

## REASONED OPINION

### Reasoned opinion on modification of the existing MRL for fluazinam in ginseng root<sup>1</sup>

European Food Safety Authority<sup>2</sup>

European Food Safety Authority (EFSA), Parma, Italy

#### ABSTRACT

In accordance with Article 6 of Regulation (EC) No 396/2005, Austria, hereafter referred to as the evaluating Member State (EMS), received an application from the company ISK Biosciences Europe NV to set the import tolerance for the active substance fluazinam in ginseng roots from the US at the level of 3 mg/kg. Austria 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 3 mg/kg for the proposed use on ginseng roots. An adequate analytical enforcement method to control the residues of fluazinam in fresh ginseng at the validated LOQ of 0.01 mg/kg is available. Although there are some indications that a liquid chromatography method is applicable for the enforcement of fluazinam in dried roots at the LOQ of 0.1 mg/kg, it would be desirable to get a full method validation. No consumer health risk is expected for the proposed MRL.

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#### KEY WORDS

fluazinam, ginseng, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, pyridine fungicide, AMPA and DAPA and AMGT

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## SUMMARY

In accordance with Article 6 of Regulation (EC) No 396/2005, Austria, hereafter referred to as the evaluating Member State (EMS), received an application from the company ISK Biosciences Europe NV to set the import tolerance for the active substance fluazinam in ginseng roots from the US at the level of 3 mg/kg. Austria 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 24 October 2013.

EFSA bases its assessment on the evaluation report submitted by the EMS, the Draft Assessment Report (DAR) prepared under Council Directive 91/414/EEC, the conclusion on the peer review of the pesticide risk assessment of the active substance fluazinam, as well as the conclusions from previous EFSA opinion on fluazinam.

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 metabolism study 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. As ginseng roots belong to the same group as potatoes EFSA concludes that the enforcement residue definition as proposed by the peer review is applicable and no additional metabolism studies are required. The current residue definition in Regulation (EC) No 396/2005 is set as fluazinam. For risk assessment residue definition derived in the peer review is the sum of fluazinam, AMPA-fluazinam, AMGT, expressed as fluazinam.

EFSA concludes that the submitted supervised residue trials are sufficient to derive a MRL proposal of 3 mg/kg for the proposed use on ginseng roots. An adequate analytical enforcement method to control the residues of fluazinam in fresh ginseng at the validated LOQ of 0.01 mg/kg is available. Although there are some indications that a liquid chromatography method is applicable for the enforcement of fluazinam in dried roots at the LOQ of 0.1 mg/kg, it would be desirable to get a full method validation.

Studies investigating the nature and magnitude of fluazinam residues in processed commodities are not available. Considering the low dietary exposure resulting from ginseng, processing studies are not required.

Since the current application is for the import tolerance the occurrence of fluazinam in rotational crops is of no relevance, investigations of residues in rotational crops are not required.

Residues of fluazinam in commodities of animal origin were not assessed in the framework of this application, since the ginseng roots are normally not fed to livestock.

Ginseng roots are not consumed in significant amounts. Thus, the long-term dietary exposure to fluazinam residues via ginseng is expected to be of minor relevance. The exposure assessment performed in a previous MRL application demonstrated that the exposure from other food treated with fluazinam is well below the toxicological reference value (33 % of the ADI). Regarding the short-term exposure, EFSA made a rough estimation using conservative assumption. The exposure of a child consuming a ginseng infusion is calculated to amount for 2.6 % of ARfD.

EFSA concludes that the residues resulting from the use of fluazinam according to the GAP authorised in the USA on ginseng roots will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a public health concern.

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

**SUMMARY TABLE**

<b>Code number<sup>(a)</sup></b>	<b>Commodity</b>	<b>Existing EU MRL (mg/kg)</b>	<b>Proposed EU MRL (mg/kg)</b>	<b>Justification for the proposal</b>
<b>Enforcement residue definition: Fluazinam</b>				
633020	Ginseng root	0.05*	3	The MRL proposal is sufficiently supported by data and no consumer health risk was identified for the use on this crop. The MRL in the country of origin (USA) is 4.5 mg/kg.

(a): According to Annex I of Regulation (EC) No 396/2005.

(\*): Indicates that the MRL is set at the limit of analytical quantification.

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## BACKGROUND

Regulation (EC) No 396/2005<sup>3</sup> 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<sup>4</sup>, repealed by Regulation (EC) No 1107/2009<sup>5</sup>, shall submit to a Member State, when appropriate, an application to set an import tolerance in accordance with the provisions of Article 7 of that Regulation.

Austria, hereafter referred to as the evaluating Member State (EMS), received an application from the company ISK Biosciences Europe NV<sup>6</sup> to set import tolerance for the active substance fluazinam in ginseng, based on the US GAPS. 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 24 October 2013.

The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2013-00842 and the following subject:

*Fluazinam- Setting of MRL for fluazinam in ginseng*

Austria proposed to raise the existing MRL of fluazinam in ginseng from the limit of quantification of 0.05\* mg/kg to 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 deadline for providing the reasoned opinion is 24 January 2014.

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<sup>3</sup> 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.

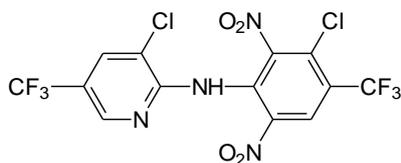
<sup>4</sup> Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.08.1991, p. 1-32.

<sup>5</sup> 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.

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## THE ACTIVE SUBSTANCE AND ITS USE PATTERN

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



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 rapporteur Member State (RMS). Fluazinam is approved under Regulation (EC) No 1107/2009 by means of Commission Directive 2008/108/EC<sup>7</sup> 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) has been peer reviewed by EFSA and an EFSA conclusion is available (EFSA, 2008).

The EU MRLs for fluazinam are established in and Annex IIIA of Regulation (EC) No 396/2005 (Appendix B). The existing EU MRL for fluazinam on ginseng is set at the LOQ of 0.05\* mg/kg. No CXLs are established for fluazinam. The MRL for residues established in the US for fluazinam in ginseng roots is 4.5 mg/kg<sup>8</sup>.

The details of the authorised GAP for fluazinam are given in Appendix A.

<sup>7</sup> 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.

<sup>8</sup> Source of information: <http://www.mrlatabase.com/results.cfm>

## ASSESSMENT

EFSA bases its assessment on the evaluation report submitted by the EMS (Austria, 2013), the Draft Assessment Report (DAR) prepared under Council Directive 91/414/EEC (Austria, 2005), the conclusion on the peer review of the pesticide risk assessment of the active substance fluazinam (EFSA, 2008), as well as the conclusions from previous EFSA opinion on fluazinam (EFSA, 2012). 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<sup>9</sup> and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (EC, 1996, 1997a-g, 2000, 2010a,b, 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 but, the data which confirmed the applicability of this method for the above mentioned matrices at the LOQ of 0.01 mg/kg were submitted in the framework of a previous MRL application (EFSA, 2012).

Under the current application, an additional GC-ECD method for fluazinam determination from fresh ginseng root at the LOQ of 0.01mg/kg was submitted. The applicability of the method for dried ginseng roots was not fully demonstrated. However in the storage stability study (see section 3.1.1.2) some indications were proved that the method, with an adaptation during the extraction steps, might be used also for dried ginseng.

Although some data are available on the EURL website<sup>10</sup> that a liquid chromatography method is applicable for the enforcement of fluazinam in dried roots at the LOQ of 0.1 mg/kg, it would be desirable to provide a detailed study confirming validation data.

#### 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 ginseng is 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 Directive 91/414/EEC (EFSA, 2008). The data were sufficient to derive toxicological reference values for fluazinam which are compiled in Table 2-1.

<sup>9</sup> 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.

<sup>10</sup> <http://www.eurl-pesticides-datapool.eu/>

**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
Trifluoroacetic acid					
ADI	EFSA	2014	0.05 mg/kg bw per day	90 d oral rat study	200
ARfD	EFSA	2014	0.05 mg/kg bw	90 d oral rat study	200

In plant metabolism studies assessed in the framework of the peer review, trifluoroacetic acid was identified as a minor metabolite. The toxicological properties were recently assessed by EFSA (EFSA, 2014) and provisional toxicological reference values were derived which can be found in Table 2-1.

### 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 (potatoes), pulses and oilseeds (peanuts), and fruits and fruiting vegetables (grapes and apples) 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 metabolism studies were performed with fluazinam labelled in the phenyl- and pyridyl- ring. The detailed information about the metabolism pathway and results are described in the previous reasoned opinion (EFSA, 2012).

Based on the metabolism study 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). The current residue definition set in Regulation (EC) No 396/2005 is identical to the residue definition for enforcement derived in the peer review.

Regarding the residue definition for the risk assessment, the peer review defined the relevant residue as the sum of fluazinam, AMPA-fluazinam, AMGT, expressed as fluazinam. In addition, the formation of very low levels of trifluoroacetic acid (TFA) was identified in primary crops (peanuts, potatoes). Since the toxicological information was not sufficient to conclude whether a separate risk assessment is required for TFA, the peer review could not finalise the risk assessment for this metabolite (EFSA, 2008). It is noted that TFA was assessed in a recent EFSA reasoned opinion (EFSA 2014). Considering that TFA was only a minor metabolite in root crops and the fact that TFA is not significantly more toxic than the parent compound, the setting of a separate residue definition for TFA or the inclusion of TFA in the risk assessment residue definition is found not necessary.

For the use of fluazinam in ginseng, EFSA concludes that the metabolism of fluazinam is sufficiently addressed and the residue definitions for enforcement and risk assessment agreed in the peer review are applicable.

### 3.1.1.2. Magnitude of residues

This MRL application is based on the residue trials performed according to the US GAP (*4 x 0.9 kg a.s/ha with a PHI of 30±1 days*). The residue trials were conducted in the US in 2003. After harvest, the samples were dried in an oven for 10 days at 55 °C, simulating commercial practices. Ginseng root were analysed for parent fluazinam only. To estimate the contribution of the metabolites included in risk assessment residue definition the conversion factor 3, derived during the peer review for potatoes was used (EFSA, 2008).

The results of the residue trials, the related risk assessment input values (highest residue, median residue, conversion factor) and the MRL proposal are summarised in Table 3-1.

The storage stability of fluazinam in primary crops was investigated during the peer review and residues of fluazinam were found to be stable at  $\leq -15$  °C for up to 26 months in root and tuber vegetables (potatoes). The storage stability of relevant fluazinam metabolites AMPA-fluazinam and AMGT has not been investigated and such studies are recommended.

A storage stability study on dried ginseng revealed a possible degradation of the residues under storage conditions. Further investigation demonstrated that these low recoveries were probably related to inappropriate extraction conditions during the analysis. Changes in the extraction procedures (soaking the samples in methanol + glacial acetic acid for 1 hour prior to homogenisation) improved the efficiency of the analytical method with acceptable recoveries of 77 %  $\pm$  2 % at fortification levels of 1 and 2 mg/kg. Based on this modified analytical method, recoveries of the fluazinam residues in the samples stored over *ca* 11 months at -18 °C was 60 % (calculated on the nominal fortification level of 1 mg/kg). Analysis of the samples at day 0 are not available and therefore, calculations of the recoveries after storage under frozen conditions based on the residue level measured at day 0 is not possible.

Although, based on the available information, the stability under frozen conditions of fluazinam residues in ginseng roots was not fully demonstrated (recovery below the threshold value of 70 % after 11 months). Considering the low contribution of ginseng in the consumer diets, EFSA is of the opinion that the data are acceptable and sufficient to derive an import tolerance of 3 mg/kg for ginseng.

**Table 3-1:** 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)	CF	Comments (e)
			Enforcement (Fluazinam)	Risk assessment (Fluazinam, AMPA-fluazinam and AMGT expressed as fluazinam)					
Ginseng (dried root)	Import (US)	Outdoor	0.37; 0.77; 0.84; 1.30	1.11; 2.31; 2.52; 3.90 (estimated values using the CF of 3 proposed for potatoes)	0.805	1.30	3	3 <sup>(d)</sup>	R <sub>ber</sub> = 2.4 R <sub>max</sub> = 2.8 MRL <sub>OECD</sub> =2.5/3

(a): NEU (Northern and Central Europe), SEU (Southern Europe and Mediterranean), EU (i.e. indoor 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 conversion factor used for enforcement to risk assessment was derived for potatoes during the peer review process.

(e): Statistical estimation of MRLs according to the EU methodology (R<sub>ber</sub>, R<sub>max</sub>; EC, 1997g) and unrounded/rounded values according to the OECD methodology (OECD, 2011).

### 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 standard hydrolysis studies. No new studies have been submitted in the framework of the current application. Specific studies to assess the transfer of fluazinam from dried root of ginseng to the commercial products (tea, ginseng flowered candy, chewable tablets or tinctures) are not available either. Considering the low dietary exposure, processing studies are not required.

### 3.1.2. Rotational crops

#### 3.1.2.1. Preliminary considerations

The residues of fluazinam in rotational crops are of no relevance for the import tolerance application.

### 3.2. Nature and magnitude of residues in livestock

Since ginseng is normally not fed to livestock, the nature and magnitude of fluazinam residues in livestock is not assessed in the framework of this application (EC, 1996).

## 4. Consumer risk assessment

In the framework of a previous MRL application a long-term dietary intake assessment was performed (EFSA, 2012), using 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<sup>11</sup> (EFSA, 2007). The estimated long term exposure accounted for 33 % of the ADI.

It is noted that in the EFSA PRIMo rev. 2 no consumption data for ginseng roots are available; also in the EFSA comprehensive food consumption database (EFSA, 2011) only very limited information is available for ginseng<sup>12</sup>. Thus, considering that ginseng roots are not a food commodity which is consumed in significant amounts, the long-term dietary exposure to fluazinam residues via ginseng is expected to be of minor relevance.

Regarding the short-term exposure, EFSA made a rough estimation, assuming a conservative scenario, where a child with a body weight of 10 kg consumes a tea infusion prepared from one tea bag (2 g) containing residues at the proposed MRL of 3 mg/kg for ginseng. The contribution of the metabolites included in the residue definition was taken into account by applying the conversion factor of 3 (see Table 3-1). In addition, a complete transfer of the residue to the infusion was assumed. Under this conservative assumption, the exposure of the child is calculated to amount for 2.6 % of ARfD.

EFSA concludes that the residues resulting from the use of fluazinam according to the GAP authorised in the USA on ginseng roots will not result in a consumer exposure exceeding the toxicological reference value 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 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.

<sup>11</sup> 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).

<sup>12</sup> There is only one consumption data available in EFSA database for ginseng root for a woman of 52 years, weighting 58 kg and consuming 4.5grams of crop.

The metabolism of fluazinam in primary crops was investigated in tuber vegetables, oilseeds and fruits. Based on the metabolism study 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. As ginseng roots belong to the same group as potatoes EFSA concludes that the enforcement residue definition as proposed by the peer review is applicable and no additional metabolism studies are required. The current residue definition in Regulation (EC) No 396/2005 is set as fluazinam. For risk assessment residue definition derived in the peer review is the sum of fluazinam, AMPA-fluazinam, AMGT, expressed as fluazinam.

EFSA concludes that the submitted supervised residue trials are sufficient to derive a MRL proposal of 3 mg/kg for the proposed use on ginseng roots. An adequate analytical enforcement method to control the residues of fluazinam in fresh ginseng at the validated LOQ of 0.01 mg/kg is available. Although there are some indications that a liquid chromatography method is applicable for the enforcement of fluazinam in dried roots at the LOQ of 0.1 mg/kg, it would be desirable to get a full method validation.

Studies investigating the nature and magnitude of fluazinam residues in processed commodities are not available. Considering the low dietary exposure resulting from ginseng, processing studies are not required.

Since the current application is for the import tolerance the occurrence of fluazinam in rotational crops is of no relevance, investigations of residues in rotational crops are not required.

Residues of fluazinam in commodities of animal origin were not assessed in the framework of this application, since the ginseng roots are normally not fed to livestock.

Ginseng roots are not consumed in significant amounts. Thus, the long-term dietary exposure to fluazinam residues via ginseng is expected to be of minor relevance. The exposure assessment performed in a previous MRL application demonstrated that the exposure from other food treated with fluazinam is well below the toxicological reference value (33 % of the ADI). Regarding the short-term exposure, EFSA made a rough estimation using conservative assumption. The exposure of a child consuming a ginseng infusion is calculated to amount for 2.6 % of ARfD.

EFSA concludes that the residues resulting from the use of fluazinam according to the GAP authorised in the USA on ginseng roots will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a public health concern.

## RECOMMENDATIONS

Code number <sup>(a)</sup>	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
<b>Enforcement residue definition: Fluazinam</b>				
633020	Ginseng root	0.05*	3	The MRL proposal is sufficiently supported by data and no consumer health risk was identified for the use on this crop. The MRL in the country of origin (USA) is 4.5 mg/kg.

(a): According to Annex I of Regulation (EC) No 396/2005.

(\*): Indicates that the MRL is set at the limit of analytical quantification.

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## APPENDICES

### Appendix A. GOOD AGRICULTURAL PRACTICE (GAPS)

Crop and/or situation (a)	Member State or Country	Product name	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		
Ginseng	US	Omega 500 F	F	Rhizoctonia root rot ( <i>Rhizoctonia solani</i> ) Alternaria blight ( <i>Alternaria panax</i> ) Botrytis blight ( <i>Botrytis cinerea</i> ) White mold ( <i>Sclerotinia sclerotiorum</i> )	SC	500 g/l	Broadcast Foliar Spray	<i>Rhizoctonia solani</i> : at transplant  <i>Alternaria panax</i> , <i>Botrytis cinerea</i> and <i>Sclerotinia sclerotiorum</i> : 1 <sup>st</sup> disease appearance	4-6	14 days	0.0295 - 0.093	950 -2000	0.591 -0.886	30	Re-entry interval = 12 hours Maximum per 3.55 kg ai/ha per growing seasons

#### 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, 4<sup>th</sup> 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, 2<sup>nd</sup> 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. EXISTING EU MAXIMUM RESIDUE LEVELS (MRLs)

(Pesticides - Web Version - EU MRLs (File created on 31/03/2014 15:19))

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, uglı 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	
130010	Apples (Crab apple)	0,3
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 cloudberrıes)	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	Curants (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	Azarele (mediterranean medlar)	0,05*
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea shallowthorn), 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), pomeac, rose apple, Brazilian 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*
213070	Parsley root	0,05*

Code number	Groups and examples of individual products to which the MRLs apply	Fluazinam (F)
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	0,05*
213090	Salsify (Scorzonerıa, 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 com	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 cabbage, red cabbage, savoy	0,05*

Code number	Groups and examples of individual products to which the MRLs apply	Fluazinam (F)
	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 comsalad)	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, curd leaf 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, glasswort)	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, sweet cicely and other Apiacea)	0,05*

Code number	Groups and examples of individual products to which the MRLs apply	Fluazinam (F)
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, chickling vetch)	0,05*
300040	Lupins	0,05*

Code number	Groups and examples of individual products to which the MRLs apply	Fluazinam (F)
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*
631030	Rose petals	0,05*
631040	Jasmine flowers	0,05*

Code number	Groups and examples of individual products to which the MRLs apply	Fluazinam (F)
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*
840040	Horseradish	0,05*
840990	Others	0,05*

Code number	Groups and examples of individual products to which the MRLs apply	Fluazinam (F)
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) Tissue	0,05*
1011000	(a) Swine	0,05*
1011010	Muscle	0,05*
1011020	Fat	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	Muscle	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	Muscle	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	Muscle	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*

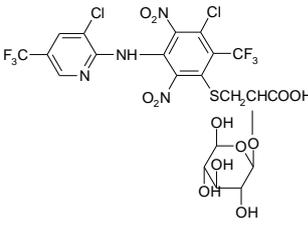
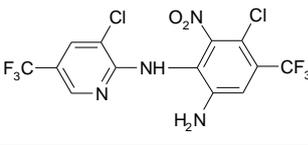
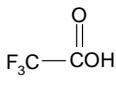
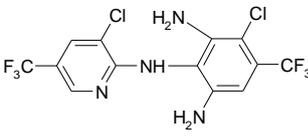
Code number	Groups and examples of individual products to which the MRLs apply	Fluazinam (F)
1015010	Muscle	0,05*
1015020	Fat	0,05*
1015030	Liver	0,05*
1015040	Kidney	0,05*
1015050	Edible offal	0,05*
1015990	Others	0,05*
1016000	(f) Poultry -chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	0,05*
1016010	Muscle	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	Muscle	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*
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)	0,05*
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	0,05*

Code number	Groups and examples of individual products to which the MRLs apply	Fluazinam (F)
1060000	(vi) Snails	0,05*
1070000	(vii) Other terrestrial animal products	0,05*

(\* ) Indicates lower limit of analytical determination

F: Fat soluble

**Appendix C. LIST OF METABOLITES AND RELATED STRUCTURAL FORMULA**

Code/Trivial name	Chemical name	Structural formula
<b>AMTG</b>	3-[[4-amino-3-[[3-chloro-5-(trifluoromethyl)-2-pyridyl]amino]-C,C,C-trifluoro-6-nitro- <i>o</i> -tolyl]thio]-2-( <i>D</i> -glucopyranosyloxy) propionic acid	
<b>AMPA</b>	2-(6-amino-3-chloro- $\alpha,\alpha,\alpha$ -trifluoro-2-nitro- <i>p</i> -toluidino)-3-chloro-5-(trifluoromethyl) pyridine	
<b>TFA</b>	Trifluoroacetic acid	
<b>DAPA</b>	3-chloro-2-(2,6-diamino-3-chloro- $\alpha,\alpha,\alpha$ -trifluoromethyl- <i>p</i> -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
ca	circa
CF	conversion factor for enforcement to risk assessment residue definition
CIPAC	Collaborative International Pesticide Analytical Council
CXL	Codex Maximum Residue Limit (Codex MRL)
DAR	Draft Assessment Report
EC	European Community
ECD	electron capture detector
EFSA	European Food Safety Authority
EMS	evaluating Member State
EU	European Union
GAP	good agricultural practice
ha	hectare
hL	hectolitre
HPLC	high performance liquid chromatography
ILV	independent laboratory validation
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram
L	litre
LOQ	limit of quantification
MRL	maximum residue level
MS/MS	tandem mass spectrometry
OECD	Organisation for Economic Co-operation and Development
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
SANCO	Directorate-General for Health and Consumers
SC	suspension concentrate
yr	year