Review of the existing maximum residue levels for tau-fluvalinate according to Article 12 of Regulation (EC) No 396/2005

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Abstract

According to Article 12 of Regulation (EC) No 396/2005, EFSA has reviewed the maximum residue levels (MRLs) currently established at European level for the pesticide active substance tau-fluvalinate. To assess the occurrence of tau-fluvalinate residues in plants, processed commodities, rotational crops and livestock, EFSA considered the conclusions derived in the framework of Commission Regulation (EC) No 33/2008 as well as the European authorisations reported by Member States (including the supporting residues data). Based on the assessment of the available data, MRL proposals were derived and a consumer risk assessment was carried out. An MRL application for modification of MRLs in products of animal origin was also considered in this review. Although no apparent risk to consumers was identified, some information required by the regulatory framework was missing. Hence, the consumer risk assessment is considered indicative only and some MRL proposals derived by EFSA still require further consideration by risk managers.

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Keywords: tau-fluvalinate, MRL review, Regulation (EC) No 396/2005, consumer risk assessment, pyrethroid, insecticide, acaricide, anilino acid

Requestor: European Commission

Question number: EFSA-Q-2009-00074; EFSA-Q-2014-00011

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Acknowledgement: EFSA wishes to thank the rapporteur Member State Denmark for the preparatory work on this scientific output.

Suggested citation: EFSA (European Food Safety Authority), Brancato A, Brocca D, Carrasco Cabrera L, De Lentdecker C, Erdos Z, Ferreira L, Greco L, Jarrah S, Kardassi D, Leuschner R, Lostia A, Lythgo C, Medina P, Miron I, Molnar T, Pedersen R, Reich H, Sacchi A, Santos M, Stanek A, Sturma J, Tarazona J, Theobald A, Vagenende B and Villamar-Bouza L, 2018. Reasoned opinion on the review of the existing maximum residue levels for tau-fluvalinate according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2018;16(11):5475, 71 pp. https://doi.org/10.2903/j.efsa.2018.5475

ISSN: 1831-4732

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

Tau-fluvalinate was included in Annex I to Directive 91/414/EEC on 1 June 2011 by Commission Directive 2011/19/EU, and has been deemed to be approved under Regulation (EC) No 1107/2009, in accordance with Commission Implementing Regulation (EU) No 540/2011, as amended by Commission Implementing Regulation (EU) No 541/2011.

As the active substance was approved after the entry into force of Regulation (EC) No 396/2005 on 2 September 2008, the European Food Safety Authority (EFSA) is required to provide a reasoned opinion on the review of the existing maximum residue levels (MRLs) for that active substance in compliance with Article 12(1) of the aforementioned regulation.

As the basis for the MRL review, on 17 July 2017, EFSA initiated the collection of data for this active substance. In a first step, Member States were invited to submit by 17 August 2017 their national Good Agricultural Practices (GAPs) in a standardised way, in the format of specific GAP forms, allowing the designated rapporteur Member State (RMS) Denmark to identify the critical GAPs in the format of a specific GAP overview file. Subsequently, Member States were requested to provide residue data supporting the critical GAPs, within a period of 1 month, by 8 December 2017. On the basis of all the data submitted by Member States and by the EU Reference Laboratories for Pesticides Residues (EURLs), EFSA asked the RMS to complete the Pesticide Residues Overview File (PROFile) and to prepare a supporting evaluation report. The PROFile, the supporting evaluation report and an updated GAP overview file were provided by the RMS to EFSA on 9 March 2018. Subsequently, EFSA performed the completeness check of these documents with the RMS. The outcome of this exercise including the clarifications provided by the RMS, if any, was compiled in the completeness check.

Based on the information provided by the RMS, Member States and the EURLs, and taking into account the conclusions derived by EFSA in the framework of Commission Regulation (EC) No 33/2008, EFSA prepared in August 2018 a draft reasoned opinion, which was circulated to Member States for consultation via a written procedure. Comments received by 27 September 2018 were considered during the finalisation of this reasoned opinion. An MRL application for modification of MRLs in products of animal origin was also considered in this review.

The following conclusions are derived.

The metabolism of tau-fluvalinate in plant was investigated in primary and rotational crops. According to the results of the metabolism studies, the residue definitions except for processed commodities for enforcement can be proposed as fluvalinate (sum of isomers) and for risk assessment as tau-fluvalinate except for cereal grains where the sum of tau-fluvalinate plus anilino acid, including their conjugates, expressed as tau-fluvalinate is derived. A specific residue definition for rotational crops is not deemed necessary since significant residues of tau-fluvalinate and metabolites are not expected. The residue definition for enforcement in processed commodities is proposed tentatively as fluvalinate (sum of isomers) only for pasteurised products and fluvalinate (sum of isomers) by default for boiled and sterilised commodities. For risk assessment, the proposed residue definition is tau-fluvalinate, 3-phenoxybenzaldehyde and diacid.

Fully validated analytical methods are available for the enforcement of the proposed residue definition in all matrices at the limit of quantification(s) (LOQ(s)) of 0.01 mg/kg. According to the EURLs, the LOQ of 0.01 mg/kg is achievable by using the QuEChERS method in routine analyses.

Available residue trials data were considered sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation, except for cucumbers, dry beans and peas, sesame and sunflower seeds and barley and oat straw, where tentative MRLs are derived and for lupine beans and sugar beet tops where trials were insufficient to derive a MRL.

Tau-fluvalinate is authorised for use on crops that might be fed to livestock. Livestock dietary burden calculations were therefore performed for different groups of livestock according to OECD guidance. The dietary burdens calculated for all groups of livestock were found to exceed the trigger value of 0.1 mg/kg DM. Behaviour of residues was therefore assessed in all commodities of animal origin.

The metabolism of tau-fluvalinate residues in livestock was investigated in lactating goats and tentatively laying hens at dose rate covering the maximum dietary burdens calculated in this review. According to the results of these studies, the residue definitions for enforcement and risk assessment in livestock commodities was proposed as fluvalinate (sum of isomers) only and sum of tau-fluvalinate and 3-phenoxybenzoic acid and anilino acid, including their conjugates, expressed as tau-fluvalinate, respectively. An analytical method for the enforcement of the proposed residue definition at the LOQ
of 0.01 mg/kg in all matrices is available. According to the EURLs, the LOQ of 0.01 mg/kg is achievable by using the QuEChERS method in routine analyses (EURLs, 2018).

Livestock feeding studies on animal were used to derive MRL and risk assessment values in milk/eggs/tissues of ruminants/poultry. Since extrapolation from ruminants to pigs is acceptable, results of the livestock feeding study on ruminants were relied upon to derive the MRL and risk assessment values in pigs. The metabolism and feeding studies in poultry were considered on a tentative basis and are still required in line with established guidelines. Storage stability of tau-fluvalinate in eggs has to be still investigated.

Chronic and acute consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 2 of the EFSA PRIMo. The exposure values calculated were compared with the toxicological reference values for tau-fluvalinate, derived by EFSA (2010). The highest chronic exposure was calculated for DE child, representing 43.8% of the acceptable daily intake (ADI), and the highest acute exposure was calculated for scarole (broadleaf variety), representing 87.4% of the ARfD. These calculations indicate that the uses assessed under this review result in a consumer exposure lower than the toxicological reference values. Although uncertainties remain due to the data gaps identified in the previous sections, this indicative exposure calculation did not indicate a risk to consumer’s health.

In addition, EFSA emphasises that the above studies do not investigate the possible impact of plant metabolism on the isomer ratio of tau-fluvalinate and that further investigation on this matter would in principle be required. Since guidance on the consideration of isomer ratios in the consumer risk assessment is not yet available, EFSA recommends that this issue is reconsidered when such guidance is available.
Background

Regulation (EC) No 396/2005 (hereinafter referred to as 'the Regulation') establishes the rules governing the setting and the review of pesticide maximum residue levels (MRLs) at European level. Article 12(1) of that Regulation stipulates that the European Food Safety Authority (EFSA) shall provide within 12 months from the date of the inclusion or non-inclusion of an active substance in Annex I to Directive 91/414/EEC a reasoned opinion on the review of the existing MRLs for that active substance.

Tau-fluvalinate was included in Annex I to Council Directive 91/414/EEC on 1 June 2011 by means of Commission Directive 2011/19/EU which has been deemed to be approved under Regulation (EC) No 1107/2009, in accordance with Commission Implementing Regulation (EU) No 540/2011, as amended by Commission Implementing Regulation (EU) No 541/2011. Therefore, EFSA initiated the review of all existing MRLs for that active substance.

By way of background information, in the framework of Commission Regulation (EC) No 33/2008 Tau-fluvalinate was evaluated by Denmark, designated as the rapporteur Member State (RMS). Subsequently, a peer review on the initial evaluation of the RMS was conducted by EFSA, leading to the conclusions as set out in the EFSA scientific report (EFSA, 2010). The approval of Tau-fluvalinate is restricted to uses as insecticide and acaricide.

According to the legal provisions, EFSA shall base its reasoned opinion in particular on the relevant assessment report prepared under Directive 91/414/EEC repealed by Regulation (EC) No 1107/2009. It should be noted, however, that, in the framework of Regulation (EC) No 1107/2009, only a few representative uses are evaluated, whereas MRLs set out in Regulation (EC) No 396/2005 should accommodate all uses authorised within the European Union (EU), and uses authorised in third countries that have a significant impact on international trade. The information included in the assessment report prepared under Regulation (EC) No 1107/2009 is therefore insufficient for the assessment of all existing MRLs for a given active substance.

To gain an overview of the pesticide residues data that have been considered for the setting of the existing MRLs, EFSA developed the Pesticide Residues Overview File (PROFile). The PROFile is an inventory of all pesticide residues data relevant to the risk assessment and MRL setting for a given active substance. This includes data on:

- the nature and magnitude of residues in primary crops;
- the nature and magnitude of residues in processed commodities;
- the nature and magnitude of residues in rotational crops;
- the nature and magnitude of residues in livestock commodities;
- the analytical methods for enforcement of the proposed MRLs.

As the basis for the MRL review, on 17 July 2017, EFSA initiated the collection of data for this active substance. In a first step, Member States were invited to submit by 17 August 2017 their Good Agricultural Practices (GAPs) that are authorised nationally, in a standardised way, in the format of specific GAP forms. In the framework of this consultation, 16 Member States provided feedback on their national authorisations of tau-fluvalinate. Based on the GAP data submitted, the designated RMS Denmark was asked to identify the critical GAPs (cGAPs) to be further considered in the assessment, in order to

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1 Regulation (EC) No 396/2005 of the European 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 and repealing Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1–16.
2 Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1–32. Repealed by Regulation (EC) No 1107/2009.
3 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 No L 58, 3.3.2011, p. 41-44.
4 Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1-50.
5 Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 1-186.
6 Commission Implementing Regulation (EU) No 541/2011 of 1 June 2011 amending Implementing Regulation (EU) No 540/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 187-188.
7 Commission Regulation (EC) No 33/2008 of 17 January 2008 laying down detailed rules for the application of Council Directive 91/414/EEC as regards a regular and an accelerated procedure for the assessment of active substances which are part of the programme of work referred to in Article 9(2) of that Directive but have not been included into its Annex I. OJ L 15, 18.1.2008, p. 5–12.
the format of a specific GAP overview file. Subsequently, in a second step, Member States were requested to provide residue data supporting the cGAPs by 8 December 2017.

On the basis of all the data submitted by Member States and the EU Reference Laboratories for Pesticides Residues (EURLs), EFSA asked Denmark to complete the PROFile and to prepare a supporting evaluation report. The PROFile, the supporting evaluation report and an updated GAP overview file, were submitted to EFSA on 9 March 2018. Subsequently, EFSA performed the completeness check of these documents with the RMS. The outcome of this exercise including the clarifications provided by the RMS, if any, was compiled in the completeness check report.

Considering all the available information, EFSA prepared in August 2018 a draft reasoned opinion which was circulated to Member States for commenting via a written procedure. All comments received by 27 September 2018 were considered by EFSA during the finalisation of the reasoned opinion. An MRL application for modification of MRLs in products of animal origin was also considered in this review.

The evaluation report submitted by the RMS (Denmark, 2018), taking into account also the information provided by Member States during the collection of data, and the EURLs report on analytical methods (EURLs, 2018) are considered as main supporting documents to this reasoned opinion and, thus, made publicly available.

In addition, further supporting documents to this reasoned opinion are the completeness check report (EFSA, 2018a) and the Member States consultation report (EFSA, 2018b). These reports are developed to address all issues raised in the course of the review, from the initial completeness check to the reasoned opinion. Furthermore, the exposure calculations for all crops reported in the framework of this review performed using the EFSA Pesticide Residues Intake Model (PRIMo) and the PROFile as well as the GAP overview file listing all authorised uses are key supporting documents and made publicly available as background documents to this reasoned opinion. A screenshot of the report sheet of the PRIMo is presented in Appendix C.

Terms of Reference

According to Article 12 of Regulation (EC) No 396/2005, EFSA shall provide a reasoned opinion on:

- the inclusion of the active substance in Annex IV to the Regulation, when appropriate;
- the necessity of setting new MRLs for the active substance or deleting/modifying existing MRLs set out in Annex II or III of the Regulation;
- the inclusion of the recommended MRLs in Annex II or III to the Regulation;
- the setting of specific processing factors as referred to in Article 20(2) of the Regulation.

The active substance and its use pattern

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 1:1 mixture of two isomers (R-α-cyano and S-α-cyano isomers) whereby fluvalinate consists of four isomers. It is noted that only tau-fluvalinate is approved in the EU.

The chemical structure of the active substance and its main metabolites are reported in Appendix F. The EU MRLs for tau-fluvalinate are established in Annex IIIA of Regulation (EC) No 396/2005. Codex maximum residue limits (CXLs) for tau-fluvalinate are not available. An overview of the MRL changes that occurred since the entry into force of the Regulation mentioned above is provided below (Table 1).

| Procedure | Legal implementation | Remarks |
|-----------|----------------------|---------|
| MRL application | Commission Regulation (EU) 2015/401(a) | Modification of the existing MRLs for tau-fluvalinate in various crops (EFSA, 2014) |
| MRL application | Commission Regulation (EU) 2017/1777(c) | Modification of the existing MRLs for tau-fluvalinate in citrus fruits (EFSA, 2017) |

MRL: maximum residue level.

(a): Commission Regulation (EU) 2015/401 of 25 February 2015 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acetamiprid, chromafenozide, cyazofamid, dicamba, difenoconazole, fenpyrazamine, fluazinam, formetanate, nicotine, penconazole, pymetrozine, pyraclostrobin, tau-fluvalinate and tebuconazole in or on certain products. OJ L 71, 14.3.2015, p. 114–156.

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For the purpose of this MRL review, all the uses of tau-fluvalinate currently authorised within the EU as submitted by the Member States during the GAP collection, have been reported by the RMS in the GAP overview file. The cGAPs identified in the GAP overview file were then summarised in the PROFile and considered in the assessment. The details of the authorised cGAP for tau-fluvalinate are given in Appendix A. No import tolerances were reported by the RMS.

Tau-fluvalinate is used as veterinary drug for treatment of honey bees against the parasitic mite *Varroa jacobsoni* (EMEA, 1995). According to Regulation (EU) No 37/2009 no MRLs are required for tau-fluvalinate used as veterinary drug on bees.

Assessment

EFSA has based its assessment on the following documents:

- the PROFile submitted by the RMS;
- the evaluation report accompanying the PROFile (Denmark, 2018);
- the draft assessment report (DAR) prepared under Council Directive 91/414/EEC (Denmark, 2006);
- the additional report (AR) and the final addendum to the draft assessment report and additional report prepared under Commission Regulation (EC) No 33/2008 (Denmark, 2009, 2010);
- the conclusion on the peer review of the pesticide risk assessment of the active substance tau-fluvalinate (EFSA, 2010);
- the previous reasoned opinions on tau-fluvalinate (EFSA, 2014, 2017).

The assessment is performed in accordance with the legal provisions of the uniform principles for evaluation and authorisation of plant protection products as set out in Commission Regulation (EU) No 546/2011 and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (European Commission, 1997a–g, 2000, 2010a,b, 2017 and OECD, 2011, 2013).

More detailed information on the available data and on the conclusions derived by EFSA can be retrieved from the list of end points reported in Appendix B.

1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

The metabolism of tau-fluvalinate was investigated after foliar treatment in fruits crops, pulses/oilseeds and cereals/leafy vegetables (Denmark, 2006) and assessed in the framework of the peer review (EFSA, 2010). In the studies on apples, wheat and alfalfa, tau-fluvalinate was radiolabelled on the aniline and benzyl ring of the molecule and in wheat in addition on the benzotri fluoride ring. Metabolism studies on corn, cotton, tomatoes, tobacco, lettuce, cabbage and beans were submitted however not considered acceptable during the peer review.

After four foliar applications of 144 g a.s./ha on apples (fruit crops), the major component identified in the apples was unchanged tau-fluvalinate, representing 29.9–38 7% (0.425–0.438 mg eq./kg) of the...
total radioactive residues (TRR) while a group of polar metabolites accounted for 29% TRR (0.408 mg eq./kg).

After two foliar applications of 60 or 600 g a.s./ha with aniline ring- and benzyl ring-labelled tau-fluvalinate on wheat, unchanged tau-fluvalinate accounted for 90–93% TRR (0.34–2.34 mg eq./kg) in ears and haulms, 67–68% TRR (2.45–3.77 mg eq./kg) in straw and 21.2–64% TRR (0.01–0.02 mg eq./kg) in grain. In grain, major metabolites of aniline-labelled tau-fluvalinate were concluded to be conjugates of anilino acid and diacid representing 64% TRR (0.05 mg eq./kg). Decarboxy-fluvalinate was identified in ears, haulms, representing 5.4–6.2% TRR (0.1–0.12 mg eq./kg), in straw with 13.9% TRR (0.51 mg eq./kg) and in grain with 6.5% TRR (0.02 mg eq./kg). In a second study on wheat with benzotrifluoride-labelled tau-fluvalinate, after two foliar applications of 65 or 510 g a.s./ha, residue levels of tau-fluvalinate in grain were very low (≤3% TRR; ≤0.012 mg eq./kg) and the major metabolic fractions were one or more conjugates of haloaniline (29.3–44.2% TRR; 0.015–0.123 mg eq./kg). In this study, residues in straw and forage were not examined.

Based on the results of the two metabolism studies on wheat also considering authorised uses for cereals, unchanged tau-fluvalinate can be present (3–64.2% TRR) in grain at harvest, whereas polar metabolites in the form of conjugates of haloaniline and anilino acid are major metabolites account for 30–64% TRR and decarboxy-fluvalinate a minor metabolite with around 6% TRR.

After one foliar application of either 0.167, 0.5 or 1.11 kg a.s./ha on alfalfa (pulses and oilseeds), the major component identified in forage, hay and seeds was tau-fluvalinate, representing 80% of TRR while decarboxy-fluvalinate was the major metabolite in forage and hay harvested 7 and 13 days after treatment at 8–9% TRR. In seeds, the major metabolite was anilino acid accounting for 12–14% TRR and its degradation product diacid for up to 2.7% TRR whereby decarboxy-fluvalinate, 3-phenoxymethylaldehyde and 3-phenoxymethanoic acid represented 5–7.5% of the TRR.

Metabolism studies on commodities representing leafy vegetables were not considered valid and studies on root crops were not available. The available data on plant metabolism provided evidence that the metabolism of tau-fluvalinate is similar in apples, wheat and alfalfa. In all the examined crops, except in wheat grain, tau-fluvalinate accounted for a major part of the residues. In wheat grain the major part of the residue was accounted for by conjugated haloaniline and conjugated anilino acid. Anilino acid and decarboxy-fluvalinate were identified as major metabolites in most of the examined crops (EFSA, 2010).

EFSA concludes that the metabolism of tau-fluvalinate is sufficiently addressed in all crops under consideration.

1.1.2. Nature of residues in rotational crops

Tau-fluvalinate is authorised on crops that may be grown in rotation. The field DT$_{90}$ reported in the soil degradation studies evaluated in the framework of the peer review was 307 days (EFSA, 2010).

One confined rotational crop study with tau-fluvalinate radiolabelled on the aniline ring was available for this review (Denmark, 2006; EFSA, 2010). Tau-fluvalinate was applied at a rate of 144 g a.s./ha onto bare soil. Crops were planted at nominal plant-back intervals (PBI) of 28–364 days after treatment (DAT). Crops planted at each interval consisted of leafy vegetable (lettuce), roots (radish) and cereals (spring and winter wheat). According to aerobic soil degradation studies performed with $^{14}$C-anilino tau-fluvalinate, the relevant soil metabolites were haloaniline and haloaniline (EFSA, 2010).

Tau-fluvalinate and the metabolite haloaniline exceed the trigger value of a DT$_{90}$ of 100 days (DT$_{90}$ of 296 and 515 days, respectively) and potential residues in rotational crops of these compounds have to be addressed. As haloaniline has a DT$_{90}$ of above 500 days, its potential for accumulation from uses in consecutive years needs to be considered.

The concentration of tau-fluvalinate derived in soil using a single first-order (SFO) DT$_{50}$ in soil of 61.1 days (longest value from field studies) as agreed by the peer review (EFSA, 2010), is 0.045 mg/kg considering the cGAPs for EU cultivated non-permanent crop reported in this Article 12 review (2 applications per year at BBCH 12–49 at a rate of 96 g a.s./ha to leafy crops with a preharvest interval (PHI) of 14 days), assuming a soil density of 1.5 kg/L, soil mixing (cultivation) depth of 20 cm and crop interception of 25%. In the confined rotational crop study performed at 1 × 144 g tau-fluvalinate/ha (applied to bare soil which was aged for 28, 119, 182 and 364 days prior to planting lettuce, radish, spring and winter wheat outdoors), mean top soil residues were up to 0.077 mg/kg which represents 1.7 N rate of the most cGAPs considered in this review (maximal application rates for leafy crops 2 × 96 g a.s./ha). It can therefore be concluded that the concentrations for tau-fluvalinate is covered by this study.
The plateau concentration of haloaniline derived in soil using an SFO DT$_{50}$ in soil of 155 days as agreed by the peer review (EFSA, 2010), taking into account accumulation over the years, is 0.0065 mg/kg considering the cGAPs for EU cultivated non-permanent crop reported in this Article 12 review (two applications per year at BBCH 12–49 at a rate of 96 g a.s./ha to leafy crops with an PHI of 14 days), assuming a soil density of 1.5 kg/L, soil mixing (cultivation) depth of 20 cm, crop interception of 25%, maximum formation in soil 28.9% applied radioactivity (AR) and the relative molecular weight compared to tau-fluvalinate. In the confined rotational crop study, haloaniline residues did not appear to be present above the limit of quantification (LOQ) of 0.003 mg/kg in soil. Although the coverage of the plateau of haloaniline cannot be demonstrated from the study, the predicted plateau concentration is also below the LOQ of 0.01 mg/kg and further studies are not required.

The metabolism and distribution of tau-fluvalinate in rotational crops is similar to the metabolic pathway observed in primary crops. Tau-fluvalinate is the main residue and major degradation products are not formed.

1.1.3. Nature of residues in processed commodities

Studies investigating the nature of residues in processed commodities were assessed (Denmark, 2009; EFSA, 2010). Studies were conducted with radiolabelled tau-fluvalinate on the aniline and benzyl ring simulating representative hydrolytic conditions for pasteurisation (20 min at 90°C, pH 4), boiling/brewing/baking (60 min at 100°C, pH 5) and sterilisation (20 min at 120°C, pH 6).

The studies demonstrated that tau-fluvalinate is readily degraded when subject to hydrolytic conditions simulating sterilisation. The level of degradation increases with temperature/pH: 0–9.1% degradation under pasteurisation, 37–59% degradation under boiling/brewing/baking and 100% degradation under sterilisation.

The main degradation products under conditions simulating boiling/brewing/baking are diacid (22.3% at pH 5, 100°C of the AR) and anilino acid (13.5% at pH 5, 100°C of the AR). Two unidentified degrades named A and B were formed from labelled benzyl tau-fluvalinate which accounted for 14.7% and 10.2%, respectively (Denmark, 2006, 2009). These compounds were not identified and considering their proportions under boiling/brewing/baking, it is recommended to address this uncertainty (data gap).

Under processing conditions representing sterilisation tau-fluvalinate remained present only at 2% of the TRR whereas diacid and 3-phenoxybenzylaldehyde (3-PBAld) represented 90.1% and 96.8% of the applied TRR for aniline- and benzyl-labelled tau-fluvalinate, respectively. Diacid and anilino acid are the main degradation products of $^{14}$C-aniline-labelled tau-fluvalinate, whereby 3-phenoxybenzylaldehyde (3-PBAld) represents the main degradation product of $^{14}$C-benzyl]-labelled tau-fluvalinate.

Based on the results of the study, it can be concluded that tau-fluvalinate is hydrolysed to 3-phenoxybenzylaldehyde and anilino acid and that anilino acid is degraded to diacid. These metabolites were observed in unprocessed plants and goat metabolism in significant amounts (Sections 1.1.1 and 2.1). It has to be noted that tau-fluvalinate is not a good marker for all processed commodities.

1.1.4. Methods of analysis in plants

In the framework of the peer-review and of a previous MRL application, analytical methods based on gas chromatography (GC) GC coupled to electron capture detection (ECD) for high water, high oil and dry commodities (sufficiently validated in apples, beans, wheat grain, straw, oilseed rape, peaches, and potatoes) with a LOQ of 0.01 mg/kg and supported by an independent laboratory validation (ILV). It was noted that this method cannot distinguish between tau-fluvalinate and fluvalinate (EFSA, 2010, 2014). This method is considered to be suitable for enforcement of fluvalinate in high water, high oil and dry commodities without distinction of tau-fluvalinate isomers.

A liquid chromatography with tandem mass spectrometry (LC-MS/MS) method for high acid content matrices detection (validated in strawberries) with a LOQ of 0.01 mg/kg and supported by an ILV was provided in the context of a later MRL application and considered sufficiently validated for the determination of tau-fluvalinate residues (without distinction of tau-fluvalinate isomers). The method is considered suitable for enforcement of high acid commodities (EFSA, 2017). During the completeness check, the EURLs provided for the analysis of tau-fluvalinate in high water, high acid, high oil content and dry commodities a gas chromatography with tandem mass spectrometry (GC-MS/MS) and a gas chromatography–triple quadrupole mass spectrometry (GC-QqQ-MS/MS) methods with a LOQ of 0.01 mg/kg. It is outlined in the EURLs report that the method used in routine analyses can distinguish between these two isomers ($R$-$\alpha$-cyano and $S$-$\alpha$-cyano configuration). It can, however, not distinguish between tau-fluvalinate and fluvalinate which consists of four isomers...
(EURLs, 2018). These methods are thus considered suitable for enforcement of fluvalinate in all four matrices without distinction of tau-fluvalinate isomers.

1.1.5. Stability of residues in plants

The storage stability of tau-fluvalinate was investigated in the framework of the peer review (EFSA, 2010). The storage stability of tau-fluvalinate was investigated in high water, high acid, high oil content, dry (high protein and starch) and specific matrices (wheat straw) (Denmark, 2006; EFSA, 2010). The available studies demonstrated storage stability for tau-fluvalinate in all four main matrices for a period of 18 months when stored at −18°C. Stability of metabolites 3-PBAld, diacid and anilino acid in individually fortified samples of peach juice and puree was reported to be at least 360 days at −18°C.

1.1.6. Proposed residue definitions

The metabolism of tau-fluvalinate was similar in all crops assessed. The parent compound was found to be a sufficient marker in three crop categories. The metabolism in rotational crops is similar to the metabolism observed in primary crops.

For enforcement purpose, the residue definition for all edible crops is fluvalinate (sum of isomers) only as agreed during the peer review noting that the primary methods for monitoring cannot distinguish between fluvalinate and tau-fluvalinate and that only tau-fluvalinate is approved as an active substance in Europe.

Tau-fluvalinate is stable under conditions simulating pasteurisation but is likely to degrade increasingly into 3-phenoxybenzaldehyde and diacid under conditions of boiling and sterilisation. Therefore, under the latter two processing conditions, tau-fluvalinate is clearly not a suitable marker. However, neither are the two main degradation products since they were not found at significant levels above the LOQ in the available studies on the magnitude of residues representative of these processes (see Section 1.2.3). The residue definition for enforcement in processed commodities is proposed on a tentative basis as fluvalinate (sum of isomers) only for pasteurised products and fluvalinate (sum of isomers) (by default) for processed commodities subjected to boiling and/or sterilisation.

Analytical methods for the enforcement of the proposed residue definition at the LOQ of 0.01 mg/kg in four main plant matrices (high water, high acid, high oil and dry commodities) are available which cannot distinguish tau-fluvalinate from fluvalinate (see Section 1.1.4).

For risk assessment in raw commodities, the parent and anilino acid are considered toxicologically relevant and thus should be considered in the consumer exposure noting that only in cereals anilino acid including conjugates was present in significant amounts (EFSA, 2010, 2014). For processed commodities (in particular under sterilisation), 3-phenoxybenzaldehyde is potentially toxicologically relevant and a data gap regarding its toxicity was identified in a previous MRL application which is still open (Denmark, 2006; EFSA, 2010, 2014). For diacid which represents a minor metabolite in the rat, toxicological information is also not available.

For cereal grains, the residue definition for risk assessment is defined as the sum of tau-fluvalinate and anilino acid, including their conjugates, calculated as tau-fluvalinate. For risk assessment for all other raw agricultural commodities, the residue definition is tau-fluvalinate only. For processed commodities 3-phenoxybenzaldehyde and diacid were identified as potential contributors to the toxicological burden under certain hydrolysis conditions. However, in the absence of a full toxicological characterisation of these compounds, it is not possible to conclude on the residue definition for risk assessment in processed commodities. Therefore, the parent compound, 3-phenoxybenzaldehyde and diacid were retained on a tentative basis. While there are indications that 3-phenoxybenzaldehyde and diacid may not be retrieved in practice (see Section 1.2.3), it is recommended to keep investigating their occurrence in any new studies assessing the magnitude of residues in processed commodities and to address the data gaps regarding their toxicity.

EFSA emphasises that the available metabolism studies do not investigate the possible impact of plant metabolism on the isomer ratio of tau-fluvalinate and further investigation on this matter would in principle be required. Since guidance on the consideration of isomer ratios in the consumer risk assessment is not yet available, EFSA recommends that this issue is reconsidered when such guidance is available.
1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

To assess the magnitude of tau-fluvalinate residues resulting from the reported GAPs, EFSA considered all residue trials reported by the RMS in its evaluation report (Denmark, 2018) as well as the residue trials evaluated in the framework of the peer review (EFSA, 2010) and in the framework of previous MRL applications (Denmark, 2013; EFSA, 2014, 2017). All residue trial samples considered in this framework were stored in compliance with the conditions for which storage stability of residues was demonstrated. Decline of residues during storage of the trial samples is therefore not expected (Denmark, 2018).

The number of residue trials and extrapolations were evaluated in accordance with the European guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs (European Commission, 2017).

Residue trials are not available to support the northern outdoor GAP for sugar beet tops and lupins and are insufficient to support the southern outdoor GAP for sugar beet tops. Therefore no MRL and risk assessment values could be derived and the following data gap was identified:

- Sugar beet tops: eight additional trials compliant with the northern outdoor GAP and six additional trials compliant with the southern outdoor GAP are still required.
- Lupins/lupine beans: two additional trials compliant with the northern outdoor GAP are still required.

For citrus, pome and stone fruits, cherries, table and wine grapes, potatoes, root and tuber vegetables, aubergines, cucurbits with edible peel, melons and water melons, broccoli, cauliflowers, Brussels sprouts, head cabbages, kohlrabies, lettuces and salad plants, bean and peas with and without pods, globe artichokes, dry beans, peas and lentils, oil seeds, cereal grains and straw, sugar beet roots and alfalfa forage, available residue trials are sufficient to derive (tentative) MRL and risk assessment values, taking note of the following considerations:

- Pome fruits: Although MRL and risk assessment values can be derived from the northern outdoor trials, one additional trial compliant with the southern outdoor GAP is still required.
- Cherries: Although MRL and risk assessment values can be derived from the southern outdoor data, eight trials compliant with the northern outdoor GAP are still required.
- Strawberries: Although MRL and risk assessment values can be derived from the southern outdoor data, four additional trials compliant with the northern outdoor GAP are still required.
- Cucumber: Although a tentative MRL and risk assessment values can be derived from the southern outdoor data, four additional trials on cucumber compliant with the southern outdoor GAP are still required.
- Globe artichokes: Although MRL and risk assessment values can be derived from the southern outdoor data one additional trial compliant with the northern outdoor GAP is still required.
- Beans and peas (dry): Although tentative MRL and risk assessment values can be derived from a reduced number of trials, six additional trials compliant with the northern outdoor GAP and four additional trials compliant with the southern outdoor GAP are still required.
- Sunflower seeds: Although tentative MRL and risk assessment values can be derived from overdosed trials on rape seeds, eight additional trials compliant with the northern outdoor GAP are still required.
- Rapeseeds/canola seeds: Although MRL and risk assessment values can be derived from the northern data, four additional trials compliant with the southern outdoor GAP are still required.
- Sugar beet roots and tops: MRL and risk assessment values for sugar beet roots can be derived based on the southern outdoor GAP, for which a no residue situation is expected. For sugar beet tops two trials are insufficient and six additional trials are required to support the southern outdoor GAP. In addition, for sugar beet roots and tops eight trials compliant with the northern outdoor GAP are still required.
- Barley and oat straw: Tentative MRL and risk assessment values can be derived from a reduced number of trials supporting the northern and southern outdoor GAPs. However, two additional trials compliant with the northern outdoor GAP and one additional trial compliant with the southern outdoor GAP are still required.
- Alfalfa forage: Although MRL and risk assessment values can be derived from the southern outdoor data, four additional trials compliant with the northern outdoor GAP are still required.
For potatoes, root and tuber vegetables, lentils and cereal grains where available residue trials are sufficient to derive MRL and risk assessment values by taking note of the following considerations:

- **Potatoes:** The number of trials supporting the southern outdoor GAP is not compliant with the data requirements for this crop since only three trials on potatoes are available and the trials supporting the northern outdoor were performed to a more cGAP. However, the reduced number and overdosed residue trials are considered acceptable in this case because all results were below the LOQ indicating that no residues are expected. Further residue trials are therefore not required.

- **Root and tuber vegetables:** The number of trials supporting the northern and southern outdoor GAPs is not compliant with the data requirements for these crops. However, the reduced number of residue trials is considered acceptable in this case because all results were below the LOQ indicating that no residues are expected. Further residue trials are therefore not required.

- **Lentils:** The two trials supporting the northern outdoor GAP are not compliant with the data requirements for minor crops; however, since both are below LOQ and this is in line with the fully supported southern outdoor GAP, a no residue situation is indicated and additional trials are not required.

- **Cereal grains:** Residue trials analysing residues according to the residue definition for risk assessment are not available however a conversion factor of 4 was proposed based on metabolism studies during the peer review. Notwithstanding of this factor, residue trials analysed simultaneously according to the residue definition for enforcement and risk assessment would be desirable.

### 1.2.2. Magnitude of residues in rotational crops

Most of the crops under consideration can be grown in rotation with other plants and therefore the possible occurrence of residues in succeeding crops resulting from the use on primary crops has to be assessed. The soil degradation studies demonstrated that the degradation rate of tau-fluvalinate in soil is moderate (DT₉₀, 307 days). Field studies were not provided and a confined rotational crop study was considered as a surrogate (Section 1.1.2).

On the basis of the results, it is concluded that radioactivity does not tend to accumulate significantly in plants grown in soil treated with labelled tau-fluvalinate. The TRR was only found above 0.01 mg/kg in whole wheat plants (0.024–0.034 mg eq./kg) sown at 28 and 119 DAT noting that after 119 days in grain 0.017 mg eq./kg were reported which corresponds to 0.01 mg eq./kg considering the most cGAP rate in this assessment (1.7 N).

It has to be noted that from the available study a conclusion as to whether it covers the plateau of the metabolite haloaniline cannot be derived because the residues were too low (below the LOQ of 0.003 mg/kg) (see Section 1.1.2).

Significant residues are not expected in succeeding crops under the cGAP conditions of this review. Therefore, for this review, further studies are not considered necessary noting that it was not possible to conclude whether significant amounts of haloaniline would accumulate in succeeding crops over time.

### 1.2.3. Magnitude of residues in processed commodities

The effect of industrial processing and/or household preparation was assessed on studies conducted on grapes, peaches and tomatoes (Denmark, 2006, 2018). An overview of all available processing studies is available in Appendix B.1.2.3. Robust processing factors (fully supported by data) could be derived for peach juice, puree, jam and canned peaches while limited processing factors (not fully supported by data) were derived for processed commodities of grapes (wines, juice, must, pomaces and raisins) and canned sterilised tomatoes.

In the available four processing studies in sterilised fruits and two in vegetable produce, it was demonstrated that residues above the LOQ of tau-fluvalinate and its metabolite 3-phenoxycbenzaldehyde and diacid were not present above the LOQ.

During this review, two processing studies on the magnitude of tau-fluvalinate in sterilised canned tomatoes were provided. In one study, tau-fluvalinate was applied at an exaggerated rate of 270.8 g a.s/ha with a PHI of 3 days to derive a processing factor and in a second study the application rate was 381.4 g a.s./ha. Following sterilisation in both studies, no residues of tau-fluvalinate or...
3-phenoxybezaldehyde in canned tomatoes were found above the LOQ of 0.01 mg/kg for tau-fluvalinate and 0.01 mg/kg for 3-phenoxybenzaldehyde (Denmark, 2018).

The available four processing studies in sterilised fruits and two in vegetables demonstrated that no residues above the LOQ are expected for tau-fluvalinate or for any metabolite such as 3-phenoxybenzaldehyde or diacid.

However, if further robust processing factors were to be required by risk managers, in particular for enforcement purposes, additional processing studies would be needed for processed commodities where a tentative processing factor is derived.

1.2.4. Proposed MRLs

The available data are considered sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation, except for sugar beet tops and lupins where no MRL could be derived and for cucumber, dry beans, dry peas and sunflower seeds where tentative MRLs are derived. Tentative MRLs were also derived for feed crops (alfalfa forage and cereal straw) in view of the future need to set MRLs in feed items.

2. Residues in livestock

Tau-fluvalinate is authorised for use on crops that might be fed to livestock. Livestock dietary burden calculations were therefore performed for different groups of livestock according to OECD guidance (OECD, 2013), which has now also been agreed upon at European level. The input values for all relevant commodities are summarised in Appendix D. The dietary burdens calculated for all groups of livestock were found to exceed the trigger value of 0.1 mg/kg dry matter (DM). Behaviour of residues was therefore assessed in all commodities of animal origin.

It is highlighted that for sugar beet tops, no residue data were available. The animal intake of tau-fluvalinate residues via this commodity has therefore not been assessed and may have been underestimated. However, this is not expected to have a major impact on the outcome of the dietary burden considering the high/overwhelming contribution of alfalfa forage and meal.

2.1. Nature of residues and methods of analysis in livestock

The metabolism of tau-fluvalinate residues in livestock was investigated in lactating goats and laying hens at dose rates covering the maximum dietary burdens calculated in this review (Denmark, 2009, 2018). The two provided goat studies were assessed in the framework of the peer-review (EFSA, 2010). In one goat study, tau-fluvalinate was radiolabelled in the 14C-aniline and in a second study in the 14C-benzyl ring of the molecule.

In the study performed on lactating goats with radiolabelled in the 14C-aniline tau-fluvalinate, the highest TRR levels were found in liver (0.549 mg eq./kg) and kidney (0.369 mg eq./kg). Lower levels were found in fat (0.129 mg eq./kg) and muscle (0.073 mg eq./kg). The study indicates that unchanged tau-fluvalinate accounted for the major residue in milk (88.09% TRR; 0.044 mg eq./kg). Tau-fluvalinate also accounted for a large part of the residue in liver (10.06% TRR), kidney (11.84% TRR), fat (20.83% TRR) and muscle (19.15% TRR). However, the largest part of the residue in these tissues (liver: 55.93% TRR; kidney: 84.47% TRR; fat: 43.64% TRR; muscle: 73.59% TRR) was accounted for by anilino acid (sum of free and conjugated form). All other identified metabolites such as haloaniline were present at lower levels (< 10% TRR).

In the second study performed on lactating goats with radiolabelled in the 14C-benzyl tau-fluvalinate, the highest TRR levels were found in kidney (1.02 mg eq./kg), liver (0.21 mg eq./kg) and milk (0.27 mg eq./kg). Lower levels were found in fat (0.04 mg eq./kg) and muscle (0.01 mg eq./kg). The study indicates that unchanged tau-fluvalinate accounted for the major residue in liver (48% TRR), muscle (40% TRR) and fat (39% TRR). In kidney, the major part of the residue accounted for 3-phenoxybenzoic acid (34% TRR) while 3-phenoxybenzoic acid glycine conjugate accounted for 18% TRR and 4-0H-3-phenoxybenzoic acid for 13% TRR. In liver, fat and muscle, 3-phenoxybenzaldehyde accounted for 7.9%, 15% and 12% TRR. The metabolism of tau-fluvalinate was concluded to involve hydrolysis and conjugation of 3-phenoxybenzoic acid with glycine followed by excretion via urine.

On a tentative basis only, a metabolism study in poultry with CF3-14C-labelled fluvalinate was considered during this review (Denmark, 2018). The study was not performed according to guidelines and was conducted with a single dosing only. From the study it can be tentatively concluded that CF3-14C-labelled fluvalinate is metabolised rapidly. Residues in eggs were below 1% of the applied dose.
with the major part being in egg yolk. The major residues in fat and egg yolks were fluvalinate, anilino acid and taurochenodeoxycholic acid conjugates of anilino acid.

EFSA concludes that the metabolism of tau-fluvalinate in livestock is with the exception of poultry adequately elucidated, and tau-fluvalinate, 3-phenoxybenzoic acid and anilino acid including conjugates, calculated as tau-fluvalinate are the most relevant components of the residues in livestock commodities. It has, however, to be noted that these metabolites should be confirmed in a metabolism study on poultry conducted according to accepted guidelines carried out with benzyl- and aniline-labelled tau-fluvalinate.

An analytical method using high-performance liquid chromatography with mass spectrometry (HPLC-MS) was fully validated for the determination of fluvalinate in all animal tissues and milk, with a LOQ of 0.01 mg/kg noting that the method cannot distinguish between tau-fluvalinate and fluvalinate (EFSA, 2010). The method is considered suitable for enforcement purposes.

The EURLs provided a GC-MS/MS QuEChERS method for tau-fluvalinate in eggs with a LOQ of 0.002 mg/kg, for honey with a LOQ of 0.01 mg/kg and for liver with a LOQ of 0.001 mg/kg (EURLs, 2018). Although a fully validated analytical method for enforcement in eggs is not available, the EURLs informed EFSA that a LOQ of 0.002 mg/kg is achievable by using the QuEChERS method in routine analyses which can notably not distinguish between tau-fluvalinate and fluvalinate (EURLs, 2018).

The storage stability of tau-fluvalinate and anilino acid was demonstrated for a period of 110 days at –18°C in muscle, fat, liver, kidney and milk (Denmark, 2009; EFSA, 2010). The storage stability of tau-fluvalinate and anilino acid in eggs was reported for 1 month at 20°C. For the metabolite 3-phenoxybenzoic acid in muscle, fat, liver and eggs, storage stability studies are still desirable.

Tau-fluvalinate was found to be a sufficient marker in livestock commodities, the residue definition for enforcement is proposed as fluvalinate (sum of isomers) only, noting that none of the methods can distinguish between tau-fluvalinate and fluvalinate.

For risk assessment, parent and anilino acid, 3-phenoxybenzoic acid including their conjugates are toxicologically relevant and thus should be considered in the consumer exposure. The metabolites are encountered in the rat metabolism and were considered covered by the toxicological profile of the parent compound (EFSA, 2010). Therefore, the residue definition for risk assessment was defined as the sum of tau-fluvalinate and anilino acid and 3-phenoxybenzoic acid including their conjugates, expressed as tau-fluvalinate.

2.2. Magnitude of residues in livestock

The magnitude of residues was evaluated in lactating cows during the peer review and in laying hen during this review (Denmark, 2006, 2018).

In the feeding study on lactating cattle, tau-fluvalinate was administered using different dosing levels ranging from 0.03, 0.149 and 0.298 mg/kg body weight (bw) per day. This study was used to derive MRL and risk assessment values in milk and tissues of ruminants. Since extrapolation from ruminants to pigs is acceptable, results of the livestock feeding study on ruminants were relied upon to derive the MRL and risk assessment values in pigs. In this study, samples of tissues and milk were analysed for tau-fluvalinate, anilino acid and 3-phenoxybenzoic acid. The storage period of the samples was covered by the conditions for which storage stability was demonstrated thus decline of residues during storage of the trial samples is not expected.

During the peer review, conversion factors between the residue definition for monitoring and the residue definition for risk assessment were derived from the highest dose group and considering molecular weight to express metabolites as fluvalinate. The following conversion factors from monitoring to risk assessment were agreed during the peer review: conversion factors of 1.3, 11.2, 10.5, 1.1 and 1.5 for risk assessment in muscle, liver, kidney, fat and milk, respectively (EFSA, 2010).

A feeding study performed with laying hen has been submitted in the framework of this review (Denmark, 2013, 2018). In this study, fluvalinate was administered using different dosing levels ranging from 0.063 to 0.63 mg/kg bw per day; however only residues in hens dosed with the highest level and only results for the parent were reported and no results for the metabolites and conjugates which are included in the residue definition for risk assessment have been provided. Considering that the parent represents 72.3% of the TRR in fat, a conversion factor of 1.4 is proposed on a tentative basis. Similarly, for eggs where the parent represented around 30% TRR a conversion factor of 3.5 was estimated by EFSA on a tentative basis.

It has to be noted that to derive conversion factors from monitoring to risk assessment at least all metabolites and conjugates in the residue definition for risk assessment should have been analysed.
which was not the case in the poultry feeding study. Therefore, a livestock feeding study investigating all compounds included in the residue definition for risk assessment is still required in order to derive more robust conversion factors.

Based on the available studies, MRL and risk assessment values were derived for animal commodities of dairy ruminants/meat ruminants/pigs, in compliance with the latest recommendations on this matter (FAO, 2009). It is noted that significant levels of compounds are only expected in dairy ruminants, meat ruminants, pigs tissues and milk while for poultry muscle, liver, kidney and eggs MRLs are proposed at the LOQ.

3. Consumer risk assessment

Chronic and acute exposure calculations for all crops reported in the framework of this review were performed using revision 2 of the EFSA PRIMo (EFSA, 2007). Input values for the exposure calculations were derived in compliance with the decision tree reported in Appendix E. Hence, input values were derived according to the internationally agreed methodologies (FAO, 2009). Conversion factors were applied for cereal grains and for animal commodities (see Appendix B.3). All input values included in the exposure calculations are summarised in Appendix D.

The exposure values calculated were compared with the toxicological reference values for tau-fluvalinate, derived by EFSA (2010). The highest chronic exposure was calculated for DE child, representing 43.8% of the acceptable daily intake (ADI), and the highest acute exposure was calculated for scarole (broadleaf variety), representing 87.4% of the ARfD. These calculations indicate that the uses assessed under this review result in a consumer exposure lower than the toxicological reference values. Although uncertainties remain due to the data gaps identified in the previous sections, this indicative exposure calculation did not indicate a risk to consumer’s health.

EFSA emphasises that the above assessment does not consider the possible impact of plant and livestock metabolism on the isomer ratio of tau-fluvalinate and further investigation on this matter would in principle be required. Since guidance on the consideration of isomer ratios in the consumer risk assessment is not yet available, EFSA recommends that this issue is reconsidered when such guidance is available.

Conclusions

The metabolism of tau-fluvalinate in plant was investigated in primary and rotational crops. According to the results of the metabolism studies, the residue definitions except for processed commodities for enforcement can be proposed as fluvalinate (sum of isomers) and for risk assessment as tau-fluvalinate except for cereal grains where the sum of tau-fluvalinate plus anilino acid, including their conjugates, expressed as tau-fluvalinate is derived. A specific residue definition for rotational crops is not deemed necessary since significant residues of tau-fluvalinate and metabolites are not expected. The residue definition for enforcement in processed commodities is proposed tentatively as fluvalinate (sum of isomers) only for pasteurised products and fluvalinate (sum of isomers) by default for boiled and sterilised commodities. For risk assessment, the proposed residue definition is tau-fluvalinate, 3-phenoxybenzaldehyde and diacid.

Fully validated analytical methods are available for the enforcement of the proposed residue definition in all matrices at the LOQs of 0.01 mg/kg. According to the EURLs, the LOQ of 0.01 mg/kg is achievable by using the QuEChERS method in routine analyses.

Available residue trials data were considered sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation, except for cucumbers, dry beans and peas, sesame and sunflower seeds and barley and oat straw, where tentative MRLs are derived and for lupine beans and sugar beet tops where trials were insufficient to derive a MRL.

Taufluvalinate is authorised for use on crops that might be fed to livestock. Livestock dietary burden calculations were therefore performed for different groups of livestock according to OECD guidance. The dietary burdens calculated for all groups of livestock were found to exceed the trigger value of 0.1 mg/kg DM. Behaviour of residues was therefore assessed in all commodities of animal origin.

The metabolism of tau-fluvalinate residues in livestock was investigated in lactating goats and tentatively laying hens at dose rate covering the maximum dietary burdens calculated in this review. According to the results of these studies, the residue definitions for enforcement and risk assessment in livestock commodities were proposed as fluvalinate (sum of isomers) only and sum of tau-fluvalinate
and 3-phenoxybenzoic acid and anilino acid, including their conjugates, expressed as tau-fluvalinate, respectively. An analytical method for the enforcement of the proposed residue definition at the LOQ of 0.01 mg/kg in all matrices is available. According to the EURLs, the LOQ of 0.01 mg/kg is achievable by using the QuEChERS method in routine analyses (EURLs, 2018).

Livestock feeding studies on animal were used to derive MRL and risk assessment values in milk/eggs/tissues of ruminants/poultry. Since extrapolation from ruminants to pigs is acceptable, results of the livestock feeding study on ruminants were relied upon to derive the MRL and risk assessment values in pigs. The metabolism and feeding studies in poultry were considered on a tentative basis and are still required in line with established guidelines. Storage stability of tau-fluvalinate in eggs has to be still investigated.

Chronic and acute consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 2 of the EFSA PRIMo. The exposure values calculated were compared with the toxicological reference values for tau-fluvalinate, derived by EFSA (2010). The highest chronic exposure was calculated for DE child, representing 43.8% of the ADI, and the highest acute exposure was calculated for scarole (broadleaf variety), representing 87.4% of the ARfD. These calculations indicate that the uses assessed under this review result in a consumer exposure lower than the toxicological reference values. Although uncertainties remain due to the data gaps identified in the previous sections, this indicative exposure calculation did not indicate a risk to consumer’s health.

In addition, EFSA emphasises that the above studies do not investigate the possible impact of plant metabolism on the isomer ratio of tau-fluvalinate and that further investigation on this matter would in principle be required. Since guidance on the consideration of isomer ratios in the consumer risk assessment is not yet available, EFSA recommends that this issue is reconsidered when such guidance is available.

**Recommendations**

MRL recommendations were derived in compliance with the decision tree reported in Appendix E of the reasoned opinion (see Table 2). All MRL values listed as ‘Recommended’ in the table are sufficiently supported by data and are therefore proposed for inclusion in Annex II to the Regulation. The remaining MRL values listed in the table are not recommended for inclusion in Annex II because they require further consideration by risk managers (see Table 2 footnotes for details). In particular, some MRLs need to be confirmed by the following data:

- additional residue trials supporting the outdoor GAPs on cucumbers, dry pulses (beans, peas and lupins) and sunflower seeds;
- a representative study investigating metabolism in poultry;
- a representative livestock feeding study in poultry analysed for parent and metabolites included in the residue definition for risk assessment;
- a validated enforcement method for eggs (noting that the EURs provided a method).

It is also noted that no final conclusion on the residue definitions in processed commodities could be drawn because of the following uncertainties:

- identification of the metabolites named as ‘A’ and ‘B’;
- toxicological information of the metabolites 3-phenoxybenzaldehyde and diacid where genotoxicity and repeated-dose toxicity (short-term toxicity) in comparison with the toxicity profile of the parent tau-fluvalinate should be addressed;
- occurrence of 3-phenoxybenzaldehyde and diacid in processed commodities subject to sterilisation processes in practice.

It is highlighted, however, that some of the MRLs derived result from a GAP in one climatic zone only, whereas other GAPs reported by the RMS were not fully supported by data. EFSA therefore identified the following data gaps which are not expected to impact on the validity of the MRLs derived but which might have an impact on national authorisations:

- additional residue trials supporting the northern outdoor GAP on cherries, strawberries, globe artichokes, lentils, sugar beet roots and alfalfa forage;
- additional residue trials supporting the southern outdoor GAP on pome fruits and rape/canola seeds;
- additional residue trials supporting the indoor GAP on melons.
If the above-reported data gaps are not addressed in the future, Member States are recommended to withdraw or modify the relevant authorisations at national level.

Minor deficiencies were also identified in the assessment but these deficiencies are not expected to impact either on the validity of the MRLs derived or on the national authorisations. The following data are therefore considered desirable but not essential:

- residue trials for cereal grains analysed simultaneously according to the residue definitions for enforcement and risk assessment;
- additional residue trials supporting the outdoor GAPs on barley and oat straw and sugar beet tops;
- storage stability study for the metabolite 3-phenoxybenzoic acid in muscle, fat, liver and eggs.

### Table 2: Summary table

| Code number | Commodity                      | Existing EU MRL (mg/kg) | Outcome of the review | MRL (mg/kg) | Comment |
|-------------|--------------------------------|-------------------------|-----------------------|-------------|---------|
|             | **Enforcement residue definition (existing): tau-fluvalinate** |                        |                       |             |         |
| 0110010     | Grapefruits                    | 0.4                     | Recommended(a)        | 0.4         |         |
| 0110020     | Oranges                        | 0.4                     | Recommended(a)        | 0.4         |         |
| 0110030     | Lemons                         | 0.4                     | Recommended(a)        | 0.4         |         |
| 0110040     | Limes                          | 0.4                     | Recommended(a)        | 0.4         |         |
| 0110050     | Mandarins                      | 0.4                     | Recommended(a)        | 0.4         |         |
| 0130010     | Apples                         | 0.3                     | Recommended(a)        | 0.3         |         |
| 0130020     | Pears                          | 0.3                     | Recommended(a)        | 0.3         |         |
| 0130030     | Quinces                        | 0.3                     | Recommended(a)        | 0.3         |         |
| 0130040     | Medlars                        | 0.3                     | Recommended(a)        | 0.3         |         |
| 0130050     | Loquats/Japanese medlars        | 0.3                     | Recommended(a)        | 0.3         |         |
| 0140010     | Apricots                       | 0.3                     | Recommended(a)        | 0.3         |         |
| 0140020     | Cherries (sweet)               | 0.5                     | Recommended(a)        | 0.4         |         |
| 0140030     | Peaches                        | 0.3                     | Recommended(a)        | 0.3         |         |
| 0151010     | Table grapes                   | 1.0                     | Recommended(a)        | 1.0         |         |
| 0151020     | Wine grapes                    | 1.0                     | Recommended(a)        | 1.0         |         |
| 0152000     | Strawberries                   | 0.5                     | Recommended(a)        | 0.3         |         |
| 0211000     | Potatoes                       | 0.01*                   | Recommended(a)        | 0.01*       |         |
| 0213010     | Beetroots                      | 0.02                    | Recommended(a)        | 0.01*       |         |
| 0213020     | Carrots                        | 0.02                    | Recommended(a)        | 0.01*       |         |
| 0213030     | Celeriacs/turnip rooted celeries | 0.01*                | Recommended(a)        | 0.01*       |         |
| 0213040     | Horseradishes                  | 0.01*                   | Recommended(a)        | 0.01*       |         |
| 0213050     | Jerusalem artichokes           | 0.01*                   | Recommended(a)        | 0.01*       |         |
| 0213060     | Parsnips                       | 0.01*                   | Recommended(a)        | 0.01*       |         |
| 0213070     | Parsley roots/Hamburg roots parsley | 0.01*              | Recommended(a)        | 0.01*       |         |
| 0213090     | Salsifies                      | 0.01*                   | Recommended(a)        | 0.01*       |         |
| 0231030     | Aubergines/eggplants           | 0.15                    | Recommended(a)        | 0.15        |         |
| 0232010     | Cucumbers                      | 0.05                    | Further consideration needed(b) | 0.02 |         |
| 0232020     | Gherkins                       | 0.01*                   | Recommended(a)        | 0.02        |         |
| 0232030     | Courgettes                     | 0.01*                   | Recommended(a)        | 0.02        |         |
| 0233010     | Melons                         | 0.09                    | Recommended(a)        | 0.09        |         |
| 0233030     | Watermelons                    | 0.01*                   | Recommended(a)        | 0.09        |         |
| 0241010     | Broccoli                       | 0.4                     | Recommended(a)        | 0.3         |         |
| 0241020     | Cauliflowers                   | 0.1                     | Recommended(a)        | 0.3         |         |
| 0242010     | Brussels sprouts               | 0.1                     | Recommended(a)        | 0.15        |         |
| Code number | Commodity                                      | Existing EU MRL (mg/kg) | MRL (mg/kg) | Outcome of the review | Comment               |
|-------------|-----------------------------------------------|-------------------------|-------------|-----------------------|-----------------------|
| 0242020     | Head cabbages                                 | 0.2                     | 0.3         | Recommended(a)        |                       |
| 0244000     | Kohlrabies                                     | 0.07                    | 0.08        | Recommended(a)        |                       |
| 0251010     | Lamb’s lettuces/corn salads                   | 0.7                     | 0.7         | Recommended(a)        |                       |
| 0251020     | Lettuces                                      | 0.7                     | 0.7         | Recommended(a)        |                       |
| 0251030     | Escaroles/broadleaved endives                 | 0.7                     | 0.7         | Recommended(a)        |                       |
| 0251040     | Cresses and other sprouts and shoots           | 0.7                     | 0.7         | Recommended(a)        |                       |
| 0251050     | Land cresses                                   | 0.7                     | 0.7         | Recommended(a)        |                       |
| 0251060     | Roman rocket/rucola                           | 0.7                     | 0.7         | Recommended(a)        |                       |
| 0251070     | Red mustards                                  | 0.7                     | 0.7         | Recommended(a)        |                       |
| 0251080     | Baby leaf crops (including brassica species)   | 0.7                     | 0.7         | Recommended(a)        |                       |
| 0260010     | Beans (with pods)                              | 0.1                     | 0.6         | Recommended(a)        |                       |
| 0260020     | Beans (without pods)                           | 0.1                     | 0.05        | Recommended(a)        |                       |
| 0260030     | Peas (with pods)                               | 0.5                     | 0.6         | Recommended(a)        |                       |
| 0260040     | Peas (without pods)                            | 0.5                     | 0.05        | Recommended(a)        |                       |
| 0270050     | Globe artichokes                              | 0.8                     | 0.8         | Recommended(a)        |                       |
| 0300010     | Beans (dry)                                    | 0.01*                   | 0.01*       | Further consideration needed(b) |                       |
| 0300020     | Lentils (dry)                                  | 0.01*                   | 0.01*       | Recommended(a)        |                       |
| 0300030     | Peas (dry)                                     | 0.02                    | 0.01*       | Further consideration needed(b) |                       |
| 0300040     | Lupins/Lupini beans (dry)                      | 0.01*                   | 0.01*       | Further consideration needed(c) |                       |
| 0401010     | Linseeds                                       | 0.02*                   | 0.02        | Recommended(a)        |                       |
| 0401040     | Sesame seeds                                   | 0.02*                   | 0.01*       | Recommended(a)        |                       |
| 0401050     | Sunflower seeds                               | 0.1                     | 0.01*       | Further consideration needed(b) |                       |
| 0401060     | Rapeseeds/canola seeds                         | 0.1                     | 0.02        | Recommended(a)        |                       |
| 0401080     | Mustard seeds                                 | 0.02*                   | 0.02        | Recommended(a)        |                       |
| 0401090     | Cotton seeds                                  | 0.1                     | 0.09        | Recommended(a)        |                       |
| 0401100     | Pumpkin seeds                                 | 0.02*                   | 0.02        | Recommended(a)        |                       |
| 0401110     | Safflower seeds                               | 0.02*                   | 0.02        | Recommended(a)        |                       |
| 0401120     | Borage seeds                                  | 0.02*                   | 0.02        | Recommended(a)        |                       |
| 0401130     | Gold of pleasure seeds                        | 0.02*                   | 0.02        | Recommended(a)        |                       |
| 0401140     | Hemp seeds                                    | 0.02*                   | 0.02        | Recommended(a)        |                       |
| 0500010     | Barley grain                                  | 0.5                     | 0.4         | Recommended(a)        |                       |
| 0500050     | Oat grain                                      | 0.5                     | 0.4         | Recommended(a)        |                       |
| 0500070     | Rye grain                                      | 0.05                    | 0.05        | Recommended(a)        |                       |
| 0500090     | Wheat grain                                    | 0.05                    | 0.05        | Recommended(a)        |                       |
| 0900010     | Sugar beet roots                              | 0.01*                   | 0.01*       | Recommended(a)        |                       |
| 1011010     | Swine muscle                                  | 0.05                    | 0.015       | Recommended(a)        |                       |
| 1011020     | Swine fat tissue                              | 0.3                     | 0.05        | Recommended(a)        |                       |
| 1011030     | Swine liver                                   | 0.01*                   | 0.01*       | Recommended(a)        |                       |
| 1011040     | Swine kidney                                  | 0.02                    | 0.01*       | Recommended(a)        |                       |
| 1012010     | Bovine muscle                                 | 0.05                    | 0.05        | Recommended(a)        |                       |
| 1012020     | Bovine fat tissue                             | 0.3                     | 0.30        | Recommended(a)        |                       |
| 1012030     | Bovine liver                                  | 0.01*                   | 0.01*       | Recommended(a)        |                       |
| 1012040     | Bovine kidney                                 | 0.02                    | 0.015       | Recommended(a)        |                       |
| 1013010     | Sheep muscle                                  | 0.05                    | 0.05        | Recommended(a)        |                       |
| 1013020     | Sheep fat tissue                              | 0.3                     | 0.30        | Recommended(a)        |                       |
| 1013030     | Sheep liver                                   | 0.01*                   | 0.01*       | Recommended(a)        |                       |
### Code number | Commodity | Existing EU MRL (mg/kg) | Outcome of the review | Comment
---|---|---|---|---
1013040 | Sheep kidney | 0.02 | 0.015 | Recommended (a)
1014010 | Goat muscle | 0.05 | 0.05 | Recommended (a)
1014020 | Goat fat tissue | 0.3 | 0.30 | Recommended (a)
1014030 | Goat liver | 0.01* | 0.01 | Recommended (a)
1014040 | Goat kidney | 0.02 | 0.015 | Recommended (a)
1015010 | Equine muscle | 0.05 | 0.05 | Recommended (a)
1015020 | Equine fat tissue | 0.3 | 0.30 | Recommended (a)
1015030 | Equine liver | 0.01* | 0.01* | Recommended (a)
1015040 | Equine kidney | 0.02 | 0.015 | Recommended (a)
1016010 | Poultry muscle | 0.01* | 0.01* | Further consideration needed (b)
1016020 | Poultry fat tissue | 0.01* | 0.03 | Further consideration needed (b)
1016030 | Poultry liver | 0.01* | 0.01* | Further consideration needed (b)
1020010 | Cattle milk | 0.05 | 0.03 | Recommended (a)
1020020 | Sheep milk | 0.05 | 0.02 | Recommended (a)
1020030 | Goat milk | 0.05 | 0.02 | Recommended (a)
1020040 | Horse milk | 0.05 | 0.03 | Recommended (a)
1030000 | Bird eggs | 0.01* | 0.01* | Further consideration needed (b)
1030000 | Other commodities of plant and/or animal origin (EC) No 1777/2017 | (EC) No 1777/2017 | – | Further consideration needed (d)

MRL: maximum residue level; CXL: codex maximum residue limit.
*: Indicates that the MRL is set at the limit of quantification.
(F): The residue definition is fat soluble.
(a): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; no CXL is available (combination G-I in Appendix E).
(b): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified (assuming the existing residue definition); no CXL is available (combination E-I in Appendix E).
(c): GAP evaluated at EU level is not supported by data but no risk to consumers was identified for the existing EU MRL (also assuming the existing residue definition); no CXL is available (combination C-I in Appendix E).
(d): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix E).

### References

Denmark, 2006. Draft assessment report on the active substance tau-fluvalinate prepared by the rapporteur Member State Denmark in the framework of Council Directive 91/414/EEC, September 2006. Available online: [www.efsa.europa.eu](http://www.efsa.europa.eu)

Denmark, 2009. Additional report to the draft assessment report on the active substance tau-fluvalinate prepared by the rapporteur Member State Denmark in the framework of Commission Regulation (EC) No 33/2008, September 2009. Available online: [www.efsa.europa.eu](http://www.efsa.europa.eu)

Denmark, 2010. Final addendum to the draft assessment report and additional report on the active substance tau-fluvalinate, compiled by EFSA, April 2010. Available online: [www.efsa.europa.eu](http://www.efsa.europa.eu)

Denmark, 2013. Draft evaluation report prepared under Article 8 of Regulation (EC) No 396/2005. Modification of MRLs for tau-fluvalinate in products of animal origin. November 2013. Available online: [www.efsa.europa.eu](http://www.efsa.europa.eu)

Denmark, 2018. Evaluation report prepared under Article 12.1 of Regulation (EC) No 396/2005. Review of the existing MRLs for tau-fluvalinate, March 2018, updated May 2018. Available online: [www.efsa.europa.eu](http://www.efsa.europa.eu)

EFSA (European Food Safety Authority), 2007. Reasoned opinion on the potential chronic and acute risk to consumers’ health arising from proposed temporary EU MRLs. EFSA Journal 2007;5(3):32r, 1141 pp. [https://doi.org/10.2903/j.efsa.2007.32r](https://doi.org/10.2903/j.efsa.2007.32r)

EFSA (European Food Safety Authority), 2010. Conclusion on the peer review of the pesticide risk assessment of the active substance tau-fluvalinate. EFSA Journal 2010;8(7):1645, 75 pp. [https://doi.org/10.2903/j.efsa.2010.1645](https://doi.org/10.2903/j.efsa.2010.1645)

EFSA (European Food Safety Authority), 2014. Reasoned opinion on the modification of the existing MRLs for tau-fluvalinate in various crops. EFSA Journal 2014;12(1):3548, 49 pp. [https://doi.org/10.2903/j.efsa.2014.3548](https://doi.org/10.2903/j.efsa.2014.3548)

EFSA (European Food Safety Authority), 2017. Reasoned opinion on the modification of the existing MRLs for tau-fluvalinate in citrus fruits. EFSA Journal 2017;15(5):4771, 20 pp. [https://doi.org/10.2903/j.efsa.2017.4771](https://doi.org/10.2903/j.efsa.2017.4771)
EFSA (European Food Safety Authority), 2018a. Completeness check report on the review of the existing MRLs of tau-fluvalinate prepared by EFSA in the framework of Article 12 of Regulation (EC) No 396/2005, 6 June 2018. Available online: www.efsa.europa.eu

EFSA (European Food Safety Authority), 2018b. Member States consultation report on the review of the existing MRLs of tau-fluvalinate prepared by EFSA in the framework of Article 12 of Regulation (EC) No 396/2005, 15 October 2018. Available online: www.efsa.europa.eu

EMEA (European Agency for the Evaluation of Medicinal Products), 1995. Committee for Veterinary Medicinal Products, Tau-Fluvalinate, Revised summary Report. EMEA/MRL/021-Rev1/95. Available online: www.ema.europa.eu/documents/mrl-report/tau-fluvalinate-revised-summary-report-committee-veterinary-medicinal-products_en.pdf (downloaded on 15/10/2018)

EURLs (European Union Reference Laboratories for Pesticide Residues), 2018. Evaluation report prepared under Article 12 of Regulation (EC) No 396/2005. Analytical methods validated by the EURLs and overall capability of official laboratories to be considered for the review of the existing MRLs for tau-fluvalinate. March 2018. Available online: www.efsa.europa.eu

European Commission, 1997a. Appendix A. Metabolism and distribution in plants. 7028/IV/95-rev., 22 July 1996.

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

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

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

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

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

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

European Commission, 2000. Residue analytical methods. For pre-registration data requirement for Annex II (part A, section 4) and Annex III (part A, section 5 of Directive 91/414. SANCO/3029/99-rev. 4.

European Commission, 2010a. Classes to be used for the setting of EU pesticide Maximum Residue Levels (MRLs). SANCO 10634/2010-rev. 0, Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting of 23-24 March 2010.

European Commission, 2010b. Residue analytical methods. For post-registration control. SANCO/825/00-rev. 8.1, 16 November 2010.

European Commission, 2017. Appendix D. Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. 7525/VI/95-rev.10.3, June 2017

FAO (Food and Agriculture Organization of the United Nations), 2009. Submission and evaluation of pesticide residues data for the estimation of Maximum Residue Levels in food and feed. Pesticide Residues. 2nd Ed. FAO Plant Production and Protection Paper 197, 264 pp.

Greece, 2017. Evaluation report prepared under Article 12 of Regulation (EC) No 396/2005. Supporting trials to be considered for the review of the existing MRLs for tau-fluvalinate, December 2017. Available online: www.efsa.europa.eu.

OECD (Organisation for Economic Co-operation and Development), 2011. OECD MRL calculator: spreadsheet for single data set and spreadsheet for multiple data set, 2 March 2011. In: Pesticide Publications/Publications on Pesticide Residues. Available online: http://www.oecd.org

OECD (Organisation for Economic Co-operation and Development), 2013. Guidance document on residues in livestock. In: Series on Pesticides No 73. ENV/JM/MONO(2013)8, 4 September 2013.

Abbreviations

| Abbreviation | Definition |
|--------------|------------|
| a.i. | active ingredient |
| 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 residue definition to risk assessment residue definition |
| cGAP | critical GAP |
| CXL | codex maximum residue limit |
## Appendix A – Summary of authorised uses considered for the review of MRLs

### A.1. Authorised outdoor uses in northern EU

| Crop and/or situation | MS or country | FG or G1 | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|---------------|----------|------------------------------------|-------------|-------------|--------------------------------|------------|---------|
|                        |               |          |                                    |             |             |                                |            |         |
| Apples                | FR            | F        | Lepidoptera, bugs, midges          | EW 240 g/L  | Foliar treatment – broadcast spraying | 52–81      | 2 14 | 28 |
| Pears                 | FR            | F        | Lepidoptera, bugs, midges          | EW 240 g/L  | Foliar treatment – broadcast spraying | 52–81      | 2 14 | 28 |
| Quinces               | FR            | F        | Lepidoptera, bugs, midges          | EW 240 g/L  | Foliar treatment – broadcast spraying | 52–81      | 2 14 | 28 |
| Medlars               | FR            | F        | Lepidoptera, bugs, midges          | EW 240 g/L  | Foliar treatment – broadcast spraying | 52–81      | 2 14 | 28 |
| Loquats               | FR            | F        | Lepidoptera, bugs, midges          | EW 240 g/L  | Foliar treatment – broadcast spraying | 52–81      | 2 14 | 28 |
| Cherries              | SK            | F        | Epicometis hirta, syn. Tropinota hirta | EW 240 g/L  | Foliar treatment – broadcast spraying | 60–67      | 2 14 | n.a. No trials on stone fruits, so extrapolation not possible |
| Table grapes          | HU            | F        | Lobesia botrana, Scaphoideus titanus | EW 240 g/L  | Foliar treatment – broadcast spraying | 67–80      | 2 14 | 21 |
| Wine grapes           | HU            | F        | Lobesia botrana, Scaphoideus titanus | EW 240 g/L  | Foliar treatment – broadcast spraying | 67–80      | 2 14 | 21 |
| Crop and/or situation | MS or country | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) |
|-----------------------|--------------|-----------------------------------|-------------|-------------|-----------------------------|-----------|
|                       |              |                                   | Type(b) Conc. a.s. Method kind Range of growth stages & season(c) Number min-max Interval between applicat. (min) a.s./hL min-max Water L/ha min-max Rate and unit Remarks | | | |
| Strawberries          | AT           | F                                 | EW 240 g/L Foliar treatment – general (see also comment field) n.a. to 85 2 10 – – | 0.048 kg a.i./ha | 7 |
| Potatoes              | BE           | F Aphids                          | EW 242 g/L Foliar treatment – general (see also comment field) 33–85 1 – – | 72 g a.i./ha | 14 |
| Carrots               | FR           | F Aphids                          | EW 240 g/L Foliar treatment – broadcast spraying 10–49 2 14 – – | 72 g a.i./ha | 14 |
| Celeriacs             | FR           | F Aphids                          | EW 240 g/L Foliar treatment – broadcast spraying 10–49 2 14 – – | 72 g a.i./ha | 14 |
| Horseradishes         | FR           | F Aphids                          | EW 240 g/L Foliar treatment – broadcast spraying 10–49 2 14 – – | 72 g a.i./ha | 14 |
| Jerusalem artichokes  | FR           | F Aphids                          | EW 240 g/L Foliar treatment – broadcast spraying 10–49 2 14 – – | 72 g a.i./ha | 14 |
| Parsnips              | FR           | F Aphids                          | EW 240 g/L Foliar treatment – broadcast spraying 10–49 2 14 – – | 72 g a.i./ha | 14 |
| Parsley roots         | FR           | F Aphids                          | EW 240 g/L Foliar treatment – broadcast spraying 10–49 2 14 – – | 72 g a.i./ha | 14 |
| Salsifies             | FR           | F Aphids                          | EW 240 g/L Foliar treatment – broadcast spraying 10–49 2 14 – – | 72 g a.i./ha | 14 |
| Melons                | FR           | F Aphids                          | EW 240 g/L Foliar treatment – broadcast spraying 15–89 2 14 – – | 48 g a.i./ha | 7 |
| Crop and/or situation | MS or country | F or G or I | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|---------------|-------------|---------------------------------|-------------|-------------|--------------------------------|------------|---------|
|                       |               |             |                                 |             | Type(a) | Conc. a.s. | Method kind | Range of growth stages & season(c) | Number min–max | Interval between applicat. (min) | a.s./hL min–max | Water L/ha min–max | Rate and unit | |
| Watermelons           | FR            | F           | Aphids                          | EW          | 240 g/L  | Foliar treatment – broadcast spraying | 15–89      | 2          | – –             | 48 g a.i./ha | 7 | Melon granted in 2014, but it was omitted to request the extrapolation from melon |
| Broccoli              | FR            | F           | Aphids, Lepidoptera             | EW          | 240 g/L  | Foliar treatment – broadcast spraying | 10–49      | 1          | – –             | 72 g a.i./ha | 7 |
| Cauliflowers          | FR            | F           | Aphids, Lepidoptera             | EW          | 240 g/L  | Foliar treatment – broadcast spraying | 10–49      | 1          | – –             | 72 g a.i./ha | 7 |
| Brussels sprouts      | FR            | F           | Aphids, Lepidoptera             | EW          | 240 g/L  | Foliar treatment – broadcast spraying | 10–49      | 1          | – –             | 72 g a.i./ha | 7 |
| Head cabbages         | FR            | F           | Aphids, Lepidoptera             | EW          | 240 g/L  | Foliar treatment – broadcast spraying | 10–49      | 1          | – –             | 72 g a.i./ha | 7 | GAP previously reported (Denmark, 2013) |
| Kohlrabies            | DK            | F           | Aphids, Lepidoptera             | EW          | 240 g/L  | Foliar treatment – broadcast spraying | 19         | 1          | – –             | 48 g a.i./ha | 7 | MRL granted in 2014, application for this use is in progress |
| Beans (with pods)     | FR            | F           | Aphids, pea moth, midges, thrips | EW          | 240 g/L  | Foliar treatment – broadcast spraying | 9–85       | 2          | 14              | 72 g a.i./ha | 7 | Residue trials from EL |
| Beans (without pods)  | FR            | F           | Aphids, pea moth, midges, thrips | EW          | 240 g/L  | Foliar treatment – broadcast spraying | 9–85       | 2          | 14              | 72 g a.i./ha | 7 | Residue trials from EL |
| Crop and/or situation | MS or country | F or G or I | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|---------------|-------------|------------------------------------|-------------|------------|-------------------------------|------------|---------|
| Peas (with pods)      | FR            | F           | Aphids, pea moth, midges, thrips   | EW 240 g/L  | Foliar treatment – broadcast spraying | 9–85          | 2 14 | – – | 72 g a.i./ha | 7 |
| Peas (without pods)   | FR            | F           | Aphids, pea moth, midges, thrips   | EW 240 g/L  | Foliar treatment – broadcast spraying | 9–85          | 2 14 | – – | 72 g a.i./ha | 7 |
| Globe artichokes      | FR            | F           | Aphids                            | EW 240 g/L  | Foliar treatment – broadcast spraying | 15–49         | 2 14 | – – | 72 g a.i./ha | 7 Residue trials from EL |
| Beans (dry)           | FR            | F           | Aphids, pea moth, midges, thrips   | EW 240 g/L  | Foliar treatment – broadcast spraying | 9–79          | 2 14 | – – | 72 g a.i./ha | 14 |
| Lentils (dry)         | FR            | F           | Aphids, pea moth, midges, thrips   | EW 240 g/L  | Foliar treatment – broadcast spraying | 9–79          | 2 14 | – – | 72 g a.i./ha | 14 |
| Peas (dry)            | FR            | F           | Aphids, pea moth, midges, thrips   | EW 240 g/L  | Foliar treatment – broadcast spraying | 9–79          | 2 14 | – – | 72 g a.i./ha | 14 |
| Lupins                | FR            | F           | Aphids, pea moth, midges, thrips   | EW 240 g/L  | Foliar treatment – broadcast spraying | 9–79          | 2 14 | – – | 72 g a.i./ha | 14 |
| Linseeds              | FR            | F           |                                   | EW 240 g/L  | Foliar treatment – broadcast spraying | 10–29         | 2 7  | – – | 48 g a.i./ha | 28 |
| Crop and/or situation | MS or country | F  | G  | Type(b) | Conc. a.s. | Application | Range of growth stages & season(c) | Number min–max | Interval between applicat. (min) | a.s./hL min–max | Water L/ha min–max | Rate and unit | PHI (days)(d) | Remarks |
|-----------------------|---------------|----|----|---------|-----------|------------|-----------------------------------|----------------|-------------------------------|----------------|----------------|--------------|-------------|---------|
| Sunflower seeds       | HU            | F  |    | EW      | 240 g/L   | Foliar treatment – broadcast spraying | 12–67               | 2                             | 14              | –                            | –             | 48 g a.i./ha | 60        | EFSA: an intended use 2 × 72 g as/ha, 14 days between treatments, PHI of 30 days was reported (Denmark, 2013), however not supported by residue trials |
| Rapeseeds             | FR            | F  |    | EW      | 240 g/L   | Foliar treatment – broadcast spraying | 31–80               | 2                             | 7               | –                            | –             | 48 g a.i./ha | 28        | A new intended use was reported with a PHI of 30 days (Denmark, 2013) |
| Mustard seeds         | FR            | F  |    | EW      | 240 g/L   | Foliar treatment – broadcast spraying | 31–80               | 2                             | 7               | –                            | –             | 48 g a.i./ha | 28        |               |
| Pumpkin seeds         | UK            | F  |    | EW      | 240 g/L   | Foliar treatment – general (see also comment field) | 69                  | 2                             | –               | –                            | –             | 48 g a.i./ha | n.a.      |               |
| Safflower seeds       | UK            | F  |    | EW      | 240 g/L   | Foliar treatment – general (see also comment field) | 69                  | 2                             | –               | –                            | –             | 48 g a.i./ha | n.a.      |               |
| Borage seeds          | FR            | F  |    | EW      | 240 g/L   | Foliar treatment – broadcast spraying | 10–29               | 2                             | 7               | –                            | –             | 48 g a.i./ha | 28        |               |
| Crop and/or situation | MS or country | F G or I | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|----------------------|--------------|---------|-----------------------------------|-------------|------------|-------------------------------|------------|---------|
| Gold of pleasure seeds | FR F | EW 240 g/L | Foliar treatment – broadcast spraying | 10–29 | 2 | 7 | – | 48 g a.i./ha | 28 |
| Hemp seeds | FR F | EW 240 g/L | Foliar treatment – broadcast spraying | 10–29 | 2 | 7 | – | 48 g a.i./ha | 28 |
| Barley | FR F | EW 240 g/L | Foliar treatment – broadcast spraying | 10–75 | 3 | 10 | – | 48 g a.i./ha | 28 |
| Oat | FR F | EW 240 g/L | Foliar treatment – broadcast spraying | 10–75 | 3 | 10 | – | 48 g a.i./ha | 28 |
| Rye | FR F | EW 240 g/L | Foliar treatment – broadcast spraying | 10–75 | 3 | 10 | – | 48 g a.i./ha | 28 |
| Wheat | FR F | EW 240 g/L | Foliar treatment – broadcast spraying | 10–75 | 3 | 10 | – | 48 g a.i./ha | 28 |
| Crop and/or situation | MS or country | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|---------------|-----------------------------------|-------------|-------------|-------------------------------|------------|---------|
| Sugar beets           | CZ            | Tetranychus urticae               | EW 240 g/L  | Foliar treatment – broadcast spraying | 32–49 | 2 | 14 | 48 g a.i./ha | 14 | A different GAP (1 × 72 g as/ha; PHI = 14 days) is authorised in SK however not supported by data. Therefore the intended use reported by CZ (2 × 48 g as/ha; interval 14 days; PHI=14 days) supported by residue trials (Denmark, 2013) is considered |
| Alfalfa (for forage)  | CZ            | Aphididae                         | EW 240 g/L  | Foliar treatment – broadcast spraying | 12–72 | 2 | – | 72 g a.i./ha | 7 | New intended use reported for CZ (Denmark, 2013) |

MS: Member State; MRL: maximum residue level; a.s.: active substance; a.i.: active ingredient; EW: emulsion, oil in water; GAP: Good Agricultural Practice; NEU: northern European Union.
(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.
(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4).
(d): PHI: minimum preharvest interval.
## A.2. Authorised outdoor uses in southern EU

| Crop and/or situation | MS or country | F G I | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|---------------|-------|-----------------------------------|-------------|-------------|-------------------------------|-----------|---------|
|                       |               |       | (a)                               |             |             |                               |           |         |
| Grapefruits           | ES            | F     | Lepidoptera, bugs, midges         | EW 240 g/L  | Foliar treatment – broadcast spraying | 96 g a.i./ha | 30 | MRL established in 2014. Registration in progress in SEU countries |
| Oranges               | ES            | F     | Lepidoptera, bugs, midges         | EW 240 g/L  | Foliar treatment – broadcast spraying | 96 g a.i./ha | 30 | MRL established in 2014. Registration in progress in SEU countries |
| Lemons                | ES            | F     | Lepidoptera, bugs, midges         | EW 240 g/L  | Foliar treatment – broadcast spraying | 96 g a.i./ha | 30 | MRL established in 2014. Registration in progress in SEU countries |
| Limes                 | ES            | F     | Lepidoptera, bugs, midges         | EW 240 g/L  | Foliar treatment – broadcast spraying | 96 g a.i./ha | 30 | MRL established in 2014. Registration in progress in SEU countries |
| Mandarins             | ES            | F     | Lepidoptera, bugs, midges         | EW 240 g/L  | Foliar treatment – broadcast spraying | 96 g a.i./ha | 30 | MRL established in 2014. Registration in progress in SEU countries |
| Apples                | FR            | F     | Lepidoptera, bugs, midges         | EW 240 g/L  | Foliar treatment – broadcast spraying | 144 g a.i./ha | 28 |         |
| Pears                 | FR            | F     | Lepidoptera, bugs, midges         | EW 240 g/L  | Foliar treatment – broadcast spraying | 144 g a.i./ha | 28 |         |
| Crop and/or situation | MS or country | FG or T | Pests or Group of pests controlled | Preparation Type (b) | Conc. a.s (c) | Method kind | Application Range of growth stages & season (c) | Number min-max | Interval between applicat. (min) | Application rate per treatment a.s./hL min-max | Water L/ha min-max | Rate and unit | PHI (days)(d) | Remarks |
|-----------------------|---------------|---------|-----------------------------------|---------------------|-------------|------------|--------------------------------|-------------|-----------------|--------------------------------|----------------|-------------|--------------|---------|
| Quinces               | FR            | F       | Lepidoptera, bugs, midges         | EW                  | 240 g/L    | Foliar treatment – broadcast spraying | 52 - 81     | 2               | 14              | –                | –            | 144 g a.i./ha | 28       |         |
| Medlars              | FR            | F       | Lepidoptera, bugs, midges         | EW                  | 240 g/L    | Foliar treatment – broadcast spraying | 52 - 81     | 2               | 14              | –                | –            | 144 g a.i./ha | 28       |         |
| Loquats              | FR            | F       | Lepidoptera, bugs, midges         | EW                  | 240 g/L    | Foliar treatment – broadcast spraying | 52 - 81     | 2               | 14              | –                | –            | 144 g a.i./ha | 28       |         |
| Apricots             | FR            | F       | Aphids                            | EW                  | 240 g/L    | Foliar treatment – broadcast spraying | 53 - 81     | 2               | 14              | –                | –            | 144 g a.i./ha | 28       |         |
| Cherries             | EL            | F       | Aphids, Rhagoletis, Anthonomus, Rhynchites | EW                  | 240 g/L    | Foliar treatment – broadcast spraying | 57 - 81     | 2               | –               | –                | 60 g a.i./ha  | 10         | Trials on apple/ pear and peaches/apricots are overdosed |
| Peaches              | FR            | F       | Lepidoptera, thrips               | EW                  | 240 g/L    | Foliar treatment – broadcast spraying | 53 - 81     | 2               | 14              | –                | –            | 144 g a.i./hl  | 28       |         |
| Table grapes         | FR            | F       | Leafhoppers, thrips, mites         | EW                  | 240 g/L    | Foliar treatment – broadcast spraying | 53 - 85     | 2               | 14              | –                | –            | 72 g a.i./ha   | 21       |         |
| Wine grapes          | FR            | F       | Leafhoppers, thrips, mites         | EW                  | 240 g/L    | Foliar treatment – broadcast spraying | 53 - 85     | 2               | 14              | –                | –            | 72 g a.i./ha   | 21       |         |
| Crop and/or situation | MS or country | F | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|--------------|---|-----------------------------------|-------------|------------|--------------------------------|------------|---------|
| Strawberries          | EL, FR       | F  | Aphids, thrips, Spodoptera        | EW 240 g/L  | Foliar treatment – broadcast spraying | 15-87 2 14 | – – | 72 g a.i./ha | 7 |
| Potatoes              | EL           | F  | Aphids, Leptinotarsa              | EW 240 g/L  | Foliar treatment – broadcast spraying | 10-49 2   | – – | 72 g a.i./ha | 14 |
| Beetroots             | EL           | F  | Aphids, Leptinotarsa              | EW 240 g/L  | Foliar treatment – broadcast spraying | 10-49 2   | – – | 72 g a.i./ha | 14 |
| Carrots               | EL, FR       | F  | Aphids                            | EW 240 g/L  | Foliar treatment – broadcast spraying | 15-49 2 14 | – – | 72 g a.i./ha | 14 |
| Jerusalem artichokes  | FR           | F  | Aphids                            | EW 240 g/L  | Foliar treatment – broadcast spraying | 10-49 2 14 | – – | 72 g a.i./ha | 14 |
| Parsnips              | FR           | F  | Aphids                            | EW 240 g/L  | Foliar treatment – broadcast spraying | 10-49 2 14 | – – | 72 g a.i./ha | 14 |
| Parsley roots         | FR           | F  | Aphids                            | EW 240 g/L  | Foliar treatment – broadcast spraying | 10-49 2 14 | – – | 72 g a.i./ha | 14 |
| Aubergines            | EL           | F  | Aphids, thrips, Helicoverpa, Spodoptera | EW 240 g/L  | Foliar treatment – broadcast spraying | 10-89 2   | – – | 48 g a.i./ha | 3 |
| Crop and/or situation | MS or country | FG or IT(a) | Pests or Group of pests controlled | Type (b) | Conc. a.s. | Method kind | Application | PHI (days)(d) | Remarks |
|-----------------------|--------------|-------------|-----------------------------------|---------|-----------|------------|------------|-------------|---------|
| Cucumbers             | EL           | F           | Aphids, thrips, *Helicoverpa* *Spodoptera* | EW      | 240 g/L   | Foliar treatment – broadcast spraying | 10–89 | 2          | –        | 48 g a.i./ha | 3       |
| Gherkins              | EL           | F           | Aphids, thrips                     | EW      | 240 g/L   | Foliar treatment – broadcast spraying | 15–89 | 2          | –        | 48 g a.i./ha | 7       |
| Courgettes            | EL           | F           | Aphids, thrips                     | EW      | 240 g/L   | Foliar treatment – broadcast spraying | 15–89 | 2          | –        | 48 g a.i./ha | 7       |
| Melons                | EL           | F           | Aphids, thrips                     | EW      | 240 g/L   | Foliar treatment – broadcast spraying | 15–89 | 2          | –        | 72 g a.i./ha | 7       |
| Watermelons           | ES           | F           | Aphididae, *Tripidae*              | EW      | 240 g/L   | Foliar treatment – broadcast spraying | 15–89 | 2          | 14       | 72 g a.i./ha | 7       |
| Broccoli              | IT           | F           |                                    |         |           | Foliar treatment – broadcast spraying | 10–49 | 1          | –        | 72 g a.i./ha | 7       |
| Cauliflowers          | EL           | F           | Aphids, thrips, *Mamestra*, *Pieris* | EW      | 240 g/L   | Foliar treatment – broadcast spraying | 10–49 | 1          | –        | 72 g a.i./ha | 7       |
| Crop and/or situation | MS or country | F G or I | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|--------------|---------|-----------------------------------|-------------|------------|-------------------------------|--------------|---------|
|                       |              |         |                                   | Type | Conc. a.s. | Method kind | Range of growth stages & season(c) | Number min-max | Interval between applicat. (min) | Water L/ha min-max | Rate and unit | |
| Brussels sprouts      | EL F         |         | Aphids, thrips, Mamestra, Pieris   | EW 240 g/L | Foliar treatment – broadcast spraying | 10–49 | 1 | – | – | 72 g a.i./ha | 7 |         |
| Head cabbages         | EL F         |         | Aphids, thrips, Mamestra, Pieris   | EW 240 g/L | Foliar treatment – broadcast spraying | 10–49 | 1 | – | – | 72 g a.i./ha | 7 | GAP previously reported (Denmark, 2013) |
| Lamb’s lettuces       | EL F         |         | Aphids, thrips, Mamestra, Pieris, Liriomyza | EW 240 g/L | Foliar treatment – broadcast spraying | 12–49 | 2 | – | – | 96 g a.i./ha | 14 |         |
| Lettuces              | EL F         |         | Aphids, thrips, Mamestra, Pieris, Liriomyza | EW 240 g/L | Foliar treatment – broadcast spraying | 12–49 | 2 | – | – | 96 g a.i./ha | 14 |         |
| Escaroles             | EL F         |         | Aphids, thrips, Mamestra, Pieris, Liriomyza | EW 240 g/L | Foliar treatment – broadcast spraying | 12–49 | 2 | – | – | 96 g a.i./ha | 14 |         |
| Cresses               | EL F         |         | Aphids, thrips, Mamestra, Pieris, Liriomyza | EW 240 g/L | Foliar treatment – broadcast spraying | 12–49 | 2 | – | – | 96 g a.i./ha | 14 |         |
| Land cresses          | EL F         |         | Aphids, thrips, Mamestra, Pieris, Liriomyza | EW 240 g/L | Foliar treatment – broadcast spraying | 12–49 | 2 | – | – | 96 g a.i./ha | 14 |         |
| Roman rocket          | EL F         |         | Aphids, thrips, Mamestra, Pieris, Liriomyza | EW 240 g/L | Foliar treatment – broadcast spraying | 12–49 | 2 | – | – | 96 g a.i./ha | 14 |         |
| Crop and/or situation | MS or country | FG or T | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|---------------|---------|-----------------------------------|-------------|------------|-------------------------------|------------|---------|
|                       |               |         |                                   |             |            |                               |            |         |
| Red mustards          | EL            | F       | Aphids, thrips, Mamestra, Pieris, Liriomyza | EW 240 g/L | Foliar treatment – broadcast spraying | 96 g a.i./ha | 14 |
| Baby leaf crops       | EL            | F       | Aphids, thrips, Mamestra, Pieris, Liriomyza | EW 240 g/L | Foliar treatment – broadcast spraying | 96 g a.i./ha | 14 |
| Beans (with pods)     | FR            | F       | Aphids, Pea moth, midges, thrips | EW 240 g/L | Foliar treatment – broadcast spraying | 72 g a.i./ha | 7 |
| Beans (without pods)  | EL            | F       | Aphids, thrips, Cydia, Contarinia | EW 240 g/L | Foliar treatment – broadcast spraying | 72 g a.i./ha | 7 |
| Peas (with pods)      | FR            | F       | Aphids, pea moth, midges, thrips | EW 240 g/L | Foliar treatment – broadcast spraying | 72 g a.i./ha | 7 Residue trials from EL |
| Peas (without pods)   | EL            | F       | Aphids, thrips, Cydia, Contarinia | EW 240 g/L | Foliar treatment – broadcast spraying | 72 g a.i./ha | 7 |
| Globe artichokes      | EL            | F       | Aphids, thrips, Spodoptera | EW 240 g/L | Foliar treatment – broadcast spraying | 72 g a.i./ha | 7 |
| Beans (dry)           | EL            | F       | Aphids, thrips, Cydia, Contarinia, Helicoverpa | EW 240 g/L | Foliar treatment – broadcast spraying | 72 g a.i./ha | 14 |
| Crop and/or situation | MS or country | FG or I | Pests or Group of pests controlled | Preparation | Type | Conc. a.s. | Method kind | Range of growth stages & season | Number min-max | Interval between application (min) | PHI (days) | Remarks |
|-----------------------|---------------|---------|-----------------------------------|-------------|-------|-----------|------------|-----------------------------|----------------|-----------------------------|------------|---------|
| Lentils (dry)         | IT            | F       | Aphididae, Triptidae, Lepidoptera and Midge | EW          | 240 g/L | Foliar treatment – broadcast spraying | 9-79        | 2               | 14                       | 72 g a.i./ha | 14 | Residue trials from EL |
| Peas (dry)            | EL            | F       | Aphids, thrips, Cydia, Contarinia, Helicoverpa | EW          | 240 g/L | Foliar treatment – broadcast spraying | 15-79       | 2               | –            | 72 g a.i./ha | 14 |
| Sesame seeds          | FR            | F       | Aphids                           | EW          | 240 g/L | Foliar treatment – broadcast spraying | 10-29       | 2               | 7            | 48 g a.i./ha | 28 |
| Sunflower seeds       | EL            | F       | Aphids                           | EW          | 240 g/L | Foliar treatment – broadcast spraying | 12-19       | 2               | 14           | 72 g a.i./ha | 60 | Only residue trials for 48 g as/ha were submitted (RMS comment). EFSA: an intended use with a PHI of 30 days was reported (Denmark, 2013) |
| Rapeseeds             | FR            | F       | Aphids, beetles                | EW          | 240 g/L | Foliar treatment – broadcast spraying | 10-80       | 2               | 7            | 48 g a.i./ha | 28 | EL reported a GAP with a PHI of 30 days (instead of 28); GAP also previously reported (Denmark, 2013) |
| Crop and/or situation | MS or country | F or Group of | Pests or Group of pests controlled | Preparation Type | Conc. a.s. | Method kind | Preparation Range of growth stages & season | Number min-max | Interval between applicat. (min) | PHI (days) | Remarks |
|----------------------|--------------|---------------|-----------------------------------|-----------------|-----------|------------|-----------------|---------------|-------------------|-----------|---------|
| Cotton seeds         | EL F         | Aphids        | EW 240 g/L Foliar treatment – broadcast spraying | 24-69           | 2        | 14        | –               | –             | 96 g a.i./ha | 7        | In the original PROFile a less critical GAP (2 × 48 g as/ha; PHI = 7 days) was not supported by trials. A new intended use (2 × 96 g as/ha, 14 days between treatment, PHI = 7 days) was reported (Denmark, 2013) supported by trials (Denmark, 2018) |
| Borage seeds         | FR F         | Pollen beetle, weevil, aphids, flea beetle | EW 240 g/L Foliar treatment – broadcast spraying | 10–29           | 2        | 7         | –               | –             | 48 g a.i./ha | 28       |         |
| Gold of pleasure seeds | FR F       | Pollen beetle, weevil, aphids, flea beetle | EW 240 g/L Foliar treatment – broadcast spraying | 31–80           | 2        | 7         | –               | –             | 48 g a.i./ha | 28       |         |
| Hemp seeds           | FR F         | Pollen beetle, weevil, aphids, flea beetle | EW 240 g/L Foliar treatment – broadcast spraying | 10–29           | 2        | 7         | –               | –             | 48 g a.i./ha | 28       |         |
| Barley               | EL F         | Aphids, midges, leafhopper, Pentatomidae | EW 240 g/L Foliar treatment – broadcast spraying | 10–75           | 3        | –         | –               | –             | 48 g a.i./ha | 30       | GAP also reported previously (Denmark, 2013) |
| Crop and/or situation | MS or country | F or G or T<sup>(a)</sup> | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)<sup>(d)</sup> | Remarks |
|-----------------------|--------------|---------------------------|---------------------------------|-------------|-----------------|-----------------------------|----------------|---------|
| Oat                   | EL F         | F                         | Aphids, midges, leafhopper, Pentadomidae | EW 240 g/L | Foliar treatment – broadcast spraying | 10–75 | 3 | – | – | 48 g a.i./ha | 30 | see barley SEU |
| Rye                   | EL F         | F                         | Aphids, midges, leafhopper, Pentadomidae | EW 240 g/L | Foliar treatment – broadcast spraying | 10–75 | 3 | – | – | 48 g a.i./ha | 30 | see barley SEU |
| Wheat                 | EL F         | F                         | Aphids, midges                  | EW 240 g/L | Foliar treatment – broadcast spraying | 10–75 | 3 | 10 | – | 48 g a.i./ha | 30 | FR reported a less critical GAP (1 × 48 g a.i./ha in autumn and 2 × 36 g a.i./ha in spring; PHI = 28 days). New intended use (3 × 48 g as/ha, 10 days interval, PHI=30 days) was also reported (Denmark, 2013) however is not supported by data |
| Sugar beets           | EL F         | F                         | Aphids, beetles, weevil         | EW 240 g/L | Foliar treatment – broadcast spraying | 15–49 | 2 | – | – | 48 g a.i./ha | 14 | See barley SEU |
### A.3. Authorised indoor uses in EU

| Crop and/or situation | MS or country | MS or country | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|---------------|---------------|-----------------------------------|-------------|-------------|--------------------------------|------------|---------|
| | | | | | | | | | |
| Alfalfa (for forage) | EL | F | Aphids, beetles, *Cydia*, *Ostrinia* | EW | 240 g/L Foliar treatment – broadcast spraying | 12–72 2 | – | – | 72 g a.i./ha | 7 | See barley SEU |
| Melons | FR | G | *Oidium* | EW | 240 g/L Foliar treatment | 89 2 14 | – | – | 48 g a.i./ha | 7 | Broadcast spraying |

**MS:** Member State; **MRL:** maximum residue level; **a..s:** active substance; **a.i.:** active ingredient; **EW:** emulsion, oil in water; **GAP:** Good Agricultural Practice; **SEU:** southern European Union.

(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.

(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.

(d): PHI: minimum preharvest interval.
### Appendix B – List of end points

#### B.1. Residues in plants

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

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

| Primary crops (available studies) | Crop groups | Crop(s) | Application(s) | Sampling (DAT) | Comment/Source |
|-----------------------------------|-------------|---------|----------------|----------------|----------------|
| Fruit crops                       | Apples      | Foliar spray, 4 × 144 g/ha | 29 | Radiolabelled active substance: [aniline-U-14C]-tau-fluvalinate and [benzyl-U-14C]-tau-fluvalinate (Denmark, 2006; EFSA, 2010) |
| Cereals/grass                     | Wheat       | Foliar spray, 2 × 60 g/ha or 2 × 600/ha (BBCH 59 and 67) | 5, 53 | Radiolabelled active substance: [aniline-U-14C]-tau-fluvalinate and [benzyl-U-14C]-tau-fluvalinate (Denmark, 2006; 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-14C]-tau-fluvalinate (Denmark, 2006; EFSA, 2010) |
| Pulses/oilseeds                   | Alfalfa     | Foliar treatment, 1 × 0.167 kg/ha, 0.5 kg/ha and 1.11 kg/ha | 44, 69 (seeds) 7, 35, 77 (forage) 13, 39, 81 (hay) | Radiolabelled active substance: [aniline-U-14C]-tau-fluvalinate and [benzyl-U-14C]-tau-fluvalinate (Denmark, 2006; EFSA, 2010) |

| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s) | PBI (DAT) | Comment/Source |
|--------------------------------------|-------------|---------|----------------|-----------|----------------|
| Root/tuber crops                     | Radish      | Bare soil, 144 g/ha | 28, 119 | Radiolabelled active substance: [aniline-U-14C]-tau-fluvalinate. Detectable residue are not expected (Denmark, 2006; EFSA, 2010) |
| Leafy crops                          | Lettuce     | Bare soil, 144 g/ha | 28, 119 | Radiolabelled active substance: [aniline-U-14C]-tau-fluvalinate. Detectable residue are not expected (Denmark, 2006; EFSA, 2010) |
| Cereal (small grain)                 | Spring wheat/ Winter wheat | Bare soil, 144 g/ha | 28, 119, 364/ 182 | Radiolabelled active substance: [aniline-U-14C]-tau-fluvalinate. Detectable residue are not expected (Denmark, 2006; EFSA, 2010) |
| Processed commodities (hydrolysis study) | Conditions | Stable? | Comment/Source |
|----------------------------------------|------------|--------|----------------|
| Pasteurisation (20 min, 90°C, pH 4)    | Yes        | Tau-fluvalinate relatively stable (0–9.1% loss) (Denmark, 2009; EFSA, 2010) |
| Baking, brewing and boiling (60 min, 100°C, pH 5) | No         | Tau-fluvalinate is extensively degraded (37–59% loss; anilino acid (13% AR), diacid (22% AR)) (Denmark, 2009; EFSA, 2010) |
| Sterilisation (20 min, 120°C, pH 6)    | No         | Tau-fluvalinate is completely degraded to 3-PBAld (97% AR), diacid (90% AR) (Denmark, 2009; EFSA, 2010) |
Can a general residue definition be proposed for primary crops? | Yes
---|---
Rotational crop and primary crop metabolism similar? | Yes
Residue pattern in processed commodities similar to residue pattern in raw commodities? | No
| Tau-fluvalinate is degraded at conditions simulating boiling (up to 60%) and completely at conditions simulating sterilisation

**Plant residue definition for monitoring (RD-Mo)**
- Plant commodities: Fluvalinate (sum of isomers)
- Processed commodities: Fluvalinate (sum of isomers) (tentative)\(^{(a)}\)
  - For pasteurised products: Fluvalinate (sum of isomers) (tentative)\(^{(a)}\)
  - For boiled and sterilised products: Fluvalinate (sum of isomers) (by default)\(^{(a)}\)

**Plant residue definition for risk assessment (RD-RA)**
- All plant commodities with exception of cereals: Tau-fluvalinate
- Cereals grains: Sum of tau-fluvalinate and anilino acid, including their conjugates, expressed as tau-fluvalinate
- Processed commodities: Tau-fluvalinate, 3-phenoxybenzaldehyde and diacid (tentative)\(^{(b)}\)

**Methods of analysis for monitoring of residues (analytical technique, matrixgroups, LOQs)**
- Matrices with high water, high acid, high oil content and dry matrices:
  - GC-ECD, validated for tau-fluvalinate 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 for tau-fluvalinate in strawberries; LOQ = 0.01 mg/kg; ILV available (EFSA, 2017)
  - GC–MS/MS method, validated for tau-fluvalinate in orange, potatoes, spring onions and avocado; LOQ = 0.01 mg/kg (EURLs, 2018)
  - GC–QqQ–MS/MS method, validated for tau-fluvalinate in barley and rice; LOQ = 0.01 mg/kg (EURLs, 2018)
- Although validated with tau-fluvalinate, these methods do not distinguish tau-fluvalinate from fluvalinate

**Review of the existing MRLs for tau-fluvalinate**

DAT: days after treatment; PBI: plant-back interval; LC–MS/MS: liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; ILV: independent laboratory validation; 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; BBCH: growth stages of mono- and dicotyledonous plants; AR: applied radioactivity; PBAd: phenoxybenzaldehyde.

\(^{(a)}\): Residues of tau-fluvalinate and its metabolites have not been found above the LOQ in the available studies. Fluvalinate is proposed by default.

\(^{(b)}\): Toxicological information on the metabolites 3-phenoxybenzaldehyde and diacid and identification of components A and B is pending.
## B.1.1.2. Stability of residues in plants

| Plant products (available studies) | Category | Commodity | T (°C) | Stability period | Compounds covered | Comment/Source |
|------------------------------------|----------|-----------|--------|-----------------|-------------------|---------------|
|                                    |          |           |        | Value | Unit |                        |               |
| High water content                 | Apples, tomatoes, melon | –18 | 18 | months | Tau-fluvalinate | Study duration 18 months (Denmark, 2006) |
| High oil content                   | Avocados and rapeseeds  | –18 | 18 | months | Tau-fluvalinate | As above |
| Dry/high protein content           | Peas (pods and seeds)  | –18 | 18 | months | Tau-fluvalinate | As above |
| Dry/High starch content            | Wheat grain        | –18 | 18 | months | Tau-fluvalinate | As above |
| Specific matrix                    | Wheat straw        | –18 | 18 | months | Tau-fluvalinate | As above |
| High acid content                  | Grapes            | –18 | 18 | months | Tau-fluvalinate | As above |
| Processed products                 | Peach juice and puree | –18 | 12 | months | Diacid | Samples were individually fortified; study duration was 360 days (Denmark, 2006) |
| Processed products                 | Peach juice and puree | –18 | 12 | months | 3-phenoxybenzaldehyde | As above |
| Processed products                 | Peach juice and puree | –18 | 12 | months | Anilino acid | As above |

## B.1.2. Magnitude of residues in plants

### B.1.2.1. Summary of residues data from the supervised residue trials – Primary crops

| Commodity                                      | Region/Indoor<sup>a</sup> | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source                                                                 | Calculated MRL (mg/kg) | HR<sup>b</sup> (mg/kg) | STMR<sup>c</sup> (mg/kg) | CF<sup>d</sup> |
|------------------------------------------------|---------------------------|----------------------------------------------------------------|------------------------------------------------------------------------------|-----------------------|-----------------------|-------------------------|----------------|
| Citrus fruits (grapefruits, oranges, lemons, limes, mandarins) | SEU                        | Trials on oranges: 0.03; 0.05; 0.06; 0.06; 0.06; 0.08; 0.13; 0.18; 0.19; 0.21; 0.25; 0.26; 0.28 | Combined data set of trials on oranges, lemons and mandarins (EFSA, 2017). Extrapolated to the whole group of citrus fruits including grapefruits, oranges, lemons, limes, mandarins. MRL<sub>OEC</sub> = 0.41 | 0.4                   | 0.26                  | 0.10                    | 1              |
| 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) |
|-----------|------------------|---------------------------------------------------------------|----------------|------------------------|---------------|---------------|-------|
| Pome fruits (apples, pears, quinces, medlars, loquats) | NEU | Trials on apples: 0.02; 0.03; 0.04; 0.05; 0.06; 0.07; 0.08; 0.09 Trials on pears: 0.16 | Combined data set of trials on apples and pears EFSA (2014). Extrapolation to the whole group of pome fruits including apples, pears, quinces, medlars, loquats applicable. MRL_{OECD} = 0.23 | | | | |
| | SEU | Trials on apples: 0.04; 0.04; 0.07; 0.07; 0.12 Trials on pears: 0.02; 0.04 | Combined data set of trials on apples and pears EFSA (2014). Extrapolation to the whole group of pome fruits including apples, pears, quinces, medlars, loquats applicable. MRL_{OECD} = 0.19 | 0.2(e) (tentative) | 0.12 | 0.04 | 1 |
| Apricots, peaches | SEU | Trials on apricots: 0.07; 0.08; 0.09; 0.09; 0.14; 0.20 Trials on peaches: 0.03; 0.08; 0.11; 0.13 | Combined data set on GAP-compliant trials on apricots (6) and peaches (4). MRL_{OECD} = 0.31 | 0.3 | 0.2 | 0.09 | 1 |
| Cherries (sweet) | NEU | – | No GAP-compliant trials available (Denmark, 2018) | – | – | – | 1 |
| | SEU | 0.05; 0.06; 0.1; 0.18 | GAP-compliant trials on cherries (Denmark, 2018). MRL_{OECD} = 0.33 | 0.4 | 0.18 | 0.08 | 1 |
| Table and wine grapes | NEU | 0.03; 0.08; 0.08; 0.1; 0.22; 0.22; 0.38; 0.58 | GAP-compliant trials on grapes (EFSA, 2014). Extrapolated to wine grapes. MRL_{OECD} = 0.96 | 1 | 0.58 | 0.16 | 1 |
| | SEU | 0.01; 0.02; 0.04; 0.07; 0.16; 0.19; 0.42; 0.48 | GAP-compliant trials on grapes (EFSA, 2014). Extrapolated to wine grapes. MRL_{OECD} = 0.91 | 0.9 | 0.48 | 0.12 | 1 |
| Strawberries | NEU | GAP-compliant trials: 0.021; 0.038; 0.070; 0.084 Overdosed (69–71 g a.s./ha): 0.018; 0.019; 0.020; 0.03 | Trials on strawberries (Denmark, 2018). MRL_{OECD} = 0.14 | 0.15(f) (tentative) | 0.08 | 0.03 | 1 |
| | SEU | 0.02; 0.02; 0.02; 0.02; 0.03; 0.04; 0.04; 0.12; 0.12 | GAP-compliant trials on strawberries (Denmark, 2018). MRL_{OECD} = 0.21 | 0.3 | 0.12 | 0.03 | 1 |
| 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) |
|---------------------------|------------------|---------------------------------------------------------------|--------------------------------------------------------------------------------|------------------------|--------------|----------------|--------|
| Potatoes                  | NEU              | < 0.01; < 0.01; < 0.01; < 0.01; < 0.01                           | Trials on potatoes with 2 instead of 1 application (EFSA, 2010; Denmark, 2018) | 0.01*                  | < 0.01       | < 0.01         | 1      |
|                           | SEU              | < 0.01; < 0.01; < 0.01                                         | GAP-compliant trials on potatoes (EFSA, 2010). Only three trials deem acceptable (see Section 1.2.1) | 0.01*                  | < 0.01       | < 0.01         | 1      |
| Beetroot Carrots, Jerusalem artichokes, parsnips, parsley roots, Celeriacs, horseradishes, salsifies | NEU              | < 0.01; < 0.01; < 0.01; < 0.01                                 | GAP-compliant trials on carrot (Denmark, 2018). Extrapolation to commodities belonging to same group with similar GAP applicable. No GAP authorised for beetroots | 0.01*                  | < 0.01       | < 0.01         | 1      |
|                           | SEU              | < 0.01; < 0.01; < 0.01; < 0.01                                 | GAP-compliant trials on carrots (Denmark, 2018). Extrapolation to commodities belonging to same group with similar GAP applicable. No GAPs authorised for celeriacs, horseradishes and salsifies | 0.01*                  | < 0.01       | < 0.01         | 1      |
| Aubergines/eggplants      | SEU              | < 0.01; 0.01; 0.02; 0.02; 0.03; 0.03; 0.05; 0.09              | GAP-compliant trials on tomatoes (EFSA, 2014; Denmark, 2018). Extrapolated to aubergines. MRL_{OECD} = 0.14 | 0.15                   | 0.09         | 0.03           | 1      |
| Cucumbers                 | SEU              | < 0.01; < 0.01; 0.01                                           | GAP-compliant trials on cucumber (Denmark, 2018). MRL_{OECD} = 0.02 | 0.02(e) (tentative)    | 0.01         | 0.01           | 1      |
| Gherkin, courgettes       | SEU              | < 0.01; < 0.01; 0.01                                           | GAP-compliant trials on cucumber (Denmark, 2018). Extrapolation to gherkins and courgettes applicable. MRL_{OECD} = 0.02 | 0.02                   | 0.01         | 0.01           | 1      |
### Commodity Region/Indoor

| Commodity          | Region/Indoor | 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) |
|--------------------|---------------|----------------------------------------------------------------|----------------------------------------------------------------------------------------------------------|------------------------|---------------|----------------|-------|
| Melons, water melons | NEU           | < 0.01; < 0.01; < 0.01; < 0.01 | GAP-compliant trials on melons (EFSA, 2014). Extrapolation to water melons applicable.                  | 0.01*                  | < 0.01        | < 0.01         | 1     |
|                    | SEU           | < 0.01; < 0.01; < 0.01; 0.01; 0.02; 0.03; 0.03; 0.04; 0.06        | GAP-compliant trials on melons (EFSA, 2014). MRLOECD = 0.09. Extrapolation to water melons applicable.    | 0.09                   | 0.06          | 0.03           | 1     |
| Melon indoor       |               | –                                                              | No trials available                                                                                      |                        |               |                |       |
| Broccoli, cauliflowers | NEU       | Trials on broccoli: 0.03; 0.05; 0.09; 0.17                     | Combined data set of GAP-compliant trials (EFSA, 2014). MRLOECD = 0.22                                | 0.3                    | 0.17          | 0.01           | 1     |
|                    | SEU           | Trials on broccoli: 0.03; 0.03; 0.06; 0.09                     | Combined data set of GAP-compliant trials (EFSA, 2014; Denmark, 2018). MRLOECD = 0.15                  | 0.15                   | 0.09          | 0.02           | 1     |
| Brussels sprouts   | NEU           | 0.01; 0.03; 0.03; 0.04                                         | GAP-compliant trials on Brussels sprouts (EFSA, 2014). MRLOECD = 0.08                                   | 0.1                    | 0.04          | 0.03           | 1     |
|                    | SEU           | 0.01; 0.02; 0.04; 0.05                                         | GAP-compliant trials on Brussels sprouts (EFSA, 2014). MRLOECD = 0.10                                   | 0.15                   | 0.05          | 0.03           | 1     |
| Head cabbages      | NEU           | 0.01; 0.01; 0.02; 0.04; 0.05; 0.06; 0.14                       | GAP-compliant trials on head cabbage (Denmark, 2013, 2018). MRLOECD = 0.21                             | 0.3                    | 0.14          | 0.04           | 1     |
|                    | SEU           | < 0.01; < 0.01; < 0.01; < 0.01                                 | GAP-compliant trials on head cabbage (Denmark, 2013, 2018). MRLOECD = 0.21                             | 0.01*                  | < 0.01        | < 0.01         | 1     |
| Kohlrabies         | NEU           | < 0.01; 0.01; 0.03                                               | GAP-compliant trials on Kohlrabi (Denmark, 2018). MRLOECD = 0.07                                        | 0.08                   | 0.03          | 0.02           | 1     |
| 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) |
|-----------|-----------------|-------------------------------------------------------------|-----------------|------------------------|--------------|----------------|-------|
| Lamb’s lettuces/corn salads, lettuces, escaroles/broadleaved endives, cresses and other sprouts and shoots, Land cresses, Roman rocket/rucola, red mustards, baby leaf crops (including brassica) | SEU | < 0.01; < 0.01; < 0.01; 0.03; 0.04; 0.04; 0.05; 0.06; 0.08; 0.5 | GAP-compliant trials on lettuce (open leaf varieties) (EFSA, 2014). Extrapolated to commodities 251010 and 251030 to 251080. MRL\textsubscript{OECD} = 0.68 | 0.7 | 0.50 | 0.04 | 1 |
| Beans and peas (with pods) | NEU | 0.02; 0.02; 0.03; 0.04; 0.06; 0.07; 0.09; 0.09; 0.12; 0.13; 0.24 | GAP-compliant trials on beans with pods (Denmark, 2018). Extrapolated to peas with pods. MRL\textsubscript{OECD} = 0.34 | 0.4 | 0.24 | 0.07 | 1 |
| | SEU | 0.01; 0.04; 0.05; 0.1; 0.1; 0.11; 0.13; 0.13; 0.22; 0.3; 0.39 | GAP-compliant trials on beans with pods (Denmark, 2018). Extrapolated to peas with pods. MRL\textsubscript{OECD} = 0.61 | 0.6 | 0.39 | 0.11 | 1 |
| Beans and peas (without pods) | NEU | Trials on beans without pods: < 0.01; < 0.01; < 0.01; < 0.01; < 0.01; 0.02; 0.02; 0.02; 0.03 | Combined data set of GAP-compliant trials on beans and peas without pods (Denmark, 2018). MRL\textsubscript{OECD} = 0.05 | 0.05 | 0.03 | 0.01 | 1 |
| | SEU | Trials on beans without pods: < 0.01; 0.01; 0.04 | Combined data set of GAP-compliant trials on beans and peas without pods (Denmark, 2018). MRL\textsubscript{OECD} = 0.05 | 0.05 | 0.04 | 0.01 | 1 |
| Globe artichokes | NEU | 0.09; 0.12; 0.17 | GAP-compliant trials on artichokes (EFSA, 2014). MRL\textsubscript{OECD} = 0.38 | 0.4(e) (tentative) | 0.17 | 0.12 | 1 |
| | SEU | < 0.01; 0.07; 0.10; 0.37 | GAP-compliant trial on artichokes (EFSA, 2014). MRL\textsubscript{OECD} = 0.78 | 0.8 | 0.37 | 0.09 | 1 |
| 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) |
|----------------------------------------|------------------|---------------------------------------------------------------|---------------------------------------------------------------------------------|------------------------|--------------|----------------|--------|
| Beans (dry), peas (dry)                | NEU              | < 0.01; < 0.01                                                | GAP-compliant trials on dry beans, not sufficient to derive MRL (Denmark, 2018). Extrapolated to dry peas. | –                     | –            | –              | 1      |
|                                        | SEU              | < 0.01; < 0.01; < 0.01; < 0.01                                  | GAP-compliant trials on dry beans (Denmark, 2018). Extrapolated to dry peas. Since no metabolism study is available, not considered a ‘no residue situation’. | 0.01*(e) (tentative) | < 0.01       | < 0.01         | 1      |
| Lentils and lupins (dry)               | NEU              | < 0.01; < 0.01                                                | GAP-compliant trials on dry beans (Denmark, 2018), not sufficient to derive MRL. Extrapolated to lentils and lupins. | –                     | –            | –              | 1      |
|                                        | SEU              | < 0.01; < 0.01; < 0.01; < 0.01                                  | GAP-compliant trials on dry beans (Denmark, 2018). Extrapolated to lentils (minor crop). No authorisation on lupins (SEU). | 0.01* | < 0.01 | < 0.01 | 1      |
| Sunflower seeds                        | NEU              | < 0.01; < 0.01; < 0.01; < 0.01; < 0.01                         | Trials on rapeseed compliant with the GAP of sunflower seeds (Denmark, 2013, 2018). Tentatively extrapolated to sunflower seeds. MRL\_OECD = 0.01 | 0.01*(g) (tentative) | 0.01 | < 0.01 | 1      |
|                                        | SEU              | –                                                             | No GAP-compliant trials available                                                  | –                     | –            | –              |        |
| Rapeseeds/canola seeds, borage seeds, Gold of pleasure seeds, hemp seeds | NEU              | < 0.01; < 0.01; < 0.01; < 0.01; < 0.01                         | GAP-compliant trials on rapeseeds (Denmark, 2013, 2018). Extrapolated to other oil seeds. MRL\_OECD = 0.01 | 0.02                  | 0.01        | < 0.01         | 1      |
| Rapeseeds/canola seeds                 | SEU              | < 0.01; < 0.01; < 0.01; < 0.01                                  | GAP-compliant trials on rapeseeds (Denmark, 2013, 2018). Extrapolated to oil seeds with similar GAP | 0.01* (e) (tentative) | < 0.01       | < 0.01         | 1      |
| Borage seeds, Gold of pleasure seeds, hemp seeds | SEU              | < 0.01; < 0.01; < 0.01; < 0.01                                  | GAP-compliant trials on rapeseeds (Denmark, 2013, 2018). Extrapolated to oil seeds with similar GAP | 0.01* | < 0.01 | < 0.01 | 1      |
| Linseeds, mustard seeds, pumpkin seeds, safflower seeds | NEU              | < 0.01; < 0.01; < 0.01; < 0.01; < 0.01; 0.01                   | GAP-compliant trials on rapeseed (Denmark, 2013, 2018). Extrapolated to other oil seeds. MRL\_OECD = 0.01 | 0.02 | 0.01 | < 0.01 | 1      |
| Commodity                     | Region/Indoor | 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) |
|-------------------------------|---------------|-----------------------------------------------------------------|---------------------------------------------------------------------------------|------------------------|---------------|-----------------|-------|
| Sesame seeds                  | SEU           | < 0.01; < 0.01; < 0.01; < 0.01                                     | GAP-compliant trials on rapeseeds (Denmark, 2013, 2018). Extrapolated to oil seeds with similar GAP | 0.01*                   | < 0.01        | < 0.01          | 1     |
| Cotton seeds                  | SEU           | < 0.01; < 0.01; < 0.01; 0.01; 0.03; 0.04; 0.05                   | GAP-compliant trials on cotton seeds (Denmark, 2018). MRLOECD = 0.09            | 0.09                   | 0.05          | 0.01            | 1     |
| Barley grains, oat grains     | NEU           | Trials with 2 instead of 3 applications: Mo: < 0.01; 0.01; 0.10; 0.14; 0.16 GAP-compliant trials: Mo: < 0.01; 0.02; 0.10; 0.13; 0.17; 0.17 RA: - | Trials on barley grains assuming that the first application has less impact on final residue (Denmark, 2013, 2018). Extrapolation to oat grains applicable. MRLOECD = 0.36 | 0.4                     | 0.17          | 0.10            | 4(h)  |
| SEU                           |               | Trial on oats with 2 instead of 3 applications: Mo: < 0.01       | Combined data set on oat and barley trials with two instead of three applications considering that the first application has less impact on the final residue (Denmark, 2018). Extrapolated to oat grains. MRLOECD = 0.36 | 0.4                     | 0.20          | 0.03            | 4(h)  |
| Wheat grains and rye grains   | NEU           | GAP-compliant trials on wheat grain: Mo: < 0.01; 0.01; < 0.01 Trials on wheat grain with 2 instead of three applications Mo: < 0.01; < 0.01; < 0.01; 0.01; 0.02 RA: - | Trials on wheat grain considering that the first application has less impact on the final residue (Denmark, 2006; Greece, 2017). Extrapolated to rye grain. MRLOECD = 0.02 | 0.03                    | 0.02          | 0.01            | 4(h)  |
| SEU                           |               | Mo: < 0.01; < 0.01; < 0.01; 0.01; 0.02; 0.03                      | Trials on wheat grain (2 × 46–51 g a.s./ha considering that the first application has less impact on the final residue (Denmark, 2006; Greece, 2017). Extrapolated to rye grain. MRLOECD = 0.04 | 0.05                    | 0.03          | 0.01            | 4(h)  |
| 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) |
|-------------------------------|-----------------|----------------------------------------------------------------|--------------------------------------------------------------------------------|-----------------------|---------------|-----------------|-------|
| Sugar beet roots              | NEU             | –                                                              | No GAP-compliant trials available. MRL_{OECD} = -                            | -                     | -             | -               | 1.00  |
|                               | SEU             | GAP-compliant trials: < 0.01; < 0.01; Overdosed (2 × 84-86 g a.s./ha) trials: < 0.01; < 0.01 | Trials on sugar beets (Denmark, 2018). A ‘no residue situation’ is anticipated for the group of root and tuber vegetables considering residues of other commodities of this group | 0.01*                 | 0.01          | < 0.01          | 1.00  |
| Alfalfa forage                | NEU             | 1.0; 1.2; 1.3; 1.4;                                           | GAP-compliant trials on alfalfa (Denmark, 2013). MRL_{OECD} = 3.68            | 4(e) (tentative)      | 1.40          | 1.25            | 1.00  |
|                               | SEU             | 0.76; 0.84; 1.22; 1.72; 1.80; 2.07; 3.42; 3.60               | GAP-compliant trials on alfalfa (Denmark, 2013, 2018). MRL_{OECD} = 6.25      | 7                     | 3.60          | 1.76            | 1.00  |
| Barley and oat straw          | NEU             | GAP-compliant trials on barley straw: 0.35; 1.3; 2.1          | GAP-compliant trials on barley straw and trials on barley straw with 2 instead of 3 applications (Denmark, 2018). MRL_{OECD} = 3.85 | 4(e) (tentative)      | 2.10          | 0.37            | 1.00  |
|                               | SEU             | Trials on barley straw: 0.54; 0.71; 0.76; 0.88; 0.9; 0.94; 0.94 | Trials on oat straw: 1.5 Combined data set of trials on barley and oat straw with 2 instead of 3 applications (Denmark, 2018). Tentatively extrapolated to oat straw. MRL_{OECD} = 2.67 | 3(e) (tentative)      | 1.50          | 0.88            | 1.00  |
| Wheat and rye straw           | NEU             | GAP-compliant trials on wheat straw: 0.5; 0.91; 0.92          | Trials on wheat straw considering that the first application has less impact on the final residue (Denmark, 2006; Greece, 2017). Extrapolated to rye straw. MRL_{OECD} = 4.11 | 5                     | 2.3           | 1.31            | 1.00  |
|                               | SEU             | 0.34; 0.4; 0.53; 0.59; 0.75; 0.92; 1.13; 1.6                  | Trials on wheat grain (2 × 46–51 g a.s./ha considering that the first application has less impact on the final residue (Denmark, 2006; Greece, 2017). Extrapolated to rye grain. MRL_{OECD} = 2.47 | 3                     | 1.60          | 0.67            | 1.00  |
| Commodity        | Region/Indoor<sup>(a)</sup> | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source                        | Calculated MRL (mg/kg) | HR<sup>(b)</sup> (mg/kg) | STMR<sup>(c)</sup> (mg/kg) | CF<sup>(d)</sup> |
|------------------|------------------------------|----------------------------------------------------------------|---------------------------------------|------------------------|--------------------------|--------------------------|-----------------|
| Sugar beet tops | NEU                          | –                                                               | No GAP-compliant trials available     | –                      | –                        | –                        | –               |
|                  | SEU                          | 0.1; 0.27                                                       | GAP-compliant trials on sugar beet tops (Denmark, 2018) | –                      | –                        | –                        | –               |

GAP: Good Agricultural Practice; OECD: Organisation for Economic Co-operation and Development; MRL: maximum residue level; a.s.: active substance.

*: Indicates that the MRL is proposed at the limit of quantification.
Mo: residue levels expressed according to the monitoring residue definition; RA: residue levels expressed according to risk assessment residue definition.
(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 (RA) refers to the whole commodity and not to the edible portion.
(c): Supervised trials median residue. The median residue for risk assessment (RA) 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.
(e): Tentative MRL derived from reduced number of trials.
(f): Tentative MRL derived from overdosed trials.
(g): Tentative MRL derived from trials with 2 instead of 1 application considering potential overestimated MRL.
(h): CF derived from metabolism study (EFSA, 2010).

**B.1.2.2. Residues in rotational crops**

| Residues in rotational and succeeding crops expected based on confined rotational crop study? | Inconclusive | Considering all authorised uses during this review, residues of tau-fluvalinate and metabolites are not expected above the LOQ. 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 |
| Residues in rotational and succeeding crops expected based on field rotational crop study? | Inconclusive | No field rotational crop study available and not considered necessary |

LOQ: limit of quantification.
### B.1.2.3. Processing factors

| Processed commodity | Number of valid studies\(^{(a)}\) | Processing Factor (PF) | Median PF | CFp\(^{(b)}\) | Comment/Source |
|---------------------|-----------------------------------|------------------------|-----------|-------------|----------------|
| Peaches, juice      | 4                                 | 0.088; 0.296; 0.65; 0.81 | < 0.47    | 1           | Denmark (2006) (Residues of 3-PBAld, anilino acid and diacid were < 0.05 mg/kg) |
| Peaches, puree      | 4                                 | 0.388; 0.618; 0.63; 0.694 | < 0.62    | 1           | Denmark (2006) (Residues of 3-PBAld, anilino acid and diacid were < 0.05 mg/kg) |
| Peaches, canned peaches | 4                                 | 0.013; 0.014; 0.028; 0.029 | < 0.02    | 1           | Denmark (2006) (tau-fluvalinate residues of all canned peach samples < 0.01 mg/kg. Residues of 3-PBAld, anilino acid and diacid were not detected) |
| Peaches, jam        | 4                                 | 0.013; 0.028; 0.029; 0.056 | < 0.03    | 1           | Denmark (2006) (tau-fluvalinate residues of all jam samples < 0.01 mg/kg. Residues of 3-PBAld, anilino acid and diacid were not detected) |
| Grapes, young wine (white, red) | 2                                 | 0.051; 0.154               | < 0.10    | 1           | Tentative\(^{(c)}\); in white and red wine, tau-fluvalinate residues were < 0.01 mg/kg and in white grapes 0.198 mg/kg (red grapes 0.065 mg/kg) (Denmark, 2013; EFSA, 2014) |
| Grapes, red juice   | 1                                 | 0.154                   | < 0.15    | 1           | Tentative\(^{(c)}\); in red grape juice, tau-fluvalinate residues were < 0.01 mg/kg and in red grapes 0.065 mg/kg (Denmark, 2013; EFSA, 2014) |
| Grapes, red must    | 1                                 | 0.154                   | < 0.15    | 1           | Tentative\(^{(c)}\); in red grape must, tau-fluvalinate residues were < 0.01 mg/kg and in red grapes 0.065 mg/kg (Denmark, 2013; EFSA, 2014) |
| Grapes, red raisins | 1                                 | 6.5                     | 6.5       | 1           | Tentative\(^{(c)}\); in red grapes, tau-fluvalinate residues of 0.065 mg/kg and in raisins of 0.425 (0.42 and 0.43) mg/kg were reported (Denmark, 2013; EFSA, 2014) |
| Grapes, red, wet pomace | 1                                 | 7                       | 7         | 1           | Tentative\(^{(c)}\); in red grapes, tau-fluvalinate residues of 0.065 mg/kg and in wet pomace of 0.455 (0.49 and 0.42) mg/kg were reported (Denmark, 2013; EFSA, 2014) |
| Grapes, red, dry pomace | 1                                 | 5.9                     | 5.9       | 1           | Tentative\(^{(c)}\); in red grapes, tau-fluvalinate residues of 0.065 mg/kg and in raisins of 0.385 (0.36 and 0.41) mg/kg were reported (Denmark, 2013; EFSA, 2014) |
| Tomatoes, canned (sterilised) | 2                                 | 0.045; 0.133              | < 0.089   | 1           | Tentative\(^{(c)}\); in tomatoes residues of 0.022 and 0.075 mg/kg and in canned tomatoes, before and after sterilisation residues of tau-fluvalinate and 3-PBAld were both < 0.01 mg/kg (Denmark, 2018) |

PF: processing factor (=Residue level in processed commodity expressed according to RD-Mo/Residue level in raw commodity expressed according to RD-Mo); CFp: conversion factor for risk assessment in processed commodity (=Residue level in processed commodity expressed according to RD-RA/Residue level in processed commodity expressed according to RD-Mo); PBAld: phenoxypentialdehyde.

\(^{(a)}\): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur).

\(^{(b)}\): Median of the individual conversion factors for each processing residues trial.

\(^{(c)}\): A tentative PF is derived based on a limited data set.
### B.2. Residues in livestock

| Relevant groups (subgroups) | Dietary burden expressed in mg/kg bw per day | Dietary burden expressed in mg/kg DM | Most critical subgroup(a) | Most critical commodity(b) | Trigger exceeded (Y/N) | Comments |
|-----------------------------|---------------------------------------------|-----------------------------------|----------------------------|----------------------------|------------------------|----------|
| Cattle (all)                | 0.0928                                      | 0.1775                            | 3.72                       | 7.40                       |                        |          |
| Cattle (dairy only)         | 0.0928                                      | 0.1737                            | 2.41                       | 4.52                       |                        |          |
| Sheep (all)                 | 0.0971                                      | 0.1864                            | 2.58                       | 4.68                       |                        |          |
| Sheep (ewe only)            | 0.0859                                      | 0.1560                            | 2.58                       | 4.68                       |                        |          |
| Swine (all)                 | 0.0300                                      | 0.0456                            | 1.00                       | 1.52                       |                        |          |
| Poultry (all)               | 0.0685                                      | 0.1039                            | 1.00                       | 1.52                       |                        |          |
| Poultry (layer only)        | 0.0685                                      | 0.1039                            | 1.00                       | 1.52                       |                        |          |

bw: body weight; DM: dry matter.

(a): When one group of livestock includes several subgroups (e.g. poultry ‘all’ including broiler, layer and turkey), the result of the most critical subgroup is identified from the maximum dietary burdens expressed as ‘mg/kg bw per day’.

(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as ‘mg/kg bw per day’.

**References:**

www.efsa.europa.eu/efsajournal 53 EFSA Journal 2018;16(11):5475
### B.2.1. Nature of residues and methods of analysis in livestock

#### B.2.1.1. Metabolism studies, methods of analysis and residue definitions in livestock

| Livestock (available studies) | Animal                  | Dose (mg/kg bw per day) | Duration (days) | Comment/Source                                                                 |
|-------------------------------|-------------------------|-------------------------|-----------------|--------------------------------------------------------------------------------|
| Laying hen                    | 0.1, 1, 10 and 100      | 1                       | The study is not compliant with the guideline. CF$_3$-$^{14}$C-labelled fluvalinate. Four birds were dosed only once and sacrificed after 24 h and metabolites were identified in tissues from two birds (Denmark, 2018) |
| Laying hen eggs               | 0.01, 0.91, 1.16        | 1                       | The study is not compliant with the guideline. CF$_3$-$^{14}$C-labelled fluvalinate. Three birds were dosed once and eggs were collected daily for 14 days (Denmark, 2018) |
| Lactating ruminants (two goats)| 0.36; 22.4              | 4                       | $^{14}$C-aniline-labelled tau-fluvalinate (Denmark, 2006) |
| Lactating ruminants (one goat)| 1                      | 3                       | $^{14}$C-benzyl-labelled tau-fluvalinate (Denmark, 2006) |
| Time needed to reach a plateau concentration in milk and eggs (days) | Milk: 11–15 | Lactating cow feeding study; in the metabolism study about 2 days in |
|---|---|---|
| Eggs: 10–14 | Yes | |
| Metabolism in rat and ruminant similar | Yes | |
| Can a general residue definition be proposed for animals? | Yes | |
| Animal residue definition for monitoring (RD-Mo) | Fluvinate (sum of isomers) | |
| Animal residue definition for risk assessment (RD-RA) | Fat, muscle, kidney, liver and milk: Sum of tau-fluvalinate and 3-phenoxybenzoic acid and anilino acid, including their conjugates, expressed as tau-fluvalinate | |
| Fat soluble residues | Yes | Log P<sub>OW</sub> of 7 for tau-fluvalinate (EFSA, 2010) |
| Methods of analysis for monitoring of residues (analytical technique, matrix groups, LOQs) | Muscle, fat, liver, kidney, milk |
| • GC–MS, LOQ tau-fluvalinate 0.01 mg/kg; in milk: 0.005 mg/kg. Confirmatory LC–MS/MS available. ILV available (Denmark, 2006; 2009; EFSA, 2010) |
| • GC–MS/MS method, validated for tau-fluvalinate in hens eggs (LOQ = 0.002 mg/kg), honey (LOQ = 0.01 mg/kg) and liver (LOQ = 0.001 mg/kg) (EURLs, 2018) |
| • Although validated with tau-fluvalinate, these methods do not distinguish tau-fluvalinate from fluvalinate |

Pow: partition coefficient between n-octanol and water; GC -MS: gas chromatography with mass spectrometry; LOQ: limit of quantification; LC -MS/MS: liquid chromatography with tandem mass spectrometry; ILV: independent laboratory validation; GC -MS/MS: gas chromatography with tandem mass spectrometry.
### B.2.1.2. Stability of residues in livestock

| Animal products (available studies) | Animal | Commodity | T (°C) | Stability period Value | Stability period Unit | Compounds covered | Comment/ Source |
|-------------------------------------|--------|-----------|--------|------------------------|-----------------------|-------------------|-----------------|
|                                     | Bovine | Muscle    | –18    | 110                    | Days                  | Tau-fluvalinate, anilino acid | Samples from feeding study (Denmark, 2006) |
|                                     | Bovine | Fat       | –18    | 110                    | Days                  | Tau-fluvalinate, anilino acid | Denmark (2006) |
|                                     | Bovine | Liver     | –18    | 110                    | Days                  | Tau-fluvalinate, anilino acid | Denmark (2006) |
|                                     | Bovine | Kidney    | –18    | 110                    | Days                  | Tau-fluvalinate, anilino acid | Denmark (2006) |
|                                     |        |           | –18    | 825                    | Days                  | 3-Phenoxy benzoic acid | Denmark (2006) |
|                                     | Bovine | Milk      | –18    | 110                    | Days                  | Tau-fluvalinate, anilino acid, 3-phenoxy benzoic acid | Denmark (2006) |
|                                     |        |           | –18    | 825                    | Days                  | 3-phenoxy benzoic acid | Denmark (2006) |
|                                     | Poultry| Eggs      | –20    | 1                      | Month                 | Tau-fluvalinate, anilino acid | Denmark (2018) |
### B.2.2. Magnitude of residues in livestock

#### B.2.2.1. Summary of the residue data from livestock feeding studies

| Animal commodity       | Residues at the closest feeding level (mg/kg) | Estimated value at 1N MRL proposal (mg/kg) | CF<sup>(c)</sup> |
|------------------------|-----------------------------------------------|-------------------------------------------|-----------------|
|                        | Mean  | Highest | STMR<sub>Mo</sub><sup>(a)</sup> (mg/kg) | HR<sub>Mo</sub><sup>(b)</sup> (mg/kg) |                  |
| **Cattle (all)**       |       |         |                                |                  |
| Muscle                 | n.r.  | 0.0500  | 0.031                           | 0.050            | 0.050 1.30       |
| Fat                    | n.r.  | 0.2700  | 0.121                           | 0.222            | 0.300 1.10       |
| Liver                  | n.r.  | 0.0100  | 0.010                           | 0.010            | 0.010 11.20      |
| Kidney                 | n.r.  | 0.0200  | 0.010                           | 0.012            | 0.015 10.50      |
| **Cattle (dairy only)**|       |         |                                |                  |
| Milk<sup>(e)</sup>     | n.r.  | 0.04    | 0.012                           | 0.023            | 0.03 1.5        |
| **Sheep (all)**        |       |         |                                |                  |
| Muscle                 | n.r.  | 0.0500  | 0.033                           | 0.050            | 0.050 1.30       |
| Fat                    | n.r.  | 0.2700  | 0.127                           | 0.225            | 0.300 1.10       |
| Liver                  | n.r.  | 0.0100  | 0.010                           | 0.010            | 0.010 11.20      |
| Kidney                 | n.r.  | 0.0200  | 0.010                           | 0.013            | 0.015 10.50      |
| **Sheep (ewe only)**   |       |         |                                |                  |
| Milk<sup>(e)</sup>     | n.r.  | 0.04    | 0.11                            | 0.02             | 0.02 1.5        |
| **Swine (all)**        |       |         |                                |                  |
| Muscle                 | n.r.  | 0.0500  | 0.010                           | 0.015            | 0.015 1.30       |
| Fat                    | n.r.  | 0.2100  | 0.020                           | 0.045            | 0.050 1.10       |
| Liver                  | n.r.  | 0.0100  | 0.010                           | 0.010            | 0.010 11.20      |
| Kidney                 | n.r.  | 0.0100  | 0.010                           | 0.010            | 0.010 10.50      |
| **Poultry (all)**      |       |         |                                |                  |
| Muscle                 | n.r.  | < 0.01  | 0.010                           | 0.010            | 0.010<sup>(h)</sup> (tentative) 1 |
| Fat                    | n.r.  | 0.150   | 0.016                           | 0.025            | 0.03<sup>(h)</sup> (tentative) 1.4 |
| Liver                  | n.r.  | < 0.01  | 0.010                           | 0.010            | 0.010<sup>(h)</sup> (tentative) 1 |
| **Poultry (layer only)**|      |         |                                |                  |
| Eggs<sup>(g)</sup>     | 0.031 | 0.04    | < 0.01                          | < 0.01           | 0.01<sup>(h)</sup> (tentative) 3.5 |

*: Indicates that the MRL is proposed at the limit of quantification.

n.r.: not reported; STMR: supervised trials median residue; HR: highest residue; MRL: maximum residue level; bw: body weight;
l: Monitoring.

(a): Median residues expressed according to the residue definition for monitoring, recalculated at the 1N rate for the median dietary burden.

(b): Highest residues expressed according to the residue definition for monitoring, recalculated at the 1N rate for the maximum dietary burden.

(c): Conversion factor to recalculate residues according to the residue definition for risk assessment.

(d): Closest feeding level and N dose rate related to the maximum dietary burden.

(e): For milk, mean was derived from samplings performed from day 1 to day 26 (daily mean of 3 cows).

(f): Since extrapolation from cattle to other ruminants and swine is acceptable, results of the livestock feeding study on ruminants were relied upon to derive the MRL and risk assessment values in sheep and swine.

(g): For eggs, mean and highest residues were derived from samplings performed from day 1 to day 28 (daily pooled egg contents according to replicate groups of laying hen).

(h): MRL is tentative because poultry metabolism study is not compliant with guidelines.
B.3. Consumer risk assessment

ARfD

Highest IESTI, according to EFSA PRIMo (rev. 2)

NESTI (% ARfD)

Assumptions made for the calculations

| ARfD | 0.05 mg/kg bw (EFSA, 2010) |
|------|----------------------------|
| Scarole (broad leaf): | 87.4% of ARfD |
| Not assessed in this review. |
| The calculation is based on the highest residue levels in the raw agricultural commodities. The contributions of commodities where no GAP was reported in the framework of this review were not included in the calculation. For cereal commodities a conversion factor of 4 was used. For animal commodities the following conversion factors were applied: ruminant/swine muscle: 1.3; fat: 1.1; liver 11.2, kidney: 10.5; poultry fat: 1.4; milk: 1.5 and eggs: 3.5. |

ADI

TMDI according to EFSA PRIMo

NTMDI, according to (to be specified)

Highest IEDI, according to EFSA PRIMo (rev. 2)

NEDI (% ADI)

Assumptions made for the calculations

| ADI | 0.005 mg/kg bw per day (EFSA, 2010) |
|-----|----------------------------------|
| Not assessed in this review. |
| Not assessed in this review. |
| 43.8 % ADI (DE child) |
| Not assessed in this review. |
| The calculation is based on the median residue levels in the raw agricultural commodities. The contributions of commodities where no GAP was reported in the framework of this review were not included in the calculation. For cereal commodities a conversion factor of 4 was used. For animal commodities the following conversion factors were applied: ruminant/swine muscle: 1.3; fat: 1.1; liver 11.2, kidney: 10.5; poultry fat: 1.4; milk: 1.5 and eggs: 3.5. |

Consumer exposure assessment through drinking water resulting from groundwater metabolite(s) according to SANCO/221/2000 rev.10 Final (25/02/2003)

Metabolite(s)

ADI (mg/kg bw per day)

Intake of groundwater metabolites (% ADI)

| Not assessed in this review |
| Not assessed in this review |
| Not assessed in this review |

ADI: acceptable daily intake; bw: body weight
### Proposed MRLs

| Code number | Commodity                          | Existing EU MRL (mg/kg) | Outcome of the review | MRL (mg/kg) | Comment |
|-------------|------------------------------------|-------------------------|-----------------------|-------------|---------|
| 0110010     | Grapefruits                        | 0.4                     | 0.4                   | 0.4         | Recommended<sup>a</sup> |
| 0110020     | Oranges                            | 0.4                     | 0.4                   | 0.4         | Recommended<sup>a</sup> |
| 0110030     | Lemons                             | 0.4                     | 0.4                   | 0.4         | Recommended<sup>a</sup> |
| 0110040     | Limes                              | 0.4                     | 0.4                   | 0.4         | Recommended<sup>a</sup> |
| 0110050     | Mandarins                          | 0.4                     | 0.4                   | 0.4         | Recommended<sup>a</sup> |
| 0130010     | Apples                             | 0.3                     | 0.3                   | 0.3         | Recommended<sup>a</sup> |
| 0130020     | Pears                              | 0.3                     | 0.3                   | 0.3         | Recommended<sup>a</sup> |
| 0130030     | Quinces                            | 0.3                     | 0.3                   | 0.3         | Recommended<sup>a</sup> |
| 0130040     | Medlars                            | 0.3                     | 0.3                   | 0.3         | Recommended<sup>a</sup> |
| 0130050     | Loquats/Japanese medlars           | 0.3                     | 0.3                   | 0.3         | Recommended<sup>a</sup> |
| 0140010     | Apricots                           | 0.3                     | 0.3                   | 0.3         | Recommended<sup>a</sup> |
| 0140020     | Cherries (sweet)                   | 0.5                     | 0.4                   | 0.4         | Recommended<sup>a</sup> |
| 0140030     | Peaches                            | 0.3                     | 0.3                   | 0.3         | Recommended<sup>a</sup> |
| 0151010     | Table grapes                       | 1                       | 1                     | 1           | Recommended<sup>a</sup> |
| 0151020     | Wine grapes                        | 1                       | 1                     | 1           | Recommended<sup>a</sup> |
| 0152000     | Strawberries                       | 0.5                     | 0.3                   | 0.3         | Recommended<sup>a</sup> |
| 0211000     | Potatoes                           | 0.01*                   | 0.01*                 | 0.01*       | Recommended<sup>a</sup> |
| 0213010     | Beetroots                          | 0.02                    | 0.01*                 | 0.01*       | Recommended<sup>a</sup> |
| 0213020     | Carrots                            | 0.02                    | 0.01*                 | 0.01*       | Recommended<sup>a</sup> |
| 0213030     | Celeriacs/turnip rooted celeries   | 0.01*                   | 0.01*                 | 0.01*       | Recommended<sup>a</sup> |
| 0213040     | Horseradishes                      | 0.01*                   | 0.01*                 | 0.01*       | Recommended<sup>a</sup> |
| 0213050     | Jerusalem artichokes               | 0.01*                   | 0.01*                 | 0.01*       | Recommended<sup>a</sup> |
| 0213060     | Parsnips                           | 0.01*                   | 0.01*                 | 0.01*       | Recommended<sup>a</sup> |
| 0213070     | Parsley roots/Hamburg roots parsley| 0.01*                   | 0.01*                 | 0.01*       | Recommended<sup>a</sup> |
| 0213090     | Salsifies                          | 0.01*                   | 0.01*                 | 0.01*       | Recommended<sup>a</sup> |
| 0231030     | Aubergines/eggplants               | 0.15                    | 0.15                  | 0.15        | Recommended<sup>a</sup> |
| 0232010     | Cucumbers                          | 0.05                    | 0.02                  | Further consideration needed<sup>b</sup> |
| 0232020     | Gherkins                           | 0.01*                   | 0.02                  | 0.02        | Recommended<sup>a</sup> |
| 0232030     | Courgettes                         | 0.01*                   | 0.02                  | 0.02        | Recommended<sup>a</sup> |
| 0233010     | Melons                             | 0.09                    | 0.09                  | 0.09        | Recommended<sup>a</sup> |
| 0233030     | Watermelons                        | 0.01*                   | 0.09                  | 0.09        | Recommended<sup>a</sup> |
| 0241010     | Broccoli                           | 0.4                     | 0.3                   | 0.3         | Recommended<sup>a</sup> |
| 0241020     | Cauliflowers                       | 0.1                     | 0.3                   | 0.3         | Recommended<sup>a</sup> |
| 0242010     | Brussels sprouts                   | 0.1                     | 0.15                  | 0.15        | Recommended<sup>a</sup> |
| 0242020     | Head cabbages                      | 0.2                     | 0.3                   | 0.3         | Recommended<sup>a</sup> |
| 0244000     | Kohlrabies                         | 0.07                    | 0.08                  | 0.08        | Recommended<sup>a</sup> |
| 0251010     | Lamb’s lettuces/corn salads        | 0.7                     | 0.7                   | 0.7         | Recommended<sup>a</sup> |
| 0251020     | Lettuces                           | 0.7                     | 0.7                   | 0.7         | Recommended<sup>a</sup> |
| 0251030     | Escaroles/broad-leaved endives     | 0.7                     | 0.7                   | 0.7         | Recommended<sup>a</sup> |
| 0251040     | Cresses and other sprouts and shoots| 0.7                     | 0.7                   | 0.7         | Recommended<sup>a</sup> |
| 0251050     | Land cresses                       | 0.7                     | 0.7                   | 0.7         | Recommended<sup>a</sup> |
| 0251060     | Roman rocket/rucola                | 0.7                     | 0.7                   | 0.7         | Recommended<sup>a</sup> |
| 0251070     | Red mustards                       | 0.7                     | 0.7                   | 0.7         | Recommended<sup>a</sup> |
| Code number | Commodity                                           | Existing EU MRL (mg/kg) | Outcome of the review |
|------------|-----------------------------------------------------|-------------------------|-----------------------|
| 0251080    | Baby leaf crops (including brassica species)       | 0.7                     | Recommended<sup>a</sup> |
| 0260010    | Beans (with pods)                                   | 0.1                     | Recommended<sup>a</sup> |
| 0260020    | Beans (without pods)                                | 0.1                     | Recommended<sup>a</sup> |
| 0260030    | Peas (with pods)                                    | 0.5                     | Recommended<sup>a</sup> |
| 0260040    | Peas (without pods)                                 | 0.5                     | Recommended<sup>a</sup> |
| 0270050    | Globe artichokes                                    | 0.8                     | Recommended<sup>a</sup> |
| 03000010   | Beans (dry)                                         | 0.01*                   | Further consideration needed<sup>b</sup> |
| 03000020   | Lentils (dry)                                       | 0.01*                   | Recommended<sup>a</sup> |
| 03000030   | Peas (dry)                                          | 0.02                    | Further consideration needed<sup>b</sup> |
| 03000040   | Lupins/Lupini beans (dry)                           | 0.01*                   | Further consideration needed<sup>c</sup> |
| 0401010    | Linseeds                                            | 0.02*                   | Recommended<sup>a</sup> |
| 0401040    | Sesame seeds                                        | 0.02*                   | Recommended<sup>a</sup> |
| 0401050    | Sunflower seeds                                     | 0.1                     | Further consideration needed<sup>b</sup> |
| 0401060    | Rapeseeds/canola seeds                              | 0.1                     | Recommended<sup>a</sup> |
| 0401080    | Mustard seeds                                       | 0.02*                   | Recommended<sup>a</sup> |
| 0401090    | Cotton seeds                                        | 0.1                     | Recommended<sup>a</sup> |
| 0401100    | Pumpkin seeds                                       | 0.02*                   | Recommended<sup>a</sup> |
| 0401110    | Safflower seeds                                     | 0.02*                   | Recommended<sup>a</sup> |
| 0401120    | Borage seeds                                        | 0.02*                   | Recommended<sup>a</sup> |
| 0401130    | Gold of pleasure seeds                              | 0.02*                   | Recommended<sup>a</sup> |
| 0401140    | Hemp seeds                                          | 0.02*                   | Recommended<sup>a</sup> |
| 05000010   | Barley grain                                        | 0.5                     | Recommended<sup>a</sup> |
| 0500050    | Oat grain                                           | 0.5                     | Recommended<sup>a</sup> |
| 0500070    | Rye grain                                           | 0.05                    | Recommended<sup>a</sup> |
| 0500090    | Wheat grain                                         | 0.05                    | Recommended<sup>a</sup> |
| 0900010    | Sugar beet roots                                    | 0.01*                   | Recommended<sup>a</sup> |
| 1011010    | Swine muscle                                        | 0.05                    | Recommended<sup>a</sup> |
| 1011020    | Swine fat tissue                                    | 0.3                     | Recommended<sup>a</sup> |
| 1011030    | Swine liver                                         | 0.01*                   | Recommended<sup>a</sup> |
| 1011040    | Swine kidney                                        | 0.02                    | Recommended<sup>a</sup> |
| 1012010    | Bovine muscle                                       | 0.05                    | Recommended<sup>a</sup> |
| 1012020    | Bovine fat tissue                                   | 0.3                     | Recommended<sup>a</sup> |
| 1012030    | Bovine liver                                        | 0.01*                   | Recommended<sup>a</sup> |
| 1012040    | Bovine kidney                                       | 0.02                    | Recommended<sup>a</sup> |
| 1013010    | Sheep muscle                                        | 0.05                    | Recommended<sup>a</sup> |
| 1013020    | Sheep fat tissue                                    | 0.3                     | Recommended<sup>a</sup> |
| 1013030    | Sheep liver                                         | 0.01*                   | Recommended<sup>a</sup> |
| 1013040    | Sheep kidney                                        | 0.02                    | Recommended<sup>a</sup> |
| 1014010    | Goat muscle                                         | 0.05                    | Recommended<sup>a</sup> |
| 1014020    | Goat fat tissue                                     | 0.3                     | Recommended<sup>a</sup> |
| 1014030    | Goat liver                                          | 0.01*                   | Recommended<sup>a</sup> |
| 1014040    | Goat kidney                                         | 0.02                    | Recommended<sup>a</sup> |
| 1015010    | Equine muscle                                       | 0.05                    | Recommended<sup>a</sup> |
| Code number | Commodity          | Existing EU MRL (mg/kg) | Outcome of the review |
|-------------|--------------------|-------------------------|------------------------|
| 1015020     | Equine fat tissue  | 0.3                     | 0.30 Recommended (a)   |
| 1015030     | Equine liver       | 0.01*                   | 0.01* Recommended (a)  |
| 1015040     | Equine kidney      | 0.02                    | 0.015 Recommended (a)  |
| 1016010     | Poultry muscle     | 0.01*                   | 0.01* Further consideration needed (b) |
| 1016020     | Poultry fat tissue | 0.01*                   | 0.03 Further consideration needed (b) |
| 1016030     | Poultry liver      | 0.01*                   | 0.01* Further consideration needed (b) |
| 1020010     | Cattle milk        | 0.05                    | 0.03 Recommended (a)   |
| 1020020     | Sheep milk         | 0.05                    | 0.02 Recommended (a)   |
| 1020030     | Goat milk          | 0.05                    | 0.02 Recommended (a)   |
| 1020040     | Horse milk         | 0.05                    | 0.03 Recommended (a)   |
| 1030000     | Bird eggs          | 0.01*                   | 0.01* Further consideration needed (b) |
| –           | Other commodities of plant and/or animal origin | (EC) No 1777/2017 | – Further consideration needed (d) |

MRL: maximum residue level; CXL: codex maximum residue limit.
*: Indicates that the MRL is set at the limit of quantification.
(a): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; no CXL is available (combination G-I in Appendix E).
(b): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified (assuming the existing residue definition); no CXL is available (combination E-I in Appendix E).
(c): GAP evaluated at EU level is not supported by data but no risk to consumers was identified for the existing EU MRL (also assuming the existing residue definition); no CXL is available (combination C-I in Appendix E).
(d): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix E).
Appendix C – Pesticide Residue Intake Model (PRIMo)

- PRIMo(EU)

### tau-Fluvalinate

| Status of the active substance | Included | Code no.  |
|--------------------------------|----------|----------|
| LOQ (mg/kg b.w.) | 0.01 | Proposed LOQ |

| Toxicological end points | ADI (mg/kg b.w. per day) | ARfD (mg/kg b.w.) |
|--------------------------|--------------------------|-------------------|
| Source of ADI | EFSA | Source of ARfD | EFSA |
| Year of evaluation | 2010 | Year of evaluation | 2010 |

| No of diets exceeding ADI |
|---------------------------|
| ---                        |

| Highest calculated TMDI values in % of ADI | Highest contributor to MS diet | Commodity/group of commodities | 2nd contributor to MS diet | Commodity/group of commodities | 3rd contributor to MS diet | Commodity/group of commodities | pTMRLs at LOQ in % of ADI |
|-------------------------------------------|-------------------------------|-----------------------------|--------------------------|-------------------------------|--------------------------|----------------------------|-----------------------------|
| 43.8 | DE child | 14.5 | Apples | 7.6 | Oranges | 5.1 | Milk and cream | 0.9 |
| 41.2 | NL child | 10.6 | Milk and cream | 7.6 | Apples | 6.2 | Oranges | 1.5 |
| 32.4 | FR toddler | 14.3 | Milk and cream | 4.0 | Oranges | 3.1 | Apples | 1.7 |
| 32.1 | IE adult | 9.9 | Barley | 4.0 | Wine grapes | 2.1 | Barley | 1.3 |
| 29.4 | WHO cluster diet B | 6.8 | Wheat | 5.7 | Wine grapes | 2.1 | Wheat | 3.2 |
| 27.7 | UK infant | 13.9 | Milk and cream | 2.6 | Oranges | 4.0 | Oranges | 5.6 |
| 25.3 | UK Toddler | 7.4 | Milk and cream | 4.6 | Sugar beet (raw) | 3.2 | Wheat | 1.2 |
| 22.7 | DK child | 4.5 | Milk and cream | 4.4 | Wheat | 3.5 | Rye | 1.1 |
| 21.5 | FR all population | 12.8 | Wine grapes | 2.8 | Wheat | 1.0 | Milk and cream | 0.4 |
| 20.7 | FR infant | 9.3 | Milk and cream | 3.0 | Apples | 1.9 | Beans (with pods) | 1.6 |
| 20.1 | ES child | 4.5 | Milk and cream | 4.3 | Oranges | 3.5 | Wheat | 0.6 |
| 20.1 | WHO Cluster diet F | 4.8 | Barley | 2.9 | Wheat | 1.9 | Milk and cream | 0.9 |
| 19.0 | NL general | 3.0 | Barley | 3.0 | Oranges | 2.4 | Milk and cream | 0.7 |
| 18.0 | PT General population | 8.0 | Wine grapes | 3.1 | Wheat | 1.3 | Apples | 1.4 |
| 17.1 | ES adult | 3.9 | Barley | 2.6 | Oranges | 1.9 | Wheat | 0.3 |
| 16.9 | WHO regional European diet | 2.6 | Barley | 2.4 | Wheat | 1.7 | Milk and cream | 1.1 |
| 16.7 | WHO cluster diet D | 5.2 | Wheat | 1.8 | Milk and cream | 1.8 | Barley | 1.1 |
| 14.7 | SE general population 90th percentile | 4.5 | Milk and cream | 2.6 | Wheat | 1.5 | Oranges | 1.2 |
| 13.1 | DK adult | 4.5 | Wine grapes | 1.9 | Milk and cream | 1.6 | Wheat | 0.5 |
| 11.1 | UK vegetarian | 2.6 | Wine grapes | 1.7 | Oranges | 1.6 | Wheat | 1.2 |
| 10.8 | IT kids/toddler | 5.3 | Wheat | 1.1 | Apples | 1.0 | Oranges | 0.3 |
| 10.1 | UK adult | 3.5 | Wine grapes | 1.3 | Wheat | 1.1 | Oranges | 1.2 |
| 9.1 | LT adult | 2.2 | Apples | 1.4 | Milk and cream | 0.9 | Rye | 0.8 |
| 8.8 | FI adult | 2.0 | Milk and cream | 1.9 | Oranges | 1.0 | Wine grapes | 0.4 |
| 8.5 | IT adult | 3.3 | Wheat | 1.0 | Apples | 0.7 | Oranges | 0.2 |
| 8.5 | FI general population | 2.5 | Apples | 1.0 | Table grapes | 0.7 | Potatoes | 0.9 |

### Chronic risk assessment – refined calculations

| Commodity/group of commodities |
|--------------------------------|
|冯roximally |

**Conclusion:**

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI. A long-term intake of residues of tau-fluvalinate is unlikely to present a public health concern.
The acute risk assessment is based on the ARfD.

For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS, an average European unit weight was used for the IESTI calculation.

In the IESTI 1 calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002); for lettuce, a variability factor of 5 was used.

In the IESTI 2 calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variability factor of 3.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

| No of commodities for which ARfD/ADI is exceeded (ESTI 1): | No of commodities for which ARfD/ADI is exceeded (ESTI 2): | No of commodities for which ARfD/ADI is exceeded (ESTI 1): | No of commodities for which ARfD/ADI is exceeded (ESTI 2): |
|--------------------------------|--------------------------------|--------------------------------|--------------------------------|
| **Highest % of ARfD/ADI Commodities pTMRL/threshold MRL (mg/kg)** | **Highest % of ARfD/ADI Commodities pTMRL/threshold MRL (mg/kg)** | **Highest % of ARfD/ADI Commodities pTMRL/threshold MRL (mg/kg)** | **Highest % of ARfD/ADI Commodities pTMRL/threshold MRL (mg/kg)** |
| Scarole (broad-leaf) 0.5/- 87.4 | Table grapes 0.5/- 76.0 | Table grapes 0.5/- 36.8 | Table grapes 0.5/- 38.8 |
| Scarole (broad-leaf) 0.5/- 76.0 | Table grapes 0.5/- 27.5 | Wine grapes 0.5/- 11.6 | Barley 0.5/- 10.6 |
| Oranges 0.26/- 69.0 | Oranges 0.26/- 13.3 | Oranges 0.26/- 11.6 | Oranges 0.26/- 10.8 |
| Grapefruit 0.26/- 46.4 | Grapefruit 0.26/- 11.0 | Lettuce 0.5/- 10.6 | Cauliflower 0.17/- |
| Apples 0.16/- 31.3 | Apples 0.16/- 25.1 | Apples 0.16/- 11.0 | Apples 0.16/- 10.6 |

**No of critical MRLs (ESTI 1):** ---

**No of critical MRLs (ESTI 2):** ---

**Conclusion:**

For processed commodities, no exceedance of the ARfD/ADI was identified.
## Appendix D – Input values for the exposure calculations

### D.1. Livestock dietary burden calculations

| Feed commodity                  | Median dietary burden | Maximum dietary burden |
|---------------------------------|-----------------------|------------------------|
| **Input value (mg/kg) Comment** | **Input value (mg/kg) Comment** |
| Risk assessment residue definition (except cereal grains): Tau-fluvalinate |
| Grapefruits, dried pulp        | 1.00 STMR × PF (10)\(^{(b)}\) | 1.00 STMR × PF (10)\(^{(b)}\) |
| Oranges, dried pulp            | 1.00 STMR × PF (10)\(^{(b)}\) | 1.00 STMR × PF (10)\(^{(b)}\) |
| Lemons, dried pulp             | 1.00 STMR × PF (10)\(^{(b)}\) | 1.00 STMR × PF (10)\(^{(b)}\) |
| Limes, dried pulp              | 1.00 STMR × PF (10)\(^{(b)}\) | 1.00 STMR × PF (10)\(^{(b)}\) |
| Mandarins, dried pulp          | 1.00 STMR × PF (10)\(^{(b)}\) | 1.00 STMR × PF (10)\(^{(b)}\) |
| Apple, pomace, wet             | 0.30 STMR × PF (5)\(^{(b)}\) | 0.30 STMR × PF (5)\(^{(b)}\) |
| Potato, culls                  | 0.01* STMR            | 0.01* HR              |
| Potato, process waste          | 0.01* STMR\(^{(a)}\) | 0.01* STMR\(^{(a)}\) |
| Potato, dried pulp             | 0.01* STMR\(^{(a)}\) | 0.01* STMR\(^{(a)}\) |
| Carrot, culls                  | 0.01* STMR            | 0.01* HR              |
| Cabbage, heads, leaves         | 0.04 STMR             | 0.14 HR               |
| Bean, seed (dry)               | 0.01* STMR            | 0.01* STMR            |
| Cowpea, seed                   | 0.01* STMR            | 0.01* STMR            |
| Pea (Field pea), seed (dry)    | 0.01* STMR            | 0.01* STMR            |
| Flaxseed/Linseed, meal         | 0.02 STMR × PF (2)\(^{(b)}\) | 0.02 STMR × PF (2)\(^{(b)}\) |
| Sunflower, meal                | 0.02 STMR × PF (2)\(^{(b)}\) | 0.02 STMR × PF (2)\(^{(b)}\) |
| Canola (Rape seed), meal       | 0.02 STMR × PF (2)\(^{(b)}\) | 0.02 STMR × PF (2)\(^{(b)}\) |
| Rape, meal                     | 0.02 STMR × PF (2)\(^{(b)}\) | 0.02 STMR × PF (2)\(^{(b)}\) |
| Cotton, undeinted seed        | 0.01 STMR             | 0.01 STMR             |
| Cotton, meal                   | 0.01 STMR × PF (1.25)\(^{(b)}\) | 0.01 STMR × PF (1.25)\(^{(b)}\) |
| Safflower, meal                | 0.02 STMR × PF (2)\(^{(b)}\) | 0.02 STMR × PF (2)\(^{(b)}\) |
| Beet, sugar, dried pulp        | 0.01* STMR\(^{(a)}\) | 0.01* STMR\(^{(a)}\) |
| Beet, sugar, ensiled pulp      | 0.01* STMR\(^{(a)}\) | 0.01* STMR\(^{(a)}\) |
| Beet, sugar, molasses          | 0.01* STMR\(^{(a)}\) | 0.01* STMR\(^{(a)}\) |
| Alfalfa, forage (green)        | 1.76 STMR             | 3.60 HR               |
| Alfalfa, hay (fodder)          | 4.40 STMR × PF (2.5)\(^{(b)}\) | 9.00 HR × PF (2.5)\(^{(b)}\) |
| Alfalfa, meal                  | 4.40 STMR × PF (2.5)\(^{(b)}\) | 9.00 HR × PF (2.5)\(^{(b)}\) |
| Alfalfa, silage                | 1.94 STMR × PF (1.1)\(^{(b)}\) | 3.96 HR × PF (1.1)\(^{(b)}\) |
| Barley, straw                  | 0.88 STMR             | 2.10 HR               |
| Oat, straw                     | 0.88 STMR             | 2.10 HR               |
| Rye, straw                     | 1.3 STMR              | 2.30 HR               |
| Triticale, straw               | 1.3 STMR              | 2.30 HR               |
| Wheat, straw                   | 1.3 STMR              | 2.30 HR               |
| Risk assessment residue definition (cereal grains): Sum of tau-fluvalinate and anilino acid, including their conjugates, expressed as tau-fluvalinate |
| Oat, grain                     | 0.40 STMR × CF (4)    | 0.40 STMR × CF (4)    |
| Rye, grain                     | 0.04 STMR × CF (4)    | 0.04 STMR × CF (4)    |
| Triticale, grain               | 0.04 STMR × CF (4)    | 0.04 STMR × CF (4)    |
| Wheat, grain                   | 0.04 STMR × CF (4)    | 0.04 STMR × CF (4)    |
| Barley, grain                  | 0.40 STMR × CF (4)    | 0.40 STMR × CF (4)    |
| Brewer’s grain, dried          | 1.32 STMR × PF (3.3)\(^{(b)}\) × CF (4) | 1.32 STMR × default PF (3.3)\(^{(b)}\) × CF (4) |
| Wheat, distiller’s grain (dry) | 0.13 STMR × PF (3.3)\(^{(b)}\) × CF (4) | 0.13 STMR × PF (3.3)\(^{(b)}\) × CF (4) |
**Feed commodity** | **Median dietary burden** | **Maximum dietary burden**
---|---|---
Wheat gluten, meal | 0.07 STMR \( \times \) PF (1.8)(b) \( \times \) CF (4) | 0.07 STMR \( \times \) PF (1.8)(b) \( \times \) CF (4)
Wheat, milled by-products | 0.28 STMR \( \times \) PF (7)(b) \( \times \) CF (4) | 0.28 STMR \( \times \) PF (7)(b) \( \times \) CF (4)

STMR: supervised trials median residue; HR: highest residue; PF: processing factor; CF: conversion factor for enforcement residue definition to risk assessment residue.

*: Indicates that the input value is proposed at the limit of quantification.

(a): For potato process waste/dried pulp, sugar beet molasses and dried and ensiled pulp no default processing factor was applied because fluvinate is applied early in the growing season and residues are expected to be below the LOQ. Concentration of residues in these commodities is therefore not expected.

(b): In the absence of processing factors supported by data, the default the processing factor was included in the calculation to consider the potential concentration of residues in these commodities.

**D.2. Consumer risk assessment**

| Commodity | **Chronic risk assessment** | **Acute risk assessment** |
|---|---|---|
| Input value (mg/kg) | Comment | Input value (mg/kg) | Comment |
| Grapefruits | 0.10 STMR | 0.26 HR |
| Oranges | 0.10 STMR | 0.26 HR |
| Lemons | 0.10 STMR | 0.26 HR |
| Limes | 0.10 STMR | 0.26 HR |
| Mandarin | 0.10 STMR | 0.26 HR |
| Apples | 0.06 STMR | 0.16 HR |
| Pears | 0.06 STMR | 0.16 HR |
| Quinces | 0.06 STMR | 0.16 HR |
| Medlars | 0.06 STMR | 0.16 HR |
| Loquats/Japanese medlars | 0.06 STMR | 0.16 HR |
| Apricots | 0.09 STMR | 0.20 HR |
| Cherries (sweet) | 0.08 STMR | 0.18 HR |
| Peaches | 0.09 STMR | 0.20 HR |
| Table grapes | 0.16 STMR | 0.58 HR |
| Wine grapes | 0.16 STMR | 0.58 HR |
| Strawberries | 0.03 STMR | 0.12 HR |
| Potatoes | 0.01* STMR | 0.01* HR |
| Beetroot | 0.01* STMR | 0.01* HR |
| Carrots | 0.01* STMR | 0.01* HR |
| Celeriacs/tunip rooted celeriacs | 0.01* STMR | 0.01* HR |
| Horseradishes | 0.01* STMR | 0.01* HR |
| Jerusalem artichokes | 0.01* STMR | 0.01* HR |
| Parsnips | 0.01* STMR | 0.01* HR |
| Parsley roots/Hamburg roots parsley | 0.01* STMR | 0.01* HR |
| Salsify | 0.01* STMR | 0.01* HR |
| Abergines/eggplants | 0.03 STMR | 0.09 HR |
| Cucumbers | 0.01 STMR (tentative) | 0.01 HR (tentative) |
| Gherkins | 0.01 STMR | 0.01 HR |

Risk assessment residue definition for plants (except cereals): Tau-fluvalinate
| Commodity                        | Input value (mg/kg) | Comment | Input value (mg/kg) | Comment |
|---------------------------------|--------------------|---------|--------------------|---------|
| Courgettes                      | 0.01               | STMR    | 0.01               | HR      |
| Melons                          | 0.03               | STMR    | 0.06               | HR      |
| Watermelons                     | 0.03               | STMR    | 0.06               | HR      |
| Broccoli                        | 0.02               | STMR    | 0.17               | HR      |
| Cauliflowers                    | 0.02               | STMR    | 0.17               | HR      |
| Brussels sprouts                | 0.03               | STMR    | 0.05               | HR      |
| Head cabbages                   | 0.04               | STMR    | 0.14               | HR      |
| Kohlrabies                      | 0.02               | STMR    | 0.03               | HR      |
| Lamb's lettuces/corn salads     | 0.04               | STMR    | 0.50               | HR      |
| Lettuces                        | 0.04               | STMR    | 0.50               | HR      |
| Escaroles/broad-leaved endives  | 0.04               | STMR    | 0.50               | HR      |
| Cresses and other sprouts and shoots | 0.04           | STMR    | 0.50               | HR      |
| Land cresses                    | 0.04               | STMR    | 0.50               | HR      |
| Roman rocket/rucoola            | 0.04               | STMR    | 0.50               | HR      |
| Red mustards                    | 0.04               | STMR    | 0.50               | HR      |
| Baby leaf crops (including brassica species) | 0.04       | STMR    | 0.50               | HR      |
| Beans (with pods)               | 0.11               | STMR    | 0.39               | HR      |
| Beans (without pods)            | 0.01               | STMR    | 0.04               | HR      |
| Peas (with pods)                | 0.11               | STMR    | 0.39               | HR      |
| Peas (without pods)             | 0.01               | STMR    | 0.04               | HR      |
| Globe artichokes                | 0.12               | STMR    | 0.37               | HR      |
| Beans (dry)                     | 0.01*              | STMR (tentative) | 0.01*           | HR (tentative) |
| Lentils (dry)                   | 0.01*              | STMR    | 0.01*              | HR      |
| Peas (dry)                      | 0.01*              | STMR (tentative) | 0.01*           | HR (tentative) |
| Lupini beans (dry)              | 0.01*              | EU MRL  | 0.01*              | EU MRL  |
| Linseeds                        | 0.01*              | STMR    | 0.01               | HR      |
| Sesame seeds                    | 0.01*              | STMR    | 0.01*              | HR      |
| Sunflower seeds                 | 0.01*              | STMR (tentative) | 0.01           | HR (tentative) |
| Rapseseeds/canola seeds         | 0.01*              | STMR    | 0.01               | HR      |
| Mustard seeds                   | 0.01*              | STMR    | 0.01               | HR      |
| Cotton seeds                    | 0.01               | STMR    | 0.05               | HR      |
| Pumpkin seeds                   | 0.01*              | STMR    | 0.01               | HR      |
| Safflower seeds                 | 0.01*              | STMR    | 0.01               | HR      |
| Borage seeds                    | 0.01*              | STMR    | 0.01*              | HR      |
| Gold of pleasure seeds          | 0.01*              | STMR    | 0.01*              | HR      |
| Hemp seeds                      | 0.01*              | STMR    | 0.01*              | HR      |
| Sugar beet roots                | 0.01*              | STMR    | 0.01*              | HR      |

**Risk assessment residue definition for cereal grains:** Sum of tau-fluvalinate and anilino acid, including their conjugates, expressed as tau-fluvalinate.

| Commodity | Input value (mg/kg) | Comment | Input value (mg/kg) | Comment |
|-----------|--------------------|---------|--------------------|---------|
| Barley grains | 0.40              | STMR<sub>Mo</sub> × CF (4) | 0.80  | HR<sub>Mo</sub> × CF (4) |
| Oat grains  | 0.40               | STMR<sub>Mo</sub> × CF (4) | 0.80  | HR<sub>Mo</sub> × CF (4) |
| Rye grains  | 0.04               | STMR<sub>Mo</sub> × CF (4) | 0.12  | HR<sub>Mo</sub> × CF (4) |
| Wheat grains| 0.04               | STMR<sub>Mo</sub> × CF (4) | 0.12  | HR<sub>Mo</sub> × CF (4) |
### Risk assessment residue definition for animal commodities: Tau-fluvalinate and 3-phenoxybenzoic acid and anilino acid, including their conjugates, expressed as tau-fluvalinate

| Commodity           | Chronic risk assessment | Acute risk assessment |
|---------------------|-------------------------|-----------------------|
|                     | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment               |
| Swine meat          | 0.02                    | 0.8 × STMR muscle +   | 0.03                | 0.8 × HR muscle +    |
|                     |                         | 0.2 × STMR fat × CF (1.3) |                | 0.2 × HR fat × CF (1.3) |
| Swine fat           | 0.02                    | STMR × CF (1.1)       | 0.05                | HR × CF (1.1)         |
| Swine liver         | 0.11                    | STMR × CF (11.2)      | 0.11                | HR × CF (11.2)        |
| Swine kidney        | 0.11                    | STMR × CF (10.5)      | 0.11                | HR × CF (10.5)        |
| Bovine and equine meat | 0.06                    | 0.8 × STMR muscle +   | 0.10                | 0.8 × HR muscle +    |
|                     |                         | 0.2 × STMR fat × CF (1.3) |                | 0.2 × HR fat × CF (1.3) |
| Bovine and equine fat | 0.13                    | STMR × CF (1.1)       | 0.24                | HR × CF (1.1)         |
| Bovine and equine liver | 0.11                    | STMR × CF (11.2)      | 0.11                | HR × CF (11.2)        |
| Bovine and equine kidney | 0.11                    | STMR × CF (10.5)      | 0.13                | HR × CF (10.5)        |
| Sheep and goat meat | 0.06                    | 0.8 × STMR muscle +   | 0.10                | 0.8 × HR muscle +    |
|                     |                         | 0.2 × STMR fat × CF (1.3) |                | 0.2 × HR fat × CF (1.3) |
| Sheep and goat fat  | 0.14                    | STMR × CF (1.1)       | 0.25                | HR × CF (1.1)         |
| Sheep and goat liver | 0.11                    | STMR × CF (11.2)      | 0.11                | HR × CF (11.2)        |
| Sheep and goat liver | 0.11                    | STMR × CF (10.5)      | 0.14                | HR × CF (10.5)        |
| Poultry meat        | 0.01                    | 0.9 × STMR muscle +   | 0.01                | 0.9 × HR muscle +    |
|                     |                         | 0.1 × STMR fat (tentative) |                | 0.1 × HR fat (tentative) |
| Poultry fat         | 0.02                    | STMR (tentative) × CF (1.4) | 0.04                | HR (tentative) × CF (1.4) |
| Poultry liver       | 0.01*                   | STMR (tentative)      | 0.01*               | HR (tentative)        |
| Cattle and horse milk | 0.02                    | STMR × CF (1.5)       | 0.04                | HR × CF (1.5)         |
| Sheep and goat milk | 0.02                    | STMR × CF (1.5)       | 0.03                | HR × CF (1.5)         |
| Birds eggs          | 0.01                    | STMR (tentative) × CF (3.5) | 0.03                | HR (tentative) × CF (3.5) |

STMR: supervised trials median residue; HR: highest residue; MRL: maximum residue level; CF: conversion factor for enforcement residue definition to risk assessment residue; Mo: monitoring.

*: Indicates that the input value is proposed at the limit of quantification.
Appendix E – Decision tree for deriving MRL recommendations

1. **Evaluation of the GAPs and available residues data at EU level**
   - GAP or DB > 0.1 mg/kg RM in EU?
     - Yes: MRL derived in Section 3?
     - No: MRL fully supported by data?
     - Yes: MRL is recommended.
     - No: Not considered for the RA.

2. **Consumer risk assessment for GAPs evaluated at EU level – EU scenarios**
   - Not considered for the RA.
   - Current EU MRL is included in the RA.
     - Risk identified?
       - Yes: Median/highest values are included in the RA.
       - No: Fall-back MRL available?
         - Yes: Tentative median/highest values are included in the RA.
         - No: Median/highest values are included in the RA.
   - Tentative median/highest values are included in the RA.
     - Risk identified?
       - Yes: Fall-back MRL available?
         - Yes: Median/highest values are included in the RA.
         - No: Not considered for the RA.
       - No: Not considered for the RA.
   - Median/highest values are included in the RA.
     - Risk identified?
       - Yes: Fall-back MRL available?
         - Yes: Median/highest values are included in the RA.
         - No: Not considered for the RA.
       - No: Not considered for the RA.

3. **Recommendations resulting from EU authorisations and import tolerances**
   - (A) Specific LOQ or default MRL?
   - (B) Specific LOQ or default MRL?
   - (C) Maintain current EU MRL?
   - (D) Specific LOQ or default MRL?
   - (E) Establish tentative EU MRL?
   - (F) Specific LOQ or default MRL?
   - (G) MRL is recommended.

Comparison with CXLs
### Appendix F – 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-toly)-D-valinate | ![Structural formula](image1) |
|                      | Clc1cc(ccc1N[C@@H](C(=O)OC(C#N)c1ccc(coc2cccc2)c1)C(C)C(F)(F)F | INISTDXBRIHGOC-XMMISQBUSAN |
|                      | Fluvalinate                           | ![Structural formula](image2) |
|                      | (RS)-α-cyano-3-phenoxybenzyl N-(2-chloro-α, α, α-trifluoro-p-toly)-DL-valinate | ![Structural formula](image3) |
|                      | 3-Phenoxybenzaldehyde (3-PBAld)       | ![Structural formula](image4) |
|                      | 3-phenoxybenzaldehyde O=Cccc(Oc2cccc2)ccc1 | MRLGCTNJRREZHZ-UHFFFAOYSA-N |
|                      | 3-phenoxybenzoic acid O=C(O)c1cc(Oc2cccc2)ccc1 | NXTDJHZGHOFSQG-UHFFFAOYSA-N |
|                      | Anilino acid                           | ![Structural formula](image5) |
|                      | N-[2-chloro-4-(trifluoromethyl) phenyl]-D-valine | ![Structural formula](image6) |
|                      | Diacid                                | ![Structural formula](image7) |
|                      | 4-[[1R]-1-carboxy-2-methylpropyl]aminoo]-3-chlorobenzoic acid | ![Structural formula](image8) |
|                      | QKMSBJLCLMYIND-SNVBAGLBSA-N            |                       |
| Code/trivial name<sup>(a)</sup> | IUPAC name/SMILES notation/InChiKey<sup>(b)</sup> | Structural formula<sup>(c)</sup> |
|-----------------|-------------------------------------------------|-----------------------------|
| Taurochenodeoxycholic acid | 2-{{[(3\alpha,5\beta,7\gamma,9\alpha,17\zeta)-3,7-dihydroxy-24-oxocholan-24-yl] amino}ethanesulfonic acid O-S(=O)(O)CCNC(=O)CC [C(=O)H](C)C1CC[C(=O)H]2[C(=O)H] 3C(C[C(=O)]12C[C(=O)]11(C)CC [C(=O)H](O)C[C(=O)H]1C[C(=O)H]3O}BHTKVEKTCKXOH- WEGSWEMCSA-N | ![Structural formula](image) |
| Haloaniline | 2-chloro-4-(trifluoromethyl) aniline Nc1ccc(cc1Cl)C(F)(F) FMBUTABXEITVNY- UHFFFAOYSA-N | ![Structural formula](image) |
| Decarboxy-fluvalinate | (2R\alpha,3R\beta; 2R\alpha,3S\beta)-3-[2-chloro-4-(trifluoromethyl) anilino]-4-methyl-2-[3-(phenoxyphenyl)pentanenitrile Clc1cc(cc1NC(C#N)c1cccc (0c2cccc2)c1)C(C)C(F)F QZCFOILLBHLVOR- UHFFFAOYSA-N | ![Structural formula](image) |

IUPAC: International Union of Pure and Applied Chemistry; SMILES: simplified molecular-input line-entry system; InChiKey: International Chemical Identifier Key.

<sup>(a)</sup> The metabolite name in bold is the name used in the conclusion.

<sup>(b)</sup> ACD/Name 2017.2.1 ACD/Labs 2017 Release (File version N40E41, Build 96719, 6 September 2017).

<sup>(c)</sup> ACD/ChemSketch 2017.2.1 ACD/Labs 2017 Release (File version C40H41, Build 99535, 14 February 2018).