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Setting of import tolerances for flubendiamide in apricots, peaches, nectarines, plums and soya beans

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Bayer CropScience AG submitted a request to the competent national authority in Greece to set import tolerances for the active substance flubendiamide in apricots, peaches, nectarines, plums and soya beans. The data submitted in support of the request were found to be sufficient to derive maximum residue level (MRL) proposals for apricots, peaches/nectarines, plums. For soya beans, further risk management considerations are required to decide the import tolerance to be set. Adequate analytical methods for enforcement are available to control the residues of flubendiamide in plant matrices. Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of residues resulting from the use of flubendiamide according to the reported agricultural practices is unlikely to present a risk to consumer health.

Keywords: flubendiamide, apricot, peach, nectarine, plum, soya bean, pesticide, MRL, consumer risk assessment

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, Bayer CropScience AG submitted an application to the competent national authority in Greece (evaluating Member State, EMS) to set import tolerances for the active substance flubendiamide in apricot, peach, nectarine, plum and soya bean. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 5 September 2016.

EFSA identified points which needed further clarification, which was requested from the EMS. The EMS provided the requested clarification and submitted an updated evaluation report to EFSA on 1 October 2017, which replaced the previously submitted evaluation report. The EMS proposed to establish maximum residue levels (MRLs) for apricots, peaches, nectarines, plums and soya beans imported from the USA at the level of 1.5 mg/kg for apricots, peaches and nectarines; 0.8 mg/kg for plums and 0.25 mg/kg for soya beans. In the USA, the MRLs are set at the level of 1.6 mg/kg for stone fruit and 0.25 mg/kg in soya beans.

EFSA based its assessment on the updated evaluation report submitted by the EMS, the draft assessment report (DAR) (and its addendum) prepared under Council Directive 91/414/EEC, the Commission review report on flubendiamide, the conclusion on the peer review of the pesticide risk assessment of the active substance flubendiamide, the Joint Meeting on Pesticide Residues (JMPR) evaluation report as well as the conclusions from previous EFSA opinions on flubendiamide.

The metabolism of flubendiamide following either spray application or direct foliar application was investigated in crops belonging to the groups of fruit crops, leafy vegetables and cereals.

Studies investigating the effect of processing on the nature of flubendiamide (hydrolysis studies) demonstrated that the active substance is stable.

As the proposed uses of flubendiamide are on imported crops, investigations of residues in rotational crops are not required.

Based on the metabolic pattern identified in metabolism studies, hydrolysis studies, the toxicological significance of metabolites and/or degradation products and considering that the metabolite NNI-0001-des-iodo was not found in measurable concentrations in the representative crops, the residue definitions for plant products were proposed as flubendiamide for enforcement and, on a provisional basis, for risk assessment.

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

Sufficiently validated analytical methods based on liquid chromatography with tandem mass spectrometry (LC–MS/MS) are available to quantify residues in the crops assessed in this application according to the enforcement residue definition. The methods enable quantification of residues at or above 0.01 mg/kg in the crops assessed (limit of quantification (LOQ)).

The available residue trials are sufficient to derive a common MRL proposal of 1.5 mg/kg for apricots and peaches, and MRLs of 0.7 and 0.4 mg/kg for plums and soya beans, respectively. The EFSA derived MRL for plums differs from the EMS proposal due to differences in the calculation method. It is noted that the USA tolerance for residues of flubendiamide in soya bean seed has been established at a value (0.25 mg/kg) which is lower than the derived MRL proposal for soya beans (0.4 mg/kg). Considering that the highest residue measured in supervised field trials is higher than the MRL established in the country of origin, it is not unlikely that soya beans treated in accordance with Good Agricultural Practice (GAP) authorised in the USA exceed the level of 0.25 mg/kg. Thus, further risk management considerations are required to decide on the appropriate MRL to be set in the European Union (EU).

A limited number of processing studies were assessed in previous EFSA reasoned opinions in the framework of Article 10 of the MRL Regulation, but these studies did not allow for the derivation of robust processing factors and no additional processing studies were submitted in the current application. Nevertheless, further processing studies are not required in this case as they are not expected to affect the outcome of the risk assessment. If more robust processing factors were to be required by risk managers, in particular for enforcement purposes, additional processing studies would be needed.

As soya beans can be used as livestock feed, a potential carry-over of flubendiamide residues into food of animal origin was assessed. The calculated livestock dietary burden exceeded the trigger value of 0.1 mg/kg dry matter (DM) for all relevant livestock groups. However, the contribution of

flubendiamide residues in soya beans to the total livestock exposure was insignificant, and therefore, a modification of the existing MRLs for commodities of animal origin was not considered necessary.

The toxicological profile of flubendiamide was assessed in the framework of the EU pesticides peer review under Directive 91/414/EEC and the data were sufficient to derive an acceptable daily intake (ADI) of 0.017 mg/kg body weight (bw) per day and an acute reference dose (ARfD) of 0.1 mg/kg bw.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). The international estimated short-term intakes (IESTI) according to EFSA PRIMo were 53% of ARfD for peaches, 28% of ARfD for apricots, 16% of ARfD for plums and 0.6% of ARfD for soya beans. Therefore, the short-term exposure did not exceed the ARfD for any of the crops assessed in this application. EFSA reiterates the previously made comment that due to the lower ARfD established in 2013 compared to the ARfD values proposed in the DAR and derived by JMPR in 2010, the risk assessment for MRLs established before 2013 should be reconsidered.

The estimated long-term dietary intake was in the range of 6–52% of the ADI. EFSA concluded that the long-term intake of residues of flubendiamide resulting from the existing and the intended uses is unlikely to present a risk to consumer health.

EFSA concluded that the proposed use of flubendiamide on apricot, peach, nectarine, plum and soya bean will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumer health.

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

Code[(a)]	Commodity	Existing EU MRL[(b)] (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Flubendiamide (F)				
0140010	Apricots	0.8	1.5	The combined submitted data on apricots and peaches are sufficient to derive a common import tolerance for apricots and peaches (USA GAPs). No consumer health concern was identified.
0140030	Peaches	0.8	1.5	The combined submitted data on apricots and peaches are sufficient to derive a common import tolerance for apricots and peaches (USA GAPs). No consumer health concern was identified.
0140040	Plums	0.01*	0.7	The submitted data are sufficient to derive an import tolerance (USA GAP). No consumer health concern was identified.
0401070	Soya beans	0.01*	Further risk management considerations required	The submitted data are sufficient to derive an import tolerance of 0.4 mg/kg (USA GAP). Considering that the MRL in the country of origin is set at the level of 0.25 mg/kg (residue definition comparable with the EU residue definition), in accordance with the guidance SANTE/2015/10595 Rev. 4, the MRL should not exceed the one approved in the exporting country taking into account possible differences in the residue definition. It is noted that the highest residue measured in supervised field trials submitted in support of the MRL application was 0.27 mg/kg, the MRL proposal of 0.25 mg/kg may not be sufficient to accommodate for the use authorised in the USA. No consumer health concern was identified.

MRL: maximum residue level; GAP: good agricultural practices; (F): Fat soluble.
*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005
(b): Existing EU MRLs established in Regulation (EU) No 364/2014.

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Background

Regulation (EC) No 396/2005[1] (hereinafter referred to as 'the MRL regulation') establishes the rules governing the setting of pesticide maximum residue levels (MRLs) at European Union (EU) level. Article 6 of the MRL regulation lays down that any party having a legitimate interest or requesting an authorisation for the use of a plant protection product in accordance with Council Directive 91/414/EEC[2], repealed by Regulation (EC) No 1107/2009[3], shall submit an application to a Member State to set an import tolerance in accordance with the provisions of Article 7 of the MRL regulation.

The applicant Bayer CropScience AG[4] submitted an application to the competent national authority in Greece, hereafter referred to as the evaluating Member State (EMS), to set import tolerances for the active substance flubendiamide in apricots, peaches, nectarines, plums and soya beans imported from the USA. This application was notified to the European Commission and the European Food Safety Authority (EFSA) and was subsequently evaluated by the EMS in accordance with Article 8 of the MRL regulation.

The EMS summarised the data provided by the applicant in an evaluation report which was submitted to the European Commission and forwarded to EFSA on 5 September 2016. The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2016-00546 and the following subject:

Flubendiamide: MRLs in various crops.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified points which needed further clarification, which was requested from the EMS. The EMS provided the requested clarification and submitted an updated evaluation report to EFSA on 1 October 2017 (Greece, 2017), which replaced the previously submitted evaluation report.

Greece proposed to raise the existing MRLs of flubendiamide in apricots and peaches/nectarines from 0.8 mg/kg to 1.5 mg/kg, and to raise the existing MRLs in plums and soya beans from the limit of quantification (LOQ) to 0.8 and 0.25 mg/kg, respectively. In the USA, the MRLs are set at the level of 1.6 mg/kg for stone fruit and 0.25 mg/kg in soya beans.

Terms of Reference

In accordance with Article 10 of Regulation (EC) No 396/2005, EFSA shall assess the application and the evaluation report and give a reasoned opinion on the risks to the consumer and where relevant to animals associated with the setting of the requested MRLs. The opinion shall include:

- an assessment of whether the analytical method for routine monitoring proposed in the application is appropriate for the intended control purposes;
- the anticipated LOQ for the pesticide/product combination;
- an assessment of the risks of the acceptable daily intake (ADI) and acute reference dose (ARfD) being exceeded as a result of the modification of the MRL;
- the contribution to the intake due to the residues in the product for which the MRLs was requested;
- any other element relevant to the risk assessment.

In accordance with Article 11 of the MRL regulation, EFSA shall give its reasoned opinion as soon as possible and at the latest within 3 months from the date of receipt of the application.

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

[1] Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, 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.
[3] 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.
[4] Bayer CropScience AG, Alfred-Nobel-Str. 50, 40789 Monheim, Germany.

The active substance and its use pattern

The uses of flubendiamide authorised in the USA in apricot, peach, nectarine, plum and soya bean, which are the basis for the current MRL application, are reported in Appendix A.

Flubendiamide is the ISO common name for 3-iodo-*N*′-(2-mesyl-1,1-dimethylethyl)-*N*-{4-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]-*o*-tolyl}phthalamide (IUPAC). The chemical structures of the active substance and its main metabolites are reported in Appendix E.

Flubendiamide was evaluated as a new active substance in the framework of Directive 91/414/EEC with Greece designated as rapporteur Member State (RMS) for the representative uses as an indoor foliar application on tomatoes and peppers. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by EFSA (2013a).

Flubendiamide was approved[5] for the use as insecticide on 1 September 2014.

The EU MRLs for flubendiamide are established in Annexes III A of Regulation (EC) No 396/2005. The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has not yet been completed. EFSA has issued several reasoned opinions on the modification of MRLs for flubendiamide (EFSA, 2010a,b, 2013b). The proposals from these reasoned opinions have been considered in recent regulations[6,7,8] for EU MRL legislation. The Codex maximum residue limits (CXLs) established by the Codex Alimentarius Commission in 2011 were implemented by Regulation (EU) No 441/2012[9] with the exception of various CXLs for which the EU raised a reservation.

Assessment

EFSA has based its assessment on the evaluation report submitted by the EMS (Greece, 2017), the DAR (and its addendum) prepared under Directive 91/414/EEC (Greece, 2008, 2013), the European Commission review report on flubendiamide (European Commission, 2014), 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 reports (FAO, 2010) as well as the conclusions from previous EFSA opinions on flubendiamide (EFSA, 2010a,b, 2013b). Information on the MRLs set in the country of origin for the requested import tolerances was provided (US EPA, 2010).

For this application, the data requirements established in Regulation (EU) No 544/2011[10] and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 1997a–g, 2000, 2010a,b, 2016, 2017; OECD, 2011, 2013). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011.[11]

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

[5] 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.

[6] Commission Regulation (EU) No 364/2014 of 4 April 2014 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for fenpyroximate, flubendiamide, isopyrazam, kresoxim-methyl, spirotetramat and thiacloprid in or on certain products. OJ L 112, 15.4.2014, p. 1–34

[7] Commission Regulation (EU) No 813/2011 of 11 August 2011 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acequinocyl, emamectin benzoate, ethametsulfuron-methyl, flubendiamide, fludioxonil, kresoxim-methyl, methoxyfenozide, novaluron, thiacloprid and trifloxystrobin in or on certain products. OJ L 208, 13.8.2011, p. 23–79

[8] Commission Regulation (EU) No 765/2010 of 25 August 2010 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for chlorothalonil, clothianidin, difenoconazole, fenhexamid, flubendiamide, nicotine, spirotetramat, thiacloprid and thiamethoxam in or on certain products. OJ L 226, 28.8.2010, p. 1–36

[9] Commission Regulation (EU) No 441/2012 of 24 May 2012 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for bifenazate, bifenthrin, boscalid, cadusafos, chlorantraniliprole, chlorothalonil, clothianidin, cyproconazole, deltamethrin, dicamba, difenoconazole, dinocap, etoxazole, fenpyroximate, flubendiamide, fludioxonil, glyphosate, metalaxyl-M, meptyldinocap, novaluron, thiamethoxam and triazophos in or on certain products. OJ L 135, 25.5.2012, p. 4–56

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

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

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 in primary crops belonging to the fruit and fruiting vegetables (apple, tomato), leafy vegetable (cabbage), and cereal (sweet corn/maize) crop groups has been investigated in the framework of the EU pesticides peer review (EFSA, 2013b; see Appendix B, Table B.1.1.1). Flubendiamide was by far the major component of the total radioactive residues (TRR) in the mature crops. The metabolite NNI-0001-des-iodo accounted for more than 10% TRR in the apple and maize. Metabolite NNI-0001-des-iodo was not identified in the rat metabolism.

The import tolerance application for soya bean is based on a USA Good Agricultural Practices (GAP) which includes the use of flubendiamide on both conventional soya bean and genetically modified soya bean, without specification of the intended traits or the genetically modified events in soya bean. EFSA requested clarification on the metabolism studies in primary crop and whether they are representative of the nature of residues expected on both conventional soya bean and genetically modified soya bean crop types. The applicant confirmed that the agricultural practice in the region includes use on genetically modified soya bean being resistant towards the herbicidal active substance glyphosate. Considering that the mechanisms of glyphosate tolerance in genetically modified plants exhibit a very specific reaction that does not influence the metabolism of other xenobiotics, the EMS assessment concluded that '*the genetic modification to induce tolerance to glyphosate is generally specific for that pesticide and does not influence the nature of flubendiamide in soya bean*' (Greece, 2017). EFSA considers that, on the basis of the available information, the metabolic transformation of flubendiamide and the nature of residues expected in primary crop is unlikely to differ in genetically modified glyphosate tolerant soya bean crops in comparison with conventional soya bean crops.

1.1.2. Nature of residues in rotational crops

Investigations of residues in rotational crops are not required for imported crops.

1.1.3. Nature of residues in processed commodities

The effect of processing on the nature of flubendiamide was investigated in the framework of the peer review. Flubendiamide was shown to be hydrolytically stable under standard processing conditions (20 min at 90°C pH 4; 60 min at 100°C pH 5; 20 min at 120°C pH 6) (Greece, 2008; EFSA, 2013a).

1.1.4. Methods of analysis in plants

Analytical methods for the determination of flubendiamide residues were assessed during the EU pesticides peer review (EFSA, 2013a). The liquid chromatography with tandem mass spectrometry (LC–MS/MS) methods allow quantifying flubendiamide and the metabolite NNI-0001-des-iodo in crops belonging to the high water content and high oil content groups of commodities with a LOQ of 0.01 mg/kg. The methods are sufficiently validated for residues of flubendiamide in the crops under consideration.

1.1.5. Stability of residues in plants

The storage stability of flubendiamide in plants stored under frozen conditions was investigated in the framework of the EU pesticides peer review (EFSA, 2013a). It was demonstrated that in crops assessed in the framework of this application, residues were stable for at least 18 months when stored at ≤ -18°C.

1.1.6. Proposed residue definitions

The peer review established the risk assessment residue definition for plant commodities on a provisional basis as parent compound only because the metabolite NNI-0001-des-iodo was not found in measurable concentrations in the representative crops (tomato and pepper; EFSA, 2013b). However, it was recommended to reconsider the residue definition in case the use pattern is extended to crops

where NNI-0001-des-iodo occurs. In such case, more information on the toxicological relevance of the metabolite would be required. Based on the metabolic pattern identified in metabolism studies, the results of hydrolysis studies, the toxicological significance of metabolites and/or degradation products, the capabilities of enforcement analytical methods, the following residue definitions were proposed:

- For enforcement in animal and plant commodities: Flubendiamide
- For risk assessment in plant commodities: Flubendiamide
- For risk assessment in animal commodities: Sum of parent flubendiamide and NNI-0001-iodo-phthalimide expressed as flubendiamide.

The same residue definitions are applicable to rotational crops and processed products. The residue definition for enforcement set in Regulation (EC) No 396/2005 is identical with the above-mentioned residue definition.

Taking into account the proposed uses assessed in this application, and that the plant metabolite NNI-0001-des-iodo (not detected in rat toxicological studies) was below the LOQ of 0.01 mg/kg in all GAP-compliant residues trials samples, EFSA concluded that these residue definitions are appropriate and no further information is required.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

In support of the MRL application for import tolerances, the applicant submitted USA residue trials performed in apricot, peach, plum and soya bean (dry seed). The samples were analysed for the parent compound in accordance with the residue definitions for enforcement and risk assessment. The samples were additionally analysed for the metabolite NNI-0001-des-iodo and residues of this metabolite were below the LOQ of 0.01 mg/kg in all GAP-compliant samples. According to the assessment of the EMS, the methods used were sufficiently validated and fit for purpose. The samples of these residue trials were stored under conditions, for which integrity of the samples has been demonstrated.

The data from the trials in apricot, peach and plum were expressed as residues in 'fruit, de-pitted' (portion analysed) since fruit samples were pitted (stone removed) prior to extraction and analysis. The applicant stated that the stone weights had not been recorded in the studies, and therefore, the residue values could not be calculated and expressed as for the weight of the whole fruit (including stone). The parts of the products to which the EU MRLs for stone fruit apply are defined in Commission Regulation (EU) No 752/2014[12] as 'whole product after removal of stems', and therefore, for the purposes of MRL enforcement, the amount of residues determined in the edible portion analysed is expressed as a concentration of the whole fruit, including the weight of the stone. The submitted residues data for stone fruits should be expressed as calculated for the weight of the whole fruit (with stone), and the MRL proposals derived accordingly. Using residues data which do not include the weight of the stones would introduce a bias into the MRL calculation overestimating the residue concentration. The applicant proposed to apply a generic correction factor to the trials data for apricot, peach and plum based on typical 14% stone weight as a proportion of whole fruit during final swell (Crisosto and Day, 2012 cited in Greece, 2017). EFSA considered that, since to the residue trials data for stone fruits were incorrectly recorded, the proposed application of a generic weight of stone correction factor to the various stone fruit crops included in the application is a suitable approach for the purposes of MRL calculations. EFSA highlights that the approach is non-standard and a source of additional uncertainty in the MRL calculation due to the application of a generic seed weight as a proportion of whole fruit correction factor to the various types of stone fruit crops. Consequently, EFSA considered that, as a worst-case scenario, the (uncorrected) highest residue (HR) and supervised trials median residue (STMR) values for pitted fruit were the appropriate basis for the purpose of risk assessment.

For all residue trials, the HR value was selected from each trial (same experimental location site) where experimental conditions differed (high/low water volume or with/without adjuvant or activator) and where peak residue was detected after the GAP minimum preharvest interval (PHI). The mean residue value was calculated from sampling replicates. Non-GAP-compliant residue trials were excluded for the calculation.

[12] Commission Regulation (EU) No 752/2014 of 24 June 2014 replacing Annex I to Regulation (EC) No 396/2005 of the European Parliament and of the Council. OJ L 208, 15.7.2014, p. 1–71.

The available residues data from the GAP-compliant supervised residue trials is summarised in Appendix B, Table B.1.2.1.

1.2.1.1. Apricots and peaches

In support of the import tolerance request, four GAP-compliant residue trials on apricot and 10 GAP-compliant residue trials on peach were provided. The trials on apricot were conducted in the USA over two seasons. The trials on peaches were conducted at different locations in the USA and nine of the trials were conducted during the same season. The number of residue trials on apricot is not sufficient to derive a MRL proposal for apricots only because apricot is a major crop in world production and normally a minimum of eight trials are needed. In accordance with the EU extrapolation rules (European Commission, 2017), the applicant proposed to combine the results on apricots and peaches to derive a common import tolerance for apricots and peaches. The number and quality of the trials on apricot and peach is sufficient to derive a common MRL of 1.5 mg/kg for apricots and peaches. The MRL derived for peaches is also applicable to nectarines and similar hybrids.

1.2.1.2. Plums

In support of the import tolerance request, ten GAP-compliant residue trials on plum were provided. The trials were conducted in the USA over two seasons. The number and quality of the trials are sufficient to derive an MRL of 0.7 mg/kg for plums. The EFSA derived MRL of 0.7 mg/kg for plums differs from the EMS proposal of 0.8 mg/kg for plums because EFSA based its calculation on the mean residue value of sampling replicates and the EMS based its calculation on the highest value of sampling replicates.

1.2.1.3. Soya bean

In support of the import tolerance request, 21 GAP-compliant residue trials on soya bean (dry seed) were provided. A further two trials were excluded from the calculation because the PHIs were not compliant with the GAP. The GAP-compliant trials were conducted at different locations in the USA. Twenty of the trials were conducted during the same season.

The import tolerance application for soya bean is based on a USA GAP which includes the use of flubendiamide on both conventional soya bean and genetically modified soya bean (see Section 1.1.1). The submitted residues trials were conducted on soya bean including genetically modified soya bean being resistant towards the herbicidal active substance glyphosate. EFSA considers that, on the basis of the available information, the magnitude of residues expected in primary crop is unlikely to be significantly influenced by the intended traits in genetically modified glyphosate tolerant soya bean crops in comparison with conventional soya bean crops. Therefore, the submitted residue trials on soya bean, including on genetically modified soya bean, are considered to be suitably representative of agricultural practices in the region.

The number and quality of the trials are sufficient to derive a MRL of 0.4 mg/kg for soya beans. It is noted that the USA tolerance for residues of flubendiamide including its metabolites and degradates[13] in soya bean seed has been established at 0.25 mg/kg (US EPA, 2010). The EMS reported that the discrepancy between the MRL derived and the established USA tolerance is a result of differences between the OECD and then used NAFTA calculation methods and differences in selection of input values where peak residue was detected after the minimum PHI (Greece, 2017).

1.2.2. Magnitude of residues in rotational crops

Investigations of residues in rotational crops are not required for imported crops.

1.2.3. Magnitude of residues in processed commodities

A limited number of processing studies were assessed in previous EFSA reasoned opinions in the framework of Article 10 of the MRL Regulation, but these studies did not allow for the derivation of robust processing factors (EFSA, 2010b, 2013b) and no additional processing studies were submitted in the current application. Nevertheless, further processing studies are not required in this case as they are not expected to affect the outcome of the risk assessment. If more robust processing factors were to be required by risk managers, in particular for enforcement purposes, additional processing studies would be needed.

[13] Compliance with the tolerance levels is to be determined by measuring only flubendiamide.

1.2.4. Proposed MRLs

The available data are considered sufficient to derive MRL proposals as well as risk assessment values for the commodities under evaluation (see Appendix B.1.2.1).

It is noted that the USA tolerance for residues of flubendiamide in soya bean seed has been established at a value (0.25 mg/kg; US EPA, 2010) which is lower than the derived MRL value for soya beans (0.4 mg/kg). In the context of an import tolerance application, the MRL to be set in the MRL Regulation should not exceed the one approved in the exporting country taking into account possible differences in the residue definition (European Commission, 2016), and thus, the import tolerance MRL for flubendiamide in soya beans should not exceed the level of 0.25 mg/kg. Considering that the HR measured in supervised field trials is higher than the MRL established in the country of origin, it is not unlikely that soya beans treated in accordance with GAP authorised in the USA exceeds the level of 0.25 mg/kg. Thus, further risk management considerations are required to decide on the appropriate MRL to be set in the EU (see also section 3).

In Section 3, EFSA assessed whether residues on these crops resulting from the uses authorised in the USA are likely to pose a consumer health risk.

2. Residues in livestock

Soya beans may be used for feed purposes. Hence, it was necessary to revise the previous livestock dietary burden calculation (EFSA, 2010b) using the OECD calculator in order to estimate whether the proposed import tolerance MRL for flubendiamide in soya beans would have an impact on the residues expected in food of animal origin. EFSA performed livestock dietary burden calculations to estimate the maximum and median animal burdens for two scenarios: one including the estimated contribution from soya beans and another excluding the contribution of soya beans. The input values for the exposure calculations for livestock are presented in Appendix D.1. The results of the dietary burden calculation including the estimated contribution from soya beans are presented in Appendix B.2 and demonstrated that the estimated exposure exceeded the trigger value of 0.1 mg/kg dry matter (DM) for all relevant livestock groups.

The results of the dietary burden calculations for the scenarios either including or excluding the estimated contribution of soya beans were found to be identical, and therefore, EFSA concluded that the estimated residues in soya bean are not expected to have an impact on the livestock dietary burden. Consequently, there is no need to propose changes to the existing MRLs in animal matrices.

3. Consumer risk assessment

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

The toxicological reference values for flubendiamide used in the risk assessment (i.e. ADI and ARfD values) were derived in the framework of the EU pesticides peer review (EFSA, 2013a).

3.1. Short-term (acute) dietary risk assessment

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

The international estimated short-term intakes (IESTI) according to EFSA PRIMo were 53% of ARfD for peaches, 28% of ARfD for apricots, 16% of ARfD for plums and 0.6% of ARfD for soya beans. Therefore, the short-term exposure did not exceed the ARfD for any of the crops assessed in this application (see Appendix B.3).

EFSA reiterates the previously made comment (EFSA, 2013b) that due to the lower ARfD established in 2013 compared to the ARfD values proposed in the DAR and derived by JMPR in 2010, the risk assessment for MRLs established before 2013 should be reconsidered.

3.2. Long-term (chronic) dietary risk assessment

The long-term exposure assessment was performed, taking into account the STMR values derived for the commodities assessed in this application; for the remaining commodities covered by the MRL regulation, the existing EU MRLs and STMR values derived in previous MRL applications were selected as input values (EFSA, 2010a,b). STMR values derived in JMPR assessment (FAO, 2010) were selected as input values where acceptable CXLs have been established in EU legislation. The complete list of input values is presented in Appendix D.2.

The estimated long-term dietary intake was in the range of 6–52% of the ADI. The contribution of residues expected in the commodities assessed in this application to the overall long-term exposure is presented in more detail in Appendix B.3.

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

Conclusions and recommendations

The data submitted in support of this import tolerance application were found to be sufficient to derive MRL proposals for all crops under consideration. For soya beans, further risk management considerations are required to decide whether the import tolerance should be set at the level of 0.4 mg/kg, which is the calculated MRL derived from the supervised field trials submitted in support of the application or at the level of the country of origin (i.e. 0.25 mg/kg). Considering that the HRs in supervised field trials were 0.27 mg/kg, it is not unlikely that the soya beans treated in compliance with the authorised GAP exceed the MRL in the country of origin. Thus, risk manager may decide not to set an import tolerance.

Adequate analytical methods for enforcement are available to control the residues of flubendiamide in plant matrices for the commodities under consideration.

Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of residues resulting from the use of flubendiamide according to the reported agricultural practices is unlikely to present a risk to consumer health.

The MRL recommendations are summarised in Appendix B.4.

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Abbreviations

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CXL	Codex maximum residue limit
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
EMS	evaluating Member State
FAO	Food and Agriculture Organization of the United Nations
GAP	Good Agricultural Practice
HR	highest residue
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ILV	independent laboratory validation
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues

LC	liquid chromatography
LOQ	limit of quantification
MRL	maximum residue level
MS/MS	tandem mass spectrometry detector
MW	molecular weight
NAFTA	North American Free Trade Agreement
NEU	northern Europe
OECD	Organisation for Economic Co-operation and Development
PBI	plant-back interval
PF	processing factor
PHI	preharvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
RA	risk assessment
RD	residue definition
RMS	rapporteur Member State
SANCO	Directorate-General for Health and Consumers
SC	suspension concentrate
SEU	southern Europe
SMILES	simplified molecular-input line-entry system
STMR	supervised trials median residue
TRR	total radioactive residue

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

Crop and/or situation	NEU, SEU, MS or country	F G or I[a]	Pests or Group of pests controlled	Preparation		Application				Application rate per treatment			PHI (days)[d]	Remarks
				Type[b]	Conc. a.s.	Method kind	Range of growth stages & season[c]	Number min–max	Interval between application (min)	kg a.s./hL min–max	Water L/ha min–max	kg a.s./ha min–max		
Apricot	USA	F	Codling moth (*Cydia pomonella*), cherry fruitworm (*Grapholita packardi*), obliquebanded leafroller (*Choristoneura rosaceana*), oriental fruit moth (*Grapholita molesta*), pandemis leafroller (*Pandemis pyrusana*)	SC	480 g/L	Foliar spray – ground	Not specified	3	7	0.075–0.150	93.25	0.070–0.140	7	Rate of product per application: 0.146–0.292 L/ha. Apply product in sufficient water volume that provides thorough coverage of plant foliage and fruit

Crop and/or situation	NEU, SEU, MS or country	F G or I[a]	Pests or Group of pests controlled	Preparation		Application				Application rate per treatment			PHI (days)[d]	Remarks
				Type[b]	Conc. a.s.	Method kind	Range of growth stages & season[c]	Number min–max	Interval between application (min)	kg a.s./hL min–max	Water L/ha min–max	kg a.s./ha min–max		
Peach	USA	F	Codling moth (*Cydia pomonella*), cherry fruitworm (*Grapholita packardi*), obliquebanded leafroller (*Choristoneura rosaceana*), oriental fruit moth (*Grapholita molesta*), pandemis leafroller (*Pandemis pyrusana*)	SC	480 g/L	Foliar spray – ground	Not specified	3	7	0.075–0.150	93.25	0.070–0.140	7	Rate of product per application: 0.146–0.292 L/ha. Apply product in sufficient water volume that provides thorough coverage of plant foliage and fruit

Crop and/or situation	NEU, SEU, MS or country	F G or I[a]	Pests or Group of pests controlled	Preparation		Application				Application rate per treatment			PHI (days)[d]	Remarks
				Type[b]	Conc. a.s.	Method kind	Range of growth stages & season[c]	Number min–max	Interval between application (min)	kg a.s./hL min–max	Water L/ha min–max	kg a.s./ha min–max		
Nectarine	USA	F	Codling moth (*Cydia pomonella*), cherry fruitworm (*Grapholita packardi*), obliquebanded leafroller (*Choristoneura rosaceana*), oriental fruit moth (*Grapholita molesta*), pandemis leafroller (*Pandemis pyrusana*)	SC	480 g/L	Foliar spray – ground	Not specified	3	7	0.075–0.150	93.25	0.070–0.140	7	Rate of product per application: 0.146–0.292 L/ha. Apply product in sufficient water volume that provides thorough coverage of plant foliage and fruit

Crop and/or situation	NEU, SEU, MS or country	F G or I[a]	Pests or Group of pests controlled	Preparation		Application				Application rate per treatment			PHI (days)[d]	Remarks
				Type[b]	Conc. a.s.	Method kind	Range of growth stages & season[c]	Number min–max	Interval between application (min)	kg a.s./hL min–max	Water L/ha min–max	kg a.s./ha min–max		
Plum	USA	F	Codling moth (*Cydia pomonella*), cherry fruitworm (*Grapholita packardi*), obliquebanded leafroller (*Choristoneura rosaceana*), oriental fruit moth (*Grapholita molesta*), pandemis leafroller (*Pandemis pyrusana*)	SC	480 g/L	Foliar spray – ground	Not specified	3	7	0.075–0.150	93.25	0.070–0.140	7	Rate of product per application: 0.146–0.292 L/ha. Apply product in sufficient water volume that provides thorough coverage of plant foliage and fruit

Crop and/or situation	NEU, SEU, MS or country	F G or I[a]	Pests or Group of pests controlled	Preparation		Application				Application rate per treatment			PHI (days)[d]	Remarks
				Type[b]	Conc. a.s.	Method kind	Range of growth stages & season[c]	Number min–max	Interval between application (min)	kg a.s./hL min–max	Water L/ha min–max	kg a.s./ha min–max		
Soybean	USA	F	Corn earworm (*Helicoverpa armigera*), fall armyworm (*Spodoptera frugiperda*), soybean looper (*Chrysodeixis includens*), tobacco budworm (*Heliothis virescens*), velvetbean caterpillar (*Anticarsia gemmatalis*)	SC	480 g/L	Foliar spray – ground	Not specified	1–2	5	0.037–0.112	93.32–93.47	0.035–0.105	14	Rate of product per application: 0.073–0.219 L/ha
Soybean	USA	F	Corn earworm (*Helicoverpa armigera*), fall armyworm (*Spodoptera frugiperda*), soybean looper (*Chrysodeixis includens*), tobacco budworm (*Heliothis virescens*), velvetbean caterpillar (*Anticarsia gemmatalis*)	SC	480 g/L	Foliar spray – aerial	Not specified	1–2	5	0.187–0.561	18.49–18.64	0.035–0.105	14	Rate of product per application: 0.073–0.219 L/ha

NEU: northern Europe; SEU: southern Europe; MS: Member State; GAP: Good Agricultural Practice; MRL: maximum residue level; a.s.: active substance; SC: suspension concentrate.
(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)**	**Remarks**
	Fruits and fruiting vegetables	Apples	1× 0.1 kg a.s./ha spray application	0, 7, 14, 28, 56	–
		Tomatoes	1× 0.5 kg a.s./ha direct foliar application	0, 7, 14, 28	–
	Leafy vegetables	Cabbage	1× 0.3 kg a.s./ha direct foliar application	21, 42	–
	Cereals	Corn	4× 0.159 kg a.s/ha spray application	Forage, sweet corn: 1 Ears, husks: 22	–
	Radiolabelled active substance: phthalic acid ring-UL-[^{14}C]; aniline ring-UL-[^{14}C] Reference: Greece (2008); EFSA (2013b)				
Rotational crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**PBI (DAT)**	
	Root/tuber crops	Turnips	1× 437 g a.s./ha, soil spray application	29, 135, 274	
	Leafy crops	Swiss chard	1× 437 g a.s./ha, soil spray application	29, 135, 274	
	Cereal (small grain)	Spring wheat	1× 437 g a.s./ha, soil spray application	29, 135, 274	
	Radiolabelled active substance: phthalic acid ring-UL-[^{14}C] Reference: Greece (2008)				
Processed commodities (hydrolysis study)	**Conditions**	**Investigated?**			
	Pasteurisation (20 min, 90°C, pH 4)	Yes			
	Baking, brewing and boiling (60 min, 100°C, pH 5)	Yes			
	Sterilisation (20 min, 120°C, pH 6)	Yes			
	Reference: Greece (2008); EFSA (2013b)				

Can a general residue definition be proposed for primary crops?	Yes
Rotational crop and primary crop metabolism similar?	Yes
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes
Plant residue definition for monitoring (RD-Mo)	Flubendiamide
Plant residue definition for risk assessment (RD-RA)	Flubendiamide Reconsideration is required whether inclusion of non-rat metabolite NNI-0001-des-iodo in risk assessment is necessary for other uses.
Conversion factor (monitoring to risk assessment)	Not applicable
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)	LC-MS/MS High water content (head cabbage, tomato, bean with pod), high oil content (olive, cotton), high starch content (wheat grain) and high acid content (citrus). Determined analyte: flubendiamide, NNI-0001-des-iodo LOQ: 0.01 mg/kg ILV + confirmatory study High water content (head cabbage, tomato), high oil content (cotton) and high starch content (wheat grain). Determined analyte: flubendiamide, NNI-0001-des-iodo LOQ: 0.01 mg/kg QuEChERS Method (confirmatory study) High water content (apple, carrot), high oil content (oilseed rape), high protein content (dry beans) and high acid content (orange). Determined analyte: flubendiamide, NNI-0001-des-iodo LOQ: 0.01 mg/kg Reference: EFSA, 2013a

DAT: days after treatment; a.s.: active substance; PBI: plant-back interval; LC: liquid chromatography; MS/MS: tandem mass spectrometry detector; LOQ: limit of quantification; ILV: independent laboratory validation; QuEChERS: Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method).

B.1.1.2. Stability of residues in plants

Plant products (available studies)	**Category**	**Commodity**	**T (°C)**	**Stability (Months/years)**
	High water content	Tomato, head cabbage, beans with pod	≤ −18°C	18 months
	High oil content	Olive	≤ −18°C	18 months
	Dry/High starch	Wheat	≤ −18°C	18 months
	High acid content	Citrus	≤ −18°C	18 months
	Reference: EFSA (2013a,b)			

B.1.2. Magnitude of residues in plants

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

Crop (supervised trials)	Region/ Indoor[a]	Residue levels observed in the supervised residue trials[b] (mg/kg)	Comments (MRL_{OECD} calculations unrounded/ rounded)	MRL calculation (mg/kg)	HR_{Mo}[c] (mg/kg)	$STMR_{Mo}$[d] (mg/kg)
Apricot, peach	USA	Apricots, pitted (stone removed): 0.145, 0.780, 0.780[h], 0.885[h] Apricots, whole fruit: 0.125[f], 0.671[f], 0.671[h],[f], 0.761[h],[f] Peaches, pitted (stone removed): 2× 0.195, 2× 0.215, 0.280, 0.295, 0.310, 0.315, 0.335, 0.385 Peaches, whole fruit: 2× 0.168[f], 2× 0.185[f], 0.241[f], 0.254[f], 0.267[f], 0.288[f], 0.315[g], 0.331[f]	Residue trials on apricot and peach compliant with USA GAPs. The combined data are sufficient to derive a common import tolerance for apricots and peaches. MRL_{OECD}: 1.17/1.50	**1.5**	0.89 (0.76)[f]	0.30 (0.26)[f]
Plum	USA	Plum, pitted (stone removed): 0.015, 0.03, 0.045, 0.08[h], 2 × 0.085, 0.115[h], 0.125, 0.395, 0.49 Plum, whole fruit: 0.013[f], 0.026[f], 0.039[f], 0.069[h],[f], 2× 0.073[f], 0.099[h],[f], 0.108[f], 0.340[f], 0.421[f]	Residue trials on plum compliant with USA GAP. MRL_{OECD}: 0.68/0.70	**0.7**	0.49 (0.42)[f]	0.09 (0.07)[f]
Soya bean (dry seed)	USA	< 0.01, 3× 0.01, 0.01[h], 0.015, 0.02[h], 0.02, 0.025, 0.025[h], 0.03[h], 0.03, 0.035[h], 0.05[h], 0.06[h], 0.065[h], 0.07, 0.1[h], 0.11[h], 0.21, 0.27[h]	Residue trials on conventional and genetically modified soya bean compliant with USA GAP. MRL_{OECD}: 0.33/0.40 USA tolerance: 0.25 mg/kg[e]	**0.4**	0.27	0.03

GAP: Good Agricultural Practice; MRL: maximum residue level; OECD: Organisation for Economic Co-operation and Development.
(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): Mean value of sampling replicates. Highest residue value from different experimental conditions selected (high/low water volume or with/without adjuvant or activator). Non-GAP-compliant residue trials were excluded for the calculation.
(c): Highest residue according to the residue definition for monitoring.
(d): Supervised trials median residue according to the residue definition for monitoring.
(e): USA tolerance for residues of flubendiamide (US EPA, 2010).
(f): Residue value corrected to whole fruit using estimated seed weight of 14% whole fruit during final swell, as reported by Crisosto and Day (2012) cited the evaluation report (Greece, 2017).
(g): Residue trial value reported for whole fruit (including stone weight) and therefore correction factor for stone weight not applied.
(h): Peak residue value detected after the GAP minimum PHI.

B.1.2.2. Conversion factors for risk assessment in plant products

Not relevant.

B.1.2.3. Residues in succeeding crops

Not relevant for import tolerance.

B.1.2.4. Processing factors

No new processing studies were submitted.

B.2. Residues in livestock

Relevant groups	Dietary burden expressed in				Most critical diet[a]	Most critical commodity[b]	Trigger exceeded (Yes/No) 0.1 mg/kg DM
	mg/kg bw per day		mg/kg DM				
	Median	Maximum	Median	Maximum			
Cattle (all diets)	0.226	0.495	7.93	17.27	Dairy cattle	Corn, field forage/silage	Yes
Cattle (dairy only)	0.226	0.495	5.87	12.88	Dairy cattle	Corn, field forage/silage	Yes
Sheep (all diets)	0.022	0.088	0.51	2.06	Lamb	Cabbage, heads	Yes
Sheep (ewe only)	0.017	0.069	0.51	2.06	Ram/Ewe	Cabbage, heads	Yes
Swine (all diets)	0.045	0.099	1.93	4.27	Swine (breeding)	Corn, field forage/silage	Yes
Poultry (all diets)	0.068	0.148	1.00	2.17	Poultry layer	Corn, field forage/silage	Yes
Poultry (layer only)	0.068	0.148	1.00	2.17	Poultry layer	Corn, field forage/silage	Yes

bw: body weight; DM: dry matter.
(a): When several diets are relevant (e.g. cattle, sheep and poultry 'all diets'), the most critical diet is identified from the maximum dietary burdens expressed as 'mg/kg bw per day'.
(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as 'mg/kg bw per day'.

B.3. Consumer risk assessment

ARfD	0.1 mg/kg bw (EFSA, 2013a)
Highest IESTI, according to EFSA PRIMo	Peaches: 53% of ARfD Apricots: 28% of ARfD Plums: 16% of ARfD Soya beans: 0.6% of ARfD
Assumptions made for the calculations	The calculation is based on the highest residue levels expected in raw agricultural commodities. The residue values for apricots, peaches and plums are based on uncorrected values for pitted fruit as a worst-case scenario.

ADI	0.017 mg/kg bw per day (EFSA, 2013a)
Highest IEDI, according to EFSA PRIMo	52% ADI (FR toddler) Contribution of crops assessed: Apricots: 0.65% of ADI Peaches: 1.0% of ADI Plums: 0.17% of ADI Soya beans: 0.12% of ADI
Assumptions made for the calculations	The calculation is based on the median residue levels derived for raw agricultural commodities. The residue values for apricots, peaches and plums are based on uncorrected values for pitted fruit as a worst-case scenario. The residue values for mammalian and other farmed terrestrial animal meat were calculated considering an estimated 80% muscle and 20% fat content.

ARfD: acute reference dose; bw: body weight; IESTI: international estimated short-term intake; PRIMo: (EFSA) Pesticide Residues Intake Model; ADI: acceptable daily intake; IEDI: international estimated daily intake.

B.4. Recommended MRLs

Code[(a)]	Commodity	Existing EU MRL[(b)] (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Flubendiamide (F)				
0140010	Apricots	0.8	1.5	The combined submitted data on apricots and peaches are sufficient to derive a common import tolerance for apricots and peaches (USA GAPs). No consumer health concern was identified.
0140030	Peaches	0.8	1.5	The combined submitted data on apricots and peaches are sufficient to derive a common import tolerance for apricots and peaches (USA GAPs). No consumer health concern was identified.
0140040	Plums	0.01*	0.7	The submitted data are sufficient to derive an import tolerance (USA GAP). No consumer health concern was identified.
0401070	Soya beans	0.01*	Further risk management considerations required	The submitted data are sufficient to derive an import tolerance of 0.4 mg/kg (USA GAP). Considering that the MRL in the country of origin is set at the level of 0.25 mg/kg (residue definition comparable with the EU residue definition), in accordance with the guidance SANTE/2015/10595 Rev. 4, the MRL should not exceed the one approved in the exporting country taking into account possible differences in the residue definition. It is noted that the highest residue measured in supervised field trials submitted in support of the MRL application was 0.27 mg/kg, the MRL proposal of 0.25 mg/kg may not be sufficient to accommodate for the use authorised in the USA. No consumer health concern was identified.

MRL: maximum residue level; GAP: good agricultural practices; (F): Fat soluble.
*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(b): Existing EU MRLs established in Regulation (EU) No 364/2014.

Appendix C – Pesticide Residue Intake Model (PRIMo)

Flubendiamide			
Status of the active substance:	NAS	Code no.	
LOQ (mg/kg bw):	0.01	Proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	0.017	ARfD (mg/kg bw):	0.1
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2013	Year of evaluation:	2013

MRLs Reg. (EU) No 364/2014.

The risk assessment has been performed on the basis of the MRLs collected from Member States in April 2006. For each pesticide/commodity, the highest national MRL was identified (proposed temporary MRL = pTMRL).
The pTMRLs have been submitted to EFSA in September 2006.

Chronic risk assessment – refined calculations

TMDI (range) in % of ADI minimum – maximum	
6	52
No of diets exceeding ADI:	---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	pTMRLs at LOQ (in % of ADI)
51.5	FR toddler	23.3	Milk and cream	18.1	Spinach	3.9	Apples	1.1
46.9	NL child	17.2	Milk and cream	9.5	Spinach	9.3	Apples	1.4
41.6	DE child	17.7	Apples	8.4	Milk and cream	5.2	Spinach	1.2
33.8	FR infant	15.1	Milk and cream	11.3	Spinach	3.7	Apples	0.8
29.5	UK Infant	22.8	Milk and cream	2.3	Apples	0.6	Sugar beet (root)	1.5
24.1	WHO Cluster diet B	5.3	Table and wine grapes	2.2	Lettuce	2.1	Spinach	1.6
21.1	ES child	7.4	Milk and cream	2.6	Lettuce	2.1	Spinach	0.9
20.9	UK Toddler	12.2	Milk and cream	2.5	Apples	1.3	Sugar beet (root)	2.2
19.1	IE adult	3.2	Spinach	2.9	Table and wine grapes	1.6	Milk and cream	1.5
16.5	NL general	3.9	Milk and cream	3.6	Spinach	2.1	Table and wine grapes	0.6
16.3	WHO cluster diet E	4.4	Table and wine grapes	1.8	Milk and cream	1.2	Apples	1.1
16.1	WHO regional European diet	2.8	Milk and cream	2.3	Lettuce	1.3	Swine: Meat	0.8
16.0	FR all population	10.2	Table and wine grapes	1.6	Milk and cream	0.7	Apples	0.5
15.8	DK child	7.4	Milk and cream	3.4	Apples	1.0	Pears	1.0
15.6	SE general population 90th percentile	7.3	Milk and cream	1.7	Spinach	1.5	Apples	0.9
15.2	ES adult	3.3	Lettuce	2.9	Milk and cream	1.9	Spinach	0.5
12.5	WHO Cluster diet F	2.3	Milk and cream	1.9	Lettuce	1.8	Table and wine grapes	0.8
12.0	PT General population	6.8	Table and wine grapes	1.5	Apples	0.6	Beans (without pods)	0.8
10.7	WHO cluster diet D	3.0	Milk and cream	1.4	Table and wine grapes	1.0	Apples	1.0
10.1	DK adult	3.6	Table and wine grapes	3.2	Milk and cream	1.2	Apples	0.4
9.4	LT adult	2.7	Apples	2.3	Milk and cream	1.0	Swine: Meat	0.4
9.4	IT adult	2.4	Spinach	2.4	Lettuce	1.2	Apples	0.4
9.2	UK vegetarian	2.2	Table and wine grapes	1.9	Milk and cream	0.9	Spinach	0.6
8.5	IT kids/toddler	1.8	Lettuce	1.5	Spinach	1.3	Apples	0.7
8.1	UK Adult	2.8	Table and wine grapes	1.8	Milk and cream	0.7	Lettuce	0.6
6.6	PL general population	3.0	Apples	0.8	Table and wine grapes	0.8	Head cabbage	0.3
6.4	FI adult	3.3	Milk and cream	0.8	Table and wine grapes	0.6	Apples	0.3

Conclusion:

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

Acute risk assessment/children – refined calculations	Acute risk assessment/adults/general population – refined calculations

The acute risk assessment is based on the ARfD.

For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS, with the critical consumption. If no data on the unit weight was available from that MS an average European unit weight was used for the IESTI calculation.

In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002); for lettuce, a variability factor of 5 was used.

In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variabilty factor of 3.

Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100% of the ARfD.

Unprocessed commodities

No of commodities for which ARfD/ADI is exceeded (IESTI 1): ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 1):** ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** ---		
IESTI 1	*)	**)	**IESTI 2**	*)	**)	**IESTI 1**	*)	**)	**IESTI 2**	*)	**)
Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
52.8	Peaches	0.89/-	38.7	Peaches	0.89/-	15.6	Peaches	0.89/-	12.1	Peaches	0.89/-
27.6	Apricots	0.89/-	22.0	Apricots	0.89/-	6.8	Apricots	0.89/-	5.7	Apricots	0.89/-
16.1	Plums	0.49/-	13.1	Plums	0.49/-	4.6	Plums	0.49/-	3.8	Plums	0.49/-
0.6	Soya bean	0.27/-	0.6	Soya bean	0.27/-	0.2	Soya bean	0.27/-	0.2	Soya bean	0.27/-
No of critical MRLs (IESTI 1)			---			**No of critical MRLs (IESTI 2)**			---		

Processed commodities

No of commodities for which ARfD/ADI is exceeded: ---				**No of commodities for which ARfD/ADI is exceeded:** ---			
		***)				***)	
Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)		Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	
65.8	Grape juice	2/-		7.7	Wine	2/-	
40.8	Apple juice	0.8/-		5.3	Apple juice	0.8/-	
14.3	Peach juice	0.8/-		1.6	Peach preserved with	0.8/-	
14.0	Pear juice	0.8/-		0.9	Quince jelly	0.8/-	
3.5	Tomato juice	0.2/-		0.8	Raisins	2/-	

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

**) pTMRL: provisional temporary MRL.

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

Conclusion:

For Flubendiamide, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.

No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

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

Appendix D – Input values for the exposure calculations

D.1. Livestock dietary burden calculations

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: Flubendiamide				
Apple pomace, wet	0.89	STMR × PF (0.25 × 3.56) (EFSA, 2010b)	0.89	STMR × PF (0.25 × 3.56) (EFSA, 2010b)
Cabbage heads, leaves	0.365	STMR JMPR (FAO, 2010)	2.7	HR JMPR (FAO, 2010)
Bean seed (dry)	0.18	STMR JMPR (FAO, 2010)	0.18	STMR JMPR (FAO, 2010)
Cowpea seed	0.18	STMR JMPR (FAO, 2010)	0.18	STMR JMPR (FAO, 2010)
Lupin seed	0.18	STMR JMPR (FAO, 2010)	0.18	STMR JMPR (FAO, 2010)
Lupin seed, meal	0.2	STMR JMPR × PF[(a)] (0.18 × 1.1) (FAO, 2010)	0.2	STMR JMPR × PF[(a)] (0.18 × 1.1) (FAO, 2010)
Pea (field pea) seed (dry)	0.18	STMR JMPR (FAO, 2010)	0.18	STMR JMPR (FAO, 2010)
Soya bean seed	0.03	STMR	0.03	STMR
Soya bean meal	0.0036	STMR × PF (0.03 × 0.12) (EFSA, 2010b)	0.0036	STMR × PF (0.03 × 0.12) (EFSA, 2010b)
Soya bean hulls	0.084	STMR × PF (0.03 × 2.8) (EFSA, 2010b)	0.084	STMR × PF (0.03 × 2.8) (EFSA, 2010b)
Cotton, undelinted seed	0.15	STMR (EFSA, 2010b)	1	HR (EFSA, 2010b)
Cotton, meal	0.003	STMR × PF (0.15 × 0.02) (EFSA, 2010b)	0.003	STMR × PF (0.15 × 0.02) (EFSA, 2010b)
Corn, field forage/silage	3.74	STMR (EFSA, 2010b)	8.41	HR (EFSA, 2010b)
Corn, field (Maize) grain	0.01	STMR (EFSA, 2010b)	0.01	STMR (EFSA, 2010b)
Corn, pop, grain	0.01	STMR (EFSA, 2010b)	0.01	STMR (EFSA, 2010b)
Corn, field, milled by-products	0.01	STMR × PF[(a)] (0.01 × 1) (EFSA, 2010b)	0.01	STMR × PF[(a)] (0.01 × 1) (EFSA, 2010b)
Corn, field, hominy meal	0.06	STMR × PF[(a)] (0.01 × 6) (EFSA, 2010b)	0.06	STMR × PF[(a)] (0.01 × 6) (EFSA, 2010b)
Corn, field, gluten feed	0.03	STMR × PF[(a)] (0.01 × 2.5) (EFSA, 2010b)	0.03	STMR × PF[(a)] (0.01 × 2.5) (EFSA, 2010b)
Corn, field, gluten, meal	0.01	STMR × PF[(a)] (0.01 × 1) (EFSA, 2010b)	0.01	STMR × PF[(a)] (0.01 × 1) (EFSA, 2010b)
Distillers grain, dried	0.03	STMR × PF[(a)] (0.01 × 3.3) (EFSA, 2010b)	0.03	STMR × PF[(a)] (0.01 × 3.3) (EFSA, 2010b)

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Rice bran/pollard	0.026	STMR × PF (0.035 × 0.75) (EFSA, 2010b)	0.026	STMR × PF (0.035 × 0.75) (EFSA, 2010b)

STMR: supervised trials median residue; HR: highest residue; PF: processing factor.
(a): In the absence of processing factors supported by data, default processing factors were included in the calculation to consider the potential concentration of residues in these commodities.

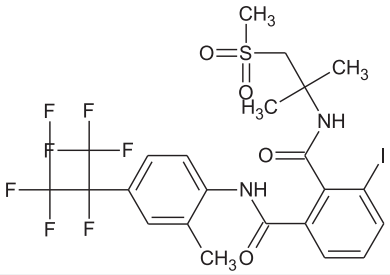
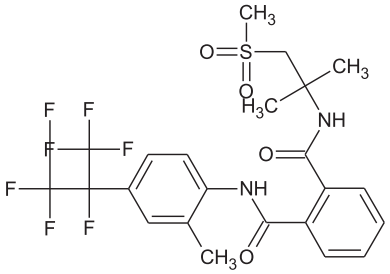
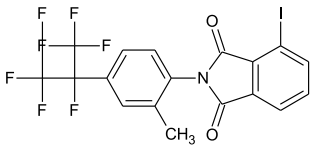
D.2. Consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: Flubendiamide (F)				
140010 **Apricots**	0.3	STMR pitted[(a)] (apricot, peach)	0.89	HR pitted[(a)] (apricot, peach)
140030 **Peaches**	0.3	STMR pitted[(a)] (apricot, peach)	0.89	HR pitted[(a)] (apricot, peach)
140040 **Plums**	0.09	STMR pitted[(a)]	0.49	HR pitted[(a)]
401070 **Soya bean**	0.03	STMR	0.27	HR
120000 Tree nuts (shelled or unshelled)	0.015	STMR (almonds, pecan nuts) (EFSA, 2010b)	Acute risk assessment was undertaken only with regard to the crops under consideration.	
130000 Pome fruit	0.25	STMR (apples, pears) (EFSA, 2010b)		
140020 Cherries	0.59	STMR (EFSA, 2010b)		
151000 Table and wine grapes	0.42	STMR (EFSA, 2010b)		
152000 Strawberries	0.06	STMR (EFSA, 2013b)		
231010 Tomatoes	0.07	STMR (EFSA, 2010b)		
231020 Peppers	0.045	STMR (EFSA, 2010b)		
231030 Aubergines	0.09	STMR (EFSA, 2010a)		
232000 Cucurbits – edible peel	0.05	STMR (EFSA, 2010a)		
233000 Cucurbits – inedible peel	0.014	STMR (EFSA, 2010a)		
234000 Sweet corn	0.01	STMR (EFSA, 2010b)		
242020 Head cabbage	0.365	STMR (FAO, 2010)		
251020 Lettuce	1.06	STMR (EFSA, 2010b)		
252010 Spinach	4.34	STMR (EFSA, 2010b)		
260010 Beans (with pods)	0.135	STMR (EFSA, 2010a)		
260020 Beans (without pods)	0.43	STMR (FAO, 2010)		
260030 Peas (with pods)	0.43	STMR (FAO, 2010)		
270030 Celery	1.7	STMR (EFSA, 2010b)		
300000 Pulses, dry	0.18	STMR (FAO, 2010)		
401090 Cotton seed	0.15	STMR (EFSA, 2010b)		
500030 Maize	0.01	STMR (EFSA, 2010b)		
500060 Rice	0.035	STMR (EFSA, 2010b)		
Other commodities of plant origin	MRL	MRLs in Regulation (EU) No 364/2014		

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: Sum of parent flubendiamide (NNI-0001) and NNI-0001-iodo-phthalimide expressed as flubendiamide (F)				
Mammalian and other farmed terrestrial animal meat	0.172	0.8 × STMR muscle + 0.2 × STMR fat[(b)] (0.8 × 0.06 + 0.2 × 0.62) (FAO, 2010)		
Mammalian and other farmed terrestrial animal fat	0.62	STMR (FAO, 2010)		
Mammalian and other farmed terrestrial animal liver	0.32	STMR (FAO, 2010)		
Mammalian and other farmed terrestrial animal kidney	0.32	STMR (FAO, 2010)		
Mammalian and other farmed terrestrial animal edible offal	0.32	STMR mammalian liver/kidney (FAO, 2010)		
1020000 Milk	0.066	STMR (FAO, 2010)		
Other commodities of animal origin	MRL	MRLs in Regulation (EU) No 364/2014		

STMR: supervised trials median residue; HR: highest residue; MRL: maximum residue level.
(a): STMR and HR values for apricots, peaches and plums are expressed as uncorrected values for pitted fruit.
(b): Consumption figures in the EFSA PRIMo are expressed as meat. Since the active substance is a fat-soluble pesticide, STMR and HR residue values were calculated considering 80% muscle and 20% fat content for mammalian meat (FAO, 2016).

Appendix E – Used compound codes

Code/trivial name	Chemical name/SMILES notation[a]	Structural formula[a]
flubendiamide NNI-0001	3-iodo-*N*′′-(2-mesyl-1,1-dimethylethyl)-*N*-{4-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]-*o*-tolyl}phthalamide O=C(Nc1ccc(cc1C)C(F)(C(F)(F)F)C(F)(F)F)c2cccc(I)c2C(=O)NC(C)(C)CS(C)(=O)=O	
NNI-0001-des-iodo	N^1-[4-(1,1,1,2,3,3,3-heptafluoropropan-2-yl)-2-methylphenyl]-N^2-[1-(methanesulfonyl)-2-methylpropan-2-yl]benzene-1,2-dicarboxamide O=C(Nc1ccc(cc1C)C(F)(C(F)(F)F)C(F)(F)F)c2ccccc2C(=O)NC(C)(C)CS(C)(=O)=O	
NNI-0001-iodo-phthalimide	2-[4-(1,1,1,2,3,3,3-heptafluoropropan-2-yl)-2-methylphenyl]-4-iodo-1*H*-isoindole-1,3(2*H*)-dione FC(F)(F)C(F)(c1ccc(c(C)c1)N3C(=O)c2cccc(I)c2C3=O)C(F)(F)F	

SMILES: simplified molecular-input line-entry system.
(a): (ACD/ChemSketch, Advanced Chemistry Development, Inc., ACD/Labs Release: 12.00 Product version: 12.00 (Build 29305, 25 Nov 2008).