REASONED OPINION

Reasoned opinion on the modification of the existing MRL for fluazinam in apples[1]

European Food Safety Authority[2]

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ABSTRACT

In accordance with Article 6 of Regulation (EC) No 396/2005, France, herewith referred to as the evaluating Member State (EMS), received an application from ISK Biosciences Europe N.V. to modify the existing MRL for the active substance fluazinam in apples. In order to accommodate for the intended use of fluazinam in SEU (Italy), France proposed to raise the existing MRL from the limit of quantification (LOQ) of 0.05 mg/kg to 0.3 mg/kg. The EMS drafted an evaluation report according to Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to EFSA.

The submitted data are sufficient to derive a MRL proposal of 0.3 mg/kg for the proposed use of fluazinam on apples in the SEU (Italy). An adequate analytical enforcement method is available to control fluazinam residues in apples at the LOQ of 0.01 mg/kg.

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

KEY WORDS

Fluazinam, apples, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, pyridine fungicide, AMPA, DAPA, AMGT.

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SUMMARY

In accordance with Article 6 of Regulation (EC) No 396/2005, France, herewith referred to as the evaluating Member State (EMS), received an application from ISK Biosciences Europe N.V. to modify the existing MRL for the active substance fluazinam in apples. In order to accommodate for the intended use of fluazinam in SEU (Italy), France proposed to raise the existing MRL from the limit of quantification (LOQ) of 0.05 mg/kg to 0.3 mg/kg. The EMS drafted an evaluation report according to Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to EFSA on 29 February 2012.

EFSA bases its assessment on the evaluation report submitted by the EMS (France, 2011), the Draft Assessment Report (DAR) prepared under Council Directive 91/414/EEC (Austria, 2005) and the conclusion on the peer review of the pesticide risk assessment of the active substance fluazinam (EFSA, 2008).

The toxicological profile of fluazinam was assessed in the framework of the peer review under Directive 91/414/EEC and the data were sufficient to derive an ADI of 0.01 mg/kg bw per day and an ARfD of 0.07 mg/kg bw.

The metabolism of fluazinam in primary crops was investigated in tuber vegetables, oilseeds and fruits. Based on the metabolic pattern in potato tubers the peer review proposed to define parent fluazinam as the relevant residue for enforcement. This definition was restricted to potatoes as the representative use for the peer review. In apples the main residue after foliar application is parent fluazinam and therefore EFSA concludes that the enforcement residue definition as proposed by the peer review is also applicable for apples and no additional metabolism studies are required. The current residue definition in Regulation (EC) No 396/2005 is set as fluazinam.

Regarding the risk assessment residue definition, the peer review noted a concern related to the formation of trifluoroacetic acid (TFAA) in primary crops (peanuts) and rotational crops. However, the available studies were not sufficient to conclude on the toxicological properties of the TFAA. The peer review therefore concluded to set a provisional risk assessment residue definition for all plant commodities as “fluazinam, AMPA-fluazinam, AMGT, expressed as fluazinam”. Low concentration of TFAA was observed in apple juice and pomace extract, but in raw apples TFAA was not identified. Considering that the application rate in metabolism studies is significantly higher than the application rate in the intended use under consideration, EFSA concludes that TFAA will be of no concern in apples treated according to the intended use. Therefore for apples the provisional risk assessment residue definition as agreed by the peer review is applicable. EFSA notes that clear provisions have to be agreed between EU Member States, European Commission and EFSA on how to address the toxicity of the TFAA and how to assess the consumer exposure to this compound not only from the use of fluazinam but any other pesticides containing the trifluoromethyl moiety.

EFSA considers that the submitted supervised residue trials data are sufficient to derive a MRL proposal of 0.3 mg/kg for the proposed use of fluazinam on apples in the SEU (Italy). An adequate analytical enforcement method is available to control fluazinam residues in apples at the LOQ of 0.01 mg/kg.

The effect of processing on the nature of fluazinam has not been investigated in a standard hydrolysis study and adequate studies would therefore be desirable. Specific studies to assess the magnitude of fluazinam residues during the processing of apples are not available and are not currently required.

Since the proposed use of fluazinam is on permanent crops, investigations of residues in rotational crops are not required.

Since the apple pomace can be fed to livestock, a potential carry-over of fluazinam residues into food of animal origin has to be assessed. The calculated dietary burdens indicate that the trigger value of 0.1 mg/kg dry matter (DM) is exceeded for meat ruminants and pigs and is mainly driven by the

existing use on potatoes. However, taking into account that in the supervised field trials the residues in potatoes were below the LOQ, the peer review concluded that in practice the intake of fluazinam residues by livestock is likely to be insignificant and a carry-over of fluazinam residues to food of animal origin is not expected. As the contribution of residues in apple pomace to the total livestock dietary burden is low, EFSA did not investigate further the nature and magnitude of fluazinam residues in livestock.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticides Residues Intake Model (PRIMo). For the calculation of the chronic exposure, EFSA used the median residue value multiplied by the conversion factor of 1.68 for risk assessment as derived from the residue trials on apples. The risk assessment values were also available for potatoes and wine grapes to refine the exposure calculation. For the remaining commodities of plant and animal origin, the existing MRLs are set at the LOQ of 0.05 mg/kg and it was assumed that no uses on these crops exist, and fluazinam metabolites, as included in the risk assessment residue definition, are not present. The existing MRLs were thus used as input values without applying a conversion factor. The acute exposure assessment was performed only with regard to apples, assuming the consumption of a large portion of the food item as reported in the national food surveys containing residues at the highest level as observed in supervised field trials. The estimated exposure was then compared with the toxicological reference values derived for fluazinam.

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake values accounted for up to 33.3% of the ADI (UK infant diet). The contribution of residues in apples to the total consumer exposure accounted for a maximum of 6.1 % of the ADI.

No acute consumer risk was identified in relation to the intended use on apples. The calculated maximum exposure in percentage of the ARfD was 35.3% for apples.

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

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

Summary table

Code number[(a)]	**Commodity**	**Existing EU MRL (mg/kg)**	**Proposed EU MRL (mg/kg)**	**Justification for the proposal**
Enforcement residue definition: Fluazinam (F)				
0130010	Apples	0.05*	0.3	The MRL proposal is sufficiently supported by data and no risk for consumers was identified for the intended SEU use.

(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 pesticide. MRL is expressed as mg/kg of fat contained in the whole product

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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 or to modify an MRL in accordance with the provisions of Article 7 of that Regulation.

France, hereafter referred to as the evaluating Member State (EMS), received an application from the company ISK Biosciences Europe N.V.[6] to modify the existing MRL for the active substance fluazinam in apples. This application was notified to the European Commission and EFSA and 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 29 November 2011.

The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2011-01260 and the following subject:

Fluazinam - Application to modify the existing MRL in apples.

France proposed to raise the existing MRL of fluazinam in apples from the limit of quantification (LOQ) of 0.05 mg/kg to 0.3 mg/kg.

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.

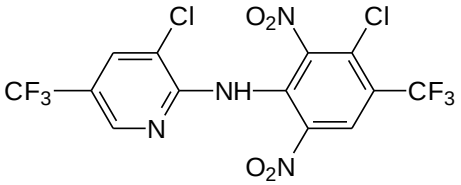
In accordance with Article 11 of that Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within three months (which may be extended to six months where more detailed evaluations need to be carried out) from the date of receipt of the application. Where EFSA requests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

In this particular case the calculated deadline for providing the reasoned opinion is 29 February 2012.

[3] Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005. OJ L 70, 16.03.2005, p. 1-16.
[4] Council Directive 91/414/EEC of 15 July 1991. 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. OJ L 309, 24.11.2009, p. 1-50.
[6] ISK Biosciences Europe N.V., Pegasus Park, De Kleetlaan, 12B, box 9, 1831, Diegem, Belgium

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

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



Molecular weight: 465.1 g/mol

Fluazinam is a pyridine fungicide. It has a protective action with activity 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. Fluazinam is fat soluble (log P_{ow} is 4.03).

Fluazinam was evaluated in the framework of Council Directive 91/414/EEC with Austria designated as a rapporteur Member State (RMS). Fluazinam is approved under Regulation (EC) No 1107/2009 by means of Commission Directive 2008/108/EC[7] for use as a fungicide only. The representative use evaluated in the peer review was foliar application on potatoes against *Phytophthora infestans*. The Draft Assessment Report (DAR) of fluazinam has been peer reviewed by EFSA and an EFSA conclusion is available (EFSA, 2008).

The EU MRLs for fluazinam are established in Annex IIIA of Regulation (EC) No 396/2005 (Appendix C). The existing EU MRL for fluazinam in apples is set at the LOQ of 0.05 mg/kg. No CXLs are established for fluazinam.

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

[7] Commission Directive 2008/108/EC of 26 November 2008, OJ L 317, 27.11.2008, p. 6-13

ASSESSMENT

EFSA bases its assessment on the evaluation report submitted by the EMS (France, 2011), the Draft Assessment Report (DAR) prepared under Council Directive 91/414/EEC (Austria, 2005) and the conclusion on the peer review of the pesticide risk assessment of the active substance fluazinam (EFSA, 2008). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011[8] and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (EC, 1996, 1997a, 1997b, 1997c, 1997d, 1997e, 1997f, 1997g, 2000, 2010a, 2010b, 2011; 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 Directive 91/414/EEC (Austria, 2005; EFSA, 2008). An HPLC-MS/MS method was proposed for the enforcement purposes. The method was validated for the determination of fluazinam residues in high water (potatoes) and high acid (grapes) content matrices at the LOQ of 0.01 mg/kg (EFSA, 2008). A requirement for an ILV was identified by the peer review. According to the EMS France, an ILV has been submitted and confirms the applicability of this method to determine fluazinam residues in the above mentioned matrices at the LOQ of 0.01 mg/kg (France, 2011).

EFSA concludes that a sufficiently validated analytical method is available to control fluazinam residues in apples at the validated LOQ of 0.01 mg/kg.

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

Analytical methods for the determination of fluazinam residues in food of animal origin have not been assessed by the peer review since due to the low livestock exposure to fluazinam residues no residue definition was proposed and consequently no analytical method was required.

2. Mammalian toxicology

The toxicological profile of the active substance fluazinam was assessed in the framework of the peer review under Directive 91/414/EEC (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 relied upon	Safety factor
Fluazinam					
ADI	EFSA	2008	0.01 mg/kg bw per day	2-yr mouse, supported by 1-yr dog	100
ARfD	EFSA	2008	0.07 mg/kg bw	Rabbit, developmental	100

[8] Commission Regulation (EU) No 546/2011 of 10 June 2011. 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 vegetables, pulses and oilseeds, and fruits and fruiting vegetables was evaluated by the RMS Austria (Austria, 2005) and reviewed by EFSA (EFSA, 2008) in the framework of the peer review under Directive 91/414/EEC. The overview of the metabolism study designs is presented in the table below.

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

Group	Crop	Label position	Application details				
			Method, F or G[(a)]	Rate	No/ Interval	Sampling	Remarks
Fruits and fruiting vegetable	Grapes	Phenyl and pyridyl	F/F	0.75	2 (1st application at 80% petal fall; 2nd application 35 days later (at bunch closure))	71 DAT	
	Apples	Phenyl and pyridyl	F/F	0.93	6/ 9, 22, 34, 34 and 30	32 DALA	
Root and tuber vegetables	Potatoes	Phenyl	F/F	0.505	4	6 and 7 DALA	
		Pyridyl	F/F	0.43	4	7 DALA	
Pulses and oilseeds	Peanuts	Phenyl	F/F, P	0.56	4 /19, 17, 18 days	55 DAT	
		Pyridyl	F/ F, P	0.56	4 /21, 22, 23 days	66 DAT	
		Phenyl and pyridyl	F/ F, P	0.56	4 /25, 30, 25 days	66 DAT	

(a): Outdoor/field use (F) or glasshouse/protected crops/indoor application (G)

No major difference in fluazinam metabolism was observed amongst the investigated 3 crop groups. First steps of the metabolic pathway of fluazinam in plants involve reduction of one or both nitro groups to form AMPA-fluazinam[9] or DAPA[10], loss of the phenyl ring chlorine by glutathione conjugation to form AMGT[11] and substitution of one nitro group by a hydroxyl group. Further metabolism proceeds through cleavage of the compound, followed by opening and fragmentation of the resulting pyridyl and nitrophenyl moieties. TFAA[12] was identified as a result of this fragmentation process, present together with other ultimate unidentified degradation products entering the carbon pool of the plant (EFSA, 2008).

The metabolic pattern in the edible part of the investigated commodities varies widely. Parent compound was found to be by far the major constituent of the residue in raw fruits (11-21% TRR in grapes and 37-45 % TRR in apples) after foliar application even for PHIs up to 71 days. It was also identified in potato tubers at low amounts together with similar amounts of structurally related

[9] See Appendix D
[10] See Appendix D
[11] See Appendix D
[12] See Appendix D

compounds (AMPA-fluazinam, AMGT), while in peanut nutmeat only trifluoroacetic acid (TFAA) derivatives were present. The metabolism study in grapes investigated the transfer of residues to wine. In wine the parent compound was not found and AMGT appeared to be a major metabolite (7-12% TRR), although present in low amounts (0.05-0.08 mg/kg) (EFSA, 2008). The processing of washed apples to juice was studied as well and the radioactivity was characterised in the apple surface wash, apple juice and pomace extract. The processing results in a significant reduction of residues (see further details in section 3.1.1.3).

Based on the metabolic pattern in potato tubers the peer review proposed to define parent fluazinam as the relevant residue for enforcement. This definition was restricted to potatoes as a representative use for the peer review. In apples the main residue after foliar application was parent fluazinam and therefore EFSA concludes that the enforcement residue definition as proposed by the peer review is also applicable for apples and no additional metabolism studies are required. The current residue definition set in Regulation (EC) No 396/2005 is identical to the enforcement residue definition derived by the peer review.

Regarding the residue definition for the risk assessment, the peer review noted a concern related to the formation of trifluoroacetic acid (TFAA) in primary crops (peanuts) and rotational crops. The formation of TFAA in the rat metabolism was not observed. TFAA might be of a potentially higher acute oral toxicity than fluazinam, and with possible teratogenic effects. This metabolite is not specific of fluazinam and can be produced through metabolic or degradation processes from a wide range of pesticides containing a C-CF_3 moiety (fluazinam, bifenthrin, saflufenacil etc.). The peer review concluded that available toxicological information is not sufficient to conclude on the toxicological properties of the TFAA and that further studies are required. Depending on the outcome of the toxicological assessment of the TFAA, it should be either added to the proposed risk assessment residue definition or considered as a separate specific entity (EFSA, 2008). The peer review therefore concluded to set a provisional risk assessment residue definition for all plant commodities as "fluazinam, AMPA-fluazinam, AMGT, expressed as fluazinam". Low concentration of TFAA was observed in apple juice and pomace extract, but in raw apples TFAA was not identified. Considering that the application rate in metabolism studies is significantly higher than the application rate in the intended use under consideration, EFSA concludes that TFAA will be of no concern in apples treated according to the intended use. Therefore for apples the provisional risk assessment residue definition as agreed by the peer review is applicable.

EFSA notes that clear provisions have to be agreed between EU Member States, European Commission and EFSA on how to address the toxicity of the TFAA and how to assess the consumer exposure to this compound not only from the use of fluazinam but any other pesticides containing trifluoromethyl moiety.

3.1.1.2. Magnitude of residues

In support of the MRL application the applicant submitted 8 GAP compliant residue trials on apples which have been performed in Italy in 2008 and 2010. The samples were analysed for parent fluazinam, AMPA-fluazinam and AMGT. The individual analytical LOQ for each of these substances was 0.01 mg/kg. To express the residues for the risk assessment, the following molecular weight conversion factors[13] were applied: 1.07 to convert AMPA-fluazinam to fluazinam and 0.68 to convert AMGT to fluazinam.

The results of the residue trials, the related risk assessment input values (highest residue, median residue, conversion factor) and the MRL proposal are summarized in Table 3-2.

The storage stability of fluazinam in primary crops is investigated and residues of fluazinam were found to be stable at ≤ -15°C for up to 26 months in matrices with high water content (potatoes)

[13] CF from AMPA fluazinam to fluazinam is 1.07 [MW fluazinam 465.1 g/mol/MW AMPA fluazinam 435.12 g/mol];
CF from AMGT to fluazinam is 0.68 [MW fluazinam 465.1 g/mol /MW AMGT 682.1]

(EFSA, 2008). The storage stability of relevant fluazinam metabolites AMPA-fluazinam and AMGT has not been investigated and such studies are recommended. The supervised residue trial samples were stored under conditions for which integrity of the samples was demonstrated (maximum of 6 months deep frozen) and therefore it is concluded that the residue data are valid with regard to storage stability of fluazinam. As fluazinam is stable for up to 26 months and since its metabolites are structurally similar, it can be assumed that no degradation occurs when apple samples are stored for a much shorter period of 6 months under deep frozen conditions.

According to the EMS, the analytical methods used to analyse supervised residue trial samples have been sufficiently validated and were proven to be fit for purpose (France, 2011).

EFSA concludes that the submitted residue data are sufficient to derive a MRL proposal of 0.3 mg/kg for the intended use of fluazinam on apples in Italy (SEU).

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

Commodity	Residue region (a)	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) (b)	Highest residue (mg/kg) (c)	MRL proposal (mg/kg)	Median CF (d)	Comments (e)
			Enforcement (Fluazinam)	**Risk assessment** (Fluazinam, AMPA-fluazinam and AMGT, expressed as fluazinam)					
Apples	SEU	Outdoor	<0.01; 0.02; <0.01; <0.01; 0.09; 0.04; 0.05[f]; 0.15[f]	0.03; 0.04; 0.03[f]; 0.03; 0.11; 0.06; 0.07[f]; 0.17[f]	0.03	0.15	0.3	1.68	R_{ber}= 0.16 R_{max}= 0.21 MRL_{OECD} = 0.25/0.3

(a): NEU (Northern and Central Europe), SEU (Southern Europe and Mediterranean), EU (*i.e.* outdoor use) or Import (country code) (EC, 2011).
(b): Median value of the individual trial results according to the enforcement residue definition.
(c): Highest value of the individual trial results according to the enforcement residue definition.
(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residues trial.
(e): Statistical estimation of MRLs according to the EU methodology (R_{ber}, R_{max}; EC, 1997g) and unrounded/rounded values according to the OECD methodology (OECD, 2011).
(f): Residues higher within a trial at a longer PHI of 70 days.

3.1.1.3. Effect of industrial processing and/or household preparation

The effect of processing on the nature of fluazinam has not been investigated in a standard hydrolysis studies. No new studies have been submitted in the framework of the current application.

In the framework of investigating the metabolism of fluazinam in primary plants, the nature of residues was studied also in processed apple commodities such as apple juice and pomace. The processing results in a significant reduction of residues. Parent fluazinam was mainly found in apple surface wash (35-42% TRR) with very low levels in pomace extract (2-3% TRR; 0.04-0.08 mg/kg) and apple juice (0.06% TRR; 0.001 mg/kg). In apple juice metabolite AMGT accounted for a maximum of 0.014 mg/kg (0.52%) and TFAA for 0.02 mg/kg (1.07%). In apple pomace AMGT accounted for 0.19-0.38% (0.004-0.01 mg/kg) and TFAA for a maximum of 0.16% (0.003 mg/kg). No details of the processing conditions are reported. The study is considered for supplementary information only and does not address the nature of fluazinam under standard processing conditions. Adequate studies investigating the effects of processing on the nature of fluazinam residues would therefore be desirable.

Specific studies to assess the magnitude of fluazinam residues during the processing of apples are not available and are currently not required.

3.1.2. Rotational crops

3.1.2.1. Preliminary considerations

Since the proposed use of fluazinam is on a permanent crop, investigations of residues in rotational crops are not required.

3.2. Nature and magnitude of residues in livestock

Apple pomace can be fed to livestock and therefore the nature and magnitude of fluazinam residues in livestock has to be further assessed in the framework of this application.

3.2.1. Dietary burden of livestock

The median and maximum dietary burdens for livestock were calculated using the agreed European methodology (EC, 1996). The input values for the dietary burden calculation were selected according to the latest FAO recommendations (FAO, 2009) considering the livestock intake from apples and potatoes, the only relevant feed crops for which the existing or intended authorisations are reported to EFSA. The existing EU MRL for fluazinam in potatoes is set at the LOQ of 0.05 mg/kg and supports an authorized use in the EU.

As a concentration of fluazinam residues was not observed in apple pomace (see section 3.1.1.3.), no processing factor was considered necessary for calculating the expected residue concentration in the feed item. To express the input values according to the risk assessment residue definition, a conversion factor of 3 as derived by the peer review was applied to the input value for potatoes (EFSA, 2008) and a conversion factor of 1.68 was applied to the input value for apples (Table 3-2). The input values for the dietary burden calculation are summarized in Table 3-3.

Table 3-3: Input values for the dietary burden calculation

Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	**Comment**	**Input value** (mg/kg)	**Comment**
Risk assessment residue definition: Fluazinam, AMPA-fluazinam and AMGT, expressed as fluazinam				

Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	**Comment**	**Input value** (mg/kg)	**Comment**
Apple pomace	0.05	Median residue (0.03)* CF (1.68)	0.05	Median residue (0.03)* CF (1.68)
Potatoes	0.03	Median residue (0.01) *CF (3) (EFSA, 2008)	0.03	Highest (0.01) *CF (3) (EFSA, 2008)

The results of the dietary burden calculation are summarized in the table below.

Table 3-4: Results of the dietary burden calculation

	Maximum dietary burden (mg/kg bw/d)	**Median dietary burden** (mg/kg bw/d)	**Highest contributing commodity**[(a)]	**Max dietary burden** (mg/kg DM)	**Trigger exceeded** (Y/N)
Risk assessment residue definition: Fluazinam, AMPA-fluazinam and AMGT, expressed as fluazinam					
Dairy ruminants	0.003	0.003	Potatoes	0.08	No
Meat ruminants	0.008	0.008	Potatoes	0.18	Yes
Poultry	0.003	0.003	Potatoes	0.04	No
Pigs	0.005	0.005	Potatoes	0.12	Yes

The calculated dietary burdens indicate that the trigger value of 0.1 mg/kg dry matter (DM) is slightly exceeded for meat ruminants and pigs and is mainly driven by the existing use on potatoes. However, taking into account that in the supervised field trials the residues in potatoes were below the LOQ, the peer review concluded that in practice the intake of fluazinam residues by livestock is likely to be insignificant and a carry-over of fluazinam residues to food of animal origin is not expected (EFSA, 2008).

As the contribution of residues in apples pomace to the total livestock dietary burden is low, EFSA did not investigate further the nature and magnitude of fluazinam residues in livestock.

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 [14] (EFSA, 2007).

For the calculation of the chronic exposure, EFSA used the median residue value multiplied by the conversion factor of 1.68 for risk assessment as derived from the residue trials on apples (see Table 3-2). The risk assessment values were available also for potatoes and wine grapes to refine the exposure calculations. For the remaining commodities of plant and animal origin, the existing MRLs as established in Annex IIIA of Regulation (EC) No 396/2005 are set the LOQ of 0.05 mg/kg. For those crops it was assumed that no uses exist and fluazinam metabolites, as included in the risk assessment residue definition, are not present. The existing MRLs were thus used as input values without applying a conversion factor.

[14] 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).

The model assumptions for the long-term exposure assessment are considered to be sufficiently conservative for a first tier exposure assessment, assuming that all food items consumed have been treated with the active substance under consideration. In reality, it is not likely that all food consumed will contain residues at the MRL or at levels of the median residue values identified in supervised field trials. However, if this first tier exposure assessment does not exceed the toxicological reference value for long-term exposure (*i.e.* the ADI), a consumer health risk can be excluded with a high probability.

The acute exposure assessment was performed only with regard to apples, assuming the consumption of a large portion of the food item as reported in the national food surveys containing residues at the highest level as observed in supervised field trials. A variability factor accounting for the inhomogeneous distribution on the individual items consumed was included in the calculation (EFSA, 2007).

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

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

Commodity	Chronic exposure assessment		Acute exposure assessment	
	Input value (mg/kg)	**Comment**	**Input value (mg/kg)**	**Comment**
Risk assessment residue definition: Fluazinam, AMPA-fluazinam and AMGT, expressed as fluazinam				
Apples	0.05	Median residue*CF (1.68) (Table 3-2)	0.25	Highest residue*CF (1.68) (Table 3-2)
Potatoes	0.03	Median residue*CF (3) (EFSA, 2008)	Acute risk assessment was undertaken only with regard to the crop under consideration.	
Wine grapes	0.35	Median residue (0.29)*CF (1.19) (France, 2011)		
Other commodities of food and animal origin	MRL	See Appendix C		

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.

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake values accounted for up to 33.3% of the ADI (UK infant diet). The contribution of residues in apples to the total consumer exposure accounted for a maximum of 6.1% of the ADI.

No acute consumer risk was identified in relation to the intended use on apples. The calculated maximum exposure in percentage of the ARfD was 35.3% for apples.

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

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The toxicological profile of fluazinam was assessed in the framework of the peer review under Directive 91/414/EEC and the data were sufficient to derive an ADI of 0.01 mg/kg bw per day and an ARfD of 0.07 mg/kg bw.

The metabolism of fluazinam in primary crops was investigated in tuber vegetables, oilseeds and fruits. Based on the metabolic pattern in potato tubers the peer review proposed to define parent fluazinam as the relevant residue for enforcement. This definition was restricted to potatoes as the representative use for the peer review. In apples the main residue after foliar application is parent fluazinam and therefore EFSA concludes that the enforcement residue definition as proposed by the peer review is also applicable for apples and no additional metabolism studies are required. The current residue definition in Regulation (EC) No 396/2005 is set as fluazinam.

Regarding the risk assessment residue definition, the peer review noted a concern related to the formation of trifluoroacetic acid (TFAA) in primary crops (peanuts) and rotational crops. However, the available studies were not sufficient to conclude on the toxicological properties of the TFAA. The peer review therefore concluded to set a provisional risk assessment residue definition for all plant commodities as "fluazinam, AMPA-fluazinam, AMGT, expressed as fluazinam". Low concentration of TFAA was observed in apple juice and pomace extract, but in raw apples TFAA was not identified. Considering that the application rate in metabolism studies is significantly higher than the application rate in the intended use under consideration, EFSA concludes that TFAA will be of no concern in apples treated according to the intended use. Therefore for apples the provisional risk assessment residue definition as agreed by the peer review is applicable. EFSA notes that clear provisions have to be agreed between EU Member States, European Commission and EFSA on how to address the toxicity of the TFAA and how to assess the consumer exposure to this compound not only from the use of fluazinam but any other pesticides containing the trifluoromethyl moiety.

EFSA considers that the submitted supervised residue trials data are sufficient to derive a MRL proposal of 0.3 mg/kg for the proposed use of fluazinam on apples in the SEU (Italy). An adequate analytical enforcement method is available to control fluazinam residues in apples at the LOQ of 0.01 mg/kg.

The effect of processing on the nature of fluazinam has not been investigated in a standard hydrolysis study and adequate studies would therefore be desirable. Specific studies to assess the magnitude of fluazinam residues during the processing of apples are not available and are not currently required.

Since the proposed use of fluazinam is on permanent crops, investigations of residues in rotational crops are not required.

Since the apple pomace can be fed to livestock, a potential carry-over of fluazinam residues into food of animal origin has to be assessed. The calculated dietary burdens indicate that the trigger value of 0.1 mg/kg dry matter (DM) is exceeded for meat ruminants and pigs and is mainly driven by the existing use on potatoes. However, taking into account that in the supervised field trials the residues in potatoes were below the LOQ, the peer review concluded that in practice the intake of fluazinam residues by livestock is likely to be insignificant and a carry-over of fluazinam residues to food of animal origin is not expected. As the contribution of residues in apple pomace to the total livestock dietary burden is low, EFSA did not investigate further the nature and magnitude of fluazinam residues in livestock.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticides Residues Intake Model (PRIMo). For the calculation of the chronic exposure, EFSA used the median residue value multiplied by the conversion factor of 1.68 for risk assessment as derived from the residue trials on apples. The risk assessment values were also available for potatoes and wine grapes to refine the exposure calculation. For the remaining commodities of plant and animal origin, the existing MRLs are set at the LOQ of 0.05 mg/kg and it was assumed that no uses on these crops exist, and fluazinam

metabolites, as included in the risk assessment residue definition, are not present. The existing MRLs were thus used as input values without applying a conversion factor. The acute exposure assessment was performed only with regard to apples, assuming the consumption of a large portion of the food item as reported in the national food surveys containing residues at the highest level as observed in supervised field trials. The estimated exposure was then compared with the toxicological reference values derived for fluazinam.

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake values accounted for up to 33.3% of the ADI (UK infant diet). The contribution of residues in apples to the total consumer exposure accounted for a maximum of 6.1 % of the ADI.

No acute consumer risk was identified in relation to the intended use on apples. The calculated maximum exposure in percentage of the ARfD was 35.3% for apples.

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

RECOMMENDATIONS

Code number[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: Fluazinam (F)				
0130010	Apples	0.05*	0.3	The MRL proposal is sufficiently supported by data and no risk for consumers was identified for the intended SEU use.

(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 pesticide. MRL is expressed as mg/kg of fat contained in the whole product

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APPENDICES

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. of a.s. (i)	method kind (f - h)	growth stage & season (j)	number min max (k)	interval min max	kg as/hL min max	water L/ha min max	kg a.s./ha min max		
Apple	SEU (ITALY)	F	*Venturia inaequalis* *Alternaria alternata*	SC	500 g/L	Broadcast air-assisted sprayer	First application from leaf development (BBCH 60) or when warning system`s forecast indicates significant disease attack up to nut size stage (BBCH 73)	1-3	7-10	0.03-0.075	1000-1500	0.5-0.75	60	

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)

B. PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

Fluazinam			
Status of the active substance:	Included	Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	0.01	ARfD (mg/kg bw):	0.07
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2008	Year of evaluation:	2008

Prepare workbook for refined calculations

Undo refined calculations

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	
32.7	FR toddler	19.8	Milk and cream,	1.5	Potatoes	1.3	Apples	
32.2	NL child	14.7	Milk and cream,	3.2	Apples	2.4	Wheat	
30.8	UK Toddler	11.4	Sugar beet (root)	10.3	Milk and cream,	2.0	Wheat	
27.7	WHO Cluster diet B	6.2	Wine grapes	4.3	Wheat	1.6	Milk and cream,	
26.2	DE child	7.1	Milk and cream,	6.1	Apples	2.1	Wheat	
22.1	IE adult	4.3	Wine grapes	1.8	Sweet potatoes	1.4	Milk and cream,	
21.4	FR infant	12.9	Milk and cream,	1.3	Carrots	1.3	Apples	
20.8	FR all population	13.8	Wine grapes	1.6	Wheat	1.3	Milk and cream,	
19.8	DK child	6.3	Milk and cream,	2.8	Wheat	2.2	Rye	
18.5	WHO cluster diet E	5.5	Wine grapes	2.0	Wheat	1.5	Milk and cream,	
17.3	ES child	6.3	Milk and cream,	2.2	Wheat	1.1	Oranges	
16.6	PT General population	8.6	Wine grapes	2.0	Wheat	1.6	Potatoes	
15.4	SE general population 90th percentile	6.2	Milk and cream,	1.6	Wheat	1.3	Potatoes	
14.3	WHO cluster diet D	3.3	Wheat	2.5	Milk and cream,	1.2	Wine grapes	
13.7	WHO Cluster diet F	2.1	Wine grapes	2.0	Milk and cream,	1.8	Wheat	
13.3	WHO regional European diet	2.4	Milk and cream,	1.5	Wheat	1.2	Potatoes	
12.6	NL general	3.3	Milk and cream,	2.2	Wine grapes	1.0	Wheat	
12.4	DK adult	4.8	Wine grapes	2.7	Milk and cream,	1.0	Wheat	
11.0	UK Adult	3.7	Wine grapes	2.0	Sugar beet (root)	1.5	Milk and cream,	
11.0	ES adult	2.5	Milk and cream,	1.4	Wine grapes	1.2	Wheat	
11.0	UK vegetarian	2.8	Wine grapes	1.9	Sugar beet (root)	1.6	Milk and cream,	
8.0	IT kids/toddler	3.3	Wheat	0.8	Other cereal	0.7	Tomatoes	
7.8	FI adult	2.8	Milk and cream,	1.1	Wine grapes	0.5	Wheat	
7.5	LT adult	2.0	Milk and cream,	1.0	Potatoes	0.9	Apples	
5.9	IT adult	2.1	Wheat	0.6	Tomatoes	0.4	Apples	
4.2	PL general population	1.0	Potatoes	1.0	Apples	0.4	Tomatoes	

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)
	35.3	Apples	0.252 / -	26.0	Apples	0.252 / -	8.1	Apples	0.252 / -	6.7	Apples	0.252 / -
	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.											

C.

EXISTING EU MAXIMUM RESIDUE LEVELS (MRLS)

(Pesticides - Web Version - EU MRLs (File created on 01/05/2012 12:11))

Code number	Groups and examples of individual products to which the MRLs apply	Fluazinam (F)
100000	1. FRUIT FRESH OR FROZEN; NUTS	
110000	(i) Citrus fruit	0,05*
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids)	0,05*
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0,05*
110030	Lemons (Citron, lemon)	0,05*
110040	Limes	0,05*
110050	Mandarins (Clementine, tangerine and other hybrids)	0,05*
110990	Others	0,05*
120000	(ii) Tree nuts (shelled or unshelled)	0,05*
120010	Almonds	0,05*
120020	Brazil nuts	0,05*
120030	Cashew nuts	0,05*
120040	Chestnuts	0,05*
120050	Coconuts	0,05*
120060	Hazelnuts (Filbert)	0,05*
120070	Macadamia	0,05*
120080	Pecans	0,05*
120090	Pine nuts	0,05*
120100	Pistachios	0,05*
120110	Walnuts	0,05*
120990	Others	0,05*
130000	(iii) Pome fruit	0,05*
130010	Apples (Crab apple)	0,05*
130020	Pears (Oriental pear)	0,05*
130030	Quinces	0,05*
130040	Medlar	0,05*
130050	Loquat	0,05*
130990	Others	0,05*
140000	(iv) Stone fruit	0,05*
140010	Apricots	0,05*
140020	Cherries (sweet cherries, sour cherries)	0,05*
140030	Peaches (Nectarines and similar hybrids)	0,05*
140040	Plums (Damson, greengage, mirabelle)	0,05*
140990	Others	0,05*
150000	(v) Berries & small fruit	

Code number	Groups and examples of individual products to which the MRLs apply	Fluazinam (F)
151000	(a) Table and wine grapes	
151010	Table grapes	0,05*
151020	Wine grapes	3
152000	(b) Strawberries	0,05*
153000	(c) Cane fruit	0,05*
153010	Blackberries	0,05*
153020	Dewberries (Loganberries, Boysenberries, and cloudberries)	0,05*
153030	Raspberries (Wineberries)	0,05*
153990	Others	0,05*
154000	(d) Other small fruit & berries	0,05*
154010	Blueberries (Bilberries cowberries (red bilberries))	0,05*
154020	Cranberries	0,05*
154030	Currants (red, black and white)	0,05*
154040	Gooseberries (Including hybrids with other ribes species)	0,05*
154050	Rose hips	0,05*
154060	Mulberries (arbutus berry)	0,05*
154070	Azarole (mediteranean medlar)	0,05*
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea sallowthorn), hawthorn, service berries, and other treeberries)	0,05*
154990	Others	0,05*
160000	(vi) Miscellaneous fruit	0,05*
161000	(a) Edible peel	0,05*
161010	Dates	0,05*
161020	Figs	0,05*
161030	Table olives	0,05*
161040	Kumquats (Marumi kumquats, nagami kumquats)	0,05*
161050	Carambola (Bilimbi)	0,05*
161060	Persimmon	0,05*
161070	Jambolan (java plum) (Java apple (water apple), pomerac, rose apple, Brazilean cherry (grumichama), Surinam cherry)	0,05*
161990	Others	0,05*
162000	(b) Inedible peel, small	0,05*
162010	Kiwi	0,05*
162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	0,05*
162030	Passion fruit	0,05*

Code number	Groups and examples of individual products to which the MRLs apply	Fluazinam (F)
162040	Prickly pear (cactus fruit)	0,05*
162050	Star apple	0,05*
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammey sapote)	0,05*
162990	Others	0,05*
163000	(c) Inedible peel, large	0,05*
163010	Avocados	0,05*
163020	Bananas (Dwarf banana, plantain, apple banana)	0,05*
163030	Mangoes	0,05*
163040	Papaya	0,05*
163050	Pomegranate	0,05*
163060	Cherimoya (Custard apple, sugar apple (sweetsop) , llama and other medium sized Annonaceae)	0,05*
163070	Guava	0,05*
163080	Pineapples	0,05*
163090	Bread fruit (Jackfruit)	0,05*
163100	Durian	0,05*
163110	Soursop (guanabana)	0,05*
163990	Others	0,05*
200000	2. VEGETABLES FRESH OR FROZEN	0,05*
210000	(i) Root and tuber vegetables	0,05*
211000	(a) Potatoes	0,05*
212000	(b) Tropical root and tuber vegetables	0,05*
212010	Cassava (Dasheen, eddoe (Japanese taro), tannia)	0,05*
212020	Sweet potatoes	0,05*
212030	Yams (Potato bean (yam bean), Mexican yam bean)	0,05*
212040	Arrowroot	0,05*
212990	Others	0,05*
213000	(c) Other root and tuber vegetables except sugar beet	0,05*
213010	Beetroot	0,05*
213020	Carrots	0,05*
213030	Celeriac	0,05*
213040	Horseradish	0,05*
213050	Jerusalem artichokes	0,05*
213060	Parsnips	0,05*

Code number	Groups and examples of individual products to which the MRLs apply	Fluazinam (F)
213070	Parsley root	0,05*
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	0,05*
213090	Salsify (Scorzonera, Spanish salsify (Spanish oysterplant))	0,05*
213100	Swedes	0,05*
213110	Turnips	0,05*
213990	Others	0,05*
220000	(ii) Bulb vegetables	0,05*
220010	Garlic	0,05*
220020	Onions (Silverskin onions)	0,05*
220030	Shallots	0,05*
220040	Spring onions (Welsh onion and similar varieties)	0,05*
220990	Others	0,05*
230000	(iii) Fruiting vegetables	0,05*
231000	(a) Solanacea	0,05*
231010	Tomatoes (Cherry tomatoes,)	0,05*
231020	Peppers (Chilli peppers)	0,05*
231030	Aubergines (egg plants) (Pepino)	0,05*
231040	Okra, lady's fingers	0,05*
231990	Others	0,05*
232000	(b) Cucurbits - edible peel	0,05*
232010	Cucumbers	0,05*
232020	Gherkins	0,05*
232030	Courgettes (Summer squash, marrow (patisson))	0,05*
232990	Others	0,05*
233000	(c) Cucurbits-inedible peel	0,05*
233010	Melons (Kiwano)	0,05*
233020	Pumpkins (Winter squash)	0,05*
233030	Watermelons	0,05*
233990	Others	0,05*
234000	(d) Sweet corn	0,05*
239000	(e) Other fruiting vegetables	0,05*
240000	(iv) Brassica vegetables	0,05*
241000	(a) Flowering brassica	0,05*
241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	0,05*
241020	Cauliflower	0,05*
241990	Others	0,05*
242000	(b) Head brassica	0,05*
242010	Brussels sprouts	0,05*
242020	Head cabbage (Pointed head	0,05*

Code number	Groups and examples of individual products to which the MRLs apply	Fluazinam (F)
	cabbage, red cabbage, savoy cabbage, white cabbage)	
242990	Others	0,05*
243000	(c) Leafy brassica	0,05*
243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	0,05*
243020	Kale (Borecole (curly kale), collards)	0,05*
243990	Others	0,05*
244000	(d) Kohlrabi	0,05*
250000	(v) Leaf vegetables & fresh herbs	0,05*
251000	(a) Lettuce and other salad plants including Brassicacea	0,05*
251010	Lamb´s lettuce (Italian cornsalad)	0,05*
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	0,05*
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curld leave endive, sugar loaf)	0,05*
251040	Cress	0,05*
251050	Land cress	0,05*
251060	Rocket, Rucola (Wild rocket)	0,05*
251070	Red mustard	0,05*
251080	Leaves and sprouts of Brassica spp (Mizuna)	0,05*
251990	Others	0,05*
252000	(b) Spinach & similar (leaves)	0,05*
252010	Spinach (New Zealand spinach, turnip greens (turnip tops))	0,05*
252020	Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glassworth)	0,05*
252030	Beet leaves (chard) (Leaves of beetroot)	0,05*
252990	Others	0,05*
253000	(c) Vine leaves (grape leaves)	0,05*
254000	(d) Water cress	0,05*
255000	(e) Witloof	0,05*
256000	(f) Herbs	0,05*
256010	Chervil	0,05*
256020	Chives	0,05*
256030	Celery leaves (fennel leaves , Coriander leaves, dill leaves, Caraway leaves, lovage, angelica,	0,05*

Code number	Groups and examples of individual products to which the MRLs apply	Fluazinam (F)
	sweet cisely and other Apiacea)	
256040	Parsley	0,05*
256050	Sage (Winter savory, summer savory,)	0,05*
256060	Rosemary	0,05*
256070	Thyme (marjoram, oregano)	0,05*
256080	Basil (Balm leaves, mint, peppermint)	0,05*
256090	Bay leaves (laurel)	0,05*
256100	Tarragon (Hyssop)	0,05*
256990	Others	0,05*
260000	(vi) Legume vegetables (fresh)	0,05*
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	0,05*
260020	Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)	0,05*
260030	Peas (with pods) (Mangetout (sugar peas))	0,05*
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0,05*
260050	Lentils	0,05*
260990	Others	0,05*
270000	(vii) Stem vegetables (fresh)	0,05*
270010	Asparagus	0,05*
270020	Cardoons	0,05*
270030	Celery	0,05*
270040	Fennel	0,05*
270050	Globe artichokes	0,05*
270060	Leek	0,05*
270070	Rhubarb	0,05*
270080	Bamboo shoots	0,05*
270090	Palm hearts	0,05*
270990	Others	0,05*
280000	(viii) Fungi	0,05*
280010	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	0,05*
280020	Wild (Chanterelle, Truffle, Morel ,)	0,05*
280990	Others	0,05*
290000	(ix) Sea weeds	0,05*
300000	3. PULSES, DRY	0,05*
300010	Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas)	0,05*
300020	Lentils	0,05*
300030	Peas (Chickpeas, field peas,	0,05*

Code number	Groups and examples of individual products to which the MRLs apply	Fluazinam (F)
	chickling vetch)	
300040	Lupins	0,05*
300990	Others	0,05*
400000	4. OILSEEDS AND OILFRUITS	0,05*
401000	(i) Oilseeds	0,05*
401010	Linseed	0,05*
401020	Peanuts	0,05*
401030	Poppy seed	0,05*
401040	Sesame seed	0,05*
401050	Sunflower seed	0,05*
401060	Rape seed (Bird rapeseed, turnip rape)	0,05*
401070	Soya bean	0,05*
401080	Mustard seed	0,05*
401090	Cotton seed	0,05*
401100	Pumpkin seeds	0,05*
401110	Safflower	0,05*
401120	Borage	0,05*
401130	Gold of pleasure	0,05*
401140	Hempseed	0,05*
401150	Castor bean	0,05*
401990	Others	0,05*
402000	(ii) Oilfruits	0,05*
402010	Olives for oil production	0,05*
402020	Palm nuts (palmoil kernels)	0,05*
402030	Palmfruit	0,05*
402040	Kapok	0,05*
402990	Others	0,05*
500000	5. CEREALS	0,05*
500010	Barley	0,05*
500020	Buckwheat	0,05*
500030	Maize	0,05*
500040	Millet (Foxtail millet, teff)	0,05*
500050	Oats	0,05*
500060	Rice	0,05*
500070	Rye	0,05*
500080	Sorghum	0,05*
500090	Wheat (Spelt Triticale)	0,05*
500990	Others	0,05*
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	0,05*
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	0,05*
620000	(ii) Coffee beans	0,05*
630000	(iii) Herbal infusions (dried)	0,05*
631000	(a) Flowers	0,05*
631010	Camomille flowers	0,05*
631020	Hybiscus flowers	0,05*

Code number	Groups and examples of individual products to which the MRLs apply	Fluazinam (F)
631030	Rose petals	0,05*
631040	Jasmine flowers	0,05*
631050	Lime (linden)	0,05*
631990	Others	0,05*
632000	(b) Leaves	0,05*
632010	Strawberry leaves	0,05*
632020	Rooibos leaves	0,05*
632030	Maté	0,05*
632990	Others	0,05*
633000	(c) Roots	0,05*
633010	Valerian root	0,05*
633020	Ginseng root	0,05*
633990	Others	0,05*
639000	(d) Other herbal infusions	0,05*
640000	(iv) Cocoa (fermented beans)	0,05*
650000	(v) Carob (st johns bread)	0,05*
700000	7. HOPS (dried) , including hop pellets and unconcentrated powder	0,05*
800000	8. SPICES	0,05*
810000	(i) Seeds	0,05*
810010	Anise	0,05*
810020	Black caraway	0,05*
810030	Celery seed (Lovage seed)	0,05*
810040	Coriander seed	0,05*
810050	Cumin seed	0,05*
810060	Dill seed	0,05*
810070	Fennel seed	0,05*
810080	Fenugreek	0,05*
810090	Nutmeg	0,05*
810990	Others	0,05*
820000	(ii) Fruits and berries	0,05*
820010	Allspice	0,05*
820020	Anise pepper (Japan pepper)	0,05*
820030	Caraway	0,05*
820040	Cardamom	0,05*
820050	Juniper berries	0,05*
820060	Pepper, black and white (Long pepper, pink pepper)	0,05*
820070	Vanilla pods	0,05*
820080	Tamarind	0,05*
820990	Others	0,05*
830000	(iii) Bark	0,05*
830010	Cinnamon (Cassia)	0,05*
830990	Others	0,05*
840000	(iv) Roots or rhizome	0,05*
840010	Liquorice	0,05*
840020	Ginger	0,05*
840030	Turmeric (Curcuma)	0,05*

Code number	Groups and examples of individual products to which the MRLs apply	Fluazinam (F)
840040	Horseradish	0,05*
840990	Others	0,05*
850000	(v) Buds	0,05*
850010	Cloves	0,05*
850020	Capers	0,05*
850990	Others	0,05*
860000	(vi) Flower stigma	0,05*
860010	Saffron	0,05*
860990	Others	0,05*
870000	(vii) Aril	0,05*
870010	Mace	0,05*
870990	Others	0,05*
900000	9. SUGAR PLANTS	0,05*
900010	Sugar beet (root)	0,05*
900020	Sugar cane	0,05*
900030	Chicory roots	0,05*
900990	Others	0,05*
1000000	10. PRODUCTS OF ANIMAL ORIGIN-TERRESTRIAL ANIMALS	0,05*
1010000	(i) Meat, preparations of meat, offals, blood, animal fats fresh chilled or frozen, salted, in brine, dried or smoked or processed as flours or meals other processed products such as sausages and food preparations based on these	0,05*
1011000	(a) Swine	0,05*
1011010	Meat	0,05*

Code number	Groups and examples of individual products to which the MRLs apply	Fluazinam (F)
1011020	Fat free of lean meat	0,05*
1011030	Liver	0,05*
1011040	Kidney	0,05*
1011050	Edible offal	0,05*
1011990	Others	0,05*
1012000	(b) Bovine	0,05*
1012010	Meat	0,05*
1012020	Fat	0,05*
1012030	Liver	0,05*
1012040	Kidney	0,05*
1012050	Edible offal	0,05*
1012990	Others	0,05*
1013000	(c) Sheep	0,05*
1013010	Meat	0,05*
1013020	Fat	0,05*
1013030	Liver	0,05*
1013040	Kidney	0,05*
1013050	Edible offal	0,05*
1013990	Others	0,05*
1014000	(d) Goat	0,05*
1014010	Meat	0,05*
1014020	Fat	0,05*
1014030	Liver	0,05*
1014040	Kidney	0,05*
1014050	Edible offal	0,05*
1014990	Others	0,05*
1015000	(e) Horses, asses, mules or hinnies	0,05*
1015010	Meat	0,05*

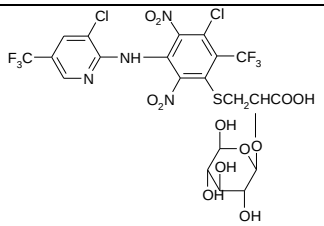
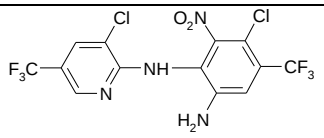
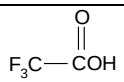
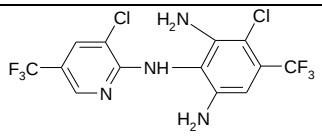
Code number	Groups and examples of individual products to which the MRLs apply	Fluazinam (F)
1015020	Fat	0,05*
1015030	Liver	0,05*
1015040	Kidney	0,05*
1015050	Edible offal	0,05*
1015990	Others	0,05*
1016000	(f) Poultry -chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	0,05*
1016010	Meat	0,05*
1016020	Fat	0,05*
1016030	Liver	0,05*
1016040	Kidney	0,05*
1016050	Edible offal	0,05*
1016990	Others	0,05*
1017000	(g) Other farm animals (Rabbit, Kangaroo)	0,05*
1017010	Meat	0,05*
1017020	Fat	0,05*
1017030	Liver	0,05*
1017040	Kidney	0,05*
1017050	Edible offal	0,05*
1017990	Others	0,05*
1020000	(ii) Milk and cream, not concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curd	0,05*
1020010	Cattle	0,05*

Code number	Groups and examples of individual products to which the MRLs apply	Fluazinam (F)
1020020	Sheep	0,05*
1020030	Goat	0,05*
1020040	Horse	0,05*
1020990	Others	0,05*
1030000	(iii) Birds' eggs, fresh preserved or cooked Shelled eggs and egg yolks fresh, dried, cooked by steaming or boiling in water, moulded, frozen or otherwise preserved whether or not containing added sugar or sweetening matter	0,05*
1030010	Chicken	0,05*
1030020	Duck	0,05*
1030030	Goose	0,05*
1030040	Quail	0,05*
1030990	Others	0,05*
1040000	(iv) Honey (Royal jelly, pollen)	
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	
1060000	(vi) Snails	
1070000	(vii) Other terrestrial animal products	

(*) Indicates lower limit of analytical determination

(F): Fat soluble

D. LIST OF METABOLITES AND RELATED STRUCTURAL FORMULA

Common name	IUPAC name	Structure
AMTG	3-[[4-amino-3-[[3-chloro-5-(trifluoromethyl)-2-pyridyl]amino]-C,C,C-trifluoro-6-nitro-o-tolyl]thio]-2-(-Dglucopyranosyloxy) propionic acid	
AMPA	2-(6-amino-3-chloro-*α,α,α*-trifluoro-2-nitro-*p*-toluidino)-3-chloro-5-(trifluoromethyl) pyridine	
TFAA	Trifluoroacetic acid	
DAPA	3-chloro-2-(2,6-diamino-3-chloro-*α,α,α*-trifluoromethyl-*p*-toluidino)-3-chloro-5-(trifluoromethyl) pyridine	

ABBREVIATIONS

ADI	acceptable daily intake
ARfD	acute reference dose
a.s.	active substance
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CAC	Codex Alimentarius Commission
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CXL	Codex Maximum Residue Limit (Codex MRL)
d	day
DALA	days after last application
DAR	Draft Assessment Report
DAT	days after treatment
DM	dry matter
EFSA	European Food Safety Authority
EMS	evaluating Member State
eq	residue expressed as a.s. equivalent
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
GAP	good agricultural practice
GS	growth stage
ha	hectare
hL	hectolitre
HPLC	high performance liquid chromatography
HR	highest residue
ILV	independent laboratory validation
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram
L	litre
LOD	limit of detection
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States

MS/MS	tandem mass spectrometry
MW	molecular weight
OECD	Organization for Economic Co-operation and Development
PF	processing factor
PHI	pre-harvest interval
P_{ow}	partition coefficient between n-octanol and water
PRIMo	(EFSA) Pesticide Residues Intake Model
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
RD	residue definition
RMS	rapporteur Member State
SC	suspension concentrate
SEU	Southern European Union
TRR	total radioactive residue
wk	week
yr	year