REGISTRATION REPORT

Part B
Section 5: Environmental Fate

Detailed summary of the risk assessment

CLOSER (GF-2626)

120 g/L Sulfoxaflor

Southern Zone

Zonal Rapporteur Member State: France

(Field F)

CORE ASSESSMENT

Applicant: DOW AgroSciences

Date: October 2017

Detailed summary of the risk assessment

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IIIA 9 FATE AND BEHAVIOUR IN THE ENVIRONMENT

Introduction

This document reviews the environmental fate and behavour data relevant for the plant protection product GF-2626 containing the active substance sulfoxaflor.

Sulfoxaflor is a new active substance which have been approved under Regulation (EC) No 1107/2009, in the Commission Implementing Regulation (EU) 2015/1295. Ireland (Pesticide Registration and Control Division, PRCD) is the rapporteur Member State (RMS).

There were two representative formulations for the EU active approval submission. These were GF-2372 (500 g/kg WG) and GF-2626 (120 g/L SC).

This current submission is for one of these two formulations, GF-2626. This is the first submission for authorisation of plant protection products containing sulfoxaflor in EU Member States.

The review report SANTE/10665/2015 rev 2 of 29 May 2015 and the EFSA conclusions (EFSA Journal 2014; 12(5):3692)) for sulfoxaflor provides data on the active substance. Where appropriate, this document refers to the conclusions of the EFSA review report (EFSA Journal 2014; 12(5):3692) of sulfoxaflor. This will be where:

- the active substance data are relied upon in the risk assessment of the formulation;
- or when the EU review concluded that additional data/information should be considered at national registration.

This Part B document only reviews data (active substance or plant protection product) and additional information that has not previously been considered within the EU review process, as part of the active approval decision. Details of the active substance, the active approval Regulation and the Commission Review Report are provided in Table #-1.

Table 9-1: Details for the active substance

Active Substance	Approval Regulation	Commission Review Report	EFSA Scientific Report
Sulfoxaflor	Reg. (EU) 2015/1295	SANTE/10665/2015 rev 2 of 29 May 2015	EFSA Journal 2014; 12(5):3692

The use pattern for sulfoxaflor evaluated in the EU assessment is illustrated in Table 9-1. The current submission includes fruiting vegetables but not cereals or cotton. In addition, uses on other field crops and orchards are now requested. The rates are increased (2 x 24 g a.s./ha or 1 x 48 g a.s./ha). The current GAP is shown in Appendix 2 of this document and the critical GAP included in Table 9-2.

Table 9-2: GAP for sulfoxaflor that was evaluated at EU level as well as the critical GAP for uses of the product GF-2626 in the southern zone of the EU

Crop and/or situation	F/G or I	Application			Application Rate per Treatment	PHI
		Stage BBCH	Max. Number	Interval (d)	g a.s./ha max	(d)
GAP at EU level evaluation						
Fruiting vegetable – Tomato, Cherry tomato, pepper, aubergine, Cucurbit, cucumber, Melon, Water melon, courgette	F/G	BBCH 20 – 39 BBCH 40 - 89 Apr-Nov (for field) Through the year (for glasshouses)	1	-	24	≥ 1
Cereals (wheat, rye, barley, oat, triticale) [w,s]	F	BBCH 40 - 89 April - July	1	-	24	21
Cotton	F	BBCH 20 – 39 BBCH 40 - 89 May - Sept	1	-	24	14
Critical GAP for GF-2626 in the southern zone of the EU						
Citrus (lemons, mandrins, oranges, grappefruits)	F	BBCH 30-85 Mar-Oct	1 2	7	48 24	
Pome/stone fruit (peaches and nectarines, Pears, Apples, Plums and cherries	F	BBCH 51-59 (pre-flowering) BBCH 69-85	1 2	-	48 24	7
Fruiting vegetables (aubergine, cucurbits (cucmbers, courgettes, melon, pumpkin, watermelon)) Pepper, Tomatoes	F	BBCH 20-87 (apr, nov)	1 2	7	48 24	1

Brassicas (broccoli, cabbage, cauliflower, brussels srpout, leafy brassicas	F	BBCH 20-49 Apr-Sept	1	-	24	7
Leafy vegetables (lettuce and other salads (brassicacea) spinach and similar	F	BBCH 20-49 Apr-Sept	1	-	24	7
Potatoes	F	BBCH 20-95 May-Aug	2	21	24	7
Beans/Peas (fresh)	F	BBCH 40-85 Apr-Jul	2	21	24	14
Ornamentals (tress and bushes, rose), bulbs and flowers	F	BBCH 12-59 All year	1 2	7	48 24	1

F, G, I = Field, glasshouse, indoor
Ground applied foliar spray.

All exposure assessments in the current evaluation use the agreed endpoints as stated in the EFSA conclusion for sulfoxaflor.

Properties considered relevant in assessing the fate of sulfoxaflor and its metabolites are shown in Table 9-2. The relevant compartments of sulfoxaflor and its metabolites are given in Table 9-3.

Table 9-3: Agreed EU physical chemical properties used in the evaluation (EFSA Journal 2014; 12(5):3692)

Property	**Sulfoxaflor**
Molar mass [g/mol]	277.3
Molecular formula	$C_{10}H_{10}F_3N_3OS$
Solubility in water [mg/L] (20 °C)	568 (pH 7, purity: 99.7 %)
Vapour pressure (at 20 °C) [Pa]	1.4×10^{-6} (purity: 99.7 %)
Log P_{OW} (n-octanol/water partition coefficient)	log $P_{O/W}$ = 0.806 at 20 °C (pH 5) (99.7%) log $P_{O/W}$ = 0.802 at 20 °C (pH 7) (99.7%) log $P_{O/W}$ = 0.799 at 20 °C (pH 9) (99.7%)
Henry's Law Constant [Pa m^3/mol]	6.83×10^{-7} at 20 °C (pH 7)
Dissociation constant	Sulfoxaflor has no measurable ionisation constant within environmental relevant pH ranges (pH 2 to 10).

Table 9-4: Sulfoxaflor and its metabolites considered in the EU assessment to require risk assessment (EFSA Journal 2014;12(5):3692)

Code number/name	Compartment(s)
Sulfoxaflor	Soil, groundwater, surface water, sediment, air
X11719474	Soil, groundwater, surface water, sediment
X11519540	Soil, groundwater, surface water
X11579457	Groundwater

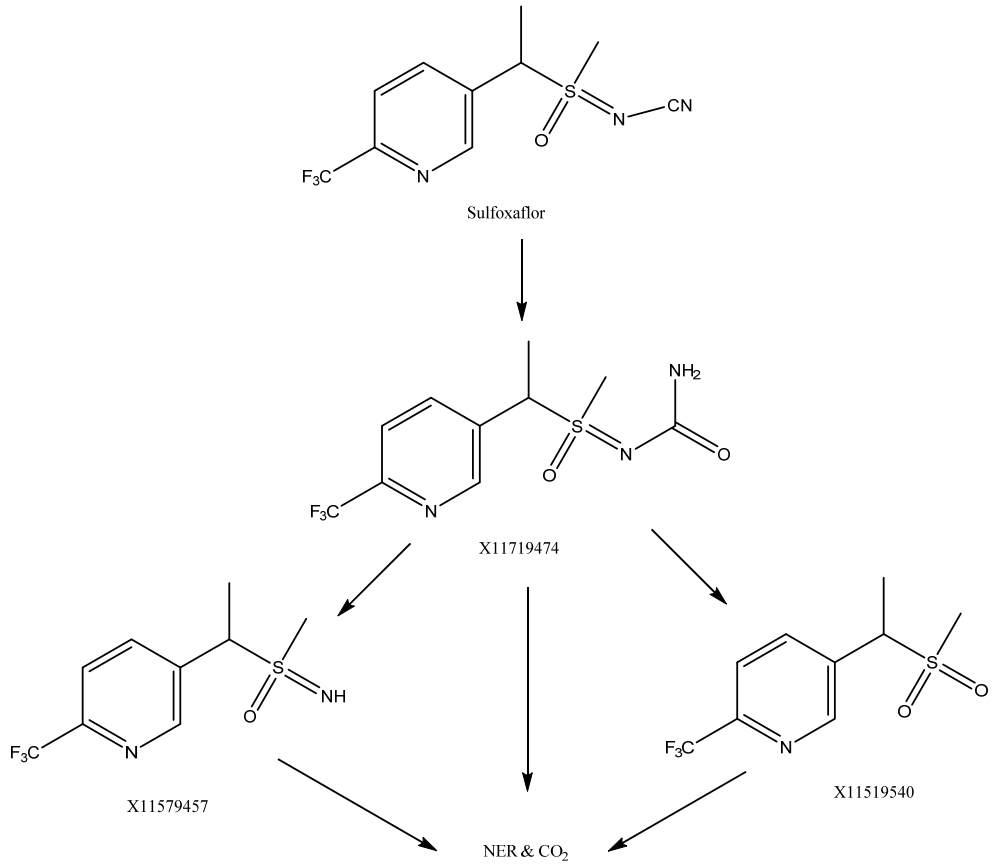
IIIA 9.1 Rate of degradation in soil (laboratory)

IIIA 9.1.1 Aerobic degradation of the preparation in soil

Route of degradation

The aerobic route of degradation of sulfoxaflor was investigated in laboratory and field conditions in a number of studies that were summarised in the DAR and EFSA conclusion (2014).
In soil under aerobic conditions the compound sulfoxaflor was rapidly and totally transformed to its primary major degradation product – X11719474 (96 to 99% AR after 24 hours), which in turn degraded to either X11519540 (max. occurrence in soil 12.2%, individual replicate) or X11579457 (max. occurrence in soil 9.2%, individual replicate). These two secondary metabolites were either mineralised (the determined overall level of mineralisation was up to ~32%) or incorporated into soil as the NER fraction (recorded in amounts up to 14.9%, individual replicate). The results of the examination of sulfoxaflor in sterilised aerobic soil showed that the whole degradation pathway leading from the parent compound to the terminal degradation products – CO_2 (and other products of mineralisation) and the non-extractable residues was predominantly biologically-mediated.
The determined degradation pathway is shown below in figure 9.1-1.

Figure 9.1-1: The proposed metabolic pathway of sulfoxaflor in soil under aerobic conditions



Soil photolysis

Soil photolysis was demonstrated not to be a relevant degradation mechanism of sulfoxaflor.

Rates of degradation

The kinetic analysis of the data showed that sulfoxaflor was a very short-lived compound in soil with lab derived DT_{50} = 0.078 day (geomean, normalised) and DT_{90} = 0.26 day (geomean, normalised).
The degradation products of sulfoxaflor were much more persistent in soil and endpoints from laboratory studies are shown in Table 9-5 to Table 9-8.

Table 9.1.1-1: Sulfoxaflor aerobic rate of degradation in soil (laboratory studies) from EFSA Journal 2014;12(5):3692

Soil		Soil properties		Incubation conditions		Kinetic model	Kinetic parameters		Evaluation of the fit			Kinetic endpoints	
Name	***Type (USDA classif.)***	***pH***	***OC [%]***	***T [°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	7.3	6.7	20	40	SFO	*k*	15.6	Very	1.00	1.9	0.044	0.15

	clay loam				(pF2)				good				
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**

Table 9.1.1-2: X11719474 aerobic rate of degradation in soil (laboratory studies) from experiments where sulfoxaflor was the precursor dosed from EFSA Journal 2014;12(5):3692

Soil		**Soil properties**		**Incubation conditions**		**Kinetic model**	**Kinetic parameters**		**Evaluation of the fit**			**Kinetic endpoints**	
Name	***Type (USDA classif.)***	***pH***	***OC [%]***	***T [°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**

Table 9.1.1-3: X11519540 aerobic rate of degradation in soil (laboratory studies where the metabolite was applied as test substance) from EFSA Journal 2014;12(5):3692

Soil		Soil properties		Incubation conditions		Kinetic model	Kinetic parameters		Evaluation of the fit			Kinetic endpoints	
Name	*Type (USDA classif.)*	*pH*	*OC [%]*	*T [°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**

Table 9.1.1-4: X11579457 aerobic rate of degradation in soil (laboratory studies where the metabolite was applied as test substance) from EFSA Journal 2014;12(5):3692

Soil		Soil properties		Incubation conditions		Kinetic model	Kinetic parameters		Evaluation of the fit			Kinetic endpoints	
Name	*Type (USDA classif.)*	*pH*	*OC [%]*	*T [°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	G	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	G	0.982	3.45	86.64	287.82
Malham	Sandy loam	6.2	3.5	20	40 (pF2)	Pseudo-SFO	k_2	0.0054	G	0.926	6.30	128.36	426.40

						(slow phase of the HS)							
LUFA 5M	Sandy loam	7.4	1.2	20	40 (pF2)	Pseudo-SFO (slow phase of the HS)	k_2	0.0020	I	0.757	5.57	346.57	1151.29
Geometric mean (n=4)												**186.67**	**620.12**

* Following abbreviations were used: I – intermediate; G- good

No data provided since the behaviour of the preparation can be predicted from that of the active substance.

IIIA 9.1.2 Anaerobic degradation of the preparation in soil

Under anaerobic conditions the transformation pathway of sulfoxaflor in soil was very similar, with the primary degradation product X11719474 forming in amounts up to 98% 4 days after flooding. However, unlike in aerobic soil, this compound was found to degrade under anaerobic conditions only through forming the NER. Neither X11519540 nor X11579457 were detected under anaerobic conditions. The level of mineralisation was very low, not surpassing 0.4%.

IIIA 9.2 Field studies

IIIA 9.2.1 Soil dissipation testing on a range of representative soils

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 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.

Active substance Sulfoxaflor

Best fit kinetic, persistence endpoint

Table 9.2.1-1: Sulfoxaflor aerobic rate of degradation in soil (field studies) from EFSA Journal 2014;12(5):3692

Trial	*Soil type (USDA*	Soil properties	Kinetic model	Kinetic parameters	Evaluation of the fit	Kinetic endpoints

	classif.)	*pH*	*OC [%]*		*Param.*	*Value*	*Visual fit**	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

* Following abbreviations were used: I – intermediate; G- good

Metabolite X11719474

Best fit kinetic, persistence endpoint

Table 9.2.1-2: X11719474 aerobic rate of degradation in soil (field studies) from experiments where sulfoxaflor was the precursor dosed from EFSA Journal 2014;12(5):3692

Trial	*Soil type (USDA classif.)*	Soil properties		Kinetic model	Kinetic parameters		Evaluation of the fit			Kinetic endpoints	
		pH	*OC [%]*		*Param.*	*Value*	*Visual fit**	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†	1001.12†
					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†	434.45†
					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†	1279.21†
					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†	1279.21†
					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†	742.77†
					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†	575.65†

					g	0.9779					
					Overall fit					1.93	410

* Following abbreviations were used: I – intermediate; G- good, VG – very good;
†The value for the *k2* representing the slow phase of the DFOP fit.

Modelling kinetic endpoint

Table 9.2.1-3: X11719474 aerobic rate of degradation in soil (field studies) from experiments where sulfoxaflor was the precursor dosed from EFSA Journal 2014;12(5):3692 - normalised to standard conditions of T = 20 0C and pF2 using Q10 = 2.58 and Walker factor = 0.7

Trial	*Soil type (USDA classif.)*	Soil properties		Kinetic model	Kinetic parameters		Evaluation of the fit			Kinetic endpoints	
		pH	*OC [%]*		*Param.*	*Value*	*Visual fit**	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**

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

Metabolite X11519540

Modelling kinetic endpoint

Table 9.2.1-4: X11519540 aerobic rate of degradation in soil (field studies where the metabolite was applied as test substance) from EFSA Journal 2014;12(5):3692 - normalised to standard conditions of T = 20 ^{0}C and pF2 using Q10 = 2.58 and Walker factor = 0.7

Trial	*Soil type (USDA classif.)*	Soil properties		Kinetic model	Kinetic parameters		Evaluation of the fit			Kinetic endpoints	
		pH	*OC [%]*		*Param.*	*Value*	*Visual fit**	R^2	χ^2 % *error*	DT_{50} *[days]*	DT_{90} *[days]*
CEMS-3993A	Silt loam	5.3	0.95	SFO	*k*	0.02571	G	0.826	14.06	27.0	90.0
CEMS-3993B	Silt loam	6.65	0.76	SFO	*k*	0.01892	G	0.879	11.55	36.6	122.0
CEMS-3993C	Loam	7.61	0.58	SFO	*k*	0.007286	I	0.659	19.04	95.1	316.0

CEMS-3993E	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**

* Following abbreviations were used: I – intermediate; G- good

IIIA 9.2.2 Soil residue testing

IIIA 9.2.3 Soil accumulation testing

According to the EFSA conclusion, field accumulation studies indicated that neither sulfoxaflor nor metabolites X11519540 or X11579457 displayed a tendency for accumulation in soil as the results of the studies on soil accumulation at two European sites indicated that there was no accumulation throughout the study duration (5 years) in any of the trials. For X11719474, on the other hand, no clear accumulation pattern was observed throughout the study duration in any of the trials. It was therefore concluded that results of model calculation should be used.

IIIA 9.2.4 Aquatic (sediment) field dissipation

This is not an EC data requirement/not required by Regulation 1107/2009.

IIIA 9.2.5 Forestry field dissipation

This is not an EC data requirement/not required by Regulation 1107/2009.

Conclusions on Aerobic degradation rates

The values selected (EFSA, 2014) to be used in risk assessments are shown in Table 9.1-9.

Table 9.2.5-1: Soil endpoints for sulfoxaflor and its metabolites (EFSA Journal 2014;12(5):3692)

Compound	Worst case DT_{50} for PEC soil [days]	Geometric mean DT_{50} normalised at 20 ^{0}C and pF2 for PEC gw [days]	Maximum occurrence in soil [%]	Formation fraction
Sulfoxaflor	7.43 (field)	0.078 (lab)	---	-
X11719474	385.08 (field)	76.61 (field)	100	1
X11519540	1155.24 (lab)	40.5 (field)	12.2	0.5
X11579457	not required	186.67 (lab)	9.2	0.5

IIIA 9.3 Mobility of the plant protection product in soil

Batch adsorption / desorption in soil was investigated in 17 soils for sulfoxaflor and metabolite X11719474, in 6 soils for metabolite X11519540 and in 7 soils for metabolite X11579457. Summary results are presented in Tables 9.3-1 to 9.3-4. No dependence upon soil pH was observed for parent sulfoxaflor or either metabolites. Sulfoxaflor and metabolite X11719474

may be classified as very highly to highly mobile in soil and metabolites X11519540 and X11579457 may be classified as very highly mobile in soil. Table 9.3-5 summarises the selected soil adsorption endpoints for sulfoxaflor and its metabolites according to EFSA (2014).

Table 9.2.5-1: Summary of the soil adsorption coefficients for Sulfoxaflor (EFSA Journal 2014;12(5):3692)

Soil type (USDA classification)	pH	OC [%]	Distribution constants		Freundlich isotherm's parameters			
			Kd [mL/g]	Kdoc [mL/g]	Kf [mL/g]	Kfoc [mL/g]	1/n	R^2
Loamy sand	7.6	1.3	0.29	22.31	0.29	22	1.06	0.966
Loam	7.3	6.7	0.93	13.88	0.81	12	0.96	0.999
Silt loam	6.2	3.5	0.47	13.43	0.4	12	0.95	0.999
Sandy loam	7.4	1.2	0.32	26.67	0.3	25	1.02	0.997
Clay loam	5.9	1.8	0.66	36.67	0.56	31	0.96	1.000
Clay loam	6.9	1.2	0.61	50.83	0.57	47	0.99	1.000
Loam	6.3	1.1	0.63	57.27	0.54	49	0.96	1.000
Sandy loam	6.4	1	0.37	37	0.33	33	0.98	0.998
Sandy clay loam	7.4	1.3	0.45	34.62	0.4	31	0.97	0.999
Clay loam	7.8	1.2	0.37	30.83	0.35	30	1	0.996
Clay loam	7.8	1.7	0.43	25.29	0.34	20	0.95	0.993
Silt loam	6.3	1.1	0.31	28.18	0.26	24	0.93	0.998
Sand	6.3	0.3	0.25	83.33	0.16	54	0.89	0.964
Loamy sand	6.2	0.8	0.57	71.25	0.43	53	0.91	0.999
Clay	7.9	1.8	1.29	71.67	1.28	71	0.98	1.000
Clay loam	6.7	1.1	0.58	52.73	0.51	46	0.97	1.000
Loam	6.9	1.8	0.68	37.78	0.52	29	0.93	0.998
Arithmetic mean			0.54	40.81	0.47	**35**	**0.96**	0.995

Table 9.2.5-2: Summary of the soil adsorption coefficients for X11719474 (EFSA Journal 2014;12(5):3692)

Soil type (USDA classification)	pH	OC [%]	Distribution constants		Freundlich isotherm's parameters			
			Kd [mL/g]	Kdoc [mL/g]	Kf [mL/g]	Kfoc [mL/g]	1/n	R^2
Loamy sand	7.6	1.3	0.2	15.38	0.18	14	1.03	0.963
Loam	7.3	6.7	0.5	7.46	0.47	7	1.00	0.999
Silt loam	6.2	3.5	0.29	8.29	0.29	8	1.03	0.997
Sandy loam	7.4	1.2	0.26	21.67	0.21	18	0.94	0.985
Clay loam	5.9	1.8	0.52	28.89	0.44	24	0.99	0.997
Clay loam	6.9	1.2	0.51	42.5	0.48	40	0.99	0.999
Loam	6.3	1.1	0.64	58.18	0.55	50	0.98	0.999
Sandy loam	6.4	1	0.24	24	0.21	21	1.01	0.992
Sandy clay loam	7.4	1.3	0.44	33.85	0.41	31	1.00	0.997
Clay loam	7.8	1.2	0.27	22.5	0.25	21	0.98	0.996
Clay loam	7.8	1.7	0.31	18.24	0.25	14	0.95	0.992
Silt loam	6.3	1.1	0.24	21.82	0.19	18	0.95	0.988
Sand	6.3	0.3	0.23	76.67	0.22	74	1.03	0.992
Loamy sand	6.2	0.8	0.28	35	0.24	30	0.98	0.996
Clay	7.9	1.8	1.32	73.33	1.24	69	1.00	1.000

Clay loam	6.7	1.1	0.54	49.09	0.49	45	0.99	1.000
Loam	6.9	1.8	0.44	24.44	0.41	23	1.03	0.994
Arithmetic mean			0.42	33.02	0.38	**30**	**0.99**	0.992

Table 9.2.5-3: Summary of the soil adsorption coefficients for X11519540 (EFSA Journal 2014;12(5):3692)

Soil type (USDA classification)	pH	OC [%]	Distribution constants		Freundlich isotherm's parameters			
			Kd [mL/g]	Kdoc [mL/g]	Kf [mL/g]	Kfoc [mL/g]	1/n	R^2
Loamy sand	7.6	1.3	0.04	3	0.01	1	1.35	0.856
Loam	7.3	6.7	0.28	4	0.39	6	0.79	0.825
Silt loam	6.2	3.5	0.2	5	0.22	6	0.96	0.976
Clay loam	5.9	1.8	0.31	17	0.36	20	0.92	0.931
Clay loam	6.9	1.2	0.26	22	0.29	24	1.01	0.995
Loam	6.3	1.1	0.31	29	0.28	25	1.04	0.993
Arithmetic mean			0.23	13.3	0.26	**14**	**1.01**	0.929

Table 9.2.5-4: Summary of the soil adsorption coefficients for X11579457 (EFSA Journal 2014;12(5):3692)

Soil type (USDA classification)	pH	OC [%]	Distribution constants		Freundlich isotherm's parameters			
			Kd [mL/g]	Kdoc [mL/g]	Kf [mL/g]	Kfoc [mL/g]	1/n	R^2
Loamy sand	7.6	1.3	0.10	8	0.15	11	0.87	0.905
Loam	7.3	6.7	0.14	2	0.13	2	1.02	0.985
Silt loam	6.2	3.5	0.08	2	0.34	10	0.55	0.907
Clay loam	5.9	1.8	0.21	12	0.79	44	0.43	0.867
Clay loam	6.9	1.2	0.21	18	0.27	23	0.91	0.994
Loam	6.3	1.1	0.26	22	0.28	26	0.97	0.99
Sandy loam	6.4	1.0	0.32	32	0.35	35	0.97	0.996
Arithmetic mean			0.19	14	0.33	**22**	**0.82**	0.949

Table 9.2.5-5: Soil adsorption endpoints for sulfoxaflor and its metabolites

Compound	Arithmetic mean Kfoc [mL/g]	Arithmetic mean 1/n	pH dependence
Sulfoxaflor	35	0.96	No
X11719474	30	0.99	No
X11519540	14	1.01	No
X11579457	22	0.82	No

IIIA 9.3.1 Column leaching

Not required. Sufficient information is available from the sorption studies on the active substance and the metabolites.

IIIA 9.3.2 Lysimeter studies

Not required. Sufficient information is available from the sorption studies and simulation modelling (see point IIIA 9.6) on the active substance and metabolites to predict leaching concentrations.

IIIA 9.3.3 Field leaching studies

Not required. Sufficient information is available from the sorption studies and simulation modelling (see point IIIA 9.6) on the active substance and metabolites to predict leaching concentrations.

IIIA 9.3.4 Volatility – laboratory study

Not required according to Regulation 1107/2009.

IIIA 9.3.5 Volatility – field study

Not required according to Regulation 1107/2009.

IIIA 9.4 Predicted environmental concentrations in soil (PECs) for the active substance

PEC_{soil} values were calculated considering standard scenario assumptions (5 cm soil depth and bulk density of 1.5 g/cm^3) and interception determined following FOCUS guidance (Generic Guidance for Tier 1 FOCUS Ground Water Assessments v2.1 (Dec. 2012)).

As the compound is not persistent, an accumulated PEC_{soil} ($PEC_{soil,accu}$) is not required.

The Table 9.4-1 below summarised the soil endpoint for sulfoxaflor according to EFSA Journal 2014;12(5):3692.

Table 9.3.5-1: Soil endpoints for sulfoxaflor (EFSA Journal 2014;12(5):3692)

Compound	Worst case DT_{50} for PEC soil [days]
Sulfoxaflor	7.43 (worst-case from field studies)

IIIA 9.4.1 Initial PECs values

In accordance with the GAP (Table 9.4.1-1) application to pome/stone fruit, brassicas and potatoes are considered for the calculations to cover worst scenarios (marked in bold font).

Table 9.4.1–1: Application schemes considered by the applicant for PECsoil calculations

Crop	Growth stage	Application rate (interval)	Interception (FOCUS, 2012)	Amount reaching soil
Citrus	BBCH 30-85	1 x 48 g as/ha	70%	14.4 g a.s./ha
Pome/stone fruit	**BBCH 51-59 (pre-flowering) BBCH 69-85**	**1 x 48 g as/ha**	**65%**	**16.8 g a.s./ha**
Fruiting veg.	BBCH 20-87	1 x 48 g as/ha	70%	14.4 g a.s./ha
Brassicas	**BBCH 20-49**	**1 x 24 g a.s./ha**	**40%**	**14.4 g a.s./ha**
Potatoes	**BBCH 20-95**	**2 x 24 g a.s./ha (21 days)**	**50%**	**2 x 12 g a.s./ha (21 days)**
Beans/Peas	BBCH 40-85	2 x 24 g a.s./ha (21 days)	70%	2 x 7.2 g a.s./ha (21 days)
Ornamentals	BBCH 12-59	1 x 48 g as/ha	65%	16.8 g a.s./ha

zRMS notes that the crop interception of 65% considered for ornamentals is too high for the growing stage of application (BBCH 12). zRMS would have selected 10% of crop interception which is more appropriate for bulbs and ornamental flowers and is a worst-case covering all intended ornamental uses.

PECsoil were thus recalculated by zRMS considering the following worst-case scenario covering all uses.

Crop	Growth stage	Application rate (interval)	Interception (FOCUS, 2012)	Amount reaching soil

Ornamentals	BBCH 12-59	1 x 48 g as/ha	10%	43.2 g a.s./ha

Table 9.4.1-1: Summary of PEC_{soil} values for sulfoxaflor following application to pome/stone fruit based on a maximum dose of 1 x 48 g as/ ha (10% interception, zRMS calculation)

Days from last application or TWA period	Actual PEC_S (mg/kg)	Maximum TWA PEC_S (mg/kg)
Initial	0.0576	-

Modelling Comments: IIIA 9.4.1	PECsoil have been recalculated by zRMS for a worst-case scenarios of 1 application of 48 g/ha with 10% minimal crop interception.
Agreed PECsoil (active substance): IIIA 9.4.1	Initial PECsoil covering all intended uses = **0.0576 mg/kg**

IIIA 9.4.2 Short-term PECs values (1-4 days after last application)

Refer to point IIIA 9.4.1 above.

IIIA 9.4.3 Long-term PECs values (from 7-100 days after last application)

Refer to point IIIA 9.4.1 above.

IIIA 9.5 Predicted environmental concentrations in soil (PECs) for major metabolites

PEC_{soil} values for metabolites X11719474 and X11519540 were calculated considering standard scenario assumptions (5 cm soil depth and bulk density of 1.5 g/cm^3) and interception determined following FOCUS guidance (Generic Guidance for Tier 1 FOCUS Ground Water Assessments v2.1 (Dec. 2012)).

The worst case DT_{50} were used as described in Table 9.5-1. As all metabolites are persistent if the worst DT_{50} are taken into account, accumulated PEC_{soil} ($PEC_{soil,accu}$) are required. These have been calculated based on plateau concentration over 5 cm as worst-case plus peak single seasons PEC_{soil} based on mixing over 5 cm.

Table 9.5-1: Soil endpoints for sulfoxaflor metabolites according to EFSA Journal 2014;12(5):3692

Compound	Molar mass	Worst case DT_{50} for PEC soil [days]	Maximum occurence in soil [%]
X11719474	295	385.08 (field)	100
X11519540	253.24	1155.24 (lab)	12.2

Since an incorrect crop interception was used by the applicant, PECsoil were recalculated by zRMS for the same application scheme as the one used for parent. In accordance with the GAP (see Table 9.4.1-1), Table 9.5-2 summarises the agronomic input parameters used for modelling. Correction for molecular weight and maximum occurrence in soil were used to adjust the application rate.

Table 9.5-2: Agronomic input used for the simulations

Compound	Crop	Application Rate reaching soil for the parent (g a.s./ha)	Correction factor (MW and % occurence in soil)	Application Rate reaching soil (g a.s./ha)
X11719474	Ornamentals	1 x 48 g a.s./ha	1.06	1x45.8
X11519540	Ornamentals	1 x 48 g a.s./ha	0.11	1x4.8

Calculated PEC_{soil} values for the proposed uses are presented in Tables 9.5.1-1 to 9.5.1-2.

IIIA 9.5.1 Initial PECs values

Table 9.5.1–1: Summary of PEC_{soil} values for X11719474 following application of sulfoxaflor, covering all intended uses

Crop	Pome/stone fruit	
Days after final application	**Actual PEC_{soil} (mg/kg)**	**Time-weighted PEC_{soil} (mg/kg)**
0	0.0610	-
PECsoil,accu	0.127 after 7 years	

Table 9.5.1–2: Summary of PEC_{soil} values for X11519540 following application of sulfoxaflor, covering all intended uses

Crop	Pome/stone fruit	
Days after final application	**Actual PEC_{soil} (mg/kg)**	**Time-weighted PEC_{soil} (mg/kg)**
0	0.0064	-
PECsoil,accu	0.032 after 18 years	

Modelling Comments: IIIA 9.5.1	PECsoil for metabolites were recalculated by zRMS for a worst-case scenario of 1 application of 48 g/ha with 10% minimal crop interception.
Agreed PECsoil (metabolites): IIIA 9.5.1	$PEC_{soil,accu}$ for metabolites reported in tables 9.5.1-1 and 9.5.1-2 are used for risk assessment.

IIIA 9.5.2 Short-term PECs values (1-4 days after last application)

Refer to point IIIA 9.5.1 above.

IIIA 9.5.3 Long-term PECs values (from 7-100 days after last application)

Refer to point IIIA 9.5.1 above.

IIIA 9.6 Predicted environmental concentrations in groundwater (PECgw)

IIIA 9.6.1 Active substance

Report:	IIIA1 9.6.1/01, Jarvis, T. and Montesano V., 2014a
Title:	Predicted Environmental Concentrations of Sulfoxaflor (as product GF-2626) and its metabolites in groundwater using the FOCUS PEARL 4.4.4 and FOCUS PELMO 5.5.3 groundwater scenarios.
Document No:	Exponent International Ltd. Report No.: 1402547.UK0-3433

Guidelines:	FOCUS (2001, 2009, 2012).
GLP	No. Not required

I. MATERIAL AND METHODS

Groundwater modelling of sulfoxaflor and its metabolites, X11719474, X11519540 and X11579457 has been undertaken using the relevant FOCUS groundwater scenarios and the FOCUS PEARL 4.4.4 and PELMO 5.5.3 models. The modelling undertaken was based on the GAP requested for product registration of GF-2626 in the southern zone of the EU for uses on citrus, pome/stone fruit, fruiting vegetables, flowering brassica, leafy brassicas, leafy vegetables, potatoes, beans, peas and ornamentals.

In accordance with the GAP, the agronomic parameters used as input for these simulations were therefore as follows:

FOCUS crop:	Citrus
Crop:	Citrus (grapefruits, oranges, lemons and mandarins)
Application:	1 x 48 g as/ha
Crop Interception:	70% (BBCH 30-85, mars-oct)
Application Timing:	1st July

FOCUS crop:	Apples
Crop:	Pome/stone fruit (apples, pears, cherries, plums, peaches and nectarines)
Application Rate:	1 x 48 g as/ha
Crop Interception:	65% (BBCH 51-59, feb) pre-flowering or (BBCH 69-85, mar-sept) post flowering
Application Timing:	1st April

FOCUS crop:	Tomato
Crop:	Tomatoes, Aubergines, Peppers and Cucurbits
Application:	1 x 48 g as/ha
Crop Interception:	70% (BBCH 20-87 Apr-Nov)
Application Timing*:	1st March or 1st May

* Two possible application timings were simulated for tomatoes, aubergines, peppers and cucurbits to cover any differences within the crops.

FOCUS crop:	Cabbage
Crop:	Flowering brassica, Brussels sprouts, Head cabbage, Leafy brassica, Lettuce, other salad plants and herbs
Application Rate:	1 x 24 g as/ha

Crop Interception: 40% (BBCH 20-49 Apr - sept)
Application Timing: 3 weeks after emergence

FOCUS crop: Potatoes
Crop: Potatoes
Application Rate: 2 x 24 g as/ha (21 days interval)
Crop Interception: 50% (BBCH 20-95, may-aug)
Application Timing: 3 weeks after emergence. Annual application simulated as a worst case, although potatoes can reasonably be expected to be grown in at most in a one in three year rotation

FOCUS crop: Beans (field and vegetables)
Crop: Beans
Application Rate: 2 x 24 g as/ha (21 days interval)
Crop Interception: 70% (BBCH 40-85, Apr-Jul)
Application Timing: 4 weeks after emergence

FOCUS crop: Peas
Crop: Peas
Application Rate: 2 x 24 g as/ha (21 days interval)
Crop Interception: 85% (BBCH 40-85 apr -jul)
Application Timing: 4 weeks after emergence

The FOCUS models do not have an ornamental crop included but it can be considered covered by application on apples, citrus and tomatoes.

The interception values were taken from Generic Guidance for Tier 1 FOCUS Ground Water Assessments v2.1 (Dec. 2012).

All compound-specific input values were as agreed in the EFSA conclusion (2014) and are summarised in Table 9.6.1-1.

Table 9.6.1-1: Sulfoxaflor and metabolites input parameters used for the simulations

Parameter	Sulfoxaflor	X11719474	X11519540	X11579457
Molecular mass [g/mol]	277.3	295.3	253.2	252.3
Vapour pressure [Pa] at 20 ºC	$1.4x10^{-6}$	$1.4x10^{-6}$	$1.4x10^{-6}$	$1.4x10^{-6}$

Solubility in water [mg/L] at 20 ºC	568	568	568	568
Henry's law constant [$Pa.m^3.mol^{-1}$] at 20 ºC	$6.83x10^{-7}$	n.r	n.r.	n.r.
Koc /Kom [mL/g], arith. mean	35/20.3	30/17.4	14/8.12	22/12.8
Freundlich exponent, arith. mean	0.96	0.99	1.01	0.82
DT_{50} soil [d]	0.1 (lab, geometric mean at 20°C and pF2)	76.6 (field – geom. mean normalised to pF2 and 20°C)	40.5(field – geom. mean normalised to pF2 and 20°C)	186.7(lab – geom. mean normalised to pF2 and 20°C)
Crop uptake factor[1]	0	0	0	0
Formation fraction	--	1 (from parent)	0.5 (from X11719474)	0.5 (from X11719474)

[1] Conservative value, n.r. = not required

II. RESULTS AND DISCUSSION

PECgw values from FOCUS PELMO 5.5.3 and PEARL 4.4.4 for sulfoxaflor and its metabolites are shown in Tables 9.6.1-2 and 9.6.1-9.

Table 9.6.1-2: PEC_{gw} (µg/l) values for sulfoxaflor and its metabolites, X11719474, X11519540 and X11579457 after application to citrus

Model	**PEARL 4.4.4**			
LOCATION	**Sulfoxaflor**	**X11719474**	**X11519540**	**X11579457**
PIACENZA	< 0.001	1.010	0.468	0.885
PORTO	< 0.001	0.755	0.335	0.420
SEVILLA	< 0.001	0.936	0.426	0.728
THIVA	< 0.001	1.239	0.659	1.509
Model	**PELMO 5.5.3**			
LOCATION	**Sulfoxaflor**	**X11719474**	**X11519540**	**X11579457**
PIACENZA	< 0.001	0.862	0.336	0.540
PORTO	< 0.001	0.713	0.289	0.346
SEVILLA	< 0.001	0.798	0.400	0.836
THIVA	< 0.001	0.966	0.452	0.966

Table 9.6.1-3: PEC_{gw} (µg/l) values for sulfoxaflor and its metabolites, X11719474, X11519540 and X11579457 after application to pome/stone fruit

Model	**PEARL 4.4.4**			
LOCATION	**Sulfoxaflor**	**X11719474**	**X11519540**	**X11579457**
CHATEAUDUN	< 0.001	2.739	1.142	1.750
HAMBURG	< 0.001	4.026	1.928	2.379
JOKIOINEN	< 0.001	3.005	1.575	1.615
KREMSMUENSTER	< 0.001	1.893	0.774	1.244
OKEHAMPTON	< 0.001	1.631	0.649	0.912
PIACENZA	< 0.001	2.058	0.804	1.777
PORTO	< 0.001	0.927	0.430	0.603
SEVILLA	< 0.001	2.993	1.287	2.200
THIVA	< 0.001	3.000	1.418	3.184
Model	**PELMO 5.5.3**			
LOCATION	**Sulfoxaflor**	**X11719474**	**X11519540**	**X11579457**
CHATEAUDUN	< 0.001	2.894	1.130	1.878
HAMBURG	< 0.001	2.409	1.077	1.480
JOKIOINEN	< 0.001	2.465	1.285	1.360
KREMSMUENSTER	< 0.001	2.313	0.892	1.412
OKEHAMPTON	< 0.001	1.899	0.653	0.897
PIACENZA	< 0.001	1.866	0.638	1.005
PORTO	< 0.001	1.055	0.410	0.606
SEVILLA	< 0.001	2.792	1.559	3.541
THIVA	< 0.001	2.507	1.163	3.015

Table 9.6.1-4: PEC_{gw} (µg/l) values for sulfoxaflor and its metabolites, X11719474, X11519540 and X11579457 after application to tomato, aubergines, peppers and cucurbits (1st March)

Model	PEARL 4.4.4			
LOCATION	**Sulfoxaflor**	**X11719474**	**X11519540**	**X11579457**
CHATEAUDUN	< 0.001	1.461	0.747	1.412
PIACENZA	< 0.001	1.071	0.482	1.207
PORTO	< 0.001	0.638	0.350	0.542
SEVILLA	< 0.001	0.480	0.301	0.916
THIVA	< 0.001	0.995	0.512	1.460
Model	**PELMO 5.5.3**			
LOCATION	**Sulfoxaflor**	**X11719474**	**X11519540**	**X11579457**
CHATEAUDUN	< 0.001	1.326	0.633	1.463
PIACENZA	< 0.001	1.216	0.577	1.011
PORTO	< 0.001	0.616	0.319	0.493
SEVILLA	< 0.001	0.643	0.393	1.173
THIVA	< 0.001	0.830	0.429	1.329

Table 9.6.1-5: PEC_{gw} (µg/l) values for sulfoxaflor and its metabolites, X11719474, X11519540 and X11579457 after application to tomato, aubergines, peppers and cucurbits (1st May)

Model	PEARL 4.4.4			
LOCATION	**Sulfoxaflor**	**X11719474**	**X11519540**	**X11579457**
CHATEAUDUN	< 0.001	1.615	0.779	1.436
PIACENZA	< 0.001	1.005	0.459	1.228
PORTO	< 0.001	0.717	0.360	0.539
SEVILLA	< 0.001	0.570	0.352	0.950
THIVA	< 0.001	1.241	0.598	1.555
Model	**PELMO 5.5.3**			
LOCATION	**Sulfoxaflor**	**X11719474**	**X11519540**	**X11579457**
CHATEAUDUN	< 0.001	1.431	0.656	1.482
PIACENZA	< 0.001	1.192	0.548	1.010
PORTO	< 0.001	0.634	0.339	0.495
SEVILLA	< 0.001	0.706	0.427	1.151
THIVA	< 0.001	0.977	0.482	1.408

Table 9.6.1-6: PEC_{gw} (µg/l) values for sulfoxaflor and its metabolites, X11719474, X11519540 and X11579457 after application to cabbage (surrogate of flowering brassica, brussels sprouts, head cabbage, leafy brassica, lettuce, other salad plants and herbs)

Model	**PEARL 4.4.4**			
LOCATION	**Sulfoxaflor**	**X11719474**	**X11519540**	**X11579457**
CHATEAUDUN	< 0.001	1.208	0.574	1.085
HAMBURG	< 0.001	1.675	0.836	1.021
JOKIOINEN	< 0.001	1.576	0.892	0.920
KREMSMUENSTER	< 0.001	1.174	0.510	0.764
PORTO	< 0.001	0.596	0.324	0.475
SEVILLA	< 0.001	0.483	0.305	0.829
THIVA	< 0.001	1.310	0.535	0.958
Model	**PELMO 5.5.3**			
LOCATION	**Sulfoxaflor**	**X11719474**	**X11519540**	**X11579457**
CHATEAUDUN	< 0.001	1.122	0.546	1.093
HAMBURG	< 0.001	1.661	0.763	0.997
JOKIOINEN	< 0.001	1.533	0.818	0.866
KREMSMUENSTER	< 0.001	1.212	0.536	0.848
PORTO	< 0.001	0.666	0.303	0.430
SEVILLA	< 0.001	0.507	0.288	0.873
THIVA	< 0.001	1.279	0.495	0.906

Table 9.6.1-7: PEC_{gw} (µg/l) values for sulfoxaflor and its metabolites, X11719474, X11519540 and X11579457 after application to potatoes

Model	**PEARL 4.4.4**			
LOCATION	**Sulfoxaflor**	**X11719474**	**X11519540**	**X11579457**
CHATEAUDUN	< 0.001	2.474	1.138	2.366
HAMBURG	< 0.001	3.031	1.441	1.775
JOKIOINEN	< 0.001	2.607	1.353	1.561
KREMSMUENSTER	< 0.001	2.170	0.913	1.405
OKEHAMPTON	< 0.001	1.983	0.789	1.063
PIACENZA	< 0.001	1.592	0.678	1.620
PORTO	< 0.001	0.861	0.458	0.768
SEVILLA	< 0.001	0.685	0.410	1.274
THIVA	< 0.001	1.830	0.933	2.681
Model	**PELMO 5.5.3**			
LOCATION	**Sulfoxaflor**	**X11719474**	**X11519540**	**X11579457**
CHATEAUDUN	< 0.001	2.097	1.052	2.232
HAMBURG	< 0.001	2.745	1.254	1.710
JOKIOINEN	< 0.001	2.530	1.202	1.392
KREMSMUENSTER	< 0.001	2.178	0.937	1.455
OKEHAMPTON	< 0.001	2.005	0.725	1.019
PIACENZA	< 0.001	1.614	0.726	1.433
PORTO	< 0.001	1.111	0.573	0.851

SEVILLA	< 0.001	0.959	0.526	1.560
THIVA	< 0.001	1.639	0.803	2.379

Table 9.6.1-8: PEC_{gw} (µg/l) values for sulfoxaflor and its metabolites, X11719474, X11519540 and X11579457 after application to beans

Model	**PEARL 4.4.4**			
LOCATION	**Sulfoxaflor**	**X11719474**	**X11519540**	**X11579457**
HAMBURG	< 0.001	2.151	1.060	1.252
KREMSMUENSTER	< 0.001	1.356	0.560	0.943
OKEHAMPTON	< 0.001	1.260	0.511	0.706
PORTO	< 0.001	0.683	0.353	0.509
THIVA	< 0.001	0.883	0.452	1.197
Model	**PELMO 5.5.3**			
LOCATION	**Sulfoxaflor**	**X11719474**	**X11519540**	**X11579457**
HAMBURG	< 0.001	1.715	0.806	1.068
KREMSMUENSTER	< 0.001	1.379	0.582	0.879
OKEHAMPTON	< 0.001	1.170	0.428	0.609
PORTO	< 0.001	0.657	0.328	0.483
THIVA	< 0.001	0.731	0.372	1.088

Field and vegetables beans give same result

Table 9.6.1-9: PEC_{gw} (µg/l) values for sulfoxaflor and its metabolites, X11719474, X11519540 and X11579457 after application to peas

Model	**PEARL 4.4.4**			
LOCATION	**Sulfoxaflor**	**X11719474**	**X11519540**	**X11579457**
CHATEAUDUN	< 0.001	0.514	0.300	0.577
HAMBURG	< 0.001	1.182	0.595	0.637
JOKIOINEN	< 0.001	0.910	0.564	0.470
OKEHAMPTON	< 0.001	0.594	0.232	0.307
Model	**PELMO 5.5.3**			
LOCATION	**Sulfoxaflor**	**X11719474**	**X11519540**	**X11579457**
CHATEAUDUN	< 0.001	0.418	0.235	0.486
HAMBURG	< 0.001	0.909	0.427	0.508
JOKIOINEN	< 0.001	0.868	0.475	0.451
OKEHAMPTON	< 0.001	0.574	0.213	0.292

Modelling Comments: IIIA 9.6.1	The PECgw provided by applicant could not be verified in detail for each scenario by zRMS since the input raw modelling files were not available. However, the same calculations were provided for Central zone and have been checked or reproduced by zRMS Poland and considered valid. For all uses except ornamentals, calculations were provided and are considered acceptable, however not totally covering the intended uses: Indeed, for all simulated crops, simulations are performed at the beginning of the possible application period and late application are missing. However, considering that: (1) Later application would consider a higher crop interception than the ones considered by applicant in its simulation (2) Safety margin is observed for active substance results towards the trigger of 0.1 µg/L (always <0.001 µg/L) (3) Consumer risk assessment carried out for the three non-relevant metabolite based on worst-case PECgw higher than those obtained for these uses (risk envelope approach) show a significant safety margin (see section 8) no additional calculations are deemed necessary in this specific case. It is considered that the PECgw performed by applicant, checked and validated by central zone zRMS are covering the intended uses. Concerning the particular use on ornamentals, it is considered that the use on trees, bushes and rose are covered by the Pome/stone fruit simulation. For the use on bulbs and flowers, no PECgw provided by applicant can be considered adequate. Central zRMS proposed additional calculations with the "cabbage" crop (single application at 48g/ha, 25% of crop interception, at emergence + 7 days). The maximum PECgw for metabolites X11719474, X11519540, X11579457 were 3.00, 2.06 and 3.19 µg/L respectively. In addition, as already indicated, the consumer risk assessment carried out for the three non-relevant metabolite is based on worst-case PECgw higher than those obtained for these uses (risk envelope approach) and show a significant safety margin (see section 8). Considering this, no additional calculations are deemed necessary to cover the use on ornamentals. Finally, it is noted that a specific use on fodder peas was sustained in France but not reported by applicant in this dRR. This use can be covered by the uses on fresh peas and beans of the current submission. However, as it might be expected that applications occur also during autmn/winter (winter fodder peas), risk assessment performed by central zRMS on winter cereals in another dossier (GF-2372) is considered also covering this particular use (Winter cereals, 2 x 24g/ha, 2 days after emergence). The maximum PECgw for metabolites X11719474, X11519540, X11579457 were 8.38, 3.74 and 5.92 µg/L respectively.

Agreed PECgw (active substance): IIIA 9.6.1	**For all intended uses :** PECgw for active substance are <0.001 µg/L for all scenarios and all intended uses. PECgw for metabolites X11719474, X11519540 and X11579457 are > 0.1 µg/L in all scenarios and often >0.75 µg/L. An assessement of the relevance according to SANCO 221/2000 of these three metabolites is available in section 8. In this document a consumer risk assessment is performed based on the worst-case PECgw of 8.38, 3.74 and 5.92 µg/L respectively for metabolites X11719474, X11519540 and X11579457 covering all the intended uses. ⇨ Although uncertainties were raised up in the simulations proposed by applicant, considering that the consumer risk assessment is based on risk envelope approach and results in a significant safety margin, it is considered **that no unacceptable risk of ground water contamination is expected for the intended uses**.

IIIA 9.6.2 Relevant (major) metabolites

Please refer to Point IIIA 9.6.1.

IIIA 9.6.3 Additional field testing

No data, not required.

IIIA 9.6.4 Information on impact on water treatment procedures

No data, not required.

IIIA 9.7 Predicted environmental concentrations in surface water (PECsw) for the active substance

In laboratory incubations in dark aerobic natural sediment water systems, sulfoxaflor exhibited moderate to medium persistence, forming the major metabolite X11719474 (max. 66% AR in total system at 88 days, max. 48 % AR in water at 76 days and 30 % AR in sediment at 88 days, as sum of isomers), with no decline of X11719474 being apparent in the experiments. Adsorption of sulfoxaflor to sediment reached a maximum o 40% AR at day 15. 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.

Sulfoxaflor is stable to hydrolysis. 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.

Table 9.6.4-1: Summay of persistence and modelling degradation rate for sulfoxaflor in water-sediment system, from EFSA Journal 2014;12(5):3692

Persistence endpoint									
System	**Whole system**			**Water phase**			**Sediment**		
	DT_{50}	**DT_{90}**	**model**	**DT_{50}**	**DT_{90}**	**model**	**DT_{50}**	**DT_{90}**	**model**
Sand-sediment system	88.86	295.20	SFO	64.18	213.20	SFO	101.93	388.62	SFO
Silt-loam sediment system	36.67	121.83	SFO	11	63	DFOP	46.21	153.51	SFO
Modelling endpoint									
System	**Whole system**			**Water phase**			**Sediment**		
	DT_{50}	**DT_{90}**	**model**	**DT_{50}**	**DT_{90}**	**model**	**DT_{50}**	**DT_{90}**	**model**
Sand-sediment system	88.86	295.20	SFO	n.d			101.93	388.62	SFO
Silt loam-sediment system	36.67	121.83	SFO	n.d			46.21	153.51	SFO
Geomean	**57.08**	**189.63**		n.d.			**68.63**	**244.25**	

Table 9.7-1 below summarises the appropriate endpoints for sulfoxaflor and its metabolites according to EFSA Journal 2014;12(5):3692 to be used in PECsw calculations

Table 9.6.4-2: Degradation kinetic endpoints for sulfoxaflor and its metabolites in water/sediment system (EFSA, 2014)

Compound	**DT_{50} water [days]**	**DT_{50} sed [days]**	**DT_{50} whole system [days]**	**Maximum occurence in water/sed system [%]**
Sulfoxaflor	57.08	68.63	57.08	---
X11719474	1000*	1000*	1000*	70.9†
X11519540	1000*	1000*	1000*	0.0001

* Conservative value
† based on single replicate

Predicted environmental concentrations values for the formulation

Single application was considered as the formulation is not considered to be maintained over time and hence will not remain present for any subsequent applications. Calculation of the PEC

values for the formulation arising from drift loading into surface water (worst case corresponds to single application to pome/stone fruit, early application) was performed using the FOCUS drift calculator in SWASH at 3 m. The results are in Table 9.7-2 below.

Parameters used in the Drift calculator:

Application rate: 422.9 g GF-2626/ha (based on 400ml/ha with density of 1.0572 g/ml)
Crop: pome/stone fruit, early application
Drift: 3 m

Table 9.6.4-3: Drift PEC values from the formulation

	PEC sw (µg/L)
Waterbody	**3 m**
Ditch	36.8194
Pond	2.9027
Stream	36.8194

Modelling Comments: IIIA 9.7	PECsw for the formulation were verified by zRMS and are validated.
Agreed PECsw: IIIA 9.7	Maximum PECsw for the formulation 36.8194 µg/L is used for risk assessement in section 6.

Predicted environmental concentrations values for the active substance and its metabolites

IIIA 9.7.1 Initial PECsw value for static water bodies

Report:	IIIA1 9.7.1/01, Jarvis, T. and Montesano V., 2014b
Title:	Predicted Environmental Concentrations of Sulfoxaflor (as product GF-2626) and its Metabolites in Surface Water using the FOCUS Surface Water Scenarios.
Document No:	Exponent International Ltd. Report No.: 1402547.UK0-1290
Guidelines:	FOCUS (2001, 2012).
GLP	No. Not required

I. MATERIAL AND METHODS

Surface water calculations of sulfoxaflor have been undertaken using the FOCUS surface water scenarios, using Steps1-2 in FOCUS and SWASH v3.1, FOCUS PRZM v3.1.1, FOCUS MACRO v5.5.3 and FOCUS TOXSWA v3.3.1. The modelling performed in this exercise was based on the GAP requested for product registration of GF-2626 in the southern zone of the EU for uses on citrus, pome/stone fruit, fruiting vegetables, flowering brassica, leafy brassicas, leafy vegetables, potatoes, beans, peas and ornamentals.

Step 1-2 was performed for all crops. In addition, Step 3 calculations were performed for pome/stone fruits.

In accordance with the GAP, the agronomic parameters used as input for these simulations were therefore as follows:

Step 1 – 2

FOCUS crop: Citrus
Crop: Citrus (grapefruits, oranges, lemons and mandarins)
Application Rate: 1 x 48 g as/ha
Crop Interception: Full canopy
Application Timing: NEU/SEU, Jun-Sep

FOCUS crop: Pome/stone fruit (early application)
Crop: Pome/stone fruit (apples, pears, cherries, plums, peaches and nectarines)
Application Rate: 1 x 48 g as/ha
Crop Interception: Average crop cover
Application Timing: NEU/SEU, Mar-May

FOCUS crop: Vegetables, fruiting
Crop: Tomatoes, Aubergines, Pepinos, Peppers and Cucurbits
Application Rate: 1 x 48 g as/ha
Crop Interception: Full crop cover
Application Timing: NEU/SEU, Mar-May/Jun-Sep

FOCUS crop: Vegetables, leafy
Crop: Flowering brassica, Brussels sprouts, Head cabbage, Leafy brassica, Lettuce, other salad plants and herbs
Application Rate: 1 x 24 g as/ha
Crop Interception: Average crop cover
Application Timing: NEU/SEU, Mar-May/Jun-Sep

FOCUS crop: Potatoes
Crop: Potatoes
Application Rate: 2 x 24 g as/ha (21 days interval)
Crop Interception: Average crop cover
Application Timing: NEU/SEU, Mar-May/Jun-Sep

FOCUS crop: Field beans
Crop: Beans

Application Rate: 2 x 24 g as/ha (21 days interval)
Crop Interception: Average crop cover
Application Timing: NEU/SEU, Mar-May/Jun-Sep

FOCUS crop: Legumes
Crop: Peas
Application Rate: 2 x 24 g as/ha (21 days interval)
Crop Interception: Average crop cover
Application Timing: NEU/SEU, Mar-May/Jun-Sep

Step 3

FOCUS crop: Pome/stone fruit (early application)
Crop: Pome/stone fruit (apples, pears, cherries, plums, peaches and nectarines)
Application: 1 x 48 g as/ha
Application Timing: 1st April to 1st May for all scenarios

The crop Interception is calculated internally by MACRO or PRZM (foliar application defined in SWASH) and the actual application dates are set by The Pesticide Application Timing calculator (PAT) within MACRO and PRZM

The FOCUS models do not have an ornamental crop included but it can be considered covered by application on citrus, pome/stone fruit and fruiting vegetables.

Sulfoxaflor endpoints used in the assessments are summarised in Table 9.7.1-1.

Table 9.7.1-1: Sulfoxaflor input parameters used for the simulations

Parameter	sulfoxaflor
Molecular mass [g/mol]	277.3
Vapour pressure [Pa] at 20 ºC	$1.4x10^{-6}$
Solubility in water [mg/L] at 20 ºC	568
Koc [mL/g], arith. mean	35
Freundlich exponent, mean	0.96
Crop uptake factor[1]	0
DT_{50} soil [d] geometric mean at 20°C and pF2	0.078 (lab. – in accordance with FOCUS SFO)
DT_{50} water [days]	57.08
DT_{50} sed [days]	68.63
DT_{50} whole system [days]	57.08

[1] conservative value

II. RESULTS AND DISCUSSION

Summary of the Step 1 & 2 maximum PECs values for sulfoxaflor can be seen in Table 9.7.1-2.

The results from Step 2 show that Step 3 may be required for sulfoxaflor only in some cases. For pome/stone fruit (early application), the results of Step 3 (Table 9.7.1-11) show that further mitigation is required for R2 and R3 Stream scenarios. As drift is the main route of entrance in all cases, a 5m no spray buffer zone was considered. The maximum Step 4 PECsw and PECsed values and the results for each individual scenario are presented in Table 9.7.1-12.

Table 9.7.1-2: Maximum Step 1 & 2 PECsw and PECsed values for Sulfoxaflor

Crop	Step	Region/ season application	Sulfoxaflor	
			PEC_{sw} [µg/L]	PEC_{sed} [µg/kg]
Citrus	1	---	17.80	6.12
	2	NEU, Jun – Sep	2.52	0.79
		SEU, Jun – Sep	2.52	0.79
Pome fruit (early)	1	---	19.96	6.83
	2	NEU, Mar – May	4.67	1.47
		SEU, Mar – May	4.67	1.47
Fruiting veg.	1	---	15.73	5.43
	2	NEU, Mar – May	0.44	0.14
		NEU, Jun – Sep	0.44	0.14
		SEU, Mar – May	0.44	0.14
		SEU, Jun – Sep	0.44	0.14
Leafy veg.	1	---	7.86	2.72
	2	NEU, Mar – May	0.22	0.07
		NEU, Jun – Sep	0.22	0.07
		SEU, Mar – May	0.22	0.07
		SEU, Jun – Sep	0.22	0.07
Potato	1	---	15.73	5.43
	2	NEU, Mar – May	0.34 (0.22)	0.11 (0.07)
		NEU, Jun – Sep	0.34 (0.22)	0.11 (0.07)
		SEU, Mar – May	0.34 (0.22)	0.11 (0.07)
		SEU, Jun – Sep	0.34 (0.22)	0.11 (0.07)
Field bean	1	---	15.73	5.43
	2	NEU, Mar – May	0.34 (0.22)	0.11 (0.07)
		NEU, Jun – Sep	0.34 (0.22)	0.11 (0.07)
		SEU, Mar – May	0.34 (0.22)	0.11 (0.07)
		SEU, Jun – Sep	0.34 (0.22)	0.11 (0.07)
Legumes	1	---	15.73	5.43
	2	NEU, Mar – May	0.34 (0.22)	0.11 (0.07)
		NEU, Jun – Sep	0.34 (0.22)	0.11 (0.07)

Crop	Step	Region/ season application	Sulfoxaflor	
			PEC_{sw} [µg/L]	**PEC_{sed} [µg/kg]**
		SEU, Mar – May	0.34 (0.22)	0.11 (0.07)
		SEU, Jun – Sep	0.34 (0.22)	0.11 (0.07)

Values in brackets represent respective single application

Table 9.7.1-1: FOCUS Step 3 and TWA PECs following application (1 x 48 g a.s./ha) of sulfoxaflor to pome/stone fruit (early application)

Scenario	D3	D4	D4	D5	D5	R1	R1	R2	R3	R4
water body	**ditch**	**pond**	**stream**	**pond**	**stream**	**pond**	**stream**	**stream**	**stream**	**stream**
Date of Application	04-Apr-92	18-Apr-85	18-Apr-85	08-Apr-78	08-Apr-78	26-Apr-84	26-Apr-84	22-Apr-77	04-Apr-80	15-Apr-84
Initial PECsw (µg/L)	**3.726**	**0.227**	**3.505**	**0.227**	**3.698**	**0.227**	**3.014**	**3.999**	**4.264**	**3.032**
Date of max. PECsw	04-Apr-92	18-Apr-85	18-Apr-85	08-Apr-78	08-Apr-78	26-Apr-84	26-Apr-84	22-Apr-77	04-Apr-80	15-Apr-84
PECsed (µg/kg)	**0.464**	**0.185**	**0.082**	**0.187**	**0.079**	**0.169**	**0.164**	**0.140**	**0.314**	**0.181**

Table 9.7.1-2: FOCUS Step 4 and TWA PECs following application (1 x 48 g a.s./ha) of sulfoxaflor to pome/stone fruit (early application) – Mitigation: 5m spray drift buffer zone

Scenario	D3	D4	D4	D5	D5	R1	R1	R2	R3	R4
water body	**ditch**	**pond**	**stream**	**pond**	**stream**	**pond**	**stream**	**stream**	**stream**	**stream**
Date of Application	04-Apr-92	18-Apr-85	18-Apr-85	08-Apr-78	08-Apr-78	26-Apr-84	26-Apr-84	22-Apr-77	04-Apr-80	15-Apr-84
Initial PECsw (µg/L)	**2.927**	**0.255**	**3.011**	**0.255**	**3.178**	**0.255**	**2.590**	**3.436**	**3.664**	**2.605**
Date of max. PECsw	04-Apr-92	18-Apr-85	18-Apr-85	08-Apr-78	08-Apr-78	26-Apr-84	26-Apr-84	22-Apr-77	04-Apr-80	15-Apr-84
PECsed (µg/kg)	**0.366**	**0.208**	**0.070**	**0.210**	**0.068**	**0.190**	**0.141**	**0.120**	**0.270**	**0.156**

Modelling Comments: IIIA 9.7.1	STEP 1-2 calculations were verified by zRMS and are validated. Is is noted that for fruiting vegetables, an "intermediate crop cover" could have been chosen as better corresponding to the earliest BBCH possible stage of application (BBCH20). For citrus, the region/season application could have been set to March/May for SEU. However, in those two cases, zRMS verified it does not change the PECsw results as drift is the major route of entry. STEP 3-4 calculation for Pome/Stone fruit could not be checked in detail by zRMS as the raw input modeling files were not available. However, during evaluation of this product in central zone, zRMS Poland reproduced the simulation to verify applicant's proposed modelling (same study submitted to central zone) and got the same results. Calculation are thus considered valid. It is noted that no late application were provided to cover post-flowering applications. However, considering that drift is clearly the major route of entry, and that later application whould consider higher crop interception value, is is considered that the PECsw provided by applicant can be used for risk assessement for the whole application period.
Agreed PECsw (active substance): IIIA 9.7.1	PECsw provided by applicant are validated and can be used for risk assessment.

IIIA 9.7.2 Initial PECsw value for slow moving water bodies

Refer to point IIIA 9.7.1 above.

IIIA 9.7.3 Short-term PECsw values for static water bodies (1-4 days after last application)

Refer to point IIIA 9.7.1 above.

IIIA 9.7.4 Short-term PECsw values for slow moving water bodies (1-4 days after last application)

Refer to point IIIA 9.7.1 above.

IIIA 9.7.5 Long-term PECsw values for static water bodies (7-42 days after last application)

Refer to point IIIA 9.7.1 above.

IIIA 9.7.6 Long-term PECsw values for slow moving water bodies (7-42 days after last application)

Refer to point IIIA 9.7.1 above.

IIIA 9.8 Predicted environmental concentrations in surface water (PECsw) for metabolites

IIIA 9.8.1 Initial PECsw value for static water bodies

Report:	IIIA1 9.7.1/01, Jarvis, T. and Montesano V., 2014b
Title:	Predicted Environmental Concentrations of Sulfoxaflor (as product GF-2626) and its Metabolites in Surface Water using the FOCUS Surface Water Scenarios.
Document No:	Exponent International Ltd. Report No.: 1402547.UK0-1290
Guidelines:	FOCUS (2001, 2012).
GLP	No. Not required

I. MATERIAL AND METHODS

Surface water calculations of sulfoxaflor metabolites have been undertaken using the FOCUS surface water scenarios and FOCUS Step 1-2 version 2.1. The modelling performed in this exercise was based on the GAP requested for product registration of GF-2626 in the southern zone of the EU for uses on citrus, pome/stone fruit, fruiting vegetables, flowering brassica, leafy brassicas, leafy vegetables, potatoes, beans, peas and ornamentals.

The FOCUS models do not have an ornamental crop included but it can be considered covered by application on citrus, pome/stone fruit and fruiting vegetables.

Metabolites endpoints used in the assessments are summarised in Table 9.8.1-1.

Table 9.8.1-1: X11719474 and X11519540, input parameters used for the simulations

Parameter	X11719474	X11519540
Molecular mass [g/mol]	295.3	253.24
Solubility in water [mg/L] at 20 ºC	8090	1000
Koc [mL/g], arith. mean	30	14
DT_{50} soil [d] geometric mean at 20°C and pF2	76.61 (field – in accordance with FOCUS SFO)	40.5 (field – in accordance with FOCUS SFO)
DT_{50} water [days]	1000*	1000*
DT_{50} sed [days]	1000*	1000*
DT_{50} whole system [days]	1000*	1000*
% formed in soil	100	12.2
% formed in water/sed system	70.9	0.0001

n.r. = not required; [1] conservative value; [*] default value

II. RESULTS AND DISCUSSION

A summary of the Step 1 & 2 maximum PECsw values for sulfoxaflor metabolites can be seen in Table 9.8.1-2.

Table 9.8.1-2: Maximum Step 1 & 2 PECsw and PECsed values for Sulfoxaflor metabolites

Crop	Step	Region/ season application	X11719474		X11519540	
			PEC_{sw} [µg/L]	PEC_{sed} [µg/kg]	PEC_{sw} [µg/L]	PEC_{sed} [µg/kg]
Citrus	1	---	18.28	5.46	1.75	0.25
	2	NEU, Jun – Sep	2.79	0.83	0.10	0.01
		SEU, Jun – Sep	3.27	0.97	0.15	0.02
Pome fruit (early)	1	---	19.91	5.93	1.75	0.25
	2	NEU, Mar – May	5.32	1.58	0.20	0.03
		SEU, Mar – May	7.22	2.15	0.39	0.05
Fruiting veg.	1	---	16.72	5.01	1.75	0.25
	2	NEU, Mar – May	1.27	0.38	0.10	0.01
		NEU, Jun – Sep	1.27	0.38	0.10	0.01
		SEU, Mar – May	2.22	0.66	0.20	0.03
		SEU, Jun – Sep	1.75	0.52	0.15	0.02
Leafy veg.	1	---	8.36	2.50	0.88	0.12
	2	NEU, Mar – May	1.11	0.33	0.10	0.01
		NEU, Jun – Sep	1.11	0.33	0.10	0.01

Crop	Step	Region/ season application	X11719474		X11519540	
			PEC_{sw} [µg/L]	PEC_{sed} [µg/kg]	PEC_{sw} [µg/L]	PEC_{sed} [µg/kg]
		SEU, Mar – May	2.06	0.62	0.20	0.03
		SEU, Jun – Sep	1.58	0.47	0.15	0.02
Potato	1	---	16.72	5.01	1.75	0.25
	2	NEU, Mar – May	1.73 (0.95)	0.52 (0.28)	0.14 (0.08)	0.02 (0.01)
		NEU, Jun – Sep	1.73 (0.95)	0.52 (0.28)	0.14 (0.08)	0.02 (0.01)
		SEU, Mar – May	3.17 (1.74)	0.95 (0.52)	0.28 (0.16)	0.04 (0.02)
		SEU, Jun – Sep	2.45 (1.35)	0.73 (0.40)	0.21 (0.12)	0.03 (0.02)
Field bean	1	---	16.72	5.01	1.75	0.25
	2	NEU, Mar – May	2.02 (1.11)	0.60 (0.33)	0.17 (0.10)	0.02 (0.01)
		NEU, Jun – Sep	2.02 (1.11)	0.60 (0.33)	0.17 (0.10)	0.02 (0.01)
		SEU, Mar – May	3.75 (2.06)	1.12 (0.62)	0.33 (0.20)	0.05 (0.03)
		SEU, Jun – Sep	2.88 (1.58)	0.86 (0.47)	0.25 (0.15)	0.04 (0.02)
Legumes	1	---	16.72	5.01	1.75	0.25
	2	NEU, Mar – May	1.73 (0.95)	0.52 (0.28)	0.14 (0.08)	0.02 (0.01)
		NEU, Jun – Sep	1.73 (0.95)	0.52 (0.28)	0.14 (0.08)	0.02 (0.01)
		SEU, Mar – May	3.17 (1.74)	0.95 (0.52)	0.28 (0.16)	0.04 (0.02)
		SEU, Jun – Sep	2.45 (1.35)	0.73 (0.40)	0.21 (0.12)	0.03 (0.02)

Values in brackets represent respective single application

Modelling Comments: IIIA 9.8.1	Is is noted that applicant used a field DT_{50} of 40.5 for metabolite X115149540 instead of the lab value of 449.86 days used at EU level. However, this field value is also reported in the LoEP as alternative recommended endpoint for calculations, it is accepted here. Calculations were checked by zRMS and are validated.
Agreed PECsw (metabolites): IIIA 9.8.1	PECsw provided by applicant can be used for risk assessment.

IIIA 9.8.2 Initial PECsw value for slow moving water bodies

Refer to point IIIA 9.8.1 above.

IIIA 9.8.3 Short-term PECsw values for static water bodies 1-4 days after last application)

Refer to point IIIA 9.8.1 above.

IIIA 9.8.4 Short-term PECsw values for slow moving water bodies 1-4 days after last application)

Refer to point IIIA 9.8.1 above.

IIIA 9.8.5 Long-term PECsw values for static water bodies 7-42 days after last application)

Refer to point IIIA 9.8.1 above.

IIIA 9.8.6 Long-term PECsw values for slow moving water bodies 7-42 days after last application)

Refer to point IIIA 9.8.1 above.

IIIA 9.9 Fate and behaviour in air

Summary details of fate and behaviour in air as in the EFSA conclusion is shown in Tables 9.9-1 and 9.9-2

Table 9.9-1: Fate and behaviour in air

Vapour pressure [Pa] at 20 ºC	1.4×10^{-6}
Photochemical oxidative degradation in air	DT_{50} of 0.647 days derived by the Atkinson model (version 4.00). OH (12 h) concentration assumed = 1.5×10^{6} [radicals/cm^3].
Volatilization	from plant surfaces (BBA guideline): not examined
	from soil surfaces (BBA guideline): not examined
Metabolites	None identified

Table 9.9-2: 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.

IIIA 9.9.1 Spray droplet size spectrum – laboratory studies

This is not an EC data requirement / not required by Regulation (EC) 1107/2009.

IIIA 9.9.2 Drift – field evaluation

This is not an EC data requirement / not required by Regulation (EC) 1107/2009.

IIIA 9.10 Other/special studies

There are no additional European requirements for formulated products.

IIIA 9.10.1 Laboratory studies

This is not an EC data requirement / not required by Regulation (EC) 1107/2009.

IIIA 9.10.2 Field studies

This is not an EC data requirement / not required by Regulation (EC) 1107/2009.

APPENDIX 1: LIST OF DATA SUBMITTED IN SUPPORT OF THE EVALUATION

Data owner: DAS = Dow AgroSciences

Annex point	**Author**	**Year**	**Title** **Source (where different from company)** **Company, Report No.** **GLP or GEP status (where relevant)** **Published or Unpublished**	**Data protection claimed Y/N**	**Data relied on**	**Owner**
IIIA 9.6.1/01	Jarvis, T. & Montesano, V.	2014a	Predicted Environmental Concentrations of Sulfoxaflor (as product GF-2626) and its metabolites in groundwater using the FOCUS PEARL 4.4.4 and FOCUS PELMO 5.5.3 groundwater scenarios. Exponent International Ltd. Report No.: 1402547.UK0-3433 Non-GLP, unpublished	Y	N	Dow agroscience

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Data relied on	Owner
IIIA 9.7.1/01	Jarvis, T. & Montesano, V.	2014b	Predicted Environmental Concentrations of Sulfoxaflor (as product GF-2626) and its Metabolites in Surface Water using the FOCUS Surface Water Scenarios. Exponent International Ltd. Report No.: 1402547.UK0-1290 Non-GLP, unpublished	Y	Y	Dow agroscience
IIIA 9.8.1/01	Jarvis, T. & Montesano, V.	2014b	Predicted Environmental Concentrations of Sulfoxaflor (as product GF-2626) and its Metabolites in Surface Water using the FOCUS Surface Water Scenarios. Exponent International Ltd. Report No.: 1402547.UK0-1290 Non-GLP, unpublished	Y	Y	Dow agroscience

APPENDIX 2: GAP

Appendix 2.1: Table of intended Core uses and GAP for GF-2626

Bulgaria	Apples, Aubergines, Beans, Brassicas [Brocolli, Cabbage, Cauliflower, Brussels sprouts, Leafy brassicas (Chinese cabbage, Kale, others)] , Bulbs, Ornamentals, Flowers , Cucurbits (Cucumber, Water Melon, Zuccini, Melon, Pumpkin, Squash), Leaf vegetables and fresh herbs (lettuce and other salad plants, spinach and similar (leaves), others in crop group) , Peach, Nectarine, Pear, Pepper, Pea, Plums, Cherries, Potatoes, Tomatoes
Croatia	Apples, Aubergines, Peach, Nectarine, Pepper, Pears, Plums, Cherries, Tomatoes
Cyprus	Aubergines, Peach, Nectarine, Pepper, Tomatoes
France	Apples, Aubergines, Beans, Brassicas [Brocolli, Cabbage, Cauliflower, Brussels sprouts, Leafy brassicas (Chinese cabbage, Kale, others)] , Cucurbits (Cucumber, Water Melon, Zuccini, Melon, Pumpkin, Squash), Leaf vegetables and fresh herbs (lettuce and other salad plants, spinach and similar (leaves), others in crop group) , Grapefruits, Lemon, Mandarin, Orange, Peach, Nectarine, Pear, Plums, Cherries, Potatoes, Pepper, Peas, Plums, Cherries, Tomatoes
Greece	Apples, Aubergines, Beans, Brassicas [Brocolli, Cabbage, Cauliflower, Brussels sprouts, Leafy brassicas (Chinese cabbage, Kale, others)] , Bulbs, Ornamentals, Flowers , Cucurbits (Cucumber, Water Melon, Zuccini, Melon, Pumpkin, Squash), Leaf vegetables and fresh herbs (lettuce and other salad plants, spinach and similar (leaves), others in crop group) , Grapefruits, Lemon, Mandarin, Orange, Peach, Nectarine, Pear, Pea, Pepper, Plums, Cherries, Potatoes, Tomatoes
Italy	Apples, Aubergines, Beans, Brassicas [Brocolli, Cabbage, Cauliflower, Brussels sprouts, Leafy brassicas (Chinese cabbage, Kale, others)] , Bulbs, Ornamentals, Flowers , Cucurbits (Cucumber, Water Melon, Zuccini, Melon, Pumpkin, Squash), Leaf vegetables and fresh herbs (lettuce and other salad plants, spinach and similar (leaves), others in crop group) , Grapefruits, Lemon, Mandarin, Orange, Peach, Nectarine, Pear, Pea, Plums, Cherries, Potatoes, Pepper, Plums, Cherries, Tomatoes
Malta	Tomatoes, Pepper, Aubergines
Portugal	Apples, Aubergines, Beans, Bulbs, Ornamentals, Flowers, Cucurbits (Cucumber, Water Melon, Zuccini, Melon, Pumpkin, Squash), Grapefruits, Lemon, Mandarin, Orange, Peach, Nectarine, Pear, Potatoes, Pepper, Peas, Plums, Cherries, Tomatoes
Spain	Apples, Aubergines, Beans, Brassicas [Brocolli, Cabbage, Cauliflower, Brussels sprouts, Leafy brassicas (Chinese cabbage, Kale, others)] , Bulbs, Ornamentals, Flowers , Cucurbits (Cucumber, Water Melon, Zuccini, Melon, Pumpkin, Squash), Leaf vegetables and fresh herbs (lettuce and other salad plants, spinach and similar (leaves), others in crop group) , Grapefruits, Lemon, Mandarin, Orange, Peach, Nectarine, Pear, Peas, Plums, Cherries, Potatoes, Pepper, Tomatoes

Crop and/or situation (a)	Member State or Country	Product Name	F or G (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI days (k)	Remarks (l)
					Type (d-f)	Conc. of a.s. (i) g/L	Method Kind (f-h)	Growth stage (j)	Number min max	Interval between applications (min)	kg as/hl min max	Water (l/ha) min max	kg as./ha min max		
Apples	South (FR, IT,	GF-2626	F	Aphids,	SC	120 g/L	Ground applied	BBCH 51-59 (pre-	1-2	7	0.0016-0.016	300-1500	0.024-0.048	7	Two applications of 24 g/ha rate would be

Crop and/or situation (a)	Member State or Country	Product Name	F or G (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI days (k)	Remarks (l)
					Type (d-f)	Conc. of a.s. (i) g/L	Method Kind (f-h)	Growth stage (j)	Number min max	Interval between applications (min)	kg as/hl min max	Water (l/ha) min max	kg as./ha min max		
	PT, ES, BG, EL, HR)			Scales			foliar spray, broadcast	flowering) Feb - BBCH 69-85 Mar-Sep							minimum 7 days interval. If higher rate than 24 g/ha is applied, only one application is possible either pre or post flowering. No spray is allowed during the flowering.
Aubergines	South (FR, BG, EL, HR, CY, MA, IT, ES, PT)	GF-2626	F	Aphids, Whiteflies	SC	120 g/L	Ground applied foliar spray, broadcast	BBCH 20-87 Apr-Nov	1-2	7	0.0016-0.0096	500 - 1500	0.024-0.048 (see Remarks)	1	Aphids: One or two applications of 0.024 g a.s./ha. Two applications would be minimum 7 days interval. Whiteflies: Either two applications of 0.024 kkg a.s./hawith a minimum 7 days interval or only one application of 0.048 kg a.s./ha.
Beans (fresh, without pods), beans (fresh, with pods)	South (FR, ES, PT, BG, EL, IT)	GF-2626	F	Aphids	SC	120 g/L	Ground applied foliar spray, broadcast	BBCH 40-85 Apr-Jul	1-2	21	0.004-0.016	150 - 1000	0.024	14	Two applications would be minimum 21 days interval
Brassicas [Brocolli, Cabbage,	South (IT, ES, BG, EL,	GF-2626	F	Aphids	SC	120 g/L	Ground applied foliar spray,	BBCH 20-49	1		0.004-0.012	200 - 1000	0.024	7	

Crop and/or situation (a)	Member State or Country	Product Name	F or G (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI days (k)	Remarks (l)
					Type (d-f)	Conc. of a.s. (i) g/L	Method Kind (f-h)	Growth stage (j)	Number min max	Interval between applications (min)	kg as/hl min max	Water (l/ha) min max	kg as./ha min max		
Cauliflower, Brussels sprouts, Leafy brassicas (Chinese cabbage, Kale, others)]	FR)						broadcast	Apr-Sep							
Bulbs, Ornamentals, Flowers	South (IT, BG, EL, ES, PT)	GF-2626	F	Aphids, Whiteflies	SC	120 g/L	Ground applied foliar spray, broadcast	BBCH 12-59 All year	1-2	7	0.0012-0.024	200 - 2000	0.024-0.048 (see Remarks)	1	Aphids: One or two applications of 0.024 kg a.s./ha. Two applications would be minimum 7 days interval. Whiteflies: Either two applications of 0.024 kkg a.s./hawith a minimum 7 days interval or only one application of 0.048 kg a.s./ha.
Cucurbits (edible peel – cucumbers, courgettes, gherkins; inedible peel – melons, pumpkins/ squash, watermelons,	South (FR, IT, ES, PT, BG, EL)	GF-2626	F	Aphids, Whiteflies	SC	120 g/L	Ground applied foliar spray, broadcast	BBCH 20-87 Apr-Nov	1-2	7	0.0016-0.0096	500 - 1500	0.024-0.048 (see Remarks)	1	Aphids: One or two applications of 0.024 kg a.s./ha. Two applications would be minimum 7 days interval. Whiteflies: Either two applications of 0.024 kkg a.s./hawith a minimum 7 days interval or only one application of 0.048 kg

Crop and/or situation (a)	Member State or Country	Product Name	F or G (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI days (k)	Remarks (l)
					Type (d-f)	Conc. of a.s. (i) g/L	Method Kind (f-h)	Growth stage (j)	Number min max	Interval between applications (min)	kg as/hl min max	Water (l/ha) min max	kg as./ha min max		
zuccini)															a.s./ha.
Grapefruit	South (ES, IT, PT, FR, EL)	GF-2626	F	Aphids, Mealybugs, Scales	SC	120 g/L	Ground applied foliar spray, broadcast	BBCH 30-85 Mar-Oct	1-2	7	0.00096-0.0096	500 - 2500	0.024 - 0.048 (see Remarks)	7	Two applications of 0.024 kg a.s./ha would be minimum 7 days interval. If higher rate than 24 g/ha is applied, only one application is possible in a year.
Leaf vegetables (Lettuce and other salad plants including Brassicacea, spinach and similar (leaves), herbs)	South (ES, IT, FR, BG, EL)	GF-2626	F	Aphids	SC	120 g/L	Ground applied foliar spray, broadcast	BBCH 20-49 Apr-Sep	1		0.004-0.012	200-1000	0.024	7	
Lemons	South (ES, IT, FR, PT, EL)	GF-2626	F	Aphids, Mealybugs, Scales	SC	120 g/L	Ground applied foliar spray, broadcast	BBCH 30-85 Mar-Oct	1-2	7	0.00096-0.0096	500 - 2500	0.024 - 0.048 (see Remarks)	7	Two applications of 0.024 kg a.s./ha would be minimum 7 days interval. If higher rate than 24 g/ha is applied, only one application is possible in a year.

Crop and/or situation (a)	Member State or Country	Product Name	F or G (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI days (k)	Remarks (l)
					Type (d-f)	Conc. of a.s. (i) g/L	Method Kind (f-h)	Growth stage (j)	Number min max	Interval between applications (min)	kg as/hl min max	Water (l/ha) min max	kg as./ha min max		
Mandarins	South (ES, IT, FR, PT, EL)	GF-2626	F	Aphids, Mealybugs, Scales	SC	120 g/L	Ground applied foliar spray, broadcast	BBCH 30-85 Mar-Oct	1-2	7	0.00096-0.0096	500 - 2500	0.024 -0.048 (see Remarks)	7	Two applications of 0.024 kg a.s./ha would be minimum 7 days interval. If higher rate than 24 g/ha is applied, only one application is possible in a year.
Oranges	South (ES, IT, FR, PT, EL)	GF-2626	F	Aphids, Mealybugs, Scales	SC	120 g/L	Ground applied foliar spray, broadcast	BBCH 30-85 Mar-Oct	1-2	7	0.00096-0.0096	500 - 2500	0.024 -0.048 (see Remarks)	7	Two applications of 0.024 kg a.s./ha would be minimum 7 days interval. If higher rate than 24 g/ha is applied, only one application is possible in a year.
Peaches and Nectarines	South (ES, IT, FR, PT, GR, CY, BG, EL, HR)	GF-2626	F	Aphids, Scales	SC	120 g/L	Ground applied foliar spray, broadcast	BBCH 51-59 (pre-flowering) Feb BBCH 69-85 Mar-Sep	1-2	7	0.0016-0.016	300-1500	0.024-0.048 (see Remarks)	7	Two applications of 24 g/ha rate would be minimum 7 days interval. If higher rate than 24 g/ha is applied, only one application is possible either pre or post flowering. No spray is allowed during the flowering.

Crop and/or situation (a)	Member State or Country	Product Name	F or G (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI days (k)	Remarks (l)
					Type (d-f)	Conc. of a.s. (i) g/L	Method Kind (f-h)	Growth stage (j)	Number min max	Interval between applications (min)	kg as/hl min max	Water (l/ha) min max	kg as./ha min max		
Pears	South (ES, IT, FR, PT, BG, EL, HR)	GF-2626	F	Aphids, Scales	SC	120 g/L	Ground applied foliar spray, broadcast	BBCH 51-59 (pre-flowering) Feb BBCH 69-85 Mar-Sep	1-2	7	0.0016-0.016	300-1500	0.024-0.048 (see Remarks)	7	Two applications of 24 g/ha rate would be minimum 7 days interval. If higher rate than 24 g/ha is applied, only one application is possible either pre or post flowering. No spray is allowed during the flowering.
Peas (fresh without pods), peas (fresh with pods)	South (BG, EL, IT, ES, PT, FR)	GF-2626	F	Aphids	SC	120 g/L	Ground applied foliar spray, broadcast	BBCH 40-85 Apr-Jul	1-2	21	0.004-0.016	150 - 1000	0.024	14	Two applications would be minimum 21 days interval
Pepper	South (BG, EL, CY, MA, IT, ES, PT, FR, HR)	GF-2626	F	Aphids, Whiteflies	SC	120 g/L	Ground applied foliar spray, broadcast	BBCH 20-87 Apr-Nov	1-2	7	0.0016-0.0096	500 - 1500	0.024-0.048 (see Remarks)	1	Aphids: One or two applications of 0.024 g a.s./ha. Two applications would be minimum 7 days interval. Whiteflies: Either two applications of 0.024 kg

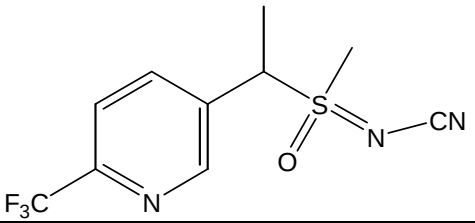
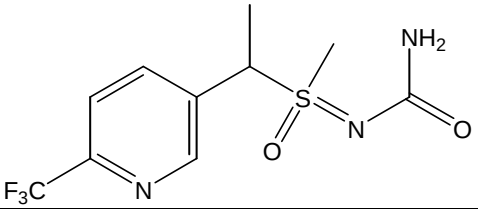
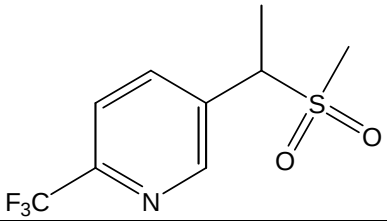
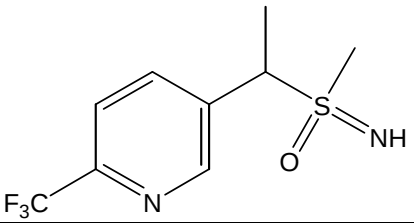
Crop and/or situation (a)	Member State or Country	Product Name	F or G (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI days (k)	Remarks (l)
					Type (d-f)	Conc. of a.s. (i) g/L	Method Kind (f-h)	Growth stage (j)	Number min max	Interval between applications (min)	kg as/hl min max	Water (l/ha) min max	kg as./ha min max		
															a.s./hawith a minimum 7 days interval or only one application of 0.048 g a.s./ha.
Plums and Cherries	South (PT, ES, BG, EL, FR, HR, IT)	GF-2626	F	Aphids, Scales	SC	120 g/L	Ground applied foliar spray, broadcast	BBCH 51-59 (pre-flowering) Feb BBCH 69-85 Mar-Sep	1-2	7	0.0016-0.016	300-1500	0.024-0.048 (see Remarks)	7	Two applications of 24 g/ha rate would be minimum 7 days interval. If higher rate than 24 g/ha is applied, only one application is possible either pre or post flowering. No spray is allowed during the flowering.
Potatoes	South (BG, EL, IT, ES, PT, FR)	GF-2626	F	Aphids	SC	120 g/L	Ground applied foliar spray, broadcast	BBCH 20 - 95 May-Aug	1-2	21	0.004-0.012	200 - 600	0.024	7	Two applications would be minimum 21 days interval.
Tomatoes	South (FR, BG, EL, HR,	GF-2626	F	Aphids, Whiteflies	SC	120 g/L	Ground applied foliar spray,	BBCH 20-87 Apr-Nov	1-2	7	0.00160.0096	500 - 1500	0.024-0.048 (see	1	Aphids: One or two applications of 0.024 g a.s./ha. Two applications

Crop and/or situation (a)	Member State or Country	Product Name	F or G (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI days (k)	Remarks (l)
					Type (d-f)	Conc. of a.s. (i) g/L	Method Kind (f-h)	Growth stage (j)	Number min max	Interval between applications (min)	kg as/hl min max	Water (l/ha) min max	kg as./ha min max		
	MA, CY, IT, ES, PT)						broadcast						Remarks)		would be minimum 7 days interval. Whiteflies: Either two applications of 0.024 kg a.s./hawith a minimum 7 days interval or only one application of 0.048 g a.s./ha.

(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used 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 plant - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) Indicate the minimum and maximum number of application possible under practical conditions of use
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

APPENDIX 3: OTHER INFORMATION

Appendix 3.1: Table of active substance and metabolites

Code Name	Chemical Name	Chemical Structure
Sulfoxaflor (parent)	[methyl(oxo){1-[6-(trifluoromethyl)-3-pyridyl]ethyl}-λ^6-sulfanylidene]cyanamide	
X11719474 (metabolite)	1-[methyl(oxido){(1*RS*)-1-[6-(trifluoromethyl)-3-pyridinyl]ethyl}-(*RS*)λ^6-sulfanylidene]urea	
X11519540 (metabolite)	5-[(1*RS*)-1-(methylsulfonyl)ethyl]-2-(trifluoromethyl)pyridine	
X11579457 (metabolite)	5-[(1*RS*)-1-(*S*-methylsulfonimidoyl)ethyl]-2-(trifluoromethyl)pyridine	

APPENDIX 4: GUIDANCE DOCUMENTS USED IN THIS ASSESSMENT

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FOCUS (2000) "FOCUS groundwater scenarios in the EU review of active substances" Report of the FOCUS Groundwater Scenarios Workgroup, EC Document Reference Sanco/321/2000 rev.2, 202pp

FOCUS (2007). "Landscape And Mitigation Factors In Aquatic Risk Assessment. Volume 1. Extended Summary and Recommendations". Report of the FOCUS Working Group on Landscape and Mitigation Factors in Ecological Risk Assessment, EC Document Reference SANCO/10422/2005 v2.0. 169 pp.

FOCUS (2008). "Pesticides in Air: Considerations for Exposure Assessment". Report of the FOCUS Working Group on Pesticides in Air, EC Document Reference SANCO/10553/2006 Rev 2 June 2008. 327 pp

FOCUS (2012) "Generic guidance for Tier 1 FOCUS groundwater assessments". Version 2.1, December 2012.

FOCUS (2012) Generic guidance for FOCUS surface water Scenarios, Version: 1.2, Date: December 2012

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SANCO (2003) Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under Council directive 91/414/EEC. Sanco/221/2000-rev.10-final, 25 February 2003.

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