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Modification of the existing maximum residue levels for tau-fluvalinate in tomatoes and watermelons

EFSA (European Food Safety Authority),
Maria Anastassiadou, Giulia Bellisai, Giovanni Bernasconi, Alba Brancato, Luis Carrasco Cabrera, Lucien Ferreira, Luna Greco, Samira Jarrah, Aija Kazocina, Renata Leuschner, Jose Oriol Magrans, Ileana Miron, Stefanie Nave, Ragnor Pedersen, Hermine Reich, Miguel Santos, Alessia Pia Scarlato, Anne Theobald, Benedicte Vagenende and Alessia Verani

Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant ADAMA Agriculture BV on behalf of ADAMA Makhteshim Ltd submitted a request to the competent national authority in Denmark to modify the existing maximum residue levels (MRL) for the active substance tau-fluvalinate in tomatoes and watermelons. The data submitted in support of the request were found to be sufficient to derive an MRL proposal for tomatoes. For watermelons, a change of the MRL recently set in the EU legislation is not required. Adequate analytical methods for enforcement are available to control the residues of tau-fluvalinate in the commodities under consideration. Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of residues resulting from the intended uses of tau-fluvalinate according to the reported agricultural practices is unlikely to present a risk to consumer health. The risk assessment shall be regarded as indicative.

Keywords: tau-fluvalinate, fluvalinate, tomatoes, watermelons, pesticide, MRL, consumer risk assessment

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Correspondence: pesticides.mrl@efsa.europa.eu

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, ADAMA Agriculture BV on behalf of ADAMA Makhteshim Ltd submitted an application to the competent national authority in Denmark (evaluating Member State, EMS) to modify the existing maximum residue levels (MRLs) for the active substance tau-fluvalinate in tomatoes and watermelons. 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 uses of tau-fluvalinate, the EMS proposed to raise the existing MRL in tomatoes to 0.15 mg/kg and in watermelons to 0.09 mg/kg. However, an MRL of 0.09 mg/kg has been recently implemented in the EU legislation for watermelons, therefore this MRL request has become obsolete.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified a data gap which was requested from the EMS. On 7 April 2021, 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 tau-fluvalinate following foliar treatment of primary crops belonging to fruit crops, pulses/oilseeds and cereals as well as in rotational crops has been investigated in the EU pesticides peer review. With exception of cereals, the main residue in the tested primary crops was the parent compound, and the metabolism in rotational crops was similar to the metabolic pathway observed in primary crops.

The nature of the residues in processed commodities (hydrolysis studies) was investigated in the framework of the EU pesticides peer review. Tau-fluvalinate showed not to be stable under conditions simulating boiling/baking/brewing and to completely degrade under sterilisation conditions. The major degradation products were 3-phenoxybenzaldehyde and diacid, for which a full toxicological characterisation is not available. Furthermore, under conditions mimicking boiling/baking/brewing, a significant amount of unknown radioactive residues was not identified. In the framework of the current application, a new hydrolysis study testing baking/boiling conditions was provided. In this new study the unknown compounds observed in the previous hydrolysis study were not formed.

Based on the metabolic pattern identified in metabolism studies, hydrolysis studies, the toxicological significance of fluvalinate and tau-fluvalinate metabolite and degradation products and the capability of the analytical enforcement method, the residue definition for enforcement in unprocessed plant products was proposed as fluvalinate (sum of isomers); for risk assessment the residue definition was proposed as tau-fluvalinate, except for cereals where the residue definition is wider. In processed commodities, the residue definition for enforcement was proposed as fluvalinate (sum of isomers) whereas for risk assessment, in addition, 3-phenoxybenzaldehyde and diacid were included (Tau-fluvalinate, 3-phenoxybenzaldehyde and diacid). The residue definitions for processed products were set on a provisional basis pending the identification of the compounds 'A' and 'B' observed in the hydrolysis studies, full toxicological information on 3-phenoxybenzaldehyde and diacid and their magnitude in processed commodities, in particular under sterilisation processes. EFSA concluded that for the crops assessed in this application the previously derived residue definitions are applicable.

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

The available residue trials were sufficient to derive an MRL proposal of 0.15 mg/kg for tomatoes. For watermelons the submitted residue trials data indicated that a change of the MRL recently set in the EU legislation is not required.

Specific studies investigating the magnitude of residues of tau-fluvalinate and its relevant degradation products in processed tomato commodities were submitted. A reduction of residues of the active substance was observed in all edible processed commodities. The degradation products included in the provisional residue definition for risk assessment, namely 3-phenoxybenzaldehyde and diacid, are not expected to occur in processed tomato products, provided that tomatoes have been treated according to the intended Good Agricultural Practice (GAP). Watermelons are usually eaten raw.

The crops under assessment can be grown in a crop rotation. Based on the available information, it was concluded that significant residue levels are unlikely to occur in rotational crops, provided that the active substance is used according to the proposed GAP.

Residues of tau-fluvalinate 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 tau-fluvalinate was assessed in the framework of the EU pesticides peer review and the data were sufficient to derive an acceptable daily intake (ADI) of 0.005 mg/kg body weight (bw) per day and an acute reference dose (ARfD) of 0.05 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 residues in tomatoes and watermelons and in all commodities for which the MRL proposals of EFSA were implemented in the EU legislation, whereas the acute risk assessment was performed only for the crops under consideration. EFSA concluded that the proposed use of tau-fluvalinate on tomatoes and watermelons will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers' health. Although not specifically affecting the intended use on tomatoes and watermelons, the chronic consumer risk assessment shall be regarded as indicative since affected by the non-standard uncertainties identified during the MRL review for the crops which are consumed after processing.

EFSA emphasises that the above assessment does not consider the possible impact of metabolism on the isomer ratio of tau-fluvalinate and further investigation on this matter would in principle be required. EFSA would therefore recommend reconsidering this point in the framework of the peer review for the renewal of approval of the active substance.

EFSA proposes to amend the existing MRLs 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: Fluvalinate (sum of isomers) resulting from the use of tau-fluvalinate[(F)]				
0231010	Tomatoes	0.01*	0.15	The submitted data are sufficient to derive an MRL proposal for the intended SEU use. A risk for the consumers is not identified. Although not specifically affecting the intended use on tomatoes, the chronic consumer risk assessment shall be regarded as indicative since affected by the non-standard uncertainties identified during MRL review for processed commodities.
0233030	Watermelons	0.09	No change required	The submitted data do not impact the previous indicative risk assessment performed in the framework of the MRL review. Although not specifically affecting the intended use on watermelons, the chronic consumer risk assessment shall be regarded as indicative since affected by the non-standard uncertainties identified during MRL review for processed commodities.

MRL: maximum residue level; SEU: southern Europe.
*: 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.

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Assessment

The European Food Safety Authority (EFSA) received an application to modify the existing maximum residue level (MRL) for tau-fluvalinate in tomatoes and watermelons. The detailed description of the intended uses of tau-fluvalinate which are the basis for the current MRL application is reported in Appendix A.

Tau-fluvalinate is the ISO common name for (*RS*)-α-cyano-3-phenoxybenzyl *N*-(2-chloro-α,α,α-trifluoro-*p*-tolyl)-D-valinate (IUPAC). Tau-fluvalinate represents a racemic (1:1) mixture of two enantiomers (*R*-α-cyano and *S*-α-cyano isomers) whereby fluvalinate consists of four isomers. Only tau-fluvalinate is approved for use in plant protection products in the European Union (EU). The chemical structure of the active substance and its main metabolites and degradation products as well as of fluvalinate are reported in Appendix E.

Tau-fluvalinate was evaluated in the framework of Directive 91/414/EEC[1] with Denmark designated as rapporteur Member State (RMS) for the representative uses as foliar treatment on potatoes and wheat. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by EFSA (2010). Tau-fluvalinate was approved[2] for the use as insecticide on 1 June 2011.

The EU MRLs for tau-fluvalinate are established in Annex II of Regulation (EC) No 396/2005[3]. EFSA has issued several reasoned opinions on the modification of MRLs for tau-fluvalinate, including the review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review). The proposals derived in the previous reasoned opinions of EFSA (2014, 2017, 2018b) have been considered in the EU MRL legislation.[4] It is noted that an MRL application for tomatoes was previously assessed by EFSA (2014), but risk managers decided not to change the existing MRLs lacking information on the degradation products expected in processed tomato products. Codex maximum limits (CXLs) have not been set for tau-fluvalinate.

In accordance with Article 6 of Regulation (EC) No 396/2005, ADAMA Agriculture BV on behalf of ADAMA Makhteshim Ltd submitted an application to the competent national authority in Denmark (evaluating Member State, EMS) to modify the existing MRLs for the active substance tau-fluvalinate in tomatoes and watermelons. 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 25 September 2018. To accommodate for the intended uses of tau-fluvalinate, the EMS proposed to raise the existing MRL in tomatoes from 0.1 to 0.15 mg/kg, and to raise the existing MRL in watermelons from the limit of quantification (LOQ) to 0.09 mg/kg. Recently, the MRL in tomatoes was lowered to the LOQ of 0.01 mg/kg and the MRL in watermelons was set at the MRL value proposed by the EMS. Therefore, the latter MRL request is obsolete.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified a data gap which was requested from the EMS. On 7 April 2021, the EMS submitted the requested information and a revised evaluation report (Denmark, 2018), which replaced the previously submitted evaluation report.

EFSA based its assessment on the evaluation report submitted by the EMS (Denmark, 2018), the draft assessment report (DAR) and its addenda (Denmark, 2006, 2009, 2010) prepared under Directive 91/414/EEC, the Commission review report on tau-fluvalinate (European Commission, 2011), the conclusion on the peer review of the pesticide risk assessment of the active substance tau-fluvalinate (EFSA, 2010) as well as the conclusions from the EFSA opinion on the review of the existing MRLs for tau-fluvalinate according to Article 12 of Regulation (EC) No 396/2005 (EFSA, 2018b).

For this application, the data requirements established in Regulation (EU) No 544/2011[5] and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 1997a–g, 2000, 2010a,b, 2017; OECD, 2011). The assessment is performed in

[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 2011/19/EU of 2 March 2011 amending Council Directive 91/414/EEC to include tau-fluvalinate as active substance and amending Decision 2008/934/EC. OJ L 58, 3.3.2011, p. 41–44.

[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: https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/active-substances/?event=search.as

[5] 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.

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[6].

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, are presented in Appendix B.

The evaluation report submitted by the EMS (Denmark, 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 tau-fluvalinate after foliar applications was assessed in fruit crops, pulses/ oilseeds and cereals in the framework of the EU pesticides peer review and the MRL review (EFSA, 2010, 2018b). Unchanged tau-fluvalinate was the main residue in the tested crops, except in wheat grain, where polar metabolites in the form of conjugates of haloaniline and anilino acid were formed (30–64% total radioactive residue (TRR)).

EFSA concluded that the metabolism of tau-fluvalinate is sufficiently addressed in the crops under consideration, which belong to the fruit crops group. However, the possible change in the stereochemistry of the active substance was not investigated in the metabolism studies and a general data gap was identified (EFSA, 2010, 2018b). It is noted that the EFSA guidance on the risk assessment of compounds that may have stereoisomers has been finalised (EFSA, 2019b). EFSA would therefore recommend to reconsider this point in the framework of the peer review for the renewal of approval of the active substance.

1.1.2. Nature of residues in rotational crops

The crops under consideration can be grown in rotation with other crops. The metabolism of tau-fluvalinate in rotational crops was assessed in the framework of the EU pesticides peer review and the MRL review (EFSA, 2010, 2018b). Tau-fluvalinate was the main residue and major metabolites were not formed. The studies, which were performed with the active substance radiolabelled in the aniline ring, did not investigate the potential varying in enantiomer ratios of tau-fluvalinate and further investigation would be in principle required (see Section 1.1.1). The metabolism of tau-fluvalinate in rotational crops was concluded to be similar to the metabolic pathway observed in primary crops.

1.1.3. Nature of residues in processed commodities

The effect of processing on the nature of tau-fluvalinate was investigated in the framework of the EU pesticides peer review with tau-fluvalinate radiolabelled on the aniline and the benzyl ring (EFSA, 2010). These studies showed that the active substance progressively degraded with increased temperature and pH, up to 60% under boiling/brewing/baking and completely (100%) under sterilisation conditions.

The major degradation products were 3-phenoxybenzaldehyde (3-PBAld) at sterilisation (96.8% of applied radioactivity (AR), benzyl radiolabelled study), diacid at boiling/baking/brewing and at sterilisation (22.3% and 90.1% of AR, respectively, aniline radiolabelled study) and anilino acid at boiling/baking/brewing (13.5% of AR, aniline radiolabelled study). Under pasteurisation conditions tau-fluvalinate showed to be relatively stable. A full toxicological characterisation of 3-phenoxybenzaldehyde and diacid is not available (EFSA, 2018b). The MRL review however noted that 3-phenoxybenzaldehyde[7] and diacid may not be retrieved in practice and recommended to keep

[6] 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.

[7] The compound 3-phenoxybenzaldehyde is also a common hydrolysis degradation product of other synthetic pyrethroids (EFSA, 2014).

investigating their occurrence in any new study assessing the magnitude of residues in processed commodities and to address the data gaps regarding their toxicity (EFSA, 2018b).

In the original hydrolysis studies, under mimic conditions of boiling/baking/brewing, a significant amount of the radioactive residue was not identified: two highly polar compounds 'A' and 'B' accounted for 14.7% and 10.2% of the AR, respectively (EFSA, 2010, 2018b). In the framework of the current application, a new hydrolysis study testing boiling/baking/brewing conditions was provided. The active substance was radiolabelled in the benzyl ring to obtain these unidentified compounds and the samples (in duplicate) were analysed within 1 day of the experiment. In this new study, tau-fluvalinate showed to be stable (91.7–94.5% of AR). The previously observed unknown compounds 'A' and 'B' were not formed and, therefore, could not be structurally determined. Although following similar extraction techniques and analyses as described in the original study, the new study was unable to reproduce the previous findings. According to the EMS, a plausible explanation for the different results could have been the use of strong acidification for a longer period during the extraction phase coupled with the very low water solubility of the parent compound, which might explain the hydrolytic instability of tau-fluvalinate in the first experiment (Denmark, 2018).

1.1.4. Methods of analysis in plants

Analytical methods for the determination of tau-fluvalinate residues in plant commodities were assessed in the framework of the EU pesticides peer review and the MRL review (EFSA, 2010, 2018b).

The methods were concluded to be sufficiently validated for the determination of tau-fluvalinate residues in all four plant matrices, including the crops under consideration (high water content matrices). The methods allow quantifying residues at or above the LOQ of 0.01 mg/kg. The LOQ of 0.01 mg/kg is achievable by using the QuEChERS method in routine analyses (EFSA, 2018b). The available enforcement methods analyse fluvalinate without distinction between tau-fluvalinate and fluvalinate (EFSA, 2010, 2018b).

EFSA concluded that sufficiently validated analytical methods are available for the enforcement of fluvalinate, as sum of any ratio of its constituent isomers, in the crops under consideration.

1.1.5. Stability of residues in plants

The storage stability of tau-fluvalinate was investigated in the framework of the EU pesticides peer review (EFSA, 2010). The available studies demonstrated that tau-fluvalinate is stable in high water, high acid, high oil content, dry commodities and in specific matrices (wheat straw) for a period of 18 months when stored under frozen conditions. Stability of 3-phenoxybenzaldehyde, diacid and anilino acid in peach juice and puree (high water processed commodities) was reported to be at least 12 months under frozen conditions.

1.1.6. Proposed residue definitions

Based on the metabolic pattern identified in metabolism studies, the results of hydrolysis studies, the toxicological significance of fluvalinate[8] and of the relevant tau-fluvalinate metabolite and degradation products, the capabilities of enforcement analytical methods, the following residue definitions were proposed by the EU pesticides peer review and the MRL review (EFSA, 2010, 2018b).

- **Residue for risk assessment**:

Unprocessed plant commodities, except cereals: Tau-fluvalinate

Unprocessed cereals: Sum of tau-fluvalinate and anilino acid, including their conjugates, expressed as tau-fluvalinate

Processed plant commodities: Tau-fluvalinate, 3-phenoxybenzaldehyde and diacid (provisional)

- **Residue definition for enforcement**:

Unprocessed plant commodities, except cereals: Fluvalinate (sum of isomers)

Processed plant commodities: Fluvalinate (sum of isomers) (provisional)

The residue definition for enforcement included in Regulation (EC) No 396/2005 is identical with the above-mentioned residue definition, but it specifies that residues are resulting from the use of tau-

[8] Fluvalinate showed to be more toxic than tau-fluvalinate (EFSA, 2010).

fluvalinate, which is the only approved active substance for use in plant protection products in the European Union. The same residue definitions are applicable to rotational crops.

For processed products, the residue definitions were set on provisional basis, pending the identification of the compounds 'A' and 'B' observed in the hydrolysis studies, full toxicological information on 3-phenoxybenzaldehyde and diacid and their magnitude in processed commodities, in particular under sterilisation processes (EFSA, 2018b).

EFSA concluded that for the crops under assessment the above residue definitions are appropriate. Considering that the new hydrolysis study, mimicking conditions of boiling/baking/brewing, was unable to reproduce the two unknown compounds (see Section 1.1.3) and that the submitted processing studies on tomatoes gave an indication that residues of 3-phenoxybenzaldehyde and diacid are not expected to occur (see Section 1.2.3.), further studies to address the uncertainties identified in the framework of the MRL review related to processed products are not necessary for the intended use on tomatoes. Watermelons are usually eaten raw, unprocessed.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

In support of the current MRL application, the applicant referred to residue trials in tomatoes and melons previously assessed by EFSA (2014, 2018b). According to the previous assessments, the storage integrity of the samples and the suitability of the analytical methods used to quantify the residues was demonstrated.

Tomatoes

The data on eight Good Agricultural Practice (GAP)-compliant residue trials performed on tomatoes in Southern Europe were re-submitted (Denmark, 2018). These studies have been previously assessed by EFSA and concluded to be sufficient to derive an MRL proposal of 0.15 mg/kg for tomatoes in support of the same southern Europe (SEU) use (EFSA, 2014). EFSA confirms the previous conclusions as valid for the present MRL request in tomatoes.

Watermelons

The results of 10 GAP-compliant residue trials performed on melons in Southern Europe were already concluded to be sufficient to derive by extrapolation an MRL proposal of 0.09 mg/kg in watermelons (EFSA, 2018b). Since this MRL proposal has been recently implemented in the EU legislation, the present MRL request on watermelons is obsolete.

The results of the residue trials, the related risk assessment input values (highest residue, median residue) and the MRL proposals are summarised in Appendix B.

1.2.2. Magnitude of residues in rotational crops

The possible transfer of tau-fluvalinate soil residues to crops that are grown in crop rotation has been assessed in the EU pesticides peer review and the MRL review (EFSA, 2010, 2018b). The available confined rotational crop studies demonstrated that significant residues (above 0.01 mg/kg) are not expected in succeeding crops planted in soil treated at 144 g/ha. The study covers the plateau for the parent tau-fluvalinate, but not that of the metabolite haloaniline which was nevertheless below the LOQ of 0.01 mg/kg. Field studies were not considered necessary (EFSA, 2018b).

Since the maximum total application rate for the crops under consideration (i.e. 2 $\times$ 72 g/ha) is equal to the application rate tested in the rotational crop studies, no residues are expected in rotational crops grown after the harvest of tomatoes and watermelons, provided that the active substance is applied according to the proposed GAP.

1.2.3. Magnitude of residues in processed commodities

Three new processing studies on tomatoes have been submitted (Denmark, 2018). Tomatoes from field trials conducted at exaggerate rate (two applications, the second 5 times the nominal application rate of the intended use) were washed and peeled or washed and processed into juice, pomace (wet and dry), puree, ketchup, paste, canned tomatoes and dried tomatoes. The raw tomatoes and the processed samples were analysed for tau-fluvalinate, 3-phenoxybenzaldehyde and diacid. The production of puree, ketchup, paste and canned tomatoes included sterilisation conditions. A reduction

of tau-fluvalinate residues was observed in all processed commodities, except in pomaces and dried tomatoes. Although the active substance was applied at an exaggerated rate, diacid was never detected (< LOD) and 3-phenoxybenzaldehyde was not detected in the 80% of the samples; only one specimen of dried pomace had quantifiable residues (0.025 mg/kg). Anyway, tomato pomace is neither used for food nor for feed consumption.

Additional two studies on processed tomatoes were assessed in the framework of the MRL review (EFSA, 2018b). Tomatoes from field treatment at exaggerated rate (one application, at 2.7 and 5 times the nominal single application rate of the intended use, respectively) were washed and peeled and then processed into sterilised canned tomatoes. Samples were analysed for the parent compound and 3-phenoxybenzaldehyde but not for diacid, which is included in the provisional residue definition for risk assessment. Tau-fluvalinate residues in canned tomatoes were < LOQ of 0.01 mg/kg. Although the active substance was applied at exaggerated rates, no residues of 3-phenoxybenzaldehyde were determined in samples of canned tomatoes before and after sterilisation.

Watermelons are usually eaten raw, unprocessed. Information on the distribution of residues in the peel and the pulp is not available as the MRL proposal was supported by extrapolation from residue trials on melons.

Overall, the available processing studies on tomatoes gave an indication that detectable residues of 3-phenoxybenzaldehyde and diacid are not expected in processed products subject to processes involving heat treatment when raw tomatoes are treated according to the intended use of tau-fluvalinate. In case of future uses of tau-fluvalinate on crops that could be eaten processed, in particular undergoing sterilisation process, the occurrence of 3-phenoxybenzaldehyde and diacid and their toxicological profile in comparison with the toxicity profile of the parent tau-fluvalinate should be addressed (EFSA, 2018b).

The summary of the available processing studies on tomatoes is given in the Appendix B. The processing factors derived should be considered as tentative, pending the finalisation of the residue definitions.

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 (see Appendix B.4). In Section 3, EFSA assessed whether residues on these crops resulting from the intended uses are likely to pose a consumer health risk.

2. Residues in livestock

The crops under consideration are not fed to animals.

3. Consumer risk assessment

EFSA performed a dietary risk assessment using revision 3.1 of the EFSA PRIMo (EFSA, 2018a, 2019a). 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 tau-fluvalinate used in the risk assessment (i.e. acceptable daily intake (ADI) and acute reference dose (ARfD) values) were derived in the framework of the EU pesticides peer review (European Commission, 2011).

Short-term (acute) dietary risk assessment

The short-term exposure assessment was performed only for tomatoes and watermelons in accordance with the internationally agreed methodology. The calculations were based on the highest residue (HR) derived from supervised field trials and the complete list of input values can be found in Appendix D.1.

The short-term exposure did not exceed the ARfD for any of the two crops assessed in this application (see Appendix B.3).

Long-term (chronic) dietary risk assessment

In the framework of the MRL review a comprehensive long-term exposure assessment was performed, taking into account the existing uses at EU level (EFSA, 2018b). EFSA updated the calculation with the median residue values (STMR) derived from the supervised residue trials submitted

in support of this MRL application for tomatoes. For watermelons, a change of the previously applied input value is not necessary. Conversion factors for risk assessment were applied for cereal grains and for animal commodities. The input values used in the exposure calculations are summarised in Appendix D.1.

The estimated long-term dietary intake was up to 66% of the ADI (Dutch toddler). The contribution of residues expected in the commodities assessed in this application to the overall long-term exposure is presented in detail in Appendix B.3.

EFSA concluded that the long-term intake of residues of tau-fluvalinate resulting from the existing and the intended uses is unlikely to present a risk to consumer health. Although not specifically affecting the intended use on tomatoes and watermelons, the chronic consumer risk assessment shall be regarded as indicative since affected by the non-standard uncertainties identified during MRL review for the crops which are consumed after processing.

Furthermore, EFSA emphasises that the above risk assessment does not consider the possible impact of plant and animal metabolism on the isomer ratio of tau-fluvalinate and further investigation on this matter would in principle be required (EFSA, 2018b). EFSA would therefore recommend reconsidering this point in the framework of the peer review for the renewal of approval of the active substance.

4. Conclusion and Recommendations

The data submitted in support of this MRL application were found to be sufficient to derive an MRL proposal for tomatoes. For watermelons a change of the MRL recently set in the EU legislation is not required.

EFSA concluded that the proposed use of tau-fluvalinate on tomatoes and watermelons will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers' health. Although not specifically affecting the intended use on tomatoes and watermelons, the chronic consumer risk assessment shall be regarded as indicative since affected by the non-standard uncertainties identified during MRL review for the crops which are consumed after processing.

The MRL recommendations are summarised in Appendix B.

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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
CF	conversion factor for enforcement to risk assessment residue definition
CXL	Codex maximum residue limit
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
EMS	evaluating Member State
EURL	EU Reference Laboratory (former Community Reference Laboratory (CRL))
EW	emulsion, oil in water
FAO	Food and Agriculture Organization of the United Nations
GAP	Good Agricultural Practice
GC-ECD	gas chromatography with electron capture detector
GC-MS/MS	gas chromatography with tandem mass spectrometry
GC-QqQ-MS/MS	gas-chromatography-triple quadrupole mass spectrometry
HR	highest residue
IEDI	international estimated daily intake
IESTI	international estimated short-term intake

ILV	independent laboratory validation
InChiKey	International Chemical Identifier Key
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
LC–MS	liquid chromatography with mass spectrometry
LC-MS/MS	liquid chromatography with tandem mass spectrometry
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
NEU	northern Europe
OECD	Organisation for Economic Co-operation and Development
PF	processing factor
PHI	preharvest interval
P_{ow}	partition coefficient between n-octanol and water
PRIMo	(EFSA) Pesticide Residues Intake Model
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
RA	risk assessment
RAC	raw agricultural commodity
RD	residue definition
RMS	rapporteur Member State
SANCO	Directorate-General for Health and Consumers
SEU	southern Europe
SMILES	simplified molecular-input line-entry system
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
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			Unit	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			
Tomatoes	SEU	F	Aphididae (1APHIF), Tobacco Budworm (*Helicoyerpa armigera*, HELIAR), Thripidae spp.	EW	240 g/L	Foliar spray	BBCH 10–89	1–2	14	14.4–36	200–500	72	g a.s./ ha	3	
Watermelons	SEU	F	Aphididae (1APHIF), Thripidae spp. (1THRIF)	EW	240 g/L	Foliar spray	BBCH 15–89	1–2	14	4.8–14.4	500–1,000	72	g a.s./ ha	7	GAP assessed in the MRL review (EFSA, 2018b).

NEU: northern European Union; SEU: southern European Union; MS; Member State; a.s.: active substance; EW: emulsion, oil in water; GAP: Good Agricultural Practice.
(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. 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**	**Crops**	**Applications**	**Sampling (DAT)**	**Comment/Source**
	Fruit crops	Apple	Foliar spray, 4 × 144 g/ha	29	Radiolabelled active substance: [aniline-U-^{14}C]-tau-fluvalinate and [benzyl-U-^{14}C]-tau-fluvalinate (EFSA, 2010)
	Cereals/ grass	Wheat	Foliar spray, 2 × 60 g/ha or 2 × 600 g/ha (BBCH 59 and 67)	5, 53	Radiolabelled active substance: [aniline-U-^{14}C]-tau-fluvalinate and [benzyl-U-^{14}C]-tau-fluvalinate (EFSA, 2010)
		Wheat	Foliar spray, 2 × 65 g/ha or 2 × 510 g/ha (BBCH 47/55 and 69)	37	Radiolabelled active substance: [benzotrifluoride-U-^{14}C]-tau-fluvalinate (EFSA, 2010)
	Pulses/ oilseeds	Alfalfa	Foliar treatment, 1 × either 167 g/ha, 500 g/ha or 1110 g/ha	44, 69 (seeds) 7, 35, 77 (forage) 13, 39, 81 (hay)	Radiolabelled active substance: [aniline-U-^{14}C]-tau-fluvalinate and [benzyl-U-^{14}C]-tau-fluvalinate (EFSA, 2010)
Rotational crops (available studies)	**Crop groups**	**Crops**	**Application**	**PBI (DAT)**	**Comment/Source**
	Root/tuber crops	Radish	Bare soil, 144 g/ha	28, 119	Radiolabelled active substance: [aniline-U-^{14}C]-tau-fluvalinate. (EFSA, 2010)
	Leafy crops	Lettuce	Bare soil, 144 g/ha	28, 119	Radiolabelled active substance: [aniline-U-^{14}C]-tau-fluvalinate. (EFSA, 2010)
	Cereal (small grain)	Spring wheat/ Winter wheat	Bare soil, 144 g/ha	28, 119, 364/182	Radiolabelled active substance: [aniline-U-^{14}C]-tau-fluvalinate. (EFSA, 2010)
Processed commodities (hydrolysis study)	**Conditions**		**Stable?**		**Comment/Source**
	Pasteurisation (20 min, 90°C, pH 4)		Yes		Radiolabelled active substance: [aniline-^{14}C]-tau-fluvalinate and [benzyl-^{14}C]-tau-fluvalinate; Tau-fluvalinate: 90.9–100% AR. (EFSA, 2010)
	Baking, brewing and boiling (60 min, 100°C, pH 5)		No		Radiolabelled active substance: [aniline-^{14}C]-tau-fluvalinate and [benzyl-^{14}C]-tau-fluvalinate; Tau-fluvalinate: 40.8–62.7% AR; Anilino acid: 13.5% AR; Diacid: 22.3% AR. (EFSA, 2010)

		Yes	Radiolabelled active substance: [benzyl-^{14}C]-tau-fluvalinate; Tau-fluvalinate: 91.7–94.5% AR. (Denmark, 2018)
	Sterilisation (20 min, 120°C, pH 6)	No	Radiolabelled active substance: [aniline-^{14}C]-tau-fluvalinate and [benzyl-^{14}C]-tau-fluvalinate; Tau-fluvalinate: < 1.7–< 2.2% AR; 3-PBAld: 96.8% AR; Diacid: 90.1% AR. (EFSA, 2010)

Can a general residue definition be proposed for primary crops?	Yes	EFSA (2010)
Rotational crop and primary crop metabolism similar?	Yes	EFSA (2010)
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Pasteurisation: yes Boiling/baking/brewing and sterilisation: no	EFSA (2018b)
Plant residue definition for monitoring (RD-Mo)	**Plant commodities**: Fluvalinate (sum of isomers), resulting from the use of tau-fluvalinate (Reg (EC) No 396/2015) Fluvalinate (sum of isomers) (EFSA, 2018b) **Processed commodities**: Fluvalinate (sum of isomers) (provisional)[(a)] (EFSA, 2018b)	
Plant residue definition for risk assessment (RD-RA)	**Plant commodities, except cereals**: Tau-fluvalinate **Cereals**: Sum of tau-fluvalinate and anilino acid, including their conjugates, expressed as tau-fluvalinate **Processed commodities**: Tau-fluvalinate, 3-phenoxybenzaldehyde and diacid (provisional)[(b)] (EFSA, 2018b)	
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)	Matrices with high water, high acid, high oil content and dry matrices: • GC-ECD, validated in apples, beans, oilseed rape, potatoes, peaches, wheat grain and straw; LOQ = 0.01 mg/kg; ILV and confirmatory GC and LC-MS methods available (EFSA, 2010; 2014) • LC–MS/MS, validated in strawberries; LOQ = 0.01 mg/kg; ILV available (EFSA, 2017) • GC–MS/MS method, validated in orange, potatoes, spring onions and avocado; LOQ = 0.01 mg/kg (EFSA, 2018b) • GC–QqQ–MS/MS method, validated in barley and rice; LOQ = 0.01 mg/kg (EFSA, 2018b) These methods do not distinguish tau-fluvalinate from fluvalinate.	

DAT: days after treatment; BBCH: growth stages of mono- and dicotyledonous plants; PBI: plant-back interval; AR: applied radioactivity; LOQ: limit of quantification; GC-ECD: gas chromatography with electron capture detector; ILV: independent laboratory validation; LC–MS: liquid chromatography with mass spectrometry; LC–MS/MS: liquid chromatography with tandem mass spectrometry; GC–MS/MS: gas chromatography with tandem mass spectrometry; GC–QqQ-MS/MS: gas-chromatography-triple quadrupole tandem mass spectrometry.

(a): For processed products undergoing boiling/baking/brewing and sterilisation, the residue definition as fluvalinate (sum of isomers) was proposed by default since residues of tau-fluvalinate and its degradation products have not been found above the LOQ in the processing studies which were assessed in the framework of the MRL review (EFSA, 2018b).

(b): Toxicological information on the metabolites 3-phenoxybenzaldehyde and diacid and identification of components A and B is pending (EFSA, 2018b). However, in a new hydrolysis study the unknown components A and B were not formed (Denmark, 2018).

B.1.1.2. Stability of residues in plants

Plant products (available studies)	Category	Commodity	T (°C)	Stability period[a]		Compounds covered	Comment/ Source
				Value	Unit		
	High water content	Apples, tomatoes, melons	–18	18	Months	Tau-fluvalinate	EFSA (2010)
	High oil content	Avocados, rapeseeds	–18	18	Months	Tau-fluvalinate	EFSA (2010)
	Dry/high protein content	Peas (pods and seeds)	–18	18	Months	Tau-fluvalinate	EFSA (2010)
	Dry/High starch content	Wheat grain	–18	18	Months	Tau-fluvalinate	EFSA (2010)
	Specific matrix	Wheat straw	–18	18	Months	Tau-fluvalinate	EFSA (2010)
	High acid content	Grapes	–18	18	Months	Tau-fluvalinate	EFSA (2010)
	Processed products	Peach juice and puree	–18	12	Months	Diacid	EFSA (2010)
	Processed products	Peach juice and puree	–18	12	Months	3-phenoxybenzaldehyde	EFSA (2010)
	Processed products	Peach juice and puree	–18	12	Months	Anilino acid	EFSA (2010)

(a): Storage stability study duration up to 18 months (unprocessed commodities) and 12 months (processed commodities).

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)	Comments/Source	Calculated MRL (mg/kg)	HR[b] (mg/kg)	STMR[c] (mg/kg)	CF[d]
Tomatoes	SEU	< 0.01; 0.01; 2 × 0.02; 2 × 0.03; 0.05; 0.09	Residue trials on tomatoes compliant with the GAP already assessed by EFSA (EFSA, 2014).	0.15	0.09	0.03	n/a
Watermelons	SEU	3 × < 0.01; 0.01; 0.02; 3 × 0.03; 0.04; 0.06	Residue trials on melons compliant with the GAP on watermelons already assessed by EFSA (EFSA, 2018b). Extrapolation to watermelons possible.	0.09	0.06	0.03	n/a

MRL: maximum residue level; GAP: Good Agricultural Practice; n/a: not applicable.
(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Indoor: indoor EU trials or Country code: if non-EU trials.
(b): Highest residue. 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.

B.1.2.2. Residues in rotational crops

Residues in rotational and succeeding crops expected based on confined rotational crop study?	No	In the confined rotational crop study performed at 144 g/ha, the transfer of tau-fluvalinate residues from the soil into succeeding crops was very low (EFSA, 2010). The confined rotational crop study covers the plateau for the parent tau-fluvalinate, however not that of the metabolite haloaniline which is nevertheless below the LOQ of 0.01 mg/kg (EFSA, 2018b).
Residues in rotational and succeeding crops expected based on field rotational crop study?	Not triggered	No field rotational crop study available; not considered necessary (EFSA, 2018b).

LOQ: limit of quantification.

B.1.2.3. Processing factors

Processed commodity	Number of valid studies[a]	Processing Factor (PF)		CF_P[b]	Comment[c]/Source
		Individual values	Median PF		
Tomato, washed and peeled	3	0.06; 2 × < 0.09	< 0.09	n/a	Tentative (Denmark, 2018)
Tomato, juice (pasteurised)	3	0.12; 0.27; 0.36	0.36	n/a	Tentative (Denmark, 2018)
Tomato, wet pomace	3	1.38; 2.64; 3.36	2.64	n/a	Tentative (Denmark, 2018)
Tomato, dried pomace	3	6.18; 6.35; 8.45	6.35	n/a	Tentative (Denmark, 2018)
Tomato, Paste (sterilised)	3	0.79; 2 × 1.00	1.00	n/a	Tentative (Denmark, 2018)
Tomato, puree (sterilised)	3	0.36; 0.55; 0.68	0.55	n/a	Tentative (Denmark, 2018)
Tomato, ketchup (sterilised)	3	0.53; 2 × 0.64	0.64	n/a	Tentative (Denmark, 2018)
Tomato, canned (sterilised)	3	0.03; 0.09; 0.18	0.09	n/a	Tentative (Denmark, 2018)
	2	< 0.05; < 0.13	< 0.09	n/a	Tentative (EFSA, 2018b) not analysed for diacid
Tomato, dried	3	1.79; 4.18; 5.55	4.18	n/a	Tentative (Denmark, 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. Median and individual conversion factors for each processing study could not be derived since the degradation products included in the provisional residue definition for risk assessment, namely 3-phenoxybenzaldehyde and diacid, are not expected to be detected in processed products which undergoes sterilisation conditions at the intended application rate.
(c): A tentative PF is derived, pending finalisation of the residue definition for risk assessment in processed products.

B.3. Residues in livestock

Not relevant.

B.4. Consumer risk assessment

ARfD	0.05 mg/kg bw (European Commission, 2011)
Highest IESTI, according to EFSA PRIMo	Tomatoes: 10% of ARfD Watermelon: 15% of ARfD
Assumptions made for the calculations	The calculation is based on the highest residue levels (HR) derived in the raw agricultural commodities (tomatoes, watermelons) based on supervised residue trials submitted in support of this MRL application. The calculation was performed with PRIMo rev. 3.1

ADI	0.005 mg/kg bw per day (European Commission, 2011)
Highest IEDI, according to EFSA PRIMo	66 % ADI (NL toddler) Contribution of crops assessed: Tomatoes: 2.15% of ADI (GEMS/Food G06) Watermelons: 0.67% of ADI (GEMS/Food G06)
Assumptions made for the calculations	The calculation is based on the median residue levels (STMR) derived for raw agricultural commodities based on supervised residue trials submitted in support of this MRL application and the STMRs as derived in the framework of the MRL review (EFSA, 2018b). For cereals, a conversion factor for risk assessment of 4 was used (EFSA, 2010). For animal commodities the following conversion factors were applied: mammals = muscle: 1.3; fat: 1.1; liver 11.2, kidney: 10.5; milk: 1.5 (EFSA, 2010) poultry= fat: 1.4; eggs: 3.5 (EFSA, 2018b). The contributions of commodities where no GAP was reported in the framework of the MRL review (EFSA, 2018b) were not included in the calculation. The risk assessment shall be regarded as indicative and affected by non-standard uncertainties identified during the MRL review for processed commodities subject to sterilisation processes (EFSA, 2018b). The calculation was performed with PRIMo rev. 3.1

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

B.5. Recommended MRLs

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Fluvalinate (sum of isomers) resulting from the use of tau-fluvalinate[(F)]				
0231010	Tomatoes	0.01*	0.15	The submitted data are sufficient to derive an MRL proposal for the intended SEU use. A risk for the consumers is not identified. Although not specifically affecting the intended use on tomatoes, the chronic consumer risk assessment shall be regarded as indicative since affected by the non-standard uncertainties identified during MRL review for processed commodities.
0233030	Watermelons	0.09	No change required	The submitted data do not impact the previous indicative risk assessment performed in the framework of the MRL review. Although not specifically affecting the intended use on watermelons, the chronic consumer risk assessment shall be regarded as indicative since affected by the non-standard uncertainties identified during MRL review for processed commodities.

MRL: maximum residue level; SEU: southern Europe.
*: 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; 2021/01/06

Fluvalinate (sum of isomers) resulting from the use of tau-fluvalinate (F)

LOQs (mg/kg) range from: 0.01 to: 0.05

Toxicological reference values

ADI (mg/kg bw per day):	0.005	ARfD (mg/kg bw):	0.05
Source of ADI:	European Commission	Source of ARfD:	European Commission
Year of evaluation:	2011	Year of evaluation:	2011

Input values

Details – chronic risk assessment | Supplementary results – chronic risk assessment | Details – acute risk assessment/children | Details – acute risk assessment/adults

Comments: MRLs according to Regulation (EU) 2020/785.

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)	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)
	66%	NL toddler	3.32	22%	Milk: Cattle	13%	Apples	5%	Pears	0.0%	66%
	49%	DE child	2.43	15%	Apples	8%	Oranges	7%	Milk: Cattle	0.1%	49%
	37%	NL child	1.84	9%	Milk: Cattle	7%	Apples	3%	Table grapes	0.0%	37%
	32%	FR child 3 15 yr	1.62	8%	Milk: Cattle	7%	Oranges	4%	Wheat	0.0%	32%
	30%	FR toddler 2 3 yr	1.48	11%	Milk: Cattle	4%	Apples	3%	Oranges	0.0%	30%
	29%	UK infant	1.45	14%	Milk: Cattle	3%	Oranges	2%	Wheat	0.0%	29%
	29%	GEMS/Food G07	1.44	5%	Barley	5%	Wine grapes	3%	Wheat		29%
	27%	GEMS/Food G08	1.36	7%	Barley	3%	Wine grapes	3%	Wheat		27%
	27%	GEMS/Food G11	1.34	6%	Barley	3%	Wine grapes	3%	Wheat		27%
	27%	GEMS/Food G15	1.33	6%	Barley	4%	Wheat	3%	Wine grapes		27%
	26%	DK child	1.29	5%	Milk: Cattle	4%	Rye	4%	Wheat		26%
	26%	DE general	1.29	4%	Milk: Cattle	4%	Barley	3%	Oranges	0.0%	26%
	25%	DE women 14-50 yr	1.23	4%	Milk: Cattle	4%	Oranges	3%	Apples	0.0%	25%
	24%	UK toddler	1.21	7%	Milk: Cattle	4%	Oranges	3%	Wheat	0.0%	24%
	23%	RO general	1.16	5%	Wine grapes	4%	Milk: Cattle	4%	Wheat	0.0%	23%
	23%	GEMS/Food G10	1.15	5%	Barley	3%	Wheat	2%	Oranges		23%
	23%	IE adult	1.14	4%	Wine grapes	2%	Oranges	2%	Wheat		23%
	22%	GEMS/Food G06	1.11	6%	Wheat	3%	Table grapes	2%	Tomatoes		22%
	21%	ES child	1.07	4%	Milk: Cattle	4%	Oranges	4%	Wheat	0.0%	21%
	21%	SE general	1.06	5%	Bovine: Muscle/meat	4%	Milk: Cattle	3%	Wheat	0.0%	21%
	19%	NL general	0.95	3%	Milk: Cattle	2%	Barley	2%	Oranges	0.0%	19%
	19%	PT general	0.93	8%	Wine grapes	3%	Wheat	1%	Apples		19%
	18%	ES adult	0.90	4%	Barley	3%	Oranges	2%	Wheat	0.0%	18%
	18%	FR adult	0.89	7%	Wine grapes	2%	Wheat	2%	Milk: Cattle	0.0%	18%
	13%	FR infant	0.66	6%	Milk: Cattle	2%	Apples	1%	Beans (with pods)	0.0%	13%
	12%	FI 3 yr	0.62	5%	Oat	1%	Apples	1.0%	Wheat	0.0%	12%
	12%	DK adult	0.59	3%	Wine grapes	2%	Milk: Cattle	1%	Apples		12%
	12%	IT toddler	0.58	5%	Wheat	1%	Apples	1.0%	Oranges		12%
	11%	UK vegetarian	0.55	3%	Wine grapes	2%	Oranges	2%	Wheat		11%
	11%	UK adult	0.54	3%	Wine grapes	1%	Wheat	1%	Oranges	0.0%	11%
	10%	LT adult	0.48	2%	Apples	1%	Milk: Cattle	0.9%	Rye		10%
	9%	IT adult	0.46	3%	Wheat	1.0%	Apples	0.7%	Oranges		9%
	9%	FI 6 yr	0.44	3%	Oat	0.8%	Wheat	0.8%	Potatoes	0.0%	9%
	6%	FI adult	0.31	1%	Oat	1.0%	Wine grapes	0.8%	Oranges		6%
	6%	PL general	0.30	2%	Apples	1%	Table grapes	0.7%	Potatoes		6%
	4%	IE child	0.19	1%	Milk: Cattle	0.9%	Wheat	0.4%	Apples	0.0%	4%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Fluvalinate (sum of isomers) resulting from the use of tau-fluvalinate (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): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
85%	Table grapes	1/0.58	42
69%	Oranges	0.4/0.26	34
44%	Pears	0.3/0.16	22
41%	Grapefruits	0.4/0.26	20
40%	Escaroles/broad-leaved	0.7/0.5	20
38%	Lettuces	0.7/0.5	19
38%	Peaches	0.3/0.2	19
34%	Apples	0.3/0.16	17
31%	Mandarins	0.4/0.26	15
20%	Cauliflowers	0.3/0.17	9.8
18%	Melons	0.09/0.06	9.1
18%	Lemons	0.4/0.26	8.9
15%	Watermelons	0.09/0.06	7.3
14%	Broccoli	0.3/0.17	7.1
14%	Apricots	0.3/0.2	7.0
13%	Globe artichokes	0.8/0.37	6.5
12%	Head cabbages	0.3/0.14	6.2
11%	Wine grapes	1/0.58	5.4
10%	Limes	0.4/0.26	5.2
10%	Tomatoes	0.15/0.09	5.2
9%	Beans (with pods)	0.6/0.39	4.5
8%	Quinces	0.3/0.16	3.9
6%	Peas (with pods)	0.6/0.39	3.2
5%	Aubergines/egg plants	0.15/0.09	2.3
4%	Barley	0.4/0.4	2.2
4%	Milk: Cattle	0.03/0.02	2.2

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Commodities	input for RA (mg/kg)	Exposure (µg/kg bw)
39%	Table grapes	1/0.58	20
28%	Wine grapes	1/0.58	14
20%	Escaroles/broad-leaved	0.7/0.5	10
16%	Oranges	0.4/	8.0
12%	Lettuces	0.7/0.5	6.1
12%	Head cabbages	0.3/	5.9
10%	Pears	0.3/	4.9
10%	Globe artichokes	0.8/	4.8
9%	Mandarins	0.4/	4.7
9%	Grapefruits	0.4/	4.6
9%	Apples	0.3/	4.5
8%	Broccoli	0.3/	4.1
8%	Cauliflowers	0.3/	3.9
7%	Peaches	0.3/0.2	3.7
6%	Beans (with pods)	0.6/	3.0
5%	Red mustards	0.7/0.5	2.7
5%	Aubergines/egg plants	0.15/	2.4
5%	Watermelons	0.09/	2.4
5%	Quinces	0.3/	2.4
5%	Melons	0.09/	2.4
5%	Lemons	0.4/	2.3
4%	Apricots	0.3/0.2	2.2
4%	Barley	0.4/0.4	1.9
4%	Limes	0.4/	1.8
4%	Cherries (sweet)	0.4/	1.8
3%	Tomatoes	0.15/	1.4

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): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
66%	Escaroles/broad-leaved endi	0.7/0.5	33
27%	Broccoli/boiled	0.3/0.17	13
24%	Cauliflowers/boiled	0.3/0.17	12
14%	Wine grapes/juice	1/0.16	7.0
11%	Oranges/juice	0.4/0.1	5.3
10%	Peaches/canned	0.3/0.2	5.2
10%	Beans (with pods)/boiled	0.6/0.39	4.9
6%	Apples/juice	0.3/0.06	3.2
4%	Pears/juice	0.3/0.06	2.0
3%	Peaches/juice	0.3/0.09	1.5
3%	Oat/boiled	0.4/0.4	1.5
3%	Barley/cooked	0.4/0.4	1.5
2%	Oat/milling (flakes)	0.4/0.4	1.2
2%	Sugar beets (root)/sugar	0.01/0.12	1.1
2%	Potatoes/fried	0.01/0.01	0.93

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/ input for RA (mg/kg)	Exposure (µg/kg bw)
20%	Escaroles/broad-leaved	0.7/0.5	10
14%	Cauliflowers/boiled	0.3/	7.1
11%	Wine grapes/wine	1/0.58	5.5
8%	Broccoli/boiled	0.3/	4.1
7%	Table grapes/raisins	1/2.73	3.3
7%	Wine grapes/juice	1/0.16	3.3
6%	Barley/beer	0.4/	2.9
4%	Apples/juice	0.3/	2.0
3%	Peaches/canned	0.3/0.2	1.6
3%	Oranges/juice	0.4/0.1	1.5
3%	Peas (with pods)/boiled	0.6/	1.3
2%	Grapefruits/juice	0.4/0.1	1.1
1%	Kohlrabies/boiled	0.08/	0.64
1%	Oat/boiled	0.4/0.4	0.61
0.9%	Sugar beets (root)/sugar	0.01/	0.44

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short-term intake of residues of Fluvalinate (sum of isomers) resulting from the use of tau-fluvalinate (F) is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

Appendix D – Input values for the exposure calculations

D.1. Consumer risk assessment

Commodity	Existing/ Proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value (mg/kg)	Comment	Input value (mg/kg)	Comment[a]
Risk assessment residue definition: Tau-fluvalinate (all plants except cereals) Sum of tau-fluvalinate and anilino acid, including their conjugates, expressed as tau-fluvalinate (cereals)						
Grapefruits	0.4	EFSA (2018b)	0.10	STMR-RAC	0.26	HR-RAC
Oranges	0.4	EFSA (2018b)	0.10	STMR-RAC	0.26	HR-RAC
Lemons	0.4	EFSA (2018b)	0.10	STMR-RAC	0.26	HR-RAC
Limes	0.4	EFSA (2018b)	0.10	STMR-RAC	0.26	HR-RAC
Mandarins	0.4	EFSA (2018b)	0.10	STMR-RAC	0.26	HR-RAC
Other citrus fruit	0.4	EFSA (2018b)	0.10	STMR-RAC	0.26	HR-RAC
Apples	0.3	EFSA (2018b)	0.06	STMR-RAC	0.16	HR-RAC
Pears	0.3	EFSA (2018b)	0.06	STMR-RAC	0.16	HR-RAC
Quinces	0.3	EFSA (2018b)	0.06	STMR-RAC	0.16	HR-RAC
Medlar	0.3	EFSA (2018b)	0.06	STMR-RAC	0.16	HR-RAC
Loquats/J. medlars	0.3	EFSA (2018b)	0.06	STMR-RAC	0.16	HR-RAC
Other pome fruit	0.3	EFSA (2018b)	0.06	STMR-RAC	0.16	HR-RAC
Apricots	0.3	EFSA (2018b)	0.09	STMR-RAC	0.20	HR-RAC
Cherries (sweet)	0.4	EFSA (2018b)	0.08	STMR-RAC	0.18	HR-RAC
Peaches	0.3	EFSA (2018b)	0.09	STMR-RAC	0.20	HR-RAC
Table grapes	1	EFSA (2018b)	0.16	STMR-RAC	0.58	HR-RAC
Wine grapes	1	EFSA (2018b)	0.16	STMR-RAC	0.58	HR-RAC
Strawberries	0.3	EFSA (2018b)	0.03	STMR-RAC	0.12	HR-RAC
Potatoes	0.01	EFSA (2018b)	0.01	STMR-RAC	0.01	HR-RAC
Beetroots	0.01	EFSA (2018b)	0.01	STMR-RAC	0.01	HR-RAC
Carrots	0.01	EFSA (2018b)	0.01	STMR-RAC	0.01	HR-RAC
Celeriacs/turnip rooted celeries	0.01	EFSA (2018b)	0.01	STMR-RAC	0.01	HR-RAC
Horseradishes	0.01	EFSA (2018b)	0.01	STMR-RAC	0.01	HR-RAC
Jerusalem artichokes	0.01	EFSA (2018b)	0.01	STMR-RAC	0.01	HR-RAC
Parsnips	0.01	EFSA (2018b)	0.01	STMR-RAC	0.01	HR-RAC
Parsley roots/Hamburg roots parsley	0.01	EFSA (2018b)	0.01	STMR-RAC	0.01	HR-RAC
Salsifies	0.01	EFSA (2018b)	0.01	STMR-RAC	0.01	HR-RAC
Tomatoes	**0.15**	**Intended**	**0.03**	**STMR-RAC**	**0.09**	**HR-RAC**
Aubergines/egg plants	0.15	EFSA (2018b)	0.03	STMR-RAC	0.09	HR-RAC
Cucumbers	0.02	EFSA (2018b)	0.01	STMR-RAC	0.01	HR-RAC
Gherkins	0.02	EFSA (2018b)	0.01	STMR-RAC	0.01	HR-RAC
Courgettes	0.02	EFSA (2018b)	0.01	STMR-RAC	0.01	HR-RAC
Other cucurbits - edible peel	0.02	EFSA (2018b)	0.01	STMR-RAC	0.01	HR-RAC
Melons	0.09	EFSA (2018b)	0.03	STMR-RAC	0.06	HR-RAC
Watermelons	**0.09**	**Intended/ MRL review**	**0.03**	**STMR-RAC**	**0.06**	**HR-RAC**
Broccoli	0.3	EFSA (2018b)	0.02	STMR-RAC	0.17	HR-RAC
Cauliflowers	0.3	EFSA (2018b)	0.02	STMR-RAC	0.17	HR-RAC
Other flowering brassica	0.3	EFSA (2018b)	0.02	STMR-RAC	0.17	HR-RAC

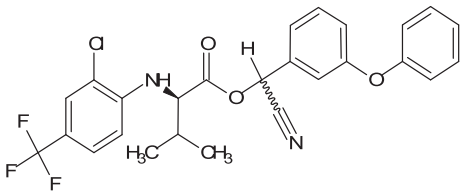
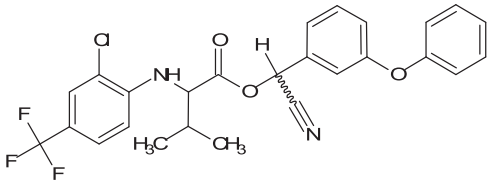
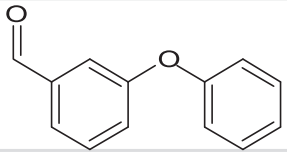
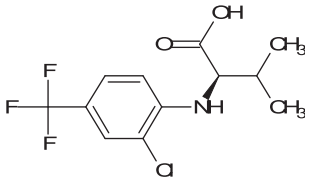
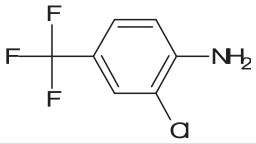
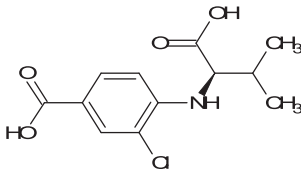
Commodity	Existing/ Proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value (mg/kg)	Comment	Input value (mg/kg)	Comment[a]
Brussels sprouts	0.15	EFSA (2018b)	0.03	STMR-RAC	0.05	HR-RAC
Head cabbages	0.3	EFSA (2018b)	0.04	STMR-RAC	0.14	HR-RAC
Kohlrabies	0.08	EFSA (2018b)	0.02	STMR-RAC	0.03	HR-RAC
Lamb's lettuce/corn salads	0.7	EFSA (2018b)	0.04	STMR-RAC	0.50	HR-RAC
Lettuces	0.7	EFSA (2018b)	0.04	STMR-RAC	0.50	HR-RAC
Escaroles/broad-leaved endives	0.7	EFSA (2018b)	0.04	STMR-RAC	0.50	HR-RAC
Cress and other sprouts and shoots	0.7	EFSA (2018b)	0.04	STMR-RAC	0.50	HR-RAC
Land cress	0.7	EFSA (2018b)	0.04	STMR-RAC	0.50	HR-RAC
Roman rocket/rucola	0.7	EFSA (2018b)	0.04	STMR-RAC	0.50	HR-RAC
Red mustards	0.7	EFSA (2018b)	0.04	STMR-RAC	0.50	HR-RAC
Baby leaf crops (incl. brassica species)	0.7	EFSA (2018b)	0.04	STMR-RAC	0.50	HR-RAC
Other lettuce and other salad plants	0.7	EFSA (2018b)	0.04	STMR-RAC	0.50	HR-RAC
Beans (with pods)	0.6	EFSA (2018b)	0.11	STMR-RAC	0.39	HR-RAC
Beans (without pods)	0.05	EFSA (2018b)	0.01	STMR-RAC	0.04	HR-RAC
Peas (with pods)	0.6	EFSA (2018b)	0.11	STMR-RAC	0.39	HR-RAC
Peas (without pods)	0.05	EFSA (2018b)	0.01	STMR-RAC	0.04	HR-RAC
Globe artichokes	0.8	EFSA (2018b)	0.12	STMR-RAC	0.37	HR-RAC
Beans	0.01	EFSA (2018b)	0.01	STMR-RAC	0.01	STMR-RAC
Lentils	0.01	EFSA (2018b)	0.01	STMR-RAC	0.01	STMR-RAC
Peas	0.01	EFSA (2018b)	0.01	STMR-RAC	0.01	STMR-RAC
Lupins/lupini beans	0.01	EFSA (2018b)	0.01	STMR-RAC	0.01	STMR-RAC
Other pulses	0.01	EFSA (2018b)	0.01	STMR-RAC	0.01	STMR-RAC
Linseeds	0.02	EFSA (2018b)	0.01	STMR-RAC	0.01	STMR-RAC
Sesame seeds	0.01	EFSA (2018b)	0.01	STMR-RAC	0.01	STMR-RAC
Sunflower seeds	0.01	EFSA (2018b)	0.01	STMR-RAC	0.01	STMR-RAC
Rapeseeds/canola seeds	0.02	EFSA (2018b)	0.01	STMR-RAC	0.01	STMR-RAC
Mustard seeds	0.02	EFSA (2018b)	0.01	STMR-RAC	0.01	STMR-RAC
Cotton seeds	0.09	EFSA (2018b)	0.01	STMR-RAC	0.01	STMR-RAC
Pumpkin seeds	0.02	EFSA (2018b)	0.01	STMR-RAC	0.01	STMR-RAC
Safflower seeds	0.02	EFSA (2018b)	0.01	STMR-RAC	0.01	STMR-RAC
Borage seeds	0.02	EFSA (2018b)	0.01	STMR-RAC	0.01	STMR-RAC
Gold of pleasure seeds	0.02	EFSA (2018b)	0.01	STMR-RAC	0.01	STMR-RAC
Hemp seeds	0.02	EFSA (2018b)	0.01	STMR-RAC	0.01	STMR-RAC
Barley	0.4	EFSA (2018b)	0.4	STMR-RAC × CF	0.40	STMR-RAC × CF
Oat	0.4	EFSA (2018b)	0.4	STMR-RAC × CF	0.40	STMR-RAC × CF
Rye	0.05	EFSA (2018b)	0.04	STMR-RAC × CF	0.04	STMR-RAC × CF
Wheat	0.05	EFSA (2018b)	0.04	STMR-RAC × CF	0.04	STMR-RAC × CF
Sugar beet roots	0.01	EFSA (2018b)	0.01	STMR-RAC	0.01	HR-RAC
Risk assessment residue definition: Tau-fluvalinate and 3-phenoxybenzoic acid and anilino acid, including their conjugates, expressed as tau-fluvalinate						
Swine: Muscle/meat[b]	0.015	EFSA (2018b)	0.02	STMR-RAC × CF	0.03	HR-RAC × CF
Swine: Fat tissue	0.05	EFSA (2018b)	0.02	STMR-RAC × CF	0.05	HR-RAC × CF

Commodity	Existing/ Proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value (mg/kg)	Comment	Input value (mg/kg)	Comment[a]
Swine: Liver	0.01	EFSA (2018b)	0.11	STMR-RAC × CF	0.11	HR-RAC × CF
Swine: Kidney	0.01	EFSA (2018b)	0.11	STMR-RAC × CF	0.11	HR-RAC × CF
Swine: Edible offal (other than liver and kidney)	0.05	EFSA (2018b)	0.02	STMR-RAC × CF	0.05	HR-RAC × CF
Bovine: Muscle/meat[b]	0.05	EFSA (2018b)	0.06	STMR-RAC × CF	0.10	HR-RAC × CF
Bovine: Fat tissue	0.3	EFSA (2018b)	0.13	STMR-RAC × CF	0.24	HR-RAC × CF
Bovine: Liver	0.01	EFSA (2018b)	0.11	STMR-RAC × CF	0.11	HR-RAC × CF
Bovine: Kidney	0.015	EFSA (2018b)	0.11	STMR-RAC × CF	0.13	HR-RAC × CF
Bovine: Edible offal (other than liver and kidney)	0.3	EFSA (2018b)	0.13	STMR-RAC × CF	0.24	HR-RAC × CF
Sheep: Muscle/meat[b]	0.05	EFSA (2018b)	0.06	STMR-RAC × CF	0.10	HR-RAC × CF
Sheep: Fat tissue	0.3	EFSA (2018b)	0.14	STMR-RAC × CF	0.25	HR-RAC × CF
Sheep: Liver	0.01	EFSA (2018b)	0.11	STMR-RAC × CF	0.11	HR-RAC × CF
Sheep: Kidney	0.015	EFSA (2018b)	0.11	STMR-RAC × CF	0.14	HR-RAC × CF
Sheep: Edible offal (other than liver and kidney)	0.3	EFSA (2018b)	0.14	STMR-RAC × CF	0.25	HR-RAC × CF
Goat: Muscle/meat[b]	0.05	EFSA (2018b)	0.06	STMR-RAC × CF	0.10	HR-RAC × CF
Goat: Fat tissue	0.3	EFSA (2018b)	0.14	STMR-RAC × CF	0.25	HR-RAC × CF
Goat: Liver	0.01	EFSA (2018b)	0.11	STMR-RAC × CF	0.11	HR-RAC × CF
Goat: Kidney	0.015	EFSA (2018b)	0.11	STMR-RAC × CF	0.14	HR-RAC × CF
Goat: Edible offal (other than liver and kidney)	0.3	EFSA (2018b)	0.14	STMR-RAC × CF	0.25	HR-RAC × CF
Equine: Muscle/meat[b]	0.05	EFSA (2018b)	0.06	STMR-RAC × CF	0.10	HR-RAC × CF
Equine: Fat tissue	0.3	EFSA (2018b)	0.13	STMR-RAC × CF	0.24	HR-RAC × CF
Equine: Liver	0.01	EFSA (2018b)	0.11	STMR-RAC × CF	0.11	HR-RAC × CF
Equine: Kidney	0.015	EFSA (2018b)	0.11	STMR-RAC × CF	0.13	HR-RAC × CF
Equine: Edible offal (other than liver and kidney)	0.3	EFSA (2018b)	0.13	STMR-RAC × CF	0.24	HR-RAC × CF
Poultry: Muscle/meat[b]	0.01	EFSA (2018b)	0.01	STMR-RAC	0.01	HR-RAC
Poultry: Fat tissue	0.02	EFSA (2018b)	0.04	STMR-RAC × CF	0.04	HR-RAC × CF
Poultry: Liver	0.01	EFSA (2018b)	0.01	STMR-RAC	0.01	HR-RAC
Poultry: Kidney	0.01	EFSA (2018b)	0.01	STMR-RAC	0.01	HR-RAC
Poultry: Edible offal (other than liver and kidney)	0.03	EFSA (2018b)	0.02	STMR-RAC × CF	0.04	HR-RAC × CF
Other farmed animals: Muscle/meat[b]	0.05	EFSA (2018b)	0.06	STMR-RAC × CF	0.10	HR-RAC × CF
Other farmed animals: Fat tissue	0.3	EFSA (2018b)	0.13	STMR-RAC × × CF	0.24	HR-RAC × CF
Other farmed animals: Liver	0.01	EFSA (2018b)	0.11	STMR-RAC × CF	0.11	HR-RAC × CF
Other farmed animals: Kidney	0.015	EFSA (2018b)	0.11	STMR-RAC × CF	0.13	HR-RAC × CF
	0.3	EFSA (2018b)	0.06	STMR-RAC × CF	0.10	HR-RAC × CF

Commodity	Existing/ Proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value (mg/kg)	Comment	Input value (mg/kg)	Comment[(a)]
Other farmed animals: Edible offal (other than liver and kidney)						
Milk: Cattle	0.03	EFSA (2018b)	0.02	STMR-RAC × CF	0.02	STMR-RAC × CF
Milk: Sheep	0.02	EFSA (2018b)	0.02	STMR-RAC × CF	0.02	STMR-RAC × × CF
Milk: Goat	0.02	EFSA (2018b)	0.02	STMR-RAC × CF	0.02	STMR-RAC × CF
Milk: Horse	0.03	EFSA (2018b)	0.02	STMR-RAC × CF	0.02	STMR-RAC × CF
Milk: Others	0.02	EFSA (2018b)	0.02	STMR-RAC × CF	0.02	STMR-RAC × × CF
Eggs: Chicken	0.01	EFSA (2018b)	0.04	STMR-RAC × CF	0.04	HR-RAC × CF
Eggs: Duck	0.01	EFSA (2018b)	0.04	STMR-RAC × CF	0.04	HR-RAC × CF
Eggs: Goose	0.01	EFSA (2018b)	0.04	STMR-RAC × CF	0.04	HR-RAC × CF
Eggs: Quail	0.01	EFSA (2018b)	0.04	STMR-RAC × CF	0.04	HR-RAC × CF
Eggs: Others	0.01	EFSA (2018b)	0.04	STMR-RAC × × CF	0.04	HR-RAC × CF
Honey and other apiculture products	0.05	EFSA (2018b)	0.05	LOQ	0.05	LOQ

MRL: maximum residue level; STMR-RAC: supervised trials median residue in raw agricultural commodity; HR-RAC: highest residue in raw agricultural commodity.
(a): Input values for the commodities which are not under consideration for the acute risk assessment are reported in grey.
(b): 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 a 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)]
Tau-fluvalinate	(*RS*)-α-cyano-3-phenoxybenzyl *N*-(2-chloro-α,α,α-trifluoro-*p*-tolyl)-D-valinate Clc1cc(ccc1N[C@@H](C(=O)OC(C#N)c1cccc(Oc2ccccc2)c1)C(C)C)C(F)(F)F INISTDXBRIBGOC-XMMISQBUSA-N	
Fluvalinate	(*RS*)-α-cyano-3-phenoxybenzyl *N*-(2-chloro-α,α,α-trifluoro-*p*-tolyl)-DL-valinate Clc1cc(ccc1NC(C(=O)OC(C#N)c1cccc(Oc2ccccc2)c1)C(C)C)C(F)(F)F INISTDXBRIBGOC-UHFFFAOYSA-N	
3-Phenoxybenzyaldehyde (3-PBAld)	3-phenoxybenzaldehyde O=Cc1cc(Oc2ccccc2)ccc1 MRLGCTNJRREZHZ-UHFFFAOYSA-N	
Anilino acid	*N*-[2-chloro-4-(trifluoromethyl) phenyl]-D-valine Clc1cc(ccc1N[C@@H](C(=O)O)C(C)C)C(F)(F)F YKSHSSFDOHACTC-SNVBAGLBSA-N	
Haloaniline	2-chloro-4-(trifluoromethyl)aniline Nc1ccc(cc1Cl)C(F)(F)F MBBUTABXEITVNY-UHFFFAOYSA-N	
Diacid	4-{[(1*R*)-1-carboxy-2-methylpropyl] amino}-3-chlorobenzoic acid Clc1cc(ccc1N[C@@H](C(=O)O)C(C)C)C(=O)O QKMSBJLCYMYIND-SNVBAGLBSA-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 2015 ACD/Labs 2015 Release (File version N20E41, Build 75170, 19 December 2014).
(c): ACD/ChemSketch 2015 ACD/Labs 2015 Release (File version C10H41, Build 75059, 17 December 2014).