Adopted: 11 March 2024

DOI: 10.2903/j.efsa.2024.8696

REASONED OPINION

efsa JOURNAL

Modification of the existing maximum residue levels for fluxapyroxad in kaki/Japanese persimmons and cultivated mushrooms

EFSA (European Food Safety Authority) | Giulia Bellisai | Giovanni Bernasconi | Luis Carrasco Cabrera | Irene Castellan | Monica del Aguila | Lucien Ferreira | German Giner Santonja | Luna Greco | Samira Jarrah | Renata Leuschner | Andrea Mioč | Stefanie Nave | Ragnor Pedersen | Hermine Reich | Silvia Ruocco | Alessia Pia Scarlato | Marta Szot | Anne Theobald | Manuela Tiramani | Alessia Verani

Correspondence:
pesticides.mrl@efsa.europa.eu

Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant BASF SE submitted two requests to the competent national authority in Spain and Ireland to modify the existing maximum residue levels (MRLs) for the active substance fluxapyroxad in kaki/Japanese persimmons and in cultivated fungi, respectively. The data submitted in support of the requests were found to be sufficient to derive MRL proposals for kaki/Japanese persimmons and cultivated fungi. Adequate analytical methods for enforcement are available to control the residues of fluxapyroxad on the commodities under consideration at the validated 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. The long-term consumer risk assessment is indicative, pending the submission of the confirmatory data requested under the MRL review.

KEYWORDS

consumer risk assessment, fluxapyroxad, fungicide, kaki/Japanese persimmons, MRL, mushrooms

CONTENTS

SUMMARY

In accordance with Article 6 of Regulation (EC) No 396/2005, BASF SE submitted two separate applications to the competent national authority in Spain and Ireland (evaluating Member States, EMSs) to modify the existing maximum residue levels (MRLs) for the active substance (a.s.) fluxapyroxad in kaki/Japanese persimmons and cultivated fungi, respectively.

The first application for an MRL in cultivated mushrooms, alongside the dossier containing the supporting data in IUCLID format, was submitted through the European Food Safety Authority (EFSA) Central Submission System on 23 September 2022. The appointed EMS Ireland assessed the dossier and declared its admissibility on 19 December 2022. The second application for an MRL in kaki/Japanese persimmons, alongside the dossier containing the supporting data in IUCLID format, was submitted through the EFSA Central Submission System on 16 January 2023 and the appointed EMS Spain declared its admissibility on 15 February 2023. Subsequently, following the implementation of the EFSA's confidentiality decision, the non-confidential versions of the dossiers were published by EFSA, and a public consultation was launched on each dossier. The consultation aimed to consult stakeholders and the public on the scientific data, studies and other information part of, or supporting, the submitted application, in order to identify whether other relevant scientific data or studies are available. The two consultations run from 7 June 2023 to 25 July 2023. Neither additional data nor comments were submitted in the framework of these consultations.

At the end of the commenting period, each EMS proceeded drafting the evaluation report, in accordance with Article 8 of Regulation (EC) No 396/2005. Both evaluation reports were submitted to the European Commission and forwarded to EFSA on 5 December 2023 and 11 January 2024 for the application on MRLs in cultivated mushrooms and MRLs in kaki/Japanese persimmons, respectively.

To accommodate for the intended use of fluxapyroxad, the EMS Ireland proposed to raise the existing MRL for cultivated fungi from the limit of quantification (LOQ) of 0.01 to 0.3 mg/kg. The EMS Spain proposed to raise the existing MRL for kaki/Japanese persimmons from the LOQ of 0.01 to 0.2 mg/kg.

EFSA assessed the applications and evaluation reports as required by Article 10 of the MRL regulation. EFSA identified points that needed further clarification for both applications and requested that the EMSs to address them. The applicant provided the requested information for each application in an updated IUCLID dossier. The additional information was duly considered by the EMSs in Ireland and Spain, who submitted a revised evaluation report to EFSA on 8 February 2024 and 7 March 2024, respectively. These updated reports replaced the previously submitted evaluation reports. For efficiency, the assessment was merged into a single reasoned opinion.

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 each EMS in the framework of the two applications, 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. The metabolism of fluxapyroxad in rotational crops was investigated in root/tuber, leafy and cereal crops after bare soil applications. Studies investigating the effect of processing on the nature of fluxapyroxad (hydrolysis studies) demonstrated that the a.s. is stable.

Based on the metabolic pattern identified in metabolism studies, hydrolysis studies and the toxicological relevance of metabolites, the residue definitions for plant products were proposed 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 commodities assessed in these applications, the metabolism of fluxapyroxad in primary crops and the possible degradation in processed products have been sufficiently addressed and that the previously derived residue definitions are applicable. As the proposed uses of fluxapyroxad are on kaki/Japanese persimmons belonging to the group of permanent crops, and on mushrooms cultivated indoor in substrates, investigations of residues in rotational crops are not required in the framework of the current applications.

A sufficiently validated analytical method based on high performance liquid chromatography with tandem mass spectrometry (HPLC-MS/MS) is available to quantify residues of fluxapyroxad in the commodities assessed in these applications according to the enforcement residue definition. The method enables quantification of residues at or above 0.01 mg/kg (LOQ) in the commodities assessed (high water content matrices). The extraction efficiency of the enforcement method available (coded L0137/01) has been proven in high water content commodities.

The available residue trials are sufficient to derive an MRL proposal of 0.2 mg/kg for kaki/Japanese persimmons by extrapolation from residue trials on apples, and to derive an MRL proposal of 0.3 mg/kg for cultivated mushrooms based on the proposed Good Agricultural Practices (GAP).

Specific studies investigating the magnitude of fluxapyroxad residues in processed commodities are not required, as the individual total theoretical maximum daily intake is expected to be below the trigger value of 10% of the ADI.

Residues of fluxapyroxad in commodities of animal origin were not assessed since the commodities under consideration in these MRL applications are normally not fed to livestock.

The toxicological profile of fluxapyroxad 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 0.02 mg/kg body weight (bw) per day and an acute reference dose (ARfD) of 0.25 mg/kg bw. The metabolite (M700F008), which is included in the residue definition for risk assessment in products of animal origin, was concluded to be of similar toxicity as the parent a.s.

The consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo). The short-term exposure assessment was performed only for the commodities assessed in the present MRL applications and did not exceed the ARfD for any of the crops assessed.

In the framework of the MRL review, a comprehensive long-term exposure assessment was performed, taking into account the existing uses at the EU level and the Codex MRLs (CXLs) that were implemented in the MRL legislation. EFSA updated the chronic risk assessment conducted in the framework of the MRL review with the median residue (STMR) values, derived in support of an MRL application submitted after the MRL review for certain root crops and coffee beans, the STMR values in support of CXLs assessed by EFSA after the MRL review and implemented in the EU MRL legislation and the STMR values derived from the residue trials submitted with the present MRL applications. The crops on which no uses or supported safe CXLs were reported in the MRL review and subsequently published EFSA outputs were excluded from the exposure calculation. The estimated long-term dietary intake accounted for a maximum of 73% of the ADI (NL toddler diet).

EFSA concluded that the proposed uses of fluxapyroxad on kaki/Japanese persimmons and cultivated mushrooms will not result in a consumer exposure exceeding the toxicological reference values and therefore are unlikely to pose a risk to consumers' health. The long-term consumer risk assessment is indicative, pending the submission of the confirmatory data requested under the MRL review.

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

Full details of all end points 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]				
0161060	Kaki/Japanese persimmons	0.01*	0.2	The submitted data are sufficient to derive an MRL proposal for the intended SEU use by extrapolation from residue trials on apples. Risk for consumers unlikely
0280010	Cultivated fungi	0.01*	0.3	The submitted data are sufficient to derive an MRL proposal for the intended indoor EU use. Risk for consumers unlikely

Abbreviations: MRL, maximum residue level; SEU, southern European Union.

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

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

[F]Fat soluble.

ASSESSMENT

The European Food Safety Authority (EFSA) received two separate applications to modify the existing maximum residue levels (MRLs) for fluxapyroxad in kaki/Japanese persimmons and in cultivated fungi. The detailed description of the intended uses of fluxapyroxad, which are the basis for the current MRL applications, is reported in Appendix A.

Fluxapyroxad is the International Organisation for Standardisation common name for 3-(difluoromethyl)-1-methyl-*N*-(3′,4′,5′-trifluoro[1,1′-biphenyl]-2-yl)-1*H*-pyrazole-4-carboxamide (IUPAC). The chemical structures of the a.s. and its main metabolites are reported in Appendix E.

Fluxapyroxad[1] was evaluated in the framework of Directive 91/414/EEC[2] with the United Kingdom designated as rapporteur Member State (RMS) for the representative uses as a foliar treatment on cereals. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by EFSA (EFSA, 2012). Fluxapyroxad was approved[3] for the use as fungicide on 1 January 2013.

The EU MRLs for fluxapyroxad are established in Annex II of Regulation (EC) No 396/2005.[4] The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has been performed (EFSA, 2020a) and the proposed modifications have been implemented in the MRL legislation. Subsequently, EFSA has issued another reasoned opinion on the modification of MRLs for fluxapyroxad (EFSA, 2020b) which was not yet considering the MRL review outcome. The proposals from this reasoned opinion have been considered in recent MRL regulation.[5] Certain Codex maximum residue limits (CXLs) have been taken over in the EU MRL legislation (FAO, 2013, 2015, 2018, 2020).

In accordance with Article 6 of Regulation (EC) No 396/2005 and following the provisions set by the 'Transparency Regulation' (EU) 2019/1381[6], the applicant BASF SE submitted two separate applications to the competent national authority in Ireland and Spain (evaluating Member States, EMSs) to modify the existing MRLs for the active substance (a.s.) fluxapyroxad in cultivated fungi and kaki/Japanese persimmons, respectively.

The first application for an MRL in cultivated mushrooms, alongside the dossier containing the supporting data in IUCLID format, was submitted through the EFSA Central Submission System on 23 September 2022. The appointed EMS Ireland assessed the dossier and declared its admissibility on 19 December 2022. The second application for an MRL in kaki/Japanese persimmons, alongside the dossier containing the supporting data in IUCLID format, was submitted through the EFSA Central Submission System on 16 January 2023 and the appointed EMS Spain declared its admissibility on 15 February 2023. Subsequently, following the implementation of the EFSA's confidentiality decision, the non-confidential versions of the dossiers were published by EFSA, and a public consultation was launched on each dossier. The consultation aimed to consult stakeholders and the public on the scientific data, studies and other information part of, or supporting, the submitted application, in order to identify whether other relevant scientific data or studies are available. The two consultations run from 7 June 2023 to 25 July 2023. No additional data nor comments were submitted in the framework of these consultations.

At the end of the commenting period, each EMS proceeded drafting the evaluation report, in accordance with Article 8 of Regulation (EC) No 396/2005. Both evaluation reports were submitted to the European Commission and forwarded to EFSA on 5 December 2023 and on 11 January2024 for the application on MRLs in cultivated mushrooms and MRLs in kaki/Japanese persimmons, respectively.

EFSA assessed the applications and evaluation reports as required by Article 10 of the MRL regulation. For efficiency, the assessment was merged in a single reasoned opinion.

EFSA identified points which needed further clarification for both applications and requested the EMSs to address them. The applicant provided the requested information for each application in an updated IUCLID dossier. The additional information was duly considered by the EMSs Ireland and Spain who submitted a revised evaluation report to EFSA on 8 February 2024 and 7 March 2024, respectively. These updated reports replaced the previously submitted evaluation reports.

EFSA based its assessment on the evaluation report submitted by each EMS (Ireland, 2023; Spain, 2023), the DAR and its final addendum prepared under Council Directive 91/414/EEC (United Kingdom, 2011a, 2011b), the Commission review report on fluxapyroxad (European Commission, 2012), the conclusion on the peer review of the pesticide risk assessment of the a.s. fluxapyroxad (EFSA, 2012), as well as the conclusions from previous EFSA opinions on fluxapyroxad (EFSA, 2011, 2015, 2016a, 2017, 2020b), including the reasoned opinion on the MRL review according to Article 12 of

[1]It should be noted that fluxapyroxad and its metabolites M700F008 and M700F048 are identified as a pesticide active substance/metabolites that meets the definition of per- and polyfluoroalkyl substances (PFAS) based on its chemical structure (https://echa.europa.eu/hot-topics/perfluoroalkyl-chemicals-pfas).

[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]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.

[4]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.

[5]For an overview of all MRL Regulations on this active substance, please consult: https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/start/screen/mrls

[6]Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC, PE/41/2019/REV/1. OJ L 231, 6.9.2019, p. 1–28.

Regulation No 396/2005 (EFSA, 2020a), and the Scientific reports in support to the preparation of an EU position for the Codex Committee on Pesticide Residues (CCPR) meetings (EFSA, 2013, 2016b, 2019b, 2021).

For these applications, the data requirements established in Regulation (EU) No 544/2011[7] and the guidance documents applicable at the date of submission of the IUCLID application are applicable (European Commission, 1997a, 1997b, 1997c, 1997d, 1997e, 1997f, 1997g, 2010, 2020, 2021, 2022; OECD, 2011). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011.[8]

It is noted that kaki/Japanese persimmons is a melliferous crop and the use of fluxapyroxad described in the current application is expected during the flowering period, however, further data is not required according to the data requirements applicable for the assessment of the submitted application.

It is noted that the EU pesticides peer review of the renewal of approval of the a.s. fluxapyroxad in accordance with Regulation (EC) No 1107/2009 is to be initiated in the near future and therefore the conclusions reported in this reasoned opinion might need to be reconsidered in the light of the outcome of the peer review.

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

The evaluation reports submitted by the EMSs (Ireland, 2023; Spain, 2023) 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.[9]

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 after foliar applications was investigated in fruits (tomatoes), pulses/oilseeds (soybean) and cereals/grasses (wheat) crop groups in the framework of the EU pesticides peer review (EFSA, 2012). Additionally, the metabolism study on cereal (wheat) seed treatment was submitted and evaluated in the context of the previous MRL application (EFSA, 2015). These studies have been re-evaluated during the MRL review for fluxapyroxad (EFSA, 2020a).

After foliar applications, fluxapyroxad was the main component of the total radioactive residues (TRR) in tomatoes, wheat and soyabeans plant parts, except in seeds, where the metabolism showed to be more extensive. In tomatoes and wheat following the foliar treatment, parent compound represented 54% of the TRR up to more than 90% TRR, while in soyabean seeds it was determined to be 7% up to 21% TRR, and the two major metabolites M700F002 and M700F048 were identified as 33.5% and 20% TRR, respectively (EFSA, 2012). The metabolic pathway of fluxapyroxad was similar in cereals following foliar application and after seed treatment (EFSA, 2015, 2020a).

Considering that the metabolism of fluxapyroxad was found to be similar in three different crop groups, the results of these studies can be extended to all crop categories (European Commission, 1997a). For the intended uses of fluxapyroxad on kaki/Japanese persimmons and cultivated mushrooms, which belong to the fruits crop group, the metabolic behaviour in primary crops is sufficiently addressed.

1.1.2 | Nature of residues in rotational crops

Fluxapyroxad is not proposed to be used on crops that can be grown in rotation.

For kaki/Japanese persimmons (permanent crop) and cultivated fungi (grown in substrate) assessed in these applications, no information is required (EFSA, 2023; European Commission, 1997c).

The Guidance on the assessment of pesticide residues in rotational crops published by EFSA in 2023 specifies that rotational crop studies shall not be required for uses of plant protection products in cultivated fungi, where rotations on the same substrate are not part of the normal agricultural practices (EFSA, 2023). EFSA is proposing to take into consideration this explanation, even though the Guidance per se is not yet applicable.

Nevertheless, studies on the nature of residues in rotation crop are available and are reported in Appendix B of this reasoned opinion for completeness.

[7]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.

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

[9]Background documents to this reasoned opinion are published on OpenEFSA portal and are available at the following link: https://open.efsa.europa.eu/study-inventory/EFSA-Q-2023-00108; https://open.efsa.europa.eu/study-inventory/EFSA-Q-2022-00877

1.1.3 | Nature of residues in processed commodities

The effect of processing on the nature of fluxapyroxad was investigated in the framework of the EU pesticides peer review (EFSA, 2012) in studies performed under standard hydrolysis conditions.

These studies showed that fluxapyroxad is hydrolytically stable under standard processing conditions such as pasteurisation, baking, brewing and boiling and sterilisation (EFSA, 2012). This conclusion was confirmed in the framework of the MRL review (EFSA, 2020a).

EFSA concluded that the nature of residues of the a.s. under standard hydrolysis conditions is sufficiently addressed, and further studies are not required for the intended uses.

1.1.4 | Analytical methods for enforcement purposes in plant commodities

The analytical method for the determination of residues of fluxapyroxad in plant commodities was assessed in the context of the EU pesticides peer review and the MRL review (EFSA, 2012, 2020a). The high performance liquid chromatography with tandem mass spectrometry (HPLC-MS/MS) method (L0137/01) and its independent laboratory validation (ILV) are sufficiently validated for the determination of the residues of fluxapyroxad in high water, high acid, high oil content and dry matrices. The method allows quantifying residues at or above the LOQ of 0.01 mg/kg. The LOQ of 0.01 mg/kg is achievable in all four main plant matrices by using the Quick, Easy, Cheap, Effective, Rugged and Safe (QuEChERS) multi-residue method in routine analyses (EFSA, 2020a).

As reported in the MRL review, according to the EU Reference Laboratories, fluxapyroxad can be monitored by the above-mentioned method in high water and high acid content commodities with a lower LOQ of 0.002 mg/kg and in dry and high oil content commodities with an LOQ of 0.005 mg/kg, and in honey with an LOQ of 0.005 mg/kg (EFSA, 2020a).

EFSA concludes that sufficiently validated analytical method is available for enforcing the proposed MRLs for fluxapyroxad in kaki/Japanese persimmons and cultivated fungi.

The extraction efficiency of the analytical method for enforcement of fluxapyroxad in high water content commodities is sufficiently demonstrated as the extraction procedure of the enforcement method based on the solvent system (i.e. methanol/water, 1/1 v/v single extraction) was cross-validated using radiolabelled sample material from the fluxapyroxad metabolism study in tomatoes (three-step extraction with methanol/water followed by two-step extraction with water) (Ireland, 2023; Spain, 2023). Overall, EFSA notes that the extraction efficiency of the analytical method applied for enforcement is proven in high water content commodities, as indicated according to the requirements of the extraction efficiency Guidance, SANTE 2017/10632 (European Commission, 2022).

1.1.5 | Storage stability of residues in plants

The storage stability of fluxapyroxad residues in plants stored under frozen conditions was investigated in the framework of the EU pesticides peer review (EFSA, 2012). The storage stability of fluxapyroxad was demonstrated for a period of 24 months at –20°C in all plant matrices and processed products.

EFSA concludes that sufficiently validated storage stability studies are available to support the use of fluxapyroxad in cultivated mushrooms and kaki (high water content commodities).

1.1.6 | Proposed residue definitions

Based on the metabolic pattern identified in metabolism studies and the results of hydrolysis studies, the toxicological relevance of metabolites, the following residue definitions were proposed in the EU pesticides peer review and the MRL review (EFSA, 2012, 2020a):

- Residue definition for enforcement: Fluxapyroxad
- Residue definition for risk assessment: Fluxapyroxad

The residue definitions apply to primary crops, rotational crops and processed products (EFSA, 2012, 2020a).

The residue definition for enforcement set in Regulation (EC) No 396/2005 is identical to the above-mentioned residue definition.

Taking into account the proposed uses assessed in these applications, 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

Kaki/Japanese persimmons

The applicant proposed to extrapolate residue data from the 8 independent and GAP-compliant trials performed on apples in Southern Europe to kaki/Japanese persimmons (Spain, 2023). Kaki are minor crops and a minimum of four trials is sufficient. This extrapolation is acceptable according to the EU technical guidelines (TG) (European Commission, 2020). It is to be noted that the SEU GAP proposed for use in kaki is identical to the SEU GAP on pome fruits authorised in the EU, and the same residue trials were already assessed by EFSA in the framework of MRL review (EFSA, 2020a). Therefore, the submitted trials are considered valid for extrapolation and are briefly summarised in the below paragraph for completeness.

The eight SEU trials were performed in Italy, Greece and Spain over two seasons, 2010 and 2011. All of the trials were of a decline design. In all residue trials, two applications were made at a single rate equivalent to 75 g a.s./ha and one at a single rate equivalent to 90 g a.s./ha. Thus, within the 25% acceptable tolerance range (European Commission, 2020). The sampling was performed from the treated and the untreated plots on Days 28–29, 34–36 (corresponding to the pre-harvest interval (PHI)) and 41–43 days after the application (Spain, 2023).

Overall, the number of trials performed on apples in Southern Europe is sufficient to derive by extrapolation an MRL proposal of 0.2 mg/kg for the intended use of fluxapyroxad on kaki/Japanese persimmon.

Cultivated fungi

In support of the intended use of cultivated fungi, the applicant submitted four independent GAP-compliant residue trials performed on two mushroom varieties grown in indoor conditions. The trials were conducted in Germany and Northern France during the growing season of 2021.

The mushrooms were cultivated in boxes containing the substrate consisting of an organic compost material, which is being used only once for each batch of cultivation (Ireland, 2023). In the four residue trials, the single application was made at the rate of ±25% of 6 kg a.s./ha (within acceptable deviation, European Commission, 2020), 5–7 days after cover-up. Subsequently, the samples from treated mushroom caps with stems were collected at the PHI of 7 and 10 days in the first study and at the PHI of 9 and 11 days in the second study.

The residue levels in mushrooms ranged between 0.052 mg/kg and 0.093 mg/kg. No residues of fluxapyroxad at or above the LOQ of the analytical method of fluxapyroxad were found in any of the untreated specimens.

Overall, the number of trials is sufficient to derive an MRL proposal of 0.3 mg/kg for the intended use of fluxapyroxad on mushrooms.

It is noted that the residues of fluxapyroxad in mushrooms are considerably higher at a PHI of 9 as compared to a PHI of 11 (fast decline in short time). It is nevertheless concluded that residues of fluxapyroxad in mushrooms will not occur above the MRL of 0.3 mg/kg because mushrooms must be harvested according to the intended use pattern at the PHI of 10 or later.

The residue data from the supervised residue trials in primary crops are summarised in Appendix B.1.2.1. Before analyses, the samples from the residue trials on mushrooms were stored under conditions for which the integrity had been demonstrated (Ireland, 2023). Samples from the submitted residue trials on apples were previously concluded to be valid (EFSA, 2020a).

The method (L0137/01) used for the analysis of residues of fluxapyroxad in kaki/Japanese persimmons and cultivated fungi is based on HPLC-MS/MS and enables quantification of residues at or above the LOQ of 0.01 mg/kg in the commodities assessed. According to the EMS, the method used to analyse samples for fluxapyroxad residues was sufficiently validated and fit for purpose (Ireland, 2023; Spain, 2023). Since the method is the same as the monitoring analytical method, the extraction efficiency can be considered proven (see Section 1.1.4).

1.2.2 | Magnitude of residues in rotational crops

Since kaki/Japanese persimmon and mushrooms are not expected to be grown in rotation (see Section 1.1.2), rotational crops studies are not deemed relevant for this application.

It is noted that, the EMS Ireland calculated the potential transfer of residues of fluxapyroxad (total amount of a.s. in the field) if mushrooms are treated according to the intended GAP in case the substrate is then used for fertilisation (Ireland, 2023). As the assessment of the fertiliser uses is not in the remit of Regulation (EC) No 396/2005, EFSA is not verifying the assessment of calculation provided in this Reasoned opinion.

1.2.3 | Magnitude of residues in processed commodities

Specific studies to assess the magnitude of fluxapyroxad residues in processed commodities were not submitted and are not required according to Regulation (EC) No 544/2011, considering that the contribution of residues in the commodities

under consideration (kaki and cultivated mushrooms) to the overall dietary exposure is expected to be individually below 10% of the ADI for any European consumer diet group (European Commission, 1997d).

1.2.4 | Proposed MRLs

The available data are considered sufficient to derive an MRL proposal of 0.2 mg/kg and MRL proposal of 0.3 mg/kg, as well as risk assessment values for the intended SEU use on kaki/Japanese persimmon and indoor use on cultivated fungi, respectively (see Appendix B.1.2.1). In Section 3 EFSA assessed whether residues on these commodities resulting from the intended uses are likely to pose a consumer health risk.

2 | RESIDUES IN LIVESTOCK

As the commodities under consideration are not normally fed to livestock, the nature and magnitude of fluxapyroxad residues in livestock are not assessed in the framework of both applications.

3 | CONSUMER RISK ASSESSMENT

EFSA performed a dietary risk assessment using revision 3.1 of the EFSA PRIMo (EFSA, 2018, 2019). This exposure assessment model contains food consumption data for different sub-groups 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 (FAO, 2016).

For the products of animal origin, the calculation is based on the STMR values and highest residue levels (HR values) derived according to the residue definition for enforcement (FAO, 2013), multiplied by the relevant conversion factors (CFrisk) derived by EFSA from ruminant and poultry feeding studies to accommodate for the risk assessment residue definition (EFSA, 2011, 2020a).

The toxicological reference values for fluxapyroxad used in the risk assessment (i.e. ADI of 0.02 mg/kg bw per day and ARfD of 0.25 mg/kg bw values) were derived in the framework of the EU pesticides peer review (European Commission, 2012). The metabolite (M700F008), which is included in the residue definition for risk assessment in products of animal origin, was concluded to be of similar toxicity as the parent a.s.

Short-term (acute) dietary risk assessment

The short-term exposure assessment was performed in accordance with the internationally agreed methodology and focused on the commodities assessed in these applications (FAO, 2016). The calculations were based on the HR (expressed according to the residue definition for risk assessment) derived from supervised field trials, and the complete list of input values can be found in Appendix D.1. The short-term exposure did not exceed the ARfD for any of the commodities assessed in these applications.

Long-term (chronic) dietary risk assessment

In the framework of the MRL review, a comprehensive long-term exposure assessment was performed, taking into account the existing uses at EU level (EFSA, 2020a). EFSA updated the chronic risk assessment conducted in the framework of the MRL review with the STMR values derived from the residue trials submitted in support of an MRL application submitted after the MRL review (EFSA, 2020b), the STMR values from residue trials submitted in support of CXLs assessed by EFSA and implemented in the EU MRL legislation (FAO, 2013, 2015, 2018, 2020[10]) and the STMR values from the residue trials submitted with the present MRL applications. The calculation was refined for bananas with residue observed in the pulp and for melons, pumpkins and watermelons with the peeling factor of 0.38 to take into account the edible portion of these commodities. Since residues from rotational crop field studies could contribute to exposure assessment, they were also considered in the calculations for the existing EU uses, when appropriate (more detail can be found in Appendix B.1.2.2.(c) of 'Summary of residues data from the combined primary uses and rotational crops' EFSA, 2020a). The input values used in the exposure calculations are summarised in Appendix D.1.

Exceedances of the ADI are not indicated for any of the consumer diet groups. The highest estimated long-term dietary exposure is reported for the NL toddler diet, representing up to 73% of the ADI of fluxapyroxad. The contribution of residues expected in kaki/Japanese persimmons and cultivated fungi to the overall long-term exposure accounted for 0.003% and 0.09% of the ADI, respectively (see Appendix B.3).

[10]The input values derived by Joint FAO/WHO Meeting on Pesticide Residues (JMPR) (FAO, 2013, 2015, 2018) for the CXLs implemented in the EU legislation have been already considered by EFSA in the framework of the MRL review (EFSA, 2020a). To be noted that the residue definition for risk assessment in plants set by JMPR is different compared to the EU and includes two plant metabolites (M700F008 and M700F048). The overall contribution of metabolites is expected to be low (EFSA, 2021).

The contribution of residues expected in the commodities assessed in these applications 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 fluxapyroxad resulting from the existing and the intended uses is unlikely to present a risk to consumer health. The long-term consumer risk assessment is indicative, pending the submission of the confirmatory data requested under the MRL review.

It is noted that the EU pesticides peer review of the renewal of approval of the a.s. fluxapyroxad in accordance with Regulation (EC) No 1107/2009 is to be initiated in the near future, and therefore the conclusions reported in this reasoned opinion might need to be reconsidered in the light of the outcome of the peer review.

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 in support of these MRL applications were found to be sufficient to derive a MRL proposal of 0.2 mg/kg for kaki/Japanese persimmons by extrapolation from residue trials on apples and a MRL proposal of 0.3 mg/kg for cultivated mushrooms.

EFSA concluded that the proposed uses of fluxapyroxad on kaki/Japanese persimmons (SEU use) and cultivated mushrooms (indoor use) will not result in a consumer exposure exceeding the toxicological reference values and therefore are unlikely to pose a risk to consumers' health. The long-term consumer risk assessment is indicative, pending the submission of the confirmatory data requested under the MRL review.

The MRL recommendations are summarised in Appendix B.4.

ABBREVIATIONS

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CCPR	Codex Committee on Pesticide Residues
CF	conversion factor for enforcement to risk assessment residue definition
CIPAC	Collaborative International Pesticide Analytical Council
CXL	Codex maximum residue limit
DALA	days after last application
DAR	draft assessment report
DAT	days after treatment
EMS	evaluating Member State
FAO	Food and Agriculture Organization of the United Nations
GAP	Good Agricultural Practice
HPLC	high performance liquid chromatography
HPLC-MS	high performance liquid chromatography with mass spectrometry
HPLC-MS/MS	high performance liquid chromatography with tandem mass spectrometry
HR	highest residue
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ILV	independent laboratory validation
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 European Union
OECD	Organisation for Economic Co-operation and Development
PBI	plant-back interval
PHI	pre-harvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
QuEChERS	Quick, Easy, Cheap, Effective, Rugged and Safe (analytical method)
RAC	raw agricultural commodity
RMS	rapporteur Member State
SC	suspension concentrate
SEU	southern European Union
STMR	supervised trials median residue
TRR	total radioactive residue
WHO	World Health Organization

ACKNOWLEDGEMENTS

EFSA wishes to thank: Stathis Anagnos, Mavriou Galini, Matteo Lazzari and Elena Taglianini for the support provided to this scientific output.

CONFLICT OF INTEREST

If you wish to access the declaration of interests of any expert contributing to an EFSA scientific assessment, please contact interestmanagement@efsa.europa.eu.

REQUESTOR

European Commission

QUESTION NUMBERS

EFSA-Q-2023-00108; EFSA- Q-2022-00877

COPYRIGHT FOR NON-EFSA CONTENT

EFSA may include images or other content for which it does not hold copyright. In such cases, EFSA indicates the copyright holder and users should seek permission to reproduce the content from the original source.

REFERENCES

EFSA (European Food Safety Authority). (2011). Reasoned opinion on the setting of new MRLs for fluxapyroxad (BAS 700 F) in various commodities of plant and animal origin. *EFSA Journal*, *9*(6), 2196. https://doi.org/10.2903/j.efsa.2011.2196

EFSA (European Food Safety Authority). (2012). Conclusion on the peer review of the pesticide risk assessment of the active substance fluxapyroxad (BAS 700 F). *EFSA Journal*, *10*(1), 2522. https://doi.org/10.2903/j.efsa.2012.2522

EFSA (European Food Safety Authority). (2013). Scientific support for preparing an EU position for the 45th session of the codex committee on pesticide residues (CCPR). *EFSA Journal*, *11*(7), 3312. https://doi.org/10.2903/j.efsa.2013.3312

EFSA (European Food Safety Authority). (2015). Reasoned opinion on the modification of the existing MRLs for fluxapyroxad in grapes and potatoes. *EFSA Journal*, *13*(9), 4223. https://doi.org/10.2903/j.efsa.2015.4223

EFSA (European Food Safety Authority). (2016a). Reasoned opinion on setting of import tolerances for fluxapyroxad in various crops. *EFSA Journal*, *14*(3), 4404. https://doi.org/10.2903/j.efsa.2016.4404

EFSA (European Food Safety Authority). (2016b). Scientific report of EFSA on scientific support for preparing an EU position in the 48th session of the codex committee on pesticide residues (CCPR). *EFSA Journal*, *14*(8), 4571. https://doi.org/10.2903/j.efsa.2016.4571

EFSA (European Food Safety Authority), Brancato, A., Brocca, D., De Lentdecker, C., Erdos, Z., Ferreira, L., Greco, L., Janossy, J., Jarrah, S., Kardassi, D., Leuschner, R., Lythgo, C., Medina, P., Miron, I., Molnar, T., Nougadere, A., Pedersen, R., Reich, H., Sacchi, A., … Villamar-Bouza, L. (2017). Reasoned opinion on the modification of the existing maximum residue levels for fluxapyroxad in various crops. *EFSA Journal*, *15*(9), 4975. https://doi.org/10.2903/j.efsa.2017.4975

EFSA (European Food Safety Authority), Brancato, A., Brocca, D., Ferreira, L., Greco, L., Jarrah, S., Leuschner, R., Medina, P., Miron, I., Nougadere, A., Pedersen, R., Reich, H., Santos, M., Stanek, A., Tarazona, J., Theobald, A., & Villamar-Bouza, L. (2018). Guidance on use of EFSA pesticide residue intake model (EFSA PRIMo revision 3). *EFSA Journal*, *16*(1), 5147. https://doi.org/10.2903/j.efsa.2018.5147

EFSA (European Food Safety Authority), Anastassiadou, M., Brancato, A., Carrasco Cabrera, L., Ferreira, L., Greco, L., Jarrah, S., Kazocina, A., Leuschner, R., Magrans, J. O., Miron, I., Pedersen, R., Raczyk, M., Reich, H., Ruocco, S., Sacchi, A., Santos, M., Stanek, A., Tarazona, J., … Verani, A. (2019a). Pesticide residue intake model- EFSA PRIMo revision 3.1 (update of EFSA PRIMo revision 3). *EFSA Supporting Publication*, *16*(3), EN-1605. https://doi.org/10.2903/sp.efsa.2019.EN-1605

EFSA (European Food Safety Authority). (2019b). Scientific report on scientific support for preparing an EU position in the 51st session of the codex committee on pesticide residues (CCPR). *EFSA Journal*, *17*(7), 5797. https://doi.org/10.2903/j.efsa.2019.5797

EFSA (European Food Safety Authority), Anastassiadou, M., Bernasconi, G., Brancato, A., Carrasco Cabrera, L., Greco, L., Jarrah, S., Kazocina, A., Leuschner, R., Magrans, J. O., Miron, I., Nave, S., Pedersen, R., Reich, H., Rojas, A., Sacchi, A., Santos, M., Stanek, A., Theobald, A., … Verani, A. (2020a). Reasoned opinion on the review of the existing maximum residue levels for fluxapyroxad according to Article 12 of regulation (EC) No 396/2005. *EFSA Journal*, *18*(1), 5984. https://doi.org/10.2903/j.efsa.2020.5984

EFSA (European Food Safety Authority), Anastassiadou, M., Bernasconi, G., Brancato, A., Carrasco Cabrera, L., Greco, L., Jarrah, S., Kazocina, A., Leuschner, R., Magrans, J. O., Miron, I., Nave, S., Pedersen, R., Reich, H., Rojas, A., Sacchi, A., Santos, M., Stanek, A., Theobald, A., … Verani, A. (2020b). Reasoned opinion on the setting of import tolerances for fluxapyroxad in certain root crops and coffee beans. *EFSA Journal*, *18*(1), 5950. https://doi.org/10.2903/j.efsa.2020.5950

EFSA (European Food Safety Authority). (2021). Scientific support for preparing an EU position for the 52nd session of the codex committee on pesticide residues (CCPR). *EFSA Journal*, *19*(8), 6766. https://doi.org/10.2903/j.efsa.2021.6766

EFSA (European Food Safety Authority), Greco, L., Janossy, J., Jarrah, S., Kazocina, A., Magrans, J. O., & Reich, H. (2023). Guidance on the assessment of pesticide residues in rotational crops. *EFSA Journal*, *21*(11), 8225. https://doi.org/10.2903/j.efsa.2023.8225

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

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

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

European Commission. (1997d). *Appendix E. Processing studies. 7035/VI/95-rev. 5*, 22 July 1997.

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

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

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

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

European Commission. (2012). *Review report for the active substance fluxapyroxad. Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 1 June 2012 in view of the approval of fluxapyroxad as active substance in accordance with Regulation (EC) No 1107/2009*. SANCO/10692/2012 Rev2, 25 March 2021, 8 pp.

European Commission. (2020). *Technical guidelines on data requirements for setting maximum residue levels, comparability of residue trials and extrapolation on residue data on products from plant and animal origin*. SANTE/2019/12752, 23 November 2020.

European Commission. (2021). *Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes*. SANTE/2020/12830, Rev.1 24. February 2021.

European Commission. (2022). *Technical Guideline on the Evaluation of Extraction Efficiency of Residue Analytical Methods*. SANTE 2017/10632, Rev. 4, 23 February 2022.

FAO (Food and Agriculture Organization of the United Nations). (2013). *Fluxapyroxad. In: Pesticide residues in food – 2012*. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 215. 51 pp.

FAO (Food and Agriculture Organization of the United Nations). (2015). *Fluxapyroxad. In: Pesticide residues in food – 2015*. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 223. 647 pp.

FAO (Food and Agriculture Organization of the United Nations). (2016). *Submission and evaluation of pesticide residues data for the estimation of Maximum Residue Levels in food and feed*. Pesticide Residues. 3rd Ed. FAO Plant Production and Protection Paper 225, 298 pp.

FAO (Food and Agriculture Organization of the United Nations). (2018). *Fluxapyroxad. In: Pesticide residues in food – 2018*. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 234. 668 pp.

FAO (Food and Agriculture Organization of the United Nations). (2020). *Fluxapyroxad. In: Pesticide residues in food –2019*. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper. 680 pp.

Ireland. (2023). *Evaluation report on the modification of MRLs for fluxapyroxad in mushrooms*. November 2023, revised in February 2024, 57 pp. www.efsa.europa.eu

OECD (Organisation for Economic Co-operation and Development). (2011). *OECD MRL calculator: Spreadsheet for single data set and spreadsheet for multiple data set, 2 march 2011*. In: Pesticide Publications/Publications on Pesticide Residues. http://www.oecd.org

Spain. (2023). *Evaluation report on the modification of MRLs for fluxapyroxad in kaki/Japanese persimmons*. December 2023, revised in month 2024, 79 pp. www.efsa.europa.eu

United Kingdom. (2011a). *Draft assessment report on the active substance BAS 700 F (fluxapyroxad) prepared by the rapporteur Member State United Kingdom in the framework of Council Directive 91/414/EEC, January 2011*. www.efsa.europa.eu

United Kingdom. (2011b). *Final addendum to the draft assessment report on the active substance BAS 700 F(fluxapyroxad) prepared by the rapporteur Member State United Kingdom in the framework of Council Directive 91/414/EEC, October 2011*. www.efsa.europa.eu

How to cite this article: EFSA (European Food Safety Authority), Bellisai, G., Bernasconi, G., Carrasco Cabrera, L., Castellan, I., del Aguila, M., Ferreira, L., Santonja, G. G., Greco, L., Jarrah, S., Leuschner, R., Mioč, A., Nave, S., Pedersen, R., Reich, H., Ruocco, S., Scarlato, A. P., Szot, M., Theobald, A., Tiramani, M., & Verani, A. (2024). Modification of the existing maximum residue levels for fluxapyroxad in kaki/Japanese persimmons and cultivated mushrooms. *EFSA Journal*, *22*(4), e8696. https://doi.org/10.2903/j.efsa.2024.8696

APPENDIX A

Summary of intended GAP triggering the amendment of existing EU MRLs

				Preparation		Application				Application rate per treatment					
Crop and/or situation	NEU, SEU, MS or country	F G or I [(a)]	Pests or Group of pests controlled	Type [b]	Conc. a.s. (g/L)	Method kind	Range of growth stages & season [c]	Number min-max	Interval between application (days) min–max	kg a.s./hL min-max	Water (L/ha) min-max	Rate min-max	Unit	PHI (days) [d]	Remarks
Kaki/Japanese persimmons	SEU	F	*Alternaria* spp. *Mycosphaerella nawae*	SC	300	Foliar spray	53–81	1–3	7	0.006–0.045	200–1500	0.09	kg a.i./ha	35	Spain (2023) Max. annual a.s.: 270 g/ha
Cultivated fungi	EU	I	*Verticillium fungicola* (VERTFU) *Dactylium dendroïdes* (DACYDE)	SC	300	Spraying	2–9 days after cover-up	1	–	0.4	1500	6.0	kg a.i./ha	10	Ireland (2023) Cultivated in substrate

Abbreviations: a.s., active substance; GAP, Good Agricultural Practice; MRL, maximum residue level; MS, Member State; NEU, northern European Union; SC, suspension concentrate; SEU, southern European Union.

[a]Outdoor or field use (F), greenhouse application (G) or indoor application (I).

[b]CropLife International Technical Monograph no 2, 7th Edition. Revised March 2017. 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 pre-harvest interval.

APPENDIX B

List of end points

B.1 | RESIDUES IN PLANTS

B.1.1 | Nature of residues and analytical methods for enforcement purposes in plant commodities

B.1.1.1 | Metabolism studies, analytical methods and residue definitions in plants

Primary crops (available studies)	Crop groups	Crops	Applications	Sampling	Comment/Source
	Fruit crops	Tomato	Foliar, 3 × 100 g a.s./ha, interval 7 days	3 DALA	Radiolabelled fluxapyroxad: aniline and pyrazole rings (EFSA, 2012)
	Cereals/grass	Wheat	Foliar, 2 × 125 g a. s./ha, BBCH 30–35, 69	36 DAT, 4, 34–35 DALA	Radiolabelled fluxapyroxad: aniline and pyrazole rings (EFSA, 2012)
			Seed treatment, 1 × 75 g a.s/100 kg (equivalent to 135 g a.s./ha)	93, 112, 161 DAT	Radiolabelled fluxapyroxad: aniline and pyrazole rings (EFSA, 2015)
	Pulses/oilseeds	Soyabean	Foliar, 3 × 60 g a. s./ha, BBCH 16–17, 51–59, 71–75	0 DAT, 34 DALA	Radiolabelled fluxapyroxad: aniline and pyrazole rings (EFSA, 2012)
Rotational crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**PBI (DAT)**	**Comment/Source**
	Root/tuber crops	White radish	Bare soil, 1 × 250 g a.s./ha	30, 120/149, 365	Studies with radiolabelled fluxapyroxad: aniline and pyrazole rings (EFSA, 2012)
	Leafy crops	Spinach	Bare soil, 1 × 250 g a.s./ha	30, 120/149, 365	
	Cereal (small grain)	Wheat	Bare soil, 1 × 250 g a.s./ha	30, 120/149, 365	
Processed commodities (hydrolysis study)	**Conditions**		**Stable?**		**Comment/Source**
	Pasteurisation (20 min, 90°C, pH 4)		Yes		EFSA (2012)
	Baking, brewing and boiling (60 min, 100°C, pH 5)		Yes		EFSA (2012)
	Sterilisation (20 min, 120°C, pH 6)		Yes		EFSA (2012)

Can a general residue definition be proposed for primary crops?	yes	For foliar applications (EFSA, 2012). For soil treatment (based on the confined rotational studies) (EFSA, 2020a).
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)	<u>Matrices with high water content, high oil content, high acid content and dry matrices (EFSA, 2012):</u> • HPLC-MS/MS, LOQ 0.01 mg/kg • Confirmatory method available • ILV available • QuEChERS (HPLC-MS/MS) for enforcement in routine analysis, LOQ 0.01 mg/kg (EFSA, 2020a). • Extraction efficiency for the HPLC method L0137/01 proven in high water content commodities (Ireland, 2023, Spain, 2023) Herbal infusions (from leaves and rots): • No method available (data gap) (EFSA, 2020a)	

DAT: days after treatment; PBI: plant-back interval; BBCH: growth stages of mono- and dicotyledonous plants; a.s.: active substance; HPLC-MS/MS: high performance liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; QuEChERS: Quick, Easy, Cheap, Effective, Rugged, and Safe; ILV: independent laboratory validation.

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[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]
Kaki/Japanese persimmons	SEU	0.012; 0.024; 0.028; 0.031; 0.047; 0.050; 0.067; 0.10	Residue trials on apples compliant with GAP on kaki already assessed by EFSA (EFSA, 2020a) Extrapolation to kaki/Japanese persimmons possible	0.2	0.10	0.039	n.a.
Cultivated fungi	EU	0.052, 0.066, 0.08, 0.093	Residue trials on cultivated fungi compliant with GAP	0.3	0.093	0.073	n.a.

Abbreviations: GAP, good agricultural practice; MRL, maximum residue level.

[a]SEU: Outdoor trials conducted in southern European Union, EU: indoor EU trials.

[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. n.a., not applicable.

B.1.2.2 | Residues in rotational crops

Residues in rotational and succeeding crops expected based on confined rotational crop study?	Not triggered	Studies available but not required (permanent or crop not grown in rotation).
Residues in rotational and succeeding crops expected based on field rotational crop study?	Not triggered	Studies available but not required (permanent or crop not grown in rotation).

B.1.2.3 | Processing factors

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

B.2 | RESIDUES IN LIVESTOCK

Not relevant.

B.3 | CONSUMER RISK ASSESSMENT

ARfD	0.25 mg/kg bw (European Commission, 2012)
Highest IESTI, according to EFSA PRIMo	Kaki/Japanese persimmons: 1.9% of ARfD (DE child diet) Cultivated fungi: 0.6% of ARfD (BE toddlers diet)
Assumptions made for the calculations	The calculation is based on the highest residue levels expected in raw agricultural commodities derived for the intended uses on Kaki/Japanese persimmons and cultivated mushrooms. Calculations performed with PRIMo revision 3.1.

ADI	0.02 mg/kg bw per day (European Commission, 2012)
Highest IEDI, according to EFSA PRIMo	73% ADI (NL toddler diet) Contribution of crops assessed: Kaki/Japanese persimmons: 0.003% of ADI (DE women diet) Cultivated fungi: 0.09% of ADI (IE adult diet)
Assumptions made for the calculations	The calculation is based on the median residue levels (STMR) derived for raw agricultural commodities derived for the intended uses on Kaki/Japanese persimmons and cultivated mushrooms. Additionally, the STMRs for the crops assessed in previous EFSA reasoned opinions and for CXLs implemented in the EU legislation were included in the calculation (EFSA, 2020a,b, 2021, FAO, 2020). The STMRs for potatoes, tropical root and tuber vegetables group, garlic, onions and shallots tentatively cover also the potential residue levels as derived from rotational crop field studies submitted in the MRL review. For bananas, residue refers to the edible portion (STMR-pulp) and for melons, pumpkins and watermelons the peeling factor of 0.38 was applied. For the products of animal origin, the calculation is based on the STMR values and highest residue levels (HR values) derived according to the residue definition for enforcement (FAO, 2013), multiplied by the relevant conversion factors (CFrisk) derived by EFSA to accommodate for the risk assessment residue definition (EFSA, 2011; 2020a). The contributions of commodities where no GAP was reported in the framework of the MRL review or safe CXLs implemented in the EU legislation were not included in the calculation. Calculations performed with PRIMo 3.1

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

B.4 | RECOMMENDED MRLS

Code[a]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Fluxapyroxad[F]				
0161060	Kaki/Japanese persimmons	0.01*	0.2	The submitted data are sufficient to derive an MRL proposal for the intended SEU use by extrapolation from residue trials on apples. Risk for consumers unlikely

(Continued)

Code[a]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
0280010	Cultivated fungi	0.01*	0.3	The submitted data are sufficient to derive an MRL proposal for the intended indoor EU use. Risk for consumers unlikely

Abbreviations: MRL, maximum residue level; SEU, southern European Union.

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

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

[F]Fat soluble.

APPENDIX C

Pesticide Residue Intake Model (PRIMo)

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Fluxapyroxad (F)

LOQs (mg/kg) range from: 0.01 to: 0.30

Toxicological reference values

ADI (mg/kg bw/day):	0.02	ARfD (mg/kg bw):	0.25
Source of ADI:	European	Source of ARfD:	European Commision
Year of evaluation:	2012	Year of evaluation:	2012

Input values

Details - chronic risk assessment | Supplementary results - chronic risk assessment

Details - acute risk assessment/children | Details - acute risk assessment/adults

Comments:

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

	Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	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	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	73%	NL toddler	14.56	16%	Apples	15%	Bananas	7%	Pears		73%
	51%	DE child	10.19	19%	Apples	8%	Oranges	4%	Bananas		51%
	40%	NL child	8.04	9%	Apples	5%	Bananas	5%	Sugar beet roots		40%
	29%	GEMS/Food G06	5.89	7%	Rice	4%	Wheat	2%	Table grapes		29%
	29%	FR child 3 15 yr	5.70	7%	Oranges	3%	Wheat	3%	Apples		29%
	28%	GEMS/Food G11	5.55	3%	Sugar canes	2%	Wine grapes	2%	Celeries		28%
	27%	GEMS/Food G07	5.44	3%	Wine grapes	3%	Oranges	2%	Wheat		27%
	26%	GEMS/Food G10	5.29	5%	Rice	2%	Wheat	2%	Oranges		26%
	26%	FR toddler 2 3 yr	5.15	5%	Apples	3%	Oranges	3%	Rice		26%
	25%	IE adult	5.06	3%	Wine grapes	2%	Bananas	2%	Oranges		25%
	25%	GEMS/Food G08	4.96	2%	Wine grapes	2%	Barley	2%	Wheat		25%
	23%	GEMS/Food G15	4.69	3%	Wheat	2%	Wine grapes	2%	Barley		23%
	23%	UK toddler	4.62	4%	Oranges	3%	Bananas	3%	Apples		23%
	22%	PT general	4.37	6%	Wine grapes	3%	Rice	2%	Potatoes		22%
	22%	UK infant	4.36	4%	Bananas	3%	Rice	3%	Oranges		22%
	22%	SE general	4.31	5%	Bananas	2%	Potatoes	2%	Wheat		22%
	22%	DK child	4.31	3%	Apples	3%	Rye	3%	Bananas		22%
	21%	DE women 14-50 yr	4.29	4%	Apples	4%	Oranges	3%	Sugar beet roots		21%
	21%	DE general	4.13	4%	Apples	3%	Oranges	3%	Sugar beet roots		21%
	20%	ES child	3.99	4%	Oranges	3%	Bananas	3%	Wheat		20%
	19%	RO general	3.75	4%	Wine grapes	3%	Wheat	2%	Apples		19%
	18%	NL general	3.67	2%	Apples	2%	Oranges	2%	Sugar beet roots		18%
	18%	FI 3 yr	3.59	4%	Bananas	2%	Rice	2%	Potatoes		18%
	16%	FR adult	3.20	5%	Wine grapes	1%	Wheat	1%	Oranges		16%
	15%	ES adult	2.95	3%	Oranges	1%	Wheat	1%	Barley		15%
	15%	IT toddler	2.94	4%	Wheat	1%	Bananas	1%	Apples		15%
	13%	FI 6 yr	2.61	2%	Bananas	2%	Rice	2%	Potatoes		13%
	12%	UK vegetarian	2.46	2%	Wine grapes	2%	Oranges	2%	Rice		12%
	12%	FR infant	2.38	3%	Apples	2%	Beans (with pods)	0.9%	Potatoes		12%
	12%	IT adult	2.36	2%	Wheat	1%	Apples	0.8%	Peaches		12%
	11%	UK adult	2.20	3%	Wine grapes	2%	Rice	1%	Oranges		11%
	10%	DK adult	2.06	2%	Wine grapes	1%	Apples	1%	Bananas		10%
	9%	LT adult	1.74	3%	Apples	1%	Potatoes	0.9%	Rice		9%
	8%	PL general	1.68	3%	Apples	2%	Potatoes	0.8%	Table grapes		8%
	8%	FI adult	1.68	0.9%	Apples	0.8%	Coffee beans	0.8%	Bananas		8%
	4%	IE child	0.89	1%	Rice	0.7%	Wheat	0.5%	Bananas		4%

Conclusion:

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

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

Acute risk assessment /children	Acute risk assessment / adults / general population
Details - acute risk assessment /children	Details - acute risk assessment/adults

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

Show results for all crops

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
77%	Celeries	9 / 5.15	193
77%	Rhubarbs	9 / 5.15	192
41%	Table grapes	3 / 1.4	102
40%	Witloofs/Belgian endives	6 / 2.5	99
33%	Florence fennels	9 / 5.15	84
31%	Oranges	1.5 / 0.59	78
29%	Escaroles/broad-leaved	4 / 1.8	72
27%	Lettuces	4 / 1.8	69
26%	Pears	0.9 / 0.47	65
24%	Chinese cabbages/pe-tsai	4 / 1.9	61
24%	Peaches	1.5 / 0.63	60
21%	Broccoli	2 / 1.27	53
20%	Apples	0.9 / 0.47	51
16%	Plums	1.5 / 0.95	40
15%	Strawberries	4 / 2.34	38

Expand/collapse list

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
38%	Florence fennels	9 / 5.15	96
33%	Celeries	9 / 5.15	82
21%	Cardoons	9 / 5.15	53
19%	Chinese cabbages/pe-tsai	4 / 1.9	48
19%	Rhubarbs	9 / 5.15	48
19%	Table grapes	3 / 1.4	47
18%	Witloofs/Belgian endives	6 / 2.5	46
15%	Escaroles/broad-leaved	4 / 1.8	36
14%	Blueberries	7 / 3.77	34
13%	Wine grapes	3 / 1.4	33
12%	Broccoli	2 / 1.27	30
11%	Chards/beet leaves	3 / 1.44	27
9%	Lettuces	4 / 1.8	22
9%	Strawberries	4 / 2.34	22
7%	Cherries (sweet)	3 / 1.86	19

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

Processed commodities

Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
93%	Florence fennels / boiled	9 / 5.15	233
89%	Witloofs / boiled	6 / 2.5	222
77%	Rhubarbs / sauce/puree	9 / 5.15	192
48%	Escaroles/broad-leaved endi	4 / 1.8	119
40%	Broccoli / boiled	2 / 1.27	100
18%	Chards/beet leaves / boiled	3 / 1.44	45
10%	Turnips / boiled	0.9 / 0.5	25
10%	Parsnips / boiled	0.9 / 0.5	25
10%	Leeks / boiled	0.7 / 0.42	24
9%	Beetroots / boiled	0.9 / 0.5	22
8%	Oranges / juice	1.5 / 0.4	21
8%	Spinaches / frozen; boiled	3 / 1.44	20
7%	Peaches / canned	1.5 / 0.63	16
5%	Salsifies / boiled	0.9 / 0.5	13
5%	Jerusalem artichokes / boilec	0.9 / 0.5	13

Expand/collapse list

Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
70%	Celeries / boiled	9 / 5.15	174
40%	Florence fennels / boiled	9 / 5.15	100
30%	Rhubarbs / sauce/puree	9 / 5.15	75
25%	Cardoons / boiled	9 / 5.15	63
18%	Witloofs / boiled	6 / 2.5	46
15%	Escaroles/broad-leaved	4 / 1.8	37
12%	Broccoli / boiled	2 / 1.27	31
8%	Beetroots / boiled	0.9 / 0.5	19
7%	Chards/beet leaves / boiled	3 / 1.44	18
5%	Spinaches / frozen; boiled	3 / 1.44	12
4%	Parsnips / boiled	0.9 / 0.5	11
4%	Turnips / boiled	0.9 / 0.5	9.5
4%	Celeriacs / boiled	0.9 / 0.5	9.1
3%	Leeks / boiled	0.7 / 0.42	7.3
2%	Oranges / juice	1.5 / 0.4	6.0

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

APPENDIX D

Input values for the exposure calculations

D.1 | CONSUMER RISK ASSESSMENT

Commodity	Existing/ Proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value[a] (mg/kg)	Comment	Input value[a] (mg/kg)	Comment[b]
Risk assessment residue definition: Fluxapyroxad[F]						
Grapefruits	0.6	FAO (2020)	0.15	STMR-RAC	0.27	HR-RAC
Oranges	1.5	FAO (2020)	0.395	STMR-RAC	0.59	HR-RAC
Lemons	1	FAO (2020)	0.38	STMR-RAC	0.46	HR-RAC
Limes	1	FAO (2020)	0.38	STMR-RAC	0.46	HR-RAC
Mandarins	1	FAO (2020)	0.38	STMR-RAC	0.46	HR-RAC
Almonds	0.04	FAO (2015)	0.01	STMR-RAC	0.03	HR-RAC
Brazil nuts	0.04	FAO (2015)	0.01	STMR-RAC	0.03	HR-RAC
Cashew nuts	0.04	FAO (2015)	0.01	STMR-RAC	0.03	HR-RAC
Chestnuts	0.04	FAO (2015)	0.01	STMR-RAC	0.03	HR-RAC
Coconuts	0.04	FAO (2015)	0.01	STMR-RAC	0.03	HR-RAC
Hazelnuts/cobnuts	0.04	FAO (2015)	0.01	STMR-RAC	0.03	HR-RAC
Macadamia	0.04	FAO (2015)	0.01	STMR-RAC	0.03	HR-RAC
Pecans	0.04	FAO (2015)	0.01	STMR-RAC	0.03	HR-RAC
Pine nut kernels	0.04	FAO (2015)	0.01	STMR-RAC	0.03	HR-RAC
Pistachios	0.04	FAO (2015)	0.01	STMR-RAC	0.03	HR-RAC
Walnuts	0.04	FAO (2015)	0.01	STMR-RAC	0.03	HR-RAC
Other tree nuts	0.04	FAO (2015)	0.01	STMR-RAC		
Apples	0.9	FAO (2013)	0.3	STMR-RAC	0.47	HR-RAC
Pears	0.9	FAO (2013)	0.3	STMR-RAC	0.47	HR-RAC
Quinces	0.9	FAO (2013)	0.3	STMR-RAC	0.47	HR-RAC
Medlar	0.9	FAO (2013)	0.3	STMR-RAC	0.47	HR-RAC
Loquats/Japanese medlars	0.9	FAO (2013)	0.3	STMR-RAC	0.47	HR-RAC
Other pome fruit	0.9	FAO (2013)	0.3	STMR-RAC		
Apricots	1.5	FAO (2015)	0.44	STMR-RAC	0.63	HR-RAC
Cherries (sweet)	3	EFSA (2020a)	0.555	STMR-RAC	1.86	HR-RAC
Peaches	1.5	EFSA (2020a)	0.44	STMR-RAC	0.63	HR-RAC
Plums	1.5	EFSA (2020a)	0.435	STMR-RAC	0.95	HR-RAC
Table grapes	3	FAO (2015)	0.47	STMR-RAC	1.4	HR-RAC
Wine grapes	3	FAO (2015)	0.47	STMR-RAC	1.4	HR-RAC
Strawberries	4	EFSA (2020a)	0.815	STMR-RAC	2.34	HR-RAC
Blueberries	7	EFSA (2020a)	2.39	STMR-RAC	3.77	HR-RAC
Kumquats	1	FAO (2020)	0.38	STMR-RAC	0.46	HR-RAC
Kaki/Japanese persimmons	0.2	**Intended use**	0.039	STMR-RAC	0.1	HR-RAC
Bananas	3	FAO (2015)	0.55	STMR-RAC pulp	0.1	HR-RAC pulp
Mangoes	0.7	EFSA (2020a)	0.18	STMR-RAC	0.37	HR-RAC
Papayas	1	FAO (2018)	0.054	STMR-RAC	0.51	HR-RAC
Potatoes[d]	0.3	EFSA (2020a)	0.09	STMR-RAC	0.12	HR-RAC
Cassava roots/ manioc[d]	0.2	EFSA (2020a)	0.2	MRL	0.08	HR-RAC
Sweet potatoes[d]	0.2	EFSA (2020a)	0.03	STMR-RAC	0.08	HR-RAC
Yams[d]	0.2	EFSA (2020a)	0.03	STMR-RAC	0.08	HR-RAC
Arrowroots[d]	0.2	EFSA (2020a)	0.03	STMR-RAC	0.08	HR-RAC

(Continued)

Commodity	Existing/ Proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value[a] (mg/kg)	Comment	Input value[a] (mg/kg)	Comment[b]
Other tropical root and tuber vegetables[d]	0.2	EFSA (2020a)	0.03	STMR-RAC		
Beetroots[d]	0.9	EFSA (2020b)	0.085	STMR-RAC	0.5	HR-RAC
Carrots[d]	0.9	EFSA (2020b)	0.085	STMR-RAC	0.5	HR-RAC
Celeriacs/turnip rooted celeries[d]	0.9	EFSA (2020b)	0.085	STMR-RAC	0.5	HR-RAC
Horseradishes[d]	0.9	EFSA (2020b)	0.085	STMR-RAC	0.5	HR-RAC
Jerusalem artichokes[d]	0.9	EFSA (2020b)	0.085	STMR-RAC	0.5	HR-RAC
Parsnips[d]	0.9	EFSA (2020b)	0.085	STMR-RAC	0.5	HR-RAC
Parsley roots/ Hamburg roots parsley[d]	0.9	EFSA (2020b)	0.085	STMR-RAC	0.5	HR-RAC
Radishes[d]	0.9	EFSA (2020b)	0.085	STMR-RAC	0.5	HR-RAC
Salsifies[d]	0.9	EFSA (2020b)	0.085	STMR-RAC	0.5	HR-RAC
Swedes/rutabagas[d]	0.9	EFSA (2020b)	0.085	STMR-RAC	0.5	HR-RAC
Turnips[d]	0.9	EFSA (2020b)	0.085	STMR-RAC	0.5	HR-RAC
Other root and tuber vegetables[d]	0.9	EFSA (2020b)	0.085	STMR-RAC		
Garlic[d]	0.2	EFSA (2020a)	0.03	STMR-RAC	0.08	HR-RAC
Onions[d]	0.2	EFSA (2020a)	0.03	STMR-RAC	0.08	HR-RAC
Shallots[d]	0.2	EFSA (2020a)	0.03	STMR-RAC	0.08	HR-RAC
Spring onions/green onions and Welsh onions[d]	0.7	EFSA (2020a)	0.185	STMR-RAC	0.42	HR-RAC
Tomatoes	0.6	FAO (2013)	0.07	STMR-RAC	0.44	HR-RAC
Sweet peppers/bell peppers	0.6	FAO (2013)	0.07	STMR-RAC	0.44	HR-RAC
Aubergines/egg plants	0.6	FAO (2013)	0.07	STMR-RAC	0.44	HR-RAC
Okra/lady's fingers	0.6	FAO (2013)	0.07	STMR-RAC	0.44	HR-RAC
Other solanacea	0.6	FAO (2013)	0.07	STMR-RAC		
Cucumbers	0.2	EFSA (2020a)	0.05	STMR-RAC	0.11	HR-RAC
Gherkins	0.2	EFSA (2020a)	0.05	STMR-RAC	0.11	HR-RAC
Courgettes	0.2	EFSA (2020a)	0.05	STMR-RAC	0.11	HR-RAC
Other cucurbits–edible peel	0.2	EFSA (2020a)	0.05	STMR-RAC		
Melons	0.15	EFSA (2020a)	0.017	STMR-RAC*PeF	0.027	HR-RAC*PeF
Pumpkins	0.15	EFSA (2020a)	0.017	STMR-RAC*PeF	0.027	HR-RAC*PeF
Watermelons	0.15	EFSA (2020a)	0.017	STMR-RAC*PeF	0.027	HR-RAC*PeF
Other cucurbits–inedible peel	0.15	EFSA (2020a)	0.0171	STMR-RAC*PeF		
Sweet corn	0.15	EFSA (2020a)	0.01	STMR-RAC	0.09	HR-RAC
Broccoli[d]	2	EFSA (2020a)	0.28	STMR-RAC	1.27	HR-RAC
Cauliflowers[d]	0.2	EFSA (2020a)	0.07	STMR-RAC	0.14	HR-RAC
Brussels sprouts[d]	0.4	EFSA (2020a)	0.05	STMR-RAC	0.14	HR-RAC
Head cabbages[d]	0.5	EFSA (2020a)	0.01	STMR-RAC	0.27	HR-RAC
Chinese cabbages/ pe-tsai[d]	4	EFSA (2020a)	0.895	STMR-RAC	1.9	HR-RAC
Kales[d]	0.15	EFSA (2020a)	0.01	STMR-RAC	0.06	HR-RAC
Kohlrabies[d]	0.15	EFSA (2020a)	0.01	STMR-RAC	0.06	HR-RAC

(Continues)

(Continued)

Commodity	Existing/ Proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value[a] (mg/kg)	Comment	Input value[a] (mg/kg)	Comment[b]
Lamb's lettuce/corn salads[d]	4	EFSA (2020a)	0.245	STMR-RAC	1.8	HR-RAC
Lettuces[d]	4	EFSA (2020a)	0.245	STMR-RAC	1.8	HR-RAC
Escaroles/broad-leaved endives[d]	4	EFSA (2020a)	0.245	STMR-RAC	1.8	HR-RAC
Cress and other sprouts and shoots[d]	4	Reg. (EU) 2018/685	0.245	STMR-RAC	1.8	HR-RAC
Land cress[d]	4	Reg. (EU) 2018/685	0.245	STMR-RAC	1.8	HR-RAC
Roman rocket/ rucola[d]	4	EFSA (2020a)	0.245	STMR-RAC	1.8	HR-RAC
Red mustards[d]	4	Reg. (EU) 2018/685	0.245	STMR-RAC	1.8	HR-RAC
Baby leaf crops (including brassica species)[d]	4	Reg. (EU) 2018/685	0.245	STMR-RAC	1.8	HR-RAC
Other lettuce and other salad plants[d,f]	4	Reg. (EU) 2018/685	0.245	STMR-RAC		
Spinaches[d]	3	EFSA (2020a)	0.055	STMR-RAC	1.44	HR-RAC
Purslanes[d]	3	EFSA (2020a)	0.055	STMR-RAC	1.44	HR-RAC
Chards/beet leaves[d]	3	EFSA (2020a)	0.055	STMR-RAC	1.44	HR-RAC
Witloofs/Belgian endives[d]	6	EFSA (2020a)	1.95	STMR-RAC	2.5	HR-RAC
Chervil[d]	3	EFSA (2020a)	0.055	STMR-RAC	1.44	HR-RAC
Chives[d]	3	EFSA (2020a)	0.055	STMR-RAC	1.44	HR-RAC
Celery leaves	3	EFSA (2020a)	0.055	STMR-RAC	1.44	HR-RAC
Parsley[d]	3	EFSA (2020a)	0.055	STMR-RAC	1.44	HR-RAC
Sage[d]	3	EFSA (2020a)	0.055	STMR-RAC	1.44	HR-RAC
Rosemary[d]	3	EFSA (2020a)	0.055	STMR-RAC	1.44	HR-RAC
Thyme[d]	3	EFSA (2020a)	0.055	STMR-RAC	1.44	HR-RAC
Basil and edible flowers[d]	3	EFSA (2020a)	0.055	STMR-RAC	1.44	HR-RAC
Laurel/bay leaves[d]	3	EFSA (2020a)	0.055	STMR-RAC	1.44	HR-RAC
Tarragon[d]	3	EFSA (2020a)	0.055	STMR-RAC	1.44	HR-RAC
Other herbs[d]	3	EFSA (2020a)	0.055	STMR-RAC		
Beans (with pods)	2	FAO (2013)	0.65	STMR-RAC	0.74	HR-RAC
Beans (without pods)	0.09	FAO (2013)	0.03	STMR-RAC	0.04	HR-RAC
Peas (with pods)	2	FAO (2013)	0.65	STMR-RAC	0.74	HR-RAC
Peas (without pods)[e]	0.3	Reg. (EU) 2021/644	0.3	MRL	0.3	MRL
Cardoons[d]	9	EFSA (2020a)	1.675	STMR-RAC	5.15	HR-RAC
Celeries[d]	9	EFSA (2020a)	1.675	STMR-RAC	5.15	HR-RAC
Florence fennels[d]	9	EFSA (2020a)	1.675	STMR-RAC	5.15	HR-RAC
Globe artichokes[d]	0.4	EFSA (2020a)	0.08	STMR-RAC	0.19	HR-RAC
Leeks[d]	0.7	EFSA (2020a)	0.185	STMR-RAC	0.42	HR-RAC
Rhubarbs[d]	9	EFSA (2020a)	1.675	STMR-RAC	5.15	HR-RAC
Cultivated fungi	0.3	**Intended use**	0.073	STMR-RAC	0.093	HR-RAC
Beans[d]	0.3	FAO (2013)	0.04	STMR-RAC	0.04	STMR-RAC
Lentils[d]	0.4	EFSA (2020a)	0.04	STMR-RAC	0.04	STMR-RAC
Peas[d]	0.4	EFSA (2020a)	0.04	STMR-RAC	0.04	STMR-RAC
Lupins/lupini beans[d]	0.2	EFSA (2020a)	0.01	STMR-RAC	0.01	STMR-RAC
Linseeds	0.9	EFSA (2020a)	0.09	STMR-RAC	0.09	STMR-RAC

(Continued)

Commodity	Existing/ Proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value[a] (mg/kg)	Comment	Input value[a] (mg/kg)	Comment[b]
Peanuts/groundnuts	0.01	EFSA (2020a)	0.01	STMR-RAC	0.01	STMR-RAC
Poppy seeds	0.9	EFSA (2020a)	0.09	STMR-RAC	0.09	STMR-RAC
Sesame seeds	0.9	EFSA (2020a)	0.09	STMR-RAC	0.09	STMR-RAC
Sunflower seeds	0.9	EFSA (2020a)	0.09	STMR-RAC	0.09	STMR-RAC
Rapeseeds/canola seeds	0.9	EFSA (2020a)	0.09	STMR-RAC	0.09	STMR-RAC
Soyabeans	0.15	EFSA (2020a)	0.01	STMR-RAC	0.01	STMR-RAC
Mustard seeds	0.9	EFSA (2020a)	0.09	STMR-RAC	0.09	STMR-RAC
Cotton seeds	0.5	FAO (2018)	0.08	STMR-RAC	0.08	STMR-RAC
Pumpkin seeds	0.9	EFSA (2020a)	0.09	STMR-RAC	0.09	STMR-RAC
Safflower seeds	0.9	EFSA (2020a)	0.09	STMR-RAC	0.09	STMR-RAC
Borage seeds	0.9	EFSA (2020a)	0.09	STMR-RAC	0.09	STMR-RAC
Gold of pleasure seeds	0.9	EFSA (2020a)	0.09	STMR-RAC	0.09	STMR-RAC
Hemp seeds	0.9	EFSA (2020a)	0.09	STMR-RAC	0.09	STMR-RAC
Castor beans	0.9	EFSA (2020a)	0.09	STMR-RAC	0.09	STMR-RAC
Oil palm fruits	0.8	FAO (2013)	0.09	STMR-RAC	0.09	STMR-RAC
Kapok	0.8	FAO (2013)	0.09	STMR-RAC	0.81	HR-RAC
Barley[d]	3	EFSA (2020a)	0.54	STMR-RAC	0.54	STMR-RAC
Maize/corn[d]	0.01	EFSA (2020a)	0.01	STMR-RAC	0.01	STMR-RAC
Oat[d]	3	EFSA (2020a)	0.54	STMR-RAC	0.54	STMR-RAC
Rice[d]	5	EFSA (2020a)	0.865	STMR-RAC	0.865	STMR-RAC
Rye[d]	0.4	EFSA (2020a)	0.115	STMR-RAC	0.115	STMR-RAC
Sorghum[d]	0.8	EFSA (2020a)	0.19	STMR-RAC	0.19	STMR-RAC
Wheat[d]	0.4	EFSA (2020a)	0.115	STMR-RAC	0.115	STMR-RAC
Coffee beans	0.2	EFSA (2020b)	0.03	STMR-RAC	0.03	STMR-RAC
Strawberry leaves[d]	30	EFSA (2020a)	0.55	STMR-RAC	14.4	HR-RAC
Rooibos[d]	30	EFSA (2020a)	0.55	STMR-RAC	14.4	HR-RAC
Mate/maté[d]	30	EFSA (2020a)	0.55	STMR-RAC	14.4	HR-RAC
Other herbal infusions (dried leaves)[d]	30	EFSA (2020a)	0.55	STMR-RAC		
Valerian root[d]	2	EFSA (2020a)	0.32	STMR-RAC	1.04	HR-RAC
Ginseng root[d]	2	EFSA (2020a)	0.32	STMR-RAC	1.04	HR-RAC
Other herbal infusions (dried roots)[d]	2	EFSA (2020a)	0.32	STMR-RAC		
Sugar beet roots[d]	0.4	EFSA (2020a)	0.12	STMR-RAC	0.15	HR-RAC
Sugar canes[d]	3	EFSA (2020a)	0.26	STMR-RAC	1.34	HR-RAC
Chicory roots[d]	0.3	EFSA (2020a)	0.07	STMR-RAC	0.21	HR-RAC
Swine: Muscle/meat[c]	0.015	FAO (2013)	0.026	STMR-RAC*CF	0.062	HR-RAC*CF
Swine: Fat tissue	0.2	FAO (2013)	0.048	STMR-RAC*CF	0.180	HR-RAC*CF
Swine: Liver	0.1	FAO (2013)	0.083	STMR-RAC*CF	0.310	HR-RAC*CF
Swine: Kidney	0.1	FAO (2013)	0.082	STMR-RAC*CF	0.31	HR-RAC*CF
Swine: Edible offal (other than liver and kidney)	0.2	Reg. (EU) 2021/644	0.048	STMR-RAC*CF	0.180	HR-RAC*CF
Bovine: Muscle/meat[c]	0.015	EFSA (2020a), FAO (2013)	0.025	STMR-RAC*CF	0.062	HR-RAC*CF
Bovine: Fat tissue	0.2	EFSA (2020a), FAO (2013)	0.047	STMR-RAC*CF	0.18	HR-RAC*CF

(Continues)

(Continued)

Commodity	Existing/ Proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value[a] (mg/kg)	Comment	Input value[a] (mg/kg)	Comment[b]
Bovine: Liver	0.1	EFSA (2020a), FAO (2013)	0.081	STMR-RAC*CF	0.31	HR-RAC*CF
Bovine: Kidney	0.1	EFSA (2020a), FAO (2013)	0.081	STMR-RAC*CF	0.31	HR-RAC*CF
Bovine: Edible offal (other than liver and kidney)	0.2	Reg. (EU) 2021/644	0.048	STMR-RAC*CF	0.180	HR-RAC*CF
Sheep: Muscle/meat[c]	0.015	EFSA (2020a), FAO (2013)	0.025	STMR-RAC*CF	0.062	HR-RAC*CF
Sheep: Fat tissue	0.2	EFSA (2020a), FAO (2013)	0.047	STMR-RAC*CF	0.18	HR-RAC*CF
Sheep: Liver	0.1	EFSA (2020a), FAO (2013)	0.081	STMR-RAC*CF	0.31	HR-RAC*CF
Sheep: Kidney	0.1	EFSA (2020a), FAO (2013)	0.081	STMR-RAC*CF	0.31	HR-RAC*CF
Sheep: Edible offal (other than liver and kidney)	0.2	Reg. (EU) 2021/644	0.047	STMR-RAC*CF	0.181	HR-RAC*CF
Goat: Muscle/meat[c]	0.015	EFSA (2020a), FAO (2013)	0.025	STMR-RAC*CF	0.062	HR-RAC*CF
Goat: Fat tissue	0.2	EFSA (2020a), FAO (2013)	0.047	STMR-RAC*CF	0.18	HR-RAC*CF
Goat: Liver	0.1	EFSA (2020a), FAO (2013)	0.081	STMR-RAC*CF	0.31	HR-RAC*CF
Goat: Kidney	0.1	EFSA (2020a), FAO (2013)	0.081	STMR-RAC*CF	0.31	HR-RAC*CF
Goat: Edible offal (other than liver and kidney)	0.2	Reg. (EU) 2021/644	0.047	STMR-RAC*CF	0.181	HR-RAC*CF
Equine: Muscle/meat[c]	0.015	EFSA (2020a), FAO (2013)	0.025	STMR-RAC*CF	0.062	HR-RAC*CF
Equine: Fat tissue	0.2	EFSA (2020a), FAO (2013)	0.047	STMR-RAC*CF	0.18	HR-RAC*CF
Equine: Liver	0.1	EFSA (2020a), FAO (2013)	0.081	STMR-RAC*CF	0.31	HR-RAC*CF
Equine: Kidney	0.1	EFSA (2020a), FAO (2013)	0.081	STMR-RAC*CF	0.31	HR-RAC*CF
Poultry: Muscle/meat[c]	0.02	EFSA (2020a), FAO (2013)	0.04	STMR-RAC*CF	0.048	HR-RAC*CF
Poultry: Fat tissue	0.05	EFSA (2020a), FAO (2013)	0.022	STMR-RAC*CF	0.05	HR-RAC*CF
Poultry: Liver	0.02	EFSA (2020a), FAO (2013)	0.022	STMR-RAC*CF	0.034	HR-RAC*CF
Poultry: Edible offal (other than liver and kidney)	0.05	Reg. (EU) 2021/644	0.022	STMR-RAC*CF	0.05	HR-RAC*CF
Other farmed animals: Muscle/meat[c]	0.015	EFSA (2020a), FAO (2013)	0.2	MRL	0.052	MRL
Other farmed animals: Fat tissue	0.2	EFSA (2020a), FAO (2013)	0.2	MRL	0.2	MRL
Other farmed animals: Liver	0.1	EFSA (2020a), FAO (2013)	0.1	MRL	0.1	MRL
Other farmed animals: Kidney	0.1	EFSA (2020a), FAO (2013)	0.1	MRL	0.1	MRL

(Continued)

Commodity	Existing/ Proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value[a] (mg/kg)	Comment	Input value[a] (mg/kg)	Comment[b]
Other farmed animals: Edible offal (other than liver and kidney)	0.2	Reg.(EU) 2021/644	0.2	MRL	0.2	MRL
Milk: Cattle	0.02	FAO (2013)	0.004	STMR-RAC*CF	0.004	STMR-RAC*CF
Milk: Sheep	0.02	FAO (2013)	0.004	STMR-RAC*CF	0.004	STMR-RAC*CF
Milk: Goat	0.02	FAO (2013)	0.004	STMR-RAC*CF	0.004	STMR-RAC*CF
Milk: Horse	0.02	FAO (2013)	0.004	STMR-RAC*CF	0.004	STMR-RAC*CF
Milk: Others	0.02	FAO (2013)	0.004	STMR-RAC*CF	0.004	STMR-RAC*CF
Eggs: Chicken	0.02	FAO (2013)	0.008	STMR-RAC*CF	0.023	HR-RAC*CF
Eggs: Duck	0.02	FAO (2013)	0.008	STMR-RAC*CF	0.023	HR-RAC*CF
Eggs: Goose	0.02	FAO (2013)	0.008	STMR-RAC*CF	0.023	HR-RAC*CF
Eggs: Quail	0.02	FAO (2013)	0.008	STMR-RAC*CF	0.023	HR-RAC*CF
Eggs: Others	0.02	FAO (2013)	0.008	STMR-RAC*CF		

Abbreviations: HR-RAC, highest residue in raw agricultural commodity; PeF, Peeling factor; STMR-RAC: supervised trials median residue in raw agricultural commodity.

[a]Figures in the table are rounded to three digits, but the calculations are normally performed with the actually calculated values (which may contain more digits). To reproduce dietary burden calculations, the unrounded values need to be used.

[b]Input values for the commodities which are not under consideration for the acute risk assessment are reported in grey.

[c]Consumption figures in the EFSA PRIMo are expressed as meat. Since the a.s. is a fat-soluble pesticides, STMR and HR residue values were calculated considering a 80%/90% muscle and 20%/10% fat content for mammal/poultry meat respectively (FAO, 2016).

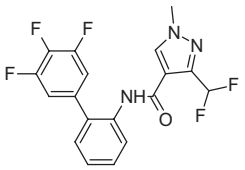
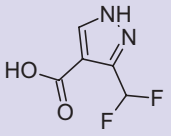
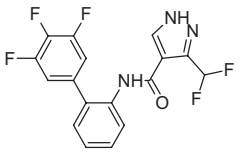
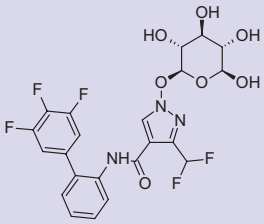
[d]Tentative MRL. EFSA identified some information as unavailable (EFSA, 2020a).

[e]Risk assessment input values to refine the calculation for peas without pods were not available in any EFSA previous output.

[f]In the MRL Regulation the MRL of 4 mg/kg for lettuces was extended to whole group of lettuces and salad plants.

APPENDIX E

Used compound codes

Code/trivial name[a]	IUPAC name/SMILES notation/InChiKey[b]	Structural formula[c]
Fluxapyroxad	3-(difluoromethyl)-1-methyl-*N*-(3′,4′,5′-trifluoro[1,1′-biphenyl]-2-yl)-1*H*-pyrazole-4-carboxamide 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′-trifluorobiphenyl-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-(*b*-*D*-glucopyranosyloxy)-*N*-(3′,4′,5′-trifluorobiphenyl-2-yl)-1*H*-pyrazole-4-carboxamide (One example of several possible glycoside structures) Fc1cc(cc(F)c1F)c1ccccc1NC(=O)c1cn(nc1C(F)F)O[C@@H]1O[C@H](CO)[C@@H](O)[C@H](O)[C@H]1O KVTPNMBJCLTHFA-GWUZYQLFSA-N	

Abbreviations: InChiKey, International Chemical Identifier Key; IUPAC, International Union of Pure and Applied Chemistry; SMILES, simplified molecular-input line-entry system.

[a]The metabolite name in bold is the name used in the conclusion.

[b]ACD/Name 2021.1.3 ACD/Labs 2021.1.3 (File Version N15E41, Build 123232, 07 July 2021).

[c]ACD/ChemSketch 2021.1.3 ACD/Labs 2021.1.3 (File Version C25H41, Build 123835, 28 August 2021).