REASONED OPINION

Reasoned opinion on the setting of a new MRL for fluazinam in tomatoes[1]

European Food Safety Authority[2]

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ABSTRACT

In accordance with Article 6 of Regulation (EC) No 396/2005, Italy, hereafter referred to as the evaluating Member State (EMS), received an application from Cheminova A/S to set a maximum residue level (MRL) for the active substance fluazinam in tomatoes. In order to accommodate for the intended use of fluazinam, Italy proposed to raise the existing MRL from the limit of quantification (LOQ) of 0.05 mg/kg to 0.3 mg/kg. Italy drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005 which was submitted to the European Commission and forwarded to EFSA. According to EFSA the data are sufficient to derive a MRL proposal of 0.3 mg/kg for the intended use on tomatoes. Adequate analytical enforcement methods are available to control the residues of fluazinam on the commodity under consideration. Based on the risk assessment results, EFSA concludes that the proposed use of fluazinam on tomatoes will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a consumer health risk.

KEY WORDS

fluazinam, tomatoes, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, aminopyridine fungicide

[1] On request from the European Commission, Question No EFSA-Q-2014-00786, approved on 15 June 2015.

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Suggested citation: EFSA (European Food Safety Authority), 2015. Reasoned opinion on the setting of a new MRL for fluazinam in tomatoes. EFSA Journal 2015;13(6):4154, 23 pp. doi:10.2903/j.efsa.2015.4154

Available online: www.efsa.europa.eu/efsajournal

SUMMARY

In accordance with Article 6 of Regulation (EC) No 396/2005, Italy, hereafter referred to as the evaluating Member State (EMS), received an application from Cheminova A/S to set a maximum residue level (MRL) for the active substance fluazinam in tomatoes. In order to accommodate for the intended use of fluazinam, Italy proposed to raise the existing MRL from the limit of quantification (LOQ) of 0.05 mg/kg to 0.3 mg/kg. Italy drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005 which was submitted to the European Commission and forwarded to EFSA on 31 October 2014.

EFSA bases its assessment on the revised evaluation report, the Draft Assessment Report (DAR) and its addendum prepared under Council Directive 91/414/EEC, the revised Commission Review Report on fluazinam, the conclusion on the peer review of the pesticide risk assessment of the active substance fluazinam and previous EFSA reasoned opinions on fluazinam.

The toxicological profile of fluazinam was assessed in the framework of the peer review under Council Directive 91/414/EEC and the data were sufficient to derive an acceptable daily intake (ADI) of 0.01 mg/kg bw per day and an acute reference dose (ARfD) of 0.07 mg/kg bw.

The metabolism of fluazinam in primary crops was investigated in root (potatoes), pulses/oilseeds (peanuts) and fruit (grapes and apples) crop groups. Considering the representative use limited to potato only, the residue definition for monitoring was set as fluazinam in the conclusion of the peer review and restricted to potato. Afterwards, EFSA concluded to apply the same residue definition for enforcement to apples (fruit crops). Pending further toxicological information with regard to the metabolite trifluoroacetic acid (TFA), the residue definition for risk assessment was provisionally defined as the sum of fluazinam, AMPA-fluazinam and AMGT, expressed as fluazinam for all plant commodities. For the use on tomatoes, EFSA concludes that the residue definition for enforcement and risk assessments proposed in the peer review are applicable. However, the residue definition for risk assessment should be reconsidered in the framework of Article 12 of Regulation (EC) No 396/2005, expected to be finalised by end 2015.

EFSA concludes that the submitted supervised residue trials are sufficient to derive a MRL proposal of 0.3 mg/kg for the intended use on tomatoes. Adequate analytical enforcement methods are available to control the residues of fluazinam on the commodity under consideration at the validated LOQ of 0.01 mg/kg.

As residues of fluazinam on tomatoes were below the trigger value of 0.1 mg/kg (except one sample) and since the contribution of these residues to the chronic consumer exposure is 1.5 % of the ADI, investigation of the effect of industrial processing on the nature and magnitude of fluazinam residues are not required. Nevertheless, processing studies on tomato were submitted and indicative processing factor (PFs) were derived for juice, paste, puree and canned tomatoes based on the assumption that the same residue definition as for primary fruit crops applies to processed tomato products. Pending the Article 12 MRL review and the finalisation of residue definitions applicable to processed commodities, EFSA does not recommend the inclusion of these PFs in Annex VI of Regulation (EC) No 396/2005.

The potential incorporation of soil residues into succeeding and rotational crops was assessed during the peer review, which concluded that the metabolism is to a large extent comparable, but TFA occurred in significant amounts and parent compound was not detected. EFSA concludes that significant residues, exceeding 0.01 mg/kg, of fluazinam are not expected in rotational crops provided that the compound is used on tomatoes according to the intended GAP. Since the confined rotational crop study suggested the potential for significant exposure to TFA residues in rotation crops, the risk for consumer exposed to this metabolite should be addressed.

Residues of fluazinam in commodities of animal origin were not assessed in the framework of this application, since tomatoes or their by-products are normally not fed to livestock.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). For the calculation of chronic exposure, EFSA used the median residue (STMR) according to the provisional residue definition for risk assessment derived from the residue trials conducted on tomatoes. STMRs were available also for potatoes, apples, wine grapes and ginseng to refine the exposure calculations; these values were multiplied by the corresponding conversion factors (CFs) for risk assessment. The MRLs for the remaining commodities of plant and animal origin set at the LOQ of 0.05 mg/kg were included in the calculation without applying any CF.

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake accounted for 33 % of the ADI with residues in tomatoes contributing for a maximum of 1.5 % to the total consumer exposure. No acute consumer risk was identified in relation to the MRL proposal for tomatoes.

With regards to TFA, a preliminary comprehensive dietary exposure assessment, taking into account different sources of the metabolite, including fluazinam (TFA concentration in primary and rotational crops) has been conducted in a previous EFSA reasoned opinion. EFSA concluded that the overall estimated dietary exposure to TFA is unlikely to pose a public health concern. On the basis of existing information, the additional consumer exposure from the intended use on tomatoes is expected to be insignificant and the conclusions reached in the previous EFSA reasoned opinion are still valid. EFSA highlights that this risk assessment should be regarded as indicative. An updated dietary risk assessment related to TFA will be performed in the framework of Article 12 of Regulation (EC) No 396/2005, if necessary.

EFSA concludes that the proposed use of fluazinam on tomatoes will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a consumer health risk.

Thus, EFSA proposes to amend the existing MRL as reported in the summary table.

SUMMARY TABLE

Code[(a)]	**Commodity**	**Existing EU MRL** (mg/kg)	**Proposed EU MRL** (mg/kg)	**Comment/Justification**
Enforcement residue definition: Fluazinam (F)				
0231010	Tomatoes	0.05*	0.3	Supported by SEU trials.

(a): According to Annex I of Regulation (EC) No 396/2005.
(*): Indicates that the MRL is set at the limit of analytical quantification.
(F): Fat-soluble.

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BACKGROUND

Regulation (EC) No 396/2005[3] establishes the rules governing the setting of pesticide MRLs at European Union level. Article 6 of that 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[4], repealed by Regulation (EC) No 1107/2009[5], shall submit to a Member State, when appropriate, an application to set a MRL in accordance with the provisions of Article 7 of that Regulation.

Italy, hereafter referred to as the EMS, received an application from the company Cheminova A/S[6] to modify the existing MRL for the active substance fluazinam in tomatoes. This application was notified to the European Commission and EFSA and was subsequently evaluated by the EMS in accordance with Article 8 of the Regulation. After completion, the evaluation report was submitted to the European Commission who forwarded the application, the evaluation report and the supporting dossier to EFSA on 21 October 2014.

The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2014-00786 and the following subject:

Fluazinam - Application to set new MRLs in tomato.

Italy proposed to raise the existing MRL of fluazinam in tomatoes from the LOQ of 0.05 mg/kg to 0.3 mg/kg. On 5 December 2014 further data requirements were identified, which prevented EFSA to conclude on the consumer risk assessment. A revised evaluation report, addressing those data requirements, was submitted by the EMS on 19 February 2015 and taken into consideration by EFSA for the finalization of this reasoned opinion.

EFSA proceeded with the assessment of the application and the evaluation report as required by Article 10 of the Regulation.

TERMS OF REFERENCE

In accordance with Article 10 of Regulation (EC) No 396/2005, EFSA shall, based on the evaluation report provided by the evaluating Member State, provide a reasoned opinion on the risks to the consumer associated with the application.

In accordance with Article 11 of that Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within three months (which may be extended to six months where more detailed evaluations need to be carried out) from the date of receipt of the application. Where EFSA requests supplementary information, the time limit laid down shall be suspended until that information has been provided.

In this particular case the deadline for providing the reasoned opinion is 17 April 2015.

[3] Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.03.2005, p. 1–16.

[4] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.08.1991, p. 1–32.

[5] 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.

[6] Cheminova A/S, PO Box 9, 7620 Lemvig, Denmark.

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Fluazinam is the ISO common name for 3-chloro-*N*-(3-chloro-5-trifluoromethyl-2-pyridyl)-α,α,α-trifluoro-2,6-dinitro-*p*-toluidine (IUPAC). The chemical structure of the compound is reported below.

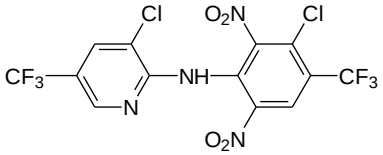

Figure 1: Structure of fluazinam. Molecular weight: 465.1 g/mol

Fluazinam is a fungicide belonging to the class of aminopyridines. It has a protective action exerted by uncoupling mitochondrial oxidative phosphorylation, inhibiting spore germination, hyphal penetration, growth and sporulation. Fluazinam is used to control grey mould, downy mildew and other fungal pathogens in several crops.

Fluazinam was evaluated in the framework of Council Directive 91/414/EEC with Austria designated as the rapporteur Member State (RMS). It was included in Annex I of this Directive by Commission Directive 2008/108/EC[7] which entered into force on 1 March 2009 for use as fungicide only. In accordance with Commission Implementing Regulation (EU) No 540/2011[8] fluazinam is approved under Regulation (EC) No 1107/2009, repealing Council Directive 91/414/EEC. The representative use evaluated in the peer review was ten foliar applications at 200 g/ha with a PHI of 7 days on potatoes. The Draft Assessment Report (DAR) of fluazinam has been peer reviewed by EFSA (EFSA, 2008).

The EU MRLs for fluazinam are established in Annex IIIA of Regulation (EC) No 396/2005. MRL proposal on apples and ginseng root were evaluated by EFSA (EFSA, 2012, 2014b) and new temporary MRLs were established through Commission Regulation (EU) No 251/2013[9] and Commission Regulation (EU) No 401/2015[10]. The existing EU MRL for fluazinam on tomatoes is set at the LOQ of 0.05 mg/kg. Codex Alimentarius has not established Codex maximum residue limits (CXLs) for fluazinam.

The details of the intended GAP for fluazinam on potatoes in southern Europe (SEU) are given in Appendix A.

ASSESSMENT

EFSA bases its assessment on the revised evaluation report submitted by the EMS (Italy, 2015), the Draft Assessment Report (DAR) and its addendum prepared under Council Directive 91/414/EEC (Austria, 2005, 2007), the revised Commission Review Report on fluazinam (European Commission, 2011b), the conclusion on the peer review of the pesticide risk assessment of the active substance fluazinam (EFSA, 2008) and previous EFSA reasoned opinions on fluazinam (EFSA, 2012, 2014b).

[7] 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. 6–13.

[8] 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, 11.06.2011, p. 1–186.

[9] Commission Regulation (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, 27.03.2013, p. 1–4.

[10] Commission Regulation (EU) No 401/2015 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, 14.03.2015, p. 114–156.

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[11] and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (European Commission, 1996, 1997a, 1997b, 1997c, 1997d, 1997e, 1997f, 1997g, 2000, 2010a, 2010b, 2011a; OECD, 2011).

1. Method of analysis

1.1. Methods for enforcement of residues in food of plant origin

Analytical methods for the determination of fluazinam residues in plant commodities were assessed during the peer review under Council Directive 91/414/EEC (Austria, 2005). Liquid chromatography coupled with tandem mass spectrometry detection (LC-MS/MS) methods are available to monitor residues of fluazinam in high water (potato) and high acid (grape) content commodities with an LOQ validated at 0.01 mg/kg (EFSA, 2008). An independent laboratory validation (ILV) was provided in the framework of a previous MRL application (EFSA, 2012).

Since the commodity under consideration belongs to the group of high water content commodities, EFSA concludes that sufficiently validated analytical methods for enforcing the proposed MRL for fluazinam are available.

1.2. Methods for enforcement of residues in food of animal origin

Analytical methods for the determination of residues in food of animal origin are not assessed in the current application, since tomatoes are normally not fed to livestock.

2. Mammalian toxicology

The toxicological profile of the active substance fluazinam was assessed in the framework of the peer review under Council Directive 91/414/EEC (European Commission, 2011b; EFSA, 2008). The data were sufficient to derive toxicological reference values for fluazinam which are compiled in Table 2-1.

Table 2-1: Overview of the toxicological reference values

	Source	Year	Value	Study	Safety factor
Fluazinam					
ADI	European	2011	0.01 mg/kg bw per day	2-yr mouse, supported by 1-yr dog	100
ARfD	Commission	2011	0.07 mg/kg bw	Rabbit, developmental	100

The toxicity of the structurally related metabolites AMPA-fluazinam and AMGT, which were observed in metabolism studies and included in the residue definition for risk assessment, was considered as covered by the toxicological studies conducted with the parent compound. TFA was observed in significant amounts in rotational crops and also in primary crop metabolism studies, but not in the rat metabolism and a data gap was identified as regards its toxicological properties (EFSA, 2008). On the basis of toxicological studies that were made available after the conclusions of the peer review of fluazinam, EFSA derive a tentative ADI of 0.05 mg/kg bw per day and a tentative ARfD of 0.05 mg/kg bw for TFA (EFSA, 2014a). Hence, the ADI of the parent compound (0.01 mg/kg bw per day) adequately covers the chronic toxicity of TFA, but the metabolite showed to be slightly more acutely toxic.

[11] 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.

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

The metabolism of fluazinam in root (potatoes), pulses/oilseeds (peanuts) and fruit (grapes and apples) crop groups was evaluated by the RMS Austria (Austria, 2005) and reviewed by EFSA (EFSA, 2008) in the framework of the peer review under Council Directive 91/414/EEC. Detailed information about the metabolism pathway is reported in the EFSA conclusions (EFSA, 2008). The overview of the metabolism study designs is presented in the table below.

Table 3-1: Summary of available metabolism studies in plants

Crop group	Crops	Application[(a)]	Sampling[(b)]	Comments
Fruit	Apple	Foliar, 6× 930 g/ha, 9 to 30 d interval (Ph & Py)	32 DALA	4.5 times the intended rate on tomato, longer PHI
	Grape	Foliar, 2× 750 g/ha, at BBCH 68 and 79, 35 d interval (Ph & Py)	71 DALA	1.25 the intended total maximum rate on tomato, longer PHI
Root	Potato	Foliar, 4× 505 g/ha (Ph) or 4× 430 g/ha (Py); 9 to 14 d interval	6 or 7 DALA	Applications 72, 86, 97 and 106 d after planting.
Pulses/Oilseeds	Peanut	Foliar, 4× 560 g/ha, 17 to 23 d interval (Ph & Py)	55 or 66 DALA	

(a): ^{14}C-Phenyl (Ph) and 2,6-^{14}C-Pyridyl (Py) labelled fluazinam.
(b): DALA, days after last application.

Considering the representative use limited to potato only, the residue definition for monitoring was set as fluazinam in the conclusion of the peer review and restricted to potatoes. Since fluazinam was found to be by far the major constituent of the residues in the metabolism studies conducted on the fruit crop group (11 to 21 % TRR in grape and 37 to 45 % TRR in apple) after foliar applications even at PHIs up to 71 days, EFSA concluded to apply the same residue definition for enforcement proposed by the peer review for apples (fruit crop group) in the framework of a previous MRL application (EFSA, 2012). The proposed residue definition for enforcement corresponds to the current residue definition set in Regulation (EC) No 396/2005.

Regarding the residue definition for the risk assessment, the peer review defined the residue for all plant commodities as the sum of fluazinam, AMPA-fluazinam and AMGT, expressed as fluazinam. In addition, the metabolite TFA was identified in primary crops (peanut foliage, potatoes and apples) but also in rotational crops. Pending the submission of further toxicological information on TFA, the residue definition for risk assessment was considered as provisional (EFSA, 2008).

For the use of fluazinam on tomatoes, EFSA concludes the residue definition for enforcement and risk assessments proposed in the peer review are applicable. However, the residue definition for risk assessment is provisional and should be reconsidered in the framework of Article 12 of Regulation (EC) No 396/2005.

3.1.1.2. Magnitude of residues

A MRL of 0.3 mg/kg is proposed from a total of eight GAP-compliant trials conducted on tomatoes in SEU over two growing seasons.

Samples from the residue trials were also analysed for AMPA-fluazinam and AMGT. The two metabolites were never found above the LOQ of 0.01 mg/kg in any sample. To express the residues

according to the provisional residue definition for risk assessment (i.e. as fluazinam equivalents), the LOQ values were summed to fluazinam as such, without adjustment for molecular weight (MW).

The results of the residue trials, the related risk assessment input values (HR, STMR) and the MRL proposal are summarised in Table 3-2.

The storage stability of fluazinam parent compound was investigated during the peer review (Austria, 2005; EFSA, 2008). Residues of fluazinam were found to be stable at ≤ -15 °C for up to 26 months in high water content matrices (potato). In the framework of the MRL application, a new storage stability study on tomato fruits was submitted (Italy, 2015). Fluazinam and AMGT residues showed to be stable for up to 26 months when stored frozen at about -20ºC. In contrast, recoveries of AMPA-fluazinam residues declined to nearly 36 % in samples stored for 26 months and AMPA-fluazinam was therefore concluded to be stable for up to 18 months only in high water content matrices (tomatoes).

Half of the submitted residue trial samples on tomatoes were stored frozen for a period not exceeding 13 months, thus for a period for which integrity of the samples was fully demonstrated. The samples from the four trials conducted in 2010 were stored for a longer period of 24 to 26 months, exceeding the storage stability demonstrated for the metabolite AMPA-fluazinam. EFSA agrees with the argumentations of the EMS (Italy, 2015) that the results for AMPA-fluazinam (<LOQ) from these four residue trials on tomatoes should be considered as valid because the no-residue situation was confirmed in the samples of raw tomatoes from the processing study conducted at an exaggerate dose rate (5N, see Section 3.1.1.3), which were stored for 14 to 15 months.

According to the EMS, the LC-MS/MS analytical method used to analyse the supervised residue trial samples has been sufficiently validated for fluazinam and its metabolites and was proven to be fit for the purpose (Italy, 2015).

EFSA concludes that the data are sufficient to derive a MRL proposal of 0.3 mg/kg for the intended field use on tomatoes in SEU.

Table 3-2: Overview of the available residues trials data

Crop (Trial GAP)	**Region/ Indoor** (a)	**Individual trial results** (mg/kg) (b)	**Recommendations/comments** (c)	**MRL** proposals (mg/kg)	**HR** (mg/kg) (d)	**STMR** (mg/kg) (e)
Enforcement residue definition: Fluazinam **Risk assessment residue definition**: Fluazinam, AMPA-fluazinam and AMGT, expressed as fluazinam (provisional)						
Tomatoes (6× 192-218 g/ha; PHI 6-8 d)	SEU	Mo: <0.01; 2× 0.01; 2× 0.03; <u>0.04</u>; 0.06; 0.16 RA: <0.03; 2× 0.03; 2 × 0.05; <u>0.06</u>; 0.08; 0.18	Residues of both AMPA-fluazinam & AMGT: 8× <0.01 mg/kg; <u>Underlined</u>: highest value measured at a longer PHI (14 days). MRL_{OECD}: 0.24/0.3	0.3	(0.16) 0.18	(0.03) 0.05

(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Indoor for indoor EU trials or Country code if non-EU trials.
(b): Individual residue levels considered for MRL calculation are reported in ascending order.
Mo: residue level according to the monitoring residue definition.
RA: residue level according to the residue definition for risk assessment. Since residues of the two metabolites were <LOQ, the values were not adjusted for MW prior to summing up.
(c): Any information/comment supporting the decision and OECD MRL calculation (e.g. MRL_{OECD} unrounded/rounded value in mg/kg).
(d) STMR: Median value of the individual trial results according to residue definition for risk assessment.
$STMR_{Mo}$: Median value of the individual trial results according to residue definition for monitoring is reported within brackets.
(e): HR: Highest value of the individual trial results according to the residue definition for risk assessment.
HR_{Mo}: Highest value of the individual trial results according to residue definition for monitoring is reported within brackets.

Since the residue definition for enforcement and risk assessment differ, CFs for risk assessment were also calculated from the results of the residue trials and are reported in the following table.

Table 3-3: Median CFs calculated at the different PHIs

PHI[(a)] (days)	0-	0+	4/3	6/8	10/11	13/14	**Comments**
Tomato	2.0	1.3	1.3	1.7	3.0	1.5	Underlined: CF at the intended PHI. CF not calculated, when fluazinam residues <LOQ.

(a): 0-/0+ for samples collected the day before/after the last application.

These CF values should be considered as overestimates since derived from default AMPA-fluazinam and AMGT residue levels below the LOQ of 0.01 mg/kg. Therefore and considering that in the metabolism studies on apples and grapes AMPA-fluazinam was not found and AMGT was in low levels (1 to 4 % TRR) compared to parent compound (11 to 45 % TRR), EFSA would not recommend the setting of a CF for the intended use on tomatoes.

3.1.1.3. Effect of industrial processing and/or household preparation

The effect of processing on the nature of fluazinam and its metabolites has not been investigated in a standard hydrolysis study and no new study has been submitted with this MRL application. Although not required, further investigation on the effect of processing on the nature of fluazinam residues would be desirable. However, information was available from the metabolism study on grapes where samples were processed in order to investigate the metabolic profile in wine. Fluazinam was not present in wine and residues were mostly composed of the AMGT and AMPA-fluazinam metabolites (Austria, 2005). The residue definition to be applicable to processed commodities is not finalised and will be considered under the Article 12 MRL review expected to be issued by end of this year.

As residues of fluazinam in tomatoes were below 0.1 mg/kg, except one value, and since the contribution of these residues to the chronic consumer exposure is low, the investigation of the effect of industrial processing on the nature and magnitude of fluazinam residues in not requested in the framework of this MRL application.

Nevertheless, the results of four processing studies on tomatoes were submitted in the framework of this MRL application (Italy, 2015). Samples were taken from two field trials conducted with two applications at five times the intended application rate (5N). Tomato fruits were harvested 7 to 8 day after last application, washed and processed to juice, paste, puree and canned tomatoes. No details on the processing procedures were provided. Samples were analysed for fluazinam, AMPA-fluazinam and AMGT. In raw tomatoes, fluazinam ranged from 0.20 to 0.52 mg/kg and both metabolites were not found (<0.01 mg/kg). In processed products, AMGT was never quantified (<0.01 mg/kg), whereas AMPA-fluazinam was detected in two juice (0.05 and 0.06 mg/kg) and four paste (up to 0.32 mg/kg) and puree (up to 0.35 mg/kg) samples. Indicative PFs and CFs for risk assessment were calculated assuming that the residue definition for enforcement and risk assessment of primary fruit crops apply to processed products. AMPA-fluazinam residues above the LOQ were converted to fluazinam equivalents using a factor 1.07[12]. The indicative factors are reported in Table 3-4.

[12] Based on the MW ratio (fluazinam/AMPA 465.1/435.1).

Table 3-4: Overview of the available processing studies

Processed commodity	Number of studies	Indicative median PF[(a)]	Indicative median CF[(b)]	Comments/individual indicative PFs
Values derived assuming the residue definition for enforcement and risk assessment of primary crops apply to processed products. All values should be regarded as indicative only.				
Tomato/washed	4	0.10	Not proposed	0.07; 2× 0.10; 0.15
Tomato/juice	4	0.34	1.6	2× 0.10; 0.57; 0.65
Tomato/paste	4	0.05	18.5	0.02; 0.04; 0.07; 0.10
Tomato/puree	4	0.09	19.6	0.02; 0.04; 0.14; 0.20
Tomato/canned	4	0.16	Not proposed	0.10; 0.15; 0.18; 0.37

(a): Median PF obtained by calculating the median of the individual PFs of each processing study.
(b): Median CF for enforcement to risk assessment obtained by calculating the median of the individual CFs of each processing study. Since residues of the metabolites were <LOQ, individual CFs were not calculated for washed and canned tomatoes.

Considering that the residue definitions for processed commodities have not been finalised, EFSA does not recommend the inclusion of the derived PFs in Annex VI of Regulation (EC) No 396/2005.

3.1.2. Rotational crops

Tomatoes can be grown in rotation with other plants and therefore the possible occurrence of residues in succeeding crops resulting from the use on primary crops has to be assessed.

3.1.2.1. Nature and magnitude of residues

The nature of fluazinam residues in rotational crops was assessed in the DAR and in the conclusion on the peer review of the active substance (Austria, 2005; EFSA, 2008). Fluazinam was applied to bare soil twice, 28 days apart, at an application rate of 1120 g/ha, for a total rate of 2240 g/ha (2N the total intended application rate on tomatoes). Barley, carrots and lettuce were planted/sown after plant-back intervals of 30, 120, and 365 days. Parent fluazinam was extensively metabolised and could not be detected in any extract from any rotational crop sample. TFA was identified as the major residue in the aqueous fraction of the phenyl-labelled study, amounting to a maximum of 0.27 mg eq/kg in lettuce, 0.18 mg eq/kg in barley grain and 0.06 mg eq/kg in carrot roots (Austria, 2005). It was considered to accumulate in plants via root uptake of water (EFSA, 2014a).

The peer review concluded that the metabolism in rotational crops was to a large extent comparable to the primary crop metabolism, but TFA occurred in significant amounts and parent compound was not detected (EFSA, 2008). EFSA concludes that significant residues (≥0.01 mg/kg) of parent fluazinam are not expected in rotational crops provided that the compound is used on tomatoes according to the intended GAP. Since the confined rotational crop study suggested the potential for significant exposure to TFA residues in rotation crops, the risk for consumer exposed to this metabolite should be addressed. A preliminary comprehensive dietary exposure assessment of TFA has been conducted in a previous EFSA reasoned opinion (EFSA, 2014a).

3.2. Nature and magnitude of residues in livestock

Since tomatoes or their by-products are not normally fed to livestock, the nature and magnitude of fluazinam residues in livestock is not assessed in the framework of this MRL application (European Commission, 1996).

4. Consumer risk assessment

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). This exposure assessment model contains the relevant European food consumption data for different sub-groups of the EU population[13] (EFSA, 2007).

For the calculation of chronic exposure, EFSA used the STMR according to the provisional residue definition for risk assessment derived from the residue trials conducted on tomatoes (see Table 3-2). STMRs were available also for potatoes, apples, wine grapes and ginseng to refine the exposure calculations; these values were multiplied by the corresponding CFs for risk assessment previously used by EFSA (EFSA, 2008, 2012, 2014b). The MRLs for the remaining commodities of plant and animal origin are set at the LOQ of 0.05 mg/kg and were used as input values without applying any CF. It was therefore assumed that the fluazinam metabolites provisionally included in the risk assessment residue definition are not present. A more realistic long-term consumer risk assessment will be performed in the framework of the on-going Article 12 MRL review, when full information on authorised uses of fluazinam and additional residue data will be available to EFSA.

The acute exposure assessment was performed only with regard to the commodity under consideration assuming the consumption of a large portion of the food items as reported in the national food surveys and that these items contained residues at the HR (see Table 3-2) as observed in supervised field trials. A variability factor accounting for the inhomogeneous distribution on the individual item consumed was included in the calculation (EFSA, 2007).

The input values used for the dietary exposure calculation are summarised in Table 4-1.

Table 4-1: Input values for the consumer dietary exposure assessment

Commodity	Chronic exposure assessment		Acute exposure assessment	
	Input (mg/kg)	**Comment**[(a)]	**Input** (mg/kg)	**Comment**
Risk assessment residue definition: Fluazinam, AMPA-fluazinam and AMGT, expressed as fluazinam (provisional)				
Tomatoes	0.05	STMR (Table 3-2)	0.18	HR (Table 3-2)
Apples	0.05	STMR× CF (1.68) (EFSA, 2012)	Acute risk assessment was undertaken only with regard to the crop under consideration	
Wine grapes	0.35	STMR× CF (1.19) (EFSA, 2012)		
Potatoes	0.03	STMR× CF (3) (EFSA, 2008)		
Ginseng	2.43	STMR× CF (3) (EFSA, 2014b)		
Other plant and animal commodities	0.05*	MRLs in Commission Regulation (EU) No 401/2015.		

(a): CFs previously used to express the residue levels according to the residue definition for risk assessment are reported in brackets.

The estimated exposure was then compared with the toxicological reference values derived for fluazinam (see Table 2-1). The results of the intake calculation are presented in Appendix B to this reasoned opinion.

[13] The calculation of the long-term exposure (chronic exposure) is based on the mean consumption data representative for 22 national diets collected from MS surveys plus 1 regional and 4 cluster diets from the WHO GEMS Food database; for the acute exposure assessment the most critical large portion consumption data from 19 national diets collected from MS surveys is used. The complete list of diets incorporated in EFSA PRIMo is given in its reference section (EFSA, 2007).

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake accounted for 33 % of the ADI (British infant). The contribution of residues in tomatoes to the total consumer exposure accounted for a maximum of 1.5 % of the ADI (WHO Cluster B). No acute consumer risk was identified in relation to the MRL proposal for tomatoes, the calculated maximum exposure being 15 % of the ARfD of fluazinam.

With regards to TFA, it is noted that this metabolite can be generated from a wide range of pesticides and other chemicals. A preliminary comprehensive dietary exposure assessment of TFA, taking into account different sources of the metabolite, including fluazinam (TFA concentration in primary and rotational crops), has been conducted in a previous EFSA reasoned opinion. EFSA concluded that the estimated overall dietary exposure to TFA is unlikely to pose a public health concern (EFSA, 2014a).

TFA concentrations in tomatoes resulting from the intended use of fluazinam are not available. In the metabolism study on apples TFA represented 1.23 % of the TRR (Austria, 2005). Based on the results of the metabolism study, the additional consumer exposure from the intended use on tomatoes is expected to be insignificant (indicative STMR 0.0001 mg/kg and HR 0.0005 mg/kg[14]). On the basis of existing information, the conclusions reached in the previous EFSA reasoned opinion are still valid. An updated dietary risk assessment related to TFA, taking into account the existing fluazinam authorised uses will be performed in the framework of Article 12 of Regulation (EC) No 396/2005, if necessary.

EFSA concludes that the intended use of fluazinam on tomatoes will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a public health concern.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The toxicological profile of fluazinam was assessed in the framework of the peer review under Council Directive 91/414/EEC and the data were sufficient to derive an acceptable daily intake (ADI) of 0.01 mg/kg bw per day and an acute reference dose (ARfD) of 0.07 mg/kg bw.

The metabolism of fluazinam in primary crops was investigated in root (potatoes), pulses/oilseeds (peanuts) and fruit (grapes and apples) crop groups. Considering the representative use limited to potato only, the residue definition for monitoring was set as fluazinam in the conclusion of the peer review and restricted to potato. Afterwards, EFSA concluded to apply the same residue definition for enforcement to apples (fruit crops). Pending further toxicological information with regard to the metabolite trifluoroacetic acid (TFA), the residue definition for risk assessment was provisionally defined as the sum of fluazinam, AMPA-fluazinam and AMGT, expressed as fluazinam for all plant commodities. For the use on tomatoes, EFSA concludes that the residue definition for enforcement and risk assessments proposed in the peer review are applicable. However, the residue definition for risk assessment should be reconsidered in the framework of Article 12 of Regulation (EC) No 396/2005, expected to be finalised by end 2015.

EFSA concludes that the submitted supervised residue trials are sufficient to derive a MRL proposal of 0.3 mg/kg for the intended use on tomatoes. Adequate analytical enforcement methods are available to control the residues of fluazinam on the commodity under consideration at the validated LOQ of 0.01 mg/kg.

As residues of fluazinam on tomatoes were below the trigger value of 0.1 mg/kg (except one sample) and since the contribution of these residues to the chronic consumer exposure is 1.5 % of the ADI, investigation of the effect of industrial processing on the nature and magnitude of fluazinam residues are not required. Nevertheless, processing studies on tomato were submitted and indicative processing factor (PFs) were derived for juice, paste, puree and canned tomatoes based on the assumption that the

[14] The 1.23 % of fluazinam STMR/HR (see Table 3-2), expressed as TFA using a CF of 0.25 based on the MW ratio (TFA: fluazinam / 114.02: 465.1).

same residue definition as for primary fruit crops applies to processed tomato products. Pending the Article 12 MRL review and the finalisation of residue definitions applicable to processed commodities, EFSA does not recommend the inclusion of these PFs in Annex VI of Regulation (EC) No 396/2005.

The potential incorporation of soil residues into succeeding and rotational crops was assessed during the peer review, which concluded that the metabolism is to a large extent comparable, but TFA occurred in significant amounts and parent compound was not detected. EFSA concludes that significant residues, exceeding 0.01 mg/kg, of fluazinam are not expected in rotational crops provided that the compound is used on tomatoes according to the intended GAP. Since the confined rotational crop study suggested the potential for significant exposure to TFA residues in rotation crops, the risk for consumer exposed to this metabolite should be addressed.

Residues of fluazinam in commodities of animal origin were not assessed in the framework of this application, since tomatoes or their by-products are normally not fed to livestock.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). For the calculation of chronic exposure, EFSA used the median residue (STMR) according to the provisional residue definition for risk assessment derived from the residue trials conducted on tomatoes. STMRs were available also for potatoes, apples, wine grapes and ginseng to refine the exposure calculations; these values were multiplied by the corresponding conversion factors (CFs) for risk assessment. The MRLs for the remaining commodities of plant and animal origin set at the LOQ of 0.05 mg/kg were included in the calculation without applying any CF.

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake accounted for 33 % of the ADI with residues in tomatoes contributing for a maximum of 1.5 % to the total consumer exposure. No acute consumer risk was identified in relation to the MRL proposal for tomatoes.

With regards to TFA, a preliminary comprehensive dietary exposure assessment, taking into account different sources of the metabolite, including fluazinam (TFA concentration in primary and rotational crops) has been conducted in a previous EFSA reasoned opinion. EFSA concluded that the overall estimated dietary exposure to TFA is unlikely to pose a public health concern. On the basis of existing information, the additional consumer exposure from the intended use on tomatoes is expected to be insignificant and the conclusions reached in the previous EFSA reasoned opinion are still valid. EFSA highlights that this risk assessment should be regarded as indicative. An updated dietary risk assessment related to TFA will be performed in the framework of Article 12 of Regulation (EC) No 396/2005, if necessary.

EFSA concludes that the proposed use of fluazinam on tomatoes will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a consumer health risk.

RECOMMENDATIONS

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/Justification
Enforcement residue definition: Fluazinam (F)				
0231010	Tomatoes	0.05*	0.3	Supported by SEU trials.

(a): According to Annex I of Regulation (EC) No 396/2005.
(*): Indicates that the MRL is set at the limit of analytical quantification.
(F): Fat-soluble.

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APPENDICES

Appendix A. Good Agricultural Practice (GAPs)

Crop and/or situation (a)	Member State or Country	F G or I (b)	Pest or group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
				type (d-f)	conc. a.s. (i)	Method kind (f-h)	Growth stage & season (j)	number min-max (k)	interval min-max	g a.s./hL min-max	Water L/ha min-max	g a.s./ha min-max		
Tomatoes	SEU	F	*Phytophthora*, *Alternaria*, *Botrytis*	SC	500 g/L	Foliar	BBCH >10	1-6	7-10 d	25	800	200	7	

Remarks:

(a) For crops, EU or other classifications, e.g. Codex, should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Technical Monograph No 2, 4th Ed., 1999 or other codes, e.g. OECD/CIPAC, should be used
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at last treatment (Growth stages of mono-and dicotyledonous plants. BBCH Monograph, 2nd Ed., 2001), including where relevant, information on season at time of application
(k) The minimum and maximum number of application possible under practical conditions of use must be provided
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions (i.e. feeding, grazing)

Appendix B. Pesticide Residue Intake Model (PRIMO)

Fluazinam			
Status of the active substance:	**approved**	Code no.	
LOQ (mg/kg bw):	0.05	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0.01**	ARfD (mg/kg bw):	**0.07**
Source of ADI:	**EC**	Source of ARfD:	**EC**
Year of evaluation:	**2011**	Year of evaluation:	**2011**

Chronic risk assessment - refined calculations

TMDI (range) in % of ADI minimum - maximum	
4	33
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)
33.3	UK Infant	19.4	Milk and cream,	5.0	Sugar beet (root)	1.3	Wheat	32.5
32.7	FR toddler	19.8	Milk and cream,	1.5	Potatoes	1.3	Apples	31.4
32.2	NL child	14.7	Milk and cream,	3.2	Apples	2.4	Wheat	29.0
30.8	UK Toddler	11.4	Sugar beet (root)	10.3	Milk and cream,	2.0	Wheat	29.8
27.7	WHO Cluster diet B	6.2	Wine grapes	4.3	Wheat	1.6	Milk and cream,	21.0
26.2	DE child	7.1	Milk and cream,	6.1	Apples	2.1	Wheat	20.1
22.1	IE adult	4.3	Wine grapes	1.8	Sweet potatoes	1.4	Milk and cream,	17.3
21.4	FR infant	12.9	Milk and cream,	1.3	Carrots	1.3	Apples	20.2
20.8	FR all population	13.8	Wine grapes	1.6	Wheat	1.3	Milk and cream,	6.7
19.8	DK child	6.3	Milk and cream,	2.8	Wheat	2.2	Rye	18.6
18.5	WHO cluster diet E	5.5	Wine grapes	2.0	Wheat	1.5	Milk and cream,	12.5
17.3	ES child	6.3	Milk and cream,	2.2	Wheat	1.1	Oranges	16.7
16.6	PT General population	8.6	Wine grapes	2.0	Wheat	1.6	Potatoes	7.5
15.4	SE general population 90th percentile	6.2	Milk and cream,	1.6	Wheat	1.3	Potatoes	14.9
14.3	WHO cluster diet D	3.3	Wheat	2.5	Milk and cream,	1.2	Wine grapes	12.7
13.7	WHO Cluster diet F	2.1	Wine grapes	2.0	Milk and cream,	1.8	Wheat	11.3
13.3	WHO regional European diet	2.4	Milk and cream,	1.5	Wheat	1.2	Potatoes	12.1
12.6	NL general	3.3	Milk and cream,	2.2	Wine grapes	1.0	Wheat	9.8
12.4	DK adult	4.8	Wine grapes	2.7	Milk and cream,	1.0	Wheat	7.2
11.0	UK Adult	3.7	Wine grapes	2.0	Sugar beet (root)	1.5	Milk and cream,	7.1
11.0	ES adult	2.5	Milk and cream,	1.4	Wine grapes	1.2	Wheat	9.2
11.0	UK vegetarian	2.8	Wine grapes	1.9	Sugar beet (root)	1.6	Milk and cream,	7.9
8.0	IT kids/toddler	3.3	Wheat	0.8	Other cereal	0.7	Tomatoes	7.6
7.8	FI adult	2.8	Milk and cream,	1.1	Wine grapes	0.5	Wheat	6.5
7.5	LT adult	2.0	Milk and cream,	1.0	Potatoes	0.9	Apples	6.5
5.9	IT adult	2.1	Wheat	0.6	Tomatoes	0.4	Apples	5.5
4.2	PL general population	1.0	Potatoes	1.0	Apples	0.4	Tomatoes	3.1

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Fluazinam 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)
	15.0	Tomatoes	0.18 / -	10.8	Tomatoes	0.18 / -	3.9	Tomatoes	0.18 / -	3.2	Tomatoes	0.18 / -
	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)			

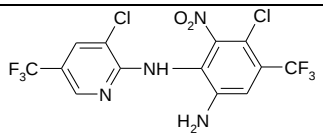
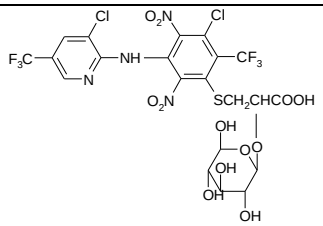
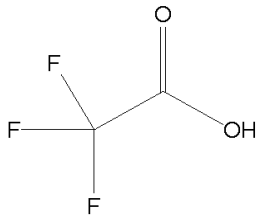
*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.
**) pTMRL: provisional temporary MRL
***) pTMRL: provisional temporary MRL for unprocessed commodity

Conclusion:

For Fluazinam 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 C. List of metabolites and related structural formula

Code/Trivial name	Chemical name	Structural formula
AMPA-fluazinam	2-(6-amino-3-chloro-α,α,α-trifluoro-2-nitro-*p*-toluidino)-3-chloro-5-(trifluoromethyl) pyridine MW: 435.12 g/mol	
AMGT	3-[[4-amino-3-[[3-chloro-5-(trifluoromethyl)-2-pyridyl]amino]-α,α,α-trifluoro-6-nitro-*o*-tolyl] thio]-2-(*β*-*D*-glucopyranosyloxy) propionic acid MW: 682.1 g/mol	
TFA (or TFAA)	Trifluoroacetic acid MW: 114.02 g/mol	

ABBREVIATIONS

ADI	acceptable daily intake
ARfD	acute reference dose
a.s.	active substance
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CF	conversion factor for enforcement to risk assessment residue definition
CIPAC	Collaborative International Pesticide Analytical Council
CXL	Codex Maximum Residue Limit (Codex MRL)
d	day
DALA	days after last application
DAR	Draft Assessment Report
EMS	evaluating Member State
eq	residue expressed as a.s. equivalent
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
GAP	good agricultural practice
GCPF	Global Crop Protection Federation (former GIFAP)
HPLC	high performance liquid chromatography
HR	highest residue
i.e.	that is (id est, Latin)
ILV	independent laboratory validation
ISO	International Organization for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
LOQ	limit of quantification
MRL	maximum residue level
MS/MS	tandem mass spectrometry
MW	molecular weight
OECD	Organisation for Economic Co-operation and Development
PF	processing factor
PHI	pre-harvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
RAC	raw agricultural commodity
RMS	rapporteur Member State
SANCO	Directorate-General for Health and Consumers
SC	suspension concentrate
SEU	southern Europe

STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
WHO	World Health Organization
yr	year