REASONED OPINION

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Modification of the existing maximum residue levels for fenpyrazamine in lettuces, salad plants, spinaches and similar leaves

European Food Safety Authority (EFSA),
Alba Brancato, Daniela Brocca, Luis Carrasco Cabrera, Chloe De Lentdecker, Lucien Ferreira, Luna Greco, Judit Janossy, Samira Jarrah, Dimitra Kardassi, Renata Leuschner, Christopher Lythgo, Paula Medina, Ileana Miron, Tunde Molnar, Alexandre Nougadere, Ragnor Pedersen, Hermine Reich, Angela Sacchi, Miguel Santos, Alois Stanek, Juergen Sturma, Jose Tarazona, Anne Theobald, Benedicte Vagenende and Laura Villamar-Bouza

Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Sumitomo Chemical Agro Europe S.A.S. submitted a request to the competent national authority in France, to modify the existing maximum residue levels (MRLs) for the active substance fenpyrazamine in lamb's lettuces, lettuces, escaroles, dandelions, cresses, land cresses, rucola, red mustards, spinaches, purslanes and chards/beet leaves. The data submitted in support of the request were found to be sufficient to derive MRL proposals for lamb's lettuces/corn salads, lettuces, escaroles/broad-leaved endives (including dandelions), cresses, land cresses, roman rocket/rucola, red mustards, spinaches, purslanes and chards/beet leaves. Adequate analytical methods for enforcement are available to control the residues of fenpyrazamine in the crops assessed in this application according to the enforcement residue definition. The methods enable quantification of residues in the crops assessed at or above 0.01 mg/kg (limit of quantification (LOQ)). Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of residues resulting from the use of fenpyrazamine on lamb's lettuces/corn salads, lettuces, cresses, land cresses, roman rocket/rucola, red mustards, spinaches, purslanes and chards/beet leaves according to the reported agricultural practice is unlikely to present a risk to consumer health. According to the internationally agreed methodology for short-term exposure estimation (IESTI), the acute reference dose (ARfD) was not exceeded for the intended use of fenpyrazamine on escaroles (97.6%), and thus, there is a narrow safety margin.

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Keywords: fenpyrazamine, lettuce, salad plants, spinach, pesticide, MRL, consumer risk assessment

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Correspondence: pesticides.mrl@efsa.europa.eu

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, Sumitomo Chemical Agro Europe S.A.S. submitted an application to the competent national authority in France (evaluating Member State, EMS), to modify the existing maximum residue levels (MRLs) for the active substance fenpyrazamine in lamb's lettuces, lettuces, escaroles, dandelions, cresses, land cresses, rucola, red mustards, spinaches, purslanes and chards/beet leaves. The EMS 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 the European Food Safety Authority (EFSA) on 29 August 2017. To accommodate for the intended uses of fenpyrazamine, the EMS proposed to raise the existing MRLs from the limit of quantification (LOQ) of 0.01 mg/kg to 8 mg/kg for lamb's lettuces/corn salads, lettuces, cresses, land cresses, roman rocket/rucola, red mustards, spinaches and similar leaves, spinaches, purslanes and chards/beet leaves; and from the LOQ of 0.01 mg/kg to 4 mg/kg for escaroles/broad-leaved endives (including dandelions).

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. Based on the conclusions derived by EFSA in the framework of the European Union (EU) pesticides peer review under Directive 91/414/EEC, the data evaluated in previous MRL assessment and the additional data provided by the EMS in the framework of the present application, the following conclusions are derived.

The metabolism of fenpyrazamine following foliar application was investigated in crops belonging to the groups of fruit crops, leafy crops and pulses/oilseeds. Studies investigating the effect of processing on the nature of fenpyrazamine (hydrolysis studies) demonstrated that the active substance is stable. In rotational crops, the major residues identified were parent fenpyrazamine and its metabolites S-2188-OH and S-2188$(OH)_2$. The peer review concluded that the metabolism of fenpyrazamine in rotational crops is similar to the pathway observed in primary crops and this conclusion was supported by the MRL review.

Based on the metabolic pattern identified in metabolism studies, hydrolysis studies, the toxicological significance of metabolites and degradation products, the residue definitions for plant products were proposed in the peer review as 'fenpyrazamine' for enforcement and 'sum of fenpyrazamine and S-2188-DC, expressed as fenpyrazamine' for risk assessment. These residue definitions are applicable to primary crops, rotational crops and processed products.

EFSA concluded that for the crops assessed in this application, metabolism of fenpyrazamine in primary and in rotational crops, and the possible degradation in processed products has been sufficiently addressed and that the previously derived residue definitions are applicable.

Sufficiently validated analytical methods are available to quantify residues of fenpyrazamine in the crops assessed in this application according to the enforcement residue definition. The methods enable quantification of residues in the crops assessed at or above 0.01 mg/kg (LOQ).

The available residue trials are sufficient to derive MRL proposals of 8 mg/kg for lamb's lettuces/corn salads, lettuces, cresses, land cresses, roman rocket/rucola, red mustards, spinaches and similar leaves, spinaches, purslanes and chards/beet leaves and a MRL proposal of 4 mg/kg for escaroles/broad-leaved endives.

Specific studies investigating the magnitude of fenpyrazamine residues in processed commodities are not required because the contribution of fenpyrazamine residues in the commodities under consideration to the estimated long-term dietary intake is low.

The occurrence (magnitude) 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, it was concluded that significant residue levels are unlikely to occur in rotational crops, provided that the active substance is used according to the proposed good agricultural practice (GAP).

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

The toxicological profile of fenpyrazamine was assessed in the framework of the peer review and the data were sufficient to derive an acceptable daily intake (ADI) of 0.13 mg/kg body weight (bw) per day and an acute reference dose (ARfD) of 0.3 mg/kg bw. The metabolite S-2188-DC included in the risk assessment residue definition was considered to be of similar toxicity as the parent compound.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). The short-term exposure did not exceed the ARfD for any of the crops assessed in this application. For the intended use on escarole, the International Estimated Short-term Intake (IESTI) according to EFSA PRIMo accounted for 97.6% of the ARfD, and thus, there is a narrow safety margin. The estimated long-term dietary intake was in the range of 0.6–5.7% of the ADI.

EFSA concluded that the intended use of fenpyrazamine on lamb's lettuces, lettuces, cresses, land cresses, rucola, red mustards, spinaches, purslanes and chards/beet leaves is unlikely to result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers' health.

EFSA proposes to amend the existing MRLs as reported in the summary table below.

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Fenpyrazamine				
0251010	Lamb's lettuces/ corn salads	0.01*	**8**	The submitted data are sufficient to derive a MRL proposal for SEU use. Risk for consumers unlikely.
0251020	Lettuces	0.01*	**8**	The submitted data are sufficient to derive a MRL proposal for SEU use. Risk for consumers unlikely.
0251030	Escaroles/ broad-leaved endives (including dandelions)	0.01*	**4**	The submitted data are sufficient to derive a MRL proposal for SEU use on escaroles, including for the intended SEU use on dandelions in the subcode of 0251030-002. According to the internationally agreed methodology for short-term exposure estimation (IESTI), the ARfD is not exceeded (97.6%), and thus, there is a narrow safety margin.
0251040	Cresses and other sprouts and shoots	0.01*	**8**	The submitted data are sufficient to derive a MRL proposal for SEU use. Risk for consumers unlikely.
0251050	Land cresses	0.01*	**8**	The submitted data are sufficient to derive a MRL proposal for SEU use. Risk for consumers unlikely.
0251060	Roman rocket/ rucola	0.01*	**8**	The submitted data are sufficient to derive a MRL proposal for SEU use. Risk for consumers unlikely.
0251070	Red mustards	0.01*	**8**	The submitted data are sufficient to derive a MRL proposal for SEU use. Risk for consumers unlikely.
0252010	Spinaches	0.01*	**8**	The submitted data are sufficient to derive a MRL proposal for SEU use. Risk for consumers unlikely.
0252020	Purslanes	0.01*	**8**	The submitted data are sufficient to derive a MRL proposal for SEU use. Risk for consumers unlikely.
0252030	Chards/beet leaves	0.01*	**8**	The submitted data are sufficient to derive a MRL proposal for SEU use. Risk for consumers unlikely.

EU MRL: European Union maximum residue levels; SEU: southern European Union; ARfD: acute reference dose.
*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.

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Assessment

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 structures of the active substance and its main metabolites are reported in Appendix E.

Fenpyrazamine was evaluated in the framework of Directive 91/414/EEC[1] with Austria, designated as rapporteur Member State (RMS) for the representative uses as a fungicide by foliar application on tomato, aubergine, pepper, cucurbits with edible peel (glasshouse) and field use on grapes. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by European Food Safety Authority (EFSA) (EFSA, 2012).

Fenpyrazamine was approved[2] for the use as fungicide on 1 January 2013. The process of renewal of the first approval has not yet been initiated.

The European Union maximum residue levels (EU MRLs) for fenpyrazamine are established in Annex III A of Regulation (EC) No 396/2005[3]. EFSA has issued several reasoned opinions on the modification of MRLs for fenpyrazamine. The proposals from these reasoned opinions have been considered in regulations[4] for EU MRL legislation. The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has been performed (EFSA, 2017), and the proposed modification has not yet been implemented in the EU MRL legislation.

In accordance with Article 6 of Regulation (EC) No 396/2005, Sumitomo Chemical Agro Europe S.A.S. submitted an application to the competent national authority in France (evaluating Member State, EMS), to modify the existing MRLs for the active substance fenpyrazamine in lamb's lettuces, lettuces, escaroles, dandelions, cresses, land cresses, rucola, red mustards, spinaches, purslanes and chards/beet leaves. The EMS 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 the EFSA on 29 August 2017. To accommodate for the intended uses of fenpyrazamine, the EMS proposed to raise the existing MRLs from the limit of quantification (LOQ) of 0.01 mg/kg to 8 mg/kg for lamb's lettuces/corn salads, lettuces, cresses, land cresses, roman rocket/rucola, red mustards, spinaches, purslanes and chards/beet leaves and from the LOQ of 0.01 mg/kg to 4 mg/kg for escaroles/broad-leaved endives (including dandelions).

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA based its assessment on the evaluation report submitted by the EMS (France, 2017), the DAR and its addendum prepared under Council Directive 91/414/EEC (Austria, 2011a,b), the European Commission review report on fenpyrazamine (European Commission, 2012), the EFSA conclusion on the peer review of the pesticide risk assessment of the active substance fenpyrazamine (EFSA, 2012) as well as the conclusion from the review of existing MRLs in accordance with Article 12 of Regulation (EC) No 396/2005 (EFSA, 2017).

For this application, the data requirements established in Regulation (EU) No 544/2011[5] and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 1997a–g, 2000, 2010a,b, 2017; OECD, 2011). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011[6].

The detailed description of the intended uses of fenpyrazamine in lettuces, lamb's lettuces, escaroles, dandelions, cresses, land cresses, rucola, red mustards, spinaches, purslanes and chards/beet leaves, which are the basis for the current MRL application, is reported in Appendix A.

[1] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.08.1991, p. 1–32.

[2] 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.

[3] Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.03.2005, p. 1–16.

[4] For an overview of all MRL Regulations on this active substance, please consult: http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=pesticide.residue.selection&language=EN

[5] Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances. OJ L 155, 11.6.2011, p. 1–66.

[6] 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.

A selected list of end points of the studies assessed by EFSA in the framework of this MRL application, including the end points of relevant studies assessed previously, submitted in support of the current MRL application, are presented in Appendix B.

The evaluation report submitted by the EMS (France, 2017) and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available as background documents to this reasoned opinion.

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 in primary crops belonging to the groups of fruit crops, leafy crops and pulses/oilseeds has been assessed in the framework of the EU pesticides peer review (EFSA, 2012). In the crops tested, parent compound was the main residue, representing more than 50% of the total radioactive residues (TRR) except in oilseed rape seeds where it represented only *ca.* 20% TRR. In addition to the parent compound, only two further compounds were identified in plants; the metabolite S-2188-DC detected up to 11% TRR in lettuce, and the metabolite S-2188-OH detected in lower proportions, below 5% TRR. For the intended uses assessed in this application, the metabolic behaviour in primary crops is sufficiently addressed.

1.1.2. Nature of residues in rotational crops

Fenpyrazamine is proposed to be used on crops that can be grown in rotation with other crops. The soil degradation field studies evaluated in the framework of the peer review indicate the DT_{90} values of fenpyrazamine range from 60 to 134 days (EFSA, 2012). The trigger value of 100 days is exceeded, and therefore, further studies investigating the nature and magnitude of residues in rotational crops are required.

In the confined rotational crop metabolism studies assessed in the framework of the peer review and confirmed in the MRL review, pyrazolyl-^{14}C-labelled fenpyrazamine was applied to bare soil, and wheat, lettuce and carrots were planted at 30-, 120- or 360-day plant back intervals (PBI). The degradation pathway of fenpyrazamine in the succeeding cereal, root and tuber vegetable and leafy crops was similar to the pathway in primary crops, where residues were mostly composed of the parent fenpyrazamine and its metabolites S-2188-OH and S-2188$(OH)_2$ (up to *ca*. 10% TRR), the latter not being observed in primary crops (EFSA, 2012). The peer review concluded that the metabolism of fenpyrazamine in rotational crops is similar to the pathway observed in primary crops (EFSA, 2012), and this conclusion was confirmed by the MRL review (EFSA, 2017). For the intended uses assessed in the present application, no further information is required.

1.1.3. Nature of residues in processed commodities

The effect of processing on the nature of fenpyrazamine was assessed in the framework of the peer review and confirmed in the MRL review. These studies showed that the fenpyrazamine is hydrolytically stable under conditions simulating processing by pasteurisation, baking/brewing/boiling and sterilisation while up to 8.6% of the applied radioactivity degraded to the metabolite S-2188-DC at sterilisation. No other degradation products were identified (EFSA, 2017).

1.1.4. Methods of analysis in plants

Analytical methods for the determination of fenpyrazamine residues were assessed during the peer review and the MRL review (EFSA, 2012, 2017). The methods are sufficiently validated for residues of fenpyrazamine in the crops under consideration. The methods allow quantifying residues at or above the LOQ of 0.01 mg/kg in high water, high acid, high oil and dry commodities.

1.1.5. Stability of residues in plants

The stability of fenpyrazamine and the metabolites S-2188-DC and S-2188-OH in plants stored under frozen conditions was investigated in the framework of the peer review (EFSA, 2012). It was

demonstrated that residues of fenpyrazamine and the metabolite S-2188-DC in the crops assessed in the present application are stable for at least 12 months when stored at −18°C.

1.1.6. Proposed residue definitions

Based on the metabolic pattern identified in metabolism studies, the results of hydrolysis studies, the toxicological significance of metabolites and/or degradation products and the capabilities of enforcement analytical methods, the following residue definitions were proposed in the framework of the peer review and confirmed in the MRL review:

- residue definition for risk assessment: sum of fenpyrazamine and S-2188-DC, expressed as fenpyrazamine
- residue definition for enforcement: fenpyrazamine

The same residue definitions are applicable to rotational crops and processed products.

The residue definition for enforcement set in Regulation (EC) No 396/2005 is identical with the above-mentioned residue definition. Taking into account the intended uses assessed in the present application, EFSA concluded that these residue definitions are appropriate and that modification is not required.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

In support of the MRL application, the applicant submitted nine residue trials performed outdoors in open-leaf variety lettuce. Trials were conducted during two seasons (summer and winter) in Greece, Italy and Spain and during one season (summer) in south France.

The residue trials were performed with three foliar spray applications at a nominal rate of 0.6 kg a.s./ha with intervals of 7 days, except in the case of two trials performed in Greece (winter) in which the second interval period was 8 days, whereas the application interval in the intended use good agricultural practices (GAPs) is 7–10 days. Lettuce samples were harvested at 7 days after last treatment (all trials) in compliance with the 7-day preharvest interval (PHI) GAPs, and further samples were harvested at either 9 (1 trial), 10 (7 trials) or 11 days (1 trial) after last treatment whereas the GAP for escaroles is a 10-day PHI. The applicant proposed to extrapolate the trial results to lamb's lettuces, cresses, land cresses, rucola, red mustards, spinaches, purslanes and chards/beet leaves (GAP defines 7-day PHI) and to escaroles, including dandelion (GAP defines 10-day PHI), in accordance with the EU extrapolation rules (European Commission, 2017). The Mann–Whitney U test indicates that the data populations from the summer trials and from the winter trials supporting the GAPs under assessment are not significantly different, and therefore, the combined summer and winter trial data sets were used to calculate the MRLs and derive risk assessment values. Overall, the trials are considered sufficiently representative of the critical GAPs for the intended uses on the commodities under consideration.

The residue trial samples were stored under conditions for which integrity has been demonstrated. The samples were analysed for the parent compound and the metabolite S-2188-DC included in the residue definition for risk assessment. According to the assessment of the EMS, the methods used were sufficiently validated and fit for purpose.

1.2.2. Magnitude of residues in rotational crops

The possible transfer of fenpyrazamine residues to crops that are grown in rotation has been assessed in EU pesticides peer review and the conclusion confirmed in the MRL review (EFSA, 2012, 2017). The present MRL application did not provide further rotational crop studies. The peer review concluded that significant accumulation of fenpyrazamine residues in soil is not expected (EFSA, 2017). Provided that the active substance is applied according to the intended use GAPs, it is concluded that significant residues in succeeding crops are not expected.

1.2.3. Magnitude of residues in processed commodities

Specific processing studies for the crops under assessment are not available. The salad plants under consideration (lamb's lettuces, lettuces, cresses, land cresses, rucola and red mustards) are usually eaten fresh, and therefore, processing data are not required. Processing of escaroles, spinaches, purslanes and

chards/beet leaves by cooking, canning or pureeing is not expected to lead to a concentration of residues and fenpyrazamine has been shown to be hydrolytically stable. Specific processing studies are not required because the contribution of fenpyrazamine residues in the commodities under consideration to the estimated long-term dietary intake is low. However, specific processing studies for the cooking of escaroles would be desirable because the short-term exposure estimate indicates a narrow safety margin and information on the magnitude of residues in processed commodities would allow for refinement of the dietary risk assessment. If processing factors were to be required by risk managers, in particular for enforcement purposes, then 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 the commodities under evaluation. In Section 3, EFSA assessed whether residues on these crops resulting from the intended uses are likely to pose a consumer health risk.

2. Residues in livestock

An assessment of residues in livestock is not required because the commodities under consideration are not usually used for feed purposes.

3. Consumer risk assessment

EFSA performed a dietary risk assessment using revision 2 of the EFSA PRIMo (EFSA, 2007). This exposure assessment model contains food consumption data for different subgroups of the EU population and allows the acute and chronic exposure assessment to be performed in accordance with the internationally agreed methodology for pesticide residues.

The toxicological reference values for fenpyrazamine used in the risk assessment (i.e. acceptance daily intake (ADI) and acute reference dose (ARfD) values) were derived in the framework of the EU pesticides peer review (EFSA, 2012). The metabolite S-2188-DC, included in the risk assessment residue definition, was considered to be of similar toxicity as the parent compound (EFSA, 2012).

3.1. Short-term (acute) dietary risk assessment

The short-term exposure assessment was performed for the commodities assessed in this application in accordance with the internationally agreed methodology (FAO, 2016). The calculations were based on the highest residue (HR) values derived from the supervised field trials and the complete list of input values can be found in Appendix D.2.

The short-term exposure estimates according to the internationally agreed methodology (IESTI) did not exceed the ARfD for any of the crops assessed in this application, and thus, a risk for consumers was not identified (see Appendix B.3). The short-term exposure estimate for the intended use on escarole accounted for 97.6% of the ARfD, and thus, there is a narrow safety margin. The short-term exposure estimate (IESTI) is based on the HR value of 3.35 mg/kg derived from nine residue trials performed on lettuces. Lacking specific processing studies, no refined exposure calculation could be performed. In the specific case of dandelions in the subcode of 0251030-002, large portion consumption of dandelion leaves is expected to be significantly less than large portion consumption of escarole, and therefore, the short-term exposure from dandelion is expected to be significantly lower than from escarole. The commodity leading to the second highest estimated short-term exposure (IESTI) was lettuce, for which the estimated exposure amounts to 49% of the ARfD.

3.2. Long-term (chronic) dietary risk assessment

In the framework of the MRL review, a comprehensive long-term exposure assessment was performed, taking into account the existing uses at EU level (EFSA, 2017). EFSA updated the calculation with the supervised trials median residue (STMR) values derived from the residue trials performed on lettuce submitted in support of the present application for MRLs in lamb's lettuces, lettuces, escaroles, dandelions, cresses, land cresses, rucola, red mustards, spinaches, purslanes and chards/beet leaves. The input values used in the exposure calculations are summarised in Appendix D.2.

The estimated long-term dietary intake was in the range of 0.6–5.7% of the ADI. The contribution of residues expected in the commodities assessed in the present application to the overall long-term exposure is presented in more detail in Appendix B.3.

EFSA concluded that the long-term intake of residues of fenpyrazamine resulting from the existing and the intended uses is unlikely to present a risk to consumer health.

4. Conclusion and Recommendations

The data submitted in support of this MRL application were found to be sufficient to derive MRL proposals for lamb's lettuces/corn salads, lettuces, escaroles/broad-leaved endives (including dandelions), cresses, land cresses, roman rocket/rucola, red mustards, spinaches, purslanes and chards/beet leaves.

Based on the dietary risk assessment performed according to the internationally agreed methodology, EFSA concluded that the intended use of fenpyrazamine on lamb's lettuces, lettuces, cresses, land cresses, rucola, red mustards, spinaches, purslanes and chards/beet leaves is unlikely to result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers' health.

The MRL recommendations are summarised in Appendix B.4.

References

Austria, 2011a. Draft Assessment Report (DAR) on the active substance fenpyrazamine prepared by the rapporteur Member State Austria in the framework of Directive 91/414/EEC, January 2011.

Austria, 2011b. Final Addendum to Draft Assessment Report on fenpyrazamine, compiled by EFSA, November 2011. Available online: www.efsa.europa.eu

EFSA (European Food Safety Authority), 2007. Reasoned opinion on the potential chronic and acute risk to consumers' health arising from proposed temporary EU MRLs. EFSA Journal 2007;5(3):32r, 1141 pp. https://doi.org/10.2903/j.efsa.2007.32r

EFSA (European Food Safety Authority), 2012. Conclusion on the peer review of the pesticide risk assessment of the active substance fenpyrazamine. EFSA Journal 2012;10(1):2496, 62 pp. https://doi.org/10.2903/j.efsa.2012.2496

EFSA (European Food Safety Authority), Brancato A, Brocca D, De Lentdecker C, Erdos Z, Ferreira L, Greco L, Janossy J, Jarrah S, Kardassi D, Leuschner R, Lythgo C, Medina P, Miron I, Molnar T, Nougadere A, Pedersen R, Reich H, Sacchi A, Santos M, Stanek A, Sturma J, Tarazona J, Theobald A, Vagenende B, Verani A and Villamar-Bouza L, 2017. Reasoned Opinion on the review of the existing maximum residue levels for fenpyrazamine according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2017;15(12):5072, 34 pp. https://doi.org/10.2903/j.efsa.2017.5072

EURL (European Union Reference Laboratories for Pesticide Residues), 2017. Evaluation Report prepared under Article 12 of Regulation (EC) No 396/2005. Analytical methods validated by the EURLs and overall capability of official laboratories to be considered for the review of the existing MRLs for fenpyrazamine, March 2017. Available online: www.efsa.europa.eu

European Commission, 1997a. Appendix I. Calculation of maximum residue level and safety intervals.7039/VI/95 22 July 1997. As amended by the document: classes to be used for the setting of EU pesticide maximum residue levels (MRLs). SANCO 10634/2010, finalised in the Standing Committee on the Food Chain and Animal Health at its meeting of 23–24 March 2010.

European Commission, 1997b. Appendix A. Metabolism and distribution in plants. 7028/IV/95-rev., 22 July 1996.

European Commission, 1997c. Appendix B. General recommendations for the design, preparation and realization of residue trials. Annex 2. Classification of (minor) crops not listed in the Appendix of Council Directive 90/642/EEC. 7029/VI/95-rev. 6, 22 July 1997.

European Commission, 1997d. Appendix C. Testing of plant protection products in rotational crops. 7524/VI/95-rev. 2, 22 July 1997.

European Commission, 1997e. Appendix E. Processing studies. 7035/VI/95-rev. 5, 22 July 1997.

European Commission, 1997f. Appendix F. Metabolism and distribution in domestic animals. 7030/VI/95-rev. 3, 22 July 1997.

European Commission, 1997g. Appendix H. Storage stability of residue samples. 7032/VI/95-rev. 5, 22 July 1997.

European Commission, 2000. Residue analytical methods. For pre-registration data requirement for Annex II (part A, section 4) and Annex III (part A, section 5 of Directive 91/414. SANCO/3029/99-rev. 4.

European Commission, 2010a. Classes to be used for the setting of EU pesticide Maximum Residue Levels (MRLs). SANCO 10634/2010-rev. 0, Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting of 23–24 March 2010.

European Commission, 2010b. Residue analytical methods. For post-registration control. SANCO/825/00-rev. 8.1, 16 November 2010.

European Commission, 2012. Review report for the active substance fenpyrazamine. Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 1 June 2012 in view of the approval of fenpyrazamine as active substance in accordance with Regulation (EC) No 1107/2009. SANCO/10690/2012 rev 2. 1 June 2012.

European Commission, 2017. Appendix D. Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. 7525/VI/95-rev. 10.3, 13 June 2017.
FAO (Food and Agriculture Organization of the United Nations), 2016. Submission and evaluation of pesticide residues data for the estimation of Maximum Residue Levels in food and feed. Pesticide Residues. 3rd Ed. FAO Plant Production and Protection Paper 225, 298 pp.
France, 2017. Evaluation Report prepared under Article 8 of Regulation (EC) No 396/2005: Modification of MRLs for fenpyrazamine in various leafy crops. July 2017, 44 pp.
OECD (Organisation for Economic Co-operation and Development), 2011. OECD MRL calculator: spreadsheet for single data set and spreadsheet for multiple data set, 2 March 2011. In: Pesticide Publications/Publications on Pesticide Residues. Available online: http://www.oecd.org

Abbreviations

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CF	conversion factor for enforcement to risk assessment residue definition
DAR	draft assessment report
DAT	days after treatment
DT_{90}	period required for 90% dissipation (define method of estimation)
EMS	evaluating Member State
eq	residue expressed as a.s. equivalent
EURL	EU Reference Laboratory (former Community Reference Laboratory (CRL))
FAO	Food and Agriculture Organization of the United Nations
GAP	Good Agricultural 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 Standardisation
IUPAC	International Union of Pure and Applied Chemistry
LC	liquid chromatography
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
MS	mass spectrometry detector
MS/MS	tandem mass spectrometry detector
NEU	northern Europe
OECD	Organisation for Economic Co-operation and Development
PBI	plant back interval
PHI	preharvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
PROFile	(EFSA) Pesticide Residues Overview File
RA	risk assessment
RD	residue definition
RMS	rapporteur Member State
SANCO	Directorate-General for Health and Consumers
SEU	southern European Union
STMR	supervised trials median residue
TRR	total radioactive residue
UV	ultraviolet (detector)
WG	water-dispersible granule
WHO	World Health Organization

Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs

Crop and/or situation	NEU, SEU, MS or country	F G or I[a]	Pests or group of pests controlled	Preparation		Application				Application rate per treatment			Unit	PHI (days)[d]	Remarks
				Type[b]	Conc. a.s.	Method kind	Range of growth stages & season[c]	Number min–max	Interval between application (min)	g a.s./hL min–max	Water L/ha min–max	Rate			
Lettuce, Lamb's lettuce, Cresses, Land cress, Rucola, Red mustard	ES, IT, PT	F	*Botrytis Cinerea* *Sclerotinia* spp.	WG	500 g/kg	Foliar	At appearance of first symptoms BBCH 13–49	3	7–10 days	60	200–1000	600	g/ha	7 days	
Cresses, Land cress, Rucola, Red mustard	FR (SEU)	F	*Botrytis Cinerea* *Sclerotinia* spp.	WG	500 g/kg	Foliar	At appearance of first symptoms BBCH 13–49	3	7–10 days	60	200–1000	600	g/ha	7 days	
Escarole, Dandelion	ES, IT, PT	F	*Botrytis Cinerea* *Sclerotinia* spp.	WG	500 g/kg	Foliar	At appearance of first symptoms BBCH 13–49	3	7–10 days	60	200–1000	600	g/ha	10 days	

Crop and/or situation	NEU, SEU, MS or country	F G or I[(a)]	Pests or group of pests controlled	Preparation		Application				Application rate per treatment			Unit	PHI (days)[(d)]	Remarks
				Type[(b)]	Conc. a.s.	Method kind	Range of growth stages & season[(c)]	Number min–max	Interval between application (min)	g a.s./hL min–max	Water L/ha min–max	Rate			
Spinach and similar leaves group. Including: Spinach, Purslane, Chard (beet leaves)	ES, IT, PT	F	*Botrytis Cinerea* *Sclerotinia* spp.	WG	500 g/kg	Foliar	At appearance of first symptoms BBCH 13–49	3	7–10 days	60	200–1000	600	g/ha	7 days	
Purslane, Chard (beet leaves)	FR (SEU)	F	*Botrytis Cinerea Sclerotinia* spp.	WG	500 g/kg	Foliar	At appearance of first symptoms BBCH 13–49	3	7–10 days	60	200–1000	600	g/ha	7 days	

NEU: northern European Union; SEU: southern European Union; MS: Member State; WG: water-dispersible granule.
(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 formulation types and international coding system.
(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)	**Comment/Source**
	Fruit crops	Grapes	Foliar, 2 × 0.75 kg a.s./ha	14, 21	Radiolabelled active substance: phenyl-UL-^{14}C-labelled and pyrazolyl-5-^{14}C-labelled fenpyrazamine (independent studies) Source: Austria (2011a)
	Leafy crops	Lettuce	Foliar, 3 × 0.85 kg a.s./ha	14, 28, 42	Radiolabelled active substance: phenyl-UL-^{14}C-labelled and pyrazolyl-UL-^{14}C-labelled fenpyrazamine (independent studies) Source: Austria (2011a)
	Pulses/oilseeds	Oil seed rape	Foliar, 2 × 0.6 kg a.s./ha	46, 115	Radiolabelled active substance: phenyl-UL-^{14}C-labelled and pyrazolyl-UL-^{14}C-labelled fenpyrazamine (independent studies) Source: Austria (2011a)
Rotational crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**PBI** (DAT)	**Comment/Source**
	Root/tuber crops	Carrots	Bare soil, 2.83 kg a.s./ha	30, 120, 365	Radiolabelled active substance: pyrazolyl-5-^{14}C-labelled fenpyrazamine Source: Austria (2011a)
	Leafy crops	Lettuce	Bare soil, 2.83 kg a.s./ha	30, 120, 365	Radiolabelled active substance: pyrazolyl-5-^{14}C-labelled fenpyrazamine Source: Austria (2011a)
	Cereal (small grain)	Wheat	Bare soil, 2.83 kg a.s./ha	30, 120, 365	Radiolabelled active substance: pyrazolyl-5-^{14}C-labelled fenpyrazamine Source: Austria (2011a)
Processed commodities (hydrolysis study)	**Conditions**		**Stable?**		**Comment/Source**
	Pasteurisation (20 min, 90°C, pH 4)		Yes		Source: Austria (2011a)
	Baking, brewing and boiling (60 min, 100°C, pH 5)		Yes		Source: Austria (2011a)
	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	
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) (EURL, 2017) • LC–QqQ-MS/MS, LOQ: 0.01 mg/kg for fenpyrazamine in dry commodities, validation data available (oat, rye, wheat) (EURL, 2017) • LC-Q-ToF, LOQ: 0.01 mg/kg for fenpyrazamine in high oil commodities, validation data available (avocado) (EURL, 2017)	

LOQ: Limit of quantification; HPLC–MS/MS: high-performance liquid chromatography with tandem mass spectrometry; LC–MS/MS: liquid chromatography with tandem mass spectrometry; QqQ: quadrupole; ToF: time of flight.

B.1.1.2. Stability of residues in plants

Plant products (available studies)	**Category**	**Commodity**	**T (°C)**	**Stability period**		**Compounds covered**	**Comment/Source**
				Value	**Unit**		
	High water content	Lettuce	−18	12	months	Fenpyrazamine S-2188-DC	Austria (2011a)
	High water content	Lettuce	−18	6	months	S-2188-OH	Austria (2011a)
	High oil content	Rape seed	−18	12	months	Fenpyrazamine S-2188-DC	Austria (2011a)
	High oil content	Rape seed	−18	12	months	S-2188-OH	Austria (2011a)
	Dry / High starch	Cereal grain	−18	12	months	Fenpyrazamine S-2188-DC	Austria (2011a)

Plant products (available studies)	Category	Commodity	T (°C)	Stability period		Compounds covered	Comment/Source
				Value	Unit		
	Dry / High starch	Cereal grain	−18	12	months	S-2188-OH	Austria (2011a)
	High acid content	Grapes	−18	12	months	Fenpyrazamine S-2188-DC	Austria (2011a)
	High acid content	Grapes	−18	12	months	S-2188-OH	Austria (2011a)

B.1.2. Magnitude of residues in plants

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

Commodity	Region/ Indoor[(a)]	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR[(b)] (mg/kg)	STMR[(c)] (mg/kg)	CF[(d)]
Lamb's lettuces Lettuces Cresses Land cresses Rucola Red mustards	SEU	**Mo:** 0.14, 0.16, 0.36, 0.37, 1.30, 1.40, 1.60, 2.50, 4.60 **RA:** 0.15, 0.19, 0.39, 0.41, 1.46, 2.03, 2.53, 2.93, 5.45	3 × 600 g/ha, PHI 7 days Residue trials on open-leaf variety lettuces compliant with GAP. Extrapolation possible to lamb's lettuces, cresses, land cresses, rucola and red mustards	**8**	**Mo:** 4.60 **RA:** 5.45	**Mo:** 1.30 **RA:** 1.46	1.2
Spinaches Purslanes Chards/beet leaves	SEU	As above	3 × 600 g/ha, PHI 7 days Residue trials on open-leaf variety lettuces compliant with GAP. Extrapolation possible to spinaches, purslanes and chards/beet leaves	**8**	**Mo:** 4.60 **RA:** 5.45	**Mo:** 1.30 **RA:** 1.46	1.2
Escaroles Dandelions	SEU	**Mo:** 0.03, 0.06, 0.09, 0.36, 0.47, 0.61, 0.66, 1.20, 2.60 **RA:** 0.04, 0.07, 0.10, 0.39, 0.50, 0.81, 0.74, 2.23, 3.35	3 × 600 g/ha, PHI 10 days Residue trials on open-leaf variety lettuces compliant with GAP. Extrapolation possible to escaroles (including dandelions)	**4**	**Mo:** 2.60 **RA:** 3.35	**Mo:** 0.47 **RA:** 0.50	1.2

MRL: maximum residue level; PHI: preharvest interval.
*: Indicates that the MRL is proposed at the limit of quantification.
(a): SEU: Outdoor trials conducted in southern Europe.
(b): Highest residue. The highest residue for risk assessment refers to the whole commodity and not to the edible portion.
(c): Supervised trials median residue. RA: The median residue for risk assessment refers to the whole commodity and not to the edible portion. Mo: Supervised trials median residue according to the residue definition for monitoring.
(d): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.

B.1.2.2. Residues in rotational crops

Residues in rotational and succeeding crops expected based on confined rotational crop study?	Yes	In the confined rotational crop residue study, evaluated during the peer review, pyrazolyl- C-labelled fenpyrazamine was applied to bare soil at a rate of 2.83 kg as/ha; wheat, lettuce and carrots were planted at 30-, 120- or 360-day PBI. Total radioactive residues (TRR) levels in the edible portions of rotational crops were found at levels up to 1.5 mg eq./kg (at 120-day PBI in immature carrot root; Austria, 2011a). Considering the study application rate represented 1.57 N of the GAP application rate for the commodities under consideration, this corresponds to estimated TRR residues in succeeding crops of up to 0.95 mg eq./kg.
Residues in rotational and succeeding crops expected based on field rotational crop study?	No	In the field rotational crop residue study, evaluated during the peer review, 'open-field' primary crop (tomato) was treated with fenpyrazamine at a rate of 3 × 600 g/ha (6 to 8 day application interval), in compliance with the intended use GAPs for the commodities under consideration in the present MRL application. Succeeding crops (carrot, lettuce, tomato and barley) were sown at 1, 4 (carrot, lettuce, barley) or 8 (tomato), and 12 months after last application, and grown to maturity. Succeeding crops were analysed for fenpyrazamine and the metabolite S-2188-OH; and residue levels in all samples were below the LOQ of 0.01 mg/kg. Insufficient information was provided in the field study to conclude whether the predicted plateau soil concentration after application of fenpyrazamine at the intended use GAPs (0.002 mg/kg soil) is covered by these studies. Nevertheless, considering that the expected plateau soil 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 (EFSA, 2017). Therefore, based on the confined and field rotational crop studies submitted, it is concluded that no residues are expected in succeeding crops, provided that the active substance is applied according to the intended use GAPs.

PBI: plant back interval; GAP: good agricultural practice; LOQ: limit of quantification.

B.1.2.3. Processing factors

No processing studies were submitted in the framework of the present MRL application.

B.2. Residues in livestock

Not relevant as the commodities under consideration are not usually used for feed purposes.

B.3. Consumer risk assessment

ARfD	0.3 mg/kg bw (EFSA, 2012)
Highest IESTI, according to EFSA PRIMo	Escarole: 97.6% of ARfD Lettuce: 48.9% of ARfD Spinach: 41.1% of ARfD
Assumptions made for the calculations	The calculation is based on the highest residue levels expected in raw agricultural commodities based on the residue definition for dietary risk assessment. The results of residue trials performed on lettuce were extrapolated to derive risk assessment values for the other commodities under consideration in the present application.

ADI	0.13 mg/kg bw (EFSA, 2012)
Highest IEDI, according to EFSA PRIMo	5.7% ADI (WHO Cluster diet B) Contribution of crops assessed: Lettuces: 0.4% of ADI Spinaches: 0.1% of ADI Chards/beet leaves: 0.04% of ADI Escaroles/broad-leaved endives: 0.01% of ADI
Assumptions made for the calculations	The calculation is based on median residue levels derived for raw agricultural commodities multiplied by the conversion factor for risk assessment and on supervised trials median residue (STMR) values according to the residue definition for dietary risk assessment (see Appendix D.2). The results of residue trials performed on lettuce were extrapolated to derive risk assessment values for the other commodities under consideration in the present application. The contributions of commodities where no GAP was reported in the framework of the MRL review were not included in the calculation.

ARfD: acute reference dose; ADI: actual daily intake; MRL: maximum residue level; GAP: good agricultural practice.

B.4. Recommended MRLs

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Fenpyrazamine				
0251010	Lamb's lettuces/ corn salads	0.01*	**8**	The submitted data are sufficient to derive a MRL proposal for SEU use. Risk for consumers unlikely.
0251020	Lettuces	0.01*	**8**	The submitted data are sufficient to derive a MRL proposal for SEU use. Risk for consumers unlikely.
0251030	Escaroles/ broad-leaved endives (including dandelions)	0.01*	**4**	The submitted data are sufficient to derive a MRL proposal for the SEU use on escaroles, including for the intended SEU use on dandelions in the sub-code of 0251030-002. According to the internationally agreed methodology for short-term exposure estimation (IESTI), the ARfD is not exceeded (97.6%), and thus, there is a narrow safety margin.
0251040	Cresses and other sprouts and shoots	0.01*	**8**	The submitted data are sufficient to derive a MRL proposal for SEU use. Risk for consumers unlikely.
0251050	Land cresses	0.01*	**8**	The submitted data are sufficient to derive a MRL proposal for SEU use. Risk for consumers unlikely.
0251060	Roman rocket/rucola	0.01*	**8**	The submitted data are sufficient to derive a MRL proposal for SEU use. Risk for consumers unlikely.
0251070	Red mustards	0.01*	**8**	The submitted data are sufficient to derive a MRL proposal for SEU use. Risk for consumers unlikely.
0252010	Spinaches	0.01*	**8**	The submitted data are sufficient to derive a MRL proposal for SEU use. Risk for consumers unlikely.
0252020	Purslanes	0.01*	**8**	The submitted data are sufficient to derive a MRL proposal for SEU use. Risk for consumers unlikely.
0252030	Chards/beet leaves	0.01*	**8**	The submitted data are sufficient to derive a MRL proposal for SEU use. Risk for consumers unlikely.

ARfD: acute reference dose; MRL: maximum residue level; SEU: southern European Union.
*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.

Appendix C – Pesticide Residue Intake Model (PRIMo)

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

EFSA-Q-2017-00638, adapted from Art.12 EFSA-Q-2012-00741.

Chronic risk assessment – refined calculations

TMDI (range) in % of ADI minimum – maximum	
1	6
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)
5.7	WHO Cluster diet B	1.9	Tomatoes	1.6	Wine grapes	0.4	Peaches	0.0
4.4	FR all population	3.5	Wine grapes	0.3	Tomatoes	0.1	Peaches	0.0
3.9	DE child	1.1	Table grapes	0.6	Tomatoes	0.5	Strawberries	0.0
3.6	PT General population	2.2	Wine grapes	0.6	Tomatoes	0.3	Peaches	0.0
3.6	IE adult	1.1	Wine grapes	0.5	Peaches	0.2	Tomatoes	0.0
2.6	NL child	0.7	Table grapes	0.4	Spinach	0.4	Tomatoes	0.0
2.5	WHO cluster diet E	1.4	Wine grapes	0.3	Tomatoes	0.1	Table grapes	0.0
2.3	FR toddler	0.8	Spinach	0.6	Strawberries	0.5	Tomatoes	0.0
2.2	IT kids/toddler	0.9	Tomatoes	0.3	Peaches	0.3	Lettuce	0.0
2.2	IT adult	0.7	Tomatoes	0.4	Lettuce	0.4	Peaches	0.0
2.2	ES adult	0.6	Lettuce	0.5	Tomatoes	0.4	Wine grapes	0.0
2.1	WHO regional European diet	0.7	Tomatoes	0.4	Lettuce	0.2	Wine grapes	0.0
1.8	DK adult	1.2	Wine grapes	0.3	Tomatoes	0.1	Peaches	0.0
1.8	ES child	0.6	Tomatoes	0.5	Lettuce	0.2	Peaches	0.0
1.7	NL general	0.6	Wine grapes	0.3	Tomatoes	0.2	Table grapes	0.0
1.7	WHO Cluster diet F	0.5	Wine grapes	0.4	Tomatoes	0.3	Lettuce	0.0
1.7	WHO cluster diet D	0.6	Tomatoes	0.3	Wine grapes	0.2	Table grapes	0.0
1.6	UK vegetarian	0.7	Wine grapes	0.4	Tomatoes	0.2	Lettuce	0.0
1.6	UK Adult	1.0	Wine grapes	0.3	Tomatoes	0.1	Lettuce	0.0
1.3	FR infant	0.5	Spinach	0.5	Strawberries	0.1	Courgettes	0.0
1.3	DK child	0.3	Tomatoes	0.3	Cucumbers	0.2	Table grapes	0.0
1.3	SE general population 90th percentile	0.5	Tomatoes	0.2	Strawberries	0.1	Peaches	0.0
1.2	UK Toddler	0.4	Tomatoes	0.2	Table grapes	0.2	Strawberries	0.0
1.2	PL general population	0.5	Tomatoes	0.3	Table grapes	0.1	Cherries	0.0
0.8	FI adult	0.3	Wine grapes	0.3	Tomatoes	0.1	Lettuce	0.0
0.8	UK Infant	0.2	Tomatoes	0.2	Strawberries	0.1	Apricots	
0.6	LT adult	0.4	Tomatoes	0.1	Lettuce	0.1	Cucumbers	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)
97.6	Scarole (broad-leaf	3.35/-	97.6	Scarole (broad-leaf	3.35/-	20.0	Lettuce	5.45/-	17.1	Purslane	5.45/-
48.9	Lettuce	5.45/-	41.1	Spinach	5.45/-	18.8	Purslane	5.45/-	16.2	Spinach	5.45/-
41.1	Spinach	5.45/-	29.3	Lettuce	5.45/-	16.2	Spinach	5.45/-	12.0	Lettuce	5.45/-
31.9	Beet leaves (chard)	5.45/-	24.2	Beet leaves	5.45/-	13.5	Beet leaves (chard)	5.45/-	11.4	Beet leaves (chard)	5.45/-
27.4	Purslane	5.45/-	20.8	Purslane	5.45/-	9.9	Scarole (broad-leaf	3.35/-	9.9	Scarole (broad-leaf endive)	3.35/-
5.6	Rocket, Rucola	5.45/-	5.6	Rocket, Rucola	5.45/-	3.4	Lamb's lettuce	5.45/-	3.4	Lamb's lettuce	5.45/-
5.1	Lamb's lettuce	5.45/-	5.1	Lamb's lettuce	5.45/-	0.7	Cress	5.45/-	0.7	Cress	5.45/-
0.5	Cress	5.45/-	0.5	Cress	5.45/-						
No of critical MRLs (IESTI 1)			---			**No of critical MRLs (IESTI 2)**			---		

Processed commodities

No of commodities for which ARfD/ADI is exceeded: ---						No of commodities for which ARfD/ADI is exceeded: ---					
		***)						***)			
Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)				Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)			

*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.

**) pTMRL: provisional temporary MRL.

***) pTMRL: provisional temporary MRL for unprocessed commodity.

Conclusion:

For 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				

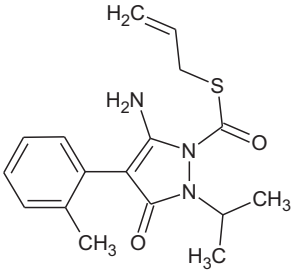
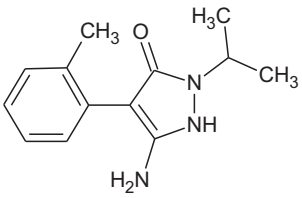
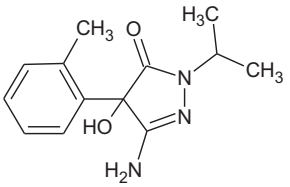
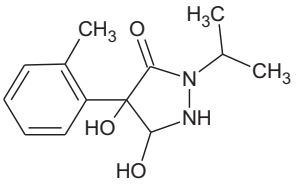
D.2. Consumer risk assessment

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				
Lamb's lettuces/corn salads	1.46	STMR	5.45	HR
Lettuces	1.46	STMR	5.45	HR
Escaroles/broad-leaved endives	0.50	STMR	3.35	HR
Cresses and other sprouts and shoots	1.46	STMR	5.45	HR
Land cresses	1.46	STMR	5.45	HR
Roman rocket/rucola	1.46	STMR	5.45	HR
Red mustards	1.46	STMR	5.45	HR
Spinaches	1.46	STMR	5.45	HR
Purslanes	1.46	STMR	5.45	HR
Chards/beet leaves	1.46	STMR	5.45	HR
Almonds	0.01	$STMR_{Mo}$ × CF (EFSA, 2017)	Acute risk assessment was undertaken only with regard to the crops under consideration.	
Apricots	1.25	$STMR_{Mo}$ × CF (EFSA, 2017)		
Cherries (sweet)	1.05	$STMR_{Mo}$ × CF (EFSA, 2017)		
Peaches	1.25	$STMR_{Mo}$ × CF (EFSA, 2017)		
Plums	0.46	$STMR_{Mo}$ × CF (EFSA, 2017)		
Table grapes	1.15	$STMR_{Mo}$ × CF (EFSA, 2017)		
Wine grapes	1.15	$STMR_{Mo}$ × CF (EFSA, 2017)		
Strawberries	1.29	$STMR_{Mo}$ × CF (EFSA, 2017)		
Blackberries	1.84	$STMR_{Mo}$ × CF (EFSA, 2017)		
Dewberries	1.84	$STMR_{Mo}$ × CF (EFSA, 2017)		
Raspberries (red and yellow)	1.84	$STMR_{Mo}$ × CF (EFSA, 2017)		
Blueberries	1.01	$STMR_{Mo}$ × CF (EFSA, 2017)		
Tomatoes	0.81	$STMR_{Mo}$ × CF (EFSA, 2017)		
Sweet peppers/bell peppers	0.92	$STMR_{Mo}$ × CF (EFSA, 2017)		

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Aubergines/eggplants	0.81	$STMR_{Mo} \times CF$ (EFSA, 2017)		
Cucumbers	0.20	$STMR_{Mo} \times CF$ (EFSA, 2017)		
Gherkins	0.20	$STMR_{Mo} \times CF$ (EFSA, 2017)		
Courgettes	0.20	$STMR_{Mo} \times CF$ (EFSA, 2017)		

STMR: supervised trials median residue (STMR); HR: Highest residue.

Appendix E – Used compound codes

Code/trivial name[(a)]	IUPAC name/SMILES notation/ InChiKey[(b)]	Structural formula[(c)]
Fenpyrazamine S-2188	*S*-allyl 5-amino-2,3-dihydro-2-isopropyl-3-oxo-4-(*o*-tolyl)-1*H*-pyrazole-1-carbothioate CC(C)N1C(=O)C(=C(N)N1C(=O)SCC=C)c2ccccc2C UTOHZQYBSYOOGC-UHFFFAOYSA-N	
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 PAVOPGYTDLNLBE-UHFFFAOYSA-N	
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 VRAARBLWVOZPFG-UHFFFAOYSA-N	
S-2188-(OH)$_2$	4,5-dihydroxy-4-(2-methylphenyl)-2-(propan-2-yl)pyrazolidin-3-one(4*RS*,5*RS*)-4,5-dihydroxy-4-(2-methylphenyl)-2-(propan-2-yl)pyrazolidin-3-one OC1(C(O)NN(C(C)C)C1 = O)c2ccccc2C KPWIWJBUTKDDMD-UHFFFAOYSA-N	

(a): The metabolite name in bold is the name used in the conclusion.
(b): ACD/Name 2015 ACD/Labs 2015 Release (File version N20E41, Build 75170, 19 Dec 2014)
(c): ACD/ChemSketch 2015 ACD/Labs 2015 Release (File version C10H41, Build 75059, 17 Dec 2014).