REGISTRATION REPORT

Part B
Section 5: Environmental Fate

Detailed summary of the risk assessment

CLOSER (GF-2626)

120 g/L Sulfoxaflor

All Zones

Zonal Rapporteur Member State: France

(Greenhouse G)

CORE ASSESSMENT

Applicant: DOW AgroSciences

Date: October 2017

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IIIA 9 FATE AND BEHAVIOUR IN THE ENVIRONMENT

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

Sulfoxaflor is a new active substance which have been appoved 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.

Studies for the active substance which have already been evaluated during the approval process are not summarised. New active substance data are only included if they are considered essential for the evaluation and a full study summary is provided.

Details of the active substance, the active approval Regulation and the Commission Review Report are provided in Table 9-1.

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

NOTE

Sulfoxaflor is also referred to as manufacture's code numbers X11422208, XR-208, XDE-208 and DE-208 in the section.

The use pattern for sulfoxaflor evaluated in the EU assessment is illustrated in Table 9-2. Of these, the current submission includes only the glasshouse uses on fruiting vegeteables. In addition, glasshouse uses on ornamentals are now requested. The application 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 and the critical GAP for protected crop uses of the product GF-2626

Crop and/or situation	N or S or MS	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	N/S	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]	N/S	F	BBCH 40 - 89 April - July	1	-	24	21
Cotton	N/S	F	BBCH 20 – 39 BBCH 40 - 89 May - Sept	1	-	24	14
Critical GAP for GF-2626 in the EU for protected crops							
Tomatoes → aubergines (including pepinos)	AT, BE, DE, IE, NL, RO, UK, BG, CY, EL, ES, FR, HR, IT, MT, PT	G	BBCH 20-87	1	-	48	1
Peppers (including chilli peppers)	AT, BE, DE, IE, NL, RO, UK, BG, CY, EL, ES, FR, HR, IT, MT, PT	G	BBCH 20-87	1	-	48	1
Cucurbits (edible peel – cucumbers, courgettes, gherkins)	AT, BE, DE, IE, NL, UK, BG, EL, ES, FR, IT, PT	G	BBCH 20-87	1	-	48	1
Cucurbits (inedible peel – melons, pumpkins/ squash, watermelons)	AT, BE, DE, IE, NL, UK, BG, EL, ES, FR, IT, PT	G	BBCH 20-87	1	-	48	1
Ornamentals	AT, BE, DE, IE, NL, UK, BG, EL, ES, IT, PT	G	BBCH 12-59	1	-	48	1

F, G, I = Field, glasshouse, indoor

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 9-3. The relevant compartments of sulfoxaflor and its metabolites are given in Table 9-4.

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

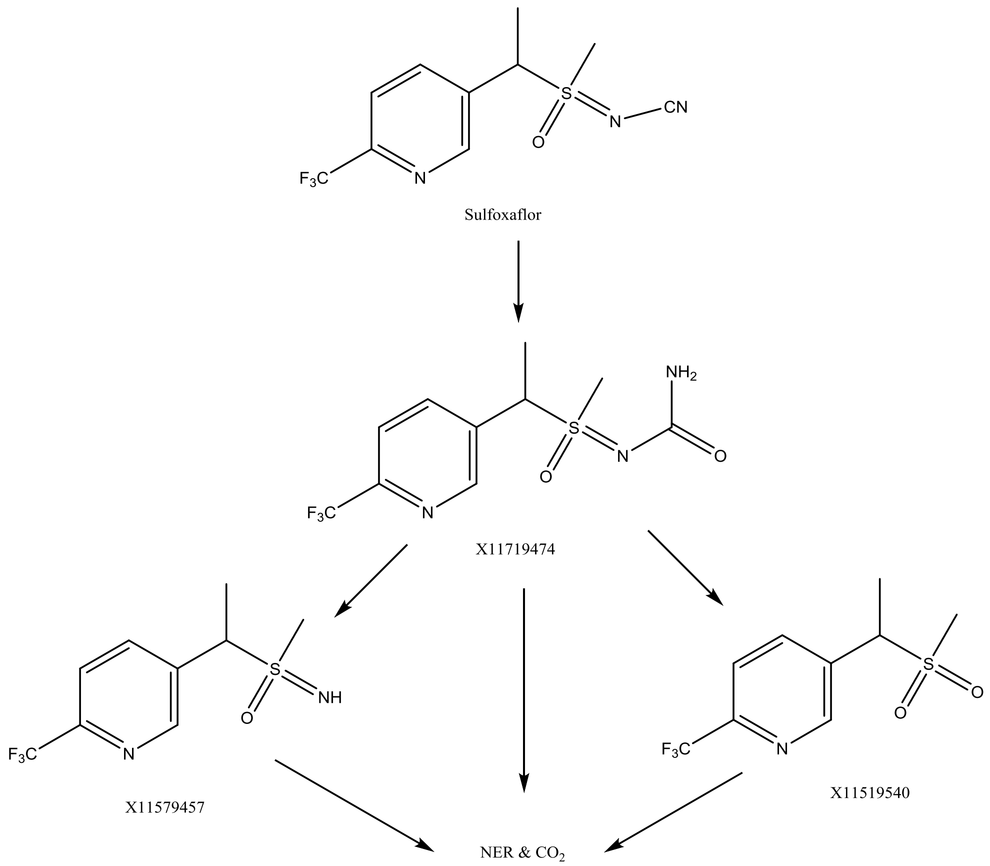
IIIA 9.1 Rate of degradation in soil (laboratory)

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 9-5 : 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 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**

Table 9-6: 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 9-7: 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 9-8: 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	k_2	0.0080	G	0.982	3.45	86.64	287.82

						HS)							
Malham	Sandy loam	6.2	3.5	20	40 (pF2)	Pseudo-SFO (slow phase of the HS)	k_2	0.0054	G	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	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

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.

<u>**Active substance Sulfoxaflor**</u>

Best fit kinetic, persistence endpoint

Table 9-9: Sulfoxaflor aerobic rate of degradation in soil (field studies) 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***	***R^2***	***χ^2 %***	***DT_{50}***	***DT_{90}***

			[%]				*fit[*]*		*error*	*[days]*	*[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 9-10: 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 9-11: 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 ^{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-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

<u>Metabolite X11519540</u>

Modelling kinetic endpoint

Table 9-12: 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 9-13: 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 9-14: 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 9-15: 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 9-16: 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 9-17: 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 9-18: 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)). The worst case field DT_{50} was used as described in Table 9.4-1. As the compound is not persistent, plateau PEC calculation was not required.

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

Table 9-19: Soil endpoints for sulfoxaflor

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

PEC_{soil} values were calculated using FOCUS guidance[1].

In accordance with the GAP application to ornamentals are considered by the applicant for the calculations to cover worst scenarios (marked in bold font).

Table 9-20: Table of intended protected uses of GF-2626

Crop	Growth stage	Application rate (interval)	Interception (FOCUS, 2012)	Amount reaching soil
Fruiting veg.	BBCH 20-87	1 x 48 g as/ha	70%	14.4 g a.s./ha
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 with 10% interception as worst-case scenario covering all uses.

Table 9-21: Summary of PEC_{soil} values for sulfoxaflor following application to protected crops 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)

[1] FOCUS (1997) Soil persistence models and EU Registration - The Final Report of the Soil Modelling Workgroup of FOCUS (Forum for the Co-ordination of Pesticide Fate Models and their Use) – 29 February 1997.

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 with 10% minimal crop interception by zRMS.
Agreed PECsoil (active substance): IIIA 9.4.1	Initial PECsoil covering all intended use in greenhouse = **0.0576 mg/kg**

IIIA 9.4.1 Initial PECs values

Refer to point IIIA 9.4.1above.

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

Refer to point IIIA 9.4.1above.

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

Refer to point IIIA 9.4.1above.

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

Overall summary

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)). 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, ~~plateau~~ PECaccu values were required. These have been calculated based on plateau concentration over 5 cm as worst-case (no tillage assumed) plus peak single seasons PEC_{soil} based on mixing over 5 cm.

Table 9.5-1 summarises the compounds input parameters

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 occurrence 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. 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 9-22: Agronomic input used for the simulations based on worst case

Compound	Crop	Application Rate (g a.s./ha)	Interception	Correction factor (MW and % occurence in soil)	Application Rate reaching soil (g metabolite /ha)
X11719474	Ornamentals	1x48	10%	1.06	1x45.8
X11519540	Ornamentals	1x48	10%	0.11	1x4.8

Calculated worst case PEC_{soil} values for the proposed uses are presented in Tables 9.5.1-1 to 9.5.1-3.

Table 9-23: Summary of PEC_{soil} values for X11719474 following application to ornamentals (zRMS calculation)

Days from last application or TWA period	Actual PEC_S (mg/kg)	Maximum TWA PEC_S (mg/kg)
Initial	0.0610	-
~~Plateau~~PECaccu (5 cm)	0.127	

Table 9-24: Summary of PEC_{soil} values for X11519540 following application to ornamentals (zRMS calculation)

Days from last application or TWA period	Actual PEC_S (mg/kg)	Maximum TWA PEC_S (mg/kg)
Initial	0.0064	-
~~Plateau~~PECaccu (5 cm)	0.032	

Modelling Comments: IIIA 9.5.1	PECsoil for metabolites were recalculated by zRMS considering max crop interception of 10% for ornamentals.
Agreed PECsoil (metabolites): IIIA 9.5.1	PECaccu for metabolites are used for risk assessment.

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

Refer to point IIIA 9.5.1above.

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

Refer to point IIIA 9.5.1above.

IIIA 9.6 Predicted environmental concentrations in groundwater (PECgw)

Applicant provided PECgw calculations made for outdoor uses to cover the indoor uses. In addition, specific calculations to address the National Requirements of Germany were provided.

However, zRMS considers that assessement of groundwater contamination is not relevant for indoor uses (it is reminded that this dossier was submitted before entry into force of EFSA guidance for protected crops).

The PECgw proposed by applicant are left below for information but were not assessed.

* * * *

Application of sulfoxaflor to protected crops (Tomatoes, Aubergines, Peppers and Cucurbits at 1 x 48 g as/ha, with 70% crop interception and Ornamentals at 1 x 48 g as/ha, with 65% crop interception) was considered for the PEC value calculation for sulfoxaflor and its major groundwater metabolites, X11719474, X11519540 and X11579457. The relevant FOCUS groundwater scenarios and the FOCUS PEARL 4.4.4 and PELMO 5.5.3 models were used. As a worst case, the standard FOCUS scenarios for outdoor uses were used as a surrogate for protected uses. The FOCUS models do not have an ornamental crop included but it can be considered covered by application on apples and tomatoes.

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 ground water scenarios
Document No:	Exponent International Ltd. Report No.: 1402547.UK0-3433
Guidelines:	FOCUS (2001, 2009, 2012).
GLP	No. Not required

Exposure models: FOCUS PEARL 4.4.4 and FOCUS PELMO 5.5.3

Scenarios used: All relevant FOCUS groundwater scenarios

Crops: Tomatoes, Aubergines, Peppers, Cucurbits and Ornamentals

Executive Summary

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 in this exercise was based on the GAP requested for product registration of GF-2626 in the EU for indoor uses on fruiting vegetables and ornamentals. All compound-specific input values were as agreed in the EFSA conclusion (2014).

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 in this exercise was based on the GAP requested for product registration of GF-2626 in the EU for indoor uses on fruiting vegetables and ornamentals.

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

FOCUS crop: Apples
Crop: Ornamentals
Application Rate: 1 x 48 g as/ha
Crop Interception: 65% (BBCH 51-59)
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)
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.

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

As a worst case, the standard FOCUS scenarios for outdoor uses were used as a surrogate for protected uses.

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 9-25: **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 from Tables 9.6.1-2 to 9.6.1-4.

Table 9-26: **PEC_{gw} (µg/l) values for sulfoxaflor and its metabolites, X11719474, X11519540 and X11579457 after application to ornamentals**

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 9-27: **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 9-28: **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

Modelling Comments: IIIA 9.6.1	zRMS considers that assessement of groundwater contamination is not relevant for indoor uses (it is reminded that this dossier was submitted before entry into force of EFSA guidance for protected crops). Please however note that the following comments and conclusions were drawn by zRMS on those calculations which were also submitted in the dRR for field uses in southern zone: 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.
Agreed PECgw (active substance): IIIA 9.6.1	Not relevant for indoor uses.

The following study is provided to address the National Requirements of Germany.

Report:	IIIA1 9.6.1/02, Jarvis, T. and Montesano V., 2014b
Title:	Predicted Environmental Concentrations of Sulfoxaflor (as product GF-2626) and its metabolites in groundwater using the FOCUS PELMO 5.5.3 model with the German national Requirements.
Document No:	Exponent International Ltd. Report No.: 1402547.UK0-5193
Guidelines:	FOCUS (2001, 2009, 2012).
GLP	No. Not required

Exposure models: FOCUS PELMO 5.5.3

Scenarios used: Hamburg and Kremsmünster

Crops: Tomatoes, aubergines, peppers, cucurbits and ornamentals

Executive Summary

Groundwater modelling of sulfoxaflor and its metabolites, X11719474, X11519540 and X11579457 has been undertaken using the Hamburg and Kremsmünster scenarios and the FOCUS PELMO 5.5.3 model. The modelling undertaken in this exercise was based on the GAP requested for uses on tomatoes, aubergines, peppers and cucurbits (strawberries used as surrogate) with an application rate of 1 x 48 g a.s./ha with 70% crop interception and ornamentals with an application rate of 1 x 48 g a.s./ha and 65% crop interception (surrogate crop: pome/stone fruit).

The compound and metabolite parameters used in the assessments were taken from in the EFSA conclusion. Input parameters for sorption and degradation were derived following a statistical evaluation of the dependency of pesticide behaviour with soil properties which was performed in accordance with Holdt *et al*., 2011, and using the recommended ‘Input_Decision_3.3’ tool.

PECgw values for sulfoxaflor were << 0.1 µg/l in both scenarios for all crops.
PECgw values for X11719474 were from 0.794 to 1.252 µg/l.
PECgw values for X11519540 were from 0.385 to 0.645 µg/l.
PECgw values for X11579457 were from 0.658 to 1.583 µg/l.
PECgw derived from bank filtration were calculated using the EXPOSIT 3.0 beta tool and the values were << 0.1 µg/l for sulfoxaflor and its metabolites.

I. MATERIAL AND METHODS

Groundwater modelling of sulfoxaflor and its metabolites, X11719474, X11519540 and X11579457 has been undertaken using the Hamburg and Kremsmünster scenarios and the FOCUS PELMO 5.5.3 model. The modelling undertaken in this exercise was based on the GAP requested for uses on tomatoes, aubergines, peppers, cucurbits and ornamentals

The compound and metabolite parameters used in the assessments are summarised in Table 9.6.1-5. Input parameters for sorption and degradation were derived following a statistical evaluation of the dependency of pesticide behaviour with soil properties which was performed in accordance with Holdt *et al*., 2011, and using the recommended ‘Input_Decision_3.3’ tool. All the information to carry out the statistical evaluation was taken from the EFSA conclusion

Table 9-29: **Sulfoxaflor and metabolites input parameters used in the assessment**

<table>
<tr><th>Parameter</th><th>Compound</th><th colspan="2">Value</th><th colspan="2">Remark</th></tr>
<tr><td rowspan="4">Molecular weight [g/mol]</td><td>Sulfoxaflor</td><td colspan="2">277.3</td><td colspan="2">EFSA conclusion</td></tr>
<tr><td>X11719474</td><td colspan="2">295.3</td><td colspan="2">EFSA conclusion</td></tr>
<tr><td>X11519540</td><td colspan="2">253.2</td><td colspan="2">EFSA conclusion</td></tr>
<tr><td>X11579457</td><td colspan="2">252.3</td><td colspan="2">EFSA conclusion</td></tr>
<tr><td rowspan="4">Solubility in water [mg/L] at 20 ºC</td><td>Sulfoxaflor</td><td colspan="2">568</td><td colspan="2">EFSA conclusion</td></tr>
<tr><td>X11719474</td><td colspan="2">568</td><td colspan="2">EFSA conclusion</td></tr>
<tr><td>X11519540</td><td colspan="2">568</td><td colspan="2">EFSA conclusion</td></tr>
<tr><td>X11579457</td><td colspan="2">568</td><td colspan="2">EFSA conclusion</td></tr>
<tr><td rowspan="4">Vapour pressure [Pa] at 20 ºC</td><td>Sulfoxaflor</td><td colspan="2">$1.4x10^{-6}$</td><td colspan="2">EFSA conclusion</td></tr>
<tr><td>X11719474</td><td colspan="2">$1.4x10^{-6}$</td><td colspan="2">EFSA conclusion</td></tr>
<tr><td>X11519540</td><td colspan="2">$1.4x10^{-6}$</td><td colspan="2">EFSA conclusion</td></tr>
<tr><td>X11579457</td><td colspan="2">$1.4x10^{-6}$</td><td colspan="2">EFSA conclusion</td></tr>
<tr><td rowspan="4">Henry’s law constant [$Pa.m^3.mol^{-1}$] at 20 ºC</td><td>Sulfoxaflor</td><td colspan="2">$6.83x10^{-7}$</td><td colspan="2">EFSA conclusion</td></tr>
<tr><td>X11719474</td><td colspan="2">n.r.</td><td colspan="2">EFSA conclusion</td></tr>
<tr><td>X11519540</td><td colspan="2">n.r.</td><td colspan="2">EFSA conclusion</td></tr>
<tr><td>X11579457</td><td colspan="2">n.r.</td><td colspan="2">EFSA conclusion</td></tr>
<tr><td>Plant uptake factor</td><td>All compounds</td><td colspan="2">0.0</td><td colspan="2">Default value at tier 1 according to German requirements</td></tr>
<tr><td colspan="6">Sorption data</td></tr>
<tr><td rowspan="7">Kf value</td><td>Sulfoxaflor</td><td colspan="2">Calculated with KOC</td><td colspan="2">According to national requirements following evaluation with Input_Decision_3.3</td></tr>
<tr><td>X11719474</td><td colspan="2">Calculated with KOC</td><td colspan="2">For the Kremsmünster scenario</td></tr>
<tr><td>X11519540</td><td colspan="2">Calculated with KOC</td><td colspan="2">For the Kremsmünster scenario</td></tr>
<tr><td>X11719474 (Hamburg)</td><td rowspan="4">Direct Input</td><td>0.38 (horizon 1-3) and 0 (horizon 4-6)</td><td>arithmetic mean, n = 17</td><td rowspan="4">evaluation with Input_Decision_3.3</td></tr>
<tr><td>X11519540 (Hamburg)</td><td>0.26 (horizon 1-3) and 0 (horizon 4-6)</td><td>arithmetic mean, n = 6</td></tr>
<tr><td>X11579457 (Hamburg)</td><td>0.33 (horizon 1-3) and 0 (horizon 4-6)</td><td>arithmetic mean, n = 7 (all soils)</td></tr>
<tr><td>X11579457 (Kremsmünster)</td><td>0.14 (horizon 1-5)</td><td>arithmetic mean, n = 2 (neutral/alkaline soils)</td></tr>
<tr><td rowspan="4">K_{OC} value [mL/g]</td><td>Sulfoxaflor</td><td colspan="2">35</td><td colspan="2">arithmetic mean of n = 17 values</td></tr>
<tr><td>X11719474</td><td colspan="2">30</td><td colspan="2">arithmetic mean of n = 17 values</td></tr>
<tr><td>X11519540</td><td colspan="2">14</td><td colspan="2">arithmetic mean of n = 6 values</td></tr>
<tr><td>X11579457</td><td colspan="2">21</td><td colspan="2">arithmetic mean of n = 7 values</td></tr>
<tr><td rowspan="5">Freundlich exponent</td><td>Sulfoxaflor</td><td colspan="2">0.965</td><td colspan="2">arithmetic mean of n = 17 values</td></tr>
<tr><td>X11719474</td><td colspan="2">0.993</td><td colspan="2">arithmetic mean of n = 17 values</td></tr>
<tr><td>X11519540</td><td colspan="2">1.012</td><td colspan="2">arithmetic mean of n = 6 values</td></tr>
<tr><td>X11579457 (Hamburg)</td><td colspan="2">0.817</td><td colspan="2">arithmetic mean of n = 7 values</td></tr>
<tr><td>X11579457</td><td colspan="2">0.945</td><td colspan="2">arithmetic mean of n = 2 values (neutral/alkaline</td></tr>
</table>

Parameter	Compound	Value	Remark
	(Kremsmünster)		soils)
Transformation			
DT_{50} [days]	Sulfoxaflor	0.1	geometric mean normalised $DegT_{50,lab}$ n = 4
	X11719474	76.6	geometric mean normalised $DegT_{50,field}$ n = 7
	X11519540	40.5	geometric mean normalised $DegT_{50,field}$ n = 4
	X11579457	186.7	geometric mean normalised $DegT_{50,lab}$ n = 4
Formation fraction	X11719474	1 from sulfoxaflor	EFSA conclusion
	X11519540	0.5 from X11719474	EFSA conclusion
	X11579457	0.5 from X11719474	EFSA conclusion

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

FOCUS crop: Apples
Crop: Ornamentals
Application Rate: 1 x 48 g as/ha
Crop Interception: 65% (BBCH 51-59)
Application Timing: 1st April

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

The FOCUS crop Tomatoes does not have Hamburg and Kremsmünster as scenarios; therefore, FOCUS crop Strawberries was considered as surrogate.

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

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

Additionally, based on the applications on ornamentals the worst-case bank filtration PECgw values were calculated using the Exposit 3.0 beta Excel spreadsheet. In this case, the application rates of the metabolites were calculated using the ratio of the molecular weights and the maximum formation observed in soil. The values used in Exposit 3.0 beta are shown in Table 9.6.1-6.

Table 9-30:**Calculation of the application rate for metabolites for the bank filtration PECgw calculation**

Compound	**X11719474**	**X11519540**	**X11579457**
Ratio of molecular weight	1.06	0.91	0.91
Max. % observed in soil	100	12.2	9.2
Application rate for pome/stone fruit (interception not considered)	1 x 50.9 g/ha	1 x 5.3 g/ha	1 x 4.0 g/ha

II. RESULTS AND DISCUSSION

PECgw values from FOCUS PELMO 5.5.3 for sulfoxaflor and its metabolites are shown in Table 9.6.1-7 to 9.6.1-9. The worst bank filtration PECgw, based on worst case application on pome/stone fruit was calculated and is shown in Table 9.6.1-10.

Table 9-31: **PEC_{gw} (µg/l) values for sulfoxaflor and its metabolites, X11719474, X11519540 and X11579457 after application to ornamentals**

Model	**PELMO 5.5.3**			
LOCATION	**Sulfoxaflor**	**X11719474**	**X11519540**	**X11579457**
HAMBURG	< 0.001	1.252	0.645	0.946
KREMSMUENSTER	< 0.001	1.201	0.581	1.583

Table 9-32: **PEC_{gw} (µg/l) values for sulfoxaflor and its metabolites, X11719474, X11519540 and X11579457 after application to tomato, aubergines, peppers and cucurbits (1st March) – Strawberries used as surrogate**

Model	**PELMO 5.5.3**			
LOCATION	**Sulfoxaflor**	**X11719474**	**X11519540**	**X11579457**
HAMBURG	< 0.001	0.905	0.451	0.667
KREMSMUENSTER	< 0.001	0.799	0.389	1.106

Table 9-33: **PEC_{gw} (µg/l) values for sulfoxaflor and its metabolites, X11719474, X11519540 and X11579457 after application to tomato, aubergines, peppers and cucurbits (1st May) – Strawberries used as surrogate**

Model	**PELMO 5.5.3**			
LOCATION	**Sulfoxaflor**	**X11719474**	**X11519540**	**X11579457**
HAMBURG	< 0.001	0.833	0.444	0.658
KREMSMUENSTER	< 0.001	0.794	0.385	1.087

Table 9-34: The worst bank filtration PEC_{gw} (µg/l) values for sulfoxaflor and its metabolites after application to ornamentals using EXPOSIT 3.0 beta

	Sulfoxaflor	**X11719474**	**X11519540**	**X11579457**
PECgw (ornamentals)	0.000 µg/l	0.002 µg/l	0.000 µg/l	0.000 µg/l
Group	4	2	2	2

III. CONCLUSION

PECgw values for sulfoxaflor were << 0.1 µg/l in both scenarios for all crops.
PECgw values for X11719474 were from 0.794 to 1.252 µg/l.
PECgw values for X11519540 were from 0.385 to 0.645 µg/l.
PECgw values for X11579457 were from 0.658 to 1.583 µg/l.
PECgw derived from bank filtration were calculated using the EXPOSIT 3.0 beta tool and the values were << 0.1 µg/l for sulfoxaflor and its metabolites.

Modelling Comments: IIIA 9.6.1	zRMS considers that assessement of groundwater contamination is not relevant for indoor uses (it is reminded that this dossier was submitted before entry into force of EFSA guidance for protected crops).Calculations were not assessed. In addition it is reminded that calculations to address National Requirements should be provided in national addendum.
Agreed PECgw (active substance): IIIA 9.6.1	

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

FATE AND BEHAVIOUR IN WATER

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 9-35: 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**	

PECsw CALCULATIONS

Calculations based on 0.1% losses

GF-2626 is applied to the glasshouse crops tomatoes, aubergines, peppers, cucurbits and ornamentals with a maximum application rate of 1 x 48 g as/ ha.

Because glasshouse or indoor application is proposed for those crops, FOCUS surface water simulations are not relevant. In accordance with the standard Dutch glasshouse model, a loss of 0.1% of the active substance to the standard surface water body (100 m long, 1 m wide, 30 cm deep) was assumed, in order to calculate the initial concentration in surface water.

An initial PECsw value of **0.016 µg/l** was calculated for sulfoxaflor.

Modelling Comments: IIIA 9.7	This dossier is submitted before the entry into force of the Guidance Document on protected crops (SANCO/12184/2014 – rev. 5.1 -14 July 2015). Thus PECsw calculation based on 0.1% losses is considered acceptable.
Agreed PECsw (active substance): IIIA 9.7	PECsw of **0.016 µg/l** can be used for risk assessement (see section 6). It is noted here that, following risk envelopp approach, the TER calculation in section 6 were calculated with PECsw calculated with TOXSWA according to the Dutch specific requirement (being higher than those validated by zRMS). No update of the TER were deemed necessary in section 6.

<u>Calculations for specific requirements of the Netherlands</u>

To cover the specific requirements of the Netherlands, TOXSWA simulations have also been undertaken as follows. Calculations to address specific national requirements should be presented in national addendum. They are reported below for information but were not assessed by zRMS.

Report:	KIIIA1 9.7/01, Jarvis, T. & Montesano, V. (2014c)
Title:	Predicted Environmental Concentrations of Sulfoxaflor (as product GF-2626) and its Metabolites in Surface Water using the TOXSWA GUI Model and the National Guidelines of The Netherlands
Document No:	1402547.UK0-13831402547
Guidelines:	Ctbg 2013[2],
GLP	No (not applicable - calculation)

Executive Summary

Surface water modelling of sulfoxaflor and its metabolite X11719474 has been undertaken using the TOXSWA GUI model (Version 1.0) and the National Guidelines of The Netherlands. The modelling was based on the GAP requested for product registration in The Netherland for uses on fruiting vegetables and ornamentals. From the GAP, the worst cases application rate for indoor uses was 1x 48 g a.s./ha. 0.1% drift was considered for indoor uses according with the Dutch guidance (2011).
After spring and autumn application, the initial maximum PEC_{sw} value for sulfoxaflor was 0.023 µg/l. The corresponding values for the metabolite X11719471 was 0.017 µg/l.

[2] Ctbg (2013), Evaluation Manual for the Authorisation of Plant protection products and Biocides according to Regulation (EC) No 1107/2009; Chapter 6 Fate and behaviour in the environment: behaviour in surface water and sediment. Version 2.0, January 2013.

Materials

Not applicable - simulation modelling.

Study Design and Methods

The TOXSWA GUI model (Version 1.0) was used to model the surface water exposure. For the GAP uses, application on ornamentals and fruiting vegetables with application rates of 1x 48 g a.s./ha were simulated. 0.1% spray drift was considered for indoor uses (fruiting vegetables and ornamentals) according with the Dutch guidance (2013).
To calculate the initial PECsw for the metabolite X11719474, correction of the parent value based on molecular weight and maximum occurrence in water/sediment studies was used. X11519540 is a soil metabolite, which is not found in water/sediment studies. Consequently no assessment is required.
The input parameters for sulfoxaflor and its metabolites are shown in Table 9.7-1.

Table 9-36: Input parameters used for modelling

Parameter	**Sulfoxaflor[1]**	
Entry routes into surface water	1% Spray drift (downward spraying technique)	
Molecular weight [g mol^{-1}]	277.3	
Water solubility [mg L^{-1}] (20°C)	568	
Vapour pressure [Pa] (20°C)	$1.4x10^{-6}$	
Exchange coefficient in liquid phase [m/d]*	1.91	
Exchange coefficient in gas phase [m/d]*	183.44	
$K_{f,oc}$ [mL g^{-1}]	35	
$K_{f,om}$ [mL g^{-1}]	20.3	
1/n [-]	0.96	
DT_{50} water [d] (20^{o}C)	57.08	
DT_{50} sediment [d] (20^{o}C)	68.63	
TOXSWA: activation energy [J mol^{-1}]**	65.4	
Metabolites	X11719474	X11519540†
Molecular Weight [g/mol]	295.3	253.2
Maximum formed in aquatic system [%]	70.9	0

[1] EFSA Journal 2014;12(5):3692
* Calculated with the exchange coefficient calculator (spreadsheet)
** Updated value
† This metabolite is only formed in soil; therefore, no assessment is required.

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

Crop:	Ornamentals/Fruiting vegetables
Application Rate:	1x 48 g a.s./ha
Scenarios:	Netherlands standard autumn and Netherlands standard spring
Drift:	0.1% (glasshouse application)

Each simulation was run for 30 days.

Results

The initial PEC_{sw} and PEC_{sed} value for sulfoxaflor after spring and autumn application to ornamentals/ fruiting vegetables are summarised in Table 9.7-2 and 9.7-3.
The initial PEC_{sw} value for sulfoxaflor metabolites are summarised in Table 9.7-4.
.

Table 9-37: PEC_{SW} for sulfoxaflor in the edge-of-field ditch following spring/autumn application

Crop	**Ornamentals/Fruiting vegetables (1 x 48 g a.s./ha)**	
Drift %	**0.1**	
Time	**Spring (µg/l)**	**Autumn (µg/l)**
Initial	0.0229	0.0229
TWA 4d	0.0220	0.0168
TWA 21d	0.0204	0.0032
TWA 28d	0.0195	0.0024

Table 9-38: PEC_{SED} for sulfoxaflor in the edge-of-field ditch following spring/autumn application

Substance	**Crop**	**Rate a.s. [kg/ha]**	**Freq.**	**drift [%]**	**PIECsediment [g a.s./m³ sediment] ***		**PIECsediment [mg a.s./kg sediment DW]****	
					spring	**autumn**	**spring**	**autumn**
Sulfoxaflor	Ornamentals/ Fruiting veg.	0.048	1	0.1	0.00002[2]	0.00002[1]	0.0003	0.0003

* TOXSWA output
** calculated as (PECsed in g/m^3 / 80 kg/m^3)*1000 (conversion of g/kg to mg/kg)
[1] 2.5 days after application
[2] 11.5 to 17 days after application

Table 9-39: Initial PEC_{SW} for sulfoxaflor metabolites in the edge-of-field ditch following spring/autumn application

Crop	**Ornamentals/Fruiting vegetables (1 x 48 g a.s./ha)**	
Drift %	**0.1**	
Time	**Spring (µg/l)***	**Autumn (µg/l)***
X11719474	0.0172	0.0172

Conclusion

Predicted environmental concentrations in surface waters (PEC_{sw}) have been generated in accordance with The National Guidance of the Netherlands using the TOXSWA GUI model (Version 1.0). After spring or autumn application, the initial maximum PEC_{sw} value for sulfoxaflor was 0.023 µg/l. The corresponding values for the metabolite X11719474 was 0.017 µg/l.

Jarvis & Montesano (2014c)

Modelling Comments: IIIA 9.7	Applicant provided calculations to address national requirements of Netherlands using the TOXSWA GUI model. They should be presented in national addendum. They are reported for information but were not assessed by zRMS.
Agreed PECsw (active substance): IIIA 9.7	-

IIIA 9.7.1 Initial PECsw value for static water bodies

Refer to point IIIA 9.7 above.

IIIA 9.7.2 Initial PECsw value for slow moving water bodies

Refer to point IIIA 9.7 above.

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

Refer to point IIIA 9.7above.

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 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 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 above.

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

GF-2626 is applied to the glasshouse crops tomatoes, aubergines, peppers, cucurbits and ornamentals with a maximum application rate of 1 x 48 g as/ ha. Because glasshouse or indoor application is proposed for those crops, FOCUS surface water simulations are not relevant. In accordance with the standard Dutch glasshouse model, a loss of 0.1% of the active substance to the standard surface water body (100 m long, 1 m wide, 30 cm deep) was assumed, in order to calculate the initial concentration in surface water.

PECsw values for the major water/sediment systems metabolites X11719474 were calculated by correcting initial parent PECsw values of 0.016 µg/l, for the molecular weight and the maximum occurrence of the metabolites in whole system water/ sediment studies.

X11519540 is a soil metabolite that is not formed in water/sediment studies; therefore, no calculation is required.

The calculated initial PECsw value for X11719474 is shown in Table 9.8-1.

Table 9-40: **Initial PECsw values for sulfoxaflor metabolites**

Compound	Correction factor for MW	% occurence in water/sediment system	Initial PECsw
X11719474	1.06	70.9	0.012 µg/l

To cover the specific requirements of the Netherlands, TOXSWA simulations have also been undertaken. Please refer to point 9.7 above.

Modelling Comments: IIIA 9.8	Applicant proposed calculation for the water metabolite X11719474 based on the PECsw calculated for parent corrected with molar ratio and maximum occurrence of the metabolite in water. This is agreed and the PECsw **0.012 µg/l** for metabolite o X11719474 is used for risk assessment.
Agreed PECsw (metabolites): IIIA 9.8	PECsw of **0.012 µg/l** can be used for risk assessement for metabolite X11719474 (see section 6).

IIIA 9.8.1 Initial PECsw value for static water bodies

Refer to point IIIA 9.8 above.

IIIA 9.8.2 Initial PECsw value for slow moving water bodies

Refer to point IIIA 9.8 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 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 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 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 above.

IIIA 9.8.7 Additional field testing

To cover the specific requirements of the Netherlands these points have been added. zRMS notes that this should have been reported in a national addendum. Data reported below were not evaluated.

9.8.7.1 Monitoring data groundwater

There are no data available regarding the presence of the substance sulfoxaflor or its metabolites in groundwater.

9.8.7.2 Monitoring data surface water

There are no data available in the Pesticide Atlas regarding the presence of the substance sulfoxaflor or its metabolites in surface water.

9.8.7.3 Drinking water criterion

It follows from the decision of the Court of Appeal on Trade and Industry of 19 August 2005 (Awb 04/37 (General Administrative Law Act)) that when considering an application, the Ctgb should, on the basis of the scientific and technical knowledge and taking into account the data submitted with the application, also judge the application according to the drinking water criterion ‘surface water intended for drinking water production’.

The assessment methodology followed is developed by the WG implementation drinking water criterion and outlined in Alterra report 1635[3].

[3] Adriaanse et al. (2008). Development of an assessment methodology to evaluate agricultural use ofplant

protection products for drinking water production from surface waters - A proposal for the registration procedure

Substances are categorized as new substances on the Dutch market (less than 3 years authorisation) or existing substances on the Dutch market (authorised for more than 3 years).

- For new substances, a pre-registration calculation is performed.
- For existing substances, the assessment is based on monitoring data of VEWIN (drinking water board).
  - If for an existing substance based on monitoring data no problems are expected by VEWIN, Ctgb follows this VEWIN assessment.
  - If for an existing substance based on monitoring data a potential problem is identified by VEWIN, Ctgb assesses whether the 90th percentile of the monitoring data meet the drinking water criterion at each individual drinking water abstraction point.

As sulfoxaflor is a new active substance, there are no data available regarding its presence in surface water at drinking water abstraction points.

The decision tree as outlined in Alterra report 1635 (2010) should be followed. The tool DROPLET (described in Alterra report 2020, 2010) to calculate concentrations on drinking water abstraction points is used for the assessment.

The following data are used for the assessment:

Input in SWASH:

Substance input parameters:

Molecular mass:	277.3 g/mol
Saturated vapour pressure:	1.4×10^{-6} Pa (20 °C)
Solubility in water:	568 mg/L (20 °C)
Arithmetic mean Kom:	20.3 L/kg
Arithmetic mean 1/n:	0.96
Factor plant uptake:	0.0 (default, 0.5 only for systemic parents)
Geometric mean DT50 Water (DT50 system):	57.08 days
Geometric mean field/lab DT50 Soil:	0.078 days
DT50 Sediment:	68.6 days
DT50 Crop:	10 days (default)

Scenario (Focus wizard):

Selected crop: pome/stone fruit early application*
Selected scenario: D3
Input in FOCUS-TOXSWA: NL Drift value 0.1% (protected crops)

in the Netherlands. Alterra-Report 1635

<u>Input in DROPLET:</u> Selected crop: tree nurseries * $f_{market:}$ 0.4 (default) $f_{additional\ dilution}$: 1 for all abstraction points, except for Andijk: 0.17 (default) Other parameters: standard settings SWASH 2.1 and DROPLET 1.0

***** More than one FOCUS-SW D3-crops are connected to the same GeoPEARL crop grouping, but only the FOCUS-SW D3-crop with the highest PEC_FOCUS_NL, D3 is used for the calculation of the PEC_Tier I at the abstraction points. As vegetables fruiting do not have a D3 scenario, it was considered pome/stone fruit (early application) as a surrogate crop with the worst case application rate of 1 x 48 g a.s./ha.

Results are summarised in Tables 9.8.7.3-1 for the predicted concentrations for each drinking water abstraction point.

Table 9-41: **Predicted concentrations at drinking water abstraction points in The Netherlands as calculated by DROPLET 1.0 for pome/stone fruit early application (surrogate of fruiting vegetables)**

Drinking water abstraction point	FOCUS D3 crop	$f_{useintensity}$ (-)	Relative Cropped Area (-)	$PEC_{drinking\ water\ abstraction\ point}$ (µg/L)
De Punt	Pome_stone_fruit_early_applns	0.000124	0.000622	0.000
Andijk	Pome_stone_fruit_early_applns	0.000258	0.001292	0.000
Nieuwegein	Pome_stone_fruit_early_applns	0.000424	0.002119	0.000
Heel	Pome_stone_fruit_early_applns	0.000189	0.000945	0.000
A'dam Rijnkanaal	Pome_stone_fruit_early_applns	0.000347	0.001737	0.000
Brakel	Pome_stone_fruit_early_applns	0.00112	0.0056	0.000
Petrusplaat	Pome_stone_fruit_early_applns	0.001064	0.005318	0.000
Twentekanaal	Pome_stone_fruit_early_applns	0.000229	0.001144	0.000
Scheelhoek	Pome_stone_fruit_early_applns	0.000861	0.004307	0.000
Bommelerwaard (subarea of Brakel)	Pome_stone_fruit_early_applns	0.000136	0.000679	0.000

Results show that for all drinking water abstraction points the predicted concentrations are below 0.1 µg/L. Therefore, the application of sulfoxaflor is not expected to exceed the drinking water criterion. The standards for surface water destined for the production of drinking water are met.

Modelling Comments: IIIA 9.8.7.3	Specific NL requirements. Not assessed by zRMS.
Agreed PEC IIIA 9.8.7.3	

IIIA 9.9 Fate and behaviour in air

Vapour pressure (at 20 °C) [Pa]	1.4×10^{-6} (purity: 99.7 %)

Henry's Law Constant [Pa m3/mol]	6.83×10^{-7} at 20 °C (pH 7)
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

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.

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 ground water scenarios. Exponent International Ltd. Report No.: 1402547.UK0-3433 Non-GLP, unpublished	Y	N	Dow agroscience
IIIA 9.6.1/02	Jarvis, T. & Montesano, V.	2014b	Predicted Environmental Concentrations of Sulfoxaflor (as product GF-2626) and its metabolites in groundwater using the FOCUS PELMO 5.5.3 model with the German National Requirements Exponent International Ltd. Report No.: 1402547.UK0-5193 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 9.7/01	Jarvis, T. & Montesano, V.	2014c	Predicted Environmental Concentrations of Sulfoxaflor (as product GF-2626) and its Metabolites in Surface Water using the TOXSWA GUI Model and the National Guidelines of The Netherlands Exponent International Ltd. Report No.: 1402547.UK0-1383 Non-GLP, unpublished	Y	N	Dow agroscience

APPENDIX 2: GAP

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

Country	Crop
Austria	Aubergines (incl. Pepinos), Bulbs, Ornamentals, Flowers, Cucurbits (Cucumber, Water Melon, Zuccini, Melon), Pepper (incl. Chilli pepper), Tomatoes
Belgium	Tomatoes, Pepper (incl. Chilli pepper), Aubergines (incl. Pepinos), Cucurbits (Cucumber, Water Melon, Zuccini, Melon), Bulbs, Ornamentals, Flowers
Bulgaria	Tomatoes, Pepper (incl. Chilli pepper), Aubergines (incl. Pepinos), Cucurbits (Cucumber, Water Melon, Zuccini, Melon), Bulbs, Ornamentals, Flowers
Croatia	Tomatoes, Pepper (incl. Chilli pepper), Aubergines (incl. Pepinos)
Cyprus	Tomatoes, Pepper (incl. Chilli pepper), Aubergines (incl. Pepinos)
France	Tomatoes, Pepper (incl. Chilli pepper), Aubergines (incl. Pepinos), Cucurbits (Cucumber, Water Melon, Zuccini, Melon) Bulbs, Ornamentals, Flowers
Germany	Aubergines (incl. Pepinos), Bulbs, Ornamentals, Flowers, Cucurbits (Cucumber, Water Melon, Zuccini, Melon), Pepper (incl. Chilli pepper), Tomatoes
Greece	Tomatoes, Pepper (incl. Chilli pepper), Aubergines (incl. Pepinos), Cucurbits (Cucumber, Water Melon, Zuccini, Melon), Bulbs, Ornamentals, Flowers
Ireland	Tomatoes, Pepper (incl. Chilli pepper), Aubergines (incl. Pepinos), Cucurbits (Cucumber, Water Melon, Zuccini, Melon), Bulbs, Ornamentals, Flowers
Italy	Tomatoes, Pepper (incl. Chilli pepper), Aubergines (incl. Pepinos), Cucurbits (Cucumber, Water Melon, Zuccini, Melon), Bulbs, Ornamentals, Flowers
Malta	Tomatoes, Pepper (incl. Chilli pepper), Aubergines (incl. Pepinos)
Netherlands	Tomatoes, Pepper (incl. Chilli pepper), Aubergines (incl. Pepinos), Cucurbits (Cucumber, Water Melon, Zuccini, Melon), Bulbs, Ornamentals, Flowers
Poland	Aubergines (incl. Pepinos), Bulbs, Ornamentals, Flowers, Cucurbits (Cucumber, Water Melon, Zuccini, Melon), Pepper (incl. Chilli pepper), Tomatoes
Portugal	Tomatoes, Pepper (incl. Chilli pepper), Aubergines (incl. Pepinos), Cucurbits (Cucumber, Water Melon, Zuccini, Melon), Bulbs, Ornamentals, Flowers
Romania	Tomatoes, Pepper (incl. Chilli pepper), Aubergines (incl. Pepinos)
Spain	Tomatoes, Pepper (incl. Chilli pepper), Aubergines (incl. Pepinos), Cucurbits (Cucumber, Water Melon, Zuccini, Melon), Bulbs, Ornamentals, Flowers
UK	Tomatoes, Pepper (incl. Chilli pepper), Aubergines (incl. Pepinos), Cucurbits (Cucumber, Water Melon, Zuccini, Melon), Bulbs, Ornamentals, Flowers

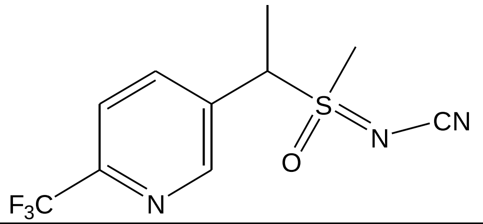
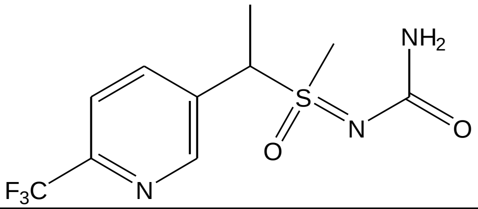
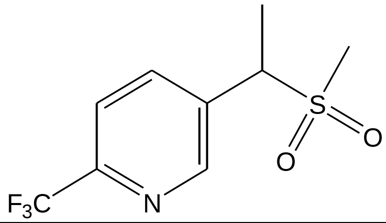
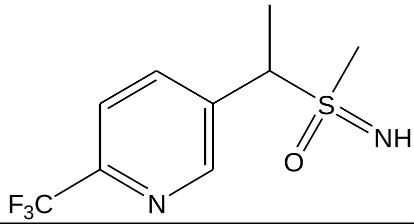
Crop and/or situation (a)	Member State or Country	Product Name	F or G (b)	Pests or Group of pests controlled (c)	Formulation		Application			Application rate per treatment			PHI days (k)	Remarks (l)
					Type (d-f)	Conc. of a.s. (i) g/L	Method Kind (f-h)	Growth stage (j)	Number min max	kg as/hl min max	Water (l/ha) min max	kg as./ha min max		
Aubergines (incl. Pepinos)	All zones (AT, BE, BG, HR, CY, FR, DE, EL, IE, IT, MA,	GF-2626	G	Aphids, Whiteflies	SC	120 g/L	Ground applied foliar spray, broadcast	BBCH 20-87 All year	1-2 (7 days min interva	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	kg as/hl min max	Water (l/ha) min max	kg as./ha min max		
	NL, PT, RO, ES, UK, PL)								l)					a.s./hawith a minimum 7 days interval or only one application of 0.048 g a.s./ha.
Bulbs, Ornamentals, Flowers	All zones (AT, BE, BG, FR, DE, EL, IE, IT, NL, PT, ES, UK, PL)	GF-2626	G	Aphids, Whiteflies	SC	120 g/L	Ground applied foliar spray, broadcast	BBCH 12-59 All year	1-2 (7 days min interval)	0.0012-0.024	200 - 2000	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 a.s./hawith a minimum 7 days interval or only one application of 0.048 g a.s./ha.
Cucurbits (edible peel – cucumbers, courgettes, gherkins; inedible peel – melons, pumpkins/ squash, Zuccini, watermelons)	All zones (AT, BE, BG, FR, DE, EL, IE, IT, NL, PT, RO, ES, UK, PL)	GF-2626	G	Aphids, Whiteflies	SC	120 g/L	Ground applied foliar spray, broadcast	BBCH 20-87 All year	1-2 (7 days min interval)	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 a.s./hawith a minimum 7 days interval or only one application of 0.048 g a.s./ha.
Pepper (incl. Chilli pepper)	All zones (AT, BE, BG, HR, CY, FR, DE, EL, IE, IT, MA,	GF-2626	G	Aphids, Whiteflies	SC	120 g/L	Ground applied foliar spray, broadcast	BBCH 20-87 All year	1-2 (7 days min interva	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	kg as/hl min max	Water (l/ha) min max	kg as./ha min max		
	NL, PT, RO, ES, UK, PL)								l)					a.s./hawith a minimum 7 days interval or only one application of 0.048 g a.s./ha.
Tomatoes	All zones (AT, BE, BG, HR, CY, FR, DE, EL, IE, IT, MA, NL, PT, RO, ES, UK, PL)	GF-2626	G	Aphids, Whiteflies	SC	120 g/L	Ground applied foliar spray, broadcast	BBCH 20-87 All year	1-2 (7 days min interval)	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 a.s./hawith a minimum 7 days interval or only one application of 0.048 g a.s./ha.

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

EC (2000), Guidance Document on Persistence in Soil, Doc 9188/VI/97 rev. 8, 12.07.2000

FOCUS (1997), Soil persistence models and EU registration, Doc. 7617/VI/96, 29.2.97.

FOCUS (2006) “Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration” Report of the FOCUS Work Group on Degradation Kinetics, EC Document Reference Sanco/10058/2005 version 2.0, 434 pp

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 (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 (2014). Generic guidance for Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration, Version: 1.1 Date: 18 December 2014

FOCUS (2014). Assessing Potential for Movement of Active Substances and their Metabolites to Ground Water in the EU. Report of the FOCUS Ground Water Work Group, EC Document Reference Sanco/13144/2010 version 3, October 2014, 613 pp.

SANCO (2011) Guidance document on the preparation and submission of dossiers for plant protection products according to the “risk envelope approach” SANCO/11244/2011 rev. 5, 14 March 2011