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

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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.

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

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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                                                                 |
|---------|-------------|-------------------------|-------------------------|---------------------------------------------------------------------------------------|
| 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-phenoxymethyl N-(2-chloro-α,α,α-trifluoro-2-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/EEC1 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 approved2 for the use as insecticide on 1 June 2011.

The EU MRLs for tau-fluvalinate are established in Annex II of Regulation (EC) No 396/20053. 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 Makhshesh 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) of 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 544/20115 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

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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.
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. 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 and diacid may not be retrieved in practice and recommended to keep

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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 fluvalinate8 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-

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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 × 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-phenoxbenzaldehyde 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-phenoxbenzaldehyde 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-phenoxbenzaldehyde 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-phenoxbenzaldehyde 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-phenoxbenzaldehyde 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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| Abbreviation | Full Form |
|--------------|-----------|
| 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<sub>ow</sub> | 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 or G or I(a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|-------------------------|----------------|------------------------------------|-------------|----------------|-------------------------------|---------------|---------|
|                       |                         |                |                                    | Type(b)     | Conc. a.s. Method kind | Range of growth stages & season(c) | Number min–max | Interval between application (min) | g a.s./hL min–max | Water L/ha min–max | Rate Unit | |
| Tomatoes              | SEU                     | F              | Aphididae (1APHIF), Tobacco Budworm (Heliothis 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 |

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) |
|                                 |             | 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-U-\(^{14}\)C]-tau-fluvalinate and [benzyl-U-\(^{14}\)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-U-\(^{14}\)C]-tau-fluvalinate and [benzyl-U-\(^{14}\)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?

Yes

Pasturisation: yes Boiling/baking/brewing and sterilisation: no

EFSA (2018b)

Plant residues 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 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-phenoxbenzaldehyde 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-phenoxbenzaldehyde 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 |
|-----------------------------------|---------------------------|--------------------------------|----------|--------------------------|-------------------|-----------------|
|                                   | 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) | CFp(b) | Comment(c)/Source |
|---------------------|---------------------------|------------------------|--------|------------------|
| Tomato, washed      | 3                         | 0.06; 2 × < 0.09       | < 0.09 | n/a              |
| and peeled          |                           |                        |        | Tentative (Denmark, 2018) |
| Tomato, juice       | 3                         | 0.12; 0.27; 0.36       | 0.36   | n/a              |
| (pasteurised)       |                           |                        |        | Tentative (Denmark, 2018) |
| Tomato, wet         | 3                         | 1.38; 2.64; 3.36       | 2.64   | n/a              |
| pomace              |                           |                        |        | Tentative (Denmark, 2018) |
| Tomato, dried       | 3                         | 6.18; 6.35; 8.45       | 6.35   | n/a              |
| pomace              |                           |                        |        | Tentative (Denmark, 2018) |
| Tomato, Paste       | 3                         | 0.79; 2 × 1.00         | 1.00   | n/a              |
| (sterilised)        |                           |                        |        | Tentative (Denmark, 2018) |
| Tomato, puree       | 3                         | 0.36; 0.55; 0.68       | 0.55   | n/a              |
| (sterilised)        |                           |                        |        | Tentative (Denmark, 2018) |
| Tomato, ketchup     | 3                         | 0.53; 2 × 0.64         | 0.64   | n/a              |
| (sterilised)        |                           |                        |        | Tentative (Denmark, 2018) |
| Tomato, canned      | 3                         | 0.03; 0.09; 0.18       | 0.09   | n/a              |
| (sterilised)        |                           |                        |        | 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              |

(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<sup>(a)</sup> | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|-------------------|-----------|------------------------|-------------------------|-----------------------|
| 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. |

**Enforcement residue definition:** Fluvalinate (sum of isomers) resulting from the use of tau-fluvalinate<sup>(F)</sup>

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

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

<sup>(a)</sup>: Commodity code number according to Annex I of Regulation (EC) No 396/2005.

<sup>(F)</sup>: Fat soluble.
Fluvalinate (sum of isomers) resulting from the use of tau-fluvalinate (F)

| Calculated exposure (mg/kg bw per day) | Highest contributor to ADI (mg/kg bw) | Percent of ADI (mg/kg bw) | Commodity/ group of commodities | % of ADI (mg/kg bw) | Commodity/ group of commodities | % of ADI (mg/kg bw) |
|---------------------------------------|--------------------------------------|-------------------------|--------------------------------|----------------|--------------------------------|----------------|
| 2.20                                  | 13% Apples                           | 0.05                    | Wheat                          | 7%            | Milk: Cattle                    | 0.1%          |
| 1.84                                  | 9% Milk: Cattle                      | 0.04                    | Oranges                        | 0.05          | Milk: Cattle                    | 0.0%          |
| 1.03                                  | 11% Milk: Cattle                     | 0.02                    | Barley                         | 0.00          | Milk: Cattle                    | 0.0%          |
| 0.80                                  | 3% Nuts                              | 0.00                    | Milk: Cattle                    | 0.0%          | Milk: Cattle                    | 0.0%          |
| 0.57                                  | 5% Wheat                             | 0.00                    | Milk: Cattle                    | 0.0%          | Milk: Cattle                    | 0.0%          |

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.
### Results for all crops

#### Unprocessed commodities

| Commodity                  | MRL/Input for RA (mg/kg) | Exposure (µg/kg bw) | ARfD/ADI (%) |
|----------------------------|---------------------------|---------------------|--------------|
| Table grapes               | 1.0/0.58                  | 42                  | 85           |
| Oranges                    | 0.4/0.26                  | 34                  | 69           |
| Pears                      | 0.3/0.16                  | 22                  | 44           |
| Grapefruits                | 0.4/0.26                  | 20                  | 41           |
| Escaroles/broad-leaved     | 0.7/0.5                  | 19                  | 38           |
| Peaches                    | 0.3/0.2                  | 19                  | 38           |
| Apples                     | 0.3/0.16                  | 17                  | 34           |
| Mandarins                  | 0.4/0.26                  | 15                  | 31           |
| Cauliflowers               | 0.3/0.17                  | 9.8                 | 20           |
| Melons                     | 0.09/0.06                | 9.1                 | 18           |
| Lemons                     | 0.4/0.26                  | 8.9                 | 18           |
| Watermelons                | 0.09/0.06                | 7.3                 | 15           |
| Broccoli                   | 0.3/0.17                  | 7.1                 | 14           |
| Apricots                   | 0.3/0.2                  | 7.0                 | 14           |
| Globe artichokes           | 0.6/0.37                 | 6.5                 | 13           |
| Head cabbages              | 0.3/0.14                 | 6.2                 | 12           |
| Wine grapes                | 1.0/0.58                  | 5.4                 | 11           |
| Limes                      | 0.4/0.26                  | 5.2                 | 10           |
| Tomatoes                   | 0.15/0.09                | 5.2                 | 10           |
| Beans (with pods)          | 0.6/0.39                 | 4.5                 | 9            |
| Quinces                    | 0.3/0.16                 | 3.9                 | 8            |
| Peas (with pods)           | 0.6/0.39                 | 3.2                 | 6            |
| Aubergines/egg plants      | 0.15/0.09                | 2.3                 | 5            |
| Barley                     | 0.4/0.4                  | 2.2                 | 4            |
| Mills: Cattia              | 0.03/0.02                | 2.2                 | 4            |

#### Processed commodities

| Commodity                  | MRL/Input for RA (mg/kg) | Exposure (µg/kg bw) | ARfD/ADI (%) |
|----------------------------|---------------------------|---------------------|--------------|
| Escaroles/broad-leaved endi| 0.7/0.5                  | 33                  | 66           |
| Broccoli/boiled            | 0.3/0.17                  | 13                  | 27           |
| Cauliflowers/boiled        | 0.3/0.17                  | 12                  | 24           |
| Wine grapes/juice           | 1.0/1.6                   | 7.0                 | 14           |
| Oranges/juice              | 0.4/0.1                  | 5.3                 | 11           |
| Peaches (with pods)/boiled | 0.3/0.2                  | 5.2                 | 10           |
| Beans (with pods)/boiled   | 0.6/0.39                 | 4.9                 | 10           |
| Quinces                    | 0.3/0.16                 | 3.9                 | 8            |
| Peas (with pods)           | 0.6/0.39                 | 3.2                 | 6            |
| Aubergines/egg plants      | 0.15/0.09                | 2.3                 | 5            |
| Barley                     | 0.4/0.4                  | 2.2                 | 4            |
| Millets                    | 0.03/0.02                | 2.2                 | 4            |

### 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)     | Input value (mg/kg)   |
|                             |                               |                 | Comment                 | 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              |
|                             |                               |                 |                         |                       |
| Oranges                     | 0.4                           | EFSA (2018b)    | 0.10                    | STMR-RAC              |
|                             |                               |                 |                         |                       |
| Lemons                      | 0.4                           | EFSA (2018b)    | 0.10                    | STMR-RAC              |
|                             |                               |                 |                         |                       |
| Limes                       | 0.4                           | EFSA (2018b)    | 0.10                    | STMR-RAC              |
|                             |                               |                 |                         |                       |
| Mandarins                   | 0.4                           | EFSA (2018b)    | 0.10                    | STMR-RAC              |
|                             |                               |                 |                         |                       |
| Other citrus fruit          | 0.4                           | EFSA (2018b)    | 0.10                    | STMR-RAC              |
|                             |                               |                 |                         |                       |
| Apples                      | 0.3                           | EFSA (2018b)    | 0.06                    | STMR-RAC              |
|                             |                               |                 |                         |                       |
| Pears                       | 0.3                           | EFSA (2018b)    | 0.06                    | STMR-RAC              |
|                             |                               |                 |                         |                       |
| Quinces                     | 0.3                           | EFSA (2018b)    | 0.06                    | STMR-RAC              |
|                             |                               |                 |                         |                       |
| Medlar                      | 0.3                           | EFSA (2018b)    | 0.06                    | STMR-RAC              |
|                             |                               |                 |                         |                       |
| Loquats/J. medlars          | 0.3                           | EFSA (2018b)    | 0.06                    | STMR-RAC              |
|                             |                               |                 |                         |                       |
| Other pome fruit            | 0.3                           | EFSA (2018b)    | 0.06                    | STMR-RAC              |
|                             |                               |                 |                         |                       |
| Apricots                    | 0.3                           | EFSA (2018b)    | 0.09                    | STMR-RAC              |
|                             |                               |                 |                         |                       |
| Cherries (sweet)            | 0.4                           | EFSA (2018b)    | 0.08                    | STMR-RAC              |
|                             |                               |                 |                         |                       |
| Peaches                     | 0.3                           | EFSA (2018b)    | 0.09                    | STMR-RAC              |
|                             |                               |                 |                         |                       |
| Table grapes                | 1                             | EFSA (2018b)    | 0.16                    | STMR-RAC              |
|                             |                               |                 |                         |                       |
| Wine grapes                 | 1                             | EFSA (2018b)    | 0.16                    | STMR-RAC              |
|                             |                               |                 |                         |                       |
| Strawberries                | 0.3                           | EFSA (2018b)    | 0.03                    | STMR-RAC              |
|                             |                               |                 |                         |                       |
| Potatoes                    | 0.01                          | EFSA (2018b)    | 0.01                    | STMR-RAC              |
|                             |                               |                 |                         |                       |
| Beetroot                    | 0.01                          | EFSA (2018b)    | 0.01                    | STMR-RAC              |
|                             |                               |                 |                         |                       |
| Carrots                     | 0.01                          | EFSA (2018b)    | 0.01                    | STMR-RAC              |
|                             |                               |                 |                         |                       |
| Celeriacs/turnip rooted celeries | 0.01                        | EFSA (2018b)    | 0.01                    | STMR-RAC              |
|                             |                               |                 |                         |                       |
| Horseradishes               | 0.01                          | EFSA (2018b)    | 0.01                    | STMR-RAC              |
|                             |                               |                 |                         |                       |
| Jerusalem artichokes        | 0.01                          | EFSA (2018b)    | 0.01                    | STMR-RAC              |
|                             |                               |                 |                         |                       |
| Parsnips                    | 0.01                          | EFSA (2018b)    | 0.01                    | STMR-RAC              |
|                             |                               |                 |                         |                       |
| Parsley roots/Hamburg roots parsley | 0.01                        | EFSA (2018b)    | 0.01                    | STMR-RAC              |
|                             |                               |                 |                         |                       |
| Salsifies                   | 0.01                          | EFSA (2018b)    | 0.01                    | STMR-RAC              |
|                             |                               |                 |                         |                       |
| **Tomatoes**                | **0.15**                      | Intended        | **0.03**                | **STMR-RAC**          |
|                             |                               |                 |                         |                       |
| Aubergines/egg plants       | 0.15                          | EFSA (2018b)    | 0.03                    | STMR-RAC              |
|                             |                               |                 |                         |                       |
| Cucumbers                   | 0.02                          | EFSA (2018b)    | 0.01                    | STMR-RAC              |
|                             |                               |                 |                         |                       |
| Ghirkins                    | 0.02                          | EFSA (2018b)    | 0.01                    | STMR-RAC              |
|                             |                               |                 |                         |                       |
| Courgettes                  | 0.02                          | EFSA (2018b)    | 0.01                    | STMR-RAC              |
|                             |                               |                 |                         |                       |
| Other cucurbits - edible peel | 0.02                        | EFSA (2018b)    | 0.01                    | STMR-RAC              |
|                             |                               |                 |                         |                       |
| Melons                      | 0.09                          | EFSA (2018b)    | 0.03                    | STMR-RAC              |
|                             |                               |                 |                         |                       |
| **Watermelons**             | **0.09**                      | Intended/ MRL review | **0.03**                | **STMR-RAC**          |
|                             |                               |                 |                         |                       |
| Broccoli                    | 0.3                           | EFSA (2018b)    | 0.02                    | STMR-RAC              |
|                             |                               |                 |                         |                       |
| Cauliflower                 | 0.3                           | EFSA (2018b)    | 0.02                    | STMR-RAC              |
|                             |                               |                 |                         |                       |
| Other flowering brassica    | 0.3                           | EFSA (2018b)    | 0.02                    | STMR-RAC              |
|                             |                               |                 |                         |                       |
| Commodity                          | Existing/Proposed MRL (mg/kg) | Source            | Chronic risk assessment | Acute risk assessment |
|-----------------------------------|-------------------------------|-------------------|-------------------------|-----------------------|
|                                   |                               |                   | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment |
| 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 |
| Rape seeds/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)   |
|                                |                               |                | Comment                 |                      |                      |              |
| Swine: Liver                   | 0.01                          | EFSA (2018b)   | 0.11                    | STMR-RAC x CF        | 0.11                | HR-RAC x CF   |
| Swine: Kidney                  | 0.01                          | EFSA (2018b)   | 0.11                    | STMR-RAC x CF        | 0.11                | HR-RAC x CF   |
| Swine: Edible offal (other than liver and kidney) | 0.05                          | EFSA (2018b)   | 0.02                    | STMR-RAC x CF        | 0.05                | HR-RAC x CF   |
| Bovine: Muscle/meat(b)         | 0.05                          | EFSA (2018b)   | 0.06                    | STMR-RAC x CF        | 0.10                | HR-RAC x CF   |
| Bovine: Fat tissue             | 0.3                           | EFSA (2018b)   | 0.13                    | STMR-RAC x CF        | 0.24                | HR-RAC x CF   |
| Bovine: Liver                  | 0.01                          | EFSA (2018b)   | 0.11                    | STMR-RAC x CF        | 0.11                | HR-RAC x CF   |
| Bovine: Kidney                 | 0.015                         | EFSA (2018b)   | 0.11                    | STMR-RAC x CF        | 0.13                | HR-RAC x CF   |
| Bovine: Edible offal (other than liver and kidney) | 0.3                           | EFSA (2018b)   | 0.13                    | STMR-RAC x CF        | 0.24                | HR-RAC x CF   |
| Sheep: Muscle/meat(b)          | 0.05                          | EFSA (2018b)   | 0.06                    | STMR-RAC x CF        | 0.10                | HR-RAC x CF   |
| Sheep: Fat tissue              | 0.3                           | EFSA (2018b)   | 0.14                    | STMR-RAC x CF        | 0.25                | HR-RAC x CF   |
| Sheep: Liver                   | 0.01                          | EFSA (2018b)   | 0.11                    | STMR-RAC x CF        | 0.11                | HR-RAC x CF   |
| Sheep: Kidney                  | 0.015                         | EFSA (2018b)   | 0.11                    | STMR-RAC x CF        | 0.14                | HR-RAC x CF   |
| Sheep: Edible offal (other than liver and kidney) | 0.3                           | EFSA (2018b)   | 0.14                    | STMR-RAC x CF        | 0.25                | HR-RAC x CF   |
| Goat: Muscle/meat(b)           | 0.05                          | EFSA (2018b)   | 0.06                    | STMR-RAC x CF        | 0.10                | HR-RAC x CF   |
| Goat: Fat tissue               | 0.3                           | EFSA (2018b)   | 0.14                    | STMR-RAC x CF        | 0.25                | HR-RAC x CF   |
| Goat: Liver                    | 0.01                          | EFSA (2018b)   | 0.11                    | STMR-RAC x CF        | 0.11                | HR-RAC x CF   |
| Goat: Kidney                   | 0.015                         | EFSA (2018b)   | 0.11                    | STMR-RAC x CF        | 0.14                | HR-RAC x CF   |
| Goat: Edible offal (other than liver and kidney) | 0.3                           | EFSA (2018b)   | 0.14                    | STMR-RAC x CF        | 0.25                | HR-RAC x CF   |
| Equine: Muscle/meat(b)         | 0.05                          | EFSA (2018b)   | 0.06                    | STMR-RAC x CF        | 0.10                | HR-RAC x CF   |
| Equine: Fat tissue             | 0.3                           | EFSA (2018b)   | 0.13                    | STMR-RAC x CF        | 0.24                | HR-RAC x CF   |
| Equine: Liver                  | 0.01                          | EFSA (2018b)   | 0.11                    | STMR-RAC x CF        | 0.11                | HR-RAC x CF   |
| Equine: Kidney                 | 0.015                         | EFSA (2018b)   | 0.11                    | STMR-RAC x CF        | 0.13                | HR-RAC x CF   |
| Equine: Edible offal (other than liver and kidney) | 0.3                           | EFSA (2018b)   | 0.13                    | STMR-RAC x CF        | 0.24                | HR-RAC x 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 x CF        | 0.04                | HR-RAC x 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 x CF        | 0.04                | HR-RAC x CF   |
| Other farmed animals: Muscle/meat(b) | 0.05                          | EFSA (2018b)   | 0.06                    | STMR-RAC x CF        | 0.10                | HR-RAC x CF   |
| Other farmed animals: Fat tissue | 0.3                           | EFSA (2018b)   | 0.13                    | STMR-RAC x CF        | 0.24                | HR-RAC x CF   |
| Other farmed animals: Liver     | 0.01                          | EFSA (2018b)   | 0.11                    | STMR-RAC x CF        | 0.11                | HR-RAC x CF   |
| Other farmed animals: Kidney    | 0.015                         | EFSA (2018b)   | 0.11                    | STMR-RAC x CF        | 0.13                | HR-RAC x CF   |
|                                | 0.3                           | EFSA (2018b)   | 0.06                    | STMR-RAC x CF        | 0.10                | HR-RAC x CF   |
### Modification of the existing maximum residue levels for tau-fluvalinate in tomatoes and watermelons

| Commodity                        | Existing/Proposed MRL (mg/kg) | Source                  | Chronic risk assessment | Acute risk assessment |
|----------------------------------|-------------------------------|-------------------------|-------------------------|-----------------------|
|                                  |                               |                         | Input value (mg/kg)     | Comment               |
| Other farmed animals:            |                               |                         |                         |                       |
| Edible offal (other than liver and kidney) |                               |                         |                         |                       |
| Milk: Cattle                     | 0.03                          | EFSA (2018b)            | 0.02                    | STMR-RAC × CF         |
| Milk: Sheep                      | 0.02                          | EFSA (2018b)            | 0.02                    | STMR-RAC × CF         |
| Milk: Goat                       | 0.02                          | EFSA (2018b)            | 0.02                    | STMR-RAC × CF         |
| Milk: Horse                      | 0.03                          | EFSA (2018b)            | 0.02                    | STMR-RAC × CF         |
| Milk: Others                     | 0.02                          | EFSA (2018b)            | 0.02                    | STMR-RAC × CF         |
| Eggs: Chicken                    | 0.01                          | EFSA (2018b)            | 0.04                    | STMR-RAC × CF         |
| Eggs: Duck                       | 0.01                          | EFSA (2018b)            | 0.04                    | STMR-RAC × CF         |
| Eggs: Goose                      | 0.01                          | EFSA (2018b)            | 0.04                    | STMR-RAC × CF         |
| Eggs: Quail                      | 0.01                          | EFSA (2018b)            | 0.04                    | STMR-RAC × CF         |
| Eggs: Others                     | 0.01                          | EFSA (2018b)            | 0.04                    | STMR-RAC × CF         |
| Honey and other apiculture products | 0.05                        | EFSA (2018b)            | 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 | ![Structure](structure1.png) |
| Fluvalinate                 | (RS)-α-cyano-3-phenoxybenzyl N-(2-chloro-α,α,α-trifluoro-p-tolyl)-DL-valinate | ![Structure](structure2.png) |
| 3-Phenoxybenzaldehyde (3-PBAld) | 3-phenoxybenzaldehyde | ![Structure](structure3.png) |
| Anilino acid                | N-[2-chloro-4-(trifluoromethyl)phenyl]-D-valine | ![Structure](structure4.png) |
| Haloaniline                 | 2-chloro-4-(trifluoromethyl)aniline            | ![Structure](structure5.png) |
| Diacid                      | 4-[(1R)-1-carboxy-2-methylpropyl] amino-3-chlorobenzoic acid | ![Structure](structure6.png) |

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).