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CONCLUSION ON PESTICIDE PEER REVIEW

Conclusion on the peer review of the pesticide risk assessment of the active substance sulfoxaflor[1]

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ABSTRACT

The conclusions of the European Food Safety Authority (EFSA) following the peer review of the initial risk assessments carried out by the competent authority of the rapporteur Member State Ireland and the co-rapporteur Member States Czech Republic, France and Poland for the pesticide active substance sulfoxaflor and the assessment of applications for maximum residue levels (MRLs) are reported. The context of the peer review was that required by Regulation (EC) No 1107/2009 of the European Parliament and of the Council. The conclusions were reached on the basis of the evaluation of the representative uses of sulfoxaflor as an insecticide on fruiting vegetables (field use and glasshouse application; tomato, cherry tomato, pepper (bell and non bell), aubergine), cucurbits (field use and glasshouse application; cucumber, water melon, courgette), spring and winter cereals (wheat, rye, barley, oats, triticale) and cotton. MRLs were assessed in almonds, pecans, apples, pears, cherries, peaches including nectarines, apricots, plums, wheat and barley grain, broccoli, cauliflower, mustard greens, cabbage, leaf and head lettuce, spinach, celery, cotton seed, oilseed rape seed, grapefruit, lemons, oranges, melons, squash (winter and summer), cucumbers, potatoes, sugar beet, carrots, soya bean, beans (pulses), fresh beans with and without pods, strawberries, tomatoes, peppers, wine and table grapes, and in animal commodities such as milk, eggs, muscle, fat, liver and kidney. The reliable endpoints concluded as being appropriate for use in regulatory risk assessment and the proposed MRLs, derived from the available studies and literature in the dossier peer reviewed, are presented. Missing information identified as being required by the regulatory framework is listed. With the available assessments a high risk to bees was not excluded for field uses and a high long-term risk was indicated for the small herbivorous mammal scenario for field uses in vegetables and in cotton.

KEY WORDS

sulfoxaflor, peer review, risk assessment, pesticide, insecticide, maximum residue level

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[1] On request from the European Commission, Question No EFSA-Q-2013-00037, approved on 12 May 2014.

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[3] Clarification is provided regarding the determination of potential endocrine disrupting properties in accordance with the interim provisions of Annex II, Point 3.6.5 of Regulation (EC) No. 1107/2009. The original Conclusion is available on request, as is a version showing all the changes that were made.

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SUMMARY

Sulfoxaflor is a new active substance for which in accordance with Article 7 of Regulation (EC) No 1107/2009 of the European Parliament and of the Council (hereinafter referred to as 'the Regulation'), the rapporteur Member State (RMS) Ireland received an application from Dow AgroSciences on 1 September 2011 for approval. In accordance with Article 8(1)(g) of the Regulation, Dow AgroSciences submitted applications for maximum residue levels (MRLs) as referred to in Article 7 of Regulation (EC) No 396/2005. Complying with Article 9 of the Regulation, the completeness of the dossier was checked by the RMS and the date of admissibility of the application was recognised as being 30 September 2011.

The RMS, Ireland, and the co-rapporteur Member States Czech Republic, France and Poland provided the initial evaluation of the dossier on sulfoxaflor in the Draft Assessment Report (DAR), which was received by the EFSA on 23 November 2012. The DAR included a proposal to set MRLs, in accordance with Article 11(2) of the Regulation. The peer review was initiated on 15 January 2013 by dispatching the DAR for consultation of the Member States and the applicant Dow AgroSciences.

Following consideration of the comments received on the DAR, it was concluded that additional information should be requested from the applicant, and that the EFSA should conduct an expert consultation in the areas of mammalian toxicology, residues, environmental fate and behaviour, ecotoxicology.

In accordance with Article 12 of the Regulation, the EFSA should adopt a conclusion on whether sulfoxaflor can be expected to meet the approval criteria provided for in Article 4 of the Regulation taking into consideration recital (10) of the Regulation and give a reasoned opinion concerning MRL applications as referred to in Article 10(1) of Regulation (EC) No 396/2005.

The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of sulfoxaflor as an insecticide on fruiting vegetables (field use and glasshouse application; tomato, cherry tomato, pepper (bell and non bell), aubergine), cucurbits (field use and glasshouse application; cucumber, water melon, courgette), spring and winter cereals (wheat, rye, barley, oats, triticale) and cotton as proposed by the applicant. MRLs were assessed in almonds, pecans, apples, pears, cherry, peach including nectarines and apricots, plum, wheat grain, barley grain, broccoli, cauliflower, mustard greens, cabbage, leaf and head lettuce, spinach, celery, cotton seed, oilseed rape seed, grapefruit, lemon, oranges, melon, squash (winter and summer), cucumber, potatoes, sugar beet, carrot, soya bean, beans (pulses), fresh beans with and without pods, strawberry, tomato, peppers, wine grapes and table grapes, and in animal commodities such as milk, eggs, muscle, fat, liver and kidney. Full details of the representative uses and the proposed MRLs can be found in Appendix A to this report.

Data were provided to confirm the efficacy of the active substance on various aphid species, when applied on fruiting vegetables, cereals and cotton, according to the representative GAPs.

A data gap was identified for a search of the scientific peer-reviewed open literature on the active substance and its relevant metabolites.

Data gaps were identified in the Section on identity and physical and chemical properties.

In the Section on mammalian toxicology a data gap was identified regarding the genotoxic potential of an impurity.

Data gaps were not identified in the Section on residues in relation to the peer review of the representative uses.

As for the MRL applications, MRLs were proposed only in cases where the data were sufficient to support the registered GAP in the exporting country. In the consumer risk assessment covering those uses, the toxicological reference values have not been exceeded.

The data available on environmental fate and behaviour are sufficient to carry out the required environmental exposure assessments at EU level for the representative uses.

Data gaps were identified in the Section on ecotoxicology. With the available assessments a high risk to bees was not excluded for field uses. A high long-term risk was indicated for the small herbivorous mammal scenario for field uses in vegetables and in cotton.

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BACKGROUND

Regulation (EC) No 1107/2009 of the European Parliament and of the Council[4] (hereinafter referred to as 'the Regulation') lays down, *inter alia*, the detailed rules as regards the procedure and conditions for approval of active substances. This regulates for the European Food Safety Authority (EFSA) the procedure for organising the consultation of Member States and the applicant(s) for comments on the initial evaluation in the Draft Assessment Report (DAR) provided by the rapporteur Member State (RMS), and the organisation of an expert consultation where appropriate.

In accordance with Article 12 of the Regulation, EFSA is required to adopt a conclusion on whether an active substance can be expected to meet the approval criteria provided for in Article 4 of the Regulation (also taking into consideration recital (10) of the Regulation) within 120 days from the end of the period provided for the submission of written comments, subject to an extension of 30 days where an expert consultation is necessary, and a further extension of up to 150 days where additional information is required to be submitted by the applicant(s) in accordance with Article 12(3).

Sulfoxaflor is a new active substance for which in accordance with Article 7 of the Regulation, the rapporteur Member State (RMS) Ireland (hereinafter referred to as the 'RMS') received an application from Dow AgroSciences on 1 September 2011 for approval of the active substance sulfoxaflor. In accordance with Article 8(1)(g) of the Regulation, Dow AgroSciences submitted applications for maximum residue levels (MRLs) as referred to in Article 7 of Regulation (EC) No 396/2005.[5] Complying with Article 9 of the Regulation, the completeness of the dossier was checked by the RMS and the date of admissibility of the application was recognised as being 30 September 2011.

The RMS and the co-rapporteur Member States Czech Republic, France and Poland provided the initial evaluation of the dossier on sulfoxaflor in the Draft Assessment Report (DAR), which was received by the EFSA on 23 November 2012 (Ireland, 2012). The DAR included a proposal to set MRL, in accordance with Article 11(2) of the Regulation. The peer review was initiated on 15 January 2013 by dispatching the DAR for consultation of the Member States and the applicant Dow AgroSciences, for consultation and comments. EFSA also provided comments. In addition, the EFSA conducted a public consultation on the DAR. The comments received were collated by the EFSA and forwarded to the RMS for compilation and evaluation in the format of a Reporting Table. The applicant was invited to respond to the comments in column 3 of the Reporting Table. The comments and the applicant's response were evaluated by the RMS in column 3.

The need for expert consultation and the necessity for additional information to be submitted by the applicant in accordance with Article 12(3) of the Regulation were considered in a telephone conference between the EFSA, the RMS, and the European Commission on 31 May 2013. On the basis of the comments received, the applicant's response to the comments and the RMS's evaluation thereof it was concluded that additional information should be requested from the applicant, and that the EFSA should conduct an expert consultation in the areas of mammalian toxicology, residues, environmental fate and behaviour, and ecotoxicology.

The outcome of the telephone conference, together with the EFSA's further consideration of the comments is reflected in the conclusions set out in column 4 of the Reporting Table. All points that were identified as unresolved at the end of the comment evaluation phase and which required further consideration, including those issues to be considered in an expert consultation, were compiled by the EFSA in the format of an Evaluation Table.

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[4] Regulation (EC) No 1107/2009 of 21 October 2009 of the European Parliament and of the Council 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.

[5] Regulation (EC) No 396/2005 of the European 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. No L 70, 16.3.2005, p. 1-16.

The conclusions arising from the consideration by the EFSA, and as appropriate by the RMS, of the points identified in the Evaluation Table, together with the outcome of the expert consultation where this took place, were reported in the final column of the Evaluation Table.

In accordance with Article 12 of the Regulation, the EFSA should adopt a conclusion on whether sulfoxaflor can be expected to meet the approval criteria provided for in Article 4 of the Regulation taking into consideration recital (10) of the Regulation and give a reasoned opinion concerning MRL applications as referred to in Article 10(1) of Regulation (EC) No 396/2005. A final consultation on the conclusions arising from the peer review of the risk assessment and on the proposed MRLs took place with Member States via a written procedure in April 2014.

This conclusion report summarises the outcome of the peer review of the risk assessment on the active substance and the representative formulation evaluated on the basis of the representative uses of sulfoxaflor as an insecticide on fruiting vegetables (field use and glasshouse application; tomato, cherry tomato, pepper (bell and non bell), aubergine), cucurbits (field use and glasshouse application; cucumber, water melon, courgette), spring and winter cereals (wheat, rye, barley, oats, triticale) and cotton as proposed by the applicant. MRLs were assessed in almonds, pecans, apples, pears, cherry, peach including nectarines and apricots, plum, wheat grain, barley grain, broccoli, cauliflower, mustard greens, cabbage, leaf and head lettuce, spinach, celery, cotton seed, oilseed rape seed, grapefruit, lemon, oranges, melon, squash (winter and summer), cucumber, potatoes, sugar beet, carrot, soya bean, beans (pulses), fresh beans with and without pods, strawberry, tomato, peppers, wine grapes and table grapes, and in animal commodities such as milk, eggs, muscle, fat, liver and kidney. A list of the relevant end points for the active substance as well as the formulation and the proposed MRLs is provided in Appendix A.

In addition, a key supporting document to this conclusion is the Peer Review Report, which is a compilation of the documentation developed to evaluate and address all issues raised in the peer review, from the initial commenting phase to the conclusion. The Peer Review Report (EFSA, 2014) comprises the following documents, in which all views expressed during the course of the peer review, including minority views where applicable, can be found:

- the comments received on the DAR,
- the Reporting Table (31 May 2013),
- the Evaluation Table (19 March 2014),
- the reports of the scientific consultation with Member State experts (where relevant),
- the comments received on the assessment of the additional information (where relevant),
- the comments received on the draft EFSA conclusion.

Given the importance of the DAR including its final addendum (compiled version of January 2014 containing all individually submitted addenda (Ireland, 2014)) and the Peer Review Report, both documents are considered respectively as background documents A and B to this conclusion.

It is recommended that this conclusion report and its background documents would not be accepted to support any registration outside the EU for which the applicant has not demonstrated to have regulatory access to the information on which this conclusion report is based.

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Sulfoxaflor is the ISO common name for [methyl(oxo){1-[6-(trifluoromethyl)-3-pyridyl]ethyl}-λ^6-sulfanylidene]cyanamide (IUPAC).

The representative formulated products for the evaluation were 'GF-2626', an aqueous suspension concentrate (SC) containing 120 g/l sulfoxaflor (11.3 % w/w) and 'GF-2372', a water dispersible granule (WG) containing 500 g/kg sulfoxaflor.

The representative uses evaluated comprise applications by foliar spraying to control sap feeding insects on fruiting vegetables, spring and winter cereals and cotton. Full details of the GAPs can be found in the list of endpoints in Appendix A.

Data were provided to confirm the efficacy of the active substance sulfoxaflor on various aphid species, when used as a single foliar application on Solanacea, cucurbits, cereals and cotton, at the dose rate of 24 g/ha, as proposed under the representative uses evaluated (European Commission, 2013).

The applicant carried out and submitted a report of their search of the scientific peer-reviewed open literature on the active substance and its relevant metabolites. The RMS did not provide a transparent evaluation of this report, or of the pertinent articles that were found. Therefore a data gap has been identified for a search of the scientific peer-reviewed open literature on the active substance and its relevant metabolites, dealing with side-effects on health, the environment and non-target species and published within the last 10 years before the date of submission of dossier, to be conducted and reported in accordance with the Guidance of EFSA on the submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 (EFSA, 2011).

CONCLUSIONS OF THE EVALUATION

1. Identity, physical/chemical/technical properties and methods of analysis

The following guidance documents were followed in the production of this conclusion: SANCO/3030/99 rev.4 (European Commission, 2000), SANCO/825/00 rev. 8.1 (European Commission, 2010) and SANCO/10597/2003 –rev. 10.1 (European Commission, 2012).

The minimum purity of sulfoxaflor technical material is 950 g/kg. No FAO specification exists.

Sulfoxaflor is 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.

The proposed specification for the technical material is based on industrial scale production and QC data, however a data gap was identified for new batch analysis data after stabilisation of the production, to confirm the specification.

The assessment of the data package revealed no issues that need to be included as critical areas of concern with respect to the identity, physical, chemical and technical properties of sulfoxaflor or the representative formulations; however a data gap was identified for shelf life study for the representative formulation GF-2626. The main data regarding the identity of sulfoxaflor and its physical and chemical properties are given in Appendix A.

Adequate analytical methods are available for the determination of sulfoxaflor in the technical material and in the representative formulations as well as for the determination of the respective impurities in the technical material.

Residues of sulfoxaflor in food and feed of plant origin can be monitored by HPLC-MS/MS with LOQs of 0.01 mg/kg in each commodity group. Adequate HPLC-MS/MS methods exist for the determination of sulfoxaflor in food of animal origin with LOQs of 0.01 mg/kg in cream, eggs, milk, liver, fat, muscle and kidney. The residue definition for monitoring in soil and water was set as sulfoxaflor and its metabolite X11719474 (which is also a mixture of two diastereomeric pairs of enantiomers). Appropriate HPLC-MS/MS methods are available for monitoring sulfoxaflor and metabolite X11719474 in soil with LOQs of 0.001 mg/kg for both compounds. Sulfoxaflor and metabolite X11719474 can be monitored in drinking water and surface water by HPLC-MS/MS with LOQs of 0.05 μg/L individually. Residues of sulfoxaflor in air can be monitored by HPLC-MS/MS with a LOQ of 0.3 $\mu g/m^3$. Analytical methods for the determination of sulfoxaflor residues in body fluids and tissues are not required as the active substance is not classified as toxic or very toxic, however a HPLC-MS/MS method exist for the determination of sulfoxaflor in urine and in blood with a LOQ of 0.05 mg/L.

2. Mammalian toxicity

The following guidance documents were followed in the production of this conclusion: SANCO/221/2000 rev. 10 - final (European Commission, 2003), SANCO/222/2000 rev. 7 (European Commission, 2004), SANCO/10597/2003 – rev. 10.1 (European Commission, 2012) and Guidance on Dermal Absorption (EFSA PPR Panel, 2012). The new proposed specification contains the impurity B2 which was not adequately tested in the toxicological studies and for which DEREK indicated an alert on genotoxicity; based on the overall body of data (e.g. structural similarity with another impurity tested at much higher levels) it can be agreed that B2 is of low concern at the proposed level, however the genotoxicity issue has to be investigated properly (data gap).

Sulfoxaflor was discussed in a peer review meeting of experts in November 2013.

Sulfoxaflor is almost completely absorbed after oral administration and poorly metabolised; more than 93 % is rapidly excreted unchanged in urine and faeces. Sulfoxaflor is harmful if swallowed (Xn; R22 and Acute Tox. 4; H302 apply; ECHA, 2014). It is not acutely toxic via dermal and inhalational routes. It is not a skin and eye irritant nor a skin sensitiser. The liver is the main target organ after repeated oral administrations, either for short or long-term exposure. The relevant subchronic NOAEL in rats is 6.36 mg/kg bw per day based on increased liver weight with positive histopathology, whereas the chronic NOAEL is 4.24 mg/kg bw per day based on non-neoplastic liver effects in rats. In a long-term toxicity study rats also showed increased testes weight, atrophy of seminiferous tubules, reduced sperm in epididymides and secretory material in accessory sex glands. Sulfoxaflor showed no genotoxic potential, but liver tumours occurred in both rats and mice, as well as Leydig cell tumours and preputial gland tumours in rats only. The carcinogenic potential of sulfoxaflor was therefore discussed in the peer review meeting: the liver tumours in mice and rats are produced by a non-genotoxic mode of action that involves the induction of hepatocellular cell proliferation (i.e. constitutive androstane receptor (CAR) mediated effect). The weight of evidence suggests that liver tumours in mice and rats are not relevant to humans. Induction of Leydig cell tumours in rat indicates a hormonal disturbance, which has potential relevance for humans; however, the testicular tumour profile, Leydig cell hormone receptors and the risk factors for Leydig cell tumours in rodents and humans are so different that the induction of rodent Leydig cell tumours is often not relevant to man. As for the preputial gland tumours the mechanism of action is unlikely to be relevant to humans as humans do not have an anatomic equivalent to rodent preputial glands; even at very high doses, there were no effects in CD-1 mouse preputial glands, clitoral glands, or other sebaceous glands, as well as no effects in other sebaceous glands occurred in male or female rats. Overall, a final consensus could not be reached with regard to the need of classifying sulfoxaflor as a carcinogen. After the peer review meeting, ECHA concluded that sulfoxaflor should not be classified as carcinogen (ECHA, 2014). Sulfoxaflor is neither a reproductive (relevant maternal, offspring and reproductive NOAELs 6.63 mg/kg bw per day) nor a developmental toxicant (relevant maternal and developmental NOAELs 11.5 mg/kg bw per day). Sulfoxaflor is not classified or proposed to be classified as toxic for reproduction category 2, in accordance with the provisions of Regulation (EC) No 1272/2008, and therefore the conditions of the interim provisions of Annex II, Point 3.6.5 of Regulation (EC) No 1107/2009 concerning human health for the consideration of endocrine disrupting properties are not met. A mode of action (MoA) study indicated that effects in the testes, epididymides, accessory sexual glands and the preputial gland were likely due to a dopamine enhancement-type MoA, not relevant to humans; furthermore, sulfoxaflor was negative for androgen and oestrogen receptor transactivation (agonism and antagonism) and for aromatase inhibition. Overall, it is unlikely that sulfoxaflor is an endocrine disruptor in mammals. The acute neurotoxicity NOAEL is 25 mg/kg based on decreased motor activity, whereas the NOAEL for repeated exposures is 7.1 mg/kg bw per day. Based on the available studies (acute and short term) metabolite X11719474 (minor rat metabolite, 0.07 – 0.5% of the administered dose in urine, and major crop metabolite) was shown to be less toxic than sulfoxaflor (but a chronic toxicity and carcinogenicity study was not available); X11579457 did not show genotoxicity acute oral toxicity potential (it is structurally close related to X11719474). X11519540 exhibits no genotoxicity and has greater acute oral toxicity than sulfoxaflor. Repeat-dose studies in the rat show that X11519540 has the liver as target organ as the parent molecule and it causes the same microscopic changes, but is of higher potency than sulfoxaflor, likely because of a longer half-life. Based on the guidance document on the assessment of the relevance of groundwater metabolites, X11519540 is not relevant; however, in case a consumers' risk assessment would be needed, the reference values of sulfoxaflor cannot be applied, whereas they can be used for X11579457 and X11719474 (for the latter the application of an additional uncertainty factor of 2 to the short term NOAEL of 32.2 mg/kg bw per day to account for the lack of a chronic NOAEL would lead to an ADI of about 0.16 mg/kg bw per day. Considering that it consists of four isomers, an extra factor of 4 would lead to an ADI similar to sulfoxaflor). The established ADI is 0.04 mg/kg bw per day, the ARfD is 0.25 mg/kg bw, the AOEL is 0.06 mg/kg bw per day. The estimated operator, worker and bystander exposure is below the AOEL. With regard to the exposure of re-entry workers to metabolite X11719474, which consists of four isomers, no concern is expected considering that the exposure to sulfoxaflor is below 4% of the AOEL.

3. Residues

The assessment in the residue Section is based on the guidance documents listed in the document 1607/VI/97 rev.2 (European Commission, 1999), the EC guideline document on MRL setting (European Commission, 2011), the JMPR recommendations on livestock burden calculations (JMPR, 2004, 2007) and OECD publication on MRL calculations (OECD, 2011).

Plant metabolism was studied in tomato, snap peas, lettuce, and rice with sulfoxaflor labelled in the [^{14}C-pyridine] ring. For each metabolism study, foliar and soil applications were studied separately. In Europe currently only registration for foliar applications is being pursued.

In all four of the plant metabolism studies, an approximate 1:1 mixture of the diastereomers of sulfoxaflor was applied. The analytical methods employed could separate the two diastereomeric pairs of enantiomers in sulfoxaflor, and there was no significant shift in the ratio of the diasteromers observed. However the residues of the metabolite X11719474 could not be resolved into its two diastereomeric pairs of enantiomers in plant matrices, while in a buffer solution no epimerisation was observed. No information is available in terms of the ratios of enantiomers present in the individual diastereomers of sulfoxaflor and of X11719474, respectively. All data reported here below refer to the sum of the four isomers of sulfoxaflor and X11719474, respectively.

Upon foliar treatment, parent sulfoxaflor was a major residue in the mature tomato fruit (26 – 35 % TRR) and foliage (28 % TRR), pods of snap pea (59 %TRR) and vines (71 % TRR), lettuce (16 % TRR), rice grain (35 % TRR) and straw (44 % TRR).

Overall, compounds X11719474 and X11721061 (conjugated form) were the pertinent metabolites in mature tomato fruit (20 – 29 % and 13 – 22 %TRR, respectively), foliage (16 % and 14 % TRR), pods of snap pea (both 13 % TRR) and vines (12 % and 7 % TRR), lettuce (30 % and 8 % TRR), rice grain

(8 % and 11 %TRR) and straw (10 % and 8 % TRR). Only low proportions of free X11721061 were observed in the mature crops (≤ 4 % TRR). Other metabolites were not significant.

Upon soil treatment - as for the rapid degradation of sufloxaflor in soil - metabolite X11719474 was the major residue in the mature crops, amounting to 60 – 73 % TRR in tomato fruit, to 90 % TRR in pods and vines of snap peas, to 49 % TRR in lettuce, and to 31 – 37 % TRR in rice straw and grain. Parent sulfoxaflor was present in a much lower proportion (tomatoes 11 – 18 % TRR; lettuce < 1 % TRR) or was not even detected (snap pea and rice). Across the crops studies, residues of X11721061, both free and conjugated were found in similar proportions to the foliar treated study. Again, other metabolites were not significant.

In a confined rotational crop study with lettuce, radish and wheat, X11719474 was the most abundant metabolite observed in all crops at all three plant-back intervals, ranging from 35 % TRR in wheat straw (120 DAT) to 88 % TRR in mature radish roots (120 DAT). There is strong indication that X11719474 may be preferentially taken up by the roots of the plants from the soil.

The identified metabolic pathways in the different primary crops and rotational crops were qualitatively similar, with metabolism of sulfoxaflor proceeding through oxidation of the cyano-carbon to yield X11719474 and loss of the sulfur side-chain to produce the metabolite X11721061. X11721061 is then conjugated with glucose, which in turn may be conjugated with a malonyl group, while quantities of the different metabolites identified varied between crops and depending on the method of application.

Based on the available metabolism data in primary and rotational crops, the metabolite X11719474 was considered quantitatively relevant. With regard to the toxicological profile of metabolite X11719474, the available acute and short term toxicity data show a lower toxicity than sulfoxaflor, however, the lack of a long term toxicity and carcinogenicity study and the fact that it consists of four isomers did not allow to reach consensus that the potential for chronic toxicity of the metabolite X11719474 is signicifanly lower than of parent. For the time being it will be assumed for the consumer risk assessment that this metabolite is as toxic as the parent compound, and the residue definition was therefore agreed as sum of sulfoxaflor and X11719474, expressed as sulfoxaflor. If this metabolite were to be demonstrated as being significantly less toxic than sulfoxaflor, only the parent compound might be considered in the residue definition for risk assessment. For monitoring the plant residue definition is proposed as sulfoxaflor only.

A study of the hydrolysis of ^{14}C-sulfoxaflor and its metabolites ^{14}C-X11719474 and ^{14}C-X11721061 under conditions simulating industrial and household food processes such as pasteurisation, baking, brewing, boiling and sterilisation showed that neither sulfoxaflor nor X11721061 were hydrolysed to any extent, while X11719474 was hydrolysed at the isocyanate moiety to compound X11579457 (0.4 – 12 %). The residue definition of parent compound and X11719474 is deemed to cover residues arising in processed plant commodities.

Metabolism of sulfoxaflor in lactating goats and laying hens was not extensive, with parent comprising 60 – 97 % of the TRR in tissues, milk and eggs. Metabolism proceeds through successive cleavage of the cyanamide and sulfone moieties, followed by reduction of the hydroxy group to give X11596066 as the terminal metabolite. Much smaller amounts of the three metabolites X11519540, X11721061, and X11596066 were found (maximum 18 % TRR). The plant metabolite X11719474 was not metabolised by lactating goats or laying hens, with only unchanged X11719474 being found in the excreta, milk, eggs and tissues.

In the ruminant metabolism studies, an approximate 1:2 mixture of the diastereomers of sulfoxaflor was applied, while the ratio of sulfoxaflor residues in the analysed animal matrices was approximately 1:1 following an equilibriumprocess. In the hen study, the ratio of the diastereomers of sulfoxaflor applied was 1:1, and no significant shift of the ratio of the diasteromers was observed. No information is available on the ratio of diastereomers of metabolite X11719474 in animal matrices, and also not on the ratios of enantiomers present in the individual diastereomers of sulfoxaflor and of X11719474, respectively.

The peer review concluded that for livestock commodities the residue definition for risk assessment should be sulfoxaflor and X11719474, with the possibility for revision in future. For monitoring the animal residue definition is proposed as sulfoxaflor only.

3.1. Representative use residues

As it regards the representative uses in fruiting vegetables (Solanaceae and curcurbits), cereals (wheat, rye, triticale, barley, oats) and cotton, sufficient GAP compliant residue trials are available. The trials analysed for residues of sulfoxaflor, X11719474 and X11721061 and were therefore suitable to assess residues according to the residue definition for risk assessment and for monitoring. The stability of the three analytes in freezer storage over the entire storage period has been demonstrated.

To assess the potential for accumulation of X11719474 in succeeding crops at various plant back intervals, field rotational crop residue trials were conducted in radish, lettuce, spring onions and barley (1N and 2N EU GAP rate) in northern and southern Europe. Only metabolite X11719474 was occasionally recovered above the LOQ; mostly in the leafy parts of the crops in rotation (radish leaves, spring onions, straw) and in the trials with the higher application rate. The residue levels of X11719474 in rotational crops were considered in the livestock dietary burden estimates where appropriate, however no MRLs are proposed in relation to rotational cropping since residues in commodities for human consumption are expected to be insignificant under EU critical GAP conditions.

Since dietary intake was significant for ruminants, a lactating cattle feeding study was conducted with a mixture of sulfoxaflor and its metabolites X11719474 and X11721061 at four different dose levels. Residues in animal commodities were estimated on the basis of this study, which were used in the consumer risk assessment and for deriving MRL proposals. A feeding study was also submitted in laying hens, however poultry intakes from the representative uses were below the trigger value.

A consumer risk assessment using revision 2 of the EFSA PRIMo was conducted for the representative uses in fruiting vegetables (Solanaceae and curcurbits), cereals (wheat, rye, triticale, barley and oats), cotton, and ruminant matrices. The chronic and acute dietary intakes were below the ADI and ARfD for all considered European consumer groups (max 2 % ADI - DK child; max 4 % ARfD - peppers, DE child). A theoretical factor of 2 may be applied to these estimates, in order to take into account for the uncertainty concerning the unknown ratio of enantiomers present in the individual diastereomers of sulfoxaflor and of X11719474, respectively. Following this approach, the toxicological reference values have not been exceeded.

In addition, the consumer exposure with regard to residues of metabolites X11719474, X11519540 and X11579457 (the three of them being livestock and/or plant metabolites, too) in groundwater used as drinking water was assessed on the basis of the predicted PEC groundwater levels in accordance with the Guidance SANCO/221/2000-rev. 10 – final (European Commission, 2003). The estimates are based on the default assumptions laid down in the WHO Guidelines (WHO, 2009) for drinking water quality for the consumer groups of adults (weighing 60 kg), toddlers (10 kg) and bottle-fed infants (5 kg) with a daily *per capita* consumption of 2 L, 1 L and 0.75 L, respectively. The additional intake through drinking water of X11719474, X11519540 and X11579457 is less than 1 % of the ADI of sulfoxaflor for all considered consumer groups.

3.2. Maximum residue levels

MRLs were assessed in almonds, pecans, apples, pears, cherries, peaches including nectarines and apricots, plums, wheat grain, barley grain, broccoli, cauliflower, mustard greens, cabbage, leaf and head lettuce, spinach, celery, cotton seed, oilseed rape seed, grapefruit, lemons, oranges, melons, squash (winter and summer), cucumbers, potatoes, sugar beet, carrots, soya bean, beans (pulses), fresh beans with and without pods, strawberries, tomatoes, peppers, wine grapes and table grapes, and in animal commodities such as milk, eggs, muscle, fat, liver and kidney.

Only those uses were assessed for which there was proof of authorisation (GAP) and MRL setting for the concerned crops in the exporting countries (see data requirement 3.1 in the evaluation table), and for which an MRL was effectively applied for. In addition, even if MRLs are currently not set in Europe for feed items, MRLs were assessed for potential feed items where applicable.

EFSA considered it appropriate to pool residue data generated according to a comparable GAP in Australia and New Zealand, and in Canada and the USA, respectively. In cases where data were insufficient to support the registered GAP in the exporting country, an MRL was not proposed (see Appendix A, listing of endpoints for details).

The livestock dietary burden was calculated using the European livestock diet, considering only those crops for which MRLs could be proposed and which might therefore be imported to Europe as either raw or processed items, plus, where appropriate, the relevant feed items in terms of the European representative uses (see listing of endpoints for details). For apple pomace a preliminary processing factor was used that has been based on one apple processing trial only, and thus further apple processing data would be necessary to reduce the uncertainty in the current estimate (data gap). The submitted MRL evaluation report and underlying information was however insufficient to assess the livestock dietary burden in the exporting countries to verify the MRLs applied for regarding potentially imported animal commodities. Therefore, the proposed MRLs in food of animal origin were merely based on the estimated residues in animal matrices according to the European livestock dietary burden calculation.

There was indication that residues of metabolite X11719474 might be significant in rotational crops grown following the application of sulfoxaflor according to the cGAP registered in the exporting non-EU countries; however, data and information submitted in the framework of the MRL application was insufficient to reliably assess potential residues of X11719474 in rotated food and feed items, that might be imported into Europe. Therefore, these potential residues of X11719474 could not be considered in the livestock and consumer exposure assessments. The missing data do not however have an impact on the proposed MRLs since X11719474 is not included in the residue definition for monitoring.

A consumer risk assessment using revision 2 of the EFSA PRIMo was conducted for the uses in the MRL application for which an MRL could effectively be proposed, and, the EU representative uses whenever more critical. The chronic (TMDI) and acute dietary intakes (IESTI) were below the ADI and ARfD for all considered European consumer groups (max ADI 27 % DE child; max 45 % ARfD – table grapes, DE child). A theoretical factor of 2 may be applied to these estimates, in order to take into account for the uncertainty concerning the unknown ratio of enantiomers present in the individual diastereomers of sulfoxaflor and of X11719474, respectively. Following this approach, the toxicological reference values have not been exceeded.

4. Environmental fate and behaviour

Sulfoxaflor was discussed at the pesticides peer review experts' teleconference for environmental fate and behaviour (TC 98) in November 2013.

In soil laboratory incubations under aerobic conditions in the dark, sulfoxaflor exhibited very low persistence, forming the major (>10 % applied radioactivity (AR)) metabolites X11719474 (max. 96 – 99 % AR after 24 hours, as sum of isomers) and X11519540 (max. 2 – 11 % AR, as sum of isomers), which exhibited moderate to high and moderate to very high persistence, respectively. A third metabolite X11579457 reached levels triggering a groundwater exposure assessment (max 0.9 – 8.5 % AR, as sum of isomers), it exhibited medium to high persistence (second slow phase DT_{50} of a biphasic fit 87 – 347 days). Mineralisation of the pyridine ring ^{14}C radiolabel to carbon dioxide accounted for 4 – 20 % AR after 99 days. The formation of unextractable residues (not extracted by acetonitrile/water) for this radiolabel accounted for 4 – 11 % AR after 99 days. In aerobic/anaerobic soil incubations (flooding and nitrogen atmosphere initiated 2 hours after dosing) sulfoxaflor formed the same major metabolite X11719474 as under solely aerobic conditions. Laboratory experiments demonstrated that sulfoxaflor and X11719474 were stable to photolysis at the soil surface. Sulfoxaflor and X11719474 exhibited very high to high mobility in soil. X11519540 and X11579457 exhibited very high soil mobility. It was concluded that the adsorption of all these substances was not pH dependent. In satisfactory field dissipation studies carried out at four sites (one each in Germany, northern France, Spain and Italy, spray application of sulfoxaflor at N and 2N rates to the soil surface on bare soil plots in May), sulfoxaflor exhibited low persistence and X11719474 exhibited moderate to high persistence. In field accumulation studies carried out at a site in Germany and a site in Italy where applications were made for five consecutive years, X11519540 and X11579457 did not accumulate. X11719474 residues appeared to have reached a relatively steady state, after 2 years of applications. In addition, satisfactory field dissipation studies for X11519540 were carried out at four sites, one each in Germany, northern France, Spain and Italy, (spray application of X11519540 to the soil surface on bare soil plots in April, May or July). Field study DT_{50} values from the available field dissipation trials were accepted as being reasonable estimates of degradation for X11719474 and X11519540, after normalisation to FOCUS reference conditions (20°C and PF2 soil moisture), using the time step normalisation procedure in accordance with FOCUS (2006) kinetics guidance.[6]

In laboratory incubations in dark aerobic natural sediment water systems, sulfoxaflor exhibited moderate to medium persistence, forming the major metabolite X11719474 (max. 35 – 48 % AR in water and 10 – 30 % AR in sediment, as sum of isomers), with no decline of X11719474 being apparent in the experiments. The unextractable sediment fraction (not extracted by acidified acetonitrile) was a sink for the pyridine ring ^{14}C radiolabel, accounting for 7 – 24 % AR at study end (103 days). Mineralisation of this radiolabel accounted for only 0.6 – 1.6 % AR at the end of the study. The rate of decline of sulfoxaflor in a laboratory sterile aqueous photolysis experiment was slow relative to that which occurred in the aerobic sediment water incubations. The necessary surface water and sediment exposure assessments (predicted environmental concentrations (PEC) calculations) were carried out for sulfoxaflor and the metabolites X11719474 and X11519540, using the FOCUS (FOCUS, 2001) step 1 and step 2 approach (version 2.1 of the Steps 1 – 2 in FOCUS calculator). Though not triggered, appropriate step 1 and step 2 calculations were also presented for metabolite X11579457. For the active substance sulfoxaflor, appropriate step 3 (FOCUS, 2001) calculations were available.[7]

The necessary groundwater exposure assessments were appropriately carried out using FOCUS (FOCUS, 2009) scenarios and the models PEARL 4.4.4 and PELMO 4.4.3[8] for the active substance sulfoxaflor and its transformation products X11719474, X11519540 and X11579457. The potential for groundwater exposure from the representative uses by sulfoxaflor above the parametric drinking water limit of 0.1 µg/L was concluded to be low in geoclimatic situations that are represented by all nine FOCUS groundwater scenarios. For the metabolites X11719474, X11519540 and X11579457, 80th percentile annual average recharge concentrations below 1 m depth were calculated to be above 0.1 µg/L for all the representative uses assessed at the pertinent FOCUS groundwater scenarios. This triggers groundwater non relevance assessments for these metabolites. In this context only for the uses on fruiting vegetables with applications in May was a concentration > 0.75 µg/L indicated, with this only being the case for X11719474.

The applicant provided appropriate information to address the effect of water treatments processes on the nature of the residues that might be present in surface water and groundwater, when surface water or groundwater are abstracted for drinking water. The conclusion of this consideration was that neither

[6] Normalisation utilised the agreed Q10 of 2.58 (following EFSA, 2007) and Walker equation coefficient of 0.7.
[7] Simulations correctly utilised the agreed Q10 of 2.58 (following EFSA, 2007) and Walker equation coefficient of 0.7.
[8] Simulations correctly utilised the agreed Q10 of 2.58 (following EFSA, 2007) and Walker equation coefficient of 0.7.

sulfoxaflor nor any of its degradation products that trigger assessment (X11719474, X11519540, X11579457) would be expected to undergo any substantial transformation due to oxidation at the disinfection stage of usual water treatment processes.

The PEC in soil, surface water, sediment, and groundwater covering the representative uses assessed can be found in Appendix A of this conclusion. For the representative glasshouse uses, specific PEC were not calculated. However the PEC available for the field uses were considered to cover the exposure levels that will occur from the glasshouse uses assessed.

5. Ecotoxicology

The following documents were considered for the risk assessments: European Commission, 2002a, b; SETAC, 2001 and EFSA, 2009.

It is noted that sulfoxaflor and its metabolites are enantiomers and the possible impact of each individual enantiomer on the environment was not evaluated. However, this uncertainty was not considered as a concern due to non persistence of sulfoxaflor in soil or because the risk assessments for aquatic and soil organisms for sulfoxaflor and its metabolites revealed a sufficient margin of safety (i.e. TER values were higher than the relevant triggers with more than a factor of 2).

With regard to the endocrine disruption potential, as discussed in section 2, some indications of interactions of sulfoxaflor (e.g. dopamine enhancement-type MoA) were observed in laboratory mammals, the toxicology experts concluded that overall, it is unlikely that sulfoxaflor is an endocrine disruptor in mammals. Some focussed studies (amphibian metamorphosis assay, fish reproduction screening assay), which are included in level 3 of the OECD Conceptual Framework (OECD, 2012) were available to address the potential endocrine activity of sulfoxaflor. These studies together with relevant information from the available reproductive or developmental studies on birds, mammals and fish (also included in level 4 of the OECD Conceptual Framework) were discussed in an expert meeting (pesticides peer review meeting 107). The experts at the meeting concluded that although no specific concerns have been identified from the available studies, no firm conclusion can be made from the available information, as in general, these studies alone are not sufficient to investigate all the relevant mechanisms and they may not be sufficient to detect all adverse effects which could be caused by an endocrine mechanism. Overall, insufficient information was available to perform an assessment of whether sulfoxaflor has endocrine disrupting properties that may cause adverse effects on non-target organisms.

On the basis of the available data and risk assessments, a low acute and long-term dietary risk to birds from the representative uses of sulfoxaflor was concluded. A low acute risk to wild mammals was also concluded, however, a high long-term risk was indicated on the basis of the available first-tier risk assessments for the small herbivorous mammal scenario in vegetables (only for field uses) and cotton (i.e. TER values of 3.81 instead of ≥ 5). Refined assessments (population modelling) were available, which focussed on the potential impact of sulfoxaflor to common vole populations in cereal fields and their surroundings. However the peer review concluded that the results of these modelling cannot be extrapolated to vegetables or cotton. Moreover, some concerns as regards to the uncertainty of some input parameters used and the validation of the model were noted. Therefore a data gap was identified for further information to address the long-term dietary risk to wild mammals for the field uses in vegetables and for cotton. For the pertinent plant metabolites and for the consumption of water, a low risk to birds and mammals was concluded.

On the basis of the available data and risk assessments, a low risk to aquatic organisms was concluded (with FOCUS step 2 PEC estimations).

First-tier risk assessments (HQ approach) for the active substance and the representative formulations indicated high risk to honey bees. Therefore higher tier studies (foliage residue contact tests and tunnel tests) were taken into consideration. The results of the foliage residue contact laboratory test indicated that mortality is not expected when bees are exposed to dry residues (aged residues) on over sprayed foliage. However, increased mortality was observed in the tunnel tests when sulfoxaflor was applied on flowering *Phacelia* during bee flight, and also when the application was in the previous evening (after bee flight). The increase in mortality was only apparent on the day of the application or on the following day. Potential adverse effects on bee brood could also not be excluded from the available data and assessments. The results and the assessments of these higher tier studies (tunnel tests) were discussed in an expert meeting (pesticides peer review meeting 107). A high risk to bees was concluded from these data by the experts at the meeting. In order to manage the risk to bees, some risk mitigation measures were proposed by the RMS for the field uses. However the experts at the meeting did not consider that the data and the assessments that were available were sufficient to demonstrate a low risk to bees for the field uses even with the proposed measures (i.e. application only when bees are not present in the crop). Therefore, a data gap was agreed to further address the risk to honey bees for the field uses. It is further noted that the available assessments for the field uses refer to honey bees and other pollinators such as wild bees are not covered.

A high risk to pollinators introduced in glasshouses where sulfoxaflor is used could also not be excluded. Therefore risk mitigation measures such us covering or removing bumble bee colonies for the application until the foliar residues have dried were proposed for these situations. However the experts at the meeting noted that some considerations to post-application exposure (as indicated by the results of the semi-field tests and the systemic properties of sulfoxaflor) needed also to be taken into account. It was also noted by some experts that protection measures for the wild pollinators visiting the glasshouses should also be considered (e.g. by keeping the glasshouses closed).

First tier risk assessments (HQ approach) for the pertinent metabolites indicated a low risk to honey bees.

On the basis of the standard tier 1 laboratory tests and the available further laboratory tests (extended laboratory and aged residue tests), a high in-field and off-field risk to non-target arthropods was indicated for the representative uses. Three field studies, which also indicated some effects on the arthropod communities, were also available. These field studies and the risk assessments were discussed in the pesticides peer review meeting 107. The meeting concluded that with the available field studies a potential for in-field population recovery for European cereal fields was demonstrated. Regarding the representative uses for vegetables and cotton, no specific field studies were available. However, a field study (south west France) designed to demonstrate the recovery potential of off-field habitats was available. It was noted that full recovery of some species within the *Bourletiellidae* family was not achieved in this study; however a recovery was demonstrated at the family level. Some uncertainties with the methodology used in this study were also noted. Overall, the experts at the meeting considered that the data available was sufficient to demonstrate a recovery potential for the southern European Member States. Extrapolation of the results of this study to other regions of Europe might also be possible with some additional data and assessments.

A low risk was concluded for earthworms and other soil macroorganisms, soil microorganisms, non-target terrestrial plants and organisms involved in biological methods for sewage treatment on the basis of the available data and assessments.

6. Overview of the risk assessment of compounds listed in residue definitions triggering assessment of effects data for the environmental compartments

6.1. Soil

Compound (name and/or code)	Persistence	Ecotoxicology
sulfoxaflor	Very low to low persistence Single first-order DT_{50} 0.041 – 0.26 days (20ºC 40 % MWHC soil moisture) Field dissipation studies single first-order DT_{50} 1.46 – 4.01 days	The risk to soil organisms was assessed as low
X11719474	Moderate to high persistence Single first-order DT_{50} 85 – 370 days (20ºC 40 % MWHC soil moisture) Field dissipation studies biphasic kinetics DT_{50} 0.43 – 97 days (DT_{90} 63 – 750 days)	The risk to soil organisms was assessed as low
X11519540	Moderate to very high persistence Biphasic kinetics DT_{50} 0.31 – 1155 days (DT_{90} > 130 – 3837 days, 20ºC 40 % MWHC)	The risk to soil organisms was assessed as low

6.2. Ground water

Compound (name and/or code)	Mobility in soil	>0.1 µg/L 1m depth for the representative uses (at least one FOCUS scenario or relevant lysimeter)	Pesticidal activity	Toxicological relevance	Ecotoxicological activity
sulfoxaflor	Very high to high mobility K_{Foc} 12 – 71 mL/g	No	Yes	Yes	The risk to aquatic organisms was assessed as low
X11719474	Very high to high mobility K_{Foc} 7 – 74 mL/g	Yes 0.121 – 0.792µg/L [(a)]	No	No (according to the Guidance Document on the relevance of groundwater metabolites) (less toxic than sulfoxaflor in acute and short term studies)	The risk to aquatic organisms was assessed as low

X11519540	Very high mobility K_{Foc} 1 – 25 mL/g	Yes 0.101 – 0.39µg/L	No	No (according to the Guidance Document on the relevance of groundwater metabolites) (Higher potency than sulfoxaflor, but no agonistic activity towards the nicotinic AChR)	The risk to aquatic organisms was assessed as low
X11579457	Very high mobility K_{Foc} 2 – 44 mL/g	Yes 0.1 – 0.73µg/L	No	No (according to the Guidance Document on the relevance of groundwater metabolites) (No genotoxicity and acute oral toxicity potential; it is structurally close related to X11719474)	The risk to aquatic organisms was assessed as low

(a): Only the Châteaudun scenario for fruiting vegetables, May applications, had concentrations > 0.75µg/L.

6.3. Surface water and sediment

Compound (name and/or code)	Ecotoxicology
sulfoxaflor	The risk to aquatic organisms was assessed as low
X11719474	The risk to aquatic organisms was assessed as low
X11519540	The risk to aquatic organisms was assessed as low

6.4. Air

Compound (name and/or code)	Toxicology
sulfoxaflor	Not acutely toxic via inhalation

7. Data gaps

This is a list of data gaps identified during the peer review process, including those areas where a study may have been made available during the peer review process but not considered for procedural reasons (without prejudice to the provisions of Article 56 of the Regulation concerning information on potentially harmful effects).

7.1. Data gaps identified for the representative uses evaluated

- A search of the scientific peer-reviewed open literature on the active substance and its relevant metabolites, dealing with side-effects on health, the environment and non-target species and published within the last 10 years before the date of submission of dossier, to be conducted and reported in accordance with the Guidance of EFSA on the submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 (EFSA, 2011; relevant for all representative uses evaluated; a report has been provided by the applicant but a transparent evaluation of it was not provided by the RMS).

- New batch analysis data after stabilisation of the production, to confirm the specification (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown, see Section 1)

- Shelf life study for the representative formulation GF-2626 (relevant for the representative uses evaluated on fruiting vegetables; submission date proposed by the applicant: unknown, study completed, report not yet submitted, see section 1).

- The genotoxic potential of the impurity B2 has to be investigated properly (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 2).

- Information to further address the long-term dietary risk to wild mammals (relevant for the representative field uses in vegetables and for cotton; submission date proposed by the applicant: unknown; see section 5).

- Information to further address the risk to honey bees for the field uses (relevant for the representative field uses; submission date proposed by the applicant: unknown; see section 5).

7.2. Data gaps identified for the maximum residue level applications

- Evidence of the authorisations granted in Australia and New Zealand for all applied for import tolerances and details concerning authorised GAPs and MRL published at national level should be provided (relevant for all import tolerances requested for Australia/New Zealand, submission date proposed by the applicant: unknown; see section 3.2).

- Additional trials on citrus, stone fruits (cherry, plum), tomato, pepper, broccoli, cauliflower, head cabbage and spinach, conducted according to the Australian/New Zealand GAPs are required to derive import tolerances (relevant for the import tolerances requested for Australia/New Zealand, submission date proposed by the applicant: unknown; see section 3.2).

- Trials conducted according to the GAPs effectively authorised in the USA, are required to derive import tolerances on citrus, pome fruits, stone fruits (cherry, peach, plum), table/wine grape, carrot, sugar beet, melon, cucumber, head cabbage wheat, barley, pulses and oilseed (cotton, rape) (relevant for the import tolerances requested for the USA, submission date proposed by the applicant: unknown; see section 3.2).

- Sufficient apple processing data are required to establish reliable processing factors for apple processed commodities (relevant for the import tolerance for apples requested for Australia/New Zealand, submission date proposed by the applicant: unknown; see section 3.2).

8. Particular conditions proposed to be taken into account to manage the risk(s) identified

8.1. Particular conditions proposed for the representative uses evaluated

No particular conditions are proposed for the representative uses evaluated.

8.2. Particular conditions proposed for the maximum residue level applications

No particular conditions are proposed for the MRL applications.

9. Concerns

9.1. Concerns for the representative uses evaluated

9.1.1. Issues that could not be finalised

An issue is listed as an issue that could not be finalised where there is not enough information available to perform an assessment, even at the lowest tier level, for the representative uses in line with the Uniform Principles in accordance with Article 29(6) of the Regulation and as set out in Commission Regulation (EU) No 546/2011[9] and where the issue is of such importance that it could, when finalised, become a concern (which would also be listed as a critical area of concern if it is of relevance to all representative uses).

An issue is also listed as an issue that could not be finalised where the available information is considered insufficient to conclude on whether the active substance can be expected to meet the approval criteria provided for in Article 4 of the Regulation.

No issues that could not be finalised were identified.

9.1.2. Critical areas of concern

An issue is listed as a critical area of concern where there is enough information available to perform an assessment for the representative uses in line with the Uniform Principles in accordance with Article 29(6) of the Regulation and as set out in Commission Regulation (EU) No 546/2011, and where this assessment does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern where the assessment at a higher tier level could not be finalised due to a lack of information, and where the assessment performed at the lower tier level does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern where in the light of current scientific and technical knowledge using guidance documents available at the time of application the active substance is not expected to meet the approval criteria provided for in Article 4 of the Regulation.

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

No critical areas of concern were identified.

9.1.3. Overview of the concerns identified for each representative use considered

(If a particular condition proposed to be taken into account to manage an identified risk, as listed in section 8, has been evaluated as being effective, then 'risk identified' is not indicated in this table.)

Representative use		**Cherry tomato, pepper, aubergine** Field	**Cherry tomato, pepper, aubergine** Glasshouse	**Cucumber, water melon, courgette** Field	**Cucumber, water melon, courgette** Glasshouse	**Wheat, rye, barley, oats, triticale** Spring	**Wheat, rye, barley, oats, triticale** Winter	**Cotton**
Operator risk	Risk identified							
	Assessment not finalised							
Worker risk	Risk identified							
	Assessment not finalised							
Bystander risk	Risk identified							
	Assessment not finalised							
Consumer risk	Risk identified							
	Assessment not finalised							
Risk to wild non target terrestrial vertebrates	Risk identified	X		X				X
	Assessment not finalised							
Risk to wild non target terrestrial organisms other than vertebrates	Risk identified	X		X		X	X	X
	Assessment not finalised							
Risk to aquatic organisms	Risk identified							
	Assessment not finalised							
Groundwater exposure active substance	Legal parametric value breached							
	Assessment not finalised							
Groundwater exposure metabolites	Legal parametric value breached							
	Parametric value of 10µg/L[(a)] breached							
	Assessment not finalised							
Comments/Remarks								

The superscript numbers in this table relate to the numbered points indicated in Sections 9.1 and 9.2. Where there is no superscript number see Section 5 for further information.

(a): Value for non relevant metabolites prescribed in SANCO/221/2000-rev 10-final, European Commission, 2003.

9.2. Issues related to the maximum residue level applications

9.2.1. Issues not finalised under the maximum residue level applications

- Import tolerances for the USA could not be proposed for most of the applied for uses since most of the submitted trials were not conducted according to the GAPs effectively authorised within the USA applying the criteria laid down in European Guidance documents in the document 1607/VI/97 rev.2 (European Commission, 1999) and the EC guideline document on MRL setting (European Commission, 2011)

- Import tolerances for Australia/New Zealand could not be proposed for some of the applied for uses as a sufficient number of trials conducted according to the supported GAPs has not been submitted. Moreover evidence provided by the applicant of the authorisations in Australia and New Zealand is missing.

9.2.2. Consumer risk identified under the maximum residue level applications

No concerns relating to consumer risk were identified under the maximum residue level applications.

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APPENDICES

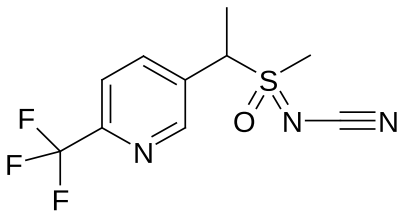
APPENDIX A – LIST OF END POINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

Identity, Physical and Chemical Properties, Details of Uses, Further Information

Active substance (ISO Common Name) ‡	Sulfoxaflor
Function (*e.g.* fungicide)	Insecticide

Rapporteur Member State	Ireland (MRL/Import tolerance proposal, CLH, Residues data, Toxicology & Metabolism, Coordination)
Co-rapporteur Member State	France (Identity, Application data, Phys.Chem, Methods of Analysis & Efficacy) Czech Republic (Eco-tox) Poland (E-Fate & Behaviour)

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	[methyl(oxo){1-[6-(trifluoromethyl)-3-pyridyl]ethyl}-λ^6-sulfanylidene]cyanamide
Chemical name (CA) ‡	*N*-[methyloxido[1-[6-(trifluoromethyl)-3-pyridinyl]ethyl]-λ^4-sulfanylidene]cyanamide
CIPAC No ‡	820
CAS No ‡	946578-00-3
EC No (EINECS or ELINCS) ‡	Not available
FAO Specification (including year of publication) ‡	No FAO specification available
Minimum purity of the active substance as manufactured ‡	950g/kg The ratio of diastereoisomers 1 and 2 is typically in the range of 40:60 to 60:40, but can vary due to epimerisation.
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	There are no impurities which are considered to be of toxicological, ecotoxicological and/or environmental concern.
Molecular formula ‡	$C_{10}\ H_{10}\ F_3\ N_3\ O\ S$
Molar mass ‡	277.3 g/mol
Structural formula ‡	

Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	112 °C (99.7 %)
Boiling point (state purity) ‡	No boiling point before decomposition
Temperature of decomposition (state purity)	167.7 °C (99.7 %)
Appearance (state purity) ‡	White powder with sharp odour (99.7 %)
	Off-white powder with a sharp odour (95.6 %)
Vapour pressure (state temperature, state purity) ‡	1.4 10^{-6} Pa (20 °C, 99.7 %)
Henry's law constant ‡	At 20°C: Unbufferred: 5.77 10^{-7} Pa.m^3/mol pH 5: 2.81 10^{-7} Pa.m^3/mol pH 7: 6.83 10^{-7} Pa.m^3/mol pH 9: 7.05 10^{-7} Pa.m^3/mol
Solubility in water (state temperature, state purity and pH) ‡	At 20°C (99.7 %): pH 5: 1380 mg/L pH 7: 568 mg/L pH 9: 551 mg/L Purified water: 6703 mg/L
Solubility in organic solvents ‡ (state temperature, state purity)	At 20°C (95.6 %) heptane: 0.242 mg/L xylene: 0.743 g/L 1,2-dichloro ethane: 39.6 g/L methanol: 93.1 g/L acetone: 217 g/L ethyl acetate: 95.2 g/L octanol: 1.66 g/L
Surface tension ‡ (state concentration and temperature, state purity)	57.5 mN/m (90 % saturated solution, 20°C, 95.6 %)
Partition co-efficient ‡ (state temperature, pH and purity)	At 20°C (99.7%) pH 5: Log Pow= 0.806 pH 7: Log Pow= 0.802 pH 9: Log Pow= 0.799
Dissociation constant (state purity) ‡	Not determinable (99.7%) Sulfoxaflor has no measurable ionisation constant within environmental relevant pH ranges (pH 2 to 10).
UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	At 25°C (99.7%) Neutral: λ_{max} 192, 211 and 260 nm ε ($M^{-1} \times cm^{-1}$): 10200, 8000, 3100 Acidic: λ_{max} 210 and 260 nm ε ($M^{-1} \times cm^{-1}$): 7800, 3100 Basic: λ_{max} 218 and 260 nm ε ($M^{-1} \times cm^{-1}$): 5900, 3100 No absorption peak after 290 nm

Flammability ‡ (state purity)	Not flammable (95.6 %)
Explosive properties ‡ (state purity)	Not explosive (95.6 %)
Oxidising properties ‡ (state purity)	Not oxidising (95.6 %)

Summary of representative uses evaluated, for which this conclusion covers all human and environmental risks

Crop and/or situation	Member State or Country	Product Name	F G or I	Pests or Group of pests controlled	Formulation		Application				Application rate per treatment			PHI (days)	Remarks
					Type	Conc. of a.s.	Method Kind	Growth stage & season	Number min max	Interval between apps. (min)	kg a.s./hL min max	water (L/ha) min max	kg a.s. /ha min max		
(a)			(b)	(c)	(d-f)	(i)	(f-h)	(j)	(k)					(l)	(m)
Fruiting vegetable – Tomato, Cherry tomato	EU	GF-2626	F	Aphids	SC	120 g/L	Broadcast foliar	BBCH 20 – 39 BBCH 40 - 89 Apr - Nov	1	N/A	0.0048 – 0.0016	500 - 1500	0.024	≥1	
Fruiting vegetable - Tomato, Cherry tomato	EU	GF-2626	G	Aphids	SC	120 g/L	Broadcast foliar	BBCH 20 – 39 BBCH 40 - 89 through the year	1	N/A	0.0048 – 0.0016	500 - 1500	0.024	≥1	
Fruiting vegetable - Pepper (Bell and non Bell)	EU	GF-2626	F	Aphids	SC	120 g/L	Broadcast foliar	BBCH 20 – 39 BBCH 40 - 89 Apr - Nov	1	N/A	0.0048 – 0.0016	500 - 1500	0.024	≥1	
Fruiting vegetable - Pepper (Bell and non Bell)	EU	GF-2626	G	Aphids	SC	120 g/L	Broadcast foliar	BBCH 20 – 39 BBCH 40 - 89 through the year	1	N/A	0.0048 – 0.0016	500 - 1500	0.024	≥1	

Crop and/or situation	Member State or Country	Product Name	F G or	Pests or Group of pests controlled	Formulation		Application				Application rate per treatment			PHI (days)	Remarks
			I		Type	Conc. of a.s.	Method Kind	Growth stage & season	Number min max	Interval between apps. (min)	kg a.s./hL min max	water (L/ha) min max	kg a.s. /ha min max		
(a)			(b)	(c)	(d-f)	(i)	(f-h)	(j)	(k)					(l)	(m)
Fruiting vegetable - Aubergine	EU	GF-2626	F	Aphids	SC	120 g/L	Broadcast foliar	BBCH 20 – 39 BBCH 40 - 89 Apr - Nov	1	N/A	0.0048 – 0.0016	500 - 1500	0.024	≥1	
Fruiting vegetable - Aubergine	EU	GF-2626	G	Aphids	SC	120 g/L	Broadcast foliar	BBCH 20 – 39 BBCH 40 - 89 through the year	1	N/A	0.0048 – 0.0016	500 - 1500	0.024	≥1	
Cucurbit - Cucumber	EU	GF-2626	F	Aphids	SC	120 g/L	Broadcast foliar	BBCH 20 – 39 BBCH 40 - 89 Apr - Nov	1	N/A	0.0048 – 0.0016	500 - 1500	0.024	≥1	
Cucurbit - Cucumber	EU	GF-2626	G	Aphids	SC	120 g/L	Broadcast foliar	BBCH 20 – 39 BBCH 40 - 89 through the year	1	N/A	0.0048 – 0.0016	500 - 1500	0.024	≥1	
Cucurbit – Melon, Water melon	EU	GF-2626	F	Aphids	SC	120 g/L	Broadcast foliar	BBCH 20 – 39 BBCH 40 - 89 Apr - Nov	1	N/A	0.0048 – 0.0016	500 - 1500	0.024	≥1	

Crop and/or situation	Member State or Country	Product Name	F G or	Pests or Group of pests controlled	Formulation		Application				Application rate per treatment			PHI (days)	Remarks
(a)			I (b)	(c)	Type (d-f)	Conc. of a.s. (i)	Method Kind (f-h)	Growth stage & season (j)	Number min max (k)	Interval between apps. (min)	kg a.s./hL min max	water (L/ha) min max	kg a.s. /ha min max	(l)	(m)
Cucurbit – Melon, Water melon	EU	GF-2626	G	Aphids	SC	120 g/L	Broadcast foliar	BBCH 20 – 39 BBCH 40 - 89 through the year	1	N/A	0.0048 – 0.0016	500 - 1500	0.024	≥1	
Cucurbit – Courgette	EU	GF-2626	F	Aphids	SC	120 g/L	Broadcast foliar	BBCH 20 – 39 BBCH 40 - 89 Apr - Nov	1	N/A	0.0048 – 0.0016	500 - 1500	0.024	≥1	
Cucurbit – Courgette	EU	GF-2626	G	Aphids	SC	120 g/L	Broadcast foliar	BBCH 20 – 39 BBCH 40 - 89 through the year	1	N/A	0.0048 – 0.0016	500 - 1500	0.024	≥1	
Cereals – Wheat (spring and winter)	EU	GF-2372	F	Aphids	WG	500 g/kg	Broadcast foliar	BBCH 40 89 April - July	1	N/A	0.016 – 0.006	150 - 400	0.024	21	
Cereals – Rye (spring and winter)	EU	GF-2372	F	Aphids	WG	500 g/kg	Broadcast foliar	BBCH 40 89 April - July	1	N/A	0.016 – 0.006	150 - 400	0.024	21	
Cereals – Barley (spring and winter)	EU	GF-2372	F	Aphids	WG	500 g/kg	Broadcast foliar	BBCH 40 89 April - July	1	N/A	0.016 – 0.006	150 - 400	0.024	21	

Crop and/or situation	Member State or Country	Product Name	F G or	Pests or Group of pests controlled	Formulation		Application				Application rate per treatment			PHI (days)	Remarks
(a)			I (b)	(c)	Type (d-f)	Conc. of a.s. (i)	Method Kind (f-h)	Growth stage & season (j)	Number min max (k)	Interval between apps. (min)	kg a.s./hL min max	water (L/ha) min max	kg a.s. /ha min max	(l)	(m)
Cereals – Oats (spring and winter)	EU	GF-2372	F	Aphids	WG	500 g/kg	Broadcast foliar	BBCH 40 89 April - July	1	N/A	0.016 – 0.006	150 - 400	0.024	21	
Cereals – Triticale (spring and winter)	EU	GF-2372	F	Aphids	WG	500 g/kg	Broadcast foliar	BBCH 40 89 April - July	1	N/A	0.016 – 0.006	150 - 400	0.024	21	
Cotton	EU	GF-2372	F	Aphids	WG	500 g/kg	Broadcast foliar	BBCH 20 – 39 BBCH 40 - 89 May - Sept	1	N/A	0.006 – 0.004	400 - 600	0.024	14	

Remarks:		
	(a) For crops the EU and Codex classifications (both) should be used. (b) Outdoor or field use (F), glasshouse application (G) or indoor application (I) (c) e.g. biting and sucking insects, soil borne insects, foliar fungi, weeds (d) e.g. wettable powder (WP),emulsifiable concentrate (EC), granule (GR) (e) GIFAP Codes - GIFAP Technical Monograph No. 2, 1989 (f) All abbreviations must be explained	(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants (i) g/kg or g/l (j) Growth stage at last treatment, including where relevant information on season at time of application (k) The minimum and maximum number of applications possible under practical conditions must be given (l) PHI - Pre-harvest interval (m) Remarks may include: Extent of use/ economic importance/restrictions (e.g. feeding/grazing)/minimal intervals between applications. Indicate uses not yet authorised.

Summary of intended uses for which MRL applications have been made in addition to the representative uses above

Important note: for these uses, only the risk for consumers associated to the presence of residues in crops has been assessed; environmental risk and risk to humans by other exposure routes have not been assessed.

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc. a.s. (i)	method kind (f-h)	range of growth stages & season (j)	number min-max (k)	Interval between application (min)	kg a.s /hL min-max (l)	Water L/ha min-max	kg a.s./ha min-max (l)		
MRL Application (according to Article 8.1(g) of Regulation (EC) No 1107/2009)															
Citrus	AU	Transform SC	F	Citrophilous Mealybug, Citrus Mealybug, Long Tailed Mealybug, Pink Wax Scale, Citricola Scale, Citrus Snow Scale, Red Scale, Kelly's Citrus Thrips	SC	240 g/L	Ground applied foliar spray	Up to BBCH 89	1-2	14	0.0096	To run-off	0.192	1	If honeybees are present in the target area during flowering see the Protection of Livestock directions.
Citrus	USA	Closer SC	F	Citrus thrips Florida red scale; Suppression only: California red scale, citricola scale	SC	240 g/L	Aerial & ground applied foliar spray	Up to BBCH 89; Only 1 Application During Bloom	1-3	14		1000-4000 ground; 35-100 air	0.1	1	Max. annual rate 0.3 kg a.i./ha
Tree nuts	USA	Closer SC	F	San Jose scale (suppressin)	SC	240 g/L	Aerial & ground applied foliar spray	Pre-bloom to mature fruit	1-3	7		1000-4000 ground; 35-100 air	0.1	7	Max. annual rate 0.3 kg a.i./ha Do not apply anytime between 3 days prior to bloom and petal fall
Tree nuts	CAN	Closer SC		San Jose scale	SC	240 g/L	Ground applied foliar spray	Pre-bloom to mature fruit	1-2	7		min.100	0.048-0.096	7	Do not apply during crop flowering or when flowering weeds are present
Pome fruit	AU	Transform SC	F	Long Tailed Mealybug,	SC	240 g/L	Ground applied	Up to BBCH 85-87	1-2	14	0.0096	Up to 2000	0.192	7	If honeybees are present in the target area during

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc. a.s. (i)	method kind (f-h)	range of growth stages & season (j)	number min-max (k)	Interval between application (min)	kg a.s /hL min-max (l)	Water L/ha min-max	kg a.s./ha min-max (l)		
				Tuber Mealybug, Wooly Apple Aphid			foliar spray								flowering see the Protection of Livestock directions.
Pome fruit	USA	Closer SC	F	Pear psylla (suppression only) San Jose scale (suppression)	SC	240 g/L	Aerial & ground applied foliar spray	Up to BBCH 85-87	1-3	7		1000-4000 ground; 35-100 air	0.1	7	Max. annual rate 0.3 kg a.i./ha Do not apply anytime between 3 days prior to bloom and petal fall
Pome Fruit	CAN	Closer SC	F	San Jose scale	SC	240 g/L	Ground applied foliar spray	Up to BBCH 85-87	1-2	7		min.100	0.048-0.096	7	Do not apply during crop flowering or when flowering weeds are present
Stone fruit	USA	Closer SC	F	San Jose scale (suppression)	SC	240 g/L	Aerial & ground applied foliar spray	Up to BBCH 85-87	1-3	7		1000-4000 ground; 35-100 air	0.1	7	Max. annual rate 0.3 kg a.i./ha Do not apply anytime between 3 days prior to bloom and petal fall
Stone Fruits	CAN	Closer SC	F	San Jose scale	SC	240 g/L	Ground applied foliar spray	Up to BBCH 85-87	1-2	7		min.100	0.048-0.096	7	Do not apply during crop flowering or when flowering weeds are present
Stone fruit	AU	Transform SC	F	Apple Dimpling Bug	SC	240 g/L	Ground applied foliar spray	Up to BBCH 85-87	1-2	14	0.0072	Up to 2000	0.144	7	If honeybees are present in the target area during flowering see the Protection of Livestock directions.
Table grape	AU	Transform SC	F	Long Tailed Mealybug	SC	240 g/L	Ground applied foliar spray	Up to BBCH 87-89	1-4	14	0.0072-0.0096	Up to 1000	0.096	7	
Table Grape	USA	Closer SC	F	Thrips (suppression)	SC	240 g/L	Aerial & ground applied foliar spray	Up to BBCH 87-89	1-3	7		200-500 ground, 35-100 air	0.1	7	Max. annual rate 0.3 kg a.i./ha Do not apply anytime between 3 days prior to bloom and petal fall

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc. a.s. (i)	method kind (f-h)	range of growth stages & season (j)	number min-max (k)	Interval between application (min)	kg a.s /hL min-max (l)	Water L/ha min-max	kg a.s./ha min-max (l)		
Table Grape	CAN	Closer SC	F	Leafhoppers (suppression only)	SC	240 g/L	Ground applied foliar spray	Up to BBCH 87-89	1-2	7		min100	0.048-0.096	7	Do not apply during crop flowering or when flowering weeds are present
Wine grape	AU	Transform SC	F	Long Tailed Mealybug	SC	240 g/L	Ground applied foliar spray	Up to BBCH68	1-2	14	0.0072	Up to 1000	0.072	n/a	
Wine Grape	USA	Closer SC	F	Thrips (suppression)	SC	240 g/L	Aerial & ground applied foliar spray	Up to BBCH 87-89	1-3	7		200-500 ground, 35-100 air	0.1	7	Max. annual rate 0.3 kg a.i./ha Do not apply anytime between 3 days prior to bloom and petal fall
Wine Grape	CAN	Closer SC	F	Leafhoppers (suppression only)	SC	240 g/L	Ground applied foliar spray	Up to BBCH 87-89	1-2	7		min100	0.048-0.096	7	Do not apply during crop flowering or when flowering weeds are present
Straw-berry	USA	Closer SC	F	Thrips (suppression)	SC	240 g/L	Aerial & ground applied foliar spray	During Bloom to fruit maturity	1-4	7		200-500 ground, 35-100 air	0.1	1	Max. annual rate 0.3 kg a.i./ha
Carrot, Sugarbeet	CAN	Closer SC	F	Aphids	SC	240 g/L	Aerial & ground applied foliar spray		1-2	7		min 500 ground, min 30 air	0.012-0.036	7	Do not apply during crop flowering or when flowering weeds are present
Carrot, Sugar beet	USA	Transform	F	Silverleaf whitefly, sweetpotato whitefly	WG	500 g/kg	Aerial & ground applied foliar spray		1-4	7		200-500 ground, 35-100 air	0.071-0.096	7	Max. annual rate 0.3 kg a.i./ha Do not apply anytime between 3 days prior to bloom and petal fall
Potato	CAN	Closer SC	F	Aphids	SC	240 g/L	Aerial & ground applied		1-2	7		min 500 ground, min 30 air	0.012-0.036	7	

Crop and/or situation (a)	**Member State or Country**	**Product name**	**F G or I** (b)	**Pests or Group of pests controlled** (c)	**Preparation**		**Application**				**Application rate per treatment**			**PHI (days)** (m)	**Remarks**
					Type (d-f)	Conc. a.s. (i)	method kind (f-h)	range of growth stages & season (j)	number min-max (k)	Interval between application (min)	kg a.s /hL min-max (l)	Water L/ha min-max	kg a.s./ha min-max (l)		
							foliar spray								
Potato	USA	Transform	F	Potato psyllid, Silverleaf whitefly, sweetpotato whitefly	WG	500 g/kg	Aerial & ground applied foliar spray		1-4	14			0.071-0.080	7	Max. annual rate 0.3 kg a.i./ha Applications During Bloom
Carrot, Sugarbeet, Potato	AU	Transform SC	F	Green peach aphid	SC	240 g/L	Aerial & ground applied foliar spray		1-4	7		min250 ground, min 30 air	0.048 - 0.072	3	
Solanaceae **Fruiting vegetables**	AU	Transform SC	F /I	Greenhouse whitefly	SC	240 g/L	Aerial & ground applied foliar spray	Up to BBCH89	1-4	7		min250 ground, min 30 air	0.096	1	
Solanaceae **Fruiting vegetables**	USA	Closer SC	F	Greenhouse Whitefly (Outdoors), Silverleaf Whitefly, Sweetpotato Whitefly, Thrips (suppression)	SC	240 g/L	Aerial & ground applied foliar spray	Up to BBCH89	1-4	7		200-500 ground; 35-100 air	0.074 – 0.078	1	Max. annual rate 0.3 kg a.i./ha Applications During Bloom
Cucurbits (pumpkin, squash, melons, cucumber)	AU	Transform SC	F	Greenhouse whitefly	SC	240 g/L	Aerial & ground applied foliar spray	Up to BBCH89	1-4	7		min250 ground, min 30 air	0.096	1	If honeybees are present in the target area during flowering see the Protection of Livestock directions.
Cucurbits	USA	Closer SC	F	silverleaf whitefly sweetpotato whitefly thrips	SC	240 g/L	Aerial & ground applied foliar	Up to BBCH89	1-4	7		200-500 ground; 35-100 air	0.074 – 0.078	1	Max. annual rate 0.3 kg a.i./ha Applications During Bloom

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc. a.s. (i)	method kind (f-h)	range of growth stages & season (j)	number min-max (k)	Interval between application (min)	kg a.s /hL min-max (l)	Water L/ha min-max	kg a.s./ha min-max (l)		
				(suppression only)			spray								
Brassica Vegetables	CAN	Closer SC	F	Aphids	SC	240 g/L	Ground applied foliar spray	Up to BBCH 49	1-2	7		min 500	0.024 – 0.036	3	Do not apply during crop flowering or when flowering weeds are present
Brassica Vegetables	USA	Closer SC	F	thrips (suppression only)	SC	240 g/L	Aerial & ground applied foliar spray	Up to BBCH 49	1-3	7		200-500 ground; 35-100 air	0.1	3	Max. annual rate 0.3 kg a.i./ha Do not apply anytime between 3 days prior to bloom and petal fall
Brassica Vegetables	AU	Transform SC	F	Greenhouse whitefly	SC	240 g/L	Aerial & ground applied foliar spray	Up to BBCH 49	1-4	7		min250 ground, min 30 air	0.096	3	
Leafy Vegetables	CAN	Closer SC	F	Aphids	SC	240 g/L	Ground applied foliar spray	Up to BBCH 49	1-2	7		min 500	0.024 – 0.036	3	Do not apply during crop flowering or when flowering weeds are present
Leafy vegetables	AU	Transform SC	F /I	Greenhouse whitefly	SC	240 g/L	Aerial & ground applied foliar spray	Up to BBCH 49	1-4	7		min250 ground, min 30 air	0.096	3	
Leafy Vegetables	USA	Closer SC	F	Thrips (suppression)	SC	240 g/L	Aerial & ground applied foliar spray	Up to BBCH 49	1-3	7		200-500 ground; 35-100 air	0.1	3	Max. annual rate 0.3 kg a.i./ha Do not apply anytime between 3 days prior to bloom and petal fall
Succulent, podded and dry beans	USA	Transform	F	Suppression only – brown stink bug, southern green stink bug	WG	500 g/kg	Aerial & ground applied foliar spray		1-4	14		200-500 ground; 35-100 air	0.071-0.080	7	Max. annual rate 0.3 kg a.i./ha Applications During Bloom

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc. a.s. (i)	method kind (f-h)	range of growth stages & season (j)	number min-max (k)	Interval between application (min)	kg a.s /hL min-max (l)	Water L/ha min-max	kg a.s./ha min-max (l)		
Barley, Wheat	CAN	Transform	F	Russian wheat aphid	WG	500 g/kg	Aerial & ground applied foliar spray	Up to BBCH 87/89	1-2	14		min100 ground min 30 air	0.025-0.050	14	PHI of 14 d grain, straw PHI of 7 d forage, fodder, hay. Do not apply during crop flowering or when flowering weeds are present
Wheat, Barley, Triticale	USA	Transform	F	Greenbug	WG	500 g/kg	Aerial & ground applied foliar spray	Up to BBCH 87/89	1-2	14		200-500 ground; 35-100 air	0.026	14	PHI of 7 d in case of grazing, forage, fodder, hay harvest. Max. annual rate 0.3 kg a.i./ha; Do not apply anytime between 3 days prior to bloom and petal fall
Wheat, Barley, Triticale	AU	Transform	F	Aphids (including Oat aphid and Corn Aphid as vectors of Barley Yellow Dwarf Virus), Grain aphid, Rose grain aphid and Green peach aphid	SC	240 g/L	Aerial & ground applied foliar spray	Up to BBCH 39	1-2	14-21		min 50 ground, min 30 air	0.0125-0.025	n/a	
Oilseed Rape	CAN	Transform	F	Aphid	WG	500 g/kg	Aerial & ground applied foliar spray	Up to BBCH 87/89	1-2	14		min100 ground min 30 air	0.050	14	Do not apply during crop flowering or when flowering weeds are present
Oilseed Rape	USA	Transform	F	Aphids	WG	500 g/kg	Aerial & ground applied foliar spray	Up to BBCH 87/89	1-2	14		200-500 ground; 35-100 air	0.026	14	Max. annual rate 0.05 kg a.i./ha. Do not apply anytime between 3 days prior to bloom and petal fall;
Oilseed	AU	Transfo	F	Aphids (including	SC	240	Aerial	BBCH 65	1-2	14		min 50	0.025-	n/a	If honeybees are present

Crop and/or situation (a)	**Member State or Country**	**Product name**	**F G or I** (b)	**Pests or Group of pests controlled** (c)	**Preparation**		**Application**				**Application rate per treatment**			**PHI (days)** (m)	**Remarks**
					Type (d-f)	Conc. a.s. (i)	method kind (f-h)	range of growth stages & season (j)	number min-max (k)	Interval between application (min)	kg a.s /hL min-max (l)	Water L/ha min-max	kg a.s./ha min-max (l)		
Rape		rm		cabbage aphid, green peach aphid and turnip aphid)		g/L	& ground applied foliar spray					ground, min 30 air	0.050		in the target area during flowering see the Protection of Livestock directions. Do not apply 1st app. in full flowering, 2nd app. must be no later than 14days post flowering. DO NOT use on canola grown as a forage crop and dual-use canola prior to grazing.
Cotton	AU	Transform SC	F	Greenhouse whitefly	SC	240 g/L	Aerial & ground applied foliar spray		1-4	14-21		min 50 ground, min 30 air	0.096	14	If honeybees are present in the target area during flowering see the Protection of Livestock directions.
Cotton	USA	Transform	F	Sweetpotato whitefly, silverleaf whitefly; Suppression only – brown stink bug, southern green stink bug, thrips	WG	500 g/kg	Aerial & ground applied foliar spray		1-4	5		50-200 ground; 35-100 air	0.071 – 0.080	14	Max. annual rate 0.3 kg a.i./ha Applications During Bloom
Soya bean	USA	Transform	F	Suppression only – brown stink bug, southern green stink bug	WG	500 g/kg	Aerial & ground applied foliar spray		1-4	14		200-500 ground; 35-100 air	0.071-0.080	7	Max. annual rate 0.3 kg a.i./ha Applications During Bloom Max 2 appl. to forage
Soya bean	AU	Transform SC	F	Greenhouse whitefly	SC	240 g/L	Aerial & ground applied foliar spray		1-4	14-21		min 50 ground, min 30 air	0.096	14	

Remarks:	(a) For crops the EU and Codex classifications (both) should be used. (b) Outdoor or field use (F), glasshouse application (G) or indoor application (I) (c) e.g. biting and sucking insects, soil borne insects, foliar fungi, weeds (d) e.g. wettable powder (WP),emulsifiable concentrate (EC), granule (GR) (e) GIFAP Codes - GIFAP Technical Monograph No. 2, 1989 (f) All abbreviations must be explained	(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants (i) g/kg or g/l (j) Growth stage at last treatment, including where relevant information on season at time of application (k) The minimum and maximum number of applications possible under practical conditions must be given (l) PHI - Pre-harvest interval (m) Remarks may include: Extent of use/ economic importance/restrictions (e.g. feeding/grazing)/minimal intervals between applications. Indicate uses not yet authorised.

Further information, Efficacy

Effectiveness (Regulation (EU) N° 284/2013, Annex Part A, point 6.2)

	Numerous efficacy trials conducted on solanacea, cucurbits, cereals and cotton with a single application at 6, 12 and 24 g/ha on different aphid species (*Aphis gossypii*, *Myzus persicae*, *Sitobion avenae*, *Metopolophium dirhodum* and *Rhopalosiphum padi*), show the dose of 24 g/ha to be at least equivalent to the reference compounds. Lower knock down effects and efficacy were observed at lower dose rates of 6 and 12 g/ha.

Adverse effects on field crops (Regulation (EU) N° 284/2013, Annex Part A, point 6.4)

	No phytotoxicity or adverse effects on the crops investigated (curcubits, solanace, cerials and cotton) were observed in the residue trials conducted up to 48 or 75 g a.s./ha (no negative impact on plant aspect and taste of the food commodities)

Observations on other undesirable or unintended side-effects (Regulation (EU) N° 284/2013, Annex Part A, point 6.5)

	No cross resistance with other classes of insecticides, including neonicotinoids. Resistance risk management is to recommend a single application per season.

Groundwater metabolites: Screening for biological activity (SANCO/221/2000-rev.10-final Step 3 a Stage 1)

	X11719474	X11519540	X11519540
Activity against target organism	No insecticidal or herbicidal activity	No insecticidal or herbicidal activity	No insecticidal or herbicidal activity

Methods of Analysis

Analytical methods for the active substance (Annex IIA, point 4.1)

Technical as (analytical technique)	LC-UV (260 nm) - Validated
Impurities in technical as (analytical technique)	LC-UV (260 nm) - Validated
Plant protection product (analytical technique)	LC-UV (260 nm) - Validated

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin	Sulfoxaflor
Food of animal origin	Sulfoxaflor
Soil	Sulfoxaflor and metabolite X11719474
Water surface	Sulfoxaflor and metabolite X11719474

drinking/ground	Sulfoxaflor and metabolite X11719474
Air	Sulfoxaflor

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	HPLC-MS/MS – validated LOQ = 0.01 mg/kg for sulfoxaflor in four groups of plants ILV available –DFG S19 applicable
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	HPLC-MS/MS – validated LOQ = 0.01 mg/kg for sulfoxaflor in meat, fat, liver, kidney, milk, eggs and cream ILV available – DFG S19 applicable
Soil (analytical technique and LOQ)	HPLC-MS/MS – validated LOQ = 0.001 mg/kg for sulfoxaflor and its metabolite X11719474 individually in soil ILV available
Water (analytical technique and LOQ)	HPLC-MS/MS – validated LOQ = 0.05 µg/L for sulfoxaflor and its metabolite X11719474 individually in water (surface, ground and drinking) ILV available
Air (analytical technique and LOQ)	HPLC-MS/MS – validated LOQ = 0.3 $\mu g/m^3$ for sulfoxaflor in air
Body fluids and tissues (analytical technique and LOQ)	HPLC-MS/MS – Validated LOQ = 0.05 mg/L for sulfoxaflor in urine and blood Method not required

Classification and proposed labelling with regard to physical and chemical data (Annex IIA, point 10)

	RMS/peer review proposal
Active substance	No classification proposed

Toxicology
Impact on Human and Animal Health

Absorption, distribution, excretion and metabolism (toxicokinetics) (Annex IIA, point 5.1)

Rate and extent of oral absorption ‡	Absorption was > 95%. Orally administered sulfoxaflor was rapidly absorbed without any apparent lag time based on Cmax times of 0.5 - 1 hr (5 mg/kg) and 2 hr (100 mg/kg).
Distribution ‡	Widely distributed.
Potential for accumulation ‡	Very low potential for accumulation, ≤ 1% of the dose remaining in tissues 7 days after a single oral / i.v. or repeated (15-daily doses) oral dosing regime.
Rate and extent of excretion ‡	Rapid and extensive excretion observed via urine (77-90%) within 24 hours, independent of dose. In total, 86 – 99% of the dose is eliminated within 24 hours.
Metabolism in animals ‡	Sulfoxaflor was poorly metabolised. More than 93% of the eliminated radioactivity in urine and faeces was parent sulfoxaflor. Only one metabolite exceeded 1.0%, a urinary glucuronide conjugate of the sulfoxaflor metabolite X11721061, which accounted for 2 – 4% of the administered dose.
Toxicologically relevant compounds ‡ (animals and plants)	Parent
Toxicologically relevant compounds ‡ (environment)	Parent

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	1000 mg/kg bw	Acute Tox. 4; H302 [Xn; R22]
Rat LD_{50} dermal ‡	> 5000 mg/kg bw	
Rat LC_{50} inhalation ‡	> 2.09 mg/l	
Skin irritation ‡	Not a skin irritant.	
Eye irritation ‡	Not an eye irritant.	
Skin sensitisation ‡	Not a skin sensitiser (LLNA)	

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Rat/Mouse: Liver (increased weight with histopathology including evidence of toxicity)	
Relevant oral NOAEL ‡	100 ppm (6.36 mg/kg bw per day): Rat 90-day dietary.	

Relevant dermal NOAEL ‡	1000 mg/kg bw per day: Rat 28-day.	
Relevant inhalation NOAEL ‡	NA	

Genotoxicity ‡ (Annex IIA, point 5.4)

	No genotoxic potential	

Long term toxicity and carcinogenicity (Annex IIA, point 5.5)

Target/critical effect ‡	Rat 12 month interim sacrifice: Liver (increased blood cholesterol, liver weight, hypertrophy, fatty change, single cell necrosis and macrophages). Rats: Increased testes weight, atrophy of seminiferous tubules, reduced sperm in epididymides and secretory material in accessory sex glands. Mouse: Increased liver weight, hypertrophy with eosinophilia, fatty change, single cell necrosis, eosinophilic/ vacuolated foci, mitosis.	
Relevant NOAEL ‡	4.24 mg/kg bw per day based on non-neoplastic liver effects.	
Carcinogenicity ‡	Rat: Liver, Leydig cell tumour load and preputial gland tumours. Mouse: Liver tumours.	

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡	Decreased post natal survival	
Relevant parental NOAEL ‡	100 ppm (6.63 mg/kg bw per day)	
Relevant reproductive NOAEL ‡	100 ppm (6.63 mg/kg bw per day)	
Relevant offspring NOAEL ‡	100 ppm (6.63 mg/kg bw per day)	

Developmental toxicity

Developmental target / critical effect ‡	Rat: Decreased foetal body weight; foetal abnormalities (forelimb flexure, bent clavicle, hindlimb rotation, convoluted/hydro-ureter).	
Relevant maternal NOAEL ‡	150 ppm (11.5 mg/kg bw per day): Rat	
Relevant developmental NOAEL ‡	150 (11.5 mg/kg bw per day): Rat	

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	A NOAEL of 25 mg/kg was selected based on	

	decreased motor activity observed on day one. Other non-specific clinical signs were reported. However, there were no treatment related histopathological findings in the central or peripheral nervous system.	
Repeated neurotoxicity ‡	NOAEL = 7.1 mg/kg bw per day (100 ppm). In the rat 90 day study there was no evidence of neurotoxicity. In the rat developmental neurotoxicity study a slight reduction in postnatal survival, decreased pup body weights, delayed righting reflex, decreased brain weight in males, and altered brain length in males and females were noted at the highest dose (400 ppm). The effects suggested general substance related toxicity rather than specific neurotoxicity.	
Delayed neurotoxicity ‡	Not investigated	

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	
Gene Expression and Cell Proliferation Analyses in X11422208 Exposed Rats and Mice.	Sulfoxaflor-induced gene expression profile in mice and liver (hepatocellular) proliferation in both mice and rats characteristic of CAR activation.
XR-208: Targeted gene expression, cell proliferation and cytochrome P450 enzymatic activity in rats.	Sulfoxaflor-induced liver effects were PB-like and appear to be CAR mediated. Males were affected more than females. Neither AhR nor PPARα were involved.
XDE-208: Mode of Action Study Investigating Liver Weight Effects in Crl:CD-1(ICR) Mice.	Sulfoxaflor -induced liver effects were consistent with CAR activation MoA; males were more sensitive than females. Neither AhR nor PPARα were involved.
XDE-208: A Study to Characterise the Induction Profile of XDE-208 in the Livers of C57BL/6J Mice.	Sulfoxaflor -induced liver effects in C57Bl/6J WT mice were similar to previously observed effects in CD1 mice
A Study to Investigate the Mode of Action for Liver Effects Observed in Regulatory Toxicology Studies by Use of Dual CAR-PXR Knockout and Humanised Mice.	In WT C57BL/6J sulfoxaflor caused the same liver effects as seen in CD1 mice. In PXR/CAR KO mice, sulfoxaflor did not induce any liver changes, demonstrating that activation of one or both of these receptors is required to elicit the liver effects seen in WT mice. In PXR/CAR humanised mice slight liver hypertrophic effects occurred but not hepatocellular proliferation. This study demonstrated that sulfoxaflor, like PB, acts via a CAR-mediated MoA and that mice carrying the human PXR and CAR receptors did not develop hepatocellular proliferation responsible for liver tumour induction. Therefore, sulfoxaflor -induced rodent liver tumours are not relevant to humans.

XDE 208: Leydig Cell Mode-of-Action Study in Crl:CD(SD) and F344/DuCrl Rats.	Support dopamine enhancement MoA for LCT promotion: decreased Prl levels at 4-wks, ~2-fold dose-dependent decreased LHR gene expression at 4-wks, decreased PrlR gene expression at 4-wks.
XDE-208 Technical: Screening for Estrogen Receptor and Androgen Receptor Binding and Transactivation and Aromatase Inhibition.	Negative for ER binding. Negative for ER and AR transactivation assays (agonism and antagonism). Negative for aromatase (CYP19) inhibition.
Effects of sulfoxaflor infusion on hypothalamic dopamine, DOPAC and HVA efflux – a microdialysis experiment in freely moving rats.	Sulfoxaflor (400µM and 2mM) produced concentration related increases in the extracellular level of dopamine in the mediobasal hypothalamus. The results indicate that sulfoxaflor causes a firing dependent increase of dopamine exocytosis from hypothalamic dopaminergic neurones. These data support the hypothesis that through its nAChR partial agonist properties sulfoxaflor increases dopamine efflux from TIDA neurones in the median eminence, and in turn, this effect is predicted to result in a decrease of prolactin secretion from the pituitary gland in the rat.
A Dietary Reproductive Toxicity Cross-Fostering Study	**Dam**: decreased feed consumption decreasedweight gain **Offspring:** Pre-natal exposure caused 100% mortality by PND4
A Study of the Effect of XDE-208 on Neonatal Survival in New Zealand White Rabbits	**Dam:** decreased food consumption/weight gain **Offspring:** No effect
Characterisation of the agonist effects of XDE-208 on mammalian muscle nicotinic acetylcholine receptors	Rat foetal nAChr binding and agonism. Rat adult/Human adult and foetal nAChr binding and non-agonism
Investigation of the critical window of exposure for fetal abnormalities and neonatal survival effects in Crl:CD(SD) rats: Phase 1	**Exposure from GD 6-16:** no adverse effect. **Exposure from GD 16:** birth pup death and skeletal defects. Abnormalities reversed in survivors by PND4.
Investigation of the critical window of exposure for fetal abnormalities and neonatal survival effects in Crl:CD(SD) rats: Phase 2	**Exposure from GD 16-18 and from GD 18-20:** no adverse effect. **Exposure from GD 20-birth:** pup death and skeletal defects. Abnormalities reversed in survivors by PND4.
Observations on the effects of XDE-208 on the phrenic nerve-hemidiaphragm preparation from new-born rat.	Sustained contracture of the isolated rat neonate diaphragm
Histopathological Evaluation Of Foetal Lung Samples From The Developmental Toxicity Study In Crl:Cd(Sd) Rats.	Foetal rat lung normal (rat dev tox study).

Studies performed on metabolites or impurities ‡	
X11719474: Probe Study to Determine Absorption, Metabolism and Elimination in F344/DuCrl Rats.	Administered ^{14}C-X11719474 was rapidly absorbed, un-metabolised and eliminated very quickly from the rat.

XR-208 Urea: Acute Oral Toxicity Screening Study in F344/DuCrl Rats.	Under the conditions of this study, the LD_{50} of X11719474 was greater than 300 mg/kg bw in female F344/DuCrl rats.
Acute Oral Toxicity Study in Rats: Acute Toxic Class Method.	Under the conditions of this study, the LD_{50} of X11719474 was greater than 5000 mg/kg bw in female F344/DuCrl rats.
X11719474: Acute dermal toxicity/skin irritation and eye irritation screening studies.	(1) The dermal LD_{50} of X11719474 was greater than 1000 mg/kg bw in female F344/DuCrl rats. (2) Acute exposure of X11719474 to the rabbit eye caused slight irritation of the conjunctiva that was reversible 24 hours after dosing.
X11719474: "Cut-down"/reduced local lymph node assay in cba/j mice.	Mice treated with 50% X11719474 displayed a stimulation index of 1.3. X11719474 did not demonstrate dermal sensitisation potential in the mouse LLNA.
X11719474: Palatability Probe Study In F344/ DuCrl Rats.	NOAEL: 500 mg/kg/day. decreased palatability; decreased BWG; decreased TRIG increased liver wt. with hypertrophy & eosinophilia
X11719474: 28-Day dietary toxicity study in f344/ducrl rats.	NOEL 2000 ppm ♂167 mg/ kg bw per day ♀184 mg/ kg bw per day increased liver wt. with hypertrophy & eosinophilia
X11719474: 90-Day Dietary Toxicity Study In F344/DuCrl Rats.	NOEL 500 ppm ♂32.2 mg/ kg bw per day ♀35.2 mg/ kg bw per day increased increased Cholesterol increased liver wt. with hypertrophy, eosinophilia, fatty change & single cell necrosis
X11719474: A dose-range finding and tolerability study in male beagle dogs.	Oral administration of the test material for 7 days was well-tolerated at doses of 50 and 100 mg/ kg bw per day in male beagle dogs.
90-Day Oral Gavage Toxicity Study in Male Beagle Dogs.	NOAEL 50 mg/ kg bw per day Absolute testicular weights did not show any dose response but there was a mean decrease of approximately 19.3% between the controls and the high dose group
Salmonella Escherichia coli Mammalian-Microsome Reverse Mutation Assay Preincubation Method with a Confirmatory Assay with Oryzalin X11719474	Negative result at highest dose 5000 µg per plate.
Evaluation Of X11719474 In An *In Vitro* Chromosomal Aberration Assay Utilising Rat Lymphocytes.	Negative result at highest dose 2953 µg/ml.
Evaluation of X11719474 in the chinese hamster ovary cell/hypoxanthine-guanine-phosphoribosyl transferase (cho/hgprt) forward mutation assay.	Negative result.
X11719474: Targeted gene expression, cell proliferation, and cytochrome p450 enzymatic activity in male F344/DuCrl rats to determine the mode of action for effects on the liver.	Liver: CAR and PXR-related molecular, enzymatic, and proliferative responses.

X11719474: Dietary Reproduction / Developmental Toxicity Screening Test in CRL:CD(SD) Rats.	NOAEL systemic 5000 ppm (396 mg/ kg bw per day) NOAEL repro 5000ppm, ♀ = 396 mg/kg/day) No significant biological effect on pup survival indices at PND1 and 4 at the highest dose relative to HCD.
X11719474: Dietary Developmental Toxicity Study in CD(SD) Rats.	NOAEL (maternal tox) 368 mg/kg/day NOAEL (embryo/foetal) 368 mg/kg bw per day Minor skeletal variations at the highest dose (368 mg/kg bw per day).
X11721061: Acute Oral Up and Down Procedure in Rats.	The acute oral LD_{50} of X11721061 was estimated to be 2000 mg/kg.
X11721061: A 1-Week Palatability Study In Male Fischer Rats.	No dose related effects
X11721061: A 28-Day Oral Dietary Toxicity Study In Fischer 344/DuCrl Rats.	NOAEL: 8000 ppm, (622 mg/kg bw per day) decreased palatability & small increased liver wt. without pathology
Salmonella – Escherichia coli/Mammalian-Microsome Reverse Mutation Assay Preincubation Method with a Confirmatory Assay with X11721061	Negative at highest dose of 5000 µg per plate
Evaluation of X11721061 in an in vitro chromosomal aberration assay utilising rat lymphocytes.	Negative at highest concentration 1920 µg/ml
Evaluation Of X11721061 In The Chinese Hamster Ovary Cell/Hypoxanthine-Guanine-Phosphoribosyl Transferase (Cho/Hgprt) Forward Mutation Assay.	Negative result.
X11596066: Acute Oral Up and Down Procedure in Rats.	The acute oral LD_{50} of X11596066 was greater than 2000 mg/kg.
Salmonella – Escherichia coli/Mammalian-Microsome Reverse Mutation Assay Preincubation Method with a Confirmatory Assay with X11596066	Negative at highest dose of 5000 µg per plate.
X11579457: Acute Oral Up and Down Procedure in Rats.	The acute oral LD_{50} of X11579457 was greater than 2000 mg/kg.
Salmonella – Escherichia coli/Mammalian-Microsome Reverse Mutation Assay Preincubation Method with a Confirmatory Assay with X11579457	Negative at highest dose of 5000 µg per plate.
Evaluation of X11579457 in an in vitro chromosomal aberration assay utilising rat lymphocytes.	Negative at highest concentration 2525 µg/ml
Evaluation of X11579457 In The Chinese Hamster Ovary Cell/Hypoxanthine-Guanine-Phosphoribosyl Transferase (Cho/Hgprt) Forward Mutation Assay.	Negative result.
X11519540: Limited absorption, distribution, metabolism and excretion in F344/NTac Rats.	Orally administered X11519540 was rapidly absorbed, poorly metabolised and eliminated slowly from the rat.

X11519540: Acute Oral Up and Down Procedure in Rats.	The acute oral LD_{50} of X11519540 was estimated to be 565.7 mg/kg.
X11519540: Palatability probe study in male F344/ DuCrl rats.	Dramatic dose dependent decreases in feed consumption with associated body weight losses. X11519540 at these targeted dietary doses was considered unpalatable, and targeted dietary doses of < 250 mg/ kg bw per day need to be used
X11519540: 28-Day dietary toxicity study in F344/DuCrl rats.	LOAEL = 7.7 mg/kg bw per day (100ppm) Treatment-related liver, thyroid, and adrenal gland effects at all dose levels. Massive increased liver wt. with hypertrophy, eosinophilia. Very slight increased nos. of mitotic figures (♂ only, 100 ppm). Many effects.
X11519540: 90-Day Dietary Toxicity Study In F344/DuCrl Rats.	NOAEL = 1.5 mg/kg bw per day (25ppm) increased liver wt. and histopathological alterations
Salmonella – Escherichia coli/Mammalian-Microsome Reverse Mutation Assay Preincubation Method with a Confirmatory Assay with X11519540	Negative at highest dose of 5000 µg per plate.
Evaluation of X11519540 in an in vitro chromosomal aberration assay utilising rat lymphocytes.	Negative at highest concentration 2540 µg/ml.
Evaluation of X11519540 In The Chinese Hamster Ovary Cell/Hypoxanthine-Guanine-Phosphoribosyl Transferase (Cho/Hgprt) Forward Mutation Assay.	Negative result.
X11519540: Targeted gene expression, cell proliferation, and cytochrome p450 enzymatic activity in male F344/DuCrl rat liver.	increased liver wt. with hypertrophy, CAR and PXR enzyme induction profile,
Characterisation of the effects of X11519540 on rat α1β1γδ muscle nicotinic acetylcholine receptors.	No significant agonist activation by X11519540 was detected, even at the highest tested concentration (3 mM).
X11519540: Dietary Reproduction/Developmental Toxicity Screening Test in CRL:CD(SD) Rats.	increased liver wt. with hypertrophy

Medical data ‡ (Annex IIA, point 5.9)

The manufacturing facility began production of sulfoxaflor in October 2010. Medical surveillance (Health Assessment) is not required for working with this chemical or raw materials, but is offered voluntarily based upon age. This group of employees is offered voluntary Medical Surveillance during the fourth quarter of each year. The 2010 Medical Surveillance data was reviewed, along with chemical exposure incidents from this group of employees. However, no health problems related to this chemical were found in employees. In addition, the Dow Acute Chemical Exposure Database contained no reports of health services for sulfoxaflor.

Dow AgroSciences is not aware of any reported clinical cases or poisoning incidents involving sulfoxaflor. There have been no studies, reports or observations with regards to effects of sulfoxaflor exposure in humans. Studies on the exposure of the general population or epidemiological studies can not exist at this time as sulfoxaflor has not been commercialised.

Sulfoxaflor is a novel insecticide that targets the insect nicotinic acetylcholine receptor. It is known to activate the foetal rat muscle nicotinic acetylcholine receptor but not the adult rat or human equivalents. If effects were to occur in humans they would most likely be from acute oral exposure and cholinergic in nature but there is no evidence to this effect at this time. Sulfoxaflor has low acute oral toxicity with an oral LD_{50} of 750 mg/kg. It has no toxicity by dermal or inhalation exposure and is a mild, transient irritant to skin and eyes. It has no known potential to cause skin contact sensitisation. Systemically, the liver is the primary target organ and effects are consistent with a phenobarbital-like mode of action.

First aid measures are aimed at prompt removal of the exposure and appropriate medical follow up, as required. Studies in animals indicate no toxicity from contact with skin at limit dose levels and no toxicity after breathing a maximum achievable respirable concentration in air. Similarly, animal studies indicate only minimal to slight transient irritation of skin and eyes and no potential for skin contact sensitisation. In animals, acute oral ingestion indicated potential for significant oral toxicity, including death at doses of 750 mg sulfoxaflor/kg body weight. Therefore, if effects were to occur in humans they would most likely be from acute oral exposure (and cholinergic in nature – see IIa 5.9.7) but there is no evidence to this effect at this time.

Ingestion: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Never give anything by mouth to an unconscious person.

Eye: Hold eyes open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes then continue rinsing eyes. Call a poison control center or doctor for treatment advice.

Skin: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

Inhalation: Move person to fresh air. If person is not breathing, call emergency services (e.g., 112, 911) or an ambulance, then give artificial respiration; if by mouth to mouth use rescuer protection (pocket mask, etc.). Call a poison control center or doctor for treatment advice.

Notes to Physician: There is no specific antidote. Treatment of exposure should be directed at the control of symptoms and the clinical condition of the patient.

No specific treatment is recommended beyond first aid described above. No specific poisoning effects are expected. Sulfoxaflor is a novel insecticide that targets the insect nicotinic acetylcholine receptor. It is known to activate the foetal rat muscle nicotinic acetylcholine receptor but not the adult rat or human equivalents. If effects were to occur in humans they would most likely be from acute oral exposure and cholinergic in nature but there is no evidence to this effect at this time. Systemically, the liver is the primary target organ and effects are consistent with a phenobarbital-like mode of action. It is rapidly absorbed from the gastro-intestinal tract and rapidly eliminated in the urine with negligible metabolism in animals – corresponding data for humans are not available.

Sulfoxaflor has no dermal toxicity even at a limit dose of 5000 mg/kg body weight. Dermal absorption from large doses of sulfoxaflor is very low and prolonged skin contact is unlikely to result in absorption of harmful amounts.

Summary (Annex IIA, point 5.10)	Value	Study	Safety factor
ADI ‡	0.04 mg/kg bw per day	2-year Rat	× 100
AOEL ‡	0.06 mg/kg bw per day	90 day rat, 90 day dog and 1yr dog.	× 100
ARfD ‡	0.25 mg/kg bw	Rat Acute Neurotoxicity study	× 100

* Correction for low oral absorption (none required).

Dermal absorption ‡ (Annex IIIA, point 7.3)

Reference Formulation (GF-2626)	For the proposed uses it is considered appropriate to use the following dermal absorption values in the human health risk assessment:	
	Suspension Concentrate (SC)	= 0.8%
	Spray dilution	= 5%
	Very dilute spray dilution	= 6%

Exposure scenarios (Annex IIIA, point 7.2)

Mixture GF-2626

Operator	**Operators:** Exposure of operators to sulfoxaflor from field applications of GF-2626 was estimated using the UK POEM and German model. The models indicate that exposure to GF-2372 is below the AOEL, even without PPE (≤ 4% of the AOEL for sulfoxaflor). Exposure of operators to sulfoxaflor from greenhouse applications of GF-2626 was estimated using the southern European (EOEM) greenhouse and the Dutch Greenhouse Models. The models indicate that exposure to GF-2626 is below the AOEL when appropriate PPE is worn (≤ 1% of the AOEL for sulfoxaflor). Even without PPE, exposures do not exceed 12% (7% in the case of the Dutch Model).
Workers	**Workers:** The estimated systemic exposure from re-entry to fruiting vegetables (worst-case exposure scenario), without wearing any personal protective clothing immediately after one application is ≤ 2.4% of the AOEL for sulfoxaflor.
Bystanders	**Bystanders:** Based on German and US EPA/UK CRD experimental data, potential exposure to incidental and residential bystanders following GF-2626 application would be less than the AOEL for Sulfoxaflor (≤ 0.2%).

Mixture GF-2372

	Operators: Exposure of operators to sulfoxaflor from application of GF-2372 to cereals and cotton was

	estimated using the UK POEM and German model. The models used indicate that exposure to GF-2372 is below the AOEL, even without PPE (≤ 20% of the AOEL for sulfoxaflor).
	Worker: The estimated systemic exposure from re-entry to cereals and cotton (worst-case exposure scenario), without wearing any personal protective clothing immediately after one application is 1.4% of the AOEL for sulfoxaflor.
	Bystander: Based on German and US EPA/UK CRD experimental data, potential exposure to incidental and residential bystanders following GF-2372 application would be less than the AOEL for sulfoxaflor (≤ 0.2%). Therefore, potential exposure of bystanders does not represent an adverse risk to human health.

Classification and proposed labelling with regard to toxicological data (Annex IIA, point 10)

Substance classified (Sulfoxaflor)	Hazard pictogram: GHS07
	Signal word: Warning
	Hazard statement: H302: Harmful if swallowed.

Substance classified (Sulfoxaflor)	Xn - Harmful
	R22 Harmful if swallowed
	S60 This material and/or its container must be disposed of as hazardous waste. S61 Avoid release to the environment. Refer to special instructions/safety data sheet.

Residues

Metabolism in plants (Annex IIA, point 6.1 and 6.7, Annex IIIA, point 8.1 and 8.6)

Plant groups covered	Tomatoes, peas, lettuce and rice.
Rotational crops	Radish, lettuce, wheat (grain, forage, straw, hay).
Metabolism in rotational crops similar to metabolism in primary crops?	Results of rotational crops studies are consistent with those of the primary crop metabolism studies.
Processed commodities	Parent sulfoxaflor and metabolite X11721061 are stable under hydrolysis conditions. The metabolite X11719474 can be considered stable to hydrolysis at pH4 and 90°C for 20 minutes but is degraded slightly with increase pH and temperature, with the formation of one degradate, X11579457, accounting for up to 11.6% of the total radioactivity.
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes.
Plant residue definition for monitoring	Parent sulfoxaflor (sulfoxaflor) only.
Plant residue definition for risk assessment	Sum of parent sulfoxaflor and metabolite X11719474, expressed as sulfoxaflor. However, 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 parent Sulfoxaflor only.
Conversion factor (monitoring to risk assessment)	None.

Metabolism in livestock (Annex IIA, point 6.2 and 6.7, Annex IIIA, point 8.1 and 8.6)

Animals covered	Goat and hen.
Time needed to reach a plateau concentration in milk and eggs	Milk: A plateau was reached in milk matrices over the course of the 5 day dosing period (*ca.* 0.2 – 0.3 mg/kg). Eggs: A steady plateau was observed in egg matrices after six days dosing (*ca.* 0.06 mg/kg).
Animal residue definition for monitoring	Parent sulfoxaflor (sulfoxaflor) only.
Animal residue definition for risk assessment	Sum of parent sulfoxaflor and metabolite X11719474, expressed as sulfoxaflor. However, 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 parent Sulfoxaflor only.
Conversion factor (monitoring to risk assessment)	None.
Metabolism in rat and ruminant similar (yes/no)	Yes. Metabolism of parent sulfoxaflor in the ruminant (goat) and rodent are similar, therefore there is no need to request a swine (pig) metabolism study.

Fat soluble residue: (yes/no)	No. Parent sulfoxaflor is not fat soluble as log $P_{o/w}$ <3. Log Pow is 0.78 for X11546257 (diastereoisomer 1) Log Pow is 0.87 for X11546258 (diastereoisomer 2) And for the PAI (both distereoisomers): Log Pow = 0.806 at pH5 Log Pow = 0.802 at pH 7 Log Pow = 0.799 at pH 9

Residues in succeeding crops (Annex IIA, point 6.6, Annex IIIA, point 8.5)

	Residues of sulfoxaflor, X11719474, X11721061, X11519540 and X11579457 are not expected to accumulate above the LOQ in food items for human consumption as it regards the representative uses in the peer review. However, residues of X11719474 may occasionally reach or exceed the LOQ in the leafy parts of root/tuber crops (radish STMR 0.01, HR 0.019) and cereals (barley straw: STMR 0.01, HR 0.018), as demonstrated by the rotational crop residue trials (1N). Since the application rates are significantly higher in non-EU countries (uses considered in the MRL application for import tolerances), residues of metabolite X11719474 could exceed the LOQ in rotational crops grown in those countries, as indicated by the confined study and rotational residue trials submitted in the framework of the peer review. No other rotational residue data but the confined metabolism study were available to assess the magnitude of residues in rotational crops grown in the exporting countries. Significant residues of X11719474 are expected in leafy vegetables, brassica leaves (and by extrapolation brassica vegetables), in root and tuber vegetables, and in cereals. No data and information is available for fruiting vegetables (incl. *Solanaceae*, cucurbits), and oilseed crops. Residues of X11719474 [in mg/kg] in the confined study (1.5 N Australia , 2 N USA cGAP rate): 30 d PBI: Lettuce – 0.368; Radish tops – 0.773; Radish Roots – 0.135, Wheat forage – 0.908, Wheat straw – 0.914, Wheat grain – 0.040 120 d PBI: Lettuce – 0.317; Radish tops – 0.329; Radish Roots – 0.077, Wheat forage – 0.185, Wheat straw – 1.344, Wheat grain – 0.047 365 d PBI: Lettuce – 0.194; Radish tops – 0.610; Radish Roots – 0.047, Wheat forage – 0.141, Wheat straw – 0.323, Wheat grain – 0.011

Stability of residues (Annex IIA, point 6 introduction, Annex IIIA, point 8 Introduction)

	Agricultural commodities (orange whole fruit, peach whole fruit, wheat grain and soya bean seed): Residues of sulfoxaflor and metabolite X11719474 are stable for at least 680 days (22 months) in agricultural commodities stored under frozen conditions. Animal matrices: The metabolism samples are radioactive labelled and therefore do not require supporting storage stability data, since the samples have been stored frozen and analysed within 6 months. The animal feeding studies contain storage stability data that cover the relevant storage time period used in the feeding studies.

Residues from livestock feeding studies (Annex IIA, point 6.4, Annex IIIA, point 8.3)

Representative uses for peer review

	Ruminant:	Poultry:	Pig:
	Conditions of requirement of feeding studies		
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)	Yes (RD_{RA}: 0.2; RD_{Mon} 0.152 mg/kg for beef cattle)	No	Not required
Potential for accumulation (yes/no):	No	No	Not required
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	Yes (for liver only)	No	Not required
	Feeding studies: In the cattle feeding study the feeding level was at 0.45 mg/kg sulfoxaflor (dose group 1) corresponding to circa 7.1x the expected dietary level for dairy cow and 3x the expected dietary level for beef cattle. Residue levels in matrices : Mean (max) mg/kg		
Muscle	0.01 (0.01) RA: 0.01 (0.015)	Not required	Not required
Liver	0.02 (0.02) RA: 0.01 (0.03)	Not required	Not required
Kidney	0.01 (0.01) RA: 0.01 (0.02)	Not required	Not required
Fat	0.01 (0.01) RA: 0.01 (0.01)	Not required	Not required
Milk	0.01 (0.01)		

	RA: 0.01 (0.01)		
Eggs		Not required	

All uses, including uses for which MRLs were proposed on basis of MRL application.

Note: The input values used for the livestock dietary burden calculations are presented below for the sake of transparency as they are not included in the assessment report or in an addendum thereof.

	Ruminant:	Poultry:	Pig:
	Conditions of requirement of feeding studies		
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)	Yes RD $_{RA}$: 1.15 RD $_{Mon}$: 1.10 for beef cattle	No [RD $_{RA}$: 0.06 RD $_{Mon}$: 0.03]	Yes RD $_{RA}$: 0.13 RD $_{Mon}$: 0.07
Potential for accumulation (yes/no):	No	No	No
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	Yes	Yes (for liver only)	
	Feeding studies: Intake by cattle between feeding level [in mg/kg diet DM] of cow dose group 1 (0.45 sulfoxaflor + 0.045 X11719474) and cow dose group 2 (2.37 sulfoxaflor + 0.237 X11719474) in cattle feeding study; intake by poultry below lowest feeding level (0.145 sulfoxaflor + 0.01 X11719474) Residue levels in matrices : Mean (max) mg/kg		
Muscle	RD $_{RA}$: 0.01 (0.071) RD$_{Mon}$: 0.01 (0.070)	RD$_{RA}$/RD$_{Mon}$: 0.01* (0.01*)	RD $_{RA}$: 0.01 (0.011) RD$_{Mon}$: 0.01* (0.01*)
Liver	RD $_{RA}$: 0.03 (0.164) RD$_{Mon}$: 0.03 (0.167)	RD$_{RA}$: 0.01 (0.013) RD$_{Mon}$: 0.01* (0.01*)	RD $_{RA}$: 0.019 (0.024) RD$_{Mon}$: 0.011 (0.012)
Kidney	RD $_{RA}$: 0.02 (0.100) RD$_{Mon}$: 0.02 (0.098)	Not investigated	RD $_{RA}$: 0.012 (0.016) RD$_{Mon}$: 0.01* (0.01*)
Fat	RD$_{RA}$:0.01(0.040) RD$_{Mon}$:0.01*(0.034)	RD$_{RA}$/RD$_{Mon}$: 0.01* (0.01*)	RD$_{RA}$/RD$_{Mon}$: 0.01* (0.01*)
Milk	RD $_{RA}$: 0.01 (0.037) RD$_{Mon}$:0.01 (0.028)		
Eggs		RD$_{RA}$/RD$_{Mon}$: 0.01* (0.01*)	

Input parameter for livestock dietary burden calculation

Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: Sum of sulfoxaflor and metabolite X11719474, expressed as sulfoxaflor				
Wheat grain	0.019	STMR	0.019	STMR
Barley grain	0.020	STMR (EU)	0.020	STMR (EU)
Rye grain	0.019	STMR (EU)	0.019	STMR (EU)
Oat grain	0.020	STMR (EU)	0.020	STMR (EU)
Wheat bran	0.04	STMR x 2.1 (PF)	0.04	STMR x 2.1 (PF)
Rye bran	0.04	STMR x 2.1 (PF)	0.04	STMR x 2.1 (PF)
Wheat straw	0.143	STMR	1.648	HR
Barley straw	0.019	STMR (EU)	0.147	HR (EU)
Rye straw	0.063	STMR (EU)	0.270	HR (EU)
Oat straw	0.019	STMR (EU)	0.147	HR (EU)
Potato	0.019	STMR	0.019	STMR
Apple pomace	0.123	STMR x 1.1 (PF)	0.123	STMR x 1.1 (PF)
Cotton seed meal	0.015	STMR (EU) x 0.8 (PF)	0.015	STMR (EU) x 0.8 (PF)
Soya meal	0.03	STMR x 1.3 (PF)	0.03	STMR x 1.3 (PF)
Rape seed meal	0.136	STMR x 2 (PF)	0.136	STMR x 2 (PF)
Cabbage	0.01	STMR (rotational crop residue trials)	0.01	HR (rotational crop residue trials)
Kale	0.01	STMR (rotational crop residue trials)	0.01	HR (rotational crop residue trials)
Sugar beet tops	0.01	STMR (rotational crop residue trials)	0.018	HR (rotational crop residue trials)
Fodder beet tops	0.01	STMR (rotational crop residue trials)	0.018	HR (rotational crop residue trials)
Monitoring residue definition: Sulfoxaflor				
Wheat grain	0.010	Median residue	0.010	Median residue
Barley grain	0.011	Median residue	0.011	Median residue
Rye grain	0.010	Median residue (EU)	0.010	Median residue (EU)
Oat grain	0.011	Median residue (EU)	0.011	Median residue (EU)
Wheat bran	0.021	Median residue x 2.1 (PF)	0.021	Median residue x 2.1 (PF)
Rye bran	0.021	Median residue (EU) x 2.1 (PF)	0.021	Median residue (EU) x 2.1 (PF)
Wheat straw	0.115	Median residue	1.600	Highest residue
Barley straw	0.011	Median residue (EU)	0.130	Highest residue (EU)

Commodity	**Median dietary burden**		**Maximum dietary burden**	
	Input value (mg/kg)	**Comment**	**Input value (mg/kg)**	**Comment**
Rye straw	0.054	Median residue (EU)	0.214	Highest residue (EU)
Oat straw	0.011	Median residue (EU)	0.130	Highest residue (EU)
Potato	0.010	Median residue	0.010	Median residue
Apple pomace	0.113	Median residue x 1.1 (PF)	0.113	Median residue x 1.1 (PF)
Cotton seed meal	0.008	Median residue (EU) x 0.8 (PF)	0.008	Median residue (EU) x 0.8 (PF)
Soya meal	0.017	Median residue x 1.3 (PF)	0.017	Median residue x 1.3 (PF)
Rape seed meal	0.090	Median residue x 2 (PF)	0.090	Median residue x 2 (PF)

Note: A default processing factor of 1.3 was applied to convert from soya bean to soya meal, and a default processing factor of 2 was applied for rape seed/ rape seed meal accordingly. For apple pomace, a preliminary processing factor of 1.1 was derived on the basis of one residue trial investigating processed apple commodities.

Summary of residues data according to the representative uses on raw agricultural commodities and feedingstuffs (Annex IIA, point 6.3, Annex IIIA, point 8.2)

Crop	Northern or Southern Region, field or glasshouse, and any other useful information	Trials results relevant to the representative uses (a)	Recommendation/comments	MRL estimated from trials according to the representative use	HR (c)	STMR (b)
Fruiting vegetables - Tomatoes	NEU (Field)	Monitoring: 10 x < 0.01, 0.011, 2 x 0.012, 0.013, 0.014, 0.019 Risk assessment: 10 x < 0.019, 0.020, 2 x 0.021, 0.022, 0.022, 0.023, 0.028	The OECD calculator was used. Unrounded OECD MRL 0.02 Rounded OECD MRL 0.02 [High uncertainty of MRL estimate. High level of censoring]	0.02	0.028	0.019
	SEU (Field)	Monitoring: 7 x 0.01, 0.011, 0.012, 0.013, 0.014, 0.018, 0.023, 0.025, 0.030, 0.046 Risk assessment: 7 x < 0.019, 0.020, 0.021, 0.022, 0.023, 0.027, 0.032, 0.034, 0.039, 0.055	The OECD calculator was used. Unrounded OECD MRL 0.06 Rounded OECD MRL 0.06	**0.06**	0.055	0.021
	Greenhouse	Monitoring: 3 x < 0.01, 0.010, 0.013, 0.021, 0.031, 0.036 Risk assessment: 3 x < 0.019, 0.019, 0.022, 0.030, 0.040, 0.045	The OECD calculator was used. Unrounded OECD MRL 0.06 Rounded OECD MRL 0.06	0.06	0.045	0.021
Fruiting vegetables - Peppers	SEU (Field)	Monitoring: 0.016, 2 x 0.017, 0.021, 0.022, 0.023, 0.028, 0.088 Risk assessment: 0.025, 2 x 0.026, 0.030, 0.031, 0.032, 0.037, 0.097	The OECD calculator was used. Unrounded OECD MRL 0.13 Rounded OECD MRL 0.15	**0.15**	0.097	0.031
	Greenhouse	Monitoring: < 0.01, 0.010, 0.011, 0.014, 0.016, 0.023, 0.025, 0.057 Risk assessment: < 0.019, 0.019, 0.020,	The OECD calculator was used. Unrounded OECD MRL 0.08 Rounded OECD MRL 0.09	0.09	0.066	0.024

Crop	Northern or Southern Region, field or glasshouse, and any other useful information	Trials results relevant to the representative uses (a)	Recommendation/comments	MRL estimated from trials according to the representative use	HR (c)	STMR (b)
		0.023, 0.025, 0.03239, 0.034, 0.066				
Cucurbit – cucumber	NEU (Field)	Monitoring: 2 x <0.01, 0.010, 0.011, 0.012, 0.014, 2 x 0.020 Risk assessment: 2x < 0.019, 0.019, 0.020, 0.021, 0.023, 2 x 0.029	The OECD calculator was used. Unrounded OECD MRL 0.03 Rounded OECD MRL 0.04	**0.03**	0.029	0.021
	SEU (Field)	Monitoring:6 x < 0.01, 0.01, 0.018 Risk assessment: 6 x <0.019, 0.019, 0.027	The OECD calculator was used. Unrounded OECD MRL 0.02 Rounded OECD MRL 0.03 [High uncertainty of MRL estimate. High level of censoring]	0.03	0.027	0.019
	Greenhouse	Monitoring: 5 x < 0.01, 0.011, 0.016, 0.017 Risk assessment: 5 x < 0.019, 0.020, 0.025, 0.026	The OECD calculator was used. Unrounded OECD MRL 0.02 Rounded OECD MRL 0.03 [High uncertainty of MRL estimate. High level of censoring]	0.03	0.026	0.019
Cucurbit - melon	SEU (Field)	Monitoring: 8 x <0.01 Risk assessment: 8 x < 0.019	The OECD calculator was used. Unrounded OECD MRL 0.01 Rounded OECD MRL 0.01 [High uncertainty of MRL estimate. High level of censoring]	0.01	0.019	0.019
	Greenhouse	Monitoring: 5 x < 0.01, 2 x 0.01, 0.016	The OECD calculator was used.	**0.02**	0.025	0.019

Crop	Northern or Southern Region, field or glasshouse, and any other useful information	Trials results relevant to the representative uses (a)	Recommendation/comments	MRL estimated from trials according to the representative use	HR (c)	STMR (b)
		Risk assessment: 5x < 0.019, 2 x 0.019, 0.025	Unrounded OECD MRL 0.02 Rounded OECD MRL 0.02 [High uncertainty of MRL estimate. High level of censoring]			
Cereals – wheat grain	NEU (Field)	Monitoring: 8 x < 0.01 Risk assessment: 8 x <0.019	The OECD calculator was used. Unrounded OECD MRL 0.01 Rounded OECD MRL 0.01 [High uncertainty of MRL estimate. High level of censoring] Extrapolation to rye, triticale possible.	0.01	0.019	0.019
	SEU (Field)	Monitoring: 7 x <0.01, 0.013 Risk assessment: 7 x <0.019, 0.022	The OECD calculator was used. Unrounded OECD MRL 0.015 Rounded OECD MRL 0.015 [High uncertainty of MRL estimate. High level of censoring] Extrapolation to rye, triticale possible.	**0.015**	0.022	0.019
Cereals – wheat straw	NEU (Field)	Monitoring: 2 x <0.01, 0.016, 0.035, 0.050. 0.052, 0.086, 0.251 Risk assessment: 2 x < 0.019, 0.025, 0.044, 0.059, 0.061, 0.095, 0.270	The OECD calculator was used. Unrounded OECD MRL 0.38 Rounded OECD MRL 0.40 Extrapolation to rye, triticale possible.	0.4	0.270	0.052

Crop	Northern or Southern Region, field or glasshouse, and any other useful information	Trials results relevant to the representative uses (a)	Recommendation/comments	MRL estimated from trials according to the representative use	HR (c)	STMR (b)
	SEU (Field)	Monitoring: < 0.01, 0.022, 0.025, 0.034, 0.074, 0.107, 0.109, 0.214 Risk assessment: < 0.019, 0.031, 0.034, 0.043, 0.083, 0.116, 0.118, 0.225	The OECD calculator was used. Unrounded OECD MRL 0.35 Rounded OECD MRL 0.40 Extrapolation to rye, triticale possible.	0.4	0.225	0.063
Cereals – barley grain	NEU (Field)	Monitoring: 2 x < 0.01, 3 x 0.011, 0.015, 0.016, 0.022 Risk assessment: 2 x < 0.019, 3 x 0.020, 0.024, 0.025, 0.031	The OECD calculator was used. Unrounded OECD MRL 0.03 Rounded OECD MRL 0.04 Extrapolation to oats possible.	0.04	0.031	0.020
	SEU (Field)	Monitoring:7 x <0.01, 0.012, 0.019, 0.025 Risk assessment: 7x < 0.019, 0.021, 0.028, 0.034	The OECD calculator was used. Unrounded OECD MRL 0.03 Rounded OECD MRL 0.04 [High uncertainty of MRL estimate. High level of censoring] Extrapolation to oats possible.	**0.04**	0.034	0.019
Cereals – barley straw	NEU (Field)	Monitoring: 5 x < 0.01, 0.038, 0.044, 0.130 Risk assessment: 5 x < 0.019, 0.047, 0.053, 0.147	The OECD calculator was used. Unrounded OECD MRL 0.20 Rounded OECD MRL 0.20 [High uncertainty of MRL estimate. High level of censoring] Extrapolation to oats possible.	0.2	0.147	0.019
	SEU (Field)	Monitoring: 5 x < 0.01, 0.011, 0.014, 0.023,	The OECD calculator was used.	0.2	0.139	0.022

Crop	Northern or Southern Region, field or glasshouse, and any other useful information	Trials results relevant to the representative uses (a)	Recommendation/comments	MRL estimated from trials according to the representative use	HR (c)	STMR (b)
		0.061, 0.126 Risk assessment: 4 x < 0.019, 0.020, 0.023, 0.032, 0.034, 0.070, 0.139	Unrounded OECD MRL 0.18 Rounded OECD MRL 0.20 Extrapolation to oats possible.			
Cotton (seed)	SEU (Field)	Monitoring:8 x <0.01 Risk assessment: 8 x < 0.019	The OECD calculator was used. Unrounded OECD MRL 0.01 Rounded OECD MRL 0.01 [High uncertainty of MRL estimate. High level of censoring]	**0.01***	0.019	0.019

(a): Numbers of trials in which particular residue levels were reported *e.g.* 3 x <0.01, 1 x 0.01, 6 x 0.02, 1 x 0.04, 1 x 0.08, 2 x 0.1, 2 x 0.15, 1 x 0.17.
(b): Supervised Trials Median Residue *i.e.* the median residue level estimated on the basis of supervised trials relating to the representative use.
(c): Highest residue.

Summary of residues data on raw agricultural commodities and feedingstuffs according to the uses in the MRL application

Crop	**Region, field or glasshouse**	**Trials results relevant to the Global GAP (a)**	**Recommendation/comments** (R_{max}, $R_{ber,}$ OECD calculations, …)	**MRL** estimated from trials according to cGAP **(mg/kg)**	**HR (mg/kg) (c)**	**STMR (mg/kg) (b)**
Citrus fruit						
Orange	Australia	Monitoring: 0.085, 0.145, 0.155, 0.325, 0.41, 0.43 Risk assessment: 0.094, 0.154, 0.164, 0.334, 0.419, 0.439	There was **insufficient data** to calculate an MRL. 8 trials are required in oranges. 8 trials in each orange and mandarin are required for a group MRL for citrus.	None proposed	-	-
Mandarin		Monitoring: 0.18, 0.28, 0.34, 0.435 Risk assessment: 0.189, 0.289, 0.349, 0.444	There was **insufficient data** to calculate an MRL. 8 trials are required in mandarins. 8 trials in each orange and mandarin are required for a group MRL for citrus.	None proposed	-	-
Grapefruit	USA	Monitoring: < 0.01, 0.011, 0.012, 0.013, 0.016, 0.024, 0.112, 0.13 Risk assessment: 0.019, 0.020, 0.021, 0.022, 0.025, 0.034, 0.122, 0.139	GAP in residue trials 2 x 0.2 kg a.i./ha → **Not compliant with authorised cGAP** 3 x 0.1 kg a.i./ha	None proposed	-	-
Lemon		Monitoring: 0.034, 0.040, 0.045, 0.083, 0.136, 0.293 Risk assessment: 0.043, 0.049, 0.055, 0.093, 0.145, 0.302	GAP in residue trials 2 x 0.2 kg a.i./ha → **Not compliant with authorised cGAP** 3 x 0.1 kg a.i./ha	None proposed	-	-
Orange		Monitoring: 0.038, 0.048, 0.062, 0.074, 0.085, 0.098, 0.112, 0.120, 0.123, 0.132, 0.136, 0.155 Risk assessment: 0.048, 0.057, 0.072,	GAP in residue trials 2 x 0.2 kg a.i./ha → **Not compliant with authorised cGAP** 3 x 0.1 kg a.i./ha	None proposed	-	-

Crop	Region, field or glasshouse	Trials results relevant to the Global GAP (a)	Recommendation/comments (R_{max}, $R_{ber,}$ OECD calculations, …)	MRL estimated from trials according to cGAP (mg/kg)	HR (mg/kg) (c)	STMR (mg/kg) (b)
		0.083,0.095, 0.107, 0.121, 0.130, 0.132, 0.141, 0.146, 0.165				
Tree nuts						
Almonds	USA	Monitoring: 5 x <0.01, 0.0125 Risk assessment: 5 x 0.019, 0.022	GAP in residue trials 2 x 0.2 kg a.i./ha → Not compliant with authorised cGAP 3 x 0.1 kg a.i./ha, however residues in 11 out of 12 trials < LOQ using exaggerated rates. Hence an MRL of 0.01* mg/kg [STMR, HR 0.019] is deemed sufficient in terms of cGAP. Sufficient number of trials in almonds and pecans to propose a group MRL for tree nuts	**0.01***	0.019	0.019
Pecans	USA	Monitoring: 6 x < 0.01 Risk assessment: 6 x 0.019				
Pome fruit						
Apples	USA	Monitoring: 0.011, 0.039, 0.040, 0.043, 0.056, 0.063, 0.064, 0.066, 0.068, 0.072, 0.102, 0.121 Risk assessment: 0.020, 0.048, 0.052, 0.050, 0.066, 0.072, 0.074, 0.076, 0.077, 0.082, 0.112, 0.131	GAP in residue trials 2 x 0.2 kg a.i./ha → **Not compliant with authorised cGAP** 3 x 0.1 kg a.i./ha Comparing data sets in apple and pear, the population is not similar according to Mann-Whitney-U Test.	None proposed	-	-
Pears		Monitoring: 0.075, 0.134, 0.155, 0.176, 0.244 Risk assessment: 0.085, 0.143, 0.165, 0.185, 0.254	GAP in residue trials 2 x 0.2 kg a.i./ha → **Not compliant with authorised cGAP** 3 x 0.1 kg a.i./ha Comparing data sets in apple and pear, the population is not similar according to Mann-Whitney-U Test.	None proposed	-	-

Crop	Region, field or glasshouse	Trials results relevant to the Global GAP (a)	Recommendation/comments (R_{max}, $R_{ber,}$ OECD calculations, …)	MRL estimated from trials according to cGAP (mg/kg)	HR (mg/kg) (c)	STMR (mg/kg) (b)
Apples	Australia, New Zealand	Monitoring: 0.05, 0.07, 0.09, 0.1, 0.14, 0.185 Risk assessment: 0.059, 0.079, 0.099, 0.109, 0.149, 0.194,	Sufficient number of trials in apples and pears for extrapolation across the crops. Unrounded OECD MRL 0.36 Rounded OECD MRL 0.4 Note: MRL applied for in apple is 0.4 mg/kg and in pear 0.5 mg/kg. MRL in exporting country is 0.5 mg/kg for both crops.	**0.4**	0.229	0.112
Pears		Monitoring: 0.105, 0.22 Risk assessment: 0.114, 0.229				
Stone fruit						
Cherry	USA	Monitoring: 0.554, 0.586, 0.760, 1.05, 1.22, 1.24 Risk assessment: 0.563, 0.595, 0.770, 1.06, 1.23, 1.26	GAP in residue trials 2 x 0.2 kg a.i./ha → **Not compliant with authorised cGAP** 3 x 0.1 kg a.i./ha	None proposed	-	-
	Australia, New Zealand	Monitoring: 0.345, 1.29 Risk assessment: 0.354, 1.30	There was **insufficient data** to calculate an MRL.	None proposed	-	-
Peaches	USA	Monitoring: 0.032, 0.0541, 0.0904, 0.1165, 0.1398, 0.1733 Risk assessment: 0.100, 0.042, 0.064, 0.183, 0.149, 0.126	GAP in residue trials 2 x 0.2 kg a.i./ha →**Not compliant with authorised cGAP** 3 x 0.1 kg a.i./ha	None proposed	-	-
Apricots	Australia, New Zealand	Monitoring: 0.16 , 0.39 Risk assessment: 0.17, 0.40	Sufficient number of trials in apricots, nectarines, peaches for extrapolation across the crops. Unrounded OECD MRL 0.49 Rounded OECD MRL 0.5 Note: MRL applied for is 0.7 mg/kg,	**0.5**	0.40	0.15
Nectarines		Monitoring: 0.13, 0.16, 0.17 , 0.18 Risk assessment: 0.14, 0.17, 0.18, 0.19				
Peaches		Monitoring: 0.02, 3x 0.11, 0.12, 0.13, 0.14, 0.22, 0.25				

Crop	Region, field or glasshouse	Trials results relevant to the Global GAP (a)	Recommendation/comments (R_{max}, R_{ber}, OECD calculations, …)	MRL estimated from trials according to cGAP (mg/kg)	HR (mg/kg) (c)	STMR (mg/kg) (b)
		Risk assessment:0.024, 3x 0.12, 0.13, 0.14, 0.15, 0.23, 0.26	MRL in exporting country is 1 mg/kg.			
Plum	USA	Monitoring: 0.031, 0.054, 0.066, 0.091, 0.107, 0.358 Risk assessment: 0.040, 0.063, 0.075, 0.100, 0.116, 0.374	GAP in residue trials 2 x 0.2 kg a.i./ha → **Not compliant with authorised cGAP** 3 x 0.1 kg a.i./ha; 8 trials are required in plums	None proposed	-	-
	Australia	Monitoring: 0.020 Risk assessment: 0.029	There was **insufficient data** to calculate an MRL.	None proposed	-	-
Berries and small fruit						
Wine grapes	Australia, New Zealand	Monitoring: 0.1, 0.11, 0.13, 0.14, 0.205, 0.35, 1.55 Risk assessment: 0.138, 0.139, 0.152, 0.178, 0.219, 0.359, 1.71	GAP in residue trials 4 x 0.96 kg a.i./ha up to BBCH 89 → **Not compliant with authorised cGAP** 2 x 0.72 kg a.i./ha up to BBCH 68 Note: MRL in exporting country is 0.01* mg/kg which correspondes to the EU default MRL.	**0.01***	0.019	0.019
	USA	Monitoring: 0.078, 0.099, 0.106, 0.119, 0.142 Risk assessment: 0.096, 0.111, 0.116, 0.128, 0.151	Application of 4 x 0.1 kg a.i./ha vs. authorised cGAP 3 x 0.1 kg a.i./ha considered acceptable (+ 25% tolerance); There was **insufficient data** to calculate an MRL. 8 trials are required in wine grapes.	None proposed	-	-
Table grapes	Australia	Monitoring: 0.01, 0.03, 0.095, 0.45, 0.555 Risk assessment: 0.019, 0.039, 0.104, 0.464, 0.593	8 trials are required in table grapes. Trials in wine grapes were conducted according to the cGAP for table grapes and were thus combined with	**2.0**	1.71	0.165

Crop	Region, field or glasshouse	Trials results relevant to the Global GAP (a)	Recommendation/comments (R_{max}, R_{ber}, OECD calculations, …)	MRL estimated from trials according to cGAP (mg/kg)	HR (mg/kg) (c)	STMR (mg/kg) (b)
		Table + Wine grapes: Monitoring: 0.01, 0.03, 0.095, 0.1, 0.11, 0.13, 0.14, 0.205, 0.35, 0.45, 0.555, 1.55 Risk assessment: 0.019, 0.039, 0.104, 0.138, 0.139, 0.152, 0.178, 0.219, 0.359, 0.464, 0.593,1.71	the table grapes data set. Population similar according to Mann-Whitney-U-Test. Unrounded OECD MRL 2.01 Rounded OECD MRL 2.0 Note: MRL applied for is 1.5 mg/kg, MRL in exporting country is 3 mg/kg			
	USA	Monitoring: 0.035, 0.042, 0.091, 0.331 Risk assessment: 0.047, 0.052, 0.101, 0.358	There was **insufficient data** to calculate an MRL.	None proposed	-	-
Strawberry	USA	Monitoring: 0.065, 0.134, 0.142, 0.183, 2x 0.191, 0.203, 0.209, 0.210 Risk assessment: 0.082, 0.144, 0.151, 0.193, 2 x 0.200, 0.212, 0.218, 0.229	Application of 4 x 0.1 kg a.i./ha vs. authorised cGAP 4 x 0.078 kg a.i./ha considered acceptable (+ 25% tolerance) Unrounded OECD MRL 0.51 Rounded OECD MRL 0.5 Note: Applied for MRL / MRL in exporting country is 0.7 mg/kg.	**0.5**	0.229	0.2
	Australia, New Zealand	Monitoring: 0.03, 0.125, 0.21, 0.49 Risk assessment: 0.039, 0.148, 0.219, 0.523	There was **insufficient data** to calculate an MRL.	None proposed	-	-
Root and tuber vegetables						
Carrot	USA	Monitoring: 2 x < 0.01, 0.010, 0.013	There was **insufficient data** to	None proposed	-	-

Crop	Region, field or glasshouse	Trials results relevant to the Global GAP (a)	Recommendation/comments (R_{max}, R_{ber}, OECD calculations, …)	MRL estimated from trials according to cGAP (mg/kg)	HR (mg/kg) (c)	STMR (mg/kg) (b)
		Risk assessment: 3 x 0.019, 0.022	calculate an MRL. High uncertainty of MRL estimate. Group extrapolation requires 8 trials each in carrots, potato, sugarbeet [small dataset]			
Potatoes	USA	Monitoring: 10 x <0.01 Risk assessment: 10 x <0.019	Application of 4 x 0.1 kg a.i./ha vs. authorised cGAP 4 x 0.071 -0.080 kg a.i./ha considered acceptable (+ 25% tolerance) Unrounded OECD MRL 0.01 Rounded OECD MRL 0.01 High uncertainty of MRL estimate. [High level of censoring] Group extrapolation requires 8 trials each in carrots, potato, sugarbeet Note: MRL applied for is 0.01 mg/kg/ MRL in exporting country is 0.05 mg/kg.	**0.01***	0.019	0.019

Crop	Region, field or glasshouse	Trials results relevant to the Global GAP (a)	Recommendation/comments (R_{max}, R_{ber}, OECD calculations, …)	MRL estimated from trials according to cGAP (mg/kg)	HR (mg/kg) (c)	STMR (mg/kg) (b)
Sugar beet	USA	Roots: Monitoring: 3 x <0.01, 2 x 0.01 Risk assessment: 4 x 0.019, 0.022	Application of 4 x 0.1 kg a.i./ha vs. authorised cGAP 4 x 0.071- 0.096 kg a.i./ha considered acceptable (+ 25% tolerance) There was **insufficient data** to calculate an MRL. 8 trials are required in sugar beet Group extrapolation requires 8 trials each in carrots, potato, sugarbeet	None proposed	-	-
		Tops: Monitoring: 0.152, 0.388, 0.421, 0.555, 1.62 Risk assessment: 0.181, 0.490, 0.498, 0.644, 1.81	Application of 4 x 0.1 kg a.i./ha vs. authorised cGAP 4 x 0.071- 0.096 kg a.i./ha considered acceptable (+ 25% tolerance).There **was insufficient data** to calculate an MRL. However, MRLs are currently not set in feed items in the EU.	None proposed	-	-
Radish root	USA	Monitoring: 3x 0.010, 0.011, 0.012, 0.014 Risk assessment: 0.019, 0.031, 0.035, 0.055, 2 x 0.079	Application of 4 x 0.1 kg a.i./ha vs. authorised cGAP 4 x 0.071- 0.096 kg a.i./ha considered acceptable (+ 25% tolerance) Unrounded OECD MRL 0.03 Rounded OECD MRL 0.04 High uncertainty of MRL estimate. [Small dataset] Note: Although sufficient data were	None proposed	-	-

Crop	Region, field or glasshouse	Trials results relevant to the Global GAP (a)	Recommendation/comments (R_{max}, R_{ber}, OECD calculations, …)	MRL estimated from trials according to cGAP (mg/kg)	HR (mg/kg) (c)	STMR (mg/kg) (b)
			available, an MRL in radish root was **not applied for.** Data can not be used for group extrapolation.			
Fruiting vegetables						
Tomato (outdoor)	USA	Monitoring: 2 x <0.01, 0.012, 0.026, 0.030, 0.047, 0.061, 0.077, 0.082, 0.085, 0.094, 0.15 Risk assessment: 2 x <0.019, 0.021, 0.035, 0.040, 0.057, 0.071, 0.086, 0.091, 0.094, 0.103, 0.159	Application of 4 x 0.1 kg a.i./ha vs. authorised cGAP 4 x 0.074- 0.078 kg a.i./ha considered acceptable (+ 25% tolerance) Unrounded OECD MRL 0.23 Rounded OECD MRL 0.30 Note: MRL applied for/MRL in exporting country is 0.7 mg/kg Extrapolation to aubergine is possible; however an MRL in aubergine was not applied for.	**0.3**	0.159	0.064
	Australia	Monitoring: 3 x 0.015, 0.025, 0.03, 0.05 Risk assessment: 3 x 0.024, 0.039, 0.128, 0.153	There was **insufficient data** to calculate an MRL. 8 trials are required for tomato.	None proposed	-	-
Peppers	Australia	Monitoring: 2x 0.01, 0.075, 0.08, 0.40, 0.44 Risk assessment: 2 x 0.019, 0.084, 0.089, 0.409, 0.449	There was **insufficient data** to calculate an MRL. 8 trials are required for peppers.	None proposed	-	-
	USA	Monitoring: 0.013, 0.015, 0.020, 0.055, 0.085, 0.087, 0.203, 0.212 Risk assessment: 0.022, 0.024, 0.029, 0.065, 0.095, 0.116, 0.212, 0.222	Application of 4 x 0.1 kg a.i./ha vs. authorised cGAP 4 x 0.074- 0.078 kg a.i./ha considered acceptable (+ 25% tolerance) Unrounded OECD MRL 0.41 Rounded OECD MRL 0.40	**0.4**	0.222	0.080

Crop	Region, field or glasshouse	Trials results relevant to the Global GAP (a)	Recommendation/comments (R_{max}, R_{ber}, OECD calculations, …)	MRL estimated from trials according to cGAP (mg/kg)	HR (mg/kg) (c)	STMR (mg/kg) (b)
			Note: MRL applied for is 0.6 mg/kg, MRL in exporting country is 0.7 mg/kg.			
Cucurbits – edible and inedible peel						
Melon	USA	Monitoring: <0.01, 0.018, 0.025, 0.032, 0.038, 0.266 Risk assessment: 0.019, 0.027, 0.034, 0.041, 0.047, 0.275	Application of 4 x 0.1 kg a.i./ha vs. authorised cGAP 4 x 0.074- 0.078 kg a.i./ha considered acceptable (+ 25% tolerance) There is **insufficient data** to calculate an MRL. 8 trials are required for melons.	None proposed	-	-
Winter squash	USA	Monitoring: <0.01, 0.011, 0.018 Risk assessment: <0.019, 0.020, 0.027	Application of 4 x 0.1 kg a.i./ha vs. authorised cGAP 3 x 0.1 kg a.i./ha considered acceptable (+ 25% tolerance); There is **insufficient data** to calculate an MRL.	None proposed	-	-
Summer squash	USA	Monitoring: 3 x < 0.01 Risk assessment: <0.019, 0.024, 0.026,	Application of 4 x 0.1 kg a.i./ha vs. authorised cGAP 3 x 0.1 kg a.i./ha considered acceptable (+ 25% tolerance); There is **insufficient data** to calculate an MRL.	None proposed	-	-
Cucumber	USA	Monitoring: <0.01, 0.014, 0.018, 0.025, 0.041, 0.071 Risk assessment: 0.023, 0.027, 0.036, 0.039, 0.050, 0.081	Application of 4 x 0.1 kg a.i./ha vs. authorised cGAP 3 x 0.1 kg a.i./ha considered acceptable (+ 25% tolerance); There is **insufficient data** to	None proposed	-	-

Crop	Region, field or glasshouse	Trials results relevant to the Global GAP (a)	Recommendation/comments (R_{max}, R_{ber}, OECD calculations, …)	MRL estimated from trials according to cGAP (mg/kg)	HR (mg/kg) (c)	STMR (mg/kg) (b)
			calculate an MRL. 8 trials are required for cucumbers.			
Brassica vegetables						
Broccoli	USA	Monitoring: 0.01, 0.029, 0.050, 0.060, 0.117, 0.393 Risk assessment: 0.025, 0.041, 0.059, 0.069, 0.141, 0.500	Application of 4 x 0.1 kg a.i./ha vs. authorised cGAP 3 x 0.1 kg a.i./ha considered acceptable (+ 25% tolerance); Unrounded OECD MRL 0.68 Rounded OECD MRL 0.70 High uncertainty of MRL estimate (small dataset) Note: MRL applied for / MRL in exporting country is 2 mg/kg.	**0.7**	0.500	0.064
Broccoli	Australia	Monitoring: 0.065, 0.07 Risk assessment: 0.074, 0.098	There was **insufficient data** to generate an MRL. 8 trials are required for cauliflower. 4 trials each in broccoli and cauliflower are required for a group MRL in flowering brassica.	None proposed	-	-
Cauliflower		Monitoring: <0.01, 0.055 Risk assessment: 0.034, 0.074				
Mustard greens *(Brassica juncea)*	USA	Monitoring: 0.286, 0.495, 0.603, 0.674, 0.771, 0.817, 0.896, 0.899 Risk assessment: 0.37, 0.531, 0.745, 0.953, 1.05, 1.20, 1.35, 1.45	Application of 4 x 0.1 kg a.i./ha vs. authorised cGAP 3 x 0.1 kg a.i./ha considered acceptable (+ 25% tolerance); Unrounded OECD MRL 2.04 Rounded OECD MRL 2.0 Extrapolation to whole group of leafy brassica is not possible since	**2.0**	1.45	1.0

Crop	Region, field or glasshouse	Trials results relevant to the Global GAP (a)	Recommendation/comments (R_{max}, R_{ber}, OECD calculations, …)	MRL estimated from trials according to cGAP (mg/kg)	HR (mg/kg) (c)	STMR (mg/kg) (b)
			trials are required in kale.			
Head Cabbage	USA	Monitoring: <0.01, 0.040, 2 x 0.097, 0.101, 0.185 Risk assessment: 0.019, 0.051, 0.112, 0.108, 0.119, 0.195	Application of 4 x 0.1 kg a.i./ha vs. authorised cGAP 3 x 0.1 kg a.i./ha considered acceptable (+ 25% tolerance); There was **insufficient data** to generate an MRL. 8 trials are required for head cabbage.	None proposed	-	-
	Australia	Monitoring: 0.01, 0.15 Risk assessment: 0.019, 0.246	There was **insufficient data** to generate an MRL. 8 trials are required for head cabbage.	None proposed	-	-
Leaf vegetables & fresh herbs						
Leaf and head lettuce	USA	Monitoring: <0.01, 0.011, 0.015, 0.178, 0.403, 0.415, , 0.577, 0.789, 1.07, 1.10, 1.59, 2.74 Risk assessment: <0.019, 0.021, 0.026, 0.187, 0.440, 0.483, 0.686, 0.839, 1.15, 1.24, 1.62, 2.87	Application of 4 x 0.1 kg a.i./ha vs. authorised cGAP 3 x 0.1 kg a.i./ha considered acceptable (+ 25% tolerance); Unrounded OECD MRL 3.96 Rounded OECD MRL 4.0	**4.0**	2.87	0.585
	Australia	Monitoring: 0.01, 2x 0.035, 0.055, 0.065, 0.17, 0.23, 0.93 Risk assessment: 0.057, 0.068, 0.101, 0.102, 0.117, 0.273, 0.300, 0.996	Unrounded OECD MRL 1.42 Rounded OECD MRL 1.50 US trials are more critical.	1.5	0.996	0.110
Spinach	USA	Monitoring: 0.041, 0.405, 1.04, 1.43, 1.87, 2.86 Risk assessment: 0.140, 0.640, 1.19, 1.49, 1.94,	Application of 4 x 0.1 kg a.i./ha vs. authorised cGAP 3 x 0.1 kg a.i./ha	**6.0**	2.99	1.34

Crop	**Region, field or glasshouse**	**Trials results relevant to the Global GAP** **(a)**	**Recommendation/comments** (R_{max}, $R_{ber,}$ OECD calculations, …)	**MRL** estimated from trials according to cGAP **(mg/kg)**	**HR (mg/kg) (c)**	**STMR (mg/kg) (b)**
		2.99	considered acceptable (+ 25% tolerance); Unrounded OECD MRL 5.36 Rounded OECD MRL 6.0 High uncertainty of MRL estimate (small dataset) Note: MRL applied for is 5 mg/kg/ MRL in exporting county is 6 mg/kg.			
	Australia	Monitoring: 0.365, 0.595 Risk assessment: 0.534, 0.712	There was **insufficient data** to generate an MRL.	None proposed.	-	-
Celery leaves	USA	Monitoring: 0.102, 0.158, 0.171, 0.198, 0.692, 0.771 Risk assessment: 0.171, 0.216, 0.231, 0.278, 0.714, 0.808	Application of 4 x 0.1 kg a.i./ha vs. authorised cGAP 3 x 0.1 kg a.i./ha considered acceptable (+ 25% tolerance); Unrounded OECD MRL 1.55 Rounded OECD MRL 1.50 High uncertainty of MRL estimate. [Small dataset] Note: MRL applied for is 1.5 mg/kg/ MRL in exporting country is 2 mg/kg.	**1.5**	0.808	0.255
Legume vegetables						
Beans (fresh)	USA	No trials	There was insufficient data to generate an MRL	None proposed	-	-
Cereals						
Wheat	USA	Grain:	GAP in residue trials 2 x 0.05 kg	None proposed	-	-

Crop	Region, field or glasshouse	Trials results relevant to the Global GAP (a)	Recommendation/comments (R_{max}, R_{ber}, OECD calculations, …)	MRL estimated from trials according to cGAP (mg/kg)	HR (mg/kg) (c)	STMR (mg/kg) (b)
		Monitoring: 4 x <0.01, 0.010, 0.015, 0.020, 0.063 Risk assessment: 4x <0.019, 0.019,0.024, 0.030, 0.072	a.i./ha →**Not compliant with authorised cGAP** 2 x 0.025 kg a.i./ha			
		Straw: Monitoring: 0.043, 0.063, 0.113, 0.114, 0.115, 0.222, 0.310, 1.60 Risk assessment:0.072, 0.102, 0.132, 0.137, 0.143, 0.247 , 0.342, 1.65				
Wheat	Canada	Grain: Monitoring: <0.01, 0.012, 0.037 Risk assessment: <0.019, 0.021, 0.046 Pooled data CAN and USA : Monitoring: 5 x <0.01, 0.010, 0.012, 0.015, 0.020, 0.037, 0.063 Risk assessment: 5x <0.019, 0.019,0.021, 0.024, 0.030, 0.046, 0.072	There was insufficient data to generate an MRL for Canada separately. Since US trials were conducted according to the cGAP for Canada, the USA and Canada datasets were pooled. Grain: Unrounded OECD MRL 0.09 Rounded OECD MRL 0.09 Extrapolation is possible to rye, triticale. However, no MRL was applied for and is currently set in the exporting countries for rye grain. Note: MRL applied for in wheat / triticale grain is 0.08 mg/kg. MRLs in exporting countries are 0.08 mg/kg (USA) and 0.1 mg/kg (CAN). In case EU MRLs might be set in feed items in future:	**0.09**	0.072	0.019
		Straw: Monitoring: 0.071, 0.170, 1.34 Risk assessment: 0.103, 0.178, 1.39 Pooled data CAN and USA : Straw: Monitoring: 0.043, 0.063, 0.071, 0.113, 0.114,		**3.0**	1.65	0.143

Crop	Region, field or glasshouse	Trials results relevant to the Global GAP (a)	Recommendation/comments (R_{max}, $R_{ber,}$ OECD calculations, …)	MRL estimated from trials according to cGAP (mg/kg)	HR (mg/kg) (c)	STMR (mg/kg) (b)
		0.115, 0.170, 0.222, 0.310, 1.34, 1.60 Risk assessment:0.072, 0.102, 0.103, 0.132, 0.137, 0.143, 0.178, 0.247 , 0.342, 1.39, 1.65	Straw (wheat / triticale): Unrounded OECD MRL 2.57 Rounded OECD MRL 3.0			
Wheat	Australia, New Zealand	Grain: Monitoring: 8 x <0.01 Risk assessment: 8 x <0.019	6 trials in Australia + 2 trials in New Zealand in accordance with the cGAP. In wheat grain, in all of the trials residues were not detectable (<LOD) at harvest. Extrapolation possible to rye, triticale. Straw: Unrounded OECD MRL 0.3 Rounded OECD MRL 0.3 US/ CAN residue trials more ciritcal.	0.01*	0.019	0.019
		Straw: Monitoring: 3 x < 0.01, 0.015, 2 x 0.02, 0.03, 0.2 Risk assessment: 3 x <0.019, 0.024, 2 x 0.029, 0.039, 0.219		0.3	0.219	0.027
Barley	USA	Grain: Monitoring: 0.033, 0.043, 0.044, 0.048, 0.072, 0.088 Risk assessment: 0.042, 0.052, 0.053, 0.057, 0.088, 0.102	GAP in residue trials 2 x 0.05 kg a.i./ha →**Not compliant with authorised cGAP** 2 x 0.025 kg a.i./ha. There was insufficient data to generate an MRL since 8 trials are required for barley.	None proposed	-	-
		Straw: Monitoring: 0.039, 0.044, 0.186, 0.195, 0.587, 0.699 Risk assessment: 0.051, 0.069, 0.204, 0.217, 0.765, 0.684	However, MRLs are currently not set in feed items in the EU.	None proposed	-	-
Barley	Canada	No trials	US trials were conducted according	None proposed	-	-

Crop	Region, field or glasshouse	Trials results relevant to the Global GAP (a)	Recommendation/comments (R_{max}, R_{ber}, OECD calculations, …)	MRL estimated from trials according to cGAP (mg/kg)	HR (mg/kg) (c)	STMR (mg/kg) (b)
			to the cGAP for Canada. However, there was **insufficient data** to generate an MRL since 8 trials are required in barley.			
Barley	Australia, New Zealand	Grain: Monitoring: 4 x <0.01 Risk assessment: 4 x <0.019	3 trials in Australia + 1 trial in New Zealand in accordance with the cGAP. In all of the trials in wheat and barley grain, residues were not detectable (<LOD) at harvest. Therefore an MRL of 0.01* mg/kg is proposed despite the limited number of trials in barley. Note: MRL applied for is 0.4 mg/kg/ MRL in exporting country (AU) is 0.01* mg/kg. Extrapolation to oats is possible; however an MRL in oats was not applied for. There was **insufficient data** to generate an MRL for barley straw. 8 trials are required for barley. However, MRLs are currently not set in feed items in the EU.	**0.01***	0.019	0.019
		Straw: Monitoring: 2 x <0.01, 0.02, 0.04 Risk assessment: <0.019, 0.019, 0.029, 0.059		None proposed	-	-
Pulses						
Beans (dry)	USA	No trials	There was **insufficient data** to generate an MRL	None proposed	-	-
Oil seed						

Crop	Region, field or glasshouse	Trials results relevant to the Global GAP (a)	Recommendation/comments (R_{max}, R_{ber}, OECD calculations, …)	MRL estimated from trials according to cGAP (mg/kg)	HR (mg/kg) (c)	STMR (mg/kg) (b)
Cotton seed	USA	Monitoring: 0.011, 0.015, 0.017, 0.023, 0.041, 0.176 Risk assessment: 0.020, 0.024, 0.027, 0.033, 0.051, 0.186	Application of 4 x 0.1 kg a.i./ha vs. authorised cGAP 4 x 0.075 kg a.i./ha considered acceptable (+ 25% tolerance) There was insufficient data to generate an MRL. 8 trials are required for cotton seed.	None proposed	-	-
	Australia	Monitoring: <0.01, 0.015, 0.04, 0.08 Risk assessment: <0.019, 0.024, 0.049, 0.089	There was insufficient data to generate an MRL. 8 trials are required for cotton seed.	None proposed	-	-
Oilseed rape	Australia	Monitoring: <0.01, 0.02, 0.06, 0.085 Risk assessment: 0.019, 0.034, 0.104, 0.107	GAP in residue trials 2 x 0.05 kg a.i./ha up to BBCH 89→ **Not compliant with authorised cGAP** 2 x 0.05 kg a.i./ha up to BBCH 65 There was insufficient data to generate an MRL. 8 trials are required for oilseed rape.	None proposed	-	-
	USA	Monitoring: 0.010, 0.017, 0.035, 0.051, 0.085 Risk assessment: 0.027, 0.045, 0.079, 0.089, 0.094	GAP in residue trials 2 x 0.05 kg a.i./ha up to BBCH 89→ **Not compliant with authorised cGAP** 2 x 0.026 kg a.i./ha There was insufficient data to generate an MRL. 8 trials are required for oilseed rape.	None proposed	-	-
	Canada	Monitoring: 0.042, 0.047, 0.072 Risk assessment: 0.052, 0.056, 0.082	There was insufficient data to generate an MRL for Canada separately. Since the US trials were conducted according to the cGAP for	**0.1**	0.094	0.068

Crop	Region, field or glasshouse	Trials results relevant to the Global GAP (a)	Recommendation/comments (R_{max}, $R_{ber,}$ OECD calculations, …)	MRL estimated from trials according to cGAP (mg/kg)	HR (mg/kg) (c)	STMR (mg/kg) (b)
		Pooled data CAN and USA : Monitoring: 0.010, 0.017, 0.035, 0.042, 0.047, 0.051, 0.072, 0.085 Risk assessment: 0.027, 0.045, 0.052, 0.056, 0.079, 0.082, 0.089, 0.094	Canada, the USA and Canada datasets were pooled. Unrounded OECD MRL 0.15 Rounded OECD MRL 0.15 Note: MRL applied for is 0.3 mg/kg. MRL in exporting country is 0.1 mg/kg. Therefore, an MRL of 0.1 is proposed. No data available on forage.			
Soya bean	USA	Monitoring: 6x <0.01, 0.010, 2 x 0.013, 0.017, 0.030, 2 x 0.034, , 0.085, 0.198 Risk assessment: 6x <0.019, 0.019, 0.022, 0.023, 0.026, 0.039, 0.043, 0.044, 0.089, 0.094, 0.224	Application of 4 x 0.1 kg a.i./ha vs. authorised cGAP 4 x 0.075 kg a.i./ha considered acceptable (+ 25% tolerance) Unrounded OECD MRL 0.23 Rounded OECD MRL 0.30 Note: MRL applied for and MRL in exporting country is 0.2 mg/kg. Therefore, an MRL of 0.2 is proposed.	**0.2**	0.224	0.023
Note: The MRL values that are highlighted in bold are the MRLs proposed to cover the particular crop/commodity. The OECD calculator was used to calculate all the MRLs, HR and STMR values in the above table.						

(a): Numbers of trials in which particular residue levels were reported *e.g.* 3x <0.01, 0.01, 6x 0.02, 0.04, 0.08, 3x 0.10, 2x 0.15, 0.17

(b): Supervised Trials Median Residue *i.e.* the median residue level estimated on the basis of supervised trials relating to the representative use

(c): Highest residue

Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8)[7]

Note: A theoretical factor of 2 may be applied to the estimates given below, in order to take into account for the uncertainty concerning the unknown ratio of enantiomers present in the individual diastereomers of sulfoxaflor and of X11719474, respectively.

For representative uses in the peer review only

ADI	0.04 mg/kg bw per day
TMDI (% ADI) according to WHO European diet	0.3% (WHO Regional European Diet)
TMDI (% ADI) according to national (to be specified) diets	EFSA Primo Model (Version 2): 1% (FR toddler, UK Infant)
IEDI (WHO European Diet) (% ADI)	EFSA Primo Model (Version 2) – using the values calculated for risk assessment purposes: 2% (DK child) 1% (FR toddler)
NEDI (specify diet) (% ADI)	Not required.
Factors included in IEDI and NEDI	Not applicable.
ARfD	0.25 mg/kg bw.
IESTI (% ARfD)	IESTI 1 – using the values calculated for risk assessment purposes: 4% (Peppers) 4% (Melons) The IESTI was lower for all other crops.
NESTI (% ARfD) according to national (to be specified) large portion consumption data	Re-calculation was not necessary.
Factors included in IESTI and NESTI	None

[7] To be done on the basis of WHO guidelines and recommendations with the deviations within the EU so far accepted (especially diets).

Risk assessment for all uses for which an MRL was proposed on the basis of either the peer review or the MRL application

ADI	0.04 mg/kg bw per day
TMDI (% ADI) according to WHO European diet	15% (WHO Cluster diet B)
TMDI (% ADI) according to national (to be specified) diets	EFSA Primo Model (Version 2): 28% (DE child)
IEDI (WHO European Diet) (% ADI)	Re-calculation was not necessary.
NEDI (specify diet) (% ADI)	Not required.
Factors included in IEDI and NEDI	Not applicable.
ARfD	0.25 mg/kg bw.
IESTI (% ARfD)	IESTI 1 : 45% Table grapes (DE child) 31% Lettuce (DE child) 27% Spinach (BE child) 22 % Chinese cabbage (NL child)

	12% Broccoli (BE child) The IESTI was lower for all other crops.
NESTI (% ARfD) according to national (to be specified) large portion consumption data	Re-calculation was not necessary.
Factors included in IESTI and NESTI	None

Processing factors (Regulation (EU) N° 544/2011, Annex Part A, point 6.5, Regulation (EU) N° 545/2011, Annex Part A, point 8.4)

Crop/ process/ processed product	Number of studies	Processing Factor (PF)		Conversion factor[a]
		Individual values	Median PF	
Barley grain → pearl barley, pot barley, bran, flour, cleaned barley, brewing malt, malt sprouts, beer, spent grains and brewer's yeast (Parent sulfoxaflor results only)	2	1.0,0.7 (pearl barley)	0.85	NA
		1.0, 0.9 (pot barley)	0.95	NA
		2.5, 1.0 (bran)	1.75	NA
		0.9, 0.8 (flour)	0.85	NA
		1.3, 0.9 (cleaned barley)	1.1	NA
		0.9, 0.9 (brewing malt)	0.9	NA
		1.3, 1.3 (malt sprouts)	1.3	NA
		0.1, 0.2 (beer)	0.15	NA
		0.1, 0.2 (spent grain)	0.15	NA
		0.2, 0.1 (brewer's yeast)	0.15	NA
Cotton seed → aspirated seed fractions, delinted seed, hulls, meal, meal presscake, crude oil, and refined oil (Parent sulfoxaflor results only)	1	23 (aspirated seed fractions)	23	NA
		1.0 (delinted seed)	1.0	NA
		1.8 (hulls)	1.8	NA
		0.8 (meal)	0.8	NA
		0.8 (meal presscake)	0.8	NA
		<0.1 (crude oil)	<0.1	NA
		<0.1 (refined oil)	<0.1	NA
Tomatoes → washed and peeled tomatoes, juice, canned tomatoes, puree, paste, and ketchup (Parent sulfoxaflor results only)	2	0.5, 0.8, 1.2 (fruit washed and peeled)	0.8	NA
		0.6, 1.0, 1.0 (juice)	1.0	NA
		0.2, 0.4, 0.8 (canned)	0.4	NA
		1.4, 2.2, 2.1 (ketchup)	2.1	NA
		1.0, 1.6, 2.0 (puree)	1.6	NA
		2.7, 4.9, 4.4 (paste)	4.4	NA
Wheat grain → cleaned grain, coarse bran, fine bran, total bran (combined coarse and fine bran), germ, middlings, shorts, whole meal flour, refined flour, whole grain bread and white bread from refined flour. (Parent sulfoxaflor results only)	2 (3 trials)	21 (aspirated grain fraction)	21	NA
		0.3, 1.0 (clean grain)	0.65	NA
		1.0, 3.1 (coarse bran)	2.1	NA
		0.3, 1.0 (fine bran)	0.65	NA
		0.4, 1.0, 3.1 (total bran)	1.0	NA
		0.5, 0.8, 2.8 (germ)	0.8	NA
		0.08, 0.2, 0.3 (middlings)	0.2	NA
		0.2, 0.6, 1.2 (shorts)	0.6	NA
		0.2, 0.4, 1.0 (whole meal flour)	0.4	NA
		0.05, <0.2, 0.2 (refined flour)	0.2	NA
		<0.2, 0.2, 0.6 (whole grain bread)	0.2	NA
		0.04, 0.1, <0.2, (white	0.1	NA

		bread)		
		<0.2 (gluten)	<0.2	NA
		<0.2 (gluten feed meal)	<0.2	NA
		<0.2 (starch)	<0.2	NA

[a]: When the residue definition for risk assessment differs from the residue definition for monitoring

Proposed MRLs (Annex IIA, point 6.7, Annex IIIA, point 8.6)

Code[(a)]	Commodity	MRL[(b)] (mg/kg)	Comments/Observations
Plant products			
Representative uses – European GAP			
0231010	Tomatoes (outdoor & indoor)	0.06	A higher MRL is proposed on the basis of the MRL application for an import tolerance.
0231030	Aubergines (outdoor & indoor)	0.06	Extrapolated from tomatoes.
0231020	Peppers (outdoor & indoor)	0.15	A higher MRL is proposed on the basis of the MRL application for an import tolerance.
0232010	Cucumbers (outdoor & indoor)	0.03	
0232030	Courgettes (outdoor & indoor)	0.03	Extrapolated from cucumber.
0233010	Melons (outdoor & indoor)	0.02	
0233030	Watermelons (outdoor & indoor)	0.02	Extrapolated from melon
0500090	Wheat (Spelt /Triticale) grain	0.015	A higher MRL is proposed on the basis of the MRL application for an import tolerence.
0500070	Rye grain	0.015	Extrapolated from wheat grain
0500010	Barley grain	0.04	
0500050	Oats	0.04	Extrapolated from barley grain
0401090	Cotton seed	0.01*	SEU only.
MRL application			
0120010	Almonds	0.01*	
0120080	Pecans	0.01*	
0130010	Apple	0.4	
0130020	Pear	0.4	
0140010	Apricots	0.5	
0140030	Peaches (Nectarines and similar hybrids)	0.5	
0151010	Table grapes	2.0	
0151020	Wine grapes	0.01*	
0152000	Strawberries	0.5	
0211000	Potatoes	0.01*	
0231010	Tomatoes	0.3	
0231020	Peppers	0.4	

0241010	Broccoli	0.7	
0243010	Mustard greens	2.0	
0251020	Lettuce	4.0	
0252010	Spinach (leaf)	6.0	
0256030	Celery (leaf)	1.5	
0401060	Rape seed	0.1	
0401070	Soya bean (seeds)	0.2	
0500090	Wheat grain	0.09	
0500010	Barley grain	0.01*	A higher MRL is proposed on the basis of the representative uses in the peer review.
Animal products – representative uses – European GAP			
1030000	Eggs	0.01*	Poultry
1016030	Liver	0.01*	
1016010	Muscle	0.01*	
1016020	Fat	0.01*	
1020000	Milk	0.01*	Ruminant (bovine, sheep, goat, horse and other farm animals) There are different commodity code numbers depending on whether the commodity is from bovine, sheep, goat or horse.
	Liver	0.02	
	Muscle	0.01*	
	Fat	0.01*	
	Kidney	0.015	
Animal products – MRL application			
1030000	Eggs	0.01*	Poultry
1016030	Liver	0.01*	
1016010	Muscle	0.01*	
1016020	Fat	0.01*	
1020000	Milk	0.03	Ruminant (bovine, sheep, goat, horse) There are different commodity code numbers depending on whether the commodity is from bovine, sheep, goat or horse.
	Liver	0.2	
	Muscle	0.07	
	Fat	0.04	
	Kidney	0.1	
1011020	Swine fat	0.01*	Pig
1011010	Swine meat	0.01*	
1011030	Swine liver	0.015	
1011040	Swine kidney	0.01	

When the MRL is proposed at the LOQ, this should be annotated by an asterisk after the figure.

Fate and Behaviour in the Environment

Route of degradation (aerobic) in soil (Annex IIA, point 7.1.1.1.1)

Mineralisation after 100 days ‡	3.9- 20.1 % after 99d, [^{14}C-pyridine]-label (n[10]= *4*) Sterile conditions: 0.2% after *90*d (n= *1*)
Non-extractable residues after 100 days ‡	3.7-11.2% after 99 d, [^{14}C-pyridine]-label (n= *4*) Sterile conditions: 5% after 90d (n= *120*)
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	X11719474 –*95.9-98.6* at *1* d (n= *4*) X11519540 –2.1-10.9 % at *81-123* d (n= *4*) X11579457 –0.9-8.5 % at 62-81d(n= *4*) [^{14}C-pyridine] label

Route of degradation in soil - Supplemental studies (Annex IIA, point 7.1.1.1.2)

Anaerobic degradation ‡

Mineralisation after 100 days	*up to* 0.3% after *4* d (after flooding), [^{14}C-pyridine]-label (n= *1*)
Non-extractable residues after 100 days	12.1 % after 120 d (after flooding), [^{14}C-pyridine]-label (n= *1*)
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	X11719474 *97.8* % at *4* d (after flooding);(n= *1*) [^{14}C-Pyridine] label

Soil photolysis ‡

Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	None – the experiment on soil photolysis demonstrated that sulfoxaflor would not undergo photodegradation on the soil surface; the same can be stated for its major soil metabolite – X11719474.

[10] n corresponds to the number of soils.

Rate of degradation in soil (Annex IIA, point 7.1.1.2, Annex IIIA, point 9.1.1)

Laboratory studies ‡

Sulfoxaflor	Aerobic conditions

Soil		Soil properties		Incubation conditions		Kinetic model	Kinetic parameter		Evaluation of the fit			Kinetic endpoints	
Name	*Type (USDA classif.)*	*pH*	*OC [%]*	*T [^{0}C]*	*moist. cont. [% WHC]*		*param.*	*value*	*Visual fit*	R^2	χ^2 *% error*	DT_{50} *[days]*	DT_{90} *[days]*
Cranwell	Loamy sand	7.6	1.3	20	40 (pF2)	SFO	*k*	8.5	Very good	1.00	0.8	0.082	0.27
Aberford	Sandy clay loam	7.3	6.7	20	40 (pF2)	SFO	*k*	15.6	Very good	1.00	1.9	0.044	0.15
Malham	Sandy loam	6.2	3.5	20	40 (pF2)	SFO	*k*	16.9	Very good	1.00	1.9	0.041	0.14
LUFA 5M	Sandy loam	7.4	1.2	20	40 (pF2)	SFO	*k*	2.7	Good	0.99	3.5	0.26	0.87
Geometric mean (n = 4)												**0.078**	**0.26**

Degradation at T = 10^{0}C and in sterile soil.

Soil		Soil properties		Incubation conditions		Kinetic model	Kinetic parameter		Evaluation of the fit			Kinetic endpoints	
Name	*Type (USDA classif.)*	*pH*	*OC [%]*	*T [^{0}C]*	*moist. cont. [% WHC]*		*param.*	*value*	*Visual fit*	R^2	χ^2 *% error*	DT_{50} *[days]*	DT_{90} *[days]*
Aberford; biologically viable soil	Sandy clay loam	7.3	6.7	10	40 (pF2)	SFO	*k*	5.0	Good	1.000	1.0	0.13	0.46
Aberford; sterilised soil	Sandy clay loam	7.3	6.7	20	40 (pF2)	FOMC	α	0.93	Good	0.984	6.1	12.87	127.07

X11719474	Aerobic conditions (kinetic fits from experiments where parent sulfoxaflor was the precursor dosed)

Soil		Soil properties		Incubation conditions		Kinetic model	Kinetic parameter		Evaluation of the fit			Kinetic endpoints	
Name	*Type (USDA classif.)*	*pH*	*OC [%]*	*T [^{0}C]*	*moist. cont. [% WHC]*		*ff from parent*	*k value*	*Visual fit*	R^2	χ^2 *% error*	DT_{50} *[days]*	DT_{90} *[days]*
Cranwell	Loamy sand	7.6	1.3	20	40 (pF2)	SFO	*0.98*	0.0025	Very good	0.984	3.5	281.95	936.61
Aberford	Sandy clay loam	7.3	6.7	20	40 (pF2)	SFO	*0.94*	0.0082	Very good	0.987	4.8	84.58	280.97
Malham	Sandy loam	6.2	3.5	20	40 (pF2)	SFO	*0.944*	0.0019	Very good	0.996	1.3	370.38	1121.10
LUFA 5M	Sandy loam	7.4	1.2	20	40 (pF2)	SFO	*0.996*	0.0025	Very good	0.986	3.0	274.27	911.10
Geometric mean (n = 4)												**221.85**	**734.20**

X11719474	Aerobic conditions (kinetic fits from experiments where parent sulfoxaflor was the precursor dosed)

Degradation at T = 10^0C and in sterile soil.

Soil		Soil properties		Incubation conditions		Kinetic model	Kinetic parameter		Evaluation of the fit			Kinetic endpoints	
Name	*Type (USDA classif.)*	*pH*	*OC [%]*	*T [^{0}C]*	*moist. cont. [% WHC]*		*param.*	*value*	*Visual fit*	*R^2*	*χ^2 % error*	*DT_{50} [days]*	*DT_{90} [days]*
Aberford; biologically viable soil	Sandy clay loam	7.3	6.7	10	40 (pF2)	SFO	*k*	0.0038	Good	0.996	1.3	184	612
Aberford; sterilised soil	Sandy clay loam	7.3	6.7	20	40 (pF2)	Not determined – the decline phase was not reached							

X11519540	Aerobic conditions (metabolite dosed)

Soil		Soil properties		Incubation conditions		Kinetic model	Kinetic parameter		Evaluation of the fit			Kinetic endpoints	
Name	*Type (USDA classif.)*	*pH*	*OC [%]*	*T [^{0}C]*	*moist. cont. [% WHC]*		*param.*	*value*	*Visual fit*	*R^2*	*χ^2 % error*	*DT_{50} [days]*	*DT_{90} [days]*
Cranwell	Loamy sand	7.6	1.3	20	40 (pF2)	Pseudo-SFO (slow phase of the HS)	k_2	0.0022	Good	0.992	2.46	315.07	1046.63
Aberford	Sandy clay loam	7.3	6.7	20	40 (pF2)	Pseudo-SFO (slow phase of the HS)	k_2	6.0 E-4	Good	0.838	3.02	1155.24	3837.62
Malham	Sandy loam	6.2	3.5	20	40 (pF2)	Pseudo-SFO (slow phase of the HS)	k_2	6.1 E-4	Good	0.938	1.79	1136.31	3774.73
LUFA 5M	Sandy loam	7.4	1.2	20	40 (pF2)	Pseudo-SFO (slow phase of the HS)	k_2	0.0070	Good	0.918	7.18	99.02	328.94
Geometric mean (n = 4)												**449.86**	**1494.39**
Cranwell	Loamy sand	7.6	1.3	20	40 (pF2)	HS	*Overall fit*					0.31	>130
LUFA 5M	Sandy loam	7.4	1.2	20	40 (pF2)	HS	*Overall fit*					75	329

X11579457	Aerobic conditions (metabolite dosed)

Soil		Soil properties		Incubation conditions		Kinetic model	Kinetic parameter		Evaluation of the fit			Kinetic endpoints	
Name	*Type (USDA classif.)*	*pH*	*OC [%]*	*T [^{0}C]*	*moist. cont. [% WHC]*		*param.*	*value*	*Visual fit*	*R^2*	*χ^2 % error*	*DT_{50} [days]*	*DT_{90} [days]*
Cranwell	Loamy sand	7.6	1.3	20	40 (pF2)	Pseudo-SFO (slow phase of the HS)	k_2	0.0022	Good	0.973	1.03	315.07	1046.63
Aberford	Sandy clay loam	7.3	6.7	20	40 (pF2)	Pseudo-SFO (slow phase of the HS)	k_2	0.0080	Good	0.982	3.45	86.64	287.82
Malham	Sandy loam	6.2	3.5	20	40 (pF2)	Pseudo-SFO (slow phase of the HS)	k_2	0.0054	Good	0.926	6.30	128.36	426.40
LUFA 5M	Sandy loam	7.4	1.2	20	40 (pF2)	Pseudo-SFO (slow phase of the HS)	k_2	0.0020	Inter-mediate	0.757	5.57	346.57	1151.29
Geometric mean (n = 4)												**186.67**	**620.12**

Field studies ‡

Sulfoxaflor	Aerobic conditions

Best fit results:

Trial	Soil type (USDA classification)	Soil properties		Kinetic model	Kinetic parameter		Evaluation of the fit			Kinetic endpoints	
		pH	*OC [%]*		*parameter*	*value*	*Visual fit[1)]*	*R^2*	*χ^2 % error*	*DT_{50} [days]*	*DT_{90} [days]*
CEMS-3990A	Silt loam	5.9	1.2	Fit not found	----	----	----	----	----	----	----
CEMS-3990B	Clay loam	7.1	2.2	SFO – stand alone	*k*	0.3665	I.	0.6392	19.18	1.89	6.28
CEMS-3990C	Clay loam	7.4	0.8	Fit not found	----	----	----	----	----	----	----
CEMS-3990D	Loam	7.2	1.3	SFO – stand alone	*k*	0.2115	I	0.8357	16.85	3.28	10.88
CEMS-4012A	Silt loam	5.9	1.2	SFO – stand alone	*k*	0.4753	G	0.8740	26.65	1.46	4.84
CEMS-4012B	Clay loam	7.1	2.2	SFO – stand alone	*k*	0.0933	G	0.9958	4.21	7.43	24.68
CEMS-4012C	Clay loam	7.4	0.8	SFO – stand alone	*k*	0.1729	I	0.7470	17.50	4.01	13.32
CEMS-4012D	Loam	7.2	1.3	SFO – stand alone	*k*	0.2201	I	0.7636	17.98	3.15	10.46

1) Following abbreviations were used: I – intermediate; G- good, VG – very good;

X11719474	Aerobic conditions (kinetic fits from experiments where parent sulfoxaflor was the precursor dosed)

Best-fit results:

Trial	Soil type (USDA classification)	Soil properties		Kinetic model	Kinetic parameter		Evaluation of the fit			Kinetic endpoints	
		pH	*OC [%]*		*parameter*	*value*	*Visual fit*[1)]	R^2	χ^2 *% error*	DT_{50} *[days]*	DT_{90} *[days]*
CEMS-3990A	Silt loam	5.9	1.2	DFOP; top down approach	k_1	0.0803	G	0.9265	18.57	8.91	31.29
					k_2	0.0023				301.37[2)]	1001.12[2)]
					g	0.9777					
					Overall fit					8.91	750
CEMS-3990B	Clay loam	7.1	2.2	SFO top down	*k*	0.0364	G	0.8731	24.97	19.06	63.33
CEMS-3990C	Clay loam	7.4	0.8	DFOP; top down approach	k_1	1.7119	VG	0.9876	12.51	0.43	1.68
					k_2	0.0053				130.78[2)]	434.45[2)]
					g	0.9531					
					Overall fit					0.43	180
CEMS-3990D	Loam	7.2	1.3	DFOP; top down approach	k_1	0.6046	G	0.9451	23.50	1.15	3.87
					k_2	0.0018				385.08[2)]	1279.21[2)]
					g	0.9959					
					Overall fit					1.15	480
CEMS-4012A	Silt loam	5.9	1.2	DFOP; top down approach	k_1	0.0794	G	0.9444	14.70	11.99	363.29
					k_2	0.0018				385.08[2)]	1279.21[2)]
					g	0.8074					
					Overall fit					11.99	550
CEMS-4012B	Clay loam	7.1	2.2	DFOP; top down approach	k_1	0.1787	G	0.9599	15.40	5.47	227.62
					k_2	0.0031				223.60[2)]	742.77[2)]
					g	0.7958					
					Overall fit					5.47	295
CEMS-4012C	Clay loam	7.4	0.8	SFO top down	*k*	0.0071	G	0.9265	18.84	97.34	323.37
CEMS-4012D	Loam	7.2	1.3	DFOP; top down approach	k_1	0.3707	VG	0.9969	6.15	1.93	6.80
					k_2	0.0040				173.29[2)]	575.65[2)]
					g	0.9779					
					Overall fit					1.93	410

1) Following abbreviations were used: I – intermediate; G- good, VG – very good;
2) The value for the k_2 representing the slow phase of the DFOP fit.

Modelling kinetic endpoints (normalised to standard conditions of T = 20^{0}C and pF2 using Q_{10} = 2.58 and Walker factor β = 0.7):

Trial	Soil type (USDA classification)	Soil properties		Kinetic model	Kinetic parameter		Evaluation of the fit			Kinetic endpoints	
		pH	*OC [%]*		*parameter*	*value*	*Visual fit*[1)]	R^2	χ^2 *% error*	DT_{50} *[days]*	DT_{90} *[days]*
CEMS-3990A	Silt loam	5.9	1.2	SFO – top-down approach	*k*	0.0085	G	0.9472	12.47	81.15	269.58
CEMS-3990B	Clay loam	7.1	2.2	SFO – top-down approach	*k*	0.0497	I	0.9091	21.23	13.95	46.35
CEMS-3990C	Clay loam	7.4	0.8	SFO – refined top-down approach	*k*	0.0050	I	0.8832	24.11	138.16	458.97
CEMS-3990D	Loam	7.2	1.3	Fit not found	*k*	----	----	----	----	----	----
CEMS-4012A	Silt loam	5.9	1.2	SFO – fitted with parent	*k*	0.0090	I	0.6631	36.49	76.92	255.52
CEMS-4012B	Clay loam	7.1	2.2	SFO – refined top-down approach	*k*	0.0122	I	0.7543	21.47	56.86	188.90
CEMS-4012C	Clay loam	7.4	0.8	SFO – top-down approach	*k*	0.0048	I	0.8431	27.62	145.02	481.73
CEMS-4012D	Loam	7.2	1.3	SFO – refined top-down approach	*k*	0.0044	VG	0.9861	5.75	156.12	518.62
Geometric mean (n = 7)										**76.61**	**254.50**

1) Following abbreviations were used: I – intermediate; G- good, VG – very good;

X11519540	Aerobic conditions (metabolite applied as test substance)

Modelling kinetic endpoints (normalised to standard conditions of T = 20^{0}C and pF2 using Q_{10} = 2.58 and Walker factor β = 0.7):

Trial	Soil type (USDA classification)	Soil properties		Kinetic model	Kinetic parameter		Evaluation of the fit			Kinetic endpoints	
		pH	*OC [%]*		*parameter*	*value*	*Visual fit*[1)]	R^2	χ^2 *% error*	DT_{50} *[days]*	DT_{90} *[days]*
CEMS-4993A	Silt loam	5.30	0.95	SFO	*k*	0.02571	G	0.826	14.06	27.0	90.0
CEMS-4993B	Silt loam	6.65	0.76	SFO	*k*	0.01892	G	0.879	11.55	36.6	122.0
CEMS-4993C	Loam	7.61	0.58	SFO	*k*	0.007286	I	0.659	19.04	95.1	316.0
CEMS-4993E	Silty clay	7.63	0.63	SFO	*k*	0.0243	G	0.908	14.09	28.5	94.8
Geometric mean (n = 4)										**40.5**	**135**

1) Following abbreviations were used: I – intermediate; G- good, VG – very good;

pH dependence ‡ (yes / no) (if yes type of dependence)	No
Soil accumulation and plateau concentration ‡	The results of the studies on soil accumulation at two European sites indicated that there was no accumulation of sulfoxaflor, X11519540 or X11579457 throughout the study duration (5 years) in any of the trials. As for the primary degradation product – X11719474, no clear accumulation pattern was observed throughout the study duration (5 years) in any of the trials. Depending on the application rate the relatively constant background concentrations of this compound werefollowing: - ~5 µg/kg soil (range 4-6 µg/kg soil), reached after 1-2 years after application for the application rate 24 g sulfoxaflor/ha; - ~10 µg/kg soil, reached after 2 years in one of the trials with application rate 48 g sulfoxaflor/ha; - ~5 µg/kg soil, reached in the second of the trials with application rate of 48 g sulfoxaflor/ha; It was therefore stated to consider the results of the model calculations (PEC_{SOIL}) as the definitive ones.

Soil kinetic endpoints for the exposure assessment:

Type of assessment	Compound	Recommended kinetic endpoints					
		Kinetic parameter		*DT_{50} [days]*	*DT_{90} [days]*	*Type of value*[1)]	*Kinetic model*
		symbol	value				
Soil exposure assessment (PEC_{SOIL})	***Sulfoxaflor***	*k*	***0.0933***	**7.43**	**24.68**	Longest field value; best-fit	SFO
	X11719474	k_2	***0.0018***	**385.08**	**1279.21**	Longest field value; best-fit	Pseudo-SFO (Slow-phase DFOP)
	X11519540	k_2	***6.4 E-4***	**1155.24**	**3837.62**	longest laboratory value	Pseudo-SFO (slow-phase HS)
	X11579457	k_2	***0.0020***	**346.57**	**1151.29**	longest laboratory value	Pseudo-SFO (slow-phase HS)
Groundwater exposure assessment (PEC_{GW})	***Sulfoxaflor***	*k*	***8.8196***	**0.078**	**0.26**	Geomean laboratory value	SFO
	X11719474	*k*	***0.0090***	**76.61**	**254.50**	Geomean field value	SFO
	X11519540	*k*	***0.01711***	**40.5**	**135**	Geomean field value-	SFO
	X11579457	k_2	***0.0037***	**186.67**	**620.12**	Geomean laboratory value	Pseudo-SFO (slow-phase HS)
Surface Water exposure assessment (PEC_{SW}/PEC_{SED})	***Sulfoxaflor***	*k*	***8.8196***	**0.078**	**0.26**	Geomean laboratory value	SFO
	X11719474	*k*	***0.0031***	**221.85**	**734.20**	Geomean laboratory value	SFO
		k	***0.0090***	**76.61**	**254.50**	Geomean field value - refinement	SFO
	X11519540	k_2	***0.0015***	**449.86**	**1494.39**	Geomean laboratory value	Pseudo-SFO (slow-phase HS)
	X11519540	*k*	***0.01711***	**40.5**	**135**	Geomean laboratory value	SFO
	X11579457	k_2	***0.0037***	**186.67**	**620.12**	Geomean laboratory value	Pseudo-SFO (slow-phase HS)

1) All values recommended for GW and SW exposure assessment are normalised.

Laboratory studies ‡

Sulfoxaflor	Anaerobic conditions (initiated 2 hours after dosing): Rapid transformation, but reliable kinetic endpoints not available

Sulfoxaflor	soil photolysis

Process: soil photolysis:												
Soil		**Soil properties**		**Incubation conditions**	**Kinetic model**	**Kinetic parameter**		**Evaluation of the fit**			**Kinetic endpoints**	
Name	***Type (USDA classif.)***	***pH***	***OC [%]***			***param.***	***value***	***Visual fit***	***R^2***	***χ^2 % error***	***DT_{50} [days]***	***DT_{90} [days]***
Lenawee	Clay loam	5.5	1.8	Irradiated, T = 30^{0}C, pF2.5	SFO	*k*	0.011[1)]	Inter-mediate	0.466	9.8	63.01	209.33
				Dark control, T = 30^{0}C, pF2.5	SFO	*k*	2.2	Good	0.998	2.2	0.31	1.05

1) The degradation rate constant after correction to represent the value expected for summer sunny day at 40^{0}N;

X11719474	Anaerobic conditions: Slow transformation, but reliable kinetic endpoints not available

X11719474	soil photolysis (kinetic fits from experiments where parent sulfoxaflor was the precursor dosed)

Process: soil photolysis:												
Soil		**Soil properties**		**Incubation conditions**	**Kinetic model**	**Kinetic parameter**		**Evaluation of the fit**			**Kinetic endpoints**	
Name	***Type (USDA classif.)***	***pH***	***OC [%]***			***param.***	***value***	***Visual fit***	R^2	χ^2 *% error*	***DT_{50} [days]***	***DT_{90} [days]***
Lenawee	Clay loam	5.5	1.8	Irradiated, T = 30°C, pF2.5	Not determined – the decline phase was not reached							
				Dark control, T = 30°C, pF2.5	SFO	*k*	0.0020	Good	0.739	0.14	354	1151.29

1) The degradation rate constant after correction to represent the value expected for summer sunny day at 40°N;

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Sulfoxaflor

Adsorption:

Soil				**Adsorption parameters**					
Soil name	***Soil type (USDA classification)***	***pH***	***OC [%]***	**Distribution constants**		***Freundlich isotherm's parameters***			
				K_d [mL/g]	K_{dOC} [mL/g]	K_f [mL/g]	K_{fOC} [mL/g]	1/n	R^2
M761 – Cranwell	Loamy sand	7.6	1.3	***0.29***	***22.31***	0.29	22	1.06	0.966
M762 – Aberford	Loam	7.3	6.7	***0.93***	***13.88***	0.81	12	0.96	0.999
M763 – Malham	Silt loam	6.2	3.5	***0.47***	***13.43***	0.40	12	0.95	0.999
M764 – LUFA 5M	Sandy loam	7.4	1.2	***0.32***	***26.67***	0.30	25	1.02	0.997
M768 – Lenawee	Clay loam	5.9	1.8	***0.66***	***36.67***	0.56	31	0.96	1.000
M770 – Pullman (2)	Clay loam	6.9	1.2	***0.61***	***50.83***	0.57	47	0.99	1.000
M771 – Fayette	Loam	6.3	1.1	***0.63***	***57.27***	0.54	49	0.96	1.000
M772 – Slagle	Sandy loam	6.4	1.0	***0.37***	***37.00***	0.33	33	0.98	0.998
M775 – Italy	Sandy clay loam	7.4	1.3	***0.45***	***34.62***	0.40	31	0.97	0.999
M776 – Spain	Clay loam	7.8	1.2	***0.37***	***30.83***	0.35	30	1.00	0.996
M780 – France	Clay loam	7.8	1.7	***0.43***	***25.29***	0.34	20	0.95	0.993
M781 – Germany	Silt loam	6.3	1.1	***0.31***	***28.18***	0.26	24	0.93	0.998
M773 – California	Sand	6.3	0.3	***0.25***	***83.33***	0.16	54	0.89	0.964
M774 – Florida	Loamy sand	6.2	0.8	***0.57***	***71.25***	0.43	53	0.91	0.999
M777 – Bearden-Lindaas	Clay	7.9	1.8	***1.29***	***71.67***	1.28	71	0.98	1.000
M778 – Pullman (3)	Clay loam	6.7	1.1	***0.58***	***52.73***	0.51	46	0.97	1.000
M779 – Lacustrine	Loam	6.9	1.8	***0.68***	***37.78***	0.52	29	0.93	0.998
			Average	***0.54***	***40.81***	**0.47**	**35**	**0.96**	**0.995**
SD				***0.26***	***20.61***	**0.26**	**16**	**0.04**	**0.011**
Minimum				***0.25***	***13.43***	**0.16**	**12**	**0.89**	**0.964**
Maximum				***1.29***	***83.33***	**1.28**	**71**	**1.06**	**1.000**

pH dependence, Yes or No	No

X11719474:

Soil				**Adsorption parameters**					
Soil name	***Soil type (USDA classification)***	***pH***	***OC [%]***	**Distribution constants**		***Freundlich isotherm's parameters***			
				K_d [mL/g]	K_{dOC} [mL/g]	K_f [mL/g]	K_{fOC} [mL/g]	1/n	R^2
M761 – Cranwell	Loamy sand	7.6	1.3	***0.2***	***15.38***	0.18	14	1.03	0.963
M762 – Aberford	Loam	7.3	6.7	***0.5***	***7.46***	0.47	7	1.00	0.999
M763 – Malham	Silt loam	6.2	3.5	***0.29***	***8.29***	0.29	8	1.03	0.997
M764 – LUFA 5M	Sandy loam	7.4	1.2	***0.26***	***21.67***	0.21	18	0.94	0.985
M768 – Lenawee	Clay loam	5.9	1.8	***0.52***	***28.89***	0.44	24	0.99	0.997
M770 – Pullman (2)	Clay loam	6.9	1.2	***0.51***	***42.50***	0.48	40	0.99	0.999
M771 – Fayette	Loam	6.3	1.1	***0.64***	***58.18***	0.55	50	0.98	0.999
M772 – Slagle	Sandy loam	6.4	1.0	***0.24***	***24.00***	0.21	21	1.01	0.992
M775 – Italy	Sandy clay loam	7.4	1.3	***0.44***	***33.85***	0.41	31	1.00	0.997
M776 – Spain	Clay loam	7.8	1.2	***0.27***	***22.50***	0.25	21	0.98	0.996
M780 – France	Clay loam	7.8	1.7	***0.31***	***18.24***	0.25	14	0.95	0.992
M781 – Germany	Silt loam	6.3	1.1	***0.24***	***21.82***	0.19	18	0.95	0.988
M773 – California	Sand	6.3	0.3	***0.23***	***76.67***	0.22	74	1.03	0.992
M774 – Florida	Loamy sand	6.2	0.8	***0.28***	***35.00***	0.24	30	0.98	0.996
M777 – Bearden-Lindaas	Clay	7.9	1.8	***1.32***	***73.33***	1.24	69	1.00	1.000
M778 – Pullman (3)	Clay loam	6.7	1.1	***0.54***	***49.09***	0.49	45	0.99	1.000
M779 – Lacustrine	Loam	6.9	1.8	***0.44***	***24.44***	0.41	23	1.03	0.994
Average				***0.42***	***33.02***	**0.38**	**30**	**0.99**	**0.992**
SD				***0.27***	***20.69***	**0.25**	**20**	**0.03**	**0.01**
Minimum				***0.20***	***7.46***	**0.18**	**7**	**0.94**	**0.963**
Maximum				***1.32***	***76.67***	**1.24**	**74**	**1.03**	**1.000**

pH dependence, Yes or No	No

X11519540:

Soil				Adsorption parameters					
Soil name	*Soil type (USDA classification)*	*pH*	*OC [%]*	Distribution constants		*Freundlich isotherm's parameters*			
				K_d [mL/g]	K_{dOC} [mL/g]	K_f [mL/g]	K_{fOC} [mL/g]	1/n	R^2
M761 – Cranwell	Loamy sand	7.6	1.3	0.04	3	0.01	1	1.35	0.856
M762 – Aberford	Loam	7.3	6.7	0.28	4	0.39	6	0.79	0.825
M763 – Malham	Silt loam	6.2	3.5	0.20	5	0.22	6	0.96	0.976
M768 – Lenawee	Clay loam	5.9	1.8	0.31	17	0.36	20	0.92	0.931
M770 – Pullman (2)	Clay loam	6.9	1.2	**0.26**	**22**	0.29	24	1.01	0.995
M771 – Fayette	Loam	6.3	1.1	0.31	29	0.28	25	1.04	0.993
			Average	**0.23**	**13.3**	**0.26**	**14**	**1.01**	**0.929**
SD				**0.10**	**10.9**	**0.14**	**11**	**0.19**	**0.073**
Minimum				**0.04**	**3**	**0.01**	**1**	**0.79**	**0.825**
Maximum				**0.31**	**29**	**0.39**	**25**	**1.35**	**0.995**

pH dependence, Yes or No	No

X11579457:

Soil				Adsorption parameters					
Soil name	*Soil type (USDA classification)*	*pH*	*OC [%]*	Distribution constants		*Freundlich isotherm's parameters*			
				K_d [mL/g]	K_{dOC} [mL/g]	K_f [mL/g]	K_{fOC} [mL/g]	1/n	R^2
M761 – Cranwell	Loamy sand	7.6	1.3	0.10	8	0.15	11	0.87	0.905
M762 – Aberford	Loam	7.3	6.7	0.14	2	0.13	2	1.02	0.985
M763 – Malham	Silt loam	6.2	3.5	0.08	2	0.34	10	0.55	0.907
M768 – Lenawee	Clay loam	5.9	1.8	0.21	12	0.79	44	0.43	0.867
M770 – Pullman (2)	Clay loam	6.9	1.2	0.21	18	0.27	23	0.91	0.994
M771 – Fayette	Loam	6.3	1.1	0.26	22	0.28	26	0.97	0.990
M772 – Slagle	Sandy loam	6.4	1.0	0.32	32	0.35	35	0.97	0.996
			Average	**0.19**	**14**	**0.33**	**22**	**0.82**	**0.949**
SD				**0.09**	**11**	**0.22**	**15**	**0.23**	**0.054**
Minimum				**0.08**	**2**	**0.13**	**2**	**0.43**	**0.867**
Maximum				**0.32**	**32**	**0.79**	**44**	**1.02**	**0.996**

pH dependence, Yes or No	No

Mobility in soil (Annex IIA, point 7.1.3, Annex IIIA, point 9.1.2)

Column leaching ‡	Not examined, not required
Aged residues leaching ‡	Not examined, not required
Lysimeter/ field leaching studies ‡	Not examined, not required

PEC (soil) (Annex IIIA, point 9.1.3)

Sulfoxaflor Method of calculation: Modelling tool – Escape ver. 1.1; Mode of calculations: parent and two metabolites in sequence; Residues treatment: residues from different application treated separately.	DT_{50} (d): *7.43* days Kinetics: *SFO* Field or Lab: *representative worst case from field studies*. Molecular weight: *277.27 g/mole*
X11719474: Method of calculation: Modelling tool – Escape ver. 1.1; Mode of calculations: parent and two metabolites in sequence; Residues treatment: residues from different application treated separately.	DT_{50} (d): *385.08* days Kinetics: *Pseudo-SFO (slow phase DFOP)* Field or Lab: *representative worst case from field studies*. Molecular weight: *295.0 g/mole* Observed maximum in soil: *100%*
X11519540: Method of calculation: Modelling tool – Escape ver. 1.1; Mode of calculations: parent and two metabolites in sequence; Residues treatmet: residues from different application treated separately.	DT_{50} (d): *1155.24* days Kinetics: *Pseudo-SFO (slow phase HS)* Field or Lab: *representative worst case from lab studies*. Molecular weight: *253.24 g/mole* Observed maximum in soil: *12.2%*
X11579457: Method of calculation: Modelling tool – Escape ver. 1.1; Mode of calculations: parent and two metabolites in sequence; Residues treatment: residues from different application treated separately	DT_{50} (d): *346.57* days Kinetics: *Pseudo-SFO (slow phase HS)* Field or Lab: *representative worst case from lab studies*. Molecular weight: *252.25 g/mole* Observed maximum in soil: *9.2%*

Application data	Crop: *Spring and Winter cereals* Depth of soil layer: *5 cm for 1-year PEC and Accumulation PEC values; 20 cm for final background concentration*. Soil bulk density: *1.5 g/cm³* % plant interception: *90%* Number of applications: *1* Interval (d): *not applicable – single application* Application rate(s): *24* g as/ha

Annual PEC_{SOIL} in 0 – 5-cm layer calculated for:									
Time period	***DAT***	**Sulfoxaflor**		***X11719474***		***X11519540***		***X11579457***	
		Actual PEC_{SOIL} [mg/kg]	**TWA PEC_{SOIL} [mg/kg]**	**Actual PEC_{SOIL} [mg/kg]**	**TWA PEC_{SOIL} [mg/kg]**	**Actual PEC_{SOIL} [mg/kg]**	**TWA PEC_{SOIL} [mg/kg]**	**Actual PEC_{SOIL} [mg/kg]**	**TWA PEC_{SOIL} [mg/kg]**
Initial	0	0.0032	----	0.0032	----	0.0002	----	0.0001	----
Short-term	1	0.0029	0.0031	0.0032	0.0032	0.0002	0.0002	0.0001	0.0001
	2	0.0027	0.0029	0.0032	0.0032	0.0002	0.0002	0.0001	0.0001
	4	0.0022	0.0027	0.0031	0.0032	0.0002	0.0002	0.0001	0.0001
Long-term	7	0.0017	0.0024	0.0031	0.0032	0.0002	0.0002	0.0001	0.0001
	14	0.0009	0.0018	0.0031	0.0031	0.0002	0.0002	0.0001	0.0001
	21	0.0005	0.0014	0.0031	0.0031	0.0002	0.0002	0.0001	0.0001
	28	0.0002	0.0011	0.0031	0.0031	0.0002	0.0002	0.0001	0.0001
	42	0.0001	0.0008	0.0030	0.0031	0.0002	0.0002	0.0001	0.0001
	50	<0.0001	0.0007	0.0029	0.0031	0.0002	0.0002	0.0001	0.0001
	100	<0.0001	0.0003	0.0027	0.0030	0.0002	0.0002	0.0001	0.0001
Assessment of the accumulation potential: background concentration in 0-20-cm soil layer for:									
Type of value:		Sulfoxaflor		*X11719474*		*X11519540*		*X11579457*	
Final background concentration in 0 – 20-cm layer		<0.0001		0.0009		0.0003		0.0001	
Obtained after		10 years		11 years		14 years		11 years	
Assessment of the accumulation potential: accumulation PEC_{SOIL} in 0 – 5-cm soil layer for:									
Time period	*DAT*	Sulfoxaflor		*X11719474*		*X11519540*		*X11579457*	
		Actual accumulation PEC_{SOIL} [mg/kg]	TWA accumulation PEC_{SOIL} [mg/kg]	Actual accumulation PEC_{SOIL} [mg/kg]	TWA accumulation PEC_{SOIL} [mg/kg]	Actual accumulation PEC_{SOIL} [mg/kg]	TWA accumulation PEC_{SOIL} [mg/kg]	Actual accumulation PEC_{SOIL} [mg/kg]	TWA accumulation PEC_{SOIL} [mg/kg]
Initial	0	0.0032	----	0.0040	----	0.0005	----	0.0002	----
Short-term	1	0.0029	0.0031	0.0040	0.0040	0.0005	0.0015	0.0002	0.0002
	2	0.0027	0.0029	0.0040	0.0040	0.0005	0.0015	0.0002	0.0002
	4	0.0022	0.0027	0.0040	0.0040	0.0005	0.0015	0.0002	0.0002
Long-term	7	0.0017	0.0024	0.0040	0.0040	0.0005	0.0015	0.0002	0.0002
	14	0.0009	0.0018	0.0040	0.0040	0.0005	0.0015	0.0002	0.0002
	21	0.0005	0.0014	0.0040	0.0040	0.0005	0.0015	0.0002	0.0002
	28	0.0002	0.0011	0.0039	0.0040	0.0005	0.0015	0.0002	0.0002
	42	0.0001	0.0008	0.0039	0.0040	0.0005	0.0015	0.0002	0.0002
	50	<0.0001	0.0007	0.0038	0.0040	0.0005	0.0015	0.0002	0.0002
	100	<0.0001	0.0003	0.0036	0.0039	0.0005	0.0015	0.0002	0.0002

Application data	Crop: *Fruiting vegetables and Cucurbits* Depth of soil layer: *5 cm for 1-year PEC and Accumulation PEC values; 20 cm for final background concentration*. Soil bulk density: *1.5 g/cm^3* % plant interception: *70%* Number of applications: *1* Interval (d): *not applicable – single application* Application rate(s): *24* g as/ha

Annual PEC_{SOIL} in 0 – 5-cm layer calculated for:									
Time period	***DAT***	**Sulfoxaflor**		***X11719474***		***X11519540***		***X11579457***	
		Actual PEC_{SOIL} [mg/kg]	**TWA PEC_{SOIL} [mg/kg]**	**Actual PEC_{SOIL} [mg/kg]**	**TWA PEC_{SOIL} [mg/kg]**	**Actual PEC_{SOIL} [mg/kg]**	**TWA PEC_{SOIL} [mg/kg]**	**Actual PEC_{SOIL} [mg/kg]**	**TWA PEC_{SOIL} [mg/kg]**
Initial	0	0.0096	----	0.0095	----	0.0006	----	0.0003	----
Short-term	1	0.0087	0.0092	0.0095	0.0095	0.0006	0.0006	0.0003	0.0003
	2	0.0080	0.0088	0.0095	0.0095	0.0006	0.0006	0.0003	0.0003
	4	0.0066	0.0080	0.0094	0.0095	0.0006	0.0006	0.0003	0.0003
Long-term	7	0.0050	0.0071	0.0094	0.0095	0.0006	0.0006	0.0003	0.0003
	14	0.0026	0.0054	0.0094	0.0094	0.0006	0.0006	0.0003	0.0003
	21	0.0014	0.0042	0.0093	0.0094	0.0006	0.0006	0.0003	0.0003
	28	0.0007	0.0034	0.0092	0.0094	0.0006	0.0006	0.0003	0.0003
	42	0.0002	0.0024	0.0089	0.0094	0.0006	0.0006	0.0003	0.0003
	50	0.0001	0.0020	0.0088	0.0093	0.0006	0.0006	0.0003	0.0003
	100	<0.0001	0.0010	0.0081	0.0090	0.0006	0.0006	0.0003	0.0003
Assessment of the accumulation potential: background concentration in 0-20-cm soil layer for:									
Type of value:		Sulfoxaflor		*X11719474*		*X11519540*		*X11579457*	
Final background concentration in 0 – 20-cm layer		<0.0001		0.0026		0.0010		0.0002	
Obtained after		10 years		11 years		11 years		11 years	
Assessment of the accumulation potential: accumulation PEC_{SOIL} in 0 – 5-cm soil layer for:									
Time period	*DAT*	Sulfoxaflor		*X11719474*		*X11519540*		*X11579457*	
		Actual accumulation PEC_{SOIL} [mg/kg]	TWA accumulation PEC_{SOIL} [mg/kg]	Actual accumulation PEC_{SOIL} [mg/kg]	TWA accumulation PEC_{SOIL} [mg/kg]	Actual accumulation PEC_{SOIL} [mg/kg]	TWA accumulation PEC_{SOIL} [mg/kg]	Actual accumulation PEC_{SOIL} [mg/kg]	TWA accumulation PEC_{SOIL} [mg/kg]
Initial	0	0.0096	----	0.0121	----	0.0016	----	0.0005	----
Short-term	1	0.0087	0.0092	0.0121	0.0121	0.0016	0.0016	0.0005	0.0005
	2	0.0080	0.0088	0.0121	0.0121	0.0016	0.0016	0.0005	0.0005
	4	0.0066	0.0080	0.0121	0.0121	0.0016	0.0016	0.0005	0.0005
Long-term	7	0.0050	0.0071	0.0120	0.0121	0.0016	0.0016	0.0005	0.0005
	14	0.0026	0.0054	0.0120	0.0121	0.0016	0.0016	0.0005	0.0005
	21	0.0014	0.0042	0.0119	0.0120	0.0016	0.0016	0.0005	0.0005
	28	0.0007	0.0034	0.0118	0.0120	0.0016	0.0016	0.0005	0.0005
	42	0.0002	0.0024	0.0116	0.0120	0.0016	0.0016	0.0005	0.0005
	50	0.0001	0.0020	0.0114	0.0119	0.0016	0.0016	0.0005	0.0005
	100	<0.0001	0.0010	0.0107	0.0116	0.0016	0.0016	0.0005	0.0005

Application data	Crop: *Cotton* Depth of soil layer: *5 cm for 1-year PEC and Accumulation PEC values; 20 cm for final background concentration*. Soil bulk density: *1.5 g/cm^3* % plant interception: *60%* Number of applications: *1* Interval (d): *not applicable – single application* Application rate(s): *24* g as/ha

Annual PEC$_{SOIL}$ in 0 – 5-cm layer calculated for:									
Time period	***DAT***	**Sulfoxaflor**		***X11719474***		***X11519540***		***X11579457***	
		Actual PEC$_{SOIL}$ [mg/kg]	**TWA PEC$_{SOIL}$ [mg/kg]**	**Actual PEC$_{SOIL}$ [mg/kg]**	**TWA PEC$_{SOIL}$ [mg/kg]**	**Actual PEC$_{SOIL}$ [mg/kg]**	**TWA PEC$_{SOIL}$ [mg/kg]**	**Actual PEC$_{SOIL}$ [mg/kg]**	**TWA PEC$_{SOIL}$ [mg/kg]**
Initial	0	0.0128	----	0.0126	----	0.0008	----	0.0004	----
Short-term	1	0.0117	0.0122	0.0126	0.0126	0.0008	0.0008	0.0004	0.0004
	2	0.0106	0.0117	0.0126	0.0126	0.0008	0.0008	0.0004	0.0004
	4	0.0088	0.0107	0.0126	0.0126	0.0008	0.0008	0.0004	0.0004
Long-term	7	0.0067	0.0094	0.0126	0.0126	0.0008	0.0008	0.0004	0.0004
	14	0.0035	0.0072	0.0125	0.0126	0.0008	0.0008	0.0004	0.0004
	21	0.0018	0.0056	0.0124	0.0126	0.0008	0.0008	0.0004	0.0004
	28	0.0009	0.0045	0.0122	0.0125	0.0008	0.0008	0.0004	0.0004
	42	0.0003	0.0032	0.0119	0.0125	0.0008	0.0008	0.0004	0.0004
	50	0.0001	0.0027	0.0118	0.0124	0.0008	0.0008	0.0004	0.0004
	100	<0.0001	0.0024	0.0107	0.0120	0.0008	0.0008	0.0004	0.0004
Assessment of the accumulation potential: background concentration in 0-20-cm soil layer for:									
Type of value:		Sulfoxaflor		*X11719474*		*X11519540*		*X11579457*	
Final background concentration in 0 – 20-cm layer		<0.0001		0.0035		0.0013		0.0003	
Obtained after		10 years		11 years		14 years		11 years	
Assessment of the accumulation potential: accumulation PEC$_{SOIL}$ in 0 – 5-cm soil layer for:									
Time period	*DAT*	Sulfoxaflor		*X11719474*		*X11519540*		*X11579457*	
		Actual accumulation PEC$_{SOIL}$ [mg/kg]	TWA accumulation PEC$_{SOIL}$ [mg/kg]	Actual accumulation PEC$_{SOIL}$ [mg/kg]	TWA accumulation PEC$_{SOIL}$ [mg/kg]	Actual accumulation PEC$_{SOIL}$ [mg/kg]	TWA accumulation PEC$_{SOIL}$ [mg/kg]	Actual accumulation PEC$_{SOIL}$ [mg/kg]	TWA accumulation PEC$_{SOIL}$ [mg/kg]
Initial	0	0.0128	----	0.0161	----	0.0022	----	0.0007	----
Short-term	1	0.0117	0.0122	0.0161	0.0161	0.0022	0.0022	0.0007	0.0007
	2	0.0106	0.0117	0.0161	0.0161	0.0022	0.0022	0.0007	0.0007
	4	0.0088	0.0107	0.0161	0.0161	0.0022	0.0022	0.0007	0.0007
Long-term	7	0.0067	0.0094	0.0161	0.0161	0.0022	0.0022	0.0007	0.0007
	14	0.0035	0.0072	0.0160	0.0161	0.0022	0.0022	0.0007	0.0007
	21	0.0018	0.0056	0.0158	0.0161	0.0022	0.0022	0.0007	0.0007
	28	0.0009	0.0045	0.0157	0.0160	0.0022	0.0022	0.0007	0.0007
	42	0.0003	0.0032	0.0154	0.0160	0.0022	0.0022	0.0007	0.0007
	50	0.0001	0.0027	0.0152	0.0159	0.0022	0.0022	0.0007	0.0007
	100	<0.0001	0.0024	0.0142	0.0155	0.0022	0.0022	0.0007	0.0007

Route and rate of degradation in water (Annex IIA, point 7.2.1)

Process	Experimental conditions	Obtained results	
		Degradation kinetics	*Identified metabolites*
Abiotic hydrolysis	pH = 5 (sterile acetate buffer); T = 25^{0}C; incubation in the absence of light (darkness); test substance: ^{14}C-Sulfoxaflor	DT_{50} > 1000 days – compound hydrolytically stable at this pH	None detected - compound hydrolytically stable at this pH
	pH = 7 (sterile TRIS buffer); T = 25^{0}C; incubation in the absence of light (darkness); test substance: ^{14}C-Sulfoxaflor	DT_{50} > 1000 days – compound hydrolytically stable at this pH	None detected - compound hydrolytically stable at this pH
	pH = 9 (sterile borate buffer); T = 25^{0}C; incubation in the absence of light (darkness); test substance: ^{14}C-Sulfoxaflor	DT_{50} > 1000 days – compound hydrolytically stable at this pH	None detected - compound hydrolytically stable at this pH
Aqueous photolysis in sterile buffered solution (direct aqueous photolysis)	Sterile TRIS buffer (pH 7); Xenon lamp working at the wavelength range λ = 290-800 nm as a light source; intensity of light 300 W/m^2; incubation temperature T = 25^{0}C; dark control samples and actinometers set alongside irradiated samples; test compounds: ^{14}C-Sulfoxaflor and ^{14}C-X11719474; study duration: 14 days	Sulfoxaflor: DT_{50} = 7500 days, DT_{90} = 24915 days (average summer day at 40N); X11719474: DT_{50} = 261 days, DT_{90} = 868 days (average summer day at 40N); The compounds are not prone to direct photolysis in the aquatic environment. Quantum yield Φ could not be determined – none of the test substances absorbed UV-Vis radiation in the environmentally relevant wavelengths range λ = 290-800 nm.	None (minor photodegradation products X11721061 and X1171892 are probably the products of the indirect photolysis related to the use of TRIS buffer).
Aqueous photolysis in natural water (direct and indirect aqueous photolysis)	Natural lake water (pH = 8.2); Xenon lamp working at the wavelength range λ = 290-800 nm as a light source; intensity of light 300 W/m^2; incubation temperature T = 25^{0}C; dark control samples and actinometers set alongside irradiated samples; test compounds: ^{14}C-Sulfoxaflor and ^{14}C-X11719474; study duration: 14 days	Sulfoxaflor: DT_{50} = 637 days, DT_{90} > 1000 days (average summer day at 40N); X11719474: DT_{50} > 1000 days, DT_{90} > 1000 days (average summer day at 40N); The compounds are not prone to photolysis, direct or indirect in the aquatic environment.	None identified
Ready biodegradability	CO_2 headspace test; incubation temperature T = 20^{0}C; inoculum: activated sludge from municipal sewage treatment plant; test compound: ^{14}C-Sulfoxaflor, reference compound: sodium benzoate; study duration: 28 days	Up to 2.5% Sulfoxaflor underwent mineralisation within 28 days. **Conclusion:** Sulfoxaflor is not ready biodegradable	Not applicable

Degradation in water / sediment

Distribution of AR in the system (including mineralisation and NER levels):

Water/ Sediment system	Characteristic of the system:			AR distribution in the system [%]:				Identified metabolites
				Max. in water phase	*Max. in sediment - extractable*	*NER*	*Minerali-sation level ($^{14}CO_2$)*	
Sand sediment system – M765	***Sediment's texture class - USDA***		sand	98.1 (95.6 – 100.6) DAT 0	20.40 (19.5 – 21.3) DAT 103	6.55 (6.4 – 6.7) DAT 103	0.55 (0.5 – 0.6) DAT 103	X11719474
	pH	Water phase	6.7					
		Sediment	6.3					
	OC content	Water phase [ppm]	6.2					
		Sediment [%]	0.6					
	Incubation temperature [^{0}C]		20					
Silt loam sediment system – M766	***Sediment's texture class - USDA***		silt loam	99.3 (98.7 – 99.9) DAT 0	46.05 (45.4 – 46.7) DAT 32	24.35 (23.0 – 25.7) DAT 103	1.6 (1.5 – 1.7) DAT 88	X11719474
	pH	Water phase	7.8					
		Sediment	7.8					
	OC content	Water phase [ppm]	6.5					
		Sediment [%]	3.9					
	Incubation temperature [^{0}C]		20					

Distribution of Sulfoxaflor and X11719474 in the system:

<table>
<tr><th rowspan="2">Water/ Sediment system</th><th rowspan="2" colspan="3">Characteristic of the system:</th><th colspan="2">Distribution of Sulfoxaflor in the system</th><th colspan="3">Distribution of X11719474 in the system</th></tr>
<tr><th>Max. in water phase [%AR]</th><th>Max. in sediment [% AR]</th><th>Max. in the system [%AR]</th><th>Max. in water phase [%AR]</th><th>Max. in sediment [% AR]</th></tr>
<tr><td rowspan="6">Sand sediment system – M765</td><td colspan="2">Sediment's texture class - USDA</td><td>sand</td><td rowspan="6">97.8
(95.6 – 100.0)

DAT 0</td><td rowspan="6">16.6
(16.1 – 17.1)

DAT 46</td><td rowspan="6">57.95
(45.0 – 70.9)

DAT 76</td><td rowspan="6">48.05
(37.9 – 58.2)

DAT 76</td><td rowspan="6">9.9
(7.1 – 12.7)

DAT 76</td></tr>
<tr><td rowspan="2">pH</td><td>Water phase</td><td>6.7</td></tr>
<tr><td>Sediment</td><td>6.3</td></tr>
<tr><td rowspan="2">OC content</td><td>Water phase [ppm]</td><td>6.2</td></tr>
<tr><td>Sediment [%]</td><td>0.6</td></tr>
<tr><td colspan="2">Incubation temperature [^{0}C]</td><td>20</td></tr>
<tr><td rowspan="6">Silt loam sediment system – M766</td><td colspan="2">Sediment's texture class - USDA</td><td>silt loam</td><td rowspan="6">98.75
(97.9 – 99.6)

DAT 0</td><td rowspan="6">40.15
(39.8 – 40.5)

DAT 15</td><td rowspan="6">65.55
(65.1 – 66.0)

DAT 88</td><td rowspan="6">35.25
(34.6 – 35.9)

DAT 88</td><td rowspan="6">30.3
(30.1 – 30.5)

DAT 88</td></tr>
<tr><td rowspan="2">pH</td><td>Water phase</td><td>7.8</td></tr>
<tr><td>Sediment</td><td>7.8</td></tr>
<tr><td rowspan="2">OC content</td><td>Water phase [ppm]</td><td>6.5</td></tr>
<tr><td>Sediment [%]</td><td>3.9</td></tr>
<tr><td colspan="2">Incubation temperature [^{0}C]</td><td>20</td></tr>
</table>

<u>Degradation kinetics of Sulfoxaflor and X11719474 in water/sediment system:</u>

Sulfoxaflor:

Persistence endpoints:											
Water/ Sediment system	**Characteristic of the system:**		**Kinetic endpoints**								
			Whole system			***Water phase***			***Sediment***		
			DT_{50} [days]	DT_{90} [days]	Kinetic model	DT_{50} [days]	DT_{90} [days]	Kinetic model	DT_{50} [days]	DT_{90} [days]	Kinetic model
Sand sediment system – M765	***Sediment's texture class - USDA***	sand	88.86	295.20	SFO; χ^2 err = 7.0; R^2 = 0.8295	64.18	213.20	SFO; χ^2 err = 6.7; R^2 = 0.9013	101.93	388.62	SFO; χ^2 err = 4.0; R^2 = 0.6562
	pH Water phase	6.7									
	pH Sediment	6.3									
	OC content Water phase [ppm]	6.2									
	OC content Sediment [%]	0.6									
	Incubation temperature [^{0}C]	20									
Silt loam sediment system – M766	***Sediment's texture class - USDA***	silt loam	36.67	121.83	SFO; χ^2 err = 6.6; R^2 = 0.9629	11	63	DFOP; χ^2 err = 4.4; R^2 = 0.9903	46.21	153.51	SFO; χ^2 err = 8.8; R^2 = 0.9006
	pH Water phase	7.8									
	pH Sediment	7.8									
	OC content Water phase [ppm]	6.5									
	OC content Sediment [%]	3.9									
	Incubation temperature [^{0}C]	20									
Modelling endpoints:											
Water/ Sediment system	**Characteristic of the system:**		**Kinetic endpoints**								
			Whole system			***Water phase***			***Sediment***		
			DT_{50} [days]	DT_{90} [days]	Kinetic model	DT_{50} [days]	DT_{90} [days]	Kinetic model	DT_{50} [days]	DT_{90} [days]	Kinetic model
Sand sediment system – M765	***Sediment's texture class - USDA***	sand	88.86	295.20	SFO; χ^2 err = 7.0; R^2 = 0.8295	Not determined - dissipation	Not determined - dissipation	Not determined - dissipation	101.93	388.62	SFO; χ^2 err = 4.0; R^2 = 0.6562
	pH Water phase	6.7									
	pH Sediment	6.3									
	OC content Water phase [ppm]	6.2									
	OC content Sediment [%]	0.6									
	Incubation temperature [^{0}C]	20									
Silt loam sediment system – M766	***Sediment's texture class - USDA***	silt loam	36.67	121.83	SFO; χ^2 err = 6.6; R^2 = 0.9629	Not determined - dissipation	Not determined - dissipation	Not determined - dissipation	46.21	153.51	SFO; χ^2 err = 8.8; R^2 = 0.9006
	pH Water phase	7.8									
	pH Sediment	7.8									
	OC content Water phase [ppm]	6.5									
	OC content Sediment [%]	3.9									
	Incubation temperature [^{0}C]	20									
Geomean value			**57.08**	**189.63**		----	----		**68.63**	**244.25**	

X11719474: degradation kinetics not determined – the decline phase not reached in the study.

PEC (surface water) and PEC sediment (Annex IIIA, point 9.2.3)

a) Winter cereals:

Parent – *Sulfoxaflor* Parameters used in FOCUSsw step 1 and 2	Version control no. of FOCUS calculator: *2.1* Molecular weight (g/mol): *277.27* Water solubility (mg/L): *673* K_{OC} (L/kg): *35* DT_{50} soil (d): *0.078* days (*Lab. In accordance with FOCUS SFO*) DT_{50} water/sediment system (d): *57.08 (geomean of two systems; SFO kinetics)* DT_{50} water (d): *57.08 (geomean of two systems; whole system value; SFO kinetics);* DT_{50} sediment (d): *68.63 (geomean of two systems; value determined using top-down approach from the maximum recorded in sediment; SFO kinetics);* Crop interception (%): *full canopy (70%)*
Parameters used in FOCUSsw step 3 (if performed)	Version control no.'s of FOCUS software: *SWASH 3.1 shell* Vapour pressure:*1.4 E-5 Pa (T = 20^{0}C) ;* Water solubility (mg/L): *673 (T = 20^{0}C)* K_{fOC}: *35 mL/g* 1/n: *0.96* *Other input parameters same as defined for calculations at STEPs 1-2*
Application rate	Crop: *Winter cereals* Crop interception: *for STEPS 1-2 full canopy (70%), for STEP 3 defined internally by the model* Number of applications: *1* Interval (d): *not applicable – single application* Application rate(s): *24* g as/ha Application window: *for calculations at STEPS 1-2 March May; for calculations at STEP 3: 01/04 – 05/05 for all scenarios*

STEP 1 results:

Time [days]	PEC_{SW} [µg/L]		PEC_{SED} [µg/kg sediment]	
	Actual	TWA	Actual	TWA
0	7.8640	----	2.6752	----
1	7.7594	7.8117	2.7158	2.6955
2	7.6657	7.7621	2.6830	2.6974
4	7.4818	7.6677	2.6186	2.6741
7	7.2141	7.5303	2.5249	2.6301
14	6.6263	7.2232	2.3192	2.5254
21	6.0863	6.9329	2.1302	2.4247
28	5.5903	6.6584	1.9566	2.3291
42	4.7163	6.1526	1.6507	2.1525
50	4.2797	5.8873	1.4979	2.0598
100	2.3319	4.5476	0.8162	1.5913

STEP 2 results:

Time [days]	North Europe				South Europe			
	PEC_{SW} [µg/L]		PEC_{SED} [µg/kg sediment]		PEC_{SW} [µg/L]		PEC_{SED} [µg/kg sediment]	
	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	0.2207	----	0.0704	----	0.2207	----	0.0704	----
1	0.2116	0.2161	0.0696	0.0700	0.2116	0.2161	0.0696	0.0700
2	0.2090	0.2132	0.0688	0.0696	0.2090	0.2132	0.0688	0.0696
4	0.2041	0.2099	0.0672	0.0688	0.2041	0.2099	0.0672	0.0688
7	0.1942	0.2048	0.0649	0.0676	0.1942	0.2048	0.0649	0.0676
14	0.1790	0.1957	0.0598	0.0650	0.1790	0.1957	0.0598	0.0650
21	0.1651	0.1878	0.0552	0.0625	0.1651	0.1878	0.0552	0.0625
28	0.1522	0.1805	0.0509	0.0601	0.1522	0.1805	0.0509	0.0601
42	0.1294	0.1671	0.0432	0.0557	0.1294	0.1671	0.0432	0.0557
50	0.1179	0.1602	0.0394	0.0534	0.1179	0.1602	0.0394	0.0534
100	0.0660	0.1248	0.0221	0.0417	0.0660	0.1248	0.0221	0.0417

STEP 3 results:

Identification of migration route:

FOCUS Scenario	Application window	Application date (determined by PAT)	Date of maximum	Identified dominant migration route
D1 – ditch	01/04 – 05/05	01/04/1982/9:00	09/04/1982/9:00	Drainage
D1 – stream	01/04 – 05/05	01/04/1982/9:00	01/04/1982/9:00	Spray Drift
D2 – ditch	01/04 – 05/05	01/04/1986/9:00	01/04/1986/9:00	Spray Drift
D2 – stream	01/04 – 05/05	01/04/1986/9:00	01/04/1986/9:00	Spray Drift
D3 – ditch	01/04 – 05/05	04/04/1992/9:00	04/04/1992/9:00	Spray Drift
D4 – pond	01/04 – 05/05	18/04/1985/9:00	18/04/1985/9:00	Spray Drift
D4 – stream	01/04 – 05/05	18/04/1985/9:00	18/04/1985/9:00	Spray Drift
D5 – pond	01/04 – 05/05	08/04/1978/9:00	08/04/1985/9:00	Spray Drift
D5 – stream	01/04 – 05/05	08/04/1985/9:00	08/04/1985/9:00	Spray Drift
D6 – ditch	01/04 – 05/05	09/04/1986/9:00	09/04/1986/9:00	Spray Drift
R1 – pond	01/04 – 05/05	26/04/1984/9:00	26/04/1986/9:00	Spray Drift
R1 – stream	01/04 – 05/05	26/04/1986/9:00	26/04/1986/9:00	Spray Drift
R3 – stream	01/04 – 05/05	04/04/1980/9:00	04/04/1980/9:00	Spray Drift
R4 – stream	01/04 – 05/05	04/05/1984/9:00	04/05/1984/9:00	Spray Drift

Numerical results:

Time [days]	FOCUS Scenario							
	D1 Ditch				D1 Stream			
	PEC_{SW} [µg/L]		PEC_{SED} [µg/kg sediment]		PEC_{SW} [µg/L]		PEC_{SED} [µg/kg sediment]	
	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	0.187[1)] 0.187[2)]	----	0.0718	----	0.120[1)] 0.120[2)]	----	0.0379	----
1	0.152	0.176	0.0717	0.0718	4.9 E-5	0.110	0.0379	0.0379
2	0.130	0.165	0.0715	0.0717	5.0 E-5	0.103	0.0376	0.0379
4	0.109	0.146	0.0710	0.0717	5.3 E-5	0.0900	0.0360	0.0378
7	0.0931	0.129	0.0700	0.0715	0.0124	0.0786	0.0290	0.0376
14	0.0741	0.107	0.0703	0.0711	0.0584	0.0641	0.0296	0.0367
21	0.0610	0.0942	0.0671	0.0709	0.0429	0.0534	0.0243	0.0348
28	0.0526	0.0846	0.0626	0.0705	0.0110	0.0404	0.0193	0.0327
42	0.0361	0.0727	0.0521	0.0690	1.98 E-3	0.0312	0.0141	0.0301
50	0.0269	0.0678	0.0462	0.0677	5.2 E-5	0.0262	0.0121	0.0281
100	0.0359	0.0419	0.0194	0.0555	7 E-6	0.0132	4.88 E-3	0.0193
Time [days]	FOCUS Scenario							
	D2 Ditch				D2 Stream			
	PEC_{SW} [µg/L]		PEC_{SED} [µg/kg sediment]		PEC_{SW} [µg/L]		PEC_{SED} [µg/kg sediment]	
	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	0.153[1)] 0.153[2)]	----	0.0310	----	0.121[1)] 0.121[2)]	----	3.99 E-3	----
1	0.128	0.139	0.0298	0.0309	3 E-6	0.0146	2.00 E-3	3.25 E-3
2	0.0998	0.127	0.0276	0.0305	1 E-6	0.0102	1.55 E-3	3.06 E-3
4	0.0444	0.0981	0.0247	0.0291	1 E-6	5.81 E-3	1.12 E-3	2.70 E-3
7	0.0117	0.0679	0.0175	0.0268	2.11 E-3	3.72 E-3	3.48 E-3	2.36 E-3
14	0.0303	0.0379	0.0149	0.0220	0.0112	3.13 E-3	1.70 E-3	1.91 E-3
21	2.04 E-4	0.0264	0.0111	0.0195	5.3 E-5	2.50 E-3	1.17 E-3	1.74 E-3
28	8.3 E-5	0.0198	9.14 E-3	0.0173	2 E-6	1.88 E-3	9.39 E-4	1.57 E-3
42	2.18 E-4	0.0133	6.81 E-3	0.0143	2.0 E-5	1.25 E-3	6.98 E-4	1.31 E-3
50	1.0 E-5	0.0112	5.79 E-3	0.0131	1 E-6	1.06 E-3	5.94 E-4	1.21 E-3
100	1.15 E-4	5.63 E-3	2.49 E-3	8.56 E-3	1.3 E-5	5.34 E-4	2.58 E-4	8.24 E-4
Time [days]	FOCUS Scenario							
	D3 Ditch				D4 Pond			
	PEC_{SW} [µg/L]		PEC_{SED} [µg/kg sediment]		PEC_{SW} [µg/L]		PEC_{SED} [µg/kg sediment]	
	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	0.152[1)] 0.152[2)]	----	0.0191	----	5.25 E-3[1)] 5.25 E-3[2)]	----	4.66 E-3	----
1	0.0688	0.118	0.0134	0.0181	5.16 E-3	5.20 E-3	4.66 E-3	4.66 E-3
2	7.32 E-3	0.0738	9.57 E-3	0.0160	5.11 E-3	5.17 E-3	4.66 E-3	4.66 E-3
4	1.55 E-4	0.0377	6.76 E-3	0.0126	5.00 E-3	5.11 E-3	4.65 E-3	4.66 E-3
7	4.3 E-5	0.0216	5.09 E-3	9.89 E-3	4.86 E-3	5.03 E-3	4.64 E-3	4.66 E-3
14	1.3 E-5	0.0108	3.54 E-3	7.14 E-3	4.56 E-3	4.87 E-3	4.58 E-3	4.65 E-3
21	7 E-6	7.21 E-3	2.82 E-3	5.84 E-3	4.22 E-3	4.71 E-3	4.49 E-3	4.64 E-3
28	5 E-6	5.41 E-3	2.35 E-3	5.03 E-3	3.92 E-3	4.55 E-3	4.35 E-3	4.62 E-3
42	2 E-6	3.61 E-3	1.69 E-3	4.03 E-3	3.42 E-3	4.26 E-3	4.00 E-3	4.58 E-3
50	2 E-6	3.03 E-3	1.43 E-3	3.64 E-3	3.14 E-3	4.10 E-3	3.79 E-3	4.54 E-3
100	2 E-6	1.52 E-3	5.48 E-4	2.88 E-3	1.73 E-3	3.24 E-3	2.65 E-3	4.21 E-3

1) Global maximum concentration, including the substance adsorbed to particles suspended in the water phase;
2) Maximum concentration of the substance dissolved in water;

Time [days]	FOCUS Scenario							
	D4 Stream				D5 Pond			
	PEC_{SW} [µg/L]		PEC_{SED} [µg/kg sediment]		PEC_{SW} [µg/L]		PEC_{SED} [µg/kg sediment]	
	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	0.121[1)] 0.121[2)]	----	3.62 E-3	----	5.25 E-3[1)] 5.25 E-3[2)]	----	4.65 E-3	----
1	2 E-6	8.19 E-3	7.33 E-4	1.43 E-3	5.15 E-3	5.19 E-3	4.64 E-3	4.65 E-3
2	1 E-6	4.09 E-3	5.23 E-4	1.03 E-3	5.09 E-3	5.16 E-3	4.64 E-3	4.64 E-3
4	<1.0 E-6	2.05 E-3	3.73 E-4	7.34 E-4	4.97 E-3	5.09 E-3	4.62 E-3	4.64 E-3
7	<1.0 E-6	1.17 E-3	2.80 E-4	5.58 E-4	4.82 E-3	5.01 E-3	4.60 E-3	4.64 E-3
14	<1.0 E-6	5.85 E-4	1.95 E-4	3.95 E-4	4.51 E-3	4.83 E-3	4.52 E-3	4.63 E-3
21	<1.0 E-6	3.90 E-4	1.55 E-4	3.21 E-4	4.25 E-3	4.68 E-3	4.42 E-3	4.62 E-3
28	<1.0 E-6	2.93 E-4	1.30 E-4	2.76 E-4	3.96 E-3	4.54 E-3	4.29 E-3	4.60 E-3
42	<1.0 E-6	1.93 E-4	9.8 E-5	2.22 E-4	3.45 E-3	4.26 E-3	3.94 E-3	4.55 E-3
50	<1.0 E-6	1.64 E-4	8.4 E-5	2.01 E-4	3.19 E-3	4.11 E-3	3.73 E-3	4.52 E-3
100	<1.0 E-6	8.2 E-5	3.5 E-5	1.28 E-4	1.81 E-3	3.29 E-3	2.54 E-3	4.21 E-3

Time [days]	FOCUS Scenario							
	D5 Stream				D6 Ditch			
	PEC_{SW} [µg/L]		PEC_{SED} [µg/kg sediment]		PEC_{SW} [µg/L]		PEC_{SED} [µg/kg sediment]	
	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	0.122[1)] 0.122[2)]	----	2.67 E-3	----	0.153[1)] 0.153[2)]	----	0.0515	----
1	1 E-6	5.31 E-3	4.70 E-4	9.09 E-4	0.146	0.149	0.0508	0.0514
2	<1.0 E-6	2.65 E-3	3.33 E-4	6.52 E-4	0.142	0.146	0.0488	0.0512
4	<1.0 E-6	1.33 E-3	2.36 E-4	4.65 E-4	0.125	0.141	0.0434	0.0504
7	<1.0 E-6	7.58 E-4	1.77 E-4	3.53 E-4	0.0710	0.123	0.0354	0.0484
14	<1.0 E-6	3.79 E-4	1.22 E-4	2.49 E-4	8.02 E-3	0.0765	0.0241	0.0423
21	<1.0 E-6	2.53 E-4	9.8 E-5	2.02 E-4	1.05 E-3	0.0521	0.0184	0.0368
28	<1.0 E-6	1.90 E-4	8.1 E-5	1.74 E-4	3.33 E-4	0.0392	0.0148	0.0325
42	<1.0 E-6	1.26 E-4	6.0 E-5	1.39 E-4	1.18 E-4	0.0262	0.0103	0.0264
50	<1.0 E-6	1.06 E-4	5.1 E-5	1.26 E-4	7.9 E-5	0.0220	8.40 E-3	0.0239
100	<1.0 E-6	5.3 E-5	2.1 E-5	8.0 E-5	1.3 E-5	0.0110	2.41 E-3	0.0147

Time [days]	FOCUS Scenario							
	R1 Pond				R1 Stream			
	PEC_{SW} [µg/L]		PEC_{SED} [µg/kg sediment]		PEC_{SW} [µg/L]		PEC_{SED} [µg/kg sediment]	
	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	5.25 E-3[1)] 5.25 E-3[2)]	----	4.14 E-3	----	0.100[1)] 0.100[2)]	----	6.03 E-3	----
1	5.15 E-3	5.19 E-3	4.14 E-3	4.14 E-3	1.3 E-5	0.0190	1.72 E-3	3.26 E-3
2	5.08 E-3	5.16 E-3	4.14 E-3	4.14 E-3	4 E-6	9.48 E-3	1.23 E-3	2.39 E-3
4	4.96 E-3	5.09 E-3	4.14 E-3	4.14 E-3	1. E-6	4.74 E-3	8.77 E-4	1.72 E-3
7	4.76 E-3	4.99 E-3	4.12 E-3	4.14 E-3	<1.0 E-6	2.71 E-3	6.56 E-4	1.31 E-3
14	4.34 E-3	4.77 E-3	4.05 E-3	4.13 E-3	<1.0 E-6	1.35 E-3	4.51 E-4	9.26 E-4
21	3.97 E-3	4.56 E-3	3.92 E-3	4.12 E-3	<1.0 E-6	9.03 E-4	3.57 E-4	7.51 E-4
28	3.59 E-3	4.36 E-3	3.77 E-3	4.10 E-3	<1.0 E-6	6.77 E-4	2.98 E-4	6.45 E-4
42	2.92 E-3	3.99 E-3	3.38 E-3	4.04 E-3	<1.0 E-6	4.52 E-4	2.19 E-4	5.16 E-4
50	2.60 E-3	3.80 E-3	3.15 E-3	3.99 E-3	<1.0 E-6	3.79 E-4	1.87 E-4	4.66 E-4
100	1.15 E-3	2.79 E-3	1.89 E-3	3.59 E-3	<1.0 E-6	1.90 E-4	7.4 E-5	2.94 E-4

1) Global maximum concentration, including the substance adsorbed to particles suspended in the water phase;
2) Maximum concentration of the substance dissolved in water;

Time [days]	FOCUS Scenario							
	R3 Stream				R4 Stream			
	PEC_{SW} [µg/L]		PEC_{SED} [µg/kg sediment]		PEC_{SW} [µg/L]		PEC_{SED} [µg/kg sediment]	
	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	0.142[1)] 0.142[2)]	----	0.0114	----	0.101[1)] 0.101[2)]	----	6.42 E-3	----
1	4.22 E-4	0.0498	4.48 E-3	8.09 E-3	1.7 E-5	0.0216	1.97 E-3	3.69 E-3
2	3.2 E-5	0.0249	3.20 E-3	6.10 E-3	5 E-6	0.0108	1.40 E-3	2.70 E-3
4	1.0 E-5	0.0125	2.28 E-3	4.44 E-3	2 E-6	5.39 E-3	9.90 E-4	1.95 E-3
7	4 E-6	7.13 E-3	1.70 E-3	3.40 E-3	1 E-6	3.08 E-3	7.37 E-4	1.48 E-3
14	1 E-6	3.57 E-3	1.18 E-3	2.41 E-3	<1.0 E-6	1.54 E-3	5.04 E-4	1.04 E-3
21	1 E-6	2.38 E-3	9.31 E-4	1.96 E-3	<1.0 E-6	1.03 E-3	3.96 E-4	8.46 E-4
28	<1.0 E-6	1.78 E-3	7.75 E-4	1.68 E-3	<1.0 E-6	7.71 E-4	3.27 E-4	7.25 E-4
42	<1.0 E-6	1.19 E-3	5.64 E-4	1.34 E-3	<1.0 E-6	5.14 E-4	2.28 E-4	5.75 E-4
50	<1.0 E-6	9.99 E-4	4.80 E-4	1.21 E-3	<1.0 E-6	4.32 E-4	1.90 E-4	5.16 E-4
100	<1.0 E-6	5.00 E-4	1.76 E-4	7.58 E-4	<1.0 E-6	2.16 E-4	6.1 E-5	3.15 E-4

1) Global maximum concentration, including the substance adsorbed to particles suspended in the water phase;
2) Maximum concentration of the substance dissolved in water;

Metabolite: **X11719474** Parameters used in FOCUSsw step 1 and 2	Molecular weight: *295.30* Water solubility (mg/L): *8090* Soil or water metabolite: *soil and water metabolite* Koc (L/kg): *30* DT_{50} soil (d): *76.61* days (*Field. In accordance with FOCUS SFO*) DT50 water/sediment system (d): *1000 (FOCUS default value)* DT_{50} water (d): *1000 (FOCUS default value)* DT_{50} sediment (d): *1000 (FOCUS default value)* Crop interception (%): *full canopy (70%)* Maximum occurrence observed: Water/sediment: *70.9%* Soil: *100%*
Parameters used in FOCUSsw step 3 (if performed)	Calculations not performed
Application rate	Crop: *Winter cereals* Number of applications: *1* Interval (d): *not applicable – parent compound* Application rate(s): *24* g as/ha Depth of water body: *as defined by the model in STEP 1-2 calculations* Application window: *March - May*
Main routes of entry	*As defined for STEP 1-2 calculations*

STEP 1 results:

Time [days]	PEC_{SW} [µg/L]		PEC_{SED} [µg/kg sediment]	
	Actual	TWA	Actual	TWA
0	8.3592	----	2.4578	----
1	8.3470	8.3531	2.5041	2.4809
2	8.3412	8.3486	2.5024	2.4921
4	8.3296	8.3420	2.4989	2.4964
7	8.3123	8.3330	2.4937	2.4963
14	8.2721	8.3126	2.4816	2.4920
21	8.2321	8.2924	2.4696	2.4865
28	8.1922	8.2724	2.4577	2.4808
42	8.1131	8.2324	2.4339	2.4691
50	8.0682	8.2098	2.4205	2.4624
100	7.7934	8.0699	2.3380	2.4207

STEP 2 results:

Time [days]	North Europe				South Europe			
	PEC_{SW} [µg/L]		PEC_{SED} [µg/kg sediment]		PEC_{SW} [µg/L]		PEC_{SED} [µg/kg sediment]	
	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	0.6360	----	0.1900	----	1.1100	----	0.3322	----
1	0.6335	0.6347	0.1899	0.1900	1.1072	1.1086	0.3319	0.3320
2	0.6330	0.6340	0.1898	0.1899	1.1064	1.1077	0.3317	0.3319
4	0.6321	0.6333	0.1896	0.1898	1.1049	1.1067	0.3312	0.3317
7	0.6308	0.6325	0.1895	0.1896	1.1026	1.1054	0.3306	0.3314
14	0.6278	0.6309	0.1891	0.1891	1.0973	1.1027	0.3290	0.3306
21	0.6247	0.6294	0.1882	0.1887	1.0920	1.1000	0.3274	0.3298
28	0.6217	0.6278	0.1873	0.1882	1.0867	1.0973	0.3258	0.3290
42	0.6157	0.6248	0.1864	0.1873	1.0762	1.0920	0.3226	0.3274
50	0.6123	0.6231	0.1846	0.1868	1.0702	1.0890	0.3208	0.3265
100	0.5914	0.6124	0.1836	0.1836	1.0338	1.0705	0.3099	0.3209

Metabolite: **X11519540** Parameters used in FOCUSsw step 1 and 2	Molecular weight: *253.24* Water solubility (mg/L): *1000* Soil or water metabolite: *soil metabolite* Koc (L/kg): *14* DT_{50} soil (d): *449.86* days (*Lab. In accordance with FOCUS SFO – long phase HS*) DT50 water/sediment system (d): *1000 (FOCUS default value)* DT_{50} water (d): *1000 (FOCUS default value)* DT_{50} sediment (d): *1000 (FOCUS default value)* Crop interception (%): *full canopy (70%)* Maximum occurrence observed: Water/sediment: *0.0001%* Soil: *12.2%*
Parameters used in FOCUSsw step 3 (if performed)	Calculations not performed

Application rate	Crop: *Winter cereals* Number of applications: *1* Interval (d): *not applicable – parent compound* Application rate(s): *24* g as/ha Depth of water body: *as defined by the model in STEP 1-2 calculations* Application window: *March - May*
Main routes of entry	*As defined for STEP 1-2 calculations*

STEP 1 results:

Time [days]	**PEC_{SW} [µg/L]**		**PEC_{SED} [µg/kg sediment]**	
	Actual	TWA	Actual	TWA
0	0.8751	----	0.1225	----
1	0.8745	0.8748	0.1224	0.1225
2	0.8739	0.8745	0.1223	0.1224
4	0.8727	0.8739	0.1222	0.1223
7	0.8708	0.8730	0.1219	0.1222
14	0.8666	0.8708	0.1213	0.1219
21	0.8624	0.8687	0.1207	0.1216
28	0.8583	0.8666	0.1202	0.1213
42	0.8500	0.8625	0.1190	0.1207
50	0.8453	0.8601	0.1183	0.1204
100	0.8165	0.8454	0.1143	0.1184

STEP 2 results:

Time [days]	**North Europe**				**South Europe**			
	PEC_{SW} [µg/L]		**PEC_{SED} [µg/kg sediment]**		**PEC_{SW} [µg/L]**		**PEC_{SED} [µg/kg sediment]**	
	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	0.0522	----	0.0073	----	0.1044	----	0.0146	----
1	0.0521	0.0522	0.0073	0.0073	0.1043	0.1043	0.0146	0.0146
2	0.0521	0.0521	0.0073	0.0073	0.1042	0.1043	0.0146	0.0146
4	0.0520	0.0521	0.0073	0.0073	0.1041	0.1042	0.0146	0.0146
7	0.0519	0.0521	0.0073	0.0073	0.1039	0.1041	0.0145	0.0146
14	0.0517	0.0519	0.0072	0.0073	0.1034	0.1039	0.0145	0.0146
21	0.0514	0.0518	0.0072	0.0073	0.1029	0.1036	0.0144	0.0145
28	0.0512	0.0517	0.0072	0.0072	0.1024	0.1034	0.0143	0.0145
42	0.0507	0.0514	0.0071	0.0072	0.1014	0.1029	0.0142	0.0145
50	0.0504	0.0513	0.0071	0.0072	0.1008	0.1026	0.0141	0.0144
100	0.0487	0.0504	0.0068	0.0071	0.0974	0.1008	0.0136	0.0141

Metabolite: **X11579457** Parameters used in FOCUSsw step 1 and 2	Molecular weight: *252.25* Water solubility (mg/L): *1000* Soil or water metabolite: *soil metabolite* Koc (L/kg): *22* DT_{50} soil (d): *186.67* days (*Lab. In accordance with FOCUS SFO – long phase HS*) DT50 water/sediment system (d): *1000 (FOCUS default value)* DT_{50} water (d): *1000 (FOCUS default value)* DT_{50} sediment (d): *1000 (FOCUS default value)* Crop interception (%): *full canopy (70%)* Maximum occurrence observed: Water/sediment: *0.0001%* Soil: *9.2%*
Parameters used in FOCUSsw step 3 (if performed)	Calculations not performed
Application rate	Crop: *Winter cereals* Number of applications: *1* Interval (d): *not applicable – parent compound* Application rate(s): *24* g as/ha Depth of water body: *as defined by the model in STEP 1-2 calculations* Application window: *March - May*
Main routes of entry	*As defined for STEP 1-2 calculations*

STEP 1 results:

Time [days]	**PEC_{SW} [µg/L]**		**PEC_{SED} [µg/kg sediment]**	
	Actual	TWA	Actual	TWA
0	0.6505	----	0.1431	----
1	0.6501	0.6503	0.1430	0.1431
2	0.6496	0.6501	0.1429	0.1430
4	0.6487	0.6496	0.1427	0.1429
7	0.6474	0.6489	0.1424	0.1428
14	0.6442	0.6474	0.1417	0.1424
21	0.6411	0.6458	0.1410	0.1421
28	0.6380	0.6442	0.1404	0.1417
42	0.6318	0.6411	0.1390	0.1410
50	0.6283	0.6394	0.1382	0.1407
100	0.6069	0.6285	0.1335	0.1383

STEP 2 results:

Time [days]	North Europe				South Europe			
	PEC_{SW} [µg/L]		PEC_{SED} [µg/kg sediment]		PEC_{SW} [µg/L]		PEC_{SED} [µg/kg sediment]	
	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	0.0385	----	0.0085	----	0.0769	----	0.0169	----
1	0.0384	0.0384	0.0085	0.0085	0.0769	0.0769	0.0169	0.0169
2	0.0384	0.0384	0.0084	0.0085	0.0768	0.0769	0.0169	0.0169
4	0.0383	0.0384	0.0084	0.0084	0.0767	0.0768	0.0169	0.0169
7	0.0383	0.0384	0.0084	0.0084	0.0765	0.0767	0.0168	0.0169
14	0.0381	0.0383	0.0084	0.0084	0.0762	0.0765	0.0168	0.0168
21	0.0379	0.0382	0.0083	0.0084	0.0758	0.0764	0.0167	0.0168
28	0.0377	0.0381	0.0083	0.0084	0.0754	0.0762	0.0166	0.0168
42	0.0374	0.0379	0.0082	0.0083	0.0747	0.0758	0.0164	0.0167
50	0.0371	0.0378	0.0082	0.0083	0.0743	0.0756	0.0163	0.0166
100	0.0359	0.0372	0.0079	0.0082	0.0718	0.0743	0.0158	0.0163

b) Spring cereals:

Parent – *Sulfoxaflor* Parameters used in FOCUSsw step 1 and 2	Version control no. of FOCUS calculator: *2.1* Molecular weight (g/mol): *277.27* Water solubility (mg/L): *673* K_{OC} (L/kg): *35* DT_{50} soil (d): *0.078* days (*Lab. In accordance with FOCUS SFO*) DT_{50} water/sediment system (d): *57.08 (geomean of two systems; SFO kinetics)* DT_{50} water (d): *57.08 (geomean of two systems; whole system value; SFO kinetics);* DT_{50} sediment (d): *68.63 (geomean of two systems; value determined using top-down approach from the maximum recorded in sediment; SFO kinetics);* Crop interception (%): *full canopy (70%)*
Parameters used in FOCUSsw step 3 (if performed)	Version control no.'s of FOCUS software: *SWASH 3.1 shell* Vapour pressure:*1.4 E-5 Pa (T = 20^{0}C) ;* Water solubility (mg/L): *673 (T = 20^{0}C)* K_{fOC}: *35 mL/g* 1/n: *0.96* *Other input parameters same as defined for calculations at STEPs 1-2*
Application rate	Crop: *Spring cereals* Crop interception: *for STEPS 1-2 full canopy (70%), for STEP 3 defined internally by the model* Number of applications: *1* Interval (d): *not applicable – single application* Application rate(s): *24* g as/ha Application window: *for calculations at STEPS 1-2 March May; for calculations at STEP 3: 01/04 – 05/05 for all scenarios*

STEP 1 results:

Time [days]	PEC_{SW} [µg/L]		PEC_{SED} [µg/kg sediment]	
	Actual	TWA	Actual	TWA
0	7.8640	----	2.6752	----
1	7.7594	7.8117	2.7158	2.6955
2	7.6657	7.7621	2.6830	2.6974
4	7.4818	7.6677	2.6186	2.6741
7	7.2141	7.5303	2.5249	2.6301
14	6.6263	7.2232	2.3192	2.5254
21	6.0863	6.9329	2.1302	2.4247
28	5.5903	6.6584	1.9566	2.3291
42	4.7163	6.1526	1.6507	2.1525
50	4.2797	5.8873	1.4979	2.0598
100	2.3319	4.5476	0.8162	1.5913

STEP 2 results:

Time [days]	North Europe				South Europe			
	PEC_{SW} [µg/L]		PEC_{SED} [µg/kg sediment]		PEC_{SW} [µg/L]		PEC_{SED} [µg/kg sediment]	
	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	0.2207	----	0.0704	----	0.2207	----	0.0704	----
1	0.2116	0.2161	0.0696	0.0700	0.2116	0.2161	0.0696	0.0700
2	0.2090	0.2132	0.0688	0.0696	0.2090	0.2132	0.0688	0.0696
4	0.2041	0.2099	0.0672	0.0688	0.2041	0.2099	0.0672	0.0688
7	0.1942	0.2048	0.0649	0.0676	0.1942	0.2048	0.0649	0.0676
14	0.1790	0.1957	0.0598	0.0650	0.1790	0.1957	0.0598	0.0650
21	0.1651	0.1878	0.0552	0.0625	0.1651	0.1878	0.0552	0.0625
28	0.1522	0.1805	0.0509	0.0601	0.1522	0.1805	0.0509	0.0601
42	0.1294	0.1671	0.0432	0.0557	0.1294	0.1671	0.0432	0.0557
50	0.1179	0.1602	0.0394	0.0534	0.1179	0.1602	0.0394	0.0534
100	0.0660	0.1248	0.0221	0.0417	0.0660	0.1248	0.0221	0.0417

STEP 3 results:

Identification of migration route:

FOCUS Scenario	Application window	Application date (determined by PAT)	Date of maximum	Identified dominant migration route
D1 – ditch	01/04 – 05/05	01/04/1982/9:00	01/04/1982/9:00	Spray Drift
D1 – stream	01/04 – 05/05	01/04/1982/9:00	01/04/1982/9:00	Spray Drift
D3 – ditch	01/04 – 05/05	04/04/1992/9:00	04/04/1992/9:00	Spray Drift
D4 – pond	01/04 – 05/05	18/04/1985/9:00	18/04/1985/9:00	Spray Drift
D4 – stream	01/04 – 05/05	18/04/1985/9:00	18/04/1985/9:00	Spray Drift
D5 – pond	01/04 – 05/05	08/04/1978/9:00	08/04/1978/9:00	Spray Drift
D5 – stream	01/04 – 05/05	08/04/1978/9:00	08/04/1978/9:00	Spray Drift
R4 – stream	01/04 – 05/05	04/05/1984/9:00	04/05/1984/9:00	Spray Drift

Numerical results:

Time [days]	FOCUS Scenario D1 Ditch PEC$_{SW}$ [µg/L] Actual	D1 Ditch PEC$_{SW}$ [µg/L] TWA	D1 Ditch PEC$_{SED}$ [µg/kg sediment] Actual	D1 Ditch PEC$_{SED}$ [µg/kg sediment] TWA	D1 Stream PEC$_{SW}$ [µg/L] Actual	D1 Stream PEC$_{SW}$ [µg/L] TWA	D1 Stream PEC$_{SED}$ [µg/kg sediment] Actual	D1 Stream PEC$_{SED}$ [µg/kg sediment] TWA
0	0.153[1)] 0.153[2)]	----	0.0268	----	0.120[1)] 0.120[2)]	----	3.38 E-3	----
1	0.122	0.138	0.0241	0.0264	2 E-6	7.65 E-3	6.82 E-4	1.33 E-3
2	0.0711	0.118	0.0202	0.0256	1 E-6	3.82 E-3	4.87 E-4	9.58 E-4
4	0.0132	0.0764	0.0148	0.0230	<1.0 E-6	1.91 E-3	3.47 E-4	6.85 E-4
7	3.03 E-4	0.0458	0.0108	0.0195	<1.0 E-6	1.09 E-3	2.61 E-4	5.20 E-4
14	3.0 E-5	0.0229	7.53 E-3	0.0146	3 E-6	5.48 E-4	1.84 E-4	3.69 E-4
21	3.6 E-5	0.0153	6.05 E-3	0.0121	2 E-6	3.66 E-4	1.48 E-4	3.01 E-4
28	4.2 E-5	0.0115	5.12 E-3	0.0105	2 E-6	2.75 E-4	1.26 E-4	2.60 E-4
42	8 E-6	7.65 E-3	3.84 E-3	8.55 E-3	1 E-6	1.84 E-4	9.6 E-5	2.10 E-4
50	4 E-6	6.43 E-3	3.32 E-3	7.78 E-3	1 E-6	1.54 E-4	8.4 E-5	1.91 E-4
100	3.7 E-5	3.23 E-3	1.48 E-3	5.05 E-3	<1.0 E-6	7.7 E-5	3.6 E-5	1.24 E-4

Time [days]	FOCUS Scenario D3 Ditch PEC$_{SW}$ [µg/L] Actual	D3 Ditch PEC$_{SW}$ [µg/L] TWA	D3 Ditch PEC$_{SED}$ [µg/kg sediment] Actual	D3 Ditch PEC$_{SED}$ [µg/kg sediment] TWA	D4 Pond PEC$_{SW}$ [µg/L] Actual	D4 Pond PEC$_{SW}$ [µg/L] TWA	D4 Pond PEC$_{SED}$ [µg/kg sediment] Actual	D4 Pond PEC$_{SED}$ [µg/kg sediment] TWA
0	0.152[1)] 0.152[2)]	----	0.0190	----	5.25 E-3[1)] 5.25 E-3[2)]	----	4.53 E-3	----
1	0.0670	0.1178	0.0130	0.0179	5.16 E-3	5.20 E-3	4.53 E-3	4.53 E-3
2	6.73 E-3	0.0726	9.46 E-3	0.0157	5.10 E-3	5.16 E-3	4.53 E-3	4.53 E-3
4	1.44 E-4	0.0371	6.67 E-3	0.0124	4.99 E-3	5.11 E-3	4.52 E-3	4.53 E-3
7	4.1 E-5	0.0212	5.01 E-3	9.73 E-3	4.85 E-3	5.03 E-3	4.51 E-3	4.53 E-3
14	1.3 E-5	0.0106	3.48 E-3	7.02 E-3	4.54 E-3	4.86 E-3	4.45 E-3	4.52 E-3
21	7 E-6	7.08 E-3	2.77 E-3	5.74 E-3	4.13 E-3	4.68 E-3	4.36 E-3	4.51 E-3
28	4 E-6	5.31 E-3	2.31 E-3	4.95 E-3	3.81 E-3	4.50 E-3	4.24 E-3	4.49 E-3
42	2 E-6	3.54 E-3	1.66 E-3	3.96 E-3	3.29 E-3	4.18 E-3	3.90 E-3	4.44 E-3
50	2 E-6	2.98 E-3	1.41 E-3	3.58 E-3	3.00 E-3	4.02 E-3	3.69 E-3	4.41 E-3
100	1 E-6	1.49 E-3	5.39 E-4	2.25 E-3	1.64 E-3	3.14 E-3	2.58 E-3	4.08 E-3

Time [days]	FOCUS Scenario D4 Stream PEC$_{SW}$ [µg/L] Actual	D4 Stream PEC$_{SW}$ [µg/L] TWA	D4 Stream PEC$_{SED}$ [µg/kg sediment] Actual	D4 Stream PEC$_{SED}$ [µg/kg sediment] TWA	D5 Pond PEC$_{SW}$ [µg/L] Actual	D5 Pond PEC$_{SW}$ [µg/L] TWA	D5 Pond PEC$_{SED}$ [µg/kg sediment] Actual	D5 Pond PEC$_{SED}$ [µg/kg sediment] TWA
0	0.118[1)] 0.118[2)]	----	2.97 E-3	----	5.25 E-3[1)] 5.25 E-3[2)]	----	4.53 E-3	----
1	1 E-6	6.76 E-3	6.00 E-4	1.17 E-3	5.15 E-3	5.19 E-3	4.52 E-3	4.53 E-3
2	<1.0 E-6	3.38 E-3	4.29 E-4	8.44 E-4	5.08 E-3	5.15 E-3	4.52 E-3	4.53 E-3
4	<1.0 E-6	1.69 E-3	3.06 E-4	6.03 E-4	4.96 E-3	5.08 E-3	4.50 E-3	4.53 E-3
7	<1.0 E-6	9.66 E-4	2.30 E-4	4.58 E-4	4.80 E-3	4.99 E-3	4.48 E-3	4.52 E-3
14	<1.0 E-6	4.83 E-4	1.60 E-4	3.24 E-4	4.48 E-3	4.81 E-3	4.39 E-3	4.52 E-3
21	<1.0 E-6	3.22 E-4	1.27 E-4	2.64 E-4	4.19 E-3	4.65 E-3	4.29 E-3	4.50 E-3
28	<1.0 E-6	2.42 E-4	1.07 E-4	2.27 E-4	3.89 E-3	4.50 E-3	4.17 E-3	4.49 E-3
42	<1.0 E-6	1.61 E-4	8.0 E-5	1.82 E-4	3.33 E-3	4.20 E-3	3.82 E-3	4.44 E-3
50	<1.0 E-6	1.35 E-4	6.9 E-5	1.65 E-4	3.07 E-3	4.04 E-3	3.61 E-3	4.41 E-3
100	<1.0 E-6	6.8 E-5	2.9 E-5	1.05 E-4	1.74 E-3	3.20 E-3	2.46 E-3	4.11 E-3

1) Global maximum concentration, including the substance adsorbed to particles suspended in the water phase;
2) Maximum concentration of the substance dissolved in water;

Time [days]	FOCUS Scenario							
	D5 Stream				R4 Stream			
	PEC_{SW} [µg/L]		**PEC_{SED} [µg/kg sediment]**		**PEC_{SW} [µg/L]**		**PEC_{SED} [µg/kg sediment]**	
	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	0.119[1)] 0.119[2)]	----	2.31 E-3	----	0.101[1)] 0.101[2)]	----	6.42 E-3	----
1	1 E-6	4.41 E-3	3.86 E-4	7.49 E-4	1.7 E-5	0.0216	1.97 E-3	3.69 E-3
2	<1.0 E-6	2.21 E-3	2.74 E-4	5.37 E-4	5 E-6	0.0108	1.40 E-3	2.70 E-3
4	<1.0 E-6	1.10 E-3	1.94 E-4	3.83 E-4	2 E-6	5.39 E-3	9.90 E-4	1.95 E-3
7	<1.0 E-6	6.31 E-4	1.45 E-4	2.90 E-4	1 E-6	3.08 E-3	7.37 E-4	1.48 E-3
14	<1.0 E-6	3.15 E-4	1.01 E-5	2.05 E-4	<1.0 E-6	1.54 E-3	5.04 E-4	1.04 E-3
21	<1.0 E-6	2.10 E-4	8.0 E-5	1.66 E-4	<1.0 E-6	1.03 E-3	3.96 E-4	8.46 E-4
28	<1.0 E-6	1.58 E-4	6.7 E-5	1.43 E-4	<1.0 E-6	7.71 E-4	3.27 E-4	7.25 E-4
42	<1.0 E-6	1.05 E-4	4.9 E-5	1.15 E-4	<1.0 E-6	5.14 E-4	2.28 E-4	5.75 E-4
50	<1.0 E-6	8.8 E-5	4.2 E-5	1.04 E-4	<1.0 E-6	4.32 E-4	1.90 E-4	5.16 E-4
100	<1.0 E-6	4.4 E-5	1.8 E-5	6.6 E-5	<1.0 E-6	2.16 E-4	6.1 E-5	3.15 E-4

1) Global maximum concentration, including the substance adsorbed to particles suspended in the water phase;
2) Maximum concentration of the substance dissolved in water;

Metabolite: **X11719474** Parameters used in FOCUSsw step 1 and 2	Molecular weight: *295.30* Water solubility (mg/L): *8090* Soil or water metabolite: *soil and water metabolite* Koc (L/kg): *30* DT_{50} soil (d): *76.61* days (*Field. In accordance with FOCUS SFO*) DT50 water/sediment system (d): *1000 (FOCUS default value)* DT_{50} water (d): *1000 (FOCUS default value)* DT_{50} sediment (d): *1000 (FOCUS default value)* Crop interception (%): *full canopy (70%)* Maximum occurrence observed: Water/sediment: *70.9%* Soil: *100%*
Parameters used in FOCUSsw step 3 (if performed)	Calculations not performed
Application rate	Crop: *Spring cereals* Number of applications: *1* Interval (d): *not applicable – parent compound* Application rate(s): *24* g as/ha Depth of water body: *as defined by the model in STEP 1-2 calculations* Application window: *March - May*
Main routes of entry	*As defined for STEP 1-2 calculations*

STEP 1 results:

Time [days]	PEC_{SW} [µg/L]		PEC_{SED} [µg/kg sediment]	
	Actual	TWA	Actual	TWA
0	8.3592	----	2.4578	----
1	8.3470	8.3531	2.5041	2.4809
2	8.3412	8.3486	2.5024	2.4921
4	8.3296	8.3420	2.4989	2.4964
7	8.3123	8.3330	2.4937	2.4963
14	8.2721	8.3126	2.4816	2.4920
21	8.2321	8.2924	2.4696	2.4865
28	8.1922	8.2724	2.4577	2.4808
42	8.1131	8.2324	2.4339	2.4691
50	8.0682	8.2098	2.4205	2.4624
100	7.7934	8.0699	2.3380	2.4207

STEP 2 results:

Time [days]	North Europe				South Europe			
	PEC_{SW} [µg/L]		PEC_{SED} [µg/kg sediment]		PEC_{SW} [µg/L]		PEC_{SED} [µg/kg sediment]	
	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	0.6360	----	0.1900	----	1.1100	----	0.3322	----
1	0.6335	0.6347	0.1899	0.1900	1.1072	1.1086	0.3319	0.3320
2	0.6330	0.6340	0.1898	0.1899	1.1064	1.1077	0.3317	0.3319
4	0.6321	0.6333	0.1896	0.1898	1.1049	1.1067	0.3312	0.3317
7	0.6308	0.6325	0.1895	0.1896	1.1026	1.1054	0.3306	0.3314
14	0.6278	0.6309	0.1891	0.1891	1.0973	1.1027	0.3290	0.3306
21	0.6247	0.6294	0.1882	0.1887	1.0920	1.1000	0.3274	0.3298
28	0.6217	0.6278	0.1873	0.1882	1.0867	1.0973	0.3258	0.3290
42	0.6157	0.6248	0.1864	0.1873	1.0762	1.0920	0.3226	0.3274
50	0.6123	0.6231	0.1846	0.1868	1.0702	1.0890	0.3208	0.3265
100	0.5914	0.6124	0.1836	0.1836	1.0338	1.0705	0.3099	0.3209

Metabolite: **X11519540** Parameters used in FOCUSsw step 1 and 2	Molecular weight: *253.24* Water solubility (mg/L): *1000* Soil or water metabolite: *soil metabolite* Koc (L/kg): *14* DT_{50} soil (d): *449.86* days (*Lab. In accordance with FOCUS SFO – long phase HS*) DT50 water/sediment system (d): *1000 (FOCUS default value)* DT_{50} water (d): *1000 (FOCUS default value)* DT_{50} sediment (d): *1000 (FOCUS default value)* Crop interception (%): *full canopy (70%)* Maximum occurrence observed: Water/sediment: *0.0001%* Soil: *12.2%*
Parameters used in FOCUSsw step 3 (if performed)	Calculations not performed

Application rate	Crop: *Spring cereals* Number of applications: *1* Interval (d): *not applicable – parent compound* Application rate(s): *24* g as/ha Depth of water body: *as defined by the model in STEP 1-2 calculations* Application window: *March - May*
Main routes of entry	*As defined for STEP 1-2 calculations*

STEP 1 results:

Time [days]	**PEC_{SW} [µg/L]**		**PEC_{SED} [µg/kg sediment]**	
	Actual	TWA	Actual	TWA
0	0.8751	----	0.1225	----
1	0.8745	0.8748	0.1224	0.1225
2	0.8739	0.8745	0.1223	0.1224
4	0.8727	0.8739	0.1222	0.1223
7	0.8708	0.8730	0.1219	0.1222
14	0.8666	0.8708	0.1213	0.1219
21	0.8624	0.8687	0.1207	0.1216
28	0.8583	0.8666	0.1202	0.1213
42	0.8500	0.8625	0.1190	0.1207
50	0.8453	0.8601	0.1183	0.1204
100	0.8165	0.8454	0.1143	0.1184

STEP 2 results:

Time [days]	**North Europe**				**South Europe**			
	PEC_{SW} [µg/L]		**PEC_{SED} [µg/kg sediment]**		**PEC_{SW} [µg/L]**		**PEC_{SED} [µg/kg sediment]**	
	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	0.0522	----	0.0073	----	0.1044	----	0.0146	----
1	0.0521	0.0522	0.0073	0.0073	0.1043	0.1043	0.0146	0.0146
2	0.0521	0.0521	0.0073	0.0073	0.1042	0.1043	0.0146	0.0146
4	0.0520	0.0521	0.0073	0.0073	0.1041	0.1042	0.0146	0.0146
7	0.0519	0.0521	0.0073	0.0073	0.1039	0.1041	0.0145	0.0146
14	0.0517	0.0519	0.0072	0.0073	0.1034	0.1039	0.0145	0.0146
21	0.0514	0.0518	0.0072	0.0073	0.1029	0.1036	0.0144	0.0145
28	0.0512	0.0517	0.0072	0.0072	0.1024	0.1034	0.0143	0.0145
42	0.0507	0.0514	0.0071	0.0072	0.1014	0.1029	0.0142	0.0145
50	0.0504	0.0513	0.0071	0.0072	0.1008	0.1026	0.0141	0.0144
100	0.0487	0.0504	0.0068	0.0071	0.0974	0.1008	0.0136	0.0141

Metabolite: **X11579457** Parameters used in FOCUSsw step 1 and 2	Molecular weight: *252.25* Water solubility (mg/L): *1000* Soil or water metabolite: *soil metabolite* Koc (L/kg): *22* DT_{50} soil (d): *186.67* days (*Lab. In accordance with FOCUS SFO – long phase HS*) DT50 water/sediment system (d): *1000 (FOCUS default value)* DT_{50} water (d): *1000 (FOCUS default value)* DT_{50} sediment (d): *1000 (FOCUS default value)* Crop interception (%): *full canopy (70%)* Maximum occurrence observed: Water/sediment: *0.0001%* Soil: *9.2%*
Parameters used in FOCUSsw step 3 (if performed)	Calculations not performed
Application rate	Crop: *Spring cereals* Number of applications: *1* Interval (d): *not applicable – parent compound* Application rate(s): *24* g as/ha Depth of water body: *as defined by the model in STEP 1-2 calculations* Application window: *March - May*
Main routes of entry	*As defined for STEP 1-2 calculations*

STEP 1 results:

Time [days]	**PEC_{SW} [µg/L]**		**PEC_{SED} [µg/kg sediment]**	
	Actual	TWA	Actual	TWA
0	0.6505	----	0.1431	----
1	0.6501	0.6503	0.1430	0.1431
2	0.6496	0.6501	0.1429	0.1430
4	0.6487	0.6496	0.1427	0.1429
7	0.6474	0.6489	0.1424	0.1428
14	0.6442	0.6474	0.1417	0.1424
21	0.6411	0.6458	0.1410	0.1421
28	0.6380	0.6442	0.1404	0.1417
42	0.6318	0.6411	0.1390	0.1410
50	0.6283	0.6394	0.1382	0.1407
100	0.6069	0.6285	0.1335	0.1383

STEP 2 results:

Time [days]	North Europe				South Europe			
	PEC_{SW} [µg/L]		PEC_{SED} [µg/kg sediment]		PEC_{SW} [µg/L]		PEC_{SED} [µg/kg sediment]	
	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	0.0385	----	0.0085	----	0.0769	----	0.0169	----
1	0.0384	0.0384	0.0085	0.0085	0.0769	0.0769	0.0169	0.0169
2	0.0384	0.0384	0.0084	0.0085	0.0768	0.0769	0.0169	0.0169
4	0.0383	0.0384	0.0084	0.0084	0.0767	0.0768	0.0169	0.0169
7	0.0383	0.0384	0.0084	0.0084	0.0765	0.0767	0.0168	0.0169
14	0.0381	0.0383	0.0084	0.0084	0.0762	0.0765	0.0168	0.0168
21	0.0379	0.0382	0.0083	0.0084	0.0758	0.0764	0.0167	0.0168
28	0.0377	0.0381	0.0083	0.0084	0.0754	0.0762	0.0166	0.0168
42	0.0374	0.0379	0.0082	0.0083	0.0747	0.0758	0.0164	0.0167
50	0.0371	0.0378	0.0082	0.0083	0.0743	0.0756	0.0163	0.0166
100	0.0359	0.0372	0.0079	0.0082	0.0718	0.0743	0.0158	0.0163

c) Fruiting vegetables and cucurbits:

Parent – *Sulfoxaflor* Parameters used in FOCUSsw step 1 and 2	Version control no. of FOCUS calculator: *2.1* Molecular weight (g/mol): *277.27* Water solubility (mg/L): *673* K_{OC} (L/kg): *35* DT_{50} soil (d): *0.078* days (*Lab. In accordance with FOCUS SFO*) DT_{50} water/sediment system (d): *57.08 (geomean of two systems; SFO kinetics)* DT_{50} water (d): *57.08 (geomean of two systems; whole system value; SFO kinetics);* DT_{50} sediment (d): *68.63 (geomean of two systems; value determined using top-down approach from the maximum recorded in sediment; SFO kinetics);* Crop interception (%): *average crop cover (50%)*
Parameters used in FOCUSsw step 3 (if performed)	Version control no.'s of FOCUS software: *SWASH 3.1 shell* Vapour pressure:*1.4 E-5 Pa (T = 20^{0}C) ;* Water solubility (mg/L): *673 (T = 20^{0}C)* K_{fOC}: *35 mL/g* 1/n: *0.96* *Other input parameters same as defined for calculations at STEPs 1-2*
Application rate	Crop: *Fruiting vegetables* Crop interception: *for STEPS 1-2 average crop canopy (50%), for STEP 3 defined internally by the model* Number of applications: *1* Interval (d): *not applicable – single application* Application rate(s): *24* g as/ha Application window: *for calculations at STEPS 1-2 March May; for calculations at STEP 3: 01/03 – 31/03 for all scenarios*

STEP 1 results:

Time [days]	PEC_{SW} [µg/L]		PEC_{SED} [µg/kg sediment]	
	Actual	TWA	Actual	TWA
0	7.8640	----	2.6752	----
1	7.7594	7.8117	2.7158	2.6955
2	7.6657	7.7621	2.6830	2.6974
4	7.4818	7.6677	2.6186	2.6741
7	7.2141	7.5303	2.5249	2.6301
14	6.6263	7.2232	2.3192	2.5254
21	6.0863	6.9329	2.1302	2.4247
28	5.5903	6.6584	1.9566	2.3291
42	4.7163	6.1526	1.6507	2.1525
50	4.2797	5.8873	1.4979	2.0598
100	2.3319	4.5476	0.8162	1.5913

STEP 2 results:

Time [days]	North Europe				South Europe			
	PEC_{SW} [µg/L]		PEC_{SED} [µg/kg sediment]		PEC_{SW} [µg/L]		PEC_{SED} [µg/kg sediment]	
	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	0.2207	----	0.0704	----	0.2207	----	0.0704	----
1	0.2116	0.2161	0.0696	0.0700	0.2116	0.2161	0.0696	0.0700
2	0.2090	0.2132	0.0688	0.0696	0.2090	0.2132	0.0688	0.0696
4	0.2041	0.2099	0.0672	0.0688	0.2041	0.2099	0.0672	0.0688
7	0.1942	0.2048	0.0649	0.0676	0.1942	0.2048	0.0649	0.0676
14	0.1790	0.1957	0.0598	0.0650	0.1790	0.1957	0.0598	0.0650
21	0.1651	0.1878	0.0552	0.0625	0.1651	0.1878	0.0552	0.0625
28	0.1522	0.1805	0.0509	0.0601	0.1522	0.1805	0.0509	0.0601
42	0.1294	0.1671	0.0432	0.0557	0.1294	0.1671	0.0432	0.0557
50	0.1179	0.1602	0.0394	0.0534	0.1179	0.1602	0.0394	0.0534
100	0.0660	0.1248	0.0221	0.0417	0.0660	0.1248	0.0221	0.0417

STEP 3 results:

Identification of migration route:

FOCUS Scenario	Application window	Application date (determined by PAT)	Date of maximum	Identified dominant migration route
D6 – ditch	01/03 – 31/03	05/03/1986/9:00	05/03/1986/9:00	Spray Drift
R2 – stream	01/03 – 31/03	01/03/1977/9:00	01/03/1977/9:00	Spray Drift
R3 – stream	01/03 – 31/03	01/03/1980/9:00	01/03/1980/9:00	Spray Drift
R4 – stream	01/03 – 31/03	05/03/1984/9:00	05/03/1984/9:00	Spray Drift

Numerical results:

Time [days]	FOCUS Scenario							
	D6 Ditch				R2 Stream			
	PEC_{SW} [µg/L]		PEC_{SED} [µg/kg sediment]		PEC_{SW} [µg/L]		PEC_{SED} [µg/kg sediment]	
	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	0.152[1)] 0.152[2)]	----	0.0190	----	0.133[1)] 0.133[2)]	----	4.92 E-3	----
1	0.0667	0.117	0.0136	0.0179	4 E-6	0.0119	1.08 E-3	2.07 E-3
2	8.17 E-3	0.0734	9.68 E-3	0.0159	1 E-65	5.95 E-3	7.63 E-4	1.49 E-3
4	1.86 E-4	0.0377	6.77 E-3	0.0125	<1.0 E-6	2.98 E-3	5.40 E-4	1.07 E-3
7	4.9 E-5	0.0216	5.06 E-3	9.85 E-3	<1.0 E-6	1.70 E-3	4.03 E-4	8.10 E-4
14	1.3 E-5	0.0108	3.48 E-3	7.09 E-3	<1.0 E-6	8.50 E-4	2.76 E-4	5.70 E-4
21	7 E-6	7.20 E-3	2.75 E-3	5.78 E-3	<1.0 E-6	5.67 E-4	2.18 E-4	4.62 E-4
28	1 E-6	5.40 E-3	2.28 E-3	4.97 E-3	<1.0 E-6	4.25 E-4	1.82 E-4	3.96 E-4
42	1 E-6	3.60 E-3	1.65 E-3	3.97 E-3	<1.0 E-6	2.83 E-4	1.34 E-4	3.16 E-4
50	<1.0 E-6	3.02 E-3	1.41 E-3	3.59 E-3	<1.0 E-6	2.38 E-4	1.15 E-4	2.86 E-4
100	<1.0 E-6	1.51 E-3	4.92 E-4	2.24 E-3	<1.0 E-6	1.19 E-4	5.1 E-5	1.82 E-4

Time [days]	FOCUS Scenario							
	R3 Stream				R4 Stream			
	PEC_{SW} [µg/L]		PEC_{SED} [µg/kg sediment]		PEC_{SW} [µg/L]		PEC_{SED} [µg/kg sediment]	
	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	0.141[1)] 0.141[2)]	----	0.0108	----	0.100[1)] 0.100[2)]	----	6.07 E-3	----
1	2.27 E-4	0.0542	4.12 E-3	7.45 E-3	1.3 E-5	0.0192	1.75 E-3	3.30 E-3
2	2.5 E-5	0.0227	2.93 E-3	5.57 E-3	4 E-6	9.60 E-3	1.25 E-3	2.40 E-3
4	8 E-6	0.0113	2.08 E-3	4.05 E-3	1 E-6	4.80 E-3	8.88 E-4	1.74 E-3
7	<1.0 E-6	6.48 E-3	1.56 E-3	3.10 E-3	<1.0 E-6	2.74 E-3	6.67 E-4	1.33E-3
14	1 E-6	3.24 E-3	1.08 E-3	2.20 E-3	<1.0 E-6	1.37 E-3	4.63 E-4	9.41 E-4
21	<1.0 E-6	2.16 E-3	8.60 E-4	1.79 E-3	<1.0 E-6	9.15 E-4	3.69 E-4	7.65 E-4
28	<1.0 E-6	1.62 E-3	7.22 E-4	1.54 E-3	<1.0 E-6	6.86 E-4	3.10 E-4	6.59 E-4
42	<1.0 E-6	1.08 E-3	5.41 E-4	1.24 E-3	<1.0 E-6	4.58 E-4	2.31 E-4	5.28 E-4
50	<1.0 E-6	9.08 E-4	4.68 E-4	1.12 E-3	<1.0 E-6	3.84 E-4	1.99 E-4	4.78 E-4
100	<1.0 E-6	4.54 E-4	1.97 E-4	7.17 E-4	<1.0 E-6	1.92 E-4	8.4 E-4	3.06 E-4

1) Global maximum concentration, including the substance adsorbed to particles suspended in the water phase;
2) Maximum concentration of the substance dissolved in water;

Metabolite: **X11719474** Parameters used in FOCUSsw step 1 and 2	Molecular weight: *295.30* Water solubility (mg/L): *8090* Soil or water metabolite: *soil and water metabolite* Koc (L/kg): *30* DT_{50} soil (d): *76.61* days (*Field. In accordance with FOCUS SFO*) DT50 water/sediment system (d): *1000 (FOCUS default value)* DT_{50} water (d): *1000 (FOCUS default value)* DT_{50} sediment (d): *1000 (FOCUS default value)* Crop interception (%): *average crop cover (50%)* Maximum occurrence observed: Water/sediment: *70.9%* Soil: *100%*
Parameters used in FOCUSsw step 3 (if performed)	Calculations not performed

Application rate	Crop: *Fruiting vegetables* Number of applications: *1* Interval (d): *not applicable – parent compound* Application rate(s): *24* g as/ha Depth of water body: *as defined by the model in STEP 1-2 calculations* Application window: *March - May*
Main routes of entry	*As defined for STEP 1-2 calculations*

STEP 1 results:

Time [days]	**PEC_{SW} [µg/L]**		**PEC_{SED} [µg/kg sediment]**	
	Actual	TWA	Actual	TWA
0	8.3592	----	2.4578	----
1	8.3470	8.3531	2.5041	2.4809
2	8.3412	8.3486	2.5024	2.4921
4	8.3296	8.3420	2.4989	2.4964
7	8.3123	8.3330	2.4937	2.4963
14	8.2721	8.3126	2.4816	2.4920
21	8.2321	8.2924	2.4696	2.4865
28	8.1922	8.2724	2.4577	2.4808
42	8.1131	8.2324	2.4339	2.4691
50	8.0682	8.2098	2.4205	2.4624
100	7.7934	8.0699	2.3380	2.4207

STEP 2 results:

Time [days]	**North Europe**				**South Europe**			
	PEC_{SW} [µg/L]		**PEC_{SED} [µg/kg sediment]**		**PEC_{SW} [µg/L]**		**PEC_{SED} [µg/kg sediment]**	
	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	0.9520	----	0.2848	----	1.7422	----	0.5217	----
1	0.9493	0.9507	0.2846	0.2847	1.7389	1.7405	0.5213	0.5215
2	0.9486	0.9498	0.2844	0.2846	1.7377	1.7394	0.5209	0.5213
4	0.9473	0.9489	0.2840	0.2844	1.7353	1.7379	0.5202	0.5209
7	0.9453	0.9478	0.2834	0.2841	1.7317	1.7360	0.5191	0.5204
14	0.9408	0.9454	0.2820	0.2834	1.7233	1.7317	0.5166	0.5191
21	0.9362	0.9431	0.2807	0.2827	1.7149	1.7275	0.5141	0.5179
28	0.9317	0.9408	0.2793	0.2820	1.7066	1.7233	0.5116	0.5166
42	0.9227	0.9363	0.2766	0.2807	1.6901	1.7150	0.5067	0.5141
50	0.9176	0.9337	0.2751	0.2799	1.6808	1.7103	0.5039	0.5127
100	0.8863	0.9178	0.2657	0.2751	1.6235	1.6812	0.4867	0.5040

Metabolite: **X11519540** Parameters used in FOCUSsw step 1 and 2	Molecular weight: *253.24* Water solubility (mg/L): *1000* Soil or water metabolite: *soil metabolite* Koc (L/kg): *14* DT_{50} soil (d): *449.86* days (*Lab. In accordance with FOCUS SFO – long phase HS*) DT50 water/sediment system (d): *1000 (FOCUS default value)* DT_{50} water (d): *1000 (FOCUS default value)* DT_{50} sediment (d): *1000 (FOCUS default value)* Crop interception (%): *full canopy (70%)* Maximum occurrence observed: Water/sediment: *0.0001%* Soil: *12.2%*
Parameters used in FOCUSsw step 3 (if performed)	Calculations not performed
Application rate	Crop: *Fruiting vegetables* Number of applications: *1* Interval (d): *not applicable – parent compound* Application rate(s): *24* g as/ha Depth of water body: *as defined by the model in STEP 1-2 calculations* Application window: *March - May*
Main routes of entry	*As defined for STEP 1-2 calculations*

STEP 1 results:

Time [days]	**PEC_{SW} [µg/L]**		**PEC_{SED} [µg/kg sediment]**	
	Actual	TWA	Actual	TWA
0	0.8751	----	0.1225	----
1	0.8745	0.8748	0.1224	0.1225
2	0.8739	0.8745	0.1223	0.1224
4	0.8727	0.8739	0.1222	0.1223
7	0.8708	0.8730	0.1219	0.1222
14	0.8666	0.8708	0.1213	0.1219
21	0.8624	0.8687	0.1207	0.1216
28	0.8583	0.8666	0.1202	0.1213
42	0.8500	0.8625	0.1190	0.1207
50	0.8453	0.8601	0.1183	0.1204
100	0.8165	0.8454	0.1143	0.1184

STEP 2 results:

Time [days]	North Europe				South Europe			
	PEC_{SW} [µg/L]		**PEC_{SED} [µg/kg sediment]**		**PEC_{SW} [µg/L]**		**PEC_{SED} [µg/kg sediment]**	
	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	0.0870	----	0.0122	----	0.1739	----	0.0244	----
1	0.0869	0.0869	0.0122	0.0122	0.1738	0.1739	0.0243	0.0243
2	0.0868	0.0869	0.0122	0.0122	0.1737	0.1738	0.0243	0.0243
4	0.0867	0.0868	0.0121	0.0122	0.1735	0.1737	0.0243	0.0243
7	0.0865	0.0868	0.0121	0.0121	0.1731	0.1735	0.0242	0.0243
14	0.0861	0.0865	0.0121	0.0121	0.1723	0.1731	0.0241	0.0242
21	0.0857	0.0863	0.0120	0.0121	0.1714	0.1727	0.0240	0.0242
28	0.0853	0.0861	0.0119	0.0121	0.1706	0.1723	0.0239	0.0241
42	0.0845	0.0857	0.0118	0.0120	0.1689	0.1714	0.0237	0.0240
50	0.0840	0.0855	0.0118	0.0120	0.1680	0.1710	0.0235	0.0239
100	0.0811	0.0840	0.0114	0.0118	0.1623	0.1680	0.0227	0.0235

Metabolite: **X11579457** Parameters used in FOCUSsw step 1 and 2	Molecular weight: *252.25* Water solubility (mg/L): *1000* Soil or water metabolite: *soil metabolite* Koc (L/kg): *22* DT_{50} soil (d): *186.67* days (*Lab. In accordance with FOCUS SFO – long phase HS*) DT50 water/sediment system (d): *1000 (FOCUS default value)* DT_{50} water (d): *1000 (FOCUS default value)* DT_{50} sediment (d): *1000 (FOCUS default value)* Crop interception (%): *average crop cover (50%)* Maximum occurrence observed: Water/sediment: *0.0001%* Soil: *9.2%*
Parameters used in FOCUSsw step 3 (if performed)	Calculations not performed
Application rate	Crop: *Fruiting vegetables* Number of applications: *1* Interval (d): *not applicable – parent compound* Application rate(s): *24* g as/ha Depth of water body: *as defined by the model in STEP 1-2 calculations* Application window: *March - May*
Main routes of entry	*As defined for STEP 1-2 calculations*

STEP 1 results:

Time [days]	PEC_{SW} [µg/L]		PEC_{SED} [µg/kg sediment]	
	Actual	TWA	Actual	TWA
0	0.6505	----	0.1431	----
1	0.6501	0.6503	0.1430	0.1431
2	0.6496	0.6501	0.1429	0.1430
4	0.6487	0.6496	0.1427	0.1429
7	0.6474	0.6489	0.1424	0.1428
14	0.6442	0.6474	0.1417	0.1424
21	0.6411	0.6458	0.1410	0.1421
28	0.6380	0.6442	0.1404	0.1417
42	0.6318	0.6411	0.1390	0.1410
50	0.6283	0.6394	0.1382	0.1407
100	0.6069	0.6285	0.1335	0.1383

STEP 2 results:

Time [days]	North Europe				South Europe			
	PEC_{SW} [µg/L]		PEC_{SED} [µg/kg sediment]		PEC_{SW} [µg/L]		PEC_{SED} [µg/kg sediment]	
	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	0.0641	----	0.0141	----	0.1282	----	0.0282	----
1	0.0640	0.0641	0.0141	0.0141	0.1281	0.1281	0.0282	0.282
2	0.0640	0.0640	0.0141	0.0141	0.1280	0.1281	0.0282	0.0282
4	0.0639	0.0640	0.0141	0.0141	0.1278	0.1280	0.0281	0.0282
7	0.0638	0.0639	0.0140	0.0141	0.1276	0.1279	0.0281	0.0281
14	0.0635	0.0638	0.0140	0.0140	0.1269	0.1276	0.0279	0.0281
21	0.0632	0.0636	0.0139	0.0140	0.1263	0.1273	0.0278	0.0280
28	0.0629	0.0635	0.0138	0.0140	0.1257	0.1269	0.0277	0.0279
42	0.0623	0.0632	0.0137	0.0139	0.1245	0.1263	0.0274	0.0278
50	0.0619	0.0630	0.0136	0.0139	0.1238	0.1260	0.0272	0.0277
100	0.0598	0.0619	0.0132	0.0136	0.1196	0.1238	0.0263	0.0272

d) Cotton:

Parent – *Sulfoxaflor* Parameters used in FOCUSsw step 1 and 2	Version control no. of FOCUS calculator: *2.1* Molecular weight (g/mol): *277.27* Water solubility (mg/L): *673* K_{OC} (L/kg): *35* DT_{50} soil (d): *0.078* days (*Lab. In accordance with FOCUS SFO*) DT_{50} water/sediment system (d): *57.08 (geomean of two systems; SFO kinetics)* DT_{50} water (d): *57.08 (geomean of two systems; whole system value; SFO kinetics);* DT_{50} sediment (d): *68.63 (geomean of two systems; value determined using top-down approach from the maximum recorded in sediment; SFO kinetics);* Crop interception (%): *average crop cover (60%)*

Parameters used in FOCUSsw step 3 (if performed)	Version control no.'s of FOCUS software: *SWASH 3.1 shell* Vapour pressure:*1.4 E-5 Pa (T = 20^{0}C) ;* Water solubility (mg/L): *673 (T = 20^{0}C)* K_{fOC}: *35 mL/g* 1/n: *0.96* *Other input parameters same as defined for calculations at STEPs 1-2*
Application rate	Crop: *Cotton* Crop interception: *for STEPS 1-2 average crop canopy (60%), for STEP 3 defined internally by the model* Number of applications: *1* Interval (d): *not applicable – single application* Application rate(s): *24* g as/ha Application window: *for calculations at STEPS 1-2 March May; for calculations at STEP 3: 01/05 – 31/05 for all scenarios*

STEP 1 results:

Time [days]	**PEC_{SW} [µg/L]**		**PEC_{SED} [µg/kg sediment]**	
	Actual	TWA	Actual	TWA
0	7.8640	----	2.6752	----
1	7.7594	7.8117	2.7158	2.6955
2	7.6657	7.7621	2.6830	2.6974
4	7.4818	7.6677	2.6186	2.6741
7	7.2141	7.5303	2.5249	2.6301
14	6.6263	7.2232	2.3192	2.5254
21	6.0863	6.9329	2.1302	2.4247
28	5.5903	6.6584	1.9566	2.3291
42	4.7163	6.1526	1.6507	2.1525
50	4.2797	5.8873	1.4979	2.0598
100	2.3319	4.5476	0.8162	1.5913

STEP 2 results:

Time [days]	**North Europe**				**South Europe**			
	PEC_{SW} [µg/L]		**PEC_{SED} [µg/kg sediment]**		**PEC_{SW} [µg/L]**		**PEC_{SED} [µg/kg sediment]**	
	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	0.2207	----	0.0704	----	0.2207	----	0.0704	----
1	0.2116	0.2161	0.0696	0.0700	0.2116	0.2161	0.0696	0.0700
2	0.2090	0.2132	0.0688	0.0696	0.2090	0.2132	0.0688	0.0696
4	0.2041	0.2099	0.0672	0.0688	0.2041	0.2099	0.0672	0.0688
7	0.1942	0.2048	0.0649	0.0676	0.1942	0.2048	0.0649	0.0676
14	0.1790	0.1957	0.0598	0.0650	0.1790	0.1957	0.0598	0.0650
21	0.1651	0.1878	0.0552	0.0625	0.1651	0.1878	0.0552	0.0625
28	0.1522	0.1805	0.0509	0.0601	0.1522	0.1805	0.0509	0.0601
42	0.1294	0.1671	0.0432	0.0557	0.1294	0.1671	0.0432	0.0557
50	0.1179	0.1602	0.0394	0.0534	0.1179	0.1602	0.0394	0.0534
100	0.0660	0.1248	0.0221	0.0417	0.0660	0.1248	0.0221	0.0417

STEP 3 results:

Identification of migration route:

FOCUS Scenario	Application window	Application date (determined by PAT)	Date of maximum	Identified dominant migration route
D6 – ditch	01/05 – 31-05	14/05/1986/9:00	14/05/1986/9:00	Spray Drift

Numerical results:

Time [days]	FOCUS Scenario			
	D6 Ditch			
	PEC_{SW} [µg/L]		**PEC_{SED} [µg/kg sediment]**	
	Actual	TWA	Actual	TWA
0	0.125[1)] 0.125[2)]	----	0.0129	----
1	0.0204	0.0762	7.53 E-3	0.0115
2	8.07 E-4	0.0414	5.28 E-3	9.47 E-3
4	5.9 E-5	0.0208	3.70 E-3	7.15 E-3
7	1.0 E-5	0.0119	2.73 E-3	5.52 E-3
14	3 E-6	5.96 E-3	1.82 E-3	3.90 E-3
21	2 E-6	3.97 E-3	1.38 E-3	3.14 E-3
28	2 E-6	2.98 E-3	1.08 E-3	2.67 E-3
42	1 E-6	1.99 E-3	7.17 E-4	2.08 E-3
50	1 E-6	1.67 E-3	5.76 E-4	1.85 E-3
100	<1.0 E-6	8.35 E-4	1.57 E-4	1.09 E-3

1) Global maximum concentration, including the substance adsorbed to particles suspended in the water phase;
2) Maximum concentration of the substance dissolved in water;

Metabolite: **X11719474** Parameters used in FOCUSsw step 1 and 2	Molecular weight: *295.30* Water solubility (mg/L): *8090* Soil or water metabolite: *soil and water metabolite* Koc (L/kg): *30* DT_{50} soil (d): *76.61* days (*Field. In accordance with FOCUS SFO*) DT50 water/sediment system (d): *1000 (FOCUS default value)* DT_{50} water (d): *1000 (FOCUS default value)* DT_{50} sediment (d): *1000 (FOCUS default value)* Crop interception (%): *average crop cover (60%)* Maximum occurrence observed: Water/sediment: *70.9%* Soil: *100%*
Parameters used in FOCUSsw step 3 (if performed)	Calculations not performed
Application rate	Crop: *Cotton* Number of applications: *1* Interval (d): *not applicable – parent compound* Application rate(s): *24* g as/ha Depth of water body: *as defined by the model in STEP 1-2 calculations* Application window: *March - May*
Main routes of entry	*As defined for STEP 1-2 calculations*

STEP 1 results:

Time [days]	PEC_{SW} [µg/L]		PEC_{SED} [µg/kg sediment]	
	Actual	TWA	Actual	TWA
0	8.3592	----	2.4578	----
1	8.3470	8.3531	2.5041	2.4809
2	8.3412	8.3486	2.5024	2.4921
4	8.3296	8.3420	2.4989	2.4964
7	8.3123	8.3330	2.4937	2.4963
14	8.2721	8.3126	2.4816	2.4920
21	8.2321	8.2924	2.4696	2.4865
28	8.1922	8.2724	2.4577	2.4808
42	8.1131	8.2324	2.4339	2.4691
50	8.0682	8.2098	2.4205	2.4624
100	7.7934	8.0699	2.3380	2.4207

STEP 2 results:

Time [days]	North Europe				South Europe			
	PEC_{SW} [µg/L]		PEC_{SED} [µg/kg dry sediment]		PEC_{SW} [µg/L]		PEC_{SED} [µg/kg dry sediment]	
	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	0.7940	----	0.2374	----	1.4261	----	0.4269	----
1	0.7914	0.7927	0.2372	0.2373	1.4230	1.4246	0.4266	0.4268
2	0.7908	0.7919	0.2371	0.2372	1.4221	1.4236	0.4263	0.4266
4	0.7897	0.7911	0.2368	0.2371	1.4201	1.4223	0.4257	0.4263
7	0.7881	0.7901	0.2363	0.2368	1.4171	1.4207	0.4248	0.4259
14	0.7843	0.7882	0.2351	0.2363	1.4103	1.4172	0.4228	0.4248
21	0.7805	0.7862	0.2340	0.2357	1.4034	1.4138	0.4207	0.4238
28	0.7767	0.7843	0.2328	0.2351	1.3967	1.4103	0.4187	0.4228
42	0.7692	0.7805	0.2306	0.2340	1.3832	1.4035	0.4147	0.4208
50	0.7649	0.7784	0.2293	0.2333	1.3755	1.3997	0.4124	0.4196
100	0.7389	0.7651	0.2215	0.2294	1.3287	1.3758	0.3983	0.4195

Metabolite: **X11519540** Parameters used in FOCUSsw step 1 and 2	Molecular weight: *253.24* Water solubility (mg/L): *1000* Soil or water metabolite: *soil metabolite* Koc (L/kg): *14* DT_{50} soil (d): *449.86* days (*Lab. In accordance with FOCUS SFO – long phase HS*) DT50 water/sediment system (d): *1000 (FOCUS default value)* DT_{50} water (d): *1000 (FOCUS default value)* DT_{50} sediment (d): *1000 (FOCUS default value)* Crop interception (%): *average crop cover (60%)* Maximum occurrence observed: Water/sediment: *0.0001%* Soil: *12.2%*
Parameters used in FOCUSsw step 3 (if performed)	Calculations not performed

Application rate	Crop: *cotton* Number of applications: *1* Interval (d): *not applicable – parent compound* Application rate(s): *24* g as/ha Depth of water body: *as defined by the model in STEP 1-2 calculations* Application window: *March - May*
Main routes of entry	*As defined for STEP 1-2 calculations*

STEP 1 results:

Time [days]	**PEC_{SW} [µg/L]**		**PEC_{SED} [µg/kg sediment]**	
	Actual	TWA	Actual	TWA
0	0.8751	----	0.1225	----
1	0.8745	0.8748	0.1224	0.1225
2	0.8739	0.8745	0.1223	0.1224
4	0.8727	0.8739	0.1222	0.1223
7	0.8708	0.8730	0.1219	0.1222
14	0.8666	0.8708	0.1213	0.1219
21	0.8624	0.8687	0.1207	0.1216
28	0.8583	0.8666	0.1202	0.1213
42	0.8500	0.8625	0.1190	0.1207
50	0.8453	0.8601	0.1183	0.1204
100	0.8165	0.8454	0.1143	0.1184

STEP 2 results:

Time [days]	**North Europe**				**South Europe**			
	PEC_{SW} [µg/L]		**PEC_{SED} [µg/kg dry sediment]**		**PEC_{SW} [µg/L]**		**PEC_{SED} [µg/kg dry sediment]**	
	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	0.0696	----	0.0097	----	0.1392	----	0.0195	----
1	0.0695	0.0696	0.0097	0.0097	0.1391	0.1391	0.0195	0.0195
2	0.0695	0.0695	0.0097	0.0097	0.1390	0.1391	0.0195	0.0195
4	0.0694	0.0695	0.0097	0.0097	0.1388	0.1390	0.0194	0.0195
7	0.0692	0.0694	0.0097	0.0097	0.1385	0.1388	0.0194	0.0194
14	0.0689	0.0692	0.0096	0.0097	0.1378	0.1385	0.0193	0.0194
21	0.0686	0.0691	0.0096	0.0097	0.1371	0.1381	0.0192	0.0193
28	0.0682	0.0689	0.0096	0.0096	0.1365	0.1378	0.0191	0.0193
42	0.0676	0.0686	0.0095	0.0096	0.1352	0.1371	0.0189	0.0192
50	0.0672	0.0684	0.0094	0.0096	0.1344	0.1368	0.0188	0.0191
100	0.0649	0.0672	0.0091	0.0094	0.1298	0.1344	0.0182	0.0188

Metabolite: **X11579457** Parameters used in FOCUSsw step 1 and 2	Molecular weight: *252.25* Water solubility (mg/L): *1000* Soil or water metabolite: *soil metabolite* Koc (L/kg): *22* DT_{50} soil (d): *186.67* days (*Lab. In accordance with FOCUS SFO – long phase HS*) DT50 water/sediment system (d): *1000 (FOCUS default value)* DT_{50} water (d): *1000 (FOCUS default value)* DT_{50} sediment (d): *1000 (FOCUS default value)* Crop interception (%): *average crop cover (60%)* Maximum occurrence observed: Water/sediment: *0.0001%* Soil: *9.2%*
Parameters used in FOCUSsw step 3 (if performed)	Calculations not performed
Application rate	Crop: *Cotton* Number of applications: *1* Interval (d): *not applicable – parent compound* Application rate(s): *24* g as/ha Depth of water body: *as defined by the model in STEP 1-2 calculations* Application window: *March - May*
Main routes of entry	*As defined for STEP 1-2 calculations*

STEP 1 results:

Time [days]	**PEC_{SW} [µg/L]**		**PEC_{SED} [µg/kg sediment]**	
	Actual	TWA	Actual	TWA
0	0.6505	----	0.1431	----
1	0.6501	0.6503	0.1430	0.1431
2	0.6496	0.6501	0.1429	0.1430
4	0.6487	0.6496	0.1427	0.1429
7	0.6474	0.6489	0.1424	0.1428
14	0.6442	0.6474	0.1417	0.1424
21	0.6411	0.6458	0.1410	0.1421
28	0.6380	0.6442	0.1404	0.1417
42	0.6318	0.6411	0.1390	0.1410
50	0.6283	0.6394	0.1382	0.1407
100	0.6069	0.6285	0.1335	0.1383

STEP 2 results:

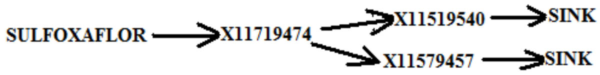
Time [days]	North Europe				South Europe			
	PEC_{SW} [µg/L]		PEC_{SED} [µg/kg dry sediment]		PEC_{SW} [µg/L]		PEC_{SED} [µg/kg dry sediment]	
	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	0.0513	----	0.0113	----	0.1025	----	0.0226	----
1	0.0512	0.0513	0.0113	0.0113	0.1025	0.1025	0.0225	0.0225
2	0.p512	0.0512	0.0113	0.0113	0.1024	0.1025	0.0225	0.0225
4	0.0511	0.0512	0.0112	0.0113	0.1023	0.1024	0.0225	0.0225
7	0.0510	0.0511	0.0112	0.0113	0.1021	0.1023	0.0225	0.0225
14	0.0508	0.0510	0.0112	0.0112	0.1016	0.1021	0.0223	0.0225
21	0.0505	0.0509	0.0111	0.0112	0.1011	0.1018	0.0222	0.0224
28	0.0503	0.0508	0.0111	0.0112	0.1006	0.1016	0.0221	0.0223
42	0.0498	0.0505	0.0110	0.0111	0.0996	0.1011	0.0219	0.0222
50	0.0495	0.0504	0.0109	0.0111	0.0991	0.1008	0.0218	0.0222
100	0.0478	0.0495	0.0105	0.0109	0.0957	0.0991	0.0210	0.0218

PEC (ground water) (Annex IIIA, point 9.2.1)

a) Winter cereals

Method of calculation and type of study: *modelling study using FOCUS GW models;*

Modelling using FOCUS model(s), with appropriate FOCUSgw scenarios, according to FOCUS guidance. Calculations were performed for parent – sulfoxaflor, and metabolites in a sequence corresponding to the determined route of degradation:



Model(s) used: *FOCUS PELMO 4.4.3, FOCUS PEARL 4.4.4*
Crop: *Winter cereals; assumed crop interception CI – 90%*

Sulfoxaflor:
Molar weight: *277.3 g/mole;*
Water solubility: *670 mg/L (20^{0}C);*
Vapour pressure: *1.4 E-6 Pa (20^{0}C);*
DT_{50}: *0.1 d (Lab.; geometric mean; normalisation to pF2, 20 °C with Q10 of 2.58).*
K_{fOC}: *35 mL/g (arithmetic mean)*;
K_{fOM} *20.3 mL/g (arithmetic mean);*
$^1/_n$= *0.96 (arithmetic mean);*
Q_{10}: *2.58*; E_a: *65.4 kJ/mole*

X11719474:
Molar weight: *295.3 g/mole;*
Water solubility: *670 mg/L (20^{0}C);*
Vapour pressure: *1.4 E-6 Pa (20^{0}C);*
DT_{50}: *75.9 d (field; geometric mean; normalisation to pF2, 20 °C with Q10 of 2.58).*
Kinetic formation fraction: *1*
K_{fOC}: *30 mL/g (arithmetic mean)*;
K_{fOM} *17.4 mL/g (arithmetic mean);*
$^1/_n$= *0.99 (arithmetic mean);*
Q_{10}: *2.58*; E_a: *65.4 kJ/mole*

X11519540:
Molar weight: *253.2 g/mole;*
Water solubility: *670 mg/L (20^{0}C);*
Vapour pressure: *1.4 E-6 Pa (20^{0}C);*
DT_{50}: *40.5 days (field, geometric mean; normalisation to pF2, 20^{0}C with Q_{10} of 2.58)*
Kinetic formation fraction: *0.5*
K_{fOC}: *14 mL/g (arithmetic mean)*;
K_{fOM} *8.12 mL/g (arithmetic mean);*
$^1/_n$= *1.01 (arithmetic mean);*
Q_{10}: *2.58*; E_a: *65.4 kJ/mole*

X11579457:
Molar weight: *252.25 g/mole;*
Water solubility: *670 mg/L (20^{0}C);*
Vapour pressure: *1.4 E-6 Pa (20^{0}C);*
DT_{50}: *187 d (lab; geometric mean; normalisation to pF2, 20 °C with Q10 of 2.58).*
Kinetic formation fraction: *0.5*
K_{fOC}: *22 mL/g (arithmetic mean)*;
K_{fOM} *12.8 mL/g (arithmetic mean);*
$^1/_n$= *0.82 (arithmetic mean);*
Q_{10}: *2.58*; E_a: *65.4 kJ/mole*

Application rate	**Sulfoxaflor:** Application rate: *0.0024* kg/ha *(value corrected for the CI).* No. of applications: *1* Time of application (month or season): *1st April and 31st July*

Application date	Modelling tool	FOCUS Scenario	80th percentile PEC_{GW} values [µg/L] for:			
			Sulfoxaflor	*X11719474*	*X11519540*	*X11579547*
1st of April, CI = 90%	*FOCUS PELMO 4.4.3*	Châteaudun	<0.001	0.026	0.065	0.135
		Hamburg	<0.001	0.056	0.089	0.092
		Jokioinen	<0.001	0.014	0.024	0.011
		Kremsmünster	<0.001	0.074	0.089	0.104
		Okehampton	<0.001	0.076	0.081	0.100
		Piacenza	<0.001	0.048	0.072	0.132
		Porto	<0.001	0.038	0.061	0.084
		Sevilla	<0.001	0.005	0.021	0.036
		Thiva	<0.001	0.006	0.029	0.107
	FOCUS PEARL 4.4.4.	Châteaudun	<0.001	0.173	0.104	0.169
		Hamburg	<0.001	0.312	0.155	0.152
		Jokioinen	<0.001	0.313	0.224	0.151
		Kremsmünster	<0.001	0.221	0.090	0.120
		Okehampton	<0.001	0.216	0.083	0.092
		Piacenza	<0.001	0.147	0.065	0.151
		Porto	<0.001	0.129	0.071	0.080
		Sevilla	<0.001	0.048	0.037	0.026
		Thiva	<0.001	0.123	0.086	0.223
31st of July, CI = 90%	*FOCUS PELMO 4.4.3*	Châteaudun	<0.001	0.041	0.098	0.164
		Hamburg	<0.001	0.151	0.180	0.187
		Jokioinen	<0.001	0.143	0.223	0.168
		Kremsmünster	<0.001	0.091	0.116	0.156
		Okehampton	<0.001	0.108	0.112	0.118
		Piacenza	<0.001	0.099	0.119	0.145
		Porto	<0.001	0.085	0.092	0.094
		Sevilla	<0.001	0.019	0.053	0.067
		Thiva	<0.001	0.031	0.089	0.162
	FOCUS PEARL 4.4.4.	Châteaudun	<0.001	0.206	0.113	0.175
		Hamburg	<0.001	0.366	0.168	0.155
		Jokioinen	<0.001	0.282	0.243	0.160
		Kremsmünster	<0.001	0.230	0.092	0.114
		Okehampton	<0.001	0.236	0.082	0.091
		Piacenza	<0.001	0.180	0.084	0.139
		Porto	<0.001	0.182	0.085	0.094
		Sevilla	<0.001	0.076	0.049	0.035
		Thiva	<0.001	0.219	0.130	0.291

b) Spring cereals

Method of calculation and type of study: *modelling study using FOCUS GW models;*

Modelling using FOCUS model(s), with appropriate FOCUSgw scenarios, according to FOCUS guidance. Calculations were performed for parent – sulfoxaflor, and metabolites in a sequence corresponding to the determined route of degradation:

SULFOXAFLOR → **X11719474** → **X11519540** → **SINK**

X11719474 → **X11579457** → **SINK**

Model(s) used: *FOCUS PELMO 4.4.3, FOCUS PEARL 4.4.4*
Crop: *Spring cereals; assumed crop interception CI – 90%*

Sulfoxaflor:
Molar weight: *277.3 g/mole;*
Water solubility: *670 mg/L (20^{0}C);*
Vapour pressure: *1.4 E-6 Pa (20^{0}C);*
DT_{50}: *0.1 d (Lab.; geometric mean; normalisation to pF2, 20 °C with Q10 of 2.58).*
K_{fOC}: *35 mL/g (arithmetic mean);*
K_{fOM} *20.3 mL/g (arithmetic mean);*
$^1/_n$= *0.96 (arithmetic mean);*
Q_{10}: *2.58*; E_a: *65.4 kJ/mole*

X11719474:
Molar weight: *295.3 g/mole;*
Water solubility: *670 mg/L (20^{0}C);*
Vapour pressure: *1.4 E-6 Pa (20^{0}C);*
DT_{50}: *75.9 d (field; geometric mean; normalisation to pF2, 20 °C with Q10 of 2.58).*
Kinetic formation fraction: *1*
K_{fOC}: *30 mL/g (arithmetic mean);*
K_{fOM} *17.4 mL/g (arithmetic mean);*
$^1/_n$= *0.99 (arithmetic mean);*
Q_{10}: *2.58*; E_a: *65.4 kJ/mole*

X11519540:
Molar weight: *253.2 g/mole;*
Water solubility: *670 mg/L (20^{0}C);*
Vapour pressure: *1.4 E-6 Pa (20^{0}C);*
DT_{50}: *40.5 days (field, geometric mean; normalisation to pF2, 20^{0}C with Q_{10} of 2.58)*
Kinetic formation fraction: *0.5*
K_{fOC}: *14 mL/g (arithmetic mean);*
K_{fOM} *8.12 mL/g (arithmetic mean);*
$^1/_n$= *1.01 (arithmetic mean);*
Q_{10}: *2.58*; E_a: *65.4 kJ/mole*

X11579457:
Molar weight: *252.25 g/mole;*
Water solubility: *670 mg/L (20^{0}C);*
Vapour pressure: *1.4 E-6 Pa (20^{0}C);*
DT_{50}: *187 d (lab; geometric mean; normalisation to pF2, 20 °C with Q10 of 2.58).*
Kinetic formation fraction: *0.5*
K_{fOC}: *22 mL/g (arithmetic mean);*
K_{fOM} *12.8 mL/g (arithmetic mean);*
$^1/_n$= *0.82 (arithmetic mean);*
Q_{10}: *2.58*; E_a: *65.4 kJ/mole*

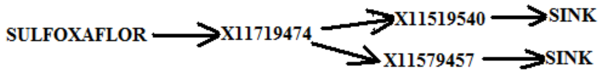
Application rate	**Sulfoxaflor:** Application rate: *0.0024* kg/ha *(value corrected for the CI).* No. of applications:*1*Time of application (month or season): *1st April and 31st July*

Application date	Modelling tool	FOCUS Scenario	80th percentile PEC_{GW} values [µg/L] for:			
			Sulfoxaflor	*X11719474*	*X11519540*	*X11579547*
1st of April, CI = 90%	***FOCUS PELMO 4.4.3***	Châteaudun	<0.001	0.020	0.051	0.102
		Hamburg	<0.001	0.045	0.084	0.083
		Jokioinen	<0.001	0.012	0.023	0.009
		Kremsmünster	<0.001	0.065	0.080	0.096
		Okehampton	<0.001	0.065	0.077	0.093
		Porto	<0.001	0.038	0.038	0.073
	FOCUS PEARL 4.4.4.	Châteaudun	<0.001	0.148	0.086	0.143
		Hamburg	<0.001	0.395	0.197	0.196
		Jokioinen	<0.001	0.262	0.176	0.132
		Kremsmünster	<0.001	0.242	0.098	0.136
		Okehampton	<0.001	0.211	0.083	0.100
		Porto	<0.001	0.121	0.060	0.075
31st of July, CI = 90%	***FOCUS PELMO 4.4.3***	Châteaudun	<0.001	0.036	0.085	0.128
		Hamburg	<0.001	0.140	0.176	0.176
		Jokioinen	<0.001	0.117	0.183	0.142
		Kremsmünster	<0.001	0.088	0.111	0.146
		Okehampton	<0.001	0.101	0.104	0.108
		Porto	<0.001	0.075	0.080	0.085
	FOCUS PEARL 4.4.4.	Châteaudun	<0.001	0.190	0.101	0.148
		Hamburg	<0.001	0.451	0.206	0.199
		Jokioinen	<0.001	0.327	0.192	0.134
		Kremsmünster	<0.001	0.251	0.103	0.132
		Okehampton	<0.001	0.246	0.088	0.096
		Porto	<0.001	0.192	0.079	0.077

c) Fruiting vegetables and cucurbits

Method of calculation and type of study: *modelling study using FOCUS GW models;*

Modelling using FOCUS model(s), with appropriate FOCUSgw scenarios, according to FOCUS guidance. Calculations were performed for parent – sulfoxaflor, and metabolites in a sequence corresponding to the determined route of degradation:



Model(s) used: *FOCUS PELMO 4.4.3, FOCUS PEARL 4.4.4*
Crop: *Tomatoes; assumed crop interception CI – 70% for applications on 1st March, 1st May and 1st June; 80% for applications on 1st September and 1st November;*

<u>Sulfoxaflor:</u>
Molar weight: *277.3 g/mole;*
Water solubility: *670 mg/L ($20^{0}C$);*
Vapour pressure: *1.4 E-6 Pa ($20^{0}C$);*
DT_{50}: *0.1 d (Lab.; geometric mean; normalisation to pF2, 20 ℃ with Q10 of 2.58).*
K_{fOC}: *35 mL/g (arithmetic mean);*
K_{fOM} *20.3 mL/g (arithmetic mean);*
$^{1}/_{n}$= *0.96 (arithmetic mean);*
Q_{10}: *2.58*; E_a: *65.4 kJ/mole*

<u>X11719474:</u>
Molar weight: *295.3 g/mole;*
Water solubility: *670 mg/L ($20^{0}C$);*
Vapour pressure: *1.4 E-6 Pa ($20^{0}C$);*
DT_{50}: *75.9 d (field; geometric mean; normalisation to pF2, 20 ℃ with Q10 of 2.58).*
Kinetic formation fraction: *1*
K_{fOC}: *30 mL/g (arithmetic mean);*
K_{fOM} *17.4 mL/g (arithmetic mean);*
$^{1}/_{n}$= *0.99 (arithmetic mean);*
Q_{10}: *2.58*; E_a: *65.4 kJ/mole*

<u>X11519540:</u>
Molar weight: *253.2 g/mole;*
Water solubility: *670 mg/L ($20^{0}C$);*
Vapour pressure: *1.4 E-6 Pa ($20^{0}C$);*
DT_{50}: *40.5 days (field, geometric mean; normalisation to pF2, $20^{0}C$ with Q_{10} of 2.58)*
Kinetic formation fraction: *0.5*
K_{fOC}: *14 mL/g (arithmetic mean);*
K_{fOM} *8.12 mL/g (arithmetic mean);*
$^{1}/_{n}$= *1.01 (arithmetic mean);*
Q_{10}: *2.58*; E_a: *65.4 kJ/mole*

<u>X11579457:</u>
Molar weight: *252.25 g/mole;*
Water solubility: *670 mg/L ($20^{0}C$);*
Vapour pressure: *1.4 E-6 Pa ($20^{0}C$);*
DT_{50}: *187 d (lab; geometric mean; normalisation to pF2, 20 ℃ with Q10 of 2.58).*
Kinetic formation fraction: *0.5*
K_{fOC}: *22 mL/g (arithmetic mean);*
K_{fOM} *12.8 mL/g (arithmetic mean);*
$^{1}/_{n}$= *0.82(arithmetic mean);*
Q_{10}: *2.58*; E_a: *65.4 kJ/mole*

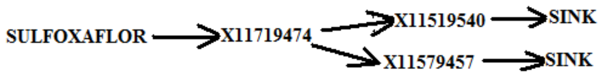
Application rate	**Sulfoxaflor:** Application rate: *0.0072* kg/ha *(value corrected for the CI) for applications on 1st March, 1st May and 1st July; 0.0048 kg/ha (value corrected for the CI) for the applications on 1st September and 1st November;* No. of applications:*1* Time of application (month or season): *1st March, 1st May, 1st July, 1st September and 1st November*

Application date	Modelling tool	FOCUS Scenario	80th percentile PEC_{GW} values [µg/L] for:			
			Sulfoxaflor	*X11719474*	*X11519540*	*X11579547*
1st of March, CI = 70%	***FOCUS PELMO 4.4.3***	Châteaudun	<0.001	0.109	0.217	0.380
		Piacenza	<0.001	0.124	0.175	0.278
		Porto	<0.001	0.077	0.127	0.214
		Sevilla	<0.001	0.047	0.131	0.365
		Thiva	<0.001	0.053	0.136	0.459
	FOCUS PEARL 4.4.4.	Châteaudun	<0.001	0.718	0.374	0.656
		Piacenza	<0.001	0.527	0.241	0.566
		Porto	<0.001	0.312	0.176	0.246
		Sevilla	<0.001	0.223	0.150	0.406
		Thiva	<0.001	0.485	0.255	0.682
1st of May, CI = 70%	***FOCUS PELMO 4.4.3***	Châteaudun	<0.001	0.163	0.295	0.598
		Piacenza	<0.001	0.163	0.261	0.472
		Porto	<0.001	0.084	0.150	0.249
		Sevilla	<0.001	0.051	0.150	0.403
		Thiva	<0.001	0.078	0.183	0.554
	FOCUS PEARL 4.4.4.	Châteaudun	<0.001	0.792	0.390	0.671
		Piacenza	<0.001	0.494	0.230	0.571
		Porto	<0.001	0.351	0.181	0.243
		Sevilla	<0.001	0.278	0.175	0.420
		Thiva	<0.001	0.605	0.298	0.730
1st of July, CI = 70%	***FOCUS PELMO 4.4.3***	Châteaudun	<0.001	0.162	0.282	0.582
		Piacenza	<0.001	0.186	0.229	0.441
		Porto	<0.001	0.133	0.188	0.258
		Sevilla	<0.001	0.065	0.190	0.390
		Thiva	<0.001	0.090	0.210	0.539
	FOCUS PEARL 4.4.4.	Châteaudun	<0.001	0.657	0.338	0.638
		Piacenza	<0.001	0.526	0.253	0.525
		Porto	<0.001	0.397	0.188	0.233
		Sevilla	<0.001	0.328	0.203	0.430
		Thiva	<0.001	0.552	0.301	0.698
1st of September, CI = 80%	***FOCUS PELMO 4.4.3***	Châteaudun	<0.001	0.127	0.206	0.375
		Piacenza	<0.001	0.281	0.220	0.312
		Porto	<0.001	0.210	0.256	0.166
		Sevilla	<0.001	0.085	0.170	0.293
		Thiva	<0.001	0.079	0.151	0.351
	FOCUS PEARL 4.4.4.	Châteaudun	<0.001	0.485	0.244	0.419
		Piacenza	<0.001	0.540	0.241	0.377
		Porto	<0.001	0.392	0.136	0.143
		Sevilla	<0.001	0.325	0.163	0.325
		Thiva	<0.001	0.376	0.202	0.461
1st of November, CI = 80%	***FOCUS PELMO 4.4.3***	Châteaudun	<0.001	0.123	0.175	0.311
		Piacenza	<0.001	0.249	0.209	0.303
		Porto	<0.001	0.266	0.149	0.168
		Sevilla	<0.001	0.157	0.200	0.377
		Thiva	<0.001	0.131	0.166	0.409
	FOCUS PEARL 4.4.4.	Châteaudun	<0.001	0.534	0.260	0.424
		Piacenza	<0.001	0.541	0.213	0.392
		Porto	<0.001	0.412	0.129	0.145
		Sevilla	<0.001	0.418	0.175	0.373
		Thiva	<0.001	0.457	0.205	0.508

d) Cotton

Method of calculation and type of study: *modelling study using FOCUS GW models;*

Modelling using FOCUS model(s), with appropriate FOCUSgw scenarios, according to FOCUS guidance. Calculations were performed for parent – sulfoxaflor, and metabolites in a sequence corresponding to the determined route of degradation:



Model(s) used: *FOCUS PELMO 4.4.3, FOCUS PEARL 4.4.4*
Crop: *Cotton; assumed crop interception CI – 60% for application on 1st May; 75% for application on 30th September*

<u>Sulfoxaflor:</u>
Molar weight: *277.3 g/mole;*
Water solubility: *670 mg/L (20^{0}C);*
Vapour pressure: *1.4 E-6 Pa (20^{0}C);*
DT_{50}: *0.1 d (Lab.; geometric mean; normalisation to pF2, 20 °C with Q10 of 2.58).*
K_{fOC}: *35 mL/g (arithmetic mean)*;
K_{fOM} *20.3 mL/g (arithmetic mean);*
$^1/_n$*= 0.96 (arithmetic mean);*
Q_{10}: *2.58*; E_a: *65.4 kJ/mole*

<u>X11719474:</u>
Molar weight: *295.3 g/mole;*
Water solubility: *670 mg/L (20^{0}C);*
Vapour pressure: *1.4 E-6 Pa (20^{0}C);*
DT_{50}: *75.9 d (field; geometric mean; normalisation to pF2, 20 °C with Q10 of 2.58).*
Kinetic formation fraction: *1*
K_{fOC}: *30 mL/g (arithmetic mean)*;
K_{fOM} *17.4 mL/g (arithmetic mean);*
$^1/_n$*= 0.99 (arithmetic mean);*
Q_{10}: *2.58*; E_a: *65.4 kJ/mole*

<u>X11519540:</u>
Molar weight: *253.2 g/mole;*
Water solubility: *670 mg/L (20^{0}C);*
Vapour pressure: *1.4 E-6 Pa (20^{0}C);*
DT_{50}: *40.5 days (field, geometric mean; normalisation to pF2, 20^{0}C with Q_{10} of 2.58)*
Kinetic formation fraction: *0.5*
K_{fOC}: *14 mL/g (arithmetic mean)*;
K_{fOM} *8.12 mL/g (arithmetic mean);*
$^1/_n$*= 1.01 (arithmetic mean);*
Q_{10}: *2.58*; E_a: *65.4 kJ/mole*

<u>X11579457:</u>
Molar weight: *252.25 g/mole;*
Water solubility: *670 mg/L (20^{0}C);*
Vapour pressure: *1.4 E-6 Pa (20^{0}C);*
DT_{50}: *187 d (lab; geometric mean; normalisation to pF2, 20 °C with Q10 of 2.58).*
Kinetic formation fraction: *0.5*
K_{fOC}: *22 mL/g (arithmetic mean)*;
K_{fOM} *12.8 mL/g (arithmetic mean);*
$^1/_n$*= 0.82 (arithmetic mean);*
Q_{10}: *2.58*; E_a: *65.4 kJ/mole*

Application rate	**Sulfoxaflor:** Application rate: *0.0096* kg/ha for application on 1st May *(value corrected for the CI); 0.0060* kg/ha for application on 30th September *(value corrected for the CI)*. No. of applications:*1* Time of application (month or season): *1st May and 30th September*

Application date	Modelling tool	FOCUS Scenario	80th percentile PEC_{GW} values [µg/L] for:			
			Sulfoxaflor	*X11719474*	*X11519540*	*X11579547*
1st of May, CI = 60%	***FOCUS PELMO 4.4.3***	Sevilla	<0.001	0.090	0.288	0.652
		Thiva	<0.001	0.071	0.226	0.752
	FOCUS PEARL 4.4.4.	Sevilla	<0.001	0.520	0.328	0.829
		Thiva	<0.001	0.616	0.360	1.003
30th of September, CI = 75%	***FOCUS PELMO 4.4.3***	Sevilla	<0.001	1.50	0.247	0.469
		Thiva	<0.001	0.177	0.242	0.556
	FOCUS PEARL 4.4.4.	Sevilla	<0.001	0.615	0.264	0.558
		Thiva	<0.001	0.626	0.294	0.683

$PEC_{(gw)}$ From lysimeter / field studies

Parent	1st year	2nd year	3rd year
Annual average (µg/L)	Not examined	Not examined	Not examined

Metabolite X	1st year	2nd year	3rd year
Annual average (µg/L)	Not examined	Not examined	Not examined

Repeat for as many metabolites as necessary

Fate and behaviour in air (Annex IIA, point 7.2.2, Annex III, point 9.3)

Direct photolysis in air ‡	*Not studied*
Quantum yield of direct phototransformation	*Not determined*
Photochemical oxidative degradation in air ‡	DT_{50} of *x0.647days* derived by the Atkinson model (version *4.00*). OH (12 h) concentration assumed = *1.5 E6 [radicals/cm³]*
Volatilisation ‡	from plant surfaces (BBA guideline): *not examined*
	from soil surfaces (BBA guideline): *not examined*
Metabolites	*None identified*

PEC (air)

Method of calculation	Calculations were not performed – they were considered not necessary as neither sulfoxaflor nor X11719474 are classified volatile or semi-volatile compounds.

PEC$_{(a)}$

Maximum concentration	Not available - Calculations were not performed – they were considered not necessary as neither sulfoxaflor nor X11719474 are classified volatile or semi-volatile compounds.

Residues requiring further assessment

Environmental occurring residues requiring further assessment by other disciplines (toxicology and ecotoxicology) and or requiring consideration for groundwater exposure.	**Surface water:** Sulfoxaflor, X11719474 and X11519540 **Ground water:** Sulfoxaflor, X11719474, X11519540 and X11579457 **Sediment:** Sulfoxaflor and X11719474 **Soil:** Sulfoxaflor, X11719474 and X11519540 **Air:** Sulfoxaflor

Monitoring data, if available (Annex IIA, point 7.4)

Soil (indicate location and type of study)	No data provided – Sulfoxaflor is a new active substance
Surface water (indicate location and type of study)	No data provided – Sulfoxaflor is a new active substance
Ground water (indicate location and type of study)	No data provided – Sulfoxaflor is a new active substance
Air (indicate location and type of study)	No data provided – Sulfoxaflor is a new active substance

Points pertinent to the classification and proposed labelling with regard to fate and behaviour data

Sulfoxaflor: Not readily biodegradable

Ecotoxicology

Effects on terrestrial vertebrates (Annex IIA, point 8.1, Annex IIIA, points 10.1 and 10.3)

Species	Test substance	Time scale	End point (mg/kg bw)	End point (mg/kg feed)
Birds				
Bobwhite quail	a.s.	Acute	LD_{50} = 676 mg/kg bw [1]	
Bobwhite quail	GF-2626	Acute	LD_{50} >2000 mg prep./kg bw LD_{50} >240 mg a.s./kg bw	
Bobwhite quail	GF-2372	Acute	LD_{50} = 1655 mg prep./kg bw LD_{50} = 827 mg a.s./kg bw	
Bobwhite quail	X11719474	Acute	LD_{50} >2250 mg/kg bw	
Bobwhite quail	X11721061	Acute	LD_{50} = 1038 mg/kg bw	
Bobwhite quail	a.s.	Short-term	LD_{50} >1152 mg/kg bw/day	LC_{50} > 5620 ppm
Mallard duck	a.s.	Short-term	LD_{50} >1049 mg/kg bw/day	LC_{50} > 5620 ppm
Bobwhite quail	a.s.	Long-term	NOAEL = 84.4 mg/kg bw per day	NOAEC = 1000 ppm
Mallard duck	a.s.	Long-term	NOAEL = 25.9 mg/kg bw per day	NOAEC = 200 ppm
Mammals				
Rat	a.s.	Acute	LD_{50} = 1000 mg/kg bw	
Mice	a.s.	Acute	LD_{50} = 750 mg/kg bw	
Rat	GF-2032	Acute	LD_{50} >5000 mg prep./kg bw LD_{50} >1100 mg a.s./kg bw	
Rat	GF-2372	Acute	LD_{50} >2000 mg prep./kg bw LD_{50} >1000 mg a.s./kg bw	
Rat	X11719474	Acute	LD_{50} >5000 mg/kg bw	
Rat	X11519540	Acute	LD_{50} = 566 mg/kg bw	

Rat	X11579457	Acute	LD_{50} >2000 mg/kg bw	
Rat	X11721061	Acute	LD_{50} = 2000 mg/kg bw	
Rat	a.s.	Long-term (2-generation repro. study)	NOAEL = 6.63 mg/kg bw per day	
Rat	X11719474	Long-term (reproduction screening test)	NOAEL = 396 mg/kg bw per day	
Rat	X11719474	Long-term (developmental toxicity study)	NOAEL = 368 mg/kg bw per day	
Additional higher tier studies				
None				

[1] In another study with zebra finch, some mortality and regurgitation has occurred at lower dose levels than in this study.

Toxicity/exposure ratios for terrestrial vertebrates (Annex IIIA, points 10.1 and 10.3)

Crop and application rate: Fruiting vegetables – 1 x 24 g a.s./ha

Indicator species/Category	Time scale	DDD	TER	Annex VI Trigger
Screening (Birds)				
Small omnivorous bird	Acute	3.81	177	10
Small omnivorous bird	Long-term	0.82	32	5
Screening (Mammals)				
Small herbivorous mammal	Acute	3.27	229	10
Small herbivorous mammal	Long-term	1.74	**3.81**	5
Tier 1				
Frugivorous mammal “rat”	Long-term	0.60	11.05	5
Small insectivorous mammal “shrew”	Long-term	0.046	144	5
Small herbivorous mammal “vole” (BBCH 10-49)	Long-term	1.74	**3.81**	5
Small herbivorous mammal “vole” (BBCH ≥50)	Long-term	0.52	12.75	5
Small omnivorous mammal “mouse” (BBCH 10-49)	Long-term	0.19	34.89	5
Small omnivorous mammal “mouse” (BBCH ≥50)	Long-term	0.055	121	5

TER_{LT} values in **bold** do not exceed the Annex VI trigger.

Crop and application rate: Cereals – 1 x 24 g a.s./ha

Indicator species/Category	Time scale	DDD	TER	Annex VI Trigger
Screening (Birds)				
Small omnivorous bird	Acute	3.81	177	10

Indicator species/Category	Time scale	DDD	TER	Annex VI Trigger
Small omnivorous bird	Long-term	0.82	32	5
Screening (Mammals)				
Small herbivorous mammal	Acute	2.84	264	10
Small herbivorous mammal	Long-term	1.16	5.72	5

Crop and application rate: Cotton – 1 x 24 g a.s./ha

Indicator species/Category	Time scale	DDD	TER	Annex VI Trigger
Screening (Birds)				
Small omnivorous bird	Acute	3.85	176	10
Small omnivorous bird	Long-term	0.83	31	5
Screening (Mammals)				
Small herbivorous mammal	Acute	3.27	229	10
Small herbivorous mammal	Long-term	1.74	**3.81**	5
Tier 1				
Small insectivorous mammal "shrew"	Long-term	0.046	144	5
Small herbivorous mammal "vole" (BBCH 40-49)	Long-term	1.74	**3.81**	5
Small herbivorous mammal "vole" (BBCH ≥50)	Long-term	0.43	15.42	5
Small omnivorous mammal "mouse" (BBCH 10-49)	Long-term	0.19	34.89	5
Small omnivorous mammal "mouse" (BBCH ≥50)	Long-term	0.046	144	5

TER_{LT} values in **bold** do not exceed the Annex VI trigger.

Toxicity data for aquatic species (most sensitive species of each group) (Annex IIA, point 8.2, Annex IIIA, point 10.2)

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1] (mg/L)
Laboratory tests				
Fish				
Cyprinodon variegatus	a.s.	96 hr (static)	Mortality, LC_{50}	266 mm
Cyprinodon variegatus	a.s.	38 d ELS (flow-through)	Growth NOEC	1.21 mm
Oncorhynchus mykiss	GF-2626	96 hr (static)	Mortality, LC_{50}	>840 prep. nom >101 a.s. nom
Oncorhynchus mykiss	GF-2372	96 hr (static renewal)	Mortality, LC_{50}	19.85 prep. nom 9.75 a.s. mm
Oncorhynchus mykiss	X11719474	96 hr (static)	Mortality, LC_{50}	>478 mm
Oncorhynchus mykiss	X11519540	96 hr (static)	Mortality, LC_{50}	>330 mm

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1] (mg/L)
Oncorhynchus mykiss	X11579457	96 hr (static)	Mortality, LC_{50}	>320 mm
Aquatic invertebrate				
Daphnia magna	a.s.	48 h (static)	Immobility, EC_{50}	>399 mm
Daphnia magna	a.s.	21 d (semi-static)	Reproduction, NOEC	12.5 nom
Daphnia magna	GF-2626	48 h (static)	Immobility, EC_{50}	>840 prep. nom >101 a.s. nom
Daphnia magna	GF-2372	48 h (static)	Immobility, EC_{50}	>100 prep. nom >50 a.s. nom
Daphnia magna	X11719474	48 h (static-renewal)	Immobility, EC_{50}	>205 mm
Daphnia magna	X11519540	48 h (static-renewal)	Immobility, EC_{50}	>350 mm
Daphnia magna	X11579457	48 h (static-renewal)	Immobility, EC_{50}	95 mm
Americamysis bahia	a.s.	96 hr (static)	Mortality, LC_{50}	0.643 mm
Americamysis bahia	a.s.	28d (flow-through)	Reproduction, NOEC	0.114 mm
Americamysis bahia	GF-2626	96 hr (static-renewal)	Mortality, LC_{50}	3.75 prep. nom 0.455 a.s. nom
Americamysis bahia	GF-2372	96 hr (static)	Mortality, LC_{50}	1.1 prep. nom 0.55 a.s. nom
Americamysis bahia	X11719474	96 h (static-renewal)	Mortality, LC_{50}	>114 mm
Americamysis bahia	X11719474	28d (flow-through)	Reproduction, NOEC	2.12 mm
Americamysis bahia	X11519540	96 h (static-renewal)	Mortality, LC_{50}	>120 mm
Americamysis bahia	X11579457	96 h (static-renewal)	Mortality, LC_{50}	>110 mm
Sediment dwelling organisms				
Chironomus dilutus	a.s.	96 h, (static, spiked water)	Mortality, LC_{50}	0.622 mm
Chironomus dilutus	a.s.	10 d, (static, spiked sediment)	Mortality, LC_{50}	0.119 mg/kg sediment [2] mm
Chironomus riparius	a.s.	28 d (static, spiked water)	NOEC	0.0384 [3] mm
Chironomus dilutus	GF-2626	96 h, (static, spiked water)	Mortality, LC_{50}	>100 prep. nom >12 a.s. nom

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1] (mg/L)
Chironomus dilutus	GF-2372	96 h, (static, spiked water)	Mortality, LC_{50}	>24 prep. nom >12 a.s.nom
Chironomus dilutus	X11719474	96 h, (static, spiked water)	Mortality, LC_{50}	>281 mm
Chironomus dilutus	X11519540	96 h, (static, spiked water)	Mortality, LC_{50}	>360 mm
Chironomus dilutus	X11579457	96 h, (static, spiked water)	Mortality, LC_{50}	88 mm
Chironomus riparius	X11719474	28 d (static)	NOEC	10.4 mm
Chironomus riparius	X11519540	28 d (static)	NOEC	10 mm
Chironomus riparius	X11579457	28 d (static)	NOEC	11 mm
Algae				
Navicula pelliculosa.	a.s.	96 h (static)	Biomass: E_bC_{50} Yield: E_yC_{50} Growth rate: E_rC_{50}	85.7 >101 >101 mm
Navicula pelliculosa	GF-2626	72 h (static)	Yield: E_yC_{50} Growth rate: E_rC_{50}	>100 prep. >12 a.s. >100 prep. >12 a.s. mm
Navicula pelliculosa	GF-2372	72 h (static)	Yield: E_yC_{50} Growth rate: E_rC_{50}	28 prep. 14 a.s. >100 prep. >50 a.s. mm
Navicula pelliculosa	X11719474	72 h (static)	Yield: E_yC_{50} Growth rate: E_rC_{50}	>124 >124 mm
Navicula pelliculosa	X11519540	72 h (static)	Yield: E_yC_{50} Growth rate: E_rC_{50}	>110 >110 mm
Navicula pelliculosa	X11579457	72 h (static)	Yield: E_yC_{50} Growth rate: E_rC_{50}	>110 >110 mm
Higher plant				
Lemna gibba	a.s.	7 d (semi-static)	Fronds, EC_{50}	>100 nom

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1] (mg/L)
Microcosm or mesocosm tests				
Indicate if not required				

1: indicate whether based on nominal ($_{nom}$) or mean measured concentrations ($_{mm}$). In the case of preparations indicate whether end points are presented as units of preparation or a.s.

2: Sediment-dosed LC_{50} reported as 0.161 mg total radioactive residues/kg sediment d.w. and corrected to active substance concentration due to metabolism during study.

3: Overlying water-dosed NOEC reported as 0.0526 mg total radioactive residues/L water (initial measured) and corrected by a factor of 73% (based on initial measured and final measured concentrations) to account for the dissipation of the active substance from the water column.

Toxicity/exposure ratios for the most sensitive aquatic organisms (Annex IIIA, point 10.2)

FOCUS Step1

Fruiting vegetables – 1 x 24 g a.s./ha – technical and formulated sulfoxaflor

Test substance	Organism	Toxicity end point (µg a.s./L)	Time scale & endpoint measured	FOCUS Step 1 max PEC_{sw} (µg a.s./L)	TER	Annex VI Trigger
Toxicity to fish						
Sulfoxaflor	Sheepshead minnow (*Cyprinodon variegatus*)	266000	acute, 96h, LC_{50}	7.864	33825	100
Sulfoxaflor	Sheepshead minnow (*Cyprinodon variegatus*)	1210	chronic, 38d, NOEC	7.864	154	10
GF-2626	Rainbow trout (*Oncorhynchus mykiss*)	>101000	acute, 96h, LC_{50}	7.864	>12843	100
Toxicity to aquatic invertebrates						
Sulfoxaflor	Mysid shrimp (*Americamysis bahia*)	643	acute, 96h, LC_{50}	7.864	**82**	100
Sulfoxaflor	Mysid shrimp (*Americamysis bahia*)	114	chronic, 28d, NOEC	7.864	15	10
GF-2626	Mysid shrimp (*Americamysis bahia*)	455	acute, 96h, LC_{50}	7.864	**58**	100
Toxicity to sediment-dwelling invertebrates						
Sulfoxaflor	*Chironomus dilutus*	622	acute, 96h, spiked water, LC_{50}	7.864	**79**	100
Sulfoxaflor	*Chironomus dilutus*	119*	acute, 10d, spiked sediment, LC_{50}	2.716* (PEC_{sed})	**44**	100
Sulfoxaflor	*Chironomus riparius*	38.4	chronic, 28d, spiked water, NOEC	7.864	80.7	10
GF-2626	*Chironomus dilutus*	>12000	acute, 96h, spiked water, LC_{50}	7.864	>1526	100
Toxicity to algae and aquatic macrophytes						
Sulfoxaflor	Freshwater diatom (*Navicula pelliculosa*)	85700	chronic, 96h, E_bC_{50}	7.864	10898	10
Sulfoxaflor	*Lemna gibba*	>100000	chronic, 7d, EC_{50}	7.864	>12716	10

Test substance	Organism	Toxicity end point (µg a.s./L)	Time scale & endpoint measured	FOCUS Step 1 max PEC_{sw} (µg a.s./L)	TER	Annex VI Trigger
GF-2626	Freshwater diatom (*Navicula pelliculosa*)	>12000	chronic, 72h, E_yC_{50}/ E_rC_{50}	7.864	>1526	10

* µg a.s./kg sediment

Fruiting vegetables – 1 x 24 g a.s./ha –Sulfoxaflor metabolites

Test substance	Organism	Toxicity end point (µg a.s./L)	Time scale & endpoint measured	FOCUS Step 1 max PEC_{sw} (µg a.s./L)	TER	Annex VI Trigger
Toxicity to fish						
X11719474	Rainbow trout (*Oncorhynchus mykiss*)	>478000	acute, 96h, LC_{50}	8.359	>57184	100
X11519540	Rainbow trout (*Oncorhynchus mykiss*)	>330000	acute, 96h, LC_{50}	0.875	>377143	100
X11579457	Rainbow trout (*Oncorhynchus mykiss*)	>320000	acute, 96h, LC_{50}	0.651	>491551	100
Toxicity to aquatic invertebrates						
X11719474	*Daphnia magna*	>205000	acute, 48h, LC_{50}	8.359	>24524	100
X11519540	*Daphnia magna*	>350000	acute, 48h, LC_{50}	0.875	>400000	100
X11579457	*Daphnia magna*	95000	acute, 48h, LC_{50}	0.651	145929	100
X11719474	Mysid shrimp (*Americamysis bahia*)	>114000	acute, 96h, LC_{50}	8.359	>13638	100
X11719474	Mysid shrimp (*Americamysis bahia*)	2120	chronic, 28d NOEC	8.359	254	10
X11519540	Mysid shrimp (*Americamysis bahia*)	>120000	acute, 96h, LC_{50}	0.875	>137143	100
X11579457	Mysid shrimp (*Americamysis bahia*)	>110000	acute, 96h, LC_{50}	0.651	>168971	100
Toxicity to sediment-dwelling invertebrates						
X11719474	*Chironomus dilutus*	>281000	acute, 96h, spiked water, LC_{50}	8.359	>33616	100
X11519540	*Chironomus dilutus*	>360000	acute, 96h, spiked water, LC_{50}	0.875	>411429	100
X11579457	*Chironomus dilutus*	88000	acute, 96h, spiked water, LC_{50}	0.651	135177	100
X11719474	*Chironomus riparius*	10400	chronic, 28d, spiked water, NOEC	8.359	1244	10
X11519540	*Chironomus riparius*	10000	chronic, 28d, spiked water, NOEC	0.875	11429	10
X11579457	*Chironomus riparius*	11000	chronic, 28d, spiked water, NOEC	0.651	16897	10
Toxicity to algae and aquatic macrophytes						
X11719474	Freshwater diatom (*Navicula pelliculosa*)	>124000	chronic, 72h, E_yC_{50}/ E_rC_{50}	8.359	>14834	10

Test substance	Organism	Toxicity end point (µg a.s./L)	Time scale & endpoint measured	FOCUS Step 1 max PEC_{sw} (µg a.s./L)	TER	Annex VI Trigger
X11519540	Freshwater diatom (*Navicula pelliculosa*)	>110000	chronic, 72h, E_yC_{50}/ E_rC_{50}	0.875	>125714	10
X11579457	Freshwater diatom (*Navicula pelliculosa*)	>110000	chronic, 72h, E_yC_{50}/ E_rC_{50}	0.651	>168971	10

Spring and winter cereals – 1 x 24 g a.s./ha – technical and formulated sulfoxaflor

Test substance	Organism	Toxicity end point (µg a.s./L)	Time scale & endpoint measured	FOCUS Step 1 max PEC_{sw} (µg a.s./L)	TER	Annex VI Trigger
Toxicity to fish						
Sulfoxaflor	Sheepshead minnow (*Cyprinodon variegatus*)	266000	acute, 96h, LC_{50}	7.864	33825	100
Sulfoxaflor	Sheepshead minnow (*Cyprinodon variegatus*)	1210	chronic, 38d, NOEC	7.864	154	10
GF-2372	Rainbow trout (*Oncorhynchus mykiss*)	9750	acute, 96h, LC_{50}	7.864	1240	100
Toxicity to aquatic invertebrates						
Sulfoxaflor	Mysid shrimp (*Americamysis bahia*)	643	acute, 96h, LC_{50}	7.864	**82**	100
Sulfoxaflor	Mysid shrimp (*Americamysis bahia*)	114	chronic, 28d, NOEC	7.864	15	10
GF-2372	Mysid shrimp (*Americamysis bahia*)	550	acute, 96h, LC_{50}	7.864	**70**	100
Toxicity to sediment-dwelling invertebrates						
Sulfoxaflor	*Chironomus dilutus*	622	acute, 96h, spiked water, LC_{50}	7.864	**79**	100
Sulfoxaflor	*Chironomus dilutus*	119*	acute, 10d, spiked sediment, LC_{50}	2.716* (PEC_{sed})	**44**	100
Sulfoxaflor	*Chironomus riparius*	38.4	chronic, 28d, spiked water, NOEC	7.864	80.7	10
GF-2372	*Chironomus dilutus*	>12000	acute, 96h, spiked water, LC_{50}	7.864	>1526	100
Toxicity to algae and aquatic macrophytes						
Sulfoxaflor	Freshwater diatom (*Navicula pelliculosa*)	85700	chronic, 96h, E_bC_{50}	7.864	10898	10
Sulfoxaflor	*Lemna gibba*	>100000	chronic, 7d, EC_{50}	7.864	>12716	10
GF-2372	Freshwater diatom (*Navicula pelliculosa*)	14000	chronic, 72h, E_yC_{50}	7.864	1780	10

* µg a.s./kg sediment

Spring and winter cereals – 1 x 24 g a.s./ha –Sulfoxaflor metabolites

Test substance	Organism	Toxicity end point (µg a.s./L)	Time scale & endpoint measured	FOCUS Step 1 max PEC_{sw} (µg a.s./L)	TER	Annex VI Trigger
Toxicity to fish						
X11719474	Rainbow trout (*Oncorhynchus mykiss*)	>478000	acute, 96h, LC_{50}	8.359	>57184	100
X11519540	Rainbow trout (*Oncorhynchus mykiss*)	>330000	acute, 96h, LC_{50}	0.875	>377143	100
X11579457	Rainbow trout (*Oncorhynchus mykiss*)	>320000	acute, 96h, LC_{50}	0.651	>491551	100
Toxicity to aquatic invertebrates						
X11719474	*Daphnia magna*	>205000	acute, 48h, LC_{50}	8.359	>24524	100
X11519540	*Daphnia magna*	>350000	acute, 48h, LC_{50}	0.875	>400000	100
X11579457	*Daphnia magna*	95000	acute, 48h, LC_{50}	0.651	145929	100
X11719474	Mysid shrimp (*Americamysis bahia*)	>114000	acute, 96h, LC_{50}	8.359	>13638	100
X11719474	Mysid shrimp (*Americamysis bahia*)	2120	chronic, 28d NOEC	8.359	254	10
X11519540	Mysid shrimp (*Americamysis bahia*)	>120000	acute, 96h, LC_{50}	0.875	>137143	100
X11579457	Mysid shrimp (*Americamysis bahia*)	>110000	acute, 96h, LC_{50}	0.651	>168971	100
Toxicity to sediment-dwelling invertebrates						
X11719474	*Chironomus dilutus*	>281000	acute, 96h, spiked water, LC_{50}	8.359	>33616	100
X11519540	*Chironomus dilutus*	>360000	acute, 96h, spiked water, LC_{50}	0.875	>411429	100
X11579457	*Chironomus dilutus*	88000	acute, 96h, spiked water, LC_{50}	0.651	135177	100
X11719474	*Chironomus riparius*	10400	chronic, 28d, spiked water, NOEC	8.359	1244	10
X11519540	*Chironomus riparius*	10000	chronic, 28d, spiked water, NOEC	0.875	11429	10
X11579457	*Chironomus riparius*	11000	chronic, 28d, spiked water, NOEC	0.651	16897	10
Toxicity to algae and aquatic macrophytes						
X11719474	Freshwater diatom (*Navicula pelliculosa*)	>124000	chronic, 72h, E_yC_{50}/ E_rC_{50}	8.359	>14834	10
X11519540	Freshwater diatom (*Navicula pelliculosa*)	>110000	chronic, 72h, E_yC_{50}/ E_rC_{50}	0.875	>125714	10
X11579457	Freshwater diatom (*Navicula pelliculosa*)	>110000	chronic, 72h, E_yC_{50}/ E_rC_{50}	0.651	>168971	10

Cotton – 1 x 24 g a.s./ha – technical and formulated sulfoxaflor

Test substance	Organism	Toxicity end point (µg a.s./L)	Time scale & endpoint measured	FOCUS Step 1 max PEC_{sw} (µg a.s./L)	TER	Annex VI Trigger
Toxicity to fish						
Sulfoxaflor	Sheepshead minnow (*Cyprinodon variegatus*)	266000	acute, 96h, LC_{50}	7.864	33825	100
Sulfoxaflor	Sheepshead minnow (*Cyprinodon variegatus*)	1210	chronic, 38d, NOEC	7.864	154	10
GF-2372	Rainbow trout (*Oncorhynchus mykiss*)	9750	acute, 96h, LC_{50}	7.864	1240	100
Toxicity to aquatic invertebrates						
Sulfoxaflor	Mysid shrimp (*Americamysis bahia*)	643	acute, 96h, LC_{50}	7.864	**82**	100
Sulfoxaflor	Mysid shrimp (*Americamysis bahia*)	114	chronic, 28d, NOEC	7.864	15	10
GF-2372	Mysid shrimp (*Americamysis bahia*)	550	acute, 96h, LC_{50}	7.864	**70**	100
Toxicity to sediment-dwelling invertebrates						
Sulfoxaflor	*Chironomus dilutus*	622	acute, 96h, spiked water, LC_{50}	7.864	**79**	100
Sulfoxaflor	*Chironomus dilutus*	119*	acute, 10d, spiked sediment, LC_{50}	2.716* (PEC_{sed})	**44**	100
Sulfoxaflor	*Chironomus riparius*	38.4	chronic, 28d, spiked water, NOEC	7.864	80.7	10
GF-2372	*Chironomus dilutus*	>12000	acute, 96h, spiked water, LC_{50}	7.864	>1526	100
Toxicity to algae and aquatic macrophytes						
Sulfoxaflor	Freshwater diatom (*Navicula pelliculosa*)	85700	chronic, 96h, E_bC_{50}	7.864	10898	10
Sulfoxaflor	*Lemna gibba*	>100000	chronic, 7d, EC_{50}	7.864	>12716	10
GF-2372	Freshwater diatom (*Navicula pelliculosa*)	14000	chronic, 72h, E_yC_{50}	7.864	1780	10

* µg a.s./kg sediment

Cotton – 1 x 24 g a.s./ha –Sulfoxaflor metabolites

Test substance	Organism	Toxicity end point (µg a.s./L)	Time scale & endpoint measured	FOCUS Step 1 max PEC_{sw} (µg a.s./L)	TER	Annex VI Trigger
Toxicity to fish						
X11719474	Rainbow trout (*Oncorhynchus mykiss*)	>478000	acute, 96h, LC_{50}	8.359	>57184	100
X11519540	Rainbow trout (*Oncorhynchus mykiss*)	>330000	acute, 96h, LC_{50}	0.875	>377143	100
X11579457	Rainbow trout (*Oncorhynchus mykiss*)	>320000	acute, 96h, LC_{50}	0.651	>491551	100
Toxicity to aquatic invertebrates						

Test substance	Organism	Toxicity end point (µg a.s./L)	Time scale & endpoint measured	FOCUS Step 1 max PEC_{sw} (µg a.s./L)	TER	Annex VI Trigger
X11719474	*Daphnia magna*	>205000	acute, 48h, LC_{50}	8.359	>24524	100
X11519540	*Daphnia magna*	>350000	acute, 48h, LC_{50}	0.875	>400000	100
X11579457	*Daphnia magna*	95000	acute, 48h, LC_{50}	0.651	145929	100
X11719474	Mysid shrimp (*Americamysis bahia*)	>114000	acute, 96h, LC_{50}	8.359	>13638	100
X11719474	Mysid shrimp (*Americamysis bahia*)	2120	chronic, 28d NOEC	8.359	254	10
X11519540	Mysid shrimp (*Americamysis bahia*)	>120000	acute, 96h, LC_{50}	0.875	>137143	100
X11579457	Mysid shrimp (*Americamysis bahia*)	>110000	acute, 96h, LC_{50}	0.651	>168971	100
Toxicity to sediment-dwelling invertebrates						
X11719474	*Chironomus dilutus*	>281000	acute, 96h, spiked water, LC_{50}	8.359	>33616	100
X11519540	*Chironomus dilutus*	>360000	acute, 96h, spiked water, LC_{50}	0.875	>411429	100
X11579457	*Chironomus dilutus*	88000	acute, 96h, spiked water, LC_{50}	0.651	135177	100
X11719474	*Chironomus riparius*	10400	chronic, 28d, spiked water, NOEC	8.359	1244	10
X11519540	*Chironomus riparius*	10000	chronic, 28d, spiked water, NOEC	0.875	11429	10
X11579457	*Chironomus riparius*	11000	chronic, 28d, spiked water, NOEC	0.651	16897	10
Toxicity to algae and aquatic macrophytes						
X11719474	Freshwater diatom (*Navicula pelliculosa*)	>124000	chronic, 72h, E_yC_{50}/ E_rC_{50}	8.359	>14834	10
X11519540	Freshwater diatom (*Navicula pelliculosa*)	>110000	chronic, 72h, E_yC_{50}/ E_rC_{50}	0.875	>125714	10
X11579457	Freshwater diatom (*Navicula pelliculosa*)	>110000	chronic, 72h, E_yC_{50}/ E_rC_{50}	0.651	>168971	10

FOCUS Step 2

Fruiting vegetables – 1 x 24 g a.s./ha – technical and formulated sulfoxaflor. Northern and southern Europe Member States.

Test substance	Organism	Toxicity end point (µg a.s./L)	Time scale & endpoint measured	FOCUS Step 2 max PEC_{sw} (µg a.s./L)	TER	Annex VI Trigger
Toxicity to aquatic invertebrates						
Sulfoxaflor	Mysid shrimp (*Americamysis bahia*)	643	acute, 96h, LC_{50}	0.221 (N & S)	2910	100

Test substance	Organism	Toxicity end point (µg a.s./L)	Time scale & endpoint measured	FOCUS Step 2 max PEC_{sw} (µg a.s./L)	TER	Annex VI Trigger
GF-2626	Mysid shrimp (*Americamysis bahia*)	455	acute, 96h, LC_{50}	0.221 (N & S)	2059	100
Toxicity to sediment-dwelling invertebrates						
Sulfoxaflor	*Chironomus dilutus*	622	acute, 96h, spiked water, LC_{50}	0.221 (N & S)	2814	100
Sulfoxaflor	*Chironomus dilutus*	119*	acute, 10d, spiked sediment, LC_{50}	0.070* (N & S) (PEC_{sed})	1700	100

* µg a.s./kg sediment

Spring and winter cereals – 1 x 24 g a.s./ha – technical and formulated sulfoxaflor. Northern and southern Europe Member States.

Test substance	Organism	Toxicity end point (µg a.s./L)	Time scale & endpoint measured	FOCUS Step 2 max PEC_{sw} (µg a.s./L)	TER	Annex VI Trigger
Toxicity to aquatic invertebrates						
Sulfoxaflor	Mysid shrimp (*Americamysis bahia*)	643	acute, 96h, LC_{50}	0.221 (N & S)	2910	100
GF-2372	Mysid shrimp (*Americamysis bahia*)	550	acute, 96h, LC_{50}	0.221 (N & S)	2489	100
Toxicity to sediment-dwelling invertebrates						
Sulfoxaflor	*Chironomus dilutus*	622	acute, 96h, spiked water, LC_{50}	0.221 (N & S)	2814	100
Sulfoxaflor	*Chironomus dilutus*	119*	acute, 10d, spiked sediment, LC_{50}	0.070* (N & S) (PEC_{sed})	1700	100

* µg a.s./kg sediment

Cotton – 1 x 24 g a.s./ha – technical and formulated sulfoxaflor. Northern and southern Europe Member States.

Test substance	Organism	Toxicity end point (µg a.s./L)	Time scale & endpoint measured	FOCUS Step 2 max PEC_{sw} (µg a.s./L)	TER	Annex VI Trigger
Toxicity to aquatic invertebrates						
Sulfoxaflor	Mysid shrimp (*Americamysis bahia*)	643	acute, 96h, LC_{50}	0.221 (N & S)	2910	100
GF-2372	Mysid shrimp (*Americamysis bahia*)	550	acute, 96h, LC_{50}	0.221 (N & S)	2489	100
Toxicity to sediment-dwelling invertebrates						
Sulfoxaflor	*Chironomus dilutus*	622	acute, 96h, spiked water, LC_{50}	0.221 (N & S)	2814	100
Sulfoxaflor	*Chironomus dilutus*	119*	acute, 10d, spiked sediment, LC_{50}	0.070* (N & S) (PEC_{sed})	1700	100

* µg a.s./kg sediment

Bioconcentration				
	Active substance	Metabolite1	Metabolite2	Metabolite3
$logP_{O/W}$	0.8			
Bioconcentration factor (BCF)	not triggered[1]			
Annex VI Trigger for the bioconcentration factor				
Clearance time (days) (CT_{50})				
(CT_{90})				
Level and nature of residues (%) in organisms after the 14 day depuration phase				

1: only required if log $P_{O/W}$ >3.

Effects on honeybees (Annex IIA, point 8.3.1, Annex IIIA, point 10.4)

Test substance	Acute oral toxicity (LD_{50} µg/bee)	Acute contact toxicity (LD_{50} µg/bee)
a.s.	0.146 (48-h)	0.379 (72-h)
GF-2626	0.539 prep. (48-h) 0.065 a.s.	2.356 prep. (48-h) 0.283 a.s.
GF-2372	0.153 prep. (48-h) 0.075 a.s.	0.448 prep. (48-h) 0.224 a.s.
GF-2032 (Bumble bee)	0.123 prep. (72-h) 0.027 a.s.	34.336 prep. (72-h) 7.554 a.s.
X11719474	>100 (96-h)	-
X11519540	>91.2 (48-h)	-
X11579457	45.7 (48-h)	-
X11721061	>103.5 (48-h)	-

Semi-field tests:

Test substance (location)	**Study treatments**	**Findings**	**Reference**
GF-2626 (Germany)	Pre-flower without bees 1) 48 g a.s./ha Evening application after bee flight 1) 24 g a.s./ha 2) 48 g a.s./ha Daytime application during bee flight	Negative effects on adult mortality: in evening application 24 g a.s./ha on day 0, in evening application 48 g a.s./ha on day 0-1, in daytime application on day 0-1. Negative effects on foraging activity: in evening application 48 g a.s./ha on day 0-2, in daytime application on day 0-1. Negative effects on bee brood cannot be excluded.	Schmitzer (2011a)

	1) 24 g a.s./ha		
GF-2626 (Germany)	Pre-flower without bees 1) 48 g a.s./ha Evening application after bee flight 1) 24 g a.s./ha Daytime application during bee flight 1) 24 g a.s./ha	Negative effects on adult mortality: in evening application on day 0, in daytime application on day 0-1. Negative effects on foraging activity: in daytime application on day 0-1. Negative effects on bee brood cannot be excluded.	Schmitzer (2011b)
GF-2626 (Germany)	Daytime application during bee flight 1) 4 g a.s./ha 2) 8 g a.s./ha 1) 24 g a.s./ha	No apparent effects on mortality, flight intensity and behaviour at test rates 4 and 8 g a.s/ha. Some transient effects on mortality, flight intensity and behaviour at test rate 24 g a.s/ha.	Schmitzer (2011c)

Hazard quotients for honey bees (Annex IIIA, point 10.4)

Crop and application rate

Test substance	Route	Hazard quotient	Annex VI Trigger
a.s.	Contact	**63**	50
a.s.	oral	**164**	50
GF-2626	Contact	**85**	50
GF-2626	oral	**369**	50
GF-2372	Contact	**107**	50
GF-2372	oral	**320**	50
X11719474	Oral	< 0.24	50
X11519540	Oral	< 0.26	50
X11579457	Oral	0.53	50
X11721061	Oral	0.23	50

Effects on other arthropod species (Annex IIA, point 8.3.2, Annex IIIA, point 10.5)

Laboratory tests with standard sensitive species

Species	Test Substance	End point	Effect (LR_{50} g/ha)
Aphidius rhopalosiphi	GF-2626	Mortality	0.0209 a.s.
Typhlodromus pyri	GF-2626	Mortality	384 a.s.
Aphidius rhopalosiphi	GF-2372	Mortality	0.0062 a.s.
Typhlodromus pyri	GF-2372	Mortality	> 384 a.s.

Fruiting vegetables, cereals and cotton - 1 x 24 g a.s./ha

Crop, application rate	**Crop scenario**	**Test species**	**LR_{50} (g a.s./ha)**	**In-field HQ**	**Off-field drift (distance)**	**Off-field HQ**	**Trigger**
Fruiting vegetables, 1 x 24 g a.s./ha	Field crops	*A. rhopalosiphi*	0.02088	**1149**	2.77% (1m)	**32**	2
		T. pyri	> 384	< 0.06		< 0.002	
Cereals, cotton, 1 x 24 g a.s./ha	Field crops	*A. rhopalosiphi*	0.0062	**3871**	2.77% (1m)	**107**	2
		T. pyri	> 384	< 0.06		< 0.002	

Further laboratory and extended laboratory studies

Specie	Life stage	Test substance	substrate	Dose	% effect
Aphidius rhopalosiphi	Adult	GF-2626	Barley seedlings	 34 17 8.5 4.25 2.13 mL GF-2626/ha 34 17 8.5 4.25 2.13 mL GF-2626/ha	Corrected mortality: 100 83.3 46.7 26.7 3.3 LR_{50} = 7.875 mL GF-2626/ha LR_{50} = 0.945 g sulfoxaflor/ha Corrected reproduction: - - -95.5 -51.5 -70.0 ER_{50} >8.5 mL GF-2626/ha ER_{50} >1.02 g sulfoxaflor/ha
Aphidius rhopalosiphi	Adult	GF-2372	Barley seedlings	 8 4 2 1 0.5 g GF-2372/ha 8 4 2 1 0.5 g GF-2372/ha	Corrected mortality: 83.3 50.0 23.3 0.0 0.0 LR_{50} = 3.90 g GF-2372/ha LR_{50} = 1.95 g sulfoxaflor/ha Corrected reproduction: - 54.4 37.9 12.5 - ER_{50} = 2 g GF-2372/ha ER_{50} = 1 g sulfoxaflor/ha

Aleochara bilineata	Adult	GF-2032	Sandy soil	 100 50 13.75 mL GF-2032/ha 100 50 13.75 mL GF-2032/ha	Corrected mortality: 0 0 0 LR_{50} >100 mL GF-2032/ha LR_{50} >24 g sulfoxaflor/ha Corrected reproduction: -2 -8 -11 ER_{50} >100 mL GF-2032/ha ER_{50} >24 g sulfoxaflor/ha
Chrysoperla carnea	Larvae	GF-2626	*Phaseolus vulgaris* leaf discs	 400 200 100 50 mL GF-2626/ha 400 200 100 50 mL GF-2626/ha	Corrected mortality: 8.3 5.6 5.6 0.0 LR_{50} >400 mL GF-2626/ha LR_{50} >48 g sulfoxaflor/ha Corrected reproduction: 4.9 -7.5 11.5 4.7 ER_{50} >400 mL GF-2626/ha ER_{50} >48 g sulfoxaflor/ha
Extended laboratory / aged residue					

Aphidius rhopalosiphi	Adults	GF-2626	Barley seedlings	0 DAT 400 200 58.33 7 DAT 400 200 58.33 14 DAT 400 200 58.33 21 DAT 400 200 58.33 28 DAT 400 200 14 DAT 400 200 58.33 21 DAT 400 200 58.33 28 DAT 400 200 mL GF-2626/ha	Corrected mortality: 100 100 100 100 83 73 53 50 23 17 4 4 10 7 Corrected reproduction: - - 3.6 18.5 -13.6 17.0 -5.4 8.5

Aphidius rhopalosiphi	Adults	GF-2372	Barley seedlings	0 DAT 96 48 14 7 DAT 96 48 14 14 DAT 96 48 14 21 DAT 96 48 28 DAT 96 7 DAT 96 48 14 14 DAT 96 48 14 21 DAT 96 48 28 DAT 96 mL GF-2372/ha	Corrected mortality: 100 100 100 93 83 47 77 47 30 65 35 21 Corrected reproduction: - - 15.8 - 7.7 3.7 - -15.5 10.8

Fruiting vegetables – 1 x 24 g a.s./ha

Test species	**Endpoints (g a.s./ha)**	**In-field PER (g a.s./ha)**	**Risk acceptable Y / N**	**Crop scenario**	**Off-field drift (distance)**	**Off-field PER (g a.s./ha)**	**Risk acceptable Y / N**
A. rhopalosiphi	LR50 = 0.945 ER_{50} > 1.02	24	**N**	Vegetables < 50 cm	2.77% (1m)	3.32	**N**
				Vegetables > 50 cm	8.02% (3m)	9.62	**N**
Ch. carnea	LR_{50} > 48 ER_{50} > 48	24	Y	Vegetables < 50 cm	2.77% (1m)	0.33	Y
				Vegetables > 50 cm	8.02% (3m)	0.96	Y
A. bilineata	LR_{50} > 24 ER_{50} > 24	24	Y	Vegetables < 50 cm	2.77% (1m)	0.33	Y
				Vegetables > 50 cm	8.02% (3m)	0.96	Y

Cereals and cotton – 1 x 24 g a.s./ha

Test species	**Endpoints (g a.s./ha)**	**In-field PER (g a.s./ha)**	**Risk acceptable Y / N**	**Crop scenario**	**Off-field drift (distance)**	**Off-field PER (g a.s./ha)**	**Risk acceptable Y / N**
A. rhopalosiphi	LR50 = 1.95 ER_{50} > 1	24	**N**	Field crops	2.77% (1m)	3.32	**N**
Ch. carnea	LR_{50} > 48 ER_{50} > 48	24	Y	Field crops	2.77% (1m)	0.33	Y
A. bilineata	LR_{50} > 24 ER_{50} > 24	24	Y	Field crops	2.77% (1m)	0.33	Y

Field tests

NTA off-field test - S.W, France

The impact of simulated drift events on arthropod populations and communities typical of grassy field margins in southern Europe was evaluated for GF-2626 at exposures equivalent to 0.3, 0.6, 1.2, 2.4, 4.8 and 9.6 g sulfoxaflor/ha.

At the community level no consistent rate related response was noted. For some test item rates faint and transient responses could be observed, but the magnitude was not related to the dose rate. At the population level no consistent dose related adverse effects from GF-2626 treatments were found, except for the collembolan taxon *Bourletiellidae* and for aphids. In all rates populations of the family *Bourletiellidae* were recovered within one or two months after application. However, recovery was not observed for some species within the *Bourletiellidae* family.

No sustained adverse effects on family levels of arthropod communities prevailing in grasslands in South-West France are likely to occur, when GF-2626 (active ingredient sulfoxaflor) is applied at rates of up to 9.6 g sulfoxaflor/ha.

Bakker, F (2011)

Cereal field test - S.W. France

GF-2372 applied once at a rate of 24 or 48 g sulfoxaflor/ha, or twice at 24 g sulfoxaflor/ha with a spray interval of 21 days, induced moderate and transient but statistically significant adverse effects on populations of certain orders (mainly *Homopetera*, *Hymenoptera* and few *Diptera* and *Collembola*). Recovery was seen for all these taxa within one or two months after the first application. There was no clear differentiation in effects related to test rate or application frequency. For few hymenopteran taxa the recovery period was slightly longer in the 2 x 24 g sulfoxaflor/ha rate. One mite taxon (*Stigmaeidae*) showed a delayed but persistent adverse effect in the 2 x 24 g sulfoxaflor/ha treatment, but differences compared to the control were statistically significant only on one sampling moment (ca 3 months after the second application). These findings were confirmed by community analyses, although the observed responses of the arthropod communities were not statistically significant for any of the GF-2372 treatments tested.

Based on De Jong *et al*. (2010), the effect of one application of GF-2372 at 24 or 48 g sulfoxaflor/ha, or two applications at 24 g sulfoxaflor/ha in a commercial cereal field in southern Europe (France), would be classified as 3 (clear response of taxa, but full recovery within two months after the first application for all but one taxon, full recovery of the community within two months after the first application).

Hence, no sustained adverse effects on arthropod communities prevailing in a commercial cereal field in southern Europe (France) are likely to occur, when GF-2372 (active ingredient sulfoxaflor) is applied at rates of up to 48 g sulfoxaflor/ha.

Roig, J (2011)

Cereal field test - the Netherlands

GF-2372 applied once at a rate of 24 or 48 g sulfoxaflor/ha, or twice at 24 g sulfoxaflor/ha with a spray interval of 22 days, induced moderate but statistically significant adverse effects on populations of certain orders (mainly *Homopetera*, *Diptera*, *Hymenoptera* and *Collembola*), but recovery was seen for almost all these taxa within one or two months after the first application. There was usually no clear differentiation in effects related to test rate or application frequency. For few hymenopteran taxa the recovery period was slightly longer in the 2 x 24 g sulfoxaflor/ha rate.

Stronger effects were observed on aphids and a few associated specialist predators (*Coccinellidae*) and parasitoids (e.g. *Aphelinidae*). Aphid populations recovered within one month after application, before natural decline (migration). Related predators and parasitoids also disappeared from the field. It is expected that adverse effects observed for the specialist predators and parasitoids were at least partly due to indirect effects of reduced host availability.

Multivariate analyses confirmed that recovery of the entire community occurred within approximately two months after the first application in all three GF-2372 treatments. Based on De Jong *et al*. (2010), the effect of one application of GF-2372 at 24 or 48 g sulfoxaflor/ha, or two applications at 24 g sulfoxaflor/ha in a commercial cereal field in northern Europe (the Netherlands), would be classified as 3 (clear response of taxa, but full recovery within two months after the first application).

Hence, no sustained adverse effects on arthropod communities prevailing in a commercial cereal field in northern Europe (the Netherlands) are likely to occur, when GF-2372 (active ingredient sulfoxaflor) is applied at rates of up to 48 g sulfoxaflor/ha.

Bakker, F (2011)

Effects on earthworms, other soil macro-organisms and soil micro-organisms (Annex IIA points 8.4 and 8.5. Annex IIIA, points, 10.6 and 10.7)

Test organism	Test substance	Time scale	End point
Earthworms			
Eisenia fetida	a.s.	Acute 14 days	LC_{50} 0.885 mg a.s./kg d.w. soil
	a.s.	Chronic 8 weeks	NOEC 0.1 mg a.s./kg d.w. soil
	GF-2626	Acute	LC_{50} 5.527 mg prep./kg d.w. soil LC_{50} 0.66 mg a.s./kg d.w. soil
	GF-2626	Chronic	NOEC 0.75 mgprep./kg d.w. soil NOEC 0.09 mg a.s./kg d.w. soil
	GF-2372	Acute	LC_{50} 1.050 mg prep./kg d.w. soil LC_{50} 0.525 mg a.s./kg d.w. soil
	GF-2372	Chronic	NOEC 0.16 mg prep./kg d.w. soil NOEC 0.08 mg a.s./kg d.w. soil
	X11719474	Acute	LC_{50} >1000 mg a.s./kg d.w. soil
	X11719474	Chronic	NOEC 10 mg a.s./kg d.w. soil
	X11519540	Chronic	NOEC 10 mg a.s./kg d.w. soil
	X11579457	Chronic	NOEC 10 mg a.s./kg d.w. soil
	X11721061	Acute	LC_{50} > 100 mg a.s./kg d.w. soil
	X11721061	Chronic	NOEC 10 mg a.s./kg d.w. soil
Other soil macro-organisms			
Folsomia candida	GF-2626	chronic, 28 d	NOEC 2.67 mg prep./kg d.w. soil NOEC 0.3204 mg a.s./kg d.w. soil
	GF-2372	chronic, 28 d	NOEC 0.16 mg prep./kg d.w. soil NOEC 0.08 mg a.s./kg d.w. soil
	X11719474	chronic, 28 d	NOEC 10 mg a.s./kg d.w. soil
	X11519540	chronic, 28 d	NOEC 10 mg a.s./kg d.w. soil
	X11579457	chronic, 28 d	NOEC 10 mg a.s./kg d.w. soil
Hypoaspis aculeifer	GF-2626	chronic, 14 d	NOEC 100 mg prep./kg d.w. soil NOEC 12 mg a.s./kg d.w. soil
	GF-2372	chronic, 14 d	NOEC 6.25 mg prep./ kg d.w. soil NOEC 3.125 mg a.s./kg d.w. soil
	X11519540	chronic, 14 d	NOEC 10 mg a.s./kg d.w. soil
	X11579457	chronic, 14 d	NOEC 5 mg a.s./kg d.w. soil
Soil micro-organisms			
Nitrogen mineralisation	a.s.		<25% by Day 28 at 0.33 mg a.s./kg d.w. soil (240 g a.s/ha)

Carbon mineralisation	a.s.		<25% by Day 28 at 0.33 mg a.s./kg d.w. soil (240 g a.s/ha)
Nitrogen mineralisation	GF-2626		<25% by Day 28 at 2.85 mg prep./kg d.w. soil (2 L prep./ha) <25% by Day 28 at 0.32 mg a.s./kg d.w. soil (240 g a.s/ha)
Carbon mineralisation	GF-2626		<25% by Day 28 at 2.85 mg prep./kg d.w. soil (2 L prep./ha) <25% by Day 28 at 0.32 mg a.s./kg d.w. soil (240 g a.s/ha)
Nitrogen mineralisation	GF-2372		<25% by Day 28 at 0.32 mg prep./kg d.w. soil (240 g prep./ha) <25% by Day 28 at 0.16 mg a.s./kg d.w. soil (120 g a.s/ha)
Carbon mineralisation	GF-2372		<25% by Day 28 at 0.32 mg prep./kg d.w. soil (240 g prep./ha) <25% by Day 28 at 0.16 mg a.s./kg d.w. soil (120 g a.s/ha)
Nitrogen mineralisation	X11719474		<25% by Day 28 at 0.16 mg a.s./kg d.w. soil (120 g a.s/ha)
Carbon mineralisation	X11719474		<25% by Day 28 at 0.16 mg a.s./kg d.w. soil (120 g a.s/ha)
Nitrogen mineralisation	X11519540		<25% by Day 28 at 0.32 mg a.s./kg d.w. soil
Carbon mineralisation	X11519540		<25% by Day 28 at 0.32 mg a.s./kg d.w. soil
Nitrogen mineralisation	X11579457		<25% by Day 43 at 0.32 mg a.s./kg d.w. soil
Carbon mineralisation	X11579457		<25% by Day 28 at 0.32 mg a.s./kg d.w. soil

Field studies

Earthworm field study:
An earthworm field study was conducted to investigate effects of GF-2626 (SC formulation containing 120 g/L of sulfoxaflor) and its metabolite X11719474 on the earthworm fauna in southern Germany.

Three application scenario were used in the study:
T1: first application of 4.8 g/ha X11719474 (plateau concentration 1) plus second application of 24 g sulfoxaflor/ha applied as GF-2626 after one week
T2: first application of 9.6 g/ha X11719474 (plateau concentration 2) plus a second application of 24 g sulfoxaflor/ha applied as GF-2626 after one week plus a third application of 24 g sulfoxaflor/ha applied as GF-2626 four weeks after the first application
T3: first application of 9.6 g/ha X11719474 (plateau concentration 2) plus a second application of 48 g sulfoxaflor./ha applied as GF-2626 after one week.

All validity criteria were met due to the high earthworm abundance, the presence of key earthworm species of different ecological types (epigeic, endogeic and anecic) and the homogeneity in abundance and species distribution at the field site. The effect of the toxic reference treatment indicated the sensitivity of the earthworm population. The time of applications during high activity of earthworms and additional irrigation in the time after the application guaranteed the exposure of earthworms to the test item and the toxic reference item.

After application of GF-2626 and its metabolite X11719474 applied to field plots no adverse effects on total earthworm numbers occurred in any of the samplings. No significant reductions in numbers and weights of earthworm species, groupings or totals were found in any of the samplings.

Hence, no sustained adverse effects on an earthworm field community are likely to occur, when GF-2626 (active ingredient sulfoxaflor) and its metabolite X11719474 are applied at rates of up to 48 g sulfoxaflor/ha and 9.6 g X11719474/ha, respectively.
Klein, O. 2012

Field study on soil micro-arthropods:
A field study was conducted to assess possible effects of GF-2626 (SC formulation containing 120 g/L of sulfoxaflor) and its metabolite X11719474 on soil living invertebrates (*Collembola*, *Acari*) under field conditions on a grassland in southern Germany. For this purpose community composition and abundance of selected soil living invertebrates were monitored over the period of one year.

Three application scenario were used in the study:
T1: first application of 4.8 g/ha X11719474 (plateau concentration 1) plus second application of 24 g sulfoxaflor/ha applied as GF-2626 after one week
T2: first application of 9.6 g/ha X11719474 (plateau concentration 2) plus a second application of 24 g sulfoxaflor/ha applied as GF-2626 after one week plus a third application of 24 g sulfoxaflor/ha applied as GF-2626 four weeks after the first application
T3: first application of 9.6 g/ha X11719474 (plateau concentration 2) plus a second application of 48 g sulfoxaflor./ha applied as GF-2626 after one week.

After application of GF-2626 and its metabolite X11719474 applied to field plots no adverse effects on soil living micro-arthropod numbers occurred in any of the samplings. No significant or persistent treatment related reductions were observed in any of the test item treatment.

Hence, no sustained adverse effects on soil micro-arthropod field communities are likely to occur, when GF-2626 (active ingredient sulfoxaflor) and its metabolite X11719474 are applied at rates of up to 48 g sulfoxaflor/ha and 9.6 g X11719474/ha, respectively.
Mack, P. 2012

Effects on soil organic matter breakdown – litter bag study:
A field study was conducted to assess possible effects of GF-2626 (SC formulation containing 120 g/L of sulfoxaflor) and its metabolite X11719474, on the breakdown of organic material under field conditions using litter bags incorporated into an agricultural field.

Two application scenario were used in the study:
T1: first application of 4.8 g/ha X11719474 (plateau concentration 1) plus second application of 24 g sulfoxaflor/ha applied as GF-2626 after 15 days
T2: first application of 9.6 g/ha X11719474 (plateau concentration 2) plus a second application of 48 g sulfoxaflor./ha applied as GF-2626 after 15 days.

The plateau application of X11719474 (4.8 g/ha and 9.6 g/ha) was applied to bare soil and incorporated into the soil to a depth of 10 cm to obtain the plateau concentration of X11719474 in soil. Clover was sown on the ground afterwards. 14 days after the first application, litterbags containing wheat straws were buried 5 cm deep. A second application of 24 g sulfoxaflor/ha and 48 g sulfoxaflor/ha applied as GF-2626 was made 15 days after the first application. The exposure concentrations of both sulfoxaflor and the metabolite X11719474 in soil after the application were satisfactorily confirmed by chemical analysis.

Sampling was conducted 1, 3, 6 and 9 months after the incorporation of the litter bags to determine the amount of organic matter decomposition relative to the control.

After 9 months the mass loss in the control and the treatments was > 60 %. The coefficient of variation in the control and test item treatment did not exceed the validity criteria of 40 % throughout the study. The study can therefore be considered to be valid.

For all sampling dates the differences between the average mass loss of the control plots and the test item plots were less than 10 %. No statistically significant difference (t-test, $p > 0.05$) in the decomposition between control and test item treatment occurred after 9 months of exposure to GF-2626 and its metabolite X11719474. The coefficient of variation in both the control and the treatments did not exceed 40 % throughout the study.

Hence, the results of the study indicate a lack of adverse effects on breakdown of organic material under field conditions when GF-2626 (active ingredient sulfoxaflor) and its metabolite X11719474 are applied at rates of up to 48 g sulfoxaflor/ha and 9.6 g X11719474/ha, respectively.
Mack, P. 2011

Toxicity/exposure ratios for soil organisms

Fruiting vegetables - 1 x 24 g a.s./ha

Test organism	Test substance	Toxicity end point (mg a.s./kg soil)	Time scale & endpoint measured	Maximum PEC_{soil} (mg a.s./kg soil)	TER	Annex VI Trigger
Eisenia fetida	Sulfoxaflor	0.885	acute, 14d, LC_{50}	0.0096	92	10
	GF-2626	0.66	acute, 14d, LC_{50}	0.0096	69	10
	X11719474	>1000	acute, 14d, LC_{50}	0.0121	>82645	10
	Sulfoxaflor	0.1	chronic, 56d, NOEC	0.0096	10.42	5
	GF-2626	0.09	chronic, 56d, NOEC	0.0096	9.38	5
	X11719474	10	chronic, 56d, NOEC	0.0121	826	5
	X11519540	10	chronic, 56d, NOEC	0.0016	6250	5
	X11579457	10	chronic, 56d, NOEC	0.0005	20000	5

Spring and winter cereals - 1 x 24 g a.s./ha

Test organism	Test substance	Toxicity end point (mg a.s./kg soil)	Time scale & endpoint measured	Maximum PEC_{soil} (mg a.s./kg soil)	TER	Annex VI Trigger
Eisenia fetida	Sulfoxaflor	0.885	acute, 14d, LC_{50}	0.0032	277	10
	GF-2372	0.525	acute, 14d, LC_{50}	0.0032	164	10
	X11719474	>1000	acute, 14d, LC_{50}	0.0040	>250000	10
	Sulfoxaflor	0.1	chronic, 56d, NOEC	0.0032	31	5
	GF-2372	0.08	chronic, 56d, NOEC	0.0032	25	5
	X11719474	10	chronic, 56d, NOEC	0.0040	25000	5
	X11519540	10	chronic, 56d, NOEC	0.0005	20000	5
	X11579457	10	chronic, 56d, NOEC	0.0002	50000	5

Cotton - 1 x 24 g a.s./ha

Test organism	Test substance	Toxicity end point (mg a.s./kg soil)	Time scale & endpoint measured	Maximum PEC_{soil} (mg a.s./kg soil)	TER	Annex VI Trigger
Eisenia fetida	Sulfoxaflor	0.885	acute, 14d, LC_{50}	0.0128	69	10
	GF-2372	0.525	acute, 14d, LC_{50}	0.0128	41	10
	X11719474	>1000	acute, 14d, LC_{50}	0.0161	>62112	10
	Sulfoxaflor	0.1	chronic, 56d, NOEC	0.0128	7.81	5
	GF-2372	0.08	chronic, 56d, NOEC	0.0128	6.25	5
	X11719474	10	chronic, 56d, NOEC	0.0161	621	5
	X11519540	10	chronic, 56d, NOEC	0.0022	4545	5
	X11579457	10	chronic, 56d, NOEC	0.0007	14286	5

Fruiting vegetables - 1 x 24 g a.s./ha

Test species	Test substance	Endpoint (mg a.s./kg dry soil)	Test design	Maximum PEC_{soil} (mg a.s./kg soil)	TER	Annex VI Trigger
Folsomia candida	GF-2372*	0.08	chronic, 28 d, NOEC	0.0096	8.3	5
	X11719474	10	chronic, 28 d, NOEC	0.0121	826	5
	X11519540	10	chronic, 28 d, NOEC	0.0016	6250	5
	X11579457	10	chronic, 28 d, NOEC	0.0005	20000	5
Hypoaspis aculeifer	GF-2372*	3.125	chronic, 14 d, NOEC	0.0096	326	5
	X11519540	10	chronic, 14 d, NOEC	0.0016	6250	5
	X11579457	5	chronic, 14 d, NOEC	0.0005	10000	5

*: note that toxicity endpoint for GF-2626 formulation is also available

Spring and winter cereals - 1 x 24 g a.s./ha

Test species	Test substance	Endpoint (mg a.s./kg dry soil)	Test design	Maximum PEC_{soil} (mg a.s./kg soil)	TER	Annex VI Trigger
Folsomia candida	GF-2372	0.08	chronic, 28 d, NOEC	0.0032	25	5

	X11719474	10	chronic, 28 d, NOEC	0.0040	2500	5
	X11519540	10	chronic, 28 d, NOEC	0.0005	20000	5
	X11579457	10	chronic, 28 d, NOEC	0.0002	50000	5
Hypoaspis aculeifer	GF-2372	3.125	chronic, 14 d, NOEC	0.0032	977	5
	X11519540	10	chronic, 14 d, NOEC	0.0005	20000	5
	X11579457	5	chronic, 14 d, NOEC	0.0002	25000	5

Cotton - 1 x 24 g a.s./ha

Test species	Test substance	Endpoint (mg a.s./kg dry soil)	Test design	Maximum PEC_{soil} (mg a.s./kg soil)	TER	Annex VI Trigger
Folsomia candida	GF-2372	0.08	chronic, 28 d, NOEC	0.0128	6.25	5
	X11719474	10	chronic, 28 d, NOEC	0.0161	621	5
	X11519540	10	chronic, 28 d, NOEC	0.0022	4545	5
	X11579457	10	chronic, 28 d, NOEC	0.0007	14286	5
Hypoaspis aculeifer	GF-2372	3.125	chronic, 14 d, NOEC	0.0128	244	5
	X11519540	10	chronic, 14 d, NOEC	0.0022	4545	5
	X11579457	5	chronic, 14 d, NOEC	0.0007	7143	5

Effects on non target plants (Annex IIA, point 8.6, Annex IIIA, point 10.8)

Preliminary screening data

A standard GLP compliant seedling emergence and vegetative vigour study was conducted according to EPA guidelines using a spray application of GF-2626 and GF-2372 at a nominal application rate of up to 96 g sulfoxaflor/ha (formulated as GF-2626) or 150 g sulfoxaflor/ha (formulated as GF-2372) on seven dicot and four monocot species. Phytotoxic effects were either absence or present at a low level. There were no phytotoxic effects of greater than 25% compared to the control.

Laboratory dose response tests

None submitted or evaluated.

Additional studies (e.g. semi-field or field studies)

Not required.

Effects on biological methods for sewage treatment (Annex IIA 8.7)

Test type/organism	end point
Activated sludge	Respiratory inhibition: 3hour EC50 >800mg a.s./L.

Ecotoxicologically relevant compounds **(consider parent and all relevant metabolites requiring further assessment from the fate section)**

Compartment	
Soil	Sulfoxaflor
Water	Sulfoxaflor
Sediment	Sulfoxaflor
Groundwater	Sulfoxaflor

Classification and proposed labelling with regard to ecotoxicological data (Annex IIA, point 10 and Annex IIIA, point 12.3)

Active substance	RMS/peer review proposal

Pictogram: **GHS09**

Signal word: **Warning**

Classification categories: **Aquatic acute 1, Aquatic chronic 1**

Hazard statements:

H400: **Very toxic to aquatic life**

H410: **Very toxic to aquatic life with long lasting effects**

M-factor: **1 (acute/chronic)**

Precautionary statements:

P273 Avoid release to the environment,

P391 Collect spillage,

P501 Dispose of contents/ container to ... (in accordance with local/ regional/ national/ international regulation (to be specified))

N Dangerous for the environment.

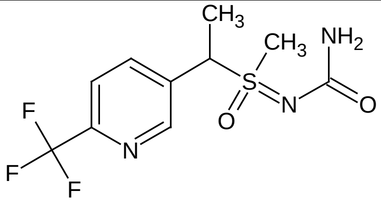
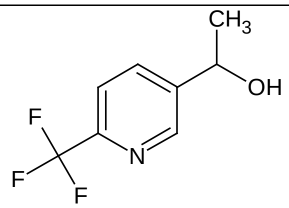
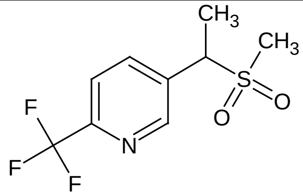
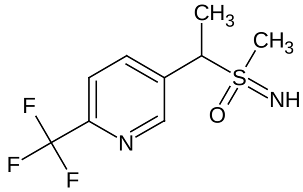
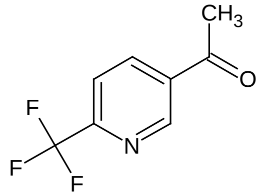
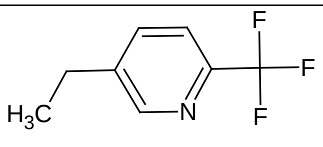
R50 Very toxic to aquatic organisms.

R53 May cause long term effects in the environment.

S60 This material and its container must be disposed of as hazardous waste.

S61 Avoid release to the environment. Refer to special instructions/Safety Data Sheet.

APPENDIX B – USED COMPOUND CODE(S)

Code/Trivial name*	Chemical name/SMILES notation**	Structural formula**
X11719474	1-[methyl(oxido){(1*RS*)-1-[6-(trifluoromethyl)-3-pyridinyl]ethyl}-(*RS*)λ^6-sulfanylidene]urea FC(F)(F)c1ccc(cn1)C(C)S(C)(=O)=NC(N)=O	
X11721061	(1*RS*)-1-[6-(trifluoromethyl)-3-pyridinyl]ethanol FC(F)(F)c1ccc(cn1)C(C)O	
X11519540	5-[(1*RS*)-1-(methylsulfonyl)ethyl]-2-(trifluoromethyl)pyridine FC(F)(F)c1ccc(cn1)C(C)S(C)(=O)=O	
X11579457	5-[(1*RS*)-1-(*S*-methylsulfonimidoyl)ethyl]-2-(trifluoromethyl)pyridine FC(F)(F)c1ccc(cn1)C(C)S(C)(=N)=O	
X11718922	1-[6-(trifluoromethyl)-3-pyridinyl]ethanone FC(F)(F)c1ccc(cn1)C(C)=O	
X11596066	5-ethyl-2-(trifluoromethyl)pyridine FC(F)(F)c1ccc(CC)cn1	

* The compound code / trivial name in bold is the name used in the conclusion.
** ACD/ChemSketch, Advanced Chemistry Development, Inc., ACD/Labs Release: 12.00 Product version: 12.00 (Build 29305, 25 Nov 2008).

ABBREVIATIONS

1/n	slope of Freundlich isotherm
λ	wavelength
ε	decadic molar extinction coefficient
°C	degree Celsius (centigrade)
µg	microgram
µm	micrometer (micron)
a.s.	active substance
AChE	acetylcholinesterase
ADE	actual dermal exposure
ADI	acceptable daily intake
AF	assessment factor
AhR	aryl hydrocarbon receptor
AOEL	acceptable operator exposure level
AP	alkaline phosphatase
AR	applied radioactivity
ARfD	acute reference dose
AST	aspartate aminotransferase (SGOT)
AV	avoidance factor
BCF	bioconcentration factor
BUN	blood urea nitrogen
bw	body weight
CAR	constitutive androstane receptor
CAS	Chemical Abstracts Service
CFU	colony forming units
ChE	cholinesterase
CI	confidence interval
CIPAC	Collaborative International Pesticides Analytical Council Limited
CL	confidence limits
cm	centimetre
d	day
DAA	days after application
DAR	draft assessment report
DAT	days after treatment
DDD	daily dietary dose
DM	dry matter
DT_{50}	period required for 50 percent disappearance (define method of estimation)
DT_{90}	period required for 90 percent disappearance (define method of estimation)
dw	dry weight
EbC_{50}	effective concentration (biomass)
EC_{50}	effective concentration
ECHA	European Chemicals Agency
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
ER_{50}	emergence rate/effective rate, median
ErC_{50}	effective concentration (growth rate)
EU	European Union
EUROPOEM	European Predictive Operator Exposure Model
f(twa)	time weighted average factor
FAO	Food and Agriculture Organization of the United Nations
FID	flame ionisation detector
FIR	Food intake rate

FOB	functional observation battery
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
g	gram
GAP	good agricultural practice
GC	gas chromatography
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GGT	gamma glutamyl transferase
GM	geometric mean
GS	growth stage
GSH	glutathion
h	hour(s)
ha	hectare
Hb	haemoglobin
Hct	haematocrit
hL	hectolitre
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HPLC-MS/MS	high performance liquid chromatography with tandem mass spectrometry
HPLC-UV	high performance liquid chromatography with ultra violet detector
HPLC-MS	high pressure liquid chromatography – mass spectrometry
HQ	hazard quotient
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint Meeting on the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
K_{doc}	organic carbon linear adsorption coefficient
kg	kilogram
K_{Foc}	Freundlich organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC_{50}	lethal concentration, median
LD_{50}	lethal dose, median; dosis letalis media
LDH	lactate dehydrogenase
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
m	metre
M/L	mixing and loading
MAF	multiple application factor
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
mg	milligram
mL	millilitre
mm	millimetre (also used for mean measured concentrations)
mN	milli-newton
MoA	mode of action
MRL	maximum residue limit or level
MS	mass spectrometry
MSDS	material safety data sheet
MTD	maximum tolerated dose
MWHC	maximum water holding capacity

NESTI	national estimated short-term intake
ng	nanogram
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
NPD	nitrogen phosphorous detector
OECD	Organisation for Economic Co-operation and Development
OM	organic matter content
Pa	pascal
PD	proportion of different food types
PEC	predicted environmental concentration
PEC_{air}	predicted environmental concentration in air
PEC_{gw}	predicted environmental concentration in ground water
PEC_{sed}	predicted environmental concentration in sediment
PEC_{soil}	predicted environmental concentration in soil
PEC_{sw}	predicted environmental concentration in surface water
pH	pH-value
PHED	pesticide handler's exposure data
PHI	pre-harvest interval
PIE	potential inhalation exposure
pK_a	negative logarithm (to the base 10) of the dissociation constant
PND	post natal day
P_{ow}	partition coefficient between *n*-octanol and water
PPARα	peroxisome proliferator-activated receptor-α
PPE	personal protective equipment
ppm	parts per million (10^{-6})
PT	proportion of diet obtained in the treated area
PTT	partial thromboplastin time
QSAR	quantitative structure-activity relationship
r^2	coefficient of determination
REACH	Registration, Evaluation, Authorisation of Chemicals Regulation
RPE	respiratory protective equipment
RUD	residue per unit dose
SC	suspension concentrate
SD	standard deviation
SFO	single first-order
SMILES	simplified molecular-input line-entry system
SSD	species sensitivity distribution
STMR	supervised trials median residue
$t_{1/2}$	half-life (define method of estimation)
TER	toxicity exposure ratio
TER_A	toxicity exposure ratio for acute exposure
TER_{LT}	toxicity exposure ratio following chronic exposure
TER_{ST}	toxicity exposure ratio following repeated exposure
TIDA	tuberoinfundibular dopamine
TLV	threshold limit value
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
TSH	thyroid stimulating hormone (thyrotropin)
TWA	time weighted average
UDS	unscheduled DNA synthesis
UV	ultraviolet
W/S	water/sediment
w/v	weight per volume

w/w	weight per weight
WBC	white blood cell
WG	water dispersible granule
WHO	World Health Organization
wk	week
yr	year