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

EFSA (European Food Safety Authority), Giulia Bellisai, Giovanni Bernasconi, Alba Brancato, Luis Carrasco Cabrera, Irene Castellan, Lucien Ferreira, German Giner, Luna Greco, Samira Jarrah, Renata Leuschner, Jose Oriol Magrans, Ileana Miron, Stefanie Nave, Ragnor Pedersen, Hermine Reich, Tobin Robinson, Silvia Ruocco, Miguel Santos, Alessia Pia Scarlato, Anne Theobald and Alessia Verani

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 modify the existing maximum residue levels (MRLs) for the active substance sulfoxaflor in lettuce and salad plants (except lettuce), beans with pods and peas without pods. The data submitted in support of the request were found to be sufficient to derive MRL proposals for all crops under consideration. Adequate analytical methods for enforcement are available to control the residues of sulfoxaflor in the commodities under consideration at the validated limit of quantification (LOQ) of 0.01 mg/kg. Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of residues resulting from the use of sulfoxaflor according to the reported agricultural practices is unlikely to present a risk to consumer health.

Keywords: sulfoxaflor, various crops, insecticide, MRL, consumer risk assessment

Requestor: European Commission
Question number: EFSA-Q-2021-00387
Correspondence: pesticides.mrl@efs.europa.eu
Declarations of interest: The declarations of interest of all scientific experts active in EFSA's work are available at https://ess.efsa.europa.eu/doi/doiweb/doisearch.

Acknowledgments: EFSA wishes to acknowledge the contribution of Stathis Anagnos, Laszlo Bura, Alja Kazocina, Andrea Mioč, Marta Szot, Aikaterini Viachou to this opinion.

Suggested citation: EFSA (European Food Safety Authority), Bellisai G, Bernasconi G, Brancato A, Carrasco Cabrera L, Castellan I, Ferreira L, Giner G, Greco L, Jarrah S, Leuschner R, Magrans JO, Miron I, Nave S, Pedersen R, Reich H, Robinson T, Ruocco S, Santos M, Scarlato AP, Theobald A and Verani A, 2022. Reasoned Opinion on the modification of the existing maximum residue levels for sulfoxaflor in various crops. EFSA Journal 2022;20(4):7283, 31 pp. https://doi.org/10.2903/j.efsa.2022.7283

ISSN: 1831-4732

© 2022 Wiley-VCH Verlag GmbH & Co. KgaA on behalf of the European Food Safety Authority.

This is an open access article under the terms of the Creative Commons Attribution-NoDerivs License, which permits use and distribution in any medium, provided the original work is properly cited and no modifications or adaptations are made.

The EFSA Journal is a publication of the European Food Safety Authority, a European agency funded by the European Union.
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 modify the existing maximum residue levels (MRLs) 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 29 June 2021. To accommodate for the intended northern Europe (NEU) and southern Europe (SEU) uses of sulfoxaflor, the EMS proposed to raise the existing MRLs from the limit of quantification (LOQ) of 0.01 to 0.15 mg/kg in lettuces and salad plants (except lettuces) and in beans with pods. In addition, the EMS proposed to raise the existing MRLs in peas without pods from the LOQ of 0.01 to 0.04 mg/kg. The Applicant also submitted good agricultural practices (GAPs) on peas with pods and beans without pods, but an MRL modification for these commodities was not formally requested. EFSA, therefore, did not perform the assessment of these data. It is further noted that these GAPs (except the NEU GAP on peas with pods) have already been assessed in a previous EFSA reasoned opinion in 2019 and the MRL proposals were derived (although not adopted yet in the EU MRL legislation).

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified points which needed further clarification, which were requested to the EMS. On 14 February 2021, the EMS submitted the requested information in a revised evaluation report (Greece, 2021), which replaced the previously submitted evaluation report.

Based on the conclusions derived by EFSA in the framework of Regulation (EC) No 1107/2009, the data evaluated under previous MRL assessments and the additional data provided by the EMS in the framework of this application, the following conclusions are derived.

The metabolism of sulfoxaflor following foliar and soil applications was investigated in crops belonging to the groups of fruit crops, leafy crops, cereals, 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).

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

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

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

EFSA concluded that for the crops assessed in this application, 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. The methods enable quantification of residues at or above the LOQ of 0.01 mg/kg in the crops assessed. Extraction efficiency is demonstrated.

The available residue trials are sufficient to derive MRL proposals of 0.2 mg/kg for lamb’s lettuce/corn salads, escaroles/broad-leaved endives, cresses and other sprouts and shoots, land cress, roman rocket/rucola, red mustards, baby leaf crops (including brassica species), other lettuce and salad plants (except lettuces), 0.15 mg/kg for beans with pods and 0.03 mg/kg for peas without pods. According to the EMS, the methods used in the analysis of samples (091031 and 150108), which are based on HPLC-MS/MS, are sufficiently validated (including extraction efficiency for the method 091031) and fit for purpose. The extraction efficiency of the method 150108, used to analyse some of the trials on lettuces, beans with pods and peas without pods, is not considered sufficiently demonstrated. Consequently, the derived MRL proposals on these commodities are affected by additional uncertainty.
The occurrence of sulfoxaflor residues in rotational crops was investigated in the framework of the EU pesticides peer review. Based on the available information on the nature and magnitude of residues, it was concluded that significant residue levels of sulfoxaflor are unlikely to occur in rotational crops, when the active substance is used according to the registered use patterns for sulfoxaflor in Europe. At the highest application rate registered in Europe, the soil metabolite X11719474 was present above the LOQ in leafy parts of rotational crops (in radish leaves at 30-day plant back interval (PBI) and in spring onions at 30- and 268-day PBI), therefore when new uses are authorised at national level, Member States might consider setting risk mitigation measures to avoid potential residues of metabolite X11719474 in rotational crops. Specific studies investigating the magnitude of sulfoxaflor residues in processed commodities were not submitted and are not required, considering that the contribution of residues in the crops under consideration to the overall dietary exposure is expected to be below 10% of the acceptable daily intake (ADI).

Residues of sulfoxaflor in commodities of animal origin were not assessed since the crops under consideration in this MRL application are normally not fed to livestock.

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) value of 0.04 mg/kg body weight (bw) per day and an ARfD of 0.25 mg/kg bw. The toxicological reference values of the parent compound also apply to the metabolite X11719474 included in the residue definition for risk assessment.

The consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo). The short-term exposure did not exceed the ARfD for any of the crops assessed in this application. The highest estimated long-term dietary intake accounted for 36% of the ADI (NL toddler diet).

EFSA concluded that the use of sulfoxaflor according to the intended good agricultural practices will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers’ health.

It must be noted that the investigation of possible risk to bees related to the use of sulfoxaflor is outside the scope of this reasoned opinion. The evaluation of the risk to bees was recently re-evaluated at EU level in the framework of the peer review of sulfoxaflor in light of confirmatory data submitted. A follow-up decision as regards the conditions of approval of the active substance has not been implemented yet in Legislation. National competent authorities at Member State level should pay attention to the bee health and bee protection when granting authorisations for plant protection products according to the provisions laid out in the Regulation (EU) 2015/1295.

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 to D.

| Code(a) | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|---------|-----------|-------------------------|-------------------------|-----------------------|
| 251000  | Lettuces and other salad plants including Brassicaceae, (except lettuces) | 0.01* | 0.2 | The submitted data are sufficient to support the intended NEU and SEU use. The MRL proposal reflects the more critical residue situation of the SEU use. Risk for consumers unlikely. |
| 260010  | Beans with pods | 0.01* | 0.15 | The submitted data are sufficient to support the intended NEU and SEU use. The MRL proposal reflects the more critical residue situation of the SEU use. Risk for consumers unlikely. |
| 260040  | Peas without pods | 0.01* | 0.03 | The submitted data are sufficient to support the NEU and SEU use. The MRL proposal reflects the more critical residue situation of the SEU use. Risk for consumers unlikely. |

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

Abstract.......................................................................................................................................................... 1
Summary...................................................................................................................................................... 3
Assessment.................................................................................................................................................. 7
1. Residues in plants ................................................................................................................................... 7
  1.1. Nature of residues and methods of analysis in plants ...................................................................... 7
    1.1.1. Nature of residues in primary crops .......................................................................................... 7
    1.1.2. Nature of residues in rotational crops ....................................................................................... 7
    1.1.3. Nature of residues in processed commodities ........................................................................... 8
    1.1.4. Analytical methods for enforcement purposes in plant commodities ..................................... 8
    1.1.5. Storage stability of residues in plants ......................................................................................... 8
    1.1.6. Proposed residue definitions ....................................................................................................... 8
  1.2. Magnitude of residues in plants ......................................................................................................... 8
    1.2.1. Magnitude of residues in primary crops ..................................................................................... 8
    1.2.2. Magnitude of residues in rotational crops .................................................................................. 11
    1.2.3. Magnitude of residues in processed commodities .................................................................... 12
    1.2.4. Proposed MRLs .......................................................................................................................... 12
  2. Residues in livestock ............................................................................................................................ 12
  3. Consumer risk assessment ................................................................................................................... 12
  4. Conclusion and Recommendations ..................................................................................................... 13
References.................................................................................................................................................... 13
Abbreviations............................................................................................................................................... 15
Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs .................. 17
Appendix B – List of end points ................................................................................................................ 19
Appendix C – Pesticide Residue Intake Model (PRIMo) ........................................................................... 26
Appendix D – Input values for the exposure calculations ....................................................................... 28
Appendix E – Used compound codes ..................................................................................................... 31
Assessment

The European Food Safety Authority (EFSA) received an application to modify the existing maximum residue levels (MRLs) for sulfoxaflor in various crops. The detailed description of the intended southern Europe (SEU) and northern Europe (NEU) uses of sulfoxaflor, which are 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). It is a mixture of two diastereomeric pairs of enantiomers in the range of 40:60 to 60:40% (w/w). 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 1107/20091 with Austria designated as rapporteur Member State (RMS) for the representative uses as a foliar treatment on fruiting vegetables, cucurbits, spring and winter cereals and cotton to control sap feeding insects. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by EFSA (EFSA, 2014a). Sulfoxaflor was approved2 for the use as insecticide on 18 August 2015. When granting national authorisations, Member States have to consider risk mitigation measures related to the risk for bees, bumble bees and other non-target arthropods.

The EU MRLs for sulfoxaflor are established in Annex II of Regulation (EC) No 396/20053. 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. After the finalisation of the EU pesticides peer review, EFSA has issued several reasoned opinions on the modification of MRLs for sulfoxaflor (EFSA, 2017b, 2019c). In addition, certain Codex maximum residue limits (CXLs) have been taken over in the EU MRL legislation4 (EFSA, 2014b, 2015, 2017a). The MRL proposals for sulfoxaflor in various crops as derived in the recent EFSA assessment (EFSA, 2019c) have not been yet adopted in the EU MRL legislation, but will be considered in the present assessment. The same refers to several CXL proposals which were evaluated by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) in 2018 and supported for the inclusion in the EU MRL legislation (FAO, 2019; EFSA, 2019d).

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 modify the existing maximum residue levels (MRLs) for the active substance sulfoxaflor in the whole group of lettuces and other salad plants (except lettuces), beans with pods and peas without pods. 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 29 June 2021. To accommodate for the intended SEU and NEU uses of sulfoxaflor, the EMS proposed to raise the existing MRLs from the limit of quantification (LOQ) of 0.01 to 0.15 mg/kg in lamb’s lettuces/corn salads, escaroles/broad-leaved endives, cresses and other sprouts and shoots, land cresses, roman rocket/rucola, red mustards, baby leaf crops, other lettuces and salad plants (except lettuces) and in beans with pods. In addition, the EMS proposed to raise the existing MRL from the LOQ of 0.01 to 0.04 mg/kg in peas without pods.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified points which needed further clarification, which were requested to the EMS. On 14 February 2021 the EMS submitted the requested information in a revised evaluation report (Greece, 2021), which replaced the previously submitted evaluation report.

EFSA based its assessment on the evaluation report submitted by the EMS (Greece, 2021), the DAR and its addendum (Ireland, 2012, 2014) prepared under Regulation (EC) 1107/2009, the Commission

---

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. OJ L 199, 29.7.2015, p. 8-11.
3 Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.03.2005, p. 1-16.
4 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
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, 2019c) and the EFSA reports based on JMPR assessments (EFSA, 2014b, 2015, 2017a, 2019d).

For this application, the data requirements established in Regulation (EU) No 544/20115 and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 1997a–g, 2000, 2010a,b, 2017, 2020; OECD, 2011). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/20116.

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, 2021) 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, 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.

For the intended use, the metabolic behaviour in primary crops is sufficiently addressed.

1.1.2. Nature of residues in rotational crops

Sulfoxaflor is proposed for use on crops that can be grown in rotation with other crops. According to the soil degradation studies evaluated in the framework of the peer review, the DT$_{90}$ value of sulfoxaflor ranged from 4.8 to 24.7 days. The DT$_{90}$ of the main soil metabolite X11719474 ranged from 63.3 to 750 days (EFSA, 2014a). The trigger value of 100 days was exceeded for the relevant soil metabolite of sulfoxaflor and therefore further studies investigating the nature and magnitude of residues in rotational crops were performed.

The metabolism of sulfoxaflor in rotational crops was investigated in the framework of the EU pesticides peer review in root/tuber crops (radish), leafy crops (lettuce) and cereals (wheat) after bare soil application (EFSA, 2014a). Sulfoxaflor rapidly degraded; X11719474 was the most abundant metabolite observed in all crops at all three plant-back intervals, ranging from 35% TRR in wheat straw (120 DAT) to 68% TRR in mature radish roots (120 DAT). It was concluded that the metabolism of sulfoxaflor in rotational crops is qualitatively similar to the metabolism of sulfoxaflor in primary crops (EFSA, 2014a).

For the proposed use assessed in this application, no further information is required.

---

5 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.
6 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.
1.1.3. 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 to be sufficiently stable under standard hydrolysis conditions.

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, 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 LOQ of 0.01 mg/kg in high-water content, high-acid content, high-oil content and dry commodities.

The crops under consideration in the present MRL application belong to the high-water content commodity group (European Commission, 2010b). Therefore, sufficiently validated methods for the enforcement of sulfoxaflor residues in peas without pods, beans with pods and lettuces and other salad plants are available.

EFSA notes that the extraction efficiency for the analytical methods for enforcement was demonstrated in the framework of the peer review (Ireland, 2012) by cross validation with the method used in the metabolism studies. This is in accordance with the EU Technical Guideline SANTE 2017/10632 on the extraction efficiency (European Commission, 2017).

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 in the crops assessed, residues of both compounds were stable for at least 22 months when stored at −20°C.

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 rotational crops and processed products. The residue definition for enforcement set in Regulation (EC) No 396/2005 is identical with the above-mentioned residue definition. EFSA concluded that these residue definitions are appropriate for the crops under assessment.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

In support of the MRL application, residue trials performed in lettuces, beans with pods and peas without pods were provided. The majority of the residue trials on these crops were already submitted in the context of a previous MRL application on various crops (EFSA, 2019c) in support of the GAPs on spinaches, similar leaves, herbs and edible flowers (NEU and SEU), beans without pods (NEU and SEU) and peas with pods (SEU). In order to reach a sufficient number of trials in support of the NEU and SEU GAPs on the crops under assessment in the current application, the Applicant submitted the following GAP-compliant trials:

- two on lettuces (open leaf) conducted in the NEU zone;
- one on lettuces (open leaf) conducted in the SEU zone;
- eight on beans with pods in support of the respective NEU GAP;
- three on beans with pods conducted in the SEU zone;
- four on peas without pods conducted in the NEU zone;
- four on peas without pods conducted in the SEU zone.

According to the extrapolation rules set in the Commission Guidelines SANTE/2019/12752 (European Commission, 2020), the newly submitted residue trials on beans with pods in support of the intended NEU use do also support the NEU GAP on peas with pods, which was proposed in the current application. However, as the NEU use is less critical than the SEU assessed in the previous EFSA output (EFSA, 2019c) for which an MRL proposal of 0.15 mg/kg was derived, no formal request for an MRL modification in peas with pods was made in the present MRL application and EFSA did not perform further assessment of these data.

The samples of residue trials were stored under conditions for which integrity of the samples has been demonstrated.

The methods used in the analysis of samples in the context of the residue trials are based on HPLC-MS/MS. The samples were analysed for the parent compound and the metabolite included in the residue definition for risk assessment. According to the assessment of the EMS, the methods used (091031 and 150108) were sufficiently validated and fit for purpose.

EFSA notes 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).

For the second analytical method, the QuEChERS method 150108, an extraction efficiency study was submitted in the framework of the current application. The EMS considers the study acceptable to demonstrate the extraction efficiency of the QuEChERS method 150108 via cross-validation against the analytical method for enforcement 091116. EFSA acknowledges that the incurred residues extracted from lettuce (high water commodity) with the enforcement method and the risk assessment method are comparable. However, the following drawbacks are highlighted:

- levels of incurred residues in treated lettuce were close to the LOQ (around the LOQ of 0.01 mg/kg for the metabolite X11719474 and around 0.02 mg/kg for the parent). Higher quantification levels would have been desirable;
- the extraction efficiency was investigated in a limited number of samples (only three replicates available). A higher number of replicates would have been desirable;
- 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.

Considering the above-mentioned sources of uncertainty, the extraction efficiency of the analytical method 150108 (used to analyse two NEU and one SEU residue trials on lettuce, four NEU and two SEU residue trials on beans with pods, four NEU and four SEU residue trials on peas without pods; see Section B.1.2.1) cannot be considered sufficiently demonstrated. Thus, the derived MRL proposals on lettuces, beans with pods and peas without pods are affected by additional uncertainty related to the lack of full details on the extraction efficiency of sulfoxaflor residues.

Lamb’s lettuce/corn salads, escaroles/broad-leaved endives, cress and other sprouts and shoots, land cresses, roman rocket/rucola, red mustards, baby leaf crops (including brassica species) (except lettuces)

NEU zone

A total of eight independent and GAP-compliant residue trials were conducted on lettuce (open leaf) during the growing seasons of 2008, 2011 and 2019 in Germany, Northern-France, Poland and United Kingdom. Each trial plot received one foliar treatment at a nominal application rate of 24 g sulfoxaflor/ha, according to the intended NEU GAP.

All trials were designed as decline studies (samples taken immediately, 1, 3, 7 (corresponding to the intended preharvest interval, PHI) and 9–11 days after the treatment).

The applicant proposes to extrapolate the residue data on open leaf lettuce to all crops belonging to the group of ‘lettuces and other salad plants including Brassicaceae’ (except lettuces). Such an extrapolation is acceptable according to EU Technical Guidelines SANTE/2019/12752 (European Commission, 2020) and is sufficiently supported by data. Based on the NEU data on lettuce, an MRL of 0.09 mg/kg was derived for the whole group of lettuces and salad plants (except lettuces).
**SEU zone**

A total of eight independent and GAP-compliant residue trials were conducted on lettuce (open leaf) during 2008, 2011 and 2019 in Bulgaria, Greece, Italy, Southern-France and Spain. Each trial plot received one foliar treatment at a nominal application rate of 24 g sulfoxaflor/ha, according to the intended SEU GAP. All trials were designed as decline studies (samples taken immediately, 1, 3, 7 (corresponding to the intended PHI) and 10 ± 1 days after the treatment).

The applicant proposes to extrapolate the residue data on open leaf lettuce to all crops belonging to the group of ‘lettuces and other salad plants’ (except lettuces). Such an extrapolation is acceptable according to EU Technical Guidelines SANTE/2019/12752 (European Commission, 2020) and is sufficiently supported by data. Based on the SEU data on lettuce, an MRL of 0.2 mg/kg was derived for the whole group of lettuces and salad plants (except lettuces).

It is noted that the EMS proposed to derive an overall MRL of 0.15 mg/kg, based on the combined NEU and SEU data sets. It must be noted that residue trials from NEU and SEU should in principle not be combined, unless the criteria for combining NEU and SEU trial data sets, described in the Technical Guidelines on MRL setting SANTE/2019/12752 (European Commission, 2020), are all met. Considering that in this case one of the criteria is not met (i.e. the MRL proposals derived for the individual data sets do not fall into the same or neighbouring MRL classes), EFSA is not in favour of combining the two data sets. Thus, EFSA proposes an MRL of 0.2 mg/kg for lettuces and other salad crops (except lettuces), based on the SEU GAP (cGAP).

**Beans with pods**

**NEU zone**

A total of eight independent and GAP-compliant NEU residue trials were conducted on beans with pods during the growing seasons of 2011, 2018 and 2019 in Germany, Hungary, Northern-France and Poland. The trial plots received two foliar treatments at a nominal application rate of 24 g sulfoxaflor/ha with last application performed at BBCH of 76–78 (one trial performed at BBCH at last application of 60) with a 21 (20 to 23) day-interval between applications. Samples were collected at the proposed PHI of 14 ± 1 days.

Decline studies were not available. However, a decline of residues was observed in samples collected throughout the sampling dates (prior to the second application (−0), immediately after the second application (0), 1, 3, 6–7, 10 ± 1 and 14 ± 1 days after the treatment); the lack of decline studies is therefore considered a minor deficiency.

Four additional trials performed with a single application were also submitted in the context of the current application. However, as a sufficient number of GAP-compliant residue trials is already available, the four underdosed trials were not considered for the MRL calculations.

Based on the NEU trials on beans with pods, an MRL of 0.05 mg/kg was derived.

**SEU zone**

A total of nine independent SEU residue trials were conducted on beans with pods during the growing seasons of 2011, 2013 and 2019 in Bulgaria, Italy, Southern-France and Spain. The trial plots received two foliar treatments at a nominal application rate of 24 g sulfoxaflor/ha, last application performed at BBCH of 71–87. The residue trials are GAP-compliant, except three trials where treatments were performed at a more critical interval between applications (14–15 days instead of 21). However, residue levels in these trials were measured at/below the LOQ of 0.01 mg/kg, indicating that the interval between applications in this case is not a critical parameter affecting final residue levels in the crop. Samples were collected at the proposed PHI of 14 ± 1 days.

Decline studies were not available. However, a decline of residues was observed in samples collected throughout the sampling dates (prior to the second application (−0), immediately after the second application (0), 1, 3, 7, 9–10 and 13–14 days after the treatment); the lack of decline studies is therefore considered a minor deficiency. The residue data indicate that an MRL of 0.15 mg/kg would be sufficient to support the SEU use.

On the basis of a more critical SEU use, EFSA proposes an MRL of 0.15 mg/kg for beans with pods.
Peas without pods

**NEU zone**

A total of eight independent and GAP-compliant NEU residue trials were conducted on peas without pods during the growing seasons of 2011, 2012 and 2018 in Germany, Northern-France and Poland. The trial plots received two foliar treatments at a nominal application rate of 24 g sulfoxaflor/ha, last application performed at BBCH of 72–86 with a 21 day-interval between applications. Samples were collected at the proposed PHI of 14 days.

Decline studies were not available. However, a decline of residues was observed in samples collected throughout the sampling dates (prior to the second application (−0), immediately after the second application (0), 1, 3, 7, 9–10 and 13–14 (corresponding to the intended PHI days after the treatment); the lack of decline studies is therefore considered a minor deficiency.

Four additional trials performed with a single application were also submitted in the context of the current application. However, as a sufficient number of GAP-compliant residue trials is already available, the four underdosed trials were not considered for the MRL calculations.

Based on the NEU trials on peas without pods an MRL of 0.01 mg/kg was derived.

**SEU zone**

A total of eight independent and GAP-compliant SEU residue trials were conducted on peas without pods during 2011, 2012 and 2018 in Greece, Italy, Southern-France and Spain. The trial plots received two foliar treatments at a nominal application rate of 24 g sulfoxaflor/ha, last application performed at BBCH of 71–81 with an interval between applications of 21–24 days (exception for one trial, with an interval between application of 27 days).

Two additional trials performed with a single application were also submitted in the context of the current application. Data from one of the trials indicate that a potential carry-over of residues from the first application cannot be excluded (residue of the metabolite X11719474 prior to the second application (−0) was 0.017 mg/kg in one trial (CEMS-5025H)) and therefore it is not possible to exclude that the lower number of applications has not an impact on the final residue levels in the crop. Considering that a sufficient number of GAP-compliant residue trials is already available, the two underdosed trials were not considered for the MRL calculations.

Decline studies were not available. However, a decline of residues in samples collected throughout the sampling dates (immediately after the second application (0), 1, 3, 7, 9–10 and 14 (corresponding to the intended PHI) days after the treatment) was observed; the lack of decline studies is therefore considered a minor deficiency. The residue data indicate that an MRL of 0.03 mg/kg would be sufficient to support the SEU use.

On the basis of a more critical SEU use, EFSA proposes an MRL of 0.03 mg/kg for peas without pods. It is noted that this proposal is lower than the one proposed by the EMS (0.04 mg/kg), which was derived from ten residue trials submitted (i.e. including the two underdosed trials).

1.2.2. Magnitude of residues in rotational crops

The possible transfer of sulfoxaflor residues to crops that are grown in a crop rotation has been assessed in EU pesticides peer review (EFSA, 2014a). The EU rotational crop field studies (24 g/ha; 48 g/ha bare soil) were representative of the registered EU uses of sulfoxaflor on primary crops. Additionally, non-EU rotational crop field trials were available for the EU pesticides peer review with significantly higher application rates investigated (400 g/ha bare soil). The details of the results of rotational crop studies are reported in Appendix B.1.2.2.

The available EU studies demonstrated that no significant residues of sulfoxaflor (residues below 0.01 mg/kg) are expected in succeeding crops (radishes, lettuces, spring onions and barley) planted in soil treated at 24 g/ha (1N for lettuce and other salad plants) and 48 g/ha (1N for peas without pods and beans with pods). Metabolite X11719474 was occasionally recovered above the LOQ, mostly in the leafy parts of the crops in rotation (radish leaves, spring onions, straw).

The non-EU studies confirmed that parent sulfoxaflor is not present in rotational crops, but significant residues of metabolite X11719474 are observed in crops at each PBI. Maximum concentration of residues in edible matrices were 0.03 mg/kg in radish roots (31-day PBI), 0.36 mg/kg in radish tops (31-day PBI) and 0.29 mg/kg in mustard green leaves (30-day PBI). Higher residues were observed in feed items and therefore the EU pesticides peer review considered the residue data of X11719474 for the livestock dietary burden estimates (EFSA, 2014a); however, no MRLs were
proposed in relation to rotational cropping since residues in commodities for human consumption are expected to be insignificant under EU critical GAP conditions.

The maximum annual application rate for the crops under consideration is comparable to the application rates tested in the EU rotational crop studies. Significant residues of sulfoxaflor are not expected in succeeding crops. However, since metabolite X11719474 was present above the LOQ in leafy parts of rotational crops (in radish leaves at 30-day PBI and in spring onions at 30- and 268-day PBI). When new uses are authorised at national level, Member States might consider setting risk mitigation measures to avoid potential residues of metabolite X11719474 in rotational crops.

1.2.3. Magnitude of residues in processed commodities

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

1.2.4. Proposed MRLs

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

2. Residues in livestock

Not relevant as lettuces and other salad plants, beans with pods and peas without pods are not intended as feed items.

3. Consumer risk assessment

EFSA performed a dietary risk assessment using revision 3.1 of the EFSA PRIMo (EFSA, 2018, 2019a). This exposure assessment model contains food consumption data for different sub-groups of the EU population and allows the acute and chronic exposure assessment to be performed 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 to be of similar toxicity to that of the parent compound (EFSA, 2014a).

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 and the complete list of input values can be found in Appendix D.1.

The short-term exposure did not exceed the ARfD for any the crops assessed in this application. The highest acute consumer exposure for lettuces and salad plants group (except lettuces) was calculated for escaroles/broad-leaved endives (1.8% of ARfD) and was lower for other crops of this group. The calculated acute exposure was 0.5% of ARfD for beans with pods and 0.3% of ARfD for peas without pods. No acute risk assessment was calculated for land cress and baby leaf crops (including brassica species) as specific consumption data are not available (see Appendix B.3).

Long-term (chronic) dietary risk assessment

The long-term exposure assessment was performed, taking into account the supervised trials median residue (STMR) values derived for the commodities assessed in this application; for the remaining commodities covered by the MRL legislation, the existing EU MRLs and the corresponding STMR values derived in the EU pesticide peer review, previous MRL applications and JMPR evaluations were selected as input values (EFSA, 2014a, 2017b; FAO, 2012, 2014, 2015). Additionally, the crops for which the MRL proposals were derived in the recent EFSA assessments or by the JMPR (EFSA, 2019c,d, FAO, 2019) but 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. However, this deviation is considered not to have a practical implication for the consumer risk assessment.

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 complete list of input values is presented in Appendix D.1.

The highest estimated long-term dietary intake accounted for 36% of the ADI (NL toddler diet). The contributions of the commodities assessed in the present MRL application to the overall long-term exposure were 0.1% of the ADI for lamb’s lettuce/corn salads (GEMS/Food G11 diet), 0.04% of the ADI for beans with pods (NL toddler diet), 0.03% of the ADI for peas without pods (UK infant diet), 0.02% of the ADI for escaroles/broad-leaved endives (NL toddler diet), 0.01% of the ADI for other lettuces and other salad plants (IT adult diet), < 0.01% of the ADI for roman rocket/rucola (GEMS/Food G06 diet), red mustards (GEMS/Food G06 diet), cress and other sprouts and shoots (GEMS/Food G10 diet). No chronic risk assessment was calculated for land cress and baby leaf crops (including brassica species) as specific consumption data are not available (see Appendix D.1).

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

EFSA concluded that the proposed use of sulfoxaflor on lettuces and other salad plants (except lettuces), beans with pods and peas without pods will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers’ health.

It must be noted that the investigation of possible risk to bees related to the use of sulfoxaflor is outside the scope of this reasoned opinion. The evaluation of the risk to bees was recently re-evaluated at EU level in the framework of the peer review of sulfoxaflor in light of confirmatory data submitted. A follow-up decision as regards the conditions of approval of the active substance has not been implemented yet in Legislation. National competent authorities at Member State level should pay attention to the bee health and bee protection when granting authorisations for plant protection products.

The MRL recommendations are summarised in Appendix B.4.

References

EFSA (European Food Safety Authority), 2014a. Conclusion on the peer review of the pesticide risk assessment of the active substance sulfoxaflor. EFSA Journal 2014;12(5):3692, 170 pp. https://doi.org/10.2903/j.efsa.2014.3692

EFSA (European Food Safety Authority), 2014b. Scientific support for preparing an EU position in the 46th Session of the Codex Committee on Pesticide Residues (CCPR). EFSA Journal 2014;12(7):3737, 182 pp. https://doi.org/10.2903/j.efsa.2014.3737

EFSA (European Food Safety Authority), 2015. Scientific support for preparing an EU position in the 46th Session of the Codex Committee on Pesticide Residues (CCPR). EFSA Journal 2015;13(7):4208, 178 pp. https://doi.org/10.2903/j.efsa.2015

EFSA (European Food Safety Authority), 2017a. Scientific Report of EFSA on scientific support for preparing an EU position in the 49th Session of the Codex Committee on Pesticide Residues (CCPR). EFSA Journal 2017;15 (7):4929, 162 pp. https://doi.org/10.2903/j.efsa.2017.4929

EFSA (European Food Safety Authority), Brancato A, Brocca D, De Lentdecker C, Erdos Z, Ferreira L, Greco L, Jarrah S, Kardassi D, Leuschner R, Lythgo C, Medina P, Miron I, Molnar T, Nougadere A, Pedersen R, Reich H, Sacchi A, Santos M, Stanek A, Sturma J, Tarazona J, Theobald A, Vagenende B, Verani A and Villamar-Bouza L, 2017b. Reasoned Opinion on the modification of the existing maximum residue levels for sulfoxaflor in grape leaves and similar species and globe artichokes. EFSA Journal 2017;15(11):5070, 23 pp. https://doi.org/10.2903/j.efsa.2017.5070

---

7 The risk assessment residue definition derived by the JMPR is ‘sulfoxaflor’, both in commodities of plant and animal origin.

8 Provided that MRL proposals assessed recently by EFSA (EFSA, 2019c) and the CXL proposals referred to in EFSA scientific report (EFSA, 2019d, FAO, 2019) for sulfoxaflor will be adopted in the EU MRL legislation.
EFSA (European Food Safety Authority), 2017c. Pesticide active substances that do not require a review of the existing maximum residue levels under Article 12 of Regulation (EC) No 396/2005. https://doi.org/10.2903/j.efsa.2017.5080. 8 pp.

EFSA (European Food Safety Authority), Brancato A, Brocca D, Ferreira L, Greco L, Jarrah S, Leuschner R, Medina P, Miron I, Nougadere A, Pedersen R, Reich H, Santos M, Stanek A, Tarazona J, Theobald A and Villamar-Bouza L, 2018. Guidance on use of EFSA Pesticide Residue Intake Model (EFSA PRIMO revision 3). EFSA Journal 2018;16(1):5147, 43 pp. https://doi.org/10.2903/j.efsa.2018.5147

EFSA (European Food Safety Authority), Anastassiadou M, Brancato A, Carrasco Cabrera L, Ferreira L, Greco L, Jarrah S, Kazocina A, Leuschner R, Magrans JO, Miron I, Pedersen R, Raczyk M, Reich H, Ruocco S, Sacchi A, Santos M, Stanek A, Tarazona J, Theobald A and Verani A, 2019a. Pesticide Residue Intake Model- EFSA PRIMO revision 3.1 (update of EFSA PRIMO revision 3). EFSA supporting publication 2019;16(3):EN-1605. https://doi.org/10.2903/j.efsa.2019.1605

EFSA (European Food Safety Authority), Abdourahime H, Anastassiadou M, Brancato A, Brocca D, Carrasco Cabrera L, De Lentdecker C, Ferreira L, Greco L, Jarrah S, Kardassi D, Leuschner R, Lostia A, Lythgo C, Medina P, Miron I, Molnar T, Nave S, Pedersen R, Raczyk M, Reich H, Ruocco S, Sacchi A, Santos M, Stanek A, Sturma J, Tarazona J, Theobald A, Vagenende B, Verani A and Villamar-Bouza L, 2019c. Reasoned opinion on the modification of the existing maximum residue levels for sulfoxaflor in various crops. EFSA Journal 2019;17(1):5587, 31 pp. https://doi.org/10.2903/j.efsa.2019.5587

EFSA (European Food Safety Authority), 2019d. Scientific Report on scientific support for preparing an EU position in the 51st Session of the Codex Committee on Pesticide Residues (CCPR). EFSA Journal, 2019;19(7):5797, 243 pp. https://doi.org/10.2903/j.efsa.2019.5797

European Commission, 1997a. Appendix A. Metabolism and distribution in plants. 7028/VI/95-rev.3, 22 July 1997.

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

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

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

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

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

European Commission, 1997g. Appendix I. Calculation of maximum residue level and safety intervals. 7039/VI/95-rev. 5, 22 July 1997.

European Commission, 1997h. Appendix J. Storage stability of residue samples. 7032/VI/95-rev. 5, 22 July 1997.

EFSA (European Food Safety Authority), Aspöck-Hargreaves C, Brancato A, Brocca D, Carrasco Cabrera L, De Lentdecker C, Ferreira L, Fink I, Greco L, Jarrah S, Kazocina A, Leuschner R, Magrans JO, Miron I, Pedersen R, Raczyk M, Reich H, Ruocco S, Sacchi A, Santos M, Stanek A, Sturma J, Tarazona J, Theobald A, Vagenende B, Verani A and Villamar-Bouza L, 2019b. Reasoned opinion on the modification of the existing maximum residue levels under Article 12 of Regulation (EC) No 396/2005. https://doi.org/10.2903/j.efsa.2019.5587

FAO (Food and Agriculture Organization of the United Nations), 2012. Sulfoxaflor. In: Pesticide residues in food – 2011. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 211.

FAO (Food and Agriculture Organization of the United Nations), 2014. Sulfoxaflor. In: Pesticide residues in food – 2013. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 219.
FAO (Food and Agriculture Organization of the United Nations), 2015. Sulfoxaflor. In: Pesticide residues in food – 2014. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 221.

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

FAO (Food and Agriculture Organization of the United Nations), 2019. Sulfoxaflor. In: Pesticide residues in food – 2018. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 234.

Greece, 2021. Evaluation report on the modification of MRLs for sulfoxaflor in various crops (lettuces and salad plants and beans with pods and peas without pods) April 2021, revised in February 2022, 102 pp. Available online: www.efsa.europa.eu

Ireland, 2012. Draft Assessment Report (DAR) on the active substance sulfoxaflor prepared by the rapporteur Member State Ireland in the framework of Directive 91/414/EEC. November 2012. Available online: www.efsa.europa.eu

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

**Abbreviations**

- a.s. active substance
- ADI acceptable daily intake
- ARFD acute reference dose
- BBCH growth stages of mono- and dicotyledonous plants
- Bw body weight
- CCPR Codex Committee on Pesticide Residues
- CF conversion factor for enforcement to risk assessment residue definition
- cGAP critical GAP
- 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
- DT$_{90}$ period required for 90% dissipation (define method of estimation)
- Dw dry weight
- EC emulsifiable concentrate
- EMS evaluating Member State
- Eq residue expressed as a.s. equivalent
- EURL EU Reference Laboratory (former Community Reference Laboratory (CRL))
- FAO Food and Agriculture Organization of the United Nations
- GAP Good agricultural practice
- GC gas chromatography
- GC-MS gas chromatography with mass spectrometry
- HPLC-MS/MS high-performance liquid chromatography with tandem mass spectrometry
- HR highest residue
- IEDI international estimated daily intake
- IESTI international estimated short-term intake
- ILV independent laboratory validation
- IPCS International Programme of Chemical Safety
- ISO International Organisation for Standardisation
- IUPAC International Union of Pure and Applied Chemistry
- JMPR Joint FAO/WHO Meeting on Pesticide Residues
- LC liquid chromatography
- LOQ limit of quantification
- MRL maximum residue level
- MS Member States
| Abbreviation | Description |
|--------------|-------------|
| MS           | mass spectrometry detector |
| MS/MS        | tandem mass spectrometry detector |
| NEU          | northern Europe |
| OECD         | Organisation for Economic Co-operation and Development |
| PBI          | plant back interval |
| PHI          | preharvest interval |
| $P_{ow}$     | partition coefficient between n-octanol and water |
| PRIMo        | (EFSA) Pesticide Residues Intake Model |
| PROFILE      | (EFSA) Pesticide Residues Overview File |
| QuEChERS     | Quick, Easy, Cheap, Effective, Rugged and Safe (analytical method) |
| Rber         | statistical calculation of the MRL by using a non-parametric method |
| Rmax         | statistical calculation of the MRL by using a parametric 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 |
| TRR          | total radioactive residue |
| 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. (g/kg) | Method kind | Range of growth stages & season(c) | Interval between application (days) min-max | g a.s./hl min-max | Water (L/ha) min-max | Rate min-max | Unit |           |
| Lettuces and salad plants(e) | NEU | F | Aphids | SC 120 g/L | Foliar treatment – broadcast spraying | BBCH 20–49 | 1 – | 2.4–12 | 200–1,000 | 24 g a.i./ha | 7 |
|                        | SEU | F | Aphids | SC 120 g/L | Foliar treatment – broadcast spraying | BBCH 20–49 | 1 – | 2.4–12 | 200–1,000 | 24 g a.i./ha | 7 |
| Peas/Beans with and without pods(f) | NEU | F | Aphids | SC 120 g/L | Foliar treatment – broadcast spraying | BBCH 12–59 BBCH 69–85 | 2 21 | 2.4–16 | 150–1,000 | 24 g a.i./ha | 14 |
|                        | SEU | F | Aphids | SC 120 g/L | Foliar treatment – broadcast spraying | BBCH 12–59 BBCH 69–85 | 2 21 | 2.4–16 | 150–1,000 | 24 g a.i./ha | 14 |

GAP on lettuces not assessed as an MRL modification for this commodity was not formally requested by the Applicant nor the EMS.

GAPs on peas with pods and beans without pods not assessed as MRL modifications for these commodities were not formally requested by the Applicant nor the EMS.

It is noted that the same NEU and SEU GAPs on beans without pods and SEU GAP on peas with pods were already assessed in EFSA (2019c).

www.efsa.europa.eu/efsajournal
Modification of the existing MRLs for sulfoxaflor in various crops

MRL: maximum residue level; GAP: Good Agricultural Practice; NEU: northern European Union; SEU: southern European Union; MS: Member State; a.s.: active substance; xx: formulation type.
(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 7th Edition. Revised March 2017. Catalogue of pesticide formulation types and international coding system.
(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.
(d): PHI – minimum pre-harvest interval.
(e): MRL modifications not requested for lettuces in the current application. An MRL of 4 mg/kg for lettuce was derived in EFSA (2014a) and implemented by the current regulation (Reg. (EU) 2018/832).
(f): MRL modification not requested for beans without pods and peas with pods in the current application. The intended NEU and SEU GAPs on beans without pods and the intended SEU GAP on peas with pods were already assessed in EFSA, 2019c. MRLs of 0.03 for beans without pods and 0.15 mg/kg for peas with pods were derived. These have not yet been implemented in the EU MRL Regulation.
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, methods of analysis and residue definitions in plants

| Primary crops | Crop groups | Crop(s) | Application(s) | Sampling (DAT) | Comment/Source |
|---------------|-------------|---------|----------------|----------------|----------------|
| Fruit crops   | Tomato      | Foliar, 4 × (200) + (200) + (125) + (75) g /ha | Immature plant (14 DAT₁; 14 DAT₂), fruit (1, 7, 14 DALA), vines (14 DALA) | Radiolabelled active substance: [14C-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 DAT₁), fruit (14, 21, 28 DALA), vines (28 DALA) | | |
| Leafy crops   | Lettuces    | Foliar, 3 × 200 g/ha | Immature plant (14 DAT₁), mature plant (7 DALA) | | |
|               | Soil, 2 × 225 g/ha | Immature plant (14 DAT₁), mature plant (14 DALA) | | |
| Cereals/grass | Rice        | Foliar, 3 × (225) + (225) + (150) g/ha | Immature plant (14 DAT₁), 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 DAT₁, 14 DAT₂), pods, vines (at maturity) | | |
|               | Soil, 1 × 450 g/ha | Immature plant (14 DAT₁), pods, vines (at maturity) | | |

| Rotational crops | 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: [14C-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 | | |
| Cereals (small grain) | Wheat | Bare soil, 1 × 600 g/ha | 30, 120, 365 | | |

| Processed commodities | Conditions | Stable? | Comment/Source |
|-----------------------|------------|---------|----------------|
| Pasteurisation (20 min, 90°C, pH 4) | Yes | Radiolabelled active substance: [14C-pyridine]-sulfoxaflor and [14C-pyridine]-X11719474 (EFSA, 2014a) |
| Baking, brewing and boiling (60 min, 100°C, pH 5) | Yes | | |
| Sterilisation (20 min, 120°C, pH 6) | Yes | | |
### 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          | sulfoxaflor       | EFSA (2014a)  |
|                                   | Peaches             | −20       | 22     | months          | X11719474         | EFSA (2014a)  |
| **High oil content**              | Soyabeans           | −20       | 22     | months          | sulfoxaflor       | EFSA (2014a)  |
|                                   | Soyabeans           | −20       | 22     | months          | X11719474         | EFSA (2014a)  |
| **Dry/High starch**               | Wheat grain         | −20       | 22     | months          | sulfoxaflor       | EFSA (2014a)  |
|                                   | Wheat grain         | −20       | 22     | months          | X11719474         | EFSA (2014a)  |
| **High acid content**             | Oranges             | −20       | 22     | months          | sulfoxaflor       | EFSA (2014a)  |
|                                   | Oranges             | −20       | 22     | months          | X11719474         | EFSA (2014a)  |

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)

DAT: days after treatment; PBI: plant-back interval; BBCH: growth stages of mono- and dicotyledonous plants; a.s.: active substance; MRL: maximum residue level; HPLC–MS/MS: high performance liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; QuEChERS: Quick, Easy, Cheap, Effective, Rugged, and Safe; ILV: independent laboratory validation.
### B.1.2. 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)  |
|--------------------------------------------------------------------------|-----------|---------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------|-----------------|--------|
| Lamb’s lettuce/corn salads, escaroles/broad-leaved endives, cress and other sprouts and shoots, land cress, roman rocket/rucola, red mustards, baby leaf crops (including brassica species), other lettuces and other salad plants (except lettuces) | NEU       | **Mo:** EFSA (2019c): 0.011(a); 0.015; 0.016; 0.017(g); 0.024; 0.062  
EFSA (2019c): 0.010(g); 0.020(g)  
Greece (2021): 0.020(g); 0.024; 0.025; 0.026(g); 0.033; 0.071  
Greece (2021): 0.019(g); 0.029(g)  
RA: EFSA (2019c): 3 x < 0.010; 0.018; 0.022(g); 0.041(g); 0.105  
Greece (2021): 0.090(g)  
Greece (2021): 3 x < 0.019; 0.027; 0.031(g); 0.050(g); 0.114  
Greece (2021): 0.099(g) | Residue trials on lettuce (open leaf varieties) compliant with NEU GAP.  
Extrapolation to the whole subgroup of lettuce and salad plants possible. | 0.09       | 0.07             | 0.03             | 1.57   |
| SEU | Mo: EFSA (2019c): 3 x < 0.010; 0.018; 0.022(g); 0.041(g); 0.105  
Greece (2021): 0.090(g)  
RA: EFSA (2019c): 3 x < 0.019; 0.027; 0.031(g); 0.050(g); 0.114  
Greece (2021): 0.099(g) | Residue trials on lettuce (open leaf varieties) compliant with GAP.  
Extrapolation to the whole subgroup of lettuce and salad plants possible. | 0.2        | 0.11             | 0.03             | 1.47   |
| Beans with pods | NEU | Mo: Greece (2021): 3 x < 0.010; 3 x < 0.010(g); 0.016; 0.034(g)  
RA: Greece (2021): 3 x < 0.019; 3 x < 0.019(g); 0.025; 0.059(g) | Residue trials on beans with pods compliant with GAP. | 0.05 | 0.06 | 0.02 | 1.94 |
| Beans with pods | SEU | Mo: EFSA, (2019c): 4 x < 0.010; 0.011; 0.088  
Greece (2021): < 0.010(h); 2 x < 0.010(g)  
RA: EFSA (2019c): 3 x < 0.019; 2 x < 0.020; 0.097  
Greece (2021): < 0.019(h); 2 x < 0.019(g) | Residue trials on beans with pods compliant with GAP. | 0.15 | 0.10 | 0.02 | 1.94 |
| 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) |
|---------------------------|------------|----------------------------------------------------------------|--------------------------------------------------------------------------------|------------------------|---------------|----------------|-------|
| Peas without pods         | NEU        | **Mo:** EFSA (2019c): 4 × < 0.010<br>Greece (2021): 4 × < 0.010\(^{(g)}\)<br><br>**RA:** EFSA (2019c): 4 × < 0.019<br>Greece (2021): 3 × < 0.019\(^{(g)}\); 0.024\(^{(g)}\) | Eight residue trials on peas without pods compliant with GAP. <br>0.01* 0.02 0.02 1.94 |                         |               |               |       |
|                           | SEU        | **Mo:** EFSA (2019c): 3 × < 0.010; 0.017<br>Greece (2021): < 0.010\(^{(g)}\); 0.011\(^{(g)},(g)\); 2 × 0.014\(^{(g)}\)<br><br>**RA:** EFSA (2019c): 3 × < 0.019; 0.090<br>Greece (2021): 0.020\(^{(g)}\); 0.020\(^{(g)},(g)\); 2 × 0.023\(^{(g)}\) | Residue trials on peas without pods compliant with GAP. <br>0.03 0.09 0.02 1.99 |                         |               |               |       |

MRL: maximum residue level; GAP: Good Agricultural Practice; Mo: monitoring; RA: risk assessment; n.r.: not relevant.

*: Indicates that the MRL is proposed at the limit of quantification; bold reflects the MRL proposal (see summary table and B.4).

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

(b): Highest residue. The highest residue for risk assessment refers to the whole commodity and not to the edible portion.

(c): Supervised trials median residue. The median residue for risk assessment refers to the whole commodity and not to the edible portion.

(d): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.

(e): Residue levels measured at longer PHI of 10 days than intended (7 days).

(f): Residue levels measured at longer PHI of 9 days than intended (7 days).

(g): Residue levels measured using the analytical method 150108, for which extraction efficiency was not sufficiently demonstrated.

(h): Residue trial disregarded in the previous EFSA assessment (EFSA, 2019c), since considered not independent. According to the new Technical Guidelines SANTE/2019/12752 (European Commission, 2020), the trial can be considered independent and the residue measured can be included in the data set for the MRL calculation.

(i): Residue level from trial performed with a higher interval between application than the intended GAP (27 days).
### B.1.2.2. Residues in rotational crops

| Residues in rotational and succeeding crops expected based on confined rotational crop study? | Yes (metabolite X11719474) |
|---|---|
| In the confined rotational crop study performed in radish, lettuces and wheat (25N rate of the intended GAPs on lettuce and other salad crops and 12.5N rate of the intended GAPs on fresh legumes), X11719474 was the most abundant metabolite observed in all crops at all PBIs (from 0.011 mg/kg in 365-day PBI in wheat grain to 1.34 mg/kg in 120-day PBI in wheat straw). In general, residues declined with increasing PBIs. Uptake of X11719474 from the soil might occur. Residues of sulfoxaflor are not expected in rotational crops (EFSA, 2014a). |

| Residues in rotational and succeeding crops expected based on field rotational crop study? | Yes |
|---|---|
| Significant residues of X11719474 were found, mostly in the leafy parts of the crops in rotation, particularly in feed items. EU studies at about 24 g/ha, rotational crops of radishes, lettuces, spring onions, barley: residues < LOQ at each PBI, except one sample of radish top (0.019 mg/kg, 30-day PBI) and one sample of barley straw (0.018 mg/kg, 30-day PBI). EU studies at about 48 g/ha, rotational crops of radishes, lettuces, spring onions, barley: residues < LOQ at each PBI in radish root, leaf lettuce and barley grain; detectable residues in spring onions (HR of 0.017 mg/kg and STMR of 0.01 mg/kg, 30-day and 268-day PBI) and radish tops (HR of 0.065 mg/kg and STMR of 0.013 mg/kg, 30-day PBI) (EFSA, 2014a). Non-EU study at about 400 g/ha, rotational crops of radishes, mustard green, sorghum, grass: significant residues of metabolite X11719474 observed at each PBI. In general, residues declined with increasing PBI. Maximum concentration of residues in radish roots (0.03 mg/kg, 31-day PBI), radish tops (0.36 mg/kg, 31-day PBI), mustard green leaves (0.29 mg/kg, 30-day PBI), sorghum forage (0.044 mg/kg, 180-day PBI), sorghum stover (0.012 mg/kg, 180-day PBI), grass forage (0.054 mg/kg, 31-day PBI) and grass hay (0.081 mg/kg, 180-day PBI). Sulfoxaflor was not quantified (< 0.01 mg/kg) in all rotated crops at all PBIs, except for one sample of radish tops (0.02 mg/kg at 124 days, but corresponding control sample positive) (EFSA, 2014a). |

GAP: Good Agricultural Practice; PBI: plant-back interval; LOQ: limit of quantification.

### B.1.2.3. Processing factors

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

### B.2. Residues in livestock

Not relevant
B.3. Consumer risk assessment

### ARfD

| Highest IESTI, according to EFSA PRIMo | 0.25 mg/kg bw (European Commission, 2015) |
|--------------------------------------|------------------------------------------|
| Escaroles/broad-leaved endives:      | 1.8% ARfD                                |
| Beans with pods:                     | 0.5% ARfD                                |
| Peas without pods:                   | 0.3% ARfD                                |
| Red mustards:                        | 0.2%                                     |
| Lamb's lettuce/corn salads:         | 0.1% ARfD                                |
| Roman rocket/rucola:                | 0.1% ARfD                                |
| Cress and other sprouts and shoots: | <0.01% ARfD                              |
| Land cress:                          | no acute RA                              |
| Baby leaf crops (including brassica species): no acute RA |

### Assumptions made for the calculations

- Calculations performed with PRIMo revision 3.1.

- The calculation is based on the highest residue levels (HR values) expected in raw agricultural commodities under assessment.

### ADI

| Highest IEDI, according to EFSA PRIMo | 0.04 mg/kg bw per day (European Commission, 2015) |
|--------------------------------------|------------------------------------------|
| Contribution of crops assessed:     |                                          |
| Lamb's lettuce/corn salads:         | 0.1% ADI (GEMS/Food G11 diet)            |
| Beans with pods:                     | 0.04% ADI (NL toddler diet)              |
| Peas without pods:                   | 0.03% ADI (UK infant diet)               |
| Escaroles/broad-leaved endives:      | 0.02% ADI (NL toddler diet)              |
| Other lettuces and other salad plants: | 0.01% ADI (IT adult diet)                |
| Roman rocket/rucola:                | < 0.01% ADI (GEMS/Food G06 diet)         |
| Red mustards:                       | < 0.01% ADI (GEMS/Food G06 diet)         |
| Cress and other sprouts and shoots: | < 0.01% ADI (GEMS/Food G10 diet)         |
| Land cress:                         | no chronic RA                            |
| Baby leaf crops (including brassica species): no chronic RA |

### Assumptions made for the calculations

- Calculations performed with PRIMo revision 3.1.

- The calculation is based on the median residue levels (STMR values) derived for the intended uses on the raw agricultural commodities under consideration according to the risk assessment residue definition.

For the remaining commodities covered by the MRL Legislation, the STMR values derived in the EU pesticide peer review, previous MRL applications and JMPR evaluations were selected as input values (EFSA, 2014a, 2017b; FAO, 2012, 2014, 2015). Additionally, the crops for which the MRL proposals were derived in the recent EFSA assessments and by the JMPR (EFSA, 2019c; FAO, 2019) but 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 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
### B.4. Recommended MRLs

| Code<sup>(a)</sup> | Commodity                                      | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|---------------------|------------------------------------------------|------------------------|-------------------------|-----------------------|
| 251000 (except 251020) | Lettuces and other salad plants including brassicaceae (except lettuces) | 0.01*                  | 0.2                     | The submitted data are sufficient to support the NEU and SEU use. The MRL proposal reflects the more critical residue situation of the SEU use. Risk for consumers unlikely. |
| 260010              | Beans with pods                                | 0.01*                  | 0.15                    | The submitted data are sufficient to support the NEU and SEU use. The MRL proposal reflects the more critical residue situation of the SEU use. Risk for consumers unlikely. |
| 260040              | Peas without pods                              | 0.01*                  | 0.03                    | The submitted data are sufficient to support the NEU and SEU use. The MRL proposal reflects the more critical residue situation of the SEU use. Risk for consumers unlikely. |

Enforcement residue definition: sulfoxaflor (sum of isomers)

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.

---

Modification of the existing MRLs for sulfoxaflor in various crops

deviation is considered not to have a practical implication for the consumer risk assessment.

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.

ARID: 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.
### Appendix C – Pesticide Residue Intake Model (PRIMo)

**Sulfoxaflor**

| Input values | Toxicological reference values |
|--------------|--------------------------------|
| Not exceeding the LOQ | EC, 2015 Source of ADI: EC, 2015 Source of ARfD: EC, 2015 |

**Modification of the existing MRLs for sulfoxaflor in various crops**

**Appendix C – Pesticide Residue Intake Model (PRIMo)**

#### Refined calculation mode

**Chronic risk assessment: JMPR methodology (IEDI/TMDI)**

| No of diets exceeding the ADI | Exposure resulting from | Comments |
|------------------------------|-------------------------|----------|
|                             |                         |          |

#### Calculated exposure

| Commodity group of commodities | Exposure (µg/kg bw per diet) | Calculated exposure (µg/kg bw per day) |
|--------------------------------|-----------------------------|----------------------------------------|
|                                |                            |                                       |

#### Input values

| Sulfoxaflor | ADI (mg/kg bw per day) | ARfD (mg/kg bw) |
|-------------|------------------------|-----------------|
|             |                        |                 |

#### Toxicological reference values

| Source of ADI | Source of ARfD |
|---------------|-----------------|
| EC, 2015      | EC, 2015        |

#### Details – chronic risk assessment

**Toxicological reference values**

| ADI (mg/kg bw per day) | ARfD (mg/kg bw) | Source of ADI | Source of ARfD | ADI (mg/kg bw per day) | ARfD (mg/kg bw) | Source of ADI | Source of ARfD |
|------------------------|-----------------|---------------|----------------|------------------------|-----------------|---------------|----------------|
|                        |                 |               |                |                        |                 |               |                |

#### Details – acute risk assessment/children

#### Details – acute risk assessment/adults

**Conclusion:** The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI. There is no evidence of residues of sulfoxaflor in cattle or species of animals that are commonly consumed in human diet. It 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.

---

www.efsa.europa.eu/efsajournal 26 EFSA Journal 2022;20(4):7283
## Unprocessed Commodities

| Highest % of ARfD/ADI Commodity | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI Commodity | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) |
|--------------------------------|--------------------------|---------------------|--------------------------------|--------------------------|---------------------|
| 50% Table grapes              | 2/2                      | 140                 | 20% Chinese cabbages/petiole   | 2/2                      | 95                  |
| 54% Spinaches                 | 6/6                      | 68                  | 20% Lettuces                   | 4/2                      | 54                  |
| 44% Lettuces                  | 4/2                      | 108                 | 15% Chinese cabbages/petiole   | 2/2                      | 67                  |
| 27% Oranges                   | 0.8/0.51                 | 68                  | 14% Chinese cabbages/petiole   | 2/2                      | 58                  |
| 26% Chinese cabbages/petiole | 2/2                      | 64                  | 10% Chinese cabbages/petiole   | 2/2                      | 52                  |
| 24% Watermelons               | 0.5/0.5                  | 61                  | 8% Watermelons                 | 0.5/0.5                  | 48                  |
| 22% Cucumbers                 | 0.4/0.4                  | 46                  | 8% Cucumbers                   | 0.5/0.5                  | 42                  |
| 19% Oranges                   | 0.8/0.51                 | 48                  | 6% Chinese cabbages/petiole    | 2/2                      | 40                  |
| 17% Chinese cabbages/petiole | 2/2                      | 64                  | 6% Chinese cabbages/petiole    | 2/2                      | 56                  |
| 15% Chinese cabbages/petiole | 0.8/0.5                  | 33                  | 5% Chinese cabbages/petiole    | 2/2                      | 28                  |
| 12% Chinese cabbages/petiole | 0.8/0.5                  | 33                  | 5% Chinese cabbages/petiole    | 2/2                      | 28                  |
| 10% Chinese cabbages/petiole | 0.8/0.5                  | 33                  | 5% Chinese cabbages/petiole    | 2/2                      | 28                  |
| 10% Chinese cabbages/petiole | 0.8/0.5                  | 33                  | 5% Chinese cabbages/petiole    | 2/2                      | 28                  |
| 10% Chinese cabbages/petiole | 0.8/0.5                  | 33                  | 5% Chinese cabbages/petiole    | 2/2                      | 28                  |
| 10% Chinese cabbages/petiole | 0.8/0.5                  | 33                  | 5% Chinese cabbages/petiole    | 2/2                      | 28                  |
| 10% Chinese cabbages/petiole | 0.8/0.5                  | 33                  | 5% Chinese cabbages/petiole    | 2/2                      | 28                  |

### Processed Commodities

| 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                       | 3/1.6/1.6               | 52                  | 20% Chinese cabbages/petiole              | 2/2                      | 95                  |
| 54% Spinaches/frozen                       | 6/6                      | 68                  | 20% Chinese cabbages/petiole              | 2/2                      | 95                  |
| 44% Lettuces                               | 4/2                      | 108                 | 15% Chinese cabbages/petiole              | 2/2                      | 95                  |
| 27% Oranges                                | 0.8/0.51                 | 68                  | 14% Chinese cabbages/petiole              | 2/2                      | 95                  |
| 26% Chinese cabbages/petiole               | 2/2                      | 64                  | 10% Chinese cabbages/petiole              | 2/2                      | 95                  |
| 24% Watermelons                            | 0.5/0.5                  | 61                  | 8% Watermelons                             | 0.5/0.5                  | 48                  |
| 22% Cucumbers                              | 0.4/0.4                  | 46                  | 8% Cucumbers                               | 0.5/0.5                  | 42                  |
| 19% Oranges                                | 0.8/0.51                 | 48                  | 6% Chinese cabbages/petiole               | 2/2                      | 40                  |
| 17% Chinese cabbages/petiole               | 2/2                      | 64                  | 6% Chinese cabbages/petiole               | 2/2                      | 40                  |
| 15% Chinese cabbages/petiole               | 0.8/0.5                  | 33                  | 5% Chinese cabbages/petiole               | 2/2                      | 28                  |
| 12% Chinese cabbages/petiole               | 0.8/0.5                  | 33                  | 5% Chinese cabbages/petiole               | 2/2                      | 28                  |
| 10% Chinese cabbages/petiole               | 0.8/0.5                  | 33                  | 5% Chinese cabbages/petiole               | 2/2                      | 28                  |
| 10% Chinese cabbages/petiole               | 0.8/0.5                  | 33                  | 5% Chinese cabbages/petiole               | 2/2                      | 28                  |

### Conclusion:

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

For processed commodities, no exceedance of the ARfD/ADI was identified.
Appendix D – Input values for the exposure calculations

D.1. Consumer risk assessment

| Commodity | Existing/ Proposed MRL (mg/kg) | Source | Chronic risk assessment | Acute risk assessment |
|-----------|-------------------------------|--------|-------------------------|-----------------------|
|           |                               |        | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment(a) |
| Lamb’s lettuce/corn salads, escaroles/broad-leaved endives, cress and other sprouts and shoots, land cress, roman rocket/rucola, red mustards, baby leaf crops (including brassica species), other lettuce and other salad plants (except lettuces) | 0.2 | MRL proposal | 0.03 | STMR-RAC | 0.11 | HR-RAC |
| Beans (with pods) | 0.15 | MRL proposal | 0.02 | STMR-RAC | 0.10 | HR-RAC |
| Peas (without pods) | 0.03 | MRL proposal | 0.02 | STMR-RAC | 0.09 | HR-RAC |
| Grapefruits | 0.15 | FAO (2015) | 0.015 | STMR-RAC | 0.10 | HR-RAC |
| Oranges | 0.8 | FAO (2015) | 0.30 | STMR-RAC | 0.10 | HR-RAC |
| Lemons | 0.4 | FAO (2015) | 0.04 | STMR-RAC | 0.10 | HR-RAC |
| Limes | 0.5 | EFSA (2019c) | 0.08 | STMR-RAC | 0.10 | HR-RAC |
| Mandarins | 0.8 | FAO (2015) | 0.30 | STMR-RAC | 0.10 | HR-RAC |
| Tree nuts | 0.03 | FAO (2019)(b) | 0.01 | STMR-RAC | 0.10 | HR-RAC |
| Apples | 0.4 | EFSA (2014a) | 0.11 | STMR-RAC | 0.10 | HR-RAC |
| Pears | 0.4 | EFSA (2014a) | 0.11 | STMR-RAC | 0.10 | HR-RAC |
| Quinces | 0.3 | FAO (2015) | 0.07 | STMR-RAC | 0.10 | HR-RAC |
| Medlar | 0.3 | FAO (2015) | 0.07 | STMR-RAC | 0.10 | HR-RAC |
| Loquats/Japanese medlars | 0.3 | FAO (2015) | 0.07 | STMR-RAC | 0.10 | HR-RAC |
| Other pome fruit | 0.3 | FAO (2015) | 0.07 | STMR-RAC | 0.10 | HR-RAC |
| Apricots | 0.5 | EFSA (2014a) | 0.15 | STMR-RAC | 0.10 | HR-RAC |
| Cherries (sweet) | 1.5 | FAO (2015) | 0.34 | STMR-RAC | 0.10 | HR-RAC |
| Peaches | 0.5 | EFSA (2014a) | 0.15 | STMR-RAC | 0.10 | HR-RAC |
| Plums | 0.5 | FAO (2015) | 0.04 | STMR-RAC | 0.10 | HR-RAC |
| Table grapes | 2 | EFSA (2014a) | 0.17 | STMR-RAC | 0.10 | HR-RAC |
| Wine grapes | 2 | FAO (2012) | 0.14 | STMR-RAC | 0.10 | HR-RAC |

Risk assessment residue definition: sulfoxaflor and metabolite X11719474, expressed as sulfoxaflor
## Table: Commodity, Existing/Proposed MRL (mg/kg), Source, Chronic risk assessment, Acute risk assessment

| Commodity                                      | Existing/Proposed MRL (mg/kg) | Source          | Chronic risk assessment | Acute risk assessment |
|------------------------------------------------|------------------------------|-----------------|-------------------------|-----------------------|
|                                                 |                               | Input value (mg/kg) | Comment (c)             | Input value (mg/kg)   | Comment(a)                  |
| Strawberries                                   | 0.5                           | EFSA (2014a)     | 0.20 STMR-RAC           |                       |                             |
| Azarole/Mediterranean medlar                   | 0.3                           | FAO (2015)       | 0.07 STMR-RAC(c)        |                       |                             |
| Kaki/Japanese persimmons                       | 0.3                           | FAO (2015)       | 0.07 STMR-RAC(c)        |                       |                             |
| Potatoes                                       | 0.03                          | EFSA (2014a)     | 0.02 STMR-RAC           |                       |                             |
| Tropical roots and tuber vegetables            | 0.03                          | FAO (2012)       | 0.01 STMR-RAC(c)        |                       |                             |
| Other root and tuber vegetables, except sugar beets and carrots | 0.03                          | FAO (2012)       | 0.01 STMR-RAC(c)        |                       |                             |
| Carrots                                        | 0.05                          | FAO (2014)       | 0.01 STMR-RAC(c)        |                       |                             |
| Garlic                                         | 0.01*                         | FAO (2012)       | 0.01 LOQ(c)             |                       |                             |
| Onions                                         | 0.01*                         | FAO (2012)       | 0.01 LOQ(c)             |                       |                             |
| Spring onions/green onions and Welsh onions   | 0.7                           | FAO (2012)       | 0.11 STMR-RAC(c)        |                       |                             |
| Tomatoes                                       | 0.3                           | EFSA (2014a)     | 0.06 STMR-RAC           |                       |                             |
| Sweet peppers/bell peppers                    | 0.4                           | EFSA (2014a)     | 0.08 STMR-RAC           |                       |                             |
| Aubergines/egg plants                          | 0.3                           | EFSA (2014a)     | 0.06 STMR-RAC           |                       |                             |
| Cucubits with edible peel                     | 0.5                           | FAO (2012)       | 0.03 STMR-RAC(c)        |                       |                             |
| Cucubits with inedible peel                   | 0.5                           | FAO (2012)       | 0.03 STMR-RAC(c)        |                       |                             |
| Sweet corn                                     | 0.01*                         | FAO (2019)(b)    | 0.01 LOQ(c)             |                       |                             |
| Broccoli                                       | 3                             | FAO (2012)       | 0.074 STMR-RAC(c)       |                       |                             |
| Cauliflowers                                   | 0.1                           | EFSA (2019c)(b)  | 0.02 STMR-RAC           |                       |                             |
| Brussels sprouts                               | 0.015                         | EFSA (2019c)(b)  | 0.02 STMR-RAC           |                       |                             |
| Head cabbages                                  | 0.4                           | FAO (2012)       | 0.10 STMR-RAC(c)        |                       |                             |
| Chinese cabbages/pe-tsai                      | 2                             | EFSA (2014a)     | 1 STMR-RAC              |                       |                             |
| Kales                                          | 1                             | EFSA (2019c)(b)  | 0.02 STMR-RAC           |                       |                             |
| Lettuces                                       | 4                             | EFSA (2014a)     | 0.59 STMR-RAC           |                       |                             |
| Spinaches                                      | 6                             | EFSA (2014a)     | 1.34 STMR-RAC           |                       |                             |
| Purslanes                                      | 0.2                           | EFSA (2019c)(b)  | 0.03 STMR-RAC           |                       |                             |
| Chards/beet leaves                             | 0.2                           | EFSA (2019c)(b)  | 0.03 STMR-RAC           |                       |                             |
| Other spinach and similar                      | 0.2                           | EFSA (2019c)(b)  | 0.03 STMR-RAC           |                       |                             |
| Grape leaves and similar species               | 2                             | EFSA (2017b)     | 0.48 STMR-RAC           |                       |                             |
| Herbs and edible flowers except celery leaves  | 0.02                          | EFSA (2019c)(b)  | 0.03 STMR-RAC           |                       |                             |
| Celery leaves                                  | 1.5                           | EFSA (2014a)     | 0.26 STMR-RAC           |                       |                             |
| Commodity                     | Existing/Proposed MRL (mg/kg) | Source                                      | Chronic risk assessment | Acute risk assessment |
|-------------------------------|------------------------------|---------------------------------------------|-------------------------|-----------------------|
|                               |                              |                                             | Input value (mg/kg)     | Comment               |
|                               |                              |                                             | Comment                 | Input value (mg/kg)   | Comment(a) |
| Beans (without pods)          | 0.03                         | EFSA (2019c)(b)                            | 0.02                    | STMR-RAC              |
| Peas (with pods)              | 0.15                         | EFSA (2019c)(b)                            | 0.02                    | STMR-RAC              |
| Celeries                      | 1.5                          | FAO (2012)                                 | 0.19                    | STMR-RAC(c)           |
| Globe artichokes              | 0.06                         | EFSA (2017b)                               | 0.02                    | STMR-RAC              |
| Beans (dry)                   | 0.3                          | FAO (2014)                                 | 0.08                    | STMR-RAC(c)           |
| Rapeseeds/canola seeds        | 0.15                         | EFSA (2014a)                               | 0.07                    | STMR-RAC              |
| Soya beans                    | 0.3                          | EFSA (2014a)                               | 0.02                    | STMR-RAC              |
| Cotton seeds                  | 0.4                          | FAO (2012)                                 | 0.02                    | STMR-RAC(c)           |
| Barley                        | 0.6                          | FAO (2012)                                 | 0.06                    | STMR-RAC(c)           |
| Maize/corn                    | 0.01*                        | FAO (2019)(b)                              | 0.01                    | LOQ(c)                |
| Oat                           | 0.06                         | EFSA (2019c)(b)                            | 0.03                    | STMR-RAC              |
| Rice                          | 1.5                          | FAO (2019)(b)                              | 1.5                     | MRL(c)                |
| Rye                           | 0.03                         | EFSA (2019c)(b)                            | 0.02                    | STMR-RAC              |
| Sorghum                       | 0.2                          | FAO (2019)(b)                              | 0.03                    | STMR-RAC(c)           |
| Wheat                         | 0.2                          | FAO (2012)                                 | 0.03                    | STMR-RAC(c)           |
| Muscle/meat (mammalians)(d)   | 0.4                          | FAO (2019)(b)                              | 0.16                    | STMR-RAC(c)           |
| Fat tissue (mammalians)(d)    | 0.2                          | FAO (2019)(b)                              | 0.06                    | STMR-RAC(c)           |
| Liver (mammalians)(d)         | 1                            | FAO (2019)(b)                              | 0.44                    | STMR-RAC(c)           |
| Kidney (mammalians)(d)        | 1                            | FAO (2019)(b)                              | 0.44                    | STMR-RAC(c)           |
| Edible offals other than liver and kidney (mammalians)(d) | 1 | FAO (2019)(b) | 0.44 | STMR-RAC(c) |
| Muscle/meat (poultry)         | 0.7                          | FAO (2019)(b)                              | 0.64                    | STMR-RAC(c)           |
| Fat tissue (poultry)          | 0.03                         | FAO (2019)(b)                              | 0.02                    | STMR-RAC(c)           |
| Liver (poultry)               | 0.3                          | FAO (2019)(b)                              | 0.18                    | STMR-RAC(c)           |
| Kidney (poultry)              | 0.3                          | FAO (2019)(b)                              | 0.18                    | STMR-RAC(c)           |
| Edible offals other than liver and kidney (poultry) | 0.3 | FAO (2019)(b) | 0.18 | STMR-RAC(c) |
| Milk                          | 0.3                          | FAO (2019)(b)                              | 0.14                    | STMR-RAC(c)           |
| Bird eggs                     | 0.1                          | FAO (2019)(b)                              | 0.07                    | STMR-RAC(c)           |

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

(a): Median residues refer to whole fruits. Data were not sufficient to derive a STMR for citrus pulp (FAO, 2015).
(b): MRLs not yet implemented by Regulation.
(c): 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).
(d): Namely, swine, bovine, sheep, goats, equine, other farmed terrestrial animals.
Appendix E – Used compound codes

| Code/trivial name<sup>(a)</sup> | IUPAC name/SMILES notation/InChiKey<sup>(b)</sup> | Structural formula<sup>(c)</sup> |
|---------------------------------|-------------------------------------------------|---------------------------------|
| Sulfoxaflor                     | [methyl(oxo){1-[6-(trifluoromethyl)-3-pyridyl]ethyl}→6-sulfanylidene]cyanamide | ![Structural formula](image) |
|                                 | 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}→6-sulfanylidene]urea | ![Structural formula](image) |
|                                 | FC(F)(F)c1ccc(cn1)C(C)S(C)(=O)=NC(N)=O          |                                 |
|                                 | YLQFVPNHUKREEW-UHFFFAOYSA-N                     |                                 |

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

<sup>(a)</sup> The metabolite name in bold is the name used in the conclusion.

<sup>(b)</sup> ACD/Name 2021.1.3 ACD/Labs 2021.1.3 (File Version N15E41, Build 123232, 7 July 2021).

<sup>(c)</sup> ACD/ChemSketch 2021.1.3 ACD/Labs 2021.1.3 (File Version C25H41, Build 123835, 28 August 2021).