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

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Dow AgroSciences submitted a request to the competent national authority in Ireland to modify the existing maximum residue levels (MRLs) for the active substance sulfoxaflor in various crops, including limes imported from Australia. The data submitted in support of the request were found to be sufficient to derive MRL proposals for limes, cauliflowers, Brussels sprouts, kales, spinach and similar leaves, herbs and edible flowers, beans without pods, peas with pods, oat, rye and triticale (wheat). Adequate analytical methods for enforcement are available to control the residues of sulfoxaflor on the commodities under consideration. Based on the risk assessment results, EFSA concluded that the use of sulfoxaflor according to the intended good agricultural practices is unlikely to present a risk to consumers’ health.

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, Dow AgroSciences submitted an application to the competent national authority in Ireland (evaluating Member State, EMS) to modify the existing maximum residue levels (MRLs) for the active substance sulfoxaflor in cauliflowers, Brussels sprouts, kales, beans (without pods), peas (with pods), spinach and similar leaves (except spinaches), herbs and edible flowers (except celery leaves), rye, oats and wheat (triticale) and in limes imported from Australia. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 7 April 2017. The EMS proposed to establish an MRL for limes imported from Australia as 0.5 mg/kg and proposed to modify the existing MRLs as follows:

- for cauliflowers from 0.04 mg/kg to 0.1 mg/kg, for Brussels sprouts from the limit of quantification (LOQ) of 0.01 mg/kg to 0.015 mg/kg, for kales from the LOQ of 0.01 mg/kg to 1 mg/kg; for the whole group spinaches and similar leaves (except spinaches) from the LOQ 0.01 mg/kg to 0.2 mg/kg, for the whole group of herbs and edible flowers (except celery leaves) from the LOQ of 0.02 mg/kg to 0.2 mg/kg; for beans (without pods) from the LOQ 0.01 mg/kg to 0.03 mg/kg, for peas (with pods) form the LOQ of 0.01 mg/kg to 0.15 mg/kg. Finally, the EMS proposed to raise the existing MRL for oat from 0.04 mg/kg to 0.06 mg/kg, for rye from 0.015 mg/kg to 0.03 mg/kg and for triticale from the LOQ 0.01 mg/kg to 0.03 mg/kg. EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified data gaps or points which needed further clarification, which were requested from the EMS. On 14 September 2018, the EMS submitted a revised evaluation report, which replaced the previously submitted evaluation report.

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

The metabolism of sulfoxaflor was investigated in primary crops belonging to the groups of fruit crops, root crops, leafy crops, cereals and pulses/oilseeds following foliar or soil application and in rotational crops (root/tuber crops, leafy crops and cereals) following application of sulfoxaflor to bare soil. Studies investigating the effect of processing of both sulfoxaflor and the plant metabolite X11719474 (hydrolysis studies) demonstrated that the substances are stable under standard hydrolysis conditions.

Based on the metabolic pattern identified in metabolism studies, hydrolysis studies, the toxicological significance of metabolite X11719474, the peer review derived the residue definitions for plant products as ‘sulfoxaflor (sum of isomers)’ for enforcement and ‘sum of sulfoxaflor and the metabolite X11719474, expressed as sulfoxaflor’ for risk assessment. These residue definitions are appropriate for primary crops including the crops under assessment and the processed products.

Sufficiently validated analytical methods are available to quantify residues according to the enforcement residue definition for the crops under consideration. The methods enable quantification of residues at or above 0.01 mg/kg (LOQ).

The available residue trials are sufficient to derive MRL proposals for all the crops assessed in this opinion.

Studies investigating the effect of processing on the magnitude of residues in cereals and citrus are available. Due to the limited data set, the processing factors (PF) derived for cereals and citrus are not recommended to be included in Annex VI of Regulation (EC) No 396/2005. For the remaining commodities, specific processing studies were not provided and are not required.

The occurrence of residues in rotational crops was investigated in the framework of the European Union (EU) pesticides peer review. Based on the available information, EFSA could not exclude that the use of sulfoxaflor according to the intended good agricultural practice (GAP) will result in significant residues of its metabolite X11719474 in rotational corps, particularly in feed items. When the new uses are authorised at national level, Member States should consider the need of setting specific risk mitigation measures to avoid the presence of the metabolite in rotational crops.

As several crops under consideration and their by-products are used as feed item, a potential carry-over into food of animal origin was assessed. The calculated livestock dietary burden exceeded the trigger value of 0.1 mg/kg dry matter (DM) for all relevant animal species. However, considering that the Codex maximum residue levels (CXL) implemented in the MRL legislation were based on higher estimates compared to the dietary burdens obtained with the EU uses, EFSA concluded that a revision of the existing MRLs for commodities of animal origin is not necessary.
The toxicological profile of sulfoxaflor was assessed in the framework of the EU pesticides peer review under Regulation (EC) No 1107/2009 and the data were sufficient to derive an acceptable daily intake (ADI) of 0.04 mg/kg body weight (bw) per day and an acute reference dose (ARfD) of 0.25 mg/kg bw. The toxicological reference values of parent compound also apply to the metabolite X11719474 included in the residue definition for risk assessment.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). 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 present a risk to consumers’ health.

EFSA proposes to amend the existing MRLs as reported in the summary table below. Full details of all end points and the consumer risk assessment can be found in Appendices B–D.

| Code(a)  | Commodity                    | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification                                                                 |
|----------|------------------------------|-------------------------|-------------------------|---------------------------------------------------------------------------------------|
| 0110040  | Lime                         | 0.01*                   | 0.5                     | The submitted data are sufficient to derive an import tolerance (AU GAP) by extrapolation from data on lemons. The MRL set in the country of origin is 0.7 mg/kg for citrus. Risk for consumers is unlikely |
| 0241020  | Cauliflower                  | 0.04                    | 0.1                     | The submitted data are sufficient to derive a MRL proposal for the NEU/SEU use by extrapolation from data on cauliflowers and broccoli. The MRL proposal reflects the most critical residue situation of the NEU use. Risk for consumers is unlikely |
| 0242010  | Brussels sprouts             | 0.01*                   | 0.015                   | The submitted data are sufficient to derive a MRL proposal for the NEU/SEU use. The MRL proposal reflects the combined NEU/SEU data set. Risk for consumers is unlikely |
| 0243020  | Kales                        | 0.01*                   | 1                       | The submitted data are sufficient to derive a MRL proposal for the NEU/SEU use. The MRL proposal reflects the most critical residue situation of the NEU use. Risk for consumers is unlikely |
| 0252000  | Spinaches and similar leaves, except spinaches (0252010) | 0.01*                   | 0.2                     | The submitted data are sufficient to derive a MRL proposal for the NEU/SEU use by extrapolation from data on open leaf lettuces. The MRL proposal reflects the most critical residue situation of the SEU use. Risk for consumers is unlikely |
| 0256000  | Herbs and edible flowers, except celery leaves (0256030) | 0.02*                   | 0.2                     | The submitted data are sufficient to derive a MRL proposal for the NEU/SEU use by extrapolation from data on open leaf lettuces. The MRL proposal reflects the most critical residue situation of the SEU use. Risk for consumers is unlikely |
| 0260020  | Beans (without pods)         | 0.01*                   | 0.03                    | The submitted data are sufficient to derive a MRL proposal for the NEU/SEU use. The MRL proposal reflects the most critical residue situation of the SEU use. Risk for consumers is unlikely |
| 0260030  | Peas (with pods)             | 0.01*                   | 0.15                    | The submitted data are sufficient to derive a MRL proposal for the SEU use by extrapolation from data on beans with pods. Risk for consumers is unlikely |
| 0500050  | Oat                          | 0.04                    | 0.06                    | The submitted data are sufficient to derive a MRL proposal for the NEU/SEU use by extrapolation from data on barely. The MRL proposal reflects the most critical residue situation of the SEU use. Risk for consumers is unlikely |
| Code\(^{(a)}\) | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|----------------|-----------|------------------------|-------------------------|-----------------------|
| 0500070        | Rye       | 0.015                  | 0.03                    | The submitted data are sufficient to derive a MRL proposal for the NEU/SEU use by extrapolation from data on wheat. The MRL proposal reflects the most critical residue situation of the NEU use. Risk for consumers is unlikely. |
| 0500090        | Wheat     | 0.2                    | no change               | The intended NEU/SEU use on triticale is sufficiently supported by data; a MRL of 0.03 mg/kg would be required. Since triticale is classified under the same code as wheat, and the existing MRL for wheat is set at the level of 0.2 mg/kg, a change of the existing MRL on wheat is not necessary. |

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

*: 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.
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Assessment

The European Food Safety Authority (EFSA) received the request to assess the application on the modification of the existing maximum residue levels (MRLs) for sulfoxaflor in various crops, including limes imported from Australia. The detailed description of the intended European Union (EU) uses and the use on limes in Australia, which are the basis for the current MRL application on sulfoxaflor, is reported in Appendix A. In Australia, sulfoxaflor is authorised for the use on citrus fruits and the MRL of 0.7 mg/kg is established based on the residue definition for enforcement as ‘parent sulfoxaflor’.

Sulfoxaflor is the ISO common name for methyl(oxo)-[1-{6-(trifluoromethyl)-3-pyridyl(ethyl)\_\(-\_6-

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 metabolite are reported in Appendix E.

Sulfoxaflor was evaluated in the framework of Regulation (EC) No 1107/2009\(^1\) with Ireland designated as rapporteur Member State (RMS). The representative uses assessed were foliar spraying treatments on fruiting vegetables, 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 (2014). Sulfoxaflor was approved\(^2\) for the use as an 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 European Union (EU) MRLs for sulfoxaflor have been assessed in the framework of the peer review established in Annex II of Regulation (EC) No 396/2005\(^3\). After the finalisation of the peer review, EFSA has issued one reasoned opinion on the modification of MRLs for sulfoxaflor on grape leaves and globe artichokes; the proposed MRLs have been considered in the EU MRL legislation.\(^4\) In 2017, certain Codex maximum residue limits (CXLs) have been implemented in Regulation (EU) 2017/405\(^5\).

In accordance with Article 6 of Regulation (EC) No 396/2005, Dow AgroSciences submitted an application to the competent national authority in Ireland (EMS) to modify the existing 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 EFSA on 7 April 2017. The EMS proposed to raise the existing MRL for sulfoxaflor for cauliflowers from 0.04 mg/kg to 0.1 mg/kg, for Brussels sprouts from the limit of quantification (LOQ) of 0.01 mg/kg to 0.015 mg/kg, for kales from the LOQ of 0.01 mg/kg to 1 mg/kg; for the whole group spinaches and similar leaves (except spinaches) from the LOQ 0.01 mg/kg to 0.2 mg/kg, for the whole group of herbs and edible flowers (except celery leaves) from the LOQ of 0.02 mg/kg to 0.2 mg/kg; for beans (without pods) from the LOQ 0.01 mg/kg to 0.03 mg/kg, for peas (with pods) form the LOQ of 0.01 mg/kg to 0.15 mg/kg. Finally, the EMS proposed to raise the existing MRL for oat from 0.04 mg/kg to 0.06 mg/kg, for rye from 0.015 mg/kg to 0.03 mg/kg and for triticale from the LOQ 0.01 mg/kg to 0.3 mg/kg. EFSA identified data gaps or points which needed further clarification, which were requested from the EMS. On 14 September 2018, the EMS submitted a revised evaluation report, which replaced the previously submitted evaluation report.

EFSA based its assessment on the revised evaluation report submitted by the EMS (Ireland, 2018), the DAR and its addendum (Ireland, 2012, 2014) prepared under Regulation (EC) 1107/2009, the Commission review report on sulfoxaflor (European Commission, 2015), the conclusion on the peer review of the pesticide risk assessment of the active substance sulfoxaflor (EFSA, 2014) as well as the conclusions from a previous EFSA opinion on sulfoxaflor (EFSA, 2017).

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

\(^2\) Commission Implementing Regulation (EU) 2015/1295 of 27 July 2015 approving the active substance sulfoxaflor, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. 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, 16.3.2005, p. 1–16.

\(^4\) For an overview of all MRL Regulations on this active substance, please consult: http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=pesticide.residue.selection&language=EN

\(^5\) Commission Regulation (EU) 2017/405 of 8 March 2017 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for sulfoxaflor in or on certain products. C/2017/1476. OJ L 63, 9.3.2017, p. 71–82.
For this application, the data requirements established in Regulation (EU) No 544/2011 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; OECD, 2011, 2013). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011.

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, are presented in Appendix B.

The revised evaluation report submitted by the EMS (Ireland, 2018) and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available as background documents to this reasoned opinion.

1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

The metabolism of sulfoxaflor in primary crops belonging to the group of fruit crops, leafy crops, cereals/grass and pulses/oilseeds has been investigated in the framework of the EU pesticides peer review (EFSA, 2014). 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. After soil applications, sulfoxaflor was present in a much lower proportion (fruit crops) or not even detected (pulses and cereals) and the metabolite X11719474 was the major residue. 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.

1.1.2. Nature of residues in rotational crops

Sulfoxaflor is proposed for use in crops that can be grown in crop rotation. The metabolism of sulfoxaflor in rotational crops was investigated in root/tuber crops, leafy crops and cereals after bare soil application in the framework of the EU pesticides peer review (EFSA, 2014). Sulfoxaflor rapidly degraded with X11719474 being the most abundant metabolite found in confined rotational crop studies.

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, 2014). Both sulfoxaflor and X11719474 were considered to be sufficiently stable under standard hydrolysis conditions.

1.1.4. Methods of analysis in plants

Sufficiently validated analytical methods are available to enforce residues of sulfoxaflor in high water content, high acid content, high oil content and dry commodities. The methods allow quantifying residues at or above the LOQ of 0.01 mg/kg (EFSA, 2014).

1.1.5. Stability of residues in plants

The stability of sulfoxaflor and the metabolite X11719474 in plants under conditions of frozen storage was investigated in the framework of the EU pesticides peer review (EFSA, 2014). It was demonstrated that in the crops assessed in this application, residues of both compounds were stable for at least 22 months.

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6 Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances. OJ L 155, 11.6.2011, p. 1-66.
7 Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127-175.
1.1.6. Proposed residue definitions

Based on the metabolic pattern identified in metabolism studies, the results of hydrolysis studies, the toxicological significance of the metabolite X11719474, the following residue definitions were proposed in the EU pesticides peer review (EFSA, 2014):

- residue definition for enforcement: Sulfoxaflor (sum of isomers).
- residue definition for enforcement set in Regulation (EC) No 396/2005 is identical with the above mentioned residue definition.
- residue definition for risk assessment: Sum of sulfoxaflor and metabolite X11719474, expressed as sulfoxaflor.

These residue definitions are appropriate for primary crops, including the crops under assessment, and processed products.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

a) Limes, imported from Australia

The applicant provided the results of six residue trials on lemons carried out in the USA and compliant with the Australian good agricultural practice (GAP). Although these data were generated outside the exporting country, the conditions of cultivation (such as cultural practices and climatic conditions) across lemon producing countries are comparable, and the results were accepted to support the import tolerance request for limes, which are classified as minor crops. The number of trials is sufficient to derive a MRL proposal of 0.5 mg/kg for limes, by extrapolation from lemons (European Commission, 2017).

The MRL set in the exporting country is 0.7 mg/kg. This MRL has been derived from a combined data set of residue trials in various citrus (oranges, mandarins, lemons and grapefruits); thus, the difference between the MRL in the country of origin and the MRL proposal derived by EFSA is explained by a different policy on setting MRLs.

b) Cauliflower, northern and southern EU use

In support of the northern Europe (NEU) GAP, the applicant provided the results of 12 residue trials: 6 trials were performed in cauliflowers and 6 trials in broccoli. Also for the southern Europe (SEU) GAP, 12 residue trials were provided (6 trials in cauliflowers and 6 trials in broccoli). All trials were compliant with the intended GAP. For each geographical zone, the number of trials is sufficient to derive a MRL from the combined data set of residues in cauliflowers and broccoli (European Commission, 2017). The NEU trials resulted in a slightly higher MRL proposal.

c) Brussels sprouts, northern and southern EU use

The results of six residue trials conducted in the NEU and four residue trials conducted in the SEU compliant with the intended GAP were submitted. The number of trials is sufficient to derive a MRL for each geographical zone. Since the trials representing the NEU and SEU use belong to the same population, the NEU and SEU data sets were pooled to calculate a more robust MRL proposal.

d) Kales, northern and southern EU use

Four residue trials conducted in the NEU and four residue trials conducted in the SEU compliant with the intended GAP were submitted. The number of trials is sufficient to derive a MRL for each geographical area. The NEU trials resulted in a slightly higher MRL proposal.

e) Spinaches and similar leaves (except spinaches) and herbs and edible flowers (except celery leaves), northern and southern EU use

In support of the application, six residue trials conducted in the NEU and seven residue trials conducted in the SEU performed in open leaf lettuces and compliant with the intended GAPs were submitted. For each geographical zone, the number of trials is sufficient to derive a MRL proposal which can be extrapolated to spinaches and similar leaves and herbs and edible flowers (European Commission, 2017). The SEU trials resulted in a slightly higher MRL proposal.
f) Beans without pods, northern and southern EU use

The results of four residue trials conducted in the NEU and four residue trials conducted in the SEU compliant with the intended GAP were submitted. The number of trials is sufficient to derive a MRL for each geographical zone. The SEU trials resulted in a slightly higher MRL proposal.

g) Peas with pods, southern EU use

The results of four residue trials conducted in the SEU on beans with pods compliant with the intended GAP on peas were submitted. The number of trials is sufficient to derive a MRL proposal for peas with pods by extrapolation from residues in beans with pods (European Commission, 2017).

h) Oat, northern and southern EU use

In support of the intended GAP in oats, nine NEU residue trials and ten SEU residue trials performed on barley were submitted. The trials were compliant with the intended GAP in oat. In each test site, side-by-side trials were conducted with different treatment regimens (1 × 24 g/ha and 2 × 24 g/ha). EFSA agreed with the approach of the EMS to select the highest residue value observed in the comparative side-by-side trials. Additionally, in some of the trials a suspension concentrate (SC) formulation was used instead of a water-dispersible granule (WG) formulation. The deviation is of no relevance as according to the guidance document and the two formulations are expected to produce comparable residues when last application occurs more than seven days prior to harvest (European Commission, 2017). For each geographical zone, the number of trials is sufficient to derive a MRL proposal which can be extrapolated to oats (European Commission, 2017). The SEU trials resulted in a higher MRL proposal.

i) Rye, northern and southern EU use

In support of the intended GAP in rye, eight NEU residue trials and eight SEU residue trials conducted on wheat were submitted. The trials were compliant with the intended GAP on rye. Also, these trials were designed as comparative trials, testing one and two applications in side-by-side plots; some trials were performed with the SC formulation, which is acceptable for the same reasons as reported under point h. For each geographical zone, the number of trials is sufficient to derive a MRL proposal which can be extrapolated to rye (European Commission, 2017). The NEU trials resulted in a higher MRL proposal.

j) Wheat (triticale), northern and southern EU use

The applicant reported a GAP for triticale for which a MRL modification was requested. According to Commission Regulation (EU) 2018/62 of 17 January 2018 replacing Annex I to Regulation (EC) No 396/2005 of the European Parliament and of the Council (Text with EEA relevance). C/2018/0138. OJ L 18, 23.1.2018, p. 1–73. Modification of existing MRLs for sulfoxaflor in various crops

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1.2.2. Magnitude of residues in rotational crops

Based on the results of the confined rotational crop metabolism studies, which were conducted at a total application rate significantly higher (12.5N) than the intended rates on the crops under assessment (maximum seasonal application rate of 48 g/ha), residues of sulfoxaflor are not expected. Metabolite X11719474 was found, mostly in the leafy parts of the crops in rotation (lettuces, radish tops, wheat forage and straw). This finding was confirmed by field studies with rotational crops conducted in the EU (radishes, lettuces, spring onions and barley) and outside the EU (radishes, mustard greens, sorghum and grass). These studies were assessed during the EU pesticides peer review (EFSA, 2014).
EFSA could not exclude that the use of sulfoxaflor according to the intended GAP will result in significant residues in rotational corps, particularly in feed items. When the new uses are authorised at national level, Member States should consider the need of setting specific risk mitigation measures to avoid the presence of the metabolite of sulfoxaflor X11719474 in rotational crops.

1.2.3. Magnitude of residues in processed commodities

Processing studies investigating the magnitude of sulfoxaflor residues in processed cereals were assessed in the framework of the EU pesticides peer review (EFSA, 2014.) Since samples were analysed for parent compound only, the processing factors derived have a limited value for the dietary risk assessment.

In this MRL application, the distribution of residues into peel and pulp and the results of processing studies in oranges and grapefruits were evaluated. Samples were analysed for sulfoxaflor and X11719474. Residues were located in the fruit peel and tended to dilute in orange juice, oil and canned orange slices. Due to the limited data set, only tentative processing factors could be derived.

For the other crops assessed in this application, significant residues (> 0.1 mg/kg) are not expected in raw commodities or, if exceeding this trigger value (i.e. kales), the individual contribution of these crops to the human diet is expected to be low. Therefore, further processing studies are not required.

1.2.4. Proposed MRLs

The available data were considered sufficient to derive MRL proposals as well as risk assessment values for all the commodities under evaluation. For triticale, the intended use does not require a change of the existing MRL in wheat (the main crop to which triticale belongs for MRL setting), which is at a higher level in the EU legislation. In Section 3, EFSA assessed whether residues on these crops resulting from the intended uses are likely to pose a consumer health risk.

Conversion factors (CF) from enforcement to risk assessment at the intended PHI have been derived from the trials with residues above the LOQ in the raw commodity (see Appendix B.1.2.1).

2. Residues in livestock

2.1. Nature of residues and methods of analysis in livestock

Several products and their by-products under consideration can be used as feed items. Therefore, EFSA calculated the livestock dietary burden in accordance with the OECD guidance document (OECD, 2013), based on the residues expected in feed derived from the crops for which the use of sulfoxaflor is authorised in the EU (assessed in the framework of the EU pesticides peer review) and the intended uses requested in this MRL application. The input values used for the dietary burden calculation are summarised in Appendix D.1.

The maximum dietary burden for cattle, sheep and swine (all diets) was 1.87, 2.04 and 0.97 mg/kg dry matter (DM), respectively. For poultry, the maximum dietary burden was 0.34 mg/kg DM (see Appendix B.2).

The current EU MRLs for muscle, fat, liver, kidney, edible offal, milks and eggs of livestock were derived from the existing Codex MRLs (CXL), which were derived taking into account the maximum dietary burden calculated at international level (i.e. 3.22 mg/kg DM for beef and dairy cattle and 0.93 mg/kg for poultry) (FAO, 2014). Considering that the dietary burden calculated for the EU is below the dietary burden calculated at international level, EFSA concluded that the intended uses will not trigger a revision of the existing MRLs for commodities of animal origin.

3. Consumer risk assessment

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). This exposure assessment model contains the relevant European food consumption data for different subgroups of the EU population (EFSA, 2007).

The estimated exposure was then compared with the acceptable daily intake (ADI) of 0.04 mg/kg body weight (bw) per day and the acute reference dose (ARfD) of 0.25 mg/kg bw derived for sulfoxaflor (European Commission, 2015). The EU pesticides peer review agreed to apply the toxicological reference values of the parent to the metabolite X11719474 (EFSA, 2014).

The most recent long-term exposure assessment performed by EFSA (EFSA, 2017) was updated with the median residue values (STMR) derived from the residue trials submitted in support of this...
MRL application. The short-term exposure was conducted only with regards to the crops under consideration, using the highest and median values in accordance with the internationally agreed methodology. The input values used for the dietary exposure calculation are summarised in Appendix D.

No long-term intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The estimated long-term dietary intake was in the range of 1.5–12% of the ADI (NL children diet). The contribution of the residues expected in the crops under consideration to the total exposure accounted individually for a maximum of 0.2% of ADI (rye). The short-term exposure did not exceed the ARfD for any of the crops considered in this application.

In the EU pesticides peer review, a theoretical factor of 2 was applied to the risk assessment in order to accommodate for the lack of information on the ratio of the enantiomers present in the individual diastereomers of sulfoxaflor and X11719474 (EFSA, 2014). Following this approach, the margin of safety of the exposure calculation is still sufficiently large to conclude that the assessed uses are unlikely to present a consumer health concern.

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 MRL proposals for limes, cauliflowers, Brussels sprouts, kales, spinach and similar leaves, herbs and edible flowers, beans without pods, peas with pods, oat, rye and triticale (wheat). EFSA concluded that the use of sulfoxaflor according to the intended good agricultural practices is unlikely to present a risk to consumers’ health.

The MRL recommendations are summarised in Appendix D.

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**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  
CXL Codex maximum residue limit  
DALA days after last application  
DAR draft assessment report  
DAT days after treatment  
DM dry matter  
EMS evaluating Member State  
FAO Food and Agriculture Organization of the United Nations  
GAP Good Agricultural Practice  
HPLC–MS/MS high-performance liquid chromatography with tandem mass spectrometry  
HR highest residue  
IEDI international estimated daily intake  
IESTI international estimated short-term intake  
ILV independent laboratory validation  
InChiKey International Chemical Identifier Key  
ISO International Organisation for Standardisation  
IUPAC International Union of Pure and Applied Chemistry  
LOQ limit of quantification  
MRL maximum residue level  
MS Member States  
NEU northern Europe  
OECD Organisation for Economic Co-operation and Development  
PBI plant-back interval  
PF processing factor  
PHI preharvest interval  
PRIMo (EFSA) Pesticide Residues Intake Model  
RA risk assessment  
RAC raw agricultural commodity
| Acronym | Definition |
|---------|------------|
| 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 |
| WG      | water-dispersible granule |
| WHO     | World Health Organization |
### Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs

| Crop and/or situation | NEU, SEU, MS or country | F G or I(a) | Pests or Group of pests controlled | Preparation Type(b) | Conc. a.s. | Method Kind | Range of growth stages and season(c) | Number min–max | Interval between application (min) | g a.s./hl min–max | Water L/ha min–max | Rate Unit | PHI (days) (d) | Remarks |
|----------------------|-------------------------|-------------|-----------------------------------|---------------------|-----------|------------|------------------------------------|----------------|--------------------------|----------------|----------------|----------|--------------|---------|
| Limes                | Australia               | F           | Mealybug, scale, thrips          | SC 240 g/L          | Foliar spray | BBCH 89    | 2 14 days                          | 9.6            | 2,000                     | 192            | 24 g/ha        | 7        | Only one application is allowed in the Sep–Dec period followed by 1 application in the March–July period. If no autumn application, 2 spring applications are possible |
| Brussels sprouts     | NEU F                   | SC 120 g/L  | Foliar spray BBCH 10–49          | 1 NA                | 4–12       | 200–1,000 | 24 g/ha |
| Cauliflowers, kales  | NEU F                   | SC 120 g/L  | Foliar spray BBCH 10–49 Oct–Nov | 1 NA                | 4–12       | 200–1,000 | 24 g/ha |
| Beans, without pods  | NEU F                   | SC 120 g/L  | Foliar spray BBCH 40–85 Apr–Jul  | 1–2 21 days         | 4–16       | 150–1,000 | 24 g/ha |
| Peas, with pods      | SEU F                   | SC 120 g/L  | Foliar spray BBCH 40–85 Apr–Jul  | 1–2 21 days         | 4–16       | 150–1,000 | 24 g/ha |
| Spinaches and similar leaves, herbs and edible flower | NEU F                   | SC 120 g/L  | Foliar spray BBCH 20–49 | 1 NA                | 4–12       | 200–1,000 | 24 g/ha |
| Oat, Rye, Triticale (Wheat) | SEU F                   | WG 500 g/kg | Foliar spray BBCH 12–87 | 1–2 21 days         | 4–16       | 100–600  | 24 g/ha |

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

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

(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. 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 preharvest interval.
Appendix B – List of end points

B.1. Residues in plants

B.1.1. Nature of residues and methods of analysis in plants

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

| Primary crops (available studies) | Crop groups | Crops | Applications | Sampling |
|----------------------------------|-------------|-------|--------------|----------|
| 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, 2014) |
|                                  | Soil, 2 × 225 g/ha | Immature plant (14 DAT₁), fruit (14, 21, 28 DALA), vines (28 DALA) |
| Leafy crops                      | Lettuce     | 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 (available studies)

| Crop groups      | Crop(s)     | Application                  | PBI (DAT) | Notes                                                                                                                                 |
|------------------|-------------|------------------------------|-----------|-------------------------------------------------------------------------------------------------------------------------------------|
| Root/tuber crops | Radish      | Bare soil, 1 x 600 g/ha     | 30, 120, 365 | Radiolabelled active substance: \(^{14}\text{C-pyridine}\)-sulfoxaflor at 1:1 diastereomer mixture. Ratio of isomers in the individual diastereomer unknown (EFSA, 2014) |
| Leafy crops      | Lettuce     | Bare soil, 1 x 600 g/ha     | 30, 120, 365 |                                                                                                                                       |
| Cereals (small grain) | Wheat   | Bare soil, 1 x 600 g/ha | 30, 120, 365 |                                                                                                                                       |

## Processed commodities (hydrolysis study)

| Conditions                              | Investigated? | Notes                                                                                                                                 |
|-----------------------------------------|----------------|-------------------------------------------------------------------------------------------------------------------------------------|
| Pasteurisation (20 min, 90°C, pH 4)      | Yes            | Radiolabelled active substance: \(^{14}\text{C-pyridine}\)-sulfoxaflor and \(^{14}\text{C-pyridine}\)-X11719474 (EFSA, 2014) |
| Baking, brewing and boiling (60 min, 100°C, pH 5) | Yes            |                                                                                                                                       |
| Sterilisation (20 min, 120°C, pH 6)      | Yes            |                                                                                                                                       |

Can a general residue definition be proposed for primary crops?  
Rotational crop and primary crop metabolism similar?  
Residue pattern in processed commodities similar to residue pattern in raw commodities?  
Plant residue definition for monitoring (RD-Mo)  
Plant residue definition for risk assessment (RD-RA)  
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)  

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

(a): ILV: independent laboratory validation. The EU pesticides peer review agreed that if metabolite X11719474 is shown to be significantly less toxic than sulfoxaflor, then the residue definition for risk assessment should be revised to parent sulfoxaflor only (EFSA, 2014).
# Stability of residues in plants

| Plant products (available studies) | Category          | Commodity | T (°C) | Stability period | Compounds covered | Comment/Source |
|-----------------------------------|-------------------|-----------|--------|------------------|-------------------|----------------|
|                                   | High water content| Peach     | –20    | 22 Months        | Sulfoxaflor       | EFSA (2014)    |
|                                   | High oil content  | Soya bean | –20    | 22 Months        | X11719474         | EFSA (2014)    |
|                                   | Dry/High starch   | Wheat grain| –20   | 22 Months        | Sulfoxaflor       | EFSA (2014)    |
|                                   | High acid content | Orange    | –20    | 22 Months        | X11719474         | EFSA (2014)    |
### B.1.2. Magnitude of residues in plants

#### B.1.2.1. Summary of residues data from the supervised residue trials

| Commodity | Region/Indoor(a) | Residue levels observed in the supervised residue trials (mg/kg)(b) | Comments/Source | Calculated MRL(c) (mg/kg) | HR (d) (mg/kg) | STMR(e) (mg/kg) | CF (f) |
|-----------|------------------|---------------------------------------------------------------|-----------------|--------------------------|----------------|----------------|--------|
| Limes     | Australia Mo: 0.034; 0.040; 0.045; 0.083; 0.136; 0.293; RA: 0.043; 0.049; 0.055; 0.093; 0.145; 0.302 | Residue trials on lemons compliant with AU GAP. MRL set in the country of origin is 0.7 mg/kg for whole citrus group X11719474: 6 × < 0.01 mg/kg Extrapolation to limes possible | 0.5 Mo: 0.29 RA: 0.30 Mo: 0.06 RA: 0.07 | 1.16 (6 trials) |
| Cauliflower NEU Mo: 9 × < 0.010; 0.020; 0.028; RA: 9 × < 0.019; 0.029; 0.037; 0.086 | Residue trials on cauliflowers (6) and broccoli (6) compliant with GAP X11719474: 12 × < 0.01 mg/kg Extrapolation to flowering brassica possible | 0.1 Mo: 0.08 RA: 0.09 Mo: 0.01 RA: 0.02 | 1.41 (4 trials) |
| Cauliflower SEU Mo: 11 × < 0.010; 0.016 RA: 11 × < 0.019; 0.025 | Residue trials on cauliflowers (6) and broccoli (6) compliant with GAP X11719474: 12 × < 0.01 mg/kg Extrapolation to flowering brassica possible | 0.02 Mo: 0.02 RA: 0.03 Mo: 0.01 RA: 0.02 |
| Brussels sprouts NEU Mo: 6 × < 0.010 RA: 6 × < 0.019 | Combined data set of NEU and SEU residue trials compliant with GAP X11719474: 10 × < 0.01 mg/kg | 0.015 Mo: 0.01 RA: 0.02 Mo: 0.01 RA: 0.02 | 1.85 (1 trial) |
| Brussels sprouts SEU Mo: 3 × < 0.010; 0.011 RA: 3 × < 0.019; 0.020 | | | |
| Kales NEU Mo: < 0.010; 0.038; 0.327 RA: < 0.019; 0.047; 0.345; 0.433 | Residue trials compliant with GAP X11719474: 2 × < 0.01; 0.01; 0.02 mg/kg | 1 Mo: 0.42 RA: 0.43 Mo: 0.18 RA: 0.20 | 1.25 (5 trials) |
| Kales SEU Mo: 2 × < 0.010; 0.014; 0.023 RA: 2 × < 0.019; 0.023; 0.032 | Residue trials compliant with GAP X11719474: 3 × < 0.01; 0.01 mg/kg | 0.04 Mo: 0.02 RA: 0.03 Mo: 0.01 RA: 0.02 |
| Commodity | Region/ Indoor<sup>(a)</sup> | Residue levels observed in the supervised residue trials (mg/kg)<sup>(b)</sup> | Comments/Source | Calculated MRL<sup>(c)</sup> (mg/kg) | HR<sup>(d)</sup> (mg/kg) | STMR<sup>(e)</sup> (mg/kg) | CF<sup>(f)</sup> |
|-----------|-----------------------------|-------------------------------------------------|------------------|-------------------------------|-----------------|-----------------|--------|
| Spinaches and similar leaves, Herbs and edible flowers | NEU | Mo: 0.011<sup>(g); 0.015; 0.016; 0.017<sup>(g); 0.024; 0.062 RA: 0.020<sup>(g); 0.024; 0.025; 0.026<sup>(g); 0.033; 0.071 Residue trials on open leaf lettuces compliant with GAP X11719474: 6 × < 0.01 mg/kg Extrapolation to spinaches and similar leaves and to herbs and edible flowers possible | 0.1 | Mo: 0.06 RA: 0.07 | Mo: 0.02 RA: 0.03 | 1.47 (10 trials) |
| | SEU | Mo: 3 × < 0.010; 0.018; 0.022<sup>(g); 0.041<sup>(g); 0.105 RA: 3 × < 0.019; 0.027; 0.031<sup>(g); 0.050<sup>(g); 0.114 Residue trials on open leaf lettuces compliant with GAP X11719474: 7 × < 0.01 mg/kg Extrapolation to spinaches and similar leaves and to herbs and edible flowers possible | 0.2 | Mo: 0.11 RA: 0.11 | Mo: 0.02 RA: 0.03 | |
| Beans (without pods) | NEU | Mo: 4 × < 0.010 RA: 4 × < 0.019 Residue trials compliant with GAP X11719474: 4 × < 0.01 mg/kg | 0.01 | Mo: 0.01 RA: 0.02 | Mo: 0.01 RA: 0.02 | 5.31 (1 trial) |
| | SEU | Mo: 3 × < 0.010; 0.017 RA: 3 × < 0.019; 0.090 Residue trials compliant with GAP X11719474: 3 × < 0.01; 0.08 mg/kg | 0.03 | Mo: 0.02 RA: 0.09 | Mo: 0.01 RA: 0.02 | |
| Peas (with pods) | SEU | Mo: 4 × < 0.010; 0.011; 0.088 RA: 3 × < 0.019; 2 × 0.020; 0.097 Residue trials on beans with pods compliant with GAP X11719474: 5 × < 0.01; 0.01 mg/kg | 0.15 | Mo: 0.09 RA: 0.10 | Mo: 0.01 RA: 0.02 | 1.85 (3 trials) |
| Oat grain | NEU | Mo: 5 × < 0.010; 2 × 0.011; 0.014<sup>(g); 0.024 RA: 5 × < 0.019; 2 × 0.020; 0.023<sup>(g); 0.033 Residue trials on barley compliant with GAP X11719474: 9 × < 0.01 mg/kg Extrapolation to oat grain possible | 0.03 | Mo: 0.02 RA: 0.03 | Mo: 0.01 RA: 0.02 | 1.41 (11 trials) |
| | SEU | Mo: 3 × < 0.010; 0.012; 2 × 0.023; 2 × 0.025; 0.031; 0.032 RA: 3 × < 0.019; 0.021; 2 × 0.032; 2 × 0.034; 0.040; 0.041 Residue trials on barley compliant with GAP X11719474: 10 × < 0.01 mg/kg Extrapolation to oat grain possible | 0.06 | Mo: 0.03 RA: 0.04 | Mo: 0.02 RA: 0.03 | |
| Oat straw | NEU | RA: 2 × < 0.019; 0.020<sup>(g); 0.021; 0.022; 0.023; 0.026; 0.051 Residue trials on barley compliant with GAP. Currently, no MRL is set for feed items X11719474: 5 × < 0.01; 2 × 0.011; 0.015 mg/kg Extrapolation to oat straw possible | – | RA: 0.05 | RA: 0.02 | NA |
| | SEU | RA: 0.023; 0.027; 0.028; 0.030; 0.033; 0.042<sup>(g); 0.070; 0.077; 0.221<sup>(g) Residue trials on barley compliant with GAP. In one SEU trial, only grain was analysed. Currently, no MRL is set for feed items. X11719474: 5 × < 0.01; 0.011; 0.018; 0.020; 0.034 mg/kg Extrapolation to oat straw possible | – | RA: 0.22 | RA: 0.03 | NA |
| Commodity                 | Region/Indoor<sup>(a)</sup> | Residue levels observed in the supervised residue trials (mg/kg)<sup>(b)</sup> | Comments/Source                                                                 | Calculated MRL<sup>(c)</sup> (mg/kg) | HR<sup>(d)</sup> (mg/kg) | STMR<sup>(e)</sup> (mg/kg) | CF<sup>(f)</sup> |
|--------------------------|-----------------------------|-----------------------------------------------------------------------------|---------------------------------------------------------------------------------|--------------------------------------|-------------------------|--------------------------|------------------|
| Triticale (wheat), Rye grain | NEU                         | Mo: 7 × < 0.010; 0.019 RA: 7 × < 0.019; 0.028                              | Residue trials on wheat compliant with GAP X11719474: 8 × < 0.01 mg/kg           | 0.03                                 | Mo: 0.02                | Mo: 0.01                 | 1.58 (2 trials)     |
|                          | SEU                         | Mo: 7 × < 0.010; 0.013 RA: 7 × < 0.019; 0.022                               | Residue trials on wheat compliant with GAP X11719474: 8 × < 0.01 mg/kg           | 0.02                                 | Mo: 0.01                | Mo: 0.01                 |                  |
| Triticale (wheat), Rye straw | NEU                         | RA: 0.020; 0.037; 0.041; 0.061; 0.073<sup>(g)</sup>; 0.091; 0.095; 0.178 | Residue trials on wheat compliant with GAP. Currently, no MRL is set for feed items X11719474: 5 × < 0.01; 0.011; 0.014; 0.022 mg/kg Extrapolation to rye straw possible | –                                    | RA: 0.18                | RA: 0.07                 | NA                |
|                          | SEU                         | RA: 0.025; 0.034; 0.086; 0.104; 0.118; 0.143; 0.238; 0.354                | Residue trials on wheat compliant with GAP. Currently, no MRL is set for feed items X11719474: 6 × < 0.01; 0.021; 0.023 mg/kg Extrapolation to rye straw possible | –                                    | RA: 0.35                | RA: 0.11                 | NA                |

MRL: maximum residue level; GAP: Good Agricultural Practice.
Mo: according to the residue definition for enforcement; RA: according to the residue definition for risk assessment.
(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Indoor: indoor EU trials or Country code: if non-EU trials.
(b): The residue refers to the whole commodity and not to the edible portion of limes; Residues of X11719474 were adjusted for molecular weight by a factor of 0.94 to express them as sulfoxaflor prior to be summed up.
(c): When more than one use was assessed, EFSA proposed the MRL from the most critical residue situation and highlighted it in bold.
(d): Highest residue. The highest residue for risk assessment refers to the whole commodity and not to the edible portion.
(e): Supervised trials median residue. The median residue for risk assessment refers to the whole commodity and not to the edible portion.
(f): Median conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment. When residues were below the LOQ according to both residue definition for enforcement and risk assessment, the CF was not calculated.
(g): Values refer to higher residue levels measured at a longer PHI than the intended GAP.
B.1.2.2. Residues in rotational crops

Residues in rotational and succeeding crops expected based on confined rotational crop study?

Yes

In the confined rotational crop study (12.5N rate the intended cGAP in this MRL application), X11719474 was the most abundant metabolite observed in all crops at all three 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 (EFSA, 2014)

Residues of sulfoxaflor are not expected in rotational crops

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 radish, lettuce, spring onion, 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 radish, lettuce, spring onion, 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)

Non-EU study at about 400 g/ha, rotational crops of radish, mustard green, sorghum, grass: significant residues observed at each PBI. In the edible plant parts, maximum concentration of residues in radish roots (0.03 mg/kg, 31-day PBI) and mustard green leaves (0.34 mg/kg, 30-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)

cGAP: critical Good Agricultural Practice; MRL: maximum residue level; PBI: plant-back interval; LOQ: limit of quantification; STMR: supervised trials median residue; HR: highest residue.

B.1.2.3. Processing factors

| Processed commodity          | Number of valid studies | Processing Factor (PF) | CFₚ((eq) | Comment/ Source |
|------------------------------|-------------------------|------------------------|---------|-----------------|
|                              | Individual values       | Median or best estimate PF |         |                 |
| Grapefruit pulp              | 3(b)                    | < 0.08, < 0.42         | < 0.4   | Tentative(c)    |
| Grapefruit, peel             | 3(b)                    | 2.61, 6.09             | 4.4     | Tentative(c)    |
| Orange pulp                  | 1                       | < 0.1                  | –       | Tentative(c)    |
| Orange peel                  | 1                       | 5.30                   | –       | Tentative(c)    |
| Orange juice                 | 1                       | < 0.14                 | –       | Tentative(c)    |
| Orange oil                   | 1                       | < 0.14                 | –       | Tentative(c)    |
| Orange, canned slices        | 1                       | < 0.14                 | –       | Tentative(c)    |
| Orange, dried pulp           | 1                       | 7.48                   | –       | Tentative(c)    |

(a): Conversion factors for risk assessment were not derived when residues according to the residue definition for both enforcement and risk assessment were below the LOQ.

(b): One study on grapefruits with residues in the RAC < LOQ was disregarded.

(c): A tentative PF is derived based on a limited data set.
### B.2. Residues in livestock

| Relevant groups (subgroups) | Dietary burden expressed in mg/kg bw per day | Most critical subgroup (a) | Most critical commodity (b) | Trigger exceeded (Y/N) |
|-----------------------------|-----------------------------------------------|----------------------------|----------------------------|------------------------|
|                             | Median  | Maximum  | Median  | Maximum  |                         |                        |
| Cattle (all)                | 0.048   | 0.060    | 1.57    | 1.87     | Dairy cattle             | Potato Process waste   | Yes                     |
| Cattle (dairy only)         | 0.048   | 0.060    | 1.25    | 1.56     | Dairy cattle             | Potato Process waste   | Yes                     |
| Sheep (all)                 | 0.048   | 0.068    | 1.44    | 2.04     | Ram/ewe                  | Potato Process waste   | Yes                     |
| Sheep (ewe only)            | 0.048   | 0.068    | 1.44    | 2.04     | Ram/ewe                  | Potato Process waste   | Yes                     |
| Swine (all)                 | 0.019   | 0.022    | 0.82    | 0.97     | Swine (breeding)         | Potato Process waste   | Yes                     |
| Poultry (all)               | 0.014   | 0.023    | 0.20    | 0.34     | Poultry layer            | Wheat Straw            | Yes                     |
| Poultry (layer only)        | 0.012   | 0.023    | 0.17    | 0.34     | Poultry layer            | Wheat Straw            | Yes                     |
| Fish                        | N/A     |          |         |          |                         |                        |                         |

bw: body weight; DM: dry matter.

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

(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as ‘mg/kg bw per day’.

### B.3. Consumer risk assessment

ARfD

| Highest IESTI, according to EFSA PRIMo | 0.25 mg/kg bw (European Commission, 2015) |
|---------------------------------------|------------------------------------------|
| Kales:                                | 11.6% of ARfD                            |
| Limes:                                | 2.42% of ARfD                            |
| Cauliflower:                          | 2.38% of ARfD                            |
| Beet leaves (chard):                  | 0.77 % of ARfD                           |
| Purslane:                             | 0.66 % of ARfD                           |
| Beans (without pods):                 | 0.25 % of ARfD                           |
| Peas (with pods):                     | 0.14 % of ARfD                           |
| Brussels sprouts:                     | 0.07% of ARfD                            |
| Chervil:                              | 0.06% of ARfD                            |
| Rye, Oat:                             | 0.05% of ARfD                            |
| Parsley, Basil:                       | 0.03% of ARfD                            |
| Other herbs and edible flowers crops: | < 0.02% of ARfD                          |

Assumptions made for the calculations

The calculation is based on the highest residue level, except for cereals, where the median residue level was used, expected in raw agricultural commodities. For limes, the highest residue refers to the whole fruit and not to the edible part.
### ADI

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

### Highest IEDI, according to EFSA PRIMO

12% ADI (Dutch child diet)

| Crop                        | Contribution of crops assessed: |
|-----------------------------|---------------------------------|
| Rye                         | 0.21 of ADI                     |
| Kale                        | 0.08 of ADI                     |
| Oats                        | 0.03 of ADI                     |
| Cauliflower, Limes          | 0.02 of ADI                     |
| Beans (without pods)        | 0.01 of ADI                     |
| Peas (with pods)            | 0.01 of ADI                     |
| Brussels sprouts            | 0.01 of ADI                     |
| Beet leaves (chard)         | 0.01 of ADI                     |
| Other spinach and similar   | 0.01 of ADI                     |
| Remaining crops: <0.01% of ADI |

### Assumptions made for the calculations

The calculation is based on the median residue levels for raw agricultural commodities that were derived in the current or in a previous assessment (EFSA, 2017)

Median residue levels related to the Codex MRLs implemented in the EU legislation refer to parent compound only, except for citrus different than limes, which concentrations were multiplied by a conversion factor for risk assessment of 1.16 derived from residue trials on lemons.

For citrus and cucurbits with inedible peel, the value refers to the whole crop.

The contributions of commodities where no GAP or safe CKILs was reported in previous EFSA evaluations were not included in the calculation.

ARFD: acute reference dose; bw: body weight; IESTI: International estimated short-term intake; PRIMO: (EFSA) Pesticide Residues Intake Model; ADI: acceptable daily intake; IEDI: international estimated daily intake; MRL: maximum residue level; CKIL: Codex maximum residue limit; GAP: Good Agricultural Practice.
## B.4. Recommended MRLs

| Code\(^{(a)}\) | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|----------------|------------|------------------------|-------------------------|-----------------------|
| 0110040        | Lime       | 0.01*                  | 0.5                     | The submitted data are sufficient to derive an import tolerance (AU GAP) by extrapolation from data on lemons. The MRL set in the country of origin is 0.7 mg/kg for citrus. Risk for consumers is unlikely |
| 0241020        | Cauliflowers | 0.04                  | 0.1                     | The submitted data are sufficient to derive a MRL proposal for the NEU/SEU use by extrapolation from data on cauliflowers and broccoli. The MRL proposal reflects the most critical residue situation of the NEU use. Risk for consumers is unlikely |
| 0242010        | Brussels sprouts | 0.01*              | 0.015                   | The submitted data are sufficient to derive a MRL proposal for the NEU/SEU use. The MRL proposal reflects the combined NEU/SEU data set. Risk for consumers is unlikely |
| 0243020        | Kales      | 0.01*                  | 1                       | The submitted data are sufficient to derive a MRL proposal for the NEU/SEU use. The MRL proposal reflects the most critical residue situation of the NEU use. Risk for consumers is unlikely |
| 0252000        | Spinaches and similar leaves, except spinaches (0252010) | 0.01*              | 0.2                     | The submitted data are sufficient to derive a MRL proposal for the NEU/SEU use by extrapolation from data on open leaf lettuces. The MRL proposal reflects the most critical residue situation of the SEU use. Risk for consumers is unlikely |
| 0256000        | Herbs and edible flowers, except celery leaves (0256030) | 0.02*              | 0.2                     | The submitted data are sufficient to derive a MRL proposal for the NEU/SEU use by extrapolation from data on open leaf lettuces. The MRL proposal reflects the most critical residue situation of the SEU use. Risk for consumers is unlikely |
| 0260020        | Beans (without pods) | 0.01*              | 0.03                    | The submitted data are sufficient to derive a MRL proposal for the NEU/SEU use. The MRL proposal reflects the most critical residue situation of the SEU use. Risk for consumers is unlikely |
| 0260030        | Peas (with pods) | 0.01*              | 0.15                    | The submitted data are sufficient to derive a MRL proposal for the SEU use by extrapolation from data on beans with pods. Risk for consumers is unlikely |
| 0500050        | Oat        | 0.04                  | 0.06                    | The submitted data are sufficient to derive a MRL proposal for the NEU/SEU use by extrapolation from data on barely. The MRL proposal reflects the most critical residue situation of the NEU use. Risk for consumers is unlikely |
| 0500070        | Rye        | 0.015                 | 0.03                    | The submitted data are sufficient to derive a MRL proposal for the NEU/SEU use by extrapolation from data on wheat. The MRL proposal reflects the most critical residue situation of the NEU use. Risk for consumers is unlikely |
| 0500090        | Wheat      | 0.2                   | No change              | The intended NEU/SEU use on triticale is sufficiently supported by data; a MRL of 0.03 mg/kg would be required. Since triticale is classified under the same code as wheat, and the existing MRL for wheat is set at the level of 0.2 mg/kg, a change of the existing MRL on wheat is not necessary |

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

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Appendix C – Pesticide Residue Intake Model (PRIMO)

### Sulfoxaflor

#### Status of the active substance:
- Approved

#### Code no.
- LOQ (mg/kg bw): 0.01
- Proposed LOQ:
- ADI (mg/kg bw per day): 0.04
- ARfD (mg/kg bw):
- Source of ADI:
- COM
- Source of ARfD:
- COM
- Year of evaluation:
- 2015
- Year of evaluation:
- 2015

#### Highest calculated TMDI values in % of ADI

| Commodity/group of commodities | MS Diet | No of diets exceeding ADI: | Of ADI | Minimum – maximum |
|-------------------------------|---------|---------------------------|--------|-------------------|
|                                |         |                           |        |                  |
| Milk and cream                 | 3.7     | 12                        | 11.2   | 12.0 NL child     |
| Apples                         | 3.4     |                           | 11.7   | 11.7 DE child     |
|                                | 5.0     |                           | 11.1   | 11.1 FR toddler   |
| Milk and cream                 | 4.8     |                           | 7.2    | 7.2 FR infant     |
|                                | 3.2     |                           | 6.0    | 6.0 WHO Cluster diet B |
| Milk and cream                 | 1.8     |                           | 6.0    | 6.0 UK Toddler    |
|                                | 1.6     |                           | 6.0    | 6.0 ES child      |
| Oranges                        | 0.9     |                           | 6.0    | 6.0 SE general population 90th percentile |
|                                | 1.1     |                           | 4.4    | 4.4 NL general    |
| Milk and cream                 | 1.0     |                           | 4.1    | 4.1 ES adult      |
|                                | 1.5     |                           | 3.7    | 3.7 WHO Cluster diet F |
| Milk and cream                 | 0.6     |                           | 3.7    | 3.7 WHO regional European diet |
|                                | 0.6     |                           | 3.6    | 3.6 WHO cluster diet E |
| Milk and cream                 | 0.5     |                           | 3.3    | 3.3 WHO cluster diet D |
|                                | 1.4     |                           | 3.2    | 3.2 FR all population |
| Milk and cream                 | 0.9     |                           | 2.9    | 2.9 PT General population |
|                                | 0.4     |                           | 2.6    | 2.6 IT kids/toddler |
| Lettuce                        | 0.7     |                           | 2.5    | 2.5 UK vegetarian |
|                                | 0.6     |                           | 2.5    | 2.5 IT adult      |
| Lettuce                        | 0.7     |                           | 2.3    | 2.3 FI adult      |
|                                | 0.7     |                           | 2.2    | 2.2 DK adult      |
| Milk and cream                 | 0.4     |                           | 2.0    | 2.0 UK Adult      |
|                                | 0.5     |                           | 2.0    | 2.0 LT adult      |
| Apples                         | 0.5     |                           | 1.5    | 1.5 PL general population |
|                                | 0.6     |                           |        |                   |

#### Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI. A long-term intake of residues of Sulfoxaflor is unlikely to present a public health concern.

### Chronic risk assessment – refined calculations

| Commodity/group of commodities | MS Diet | TMDI (range) in % of ADI | 3rd contributor to MS diet | pTMRLs at LOQ (in % of ADI) |
|--------------------------------|---------|--------------------------|---------------------------|-----------------------------|
| Milk and cream                 | 3.7     | 0.0                      | 0.1                       |
| Apples                         | 3.4     | 0.0                      | 0.1                       |
|                                | 5.0     | 0.0                      | 0.1                       |
| Milk and cream                 | 4.8     | 0.0                      | 0.1                       |
|                                | 3.2     | 0.0                      | 0.1                       |
| Milk and cream                 | 1.8     | 0.0                      | 0.1                       |
|                                | 1.6     | 0.0                      | 0.1                       |
| Oranges                        | 0.9     | 0.0                      | 0.1                       |
|                                | 1.1     | 0.0                      | 0.1                       |
| Milk and cream                 | 1.0     | 0.0                      | 0.1                       |
|                                | 1.5     | 0.0                      | 0.1                       |
| Milk and cream                 | 0.6     | 0.0                      | 0.1                       |
|                                | 0.6     | 0.0                      | 0.1                       |
| Milk and cream                 | 0.5     | 0.0                      | 0.1                       |
|                                | 0.5     | 0.0                      | 0.1                       |
| Milk and cream                 | 0.4     | 0.0                      | 0.1                       |
|                                | 0.4     | 0.0                      | 0.1                       |
| Milk and cream                 | 0.3     | 0.0                      | 0.1                       |
|                                | 0.3     | 0.0                      | 0.1                       |
| Milk and cream                 | 0.2     | 0.0                      | 0.1                       |
|                                | 0.2     | 0.0                      | 0.1                       |
| Milk and cream                 | 0.1     | 0.0                      | 0.1                       |
|                                | 0.1     | 0.0                      | 0.1                       |

### Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI. A long-term intake of residues of Sulfoxaflor is unlikely to present a public health concern.
Acute risk assessment/children – refined calculations

| Commodity          | pTMRL/Threshold MRL (mg/kg) | pTMRL/Threshold MRL (mg/kg) | pTMRL/Threshold MRL (mg/kg) | pTMRL/Threshold MRL (mg/kg) |
|--------------------|-----------------------------|-----------------------------|-----------------------------|-----------------------------|
| Kale               | 0.43/-                      | 0.43/-                      | 0.43/-                      | 0.43/-                      |
| Limes              | 0.3/-                       | 0.3/-                       | 0.3/-                       | 0.3/-                       |
| Cauliflower        | 0.09/-                      | 0.09/-                      | 0.09/-                      | 0.09/-                      |
| Beets (chard)      | 0.11/-                      | 0.11/-                      | 0.11/-                      | 0.11/-                      |
| Purslane           | 0.11/-                      | 0.11/-                      | 0.11/-                      | 0.11/-                      |
| Beans (without pods) | 0.09/-                     | 0.09/-                      | 0.09/-                      | 0.09/-                      |
| Peas (with pods)   | 0.1/-                       | 0.1/-                       | 0.1/-                       | 0.1/-                       |
| Brussels sprouts   | 0.019/-                     | 0.019/-                     | 0.019/-                     | 0.019/-                     |
| Chervil            | 0.11/-                      | 0.11/-                      | 0.11/-                      | 0.11/-                      |
| Rye                | 0.02/-                      | 0.02/-                      | 0.02/-                      | 0.02/-                      |
| Oats               | 0.03/-                      | 0.03/-                      | 0.03/-                      | 0.03/-                      |
| Parsley            | 0.11/-                      | 0.11/-                      | 0.11/-                      | 0.11/-                      |
| Basil              | 0.11/-                      | 0.11/-                      | 0.11/-                      | 0.11/-                      |
| Thyme              | 0.11/-                      | 0.11/-                      | 0.11/-                      | 0.11/-                      |
| Rosemary           | 0.11/-                      | 0.11/-                      | 0.11/-                      | 0.11/-                      |
| Chives             | 0.11/-                      | 0.11/-                      | 0.11/-                      | 0.11/-                      |
| Bay leaves (laurel)| 0.11/-                      | 0.11/-                      | 0.11/-                      | 0.11/-                      |
| Sage               | 0.11/-                      | 0.11/-                      | 0.11/-                      | 0.11/-                      |

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

**Conclusion:**
For Sulfoxaflor, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available. No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

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

## D.1. Livestock dietary burden calculations

| Feed commodity                | Median dietary burden | Maximum dietary burden |
|------------------------------|-----------------------|------------------------|
|                              | Input value (mg/kg)   | Comment(a)             |
| Barley, straw                | 0.022                 | STMR (EFSA, 2014)      |
| Beet, mangel                 | 0.013                 | STMR rotational(b)     |
| Beet, sugar                  | 0.013                 | STMR rotational(b)     |
| Cabbage, heads leaves        | 0.013                 | STMR rotational(b)     |
| Kales                        | 0.200                 | STMR                   |
| Oat straw                    | 0.030                 | STMR                   |
| Rye, straw                   | 0.110                 | STMR                   |
| Triticale, straw             | 0.110                 | STMR                   |
| Wheat straw                  | 0.143                 | STMR (EFSA, 2014)      |
| Potato culls                 | 0.019                 | STMR (EFSA, 2014)      |
| Barley, grain                | 0.020                 | STMR (EFSA, 2014)      |
| Cotton seeds                 | 0.019                 | STMR (EFSA, 2014)      |
| Oat grain                    | 0.030                 | STMR                   |
| Rye, grain                   | 0.019                 | STMR                   |
| Soya bean seed               | 0.023                 | STMR (EFSA, 2014)      |
| Triticale grain              | 0.019                 | STMR                   |
| Wheat grain                  | 0.019                 | STMR (EFSA, 2014)      |
| Apple, pomace wet            | 0.123                 | STMR × PF (EFSA, 2014) |
| Beet, sugar, dried pulp      | 0.180                 | STMR rotational(b)     |
| Beet, sugar, ensiled pulp    | 0.030                 | STMR (EFSA, 2014)      |
| Beet, sugar, molasses        | 0.280                 |                      |
| Brewer’s grain dried         | 0.066                 | STMR (EFSA, 2014) × (PF)|
| Rape seed, meal              | 0.136                 | STMR × PF (EFSA, 2014) |
| Citrus, dried pulp           | 2.275                 | STMR (orange) × CF × PF|
| Cotton, meal                 | 0.015                 | STMR × PF (EFSA, 2014) |
| Distiller’s grain dried      | 0.063                 | STMR (EFSA, 2014) × (PF)|
| Potato process waste         | 0.380                 | STMR (EFSA, 2014) × (PF)|
| Potato dried pulp            | 0.722                 | STMR (EFSA, 2014) × (PF)|
| Soybean, meal                | 0.030                 | STMR (EFSA, 2014) × PF |
| Soybean, hulls               | 0.035                 | STMR (EFSA, 2014) × PF |
| Wheat gluten, meal           | 0.0004                | STMR × PF (EFSA, 2014) |
| Wheat, milled by-prdts       | 0.004                 | STMR × PF (EFSA, 2014) |

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

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

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

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### D.2. Consumer risk assessment

| Commodity                          | Input value (mg/kg) | Comment            | Input value (mg/kg) | Comment            |
|------------------------------------|---------------------|--------------------|---------------------|--------------------|
| Grapefruits                        | 0.01                | STMR (EFSA, 2017)  | 0.01                | STMR (EFSA, 2017)  |
| Oranges                            | 0.30                | STMR (EFSA, 2017)  | 0.30                | STMR (EFSA, 2017)  |
| Lemons                             | 0.04                | STMR (EFSA, 2017)  | 0.04                | STMR (EFSA, 2017)  |
| Limes                              | 0.07                | STMR               | 0.30                | HR                |
| Mandarins                          | 0.30                | STMR (EFSA, 2017)  | 0.30                | STMR (EFSA, 2017)  |
| Tree nuts                          | 0.02                | STMR (EFSA, 2017)  | 0.02                | STMR (EFSA, 2017)  |
| Apples, pears                      | 0.11                | STMR (EFSA, 2017)  | 0.11                | STMR (EFSA, 2017)  |
| Quinces, Medlar                    | 0.07                | STMR (a) (EFSA, 2017) | 0.07                | STMR (a) (EFSA, 2017) |
| Loquats/Japanese medlars           | 0.07                | STMR (a) (EFSA, 2017) | 0.07                | STMR (a) (EFSA, 2017) |
| Other pome fruits                  | 0.07                | STMR (a) (EFSA, 2017) | 0.07                | STMR (a) (EFSA, 2017) |
| Apricots, Peaches                  | 0.15                | STMR (EFSA, 2017)  | 0.15                | STMR (EFSA, 2017)  |
| Cherries (sweet)                   | 0.34                | STMR (a) (EFSA, 2017) | 0.34                | STMR (a) (EFSA, 2017) |
| Plums                              | 0.04                | STMR (a) (EFSA, 2017) | 0.04                | STMR (a) (EFSA, 2017) |
| Table grapes                       | 0.17                | STMR (EFSA, 2017)  | 0.17                | STMR (EFSA, 2017)  |
| Wine grapes                        | 0.14                | STMR (a) (EFSA, 2017) | 0.14                | STMR (a) (EFSA, 2017) |
| Strawberries                       | 0.20                | STMR (EFSA, 2017)  | 0.20                | STMR (EFSA, 2017)  |
| Azaroles/Mediterranean medlars     | 0.07                | STMR (a) (EFSA, 2017) | 0.07                | STMR (a) (EFSA, 2017) |
| Kaki/Japanese persimmons           | 0.07                | STMR (a) (EFSA, 2017) | 0.07                | STMR (a) (EFSA, 2017) |
| Potatoes                           | 0.02                | STMR (EFSA, 2017)  | 0.02                | STMR (EFSA, 2017)  |
| Tropical root and tuber veget.     | 0.01                | STMR (a) (EFSA, 2017) | 0.01                | STMR (a) (EFSA, 2017) |
| Other root and tuber vegetables,   | 0.01                | STMR (a) (EFSA, 2017) | 0.01                | STMR (a) (EFSA, 2017) |
| except carrots and sugar beets     |                     |                    |                     |                    |
| Carrots                            | 0.01                | STMR (a) (EFSA, 2017) | 0.01                | STMR (a) (EFSA, 2017) |
| Garlic                             | 0.01                | STMR (EFSA, 2017)  | 0.01                | STMR (EFSA, 2017)  |
| Onions                             | 0.01                | STMR (a) (EFSA, 2017) | 0.01                | STMR (a) (EFSA, 2017) |
| Spring onions/green Welsh onions   | 0.11                | STMR (a) (EFSA, 2017) | 0.11                | STMR (a) (EFSA, 2017) |
| Tomatoes                           | 0.06                | STMR (EFSA, 2017)  | 0.06                | STMR (EFSA, 2017)  |
| Sweet peppers/bell peppers         | 0.08                | STMR (EFSA, 2017)  | 0.08                | STMR (EFSA, 2017)  |
| Aubergines/eggplants               | 0.06                | STMR (EFSA, 2017)  | 0.06                | STMR (EFSA, 2017)  |
| Cucurbits with edible peel         | 0.03                | STMR (a) (EFSA, 2017) | 0.03                | STMR (a) (EFSA, 2017) |
| Cucurbits with inedible peel       | 0.03                | STMR (a) (EFSA, 2017) | 0.03                | STMR (a) (EFSA, 2017) |
| Broccoli                           | 0.07                | STMR (a) (EFSA, 2017) | 0.07                | STMR (a) (EFSA, 2017) |
| Cauliflowerways                    | 0.02                | STMR               | 0.09                | HR                |
| Brussels sprouts                   | 0.02                | STMR               | 0.02                | HR                |
| Head cabbages                      | 0.10                | STMR (a) (EFSA, 2017) | 0.10                | STMR (a) (EFSA, 2017) |
| Chinese cabbages/pe-tsai           | 1.00                | STMR (EFSA, 2017)  | 1.00                | STMR (EFSA, 2017)  |
| Kale                               | 0.20                | STMR               | 0.43                | HR                |
| Lettuces                           | 0.59                | STMR (EFSA, 2017)  | 0.59                | STMR (EFSA, 2017)  |
| Spinaches                          | 1.34                | STMR (EFSA, 2017)  | 1.34                | STMR (EFSA, 2017)  |
| Purslane                           | 0.03                | STMR               | 0.11                | HR                |
| Beet leaves (chard)                | 0.03                | STMR               | 0.11                | HR                |
| Other spinach and similar          | 0.03                | STMR               | 0.11                | HR                |
| Grape leaves and similar           | 0.48                | STMR (EFSA, 2017)  | 0.48                | STMR (EFSA, 2017)  |
| Celery leaves and similar          | 0.26                | STMR (a) (EFSA, 2017) | 0.26                | STMR (a) (EFSA, 2017) |

Acute risk assessment performed only for the crops under consideration.
| Commodity                                                                 | Chronic risk assessment | Acute risk assessment |
|--------------------------------------------------------------------------|-------------------------|-----------------------|
|                                                                          | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment |
| Herbs and edible flowers, except celery leaves                           | 0.03 STMR               | 0.11 HR               |
| Beans, without pods                                                      | 0.02 STMR               | 0.09 HR               |
| Peas with pods                                                           | 0.02 STMR               | 0.10 HR               |
| Celeries                                                                 | 0.19 STMR (a) (EFSA, 2017) | HR               |
| Globe artichokes                                                         | 0.02 STMR (EFSA, 2017) | HR               |
| Beans (dry)                                                              | 0.08 STMR (a) (EFSA, 2017) | HR               |
| Rapeseeds/canola seeds                                                   | 0.07 STMR (EFSA, 2017) | HR               |
| Soya beans                                                               | 0.02 STMR (EFSA, 2017) | HR               |
| Cotton seeds                                                             | 0.02 STMR (a) (EFSA, 2017) | HR               |
| Barley                                                                   | 0.06 STMR (a) (EFSA, 2017) | HR               |
| Oats                                                                     | 0.03 STMR               | 0.03 STMR            |
| Rye                                                                      | 0.02 STMR               | 0.02 STMR            |
| Wheat                                                                    | 0.03 STMR (a) (EFSA, 2017) | HR               |
| Muscle (mammalians)(b)                                                   | 0.05 STMR (a) (EFSA, 2017) | HR               |
| Fat tissue (mammalians)(b)                                               | 0.03 STMR (a) (EFSA, 2017) | HR               |
| Liver (mammalians)(b)                                                    | 0.13 STMR (a) (EFSA, 2017) | HR               |
| Kidney (mammalians)(b)                                                   | 0.13 STMR (a) (EFSA, 2017) | HR               |
| Edible offal (mammalians)(b)                                             | 0.13 STMR (a) (EFSA, 2017) | HR               |
| Muscle (poultry)                                                         | 0.02 STMR (a) (EFSA, 2017) | HR               |
| Fat tissue (poultry)                                                     | 0.01 STMR (a) (EFSA, 2017) | HR               |
| Liver, kidney (poultry)                                                  | 0.05 STMR (a) (EFSA, 2017) | HR               |
| Edible offal (poultry)                                                   | 0.05 STMR (a) (EFSA, 2017) | HR               |
| Milks                                                                     | 0.05 STMR (a) (EFSA, 2017) | HR               |
| Birds eggs                                                               | 0.01 STMR (a) (EFSA, 2017) | HR               |

STMR: supervised trials median residue; CF: conversion factor for enforcement to risk assessment residue definition; HR: highest residue.

(a): 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. EFSA concluded this deviation does not have a practical implication for the consumer risk assessment. Except cherries (up to 0.03 mg/kg), concentrations of this metabolite were at or close to the LOQ of 0.01 mg/kg (EFSA, 2015).

(b): 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}-\(\lambda\)-6-sulfanylidene]cyanamide FC(F)(F)c1ccc(cn1)C(C)S(C)(=O)=NC#N ZVQOOHYFBIDMTQ-UHFFFAOYSA-N | ![Structural formula for sulfoxaflor](image) |
| X11719474                     | \(N,N\)-[methyl(oxo){1-[6-(trifluoromethyl)pyridin-3-yl]ethyl}-\(\lambda\)-6-sulfanylidene]urea FC(F)(F)c1ccc(cn1)C(C)S(C)(=O)=NC(N)=O YLQFVPNHUKREEW-UHFFFAOYSA-N | ![Structural formula for X11719474](image) |

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

(a): The metabolite name in bold is the name used in the conclusion.
(b): ACD/Name 2015 ACD/Labs 2015 Release (File version N20E41, Build 75170, 19 December 2014).
(c): ACD/ChemSketch 2015 ACD/Labs 2015 Release (File version C10H41, Build 75059, 17 December 2014).