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Modification of the existing maximum residue levels for sulfoxaflor in grape leaves and similar species, and globe artichokes

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Dow AgroSciences Ltd submitted two separate requests to the competent national authority in France to modify the existing maximum residue levels (MRLs) for the active substance sulfoxaflor in grape leaves and globe artichokes. The data submitted in support of the requests were found to be sufficient to derive MRLs proposals of 2 mg/kg in grape leaves and similar species and of 0.06 mg/kg in globe artichokes. Adequate analytical methods for enforcement are available to control the residues of sulfoxaflor in the commodities under consideration. Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of residues resulting from the uses of sulfoxaflor on grape leaves and similar species and globe artichokes according to the reported 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 Ltd submitted two applications to the competent national authority in France (evaluating Member State (EMS)) to modify the existing maximum residue levels (MRLs) for the active substance sulfoxaflor in globe artichokes and grape leaves, respectively. The EMS drafted the related evaluation reports in accordance with Article 8 of Regulation (EC) No 396/2005 which were submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA).

EFSA based its assessment on the evaluation reports submitted by the EMS, the draft assessment report (DAR) and its final addendum prepared under Regulation (EC) No 1107/2009, the Commission review report on sulfoxaflor, the conclusion on the peer review of the pesticide risk assessment of the active substance sulfoxaflor, the Joint Meeting on Pesticide Residues (JMPR) evaluation reports and the related EFSA scientific reports.

The metabolism of sulfoxaflor following foliar applications was investigated in crops belonging to the groups of fruit crops, leafy crops, cereals and pulses/oilseeds. Studies investigating the effect of processing on the nature of residues demonstrated that the active substance and the metabolite X11719474 are sufficiently stable under standard hydrolysis conditions. In rotational crops, sulfoxaflor was extensively metabolised with the metabolite X11719474 being major component of residues.

Based on the metabolic pattern identified in metabolism studies the hydrolysis studies, the toxicological significance of metabolite X11719474 and the capability of the enforcement analytical method, the peer review concluded on a residue definition for enforcement in plant products as sulfoxaflor (sum of isomers). For risk assessment, the residue definition was proposed as the sum of sulfoxaflor and the metabolite X11719474, expressed as sulfoxaflor. 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 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 are available to quantify residues in the crops assessed in this application with a limit of quantification (LOQ) at or above 0.01 mg/kg.

The available residue trials are sufficient to derive MRL proposals of 2 mg/kg for grape leaves and similar species and of 0.06 mg/kg for globe artichokes.

Specific studies investigating the magnitude of sulfoxaflor residues in processed grape leaf and globe artichoke commodities are not required. The individual total theoretical maximum daily intake (TMDI) is expected to be below the trigger value of 10% of the acceptable daily intake (ADI).

As the proposed uses of sulfoxaflor are on permanent or semi-permanent crops, investigations of residues in rotational crops were not required. Likewise, residues of sulfoxaflor in commodities of animal origin were not assessed since these two crops are normally not fed to livestock.

The toxicological profile of sulfoxaflor was assessed in the framework of the EU pesticides peer review and the data were sufficient to derive an ADI of 0.04 mg/kg body weight (bw) per day and an acute reference dose (ARfD) of 0.25 mg/kg bw. The toxicological reference values of parent compound 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). For the long-term exposure, EFSA considered the residues potentially derived from the intended uses under assessment. For the remaining commodities covered by the MRL regulation, the existing EU MRLs and STMR values previously derived from a previous MRL application and from the Codex MRLs (CXLs) and transposed in EU legislation were used. The short-term risk assessment was performed only with regard to the crops under consideration.

EFSA concluded that the proposed uses of sulfoxaflor on grape leaves and similar species and globe artichokes will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers' health.

Code ^(a)	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Sulfoxaflor (sum of isomers)				
0253000	Grape leaves and similar species	0.01*	2	The submitted data are sufficient to derive a MRL proposal for the intended NEU/SEU uses. A consumer health concern was not identified
0270050	Globe artichokes	0.01*	0.06	The submitted data are sufficient to derive a MRL proposal for the intended SEU use. A consumer health concern was not identified

MRL: maximum residue level; 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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Background

Regulation (EC) No 396/2005¹ (hereinafter referred to as 'the MRL regulation') establishes the rules governing the setting of pesticide maximum residue levels (MRLs) at European Union (EU) level. Article 6 of the MRL regulation lays down that any party having a legitimate interest or requesting an authorisation for the use of a plant protection product in accordance with Directive 91/414/EEC², repealed by Regulation (EC) No 1107/2009³, shall submit an application to a Member State to modify a MRL in accordance with the provisions of Article 7 of the MRL regulation.

The applicant Dow AgroSciences Ltd⁴ submitted two applications to the competent national authority in France, hereafter referred to as the evaluating Member State (EMS), to modify the existing MRLs for the active substance sulfoxaflor in globe artichokes and grape leaves, respectively. These applications were notified to the European Commission and the European Food Safety Authority (EFSA), and were subsequently evaluated by the EMS in accordance with Article 8 of the MRL regulation.

The EMS summarised the data provided by the applicant in two evaluation reports which were submitted to the European Commission and forwarded to EFSA on 10 November 2016 and 29 August 2017. The applications were included in the EFSA Register of Questions with the reference number EFSA-Q-2016-00716 and EFSA-Q-2017-00637 and the following subjects:

Sulfoxaflor – MRL in artichokes

Sulfoxaflor – MRL in grape leaves

France proposed to raise the existing MRL of sulfoxaflor in globe artichokes (0270050) from the limit of quantification (LOQ) of 0.01 to 0.06 mg/kg and for grape leaves and similar species (0253000) from the limit of quantification 0.01 to 2 mg/kg.

EFSA assessed the applications and the evaluation reports as required by Article 10 of the MRL regulation. For reasons of efficiency, EFSA combined both applications in a single reasoned opinion.

Terms of Reference

In accordance with Article 10 of Regulation (EC) No 396/2005, EFSA shall assess the application and the evaluation report and give a reasoned opinion on the risks to the consumer and where relevant to animals associated with the setting of the requested MRLs. The opinion shall include:

- an assessment of whether the analytical method for routine monitoring proposed in the application is appropriate for the intended control purposes;
- the anticipated LOQ for the pesticide/product combination;
- an assessment of the risks of the acceptable daily intake (ADI) and acute reference dose (ARfD) being exceeded as a result of the modification of the MRL;
- the contribution to the intake due to the residues in the product for which the MRLs was requested;
- any other element relevant to the risk assessment.

In accordance with Article 11 of the MRL regulation, EFSA shall give its reasoned opinion as soon as possible and at the latest within 3 months from the date of receipt of the application.

The evaluation reports submitted by the EMS (France, 2016, 2017) 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 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.

² Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1–32.

³ 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.

⁴ Dow AgroSciences Ltd, 3B Park Square, OX14 4RN, Abingdon, United Kingdom.

The active substance and its use pattern

The detailed description of the intended uses of sulfoxaflor, which are the basis for the current MRL applications, is reported in Appendix A.⁵

Sulfoxaflor is the ISO common name for [methyl(oxo){1-[6-(trifluoromethyl)-3-pyridyl]ethyl}-λ⁶-sulfanylidene]cyanamide (IUPAC). Sulfoxaflor is composed by a mixture of two diastereomeric pairs of enantiomers in the range of 40:60 to 60:40% (w/w). Both (*E*)- and (*Z*)-isomers (involving the *S*=*N* double bond and the cyano group) exist, but they rapidly interconvert at ambient temperatures (EFSA, 2014a). The chemical structures of the active substance and its main metabolites are reported in Appendix E.

Sulfoxaflor was evaluated in the framework of Regulation (EC) No 1107/2009 with Ireland designated as rapporteur Member State (RMS) for the representative uses by foliar spraying to control sap feeding insects on fruiting vegetables, spring and winter cereals and cotton. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by EFSA (EFSA, 2014a).

Sulfoxaflor was approved⁶ for the use as an insecticide on 18 August 2015.

The EU MRLs for sulfoxaflor are established in Annex II A of Regulation (EC) No 396/2005. The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has not yet been performed.

Assessment

EFSA has based its assessment on the evaluation reports submitted by the EMS (France, 2016, 2017), the DAR and its final addendum prepared under Regulation (EC) No 1107/2009 (Ireland, 2012, 2014), the European Commission review report on sulfoxaflor (European Commission, 2015), the conclusion on the peer review of the pesticide risk assessment of the active substance sulfoxaflor (EFSA, 2014a), the JMPR Evaluation reports (FAO, 2011, 2013, 2014) as well as the related EFSA scientific reports (EFSA, 2012, 2014b, 2015).

For these applications, the data requirements established in Regulation (EU) No 544/2011⁷ 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). 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 546/2011⁸.

A selected list of end points of the studies assessed by EFSA in the framework of the EU pesticides peer review, including the end points of studies submitted in support of the current MRL applications, are presented in Appendix B.

1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

The metabolism of sulfoxaflor in primary crops belonging to the group of fruit crops, leafy crops, cereals/grass and pulses/oilseeds has been investigated in the framework of the EU pesticides peer review (EFSA, 2014a). After foliar applications, parent sulfoxaflor represented a major component of final residues (16–71% of total radioactive residue (TRR)) with X11719474 as the most relevant 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.

⁵ According to the specific provisions of Commission Implementing Regulation (EU) 2015/1295, MS when granting an authorisation shall pay particular attention to the risk to bee and other non-target arthropods. Conditions of use shall include risk mitigation measures, where appropriate. It is noted that for the intended GAPs assessed in this reasoned opinion no further information was provided as regards the risk mitigation measures related to bees and other non-target arthropods.

⁶ 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.

⁷ 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.

⁸ 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.

An approximate 1:1 mixture of the diastereomers of sulfoxaflor was applied in the metabolism studies and no significant shift in their ratio was observed. Information was not available in terms of the ratios of enantiomers present in the individual diastereomers of sulfoxaflor and of the metabolite X11719474, respectively. Hence, residues refer to the sum of isomers of sulfoxaflor and of X11719474.

For the intended uses on grape leaves and globe artichokes (leafy crop group), the metabolic behaviour in primary crops is sufficiently addressed.

1.1.2. Nature of residues in rotational crops

Sulfoxaflor is proposed for use in grapevines and globe artichokes that are not reported to be grown in crop rotation (OECD, 2007). Although not required in the current MRL applications, a rotational crop metabolism study was submitted and assessed in the framework of the EU pesticides peer review (EFSA, 2014a). Details of the study are presented in Appendix B.

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 hydrolytically 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 commodities, to which the crops under consideration belong. The methods allow quantifying residues at or above the LOQ of 0.01 mg/kg (EFSA, 2014a).

1.1.5. 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 in the framework of this application, residues 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 the metabolite X11719474, the capabilities of enforcement analytical methods, the following residue definitions were proposed in the EU pesticides peer review:

- residue definition for risk assessment: Sulfoxaflor (sum of isomers);
- residue definition for enforcement: 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 and no further information is required.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

In support of the MRL applications, the applicant submitted residue trials performed in grape leaves and globe artichokes. The samples were analysed for the parent compound and the metabolite X11719474, included in the residue definition for risk assessment.

According to the assessment of the EMS, the samples of these residue trials were analysed with methods appropriately validated and stored under conditions for which their integrity was demonstrated (France, 2016, 2017).

1.2.1.1. Grape leaves

Eight Good Agricultural Practice (GAP)-complaint residue trials on grape leaves conducted in the northern Europe (NEU) and southern Europe (SEU) (four trials per region) over a single season were provided. Taking into account the limited contribution of this crop to the dietary exposure, further data from an additional season were not requested. Since belonging to similar populations (U-test, 5%), results from each dataset were combined to derive a MRL proposal of 2 mg/kg.

1.2.1.2. Globe artichokes

Four residue trials on globe artichokes conducted in the SEU over two seasons were provided. All trials were performed in Spain according to the intended GAP but with a longer interval between the two foliar applications of 21 days instead of 14 days.

The submitted trials showed that residues declined during the 13- to 15-day sampling period. Seven days after the last application (the intended preharvest interval (PHI)), only two samples contained quantifiable residues (about 83–88% less than the amount measured immediately after the second application); 13–15 days after the last application, no residues were found (< LOQ). The argumentation of the applicant that the longer interval of 21 days between the two applications is not expected to have a significant impact on terminal residues after the last application and on the validity of the MRL proposal of 0.06 mg/kg is acceptable.

1.2.2. Magnitude of residues in rotational crops

Not relevant as grapes and globe artichokes are not reported to be grown in crop rotation.

1.2.3. Magnitude of residues in processed commodities

Processing studies investigating the magnitude of sulfoxaflor and X11719474 residues in processed grape leaves and globe artichokes were not provided and are not required. The individual contribution of the commodities under consideration to the total theoretical maximum daily intake (TMDI) is expected to be below the trigger value of 10% of the ADI. Furthermore, significant residues (> 0.1 mg/kg) are not expected in globe artichokes following the intended use.

1.2.4. Proposed MRLs

The available data were 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 globe artichokes and grape leaves are not used for feed purposes.

3. Consumer risk assessment

EFSA performed a dietary risk assessment using revision 2 of the EFSA PRIMo (EFSA, 2007). 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 toxicological reference values established for sulfoxaflor apply to the metabolite X11719474 (EFSA, 2014a).

3.1. Short-term (acute) dietary risk assessment

The short-term exposure assessment was performed for the commodities assessed in these applications taking into account the highest residue (HR) values derived from supervised field trials. The complete list of input values can be found in Appendix D.2.

The short-term exposure did not exceed the ARfD for any the crops assessed in this application (see Appendix B.3).

3.2. 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 these applications. For the remaining commodities covered by the MRL regulation, the existing EU MRLs and STMR values derived from a previous MRL application assessed in the framework of the EU pesticides peer review and from the Codex MRLs (CXLs) transposed in EU legislation were selected as input values (FAO, 2011, 2013, 2014; EFSA, 2014a). The complete list of input values is presented in Appendix D.2.

The estimated long-term dietary intake was in the range of 2–11% of the ADI. The contribution of residues expected in the commodities assessed in this application to the overall long-term exposure is presented in more detail in Appendix B.3.

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.

Conclusions and recommendations

The data submitted in support of the MRL applications were found to be sufficient to derive MRL proposals for grape leaves and similar species and globe artichokes. Adequate analytical methods for enforcement are available to control the residues of sulfoxaflor in plant matrices, including the commodities under consideration.

Based on the risk assessment results, EFSA concluded that the short-term and long-term intakes of residues resulting from the uses of sulfoxaflor according to the intended agricultural practices are unlikely to present a risk to consumers' health.

The MRL recommendations are summarised in Appendix B.4.

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Abbreviations

a.s.	active substance
ADI	acceptable daily intake
AR	applied radioactivity
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CCPR	Codex Committee on Pesticide Residues
CF	conversion factor for enforcement to risk assessment residue definition
CXL	Codex maximum residue limit
DALA	days after last application
DAR	draft assessment report
DAT	days after treatment
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
UESTI	international estimated short-term intake
ILV	independent laboratory validation
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry

JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LOQ	limit of quantification
Mo	monitoring
MRL	maximum residue level
MS	Member States
MW	molecular weight
NEU	northern Europe
OECD	Organisation for Economic Co-operation and Development
PBI	plant-back interval
PHI	preharvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
RA	risk assessment
RD	residue definition
RMS	rapporteur Member State
SANCO	Directorate-General for Health and Consumers
SC	suspension concentrate
SEU	southern Europe
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
WHO	World Health Organization

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

Crop and/or situation	NEU, SEU, MS or country	F G or I ^(a)	Pests or group of pests controlled	Preparation		Application				Application rate per treatment			PHI (days) ^(d)	Remarks
				Type ^(b)	Conc. a.s.	Method kind	Range of growth stages & season ^(c)	Number min–max	Interval between application (min)	g a.s./hL min–max	Water L/ha min–max	g a.s./ha min–max		
Grape leaves	NEU	F	<i>Planococcus</i> sp., <i>Lecanium</i> sp., <i>Scaphoideus titanus</i> , <i>Empoasca</i> sp.	SC	120 g/L	Foliar spray	BBCH 11-87 (Feb–Oct)	1	N/A	3.2–24	200–1,500	48	7	Authorisation intended in FR, EL, ES, IT, PT
	SEU													
Globe artichokes	SEU	F	Aphids (all stages)	SC	120 g/L	Foliar spray	BBCH 40-89 (Mar–Nov)	1–2	14	1.6–8	300–1,500	24	7	Authorisation intended in ES, IT, PT

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

(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 plants: 14 DAT ₁ ; 14 DAT ₂ Fruits: 1, 7, 14 DALA Mature vines: 14 DALA
			Soil, 2 × 225 g/ha	Immature plants: 14 DAT ₁ Fruits: 14, 21, 28 DALA Mature vines: 28 DALA
	Leafy crops	Lettuce	Foliar, 3 × 200 g/ha	Immature plants: 14 DAT ₁ Mature plants: 7 DALA
			Soil, 2 × 225 g/ha	Immature plants: 14 DAT ₁ Mature plants: 14 DALA
	Cereals/ grass	Rice	Foliar, 3 × (225) + (225) + (150) g/ha	Immature plants: 14 DAT ₁ Mature grain, straw, hulls
			Soil, 1 × 400 g/ha, BBCH 13–14	Immature plants: 14, 28 DAT Mature grain, straw, hulls
	Pulses/ oilseeds	Snap Pea	Foliar, 3 × 200 g/ha	Immature plants: 14 DAT ₁ , 14 DAT ₂ Mature pods Mature vines
			Soil, 1 × 450 g/ha	Immature plants: 14 DAT ₁ Mature pods Mature vines
Radiolabelled active substance: [¹⁴ C-pyridine]-sulfoxaflor at 1:1 mixture of diastereomers. Ratio of isomers in the individual diastereomer unknown. Reference: Ireland (2012), EFSA (2014a)				
Rotational crops (available studies)	Crop groups	Crop(s)	Application	PBI (DAT)
	Root/tuber crops	Radish	Bare soil, 1 × 600 g/ha	30, 120, 365
	Leafy crops	Lettuce	Bare soil, 1 × 600 g/ha	30, 120, 365
	Cereal (small grain)	Wheat	Bare soil, 1 × 600 g/ha	30, 120, 365
Comments: [¹⁴ C-pyridine]-sulfoxaflor at 1:1 mixture of diastereomers. Ratio of isomers in the individual diastereomer unknown. Very little quantities of sulfoxaflor were found in plant samples. X11719474 was the most abundant metabolite in all crops at all three plant-back intervals. Reference: Ireland (2012), EFSA (2014a)				
Processed commodities (hydrolysis study)	Conditions			Investigated?
	Pasteurisation (20 min, 90°C, pH 4)			Yes
	Baking, brewing and boiling (60 min, 100°C, pH 5)			Yes
	Sterilisation (20 min, 120°C, pH 6)			Yes
	Comment: [¹⁴ C-pyridine]-sulfoxaflor and [¹⁴ C-pyridine]-X11719474. Sulfoxaflor and X11719474 were concluded to be stable under hydrolysis conditions (> 99.6% and > 89.1% AR, respectively). The only transformation that occurred was for X11719474, which slightly degraded with increase pH and temperature forming X11579457 (0.4–11.6% AR). Reference: EFSA (2014a)			

DAT: days after treatment; DALA: days after last application; PBI: plant-back interval; AR: applied radioactivity.

Can a general residue definition be proposed for primary crops?	Yes
Rotational crop and primary crop metabolism similar?	Yes
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes
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 (It was agreed that if metabolite X11719474 is shown to be significantly less toxic than sulfoxaflor, then the residue definition for risk assessment will become patent sulfoxaflor only)
Conversion factor (monitoring to risk assessment)	Grape leaves and similar species: see Table B.1.2.2 Globe artichokes: see Table B.1.2.2
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)	Matrices with high water content: HPLC–MS/MS, LOQ 0.01 mg/kg ILV available – DFG S19 applicable (EFSA, 2014a)

B.1.1.2. Stability of residues in plants

Plant products (available studies)	Category	Commodity	T (°C)	Stability (months/years)
	High water content	Peach	–20	22 months
Comment: Stability of both sulfoxaflor and X11719474. Reference: EFSA (2014a)				

B.1.2. Magnitude of residues in plants

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

Crop	Region/indoor ^(a)	Residue levels observed in the supervised residue trials ^(b) (mg/kg)	Comments (OECD calculations)	MRL proposals (mg/kg)	HR _{Mo} ^(c) (mg/kg)	STMR _{Mo} ^(d) (mg/kg)	CF ^(e)
Grape leaves	NEU	Mo: 0.09; 0.23; 0.40; 1.06 RA: 0.26; 0.40; 0.55; 1.17	Data sets merged (U-test, 5%) X11719474: 0.12–0.23 mg/kg OECD (unrounded): 1.75	2	1.06 (1.18)	0.32 (0.48)	1.5
	SEU	Mo: 0.10; 0.12; 0.55; 0.98 RA: 0.34; 0.26; 0.75; 1.18					
Globe artichokes	SEU	Mo: 2 × < 0.01; 0.01; 0.03 RA: 2 × < 0.02; 0.02; 0.04	X11719474: 4 × < 0.01 mg/kg OECD (unrounded): 0.06	0.06	0.03 (0.04)	0.01 (0.02)	1.5

MRL: maximum residue level; OECD: Organisation for Economic Co-operation and Development.

(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): Mo: residue level according to the monitoring residue definition.

RA: residue level according to the residue definition for risk assessment. A conversion factor of 0.94 was used to express the concentrations of X11719474 as parent equivalents (MW sulfoxaflor/MW X11719474 = 277.27/295.00) prior to be summed up.

(c): Highest residue (HR) according to the residue definition for monitoring. HR according to the residue definition for risk assessment is reported in brackets.

(d): Supervised trials median residue (STMR) according to the residue definition for monitoring. STMR according to the residue definition for risk assessment is reported in brackets.

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

B.1.2.2. Residues in succeeding crops

Confined rotational crop study
(quantitative aspect)

Not relevant

Field rotational crop study

Not relevant

B.1.2.3. Processing factors

Not relevant.

B.2. Residues in livestock

Not relevant.

B.3. Consumer risk assessment

ARfD

0.25 mg/kg bw (European Commission, 2015)

Highest IESTI, according to EFSA PRIMo

Grape leaves and similar species: 1.0% of ARfD
Globe artichokes: 0.3% of ARfD

Assumptions made for the calculations

The calculation is based on the highest residue levels derived for raw agricultural commodities according to the residue definition for risk assessment

ADI

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

Highest IEDI, according to EFSA PRIMo

11% ADI (Dutch child diet)
Contribution of crops assessed:
Grape leaves and similar species: < 0.01% of ADI
Globe artichokes: < 0.01% of ADI

Assumptions made for the calculations

The calculation is based on the median residue levels derived for raw agricultural commodities plus the existing MRLs (LOQ) in Regulation (EC) No 396/2005. Median residue levels for the intended uses in grape leaves and globe artichokes and for the uses previously assessed by EFSA in the EU pesticides peer review comply with the residue definition for risk assessment. Median residue levels for the Codex MRLs implemented in the EU legislation refer to parent compound only

B.4. Recommended MRLs

Code ^(a)	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Sulfoxaflor (sum of isomers)				
0253000	Grape leaves and similar species	0.01*	2	The submitted data are sufficient to derive a MRL proposal for the intended NEU/SEU uses. A consumer health concern was not identified
0270050	Globe artichokes	0.01*	0.06	The submitted data are sufficient to derive a MRL proposal for the intended SEU use. A consumer health concern was not identified

MRL: maximum residue level; 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.

Appendix C – Pesticide Residue Intake Model (PRIMo)

Sulfoxaflor			
Status of the active substance:	Approved	Code no.:	
LOQ (mg/kg bw):		Proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	0.04	ARfD (mg/kg bw):	0.25
Source of ADI:	COM	Source of ARfD:	COM
Year of evaluation:	2015	Year of evaluation:	2015

MRLs according to Reg. (EU) 2017/405, except the crops under consideration (grape leaves and globe artichokes).

Chronic risk assessment – refined calculations								
		TMDI (range) in % of ADI minimum – maximum						
		2 11						
		No of diets exceeding ADI:						

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	pTMRLs at LOQ (in % of ADI)
11.0	NL child	3.5	Milk and milk products: Cattle	2.0	Oranges	1.7	Apples	
11.0	DE child	3.3	Apples	2.5	Oranges	1.7	Milk and milk products: Cattle	
6.9	FR infant	3.1	Milk and milk products: Cattle	1.5	Spinach	0.7	Apples	
6.0	FR toddler	2.4	Spinach	1.3	Oranges	0.7	Apples	
6.0	WHO Cluster diet B	0.6	Wine grapes	0.6	Oranges	0.5	Wheat	
5.7	ES child	1.5	Milk and milk products: Cattle	1.4	Oranges	0.6	Lettuce	
4.6	IE adult	0.7	Oranges	0.4	Wine grapes	0.4	Spinach	
4.3	SE general population 90th percentile	1.5	Milk and milk products: Cattle	0.5	Chinese cabbage	0.5	Oranges	
4.1	NL general	1.0	Oranges	0.8	Milk and milk products: Cattle	0.5	Spinach	
3.9	ES adult	0.8	Oranges	0.8	Lettuce	0.6	Milk and milk products: Cattle	
3.6	UK Toddler	1.3	Oranges	0.6	Sugar beet (root)	0.5	Apples	
3.6	WHO regional European diet	0.6	Milk and milk products: Cattle	0.6	Lettuce	0.3	Oranges	
3.5	WHO Cluster diet F	0.6	Oranges	0.5	Milk and milk products: Cattle	0.4	Lettuce	
3.5	WHO cluster diet E	0.6	Wine grapes	0.4	Milk and milk products: Cattle	0.3	Oranges	
3.2	WHO cluster diet D	0.6	Milk and milk products: Cattle	0.5	Chinese cabbage	0.4	Wheat	
3.1	FR all population	1.4	Wine grapes	0.3	Milk and milk products: Cattle	0.2	Wheat	
2.8	PT General population	0.9	Wine grapes	0.4	Oranges	0.3	Apples	
2.6	UK Infant	0.8	Oranges	0.4	Apples	0.3	Sugar beet (root)	
2.5	IT kids/toddler	0.4	Lettuce	0.4	Wheat	0.3	Oranges	
2.5	DK child	0.6	Apples	0.3	Wheat	0.2	Rye	
2.4	IT adult	0.6	Lettuce	0.3	Spinach	0.3	Wheat	
2.1	UK vegetarian	0.6	Oranges	0.3	Wine grapes	0.2	Lettuce	
1.9	LT adult	0.5	Apples	0.5	Milk and milk products: Cattle	0.2	Potatoes	
1.7	UK Adult	0.4	Wine grapes	0.4	Oranges	0.2	Lettuce	
1.5	FI adult	0.6	Oranges	0.1	Lettuce	0.1	Apples	
1.5	PL general population	0.6	Apples	0.2	Potatoes	0.1	Tomatoes	
1.5	DK adult	0.5	Wine grapes	0.2	Apples	0.1	Wheat	

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	Acute risk assessment/adults/general population – refined calculations
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The acute risk assessment is based on the ARfD.
 For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS, an average European unit weight was used for the IESTI calculation.
 In the IESTI 1 calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002); for lettuce, a variability factor of 5 was used.
 In the IESTI 2 calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variability factor of 3.
Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100% of the ARfD.

Unprocessed commodities	No of commodities for which ARfD/ADI is exceeded (IESTI 1): ---			No of commodities for which ARfD/ADI is exceeded (IESTI 2): ---			No of commodities for which ARfD/ADI is exceeded (IESTI 1): ---			No of commodities for which ARfD/ADI is exceeded (IESTI 2): ---		
	IESTI 1 *) **)			IESTI 2 *) **)			IESTI 1 *) **)			IESTI 2 *) **)		
	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
	1.0 0.3	Vine leaves (grape) Globe artichokes	1.18/- 0.04/-	0.7 0.2	Vine leaves (grape) Globe artichokes	1.18/- 0.04/-	0.2	Globe artichokes	0.04/-	0.1	Globe artichokes	0.04/-
No of critical MRLs (IESTI 1) ---			No of critical MRLs (IESTI 2) ---			No of critical MRLs (IESTI 1) ---			No of critical MRLs (IESTI 2) ---			

Processed commodities	No of commodities for which ARfD/ADI is exceeded: ---			No of commodities for which ARfD/ADI is exceeded: ---		
	***)			***)		
	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)

*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.
 **) pTMRL: provisional temporary MRL.
 ***) pTMRL: provisional temporary MRL for unprocessed commodity.

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

Not relevant.

D.2. Consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment ^(a)	Input value (mg/kg)	Comment
Grape leaves and similar spices	0.48	STMR	1.18	HR
Globe artichokes	0.02	STMR	0.04	HR
Grapefruits ^(b)	0.01	STMR (FAO, 2014)		
Oranges ^(b)	0.26	STMR (FAO, 2014)		
Lemons ^(b)	0.04	STMR (FAO, 2014)		
Mandarins ^(b)	0.26	STMR (FAO, 2014)		
Tree nuts	0.02	STMR (EFSA, 2014a)		
Apples, pears	0.11	STMR (EFSA, 2014a)		
Quinces, Medlars	0.07	STMR (FAO, 2014)		
Loquats/Japanese medlars	0.07	STMR (FAO, 2014)		
Other pome fruits	0.07	STMR (FAO, 2014)		
Apricots, Peaches	0.15	STMR (EFSA, 2014a)		
Cherries (sweet)	0.34	STMR (FAO, 2014)		
Plums	0.04	STMR (FAO, 2014)		
Table grapes	0.17	STMR (EFSA, 2014a)		
Wine grapes	0.14	STMR (FAO, 2011)		
Strawberries	0.20	STMR (EFSA, 2014a)		
Azaroles/Mediter. medlars	0.07	STMR (FAO, 2014)		
Kaki/Japanese persimmons	0.07	STMR (FAO, 2014)		
Potatoes	0.02	STMR (EFSA, 2014a)		
Tropical root and tuber vegetables	0.01	STMR (FAO, 2011)		
Other root and tuber vegetables except carrots and sugar beets	0.01	STMR (FAO, 2011)		
Carrots	0.01	STMR (FAO, 2013)		
Garlic	0.01	STMR (FAO, 2011)		
Onions	0.01	STMR (FAO, 2011)		
Spring onions/green Welsh onions	0.11	STMR (FAO, 2011)		
Tomatoes	0.06	STMR (EFSA, 2014a)		
Sweet peppers/bell peppers	0.08	STMR (EFSA, 2014a)		
Aubergines/eggplants	0.06	STMR (EFSA, 2014a)		
Cucurbits with edible peel	0.03	STMR (FAO, 2011)		
Cucurbits with inedible peel	0.03	STMR (FAO, 2011)		
Broccoli	0.07	STMR (FAO, 2011)		
Cauliflowers	0.01	STMR (FAO, 2011)		
Head cabbages	0.10	STMR (FAO, 2011)		
Chinese cabbages/pe-tsai	1.00	STMR (EFSA, 2014a)		
Lettuces	0.59	STMR (EFSA, 2014a)		
Spinaches	1.34	STMR (EFSA, 2014a)		
Celery leaves	0.26	STMR (EFSA, 2014a)		
Celeries	0.19	STMR (FAO, 2011)		
Beans (dry)	0.08	STMR (FAO, 2013)		
Rapeseeds/canola seeds	0.07	STMR (EFSA, 2014a)		

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment ^(a)	Input value (mg/kg)	Comment
Soybeans	0.02	STMR (EFSA, 2014a)		
Cotton seeds	0.02	STMR (FAO, 2011)		
Barley	0.06	STMR (FAO, 2011)		
Oats	0.02	STMR (EFSA, 2014a)		
Rye	0.02	STMR (EFSA, 2014a)		
Wheat	0.03	STMR (FAO, 2011)		
Muscle (mammalians) ^(c)	0.04	STMR (FAO, 2011)		
Fat tissue (mammalians) ^(c)	0.03	STMR (FAO, 2014)		
Liver (mammalians) ^(c)	0.12	STMR (FAO, 2011)		
Kidney (mammalians) ^(c)	0.12	STMR (FAO, 2011)		
Edible offal (mammalians) ^(c)	0.12	STMR (FAO, 2011)		
Muscle (poultry)	0.01	STMR (FAO, 2011)		
Fat tissue (poultry)	0.01	STMR (FAO, 2014)		
Liver, kidney (poultry)	0.04	STMR (FAO, 2011)		
Edible offal (poultry)	0.04	STMR (FAO, 2011)		
Milks	0.05	STMR (FAO, 2011)		
Birds eggs	0.01	STMR (FAO, 2011)		
Other products	Existing MRL (LOQ) as in Regulation (EU) 2017/405			

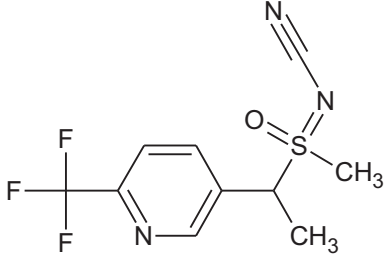
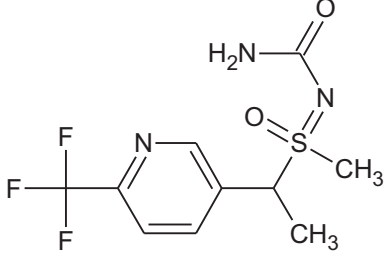
STMR: supervised trials median residue; HR: highest residue; MRL: maximum residue level; LOQ: limit of quantification.

(a): All STMRs derived by the FAO refer to residues of parent compound only and do not comply with the risk assessment residue definition at EU level, which includes also metabolite X11719474. In a recent consumer risk assessment, 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): Median residues refer to whole fruits. Data were not sufficient to derive a STMR for citrus pulp (FAO, 2014).

(c): Namely, swine, bovine, sheep, goats, equine, other farmed terrestrial animals.

Appendix E – Used compound codes

Code/trivial name	Chemical name/SMILES notation ^(a)	Structural formula ^(a)
Sulfoxaflor	[methyl(oxo){1-[6-(trifluoromethyl)-3-pyridyl]ethyl}-λ ⁶ -sulfanylidene]cyanamide <chem>FC(F)(F)c1ccc(cn1)C(C)S(C)(=O)=NC#N</chem>	
X11719474	<i>N</i> -[methyl(oxo){1-[6-(trifluoromethyl)pyridin-3-yl]ethyl}-λ ⁶ -sulfanylidene]urea <chem>FC(F)(F)c1ccc(cn1)C(C)S(C)(=O)=NC(N)=O</chem>	

SMILES: simplified molecular-input line-entry system.

(a): (ACD/ChemSketch, Advanced Chemistry Development, Inc., ACD/Labs Release: 12.00 Product version: 12.00 (Build 29305, 25 Nov 2008)).