REASONED OPINION

APPROVED: 11 April 2020
doi: 10.2903/j.efsa.2020.6150

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

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Abstract

According to Article 12 of Regulation (EC) No 396/2005, EFSA has reviewed the maximum residue levels (MRLs) currently established at European level for the pesticide active substance flubendiamide. To assess the occurrence of flubendiamide residues in plants, processed commodities, rotational crops and livestock, EFSA considered the conclusions derived in the framework of Commission Regulation (EU) No 188/2011, the MRLs established by the Codex Alimentarius Commission as well as the import tolerances (including the supporting residues data). No European authorisation was reported by Member States. Based on the assessment of the available data, MRL proposals were derived and a consumer risk assessment was carried out. Some information required by the regulatory framework was missing and a possible acute risk to consumers was identified. Hence, the consumer risk assessment is considered indicative only, some MRL proposals derived by EFSA still requires further consideration by risk managers and measures for reduction of the consumer exposure should also be considered.

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Keywords: flubendiamide, MRL review, Regulation (EC) No 396/2005, consumer risk assessment, insecticide

Requestor: European Commission
Question number: EFSA-Q-2014-00454
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Acknowledgement: EFSA wishes to Chris Anagnostopoulos, Laszlo Bura, Georgios Chatzisotiriou, Viktoria Krivova, Silvia Ruocco and Viktor Toth for the support provided to this scientific output and the rapporteur Member State Greece for the preparatory work on this scientific output.

Suggested citation: EFSA (European Food Safety Authority), Anastassiadou M, Bernasconi G, Brancato A, Carrasco Cabrera L, Greco L, Jarrah S, Kazocina A, Leuschner R, Magrans JO, Miron I, Nave S, Pedersen R, Reich H, Rojas A, Sacchi A, Santos M, Stanek A, Theobald A, Vagenende B and Verani A, 2020. Reasoned opinion on the review of the existing maximum residue levels for flubendiamide according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2020;18(6):6150, 50 pp. https://doi.org/10.2903/j.efsa.2020.6150

ISSN: 1831-4732

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Summary

Flubendiamide was approved on 1 September 2014 by means of Commission Implementing Regulation (EU) No 632/2014 in the framework of Regulation (EC) No 1107/2009 as amended by Commission Implementing Regulations (EU) No 540/2011 and 541/2011.

As the active substance was approved after the entry into force of Regulation (EC) No 396/2005 on 2 September 2008, the European Food Safety Authority (EFSA) is required to provide a reasoned opinion on the review of the existing maximum residue levels (MRLs) for that active substance in compliance with Article 12(1) of the aforementioned regulation.

As the basis for the MRL review, on 17 September 2018, EFSA initiated the collection of data for this active substance. In a first step, Member States were invited to submit by 17 October 2018 their national Good Agricultural Practices (GAPs) in a standardised way, in the format of specific GAP forms, allowing the designated rapporteur Member State, Greece, to identify the critical GAPs in the format of a specific GAP overview file. Subsequently, Member States were requested to provide residue data supporting the critical GAPs, within a period of 1 month, by 22 February 2019. On the basis of all the data submitted by Member States and by the EU Reference Laboratories for Pesticides Residues (EURLs), EFSA asked the RMS to complete the Pesticide Residues Overview File (PROFile) and to prepare a supporting evaluation report. The PROFile and evaluation report, together with Pesticide Residues Intake Model (PRIMo) calculations were provided by the RMS to EFSA on 22 July 2019. Subsequently, EFSA performed the completeness check of these documents with the RMS. The outcome of this exercise including the clarifications provided by the RMS, if any, was compiled in the completeness check report.

Based on the information provided by the RMS, Member States and the EURLs, and taking into account the conclusions derived by EFSA in the framework of Commission Regulation (EU) No 188/2011 and the MRLs established by the Codex Alimentarius Commission, EFSA prepared in February 2020 a draft reasoned opinion, which was circulated to Member States and EURLs for consultation via a written procedure. Comments received by 12 March 2020 were considered during the finalisation of this reasoned opinion. The following conclusions are derived.

The metabolism of flubendiamide in plants was investigated in primary and rotational crops. According to the results of the metabolism studies, the residue definition for enforcement and risk assessment can be proposed as flubendiamide. This residue definition is also applicable to processed commodities. Nonetheless, the residue definition may be reconsidered, in case the use pattern is extended to crops where flubendiamide-des-iodo may occur at significant levels. Fully validated analytical methods are available for the enforcement of the proposed residue definition in all major matrices at the limit of quantification (LOQ) of 0.01 mg/kg. According to the EURLs, the LOQ of 0.01 mg/kg is achievable by using the QuEChERS method in routine analyses.

Available residue trials data were considered sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation, except for potatoes, cucumbers, melons, broccoli, cauliflowers, Chinese cabbage, kales, beans/peas with pods, and tea, where the available data were insufficient to derive (tentative) MRLs.

For processed commodities, robust processing factors could be derived for strawberry, while tentative processing factors (not fully supported by data) were derived for apples, plums, grapes, tomatoes, Soyabeans, cotton seeds, maize and rice.

Flubendiamide is authorised for use on crops that might be fed to livestock. Livestock dietary burden calculations were therefore performed for different groups of livestock according to OECD guidance. The dietary burdens calculated for cattle and sheep were found to exceed the trigger value of 0.1 mg/kg DM. Behaviour of residues was therefore assessed in these groups of livestock.

The metabolism of flubendiamide residues in livestock was investigated in lactating goats and laying hens at dose rate covering the maximum dietary burdens calculated in this review. According to the results of these studies, the residue definition for enforcement is proposed as flubendiamide only and for risk assessment as sum of flubendiamide and flubendiamide-iodo-phthalimide, expressed as flubendiamide. An analytical method for the enforcement of the proposed residue definition at the LOQ of 0.01 mg/kg in all matrices is available. According to the EURLs, a screening detection limit (SDL) in milk, meat and honey, of 0.0025 mg/kg and in eggs, a SDL of 0.005 mg/kg are achievable.

Livestock feeding study on dairy cow was used to derive MRL and risk assessment values in milk and tissues of ruminants.

Chronic and acute consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 3.1 of the EFSA PRIMo. For those commodities...
where data were insufficient to derive an MRL, EFSA considered the existing EU MRL for an indicative calculation. For lettuce, an exceedance of the ARfD was identified representing 224% of the ARfD (EU1) and no fall-back GAP is available. Excluding lettuce, the highest chronic exposure is 31% of the ADI for the Dutch toddler and the highest acute exposure amounted to 98% of the ARfD for celeries (EU2). Based on these calculations, a risk to consumers was identified for lettuces and no further refinements of the risk assessment were possible. For the remaining commodities, although some major uncertainties remain due to the data gaps identified in the previous sections, the indicative exposure calculation did not indicate a risk to consumers.

Apart from the MRLs evaluated in the framework of this review, internationally recommended CXLs have also been established for flubendiamide. Additional calculations of the consumer exposure, considering these CXLs, were therefore carried out and exceedances of the ARfD were identified (CX1) for the existing CXLs in broccoli (112%), head cabbages (119%), kohlrabies (140%), lettuces (152%) and cauliflowers (156%). Excluding these CXLs from the calculation, the highest chronic exposure represented 63% of the ADI (Dutch toddler) and the highest acute exposure amounted to 98% of the ARfD (celeries) (CX2). Based on these calculations, EFSA concludes that the CXLs for flubendiamide are not of concern for European consumers, except for the CXLs on broccoli, head cabbages, kohlrabies, lettuces and cauliflowers where a potential risk to consumers was identified and no further refinements of the risk assessment were possible.
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Review of the existing MRLs for flubendiamide

Background

Regulation (EC) No 396/2005¹ (hereinafter referred to as 'the Regulation') establishes the rules governing the setting and the review of pesticide maximum residue levels (MRLs) at European level. Article 12(1) of that Regulation stipulates that the European Food Safety Authority (EFSA) shall provide within 12 months from the date of the inclusion or non-inclusion of an active substance in Annex I to Directive 91/414/EEC² a reasoned opinion on the review of the existing MRL for that active substance.

As flubendiamide was approved on 1 September 2014 by means of Commission Implementing Regulation (EU) No 632/2014⁴ in the framework of Regulation (EC) No 1107/2009⁢⁴ as amended by Commission Implementing Regulations (EU) No 540/2011⁵ and 541/2011⁶, EFSA initiated the review of all existing MRLs for that active substance.

By way of background information, in the framework of Commission Regulation (EU) No 188/2011⁷, flubendiamide was evaluated by Greece, designated as rapporteur Member State (RMS). Subsequently, a peer review on the initial evaluation of the RMS was conducted by EFSA, leading to the conclusions as set out in the EFSA scientific output (EFSA, 2013a). Flubendiamide is approved as insecticide.

According to the legal provisions, EFSA shall base its reasoned opinion in particular on the relevant assessment report prepared under Directive 91/414/EEC repealed by Regulation (EC) No 1107/2009. It should be noted, however, that, in the framework of Regulation (EC) No 1107/2009, only a few representative uses are evaluated, whereas MRLs set out in Regulation (EC) No 396/2005 should accommodate all uses authorised within the European Union (EU), and uses authorised in third countries that have a significant impact on international trade. The information included in the assessment report prepared under Regulation (EC) No 1107/2009 is therefore insufficient for the assessment of all existing MRLs for a given active substance.

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

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

As the basis for the MRL review, on 17 September 2018, EFSA initiated the collection of data for this active substance. In a first step, Member States were invited to submit by 17 October 2018 their Good Agricultural Practices (GAPs) that are authorised nationally, in a standardised way, in the format of specific GAP forms. In the framework of this consultation, 11 Member States provided feedback on their national authorisations of flubendiamide. No European authorisation was reported by Member States. Based on the information submitted, the designated RMS, Greece, was asked to identify the critical GAPs to be further considered in the assessment, in the format of a specific GAP overview file.

¹ Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin, and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1–16.
² Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1–32. Repealed by Regulation (EC) No 1107/2009.
³ Commission Implementing Regulation (EU) No 632/2014 of 13 May 2014 approving the active substance flubendiamide, 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 175, 14.6.2014, p. 1–5.
⁴ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.
⁵ Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 1–186.
⁶ Commission Implementing Regulation (EU) No 541/2011 of 1 June 2011 amending Implementing Regulation (EU) No 540/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 187–188.
⁷ Commission Regulation (EU) No 188/2011 of 25 February 2011 laying down detailed rules for the implementation of Council Directive 91/414/EEC as regards the procedure for the assessment of active substances which were not on the market 2 years after the date of notification of that Directive. OJ No L 53, 26.2.2011, p. 51–55.
Subsequently, in a second step, Member States were requested to provide residue data supporting the critical GAPs by 22 February 2019.

On the basis of all the data submitted by Member States and the EU Reference Laboratories for Pesticides Residues (EURLs), EFSA asked Greece to complete the PROFile and to prepare a supporting evaluation report. The PROFile and the supporting evaluation report, together with the Pesticide Residues Intake Model (PRIMo) calculations were submitted to EFSA on 22 July 2019. Subsequently, EFSA performed the completeness check of these documents with the RMS. The outcome of this exercise including the clarifications provided by the RMS, if any, was compiled in the completeness check report.

Considering all the available information, and taking into account the MRLs established by the Codex Alimentarius Commission (CAC) (i.e. codex maximum residue limit; CXLs), EFSA prepared in February 2020 a draft reasoned opinion, which was circulated to Member States and EURLs for commenting via a written procedure. All comments received by 13 March 2020 were considered by EFSA during the finalisation of the reasoned opinion.

The evaluation report submitted by the RMS (Greece, 2019), taking into account also the information provided by Member States during the collection of data, and the EURLs report on analytical methods (EURLs, 2019) are considered as main supporting documents to this reasoned opinion and, thus, made publicly available. It is noted that only import tolerances, and no European authorised uses were reported.

In addition, further supporting documents to this reasoned opinion are the completeness check report (EFSA, 2020a) and the Member States consultation report (EFSA, 2020b). These reports are developed to address all issues raised in the course of the review, from the initial completeness check to the reasoned opinion. Furthermore, the exposure calculations for all crops reported in the framework of this review performed using the EFSA Pesticide Residues Intake Model (PRIMo) and the PROFile as well as the GAP overview file listing all import tolerances are key supporting documents and made publicly available as background documents to this reasoned opinion. A screenshot of the report sheet of the PRIMo is presented in Appendix C.

Terms of Reference

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

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

The active substance and its use pattern

Flubendiamide is the ISO common name for 3-iodo-N’-(2-mesy1-1,1-dimethylethyl)-N-4-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethy1]-o-tolyl]phthalamide (IUPAC).

The chemical structure of the flubendiamide and its main metabolites is reported in Appendix F.

The EU MRLs for flubendiamide are established in Annex IIIA of Regulation (EC) No 396/2005. Codex maximum residue limits (CXLs) for flubendiamide were also established by the Codex Alimentarius Commission (CAC). An overview of the MRL changes that occurred since the entry into force of the Regulation mentioned above is provided below (Table 1).

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

| Procedure                | Legal implementation | Remarks                                                                 |
|--------------------------|----------------------|-------------------------------------------------------------------------|
| MRL application          | Regulation (EU) No 2018/832 | Import tolerances from USA for apricots, peaches, plums, Soyabeanse (EFSA, 2018a) |
| MRL application          | Regulation (EU) No 364/2014 | Strawberries (EFSA, 2013b)                                             |
| Implementation of CAC 2011 | Regulation (EC) No 441/2012 | Head cabbage, beans (with and without pods), pulses dry, mammalian and other farmed terrestrial animal (meat, fat, liver, kidney, edible offal), milk (EFSA, 2011) |
For the purpose of this MRL review, all the uses of flubendiamide currently authorised in third countries as submitted by the Member States during the GAP collection have been reported by the RMS in the GAP overview file. No European authorised uses were reported by Member States.

The critical GAPs identified in the GAP overview file were then summarised in the PROFile and considered in the assessment. The details of the authorised critical GAPs for flubendiamide are given in Appendix A.

**Assessment**

EFSA has based its assessment on the following documents:

- the PROFile submitted by the RMS;
- the evaluation report accompanying the PROFile (Greece, 2019);
- the renewal assessment report (RAR) and its addenda prepared in the framework of Directive 91/414/EEC (Greece, 2008, 2013);
- the conclusion on the peer review of the pesticide risk assessment of the active substance flubendiamide (EFSA, 2013a);
- the Joint Meeting on Pesticide residues (JMPR) Evaluation report (FAO, 2010);
- the previous reasoned opinions on flubendiamide (EFSA, 2010a,b, 2013b, 2018a).

The assessment is performed in accordance with the legal provisions of the uniform principles for evaluation and authorisation of plant protection products as set out in Commission Regulation (EU) No 546/2011 and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (European Commission, 1997a–g, 2000, 2010a,b, 2017; OECD, 2011, 2013).

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

1. **Residues in plants**

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

1.1.1. **Nature of residues in primary crops**

The metabolism of flubendiamide was investigated after foliar treatment in fruits, leafy vegetables and cereals (Greece, 2008) and assessed in the framework of the peer review (EFSA, 2013a). The studies used two different radiolabel positions, in the aniline ring and in the phthalic acid ring of the molecule.

Tomatoes, apples and cabbages were treated with a foliar application of 100, 500 and 300 g a.s./ha, respectively, while maize was treated with four foliar applications of 168 g a.s./ha at 7-day intervals. Samples were taken at various time points between application and maturity (see Appendix B.1.1.1). In all cases, parent remained by far the major component of the total radioactive residues (TRR) accounting for 50–94% TRR in the mature crops. Flubendiamide-des-iodo was found with both labels, in apple fruits in the range of 4.2–18.2% TRR (up to 0.002 mg eq./kg) and in maize forage and fodder accounting for 5–18% of the TRR (up to 0.05 mg eq./kg). All other metabolites were detected below 10% TRR (individually < 1% to 6% TRR).

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8 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, 11.06.2011, p. 127–175.
Overall, a similar metabolic pathway was observed in all crops. The metabolism of flubendiamide is limited, with flubendiamide-des-iodo being the only metabolite detected above 10% TRR, but at low absolute levels.

It is noted that the metabolism of flubendiamide was not considered to be different in genetically modified glyphosate tolerant Soyabeans crops compared to conventional crops (EFSA, 2018a).

1.1.2. Nature of residues in rotational crops

Flubendiamide is only authorised for imported crops for which investigations of residues in rotational crops are not required. Nevertheless, the available confined rotational crop study assessed during the peer review is summarised for completeness. Flubendiamide is a very persistent substance with a biphasic kinetics, the DT$_{90}$ is up to 1000 days according to the field dissipation studies evaluated in the framework of the peer review (EFSA, 2013a).

One confined rotational crop study with flubendiamide radiolabelled on the phthalic acid ring was available for this review (Greece, 2008; EFSA, 2013a). Flubendiamide was applied at a rate of 437 g a.s./ha onto bare soil. Swiss chard (leafy crop), spring wheat (cereals) and turnips (root crop) were planted at plant back intervals (PBI) of 29, 135 and 274 days after treatment (DAT). Besides wheat forage and hay, all other samples were taken at maturity.

Residues in all crops were relatively low and declined over time with highest TRRs observed in wheat straw (0.07 mg eq./kg) and Swiss chards (0.022 mg eq./kg) at 29 DAT. In grain, turnip leaves and turnip roots residues amounted to a maximum of 0.011 mg eq./kg for all rotations. Flubendiamide was detected up to 0.038 and 0.027 mg/kg in wheat straw and hay, respectively, and up to 0.015 mg/kg in Swiss chards, whereas in all other crop samples parent remained below 0.01 mg/kg. Flubendiamide-des-iodo and other minor metabolites were detected, but not at significant levels.

EFSA concludes that the metabolism and distribution of flubendiamide in rotational crops is similar to the metabolic pathway observed in primary crops.

1.1.3. Nature of residues in processed commodities

Studies investigating the nature of residues in processed commodities were assessed (Greece, 2008; EFSA, 2013a). Studies were conducted with radiolabelled flubendiamide on the phthalic acid ring simulating representative hydrolytic conditions for pasteurisation (20 min at 90°C, pH 4), boiling/brewing/baking (60 min at 100°C, pH 5) and sterilisation (20 min at 120°C, pH 6). Flubendiamide was stable to hydrolysis under standard conditions of pasteurisation, baking/brewing/boiling and sterilisation (Greece, 2008; EFSA, 2013a).

1.1.4. Methods of analysis in plants

During the peer review, a hyphenated analytical method based on high-performance liquid chromatography (HPLC) coupled to MS/MS detection was fully validated in high water- (head cabbage, tomato, bean with pods), high oil- (olive, cotton), high acid content (citrus) and dry (wheat grain) commodities. The method is considered suitable for enforcing flubendiamide in all four main matrices with a limit of quantification (LOQ) of 0.01 mg/kg. The primary method is supported by an independent laboratory validation (ILV) (EFSA, 2013a).

According to the EURLs, flubendiamide can be routinely monitored by a QuEChERS method coupled to HPLC-MS/MS, with an LOQ of 0.01 mg/kg for the routine analysis in high water content, high acid content, high oil content and dry commodities (EURLs, 2019).

1.1.5. Stability of residues in plants

The storage stability of flubendiamide and its metabolite flubendiamide-des-iodo was investigated in the framework of the peer review (EFSA, 2013a).

In high water content (tomato, head cabbage, beans with pods), high acid content (citrus), high oil content (olive) matrices and dry/high starch content (wheat) commodities, the storage stability for flubendiamide and its metabolite flubendiamide-des-iodo was demonstrated for at least 18 months, and for grape must (processed product) for at least 12 months, when stored at –18°C (see Appendix B.1.1.2; EFSA, 2013a).
1.1.6. Proposed residue definitions

The metabolism of flubendiamide following foliar applications was similar in all crops assessed. Flubendiamide was the major component of the residues. The main metabolite, flubendiamide-des-iodo accounted for more than 10% of the residues in apples, however at very low levels (up to 0.002 mg eq./kg), and in maize forage and fodder (up to 0.05 eq./kg). The metabolism in rotational crops is similar to the metabolism observed in primary crops and the processing is not expected to modify the nature of residues.

As flubendiamide was found to be a sufficient marker in fruits, leafy vegetables and cereals, the residue definition for enforcement is proposed as flubendiamide only.

An analytical method for the enforcement of the proposed residue definition at the LOQ of 0.01 mg/kg in all four main plant matrices is available (EFSA, 2013a). According to the EURLs, the LOQ of 0.01 mg/kg is achievable by using the QuEChERS method in routine analyses (EURLs, 2019).

The peer review established the risk assessment residue definition for plant commodities as parent compound only on a provisional basis, pending on the occurrence of flubendiamide-des-iodo in the residue trials supporting the uses assessed (EFSA, 2013a). Taking into account the results of the metabolism studies, and that the metabolite flubendiamide-des-iodo was below the LOQ of 0.01 mg/kg in all the residue trials assessed in the current MRL review, EFSA proposes that the residue definition for risk assessment as parent only is still appropriate for the uses under assessment. Nonetheless, the residue definition may be reconsidered, in case the use pattern is extended to crops where flubendiamide-des-iodo may occur at significant levels. In such case, as the toxicological data on this metabolite is limited (EFSA, 2013a), more information on its toxicological relevance would be required.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

To assess the magnitude of flubendiamide residues resulting from the reported GAPs, EFSA considered all residue trials reported in the framework of previous MRL applications (EFSA, 2010b, 2018a). All residue trial samples considered in this framework were stored in compliance with the conditions for which storage stability of residues was demonstrated. Decline of residues during storage of the trial samples is therefore not expected.

The number of residue trials and extrapolations was evaluated in accordance with the European guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs (European Commission, 2017).

Residue trials are not available to support the import tolerances on potatoes, cucumbers, melons, broccoli, cauliflowers, Chinese cabbage, kales, beans/peas with pods and tea. Therefore, MRL and risk assessment values could not be derived for these crops and the following data gaps were identified:

- Potatoes: eight trials compliant with the import tolerance GAP are required.
- Cucumbers: eight trials compliant with the import tolerance GAP are required.
- Melons: eight trials compliant with the import tolerance GAP are required.
- Broccoli: four trials compliant with the import tolerance GAP are required.
- Cauliflowers: eight trials compliant with the import tolerance GAP are required.
- Chinese cabbage, kales: four trials compliant with the import tolerance GAP are required.
- Beans with pods: eight trials compliant with the import tolerance GAP are required.
- Peas with pods: four trials compliant with the import tolerance GAP are required.
- Tea: eight trials compliant with the import tolerance GAP are required.

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

- Soyabean: the residue trials on Soyabean, including on genetically modified (glyphosate tolerant) Soyabean, are considered to be suitably representative of agricultural practices in the non-European region where it is authorised (EFSA, 2018a). Further residue trials are not required.
1.2.2. Magnitude of residues in rotational crops

There were no studies investigating the magnitude of residues in rotational crops available for this review. However, flubendiamide is only authorised for imported crops for which investigations of residues in rotational crops are not required.

1.2.3. Magnitude of residues in processed commodities

The effect of industrial processing and/or household preparation was assessed on studies conducted on apples, plums, grapes, strawberries, tomatoes, Soyabeans, cotton seeds, maize and rice (EFSA, 2010b, 2013a,b). An overview of all available processing studies is available in Appendix B.1.2.3. Robust processing factors (fully supported by data) could be derived for strawberry jam and preserve strawberry, while tentative processing factors (not fully supported by data) were derived for apple juice and wet pomace, prunes (dried), raisins, grape juice, tomato paste and juice, refined oil, milk, meal and hulls from Soyabeans, crude oil and meal/press cake from cotton seeds, flour, meal, grits and starch from maize as well as for polished and bran rice.

Further processing studies are not required as they are not expected to affect the outcome of the risk assessment. However, if more robust processing factors were to be required by risk managers, in particular for enforcement purposes, additional processing studies would be needed.

1.2.4. Proposed MRLs

The available data are considered sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation, except for potatoes, cucumbers, melons, broccoli, cauliflower, Chinese cabbage, kales, beans/peas with pods and tea, where the available data were insufficient to derive (tentative) MRLs.

2. Residues in livestock

Flubendiamide is authorised for use on several crops such as pome fruits, maize, Soyabeans, cotton that might be feed to livestock. Livestock dietary burden calculations were therefore performed for different groups of livestock according to OECD guidance (OECD, 2013), which has now also been agreed upon at European level. The input values for all relevant commodities are summarised in Appendix D. The dietary burdens calculated for cattle and sheep were found to exceed the trigger value of 0.1 mg/kg dry matter (DM). Behaviour of residues was therefore assessed in these groups of livestock.

It is highlighted that for several feed items, no residue data were available (potato, kale). The animal intake of flubendiamide residues via these commodities has therefore not been assessed and may have been underestimated. However, this is not expected to have an impact on the outcome of the dietary burden considering that both have an EU MRL set at the LOQ; therefore, no residues are expected in these crops.

2.1. Nature of residues and methods of analysis in livestock

The metabolism of flubendiamide residues in livestock was investigated in lactating goats and laying hens at dose rates covering the maximum dietary burdens calculated in this review (Greece, 2008). These studies were assessed in the framework of the peer review for information only, as the representative crops were not feed items (EFSA, 2013a).

In the metabolism study on lactating goats, animals were fed for 4 days with 5 mg/kg bw per day or 4.83 mg/kg bw per day of flubendiamide radiolabelled on the aniline ring or phthalic acid ring of the molecule, respectively. The highest TRR were found, up to 20.9 and 13.15 mg eq./kg in fat and liver, respectively (aniline ring-labelled flubendiamide). In milk and other tissues, it ranged from 1.44 to 4.42 mg eq./kg. In milk and edible tissues (muscle, fat, liver, kidney), flubendiamide was the predominant component of the residues accounting for 72.4–92.6% TRR. Flubendiamide-iodo-phthalimide (A-14) was also detected in relevant portions in milk (11.4–17% TRR) and fat (10.6–24% TRR). Other metabolites could only be detected at very low levels (< 5.1% TRR).

Although not required, the metabolism studies in laying hens are reported for completeness. Laying hens were fed for 14 days with 1 mg/kg bw per day of flubendiamide radiolabelled on the aniline ring or phthalic acid ring of the molecule. The highest TRR were found in fat and eggs (12.35 and 9.3 mg eq./kg, respectively); in other tissues, lower levels were found (0.38–3.6 mg eq./kg). In eggs and
edible tissues, the parent compound was the predominant component of the residues accounting for 81.9–97.9% TRR. All other identified metabolites were present at lower levels (≤ 8.8% TRR).

As the parent compound is a sufficient marker in livestock commodities, the residue definition for enforcement is proposed as flubendiamide only. The residue for risk assessment was proposed by the peer review as the sum of flubendiamide and flubendiamide-iodo-phthalimide, expressed as flubendiamide, which is considered still applicable. Based on the preferential accumulation of residues in fatty tissues, the residue definition is considered fat soluble.

An analytical method using HPLC-MS/MS for the enforcement of the proposed residue definition at the LOQ of 0.01 mg/kg in all animal matrices is available (EFSA, 2013a). According to the EURLs, the screening data generated for commodities of animal origin show that flubendiamide can be monitored in milk, meat and honey with a screening detection limit (SDL) of 0.0025 mg/kg and in eggs with an SDL of 0.005 mg/kg (EURLs, 2019).

EFSA concludes that the metabolism of flubendiamide in livestock is adequately elucidated, and flubendiamide and its metabolite flubendiamide-iodo-phthalimide are the most relevant components of the residues in livestock commodities (see Appendix B.2.1.1).

### 2.2. Magnitude of residues in livestock

In the framework of the peer review, feeding studies were performed with dairy cows, and laying hens (Greece, 2008). As the dietary burden only exceeded the trigger value for ruminants, only the feeding study with dairy cows will be detailed. In this study, flubendiamide was administered using different dosing levels ranging from 0.096 (8.7N) to 1.92 (174N) mg/kg bw per day. In milk, the plateau was reached by day 7–8, at a maximum of 0.11 mg/kg for the highest dose level (174N), whereas for the closest level (10.7N), residues in milk remained at or below the LOQ of 0.01 mg/kg in all samples.

The study performed on dairy cows was used to derive MRL and risk assessment values in milk and tissues of ruminants, in compliance with the latest recommendations on this matter (FAO, 2009). In this study, samples were analysed for flubendiamide and flubendiamide-iodo-phthalimide. Although storage stability studies are not available, as all samples of the feeding studies were stored at least at –18°C and analysed within 30 days of collection, decline of residues during storage of the trial samples is not expected (EFSA, 2013a).

It is noted that MRLs for ruminant commodities are proposed at the LOQ. MRLs for pigs and poultry products are not required because pigs and poultry are not expected to be exposed to significant levels of flubendiamide residues.

### 3. Consumer risk assessment

In the framework of this review, only the uses of flubendiamide reported by the RMS in Appendix A were considered; however, the use of flubendiamide was previously also assessed by the JMPR (FAO, 2010). The CXLs, resulting from this assessment by JMPR and adopted by the CAC, are now international recommendations that need to be considered by European risk managers when establishing MRLs. To facilitate consideration of these CXLs by risk managers, the consumer exposure was calculated both with and without consideration of the existing CXLs.

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

Chronic and acute exposure calculations for all crops reported in the framework of this review were performed using revision 3.1 of the EFSA PRIMo (EFSA, 2018b, 2019). Input values for the exposure calculations were derived in compliance with the decision tree reported in Appendix E. Hence, for those commodities where an MRL could be derived by EFSA in the framework of this review, input values were derived according to the internationally agreed methodologies (FAO, 2009). For those commodities where data were insufficient to derive an MRL in Section 1, EFSA considered the existing EU MRL for an indicative calculation. All input values included in the exposure calculations are summarised in Appendix D.

The exposure values calculated were compared with the toxicological reference values for flubendiamide, derived by EFSA (2013a). The highest chronic exposure was calculated for Dutch

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9 Dose rate recalculated assuming body weight of 650 kg dairy cattle and feed intake of 25 kg per day (OECD, 2013).
toddler, representing 32% of the acceptable daily intake (ADI). With regard to the acute exposure, however, an exceedance of the ARfD was identified for lettuce, representing 224% of the ARfD. A second exposure calculation (scenario EU2) was therefore performed, excluding this crop as no other GAP is authorised for lettuces. According to the results of this second calculation, the highest chronic exposure declined to 31% of the ADI for the Dutch toddler; the highest acute exposure is then calculated for celeries, representing 98% of the ARfD.

Based on these calculations, a risk to consumers was identified for lettuces and no further refinements of the risk assessment were possible. For the remaining commodities, although some major uncertainties remain due to the data gaps identified in the previous sections, the indicative exposure calculation did not indicate a risk to consumers.

3.2. Consumer risk assessment with consideration of the existing CXLs

To include the CXLs in the calculations of the consumer exposure, CXLs were compared with the EU MRL proposals in compliance with Appendix E and all data relevant to the consumer exposure assessment have been collected from JMPR evaluations. An overview of the input values used for this exposure calculation is also provided in Appendix D.

Chronic and acute exposure calculations were also performed using revision 3.1 of the EFSA PRIMO and the exposure values calculated were compared with the toxicological reference values derived for flubendiamide. The highest chronic exposure was calculated for Dutch toddler, representing 63% of the ADI. With regard to the acute exposure, however, an exceedance of the ARfD was identified for broccoli (112%), head cabbages (119%), kohlrabies (140%), lettuces (152%) and cauliflowers (156%). A second exposure calculation (scenario CX2) was therefore performed, excluding the CXLs for these crops. According to the results of this second calculation, the highest chronic exposure remained unchanged and the highest acute exposure is then calculated for celeries, representing 98% of the ARfD. Based on these calculations, EFSA concludes that the CXLs for flubendiamide are not of concern for European consumers, except for the CXLs on broccoli, head cabbages, kohlrabies, lettuces and cauliflowers where a potential risk to consumers was identified and no further refinements of the risk assessment were possible.

Conclusions

The metabolism of flubendiamide in plants was investigated in primary and rotational crops. According to the results of the metabolism studies, the residue definition for enforcement and risk assessment can be proposed as flubendiamide. This residue definition is also applicable to processed commodities. Nonetheless, the residue definition may be reconsidered, in case the use pattern is extended to crops where flubendiamide-des-iodo may occur at significant levels. Fully validated analytical methods are available for the enforcement of the proposed residue definition in all major matrices at the LOQ of 0.01 mg/kg. According to the EULRs, the LOQ of 0.01 mg/kg is achievable by using the QuEChERS method in routine analyses.

Available residue trials data were considered sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation, except for potatoes, cucumbers, melons, broccoli, cauliflowers, Chinese cabbage, kales, beans/peas with pods, and tea, where the available data were insufficient to derive (tentative) MRLs.

For processed commodities, robust processing factors could be derived for strawberry, while limited processing factors (not fully supported by data) were derived for apples, plums, grapes, tomatoes, Soyabeans, cotton seeds, maize and rice.

Flubendiamide is authorised for use on crops that might be fed to livestock. Livestock dietary burden calculations were therefore performed for different groups of livestock according to OECD guidance. The dietary burdens calculated for cattle and sheep were found to exceed the trigger value of 0.1 mg/kg DM. Behaviour of residues was therefore assessed in these groups of livestock.

The metabolism of flubendiamide residues in livestock was investigated in lactating goats and laying hens at dose rate covering the maximum dietary burdens calculated in this review. According to the results of these studies, the residue definition for enforcement is proposed as flubendiamide only and for risk assessment as sum of flubendiamide and flubendiamide-iodo-phthalimide, expressed as flubendiamide. An analytical method for the enforcement of the proposed residue definition at the LOQ of 0.01 mg/kg in all matrices is available. According to the EULRs, in milk, meat and honey, an SDL of 0.0025 mg/kg and in eggs an SDL of 0.005 mg/kg is achievable.

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Livestock feeding study on dairy cow was used to derive MRL and risk assessment values in milk and tissues of ruminants.

Chronic and acute consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 3.1 of the EFSA PRIMo. For those commodities where data were insufficient to derive an MRL, EFSA considered the existing EU MRL for an indicative calculation. For lettuce, an exceedance of the ARfD was identified representing 224% of the ARfD (EU1) and no fall-back GAP is available. Excluding lettuce, the highest chronic exposure is 31% of the ADI for the Dutch toddler and the highest acute exposure amounted to 98% of the ARfD for celeries (EU2). Based on these calculations, a risk to consumers was identified for lettuces and no further refinements of the risk assessment were possible. For the remaining commodities, although some major uncertainties remain due to the data gaps identified in the previous sections, the indicative exposure calculation did not indicate a risk to consumers.

Apart from the MRLs evaluated in the framework of this review, internationally recommended CXLs have also been established for flubendiamide. Additional calculations of the consumer exposure, considering these CXLs, were therefore carried out and exceedances of the ARfD (CX1) were identified for the existing CXLs in broccoli (112%), head cabbages (119%), kohlrabies (140%), lettuces (152%) and cauliflowers (156%). Excluding these CXLs from the calculation (CX2), the highest chronic exposure represented 63% of the ADI (Dutch toddler) and the highest acute exposure amounted to 98% of the ARfD (celeries). Based on these calculations, EFSA concludes that the CXLs for flubendiamide are not of concern for European consumers, except for the CXLs on broccoli, head cabbages, kohlrabies, lettuces and cauliflowers where a potential risk to consumers was identified and no further refinements of the risk assessment were possible.

Recommendations

MRL recommendations were derived in compliance with the decision tree reported in Appendix E of the reasoned opinion (see Table 2). All MRL values listed as ‘Recommended’ in the table are sufficiently supported by data and are therefore proposed for inclusion in Annex II to the Regulation. The remaining MRL values listed in the table require further consideration by risk managers (see Table 2 footnotes for details). In particular, existing EU MRLs need to be confirmed by the following data:

- additional residue trials on potatoes, broccoli, cauliflowers, Chinese cabbage and kales.

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

- additional residue trials on cucumbers, melons, beans/peas with pods and tea.

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

Table 2: Summary table

| Code number | Commodity    | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review | Comment |
|-------------|--------------|-------------------------|----------------------|-----------------------|---------|
| 120010      | Almonds      | 0.1                     | 0.1                  | 0.1                   | Recommended(*) |
| 120020      | Brazil nuts  | 0.1                     | 0.1                  | 0.1                   | Recommended(*) |
| 120030      | Cashew nuts  | 0.1                     | 0.1                  | 0.1                   | Recommended(*) |
| 120040      | Chestnuts    | 0.1                     | 0.1                  | 0.1                   | Recommended(*) |
| 120050      | Coconuts     | 0.1                     | 0.1                  | 0.1                   | Recommended(*) |
| 120060      | Hazelnuts    | 0.1                     | 0.1                  | 0.1                   | Recommended(*) |
| 120070      | Macadamia    | 0.1                     | 0.1                  | 0.1                   | Recommended(*) |
| 120080      | Pecans       | 0.1                     | 0.1                  | 0.1                   | Recommended(*) |
| 120090      | Pine nuts    | 0.1                     | 0.1                  | 0.1                   | Recommended(*) |

Enforcement residue definition: Flubendiamide(*)
| Code number | Commodity      | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review | Comment          |
|-------------|----------------|-------------------------|----------------------|-----------------------|------------------|
| 120100      | Pistachios     | 0.1                     | 0.1                  | 0.1                   | Recommended(a)   |
| 120110      | Walnuts        | 0.1                     | 0.1                  | 0.1                   | Recommended(a)   |
| 130010      | Apples         | 0.8                     | 0.8                  | 0.9                   | Recommended(b)   |
| 130020      | Pears          | 0.8                     | 0.8                  | 0.9                   | Recommended(b)   |
| 130030      | Quinces        | 0.8                     | 0.8                  | 0.9                   | Recommended(b)   |
| 130040      | Medlar         | 0.8                     | 0.8                  | 0.9                   | Recommended(b)   |
| 130050      | Loquat         | 0.8                     | 0.8                  | 0.9                   | Recommended(b)   |
| 140010      | Apricots       | 1.5                     | 2                    | 2                     | Recommended(a)   |
| 140020      | Cherries       | 2                       | 2                    | 2                     | Recommended(g)   |
| 140030      | Peaches        | 1.5                     | 2                    | 2                     | Recommended(g)   |
| 140040      | Plums          | 0.7                     | 2                    | 2                     | Recommended(g)   |
| 151010      | Table grapes   | 2                       | 2                    | 2                     | Recommended(g)   |
| 151020      | Wine grapes    | 2                       | 2                    | 2                     | Recommended(g)   |
| 211000      | Potatoes       | 0.01*                   | –                    | 0.01*                 | Further consideration needed(c) |
| 231010      | Tomatoes       | 0.2                     | 2                    | 2                     | Recommended(g)   |
| 231020      | Peppers        | 0.2                     | 0.7                  | 0.7                   | Recommended(g)   |
| 232010      | Cucumbers      | 0.15                    | 0.2                  | 0.2                   | Recommended(g)   |
| 232020      | Gherkins       | 0.15                    | 0.2                  | 0.2                   | Recommended(g)   |
| 232030      | Courgettes     | 0.15                    | 0.2                  | 0.2                   | Recommended(g)   |
| 233010      | Melons         | 0.06                    | 0.2                  | 0.2                   | Recommended(g)   |
| 233020      | Pumpkins       | 0.06                    | 0.2                  | 0.2                   | Recommended(g)   |
| 233030      | Watermelons    | 0.06                    | 0.2                  | 0.2                   | Recommended(g)   |
| 234000      | Sweet corn     | 0.02                    | 0.02                 | 0.02                  | Recommended(g)   |
| 241010      | Broccoli       | 0.01*                   | 4                    | 0.01*                 | Further consideration needed(f) |
| 241020      | Cauliflower    | 0.01*                   | 4                    | 0.01*                 | Further consideration needed(f) |
| 242010      | Brussels sprouts | 0.01*                | 4                    | 4                     | Recommended(g)   |
| 242020      | Head cabbage   | 4                       | 4                    | –                     | Further consideration needed(g) |
| 243010      | Chinese cabbage | 0.01*                | –                    | 0.01*                 | Further consideration needed(c) |
| 243020      | Kale           | 0.01*                   | –                    | 0.01*                 | Further consideration needed(f) |
| 244000      | Kohlrabi       | 0.01*                   | 4                    | –                     | Further consideration needed(g) |
| 251020      | Lettuce        | 7                       | 7                    | –                     | Further consideration needed(g) |
| 260010      | Beans (fresh, with pods) | 0.5                 | 2                    | 2                     | Recommended(g)   |
| 260020      | Beans (fresh, without pods) | 0.5                | 2                    | 2                     | Recommended(g)   |
| 260030      | Peas (fresh, with pods) | 1.5                 | 2                    | 2                     | Recommended(g)   |
| 260040      | Peas (fresh, without pods) | 0.01*               | 2                    | 2                     | Recommended(g)   |
| 260050      | Lentils (fresh) | 0.01*                | 2                    | 2                     | Recommended(g)   |
| 270030      | Celery         | 5                       | 5                    | 6                     | Recommended(g)   |
| 300010      | Beans (dry)    | 1                       | 1                    | 1                     | Recommended(g)   |
| 300020      | Lentils (dry)  | 1                       | 1                    | 1                     | Recommended(g)   |
| 300030      | Peas (dry)     | 1                       | 1                    | 1                     | Recommended(g)   |
| 300040      | Lupins (dry)   | 1                       | 1                    | 1                     | Recommended(g)   |
| 401070      | Soyabeans      | 0.3                     | –                    | 0.3                   | Recommended(i)   |
| 401090      | Cotton seed    | 1.5                     | 1.5                  | 1.5                   | Recommended(g)   |
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| Code number | Commodity | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review | Comment |
|-------------|-----------|-------------------------|----------------------|-----------------------|---------|
| 500030      | Maize grain | 0.02                    | 0.02                 | 0.02                  | Recommended<sup>(b)</sup> |
| 500060      | Rice grain  | 0.2                     | –                    | 0.3                   | Recommended<sup>(i)</sup> |
| 610000      | Tea (dried leaves and stalks, fermented or otherwise of {Camellia sinensis}) | 0.02*              | 50                   | 50                    | Recommended<sup>(d)</sup> |
| 1011010     | Swine meat  | 2                       | 2                    | 2                     | Recommended<sup>(e)</sup> |
| 1011020     | Swine fat (free of lean meat) | 2                       | 2                    | 2                     | Recommended<sup>(e)</sup> |
| 1011030     | Swine liver | 1                       | 1                    | 1                     | Recommended<sup>(e)</sup> |
| 1011040     | Swine kidney | 1                       | 1                    | 1                     | Recommended<sup>(e)</sup> |
| 1012010     | Bovine meat | 2                       | 2                    | 2                     | Recommended<sup>(e)</sup> |
| 1012020     | Bovine fat  | 2                       | 2                    | 2                     | Recommended<sup>(e)</sup> |
| 1012030     | Bovine liver | 1                       | 1                    | 1                     | Recommended<sup>(e)</sup> |
| 1012040     | Bovine kidney | 1                       | 1                    | 1                     | Recommended<sup>(e)</sup> |
| 1013010     | Sheep meat  | 2                       | 2                    | 2                     | Recommended<sup>(e)</sup> |
| 1013020     | Sheep fat   | 2                       | 2                    | 2                     | Recommended<sup>(e)</sup> |
| 1013030     | Sheep liver | 1                       | 1                    | 1                     | Recommended<sup>(e)</sup> |
| 1013040     | Sheep kidney | 1                       | 1                    | 1                     | Recommended<sup>(e)</sup> |
| 1014010     | Goat meat   | 2                       | 2                    | 2                     | Recommended<sup>(e)</sup> |
| 1014020     | Goat fat    | 2                       | 2                    | 2                     | Recommended<sup>(e)</sup> |
| 1014030     | Goat liver  | 1                       | 1                    | 1                     | Recommended<sup>(e)</sup> |
| 1014040     | Goat kidney | 1                       | 1                    | 1                     | Recommended<sup>(e)</sup> |
| 1015010     | Horse meat  | 2                       | 2                    | 2                     | Recommended<sup>(e)</sup> |
| 1015020     | Horse fat   | 2                       | 2                    | 2                     | Recommended<sup>(e)</sup> |
| 1015030     | Horse liver | 1                       | 1                    | 1                     | Recommended<sup>(e)</sup> |
| 1015040     | Horse kidney | 1                       | 1                    | 1                     | Recommended<sup>(e)</sup> |
| 1020010     | Cattle milk | 0.1                     | 0.1                  | 0.1                   | Recommended<sup>(e)</sup> |
| 1020020     | Sheep milk  | 0.1                     | 0.1                  | 0.1                   | Recommended<sup>(e)</sup> |
| 1020030     | Goat milk   | 0.1                     | 0.1                  | 0.1                   | Recommended<sup>(e)</sup> |
| 1020040     | Horse milk  | 0.1                     | 0.1                  | 0.1                   | Recommended<sup>(e)</sup> |
| –           | Other commodities of plant and/or animal origin | See Reg. 832/2018   | –                    | –                     | Further consideration needed<sup>(j)</sup> |

MRL: maximum residue level; CXL: codex maximum residue limit.
*: Indicates that the MRL is set at the limit of quantification.
(F): The residue definition is fat-soluble.
(a): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level, which is also fully supported by data, leads to a lower MRL (combination H-VII in Appendix E).
(b): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; existing CXL is covered by the recommended MRL (combination H-III in Appendix E).
(c): GAP evaluated at EU level is not supported by data but no risk to consumers was identified for the existing EU MRL (also assuming the existing residue definition); no CXL is available (combination D-I in Appendix E).
(d): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level is not supported by data, but the existing EU MRL is lower than the existing CXL (combination D-VII in Appendix E).
(e): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; there are no relevant authorisations or import tolerances reported at EU level (combination A-VII in Appendix E).
(f): GAP evaluated at EU level is not supported by data, but no risk to consumers was identified for the existing EU MRL (also assuming the existing residue definition); CXL is higher, supported by data but a risk to consumers cannot be excluded (combination D-VI in Appendix E).
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(g): There are no relevant authorisations or import tolerances reported at EU level; CXL is supported by data but a risk to consumers cannot be excluded. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-VI in Appendix E).

(h): GAP evaluated at EU level is fully supported by data, but a risk to consumers cannot be excluded; CXL is supported by data, but a risk to consumers can also not be excluded. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination G-VI in Appendix E).

(i): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; no CXL is available (combination H-I in Appendix E).

(j): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix E).

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Abbreviations

- **a.i.** active ingredient
- **a.s.** flubendiamide
- **ADI** acceptable daily intake
- **AR** applied radioactivity
- **ARfD** acute reference dose
- **BBCH** growth stages of mono- and dicotyledonous plants
- **bypdts** milling by-products
- **bw** body weight
- **CAC** Codex Alimentarius Commission
- **CAS** Chemical Abstract Service
- **CCPR** Codex Committee on Pesticide Residues
- **CF** conversion factor for enforcement residue definition to risk assessment residue definition
- **CIRCA** (EU) Communication & Information Resource Centre Administrator
- **CS** capsule suspension
- **CV** coefficient of variation (relative standard deviation)
- **CXL** codex maximum residue limit
- **DAR** draft assessment report
- **DAT** days after treatment
- **DB** dietary burden
- **DM** dry matter
- **DP** dustable powder
- **DS** powder for dry seed treatment
- **DT90** period required for 90% dissipation (define method of estimation)
- **EC** emulsifiable concentrate
- **EDI** estimated daily intake
- **EMS** evaluating Member State
- **EURLs** European Union Reference Laboratories for Pesticide Residues (former CRLs)
- **FAO** Food and Agriculture Organization of the United Nations
- **FID** flame ionisation detector
- **GAP** Good Agricultural Practice
Review of the existing MRLs for flubendiamide

- GC: gas chromatography
- GC-FID: gas chromatography with flame ionisation detector
- GC-MS: gas chromatography with mass spectrometry
- GC-MS/MS: gas chromatography with tandem mass spectrometry
- GS: growth stage
- HPLC: high-performance liquid chromatography
- HPLC-MS: high-performance liquid chromatography with mass spectrometry
- HPLC-MS/MS: high-performance liquid chromatography with tandem mass spectrometry
- HR: highest residue
- IEDI: international estimated daily intake
- IEStI: international estimated short-term intake
- ILV: independent laboratory validation
- ISO: International Organisation for Standardization
- IUPAC: International Union of Pure and Applied Chemistry
- JMPR: Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
- LC: liquid chromatography
- LC-MS/MS: liquid chromatography with tandem mass spectrometry
- LOQ: limit of quantification
- Mo: monitoring
- MRL: maximum residue level
- MS: Member States
- MS/MS: mass spectrometry detector
- MS/MS: tandem mass spectrometry detector
- MW: molecular weight
- NEU: northern European Union
- OECD: Organisation for Economic Co-operation and Development
- PBI: plant back interval
- PF: processing factor
- PHI: preharvest interval
- \( P_{ow} \): partition coefficient between \( n \)-octanol and water
- ppm: parts per million \( (10^{-6}) \)
- PRIMo: (EFSA) Pesticide Residues Intake Model
- PROFFile: (EFSA) Pesticide Residues Overview File
- QuEChERS: Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
- RA: risk assessment
- RD: residue definition
- RAC: raw agricultural commodity
- RD: residue definition
- RMS: rapporteur Member State
- SANCO: Directorate-General for Health and Consumers
- SC: suspension concentrate
- SEU: southern European Union
- SMILES: simplified molecular-input line-entry system
- SL: soluble concentrate
- SP: water soluble powder
- STMR: supervised trials median residue
- TAR: total applied radioactivity
- TMDI: theoretical maximum daily intake
- TRR: total radioactive residue
- UV: ultraviolet (detector)
- WG: water dispersible granule
- WHO: World Health Organization
- WP: wettable powder
## Appendix A – Summary of authorised uses considered for the review of MRLs

### A.1. Import tolerance

| Crop and/or situation | MS or country | F G or I(a) | Preparation | Method kind | Range of growth stages & season(c) | Number min-max | Interval between application (min) | PHI (days)(d) | Remarks |
|-----------------------|---------------|-------------|-------------|-------------|-----------------------------------|----------------|-----------------------------------|---------------|---------|
| Tree nuts             | USA           | F SC        | 480         | Foliar treatment – broadcast spraying | – 3 7 | – – | 140 g a.i./ha | 14 – |
| Apples                | US            | F SC        | 480         | Foliar treatment – broadcast spraying | – 3 7 | – – | 175 g a.i./ha | 14 – |
| Pears                 | US            | F SC        | 480         | Foliar treatment – broadcast spraying | – 3 7 | – – | 175 g a.i./ha | 14 – |
| Quinces               | US            | F SC        | 480         | Foliar treatment – broadcast spraying | – 3 7 | – – | 175 g a.i./ha | 14 – |
| Medlars               | US            | F SC        | 480         | Foliar treatment – broadcast spraying | – 3 7 | – – | 175 g a.i./ha | 14 – |
| Loquats               | US            | F SC        | 480         | Foliar treatment – broadcast spraying | – 3 7 | – – | 175 g a.i./ha | 14 – |
| Apricots              | US            | F SC        | 480         | Foliar treatment – broadcast spraying | – 3 7 | – – | 140 g a.i./ha | 7 Rate of product per application: 0.146–0.292 L/ha |
| Cherries              | US            | F SC        | 480         | Foliar treatment – broadcast spraying | – 3 7 | – – | 140 g a.i./ha | 7 – |
| Peaches               | US            | F SC        | 480         | Foliar treatment – broadcast spraying | – 3 7 | – – | 140 g a.i./ha | 7 See apricots |
| Plums                 | US            | F SC        | 480         | Foliar treatment – broadcast spraying | – 3 7 | – – | 140 g a.i./ha | 7 Rate of product per application: 0.146–0.292 L/ha |
| Table grapes          | US            | F SC        | 480         | Foliar treatment – broadcast spraying | – 3 5 | – – | 140 g a.i./ha | 7 – |
| Wine grapes           | US            | F SC        | 480         | Foliar treatment – broadcast spraying | – 3 5 | – – | 140 g a.i./ha | 7 – |
| Crop and/or situation | MS or country | Type(b) | Conc. a.s. | Method kind | Range of growth stages & season(c) | Number min–max | Interval between application (min) | a.s./hl min–max | Water L/ha min–max | Rate and unit | PHI (days)(d) | Remarks |
|-----------------------|---------------|---------|------------|-------------|-----------------------------------|----------------|-----------------------------------|----------------|-----------------|--------------|-------------|---------|
| Potatoes              | ZA            | F       | –          | –           | Foliar treatment – broadcast spraying | –              | 4                                | –              | –              | 24 g a.i./ha  | 14          | –       |
| Tomatoes              | AU            | F       | –          | –           | Foliar treatment – broadcast spraying | –              | 3                                | –              | –              | 72 g a.i./ha  | 1           | –       |
| Sweet peppers        | AU            | F       | –          | –           | Foliar treatment – broadcast spraying | –              | 3                                | –              | –              | 72 g a.i./ha  | 1           | –       |
| Cucumbers             | AU            | F       | –          | –           | Foliar treatment – broadcast spraying | –              | 3                                | –              | –              | 72 g a.i./ha  | 1           | –       |
| Melons                | AU            | F       | –          | –           | Foliar treatment – broadcast spraying | –              | 3                                | –              | –              | 72 g a.i./ha  | 1           | –       |
| Sweet corn            | AU            | F       | –          | –           | Foliar treatment – broadcast spraying | –              | 2                                | –              | –              | 72 g a.i./ha  | 1           | –       |
| Broccoli              | AU            | F       | –          | –           | Foliar treatment – broadcast spraying | –              | 3                                | –              | –              | 48 g a.i./ha  | 3           | –       |
| Cauliflowers          | AU            | F       | –          | –           | Foliar treatment – broadcast spraying | –              | 3                                | –              | –              | 48 g a.i./ha  | 3           | –       |
| Chinese cabbages      | AU            | F       | –          | –           | Foliar treatment – broadcast spraying | –              | 3                                | –              | –              | 48 g a.i./ha  | 3           | –       |
| Kales                 | AU            | F       | –          | –           | Foliar treatment – broadcast spraying | –              | 3                                | –              | –              | 48 g a.i./ha  | 3           | –       |
| Lettuces              | US            | F       | WG 24      | 24          | Foliar treatment – broadcast spraying | –              | 5                                | 3              | –              | 50 g a.i./ha  | 1           | Exceedance of the ARfD observed |
| Beans (with pods)     | AU            | F       | –          | –           | Foliar treatment – broadcast spraying | –              | 3                                | –              | –              | 72 g a.i./ha  | 1           | –       |
| Peas (with pods)      | AU            | F       | –          | –           | Foliar treatment – broadcast spraying | –              | 3                                | –              | –              | 72 g a.i./ha  | 1           | –       |
| Celeries              | US            | F       | –          | –           | Foliar treatment – broadcast spraying | –              | 1                                | –              | –              | 50 g a.i./ha  | 1           | –       |
### Review of the existing MRLs for flubendiamide

| Crop and/or situation | MS or country | CG or G or I(a) | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|---------------|-----------------|-------------|-------------|---------------------------------|---------------|---------|
| Soyabean              | US            | F               | SC 480     | Foliar treatment – broadcast spraying | – 2 5        | 105 g a.i./ha                   | 14          |
| Cotton seeds          | US            | F               | SC 480     | Foliar treatment – broadcast spraying | – 3 5        | 105 g a.i./ha                   | 28          |
| Maize                 | IN            | F               | WDG 24     | Foliar treatment – broadcast spraying | – 3 15       | 25 g a.i./ha                    | 30          |
| Rice                  | JP            | F               | – 24       | Foliar treatment – broadcast spraying | – 1 –        | 400 g a.i./ha                   | 7           |

MS: Member State; a.s.: active substance; a.i.: active ingredient.
(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide.
(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.
(d): PHI – minimum preharvest interval.
Appendix B – List of end points

B.1. Residues in plants

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

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

| Primary crops (available studies) | Crop groups | Crop(s) | Application(s) | Sampling (DAT) | Comment/Source |
|----------------------------------|-------------|---------|----------------|----------------|----------------|
| Fruits and fruiting vegetables   | Apples      | Foliar, 1 x 0.1 kg a.s./ha | 0, 7, 14, 28, 56 |
|                                  | Tomatoes    | Foliar, 1 x 0.5 kg a.s./ha | 0, 7, 14, 28 |
| Leafy crops                     | Cabbage     | Foliar, 1 x 0.3 kg a.s./ha | 21, 42 |
| Cereals/grass                   | Maize       | Foliar, 4 x 0.168 kg a.s./ha, 7 days interval | 29, 135, 274 Radiolabelled active substance: phthalic acid ring-UL-[14C] or aniline ring-UL-[14C] Reference: Greece (2008), EFSA (2013a) Forage, Sweet corn: 1 Ears, husks: 22 |

| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s) | PBI (DAT) | Comment/Source |
|--------------------------------------|-------------|---------|----------------|-----------|----------------|
| Root/tuber crops                    | Turnips     | 1 x 437 g a.s./ha, soil spray application | 29, 135, 274 Radiolabelled active substance: phthalic acid ring-UL-[14C] or aniline ring-UL-[14C] Reference: Greece (2008), EFSA (2013a) |
| Leafy crops                         | Swiss chard | 1 x 437 g a.s./ha, soil spray application | 29, 135, 274 |
| Cereal (small grain)                | Spring wheat| 1 x 437 g a.s./ha, soil spray application | 29, 135, 274 |

| Processed commodities (hydrolysis study) | Conditions | Stable? | Comment/Source |
|------------------------------------------|------------|---------|----------------|
|                                         | Pasteurisation (20 min, 90°C, pH 4) | Yes | EFSA (2013a) |
|                                         | Baking, brewing and boiling (60 min, 100°C, pH 5) | Yes | EFSA (2013a) |
|                                         | Sterilisation (20 min, 120°C, pH 6) | Yes | EFSA (2013a) |
Can a general residue definition be proposed for primary crops?

Yes

Inclusion of non-rat metabolite flubendiamide-des-iodo in residue definition for risk assessment may need to be reconsidered for new uses to be granted in the future.

Rotational crop and primary crop metabolism similar?

Yes

EFSA (2013a)

Residue pattern in processed commodities similar to residue pattern in raw commodities?

Yes

EFSA (2013a)

Plant residue definition for monitoring (RD-Mo)

Flubendiamide

Plant residue definition for risk assessment (RD-RA)

Flubendiamide

Methods of analysis for monitoring of residues (analytical technique, matrix groups, LOQs)

HPLC–MS/MS

High water content (head cabbage, tomato and bean with pod), high oil content (olive and cotton), high acid content (citrus) and dry commodities (wheat grain)

LOQ 0.01 mg/kg

ILV available

Reference: EFSA (2013a)

LOQ of 0.01 mg/kg is achievable in all major matrices by using the QuEChERS method in routine analyses (EURLs, 2019)

B.1.1.2. Stability of residues in plants

| Plant products (available studies) | Category | Commodity | T (°C) | Stability period | Compounds covered | Comment/Source |
|-----------------------------------|----------|-----------|--------|-----------------|-------------------|----------------|
|                                    | High water content | Tomato, head cabbage, beans with pods | −18°C | 18 Months | Flubendiamide and flubendiamide-des-iodo | EFSA (2013a) |
|                                    | High oil content | Olive | −18°C | 18 Months | Flubendiamide and flubendiamide-des-iodo | EFSA (2013a) |
|                                    | Dry/High starch content | Wheat | −18°C | 18 Months | Flubendiamide and flubendiamide-des-iodo | EFSA (2013a) |
|                                    | High acid content | Citrus | −18°C | 18 Months | Flubendiamide and flubendiamide-des-iodo | EFSA (2013a) |
|                                    | Processed products | Grape must | −18°C | 12 Months | Flubendiamide and flubendiamide-des-iodo | EFSA (2013a) |

a.s.: active substance; DAT: days after treatment; PBI: plant-back interval; HPLC–MS/MS: high-performance liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; ILV: independent laboratory validation; QuEChERS: Quick, Easy, Cheap, Effective, Rugged, and Safe.
### B.1.2. Magnitude of residues in plants

#### B.1.2.1. Summary of residues data from the supervised residue trials – Primary crops

| 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) |
|----------------------------|------------------|-------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------|------------------------|--------------|-----------------|-------|
| Tree nuts                  | Import (US)      | Almonds: $2 \times < 0.01; 2 \times 0.02; 0.05$ Pecan nuts: $2 \times < 0.01; 0.01; 0.02; 0.03$ | Combined data set on almonds and pecans compliant with the GAP (EFSA, 2010b). Extrapolation to tree nuts is applicable MRL\textsubscript{OECD} = 0.07 | 0.07                   | 0.05         | 0.02            | 1.00  |
| Pome fruits                | Import (US)      | Apples: $0.13; 2 \times 0.18; 0.19; 0.21; 2 \times 0.23; 0.27; 0.3; 0.41; 0.47; 0.48$ Pears: $0.09; 0.23; 0.33; 0.36; 0.37; 0.59$ | Combined data set on apples and pears compliant with the GAP (EFSA, 2010b). Extrapolation to pome fruits is applicable MRL\textsubscript{OECD} = 0.88 | 0.90                   | 0.59         | 0.25            | 1.00  |
| Cherries (sweet)           | Import (US)      | $0.19; 0.25; 0.48; 0.57; 0.6; 0.63; 0.99; 1.0$                                                                                   | Residue trials on cherries compliant with the GAP (EFSA, 2010b)                 | 2.00                   | 1.00         | 0.59            | 1.00  |
| Peaches                    | Import (US)      | Apricots: $0.13; 2 \times 0.67; 0.76$ Peaches: $2 \times 0.17; 2 \times 0.19; 0.24; 0.25; 0.27; 0.29; 0.32; 0.33$ | Combined dataset on peaches and apricots compliant with the GAP (EFSA., 2018a). Extrapolation to apricots and peaches is applicable MRL\textsubscript{OECD} = 1.17 | 1.50                   | 0.76         | 0.26            | 1.00  |
| Plums                      | Import (US)      | $0.01; 0.03; 0.04; 0.07; 2 \times 0.07; 0.1; 0.11; 0.34; 0.42$                                                                   | Trials on plums compliant with the GAP (EFSA, 2018a) MRL\textsubscript{OECD} = 0.68 | 0.70                   | 0.42         | 0.07            | 1.00  |
| Table grapes               | Import (US)      | $0.12; 0.19; 2 \times 0.2; 0.22; 0.4; 0.43; 0.47; 0.67; 0.68; 0.69; 0.81$                                                      | Trials on table grapes compliant the with GAP (EFSA, 2010b). Extrapolation to wine grapes is possible MRL\textsubscript{OECD} = 1.39 | 1.50                   | 0.81         | 0.42            | 1.00  |
| Potatoes                   | Import (ZA)      | –                                                                                                                             | No data available MRL\textsubscript{OECD} = –                                  | –                      | –            | –              | –     |
| Tomatoes                   | Import (AU)      | $0.01; 0.03; 2 \times 0.04; 0.05; 2 \times 0.07; 0.08; 2 \times 0.09; 0.14; 0.18$                                       | Trials on tomatoes compliant with the GAP (EFSA, 2010b) MRL\textsubscript{OECD} = 0.27 | 0.30                   | 0.18         | 0.07            | 1.00  |
| Sweet peppers/bell peppers| Import (AU)      | $2 \times < 0.01; 0.02; 2 \times 0.04; 0.05; 0.09; 2 \times 0.1; 0.14$                                                     | Trials on peppers compliant with the GAP (EFSA, 2010b) MRL\textsubscript{OECD} = 0.24 | 0.30                   | 0.14         | 0.05            | 1.00  |
| Commodity                  | Region Indoor | 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) |
|---------------------------|---------------|-----------------------------------------------------------------|----------------------------------------------------------------------------------|------------------------|--------------|-----------------|-------|
| Cucumbers                 | Import (AU)   | –                                                               | No data available                                                               | –                      | –            | –               | –     |
| Melons                    | Import (AU)   | –                                                               | No data available                                                               | –                      | –            | –               | –     |
| Sweet corn                | Import (US)   | 11 × < 0.01                                                     | Overdosed residue trials on sweet corn acceptable as residues are below the LOQ. (EFSA, 2010b) MRL\textsubscript{OECD} = 0.01 | 0.01*                  | 0.01         | 0.01            | 1.00  |
| Broccoli, cauliflowers, Chinese cabbages, kales | Import (AU)   | –                                                               | No data available                                                               | –                      | –            | –               | –     |
| Lettuces                  | Import (US)   | 0.12; 0.47; 0.67; 0.71; 0.97; 1.14; 1.16; 1.27; 1.63; 5.89 | Trials on lettuce compliant with the GAP (EFSA, 2010b) MRL\textsubscript{OECD} = 7.94 | 8.00                   | 5.89         | 1.06            | 1.00  |
| Beans/peas (with pods)   | Import (AU)   | –                                                               | No data available                                                               | –                      | –            | –               | –     |
| Celeries                  | Import (US)   | 0.81; 1.2; 1.32; 2.08; 2.31; 2.62 | Trials on celery compliant with the GAP (EFSA, 2010b) MRL\textsubscript{OECD} = 5.17 | 6.00                   | 2.62         | 1.70            | 1.00  |
| Soyabees                  | Import (US)   | < 0.01; 4 × 0.01; 3 × 0.02; 4 × 0.03; 0.04; 0.05; 0.06; 2 × 0.07; 0.1; 0.11; 0.21; 0.27 | Residue trials on conventional and genetically modified Soyabees compliant with US GAP (EFSA, 2010b, 2018a) MRL\textsubscript{OECD} = 0.33 | 0.30\textsuperscript{(c)} | 0.27         | 0.03            | 1.00  |
| Cotton seeds              | Import (US)   | < 0.01; 0.02; 0.03; 0.11; 2 × 0.12; 0.18; 0.19; 0.25; 0.28; 0.37; 1.0 | Trials on cotton compliant with the GAP (EFSA, 2010b) MRL\textsubscript{OECD} = 1.3 | 1.50                   | 1.00         | 0.15            | 1.00  |
| Maize/corn grains         | Import (US)   | 18 × < 0.01; 0.02 | Trials on maize compliant with the GAP (EFSA, 2010b) MRL\textsubscript{OECD} = 0.02 | 0.02                   | 0.02         | 0.01            | 1.00  |
| Rice grains               | Import (IN)   | 4 × < 0.01; 0.02; 0.03; 2 × 0.04; 0.05; 0.06; 0.11; 0.2 | Trials on rice compliant with the GAP (EFSA, 2010b) MRL\textsubscript{OECD} = 0.27 | 0.30                   | 0.20         | 0.04            | 1.00  |
| Teas                      | Import (JP)   | –                                                               | No data available                                                               | –                      | –            | –               | –     |

GAP: Good Agricultural Practice; OECD: Organisation for Economic Co-operation and Development; MRL: maximum residue level.

www.efsa.europa.eu/efsajournal
Mo: residue levels expressed according to the monitoring residue definition; RA: residue levels expressed according to risk assessment residue definition.
*: Indicates that the MRL is proposed at the limit of quantification.
(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Indoor: indoor EU trials or Country code: if non-EU trials.
(b): Highest residue. The highest residue for risk assessment (RA) refers to the whole commodity and not to the edible portion.
(c): Supervised trials median residue. The median residue for risk assessment (RA) refers to the whole commodity and not to the edible portion.
(d): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.
(e): Calculated MRL aligned with the EU Regulation as MRL in country of origin lower.
B.1.2.2. Residues in rotational crops

Not relevant, only import tolerance authorised.

B.1.2.3. Processing factors

| Processed commodity          | Number of valid studies | Processing Factor (PF) | Comment/Source          |
|-----------------------------|-------------------------|------------------------|-------------------------|
|                             |                         | Individual values      | Median PF               |
|                             |                         |                        |                        |
| Apples, juice               | 1                       |                        | 0.06                    |
| Apples, wet pomace          | 1                       |                        | 3.56                    |
| Plums, dried (prunes)       | 1                       |                        | 0.97                    |
| Strawberries, jam           | 4                       | 0.1; 0.2; < 0.3; < 0.4;| 0.2                    |
| Strawberries, preserved     | 4                       | 0.1; 0.2; < 0.3; < 0.4;| 0.2                    |
| Table grapes, dried (prunes)| 1                       |                        | 0.30                    |
| Wine grapes, juice          | 1                       |                        | 0.08                    |
| Tomatoes, paste             | 2                       | 3.65; 5.05             | 4.33                    |
| Tomatoes, juice             | 2                       | n.r.                   | < 0.42                  |
| Soyabean, refined oil       | 1                       |                        | < 0.04                  |
| Soyabean, meal              | 1                       |                        | 0.12                    |
| Soyabean, milk              | 1                       |                        | < 0.04                  |
| Soyabean, hulls             | 1                       |                        | 2.80                    |
| Cotton seeds, crude oil     | 1                       |                        | < 0.02                  |
| Cotton seeds, meal/press cake| 1                   |                        | < 0.02                  |
| Maize, flour/meal/grits     | 1                       |                        | 2.00                    |
| Maize, starch (wet milling) | 1                       |                        | < 0.03                  |
| Rice, polished              | 1                       |                        | < 0.25                  |
| Rice, bran                  | 1                       |                        | 0.75                    |

PF: Processing factor (Residue level in processed commodity expressed according to RD-Mo/Residue level in raw commodity expressed according to RD-Mo); n.r. not reported.

(a): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur).
(b): A tentative PF is derived based on a limited dataset.

B.2. Residues in livestock

| Relevant groups (subgroups) | Dietary burden expressed in | Most critical subgroup (b) | Most critical commodity (b) | Trigger exceeded (Yes/No) |
|-----------------------------|----------------------------|-----------------------------|-----------------------------|---------------------------|
|                             | mg/kg bw per day | mg/kg DM | Median | Maximum | Median | Maximum | | |
| Cattle (all)                | 0.011           | 0.011 | 0.45   | 0.45    | Beef cattle | Apple pomace, wet | Yes |
| Cattle (dairy only)         | 0.009           | 0.009 | 0.24   | 0.24    | Dairy cattle | Apple pomace, wet | Yes |
| Sheep (all)                 | 0.010           | 0.010 | 0.23   | 0.23    | Lamb | Apple pomace, wet | Yes |
| Sheep (ewe only)            | 0.008           | 0.008 | 0.23   | 0.23    | Ram/Ewe | Apple pomace, wet | Yes |
| Swine (all)                 | 0.001           | 0.001 | 0.02   | 0.02    | Swine (finishing) | Corn, field milled bypds | No |
| Poultry (all)               | 0.001           | 0.001 | 0.02   | 0.02    | Poultry broiler | Corn, field milled bypds | No |
| Poultry (layer only)        | 0.001           | 0.001 | 0.02   | 0.02    | Poultry layer | Corn, field milled bypds | No |

bw: body weight; DM: dry matter; bypds: milling by-products.
When one group of livestock includes several subgroups (e.g. poultry ‘all’ including broiler, layer and turkey), the result of the most critical subgroup is identified from the maximum dietary burdens expressed as ‘mg/kg bw per day’.

The most critical commodity is the major contributor identified from the maximum dietary burden expressed as ‘mg/kg bw per day’.

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

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

| Livestock (available studies) | Animal                  | Dose (mg/kg bw/d) | Duration (days) | Comment/Source                                                                 |
|-------------------------------|-------------------------|-------------------|-----------------|-------------------------------------------------------------------------------|
|                               | Laying hen              | 1                 | 14              | Radiolabelled active substance: phthalic acid ring-UL-[14C] or aniline ring-UL-[14C] Reference: Greece (2008), EFSA (2013a) |
|                               | Lactating ruminants     | 4.83 and 5        | 4               | Lactating goat. Radiolabelled active substance: phthalic acid ring-UL-[14C] and aniline ring-UL-[14C] Reference: Greece (2008), EFSA (2013a) |

**Time needed to reach a plateau concentration in milk and eggs (days)**

- Milk: 7-8EFSA (2013a)
- Eggs: 13EFSA (2013a)

**Metabolism in rat and ruminant similar**

- YesEFSA (2013a)

**Can a general residue definition be proposed for animals?**

- YesEFSA (2013a)

**Animal residue definition for monitoring (RD-Mo)**

Flubendiamide

**Animal residue definition for risk assessment (RD-RA)**

Sum of flubendiamide and flubendiamide-iodo-phthalimide, expressed as flubendiamide

**Fat soluble residues**

- Yes

Based on preferential accumulation of residues in fatty tissues in the livestock studies.

**Methods of analysis for monitoring of residues (analytical technique, matrix groups, LOQs)**

- Muscle, liver, kidney, fat, milk and poultry eggs:
  - HPLC–MS/MS, LOQ of 0.01 mg/kg
  - ILV available (muscle, fat and eggs)
  (Greece, 2008; EFSA, 2013a)

EURLs: in milk, meat and honey a screening detection limit (SDL) of 0.0025 mg/kg, and in eggs an SDL of 0.005 mg/kg is achievable (EURLs, 2019).

bw: body weight; HPLC–MS/MS: high-performance liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; ILV: independent laboratory validation.

**B.2.1.2. Stability of residues in livestock**

Storage stability studies are not available. As all samples of the feeding studies were stored ≤ −18°C and analysed within 30 days of collection, further storage stability studies are not required (EFSA, 2013a).
### B.2.2. Magnitude of residues in livestock

#### B.2.2.1. Summary of the residue data from livestock metabolism studies

| Animal commodity | Residues at the closest feeding level (mg/kg) | Estimated value at 1N proposal (mg/kg) | MRL | CF<sup>(c)</sup> |
|------------------|---------------------------------------------|--------------------------------------|-----|-----------------|
|                  | Mean Highest | STMR<sub>Mo</sub><sup>(a)</sup> (mg/kg) | HR<sub>Mo</sub><sup>(b)</sup> (mg/kg) |     |                 |
| Cattle (all)     | – Closest feeding level (0.09 mg/kg bw; 8.7 N rate)<sup>(d)</sup> | | | | |
| Muscle           | 0.01 0.01 | 0.00 | 0.00 | 0.01* | 1 |
| Fat              | 0.06 0.08 | 0.01 | 0.01 | 0.01* | 1 |
| Liver            | 0.04 0.06 | 0.01 | 0.01 | 0.01* | 1 |
| Kidney           | 0.05 0.06 | 0.01 | 0.01 | 0.01* | 1 |
| Cattle (dairy only) – Closest feeding level (0.09 mg/kg bw; 10.7 N rate)<sup>(d)</sup> | | | | | |
| Milk<sup>(e)</sup> | 0.01 n.a. | 0.001 | 0.001 | 0.01* | 1 |
| Sheep (all)<sup>(f)</sup> – Closest feeding level (0.09 mg/kg bw; 10 N rate)<sup>(d)</sup> | | | | | |
| Muscle           | 0.01 0.01 | 0.00 | 0.00 | 0.01* | 1 |
| Fat              | 0.06 0.08 | 0.01 | 0.01 | 0.01* | 1 |
| Liver            | 0.04 0.06 | 0.00 | 0.01 | 0.01* | 1 |
| Kidney           | 0.05 0.06 | 0.01 | 0.01 | 0.01* | 1 |
| Sheep (ewe only)<sup>(f)</sup> – Closest feeding level (0.09 mg/kg bw; 14.8 N rate)<sup>(d)</sup> | | | | | |
| Milk<sup>(e)</sup> | 0.01 n.a. | 0.001 | 0.001 | 0.01* | 1 |

*: Indicates that the MRL is proposed at the limit of quantification.

n.a.: not applicable.

(a): Median residues expressed according to the residue definition for monitoring, recalculated at the 1N rate for the median dietary burden.

(b): Highest residues expressed according to the residue definition for monitoring, recalculated at the 1N rate for the maximum dietary burden.

(c): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.

(d): Closest feeding level and N dose rate related to the maximum dietary burden.

(e): For milk, mean was derived from samplings performed from day D1 to day D4 (daily mean of 1 goat per label).

(f): Since extrapolation from cattle to other ruminants is acceptable, results of the livestock metabolism study on ruminants were relied upon to derive the MRL and risk assessment values in sheep.
## B.3. Consumer risk assessment

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

| ARfD | 0.1 mg/kg bw (EFSA, 2013a) |
|------|---------------------------|
| Highest IESTI, according to EFSA PRIMo (rev.3.1) | **Scenario EU1** (without risk mitigation measures): Lettuce: 224% of ARfD  
**Scenario EU2** (with risk mitigation measures): Celeries: 98% of ARfD |
| NESTI (% ARfD) | Not assessed in this review |
| Assumptions made for the calculations | **Scenario EU1** (without risk mitigation measures): The calculation is based on the highest residue levels expected in raw agricultural commodities, except for bulk commodities (soyabeans, cotton seeds, maize/corn, rice, and milk) where the median residue levels was applied and the EU MRL was used for potatoes, cucumbers, melons, broccoli, cauliflowers, Chinese cabbages/pe-tsai, kales, peas/beans with pods, tea  
**Scenario EU2** (with risk mitigation measures): The highest residue level in lettuce was disregarded and replaced by the LOQ, as no authorised fall-back GAP was reported |

| ADI | 0.017 mg/kg bw per day (EFSA, 2013a) |
|------|-----------------------------------|
| TMDI according to EFSA PRIMo | Not assessed in this review |
| NTMDI, according to (to be specified) | Not assessed in this review |
| Highest IEDI, according to EFSA PRIMo (rev.3.1) | **Scenario EU1** (without risk mitigation measures): 32% ADI (NL toddler)  
**Scenario EU2** (with risk mitigation measures): 31% ADI (NL toddler) |
| NEDI (% ADI) | Not assessed in this review |
| Assumptions made for the calculations | **Scenario EU1** (without risk mitigation measures): The calculation is based on the median residue levels derived for raw agricultural commodities, except for potatoes, cucumbers, melons, broccoli, cauliflowers, Chinese cabbages/pe-tsai, kales, peas/beans with pods, tea where the EU MRL was used. The contributions of commodities where no GAP was reported in the framework of the MRL review were not included in the calculation  
**Scenario EU2** (with risk mitigation measures): The median residue level in lettuce was disregarded, as no authorised fall-back GAP was reported |

ARfD: acute reference dose; bw: body weight; NESTI: national estimated short-term intake; PRIMo: (EFSA) Pesticide Residues Intake Model; IESTI: international estimated short-term intake; MRL: maximum residue level; LOQ: limit of quantification; GAP: Good Agricultural Practice.
Consumer exposure assessment through drinking water resulting from groundwater metabolite(s) according to SANCO/221/2000 rev.10 Final (25/02/2003)

| Metabolite(s)                                      | Not assessed in this review |
|---------------------------------------------------|-----------------------------|
| ADI (mg/kg bw per day)                            | Not assessed in this review |
| Intake of groundwater metabolites (% ADI)         | Not assessed in this review |

**B.3.2. Consumer risk assessment with consideration of the existing CXLs**

**ARfD**

| Highest IESTI, according to EFSA PRIMo (rev.3.1) |
|--------------------------------------------------|
| Scenario CX1: Cauliflowers: 156% of ARfD         |
| Lettuces: 152% of ARfD                          |
| Kohlrabies: 140% of ARfD                        |
| Head cabbages: 119% of ARfD                     |
| Broccoli: 112% of ARfD                         |
| Scenario CX2: Celeries: 98% of ARfD             |

**NESTI (% ARfD)**

Not assessed in this review

**Assumptions made for the calculations**

**Scenario CX1:**
For those commodities having a CXL higher than the EU (scenario EU2) MRL proposal, highest residue levels applied in the EU scenario were replaced by the highest residue levels derived by JMPR

**Scenario CX2:**
The same calculation was performed as in scenario CX1, except the highest residue level derived by JMPR for cauliflowers, lettuces, kohlrabies, head cabbages, and broccoli were disregarded

**ADI**

| 0.017 mg/kg bw per day (EFSA, 2013a) |

**TMDI according to EFSA PRIMo**

Not assessed in this review

**NTMDI, according to (to be specified)**

Not assessed in this review

**Highest IEDI, according to EFSA PRIMo (rev.3.1)**

| 63% ADI (NL toddler) |

**NEDI (% ADI)**

Not assessed in this review

**Assumptions made for the calculations**

**Scenario CX1:**
For those commodities having a CXL higher than the EU MRL proposal, median residue levels applied in the EU scenario 2 were replaced by the median residue levels derived by JMPR

**Scenario CX2:**
The same calculation was performed as in scenario CX1, except the median residue levels derived by JMPR were disregarded for cauliflowers, lettuces, kohlrabies, head cabbages, and broccoli

ADI: acceptable daily intake; bw: body weight; IEDI: international estimated daily intake; NEDI: national estimated daily intake; PRIMo: (EFSA) Pesticide Residues Intake Model; IESTI: international estimated short-term intake.; MRL: maximum residue level; CXL: codex maximum residue limit.
### B.4. Proposed MRLs

| Code number | Commodity         | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review | Comment |
|-------------|-------------------|-------------------------|----------------------|-----------------------|---------|
| 120010      | Almonds           | 0.1                     | 0.1                  | 0.1                   | Recommended |
| 120020      | Brazil nuts       | 0.1                     | 0.1                  | 0.1                   | Recommended |
| 120030      | Cashew nuts       | 0.1                     | 0.1                  | 0.1                   | Recommended |
| 120040      | Chestnuts         | 0.1                     | 0.1                  | 0.1                   | Recommended |
| 120050      | Coconuts          | 0.1                     | 0.1                  | 0.1                   | Recommended |
| 120060      | Hazelnuts         | 0.1                     | 0.1                  | 0.1                   | Recommended |
| 120070      | Macadamia         | 0.1                     | 0.1                  | 0.1                   | Recommended |
| 120080      | Pecans            | 0.1                     | 0.1                  | 0.1                   | Recommended |
| 120090      | Pine nuts         | 0.1                     | 0.1                  | 0.1                   | Recommended |
| 120100      | Pistachios        | 0.1                     | 0.1                  | 0.1                   | Recommended |
| 120110      | Walnuts           | 0.1                     | 0.1                  | 0.1                   | Recommended |
| 130010      | Apples            | 0.8                     | 0.8                  | 0.9                   | Recommended |
| 130020      | Pears             | 0.8                     | 0.8                  | 0.9                   | Recommended |
| 130030      | Quinces           | 0.8                     | 0.8                  | 0.9                   | Recommended |
| 130040      | Medlar            | 0.8                     | 0.8                  | 0.9                   | Recommended |
| 130050      | Loquat            | 0.8                     | 0.8                  | 0.9                   | Recommended |
| 140010      | Apricots          | 1.5                     | 2                    | 2                     | Recommended |
| 140020      | Cherries          | 2.0                     | 2                    | 2                     | Recommended |
| 140030      | Peaches           | 1.5                     | 2                    | 2                     | Recommended |
| 140040      | Plums             | 0.7                     | 2                    | 2                     | Recommended |
| 151010      | Table grapes      | 2.0                     | 2                    | 2                     | Recommended |
| 151020      | Wine grapes       | 2.0                     | 2                    | 2                     | Recommended |
| 211000      | Potatoes          | 0.01*                   | –                    | 0.01*                 | Further consideration needed |
| 231010      | Tomatoes          | 0.2                     | 2                    | 2                     | Recommended |
| 231020      | Peppers           | 0.2                     | 0.7                  | 0.7                   | Recommended |
| 232010      | Cucumbers         | 0.15                    | 0.2                  | 0.2                   | Recommended |
| 232020      | Gherkins          | 0.15                    | 0.2                  | 0.2                   | Recommended |
| 232030      | Courgettes        | 0.15                    | 0.2                  | 0.2                   | Recommended |
| 233010      | Melons            | 0.06                    | 0.2                  | 0.2                   | Recommended |
| 233020      | Pumpkins          | 0.06                    | 0.2                  | 0.2                   | Recommended |
| 233030      | Watermelons       | 0.06                    | 0.2                  | 0.2                   | Recommended |
| 234000      | Sweet corn        | 0.02                    | 0.02                 | 0.02                  | Recommended |
| 241010      | Broccoli          | 0.01*                   | 4                    | 0.01*                 | Further consideration needed |
| 241020      | Cauliflower       | 0.01*                   | 4                    | 0.01*                 | Further consideration needed |
| 242010      | Brussels sprouts  | 0.01*                   | 4                    | 4                     | Recommended |
| 242020      | Head cabbage      | 4.0                     | 4                    | –                     | Further consideration needed |
| 243010      | Chinese cabbage   | 0.01*                   | –                    | 0.01*                 | Further consideration needed |
| 243020      | Kale              | 0.01*                   | –                    | 0.01*                 | Further consideration needed |
| 244000      | Kohlrabi          | 0.01*                   | 4                    | –                     | Further consideration needed |
| 251020      | Lettuce           | 7.0                     | 7                    | –                     | Further consideration needed |
| 260010      | Beans (fresh, with pods) | 0.5 | 2 | 2 | Recommended |
| 260020      | Beans (fresh, without pods) | 0.5 | 2 | 2 | Recommended |

**Enforcement residue definition:** Flubendiamide

Review of the existing MRLs for flubendiamide.
### Review of the existing MRLs for flubendiamide

| Code number | Commodity | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review | Comment |
|-------------|-----------|-------------------------|----------------------|-----------------------|---------|
| 260030      | Peas (fresh, with pods) | 1.5 | 2 | 2 | Recommended<sup>(d)</sup> |
| 260040      | Peas (fresh, without pods) | 0.01* | 2 | 2 | Recommended<sup>(e)</sup> |
| 260050      | Lentils (fresh) | 0.01* | 2 | 2 | Recommended<sup>(e)</sup> |
| 270030      | Celery | 5 | 5 | 6 | Recommended<sup>(a)</sup> |
| 300010      | Beans (dry) | 1 | 1 | 1 | Recommended<sup>(a)</sup> |
| 300020      | Lentils (dry) | 1 | 1 | 1 | Recommended<sup>(a)</sup> |
| 300030      | Peas (dry) | 1 | 1 | 1 | Recommended<sup>(a)</sup> |
| 300040      | Lupins (dry) | 1 | 1 | 1 | Recommended<sup>(a)</sup> |
| 401070      | Soyabees | 0.3 | – | 0.3 | Recommended<sup>(j)</sup> |
| 401090      | Cotton seed | 1.5 | 1.5 | 1.5 | Recommended<sup>(b)</sup> |
| 500030      | Maize grain | 0.02 | 0.02 | 0.02 | Recommended<sup>(b)</sup> |
| 500060      | Rice grain | 0.2 | – | 0.3 | Recommended<sup>(i)</sup> |
| 610000      | Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis) | 0.02* | 50 | 50 | Recommended<sup>(e)</sup> |
| 1011010     | Swine meat | 2 | 2 | 2 | Recommended<sup>(e)</sup> |
| 1011020     | Swine fat (free of lean meat) | 2 | 2 | 2 | Recommended<sup>(e)</sup> |
| 1011030     | Swine liver | 1 | 1 | 1 | Recommended<sup>(e)</sup> |
| 1011040     | Swine kidney | 1 | 1 | 1 | Recommended<sup>(e)</sup> |
| 1012010     | Bovine meat | 2 | 2 | 2 | Recommended<sup>(a)</sup> |
| 1012020     | Bovine fat | 2 | 2 | 2 | Recommended<sup>(a)</sup> |
| 1012030     | Bovine liver | 1 | 1 | 1 | Recommended<sup>(a)</sup> |
| 1012040     | Bovine kidney | 1 | 1 | 1 | Recommended<sup>(a)</sup> |
| 1013010     | Sheep meat | 2 | 2 | 2 | Recommended<sup>(a)</sup> |
| 1013020     | Sheep fat | 2 | 2 | 2 | Recommended<sup>(a)</sup> |
| 1013030     | Sheep liver | 1 | 1 | 1 | Recommended<sup>(a)</sup> |
| 1013040     | Sheep kidney | 1 | 1 | 1 | Recommended<sup>(a)</sup> |
| 1014010     | Goat meat | 2 | 2 | 2 | Recommended<sup>(a)</sup> |
| 1014020     | Goat fat | 2 | 2 | 2 | Recommended<sup>(a)</sup> |
| 1014030     | Goat liver | 1 | 1 | 1 | Recommended<sup>(a)</sup> |
| 1014040     | Goat kidney | 1 | 1 | 1 | Recommended<sup>(a)</sup> |
| 1015010     | Horse meat | 2 | 2 | 2 | Recommended<sup>(a)</sup> |
| 1015020     | Horse fat | 2 | 2 | 2 | Recommended<sup>(a)</sup> |
| 1015030     | Horse liver | 1 | 1 | 1 | Recommended<sup>(a)</sup> |
| 1015040     | Horse kidney | 1 | 1 | 1 | Recommended<sup>(a)</sup> |
| 1020010     | Cattle milk | 0.1 | 0.1 | 0.1 | Recommended<sup>(i)</sup> |
| 1020020     | Sheep milk | 0.1 | 0.1 | 0.1 | Recommended<sup>(i)</sup> |
| 1020030     | Goat milk | 0.1 | 0.1 | 0.1 | Recommended<sup>(i)</sup> |
| 1020040     | Horse milk | 0.1 | 0.1 | 0.1 | Recommended<sup>(i)</sup> |

-- Other commodities of plant and/or animal origin

See Reg. 832/2018

Further consideration needed<sup>(i)</sup>

MRL: maximum residue level; CXL: codex maximum residue limit.

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

(F): The residue definition is fat soluble.
(a): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level, which is also fully supported by data, leads to a lower MRL (combination H-VII in Appendix E).

(b): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; existing CXL is covered by the recommended MRL (combination H-III in Appendix E).

(c): GAP evaluated at EU level is not supported by data but no risk to consumers was identified for the existing EU MRL (also assuming the existing residue definition); no CXL is available (combination D-I in Appendix E).

(d): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level is not supported by data, but the existing EU MRL is lower than the existing CXL (combination D-VII in Appendix E).

(e): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; there are no relevant authorisations or import tolerances reported at EU level (combination A-VII in Appendix E).

(f): GAP evaluated at EU level is not supported by data, but no risk to consumers was identified for the existing EU MRL (also assuming the existing residue definition); CXL is higher, supported by data but a risk to consumers cannot be excluded (combination D-VI in Appendix E).

(g): There are no relevant authorisations or import tolerances reported at EU level; CXL is supported by data, but a risk to consumers cannot be excluded. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-VI in Appendix E).

(h): GAP evaluated at EU level is fully supported by data but a risk to consumers cannot be excluded; CXL is supported by data but a risk to consumers can also not be excluded. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination G-VI in Appendix E).

(i): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; no CXL is available (combination H-I in Appendix E).

(j): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix E).
Appendix C – Pesticide Residue Intake Model (PRIMo)

### PRIMo(EU1)

- **LOQs (mg/kg) range from:** 0.01 to 0.01
- **ADI (mg/kg bw per day):** 0.017
- **ARfD (mg/kg bw):** 0.1
- **Source of ADI:** EFSA
- **Source of ARfD:** EFSA

**EFSA PRIMo revision 3.1; 2019/03/19**

**Year of evaluation:** 2013

**No of diets exceeding the ADI:** ---

| Calculated exposure (% of ADI) | MS Diet | Exposure (g/kg per day) | Highest contributor to MS diet as % of ADI | Commodity/group of commodities | 2nd contributor to MS diet as % of ADI | Commodity/group of commodities | 3rd contributor to MS diet as % of ADI | Commodity/group of commodities | MRLs set at the LOQ (in % of ADI) | Commodities not under assessment (in % of ADI) |
|-------------------------------|---------|------------------------|------------------------------------------|---------------------------------|-------------------------------------|---------------------------------|----------------------------------|---------------------------------|---------------------------------|---------------------------------|
| 30% IE child                  | 0.17    | 0.3%                   | Table grapes (0.17%)                     | Table grapes                    | 0.0%                               | Apples                          | 0.0%                             | Wine grapes                     | 0.0%                            | 0.0%                            |
| 27% OC child                  | 0.30    | 1%                     | Table grapes (0.30%)                     | Table grapes                    | 0.0%                               | Apples                          | 0.0%                             | Wine grapes                     | 0.0%                            | 0.0%                            |
| 21% NL child                  | 0.25    | 1%                     | Table grapes (0.25%)                     | Table grapes                    | 0.0%                               | Apples                          | 0.0%                             | Wine grapes                     | 0.0%                            | 0.0%                            |
| 12% GEMS/Food G07             | 0.27    | 4%                     | Wine grapes (0.27%)                      | Table grapes                    | 0.0%                               | Apples                          | 0.0%                             | Wine grapes                     | 0.0%                            | 0.0%                            |
| 12% GEMS/Food G11             | 0.24    | 3%                     | Table grapes (0.24%)                     | Table grapes                    | 0.0%                               | Apples                          | 0.0%                             | Wine grapes                     | 0.0%                            | 0.0%                            |
| 11% PT general                | 0.13    | 4%                     | Wine grapes (0.13%)                      | Table grapes                    | 0.0%                               | Apples                          | 0.0%                             | Wine grapes                     | 0.0%                            | 0.0%                            |
| 10% IE adult                  | 0.12    | 4%                     | Wine grapes (0.12%)                      | Table grapes                    | 0.0%                               | Apples                          | 0.0%                             | Wine grapes                     | 0.0%                            | 0.0%                            |
| 10% GEMS/Food G06             | 0.16    | 4%                     | Wine grapes (0.16%)                      | Table grapes                    | 0.0%                               | Apples                          | 0.0%                             | Wine grapes                     | 0.0%                            | 0.0%                            |
| 10% GEMS/Food G15             | 0.16    | 3%                     | Table grapes (0.16%)                     | Table grapes                    | 0.0%                               | Apples                          | 0.0%                             | Wine grapes                     | 0.0%                            | 0.0%                            |
| 10% GEMS/Food G08             | 0.15    | 2%                     | Table grapes (0.15%)                     | Table grapes                    | 0.0%                               | Apples                          | 0.0%                             | Wine grapes                     | 0.0%                            | 0.0%                            |
| 10% RO general                | 0.14    | 2%                     | Table grapes (0.14%)                     | Table grapes                    | 0.0%                               | Apples                          | 0.0%                             | Wine grapes                     | 0.0%                            | 0.0%                            |
| 9% GEMS/Food G10              | 0.13    | 4%                     | Wine grapes (0.13%)                      | Table grapes                    | 0.0%                               | Apples                          | 0.0%                             | Wine grapes                     | 0.0%                            | 0.0%                            |
| 9% DE women 14-50 yr          | 0.12    | 3%                     | Wine grapes (0.12%)                      | Table grapes                    | 0.0%                               | Apples                          | 0.0%                             | Wine grapes                     | 0.0%                            | 0.0%                            |
| 8% PT adult                   | 0.11    | 3%                     | Wine grapes (0.11%)                      | Table grapes                    | 0.0%                               | Apples                          | 0.0%                             | Wine grapes                     | 0.0%                            | 0.0%                            |
| 9% FR toddler 2-3 yr          | 0.12    | 2%                     | Table grapes (0.12%)                     | Table grapes                    | 0.0%                               | Apples                          | 0.0%                             | Wine grapes                     | 0.0%                            | 0.0%                            |
| 7% NL general                 | 0.10    | 3%                     | Wine grapes (0.10%)                      | Table grapes                    | 0.0%                               | Apples                          | 0.0%                             | Wine grapes                     | 0.0%                            | 0.0%                            |
| 6% IT adult                   | 0.09    | 2%                     | Table grapes (0.09%)                     | Table grapes                    | 0.0%                               | Apples                          | 0.0%                             | Wine grapes                     | 0.0%                            | 0.0%                            |
| 6% IT toddler                 | 0.08    | 2%                     | Table grapes (0.08%)                     | Table grapes                    | 0.0%                               | Apples                          | 0.0%                             | Wine grapes                     | 0.0%                            | 0.0%                            |
| 6% DK adult                   | 0.07    | 2%                     | Table grapes (0.07%)                     | Table grapes                    | 0.0%                               | Apples                          | 0.0%                             | Wine grapes                     | 0.0%                            | 0.0%                            |
| 5% PL general                 | 0.05    | 2%                     | Table grapes (0.05%)                     | Table grapes                    | 0.0%                               | Apples                          | 0.0%                             | Wine grapes                     | 0.0%                            | 0.0%                            |
| 5% UK vegetation              | 0.05    | 2%                     | Table grapes (0.05%)                     | Table grapes                    | 0.0%                               | Apples                          | 0.0%                             | Wine grapes                     | 0.0%                            | 0.0%                            |
| 5% UK toddler                 | 0.04    | 2%                     | Table grapes (0.04%)                     | Table grapes                    | 0.0%                               | Apples                          | 0.0%                             | Wine grapes                     | 0.0%                            | 0.0%                            |
| 5% UK adult                   | 0.03    | 2%                     | Table grapes (0.03%)                     | Table grapes                    | 0.0%                               | Apples                          | 0.0%                             | Wine grapes                     | 0.0%                            | 0.0%                            |
| 5% FR child                   | 0.03    | 2%                     | Table grapes (0.03%)                     | Table grapes                    | 0.0%                               | Apples                          | 0.0%                             | Wine grapes                     | 0.0%                            | 0.0%                            |
| 4% UK infant                  | 0.03    | 2%                     | Table grapes (0.03%)                     | Table grapes                    | 0.0%                               | Apples                          | 0.0%                             | Wine grapes                     | 0.0%                            | 0.0%                            |
| 4% LT adult                   | 0.02    | 2%                     | Table grapes (0.02%)                     | Table grapes                    | 0.0%                               | Apples                          | 0.0%                             | Wine grapes                     | 0.0%                            | 0.0%                            |
| 4% FR 2 yr                    | 0.02    | 2%                     | Table grapes (0.02%)                     | Table grapes                    | 0.0%                               | Apples                          | 0.0%                             | Wine grapes                     | 0.0%                            | 0.0%                            |
| 4% FR adult                   | 0.02    | 1%                     | Table grapes (0.02%)                     | Table grapes                    | 0.0%                               | Apples                          | 0.0%                             | Wine grapes                     | 0.0%                            | 0.0%                            |
| 3% FI 6 yr                    | 0.02    | 2%                     | Table grapes (0.02%)                     | Table grapes                    | 0.0%                               | Apples                          | 0.0%                             | Wine grapes                     | 0.0%                            | 0.0%                            |
| 2% OE child                   | 0.02    | 1%                     | Table grapes (0.02%)                     | Table grapes                    | 0.0%                               | Apples                          | 0.0%                             | Wine grapes                     | 0.0%                            | 0.0%                            |
| 1% IE child                   | 0.02    | 0%                     | Table grapes (0.02%)                     | Table grapes                    | 0.0%                               | Apples                          | 0.0%                             | Wine grapes                     | 0.0%                            | 0.0%                            |

**Conclusion:**
- The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
- The long-term intake of residues of flubendiamide (F) is unlikely to present a public health concern.

**Flubendiamide (F) - Toxicological reference values**

| Input values | Details – chronic risk assessment | Supplementary results – chronic risk assessment | Details – acute risk assessment/children | Details – acute risk assessment/adults |
|--------------|-----------------------------------|-----------------------------------------------|-----------------------------------------|---------------------------------------|
| Normal mode  | Chronic risk assessment: JMPR methodology (IEDI/TMDI) | | | |

The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.

The long-term intake of residues of flubendiamide (F) is unlikely to present a public health concern.

**Review of the existing MRLs for flubendiamide**

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### Acute risk assessment / children

The acute risk assessment is based on the ARfD. The calculation is based on the large portion of the most critical consumer group.

#### Unprocessed commodities

| Commodity | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI | Commodity | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI |
|-----------|--------------------------|---------------------|-----------------------|-----------|--------------------------|---------------------|-----------------------|
| Lettuces  | 8.59/5.89               | 224                 | 224%                  | Lettuce   | 8.59/5.89               | 72                  | 72%                   |
| Celeries  | 6.02/4.98               | 98                  | 98%                   | Celeries  | 6.02/4.98               | 42                  | 42%                   |
| Pears     | 0.90/0.59               | 82                  | 82%                   | Table grapes | 1.50/0.81 | 27%                  | 1.50/0.81             | 19%                   |
| Apples    | 0.90/0.59               | 64                  | 84%                   | Apples    | 0.90/0.59               | 18                  | 18%                   |
| Table grapes | 1.50/0.81 | 59                  | 59%                   | Table grapes | 1.50/0.81 | 17%                  | 1.50/0.81             | 14%                   |
| Apricots  | 1.50/0.76               | 27                  | 27%                   | Apricots  | 1.50/0.76               | 14%                  | 14%                   |
| Plums     | 0.70/0.42               | 18                  | 18%                   | Plums     | 0.70/0.42               | 10%                  | 10.0%                 |
| Grapes    | 0.90/0.59               | 15                  | 15%                   | Grapes    | 0.90/0.59               | 9                   | 9.0                   |
| Peas (with pods) | 1.91/1.5 | 12                  | 12%                   | Peas (with pods) | 1.91/1.5 | 8%                   | 1.91/1.5              | 8.3%                  |
| Pears (sweet) | 2/1               | 12                  | 12%                   | Pelargon | 0.7/0.42               | 7%                  | 7.0/0.42              | 7.5%                  |
| Tomatoes  | 0.30/0.18               | 10                  | 10%                   | Tomatoes  | 0.30/0.18               | 5%                  | 5.0                   |
| Cucumbers | 0.19/0.15               | 9.8                 | 9.8%                  | Cucumbers | 0.19/0.15               | 4%                  | 4.0                   |
| Melon     | 0.06/0.06               | 9.1                 | 9%                    | Melon     | 0.06/0.06               | 3%                  | 3.0                   |
| Sweet peppers/bell peppers | 0.30/0.14 | 8.3     | 8%                    | Sweet peppers/bell peppers | 0.30/0.14 | 3%                  | 3.0                   |

#### Processed commodities

| Commodity | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI | Commodity | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI |
|-----------|--------------------------|---------------------|-----------------------|-----------|--------------------------|---------------------|-----------------------|
| Peaches/canned | 1.50/0.76 | 20                 | 20%                   | Peaches/canned | 1.50/0.76 | 88%                  | 1.50/0.76             | 88%                   |
| Peaches/juice | 0.90/0.59 | 8.1                | 8%                    | Peaches/juice | 0.90/0.59 | 8%                   | 0.90/0.59             | 7.7%                  |
| Peas (with pods)/boiled | 0.50/0.43 | 6.3                | 6%                    | Peas (with pods)/boiled | 0.50/0.43 | 6%                   | 0.50/0.43             | 6.2%                  |
| Peas/juice | 1.50/0.76               | 4.3                 | 4%                    | Peas (with pods)/boiled | 1.50/0.76 | 4%                   | 1.50/0.76             | 4.1%                  |
| Potatoes/fried | 0.01/0.01 | 0.93              | 0.93%                 | Potatoes/fried | 0.01/0.01 | 0.6%                 | 0.01/0.01             | 0.57%                 |
| Apples/juice | 0.50/0.22 | 0.81              | 0.81%                 | Apples/juice | 0.50/0.22 | 0.5%                 | 0.50/0.22             | 0.50%                 |
| Broccoli/boiled | 0.01/0.01 | 0.79              | 0.79%                 | Broccoli/boiled | 0.01/0.01 | 0.4%                 | 0.01/0.01             | 0.42%                 |
| Quinoa/cereal | 0.50/0.25 | 0.76              | 0.76%                 | Quinoa/cereal | 0.50/0.25 | 0.3%                 | 0.50/0.25             | 0.31%                 |
| Cabbage/broccoli | 0.01/0.01 | 0.70              | 0.70%                 | Cabbage/broccoli | 0.01/0.01 | 0.3%                 | 0.01/0.01             | 0.30%                 |
| Plums/juice | 0.70/0.42               | 0.69                | 0.69%                 | Plums/juice | 0.70/0.42               | 0.2%                 | 0.70/0.42             | 0.24%                 |
| Tomatoes/sauce/puree | 0.30/0.07 | 0.67              | 0.67%                 | Tomatoes/sauce/puree | 0.30/0.07 | 0.1%                 | 0.30/0.07             | 0.14%                 |
| Potatoes/dried (flakes) | 0.01/0.01 | 0.59              | 0.59%                 | Potatoes/dried (flakes) | 0.01/0.01 | 0.1%                 | 0.01/0.01             | 0.13%                 |
| Tomatoes/juice | 0.30/0.07 | 0.56              | 0.56%                 | Tomatoes/juice | 0.30/0.07 | 0.08%                 | 0.30/0.07             | 0.08%                 |
| Kale/stems | 0.01/0.01               | 0.28                | 0.28%                 | Kale/bread | 0.01/0.01 | 0.06%                 | 0.01/0.01             | 0.06%                 |

Conclusion: The estimated short term intake (IESTI) exceeded the toxicological reference value for 1 commodities. For processed commodities, no exceedance of the ARfD was identified.

### Results for all crops

| Commodity | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI |
|-----------|--------------------------|---------------------|-----------------------|

#### Results for adults

No of commodities for which ARfD/ADI is exceeded (IESTI): 1

### Unprocessed commodities

| Commodity | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI |
|-----------|--------------------------|---------------------|-----------------------|

#### Processed commodities

| Commodity | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI |
|-----------|--------------------------|---------------------|-----------------------|

Conclusion: The estimated short term intake (IESTI) exceeded the toxicological reference value for 1 commodities.

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

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### Flubendiamide (F)

#### Toxicological reference values

| LOQ (mg/kg) range from: | 0.01 to: 0.01 |
|-------------------------|----------------|

| ADI (mg/kg bw per day): | 0.017 |
|--------------------------|-------|
| ARfD (mg/kg bw): | 0.1 |

| Source of ADI: | EFSA |
|----------------|-------|
| Source of ARfD: | EFSA |

#### EFSA PRIMO revision 3.1; 2019/03/19

Year of evaluation: 2013

#### No of diets exceeding the ADI : ---

| Calculated exposure (% of ADI) | Exposure (µg/kg bw per day) | Highest contributor to MS diet | 2nd contributor to MS diet | 3rd contributor to MS diet | Commodity/group of commodities | MRLs set at the LOQ (in % of ADI) | Commodity/group of commodities | Source of ADI: EFSA |
|-------------------------------|-------------------------------|--------------------------------|---------------------------|-----------------------------|-------------------------------|-------------------------------|-------------------------------|-----------------------------|
| 31% 5.35 16% 6% 4% Table grapes 0.3% 31% | 5.35 16% 6% 4% Table grapes 0.3% 31% | 5.35 16% 6% 4% Table grapes 0.3% 31% | 5.35 16% 6% 4% Table grapes 0.3% 31% | 5.35 16% 6% 4% Table grapes 0.3% 31% | 5.35 16% 6% 4% Table grapes 0.3% 31% | 5.35 16% 6% 4% Table grapes 0.3% 31% | 5.35 16% 6% 4% Table grapes 0.3% 31% | 5.35 16% 6% 4% Table grapes 0.3% 31% |
| 27% 4.56 18% 3% 2% Cherries (sweet) 0.2% 27% | 4.56 18% 3% 2% Cherries (sweet) 0.2% 27% | 4.56 18% 3% 2% Cherries (sweet) 0.2% 27% | 4.56 18% 3% 2% Cherries (sweet) 0.2% 27% | 4.56 18% 3% 2% Cherries (sweet) 0.2% 27% | 4.56 18% 3% 2% Cherries (sweet) 0.2% 27% | 4.56 18% 3% 2% Cherries (sweet) 0.2% 27% | 4.56 18% 3% 2% Cherries (sweet) 0.2% 27% | 4.56 18% 3% 2% Cherries (sweet) 0.2% 27% |
| 16% 2.67 9% 3% 2% Pears 0.2% 16% | 2.67 9% 3% 2% Pears 0.2% 16% | 2.67 9% 3% 2% Pears 0.2% 16% | 2.67 9% 3% 2% Pears 0.2% 16% | 2.67 9% 3% 2% Pears 0.2% 16% | 2.67 9% 3% 2% Pears 0.2% 16% | 2.67 9% 3% 2% Pears 0.2% 16% | 2.67 9% 3% 2% Pears 0.2% 16% | 2.67 9% 3% 2% Pears 0.2% 16% |
| 11% 1.94 3% 2% 2% Apples 0.2% 11% | 1.94 3% 2% 2% Apples 0.2% 11% | 1.94 3% 2% 2% Apples 0.2% 11% | 1.94 3% 2% 2% Apples 0.2% 11% | 1.94 3% 2% 2% Apples 0.2% 11% | 1.94 3% 2% 2% Apples 0.2% 11% | 1.94 3% 2% 2% Apples 0.2% 11% | 1.94 3% 2% 2% Apples 0.2% 11% | 1.94 3% 2% 2% Apples 0.2% 11% |
| 10% 1.66 3% 1% 1% Apples 0.2% 10% | 1.66 3% 1% 1% Apples 0.2% 10% | 1.66 3% 1% 1% Apples 0.2% 10% | 1.66 3% 1% 1% Apples 0.2% 10% | 1.66 3% 1% 1% Apples 0.2% 10% | 1.66 3% 1% 1% Apples 0.2% 10% | 1.66 3% 1% 1% Apples 0.2% 10% | 1.66 3% 1% 1% Apples 0.2% 10% | 1.66 3% 1% 1% Apples 0.2% 10% |

#### Chronic risk assessment: JMPR methodology (IEDI/TMDI)

Conclusions:

- The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
- The long-term intake of residues of flubendiamide (F) is unlikely to present a public health concern.
### Acute risk assessment/children

The acute risk assessment is based on the ARfD. The calculation is based on the large portion of the most critical consumer group.

### Results for children

| Commodity | Highest % of ARfD/ADI | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) | Commodity | Highest % of ARfD/ADI | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) |
|-----------|------------------------|--------------------------|---------------------|-----------|------------------------|--------------------------|---------------------|
| Celeries  | 98%                    | 6.62/2.62                | 98                  | Celeries  | 42%                    | 6.62/2.62                | 42                  |
| Pears     | 82%                    | 0.9/0.59                 | 82                  | Pears     | 27%                    | 0.9/0.59                 | 27                  |
| Peaches   | 72%                    | 1.5/0.76                 | 72                  | Peaches   | 19%                    | 1.5/0.76                 | 19                  |
| Apples    | 59%                    | 0/0.59                   | 59                  | Apples    | 17%                    | 0.9/0.59                 | 17                  |
| Apricots  | 27%                    | 1.5/0.76                 | 27                  | Apricots  | 14%                    | 1.5/0.76                 | 14                  |
| Plums     | 18%                    | 0.7/0.42                 | 18                  | Plums     | 10%                    | 0.7/0.42                 | 10                  |
| Quinces   | 15%                    | 0.9/0.59                 | 15                  | Quinces   | 9%                     | 0.9/0.59                 | 9                   |
| Peas (with pods) | 12%          | 1.5/1.5                  | 12                  | Peas (with pods) | 8%          | 1.5/1.5                  | 8                   |
| Apricots  | 12%                    | 0.9/0.59                 | 12                  | Apricots  | 7%                     | 0.7/0.42                 | 7                   |
| Tomatoes  | 10%                    | 0.3/0.18                 | 10                  | Tomatoes  | 5%                     | 0.3/0.18                 | 5                   |
| Cucumbers | 10%                    | 0.15/0.76                | 9.8                 | Cucumbers | 4%                     | 0.15/0.76                | 4                   |
| Melons    | 9%                     | 0.06/0.59                | 9.1                 | Melons    | 4%                     | 0.06/0.59                | 4                   |
| Sweet peppers / bell peppers | 8% | 0.3/0.14 | 8.3 | Sweet peppers / bell peppers | 4% | 0.3/0.14 | 4 |
| Medlar    | 8%                     | 0.09/0.59                | 8.2                 | Medlar    | 3%                     | 0.09/0.59                | 3                   |

### Results for adults

| Commodity | Highest % of ARfD/ADI | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) | Commodity | Highest % of ARfD/ADI | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) |
|-----------|------------------------|--------------------------|---------------------|-----------|------------------------|--------------------------|---------------------|
| Peaches/canned | 20%          | 1.5/0.76 | 20 | Peaches/canned | 88%      | 1.5/0.76 | 88 |
| Pears/boiled | 8%          | 0.9/0.59 | 8.1 | Pears/boiled | 8%      | 0.9/0.59 | 8 |
| Beans (with pods) | 6%          | 0.5/0.5 | 5.3 | Beans (with pods) | 6% | 0.5/0.5 | 6 |
| Peaches/juice | 4%          | 1.5/0.26 | 4.3 | Peaches/juice | 4%    | 1.5/0.26 | 4 |
| Apple/juice | 0.9/0.22 | 0.92 | 0.5 | Apple/juice | 5%     | 0.9/0.22 | 0.5 |
| Broccoli/juice | 0.1/0.01 | 0.79 | 0.4 | Broccoli/juice | 0.4%  | 0.1/0.01 | 0.4 |
| Quinces/jam | 0.05/0.25 | 0.76 | 0.3% | Quinces/jam | 0.3%   | 0.05/0.25 | 0.3 |
| Cauliflowers / boiled | 0.7% | 1.5/0.03 | 1.5 | Cauliflowers / boiled | 0.7% | 1.5/0.03 | 1.5 |
| Tomatoes/australian puree | 0.8% | 0.3/0.07 | 0.6% | Tomatoes/australian puree | 0.8% | 0.3/0.07 | 0.6 |
| Potatoes/boiled | 0.6% | 0.05/0.05 | 0.5% | Potatoes/boiled | 0.6% | 0.05/0.05 | 0.5 |
| Potatoes/australian puree | 0.6% | 0.05/0.05 | 0.5% | Potatoes/australian puree | 0.6% | 0.05/0.05 | 0.5 |
| Tomatoes/puree / juice | 0.6% | 0.05/0.05 | 0.5% | Tomatoes/puree / juice | 0.6% | 0.05/0.05 | 0.5 |

### Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)

| Commodity | Highest % of ARfD/ADI | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) |
|-----------|------------------------|--------------------------|---------------------|
| Peaches/canned | 20%          | 1.5/0.76 | 20
| Pears/boiled | 8%          | 0.9/0.59 | 8.1
| Beans (with pods) | 6%          | 0.5/0.5 | 5.3
| Peaches/juice | 4%          | 1.5/0.26 | 4.3
| Apple/juice | 0.9/0.22 | 0.92 | 0.5
| Broccoli/juice | 0.1/0.01 | 0.79 | 0.4
| Quinces/jam | 0.05/0.25 | 0.76 | 0.3
| Cauliflowers / boiled | 0.7% | 1.5/0.03 | 1.5
| Tomatoes/australian puree | 0.8% | 0.3/0.07 | 0.6
| Potatoes/boiled | 0.6% | 0.05/0.05 | 0.5
| Potatoes/australian puree | 0.6% | 0.05/0.05 | 0.5
| Tomatoes/puree / juice | 0.6% | 0.05/0.05 | 0.5

### Conclusion:

No exceedance of the toxicological reference value was identified for any unprocessed commodity. A short term intake of residues of flubendiamide (F) is unlikely to present a public health risk. For processed commodities, no exceedance of the ARfD/ADI was identified.

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Review of the existing MRLs for flubendiamide

Flubendiamide (F)

| Toxicological reference values |
|--------------------------------|
| LOQ (mg/kg)                  | 0.01 |
| MRL (mg/kg)                  | 0.1 |

Source of MRL: EFSA

In鳅u values

Flubendiamide (F)

LOQs (mg/kg) range from: 0.01 to: 0.1

Details – chronic risk

ADI (mg/kg bw per day): 0.1

Details – acute risk

ARfD (mg/kg bw per day): 2013

Source of ADI: EFSA

Year of evaluation: EFSA PRIMo revision 3.1; 2019/03/19

Comments:

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

| Commodity/ group of commodities | 3rd contributor to MS | 2nd contributor to MS | Highest contributor to Exposure (in % of ADI) |
|---------------------------------|-----------------------|-----------------------|--------------------------------------------|
| Milk:  Cattle                   | 63%                   | 10.79                 | 23%                                        |
| Diet                            |                       |                       |                                             |
| NL toddler                      | 35%                   | 6.98                  | 18%                                        |
| IE adult                        | 32%                   | 5.48                  | 9%                                         |
| NL child                        | 32%                   | 5.46                  | 9%                                         |
| UK child                        | 27%                   | 4.57                  | 7%                                          |
| GENMo/FoodG06                   | 27%                   | 4.53                  | 7%                                          |
| GENMo/FoodG07                   | 25%                   | 4.28                  | 5%                                          |
| RR closed 3 15 y                | 24%                   | 4.06                  | 11%                                         |
| GENMo/FoodG08                   | 22%                   | 3.63                  | 8%                                          |
| DE women ages 14-60 y           | 22%                   | 3.74                  | 7%                                          |
| RO general                      | 22%                   | 3.73                  | 7%                                          |
| GENMo/FoodG10                   | 22%                   | 3.70                  | 4%                                          |
| 21% DC general                  | 3.63                  | 3%                    |                                             |
| 21% UK toddler                  | 3.59                  | 3%                    |                                             |
| 18% SE general                  | 3.11                  | 3%                    |                                             |
| 18% IC child                    | 3.10                  | 3%                    |                                             |
| 18% NL general                  | 3.08                  | 3%                    |                                             |
| 18% UK preteen                  | 2.79                  | 7%                    |                                             |
| 16% UC adult                    | 2.74                  | 7%                    |                                             |
| 16% UC child                    | 2.68                  | 5%                    |                                             |
| 15% PT general                  | 2.61                  | 6%                    |                                             |
| 15% IC adult                    | 2.53                  | 3%                    |                                             |
| 13% CI adult                    | 2.22                  | 7%                    |                                             |
| 12% IT adult                    | 1.96                  | 4%                    |                                             |
| 11% IT toddler                  | 1.93                  | 3%                    |                                             |
| 9% LT adult                     | 1.52                  | 3%                    |                                             |
| 9% Ps general                   | 1.46                  | 3%                    |                                             |
| 7% Fl-3 y                       | 1.05                  | 1%                    |                                             |
| 5% Fl adult                     | 0.91                  | 1%                    |                                             |
| 5% Fl-Y                        | 0.87                  | 0.9%                  |                                             |
| 4% IE child                     | 0.86                  | 1%                    |                                             |

Calculations:

The extraneous long-term dietary intake (TMDI/IEDI/EDED) was below the ADI.

The acute intake of residues of flubendiamide (F) is unlikely to present a public health concern.

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The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

### Acute Risk Assessment

#### Results for Children

| Commodity              | MRL/Input for RA (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI |
|------------------------|--------------------------|---------------------|-----------------------|
| Cauliflowers           | 4.27                     | 196                 | 156%                  |
| Lettuces               | 7.4                      | 152                 | 152%                  |
| Kohlrabies             | 4.27                     | 140                 | 140%                  |
| Head cabbages          | 4.27                     | 119                 | 119%                  |
| Broccoli               | 4.27                     | 112                 | 112%                  |
| Celeries               | 62.62                    | 98                  | 98%                   |
| Peaches                | 2.1                      | 95                  | 95%                   |
| Pears                  | 0.9059                   | 82                  | 82%                   |
| Apples                 | 0.9059                   | 64                  | 64%                   |
| Table grapes           | 20.81                    | 59                  | 59%                   |
| Plums                  | 2.1                      | 42                  | 42%                   |
| Tomatoes               | 20.63                    | 37                  | 37%                   |
| Tea (dried leaves)     | 50/23                    | 35                  | 35%                   |
| Brussels sprouts       | 4.27                     | 23                  | 23%                   |

#### Results for Adults

| Commodity              | MRL/Input for RA (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI |
|------------------------|--------------------------|---------------------|-----------------------|
| Head cabbages          | 42.7                     | 114                 | 114%                  |
| Cauliflowers           | 42.7                     | 64                  | 64%                   |
| Kohlrabies             | 42.7                     | 63                  | 63%                   |
| Lettuices              | 71                      | 49                  | 49%                   |
| Broccoli               | 62.62                    | 42                  | 42%                   |
| Celeries               | 42.7                     | 38                  | 38%                   |
| Peaches                | 2.1                      | 27                  | 27%                   |
| Pears                  | 2.1                      | 19                  | 19%                   |
| Peaches                | 2.1                      | 19                  | 19%                   |
| Table grapes           | 0.9059                   | 18                  | 18%                   |
| Plums                  | 2.1                      | 18                  | 18%                   |
| Apples                 | 0.9059                   | 17                  | 17%                   |
| Pears (dried leaves)   | 50/23                    | 16                  | 16%                   |
| Brussels sprouts       | 4.27                     | 11                  | 11%                   |

### Processed Commodities

#### Results for Children

| Commodity              | MRL/Input for RA (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI |
|------------------------|--------------------------|---------------------|-----------------------|
| Broccoli/boiled        | 4.27                     | 213                 | 213%                  |
| Cauliflowers/boiled    | 4.27                     | 188                 | 188%                  |
| Peaches/canned         | 2.1                      | 26                  | 26%                   |
| Beans (with pods)/boiled | 2.1                     | 11                  | 11%                   |
| Peaches/juice          | 20.59                    | 9.8                 | 9.8%                  |
| Pears/juice            | 0.9025                   | 8.1                 | 8.1%                  |
| Tea (dried leaves)     | 50/23                    | 8.1                 | 8.1%                  |
| Pumpkins/boiled        | 20/09                    | 8.0                 | 8.0%                  |
| Plums/juice            | 20.59                    | 5.6                 | 5.6%                  |
| Lentils/boiled         | 10/59                    | 4.8                 | 4.8%                  |
| Peas (with pods)/canned | 15/24                   | 4.2                 | 4.2%                  |
| Peas (without pods)/canned | 20/43                 | 3.4                 | 3.4%                  |
| Tomatoes/sauce/puree   | 20.35                    | 3.3                 | 3.3%                  |
| Courgettes/boiled      | 0.20/09                  | 2.0                 | 2.0%                  |

#### Results for Adults

| Commodity              | MRL/Input for RA (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI |
|------------------------|--------------------------|---------------------|-----------------------|
| Cauliflowers/boiled    | 42.7                     | 112                 | 112%                  |
| Broccoli/boiled        | 42.7                     | 65                 | 65%                   |
| Kohlrabies/boiled      | 42.7                     | 57                 | 57%                   |
| Lettuices/boiled       | 71                      | 44                 | 44%                   |
| Pears/boiled           | 2.1                      | 19                 | 19%                   |
| Pears (dried leaves)   | 50/23                    | 16                 | 16%                   |
| Brussels sprouts/boiled | 4.27                    | 11                 | 11%                   |

### Conclusion

The estimated short term intake (ESTI) exceeded the toxicological reference value for 5 commodities. For processed commodities, the toxicological reference value was exceeded in one or several cases.
Review of the existing MRLs for flubendiamide

#### Flubendiamide (F)

![Image](45x80 to 134x216)

**Toxicological reference values**

- **ADI (mg/kg bw per day):** 0.017
- **ARfD (mg/kg bw):** 0.1

**Details – chronic risk assessment**

- *Input values*
  - **Flubendiamide (F):** 0.01
  - **LOQs (mg/kg) range from:** 0.01 to:

**Details – acute risk assessment**

- **Supplementary results – chronic risk assessment**
- **Supplementary results – acute risk assessment/children**
- **Supplementary results – acute risk assessment/adults**

**Input values**

- **EFSA Source of ADI:** 2013
- **Year of evaluation:** 2013
- **EFSA PRIMo revision 3.1; 2019/03/19**

**Normal mode**

**Chronic risk assessment: JMPR methodology (IEDI/TMDI)**

| Commodity/diet | No of diets exceeding the ADI | Exposure leading to ADI (µg/kg bw per day) | Highest contributor to MS | 2nd contributor to MS | 3rd contributor to MS | % of ADI | % of ADI | % of ADI |
|----------------|-----------------------------|------------------------------------------|--------------------------|----------------------|----------------------|---------|---------|---------|
| FLU (mg/kg) range from | E 67 | E 07 | E 01 | FLU (mg/kg) | LOQs (mg/kg) | Source of ADI | EFSA | Source of ADI | EFSA |
| FLU (mg/kg) | LOQs (mg/kg) | Source of ADI | EFSA | Source of ADI | EFSA | Normal mode | Chronic risk assessment: JMPR methodology (IEDI/TMDI) | Chronic risk assessment: JMPR methodology (IEDI/TMDI) | Chronic risk assessment: JMPR methodology (IEDI/TMDI) | Chronic risk assessment: JMPR methodology (IEDI/TMDI) |
| FLU (mg/kg) | LOQs (mg/kg) | Source of ADI | EFSA | Source of ADI | EFSA | Normal mode | Chronic risk assessment: JMPR methodology (IEDI/TMDI) | Chronic risk assessment: JMPR methodology (IEDI/TMDI) | Chronic risk assessment: JMPR methodology (IEDI/TMDI) | Chronic risk assessment: JMPR methodology (IEDI/TMDI) |
| FLU (mg/kg) | LOQs (mg/kg) | Source of ADI | EFSA | Source of ADI | EFSA | Normal mode | Chronic risk assessment: JMPR methodology (IEDI/TMDI) | Chronic risk assessment: JMPR methodology (IEDI/TMDI) | Chronic risk assessment: JMPR methodology (IEDI/TMDI) | Chronic risk assessment: JMPR methodology (IEDI/TMDI) |
| FLU (mg/kg) | LOQs (mg/kg) | Source of ADI | EFSA | Source of ADI | EFSA | Normal mode | Chronic risk assessment: JMPR methodology (IEDI/TMDI) | Chronic risk assessment: JMPR methodology (IEDI/TMDI) | Chronic risk assessment: JMPR methodology (IEDI/TMDI) | Chronic risk assessment: JMPR methodology (IEDI/TMDI) |
| FLU (mg/kg) | LOQs (mg/kg) | Source of ADI | EFSA | Source of ADI | EFSA | Normal mode | Chronic risk assessment: JMPR methodology (IEDI/TMDI) | Chronic risk assessment: JMPR methodology (IEDI/TMDI) | Chronic risk assessment: JMPR methodology (IEDI/TMDI) | Chronic risk assessment: JMPR methodology (IEDI/TMDI) |

**Conclusion:**

The estimated long-term intake (TMDI/NEEDI/WHOEDI) was below the ADI.

The long-term intake of residues of flubendiamide (F) is unlikely to present a public health concern.
The acute risk assessment is based on the ARfD. The calculation is based on the large portion of the most critical consumer group.

### Show results for all crops

#### Results for children

| Commodity | MRL/Input for RA (mg/kg) | Exposure (µg/kg bw) | % of ARfD/ADI | Commodity | MRL/Input for RA (mg/kg) | Exposure (µg/kg bw) |
|-----------|--------------------------|---------------------|---------------|-----------|--------------------------|---------------------|
| Cauliflowers | 0.01/2.7 | 156 | 156% | Broccoli | 0.01/2.7 | 64 |
| Broccoli | 0.01/2.7 | 112 | 112% | Cauliflowers | 0.01/2.7 | 63 |
| Celeries | 6/2.62 | 98 | 98% | Celeries | 6/2.62 | 42 |
| Peaches | 2/1 | 95 | 95% | Table grapes | 20.81 | 27 |
| Pears | 0.90/0.59 | 62 | 62% | Pears | 0.90/0.59 | 19 |
| Apples | 0.90/0.59 | 64 | 64% | Peaches | 2/1 | 19 |
| Table grapes | 20.81 | 59 | 59% | Pears | 0.90/0.59 | 18 |
| Plums | 2/1 | 42 | 42% | Plums | 2/1 | 18 |
| Tomatoes | 20.83 | 37 | 37% | Apples | 0.90/0.59 | 17 |
| Tea (dried leaves of Camellia) | 50/23 | 35 | 35% | Brussels sprouts | 4/2.7 | 16 |
| Apricots | 2/1 | 35 | 35% | Tea (dried leaves of Camellia) | 50/23 | 12 |
| Brussels sprouts | 4/2.7 | 23 | 23% | Apricots | 2/1 | 11 |
| Sweet peppers/bell peppers | 0.70/0.37 | 22 | 22% | Brussels sprouts | 4/2.7 | 8.0 |
| Quinces | 0.90/0.59 | 15 | 15% | Tomatoes | 20.83 | 10.0 |
| Melons | 0.20/0.09 | 14 | 14% | Quinces | 0.90/0.59 | 5.0 |

#### Results for adults

| Commodity | MRL/Input for RA (mg/kg) | Exposure (µg/kg bw) | % of ARfD/ADI | Commodity | MRL/Input for RA (mg/kg) | Exposure (µg/kg bw) |
|-----------|--------------------------|---------------------|---------------|-----------|--------------------------|---------------------|
| Cauliflowers | 0.01/2.7 | 156 | 156% | Broccoli | 0.01/2.7 | 64 |
| Broccoli | 0.01/2.7 | 112 | 112% | Cauliflowers | 0.01/2.7 | 63 |
| Celeries | 6/2.62 | 98 | 98% | Celeries | 6/2.62 | 42 |
| Peaches | 2/1 | 95 | 95% | Table grapes | 20.81 | 27 |
| Pears | 0.90/0.59 | 62 | 62% | Pears | 0.90/0.59 | 19 |
| Apples | 0.90/0.59 | 64 | 64% | Peaches | 2/1 | 19 |
| Table grapes | 20.81 | 59 | 59% | Pears | 0.90/0.59 | 18 |
| Plums | 2/1 | 42 | 42% | Plums | 2/1 | 18 |
| Tomatoes | 20.83 | 37 | 37% | Apples | 0.90/0.59 | 17 |
| Tea (dried leaves of Camellia) | 50/23 | 35 | 35% | Brussels sprouts | 4/2.7 | 16 |
| Apricots | 2/1 | 35 | 35% | Tea (dried leaves of Camellia) | 50/23 | 12 |
| Brussels sprouts | 4/2.7 | 23 | 23% | Apricots | 2/1 | 11 |
| Sweet peppers/bell peppers | 0.70/0.37 | 22 | 22% | Brussels sprouts | 4/2.7 | 8.0 |
| Quinces | 0.90/0.59 | 15 | 15% | Tomatoes | 20.83 | 10.0 |
| Melons | 0.20/0.09 | 14 | 14% | Quinces | 0.90/0.59 | 5.0 |

### Conclusion

The estimated short term intake (IESTI) exceeded the toxicological reference value for 2 commodities.

For processed commodities, the toxicological reference value was exceeded in one or several cases.
## 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                |
| Coconut, meal (a)               | 0.02                  | STMR x default PF (1.5)| 0.02                | STMR x default PF (1.5)|
| Apple, pomace, wet              | 0.89                  | STMR x PF (3.56)       | 0.89                | STMR x PF (3.56)       |
| Soyabean, seed                  | 0.03                  | STMR                  | 0.03                | STMR                   |
| Soyabean, meal                  | 0.00                  | STMR x PF (0.12)      | 0.00                | STMR x PF (0.12)      |
| Soyabean, hulls                 | 0.08                  | STMR x PF (2.8)       | 0.08                | STMR x PF (2.8)       |
| Cotton, undelinted seed         | 0.15                  | STMR                  | 0.15                | STMR                   |
| Cotton, meal                    | 0.00                  | STMR x PF (0.02)      | 0.00                | STMR x PF (0.02)      |
| Corn, field (Maize), grain      | 0.01*                 | STMR                  | 0.01*               | STMR                   |
| Corn, pop, grain                | 0.01*                 | STMR                  | 0.01*               | STMR                   |
| Corn, field, milled by-pdts (b)| 0.02                  | STMR                  | 0.02                | STMR                   |
| Corn, field, hominy meal (b)    | 0.01*                 | STMR                  | 0.01*               | STMR                   |
| Corn, field, distiller’s grain (dry) (b) | 0.01* | STMR | 0.01* | STMR |
| Corn, field, gluten feed (b)    | 0.01*                 | STMR                  | 0.01*               | STMR                   |
| Corn, field, gluten, meal (b)   | 0.01*                 | STMR                  | 0.01*               | STMR                   |
| Rice, bran/pollard              | 0.03                  | STMR x PF (0.75)      | 0.03                | STMR x PF (0.75)      |

**Risk assessment residue definition:** flubendiamide

STMR: supervised trials median residue; HR: highest residue; PF: processing factor.

* Indicates that the input value is proposed at the limit of quantification.

(a): In the absence of processing factors supported by data, a default processing factor was included in the calculation to consider the potential concentration of residues in this commodity.

(b): For processed commodities from corn, no processing factor was applied because flubendiamide residues are expected to be below the LOQ. Concentration of residues in these commodities is therefore not expected.

### D.2. Consumer risk assessment without consideration of the existing CXLs

| Commodity                      | Chronic risk assessment | Acute risk assessment |
|--------------------------------|-------------------------|-----------------------|
|                                | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment               |
| Risk assessment residue definition: flubendiamide |                         |                       |                       |                       |
| Tree nuts                      | 0.02                    | STMR                  | 0.05                 | HR                    |
| Pome fruits                    | 0.25                    | STMR                  | 0.59                 | HR                    |
| Apricots                       | 0.26                    | STMR                  | 0.76                 | HR                    |
| Cherries (sweet)               | 0.59                    | STMR                  | 1                    | HR                    |
| Peaches                        | 0.26                    | STMR                  | 0.76                 | HR                    |
| Plums                          | 0.07                    | STMR                  | 0.42                 | HR                    |
| Table grapes                   | 0.42                    | STMR                  | 0.81                 | HR                    |
| Wine grapes                    | 0.42                    | STMR                  | 0.81                 | HR                    |
| Commodity                          | Chronic risk assessment | Acute risk assessment |
|-----------------------------------|-------------------------|-----------------------|
|                                   | Input value (mg/kg)     | Comment               | Input value (mg/kg)     | Comment               |
| Potatoes                          | 0.01*                   | EU MRL                | 0.01*                   | EU MRL                |
| Tomatoes                          | 0.07                    | STMR                  | 0.18                    | HR                    |
| Sweet peppers/bell peppers        | 0.05                    | STMR                  | 0.14                    | HR                    |
| Cucumbers                         | 0.15                    | EU MRL                | 0.15                    | EU MRL                |
| Melons                            | 0.06                    | EU MRL                | 0.06                    | EU MRL                |
| Sweet corn                        | 0.01*                   | STMR                  | 0.01*                   | HR                    |
| Broccoli                          | 0.01*                   | EU MRL                | 0.01*                   | EU MRL                |
| Cauliflowers                      | 0.01*                   | EU MRL                | 0.01*                   | EU MRL                |
| Chinese cabbages/pe-tsai          | 0.01*                   | EU MRL                | 0.01*                   | EU MRL                |
| Kales                             | 0.01*                   | EU MRL                | 0.01*                   | EU MRL                |
| Lettuces                          | 1.06/-                  | EU1: STMR/EU2: –      | 5.89/-                  | EU1: HR/EU2: –        |
| Beans (with pods)                 | 0.5                     | EU MRL                | 0.5                     | EU MRL                |
| Peas (with pods)                  | 1.5                     | EU MRL                | 1.5                     | EU MRL                |
| Celeries                          | 1.7                     | STMR                  | 2.62                    | HR                    |
| Soyabeans                         | 0.03                    | STMR                  | 0.03                    | STMR                  |
| Cotton seeds                      | 0.15                    | STMR                  | 0.15                    | STMR                  |
| Maize/corn                        | 0.01*                   | STMR                  | 0.01*                   | STMR                  |
| Rice                              | 0.04                    | STMR                  | 0.04                    | STMR                  |
| Tea (dried leaves of Camellia sinensis) | 0.02                | EU MRL                | 0.02                    | EU MRL                |

Risk assessment residue definition 2: Sum of flubendiamide and flubendiamide-iodo-phthalimide, expressed as flubendiamide

| Commodity                          | Input value (mg/kg)     | Comment             | Input value (mg/kg)     | Comment             |
|-----------------------------------|-------------------------|---------------------|-------------------------|---------------------|
| Bovine, equine: Muscle/meat        | 0.002                   | 0.8 × STMR muscle + 0.2 × STMR fat | 0.0024                   | 0.8 × HR muscle + 0.2 × HR fat |
| Bovine, equine: Fat tissue         | 0.006                   | STMR                | 0.008                    | HR                  |
| Bovine, equine: Liver              | 0.004                   | STMR                | 0.006                    | HR                  |
| Bovine, equine: Kidney             | 0.005                   | STMR                | 0.006                    | HR                  |
| Sheep, goat: Muscle/meat           | 0.002                   | 0.8 × STMR muscle + 0.2 × STMR fat | 0.0022                   | 0.8 × HR muscle + 0.2 × HR fat |
| Sheep, goat: Fat tissue            | 0.006                   | STMR                | 0.007                    | HR                  |
| Sheep, goat: Liver                 | 0.004                   | STMR                | 0.005                    | HR                  |
| Sheep, goat: Kidney                | 0.004                   | STMR                | 0.005                    | HR                  |
| Milk: Cattle, sheep, goat, horse   | 0.001                   | STMR                | 0.001                    | STMR                |

*: Indicates that the input value is proposed at the limit of quantification.
D.3. Consumer risk assessment with consideration of the existing CXLs

| Commodity                  | Chronic risk assessment | Acute risk assessment |
|----------------------------|-------------------------|-----------------------|
|                            | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment               |
| Tree nuts                  | 0.02 STMR (CXL)         |                       | 0.05 HR (CXL)       |
| Pome fruits                | 0.25 STMR               |                       | 0.59 HR             |
| Apricots                   | 0.59 STMR (CXL)         |                       | 1 HR (CXL)          |
| Cherries (sweet)           | 0.59 STMR (CXL)         |                       | 1 HR (CXL)          |
| Peaches                    | 0.59 STMR (CXL)         |                       | 1 HR (CXL)          |
| Plums                      | 0.59 STMR (CXL)         |                       | 1 HR (CXL)          |
| Table grapes               | 0.42 STMR (CXL)         |                       | 0.81 HR (CXL)       |
| Wine grapes                | 0.42 STMR (CXL)         |                       | 0.81 HR (CXL)       |
| Tomatoes                   | 0.35 STMR (CXL)         |                       | 0.63 HR (CXL)       |
| Sweet peppers/bell peppers| 0.09 STMR (CXL)         |                       | 0.37 HR (CXL)       |
| Cucumbers                  | 0.05 STMR (CXL)         |                       | 0.09 HR (CXL)       |
| Gherkins                   | 0.05 STMR (CXL)         |                       | 0.09 HR (CXL)       |
| Courgettes                 | 0.05 STMR (CXL)         |                       | 0.09 HR (CXL)       |
| Melons                     | 0.05 STMR (CXL)         |                       | 0.09 HR (CXL)       |
| Pumpkins                   | 0.05 STMR (CXL)         |                       | 0.09 HR (CXL)       |
| Watermelons                | 0.05 STMR (CXL)         |                       | 0.09 HR (CXL)       |
| Sweet corn                 | 0.01* STMR (CXL)        |                       | 0.01* HR (CXL)      |
| Broccoli                   | 0.35/0.01* CX1: STMR (CXL)/CX2: EU MRL | 2.7/0.01* CX1: HR (CXL)/CX2: EU MRL |
| Cauliflowes                | 0.35/0.01* CX1: STMR (CXL)/CX2: EU MRL | 2.7/0.01* CX1: HR (CXL)/CX2: EU MRL |
| Brussels sprouts           | 0.35 STMR (CXL)         |                       | 2.7 HR (CXL)        |
| Head cabbages              | 0.35/0.01* CX1: STMR (CXL)/CX2: EU MRL | 2.7/0.01* CX1: HR (CXL)/CX2: EU MRL |
| Kohlrabies                 | 0.35/– CX1: STMR (CXL)/CX2: – | 2.7/– CX1: HR (CXL)/CX2: – |
| Lettuces                   | 1.7/– CX1: STMR (CXL)/CX2: – | 4/– CX1: HR (CXL)/CX2: – |
| Beans (with pods)          | 0.43 CX1: STMR (CXL)    |                       | 0.9 HR (CXL)        |
| Beans (without pods)       | 0.43 STMR (CXL)         |                       | 0.9 HR (CXL)        |
| Peas (with pods)           | 0.43 STMR (CXL)         |                       | 0.9 HR (CXL)        |
| Peas (without pods)        | 0.43 STMR (CXL)         |                       | 0.9 HR (CXL)        |
| Lentils (fresh)            | 0.43 STMR (CXL)         |                       | 0.9 HR (CXL)        |
| Celeries                   | 1.7 STMR                |                       | 2.62 HR             |
| Beans                      | 0.18 STMR (CXL)         |                       | 0.59 HR (CXL)       |
| Lentils                    | 0.18 STMR (CXL)         |                       | 0.59 HR (CXL)       |
| Peas                       | 0.18 STMR (CXL)         |                       | 0.59 HR (CXL)       |
| Lupins/lupini beans        | 0.18 STMR (CXL)         |                       | 0.59 HR (CXL)       |
| Soyabeans                  | 0.03 STMR               |                       | 0.03 STMR           |
| Cotton seeds               | 0.15 STMR               |                       | 0.15 STMR           |
| Maize/corn                 | 0.01 STMR               |                       | 0.01 STMR           |
| Rice                       | 0.04 STMR               |                       | 0.04 STMR           |

Risk assessment residue definition: flubendiamide
Review of the existing MRLs for flubendiamide

| Commodity                        | Chronic risk assessment | Acute risk assessment |
|----------------------------------|-------------------------|-----------------------|
|                                  | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment               |
| Tea (dried leaves of Camellia sinensis) | 23                      | STMR (CXL)            | 23                  | STMR (CXL)            |

**Risk assessment residue definition 2**: Sum of flubendiamide and flubendiamide-iodo-phthalimide, expressed as flubendiamide

| Commodity                        | Chronic risk assessment | Acute risk assessment |
|----------------------------------|-------------------------|-----------------------|
| Bovine, equine, sheep, goat:     | 0.06 0.8 × STMR (CXL)   | 0.13 0.8 × HR (CXL)   |
| Muscle/meat                      | muscle + 0.2 × STMR (CXL) fat | muscle + 0.2 × HR (CXL) fat |
| Bovine, equine, sheep, goat:     | 0.62 STMR (CXL)         | 1.2 HR (CXL)          |
| Fat tissue                       |                         |                       |
| Bovine, equine, sheep, goat:     | 0.32 STMR (CXL)         | 0.57 HR (CXL)         |
| Liver                            |                         |                       |
| Bovine, equine, sheep, goat:     | 0.32 STMR (CXL)         | 0.57 HR (CXL)         |
| Kidney                           |                         |                       |
| Milk: Cattle, sheep, goat, horse | 0.07 STMR (CXL)         | 0.07 STMR (CXL)       |

*: Indicates that the input value is proposed at the limit of quantification.
Appendix E – Decision tree for deriving MRL recommendations

Evaluation of the GAPs and available residues data at EU level

- GAP or DB > 0.1 mg/kg GM in EU
  - Yes
    - MRL and RA derived in Section 3?
      - Yes
        - MRL fully supported by data?
          - Yes
          - No
      - No
    - No
- No

Consumer risk assessment for GAPs evaluated at EU level – EU scenarios

- Not considered for the RA.
- Not considered for the RA.
- Current EU MRL is included in the RA.
- Tentative median/highest values are included in the RA.
- Median/highest values are included in the RA.

- Risk identified?
  - Yes
    - Risk identified?
      - Yes
        - Fall-back MRL available?
          - Yes
          - No
      - No
    - No

Recommendations resulting from EU authorisations and import tolerances

- Specific LOQ or default MRL?
- Specific LOQ or default MRL?
- Specific LOQ or default MRL?
- Specific LOQ or default MRL?
- Specific LOQ or default MRL?
- Specific LOQ or default MRL?
- Specific LOQ or default MRL?
- MRL is recommended.

Comparison with CILOs
Comparison of the EU recommendation with the existing CXL

- CXL available?
  - Yes
    - RD comparable?
      - Yes
        - CXL higher?
          - Yes
            - Result EU assessment
          - No
            - Input values for the RA remain unchanged.
        - No
          - CXL supported by data?
            - Yes
              - CXL is included in the RA.
            - No
              - Risk identified?
                - Yes
                  - Consumer risk assessment with consideration of the existing CXL
                - No
                  - Risk identified?
                    - Yes
                      - Recommendations with consideration of the existing CXL
                    - No
                      - Recommendations with consideration of the existing CXL

- CXL available?
  - No
    - CXL higher?
      - Yes
        - Result EU assessment
      - No
        - Input values for the RA remain unchanged.

Consumer risk assessment with consideration of the existing CXL

- CXL supported by data?
  - Yes
    - CXL is included in the RA.
  - No
    - Risk identified?
      - Yes
        - Recommendations with consideration of the existing CXL
      - No
        - Recommendations with consideration of the existing CXL

Recommendations with consideration of the existing CXL

- CXL higher?
  - Yes
    - Maintain EU recommendation; higher CXL is not safe for consumer.
  - No
    - Maintain current CXL or EU recommendation; higher CXL is not safe for consumer.

Maintain EU recommendation indicating that no CXL is available.
Maintain EU recommendation indicating CXL is not compatible.
Maintain EU recommendation indicating that CXL is covered.
Maintain current CXL or EU recommendation; higher CXL is not safe for consumer.
Maintain EU recommendation; higher CXL is not safe for consumer.
CXL is recommended; EU recommendation is covered as well.
### Appendix F – Used compound codes

| Code/trivial name<sup>(a)</sup> | IUPAC name/SMILES notation/InChiKey<sup>(b)</sup> | Structural formula<sup>(c)</sup> |
|-------------------------------|-----------------------------------------------|-------------------------------|
| flubendiamide NNI-0001        | 3-iodo-N′-(2-mesityl-1,1-dimethyl-ethyl)-N-[4-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]-α-tolyl]-phthalamide | ![Structural formula](image1) |
| flubendiamide-des-iodo (NNI-0001-des-iodo) | N<sup>1</sup>-[4-(1,1,1,2,3,3,3-heptafluoropropan-2-yl)-2-methylphenyl]-N<sup>2</sup>-[1-(methanesulfonyl)-2-methylpropan-2-yl]benzene-1,2-dicarboxamide | ![Structural formula](image2) |
| flubendiamide -iodo-phthalimide (NNI-0001-iodo-phthalimide) | 2-[4-(1,1,1,2,3,3,3-heptafluoropropan-2-yl)-2-methylphenyl]-4-iodo-1H-isindole-1,3(2H)-dione | ![Structural formula](image3) |

<sup>(a)</sup>: The metabolite name in bold is the name used in the conclusion.

<sup>(b)</sup>: ACD/Name 2019.1.1 ACD/Labs 2019 Release (File version N05E41, Build 110555, 18 July 2019).

<sup>(c)</sup>: ACD/ChemSketch 2019.1.1 ACD/Labs 2019 Release (File version C05H41, Build 110712, 24 July 2019).