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Setting of import tolerances for fluxapyroxad in certain root crops and coffee beans

European Food Safety Authority (EFSA),
Maria Anastassiadou, Giovanni Bernasconi, Alba Brancato, Luis Carrasco Cabrera, Luna Greco, Samira Jarrah, Aija Kazocina, Renata Leuschner, Jose Oriol Magrans, Ileana Miron, Stefanie Nave, Ragnor Pedersen, Hermine Reich, Alejandro Rojas, Angela Sacchi, Miguel Santos, Alois Stanek, Anne Theobald, Benedicte Vagenende and Alessia Verani

Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant BASF SE submitted a request to the competent national authority in the United Kingdom to set import tolerances for the active substance fluxapyroxad for certain root crops and for coffee beans produced in the US and Brazil. The data submitted in support of the request were found to be sufficient to derive maximum residue level (MRL) proposals for the crops assessed. Adequate analytical methods for enforcement are available to control the residues of fluxapyroxad in the products concerned at the validated limit of quantification (LOQ) of 0.01 mg/kg. Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of residues resulting from the use of fluxapyroxad according to the reported agricultural practices is unlikely to present a risk to consumer health.

Keywords: Fluxapyroxad, coffee beans, root crop, pesticide, MRL, consumer risk assessment

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Correspondence: pesticides.mrl@efsa.europa.eu

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, BASF SE submitted an application to the competent national authority in the United Kingdom (evaluating Member State (EMS)) to set import tolerances for the active substance fluxapyroxad in various crops. 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 20 June 2019. The EMS proposed to establish maximum residue levels (MRLs) for coffee beans imported from Brazil at the level of 0.15 mg/kg and for the crops belonging to the group of other root and tuber vegetables (except sugar beets) imported from the United States at 0.9 mg/kg.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC, the data evaluated under previous MRL assessments and the additional data provided by the EMS in the framework of this application, the following conclusions are derived.

The metabolism of fluxapyroxad following foliar applications was investigated in crops belonging to the groups of fruit crops, cereals/grass and pulses/oilseeds and following seed treatment in cereals. On rotational crops, metabolism was investigated in root/tuber, leafy and cereal crops after bare soil application. Studies investigating the effect of processing on the nature of fluxapyroxad (hydrolysis studies) demonstrated that the active substance is stable. Based on the metabolic pattern identified in metabolism studies, hydrolysis studies and the toxicological significance of metabolites, the European Union (EU) pesticides peer review agreed on a residue definition for plant products as 'fluxapyroxad' for enforcement and risk assessment. These residue definitions are applicable to primary crops, rotational crops and processed products.

EFSA concluded that for the crops assessed in this application, the metabolism of fluxapyroxad 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 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 (limit of quantification (LOQ)) in the crops assessed.

The available residue trials are sufficient to derive MRL proposals of 0.9 mg/kg for the crops belonging to the group of other root and tuber vegetables (except sugar beets) (crop code 0213000) by extrapolation from residue trials in carrots. For radishes, sufficient residue trials are available to derive an MRL proposal, which is lower than the existing EU MRL. For Jerusalem artichokes, the MRL derived by extrapolation from data on carrots (0.9 mg/kg) is significantly higher than the MRL set in the country of origin (0.02 mg/kg). For coffee beans, a risk management decision needs to be taken between the two possible MRL options: 0.2 mg/kg as established in the country of origin or 0.3 mg/kg derived using the OECD calculator tool.

As the proposed uses of fluxapyroxad are on imported crops, investigations of residues in rotational crops are not required. However, fluxapyroxad exhibited high persistence in soil and the possibility of residues of fluxapyroxad to be present in rotational crops cannot be excluded.

Although some of the crops under assessment (carrots, swedes and turnips) and their by-products are used as feed products, a modification of the existing MRLs for commodities of animal origin was considered unnecessary.

The toxicological profile of fluxapyroxad was assessed in the framework of the EU pesticides peer review and the data were sufficient to derive an acceptable daily intake (ADI) of 0.02 mg/kg body weight (bw) per day and an acute reference dose (ARfD) of 0.25 mg/kg bw. The metabolite included in the residue definition for risk assessment in products of animal origin was concluded to be of similar toxicity as the parent active substance.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). No concerns from long-term exposure to fluxapyroxad were identified for any of the European diets incorporated in the EFSA PRIMo. The estimated long-term dietary intake of fluxapyroxad was in the range of 6–37% of the acceptable daily intake (ADI). The contribution of residues in the root and tuber vegetables and coffee beans under assessment to the total consumer exposure was low. Regarding the risk assessment for the short-term consumption of the crops under assessment, the acute exposure did not identify any concerns for human health.

EFSA concluded that the proposed use of fluxapyroxad on other root and tuber vegetables, except sugar beets, and coffee will not result in a consumer exposure exceeding the toxicological reference values set for fluxapyroxad and therefore is unlikely to pose a risk to consumers' health.

The review of the existing MRLs under Article 12 of Regulation 396/2005 is not yet finalised; therefore, the conclusions reported in this reasoned opinion may need to be reconsidered in the light of the outcome of the MRL review.

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

Full details of all endpoints and the consumer risk assessment can be found in Appendices B–D.

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Fluxapyroxad[(F)]				
213010	Beetroots	0.3	0.9	The requested import tolerance (USA) is sufficiently supported by data (extrapolation from residue data on carrots). MRL in the country of origin is set at 0.9 mg/kg Risk for consumer unlikely
213020	Carrots	0.3	0.9	The requested import tolerance (USA) is sufficiently supported by data. MRL in the country of origin is set at 0.9 mg/kg Risk for consumer unlikely
213030	Celeriacs/turnip rooted celeries	0.3	0.9	The requested import tolerance (USA) is sufficiently supported by data (extrapolation from residue data on carrots). MRL in the country of origin is set at 0.9 mg/kg Risk for consumer unlikely
213040	Horseradishes	0.3	0.9	
213050	Jerusalem artichokes	0.3	Risk management decision 0.02 or 0.9	The requested import tolerance (USA) is sufficiently supported by data (extrapolation from residue data on carrots). The US MRL for Jerusalem artichokes is set at 0.02 mg/kg Risk for consumer unlikely
213060	Parsnips	0.3	0.9	The requested import tolerance (USA) is sufficiently supported by data (extrapolation from residue data on carrots). MRL in the country of origin is set at 0.9 mg/kg Risk for consumer unlikely
213070	Parsley roots/ Hamburg roots parsley	0.3	0.9	
213080	Radishes	0.3	Risk management decision 0.9 or no change	The requested import tolerance (USA) is sufficiently supported by data. Based on residue trials compliant with the US GAP on radishes, an MRL proposal of 0.2 g/kg is derived, which is lower than the existing MRLRisk manager to decide whether to set the MRL at 0.9 mg/kg based on extrapolation from residue data on carrots or maintain the current value MRL in the country of origin is set at 0.9 mg/kg Risk for consumer unlikely
213090	Salsifies	0.3	0.9	The requested import tolerance (USA) is sufficiently supported by data (extrapolation from residue data on carrots). MRL in the country of origin is set at 0.9 mg/kg Risk for consumer unlikely
213100	Swedes/ rutabagas	0.3	0.9	
213110	Turnips	0.3	0.9	
620000	Coffee beans	0.01*	Risk management decision 0.2 or 0.3	The import tolerance request from Brazil is sufficiently supported by data. Recently, a Codex MRL (CXL) of 0.15 mg/kg was adopted which was acceptable for the EU; the CXL was derived for a similar Brazilian GAP, supported by a different set of residue trials Risk manager to decide whether to set the MRL of 0.2 mg/kg as established in the country of origin or the MRL of 0.3 mg/kg derived using the OECD calculator Risk for consumer unlikely

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

*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).

(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.

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Assessment

The European Food Safety Authority (EFSA) received an application from BASF SE to set import tolerances for the active substance fluxapyroxad in various crops. The detailed description of the notified uses of fluxapyroxad in Brazil for coffee beans and in the United States for the group of other root and tuber vegetables (except sugar beets), which are the basis for the current maximum residue level (MRL) application, is reported in Appendix A.

Fluxapyroxad is the ISO common name for 3-(difluoromethyl)-1-methyl-2′-(3,4,5-trifluorophenyl)-1*H*-pyrazole-4-carboxanilide (IUPAC). The chemical structures of the active substance and its main metabolite are reported in Appendix E.

Fluxapyroxad is an active substance approved in accordance with Regulation (EC) No 1107/2009[1] by Regulation (EU) No 589/2012[2] which entered into force on 1 January 2013. It is approved for use as a fungicide. The representative uses evaluated in the EU pesticides peer review were spray applications on cereals. The Draft Assessment Report (DAR) of fluxapyroxad has been peer reviewed by EFSA.

The EU MRLs for fluxapyroxad are established in Annex III of Regulation (EC) No 396/2005[3]. The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) is currently on going. EFSA has issued several reasoned opinions on the modification of MRLs for fluxapyroxad (EFSA, 2011, 2015, 2016, 2017). The proposals from these EFSA opinions have been considered in the EU MRL legislation[4]; the last modification of the MRLs has been introduced by Regulation (EU) 2018/685[5]. In addition, certain Codex MRLs have been taken over in the EU legislation.

In accordance with Article 6 of Regulation (EC) No 396/2005, BASF SE submitted the application to the competent national authority in the United Kingdom (evaluating Member State (EMS)) on 24 March 2017 to set import tolerances for the active substance fluxapyroxad in certain root crops and in coffee beans. 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 EFSA on 20 June 2019. The EMS proposed to establish MRLs for coffee beans imported from Brazil at the level of 0.15 mg/kg and for the crops belonging to the group of other root and tuber vegetables (except sugar beets) imported from the USA at 0.9 mg/kg.

EFSA based its assessment on the evaluation report submitted by the EMS (United Kingdom, 2019), the DAR and its final addendum prepared under Directive 91/414/EEC (United Kingdom, 2011a,b), the Commission review report on fluxapyroxad (European Commission, 2012), the conclusion on the peer review of the pesticide risk assessment of the active substance fluxapyroxad (EFSA, 2012), the JMPR reports (FAO, 2012, 2015, 2018) as well as the conclusions from previous EFSA opinions on fluxapyroxad (EFSA, 2011, 2015, 2016, 2017) and scientific reports (EFSA, 2013, 2019).

For this application, the data requirements established in Regulation (EU) No 544/2011[6] and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 1997a–g, 2000, 2010a,b, 2017; OECD, 2011, 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[7].

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[1] 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

[2] Commission Implementing Regulation (EU) No 589/2012 of 4 July 2012 approving the active substance fluxapyroxad, 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 L175, 5.7.2012, p. 7–10.

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

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

[5] Commission Regulation (EU) 2018/685 of 3 May 2018 amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for abamectin, beer, fluopyram, fluxapyroxad, maleic hydrazide, mustard seeds powder and tefluthrin in or on certain products. C/2018/2607. OJ L 121, 16.5.2018, p. 1–29

[6] 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.

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

As the review of the existing MRLs under Article 12 of Regulation 396/2005 is not yet finalised, the conclusions reported in this reasoned opinion may need to be reconsidered in the light of the outcome of the MRL review.

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

The evaluation report submitted by the EMS (United Kingdom, 2019) and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available as background documents to this reasoned opinion.

1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

The metabolism of fluxapyroxad in primary crops was investigated in fruits, pulses/oilseeds and cereals/grass crop groups following foliar applications (EFSA, 2012) and in cereals following seed treatment (EFSA, 2015). After foliar applications, fluxapyroxad was the main component of the total radioactive residues (TRR) in tomatoes, wheat and soya beans plant parts, except in seeds. The metabolism showed to be more extensive in soya bean seeds with metabolites M700F002 and M700F048 being the predominant part of the total residues (EFSA, 2012).

For root crops, no specific metabolism studies are available. However, since metabolism was found to be similar in three different crop groups, it can be reasonably assumed that in root crops the metabolism is comparable. The assumption that metabolism of fluxapyroxad in root crops proceeds in the same way as in other crop groups is confirmed by the findings of metabolism studies in rotational crops (see Section 1.1.2).

The metabolism study in fruit crops is considered representative for coffee beans.

Overall, plant metabolism is sufficiently elucidated for the crops under consideration.

1.1.2. Nature of residues in rotational crops

In the framework of the EU pesticides peer review, the metabolism of fluxapyroxad was investigated in rotational crops (radishes, spinaches and wheat) and was concluded to be similar as in the primary crops (EFSA, 2012). Although residues of fluxapyroxad in rotational crops are not of relevance for the assessment of import tolerance requests, these studies are considered as a source of information to confirm the assumption that metabolism in root crops is comparable with metabolic behaviour observed in other primary corps (see Section 1.1.1).

1.1.3. Nature of residues in processed commodities

Standard hydrolysis studies simulating the effect on the nature of fluxapyroxad residues under processing conditions representative of pasteurisation, boiling and sterilisation were assessed during the EU pesticides peer review and it was concluded that the compound is hydrolytically stable under the representative conditions (EFSA, 2012).

1.1.4. Methods of analysis in plants

Analytical methods for the determination of fluxapyroxad residues in plant commodities were assessed during the EU pesticides peer review (EFSA, 2012); it was concluded that high-performance liquid chromatography with tandem mass spectrometry (HPLC–MS/MS) and ultra-performance liquid chromatography with tandem mass spectrometry (UPLC–MS/MS) methods have been adequately validated to enforce fluxapyroxad residues in all major crop groups (high water, high acid, high oil content and dry matrices) at the limit of quantification (LOQ) of 0.01 mg/kg.

According to the current EU guidance for analytical methods for enforcement (European Commission, 2000), coffee is classified as a crop which is difficult to analyse and for which a fully validated analytical method would be required.

Taking into account that validation data are available for all four crop groups and that the HPLC method used to analyse the samples from the residue trials on coffee beans (green beans) was successfully validated, EFSA agrees with the conclusion of the EMS that the analytical method is also suitable to enforce MRLs of fluxapyroxad in coffee beans (United Kingdom, 2019).

Overall, EFSA concludes that sufficiently validated analytical methods are available to enforce the proposed MRLs for fluxapyroxad in crops covered by this assessment.

1.1.5. Storage stability of residues in plants

Storage stability of fluxapyroxad in plant matrices was investigated during the EU pesticides peer review EFSA, 2012). Fluxapyroxad was stable deep frozen (−20°C) in matrices with high water content, high starch content, high protein content, high oil content and high acid content for 24 months.

1.1.6. Proposed residue definitions

The EU pesticides peer review concluded on a residue definition for plant products as 'Fluxapyroxad' for both monitoring and risk assessment for all crops (EFSA, 2012).

The current residue definition set in Regulation (EC) No 396/2005 is identical to the residue definition for enforcement derived in the EU pesticides peer review. The residue is applicable to primary crops, rotational crops and processed products.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

- Other root and tuber vegetables except sugar beets (carrots, beetroots, celeriacs/turnip rooted celeries, horseradishes, Jerusalem artichokes, parsnips, parsley roots/Hamburg roots parsley, radishes, salsifies, swedes/rutabagas, turnips)

The applicant submitted seven residue trials on carrots and five on radishes performed in the different regions of the United States; these studies were already assessed by EFSA in a previous reasoned opinion (EFSA, 2016). To complete the data set, one additional residue trial conducted on carrots in the USA in 2014 was provided. All trials were compliant with the notified USA Good Agricultural Practice (GAP), except the new trial where samples were collected at different intervals after the last treatment (i.e. 0, 3, 10 and 14 days) but not at the intended preharvest interval (PHI) of 7 days. EFSA agrees with the EMS that the trial is acceptable, considering that the residue concentration remained at a constant level at the different sampling points (ranging from 0.061 mg/kg at day 0 to 0.066 mg/kg 14 days after the last treatment. The highest residue level was measured at day 10).

The EMS proposed to combine the trials on carrots (8) with the trials on radishes (5) to derive an import tolerance for the whole group of 'other root and tuber vegetables except sugar beets'.

Extrapolation from a combined data set on carrots and radishes is not foreseen at EU level. According to the EU guidance document, the data set of 8 trials on carrots alone is sufficient to extrapolate residues to the group of roots and tubers, including radishes (European Commission, 2017).

The number of trials available on radishes, which are a minor crop, is sufficient to support the notified use on radishes.

- Coffee beans

The applicant submitted eight residue trials performed in Brazil over two seasons. All trials were slightly underdosed, but within the 25% tolerance in application rate and the other parameters were compliant with the Brazilian GAP. The number of trials available is sufficient to support the notified use. Based on the OECD calculator an MRL of 0.3 mg kg is derived, which is higher than the MRL of 0.2 mg/kg set in the country of origin.

The analytical methods used to analyse the residue trials on carrots and coffee beans have been sufficiently validated (United Kingdom, 2019). The trials samples were stored for a maximum period of 17 months (carrots) and 10 months (coffee beans) under conditions for which integrity of the samples was demonstrated. Thus, it is concluded that the residue data are valid with regard to storage stability of fluxapyroxad.

1.2.2. Magnitude of residues in rotational crops

Fluxapyroxad exhibited high persistence in soil and the possibility of residues of fluxapyroxad to be present in rotational crops cannot be excluded. However, the residues of fluxapyroxad in rotational crops are not of relevance for the assessment of import tolerance requests.

1.2.3. Magnitude of residues in processed commodities

Specific studies to assess the magnitude of fluxapyroxad residues during the processing of the crops under consideration were not provided and are not required considering the low contribution of each individual commodity to the consumer exposure (< 10% theoretical maximum daily intake (TMDI)) (European Commission, 1997d).

1.2.4. Proposed MRLs

EFSA concluded that the data submitted are sufficient to derive MRL proposals of 0.9 mg/kg for the use of fluxapyroxad authorised in the United States for beetroots, carrots, celeriacs/turnip rooted celeries, horseradishes, Jerusalem artichokes, parsnips, parsley roots/Hamburg roots parsley, salsifies, swedes/rutabagas and turnips and for the other root and tuber vegetables (code number 0213000). The MRL proposals were derived by extrapolation from the data set of residue trials on carrots. The current USA MRLs are set at the same level, except for Jerusalem artichokes where the USA MRL is 0.02 mg/kg.[8]

For radishes, the number of available residue trials is sufficient to derive an MRL proposal of 0.2 mg/kg. In the United States, the current MRL is established at the level of 0.9 mg/kg.

For coffee beans, EFSA calculated an MRL proposal of 0.3 mg/kg which is slightly higher than the MRL established in the country of origin (0.2 mg/kg). The EMS proposed a slightly lower MRL of 0.15 mg/kg based on proportionally scaled residue trials. Since the submitted trials were performed with application rates that were within the acceptable deviation of 25%, EFSA did not consider scaling appropriate. Further risk management considerations are required whether the MRL should be established at the level calculated with the OECD calculator (0.3 mg/kg) or at the level of the MRL in the country of origin (0.2 mg/kg).

It is noted that in 2019 a Codex MRL (CXL) of 0.15 mg/kg was adopted (FAO, 2018), which was set for a Brazilian GAP which is similar (slightly more critical) than the GAP reported in the MRL application (3 × 100 g ai/ha, 45 days PHI). The EU supported this CXL.

2. Residues in livestock

EFSA updated the most recent livestock dietary burden calculation (EFSA, 2017), including the residues in the crop under consideration in this MRL application. The results of the updated dietary burden are reported in Section B.2 and the details on the input values are presented in Appendix D.2.

The existing EU MRLs for commodities of animal origin are based on CXLs that have been taken over in EU legislation in 2017.[9] Considering that the dietary burden calculated by JMPR in 2015 and 2018 when additional CXLs for feed items were derived, was higher than the calculated EU dietary burden (FAO, 2015, 2018), EFSA concluded that a modification of the existing MRLs in products of animal origin is not required.

3. Consumer risk assessment

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). This exposure assessment model contains the relevant European food consumption data for different sub-groups of the EU population (EFSA, 2007).

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[8] The food classification differs in the US: beetroots, carrots, celeriac, horseradishes, parsnips, parsley roots, radishes, salsify, swedes and turnips belong to the group of root vegetables (except sugar beets) sub-group 1.B, whereas Jerusalem artichokes belong to the tuberous and corn vegetables subgroup 1.C. For the latter, a lower tolerance of 0.02 mg/kg is set in the country of origin.

[9] Commission Regulation (EU) 2017/626 of 31 March 2017 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 acetamiprid, cyantraniliprole, cypermethrin, cyprodinil, difenoconazole, ethephon, fluopyram, flutriafol, fluxapyroxad, imazapic, imazapyr, lambda-cyhalothrin, mesotrione, profenofos, propiconazole, pyrimethanil, spirotetramat, tebuconazole, triazophos and trifloxystrobin in or on certain products. C/2017/2035. OJ L 96, 7.4.2017, p. 1–43.

The toxicological profile of fluxapyroxad was assessed in the framework of the EU pesticides peer review and the data were sufficient to derive an acceptable daily intake (ADI) of 0.02 mg/kg body weight (bw) per day and an ARfD of 0.25 mg/kg bw (European Commission, 2012).

For the calculation of the chronic exposure to fluxapyroxad, EFSA updated the most recent risk assessment (EFSA, 2017) for the root and tuber vegetables under assessments and for coffee beans with the supervised trials median residue (STMR) values derived from residue trials in carrots and coffee beans. For radishes, the most critical STMR derived by extrapolation from carrots, instead of the STMR derived from the residue trials on this crop was used for a conservative approach. For tropical root and tuber vegetables and potatoes, the default MRL of 0.1 mg/kg which reflects residues expected in rotational crop was used for the calculation. The STMRs for the Codex MRLs recently adopted by CAC which were supported by the EU were also included in the calculation (FAO, 2018; EFSA, 2019).

The acute risk assessment was performed only for the crops under assessment using the highest residue derived from the residue trials on carrots and on coffee beans.

The details on the input values are presented in Appendix D.2.

No concerns from long-term exposure to fluxapyroxad were identified for any of the European diets incorporated in the EFSA PRIMo. The estimated long-term dietary intake of fluxapyroxad was in the range of 6–37% of the ADI (DE child diet). The contribution of the root and tuber crops under assessment accounted for up to 1.19% of the ADI (carrots); for coffee beans the exposure accounted for up to 0.05% of the ADI.

Regarding the risk assessment for the short-term consumption of the crops under assessment, the acute exposure did not identify any concerns for human health (highest exposure is calculated for carrots (15.2% of ARfD)).

For further details on the exposure calculations, a screenshot of the Report sheet of the PRIMo is presented in Appendix C.

4. Conclusion and Recommendations

The data submitted were found to be sufficient to derive an MRL proposal of 0.9 mg/kg for beetroots, carrots, celeriac, horseradish, parsnip, parsley root, salsify, swedes/rutabaga and turnips imported from the USA. For radishes, the existing MRL of 0.3 mg/kg covers the US use for which an MRL proposal of 0.2 mg/kg was derived. The US MRL for all these crops is established at the level of 0.9 mg/kg; the same residue definition applies in the USA.

For Jerusalem artichokes EFSA derived an MRL proposal of 0.9 mg/kg by extrapolation from carrots. Further risk manager considerations are required, whether the MRL should be raised, taking into account that the US MRL for this crop is set at the level of 0.02 mg/kg.

The data submitted were also found to be sufficient to derive an MRL proposal of 0.3 mg/kg for coffee beans imported from Brazil. The proposed MRL is higher than the values set in the country of origin (0.2 mg/kg). Risk management considerations are required, whether the MRL should be established at the level calculated with the OECD calculator (0.3 mg/kg) or at the level of the MRL in the country of origin (0.2 mg/kg), taking into account that the recently adopted Codex MRL will be established at the level of 0.15 mg/kg.

EFSA concluded that the short-term and long-term intake of residues resulting from the use of fluxapyroxad 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
CAC	Codex Alimentarius Commission
CCPR	Codex Committee on Pesticide Residues
CF	conversion factor for enforcement to risk assessment residue definition
CXL	Codex maximum residue limit
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
EC	emulsifiable concentrate
EMS	evaluating Member State
FAO	Food and Agriculture Organization of the United Nations
GAP	Good Agricultural Practice
HPLC–MS/MS	high-performance liquid chromatography with tandem mass spectrometry
HR	highest residue
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
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
RA	risk assessment
RD	residue definition
SANCO	Directorate-General for Health and Consumers
SEU	southern Europe
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
UPLC–MS/MS	ultra-performance liquid chromatography with tandem mass spectrometry
WHO	World Health Organization

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

Crop and/or situation	NEU, SEU, MS or country	F G or I[(a)]	Pests or group of pests controlled	Preparation		Application				Application rate per treatment				PHI (days)[(d)]	Remarks
				Type[(b)]	Conc. a.s.	Method kind	Range of growth stages & season[(c)]	Number min–max	Interval between application (min)	g a.s./hL min–max	Water L/ha min–max	Rate	Unit		
Parsley roots/ Hamburg roots parsley Radishes Salsifies Swedes/ rutabagas Turnips	United States of America	F	'Alternaria leaf spot/blight (*Alternaria* spp.) Powdery mildew (*Erysiphe* spp., *Leveillula* spp.) Cercospora leaf spot/blight (*Cercospora* spp.) Suppression Only: Sclerotinia white mould/ cottony rot (*Sclerotinia sclerotiorum*) Southern blight (*Sclerotium rolfsii*)'	EC	62.5 g/L	Foliar treatment – broadcast spraying	See remarks	1–3	7			75–100	g/ha	7	GAP of 'Imbrex' label Application: begin applications prior to disease development (continue if conditions are conducive for disease development) Water amount: aerial application: > 19 L/ha; ground application: thorough coverage; sprinkler application: < 126,945 L/ha

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)	g a.s./hL min–max	Water L/ha min–max	Rate	Unit		
Coffee beans	Brazil	F	Rust (*Hemileia vastatrix*), Gray leaf spot (*Cercospora coffeicola*)	EC	50 g/L	Foliar treatment – broadcast spraying	See remarks	1–3			400–5,000	50–75	g/ha	45	GAP of 'Versatilis XE and Sesitra' label Note: application interval not specified on the label (re-apply when infection rate is again up to 5%) The formulation contains 50 g/L fluxapyroxad, 81 g/L pyraclostrobin and 50 g/L epoxiconazole

NEU: northern European Union; SEU: southern European Union; MS: Member State; a.s.: active substance; EC: emulsifiable concentrate; GAP: detector; MRL: maximum residue level.
(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide formulation types and international coding system.
(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.
(d): PHI: minimum preharvest interval.

Appendix B – List of end points

B.1. Residues in plants

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

B.1.1. Metabolism studies, methods of analysis and residue definitions in plants

Primary crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**Sampling**[(a)] **(DAT)**	**Comment/source**
	Fruit crops	Tomatoes	Foliar: 3 × 100 g/ha	3 DAT_3	Radiolabelling: [Aniline-U-^{14}C]-fluxapyroxad and [Pyrazole-4-^{14}C]-fluxapyroxad (EFSA, 2012)
	Pulses and oilseeds	Soya beans	Foliar: 3 × 60 g/ha, BBCH 16/17, 51-59 and 71-75	0 DAT_1, 34 DAT_3	Radiolabelling: [Aniline-U-^{14}C]-fluxapyroxad and [Pyrazole-4-^{14}C]-fluxapyroxad (EFSA, 2012)
	Cereals	Wheat	Foliar: 2 × 125 g/ha, BBCH 30/35, 69	36 DAT_1, 4, 34–35 DAT_2	Radiolabelling: [Aniline-U-^{14}C]-fluxapyroxad and [Pyrazole-4-^{14}C]-fluxapyroxad (EFSA, 2012)
			Seed treatment, 1 × 75 g/100 kg (equivalent to 135 g/ha)	93, 112 161 DAT	Radiolabelling: [Aniline-U-^{14}C]-fluxapyroxad and [Pyrazole-4-^{14}C]-fluxapyroxad (EFSA, 2015)
Rotational crops (available studies)	**Crop groups**	**Crop(s)**	**Application**[(a)]	**PBI (DAT)**	**Comment/source**
	Root/tuber crops	Radishes	Bare soil, 1 × 250 g/ha	30, 120/149, 365	Radiolabelling: [Aniline-U-^{14}C]-fluxapyroxad and [Pyrazole-4-^{14}C]-fluxapyroxad (EFSA, 2012)
	Leafy crops	Spinaches			
	Cereal	Wheat			
Processed commodities (hydrolysis study)	**Conditions**			**Stable?**	**Comment/Source**
	Pasteurisation (20 min, 90°C, pH 4)			Yes	Radiolabelling: [Pyrazole-4-^{14}C]-fluxapyroxad (EFSA, 2012)
	Baking, brewing and boiling (60 min, 100°C, pH 5)			Yes	Radiolabelling: [Pyrazole-4-^{14}C]-fluxapyroxad (EFSA, 2012)
	Sterilisation (20 min, 120°C, pH 6)			Yes	Radiolabelling: [Pyrazole-4-^{14}C]-fluxapyroxad (EFSA, 2012)
	Other processing conditions			–	–

PBI: plant-back interval; DAT: days after treatment.
(a): DAT- Days After Treatment, DATx, days after treatment x, e.g. DAT2: day after 2nd treatment.

Can a general residue definition be proposed for primary crops?	Yes	EFSA (2012)
Rotational crop and primary crop metabolism similar?	Yes	EFSA (2012)
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes	EFSA (2012)
Plant residue definition for monitoring (RD-Mo)	Fluxapyroxad	
Plant residue definition for risk assessment (RD-RA)	Fluxapyroxad	
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)	Matrices with high water content, high oil content, high acid content and dry matrices: HPLC–MS/MS, LOQ 0.01 mg/kg (EFSA, 2012) UPLC–MS/MS -LOQ 0.01 mg/kg (EFSA, 2012)	

BBCH: growth stages of mono- and dicotyledonous plants; HPLC–MS/MS: high-performance liquid chromatography with tandem mass spectrometry; UPLC–MS/MS: ultra-performance liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification.

B.1.1.2. Stability of residues in plants

Plant products (available studies)	**Category**	**Commodity**	**T (°C)**	**Stability period**		**Compounds covered**	**Comment/source**
				Value	**Unit**		
	High water content	Apple, tomato, potato	–20	24	Months	Fluxapyroxad	EFSA (2012)
	High oil content	Soybean, avocado	–20	24	Months	Fluxapyroxad	EFSA (2012)
	High protein content	Dried pea	–20	24	Months	Fluxapyroxad	EFSA (2012)
	High acid content	Grape, Lemon	–20	24	Months	Fluxapyroxad	EFSA (2012)
	Dry/High starch	Cereal grain	–20	24	Months	Fluxapyroxad	EFSA (2012)

B.1.2. Magnitude of residues in plants

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

Commodity	**Region/ indoor**[(a)]	**Residue levels observed in the supervised residue trials (mg/kg)**	**Comments/source**	**Calculated MRL (mg/kg)**	**HR**[(b)] **(mg/kg)**	**STMR**[(c)] **(mg/kg)**	**CF**[(d)]
Beetroots, carrots, celeriacs/turnip rooted celeries, horseradishes, Jerusalem artichokes, parsnips, parsley roots/ Hamburg roots parsley, salsifies, swedes/ rutabagas and turnips	USA	0.04; 0.05; 0.06; <u>0.07</u>; 0.10; 0.10; 0.35; 0.50	Residue trials on carrots compliant with GAP. Underlined value with sample collected at PHI of 10 days instead of PHI of 7 days. Extrapolation to the group 'other root and tuber vegetables, except sugar beet' is possible The MRL proposal corresponds to the MRL set in the country of origin, except for Jerusalem artichokes, where the USA MRL is set at the level of 0.02 mg/kg	0.9	0.50	0.09	1
Radishes	USA	0.03; 0.04; 0.05; 0.10; 0.10	Residue trials on radishes compliant with GAP. The data set alone is sufficient to derive an MRL for this individual crop. The value is proposed to risk manager as alternative of the MRL derived for the whole group by extrapolation The MRL in the country of origin is set at 0.9 mg/kg	0.2	0.10	0.05	1

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)]
Coffee beans	BR	< 0.01; < 0.01; 0.02; 0.03; 0.03; 0.04; 0.10; 0.13	Residue trials compliant with GAP (± 25% tolerance in application rate). Based on the OECD calculator an MRL of 0.3 mg kg is derived, which is higher than the MRL of 0.2 mg/kg set in the country of origin	0.3	0.13	0.03	1

MRL: maximum residue level; GAP: Good Agricultural Practice; 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. BR, Brazil; US, United States.
(b): Highest residue. The highest residue for risk assessment refers to the whole commodity and not to the edible portion.
(c): Supervised trials median residue. The median residue for risk assessment 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.

B.1.2.2. Residues in rotational crops

Residues in rotational and succeeding crops expected based on confined rotational crop study?	Not triggered	Study available but not required (imported crops)
Residues in rotational and succeeding crops expected based on field rotational crop study?	Not triggered	Study available but not required (imported crops)

B.1.2.3. Processing factors

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

B.2. Residues in livestock

Relevant groups	Dietary burden expressed in				Most critical diet[(a)]	Most critical commodity[(b)]		Trigger exceeded (Yes/No)	Previous assessment[(c)]
	mg/kg bw per day		mg/kg DM					0.10	Max burden
	Median	Maxi-mum	Median	Maxi-mum				mg/kg DM	mg/kg DM
Cattle (all diets)	0.223	0.335	5.80	8.71	Dairy cattle	Beet, sugar	Tops	Yes	45.2 (AU) FAO (2018)
Cattle (dairy only)	0.223	0.335	5.80	8.71	Dairy cattle	Beet, sugar	Tops	Yes	42.4 (AU) FAO (2018)
Sheep (all diets)	0.261	0.444	6.14	10.45	Lamb	Barley	Straw	Yes	
Sheep (ewe only)	0.205	0.348	6.14	10.45	Ram/Ewe	Barley	Straw	Yes	
Swine (all diets)	0.063	0.118	2.75	5.10	Swine (breeding)	Beet, sugar	Tops	Yes	
Poultry (all diets)	0.113	0.166	1.66	2.43	Poultry layer	Rice	Bran/ pollard	Yes	8.53 (EU) FAO (2015)
Poultry (layer only)	0.113	0.166	1.66	2.43	Poultry layer	Rice	Bran/ pollard	Yes	8.53 (EU) FAO, 2015

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'.
(c): The current MRLs for animal products are Codex MRLs that were taken over in the EU MRL legislation. The Codex MRLs were derived considering the highest dietary burden calculated for the different geographical regions: Australia (AU) or Europe (EU).

B.3. Consumer risk assessment

ARfD	0.25 mg/kg bw (European Commission, 2012)
Highest IESTI, according to EFSA PRIMo	Carrots: 15.2% of ARfD Celeriac: 13.3% of ARfD Swedes: 12.4% of ARfD Beetroot: 10.5% of ARfD Salsify: 9.4% of ARfD Parsnips: 8.7% of ARfD Turnips: 8.6% of ARfD Radishes: 5.3% of ARfD Parsley root: 0.5% of ARfD Coffee beans: Horseradish: 0.04 % of ARfD
Assumptions made for the calculations	The calculation is based on the highest residue levels expected in the crops under consideration. For radishes, the HR derived by extrapolation from residue trials on carrots was used as worst case scenario Calculations performed with PRIMo revision 2

ADI	0.02 mg/kg bw per day (European Commission, 2012)
Highest IEDI, according to EFSA PRIMo	37.1% ADI (DE child) Contribution of crops assessed: Beetroot: 0.31% of ADI Carrots: 1.19% of ADI Celeriac: 0.06% of ADI Horseradish: 0.02% of ADI Jerusalem artichokes: 0.04% of ADI Parsnips: 0.28% of ADI Parsley root: 0.03% of ADI Radishes: 0.03% of ADI Salsify: 0.04% of ADI Swedes: 0.12% of ADI Turnips: 0.12% of ADI Coffee beans: 0.05% of ADI
Assumptions made for the calculations	The calculation was performed considering the STMR values obtained from the residue trials on carrots for the group of other root and tuber vegetables (USA) and for coffee beans (Brazil). Additionally, the median residue levels for the crops assessed in previous EFSA reasoned opinions and for safe CXLs implemented in the EU legislation were included in the calculation. The STMRs for the Codex MRL recently assessed by EFSA and for which the European Commission did not raise any reservation were also included in the calculation (EFSA, 2019) STMRs of grapefruits, oranges and bananas refer to the edible portion of the crop For tropical root and tuber crops and for potatoes, the default MRL of 0.1 mg/kg was used as proposed by the EU pesticides peer review (EFSA, 2012). The STMR for products of animal origin were multiplied by a CF from 1.5 to 3.9 to accommodate for the residue definition for risk assessment (EFSA, 2011) For the remaining commodities, the existing MRLs have been used Calculations performed with PRIMo revision 2

ARfD: acute reference dose; bw: body weight; IESTI: international estimated short-term intake; PRIMo: (EFSA) Pesticide Residues Intake Model; HR: highest residue; ADI: acceptable daily intake; IEDI: international estimated daily intake; STMR: supervised trials median residue; MRL: maximum residue level; CF: conversion factor for enforcement to risk assessment residue definition.

B.4. Recommended MRLs

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Fluxapyroxad[(F)]				
213010	Beetroots	0.3	0.9	The requested import tolerance (USA) is sufficiently supported by data (extrapolation from residue data on carrots). MRL in the country of origin is set at 0.9 mg/kg Risk for consumer unlikely
213020	Carrots	0.3	0.9	The requested import tolerance (USA) is sufficiently supported by data. MRL in the country of origin is set at 0.9 mg/kg Risk for consumer unlikely
213030	Celeriacs/turnip rooted celeries	0.3	0.9	The requested import tolerance (USA) is sufficiently supported by data (extrapolation from residue data on carrots). MRL in the country of origin is set at 0.9 mg/kg Risk for consumer unlikely
213040	Horseradishes	0.3	0.9	
213050	Jerusalem artichokes	0.3	Risk management decision 0.02 or 0.9	The requested import tolerance (USA) is sufficiently supported by data (extrapolation from residue data on carrots). The US MRL for Jerusalem artichokes is set at 0.02 mg/kg Risk for consumer unlikely
213060	Parsnips	0.3	0.9	The requested import tolerance (USA) is sufficiently supported by data (extrapolation from residue data on carrots). MRL in the country of origin is set at 0.9 mg/kg Risk for consumer unlikely
213070	Parsley roots/ Hamburg roots parsley	0.3	0.9	
213080	Radishes	0.3	Risk management decision 0.9 or no change	The requested import tolerance (USA) is sufficiently supported by data. Based on residue trials compliant with the US GAP on radishes, an MRL proposal of 0.2 g/kg is derived, which is lower than the existing MRL Risk manager to decide whether to set the MRL at 0.9 mg/kg based on extrapolation from residue data on carrots or maintain the current value MRL in the country of origin is set at 0.9 mg/kg Risk for consumer unlikely
213090	Salsifies	0.3	0.9	The requested import tolerance (USA) is sufficiently supported by data (extrapolation from residue data on carrots). MRL in the country of origin is set at 0.9 mg/kg Risk for consumer unlikely
213100	Swedes/ rutabagas	0.3	0.9	
213110	Turnips	0.3	0.9	
620000	Coffee beans	0.01*	Risk management decision 0.2 or 0.3	The import tolerance request from Brazil is sufficiently supported by data. Recently, a Codex MRL (CXL) of 0.15 mg/kg was adopted which was acceptable for the EU; the CXL was derived for a similar Brazilian GAP, supported by a different set of residue trials Risk manager to decide whether to set the MRL of 0.2 mg/kg as established in the country of origin or the MRL of 0.3 mg/kg derived using the OECD calculator Risk for consumer unlikely

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

*: 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.

(F): Fat soluble.

Appendix C – Pesticide Residue Intake Model (PRIMo)

Fluxapyroxad			
Status of the active substance:		Code no.	
LOQ (mg/kg bw):	0.01	Proposed LOQ:	0.01
Toxicological end points			
ADI (mg/kg bw per day):	**0.02**	ARfD (mg/kg bw):	**0.25**
Source of ADI:	**COM**	Source of ARfD:	**COM**
Year of evaluation:	**2012**	Year of evaluation:	**2012**

MRLs according to Regulation (EU) No 2017/626, execept those under assessment.

Chronic risk assessment – refined calculations

TMDI (range) in % of ADI
minimum – maximum
6 37

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)
37.1	DE child	18.1	Apples	3.0	Table grapes	2.5	Wheat	0.9
31.2	NL child	9.5	Apples	2.9	Potatoes	2.8	Wheat	1.5
28.8	WHO Cluster diet B	5.1	Wheat	4.2	Wine grapes	2.3	Rice	0.6
27.7	IE adult	3.3	Barley	2.9	Wine grapes	2.1	Rhubarb	0.6
21.6	FR toddler	3.9	Apples	3.6	Beans (with pods)	2.6	Strawberries	0.2
21.1	WHO cluster diet E	3.8	Wine grapes	2.4	Wheat	2.2	Barley	0.3
19.8	PT General population	5.8	Wine grapes	3.4	Rice	2.7	Potatoes	0.1
18.7	FR all population	9.4	Wine grapes	2.0	Wheat	1.3	Witloof	0.2
18.0	UK Toddler	4.6	Sugar beet (root)	2.6	Apples	2.5	Rice	0.2
17.4	FR infant	3.8	Apples	2.7	Beans (with pods)	2.1	Potatoes	1.1
17.2	DK child	3.5	Apples	3.3	Wheat	2.7	Rye	0.0
17.2	WHO cluster diet D	3.9	Wheat	2.4	Rice	2.0	Potatoes	0.3
15.4	WHO regional European diet	2.0	Potatoes	1.8	Wheat	1.0	Apples	0.3
15.3	UK Infant	2.7	Rice	2.3	Apples	2.0	Sugar beet (root)	0.2
14.9	WHO Cluster diet F	2.2	Wheat	1.7	Potatoes	1.6	Barley	0.3
14.4	ES child	2.7	Wheat	2.1	Rice	1.7	Apples	0.7
14.3	NL general	1.8	Apples	1.5	Wine grapes	1.4	Witloof	0.4
14.2	SE general population 90th percentile	2.1	Potatoes	1.9	Wheat	1.7	Rice	0.6
12.7	IT kids/toddler	4.0	Wheat	1.3	Apples	0.8	Rice	0.1
12.2	ES adult	1.4	Wheat	1.4	Lettuce	1.3	Barley	0.3
11.0	IT adult	2.5	Wheat	1.2	Apples	1.0	Lettuce	0.1
10.2	UK vegetarian	1.9	Wine grapes	1.6	Rice	1.2	Wheat	0.1
9.7	DK adult	3.3	Wine grapes	1.2	Wheat	1.2	Apples	0.0
9.3	UK Adult	2.5	Wine grapes	1.6	Rice	1.0	Wheat	0.1
8.9	LT adult	2.8	Apples	1.6	Potatoes	0.9	Rice	0.2
8.0	PL general population	3.1	Apples	1.7	Potatoes	0.8	Table grapes	0.0
5.6	FI adult	0.7	Wine grapes	0.6	Potatoes	0.6	Apples	0.1

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Fluxapyroxad 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):** ---		
IESTI 1	*)	**)	**IESTI 2**	*)	**)
Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
15.2	Carrots	0.6/-	13.3	Celeriac	0.6/-
13.3	Celeriac	0.6/-	12.4	Swedes	0.6/-
12.4	Swedes	0.6/-	10.9	Carrots	0.6/-
10.5	Beetroot	0.6/-	7.8	Beetroot	0.6/-
9.4	Salsify	0.6/-	6.7	Salsify	0.6/-
8.7	Parsnips	0.6/-	6.2	Parsnips	0.6/-
8.6	Turnips	0.6/-	6.2	Turnips	0.6/-
5.3	Radishes	0.6/-	3.8	Radishes	0.6/-
0.5	Parsley root	0.6/-	0.3	Parsley root	0.6/-
0.04	Horseradish	0.6/-	0.04	Coffee beans	0.13/-
0.04	Coffee beans	0.13/-	0.03	Horseradish	0.6/-
No of critical MRLs (IESTI 1)			---		

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**	*)	**)
Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
5.7	Swedes	0.6/-	5.7	Swedes	0.6/-
4.0	Celeriac	0.6/-	4.0	Celeriac	0.6/-
3.4	Parsnips	0.6/-	2.6	Beetroot	0.6/-
3.3	Beetroot	0.6/-	2.5	Parsnips	0.6/-
2.8	f	#N/A	2.3	Carrots	0.6/-
2.7	Radishes	0.6/-	1.9	Radishes	0.6/-
2.6	Salsify	0.6/-	1.8	Salsify	0.6/-
2.5	Turnips	0.6/-	1.8	Turnips	0.6/-
1.4	Jerusalem artichokes	0.6/-	1.1	Jerusalem artichokes	0.6/-
0.2	Horseradish	0.6/-	0.1	Horseradish	0.6/-
0.2	Parsley root	0.6/-	0.1	Parsley root	0.6/-
0.1	Coffee beans	0.13/-	0.1	Coffee beans	0.13/-
No of critical MRLs (IESTI 2)			---		

Processed commodities

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

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

Conclusion:

For Fluxapyroxad, 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. Input values for the dietary burden calculation

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Barley/oat, straw	4.33	STMR (EFSA, 2011)	10.11	HR (EFSA, 2011)
Beet, fodder	0.04	STMR (EFSA, 2011)	0.07	HR (EFSA, 2011)
Beet, sugar tops	2.57	STMR (EFSA, 2011)	4.17	HR (EFSA, 2011)
Cabbage, head leaves	0.01	STMR (EFSA, 2017)	0.27	HR (EFSA, 2017)
Kale leaves, forage	0.07	MRL (EFSA, 2017)	0.07	MRL (EFSA, 2017)
Rye/wheat, straw	2.13	STMR (EFSA, 2011)	8.32	HR (EFSA, 2011)
Carrot culls	0.09	STMR	0.5	HR
Cassava/tapioca	0.01	STMR (EFSA, 2017)	0.01	HR (EFSA, 2017)
Potatoes	0.02	STMR (EFSA, 2015)	0.07	HR (EFSA, 2015)
Swedes/turnips	0.09	STMR (carrots)	0.5	HR (carrots)
Barley/oat, grain	0.54	STMR (EFSA, 2011)		
Wheat/rye, grain	0.12	STMR (EFSA, 2011)		
Bean/lupins, dry	0.04	STMR (EFSA, 2011)		
Peas (dry)	0.04	STMR (FAO, 2012)		
Maize grain	0.01	STMR (EFSA, 2011)		
Cotton seeds	0.07	STMR (FAO, 2015)		
Sorghum grain	0.20	STMR (FAO, 2015)		
Soybean seeds	0.01	STMR (EFSA, 2011)		
Apple, wet pomace	1.38 (0.3 × 4.6)	STMR (FAO, 2012), PF (EFSA, 2011)		
Beet, sugar dry pulp	0.07 (0.04 × 1.74)	STMR × PF[(a)] (EFSA, 2011)		
Beet, sugar ensiled pulp	0.12 (0.04 × 3)	STMR (EFSA, 2011) × PF (3)		
Beet, sugar molasses	0.03 (0.04 × 0.80)	STMR × PF[(a)] (EFSA, 2011)		
Brewer's grain dry pulp	1.78 (0.54 × 3.3)	STMR × PF (EFSA, 2011)		
Citrus, dry pulp	0.007 (0.07 × 0.1)	STMR × PF (EFSA, 2017)		
Coconut meal	0.02 (0.01 × 1.5)	STMR (FAO, 2015) × PF (1.5)		
Corn, field milled by-pdts	0.01 (0.01 × 1)	STMR (EFSA, 2011)-PF (1)		
Corn, field hominy meal	0.06 (0.01 × 6)	STMR (EFSA, 2011)-PF (6)		
Corn, field gluten feed	0.03 (0.01 × 2.5)	STMR (EFSA, 2011)-PF (2.5)		
Corn, field gluten, meal	0.01 (0.01 × 1)	STMR (EFSA, 2011)-PF (1)		
Cotton meal	0.004 (0.07 × 0.06)	STMR × PF[(a)] (FAO, 2015)		
Distiller's grain	0.40 (0.12 × 3.3)	STMR (EFSA, 2011)-PF (3.3)		
Linseed meal	0.04 (0.09 × 0.44)	STMR × PF (EFSA, 2011)		
Lupin seed meal	0.04 (0.04 × 1.1)	STMR (EFSA, 2011)-PF (1.1)		
Peanut meal	0.001 (0.01× 0.12)	STMR-PF[(a)] (EFSA, 2011)		
Potato, process waste	0.10 (0.02 × 5.00)	STMR-PF (EFSA, 2011)		
Potato, dried pulp	0.16 (0.02 × 8.00)	STMR-PF (EFSA, 2011)		
Rape/canola seed meal	0.05 (0.12 × 0.44)	STMR-PF[(a)] (EFSA, 2011)		
Rice, bran/pollard	9.40 (0.94 × 10)	STMR (FAO, 2015) × PF (10)		
Safflower seed meal	0.18 (0.09 × 2)	STMR (EFSA, 2011) × PF (2)		
Soybean meal	0.013 (0.01× 1.3)	STMR-PF (EFSA, 2011)		
Soybean hulls	0.13 (0.01 × 13)	STMR (EFSA, 2011)-PF (13)		

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Sugarcane molasses	8.32 (0.26 × 32)	STMR (EFSA, 2016)-PF (32)		
Sunflower seed	0.011 (0.09× 0.12)	STMR (EFSA, 2011) × PF(FAO, 2012)		
Wheat gluten meal	0.22 (0.12 × 1.8)	STMR (EFSA, 2011)-PF (1.8)		
Wheat milled by-products	0.84 (0.12 × 7)	STMR (EFSA, 2011)-PF (7)		

STMR: supervised trials median residue; HR: highest residue; PF: processing factor.
(a): Indicative processing factor as based only on two trials.

D.2. Input values for consumer risk assessment

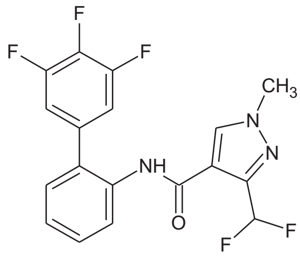
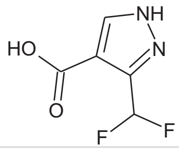
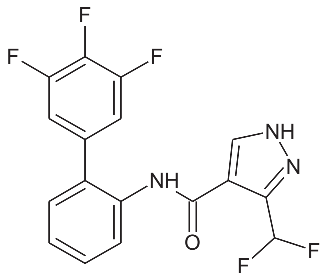
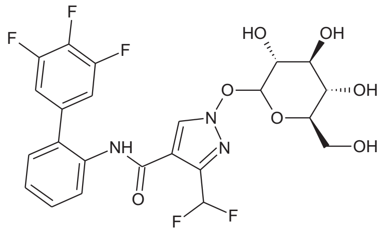
Commodity	Chronic exposure assessment		Acute exposure assessment[c]	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Risk assessment residue definition for plants: Fluxapyroxad **Risk assessment residue definition for products of animal origin:** Fluxapyroxad (BAS 700F) and metabolite M700F008 expressed as parent equivalent				
Other root & tuber vegetables, except sugar beet	0.09	STMR (carrots)	0.50	HR (carrots)
Coffee beans	0.03	STMR	0.13	HR
Grapefruits	0.01	STMR-pulp (EFSA, 2017)		
Tropical root and tuber vegetables	0.10	MRL[(a)] (EFSA, 2017)		
Herbal infusions from roots, Roots and rhizome spices	0.04	STMR (EFSA, 2017)		
Spring onions, leeks	0.13	STMR (EFSA, 2017)		
Broccoli	0.28	STMR (EFSA, 2016)		
Cauliflower	0.01	STMR (EFSA, 2017)		
Brussels sprouts	0.05	STMR (EFSA, 2017)		
Head cabbages	0.01	STMR (EFSA, 2017)		
Lettuces and salad plants, except lettuces and baby leaf crops (including brassica species)	0.25	STMR (EFSA, 2017)		
Lettuces	0.51	STMR (FAO, 2015)		
Baby leaf crops (including brassica species	0.25	STMR (EFSA, 2017)		
Spinaches and similar leaves, Herbs and edible flowers	0.06	STMR (EFSA, 2017)		
Witloofs	1.95	STMR (EFSA, 2017)		
Globe artichokes	0.07	STMR (EFSA, 2017)		
Chicory roots	0.07	STMR (EFSA, 2017)		
Oranges	0.01	STMR-pulp (FAO, 2015)		
Tree nuts	0.01	STMR (EFSA, 2016)		
Pome fruits	0.30	STMR (FAO, 2012)		
Apricots	0.44	STMR (EFSA, 2011)		
Cherries	0.56	STMR (EFSA, 2016)		
Peaches	0.47	STMR (FAO, 2015)		

Commodity	Chronic exposure assessment		Acute exposure assessment[c]	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Plums	0.44	STMR (EFSA, 2011)		
Grapes	0.47	STMR (FAO, 2015)		
Strawberries	0.82	STMR (EFSA, 2016)		
Blueberries	2.39	STMR (EFSA, 2016)		
Banana	0.06	STMR-pulp (FAO, 2015)		
Mangoes	0.18	STMR (EFSA, 2016)		
Papaya	0.05	STMR (FAO, 2018)		
Potatoes	0.10	MRL[a] (EFSA, 2017)		
Tomatoes	0.07	STMR (FAO, 2012)		
Peppers	0.07	STMR (FAO, 2012)		
Aubergines (egg plants)	0.07	STMR (FAO, 2012)		
Okra, lady's fingers	0.07	STMR (FAO, 2012)		
Cucurbits edible peel	0.05	STMR (EFSA, 2016)		
Cucurbits inedible peel	0.05	STMR (EFSA, 2016)		
Sweet corns	0.01	STMR (EFSA, 2011)		
Broccoli	0.28	STMR (EFSA, 2016)		
Chinese cabbages	0.90	STMR (EFSA, 2016)		
Beans and peas, with pods	0.65	STMR (FAO, 2012)		
Beans and peas, without pods	0.03	STMR (FAO, 2012)		
Celery, rhubarb, fennel, cardoon	1.68	STMR (EFSA, 2016)		
Peas, lentils (dry)	0.04	STMR (FAO, 2012)		
Beans, lupins (dry)	0.04	STMR (EFSA, 2011)		
Linseed, poppy seed, sesame seed, mustard seed, pumpkin seed, safflower, borage, gold of pleasure, hempseed, castor bean, other oilseed	0.09	STMR (EFSA, 2011)		
Peanuts	0.01	STMR (EFSA, 2011)		
Sunflower seeds	0.06	STMR (EFSA, 2011)		
Rapeseeds	0.12	STMR (EFSA, 2011)		
Soya beans	0.01	STMR (EFSA, 2011)		
Cotton seeds	0.08	STMR (FAO, 2018)		
Barley, oats	0.54	STMR (EFSA, 2011)		
Maize	0.01	STMR (EFSA, 2011)		
Rice (husked)	0.86	STMR (EFSA, 2016)		
Sorghum	0.20	STMR (FAO, 2015)		
Rye, wheat	0.12	STMR (EFSA, 2011)		
Sugar beets (roots)	0.04	STMR (EFSA, 2011)		
Sugar cane	0.26	STMR (EFSA, 2016)		
Muscle/meat from mammalians	0.05	STMR meat[b] (EFSA, 2011, 2017)		
Fat tissue from mammalians	0.07	STMR (0.047) × CF (1.5) (EFSA, 2011, 2017)		
Liver from mammalians	0.32	STMR (0.081) × CF (3.9) (EFSA, 2011, 2017)		

Commodity	Chronic exposure assessment		Acute exposure assessment[(c)]	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Kidney from mammalians	0.05	STMR (0.024) × CF (2) (EFSA, 2011, 2017)		
Edible offal from mammalians	0.32	STMR (0.081) × CF (3.9) (EFSA, 2011, 2017)		
Other tissues from mammalians	0.20	MRL (0.1) × CF (2) (EFSA, 2011, 2017)		
Muscle from poultry	0.04	STMR meat[(b)] (EFSA, 2011, 2017)		
Fat tissue from poultry	0.04	STMR (0.021) × CF (2) (EFSA, 2011, 2017)		
Liver from poultry	0.04	STMR (0.021) × CF (2) (EFSA, 2011, 2017)		
Kidney from poultry	0.04	MRL (0.02) × CF (2) (EFSA, 2011, 2017)		
Edible offal from poultry	0.04	MRL (0.01) × CF (2) (EFSA, 2011, 2017)		
Milk	0.01	STMR (0.004) × CF (2) (EFSA, 2011, 2017)		
Birds eggs	0.01	STMR (0.006) × CF (2) (EFSA, 2011, 2017)		
Other plant and animal commodities	MRL	MRLs in Regulation (EU) No 2018/685		

STMR: supervised trials median residue; HR: highest residue; CF: conversion factor; MRL: maximum residue level.
(a): EFSA used the existing MRL of 0.1 mg/kg as proposed by the EU pesticides peer review to cover worst-case scenario of residues potentially arising from rotational sources.
(b): Consumption figures in the EFSA PRIMo are expressed as meat. STMR values (mammalian muscle < 0.02 mg/kg × CF 2 and fat 0.05 mg/kg × CF 1.5; poultry muscle < 0.02 mg/kg × CF 2 and fat 0.02 mg/kg × CF 2) were calculated considering 80%/90% muscle and 20%/10% fat content for mammalian/poultry meat, respectively (FAO, 2016).
(c): Acute risk assessment undertaken only with regard to the crops under consideration.

Appendix E – Used compound codes

Code/trivial name[(a)]	IUPAC name/SMILES notation/InChiKey[(b)]	Structural formula[(c)]
fluxapyroxad	3-(difluoromethyl)-1-methyl-2′-(3,4,5-trifluorophenyl)-1*H*-pyrazole-4-carboxanilide FC(F)c1nn(C)cc1C(=O)Nc1ccccc1c1cc(F)c(F)c(F)c1 SXSGXWCSHSVPGB-UHFFFAOYSA-N	
M700F002	3-(difluoromethyl)-1*H*-pyrazole-4-carboxylic acid OC(=O)c1c[NH]nc1C(F)F IGQNDARULCASRN-UHFFFAOYSA-N	
M700F008	3-(difluoromethyl)-*N*-(3′,4′,5′-trifluoro[biphenyl]-2-yl)-1*H*-pyrazole-4-carboxamide O=C(Nc1ccccc1c1cc(F)c(F)c(F)c1)c1c[NH]nc1C(F)F SYGSBKQBCWBROS-UHFFFAOYSA-N	
M700F048	3-(difluoromethyl)-1-(D-glucopyranosyloxy)-*N*-(3′,4′,5′-trifluoro[biphenyl]-2-yl)-1*H*-pyrazole-4-carboxamide	

IUPAC: International Union of Pure and Applied Chemistry; SMILES: simplified molecular-input line-entry system; InChiKey: International Chemical Identifier Key.
(a): The metabolite name in bold is the name used in the conclusion.
(b): ACD/Name 2019.1.1 ACD/Labs 2019 Release (File version N05E41, Build 110555, 18 July 2019).
(c): ACD/ChemSketch 2019.1.1 ACD/Labs 2019 Release (File version C05H41, Build 110712, 24 July 2019).