXL (2004)	0.01	STMR-RAC	0.01	HR-RAC
110040	Limes	0.02	CXL (2004)	0.01	STMR-RAC	0.01	HR-RAC
110050	Mandarins	0.02	CXL (2004)	0.01	STMR-RAC	0.01	HR-RAC
120010	Almonds	0.02*	EFSA (2022)	0.02	STMR-RAC × CF(1)	0.02	HR-RAC × CF (1)
120020	Brazil nuts	0.02*	EFSA (2022)	0.02	STMR-RAC × CF(1)	0.02	HR-RAC × CF (1)
120030	Cashew nuts	0.02*	EFSA (2022)	0.02	STMR-RAC × CF(1)	0.02	HR-RAC × CF (1)
120040	Chestnuts	0.02*	EFSA (2022)	0.02	STMR-RAC × CF(1)	0.02	HR-RAC × CF (1)
120050	Coconuts	0.02*	EFSA (2022)	0.02	STMR-RAC × CF(1)	0.02	HR-RAC × CF (1)
120060	Hazelnuts/ cobnuts	0.02*	CXL (2004)	0.02	STMR-RAC	0.02	HR-RAC
120070	Macadamia	0.02*	EFSA (2022)	0.02	STMR-RAC × CF(1)	0.02	HR-RAC × CF (1)
120080	Pecans	0.02*	EFSA (2022)	0.02	STMR-RAC × CF(1)	0.02	HR-RAC × CF (1)
120090	Pine nut kernels	0.02*	EFSA (2022)	0.02	STMR-RAC × CF(1)	0.02	HR-RAC × CF (1)
120100	Pistachios	0.02*	EFSA (2022)	0.02	STMR-RAC × CF(1)	0.02	HR-RAC × CF (1)
120110	Walnuts	0.02*	CXL (2004)	0.02	STMR-RAC	0.02	HR-RAC
130010	Apples	0.2	CXL (2004)	0.03	STMR-RAC	0.08	HR-RAC
130020	Pears	0.09	EFSA (2022)	0.02	STMR-RAC × CF(1)	0.07	HR-RAC × CF (1)
130030	Quinces	0.1	EFSA (2022)	0.03	STMR-RAC × CF(1)	0.08	HR-RAC × CF (1)
130040	Medlar	0.1	EFSA (2022)	0.03	STMR-RAC × CF(1)	0.08	HR-RAC × CF (1)
130050	Loquats/ Japanese medlars	0.1	EFSA (2022)	0.03	STMR-RAC × CF(1)	0.08	HR-RAC × CF (1)
140010	Apricots	0.15	EFSA (2022)	0.03	STMR-RAC × CF(1)	0.08	HR-RAC × CF (1)
140020	Cherries (sweet)	0.1	EFSA (2022)	0.04	STMR-RAC × CF(1)	0.05	HR-RAC × CF (1)
140030	Peaches	0.15	EFSA (2022)	0.03	STMR-RAC × CF(1)	0.08	HR-RAC × CF (1)
140040	Plums	0.1	EFSA (2022)	0.01	STMR-RAC × CF(1)	0.06	HR-RAC × CF (1)

Code	Commodity	Existing/ proposed MRL	Source/ type of MRL	Chronic risk assessment		Acute risk assessment	
				Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
151010	Table grapes	0.2	CXL (2004)	0.04	STMR-RAC	0.09	HR-RAC
151020	Wine grapes	0.2	CXL (2004)	0.04	STMR-RAC	0.09	HR-RAC
152000	Strawberries	0.2	CXL (2004)	0.02	STMR-RAC	0.1	HR-RAC
153010	Blackberries	0.08	EFSA (2022)	0.03	STMR-RAC × CF(1)	0.04	HR-RAC × CF (1)
153020	Dewberries	0.08	EFSA (2022)	0.03	STMR-RAC × CF(1)	0.04	HR-RAC × CF (1)
153030	Raspberries (red and yellow)	0.08	EFSA (2022)	0.03	STMR-RAC × CF(1)	0.04	HR-RAC × CF (1)
154010	Blueberries	0.6	EFSA (2022)	0.08	STMR-RAC × CF(1)	0.3	HR-RAC × CF (1)
154020	Cranberries	0.6	EFSA (2022)	0.08	STMR-RAC × CF(1)	0.3	HR-RAC × CF (1)
154030	Currants (red, black and white)	0.6	EFSA (2022)	0.08	STMR-RAC × CF(1)	0.3	HR-RAC × CF (1)
154040	Gooseberries (green, red and yellow)	0.6	EFSA (2022)	0.08	STMR-RAC × CF(1)	0.3	HR-RAC × CF (1)
154050	Rose hips	0.6	EFSA (2022)	0.08	STMR-RAC × CF(1)	0.3	HR-RAC × CF (1)
154060	Mulberries (black and white)	0.6	EFSA (2022)	0.08	STMR-RAC × CF(1)	0.3	HR-RAC × CF (1)
154070	Azarole/ Mediterranean medlar	0.6	EFSA (2022)	0.08	STMR-RAC × CF(1)	0.3	HR-RAC × CF (1)
154080	Elderberries	0.6	EFSA (2022)	0.08	STMR-RAC × CF(1)	0.3	HR-RAC × CF (1)
161030	Table olives	1	EFSA (2015)	0.21	STMR-RAC	0.31	HR-RAC
211000	Potatoes	0.01*	CXL (2004)	0.01	STMR-RAC	0.01	HR-RAC
213010	Beetroots	0.02*	EFSA (2022)	0.02	STMR-RAC × CF(1)	0.02	HR-RAC × CF (1)
213020	Carrots	0.02	CXL (2004)	0.01	STMR-RAC	0.02	HR-RAC
213030	Celeriacs/ turnip rooted celeries	0.02*	EFSA (2022)	0.02	STMR-RAC × CF(1)	0.02	HR-RAC × CF (1)
213040	Horseradishes	0.02*	EFSA (2022)	0.02	STMR-RAC × CF(1)	0.02	HR-RAC × CF (1)
213050	Jerusalem artichokes	0.02*	EFSA (2022)	0.02	STMR-RAC × CF(1)	0.02	HR-RAC × CF (1)
213060	Parsnips	0.02*	EFSA (2022)	0.02	STMR-RAC × CF(1)	0.02	HR-RAC × CF (1)
213070	Parsley roots/ Hamburg roots parsley	0.02*	EFSA (2022)	0.02	STMR-RAC × CF(1)	0.02	HR-RAC × CF (1)
213080	Radishes	0.02*	EFSA (2022)	0.02	STMR-RAC × CF(1)	0.02	HR-RAC × CF (1)
213090	Salsifies	0.02*	EFSA (2022)	0.02	STMR-RAC × CF(1)	0.02	HR-RAC × CF (1)

Code	Commodity	Existing/ proposed MRL	Source/ type of MRL	Chronic risk assessment		Acute risk assessment	
				Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
213100	Swedes/ rutabagas	0.02*	EFSA (2022)	0.02	STMR-RAC × CF(1)	0.02	HR-RAC × CF (1)
213110	Turnips	0.02*	EFSA (2022)	0.02	STMR-RAC × CF(1)	0.02	HR-RAC × CF (1)
220010	Garlic	0.06	EFSA (2022)	0.02	STMR-RAC × CF(1)	0.04	HR-RAC × CF (1)
220020	Onions	0.06	EFSA (2022)	0.02	STMR-RAC × CF(1)	0.04	HR-RAC × CF (1)
220030	Shallots	0.06	EFSA (2022)	0.02	STMR-RAC × CF(1)	0.04	HR-RAC × CF (1)
220040	Spring onions/ green onions and Welsh onions	0.3	EFSA (2022)	0.06	STMR-RAC × CF(1)	0.13	HR-RAC × CF (1)
231010	Tomatoes	0.1	Proposed (EFSA, 2022)	0.03	STMR-RAC × CF(1)	0.07	HR-RAC × CF (1)
231020	Sweet peppers/bell peppers	0.15	EFSA (2022)	0.03	STMR-RAC × CF(1)	0.07	HR-RAC × CF (1)
231030	Aubergines/ egg plants	0.4	EFSA (2022)	0.06	STMR-RAC × CF(1)	0.2	HR-RAC × CF (1)
231040	Okra/lady's fingers	0.15	Proposed (EFSA, 2022)	0.03	STMR-RAC × CF(1)	0.07	HR-RAC × CF (1)
232010	Cucumbers	0.2	CXL (2004)	0.02	STMR-RAC	0.09	HR-RAC
232020	Gherkins	0.2	CXL (2004)	0.02	STMR-RAC	0.09	HR-RAC
232030	Courgettes	0.2	CXL (2004)	0.02	STMR-RAC	0.09	HR-RAC
232990	Other cucurbits - edible peel	0.2	CXL (2004)	0.02	STMR-RAC		
233010	Melons	0.02*	EFSA (2022)	0.02	STMR-RAC × CF(1)	0.02	HR-RAC × CF (1)
233020	Pumpkins	0.2	CXL (2004)	0.02	STMR-RAC	0.09	HR-RAC
233030	Watermelons	0.02*	EFSA (2022)	0.02	STMR-RAC × CF(1)	0.02	HR-RAC × CF (1)
234000	Sweet corn	0.02*	CXL (2004)	0.02	STMR-RAC	0.02	HR-RAC
241010	Broccoli	0.1	CXL (2004)	0.02	STMR-RAC	0.04	HR-RAC
241020	Cauliflowers	0.1	CXL (2004)	0.02	STMR-RAC	0.04	HR-RAC
241990	Other flowering brassica	0.1	CXL (2004)	0.02	STMR-RAC		
242010	Brussels sprouts	0.01*	EFSA (2022)	0.01	STMR-RAC × CF(1)	0.01	HR-RAC × CF (1)
242020	Head cabbages	0.01*	EFSA (2022)	0.01	STMR-RAC × CF(1)	0.01	HR-RAC × CF (1)
243010	Chinese cabbages/pe-tsai	0.2	EFSA (2022)	0.02	STMR-RAC × CF(1)	0.11	HR-RAC × CF (1)
243020	Kales	0.15	EFSA (2018a)	0.0625	STMR-RAC × CF (1.25)	0.1625	HR-RAC*CF (1.25)
244000	Kohlrabies	0.01*	EFSA (2022)	0.01	STMR-RAC × CF(1)	0.01	HR-RAC × CF (1)

Code	Commodity	Existing/ proposed MRL	Source/ type of MRL	Chronic risk assessment		Acute risk assessment	
				Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
251010	Lamb's lettuce/ corn salads	2	CXL (2006)	0.125	STMR-RAC	1	HR-RAC
251040	Cress and other sprouts and shoots	2	CXL (2006)	0.125	STMR-RAC	1	HR-RAC
251050	Land cress	2	CXL (2006)	0.125	STMR-RAC	1	HR-RAC
251060	Roman rocket/ rucola	2	CXL (2006)	0.125	STMR-RAC	1	HR-RAC
251070	Red mustards	2	CXL (2006)	0.125	STMR-RAC	1	HR-RAC
251080	Baby leaf crops (including brassica species)	2	CXL (2006)	0.125	STMR-RAC	1	HR-RAC
253000	Grape leaves and similar species	2	CXL (2006)	0.125	STMR-RAC	1	HR-RAC
254000	Watercress	2	CXL (2006)	0.125	STMR-RAC	1	HR-RAC
255000	Witloofs/ Belgian endives	0.02*	EFSA (2015)	0.02	STMR-RAC × CF(1)	0.02	HR-RAC × CF (1)
256010	Chervil	2	CXL (2006)	0.125	STMR-RAC	1	HR-RAC
256020	Chives	1.5	EFSA (2022)	0.1105	STMR-RAC × CF (1.3)	1.3	HR-RAC × CF (1.3)
256030	Celery leaves	1.5	EFSA (2022)	0.1105	STMR-RAC × CF (1.3)	1.3	HR-RAC × CF (1.3)
256040	Parsley	1.5	EFSA (2022)	0.1105	STMR-RAC × CF (1.3)	1.3	HR-RAC × CF (1.3)
256050	Sage	1.5	EFSA (2022)	0.1105	STMR-RAC × CF (1.3)	1.3	HR-RAC × CF (1.3)
256060	Rosemary	1.5	EFSA (2022)	0.1105	STMR-RAC × CF (1.3)	1.3	HR-RAC × CF (1.3)
256070	Thyme	1.5	EFSA (2022)	0.1105	STMR-RAC × CF (1.3)	1.3	HR-RAC × CF (1.3)
256080	Basil and edible flowers	1.5	EFSA (2022)	0.1105	STMR-RAC × CF (1.3)	1.3	HR-RAC × CF (1.3)
256090	Laurel/bay leaves	1.5	EFSA (2022)	0.1105	STMR-RAC × CF (1.3)	1.3	HR-RAC × CF (1.3)
256100	Tarragon	1.5	EFSA (2022)	0.1105	STMR-RAC × CF (1.3)	1.3	HR-RAC × CF (1.3)
256990	Other herbs	1.5	EFSA (2022)	0.1105	STMR-RAC × CF (1.3)		
260010	Beans (with pods)	0.2	CXL (2004)	0.01	STMR-RAC	0.14	HR-RAC
260020	Beans (without pods)	0.2	CXL (2004)	0.01	STMR-RAC	0.14	HR-RAC
260030	Peas (with pods)	0.2	CXL (2004)	0.01	STMR-RAC	0.14	HR-RAC
260040	Peas (without pods)	0.2	CXL (2004)	0.01	STMR-RAC	0.14	HR-RAC
260050	Lentils (fresh)	0.2	CXL (2004)	0.01	STMR-RAC	0.14	HR-RAC

Code	Commodity	Existing/ proposed MRL	Source/ type of MRL	Chronic risk assessment		Acute risk assessment	
				Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
270010	Asparagus	0.01*	EFSA (2015)	0.01	STMR-RAC	0.01	HR-RAC
270030	Celeries	0.3	EFSA (2017)	0.075	STMR-RAC*CF (1.25)	0.2	HR-RAC × CF (1.25)
270040	Florence fennels	0.3	EFSA (2017)	0.075	STMR-RAC*CF (1.25)	0.2	HR-RAC × CF (1.25)
270060	Leeks	0.3	EFSA (2022)	0.06	STMR-RAC*CF(1)	0.13	HR-RAC × CF (1)
270070	Rhubarbs	0.3	EFSA (2017)	0.075	STMR-RAC*CF (1.25)	0.2	HR-RAC × CF (1.25)
280010	Cultivated fungi	0.05	CXL (2004)	0.02	STMR-RAC	0.03	HR-RAC
300010	Beans	1	CXL (2004)	0.5	STMR-RAC	0.5	HR-RAC
300020	Lentils	1	CXL (2004)	0.5	STMR-RAC	0.5	HR-RAC
300030	Peas	1	CXL (2004)	0.5	STMR-RAC	0.5	HR-RAC
300040	Lupins/lupini beans	1	CXL (2004)	0.5	STMR-RAC	0.5	HR-RAC
401010	Linseeds	0.02*	EFSA (2015)	0.02	STMR-RAC*CF(1)	0.02	STMR-RAC × CF (1)
401030	Poppy seeds	0.2	EFSA (2015)	0.05	STMR-RAC*CF(1)	0.05	STMR-RAC × CF (1)
401040	Sesame seeds	0.02*	EFSA (2015)	0.01	STMR-RAC*CF(1)	0.01	STMR-RAC × CF (1)
401050	Sunflower seeds	0.05	CXL (2004)	0.05	STMR-RAC	0.05	STMR-RAC
401060	Rapeseeds/ canola seeds	0.2	CXL (2017)	0.07	STMR-RAC	0.07	STMR-RAC
401080	Mustard seeds	0.07*	EFSA (2015)	0.05	STMR-RAC × CF(1)	0.05	STMR-RAC × CF (1)
401090	Cotton seeds	0.02*	EFSA (2015)	0.01	STMR-RAC × CF(1)	0.01	STMR-RAC × CF (1)
401100	Pumpkin seeds	0.02*	EFSA (2015)	0.01	STMR-RAC × CF(1)	0.01	STMR-RAC × CF (1)
401110	Safflower seeds	0.02*	EFSA (2015)	0.01	STMR-RAC × CF(1)	0.01	STMR-RAC × CF (1)
401120	Borage seeds	0.2	EFSA (2015)	0.05	STMR-RAC × CF(1)	0.05	STMR-RAC × CF (1)
401130	Gold of pleasure seeds	0.07*	EFSA (2015)	0.05	STMR-RAC × CF(1)	0.05	STMR-RAC × CF (1)
401140	Hemp seeds	0.2	EFSA (2015)	0.05	STMR-RAC × CF(1)	0.05	STMR-RAC × CF (1)
401150	Castor beans	0.2	EFSA (2015)	0.05	STMR-RAC × CF(1)	0.05	STMR-RAC × CF (1)
402010	Olives for oil production	0.6	EFSA (2022)	0.2394	STMR-RAC × CF(1)	0.2394	STMR-RAC × CF (1)
500010	Barley	2	CXL (2004)	0.7	STMR-RAC	0.7	HR-RAC
500020	Buckwheat and other pseudo-cereals	2	CXL (2004)	0.7	STMR-RAC	0.7	HR-RAC
500030	Maize/corn	2	CXL (2004)	0.7	STMR-RAC	0.7	HR-RAC

Code	Commodity	Existing/ proposed MRL	Source/ type of MRL	Chronic risk assessment		Acute risk assessment	
				Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
500040	Common millet/proso millet	2	CXL (2004)	0.7	STMR-RAC	0.7	HR-RAC
500050	Oat	2	CXL (2004)	0.7	STMR-RAC	0.7	HR-RAC
500060	Rice	1	EFSA (2022)	0.45	STMR-RAC × CF(1)	0.45	HR-RAC × CF (1)
500070	Rye	2	CXL (2004)	0.7	STMR-RAC	0.7	HR-RAC
500080	Sorghum	2	CXL (2004)	0.7	STMR-RAC	0.7	HR-RAC
500090	Wheat	1	EFSA (2022)	0.45	STMR-RAC × CF(1)	0.45	HR-RAC × CF (1)
610000	Tea (dried leaves of Camellia sinensis)	5	CXL (2004)	2.2	STMR-RAC	2.2	STMR-RAC
631010	Chamomille	9	EFSA (2022)	0.78	STMR-RAC × CF (1.3)	9.1	HR-RAC × CF (1.3)
631020	Hibiscus/ roselle	9	EFSA (2022)	0.78	STMR-RAC × CF (1.3)	9.1	HR-RAC × CF (1.3)
631030	Rose	9	EFSA (2022)	0.78	STMR-RAC × CF (1.3)	9.1	HR-RAC × CF (1.3)
631040	Jasmine	9	EFSA (2022)	0.78	STMR-RAC × CF (1.3)	9.1	HR-RAC × CF (1.3)
631050	Lime/linden	9	EFSA (2022)	0.78	STMR-RAC × CF (1.3)	9.1	HR-RAC × CF (1.3)
631990	Other herbal infusions (dried flowers)	9	EFSA (2022)	0.78	STMR-RAC × CF (1.3)		
632010	Strawberry leaves	9	EFSA (2022)	0.78	STMR-RAC × CF (1.3)	9.1	HR-RAC × CF (1.3)
632020	Rooibos	9	EFSA (2022)	0.78	STMR-RAC × CF (1.3)	9.1	HR-RAC × CF (1.3)
632030	Mate/maté	9	EFSA (2022)	0.78	STMR-RAC × CF (1.3)	9.1	HR-RAC × CF (1.3)
632990	Other herbal infusions (dried leaves)	9	EFSA (2022)	0.78	STMR-RAC × CF (1.3)		
633010	Valerian root	0.3	EFSA (2022)	0.07	STMR-RAC × CF(1)	0.14	HR-RAC × CF (1)
633020	Ginseng root	0.3	EFSA (2022)	0.07	STMR-RAC × CF(1)	0.14	HR-RAC × CF (1)
633990	Other herbal infusions (dried roots)	0.3	EFSA (2022)	0.07	STMR-RAC × CF(1)		
650000	Carobs/Saint John's bread	0.7	EFSA (2022)	0.365	STMR-RAC × CF(1)	0.405	HR-RAC × CF (1)
820010	Allspice/ pimento	0.03	CXL (2011)	0.03	STMR-RAC	0.03	HR-RAC
820020	Sichuan pepper	0.03	CXL (2011)	0.03	STMR-RAC	0.03	HR-RAC
820030	Caraway	0.03	CXL (2011)	0.03	STMR-RAC	0.03	HR-RAC
820040	Cardamom	0.03	CXL (2011)	0.03	STMR-RAC	0.03	HR-RAC

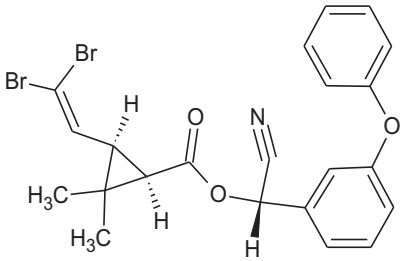
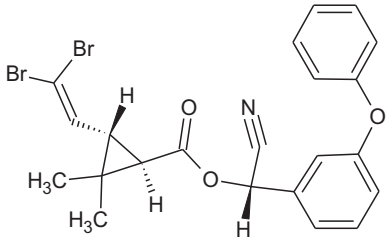
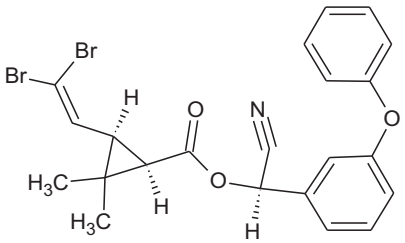
Code	Commodity	Existing/ proposed MRL	Source/ type of MRL	Chronic risk assessment		Acute risk assessment	
				Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
820050	Juniper berry	0.03	CXL (2011)	0.03	STMR-RAC	0.03	HR-RAC
820060	Peppercorn (black, green and white)	0.03	CXL (2011)	0.03	STMR-RAC	0.03	HR-RAC
820070	Vanilla pods	0.03	CXL (2011)	0.03	STMR-RAC	0.03	HR-RAC
820080	Tamarind	0.03	CXL (2011)	0.03	STMR-RAC	0.03	HR-RAC
820990	Other spices (fruits)	0.03	CXL (2011)	0.03	STMR-RAC		
840010	Liquorice	0.5	CXL (2011)	0.05	STMR-RAC	0.33	HR-RAC
840020	Ginger	0.5	CXL (2011)	0.05	STMR-RAC	0.33	STMR-RAC
840030	Turmeric/ curcuma	0.5	CXL (2011)	0.05	STMR-RAC	0.33	HR-RAC
840040	Horseradish, root spices	0.5	CXL (2011)	0.05	STMR-RAC	0.33	HR-RAC
900010	Sugar beet roots	0.02*	EFSA (2022)	0.02	STMR-RAC × CF(1)	0.02	HR-RAC × CF (1)
900030	Chicory roots	0.04	EFSA (2022)	0.01	STMR-RAC × CF(1)	0.02	HR-RAC × CF (1)
1011010	Swine: Muscle/ meat	0.03	EFSA (2015)	0.055	STMR-RAC	0.061	HR-RAC
1011020	Swine: Fat tissue	0.5	EFSA (2015)	0.155	STMR-RAC	0.186	HR-RAC
1011030	Swine: Liver	0.03*	EFSA (2015)	0.03	STMR-RAC	0.03	HR-RAC
1011040	Swine: Kidney	0.03*	EFSA (2015)	0.03	STMR-RAC	0.03	HR-RAC
1011050	Swine: Edible offals (other than liver and kidney)	0.5	EFSA (2015)	0.155	STMR-RAC	0.186	HR-RAC
1012010	Bovine: Muscle/meat	0.03	EFSA (2015)	0.055	STMR-RAC	0.061	HR-RAC
1012020	Bovine: Fat tissue	0.5	EFSA (2015)	0.155	STMR-RAC	0.186	HR-RAC
1012030	Bovine: Liver	0.03*	EFSA (2015)	0.03	STMR-RAC	0.03	HR-RAC
1012040	Bovine: Kidney	0.03*	EFSA (2015)	0.03	STMR-RAC	0.03	HR-RAC
1012050	Bovine: Edible offals (other than liver and kidney)	0.5	EFSA (2015)	0.155	STMR-RAC	0.186	HR-RAC
1013010	Sheep: Muscle/ meat	0.03	EFSA (2015)	0.055	STMR-RAC	0.061	HR-RAC
1013020	Sheep: Fat tissue	0.5	EFSA (2015)	0.155	STMR-RAC	0.186	HR-RAC
1013030	Sheep: Liver	0.03*	EFSA (2015)	0.03	STMR-RAC	0.03	HR-RAC
1013040	Sheep: Kidney	0.03*	EFSA (2015)	0.03	STMR-RAC	0.03	HR-RAC
1013050	Sheep: Edible offals (other than liver and kidney)	0.5	EFSA (2015)	0.155	STMR-RAC	0.186	HR-RAC
1014010	Goat: Muscle/ meat	0.03	EFSA (2015)	0.055	STMR-RAC	0.061	HR-RAC

Code	Commodity	Existing/ proposed MRL	Source/ type of MRL	Chronic risk assessment		Acute risk assessment	
				Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
1014020	Goat: Fat tissue	0.5	EFSA (2015)	0.155	STMR-RAC	0.186	HR-RAC
1014030	Goat: Liver	0.03*	EFSA (2015)	0.03	STMR-RAC	0.03	HR-RAC
1014040	Goat: Kidney	0.03*	EFSA (2015)	0.03	STMR-RAC	0.03	HR-RAC
1014050	Goat: Edible offals (other than liver and kidney)	0.5	EFSA (2015)	0.155	STMR-RAC	0.186	HR-RAC
1015010	Equine: Muscle/meat	0.03	EFSA (2015)	0.055	STMR-RAC	0.061	HR-RAC
1015020	Equine: Fat tissue	0.5	EFSA (2015)	0.155	STMR-RAC	0.186	HR-RAC
1015030	Equine: Liver	0.03*	EFSA (2015)	0.03	STMR-RAC	0.03	HR-RAC
1015040	Equine: Kidney	0.03*	EFSA (2015)	0.03	STMR-RAC	0.03	HR-RAC
1015050	Equine: Edible offals (other than liver and kidney)	0.5	EFSA (2015)	0.155	STMR-RAC	0.186	HR-RAC
1016010	Poultry: Muscle/meat	0.02*	EFSA (2015)	0.0218	STMR-RAC	0.027	HR-RAC
1016020	Poultry: Fat tissue	0.1	EFSA (2015)	0.038	STMR-RAC	0.09	HR-RAC
1016030	Poultry: Liver	0.02*	EFSA (2015)	0.02	STMR-RAC	0.02	HR-RAC
1016040	Poultry: Kidney	0.02*	EFSA (2015)	0.02	STMR-RAC	0.02	HR-RAC
1016050	Poultry: Edible offals (other than liver and kidney)	0.02*	EFSA (2015)	0.02	STMR-RAC	0.02	HR-RAC
1017010	Other farmed animals: Muscle/meat	0.03	EFSA (2015)	0.155	STMR-RAC	0.061	HR-RAC
1017020	Other farmed animals: Fat tissue	0.5	EFSA (2015)	0.155	STMR-RAC	0.186	HR-RAC
1017030	Other farmed animals: Liver	0.03*	EFSA (2015)	0.03	STMR-RAC	0.03	HR-RAC
1017040	Other farmed animals: Kidney	0.03*	EFSA (2015)	0.03	STMR-RAC	0.03	HR-RAC
1017050	Other farmed animals: Edible offals (other than liver and kidney)	0.5	EFSA (2015)	0.155	STMR-RAC	0.186	HR-RAC
1020010	Milk: Cattle	0.05	EFSA (2015)	0.017	STMR-RAC	0.017	STMR-RAC
1020020	Milk: Sheep	0.05	EFSA (2015)	0.017	STMR-RAC	0.017	STMR-RAC
1020030	Milk: Goat	0.05	EFSA (2015)	0.017	STMR-RAC	0.017	STMR-RAC
1020040	Milk: Horse	0.05	EFSA (2015)	0.017	STMR-RAC	0.017	STMR-RAC
1030010	Eggs: Chicken	0.02*	EFSA (2015)	0.02	STMR-RAC	0.02	HR-RAC
1030020	Eggs: Duck	0.02*	EFSA (2015)	0.02	STMR-RAC	0.02	HR-RAC
1030030	Eggs: Goose	0.02*	EFSA (2015)	0.02	STMR-RAC	0.02	HR-RAC

Code	Commodity	Existing/ proposed MRL	Source/ type of MRL	Chronic risk assessment		Acute risk assessment	
				Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
1030040	Eggs: Quail	0.02*	EFSA (2015)	0.02	STMR-RAC	0.02	HR-RAC
1030990	Eggs: Others	0.02*	EFSA (2015)	0.02	STMR-RAC		

*: Indicates that the value is at the limit of analytical quantification (LOQ).
STMR-RAC: supervised trials median residue in raw agricultural commodity; HR-RAC: highest residue in raw agricultural commodity; CF: conversion factor for risk assessment; CXL: Codex MRL in place (https://www.fao.org/fao-who-codexalimentarius/codex-texts/dbs/pestres/pesticide-detail/en/?p_id=135).
For animal commodities: Consumption figures in the EFSA PRIMo are expressed as meat. Since the a.s. is a fat-soluble pesticide, STMR and HR residue values were calculated considering an 80%/90% muscle and 20%/10% fat content for mammal/poultry meat, respectively (FAO, 2016).

Appendix E – Used compound codes

Code/trivial name[a]	IUPAC name/SMILES notation/InChiKey[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 2021.1.3 ACD/Labs 2021.1.3 (File Version N15E41, Build 123232, 7 July 2021).
(c): ACD/ChemSketch 2021.1.3 ACD/Labs 2021.1.3 (File Version C25H41, Build 123835, 28 August 2021).