REASONED OPINION

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

European Food Safety Authority

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 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.

KEY WORDS

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

1 On request from European Commission, Question No EFSA-Q-2012-00403 and EFSA-Q-2012-00729, approved on 27 November 2012.
2 Correspondence: pesticides.mrl@efs.a.europa.eu

Modification of the existing MRLs for fenpyrazamine in almonds, stone and berry fruits

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 commodities under consideration. The calculated maximum exposure in percentage of the ADI was 59.3 % for wine grapes, 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**

<table>
<thead>
<tr>
<th>Code number(a)</th>
<th>Commodity</th>
<th>Existing EU MRL (mg/kg)</th>
<th>Proposed EU MRL (mg/kg)</th>
<th>Justification for the proposal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enforcement residue definition: fenpyrazamine</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>120010</td>
<td>Almonds</td>
<td>0.01*</td>
<td>0.01* (provisional)</td>
<td>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.</td>
</tr>
<tr>
<td>140030</td>
<td>Peaches (nectarines and similar hybrids)</td>
<td>0.01*</td>
<td>4</td>
<td>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.</td>
</tr>
</tbody>
</table>
Modification of the existing MRLs for fenpyrazamine in almonds, stone and berry fruits

<table>
<thead>
<tr>
<th>Code number(a)</th>
<th>Commodity</th>
<th>Existing EU MRL (mg/kg)</th>
<th>Proposed EU MRL (mg/kg)</th>
<th>Justification for the proposal</th>
</tr>
</thead>
<tbody>
<tr>
<td>140010</td>
<td>Apricots</td>
<td>0.01*</td>
<td>No new proposal</td>
<td>The submitted residue data on peaches are not sufficient to derive a MRL proposal by extrapolation.</td>
</tr>
<tr>
<td>151000</td>
<td>Table and wine grapes</td>
<td>3</td>
<td>3</td>
<td>An amendment of the existing MRL is not necessary. The import tolerance is sufficiently supported by data and no risk for consumers was identified.</td>
</tr>
<tr>
<td>152000</td>
<td>Strawberries</td>
<td>0.01*</td>
<td>3</td>
<td>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.</td>
</tr>
</tbody>
</table>

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

Regulation (EC) No 396/2005\(^1\) establishes the rules governing the setting of pesticide MRLs at European Union level. Article 6 of that Regulation lays down that any party having a legitimate interest or requesting an authorisation for the use of a plant protection product in accordance with Council Directive 91/414/EEC\(^4\), repealed by Regulation (EC) No 1107/2009\(^5\), shall submit to a Member State, when appropriate, an application to set 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 SAS\(^6\) 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

\(^6\) 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 2012 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.

\[
\text{N} \text{H}_2 \text{N} \begin{array}{c}
\text{O} \\
\text{S} \\
\text{O}
\end{array} \begin{array}{c}
\text{N} \\
\text{H}_2 \text{N} \\
\text{O} \\
\text{S} \\
\text{O}
\end{array}
\]

Molecular weight: 331.43 g/mol

Fenpyrazamine is a non-systemic fungicide belonging to the pyrazole 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 595/2012, 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 322/2012. 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 domain, 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.

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


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

<table>
<thead>
<tr>
<th>Source</th>
<th>Year</th>
<th>Value</th>
<th>Study relied upon</th>
<th>Safety factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fenpyrazamine</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADI</td>
<td>EC</td>
<td>2012</td>
<td>0.13 mg/kg bw per day</td>
<td>Rat, 2 yr study</td>
</tr>
<tr>
<td>ARfD</td>
<td>EC</td>
<td>2012</td>
<td>0.3 mg/kg bw</td>
<td>Rabbit, developmental study</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Group</th>
<th>Crop</th>
<th>Label position</th>
<th>Application details</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fruits and fruiting vegetable</td>
<td>grapes</td>
<td>Phenyl-14C</td>
<td>Foliar, G 0.75 kg a.s./ha 2 (14 d)</td>
<td>Samples: berries, foliage</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Pyrazolyl-5-14C</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Leafy vegetables</td>
<td>lettuce</td>
<td>Phenyl-14C</td>
<td>Foliar, G 0.85 kg a.s./ha 3 (14 d)</td>
<td>14 DALA</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Pyrazolyl-5-14C</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pulses and oilseeds</td>
<td>rapeseed</td>
<td>Phenyl-14C</td>
<td>Foliar, G 0.6 kg a.s./ha 2 (60 d)</td>
<td>Samples: forage, haulm, seed</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Pyrazolyl-5-14C</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(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-OH\textsuperscript{12}\textsuperscript{(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.

\textsuperscript{12} S-2188-OH: 5-amino-2,4-dihydro-4-hydroxy-2-isopropyl-4-(o-tolyl)pyrazol-3-one.
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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
Modification of the existing MRLs for fenpyrazamine in almonds, stone and berry fruits

with high water (lettuce), high acid (grapes), and high oil (rapeseed) content as well as in dry matrices (cereal grains) when stored stabilised at \(-18^\circ\text{C}\) 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

<table>
<thead>
<tr>
<th>Commodity</th>
<th>Residue region (a)</th>
<th>Outdoor /Indoor</th>
<th>Individual trial results (mg/kg)</th>
<th>Median residue (mg/kg) (b)</th>
<th>Highest residue (mg/kg) (c)</th>
<th>MRL proposal (mg/kg)</th>
<th>Median CF (d)</th>
<th>Comments (e)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Enforcement (fenpyrazamine)</td>
<td>Risk assessment</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Fenpyrazamine: 5 x &lt;0.01</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>S-2188-DC: 5 x &lt;0.01</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2N application rate:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Fenpyrazamine: 2 x &lt;0.01</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>S-2188-DC: 2 x &lt;0.01</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Median residue CF (d) (e)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Enforcement residue definition: fenpyrazamine</td>
<td>Risk assessment (sum of fenpyrazamine and S-2188-DC expressed as fenpyrazamine)</td>
<td>Median residue (mg/kg) (b)</td>
<td>Highest residue (mg/kg) (c)</td>
<td>MRL proposal (mg/kg)</td>
<td>Median CF (d)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Almonds Import (US) Outdoor</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Fenpyrazamine: 0.33; 0.53; 0.55; 0.71; 0.8; 0.88; 0.91; 0.93; 1.01; 1.06; 1.09; 1.10; 1.24; 2.08</td>
<td>0.37; 0.62; 0.66; 0.95; 1.03; 1.07; 1.18; 1.26; 1.28; 1.3; 1.39; 1.43; 1.61; 3.17</td>
<td>0.92</td>
<td>2.08</td>
<td>3</td>
<td>1.2</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>S-2188-DC: 0.03; 0.06; 0.08; 0.17; 0.16; 0.13; 0.19; 0.32; 0.19; 0.17; 0.12; 0.36; 0.13; 0.76</td>
<td>0.5; 0.58; 0.59; 0.94; 0.99; 1.22; 1.49; 1.8</td>
<td>0.88</td>
<td>1.7</td>
<td>3</td>
<td>1.1</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>EU Indoor (g)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Fenpyrazamine: 0.24; 0.28; 0.35; 0.45; 0.76; 0.86; 0.92; 1.4</td>
<td>0.28; 0.36; 0.47; 0.54; 1.0; 1.07; 1.15; 2.03</td>
<td>0.61</td>
<td>1.4</td>
<td>3</td>
<td>1.2</td>
</tr>
</tbody>
</table>

Enforcement residue definition: fenpyrazamine

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; 1.09; 1.10; 1.24; 2.08
S-2188-DC: 0.03; 0.06; 0.08; 0.17; 0.16; 0.13; 0.19; 0.32; 0.19; 0.17; 0.12; 0.36; 0.13; 0.76

Median residue CF (d) (e)

R_{max} = 2.09
MRL_{OECD} = 2.8/3

R_{max} = 2.32
MRL_{OECD} = 2.69/3

R_{max} = 1.94
MRL_{OECD} = 2.26/3

Modification of the existing MRLs for fenpyrazamine in almonds, stone and berry fruits

EFSA Journal 2012;10(11):2989
Modification of the existing MRLs for fenpyrazamine in almonds, stone and berry fruits

<table>
<thead>
<tr>
<th>Commodity</th>
<th>Residue region (a)</th>
<th>Outdoor /Indoor</th>
<th>Individual trial results (mg/kg)</th>
<th>Enforcement (fenpyrazamine)</th>
<th>Risk assessment (sum of fenpyrazamine and S-2188-DC&lt;sup&gt;(b)&lt;/sup&gt; expressed as fenpyrazamine)</th>
<th>Median residue (mg/kg)</th>
<th>Highest residue (mg/kg)</th>
<th>MRL proposal (mg/kg)</th>
<th>Median CF</th>
<th>Comments (e)</th>
</tr>
</thead>
<tbody>
<tr>
<td>NEU Outdoor</td>
<td>Fenpyrazamine: 0.3; 0.64; 0.65&lt;sup&gt;(b)&lt;/sup&gt;; 1.3 &lt;br&gt; S-2188-DC: 0.06; 0.13; 0.13&lt;sup&gt;(b)&lt;/sup&gt;; 0.1</td>
<td>0.39; 0.83&lt;sup&gt;(b)&lt;/sup&gt;; 0.84; 1.44</td>
<td>0.65</td>
<td>1.3</td>
<td>-</td>
<td>-</td>
<td>The number of residue trials is not sufficient to derive a MRL proposal for the intended NEU and SEU uses.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SEU Outdoor</td>
<td>Fenpyrazamine: 0.28; 0.47; 0.54; 1.4 &lt;br&gt; S-2188-DC: 0.09; 0.16; 0.19; 0.18</td>
<td>0.41; 0.7; 0.81; 1.66</td>
<td>0.51</td>
<td>1.6</td>
<td>-</td>
<td>-</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NEU Outdoor</td>
<td>Fenpyrazamine: 0.36; 0.61; 0.76&lt;sup&gt;(b)&lt;/sup&gt;; 1.5 &lt;br&gt; S-2188-DC: 0.26; 0.11; 0.24&lt;sup&gt;(b)&lt;/sup&gt;; 0.06</td>
<td>0.73; 0.77; 1.1&lt;sup&gt;(b)&lt;/sup&gt;; 1.59</td>
<td>0.69</td>
<td>1.5</td>
<td>3</td>
<td>1.4</td>
<td>R&lt;sub&gt;min&lt;/sub&gt;= 2.63 &lt;br&gt;R&lt;sub&gt;max&lt;/sub&gt;= 3.33 &lt;br&gt;MRL&lt;sub&gt;OECD&lt;/sub&gt; = 2.77/3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SEU Outdoor</td>
<td>Fenpyrazamine: 0.44&lt;sup&gt;(b)&lt;/sup&gt;; 0.55; 0.7; 0.85&lt;sup&gt;(b)&lt;/sup&gt;; &lt;br&gt; S-2188-DC: 0.31&lt;sup&gt;(b)&lt;/sup&gt;; 0.04; 0.17; 0.28&lt;sup&gt;(b)&lt;/sup&gt;; &lt;br&gt; &lt;sup&gt;(b)&lt;/sup&gt;&lt;br&gt; 0.61; 0.88&lt;sup&gt;(b)&lt;/sup&gt;; 0.94; 0.95; 1.12; 1.25&lt;sup&gt;(b)&lt;/sup&gt;; 1.26; 2.51</td>
<td>0.9</td>
<td>2.5</td>
<td>4</td>
<td>1.2</td>
<td>R&lt;sub&gt;min&lt;/sub&gt;= 2.13 &lt;br&gt;R&lt;sub&gt;max&lt;/sub&gt;= 3.05 &lt;br&gt;MRL&lt;sub&gt;OECD&lt;/sub&gt; = 3.58/4</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Apricots</td>
<td>NEU Outdoor</td>
<td>-</td>
<td>-</td>
<td>No residue trials available. At least 4 trials on apricots are required to support the MRL proposal.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Modification of the existing MRLs for fenpyrazamine in almonds, stone and berry fruits

<table>
<thead>
<tr>
<th>Commodity</th>
<th>Residue region</th>
<th>Outdoor /Indoor</th>
<th>Individual trial results (mg/kg)</th>
<th>Risk assessment (sum of fenpyrazamine and S-2188-DC expressed as fenpyrazamine)</th>
<th>Median residue (mg/kg)</th>
<th>Highest residue (mg/kg)</th>
<th>MRL proposal (mg/kg)</th>
<th>Median CF</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>SEU</td>
<td>Outdoor</td>
<td>-</td>
<td>-</td>
<td>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).</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(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 ($R_{max}$; 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**

<table>
<thead>
<tr>
<th>Processed commodity</th>
<th>Number of studies</th>
<th>Median PF (a)</th>
<th>Median CF (b)</th>
<th>Individual PF</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Enforcement residue definition: fenpyrazamine</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Grape, (pasteurised) juice</td>
<td>5</td>
<td>0.16</td>
<td>1.5</td>
<td>0.06; 0.09; 0.016; 0.31 (EFSA, 2011, 2012) 2.02</td>
</tr>
<tr>
<td>Grape, raisins</td>
<td>4</td>
<td>1.65</td>
<td>1.1</td>
<td>1.62; 1.67; 2.8 (EFSA, 2011, 2012) 1.06</td>
</tr>
</tbody>
</table>

(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 DT$_{90}$ 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

<table>
<thead>
<tr>
<th>Crop group</th>
<th>Crop sown</th>
<th>Label position</th>
<th>Application details</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Method</td>
<td>Rate (kg a.s./ha)</td>
</tr>
<tr>
<td>fenpyrazamine</td>
<td></td>
<td></td>
<td>Bare soil application</td>
<td>1 x 2.83</td>
</tr>
<tr>
<td>Leafy vegetable</td>
<td>Lettuce</td>
<td>Pyrazolyl-5,14C</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Root/tuber</td>
<td>Carrots</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>vegetables</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cereals</td>
<td>Wheat</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n.r.: not reported in the DAR (Austria, 2011).</td>
<td></td>
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</tr>
</tbody>
</table>

Residues were mostly composed of the parent fenpyrazamine and two metabolites (S-2188-OH and S-2188(OH)2). 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 population (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

<table>
<thead>
<tr>
<th>Commodity</th>
<th>Chronic exposure assessment</th>
<th>Acute exposure assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Input value (mg/kg)</td>
<td>Comment</td>
</tr>
<tr>
<td><strong>Risk assessment residue definition: sum of fenpyrazamine and S-2188-DC expressed as fenpyrazamine</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Almonds</td>
<td>0.02 (0.01*2)</td>
<td>Median residue*CF (import, US)</td>
</tr>
<tr>
<td>Grapes</td>
<td>1.10 (0.92*1.2)</td>
<td>Median residue*CF (import, US)</td>
</tr>
<tr>
<td>Strawberries</td>
<td>0.97 (0.88*1.1)</td>
<td>Median residue*CF (import, US)</td>
</tr>
<tr>
<td>Peaches</td>
<td>1.08 (0.9*1.2)</td>
<td>Median residue*CF (outdoor, SEU)</td>
</tr>
<tr>
<td>Tomatoes, aubergines</td>
<td>0.78</td>
<td>Median residue*CF (EFSA, 2011)</td>
</tr>
<tr>
<td>Peppers</td>
<td>0.9</td>
<td>Median residue*CF (EFSA, 2011)</td>
</tr>
</tbody>
</table>

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).
Modification of the existing MRLs for fenpyrazamine in almonds, stone and berry fruits

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

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 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**

<table>
<thead>
<tr>
<th>Code number(a)</th>
<th>Commodity</th>
<th>Existing EU MRL (mg/kg)</th>
<th>Proposed EU MRL (mg/kg)</th>
<th>Justification for the proposal</th>
</tr>
</thead>
</table>
| 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. |

(*): Indicates that the MRL is set at the limit of analytical quantification.
Modification of the existing MRLs for fenpyrazamine in almonds, stone and berry fruits

REFERENCES


Austria, 2012b. Evaluation report on the setting of MRLs for fenpyrazamine in peaches (nectarines and similar hybrids), apricots and strawberries prepared by the evaluating Member State Austria under Article 8 of Regulation (EC) No 396/2005, June 2012, 52 pp.


EC (European Commission), 1997a. Appendix A. Metabolism and distribution in plants. 7028/IV/95-rev.3.


EC (European Commission), 1997d. Appendix E. Processing studies. 7035/VI/95-rev.5.

EC (European Commission), 1997e. Appendix F. Metabolism and distribution in domestic animals. 7030/VI/95-rev.3.


EC (European Commission), 1997g. Appendix I. Calculation of maximum residue level and safety intervals. 7039/VI/95.


EC (European Commission), 2010b. Residue analytical methods. For post-registration control. SANCO/825/00-rev.8.1.


EFSA (European Food Safety Authority), 2007. Reasoned opinion on the potential chronic and acute risk to consumers health arising from proposed temporary EU MRLs.


Modification of the existing MRLs for fenpyrazamine in almonds, stone and berry fruits


## APPENDICES

### A. GOOD AGRICULTURAL PRACTICE (GAPs)

<table>
<thead>
<tr>
<th>Crop and/or situation</th>
<th>Member State or Country</th>
<th>Pest or group of pests controlled</th>
<th>Formulation</th>
<th>Application method and kind</th>
<th>Application rate per treatment</th>
<th>PHI (days)</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Almonds</td>
<td>US</td>
<td><strong>F</strong> Botrytis</td>
<td>SC</td>
<td>436 g/L</td>
<td>Foliar</td>
<td>3</td>
<td>0.42</td>
</tr>
<tr>
<td>Grapes</td>
<td>US</td>
<td><strong>F</strong> Botrytis</td>
<td>SC</td>
<td>436 g/L, 500 g/kg</td>
<td>Foliar</td>
<td>3</td>
<td>0.56</td>
</tr>
<tr>
<td>Strawberries</td>
<td>US</td>
<td><strong>F</strong> Botrytis</td>
<td>SC</td>
<td>436 g/L, 500 g/kg</td>
<td>Foliar</td>
<td>3</td>
<td>0.56</td>
</tr>
<tr>
<td></td>
<td>AT</td>
<td><strong>F</strong> Botrytis</td>
<td>WG</td>
<td>500 g/kg</td>
<td>Foliar BBCH 59-89</td>
<td>3 7</td>
<td>500-2000</td>
</tr>
<tr>
<td></td>
<td>BE, CZ, DE, IE, UK, HU, NL, PL, RO, SK, SL</td>
<td><strong>F</strong> Botrytis</td>
<td>WG</td>
<td>500 g/kg</td>
<td>Foliar BBCH 61-87</td>
<td>3 7</td>
<td>500-2000</td>
</tr>
<tr>
<td></td>
<td>BG, CY, EL, ES, FR, PT</td>
<td><strong>F</strong> Botrytis</td>
<td>WG</td>
<td>500 g/kg</td>
<td>Foliar BBCH 61-87</td>
<td>3 7</td>
<td>100-1200</td>
</tr>
<tr>
<td></td>
<td>IT</td>
<td><strong>F</strong> Botrytis</td>
<td>WG</td>
<td>500 g/kg</td>
<td>Foliar BBCH 61-87</td>
<td>3 7</td>
<td>300-1000</td>
</tr>
<tr>
<td></td>
<td>AT</td>
<td><strong>P</strong> Botrytis</td>
<td>WG</td>
<td>500 g/kg</td>
<td>Foliar BBCH 59-89</td>
<td>3 7</td>
<td>500-2000</td>
</tr>
<tr>
<td></td>
<td>BE, BG, CY, CZ, DE, DK, EL, ES, FR, HU, IE, LT, LV, PL, PT</td>
<td><strong>P</strong> Botrytis</td>
<td>WG</td>
<td>500 g/kg</td>
<td>Foliar BBCH 61-87</td>
<td>3 7</td>
<td>100-2000</td>
</tr>
</tbody>
</table>

**Notes:**
- A: Appendices
- P: Pre-study
- PHI: Pre-harvest interval
- kg as/L:
- kg a.s./ha:
- GAP: Good Agricultural Practice
<table>
<thead>
<tr>
<th>Crop and/or situation</th>
<th>Member State or Country</th>
<th>F G or I</th>
<th>Pest or group of pests controlled</th>
<th>Formulation</th>
<th>Application</th>
<th>Application rate per treatment</th>
<th>PHI (days)</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NL, RO, SE, SK, SL, UK</td>
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<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IT</td>
<td>P††</td>
<td>Botrytis</td>
<td>WG 500 g/kg</td>
<td>Foliar BBCH 61-87</td>
<td>3</td>
<td>7</td>
<td>300-1000</td>
<td>0.6</td>
</tr>
<tr>
<td>Peaches, nectarines, apricots</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AT</td>
<td>F</td>
<td>Monilia laxa, M. fructigena</td>
<td>WG 500 g/kg</td>
<td>Foliar BBCH 57-89</td>
<td>3</td>
<td>7</td>
<td>300-1500</td>
<td>0.6</td>
</tr>
<tr>
<td>CZ, DE, HU, PL, RO, SK, SL</td>
<td>F</td>
<td>Monilia spp.</td>
<td>WG 500 g/kg</td>
<td>Foliar BBCH 61-87</td>
<td>3</td>
<td>7</td>
<td>500-1500</td>
<td>0.6</td>
</tr>
<tr>
<td>BG, CY, EL, ES, FR, PT</td>
<td>F</td>
<td>Monilia spp.</td>
<td>WG 500 g/kg</td>
<td>Foliar BBCH 61-87</td>
<td>3</td>
<td>7</td>
<td>500-1500</td>
<td>0.6</td>
</tr>
<tr>
<td>IT</td>
<td>F</td>
<td>Monilia spp.</td>
<td>WG 500 g/kg</td>
<td>Foliar BBCH 61-87</td>
<td>3</td>
<td>7</td>
<td>500-1500</td>
<td>0.6</td>
</tr>
</tbody>
</table>

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. (f) All abbreviations used must be explained. (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench. (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated. (i) g/kg or g/l. (j) Growth stage at last treatment (Growth stages of mono- and dicotyledonous plants. BBCH Monograph, 2nd Ed., 2001), including where relevant, information on season at time of application. (k) The minimum and maximum number of application possible under practical conditions of use must be provided. (l) PHI - minimum pre-harvest interval. (m) Remarks may include: Extent of use/economic importance/restrictions (i.e. feeding, grazing).
### B. Pesticide Residues Intake Model (PRIMo)

#### Fenpyrazamide

<table>
<thead>
<tr>
<th>Status of the active substance:</th>
<th>approved</th>
</tr>
</thead>
<tbody>
<tr>
<td>Code no.</td>
<td></td>
</tr>
<tr>
<td>LOQ (mg/kg bw):</td>
<td>0.01</td>
</tr>
</tbody>
</table>

#### Toxicological end points

| ADI (mg/kg bw/day): | 0.13 |
| Source of ADI: | EC |
| ARfD (mg/kg bw): | 0.3 |
| Source of ARfD: | EC |
| Year of evaluation: | 2012 |

#### Chronic risk assessment - refined calculations

<table>
<thead>
<tr>
<th>Commodity / group of commodities</th>
<th>TMDI (range) in % of ADI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minimum</td>
<td>Maximum</td>
</tr>
<tr>
<td>1</td>
<td>5</td>
</tr>
</tbody>
</table>

| No of diets exceeding ADI: | |

<table>
<thead>
<tr>
<th>Commodity / group of commodities</th>
<th>3rd contributor to MS diet (in % of ADI)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Commodity / group of commodities</th>
<th>2nd contributor to MS diet (in % of ADI)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Commodity / group of commodities</th>
<th>1st contributor to MS diet (in % of ADI)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Commodity / group of commodities</th>
<th>5.0 WHO Cluster diet B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Commodity / group of commodities</td>
<td>4.1 FR all population</td>
</tr>
<tr>
<td>Commodity / group of commodities</td>
<td>3.6 PT General population</td>
</tr>
<tr>
<td>Commodity / group of commodities</td>
<td>2.9 DE child</td>
</tr>
<tr>
<td>Commodity / group of commodities</td>
<td>2.8 IE adult</td>
</tr>
<tr>
<td>Commodity / group of commodities</td>
<td>2.3 WHO cluster diet E</td>
</tr>
<tr>
<td>Commodity / group of commodities</td>
<td>1.9 NL child</td>
</tr>
<tr>
<td>Commodity / group of commodities</td>
<td>1.8 DK adult</td>
</tr>
<tr>
<td>Commodity / group of commodities</td>
<td>1.7 FR toddler</td>
</tr>
<tr>
<td>Commodity / group of commodities</td>
<td>1.6 WHO regional European diet</td>
</tr>
<tr>
<td>Commodity / group of commodities</td>
<td>1.6 IT kids/toddler</td>
</tr>
<tr>
<td>Commodity / group of commodities</td>
<td>1.5 WHO cluster diet D</td>
</tr>
<tr>
<td>Commodity / group of commodities</td>
<td>1.4 IT adult</td>
</tr>
<tr>
<td>Commodity / group of commodities</td>
<td>1.4 UK vegetarian</td>
</tr>
<tr>
<td>Commodity / group of commodities</td>
<td>1.4 WHO Cluster diet F</td>
</tr>
<tr>
<td>Commodity / group of commodities</td>
<td>1.4 ES adult</td>
</tr>
<tr>
<td>Commodity / group of commodities</td>
<td>1.4 DK child</td>
</tr>
<tr>
<td>Commodity / group of commodities</td>
<td>1.3 NL general</td>
</tr>
<tr>
<td>Commodity / group of commodities</td>
<td>1.3 UK Toddler</td>
</tr>
<tr>
<td>Commodity / group of commodities</td>
<td>1.2 SE general population 90th percentile</td>
</tr>
<tr>
<td>Commodity / group of commodities</td>
<td>1.0 FR infant</td>
</tr>
<tr>
<td>Commodity / group of commodities</td>
<td>1.0 PL general population</td>
</tr>
<tr>
<td>Commodity / group of commodities</td>
<td>1.0 UK infant</td>
</tr>
<tr>
<td>Commodity / group of commodities</td>
<td>0.8 FI adult</td>
</tr>
<tr>
<td>Commodity / group of commodities</td>
<td>0.6 LT adult</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Commodity / group of commodities</th>
<th>Commodity / group of commodities</th>
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</thead>
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<tr>
<th>Commodity / group of commodities</th>
<th>Commodity / group of commodities</th>
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<tr>
<th>Commodity / group of commodities</th>
<th>Commodity / group of commodities</th>
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<th>Commodity / group of commodities</th>
<th>Commodity / group of commodities</th>
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</thead>
</table>

<table>
<thead>
<tr>
<th>Commodity / group of commodities</th>
<th>Commodity / group of commodities</th>
</tr>
</thead>
</table>

### Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI. A long-term intake of residues of Fenpyrazamide is unlikely to present a public health concern.
Modification of the existing MRLs for fenpyrazamine in almonds, stone and berry fruits

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 lead to an exposure equivalent to 100% of the ARfD.

### Acute risk assessment /children - refined calculations

<table>
<thead>
<tr>
<th>Commodity</th>
<th>pTMRL/ threshold MRL (mg/kg)</th>
<th>ARfD/ADI</th>
<th>Proportion (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peaches</td>
<td>3 / -</td>
<td>54.8</td>
<td>9.7</td>
</tr>
<tr>
<td>Table grapes</td>
<td>2.496 / -</td>
<td>19.8</td>
<td>13.6</td>
</tr>
<tr>
<td>Wine grapes</td>
<td>2.5 / -</td>
<td>13.6</td>
<td>3 / -</td>
</tr>
<tr>
<td>Almonds</td>
<td>0.02 / -</td>
<td>0.0</td>
<td>0.0</td>
</tr>
</tbody>
</table>

For processed commodities, no exceedance of the ARfD/ADI was identified.

### Acute risk assessment /adults / general population - refined calculations

<table>
<thead>
<tr>
<th>Commodity</th>
<th>pTMRL/ threshold MRL (mg/kg)</th>
<th>ARfD/ADI</th>
<th>Proportion (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peaches</td>
<td>3 / -</td>
<td>54.8</td>
<td>9.7</td>
</tr>
<tr>
<td>Table grapes</td>
<td>2.496 / -</td>
<td>19.8</td>
<td>13.6</td>
</tr>
<tr>
<td>Wine grapes</td>
<td>2.5 / -</td>
<td>13.6</td>
<td>3 / -</td>
</tr>
<tr>
<td>Almonds</td>
<td>0.02 / -</td>
<td>0.0</td>
<td>0.0</td>
</tr>
</tbody>
</table>

For processed commodities, no exceedance of the ARfD/ADI was identified.

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.
### C. EXISTING EU MAXIMUM RESIDUE LEVELS (MRLs)

(Con Pesticides - Web Version - EU MRLs ((File created on 30/10/2012 16:52))

<table>
<thead>
<tr>
<th>Code number</th>
<th>Groups and examples of individual products to which the MRLs apply</th>
<th>Fenpyrazamine</th>
</tr>
</thead>
<tbody>
<tr>
<td>10000</td>
<td>1. FRUIT FRESH OR FROZEN: NUTS</td>
<td></td>
</tr>
<tr>
<td>11000</td>
<td>(a) Citrus fruit</td>
<td></td>
</tr>
<tr>
<td>11010</td>
<td>Grapefruit (Shaddock, pomelo, sweeties, tangolo, shig and other hybrids)</td>
<td>0.01*</td>
</tr>
<tr>
<td>11020</td>
<td>Oranges (bitter orange, chirono and other hybrids)</td>
<td>0.01*</td>
</tr>
<tr>
<td>11030</td>
<td>Limes</td>
<td>0.01*</td>
</tr>
<tr>
<td>11050</td>
<td>Mandarin (Clementine, tangarine and other hybrids)</td>
<td>0.01*</td>
</tr>
<tr>
<td>11090</td>
<td>Others</td>
<td>0.01*</td>
</tr>
<tr>
<td>12000</td>
<td>(a) Tree nuts (shelled or unshelled)</td>
<td>0.01*</td>
</tr>
<tr>
<td>12010</td>
<td>Almonds</td>
<td>0.01*</td>
</tr>
<tr>
<td>12030</td>
<td>Brazil nuts</td>
<td>0.01*</td>
</tr>
<tr>
<td>12040</td>
<td>Chestnuts</td>
<td>0.01*</td>
</tr>
<tr>
<td>12050</td>
<td>Coconut</td>
<td>0.01*</td>
</tr>
<tr>
<td>12060</td>
<td>Hazelnut</td>
<td>0.01*</td>
</tr>
<tr>
<td>12070</td>
<td>Macadamia</td>
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</tr>
<tr>
<td>12080</td>
<td>Pecans</td>
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</tr>
<tr>
<td>12090</td>
<td>Pine nuts</td>
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<tr>
<td>12094</td>
<td>Pouchas</td>
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<tr>
<td>12100</td>
<td>Walnuts</td>
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</tr>
<tr>
<td>12090</td>
<td>Others</td>
<td>0.01*</td>
</tr>
<tr>
<td>13000</td>
<td>(a) Pome fruit (apple)</td>
<td>0.01*</td>
</tr>
<tr>
<td>13020</td>
<td>Apples (Cash apple)</td>
<td>0.01*</td>
</tr>
<tr>
<td>13030</td>
<td>Pears (Oriental pear)</td>
<td>0.01*</td>
</tr>
<tr>
<td>13040</td>
<td>Dates</td>
<td>0.01*</td>
</tr>
<tr>
<td>13050</td>
<td>Loquat</td>
<td>0.01*</td>
</tr>
<tr>
<td>13090</td>
<td>Others</td>
<td>0.01*</td>
</tr>
<tr>
<td>14000</td>
<td>(i) Stone fruit</td>
<td>0.01*</td>
</tr>
<tr>
<td>14010</td>
<td>Apricots</td>
<td>0.01*</td>
</tr>
<tr>
<td>14020</td>
<td>Cherries (sweet cherries, sour cherries)</td>
<td>0.01*</td>
</tr>
<tr>
<td>14030</td>
<td>Peaches (Nectarines and similar hybrids)</td>
<td>0.01*</td>
</tr>
<tr>
<td>14040</td>
<td>Plums (Damson, greengage, prunella)</td>
<td>0.01*</td>
</tr>
<tr>
<td>14090</td>
<td>Others</td>
<td>0.01*</td>
</tr>
<tr>
<td>15000</td>
<td>(ii) Berries &amp; small fruit</td>
<td>0.01*</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Code number</th>
<th>Groups and examples of individual products to which the MRLs apply</th>
<th>Fenpyrazamine</th>
</tr>
</thead>
<tbody>
<tr>
<td>15100</td>
<td>(a) Table and wine grapes</td>
<td>3</td>
</tr>
<tr>
<td>15101</td>
<td>Table grapes</td>
<td>3</td>
</tr>
<tr>
<td>15102</td>
<td>Wine grapes</td>
<td>3</td>
</tr>
<tr>
<td>15120</td>
<td>(b) Stone fruits</td>
<td>0.01*</td>
</tr>
<tr>
<td>15300</td>
<td>(c) Cane fruit</td>
<td>0.01*</td>
</tr>
<tr>
<td>15350</td>
<td>Blackberries</td>
<td>0.01*</td>
</tr>
<tr>
<td>15352</td>
<td>Deberries (loganberries, Boysenberries, and clydeberries)</td>
<td>0.01*</td>
</tr>
<tr>
<td>15352</td>
<td>Raspberries (Wineberries)</td>
<td>0.01*</td>
</tr>
<tr>
<td>15390</td>
<td>Others</td>
<td>0.01*</td>
</tr>
<tr>
<td>15400</td>
<td>(d) Other small fruit &amp; berries</td>
<td>0.01*</td>
</tr>
<tr>
<td>15401</td>
<td>Blueberries (Ribes fruticosus (red hybrids))</td>
<td>0.01*</td>
</tr>
<tr>
<td>15402</td>
<td>Cranberries</td>
<td>0.01*</td>
</tr>
<tr>
<td>15403</td>
<td>Carrisins (red, black and white)</td>
<td>0.01*</td>
</tr>
<tr>
<td>15405</td>
<td>Gooseberries (including hybrids with other ribes species)</td>
<td>0.01*</td>
</tr>
<tr>
<td>15406</td>
<td>Ribes</td>
<td>0.01*</td>
</tr>
<tr>
<td>15409</td>
<td>Mulberries (arbutus berry)</td>
<td>0.01*</td>
</tr>
<tr>
<td>15407</td>
<td>Azorole (mediterranean medlar)</td>
<td>0.01*</td>
</tr>
<tr>
<td>15408</td>
<td>Elderberries (Black chokeberry (alabatre), mountain ash, azarole, blackthorn (sea saltberries), hawthorn, service berries, and other tommers (sized Annomazeria))</td>
<td>0.01*</td>
</tr>
<tr>
<td>15409</td>
<td>Others</td>
<td>0.01*</td>
</tr>
<tr>
<td>16000</td>
<td>(v) Miscellaneous fruit</td>
<td>0.01*</td>
</tr>
<tr>
<td>16100</td>
<td>(a) Edible peel</td>
<td>0.01*</td>
</tr>
<tr>
<td>16102</td>
<td>Dates</td>
<td>0.01*</td>
</tr>
<tr>
<td>16105</td>
<td>Figs</td>
<td>0.01*</td>
</tr>
<tr>
<td>16106</td>
<td>Table olives</td>
<td>0.01*</td>
</tr>
<tr>
<td>16107</td>
<td>Kamquats (Momor kumquat, oranges kumquat)</td>
<td>0.01*</td>
</tr>
<tr>
<td>16109</td>
<td>Carobena (Bilimbi)</td>
<td>0.01*</td>
</tr>
<tr>
<td>16100</td>
<td>Persimmons</td>
<td>0.01*</td>
</tr>
<tr>
<td>16105</td>
<td>Japanese plum (toda apple) (water apple), pomocit, rose apple,</td>
<td>0.01*</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Code number</th>
<th>Groups and examples of individual products to which the MRLs apply</th>
<th>Fenpyrazamine</th>
</tr>
</thead>
<tbody>
<tr>
<td>16190</td>
<td>Others</td>
<td>0.01*</td>
</tr>
<tr>
<td>16300</td>
<td>(b) Edible peel</td>
<td>0.01*</td>
</tr>
<tr>
<td>16302</td>
<td>Kwi</td>
<td>0.01*</td>
</tr>
<tr>
<td>16230</td>
<td>Leche (Litchi) (Pulasan, rambutan (flame litchi))</td>
<td>0.01*</td>
</tr>
<tr>
<td>16200</td>
<td>Passam fruit</td>
<td>0.01*</td>
</tr>
<tr>
<td>16240</td>
<td>Pickle pear (cactus fruit)</td>
<td>0.01*</td>
</tr>
<tr>
<td>16260</td>
<td>Star apple</td>
<td>0.01*</td>
</tr>
<tr>
<td>16260</td>
<td>American persimmon (Virgina kaki) (Black, white, green, papaya, orange, chinotto, tangelo, pomelo, sweeties, tangelo, and marmaline sops)</td>
<td>0.01*</td>
</tr>
<tr>
<td>16200</td>
<td>Others</td>
<td>0.01*</td>
</tr>
<tr>
<td>16000</td>
<td>(c) Edible peel</td>
<td>0.01*</td>
</tr>
<tr>
<td>16000</td>
<td>Avocados</td>
<td>0.01*</td>
</tr>
<tr>
<td>16020</td>
<td>Bananas (Dwarf banana, plantain, apple banana)</td>
<td>0.01*</td>
</tr>
<tr>
<td>16030</td>
<td>Mangos</td>
<td>0.01*</td>
</tr>
<tr>
<td>16040</td>
<td>Papaya</td>
<td>0.01*</td>
</tr>
<tr>
<td>16050</td>
<td>Fuyu</td>
<td>0.01*</td>
</tr>
<tr>
<td>16060</td>
<td>Cherimoya (Castard apple, sugar apple (sweetwater), jimsa and other medium sized Amanoceae)</td>
<td>0.01*</td>
</tr>
<tr>
<td>16070</td>
<td>Gauva</td>
<td>0.01*</td>
</tr>
<tr>
<td>16080</td>
<td>Pineapples</td>
<td>0.01*</td>
</tr>
<tr>
<td>16090</td>
<td>Breadfruit (Jackfruit)</td>
<td>0.01*</td>
</tr>
<tr>
<td>16100</td>
<td>Horseradish</td>
<td>0.01*</td>
</tr>
<tr>
<td>16100</td>
<td>Scousep (guanabana)</td>
<td>0.01*</td>
</tr>
<tr>
<td>16100</td>
<td>Arrowroot</td>
<td>0.01*</td>
</tr>
<tr>
<td>16000</td>
<td>2. VEGETABLES FRESH OR FROZEN</td>
<td>0.01*</td>
</tr>
<tr>
<td>21200</td>
<td>Others</td>
<td>0.01*</td>
</tr>
<tr>
<td>21300</td>
<td>Mexican yam bean</td>
<td>0.01*</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Code number</th>
<th>Groups and examples of individual products to which the MRLs apply</th>
<th>Fenpyrazamine</th>
</tr>
</thead>
<tbody>
<tr>
<td>21200</td>
<td>(a) Fruits</td>
<td>0.01*</td>
</tr>
<tr>
<td>21200</td>
<td>(b) Tropical root and tuber vegetables</td>
<td>0.01*</td>
</tr>
<tr>
<td>21200</td>
<td>Cucumbers</td>
<td>0.01*</td>
</tr>
<tr>
<td>21200</td>
<td>Gherkins</td>
<td>0.01*</td>
</tr>
<tr>
<td>21200</td>
<td>Cucumber squash and marron (passion)</td>
<td>0.01*</td>
</tr>
<tr>
<td>21200</td>
<td>Others</td>
<td>0.01*</td>
</tr>
<tr>
<td>21300</td>
<td>(c) Cucurbits--edible peel</td>
<td>0.01*</td>
</tr>
<tr>
<td>21300</td>
<td>Chayotes</td>
<td>0.01*</td>
</tr>
<tr>
<td>21300</td>
<td>Similar tovarianan (Summer squash, marrows (passion)</td>
<td>0.01*</td>
</tr>
<tr>
<td>21200</td>
<td>Others</td>
<td>0.01*</td>
</tr>
<tr>
<td>21300</td>
<td>(d) Cucurbits--edible peel</td>
<td>0.01*</td>
</tr>
<tr>
<td>21300</td>
<td>Maloku (Kiwano)</td>
<td>0.01*</td>
</tr>
</tbody>
</table>

---

**Modification of the existing MRLs for fenpyrazamine in almonds, stone and berry fruits**
### Modification of the existing MRLs for fenpyrazamine in almonds, stone and berry fruits

<table>
<thead>
<tr>
<th>Code number</th>
<th>Groups and examples of individual products to which the MRLs apply</th>
<th>Fenpyrazamine</th>
</tr>
</thead>
<tbody>
<tr>
<td>23000</td>
<td>Pumpkin (Winter squash)</td>
<td>0.01*</td>
</tr>
<tr>
<td>23000</td>
<td>Watermelon</td>
<td>0.01*</td>
</tr>
<tr>
<td>23000</td>
<td>Others</td>
<td>0.01*</td>
</tr>
<tr>
<td>25000</td>
<td>(d) Sweet corn</td>
<td>0.01*</td>
</tr>
<tr>
<td>25000</td>
<td>(e) Leafy vegetables &amp; fresh herbs</td>
<td>0.01*</td>
</tr>
<tr>
<td>25100</td>
<td>(a) Lettuce and other salad plants including Brassica species</td>
<td>0.01*</td>
</tr>
<tr>
<td>25100</td>
<td>(b) Lettuce (Italian cos/endive)</td>
<td>0.01*</td>
</tr>
<tr>
<td>25100</td>
<td>(c) Lettuce (Heads lettuce, kohlrabi)</td>
<td>0.01*</td>
</tr>
<tr>
<td>25100</td>
<td>(d) Kohlrabi</td>
<td>0.01*</td>
</tr>
<tr>
<td>25200</td>
<td>(v) Leafy vegetables &amp; fresh herbs</td>
<td>0.01*</td>
</tr>
<tr>
<td>25300</td>
<td>(a) Lettuce and other salad plants including Brassica species</td>
<td>0.01*</td>
</tr>
<tr>
<td>25300</td>
<td>(b) Lettuce (Italian cos/endive)</td>
<td>0.01*</td>
</tr>
<tr>
<td>25300</td>
<td>(c) Lettuce (Heads lettuce, kohlrabi)</td>
<td>0.01*</td>
</tr>
<tr>
<td>25300</td>
<td>(d) Kohlrabi</td>
<td>0.01*</td>
</tr>
<tr>
<td>25400</td>
<td>(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)</td>
<td>0.01*</td>
</tr>
<tr>
<td>25500</td>
<td>(ii) Cocoa (fermented products)</td>
<td>0.01*</td>
</tr>
<tr>
<td>25500</td>
<td>(iii) Lime (Linden)</td>
<td>0.01*</td>
</tr>
<tr>
<td>25600</td>
<td>(iv) Cocoa (fermented products)</td>
<td>0.01*</td>
</tr>
<tr>
<td>25700</td>
<td>(a) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)</td>
<td>0.01*</td>
</tr>
<tr>
<td>25800</td>
<td>(ii) Cocoa (fermented products)</td>
<td>0.01*</td>
</tr>
<tr>
<td>25900</td>
<td>(iii) Lime (Linden)</td>
<td>0.01*</td>
</tr>
</tbody>
</table>
Modification of the existing MRLs for fenpyrazamine in almonds, stone and berry fruits

<table>
<thead>
<tr>
<th>Code number</th>
<th>Groups and examples of individual products to which the MRLs apply</th>
<th>Fenpyrazamine</th>
</tr>
</thead>
<tbody>
<tr>
<td>1013000</td>
<td>(v) Flower stigma</td>
<td>0.01*</td>
</tr>
<tr>
<td>1013010</td>
<td>Mace</td>
<td>0.01*</td>
</tr>
<tr>
<td>1013020</td>
<td>Others</td>
<td>0.01*</td>
</tr>
<tr>
<td>1013030</td>
<td>Others</td>
<td>0.01*</td>
</tr>
<tr>
<td>1013040</td>
<td>Others</td>
<td>0.01*</td>
</tr>
<tr>
<td>1013050</td>
<td>Edible offal</td>
<td>0.01*</td>
</tr>
<tr>
<td>1013060</td>
<td>Others</td>
<td>0.01*</td>
</tr>
<tr>
<td>1013070</td>
<td>Others</td>
<td>0.01*</td>
</tr>
<tr>
<td>1013080</td>
<td>Others</td>
<td>0.01*</td>
</tr>
<tr>
<td>1013090</td>
<td>Others</td>
<td>0.01*</td>
</tr>
<tr>
<td>1013100</td>
<td>(c) Sheep</td>
<td>0.01*</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Code number</th>
<th>Groups and examples of individual products to which the MRLs apply</th>
<th>Fenpyrazamine</th>
</tr>
</thead>
<tbody>
<tr>
<td>1014000</td>
<td>(a) Milk and cream, not concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curd</td>
<td>0.01*</td>
</tr>
<tr>
<td>1014010</td>
<td>Chicken</td>
<td>0.01*</td>
</tr>
<tr>
<td>1014020</td>
<td>Duck</td>
<td>0.01*</td>
</tr>
<tr>
<td>1014030</td>
<td>Goose</td>
<td>0.01*</td>
</tr>
<tr>
<td>1014040</td>
<td>Duck</td>
<td>0.01*</td>
</tr>
<tr>
<td>1014050</td>
<td>Others</td>
<td>0.01*</td>
</tr>
<tr>
<td>1014060</td>
<td>(v) Honey (Royal jelly, pollen)</td>
<td>0.01*</td>
</tr>
<tr>
<td>1014070</td>
<td>(v) Amphibians and reptiles (Frog legs, crocodiles)</td>
<td>0.01*</td>
</tr>
<tr>
<td>1014080</td>
<td>(v) Amphibians and reptiles (Frog legs, crocodiles)</td>
<td>0.01*</td>
</tr>
<tr>
<td>1014090</td>
<td>(v) Amphibians and reptiles (Frog legs, crocodiles)</td>
<td>0.01*</td>
</tr>
</tbody>
</table>

(*) 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
DT₉₀ 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
hlL hectolitre
i.e. that is (id est, Latin)
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
Modification of the existing MRLs for fenpyrazamine in almonds, stone and berry fruits

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>NEU</td>
<td>northern European Union</td>
</tr>
<tr>
<td>OECD</td>
<td>Organisation for Economic Co-operation and Development</td>
</tr>
<tr>
<td>PF</td>
<td>processing factor</td>
</tr>
<tr>
<td>PHI</td>
<td>pre-harvest interval</td>
</tr>
<tr>
<td>PRIMo</td>
<td>(EFSA) Pesticide Residues Intake Model</td>
</tr>
<tr>
<td>Rₙₙₑᵣ</td>
<td>statistical calculation of the MRL by using a non-parametric method</td>
</tr>
<tr>
<td>Rₚₑᵣₓ</td>
<td>statistical calculation of the MRL by using a parametric method</td>
</tr>
<tr>
<td>RAC</td>
<td>raw agricultural commodity</td>
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<tr>
<td>RMS</td>
<td>rapporteur Member State</td>
</tr>
<tr>
<td>SC</td>
<td>suspension concentrate</td>
</tr>
<tr>
<td>SEU</td>
<td>Southern European Union</td>
</tr>
<tr>
<td>TMDI</td>
<td>theoretical maximum daily intake</td>
</tr>
<tr>
<td>TRR</td>
<td>total radioactive residue</td>
</tr>
<tr>
<td>US(A)</td>
<td>United States of America</td>
</tr>
<tr>
<td>WG</td>
<td>water dispersible granule</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organisation</td>
</tr>
<tr>
<td>YF</td>
<td>yield factor</td>
</tr>
<tr>
<td>yr</td>
<td>year</td>
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</table>