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Setting of import tolerances for sulfoxaflor in various crops

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Dow AgroSciences Ltd submitted a request to the competent national authority in Greece to set an import tolerance for the active substance sulfoxaflor in various crops. The data submitted in support of the request were found to be sufficient to derive import tolerance proposals for cane fruits, blueberries, avocados, mangoes, pineapples, asparagus, globe artichokes, sunflower seeds and coffee beans. Adequate analytical methods for enforcement are available to control the residues of sulfoxaflor in plant matrices under consideration at the validated LOQ of 0.01 mg/kg. Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of residues resulting from the use of sulfoxaflor according to the reported agricultural practices is unlikely to present a risk to consumer health.

Keywords: sulfoxaflor, various crops, import tolerance, pesticide, MRL, consumer risk assessment

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, Dow AgroSciences Ltd submitted an application to the competent national authority in Greece (evaluating Member State, EMS) to set import tolerances for the active substance sulfoxaflor in various crops. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 7 April 2022. The EMS proposed to establish maximum residue levels (MRLs) for cane fruits, blueberries, avocados, mangoes, pineapples, asparagus, globe artichokes, sunflower seeds and coffee beans imported from the USA, Vietnam and Kenya at the levels of 1.5 mg/kg, 2.0 mg/kg, 0.15 mg/kg, 0.3 mg/kg, 0.09 mg/kg, 0.015 mg/kg, 0.9 mg/kg, 0.4 mg/kg, 0.3 mg/kg, respectively.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified points in need of further clarification, which were requested from the EMS. On 15 February 2023, the EMS submitted the requested information and a revised evaluation report (Greece, 2022), 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 in 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. Investigations of residues in rotational crops are not required because the authorised uses of sulfoxaflor are on imported crops.

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 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 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 detection (HPLC–MS/MS) are available to quantify residues in the crops assessed in this application according to the enforcement residue definition. In the framework of this assessment, the EMS proposes the QuEChERS EN 15662 method (LC–MS/MS) to be used for enforcement purposes in difficult matrices (coffee, tea, tobacco and hops). The method has been sufficiently validated for the determination of sulfoxaflor and metabolite X11719474 in these matrices, at the LOQ 0.01 mg/kg for individual analytes and an independent laboratory validation (ILV) was provided for coffee, tea and hops.

The available residue trials are sufficient to derive MRL proposals of 1.5 mg/kg for cane fruits, of 2.0 mg/kg for blueberries, of 0.15 mg/kg for avocados, of 0.3 mg/kg for mangoes, of 0.09 mg/kg for pineapples, of 0.015 mg/kg for asparagus, of 0.9 mg/kg for globe artichokes, of 0.4 mg/kg for sunflower seeds and of 0.3 mg/kg for coffee beans.

Specific studies investigating the magnitude of sulfoxaflor residues in processed commodities are in principle not required because the individual contribution of the crops assessed in this application to the total theoretical maximum daily intake (TMDI) is well below 1% of the ADI.

Nevertheless, several processing studies were provided to investigate the effect of processing on the magnitude of sulfoxaflor residues in processed commodities of pineapples, sunflower seeds and coffee beans and in mangoes pulp. The number of processing studies was insufficient to derive robust processing factors, except for avocados, where the derived processing factor is recommended to be included in Annex VI of Regulation (EC) No 396/2005:

PF according to the residue definition for monitoring:

- Avocado/pulp: 0.63.

PF according to the residue definition for risk assessment:

- Avocado/pulp: 0.75.

As sunflower seeds and/or their by-products can be used as feed products, a potential residue carry-over into the food of animal origin was assessed. The calculated livestock dietary burden exceeded the trigger value of 0.1 mg/kg dry matter (DM) for all relevant species/animal species. However, the contribution of sulfoxaflor residues in sunflower seeds to the total livestock exposure was insignificant, and therefore, a modification of the existing MRLs for commodities of animal origin was considered unnecessary.

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 acceptable daily intake (ADI) of 0.04 mg/kg body weight (bw) per day and an acute reference dose (ARfD) of 0.25 mg/kg bw. The metabolites included in the residue definition are 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 and ranged from 0.012% ARfD for coffee beans up to 3.9% ARfD for mangoes. The highest estimated long-term dietary intake accounted for 37% of the ADI (NL toddler diet) with contributions ranging between the crops under assessment from 0.01% of the ADI for asparagus (IE adult diet) and avocados (GEMS/Food G11 diet), respectively, up to 0.61% ADI (FI adult diet) for coffee beans.

EFSA concluded that the existing and the authorised uses assessed under the present application 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: Sulfoxaflor (sum of isomers)				
0153000	Cane fruits	0.01*	1.5	The submitted data are sufficient to derive an import tolerance (US GAP). Risk for consumers is unlikely. The tolerance established in the USA for sulfoxaflor in cane berries is 1.5 mg/kg. A Codex MRL of 1.5 mg/kg, for which EFSA flagged no reservations, was adopted by the Codex Alimentarius Commission in 2022.
0154010	Blueberries	0.01*	2.0	The submitted data are sufficient to derive an import tolerance (US GAP). Risk for consumers is unlikely. The tolerance established in the USA for sulfoxaflor on blueberries is 2.0 mg/kg. A Codex MRL of 1.5 mg/kg on blueberries, for which EFSA flagged no reservations, was adopted by the Codex Alimentarius Commission in 2022.
0163010	Avocados	0.01*	0.15	The submitted data are sufficient to derive an import tolerance (US GAP). Risk for consumers is unlikely. The tolerance established in the USA for sulfoxaflor in avocados is 0.15 mg/kg. A Codex MRL of 0.15 mg/kg on avocados, for which EFSA flagged no reservations, was adopted by the Codex Alimentarius Commission in 2022.
0163030	Mangoes	0.01*	0.3	The submitted data are sufficient to derive an import tolerance (Kenyan GAP). Risk for consumers is unlikely. A tolerance is not established in Kenya at a national level. However, a Codex MRL of 0.3 mg/kg on mangoes, for which EFSA flagged no reservations, was adopted by the Codex Alimentarius Commission in 2022.

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
0163080	Pineapples	0.01*	0.09	The submitted data are sufficient to derive an import tolerance (US GAP). Risk for consumers is unlikely. The tolerance established in the USA for sulfoxaflor on pineapples is 0.1 mg/kg. A Codex MRL is not in place.
0270010	Asparagus	0.01*	0.015	The submitted data are sufficient to derive an import tolerance (US GAP). Risk for consumers is unlikely. The tolerance established in the USA for sulfoxaflor on asparagus is 0.01 mg/kg. A Codex MRL of 0.015 mg/kg on asparagus, for which EFSA flagged no reservations, was adopted by the Codex Alimentarius Commission in 2022.
0270050	Globe artichokes	0.06	0.9	The submitted data are sufficient to derive an import tolerance (US GAP). Risk for consumers is unlikely. The tolerance established in the USA for sulfoxaflor on globe artichokes is 0.7 mg/kg; however, a Codex MRL for sulfoxaflor on globe artichokes of 0.9 mg/kg has been proposed by JMPR but the Codex Alimentarius Commission meeting has not taken place yet.
0401050	Sunflower seeds	0.02*	0.4	The submitted data are sufficient to derive an import tolerance (US GAP). Risk for consumers is unlikely. The tolerance established in the USA for sulfoxaflor on sunflower seeds is 0.3 mg/kg; however, a Codex MRL for sulfoxaflor on sunflower seeds of 0.4 mg/kg has been proposed by JMPR but the Codex Alimentarius Commission meeting has not taken place yet.
0620000	Coffee beans	0.05*	0.3	The submitted data are sufficient to derive an import tolerance (Vietnamese GAP). Risk for consumers is unlikely. A tolerance is not established in Vietnam at a national level. However, a Codex MRL of 0.3 mg/kg on coffee beans, for which EFSA flagged no reservations, was adopted by the Codex Alimentarius Commission in 2022.

MRL: maximum residue level; NEU: northern Europe; SEU: southern Europe; GAP: Good Agricultural Practice.
*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.

Table of contents

Assessment

The European Food Safety Authority (EFSA) received an application to set an import tolerance for the active substance sulfoxaflor in various crops. The detailed description of the existing uses of sulfoxaflor authorised in Kenya, the United States of America and Vietnam in various crops, which is the basis for the current MRL application, is reported in Appendix A.

Sulfoxaflor is the ISO common name for methyl(oxo){1-[6-(trifluoromethyl)-3-pyridyl]ethyl}-λ6-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[1] with Austria designated as rapporteur Member State (RMS) for the representative use(s) 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 (2014a)). Sulfoxaflor was approved[2] for the use as 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. Recently, approval restrictions[3] were agreed by risk managers that '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[4]. 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 regulation.[5] Certain Codex maximum residue limits (CXLs) have 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) 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 (EFSA, 2019c, 2022b; FAO, 2019, 2021, 2023).

In 2022, Codex Alimentarius Commission (CAC) adopted a number of Codex MRLs, some of them being higher than the existing EU MRLs (JMPR meeting 2021 (FAO, 2021)). As the EU did not express a reservation in the 53rd session of Codex Committee for Pesticide Residues (CCPR) (EFSA, 2022b; FAO, 2022, 2022), for the Codex MRL proposals and as no consumer exposure concerns were identified, the CXLs for asparagus, avocados, bush berries including blueberries, cane berries, coffee beans and mangoes are expected to be implemented in the EU legislation.

In accordance with Article 6 of Regulation (EC) No 396/2005, Dow AgroSciences Ltd submitted an application to the competent national authority in Greece (evaluating Member State, EMS) to set import tolerances for the active substance sulfoxaflor in various crops. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 7 April 2022. The EMS proposed to establish maximum residue levels (MRLs) for cane fruits, blueberries, avocados, mangoes, pineapples, asparagus, globe artichokes, sunflower seeds and coffee beans imported from

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

[2] Commission Implementing Regulation (EU) 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.

[3] 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

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

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

Kenya, USA and Vietnam at the level of 1.5 mg/kg, 2.0 mg/kg, 0.15 mg/kg, 0.3 mg/kg, 0.09 mg/kg, 0.015 mg/kg, 0.9 mg/kg, 0.4 mg/kg, 0.3 mg/kg, respectively.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified points that needed further clarification, which were requested from the EMS. On 15 February 2023, the EMS submitted the requested information and a revised evaluation report (Greece, 2022), which replaced the previously submitted evaluation report.

EFSA based its assessment on the evaluation report submitted by the EMS (Greece, 2022), 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, 2022) and the EFSA reports based on JMPR assessments (EFSA, 2014b, 2015, 2017a, 2019c, 2022b).

For this application, the data requirements established in Regulation (EU) No 544/2011[6] and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 1997a–g, 2010, 2017, 2020, 2021; 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[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 (Greece, 2022) and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available as background documents to this reasoned opinion.

1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

The metabolism of 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). 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).

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).

For the authorised uses under consideration, the metabolic behaviour in primary crops is sufficiently addressed.

1.1.2. Nature of residues in rotational crops

Investigations of residues in rotational crops are not required for imported crops. Therefore, for the uses assessed in this application, no further information is required.

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).

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

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

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 high-performance liquid chromatography with tandem mass spectrometry detection (HPLC–MS/MS), are sufficiently validated for the quantification of residues of sulfoxaflor at or above the limit of quantification (LOQ) of 0.01 mg/kg in high water content, high acid content, high oil content and dry commodities.

The crops under consideration in this import tolerance MRL application belong to the high water, high acid and high oil content commodity groups. Moreover, coffee beans are included in the group of difficult to analyse matrices or 'no group' for which full validation data shall be presented to prove the suitability of the method (European Commission, 2021).

EFSA concluded previously that the extraction efficiency for the analytical methods for enforcement (091116 and 091031) was demonstrated in the framework of the peer review (Ireland, 2012) by cross validation with the method used in the metabolism studies (study 101569; Ireland, 2012). This is considered in accordance with the EU Technical Guideline SANTE 2017/10632 on extraction efficiency (European Commission, 2017; EFSA, 2022a).

In the framework of this assessment, the EMS proposes the QuEChERS EN 15662 (2 mass transitions) method to be used for enforcement purposes including difficult matrices (coffee, tea, tobacco and hops (Greece, 2022). The method has been sufficiently validated for the determination of sulfoxaflor and X11719474 in these matrices, using LC–MS/MS at the LOQ 0.01 mg/kg for individual analytes. An ILV was provided for coffee beans, tea and hops (Greece, 2022). It is to be noted that a metabolism study on coffee beans is not available and therefore for this specific commodity extraction efficiency could not be demonstrated. Nevertheless, the metabolism studies do not cover a high acid commodity where it is noted that the current guidance allows for bridging between high water content and acidic matrices for slightly acidic matrices, such as tomato, and a high oil content commodities which would be required according to the guidance and therefore for these commodities, extraction efficiency cannot be considered as demonstrated.

EFSA concludes that sufficiently validated methods for the enforcement of sulfoxaflor residues in globe artichokes, asparagus, avocados, blueberries, cane fruits, mangoes, pineapples, sunflower seeds and for coffee beans are available at the validated LOQ of 0.01 mg/kg.

Further considerations on extraction efficiency

To address the extraction efficiency of QuEChERS method EN 15662, the applicant refers to the extraction efficiency study for QuEChERS EN 150108 (two mass transitions) which was previously assessed by EFSA and uses a similar extraction system (Greece, 2021; EFSA, 2022a).

EFSA acknowledges that the position of the EMS (Greece, 2021) in the previous EFSA assessment (EFSA, 2022a), however, highlights several shortcomings which would need to be addressed to fully confirm the comparable extraction efficiency of both methods:

- levels of incurred residues in treated high water (lettuce), high acid (grapes) and dry commodities (dry beans) were close to the LOQ; the samples shall contain residues at higher levels to allow proper quantification;
- the extraction efficiency was investigated in a limited number of samples; only three replicates were available, whereas at least five replicates would be required to sufficiently demonstrate recovery (European Commission, 2021).
- extraction efficiency was investigated via an indirect cross-validation performed against the analytical method for enforcement. This is not in line with the Technical Guidelines on Extraction Efficiency (European Commission, 2017), which indicates that cross-validation should be performed against the analytical method used in metabolism studies.

EFSA would recommend reconsidering the identified uncertainties on extraction efficiency in this section by risk managers in future revisions of the guidance and in the framework of the peer review for the renewal of approval of the active substance.

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 (EFSA, 2014a).

Furthermore, during the current application, it was demonstrated that both compounds are stable at least up to 24.5 months in high water, high acid and high oil commodities (Greece, 2022). The stability in coffee is considered as covered by the substantial available body of evidence in all groups of plant commodities; moreover, coffee beans are classified as high oil content matrix according to OECD guideline on the stability of pesticides in stored commodities (OECD, 2007).

For the authorised uses, the information on the stability of sulfoxaflor residues is sufficient.

1.1.6. Proposed residue definitions

Based on the metabolic pattern identified in metabolism studies, the results of hydrolysis studies, the toxicological significance 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. 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 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 import tolerance application, residue trials performed on raspberries, blackberries, blueberries, avocados, mangoes, pineapples, asparagus, globe artichokes and sunflower were submitted. The samples of the residue trials were stored under conditions for which the integrity of the samples has been demonstrated.

All trials on the crops with authorised uses in the United States have been performed with a formulation containing the adjuvant in line with the registered labels for the use of sulfoxaflor in the USA (Greece, 2022).

The methods (091116, 091031) used for the analysis of samples in the context of the residue trials are based on high-performance liquid chromatography with tandem mass spectrometry (HPLC-MS/MS). The samples were analysed for the parent compound and the metabolite included in the residue definition for risk assessment. The conversion factors (CFs) for the risk assessment were derived from the submitted residue data. According to the assessment of the EMS, the methods used were sufficiently validated and fit for purpose (Greece, 2022).

EFSA noted that the extraction efficiency of the analytical method 091031 is demonstrated according to the Technical Guideline SANTE 2017/10632 (European Commission, 2017), considering that the extraction conditions are comparable to those used in the analytical method for enforcement (091116), where extraction efficiency was proven (see Section 1.1.4) (EFSA, 2022a).

In this import tolerance application, for residue trials on raspberries, blackberries, blueberries, asparagus, globe artichokes (study 10858), sunflower seeds (study 11095), the official control method (091116) was used. For residue trials on avocados and pineapples method 091031 was used which has comparable extraction conditions to those used in the analytical method for enforcement (091116), where extraction efficiency was considered as proven (EFSA, 2022a).

However, considering the identified sources of uncertainty for the extraction efficiency of the QuEChERS methods (see Section 1.1.4) which were used to analyse the samples of the residue trials on mangoes and coffee beans (QuEChERS EN 15662), on pineapples (QuEChERS EN 150108), on globe artichokes (study 210115) and sunflower seeds (study 210116) (QuEChERS CEMS 7319 with an equivalent extraction system as QuEChERS EN 15662), the derived MRL proposals for these commodities are affected by additional non-standard uncertainty.

1.2.1.1. Cane fruits (blackberries, dewberries, raspberries and other cane fruits)

Authorised US good agricultural practices (GAPs) on cane fruits: *1–4 × (26–101) g a.s./ha, interval 7 days, PHI 1 day (298 g a.s./ha maximum annual application rate)*.

In support of the authorised critical GAPs of sulfoxaflor in the USA, the applicant submitted three residue trials on blackberries and four residue trials on raspberries performed in USA and Canada in 2014 compliant with a GAP of 3 × 100 (98.7–105) g a.s./ha; interval 7 days, PHI: 1 day. Two trials on raspberries represented decline trials. All except of one trial on blackberries were performed using an adjuvant (0.025% up to 0.5%) (Greece, 2022).

The applicant proposed to extrapolate the merged residue data on raspberries and blackberries to the whole group of cane fruits which is acceptable according to EU guidance documents (European Commission, 2020a). It is concluded that an MRL of 1.5 mg/kg would be sufficient to support the authorised outdoor use of sulfoxaflor on cane fruits.

The samples of these residue trials were stored under conditions for which integrity of the samples is demonstrated (Greece, 2022).

A Codex MRL of 1.5 mg/kg[8] for sulfoxaflor on cane berries is set (enforcement residue definition 'sulfoxaflor') for which EFSA expressed no reservation (EFSA, 2022b; FAO (Food and Agriculture Organization of the United Nations), 2022). The tolerance established in the USA[9] for sulfoxaflor on cane berries[10] is 1.5 mg/kg for the residue definition expressed as parent sulfoxaflor.

1.2.1.2. Blueberry

Authorised critical US good agricultural practices (GAP) on blueberries: *1–4 × (26–101) g a.s./ha, interval 7 days, PHI 1 day (298 g a.s./ha maximum annual application rate)*.

In support of the authorised GAPs of sulfoxaflor in the USA, the applicant submitted 12 residue trials including two decline trials on blueberries performed in USA and Canada in 2014 compliant with a GAP of 3 × 100 (98.2–105.7) g a.s./ha; interval 7 days, PHI: 1 day. Two trials on raspberries represented decline trials. All trials were performed using an adjuvant (0.025% up to 0.25%) (Greece, 2022).

The samples of these residue trials were stored under conditions for which integrity of the samples is demonstrated (Greece, 2022).

The current residue data set is sufficient to derive an MRL proposal of 2 mg/kg for blueberries in support of the authorised GAPs of sulfoxaflor on blueberries in the USA.

A Codex MRL of 2 mg/kg[8] for sulfoxaflor is set for bush berries subgroup 13–07B which includes blueberries, for which EFSA expressed no reservation (EFSA, 2022b; FAO (Food and Agriculture Organization of the United Nations), 2022). The tolerance established in the USA[9] for sulfoxaflor in blueberries[10] is 2.0 mg/kg.

1.2.1.3. Avocados

Authorised critical US good agricultural practices (GAPs) on avocados: *1–4 × (26–101) g a.s./ha, interval 7 days, PHI 7 days (298 g a.s./ha maximum annual application rate)*.

In support of the authorised GAPs of sulfoxaflor in the USA, the applicant submitted five residue trials including two decline trials on avocados performed in the USA during the 2014 growing season compliant with a GAP of 3 × 100 (91–127) g a.s./ha; interval 7 days, PHI: 7 days. All trials were performed using an adjuvant (the percentage was not specified) (Greece, 2022). The residue trials also provide information on the residue distribution in the pulp of avocados.

In a second study, three residue trials in avocados performed in Australia during the 2016 growing season were provided which were not compliant with the GAP concerning the number of applications (2 or 4), the application rates (120–213 g a.s./ha) and the interval between applications (≥ 21 days). These trials were not considered valid to derive the MRL proposal by the EMS (Greece, 2022) and EFSA.

The samples of these residue trials were stored under conditions for which integrity of the samples is demonstrated (Greece, 2022).

8 Report of the 53rd session of the Codex Committee on Pesticide Residues REP22/PR53: https://www.fao.org/fao-who-codexalimentarius/sh-proxy/zh/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-718-53%252FREPORT%252FFINAL%252520REPORT%252FREP22_PR53e.pdf

9 https://www.ecfr.gov/current/title-40/chapter-I/subchapter-E/part-180/subpart-C/section-180.668

10 https://www.law.cornell.edu/cfr/text/40/180.41

The current residue data set is sufficient to derive an MRL proposal of 0.15 mg/kg for avocados in support of the authorised GAPs of sulfoxaflor on avocados in the USA.

A Codex MRL of 0.15 mg/kg[8] for sulfoxaflor is set for avocados for which EFSA expressed no reservation (EFSA, 2022b; FAO/WHO Food Standards Programme Codex Alimentarius Commission, 2022). The tolerance established in the USA[9] for sulfoxaflor in avocados is 0.15 mg/kg.

1.2.1.4. Mangoes

Authorised critical Kenyan good agricultural practice (GAP) on mangoes: *1–3 × 96 g a.s./ha, interval 14 days, PHI 3 days (according to product label provided: do not apply more than three applications to any crop in any one season and not more than two consecutive ones)*.

In support of the authorised GAP of sulfoxaflor in Kenya, the applicant submitted six residue trials including four decline trials on mangoes performed in Ghana (2), Kenya (2), Senegal (1) and Uganda (1) during the 2016–2018 growing season compliant with a GAP of 2 × 96 g a.s./ha; interval 14 (5 trials) to 15 (trial in Senegal) days, PHI: 3 days (Greece, 2022). The trials were performed with two applications instead of three, thus slightly deviating from the authorised GAP. However, as three consecutive applications are not permitted (see Appendix A) and as decline trials indicate residue decline within 3–14 days with exception of an outliner in one trial at 10 days, it is not expected that the third application performed at longer intervals would have an impact on the final residues in the crop. This conclusion is supported by JMPR which assessed the same GAP in 2021 and concluded that residue decline data for mangoes indicate a half-life of sulfoxaflor of approximately 3 days and that based on the half-life, a first application (31 days before harvest) would not contribute significantly to residues at harvest (FAO, 2021). The trials were therefore considered valid to support the authorised GAP in Kenya.

The samples of these residue trials were stored under conditions for which integrity of the samples is demonstrated (Greece, 2022).

The current residue data set is sufficient to derive an MRL proposal of 0.3 mg/kg for mangoes in support of the authorised GAPs of sulfoxaflor on mangoes in Kenya.

Tolerances are not established in Kenya at a national level. It is referred to the Codex Alimentarius Commission, where a Codex MRL of 0.3 mg/kg[8] for sulfoxaflor is set for mangoes for which EFSA expressed no reservation (EFSA, 2022b; FAO (Food and Agriculture Organization of the United Nations), 2022).

1.2.1.5. Pineapples

Authorised critical US GAP on pineapples: *1–2 × 101 g a.s./ha, interval 14 days, PHI 7 days (202 g a.s./ha maximum annual application rate)*.

In support of the authorised GAP of sulfoxaflor in the USA, the applicant submitted eight residue trials including four decline trials on pineapples performed in Costa Rica (5) and the USA (3) during the 2012 growing season compliant with a GAP of 2 × 100 g a.s./ha; interval 14 days, PHI: 1 day. Two trials (one in Costa Rica and one in the USA) were not independent, and from these trials, the highest residue value was selected for the data set. Six additional GAP compliant residue trials, including three decline trials (PHIs 0, 1, 7, 14, 21 and 28 days) performed in the USA during the 2021–2022 growing season are available (Greece, 2022). In total, data from 12 residue trials were included in the final residue data set.

The samples of these residue trials were stored under conditions for which integrity of the samples is demonstrated (Greece, 2022).

The current residue data set is sufficient to derive an MRL proposal of 0.09 mg/kg for pineapples in support of the authorised GAPs of sulfoxaflor on pineapples in the USA.

The tolerance established in the USA[9] for sulfoxaflor in pineapples is 0.1 mg/kg. A Codex MRL for pineapples is not in place.

1.2.1.6. Asparagus

Authorised critical US GAP on asparagus: *1–4 × 101 g a.s./ha, interval 7 days, PHI: not applicable (to be applied to mature asparagus ferns only post-harvest of spears; 298 g a.s./ha maximum annual application rate)*.

In support of the authorised GAP of sulfoxaflor in the USA, the applicant submitted eight residue trials on asparagus performed in the USA during the 2014 growing season compliant with a GAP of 3 × 100 (99.8–105.4) g a.s./ha; interval 6–8 days, PHI: 126–302 days (Greece, 2022).

The samples of these residue trials were stored under conditions for which integrity of the samples is demonstrated (Greece, 2022).

The current residue data set is sufficient to derive an MRL proposal of 0.015 mg/kg for asparagus in support of the authorised GAPs of sulfoxaflor on asparagus in the USA.

A Codex MRL of 0.015 mg/kg[8] for sulfoxaflor is set for asparagus for which EFSA expressed no reservation (EFSA, 2022b; FAO, 2022). The tolerance established in the USA[9] for sulfoxaflor in asparagus is 0.01 mg/kg.

1.2.1.7. Globe artichokes

Authorised critical US GAP on globe artichokes: *1–4 × 101 g a.s./ha, interval 7 days, PHI: 3 days (298 g a.s./ha maximum annual application rate)*.

In support of the authorised GAP of sulfoxaflor in the USA, the applicant submitted four residue trials on globe artichokes performed in the USA during the 2014 growing season compliant with a GAP of 3 × 100 (98.2–103.7) g a.s./ha; interval 7 days, PHI: 3 days.

The samples of these residue trials were stored under conditions for which integrity of the samples is demonstrated, notwithstanding the fact that samples were stored for up to 778 days and storage stability was demonstrated for 680 days which is not thought to impact the stability of the samples (Greece, 2022).

The current residue data set is sufficient to derive an MRL proposal of 0.9 mg/kg for globe artichokes in support of the authorised GAPs of sulfoxaflor on asparagus in the USA.

The Joint FAO/WHO Meeting on Pesticide Residues proposed a Codex MRL for sulfoxaflor on globe artichokes of 0.9 mg/kg considering the same GAP and residue trials as assessed in this application (FAO, 2023). The tolerance currently established in the USA[9] for sulfoxaflor in globe artichokes is 0.7 mg/kg.

1.2.1.8. Sunflower seeds

Authorised critical US GAP on sunflower seeds: *1–2 × 101 g a.s./ha, interval 7 days, PHI: 14 days (193 g a.s./ha maximum annual application rate)*.

In support of the authorised GAP of sulfoxaflor in the USA, the applicant submitted 13 residue trials on sunflower including three decline trials performed in the USA during the 2013 and 2021 growing seasons compliant with a GAP of 2 × 100 (98.6–107.6) g a.s./ha; interval 7 days, PHI: 14 days. Each trial was performed using an adjuvant. Four trials performed during the 2013 growing season were not considered as independent; from replicate trials the highest value was selected. In total, nine GAP compliant residue trials were considered for the residue data set.

The samples of these residue trials were stored under conditions for which integrity of the samples is demonstrated, notwithstanding the fact that samples were stored for up to 868 days which is not thought to impact the stability of the samples because storage stability was demonstrated for 680 days and new data demonstrate stability for 736 days (Greece, 2022).

The current residue data set is sufficient to derive an MRL proposal of 0.4 mg/kg for sunflower seeds in support of the authorised GAPs of sulfoxaflor on asparagus in the USA.

The Joint FAO/WHO Meeting on Pesticide Residues proposed a Codex MRL for sulfoxaflor on sunflower seeds of 0.4 mg/kg considering the same GAP and residue trials as assessed in this application (FAO, 2023). The tolerance currently established in the USA[9] for sulfoxaflor in sunflower is 0.3 mg/kg.

1.2.1.9. Coffee beans

Authorised critical Vietnamese GAP on coffee beans: *1 × 75 g a.s./ha, PHI 3 days*.

In support of the authorised GAP of sulfoxaflor in Vietnam, the applicant submitted 10 residue trials on coffee including five decline trials performed in Vietnam during the 2019 growing season compliant with a GAP of 1 × 75 g a.s./ha; PHI: 3 days.

It is concluded that an MRL of 0.3 mg/kg would be sufficient to support the authorised outdoor use of sulfoxaflor in Vietnam on coffee beans (peeled and sundried). For coffee beans in the EU legislation[11] the part of the crop to which the MRL is applicable is referred to as 'green beans', without further specifications on the state of processing. For the present assessment, the data on

[11] COMMISSION REGULATION (EU) 2018/62 of 17 January 2018 replacing Annex I to Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23.1.208; OJ L 18/1-73

unprocessed, peeled beans are considered compliant with the definition for green beans, as specified in the MRL legislation.

The samples of these residue trials were stored for up to 179 days under conditions for which integrity in all main commodity groups for at least 680 days was demonstrated (Greece, 2022). Thus, residue trial samples are considered as stored under conditions not affecting the integrity of the samples.

Tolerances on a national level are not established in Vietnam. It is referred to the Codex Alimentarius Commission, where a Codex MRL of 0.3 mg/kg[8] for sulfoxaflor is set for coffee beans for which EFSA expressed no reservation (EFSA, 2022b; FAO, 2022).

The residue trial data are summarised in Appendix B.1.2.1.

1.2.2. Magnitude of residues in rotational crops

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

1.2.3. Magnitude of residues in processed commodities

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

Nevertheless, studies investigating the magnitude of sulfoxaflor residues in processed commodities (one study on pineapples (peeled fruits; peel; juice; process residues (wet bran)), one study on sunflower (sunflower meal and refined oil), two studies on coffee (roasted beans and instant coffee), two studies on mangoes (pulp and peel) and five studies on avocados (pitted fruit and pulp) were submitted with this application (Greece, 2022).

Processing studies in roasted coffee beans, peeled mangoes, avocados pulp and pineapples juice, pineapples process residues (wet bran), sunflower meal and sunflower refined oil demonstrated that residues were reduced whereby in instant coffee, a concentration of residues was observed (Greece, 2022). The number of submitted studies in all crops, except avocados, was considered insufficient to derive robust processing factors.

The number and quality of the processing studies is sufficient to derive robust processing factors for avocados pulp which are recommended to be included in Annex VI of Regulation (EC) No 396/2005.

The processing trials are summarised in Appendix B.1.2.3.

1.2.4. Proposed MRLs

The available data are considered sufficient to derive MRL proposals as well as risk assessment values for the commodities under evaluation (see Appendix B.1.2.1). In Section 3, EFSA assessed whether residues on the crops resulting from the uses authorised in Kenya, the USA and Vietnam are likely to pose a health risk to consumers.

2. Residues in livestock

Sunflower seeds (meal) may be used for feed purposes. Hence, it was necessary to perform a dietary burden calculation for livestock to estimate whether the authorised use of sulfoxaflor on sunflower and residues in imported sunflower seeds would have an impact on the residues expected in food of animal origin. Therefore, the previous calculation was updated (EFSA, 2019a,b) with the risk assessment values as derived for sunflower seeds from the submitted residue trials.

The input values for the exposure calculations for livestock are presented in Appendix D.1. The results of the dietary burden calculation are presented in Section B.2 and demonstrated that the exposure of all animal species did not increase with the consideration of sunflower seeds of this assessment. Therefore, further consideration of residues in livestock were not considered necessary in the context of this application.

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 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 sulfoxaflor 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 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 B.4.

Short-term (acute) dietary risk assessment

The short-term exposure assessment was performed only for the commodities assessed in this application in accordance with the internationally agreed methodology (FAO, 2016). The calculations were based on the highest residue (HR) derived from supervised field trials with exception of bulk materials such as sunflower seeds and coffee beans where the standardised median residue (STMR) values were used.

The short-term exposure did not exceed the ARfD for any the crops assessed in this application. The highest acute consumer exposure was calculated for mangoes (3.9% of ARfD). The calculated acute exposure was 3.2% of ARfD for blackberries, 0.5% of ARfD for dewberries, 2.8% of ARfD for raspberries (for 'other cane fruits', no calculation could be performed), 0.9% of ARfD for avocados, 1.5% of ARfD for pineapples, 0.2% of ARfD for asparagus, 2,9% of ARfD for globe artichokes, 0.1% of ARfD for sunflower seeds and 0.012% of ARfD for coffee beans (see 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, 2017; FAO, 2012, 2014, 2015). Additionally, the crops for which the MRL proposals were derived in the recent EFSA assessments or by the JMPR for which EFSA expressed no reservations (EFSA, 2019c, 2022a,b; FAO, 2019, 2022, 2023) 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.[12] However, this deviation is considered not to have a practical implication for the consumer risk assessment (EFSA, 2022).

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

The highest estimated long-term dietary intake accounted for 37% of the ADI[13] (NL toddler diet). The contributions of the commodities assessed in the present MRL application to the overall long-term exposure were low: 0.13% of the ADI for blackberries (IE adult diet), 0.03% of the ADI for dewberries (SE general diet), 0.21% of the ADI for raspberries (FI 3 years diet), 0.03% of the ADI for blueberries (NL toddler diet), 0.01% of the ADI for avocados (IE adult diet), 0.04% of the ADI for mangoes (IE adult diet), 0.1% of the ADI for pineapples (GEMS/Food G11), 0.01% for asparagus (IE adult diet), 0.06% for globe artichokes (IE adult diet), 0.09% for sunflower seeds (RO general diet) and 0.61% for coffee beans (FI adult diet).

EFSA concluded that the long-term intake of residues of sulfoxaflor resulting from the existing and the authorised 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.

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: cane fruits, blueberries, avocados, mangoes, pineapples, asparagus, globe artichokes, sunflower seeds and coffee beans.

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

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

EFSA concluded that the proposed import tolerances 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.

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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
CF	conversion factor for enforcement to risk assessment residue definition
CS	capsule suspension
CV	coefficient of variation (relative standard deviation)
CXL	Codex maximum residue limit
DALA	days after last application
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
DP	dustable powder
DS	powder for dry seed treatment
DT_{90}	period required for 90% dissipation (define method of estimation)
dw	dry weight
EC	emulsifiable concentrate
ECD	electron capture detector
EDI	estimated daily intake
EMS	evaluating Member State
eq	residue expressed as a.s. equivalent
ESI	electrospray ionisation
EURL	EU Reference Laboratory (former Community Reference Laboratory (CRL))
FAO	Food and Agriculture Organisation of the United Nations
FID	flame ionisation detector
FLD	fluorescence detector
FPD	flame photometric detector
GAP	Good Agricultural Practice
GC–MS	gas chromatography with mass spectrometry
HPLC	high performance liquid chromatography
HPLC-MS	high performance liquid chromatography with mass spectrometry
HPLC-MS/MS	high performance liquid chromatography with tandem mass spectrometry
HPLC-UVD	high performance liquid chromatography with ultra-violet detector
HR	highest residue
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ILV	independent laboratory validation
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LOQ	limit of quantification
MRL	maximum residue level
MS	mass spectrometry detector
MS	Member States
MS/MS	tandem mass spectrometry detector
NEU	northern Europe
OECD	Organisation for Economic Co-operation and Development

PBI	plant back interval
PF	processing factor
PHI	preharvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
RA	risk assessment
RAC	raw agricultural commodity
RD	residue definition
RMS	rapporteur Member State
SANCO	Directorate-General for Health and Consumers
SC	suspension concentrate
SEU	southern Europe
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
WG	water-dispersible granule
WHO	World Health Organization

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

Crop and/or situation	NEU, SEU, MS or country	F G or I[(a)]	Pests or Group of pests controlled	Preparation		Application				Application rate per treatment				PHI (days)[(d)]	Remarks
				Type[(b)]	Conc. a.s	Method kind	Range of growth stages and season[(c)]	Number min–max	Interval between application (min)	g a.s./hL min–max	Water L/ha min–max	Rate	Unit		
Cane fruits including blackberries, dewberries, raspberries (red and yellow) and other cane fruits	USA	F	Aphids, leafhopper, mealybugs, plant bugs, scales (suppression), stink bugs (suppression), thrips (suppression)	WG	500 g/kg (50%)	Foliar treatment – broadcast spraying	Up to mature fruit stage (BBCH 87)	1–4	7	Not specified	28–94	101*	g a.s./ha	1	* Max. 298 g a.s./ha/year. The registered labels for sulfoxaflor on blackberries, raspberries, indicate use of a surfactant.
Blueberries	USA	F	Scales (suppression), stink bugs (suppression), thrips (suppression)	WG	240 g/L (21.8%)	Foliar treatment – broadcast spraying	Up to mature fruit stage (BBCH 87)	1–4	7	Not specified	28–94	101*	g a.s./ha	1	* Max. 298 g a.s./ha/year. The registered labels for sulfoxaflor on blueberries indicate use of a surfactant.

Crop and/or situation	NEU, SEU, MS or country	F G or I[(a)]	Pests or Group of pests controlled	Preparation		Application				Application rate per treatment				PHI (days)[(d)]	Remarks
				Type[(b)]	Conc. a.s	Method kind	Range of growth stages and season[(c)]	Number min–max	Interval between application (min)	g a.s./hL min–max	Water L/ha min–max	Rate	Unit		
Avocados	USA	F	Thrips (suppression), aphids	SC	240 g/L (21.8%)	Foliar treatment – broadcast spraying	Up to BBCH 79 (mature fruit stage) [see remarks]	1–4	7	Not specified	28–94	101*	g a.s./ha	7	Application timing: Do not apply between 3 days prior to bloom and until after petal fall * Max. 298 g a.s./ha/year. The registered labels for sulfoxaflor on avocados indicate use of a surfactant.
Mangoes	Kenya	F	Mealy bugs	SC	240 g/L	Foliar treatment – broadcast spraying	Up to BBCH 81 (beginning of fruit colouring (Colour-Break)	1–3	14	Not specified	Not specified	96	g a.s./ha	3	Do not apply more than 3 applications in any one season, and not more than 2 consecutive applications.
Pineapples	USA	F	Mealy bugs	SC	240 g/L (21.8%)	Foliar treatment – broadcast spraying	Up to mature fruit stage (BBCH 87)	1–2	14	Not specified	28–94	101*	g a.s./ha	7	* Max. 202 g a.s./ha/year. The registered labels for sulfoxaflor on pineapples indicate use of a surfactant.

Crop and/or situation	NEU, SEU, MS or country	F G or I[(a)]	Pests or Group of pests controlled	Preparation		Application				Application rate per treatment				PHI (days)[(d)]	Remarks
				Type[(b)]	Conc. a.s	Method kind	Range of growth stages and season[(c)]	Number min–max	Interval between application (min)	g a.s./hL min–max	Water L/ha min–max	Rate	Unit		
Asparagus	USA	F	Thrips (suppression), aphids	SC	240 g/L (21.8%)	Foliar treatment – broadcast spraying	Fruiting – mature ferns	1–4	7	Not specified	28–94	101*	g a.s./ ha	[see remarks]	PHI: Apply to asparagus ferns only after harvest of spears * Max. 298 g a.s./ha/year. The registered label for sulfoxaflor on asparagus indicates use of a surfactant.
Globe artichokes	USA	F	Whitefly (suppression); Aphids, plant bugs	SC	240 g/L (21.8%)	Foliar treatment – broadcast spraying	40–89	1–4	7	Not specified	28–94	101*	g a.s./ ha	3	* Max. 298 g a.s./ha/year. The registered labels for the use of sulfoxaflor on globe artichokes indicate use of a surfactant.
Sunflower seeds	USA	F	Thrips (suppression only), plant bugs, aphids	SC	240 g/L	Foliar treatment – broadcast spraying	Up to mature head stage (BBCH 87)	1–2	7	Not specified	28–94	101*	g a.s./ ha	14	* Max. 193 g a.s./ha/year. The registered labels for sulfoxaflor on sunflower indicate use of a surfactant.

Crop and/or situation	NEU, SEU, MS or country	F G or I[(a)]	Pests or Group of pests controlled	Preparation		Application				Application rate per treatment				PHI (days)[(d)]	Remarks
				Type[(b)]	Conc. a.s	Method kind	Range of growth stages and season[(c)]	Number min–max	Interval between application (min)	g a.s./hL min–max	Water L/ha min–max	Rate	Unit		
Coffee beans	Vietnam	F	Mealy bugs	WG	500 g/kg	Foliar treatment – broadcast spraying	Up to mature fruit stage (BBCH 88)	1	n/a	Not specified	max 600	75	g a.s./ha	3	Application rate (g a.s./ha) calculated based on specified product weight and water volume (0.25 g product/ L water).

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

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

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

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

(d): PHI – minimum pre-harvest interval.

Appendix B – List of end points

B.1. Residues in plants

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

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

Primary crops (available studies)	**Crop groups**	**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 (Greece, 2022).	

DAT: days after treatment; PBI: plant-back interval; BBCH: growth stages of mono- and dicotyledonous plants; a.s.: active substance; MRL: maximum residue level; LC–MS/MS: liquid chromatography with tandem mass spectrometry; 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) (Greece, 2022)
		Asparagus	–20	304	Days	Sulfoxaflor, X11719474, X117121061	The study was terminated after 304 days (Greece, 2022)

Plant products (available studies)	Category	Commodity	T (°C)	Stability period		Compounds covered	Comment/Source
				Value	Unit		
	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) (Greece, 2022)
	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) (Greece, 2022)
		Blueberries	–20	756	Days	Sulfoxaflor, X11719474, X117121061	The study was terminated after 756 days (25 months) (Greece, 2022)
	Other	Sunflower seeds, meal	–20	685	Days	Sulfoxaflor, X11719474, X117121061	The study was terminated after 685 days (Greece, 2022)
		Sunflower seeds, refined oil	–20	696	Days	Sulfoxaflor, X11719474, X117121061	The study was terminated after 696 days (Greece, 2022)

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)]
Cane fruits	USA	**Raspberries** **Mo:** 0.236; 0.405; 0.443 0.536 **RA:** 0.245; 0.414; 0.457; 0.551 **Blackberries** **Mo:** 0.277; 0.490; 0.744 **RA:** 0.290; 0.505; 0.756 **Combined data set** **Mo:** 0.236; 0.277; 0.405; 0.443; 0.490; 0.536; 0.744 **RA:** 0.245; 0.290; 0.414; 0.457; 0.505; 0.551; 0.756 **CFs**: 1.04; 1.05; 1.02; 1.03; 1.03; 1.02; 1.01	Residue trials on raspberries and blackberries compliant with the authorised GAP. Underlined trials were performed in Canada, the remaining trials in the USA. The residue data on raspberries and blackberries were combined; an extrapolation to the whole group of cane fruits is acceptable (European Commission, 2020a).	**1.5**	Mo: 0.74 RA: **0.756**	Mo: 0.44 RA: **0.46**	1.03
Blueberry	USA	**Mo:** 0.155; 0.170; 0.268; 0.298; 0.310; 0.387; 0.392; 0.418; 0.425; 1.27 **RA:** 0.164; 0.179; 0.277; 0.307; 0.319; 0.396; 0.408; 0.427; 0.442; 1.28 **CFs**: 1.06; 1.05; 1.03; 1.03; 1.03; 1.02; 1.04; 1.02; 1.04; 1.01	GAP compliant trials on blueberries. 0.025–0.25% adjuvant used in all trials. Underlined trials were performed in Canada, the remaining trials in the USA (Greece, 2022).	**2.0**	Mo: 1.27 RA: **1.28**	Mo: 0.35 RA: **0.36**	1.03
Avocados	USA	**Mo:** 0.0126[(e)]; 0.0186; 0.0490; 0.0501; 0.0659[(f)], **RA:** 0.0220[(e)]; 0.0279; 0.0583; 0.0594; 0.0752[(f)] **RA_{pulp}:** < 0.019; 0.0211; 0.436; 0.0204; 0.0341[(g)]; **CFs**: 1.75; 1.5; 1.19; 1.19; 1.14	Residue trials on avocado compliant with maximum annual application rate of 298 g a.s./ha according to GAP of 3 × 100 g a.s./ha; interval 7 days, PHI: 7 days. Each trial was performed using an adjuvant however the amount is not quantified.[(f)] Higher residue at PHI of 14 days (Greece, 2022).	**0.15**	Mo: 0.07 RA: 0.075 RA_{pulp}: **0.04**	Mo: 0.05 RA: 0.06 RA_{pulp}: **0.02**	1.19

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)]
Mangoes	Kenya	**Mo:** 0.027; 0.037; 0.039; 0.054; 0.103; 0.114 **RA:** 0.036; 0.046; 0.048; 0.063; 0.112; 0.123 **CFs**: 1.33; 1.24; 1.23; 1.17; 1.09; 1.08	GAP compliant trials on mangoes with restrictions on number of annual and consecutive applications according to GAP of 2 × 100 (90.9–100.9) g a.s./ha; interval 14 days, PHI: 3 days considering that an additional application at an early stage will not affect the final residue (Greece, 2022); Trials performed in Uganda (1); Ghana (2), Senegal (1) and in Kenya (2). Underlined values refer to the Kent variety; the remaining two values to the apple variety [for information: For the Kent variety, the pit was 9% of the total fruit weight; for the apple variety 7%.] (Greece, 2022). The data on pulp available from two trials but not sufficient to derive RA values for the pulp (Table B.1.2.3).	**0.30**	Mo: 0.11 RA: **0.12**	Mo: 0.05 RA: **0.06**	1.2
Pineapples	USA	**Mo:** 0.011**;** 0.0117[(f)]; 0.020; 0.0202[(h)]; 0.0220[(h)]; 0.0270[(h)]; 0.030; 0.034; 0.035[(h)]; 0.0417; 0.0513; 0.057 **RA:** 0.020; 0.0211[(f)]; 0.029; 0.0296[(h)]; 0.0314[(h)]; 0.0363[(h)]; 0.039; 0.043; 0.044[(h)]; 0.0511; 0.0607; 0.066 **CFs:** 1.82; 1.80; 1.45; 1.47; 1.43; 1.34; 1.3; 1.26; 1.26; 1.23; 1.18; 1.16	GAP compliant trials on pineapples with restrictions on number of annual and consecutive applications according to GAP of 2 × 100 (98–103.5) g a.s./ha; interval 14 days, PHI: 7 days; Trials No 1, 3, 7 and 8 were performed in the USA with 0.1% adjuvant and trials 9, 10, 11 and 12 with 0.125% adjuvant, respectively. The remaining trials were performed in Costa Rica with 0.1% adjuvant added (Greece, 2022).	**0.09**	Mo: 0.057 RA: **0.066**	Mo: 0.029 RA: **0.038**	1.32
Asparagus	USA	**Mo:** 5 × < 0.01; 0.01063 **RA:** 5 × < 0.019; 0.0196 **CFs:** 5 × 1; 1.84	GAP compliant trials on asparagus with restrictions on number of annual and consecutive applications according to GAP of 3 × 100 (99.8–105.4) g a.s./ha; interval 6–8 days, PHI: 126–302 days; The trials were performed in the USA with 0.25% adjuvant added to three trials. Three trials with residues below the LOQ had added adjuvant of 0.04%, 0.07% and 0.3% adjuvant added (Greece, 2022).	**0.20**	Mo: 0.01 RA: **0.02**	Mo: 0.01 RA: **0.02**	1

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)]
Globe artichokes	USA	**Mo:** 0.217; 0.226; 0.260; 0.41 **RA:** 0.226; 0.235; 0.269; 0.416 **CFs:** 1.04; 1.04; 1.03; 1.01	GAP compliant trials on globe artichokes with restrictions on number of annual and consecutive applications according to GAP of 3 × 100 (98.2–104) g a.s./ha; interval 7–9 days, PHI: 3 days. The trials were performed in the USA with adjuvants ranging from 0.06% to 0.63%, except the 4th trial which was done in Canada with 0.25% adjuvant (Greece, 2022).	**0.90**	Mo: 0.41 RA: **0.42**	Mo: 0.24 RA: **0.25**	1.04
Sunflower seeds	USA	**Mo:** < 0.01; 0.014; 0.0185; 0.024; 0.047; 0.076[(f)]; 0.091; 0.149; 0.190 **RA:** < 0.019; 0.023; 0.0275; 0.033; 0.056; 0.085[(f)]; 0.100; 0.158; 0.199 **CFs:** 1; 1.64; 1.49; 1.38; 1.19; 1.12; 1.10; 1.06; 1.05	GAP compliant trials on sunflower seeds with restrictions on number of annual applications according to GAP of 2 × 100 (98.6–107.5) g a.s./ha; interval 7 days, PHI: 14–15 days; [(f)] residue at PHI of 21 day. The trials were performed in the USA with adjuvants ranging from 0.06% to 1% (Greece, 2022).	**0.40**	Mo: 0.19 RA: **0.199**	Mo: 0.047 RA: **0.056**	1.12
Coffee beans	Vietnam	**Mo:** < 0.01; 2 × 0.01;0.01[(f)]; 0.03[(f)]; 0.04[(f)]; 0.05; 0.06; 0.09[(f)]; 0.15 **RA:** < 0.019; 2 × 0.019; 0.019[(f)]; 0.039[(f)]; 0.049[(f)]; 0.059; 0.069; 0.099[(f)]; 0.16 **CFs:** 1; 3 × 1.9; 1.3; 1.23; 1.18; 1.15; 1.1; 1.07	GAP compliant trials on coffee beans (peeled and sun dried) according to GAP of 1 × 75 g a.s./ha; PHI: 3 days. [(f)]residue of 5th and 6th trial at PHI of 15 days, of 7th trial at PHI of 7 days and of 10th trial at PHI of 21 days (Greece, 2022).	**0.30**	Mo: 0.15 RA: **0.16**	Mo: 0.035 RA: **0.044**	1.2

MRL: maximum residue level; GAP: good agricultural practice; Mo: monitoring; 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 (derived was the median value) to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.
(e): The 2nd application was 127 g a.s./ha and slightly above 25% deviation which is not considered as concern since the other two were 96 and 91 g a.s./ha, altogether not exceeding the annual limit of 300 g a.s./ha (Greece, 2022).
(f): Higher residue at longer PHI.
(g): The residue values for pulp refer to a PHI of 7 days because for avocados pulp, no information was available at the PHI of 14 days where higher residues were reported for whole fruits. A consideration of this value has no impact on the HR and STMR values.
(h): Shorter PHI of 6 days.

B.1.2.2. Residues in rotational crops

Residues in rotational and succeeding crops expected based on confined rotational crop study?	Not triggered	Investigations of residues in rotational crops are not required for imported crops.
Residues in rotational and succeeding crops expected based on field rotational crop study?	Not triggered	

B.1.2.3. Processing factors

Processed commodity	Number of valid studies[(a)]	Processing Factor (PF)		CF_P[(b)]	Comment/Source
		Individual values	Median PF		
Avocados, pitted fruit with peel	5	Mo: 1.19; 1.16; 1.16; 1.09; 1.13 RA: 1.16; 1.14; 1.14; 1.05; 1.09	1.16	1	Greece (2022)
Avocados, pitted fruit with peel	5	Mo: 1.19; 1.16; 1.16; 1.09; 1.13 RA: 1.16; 1.14; 1.14; 1.05; 1.09	1.16	1	Greece (2022)
Avocado, pulp	5	Mo: 0.22; 0.40[(c)]; 0.63; 0.70; < 0.79[(d)] RA: 0.34; 0.48[(c)]; 0.76; 0.75; < 0.83[(d)]	0.63	1.2	Greece (2022)
Mango, pulp	2	Mo: < 0.09[(d)]; 1.03 RA: < 0.15[(d)]; 1.03	1	1	Tentative[(e)] (Greece, 2022)
Pineapple, peeled fruit	1	Mo: 0.155 RA: 0.204	0.155	1.3	Tentative[(e)] (Greece, 2022)
Pineapple, juice	1	Mo: 0.088 RA: 0.139	0.088	1.58	Tentative[(e)] (Greece, 2022)
Pineapple, wet bran	1	Mo: 0.101 RA: 0.152	0.10	1.5	Tentative[(e)] (Greece, 2022)
Sunflower, meal	1	Mo: < 0.71 RA: < 0.83	< 0.71	–	Tentative[(e)] (Greece, 2022) Residues in RAC: Mo: 0.014 mg/kg and RA: 0.023 mg/kg; in sunflower meal and refined oil: Mo: < 0.01 mg/kg; RA: < 0.019 mg/kg.
Sunflower, refined oil	1	Mo: < 0.71 RA: < 0.83	< 0.71	–	
Coffee, roasted beans	2	Mo: 0.45; 0.49 RA: 0.45; 0.51	0.47	1.1	Tentative[(e)] (Greece, 2022)
Coffee, instant coffee	2	Mo: 2.8; 2.9 RA: 2.8; 2.8	2.9	1.0	Tentative[(e)] (Greece, 2022)

(a): PF: processing factor; Mo: monitoring; RA: risk assessment. Studies with residues in the raw agricultural commodities (RAC) at or close to the LOQ were disregarded (unless concentration may occur).
(b): Conversion factor for risk assessment in the processed commodity; median of the individual conversion factors for each processing residues trial.
(c): The processing factor (PF) is based on residues in whole fruit and pulp at a PHI of 7 days by noting that higher residues were reported at a PHI of 14 days (see Table B.1.2.1) however for a PHI of 14 days, residue data for pulp were not reported.
(d): Residues in pulp below the LOQ of 0.01 mg/kg for monitoring and below the LOQ of 0.019 mg/kg for risk assessment.
(e): A tentative PF is derived based on a limited data set noting that for the current assessment, the data requirement according to Commission Regulation (EU) No 544/2011 apply (a balance study and at least 3 follow-up processing studies are required). According to the new data requirements (Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, 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, OJ L93, 3.4.2013 p. 1) however two processing studies with less than 50% divergence would be considered as sufficient.

B.2. Residues in livestock

Dietary burden calculation according to OECD (2013).

Relevant groups (sub-groups)	Dietary burden expressed in mg/kg				Most critical subgroup[(a)]	Most critical commodity[(b)]	Trigger exceeded (Y/N)	Previous assessments EFSA (2019b)
	bw per day		DM				0.1 mg/kg DM	Max burden
	Median	Max	Median	Max				mg/kg DM
Cattle (all)	0.048	0.060	1.57	1.87	Dairy cattle	Potato pw	Y	1.87
Cattle (dairy only)	0.048	0.060	1.25	1.56	Dairy cattle	Potato pw	Y	1.56
Sheep (all)	0.048	0.068	1.44	2.04	Ram/Ewe	Potato pw	Y	2.04
Sheep (ewe only)	0.048	0.068	1.44	2.04	Ram/Ewe	Potato pw	Y	2.04
Swine (all)	0.019	0.022	0.82	0.97	Swine (breeding)	Potato pw	Y	0.97
Poultry (all)	0.014	0.023	0.20	0.34	Poultry layer	Wheat straw	Y	0.34
Poultry (layer only)	0.012	0.023	0.17	0.34	Poultry layer	Wheat straw	Y	0.34
Fish	N/A							

bw: body weight; DM: dry matter; Max: maximum dietary burden; pw: process waste.
Metabolism of parent sulfoxaflor in the ruminant (goat) and rodent are similar, extrapolation from ruminants is possible (EFSA, 2014a).
(a): When 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'.
(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as 'mg/kg bw per day'.

B.3. Consumer risk assessment

ARfD	0.25 mg/kg bw (European Commission, 2015)
Highest IESTI, according to EFSA PRIMo	Crops assessed: Blackberries: 3.2% of ARfD (UK toddler) Dewberries: 0.5% of ARfD (UK toddler) Raspberries: 2.8% of ARfD (IE child) Other cane fruits: no data available Blueberries: 3.1% of ARfD (NL child) Avocados: 1.5% of ARfD (DE child) Mangoes: 3.9% of ARfD (NL toddler) Pineapples: 1.5% ARfD (UK 4-6 years) Asparagus: 0.2% of ARfD (NL child) Globe artichokes: 2.9% of ARfD (FR 11-14 years) Sunflower seeds: 0.1% of ARfD (DE child) Coffee beans: 0.012% of ARfD (FR 11-14 years)
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, except for sunflower seeds and coffee beans where the STMR values are used. For avocados, HR values reported in pulp were considered. For mangoes on the other hand limited data were available for pulp and therefore as a worse-case, residues (HR values) in whole fruits were considered. 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 diet) Highest contribution of crops assessed: Blackberries: 0.13% of ADI (IE adult diet) Dewberries: 0.03% of ADI (SE general diet) Raspberries: 0.21% of ADI (FI 3 year diet) Other cane fruits: no data available Blueberries: 0.03% of ADI (NL toddler diet) Avocados: 0.01% of ADI (IE adult diet) Mangoes: 0.04% of ADI (IE adult diet) Pineapples: 0.1% ADI (GEMS/Food G11 diet) Asparagus: 0.01% of ADI (IE adult diet) Globe artichokes: 0.06% of ADI (IE adult diet) Sunflower seeds: 0.09% of ADI (RO general diet) Coffee beans: 0.61% of ADI (FI adult diet)
Assumptions made for the calculations	The calculation is based on the median residue levels (STMR values) derived for raw agricultural commodities for the proposed import tolerances according to the residue definition for risk assessment. For avocados, STMR values reported in pulp were considered. For mangoes on the other hand limited data were available for pulp and therefore as a worse-case, residues (STMR values) in whole fruits were considered. 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, the crops for which the MRL proposals were derived in the recent EFSA assessments and by the JMPR (EFSA, 2019b, 2019c, 2022a, 2022b; FAO, 2019, 2022, 2023) for which EFSA expressed no reservations which were adopted by the Codex Alimentarius Commission, are however 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 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 MRL review, previous EFSA assessments or by FAO/JMPR and supported by EFSA, 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	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Sulfoxaflor (sum of isomers)				
0153000	Cane fruits	0.01*	1.5	The submitted data are sufficient to derive an import tolerance (US GAP). Risk for consumers is unlikely. The tolerance established in the USA for sulfoxaflor in cane berries is 1.5 mg/kg. A Codex MRL of 1.5 mg/kg, for which EFSA flagged no reservations, was adopted by the Codex Alimentarius Commission in 2022.
0154010	Blueberries	0.01*	2.0	The submitted data are sufficient to derive an import tolerance (US GAP). Risk for consumers is unlikely. The tolerance established in the USA for sulfoxaflor on blueberries is 2.0 mg/kg. A Codex MRL of 1.5 mg/kg on blueberries, for which EFSA flagged no reservations, was adopted by the Codex Alimentarius Commission in 2022.
0163010	Avocados	0.01*	0.15	The submitted data are sufficient to derive an import tolerance (US GAP). Risk for consumers is unlikely. The tolerance established in the USA for sulfoxaflor in avocados is 0.15 mg/kg. A Codex MRL of 0.15 mg/kg on avocados, for which EFSA flagged no reservations, was adopted by the Codex Alimentarius Commission in 2022.
0163030	Mangoes	0.01*	0.3	The submitted data are sufficient to derive an import tolerance (Kenyan GAP). Risk for consumers is unlikely. A tolerance is not established in Kenya at a national level. However, a Codex MRL of 0.3 mg/kg on mangoes, for which EFSA flagged no reservations, was adopted by the Codex Alimentarius Commission in 2022.
0163080	Pineapples	0.01*	0.09	The submitted data are sufficient to derive an import tolerance (US GAP). Risk for consumers is unlikely. The tolerance established in the USA for sulfoxaflor on pineapples is 0.1 mg/kg. A Codex MRL is not in place.
0270010	Asparagus	0.01*	0.015	The submitted data are sufficient to derive an import tolerance (US GAP). Risk for consumers is unlikely. The tolerance established in the USA for sulfoxaflor on asparagus is 0.01 mg/kg. A Codex MRL of 0.015 mg/kg on asparagus, for which EFSA flagged no reservations, was adopted by the Codex Alimentarius Commission in 2022.
0270050	Globe artichokes	0.06	0.9	The submitted data are sufficient to derive an import tolerance (US GAP). Risk for consumers is unlikely. The tolerance established in the USA for sulfoxaflor on globe artichokes is 0.7 mg/kg; however, a Codex MRL for sulfoxaflor on globe artichokes of 0.9 mg/kg has been proposed by JMPR, but the Codex Alimentarius Commission meeting has not taken place yet.
0401050	Sunflower seeds	0.02*	0.4	The submitted data are sufficient to derive an import tolerance (US GAP). Risk for consumers is unlikely. The tolerance established in the USA for sulfoxaflor on sunflower seeds is 0.3 mg/kg, however a Codex MRL for sulfoxaflor on sunflower seeds of 0.4 mg/kg has been proposed by JMPR but the Codex Alimentarius Commission meeting has not taken place yet.

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
0620000	Coffee beans	0.05*	0.3	The submitted data are sufficient to derive an import tolerance (Vietnamese GAP). Risk for consumers is unlikely. A tolerance is not established in Vietnam at a national level. However, a Codex MRL of 0.3 mg/kg on coffee beans, for which EFSA flagged no reservations, was adopted by the Codex Alimentarius Commission in 2022.

MRL: maximum residue level; NEU: northern Europe; SEU: southern Europe; GAP: Good Agricultural Practice.
*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.

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 per 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	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
37%	NL toddler	14.82	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	8.03	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	7.15	9%	Milk: Cattle	2%	Apples	1%	Oranges	0.0%	18%
17%	FR child 3 15 yr	6.94	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	5.64	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	4.95	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	4.39	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 G11	3.94	3%	Milk: Cattle	1%	Poultry: Muscle/meat	1%	Rice	0.0%	10%
10%	GEMS/Food G15	3.93	2%	Milk: Cattle	2%	Poultry: Muscle/meat	1%	Rice	0.0%	10%
9%	DE women 14-50 yr	3.78	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	3.63	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	3.22	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	1.81	2%	Rice	0.3%	Mandarins	0.3%	Apples	0.0%	5%
4%	FI 6 yr	1.45	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	1.30	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	1.04	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): ---

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)	Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
58%	Table grapes	2/2	146	27%	Table grapes	2/2	68
54%	Spinaches	6/6	136	20%	Chinese cabbages/pe-tsai	2/2	51
44%	Lettuces	4/2.87	109	19%	Wine grapes	2/2	47
30%	Melons	0.5/0.5	76	15%	Broccoli	3/1.6	38
27%	Oranges	0.8/0.51	68	14%	Lettuces	4/2.87	35
27%	Broccoli	3/1.6	67	10%	Spinaches	6/6	24
26%	Chinese cabbages/pe-tsai	2/2	64	10%	Celeries	1.5/1.5	24
24%	Watermelons	0.5/0.5	61	8%	Watermelons	0.5/0.5	20
22%	Celeries	1.5/1.5	56	8%	Melons	0.5/0.5	20
22%	Pears	0.4/0.4	55	6%	Oranges	0.8/0.51	16
19%	Peaches	0.5/0.5	48	6%	Cucumbers	0.5/0.5	14
17%	Apples	0.4/0.4	43	5%	Rice	1.5/1.5	13
13%	Cucumbers	0.5/0.5	33	5%	Cherries (sweet)	1.5/1.24	12
12%	Mandarins	0.8/0.51	30	5%	Pears	0.4/0.4	12
10%	Sweet peppers/bell peppers	0.4/0.4	24	5%	Blueberries	2/1.28	12

Expand/collapse list

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): ---

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)	Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
50%	Broccoli/boiled	3/1.6	126	20%	Celeries/boiled	1.5/1.5	51
33%	Spinaches/frozen; boiled	6/6	83	20%	Spinaches/frozen; boiled	6/6	50
18%	Pumpkins/boiled	0.5/0.5	44	15%	Broccoli/boiled	3/1.6	39
7%	Courgettes/boiled	0.5/0.5	18	11%	Pumpkins/boiled	0.5/0.5	28
6%	Oranges/juice	0.8/0.3	16	8%	Wine grapes/wine	2/2	19
5%	Peaches/canned	0.5/0.5	13	5%	Table grapes/raisins	2/9.4	12
5%	Kales/boiled	1/0.43	12	5%	Courgettes/boiled	0.5/0.5	11
5%	Gherkins/pickled	0.5/0.5	11	2%	Rice/milling (polishing)	1.5/0.6	5.8
4%	Currants (red, black and whit	2/0.39	11	2%	Currants (red, black and	2/0.39	5.0
4%	Rice/milling (polishing)	1.5/0.6	9.2	2%	Oranges/juice	0.8/0.3	4.6
3%	Escaroles/broad-leaved endiv	0.2/0.11	7.3	2%	Peaches/canned	0.5/0.5	4.1
3%	Cauliflowers/boiled	0.1/0.09	6.3	1%	Cauliflowers/boiled	0.1/0.09	3.7
2%	Wine grapes/juice	2/0.14	6.1	1%	Apples/juice	0.4/0.11	3.7
2%	Apples/juice	0.4/0.11	6.0	1%	Wine grapes/juice	2/0.14	2.9
2%	Raspberries/juice	1.5/0.46	5.3	0.9%	Escaroles/broad-leaved	0.2/0.11	2.2

Expand/collapse list

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. Livestock dietary burden calculations

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment[(a)]	Input value (mg/kg)	Comment
Risk assessment residue definition: sum of sulfoxaflor and metabolite X11719474, expressed as sulfoxaflor				
Barley, straw	0.022	STMR (EFSA, 2014a,b)	0.147	HR (EFSA, 2014a,b)
Beet, mangel	0.013	STMR rotational[(b)] (EFSA, 2019b)	0.065	HR rotational[(b)] (EFSA, 2019b)
Beet, sugar	0.013	STMR rotational[(b)] (EFSA, 2019b)	0.065	HR rotational[(b)] (EFSA, 2019b)
Cabbage, heads leaves	0.013	STMR rotational[(b)] (EFSA, 2019b)	0.065	HR rotational[(b)] (EFSA, 2019b)
Kales	0.200	STMR (EFSA, 2019b)	0.430	HR (EFSA, 2019b)
Oat straw	0.030	STMR (EFSA, 2019b)	0.220	HR (EFSA, 2019b)
Rye, straw	0.110	STMR (EFSA, 2019b)	0.350	HR (EFSA, 2019b)
Triticale, straw	0.110	STMR (EFSA, 2019b)	0.350	HR (EFSA, 2019b)
Wheat straw	0.143	STMR (EFSA, 2014a,b)	1.648	HR (EFSA, 2014a,b)
Potato culls	0.019	STMR (EFSA, 2014a,b)	0.019	HR (EFSA, 2014a,b)
Barley, grain	0.020	STMR (EFSA, 2014a,b)	0.020	STMR (EFSA, 2014a,b)
Cotton seeds	0.019	STMR (EFSA, 2014a,b)	0.019	STMR (EFSA, 2014a,b)
Oat grain	0.030	STMR (EFSA, 2019b)	0.030	STMR (EFSA, 2019b)
Rye, grain	0.019	STMR (EFSA, 2019b)	0.019	STMR (EFSA, 2019b)
Soyabean seed	0.023	STMR (EFSA, 2014a,b)	0.023	STMR (EFSA, 2014a,b)
Triticale grain	0.019	STMR (EFSA, 2019b)	0.019	STMR (EFSA, 2019b)
Wheat grain	0.019	STMR (EFSA, 2014a,b)	0.019	STMR (EFSA, 2014a,b)
Apple, pomace wet	0.123	STMR × PF (EFSA, 2014a,b)	0.123	STMR × PF (EFSA, 2014a,b)
Beet, sugar, dried pulp	0.180	STMR rotational (EFSA, 2014a,b) × (PF)	0.180	STMR rotational (EFSA, 2014a,b) × (PF)
Beet, sugar, ensiled pulp	0.030		0.030	
Beet, sugar, molasses	0.280		0.280	
Brewer's grain dried	0.066	STMR (EFSA, 2014a,b) × (PF)	0.066	STMR (EFSA, 2014a,b) × (PF)
Rape seed, meal	0.136	STMR × PF (EFSA, 2014a,b)	0.136	STMR × PF (EFSA, 2014a,b)
Citrus, dried pulp	2.275	STMR (orange) × CF × PF (EFSA, 2019b)	2.275	STMR (orange) × CF × PF (EFSA, 2019b)
Cotton, meal	0.015	STMR × PF (EFSA, 2014a,b)	0.015	STMR × PF (EFSA, 2014a,b)
Distiller's grain dried	0.063	STMR (EFSA, 2014a,b) × (PF)	0.063	STMR (EFSA, 2014a,b) × (PF)
Potato process waste	0.380	STMR (EFSA, 2014a,b) × (PF)	0.380	STMR (EFSA, 2014a,b) × (PF)
Potato dried pulp	0.722	STMR (EFSA, 2014a,b) × (PF)	0.722	STMR (EFSA, 2014a,b) × (PF)
Soybean, meal	0.030	STMR (EFSA, 2014a,b) × PF	0.030	STMR (EFSA, 2014a,b) × PF
Soybean, hulls	0.035	STMR (EFSA, 2014a,b) × PF	0.035	STMR (EFSA, 2014a,b) × PF
Sunflower, meal	**0.056**	**STMR (Table in B.1.2.1) × PF**	**0.056**	**STMR (Table in B.1.2.1) × PF**
Wheat gluten, meal	0.0004	STMR × PF (EFSA, 2014a,b)	0.0004	STMR × PF (EFSA, 2014a,b)
Wheat, milled by-prdts	0.004	STMR × PF (EFSA, 2014a,b)	0.004	STMR × PF (EFSA, 2014a,b)

STMR: supervised trials median residue; HR: highest residue; PF: processing factor; CF: conversion factor.

(a): For beet root and potato by-products and for brewer's, distilled grain dried and sunflower meal in the absence of processing factors supported by data, default processing factors of 18, 3, 28, 20, 38, 3.3 and 2 were, respectively, included in the calculation to consider the potential concentration of residues in these commodities.

(b): As a worst case, highest residues of X11719474 observed in rotational crops from the EU field rotation crop study at 1 N the intended critical use were included (EFSA, 2019b).

D.2. Consumer risk assessment

Commodity	Existing/ Proposed MRL[(a)] (mg/kg)	Type of MRL/source	Chronic risk assessment		Acute risk assessment	
			Input value (mg/kg)[(b)]	Comment	Input value (mg/kg)[(b)]	Comment
Risk assessment residue definition: Sum of sulfoxaflor and metabolite X11719474, expressed as sulfoxaflor						
Blackberries	1.5	**Proposed MRL**	0.457	STMR-RAC	0.756	HR-RAC
Blackberries	1.5	**Proposed MRL**	0.457	STMR-RAC	0.756	HR-RAC
Dewberries	1.5	**Proposed MRL**	0.457	STMR-RAC	0.756	HR-RAC
Raspberries (red and yellow)	1.5	**Proposed MRL**	0.457	STMR-RAC	0.756	HR-RAC
Other cane fruit	1.5	**Proposed MRL**	0.457	STMR-RAC		
Blueberries	2	**Proposed MRL**	0.358	STMR-RAC	1.28	HR-RAC
Avocados	0.15	**Proposed MRL**	0.021	STMR-pulp	0.044	HR-pulp
Mangoes	0.3	**Proposed MRL**	0.056	STMR-RAC	0.123	HR-RAC
Pineapples	0.09	**Proposed MRL**	0.066	STMR-RAC	0.038	HR-RAC
Asparagus	0.015	**Proposed MRL**	0.019	STMR-RAC	0.02	HR-RAC
Globe artichokes	0.9	**Proposed MRL**	0.252	STMR-RAC	0.416	HR-RAC
Sunflower seeds	0.4	**Proposed MRL**	0.056	STMR-RAC	0.056	STMR-RAC
Coffee beans	0.3	**Proposed MRL**	0.044	STMR-RAC	0.044	STMR-RAC
Grapefruits	0.15	Existing MRL (FAO, 2015)	0.0145	STMR-RAC[(c)] (0.013) × CF (1.16) (EFSA, 2019c)	Acute risk assessment performed only for the crops under consideration	
Oranges	0.8	Existing MRL (FAO, 2015)	0.3016	STMR-RAC[(c)] (0.26) × CF (1.16) (EFSA, 2019c)		
Lemons	0.4	Existing MRL (FAO, 2015)	0.04408	STMR-RAC[(c)] (0.038) × CF (1.16) (EFSA, 2019c)		
Limes	0.5	Proposed MRL (EFSA, 2019c[(d)])	0.0812	STMR-RAC (0.070) × CF (1.16)		
Mandarins	0.8	Existing MRL (FAO, 2015)	0.3016	STMR-RAC[(c)] (0.013) × CF (1.16) (EFSA, 2019c)		
Almonds	0.03	Proposed MRL (FAO, 2019[(d)])	0.01	STMR-RAC[(e)]		
Brazil nuts	0.03	Proposed MRL (FAO, 2019[(d)])	0.01	STMR-RAC[(e)]		
Cashew nuts	0.03	Proposed MRL (FAO, 2019[(d)])	0.01	STMR-RAC[(e)]		

Commodity	Existing/Proposed MRL[(a)] (mg/kg)	Type of MRL/source	Chronic risk assessment		Acute risk assessment	
			Input value (mg/kg)[(b)]	Comment	Input value (mg/kg)[(b)]	Comment
Chestnuts	0.03	Proposed MRL (FAO, 2019[(d)])	0.01	STMR-RAC[(e)]		
Coconuts	0.03	Proposed MRL (FAO, 2019[(d)])	0.01	STMR-RAC[(e)]		
Hazelnuts/cobnuts	0.03	Proposed MRL (FAO, 2019[(d)])	0.01	STMR-RAC[(e)]		
Macadamia	0.03	Proposed MRL (FAO, 2019[(d)])	0.01	STMR-RAC[(e)]		
Pecans	0.03	Proposed MRL (FAO, 2019[(d)])	0.01	STMR-RAC[(e)]		
Pine nut kernels	0.03	Proposed MRL (FAO, 2019[(d)])	0.01	STMR-RAC[(e)]		
Pistachios	0.03	Proposed MRL (FAO, 2019[(d)])	0.01	STMR-RAC[(e)]		
Walnuts	0.03	Proposed MRL (FAO, 2019[(d)])	0.01	STMR-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		
Pears	0.4	Existing MRL (EFSA, 2014a)	0.11	STMR-RAC		
Quinces	0.3	Existing MRL (FAO, 2015)	0.067	STMR-RAC[(e)]		
Medlar	0.3	Existing MRL (FAO, 2015)	0.067	STMR-RAC[(e)]		
Loquats/Japanese medlars	0.3	Existing MRL (FAO, 2015)	0.067	STMR-RAC[(e)]		
Other pome fruit	0.3	Existing MRL (FAO, 2015)	0.067	STMR-RAC[(e)]		
Apricots	0.5	Existing MRL (EFSA, 2014a)	0.15	STMR-RAC		
Cherries (sweet)	1.5	Existing MRL (FAO, 2015)	0.34	STMR-RAC[(e)]		
Peaches	0.5	Existing MRL (EFSA, 2014a)	0.15	STMR-RAC		
Plums	0.5	Existing MRL (FAO, 2015)	0.038	STMR-RAC[(e)]		
Table grapes	2	Existing MRL (EFSA, 2014a)	0.17	STMR-RAC		
Wine grapes	2	Existing MRL (FAO, 2012)	0.14	STMR-RAC[(e)]		
Strawberries	0.5	Existing MRL (EFSA, 2014a)	0.2	STMR-RAC		
Currants (red, black and white)	2	Proposed MRL (FAO, 2022[(d)])	0.39	STMR-RAC[(e)]		
Gooseberries	2	Proposed MRL (FAO, 2022[(d)])	0.39	STMR-RAC[(e)]		
Rose hips	2	Proposed MRL (FAO, 2021[(d)])	0.39	STMR-RAC[(e)]		
Azarole/Mediteranean medlar	0.3	Existing MRL (FAO, 2015)	0.07	STMR-RAC[(e)]		
Kaki/Japanese persimmons	0.3	Existing MRL (FAO, 2015)	0.07	STMR-RAC[(e)]		
Potatoes	0.03	Existing MRL (EFSA, 2014a)	0.02	STMR-RAC		
Cassava roots/manioc	0.03	Existing MRL (FAO, 2012)	0.01	STMR-RAC[(e)]		
Sweet potatoes	0.03	Existing MRL (FAO, 2012)	0.01	STMR-RAC[(e)]		
Yams	0.03	Existing MRL (FAO, 2012)	0.01	STMR-RAC[(e)]		
Arrowroots	0.03	Existing MRL (FAO, 2012)	0.01	STMR-RAC[(e)]		
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)]		
Carrots	0.05	Existing MRL (FAO, 2014)	0.01	STMR-RAC[(e)]		
Celeriacs/turnip-rooted celeries	0.03	Existing MRL (FAO, 2012)	0.01	STMR-RAC[(e)]		
Horseradishes	0.03	Existing MRL (FAO, 2012)	0.01	STMR-RAC[(e)]		

Commodity	Existing/ Proposed MRL[(a)] (mg/kg)	Type of MRL/source	Chronic risk assessment		Acute risk assessment	
			Input value (mg/kg)[(b)]	Comment	Input value (mg/kg)[(b)]	Comment
Jerusalem artichokes	0.03	Existing MRL (FAO, 2012)	0.01	STMR-RAC[(e)]		
Parsnips	0.03	Existing MRL (FAO, 2012)	0.01	STMR-RAC[(e)]		
Parsley roots/ Hamburg roots parsley	0.03	Existing MRL (FAO, 2012)	0.01	STMR-RAC[(e)]		
Radishes	0.03	Existing MRL (FAO, 2012)	0.01	STMR-RAC[(e)]		
Salsifies	0.03	Existing MRL (FAO, 2012)	0.01	STMR-RAC[(e)]		
Swedes/rutabagas	0.03	Existing MRL (FAO, 2012)	0.01	STMR-RAC[(e)]		
Turnips	0.03	Existing MRL (FAO, 2012)	0.01	STMR-RAC[(e)]		
Other roots and tuber vegetables	0.03	Existing MRL (FAO, 2012)	0.01	STMR-RAC[(e)]		
Garlic	0.01*	Existing MRL (FAO, 2012)	0.01	LOQ[(e)]		
Onions	0.01*	Existing MRL (FAO, 2012)	0.01	LOQ[(e)]		
Spring onions/ green onions and Welsh onions	0.7	Existing MRL (FAO, 2012)	0.11	STMR-RAC[(e)]		
Tomatoes	0.3	Existing MRL (EFSA, 2014a)	0.06	STMR-RAC		
Sweet peppers/ bell peppers	0.4	Existing MRL (EFSA, 2014a)	0.08	STMR-RAC		
Aubergines/egg plants	0.3	Existing MRL (EFSA, 2014a)	0.06	STMR-RAC		
Cucumbers	0.5	Existing MRL (FAO, 2012)	0.03	STMR-RAC[(e)]		
Gherkins	0.5	Existing MRL (FAO, 2012)	0.03	STMR-RAC[(e)]		
Courgettes	0.5	Existing MRL (FAO, 2012)	0.03	STMR-RAC[(e)]		
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)]		
Pumpkins	0.5	Existing MRL (FAO, 2012)	0.03	STMR-RAC[(e)]		
Watermelons	0.5	Existing MRL (FAO, 2012)	0.03	STMR-RAC[(e)]		
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[(e)]		
Broccoli	3	FAO (2012)	0.074	STMR-RAC[(e)]		
Cauliflowers	0.1	Proposed MRL (EFSA, 2019b[(d)])	0.02	STMR-RAC		
Brussels sprouts	0.015	Proposed MRL (EFSA, 2019b[(d)])	0.02	STMR-RAC		
Head cabbages	0.4	Existing MRL (FAO, 2012)	0.099	STMR-RAC[(e)]		
Chinese cabbages/ pe-tsai	2	Existing MRL (EFSA, 2014a)	1	STMR-RAC		
Kales	1	Proposed MRL (EFSA, 2019b[(d)])	0.02	STMR-RAC		
Lamb's lettuce/ corn salads	0.2	Proposed MRL (EFSA, 2022a[(d)])	0.03	STMR-RAC		
Lettuces	4	Existing MRL (EFSA, 2014a)	0.585	STMR-RAC		
Escaroles/broad-leaved endives	0.2	Proposed MRL (EFSA, 2022a[(d)])	0.03	STMR-RAC		
Cress and other sprouts and shoots	0.2	Proposed MRL (EFSA, 2022a[(d)])	0.03	STMR-RAC		

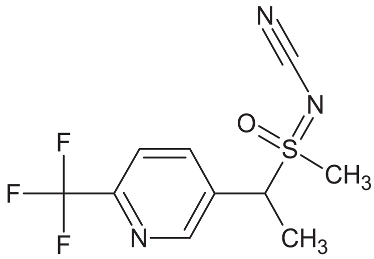
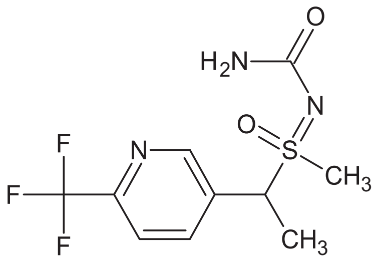
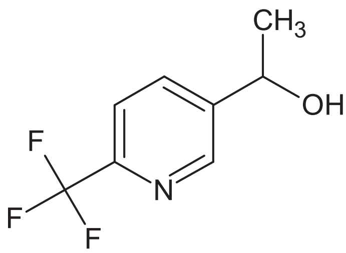
Commodity	Existing/ Proposed MRL[(a)] (mg/kg)	Type of MRL/source	Chronic risk assessment		Acute risk assessment	
			Input value (mg/kg)[(b)]	Comment	Input value (mg/kg)[(b)]	Comment
Land cress	0.2	Proposed MRL (EFSA, 2022a[(d)])	0.03	STMR-RAC		
Roman rocket/ rucola	0.2	Proposed MRL (EFSA, 2022a[(d)])	0.03	STMR-RAC		
Red mustards	0.2	Proposed MRL (EFSA, 2022a[(d)])	0.03	STMR-RAC		
Baby leaf crops (including brassica species)	0.2	Proposed MRL (EFSA, 2022a[(d)])	0.03	STMR-RAC		
Other lettuce and other salad plants	0.2	Proposed MRL (EFSA, 2022a[(d)])	0.03	STMR-RAC		
Spinaches	6	Existing MRL (EFSA, 2014a)	1.34	STMR-RAC		
Purslanes	0.2	Proposed MRL (EFSA, 2019b[(d)])	0.03	STMR-RAC		
Chards/beet leaves	0.2	Proposed MRL (EFSA, 2019b[(d)])	0.03	STMR-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		
Chervil	0.02	Proposed MRL (EFSA, 2019b[(d)])	0.03	STMR-RAC		
Chives	0.02	Proposed MRL (EFSA, 2019b[(d)])	0.03	STMR-RAC		
Celery leaves	1.5	EFSA (2014a)	0.255	STMR-RAC		
Parsley	0.02	Proposed MRL (EFSA, 2019b[(d)])	0.03	STMR-RAC		
Sage	0.02	Proposed MRL (EFSA, 2019b[(d)])	0.03	STMR-RAC		
Rosemary	0.02	Proposed MRL (EFSA, 2019b[(d)])	0.03	STMR-RAC		
Thyme	0.02	Proposed MRL (EFSA, 2019b[(d)])	0.03	STMR-RAC		
Basil and edible flowers	0.02	Proposed MRL (EFSA, 2019b[(d)])	0.03	STMR-RAC		
Laurel/bay leaves	0.02	Proposed MRL (EFSA, 2019b[(d)])	0.03	STMR-RAC		
Tarragon	0.02	Proposed MRL (EFSA, 2019b[(d)])	0.03	STMR-RAC		
Other herbs	0.02	Proposed MRL (EFSA, 2019b[(d)])	0.03	STMR-RAC		
Beans (with pods)	0.15	Existing MRL (EFSA, 2022a[(d)])	0.02	STMR-RAC		
Beans (without pods)	0.03	Proposed MRL (EFSA, 2019b[(d)])	0.02	STMR-RAC		
Peas (with pods)	0.15	Proposed MRL (EFSA, 2019b[(d)])	0.02	STMR-RAC		
Peas (without pods)	0.03	Proposed MRL (EFSA, 2022a[(d)])	0.02	STMR-RAC		
Celeries	1.5	Existing MRL (FAO, 2012)	0.19	STMR-RAC[(e)]		
Beans	0.3	Existing MRL (FAO, 2014)	0.08	STMR-RAC[(e)]		
Rapeseeds/canola seeds	0.15	Existing MRL (EFSA, 2014a)	0.07	STMR-RAC		
Soyabeans	0.3	Existing MRL (EFSA, 2014a)	0.02	STMR-RAC		
Cotton seeds	0.4	Existing MRL (FAO, 2012)	0.02	STMR-RAC[(e)]		
Barley	0.6	Existing MRL (FAO, 2012)	0.06	STMR-RAC[(e)]		
Maize/corn	0.01*	Proposed MRL (FAO, 2019[(d)])	0.01*	LOQ[(e)]		
Oat	0.06	Proposed MRL (EFSA, 2019b[(d)])	0.03	STMR-RAC		
Rice	1.5	Proposed MRL (FAO, 2019[(d)])	1.5	MRL[(e)]		
Rye	0.03	Proposed MRL (EFSA, 2019b[(d)])	0.02	STMR-RAC		
Sorghum	0.2	Proposed MRL (FAO, 2019[(d)])	0.03	STMR-RAC[(e)]		

Commodity	Existing/ Proposed MRL[(a)] (mg/kg)	Type of MRL/source	Chronic risk assessment		Acute risk assessment	
			Input value (mg/kg)[(b)]	Comment	Input value (mg/kg)[(b)]	Comment
Wheat	0.2	FAO (2012)	0.03	STMR-RAC[(e)]		
Swine: Muscle/ meat	0.4	Proposed MRL (FAO, 2019[(d)])	0.16	STMR-RAC[(e)]		
Swine: Fat tissue	0.2	Proposed MRL (FAO, 2019[(d)])	0.06	STMR-RAC[(e)]		
Swine: Liver	1	Proposed MRL (FAO, 2019[(d)])	0.44	STMR-RAC[(e)]		
Swine: Kidney	1	Proposed MRL (FAO, 2019[(d)])	0.44	STMR-RAC[(e)]		
Swine: Edible offals (other than liver and kidney)	1	Proposed MRL (FAO, 2019[(d)])	0.44	STMR-RAC[(e)]		
Bovine: Muscle/ meat	0.4	Proposed MRL (FAO, 2019[(d)])	0.16	STMR-RAC[(e)]		
Bovine: Fat tissue	0.2	Proposed MRL (FAO, 2019[(d)])	0.06	STMR-RAC[(e)]		
Bovine: Liver	1	Proposed MRL (FAO, 2019[(d)])	0.44	STMR-RAC[(e)]		
Bovine: Kidney	1	Proposed MRL (FAO, 2019[(d)])	0.44	STMR-RAC[(e)]		
Bovine: Edible offals (other than liver and kidney)	1	Proposed MRL (FAO, 2019[(d)])	0.44	STMR-RAC[(e)]		
Sheep: Muscle/ meat	0.4	Proposed MRL (FAO, 2019[(d)])	0.16	STMR-RAC[(e)]		
Sheep: Fat tissue	0.2	Proposed MRL (FAO, 2019[(d)])	0.06	STMR-RAC[(e)]		
Sheep: Liver	1	Proposed MRL (FAO, 2019[(d)])	0.44	STMR-RAC[(e)]		
Sheep: Kidney	1	Proposed MRL (FAO, 2019[(d)])	0.44	STMR-RAC[(e)]		
Sheep: Edible offals (other than liver and kidney)	1	Proposed MRL (FAO, 2019[(d)])	0.44	STMR-RAC[(e)]		
Goat: Muscle/ meat	0.4	Proposed MRL (FAO, 2019[(d)])	0.16	STMR-RAC[(e)]		
Goat: Fat tissue	0.2	Proposed MRL (FAO, 2019[(d)])	0.06	STMR-RAC[(e)]		
Goat: Liver	1	Proposed MRL (FAO, 2019[(d)])	0.44	STMR-RAC[(e)]		
Goat: Kidney	1	Proposed MRL (FAO, 2019[(d)])	0.44	STMR-RAC[(e)]		
Goat: Edible offals (other tha liver and kindey)	1	Proposed MRL (FAO, 2019[(d)])	0.44	STMR-RAC[(e)]		
Equine: Muscle/ meat	0.4	Proposed MRL (FAO, 2019[(d)])	0.16	STMR-RAC[(e)]		
Equine: Fat tissue	0.2	Proposed MRL (FAO, 2019[(d)])	0.06	STMR-RAC[(e)]		
Equine: Liver	1	Proposed MRL (FAO, 2019[(d)])	0.44	STMR-RAC[(e)]		
Equine: Kidney	1	Proposed MRL (FAO, 2019[(d)])	0.44	STMR-RAC[(e)]		
Equine: Edible offals (other than liver and kidney)	1	Proposed MRL (FAO, 2019[(d)])	0.44	STMR-RAC[(e)]		
Poultry: Muscle/ meat	0.7	Proposed MRL (FAO, 2019[(d)])	0.64	STMR-RAC[(e)]		
Poultry: Fat tissue	0.03	Proposed MRL (FAO, 2019[(d)])	0.02	STMR-RAC[(e)]		
Poultry: Liver	0.3	Proposed MRL (FAO, 2019[(d)])	0.18	STMR-RAC[(e)]		
Poultry: Kidney	0.3	Proposed MRL (FAO, 2019[(d)])	0.18	STMR-RAC[(e)]		

Commodity	Existing/ Proposed MRL[(a)] (mg/kg)	Type of MRL/source	Chronic risk assessment		Acute risk assessment	
			Input value (mg/kg)[(b)]	Comment	Input value (mg/kg)[(b)]	Comment
Poultry: Edible offals (other than liver and kideny)	0.3	Proposed MRL (FAO, 2019[(d)])	0.18	STMR-RAC[(e)]		
Other farmed animals: Muscle/ meat	0.4	Proposed MRL (FAO, 2019[(d)])	0.06	STMR-RAC[(e)]		
Other farmed animals: Fat tissue	0.2	Proposed MRL (FAO, 2019[(d)])	0.06	STMR-RAC[(e)]		
Other farmed animals: Liver	1	Proposed MRL (FAO, 2019[(d)])	0.44	STMR-RAC[(e)]		
Other farmed animals: Kidney	1	Proposed MRL (FAO, 2019[(d)])	0.44	STMR-RAC[(e)]		
Other farmed animals: Edible offals (other than liver and kidney)	1	Proposed MRL (FAO, 2019[(d)])	0.44	STMR-RAC[(e)]		
Milk: Cattle	0.3	Proposed MRL (FAO, 2019[(d)])	0.14	STMR-RAC[(e)]		
Milk: Sheep	0.3	Proposed MRL (FAO, 2019[(d)])	0.14	STMR-RAC[(e)]		
Milk: Goat	0.3	Proposed MRL (FAO, 2019[(d)])	0.14	STMR-RAC[(e)]		
Milk: Horse	0.3	Proposed MRL (FAO, 2019[(d)])	0.14	STMR-RAC[(e)]		
Milk: Others	0.3	Proposed MRL (FAO, 2019[(d)])	0.14	STMR-RAC[(e)]		
Eggs: Chicken	0.1	Proposed MRL (FAO, 2019[(d)])	0.07	STMR-RAC[(e)]		
Eggs: Duck	0.1	Proposed MRL (FAO, 2019[(d)])	0.07	STMR-RAC[(e)]		
Eggs: Goose	0.1	Proposed MRL (FAO, 2019[(d)])	0.07	STMR-RAC[(e)]		
Eggs: Quail	0.1	Proposed MRL (FAO, 2019[(d)])	0.07	STMR-RAC[(e)]		
Eggs: Others	0.1	Proposed MRL (FAO, 2019[(d)])	0.07	STMR-RAC[(e)]		
Other crops/ commodities						

STMR-RAC: supervised trials median residue in raw agricultural commodity; HR-RAC: highest residue in raw agricultural commodity; PeF: Peeling factor. PRIMo vs. 3.1 calculations were performed in the 'refined calculation mode'.
*: Indicates that the value is proposed at the limit of quantification.
(a):MRLs were calculated based on residue values according to the residue definition for enforcement.
(b): Figures in the table are rounded to two 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.
(c): Median residues refer to whole fruits. Data were not sufficient to derive an STMR for citrus pulp (FAO, 2015).
(d): MRLs not yet implemented by Regulation.
(e): All STMRs derived by Codex 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, 2019d, 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}-λ6-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	
X11721061	(1RS)-1-[6-(trifluoromethyl)-3-pyridinyl]ethanol FC(F)(F)c1ccc(cn1)C(C)O JGVSFNXTWYOUFV-UHFFFAOYSA-N	

IUPAC: International Union of Pure and Applied Chemistry; SMILES: simplified molecular-input line-entry system; InChiKey: International Chemical Identifier Key.
(a): The metabolite name in bold is the name used in the conclusion.
(b): ACD/Name 2020.2.1 ACD/Labs 2020 Release (File version N15E41, Build 116563, 15 June 2020).
(c): ACD/ChemSketch 2020.2.1 ACD/Labs 2020 Release (File version C25H41, Build 121153, 22 March 2021).