

REASONED OPINION

Reasoned opinion on the modification of the existing MRLs for fenpyrazamine in almonds, grapes, apricots, peaches and strawberries¹

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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 Sumitomo Chemical Agro Europe SAS to set import tolerances for the active substance fenpyrazamine in almonds, grapes and strawberries from the United States of America (USA). Austria received a second application from the above cited company to modify the existing MRLs for fenpyrazamine in peaches, including nectarines, apricots and strawberries reflecting the intended uses in the EU. Austria proposed the MRL of 3 mg/kg in strawberries, peaches and apricots, 0.01 mg/kg in almonds, which corresponds to the limit of quantification (LOQ), whereas no amendment of the existing MRL of 3 mg/kg for grapes was required. Austria drafted two separate evaluation reports in accordance with Article 8 of Regulation (EC) No 396/2005, which were submitted to the European Commission and forwarded to EFSA. According to EFSA the data are sufficient to derive the following MRL proposal: 0.01*mg/kg for almonds, 3 mg/kg for strawberries and 4 mg/kg for peaches, including nectarines and similar hybrids. An amendment of the existing MRL on grapes is not necessary, while the data are not sufficient to propose a MRL for the intended uses on apricots. Adequate analytical enforcement methods are available to control the residues of fenpyrazamine in the crops under consideration. Based on the risk assessment results, EFSA concludes that the proposed uses of fenpyrazamine on almonds, grapes, peaches and strawberries will not result in a consumer exposure exceeding the toxicological reference values and therefore are unlikely to pose a consumer health risk.

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KEY WORDS

Fenpyrazamine, almonds, stone and berry fruits, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, pyrizole, S-2188-DC.

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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 Sumitomo Chemical Agro Europe SAS to set import tolerances for the active substance fenpyrazamine in almonds, grapes and strawberries from the United States of America (USA). In order to accommodate for the uses of fenpyrazamine, Austria proposed to set the MRLs in strawberries at 3 mg/kg and in almonds at 0.01 mg/kg, which corresponds to the limit of quantification (LOQ), whereas no amendment of the existing MRL for grapes was required. 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 21 March 2012.

In accordance with Article 6 of Regulation (EC) No 396/2005, Austria received a second application from the above cited company to modify the existing MRLs for the active substance fenpyrazamine in peaches, apricots and strawberries reflecting the intended uses in the EU. In order to accommodate for the intended uses of fenpyrazamine, Austria proposed to raise the existing MRLs from the LOQ of 0.01 mg/kg to 3 mg/kg in all the intended crops. 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 July 2012.

For reasons of efficiency EFSA combined both applications in one reasoned opinion. EFSA bases its assessment on the evaluation reports submitted by the EMS, the Draft Assessment Report (DAR) prepared under Council Directive 91/414/EEC, the Commission Review Report on fenpyrazamine, the conclusion on the peer review of the pesticide risk assessment of the active substance fenpyrazamine as well as the conclusion from a previous EFSA opinion on fenpyrazamine.

The toxicological profile of fenpyrazamine was assessed in the framework of the approval of the active substance under Regulation (EC) No 1107/2009 and the data were sufficient to derive an ADI of 0.13 mg/kg bw per day and an ARfD of 0.3 mg/kg bw.

The metabolism of fenpyrazamine in primary crops was investigated after foliar application on three different crop groups: fruit and fruiting vegetables (grapes), leafy vegetables (lettuce) and pulses/oilseeds (oilseed rape). From these studies, the peer review concluded to establish the residue definition for enforcement as fenpyrazamine and for risk assessment as the sum of fenpyrazamine and S-2188-DC, expressed as fenpyrazamine. For the use on the crops under consideration, EFSA concludes that the metabolism of fenpyrazamine in primary crops is sufficiently addressed and that the agreed residue definitions are applicable.

EFSA considers that the submitted supervised residue trials are sufficient to derive the following MRL proposal: 0.01*mg/kg for almonds, 3 mg/kg for strawberries and 4 mg/kg for peaches, including nectarines and similar hybrids. An amendment of the existing MRL on grapes is not necessary, while the data are not sufficient to propose a MRL for the intended uses on apricots. The MRL proposal on almonds is considered provisional because the residue trial samples were stored for a period for which the validity of the results is not fully demonstrated. Adequate analytical enforcement methods are available to control the residues of fenpyrazamine in the crops under consideration at the validated LOQ of 0.01 mg/kg.

Based on the results of hydrolysis studies on the effect of processing on the nature of fenpyrazamine residues, the peer review concluded that for processed commodities the same residue definitions as for raw agricultural commodities (RAC) apply. Specific studies investigating the magnitude of fenpyrazamine residues in processed grapes (juice and raisins) were submitted. Taking into account these studies, the processing factors derived during the peer review and in a previous reasoned opinion have to be slightly modified. Thus, the following revised processing factors are recommended to be included in Annex VI of Regulation (EC) No 396/2005:

- Grape, juice: 0.16
- Grape, raisins: 1.65

The occurrence of fenpyrazamine residues in rotational crops was investigated in the framework of the peer review. Based on the available information on the nature and magnitude of residues in succeeding crops, EFSA concludes that significant residue levels are unlikely to occur in rotational crops provided that the compound is used on strawberries according to the proposed GAP (Good Agricultural Practice).

Residues of fenpyrazamine in commodities of animal origin were not assessed in the framework of this application, since the products under consideration are normally not fed to livestock.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticides Residue Intake Model (PRIMo). For the calculation of the exposure, EFSA used the median residue and the higher residue values multiplied by the corresponding conversion factor (CF) for risk assessment as derived from the residue trials on almonds, grapes, strawberries and peaches and the median residue values (multiplied by the corresponding CF) as reported in a previously issued EFSA reasoned opinion. The acute exposure assessment was performed only with regard to the commodities under consideration. The estimated exposure was then compared with the toxicological reference values derived for fenpyrazamine.

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake accounted for 5 % of the ADI (WHO Cluster diet B). The contribution of residues among the crops assessed accounted for a maximum of 3.4 % of the ADI (wine grapes). No acute consumer risk was identified in relation to the MRL proposals for the crops under consideration. The calculated maximum exposure in percentage of the ARfD was 59.3 % for peaches, 54.5 % for table grapes, 9.7 % for strawberries and 6.5 % in wine grapes. The acute exposure via residues in almonds is negligible.

EFSA concludes that the proposed uses of fenpyrazamine on almonds, grapes, peaches and strawberries will not result in a consumer exposure exceeding the toxicological reference values and therefore are unlikely to pose a consumer health risk.

It is noted that fenpyrazamine is under review by the US authorities. According to the information available on the public domain this active substance has not yet been approved. Therefore, EFSA recommends that the registration status should be confirmed before the proposed import tolerance on almonds is included in Annex III of Regulation (EC) No 396/2005.

EFSA proposes to amend the existing MRLs 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: fenpyrazamine				
120010	Almonds	0.01*	0.01* (provisional)	The derived MRL (import tolerance) is supported by data and no risk for consumers was identified for the import tolerance request. The validity of the residue trial data is further to be demonstrated by providing adequate storage stability studies.
140030	Peaches (nectarines and similar hybrids)	0.01*	4	The MRL proposal based on an intended use in SEU is sufficiently supported by data and no risk for consumers was identified for the intended uses in NEU and SEU.

Code number ^(a)	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
140010	Apricots	0.01*	No new proposal	The submitted residue data on peaches are not sufficient to derive a MRL proposal by extrapolation.
151000	Table and wine grapes	3	3	An amendment of the existing MRL is not necessary. The import tolerance is sufficiently supported by data and no risk for consumers was identified.
152000	Strawberries	0.01*	3	The MRL proposal is sufficiently supported by data and no risk for consumers was identified for the intended uses under protected conditions in EU and for the import tolerance request. The submitted residue data are not sufficient to derive a MRL proposal for the outdoor use in NEU and SEU.

(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 396/2005³ 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/EEC⁴, repealed by Regulation (EC) No 1107/2009⁵, shall submit to a Member State, when appropriate, an application to set import tolerances or to set MRLs in accordance with the provisions of Article 7 of that Regulation.

Austria, hereafter referred to as the evaluating Member State (EMS), received from the company Sumitomo Chemical Agro Europe SAS⁶ an application to set import tolerances for the active substance fenpyrazamine in almonds, strawberries and grapes. 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.

Austria received a second application from the above cited company to modify the existing MRLs for the active substance fenpyrazamine in peaches, including nectarines and other hybrids, apricots and strawberries to reflect the intended uses in the EU. 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 reports were submitted to the European Commission who forwarded the applications, the evaluation reports and the supporting dossiers to EFSA on 21 March 2012 and 24 July 2012, respectively.

The applications were included in the EFSA Register of Questions with the reference number EFSA-Q-2012-00403 and EFSA-Q-2012-00729 and the following subjects:

Fenpyrazamine - Application to modify the existing MRLs in almonds, grapes and strawberries.

Fenpyrazamine - Application to modify the existing MRLs in apricots, peaches and strawberries.

In the first evaluation report Austria proposed to set import tolerances on almonds at the LOQ of 0.01 mg/kg and on strawberries and grapes at 3 mg/kg (Austria, 2012a). In the second evaluation report Austria proposed to raise the existing MRLs of fenpyrazamine in peaches, including nectarines and other hybrids, apricots and strawberries from the LOQ of 0.01 mg/kg to 3 mg/kg (Austria, 2012b).

EFSA proceeded with the assessment of the applications and the evaluation reports as required by Article 10 of the Regulation. For reasons of efficiency, EFSA combined both applications in one reasoned opinion.

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

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.

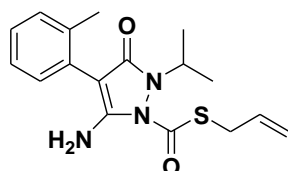
⁶ Sumitomo Chemical Agro Europe SAS, 2 rue Claude Chappe, Parc d'Affaires de Crécy, 69771, Saint Didier Au Mont d'Or, France.

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 21 June 2102 and 24 October 2012, respectively.

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Fenpyrazamine is the ISO common name for *S*-allyl 5-amino-2,3-dihydro-2-isopropyl-3-oxo-4-(*o*-tolyl) pyrazole-1-carbothioate (IUPAC). The chemical structure of the compound is reported below.



Molecular weight: 331.43 g/mol

Fenpyrazamine is a non-systemic fungicide belonging to the pyrizole chemical family. It is used for the control of grey mould (*Botrytis*). Although the compound is classified as non-systemic, limited translocation in plants was observed. Fenpyrazamine shows its fungicidal activity through inhibition of germ tube elongation and mycelium elongation. However, the exact biochemical mechanism of the fungicidal activity is not yet clarified.

Fenpyrazamine was evaluated in the framework of Council Directive 91/414/EEC with Austria designated as rapporteur Member State (RMS). It was approved for use as fungicide in accordance with Regulation (EC) No 1107/2009 by Commission Implementing Regulation (EU) No 595/2012⁷, which enters into force on 1 January 2013. The representative uses assessed in the peer review were foliar applications in glasshouses on tomato, aubergine, pepper, and cucurbits with edible peel, and field use on grapes. The Draft Assessment Report (DAR) of fenpyrazamine has been peer reviewed by EFSA (EFSA, 2012).

The EU MRLs for fenpyrazamine are established in Annexes IIIA of Regulation (EC) No 396/2005 (Appendix C). MRL proposals for grapes, tomatoes, peppers, aubergines and cucurbits with edible peel were evaluated by EFSA (EFSA, 2011) and new MRLs were established through the Commission Regulation (EC) No 322/2012⁸. The existing EU MRLs for fenpyrazamine are set at the LOQ of 0.01 mg/kg on almonds, apricots, peaches and strawberries while are at 3 mg/kg on grapes. Codex Alimentarius has not established CXLs for fenpyrazamine.

The details of the intended US GAPs on which the import tolerance request is based are given in Appendix A. It is noted that the authorisation process in the USA is still ongoing; according to the information available on the public domain⁹, a decision is expected within the first half of 2013. Appendix A includes also the details of the intended European GAPs which are the basis for the MRL request on peaches, apricots and strawberries.

⁷ Commission Implementing Regulation (EU) No 595/2012 of 5 July 2012. OJ L 176, 06.07.2012, pp. 46-49.

⁸ Commission Regulation (EU) No 322/2012 of 16 April 2012. OJ L 105, 17.04.2012, pp. 1-40.

⁹ US Environmental Protection Agency (EPA) web site: <http://www.epa.gov/opprd001/workplan/newchem.html>

ASSESSMENT

EFSA bases its assessment on the evaluation reports submitted by the EMS (Austria, 2012a, 2012b), the Draft Assessment Report (DAR) prepared under Council Directive 91/414/EEC (Austria, 2011), the Commission Review Report on fenpyrazamine (EC, 2012), the conclusion on the peer review of the pesticide risk assessment of the active substance fenpyrazamine (EFSA, 2012) as well as the conclusion from a previous EFSA opinion on fenpyrazamine (EFSA, 2011). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011¹⁰ 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 fenpyrazamine residues in plant commodities were assessed in the framework of the approval of the active substance under Regulation (EC) No 1107/2009 (Austria, 2011; EFSA, 2012).

The multi-residue method DFG S19 (extended and revised), using liquid chromatography coupled with tandem mass spectrum detection (LC-MS/MS), was adequately validated to control and monitor fenpyrazamine residues in high water (tomatoes, peppers, carrots), high acid (grapes) and high oil (oilseed rape) content commodities and in dry commodities (cereals) with an LOQ of 0.01 mg/kg (EFSA, 2012).

Since the commodities under consideration belong to the group of high water and high oil content commodities, EFSA concludes that a sufficiently validated analytical method for enforcing the proposed MRLs for fenpyrazamine on the crops under consideration is available.

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

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

2. Mammalian toxicology

The toxicological profile of the active substance fenpyrazamine was assessed in the framework of the approval of the active substance under Regulation (EC) No 1107/2009 (EFSA, 2012; EC, 2012). The data were sufficient to derive toxicological reference values for fenpyrazamine which are compiled in Table 2-1.

Table 2-1: Overview of the toxicological reference values

	Source	Year	Value	Study relied upon	Safety factor
Fenpyrazamine					
ADI	EC	2012	0.13 mg/kg bw per day	Rat, 2 yr study	100
ARfD	EC	2012	0.3 mg/kg bw	Rabbit, developmental study	100

¹⁰ Commission Regulation (EU) No 546/2011 of 10 June 2011. OJ L 155, 11.06.2011, pp. 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 fenpyrazamine after foliar application was investigated in grapes, lettuce and oilseed rape, representing the crop groups of fruit and fruiting vegetables, leafy vegetables and pulses/oilseeds. The details of the metabolism studies are reported in the DAR and a previous EFSA reasoned opinion (Austria, 2011; EFSA, 2011). The overview of the metabolism study designs is presented in the table below.

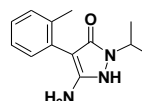
Table 3-1: Summary of available metabolism studies in plants

Group	Crop	Label position	Application details				
			Method, F or G ^(a)	Rate	No/ Interval	Sampling	Remarks
Fruits and fruiting vegetable	grapes	Phenyl- ¹⁴ C	Foliar, G	0.75 kg a.s./ha	2 (14 d)	14, 21 DALA	Samples: berries, foliage
		Pyrazolyl-5- ¹⁴ C					
Leafy vegetables	lettuce	Phenyl- ¹⁴ C	Foliar, G	0.85 kg a.s./ha	3 (14 d)	14 DALA	
		Pyrazolyl-5- ¹⁴ C					
Pulses and oilseeds	rapeseed	Phenyl- ¹⁴ C	Foliar, G	0.6 kg a.s./ha	2 (60 d)	46 d after 1 st appl. (forage), 45 DALA (haulm, seed)	Samples: forage, haulm, seed
		Pyrazolyl-5- ¹⁴ C					

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

The metabolism of fenpyrazamine was comparable in all the investigated crops. The parent fenpyrazamine was the major component of radioactive residues (50 % to 94 % of the TRR in grapes and lettuce collected 14 to 21 days after the last application and about 20 % of the TRR in rape seeds). In addition to the parent compound, the metabolite S-2188-DC¹¹ was found in all the metabolism studies but was present in relevant concentrations only in lettuce (up to 11 % of TRR). Furthermore, this compound was detected in significant amounts in the supervised residue trials conducted on grapes (up to 0.39 mg/kg). Since the metabolite S-2188-DC was a major metabolite in the rat metabolism study as well, its toxicity was considered as adequately covered by the toxicological profile of the parent fenpyrazamine (EFSA, 2012).

¹¹ S-2188-DC: 5-amino-1,2-dihydro-2-isopropyl-4-(o-tolyl)pyrazol-3-one.



The metabolism of fenpyrazamine in plants was seen to be limited and to proceed by the cleavage of the carbamate bound on the pyrazolyl moiety to give the metabolite S-2188-DC which, by hydroxylation, forms the metabolite S-2188-OH¹² (EFSA, 2012).

Based on the plant metabolism studies, the peer review established the residue definition for monitoring as fenpyrazamine and for risk assessment as sum of fenpyrazamine and S-2188-DC, expressed as fenpyrazamine (EFSA, 2012). The current residue definition set in Regulation (EC) No 396/2005 is identical to the residue definition for enforcement derived during the peer review.

For the uses on the crops under consideration, EFSA concludes that the metabolism of fenpyrazamine 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

All samples from the supervised residue trials were analysed for both the parent compound and the metabolite S-2188-DC. To comply with the residue definition established for risk assessment, for each pair of residues, the concentration of the metabolite was first converted into parent equivalents by using a conversion factor of 1.43 based on the ratio between the molecular weights of the two compounds and then added to the fenpyrazamine residue.

a. Almonds

Import tolerance: five GAP-compliant residue trials (one designed as decline study) and two additional trials at twice the intended application rate performed at different sites in the USA during a single season were submitted. No residues of both fenpyrazamine and S-2188-DC were determined in the samples, even at the exaggerated rate. Considering that tree nuts are not classified as major crops worldwide (EC, 2011), EFSA concludes that the number of trials is sufficient to derive an import tolerance proposal of 0.01 mg/kg (LOQ) for almonds. A conversion factor (CF) for enforcement to risk assessment of 2 was calculated from the residue data.

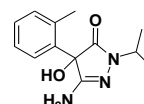
b. Table and wine grapes

Import tolerance: fourteen GAP-compliant field residue trials (two designed as decline studies) performed at different sites in the USA and Canada during different seasons on table and wine grapes were submitted. Five studies were performed with the water dispersible granule (WG) formulation, six studies with the suspension concentrate (SC) formulation and three trials were designed as side-by-side bridging trials comparing the WG and SC formulation. The results were combined in a single dataset since comparable residues were observed (the data showed to belong to a similar population, Mann-Whitney U-Test, FAO, 2009). The number of trials is sufficient to derive an import tolerance proposal of 3 mg/kg for grapes and a CF of 1.2.

c. Strawberries

Import tolerance: eight GAP-compliant field residue trials (two designed as decline studies) performed at different sites in the USA and Canada during different seasons were submitted. Three studies were performed with the water dispersible granule (WG) formulation, two studies with the suspension concentrate (SC) formulation and three trials were designed as side-by-side bridging trials comparing the WG and SC formulation. The results were combined in a single dataset since comparable residues were observed (the data showed to belong to a similar population, Mann-Whitney U-Test, FAO, 2009). The number of trials is sufficient to derive an import tolerance proposal of 3 mg/kg and a CF of 1.1.

¹² S-2188-OH: 5-amino-2,4-dihydro-4-hydroxy-2-isopropyl-4-(o-tolyl)pyrazol-3-one.



Indoor-EU: eight GAP-compliant residue trials (four designed as decline studies) performed under plastic tunnel conditions (seven trials) and in greenhouse (one trial) during two different seasons were submitted. Since strawberries are classified as major crops in the EU (EC, 2011), the number of trials is sufficient to derive a MRL proposal of 3 mg/kg for the indoor use on strawberries and a CF of 1.2.

Outdoor-NEU: four GAP-compliant field residue trials (two designed as decline studies) performed during a single season were submitted. Since strawberries are classified as major crops in NEU (EC, 2011), the data are not sufficient to derive a MRL proposal.

Outdoor-SEU: four GAP-compliant field residue trials (two designed as decline studies) performed during two different seasons were submitted. Since strawberries are classified as major crops in SEU (EC, 2011), the data are not sufficient to derive a MRL proposal.

EFSA concludes that the use on strawberries imported from the USA is the most critical use to derive the MRL proposal and the risk assessment input values.

d. Peaches, including nectarines and similar hybrids

Outdoor-NEU: four GAP-compliant field residue trials (two designed as decline studies) performed during two different seasons were submitted. Peaches are classified as a minor crop in NEU (EC, 2011), therefore the number of trials is sufficient to derive a MRL proposal of 3 mg/kg and a CF of 1.4.

Outdoor-SEU: eight GAP-compliant field residue trials (four designed as decline studies) performed during two different seasons were submitted. Peaches are classified as a major crop in SEU (EC, 2011), therefore the number of trials is sufficient to derive a MRL proposal of 4 mg/kg and a CF of 1.2.

EFSA concludes that the intended use in SEU is the most critical use to derive the MRL proposal and the risk assessment input values on peaches, including nectarines and similar hybrids.

e. Apricots

Outdoor-NEU: no residues trials were submitted on apricots and the applicant proposed to extrapolate the residues from the trials performed on peaches since the GAPs are identical. According to the latest revision 9 of the EU guidance document, the proposed extrapolation is not acceptable. At least four residue trials on apricots are required (EC, 2011).

Outdoor-SEU: no residues trials were submitted on apricots and the applicant proposed to extrapolate residues from the trials performed on peaches since the GAPs are identical. According to the latest revision 9 of the EU guidance document, the proposed extrapolation is not acceptable. At least 4 residue trials on apricots are required.

It is noted that the applicant submitted as additional information residue trials on plums (four NEU and two SEU trials) and cherries (two NEU and two SEU trials) performed at the same GAP as the other stone fruits. However, the extrapolation from plums and cherries to apricots is not foreseen in the EU (EC, 2011).

EFSA concludes that the submitted data are not sufficient to derive a MRL proposal for the intended use on apricots in NEU and SEU.

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

The storage stability of fenpyrazamine in primary crops was assessed during the peer review (Austria, 2011, EFSA, 2012). Residues of fenpyrazamine and the metabolite S-2188-DC were stable in matrices

with high water (lettuce), high acid (grapes), and high oil (rapeseed) content as well as in dry matrices (cereal grains) when stored stabilised at $\leq -18^{\circ}\text{C}$ for up to 12 months. An additional storage stability trial on grapes submitted in the framework of the import tolerance request showed that residues of fenpyrazamine are stable under frozen condition for up to 35 months (Austria, 2012a). Since the samples from the supervised residue trials on grapes, strawberries and peaches were stored under conditions for which integrity of the samples was demonstrated (Austria, 2012a, 2012b), EFSA concludes that the results from the residue data on strawberries, grapes and peaches are valid.

The samples from the residue trials on almonds were stored for up to 818 days, thus exceeding the period assessed in the stability studies. Results from a storage stability study on almond hull samples submitted by the applicant confirmed that fenpyrazamine is stable in the outer shell for at least 440 days (Austria, 2012a). The longer storage period is not expected to have affected the results of the residue field trials. However, the validity of residue trial data in the shelled almonds is further to be demonstrated by providing adequate storage stability studies.

According to the EMS, the analytical methods used to analyse the supervised residue trial samples have been sufficiently validated and were proven to be fit for purpose (Austria, 2012a, 2012b).

EFSA concludes that the data are sufficient to derive the following MRL proposal: 0.01*mg/kg for almonds, 3 mg/kg for strawberries and 4 mg/kg for peaches, including nectarines and similar hybrids. An amendment of the existing MRL on grapes is not necessary, while the data are not sufficient to propose a MRL for the intended uses on apricots.

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 (fenpyrazamine)	Risk assessment (sum of fenpyrazamine and S-2188-DC ^(f) expressed as fenpyrazamine)					
Enforcement residue definition: fenpyrazamine									
Almonds	Import (US)	Outdoor	Fenpyrazamine: 5 x <0.01	5 x <0.02	0.01	0.01	0.01*	2	
			S-2188-DC: 5 x <0.01						
			2N application rate: Fenpyrazamine: 2 x <0.01 S-2188-DC: 2 x <0.01						Supportive information
Table ↔ Wine grapes	Import (US)	Outdoor	Fenpyrazamine: 0.33; 0.53; 0.55; 0.71; 0.8; 0.88; 0.91; 0.93; 1.01; 1.06 ^(h) ; 1.09; 1.10; 1.24; 2.08 S-2188-DC: 0.03; 0.06; 0.08; 0.17 ^(h) ; 0.16; 0.13; 0.19; 0.32; 0.19; 0.17; 0.12; 0.36; 0.13; 0.76	0.37; 0.62; 0.66; 0.95; 1.03; 1.07; 1.18; 1.26; 1.28; 1.3 ^(h) ; 1.39; 1.43; 1.61; 3.17	0.92	2.08	3	1.2	R _{ber} = 2.19 R _{max} = 2.09 MRL _{OECD} = 2.8/3
Strawberries	Import (US)	Outdoor	Fenpyrazamine: 0.39; 0.41; 0.54; 0.87; 0.88; 0.95; 1.3; 1.7 S-2188-DC: 0.14; 0.06; 0.03; 0.05; 0.08; 0.19; 0.13; 0.07	0.5; 0.58; 0.59; 0.94; 0.99; 1.22; 1.49; 1.8	0.88	1.7	3	1.1	R _{ber} = 2.43 R _{max} = 2.32 MRL _{OECD} = 2.69/3
	EU	Indoor ^(g)	Fenpyrazamine: 0.24; 0.28; 0.35 ^(h) ; 0.45; 0.76; 0.86; 0.92; 1.4	0.28; 0.36 ^(h) ; 0.47; 0.54; 1.0; 1.07; 1.15; 2.03	0.61	1.4	3	1.2	R _{ber} = 1.81 R _{max} = 1.94 MRL _{OECD} = 2.26/3

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 (fenpyrazamine)	Risk assessment (sum of fenpyrazamine and S-2188-DC ^(h) expressed as fenpyrazamine)					
			<i>S-2188-DC</i> : 0.03; 0.13; 0.01 ^(h) ; 0.06; 0.22; 0.1; 0.16; 0.44						
	NEU	Outdoor	<i>Fenpyrazamine</i> : 0.3; 0.64; 0.65 ^(h) ; 1.3 <i>S-2188-DC</i> : 0.06; 0.13; 0.13 ^(h) ; 0.1	0.39; 0.83 ^(h) ; 0.84; 1.44	0.65	1.3	-	-	The number of residue trials is not sufficient to derive a MRL proposal for the intended NEU and SEU uses.
	SEU	Outdoor	<i>Fenpyrazamine</i> : 0.28; 0.47; 0.54; 1.4 <i>S-2188-DC</i> : 0.09; 0.16; 0.19; 0.18	0.41; 0.7; 0.81; 1.66	0.51	1.6	-	-	
Peaches, including nectarines, similar hybrids	NEU	Outdoor	<i>Fenpyrazamine</i> : 0.36; 0.61; 0.76 ^(h) ; 1.5 <i>S-2188-DC</i> : 0.26; 0.11, 0.24 ^(h) ; 0.06	0.73; 0.77; 1.1 ^(h) ; 1.59	0.69	1.5	3	1.4	R _{ber} = 2.63 R _{max} = 3.33 MRL _{OECD} = 2.77/3
	SEU	Outdoor	<i>Fenpyrazamine</i> : 0.44 ^(h) ; 0.55; 0.7; 0.85 ^(h) ; 0.94; 0.95; 1.1; 2.5 <i>S-2188-DC</i> : 0.31 ^(h) ; 0.04; 0.17; 0.28 ^(h) ; <0.01; 0.12; 0.12; <0.01	0.61; 0.88 ^(h) ; 0.94; 0.95; 1.12; 1.25 ^(h) ; 1.26; 2.51	0.9	2.5	4	1.2	R _{ber} = 2.13 R _{max} = 3.05 MRL _{OECD} = 3.58/4
Apricots	NEU	Outdoor	-	-	No residue trials available. At least 4 trials on apricots are required to support the MRL proposal.				

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 (fenpyrazamine)	Risk assessment (sum of fenpyrazamine and S-2188-DC ^(f) expressed as fenpyrazamine)					
	SEU	Outdoor	-	-	No residue trials available. At least 4 trials on apricots are required to support the MRL proposal by extrapolation from combined data on peaches and apricots (EC, 2011).				

(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 median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residue 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 of S-2188-DC were converted in fenpyrazamine equivalents by using the factor of 1.43 obtained from the molecular weight ratio of the compounds (fenpyrazamine/S-2188-DC = 331.4/231.3).

(g): Protected (plastic tunnel) conditions.

(h): Highest values measured in the decline studies at a longer PHI (4 days for grapes and 3 days for strawberries and peaches) than the PHI of the intended GAP.

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

3.1.1.3. Effect of industrial processing and/or household preparation

The effect of processing on the nature of fenpyrazamine was investigated in studies performed at three test conditions representing pasteurisation, baking/brewing/boiling and sterilisation (20 minutes at 90°C, pH 4; 60 minutes at 100°C pH 5; 20 minutes at 120°C, pH 6). The studies were reported in the DAR and in the conclusion on the peer review (Austria, 2011; EFSA, 2012). EFSA concluded that the active substance is hydrolytically stable under standard hydrolysis conditions even if a slight degradation to the metabolite S-2188-DC was observed under conditions simulating sterilisation (8.6 % of the applied radioactivity). No other hydrolysis products were formed. Therefore, the same residue definitions for monitoring and risk assessment set for raw agricultural commodities (RAC) apply to processed commodities (EFSA, 2012).

Specific studies to assess the magnitude of fenpyrazamine residues during the processing of the products under consideration are not necessary as the total theoretical maximum daily intake (TMDI) amounts to less than 10 % of the ADI (EC, 1997d).

However, in addition to the processing studies assessed in the framework of the peer review and a previous MRL application (EFSA, 2011, 2012) the applicant has submitted additional processing studies on grapes (juice and raisins) (Austria, 2012a). In Table 3-3 the updated results on processing studies for grape juice and raisins are reported.

Table 3-3: Overview of the available processing studies on grape juice and raisins

Processed commodity	Number of studies	Median PF ^(a)	Median CF ^(b)	Individual PF
Enforcement residue definition: fenpyrazamine				
Risk assessment residue definition: sum of fenpyrazamine and S-2188-DC expressed as fenpyrazamine				
Grape, juice (pasteurised)	5	0.16	1.5	0.06; 0.09; 0.016; 0.31 (EFSA, 2011, 2012)
				2.02
Grape, raisins	4	1.65	1.1	1.62; 1.67; 2.8 (EFSA, 2011, 2012)
				1.06

(a): The median processing factor is obtained by calculating the median of the individual processing factors of each processing study.

(b): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors of each processing study.

The following revised processing factors for grapes are recommended to be included in Annex VI of Regulation (EC) No 396/2005:

- Grape, juice: 0.16
- Grape, raisins: 1.65

3.1.2. Rotational crops

3.1.2.1. Preliminary considerations

Strawberries can be grown in rotation with other plants and therefore the possible occurrence of residues in succeeding crops resulting from the use on primary crops has to be assessed. The soil degradation studies demonstrated that the degradation rate of fenpyrazamine is moderate; the maximum field DT₉₀ was 133.9 days (EFSA, 2012), which is above the trigger value of 100 days. Thus, further studies investigating the nature and magnitude of the compound uptake in rotational crops are required (EC, 1997c).

3.1.2.2. Nature of residues

The metabolism of fenpyrazamine in rotational crops was assessed during the peer review (EFSA, 2012). The details of the metabolism studies are reported in the DAR and a previous EFSA reasoned opinion (Austria, 2011; EFSA, 2011). The overview of the study designs is presented in the table below.

Table 3-4: Overview of the available confined rotational crop studies

Crop group	Crop sown	Label position	Application details				Remarks
			Method	Rate (kg a.s./ha)	Sowing intervals	Harvest time	
fenpyrazamine							
Leafy vegetable	Lettuce	Pyrazolyl-5- ¹⁴ C	Bare soil application	1 x 2.83	30, 120, 35 DAT	n.r.	All the rotational crops grown to maturity.
Root/tuber vegetables	Carrots						
Cereals	Wheat						

n.r.: not reported in the DAR (Austria, 2011).

Residues were mostly composed of the parent fenpyrazamine and two metabolites (S-2188-OH and S-2188(OH)₂¹³). Metabolite S-2188-DC detected in primary crops was not detected in rotational crops, except in wheat forage (1% TRR).

The peer review concluded that the metabolism of the active substance in rotational crops is similar to the pathway observed in primary crops and the same residue definitions as for RAC apply (EFSA, 2012).

3.1.2.3. Magnitude of residues

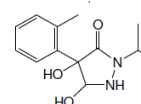
Rotational field crop studies in carrot, lettuce, tomato and barley were assessed in the DAR and in the conclusion of the peer review (Austria, 2011; EFSA, 2012). The studies were performed using tomato as primary crop treated at the application rate of 3 x 0.6 kg a.s./ha with 6-8 d-intervals in compliance with the intended European use. No residues of fenpyrazamine or its metabolite S-2188-OH were found above the LOQ of the analytical method (0.01 mg/kg) in the succeeding crops sown 1, 4 (or 8), and 12 months after the final application on the primary tomato crop.

Based on the available information on the nature and magnitude of the residues, EFSA concludes that relevant residue levels are unlikely to occur in rotational crops provided that the compound is used on strawberries according to the proposed GAP.

3.2. Nature and magnitude of residues in livestock

Since the crops under considerations are not normally fed to livestock, the nature and magnitude of fenpyrazamine residues in livestock is not assessed in the framework of this application (EC, 1996).

¹³ S-2188-(OH)₂: 4,5-dihydroxy-4-(2-methylphenyl)-2-(propan-2-yl)pyrazolidin-3-one.



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 population¹⁴ (EFSA, 2007).

For the calculation of chronic exposure, EFSA used the median residue values multiplied by the corresponding conversion factor (CF) for risk assessment as derived from the residue trials on almonds, grapes, strawberries and peaches (see Table 3-2) and the median residue values multiplied by the corresponding CFs as reported in a previously issued EFSA reasoned opinion (EFSA, 2011). For the remaining commodities of plant and animal origin, the existing MRLs as established in Annex IIIA of Regulation (EC) No 396/2005 were used as input values.

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 the commodities under consideration assuming the consumption of a large portion of the food items as reported in the national food surveys and that these items contained residues at the highest level as observed in supervised field trials. The highest residue values were multiplied by the corresponding CF as well. 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 summarised 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: sum of fenpyrazamine and S-2188-DC expressed as fenpyrazamine				
Almonds	0.02 (0.01*2)	Median residue*CF (import, US)	0.02 (0.01*2)	Highest residue*CF (import, US)
Grapes	1.10 (0.92*1.2)	Median residue*CF (import, US)	2.50 (2.08*1.2)	Highest residue*CF (import, US)
Strawberries	0.97 (0.88*1.1)	Median residue*CF (import, US)	1.87 (1.7*1.1)	Highest residue*CF (import, US.)
Peaches	1.08 (0.9*1.2)	Median residue*CF (outdoor, SEU)	3.00 (2.5*1.2)	Highest residue*CF (outdoor, SEU)
Tomatoes, aubergines	0.78	Median residue*CF (EFSA, 2011)	Acute risk assessment was undertaken only with regard to the crops under consideration.	
Peppers	0.9	Median residue*CF (EFSA, 2011)		

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).

Commodity	Chronic exposure assessment		Acute exposure assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Cucurbits, edible peel	0.21	Median residue*CF (EFSA, 2011)		
Other commodities of plant and animal origin	0.01	Existing MRLs		

The estimated exposure was then compared with the toxicological reference values derived for fenpyrazamine (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 accounted for 5 % of the ADI (WHO Cluster diet B). The contribution of residues in the crops under consideration to the total consumer exposure accounted for a maximum of 3.4 % of the ADI for wine grapes (FR all population), 1.1 % of the ADI for table grapes (DE child diet) and less than 0.5 % of the ADI for both peaches (IE adult diet) and strawberries (FR toddler diet).

No acute consumer risk was identified in relation to the MRL proposals for the crops under consideration. The calculated maximum exposure in percentage of the ARfD was 59.3 % for peaches, 54.5 % for table grapes, 9.7 % for strawberries and 6.5 % for wine grapes. No consumption data for almonds are incorporated in the EFSA PRIMo (EFSA, 2007).

EFSA concludes that the intended use of fenpyrazamine on almonds, grapes, peaches (including nectarines and hybrids) and strawberries will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a public health concern.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The toxicological profile of fenpyrazamine was assessed in the framework of the approval of the active substance under Regulation (EC) No 1107/2009 and the data were sufficient to derive an ADI of 0.13 mg/kg bw per day and an ARfD of 0.3 mg/kg bw.

The metabolism of fenpyrazamine in primary crops was investigated after foliar application on three different crop groups: fruit and fruiting vegetables (grapes), leafy vegetables (lettuce) and pulses/oilseeds (oilseed rape). From these studies, the peer review concluded to establish the residue definition for enforcement as fenpyrazamine and for risk assessment as the sum of fenpyrazamine and S-2188-DC, expressed as fenpyrazamine. For the use on the crops under consideration, EFSA concludes that the metabolism of fenpyrazamine in primary crops is sufficiently addressed and that the agreed residue definitions are applicable.

EFSA considers that the submitted supervised residue trials are sufficient to derive the following MRL proposal: 0.01*mg/kg for almonds, 3 mg/kg for strawberries and 4 mg/kg for peaches, including nectarines and similar hybrids. An amendment of the existing MRL on grapes is not necessary, while the data are not sufficient to propose a MRL for the intended uses on apricots. The MRL proposal on almonds is considered provisional because the residue trial samples were stored for a period for which the validity of the results is not fully demonstrated. Adequate analytical enforcement methods are available to control the residues of fenpyrazamine in the crops under consideration at the validated LOQ of 0.01 mg/kg.

Based on the results of hydrolysis studies on the effect of processing on the nature of fenpyrazamine residues, the peer review concluded that for processed commodities the same residue definitions as for raw agricultural commodities (RAC) apply. Specific studies investigating the magnitude of fenpyrazamine residues in processed grapes (juice and raisins) were submitted. Taking into account these studies, the processing factors derived during the peer review and in a previous reasoned opinion have to be slightly modified. Thus, the following revised processing factors are recommended to be included in Annex VI of Regulation (EC) No 396/2005:

- Grape, juice: 0.16
- Grape, raisins: 1.65

The occurrence of fenpyrazamine residues in rotational crops was investigated in the framework of the peer review. Based on the available information on the nature and magnitude of residues in succeeding crops, EFSA concludes that significant residue levels are unlikely to occur in rotational crops provided that the compound is used on strawberries according to the proposed GAP (Good Agricultural Practice).

Residues of fenpyrazamine in commodities of animal origin were not assessed in the framework of this application, since the products under consideration are normally not fed to livestock.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticides Residue Intake Model (PRIMO). For the calculation of the exposure, EFSA used the median residue and the higher residue values multiplied by the corresponding conversion factor (CF) for risk assessment as derived from the residue trials on almonds, grapes, strawberries and peaches and the median residue values (multiplied by the corresponding CF) as reported in a previously issued EFSA reasoned opinion. The acute exposure assessment was performed only with regard to the commodities under consideration. The estimated exposure was then compared with the toxicological reference values derived for fenpyrazamine.

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake accounted for 5 % of the ADI (WHO Cluster diet B).

The contribution of residues among the crops assessed accounted for a maximum of 3.4 % of the ADI (wine grapes). No acute consumer risk was identified in relation to the MRL proposals for the crops under consideration. The calculated maximum exposure in percentage of the ARfD was 59.3 % for peaches, 54.5 % for table grapes, 9.7 % for strawberries and 6.5 % in wine grapes. The acute exposure via residues in almonds is negligible.

EFSA concludes that the proposed uses of fenpyrazamine on almonds, grapes, peaches and strawberries will not result in a consumer exposure exceeding the toxicological reference values and therefore are unlikely to pose a consumer health risk.

RECOMMENDATIONS

Code number ^(a)	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: fenpyrazamine				
120010	Almonds	0.01*	0.01* (provisional)	The derived MRL (import tolerance) is supported by data and no risk for consumers was identified for the import tolerance request. The validity of the residue trial data is further to be demonstrated by providing adequate storage stability studies.
140030	Peaches (nectarines and similar hybrids)	0.01*	4	The MRL proposal based on an intended use in SEU is sufficiently supported by data and no risk for consumers was identified for the intended uses in NEU and SEU.
140010	Apricots	0.01*	No new proposal	The submitted residue data on peaches are not sufficient to derive a MRL proposal by extrapolation.
151000	Table and wine grapes	3	3	An amendment of the existing MRL is not necessary. The import tolerance is sufficiently supported by data and no risk for consumers was identified.
152000	Strawberries	0.01*	3	The MRL proposal is sufficiently supported by data and no risk for consumers was identified for the intended uses under protected conditions in EU and for the import tolerance request. The submitted residue data are not sufficient to derive a MRL proposal for the outdoor use in NEU and SEU.

(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

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		
Almonds	US	F	<i>Botrytis</i>	SC	436 g/L	Foliar		3				0.42	21	GAP for import
Grapes	US	F	<i>Botrytis</i>	SC WG	436 g/L 500 g/kg	Foliar		3				0.56	3	GAP for import
Strawberries	US	F	<i>Botrytis</i>	SC WG	436 g/L 500 g/kg	Foliar		3				0.56	0	GAP for import
	AT	F	<i>Botrytis</i>	WG	500 g/kg	Foliar	BBCH 59-89	3	7		500-2000	0.6	1	cGAP for NEU
	BE, CZ, DE, IE, UK, HU, NL, PL, RO, SK, SL	F	<i>Botrytis</i>	WG	500 g/kg	Foliar	BBCH 61-87	3	7		500-2000	0.6	1	
	BG, CY, EL, ES, FR, PT	F	<i>Botrytis</i>	WG	500 g/kg	Foliar	BBCH 61-87	3	7		100-1200	0.6	1	cGAP for SEU
	IT	F	<i>Botrytis</i>	WG	500 g/kg	Foliar	BBCH 61-87	3	7		300-1000	0.6	3	
	AT	P ⁽¹⁾	<i>Botrytis</i>	WG	500 g/kg	Foliar	BBCH 59-89	3	7		500-2000	0.6	1	cGAP for EU
	BE, BG, CY, CZ, DE, DK, EL, ES, FR, HU, IE, LT, LV, PL, PT,	P ⁽¹⁾	<i>Botrytis</i>	WG	500 g/kg	Foliar	BBCH 61-87	3	7		100-2000	0.6	1	

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		
	NL, RO, SE, SK, SL, UK													
	IT	P ⁽¹⁾	<i>Botrytis</i>	WG	500 g/kg	Foliar	BBCH 61-87	3	7		300-1000	0.6	3	
Peaches, nectarines, apricots	AT	F	<i>Monilia laxa</i> , <i>M. fructigena</i>	WG	500 g/kg	Foliar	BBCH 57-89	3	7		300-1500	0.6	1	cGAP for NEU
	CZ, DE, HU, PL, RO, SK, SL	F	<i>Monilia</i> spp.	WG	500 g/kg	Foliar	BBCH 61-87	3	7		500-1500	0.6	1	
	BG, CY, EL, ES, FR, PT	F	<i>Monilia</i> spp.	WG	500 g/kg	Foliar	BBCH 61-87	3	7		500-1500	0.6	1	cGAP for SEU
	IT	F	<i>Monilia</i> spp.	WG	500 g/kg	Foliar	BBCH 61-87	3	7		500-1500	0.6	3	

- 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
 - (1) Protected (plastic tunnel) conditions (P).
 - (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)

<div> <div>Fenpyrazamide</div> <div> <div>Status of the active substance: approved</div> <div>Code no.</div> </div> <div> <div>LOQ (mg/kg bw): 0.01</div> <div>proposed LOQ:</div> </div> <div>Toxicological end points</div> <div> <div>ADI (mg/kg bw/day): 0.13</div> <div>ARfD (mg/kg bw): 0.3</div> </div> <div> <div>Source of ADI: EC</div> <div>Source of ARfD: EC</div> </div> <div> <div>Year of evaluation: 2012</div> <div>Year of evaluation: 2012</div> </div> </div>									
Chronic risk assessment - refined calculations									
				TMDI (range) in % of ADI minimum - maximum					
				1 5					
				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	pTMRs at LOQ (in % of ADI)
	5.0	WHO Cluster diet B	1.9	Tomatoes	1.5	Wine grapes	0.4	Peaches	0.3
	4.1	FR all population	3.4	Wine grapes	0.3	Tomatoes	0.1	Peaches	0.1
	3.5	PT General population	2.1	Wine grapes	0.5	Tomatoes	0.3	Peaches	0.1
	2.9	DE child	1.1	Table grapes	0.6	Tomatoes	0.4	Strawberries	0.4
	2.8	IE adult	1.1	Wine grapes	0.5	Peaches	0.2	Tomatoes	0.3
	2.3	WHO cluster diet E	1.4	Wine grapes	0.3	Tomatoes	0.1	Table grapes	0.2
	1.9	NL child	0.6	Table grapes	0.4	Tomatoes	0.2	Milk and cream,	0.5
	1.8	DK adult	1.2	Wine grapes	0.2	Tomatoes	0.1	Peaches	0.1
	1.7	FR toddler	0.5	Tomatoes	0.5	Strawberries	0.3	Milk and cream,	0.5
	1.6	WHO regional European diet	0.7	Tomatoes	0.2	Wine grapes	0.2	Peaches	0.2
	1.6	IT kids/toddler	0.9	Tomatoes	0.3	Peaches	0.1	Table grapes	0.1
	1.5	WHO cluster diet D	0.6	Tomatoes	0.3	Wine grapes	0.2	Table grapes	0.2
	1.4	UK Adult	0.9	Wine grapes	0.3	Tomatoes	0.0	Table grapes	0.1
	1.4	UK vegetarian	0.7	Wine grapes	0.4	Tomatoes	0.1	Table grapes	0.1
	1.4	IT adult	0.7	Tomatoes	0.3	Peaches	0.1	Table grapes	0.1
	1.4	WHO Cluster diet F	0.5	Wine grapes	0.4	Tomatoes	0.1	Table grapes	0.2
	1.4	ES adult	0.5	Tomatoes	0.4	Wine grapes	0.2	Peaches	0.1
	1.4	DK child	0.3	Tomatoes	0.3	Cucumbers	0.2	Table grapes	0.3
	1.3	NL general	0.5	Wine grapes	0.3	Tomatoes	0.2	Table grapes	0.2
	1.3	UK Toddler	0.4	Tomatoes	0.2	Table grapes	0.2	Sugar beet (root)	0.5
	1.2	SE general population 90th percentile	0.5	Tomatoes	0.1	Peppers	0.1	Strawberries	0.2
	1.2	ES child	0.6	Tomatoes	0.2	Peaches	0.1	Milk and cream,	0.3
	1.0	FR infant	0.4	Strawberries	0.2	Milk and cream,	0.1	Courgettes	0.3
	1.0	PL general population	0.5	Tomatoes	0.3	Table grapes	0.1	Peppers	0.1
	1.0	UK Infant	0.3	Milk and cream,	0.2	Tomatoes	0.2	Strawberries	0.5
	0.8	FI adult	0.3	Wine grapes	0.3	Tomatoes	0.1	Strawberries	0.1
	0.6	LT adult	0.4	Tomatoes	0.1	Cucumbers	0.0	Milk and cream,	0.1
Conclusion: The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRs were below the ADI. A long-term intake of residues of Fenpyrazamide 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 variability 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		
	*)			*)			*)			*)		
	**) pTMRL/ threshold MRL (mg/kg)			**) pTMRL/ threshold MRL (mg/kg)			**) pTMRL/ threshold MRL (mg/kg)			**) pTMRL/ threshold MR (mg/kg)		
	Highest % of ARfD/ADI	Commodities		Highest % of ARfD/ADI	Commodities		Highest % of ARfD/ADI	Commodities		Highest % of ARfD/ADI	Commodities	
	59.3	Peaches	3 / -	54.5	Table grapes	2.496 / -	26.4	Table grapes	2.496 / -	26.4	Table grapes	2.496 / -
	54.5	Table grapes	2.496 / -	43.5	Peaches	3 / -	19.8	Wine grapes	2.5 / -	19.8	Wine grapes	2.5 / -
	9.7	Strawberries	1.87 / -	9.7	Strawberries	1.87 / -	17.5	Peaches	3 / -	13.6	Peaches	3 / -
	6.5	Wine grapes	2.5 / -	6.5	Wine grapes	2.5 / -	3.3	Strawberries	1.87 / -	3.3	Strawberries	1.87 / -
	0.0	Almonds	0.02 / -	0.0	Almonds	0.02 / -	0.0	Almonds	0.02 / -	0.0	Almonds	0.02 / -
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:			No of commodities for which ARfD/ADI is exceeded:			No of commodities for which ARfD/ADI is exceeded:		
	***)			***)			***)			***)		
	**) pTMRL/ threshold MRL (mg/kg)			**) pTMRL/ threshold MRL (mg/kg)			**) pTMRL/ threshold MRL (mg/kg)			**) pTMRL/ threshold MRL (mg/kg)		
	Highest % of ARfD/ADI	Processed commodities		Highest % of ARfD/ADI	Processed commodities		Highest % of ARfD/ADI	Processed commodities		Highest % of ARfD/ADI	Processed commodities	
*) 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 Fenpyrazamide 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 30/10/2012 16:52)

Code number	Groups and examples of individual products to which the MRLs apply	Fenpyrazamine
100000	1. FRUIT FRESH OR FROZEN; NUTS	
110000	(i) Citrus fruit	0,01*
110010	Grapefruit (Shaddocks, pomelos, sweets, tangelo, ugli and other hybrids)	0,01*
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0,01*
110030	Lemons (Citron, lemon)	0,01*
110040	Limes	0,01*
110050	Mandarins (Clementine, tangerine and other hybrids)	0,01*
110990	Others	0,01*
120000	(ii) Tree nuts (shelled or unshelled)	0,01*
120010	Almonds	0,01*
120020	Brazil nuts	0,01*
120030	Cashew nuts	0,01*
120040	Chestnuts	0,01*
120050	Coconuts	0,01*
120060	Hazelnuts (Filbert)	0,01*
120070	Macadamia	0,01*
120080	Pecans	0,01*
120090	Pine nuts	0,01*
120100	Pistachios	0,01*
120110	Walnuts	0,01*
120990	Others	0,01*
130000	(iii) Pome fruit	0,01*
130010	Apples (Crab apple)	0,01*
130020	Pears (Oriental pear)	0,01*
130030	Quinces	0,01*
130040	Medlar	0,01*
130050	Loquat	0,01*
130990	Others	0,01*
140000	(iv) Stone fruit	0,01*
140010	Apricots	0,01*
140020	Cherries (sweet cherries, sour cherries)	0,01*
140030	Peaches (Nectarines and similar hybrids)	0,01*
140040	Plums (Damson, greengage, mirabelle)	0,01*
140990	Others	0,01*
150000	(v) Berries & small fruit	

Code number	Groups and examples of individual products to which the MRLs apply	Fenpyrazamine
151000	(a) Table and wine grapes	3
151010	Table grapes	3
151020	Wine grapes	3
152000	(b) Strawberries	0,01*
153000	(c) Cane fruit	0,01*
153010	Blackberries	0,01*
153020	Dewberries (Loganberries, Boysenberries, and cloudberrries)	0,01*
153030	Raspberries (Wineberries)	0,01*
153990	Others	0,01*
154000	(d) Other small fruit & berries	0,01*
154010	Blueberries (Bilberries cowberries (red bilberries))	0,01*
154020	Cranberries	0,01*
154030	Currants (red, black and white)	0,01*
154040	Gooseberries (Including hybrids with other ribes species)	0,01*
154050	Rose hips	0,01*
154060	Mulberries (arbutus berry)	0,01*
154070	Azarole (mediterranean medlar)	0,01*
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea sallowthorn), hawthorn, service berries, and other treeberries)	0,01*
154990	Others	0,01*
160000	(vi) Miscellaneous fruit	0,01*
161000	(a) Edible peel	0,01*
161010	Dates	0,01*
161020	Figs	0,01*
161030	Table olives	0,01*
161040	Kumquats (Marumi kumquats, nagami kumquats)	0,01*
161050	Carambola (Bilimbi)	0,01*
161060	Persimmon	0,01*
161070	Jambolan (java plum) (Java apple (water apple), pomarac, rose apple,	0,01*

Code number	Groups and examples of individual products to which the MRLs apply	Fenpyrazamine
	Brazilian cherry (grumichama), Surinam cherry)	
161990	Others	0,01*
162000	(b) Inedible peel, small	0,01*
162010	Kiwi	0,01*
162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	0,01*
162030	Passion fruit	0,01*
162040	Prickly pear (cactus fruit)	0,01*
162050	Star apple	0,01*
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammeey sapote)	0,01*
162990	Others	0,01*
163000	(c) Inedible peel, large	0,01*
163010	Avocados	0,01*
163020	Bananas (Dwarf banana, plantain, apple banana)	0,01*
163030	Mangoes	0,01*
163040	Papaya	0,01*
163050	Pomegranate	0,01*
163060	Cherimoya (Custard apple, sugar apple (sweetsop) , llana and other medium sized Annonaceae)	0,01*
163070	Guava	0,01*
163080	Pineapples	0,01*
163090	Bread fruit (Jackfruit)	0,01*
163100	Durian	0,01*
163110	Soursop (guanabana)	0,01*
163990	Others	0,01*
200000	2. VEGETABLES FRESH OR FROZEN	
210000	(i) Root and tuber vegetables	0,01*
211000	(a) Potatoes	0,01*
212000	(b) Tropical root and tuber vegetables	0,01*
212010	Cassava (Dasheen, eddoe (Japanese taro), tannia)	0,01*
212020	Sweet potatoes	0,01*
212030	Yams (Potato bean (yam	0,01*

Code number	Groups and examples of individual products to which the MRLs apply	Fenpyrazamine
	bean), Mexican yam bean)	
212040	Arrowroot	0,01*
212990	Others	0,01*
213000	(c) Other root and tuber vegetables except sugar beet	0,01*
213010	Beetroot	0,01*
213020	Carrots	0,01*
213030	Celeriac	0,01*
213040	Horseradish	0,01*
213050	Jerusalem artichokes	0,01*
213060	Parsnips	0,01*
213070	Parsley root	0,01*
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	0,01*
213090	Salsify (Scorzonera, Spanish salsify (Spanish oysterplant))	0,01*
213100	Swedes	0,01*
213110	Turnips	0,01*
213990	Others	0,01*
220000	(ii) Bulb vegetables	0,01*
220010	Garlic	0,01*
220020	Onions (Silverskin onions)	0,01*
220030	Shallots	0,01*
220040	Spring onions (Welsh onion and similar varieties)	0,01*
220990	Others	0,01*
230000	(iii) Fruiting vegetables	
231000	(a) Solanacea	
231010	Tomatoes (Cherry tomatoes,)	3
231020	Peppers (Chilli peppers)	3
231030	Aubergines (egg plants) (Pepino)	3
231040	Okra, lady's fingers	0,01*
231990	Others	0,01*
232000	(b) Cucurbits - edible peel	0,7
232010	Cucumbers	0,7
232020	Gherkins	0,7
232030	Courgettes (Summer squash, marrow (patisson))	0,7
232990	Others	0,7
233000	(c) Cucurbits-inedible peel	0,01*
233010	Melons (Kiwano)	0,01*

Code number	Groups and examples of individual products to which the MRLs apply	Fenpyrazamine
233020	Pumpkins (Winter squash)	0,01*
233030	Watermelons	0,01*
233990	Others	0,01*
234000	(d) Sweet corn	0,01*
239000	(e) Other fruiting vegetables	0,01*
240000	(iv) Brassica vegetables	0,01*
241000	(a) Flowering brassica	0,01*
241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	0,01*
241020	Cauliflower	0,01*
241990	Others	0,01*
242000	(b) Head brassica	0,01*
242010	Brussels sprouts	0,01*
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0,01*
242990	Others	0,01*
243000	(c) Leafy brassica	0,01*
243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	0,01*
243020	Kale (Borecole (curly kale), collards)	0,01*
243990	Others	0,01*
244000	(d) Kohlrabi	0,01*
250000	(v) Leaf vegetables & fresh herbs	0,01*
251000	(a) Lettuce and other salad plants including Brassicaceae	0,01*
251010	Lamb's lettuce (Italian comsalad)	0,01*
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	0,01*
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curd leaf endive, sugar loaf)	0,01*
251040	Cress	0,01*
251050	Land cress	0,01*
251060	Rocket, Rucola (Wild rocket)	0,01*
251070	Red mustard	0,01*
251080	Leaves and sprouts of Brassica spp (Mizuna)	0,01*

Code number	Groups and examples of individual products to which the MRLs apply	Fenpyrazamine
251990	Others	0,01*
252000	(b) Spinach & similar (leaves)	0,01*
252010	Spinach (New Zealand spinach, turnip greens (turnip tops))	0,01*
252020	Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glasswort)	0,01*
252030	Beet leaves (chard) (Leaves of beetroot)	0,01*
252990	Others	0,01*
253000	(c) Vine leaves (grape leaves)	0,01*
254000	(d) Water cress	0,01*
255000	(e) Witloof	0,01*
256000	(f) Herbs	0,01*
256010	Chervil	0,01*
256020	Chives	0,01*
256030	Celery leaves (fennel leaves, Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cicely and other Apiacea)	0,01*
256040	Parsley	0,01*
256050	Sage (Winter savory, summer savory,)	0,01*
256060	Rosemary	0,01*
256070	Thyme (marjoram, oregano)	0,01*
256080	Basil (Balm leaves, mint, peppermint)	0,01*
256090	Bay leaves (laurel)	0,01*
256100	Tarragon (Hyssop)	0,01*
256990	Others	0,01*
260000	(vi) Legume vegetables (fresh)	0,01*
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	0,01*
260020	Beans (without pods) (Broad beans, Flageolet, jack bean, lima bean, cowpea)	0,01*
260030	Peas (with pods) (Mangetout (sugar peas))	0,01*
260040	Peas (without pods) (Garden pea, green pea,	0,01*

Code number	Groups and examples of individual products to which the MRLs apply	Fenpyrazamine
	chickpea)	
260050	Lentils	0,01*
260990	Others	0,01*
270000	(vii) Stem vegetables (fresh)	0,01*
270010	Asparagus	0,01*
270020	Cardoons	0,01*
270030	Celery	0,01*
270040	Fennel	0,01*
270050	Globe artichokes	0,01*
270060	Leek	0,01*
270070	Rhubarb	0,01*
270080	Bamboo shoots	0,01*
270090	Palm hearts	0,01*
270990	Others	0,01*
280000	(viii) Fungi	0,01*
280010	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	0,01*
280020	Wild (Chanterelle, Truffle, Morel,)	0,01*
280990	Others	0,01*
290000	(ix) Sea weeds	0,01*
300000	3. PULSES, DRY	0,01*
300010	Beans (Broad beans, navy beans, flageolet, jack beans, lima beans, field beans, cowpeas)	0,01*
300020	Lentils	0,01*
300030	Peas (Chickpeas, field peas, chickling vetch)	0,01*
300040	Lupins	0,01*
300990	Others	0,01*
400000	4. OILSEEDS AND OILFRUITS	0,01*
401000	(i) Oilseeds	0,01*
401010	Linseed	0,01*
401020	Peanuts	0,01*
401030	Poppy seed	0,01*
401040	Sesame seed	0,01*
401050	Sunflower seed	0,01*
401060	Rape seed (Bird rapeseed, turnip rape)	0,01*
401070	Soya bean	0,01*
401080	Mustard seed	0,01*
401090	Cotton seed	0,01*
401100	Pumpkin seeds	0,01*
401110	Safflower	0,01*
401120	Borage	0,01*
401130	Gold of pleasure	0,01*
401140	Hempseed	0,01*

Code number	Groups and examples of individual products to which the MRLs apply	Fenpyrazamine
401150	Castor bean	0,01*
401990	Others	0,01*
402000	(ii) Oilfruits	0,01*
402010	Olives for oil production	0,01*
402020	Palm nuts (palmoil kernels)	0,01*
402030	Palmfruit	0,01*
402040	Kapok	0,01*
402990	Others	0,01*
500000	5. CEREALS	0,01*
500010	Barley	0,01*
500020	Buckwheat	0,01*
500030	Maize	0,01*
500040	Millet (Foxtail millet, teff)	0,01*
500050	Oats	0,01*
500060	Rice	0,01*
500070	Rye	0,01*
500080	Sorghum	0,01*
500090	Wheat (Spelt) Triticale	0,01*
500990	Others	0,01*
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	0,01*
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	0,01*
620000	(ii) Coffee beans	0,01*
630000	(iii) Herbal infusions (dried)	0,01*
631000	(a) Flowers	0,01*
631010	Camomille flowers	0,01*
631020	Hybiscus flowers	0,01*
631030	Rose petals	0,01*
631040	Jasmine flowers	0,01*
631050	Lime (linden)	0,01*
631990	Others	0,01*
632000	(b) Leaves	0,01*
632010	Strawberry leaves	0,01*
632020	Rooibos leaves	0,01*
632030	Maté	0,01*
632990	Others	0,01*
633000	(c) Roots	0,01*
633010	Valerian root	0,01*
633020	Ginseng root	0,01*
633990	Others	0,01*
639000	(d) Other herbal infusions	0,01*
640000	(iv) Cocoa (fermented beans)	0,01*
650000	(v) Carob (st johns bread)	0,01*
700000	7. HOPS (dried), including hop pellets and	0,01*

Code number	Groups and examples of individual products to which the MRLs apply	Fenpyrazamine
	unconcentrated powder	
800000	8. SPICES	0,01*
810000	(i) Seeds	0,01*
810010	Anise	0,01*
810020	Black caraway	0,01*
810030	Celery seed (Lovage seed)	0,01*
810040	Coriander seed	0,01*
810050	Cumin seed	0,01*
810060	Dill seed	0,01*
810070	Fennel seed	0,01*
810080	Fenugreek	0,01*
810090	Nutmeg	0,01*
810990	Others	0,01*
820000	(ii) Fruits and berries	0,01*
820010	Allspice	0,01*
820020	Anise pepper (Japan pepper)	0,01*
820030	Caraway	0,01*
820040	Cardamom	0,01*
820050	Juniper berries	0,01*
820060	Pepper, black and white (Long pepper, pink pepper)	0,01*
820070	Vanilla pods	0,01*
820080	Tamarind	0,01*
820990	Others	0,01*
830000	(iii) Bark	0,01*
830010	Cinnamon (Cassia)	0,01*
830990	Others	0,01*
840000	(iv) Roots or rhizome	0,01*
840010	Liquorice	0,01*
840020	Ginger	0,01*
840030	Turmeric (Curcuma)	0,01*
840040	Horseradish	0,01*
840990	Others	0,01*
850000	(v) Buds	0,01*
850010	Cloves	0,01*
850020	Capers	0,01*
850990	Others	0,01*

Code number	Groups and examples of individual products to which the MRLs apply	Fenpyrazamine
860000	(vi) Flower stigma	0,01*
860010	Saffron	0,01*
860990	Others	0,01*
870000	(vii) Aril	0,01*
870010	Mace	0,01*
870990	Others	0,01*
900000	9. SUGAR PLANTS	0,01*
900010	Sugar beet (root)	0,01*
900020	Sugar cane	0,01*
900030	Chicory roots	0,01*
900990	Others	0,01*
1000000	10. PRODUCTS OF ANIMAL ORIGIN-TERRESTRIAL ANIMALS	0,01*
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	0,01*
1011000	(a) Swine	0,01*
1011010	Meat	0,01*
1011020	Fat free of lean meat	0,01*
1011030	Liver	0,01*
1011040	Kidney	0,01*
1011050	Edible offal	0,01*
1011990	Others	0,01*
1012000	(b) Bovine	0,01*
1012010	Meat	0,01*
1012020	Fat	0,01*
1012030	Liver	0,01*
1012040	Kidney	0,01*
1012050	Edible offal	0,01*
1012990	Others	0,01*
1013000	(c) Sheep	0,01*

Code number	Groups and examples of individual products to which the MRLs apply	Fenpyrazamine
1013010	Meat	0,01*
1013020	Fat	0,01*
1013030	Liver	0,01*
1013040	Kidney	0,01*
1013050	Edible offal	0,01*
1013990	Others	0,01*
1014000	(d) Goat	0,01*
1014010	Meat	0,01*
1014020	Fat	0,01*
1014030	Liver	0,01*
1014040	Kidney	0,01*
1014050	Edible offal	0,01*
1014990	Others	0,01*
1015000	(e) Horses, asses, mules or hinnies	0,01*
1015010	Meat	0,01*
1015020	Fat	0,01*
1015030	Liver	0,01*
1015040	Kidney	0,01*
1015050	Edible offal	0,01*
1015990	Others	0,01*
1016000	(f) Poultry -chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	0,01*
1016010	Meat	0,01*
1016020	Fat	0,01*
1016030	Liver	0,01*
1016040	Kidney	0,01*
1016050	Edible offal	0,01*
1016990	Others	0,01*
1017000	(g) Other farm animals (Rabbit, Kangaroo)	0,01*
1017010	Meat	0,01*
1017020	Fat	0,01*
1017030	Liver	0,01*
1017040	Kidney	0,01*
1017050	Edible offal	0,01*
1017990	Others	0,01*

Code number	Groups and examples of individual products to which the MRLs apply	Fenpyrazamine
1020000	(ii) Milk and cream, not concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curd	0,01*
1020010	Cattle	0,01*
1020020	Sheep	0,01*
1020030	Goat	0,01*
1020040	Horse	0,01*
1020990	Others	0,01*
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	0,01*
1030010	Chicken	0,01*
1030020	Duck	0,01*
1030030	Goose	0,01*
1030040	Quail	0,01*
1030990	Others	0,01*
1040000	(iv) Honey (Royal jelly, pollen)	0,01*
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	0,01*
1060000	(vi) Snails	0,01*
1070000	(vii) Other terrestrial animal products	0,01*

(*) Indicates lower limit of analytical determination

ABBREVIATIONS

ADI	acceptable daily intake
ARfD	acute reference dose
a.s.	active substance
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CIPAC	Collaborative International Pesticide Analytical Council
CXL	Codex Maximum Residue Limit (Codex MRL)
d	day
DALA	days after last application
DAR	Draft Assessment Report
DAT	days after treatment
DT ₉₀	period required for 90 % dissipation (define method of estimation)
EC	European Community
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
GCPF	Global Crop Protection Federation (former GIFAP)
GLP	Good Laboratory Practice
ha	hectare
hL	hectolitre
i.e.	that is (id est, <i>Latin</i>)
IPCS	International Programme of Chemical Safety
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram
L	litre
LC	liquid chromatography
LOQ	limit of quantification
MS/MS	tandem mass spectrometry
MRL	maximum residue level

NEU	northern European Union
OECD	Organisation for Economic Co-operation and Development
PF	processing factor
PHI	pre-harvest interval
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
RAC	raw agricultural commodity
RMS	rapporteur Member State
SC	suspension concentrate
SEU	Southern European Union
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
US(A)	United States of America
WG	water dispersible granule
WHO	World Health Organisation
YF	yield factor
yr	year