REASONED OPINION

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Modification of the existing maximum residue levels for tau-fluvalinate in citrus fruits

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Adama Irvita N.V. submitted a request to the competent national authority in Denmark to modify the existing maximum residue levels (MRLs) for the active substance tau-fluvalinate in citrus fruits. The data submitted in support of the request were found to be sufficient to derive a MRL proposal of 0.4 mg/kg for citrus fruit under consideration. Adequate analytical methods for enforcement are available to control the residues of tau-fluvalinate in the commodities under consideration. Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of residues resulting from the use of tau-fluvalinate on citrus fruits according to the reported agricultural practice is unlikely to present a risk to consumer health.

Keywords: tau-fluvalinate, citrus fruits, orange, mandarin, lemon, limes, grapefruit, pesticide, MRL, consumer risk assessment

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Adama Irvita N.V. submitted an application to the competent national authority in Denmark (evaluating Member State (EMS)) to modify the existing maximum residue levels (MRLs) for the active substance tau-fluvalinate in citrus fruits. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 5 February 2016. To accommodate for the intended uses of tau-fluvalinate on citrus fruit in the southern Europe (SEU), the EMS proposed to raise the existing MRL from 0.1 mg/kg to 0.4 mg/kg.

EFSA based its assessment on the evaluation report submitted by the EMS, the draft assessment report (DAR), the Additional report and addendum to Additional report prepared under Council Directive 91/414/EEC, the conclusion on the peer review of the pesticide risk assessment of the active substance tau-fluvalinate as well as the conclusions from a previous EFSA opinion on tau-fluvalinate.

The metabolism of tau-fluvalinate following foliar application was investigated in crops belonging to the groups of fruit crops, cereals/grass and pulses/oilseeds.

Studies investigating the effect of processing on the nature of tau-fluvalinate (hydrolysis studies) demonstrated that the active substance degrades under sterilisation and boiling conditions to diacid, 3-phenoxybenzaldehyde (3-PBAld) and anilino acid, whereas under pasteurisation process tau-fluvalinate is relatively stable.

As the proposed uses of tau-fluvalinate are on permanent crops, investigations of residues in rotational crops are not required.

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

- for risk assessment: tau-fluvalinate in all edible crops, except cereal grain for which residue definition is 'tau-fluvalinate plus anilino acid, including conjugates, calculated as tau-fluvalinate', using a conversion factor of 4.
- for enforcement: fluvalinate, since the analytical enforcement methods cannot differentiate between fluvalinate and tau-fluvalinate.

These residue definitions are applicable to primary and rotational crops. For processed commodities depending on the type of processing applied, a separate residue definition for the risk assessment might be needed, considering the magnitude and toxicological relevance of degradation products. The relevant process for the processing of citrus fruits into juice and fruit preserves is pasteurisation, and therefore, the residue definition for risk assessment and enforcement in processed citrus products is the same as for raw agricultural commodities.

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

Sufficiently validated analytical method based on liquid chromatography–tandem mass spectrometry detector (LC–MS/MS) is available to quantify residues at or above 0.01 mg/kg (limit of quantification) in citrus fruits according to the enforcement residue definition.

The available residue trials are sufficient to derive a MRL proposal of 0.4 mg/kg for the whole group of citrus fruits.

Specific studies investigating the magnitude of tau-fluvalinate residues in processed commodities are not required, as significant residues are not expected in raw agricultural commodity (RAC) and the total theoretical maximum daily intake (TMDI) is below the trigger value of 10% of the acceptable daily intake (ADI).

Citrus fruit by-products (dried pulp) can be used for livestock feed purposes. However, EFSA and the EMS agreed that for consistency reasons magnitude of tau-fluvalinate residues in the livestock will be assessed under Article 12 of Regulation (EC) No 396/2005, considering livestock dietary exposure to tau-fluvalinate residues from the intake of all feed crops on which there are currently authorised uses in Europe.

The toxicological profile of tau-fluvalinate was assessed in the framework of the EU pesticides peer review under Directive 91/414/EEC and the data were sufficient to derive an ADI of 0.005 mg/kg body weight (bw) per day and an acute reference dose (ARfD) of 0.05 mg/kg bw.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). The long-term exposure assessment was performed taking into account the supervised trials median residue (STMR) values in citrus fruit pulp derived from residue trials assessed in this application; for the remaining commodities covered by the MRL regulation, the existing EU MRLs and STMR values derived in previous MRL applications were selected as input values. The estimated long-term dietary intake was in the range of 10–73% of the ADI.

The short-term exposure assessment was performed for citrus fruits using the highest residue (HR) values in citrus fruit pulp as derived from supervised field trials. The short-term exposure did not exceed the ARfD for any of the crops assessed in this application.

EFSA concluded that the proposed use of tau-fluvalinate on citrus fruits will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers' health.

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

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Tau-fluvalinate[(F)]				
0100000	Citrus fruits	0.1	0.4	The submitted data are sufficient to derive a MRL proposal for the SEU use. No consumer health concern was identified The impact of residues in citrus dried pulp to livestock dietary burden will be assessed under Article 12 of Regulation (EC) No 396/2005

MRL: maximum residue level; SEU: southern Europe.
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(F): Fat soluble.

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Background

Regulation (EC) No 396/2005[1] (hereinafter referred to as the MRL regulation) establishes the rules governing the setting of pesticide maximum residue levels (MRLs) at European Union (EU) level. Article 6 of the MRL regulation lays down that any party having a legitimate interest or requesting an authorisation for the use of a plant protection product in accordance with Council Directive 91/414/EEC[2], repealed by Regulation (EC) No 1107/2009[3], shall submit an application to a Member State to modify a MRL in accordance with the provisions of Article 7 of the MRL regulation.

The applicant Adama Irvita N.V.[4] submitted an application to the competent national authority in Denmark, hereafter referred to as the evaluating Member State (EMS), to modify the existing MRLs for the active substance tau-fluvalinate in citrus fruits. This application was notified to the European Commission and the European Food Safety Authority (EFSA) and was subsequently evaluated by the EMS in accordance with Article 8 of the MRL regulation.

The EMS summarised the data provided by the applicant in an evaluation report which was submitted to the European Commission and forwarded to EFSA on 5 February 2016. The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2016-00118 and the following subject:

Tau-fluvalinate: Application to modify MRL(s) in citrus fruits

The EMS proposed to raise the existing MRLs of tau-fluvalinate in citrus fruits from 0.1 mg/kg to 0.4 mg/kg.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified data gaps which needed further clarification, which were requested from the EMS. On June 2016 the EMS submitted the revised evaluation report (Denmark, 2016), which replaced the previously submitted evaluation report.

Terms of Reference

In accordance with Article 10 of Regulation (EC) No 396/2005, EFSA shall assess the application and the evaluation report and give a reasoned opinion on the risks to the consumer and where relevant to animals associated with the setting of the requested MRLs. The opinion shall include:

- an assessment of whether the analytical method for routine monitoring proposed in the application is appropriate for the intended control purposes;
- the anticipated limit of quantification (LOQ) for the pesticide/product combination;
- an assessment of the risks of the acceptable daily intake (ADI) and acute reference dose (ARfD) being exceeded as a result of the modification of the MRL;
- the contribution to the intake due to the residues in the product for which the MRLs was requested;
- any other element relevant to the risk assessment.

In accordance with Article 11 of the MRL regulation, EFSA shall give its reasoned opinion as soon as possible and at the latest within 3 months from the date of receipt of the application.

The evaluation report submitted by the EMS (Denmark, 2016) and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available as background documents to this reasoned opinion. Furthermore, a screenshot of the Report sheet of the PRIMo is presented in Appendix C.

The active substance and its use pattern

The detailed description of the intended uses of tau-fluvalinate in citrus fruits, which are the basis for the current MRL application, is reported in Appendix A.

Tau-fluvalinate is the International Organisation for Standardisation (ISO) common name for (*RS*)-α-cyano-3-phenoxybenzyl *N*-(2-chloro-α,α,α-trifluoro-*p*-tolyl)-D-valinate (International Union of Pure and

[1] Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1–16.
[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.
[3] 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.
[4] Adama Irvita N.V., Avenue de la Cristallerie 6, 92316, Sèvres Cedex, France.

Applied Chemistry (IUPAC)). Tau-fluvalinate is a 1:1 mixture of (*R*)-α-cyano and (*S*)-α-cyano isomers. The chemical structures of the active substance and its main metabolites are reported in Appendix E.

Tau-fluvalinate was evaluated in the framework of Directive 91/414/EEC with Denmark designated as rapporteur Member State (RMS) for the representative uses as foliar applications on potatoes and wheat. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by EFSA (EFSA, 2010). In accordance with Commission Implementing Regulation (EU) No 540/2011[5] tau-fluvalinate is approved under Regulation (EC) No 1107/2009, repealing Council Directive 91/414/EEC.

Tau-fluvalinate was approved[6] for the use as insecticide on 1 June 2011.

The EU MRLs for tau-fluvalinate are established in Annex III A of Regulation (EC) No 396/2005. The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has not yet been completed.

Assessment

EFSA has based its assessment on the evaluation report submitted by the EMS (Denmark, 2016), the DAR (Denmark, 2006), the Additional report and addendum to Additional report (Denmark, 2009, 2010) prepared under Council Directive 91/414/EEC, the conclusion on the peer review of the pesticide risk assessment of the active substance tau-fluvalinate (EFSA, 2010), as well as the conclusions from a previous EFSA opinion on tau-fluvalinate (EFSA, 2014).

For this application, the data requirements established in Regulation (EU) No 544/2011[7] and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 1997a–g, 2000, 2010a,b, 2016; OECD, 2007, 2011). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011.[8]

A selected list of end points of the studies assessed by EFSA in the framework of the MRL review, including the end points of studies submitted in support of the current MRL application, are presented 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 in primary corps belonging to the group of fruit crops, cereals/grass and pulses/oilseeds has been investigated in the framework of the EU pesticides peer review (Denmark, 2006, 2009; EFSA, 2010).

In all examined crops, except in wheat grain, tau-fluvalinate accounted for a major part of the residues. In wheat grain, the major residues were conjugated haloaniline and conjugated anilino acid. For the intended use on citrus fruits, the metabolic behaviour in primary crops is sufficiently addressed.

1.1.2. Nature of residues in rotational crops

As the proposed use of tau-fluvalinate is on permanent crops, investigation of residues in rotational crops is not required.

1.1.3. Nature of residues in processed commodities

The effect of processing on the nature of tau-fluvalinate was investigated in the framework of the EU pesticides peer review (Denmark, 2006, 2009). These studies showed that tau-fluvalinate is completely degraded under conditions simulating sterilisation and extensively degraded under

[5] Commission Implementing Regulation (EU) No 540/2011 of 23 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 Directive 2011/19/EU of 2 March 2011 amending Council Directive 91/414/EEC to include tau-fluvalinate as active substance and amending Decision 2008/934/EC. OJ L 58, 3.3.2011, p. 41–58.

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

[8] Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.

conditions simulating brewing, baking and boiling. The major degradation products were 3-phenoxybenzaldehyde (3-PBAld), anilino acid and diacid. Under pasteurisation conditions, tau-fluvalinate is relatively stable.

The peer review did not propose the residue definition for processed commodities since the need for processing studies was not triggered (EFSA, 2010). The relevant process for the processing of citrus fruits into juice and fruit preserves is pasteurisation (OECD, 2007). Since tau-fluvalinate is stable under pasteurisation, it can be concluded that the residue definition for risk assessment and enforcement in processed citrus products is the same as for raw agricultural commodities.

1.1.4. Methods of analysis in plants

Analytical methods for the determination of tau-fluvalinate residues were assessed during the EU pesticides peer review in matrices with high starch content (potatoes, wheat) (EFSA, 2010).

New study in high acid content matrices (strawberries) was submitted with the current MRL application (Denmark, 2016). A liquid chromatography–tandem mass spectrometry detector (LC–MS/MS) method was sufficiently validated for the determination of tau-fluvalinate residues in high acid content matrices at the LOQ of 0.01 mg/kg. An independent laboratory validation (ILV) for this method has been performed.

1.1.5. Stability of residues in plants

The storage stability of tau-fluvalinate in plants stored under frozen conditions was investigated in the framework of the EU pesticides peer review (EFSA, 2010). It was demonstrated that in high acid content matrices relevant for the crops assessed in the framework of this application, residues are stable for at least 18 months when stored at $\leq -18°C$.

1.1.6. Proposed residue definitions

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

- Residue definition for risk assessment: **tau-fluvalinate** in all edible crops, except cereal grain for which residue definition is 'tau-fluvalinate plus anilino acid, including conjugates, calculated as tau-fluvalinate', using a conversion factor of 4.
- Residue definition for enforcement: **fluvalinate** since the analytical enforcement methods cannot differentiate between fluvalinate and tau-fluvalinate (EFSA, 2010).

The residue definition for enforcement in Regulation (EC) No 396/2005 is set as 'tau-fluvalinate'. However, as only tau-fluvalinate is approved in the EU, the setting of an enforcement residue definition containing additional isomers is of low relevance for MRL enforcement.

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

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

In support of the MRL application, the applicant submitted residue trials performed on lemons, oranges and mandarins. The samples were analysed for the parent compound tau-fluvalinate. According to the assessment of the EMS, the methods used were sufficiently validated and fit for purpose.

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

1.2.1.1. Oranges, lemon and mandarins

In support of the southern Europe good agricultural practices (SEU GAP), eight GAP-compliant residue trials on oranges, eight GAP-compliant residue trials on lemons and two GAP-compliant residue trials on mandarins were submitted. Trials were conducted in Spain, Greece and Italy in 2009, 2011 and 2014. Residues in citrus fruit pulp were analysed separately and were in all cases below the LOQ of 0.01 mg/kg. In accordance with the EU extrapolation rules (European Commission, 2016), the

applicant proposed to extrapolate the results to citrus fruit group. The number and quality of the trials is sufficient to derive a MRL proposal of 0.4 mg/kg for the whole group of citrus fruits.

1.2.2. Magnitude of residues in rotational crops

As the proposed use of tau-fluvalinate is on permanent crops, investigation of residues in rotational crops is not required.

1.2.3. Magnitude of residues in processed commodities

New studies investigating the effect of processing on the magnitude of tau-fluvalinate residues in processed citrus fruit commodities have not been submitted in the framework of the current application and are not necessary, as residues in citrus fruit pulp were in all trials below the LOQ of 0.01 mg/kg and the individual contribution of citrus fruits to the total theoretical maximum daily intake (TMDI) is below 10% ADI.

1.2.4. Proposed MRLs

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

2. Residues in livestock

Since citrus fruit by-products (dried pulp) can be used for feed purposes, the possible transfer of residues to food of animal origin should be assessed. However, considering the low residues in fresh citrus pulp (< 0.01 mg/kg), the commodity is not expected to have a major impact on the overall dietary burden. An update of the previously calculated dietary burden (EFSA, 2014) and a possible revision of the existing MRLs for food of animal origin should be performed in the framework of the MRL review under Article 12 of Regulation (EC) No 396/2005, taking into account all authorised uses on potential feed items.

3. Consumer risk assessment

EFSA performed a dietary risk assessment using revision 2 of the EFSA PRIMo (EFSA, 2007). This exposure assessment model contains food consumption data for different subgroups of the EU population and allows the acute and chronic exposure assessment to be performed in accordance with the internationally agreed methodology for pesticide residues (FAO, 2016).

The toxicological reference values for tau-fluvalinate used in the risk assessment (i.e. ADI and ARfD values) were derived in the framework of the EU pesticides peer review (EFSA, 2010).

3.1. Short-term (acute) dietary risk assessment

The short-term exposure assessment was performed, taking into account the highest residue (HR) values in the citrus fruit pulp derived from supervised field trials and the complete list of input values can be found in Appendix D.2.

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

3.2. Long-term (chronic) dietary risk assessment

The long-term exposure assessment was performed, taking into account the supervised trials median residue (STMR) values in citrus fruit pulp derived from residue trials assessed in this application; for the remaining commodities covered by the MRL regulation, the existing EU MRLs and STMR values derived in previous MRL applications were selected as input values (EFSA, 2014). The complete list of input values is presented in Appendix D.2.

The estimated long-term dietary intake was in the range of 10–73% of the ADI. The contribution of residues expected in the commodities assessed in this application to the overall long-term exposure is presented in more detail in Appendix B.3.

EFSA concluded that the long-term intake of residues of tau-fluvalinate resulting from the existing and the intended uses is unlikely to present a risk to consumer health.

Conclusions and recommendations

The data submitted in support of this MRL application were found to be sufficient to derive MRL proposals for all citrus fruits under consideration.

Adequate analytical methods for enforcement are available to control the residues of tau-fluvalinate in citrus fruits.

Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of residues resulting from the use of tau-fluvalinate on citrus fruits according to the reported agricultural practice is unlikely to present a risk to consumer health.

The MRL recommendations are summarised in Appendix B.4.

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Abbreviations

3-PBAld	3-phenoxybenzaldehyde
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
DAR	draft assessment report
DAT	days after treatment
EMS	evaluating Member State
EW	emulsion, oil in water
FAO	Food and Agriculture Organization of the United Nations
GAP	Good Agricultural Practice
HR	highest residue
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ILV	independent laboratory validation
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
LC	liquid chromatography
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
MS/MS	tandem mass spectrometry detector
NEU	Northern Europe
OECD	Organisation for Economic Co-operation and Development
PBI	plant back interval
PHI	preharvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
RA	risk assessment
RAC	raw agricultural commodity
RD	residue definition
RMS	rapporteur Member State
SEU	southern Europe
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
WHO	World Health Organization

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

Crop and/or situation	NEU, SEU, MS or country	F G or I[a]	Pests or group of pests controlled	Preparation		Application				Application rate per treatment			PHI (days)[d]	Remarks
				Type[b]	Conc. a.s.	Method kind	Range of growth stages & season[c]	Number min–max	Interval between application (min)	g a.s./hL min–max	Water L/ha min–max	g a.s./ha min–max		
Citrus fruits	SEU	F	Aphididae, mites, scales, citrus flower moth	EW	240	Foliar spray	All stages	1–2	14	1.92–9.6	1,000–2,500	36–96	30	–

GAP: Good Agricultural Practice; NEU: northern Europe; SEU: southern Europe; MS: Member State; EW: emulsion, oil in water; a.s.: active substance.
(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 pre-harvest 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)**
	Fruit crops	Apples	Foliar spray, 4 × 144 g/ha	29
	Root crops	–	–	–
	Leafy crops	–	–	–
	Cereals/grass	Wheat	Foliar spray, 2 × 60 g/ha or 2 × 600 g/ha (BBCH 59 and 67) Foliar spray, 2 × 65 g/ha or 2 × 510 g/ha (BBCH 47–55 and 69)	53 37
	Pulses/oilseeds	Alfalfa	Foliar spray, 3 plots: 1 × 167 g/ha, 1,110 g/ha and 500 g/ha	77 (forage), 81 (hay), 69 (seeds)
	Miscellaneous	–	–	–
	Radiolabelled active substance: [aniline-U-^{14}C]-tau-fluvalinate and [benzyl-U-^{14}C]-tau-fluvalinate: wheat, apples, alfalafa [Benzotrifluoride-U-^{14}C]-tau-fluvalinate: wheat only (Denmark, 2006; EFSA, 2010)			
Rotational crops (available studies)	**Crop groups**	**Crops**	**Application**	**PBI (DAT)**
	Root/tuber crops	Radish	Soil, 144 g/ha	28, 119
	Leafy crops	Lettuce	Soil, 144 g/ha	28, 119
	Cereal (small grain)	Wheat	Soil, 144 g/ha	28, 119, 182, 364
	Other	–	–	–
	Detectable residues are not expected in succeeding crops (EFSA, 2010)			
Processed commodities (hydrolysis study)	**Conditions**		**Investigated?**	
	Pasteurisation (20 min, 90°C, pH 4)		Yes	
	Baking, brewing and boiling (60 min, 100°C, pH 5)		Yes	
	Sterilisation (20 min, 120°C, pH 6)		Yes	
	Pasteurisation: tau-fluvalinate Baking, brewing, boiling: tau fluvalinate, anilino acid (13% AR), diacid (22% AR) Sterilisation: 3-PBAld (97% AR), diacid (90% AR) (Denmark, 2007, 2009)			

AR: applied radioactivity; BBCH: growth stages of mono- and dicotyledonous plants; DAT: days after treatment; PBI: plant back interval.

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
Plant residue definition for monitoring (RD-Mo)	Fluvalinate (EFSA, 2010) Tau-fluvalinate (Regulation (EC) No 396/2005)
Plant residue definition for risk assessment (RD-RA)	Tau-fluvalinate Cereals:Tau-fluvalinate + anilino acid (incl. conjugates), calculated as tau-fluvalinate
Conversion factor (monitoring to risk assessment)	Cereal grain: 4
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)	Dry (high protein/starch content) matrices (wheat, potatoes): GC-ECD, LOQ 0.01 mg/kg (EFSA, 2010) Matrices with high acid content (strawberries): LC-MS/MS, 0.01 mg/kg. ILV available (Denmark, 2016)

B.1.1.2. Stability of residues in plants

Plant products (available studies)	**Category**	**Commodity**	**T (°C)**	**Stability (months/years)**
	High water content	Tomatoes, apples, melon	≤ −18	18 months
	High oil content	Avocado, rape seed	≤ −18	18 months
	Dry/High starch	Wheat grain, straw	≤ −18	18 months
	Dry/High protein	Peas (pod and seed)	≤ −18	18 months
	High acid content	Grapes	≤ −18	18 months
	Study duration 18 months (Denmark, 2009; EFSA, 2010)			

B.1.2. Magnitude of residues in plants

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

Crop (supervised trials)	Region/ indoor[a]	Residue levels observed in the supervised residue trials (mg/kg)	Comments (OECD calculations)	MRL proposals (mg/kg)	HR_{Mo}[b] (mg/kg)	$STMR_{Mo}$[c] (mg/kg)	CF[d]
Oranges	SEU	**Mo:** 0.03; 2 × 0.05; 3 × 0.06; 0.08; 0.13 **RA:** 0.03; 2 × 0.05; 3 × 0.06; 0.08; 0.13 Pulp: **Mo:** 8 × < 0.01 **RA:** 8 × < 0.01	Residue data combined and extrapolated to the whole group of **citrus fruits**	**0.4**	0.26 Pulp: < 0.01	0.10 Pulp: < 0.01	1
Lemons	SEU	**Mo**: 0.063; 2 × 0.12; 0.18; 0.19; 0.21; 0.25; 0.26 **RA:** 0.063; 2 × 0.12; 0.18; 0.19; 0.21; 0.25; 0.26 Pulp: **Mo:** 8 × < 0.01 **RA:** 8 × < 0.01					
Mandarins	SEU	**Mo:** 0.08; 0.12 **RA:** 0.08; 0.12 Pulp: **Mo:** 2 × < 0.01 **RA:** 2 × < 0.01					

MRL: maximum residue level; OECD: Organisation for Economic Co-operation and Development.
(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 according to the residue definition for monitoring.
(c): Supervised trials median residue according to the residue definition for monitoring.
(d): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.

B.1.2.2. Residues in succeeding crops

Citruses are permanent crops and therefore residues in succeeding crops are not relevant.

B.1.2.3. Processing factors

New processing studies have not been submitted in the framework of the current application.

B.2. Residues in livestock

Residues in the livestock from the intake of citrus dried pulp will be considered under Article 12 of Regulation (EC) No 396/2005, considering all uses of tau-fluvalinate on crops that can be used as a livestock feed.

B.3. Consumer risk assessment

ARfD	0.05 mg/kg bw (EFSA, 2010)
Highest IESTI, according to EFSA PRIMo	Oranges: 3 % of ARfD
Assumptions made for the calculations	The calculation is based on the highest residue levels expected in the raw agricultural commodities according to the intended use

ARfD: acute reference dose; IESTI: international estimated short-term intake; PRIMo: (EFSA) Pesticide Residues Intake Model.

ADI	0.005 mg/kg bw per day (EFSA, 2010)
Highest IEDI, according to EFSA PRIMo	73 % ADI (NL child diet) Contribution of crops assessed: Grapefruit: 0.14 % of ADI Oranges: 0.8 % of ADI Lemons: 0.06 % of ADI Limes: 0.03 % ADI Mandarins: 0.15 % ADI
Assumptions made for the calculations	The calculation is based on the median residue levels derived for citrus and commodities previously assessed by EFSA (EFSA, 2014); for the remaining crops the existing MRL was used as input value for the risk assessment

PRIMo: (EFSA) Pesticide Residues Intake Model; ADI: acceptable daily intake; IEDI: international estimated daily intake.

B.4. Recommended MRLs

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: tau-fluvalinate[(F)]				
0100000	Citrus fruits	0.1	0.4	The submitted data are sufficient to derive a MRL proposal for the SEU use. No consumer health concern was identified The impact of residues in citrus dried pulp to livestock dietary burden will be assessed under Article 12 of Regulation (EC) No 396/2005

MRL: maximum residue level; SEU: southern Europe.
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(F): Fat soluble.

Appendix C – Pesticide Residue Intake Model (PRIMo)

Tau-fluvalinate			
Status of the active substance:	Approved	Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	0.005	ARfD (mg/kg bw):	0.05
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2010	Year of evaluation:	2010

Prepare workbook for refined calculations

Undo refined calculations

Chronic risk assessment – refined calculations

TMDI (range) in % of ADI minimum–maximum	
10	73
No of diets exceeding ADI:	---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	pTMRLs at LOQ (in % of ADI)
73	NL child	29	Milk and cream,	8	Apples	5	Wheat	
69	FR toddler	40	Milk and cream,	6	Strawberries	3	Peas (without pods)	
64	UK Infant	39	Milk and cream,	6	Peas (without pods)	3	Wheat	
61	DE child	14	Apples	14	Milk and cream,	5	Strawberries	
54	IE adult	12	Barley	5	Maize	4	Wine grapes	
50	WHO Cluster diet B	9	Wheat	6	Wine grapes	5	Maize	
45	FR infant	26	Milk and cream,	5	Strawberries	3	Apples	
45	UK Toddler	21	Milk and cream,	5	Sugar beet (root)	4	Wheat	
43	WHO cluster diet E	8	Barley	5	Wine grapes	4	Wheat	
37	DK child	13	Milk and cream,	6	Wheat	4	Rye	
32	WHO regional European diet	5	Milk and cream,	3	Barley	3	Wheat	
31	WHO Cluster diet F	6	Barley	4	Milk and cream,	4	Wheat	
31	ES child	13	Milk and cream,	4	Wheat	1	Bovine: Meat	
30	WHO cluster diet D	7	Wheat	5	Milk and cream,	2	Barley	
29	SE general population 90th percentile	12	Milk and cream,	3	Wheat	3	Head cabbage	
28	NL general	7	Milk and cream,	4	Barley	2	Wheat	
27	FR all population	13	Wine grapes	3	Wheat	3	Milk and cream,	
23	PT General population	8	Wine grapes	4	Wheat	2	Peas (without pods)	
23	ES adult	5	Milk and cream,	5	Barley	2	Wheat	
19	DK adult	5	Milk and cream,	4	Wine grapes	2	Wheat	
17	LT adult	4	Milk and cream,	2	Apples	2	Head cabbage	
17	IT kids/toddler	7	Wheat	2	Other cereal	1	Strawberries	
17	UK vegetarian	3	Milk and cream,	3	Wine grapes	2	Wheat	
16	UK Adult	3	Wine grapes	3	Milk and cream,	2	Wheat	
15	FI adult	6	Milk and cream,	1	Wheat	1	Wine grapes	
13	IT adult	4	Wheat	1	Apples	1	Peas (without pods)	
10	PL general population	2	Apples	1	Head cabbage	1	Plums	

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.

Acute risk assessment /children - refined calculations	Acute risk assessment / adults / general population - refined calculations

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 variabilty factor of 3.

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

Unprocessed commodities

No of commodities for which ARfD/ADI is exceeded (IESTI 1): ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 1):** ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** ---		
IESTI 1	*)	**)	**IESTI 2**	*)	**)	**IESTI 1**	*)	**)	**IESTI 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)
3	Oranges	0.01 / -	2	Oranges	0.01 / -	0.5	Oranges	0.01 / -	0.4	Oranges	0.01 / -
2	Grapefruit	0.01 / -	2	Grapefruit	0.01 / -	0.4	Grapefruit	0.01 / -	0.3	Grapefruit	0.01 / -
1	Mandarins	0.01 / -	1	Mandarins	0.01 / -	0.3	Mandarins	0.01 / -	0.2	Mandarins	0.01 / -
1	Lemons	0.01 / -	1	Lemons	0.01 / -	0.1	Lemons	0.01 / -	0.1	Lemons	0.01 / -
0	Limes	0.01 / -	0	Limes	0.01 / -	0.1	Limes	0.01 / -	0.1	Limes	0.01 / -
No of critical MRLs (IESTI 1) ---						**No of critical MRLs (IESTI 2)** ---					

Processed commodities

No of commodities for which ARfD/ADI is exceeded: ---				**No of commodities for which ARfD/ADI is exceeded:** ---		
		***)				***)
Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)		Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)
65.8	Grape juice	1 / -		7.7	Wine	1 / -
30.6	Apple juice	0.3 / -		3.9	Apple juice	0.3 / -
16.0	Elderberry juice	0.5 / -		2.0	Orange juice	0.1 / -
12.0	Raspberries juice	0.5 / -		1.2	Peach preserved with	0.3 / -
10.7	Peach juice	0.3 / -		0.8	Raisins	1 / -

*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.

**) pTMRL: provisional temporary MRL

***) pTMRL: provisional temporary MRL for unprocessed commodity

Conclusion:

For Tau-fluvalinate, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.

No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

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

Will be considered under Article 12 of Regulation (EC) No 396/2005.

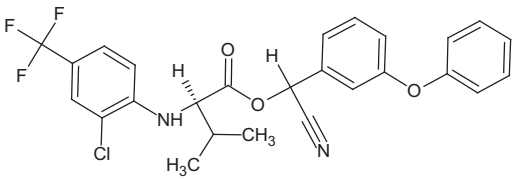
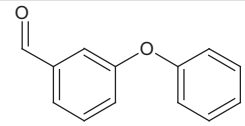
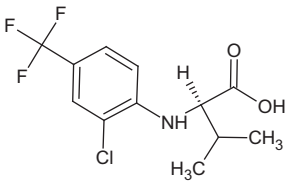
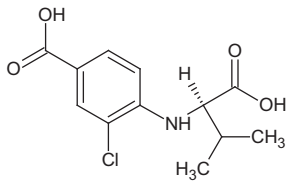
D.2. Consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Citrus fruits	0.10	STMR	0.26	HR
Pome fruit, peaches, apricots, table and wine grapes, tomatoes, aubergines, melons, broccoli, Brussels sprouts, kohlrabi, lettuce and similar group, globe artichokes	STMR	EFSA (2014)	–	–
Other food commodities of plant and animal origin	MRL	Regulation (EC) No 2015/846[(a)]	–	–

HR: highest residue; STMR: supervised trials median residue; MRL: maximum residue level.

(a): Commission Regulation (EU) 2015/846 of 28 May 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, ametoctradin, amisulbrom, bupirimate, clofentezine, ethephon, ethirimol, fluopicolide, imazapic, propamocarb, pyraclostrobin and tau-fluvalinate in or on certain products. OJ L 140, 5.6.2015, p. 1–49.

Appendix E – Used compound codes

Code/trivial name	Chemical name	Structural formula
Tau-fluvalinate	(*RS*)-α-Cyano-3-phenoxybenzyl *N*-(2-chloro-α,α,α-trifluoro-*p*-tolyl)-D-valinate Clc3cc(ccc3N[C@@H](C(=O)OC(C#N)c2cccc(Oc1ccccc1)c2)C(C)C)C(F)(F)F	
3-Phenoxybenzaldehyde (3-PBAld)	3-Phenoxybenzaldehyde O=Cc2cc(Oc1ccccc1)ccc2	
Anilino acid	*N*-[2-Chloro-4-(trifluoromethyl) phenyl]-D-valine Clc1cc(ccc1N[C@H](C(=O)O)C(C)C)C(F)(F)F	
Diacid	4-{[(1*R*)-1-Carboxy-2-methylpropyl]amino}-3-chlorobenzoic acid Clc1cc(ccc1N[C@@H](C(=O)O)C(C)C)C(=O)O	
Haloaniline	2-Chloro-4-(trifluoromethyl)aniline Nc1ccc(cc1Cl)C(F)(F)F