Approved: 27 November 2023

DOI: 10.2903/j.efsa.2023.8481

REASONED OPINION

efsa JOURNAL

Modification of the existing maximum residue levels for sulfoxaflor in various commodities

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 | Ileana Miron | Stefanie Nave | Ragnor Pedersen | Hermine Reich | Silvia Ruocco | Miguel Santos | Alessia Pia Scarlato | Marta Szot | Anne Theobald | Manuela Tiramani | Alessia Verani

Correspondence:
pesticides.mrl@efsa.europa.eu

Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the Federal Public Service (FPS) Health, Food chain Safety and Environment submitted a request on behalf of Belgium (evaluating Member State, EMS) to modify the existing maximum residue levels (MRL) in okra/lady's fingers and various leaf vegetables, herbs and edible flowers. The data submitted in support of the request were found to be sufficient to derive MRL proposals for all crops under assessment. Adequate analytical methods for enforcement are available to control the residues of sulfoxaflor in plant matrices under consideration at the validated limit of quantification (LOQ) of 0.01 mg/kg. Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of residues resulting from the use of sulfoxaflor according to the reported agricultural practices is unlikely to present a risk to consumer health.

KEYWORDS

consumer risk assessment, MRL, pesticide, sulfoxaflor, various crops

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SUMMARY

In accordance with Article 6 of Regulation (EC) No 396/2005, the Federal Public Service (FPS) Health, Food chain Safety and Environment submitted a request on behalf of Belgium (evaluating Member State, EMS to modify the existing maximum residue levels (MRLs) for the active substance sulfoxaflor in okra/lady's fingers, crops belonging to the group lettuces and salad plants (except lettuces), watercresses, purslanes, chard/beet leaves and crops of the group herbs and edible flowers (except celery leaves), resulting from the intended indoor uses of sulfoxaflor.

The application, alongside the dossier containing the supporting data in IUCLID format, was submitted through the EFSA Central Submission System on 11 January 2023. The appointed EMS Belgium declared its admissibility on 20 January 2023. 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 was 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 ran from 20 April 2023 to 11 May 2023. No additional data or comments were submitted in the framework of the consultation.

At the end of the commenting period, the EMS proceeded to draft 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 31 May 2023. To accommodate for the intended indoor uses of sulfoxaflor, the EMS proposed to raise the existing MRL in okra/lady's fingers from the limit of quantification (LOQ) of 0.01 to 0.07 mg/kg. For the crops belonging to the group lettuces and salads (except lettuces) and for purslanes, chards/beet leaves and watercresses, the EMS proposed to raise the existing MRLs from the LOQ of 0.01 to 0.7 mg/kg. Finally, the EMS proposed to raise the existing MRLs in herbs and edible flowers (except celery leaves) from the LOQ of 0.02 to 0.7 mg/kg.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified data points which needed further clarification and requested the EMS to address them. On 26 October 2023, the EMS provided the requested information in an updated IUCLID dossier alongside a revised evaluation report (Belgium, 2023), 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, and the additional data provided by the EMS in the framework of this application, the following conclusions are derived.

The metabolism of sulfoxaflor following foliar and soil applications was investigated in crops belonging to the groups of fruit crops, leafy crops, cereals and pulses/oilseeds. After foliar applications, parent sulfoxaflor was the most significant residue (16%–71% of total radioactive residue [TRR]) with the metabolite X11719474 as a major metabolite in mature crops (7%–30% TRR). After soil applications, sulfoxaflor was present in a much lower proportion (up to 18% TRR in fruit crops and below 1% TRR in leafy crops) or not even detected (pulses and cereals) and the metabolite X11719474 was the major residue (31%–90% TRR). No significant shift was reported for the diastereomer ratios of sulfoxaflor and X11719474.

Studies investigating the effect of processing on the nature of sulfoxaflor (hydrolysis studies) demonstrated that the sulfoxaflor and metabolite X11719474 are stable.

In rotational crops, the major residue identified was the metabolite X11719474, ranging from 35% TRR in wheat straw (120 DAT) to 88% TRR in mature radish roots (120 DAT), while the parent rapidly degraded.

Based on the metabolic pattern identified in metabolism studies, hydrolysis studies and the toxicological relevance of metabolites, the residue definitions for plant products were proposed as 'sulfoxaflor (sum of isomers)' for enforcement and 'sum of sulfoxaflor and metabolite X11719474, expressed as sulfoxaflor' for risk assessment. These residue definitions are applicable to primary crops, rotational crops and processed products.

EFSA concluded that for the crops assessed in this application, the metabolism of sulfoxaflor in primary and in rotational crops, and the possible degradation in processed products have 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 detection (HPLC–MS/MS) are available to quantify residues in the crops assessed in this application according to the enforcement residue definition. The methods enable the quantification of residues at or above the LOQ of 0.01 mg/kg in the crops assessed. The extraction efficiency of the enforcement method for the determination of sulfoxaflor residues in high-water content matrices was proven.

The available residue trials are sufficient to derive an MRL proposal of 0.07 mg/kg for okra/lady's fingers and of 0.7 mg/kg for crops belonging to the group lettuces and salads (except lettuces), for purslanes, chards/beet leaves, watercresses and for herbs and edible flowers (except celery leaves).

Specific studies investigating the magnitude of sulfoxaflor residues in processed commodities are not required, as the individual contribution of the crops under assessment to the total theoretical maximum daily intake (TMDI) is below the trigger value of 10% of the acceptable daily intake (ADI).

The occurrence of sulfoxaflor residues in rotational crops was investigated in the framework of the EU pesticides peer review. Based on the available information on the nature and magnitude of residues, it was concluded that significant residue levels of parent sulfoxaflor are unlikely to occur in rotational crops when the active substance is used according to the registered use patterns for sulfoxaflor in Europe. According to the available studies, metabolite X11719474 was considered by the peer review to be quantitatively relevant in rotational crops. For the indoor uses under consideration EFSA concludes, that significant residues of sulfoxaflor are not expected in crops grown in rotation with the crops under

consideration. Regarding the magnitude of metabolite X11719474, it is concluded that residues above 0.01 mg/kg might occur in succeeding crops and therefore when new indoor uses are authorised at the national level, Member States might consider using plant production systems that exclude crop rotation in used substrates or setting risk mitigation measures to avoid potential residues of metabolite X11719474 in rotational crops.

Residues of sulfoxaflor in commodities of animal origin were not assessed since the crops under consideration in this MRL application are not considered as relevant fed items to livestock according to the current guidance.

The toxicological profile of sulfoxaflor 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 ADI of 0.04 mg/kg body weight (bw) per day and an acute reference dose (ARfD) of 0.25 mg/kg bw. The metabolite included in the risk assessment residue definition is of similar toxicity as the parent active substance.

The consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo). The short-term exposure did not exceed the ARfD for any of the crops assessed in this application. The highest acute consumer exposure was calculated for escaroles (7.4% of ARfD) followed by chards/beet leaves (2.9% of the ARfD). The highest estimated long-term dietary intake accounted for 37% of the ADI (NL toddler diet). The contributions of the commodities assessed in the present MRL application to the overall long-term exposure were low with escaroles contributing to 0.24% of the ADI (NL toddler diet) and the remaining commodities contributing individually to less than 0.1% of the ADI.

EFSA concluded that the existing and the intended uses assessed under the present application will not result in a consumer exposure exceeding the toxicological reference values and therefore are 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: Sulfoxaflor (sum of isomers)				
0231040	Okra/lady's fingers	0.01*	0.07	The submitted data are sufficient to derive MRL proposals for the intended EU indoor use. Risk for consumers is unlikely
0251010	Lamb's lettuces/corn salads	0.01*	0.7	
0251030	Escaroles/broad-leaved endives	0.01*	0.7	
0251040	Cresses and other sprouts and shoots	0.01*	0.7	
0251050	Land cresses	0.01*	0.7	
0251060	Roman rocket/rucola	0.01*	0.7	
0251070	Red mustards	0.01*	0.7	
0251080	Baby leaf crops (including brassica species)	0.01*	0.7	
0252020	Purslanes	0.01*	0.7	
0252030	Chards/beet leaves	0.01*	0.7	
0254000	Watercresses	0.01*	0.7	
0256010	Chervil	0.02*	0.7	
0256020	Chives	0.02*	0.7	
0256040	Parsley	0.02*	0.7	
0256050	Sage	0.02*	0.7	
0256060	Rosemary	0.02*	0.7	
0256070	Thyme	0.02*	0.7	
0256080	Basil and edible flowers	0.02*	0.7	
0256090	Laurel/bay leaves	0.02*	0.7	
0256100	Tarragon	0.02*	0.7	

Abbreviations: GAP, Good Agricultural Practice; MRL, maximum residue level.

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

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

ASSESSMENT

The European Food Safety Authority (EFSA) received an application to modify the existing maximum residue level (MRL) for sulfoxaflor in okra/lady's fingers and various leaf vegetables, herbs and edible flowers. A detailed description of the intended indoor uses of sulfoxaflor, which are the basis for the current MRL application, is reported in Appendix A.

Sulfoxaflor[1] is the ISO common name for [methyl(oxo){1-[6-(trifluoromethyl)-3-pyridyl]ethyl}-λ^6-sulfanylidene]cyanamide (IUPAC). The chemical structures of the active substance and its main metabolites are reported in Appendix E.

Sulfoxaflor was evaluated in the framework of Regulation (EC) No 1107/2009[2] with Ireland designated as rapporteur Member State (RMS) for the representative uses as a foliar treatment on fruiting vegetables, cucurbits, spring and winter cereals and cotton to control sap-feeding insects. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by EFSA (EFSA, 2014a). Sulfoxaflor was approved[3] for the use as an insecticide on 18 August 2015. When granting national authorisations, Member States need to consider risk mitigation measures related to the risk for bees, bumble bees and other non-target arthropods. In 2022, approval restrictions[4] were agreed by risk managers in which only uses in permanent greenhouses may be authorised with a grace period of 19 May 2023 at the latest to allow withdrawal or amendment of authorisations for plant protection products containing sulfoxaflor that do not comply with the restricted conditions of approval.

EU MRLs for sulfoxaflor are established in Annex II of Regulation (EC) No 396/2005.[5] A review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) is not required (EFSA, 2017c). Proposals for setting MRLs covering the representative uses according to good agricultural practices (GAP) in the EU were assessed during the approval of sulfoxaflor under Regulation (EC) No 1107/2009 and implemented in Regulation in accordance with Article 11(2) of the Regulation (EC) 1107/2009. EFSA has issued several reasoned opinions on the modification of MRLs for sulfoxaflor. The proposals from these reasoned opinions have been considered in recent MRL regulations.[6] Certain Codex maximum residue limits (CXLs) have also been taken over in the EU MRL legislation. The MRL proposals for sulfoxaflor in various crops as derived in the recent EFSA assessments (EFSA, 2019b, 2022a, 2023a) have not been yet adopted in the EU MRL legislation but will nevertheless be considered in the present consumer risk assessment. The same refers to several CXL proposals which were evaluated by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) and are supported for the inclusion in the EU MRL legislation (CAC, 2022; EFSA, 2019c, 2022b; FAO, 2019, 2021). In the framework of the preparation of the EU position for the 54th Session of the Codex Committee on Pesticide Residues (CCPR), EFSA recently issued a scientific report on Codex MRL proposals for sulfoxaflor in various plant commodities (EFSA, 2023b; FAO, 2023). However, it is noted that the proposed Codex MRLs for globe artichokes and sunflower seeds are already covered by a recent import tolerance opinion (EFSA, 2023a).

On 11 January 2023, in accordance with Article 6 of Regulation (EC) No 396/2005 and following the provisions set by the 'Transparency Regulation' (EU) 2019/1381,[7] the Federal Public Service (FPS) Health, Food chain Safety and Environment submitted on behalf of Belgium submitted an application, alongside the dossier containing the supporting data using the IUCLID format.

The EMS Belgium declared its admissibility on 20 January 2023. 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 was 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 ran from 20 April 2023 to 11 May 2023. No additional data or comments were submitted in the framework of the consultation.

At the end of the commenting period, the EMS proceeded to draft 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 31 May 2023. To accommodate for the intended indoor uses of sulfoxaflor, the EMS proposed to raise the existing MRL in okra/lady's fingers from the limit of quantification (LOQ) of 0.01 to 0.07 mg/kg. For the crops belonging to the group lettuces and salads (except lettuces) and for purslanes, chards/beet leaves and watercresses, the

[1]It should be noted that sulfoxaflor and its metabolite X11719474 are identified as a pesticide active substance/metabolite that meet the definition of per- and polyfluoroalkyl substances (PFAS) based on their chemical structures. https://echa.europa.eu/hot-topics/perfluoroalkyl-chemicals-pfas

[2]Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.

[3]Commission Implementing Regulation (EU) 2015/1295 of 27 July 2015 approving the active substance sulfoxaflor, 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. OJL 199, 29.7.2015, p. 8–11.

[4]Commission Implementing Regulation (EU) 2022/686 of 28 April 2022 amending Implementing Regulations (EU) 2015/1295 and (EU) No 540/2011 as regards the conditions of approval of the active substance sulfoxaflor https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32022R0686&from=EN

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

[6]For an overview of all MRL Regulations on this active substance, please consult: https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/active-substances/?event=search.as

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

EMS proposed to raise the existing MRLs from the LOQ of 0.01 to 0.7 mg/ha. Finally, the EMS proposed to raise the existing MRLs in herbs and edible flowers (except celery leaves) from the LOQ of 0.02 to 0.7 mg/kg.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified data points which needed further clarification and requested the EMS to address them. On 26 October 2023, Belgium provided the requested information in an updated IUCLID dossier alongsidea duly revised evaluation report (Belgium, 2023), which replaced the previously submitted evaluation report.

EFSA based its assessment on the evaluation report submitted by the EMS (Belgium, 2023), the DAR and its addendum (Ireland, 2012, 2014) prepared under Regulation (EC) 1107/2009, the Commission review report on sulfoxaflor (European Commission, 2015), the conclusion on the peer review of the pesticide risk assessment of the active substance sulfoxaflor (EFSA, 2014a), as well as the conclusions from previous EFSA opinions on sulfoxaflor (EFSA, 2017b, 2019b, 2022a, 2023a) and the EFSA reports based on JMPR assessments (EFSA, 2014b, 2015, 2017a, 2019c, 2022b, 2023b).

For this application, the data requirements established in Regulation (EU) No 544/2011[8] and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 1997a, 1997b, 1997c, 1997d, 1997e, 1997f, 1997g, 2010, 2020a, 2020b, 2022; OECD, 2007, 2011, 2013). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011.[9]

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 (Belgium, 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.[10]

1 | RESIDUES IN PLANTS

1.1 | Nature of residues and methods of analysis in plants

1.1.1 | Nature of residues in primary crops

The metabolism of sulfoxaflor in primary crops belonging to the group of fruit crops, leafy crops, cereals/grass and pulses/oilseeds has been investigated in the framework of the EU pesticides peer review (EFSA, 2014a). Following foliar applications, the primary residue was the parent sulfoxaflor, accounting for 16%–71% of the total radioactive residue (TRR). The metabolite X11719474 was the major metabolite in mature crops (7%–30% TRR). After soil applications, sulfoxaflor was present in a much lower proportion (up to 18% TRR in fruit crops and below 1% TRR in leafy crops) or not even detected (pulses and cereals). The metabolite X11719474 was the major residue (31%–90% TRR).

In the metabolism studies, no significant shift was reported for the diastereomer ratios. Information on the ratio of the enantiomers present in the individual diastereomers of sulfoxaflor and X11719474 was not available. Nonetheless, the EU pesticides peer review did not identify the need for additional data (EFSA, 2014a).

Overall, the metabolic behaviour in primary crops for the intended uses under assessment was deemed adequately addressed.

1.1.2 | Nature of residues in rotational crops

The proposed uses of sulfoxaflor are on crops that can be grown in rotation with other crops. According to the soil degradation studies evaluated in the framework of the peer review, the DT_{90} value of sulfoxaflor ranged from 4.8 to 24.7 days. The DT_{90} of the main soil metabolite X11719474 ranged from 63.3 to 750 days (EFSA, 2014a). Since the trigger value of 100 days was exceeded for the metabolite X11719474, studies investigating the nature of residues in rotational crops were required (European Commission, 1997c). Confined rotational crop studies in root/tuber crops (radish), leafy crops (lettuces) and cereals (wheat) were assessed in the EU pesticides peer review after bare soil application of parent sulfoxaflor (EFSA, 2014a). Sulfoxaflor rapidly degraded and X11719474 was the most abundant metabolite observed in all crops at all three plant back intervals, ranging from 35% TRR in wheat straw (120 DAT) to 88% TRR in mature radish roots (120 DAT). Based on the results of the confined rotational crop study, it was concluded that metabolite X11719474 is the relevant residue in rotational crops and that the metabolism of sulfoxaflor in rotational crops is similar to the pathways observed in primary crops (EFSA, 2014a).

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

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

[10]Background documents to this reasoned opinion are published on OpenEFSA portal and are available at the following link: https://open.efsa.europa.eu/study-inventory/EFSA-Q-2023-00038

1.1.3 | Nature of residues in processed commodities

The effect of processing on the nature of sulfoxaflor and its metabolite X11719474 was investigated in the framework of the EU pesticides peer review (EFSA, 2014a). Both sulfoxaflor and X11719474 were considered sufficiently stable under standard hydrolysis conditions (EFSA, 2014a).

1.1.4 | Analytical methods for enforcement purposes in plant commodities

Analytical methods for the determination of sulfoxaflor residues in plant matrices were assessed during the EU pesticides peer review (EFSA, 2014a). The methods (091116 and 091031), based on HPLC–MS/MS, are sufficiently validated for the quantification of residues of sulfoxaflor at or above the LOQ of 0.01 mg/kg in high-water content, high-acid content, high-oil content and dry commodities. In addition, the extraction efficiency according to the extraction efficiency Technical Guideline (European Commission, 2022) was demonstrated in the framework of the peer review, by cross-validation with the method used in the metabolism studies (study 101569; Ireland, 2012).

EFSA concluded that for the crops under consideration in the present MRL applications (concerning high-water content matrices), sufficiently validated analytical methods are available.

1.1.5 | Storage stability of residues in plants

The storage stability of sulfoxaflor and the metabolite X11719474 in plants stored under frozen conditions was investigated in the framework of the EU pesticides peer review (EFSA, 2014a). It was demonstrated that sulfoxaflor and metabolite X11719474 were stable in matrices of high-water, high-acid, dry/high-starch and high-oil content for at least 22 months when stored at –20°C (EFSA, 2014a).

Furthermore, during a previous MRL application, it was demonstrated that both compounds are stable for at least up to 24.5 months in high-water, high-acid and high-oil commodities when stored at –20°C (EFSA, 2023a).

1.1.6 | Proposed residue definitions

Based on the metabolic pattern identified in metabolism studies, the results of hydrolysis studies, the toxicological relevance of sulfoxaflor and its metabolite X11719474 and the capabilities of enforcement analytical methods, the following residue definitions were proposed (EFSA, 2014a):

- residue definition for enforcement: sulfoxaflor (sum of isomers);
- residue definition for risk assessment: sum of sulfoxaflor and metabolite X11719474, expressed as sulfoxaflor.

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

EFSA concluded that these residue definitions are appropriate for the crops under assessment.

It is to be noted that the residue definition for monitoring and risk assessment derived for plant commodities by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) is parent sulfoxaflor only and does not include metabolite X11719474 for risk assessment (FAO, 2021).

1.2 | Magnitude of residues in plants

1.2.1 | Magnitude of residues in primary crops

In support of the intended indoor uses, the applicant submitted residue trials performed on sweet pepper/bell peppers and lettuces (open leaf varieties). The samples were analysed for parent sulfoxaflor and metabolite X11719474 achieving an individual LOQ of 0.01 mg/kg. Before analyses, the samples were stored under conditions for which the integrity had been demonstrated. According to the EMS, the methods of analysis used in the residue trials were sufficiently validated and fit for purpose (Belgium, 2023). In order to derive data according to the risk assessment residue definition, residues of metabolite X11719474 were expressed as parent sulfoxaflor by using a molecular weight conversion factor of 0.939. In cases where residues of metabolite were below the LOQ, the risk assessment residues were assumed to be present at 0.01 mg/kg, thus accounting for a worst-case situation.

The extraction efficiency of the method of analysis 091031 used on the residue trials in sweet pepper/bell peppers has been already proven (see Section 1.1.4). In lettuce trials, the extraction solvent acetonitrile/water, 2/1, v/v (following the QuEChERS method CAM-0157/001) was used. However, this is not considered comparable with the extraction systems used in the metabolism studies on lettuce, where an extraction with acetonitrile/water, 4/1, v/v followed by a second methanolic

base extraction was needed to extract > 70% TRR. Therefore, the extraction efficiency is not considered demonstrated for the method used in the residue trials on lettuces (European Commission, 2022), thus introducing additional uncertainty for the present assessment.

Okra/lady's fingers (EU greenhouse; foliar application): 1 × 48 g a.s./ha, BBCH 21–87, pre-harvest interval (PHI) 1 day

In support of the intended uses on okra/lady's fingers, the applicant provided eight indoor residue trials on sweet pepper/bell peppers. The applicant proposes to extrapolate residue data in pepper to okra/lady's fingers. Such an extrapolation is allowed by the EU Technical guidelines (European Commission, 2020a). Four of the trials were already evaluated by EFSA in the context of the pesticide peer review (monograph study CEMR-4702; Ireland, 2012) in support of an EU indoor GAP on peppers. All the trials were compliant with the intended GAP on okra/lady's fingers and performed in different countries in northern and southern Europe during the growing seasons of 2010 and 2011.

The number of trials is sufficient to derive an MRL proposal of 0.07 mg/kg for the intended use of sulfoxaflor in okra/lady's fingers. The residues of the metabolite X11719474 were below the LOQ in all samples (< 0.01 mg/kg).

Lamb's lettuces/corn salads, escaroles/broad-leaved endives, cresses and other sprouts and shoots, land cresses, roman rocket/rucola, red mustards, baby leaf crops (including brassica species), purslanes, chards/beet leaves, watercress, chervil, chives, parsley, sage, rosemary, thyme, basil and edible flowers, laurel/bay leaves and tarragon (EU greenhouse, foliar treatment): 1 × 24 g a.s./ha; PHI: 7 days.

In support of the intended indoor use of sulfoxaflor on the crops belonging to the group lettuces and salads (except lettuces), for purslanes, chards/beet leaves, watercresses and for herbs and edible flowers (except celery leaves), the applicant submitted eight GAP-compliant trials performed on lettuces (open leaf varieties). Extrapolation from open leaf varieties of lettuces to the above-mentioned crops is proposed by the applicant and is possible according to the technical guidelines (European Commission, 2020a). The trials were performed in indoor conditions in different countries in northern and southern Europe during the growing seasons of 2017 and 2019.

The number of trials is sufficient to derive an MRL proposal of 0.7 mg/kg for the intended use of sulfoxaflor. The residues of the metabolite X11719474 were below the LOQ in all samples (< 0.01 mg/kg).

1.2.2 | Magnitude of residues in rotational crops

According to the Commission Implementing Regulation (EU) 2022/686, only indoor uses of sulfoxaflor can be authorised in Europe. For the indoor uses under consideration, the applicant did not provide information on the production methods (type of substrate used, end-use/cycle of substrate) which would allow excluding occurrence of sulfoxaflor residues in rotational crops and therefore the magnitude of sulfoxaflor residues in rotational crops was further investigated in the present assessment.

The occurrence of sulfoxaflor residues in rotational crops was investigated in the framework of the EU pesticides peer review in rotational crop field studies performed at 24 g/ha and 48 g/ha of sulfoxaflor on bare soil. Additionally, non-EU rotational crop field trials performed at a significantly higher application rate (400 g/ha bare soil) were available (EFSA, 2014a). The details of the results of rotational crop studies are reported in Appendix B.1.2.2.

The available EU studies demonstrated that no significant residues of parent sulfoxaflor (residues below 0.01 mg/kg) are expected in succeeding crops (radishes, lettuces, spring onions and barley) planted in soil treated at 24 g/ha (1N for the application intended on some leaf vegetables, herbs and edible flowers) and 48 g/ha (1N for okra/lady's finger). Metabolite X11719474 was occasionally recovered above the LOQ in radish leaves, spring onions and barley straw at 30-day PBI when sulfoxaflor was applied at 24 g/ha and at all PBI when the substance was applied at 48g/ha with the highest resides measured at 30-day PBI (0.065 mg/kg radish leaves and 0.017 mg/kg spring onion and barley straw). The non-EU studies (performed at 8N for okra/lady's finger GAP) confirmed that parent sulfoxaflor is not present in rotational crops. However, significant residues of metabolite X11719474 were observed in crops at each PBI (maximum residue 0.03 mg/kg in radish roots (31-day PBI), 0.36 mg/kg in radish tops (31-day PBI) and 0.29 mg/kg in mustard green leaves (30-day PBI)). Higher residues were observed in feed items and therefore the EU pesticides peer review considered the residue data of X11719474 for the livestock dietary burden estimates (EFSA, 2014a). No MRLs were proposed for rotational cropping since residues in commodities for human consumption were expected to be insignificant under the EU critical GAP conditions.

The maximum annual application rate for the crops under consideration is comparable to the application rates tested in the EU rotational crop studies. Significant residues of parent sulfoxaflor are not expected in succeeding crops. However, since metabolite X11719474 was present above the LOQ in the leafy parts of some rotational crops, when new indoor uses are authorised at the national level, Member States might consider using plant production systems that exclude crop rotation in used substrates or setting risk mitigation measures to avoid potential residues of metabolite X11719474 in rotational crops.

1.2.3 | Magnitude of residues in processed commodities

Specific studies investigating the magnitude of sulfoxaflor residues in processed commodities are in principle not required because the individual contribution of residues from the crops under consideration in this assessment to the overall dietary exposure is below 10% of the ADI (European Commission, 1997d).

1.2.4 | Proposed MRLs

The available data are considered sufficient to derive MRL proposals as well as risk assessment values for the commodities under evaluation. In Section 3 EFSA assessed whether residues on these crops resulting from the intended uses are likely to pose a consumer health risk.

2 | RESIDUES IN LIVESTOCK

Not assessed, as the crops under assessment are not considered as a relevant fed item to livestock according to the current guidance (OECD, 2013).

3 | CONSUMER RISK ASSESSMENT

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

The toxicological reference values for sulfoxaflor used in the risk assessment (i.e. ADI of 0.04 mg/kg bw per day and ARfD of 0.25 mg/kg bw) were derived in the framework of the EU pesticides peer review (European Commission, 2015). The metabolite included in the risk assessment residue definition was considered of similar toxicity to that of the parent compound (EFSA, 2014a).

The input values used in the exposure calculations are summarised in Appendix D.1.

Short-term (acute) dietary risk assessment

The short-term exposure assessment was performed in accordance with the internationally agreed methodology and focused on the commodities assessed in this application (FAO, 2016). The calculations were based on the highest residue (HR) derived from supervised field trials.

The short-term exposure did not exceed the ARfD for any of the crops assessed in this application. The highest acute consumer exposure was calculated for escaroles (7.4% of ARfD) followed by chards/beet leaves (2.9% of the ARfD). For the remaining commodities the calculated acute exposure was ≤ 1% of ARfD. It is noted that no consumption data was available for okra/lady's fingers, land cress, baby leaf crops (no consumption for both adults and children), red mustards, purslanes and tarragon (no consumption for children). Since exposure calculations performed with the major crops representing the commodity groups of these minor commodities indicate no acute exposure concerns, it is unlikely that acute intake concerns will be associated with the consumption of okra/lady's fingers, land cress, baby leaf crops, red mustards, purslanes and tarragon (Appendix B.3).

Long-term (chronic) dietary risk assessment

The long-term exposure assessment was performed taking into account the STMR values derived for the commodities assessed in this application. For the remaining commodities covered by the MRL legislation, the existing EU MRLs and the corresponding STMR values derived in the EU pesticide peer review, previous MRL applications and JMPR evaluations were selected as input values (EFSA, 2014a, 2017b; FAO, 2012, 2014, 2015). Additionally, CXL proposals which were evaluated by the JMPR and supported for inclusion in the EU MRL legislation (CAC, 2022; EFSA, 2019c, 2022b; FAO, 2019, 2021) and the crops for which MRL proposals were derived in recent EFSA assessments (EFSA, 2019a, 2022a, 2023a) which so far have not been implemented in the EU MRL legislation, were also included in the calculations.

For those commodities for which the existing EU MRL is set based on CXL, the residue data according to the EU risk assessment residue definition are not available.[11] However, this deviation is considered not to have a practical implication for the consumer risk assessment (EFSA, 2022a).

The crops on which no uses have been reported in the pesticide peer review or the subsequent EFSA outputs were not included in the exposure calculation.

The highest estimated long-term dietary intake accounted for 37% of the ADI[12] (NL toddler diet). The contributions of the commodities assessed in the present MRL application to the overall long-term exposure were low with escaroles contributing to 0.24% of the ADI (NL toddler) and the remaining commodities contributing individually to less than 0.1% of the ADI.

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

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

[11]The risk assessment residue definition derived by the JMPR is 'sulfoxaflor', both in commodities of plant and animal origin.

[12]Provided that MRL proposals assessed recently by EFSA (EFSA, 2019c, 2022a, 2023a) and the CXL proposals referred to in EFSA scientific report (EFSA, 2019c, FAO, 2019, 2021) and currently under assessment (EFSA, 2022b) for sulfoxaflor will be adopted in the EU MRL legislation.

4 | CONCLUSION AND RECOMMENDATIONS

The data submitted in support of this MRL application were found to be sufficient to derive an MRL proposal for all crops under consideration: okra/lady's fingers, lamb's lettuce/corn salads, escaroles/broad-leaved endives, cress and other sprouts and shoots, land cress, roman rocket/rucola, red mustards, baby leaf crops (including brassica species), purslanes, chards/beet leaves, watercress, chervil, chives, parsley, sage, rosemary, thyme, basil and edible flowers, laurel/bay leaves and tarragon.

EFSA concluded that the intended indoor uses for sulfoxaflor on the crops under consideration will not result in a 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.4.

ABBREVIATIONS

a.s.	active substance
ADI	acceptable daily intake
AR	applied radioactivity
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CAC	Codex Alimentarius Commission
CCPR	Codex Committee on Pesticide Residues
cGAP	critical GAP
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)
EC	emulsifiable concentrate
EMS	evaluating Member State
eq	residue expressed as a.s. equivalent
EURL	EU Reference Laboratory (former Community Reference Laboratory (CRL))
FAO	Food and Agriculture Organization of the United Nations
GAP	Good Agricultural Practice
GLP	Good Laboratory 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
ILV	independent laboratory validation
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LOD	limit of detection
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
MW	molecular weight
NEU	northern Europe
OECD	Organisation for Economic Co-operation and Development
PBI	plant back interval
PF	processing factor
PHI	pre-harvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
PROFile	(EFSA) Pesticide Residues Overview File
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
RA	risk assessment
RAC	raw agricultural commodity
RD	residue definition
RMS	rapporteur Member State
RPF	relative potency factor
SEU	southern Europe
STMR	supervised trials median residue

TMDI	theoretical maximum daily intake
TRR	total radioactive residue
WHO	World Health Organization

ACKNOWLEDGEMENTS

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

CONFLICT OF INTEREST

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

REQUESTOR

European Commission

QUESTION NUMBER

EFSA-Q-2023-00038

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How to cite this article: EFSA (European Food Safety Authority), Bellisai, G., Bernasconi, G., Cabrera, L. C., Castellan, I., del Aguila, M., Ferreira, L., Giner Santonja, G., Greco, L., Jarrah, S., Leuschner, R., Miron, I., Nave, S., Pedersen, R., Reich, H., Ruocco, S., Santos, M., Scarlato, A. P., Szot, M., … Verani, A. (2023). Modification of the existing maximum residue levels for sulfoxaflor in various commodities. *EFSA Journal*, *21*(12), e8481. https://doi.org/10.2903/j.efsa.2023.8481

APPENDIX A

Summary of intended GAP triggering the amendment of existing EU MRLs

				Preparation		Application				Application rate per treatment					
Crop and/or situation	NEU, SEU, MS or country	F G or I[a]	Pests or group of pests controlled	Type[b]	Conc. a.s.	Method kind	Range of growth stages and 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	PHI (days)[d]	Remarks
Okra/lady's fingers	EU	G	Aphids – Aphididae - 1APHIF Whitefly TRIAVA	SC	120 g/L	Foliar	21–87	1	n.a.	[1.2–2.4]–[2.4–4.8]	1000–2000	24–48 (9.6–19.2 LWA)	g a.s / ha	1	Aphids: 1–2 applications of 24 g a.s./ha. Two applications would be with a minimum of 7 days interval. Whiteflies: Either 2 applications of 24 g a.s./ha with a minimum 7 days interval or only 1 application of 48 g a.s./ha A conversion factor (Cf)[e] of 2.5 from hectare ground to hectare leaf wall area is used
Lamb's lettuces/ corn salads	EU	G	Aphids – Aphididae - 1APHIF	SC	120 g/L	foliar	12–49	1	n.a.	2.4–8.0	300–1000	24	g a.s/ ha	7	
Escaroles/ broad-leaved endives	EU	G	Aphids – Aphididae - 1APHIF	SC	120 g/L	Foliar	12–49	1	n.a.	2.4–8.0	300–1000	24	g a.s/ ha	7	
Cresses and other sprouts and shoots	EU	G	Aphids – Aphididae - 1APHIF	SC	120 g/L	Foliar	12–49	1	n.a.	2.4–8.0	300–1000	24	g a.s/ ha	7	
Land cresses	EU	G	Aphids – Aphididae - 1APHIF	SC	120 g/L	Foliar	12–49	1	n.a.	2.4–8.0	300–1000	24	g a.s/ ha	7	
Roman rocket/ rucola	EU	G	Aphids – Aphididae - 1APHIF	SC	120 g/L	Foliar	12–49	1	n.a.	2.4–8.0	300–1000	24	g a.s/ ha	7	

(Continues)

(Continued)

				Preparation		Application				Application rate per treatment					
Crop and/or situation	NEU, SEU, MS or country	F G or I[a]	Pests or group of pests controlled	Type[b]	Conc. a.s.	Method kind	Range of growth stages and 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	PHI (days)[d]	Remarks
Red mustards	EU	G	Aphids – Aphididae - 1APHIF	SC	120 g/L	Foliar	12–49	1	n.a.	2.4–8.0	300–1000	24	g a.s/ ha	7	
Baby leaf crops (including brassica species)	EU	G	Aphids – Aphididae - 1APHIF	SC	120 g/L	Foliar	12–49	1	n.a.	2.4–8.0	300–1000	24	g a.s/ ha	7	
Purslanes	EU	G	Aphids – Aphididae - 1APHIF	SC	120 g/L	Foliar	12–49	1	n.a.	2.4–8.0	300–1000	24	g a.s/ ha	7	
Chards/beet leaves	EU	G	Aphids – Aphididae - 1APHIF	SC	120 g/L	Foliar	12–49	1	n.a.	2.4–8.0	300–1000	24	g a.s/ ha	7	
Watercress	EU	G	Aphids – Aphididae - 1APHIF	SC	120 g/L	Foliar	12–49	1	n.a.	2.4–8.0	300–1000	24	g a.s/ ha	7	
Chervil Chives Parsley Sage Rosemary Thyme Basil and edible flowers Laurel/bay leaves Tarragon	EU	G	Aphids – Aphididae - 1APHIF	SC	120 g/L	Foliar	12–49	1	n.a.	2.4–8.0	300–1000	24	g a.s/ ha	7	

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

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

[b]CropLife International Technical Monograph no 2, 7th Edition. Revised March 2017. Catalogue of pesticide formulation types and international coding system.

[c]Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3–8263–3152-4), including, where relevant, information on season at time of application.

[d]PHI – minimum pre-harvest interval.

[e]Cf: ratio ha LWA/ha ground surface = (2 × H)/E where H = treated height of the plants (in m), E = distance between 2 parallel rows (in m) and 2 for both sides of the hedge.

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	Crop(s)	Application(s)	Sampling (DAT)	Comment/source
	Fruit crops	Tomato	Foliar, 4 × (200) + (200) + (125) + (75) g/ha	Immature plant (14 DAT_1; 14 DAT_2), fruit (1, 7, 14 DALA), vines (14 DALA)	Radiolabelled active substance: [^{14}C-pyridine]-sulfoxaflor at 1:1 diastereomer mixture. Ratio of isomers in the individual diastereomer unknown (EFSA, 2014a)
			Soil, 2 × 225 g/ha	Immature plant (14 DAT_1), fruit (14, 21, 28 DALA), vines (28 DALA)	
	Leafy crops	Lettuces	Foliar, 3 × 200 g/ha	Immature plant (14 DAT_1), mature plant (7 DALA)	
			Soil, 2 × 225 g/ha	Immature plant (14 DAT_1), mature plant (14 DALA)	
	Cereals/grass	Rice	Foliar, 3 × (225) + (225) + (150) g/ha	Immature plant (14 DAT_1), grain, straw hulls (at maturity)	
			Soil, 1 × 400 g/ha, BBCH 13–14	Immature plant (14, 28 DAT), grain, straw, hulls (at maturity)	
	Pulses/oilseeds	Snap pea	Foliar, 3 × 200 g/ha	Immature plant (14 DAT_1, 14 DAT_2), pods, vines (at maturity)	
			Soil, 1 × 450 g/ha	Immature plant (14 DAT_1), pods, vines (at maturity)	

Rotational crops (available studies)	Crop groups	Crop(s)	Application(s)	PBI (DAT)	Comment/source
	Root/tuber crops	Radish	Bare soil, 1 × 600 g/ha	30, 120, 365	Radiolabelled active substance: [^{14}C-pyridine]-sulfoxaflor at 1:1 diastereomer mixture. Ratio of isomers in the individual diastereomer unknown (EFSA, 2014a)
	Leafy crops	Lettuces	Bare soil, 1 × 600 g/ha	30, 120, 365	
	Cereal (small grain)	Wheat	Bare soil, 1 × 600 g/ha	30, 120, 365	

Processed commodities (hydrolysis study)	Conditions	Stable?	Comment/Source
	Pasteurisation (20 min, 90°C, pH 4)	Yes	Radiolabelled active substance: [^{14}C-pyridine]-sulfoxaflor and [^{14}C-pyridine]-X11719474 (EFSA, 2014a)
	Baking, brewing and boiling (60 min, 100°C, pH 5)	Yes	
	Sterilisation (20 min, 120°C, pH 6)	Yes	

Can a general residue definition be proposed for primary crops?	yes	EFSA, 2014a
Rotational crop and primary crop metabolism similar?	yes	EFSA, 2014a
Residue pattern in processed commodities similar to residue pattern in raw commodities?	yes	EFSA, 2014a
Plant residue definition for monitoring (RD-Mo)	Sulfoxaflor (sum of isomers)	
Plant residue definition for risk assessment (RD-RA)	Sum of sulfoxaflor and metabolite X11719474, expressed as sulfoxaflor	
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)	Matrices with high water content, high oil content, high acid content and dry matrices: HPLC–MS/MS, LOQ 0.01 mg/kg, ILV available – DFG S19 applicable (EFSA, 2014a); QuEChERS EN 15662 (2 mass transitions) validated for sulfoxaflor and X11719474 in difficult to analyse matrix: coffee beans, hops, tea and tobacco: LC–MS/MS, LOQ 0.01 mg/kg, ILV available for coffee beans, tea and hops (EFSA, 2023a).	

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

B.1.1.2 | Stability of residues in plants

Plant products (available studies)	Category	Commodity	T (°C)	Stability period		Compounds covered	Comment/source
				Value	Unit		
	High-water content	Peaches	–20	22	Months	Sulfloxaflor, X11719474	EFSA (2014a)
		Globe artichokes	–20	735	Days	Sulfoxaflor, X11719474, X117121061	The study was terminated after 735 days (24.5 months) (EFSA, 2023a)
		Asparagus	–20	304	Days	Sulfoxaflor, X11719474, X117121061	The study was terminated after 304 days (EFSA, 2023a)
	High-oil content	Soyabeans	–20	22	Months	Sulfloxaflor, X11719474	EFSA (2014a)
		Sunflower seeds	–20	736	Days	Sulfoxaflor, X11719474, X117121061	The study was terminated after 736 days (24.5 months) (EFSA, 2023a)
	Dry/high starch	Wheat grain	–20	22	Months	Sulfloxaflor, X11719474	EFSA (2014a)
	High-acid content	Oranges	–20	22	Months	Sulfloxaflor, X11719474	EFSA (2014a)
		Raspberry Blackberry	–20	549	Days	Sulfoxaflor, X11719474, X117121061	The study was terminated after 549 days (ca. 20 months) (EFSA, 2023a)
		Blueberries	–20	756	Days	Sulfoxaflor, X11719474, X117121061	The study was terminated after 756 days (25 months) (EFSA, 2023a)
	Other	Sunflower seeds, meal	–20	685	Days	Sulfoxaflor, X11719474, X117121061	The study was terminated after 685 days (EFSA, 2023a)
		Sunflower seeds, refined oil	–20	696	Days	Sulfoxaflor, X11719474, X117121061	The study was terminated after 696 days (EFSA, 2023a)

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]
Okra/lady's fingers	EU	**Mo: 3** × 0.017; 2 × 0.020; 0.021; 2 × 0.035 **RA[e]:** 3 × 0.026; 2 × 0.029; 0.030; 2 × 0.044 **CFs:** 3 × 1.53; 2 × 1.45; 1.42; 2 × 1.26	Residue trials on sweet peppers/bell peppers compliant with GAP. In accordance with SANTE/2019/12752 (European Commission, 2020a), trials on pepper can be used to support uses on okra/lady's fingers. Residues of X11719474 were below the LOQ of 0.01 mg/kg in all the residue trials	0.07	**Mo:** 0.035 **RA:** 0.044	**Mo:** 0.02 **RA:** 0.03	1.45
Lettuces and salad plants (except lettuces); watercresses; purslanes; chard/beet leaves; herbs and edible flowers (except celery leaves)	EU	**Mo:** < 0.01, 0.024, 0.03, 0.034, 0.05, 0.108, 0.15, 0.452 **RA[e]:** < 0.019, 0.033, 0.039, 0.043, 0.059, 0.117, 0.159, 0.461 **CFs:** 1; 1.38; 1.15; 1.26; 1.18; 1.08; 1.06; 1.02	Residue trials on lettuces (open leaf varieties) compliant with GAP. In accordance with SANTE/2019/12752 (European Commission, 2020a), trials on lettuce (open leaf varieties) can be used to support the intended uses on lettuces and salad plants (except lettuces), watercresses, purslanes, chard/beet leaves and herbs and edible flowers (except celery leaves). Residues of X11719474 were below the LOQ of 0.01 mg/kg in all the residue trials	0.70	**Mo:** 0.45 **RA:** 0.46	**Mo:** 0.04 **RA:** 0.05	1.22

Abbreviations: GAP, Good Agricultural Practice; LOQ, limit of quantification; Mo, monitoring; MRL, maximum residue level; RA, risk assessment.

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

[a]NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, EU: indoor EU trials or Country code: if non-EU trials.

[b]Highest residue. The highest residue for risk assessment refers to the whole commodity and not to the edible portion.

[c]Supervised trials median residue. The median residue for risk assessment refers to the whole commodity and not to the edible portion.

[d]Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.

[e]Risk assessment residue definition: sum of sulfoxaflor and metabolite X11719474, expressed as sulfoxaflor. Metabolite X11719474 were added to the sulfoxaflor residues applying a conversion factor for MW of 0.939 (the molecular weight of Sulfoxaflor is 277.3 g/mol and 295.3 g/mol for X11719474).

B.1.2.2 | Residues in rotational crops

Residues in rotational and succeeding crops expected based on confined rotational crop study?	Yes (metabolite X11719474)	In the confined rotational crop study performed in radish, lettuces and wheat (25N rate of the intended GAPs on some leaf vegetables, herbs and edible flowers and 12.5N rate of the intended GAPs on okra/lady's finger), X11719474 was the most abundant metabolite observed in all crops at all PBIs (from 0.011 mg/kg in 365-day PBI in wheat grain to 1.34 mg/kg in 120-day PBI in wheat straw). In general, residues declined with increasing PBIs. Uptake of X11719474 from the soil might occur. Residues of sulfoxaflor are not expected in rotational crops (EFSA, 2014a).
Residues in rotational and succeeding crops expected based on field rotational crop study?	Yes	Residues of parent sulfoxaflor are not expected to occur at significant levels in rotational crops according to available field studies. Significant residues of X11719474 were found, mostly in the leafy parts of the crops in rotation, particularly in feed items. EU studies at about 24 g/ha, rotational crops of radishes (root, tops), lettuces, spring onions, barley (grain, straw): residues of metabolite X11719474 < LOQ at each PBI, except one sample of radish top (0.019 mg/kg, 30-day PBI) and one sample of barley straw (0.018 mg/kg, 30-day PBI). EU studies at about 48 g/ha, rotational crops of radishes (root, tops), lettuces, spring onions, barley (grain, straw): residues of X11719474 < LOQ at each PBI in radish root, leaf lettuce and barley grain; detectable residues of X11719474 > LOQ at each PBI in radish tops and spring onion and only at 30-day PBI in barley straw. Highest residues measured at 30-day PBI (radish tops: HR 0.065 mg/kg and STMR 0.013 mg/kg; spring onions and barley straw: HR 0.017 mg/kg and STMR of 0.01 mg/kg) (EFSA, 2014a). Non-EU study at about 400 g/ha, rotational crops of radishes, mustard green, sorghum, grass: significant residues of metabolite X11719474 observed at each PBI. In general, residues declined with increasing PBI. Maximum concentration of X11719474 residues in radish roots (0.03 mg/kg, 31-day PBI), radish tops (0.36 mg/kg, 31-day PBI), mustard green leaves (0.29 mg/kg, 30-day PBI), sorghum forage (0.044 mg/kg, 180-day PBI), sorghum stover (0.012 mg/kg, 180-day PBI), grass forage (0.054 mg/kg, 31-day PBI) and grass hay (0.081 mg/kg, 180-day PBI). Sulfoxaflor was not quantified (< 0.01 mg/kg) in all rotated crops at all PBIs, except for one sample of radish tops (0.02 mg/kg at 124 days, but corresponding control sample positive) (EFSA, 2014a)

B.1.2.3 | Processing factors

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

B.2 | RESIDUES IN LIVESTOCK

Not relevant

B.3 | CONSUMER RISK ASSESSMENT

ARfD	0.25 mg/kg bw (European Commission, 2015)
Highest IESTI, according to EFSA PRIMo	**Contribution of crops assessed:** Escaroles/broad-leaved endives: 7.4 % of ARfD Chards/beet leaves: 2.9% of ARfD Other commodities under consideration: exposure individually less than 1% of the ARfD
Assumptions made for the calculations	The calculation is based on the highest residue levels expected in raw agricultural commodities according to the residue definition for risk assessment. No consumption data was available for okra/lady's fingers, land cress, baby leaf crops (no consumption for adults and children), red mustards, purslanes and tarragon (no consumption for children). Since exposure calculations performed with the major crops representing the commodity groups of these minor commodities indicate no acute exposure concerns, it is unlikely that acute intake concerns will be associated with the consumption of okra/lady's fingers, land cress, baby leaf crops, red mustards, purslanes and tarragon. Calculations performed with PRIMo revision 3.1

ADI	0.04 mg/kg bw per day (European Commission, 2015)
Highest IEDI, according to EFSA PRIMo	37% ADI (NL toddler) **Contribution of crops assessed:** Escaroles/broad-leaved endives: 0.24% of ADI (NL toddler diet) Other commodities under consideration: exposure individually less than 0.1% of the ADI
Assumptions made for the calculations	The calculation is based on the median residue levels (STMR values) derived from submitted residue trials for the intended uses on the raw agricultural commodities under consideration according to the risk assessment residue definition. For the remaining commodities covered by the MRL Legislation, the STMR values derived in the EU pesticide peer review, previous MRL applications and JMPR evaluations were selected as input values (EFSA, 2014a, 2017b; FAO, 2012, 2014, 2015). Additionally, CXL proposals which were evaluated by the JMPR and supported for inclusion in the EU MRL legislation (CAC,

2022; FAO, 2019, 2021; EFSA, 2019c, 2022b) and the crops for which MRL proposals were derived in recent EFSA assessments (EFSA, 2019b, 2022a, 2023a)) and have not been implemented in the EU MRL legislation yet, were also included in the calculations.
For those commodities for which the existing EU MRLs are set based on CXLs, the residue data according to the EU risk assessment residue definition are not available (i.e., data refer to parent sulfoxaflor only). However, this deviation is considered not to have a practical implication for the consumer risk assessment.

The contributions of commodities where no GAP was considered in the framework of the EU pesticides peer review or in subsequent EFSA outputs were not included in the calculation.

Calculations performed with PRIMo revision 3.1

ARfD: acute reference dose; bw: body weight; IESTI: international estimated short-term intake; PRIMo: (EFSA) Pesticide Residues Intake Model; ADI: acceptable daily intake; IEDI: international estimated daily intake; MRL: maximum residue level; STMR: supervised trials median residue; CXL: codex maximum residue limit.

B.4 | RECOMMENDED MRLS

Code[a]	Commodity	ExistingEU MRL (mg/kg)	ProposedEU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Sulfoxaflor (sum of isomers)				
0231040	Okra/lady's fingers	0.01*	0.07	The submitted data are sufficient to derive MRL proposals for the intended EU indoor use. Risk for consumers is unlikely
0251010	Lamb's lettuces/corn salads	0.01*	0.7	
0251030	Escaroles/broad-leaved endives	0.01*	0.7	
0251040	Cresses and other sprouts and shoots	0.01*	0.7	
0251050	Land cresses	0.01*	0.7	
0251060	Roman rocket/rucola	0.01*	0.7	
0251070	Red mustards	0.01*	0.7	
0251080	Baby leaf crops (including brassica species)	0.01*	0.7	
0252020	Purslanes	0.01*	0.7	
0252030	Chards/beet leaves	0.01*	0.7	
0254000	Watercresses	0.01*	0.7	
0256010	Chervil	0.02*	0.7	
0256020	Chives	0.02*	0.7	
0256040	Parsley	0.02*	0.7	
0256050	Sage	0.02*	0.7	
0256060	Rosemary	0.02*	0.7	
0256070	Thyme	0.02*	0.7	
0256080	Basil and edible flowers	0.02*	0.7	
0256090	Laurel/bay leaves	0.02*	0.7	
0256100	Tarragon	0.02*	0.7	

Abbreviations: GAP, Good Agricultural Practice; MRL, maximum residue level.

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

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

APPENDIX C

Pesticide Residue Intake Model (PRIMo)

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

sulfoxaflor

LOQs (mg/kg) range from: 0.01 to: 0.05

Toxicological reference values

ADI (mg/kg bw/day):	0.04	ARfD (mg/kg bw):	0.25
Source of ADI:	EC, 2015	Source of ARfD:	EC, 2015
Year of evaluation:		Year of evaluation:	

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 : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

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)	Exposure resulting from: commodities not under assessment (in % of ADI)
37%	NL toddler	14.90	21%	Milk: Cattle	3%	Apples	2%	Spinaches	0.0%	37%
20%	UK infant	8.07	14%	Milk: Cattle	2%	Rice	1.0%	Oranges	0.0%	20%
20%	DE child	8.04	7%	Milk: Cattle	3%	Apples	3%	Oranges	0.0%	20%
19%	FR toddler 2 3 yr	7.41	10%	Milk: Cattle	2%	Rice	1%	Oranges	0.0%	19%
18%	NL child	7.18	9%	Milk: Cattle	2%	Apples	1%	Oranges	0.0%	18%
17%	FR child 3 15 yr	6.95	8%	Milk: Cattle	3%	Oranges	2%	Rice	0.0%	17%
15%	UK toddler	5.86	7%	Milk: Cattle	2%	Rice	1%	Oranges	0.0%	15%
14%	GEMS/Food G10	5.65	5%	Rice	2%	Poultry: Muscle/meat	2%	Milk: Cattle	0.0%	14%
14%	ES child	5.48	4%	Milk: Cattle	2%	Poultry: Muscle/meat	2%	Rice	0.0%	14%
12%	GEMS/Food G06	4.96	6%	Rice	1.0%	Poultry: Muscle/meat	0.9%	Milk: Cattle	0.0%	12%
12%	SE general	4.64	4%	Milk: Cattle	2%	Bovine: Muscle/meat	2%	Rice	0.0%	12%
11%	GEMS/Food G07	4.40	2%	Milk: Cattle	2%	Poultry: Muscle/meat	1%	Rice	0.0%	11%
11%	DK child	4.29	4%	Milk: Cattle	1%	Rice	0.9%	Swine: Muscle/meat	0.0%	11%
10%	RO general	4.05	4%	Milk: Cattle	1%	Poultry: Muscle/meat	0.9%	Rice	0.0%	10%
10%	GEMS/Food G15	3.96	2%	Milk: Cattle	2%	Poultry: Muscle/meat	1%	Rice	0.0%	10%
10%	GEMS/Food G11	3.94	3%	Milk: Cattle	1%	Poultry: Muscle/meat	1%	Rice	0.0%	10%
9%	DE women 14-50 yr	3.79	4%	Milk: Cattle	1%	Oranges	0.7%	Apples	0.0%	9%
9%	GEMS/Food G08	3.68	2%	Milk: Cattle	1%	Poultry: Muscle/meat	1%	Rice	0.0%	9%
9%	DE general	3.64	4%	Milk: Cattle	1%	Oranges	0.7%	Apples	0.0%	9%
9%	FR infant	3.59	6%	Milk: Cattle	0.9%	Spinaches	0.5%	Apples	0.0%	9%
8%	NL general	3.23	3%	Milk: Cattle	0.8%	Oranges	0.6%	Poultry: Muscle/meat	0.0%	8%
8%	IE adult	3.20	2%	Milk: Cattle	0.9%	Rice	0.8%	Oranges	0.0%	8%
8%	ES adult	3.12	2%	Milk: Cattle	1%	Poultry: Muscle/meat	1.0%	Oranges	0.0%	8%
6%	PT general	2.44	3%	Rice	0.9%	Wine grapes	0.5%	Oranges	0.0%	6%
6%	FR adult	2.34	2%	Milk: Cattle	0.8%	Wine grapes	0.6%	Rice	0.0%	6%
5%	UK adult	2.07	1%	Rice	1%	Milk: Cattle	0.7%	Poultry: Muscle/meat	0.0%	5%
5%	UK vegetarian	1.95	1%	Rice	1%	Milk: Cattle	0.7%	Oranges	0.0%	5%
5%	DK adult	1.94	2%	Milk: Cattle	0.4%	Poultry: Muscle/meat	0.4%	Swine: Muscle/meat	0.0%	5%
5%	LT adult	1.86	1%	Milk: Cattle	0.8%	Rice	0.5%	Apples	0.0%	5%
5%	FI 3 yr	1.83	2%	Rice	0.3%	Mandarins	0.3%	Apples	0.0%	5%
4%	FI 6 yr	1.46	2%	Rice	0.2%	Mandarins	0.2%	Potatoes	0.0%	4%
3%	IT toddler	1.39	0.7%	Rice	0.5%	Wheat	0.4%	Lettuces	0.0%	3%
3%	IT adult	1.31	0.7%	Rice	0.6%	Lettuces	0.3%	Spinaches	0.0%	3%
3%	IE child	1.27	1%	Milk: Cattle	1%	Rice	0.2%	Poultry: Muscle/meat	0.0%	3%
3%	FI adult	1.05	0.6%	Coffee beans	0.5%	Rice	0.3%	Oranges	0.0%	3%
2%	PL general	0.62	0.6%	Apples	0.2%	Potatoes	0.1%	Table grapes	0.0%	2%

Conclusion:

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

The long-term intake of residues of sulfoxaflor 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

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
58%	Table grapes	2 / 2	146
54%	Spinaches	6 / 6	136
44%	Lettuces	4 / 2.87	109
30%	Melons	0.5 / 0.5	76
27%	Oranges	0.8 / 0.51	68
27%	Broccoli	3 / 1.6	67
26%	Chinese cabbages/pe-tsai	2 / 2	64
24%	Watermelons	0.5 / 0.5	61
22%	Celeries	1.5 / 1.5	56
22%	Pears	0.4 / 0.4	55
19%	Peaches	0.5 / 0.5	48
17%	Apples	0.4 / 0.4	43
13%	Cucumbers	0.5 / 0.5	33
12%	Mandarins	0.8 / 0.51	30
9%	Courgettes	0.5 / 0.5	23

Expand/collapse list

Results for adults

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
27%	Table grapes	2 / 2	68
20%	Chinese cabbages/pe-tsai	2 / 2	51
19%	Wine grapes	2 / 2	47
15%	Broccoli	3 / 1.6	38
14%	Lettuces	4 / 2.87	35
10%	Spinaches	6 / 6	24
10%	Celeries	1.5 / 1.5	24
8%	Watermelons	0.5 / 0.5	20
8%	Melons	0.5 / 0.5	20
6%	Oranges	0.8 / 0.51	16
6%	Cucumbers	0.5 / 0.5	14
5%	Rice	1.5 / 1.5	13
5%	Cherries (sweet)	1.5 / 1.24	12
5%	Pears	0.4 / 0.4	12
5%	Blueberries	2 / 1.28	12

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

Processed commodities

Results for children

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
50%	Broccoli / boiled	3 / 1.6	126
33%	Spinaches / frozen; boiled	6 / 6	83
18%	Pumpkins / boiled	0.5 / 0.5	44
12%	Escaroles/broad-leaved endives / boiled	0.7 / 0.46	30
7%	Courgettes / boiled	0.5 / 0.5	18
6%	Oranges / juice	0.8 / 0.3	16
6%	Chards/beet leaves / boiled	0.7 / 0.46	14
5%	Peaches / canned	0.5 / 0.5	13
5%	Kales / boiled	1 / 0.43	12
5%	Gherkins / pickled	0.5 / 0.5	11
4%	Currants (red, black and white) / juice	2 / 0.39	11
4%	Rice / milling (polishing)	1.5 / 0.6	9.2
3%	Cauliflowers / boiled	0.1 / 0.09	6.3
2%	Wine grapes / juice	2 / 0.14	6.1
2%	Apples / juice	0.4 / 0.11	6.0

Expand/collapse list

Results for adults

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
20%	Celeries / boiled	1.5 / 1.5	51
20%	Spinaches / frozen; boiled	6 / 6	50
15%	Broccoli / boiled	3 / 1.6	39
11%	Pumpkins / boiled	0.5 / 0.5	28
8%	Wine grapes / wine	2 / 2	19
5%	Table grapes / raisins	2 / 9.4	12
5%	Courgettes / boiled	0.5 / 0.5	11
4%	Escaroles/broad-leaved endives / boiled	0.7 / 0.46	9.4
2%	Rice / milling (polishing)	1.5 / 0.6	5.8
2%	Chards/beet leaves / boiled	0.7 / 0.46	5.8
2%	Currants (red, black and white) / juice	2 / 0.39	5.0
2%	Oranges / juice	0.8 / 0.3	4.6
2%	Peaches / canned	0.5 / 0.5	4.1
1%	Cauliflowers / boiled	0.1 / 0.09	3.7
1%	Apples / juice	0.4 / 0.11	3.7

Conclusion:

No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short term intake of residues of sulfoxaflor is unlikely to present a public health risk.

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

APPENDIX D

Input values for the exposure calculations

D.1 | CONSUMER RISK ASSESSMENT

Commodity	Existing/ proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value[a] (mg/kg)	Comment	Input value[a] (mg/kg)	Comment[b]
Risk assessment residue definition: sum of sulfoxaflor and metabolite X11719474, expressed as sulfoxaflor						
Grapefruits	0.15	Existing MRL (FAO, 2015)	0.01	STMR-RAC[c] (0.013) × CF (1.16) (EFSA, 2019b)	0.08	HR-RAC[c] (0.066) × CF (1.16) (EFSA, 2019b)
Oranges	0.8	Existing MRL (FAO, 2015)	0.3	STMR-RAC[c] (0.26) × CF (1.16) (EFSA, 2019b)	0.51	HR-RAC[c] (0.44) × CF (1.16) (EFSA, 2019b)
Lemons	0.4	Existing MRL (FAO, 2015)	0.04	STMR-RAC[c] (0.038) × CF (1.16) (EFSA, 2019b)	0.2	HR-RAC[c] (0.17) × CF (1.16) (EFSA, 2019b)
Limes	0.5	Proposed MRL (EFSA, 2019b[d])	0.08	STMR-RAC (0.070) × CF (1.16)	0.35	HR-RAC (0.3) × CF (1.16)
Mandarins	0.8	Existing MRL (FAO, 2015)	0.3	STMR-RAC[c] (0.013) × CF (1.16) (EFSA, 2019b)	0.51	HR-RAC[c] (0.44) × CF (1.16) (EFSA, 2019b)
Almonds	0.03	Proposed MRL (FAO, 2019[d])	0.01	STMR-RAC[e]	0.02	HR-RAC[e]
Brazil nuts	0.03	Proposed MRL (FAO, 2019[d])	0.01	STMR-RAC[e]	0.02	HR-RAC[e]
Cashew nuts	0.03	Proposed MRL (FAO, 2019[d])	0.01	STMR-RAC[e]	0.02	HR-RAC[e]
Chestnuts	0.03	Proposed MRL (FAO, 2019[d])	0.01	STMR-RAC[e]	0.02	HR-RAC[e]
Coconuts	0.03	Proposed MRL (FAO, 2019[d])	0.01	STMR-RAC[e]	0.02	HR-RAC[e]
Hazelnuts/ cobnuts	0.03	Proposed MRL (FAO, 2019[d])	0.01	STMR-RAC[e]	0.02	HR-RAC[e]
Macadamia	0.03	Proposed MRL (FAO, 2019[d])	0.01	STMR-RAC[e]	0.02	HR-RAC[e]
Pecans	0.03	Proposed MRL (FAO, 2019[d])	0.01	STMR-RAC[e]	0.02	HR-RAC[e]
Pine nut kernels	0.03	Proposed MRL (FAO, 2019[d])	0.01	STMR-RAC[e]	0.02	HR-RAC[e]
Pistachios	0.03	Proposed MRL (FAO, 2019[d])	0.01	STMR-RAC[e]	0.02	HR-RAC[e]
Walnuts	0.03	Proposed MRL (FAO, 2019[d])	0.01	STMR-RAC[e]	0.02	HR-RAC[e]
Other tree nuts	0.03	Proposed MRL (FAO, 2019[d])	0.01	STMR-RAC[e]		
Apples	0.4	Existing MRL (EFSA, 2014a)	0.11	STMR-RAC	0.4	MRL
Pears	0.4	Existing MRL (EFSA, 2014a)	0.11	STMR-RAC	0.4	MRL
Quinces	0.3	Existing MRL (FAO, 2015)	0.07	STMR-RAC[e]	0.23	HR-RAC[e]
Medlar	0.3	Existing MRL (FAO, 2015)	0.07	STMR-RAC[e]	0.23	HR-RAC[e]
Loquats/Japanese medlars	0.3	Existing MRL (FAO, 2015)	0.07	STMR-RAC[e]	0.23	HR-RAC[e]
Other pome fruit	0.3	Existing MRL (FAO, 2015)	0.07	STMR-RAC[e]		
Apricots	0.5	Existing MRL (EFSA, 2014a)	0.15	STMR-RAC	0.5	MRL
Cherries (sweet)	1.5	Existing MRL (FAO, 2015)	0.34	STMR-RAC[e]	1.24	HR-RAC[e]
Peaches	0.5	Existing MRL (EFSA, 2014a)	0.15	STMR-RAC	0.5	MRL
Plums	0.5	Existing MRL (FAO, 2015)	0.04	STMR-RAC[e]	0.26	HR-RAC[e]
Table grapes	2	Existing MRL (EFSA, 2014a)	0.17	STMR-RAC	2	MRL
Wine grapes	2	Existing MRL (FAO, 2012)	0.14	STMR-RAC[e]	2	MRL
Strawberries	0.5	Existing MRL (EFSA, 2014a)	0.2	STMR-RAC	0.5	MRL
Blackberries	1.5	Proposed MRL (EFSA, 2023a[d])	0.46	STMR-RAC	0.76	HR-RAC
Dewberries	1.5	Proposed MRL (EFSA, 2023a[d])	0.46	STMR-RAC	0.76	HR-RAC
Raspberries (red and yellow)	1.5	Proposed MRL (EFSA, 2023a[d])	0.46	STMR-RAC	0.76	HR-RAC
Other cane fruit	1.5	Proposed MRL (EFSA, 2023a[d])	0.46	STMR-RAC		

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Commodity	Existing/ proposed MRL (mg/ kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value[a] (mg/kg)	Comment	Input value[a] (mg/kg)	Comment[b]
Blueberries	2	Proposed MRL (EFSA, 2023a[d])	0.36	STMR-RAC	1.28	HR-RAC
Currants (red, black and white)	2	Proposed MRL (FAO, 2021[d])	0.39	STMR-RAC[e]	1.4	HR-RAC[e]
Gooseberries (green, red and yellow)	2	Proposed MRL (FAO, 2021[d])	0.39	STMR-RAC[e]	1.4	HR-RAC[e]
Rose hips	2	Proposed MRL (FAO, 2021[d])	0.39	STMR-RAC[e]	1.4	HR-RAC[e]
Azarole/ Mediteranean medlar	0.3	FAO (2015)	0.07	STMR-RAC[e]	0.3	MRL
Kaki/Japanese persimmons	0.3	FAO (2015)	0.07	STMR-RAC[e]	0.3	MRL
Avocados	0.15	Proposed MRL (EFSA, 2023a[d])	0.02	STMR-RAC	0.04	HR-RAC
Mangoes	0.3	Proposed MRL (EFSA, 2023a[d])	0.06	STMR-RAC	0.12	HR-RAC
Pineapples	0.09	Proposed MRL (EFSA, 2023a[d])	0.07	STMR-RAC	0.04	HR-RAC
Potatoes	0.03	Existing MRL (FAO, 2012)	0.02	STMR-RAC (EFSA, 2014a)	0.03	MRL
Cassava roots/ manioc	0.03	Existing MRL (FAO, 2012)	0.01	STMR-RAC[e]	0.03	MRL
Sweet potatoes	0.03	Existing MRL (FAO, 2012)	0.01	STMR-RAC[e]	0.03	MRL
Yams	0.03	Existing MRL (FAO, 2012)	0.01	STMR-RAC[e]	0.03	MRL
Arrowroots	0.03	Existing MRL (FAO, 2012)	0.01	STMR-RAC[e]	0.03	MRL
Other tropical root and tuber vegetables	0.03	Existing MRL (FAO, 2012)	0.01	STMR-RAC[e]		
Beetroots	0.03	Existing MRL (FAO, 2012)	0.01	STMR-RAC[e]	0.03	MRL
Carrots	0.05	Existing MRL (FAO, 2014)	0.01	STMR-RAC[e]	0.03	HR-RAC[e]
Celeriacs/turnip rooted celeries	0.03	Existing MRL (FAO, 2012)	0.01	STMR-RAC[e]	0.03	MRL
Horseradishes	0.03	Existing MRL (FAO, 2012)	0.01	STMR-RAC[e]	0.03	MRL
Jerusalem artichokes	0.03	Existing MRL (FAO, 2012)	0.01	STMR-RAC[e]	0.03	MRL
Parsnips	0.03	Existing MRL (FAO, 2012)	0.01	STMR-RAC[e]	0.03	MRL
Parsley roots/ Hamburg roots parsley	0.03	Existing MRL (FAO, 2012)	0.01	STMR-RAC[e]	0.03	MRL
Radishes	0.03	Existing MRL (FAO, 2012)	0.01	STMR-RAC[e]	0.03	MRL
Salsifies	0.03	Existing MRL (FAO, 2012)	0.01	STMR-RAC[e]	0.03	MRL
Swedes/rutabagas	0.03	Existing MRL (FAO, 2012)	0.01	STMR-RAC[e]	0.03	MRL
Turnips	0.03	Existing MRL (FAO, 2012)	0.01	STMR-RAC[e]	0.03	MRL
Other root and tuber vegetables	0.03	Existing MRL (FAO, 2012)	0.01	STMR-RAC[e]		
Garlic	0.01	Existing MRL (FAO, 2012)	0.01	LOQ	0.01	LOQ
Onions	0.01	Existing MRL (FAO, 2012)	0.01	LOQ	0.01	LOQ

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Commodity	Existing/ proposed MRL (mg/ kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value[a] (mg/kg)	Comment	Input value[a] (mg/kg)	Comment[b]
Spring onions/ green onions and Welsh onions	0.7	Existing MRL (FAO, 2012)	0.11	STMR-RAC[e]	0.39	HR-RAC[e]
Tomatoes	0.3	Existing MRL (EFSA, 2014a)	0.06	STMR-RAC	0.3	MRL
Sweet peppers/ bell peppers	0.4	Existing MRL (EFSA, 2014a)	0.08	STMR-RAC	0.222	HR-RAC
Aubergines/egg plants	0.3	Existing MRL (EFSA, 2014a)	0.06	STMR-RAC	0.3	MRL
Okra/lady's fingers	**0.07**	**MRL proposal**	**0.03**	**STMR-RAC**	**0.04**	**HR-RAC**
Cucumbers	0.5	Existing MRL (FAO, 2012)	0.03	STMR-RAC[e]	0.5	MRL
Gherkins	0.5	Existing MRL (FAO, 2012)	0.03	STMR-RAC[e]	0.5	MRL
Courgettes	0.5	Existing MRL (FAO, 2012)	0.03	STMR-RAC[e]	0.5	MRL
Other cucurbits - edible peel	0.5	Existing MRL (FAO, 2012)	0.03	STMR-RAC[e]		
Melons	0.5	Existing MRL (FAO, 2012)	0.03	STMR-RAC[e]	0.5	MRL
Pumpkins	0.5	Existing MRL (FAO, 2012)	0.03	STMR-RAC[e]	0.5	MRL
Watermelons	0.5	Existing MRL (FAO, 2012)	0.03	STMR-RAC[e]	0.5	MRL
Other cucurbits - inedible peel	0.5	Existing MRL (FAO, 2012)	0.03	STMR-RAC[e]		
Sweet corn	0.01	Proposed MRL (FAO, 2019[d])	0.01	LOQ	0.01	LOQ
Broccoli	3	Existing MRL (FAO, 2012)	0.07	STMR-RAC[e]	1.6	HR-RAC[e]
Cauliflowers	0.1	Proposed MRL (EFSA, 2019b[d])	0.02	STMR-RAC	0.09	HR-RAC
Brussels sprouts	0.015	Proposed MRL (EFSA, 2019b[d])	0.02	STMR-RAC	0.02	HR-RAC
Head cabbages	0.4	Existing MRL (FAO, 2012)	0.1	STMR-RAC[e]	0.19	HR-RAC[e]
Chinese cabbages/ pe-tsai	2	Existing MRL (EFSA, 2014a)	1	STMR-RAC	2	MRL
Kales	1	Proposed MRL (EFSA, 2019b[d])	0.02	STMR-RAC	0.43	HR-RAC
Lamb's lettuce/ corn salads	**0.7**	**MRL proposal**	**0.05**	**STMR-RAC**	**0.46**	**HR-RAC**
Lettuces	4	Existing MRL (EFSA, 2014a)	0.59	STMR-RAC	2.87	HR-RAC
Escaroles/ broad-leaved endives	**0.7**	**MRL proposal**	**0.05**	**STMR-RAC**	**0.46**	**HR-RAC**
Cress and other sprouts and shoots	**0.7**	**MRL proposal**	**0.05**	**STMR-RAC**	**0.46**	**HR-RAC**
Land cress	**0.7**	**MRL proposal**	**0.05**	**STMR-RAC**	**0.46**	**HR-RAC**
Roman rocket/ rucola	**0.7**	**MRL proposal**	**0.05**	**STMR-RAC**	**0.46**	**HR-RAC**
Red mustards	**0.7**	**MRL proposal**	**0.05**	**STMR-RAC**	**0.46**	**HR-RAC**
Baby leaf crops (including brassica species)	**0.7**	**MRL proposal**	**0.05**	**STMR-RAC**	**0.46**	**HR-RAC**
Other lettuce and other salad plants	**0.7**	**MRL proposal**	**0.05**	**STMR-RAC**		
Spinaches	6	Existing MRL (EFSA, 2014a)	1.34	STMR-RAC	6	MRL
Purslanes	**0.7**	**MRL proposal**	**0.05**	**STMR-RAC**	**0.46**	**HR-RAC**

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Commodity	Existing/ proposed MRL (mg/ kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value[a] (mg/kg)	Comment	Input value[a] (mg/kg)	Comment[b]
Chards/beet leaves	**0.7**	**MRL proposal**	**0.05**	**STMR-RAC**	**0.46**	**HR-RAC**
Other spinach and similar	0.2	Proposed MRL (EFSA, 2019b[d])	0.03	STMR-RAC		
Grape leaves and similar species	2	Existing MRL (EFSA, 2017b)	0.48	STMR-RAC	1.18	HR-RAC
Watercress	**0.7**	**MRL proposal**	**0.05**	**STMR-RAC**	**0.46**	**HR-RAC**
Chervil	**0.7**	**MRL proposal**	**0.05**	**STMR-RAC**	**0.46**	**HR-RAC**
Chives	**0.7**	**MRL proposal**	**0.05**	**STMR-RAC**	**0.46**	**HR-RAC**
Celery leaves	1.5	Proposed MRL (EFSA, 2019b[d])	0.26	STMR-RAC	0.81	HR-RAC
Parsley	**0.7**	**MRL proposal**	**0.05**	**STMR-RAC**	**0.46**	**HR-RAC**
Sage	**0.7**	**MRL proposal**	**0.05**	**STMR-RAC**	**0.46**	**HR-RAC**
Rosemary	**0.7**	**MRL proposal**	**0.05**	**STMR-RAC**	**0.46**	**HR-RAC**
Thyme	**0.7**	**MRL proposal**	**0.05**	**STMR-RAC**	**0.46**	**HR-RAC**
Basil and edible flowers	**0.7**	**MRL proposal**	**0.05**	**STMR-RAC**	**0.46**	**HR-RAC**
Laurel/bay leaves	**0.7**	**MRL proposal**	**0.05**	**STMR-RAC**	**0.46**	**HR-RAC**
Tarragon	**0.7**	**MRL proposal**	**0.05**	**STMR-RAC**	**0.46**	**HR-RAC**
Other herbs	**0.7**	**MRL proposal**	**0.05**	**STMR-RAC**		
Beans (with pods)	0.15	Existing MRL (EFSA, 2022a[d])	0.02	STMR-RAC	0.1	HR-RAC
Beans (without pods)	0.03	Proposed MRL (EFSA, 2019b[d])	0.02	STMR-RAC	0.09	HR-RAC
Peas (with pods)	0.15	Proposed MRL (EFSA, 2019b[d])	0.02	STMR-RAC	0.1	HR-RAC
Peas (without pods)	0.03	Existing MRL (EFSA, 2022a[d])	0.02	STMR-RAC	0.09	HR-RAC
Asparagus	0.015	Proposed MRL (EFSA, 2023a[d])	0.02	STMR-RAC	0.02	HR-RAC
Celeries	1.5	Existing MRL (FAO, 2012)	0.19	STMR-RAC[e]	1.5	MRL
Globe artichokes	0.9	Proposed MRL (EFSA, 2023a[d])	0.25	STMR-RAC	0.42	HR-RAC
Beans	0.3	Existing MRL (FAO, 2014)	0.08	STMR-RAC[e]	0.08	STMR-RAC[e]
Sunflower seeds	0.4	Proposed MRL (EFSA, 2023a[d])	0.06	STMR-RAC	0.06	STMR-RAC
Rapeseeds/canola seeds	0.15	Existing MRL (EFSA, 2014a)	0.07	STMR-RAC	0.07	STMR-RAC
Soyabeans	0.3	Existing MRL (EFSA, 2014a)	0.02	STMR-RAC	0.02	STMR-RAC
Cotton seeds	0.4	Existing MRL (FAO, 2012)	0.02	STMR-RAC[e]	0.02	STMR-RAC[e]
Barley	0.6	Existing MRL (FAO, 2012)	0.06	STMR-RAC[e]	0.06	STMR-RAC[e]
Maize/corn	0.01*	Existing MRL (FAO, 2019[d])	0.01*	LOQ	0.01*	LOQ
Oat	0.06	Proposed MRL (EFSA, 2019b[d])	0.03	STMR-RAC	0.03	STMR-RAC
Rice	1.5	Proposed MRL (FAO, 2019[d])	1.5	MRL	1.5	MRL
Rye	0.03	Proposed MRL (EFSA, 2019b[d])	0.02	STMR-RAC	0.02	STMR-RAC
Sorghum	0.2	Proposed MRL (FAO, 2019[d])	0.03	STMR-RAC[e]	0.03	STMR-RAC[e]
Wheat	0.2	FAO (2012)	0.03	STMR-RAC[e]	0.03	STMR-RAC[e]
Coffee beans	0.3	Proposed MRL (EFSA, 2023a[d])	0.04	STMR-RAC	0.04	STMR-RAC

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Commodity	Existing/ proposed MRL (mg/ kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value[a] (mg/kg)	Comment	Input value[a] (mg/kg)	Comment[b]
Swine: Muscle/ meat	0.4	Proposed MRL (FAO, 2019[d])	0.16	STMR-RAC[e]	0.39	HR-RAC[e]
Swine: Fat tissue	0.2	Proposed MRL (FAO, 2019[d])	0.06	STMR-RAC[e]	0.19	HR-RAC[e]
Swine: Liver	1	Proposed MRL (FAO, 2019[d])	0.44	STMR-RAC[e]	0.95	HR-RAC[e]
Swine: Kidney	1	Proposed MRL (FAO, 2019[d])	0.44	STMR-RAC[e]	0.95	HR-RAC[e]
Swine: Edible offal (other than liver and kidney)	1	Proposed MRL (FAO, 2019[d])	0.44	STMR-RAC[e]	0.95	HR-RAC[e]
Bovine: Muscle/ meat	0.4	Proposed MRL (FAO, 2019[d])	0.16	STMR-RAC[e]	0.39	HR-RAC[e]
Bovine: Fat tissue	0.2	Proposed MRL (FAO, 2019[d])	0.06	STMR-RAC[e]	0.19	HR-RAC[e]
Bovine: Liver	1	Proposed MRL (FAO, 2019[d])	0.44	STMR-RAC[e]	0.95	HR-RAC[e]
Bovine: Kidney	1	Proposed MRL (FAO, 2019[d])	0.44	STMR-RAC[e]	0.95	HR-RAC[e]
Bovine: Edible offal (other than liver and kidney)	1	Proposed MRL (FAO, 2019[d])	0.44	STMR-RAC[e]	0.95	HR-RAC[e]
Sheep: Muscle/ meat	0.4	Proposed MRL (FAO, 2019[d])	0.16	STMR-RAC[e]	0.39	HR-RAC[e]
Sheep: Fat tissue	0.2	Proposed MRL (FAO, 2019[d])	0.06	STMR-RAC[e]	0.19	HR-RAC[e]
Sheep: Liver	1	Proposed MRL (FAO, 2019[d])	0.44	STMR-RAC[e]	0.95	HR-RAC[e]
Sheep: Kidney	1	Proposed MRL (FAO, 2019[d])	0.44	STMR-RAC[e]	0.95	HR-RAC[e]
Sheep: Edible offal (other than liver and kidney)	1	Proposed MRL (FAO, 2019[d])	0.44	STMR-RAC[e]	0.95	HR-RAC[e]
Goat: Muscle/ meat	0.4	Proposed MRL (FAO, 2019[d])	0.16	STMR-RAC[e]	0.39	HR-RAC[e]
Goat: Fat tissue	0.2	Proposed MRL (FAO, 2019[d])	0.06	STMR-RAC[e]	0.19	HR-RAC[e]
Goat: Liver	1	Proposed MRL (FAO, 2019[d])	0.44	STMR-RAC[e]	0.95	HR-RAC[e]
Goat: Kidney	1	Proposed MRL (FAO, 2019[d])	0.44	STMR-RAC[e]	0.95	HR-RAC[e]
Goat: Edible offal (other than liver and kidney)	1	Proposed MRL (FAO, 2019[d])	0.44	STMR-RAC[e]	0.95	HR-RAC[e]
Equine: Muscle/ meat	0.4	Proposed MRL (FAO, 2019[d])	0.16	STMR-RAC[e]	0.39	HR-RAC[e]
Equine: Fat tissue	0.2	Proposed MRL (FAO, 2019[d])	0.06	STMR-RAC[e]	0.19	HR-RAC[e]
Equine: Liver	1	Proposed MRL (FAO, 2019[d])	0.44	STMR-RAC[e]	0.95	HR-RAC[e]
Equine: Kidney	1	Proposed MRL (FAO, 2019[d])	0.44	STMR-RAC[e]	0.95	HR-RAC[e]
Equine: Edible offal (other than liver and kidney)	1	Proposed MRL (FAO, 2019[d])	0.44	STMR-RAC[e]	0.95	HR-RAC[e]
Poultry: Muscle/ meat	0.7	Proposed MRL (FAO, 2019[d])	0.64	STMR-RAC[e]	0.64	HR-RAC[e]
Poultry: Fat tissue	0.03	Proposed MRL (FAO, 2019[d])	0.02	STMR-RAC[e]	0.02	HR-RAC[e]
Poultry: Liver	0.3	Proposed MRL (FAO, 2019[d])	0.18	STMR-RAC[e]	0.18	HR-RAC[e]
Poultry: Kidney	0.3	Proposed MRL (FAO, 2019[d])	0.18	STMR-RAC[e]	0.18	HR-RAC[e]
Poultry: Edible offal (other than liver and kidney)	0.3	Proposed MRL (FAO, 2019[d])	0.18	STMR-RAC[e]	0.18	HR-RAC[e]

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Commodity	Existing/ proposed MRL (mg/ kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value[a] (mg/kg)	Comment	Input value[a] (mg/kg)	Comment[b]
Other farmed animals: Muscle/meat	0.4	Proposed MRL (FAO, 2019[d])	0.06	STMR-RAC[e]	0.39	HR-RAC[e]
Other farmed animals: Fat tissue	0.2	Proposed MRL (FAO, 2019[d])	0.06	STMR-RAC[e]	0.19	HR-RAC[e]
Other farmed animals: Liver	1	Proposed MRL (FAO, 2019[d])	0.44	STMR-RAC[e]	0.95	HR-RAC[e]
Other farmed animals: Kidney	1	Proposed MRL (FAO, 2019[d])	0.44	STMR-RAC[e]	0.95	HR-RAC[e]
Other farmed animals: Edible offal (other than liver and kidney)	1	Proposed MRL (FAO, 2019[d])	0.44	STMR-RAC[e]	0.95	HR-RAC[e]
Milk: Cattle	0.3	Proposed MRL (FAO, 2019[d])	0.14	STMR-RAC[e]	0.14	STMR-RAC[e]
Milk: Sheep	0.3	Proposed MRL (FAO, 2019[d])	0.14	STMR-RAC[e]	0.14	STMR-RAC[e]
Milk: Goat	0.3	Proposed MRL (FAO, 2019[d])	0.14	STMR-RAC[e]	0.14	STMR-RAC[e]
Milk: Horse	0.3	Proposed MRL (FAO, 2019[d])	0.14	STMR-RAC[e]	0.14	STMR-RAC[e]
Milk: Others	0.3	Proposed MRL (FAO, 2019[d])	0.14	STMR-RAC[e]	0.14	STMR-RAC[e]
Eggs: Chicken	0.1	Proposed MRL (FAO, 2019[d])	0.07	STMR-RAC[e]	0.07	HR-RAC[e]
Eggs: Duck	0.1	Proposed MRL (FAO, 2019[d])	0.07	STMR-RAC[e]	0.07	HR-RAC[e]
Eggs: Goose	0.1	Proposed MRL (FAO, 2019[d])	0.07	STMR-RAC[e]	0.07	HR-RAC[e]
Eggs: Quail	0.1	Proposed MRL (FAO, 2019[d])	0.07	STMR-RAC[e]	0.07	HR-RAC[e]
Eggs: Others	0.1	Proposed MRL (FAO, 2019[d])	0.07	STMR-RAC[e]		

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

[a]Figures in the table are rounded to 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.

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

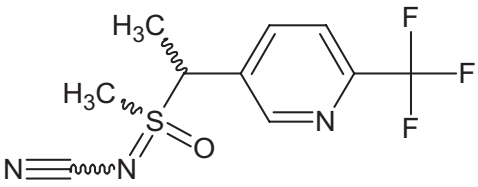
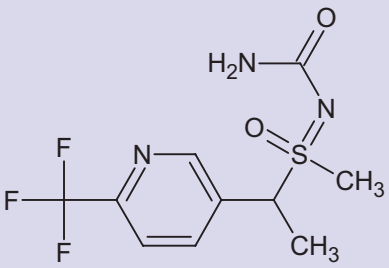
[c]Median residues refer to whole fruits. Data were not sufficient to derive a STMR for citrus pulp (FAO, 2015).

[d]MRLs not yet implemented by Regulation.

[e]All STMRs and HRs derived by Codex (except citrus different than limes, where a conversion factor for risk assessment of 1.16 was used) refer to residues of parent compound only and do not comply with the risk assessment residue definition at EU level, which includes also the metabolite X11719474. Considering the low concentration and the toxicological profile of the metabolite, EFSA concluded this deviation does not have a practical implication for the consumer risk assessment. Except for cherries (up to 0.03 mg/kg) and cereal straw (up to 0.034 mg/kg), concentrations of this metabolite were at or close to the LOQ of 0.01 mg/kg (EFSA, 2015, 2019b, 2022a).

APPENDIX E

Used compound codes

Code/trivial name[a]	IUPAC name/SMILES notation/InChiKey[b]	Structural formula[c]
sulfoxaflor	[methyl(oxo){1-[6-(trifluoromethyl)-3-pyridyl]ethyl}-λ^6-sulfanylidene]cyanamide FC(F)(F)c1ccc(cn1)C(C)S(C)(=O)=NC#N ZVQOOHYFBIDMTQ-UHFFFAOYSA-N	
X11719474	*N* N-[methyl(oxo){1-[6-(trifluoromethyl)pyridin-3-yl]ethyl}-λ6-sulfanylidene]urea FC(F)(F)c1ccc(cn1)C(C)S(C)(=O)=NC(N)=O YLQFVPNHUKREEW-UHFFFAOYSA-N	

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

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

[b]ACD/Name 2021.1.3 ACD/Labs 2021.1.3 (File Version N15E41, Build 123232, 7 July 2021).

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