

Review of the existing MRLs for fenamidone

Competent Authority Draft Reasoned Opinion

- Prepared under Article 12 of Regulation (EC) No 396/2005
- Reference Number: COP 2021/00529

June 2022

DRAFT

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Summary

This assessment is a draft only and outlines proposed recommendations for the MRLs for the active substance fenamidone.

According to Article 12 of Regulation (EC) No 396/2005,¹ HSE as a competent authority has reviewed the Maximum Residue Levels (MRLs) currently established in Great Britain (GB) for the pesticide active substance fenamidone. This review of the MRLs has been undertaken by HSE under the GB regulatory regime following the UK leaving the EU. It was required following the earlier non-approval decision for the active substance fenamidone under the EU plant protection product regulatory regime (Regulation (EC) No 1107/2009),² and the subsequent withdrawal of all plant protection authorisations in GB. This EU non-approval decision came into force while the UK was still an EU Member State and was therefore retained in the national regulatory regime after the UK's departure from the EU.

Based on the review of the MRLs, HSE prepared a Reasoned Opinion (RO). HSE took into account the assessment report and EFSA Conclusion prepared under Regulation (EC) No 1107/2009 for the renewal of the approval of the active substance (the renewal assessment).

Fenamidone does not meet the requirements to be exempt from MRLs and therefore it is not suitable for inclusion in Part 4 (active substances not subject to MRLs) of the GB MRL Statutory Register.

Sufficiently validated analytical methods for the determination of fenamidone in plants and animals are available to enforce MRLs at an LOQ of 0.01 mg/kg.

Toxicological reference could not be established for fenamidone; there is evidence of a potential genotoxic risk to consumers.

The renewal assessment considered plant and animal metabolism data, processing studies, rotational crop data, residue trials and animal feeding studies: several data gaps within the residues assessment were identified.

¹ Retained [Regulation \(EC\) No 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin](#) (as it applies in Great Britain, pursuant to the European Union (Withdrawal) Act 2018 and European Union (Withdrawal Agreement Act 2020). Great Britain ("GB") refers to England, Scotland and Wales. All references to this regulation are the retained regulation as it applies in GB.

² EU [Regulation \(EC\) No 1107/2009 concerning the placing of plant protection products on the market](#). All references to this regulation are the EU regulation as it applied to the UK as an EU MS.

In the renewal assessment, only a provisional residue definition for risk assessment (RD-RA) in plants was recommended:

Leafy and fruit crop groups:

- Fenamidone and RPA 410193

Root crop group:

- Fenamidone and RPA 410193 and RPA 413255

As a result of this review, no additional conclusions are made on a suitable residue definition for risk assessment for plants. The EFSA Conclusion remains applicable in the absence of additional information.

The residue definition for enforcement (RD-Enf) was recommended as:

- Fenamidone

This residue definition is the same as the current RD-Enf in the GB MRL Statutory Register.

In the renewal assessment, the residue definition for both risk assessment (RD-RA) and enforcement (RD-Enf) for livestock was recommended as:

- Fenamidone, RPA 412636 and RPA 412708

Both the RD-RA and RD-Enf for livestock should be regarded as provisional pending an agreement on the RD-RA for plants and a further toxicological assessment of fenamidone and the metabolites. Therefore, HSE recommends that the current RD-Enf of fenamidone is retained in the GB MRL Statutory Register. As a result of this review, no additional conclusions are made on a suitable residue definition for risk assessment for livestock. The EFSA Conclusion remains applicable in the absence of additional information.

The data provided for the renewal assessment are not sufficient to establish robust processing factors for fenamidone. At this time, Part 6 of the GB MRL Statutory Register has not been established.

Proposed Recommendations

Based on the risk assessment conducted in the renewal assessment, HSE concludes that harmful effects on human health cannot be excluded for residues of fenamidone occurring in food. This includes evidence of a potential genotoxic risk to consumers. This conclusion applies to all the current GB MRLs in the Statutory Register. As the required level of

protection has not been met, HSE proposes that all MRLs are set at the limit of quantification.

The MRLs proposed by HSE are outlined in Table 8.1.

The MRLs should be established on the basis of the following residue definitions:

The residue definition for enforcement (RD-Enf) in plants:

- Fenamidone

The residue definition for enforcement (RD-Enf) in animals:

- Fenamidone

Notification of the proposed MRLs

To meet the UK's international trade obligations, the measures have been notified to the World Trade Organization (WTO). The WTO/SPS notification can be found at the following link and searching for fenamidone and United Kingdom as the notifying member:

[Home - ePing SPS&TBT platform \(epingalert.org\)](http://epingalert.org)

- **There may be a delay between publication of this draft RO and the notification appearing in the Sanitary and Phytosanitary Information Management System**
- **The notification includes the proposed date of adoption/publication and the proposed date of entry in force of the new MRLs.**

Background

Article 12 of Regulation (EC) No 396/2005 requires the Competent Authority to undertake a review of the GB Maximum Residue Levels (MRLs).

A non-approval decision,³ was delivered for fenamidone on 24 July 2018 and all plant protection product authorisations in GB have been withdrawn. HSE therefore initiated a review of the current MRLs taking into account the assessment report and EFSA Conclusion prepared under Regulation (EC) No 1107/2009 for the renewal of the approval of the active substance (the renewal assessment). As outlined in Article 12 (3) of Regulation (EC) No 396/2005 the following points have been considered within this review:

- The existing MRLs for fenamidone set out in Part 2 or 3 of the GB MRL Statutory Register
- The necessity of setting a new MRL for fenamidone, or its inclusion in Part 4 of the MRLs register
- Specific processing factors as referred to in Article 20(2) that may be needed for fenamidone
- MRLs which the competent authority may consider including in Part 2 or 3 of the MRLs register and those MRLs related to fenamidone which may be deleted

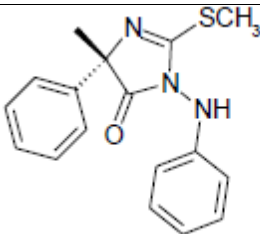
This review is the basis of HSE's draft reasoned opinion: HSE recommends that all the MRLs for fenamidone are lowered to the limit of quantification.

³ [Commission Implementing Regulation \(EU\) 2018/1043 of 24 July 2018](#) concerning the non-renewal of approval of the active substance fenamidone, 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 Commission Implementing Regulation (EU) No 540/2011. The non-approval decision adopted when the UK was an EU MS.

The active substance and its use pattern

Information on the active substance fenamidone is outlined in Table 0.1.

Table 0.1 Information on the active substance

Common name (ISO)	Fenamidone
Chemical name (IUPAC)	(S)-1-anilino-4-methyl-2-methylthio-4-phenylimidazolin-5-one
CAS number	161326-34-7
Structural formula	
Molecular formula	C ₁₇ H ₁₇ N ₃ OS
Molecular mass	311.4 g/mol

Fenamidone is not an approved active substance in GB and all plant protection product authorisations have been withdrawn.

A Renewal Assessment Report (RAR) (Czech Republic, 2015) and an EFSA Conclusion on the peer review of the renewal assessment (EFSA, 2016) are available.

MRLs are established for fenamidone in Part 2 of the GB MRL Statutory Register.

Fenamidone is a fungicide controlling pathogenic fungi from all groups including the oomycetes. It inhibits mitochondrial respiration by blocking electron transport at the level of the enzyme ubiquinone: cytochrome c oxidoreductase (Complex III).

The following Codex MRLs (CXLs) are available for fenamidone (Codex Pesticide Residues in food online database).

Table 0.2 CXLs for fenamidone

Commodity	CXL (mg/kg)	Comments	Year of adoption
Beans, except broad bean and soya bean	0.8	The CXLs are not recommended for adoption as harmful effects on human health cannot be	2015
Beans, shelled	0.15		2015

Commodity	CXL (mg/kg)	Comments	Year of adoption
Cabbages, head	0.9	excluded for residues of fenamidone occurring in food	2015
Carrot	0.2		2015
Celery	40		2015
Cotton seed	0.02*		2015
Edible offal (mammalian)	0.01 *		2015
Eggs	0.01*		2015
Flowerhead brassicas (includes Broccoli: Broccoli, Chinese and cauliflower)	4		2015
Fruiting vegetables other than cucurbits	1.5		2015
Fruiting vegetables, cucurbits (except chilli pepper, fungi, sweet corn)	0.2		2015
Garlic	0.15		2015
Grapes	0.6		2015
Leek	0.3		2015
Lettuce, head	20		2015
Lettuce, leaf	0.9		2015
Meat (from mammals other than marine mammals)	0.01* (fat)		2015
Milk fats	0.02		2015
Milks	0.01*		2015
Onion, bulb	0.15		2015
Onion, Welsh	3		2015
Peppers chili	4		2015
Peppers chili, dried	30	2015	

Commodity	CXL (mg/kg)	Comments	Year of adoption
Potato	0.02*		2015
Poultry fats	0.01		2015
Poultry meat	0.01* (fat)		2015
Poultry, edible offal of	0.01*		2015
Shallot	0.15		2015
Spring onion	3		2015
Strawberry	0.04		2015
Sunflower seed	0.02*		2015
Tomato ketchup	3		2015
Tomato paste	4		2015
Witloof chicory (sprouts)	0.01*		2015

* denotes an MRL at the limit of quantification/ limit of determination

The CXL database is available at the following link:

<http://www.fao.org/fao-who-codexalimentarius/codex-texts/dbs/pestres/en/>

Assessment

1 Methods of Analysis

1.1 Methods for enforcement and monitoring of residues in food of plant origin

The current residue definition for enforcement is:

- Fenamidone

No changes to this residue definition are proposed as a result of this review.

Analytical methods for the determination of fenamidone in plant commodities (all crop groups) were considered in the renewal assessment. The GC-MS method was validated with an LOQ of 0.01 mg/kg.

Enforcement of MRLs for products of plant origin at an LOQ of 0.01 mg/kg has been demonstrated.

No specific analytical methods are available for the difficult to analyse matrices. Therefore, the default uncertainty factors outlined as footnotes for Table 8.1 will be applied.

1.2 Methods for enforcement and monitoring of residues in food of animal origin

The current residue definition for enforcement is:

- Fenamidone

No changes to this residue definition are proposed as a result of this review.

An analytical method for the determination of fenamidone in animal commodities (milk, kidney, liver, meat, egg and fat) was considered for the renewal of approval of the active substance. The LC-MS/MS method was validated with an LOQ of 0.01 mg/kg.

Enforcement of MRLs for products of animal origin at an LOQ of 0.01 mg/kg has been demonstrated.

2 Mammalian toxicology

Toxicological reference could not be established for fenamidone; there is evidence of a potential genotoxic risk to consumers.

Toxicological data were provided for the plant metabolites RPA 412636 and RPA 410193.

The toxicological data for the plant metabolite RPA 412636 indicated that the metabolite has a different toxicological profile than the parent compound; based on the available data an ADI of 0.0064 mg/kg bw/day was established. An ARfD was not agreed and would require further consideration.

For the plant metabolite RPA 410193 an ADI of 0.0094 mg/kg bw/day was established. An ARfD was not agreed and would require further consideration.

3 Residues in Plants

The renewal assessment should be consulted for all the available data to support residues in plants.

The consideration of the inclusion in Part 4 of the GB MRL Statutory Register

Fenamidone does not meet the requirements to be exempt from MRLs:

- Active substances approved as a basic substance
- Active substances listed Part 1 of the GB MRL Statutory Register
- Active substances with no identified hazards
- The consumer exposure associated with the use of the active substance as a PPP is negligible compared to other sources/natural background exposure
- The method of application of the PPP will lead to no consumer exposure

Therefore, HSE does not recommend that fenamidone is included in Part 4 (active substances not subject to MRLs) of the GB MRL Statutory Register.

All authorisations in GB have been withdrawn on the basis of the non-approval decision for fenamidone. As outlined in section 7 of this Reasoned Opinion, the renewal assessment establishes that harmful effects for human health cannot be excluded and therefore the required level of protection has not been met.

HSE recommends that all MRLs for products of plant origin are set at the limit of quantification. Therefore, no additional residues data are presented in this Reasoned Opinion. The following is a summary only of the available information from the renewal assessment:

Residues in primary crops

The metabolism in fruit crops (grapes and tomatoes), root crops (potatoes and carrots) and leafy crops (lettuces) following foliar application was assessed in the renewal assessment. The data were sufficient to establish a residue definition for enforcement as fenamidone. In leafy crops and fruits the major analytes were fenamidone and RPA 410193. In root crops these two analytes were also the major analytes along with RPA 413255. The metabolites RPA 412636 (free and conjugate) and RPA 412708 were also found in crops. Owing to the lack of toxicological data on fenamidone and the metabolites it was not possible to conclude on the residue definition for risk assessment.

Residues in rotational crops

With respect to residues in rotational crops, all UK authorisations have been withdrawn and therefore no residues in crops grown in rotation in GB are expected.

The data assessed in the renewal assessment identified a range of metabolites that may occur in rotational crops. The relative importance of these for dietary exposure is not known in the absence of toxicological reference values for fenamidone. A further consideration of rotational crops will be required in order to establish substantive MRLs.

Residues in processed commodities

The standard hydrolysis study demonstrated that fenamidone was degraded to RPA 410193 and RPA 412708. The relative importance of these for dietary exposure is not known in the absence of toxicological reference values for fenamidone. A further consideration of residues in processed commodities will be required in order to establish substantive MRLs.

The data provided for the renewal assessment are not sufficient to establish processing factors for fenamidone.

Residue definitions for enforcement

Within the renewal assessment, the residue definition for enforcement (RD-Enf) was recommended as:

- Fenamidone

This is the same as the current RD-Enf in the GB MRL Statutory Register.

Residue definitions for risk assessment

Within the renewal assessment, a provisional residue definition for enforcement (RD-Enf) was proposed:

Leafy and fruit crop groups:

- Fenamidone and RPA 410193

Root crop group:

- Fenamidone and RPA 410193 and RPA 413255

The RD-RA is only provisional pending the availability of a full toxicological assessment for fenamidone, agreement on the toxicological reference values for fenamidone and additional data to address the toxicity of the fenamidone metabolites. Based on the available data, it is not known if the residues should be summed or determined separately. The full details are available in the EFSA Conclusion.

As a result of this review, no additional conclusions are made on a suitable residue definition for risk assessment. The provisional residue definition outlined in the EFSA Conclusion remains applicable for risk assessment in the absence of additional information.

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4 Residues in livestock

The renewal assessment should be consulted for all the available data to support residues in livestock.

As outlined in Section 3, the residue definitions for plants are only provisional. It is therefore not known what specific residues will occur in animal feeds. Hence, it is not known what residues livestock will be exposed to and it not possible to undertake an accurate assessment of the livestock dietary burden.

Livestock metabolism data were assessed in the renewal assessment. Acceptable data for ruminants and poultry undertaken using fenamidone are available. The major metabolites were fenamidone, RPA 412636 and RPA 412708. In the absence of a robust RD-RA for plants the full extent of the residues that livestock may be exposed to is not known and further livestock metabolism data may be required. It is not possible to establish a robust residue definition for risk assessment for livestock. HSE recommends that all MRLs for products of animal origin are set at the limit of quantification.

Residue definitions for enforcement

Within the renewal assessment, a residue definition for enforcement (RD-Enf) was recommended as:

- Fenamidone, RPA 412636 and RPA 412708

Residue definitions for risk assessment

Within the renewal assessment, a provisional residue definition for risk assessment (RD-RA) was proposed:

- Fenamidone, RPA 412636 and RPA 412708

In the absence of an agreed RD-RA for plants, it is not possible to determine suitable residue definitions for livestock. In addition, without further toxicity data it is not known if livestock exposure to the metabolites RPA 412636 and RPA 412708 should be considered with fenamidone (summed residues) or separately. The available toxicity data from the renewal assessment for the metabolite RPA 412636 indicated that this metabolite has a different toxicological profile than fenamidone.

As HSE is recommending all MRLs are lowered to the LOQ, then a default RD-Enf of fenamidone is recommended. This is the current RD-Enf in the GB MRL Statutory Register.

As a result of this review, no additional conclusions are made on a suitable residue definition for risk assessment. The provisional residue definition outlined in the EFSA Conclusion remains applicable for risk assessment in the absence of additional information.

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5 Residues in honey

The potential for residues arising in honey is not relevant as there are no authorisations in GB. The MRL for honey should be set at the default LOQ MRL (for honey) of 0.05* mg/kg. This is based on a RD-Enf of fenamidone.

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6 MRLs for products not covered in sections 3 and 4

This section is to cover MRLs that can be extrapolated to other products included in Part 1 of the GB MRL Statutory Register but are not covered in sections 3 and 4 of this review. Examples include MRLs for edible offals (other than liver and kidney) or MRLs to cover products derived from other species such as goat or equine.

The MRLs for fenamidone for all products of plant and animal origin are recommended to be set at the limit of quantification and therefore a consideration of the extrapolation of MRLs to additional products is not required.

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7 Consumer risk assessment

7.1 Dietary Exposure

The following issues were identified in the renewal assessment that are relevant to consumer exposure:

- No toxicological reference values were established for fenamidone; there is evidence of a potential genotoxic risk to consumers.
- It is not possible to establish residues definitions for risk assessment for plants and livestock. Consequently, it is not known what residues humans and livestock may be exposed to as a result of crops treated with fenamidone. The risk assessment is unable to demonstrate that the necessary requirements are satisfied.
- The consumer risk assessment from the consumption of water was unable to demonstrate that the necessary requirements are satisfied (See point 7.2, noting this issue would be applicable to authorisations in GB only).

The full list of issues identified in the renewal assessment are available in the EFSA Conclusion. The outcome of the risk assessment for the renewal of fenamidone is directly relevant to all uses and hence all GB MRLs in the Statutory Register. Therefore, consumer intake estimations have not been performed.

Based on the risk assessment conducted in the renewal assessment, HSE concludes that harmful effects on human health cannot be excluded for residues of fenamidone occurring in food. This includes evidence of a potential genotoxic risk for consumers. Consequently, the required level of protection has not been met.

7.2 Other routes of exposure

As there are no authorisations in GB then exposure as a result of metabolites being present in drinking water/ground water is not of concern.

8 The draft conclusion of the competent authority

This assessment is a draft only and outlines proposed recommendations for the MRLs for the active substance fenamidone.

According to Article 12 of Regulation (EC) No 396/2005 HSE as a competent authority has reviewed the Maximum Residue Levels (MRLs) currently established in Great Britain (GB) for the pesticide active substance fenamidone. This review of the MRLs has been undertaken by HSE under the GB regulatory regime following the UK leaving the EU. It was required following the earlier non-approval decision for the active substance fenamidone under the EU plant protection product regulatory regime (Regulation (EC) No 1107/2009), and the subsequent withdrawal of all plant protection authorisations in GB. This EU non-approval decision came into force while the UK was still an EU Member State and was therefore retained in the national regulatory regime after the UK's departure from the EU.

Based on the review of the MRLs, HSE prepared a Reasoned Opinion (RO). HSE took into account the assessment report and EFSA Conclusion prepared under Regulation (EC) No 1107/2009 for the renewal of the approval of the active substance (the renewal assessment).

Fenamidone does not meet the requirements to be exempt from MRLs and therefore it is not suitable for inclusion in Part 4 (active substances not subject to MRLs) of the GB MRL Statutory Register.

Sufficiently validated analytical methods for the determination of fenamidone in plants and animals are available to enforce MRLs at an LOQ of 0.01 mg/kg.

Toxicological reference could not be established for fenamidone; there is evidence of a potential genotoxic risk for consumers.

The renewal assessment considered plant and animal metabolism data, processing studies, rotational crop data, residue trials and animal feeding studies: several data gaps within the residues assessment were identified.

In the renewal assessment, only a provisional residue definition for risk assessment (RD-RA) in plants was recommended:

Leafy and fruit crop groups:

- Fenamidone and RPA 410193

Root crop group:

- Fenamidone and RPA 410193 and RPA 413255

As a result of this review, no additional conclusions are made on a suitable residue definition for risk assessment for plants. The EFSA Conclusion remains applicable in the absence of additional information.

The residue definition for enforcement (RD-Enf) was recommended as:

- Fenamidone

This residue definition is the same as the current RD-Enf in the GB MRL Statutory Register.

In the renewal assessment, the residue definition for both risk assessment (RD-RA) and enforcement (RD-Enf) for livestock was recommended as:

- Fenamidone, RPA 412636 and RPA 412708

Both the RD-RA and RD-Enf for livestock should be regarded as provisional pending an agreement on the RD-RA for plants and a further toxicological assessment of fenamidone and the metabolites. Therefore, HSE recommends that the current RD-Enf of fenamidone is retained in the GB MRL Statutory Register. As a result of this review, no additional conclusions are made on a suitable residue definition for risk assessment for livestock. The EFSA Conclusion remains applicable in the absence of additional information.

The data provided for the renewal assessment are not sufficient to establish robust processing factors for fenamidone. It is noted that at this time Part 6 of the GB MRL Statutory Register has not been established.

Proposed Recommendations

Based on the risk assessment conducted in the renewal assessment, HSE concludes that harmful effects on human health cannot be excluded for residues of fenamidone occurring in food. This includes evidence of a potential genotoxic risk to consumers. This conclusion applies to all the current GB MRLs in the Statutory Register. As the required level of protection has not been met, HSE proposes that all MRLs are set at the limit of quantification.

The MRLs proposed by HSE are outlined in Table 8.1.

The MRLs should be established on the basis of the following residue definitions:

The residue definition for enforcement (RD-Enf) in plants:

- Fenamidone

The residue definition for enforcement (RD-Enf) in animals:

- Fenamidone

Notification of the proposed MRLs

To meet the UK's international trade obligations, the measures have been notified to the World Trade Organization (WTO). The WTO/SPS notification can be found at the following link and searching for fenamidone and United Kingdom as the notifying member:

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- **There may be a delay between publication of this draft RO and the notification appearing in the Sanitary and Phytosanitary Information Management System**
- **The notification includes the proposed date of adoption/publication and the proposed date of entry in force of the new MRLs.**

Table 8.1 MRLs proposed by HSE

Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)
Enforcement residue definition for products of plant origin: Fenamidone			
0100000	FRUITS, FRESH or FROZEN; TREE NUTS	-	-
0110000	Citrus fruits	-	-
0110010	Grapefruits	0.01*	0.01*
0110020	Oranges	0.01*	0.01*
0110030	Lemons	0.01*	0.01*
0110040	Limes	0.01*	0.01*
0110050	Mandarins	0.01*	0.01*
0110990	Others - Citrus Fruit	0.01*	0.01*
0120000	Tree Nuts	-	-
0120010	Almonds	0.01*	0.01*
0120020	Brazil nuts	0.01*	0.01*
0120030	Cashew nuts	0.01*	0.01*
0120040	Chestnuts	0.01*	0.01*
0120050	Coconuts	0.01*	0.01*
0120060	Hazelnuts/cobnuts	0.01*	0.01*
0120070	Macadamias	0.01*	0.01*
0120080	Pecans	0.01*	0.01*

The review of the existing MRLs for fenamidone – proposed MRLs

Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)
0120090	Pine nut kernels	0.01*	0.01*
0120100	Pistachios	0.01*	0.01*
0120110	Walnuts	0.01*	0.01*
0120990	Others - Tree nuts	0.01*	0.01*
0130000	Pome fruits	-	-
0130010	Apples	0.01*	0.01*
0130020	Pears	0.01*	0.01*
0130030	Quinces	0.01*	0.01*
0130040	Medlars	0.01*	0.01*
0130050	Loquats/Japanese medlars	0.01*	0.01*
0130990	Others - Pome fruit	0.01*	0.01*
0140000	Stone fruits	-	-
0140010	Apricots	0.01*	0.01*
0140020	Cherries (sweet)	0.01*	0.01*
0140030	Peaches	0.01*	0.01*
0140040	Plums	0.01*	0.01*
0140990	Others - Stone fruit	0.01*	0.01*
0150000	Berries and small fruits	-	-
0151000	Grapes	-	-

The review of the existing MRLs for fenamidone – proposed MRLs

Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)
0151010	Table grapes	0.6	0.01*
0151020	Wine grapes	0.6	0.01*
0152000	Strawberries	-	-
0152000	Strawberries	0.04	0.01*
0153000	Cane fruits	-	-
0153010	Blackberries	0.01*	0.01*
0153020	Dewberries	0.01*	0.01*
0153030	Raspberries (red and yellow)	0.01*	0.01*
0153990	Others - Cane fruit	0.01*	0.01*
0154000	Other small fruits and berries	-	-
0154010	Blueberries	0.01*	0.01*
0154020	Cranberries	0.01*	0.01*
0154030	Currants (black, red and white)	0.01*	0.01*
0154040	Gooseberries (green, red and yellow)	0.01*	0.01*
0154050	Rose hips	0.01*	0.01*
0154060	Mulberries (black and white)	0.01*	0.01*

The review of the existing MRLs for fenamidone – proposed MRLs

Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)
0154070	Azaroles/Mediterranean medlars	0.01*	0.01*
0154080	Elderberries	0.01*	0.01*
0154990	Others - Other small fruit and berries	0.01*	0.01*
0160000	Miscellaneous fruits with	-	-
0161000	Edible peel	-	-
0161010	Dates	0.01*	0.01*
0161020	Figs	0.01*	0.01*
0161030	Table olives	0.01*	0.01*
0161040	Kumquats	0.01*	0.01*
0161050	Carambolas	0.01*	0.01*
0161060	Kaki/Japanese persimmons	0.01*	0.01*
0161070	Jambuls/jambolans	0.01*	0.01*
0161990	Others - Edible peel	0.01*	0.01*
0162000	Inedible peel, small	-	-
0162010	Kiwi fruits (green, red, yellow)	0.01*	0.01*
0162020	Litchis/lychees	0.01*	0.01*
0162030	Passionfruits/maracujas	0.01*	0.01*

The review of the existing MRLs for fenamidone – proposed MRLs

Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)
0162040	Prickly pears/cactus fruits	0.01*	0.01*
0162050	Star apples/cainitos	0.01*	0.01*
0162060	American persimmons/Virginia kaki	0.01*	0.01*
0162990	Others - Inedible peel, small	0.01*	0.01*
0163000	Inedible peel, large	-	-
0163010	Avocados	0.01*	0.01*
0163020	Bananas	0.01*	0.01*
0163030	Mangoes	0.01*	0.01*
0163040	Papayas	0.01*	0.01*
0163050	Granate apples/pomegranates	0.01*	0.01*
0163060	Cherimoyas	0.01*	0.01*
0163070	Guavas	0.01*	0.01*
0163080	Pineapples	0.01*	0.01*
0163090	Breadfruits	0.01*	0.01*
0163100	Durians	0.01*	0.01*
0163110	Soursops/guanabanas	0.01*	0.01*

The review of the existing MRLs for fenamidone – proposed MRLs

Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)
0163990	Others - Inedible peel, large	0.01*	0.01*
0200000	VEGETABLES, FRESH or FROZEN	-	-
0210000	Root and tuber vegetables	-	-
0211000	Potatoes	-	-
0211000	Potatoes	0.02*	0.01*
0212000	Tropical root and tuber vegetables	-	-
0212010	Cassava roots/manioc	0.01*	0.01*
0212020	Sweet potatoes	0.01*	0.01*
0212030	Yams	0.01*	0.01*
0212040	Arrowroots	0.01*	0.01*
0212990	Others - Tropical root and tuber vegetables	0.01*	0.01*
0213000	Other root and tuber vegetables except sugar beets	-	-
0213010	Beetroots	0.15	0.01*
0213020	Carrots	0.2	0.01*

The review of the existing MRLs for fenamidone – proposed MRLs

Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)
0213030	Celeriacs/turnip rooted celeries	0.15	0.01*
0213040	Horseradishes	0.15	0.01*
0213050	Jerusalem artichokes	0.15	0.01*
0213060	Parsnips	0.15	0.01*
0213070	Parsley roots/Hamburg roots parsley	0.15	0.01*
0213080	Radishes	0.15	0.01*
0213090	Salsifies	0.15	0.01*
0213100	Swedes/rutabagas	0.15	0.01*
0213110	Turnips	0.15	0.01*
0213990	Others - Other root and tuber vegetables except sugar beet	0.15	0.01*
0220000	Bulb vegetables	-	
0220010	Garlic	0.2	0.01*
0220020	Onions	0.2	0.01*
0220030	Shallots	0.2	0.01*
0220040	Spring onions/green onions and Welsh onions	3	0.01*

The review of the existing MRLs for fenamidone – proposed MRLs

Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)
0220990	Others - bulb vegetables	0.01*	0.01*
0230000	Fruiting vegetables	-	
0231000	Solanaceae and Malvaceae	-	-
0231010	Tomatoes	1	0.01*
0231020	Sweet peppers/bell peppers	1	0.01*
0231030	Aubergines/eggplants	1	0.01*
0231040	Okra/lady's fingers	0.01*	0.01*
0231990	Others - Solanacea	0.01*	0.01*
0232000	Cucurbits with edible peel	-	-
0232010	Cucumbers	0.2	0.01*
0232020	Gherkins	0.2	0.01*
0232030	Courgettes	0.2	0.01*
0232990	Others - Cucurbits-edible peel	0.2	0.01*
0233000	Cucurbits with inedible peel	-	
0233010	Melons	0.2	0.01*
0233020	Pumpkins	0.2	0.01*

The review of the existing MRLs for fenamidone – proposed MRLs

Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)
0233030	Watermelons	0.2	0.01*
0233990	Others - Cucurbits - inedible peel	0.2	0.01*
0234000	Sweet corn	-	-
0234000	Sweet corn	0.01*	0.01*
0239000	Other fruiting vegetables	-	-
0239000	Other fruiting vegetables	0.01*	0.01*
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	-	-
0241000	Flowering brassica	-	-
0241010	Broccoli	5	0.01*
0241020	Cauliflowers	0.01*	0.01*
0241990	Others - Flowering Brassicas	0.01*	0.01*
0242000	Head brassica	-	-
0242010	Brussels sprouts	0.01*	0.01*
0242020	Head cabbages	0.9	0.01*
0242990	Others - Head Brassicas	0.01*	0.01*
0243000	Leafy brassica	-	-

The review of the existing MRLs for fenamidone – proposed MRLs

Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)
0243010	Chinese cabbages/pe-tsai	55	0.01*
0243020	Kales	0.01*	0.01*
0243990	Others - Leafy Brassicas	0.01*	0.01*
0244000	Kohlrabies	-	-
0244000	Kohlrabies	0.01*	0.01*
0250000	Leaf vegetables, herbs and edible flowers	-	-
0251000	Lettuces and salad plants	-	-
0251010	Lamb's lettuces/corn salads	4	0.01*
0251020	Lettuces	3	0.01*
0251030	Escaroles/broad-leaved endives	4	0.01*
0251040	Cresses and other sprouts and shoots	4	0.01*
0251050	Land cresses	4	0.01*
0251060	Roman rocket/rucola	4	0.01*
0251070	Red mustards	4	0.01*

The review of the existing MRLs for fenamidone – proposed MRLs

Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)
0251080	Baby leaf crops (including brassica species)	4	0.01*
0251990	Others - Lettuce and other salad plants including brassica	0.01*	0.01*
0252000	Spinaches and similar leaves	-	-
0252010	Spinaches	6	0.01*
0252020	Purslanes	6	0.01*
0252030	Chards/beet leaves	6	0.01*
0252990	Others - Spinach and similar (leaves)	6	0.01*
0253000	Grape leaves and similar species	-	-
0253000	Grape leaves and similar species	0.01*	0.01*
0254000	Watercresses	-	-
0254000	Watercresses	0.01*	0.01*
0255000	Witloofs/Belgian endives	-	-
0255000	Witloofs/Belgian endives	0.01*	0.01*
0256000	Herbs and edible flowers	-	-

The review of the existing MRLs for fenamidone – proposed MRLs

Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)
0256010	Chervil	6	0.02*
0256020	Chives	6	0.02*
0256030	Celery leaves	6	0.02*
0256040	Parsley	6	0.02*
0256050	Sage	6	0.02*
0256060	Rosemary	6	0.02*
0256070	Thyme	6	0.02*
0256080	Basil and edible flowers	6	0.02*
0256090	Laurel/bay leaves	6	0.02*
0256100	Tarragon	6	0.02*
0256990	Others - Herbs	6	0.02*
0260000	Legume vegetables	-	-
0260010	Beans (with pods)	0.8	0.01*
0260020	Beans (without pods)	0.15	0.01*
0260030	Peas (with pods)	0.01*	0.01*
0260040	Peas (without pods)	0.01*	0.01*
0260050	Lentils	0.01*	0.01*
0260990	Others - Legume vegetables (fresh)	0.01*	0.01*
0270000	Stem vegetables	-	-

The review of the existing MRLs for fenamidone – proposed MRLs

Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)
0270010	Asparagus	0.01*	0.01*
0270020	Cardoons	4	0.01*
0270030	Celeries	4	0.01*
0270040	Florence fennels	4	0.01*
0270050	Globe artichokes	0.01*	0.01*
0270060	Leeks	0.3	0.01*
0270070	Rhubarbs	4	0.01*
0270080	Bamboo shoots	0.01*	0.01*
0270090	Palm hearts	0.01*	0.01*
0270990	Others - Stem vegetables (fresh)	0.01*	0.01*
0280000	Fungi, mosses and lichens	-	-
0280010	Cultivated fungi	0.01*	0.01*
0280020	Wild fungi	0.01*	0.01*
0280990	Mosses and lichens	0.01*	0.01*
0290000	Algae and prokaryotes organisms	-	-
0290000	Algae and prokaryotes organisms	0.01*	0.01*
0300000	PULSES, DRY	-	-

The review of the existing MRLs for fenamidone – proposed MRLs

Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)
0300010	Beans	0.01*	0.01*
0300020	Lentils	0.01*	0.01*
0300030	Peas	0.01*	0.01*
0300040	Lupins/lupini beans	0.01*	0.01*
0300990	Others - pulses	0.01*	0.01*
0400000	OILSEEDS AND OIL FRUITS	-	-
0401000	Oilseeds	-	-
0401010	Linseeds	0.01*	0.01*
0401020	Peanuts/groundnuts	0.01*	0.01*
0401030	Poppy seeds	0.01*	0.01*
0401040	Sesame seeds	0.01*	0.01*
0401050	Sunflower seeds	0.02*	0.01*
0401060	Rapeseeds/canola seeds	0.01*	0.01*
0401070	Soyabeans	0.01*	0.01*
0401080	Mustard seeds	0.01*	0.01*
0401090	Cotton seeds	0.02*	0.01*
0401100	Pumpkin seeds	0.01*	0.01*
0401110	Safflower seeds	0.01*	0.01*

The review of the existing MRLs for fenamidone – proposed MRLs

Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)
0401120	Borage seeds	0.01*	0.01*
0401130	Gold of pleasure seeds	0.01*	0.01*
0401140	Hemp seeds	0.01*	0.01*
0401150	Castor beans	0.01*	0.01*
0401990	Others - Oilseeds	0.01*	0.01*
0402000	Oil fruits	-	-
0402010	Olives for oil production	0.01*	0.01*
0402020	Oil palms kernels	0.01*	0.01*
0402030	Oil palms fruits	0.01*	0.01*
0402040	Kapok	0.01*	0.01*
0402990	Others - Oilfruits	0.01*	0.01*
0500000	CEREALS	-	-
0500010	Barley	0.01*	0.01*
0500020	Buckwheat and other pseudocereals	0.01*	0.01*
0500030	Maize/corn	0.01*	0.01*
0500040	Common millet/proso millet	0.01*	0.01*
0500050	Oat	0.01*	0.01*
0500060	Rice	0.01*	0.01*

The review of the existing MRLs for fenamidone – proposed MRLs

Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)
0500070	Rye	0.01*	0.01*
0500080	Sorghum	0.01*	0.01*
0500090	Wheat	0.01*	0.01*
0500990	Others - cereals	0.01*	0.01*
0600000	TEAS, COFFEE, HERBAL INFUSIONS, COCOA AND CAROBS	-	-
0610000	Teas	-	-
0610000	Teas	0.05*	0.05*
0620000	Coffee beans	-	-
0620000	Coffee beans	0.05*	0.05*
0630000	Herbal infusions from Dried product	-	-
0631000	Flowers	-	-
0631010	Chamomile	0.05*	0.05*
0631020	Hibiscus/roselle	0.05*	0.05*
0631030	Rose	0.05*	0.05*
0631040	Jasmine	0.05*	0.05*
0631050	Lime/linden	0.05*	0.05*
0631990	Others - Flowers	0.05*	0.05*

The review of the existing MRLs for fenamidone – proposed MRLs

Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)
0632000	Leaves and herbs	-	-
0632010	Strawberry	0.05*	0.05*
0632020	Rooibos	0.05*	0.05*
0632030	Mate	0.05*	0.05*
0632990	Others - Herbal infusions (leaves and herbs)	0.05*	0.05*
0633000	Roots	-	-
0633010	Valerian	0.05*	0.05*
0633020	Ginseng	0.05*	0.05*
0633990	Others - Roots	0.05*	0.05*
0639000	Other herbal Infusions - Parts of the plant other than flowers, leaves and herbs, and roots	-	-
0639000	Any other parts of the plant	0.05*	0.05*
0640000	Cocoa beans	-	-
0640000	Cocoa beans	0.05*	0.05*
0650000	Carobs/Saint John's breads	-	-

The review of the existing MRLs for fenamidone – proposed MRLs

Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)
0650000	Carobs/Saint John's breads	0.05*	0.05*
0700000	HOPS	-	-
0700000	Hops	0.05*	0.05*
0800000	SPICES	-	-
0810000	Seed spices	-	-
0810010	Anise/aniseed	0.05*	0.05*
0810020	Black caraway/black cumin	0.05*	0.05*
0810030	Celery seed	0.05*	0.05*
0810040	Coriander seed	0.05*	0.05*
0810050	Cumin seed	0.05*	0.05*
0810060	Dill seed	0.05*	0.05*
0810070	Fennel seed	0.05*	0.05*
0810080	Fenugreek	0.05*	0.05*
0810090	Nutmeg	0.05*	0.05*
0810990	Others - Seeds	0.05*	0.05*
0820000	Fruit spices	-	-
0820010	Allspice/pimento	0.05*	0.05*
0820020	Sichuan pepper	0.05*	0.05*

The review of the existing MRLs for fenamidone – proposed MRLs

Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)
0820030	Caraway	0.05*	0.05*
0820040	Cardamom	0.05*	0.05*
0820050	Juniper berry	0.05*	0.05*
0820060	Peppercorn (black, green and white)	0.05*	0.05*
0820070	Vanilla	0.05*	0.05*
0820080	Tamarind	0.05*	0.05*
0820990	Others - Fruit spices	0.05*	0.05*
0830000	Bark spices	-	-
0830010	Cinnamon	0.05*	0.05*
0830990	Others - Bark	0.05*	0.05*
0840000	Root and rhizome spices	-	-
0840010	Liquorice	0.05*	0.05*
0840020	Ginger	0.05*	0.05*
0840030	Turmeric/curcuma	0.05*	0.05*
0840040	Horseradish	0.05	0.05*
0840990	Others - Roots or rhizome	0.05*	0.05*
0850000	Bud spices	-	-
0850010	Cloves	0.05*	0.05*

The review of the existing MRLs for fenamidone – proposed MRLs

Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)
0850020	Capers	0.05*	0.05*
0850990	Others - Buds	0.05*	0.05*
0860000	Flower pistil spices	-	-
0860010	Saffron	0.05*	0.05*
0860990	Others - Flower pistil spices	0.05*	0.05*
0870000	Aril spices	-	-
0870010	Mace	0.05*	0.05*
0870990	Others - Aril spices	0.05*	0.05*
0900000	SUGAR PLANTS	-	-
0900010	Sugar beet roots	0.01*	0.01*
0900020	Sugar canes	0.01*	0.01*
0900030	Chicory roots	0.01*	0.01*
0900990	Others - Sugar plants	0.01*	0.01*
Enforcement residue definition for products of animal origin: Fenamidone			
1000000	PRODUCTS OF ANIMAL ORIGIN - TERRESTRIAL ANIMALS	-	-
1010000	Commodities from	-	-
1011000	Swine	-	-

The review of the existing MRLs for fenamidone – proposed MRLs

Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)
1011010	Muscle - swine	0.01*	0.01*
1011020	Fat - swine	0.01*	0.01*
1011030	Liver - swine	0.01*	0.01*
1011040	Kidney - swine	0.01*	0.01*
1011050	Edible offals (other than liver and kidney) - swine	0.01*	0.01*
1011990	Others - swine	0.01*	0.01*
1012000	Bovine	-	-
1012010	Muscle - bovine	0.01*	0.01*
1012020	Fat - bovine	0.01*	0.01*
1012030	Liver - bovine	0.01*	0.01*
1012040	Kidney - bovine	0.01*	0.01*
1012050	Edible offals (other than liver and kidney) - bovine	0.01*	0.01*
1012990	Others - bovine	0.01*	0.01*
1013000	Sheep	-	-
1013010	Muscle - sheep	0.01*	0.01*
1013020	Fat - sheep	0.01*	0.01*
1013030	Liver - sheep	0.01*	0.01*

The review of the existing MRLs for fenamidone – proposed MRLs

Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)
1013040	Kidney - sheep	0.01*	0.01*
1013050	Edible offals (other than liver and kidney) - sheep	0.01*	0.01*
1013990	Others - sheep	0.01*	0.01*
1014000	Goat	-	-
1014010	Muscle - goat	0.01*	0.01*
1014020	Fat - goat	0.01*	0.01*
1014030	Liver - goat	0.01*	0.01*
1014040	Kidney - goat	0.01*	0.01*
1014050	Edible offals (other than liver and kidney) - goat	0.01*	0.01*
1014990	Others - goat	0.01*	0.01*
1015000	Equine	-	-
1015010	Muscle - equine	0.01*	0.01*
1015020	Fat - equine	0.01*	0.01*
1015030	Liver - equine	0.01*	0.01*
1015040	Kidney - equine	0.01*	0.01*
1015050	Edible offals (other than liver and kidney) - equine	0.01*	0.01*
1015990	Others - equine	0.01*	0.01*

The review of the existing MRLs for fenamidone – proposed MRLs

Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)
1016000	Poultry	-	-
1016010	Muscle - poultry	0.01*	0.01*
1016020	Fat - poultry	0.01*	0.01*
1016030	Liver - poultry	0.01*	0.01*
1016040	Kidney - poultry	0.01*	0.01*
1016050	Edible offals (other than liver and kidney) - poultry	0.01*	0.01*
1016990	Others - poultry	0.01*	0.01*
1017000	Other farmed terrestrial animals	-	-
1017010	Muscle - other farmed terrestrial animals	0.01*	0.01*
1017020	Fat - other farmed terrestrial animals	0.01*	0.01*
1017030	Liver - other farmed terrestrial animals	0.01*	0.01*
1017040	Kidney - other farmed terrestrial animals	0.01*	0.01*
1017050	Edible offals (other than liver and kidney) - other	0.01*	0.01*

The review of the existing MRLs for fenamidone – proposed MRLs

Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)
	farmed terrestrial animals		
1017990	Others - Other farm animals	0.01*	0.01*
1020000	Milk	-	-
1020010	Cattle - milk	0.01*	0.01*
1020020	Sheep - milk	0.01*	0.01*
1020030	Goat - milk	0.01*	0.01*
1020040	Horse - milk	0.01*	0.01*
1020990	Others - Milk and cream	0.01*	0.01*
1030000	Birds eggs	-	-
1030010	Chicken - eggs	0.01*	0.01*
1030020	Duck - eggs	0.01*	0.01*
1030030	Geese - eggs	0.01*	0.01*
1030040	Quail - eggs	0.01*	0.01*
1030990	Others - Birds' eggs	0.01*	0.01*
1040000	Honey and other apiculture products	-	-
1040000	Honey and other apiculture products	0.05*	0.05*
1050000	Amphibians and reptiles	-	-

Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)
1050000	Amphibians and reptiles	0.01*	0.01*
1060000	Terrestrial invertebrate animals	-	-
1060000	Terrestrial invertebrate animals	0.01*	0.01*
1070000	Wild terrestrial vertebrate animals	-	-
1070000	Wild terrestrial vertebrate animals	0.01*	0.01*

* denotes an MRL at the limit of quantification/ limit of determination

MRL changes are highlighted in **bold**

Notes

- Herbs and edible flowers (code 0256000) are regarded as difficult to analyse matrices and therefore the default LOQ MRL for these products should be set at 2 x 0.01* mg/kg
- Teas, coffee, herbal infusions, cocoa and carobs (code 0600000), hops (code 0700000) and spices (code 0800000) are regarded as difficult to analyse matrices and therefore the default LOQ MRL for these products should be set at 5 x 0.01* mg/kg
- The default LOQ MRL for honey is 0.05* mg/kg

References

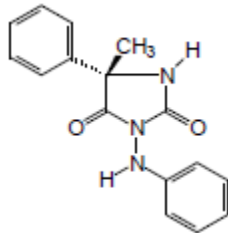
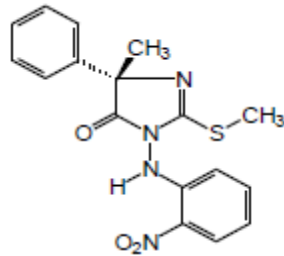
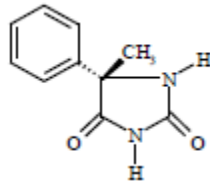
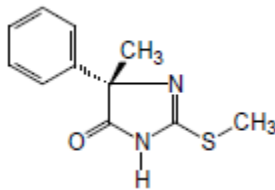
Czech Republic, 2015. Renewal Assessment Report (RAR) on the active substance fenamidone, prepared by the rapporteur Member State Czech Republic in the framework of Regulation (EC) No 1107/2009, February 2015

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Appendix A – Compound codes

Table A.1 List of metabolites identified

Code/Trivial name	Chemical name (IUPAC)	Structural formula
RPA 410193	(S)-5-Methyl-5-phenyl-3-(phenylamino)-2,4-imidazolidine-dione	
RPA 413255	(5S)-5-methyl-2-(methylthio)-3-(2-nitrophenyl)amino-5-phenyl-3,5-dihydro-4H-imidazol-4-one	
RPA 412636	(5S)-5-methyl-5-phenylimidazolidine-2,4-dione	
RPA 412708	(5S)-5-methyl-2-(methylthio)-5-phenyl-3,5-dihydro-4H-imidazol-4-one	

Appendix B – Abbreviations

Acute_consumer_ver1.2 UK consumer model for acute dietary intake assessments

ADI acceptable daily intake

ADME absorption, distribution, metabolism and excretion

ALARA Principle as low as reasonably achievable

Animal model 2017 EFSA model used to calculate the dietary burden of livestock using the OECD feeding studies

ARfD acute reference dose

a.s. active substance

BBCH growth stages of mono- and dicotyledonous plants

bw body weight

CA Competent authority

Chronic_consumer_ver1.1 UK consumer model for chronic dietary intake assessments

CRD Chemicals Regulation Division of the HSE

CXL Codex maximum residue level

DA Devolved Administrations

DAR draft assessment report

DAT days after treatment

Defra Department of Environment, Food and Rural Affairs

DT90 period required for 90% dissipation (define method of estimation)

DT 50 period required for 50 % dissipation (define method of estimation)

FAO Food and Agriculture Organization of the United Nations

GAP Good Agricultural Practice

HPLC-MS/MS high-performance liquid chromatography with tandem mass spectrometry

HPLC-UVD high-performance liquid chromatography with ultraviolet detector

HR highest residue

HSE Health and Safety Executive

IEDI international estimated daily intake

IESTI international estimated short-term intake

ISO International Organisation for Standardisation

IUPAC International Union of Pure and Applied Chemistry

JMPR Joint FAO/WHO Meeting on Pesticide Residues

LOD limit of detection or limit of determination (should be defined)

LOQ limit of quantification

NB the limit of quantification and limit of determination are the same.

Regulation (EC) No 396/2005 refers to the limit of determination

Regulation (EC) No 1107/2009 refers to the limit of quantification

MRLs marked with an asterisk (e.g. 0.01* mg/kg) are MRLs set at the limit of quantification/determination

MRL maximum residue level

NEDI national estimated daily intake

NESTI national estimated short-term intake

NRL National reference laboratory

OECD Organisation for Economic Co-operation and Development

PBI plant-back interval

PHI preharvest interval

POAO products of animal origin

PRIMo (EFSA) Pesticide Residues Intake Model

QuEChERS Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)

RA risk assessment

RAR Renewal Assessment Report

RD residue definition

RD-Enf residue definition for enforcement (also referred to as RD-Mo i.e. residue definition for monitoring)

RD-RA residue definition for risk assessment

RTI re-treatment interval

SC suspension concentrate

STMR supervised trials median residue

TRR total radioactive residue

WG water-dispersible granule

WHO World Health Organization

DRAFT

