REASONED OPINION

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Review of the existing maximum residue levels for fenpyrazamine according to Article 12 of Regulation (EC) No 396/2005

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Abstract

According to Article 12 of Regulation (EC) No 396/2005, EFSA has reviewed the maximum residue levels (MRLs) currently established at European level for the pesticide active substance fenpyrazamine. To assess the occurrence of fenpyrazamine residues in plants, processed commodities, rotational crops and livestock, EFSA considered the conclusions derived in the framework of Directive 91/414/EEC as well as the European authorisations reported by Member States (including the supporting residues data). Based on the assessment of the available data, MRL proposals were derived and a consumer risk assessment was carried out. Although no apparent unacceptable risk to consumers was identified, some information required by the regulatory framework was missing. Hence, the consumer risk assessment is considered indicative only and one MRL proposal derived by EFSA still requires further consideration by risk managers.

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Keywords: fenpyrazamine, MRL review, Regulation (EC) No 396/2005, consumer risk assessment, pyrizole, fungicide

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Summary

Fenpyrazamine was included in Annex I to Directive 91/414/EEC on 1 January 2013 by Commission Implementing Regulation (EC) No 595/2012, and has been deemed to be approved under Regulation (EC) No 1107/2009, in accordance with Commission Implementing Regulation (EU) No 540/2011, as amended by Commission Implementing Regulation (EU) No 541/2011. As the active substance was approved after the entry into force of Regulation (EC) No 396/2005 on 2 September 2008, the European Food Safety Authority (EFSA) is required to provide a reasoned opinion on the review of the existing maximum residue levels (MRLs) for that active substance in compliance with Article 12(1) of the aforementioned regulation. To collect the relevant pesticide residues data, EFSA asked Austria, as the designated rapporteur Member State (RMS), to complete the Pesticide Residues Overview File (PROFile) and to prepare a supporting evaluation report. The PROFile and evaluation report provided by the RMS were made available to the Member States. A request for additional information was addressed to the Member States in the framework of a completeness check period, which was initiated by EFSA on 25 January 2017 and finalised on 24 March 2017. After having considered all the information provided, EFSA prepared a completeness check report which was made available to Member States on 22 May 2017.

EFSA prepared in August 2017 a draft reasoned opinion, which was circulated to Member States for consultation via a written procedure based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC and the additional information provided by the RMS and Member States, Comments received by 25 September 2017 were considered during the finalisation of this reasoned opinion. The following conclusions are derived.

The metabolism of fenpyrazamine following foliar application was studied in grapevine (fruit crop), lettuce (leafy crop) and oilseed rape (pulses/oilseed) with the test substance labelled either on the phenyl- or pyrazolyl moiety. The metabolism of fenpyrazamine was comparable in all crops investigated. Standard processing studies evidenced that fenpyrazamine was stable under conditions simulating processing by pasteurisation, baking/brewing/boiling and sterilisation.

Following review of the available metabolism studies, the residue definition for enforcement was proposed as parent compound fenpyrazamine only and for risk assessment as the sum of parent and S-1188-DC, expressed as fenpyrazamine. The same definitions are applicable to rotational crops and processed commodities.

A validated liquid chromatography with tandem mass spectrometric (LC–MS/MS) method is available to enforce the proposed residue definition in plant with a limit of quantification (LOQ) of 0.01 mg/kg in high water and high oil content, acidic and dry commodities.

All residue trials were analysed for both the parent fenpyrazamine and the metabolite S-2188-DC. The available data are considered sufficient to derive MRL proposals as well as risk assessment values for apricots, cherries, peaches, plums, table and wine grapes, blackberries, dewberries, raspberries blueberries, tomatoes, peppers, aubergines and cucurbits with edible peel. For almonds, only a tentative MRL could be derived.

Residues of fenpyrazamine, S-2188-DC and S-2188-OH above LOQ are not expected in crops grown in rotation according to the supported use pattern and based on the submitted rotational crop field study. Robust processing factors could be derived for grape juice, white wine, red wine, wet pomace and raisins.

Fenpyrazamine is not authorised for use on crops that might be fed to livestock. Therefore, further investigation of the occurrence of residues in commodities of animal origin is not required and the setting of MRLs in these commodities is not considered necessary. However, available metabolism studies performed on goat and hen indicated that fenpyrazamine and S-2188-DC should be defined as the residue definition for monitoring while for risk assessment the inclusion of metabolites S-2188-CH_2OH-DC and MZZP should be considered. A method for enforcement of fenpyrazamine and/or its metabolites in animal commodities is currently not available and at present not required. The EURLs provided a screening quantitative method for fenpyrazamine in honey, muscle (red meat, white meat, fish) and milk and milk products with a screening detection limit (SDL) of 0.005 mg/kg for monitoring purposes.

Chronic and acute consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). According to the results of this calculation, the highest chronic exposure represented 5.1% of the acceptable daily intake (ADI) (WHO, cluster diet B) and the highest acute exposure amounted to 78.2% of the acute reference dose (ARfD) (peaches).

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Background

Regulation (EC) No 396/2005[1] (hereinafter referred to as 'the Regulation') establishes the rules governing the setting and the review of pesticide maximum residue levels (MRLs) at European level. Article 12(1) of that Regulation stipulates that the European Food Safety Authority (EFSA) shall provide, within 12 months from the date of the inclusion or non-inclusion of an active substance in Annex I to Directive 91/414/EEC[2] a reasoned opinion on the review of the existing MRLs for that active substance. As fenpyrazamine was included in Annex I to Council Directive 91/414/EEC on 1 January 2013 by means of Commission Implementing Regulation (EU) No 595/2012[3], and has been deemed to be approved under Regulation (EC) No 1107/2009[4], in accordance with Commission Implementing Regulation (EU) No 540/2011[5], as amended by Commission Implementing Regulation (EU) No 541/2011[6], EFSA initiated the review of all existing MRLs for that active substance.

According to the legal provisions, EFSA shall base its reasoned opinion in particular on the relevant assessment report prepared under Directive 91/414/EEC. It should be noted, however, that, in the framework of Directive 91/414/EEC, only a few representative uses are evaluated, whereas MRLs set out in Regulation (EC) No 396/2005 should accommodate all uses authorised within the European Union (EU), and uses authorised in third countries that have a significant impact on international trade. The information included in the assessment report prepared under Directive 91/414/EEC is therefore insufficient for the assessment of all existing MRLs for a given active substance.

To gain an overview of the pesticide residues data that have been considered for the setting of the existing MRLs, EFSA developed the Pesticide Residues Overview File (PROFile). The PROFile is an inventory of all pesticide residues data relevant to the risk assessment and MRL setting for a given active substance. This includes data on:

- the nature and magnitude of residues in primary crops;
- the nature and magnitude of residues in processed commodities;
- the nature and magnitude of residues in rotational crops;
- the nature and magnitude of residues in livestock commodities;
- the analytical methods for enforcement of the proposed MRLs.

Austria, the designated rapporteur Member State (RMS) in the framework of Directive 91/414/EEC, was asked to complete the PROFile for fenpyrazamine and to prepare a supporting evaluation report (Austria, 2013). The PROFile and the supporting evaluation report were submitted to EFSA on 11 March 2013 and made available to the Member States. A request for additional information was addressed to the Member States in the framework of a completeness check period which was initiated by EFSA on 25 January 2017 and finalised on 24 March 2017. Additional evaluation reports were submitted by Belgium, Germany, Italy and the European Union Reference Laboratories for Pesticide Residues (Belgium, 2017; EURLs, 2017; Germany, 2017; Italy, 2017) and, after having considered all the information provided by RMS and Member States, EFSA prepared a completeness check report which was made available to all Member States on 22 May 2017. Further clarifications were sought from Member States via a written procedure in May–June 2017.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC and the additional information provided by the Member States, EFSA prepared in August 2017 a draft reasoned opinion, which was submitted to Member States for commenting via a written procedure. All

[1] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1–16.

[2] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1–32. Repealed by Regulation (EC) No 1107/2009.

[3] Commission Implementing Regulation (EU) No 595/2012 of 5 July 2012 approving the active substance fenpyrazamine, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. OJ L 176, 6.7.2012, p. 46–49.

[4] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.

[5] Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 1–186.

[6] Commission Implementing Regulation (EU) No 541/2011 of 1 June 2011 amending Implementing Regulation (EU) No 540/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 187–188.

comments received by 25 September 2017 were considered by EFSA during the finalisation of the reasoned opinion.

The evaluation report submitted by the RMS (Austria, 2013) and the evaluation reports submitted by Member States Belgium, Germany, Italy and the European Union Reference Laboratories for Pesticide Residues (Belgium, 2017; EURL, 2017; Germany, 2017; Italy, 2017) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available.

In addition, key supporting documents to this reasoned opinion are the completeness check report (EFSA, 2017a) and the Member States consultation report (EFSA, 2017b). These reports are developed to address all issues raised in the course of the review, from the initial completeness check to the reasoned opinion. Also, the chronic and acute exposure calculations for all crops reported in the framework of this review performed using the EFSA Pesticide Residues Intake Model (PRIMo) (excel file) and the PROFile are key supporting documents and made publicly available as background documents to this reasoned opinion. Furthermore, a screenshot of the Report sheet of the PRIMo is presented in Appendix C.

Terms of Reference

According to Article 12 of Regulation (EC) No 396/2005, EFSA shall provide a reasoned opinion on:

- the inclusion of the active substance in Annex IV to the Regulation, when appropriate;
- the necessity of setting new MRLs for the active substance or deleting/modifying existing MRLs set out in Annex II or III of the Regulation;
- the inclusion of the recommended MRLs in Annex II or III to the Regulation;
- the setting of specific processing factors as referred to in Article 20(2) of the Regulation.

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).

Fenpyrazamine is a non-systemic fungicide belonging to the pyrizole chemical family. It is used for the control of grey mould (*Botrytis*). Although it is classified as non-systemic, limited translocation in plants was observed. Fenpyrazamine shows its fungicidal activity through inhibition on germ tube elongation and mycelium elongation. However, the biochemical mechanism of fungicidal activity is not clarified (EFSA, 2012a).

The chemical structure of the active substance and its main metabolites are reported in Appendix F.

Fenpyrazamine was evaluated as a new active substance in the framework of Directive 91/414/EEC with Austria designated as the RMS. The representative uses supported for the peer review process were as a foliar application as a fungicide on tomato, aubergine, pepper, cucurbits with edible peel (glasshouse), and field use on grapes. Following the peer review, which was carried out by EFSA (2012a), it was approved in accordance with Regulation (EC) No 1107/2009 by Commission Implementing Regulation (EU) No 595/2012, which entered into force on 1 January 2013. According to Regulation (EU) No 540/2011, as amended by Commission Implementing Regulation (EU) No 541/2011, fenpyrazamine is deemed to be approved under Regulation (EC) No 1107/2009. After the Annex I inclusion, confirmatory data in the area of physical chemical proprieties addressing the confirmatory data identified during the peer review were submitted in the framework of the Directive 91/414/EEC and assessed by EFSA (2014a).

The EU MRLs for fenpyrazamine are established in Annexes IIIA of Regulation (EC) No 396/2005 and CXL(s) for fenpyrazamine are not available. An overview of the MRL changes that occurred since the entry into force of the Regulation mentioned above is provided below (Table 1).

Table 1: Overview of the MRL changes since the entry into force of Regulation (EC) No 396/2005

Procedure	Legal implementation	Remarks
MRL application under Article 10 of the Reg. 396/2005 (EFSA, 2016)	Regulation (EU) No 2016/1902	Modification of MRLs in blueberries and cane fruits
MRL application under Article 10 of the Reg. 396/2005 (EFSA, 2014a,b)	Regulation (EU) No 2015/401	Modification of MRLs in apricots, cherries, plums

Procedure	Legal implementation	Remarks
MRL modification under Article 10 of the Reg. 396/2005 (EFSA, 2012a,b)	Regulation (EU) No 500/2013	Modification of MRLs in peaches and strawberries
MRL modification under Article 10 of the Reg. 396/2005 (EFSA, 2011)	Regulation (EU) No 322/2012	Modification of MRLs in table and wine grapes, tomatoes, peppers, aubergines, cucurbits with edible peel

For the purpose of this MRL review, the critical uses of fenpyrazamine currently authorised within the EU, as well as uses authorised in third countries that might have a significant impact on international trade, have been collected by the RMS and reported in the PROFile. The additional good agricultural practices (GAPs) reported by Member States during the completeness check were also considered. The details of the authorised GAPs for fenpyrazamine are given in Appendix A.

Assessment

EFSA has based its assessment on the PROFile submitted by the RMS, the evaluation report accompanying the PROFile (Austria, 2013), the draft assessment report (DAR) and its addendum prepared under Council Directive 91/414/EEC (Austria, 2011a,b), the conclusion on the peer review of the pesticide risk assessment of the active substance fenpyrazamine (EFSA, 2012a), the previous reasoned opinions on fenpyrazamine (EFSA, 2011, 2012b, 2014b, 2016) as well as the evaluation reports submitted during the completeness check (Belgium, 2017; EURL, 2017; Germany, 2017; Italy, 2017). The assessment is performed in accordance with the legal provisions of the uniform principles for evaluation and authorisation of plant protection products as set out in Commission Regulation (EU) No 546/2011[7] and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (European Commission, 1997a–g, 2000, 2010a,b, 2016; OECD, 2011, 2013).

More detailed information on the available data and on the conclusions derived by EFSA can be retrieved from the list of end points reported in Appendix B.

1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

The metabolism of fenpyrazamine following foliar application was studied in grapevine (fruit crop), lettuce (leafy crop) and oilseed rape (pulses/oilseed) with the test substance labelled on the phenyl- or pyrazolyl moiety in two independent studies for each crop. The metabolism of fenpyrazamine was comparable in all crops investigated.

The parent fenpyrazamine was the major component of radioactive residues with the majority found in surface rinses (88–95% total radioactive residue (TRR) (13.8–41.5 mg/kg) in grapes; 81–92% TRR (96–260 mg/kg) in grape foliage; 71–72% TRR (8.19–8.63 mg/kg) in lettuce; 61–67% TRR (0.88–1.22 mg/kg) in immature foliage of oil seed rape; 50–60% TRR (1.42–1.48 mg/kg) in oilseeds rape haulm and 16–22% TRR (0.005–0.007 mg/kg) in seeds) (Austria, 2011a).

In addition to the parent, the metabolite S-2188-DC was common to all crop metabolism studies and was found in lettuce leaves and in oilseed rape haulms at levels above 10% TRR and in grapes at levels of 1–5% TRR (0.22–1.17 mg/kg). The metabolite S-2188-OH was further common to all crop metabolism studies, however, below levels of 10% TRR in all crops (Austria, 2011a).

1.1.2. Nature of residues in rotational crops

Fenpyrazamine is authorised for use on strawberries, tomatoes, peppers, cucurbits with edible peel which may be grown in rotation. According to the soil degradation studies evaluated in the framework of the peer review, periods required for 90% dissipation (DT_{90} values) of fenpyrazamine in field studies

[7] Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.

up to 134 days, which is higher than the trigger value of 100 days (EFSA, 2012a). Therefore, further investigation of residues in rotational crops was performed and evaluated.

During the peer review, the metabolism in rotational crops was studied in lettuce, carrots and wheat grown after soil application of pyrazolyl-5-^{14}C-labelled fenpyrazamine at 2.83 kg a.s./ha (corresponding to 4.7 N maximum rate). Since no cleavage of the bridge between the phenyl- and pyrazolyl ring was observed, labelling of one moiety was considered sufficient.

The metabolism of fenpyrazamine in three rotational crop studies covering cereals, root and tuber vegetables, and leafy crops was similar to the pathway in primary crops although the presence of the major metabolite S-2188-DC of the total residues in primary crops was found only in rotated wheat straw and grain and not in the edible parts of the other rotated crops because it was rapidly hydroxylated into S-2188-OH.

During the peer review, it was concluded that the metabolism of fenpyrazamine in rotational crops is similar to the pathway observed in primary crops (EFSA, 2012a). This conclusion is supported in this review.

1.1.3. Nature of residues in processed commodities

The effect of processing under standard hydrolyses conditions on the nature of residues was investigated in the framework of the peer review (Austria, 2011a). The residue behaviour of pyrazolyl-labelled fenpyrazamine was studied under conditions simulating pasteurisation (20 min at 90°C, pH 4), baking/brewing/boiling (60 min at 100°C, pH 5) and sterilisation (20 min at 120°C, pH 6) in compliance with good laboratory practice (GLP). Since no cleavage of the bridge between the phenyl- and pyrazolyl ring was observed, labelling of one moiety was considered sufficient.

From these studies, it can be concluded that fenpyrazamine as major compound (99–101% before and 97–102% after incubation) is stable under conditions simulating processing by pasteurisation, baking/brewing/boiling and sterilisation while up to 8.6% of the applied radioactivity degraded into the metabolite S-2188-DC at sterilisation. No other degradation product was identified.

1.1.4. Methods of analysis in plants

A liquid chromatography with tandem mass spectrometric (LC–MS/MS) method is available for monitoring fenpyrazamine in all plant matrices with a limit of quantification (LOQ) of 0.01 mg/kg. The method is validated in high water, high acid, high oil and dry commodities (Austria, 2011a).

Furthermore, the EURLs provided a Quick, Easy, Cheap, Effective, Rugged, and Safe (QuEChERS) method for fenpyrazamine using LC–MS/MS supported by validation data in high water content and high acid content commodities, a LC–QqQ-MS/MS method for dry commodities and a LC-Q-ToF method for high oil content commodities with a LOQ of 0.01 mg/kg (EURLs, 2017).

1.1.5. Stability of residues in plants

In the framework of the peer review, storage stability of fenpyrazamine and S-2188-DC together in one study was demonstrated in high acid, high water, high oil content and dry commodities at −18°C for 12 months. The metabolite S-2188-OH was investigate in an independent study and was stable in high acid, high oil and dry commodities for 12 months and in high water content commodities for 6 months at −18°C (EFSA, 2012a). A data gap was identified for almonds for storage stability study to confirm stability of fenpyrazamine and S-2188-DC in the samples for 818 days at −18°C (EFSA, 2012b).

1.1.6. Proposed residue definitions

As the parent was shown to be the major component of the residues, the peer review concluded that the definition for monitoring can be limited to parent fenpyrazamine. For risk assessment, considering that metabolite S-2188-DC was present at up to 11% TRR in lettuce (1.2 mg/kg) and detected in significant amounts in the supervised residue trials on grape, the definition was proposed as 'sum of fenpyrazamine and S-2188-DC, expressed as fenpyrazamine' (EFSA, 2012a).

Following review of the available metabolism studies, EFSA confirms that the residue definitions derived during the peer review are still considered valid. The same definitions are applicable to rotational crops and processed commodities.

A fully validated analytical method is available for the enforcement of the proposed residue definition in high water, high acid, high oil content and dry commodities with a LOQ of 0.01 mg/kg, respectively.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

To assess the magnitude of fenpyrazamine residues resulting from the reported GAPs, EFSA considered all residue trials reported by the RMS in its evaluation report (Austria, 2013), including residue trials evaluated in the framework of the previous MRL applications (EFSA, 2011, 2012b, 2014b, 2016) and additional data submitted during the completeness check (Belgium, 2017; Germany, 2017; Italy, 2017).

Residue trial samples considered in this framework were stored in compliance with the demonstrated storage conditions with the exception of almonds supporting the import tolerance (US) which were stored for 818 days. Decline of residues during storage of the trial samples is not expected, except for the samples of almonds. Therefore, the validity of the residue trials supporting the import tolerance GAP on almonds is further to be demonstrated by providing adequate storage stability studies.

The number of residue trials and extrapolations were evaluated in accordance with the European guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs (European Commission, 2016).

All residue trials were analysed for both the parent fenpyrazamine and the metabolite S-2188-DC. For an expression of the magnitude of residue according to the residue definition for risk assessment for each pair of residues, the concentration of the metabolite was first converted into parent equivalent by using a molecular conversion factor of 1.43 based on the ratio between the molecular weights of the two compounds and was then added to the fenpyrazamine residue.

For all crops, available residue trials are sufficient to derive MRL and risk assessment values, taking note of the following considerations:

- Strawberries: only four trials on strawberries are available to support the northern and southern outdoor GAP, respectively. Although a MRL was derived from the fully supported EU indoor GAP and import tolerance (US), four additional trials on strawberries to support the northern EU outdoor GAP and four additional trials on strawberries to support the southern EU outdoor GAP are still required.
- Blueberries: one out of the seven available trials is overdosed at second application; however, since the residue level at harvest was within the range of the other GAP-compliant trials it is considered acceptable. Therefore, no additional trials are required.

It is noted that for tomatoes, peppers, aubergines and cucurbits with edible peel, more critical indoor GAPs not supported by data are authorised in Belgium (see comment field of the GAP table in Appendix A for details).

1.2.2. Magnitude of residues in rotational crops

In the confined rotational crop studies evaluated during the peer review (see also Section 1.1.2), total TRRs recovered in all edible parts of rotational crops were very low with exception of mature carrot where fenpyrazamine was found at 0.57 mg eq./kg (30 days after treatment (DAT)) and 0.17 mg eq./kg (120 DAT). Considering that the application rate represented 4.7 N maximum rate, this is corresponding to 0.12 mg eq./kg and 0.08 mg eq./kg, respectively.

Considering the critical GAPs (cGAPs) reported in this review (three applications at BBCH 61–87 at a rate of 600 g a.s./ha), assuming a soil density of 1.5 g/L, soil depth of 5 cm, crop interception of 80% and considering a DT_{50} in soil of 20.5 days, the plateau concentration derived in soil during the peer review, taking into account accumulation over the years, is 0.002 mg/kg soil over three years (EFSA, 2012a,b).

A rotational field crops study was performed in southern Europe (Spain and Italy). The tomato primary crop was treated at the application rate of 3 × 0.6 kg a.s./ha with a 6–8 days interval and was harvested 3 days after application. The application rate is covering the authorised GAP rate (Appendix A). The succeeding crops (carrot, lettuce, tomato and barley) were sown 1 month,

4 months (8 months in case of tomato) and 12 months after the last application on tomatoes and were grown to maturity.

At harvest, the edible parts of the rotational crops were analysed for the residues of fenpyrazamine and its metabolite S-2188-OH, none of which 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.

In this study, information on the soil used, soil cultivation practice (soil density, soil ploughing (mixing) depth is provided; however, the fenpyrazamine soil concentration in the root zone was not available. Therefore, it is not possible to conclude whether the plateau concentration expected after use of fenpyrazamine at the cGAP (0.002 mg/kg soil) is covered by these studies. Nevertheless, considering that the indicative plateau concentration is below the LOQ of 0.01 mg/kg, it can be concluded that a significant accumulation of fenpyrazamine in soil is not expected.

Therefore, based on the submitted confined and rotational crop field studies, it is concluded that residues of fenpyrazamine, S-2188-DC and S-2188-OH above the LOQ are not expected in crops grown in rotation according to the supported use pattern.

1.2.3. Magnitude of residues in processed commodities

Studies investigating the magnitude of residues using grapes for wine, juice, wet pomace and raisin production were evaluated during the peer review (Austria, 2011a,b). An overview of these studies is given in Appendix B.1.2.3.

Robust processing factors could be derived for grape juice, grape white wine, red wine, grape wet pomace and raisins analysed for fenpyrazamine and S-2188-DC. Further processing studies are not required as they are not expected to affect the outcome of the risk assessment. However, if more robust processing factors were to be required by risk managers, in particular for enforcement purposes, additional processing studies would be needed.

1.2.4. Proposed MRLs

The available data are considered sufficient to derive MRL proposals as well as risk assessment values for all commodities under assessment except for almonds, for which only tentative MRLs could be derived.

2. Residues in livestock

Fenpyrazamine is not authorised for use on crops that might be fed to livestock. Further investigation of the occurrence of residues in commodities of animal origin is not required and the setting of MRLs in these commodities is not considered necessary (European Commission, 2012). Nevertheless, goat and poultry metabolism studies are available and were assessed for completeness. The metabolism in rats, poultry and ruminants was similar. Contrary to plants, the metabolism in animals was more extensive and more complex, with numerous metabolites or fractions characterised, all accounting for very low levels (0.01–0.05 mg/kg).

Studies on hen and goats were performed with ^{14}C-fenpyrazamine labelled on the pyrazolyl moiety only, as no cleavage of the bridge between phenyl- and pyrazolyl rings occurred in the rat metabolism. Only 0.2% and 0.8% of the administered radioactivity was recovered in poultry (fed 0.7 mg/kg body weight (bw) per day for 7 days) and goat (fed 0.36 mg/kg bw per day for 5 days) matrices, respectively.

In hens, the TRR levels in egg, muscle, fat, liver and blood were very low. Fenpyrazamine was present at very low levels in egg yolk and egg white (0.001 mg/kg; 3.5% TRR), fat (0.008 mg/kg; 42.6% TRR) and liver (0.004 mg/kg; 2.1% TRR). The metabolite S-2188-DC was detected at very low levels in egg (0.004 mg/kg; 25.1% TRR), muscle (0.001 mg/kg; 4.5% TRR) and liver (0.005 mg/kg; 2.1% TRR). Dealkylation of S-2188-DC resulted in formation of MPPZ (chromatographic peaks not resolved) which was reported in eggs, muscle and liver above 10% TRR (15.9–34.1% TRR).

Fenpyrazamine was only found in goat liver (0.03 mg/kg; 13.7% TRR) and fat (0.002 mg/kg; 17.5% TRR). Metabolite S-2188-DC was found in milk (0.002 mg/kg; 8.6% TRR), muscle (0.003 mg/kg; 24.9% TRR), liver (0.04 mg/kg; 17.1% TRR), kidney (0.04 mg/kg; 21.5% TRR) and fat (0.002 mg/kg; 25.9% TRR). Metabolite S-2188-CH_2OH-DC (free and conjugated) was reported above 10% TRR (12.7–29.2% TRR) in muscle, kidney and liver.

During the peer review, metabolism studies performed on domestic animals (goat and hen) indicated that fenpyrazamine and S-2188-DC should be defined as the residue definition for monitoring and for risk assessment the inclusion of metabolites S-2188-CH_2OH-DC (relevant for ruminant matrices) and MZZP (relevant for poultry matrices) was proposed (EFSA, 2012a). During this review, these residue definitions for monitoring and risk assessment are still considered relevant. Nevertheless, it is underlined that the proposed residue definitions may need to be reconsidered in case uses on crops fed to livestock are authorised in the future.

A method for enforcement of fenpyrazamine and/or its metabolites was not provided during the peer review. During this review the EURLs provided a screening LC–MS-Q-ToF quantitative method for fenpyrazamine which is supported by validation data for honey, muscle (red meat, white meat, fish), and milk and milk products with a screening detection limit (SDL) of 0.005 mg/kg (EURLs, 2017).

Storage stability of fenpyrazamine and metabolites (including S-2188-DC, MPZZ, S-2188-OH, S-2188-CH_2OH-DC) was demonstrated indicatively for 9 and 4 months in frozen stored samples of the goat and hen metabolism studies, respectively. It is reported that samples were stored frozen without specifying the storage temperature; however, it is assumed that it was at −18°C (Austria, 2011a).

3. Consumer risk assessment

Chronic and acute exposure calculations for all crops reported in the framework of this review were performed using revision 2 of the EFSA PRIMo (EFSA, 2007). Input values for the exposure calculations were derived in compliance with the decision tree reported in Appendix E. Hence, for those commodities where a (tentative) MRL could be derived by EFSA in the framework of this review, input values were derived according to the internationally agreed methodologies (FAO, 2009). All input values included in the exposure calculations are summarised in Appendix D.

The exposures calculated were compared with the toxicological reference values for fenpyrazamine, derived by EFSA (2012a) under Directive 91/414/EEC. The highest chronic exposure was calculated for WHO cluster diet B, representing 5.1% of the acceptable daily intake (ADI), and the highest acute exposure was calculated for peaches, representing 78.2% of the ARfD. Based on these calculations, EFSA concludes that although uncertainties remain due to the data gaps identified in the previous sections, this indicative exposure calculation did not indicate an unacceptable risk to consumers.

Conclusions

The metabolism of fenpyrazamine following foliar application was studied in grapevine (fruit crop), lettuce (leafy crop) and oilseed rape (pulses/oilseed) with the test substance labelled either on the phenyl- or pyrazolyl moiety. The metabolism of fenpyrazamine was comparable in all crops investigated. Standard processing studies evidenced that fenpyrazamine was stable under conditions simulating processing by pasteurisation, baking/brewing/boiling and sterilisation.

Following review of the available metabolism studies, the residue definition for enforcement was proposed as parent compound fenpyrazamine only and for risk assessment as the sum of parent and S-1188-DC, expressed as fenpyrazamine. The same definitions are applicable to rotational crops and processed commodities.

A validated LC–MS/MS method is available to enforce the proposed residue definition in plant with a LOQ of 0.01 mg/kg in high water and high oil content, acidic and dry commodities.

All residue trials were analysed for both the parent fenpyrazamine and the metabolite S-2188-DC. The available data are considered sufficient to derive MRL proposals as well as risk assessment values for apricots, cherries, peaches, plums, table and wine grapes, blackberries, dewberries, raspberries blueberries, tomatoes, peppers, aubergines and cucurbits with edible peel. For almonds, only a tentative MRL could be derived.

Residues of fenpyrazamine, S-2188-DC and S-2188-OH above LOQ are not expected in crops grown in rotation according to the supported use pattern and based on the submitted rotational crop field study. Robust processing factors could be derived for grape juice, white wine, red wine, wet pomace and raisins.

Fenpyrazamine is not authorised for use on crops that might be fed to livestock. Therefore, further investigation of the occurrence of residues in commodities of animal origin is not required and the setting of MRLs in these commodities is not considered necessary. However, available metabolism studies performed on goat and hen indicated that fenpyrazamine and S-2188-DC should be defined as the residue definition for monitoring while for risk assessment the inclusion of metabolites S-2188-CH_2OH-DC

and MZZP should be considered. A method for enforcement of fenpyrazamine and/or its metabolites in animal commodities is currently not available and at present not required. The EURLs provided a screening quantitative method for fenpyrazamine for honey, muscle (red meat, white meat, fish) and milk and milk products with a SDL of 0.005 mg/kg.

Chronic and acute consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 2 of the EFSA PRIMo. According to the results of this calculation, the highest chronic exposure represented 5.1% of the ADI (WHO, cluster diet B) and the highest acute exposure amounted to 78.2% of the ARfD (peaches).

Recommendations

MRL recommendations were derived in compliance with the decision tree reported in Appendix E of the reasoned opinion (see Table 2). All MRL values listed as 'Recommended' in the table are sufficiently supported by data and are therefore proposed for inclusion in Annex II to the Regulation. The remaining MRL values listed in the table are not recommended for inclusion in Annex II because they require further consideration by risk managers (see Table 2 footnotes for details). In particular, some tentative MRLs need to be confirmed by the following data:

- a representative storage stability study covering fenpyrazamine and S-2188-DC for the storage period of samples of almond residue trials (818 days at −18°C) or four new residue trials on almonds supporting the import tolerance (US) with the residue samples stored according to the demonstrated storage stability conditions.

It is highlighted, however, that some of the MRLs derived result from a GAP in one climatic zone only, whereas other GAPs reported by the RMS were not fully supported by data. EFSA therefore identified the following data gaps which are not expected to impact on the validity of the MRLs derived but which might have an impact on national authorisations:

- Additional trials on strawberries;

It is also noted that for tomatoes, peppers, aubergines and cucurbits with edible peel, more critical indoor GAPs not supported by data are authorised in Belgium (see comment field of the GAP table in Appendix A for details).

If the above-reported data gaps are not addressed in the future, Member States are recommended to withdraw or modify the relevant authorisations at national level.

Table 2: Proposed MRLs.

Code number[(a)]	Commodity	Existing EU MRL (mg/kg)	Outcome of the review	
			MRL (mg/kg)	Comment
Enforcement residue definition: fenpyrazamine				
0120010	Almonds	0.01*	0.01*	Further consideration needed[(b)]
0140010	Apricots	5	5	Recommended[(c)]
0140020	Cherries (sweet)	4	4	Recommended[(c)]
0140030	Peaches	4	5	Recommended[(c)]
0140040	Plums	3	3	Recommended[(c)]
0151010	Table grapes	3	3	Recommended[(c)]
0151020	Wine grapes	3	3	Recommended[(c)]
0152000	Strawberries	3	3	Recommended[(c)]
0153010	Blackberries	5	5	Recommended[(c)]
0153020	Dewberries	5	5	Recommended[(c)]
0153030	Raspberries (red and yellow)	5	5	Recommended[(c)]
0154010	Blueberries	4	4	Recommended[(c)]
0231010	Tomatoes	3	3	Recommended[(c)]
0231020	Sweet peppers/bell peppers	3	3	Recommended[(c)]

Code number[a]	Commodity	Existing EU MRL (mg/kg)	Outcome of the review	
			MRL (mg/kg)	Comment
0231030	Aubergines/eggplants	3	3	Recommended[c]
0232010	Cucumbers	0.7	0.7	Recommended[c]
0232020	Gherkins	0.7	0.7	Recommended[c]
0232030	Courgettes	0.7	0.7	Recommended[c]
–	Other commodities of plant and animal origin	See Regulation (EC) No 149/2008	–	Further consideration needed[d]

MRL: maximum residue level; CXL: codex maximum residue limit.
*: Indicates that the MRL is set/proposed at the limit of quantification.
(a): Commodity code number, as listed in Annex I of Regulation (EC) No 396/2005.
(b): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified (assuming the existing residue definition); no CXL is available (combination E-I in Appendix E).
(c): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; no CXL is available (combination G-I in Appendix E).
(d): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix E).

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Abbreviations

a.i.	active ingredient
a.s.	active substance
ADI	acceptable daily intake
AR	applied radioactivity
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CF	conversion factor for enforcement residue definition to risk assessment residue definition
cGAP	critical GAP
CXL	codex maximum residue limit
DAR	draft assessment report
DAT	days after treatment
DB	dietary burden
DM	dry matter
DT_{90}	period required for 90% dissipation (define method of estimation)
EMS	evaluating Member State
eq	residue expressed as a.s. equivalent
EURLs	European Union Reference Laboratories for Pesticide Residues (former CRLs)
FAO	Food and Agriculture Organization of the United Nations

GAP	Good Agricultural Practice
GLP	Good Laboratory Practice
HPLC–MS/MS	high performance liquid chromatography with tandem mass spectrometry
HR	highest residue
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ILV	independent laboratory validation
ISO	International Organisation for Standardization
IUPAC	International Union of Pure and Applied Chemistry
LC–MS/MS	liquid chromatography with tandem mass spectrometry
LOQ	limit of quantification
Mo	monitoring
MRL	maximum residue level
MS	Member States
MS/MS	tandem mass spectrometry detector
NEU	northern European Union
OECD	Organisation for Economic Co-operation and Development
PBI	plant-back interval
PF	processing factor
PHI	pre-harvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
PROFile	(EFSA) Pesticide Residues Overview File
Q-ToF	quadrupole time of flight
QqQ	triple quadrupole
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
RA	risk assessment
RD	residue definition
RAC	raw agricultural commodity
RD	residue definition
RMS	rapporteur Member State
SANCO	Directorate-General for Health and Consumers
SC	suspension concentrate
SDL	screening detection limit
SEU	southern European Union
SMILES	simplified molecular-input line-entry system
STMR	supervised trials median residue
ToF	time-of-flight
TRR	total radioactive residue
WG	water-dispersible granule
WHO	World Health Organization

Appendix A – Summary of authorised uses considered for the review of MRLs

Crop		Region	Outdoor/ indoor[a]	Member state or country	Pest controlled	Formulation			Application										PHI or waiting period (days)[d]	Comments (max. 250 characters)
Common name	Scientific name					Type[b]	Content		Method	Growth stage[c]		Number		Interval (days)		Rate				
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.	Min.	Max.	Unit		
Critical outdoor GAPs for northern Europe																				
Apricots	*Armeniaca vulgaris,* syn: *Prunus armeniaca*	NEU	Outdoor	AT, DE	*Monilia laxa*, *Monilia fructigena*	WG	500.0	g/kg	Foliar treatment – spraying	57	87		3	3	7	0.40	0.60	kg a.i./ha	1	–
Cherries	*Cerasus avium,* syn: *Prunus avium*	NEU	Outdoor	AT, DE	*Monilia laxa*, *Monilia fructigena*	WG	500.0	g/kg	Foliar treatment – spraying	57	87		3	3	7	0.40	0.60	kg a.i./ha	1	–
Peaches	*Persica vulgaris,* syn: *Prunus persica*	NEU	Outdoor	AT, CZ, HU, PL, RO, SK, SL	*Monilia laxa*, *Monilia fructigena*	WG	500.0	g/kg	Foliar treatment – spraying	57	87		3	7	7	0.40	0.60	kg a.i./ha	1	Including nectarines and similar hybrids (EFSA, 2012b)
Plums	*Prunus domestica*	NEU	Outdoor	AT, DE	*Monilia laxa*, *Monilia fructigena*	WG	500.0	g/kg	Foliar treatment – spraying	57	87		3	3	7	0.40	0.60	kg a.i./ha	1	–
Table grapes	*Vitis vinifera*	NEU	Outdoor	AT, BE, DE, CZ, HU, RO, SL, SK, UK	*Botrytis*	WG	500.0	g/kg	Foliar treatment – spraying	61	87		1			0.30	0.60	kg a.i./ha	14	–
Wine grapes	*Vitis vinifera*	NEU	Outdoor	AT, BE, DE, CZ, HU, RO, SL, SK, UK	*Botrytis*	WG	500.0	g/kg	Foliar treatment – spraying	61	87		1			0.30	0.60	kg a.i./ha	14	–
Strawberries	*Fragaria x ananassa*	NEU	Outdoor	AT, BE, CZ, HU, IE, NL, PL, RO, SK, SL, UK	*Botrytis*	WG	500.0	g/kg	Foliar treatment – spraying	59	89		3	7	14	0.40	0.60	kg a.i./ha	1	–
Critical outdoor GAPs for southern Europe																				
Apricots	*Armeniaca vulgaris,* syn: *Prunus armeniaca*	SEU	Outdoor	BG, CY, EL, FR, ES, PT	*Monilia* sp.	WG	500.0	g/kg	Foliar treatment – spraying	61	87		3		7	0.40	0.60	kg a.i./ha	1	–
Cherries	*Cerasus avium,* syn: *Prunus avium*	SEU	Outdoor	BG, CY, EL, FR, ES, PT	*Monilia* sp.	WG	500.0	g/kg	Foliar treatment – spraying	61	87		3		7	0.40	0.60	kg a.i./ha	1	–

Crop		Region	Outdoor/ indoor[a]	Member state or country	Pest controlled	Formulation			Application											PHI or waiting period (days)[d]	Comments (max. 250 characters)
Common name	Scientific name					Type[b]	Content		Method	Growth stage[c]		Number		Interval (days)		Rate				
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.	Min.	Max.	Unit		
Peaches	*Persica vulgaris,* syn: *Prunus persica*	SEU	Outdoor	BG, CY, ES, FR, GR, PT	*Monilia* sp.	WG	500.0	g/kg	Foliar treatment – spraying	61	87		3	7	7	0.40	0.60	kg a.i./ha	1	Including nectarines and similar hybrids (EFSA, 2012b)
Plums	*Prunus domestica*	SEU	Outdoor	BG, CY, EL, FR, ES, PT	*Monilia* sp.	WG	500.0	g/kg	Foliar treatment – spraying	61	87		3		7	0.40	0.60	kg a.i./ha	1	–
Table grapes	*Vitis vinifera*	SEU	Outdoor	BG, CY, ES, FR, GR, PT	*Botrytis*	WG	500.0	g/kg	Foliar treatment – spraying	61	87		1		7	0.40	0.60	kg a.i./ha	7	–
Wine grapes	*Vitis vinifera*	SEU	Outdoor	BG, CY, ES, FR, GR, PT	*Botrytis*	WG	500.0	g/kg	Foliar treatment – spraying	61	87		1		7	0.40	0.60	kg a.i./ha	14	–
Strawberries	*Fragaria x ananassa*	SEU	Outdoor	BG, CY, ES, FR, GR, IT, PT	*Botrytis*	WG	500.0	g/kg	Foliar treatment – spraying	61	87		3	7	14	0.40	0.60	kg a.i./ha	1	–
Critical indoor GAPs for northern and southern Europe (including post-harvest treatments)																				
Strawberries	*Fragaria x ananassa*	NEU/SEU	Indoor	AT, BG, CY, CZ, DE, DK, ES, FR, GR, HU, IE, LT, LV, NL, PL, PT, RO, SE, SK, SL, UK	*Botrytis*	WG	500.0	g/kg	Foliar treatment – spraying	59	89		3	7	14	0.40	0.60	kg a.i./ha	1	–
Tomatoes	*Lycopersicon esculentum*	NEU/SEU	Indoor	AT, BG, CY, CZ, DE, DK, ES, FR, GR, HU, IE, IT, LT, LV, NL, PL, PT, RO, SE, SK, SL, UK	*Botrytis*	WG	500.0	g/kg	Foliar treatment – spraying	61	87		3	10	14	0.40	0.60	kg a.i./ha	1	A more critical GAP is authorised in Belgium (BBCH 61-87, 3 applications, interval 7–10 days, 1 kg a.s./ha); however, not supported by data
Sweet peppers	*Capsicum annuum*	NEU/SEU	Indoor	AT, BG, CY, CZ, DE, DK, ES, FR, GR, HU, IE, LT, LV, NL, PL, PT, RO, SE, SK, SL, UK	*Botrytis*	WG	500.0	g/kg	Foliar treatment – spraying	61	87		3	10	14	0.40	0.60	kg a.i./ha	1	A more critical GAP is authorised in Belgium (BBCH 61-87, 3 applications, interval 7–10 days, 1 kg a.s./ha); however, not supported by data

Crop		Region	Outdoor/ indoor[a]	Member state or country	Pest controlled	Formulation			Application											PHI or waiting period (days)[d]	Comments (max. 250 characters)
Common name	Scientific name					Type[b]	Content		Method	Growth stage[c]		Number		Interval (days)		Rate				
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.	Min.	Max.	Unit		
Aubergines	*Solanum melongena*	NEU/SEU	Indoor	AT, BG, CY, CZ, DE, DK, ES, FR, GR, HU, IE, LT, LV, NL, PL, PT, RO, SE, SK, SL, UK	*Botrytis*	WG	500.0	g/kg	Foliar treatment – spraying	61	87		3	10	14	0.40	0.60	kg a.i./ha	1	A more critical GAP is authorised in Belgium (BBCH 61-87, 3 applications, interval 7–10 days, 1 kg a.s./ha); however, not supported by data
Cucumbers	*Cucumis sativus*	NEU/SEU	Indoor	AT, BG, CY, CZ, DE, DK, ES, FR, GR, HU, IE, LT, LV, NL, PL, PT, RO, SE, SK, SL, UK	*Botrytis*	WG	500.0	g/kg	Foliar treatment – spraying	61	87		3	10	14	0.40	0.60	kg a.i./ha	1	A more critical GAP is authorised in Belgium (BBCH 61-87, 3 applications, interval 7–10 days, 1 kg a.s./ha); however, not supported by data
Gherkins	*Cucumis sativus*	NEU/SEU	Indoor	AT, BG, CY, CZ, DE, DK, ES, FR, GR, HU, IE, IT, LT, LV, NL, PL, PT, RO, SE, SK, SL, UK	*Botrytis*	WG	500.0	g/kg	Foliar treatment – spraying	61	87		3	10	14	0.40	0.60	kg a.i./ha	1	A more critical GAP is authorised in Belgium (BBCH 61-87, 3 applications, interval 7–10 days, 1 kg a.s./ha); however, not supported by data
Courgettes	*Cucurbita pepo* Zucchini group	NEU/SEU	Indoor	AT, BG, CY, CZ, DE, DK, ES, FR, GR, HU, IE, LT, LV, NL, PL, PT, RO, SE, SK, SL, UK	*Botrytis*	WG	500.0	g/kg	Foliar treatment – spraying	61	87		3	10	14	0.40	0.60	kg a.i./ha	1	A more critical GAP is authorised in Belgium (BBCH 61-87, 3 applications, interval 7–10 days, 1 kg a.s./ha); however, not supported by data
Critical GAPs for import tolerances (non-European indoor, outdoor or post-harvest treatments)																					
Almonds	*Amygdalus communis,* syn: *Prunus dulcis*	Non-EU	Outdoor	US	*Botrytis*	SC	436.0	g/L	Foliar treatment – spraying	65	81		3				0.42	kg a.i./ha	21	Type of formulation also WG (500 g fenpyrazamine/kg)
Table grapes	*Vitis vinifera*	Non-EU	Outdoor	US	*Botrytis*	SC	436.0	g/L	Foliar treatment – spraying	81	85		3				0.56	kg a.i./ha	3	See almonds

Crop		Region	Outdoor/ indoor[a]	Member state or country	Pest controlled	Formulation			Application										PHI or waiting period (days)[d]	Comments (max. 250 characters)
Common name	Scientific name					Type[b]	Content		Method	Growth stage[c]		Number		Interval (days)		Rate				
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.	Min.	Max.	Unit		
Wine grapes	*Vitis vinifera*	Non-EU	Outdoor	US	*Botrytis*	SC	436.0	g/L	Foliar treatment – spraying	81	85		3				0.56	kg a.i./ha	3	See almonds
Strawberries	*Fragaria x ananassa*	non-EU	Outdoor	US	*Botrytis*	WG	500.0	g/kg	Foliar treatment – spraying	81	87		4				0.56	kg a.i./ha	0	See almonds
Blackberries	*Rubus* sect. *Rubus*	Non-EU	Outdoor	US	*Botrytis*	SC	436.0	g/kg	Foliar treatment – spraying				3	7	10		0.56	kg a.i./ha	0	Max. 3 applications per season. Max. 1,680 g/ha per season. First application at early bloom
Dewberries	*Rubus caesius*	Non-EU	Outdoor	US	*Botrytis*	SC	436.0	g/kg	Foliar treatment – spraying				3	7	10		0.56	kg a.i./ha	0	See blackberries
Raspberries	*Rubus idaeus*	Non-EU	Outdoor	US	*Botrytis*	SC	436.0	g/kg	Foliar treatment – spraying				3	7	10		0.56	kg a.i./ha	0	See blackberries
Blueberries	*Vaccinium angustifolium; Vaccinium corymbosum; Vaccinium formosum; Vaccinium virgatum*	Non-EU	Outdoor	US	*Botrytis*	SC	436.0	g/kg	Foliar treatment – spraying				3	7	10		0.56	kg a.i./hL	0	Max. 3 applications per season. Max. 1,680 g/ha per season. Application when condition favour disease development and prior to infection

GAP: Good Agricultural Practice; BBCH: growth stages of mono- and dicotyledonous plants; PHI: preharvest interval; NEU: northern European Union; SEU: southern European Union; a.i.: active ingredient; SC: suspension concentrate; WG: water-dispersible granule; MS: Member State.
(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide.
(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.
(d): PHI: minimum preharvest interval.

Appendix B – List of end points

B.1. Residues in plants

B.1.1. Nature of residues and methods of analysis in plants

B.1.1.1. Metabolism studies, methods of analysis and residue definitions in plants

Primary crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**Sampling (DAT)**
	Fruit crops	Grapes	Foliar, 2 × 0.75 kg a.s./ha	14, 21
	Leafy crops	Lettuce	Foliar, 3 × 0.85 kg a.s./ha	14, 28, 42
	Pulses/oilseeds	Oil seed rape	Foliar, 2 × 0.6 kg a.s./ha	46, 115
	Source: Austria (2011a)			
Rotational crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**PBI (DAT)**
	Root/tuber crops	Carrots	Bare soil, 2.83 kg a.s./ha	30, 120, 365
	Leafy crops	Lettuce	Bare soil, 2.83 kg a.s./ha	30, 120, 365
	Cereal (small grain)	Wheat	Bare soil, 2.83 kg a.s./ha	30, 120, 365
	Source: Austria (2011a)			
Processed commodities (hydrolysis study)	**Conditions**		**Investigated?**	
	Pasteurisation (20 min, 90°C, pH 4)		Yes	
	Baking, brewing and boiling (60 min, 100°C, pH 5)		Yes	
	Sterilisation (20 min, 120°C, pH 6)		Yes	
	Source: Austria (2011a)			

Can a general residue definition be proposed for primary crops?	Yes
Rotational crop and primary crop metabolism similar?	Yes
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes
Plant residue definition for monitoring (RD-Mo)	Fenpyrazamine
Plant residue definition for risk assessment (RD-RA)	Sum of fenpyrazamine and S-2188-DC, expressed as fenpyrazamine
Conversion factor (monitoring to risk assessment)	See Appendix B.1.2.1
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)	High water, high acid, high oil and dry commodities: • HPLC–MS/MS (DFG 19), LOQ: 0.01 mg/kg for fenpyrazamine in carrots, peppers, grapes, rape seed, and cereal (grain and straw), respectively; validation data and ILV available (Austria, 2011a) • LC–MS/MS, LOQ: 0.01 mg/kg for fenpyrazamine, in high water and high acid commodities, validation data available (spinach, lemon) (EURLs, 2017) • LC–QqQ-MS/MS, LOQ: 0.01 mg/kg for fenpyrazamine in dry commodities, validation data available (oat, rye, wheat) (EURLs, 2017) • LC-Q-ToF, LOQ: 0.01 mg/kg for fenpyrazamine in high oil commodities, validation data available (avocado) (EURLs, 2017)

a.s.: active substance; DAT: days after treatment; PBI: plant-back interval; HPLC–MS/MS: high-performance liquid chromatography with tandem mass spectrometry; LC–MS/MS: liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; ILV: independent laboratory validation; QqQ: triple quadrupole; ToF: time-of-flight.

B.1.1.2. Stability of residues in plants

Plant products (available studies)	**Category**	**Commodity**	**T (°C)**	**Stability (months)**
	High water content	Lettuce	−18	12
	High oil content	Rape seed	−18	12
	Dry/high starch	Cereal grain	−18	12
	High acid content	Grapes	−18	12
	Two different storage stability studies are available: one investigating the stability of fenpyrazamine and S-2188-DC and a separate study investigating the metabolite S-2188-OH, alone for which in high water content commodities stability was demonstrated for 6 months only. Source: Austria (2011a)			

B.1.2. Magnitude of residues in plants

B.1.2.1. Summary of residues data from the supervised residue trials

Crop	Region/ indoor[a]	Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg)	Recommendations/comments (OECD calculations)	MRL proposals (mg/kg)	HR_{Mo} (mg/kg)[b]	$STMR_{Mo}$ (mg/kg)[c]	CF[d]
Almonds	Import (US)	**Mo:** < 0.01; < 0.01; < 0.01; < 0.01;< 0.01 **RA:** < 0.02; < 0.02; < 0.02; < 0.02;< 0.02	GAP-compliant trials on almonds (EFSA, 2012b; Austria, 2013)	0.01*[e] (tentative)	0.01	0.01	1.0[f]
Apricots and peaches	NEU	**Apricots:** **Mo:** 0.43; 0.52 **RA:** 0.58; 0.67 **Peaches:** **Mo:** 0.36; 0.61; 0.76; 1.5 **RA:** 0.73; 0.77; 1.1; 1.59	Combined data set of trials on apricots (2) and peaches (4) compliant with GAP (Austria, 2013; EFSA, 2014b)	3	1.50	0.57	1.3
	SEU	**Apricots:** **Mo:** 0.89; 1.1; 1.6; 3.0 **RA:** 1.15; 1.57; 1.93; 3.79 **Peaches:** **Mo:** 0.44; 0.55; 0.7; 0.85; 0.94; 0.95; 1.1; 1.6; 2.5 **RA:** 0.61; 0.88; 0.94; 0.95; 1.12; 1.25; 1.26; 2.51	Combined data set of trials on apricots (4) and peaches (8) compliant with GAP (Austria, 2013; EFSA, 2014b)	5	3.00	0.95	1.3
Cherries (sweet)	NEU	**Mo:** 0.33; 0.36; 0.41; 0.54; 0.60; 0.82; 1.8; 1.9 **RA:** 0.47; 0.48; 0.59; 0.61; 0.70; 1.01; 1.94; 2.17	GAP-compliant trials on cherries (EFSA, 2014b)	4	1.90	0.57	1.2
	SEU	**Mo:** 0.34; 0.61; 1.0; 1.0 **RA:** 0.45; 0.78; 1.23; 1.37	GAP-compliant trials on cherries (EFSA, 2014b)	3	1.00	0.81	1.3

Crop	Region/ indoor[a]	Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg)	Recommendations/comments (OECD calculations)	MRL proposals (mg/kg)	HR_{Mo} (mg/kg)[b]	$STMR_{Mo}$ (mg/kg)[c]	CF[d]
Plums	NEU	**Mo:** 0.12; 0.18; 0.19; 0.33; 0.40; 0.67; 0.84; 1.5 **RA:** 0.77; 0.93; 0.15; 0.21; 0.49; 1.69; 0.42; 0.22	GAP-compliant trials on plums (EFSA, 2014b)	3	1.50	0.37	1.2
	SEU	**Mo:** 0.23; 0.23; 0.30; 0.36; 0.40; 0.56; 0.70; 0.87; 0.70 **RA:** 0.26; 0.83; 1.1; 0.67; 0.37; 0.43; 0.47; 0.44	GAP-compliant trials on plums (EFSA, 2014b)	1.5	0.87	0.38	1.2
Table and wine grapes	Import (US)	**Mo:** 0.33; 0.53; 0.55; 0.71; 0.80; 0.88; 0.93; 0.91; 1.01; 1.06; 1.09; 1.10; 1.24; 2.08 **RA:** 0.37; 0.62; 0.66; 0.95; 1.03; 1.07; 1.39; 1.18; 1.28; 1.30; 1.26; 1.62; 1.43; 3.17	GAP-compliant trials on grapes (EFSA, 2012b; Austria, 2013)	3	2.08	0.92	1.3
	NEU	**Mo:** 0.18; 0.23; 0.23; 0.29; 0.49; 0.52; 0.54; 0.74 **RA:** 0.22; 0.29; 0.26; 0.33; 0.60; 0.69; 0.63; 0.85	GAP-compliant trials on grapes (Austria, 2011a,b, 2013; EFSA, 2011)	1.5	0.74	0.39	1.2
	SEU	**Mo:** 0.06; 0.08; 0.13; 0.15; 0.37; 0.62; 1.00; 1.20 **RA:** 0.07; 0.09; 0.16; 0.16; 0.44; 0.91; 1.11; 1.59	GAP-compliant trials on grapes (Austria, 2011a,b, 2013; EFSA, 2011)	3	1.20	0.26	1.1
Strawberries	Import (US)	**Mo:** 0.39; 0.41; 0.54; 0.87; 0.88; 0.95; 1.3; 1.7 **RA:** 0.5; 0.58; 0.59; 0.94; 0.99; 1.22; 1.49; 1.8	GAP-compliant trials on strawberries (EFSA, 2012b; Austria, 2013)	3	1.70	0.88	1.1
	NEU	**Mo:** 0.3; 0.64; 0.65; 1.3 **RA:** 0.39; 0.83; 0.84; 1.44	GAP-compliant trials on strawberries (EFSA, 2012b; Austria, 2013)	3[g] (tentative)	1.30	0.65	1.3
	SEU	**Mo:** 0.28; 0.47; 0.54; 1.4 **RA:** 0.41; 0.7; 0.81; 1.66	GAP-compliant trials on strawberries (EFSA, 2012b; Austria, 2013)	3[g] (tentative)	1.40	0.51	1.5
	EU	**Mo:** 0.24; 0.28; 0.35; 0.45; 0.76; 0.86; 0.92; 1.4 **RA:** 0.28; 0.36; 0.47; 0.54; 1.0; 1.07; 1.15; 2.03	GAP-compliant trials on strawberries (EFSA, 2012b)	3	1.40	0.61	1.3

Crop	Region/ indoor[a]	Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg)	Recommendations/comments (OECD calculations)	MRL proposals (mg/kg)	HR_{Mo} (mg/kg)[b]	$STMR_{Mo}$ (mg/kg)[c]	CF[d]
Blackberries, dewberries, raspberries	Import (US)	**Blackberries:** **Mo:** 0.53; 1.60; 2.81 **RA:** 0.62; 1.86; 3.22 **Raspberries:** **Mo:** 1.2; 1.55; 1,90 **RA:** 1.47; 2.04; 2.21	Combined data set on raspberries (3) and on blackberries (3) compliant with GAP (EFSA, 2016). Tentatively extrapolated to dewberries	5	2.81	1.58	1.2
Blueberries	Import (US)	**Mo:** 0.15; 0.35; 0.74; 0.92; 1.04; 1.80; 2.31; 0.38 **RA:** 0.22; 0.49; 0.85; 1.11; 1.27; 2.03; 2.80; 0.51	GAP-compliant trials on blueberries (7) and one (underlined) with a second exaggerated application rate of 1,139 g/ha (EFSA, 2016). The last trial was included because last application was at requested dose rate (555 g/ha) and residue level at harvest within range of other residues (EFSA, 2016)	4	2.31	0.83	1.2
Tomatoes and aubergines	EU	**Mo:** 0.56; 0.65; 0.66; 0.71; 0.85; 1.40; 1.50; 1.80**RA:** 0.65; 0.67; 0.71; 0.74; 0.88; 1.43; 1.53; 1.83	GAP-compliant trials on tomatoes (EFSA, 2011; Austria, 2013)	3	1.80	0.78	1.0
Sweet peppers/bell peppers	EU	**Mo:** 0.47; 0.58; 0.60; 0.69; 0.94; 1.20; 1.30; 1.40 **RA:** 0.53; 0.61; 0.75; 0.80; 1.00; 1.44; 1.46; 1.54	GAP-compliant trials on peppers (EFSA, 2011; Austria, 2013)	3	1.40	0.82	1.1
Cucurbits with edible peel (Cucumbers, gherkins, courgettes)	EU	**Mo:** 0.12; 0.14; 0.15; 0.16; 0.22; 0.25; 0.33; 0.34 **RA:** 0.13; 0.16; 0.17; 0.17; 0.23; 0.26; 0.34; 0.38	GAP-compliant residue trials on cucumber (EFSA, 2011; Austria, 2013)	0.7	0.34	0.19	1.1

GAP: Good Agricultural Practice; OECD: Organisation for Economic Co-operation and Development; MRL: maximum residue level; Mo: monitoring; RA: risk assessment.
*: Indicates that the MRL is proposed at the limit of quantification.
(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Indoor: indoor EU trials or Country code: if non-EU trials.
(b): Highest residue according to the residue definition for monitoring.
(c): Supervised trials median residue according to the residue definition for monitoring.
(d): Conversion factor for risk assessment; median of the individual conversion factors at the supported PHI for each residues trial.
(e): Tentative MRL is derived from trials with samples stored for a period not covered by the available storage stability studies.
(f): Since both parent and the metabolite S-2188-DC were below LOQ, a conversion factor of 1 is proposed for risk assessment.
(g): Tentative MRL derived from reduced number of trials.

B.1.2.2. Residues in succeeding crops

Confined rotational crop study (quantitative aspect)	In the confined rotational crop studies evaluated during the peer review (see also Section 1.2.2), total radioactive residues (TRR) recovered in all edible parts of rotational crops were very low with exception of mature carrot where fenpyrazamine was found at 0.57 mg eq./kg (30 DAT) and 0.17 mg eq./kg (120 DAT). Considering that the application rate represented 4.7 N maximum rate, this is corresponding to 0.12 mg eq./kg and 0.08 mg eq./kg, respectively
Field rotational crop study	In succeeding crops (carrot, lettuce, tomato and barley) sown 1 month, 4 months (8 months in case of tomato) and 12 months after the last application (GAP rate) on tomatoes, were grown to maturity. Residues of fenpyrazamine and its metabolite S-2188-OH were below the LOQ of the analytical method (0.01 mg/kg). It is concluded that a significant accumulation of fenpyrazamine in soil and residues of fenpyrazamine above the LOQ are not expected in rotational crops

DAT: days after treatment; GAP: Good Agricultural Practice; LOQ: limit of quantification.

B.1.2.3. Processing factors

Processed commodity	Number of studies[a]	Processing factor (PF)		CF_P[b]
		Individual values	Median PF	
Robust processing factors (sufficiently supported by data)				
Grape, white wine	3	0.60; 0.78; 1.38	0.78	1.3
Grape, red wine (heated most)	3	0.19; 0.28; 0.48	0.28	3.4
Grape juice, pasteurised	4	0.06; 0.09; 0.16; 0.31	0.13	1.6
Grape, raisins	3	1.62; 1.67; 2.8	1.67	1.1
Grape, wet pomace	4	0.65; 1.4; 2.23; 6.29	1.82	1.04

(a): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur).
(b): Conversion factor for risk assessment in the processed commodity; median of the individual conversion factors for each processing residues trial.

B.2. Residues in livestock

Relevant groups	Dietary burden expressed in				Most critical diet	Most critical commodity	Trigger exceeded (Y/N)
	mg/kg bw per day		mg/kg DM				
	Med.	Max.	Med.	Max.			
Commodities under assessment are not fed to livestock.							

B.2.1. Nature of residues and methods of analysis in livestock

B.2.1.1. Metabolism studies, methods of analysis and residue definitions in livestock

Livestock (available studies)	Animal	Dose (mg/kg bw per day)	Duration (days)	N rate/comment
	Laying hen	0.70	7	Commodities under assessment are not fed to livestock
	Lactating goat	0.36	5	Commodities under assessment are not fed to livestock
	Source: Austria (2011a)			

bw: body weight.

Time needed to reach a plateau concentration in milk and eggs (days)	Three to four days for milk and two to three days for egg white (six for egg yolk)
Metabolism in rat and ruminant similar (Yes/No)	Yes
Animal residue definition for monitoring (RD-Mo)	Sum of fenpyrazamine and S-2188-DC, expressed as fenpyrazamine
Animal residue definition for risk assessment (RD-RA)	Sum of fenpyrazamine, S-2188-DC, S-2188-CH_2OH-DC and MPPZ, expressed as fenpyrazamine (provisional)
Conversion factor (monitoring to risk assessment)	Not derived (commodities under assessments not fed to live stock)
Fat soluble residues (Yes/No)	No
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)	Not required and not provided during peer review Screening quantitative method: • LC–MS-Q-ToF, SDL: 0.005 mg/kg for fenpyrazamine in animal commodities, validation data available (honey, muscle (red meat, white fish, fish), milk and milk products) (EURLs, 2017)

LC: liquid chromatography; MS: mass spectrometry; Q-ToF: quadrupole time of flight; SDL: screening detection limit.

B.2.1.2. Stability of residues in livestock

Animal products (available studies)	**Animal**	**Commodity**	**T (°C)**	**Stability (months)**
	Laying hen lactating goat	Muscle	–18	4 9
	Laying hen lactating goat	Liver	–18	4 9
	Laying hen lactating goat	Kidney	–18	4 9
	Lactating goat	Milk	–18	9
	Laying hen	Egg	–18	4
	Storage stability studies are not available and not required. In the metabolism studies, fenpyrazamine and metabolites (including S-2188-DC, MPZZ, S-2188-OH, S-2188-CH_2OH-DC) were stable in animal tissues, milk and eggs for the whole duration of the studies (9 months for lactating goats and 4 months for laying hens). Source: Austria (2011a)			

B.2.2. Magnitude of residues in livestock

B.2.2.1. Summary of the residue data from livestock feeding studies

Animal commodity	**Residues at the closest feeding level (mg/kg)**		**Estimated value at 1N**		**MRL proposal (mg/kg)**	**CF**
	Mean	**Highest**	**STMR (mg/kg)**	**HR (mg/kg)**		
No studies available and not required since fenpyrazamine is not authorised for use on crops fed to livestock						

B.3. Consumer risk assessment

B.3.1. Consumer risk assessment without consideration of the existing CXLs

ADI	0.13 mg/kg bw per day (EFSA, 2012a)
Highest IEDI, according to EFSA PRIMo	5.1% ADI (WHO, cluster diet B)
Assumptions made for the calculations	The calculation is based on the median residue levels in the raw agricultural commodities multiplied for the CF derived from the residue trials (Appendix B.1.2.1) The contributions of commodities where no GAP was reported in the framework of this review were not included in the calculation

ARfD	0.3 mg/kg bw (EFSA, 2012a)
Highest IESTI, according to EFSA PRIMo	78.2% ARfD (peaches)
Assumptions made for the calculations	The calculation is based on the highest residue levels in the raw agricultural commodities multiplied for the CF derived from residue trials (Appendix B.1.2.1)

ADI: acceptable daily intake; bw: body weight; IEDI: international estimated daily intake; PRIMo: (EFSA) Pesticide Residues Intake Model; WHO: World Health Organization; ARfD: acute reference dose; IESTI: international estimated short-term intake; CF: conversion factor for enforcement residue definition to risk assessment residue definition; GAP: Good Agricultural Practice.

B.4. Proposed MRLs

Code number[a]	Commodity	Existing EU MRL (mg/kg)	Outcome of the review	
			MRL (mg/kg)	Comment
Enforcement residue definition: fenpyrazamine				
0120010	Almonds	0.01*	0.01*	Further consideration needed[b]
0140010	Apricots	5	5	Recommended[c]
0140020	Cherries (sweet)	4	4	Recommended[c]
0140030	Peaches	4	5	Recommended[c]
0140040	Plums	3	3	Recommended[c]
0151010	Table grapes	3	3	Recommended[c]
0151020	Wine grapes	3	3	Recommended[c]
0152000	Strawberries	3	3	Recommended[c]
0153010	Blackberries	5	5	Recommended[c]
0153020	Dewberries	5	5	Recommended[c]
0153030	Raspberries (red and yellow)	5	5	Recommended[c]
0154010	Blueberries	4	4	Recommended[c]
0231010	Tomatoes	3	3	Recommended[c]
0231020	Sweet peppers/bell peppers	3	3	Recommended[c]
0231030	Aubergines/eggplants	3	3	Recommended[c]
0232010	Cucumbers	0.7	0.7	Recommended[c]
0232020	Gherkins	0.7	0.7	Recommended[c]

Code number[(a)]	Commodity	Existing EU MRL (mg/kg)	Outcome of the review	
			MRL (mg/kg)	Comment
0232030	Courgettes	0.7	0.7	Recommended[(c)]
–	Other commodities of plant and animal origin	See Regulation (EC) No 149/2008	–	Further consideration needed[(d)]

MRL: maximum residue level; CXL: codex maximum residue limit.
*: Indicates that the MRL is set/proposed at the limit of quantification.
(a): Commodity code number, as listed in Annex I of Regulation (EC) No 396/2005.
(b): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified (assuming the existing residue definition); no CXL is available (combination E-I in Appendix E).
(c): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; no CXL is available (combination G-I in Appendix E).
(d): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix E).

Appendix C – Pesticide Residue Intake Model (PRIMo)

- PRIMo(EU)

Fenpyrazamine			
Status of the active substance:	Included	Code no.	
LOQ (mg/kg bw):	0.01	Proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	0.13	ARfD (mg/kg bw):	0.3
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2012	Year of evaluation:	2012

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	pTMRLs at LOQ (in % of ADI)
5.1	WHO Cluster diet B	1.9	Tomatoes	1.6	Wine grapes	0.4	Peaches	0.0
4.3	FR all population	3.5	Wine grapes	0.3	Tomatoes	0.1	Peaches	0.0
3.6	PT General population	2.2	Wine grapes	0.6	Tomatoes	0.3	Peaches	0.0
3.5	DE child	1.1	Table grapes	0.6	Tomatoes	0.5	Strawberries	0.0
3.3	IE adult	1.1	Wine grapes	0.5	Peaches	0.2	Tomatoes	0.0
2.4	WHO cluster diet E	1.4	Wine grapes	0.3	Tomatoes	0.1	Table grapes	0.0
2.0	NL child	0.7	Table grapes	0.4	Tomatoes	0.2	Strawberries	0.0
1.8	DK adult	1.2	Wine grapes	0.3	Tomatoes	0.1	Peaches	0.0
1.8	IT kids/toddler	0.9	Tomatoes	0.3	Peaches	0.1	Strawberries	0.0
1.6	WHO regional European diet	0.7	Tomatoes	0.2	Wine grapes	0.2	Peaches	0.0
1.6	WHO cluster diet D	0.6	Tomatoes	0.3	Wine grapes	0.2	Table grapes	0.0
1.6	IT adult	0.7	Tomatoes	0.4	Peaches	0.1	Table grapes	0.0
1.4	FR toddler	0.6	Strawberries	0.5	Tomatoes	0.2	Table grapes	0.0
1.4	UK vegetarian	0.7	Wine grapes	0.4	Tomatoes	0.1	Strawberries	0.0
1.4	UK Adult	1.0	Wine grapes	0.3	Tomatoes	0.0	Strawberries	0.0
1.4	ES adult	0.5	Tomatoes	0.4	Wine grapes	0.2	Peaches	0.0
1.3	NL general	0.6	Wine grapes	0.3	Tomatoes	0.2	Table grapes	0.0
1.3	WHO Cluster diet F	0.5	Wine grapes	0.4	Tomatoes	0.1	Table grapes	0.0
1.2	SE general population 90th percentile	0.5	Tomatoes	0.2	Strawberries	0.1	Peaches	0.0
1.2	DK child	0.3	Tomatoes	0.3	Cucumbers	0.2	Table grapes	0.0
1.1	UK Toddler	0.4	Tomatoes	0.2	Table grapes	0.2	Strawberries	0.0
1.1	PL general population	0.5	Tomatoes	0.3	Table grapes	0.1	Cherries	0.0
1.1	ES child	0.6	Tomatoes	0.2	Peaches	0.1	Peppers	0.0
0.8	FR infant	0.5	Strawberries	0.1	Courgettes	0.1	Tomatoes	0.0
0.7	FI adult	0.3	Wine grapes	0.3	Tomatoes	0.1	Strawberries	0.0
0.7	UK Infant	0.2	Tomatoes	0.2	Strawberries	0.1	Apricots	
0.6	LT adult	0.4	Tomatoes	0.1	Cucumbers	0.0	Strawberries	0.0

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of fenpyrazamine is unlikely to present a public health concern.

	Acute risk assessment/children – refined calculations						Acute risk assessment/adults/general population – refined calculations					
	The acute risk assessment is based on the ARfD. For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS, an average European unit weight was used for the IESTI calculation. In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002); for lettuce, a variability factor of 5 was used. In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variabilty factor of 3. **Threshold MRL** is the calculated residue level which would leads to an exposure equivalent to 100% of the ARfD.											
Unprocessed commodities	**No of commodities for which ARfD/ADI is exceeded (IESTI 1):** ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 1):** ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** ---		
	IESTI 1	***)**	****)**	**IESTI 2**	***)**	****)**	**IESTI 1**	***)**	****)**	**IESTI 2**	***)**	****)**
	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
	78.2	Peaches	3.95594812164	57.4	Peaches	3.95594812164	27.4	Table grapes	2.59349150009	27.4	Table grapes	2.59349150009
	56.6	Table grapes	2.59349150009	56.6	Table grapes	2.59349150009	23.0	Peaches	3.95594812164	20.5	Wine grapes	2.59349150009
	40.8	Apricots	3.95594812164	32.7	Apricots	3.95594812164	20.5	Wine grapes	2.59349150009	17.9	Peaches	3.95594812164
	36.0	Tomatoes	1.85945701357	26.1	Tomatoes	1.85945701357	15.4	Aubergines (egg	1.85945701357	15.4	Aubergines (egg plants)	1.85945701357
	33.1	Peppers	1.57551554828	23.6	Peppers	1.57551554828	10.1	Apricots	3.95594812164	8.4	Apricots	3.95594812164
	No of critical MRLs (IESTI 1) ---						**No of critical MRLs (IESTI 2)** ---					
Processed commodities	**No of commodities for which ARfD/ADI is exceeded:** ---						**No of commodities for which ARfD/ADI is exceeded:** ---					
			*****)**						*****)**			
	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)				Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)			
	28.4	Grape juice	2.59349150009				3.3	Wine	2.59349150009			
	23.6	Peach juice	3.95594812164				2.7	Peach preserved with syrup	3.95594812164			
			58 / -						58 / -			
	13.1	Raspberries juice	3.27782174776				1.2	Tomato (preserved-	1.85945701357			
	10.8	Tomato juice	1.85945701357				0.4	Raisins	2.59349150009			
	8.4	Plums juice	1.81398809523									
	*) 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 fenpyrazamine, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available. No exceedance of the ARfD/ADI was identified for any unprocessed commodity. For processed commodities, no exceedance of the ARfD/ADI was identified.											

Appendix D – Input values for the exposure calculations

D.1. Livestock dietary burden calculations

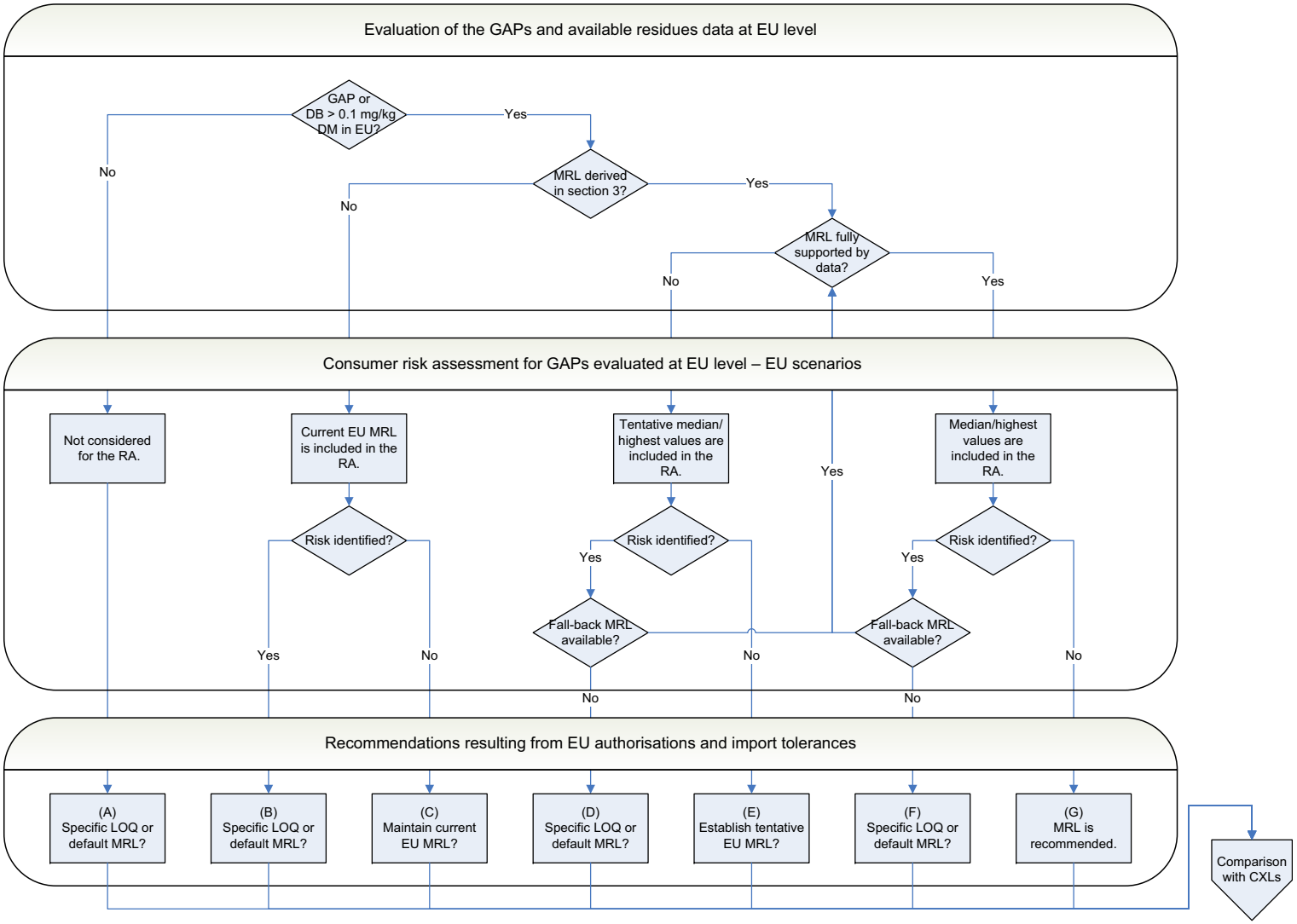
Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Commodities under assessment are not fed to livestock				

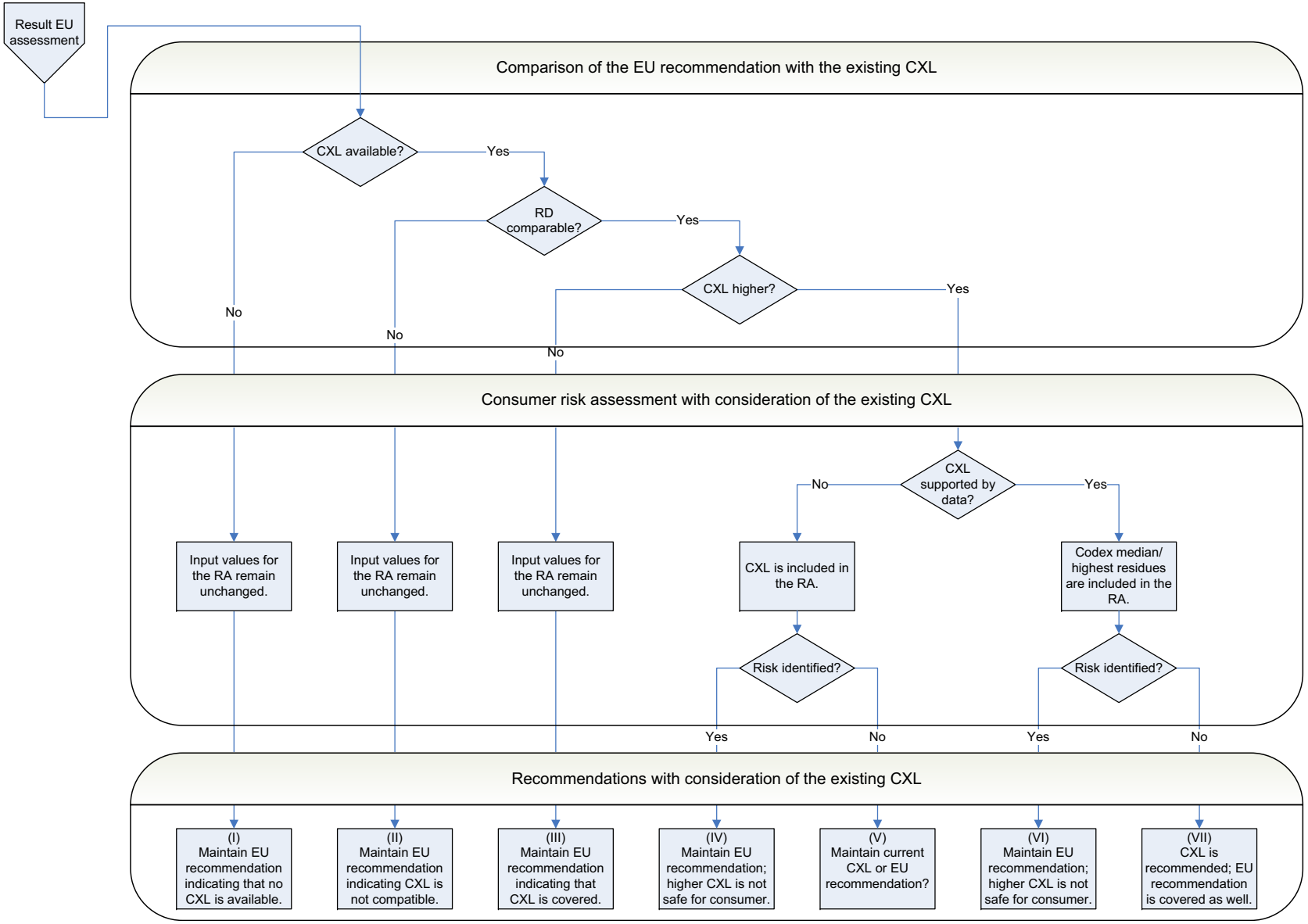
D.2. Consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: fenpyrazamine and S-2188-DC, expressed as fenpyrazamine				
Almonds	0.01*	$STMR_{Mo}$ × CF (tentative)	0.01*	HR_{Mo} × CF (tentative)
Apricots	1.25	$STMR_{Mo}$ × CF	3.96	HR_{Mo} × CF
Cherries (sweet)	1.05	$STMR_{Mo}$ × CF	2.47	HR_{Mo} × CF
Peaches	1.25	$STMR_{Mo}$ × CF	3.96	HR_{Mo} × CF
Plums	0.46	$STMR_{Mo}$ × CF	1.81	HR_{Mo} × CF
Table grapes	1.15	$STMR_{Mo}$ × CF	2.59	HR_{Mo} × CF
Wine grapes	1.15	$STMR_{Mo}$ × CF	2.59	HR_{Mo} × CF
Strawberries	1.29	$STMR_{Mo}$ × CF	2.51	HR_{Mo} × CF
Blackberries	1.84	$STMR_{Mo}$ × CF	3.28	HR_{Mo} × CF
Dewberries	1.84	$STMR_{Mo}$ × CF	3.28	HR_{Mo} × CF
Raspberries (red and yellow)	1.84	$STMR_{Mo}$ × CF	3.28	HR_{Mo} × CF
Blueberries	1.01	$STMR_{Mo}$ × CF	2.81	HR_{Mo} × CF
Tomatoes	0.81	$STMR_{Mo}$ × CF	1.86	HR_{Mo} × CF
Sweet peppers/bell peppers	0.92	$STMR_{Mo}$ × CF	1.58	HR_{Mo} × CF
Aubergines/eggplants	0.81	$STMR_{Mo}$ × CF	1.86	HR_{Mo} × CF
Cucumbers	0.20	$STMR_{Mo}$ × CF	0.36	HR_{Mo} × CF
Gherkins	0.20	$STMR_{Mo}$ × CF	0.36	HR_{Mo} × CF
Courgettes	0.20	$STMR_{Mo}$ × CF	0.36	HR_{Mo} × CF

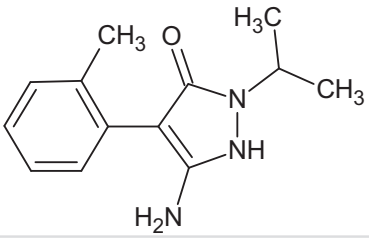
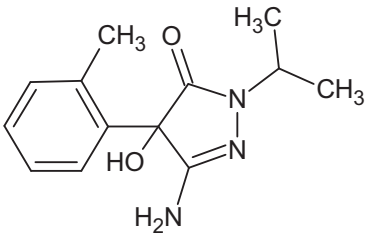
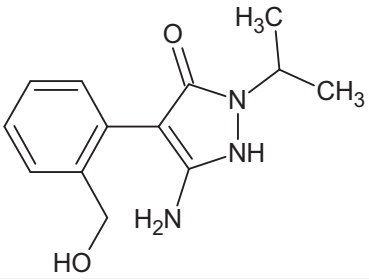
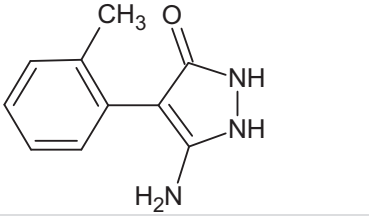
STMR: supervised trials median residue; Mo: monitoring; CF: conversion factor for enforcement residue definition to risk assessment residue definition; HR: highest residue.
*: Indicates that the input value is proposed at the limit of quantification.

Appendix E – Decision tree for deriving MRL recommendations




Result EU assessment
Comparison of the EU recommendation with the existing CXL
CXL available?
Yes
No
RD comparable?
Yes
No
CXL higher?
Yes
No
Consumer risk assessment with consideration of the existing CXL
Input values for the RA remain unchanged.
Input values for the RA remain unchanged.
Input values for the RA remain unchanged.
CXL supported by data?
No
Yes
CXL is included in the RA.
Codex median/ highest residues are included in the RA.
Risk identified?
Risk identified?
Yes
No
Yes
No
Recommendations with consideration of the existing CXL
(I) Maintain EU recommendation indicating that no CXL is available.
(II) Maintain EU recommendation indicating CXL is not compatible.
(III) Maintain EU recommendation indicating that CXL is covered.
(IV) Maintain EU recommendation; higher CXL is not safe for consumer.
(V) Maintain current CXL or EU recommendation?
(VI) Maintain EU recommendation; higher CXL is not safe for consumer.
(VII) CXL is recommended; EU recommendation is covered as well.

Appendix F – Used compound codes

Code/trivial name	Chemical name	Structural formula
S-2188-DC	5-amino-4-(2-methylphenyl)-2-(propan-2-yl)-1,2-dihydro-3*H*-pyrazol-3-one O=C2C(c1ccccc1C)=C(N)NN2C(C)C	
S-2188-OH	(4*RS*)-5-amino-4-hydroxy-4-(2-methylphenyl)-2-(propan-2-yl)-2,4-dihydro-3*H*-pyrazol-3-one OC1(C(=O)N(N=C1N)C(C)C)c2ccccc2C	
S-2188-CH_2OH-DC	5-amino-4-[2-(hydroxymethyl)phenyl]-2-(propan-2-yl)-1,2-dihydro-3*H*-pyrazol-3-one O=C2C(c1ccccc1CO)=C(N)NN2C(C)C	
MPPZ	5-amino-4-(2-methylphenyl)-1,2-dihydro-3*H*-pyrazol-3-one NC=2NNC(=O)C=2c1ccccc1C	
Fenpyrazamine (S-2188)	*S*-allyl 5-amino-2,3-dihydro-2-isopropyl-3-oxo-4-(*o*-tolyl)pyrazole-1-carbothioate CC(C)N1C(=O)C(=C(N)N1C(=O)SCC=C)c2ccccc2C	