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

European Food Safety Authority (EFSA)

Abstract

According to Article 12 of Regulation (EC) No 396/2005, the European Food Safety Authority (EFSA) has reviewed the maximum residue levels (MRLs) currently established at European level for the pesticide active substance fluazinam. In order to assess the occurrence of fluazinam residues in plants, processed commodities, rotational crops and livestock, EFSA considered the conclusions derived in the framework of Directive 91/414/EEC as well as the import tolerances and European authorisations reported by Member States (incl. the supporting residues data). Based on the assessment of the available data, MRL proposals were derived and a consumer risk assessment was carried out. Although no apparent risk to consumers was identified, some information required by the regulatory framework was found to be missing. Hence, the consumer risk assessment is considered indicative only and some MRL proposals derived by EFSA still require further consideration by risk managers.

Keywords: fluazinam, MRL review, Regulation (EC) No 396/2005, consumer risk assessment, pyridine, fungicide, trifluoroacetic acid (TFA)

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Summary

Fluazinam was included in Annex I to Directive 91/414/EEC on 1 March 2009 by Commission Directive 2008/108/EC, 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, 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. In order to collect the relevant pesticide residues data, EFSA asked Austria, as the designated rapporteur Member State (RMS), to complete the Pesticide Residues Overview File (PROFile) and to prepare a supporting evaluation report. The PROFile and evaluation report provided by the RMS were made available to the Member States. A request for additional information was addressed to the Member States in the framework of a completeness check period which was initiated by EFSA on 13 February 2015 and finalised on 13 April 2015. After having considered all the information provided, EFSA prepared a completeness check report which was made available to Member States on 8 May 2015.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC and the additional information provided by the RMS and Member States, EFSA prepared in June-July 2015 a draft reasoned opinion, which was circulated to Member States for consultation via a written procedure. Comments received by 31 July 2015 were considered during the finalisation of this reasoned opinion. The following conclusions are derived.

The metabolism of fluazinam has been investigated in three different crop groups as well as in rotational crops. Based on these studies, the residue definition for monitoring in raw commodities was proposed as fluazinam only. Validated analytical methods for enforcement of the proposed residue definition in high water content, acidic and dry commodities are available. An appropriate radiolabeled hydrolysis study was not reported but, based on the available data, the monitoring residue definition in processed commodities was tentatively proposed as the sum of fluazinam, AMPA-fluazinam and AMGT, expressed as fluazinam. There are indications that AMPA-fluazinam and AMPGT can be enforced in watery and acidic processed commodities. Finally, as AMPA-fluazinam and AMGT may contribute in a significant extent to the toxicological burden, a general risk assessment residue definition was proposed as the sum of fluazinam, AMPA-fluazinam and AMGT, expressed as fluazinam.

It noted that the ubiquitous metabolite trifluoroacetic acid (TFA) was observed in peanuts and rotational crops. However, as this compound is not specific to the use of fluazinam, a separate residue definition including TFA was not considered by EFSA. Furthermore, an overall risk assessment for this metabolite was previously carried by EFSA and, in spite of certain uncertainties highlighted for cane fruits and dry beans, this assessment is covering the use of fluazinam as a pesticide.

The available residue trials allowed EFSA assessing the magnitude of residues resulting from the authorised GAPs reported in this review. MRL proposals, risk assessment values and conversion factors were derived for all commodities under evaluation. Nevertheless, due to the several data gaps identified in this review, all the MRL proposals are tentative, except for potatoes, onions, shallots and tomatoes. In addition, studies investigating the magnitude of residues in processed commodities of wine grapes and tomatoes allowed EFSA to derive processing factors for enforcement and risk assessment in grapes dry pomace, must, red and white wine as well as in peeled and canned tomatoes, tomatoes sauce, paste and juice. Nevertheless, in the absence of an appropriate radiolabeled study investigating the nature of residues in processed commodities, these processing factors remain tentative.

Fluazinam is authorised for use on apples, potatoes and dry beans that might be fed to livestock. However, the calculated dietary burden for meat ruminants was only 0.15 mg/kg dry matter (DM) and may have been overestimated because of several conservative assumptions such as the default processing factor for apples dry pomace and the use of the limit of quantification (LOQ) in potatoes. Moreover, the metabolism of fluazinam was investigated in lactating goats and the available results demonstrated that the relevant compounds are expected to remain below 0.004 mg/kg in animal tissues and products. Consequently, EFSA concluded that MRLs for fluazinam in animal commodities were not required.

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 highest chronic exposure represented 31.8% of the ADI (FR all population) and the highest acute exposure amounted to 35.7% of the acute reference dose (ARfD) (apples).

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Background

Regulation (EC) No 396/2005[1] 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 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[2] a reasoned opinion on the review of the existing MRLs for that active substance. As fluazinam was included in Annex I to Council Directive 91/414/EEC on 01 March 2009 by means of Commission Directive 2008/108/EC,[3] and has been deemed to be approved under Regulation (EC) No 1107/2009,[4] in accordance with Commission Implementing Regulation (EU) No 540/2011,[5] as amended by Commission Implementing Regulation (EU) No 541/2011,[6] EFSA initiated the review of all existing MRLs for that active substance.

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

In order 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 and;
- the analytical methods for enforcement of the proposed MRLs.

Austria, the designated rapporteur Member State (RMS) in the framework of Directive 91/414/EEC, was asked to complete the PROFile for fluazinam and to prepare a supporting evaluation report (Austria, 2011). The PROFile and the supporting evaluation report were submitted to EFSA on 5 July 2011 and made available to the Member States. A request for additional information was addressed to the Member States in the framework of a completeness check period which was initiated by EFSA on 13 February 2015 and finalised on 13 April 2015. Additional evaluation reports were submitted by Belgium, France, Italy, the Netherlands and Sweden, (Belgium, 2015; France, 2015; Italy, 2015; Netherlands, 2015; Sweden, 2015) and after having considered all the information provided by RMS and Member States, EFSA prepared a completeness check report which was made available to all Member States on 8 May 2015. Further clarifications were sought from Member States via a written procedure in May 2015.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC, and the additional information provided by the Member States, EFSA prepared in June-July 2015 a draft

[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 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 2008/108/EC of 26 November 2008 amending Council Directive 91/414/EEC to include flutolanil, benfluralin, fluazinam, fuberidazole and mepiquat as active substances. OJ L 317, 27.11.2008, p. 6–8.

[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.

reasoned opinion, which was submitted to Member States for commenting via a written procedure. All comments received by 31 July 2015 were considered by EFSA during the finalisation of the reasoned opinion.

The evaluation report submitted by the RMS (Austria, 2011), and the evaluation reports submitted by Member States Belgium, France, Italy, the Netherlands and Sweden (Belgium, 2015; France, 2015; Italy, 2015; Netherlands, 2015; Sweden, 2015) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available.

In addition, key supporting documents to this reasoned opinion are the completeness check report (EFSA, 2015a) and the Member States consultation report (EFSA, 2015b). These reports are developed to address all issues raised in the course of the review, from the initial completeness check to the reasoned opinion. Also the chronic and acute exposure calculations for all crops reported in the framework of this review performed using the EFSA Pesticide Residues Intake Model (PRIMo) are key supporting documents and made publicly available. Considering the importance of the completeness check and consultation report, all documents are considered as background documents to this reasoned opinion and, thus, are made publicly available.

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

Fluazinam is the ISO common name for 3-chloro-*N*-(3-chloro-5-trifluoromethyl-2-pyridyl)-trifluoro-2, 6-dinitro-p-toluidine (IUPAC).

Fluazinam belongs to the group of pyridine compounds which are used as fungicides. Fluazinam is a fungicide with protective action against fungi from the class of *Oomycetes*. It uncouples mitochondrial oxidative phosphorylation, inhibiting spore germination, hyphal penetration, growth and sporulation. Fluazinam is used to control grey mould and downy mildew on vines; apple scab; southern blight and white mould on peanuts and late blight and tuber blight on potatoes.

The chemical structure of the active substance and its main metabolites are reported in Appendix E.

Fluazinam was evaluated in the framework of Directive 91/414/EEC with Austria designated as rapporteur Member State (RMS). The representative use supported for the peer review process was foliar spraying to potatoes against late blight and tuber blight (*Phytophtora infestans*). Following the peer review, which was carried out by EFSA, a decision on inclusion of the active substance in Annex I to Directive 91/414/EEC was published by means of Commission Directive 2008/108/EC, which entered into force on 1 March 2009. According to Regulation (EU) No 540/2011, fluazinam is deemed to have been approved under Regulation (EC) No 1107/2009. This approval is restricted to uses as fungicide only.

The EU MRLs for fluazinam are established in Annex IIIA of Regulation (EC) No 396/2005 and codex maximum residue limit(s) (CXL(s)) for fluazinam are not available. An overview of the MRL changes that occurred since the entry into force of the abovementioned regulation is provided below.

Table 1: Overview of the MRL changes since the entry into force of Regulation (EC) No 396/2005

Procedure	Legal implementation	Remarks
MRL application	Regulation (EU) No 251/2013[7]	Modification of the existing MRL for fluazinam in apples
MRL application	Regulation (EU) No 2015/401[8]	Modification of the existing MRL for fluazinam in ginseng root
MRL application	Not yet legally implemented	Modification of the existing MRL for fluazinam in tomatoes

For the purpose of this MRL review, the critical uses of fluazinam currently authorised within the EU as well as uses authorised in third countries that might have a significant impact on international trade, have been collected by the RMS and reported in the PROFile. The additional good agricultural practices (GAPs) reported by Member States during the completeness check were also considered. The details of the authorised GAPs for fluazinam are given in Appendix A.

Assessment

EFSA has based its assessment on the PROFile submitted by the RMS, the evaluation report accompanying the PROFile (Austria, 2011), the draft assessment report (DAR) and its addenda prepared under Council Directive 91/414/EEC (Austria, 2006), the review report on fluazinam (European Commission, 2011), the conclusion on the peer review of the pesticide risk assessment of the active substance fluazinam (EFSA, 2008), the previous reasoned opinions on fluazinam (EFSA, 2012, 2014a, 2014b, 2015c) as well as the evaluation reports submitted during the completeness check (Belgium, 2015; France, 2015; Italy, 2015; Netherlands, 2015; Sweden, 2015). 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[9] and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (European Commission, 1996, 1997a-g, 2000, 2010a, b, 2011 and OECD, 2011).

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 in plants

1.1.1. Nature of residues in primary crops

The nature of fluazinam residues in primary crops has been investigated on three different crop groups which are fruit crops, root crops and pulses/oilseeds (EFSA, 2008). The metabolic pathway is generally similar in these crops but the metabolic pattern in the edible part of the investigated commodities varies. After foliar application, parent compound was found to be the major constituent of the residue in fruit crops (11-45% total radioactive residue (TRR)) while AMGT (10.4% TRR) and AMPA-fluazinam (5% TRR) were the main identified metabolites (see Appendix E). The same pattern was observed in potato tubers except that levels of fluazinam and metabolites were not significant (<0.001 mg/kg) and that incorporation to starch was more predominant (47% TRR). In peanuts however, only trifluoroacetic acid (TFA) derivatives were present, which indicates a more extensive

[7] Commission Directive (EU) No 251/2013 of 22 March 2013 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 aminopyralid, bifenazate, captan, fluazinam, fluopicolide, folpet, kresoxim-methyl, penthiopyrad, proquinazid, pyridate and tembotrione in or on certain products. OJ L 88, 27.3.2013, p. 1–44.

[8] Commission Directive (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.

[9] 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, 11.06.2011, p. 127–175.

metabolism involving the opening and fragmentation of the pyridyl and nitrophenyl moieties (see Appendix E).

A primary crop metabolism study for soil treatment in fruit crops is not available but, the results of the confined rotational crops studies (carrot, lettuce, barley) were considered to assess the authorised GAP for soil treatment in cane fruits.

1.1.2. Nature of residues in rotational crops

Confined rotational crop studies using carrot, lettuce and barley planted in soil treated with fluazinam were assessed during the peer review (EFSA, 2008). The plant-back intervals investigated were 30, 120 and 365 days and the application rate tested in the experiments cover the most critical GAPs authorised within Europe. In contrast to what was observed in primary crops, fluazinam or its related compounds based on the two-ring structure are not found in rotational crops. Residues in rotational crops are fragments from either the phenyl or pyridine ring after extensive metabolic degradation of the parent compound. TFA was present in significant amounts in lettuce (0.068 mg TFA/kg), barley grains (0.045 mg TFA/kg) and carrots (0.014 mg TFA/kg). Radioactivity was also incorporated into natural plant products such as starch. Therefore, the metabolic pattern depicted in rotational crops is more extensive but does not present major difference compared to primary crops.

1.1.3. Nature of residues in processed commodities

The effect of processing on the nature of fluazinam residues was not investigated in the framework of the peer review. In the framework of the present review, a study investigating the nature of residues through boiling/brewing/baking (60 minutes at 100°C, pH 5) and sterilisation (20 minutes at 120°C, pH 6) was provided by France (France, 2015). However, as this study was not performed with radiolabeled material and does not provide information on pasteurisation, it is still insufficient to conclude on the residue pattern in processed commodities. Indicative results of this study show that fluazinam is not stable during sterilisation but the degradation products were not identified. Nevertheless, the available studies on the magnitude of the residue in processed commodities provide further information on the nature of the residues in these items. In processed commodities of wine grapes and tomatoes, fluazinam and its metabolites AMPA-fluazinam and AMGT were found in significant levels. Moreover, the parent compound was fully degraded in white and red wines (see also section 1.2.3). Nevertheless, major uncertainty remains on this concern and a radiolabeled study investigating the effect of processing on the nature of fluazinam residues is therefore required. This is particularly relevant to finalise the risk assessment in apples, pears and wine grapes, which can be subject to such hydrolytic conditions, and which are significant contributors to the chronic/acute exposures.

1.1.4. Methods of analysis in plants

During the peer review, an analytical method using HPLC-MS/MS was validated for enforcement of fluazinam in high water and high acid content commodities with a limit of quantification (LOQ) of 0.01 mg/kg. A confirmatory method was not necessary but an independent laboratory validation (ILV) was required (EFSA, 2008). As two independent laboratory validations (ILVs) have been provided after the peer review (EFSA, 2012; France, 2015), this method is now fully validated. In addition, another analytical method using HPLC-MS/MS have been reported and evaluated by Italy. This method was validated for the enforcement of fluazinam, AMPA-fluazinam and AMGT with an LOQ of 0.01 mg/kg (for each compound) in high water and high acid content commodities. This method was validated for two different ion transitions and therefore no confirmation method was required (Italy, 2015). Nevertheless, an ILV is not available for the determination of metabolites AMPA-fluazinam and AMGT.

In its evaluation report, the RMS indicated that fluazinam could be enforced with an LOQ of 0.01 mg/kg in dry commodities but the validity of this method for enforcement was not demonstrated (Austria, 2011). However, the multi-residue QuEChERS method in combination with HPLC-MS/MS, as described by CEN (2008), is reported and sufficiently validated for analysis of fluazinam with an LOQ of 0.02 mg/kg in dry commodities (EURL, 2015).

In the framework of a routine MRL evaluation, an analytical method using GC-ECD was reported for analysis of fluazinam in fresh ginseng root with an LOQ of 0.01 mg/kg. However, the applicability of this method was not fully demonstrated for dried ginseng roots, which is deemed as a specific matrix (EFSA, 2014b). Therefore, a full validation for this method is still required.

Hence, it is concluded that fluazinam can be enforced in high water and acidic commodities with an LOQ of 0.01 g/kg and in dry commodities with an LOQ of 0.02 mg/kg. There are indications that fluazinam can also be enforced in ginseng roots with an LOQ of 0.02 mg/kg. In addition, another method is available to enforce metabolites AMPA-fluazinam and AMGT in high water and acidic commodities (with an LOQ of 0.01 mg/kg for each compound) but is not fully validated (ILV is missing).

1.1.5. Stability of residues in plants

Storage stability of fluazinam was demonstrated in high water content (26 months), high acid content (36 months) and dry (26 months) commodities as well as in ginseng roots (11 months) when stored deep frozen.

The stability of metabolites AMGT and AMPA-fluazinam was also evaluated in high water content and high acid content commodities. In high water content commodities, AMGT was stable for a period of 26 months while AMPA-fluazinam was concluded to be stable up to 18 months only. In high acid content commodities, the stability of AMGT and AMPA-fluazinam was demonstrated for a period of 36 months.

1.1.6. Proposed residue definitions

Based on all the available data, EFSA concludes that fluazinam is an appropriate marker compound in fruit crops (following foliar treatment) and in root crops. In cane fruit (after soil treatment) and dry beans, fluazinam is expected to be extensively degraded but, as the degradation products are not specific to the use of fluazinam, parent compound remains by default the only relevant marker. Therefore, the residue definition for monitoring in raw commodities is proposed as fluazinam only. Validated analytical methods for enforcement of the proposed residue definition in high water content, acidic and dry commodities are available. In processed commodities which are subject to hydrolytic conditions, fluazinam can be fully degraded. Therefore, the monitoring residue definition should include AMPA-fluazinam and AMGT but, in the absence of an appropriate radiolabeled study, this is only a tentative proposal. There are indications that AMPA-fluazinam and AMPGT can be enforced in watery and acidic processed commodities; if the proposed residue definition for monitoring in processed commodities is confirmed in the future, an ILV would be required for the analysis of the metabolites. Metabolites AMPA-fluazinam and AMGT may contribute in a significant extent to the toxicological burden in fruits crops and processed items. Consequently, the risk assessment residue definition is proposed as the sum of fluazinam, AMPA-fluazinam and AMGT, expressed as fluazinam, for both raw and processed commodities.

EFSA acknowledges that the extensive metabolism observed in peanuts and rotational crops might lead to the significant presence of trifluoroacetic acid (TFA). This issue is particularly relevant when assessing the authorised GAPs on dry beans (covered by the metabolism study performed in peanuts) and cane fruits (covered by confined rotational crops studies) as well as rotational crops. However, a separate residue definition for monitoring including TFA was not considered because this compound is not specific to the use of fluazinam. It is noted that a risk assessment regarding the overall exposure to TFA was performed in a previous EFSA reasoned opinion (EFSA, 2014a). In this opinion, it was concluded that TFA is not more toxic that the parent compound and the exposure calculations were performed by taking into account the presence of TFA arising from fluazinam in primary and rotational crops (see also section 3.2). EFSA still relies on this assessment but highlights that uncertainty needs to be addressed with regards to the authorised GAPs on dry beans and cane fruits (see also section 1.2.1).

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

To assess the magnitude of fluazinam residues resulting from the reported GAPs, EFSA considered all residue trials reported by the RMS in its evaluation report (Austria, 2011), including residue trials evaluated in the framework of the peer review (EFSA, 2008) or in the framework of a previous MRL application (EFSA, 2012, 2014b, 2015c) and additional data submitted during the completeness check (France, 2015; Italy, 2015). All residue trial samples considered in this framework were stored in compliance with the storage conditions demonstrated in section 1.1.5. Decline of residues during storage of the trial samples is therefore not expected.

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, 2011).

For table grapes, the number of residue trials reported is not compliant with the data requirements, only tentative MRL and risk assessment values could be derived by EFSA and the following data gap was identified:

- Table grapes: 4 additional trials on table grapes compliant with the southern outdoor GAP are required. It is noted that higher levels of metabolite AMGT were found in table grapes compared to other fruits crops. As a longer (pre-harvest interval) PHI is authorised in this GAP (with a last application at crop growth stage BBCH 69), EFSA assumes that this might allow a further degradation of the parent compound into its metabolite compared to other GAPs. EFSA is of the opinion that decline studies would be very useful to conclude on this issue. Therefore, the 4 additional residue trials should ideally be decline studies.

For cane fruits and beans (dry), metabolites AMGT and AMPA-fluazinam were not analysed in the available residue trials. However, this is not deemed necessary since these metabolites are not expected to occur in cane fruits (following soil treatment) and dry beans (based on the peanuts metabolism study). The available residue trials are sufficient to derive tentative MRL and risk assessment values but uncertainty remains regarding the presence of TFA residues; the following consideration were made by EFSA:

- Cane fruits (raspberries, dewberries and blackberries): two residue trials compliant with the northern outdoor GAP confirm the absence of fluazinam in these crops (see also section 1.1.2). However, as discussed in section 1.1.6, uncertainty remains regarding the presence of TFA in these crops where an extensive degradation of fluazinam and fluazinam related compounds based on the two rings structure is expected. Therefore, only tentative MRL and risk assessment values are proposed in these crops. Residue trials analysing for TFA residue levels are required to support the southern outdoor GAP (4 trials) and the indoor GAP (4 trials) are required.
- Beans (dry): the available residue trials confirm the absence of fluazinam in these crops (see also section 1.1.2). However, for the same reasons as reported for cane fruits, 8 residue trials compliant with the northern outdoor GAP and analysing for TFA residue levels are required. Meanwhile, tentative MRL and risk assessment values are derived.

For all other crops, available residue trials are sufficient to derive MRL and risk assessment values, taking note of the following considerations:

- Wine grapes: appropriate MRL and risk assessment values can be derived from the 13 southern data while only 6 trials compliant with the northern GAP are available. Considering that the southern GAP is more critical (MRL=3 mg/kg) than the northern GAP (MRL=1 mg/kg), 2 additional trials compliant with the northern GAP are only deemed desirable.
- Potatoes, onions, shallots, herbal infusions (roots): although sufficient data sets for parent fluazinam are available to support all the authorised GAPs for these crops, residue trials analysing for AMPA-fluazinam and AMGT are not available. Nevertheless, according to the metabolism study performed on potatoes, significant levels of AMPA-fluazinam and AMGT are not expected in root crops. Therefore, further data for these metabolites are not required.
- Potatoes (NEU): the northern GAP considered in this review (12 applications at 0.2 kg active substance (a.s.)/ha; PHI: 7 days) is supported by data (see above). However, another GAP was reported by Belgium (6 applications at 0.2 kg a.s./ha; PHI: 1 day). As this GAP is not supported by data, EFSA could not consider it to derive MRL and risk assessment values.

Nevertheless, as this GAP might be more critical than the one considered in this review, 8 residue trials compliant with the Belgian GAP are required.

1.2.2. Magnitude of residues in rotational crops

Based on the confined rotational crop study evaluated during the peer review (see also section 1.1.2.), fluazinam or its main metabolites are not expected to occur in rotational crops. In addition, the confined rotational crop study provides useful results on magnitude of TFA in lettuce, barley grains and carrots (see section 1.1.2). Therefore, rotational crops field trials not required.

1.2.3. Magnitude of residues in processed commodities

After the peer review, several studies investigating the magnitude of residues in processed commodities were reported for wine grapes (Italy, 2015) and tomatoes (EFSA, 2015c). An overview of all available processing studies is available in Appendix B.1.2.3. Assuming a tentative residue definition for monitoring and risk assessment being the sum of fluazinam, AMPA-fluazinam and AMGT, expressed as fluazinam (see also section 1.1.6), processing factors were derived for processed commodities of wine grapes (dry pomace, must, red and white wine) and tomatoes (peeled and canned, sauce, paste, juice). For tomatoes, it is noted that the reported processing factors (PF) are different compared to the ones derived in the previous EFSA opinion (EFSA, 2015c) as they are now based on a tentative monitoring residue definition including AMPA-fluazinam and AMGT.

It is highlighted that an appropriate radiolabeled study investigating the nature of residues in processed commodities was required (see section 1.1.3) and is particularly necessary to finalise the risk assessment in apples, pears and wine grapes which are significant contributors to chronic/acute exposures. Meanwhile, further studies investigating the magnitude of the residues are not required.

1.2.4. Proposed MRLs

Consequently, the available data are considered sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation. Furthermore, the residue trials allow deriving conversion factors for risk assessment in apples, pears and grapes (table and wine) and tomatoes. For root crops (except dry roots herbal infusions), cane fruits and dry beans, a conversion factor of 1 is proposed considering that significant levels of AMPA-fluazinam and AMGT were not observed in the supporting metabolism studies (see section 1.1). In herbal infusions (dry roots), the conservative conversion factor of 3 was proposed for the import tolerance GAP considering that significant fluazinam residue levels were observed in the residue trials (EFSA, 2014b). Nevertheless, due to the several data gaps identified in this review, all the MRL proposals are tentative, except for potatoes, onions, shallots and tomatoes.

2. Residues in livestock

Fluazinam is authorised for use on apples, potatoes and dry beans that might be fed to livestock. Livestock dietary burdens were therefore calculated for different groups of livestock using the agreed European methodology (European Commission, 1996). The input values for all relevant commodities have been selected according to the recommendations of JMPR (FAO, 2009) and are summarised in Appendix C.1. The calculated dietary burden for meat ruminants was 0.15 mg/kg dry matter (DM), which is slightly exceeding the trigger value of 0.1 mg/kg DM. Therefore, behaviour of residues should normally be assessed in this group of livestock. However, the following considerations are made by EFSA:

- The dietary burden is close to the trigger value and is mainly driven by apple pomaces and potatoes. For apple pomaces, the default processing factor of 2.5 was considered and might be refined. For potatoes, the LOQ of 0.01 mg/kg was considered while the metabolism study indicates residues <0.001 mg/kg.
- In the ruminant metabolism study, which is overdosed by a factor of 54 compared to the calculated dietary burden (see Appendix B.2.1.1), parent fluazinam was not detected and the major metabolites identified were AMPA-fluazinam (max 0.126 mg residue expressed as a.s. equivalent (eq)/kg) and DAPA (max 0.078 mg eq/kg). Their levels at the calculated dietary burden are therefore not expected to exceed the value of 0.004 mg eq/kg.

Consequently, EFSA is of the opinion that MRLs for fluazinam in animal commodities are not required. Nevertheless, if a residue definition for ruminant commodities would be needed in the future, it should include AMPA-fluazinam and/or DAPA (see Appendix E) for enforcement purpose and the sum of these two compounds for the risk assessment.

3. Consumer risk assessment

3.1. Risk assessment for fluazinam, AMPA-fluazinam and AMGT

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 D. Hence, for those commodities where a (tentative) MRL could be derived by EFSA in the framework of this review, input values were derived according to the internationally agreed methodologies (FAO, 2009). All input values included in the exposure calculations are summarised in Appendix C.2.

The exposures calculated were compared with the toxicological reference values for fluazinam, derived by EFSA (2008) under Directive 91/414/EEC. The highest chronic exposure was calculated for French population (all), representing 31.8% of the acceptable daily intake (ADI), and the highest acute exposure was calculated for apples, representing 35.7% of the ARfD. Although uncertainties remain due to the data gaps identified in the previous sections, this indicative exposure calculation did not indicate a risk to consumers.

3.2. Risk assessment for trifluoroacetic acid (TFA)

A separate residue definition for trifluoroactic acid (TFA) or its inclusion in the risk assessment residue definition for fluazinam was not deemed necessary (also section 1.1.6). TFA is an ubiquitous compound which can occur from different sources. The risk assessment regarding the overall exposure to metabolite TFA was performed in a previous EFSA reasoned opinion (EFSA, 2014a). In this opinion, the exposure calculations were performed by taking into account the TFA concentration resulting from the use of pesticides which are possible sources of TFA (including fluazinam) and all environmental contaminations. In these calculations, the highest chronic exposure was calculated for German children, representing 5% of the ADI, and the highest acute exposure was calculated for potatoes, representing 24.6% of the ARfD (EFSA, 2014a). In the framework of the present review, EFSA still relies on this assessment but highlights two major uncertainties with regards to the authorised GAPs for fluazinam:

- Cane fruits (soil treatment): For fruits crops, TFA residue levels arising from succeeding crops treated with fluazinam were considered as the most critical input values in EFSA, 2014a. As a worst case estimation, the residue level observed in lettuce confined rotational crops study was considered for all fruit crops (0.068 mg TFA/kg). Although this might cover the TFA residue levels resulting from the authorised soil treatment with fluazinam, residue trials analysing for TFA in cane fruits in accordance with the authorised GAP are still required (see section 1.2.1).
- Beans (dry): For pulses, TFA residue level arising from the use of saflufenacil (0.165 mg TFA/kg) was considered as the most critical input values in EFSA, 2014a. Although this might cover the TFA residue levels resulting from the authorised foliar treatment with fluazinam, residue trials analysing for TFA in dry beans in accordance with the authorised GAP are still required (see section 1.2.1).

According to the metabolism studies, significant TFA residues are not expected from foliar treatments on fruit crops and root crops. Therefore, the other GAPs authorised for fluazinam are not of concern with regard to the assessment to TFA residues.

Conclusions

The metabolism of fluazinam has been investigated in three different crop groups, as well as in rotational crops. Based on these studies, the residue definition for monitoring in raw commodities was proposed as fluazinam only. Validated analytical methods for enforcement of the proposed residue definition in high water content, acidic and dry commodities are available. An appropriate radiolabeled hydrolysis study was not reported but, based on the available data, the monitoring residue definition in processed commodities was tentatively proposed as the sum of fluazinam, AMPA-fluazinam and AMGT, expressed as fluazinam. There are indications that AMPA-fluazinam and AMPGT can be enforced in watery and acidic processed commodities. Finally, as AMPA-fluazinam and AMGT may contribute in a significant extent to the toxicological burden, a general risk assessment residue definition was proposed as the sum of fluazinam, AMPA-fluazinam and AMGT, expressed as fluazinam.

It noted that the ubiquitous metabolite TFA was observed in peanuts and rotational crops. However, as this compound is not specific to the use of fluazinam, a separate residue definition including TFA was not considered by EFSA. Furthermore, an overall risk assessment for this metabolite was previously carried by EFSA and, in spite of certain uncertainties highlighted for cane fruits and dry beans, this assessment is covering the use of fluazinam as a pesticide.

The available residue trials allowed EFSA assessing the magnitude of residues resulting from the authorised GAPs reported in this review. MRL proposals, risk assessment values and conversion factors were derived for all commodities under evaluation. Nevertheless, due to the several data gaps identified in this review, all the MRL proposals are tentative, except for potatoes, onions, shallots and tomatoes. In addition, studies investigating the magnitude of residues in processed commodities of wine grapes and tomatoes allowed EFSA to derive processing factors for enforcement and risk assessment in grapes dry pomace, must, red and white wine as well as in peeled and canned tomatoes, tomatoes sauce, paste and juice. Nevertheless, in the absence of an appropriate radiolabeled study investigating the nature of residues in processed commodities, these processing factors remain tentative.

Fluazinam is authorised for use on apples, potatoes and dry beans that might be fed to livestock. However, the calculated dietary burden for meat ruminants was only 0.15 mg/kg DM and may have been overestimated because of several conservative assumptions such as the default processing factor for apples dry pomace and the use of the LOQ in potatoes. Moreover, the metabolism of fluazinam was investigated in lactating goats and the available results demonstrated that the relevant compounds are expected to remain below 0.004 mg/kg in animal tissues and products. Consequently, EFSA concluded that MRLs for fluazinam in animal commodities were not required.

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 highest chronic exposure represented 31.8% of the ADI (FR all population) and the highest acute exposure amounted to 35.7% of the ARfD (apples).

Recommendations

MRL recommendations were derived in compliance with the decision tree reported in Appendix D of the reasoned opinion (see summary table). 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 summary table footnotes for details). In particular, some tentative MRLs need to be confirmed by the following data:

- a radiolabeled study investigating the nature of residues in processed commodities (required to finalise the risk assessment for apples, pears and wine grapes);
- a full validation of the analytical method for enforcement in ginseng (roots);
- 4 additional residue trials (with decline studies) supporting the southern outdoor GAP on table grapes;
- residue trials analysing for TFA and supporting the southern outdoor GAP (4 trials) and the indoor GAP (4 trials) on cane fruits;
- 8 residue trials analysing for TFA and supporting the northern outdoor GAP on beans (dry).

Furthermore, it is highlighted that the MRL derived for potatoes results from a GAP authorised in the Netherlands while a different GAP reported by Belgium was not supported by data. EFSA therefore identified the following data gap which is not expected to impact on the validity of the MRL derived but which might have an impact on national authorisation(s):

- 8 additional residue trials supporting the Belgian outdoor GAP on potatoes (6 applications at 0.2 kg a.s./ha; PHI: 1 day).

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:

- 2 additional residue trials supporting the northern GAP on wine grapes.

Table 2: Summary table

Code number	Commodity	Existing EU MRL (mg/kg)	Outcome of the review	
			MRL (mg/kg)	Comment
Enforcement residue definition : fluazinam				
130010	Apples	0.3	0.3	Further consideration needed (a)
130020	Pears	0.05*	0.3	Further consideration needed (a)
151010	Table grapes	0.05*	0.01*	Further consideration needed (a)
151020	Wine grapes	3	3	Further consideration needed (a)
153010	Blackberries	0.05*	0.01*	Further consideration needed (a)
153020	Dewberries	0.05*	0.01*	Further consideration needed (a)
153030	Raspberries	0.05*	0.01*	Further consideration needed (a)
211000	Potatoes	0.05*	0.02	Recommended (b)
220020	Onions	0.05*	0.01*	Recommended (b)
220030	Shallots	0.05*	0.01*	Recommended (b)
231010	Tomatoes	0.05*	0.3	Recommended (b)
300010	Beans (dry)	0.05*	0.02*	Further consideration needed (a)
633000	Herbal infusions (dried, roots)	3	3	Further consideration needed (a)
-	Other products of plant and/or animal origin	See regulation 2015/401	-	Further consideration needed (c)

*: Indicates that the MRL is set at the limit of quantification.
(a): 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 D).
(b): 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 D).
(c): 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 D).

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Abbreviations

a.i.	active ingredient
a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CAS	Chemical Abstract Service
CEN	European Committee for Standardization (Comité Européen de Normalisation)
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CXL	codex maximum residue limit
d	day
DAR	Draft Assessment Report (prepared under Council Directive 91/414/EEC)
DAT	days after treatment
DB	dietary burden
DM	dry matter
DT_{90}	period required for 90 percent dissipation (define method of estimation)
EC	European Commission
eq	residue expressed as a.s. equivalent
FAO	Food and Agriculture Organization of the United Nations
GAP	good agricultural practice
GC-ECD	gas chromatography with electron capture detector
HPLC-MS/MS	high performance liquid chromatography with tandem mass spectrometry
IEDI	international estimated daily intake
IESTI	international estimate of short-term intake
ILV	independent laboratory validation
ISO	International Organisation for Standardization
IUPAC	International Union of Pure and Applied Chemistry
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
NEU	northern European Union
OECD	Organisation for Economic Co-operation and Development
PF	processing factor
PHI	pre-harvest interval

P_{ow}	partition coefficientn-octanol/water
PRIMo	(EFSA) Pesticide Residues Intake Model
PROFile	(EFSA) Pesticide Residues Overview File
R_{ber}	statistical calculation of the MRL by using a non-parametric method
R_{max}	statistical calculation of the MRL by using a parametric method
RA	risk assessment
RAC	raw agricultural commodity
RD	residue definition
RMS	rapporteur Member State
SEU	southern European Union
TFA	trifluoroacetic acid
TRR	total radioactive residue

Appendix A – Summary of authorised uses considered for the review of MRLs

Critical outdoor GAPs for Northern Europe

Crop: Common name	Crop: Scientific name	Region	Outdoor/ Indoor	Member state or country	Pest controlled	Formulation: Type	Formulation: Content Conc.	Formulation: Content Unit	Application: Method	Growth stage: From BBCH	Growth stage: Until BBCH	Number: Min.	Number: Max.	Interval (days): Min.	Interval (days): Max.	Rate: Min.	Rate: Max.	Rate: Unit	PHI or waiting period (days)	Comments (max. 250 characters)
Wine grapes	*Vitis euvitis*	NEU	Outdoor	FR	Botrytis spp., Plasmopara spp.	SC	500.0	g/L	Foliar treatment - spraying	69	n.a.	1	3	21			0.75	kg a.i./ha	21	3 applications can be done from "end of flowering", "bunch closure" or "colour change", until "ripening". Total authorised rate per season: 2.25 kg a.s./ha
Blackberries	*Rubus fruticosus*	NEU	Outdoor	UK	Fungus	SC	500.0	g/L	Soil treatment - general (see also comment field)	0	0	1	2				0.75	kg a.i./ha	n.a.	Band spray (applied to base of canes). Latest application before the end of March in the year of harvest. Total authorised rate per season: 1.5 kg a.s./ha
Dewberries	*Rubus ceasius*	NEU	Outdoor	UK	Fungus	SC	500.0	g/L	Soil treatment - general (see also comment field)	0	0	1	2				0.75	kg a.i./ha	n.a.	Band spray (applied to base of canes). Latest application before the end of March in the year of harvest. Total authorised rate per season: 1.5 kg a.s./.ha

Critical outdoor GAPs for Northern Europe																				
Crop		**Region**	**Outdoor/ Indoor**	**Member state or country**	**Pest controlled**	**Formulation**			**Application**										**PHI or waiting period (days)**	**Comments (max. 250 characters)**
Common name	**Scientific name**					**Type**	**Content**		**Method**	**Growth stage**		**Number**		**Interval (days)**		**Rate**				
							Conc.	**Unit**		**From BBCH**	**Until BBCH**	**Min.**	**Max.**	**Min.**	**Max.**	**Min.**	**Max.**	**Unit**		
Raspberries	*Rubus idaeus*	NEU	Outdoor	UK	Fungus	SC	500.0	g/L	Soil treatment - general (see also comment field)	0	0	1	2				0.75	kg a.i./ha	n.a.	Band spray (applied to base of canes). Latest application before the end of March in the year of harvest. Total authorised rate per season: 1.5 kg a.s./ha
Potatoes	*Tuber form Solanum Spp*	NEU	Outdoor	NL	Phytophtora	SC	500.0	g/L	Foliar treatment - spraying	0	97	1	12	7	10		0.20	kg a.i./ha	7	Total authorised rate per season: 2.4 kg a.s./ha. Also authorised in BE with 6 app. at 0.2 kg a.s./ha; PHI 1 day).
Onions	*Allium cepa*	NEU	Outdoor	NL	Botrytis cinerea	SC	500.0	g/L	Foliar treatment - spraying	n.a.	n.a.	3	10	7	10		0.25	kg a.i./ha	28	Total authorised rate per season 2.5 kg a.s./ha.
Shallots	*Allium ascalonicum (Allium cepa var. aggregatum)*	NEU	Outdoor	NL	Botryotinia squamosa	SC	500.0	g/L	Foliar treatment - spraying	10	n.a.	3	10	7	10		0.25	kg a.i./ha	28	-
Herbal infusions (roots)	*Not specified*	NEU	Outdoor	NL	Phytophtora cactorum	SC	500.0	g/L	Foliar treatment - spraying	15	91	3	7	7	10		0.25	kg a.i./ha	7	The item herbal infusion (roots) includes the use on ginseng.

Critical outdoor GAPs for Southern Europe

Crop		Region	Outdoor/ Indoor	Member state or country	Pest controlled	Formulation			Application										PHI or waiting period (days)	Comments (max. 250 characters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Rate				
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.	Min.	Max.	Unit		
Apples	*Malus domesticus*	SEU	Outdoor	IT	Venturia inaequalis	SC	500.0	g/L	Foliar treatment - spraying	60	79	1	3	6	14	0.70	0.80	kg a.i./ha	60	Total authorised rate = 2.25 kg a.s./ha (GAP also assessed in EFSA, 2012).
Pears	*Pyrus communis*	SEU	Outdoor	IT	Stemphylium vesicarium, venturia pyrina	SC	500.0	g/L	Foliar treatment - spraying	59	77	1	4	6	10	0.50	0.75	kg a.i./ha	63	-
Table grapes	*Vitis euvitis*	SEU	Outdoor	EL	Botrytis spp., Plasmopara spp.	SC	500.0	g/L	Foliar treatment - spraying	n.a.	69	1	1				0.75	kg a.i./ha	n.a.	-
Wine grapes	*Vitis euvitis*	SEU	Outdoor	CY, EL	Botrytis cinerea	SC	500.0	g/L	Foliar treatment - spraying	61	89	1	4				0.75	kg a.i./ha	21	Four applications can be done from "bloom", "bunch closure" or "colour change", until "ripening". Total authorised rate per season: 3 kg a.s./ha.
Potatoes	*Tuber form Solanum Spp*	SEU	Outdoor	IT, FR	Phytophtora infestans	SC	500.0	g/L	Foliar treatment - spraying	0	97	1	10				0.20	kg a.i./ha	7	Total authorised rate per season: 2 kg as/ha.
Tomatoes	*Lycopersicum esculentum*	SEU	Outdoor	IT	Phytophtora, Alternaria, Botrytis	SC	500.0	g/L	Foliar treatment - spraying	10		1	6	7	10		0.20	kg a.i./ha	7	GAP assessed in EFSA, 2015.

Critical Indoor GAPs for Northern and Southern Europe (incl. post-harvest treatments)																				
Crop		**Region**	**Outdoor/ Indoor**	**Member state or country**	**Pest controlled**	**Formulation**			**Application**										**PHI or waiting period (days)**	**Comments (max. 250 characters)**
Common name	**Scientific name**					**Type**	**Content**		**Method**	**Growth stage**		**Number**		**Interval (days)**		**Rate**				
							Conc.	**Unit**		**From BBCH**	**Until BBCH**	**Min.**	**Max.**	**Min.**	**Max.**	**Min.**	**Max.**	**Unit**		
Blackberries	*Rubus fruticosus*	NEU/SEU	Indoor	UK	Fungus	SC	500.0	g/L	Soil treatment - general (see also comment field)	0	0	1	2				0.75	kg a.i./ha	n.a.	Band spray (applied to base of canes). Latest application before the end of March in the year of harvest. Total authorised rate per season: 1.5 kg a.s./ha.
Dewberries	*Rubus ceasius*	NEU/SEU	Indoor	UK	Fungus	SC	500.0	g/L	Soil treatment - general (see also comment field)	0	0	1	2				0.75	kg a.i./ha	n.a.	Band spray (applied to base of canes). Latest application before the end of March in the year of harvest. Total authorised rate per season: 1.5 kg as/ha.
Raspberries	*Rubus idaeus*	NEU/SEU	Indoor	UK	Fungus	SC	500.0	g/L	Soil treatment - general (see also comment field)	0	0	1	2				0.75	kg a.i./ha	n.a.	Band spray (applied to base of canes). Latest application before the end of March in the year of harvest. Total authorised rate per season: 1.5 kg a.s./ha.

Critical GAPs for Import Tolerances (non-European indoor, outdoor or post-harvest treatments)

Crop		Region	Outdoor/ Indoor	Member state or country	Pest controlled	Formulation			Application										PHI or waiting period (days)	Comments (max. 250 characters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Rate				
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.	Min.	Max.	Unit		
Beans (dry)	*Phaseolus vulgaris*	non-EU	Outdoor	US, CA	White mold	SC	500.0	g/L	Foliar treatment - spraying	61	71	1	2	7	10		0.50	kg a.i./ha	30	Total authorised rate per season: 1 kg a.s./ha.
Herbal infusions (roots)	*Not specified*	non-EU	Outdoor	US	Rhizoctonia root rot, Alternaria blight, Botrytis blight, White mold.	SC	500.0	g/L	Foliar treatment - spraying	n.a.	n.a.	4	6	14		0.59	0.89	kg a.i./ha	30	GAP assessed in EFSA, 2014. The total amount per season should not exceed 3.55 kg a.i./ha.

a.i. : active ingredient; BBCH: growth stages of mono- and dicotyledonous plants; FR: France; UK: the United Kingdom; NL: Netherlands; IT: Italy; EL: Hellas; CY: Cyprus; US: United States; CA: Canada; n.a. not applicable; 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; PHI: pre-harvest interval; SC: suspension concentrate

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

<table>
<tr><td rowspan="6">Primary crops
(available studies)</td><th>Crop groups</th><th>Crop(s)</th><th colspan="2">Application(s)</th><th>Sampling
(DAT)</th></tr>
<tr><td rowspan="2">Fruit crops</td><td>Grapes</td><td colspan="2">Foliar, 2 × 0.75 kg a.s./ha</td><td>71</td></tr>
<tr><td>Apples</td><td colspan="2">Foliar, 6 × 0.93 kg a.s./ha</td><td>32</td></tr>
<tr><td>Root crops</td><td>Potatoes</td><td colspan="2">Foliar, 4 × 0.43 kg a.s./ha or,
Foliar, 4 × 0.51 kg a.s./ha</td><td>6
7</td></tr>
<tr><td>Pulses/Oilseeds</td><td>Peanuts</td><td colspan="2">Foliar, 4 × 0.56 kg a.s./ha</td><td>55, 66</td></tr>
<tr><td colspan="5">Source: EFSA, 2008</td></tr>
<tr><td rowspan="5">Rotational crops
(available studies)</td><th>Crop groups</th><th>Crop(s)</th><th colspan="2">Application(s)</th><th>PBI
(DAT)</th></tr>
<tr><td>Root/tuber crops</td><td>Carrot</td><td colspan="2">Bare soil, 2 × 1.12 kg a.s./ha</td><td>30, 120, 365</td></tr>
<tr><td>Leafy crops</td><td>Lettuce</td><td colspan="2">Bare soil, 2 × 1.12 kg a.s./ha</td><td>30, 120, 365</td></tr>
<tr><td>Cereal (small grain)</td><td>Barley</td><td colspan="2">Bare soil, 2 × 1.12 kg a.s./ha</td><td>30, 120, 365</td></tr>
<tr><td colspan="5">Source: EFSA, 2008
<u>Note:</u> results of these studies are considered to cover the primary crop metabolism for soil treatment in fruit crops (ie. cane fruits).</td></tr>
<tr><td rowspan="5">Processed commodities
(hydrolysis study)</td><th colspan="3">Conditions</th><th colspan="2">Investigated?</th></tr>
<tr><td colspan="3">Pasteurisation (20 min, 90°C, pH 4)</td><td colspan="2">No</td></tr>
<tr><td colspan="3">Baking, brewing and boiling (60 min, 100°C, pH 5)</td><td colspan="2">Yes[(a)]</td></tr>
<tr><td colspan="3">Sterilisation (20 min, 120°C, pH 6)</td><td colspan="2">Yes[(a)]</td></tr>
<tr><td colspan="5">Source: France, 2015
(a): Studies not performed with radiolabeled material; results are only indicative.</td></tr>
</table>

Can a general residue definition be proposed for primary crops?	Yes
Rotational crop and primary crop metabolism similar?	Yes (metabolism in rotational crops is more extensive: fluazinam is not detected while metabolite TFA is significant in rotational crops).
Residue pattern in processed commodities similar to residue pattern in raw commodities?	No (but an appropriate study is still required).
Plant residue definition for monitoring (RD-Mo)	Raw commodities: fluazinam Processed commodities: sum of fluazinam, AMPA-fluazinam and AMGT, expressed as fluazinam (tentative)[10]
Plant residue definition for risk assessment (RD-RA)	Sum of fluazinam, AMPA-fluazinam and AMGT, expressed as fluazinam[11]
Conversion factor (monitoring to risk assessment)	Not derived from the metabolism studies (see summary of residues data from the supervised residue trials).
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)	Fluazinam: • HPLC-MS/MS; LOQ: 0.01 mg/kg. Validated in high water (EFSA, 2008, 2012) and acidic (France, 2015) commodities. • HPLC-MS/MS (QuEChERS); LOQ 0.02 mg/kg. Validated in dry commodities (EURL, 2015). • GC-ECD; LOQ: 0.01 mg/kg. Not fully validated in dried ginseng roots (EFSA, 2014b). Metabolites AMPA-fluazinam and AMGT: • HPLC-MS/MS; LOQ: 0.01 mg/kg. Validated in high water and acidic commodities (Italy, 2015). An ILV is missing.

[10] The proposal for a residue definition for monitoring specific to processed commodities is new compared to the conclusion of the peer review. It should only apply to processed commodities subject to hydrolysis conditions such as boiling, baking, cooking, pasteurisation and sterilisation. However, it should still be confirmed by a validated hydrolysis study.

[11] The metabolite TFA is significantly formed in pulses, oilseeds and/or after soil treatment. A separate residue definition is not proposed because TFA is not specific to fluazinam. However, when uses are authorised on pulses, oilseeds and/or for soil treatment, residue data for metabolite TFA should also be provided in order to update the risk assessment relative to this compound.

B.1.1.2. Stability of residues in plants

Plant products (available studies)	Category	Commodity	T (°C)	Stability (Months/years)
	Fluazinam			
	High water content	Potatoes	-15	26 months
	High acid content	Grapes (raw and processed)	-21	36 months
	Dry	Green coffee beans (12.5 % moisture)	-15	26 months
	Others	Dried ginseng (herbal infusions)	-18	11 months
	Sources: High water content (EFSA, 2008); High acid content (France, 2015); Dry commodities (Austria, 2006). Others (incl. herbal infusions): Although recovery was only 60%, the available data were deemed acceptable considering that ginseng roots are very minor crops (EFSA, 2014b).			
	AMGT			
	High water content	Tomatoes	-20	26 months
	High acid content	Grapes (raw and processed)	-21	36 months
	Sources: High water content commodities (EFSA, 2015c); High acid content (France, 2015). No study available for dry commodities and dried ginseng but AMGT is not of concern in dry beans and ginseng root is a very minor crop.			
	AMPA-fluazinam			
	High water content	Tomatoes	-20	≤18 months
	High acid content	Grapes (raw and processed)	-21	36 months
	Sources: High water content commodities (EFSA, 2015c); High acid content (France, 2015). No study available for dry commodities and dried ginseng but AMPA-fluazinam is not of concern in dry beans and ginseng root is a very minor crop.			

B.1.2. Magnitude of residues in plants

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

Crop	Region/ Indoor (a)	Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg)	Recommendations/comments (OECD calculations)	MRL proposals (mg/kg)	HR_{Mo} (mg/kg) (b)	$STMR_{Mo}$ (mg/kg) (c)	CF (d)
Apples	SEU	**Mo:** <0.01; <0.01; <0.01; 0.02; 0.04; 0.09(e); 0.09; 0.15(e) **RA:** 0.04; 0.04; <0.03; 0.04; 0.058; 0.115; 0.115; 0.162	Trials compliant with GAP (Austria, 2011). Rber = 0.18 Rmax = 0.22 MRL_{OECD} = 0.26	0.30(f) (tentative)	0.15	0.03	1.7
Pears	SEU	**Mo:** <0.01; <0.01; <0.01; 0.02; 0.04; 0.09(e); 0.09; 0.15(e); <0.01; 0.015 **RA:** 0.04; 0.04; <0.03; 0.04; 0.058; 0.115; 0.115; 0.162; -; -	8 trials extrapolated from apples (performed with 3 applications instead of 2) and 2 GAP-compliant trials performed on pears (Italy, 2015). Rber = 0.18 Rmax = 0.19 MRL_{OECD} = 0.24	0.30(f) (tentative)	0.15	0.02	1.7
Table grapes	SEU	**Mo:** 4 ×<0.01 **RA:** <0.03; <0.03; 0.065; 0.12	Trials compliant with GAP (Austria, 2011).	0.01*(g) (tentative)	0.01	0.01	5
Wine grapes	NEU	**Mo:** <0.01; 0.02; 0.19; 0.25; 0.32; 0.51 **RA:** <0.03; 0.04; 0.25; 0.289; 0.366; 0.626	Trials compliant with GAP (Austria, 2011; France, 2015). Rber = 0.74 Rmax = 0.92 MRL_{OECD} = 0.98	1(f) (tentative)	0.51	0.22	1.3
	SEU	**Mo:** 0.064; 0.08; 0.13; 0.22; 0.5; 0.535; 0.6; 0.61; 0.71; 0.778; 0.97; 1.45; 1.47 **RA:** -; -; 0.193; 0.367; -; 0.663; -; 0.729; 0.815; 0.837; 1.103; 1.555; 1.708	Trials compliant with GAP (Austria, 2011). Rber = 1.75 Rmax = 1.86 MRL_{OECD} = 2.48	**3(f) (tentative)**	**1.47**	**0.60**	**1.3**
Raspberries Dewberries Blackberries	NEU	**Mo:** 2 × <0.05 **RA: -**	Northern trials on raspberries compliant with GAP (Austria, 2011). Significant levels of fluazinam, AMPA-fluazinam and AMGT are not expected following soil treatment but concern remains for TFA.	0.01*(h) (tentative)	0.01	0.01	1
	Indoor	**Mo:** - **RA: -**		-	-	-	-

Crop	Region/ Indoor (a)	Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg)	Recommendations/comments (OECD calculations)	MRL proposals (mg/kg)	HR_{Mo} (mg/kg) (b)	$STMR_{Mo}$ (mg/kg) (c)	CF (d)
Potatoes	NEU	**Mo:** 18 × <0.01; 0.013 **RA: -**	Trials performed with 9-11 applications instead of 12 are deemed acceptable (Austria, 2011). According to the metabolism study, metabolites AMPA-fluazinam and AMGT remain below LOQ. Rber = 0.02 Rmax = 0.01 MRL_{OECD} = 0.01	**0.02**	**0.01**	**0.01**	1
	SEU	**Mo:** 11 × <0.01 **RA: -**	Trials compliant with GAP (Austria, 2011). According to the metabolism study, metabolites AMPA-fluazinam and AMGT remain below LOQ.	0.01*	0.01	0.01	1
Onions Shallots	NEU	**Mo:** 4 × <0.02; 8 × <0.05 **RA: -**	Combined data set of residue trials performed on onions with 4-7 × 0.2 kg a.s./ha, or 8 × 0.4 kg as/ha, or 4 × 0.25 kg a.s./ha. In decline studies (PHI from 29 to 7 days), all samplings showed residues <LOQ (Austria. 2011). The metabolism study confirms that residues levels are below LOQ for all compounds.	0.01*	0.01	0.01	1
Tomatoes	SEU	**Mo:** <0.01; 2 × 0.01; 2 × 0.03; 0.04; 0.06; 0.16 **RA:** <0.03; 2 × 0.03; 2 × 0.05; 0.06; 0.08; 0.18	Trials compliant with GAP. Residues of both AMPA-fluazinam and AMGT are <0.01 mg/kg; a CF of 1 can be derived (EFSA, 2015c).	0.3	0.16	0.03	1
Beans (dry)	Import tolerance	**Mo:** 3 × <0.01; 0.01 **RA: -**	Trials compliant with GAP (Austria, 2011). Significant levels of fluazinam, AMPA-fluazinam and AMGT are not expected in pulses but concern remains for trifluoacteic acid (TFA). Rber = 0.02 Rmax = 0.01 MRL_{OECD} = 0.02	0.02*(h) (tentative)	0.01	0.01	1

Crop	Region/ Indoor (a)	Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg)	Recommendations/comments (OECD calculations)	MRL proposals (mg/kg)	HR_{Mo} (mg/kg) (b)	$STMR_{Mo}$ (mg/kg) (c)	CF (d)
Herbal infusions (dried, roots)	Import tolerance	**Mo:** 0.37; 0.77; 0.84; 1.30 **RA: -**	Trials performed on ginseng roots compliant with GAP. No data available for AMPA-fluazinam and AMGT. According to the metabolism study, parent residue level is higher than each metabolite level. Therefore, the conservative CF of 3 is proposed (EFSA, 2014b). Rber = 2.37 Rmax = 2.78 MRL_{OECD} = 2.46	3[(i)] (tentative)	1.30	0.81	3
	NEU	**Mo:** 18 × <0.01; 0.013 **RA: -**	Extrapolation from potatoes residue trials - performed with 9 to 11 applications instead of 7 - is deemed acceptable. According to the metabolism study, AMPA and AMGT are also below LOQ. Rber = 0.02 Rmax = 0.01 MRL_{OECD} = 0.01	0.02[(i)] (tentative)	0.01	0.01	1

* Indicates that the MRL is proposed at the limit of quantification.
(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 for risk assessment; median of the individual conversion factors at the supported PHI for each residues trial.
(e): Higher residue levels were observed at different PHI (within the 25% range): 0.09 mg/kg (45 days) and 0.15 mg/kg (70 days).
(f): MRL proposal is tentative because the nature of residues in processed commodities is not elucidated.
(g): MRL proposal is tentative because additional residue trials are still required.
(h): MRL proposal is tentative because additional data on TFA residue levels are still required.
(i): MRL proposal is tentative because the available analytical method for monitoring is not fully validated for dry ginseng (see also EFSA, 2014b).

B.1.2.2. Residues in succeeding crops

Confined rotational crop study (quantitative aspect)	Fluazinam, AMPA-fluazinam and AMGT were not found in rotational crops. Metabolite TFA was present at significant levels in lettuce (0.27 mg eq/kg - 0.068 mg TFA/kg), barley grains (0.18 mg eq/kg - 0.045 mg TFA/kg) and carrots (0.06 mg eq/kg - 0.014 mg TFA/kg).
Field rotational crop study	Field rotational crop studies were not required and not reported.

B.1.2.3. Processing factors

Processed commodity	Number of studies[(a)]	Processing Factor (PF)		CF_P[(b)]
		Individual values	Median PF	
Indicative processing factors (tentative residue definition)				
Wines grapes, dry pomace[(c)]	8	4.4; 5.6; 9.1; 9.8; 10.7; 12.8; 16.5; 34.1	10.3	1
Wine grapes, must[(c)]	8	0.18; 0.25; 0.27; 0.51; 0.57; 0.61; 0.78; 1.9	0.54	1
Wines grapes, red wine (unheated)[(c)]	4	<0.01; 0.01; 0.08; 0.19	0.04	1
Wine grapes, white wine[(c)]	4	0.05; 0.07; 0.11; 0.16	0.09	1
Tomatoes, peeled and canned[(d)]	4	0.17; 0.25; 0.25; 0.40	0.25	1
Tomatoes, sauce[(d)]	4	0.72; 0.75; 0.80; 1.2	0.78	1
Tomatoes, paste[(d)]	4	0.69; 0.76; 0.85; 0.93	0.80	1
Tomatoes, juice[(d)]	4	0.17; 0.20; 0.77; 0.82	0.48	1

(a): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur)
(b): Conversion factor for risk assessment in the processed commodity; as the tentative monitoring residue definition for processed commodities includes fluazinam, AMPA-fluazinam and AMGT, a CFp of 1 is reported
(c): Source: Italy, 2015
(d): Source: EFSA, 2015c but PF were recalculated considering the monitoring residue definition including AMPA-fluazinam and AMGT

B.2. Residues in livestock

	Median dietary burden (mg/kg bw per day)	**Maximum dietary burden** (mg/kg bw per day)	**Highest contributing commodity**[(a)]	**Max dietary burden** (mg/kg DM)	**Trigger exceeded** (Y/N)
Dairy ruminants	0.0020	0.0022	Apple pomace	0.062	N
Meat ruminants	0.0060	0.0065	Apple pomace	0.151	Y
Poultry	0.0011	0.0013	Potatoes	0.021	N
Pigs	0.0018	0.0023	Potatoes	0.057	N

DM:dry matter; Bw: body weight; N: No; Y: Yes;
(a): Calculated for the maximum dietary burden

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/day)	**Duration** (days)	**N rate/comment**
	Laying hen	0.76	4	580 N
	Lactating goat	0.35	4	54 N/ meat ruminants 160 N/ dairy ruminants
	Source: EFSA, 2008 Fluazinam was not detected and the major metabolites identified did not exceed 0.126 mg eq/kg and 0.078 mg eq/kg (in lactating goat). Residue levels at the calculated dietary burden are therefore not expected to exceed 0.004 mg eq/kg (worst case considering dietary burden in meat ruminants). EFSA concluded that MRLs for fluazinam in animal commodities are not required.			

Time needed to reach a plateau concentration in milk and eggs (days)	Milk: plateau level reached after 4 days. Eggs; plateau level not reached after 4 days.
Metabolism in rat and ruminant similar (Yes/No)	Yes
Animal residue definition for monitoring (RD-Mo)	No proposal – MRLs not needed
Animal residue definition for risk assessment (RD-RA)	No proposal – MRLs not needed
Conversion factor (monitoring to risk assessment)	-
Fat soluble residues (Yes/No)	Not relevant
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)	No - MRL not needed

B.2.1.2. Stability of residues in livestock

Animal products (available studies)	**Animal**	**Commodity**	**T** (°C)	**Stability** (Months/years)
	No study reported.			

B.2.2. Magnitude of residues in livestock

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

No study reported.

B.3. Consumer risk assessment

ADI	0.01 mg/kg bw per day (EFSA, 2008)
Highest IEDI, according to EFSA PRIMo	31.8% ADI (French all population)
Assumptions made for the calculations	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.

ARfD	0.07 mg/kg bw (EFSA, 2008)
Highest IESTI, according to EFSA PRIMo	35.7 % ARfD (apples)
Assumptions made for the calculations	The calculation is based on the highest residue levels in the raw agricultural commodities.

B.4. Proposed MRLs

Code number	Commodity	Existing EU MRL (mg/kg)	Outcome of the review	
			MRL (mg/kg)	Comment
Enforcement residue definition : fluazinam				
130010	Apples	0.3	0.3	Further consideration needed[(a)]
130020	Pears	0.05*	0.3	Further consideration needed[(a)]
151010	Table grapes	0.05*	0.01*	Further consideration needed[(a)]
151020	Wine grapes	3	3	Further consideration needed[(a)]
153010	Blackberries	0.05*	0.01*	Further consideration needed[(a)]
153020	Dewberries	0.05*	0.01*	Further consideration needed[(a)]
153030	Raspberries	0.05*	0.01*	Further consideration needed[(a)]
211000	Potatoes	0.05*	0.02	Recommended[(b)]
220020	Onions	0.05*	0.01*	Recommended[(b)]
220030	Shallots	0.05*	0.01*	Recommended[(b)]
231010	Tomatoes	0.05*	0.3	Recommended[(b)]
300010	Beans (dry)	0.05*	0.02*	Further consideration needed[(a)]
633000	Herbal infusions (dried, roots)	3	3	Further consideration needed[(a)]
-	Other products of plant and/or animal origin	See Regulation 2015/401	-	Further consideration needed[(c)]

(*): Indicates that the MRL is set at the limit of quantification.
(a): 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 D).
(b): 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 D).
(c): 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 D).

Appendix C – Input values for the exposure calculations

C.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: Sum of fluazinam, AMPA-fluazinam and AMGT, expressed as fluazinam				
Apple pomace	0.08	$STMR_{Mo} \times CF \times 2.5$(a)	0.08	$STMR_{Mo} \times CF \times 2.5$(a)
Beans (dry)	0.01	$STMR_{Mo} \times CF$	0.01	$STMR_{Mo} \times CF$
Potatoes	0.01*	$STMR_{Mo} \times CF$	0.01	$HR_{Mo} \times CF$

* Indicates that the input value is proposed at the limit of quantification. STMR: supervised trials median residue; HR: highest residue; CF: conversion factor for enforcement to risk assessment residue definition

(a): For apple pomace, in the absence of processing factors supported by data, default processing factors of 2.5 was included in the calculation in order to consider the potential concentration of residues in these commodities.

C.2. Consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: Sum of fluazinam, AMPA-fluazinam and AMGT, expressed as fluazinam				
Apples	0.05	$STMR_{Mo} \times CF$ (tentative)	0.26	$HR_{Mo} \times CF$ (tentative)
Pears	0.03	$STMR_{Mo} \times CF$ (tentative)	0.26	$HR_{Mo} \times CF$ (tentative)
Table grapes	0.05	$STMR_{Mo} \times CF$ (tentative)	0.05	$HR_{Mo} \times CF$ (tentative)
Wine grapes	0.78	$STMR_{Mo} \times CF$ (tentative)	1.9	$HR_{Mo} \times CF$ (tentative)
Blackberries	0.01*	$STMR_{Mo} \times CF$ (tentative)	0.01*	$HR_{Mo} \times CF$ (tentative)
Dewberries	0.01*	$STMR_{Mo} \times CF$ (tentative)	0.01*	$HR_{Mo} \times CF$ (tentative)
Raspberries	0.01*	$STMR_{Mo} \times CF$ (tentative)	0.01*	$HR_{Mo} \times CF$ (tentative)
Potatoes	0.01*	$STMR_{Mo} \times CF$	0.01	$HR_{Mo} \times CF$
Onions	0.01*	$STMR_{Mo} \times CF$	0.01*	$HR_{Mo} \times CF$
Shallots	0.01*	$STMR_{Mo} \times CF$	0.01*	$HR_{Mo} \times CF$
Tomatoes	0.03	$STMR_{Mo} \times CF$	0.16	$HR_{Mo} \times CF$
Beans (dry)	0.01	$STMR_{Mo} \times CF$ (tentative)	0.01	$HR_{Mo} \times CF$ (tentative)
Herbal infusions (dried, roots)	2.4	$STMR_{Mo} \times CF$ (tentative)	3.9	$HR_{Mo} \times CF$ (tentative)

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

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

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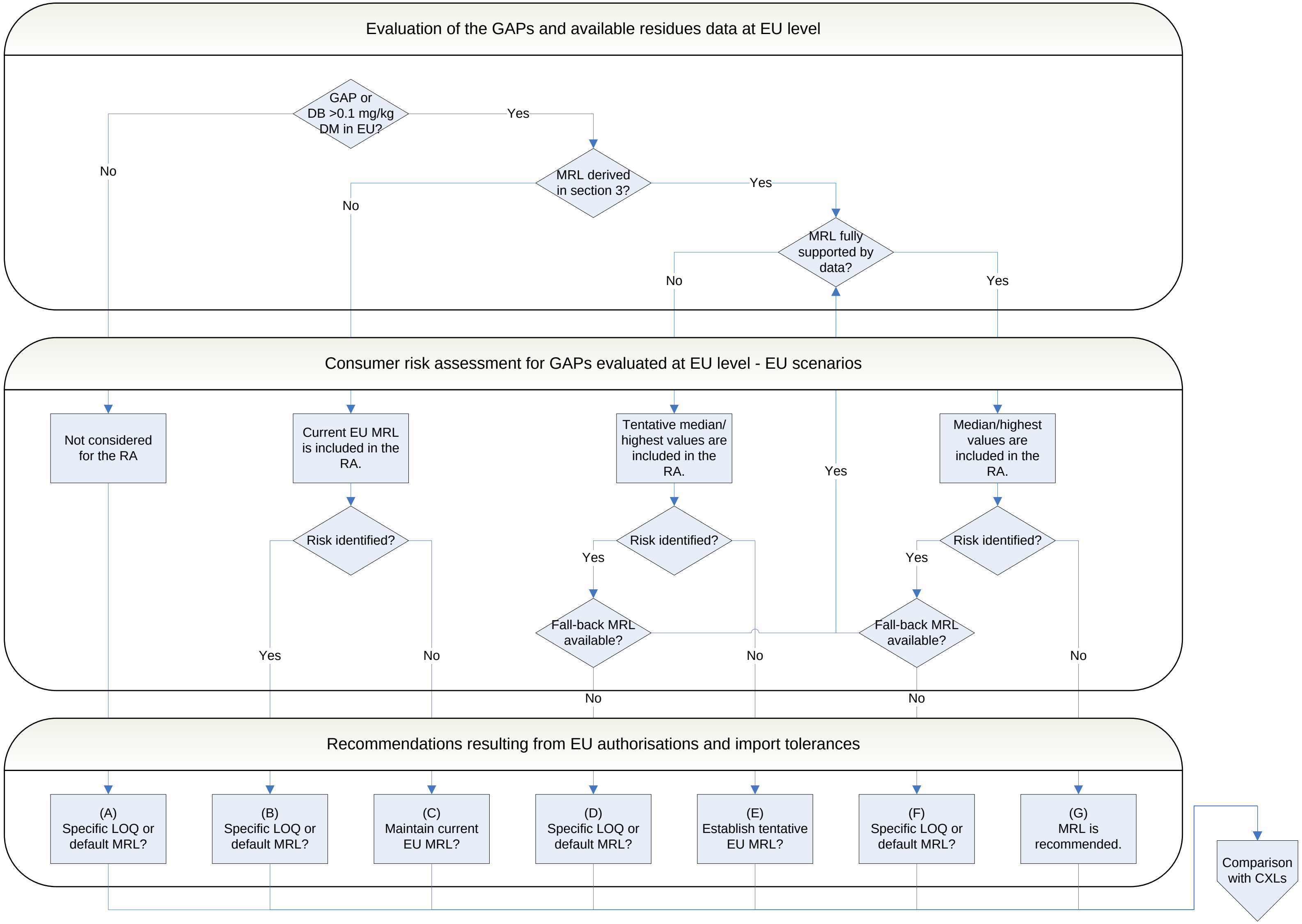
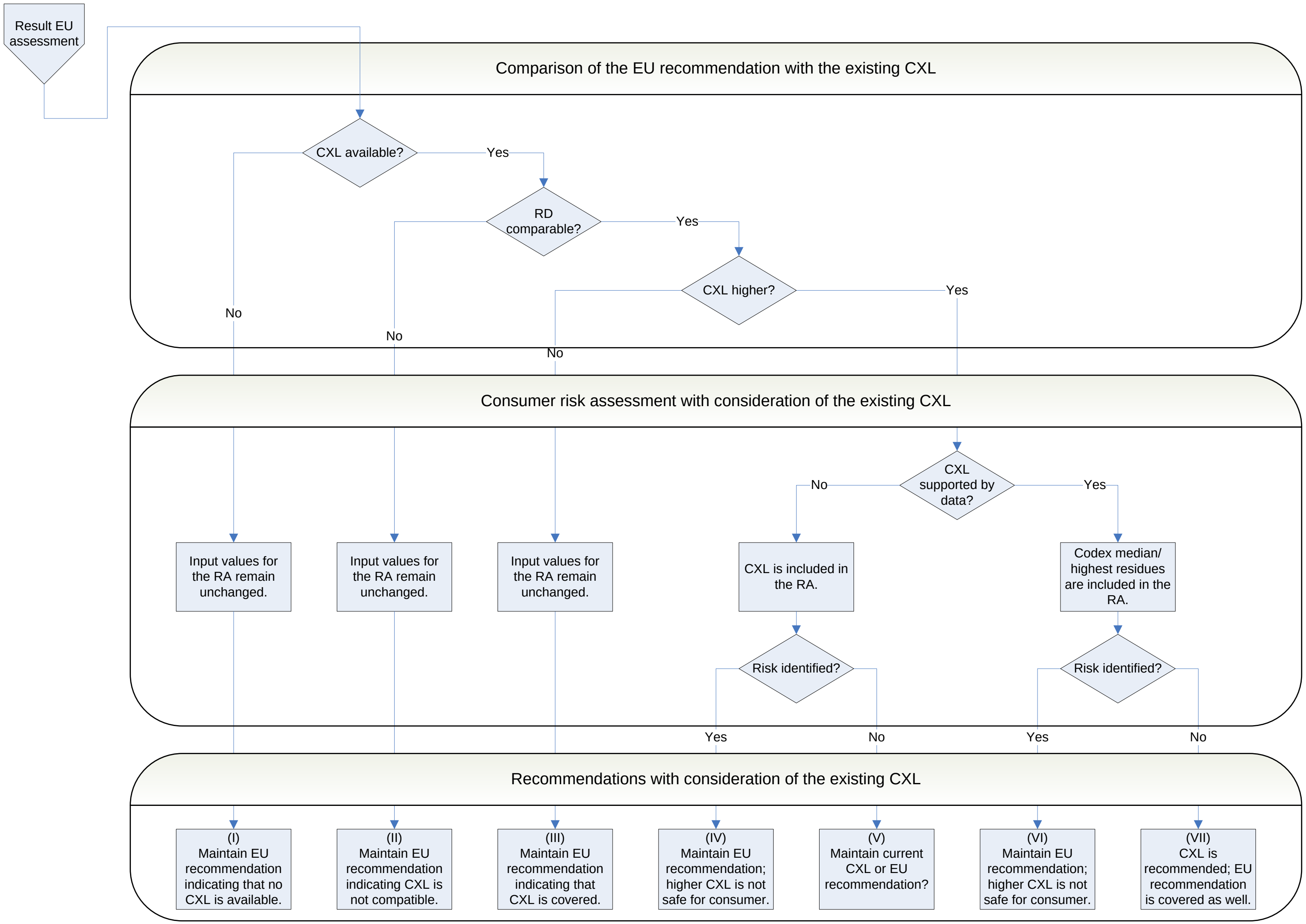
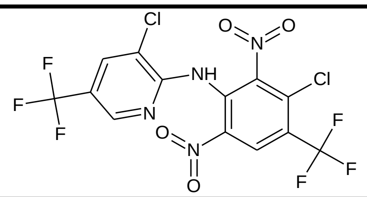
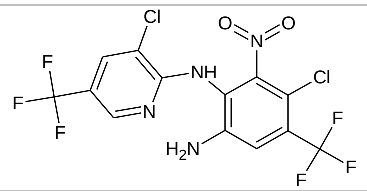
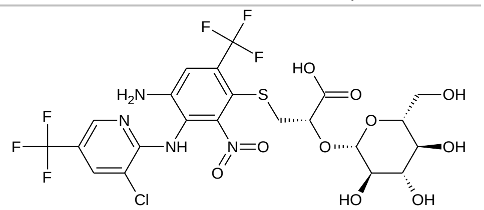
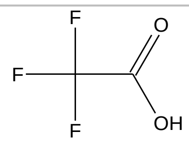
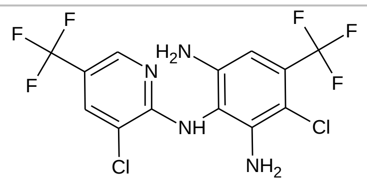
Appendix D – Decision tree for deriving MRL recommendations




Result EU assessment
Comparison of the EU recommendation with the existing CXL
CXL available?
Yes
No
RD comparable?
Yes
No
CXL higher?
Yes
No
Consumer risk assessment with consideration of the existing CXL
CXL supported by data?
No
Yes
Input values for the RA remain unchanged.
Input values for the RA remain unchanged.
Input values for the RA remain unchanged.
CXL is included in the RA.
Codex median/ highest residues are included in the RA.
Risk identified?
Risk identified?
Yes
No
Yes
No
Recommendations with consideration of the existing CXL
(I) Maintain EU recommendation indicating that no CXL is available.
(II) Maintain EU recommendation indicating CXL is not compatible.
(III) Maintain EU recommendation indicating that CXL is covered.
(IV) Maintain EU recommendation; higher CXL is not safe for consumer.
(V) Maintain current CXL or EU recommendation?
(VI) Maintain EU recommendation; higher CXL is not safe for consumer.
(VII) CXL is recommended; EU recommendation is covered as well.

Appendix E – Used compound code(s)

Code/trivial name	Chemical name/SMILES notation[(a)]	Structural formula[(a)]
Fluazinam	3-chloro-*N*-(3-chloro-5-trifluoromethyl-2-pyridyl)-α,α,α-trifluoro-2,6-dinitro-*p*-toluidine O=N(=O)c2cc(c(Cl)c(c2Nc1ncc(cc1Cl)C(F)(F)F)N(=O)=O)C(F)(F)F	
AMPA-fluazinam	4-chloro-N^2-[3-chloro-5-(trifluoromethyl)-2-pyridinyl]-3-nitro-5-(trifluoromethyl)-1,2-benzenediamine FC(F)(F)c2cc(N)c(Nc1ncc(cc1Cl)C(F)(F)F)c(N(=O)=O)c2Cl	
AMGT	(2*S*)-3-{[4-amino-3-{[3-chloro-5-(trifluoromethyl)-2-pyridinyl]amino}-2-nitro-6-(trifluoromethyl)phenyl]thio}-2-(β-D-glucopyranosyloxy)propanoic acid FC(F)(F)c1cc(Cl)c(nc1)Nc3c(N)cc(c(SC[C@@H](O[C@@H]2O[C@H](CO)[C@@H](O)[C@H](O)[C@H]2O)C(=O)O)c3N(=O)=O)C(F)(F)F	
Trifluoroacetic acid	trifluoroacetic acid FC(F)(F)C(=O)O	
DAPA	4-chloro-N^2-[3-chloro-5-(trifluoromethyl)-2-pyridinyl]-5-(trifluoromethyl)-1,2,3-benzenetriamine FC(F)(F)c2cc(N)c(Nc1ncc(cc1Cl)C(F)(F)F)c(N)c2Cl	

(a): (ACD/ChemSketch, Advanced Chemistry Development, Inc., ACD/Labs Release: 12.00 Product version: 12.00 (Build 29305, 25 Nov 2008).