

Modification of the existing maximum residue levels and setting import tolerances for flupyradifurone and difluoroacetic acid (DFA) in various crops

European Food Safety Authority (EFSA) | Giulia Bellisai | Giovanni Bernasconi | Luis Carrasco Cabrera | Irene Castellan | Monica del Aguila | Lucien Ferreira | German Giner Santonja | Luna Greco | Samira Jarrah | Renata Leuschner | Javier Martinez Perez | Ileana Miron | Stefanie Nave | Ragnor Pedersen | Hermine Reich | Silvia Ruocco | Miguel Santos | Alessia Pia Scarlato | 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 Bayer AG, Crop Science Division submitted a request to the competent national authority in the Netherlands to modify the existing maximum residue levels (MRL) and to set import tolerances for flupyradifurone and its metabolite difluoroacetic acid (DFA) in various plant commodities. The data submitted in support of the request were found to be sufficient to derive MRL proposals for flupyradifurone and DFA in avocados, mangoes, papayas, asparagus, sesame seeds, sunflower seeds, sugar beet roots and chicory roots. Adequate analytical methods for enforcement are available to control the residues of flupyradifurone and DFA in plant matrices under consideration at the validated limits of quantification (LOQs) of 0.01 and 0.007 mg/kg, respectively. Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of flupyradifurone and DFA residues resulting from the use of flupyradifurone according to the reported agricultural practices is unlikely to present a risk to consumer health.

KEYWORDS

consumer risk assessment, difluoroacetic acid (DFA), flupyradifurone, import tolerance, MRL, pesticide, various crops

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CONTENTS

Abstract.....	1
Summary	3
Assessment.....	7
1. Residues In Plants.....	8
1.1. Nature of residues and methods of analysis in plants.....	8
1.1.1. Nature of residues in primary crops.....	8
1.1.2. Nature of residues in rotational crops.....	8
1.1.3. Nature of residues in processed commodities	9
1.1.4. Analytical methods for enforcement purposes in plant commodities.....	9
1.1.5. Storage stability of residues in plants	9
1.1.6. Proposed residue definitions.....	9
1.2. Magnitude of residues in plants.....	10
1.2.1. Magnitude of residues in primary crops	10
1.2.2. Magnitude of residues in rotational crops	12
1.2.3. Magnitude of residues in processed commodities.....	13
1.2.4. Proposed MRLs.....	13
2. Residues In Livestock	14
3. Residues In Honey.....	14
4. Consumer Risk Assessment.....	14
5. Conclusion and Recommendations.....	15
Abbreviations	16
Acknowledgements	17
Conflict of Interest	17
Requestor	17
Question Number	17
Copyright For Non-EFSA Content	17
References.....	17
Appendix A.....	19
Appendix B.....	20
Appendix C.....	30
Appendix D.....	34
Appendix E	46
Appendix F	47

SUMMARY

In accordance with Article 6 of Regulation (EC) No 396/2005, Bayer AG Crop Science Division submitted an application to the competent national authority in the Netherlands (evaluating Member State, EMS) to modify the existing maximum residue levels (MRLs) and to set import tolerances for the active substance flupyradifurone and its metabolite DFA in various plant commodities.

The application, alongside the dossier containing the supporting data in IUCLID format, was submitted through the European Food Safety Authority (EFSA) Central Submission System on 9 May 2022. The appointed EMS, the Netherlands, assessed the dossier and declared its admissibility on 15 June 2022. Subsequently, following the implementation of the EFSA's confidentiality decision, the non-confidential version of the dossier was published by EFSA, and a public consultation launched on the 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 consultation run from 24 March 2023 to 14 April 2023. No additional data nor comments were submitted in the framework of the consultation.

At the end of the commenting period, the EMS proceeded drafting the 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 03 May 2023. To accommodate for the intended uses of flupyradifurone in Europe and the authorised uses in the United States of America (USA) and Brazil, the EMS proposed to raise the existing MRLs for flupyradifurone and/or DFA in avocados, mangoes, papayas, asparagus, sesame seeds, sunflower seeds, sugar beet roots and chicory roots.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified points which needed further clarification and requested the EMS to address them. On 6 June 2023, the EMS provided the requested information in a revised evaluation report, which replaced the previously submitted evaluation report.

Based on the conclusions derived by EFSA in the framework of Regulation (EC) No 1107/2009, the data evaluated under previous MRL assessments, the statement on the active substance flupyradifurone issued by EFSA Panel on Plant Protection Products and their Residues (PPR) and the additional data provided by the EMS in the framework of this application, the following conclusions are derived.

The metabolism of flupyradifurone was investigated following foliar applications in fruit crops, pulses/oilseeds and cereals, by soil granule/drench applications in fruit crops, root crops and cereals and by seed dressing in root crops. The EU pesticides peer review concluded that in primary crops, flupyradifurone was expected to be the major component. Following the soil application, significant proportions of DFA were observed; the data from residue trials confirmed that DFA is relevant plant metabolite of flupyradifurone.

In rotational crops, DFA is the major component of the residues identified. The presence of DFA is mostly the result of its uptake from soil, where DFA is formed as the major metabolite of flupyradifurone.

Studies investigating the effect of processing on the nature of flupyradifurone (hydrolysis studies) demonstrated that the active substance is stable. Studies investigating the effect of processing on the nature of DFA are not available. However, considering the structural similarity of DFA with trifluoroacetic acid (TFA), which is very stable under hydrolysis conditions, EFSA concluded that DFA is unlikely to degrade under standard hydrolytic conditions.

Based on the metabolic pattern identified in metabolism studies, hydrolysis studies, the toxicological relevance of metabolites, the following residue definitions were proposed:

- Residue definition for risk assessment: Sum of flupyradifurone and DFA, expressed as flupyradifurone
- Residue definitions for enforcement: (1) Flupyradifurone; (2) Difluoroacetic acid (DFA), expressed as DFA.

The residue definitions are applicable to primary crops, rotational crops, processed products and honey. The two residue definitions for enforcement in Regulation (EC) No 396/2005 are the same as the above-mentioned residue definitions, just the second residue definition is simplified in the way it is expressed and reported as 'Difluoroacetic acid (DFA)'. In the United States of America (USA) and Brazil, the established enforcement residue definition is only parent flupyradifurone.

EFSA concluded that for the crops assessed in this application, metabolism of flupyradifurone 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 high-performance liquid chromatography with tandem mass spectrometry (HPLC-MS/MS) are available to quantify residues of flupyradifurone and DFA separately in the commodities assessed in this application according to the enforcement residue definitions. The methods enable quantification of flupyradifurone residues at or above 0.01 mg/kg (LOQ) and of DFA at or above 0.007 mg/kg (LOQ). Extraction efficiency of the enforcement method is sufficiently demonstrated in both high water content and high oil content commodities for flupyradifurone, whereas in high water content commodities only for DFA.

The available residue trials performed in the EU, Brazil and USA are sufficient to derive MRL proposals for flupyradifurone and DFA in avocados, mangoes, papayas, asparagus, sesame seeds, sunflower seeds, sugar beet roots and chicory roots. The MRL proposals for DFA take into consideration the expected contribution of residues taken up via the roots.

Flupyradifurone exhibits high soil persistence, forming DFA as its soil metabolite. The gradual formation of DFA results in its uptake in rotational crops. The occurrence of flupyradifurone and DFA residues in rotational crops was investigated in the framework of the EU pesticides peer review and in previous EFSA assessments. A wide range of rotational crop studies were available, which indicated a significant uptake of metabolite DFA in rotational crops. Thus, and as stated above, EFSA derived MRL proposals for DFA in commodities based on residue trials performed after direct treatment of the annual crop (primary crop treatment), adding contribution of residues that are expected from the soil uptake of DFA.

For sunflower seeds, sesame seeds, sugar beets and chicory roots, the expected soil uptake of DFA residues in rotational crops was identified to be significant, and thus, it may affect the MRL values for DFA. For these commodities, in order to quantify the contribution of soil residues to the overall residue levels in the harvested commodities, two MRL proposals for DFA were derived: an MRL proposal accounting for residues only from primary crop treatment and a combined MRL proposal, which reflects residues of DFA from the primary crop treatment and expected from the soil uptake in rotational crops. A risk management consideration is required on whether to support the setting of MRLs on the basis of residue soil uptake or to propose implementation of restrictions or risk mitigation measures to avoid residues in rotational crops.

Specific studies investigating the magnitude of flupyradifurone and DFA residues in processed commodities are not required. The total theoretical maximum daily intake (TMDI) for the individual products under assessment is less than 10% of the acceptable daily intake (ADI) and/or significant residues of flupyradifurone (above 0.1 mg/kg) were not observed in primary crops. New tentative processing factors were derived, based on one processing study, for sesame oil, sunflower meal and sunflower oil. Peeling factors were derived for mangoes.

As the sugar beet tops and the by-products of sugar beet roots and sunflower seeds can be fed to livestock, a potential carry-over into food of animal origin was assessed. Separate livestock exposures to flupyradifurone and DFA residues calculated in previous EFSA assessments (also considering the potential intake from rotational crops) were now updated for the relevant EU livestock diets. Input values according to the enforcement residue definition were used. The results indicate that the trigger value of 0.1 mg/kg dry matter (DM) is exceeded for all livestock species, both for flupyradifurone and DFA. Compared to previous calculations in a recent EFSA assessment, the dietary burden is only slightly higher for certain livestock diets and for DFA only. Since the contribution of the products and their by-products under consideration to the total livestock exposure is insignificant, a modification of the MRLs for flupyradifurone and for DFA in commodities of animal origin as recently proposed by EFSA is not required.

The toxicological profile of flupyradifurone was assessed in the framework of the EU pesticides peer review under Regulation (EC) No 1107/2009 and the data were sufficient to derive an acceptable daily intake (ADI) of 0.064 mg/kg body weight (bw) per day and an acute reference dose (ARfD) of 0.15 mg/kg bw. The toxicological reference values are also applicable to its metabolite DFA.

The consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMO). The exposure was calculated according to the risk assessment residue definition (sum of flupyradifurone and DFA, expressed as flupyradifurone) and compared with the toxicological reference values as derived for flupyradifurone. EFSA performed two separate consumer exposure calculations in order to estimate the exposure from primary crops and products of animal origin (scenario 1) and rotational crops (scenario 2). This approach was chosen to provide risk managers additional information to decide on risk management options as regards residues in rotational crops, i.e. whether MRLs should be established to cover residues in rotational crops or whether other restrictions would be appropriate to avoid residues in untreated crops.

The input values in scenario 1 were derived from the submitted residue trials for plant commodities under assessment and those available from previous EFSA assessments. The crops for which no safe uses have been reported in the EU pesticides peer review or in subsequent EFSA outputs were excluded from the exposure calculation. In scenario 2, the input values that were derived from rotational crop studies in the previous EFSA assessments were updated with the residues expected in sugar beet roots and chicory roots from the uptake from soil. The two short-term risk assessments were performed for the commodities assessed in the present application only.

The long-term dietary exposure in scenario 1 accounted for a maximum of 55% of the ADI for NL toddler diet. For scenario 2, the exposure accounted for up to 17% of the ADI for GEMS/Food G06 diet and 16% of the NL toddler diet. The highest combined exposure from scenario 1 and scenario 2 was identified for the Dutch toddler diet, accounting for a maximum of **71% of the ADI**. The overall exposure to flupyradifurone and DFA is unlikely to pose a chronic consumer intake concern. In the short-term dietary exposure according to scenario 1 and scenario 2, no exceedances of the ARfD were identified for the commodities under consideration.

EFSA concluded that the proposed and authorised (import tolerance) uses of flupyradifurone under assessment on various crops will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers' health.

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: Flupyradifurone				
0163010	Avocados	0.6	No change	The submitted data are sufficient to derive an import tolerance proposal of 0.6 mg/kg for flupyradifurone. Same MRL (tolerance) value of 0.6 mg/kg is set in the country of origin (USA) A modification of the existing MRL, which corresponds to the Codex MRL (CXL) taken over in the EU MRL Regulation, is not required. Risk for consumers unlikely
0163030	Mangoes	0.01*	0.7	The submitted data are sufficient to derive an import tolerance. Same MRL value of 0.7 mg/kg is set for flupyradifurone in the country of origin (Brazil). Risk for consumers unlikely
0163040	Papayas	0.01*	0.4	The submitted data are sufficient to derive an import tolerance. Same MRL value of 0.4 mg/kg is set for flupyradifurone in the country of origin (Brazil). Risk for consumers unlikely
0270010	Asparagus	0.01*	No change	The submitted data are sufficient to derive an import tolerance proposal for flupyradifurone. A modification of the existing MRL is not required. According to the authorised US use assessed, flupyradifurone residues are not anticipated above the LOQ of 0.01 mg/kg. An MRL (tolerance) of 0.01 mg/kg is set in the country of origin. Risk for consumers unlikely
0401040	Sesame seeds	0.01*	3	The submitted data are sufficient to derive an import tolerance. Same MRL (tolerance) value of 3 mg/kg is set in the country of origin (USA). Risk for consumers unlikely A Codex MRL proposal for flupyradifurone of 3 mg/kg, based on the same data set, is under assessment at EU level
0401050	Sunflower seeds	0.01*	0.7 or 0.8 Further risk management consideration required	The submitted data are sufficient to derive an import tolerance of 0.8 mg/kg (highest residue of flupyradifurone observed among the eight trials available is 0.44 mg/kg). The MRL (tolerance) for residues established in the USA for flupyradifurone is lower (0.7 mg/kg) as additional trials were taken into consideration. EFSA disregarded those trials, being not independent according to the EU guidelines. Risk for consumers is unlikely In a recent MRL assessment, EFSA ^b proposed an MRL of 0.07 mg/kg based on a SEU use. A Codex MRL proposal for flupyradifurone of 0.8 mg/kg, based on the same data set submitted in the present MRL application, is under assessment at EU level
0900010	Sugar beet roots	0.01*	No change	The submitted data are sufficient to support the intended NEU foliar and seed uses in EU. A modification of the existing MRL is not required. Flupyradifurone residues are not anticipated above the LOQ of 0.01 mg/kg. Risk for consumers unlikely
0900030	Chicory roots	0.01*	No change	The submitted data are sufficient to support the intended NEU foliar use by extrapolation from data in sugar beet roots. A modification of the existing MRL is not required. Flupyradifurone residues are not anticipated above the LOQ of 0.01 mg/kg. Risk for consumers unlikely
Enforcement residue definition: Difluoroacetic acid (DFA)				
0163010	Avocados	0.02*	0.15	The submitted data are sufficient to derive an import tolerance proposal for DFA (US use). No MRL (tolerance) is set for DFA in the country of origin as a separated enforcement residue definition is not established. Risk for consumers unlikely
0163030	Mangoes	0.02*	0.2	The submitted data are sufficient to derive an import tolerance proposal for DFA (Brazilian use). No MRL is set for DFA in the country of origin as the residue definition for enforcement is restricted to parent compound. Risk for consumers unlikely
0163040	Papayas	0.02*	0.2	The submitted data are sufficient to derive an import tolerance proposal for DFA (Brazilian use). No MRL is set for DFA in the country of origin as a separated enforcement residue definition is not established. Risk for consumers unlikely
0270010	Asparagus	0.2	0.5	The submitted data are sufficient to derive an import tolerance proposal for DFA (US use). No MRL (tolerance) is set for DFA in the country of origin as a separated enforcement residue definition is not established. Risk for consumers unlikely

Code ^a	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
0401040	Sesame seeds	0.05	0.8 or 0.9 Further risk management considerations required.	Direct treatment of the crop with flupyradifurone (primary crop treatment) would require an MRL of 0.8 mg/kg. The MRL proposal derived based on the US use reflecting direct treatment combined with residues expected to be taken up via roots would require an MRL of 0.9 mg/kg. Risk for consumers unlikely in both scenarios
0401050	Sunflower seeds	0.05	Previous MRL proposal (i.e. 0.09 or 0.15 mg/kg) covers the US use under assessment	Direct treatment of the crop with flupyradifurone (primary crop treatment) would require an MRL at the LOQ of 0.02 mg/kg. The MRL proposal derived based on the US use reflecting direct treatment combined with residues expected to be taken up via roots would require an MRL of 0.05 mg/kg In a recent MRL assessment, EFSA ^b proposed higher MRL for DFA at 0.09 and 0.15 mg/kg, respectively, for both scenarios based on an EU use, that cover the present US use
0900010	Sugar beet roots	0.02*	0.02 or 0.09 Further risk management considerations required	Direct treatment of the crop with flupyradifurone (primary crop treatment) would require an MRL of 0.02 mg/kg. The MRL proposal for EU uses reflecting direct treatment combined with residues expected to be taken up via roots would require an MRL of 0.09 mg/kg. Risk for consumers unlikely in both scenarios
0900030	Chicory roots	0.02*	0.02 or 0.09 Further risk management considerations required	Direct treatment of the crop with flupyradifurone (primary crop treatment) would require an MRL of 0.02 mg/kg. The MRL proposal for EU uses reflecting direct treatment combined with residues expected to be taken up via roots would require an MRL of 0.09 mg/kg. Risk for consumers unlikely in both scenarios

Abbreviations: MRL, maximum residue level; NEU, northern Europe; SEU, southern Europe.

^aCommodity code number according to Annex I of Regulation (EC) No 396/2005.

^bReasoned Opinion on the modification of the existing maximum residue levels and setting of import tolerances for flupyradifurone and DFA in various crops and animal commodities. *EFSA Journal* 2023;21(7):8081, 104 pp. <https://doi.org/10.2903/j.efsa.2023.8081>.

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

ASSESSMENT

The European Food Safety Authority (EFSA) received an application to modify the existing maximum residue levels (MRLs) and to set import tolerances for flupyradifurone and its metabolite difluoroacetic acid (DFA) in various plant commodities on the basis of intended flupyradifurone uses in the EU and authorised uses in the United States of America (USA) and Brazil. The detailed description of the intended and authorised uses, which are the basis for the current MRL application, is reported in Appendix A.

Flupyradifurone is the ISO common name for 4-[[[6-chloro-3-pyridyl)methyl]](2,2-difluoroethyl)amino]furan-2(5*H*)-one (IUPAC). The chemical structures of the active substance and its main metabolites are reported in Appendix F.

Flupyradifurone was evaluated in the framework of Regulation (EC) No 1107/2009¹ with the Netherlands designated as rapporteur Member State (RMS) for the representative uses as a foliar treatment on hops and lettuce. The draft assessment report (DAR) also included a proposal to set maximum residue levels (MRL application), in accordance with Article 11 (2) of the Regulation (EC) 1107/2009. The DAR prepared by the RMS has been peer reviewed by EFSA (2015a), where some information was identified as unavailable (data gaps) and tentative MRLs were derived for those uses which were not fully supported by data. Furthermore, the conclusion also addressed the assessment required from EFSA under Article 12 of Regulation (EC) No 396/2005. Flupyradifurone was approved² for the use as insecticide on 9 December 2015. The process of renewal of the first approval has not yet been initiated.

The data gaps identified by EFSA as well as new EU uses and authorised uses of flupyradifurone in third countries (import tolerance request) were assessed in an EFSA reasoned opinion (EFSA, 2020b).

EFSA has assessed uses of flupyradifurone on rape seeds, mustard seeds and okra/lady's finger (EFSA, 2020a, 2021). The proposals from these reasoned opinions have been considered in MRL regulations.³ In addition, certain Codex maximum residue limits (CXLs) have been taken over in the EU MRL legislation according to Commission Regulation (EU) 2022/1324.⁴ Moreover, EFSA in a reasoned opinion recently assessed various intended EU uses and uses authorised in third countries (EFSA, 2023b). The proposed higher MRLs and import tolerances have not yet been adopted in an MRL regulation. Furthermore, EFSA provided scientific support for the preparation of the 54th Session of the Codex Committee on Pesticide Residues (CCPR) meeting (EFSA, 2023a). Specifically, EFSA assessed CXL proposals for flupyradifurone in pineapple, sunflower seeds and sesame seeds (FAO, 2023). EFSA Panel on Plant Protection Products and their Residues has issued a statement on the active substance flupyradifurone in the context of concerns that this substance may pose high risks to humans and the environment raised by the French authorities (EFSA PPR Panel, 2022). With regard to human health, the PPR Panel concluded that the additional information did not modify the conclusions reached in the evaluation by EFSA (2015a).

In accordance with Article 6 of Regulation (EC) No 396/2005 and following the provisions set by the 'Transparency Regulation' (EU) 2019/1381,⁵ the applicant Bayer AG, Crop Science Division submitted on 09 May 2022 an application to the competent national authority in the Netherlands alongside the dossier containing the supporting data using the IUCLID format.

The appointed EMS, the Netherlands, assessed the dossier and declared its admissibility on 15 June 2022. Subsequently, following the implementation of the EFSA's confidentiality decision, the non-confidential version of the dossier was published by EFSA, and a public consultation launched on the 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 consultation run from 24 March 2023 to 14 April 2023. No additional data nor comments were submitted in the framework of the consultation. At the end of the commenting period, the EMS proceeded drafting the evaluation report, in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the EFSA on 03 May 2023.

To accommodate for the intended uses of flupyradifurone in Europe and the authorised uses in the United States of America (USA) and Brazil, the EMS proposed to raise the existing MRLs for flupyradifurone and/or DFA in avocados, mangoes, papayas, asparagus, sesame seeds, sunflower seeds, sugar beet roots and chicory roots.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified points which needed further clarification, which were requested from the EMS. On 6 June 2023, the EMS provided the requested information in a revised evaluation report, which replaced the previously submitted evaluation report.

EFSA based its assessment on the evaluation report submitted by the EMS (Netherlands, 2023), the draft assessment report (DAR) and its addenda (Netherlands, 2014, 2015) prepared under Regulation (EC) 1107/2009, the Commission review

¹Regulation (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, pp. 1–50.

²Commission Implementing Regulation (EU) 2015/2084 of 18 November 2015 approving the active substance flupyradifurone, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 OJ L 302, 19.11.2015, pp. 89–92.

³For 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>.

⁴Commission Regulation (EU) 2022/1324 of 28 July 2022 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 benzovindiflupyr, boscalid, fenazaquin, fluzifop-P, flupyradifurone, fluxapyroxad, fosetyl-AI, isofetamid, metaflumizone, pyraclostrobin, spirotriamat, thiabendazole and tolclofos-methyl in or on certain products. OJ L 200, 29.7.2022, pp. 68–108.

⁵Regulation (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, pp. 1–28.

report on flupyradifurone (European Commission, 2015), the conclusion on the peer review of the pesticide risk assessment of the active substance flupyradifurone (EFSA, 2015a), as well as the conclusions from previous EFSA opinions on flupyradifurone (EFSA, 2016; 2020a, 2020b, 2021, 2023a, 2023b).

For this application, the data requirements established in Regulation (EU) No 544/2011⁶ 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; OECD, 2011, 2018). 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

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 (Netherlands, 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.⁸

1 | RESIDUES IN PLANTS

1.1 | Nature of residues and methods of analysis in plants

1.1.1 | Nature of residues in primary crops

Flupyradifurone metabolism in primary crops was investigated in the framework of the EU pesticides peer review in four crop groups (representatives of fruits, pulses and oilseeds, root crops and cereals) either by foliar applications (fruits, apple; pulses/oilseeds, cotton; cereals, rice), by soil granule/drench applications (fruits, tomato; root crops, potato; cereals, rice) and by seed treatment (root crops only, potato) (EFSA, 2015a). The metabolism in primary crops was seen to be similar in all plant groups investigated. Flupyradifurone was consistently observed as the major component of the radioactive residues after foliar use, accounting for ca. 25%–88% total radioactive residue (TRR) in all plant parts analysed.

In tomato fruits, following the soil drench application, significant proportions (87% TRR) and levels (0.17 mg/kg) of the metabolite difluoroacetic acid (DFA) were observed. DFA residues (expressed as DFA equivalent) were observed in the range of 0.04–0.23 mg/kg in apple fruits, potato tuber, cotton seed and rice grain, irrespective of the mode of application in field trials assessed in the EU pesticides peer review. DFA is a major metabolite in rotational crops (see Section 1.1.2).

The EU pesticides peer review considered parent flupyradifurone and its metabolite DFA to be the main residues of toxicological significance in the crops investigated. The metabolism of flupyradifurone in maize, cotton, soyabean and potato with genetical modifications to introduce herbicide tolerance, insect resistance was not altered and a specific residue definition for genetically modified (GM) crops was not considered necessary (EFSA PPR Panel, 2022).

For the intended and authorised uses under consideration, it is concluded that the metabolic behaviour in primary crops is sufficiently addressed.

1.1.2 | Nature of residues in rotational crops

Flupyradifurone is proposed to be used or is authorised on several crops that can be grown in rotation with other crops. According to the soil degradation studies evaluated in the framework of the EU pesticides peer review, flupyradifurone exhibits moderate to high persistence in the soil with the maximum $DT_{90,field}$ value of more than 1000 days. The relevant soil metabolites of flupyradifurone (6-CNA and DFA) exhibited very low to moderate and moderate to medium persistence with maximum $DT_{90,lab}$ values of 121 and 244 days, respectively (EFSA, 2015a). The 6-CNA metabolite was not identified by the peer review experts as relevant residue in rotational crops and was thus not further considered in this assessment.

The nature of flupyradifurone in rotational crops (turnips, Swiss chards and wheat) was investigated in the framework of the EU pesticides peer review after bare soil application of the active substance flupyradifurone at rate of 436 g/ha (EFSA, 2015a). Rotational crops were planted 29, 135 and 296 days after the soil treatment. In rotational crops, flupyradifurone and its metabolites flupyradifurone-hydroxy (M8 metabolite), 6-CNA and their conjugates were found to be the major components of the radioactive residues. These radiolabelled studies did not include labelling of the active substance on the difluoroethyl amino group, but the EU pesticides peer review did not consider it as a data gap since rotational crop field trials confirmed that DFA is the main component in rotational crops. The presence of DFA is mostly due to the direct uptake of DFA residues formed in the soil from parent flupyradifurone (EFSA, 2015a).

⁶Commission 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, pp. 1–66.

⁷Commission 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, pp. 127–175.

⁸Background 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-2022-00370>.

EFSA concludes that for the uses under consideration, the metabolism of flupyradifurone in rotational crops is addressed and further studies are not required.

1.1.3 | Nature of residues in processed commodities

The effect of processing on the nature of flupyradifurone was investigated in the framework of the EU pesticides peer review (EFSA, 2015a). Standard hydrolysis studies showed that flupyradifurone is hydrolytically stable under standard processing conditions of pasteurisation, baking/brewing/boiling and sterilisation.

The effect of processing on the nature of DFA has not been investigated. Considering the similarity of the structures between trifluoroacetic acid (TFA) and DFA, a read-across for DFA endpoint was considered by using data from the same endpoint from TFA (EFSA, 2020b). The TFA has been widely studied due to its wide use in the organic chemistry and is, due to its structure (complete fluoride ion substitution), very stable and thus has no potential for hydrolytic degradation. EFSA agreed to conclude by analogy that DFA is stable under standard hydrolysis conditions.

1.1.4 | Analytical methods for enforcement purposes in plant commodities

The availability of analytical enforcement methods for the determination of flupyradifurone and DFA in plant matrices including hops was investigated in the framework of the EU pesticides peer review (EFSA, 2015a).

It was concluded that an analytical method [extraction with acetonitrile/water (4/1, v/v) with 2.2 mL/L formic acid, analysis using high-performance liquid chromatography with tandem mass spectrometry (HPLC-MS/MS)] is sufficiently validated for the determination of flupyradifurone and DFA residues separately; LOQs achievable with the method were 0.01 and 0.007 mg/kg for flupyradifurone and for DFA, respectively, in plant matrices with high water (lettuces), high starch (wheat, potatoes), high acid (oranges) and high oil content (rapeseeds). In hops, the validated LOQs for the determination of flupyradifurone and of DFA were 0.05 and 0.03 mg/kg, respectively.

It was concluded that for the commodities under consideration that belong to high water and high oil content commodities sufficiently validated methods are available to enforce flupyradifurone and DFA.

The efficiency of the extraction procedures used in the analytical method for enforcement of flupyradifurone and DFA was discussed in a previous MRL application (EFSA, 2023b). For flupyradifurone, the extractability of the method in high water content, high oil content and dry commodities was demonstrated by radio-cross validation using radiolabelled sample material from the flupyradifurone metabolism studies, in line with the extraction efficiency Technical Guideline (European Commission, 2022). Similarly, the efficiency of the extraction procedures used in the analytical method for enforcement of DFA in high water content commodities was demonstrated by radio-cross validation using radiolabelled sample material from the flupyradifurone metabolism study in tomato. However, due to the lack of DFA radiolabelled material in high oil content commodities (matrices under assessment in this MRL application), the extraction efficiency of the method could not be investigated according to the extraction efficiency Technical Guideline (European Commission, 2022). Further investigation on this matter would be required. Therefore, EFSA recommends reconsidering this point in the context of the EU peer review for the renewal of the approval of flupyradifurone.

1.1.5 | Storage stability of residues in plants

The storage stability of flupyradifurone and DFA has been investigated in the EU pesticides peer review (EFSA, 2015a) as well as in a previously issued EFSA reasoned opinion (EFSA, 2020b). The freezer storage stability of flupyradifurone and DFA residues is confirmed at -18°C for 52 months in matrices with high water content, high acid content, high oil content, high protein content and high starch content (EFSA, 2020b). Therefore, it has been demonstrated that in the commodities assessed in the framework of this application, residues are stable for at least 52 months when stored at -18°C .

1.1.6 | Proposed residue definitions

Based on the metabolic pattern identified in metabolism studies, the results of hydrolysis studies, the toxicological relevance of metabolites, the following residue definitions were proposed by the EU pesticides peer review (EFSA, 2015a):

- residue definition for enforcement:
 - flupyradifurone
 - difluoroacetic acid (DFA), expressed as DFA.

- residue definition for risk assessment:
 - sum of flupyradifurone and DFA, expressed as flupyradifurone.

The residue definitions are applicable to primary and rotational crops and processed products. The residue definitions for enforcement set in Regulation (EC) No 396/2005 are the same as the above-mentioned residue definitions, just the second residue definition is simplified in the way it is expressed and reported as 'difluoroacetic acid (DFA)'.

Taking into account the proposed uses assessed in this application, EFSA concludes that these residue definitions are appropriate, and no modification/no further information is required.

1.2 | Magnitude of residues in plants

1.2.1 | Magnitude of residues in primary crops

In support of the MRL application, the applicant submitted residue trials conducted with sugar beets, avocado, mango, papaya, asparagus, sesame and sunflower. EFSA notes that data requirements that are set in Regulation (EU) No 544/2011 specify that trials have to be carried out over a minimum of two growing seasons. However, for certain crops, submitted trials were conducted within a single growing season. This deviation was considered of minor importance and accepted since the trials were conducted in different geographical sites (spread out over the exporting countries) that reflected the variability in production system and environmental conditions (e.g. weather, soil), while date of treatments was significantly different for most trials.

The samples were analysed for flupyradifurone and DFA separately, in accordance with the residue definitions for monitoring and risk assessment, with validated analytical methods that fitted the purpose (Netherlands, 2023). It is noted that the extraction efficiency of the analytical method (RV-001-P10-02 and -03, method 01304) used for the quantification of residues in samples collected from the supervised trials performed on sugar beet, mango, papaya, asparagus (high water content commodities), avocado, sesame, sunflowers (high oil content commodities) was demonstrated by radio-cross validation for flupyradifurone in mango, papaya, asparagus, sugar beets (high water content commodities) for DFA (EFSA, 2023b). Due to the lack of DFA radiolabelled material in matrices other than high-water content matrices (such as avocado and oilseeds), the extraction efficiency of the method for quantification of DFA in high oil content matrices could not be investigated according to the extraction efficiency Technical Guideline (European Commission, 2022), adding non-standard uncertainties on the risk assessment.

The sum of both compounds was calculated to perform dietary exposure for consumers in line with the residue definition for risk assessment.⁹ If higher residues were found at sampling points later than the reported PHI (mangoes, papayas, avocados, sunflower and sesame seeds) or the highest residues in case of early applications (sugar beets, chicory roots, asparagus), these higher values were selected for deriving the MRL proposals and input values for risk assessment. The samples of the residue trials were stored under conditions for which integrity of the samples has been demonstrated (Netherlands, 2023). It is noted that in several US trials supporting import tolerances, a non-ionic surfactant was added in the tank mix before spraying, which could have affected the residue situation in the harvested commodity. The applicant explained that the formulated product label does not routinely recommend using an adjuvant, but there are no restriction or preclusion in using it. Therefore, this event is possible, and residue trials submitted are representative for the use in the field in the USA.

Sugar beets

NEU, SEU (seed treatment): 1 × 30 g a.s./ha, BBCH 00, PHI not applicable (n.a.).

In support of the intended seed treatment on sugar beets applicant submitted 16 GAP-compliant residue trials (8 NEU and 8 SEU). Trials were designed as decline studies, including three sampling points at maturity of the commodity. In all trials, flupyradifurone was below the LOQ of 0.01 mg/kg in the roots, while DFA was estimated up to 0.014 mg/kg. Residues were measured also in sugar beet tops that can be used as feed item. NEU and SEU data sets showed to belong to similar populations (*U*-test, 5%) and individual MRLs fall into the same or neighbouring MRL class. Thus, data sets were combined for calculations (European Commission, 2020). Data are sufficient to derive MRLs from the primary use on sugar beet seeds for flupyradifurone at the LOQ of 0.01 mg/kg and for DFA at 0.015 mg/kg.

NEU (foliar application): 1 × 50 g a.s./ha, BBCH 10–19, PHI n.a.

In support of the intended foliar use, applicant submitted eight GAP compliant residue trials. Trials were conducted during growing seasons 2018 and 2019 in the NEU. Trials were designed as decline studies, including three sampling points at maturity of the commodity. In all trials, flupyradifurone was below the LOQ of 0.01 mg/kg in the roots and the leaves of the sugar beets. DFA was also below the LOQ in the roots with the exception of one trial found at 0.013 mg/kg, while determined in the leaves in most trials up to 0.026 mg/kg. Data are sufficient to derive MRLs for sugar beet roots from the primary foliar treatment on sugar beets at the level of the LOQ of 0.01 mg/kg for flupyradifurone, and at 0.02 mg/kg for DFA.

⁹To express residues of DFA as flupyradifurone equivalent, the molecular weight (MW) conversion factor of 3 is applied to residues of DFA, regardless of being below or above the LOQ, prior to be summed up. MW of flupyradifurone (288): MW of DFA (96).

Chicory roots

NEU (foliar application): 1 × 50 g a.s./ha, BBCH 10–19, PHI n.a.

In support of the intended use on chicory roots, applicant proposes to extrapolate residue data on sugar beets. According to the Technical Guidance, such an extrapolation is acceptable (European Commission, 2020). Data are sufficient to derive MRLs for chicory roots from the primary foliar treatment on chicory at the level of the LOQ of 0.01 mg/kg for flupyradifurone and at 0.02 mg/kg for DFA.

Mangoes

Brazil (foliar application): 2 × 200 g a.s./ha, interval 7 days, PHI 3 days.

In support of the import tolerance for the authorised use in Brazil, applicant submitted five GAP compliant trials. Trials were performed in Brazil during growing season 2019 and were all designed as decline studies. Mangoes were sampled 3, 7, 14, 21 and 28 days after the last treatment. Peel and pulp were analysed for compounds included in the residue definitions. Number of trials is sufficient to derive an import tolerance for mangoes at 0.7 mg/kg for flupyradifurone and at 0.2 mg/kg for DFA. In Brazil, the same MRL value is set for flupyradifurone, while no MRLs are established for DFA.

It is noted that CCPR did not advance for adoption the CXL proposal of 0.7 mg/kg for mangoes derived from the same set of Brazilian trials. Since the total residues (sum of flupyradifurone, DFA and 6-CNA, expressed as parent equivalents) did not appear to reach a plateau in three of the five decline trials, JMPR concluded that input values for dietary exposure (HR/STMR) could not be estimated (FAO, 2023). From the results of the residue trials, metabolite DFA is formed and increases over time leading to the rapid decline of the active substance after the reported PHI of 3 days (first sampling point of the five residue trials designed as decline trials). The residue behaviour is known and observed in other crops treated with flupyradifurone. In three of the five trials submitted, a distinct decline of the total residues (sum of flupyradifurone and DFA, expressed as flupyradifurone) was not observed up to the last sampling point, 28 days after last application (DALA), in the mango pulp, whereas in the other two trials, the peak of the total residue was achieved at 21 DALA. Total residue levels in the pulp were comparable (in three trials, a plateau was not reached: 0.25, 0.31, and 0.35 mg/kg) to those in the trials where a peak was achieved (in two trials, a peak achieved at 21 DALA 0.21 and 0.28 mg/kg). Presumably, DFA is derived from metabolisation in the plant and from the uptake by the roots from soil (fraction of the product that reaches the soil directly when applied to the trees or by foliar wash-off). Although all five trials (100%) were designed as decline studies with five sampling points as recommended in the EU guidelines (European Commission, 2020), a robust conclusion on DFA and, consequently, on the total residue behaviour over the time cannot be drawn.

Higher residues of DFA cannot be excluded at longer sampling points although not expected to be of a significant higher magnitude than those observed in the available five trials, based on the comparable residue levels observed between the trials reaching a plateau at 21 DALA and the trials not showing a plateau at 28 DALA. However, the use of input values for risk assessment derived from these trials is introducing a non-standard uncertainty in the dietary risk assessment.

Papayas

Brazil (foliar application): 2 × 200 g a.s./ha, interval 7 days, PHI 3 days.

In support of the import tolerance for the Brazilian use on papayas, applicant submitted five GAP compliant trials. Trials on papayas were performed in Brazil during growing season 2018 and were all designed as decline studies. Papayas were sampled 3, 7, 14, 21 and 28 days after the last treatment. Number of trials is sufficient to derive an import tolerance for papayas at 0.4 mg/kg for flupyradifurone and at 0.2 mg/kg for DFA. In Brazil, the same MRL value is set for flupyradifurone, while no MRLs are established for DFA.

Also, for papayas and for the same reasons as for mangoes, CCPR did not adopt the CXL of 0.4 mg/kg derived from the same set of Brazilian trials (FAO, 2023). EFSA noticed the same residue behaviour in papayas as in mangoes.

In two out of the five trials submitted, the total residue peak was achieved at 21 DALA and residues were in the same range (0.18 and 0.20 mg/kg) as in the three trials where no peak was achieved at the last sampling point of 28 DALA (0.13, 0.18, and 0.25 mg/kg). The same conclusion as for mangoes is reached for papayas.

DFA residues increase at longer sampling points. Higher residues of DFA cannot be excluded at longer sampling points although not expected to be of a significant higher magnitude than those observed in the available five trials, based on the comparable residue levels observed between the trials reaching a plateau at 21 DALA and the trials not showing a plateau at 28 DALA.

Avocados

USA (foliar application): 2 × 204 g a.s./ha, interval 14 days, PHI 1 day.

In support of the import tolerance for the authorised US use on avocados, applicant submitted four GAP compliant trials. Trials on avocados were performed in the USA during growing season 2013. Two of the trials were designed as decline studies. In the harvest trials, avocado fruit samples were collected at the PHI (1 day after last application) and in the decline trials, immediately after last application and 1, 7, 14, 21 and 28 days after last application. For each sampling point, duplicate samples were collected from which the mean value was used for calculations. In each trial, side-by-side tests were performed, where plots were treated with the same flupyradifurone application rate per hectare but different water volume. From these tests, the higher residues were selected.

Existing EU MRL for flupyradifurone (i.e. 0.6 mg/kg), derived from the same set of trials, is the CXL taken over in the EU legislation by the Commission Regulation (EU) 2022/1324. Thus, a change of the MRL is not required for flupyradifurone. Number of trials is sufficient to set an EU MRL for DFA at 0.15 mg/kg for avocados imported from the USA.

Asparagus

USA (foliar application): 2 × 204 g a.s./ha, interval 30 days, at fern stage PHI n.a.

In support of the import tolerance for the authorised use on asparagus, applicant submitted eight GAP compliant trials. In all trials, asparagus spears were collected in the following growing season once in each trial, approximately 123–276 days after the last application. In each treated plot, duplicate samples were collected, and the mean residue value was used for calculations. Flupyradifurone was below the LOQ of 0.01 mg/kg, while DFA amounted up to 0.24 mg/kg, deriving an MRL proposal of 0.5 mg/kg.

Sunflower seeds

USA (foliar application): 2 × 204 g a.s./ha, interval 10 days, PHI 14 days.

In support of the import tolerance for sunflower seeds, eight GAP-compliant residue trials are available. In seven harvest trials, sunflower seed samples were collected at the PHI (13–15 days after the last application) and in a single decline trial 5, 9, 19 and 23 days after last application.

Two residue trials (11674.16-ND238 and 11674.16-ND239) were performed in the same area and treatment dates differed by 21 days. According to the Technical Guidelines (European Commission, 2020), difference between treatment dates should be significant, namely more than 30 days, as to consider two trials sufficiently independent. Applicant provided additional information in support of the validity of both trials, such as crop variety and its individual characteristics. EMS took into account treatment dates and environmental conditions during treatments, and secondarily differences in characteristics of the plants and seeds and expressed their view that the two trials can be considered as independent. EFSA concluded that the deviation to the guidelines can be considered minor for this case and all eight trials were accounted for MRL estimation. The same approach was followed by the Codex Alimentarius and a CXL of 0.8 mg/kg has been proposed on the basis of the same eight independent residue trials (EFSA, 2023a; FAO, 2023).

Flupyradifurone ranged from 0.01 to 0.44 mg/kg, resulting to an MRL proposal of 0.8 mg/kg. In the USA, a tolerance is set at lower level of 0.7 mg/kg, since derived based on 10 trials (same set of eight trials plus two additional trials 11674.16-ND240 and 11674.16-SD358 that were now disregarded for this application as considered not being independent). The highest residue of flupyradifurone observed among the eight trials is 0.44 mg/kg. DFA was below the LOQ of the method (i.e. 0.017 mg/kg). It is noted that a higher MRL¹⁰ for DFA has been proposed for risk management consideration by EFSA on the basis of an intended SEU use (EFSA, 2023b), but has not yet been implemented by the MRL Regulation.

Sesame seeds

USA (foliar application): 2 × 204 g a.s./ha, interval 10 days, PHI 14 days.

In support of the import tolerance, applicant submitted four US GAP-compliant trials with sesame. In three harvest trials, sesame seed samples were collected 14–19 days after the last application and in a single decline trial 5, 10, 14, 21 and 27 days after last application. In harvest trial number 11725.16-NM263 sampling was performed at a PHI of 19 days, being above the acceptable +25% range (European Commission, 2020). Since residues were within the range of those of the remaining three trials, this trial was considered for calculations. It is further noted that in the trials, different agronomic practices were applied on the harvested plants/seeds. Certain harvesting and drying methods were applied to lower the moisture in seeds (e.g. different harvesting technics (by hand, or mechanically), different drying periods or drying methods). EMS considered different harvest and drying practices applied in the field trials to be representative of the range of the realistic conditions of the US use. EFSA concluded that all trials are appropriate to derive an import tolerance for the authorised US use.

The number of trials is sufficient to derive an import tolerance for sesame seeds at 3 mg/kg for flupyradifurone, and at 0.8 mg/kg for DFA due to the primary use on sesame. In the USA, the same tolerance for residues is set for flupyradifurone, while no MRLs are established for DFA. It is noted that a CXL for flupyradifurone has been proposed on the basis of the same data set and is under assessment at EU level (EFSA, 2023a; FAO, 2023).

1.2.2 | Magnitude of residues in rotational crops

Flupyradifurone is highly persistent in soil and can be taken up by plants directly or in a form of its degradation product DFA, in addition to residues that result from the primary crop treatment. Moreover, the accumulation of residues in the soil with a subsequent uptake of residues by rotational crops from multi-annual use of flupyradifurone cannot be excluded. Thus, the magnitude of residue uptake in rotational crops via soil has to be investigated for the EU uses considered in this application as well as for the imported crops for which import tolerances have been requested.

A wide range of rotational crop field studies were submitted for the EU pesticides peer review and in the framework of a previous MRL assessment (EFSA, 2015a, 2020b). Studies indicate a significant uptake of metabolite DFA in rotational crops. In rotational crops field trials submitted, parent flupyradifurone was below the LOQ of 0.01 mg/kg in all edible plant matrices at all plant back intervals (PBI) (except one barley grain sample containing residues at the LOQ of 0.01 mg/kg and lettuce

¹⁰Direct treatment of the sunflowers with flupyradifurone (primary crop treatment) would require an MRL of 0.09 mg/kg; Considering the direct treatment and residues taken up via roots would require an MRL of 0.15 mg/kg. SEU GAP: 2 × 56.25 g/ha, 14-day interval, BBCH 31–69, PHI n.a. (EFSA, 2023b).

at 0.03 mg/kg). DFA residues were present in all edible plant matrices at all PBI, indicating that DFA is gradually formed in the soil from flupyradifurone and taken up by the crops.

In the previous EFSA assessments, the occurrence of DFA residues in rotational crops has been investigated, considering the estimated plateau soil concentrations of flupyradifurone from the critical primary crop uses after multi-annual uses and comparing these values with the residue soil concentrations of flupyradifurone in the available rotational crop studies (EFSA, 2020b). The critical primary crop GAPs for Europe represent a worst-case scenario for soil compared to the intended foliar use on sugar beets and chicory roots.

According to the OECD guidance document on residues in rotational crops, the application rate in the rotational crop field studies should be the maximum seasonal application rate (on the primary crop) plus the application rate corresponding to residues in the soil from the long-term use of the active substance (soil plateau levels) (OECD, 2018). In order to investigate whether the available rotational crop studies are sufficiently representative for the critical intended and authorised (import tolerance) flupyradifurone GAPs on primary crops, the approaches reported in detail below have been followed in the previous EFSA assessments and in the present one.

(A) Primary crop intended EU uses (sugar beets/chicory roots: 1×50 g/ha, BBCH 10–19)

According to previous EFSA output (EFSA, 2020b), the worst-case long-term flupyradifurone soil plateau concentration [reflecting the critical EU application rates (2×125 g/ha)] was estimated as 0.062 mg/kg (DT_{50} 462 days, indoor application on lettuce at 2×0.125 kg a.s./ha, crop interception 25%, 10-day interval, residue distribution over 20 cm soil). This value was compared with the determined geometrical mean soil concentrations of flupyradifurone in soil from the rotational crop residue trials (0.029 mg/kg, highest value at the PBI of 107–204 days, after application of 300 g flupyradifurone/ha). The residue trials were considered underdosed and a scaling factor of **2.06** to derive risk assessment values for DFA in rotational crops reflecting the rotational crop uptake of DFA following the use of flupyradifurone on primary crops in Europe according to the critical use patterns under assessment.

(B) Primary crop import tolerance uses (oilseeds: 2×204 g/ha, 10 days interval, PHI 14 days)

According to previous EFSA output (EFSA, 2020b), the worst-case long-term flupyradifurone soil plateau concentration [from critical authorised uses in North America (2×205 g/ha)] was estimated using the EU soil dissipation data. The following input parameters were used: DT_{50} 462 days, application of 2×205 g/ha, interval between applications 7 days, crop interception 70%, residue distribution over 20 cm soil; the method of the calculation: Double First Order in Parallel (DFOP). The plateau concentration in soil was calculated at 0.0416 mg/kg. This value was compared to the geometrical mean soil concentration of flupyradifurone in soil from the rotational crop residue trials (0.029 mg/kg, 20 cm soil). The available residue data from rotational crop field trials were scaled up by a factor of **1.4** to derive risk assessment values for DFA in rotational crops reflecting the rotational crop uptake of DFA following the use of flupyradifurone on primary crops in USA according to the critical use patterns under assessment.

In order to estimate an MRL proposal for crops that can be both treated as a primary crop and take up DFA residues from the soil, the HR value in the respective rotational crop/rotational crop group was summed with the MRL proposal derived for the primary crop belonging to the same crop group as respective rotational crop. Value was then rounded to the nearest upper MRL class to derive the final MRL proposal (European Commission, 2010). The approach on the calculation of the MRL proposals for DFA is in line with the previous EFSA assessment (EFSA, 2020b). The MRL proposals for DFA residues in crops that can be treated as primary crops and simultaneously rotated in soil containing potential residues of DFA are summarised in Table E1 of Appendix E.

1.2.3 | Magnitude of residues in processed commodities

Specific processing studies for the crops under assessment are not available and are not necessary because the total theoretical maximum daily intake (TMDI) for the individual crops under assessment is expected to be less than 10% of the ADI and/or significant residues of flupyradifurone (above 0.1 mg/kg) were not observed in primary crops. In the frame of the present MRL application, data on the processing of oilseeds were submitted. Based on limited data set [one trial instead of the number required by Regulation (EU) No 544/2011], tentative processing factors for sesame oil, sunflower meal and sunflower oil were calculated. Furthermore, the applicant assessed the distribution of residues in the peel and the pulp of mangoes in five decline residue trials. From these data, EFSA derived peeling factors at different time points.

1.2.4 | Proposed MRLs

The available data are considered sufficient to derive new MRL proposals for **flupyradifurone** in mangoes, papayas, asparagus, sesame seeds and sunflower seeds. For avocados, sugar beet roots and chicory roots, there is no need to modify the existing EU MRLs. The MRL proposal for the import tolerance requests corresponds to the value set in the countries of origin, except for sunflower seeds.

The available data are considered sufficient to derive new MRL proposals for **DFA** in avocados, mangoes, papayas and asparagus. For the crops that can be grown in rotation (sunflower seeds, sesame seeds, sugar beet roots and chicory roots), two MRL proposals were derived for risk managers to consider: an MRL proposal accounting for residues expected from the use as primary crop treatment and a combined MRL proposal, which reflects residues in the crop from the use on the primary crop treatment and from the potential soil uptake. No MRL (tolerance) is set for DFA in the countries of origin as a separated enforcement residue definition is not established.

To be noted that for sunflower seeds, EFSA recently proposed a higher MRL for DFA based on a SEU use (EFSA, 2023b) that has not yet been discussed at the Standing Committee on Plants, Animals, Food and Feed (PAFF Committee).

2 | RESIDUES IN LIVESTOCK

Sugar beet tops and by-products of sugar beet roots and sunflower seeds (the latter imported into the EU) can be fed to EU livestock. The EU livestock can be exposed to residues of flupyradifurone (mainly via primary crops) and to DFA residues (from residues in rotational crops but also from primary crops as metabolite of flupyradifurone).

The livestock exposures were calculated in the previous EFSA outputs (EFSA, 2020b, 2023b) separately for flupyradifurone and DFA considering the livestock intake of primary and rotational crops grown in the EU as well as from the import tolerances. Food crops imported to Europe can enter livestock feed chain (EFSA, 2015b). Input values according to the enforcement residue definitions of flupyradifurone and of DFA were used for the calculations. EFSA now updated the calculation with the residues from the new intended EU uses and from the authorised use on sunflowers in the USA. The exposure was calculated according to the OECD methodology using the Animal model 2017. In a previous assessment, higher DFA residues were detected in EU trials with sunflower seeds (EFSA, 2023b). These risk assessment values were used for calculations as representing a worsted case.

The input values are presented in Appendix D.1. The trigger value of 0.1 mg/kg DM is exceeded for all livestock species (Appendix B.2). Livestock dietary burdens remain at the same levels as in the last assessment for flupyradifurone and only slightly increase for a maximum of 0.02 mg/kg DM in a few livestock (dairy cattle, sheep and swine diets) for DFA (EFSA, 2023b); that implies that the contributions of the commodities under consideration to the livestock exposure is insignificant. Major contributing feed items to the exposure is given by the existing uses on kale and swede.

Since the uses assessed in the framework of this application do not have an impact on the livestock dietary burdens reported in a previous EFSA reasoned opinion (EFSA, 2023b), the carry-over of residues into food of animal commodities was not further investigated in the framework of the current application and the conclusions drawn in the previous assessment are applicable. A modification of the MRLs for the commodities of animal origin (existing and as proposed for modification) is not necessary.

3 | RESIDUES IN HONEY

Investigation of residues in honey is not required according to the data requirements applicable for the assessment of the submitted applications.

4 | CONSUMER RISK ASSESSMENT

EFSA performed a dietary risk assessment using revision 3.1 of the EFSA PRIMo (EFSA, 2019, 2018). This exposure assessment model contains food consumption data for different subgroups of the EU population and allows the acute and chronic exposure assessment to be performed in accordance with the internationally agreed methodology for pesticide residues (FAO, 2016).

The toxicological reference values for flupyradifurone used in the risk assessment (i.e. ADI and ARfD values) were derived in the framework of the EU pesticides peer review (European Commission, 2015). The toxicological reference values are also applicable to its metabolite DFA (EFSA, 2015a).

In line with the methodology applied in the previous assessments for flupyradifurone, EFSA performed two separate consumer exposure calculations in order to estimate separately the exposure resulting from primary treatment (including also products of animal origin) and the exposure resulting from residues expected to be taken up from crops which can grow in rotation with other crops. Input values were in accordance with the risk assessment residue definition in plant and livestock commodities (sum of flupyradifurone and the DFA, expressed as flupyradifurone). This approach was chosen to provide risk managers additional information to decide on risk management options as regards residues in rotational crops, e.g. whether MRLs should be established to cover residues in rotational crops or whether other restrictions would be appropriate to avoid residues in untreated crops.

Scenario 1: Exposure to residues resulting from treated primary crops and animal commodities.

In order to calculate chronic consumer exposure to residues of flupyradifurone and DFA, the median residue values expressed according to the residue for risk assessment (STMR-RA) as derived for the crops under consideration from the submitted supervised residue trials (Appendix B.1.2.1) were used as input values. For mangoes, residues in pulp were

considered for calculations. For the remaining commodities of plant and animal origin, the risk assessment values as reported in the previous EFSA assessments (EFSA, 2015a, 2016, 2020a, 2020b, 2021, 2023b) and by the JMPR (FAO, 2019) were available to refine the exposure calculation. For citrus and watermelons, input values correspond to the residues in the edible portion. The crops for which no safe uses have been reported in the EU pesticides peer review or in subsequent EFSA outputs were excluded from the exposure calculation, assuming there is no use on these crops.

The acute consumer exposure to residues of flupyradifurone and DFA was calculated only for the commodities under consideration using the highest residue values expressed according to the residue definition for risk assessment (HR-RA) as derived for the crops under consideration from the submitted supervised residue trials (Appendix B.1.2.1); for bulked products (e.g. oilseeds), the STMR-RA was considered. For mangoes, the residues in pulp were included for calculations.

Scenario 2: Exposure to residues from plant commodities that are grown as rotational crops (untreated).

The exposure assessment as calculated in the previous EFSA outputs (EFSA, 2020a, 2020b, 2021, 2023b) was updated by adding the estimated residues in sugar beet roots and chicory roots from the uptake from soil, when grown in rotation in soil containing plateau residue concentrations. Residues were expressed as flupyradifurone equivalents, using the molecular weight conversion factor (3). The acute exposure assessment was performed only with regard to the commodities under consideration.

An overview of input values for consumer exposure assessment is provided in Appendix D.2. The calculated exposures were then compared with the toxicological reference values as derived for flupyradifurone. To be noted that the risk assessment input values corresponding to the CXLs taken over in the EU legislation (cane fruits, avocados and hops) would overestimate consumer exposure to a certain extent because including also residues of the minor metabolite 6-CNA.

The estimated long-term dietary exposure in scenario 1 (consumer exposure due to primary crop treatment and residues in animal commodities) accounted for a maximum of 55% of the ADI (NL toddler diet); for scenario 2 (consumer exposure from the intake of DFA residues taken up by crops from the soil which was previously treated with flupyradifurone), accounted for up to 17% of the ADI for GEMS/Food G06 diet and 16% of the NL toddler diet (EFSA, 2021). The highest combined exposure (sum of exposure from scenario 1 and from scenario 2) accounts for a maximum of **71% of the ADI** for the Dutch toddler diet. The overall exposure to flupyradifurone and DFA is unlikely to pose a chronic consumer intake concern.

In the short-term dietary exposure according to scenario 1 and scenario 2, no exceedances of the ARfD were identified for the crops under consideration. The combined acute exposure, which was derived as the sum of individual crop exposures calculated under scenario 1 and scenario 2, for the annual crops under consideration accounted for a maximum of 0.8% of ARfD for sesame seeds.

There are no specific data for the acute consumption of sugar beet roots. However, its contribution to the overall dietary exposure is of minor relevance.

The results of the consumer exposure assessment are presented in more detail in Appendix B.4.

EFSA concluded that the long-term and short-term intake of residues of flupyradifurone and DFA resulting from the existing and the intended uses and from the import tolerance requested is unlikely to present a risk to consumer health.

The estimated short-term and long-term exposures for mangoes and papayas are affected by a non-standard uncertainty related to the lack of exhaustive information on the residue decline for the metabolite DFA which was judged to have an acceptable impact on the consumer risk assessment. A robust conclusion that residues are stable or decrease after 28 days from last foliar application when trees are treated according to the reported Brazilian GAP cannot be reached from the submitted data. However, EFSA is of the opinion that the data available can be used to estimate input values for the consumer risk assessment since, if higher residues occur at longer sampling points, they are not expected to be of a significant higher magnitude than those observed in the available five trials, based on the comparable residue levels observed between the trials reaching a plateau at 21 DALA and the trials not showing a plateau at 28 DALA. Furthermore, to avoid quality loss since easily perishable due to the ripening process, the fruits for export are likely to be harvested early, at commercial maturity (mature green stage) than at later more mature stages. Finally, the large margin of safety of the exposure calculations is noted for these two commodities (see Appendix B.3).

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

5 | CONCLUSION AND RECOMMENDATIONS

The data submitted in support of this MRL application were found to be sufficient to derive MRL proposals for **flupyradifurone** in mangoes, papayas, sesame seeds and sunflower seeds. For avocados, asparagus, sugar beet roots and chicory roots, an MRL amendment is not required.

The data submitted in support of this MRL application were found to be sufficient to derive MRL proposals for **DFA** in avocados, mangoes, papayas and asparagus. For sesame seeds, sunflower seeds, sugar beet roots and chicory roots, the expected soil uptake of DFA residues in rotational crops was identified to be significant, and thus, it may affect the MRL values for DFA. For these crops, in order to quantify the contribution of soil residues to the overall residue levels in the harvested commodities, two MRL proposals were derived: An MRL proposal accounting for residues expected only from primary crop treatment and a combined MRL proposal, which reflects residues in a crop from the primary crop treatment and from the soil uptake in rotational crops. A risk management consideration is required on whether to support the setting of MRLs on the basis of residue soil uptake or to propose implementation of risk mitigation measures to avoid residues in rotational crops.

EFSA performed two consumer exposure calculations in order to estimate separately the exposure from primary treated (including also products of animal origin) (scenario 1) and rotational crops (scenario 2). This approach was chosen to show the contribution of residues in rotational crops to the overall consumer exposure. The overall combined chronic consumer exposure (71% of the ADI for NL toddler diet) was estimated as the sum of scenario 1 and 2 and accounts for the worst-case scenario when risk mitigation measures for restricting residues in rotational crops are not in place in the EU. No acute consumer intake concerns were identified for the commodities under assessment.

Under these conditions, EFSA concluded that the proposed European uses and authorised US and Brazilian (import tolerance) uses of flupyradifurone on the crops under assessment will not result in an overall consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers' health.

The MRL recommendations are summarised in Appendix B.5.

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
CXL	Codex maximum residue limit
DALA	days after last application
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
DT ₉₀	period required for 90% dissipation (define method of estimation)
dw	dry weight
EC	emulsifiable concentrate
eq	residue expressed as a.s. equivalent
FAO	Food and Agriculture Organisation 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	mass spectrometry detector
MS	Member States
MS/MS	tandem mass spectrometry detector
MW	molecular weight
NEU	northern Europe
OECD	Organisation for Economic Co-operation and Development
PBI	plant back interval
PF	processing factor
PHI	preharvest interval
P _{ow}	partition coefficient between n-octanol and water
PRIMo	(EFSA) Pesticide Residues Intake Model
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
RA	risk assessment
RAC	raw agricultural commodity
RD	residue definition
RMS	rappporteur Member State
RPF	relative potency factor
SANCO	Directorate-General for Health and Consumers
SC	suspension concentrate
SEU	southern Europe
SG	water-soluble granule
SL	soluble concentrate
SP	water-soluble powder

STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
WHO	World Health Organization

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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

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APPENDIX A

Summary of intended and authorised GAPs triggering the amendment of existing EU MRLs

Crop and/or situation	NEU, SEU, MS or country	F or I ^a	Pests or group of pests controlled	Preparation		Application				Application rate per treatment				PHI (days)	Remarks
				Type ^b	Conc. a.s. (g/L)	Method kind	Range of growth stages & season ^c	Number Min-max	Interval between application (days) Min-max	g a.s./hL Min-max	Water (L/ha) Min-max	Rate Min-max	Unit		
Intended EU uses															
Sugar beets (incl. fodder beet)	NEU, SEU	F	<i>Agriotes</i> sp., <i>Atomaria linearis</i> , <i>Pegomya hyoscyami</i> , <i>Chaetocnema tibialis</i>	FS	480	Seed treatment	00	1	–	–	–	30	g a.s./ha	–	Unit size: 100,000 seeds; product loading: 0.04167 L/unit; slurry volume: 0.15–0.3 L/unit; sowing density: 1–1.5 units/ha; TGW: 23.6–31.2 g; seed loading: 0.4167 µL/seed
Sugar beets (incl. fodder beet)	NEU	F	Aphids	SL	200	Foliar spraying	10–19	1	–	16.6–33.3	150–300	50	g a.s./ha	–	
Chicory roots	NEU	F	Aphids	SL	200	Foliar spraying	10–19	1	–	16.6–33.3	150–300	50	g a.s./ha	–	
Uses authorised in countries outside the EU															
Mangoes	Brazil	F	Mediterranean fruit fly, scales, aphids	SL	200	Foliar spraying	–	2	7	15–66.6	300–1000	150–200	g a.s./ha	3	
Papayas	Brazil	F	Bean leafhopper	SL	200	Foliar spraying	–	2	7	15–66.6	300–1000	150–200	g a.s./ha	3	
Avocados	USA	F	Aphids, Whiteflies, Avocado thrips	SL	200	Foliar spraying	–	2	14	–	93.5–233.8	153–204	g a.s./ha	1	Maximum rate 0.409 kg a.s./ha/year
Asparagus	USA	F	Aphids	SL	200	Foliar spraying	Vegetative (fern stage)	2	30	–	28.1–93.5	102–204	g a.s./ha	–	Application to green parts of the crops after the harvest of the asparagus spears. Maximum rate 0.409 kg a.s./ha/year
Sunflowers	USA	F	Aphids Leafhoppers <i>Lygus</i> spp. Whiteflies	SL	200	Foliar spraying	–	2	10	–	28.1–93.5	102–204	g a.s./ha	14	Maximum rate 0.409 kg a.s./ha/year
Sesame	USA	F	Aphids <i>Lygus</i> spp. Whiteflies	SL	200	Foliar spraying	–	2	10	–	28.1–93.5	102–204	g a.s./ha	14	Maximum rate 0.409 kg a.s./ha/year

Abbreviations: a.s., active substance; FS, Flowable concentrate for seed treatment; GAP, Good Agricultural Practice; MRL, maximum residue level; MS, Member State; NEU, northern European Union; PHI, minimum pre-harvest interval; SEU, southern European Union; SL, Soluble concentrate; TGW, thousand grain weight.

^aOutdoor or field use (F), greenhouse application (G) or indoor application (I).

^bCropLife International Technical Monograph no 2, 7th Edition. Revised March 2017. Catalogue of pesticide formulation types and international coding system.

^cGrowth 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.

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	Apple	Foliar (a) 1 × 86 g/ha/metre canopy height (CH); BBCH 69 (b) 2 × 86 g/ha/m CH; BBCH 69	(a) 89 DAT (b) 14 DALA	Radiolabelled active substance: [furanone-4- ¹⁴ C], [pyridinylmethyl- ¹⁴ C] and flupyradifurone (EFSA, 2015a)	
	Tomato	Soil drench, 2 × 300 g/ha, BBCH 14–15, interval 14 days	56–73 DALA	Radiolabelled active substance: [furanone-4- ¹⁴ C], [pyridinylmethyl- ¹⁴ C] and [ethyl-1- ¹⁴ C] flupyradifurone (EFSA, 2015a)	
Root crops	Potato	In furrow (soil spraying), 1 × 626 g/ha, BBCH 03	97 DAT	Radiolabelled active substance: [furanone-4- ¹⁴ C] and [pyridinylmethyl- ¹⁴ C] flupyradifurone (EFSA, 2015a)	
		Seed treatment, 1 × 254 g/ha, BBCH 03	97 DAT		
Cereals/grass	Rice	Foliar, 175 g/ha, BBCH 13/15 + 240 g/ha, BBCH 87–89	29 DALA	Radiolabelled active substance: [furanone-4- ¹⁴ C] and [pyridinylmethyl- ¹⁴ C] flupyradifurone (EFSA, 2015a)	
		Soil (granules) at planting, 1 × 409–434 g/ha, BBCH 13/15	127 DAT	Radiolabelled active substance: [furanone-4- ¹⁴ C] and [pyridinylmethyl- ¹⁴ C] flupyradifurone (EFSA, 2015a)	
Pulses/oilseeds	Cotton	Foliar (a) 1 × 210 g/ha, BBCH 15–18 (b) 210 + 175 g/ha, BBCH 15–18	(a) 169 DAT (b) 14–15 DALA	Radiolabelled active substance: [furanone-4- ¹⁴ C] and [pyridinylmethyl- ¹⁴ C] flupyradifurone (EFSA, 2015a)	
Rotational crops (available studies)					
Crop groups	Crops	Application	PBI (DAT)	Comment/source	
Root/tuber crops	Turnips	Soil, 1 × 436 g/ha	29, 135, 296	Radiolabelled active substance: [furanone-4- ¹⁴ C] and [pyridinylmethyl- ¹⁴ C] flupyradifurone (EFSA, 2015a)	
Leafy crops	Swiss chard				
Cereal (small grain)	Wheat				
Processed commodities (hydrolysis study)					
Conditions	Stable?	Comment/source			
Pasteurisation (20 min, 90°C, pH 4)	Flupyradifurone: yes DFA: not investigated, but considered stable	A read-across approach by using TFA (EFSA, 2015a, 2020b)			
Baking, brewing and boiling (60 min, 100°C, pH 5)	Flupyradifurone: yes DFA: not investigated, but considered stable				
Sterilisation (20 min, 120°C, pH 6)	Flupyradifurone: yes DFA: not investigated, but considered stable				

Can a general residue definition be proposed for primary crops?	Yes	EFSA (2015)
Rotational crop and primary crop metabolism similar?	Yes	EFSA (2015)
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes	EFSA (2015)
Plant residue definition for monitoring (RD-Mo)	Two separate residue definitions (Reg (EU) 396/2005): 1) Flupyradifurone 2) Difluoroacetic acid (DFA)	
Plant residue definition for risk assessment (RD-RA)	Sum of flupyradifurone and DFA, expressed as flupyradifurone (EFSA, 2015a)	
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)	<p>Matrices with high water content (lettuce), high starch content (wheat, potato), high acid content (oranges), high oil content (rapeseed):</p> <ul style="list-style-type: none"> HPLC-MS/MS method 01330 with acetonitrile/water (4/1, v/v) with 2.2 mL/L formic acid extraction. LOQ 0.01 mg/kg (flupyradifurone); LOQ 0.007 mg/kg (DFA, expressed as DFA); <p>(EFSA, 2015a)</p> <ul style="list-style-type: none"> Extraction efficiency proven in high water content, high oil content and dry commodities (flupyradifurone) and in high water content but not in high oil content commodities (DFA). <p>(EFSA, 2023a)</p> <p>Hops:</p> <ul style="list-style-type: none"> HPLC-MS/MS method 01330 with acetonitrile/water (4/1, v/v) with 2.2 mL/L formic acid extraction. LOQ 0.05 mg/kg (flupyradifurone); LOQ 0.03 mg/kg (DFA, expressed as DFA). <p>(EFSA, 2015a)</p>	

DAT: days after treatment; PBI: plant-back interval; BBCH: growth stages of mono- and dicotyledonous plants; HPLC-MS/MS: high performance liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification.

B.1.1.2 | Storage stability of residues in plants

Plant products (available studies)	Category	Commodity	T (°C)	Stability period		Compounds covered	Comment/source
				Value	Unit		
	High water content	Spinaches, sugar canes, tomatoes	-18	52	Months	Flupyradifurone, DFA	EFSA (2020b)
	High oil content	Soybean seeds	-18	52	Months	Flupyradifurone, DFA	
	High protein content	Bean seeds	-18	52	Months	Flupyradifurone, DFA	
	Dry/high starch	Wheat grain	-18	52	Months	Flupyradifurone, DFA	
	High acid content	Oranges	-18	52	Months	Flupyradifurone, DFA	
	Others	Coffee beans	-18	52	Months	Flupyradifurone, DFA	

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
Sugar beet roots (seed treatment)	NEU	Mo (FPF): 8 × < 0.01 Mo (DFA): 7 × < 0.007; 0.009 RA: 7 × < 0.03; 0.037 ^e	Residue trials on sugar beets compliant with the intended EU uses N-EU and S-EU data sets merged since statistically similar (<i>U</i> -test, 5%) and individual MRLs fall into the same or neighbouring MRL class	Mo (FPF): 0.01* Mo (DFA): 0.015	Mo (FPF): 0.01 Mo (DFA): 0.014 RA: 0.052	Mo (FPF): 0.01 Mo (DFA): 0.007 RA: 0.03	n.r.
	SEU	Mo (FPF): 8 × < 0.01 Mo (DFA): 7 × < 0.007; 0.014 ^e RA: 7 × < 0.03; 0.052 ^e					
Sugar beet tops (seed treatment)	NEU	Mo (FPF): 7 × < 0.01; 0.016 ^e Mo (DFA): 7 × < 0.007; 0.02 ^e RA: 6 × < 0.03; 0.036 ^e ; 0.070 ^e	Residue trials on sugar beets compliant with the intended EU uses. Sugar beet tops analysed for residues to derive input values for livestock dietary burden N-EU and S-EU data sets merged since statistically similar (<i>U</i> -test, 5%)	n.r.	Mo (FPF): 0.016 Mo (DFA): 0.021 RA: 0.073	Mo (FPF): 0.01 Mo (DFA): 0.007 RA: 0.03	n.r.
	SEU	Mo (FPF): 8 × < 0.01 Mo (DFA): 5 × < 0.007; 0.012; 0.015 ^e ; 0.021 ^e RA: 5 × < 0.03; 0.045; 0.054 ^e ; 0.073 ^e					
Sugar beet roots, chicory roots (foliar treatment)	NEU	Mo (FPF): 8 × < 0.01 Mo (DFA): 7 × < 0.007; 0.013 RA: 7 × < 0.03; 0.048	Residue trials on sugar beets compliant with the intended NEU use. The submitted data are sufficient to derive MRL proposals for the NEU use Extrapolation to chicory roots possible	Mo (FPF): 0.01* Mo (DFA): 0.02	Mo (FPF): 0.01 Mo (DFA): 0.013 RA: 0.048	Mo (FPF): 0.01 Mo (DFA): 0.007 RA: 0.03	n.r.
Sugar beet tops (foliar treatment)	NEU	Mo (FPF): 8 × < 0.01 Mo (DFA): < 0.007; 0.007 ^e ; 0.008; 0.008 ^e ; 0.009 ^e ; 0.01 ^e ; 0.016 ^e ; 0.026 ^e RA: < 0.03; 0.03 ^e ; 0.034 ^e ; 0.035; 0.037 ^e ; 0.041 ^e ; 0.057 ^e ; 0.089 ^e	Residue trials on sugar beets compliant with the intended NEU use. Sugar beet tops analysed for residues to derive input values for livestock dietary burden	n.r.	Mo (FPF): 0.01 Mo (DFA): 0.026 RA: 0.089	Mo (FPF): 0.01 Mo (DFA): 0.009 RA: 0.036	n.r.
Mangoes	Brazil	Mo (FPF): 0.14; 0.20; 0.22; 0.23; 0.3 Mo (DFA): 0.05 ^e ; 0.058 ^e ; 0.062 ^e ; 0.073 ^e ; 0.082 ^e RA: 0.25; 0.26 ^e ; 0.28; 0.3 ^e ; 0.38 ^e <u>Pulp:</u> 0.21 ^e ; 0.25 ^e ; 0.28 ^e ; 0.31 ^e ; 0.35 ^e	Residue trials on mangoes compliant with GAP	Mo (FPF): 0.7 Mo (DFA): 0.2	Mo (FPF): 0.3 Mo (DFA): 0.082 RA: 0.38 RA-pulp: 0.35	Mo (FPF): 0.22 Mo (DFA): 0.062 RA: 0.28 RA-pulp: 0.28	n.r.
Papayas	Brazil	Mo (FPF): 0.02; 0.07; 0.1; 0.11; 0.2 Mo (DFA): 0.037 ^e ; 0.04 ^e ; 0.05 ^e ; 0.057 ^e ; 0.08 ^e RA: 0.16; 2 × 0.18 ^e ; 0.25; 0.25 ^e	Residue trials on papayas compliant with GAP	Mo (FPF): 0.4 Mo (DFA): 0.2	Mo (FPF): 0.2 Mo (DFA): 0.08 RA: 0.25	Mo (FPF): 0.1 Mo (DFA): 0.05 RA: 0.18	n.r.
Avocados	USA	Mo (FPF): 0.026; 0.19; 0.22; 0.24 Mo (DFA): 3 × < 0.017; 0.074 ^e RA: 0.076; 0.27; 0.29; 0.31 ^e	Residue trials on avocados compliant with GAP	Mo (FPF): 0.6 Mo (DFA): 0.15	Mo (FPF): 0.24 Mo (DFA): 0.074 RA: 0.31	Mo (FPF): 0.21 Mo (DFA): 0.017 RA: 0.28	n.r.

(Continues)

(Continued)

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
Asparagus	USA	Mo (FPF): 8 × < 0.01 Mo (DFA): < 0.017; 0.054; 0.071; 0.086; 0.088; 0.098; 2 × 0.24 RA: < 0.06; 0.17; 0.22; 0.27; 0.27; 0.30; 2 × 0.72	Residue trials on asparagus compliant with GAP	Mo (FPF): 0.01 ^f Mo (DFA): 0.5	Mo (FPF): 0.01 Mo (DFA): 0.24 RA: 0.72	Mo (FPF): 0.01 Mo (DFA): 0.087 RA: 0.27	n.r.
Sunflower seeds	USA	Mo (FPF): 0.014; 2 × 0.028; 0.040; 0.14; 0.17; 0.25; 0.44 Mo (DFA): 8 × < 0.017 RA: 0.064; 2 × 0.078; 0.090; 0.19; 0.22; 0.30; 0.49	Residue trials on sunflowers compliant with GAP	Mo (FPF): 0.8 Mo (DFA): 0.02 ^f	Mo (FPF): 0.44 Mo (DFA): 0.017 RA: 0.49	Mo (FPF): 0.09 Mo (DFA): 0.017 RA: 0.14	n.r.
Sesame seeds	USA	Mo (FPF): 0.10; 0.12; 0.38; 1.08 Mo (DFA): 0.032; 0.037; 0.045; 0.35 ^e RA: 0.23; 0.24; 1.18; 1.27 ^e	Residue trials on sesame compliant with GAP	Mo (FPF): 3 Mo (DFA): 0.8	Mo (FPF): 1.08 Mo (DFA): 0.35 RA: 1.27	Mo (FPF): 0.25 Mo (DFA): 0.041 RA: 0.71	n.r.

Abbreviations: GAP, Good Agricultural Practice; Mo, monitoring; MRL, maximum residue level; n.r., not relevant; RA, residues according to residue definitions for risk assessment.

^aNEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, EU: indoor EU trials or Country code: if non-EU trials.

^bHighest residue. The highest residue for risk assessment refers to the whole commodity and not to the edible portion.

^cSupervised trials median residue. The median residue for risk assessment refers to the whole commodity and not to the edible portion.

^dConversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.

^ePeak residue level detected from the decline residue trials submitted at interval after the intended/authorised PHI or after the first commercial harvest when a PHI is not specified.

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

B.1.2.2 | Residues in rotational crops

Residues in rotational and succeeding crops expected based on confined rotational crop study?	Yes	EFSA (2015a, 2020a)
Residues in rotational and succeeding crops expected based on field rotational crop study?	Yes	<p>Field rotational crop studies in NEU/SEU at 200 g/ha on bare soil (25-30 days PBI) or on lettuce as primary crop (61-145 and 266-329 days PBI) indicate residues of flupyradifurone in edible matrices at ≤ 0.01 mg/kg, except in lettuce head (one sample: 0.03 mg/kg) and in barley straw (two samples: 0.02 and 0.04 mg/kg). Metabolite DFA was present at significant levels, requiring setting of MRLs for this compound in rotational crops (EFSA, 2015a).</p> <p>Field rotational crop studies, performed at 300 g/ha on bare soil (21-30, 107-204 and 273-365 days PBI) or at 175-185 g/ha on bare soil (107-204 and 273-365 days PBI). Residues of flupyradifurone were $< \text{LOQ}$ of 0.01 mg/kg in all crops at all PBI, except in one sample of barley grain (0.01 mg/kg, 2nd rotation) and in barley straw (0.02 and 0.03 mg/kg 2nd rotation; 0.02 mg/kg 3rd rotation). Residues of DFA (expressed as DFA) were observed at significant levels and these data are in detail reported in the previous assessment by EFSA (EFSA, 2020a).</p>

B.1.2.3 | Processing factors

Processed commodity	Number of valid studies	Processing factor (PF)						Comment/source
		Individual values			Median PF			
		FPF	DFA	RA	FPF	DFA	RA	
Sesame, oil	1	0.13	0.17	0.12	0.13	0.17	0.12	Tentative ^a
Sunflower, meal	1	1.2	n.c. ^b	1.2	1.2	–	1.2	Netherlands (2023)
Sunflower, oil	1	0.04	n.c. ^b	0.18	0.04	–	0.18	
Mango, peeled (PHI 3 days)	5	0.07; 2 × 0.09; 0.14; 0.19	4 × n.c. ^b ; 0.90	0.24; 2 × 0.27; 0.33; 0.37	0.09	0.90	0.27	Netherlands (2023)
Mango, peeled (PHI 7 days)	5	2 × 0.27; 0.28; 0.40; 0.47	n.c. ^b ; 0.95; 1.02; 1.07; 1.86	0.44; 0.48; 0.53; 0.69; 0.71	0.28	1.05	0.53	
Mango, peeled (PHI 14 days)	5	0.34; 0.40; 0.43; 0.46; 0.65	0.34; 0.92; 0.93; 1.14; 1.40	0.58; 0.75; 0.76; 0.80; 0.85	0.43	0.93	0.76	
Mango, peeled (PHI 21 days)	5	0.50; 0.56; 0.71; 0.74; 0.83	0.83; 1.14; 1.18; 1.20; 1.40	0.86; 0.93; 0.99; 1.10; 1.30	0.71	1.18	0.99	
Mango, peeled (PHI 28 days)	5	< 0.01 ; 0.33; 0.50; 0.56; 0.86	0.86; 1.08; 1.20; 1.26; 1.33	0.84; 0.93; 1.10; 1.18; 1.30	0.42	1.20	1.10	

Abbreviations: DFA, difluoroacetic acid; FPF, flupyradifurone; n.c., not calculated; PF, processing factor; PHI, preharvest interval; RA, residues according to the residue definition for risk assessment.

^aA tentative PF is derived based on a limited dataset.

^bDFA was below the LOQ in raw and processed commodities.

B.2 | RESIDUES IN LIVESTOCK

Dietary burden for EU livestock according to OECD (2013) considering primary and rotational crops grown in the EU as well as imported feed items and their by-products.

Flupyradifurone

Dietary burden calculated for the intake of flupyradifurone residues.

Relevant groups (subgroups)	Dietary burden expressed in				Most critical subgroup ^a	Most critical commodity ^b	Trigger (0.1 mg/kg DM) exceeded (Y/N) max burden	DB calculated in previous assessment (mg/kg DM) (EFSA, 2023b)
	mg/kg bw per day		mg/kg DM					
	Median	Maximum	Median	Maximum				
Cattle (all)	0.073	0.180	2.04	5.87	Dairy cattle	Kale leaves	Y	5.87
Cattle (dairy only)	0.073	0.180	1.89	4.68	Dairy cattle	Kale leaves	Y	4.68
Sheep (all)	0.052	0.221	1.49	5.20	Lamb	Swede roots	Y	5.20
Sheep (ewe only)	0.050	0.173	1.49	5.20	Ram/Ewe	Swede roots	Y	5.20
Swine (all)	0.031	0.100	1.33	4.35	Swine (breeding)	Kale leaves	Y	4.35
Poultry (all)	0.037	0.095	0.52	1.38	Poultry layer	Swede roots	Y	1.38
Poultry (layer only)	0.035	0.095	0.51	1.38	Poultry layer	Swede roots	Y	1.38

Abbreviations: bw, body weight; DB, dietary burden; DM, dry matter.

^aWhen one group of livestock includes several subgroups (e.g. poultry 'all' including broiler, layer and turkey), the result of the most critical subgroup is identified from the maximum dietary burdens expressed as 'mg/kg bw per day'.

^bThe most critical commodity is the major contributor identified from the maximum dietary burden expressed as 'mg/kg bw per day'.

Difluoroacetic acid (DFA), expressed as DFA

Dietary burden calculated for the intake of DFA residues expected in primary and in rotational crops.

Relevant groups (subgroups)	Dietary burden expressed in				Most critical subgroup ^a	Most critical commodity ^b	Trigger (0.1 mg/kg DM) exceeded (Y/N) max burden	DB calculated in previous assessment (mg/kg DM) (EFSA, 2023b)
	mg/kg bw per day		mg/kg DM					
	Median	Maximum	Median	Maximum				
Cattle (all)	0.043	0.066	1.17	2.13	Dairy cattle	Kale leaves	Y	2.13
Cattle (dairy only)	0.043	0.066	1.11	1.71	Dairy cattle	Kale leaves	Y	1.63
Sheep (all)	0.043	0.071	1.02	1.68	Lamb	Kale leaves	Y	1.66
Sheep (ewe only)	0.033	0.056	1.00	1.68	Ram/Ewe	Swede roots	Y	1.66
Swine (all)	0.022	0.044	0.90	1.74	Swine (finishing)	Swede roots	Y	1.73
Poultry (all)	0.036	0.050	0.53	0.73	Poultry layer	Swede roots	Y	0.73
Poultry (layer only)	0.036	0.050	0.53	0.73	Poultry layer	Swede roots	Y	0.73

Abbreviations: bw, body weight; DB, dietary burden; DM, dry matter.

^aWhen one group of livestock includes several subgroups (e.g. poultry 'all' including broiler, layer and turkey), the result of the most critical subgroup is identified from the maximum dietary burdens expressed as 'mg/kg bw per day'.

^bThe most critical commodity is the major contributor identified from the maximum dietary burden expressed as 'mg/kg bw per day'.

B.3 | RESIDUES IN HONEY

Investigation of residues in honey is not required according to the data requirements applicable for the assessment of the submitted applications.

B.4 | CONSUMER RISK ASSESSMENT

ARfD

Highest IESTI, according to EFSA PRIMo

0.15 mg/kg bw (European Commission, 2015)

Scenario 1 Exposure from residues in primary crops under assessment:

Mangoes: 18.3% of ARfD (critical children diet)
 Avocados: 10.4% of ARfD (critical children diet)
 Asparagus: 9.2% of ARfD (critical children diet)
 Papayas: 7.1% of ARfD (critical children diet)
 Sesame seeds: 0.7% of ARfD (critical children diet)
 Sunflower seeds: 0.3% of ARfD (critical children diet)
 Chicory roots: 0.01% of ARfD (critical adult diet)
 Sugar beet roots: for children and adults no acute risk assessment possible due to lacking consumption data.

Scenario 2 Exposure from residues in rotational crops (residues taken up via soil, without primary crop treatment):

Sunflower seeds: 0.2% of ARfD (critical children diet)
 Sesame seeds: 0.1% of ARfD (critical children diet)
 Chicory roots: 0.1% of ARfD (critical adult diet)
 Sugar beet roots: for children and adults no acute risk assessment possible due to lacking consumption data.

Combined exposure (scenario 1 + scenario 2) (for annual crops under consideration, taking into account the primary crop treatment and residues taken up via soil)

Sesame seeds: 0.8% of ARfD (critical children diet)
 Sunflower seeds: 0.5% of ARfD (critical children diet)
 Chicory roots: 0.1% of ARfD (critical adult diet)
 Sugar beet roots: for children and adults no acute risk assessment possible due to lacking consumption data.

Assumptions made for the calculations

Scenario 1) The calculation is based on the highest residue (HR) levels according to the residue definition for risk assessment in commodities under assessment from primary treatment, except for bulk commodities (sunflower and sesame seeds) for which the median residue was used. For mangoes HR reflects residue in the edible portion (pulp).**Scenario 2)** The calculation is based on DFA and flupyradifurone residues (HR or STMR) taken up via roots by annual oilseed crops under assessment grown in soil containing residues at the soil plateau concentrations. The **combined exposure** represents the sum of exposure from the intake of annual crop treated as primary crop (scenario 1) and the exposure to residues in the respective crop, if grown as rotational crop (scenario 2).

All calculations were performed with PRIMo rev. 3.1.

ADI

Highest IEDI, according to EFSA PRIMo

0.064 mg/kg bw per day (European Commission, 2015)

Scenario 1) Exposure from residues in treated primary plant commodities and in commodities of animal origin:

Assumptions made for the calculations

<p>55% of the ADI (NL toddler diet) Maximum contribution of plant commodities under consideration is: Mangoes: 0.11% of ADI (IE adult) Avocados: 0.08% of ADI (IE adult) Asparagus: 0.1% of ADI (IE adult) Papayas: < 0.01% of ADI (SE general) Sesame seeds: 0.05% of ADI (GEMS/Food G06) Sunflower seeds: 0.15% of ADI (RO general) Chicory roots: 0.02% of ADI (GEMS/Food G11) Sugar beet roots: 0.41% of ADI (NL child)</p> <p>Scenario 2) Exposure from residues in rotational crops (no treatment) (EFSA, 2021): 17% ADI (GEMS/Food G06) 16% ADI (NL toddler diet)</p> <p>Combined chronic exposure (scenario 1 + scenario 2): 71% ADI (NL toddler diet)</p>
<p>Scenario 1) The calculation is based on the median residue levels (STMR) according to the residue definition for risk assessment expected from primary treatment for the crops under assessment. For mangoes, residues in the pulp were considered. For the remaining commodities of plant and animal origin, the STMR as derived in the previous EFSA assessments (EFSA, 2015a, 2016, 2020a,b, 2021, 2023a) and by the JMPR (FAO, 2019) were used. For citrus and watermelons, input values correspond to the residues in the edible portion. The crops for which no safe uses have been reported in the EU pesticides peer review or in subsequent EFSA outputs were excluded from the exposure calculation.</p> <p>Scenario 2) The calculation is based on DFA and flupyradifurone residues (STMR) taken up via roots by annual crops grown in soil containing residues at the soil plateau concentrations. The perennial crops and animal commodities were excluded from the exposure calculation (EFSA, 2020a, 2021).</p> <p>Combined long-term exposure was determined for the diet for which the highest total exposure was estimated (i.e., NL toddler diet in this case) from residue intake from primary crops, animal commodities (scenario 1) and from residues in rotational crop (scenario 2). All calculations were performed with PRIMo rev. 3.1.</p>

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; STMR: supervised trials median residue; JMPR: Joint FAO/WHO Meeting on Pesticide Residues.

B.5 | RECOMMENDED MRLS

Code ^a	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Flupyradifurone				
0163010	Avocados	0.6	No change	The submitted data are sufficient to derive an import tolerance proposal of 0.6 mg/kg for flupyradifurone. Same MRL (tolerance) value of 0.6 mg/kg is set in the country of origin (USA) A modification of the existing MRL, which corresponds to the Codex MRL (CXL) taken over in the EU MRL Regulation, is not required. Risk for consumers unlikely
0163030	Mangoes	0.01*	0.7	The submitted data are sufficient to derive an import tolerance. Same MRL value of 0.7 mg/kg is set for flupyradifurone in the country of origin (Brazil). Risk for consumers unlikely
0163040	Papayas	0.01*	0.4	The submitted data are sufficient to derive an import tolerance. Same MRL value of 0.4 mg/kg is set for flupyradifurone in the country of origin (Brazil). Risk for consumers unlikely
0270010	Asparagus	0.01*	No change	The submitted data are sufficient to derive an import tolerance proposal for flupyradifurone. A modification of the existing MRL is not required. According to the authorised US use assessed, flupyradifurone residues are not anticipated above the LOQ of 0.01 mg/kg. An MRL (tolerance) of 0.01 mg/kg is set in the country of origin. Risk for consumers unlikely
0401040	Sesame seeds	0.01*	3	The submitted data are sufficient to derive an import tolerance. Same MRL (tolerance) value of 3 mg/kg is set in the country of origin (USA). Risk for consumers unlikely A Codex MRL proposal for flupyradifurone of 3 mg/kg, based on the same data set, is under assessment at EU level
0401050	Sunflower seeds	0.01*	0.7 or 0.8 Further risk management consideration required	The submitted data are sufficient to derive an import tolerance of 0.8 mg/kg (highest residue of flupyradifurone observed among the eight trials available is 0.44 mg/kg). The MRL (tolerance) for residues established in the USA for flupyradifurone is lower (0.7 mg/kg) as additional trials were taken into consideration. EFSA disregarded those trials, being not independent according to the EU guidelines. Risk for consumers is unlikely In a recent MRL assessment, EFSA ^b proposed an MRL of 0.07 mg/kg based on a SEU use. A Codex MRL proposal for flupyradifurone of 0.8 mg/kg, based on the same data set submitted in the present MRL application, is under assessment at EU level
0900010	Sugar beet roots	0.01*	No change	The submitted data are sufficient to support the intended NEU foliar and seed uses in EU. A modification of the existing MRL is not required. Flupyradifurone residues are not anticipated above the LOQ of 0.01 mg/kg. Risk for consumers unlikely
0900030	Chicory roots	0.01*	No change	The submitted data are sufficient to support the intended NEU foliar use by extrapolation from data in sugar beet roots. A modification of the existing MRL is not required. Flupyradifurone residues are not anticipated above the LOQ of 0.01 mg/kg. Risk for consumers unlikely
Enforcement residue definition: Difluoroacetic acid (DFA)				
0163010	Avocados	0.02*	0.15	The submitted data are sufficient to derive an import tolerance proposal for DFA (US use). No MRL (tolerance) is set for DFA in the country of origin as a separated enforcement residue definition is not established. Risk for consumers unlikely
0163030	Mangoes	0.02*	0.2	The submitted data are sufficient to derive an import tolerance proposal for DFA (Brazilian use). No MRL is set for DFA in the country of origin as the residue definition for enforcement is restricted to parent compound. Risk for consumers unlikely
0163040	Papayas	0.02*	0.2	The submitted data are sufficient to derive an import tolerance proposal for DFA (Brazilian use). No MRL is set for DFA in the country of origin as a separated enforcement residue definition is not established. Risk for consumers unlikely
0270010	Asparagus	0.2	0.5	The submitted data are sufficient to derive an import tolerance proposal for DFA (US use). No MRL (tolerance) is set for DFA in the country of origin as a separated enforcement residue definition is not established. Risk for consumers unlikely

Code ^a	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
0401040	Sesame seeds	0.05	0.8 or 0.9 Further risk management considerations required	Direct treatment of the crop with flupyradifurone (primary crop treatment) would require an MRL of 0.8 mg/kg. The MRL proposal derived based on the US use reflecting direct treatment combined with residues expected to be taken up via roots would require an MRL of 0.9 mg/kg. Risk for consumers unlikely in both scenarios
0401050	Sunflower seeds	0.05	Previous MRL proposal (i.e. 0.09 or 0.15 mg/kg) covers the US use under assessment	Direct treatment of the crop with flupyradifurone (primary crop treatment) would require an MRL at the LOQ of 0.02 mg/kg. The MRL proposal derived based on the US use reflecting direct treatment combined with residues expected to be taken up via roots would require an MRL of 0.05 mg/kg In a recent MRL assessment EFSA ^b proposed higher MRL for DFA at 0.09 and 0.15 mg/kg, respectively, for both scenarios based on an EU use, that cover the present US use
0900010	Sugar beet roots	0.02*	0.02 or 0.09 Further risk management considerations required	Direct treatment of the crop with flupyradifurone (primary crop treatment) would require an MRL of 0.02 mg/kg. The MRL proposal for EU uses reflecting direct treatment combined with residues expected to be taken up via roots would require an MRL of 0.09 mg/kg. Risk for consumers unlikely in both scenarios
0900030	Chicory roots	0.02*	0.02 or 0.09 Further risk management considerations required	Direct treatment of the crop with flupyradifurone (primary crop treatment) would require an MRL of 0.02 mg/kg. The MRL proposal for EU uses reflecting direct treatment combined with residues expected to be taken up via roots would require an MRL of 0.09 mg/kg. Risk for consumers unlikely in both scenarios

Abbreviations: GAP, Good Agricultural Practice; MRL, maximum residue level; NEU, northern Europe; SEU, southern Europe.

^aCommodity code number according to Annex I of Regulation (EC) No 396/2005.

^bReasoned Opinion on the modification of the existing maximum residue levels and setting of import tolerances for flupyradifurone and DFA in various crops and animal commodities. *EFSA Journal* 2023;21(7):8081, 104 pp. <https://doi.org/10.2903/j.efsa.2023.8081>.

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

APPENDIX C

Pesticide Residue Intake Model (PRIMo)

- Post_TR_EFSA_Q_2022_00370_Flupyradifurone_DFA_primary crops_PRIMo_rev.3.1



Flupyradifurone			
LOQs (mg/kg) range from:	0.01	to:	6.0
Toxicological reference values			
ADI (mg/kg bw/day):	0.064	ARID (mg/kg bw):	0.15
Source of ADI:	EC	Source of ARID:	EC
Year of evaluation:	2015	Year of evaluation:	2015

Input values

Details - chronic risk assessment

Supplementary results - chronic risk assessment

Details - acute risk assessment/children

Details - acute risk assessment/adults

Chronic risk assessment: JMPR methodology (IEDI/TMDI)											
No of diets exceeding the ADI : ---											Exposure resulting from
Calculated exposure (% of ADI)	MS Diet	Exposure (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	MRLs set at the LOQ (in % of ADI)		
									commodities not under assessment (in % of ADI)	commodities not under assessment (in % of ADI)	
55%	NL toddler	35.16	32%	Milk: Cattle	5%	Apples	4%	Wheat	0.1%	55%	
32%	DE child	20.26	10%	Milk: Cattle	5%	Apples	4%	Wheat	0.1%	32%	
31%	UK infant	19.63	21%	Milk: Cattle	3%	Wheat	2%	Bovine: Muscle/meat	0.0%	31%	
29%	NL child	18.30	13%	Milk: Cattle	4%	Wheat	3%	Apples	0.1%	29%	
27%	FR toddler 2-3 yr	17.41	16%	Milk: Cattle	3%	Wheat	2%	Bovine: Muscle/meat	0.0%	27%	
27%	FR child 3-15 yr	17.14	12%	Milk: Cattle	5%	Wheat	3%	Bovine: Muscle/meat	0.0%	27%	
24%	DK child	15.40	7%	Milk: Cattle	6%	Rye	4%	Wheat	0.0%	24%	
23%	SE general	14.55	8%	Bovine: Muscle/meat	7%	Milk: Cattle	3%	Wheat	0.1%	23%	
22%	UK toddler	14.35	11%	Milk: Cattle	4%	Wheat	2%	Bovine: Muscle/meat	0.0%	22%	
20%	ES child	12.71	7%	Milk: Cattle	5%	Wheat	2%	Bovine: Muscle/meat	0.0%	20%	
19%	GEMS/Food G07	12.12	4%	Wheat	3%	Milk: Cattle	2%	Bovine: Muscle/meat	0.1%	19%	
18%	GEMS/Food G15	11.71	5%	Wheat	4%	Milk: Cattle	1.0%	Barley	0.1%	18%	
18%	GEMS/Food G08	11.59	4%	Wheat	3%	Milk: Cattle	1%	Barley	0.1%	18%	
18%	RO general	11.46	6%	Milk: Cattle	5%	Wheat	2%	Wine grapes	0.0%	18%	
18%	GEMS/Food G10	11.41	4%	Wheat	3%	Milk: Cattle	2%	Bovine: Muscle/meat	0.1%	18%	
18%	GEMS/Food G11	11.34	4%	Milk: Cattle	4%	Wheat	1%	Bovine: Muscle/meat	0.1%	18%	
17%	GEMS/Food G06	10.90	7%	Wheat	1%	Milk: Cattle	1%	Table grapes	0.1%	17%	
16%	DE general	10.34	7%	Milk: Cattle	2%	Wheat	1%	Apples	0.0%	16%	
16%	DE women 14-50 yr	10.32	7%	Milk: Cattle	2%	Wheat	1%	Apples	0.0%	16%	
15%	IE adult	9.62	2%	Wheat	2%	Milk: Cattle	1%	Wine grapes	0.1%	15%	
14%	FR infant	8.89	9%	Milk: Cattle	0.8%	Wheat	0.7%	Apples	0.0%	14%	
13%	NL general	8.40	5%	Milk: Cattle	2%	Wheat	1%	Bovine: Muscle/meat	0.0%	13%	
12%	ES adult	7.65	3%	Milk: Cattle	2%	Wheat	1%	Bovine: Muscle/meat	0.0%	12%	
12%	FR adult	7.39	2%	Milk: Cattle	2%	Wheat	2%	Wine grapes	0.0%	11%	
11%	IT toddler	6.72	7%	Wheat	0.5%	Lettuces	0.4%	Apples	0.0%	10%	
10%	PT general	6.64	4%	Wheat	2%	Wine grapes	0.5%	Potatoes	0.0%	10%	
9%	DK adult	5.62	3%	Milk: Cattle	1%	Wheat	0.9%	Bovine: Muscle/meat	0.0%	9%	
8%	IT adult	5.24	4%	Wheat	0.7%	Lettuces	0.4%	Other herbs	0.0%	8%	
8%	UK adult	4.89	2%	Wheat	2%	Milk: Cattle	1%	Bovine: Muscle/meat	0.0%	8%	
7%	LT adult	4.71	2%	Milk: Cattle	1%	Rye	1%	Wheat	0.0%	7%	
7%	UK vegetarian	4.61	2%	Wheat	2%	Milk: Cattle	0.8%	Wine grapes	0.0%	7%	
6%	FI 3 yr	3.76	1%	Wheat	0.7%	Oat	0.7%	Rye	0.0%	6%	
5%	FI adult	3.30	2%	Coffee beans	0.7%	Rye	0.3%	Wheat	0.0%	5%	
5%	FI 6 yr	3.03	1.0%	Wheat	0.6%	Rye	0.4%	Oat	0.0%	5%	
4%	IE child	2.55	2%	Milk: Cattle	1%	Wheat	0.1%	Apples	0.0%	4%	
3%	PL general	1.84	0.9%	Apples	0.3%	Potatoes	0.3%	Table grapes	0.0%	3%	

Conclusion:
 The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
 The long-term intake of residues of Flupyradifurone is unlikely to present a public health concern.
 DISCLAIMER: Dietary data from the UK were included in PRIMo when the UK was a member of the European Union.

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. **DISCLAIMER:** Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.
 The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

Unprocessed commodities	Results for children				Results for adults			
	No. of commodities for which ARfD/ADI is exceeded (IESTI):				---			
	IESTI				IESTI			
	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
95%	Table grapes	3 / 1.95	142	44%	Table grapes	3 / 1.95	66	
81%	Lettuces	6 / 3.2	122	40%	Chards/beet leaves	6 / 3.2	60	
78%	Oranges	3 / 0.88	117	37%	Chinese cabbages/pe-tsai	4 / 2.2	56	
70%	Peaches	1.5 / 1.1	105	32%	Aubergines/egg plants	1 / 1.8	49	
65%	Sweet peppers/bell peppers	0.9 / 1.65	98	31%	Wine grapes	3 / 1.95	46	
65%	Kales	4 / 2.2	97	28%	Kales	4 / 2.2	42	
64%	Pears	0.6 / 0.69	96	26%	Lettuces	6 / 3.2	39	
50%	Apples	0.6 / 0.69	74	24%	Blackberries	6 / 4.3	35	
48%	Spinaches	6 / 3.2	72	18%	Oranges	3 / 0.88	27	
47%	Chinese cabbages/pe-tsai	4 / 2.2	71	18%	Sweet peppers/bell peppers	0.9 / 1.65	27	
46%	Grapefruits	3 / 0.88	69	16%	Blueberries	4 / 2.59	24	
33%	Chards/beet leaves	6 / 3.2	50	15%	Swedes/rutabagas	0.9 / 0.68	23	
32%	Cauliflowers	0.6 / 0.82	48	15%	Raspberries (red and yellow)	6 / 4.3	23	
31%	Blackberries	6 / 4.3	46	15%	Parsley	40 / 18.2	22	
30%	Aubergines/egg plants	1 / 1.8	45	14%	Pears	0.6 / 0.69	21	
Expand/collapse list								
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)								

Processed commodities	Results for children				Results for adults			
	No of processed commodities for which ARfD/ADI is exceeded (IESTI):				---			
	IESTI				IESTI			
	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
66%	Chards/beet leaves / boiled	6 / 3.2	100	27%	Chards/beet leaves / boiled	6 / 3.2	40	
43%	Broccoli / boiled	0.6 / 0.82	65	23%	Cauliflowers / boiled	0.6 / 0.82	34	
40%	Kales / boiled	4 / 2.2	61	18%	Spinaches / frozen; boiled	6 / 3.2	26	
38%	Cauliflowers / boiled	0.6 / 0.82	57	18%	Beetroots / boiled	0.9 / 0.68	26	
30%	Spinaches / frozen; boiled	6 / 3.2	45	13%	Broccoli / boiled	0.6 / 0.82	20	
23%	Turnips / boiled	0.9 / 0.68	34	12%	Wine grapes / wine	3 / 1.95	18	
23%	Parsnips / boiled	0.9 / 0.68	34	10%	Courgettes / boiled	0.6 / 0.66	15	
20%	Beetroots / boiled	0.9 / 0.68	30	10%	Parsnips / boiled	0.9 / 0.68	14	
19%	Peaches / canned	1.5 / 1.1	29	9%	Purslanes / boiled	6 / 3.2	13	
18%	Wine grapes / juice	3 / 0.62	27	9%	Turnips / boiled	0.9 / 0.68	13	
16%	Courgettes / boiled	0.6 / 0.66	23	9%	Wine grapes / juice	3 / 0.62	13	
12%	Oranges / juice	3 / 0.34	18	8%	Celeriacs / boiled	0.9 / 0.68	12	
12%	Salsifies / boiled	0.9 / 0.68	18	7%	Table grapes / raisins	3 / 9.17	11	
12%	Jerusalem artichokes / boiled	0.9 / 0.68	17	6%	Apples / juice	0.6 / 0.28	9.3	
11%	Raspberries / juice	6 / 1.4	16	6%	Peaches / canned	1.5 / 1.1	9.0	
Expand/collapse list								

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

- Post_TR_EFSA_Q_2022_00370_Flupyradifurone_DFA_rotational crops_PRIMo_rev.3.1



Flupyradifurone			
LOQs (mg/kg) range from:	0.01	to:	0.05
Toxicological reference values			
ADI (mg/kg bw/day):	0.064	ARID (mg/kg bw):	0.15
Source of ADI:	EC	Source of ARID:	EC
Year of evaluation:	2015	Year of evaluation:	2015

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	Exposure (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)
TMDI/NEDI/IEDI calculation (based on average food consumption)	GEMS/Food G06	11.05	5%	Wheat	3%	Tomatoes	1%	Watermelons	17%
	NL toddler	10.34	5%	Maize/corn	3%	Wheat	2%	Potatoes	16%
	DK child	7.14	4%	Rye	3%	Wheat	2%	Cucumbers	11%
	IE adult	7.06	2%	Wheat	1%	Peas	1%	Sweet potatoes	11%
	RO general	6.97	3%	Wheat	2%	Tomatoes	1%	Potatoes	11%
	UK toddler	6.81	4%	Beans	3%	Wheat	1%	Potatoes	11%
	GEMS/Food G15	6.69	3%	Wheat	1%	Potatoes	1%	Tomatoes	10%
	GEMS/Food G10	6.57	3%	Wheat	1%	Tomatoes	1%	Potatoes	10%
	FR child 3-15 yr	6.49	3%	Wheat	0.9%	Lentils	0.9%	Beans	10%
	GEMS/Food G08	6.16	3%	Wheat	1%	Potatoes	1%	Tomatoes	10%
	IT toddler	5.89	4%	Wheat	1%	Tomatoes	1%	Other cereals	9%
	UK infant	5.72	2%	Beans	2%	Wheat	1%	Potatoes	9%
	PT general	5.72	3%	Wheat	2%	Potatoes	0.9%	Tomatoes	9%
	GEMS/Food G07	5.65	3%	Wheat	1%	Potatoes	1%	Tomatoes	9%
	ES child	5.63	3%	Wheat	1%	Lentils	1.0%	Tomatoes	9%
	NL child	5.52	3%	Wheat	1%	Sugar beet roots	1%	Potatoes	9%
	GEMS/Food G11	5.32	2%	Wheat	1%	Potatoes	0.9%	Tomatoes	8%
	DE child	5.26	3%	Wheat	1.0%	Tomatoes	0.9%	Potatoes	8%
	FR toddler 2-3 yr	4.85	2%	Wheat	1%	Beans (with pods)	0.7%	Potatoes	8%
	SE general	4.78	2%	Wheat	1%	Potatoes	0.7%	Tomatoes	7%
	FI 3 yr	4.39	2%	Potatoes	1.0%	Cucumbers	0.8%	Wheat	7%
	IT adult	4.17	3%	Wheat	1%	Tomatoes	0.5%	Other cereals	7%
	UK vegetarian	3.82	2%	Beans	1%	Wheat	0.6%	Tomatoes	6%
	FI 6 yr	3.77	1%	Potatoes	0.7%	Cucumbers	0.7%	Wheat	6%
	ES adult	3.60	2%	Wheat	0.8%	Tomatoes	0.5%	Lentils	6%
	NL general	3.38	1%	Wheat	0.9%	Potatoes	0.5%	Sugar beet roots	5%
	DE women 14-50 yr	3.27	1%	Wheat	0.8%	Sugar beet roots	0.7%	Tomatoes	5%
	DE general	3.24	1%	Wheat	0.7%	Sugar beet roots	0.6%	Tomatoes	5%
	FR adult	3.09	1%	Wheat	0.6%	Beans	0.4%	Tomatoes	5%
	LT adult	2.81	1%	Potatoes	0.7%	Rye	0.7%	Wheat	4%
	UK adult	2.74	1%	Wheat	1%	Beans	0.5%	Potatoes	4%
	FR infant	2.57	0.7%	Beans (with pods)	0.7%	Potatoes	0.5%	Wheat	4%
DK adult	2.01	0.8%	Wheat	0.5%	Tomatoes	0.5%	Potatoes	3%	
PL general	1.98	1%	Potatoes	0.9%	Tomatoes	0.2%	Head cabbages	3%	
FI adult	1.83	0.5%	Tomatoes	0.5%	Rye	0.4%	Potatoes	3%	
IE child	1.03	0.8%	Wheat	0.2%	Potatoes	0.2%	Rice	2%	
Conclusion: The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI. The long-term intake of residues of Flupyradifurone is unlikely to present a public health concern. DISCLAIMER: Dietary data from the UK were included in PRIMo when the UK was a member of the European Union.									

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. **DISCLAIMER:** Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.
 The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

Unprocessed commodities	Results for children				Results for adults			
	No. of commodities for which ARfD/ADI is exceeded (IESTI):				No. of commodities for which ARfD/ADI is exceeded (IESTI):			
	---				---			
	IESTI				IESTI			
	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
	86%	Melons	0 / 0.85	129	23%	Watermelons	0 / 0.85	35
	69%	Watermelons	0 / 0.85	104	22%	Melons	0 / 0.85	33
	55%	Potatoes	0 / 0.54	83	16%	Cucumbers	0 / 0.85	24
	39%	Beans	0 / 3.19	58	15%	Aubergines/egg plants	0 / 0.85	23
	37%	Cucumbers	0 / 0.85	56	14%	Beans	0 / 3.19	21
34%	Sweet peppers/bell peppers	0 / 0.85	51	13%	Courgettes	0 / 0.85	20	
33%	Tomatoes	0 / 0.85	49	13%	Lentils	0 / 3.19	20	
26%	Courgettes	0 / 0.85	40	12%	Beans (with pods)	0 / 2.27	18	
18%	Leeks	0 / 0.47	28	11%	Head cabbages	0 / 0.4	17	
17%	Beans (with pods)	0 / 2.27	26	11%	Potatoes	0 / 0.54	16	
15%	Cauliflowers	0 / 0.4	23	10%	Yams	0 / 0.54	15	
15%	Pumpkins	0 / 0.85	23	9%	Sweet peppers/bell peppers	0 / 0.85	14	
14%	Lentils	0 / 3.19	21	9%	Tomatoes	0 / 0.85	13	
14%	Aubergines/egg plants	0 / 0.85	21	8%	Pumpkins	0 / 0.85	12	
14%	Peas	0 / 3.19	21	8%	Peas (without pods)	0 / 2.27	12	
Expand/collapse list								
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)								

Processed commodities	Results for children				Results for adults			
	No of processed commodities for which ARfD/ADI is exceeded (IESTI):				No of processed commodities for which ARfD/ADI is exceeded (IESTI):			
	---				---			
	IESTI				IESTI			
	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
	50%	Pumpkins / boiled	0 / 0.85	75	31%	Pumpkins / boiled	0 / 0.85	47
	34%	Potatoes / fried	0 / 0.54	50	15%	Beans / canned	0 / 3.19	23
	21%	Broccoli / boiled	0 / 0.4	32	13%	Courgettes / boiled	0 / 0.85	19
	20%	Courgettes / boiled	0 / 0.85	30	11%	Cauliflowers / boiled	0 / 0.4	17
	19%	Beans (with pods) / boiled	0 / 2.27	28	11%	Celeries / boiled	0 / 0.47	16
19%	Cauliflowers / boiled	0 / 0.4	28	8%	Beans (without pods) / boiled	0 / 2.27	12	
18%	Sweet potatoes / boiled	0 / 0.54	27	7%	Cassava roots / boiled	0 / 0.54	10	
18%	Leeks / boiled	0 / 0.47	27	6%	Broccoli / boiled	0 / 0.4	9.6	
17%	Lentils / boiled	0 / 3.19	26	6%	Florence fennels / boiled	0 / 0.47	9.1	
17%	Witloofs / boiled	0 / 0.29	26	6%	Kohlrabies / boiled	0 / 0.4	8.5	
15%	Peas / canned	0 / 1.28	23	6%	Peas / canned	0 / 1.28	8.5	
14%	Florence fennels / boiled	0 / 0.47	21	6%	Sweet potatoes / boiled	0 / 0.54	8.3	
13%	Gherkins / pickled	0 / 0.85	20	5%	Leeks / boiled	0 / 0.47	8.2	
13%	Escaroles/broad-leaved endives / boiled	0 / 0.29	19	5%	Beetroots / boiled	0 / 0.21	8.2	
12%	Rhubarbs / sauce/puree	0 / 0.47	18	5%	Peas (with pods) / boiled	0 / 2.27	7.8	
Expand/collapse list								

Conclusion:
 No exceedance of the toxicological reference value was identified for any unprocessed commodity.
 A short term intake of residues of Flupyradifurone 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 | LIVESTOCK DIETARY BURDEN CALCULATIONS

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value ^a (mg/kg)	Comment	Input value ^a (mg/kg)	Comment
Residue definition for enforcement: Flupyradifurone				
Sugar beet, tops	0.01	STEFAMR (NEU)	0.02	HR (NEU)
Sugar beet, dried pulp	0.18	STMR (EU) × PF (18) ^b	0.18	STMR (EU) × PF (18) ^b
Sugar beet, ensiled pulp	0.03	STMR (EU) × PF (3) ^b	0.03	STMR (EU) × PF (3) ^b
Sugar beet, molasses	0.28	STMR (EU) × PF (28) ^b	0.28	STMR (EU) × PF (28) ^b
Sunflower meal	0.18	STMR (USA) × PF (2) ^b	0.18	STMR (USA) × PF (2) ^b
Kale leaves	0.85	STMR (EFSA, 2023b)	2.10	HR (EFSA, 2023b)
Apple, wet pomace	0.18	STMR × PF (1.6) (EFSA, 2015a)	0.18	STMR × PF (1.6) (EFSA, 2015a)
Citrus, dried pulp	2.07	STMR (mandarins) × PF (4.6) (EFSA, 2020b)	2.07	STMR (mandarins) × PF (4.6) (EFSA, 2020b)
Head cabbage	0.05	STMR (SEU) (EFSA, 2020b)	0.13	HR (SEU) (EFSA, 2020b)
Coconut meal	0.02	STMR × PF (1.5) ^b (EFSA, 2020b)	0.02	STMR × PF (1.5) ^b (EFSA, 2020b)
Potato culls, cassava/ tapioca roots	0.01	STMR (EFSA, 2020b)	0.04	HR (EFSA, 2020b)
Potato process waste	0.2	STMR × PF (20) (EFSA, 2020b)	0.2	STMR × PF (20) (EFSA, 2020b)
Potato dried pulp	0.38	STMR × PF (38) (EFSA, 2020b)	0.38	STMR × PF (38) (EFSA, 2020b)
Carrot culls, swede, roots, turnip roots	0.02	STMR (EFSA, 2020b)	0.6	HR (EFSA, 2020b)
Dry beans, lupins, cowpeas, peas	0.57	STMR (USA) (EFSA, 2020b)	0.57	STMR (USA) (EFSA, 2020b)
Lupin seed meal	0.63	STMR × PF (1.1) (EFSA, 2020b)	0.63	STMR × PF (1.1) (EFSA, 2020b)
Peanut meal	0.02	STMR × PF (2) (EFSA, 2020b)	0.02	STMR × PF (2) (EFSA, 2020b)
Soybean seed	0.06	STMR (EFSA, 2020b)	0.06	STMR (EFSA, 2020b)
Soybean meal	0.07	STMR × PF (1.1) (EFSA, 2020b)	0.07	STMR × PF (1.1) (EFSA, 2020b)
Soybean hulls	0.04	STMR × PF (0.6) (EFSA, 2020b)	0.04	STMR × PF (0.6) (EFSA, 2020b)
Rape seed meal	0.18	STMR × PF (2) ^b (EFSA, 2020a)	0.18	STMR × PF (2) ^b (EFSA, 2020a)
Cotton seed	0.02	STMR (USA) (EFSA, 2020b)	0.02	STMR (USA) (EFSA, 2020b)
Cotton seed meal	0.02	STMR × PF (1) (EFSA, 2020b)	0.02	STMR × PF (1) (EFSA, 2020b)
Barley grain	0.45	STMR (EFSA, 2020b)	0.45	STMR (EFSA, 2020b)
Barley, brewer's grain	0.45	STMR × PF (1) (EFSA, 2020b)	0.45	STMR × PF (1) (EFSA, 2020b)
Barley straw	0.5	STMR (SEU) (EFSA, 2023a)	4.8	HR (SEU) (EFSA, 2023a)
Millet grain	0.01	STMR (USA) (EFSA, 2023a)	0.01	STMR (USA) (EFSA, 2023a)
Millet straw/stover	0.18	STMR (SEU) (EFSA, 2023a)	0.46	HR (SEU) (EFSA, 2023a)
Maize grain	0.01	STMR (EFSA, 2020b)	0.01	STMR (EFSA, 2020b)
Maize, milled by-products, hominy meal, gluten feed, gluten meal	0.01	STMR × PF (1) (EFSA, 2020b)	0.01	STMR × PF (1) (EFSA, 2020b)
Maize, stover	0.16	STMR (NEU) (EFSA, 2023b)	0.45	HR (NEU) (EFSA, 2023b)
Oat grain	0.45	STMR (USA) (EFSA, 2023b)	0.45	STMR (USA) (EFSA, 2023b)
Oat straw	0.11	STMR (NEU) (EFSA, 2023b)	0.69	HR (NEU) (EFSA, 2023b)
Sorghum grain	0.51	STMR (EFSA, 2020b)	0.51	STMR (EFSA, 2020b)
Wheat grain	0.15	STMR (EFSA, 2020b)	0.15	STMR (EFSA, 2020b)
Wheat straw	0.43	STMR (SEU) (EFSA, 2023b)	2.6	HR (SEU) (EFSA, 2023a)
Distiller's grain dried (from wheat)	0.50	STMR × PF (3.3) (EFSA, 2020b)	0.50	STMR × PF (3.3) (EFSA, 2020b)
Wheat gluten meal	0.15	STMR × PF (1) (EFSA, 2020b)	0.15	STMR × PF (1) (EFSA, 2020b)

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value ^a (mg/kg)	Comment	Input value ^a (mg/kg)	Comment
Wheat, milled by-products	0.36	STMR×PF (bran, 2.4) (EFSA, 2020b)	0.36	STMR×PF (bran, 2.4) (EFSA, 2020b)
Rye grain	0.15	STMR (USA) (EFSA, 2023b)	0.15	STMR (USA) (EFSA, 2023a)
Rye straw	0.43	STMR (SEU) (EFSA, 2023b)	2.6	HR (SEU) (EFSA, 2023b)

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

^aFigures in the table are rounded to 2 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.

^bThe default processing factor, that is included in Animal model 2017, was used for the calculations to consider the potential concentration of residues in these commodities.

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value ^a (mg/kg)	Comment	Input value ^a (mg/kg)	Comment
Residue definition for enforcement: Difluoroacetic acid (DFA)				
Sugar beet, tops	0.03	STMR (0.009) + STMR (0.02; lettuce RC at EU plateau)	0.11	HR (0.026) + HR (0.08; lettuce RC at EU plateau)
Sugar beet, dried pulp	0.85	STMR (0.007) + STMR (0.04; root crops RC at EU plateau) × PF (18) ^b	0.085	STMR (0.007) + STMR (0.04; root crops RC at EU plateau) × PF (18) ^b
Sugar beet, ensiled pulp	0.14	STMR (0.007) + STMR (0.04; root crops RC at EU plateau) × PF (3) ^b	0.14	STMR (0.007) + STMR (0.04; root crops RC at EU plateau) × PF (3) ^b
Sugar beet, molasses	1.32	STMR (0.007) + STMR (0.04; root crops RC at EU plateau) × PF (28) ^b	1.32	STMR (0.007) + STMR (0.04; root crops RC at EU plateau) × PF (28) ^b
Sunflower seeds, meal	0.11	STMR (0.024) + STMR (0.03 rape seed RC at EU plateau) × PF (2) ^b (EFSA, 2023b)	0.11	STMR (0.024) + STMR (0.03 rape seed RC at EU plateau) × PF (2) ^b (EFSA, 2023b)
Kale leaves	0.25	STMR (0.15) + STMR (0.10; brassica RC at EU plateau) (EFSA, 2023b)	0.43	HR (0.3) + HR (0.13, brassica RC at EU plateau) (EFSA, 2023b)
Maize grain	0.07	STMR (0.01) + STMR (0.06, maize grain RC at EU plateau) (EFSA, 2023b)	0.07	STMR (0.01) + STMR (0.06, maize grain RC at EU plateau) (EFSA, 2023b)
Maize, milled by-products, hominy meal, gluten feed, gluten meal	0.07	STMR (0.01) + STMR (0.06, maize grain RC at EU plateau) × PF (1) ^c (EFSA, 2023b)	0.07	STMR (0.01) + STMR (0.06, maize grain RC at EU plateau) × PF (1) ^c (EFSA, 2023b)
Barley grain	0.19	STMR (0.05) + STMR (0.14, barley grain RC at EU plateau) (EFSA, 2023b)	0.19	STMR (0.05) + STMR (0.14, barley grain RC at EU plateau) (EFSA, 2023b)
Barley straw	0.08	STMR (0.02) + STMR (0.06, barley straw RC at EU plateau) (EFSA, 2023a)	0.65	HR (0.58) + HR (0.07, barley straw RC at EU plateau) (EFSA, 2023a)
Barley, brewer's grain	0.19	STMR (0.05) barley grain + STMR (0.14, barley grain RC at EU plateau) × PF (1) ^c (EFSA, 2023b)	0.19	STMR (0.05) barley grain + STMR (0.14, barley grain RC at EU plateau) × PF (1) ^c (EFSA, 2023b)
Millet grain	0.07	STMR (0.01) + STMR (0.06, maize grain RC at EU plateau) (EFSA, 2023b)	0.07	STMR (0.01) + STMR (0.06, maize grain RC at EU plateau) (EFSA, 2023b)
Millet straw, maize stover	0.031	STMR (0.011) + STMR (0.02, maize stover RC at EU plateau) (EFSA, 2023b)	0.072	HR (0.022) + HR (0.05, maize stover RC at EU plateau) (EFSA, 2023b)
Wheat grain	0.26	STMR (0.12; NEU) + STMR (0.14, barley grain RC at EU plateau) (EFSA, 2023b)	0.26	STMR (0.12; NEU) + STMR (0.14, barley grain RC at EU plateau) (EFSA, 2023b)
Wheat straw	0.10	STMR (0.04) + STMR (0.06, barley straw RC at EU plateau) (EFSA, 2023b)	0.24	HR (0.17) + HR (0.07, barley straw RC at EU plateau) (EFSA, 2023b)
Distiller's grain dried (from wheat)	0.86	STMR (wheat grain, see above) × PF (3.3) ^b (EFSA, 2020b)	0.86	STMR (wheat grain, see above) × PF (3.3) ^b (EFSA, 2020b)
Wheat gluten meal	0.10	STMR (wheat grain, see above) × PF (0.4) (EFSA, 2020b)	0.10	STMR (wheat grain, see above) × PF (0.4) (EFSA, 2020b)
Wheat, milled by-products	0.28	STMR×PF (bran, 1.07) (EFSA, 2020b)	0.28	STMR×PF (bran, 1.07) (EFSA, 2020b)

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value ^a (mg/kg)	Comment	Input value ^a (mg/kg)	Comment
Rye grain	0.26	STMR (0.12; NEU) + STMR (0.14, barley grain RC at EU plateau) (EFSA, 2023b)	0.26	STMR (0.12; NEU) + STMR (0.14, barley grain RC at EU plateau) (EFSA, 2023b)
Rye straw	0.10	STMR (0.04) + STMR (0.06, barley straw RC at EU plateau) (EFSA, 2023b)	0.24	HR (0.17) + HR (0.07, barley straw RC at EU plateau) (EFSA, 2023b)
Oat grain	0.19	STMR (0.05) + STMR (0.14, barley grain RC at EU plateau) or (STMR 0.1; USA) + STMR (0.09, barley grain RC at USA plateau) (EFSA, 2023b)	0.19	STMR (0.05) + STMR (0.14, barley grain RC at EU plateau) or (STMR 0.1; USA) + STMR (0.09, barley grain RC at USA plateau) (EFSA, 2023b)
Oat straw	0.08	STMR (0.02) + STMR (0.06, barley straw RC at EU plateau) (EFSA, 2023b)	0.11	HR (0.04) + HR (0.07, barley straw RC at EU plateau) (EFSA, 2023b)
Rape seed meal	0.12	STMR × PF (2) ^b (EFSA, 2020a)	0.12	STMR × PF (2) ^b (EFSA, 2020a)
Apple, wet pomace	0.08	STMR × PF ^c (EFSA, 2015a)	0.08	STMR × PF ^c (EFSA, 2015a)
Citrus, dried pulp	0.03	STMR (mandarins) × PF (1.5) (EFSA, 2020b)	0.03	STMR (mandarins) × PF (1.5) (EFSA, 2020b)
Coconut meal	0.03	STMR × PF (1.5) ^b (EFSA, 2020b)	0.03	STMR × PF (1.5) ^b (EFSA, 2020b)
Head cabbage	0.15	STMR + STMR (brassica rotational crop (RC) at EU plateau) (EFSA, 2020b)	0.22	HR + HR (brassica rotational crop (RC) at EU plateau) (EFSA, 2020b)
Potato culls, cassava/tapioca roots	0.08	STMR (potato RC at EU plateau) (EFSA, 2020b)	0.18	HR (potato RC at EU plateau) (EFSA, 2020b)
Potato process waste, dried pulp	0.08	STMR (potato RC at EU plateau) × PF (1) (EFSA, 2020b)	0.18	HR (potato RC at EU plateau) × PF (1) (EFSA, 2020b)
Carrot culls, swede, roots, turnip roots	0.07	STMR + STMR (carrot/turnip RC at US plateau) (EFSA, 2020b)	0.25	HR + HR (carrot/turnip RC at US plateau) (EFSA, 2020b)
Dry lupins, cowpeas, peas, beans	1.14	STMR + STMR (pea RC at EU plateau) (EFSA, 2020b)	1.14	STMR + STMR (pea RC at EU plateau) (EFSA, 2020b)
Lupin seed meal	1.25	STMR pea + STMR (pea RC at EU plateau) × PF (1.1) ^b (EFSA, 2020b)	1.25	STMR pea + STMR (pea RC at EU plateau) × PF (1.1) ^b (EFSA, 2020b)
Peanut meal	0.08	STMR (peanut) + STMR (rape seed RC at US plateau) × PF (2) ^b (EFSA, 2020b)	0.08	STMR (peanut) + STMR (rape seed RC at US plateau) × PF (2) ^b (EFSA, 2020b)
Linseed, safflower meal	0.06	STMR (rape seed RC at EU plateau) × PF (2) ^b (EFSA, 2020b)	0.06	STMR (rape seed RC at EU plateau) × PF (2) ^b (EFSA, 2020b)
Soybean seed	0.05	STMR + STMR (RC rape seed at NA plateau) (EFSA, 2020b)	0.05	STMR + STMR (RC rape seed at NA plateau) (EFSA, 2020b)
Soybean meal	0.07	STMR (soybean seed) + STMR (rape seed RC at NA plateau) × PF (1.3) ^b (EFSA, 2020b)	0.07	STMR (soybean seed) + STMR (rape seed RC at NA plateau) × PF (1.3) ^b (EFSA, 2020b)
Soybean hulls	0.05	STMR (soybean seed) + STMR (rape seed RC at NA plateau) × PF (0.9) (EFSA, 2020b)	0.05	STMR (soybean seed) + STMR (rape seed RC at NA plateau) × PF (0.9) (EFSA, 2020b)
Cotton seed	0.05	STMR + STMR (rape seed RC at EU plateau) (EFSA, 2020b)	0.05	STMR + STMR (rape seed RC at EU plateau) (EFSA, 2020b)
Cotton seed meal	0.07	STMR (rape seed RC at EU plateau) × PF (1.3) ^b (EFSA, 2020b)	0.07	STMR (rape seed RC at EU plateau) × PF (1.3) ^b (EFSA, 2020b)
Sorghum grain	0.11	STMR + STMR (barley grain RC at NA plateau) (EFSA, 2020b)	0.11	STMR + STMR (barley grain RC at NA plateau) (EFSA, 2020b)
Triticale	0.09	STMR (barley grain RC at NA plateau) (EFSA, 2020b)	0.09	STMR (barley grain RC at NA plateau) (EFSA, 2020b)
Forages of alfalfa, clover, trefoil, grass, cereals (except maize), oilseeds (except rape) and legumes, clover silage	0.04	STMR (barley forage RC at EU plateau) (EFSA, 2020b)	0.09	HR (barley forage RC at EU plateau) (EFSA, 2020b)

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value ^a (mg/kg)	Comment	Input value ^a (mg/kg)	Comment
Alfalfa hay, meal	0.10	STMR (barley forage RC at EU plateau) × PF (2.5) (EFSA, 2020b)	0.23	HR (barley forage RC at EU plateau) × PF (2.5) (EFSA, 2020b)
Alfalfa silage	0.04	STMR (barley forage RC at EU plateau) × PF (1.1) ^b (EFSA, 2020b)	0.1	HR (barley forage RC at EU plateau) × PF (1.1) ^b (EFSA, 2020b)
Rape forage	0.07	STMR (rape forage RC at EU plateau) (EFSA, 2020b)	0.18	HR (rape forage RC at EU plateau) (EFSA, 2020b)
Maize forage	0.03	STMR (maize forage RC at EU plateau) (EFSA, 2020b)	0.04	HR (maize forage RC at EU plateau) (EFSA, 2020b)
Straw of cereals (other than mentioned above)	0.06	STMR (barley straw RC at EU plateau) (EFSA, 2020b)	0.07	HR (barley straw RC at EU plateau) (EFSA, 2020b)
Silage of cereals	0.05	STMR (barley forage RC at EU plateau) × PF (1.3) ^b (EFSA, 2020b)	0.12	HR (barley forage RC at EU plateau) × PF (1.3) ^b (EFSA, 2020b)
Grass, pea silage	0.06	STMR (barley forage RC at EU plateau) × PF (1.6) ^b (EFSA, 2020b)	0.14	HR (barley forage RC at EU plateau) × PF (1.6) ^b (EFSA, 2020b)
Soybean, sorghum silage	0.02	STMR (barley forage RC at EU plateau) × PF (0.5) ^b (EFSA, 2020b)	0.05	HR (barley forage RC at EU plateau) × PF (0.5) ^b (EFSA, 2020b)
Clover, oat hay	0.12	STMR (barley forage RC at EU plateau) × PF (3) ^b (EFSA, 2020b)	0.27	HR (barley forage RC at EU plateau) × PF (3) ^b (EFSA, 2020b)
Cowpea, triticale hay	0.12	STMR (barley forage RC at EU plateau) × PF (2.9) ^b (EFSA, 2020b)	0.26	HR (barley forage RC at EU plateau) × PF (2.9) ^b (EFSA, 2020b)
Grass, pea, wheat hay	0.14	STMR (barley forage RC at EU plateau) × PF (3.5) ^b (EFSA, 2020b)	0.32	HR (barley forage RC at EU plateau) × PF (3.5) ^b (EFSA, 2020b)
Soybean hay	0.06	STMR (barley forage RC at EU plateau) × PF (1.5) ^b (EFSA, 2020b)	0.14	HR (barley forage RC at EU plateau) × PF (1.5) ^b (EFSA, 2020b)
Trefoil hay	0.11	STMR (barley forage RC at EU plateau) × PF (2.8) ^b (EFSA, 2020b)	0.25	HR (barley forage RC at EU plateau) × PF (2.8) ^b (EFSA, 2020b)
Tops of beet mangel and turnips	0.02	STMR (lettuce RC at EU plateau) (EFSA, 2020b)	0.08	HR (lettuce RC at EU plateau) (EFSA, 2020b)

Abbreviations: EU, European Union; HR, highest residue; NA, North America; PF, processing factor; RC, rotational crop; STMR, supervised trials median residue.

^aFigures in the table are rounded to 2 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.

^bThe default processing factor, that is included in Animal model 2017, was used for the calculations to consider the concentration of residues in these commodities.

^cNo accumulation of residues expected according to processing studies (EFSA, 2015a; EFSA, 2020b).

D.2 | CONSUMER RISK ASSESSMENT

(a) Scenario 1: Exposure to residues from the intake of primary crops and commodities of animal origin

Commodity	Existing/proposed FPF MRL ^a (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value ^b (mg/kg)	Comment	Input value ^b (mg/kg)	Comment ^c
Risk assessment residue definition: Flupyradifurone and the DFA, expressed as flupyradifurone						
Grapefruits	3	EFSA (2020b)	0.136	STMR-RAC × PeF (0.4)	0.88	HR-RAC × PeF
Oranges	3	EFSA (2020b)	0.136	STMR-RAC × PeF (0.4)	0.88	HR-RAC × PeF
Lemons	1.5	EFSA (2020b)	0.14	STMR-RAC × PeF (0.4)	0.292	HR-RAC × PeF
Limes	1.5	EFSA (2020b)	0.14	STMR-RAC × PeF (0.4)	0.292	HR-RAC × PeF
Mandarins	1.5	EFSA (2020b)	0.2	STMR-RAC × PeF (0.4)	0.396	HR-RAC × PeF
Other citrus fruit	0.01* (3)	EFSA (2023b)	0.136	STMR-RAC × PeF	0.88	HR-RAC × PeF
Almonds	0.02	EFSA (2020b)	0.06	STMR-RAC	0.11	HR-RAC
Brazil nuts	0.02	EFSA (2020b)	0.06	STMR-RAC	0.11	HR-RAC
Cashew nuts	0.02	EFSA (2020b)	0.06	STMR-RAC	0.11	HR-RAC
Chestnuts	0.02	EFSA (2020b)	0.06	STMR-RAC	0.11	HR-RAC
Coconuts	0.02	EFSA (2020b)	0.06	STMR-RAC	0.11	HR-RAC

Commodity	Existing/ proposed FPF MRL ^a (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value ^b (mg/kg)	Comment	Input value ^b (mg/kg)	Comment ^c
Hazelnuts/cobnuts	0.02	EFSA (2020b)	0.06	STMR-RAC	0.11	HR-RAC
Macadamia	0.02	EFSA (2023b)	0.19	STMR-RAC	0.37	HR-RAC
Pecans	0.02	EFSA (2020b)	0.06	STMR-RAC	0.11	HR-RAC
Pine nut kernels	0.02	EFSA (2020b)	0.06	STMR-RAC	0.11	HR-RAC
Pistachios	0.02	EFSA (2020b)	0.06	STMR-RAC	0.11	HR-RAC
Walnuts	0.02	EFSA (2020b)	0.06	STMR-RAC	0.11	HR-RAC
Other tree nuts	0.02	EFSA (2020b)	0.06	STMR-RAC	–	–
Apples	0.6	EFSA (2020b)	0.28	STMR-RAC	0.69	HR-RAC
Pears	0.6	EFSA (2020b)	0.28	STMR-RAC	0.69	HR-RAC
Quinces	0.6	EFSA (2020b)	0.28	STMR-RAC	0.69	HR-RAC
Medlar	0.6	EFSA (2020b)	0.28	STMR-RAC	0.69	HR-RAC
Loquats/Japanese medlars	0.6	EFSA (2020b)	0.28	STMR-RAC	0.69	HR-RAC
Other pome fruit	0.6	EFSA (2020b)	0.28	STMR-RAC	–	–
Apricots	0.01* (1)	EFSA (2023b)	0.37	STMR-RAC	1.10	HR-RAC
Cherries (sweet)	0.01* (2)	EFSA (2023b)	0.65	STMR-RAC	0.96	HR-RAC
Peaches	0.01* (1.5)	EFSA (2023b)	0.35	STMR-RAC	1.10	HR-RAC
Plums	0.01* (0.4)	EFSA (2023b)	0.22	STMR-RAC	0.59	HR-RAC
Other stone fruits	0.01* (1.5)	EFSA (2023b)	0.35	STMR-RAC	1.10	HR-RAC
Table grapes	3	EFSA (2020b)	0.62	STMR-RAC	1.95	HR-RAC
Wine grapes	3	EFSA (2020b)	0.62	STMR-RAC	1.95	HR-RAC
Strawberries	0.4	EFSA (2016)	0.15	STMR-RAC	0.22	HR-RAC
Blackberries	6	FAO (2019)	1.4	STMR-RAC	4.3	HR-RAC
Dewberries	6	FAO (2019)	1.4	STMR-RAC	4.3	HR-RAC
Raspberries (red and yellow)	6	FAO (2019)	1.4	STMR-RAC	4.3	HR-RAC
Other cane fruit	6	FAO (2019)	1.4	STMR-RAC	–	–
Blueberries	4	EFSA (2020b)	0.86	STMR-RAC	2.59	HR-RAC
Cranberries	0.01* (0.7)	EFSA (2023b)	0.16	STMR-RAC	0.39	HR-RAC
Currants (red, black and white)	0.01* (0.7)	EFSA (2023b)	0.16	STMR-RAC	0.39	HR-RAC
Gooseberries (green, red and yellow)	0.01* (0.7)	EFSA (2023b)	0.16	STMR-RAC	0.39	HR-RAC
Rose hips	0.01* (0.7)	EFSA (2023b)	0.16	STMR-RAC	0.39	HR-RAC
Mulberries (black and white)	0.01* (0.7)	EFSA (2023b)	0.16	STMR-RAC	0.39	HR-RAC
Azarole/Mediterranean medlar	0.01* (0.7)	EFSA (2023b)	0.16	STMR-RAC	0.39	HR-RAC
Elderberries	0.01* (0.7)	EFSA (2023b)	0.16	STMR-RAC	0.39	HR-RAC
Other small fruit & berries	0.01* (0.7)	EFSA (2023b)	0.16	STMR-RAC	–	–
Table olives	5	EFSA (2020b)	0.5	STMR-RAC	3.3	HR-RAC
Avocados	0.6/0.6	New IT/(FAO, 2019)	0.28	STMR-RAC	0.31	HR-RAC

Commodity	Existing/ proposed FPF MRL ^a (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value ^b (mg/kg)	Comment	Input value ^b (mg/kg)	Comment ^c
Mangoes	0.01*/0.7	New (IT)	0.28	STMR-RAC (pulp)	0.35	HR-RAC (pulp)
Papayas	0.01*/0.4	New (IT)	0.18	STMR-RAC	0.25	HR-RAC
Potatoes	0.05	EFSA (2020b)	0.06	STMR-RAC	0.10	HR-RAC
Cassava roots/ manioc	0.05	EFSA (2020b)	0.06	STMR-RAC	0.10	HR-RAC
Sweet potatoes	0.05	EFSA (2020b)	0.06	STMR-RAC	0.10	HR-RAC
Yams	0.05	EFSA (2020b)	0.06	STMR-RAC	0.10	HR-RAC
Arrowroots	0.05	EFSA (2020b)	0.06	STMR-RAC	0.10	HR-RAC
Other tropical root and tuber vegetables	0.05	EFSA (2020b)	0.06	STMR-RAC	–	–
Beetroots	0.9	EFSA (2020b)	0.15	STMR-RAC	0.68	HR-RAC
Carrots	0.9	EFSA (2020b)	0.15	STMR-RAC	0.68	HR-RAC
Celeriacs/turnip- rooted celeries	0.9	EFSA (2020b)	0.15	STMR-RAC	0.68	HR-RAC
Horseradishes	0.9	EFSA (2020b)	0.15	STMR-RAC	0.68	HR-RAC
Jerusalem artichokes	0.9	EFSA (2020b)	0.15	STMR-RAC	0.68	HR-RAC
Parsnips	0.9	EFSA (2020b)	0.15	STMR-RAC	0.68	HR-RAC
Parsley roots/ Hamburg roots parsley	0.9	EFSA (2020b)	0.15	STMR-RAC	0.68	HR-RAC
Radishes	0.9	EFSA (2020b)	0.15	STMR-RAC	0.68	HR-RAC
Salsifies	0.9	EFSA (2020b)	0.15	STMR-RAC	0.68	HR-RAC
Swedes/rutabagas	0.9	EFSA (2020b)	0.15	STMR-RAC	0.68	HR-RAC
Turnips	0.9	EFSA (2020b)	0.15	STMR-RAC	0.68	HR-RAC
Other root and tuber vegetables	0.9	EFSA (2020b)	0.15	STMR-RAC	–	–
Tomatoes	0.7	EFSA (2015a)	0.12	STMR-RAC	0.47	HR-RAC
Sweet peppers/bell peppers	0.9	EFSA (2020b)	0.24	STMR-RAC (foliar)	1.65	HR-RAC (soil)
Aubergines/egg plants	1	EFSA (2020b)	0.20	STMR-RAC	1.8	HR-RAC
Okra/lady's fingers	0.9	EFSA (2021)	0.26	STMR-RAC	0.60	HR-RAC
Cucumbers	0.6	EFSA (2015a)	0.13	STMR-RAC	0.66	HR-RAC
Gherkins	0.6	EFSA (2015a)	0.13	STMR-RAC	0.66	HR-RAC
Courgettes	0.6	EFSA (2015a)	0.13	STMR-RAC	0.66	HR-RAC
Other cucurbits – edible peel	0.6	EFSA (2015a)	0.13	STMR-RAC		
Watermelons	0.15	EFSA (2015a)	0.065	STMR-RAC (pulp)	0.19	HR-RAC (pulp)
Sweet corn	0.05	EFSA (2020b)	0.13	STMR-RAC	0.25	HR-RAC
Broccoli	0.6	EFSA (2020b)	0.27	STMR-RAC	0.82	HR-RAC
Cauliflowers	0.6	EFSA (2020b)	0.27	STMR-RAC	0.82	HR-RAC
Other flowering brassica	0.6	EFSA (2020b)	0.27	STMR-RAC	–	–
Brussels sprouts	0.09	EFSA (2020b)	0.16	STMR-RAC	0.31	HR-RAC
Head cabbages	0.3	EFSA (2020b)	0.21	STMR-RAC	0.29	HR-RAC
Chinese cabbages/ pe-tsai	0.01* (4)	EFSA (2023b)	1.30	STMR-RAC	2.20	HR-RAC
Kales	5 (4)	EFSA (2023b)	1.30	STMR-RAC	2.20	HR-RAC

Commodity	Existing/ proposed FPF MRL ^a (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value ^b (mg/kg)	Comment	Input value ^b (mg/kg)	Comment ^c
Other leafy brassica	0.01* (4)	EFSA (2023b)	1.30	STMR-RAC	–	–
Kohlrabies	0.09	EFSA (2020b)	0.19	STMR-RAC	0.25	HR-RAC
Lamb's lettuce/corn salads	6	EFSA (2020b)	1.36	STMR-RAC	3.20	HR-RAC
Lettuces	6	EFSA (2020b)	1.12	STMR-RAC	3.20	HR-RAC
Escaroles/broad- leaved endives	0.07	EFSA (2020b)	0.07	STMR-RAC	0.07	HR-RAC
Cress and other sprouts and shoots	6	EFSA (2020b)	1.36	STMR-RAC	3.20	HR-RAC
Land cress	6	EFSA (2020b)	1.36	STMR-RAC	3.20	HR-RAC
Roman rocket/ rucola	6	EFSA (2020b)	1.36	STMR-RAC	3.20	HR-RAC
Red mustards	6	EFSA (2020b)	1.36	STMR-RAC	3.20	HR-RAC
Baby leaf crops (including brassica species)	6	EFSA (2020b)	1.36	STMR-RAC	3.20	HR-RAC
Other lettuce and other salad plants	6	EFSA (2020b)	1.36	STMR-RAC	–	–
Spinaches	6	EFSA (2020b)	1.36	STMR-RAC	3.20	HR-RAC
Purslanes	6	EFSA (2020b)	1.36	STMR-RAC	3.20	HR-RAC
Chards/beet leaves	6	EFSA (2020b)	1.36	STMR-RAC	3.20	HR-RAC
Other spinach and similar	6	EFSA (2020b)	1.36	STMR-RAC	–	–
Grape leaves and similar species	0.03	EFSA (2020b)	0.03	STMR-RC	0.03	HR-RC
Watercress	0.07	EFSA (2020b)	0.01	STMR-RAC	0.06	HR-RAC
Witloofs/Belgian endives	0.07	EFSA (2020b)	0.01	STMR-RAC	0.06	HR-RAC
Chervil	6 (40)	EFSA (2023b)	15.90	STMR-RAC	18.20	HR-RAC
Chives	6 (40)	EFSA (2023b)	15.90	STMR-RAC	18.20	HR-RAC
Celery leaves	6 (40)	EFSA (2023b)	15.90	STMR-RAC	18.20	HR-RAC
Parsley	6 (40)	EFSA (2023b)	15.90	STMR-RAC	18.20	HR-RAC
Sage	6 (40)	EFSA (2023b)	15.90	STMR-RAC	18.20	HR-RAC
Rosemary	6 (40)	EFSA (2023b)	15.90	STMR-RAC	18.20	HR-RAC
Thyme	6 (40)	EFSA (2023b)	15.90	STMR-RAC	18.20	HR-RAC
Basil and edible flowers	6 (40)	EFSA (2023b)	15.90	STMR-RAC	18.20	HR-RAC
Laurel/bay leaves	6 (40)	EFSA (2023b)	15.90	STMR-RAC	18.20	HR-RAC
Tarragon	6 (40)	EFSA (2023b)	15.90	STMR-RAC	18.20	HR-RAC
Other herbs	6 (40)	EFSA (2023b)	15.90	STMR-RAC	–	–
Beans (with pods)	0.5	EFSA (2020b)	0.19	STMR-RAC	0.37	HR-RAC
Beans (without pods)	0.4	EFSA (2020b)	0.16	STMR-RAC	0.36	HR-RAC

Commodity	Existing/ proposed FPF MRL ^a (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value ^b (mg/kg)	Comment	Input value ^b (mg/kg)	Comment ^c
Peas (with pods)	0.5	EFSA (2020b)	0.19	STMR-RAC	0.37	HR-RAC
Peas (without pods)	0.4	EFSA (2020b)	0.16	STMR-RAC	0.36	HR-RAC
Lentils (fresh)	0.4	EFSA (2020b)	0.16	STMR-RAC	0.36	HR-RAC
Asparagus	0.01*/0.01*	New (IT)	0.27	STMR-RAC	0.72	HR-RAC
Celeries	0.01*	EFSA (2020b)	0.01	LOQ	0.01	LOQ
Beans	3	EFSA (2020b)	0.79	STMR-RAC	0.79	STMR-RAC
Lentils	3	EFSA (2020b)	0.79	STMR-RAC	0.79	STMR-RAC
Peas	3	EFSA (2020b)	0.79	STMR-RAC	0.79	STMR-RAC
Lupins/lupini beans	3	EFSA (2020b)	0.79	STMR-RAC	0.79	STMR-RAC
Other pulses	3	EFSA (2020b)	0.79	STMR-RAC		
Peanuts/ groundnuts	0.04	EFSA (2020b)	0.06	STMR-RAC	0.06	STMR-RAC
Sesame seeds	0.01*/3	New (IT)	0.71	STMR-RAC	0.71	STMR-RAC
Sunflower seeds	0.01*/0.7 or 0.8	New (IT)	0.14	STMR-RAC	0.14	STMR-RAC
Rapeseeds/canola seeds	0.3	(EFSA, 2020a)	0.23	STMR-RAC	0.23	STMR-RAC
Soyabeans	1.5	EFSA (2020b)	0.15	STMR-RAC	0.15	STMR-RAC
Mustard seeds	0.3	EFSA (2020b)	0.23	STMR-RAC	0.23	STMR-RAC
Cotton seeds	0.8	EFSA (2020b)	0.17	STMR-RAC	0.17	STMR-RAC
Olives for oil production	5	EFSA (2020b)	0.5	STMR-RAC	0.5	STMR-RAC
Barley	3	EFSA (2020b)	0.81	STMR-RAC	0.81	STMR-RAC
Maize/corn	0.02	EFSA (2020b)	0.06	STMR-RAC	0.06	STMR-RAC
Common millet/ proso millet	0.01* (0.02)	EFSA (2023b)	0.06	STMR-RAC	0.06	STMR-RAC
Oat	0.01* (3)	EFSA (2023b)	0.81	STMR-RAC	0.81	STMR-RAC
Rye	0.01* (1)	EFSA (2023b)	0.65	STMR-RAC	0.65	STMR-RAC
Sorghum	3	EFSA (2020b)	0.64	STMR-RAC	0.64	STMR-RAC
Wheat	1	EFSA (2020b)	0.65	STMR-RAC	0.65	STMR-RAC
Coffee beans	1	EFSA (2020b)	0.24	STMR-RAC	0.24	STMR-RAC
Cocoa beans	0.05	EFSA (2020b)	0.07	STMR-RAC	0.11	HR-RAC
Hops	10	FAO (2019)	3.55	STMR-RAC	8.10	HR-RAC
Sugar beet roots	0.01*/0.01*	New intended use	0.03	STMR-RAC (seed treatment)	0.052	HR-RAC (seed treatment)
Chicory roots	0.01*/0.01*	New intended use	0.03	STMR-RAC (foliar treatment)	0.048	HR-RAC (foliar treatment)
Swine: Muscle/meat	0.03	EFSA (2020b)	0.16	STMR-RAC STMR DFA (EU intake) + STMR FPF (EU intake)	0.38	HR-RAC HR DFA (EU intake) + HR FPF (EU intake)
Swine: Fat tissue	0.015 (0.02)	EFSA (2023b)	0.17	STMR-RAC STMR DFA (EU intake) + STMR FPF (EU intake)	0.57	HR-RAC HR DFA (EU intake) + HR FPF (EU intake)
Swine: Liver	0.08 (0.1)	EFSA (2023b)	0.15	STMR-RAC STMR DFA (EU intake) + STMR FPF (EU intake)	0.38	HR-RAC HR DFA (EU intake) + HR FPF (EU intake)

Commodity	Existing/ proposed FPF MRL ^a (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value ^b (mg/kg)	Comment	Input value ^b (mg/kg)	Comment ^c
Swine: Kidney	0.09 (0.15)	EFSA (2023b)	0.25	STMR-RAC STMR DFA (EU intake) + STMR FPF (EU intake)	0.63	HR-RAC HR DFA (EU intake) + HR FPF (EU intake)
Swine: Edible offal (other than liver and kidney)	0.09 (0.15)	EFSA (2023b)	0.25	STMR-RAC STMR DFA (EU intake) + STMR FPF (EU intake)	0.63	HR-RAC HR DFA (EU intake) + HR FPF (EU intake)
Bovine: Muscle/ meat	0.3	EFSA (2020b)	1.10	STMR-RAC Tolerance FPF (US intake) + STMR FPF (US intake)	1.22	HR-RAC Tolerance FPF (US intake) + HR FPF (US intake)
Bovine: Fat tissue	0.2	EFSA (2020b)	1.03	STMR-RAC Tolerance FPF (US intake) + STMR DFA (US intake)	1.48	HR-RAC Tolerance FPF (US intake) + HR DFA (US intake)
Bovine: Liver	1	EFSA (2020b)	1.74	STMR-RAC Tolerance FPF (US intake) + STMR DFA (US intake)	1.91	HR-RAC Tolerance FPF (US intake) + HR DFA (US intake)
Bovine: Kidney	1	EFSA (2020b)	2.24	STMR-RAC Tolerance FPF (US intake) + STMR DFA (US intake)	2.39	HR-RAC Tolerance FPF (US intake) + HR DFA (US intake)
Bovine: Edible offal (other than liver and kidney)	1	EFSA (2020b)	2.24	STMR-RAC Tolerance FPF (US intake) + STMR DFA (US intake)	2.39	HR-RAC Tolerance FPF (US intake) + HR DFA (US intake)
Sheep: Muscle/ meat	0.3	EFSA (2020b)	0.54	STMR-RAC Tolerance FPF (US intake) + STMR DFA (EU intake)	0.84	HR-RAC Tolerance FPF (US intake) + HR DFA (EU intake)
Sheep: Fat tissue	0.2	EFSA (2020b)	0.38	STMR-RAC Tolerance FPF (US intake) + STMR DFA (EU intake) (EFSA, 2020b)	0.881	HR-RAC HR DFA (EU intake) + HR FPF (EU intake)
Sheep: Liver	1	EFSA (2020b)	1.21	STMR-RAC Tolerance FPF (US intake) + STMR DFA (EU intake)	1.39	HR-RAC Tolerance FPF (US intake) + HR DFA (EU intake)
Sheep: Kidney	1	EFSA (2020b)	1.39	STMR-RAC Tolerance FPF (US intake) + STMR DFA (EU intake)	1.72	HR-RAC Tolerance FPF (US intake) + HR DFA (EU intake)
Sheep: Edible offals (other than liver and kidney)	1	EFSA (2020b)	1.39	STMR-RAC Tolerance FPF (US intake) + STMR DFA (EU intake)	1.72	HR-RAC Tolerance FPF (US intake) + HR DFA (EU intake)
Goat: Muscle/meat	0.3	EFSA (2020b)	0.54	STMR-RAC Tolerance FPF (US intake) + STMR DFA (EU intake)	0.84	HR-RAC Tolerance FPF (US intake) + HR DFA (EU intake)
Goat: Fat tissue	0.2	EFSA (2020b)	0.38	STMR-RAC Tolerance FPF (US intake) + STMR DFA (EU intake) (EFSA, 2020b)	0.881	HR-RAC HR DFA (EU intake) + HR FPF (EU intake)
Goat: Liver	1	EFSA (2020b)	1.21	STMR-RAC Tolerance FPF (US intake) + STMR DFA (EU intake)	1.39	HR-RAC Tolerance FPF (US intake) + HR DFA (EU intake)

Commodity	Existing/ proposed FPF MRL ^a (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value ^b (mg/kg)	Comment	Input value ^b (mg/kg)	Comment ^c
Goat: Kidney	1	EFSA (2020b)	1.39	STMR-RAC Tolerance FPF (US intake) + STMR DFA (EU intake)	1.72	HR-RAC Tolerance FPF (US intake) + HR DFA (EU intake)
Goat: Edible offal (other than liver and kidney)	1	EFSA (2020b)	1.39	STMR-RAC Tolerance FPF (US intake) + STMR DFA (EU intake)	1.72	HR-RAC Tolerance FPF (US intake) + HR DFA (EU intake)
Equine: Muscle/ meat	0.3	EFSA (2020b)	1.10	STMR-RAC Tolerance FPF (US intake) + STMR DFA (US intake)	1.22	HR-RAC Tolerance FPF (US intake) + HR DFA (US intake)
Equine: Fat tissue	0.2	EFSA (2020b)	1.03	STMR-RAC Tolerance FPF (US intake) + STMR DFA (US intake)	1.48	HR-RAC Tolerance FPF (US intake) + HR DFA (US intake)
Equine: Liver	1	EFSA (2020b)	1.74	STMR-RAC Tolerance FPF (US intake) + STMR DFA (US intake)	1.91	HR-RAC Tolerance FPF (US intake) + HR DFA (US intake)
Equine: Kidney	1	EFSA (2020b)	2.24	STMR-RAC Tolerance FPF (US intake) + STMR DFA (US intake)	2.39	HR-RAC Tolerance FPF (US intake) + HR DFA (US intake)
Equine: Edible offal (other than liver and kidney)	1	EFSA (2020b)	2.24	STMR-RAC Tolerance FPF (US intake) + STMR DFA (US intake)	2.39	HR-RAC Tolerance FPF (US intake) + HR DFA (US intake)
Poultry: Muscle/ meat	0.01	EFSA (2020b, 2023b)	0.32	STMR-RAC Tolerance FPF (US intake) + STMR DFA (US intake)	0.39	HR-RAC HR DFA (EU intake) + HR FPF (EU intake)
Poultry: Fat tissue	0.01	EFSA (2020b, 2023b)	0.09	STMR-RAC Tolerance FPF (US intake) + STMR DFA (US intake)	0.102	HR-RAC HR DFA (EU intake) + HR FPF (EU intake)
Poultry: Liver	0.01	EFSA (2020b)	0.68	STMR-RAC STMR DFA (EU intake) + STMR FPF (EU intake)	0.692	HR-RAC HR DFA (EU intake) + HR FPF (EU intake)
Poultry: Kidney	0.01	EFSA (2020b)	0.68	STMR-RAC STMR DFA (EU intake) + STMR FPF (EU intake)	0.692	HR-RAC HR DFA (EU intake) + HR FPF (EU intake)
Poultry: Edible offal (other than liver and kidney)	0.01	EFSA (2020b)	0.68	STMR-RAC STMR DFA (EU intake) + STMR FPF (EU intake)	0.692	HR-RAC HR DFA (EU intake) + HR FPF (EU intake)
Milk: Cattle	0.15	EFSA (2020b)	0.34	STMR-RAC Tolerance FPF (US intake) + STMR DFA (US intake)	0.34	STMR-RAC Tolerance FPF (US intake) + STMR DFA (US intake)
Milk: Sheep	0.15	EFSA (2020b)	0.18	STMR-RAC Tolerance FPF (US intake) + STMR DFA (EU intake)	0.18	STMR-RAC Tolerance FPF (US intake) + STMR DFA (EU intake)
Milk: Goat	0.15	EFSA (2020b)	0.18	STMR-RAC Tolerance FPF (US intake) + STMR DFA (US intake)	0.18	STMR-RAC Tolerance FPF (US intake) + STMR DFA (EU intake)

Commodity	Existing/ proposed FPF MRL ^a (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value ^b (mg/kg)	Comment	Input value ^b (mg/kg)	Comment ^c
Eggs: Chicken	0.01	EFSA (2020b)	0.25	STMR-RAC Tolerance FPF (US intake) + STMR DFA (US intake)	0.31	HR-RAC HR DFA (EU intake) + HR FPF (EU intake)
Eggs: Duck	0.01	EFSA (2020b)	0.25	STMR-RAC Tolerance FPF (US intake) + STMR DFA (US intake)	0.31	HR-RAC HR DFA (EU intake) + HR FPF (EU intake)
Eggs: Goose	0.01	EFSA (2020b)	0.25	STMR-RAC Tolerance FPF (US intake) + STMR DFA (US intake)	0.31	HR-RAC HR DFA (EU intake) + HR FPF (EU intake)
Eggs: Quail	0.01	EFSA (2020b)	0.25	STMR-RAC Tolerance FPF (US intake) + STMR DFA (US intake)	0.31	HR-RAC HR DFA (EU intake) + HR FPF (EU intake)
Eggs: Others	0.01	EFSA (2020b)	0.25	STMR-RAC Tolerance FPF (US intake) + STMR DFA (US intake)	-	-
Honey and other apiculture products	0.05* (2)	EFSA (2023b)	0.36	STMR-RAC	0.92	HR-RAC

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

^aMRL proposals recently assessed by EFSA (EFSA, 2023b) not yet discussed at Standing Committee on Plants, Animals, Food and Feed (PAFF Committee) are reported between brackets.

^bFigures in the table are rounded to 2 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.

^cInput values for the commodities which are not under consideration for the acute risk assessment are reported in grey.

(b) Scenario 2: Exposure to flupyradifurone and DFA residues (expressed as flupyradifurone) from rotational crops

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value ^a (mg/kg)	Comment	Input value ^a (mg/kg)	Comment
Strawberries	0.33	STMR DFA RC strawberry at EU plateau (EFSA, 2020b)	0.74	HR DFA RC strawberry at EU plateau (EFSA, 2020b)
Potatoes, tropical root and tuber vegetables	0.23	STMR DFA in RC potatoes at EU plateau (EFSA, 2020b)	0.54	HR DFA in RC potatoes at EU plateau (EFSA, 2020b)
Root and tuber vegetables (except sugar beets)	0.11	STMR DFA in RC carrot/turnip at EU plateau (EFSA, 2020b)	0.21	HR DFA in RC carrot/turnip at EU plateau (EFSA, 2020b)
Bulb vegetables	0.13	STMR DFA in RC onions at EU plateau (EFSA, 2020b)	0.33	HR DFA in RC onions at EU plateau (EFSA, 2020b)
Tomatoes, aubergines, peppers	0.62	STMR DFA in RC cucumber at EU plateau (EFSA, 2020b)	0.85	HR DFA in RC cucumber at EU plateau (EFSA, 2020b)
Okra/lady's fingers	0.62	STMR (EFSA, 2021)	0.85	HR (EFSA, 2021)
Cucurbits (edible peel)	0.62	STMR DFA in RC cucumber at EU plateau (EFSA, 2020b)	0.85	HR DFA in RC cucumber at EU plateau (EFSA, 2020b)
Cucurbits (inedible peel)	0.62	STMR DFA in RC cucumbers at EU plateau (EFSA, 2020b)	0.85	HR DFA in RC cucumbers at EU plateau (EFSA, 2020b)
Sweet corn	0.17	STMR DFA in RC maize grain at EU plateau (EFSA, 2020b)	0.23	HR DFA in RC maize grain at EU plateau (EFSA, 2020b)
Brassica vegetables	0.3	STMR DFA in RC cauliflower/broccoli at EU plateau (EFSA, 2020b)	0.4	HR DFA in RC cauliflower/broccoli at EU plateau (EFSA, 2020b)
Lettuce and other salad plants Herbs and edible flowers Spinach and similar	0.08	STMR flupyradifurone (0.01 mg/kg) at EU plateau + STMR DFA in RC lettuce at EU plateau (EFSA, 2020b)	0.29	HR flupyradifurone (0.06 mg/kg) lettuce at EU plateau + HR DFA in RC lettuce at EU plateau (EFSA, 2020b)

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value ^a (mg/kg)	Comment	Input value ^a (mg/kg)	Comment
Grape leaves, watercress, witloofs/Belgian endives	0.08	STMR flupyradifurone (0.01 mg/kg) at EU plateau + STMR DFA in RC lettuce at EU plateau (EFSA, 2020b)	0.29	HR flupyradifurone (0.06 mg/kg) lettuce at EU plateau + HR DFA in RC lettuce at EU plateau (EFSA, 2020b)
Legume vegetables	0.98	STMR DFA in RC beans with pods at EU plateau (EFSA, 2020b)	2.27	HR DFA in RC beans with pods at EU plateau (EFSA, 2020b)
Stem vegetables	0.14	STMR DFA in RC leek at EU plateau (EFSA, 2020b)	0.47	HR DFA in RC leek at EU plateau (EFSA, 2020b)
Pulses	3.19	STMR DFA in RC peas (dry) at EU plateau (EFSA, 2020b)	3.19	STMR DFA in RC peas (dry) at EU plateau (EFSA, 2020b)
Oilseeds (incl. sesame seeds, sunflower seeds)	0.09	STMR DFA in RC rapeseed at EU plateau (EFSA, 2020b)	0.09	STMR DFA in RC rapeseed at EU plateau (EFSA, 2020b)
Cereals	0.43	STMR flupyradifurone (0.01 mg/kg) barley grain at EU plateau + STMR DFA (0.42 mg/kg) in RC barley grain at EU plateau (EFSA, 2020b)	0.43	STMR flupyradifurone (0.01 mg/kg) barley grain at EU plateau + STMR DFA (0.42 mg/kg) in RC barley grain at EU plateau (EFSA, 2020b)
Sugar beet roots, chicory roots	0.11	STMR DFA in RC carrot/turnip at EU plateau (EFSA, 2020b)	0.21	HR DFA in RC carrot/turnip at EU plateau (EFSA, 2020b)

Abbreviations: EU, European Union; HR, highest residue; RC, rotational crop; STMR, supervised trials median residue.

^aFigures in the table are rounded to 2 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.

APPENDIX E

Residues of DFA in rotational crops

TABLE E1 MRL proposals for DFA for plant products (in mg/kg).

Crop under assessment	Origin of the GAP	MRL proposal (primary crop treatment)	HR (representative rotational crop at EU plateau soil concentration for flupyradifurone) (EFSA, 2020b)	HR in rotational crops (at US/CA plateau soil concentration flupyradifurone) (EFSA, 2020b)	MRL primary crop + HR for RC	MRL proposal ^a
Sunflowers	USA	0.02*	–	0.03 (rape seeds)	0.05	0.05 ^b
Sesame	USA	0.8	–	0.03 (rape seeds)	0.83	0.9
Sugar beets (foliar treatment)	EU	0.02	0.07 (turnips/carrots)	–	0.09	0.09
Chicory roots	EU	0.02	0.07 (turnips/carrots)	–	0.09	0.09

Abbreviations: HR, highest residue; MRL, maximum residue level.

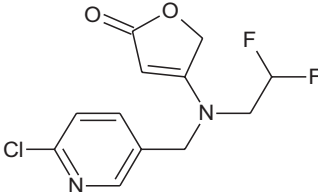
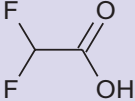
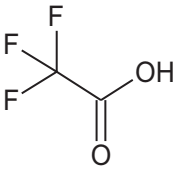
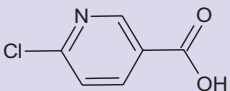
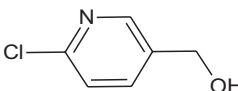
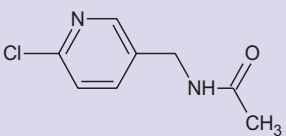
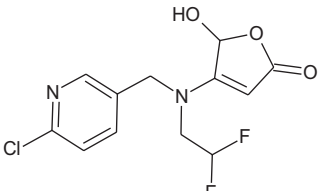
^aThe MRL proposals representing the critical GAP for the commodity under assessment is highlighted in bold.

^bA higher MRL has been proposed by EFSA (2023b) at 0.15 mg/kg to cover primary use and uptake from the soil from rotational crops.

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

APPENDIX F

Used compound codes

Code/trivial name ^a	IUPAC name/SMILES notation/InChiKey ^b	Structural formula ^c
Flupyradifurone	4-[(6-chloro-3-pyridyl)methyl](2,2-difluoroethyl)amino) furan-2(5H)-one FC(F)CN(Cc1ccc(Cl)nc1)C1=CC(=O)OC1 QOYTRGFOFZKNF-UHFFFAOYSA-N	
DFA	difluoroacetic acid FC(F)C(=O)O PBWZKZYHONABL-N-UHFFFAOYSA-N	
TFA	Trifluoroacetic acid FC(F)(F)C(=O)O DTQVDTLACAAQTR-UHFFFAOYSA-N	
6-CNA	6-chloropyridine-3-carboxylic acid OC(=O)c1cnc(Cl)cc1 UAWMVMPAYRWUFX-UHFFFAOYSA-N	
CHMP 6-CPA (6-chloro-picolylalcohol)	(6-chloropyridin-3-yl)methanol OCc1cnc(Cl)cc1 GOXYBEXWMJZLJB-UHFFFAOYSA-N	
Acetyl-AMCP	N-[(6-chloropyridin-3-yl)methyl]acetamide Clc1ccc(CNC(C)=O)cn1 PKLYKZAYVXYVQX-UHFFFAOYSA-N	
Flupyradifurone-hydroxy M8 metabolite	4-[(6-chloropyridin-3-yl)methyl](2,2-difluoroethyl) amino)-5-hydroxyfuran-2(5H)-one VCISBQOTABLQEA-UHFFFAOYSA-N OC1OC(=O)C=C1N(CC(F)F)Cc1ccc(Cl)nc1	

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

^aThe metabolite name in bold is the name used in the conclusion.

^bACD/Name 2021.1.3 ACD/Labs 2021.1.3 (File Version N15E41, Build 123232, 07 Jul 2021).

^cACD/ChemSketch 2021.1.3 ACD/Labs 2021.1.3 (File Version C25H41, Build 123835, 28 Aug 2021).