REGISTRATION REPORT

Part B
Section 6: Ecotoxicological Studies

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

Table of Contents

IIIA 10 ECOTOXICOLOGICAL STUDIES

Introduction

This document summarises the ecotoxicological effects of the plant protection product GF-2626 containing the active substance sulfoxaflor, and where appropriate, the active substance and potentially relevant metabolites and evaluates the potential risk to various representatives of terrestrial, aquatic and soil organisms. A risk assessment according to Uniform Principles is provided which demonstrates that use of the product in accordance with the proposed label does not represent an unacceptable risk to the environment.

Sulfoxaflor is a new active substance which has been approuved since 18/08/2015 in the EU. Ireland (Pesticide Registration and Control Division, PRCD) is the rapporteur Member State (RMS). A dossier for the active substance was submitted by Dow AgroSciences, under Regulation (EC) 1107/2009, to the RMS in July 2011.

The active substance submission followed a zonal approach where the evaluation was shared by four Member States participating under a work-share umbrella as follows: Ireland - RMS, lead reviewer for the sections Toxicology, Residues and Metabolism along with coordination of the work-share project. France: Lead reviewer for the sections Identity/Physical-Chemical properties, Methods of Analysis and Efficacy/Biology. Poland: Lead reviewer for the section Environmental Fate. Czech Republic: Lead reviewer for the section Ecotoxicology.

The Draft Assessment Report (DAR) on sulfoxaflor was finalised and distributed by Ireland in November 2012, with a recommendation for approval of the active substance according to Regulation (EC) 1107/2009. The EFSA peer review process was conducted and the EFSA conclusion was published in May 2014.

Dow AgroSciences submitted an EU MRL dossier to the RMS, Ireland, in April 2011. The EU MRL evaluation was integrated with the active substance evaluation under 1107/2009. The adoption of MRL/Import tolerances was therefore aligned with the same timing as that of the active substance approval.

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 proposed zonal RMS for Central Zone and Southern Zone are Ireland and France respectively.

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 #-1.

Table #-1: Details for the active substance

Active Substance	Approval Regulation	Commission Review Report	EFSA Scientific Report
Sulfoxaflor	Reg. (EU) 2015/1295 (27 July 2015)	SANTE/10665/2015 rev 2 (29 May 2015)	EFSA Journal 2014; 12(5):3692

Information on the detailed composition of GF-2626 can be found in the confidential dossier of this submission (Registration Report - Part C).

According to Regulation (EU) 2015/1295, the applicant shall submit confirmatory information as regards:

(a) the risk to honey bees via the different routes of exposure, in particular nectar, pollen, guttation fluid and dust;

(b) risk to honey bees foraging in nectar or pollen in succeeding crops and flowering weeds;

(c) the risk to pollinators other than honey bees;

(d) the risk to bee brood.

The applicant shall submit that information to the Commission, the Member States and the Authority by 18 August 2017.

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 10-2. This section for GF-2626 includes glasshouse uses on fruiting vegetables and ornamentals. The application rate is increased (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 10-2.

Table 10-2: 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
			Stage BBCH	Max.	Interval	g a.s./ha
				Number	(days)	max
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
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
Cucurbits (edible peel – cucumbers, courgettes, gherkins)	AT, BE, DE, IE, NL, UK, BG, EL, ES, FR, IT, PT	G	BBCH 20-87	1	-	48
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
Ornamentals	AT, BE, DE, IE, NL, UK, BG, EL, ES, IT, PT	G	BBCH 12-59	1	-	48

F, G, I = Field, glasshouse, indoor
N, S = Northern zone and Southern Zones

Appendix 1 of this document contains the list of references included in this document for support of the evaluation.

Appendix 2 of this document is the table of intended uses for GF-2626

Table 10-3: Agreed EU physical-chemical properties for sulfoxaflor used in this evaluation (EFSA Journal 2014; 12(5):3692)

Property	**Sulfoxaflor**
Molar mass	277.3 g/mol
Molecular formula	C_{10} H_{10} F_3 N_3 O S
Solubility in water	At 20°C, 99.7%: pH 5: 1380 mg/L pH 7: 568 mg/L pH 9: 551 mg/L
Vapour pressure	1.4 x 10^{-6} Pa (20°C, 99.7%)
log P_{OW}	At 20°C, 99.7%: pH 5: 0.806 pH 7: 0.802 pH 9: 0.799
Henry's Law Constant	At 20°C: Unbufferred: 5.77 10^{-7} Pa.m^3/mol pH 5: 2.81 10^{-7} Pa.m^3/mol pH 7: 6.83 10^{-7} Pa.m^3/mol pH 9: 7.05 10^{-7} Pa.m^3/mol
Photolytic stability	Compound is not prone to direct (in sterile buffered solution) and to direct and indirect (in natural water) aqueous photolysis
Hydrolytic stability	Compound hydrolytically stable at pH=5, pH=7 and pH=9

Consideration of metabolites

Table 10-4: 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 10.1 Effects on Birds

The uses of GF-2626 on fruiting vegetables and ornamentals grown under protection will not lead to significant exposure of natural populations of birds, thus the risk to this wildlife group is considered to be negligible.

IIIA 10.1.1 Acute toxicity exposure ratio (TER_A)

Not required.

IIIA 10.1.2 Short and long-term toxicity exposure ratios (TER_{ST} and TER_{LT})

Not required.

IIIA 10.1.3 Baits: Concentration of active substance in bait in mg/kg

Not required.

IIIA 10.1.4 Pellets, granules, prills or treated seed

Not required.

IIIA 10.1.5 Size and shape of pellet, granule or prill

Not required.

IIIA 10.1.6 Acute toxicity of the formulation

Not required.

IIIA 10.1.7 Supervised cage or field trials

Not required.

IIIA 10.1.8 Acceptance of bait, granules or treated seeds (palatability testing)

Not required.

IIIA 10.1.9 Effects of secondary poisoning

Not required.

IIIA 10.2 Effects on Aquatic Organisms

Overall summary

The EU agreed endpoints for the effects of sulfoxaflor, its potentially relevant metabolites and GF-2626 to aquatic life are listed in Tables 10.2-1 and 10.2-2. No additional data have been submitted with this dossier.

Table 10.2-1: EU Endpoints - Toxicity of sulfoxaflor to aquatic species

Compound	Test species	Endpoint	EU agreed endpoints* (mg/L)
Fish			
Sulfoxaflor	*Cyprinodon variegatus*	96-h LC_{50}	**266 (mm)**
X11719474	*Oncorhynchus mykiss*	96-h LC_{50}	**>478 (mm)**
X11519540	*Oncorhynchus mykiss*	96-h LC_{50}	**>330 (mm)**
Sulfoxaflor	*Cyprinodon variegatus*	38-d NOEC	**1.21 (mm)**
Invertebrates			
Sulfoxaflor	*Daphnia magna*	48-h EC_{50}	**>399 (mm)**
X11719474	*Daphnia magna*	48-h EC_{50}	**>205 (mm)**
X11519540	*Daphnia magna*	48-h EC_{50}	**>350 (mm)**
Sulfoxaflor	*Daphnia magna*	21-d NOEC	**12.5 (nom)**
Sulfoxaflor	*Americamysis bahia*	96-h LC_{50}	**0.643 (mm)**
X11719474	*Americamysis bahia*	96-h LC_{50}	**>114 (mm)**
X11519540	*Americamysis bahia*	96-h LC_{50}	**>120 (mm)**
Sulfoxaflor	*Americamysis bahia*	28-d NOEC	**0.114 (mm)**
X11719474	*Americamysis bahia*	28-d NOEC	**2.12 (mm)**
Sulfoxaflor	*Chironomus dilutus*	96-h LC_{50}	**0.622 (mm)**
Sulfoxaflor	*Chironomus dilutus*	10-d LC_{50}	**0.119 mg/kg sediment (mm)**
X11719474	*Chironomus dilutus*	96-h LC_{50}	**>281 (mm)**
X11519540	*Chironomus dilutus*	96-h LC_{50}	**>360 (mm)**
Sulfoxaflor	*Chironomus riparius*	28-d NOEC	**0.0384 (mm)**

Compound	Test species	Endpoint	EU agreed endpoints* (mg/L)
X11719474	*Chironomus riparius*	28-d NOEC	**10.4 (mm)**
X11519540	*Chironomus riparius*	28-d NOEC	**10 (mm)**
Algae			
Sulfoxaflor	*Navicula pelliculosa*	72-h E_bC_{50} 72-h E_yC_{50} 72-h E_rC_{50}	**85.7 (mm)** >101 (mm) >101 (mm)
X11719474	*Navicula pelliculosa*	72-h E_yC_{50} 72-h E_rC_{50}	**>124 (mm)** >124 (mm)
X11519540	*Navicula pelliculosa*	72-h E_yC_{50} 72-h E_rC_{50}	**>110 (mm)** >110 (mm)
Higher plant			
Sulfoxaflor	*Lemna gibba*	7 day EC_{50}	**>100 (nom)**

* EFSA Journal 2014; 12(5):3692.
Endpoints used in the risk assessment are in **bold**.

Table 10.2-3: EU Endpoints - Toxicity of GF-2626 to aquatic species

Compound	Test species	Endpoint	EU agreed endpoints* (mg/L)
GF-2626	*Oncorhynchus mykiss*	96-h LC_{50}	**>840 (nom)**
GF-2626	*Daphnia magna*	48-h EC_{50}	**>840 (nom)**
GF-2626	*Americamysis bahia*	96-h LC_{50}	**3.79 (nom)**
GF-2626	*Chironomus dilutus*	96-h LC_{50}	**>100 (nom)**
GF-2626	*Navicula pelliculosa*	72-h E_yC_{50} 72-h E_rC_{50}	**>100 (mm)** >100 (mm)

* EFSA Journal 2014; 12(5):3692
Endpoints used in the risk assessment are in **bold**.

Classification of the active substance:

Active substances	Reference	New classification (CLP) 2nd ATP to the regulation 1272/2008	
		Hazard category	Code H
Sulfoxaflor	zRMS proposal	Aquatic acute 1 Aquatic chronic 1	H400 Very toxic to aquatic life H410 Very toxic to aquatic life with long lasting effects.

Proposal of classification of the preparation

Preparation	Reference	New classification (CLP) 2nd ATP to the regulation 1272/2008

		Hazard category	Code H
GF-2626 (CLOSER)	zRMS proposal	Aquatic chronic 2[1]	H411 Toxic to aquatic life with long lasting effects.

[1]Determined by calculation based on the aquatic toxicity of the active substance and principal constituents of the preparation assuming a chronic M factor of 1.

The available toxicity data indicate that the preparation does not seem to be more toxic than expected. Then, the risk assessment for aquatic organisms is based on active substance.

The aquatic risk assessment has been conducted on the basis of the critical GAP of GF-2626 as summarised in Table 10-2.

The aquatic risk assessment has been conducted in line with the Guidance Document on Aquatic Ecotoxicology (SANCO/3268/2001) using initial aquatic PEC values calculated in accordance with the Dutch guidance (2011). Although, this PEC couldn't be assessed by zRMS (NL specific requirements) they're considered worst-case compared to the PEC based on a loss of 0.1% of the active substance.
Please refer to Part B, Section 5, Protected crops, Points IIIA 9.7 and IIIA 9.8 of this submission for PEC calculation details.

zRMS comment:

Metabolites considerations:
X11519540 is a soil metabolite that is not formed in water/sediment studies; therefore, no calculation and assessment is required for indoor uses."

IIIA 10.2.1 Toxicity exposure ratios

IIIA 10.2.1.1 TER_A for fish

TER_A values for fish have been determined for the active substance and its metabolite. The acute risk assessment for fish is summarised in the following table.

Table 10.2.1.1-1: Fish acute TER values after spring and autumn indoor application of GF-2626 to ornamentals/ fruiting vegetables

Substance	Critical endpoint (µg/L)	Max initial PEC_{SW} (µg/L)	TER_A [100]
Sulfoxaflor	266000	0.023	11565217
X11719474	>478000	0.017	>28117647

The above TER_A values for sulfoxaflor and its metabolite are greater than the trigger value of 100 demonstrating an acceptable acute risk to fish for the proposed indoor uses of GF-2626.

IIIA 10.2.1.2 TER_{LT} for fish

A TER_{LT} value for fish has been determined for the active substance. The long-term risk assessment for fish is summarised in the following table.

Table 10.2.1.2-1 Fish long-term TER value after spring and autumn indoor application of GF-2626 to ornamentals/ fruiting vegetables

Substance	Critical endpoint (µg/L)	Max initial PEC_{SW} (µg/L)	TER_{LT} [10]
Sulfoxaflor	1210	0.023	52609

The above TER_{LT} value for sulfoxaflor is greater than the trigger value of demonstrating an acceptable long-term risk to fish for the proposed indoor uses of GF-2626.

IIIA 10.2.1.3 TER_A for *Daphnia*

TER_A values for *Daphnia* have been determined for the active substance and its metabolite. The acute risk assessment for *Daphnia* is summarised in the following table.

Table 10.2.1.3-1 Aquatic invertebrate acute TER values after spring and autumn indoor application of GF-2626 to ornamentals/ fruiting vegetables

Substance	Critical endpoint (µg/L)	Max initial PEC_{SW} (µg/L)	TER_A [100]
Sulfoxaflor	>399000	0.023	>17347826
X11719474	>205000	0.017	>12058824

The above TER_A values for sulfoxaflor and its metabolite are greater than the trigger value of 100 demonstrating an acceptable acute risk to *Daphnia* for the proposed indoor uses of GF-2626.

IIIA 10.2.1.4 TER_{LT} for *Daphnia*

A TER_{LT} value for *Daphnia* has been determined for the active substance. The long-term risk assessment for *Daphnia* is summarised in the following table.

Table 10.2.1.4-1: Aquatic invertebrate long-term TER value after spring and autumn indoor application of GF-2626 to ornamentals/ fruiting vegetables

Substance	Critical endpoint (µg/L)	Max initial PEC_{SW} (µg/L)	TER_{LT} [10]
Sulfoxaflor	12500	0.023	543478

The above TER_{LT} value for sulfoxaflor is greater than the trigger value of 10 demonstrating an acceptable long-term risk to *Daphnia* for the proposed indoor uses of GF-2626.

IIIA 10.2.1.5 TER_A for aquatic insect

TER_A values for *Chironomus* have been determined for the active substance and its metabolite. For the active substance a second TER_A has been calculated based on the PECsed value and an acute toxicity endpoint from a study exposing *Chironomus* to spiked sediment. The acute risk assessment for *Chironomus* is summarised in the following table.

Table 10.2.1.5-1: Aquatic insect acute TER values after spring and autumn indoor application of GF-2626 to ornamentals/ fruiting vegetables

Substance	**Critical endpoint (µg/L)**	**Max initial PEC_{SW} (µg/L)**	**TER_A [100]**
Sulfoxaflor	622	0.023	27043
X11719474	>281000	0.017	>16529412
Substance	**Critical endpoint (µg/kg sediment)**	**PEC_{sed} (µg/kg sediment)**	**TER_A [100]**
Sulfoxaflor	119	0.3	397

The above calculated TER_A values for sulfoxaflor and its metabolite are greater than the trigger value demonstrating an acceptable acute risk to *Chironomus* for the proposed indoor uses of GF-2626.

IIIA 10.2.1.6 TER_{LT} for aquatic insect

TER_{LT} values for *Chironomus* have been determined for the active substance and its metabolite. The long-term risk assessment for *Chironomus* is summarised in the following table.

Table 10.2.1.6-1: Aquatic insect long-term TER values after spring and autumn indoor application of GF-2626 to ornamentals/ fruiting vegetables

Substance	**Critical endpoint (µg/L)**	**Max initial PEC_{SW} (µg/L)**	**TER_{LT} [10]**
Sulfoxaflor	38.4	0.023	1670
X11719474	10400	0.017	611765

The above calculated the TER_{LT} values for sulfoxaflor and its metabolite are greater than the trigger value demonstrating an acceptable risk to *Chironomus* for the proposed indoor uses of GF-2626.

IIIA 10.2.1.7 TER_A for aquatic crustacean

TER_A values for *Americamysis bahia* have been determined for active substance and its metabolite. The acute risk assessment for *Americamysis bahia* is summarised in the following table.

Table 10.2.1.7-1: Aquatic crustacean acute TER values after spring and autumn indoor application of GF-2626 to ornamentals/ fruiting vegetables

Substance	Critical endpoint (µg/L)	Max initial PEC_{SW} (µg/L)	TER_A [100]
Sulfoxaflor	643	0.023	27957
X11719474	>114000	0.017	>6706000

The above calculated TER_A values for sulfoxaflor and its metabolite are greater than the trigger value demonstrating an acceptable risk to *Americamysis bahia* for the proposed indoor uses of GF-2626.

IIIA 10.2.1.8 TER_{LT} for aquatic crustacean

TER_{LT} values for *Americamysis bahia* have been determined for the active substance and the metabolite X11719474. The long-term risk assessment for *Americamysis bahia* is summarised in the following table.

Table 10.2.1.8-1: Aquatic crustacean long-term TER values after spring and autumn indoor application of GF-2626 to ornamentals/ fruiting vegetables

Substance	Critical endpoint (µg/L)	Max initial PEC_{SW} (µg/L)	TER_{LT} [10]
Sulfoxaflor	114	0.023	4957
X11719474	2120	0.017	124706

The above calculated TER_{LT} values for sulfoxaflor and its metabolite are greater than the trigger value of 10 demonstrating an acceptable risk to *Americamysis bahia* for the proposed indoor uses of GF-2626.

IIIA 10.2.1.9 TER_A for aquatic gastropod mollusc

Not required.

IIIA 10.2.1.10 TER_{LT} for aquatic gastropod mollusc

Not required.

IIIA 10.2.1.11 TER_{LT} for algae

TER_{LT} values for algae have been determined for the active substance and its metabolite. The risk assessment for algae is summarised in the following table.

Table 10.2.1.11-1: Algal TER values after spring and autumn indoor application of GF-2626 to ornamentals/ fruiting vegetables

Substance	Critical endpoint (µg/L)	Max initial PEC_{SW} (µg/L)	TER_{LT} [10]
Sulfoxaflor	85700	0.023	3726087
X11719474	>124000	0.017	>7294118

The above TER_{LT} values for sulfoxaflor and its metabolite are greater than the trigger value of 10 demonstrating an acceptable risk to algae for the proposed indoor uses of GF-2626.

IIIA 10.2.1.12 Risk for aquatic plants

A TER_{LT} value for aquatic plants has been determined for the active substance. The risk assessment for aquatic plants is summarised in the following table.

Table 10.2.1.12-1: Aquatic macrophytes TER value after spring and autumn indoor application of GF-2626 to ornamentals/ fruiting vegetables

Substance	Critical endpoint (µg/L)	Max initial PEC_{SW} (µg/L)	TER_{LT} [10]
Sulfoxaflor	>100000	0.023	>4347826

The above TER_{LT} for sulfoxaflor is greater than the trigger value of 10 demonstrating an acceptable long-term risk to aquatic plants for the proposed indoor uses of GF-2626.

IIIA 10.2.2 Acute toxicity of the formulation

IIIA 10.2.2.1 Fish

The following fish acute toxicity study performed on GF-2626 was assessed in the EU review and is available in the DAR (2013) Annex B.9.

Report:	**IIIA 10.2.2.1/01, [redacted] (2011a)**
Title:	GF-2626: Acute Toxicity to the Rainbow Trout, *Oncorhynchus mykiss*, Determined Under Static Test Conditions.
Document No:	Dow Study ID: 101909
Guidelines:	OECD 203
GLP	Yes

Study Comments:	Already reviewed in the EU DAR for Sulfoxaflor (2013)

IIIA 10.2.2.1/01	
Agreed Endpoints: IIIA 10.2.2.1/01	96-hour LC_{50} >840 mg GF-2626/L (equivalent to >101 mg Sulfoxaflor/L)

IIIA 10.2.2.2 Aquatic invertebrates (*Daphnia*)

The following *Daphnia* acute toxicity study performed on GF-2626 was assessed in the EU review and is available in the DAR (2013) Annex B.9.

Report:	**IIIA 10.2.2.2/01, Bergfield, A. (2011b)**
Title:	GF-2626: Acute Toxicity to the Water Flea, *Daphnia magna*, Determined Under Static Test Conditions.
Document No:	Dow Study ID: 101910
Guidelines:	OECD 202
Deviations:	None
GLP	Yes

Study Comments: IIIA 10.2.2.2/01	Already reviewed in the EU DAR for Sulfoxaflor (2013)
Agreed Endpoints: IIIA 10.2.2.2/01	48-hour EC_{50} >840 mg GF-2626/L (equivalent to >101 mg Sulfoxaflor/L)

IIIA 10.2.2.3 Algae

The following algae toxicity study performed on GF-2626 was assessed in the EU review and is available in the DAR (2013) Annex B.9.

Report:	**IIIA 10.2.2.3/01, Rebstock, M. (2011)**
Title:	GF-2626: Growth Inhibition Test with the Freshwater Diatom, *Navicula pelliculosa*.
Document No:	Dow Study ID: 101911
Guidelines:	OECD Guideline 201
GLP	Yes

Study Comments: IIIA 10.2.2.3/01	Already reviewed in the EU DAR for Sulfoxaflor (2013)
Agreed Endpoints: IIIA 10.2.2.3/01	72-hour ErC_{50} and EyC_{50} > 100 mg GF-2626/L (equivalent to >12 mg Sulfoxaflor/L) NOEC = 100 mg GF-2626/L (equivalent to >12 mg Sulfoxaflor/L)

IIIA 10.2.2.4 Marine or estuarine organisms

The following toxicity study with the Mysid Shrimp performed on GF-2626 was assessed in the EU review and is available in the DAR (2013) Annex B.9.

Report:	**IIIA 10.2.2.4/01, Bergfield, A. (2011c)**
Title:	GF-2626: Acute Toxicity to the Mysid Shrimp, *Americamysis bahia*, Determined Under Static-Renewal Conditions.
Document No:	Dow Study ID: 101998.
Guidelines:	OPPTS 850.1035
GLP	Yes

Study Comments: IIIA 10.2.2.4/01	Already reviewed in the EU DAR for Sulfoxaflor (2013).
Agreed Endpoints: IIIA 10.2.2.4/01	96-hour LC_{50} = 3.79 mg GF-2626/L (equivalent to 0.455 mg Sulfoxaflor/L)

IIIA 10.2.2.5 Marine sediment invertebrates

Not required.

IIIA 10.2.3 Microcosm or mesocosm study

A microcosm or mesocosm study is not required for GF-2626 as the risk assessments above indicate an acceptable risk.

IIIA 10.2.4 Residue data in fish

Studies providing residue data in fish are not required for GF-2626 as the active substance has low potential to partition to or remain in fish tissues.

IIIA 10.2.5 Chronic toxicity to fish

IIIA 10.2.5.1 28 day study

Not required.

IIIA 10.2.5.2 Fish early life stage test

Not required.

IIIA 10.2.5.3 Fish life cycle test

Not required.

IIIA 10.2.6 Chronic toxicity to aquatic invertebrates

IIIA 10.2.6.1 21 day test (*Daphnia magna*)

Not required.

IIIA 10.2.6.2 Aquatic insect

The following acute toxicity study with the Midge, *Chironomus dilutus* performed on GF-2626 was assessed in the EU review and is available in the DAR (2013) Annex B.9.

Report:	**IIIA 10.2.6.2/01, Gerke, A. (2010)**
Title:	GF-2626: Acute 96 Hour Toxicity to the Midge, *Chironomus dilutus*, Determined Under Static Test Conditions.
Document No:	Dow Study ID: 101303
Guidelines:	OECD Guideline 202, ASTM E729
GLP	Yes

Study Comments: IIIA 10.2.6.2/01	Already reviewed in the EU DAR for Sulfoxaflor (2013).
Agreed Endpoints: IIIA 10.2.6.2/01	Based on nominal concentrations, the estimated 96-hour LC_{50} > 100 mg GF-2626/L (equivalent to >12 mg Sulfoxaflor/L)

IIIA 10.2.6.3 Aquatic gastropod mollusc

Not required.

IIIA 10.2.7 Accumulation in aquatic non-target organisms

Bioaccumulation of the active substance under natural conditions is not expected to occur (refer to Section 10.2.4) and a study is not necessary to determine bioaccumulation in aquatic non-target organisms.

IIIA 10.3 Effects on Terrestrial Vertebrates Other Than Birds

The uses of GF-2626 on fruiting vegetables and ornamentals grown under permanent covered crops will not lead to significant exposure of natural populations of mammals, thus the risk to this wildlife group is considered to be negligible.

IIIA 10.3.1 Toxicity exposure ratios

Not required.

IIIA 10.3.2 Other studies

Not required.

IIIA 10.3.3 Supervised cage or field trials

Not required.

IIIA 10.4 Effects on Bees

GF-2626 was one of the representative formulations in the EU review of sulfoxaflor. However new risk assessment parameters are now considered in the assessment of risk to bees and hence an appropriate risk assessment with the proposed use pattern is provided and is considered adequate. The risk assessment has been conducted in line with the Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002 rev. 2 final).

The critical endpoints employed in the risk assessment for bees are indicated in Tables 10.4-1 to 10.4-3.

Table 10.4-1: EU Endpoints - Toxicity of sulfoxaflor and its metabolites to honeybees

Compound	Test species	Endpoint	EU agreed endpoints*
			Value (µg/bee)
Sulfoxaflor	*Apis mellifera*	Acute oral LD_{50}	0.146
Sulfoxaflor	*Apis mellifera*	Acute contact LD_{50}	0.379
X11719474	*Apis mellifera*	Acute oral LD_{50}	> 100
X11519540	*Apis mellifera*	Acute oral LD_{50}	> 91.2
X11579457	*Apis mellifera*	Acute oral LD_{50}	45.7
X11721061	*Apis mellifera*	Acute oral LD_{50}	> 103.5
GF-2032	*Bombus terrestris*	Acute oral LD_{50}	0.027 (a.s.)
GF-2032	*Bombus terrestris*	Acute oral LD_{50}	7.554 (a.s.)
GF-2032	*Apis mellifera*	Laboratory foliar residue toxicity test	No significant adverse effects to bees when exposed to foliar residues of GF-2032 treated 3, 6 or 24 hours previously at 200 g Sulfoxaflor/ha.
GF-2372	*Apis mellifera*	Laboratory foliar residue toxicity test	No significant adverse effects to bees when exposed to foliar residues of GF-2372 treated 3, 6 or 24 hours previously at 100 and 200 g Sulfoxaflor/ha.

* EFSA Journal 2014; 12(5):3692 and DAR (2013)

Table 10.4-2: EU Endpoints - Toxicity of GF-2626 to honeybees

Compound	Test species	Endpoint	EU agreed endpoints*
			Value (µg a.s./bee)
GF-2626	*Apis mellifera*	Acute oral LD_{50}	0.065
		Acute contact LD_{50}	0.283

* EFSA Journal 2014; 12(5):3692

Table 10.4-3 EU Endpoints - semi-field tests

Test substance (location)	Study treatments	Findings	Reference *
GF-2626 (Germany)	Pre-flowering without bees: 1) 48 g a.s./ha Evening application after bee flight: 1) 24 g a.s./ha 2) 48 g a.s./ha Daytime application during bee flight: 1) 24 g a.s./ha	Negative effects on adult mortality: in evening application 24 g a.s./ha on day 0, in evening application 48 g a.s./ha on day 0-1, in daytime application on day 0-1. Negative effects on foraging activity: in evening application 48 g a.s./ha on day 0-2, in daytime application on day 0-1. Negative effects on bee brood cannot be excluded.	Schmitzer (2011a)
GF-2626 (Germany)	Pre-flowering without bees: 1) 48 g a.s./ha Evening application after bee flight: 1) 24 g a.s./ha Daytime application during bee flight: 1) 24 g a.s./ha	Negative effects on adult mortality: in evening application on day 0, in daytime application on day 0-1. Negative effects on foraging activity: in daytime application on day 0-1. Negative effects on bee brood cannot be excluded.	Schmitzer (2011b)
GF-2626 (Germany)	Daytime application during bee flight 1) 4 g a.s./ha 2) 8 g a.s./ha 1) 24 g a.s./ha	GF-2626 at all rates and treatment scenarios: No effects on mortality, flight intensity and behaviour	Schmitzer (2011c)

* EFSA Journal 2014; 12(5):3692

Both the active substance and formulation data have been used to calculate hazard quotients (HQs). A summary of the proposed GAP for GF-2626 is provided in Table 10-2. The maximum proposed rate of use (equivalent to 48 g a.s./ha) has been considered in the following risk assessment.

IIIA 10.4.1 Hazard quotients for bees

The uses of GF-2626 on fruiting vegetables and ornamentals grown under permanent covered crops will not lead to significant exposure of natural populations of bees thus the risk to this wildlife group is considered to be negligible.

The acute oral and contact HQ has been provided to assess the risk to GF-2626 to honey bee and bumble bee colonies used in permanent covered crop for foraging.

IIIA 10.4.1.1 Oral exposure Q_{HO}

The acute oral risk assessment for honeybees is summarised in the table below.

Table 10.4.1.1-1: Acute oral risk to bees from exposure to sulfoxaflor, metabolites and GF-2626

Test species	Test substance	Application rate (g a.s./ha)	LD_{50} (µg a.s./bee)	Q_{HO}
Honey bee	GF-2626	48	0.065	**738**
Honey bee	Sulfoxaflor		0.146	**329**
Honey bee	X11719474*		> 100	< 0.48
Honey bee	X11519540*		> 91.2	< 0.53
Honey bee	X11579457*		45.7	1.05
Honey bee	X11721061*		> 103.5	< 0.46

HQs shown in bold are above the relevant trigger
*Risk assessment conducted assuming 100% formation of metabolites as a worst-case approach

The above calculated oral hazard quotients for sulfoxaflor and GF-2626 are above the trigger of 50 indicating the need for a refined risk assessment.

The hazard quotients for all metabolites are below the trigger of 50, indicating that all metabolites of sulfoxaflor pose an acceptable acute oral risk to bees.

IIIA 10.4.1.2 Contact exposure Q_{HC}

The acute contact risk assessment for honeybees is summarised in the table below.

Table 10.4.1.2-1: Acute contact risk to bees from exposure to sulfoxaflor and GF-2626

Test species	Test substance	Application rate (g a.s./ha)	LD_{50} (µga.s./bee)	Q_{HC}
Honey bee	GF-2626	48	0.283	**170**
Honey bee	Sulfoxaflor		0.379	**127**

HQs shown in **bold** are above the relevant trigger

The above calculated contact hazard quotients for sulfoxaflor and GF-2626 are above the trigger of 50 indicating the need for a refined risk assessment.

Refined risk assessment (oral and contact exposure) proposed by the notifier:

The first tier risk assessments demonstrate a potential acute risk to honeybees *via* oral and contact exposure following the proposed uses of GF-2626. Therefore, higher tier studies should be taken into consideration. A foliar residue contact laboratory study with the similar SC formulation GF-2032 (IIIA 10.4.3/01) and semi-field studies with GF-2626 (IIIA 10.4.7/01 to

10.4.7/03) are available. The available studies were all GLP compliant and conducted in line with standard guidelines.

Foliar residues contact laboratory study

The EFSA Conclusion (2014) states that "*The results of foliage residue contact laboratory test indicated that mortality is not expected when bees are exposed to dry residues (aged residues) on over sprayed foliage.*" In this study, the toxicity of GF-2032 residues on foliage to honeybees was assessed in a 24 hour study. Bees were exposed to alfalfa foliage sprayed with GF-2032 at a nominal rate of 200 g a.s./ha. The residues were allowed to weather in the field for 3, 6 and 24 hours before being placed in cages and the bees exposed in the laboratory. Contact time for the bees was 24 hours. No significant adverse effects on the bees were observed after exposure to foliar residues from application at a rate of 200 g a.s./ha, after ageing for 3, 6 or 24 hours. As this rate is over x4 the proposed maximum application rate (48 g a.s./ha), this study clearly demonstrates an acceptable risk to bees from contact exposure following the proposed uses of GF-2626.

Semi-field data

However, the EFSA Conclusion (2014) also states that "*increased mortality was observed in the tunnel tests when sulfoxaflor was applied on flowering Phacelia during bee flight, and also when the application was in the previous evening (after bee flight). The increase in mortality was only apparent on the day of the application or on the following day. Potential adverse effects on bee brood could not be excluded from the available data and assessment."*

Further information is given on this in the DAR (2013), which states that; "*In two of the studies detailed assessments on brood following OECD 75 guideline and on colony condition and strength were made up to approximately 4 weeks after exposure. No adverse impacts on colony health or performance were noted between the control colonies and those exposed to applications of sulfoxaflor at any of the treatments tested, except for the parameter of brood termination rate with rather questionable results."*

The results for brood termination rate were concluded to be questionable due to the relatively high loss of eggs in the control, high variability in the brood termination rate among individual replicates and poor statistical power of these measures.

Therefore, the results in terms of mortality and brood termination rate from each of the three semi-field studies have been considered in further detail below.

I) Schmitzer (2011a); IIIA 10.4.7/01

This study assessed the effects of GF-2626 on honeybee colonies, including brood development, when bees were enclosed within tunnels containing *Phacelia tanacetifolia* for 7 to 10 days. Observations then continued for up to 27 days after application. The following scenarios were assessed:

- 48 g a.s./ha - pre-flowering
- 24 and 48 g a.s./ha - evening application after bee flight

- 24 g a.s./ha - during bee flight

Only the first two scenarios will be focused on here, as GF-2626 is not proposed for use when bees are actively foraging. With regards mortality of worker bees the following results were found (refer to Table IIIA 10.4.7/01-2 for full details):

48 g a.s./ha before flowering:
No statistically significant differences in mortality compared to control up to day 7 a.a., statistically significant differences on day 9 a.a. (mean mortality of 0.0 and 6.0 in the control and treatment group, respectively) and also in mean days 8 to 27 a.a. (mean mortality of 2.2 and 3.53 bees in the control and treatment group, respectively) and mean days 0 to 27 a.a. (mean mortality of 7.1 and 10.9 bees in the control and treatment group, respectively).

24 g a.s./ha evening application after bee flight:
Statistically significant differences in mortality compared to control on day 0 (mean mortality of 17.3 and 79.3 in the control and treatment group, respectively) and on day 9 a.a. (mean mortality of 0.0 and 3.3 in the control and treatment group, respectively).

48 g a.s./ha evening application after bee flight:
Statistically significant differences in mortality compared to control on day 0 (mean mortality of 17.3 and 113.7 in the control and treatment group, respectively), on day 1 a.a. (mean mortality of 9.7 and 39.0 in the control and treatment group, respectively), on day 9 a.a. (mean mortality of 0.0 and 3.3 in the control and treatment group, respectively), on day 16 a.a. (mean mortality of 0.7 and 7.0 in the control and treatment group, respectively) and also in mean days 8 to 27 a.a. (mean mortality of 2.2 and 4.27 in the control and treatment group, respectively).

Although, there were some statistically significant effects observed, these levels of mortality were generally very low, falling within the range of the mean mortality observed pre-treatment in all test groups (8.3 to 31.7 bees) and within the mean mortality observed in the control group from day 0 to 27 a.a. (0.0 to 33.3 bees). Only mortality in the 24 and 48 g a.s./ha (after bee flight) treatment groups at day 0 were out-with these ranges (mean mortality of 79.3 and 113.7 bees). However, this mortality is still low, especially when the size of the colonies are considered; mean number of bees per colony in the six treatment groups one day before application was 2610 to 3600 per colony, representing a transient decrease of 3.0 to 4.4 % of colony strength. Overall, these levels of mortality can be concluded not to be ecologically relevant.

With regards to effects on the brood termination rate, following the assessment of single cells from the egg stage to successfully hatched worker bees, the mean termination rate in the control was 56.39%. It was considered in the DAR (2013) that the surrounding conditions where colonies were exposed during such a trial lead to this relatively high number of loss of eggs. The reason for this was thought to be the artificial housing, colony size and limited space of the colonies as well as weather conditions.

The brood termination rate was similar in the test groups; 48 g a.s./ha pre-flowering (58.06%) and 24 and 48 g a.s./ha in the evening (70.56 and 47.22%, respectively). Refer to Table IIIA

10.4.7/01-8 for further details. There were no statistically significant differences in brood termination rate in any test item group compared to the control.

II) Schmitzer (2011b); IIIA 10.4.7/02

This study assessed the effects of GF-2626 on honeybee colonies, including brood development, when bees were enclosed within tunnels containing *Phacelia tanacetifolia* for 7 to 10 days. Observations then continued for up to 27 days after application. The following scenarios were assessed:

- 48 g a.s./ha - pre-flowering
- 24 g a.s./ha - evening application after bee flight
- 24 g a.s./ha - during bee flight

Only the first two scenarios will be focused on here, as GF-2626 is not proposed for use when bees are actively foraging. With regards mortality of worker bees the following results were found (refer to Table IIIA 10.4.7/02-2 for full details):

48 g a.s./ha before flowering:
Statistically significant differences in mortality compared to the control on day 9 a.a. (mean mortality of 1.7 and 8.7 in the control and treatment group, respectively) and also in mean days 0 to 7 a.a. (mean mortality of 20.4 and 29.17 in the control and treatment group, respectively)

24 g a.s./ha evening application after bee flight:
Statistically significant differences in mortality compared to the control on day 0 (mean mortality of 26.7 and 81.7 in the control and treatment group, respectively) and on day 12 a.a. (mean mortality of 0.0 and 3.3 in the control and treatment group, respectively).

Although there were some statistically significant effects observed, these levels of mortality were generally very low and comparable to the range of mean mortality observed pre-treatment in all test groups (6.0 to 24.7 bees) and within the mean mortality observed in the control group from day 0 to 27 a.a. (0.0 to 43.7 bees). Only mortality in the 24 g a.s./ha (after bee flight) treatment group at day 0 was out-with these ranges (mean mortality of 81.7 bees). However, this mortality is still low, especially when the size of the colonies are considered; mean number of bees per colony in the six treatment groups one day before application was 2460 to 3300 per colony, representing a transient decrease of 3.3% of colony strength. Overall, these levels of mortality can be concluded not to be ecologically relevant.

With regards effects on the brood termination rate, following the assessment of single cells from the egg stage to successfully hatched worker bees, the mean termination rate in the control was 65.28%. It was considered in the DAR (2013) that the surrounding conditions where colonies were exposed during such a trial lead to this relatively high number of loss of eggs. The reason for this was thought to be the artificial housing, colony size and limited space of the colonies as well as weather conditions.

The brood termination rate was similar or lower in the test groups; 48 g a.s./ha pre-flowering (65.56%) and 24 g a.s./ha in the evening (44.17%). There were no statistically significant differences in brood termination rate in any test item group compared to the control.

III) Schmitzer (2011c); IIIA 10.4.7/03

As this study only assessed daytime application during bee flight it has not been considered here. Furthermore, the reduced amount of brood stages in bee colonies, because of the progressed season, limits the utility of the study for evaluation of effects of the test substance on bee brood.

ZRMS Conclusions:

Based on foliar residue test with the similar formulation of sulfoxaflor (GF-2032): no significant adverse effects on the bees were observed after exposure to foliar residues from application at a rate of 200 g a.s./ha, after ageing for 3, 6 or 24 hours. As this rate is over 4 times the proposed maximum application rate (48 g a.s./ha), this study demonstrates an acceptable risk to bees from contact exposure following the proposed uses of sulfoxaflor.

However, the application is done with a different preparation than GF-2626 and the tested crop was alfalfa instead of fruiting vegetables. Moreover, based on semi-field studies, significant mortality on bees are observed at maximum rate of 48 g a.s./ha after bee flight and before flowering. The increase in mortality was only apparent on the day of the application or on the following day. Potential adverse effects on bee brood could also not be excluded from the available data and assessments.

Furthermore, a higher oral toxicity is observed with the similar formulation GF-2032 on bumble bee (0.027 µg a.s./bee) than on honey bee (0.146 µg a.s./bee). This indicates a possible higher sensibility of bumble bees to sulfoxaflor.

Therefore, a position paper based on a study has been provided by the notifier during the reviewing of GF-2626 by Czech Republic for central zone (summaries presented below). zRMS France choose to take into account those informations in the refined risk for bees. According to central zone assessment:

The position paper is mainly based on the semi-field study by Liepold (2011; IIIA 10.4.7/04; not evaluated in EU review) which investigated the residues of sulfoxaflor, and the main plant metabolite X11719474, in pollen, nectar and plants following application to *Phacelia*. GF-2626 was applied at 24 and 48 g a.s./ha (T1 and T2) before the onset of flowering (BBCH 58) in three replicate tunnels. In separate tunnels GF-2626 was applied at 24 and 48 g a.s./ha (T3 and T4) during flowering (BBCH 64) and honey bee foraging. In order to evaluate the magnitude of residues of the test item GF-2626 and metabolite X11719474, nectar stomachs from forager bees, pollen samples from pollen traps and plants of *Phacelia* were taken for analysis. Samples were taken on day 0 after the application and on days +5 and +6.

The results showed that, when applications of GF-2626 at 24 and 48 g a.s./ha were made 5 days before flowering, residues of sulfoxaflor and X11719474 were not detectable or were below the LOQ in pollen and nectar samples taken during full flowering. Additionally, following

applications of GF-2626 during flowering, low levels of sulfoxaflor and X11719474 were present in nectar (maximum of 0.0889 mg/kg of sulfoxaflor), and these levels rapidly declined to be below the level of quantification in nectar at 6 days after application. In pollen, levels were slightly higher (maximum of 0.809 mg/kg) but also declined rapidly to 0.0325 mg/kg, when applied at 48 g a.s./ha. From this study it can be concluded that residues of sulfoxaflor are not persistent in plant material, and that honey bees will not be exposed to residues of sulfoxaflor in pollen and nectar following pre-flowering applications.

zRMS considers that the introduction of pollinator in glasshouse will be done usually at flowering period. Then, zRMS considers that a re-introduction of pollinator's colonies in permanent covered crops must be realised at least 6 days after spray dried. To protect the wild pollinators, structure covering the crops should be closed during the application and during a period of 6 days after application. Even bumble bees are considered more sensitive to sulfoxaflor than bees, the period of 6 days after spray is considered sufficient to have an acceptable risk to pollinator's colonies.

IIIA 10.4.2 Acute toxicity of the formulation to bees

IIIA 10.4.2.1 Oral

The following acute oral toxicity study with the honeybee performed on GF-2626 was assessed in the EU review and is available in the DAR (2013) Annex B.9.

Report:	**IIIA 10.4.2.1/01, Vinall, S. (2010a)**
Title:	Laboratory bioassay to determine the acute oral toxicity of GF-2626 to the honeybee, *Apis mellifera*.
Document No:	Dow Study ID: 10-11
Guidelines:	OECD 213
GLP	Yes

Study Comments: IIIA 10.4.2.1/01	Already reviewed in the EU DAR for Sulfoxaflor (2013).
Agreed Endpoints: IIIA 10.4.2.1/01	48-hour oral LD_{50} = 0.539 µg GF-2626/bee (equivalent to 0.065 µg Sulfoxaflor/bee)

IIIA 10.4.2.2 Contact

The following acute contact toxicity study with the honeybee performed on GF-2626 was assessed in the EU review and is available in the DAR (2013) Annex B.9.

Report:	**IIIA 10.4.2.2/01, Vinall, S. (2010b)**

Title:	Laboratory bioassay to determine the acute contact toxicity of GF-2626 to the honeybee, *Apis mellifera*.
Document No:	Dow Study ID: 10-10
Guidelines:	OECD 214
GLP	Yes

Study Comments: IIIA 10.4.2.2/01	Already reviewed in the EU DAR for Sulfoxaflor (2013).
Agreed Endpoints: IIIA 10.4.2.2/01	48-hour contact LD_{50} = 2.356 µg GF-2626/bee (equivalent to 0.283 µg Sulfoxaflor/bee)

IIIA 10.4.3 Effects on bees of residues on crops

The following toxicity of residues on foliage to the honeybee performed on GF-2032 was assessed in the EU review and is available in the DAR (2013) Annex B.9.

Report:	**IIIA 10.4.3/01, Lee, B. (2008)**
Title:	GF-2032: Toxicity of Residues on Foliage to the Honeybee, *Apis mellifera*.
Document No:	Dow Study ID: 080082
Guidelines:	U.S. EPA FIFRA Subdivision L, Section 141-2 U.S. EPA OPPTS Guideline 850.3030
GLP	Yes

Study Comments: IIIA 10.4.3./01	Already reviewed in the EU DAR for Sulfoxaflor (2013).
Agreed Endpoints: IIIA 10.4. 3./01	No significant adverse effects to bees when exposed to foliar residues of GF-2032 treated 3, 6 or 24 hours previously at 200 g Sulfoxaflor/ha, were determined

IIIA 10.4.4 Cage tests

No data submitted.

IIIA 10.4.5 Field tests

No data submitted.

IIIA 10.4.6 Investigation into special effects

IIIA 10.4.6.1 Larval toxicity

No data submitted.

IIIA 10.4.6.2 Long residual effects

No data submitted.

IIIA 10.4.6.3 Disorienting effects on bees

No data submitted.

IIIA 10.4.7 Tunnel tests

The following toxicity of field tests with honeybee performed on GF-2626 was assessed in the EU review and is available in the DAR (2013) Annex B.9.

Report:	**IIIA 10.4.7/01, Schmitzer, S (2011a)**
Title:	Study on the Effect of GF-2626 on Honey Bee Brood (*Apis mellifera* L.) under Semi-Field Conditions - Tunnel Test.
Document No:	Dow Study ID: 80755
Guidelines:	OEPP/EPPO guideline No. 170 (3) (OEPP/EPPO, 2001) OECD No. 75 ENV/JM/MONO(2007)22.
GLP	Yes

Study Comments: IIIA 10.4.7./01	Already reviewed in the EU DAR for Sulfoxaflor (2013).
Agreed Endpoints: IIIA 10.4. 7./01	The potential effects of GF-2626 on honey bee colonies including brood development was assessed by exposing honey bees under the realistic but severe conditions of a semi-field (tunnel) test. For honey bees and colonies exposed to pre-flower treatment with 48 g sulfoxaflor/ha, to dried residues applied at 24 and 48 g sulfoxaflor/ha after bee flight and to direct exposure to 24 g sulfoxaflor/ha, no effects on mortality, flight intensity and behaviour were observed. Although significant effect on worker bee mortality on day 0 after application were observed in the 24 and 48 g a.s./ha after bee flight group and in the 24 g a.s./ha during bee flight group. In the 48 g a.s./ha after bee flight group

	and 24 g a.s./ha during bee flight group, the negative effects on mortality were observed also on the following day (day 1 a.a.). In these two test groups, significant effects on foraging activity were noticed on day 0 after application, observed also on days 1 and 2 a.a. in the 48 g a.s./ha after bee flight group and on day 1 a.a. in the 24 g a.s./ha during bee flight group. No effects on colony development, colony strength or bee brood were observed after exposure of the bees to pre-flower treatment with 48 g sulfoxaflor/ha, to dried residues applied at 48 g sulfoxaflor/ha after bee flight and to direct exposure to 24 g sulfoxaflor/ha. Following the application of 24 g sulfoxaflor/ha after the bee flight, brood termination rate of the bee colonies was higher compared to the control. Since this was not obvious in the higher rate with 48 g sulfoxaflor/ha and after direct application to the bees to 24 g sulfoxaflor/ha, this must be seen as not a test item related effect. No significant negative effects on pupae mortality, colony condition, colony strength and brood compensation index were noticed in any test item group compared to control. Clear adverse effects were observed in the reference item treated colonies (Insegar (300 g fenoxycarb/ha). No adverse effect on the overall survival of the colonies could be observed after application of GF-2626 at all rates and treatment scenarios.

Report:	**IIIA 10.4.7/02, Schmitzer, S (2011b)**
Title:	Study on the Effect of GF-2626 on Honey Bees and their Brood (*Apis mellifera* L.) under Semi-Field Conditions - Tunnel Test.
Document No:	Dow Study ID: 101599
Guidelines:	OEPP/EPPO guideline No. 170 (3) (OEPP/EPPO, 2001) OECD No. 75 ENV/JM/MONO(2007)22.
GLP	Yes

Study Comments: IIIA 10.4.7./02	Already reviewed in the EU DAR for Sulfoxaflor (2013).
Agreed Endpoints: IIIA 10.4. 7./02	The potential effects of GF-2626 on honey bee colonies including brood development was assessed by exposing honey bees under the realistic but severe conditions of a semi-field (tunnel) test. For honey bees and colonies exposed to pre-flower treatment with 48 g sulfoxaflor/ha, to dried residues applied at 24 g sulfoxaflor/ha after bee flight and to direct exposure to 24 g sulfoxaflor/ha, no effects on mortality, flight intensity and behaviour were observed. Although significant effect on worker bee mortality on day 0 after application were observed in the 24 g a.s./ha after bee flight group and in the 24 g a.s./ha

	during bee flight group. In the 24 g a.s./ha during bee flight group, the negative effects on mortality were observed also on the following day (day 1 a.a.). In this test group, significant effects on foraging activity were noticed on day 0 after application, observed also on day 1 a.a. No effects on colony development, colony strength or bee brood were observed after exposure of the bees to pre-flower treatment with 48 g sulfoxaflor/ha, to dried residues applied at 24 g sulfoxaflor/ha after bee flight and to direct exposure to 24 g sulfoxaflor/ha. No significant negative effects on pupae mortality, colony condition, colony strength and brood compensation index were noticed in any test item group compared to control. Clear adverse effects were observed in both reference item treatment groups, after treatment with Insegar (300 g fenoxycarb/ha) or Perfekthion EC (600 g dimethoate/ha), respectively. No adverse effect on the overall survival of the colonies could be observed also 60 days after application of GF-2626 at all rates and treatment scenarios. No adverse effect on the overall survival of the colonies could be observed after application of GF-2626 at all rates and treatment scenarios.

Report:	**IIIA 10.4.7/03, Schmitzer, S (2011c)**
Title:	Toxicity Testing of GF-2626 on Honey Bees (*Apis mellifera* L.) under Semi-Field Conditions - Tunnel Test.
Document No:	Dow Study ID: 101602
Guidelines:	OEPP/EPPO guideline No. 170 (3) (OEPP/EPPO, 2001)
GLP	Yes

Study Comments: IIIA 10.4.7./03	Already reviewed in the EU DAR for Sulfoxaflor (2013).
Agreed Endpoints: IIIA 10.4. 7./03	The development of the colony strength among the colonies in all treatment groups followed more or less the same pattern. Following the start of the study the colony strength was decreasing in all treatment groups. Given the time of the season it is clear that there is no large growth in bee brood. Since these patterns are very similar it can be concluded that there was no test item related influence on the overall strength of the colonies. Strongest decrease was seen in both reference item treated groups. For honey bees and colonies exposed to GF-2626 applied at 4, 8 and 24 g sulfoxaflor/ha during bee flight no effects on mortality, flight intensity,

	behaviour or brood and overall colony condition were observed.

Following reports has been provided by the Notifierduring the assesslent by the Czech Republic of the Central Zone registration.

Report:	**IIIA 10.4.7/04, Liepold K. (2011)**
Title:	A Semi-field Study to Investigate Residues in Honeybee Products (*Apis mellifera carnica* L.; (Hymenoptera, Apidae) in *Phacelia tanacetifolia* in Germany in 2010.
Document No:	Study Code S10-01824. Dow AgroSciences unpublished report no. 2009317. DAS Study ID: 110414.
Guidelines:	IVA (BEUTEL et al., 1992), EU (1997)
GLP	Yes

Test material

Test item:	GF-2626
Purity:	128 g/L XDE-208 (analysed)
Description:	Off-white to tan liquid
Lot No./Batch No. :	E-3144-36

Test system

Organism (Species):	Honey bee, *Apis mellifera carnica* L. (Hymenoptera, Apidae)
Study Type:	Semi-field study
GLP Status:	GLP
Guidelines followed:	IVA (BEUTEL et al., 1992), EU (1997)
Guideline deviations reported by Study Director:	None.
Study design:	Application before flowering in treatment groups T1 and T2 and application during flowering and during daily bee-flight in treatment groups T3 and T4. Nectar stomachs from forager bees, pollen samples from pollen traps and plants of *Phacelia tanacetifolia* were taken for analysis on day of application during bee flight, 5 and 6 days after application during bee flight. The condition of the colonies and bee brood was assessed once before set-up of the colonies in the tunnels. 1 replicate (tunnel) per treatment group, each consisting of 1 honey bee colony.
Test concentrations:	24 g a.i./ha (T1 and T3), 48 g a.i./ha (T2 and T4)

Methodology

This study included five treatment groups. The test item GF-2626 (active substance: XDE-208) was applied at rates of 24 g a.i./ha (treatment groups T1 and T3) and 48 g a.i./ha (treatment groups T2 and T4) in separated tunnels. A fifth group (tunnel) left untreated served as control. Applications in treatment group T1 and T2 were conducted before flowering; applications in treatment group T3 and T4 were made during flowering and during daily bee-flight. All applications were made with a rate of 400 L water/ha.

The effect of the test item was examined on commercial bee colonies in tunnels (approx. 200 m2) placed on plots with *Phacelia tanacetifolia*. Condition of the colonies and the development of the bee brood were assessed once before the start of exposure of the honeybees in the tunnels. In order to evaluate the magnitude of residues of the test item GF-2626 nectar stomachs from forager bees, pollen samples from pollen traps and plants of *Phacelia tanacetifolia* were taken for analysis.

Results

The colony strength before set-up in the tunnels ranged from 17511 to 23888 honeybees in the different treatment groups and the control. Regarding the brood development, it can be stated that all colonies of all treatment groups (T1, T2, T3, T4 and control) had brood of all stages (eggs, larvae, sealed brood). Food (nectar and pollen) was also present in all colonies with a higher percentage of nectar (13.28 % to 37.50%) compared to pollen (7.34 % to 13.28 %).
No residues of XDE-208 and its metabolite X11719474 at or above the respective limit of detection (LOD) levels (0.003 mg/kg for plants, nectar and pollen) were found in any of the untreated control samples. In nectar samples from forager bees no residues of X11719474 were detected in all treatment groups for sampling 1 and 2. In sampling 3 (DAA6) residues were found in treatment group T2 and T4. However these residues were below the limit of quantification (LOQ 0.01 mg/kg). For treatment groups T1 and T2 no residues of XDE-208 were detected for all sampling dates. In treatment group T3 a mean (of 3 samples) of 0.0441 mg/kg was determined in sampling 1 (DAA0). In sampling 2 and 3 residues were below LOQ (0.01 mg/kg). Residues of XDE-208 in treatment group T4 were 0.0647 mg/kg (mean of 3 samples) in sampling 1 (DAA0), declined to 0.0109 in sampling 2 (DAA5) and were below LOQ for sampling 3 (DAA6).

In pollen samples from pollen traps no residues of XDE-208 and its metabolite X11719474 were determined in treatment group T1 for all samplings. In treatment group T2 residues of XDE-208 and X11719474 were below LOQ (0.01 mg/kg) or below LOD (0.003 mg/kg) for all sampling dates. No residues of the metabolite X11719474 were detected for all samplings in treatment group T3. The residues of XDE-208 in pollen in treatment group T3 ranged from 0.290 mg/kg to 0.0160 mg/kg. In treatment group T4 residues of XDE-208 declined from 0.809 mg/kg in sampling 1 (DAA0) to 0.0325 mg/kg in sampling 3 (DAA6) and residues of the metabolite X11719474 were below LOQ (0.01 mg/kg) or LOD (0.003 mg/kg).

In whole *Phacelia tanacetifolia* plants residues of XDE-208 and X11719474 in treatment group T1 were below LOQ (0.01 mg/kg) or LOD (0.003 mg/kg). In treatment group T2 residues of XDE-208 found in sampling 1 (DAA0) were 0.0342 mg/kg, whereas no residues were detected in the following samplings (DAA5 and DAA6). Residues of the metabolite X11719474 were below LOQ (0.01 mg/kg) for sampling 1 and 2; 0.0113 mg/kg were found in sampling 3 (DAA6). In treatment group T3 the residues of XDE-208 ranged from 0.516 to 0.0480 mg/kg. The metabolite X11719474 was not detectable in treatment group T3 for sampling 1 (DAA0) and was below the LOQ (0.01 mg/kg) for the subsequent samplings. In treatment group T4 residues of XDE-208 in plants were determined between 1.48 and 0.0507 mg/kg. The metabolite X11719474 was below LOQ (0.01 mg/kg) for sampling 1 (DAA0) and 2 (DAA5) and 0.0147 mg/kg for sampling 3 (DAA6).

A summary of the sulfoxaflor and X11719474 residues found in nectar, pollen and plants is presented in Tables 3, 4 and 5 below.

Table 3: Results of nectar analysis

Timing	Treatment	Application rate (g a.s./ha)	Sulfoxaflor residues (mg/kg)	X11719474 residues (mg/kg)
0 DAA	C	-	nd	nd
			nd	nd

			nd	nd
	T1	24	nd	nd
			nd	nd
			nd	nd
	T2	48	nd	nd
			nd	nd
			nd	nd
	T3	24	0.0438	nd
			0.0462	nd
			0.0424	nd
	T4	48	0.0889	nd
			0.0548	nd
			0.0503	nd
5 DAA	C	-	nd	nd
			nd	nd
			nd	nd
	T1	24	nd	nd
			nd	nd
			nd	nd
	T2	48	nd	nd
			nd	nd
			nd	nd
	T3	24	<LOQ (0.005)	nd
			<LOQ (0.005)	nd
			<LOQ (0.004)	nd
	T4	48	0.0106	nd
			0.0110	nd
			0.0111	nd
6 DAA	C	-	nd	nd
			nd	nd
			nd	nd
	T1	24	nd	nd
			nd	nd
			nd	nd
	T2	48	nd	<LOQ (0.004)
			nd	<LOQ (0.004)
			nd	<LOQ (0.004)
	T3	24	<LOQ (0.004)	nd
			<LOQ (0.004)	nd
			<LOQ (0.005)	nd
	T4	48	<LOQ (0.0097)	<LOQ (0.003)
			<LOQ (0.006)	<LOQ (0.004)
			<LOQ (0.008)	<LOQ (0.004)

DAA: days after application during bee flight
C: untreated; T1/T2/T3/T4: test item group 1/2/3/4
n.d.: not detected (residue value was less than 30% of the LOQ, 0.003 mg/kg)
Values between 0.003 mg/kg (30% of the LOQ) and 0.01 mg/kg (LOQ) are reported as < LOQ

Table 4: Results of pollen analysis

Timing	Treatment	Application rate (g a.s./ha)	Sulfoxaflor residues (mg/kg)	X11719474 residues (mg/kg)
0 DAA	C	-	nd	nd
	T1	24	nd	nd
	T2	48	<LOQ (0.005)	nd
	T3	24	0.290	nd
	T4	48	0.809	<LOQ (0.004)
5 DAA	C	-	nd	nd
	T1	24	nd	nd
	T2	48	nd	nd
	T3	24	<LOQ (0.003)	nd
	T4	48	0.0191	nd
6 DAA	C	-	nd	nd
	T1	24	nd	nd
	T2	48	nd	<LOQ (0.004)
	T3	24	0.0160	nd
	T4	48	0.0325	nd

DAA: days after application during bee flight
C: untreated; T1/T2/T3/T4: test item group 1/2/3/4
n.d.: not detected (residue value was less than 30% of the LOQ, 0.003 mg/kg)
Values between 0.003 mg/kg (30% of the LOQ) and 0.01 mg/kg (LOQ) are reported as < LOQ

Table 5: Results of whole plant analysis

Timing	Treatment	Application rate (g a.s./ha)	Sulfoxaflor residues (mg/kg)	X11719474 residues (mg/kg)
0 DAA	C	-	Nd	nd
	T1	24	<LOQ (0.009/0.009)	<LOQ (0.004/0.003)
	T2	48	0.0342	<LOQ (0.006)
	T3	24	0.516	nd
	T4	48	1.48	<LOQ (0.009)
5 DAA	C	-	nd/nd	nd/nd
	T1	24	<LOQ (0.004/0.004)	<LOQ (0.005/0.005)
	T2	48	nd/nd	<LOQ (0.0099/0.00999)
	T3	24	0.0274	<LOQ (0.004)
	T4	48	0.0520	<LOQ (0.009)
6 DAA	C	-	Nd	nd
	T1	24	Nd	<LOQ (0.009)
	T2	48	Nd	0.0113
	T3	24	0.0480	<LOQ (0.007)
	T4	48	0.0507	nd

DAA: days after application during bee flight
C: untreated; T1/T2/T3/T4: test item group 1/2/3/4
n.d.: not detected (residue value was less than 30% of the LOQ, 0.003 mg/kg)
Values between 0.003 mg/kg (30% of the LOQ) and 0.01 mg/kg (LOQ) are reported as < LOQ

Conclusions
Residues of XDE-208 and its metabolite X11719474 were determined in plant tissue after an application before and during flowering. In pollen samples quantifiable residues of XDE-208 were determined in treatment groups T3 and T4 with an application during flowering and daily bee-flight. Quantifiable residues of XDE-208 were determined in nectar samples at DAA0 in treatment group T3 (24 g a.i./ha) and at DAA0 and DAA5 in treatment group T4 (48 g a.i./ha). Residues of the parent are at the highest level in samples after application and decline in later samplings. Residues of the metabolite were measured at day 6 above LOQ.

Study Comments: IIIA 10.4.7/04	-
Agreed Endpoints: IIIA 10.4.7/04	The results show that, when applications of GF-2626 at 24 and 48 g a.s./ha were made 5 days before flowering, residues of sulfoxaflor and X11719474 were not detectable or were below the LOQ in pollen and nectar samples taken during full flowering. Additionally, following applications of GF-2626 during flowering, low levels of sulfoxaflor and X11719474 were present in nectar (maximum of 0.0889 mg/kg of sulfoxaflor), and these levels rapidly declined to be below the level of quantification in nectar at 6 days after application. In pollen, levels were slightly higher (maximum of 0.809 mg/kg) but also declined rapidly to 0.0325 mg/kg, when applied at 48 g a.s./ha.

Report:	**IIIA 10.4.7/05, anonymous (2016)**
Title:	Pre-Flowering Applications of Sulfoxaflor: Exposure and Effects on Honey bees
Document No:	-
Guidelines:	n.a.
GLP	n.a.

Summary

To investigate the risk of pre-flowering applications of sulfoxaflor to foraging honey bees, field trials were conducted to determine exposure in pollen and nectar, and to evaluate effects on mortality, foraging activity and brood development of bees. Residues were not detected (or were below the limit of quantification) in the pollen and nectar of flowering crops following an application of sulfoxaflor made 4 days before the onset of flowering. Based on the negligible exposure, the corresponding risk is also expected to be low.

This assumption of low risk has been confirmed in tunnel trials conducted in *Phacelia* that show pre-flowering applications of sulfoxaflor at 48 g a.s./ha had no effect on honey bee mortality, foraging activity and development of brood. The low risk to bees from pre-flowering applications can be

explained by the short persistence of sulfoxaflor in plant material and soil combined with the low toxicity of metabolites formed.

1. Introduction

Sulfoxaflor has a short persistence in crop plants, having an average DT_{50} of 7.5 days and a median DT_{50} of 5.5 days based on an extensive data base that includes 29 different crops and 316 decline events on fruits, vegetables, leaves, forage, seeds, grain and root/tuber commodities. Persistence of sulfoxaflor in soil is also short with a maximum soil field DT_{50} of 7.4 days.

Additionally, the metabolites of sulfoxaflor are known to have low toxicity to honey bees, as shown in the table below.

Table 1: Toxicity of sulfoxaflor and metabolites to honey bees (OECD 213 guideline studies conducted to GLP)

Test substance	Acute oral toxicity (LD_{50} µg a.s./bee)
Sulfoxaflor	0.146 (48h)
X11719474 (plant and major soil metabolite)	>100 (96h)
X11519540 (minor soil metabolite)	>91.2 (48h)
X11579457 (minor soil metabolite)	45.7 (48h)
X11721061 (plant metabolite)	>103.5 (48h)

It therefore follows that pre-flowering applications of sulfoxaflor are likely to show low risk to foraging honey bees. To investigate this assumption, pre-flowering applications of sulfoxaflor have been made to *Phacelia;* pollen and nectar have subsequently been collected from the crop when in flower and analysis of residues conducted. The effects of pre-flowering sulfoxaflor applications on the mortality and foraging activity of honey bees have also been investigated. This paper summarises the studies and provides a position on the acceptable risk to honey bees of pre-flowering sulfoxaflor applications.

2. Exposure of sulfoxaflor to bees in pollen and nectar following pre-flowering applications

A semi-field study has been conducted to investigate the residues of sulfoxaflor, and the main plant metabolite X11719474, in pollen, nectar and plants following application to *Phacelia* (Liepold, 2011[1]). A 120 g/L SC sulfoxaflor formulation (GF-2626) was applied at 24 and 48 g a.s./ha (T1 and T2) before the onset of flowering (BBCH 58) in three replicate tunnels. In separate tunnels GF-2626 was applied at 24 and 48 g a.s./ha (T3 and T4) during flowering (BBCH 64) and honey bee foraging. In order to evaluate the magnitude of residues of the test item GF-2626 and metabolite X11719474, nectar stomachs from forager bees, pollen samples from pollen traps and plants of *Phacelia* were taken for analysis. Samples were taken on day 0 after the application and on days +5 and +6. A summary of the application and sampling regime is presented in the table below and a full study summary is provided in the Appendix.

Table 2: Timing of GF-2626 application and sampling for residue analysis

Activity	DAA*	Date
Application before flowering (T1 and T2) BBCH 58	-10	15 Jul 2010

[1] Liepold, K. (2011). GF-2626: A semi-field study to investigate residues in honeybee products (*Apis mellifera carnica* L.; Hymenoptera, Apidae) in *Phacelia tanacetifolia* in Germany in 2010. Dow AgroSciences internal report no. 2009317.

Brood assessment	-7	18 Jul 2010
Set up of the colonies in the tunnels	-6	19 Jul 2010
Application during flowering and bee-flight (T3 and T4) BBCH 64	0	25 Jul 2010
1st sampling of forager bees, pollen from pollen traps and whole plants	0	25 Jul 2010
2nd sampling of forager bees, pollen from pollen traps and whole plants	+5	30 Jul 2010
3rd sampling of forager bees, pollen from pollen traps and whole plants	+6	31 Jul 2010

*DAA: Days after application during bee flight

Colonies are generally moved into the tunnel when the crop has started to flower, it can therefore be assumed that, in this particular study, the pre-flowering application was made 4 days before the start of flowering. Additionally, the 1st sampling of pollen and nectar for residue analysis was made 10 days after the pre-flowering application.

A summary of the sulfoxaflor and X11719474 residues found in nectar, pollen and plants is presented in Tables 3, 4 and 5 below.

Table 3: Results of nectar analysis

Timing	Treatment	Application rate (g a.s./ha)	Sulfoxaflor residues (mg/kg)	X11719474 residues (mg/kg)
0 DAA	C	-	nd	nd
			nd	nd
			nd	nd
	T1	24	nd	nd
			nd	nd
			nd	nd
	T2	48	nd	nd
			nd	nd
			nd	nd
	T3	24	0.0438	nd
			0.0462	nd
			0.0424	nd
	T4	48	0.0889	nd
			0.0548	nd
			0.0503	nd
5 DAA	C	-	nd	nd
			nd	nd
			nd	nd
	T1	24	nd	nd
			nd	nd
			nd	nd
	T2	48	nd	nd
			nd	nd
			nd	nd
	T3	24	<LOQ (0.005)	nd
			<LOQ (0.005)	nd
			<LOQ (0.004)	nd
	T4	48	0.0106	nd
			0.0110	nd
			0.0111	nd

6 DAA	C	-	nd	nd
			nd	nd
			nd	nd
	T1	24	nd	nd
			nd	nd
			nd	nd
	T2	48	nd	<LOQ (0.004)
			nd	<LOQ (0.004)
			nd	<LOQ (0.004)
	T3	24	<LOQ (0.004)	nd
			<LOQ (0.004)	nd
			<LOQ (0.005)	nd
	T4	48	<LOQ (0.0097)	<LOQ (0.003)
			<LOQ (0.006)	<LOQ (0.004)
			<LOQ (0.008)	<LOQ (0.004)

DAA: days after application during bee flight
C: untreated; T1/T2/T3/T4: test item group 1/2/3/4
n.d.: not detected (residue value was less than 30% of the LOQ, 0.003 mg/kg)
Values between 0.003 mg/kg (30% of the LOQ) and 0.01 mg/kg (LOQ) are reported as < LOQ

Table 4: Results of pollen analysis

Timing	Treatment	Application rate (g a.s./ha)	Sulfoxaflor residues (mg/kg)	X11719474 residues (mg/kg)
0 DAA	C	-	nd	nd
	T1	24	nd	nd
	T2	48	<LOQ (0.005)	nd
	T3	24	0.290	nd
	T4	48	0.809	<LOQ (0.004)
5 DAA	C	-	nd	nd
	T1	24	nd	nd
	T2	48	nd	nd
	T3	24	<LOQ (0.003)	nd
	T4	48	0.0191	nd
6 DAA	C	-	nd	nd
	T1	24	nd	nd
	T2	48	nd	<LOQ (0.004)
	T3	24	0.0160	nd
	T4	48	0.0325	nd

DAA: days after application during bee flight
C: untreated; T1/T2/T3/T4: test item group 1/2/3/4
n.d.: not detected (residue value was less than 30% of the LOQ, 0.003 mg/kg)
Values between 0.003 mg/kg (30% of the LOQ) and 0.01 mg/kg (LOQ) are reported as < LOQ

Table 5: Results of whole plant analysis

Timing	Treatment	Application rate (g a.s./ha)	Sulfoxaflor residues (mg/kg)	X11719474 residues (mg/kg)
0 DAA	C	-	Nd	nd
	T1	24	<LOQ (0.009/0.009)	<LOQ (0.004/0.003)
	T2	48	0.0342	<LOQ (0.006)
	T3	24	0.516	nd
	T4	48	1.48	<LOQ (0.009)

Timing	Treatment	Application rate (g a.s./ha)	Sulfoxaflor residues (mg/kg)	X11719474 residues (mg/kg)
5 DAA	C	-	nd/nd	nd/nd
	T1	24	<LOQ (0.004/0.004)	<LOQ (0.005/0.005)
	T2	48	nd/nd	<LOQ (0.0099/0.00999)
	T3	24	0.0274	<LOQ (0.004)
	T4	48	0.0520	<LOQ (0.009)
6 DAA	C	-	Nd	nd
	T1	24	Nd	<LOQ (0.009)
	T2	48	Nd	0.0113
	T3	24	0.0480	<LOQ (0.007)
	T4	48	0.0507	nd

DAA: days after application during bee flight
C: untreated; T1/T2/T3/T4: test item group 1/2/3/4
n.d.: not detected (residue value was less than 30% of the LOQ, 0.003 mg/kg)
Values between 0.003 mg/kg (30% of the LOQ) and 0.01 mg/kg (LOQ) are reported as < LOQ

The results show that, when applications of GF-2626 at 24 and 48 g a.s./ha were made 4 days before flowering, residues of sulfoxaflor and X11719474 were not detectable or were below the LOQ in pollen and nectar samples taken during full flowering. Additionally, following applications of GF-2626 during flowering, low levels of sulfoxaflor and X11719474 were present in nectar (maximum of 0.0889 mg/kg of sulfoxaflor), and these levels rapidly declined to be below the level of quantification in nectar at 6 days after application. In pollen, levels were slightly higher (maximum of 0.809 mg/kg) but also declined rapidly to 0.0325 mg/kg, when applied at 48 g a.s./ha. From this study it can be concluded that residues of sulfoxaflor are not persistent in plant material, and that honey bees will not be exposed to residues of sulfoxaflor in pollen and nectar following pre-flowering applications.

3. Effects of pre-flowering applications on bees

Two semi-field tunnel trials have been conducted to investigate the effects of applying sulfoxaflor before flowering on honey bees foraging on *Phacelia* in tunnels (Schmitzer, 2011a[2] and 2011b[3]). In both studies, a 120 g/L SC sulfoxaflor formulation (GF-2626) was applied to the crop before flowering at 48 g a.s./ha in three replicate tunnels. Five days after the application, bees were introduced to the tunnels as the crop started flowering and the exposure period lasted 10 days. Mortality, foraging activity, condition of the colonies and development of the brood was assessed until the end of the trial. In one trial 2 reference tunnels were used with fenoxycarb applied at 300 g a.s./ha and dimethoate applied at 600 g a.s./ha in separate tunnels, and in the second trial fenoxycarb was applied at 300 g a.s./ha. The results from both trials are summarised in Table 5 and 6 below.

[2] Schmitzer, S. (2011a). Study on the Effect of GF-2626 on Honey Bees and their Brood (*Apis mellifera* L.) under Semi-Field Conditions - Tunnel Test. Dow AgroSciences internal report no. 2009052.

[3] Schmitzer, S. (2011b). Study on the Effect of GF-2626 on Honey Bee Brood (*Apis mellifera* L.) under Semi-Field Conditions - Tunnel Test. Dow AgroSciences internal report no. 2008981.

Table 5: Effects of sulfoxaflor on honey bees and their brood under semi-field conditions (trial 1)

Parameter	Treatment [1)]			
	Control	Pre-flowering GF-2626 (48 g a.s./ha)	Reference Item Insegar (0.3 kg a.s./ha)	Reference Item Perfekthion (0.6 kg a.s./ha)
Mean mortality of worker bees / colony / day [%] during				
pre-application phase [2)]	10.6	18.6 (n.s.)	12.8 (n.s.)	12.8 (n.s.)
exposure phase in the tunnels [2)]	20.4	29.2 (n.s.)	22.5 (n.s.)	164.1 (*)
phase outside the tunnels [3)]	2.5	2.6 (n.s.)	3.0 (n.s.)	5.9 (*)
overall after application	7.6	10.2 (n.s.)	8.5 (n.s.)	51.1 (*)
Total mortality of larvae and pupae [n] during				
pre-application phase [2)]	4	0 (n.s.)	5 (n.s.)	1 (n.s.)
exposure phase in the tunnels [2)]	7	5 (n.s.)	20 (n.s.)	1 (n.s.)
phase outside the tunnels [3)]	0	1 (n.s.)	97 (*)	0 (n.s.)
overall after application	7	6 (n.s.)	117 (*)	1 (n.s.)
Mean foraging activity / m² / colony / day [n] during				
pre-application phase	10.7	10.0 (n.s.)	7.3 (n.s.)	10.0 (n.s.)
exposure phase in the tunnels	14.3	12.9 (n.s.)	12.4 (n.s.)	0.5 (*)
Mean brood termination rate [%]	65.3	65.6 (n.s.)	98.6 (n.s.)	100.0 (n.s.)

1) Each with three tunnels (replicate)
2) mean number of dead honeybees per day and colony found in dead bee traps and on gauze strips in the tunnels
3) mean number of dead honeybees per day and colony found in dead bee traps, only
Statistic: Dunnett`s t-test (mortality, foraging activity, termination rate), α=0.05, one-sided greater or one-sided smaller (foraging activity, brood indices)
n.s. = not statistically significant compared to the control;* = statistically significant compared to the control

Table 6: Effects of sulfoxaflor on honey bees and their brood under semi-field conditions (trial 2)

Parameter	Treatment [1)]		
	Control	Pre-flowering GF-2626 (48 g a.s./ha)	Reference Item Insegar (0.3 kg a.s./ha)
Mean mortality of worker bees / colony / day [%] during			
pre-application phase [2)]	15.2	16.7 (n.s.)	15.4 (n.s.)
exposure phase in the tunnels [2)]	19.3	29.5 (n.s.)	19.3 (n.s.)
phase outside the tunnels [3)]	2.2	3.5 (n.s.)	2.7 (n.s.)
overall after application	7.1	11.0 (n.s.)	7.4 (n.s.)
Total mortality of larvae and pupae [n] during			
pre-application phase [2)]	0	0 (n.d.)	0 (n.d.)
exposure phase in the tunnels [2)]	2	0 (n.s.)	2 (n.s.)
phase outside the tunnels [3)]	0	5 (n.s.)	529 (*)
overall after application	2	5 (n.s.)	531 (*)
Mean foraging activity / m² / colony / day [n] during			
pre-application phase	13.0	12.9 (n.s.)	12.7 (n.s.)
exposure phase in the tunnels	25.0	22.1 (n.s.)	24.6 (n.s.)
Mean brood termination rate [%]	56.4	58.1 (n.s.)	98.1 (*)

1) each with three tunnels (replicate)
2) mean number of dead honeybees per day and colony found in dead bee traps and on gauze strips in the tunnels
3) mean number of dead honeybees per day and colony found in dead bee traps, only
Statistic: Dunnett`s t-test (mortality, foraging activity) or Student t-test (termination rate), α=0.05, one-sided greater (mortality and termination rate) or one-sided smaller (foraging activity, brood indices)
n.s. = not statistically significant compared to the control;* = statistically significant compared to the control;
n.d. = not determined

The results from both semi-field tunnel trials show there were no effects on mortality of worker bees, larvae and pupae from pre-flowering applications of sulfoxaflor at 48 g a.s./ha. The control mean brood termination rate in both trials was high making a conclusion on brood development difficult, but the toxic standards clearly had a significant effect and sulfoxaflor was similar to the control, thus implying that if sulfoxaflor affected the brood it would have been identified in the study.

4. Conclusions

Sulfoxaflor is not persistent in plant material or soil, having a mean DT_{50} in plants of 7.5 days and a maximum field DT_{50} in soil of 7.4 days. The short persistence of sulfoxaflor is evident in the field work conducted to investigate the risk of pre-flowering applications to honey bees. Residues were not detected (or were below the limit of quantification) in the pollen and nectar of flowering crops following an application of sulfoxaflor made 4 days before the onset of flowering. The negligible exposure therefore means that subsequent risk to foraging bees will also be low. This has been confirmed in tunnel trials conducted in *Phacelia* that showed pre-flowering applications of sulfoxaflor at 48 g a.s./ha had no effect on honey bee mortality, foraging activity and development of brood.

Study Comments: IIIA 10.4.7/05	-
Agreed Endpoints: IIIA 10.4.7/05	It is concluded that the risk to honeybees is acceptable when the product is applied before flowering. Pre-flowering application made 5 days before flowering is considered sufficiently protective by ZcoRMS.

IIIA 10.5 Effects on Arthropods Other Than Bees

The critical endpoints employed in the risk assessment for non-target arthropods are indicated in the table below.

Table 10.5-1: EU Endpoints - Toxicity of GF-2626, GF-2032 and GF-2372 to arthropods other than bees

Compound	Test species	Test substrate	EU agreed endpoints*	
Laboratory study				
GF-2626	*Aphidius rhopalosiphi*	Glass plate	Mortality: LR_{50} = 0.0209 g a.s./ha	
GF-2626	*Typhlodromus pyri*	Glass plate	Mortality: LR_{50} = 384 g a.s./ha	
Extended laboratory study				
GF-2626	*Aphidius rhopalosiphi*	Barley seedlings	Mortality: LR_{50} = 0.945 g a.s./ha Reproduction: ER_{50} > 1.02 g a.s./ha	
GF-2032	*Aleochara bilineata*	Sandy soil	Mortality: LR_{50} > 24 g a.s./ha Reproduction: ER_{50} > 24 g a.s./ha	
GF-2626	*Chrysoperla carnea*	*Phaseolus vulgaris* leaf discs	Mortality: LR_{50} > 48 g a.s./ha Reproduction: ER_{50} > 48 g a.s./ha	
Aged residue study				
GF-2626	*Aphidius rhopalosiphi*	Barley seedlings	0 DAT 400 200 58.33 7 DAT 400 200 58.33 14 DAT 400 200 58.33 21 DAT 400 200 58.33 28 DAT 400 200	Corrected mortality: 100 100 100 100 83 73 53 50 23 17 4 4 10 7

			14 DAT 400 200 58.33 21 DAT 400 200 58.33 28 DAT 400 200 mL GF-2626/ha	Corrected reproduction: - - 3.6 18.5 -13.6 17.0 -5.4 8.5
Field or semi-field tests				
GF-2372	**Cereal field test - S.W. France** GF-2372 applied once at a rate of 24 or 48 g Sulfoxaflor/ha, or twice at 24 g Sulfoxaflor/ha with a spray interval of 21 days, induced moderate and transient but statistically significant adverse effects on populations of certain orders (mainly Homopetera, Hymenoptera and few Diptera and Collembola). Recovery was seen for all these taxa within one or two months after the first application. There was no clear differentiation in effects related to test rate or application frequency. For few hymenopteran taxa the recovery period was slightly longer in the 2 x 24 g Sulfoxaflor/ha rate. One mite taxon (Stigmaeidae) showed a delayed but persistent adverse effect in the 2 x 24 g Sulfoxaflor/ha treatment, but differences compared to the control were statistically significant only on one sampling moment (*ca.* 3 months after the second application). These findings were confirmed by community analyses, although the observed responses of the arthropod communities were not statistically significant for any of the GF-2372 treatments tested. Based on De Jong *et al.* (2010), the effect of one application of GF-2372 at 24 or 48 g Sulfoxaflor/ha, or two applications at 24 g Sulfoxaflor/ha in a commercial cereal field in Southern Europe (France), would be classified as 3 (clear response of taxa, but full recovery within two months after the first application for all but one taxon, full recovery of the community within two months after the first application). Hence, no sustained adverse effects on arthropod communities prevailing in a commercial cereal field in Southern Europe (France) are likely to occur, when GF-2372 (active ingredient Sulfoxaflor) is applied at rates of up to 48 g Sulfoxaflor/ha.		
GF-2372	**Cereal field test - the Netherlands** GF-2372 applied once at a rate of 24 or 48 g Sulfoxaflor/ha, or twice at 24 g Sulfoxaflor/ha with a spray interval of 22 days, induced moderate but statistically significant adverse effects on populations of certain orders (mainly Homopetera, Diptera, Hymenoptera and Collembola), but recovery was seen for almost all these taxa within one or two months after the first application. There was usually no clear differentiation in effects related to test rate or application frequency. For few hymenopteran taxa the recovery period was slightly longer in the 2 x 24 g Sulfoxaflor/ha rate. Stronger effects were observed on aphids and a few associated specialist predators (Coccinellidae) and parasitoids (e.g. Aphelinidae). Aphid populations recovered within one month after application, before natural decline (migration). Related predators and parasitoids also disappeared from the field. It is expected that adverse effects observed for the specialist predators and parasitoids were at least partly due to indirect effects of reduced host availability. Multivariate analyses confirmed that recovery of the entire community occurred within			

	approximately two months after the first application in all three GF-2372 treatments. Based on De Jong *et al.* (2010), the effect of one application of GF-2372 at 24 or 48 g Sulfoxaflor/ha, or two applications at 24 g Sulfoxaflor/ha in a commercial cereal field in Northern Europe (The Netherlands), would be classified as 3 (clear response of taxa, but full recovery within two months after the first application). Hence, no sustained adverse effects on arthropod communities prevailing in a commercial cereal field in Northern Europe (The Netherlands) are likely to occur, when GF-2372 (active ingredient Sulfoxaflor) is applied at rates of up to 48 g Sulfoxaflor/ha.
GF-2626	**NTA off-field test - S.W, France** The impact of simulated drift events on arthropod populations and communities typical of grassy field margins in Southern Europe was evaluated for GF-2626 at exposures equivalent to 0.3, 0.6, 1.2, 2.4, 4.8 and 9.6 g Sulfoxaflor/ha. At the community level no consistent rate related response was noted. For some test item rates faint and transient responses could be observed, but the magnitude was not related to the dose rate. At the population level no consistent dose related adverse effects from GF-2626 treatments were found, except for the collembolan taxon Bourletiellidae and for aphids. In all rates populations of the family Bourletiellidae were recovered within one or two months after application. Hence, no sustained adverse effects on arthropod communities prevailing in grasslands in South-West France are likely to occur, when GF-2626 (active ingredient Sulfoxaflor) is applied at rates of up to 9.6 g Sulfoxaflor/ha.

* EFSA Journal 2014; 12(5):3692

Risk Assessment for Arthropods other than Bees

The risk assessment for non-target arthropods for GF-2626 is based on the rates of 2 x 24 g a.s./ha or 1 x 48 g a.s./ha for non-target arthropod populations present in the in-field area. Typically, another area of risk is to non-target arthropod populations present in the off-field area where these species are exposed to spray drift at the time of application. However, for greenhouses, the off-field risk assessment is not required and can be omitted.

First tier risk assessment

A risk assessment for these scenarios may be conducted using the Hazard Quotient approach in ESCORT 2 (Guidance Document on Terrestrial Ecotoxicology: SANCO/10329/2002).

From the results in Table 10.5-1, the LR_{50} values for GF-2626 to the indicator species *T. pyri* and *A. rhopalosiphi*, under laboratory conditions, were estimated to be greater than 384 and equal to 0.0209 g a.s./ha, respectively. These values will be taken to represent the realistic worst case end point for non-target arthropods exposed to GF-2626. The risk assessment is presented in the table below.

Table 10.5-3: Risk to non-target arthropods from applications of GF-2626 – laboratory data

Scenario	Species	Exposure (g a.s./ha)	Correction factor	VDF	LR_{50} (g a.s./ha)	HQ
Greenhouse uses on Tomatoes, Pepper (incl. Chilli pepper), Aubergines (incl. Pepinos), Cucurbits (Cucumber, Water Melon, Zuccini, Melon), Bulbs, Ornamentals, Flowers: 1 x 48 g a.s./ha						
In-field	*T. pyri*	48	N/A	N/A	>384	0.125
	A. rhopalosiphi	48	N/A	N/A	0.0209	**2297**

N/A: not applicable.
VDF: Vegetation distribution factor
HQs shown in **bold** are greater than the trigger value of 2

The in-field HQs for *T. pyri* are below the trigger value of 2, indicating an acceptable risk, and no further testing is required on this species. The in-field HQ for *A. rhopalosiphi* is greater than the trigger value of 2, indicating the need for a higher tier risk assessment.

Higher tier risk assessment

Under ESCORT 2, given that for one indicator species the in-field first tier HQ of 2 has been breached, in addition to further higher tier testing with the standard first tier indicator species, two additional crop relevant species are required to be tested. This requirement has been addressed by providing details of extended laboratory studies with the standard indicator species, plus the foliar dwelling predator *Chrysoperla carnea* and the ground dwelling parasitoid *Aleochara bilineata*. It is noted that, the study on *A. bilineata* was conducted with a different formulation (GF-2032, a SC formulation similar to GF-2626; containing 22% wt/wt sulfoxaflor.). However, in line with the approach taken in the DAR (2013), since similar levels of toxicity to non-target arthropods were proved in the laboratory studies then the results for GF-2032 can be extrapolated to the formulation GF-2626.

In addition, details have been provided for laboratory ‘aged residue‘ studies with *A. rhopalosiphi* and GF-2626, for two non-target arthropod field studies with GF-2372 conducted in cereals in south-west France and in Netherlands and a field study with GF-2626 simulating drift events on non-target arthropod communities of grassy field margins in south-west France.

Extended laboratory data

The extended laboratory data for *A. rhopalosiphi*, *A. bilineata* and *C. carnea* have been used in a higher tier risk assessment.

Under ESCORT 2, lethal and sublethal effects in extended laboratory of ≥ 50% following exposure at predicted in-field and off-field exposure rates, indicate the need for a further assessment of the impact on non-target arthropod populations. The in-field greenhouse predicted exposure rate (PER) and corresponding risk assessment are presented in the table below.

Table 10.5-4: Risk to non-target arthropods from applications of GF-2626 – Extended laboratory data – lethal and sublethal effects

Species	Endpoints (g a.s./ha)	In-field PER (g a.s./ha)	Risk acceptable Y/N
Greenhouse uses on Tomatoes, Pepper (incl. Chilli pepper), Aubergines (incl. Pepinos), Cucurbits (Cucumber, Water Melon, Zuccini, Melon), Bulbs, Ornamentals, Flowers: 1 x 48 g a.s./ha			
A. rhopalosiphi	LR_{50} = 0.945 ER_{50} > 1.02	48	**N**
C. carnea	LR_{50} > 48 ER_{50} > 48		Y
A. bilineata	LR_{50} > 24 ER_{50} > 24		Cannot be excluded

By comparison of the in-field exposure value (PER) to the extended laboratory endpoints an unacceptable in-field risk is indicated to *A. rhopalosiphi* and for *A. bilineata* in-field risk cannot be excluded because the study did not test the maximum rate of application of 48 g a.s./ha intended for greenhouse uses. An acceptable in-field risk was indicated for the green lacewing *C. carnea*. This indicates that applications of GF-2626 may be harmful to species of parasitoid wasps that may be used in greenhouses and that the risk to ground-dwelling beetles cannot be excluded due to a lack of appropriate data. Consequently, further consideration of additional information is necessary to confirm that the most sensitive organisms are species of parasitoid wasps and to confirm whether ground-dwelling beetles are indeed sensitive to GF-2626 at the maximum tested rate of 48 g a.s./ha under field test conditions.

Aged residue studies and field tests

Laboratory and extended laboratory toxicity studies determined *A. rhopalosiphi* to be the most sensitive (and the only adversely affected) tested species. These findings were confirmed by the results of the field studies. Furthermore, ground-dwelling beetles were not affected in field tests of the maximum rate of 48 g a.s./ha.

Two field studies were conducted in cereals in south-west France and in Netherland using GF-2372. Since similar levels of toxicity of GF-2626 and GF-2372 to NTA were proved in laboratory toxicity studies, an extrapolation of toxicity data may be made between the two formulations.

I) In-field risk assessment for NTA

Under ESCORT 2, lethal and sublethal effects in aged residue studies of ≤ 50% following exposure at predicted in-field and off-field exposure rates, indicate an acceptable risk. In an aged residue test on the most sensitive species, *A. rhopalosiphi*, carried out with GF-2626 at test rates representative of in-field exposure (48 and 24 g a.s./ha), less than 50% effects were noted on mortality and parasitism when aged for 21 days. In comparison with 100% mortality when exposed to freshly treated foliage, a distinct decline in potential adverse effects with time after treatment is demonstrated. These findings are also supported by the results of the cereals field

studies. **The results of this study may be used to set a withholding period of 21 days after application of sulfoxaflor in greenhouses after which parasitoid wasps may be introduced for biological control of pests.**

Two field tests were conducted to investigate in-field effect on non-target arthropods in commercial cereal field. One test was located in the Netherlands and the other in south-west France. In both cases the test item was GF-2372 and was tested according to three different application scenarios. One treatment was applied twice with approximately a 3 week spray interval at a rate of 24 g a.s./ha. In addition two single application treatments were tested, at 24 g and at 48 g a.s./ha. The first applications for each test were performed in spring 2010 for all three treatment scenarios.

Effects were similar in both tests. GF-2372 applied once at a rate of 24 or 48 g a.s./ha, or twice at 24 g a.s/ha with a spray interval of 21 days, induced moderate and transient but statistically significant adverse effects on populations of certain orders (mainly Homopetera, Hymenoptera, Diptera and Collembola). Recovery was seen for all these taxa within one or two months after the first application. There was no clear differentiation in effects related to test rate or application frequency. For few hymenopteran taxa the recovery period was slightly longer in the 2 x 24 g a.s./ha rate. In the southern test one mite taxon (Stigmaeidae) showed a delayed but persistent adverse effect in the 2 x 24 g a.s./ha treatment, but differences compared to the control were statistically significant only on one sampling moment (*ca*. 3 months after the second application). This was not observed in the northern test. Stronger effects were observed on aphids and a few associated specialist predators (Coccinellidae) and parasitoids (e.g. Aphelinidae). Aphid populations recovered within one month after application, before natural decline (migration). Related predators and parasitoids also disappeared from the field. It is expected that adverse effects observed for the specialist predators and parasitoids were at least partly due to indirect effects of reduced host availability. Multivariate analyses confirmed that recovery of the entire community occurred within approximately two months after the first application in all three GF-2372 treatments for both tests.

Based on the results of two cereal field studies, and given the lack of persistence of effect from exposure to treated foliage (as demonstrated in the above mentioned aged residue studies with *Aphidius*), long-term adverse effects persisting to the following season are considered unlikely.

It was concluded that although the proposed use of sulfoxaflor may adversely affect some ‘in-field’ non-target arthropod populations, such affects are unlikely to be long-term, and the potential for re-colonisation and recovery within a year was demonstrated.

Conclusions

The proposed uses of sulfoxaflor (formulated as GF-2626) may have an initial adverse effect on some non-target arthropod populations present within the ‘in-field‘ treated area.

However, long-term adverse effects from treatment are unlikely, and the potential for recovery within a year was demonstrated on cereal fields. The results of the field tests confirm that the most sensitive species were parasitoid wasps and that ground-dwelling beetles were not affected by application of sulfoxaflor at 48 g a.s./ha. Because populations of beneficial arthropods are

actively managed by growers within greenhouses and because the potential for natural recolonization is limited, it is appropriate to make a recommendation to mitigate risk for parasitoid wasps used as biological control agents in greenhouses, based on the results of the aged residue tests, as follows: **"Following application of sulfoxaflor in greenhouses, wait for a period of 21 days before introducing parasitoid wasps as biological control agents"**

ZRMS Conclusions:

Field studies cannot be omitted since effects on arthropods communities are observed. Then, considering that a recovery of the entire community in approximately two months is observed for a double application at 24 g sulfoxaflor/ha (21 days interval), zRMS proposes the following recommendation : **Following application of sulfoxaflor in greenhouses, wait for a period of 2 months before introducing beneficial organisms as biological control agents"**

IIIA 10.5.1 Using artificial substrates

The following *Aphidius rhopalosiphi* glass-plate toxicity study performed on GF-2626 was assessed in the EU review and is available in the DAR (2013) Annex B.9.

Report:	**IIIA 10.5.1/01, Stevens, J. (2010a)**
Title:	A rate-response laboratory test to determine the effects of GF-2626 on the parasitic wasp, *Aphidius rhopalosiphi* (Hymenoptera: Braconidae).
Document No:	Dow Study ID: 10-13
Guidelines:	Mead-Briggs *et al.* (2000)
GLP	Yes

Study Comments: IIIA 10.5.1/01	Already reviewed in the EU DAR for Sulfoxaflor (2013)
Agreed Endpoints: IIIA 10.5.1/01	The 48-h LR50 = 0.174 mL formulation/ha (nominally 20.88 mg Sulfoxaflor/ha).

The following *Typhlodromus pyri* glass-plate toxicity study performed on GF-2626 was assessed in the EU review and is available in the DAR (2013) Annex B.9.

Report:	**IIIA 10.5.1/02, Fallowfield, L. (2010a)**
Title:	A rate-response laboratory test to determine the effects of GF-2626 on the predatory mite, *Typhlodromus pyri* (Acari: Phytoseiidae).
Document No:	Dow Study ID: 10-12
Guidelines:	Blümel *et al.* (2000)

GLP	Yes

Study Comments: IIIA 10.5.1/02	Already reviewed in the EU DAR for Sulfoxaflor (2013)
Agreed Endpoints: IIIA 10.5.1/02	7-day LR_{50} = 3200 mL GF-2626/ha (equivalent to 384 g Sulfoxaflor/ha).

IIIA 10.5.2 Extended laboratory studies

The following extended laboratory toxicity study with *Aphidius rhopalosiphi* performed on GF-2626 was assessed in the EU review and is available in the DAR (2013) Annex B.9.

Report:	**IIIA 10.5.2/01, Stevens, J. (2010b)**
Title:	A rate-response extended laboratory bioassay to determine the effects of GF-2626 on the parasitic wasp, *Aphidius rhopalosiphi* (Hymenoptera, Braconidae).
Document No:	Dow Study ID: 10-29
Guidelines:	Mead-Briggs *et al.* (2009)
GLP	Yes

Study Comments: IIIA 10.5.2/01	Already reviewed in the EU DAR for Sulfoxaflor (2013)
Agreed Endpoints: IIIA 10.5.2/01	48-hour LR_{50} = 7.875 mL GF-2626/ha (equivalent to 0.945 g sulfoxaflor/ha)

The following extended laboratory toxicity study with *Aleochara bilineata* performed on GF-2032 was assessed in the EU review and is available in the DAR (2013) Annex B.9.

Report:	**IIIA 10.5.2/02, Spincer, D. (2009)**
Title:	An extended laboratory test to determine the effects of fresh residues of GF-2032 on the rove beetle, *Aleochara bilineata* (Coleoptera; Staphylinidae).
Document No:	Dow Study ID: 080089

Guidelines:	Grimm *et al.* (2000)
GLP	Yes

Study Comments: IIIA 10.5.2/02	Already reviewed in the EU DAR for Sulfoxaflor (2013)
Agreed Endpoints: IIIA 10.5.2/02	LR_{50} /ER_{50} >100 mL GF- 2032/ha (equivalent to 24 g Sulfoxaflor/ha)

The following extended laboratory toxicity study with *Chrysoperla carnea* performed on GF-2626 was assessed in the EU review and is available in the DAR (2013) Annex B.9.

Report:	**IIIA 10.5.2/03, Spincer, D. (2011)**
Title:	A rate-response extended laboratory test to determine the effects of GF-2626 on the green lacewing, *Chrysoperla carnea* (Neuroptera, Chrysopidae).
Document No:	Dow Study ID: 101310;
Guidelines:	Vogt *et al.* (2000)
GLP	Yes

Study Comments: IIIA 10.5.2/03	Already reviewed in the EU DAR for Sulfoxaflor (2013)
Agreed Endpoints: IIIA 10.5.2/03	LR_{50} /ER_{50} >400 mL GF-2626/ha (equivalent to 48 g Sulfoxaflor/ha)

Aged residue study

The following aged residue study with *Aphidius rhopalosiphi* performed on GF-2626 was assessed in the EU review and is available in the DAR (2013) Annex B.9.

Report:	**IIIA 10.5.2/04, Stevens, J. (2011)**
Title:	An aged-residue extended laboratory test to determine the effects of GF-2626 on the parasitic wasp, *Aphidius rhopalosiphi* (Hymenoptera, Braconidae).
Document No:	Dow Study ID: 10-14

Guidelines:	Mead-Briggs *et al.* (2009)
GLP	Yes

Study Comments: IIIA 10.5.2/04	Already reviewed in the EU DAR for Sulfoxaflor (2013)
Agreed Endpoints: IIIA 10.5.2/04	The effects of both fresh and field-aged foliar residues of GF-2626 on the parasitic wasp, *Aphidius rhopalosiphi*, were evaluated under extended laboratory test conditions. Although fresh residues of GF-2626 were harmful to the test insects at treatment rates of 58.33, 200 and 400 mL product/ha, the aged residues showed a clear decline in effects over time. At a treatment rate of 58.33 mL product/ha, the effects of residues were no longer unacceptable by 14 days after treatment. At treatment rates of 200 and 400 mL product/ha, the effects of residues were no longer unacceptable by 21 days after treatment.

IIIA 10.5.3 Semi-field tests

No semi-field data submitted.

IIIA 10.5.4 Field tests

The following field test performed on GF-2372 in SW France was assessed in the EU review and is available in the DAR (2013) Annex B.9.

Report:	**IIIA 10.5.4/01, Roig, J. (2011)**
Title:	A field trial to determine the effects of GF-2372 (a 50% WG formulation of Sulfoxaflor) on the non-target arthropod fauna of arable land after one and two applications to a wheat crop South West France.
Document No:	Dow Study ID: 101030;
Guidelines:	IOBC (Hassan, 1992), Anonymous (1992), ESCORT (Barrett et al., 1994), Brown (1998) and IOBC, BART and EPPO Joint Initiative (Candolfi et al., 2000), De Jong 2010 *et al.* (2010)
GLP	Yes

Study Comments:	Already reviewed in the EU DAR for Sulfoxaflor (2013)

IIIA 10.5.4/02	
Agreed Endpoints: IIIA 10.5.4/02	The reference item treatment (one application with dimethoate at 320 g a.s/ha and one application with lambdacyhalothrin at 40 g a.s./ha with a 21 day spray interval) induced severe and statistically significant effects on populations in all arthropod orders. At the end of the season the community as a whole had recovered, but at the population level some adverse effects persisted throughout the sampling period until spring next season. GF-2372 applied once at a rate of 24 or 48 g Sulfoxaflor/ha, or twice at 24 g Sulfoxaflor/ha with a spray interval of 21 days, induced moderate and transient but statistically significant adverse effects on populations of certain orders (mainly Homoptera, Hymenoptera and few Diptera and Collembola). Recovery was seen for all these taxa within one or two months after the first application. There was no clear differentiation in effects related to test rate or application frequency. For few hymenopteran taxa the recovery period was slightly longer in the 2 x 24 g Sulfoxaflor/ha rate. One mite taxon (Stigmaeidae) showed a delayed but persistent adverse effect in the 2 x 24 g Sulfoxaflor/ha treatment, but differences compared to the control were statistically significant only on one sampling moment (ca 3 months after the second application). These findings were confirmed by community analyses, although the observed responses of the arthropod communities were not statistically significant for any of the GF-2372 treatments tested. It is concluded, that no sustained adverse effects on arthropod communities prevailing in a commercial cereal field in Southern Europe (France) are likely to occur, when GF-2372 (active ingredient Sulfoxaflor) is applied at rates of up to 48 g Sulfoxaflor/ha.

The following field test performed on GF-2372 in the Netherlands was assessed in the EU review and is available in the DAR (2013) Annex B.9.

Report:	**IIIA 10.5.4/02, Bakker, F. (2011)**
Title:	A field trial to determine the effects of GF-2372 (a 50% WG formulation of Sulfoxaflor) on the non-target arthropod fauna of arable land after one and two applications to a wheat crop in the Netherlands
Document No:	Dow Study ID: 101031
Guidelines:	IOBC (Hassan, 1992), Anonymous (1992), ESCORT (Barrett et al., 1994), Brown (1998) and IOBC, BART and EPPO Joint Initiative (Candolfi et al., 2000), De Jong 2010 *et al.* (2010)
GLP	Yes

Study Comments: IIIA 10.5.4/03	Already reviewed in the EU DAR for Sulfoxaflor (2013)
Agreed Endpoints: IIIA 10.5.4/03	The reference item treatment (one application with dimethoate at 320 g a.s./ha and one application with lambdacyhalothrin at 40 g a.s./ha with a 22 day spray interval) induced severe and statistically significant effects on populations in all arthropod orders. At the end of the season the community as a whole had recovered, but at the population level some adverse effects persisted throughout the sampling period until spring next season. GF-2372 applied once at a rate of 24 or 48 g Sulfoxaflor/ha, or twice at 24 g a.s/ha with a spray interval of 22 days, induced moderate but statistically significant adverse effects on populations of certain orders (mainly Homopetera, Diptera, Hymenoptera and Collembola), but recovery was seen for almost all these taxa within one or two months after the first application. There was usually no clear differentiation in effects related to test rate or application frequency. For few hymenopteran taxa the recovery period was slightly longer in the 2 x 24 g Sulfoxaflor/ha rate. Stronger effects were observed on aphids and a few associated specialist predators (Coccinellidae) and parasitoids (e.g. Aphelinidae). Aphid populations recovered within one month after application, before natural decline (migration). Related predators and parasitoids also disappeared from the field. It is expected that adverse effects observed for the specialist predators and parasitoids were at least partly due to indirect effects of reduced host availability. Multivariate analyses confirmed that recovery of the entire community occurred within approximately two months after the first application in all three GF-2372 treatments. No sustained adverse effects on arthropod communities prevailing in a commercial cereal field in Northern Europe (The Netherlands) are likely to occur, when GF-2372 (active ingredient Sulfoxaflor) is applied at rates of up to 48 g Sulfoxaflor/ha.

IIIA 10.6 Effects on Earthworms and Other Soil Non-target Macro-organisms

Overall summary

GF-2626 was one of the representative formulations in the EU review of sulfoxaflor. However new risk assessment parameters are now considered in the assessment of risk to earthworms and soil macro-organisms and hence an appropriate risk assessment with the proposed use pattern is provided and is considered adequate. The risk assessment has been conducted in line with the Terrestrial Guidance Document (SANCO/10329/2002, rev. 2 final).

The critical endpoints employed in the risk assessment for earthworms and other soil non-target organisms are indicated in the tables below.

Table 10.6-1: EU Endpoints - Toxicity of sulfoxaflor and relevant soil metabolites X11719474 and X11519540 to earthworms and soil macro-organisms

Compound	Test species	Test design	EU agreed endpoints* (mg/kg soil)
Earthworms			
Sulfoxaflor	*Eisenia fetida*	acute, 14 days (10% peat in test soil)	**LC_{50} = 0.885**
X11719474		acute, 14 days (10% peat in test soil)	**LC_{50} >1000****
Sulfoxaflor	*Eisenia fetida*	chronic, 56 days (10% peat in test soil)	**NOEC = 0.1**
X11719474		chronic, 56 days (10% peat in test soil)	**NOEC = 10****
X11519540		chronic, 56 days (10% peat in test soil)	**NOEC = 10****
Other soil non-target organisms			
X11719474	*Folsomia candida*	chronic, 28 d (5% peat in test soil)	**NOEC = 10****
X11519540			**NOEC = 10****
X11519540	*Hypoaspis aculeifer*	chronic, 14 d (5% peat in test soil)	**NOEC = 10****

* EFSA Journal (2014); 12(5):3692
** The highest concentration tested.
Endpoints used in the risk assessment are in **bold**.
The EPPO correction factor (2) does not need to be applied to the endpoints as the log Pow of sulfoxaflor is < 2

The available data for GF-2626 are summarised in the following table.

Table 10.6-2: EU Endpoints - Toxicity of GF-2626 to earthworms and soil macro-invertebrates

Compound	Test species	Test design	EU agreed endpoints*
GF-2626	*Eisenia foetida*	acute, 14 days (10% peat in test soil)	LC_{50} = 5.527 mg GF-2626/kg **LC_{50} = 0.66 mg sulfoxaflor/kg**
	Eisenia foetida	chronic, 56 days (10% peat in test soil)	NOEC = 0.75 mg GF-2626/kg **NOEC = 0.09 mg sulfoxaflor/kg**
	Folsomia candida	chronic, 28 d (5% peat in test soil)	NOEC = 2.67 mg GF-2626/kg **NOEC = 0.3204 mg sulfoxaflor/kg**
	Hypoaspis aculeifer	chronic, 14 d (5% peat in test soil)	NOEC = 100 mg GF-2626/kg **NOEC = 12 mg sulfoxaflor/kg**

Field study on earthworms:

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

Three application scenario were used in the study:

T1: first application of 4.8 g/ha X11719474 (plateau concentration 1) plus second application of 24 g Sulfoxaflor/ha applied as GF-2626 after one week

T2: first application of 9.6 g/ha X11719474 (plateau concentration 2) plus a second application of 24 g Sulfoxaflor/ha applied as GF-2626 after one week plus a third application of 24 g Sulfoxaflor/ha applied as GF-2626 four weeks after the first application

T3: first application of 9.6 g/ha X11719474 (plateau concentration 2) plus a second application of 48 g Sulfoxaflor./ha applied as GF-2626 after one week.

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

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

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

Field study on soil micro-arthropods:

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

Three application scenario were used in the study:

T1: first application of 4.8 g/ha X11719474 (plateau concentration 1) plus second application of 24 g Sulfoxaflor/ha applied as GF-2626 after one week

T2: first application of 9.6 g/ha X11719474 (plateau concentration 2) plus a second application of 24 g Sulfoxaflor/ha applied as GF-2626 after one week plus a third application of 24 g Sulfoxaflor/ha applied as GF-2626 four weeks after the first application

T3: first application of 9.6 g/ha X11719474 (plateau concentration 2) plus a second application of 48 g Sulfoxaflor./ha applied as GF-2626 after one week.

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

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

* EFSA Journal (2014); 12(5):3692
The EPPO correction factor (2) does not need to be applied to the endpoints as the log Pow of sulfoxaflor is < 2.
Endpoints used in the risk assessment are in **bold**.

In accordance with the GAP (Table 10-2), applications to ornamentals (1 x 48 g a.s./ha) has been assessed as the worst case scenario.

PEC_{soil} values for sulfoxaflor and for its potentially relevant metabolites (X11719474 and X11519540) following applications to ornamentals (worst case) are summarised in Section 5, Points IIIA 9.4 and IIIA 9.5, respectively.

IIIA 10.6.1 Toxicity exposure ratios, TER_A and TER_{LT}

Acute risk

Acute toxicity exposure ratios (TERs) for the proposed protected uses of GF-2626 in ornamentals (worst case scenario) are presented in Table 10.6.1-1.

Table 10.6.1-1: Acute TER values for earthworms

Test compound	Crop	LC_{50} (mg a.s./kg)	PECsoil (mg a.s./kg)	TER_A	Trigger value
GF-2626	Ornamentals	0.66 (a.s.)	0.0576	11.5	10
Sulfoxaflor		0.885	0.0576	15.4	
X11719474		> 1000	0.127 (plateau)	>7000	

All the acute TER values are higher than the acute trigger value of 10, indicating that protected uses GF-2626 pose an acceptable acute risk to earthworms.

Long-term risk

Long-term toxicity exposure ratios (TERs) for the proposed protected uses of GF-2626 in ornamentals (worst case scenario) are presented in Tables 10.6.1-2 and 10.6.1-3.

Table 10.6.1-2: Chronic TER values for earthworms

Substance	Crop	NOEC (mg a.s./kg)	PECsoil (mg a.s./kg)	TER_{LT}	Trigger value
GF-2626	Ornamentals	0.09	0.0576	**1.6**	5
Sulfoxaflor		0.1	0.0576	**1.7**	
X11719474		10	0.127 (plateau)	78.7	
X11519540		10	0.032 (plateau)	312.5	

TERs in **bold** are below the trigger value

The resulting TER_{LT} values for sulfoxaflor relevant soil metabolites are above the trigger value of 5 indicating an acceptable chronic risk to earthworms. However, the TER_{LT} values for sulfoxaflor and GF-2626 are below the trigger value of 5 indicating a potential long-term risk to earthworms from the proposed protected uses of GF-2626. Although, these TER_{LT} values are based on the worst-case initial PECsoil values and conservative endpoints from laboratory studies.

The results of the earthworm field study indicated a lack of adverse effects on earthworm field community under field conditions when GF-2626 and its metabolite X11719474 are applied at rates of up to 48 g sulfoxaflor/ha and 9.6 g X11719474/ha, respectively in field uses. Therefore, it can be concluded that the proposed protected uses of GF-2626 on fruiting vegetables and ornamentals pose an acceptable risk to earthworms.

Table 10.6.1-3: Chronic TER values for soil macro-organisms

Substance	Crop	NOEC (mg a.s./kg)	PECsoil (mg a.s./kg)	TER_{LT}	Trigger value
Folsomia candida					
GF-2626	Ornamentals	0.3204	0.0576	5.5	5
X11719474		10	0.127 (plateau)	78.7	
X11519540		10	0.032 (plateau)	312.5	
Hypoaspis aculeifer					
GF-2626	Ornamentals	12	0.0576	208.3	5
X11519540		10	0.032 (plateau)	312.5	

The resulting TER_{LT} values for GF-2626 and sulfoxaflor soil metabolites are all above the trigger value of 5, indicating an acceptable chronic risk to both soil macro-organisms from the proposed protected uses GF-2626.

These finding are supported by the results of the field study on soil micro-arthropods (Collembola, Acari), that indicated a lack of adverse effects on soil micro-arthropod field

communities under field conditions when GF-2626 and its metabolite X11719474 are applied at rates of up to 48 g Sulfoxaflor/ha and 9.6 g X11719474/ha, respectively. Therefore, it can be concluded that the proposed protected uses of GF-2626 on fruiting vegetables and ornamentals pose an acceptable risk to soil macro-organisms.

IIIA 10.6.2 Acute toxicity

The following acute toxicity study with earthworms performed on GF-2626 was assessed in the EU review and is available in the DAR (2013) Annex B.9.

Report:	**IIIA 10.6.2/01, McCormac, A. (2010a)**
Title:	Determination of acute toxicity of GF-2626 to the earthworm *Eisenia fetida* in an artificial soil substrate.
Document No:	Dow Study ID: 101913
Guidelines:	OECD 207
GLP	Yes

Study Comments: IIIA 10.6.2/01	Already reviewed in the EU DAR for Sulfoxaflor (2013)
Agreed Endpoints: IIIA 10.6.2/01	LC_{50} = 5.527 mg GF-2626/kg soil dry weight (equivalent to 0.66 mg Sulfoxaflor/kg soil)

IIIA 10.6.3 Sublethal effects

The following chronic toxicity study with earthworms performed on GF-2626 was assessed in the EU review and is available in the DAR (2013) Annex B.9.

Report:	**IIIA 10.6.3/01, McCormac, A. (2010b)**
Title:	Determination of chronic (sub-lethal) toxicity of GF-2626 to the earthworm *Eisenia fetida* in an artificial soil substrate.
Document No:	Dow Study ID: 101304
Guidelines:	OECD 222
GLP	Yes

Study Comments: IIIA 10.6.3/01	Already reviewed in the EU DAR for Sulfoxaflor (2013)
Agreed Endpoints:	In artificial soil containing 10% peat as the test substrate: 56-days NOEC = 0.75 mg GF-2626/kg soil dry weight (equivalent to 0.09

IIIA 10.6.3/01	mg Sulfoxaflor/kg soil)

IIIA 10.6.4 Field tests

The following field study with earthworms performed on GF-2626 was assessed in the EU review and is available in the DAR (2013) Annex B.9.

Report:	**IIIA 10.6.4/01, Klein, O. (2012)**
Title:	Field Study to Evaluate the Effects of Sulfoxaflor (as GF-2626 12% SC formulation) and its primary soil metabolite X11719474 on Earthworms in Southern Germany.
Document No:	Dow Study ID: 110844
Guidelines:	Kula & Kula (1994 - BBA guideline for testing the effects of pesticides on earthworms in the field), ISO Guideline 11268-3 (1999), ISO Guideline 23611-1 (2006)
GLP	Yes

Study Comments: IIIA 10.6.4/01	Already reviewed in the EU DAR for Sulfoxaflor (2013)
Agreed Endpoints: IIIA 10.6.4/01	After application of GF-2626 and its metabolite X11719474 applied to field plots no adverse effects on total earthworm numbers occurred in any of the samplings. No significant reductions in numbers and weights of earthworm species, groupings or totals were found in any of the samplings. No sustained adverse effects on an earthworm field community are likely to occur, when GF-2626 (active ingredient Sulfoxaflor) and its metabolite X11719474 are applied at rates of up to 48 g Sulfoxaflor/ha and 9.6 g X11719474/ha, respectively**.**

IIIA 10.6.5 Residue content of earthworms

Based on the acceptable risk to earthworms following the proposed uses of GF-2626 and on the low bioaccumulation tendency of sulfoxaflor, studies to determine the residue content of earthworms are not required.

IIIA 10.6.6 Effects on other non-target macro-organisms

Data on effects on soil macro-organisms other than earthworms are only required where the field DT_{90} is > 100 days.

The maximum field DT_{90f} for sulfoxaflor is estimated to be 24.68 days (Section 5, Point IIIA 9.1). Therefore, studies on the effects of sulfoxaflor on other non-target macro-organisms are not triggered because the DT_{90f} is less than 100 days.

For the relevant soil metabolites X11719474 and X11519540 the maximum field DT_{90f} values are 1279 and 3838 days, respectively (Section 5, Point IIIA 9.1). Given that the DT_{90f} is > 100 days the need to address effects on other non-target macro-organisms is triggered and collembola (*Folsomia candida*) reproductive toxicity studies and gammasid mite (*Hypoaspis aculeifer*) reproductive toxicity studies for these metabolites have been provided. A study on the effects of metabolite X11719474 on the soil mite *Hypoaspis aculeifer* was not submitted as a higher tier litter bag study had been carried out with GF-2626 and metabolite X11719474 (ref to Section IIIA 10.6.7).

The following reproductive toxicity studies with collembola (*Folsomia candida*) and gammasid mite (*Hypoaspis aculeifer*) performed on GF-2626 were assessed in the EU review and is available in the DAR (2013) Annex B.9.

Report:	**IIIA 10.6.6/01, Witte, B. (2010)**
Title:	Effects of GF-2626 on Reproduction of the Collembola *Folsomia candida* in Artificial Soil with 5% Peat.
Document No:	Dow Study ID: 101311.
Guidelines:	OECD 232 (2009), ISO 11267 (1999)
GLP	Yes

Study Comments: IIIA 10.6.6/01	Already reviewed in the EU DAR for Sulfoxaflor (2013)
Agreed Endpoints: IIIA 10.6.6/01	28 days NOEC = 2.67 mg GF-2626/kg soil dry weight (equivalent to 0.3204 mg Sulfoxaflor/kg).

Report:	**IIIA 10.6.6/02, Witte, B. (2011)**
Title:	GF-2626: Effects of GF-2626 on Reproduction of the Predatory Mite *Hypoaspis aculeifer* in Artificial Soil with 5% Peat.
Document No:	Dow Study ID: 102001
Guidelines:	OECD 226 (2008)
GLP	Yes

Study Comments:	Already reviewed in the EU DAR for Sulfoxaflor (2013)

IIIA 10.6.6/02	
Agreed Endpoints: IIIA 10.6.6/02	14-day NOEC = 100 mg GF-2626/kg soil (equivalent to 12 mg sulfoxaflor/kg)

The following study on micro-arthropod field community performed on GF-2626 and the metabolite X11719474 was assessed in the EU review and is available in the DAR (2013) Annex B.9.

Report:	**IIIA 10.6.6/03, Mack, P. (2012)**
Title:	Field Study to Evaluate the Effects of Sulfoxaflor (as GF-2626 12% SC formulation) and its primary soil metabolite X11719474 on Soil Micro-Arthropods in Southern Germany.
Document No:	Dow Study ID: 110845
Guidelines:	ISO Guideline 23611-2 (2006), OECD 56 (2006)
GLP	Yes

Study Comments: IIIA 10.6.6/03	Already reviewed in the EU DAR for Sulfoxaflor (2013)
Agreed Endpoints: IIIA 10.6.6/03	After application of GF-2626 and its metabolite X11719474 applied to field plots no adverse effects on soil living micro-arthropod numbers occurred in any of the samplings. No significant or persistent treatment related reductions were observed in any of the test item treatment. Hence, no sustained adverse effects on soil microarthropod field communities are likely to occur, when GF-2626 (active ingredient Sulfoxaflor) and its metabolite X11719474 are applied at rates of up to 48 g Sulfoxaflor/ha and 9.6 g X11719474/ha, respectively.

IIIA 10.6.7 Effects on organic matter breakdown

Data on the impact on soil organic matter breakdown are only required where the field DT_{90} is >365 days.

The maximum field DT_{90f} for Sulfoxaflor is estimated to be 24.68 days (Section 5, Point IIIA 9.1). Therefore, studies on the effects of Sulfoxaflor on organic matter breakdown are not triggered because the DT_{90f} is less than 100 days.

For the relevant soil metabolites X11719474 and X11519540 the maximum field DT_{90f} values are 1279 and 3838 days, respectively (Section 5, Point IIIA 9.1). Given the high soil persistence

of the metabolites X11719474 and X11519540 (DT_{90}'s > 365 days), data on the impact on organic matter breakdown are required. A litter bag study carried out with GF-2626 and the metabolite X11719474 has been submitted. Since no impact on the organic matter breakdown was determined in this study (conducted up to 48 g sulfoxaflor/ha plus 9.6 g X11719474/ha), and given no effects of the metabolite X11519540 on the reproduction of Collembola and gammasid mites were reported, no further studies are needed.

The following study on effects on organic matter breakdown performed on GF-2626 and the metabolite X11719474 was assessed in the EU review and is available in the DAR (2013) Annex B.9.

Report:	**IIIA 10.6.7/01, Mack, P. (2011)**
Title:	Field Study to Evaluate the Effects of Sulfoxaflor (as GF-2626 12% SC formulation) and its primary soil metabolite X11719474 on the Decomposition of Organic Matter in the Field.
Document No:	Dow Study ID: 110602
Guidelines:	"EPFES" workshop, Lisbon, April 2002 (RÖMBKE et al. 2003), OECD 56 (2006)
GLP	Yes

Study Comments: IIIA 10.6.7/01	Already reviewed in the EU DAR for Sulfoxaflor (2013)
Agreed Endpoints: IIIA 10.6.7/01	Sulfoxaflor (as GF-2626) and its metabolite X11719474 had no adverse effects on the breakdown of buried organic material (straw) compared to a water treated control after exposure of about 1, 3, 6 and 9 months

IIIA 10.7 Effects on Soil Microbial Activity

Overall summary

Effects on soil microbial activity of GF-2626 were evaluated as part of the EU review of sulfoxaflor. An appropriate risk assessment has been conducted in line with the Terrestrial Guidance Document (SANCO/10329/2002, rev. 2 final) and is considered adequate.

The endpoints employed in the risk assessment for effects on soil microbial activity are indicated in Table 10.7-1.

Table 10.7-1: EU Endpoints – Effects of sulfoxaflor, GF-2626 and relevant soil metabolites on soil microbial activity

Compound	Test type	EU agreed endpoints*
Sulfoxaflor	N transformation	< 25 % effect at day 28 at 0.33 mg a.s./kg d.w. soil (240 g a.s./ha)
	C transformation	< 25 % effect at day 28 at 0.33 mg a.s./kg d.w. soil (240 g a.s./ha)
GF-2626	N transformation	< 25 % effect at day 28 at 2.85 mg prep./kg d.w. soil 0.32 mg a.s./kg d.w. soil (240 g a.s./ha)
	C transformation	< 25 % effect at day 28 at 2.85 mg prep./kg d.w. soil 0.32 mg a.s./kg d.w. soil (240 g a.s./ha)
X11719474	N transformation	< 25 % effect at day 28 at 0.16 mg a.s./kg d.w. soil (120 g a.s./ha)
	C transformation	< 25 % effect at day 28 at 0.16 mg a.s./kg d.w. soil (120 g a.s./ha)
X11519540	N transformation	< 25 % effect at day 28 at 0.32 mg a.s./kg d.w. soil (240 g a.s./ha)
	C transformation	< 25 % effect at day 28 at 0.32 mg a.s./kg d.w. soil (240 g a.s./ha)

* EFSA Journal (2014); 12(5):3692

In accordance with the GAP (Table 10-2) applications to ornamentals are used as a worst case scenario.

PEC_{soil} values for sulfoxaflor and for the potentially relevant metabolites (X11719474 and X11519540) following applications to fruiting vegetables and ornamentals (worst-case) are summarised in Section 5, Points IIIA 9.4 and IIIA 9.5, respectively.

Conclusion

TERs are summarised in Table 10.7-2.

Table 10.7-3: Minimum TERs for soil microbial activity after protected uses of GF-2626 on ornamentals (worst-case scenarios)

Substance	Test type	Timescale	Maximum PECsoil (mg/kg soil)	NOEC (mg/kg soil)	TER
Ornamentals					
GF-2626	N transformation	28 days	0.0576	0.32 (a.s.)	5.6
	C transformation	28 days			
Sulfoxaflor	N transformation	28 days	0.0576	0.33	5.7
	C transformation	28 days			
X11719474	N transformation	28days	0.127	0.16	1.3
	C transformation	28 days			
X11519540	N transformation	28 days	0.032	0.32	10
	C transformation	28 days			

The TER values are all above 1, indicating that the predicted environmental concentrations of GF-2626, sulfoxaflor and the metabolites X11719474 and X11519540 from the proposed protected uses of GF-2626 on fruiting vegetables and ornamentals will have no unacceptable effects on soil microorganisms.

IIIA 10.7.1 Laboratory testing

The following soil microbial toxicity study performed on GF-2626 was assessed in the EU review and is available in the DAR (2013) Annex B.9.

Report:	**IIIA 10.7.1/01, Feil, N. (2011)**
Title:	Effects of GF-2626 on the Activity of the Soil Microflora in the Laboratory
Document No:	Dow Study ID: 101912 & 101917
Guidelines:	OECD 216, 217
GLP	Yes

Study Comments: IIIA 10.7.1/01	Already reviewed in the EU DAR for Sulfoxaflor (2013)
Agreed Endpoints: IIIA 10.7.1/01	The results indicate a lack of adverse effects on soil microbial respiration and nitrogen transformation at the maximum test dose of 2.85 mg GF-2626/kg soil dry weight, i.e. 0.32 mg Sulfoxaflor/kg soil dry weight (corresponding to the application rate of 2 L GF-2626/ha, i.e. equal to 240 g Sulfoxaflor/ha).

IIIA 10.7.2 Additional testing

No additional studies with GF-2626 are required.

IIIA 10.8 Effects on Non-Target Plants

IIIA 10.8.1 Terrestrial plants

The uses of GF-2626 on fruiting vegetables and ornamentals grown under protection will not lead to significant exposure of non-target plants, thus the risk to this wildlife group is considered to be negligible.

IIIA 10.9 Other Non-Target Species (Flora and Fauna)

The uses of GF-2626 on fruiting vegetables and ornamentals grown under protection will not lead to significant exposure of non-target plants, thus the risk to this wildlife group is considered to be negligible.

IIIA 10.10 Other/Special Studies

No other studies are available.

IIIA 10.11 Summary and Evaluation of Points 9 and 10.1-10.10

IIIA 10.11.1 Predicted distribution and fate in the environment and time courses involved

The predicted distribution and fate of GF-2626 in the environment is described in Part B, Section 5.

IIIA 10.11.2 Non-target species at risk and extent of potential exposure

Birds and mammals

The uses of GF-2626 on fruiting vegetables and ornamentals grown under protection will not lead to significant exposure of natural populations of birds and mammals, thus the risk to this wildlife group is considered to be negligible.

Aquatic organisms

The risk to aquatic organisms was assessed based on the Aquatic Guidance Document (Sanco/ 3268/2001) using initial aquatic PEC values calculated in accordance with the standard Dutch glasshouse model.

An acceptable risk to aquatic organisms has been demonstrated for the indoor uses of GF-2626 on fruiting vegetables and ornamentals, without the need for risk mitigation measures.

Effects on bees

The uses of GF-2626 on fruiting vegetables and ornamentals grown under protection will not lead to significant exposure of natural populations of bees, thus the risk to this wildlife group is considered to be negligible.

ZRMS considers that a re-introduction of pollinator's colonies in permanent covered crops must be realised at least 6 days after spray dried. To protect the wild pollinators, structure covering the crops should be closed during the application and during a period of 6 days after application.

Effects on other non-target arthropod species

The uses of GF-2626 on fruiting vegetables and ornamentals grown under protection will not lead to significant exposure of natural populations of non-target arthropods, thus the risk to this wildlife group is considered to be negligible.

Following application of sulfoxaflor in greenhouses, wait for a period of 2 months before introducing beneficial organisms as biological control agents"

Effects on earthworms and other soil macro-organisms

The risk to earthworms and other soil macro-invertebrates was assessed in line with the Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002). The calculated TER_A values were greater than the trigger value for GF-2626, sulfoxaflor and the metabolite X11719474, indicating acceptable acute risk to earthworms from the proposed protected uses of

GF-2626. The calculated TER_{LT} values for other soil macro-organisms were greater than the trigger value for GF-2626 and the potentially relevant metabolites X11719474 and X11519540, indicating an acceptable chronic risk to other soil non-target organisms from the proposed uses of GF-2626. The calculated TER_{LT} values for earthworms were also greater than the trigger value for the potentially relevant metabolites X11719474 and X11519540. However, the TER_{LT} values for GF-2626 and sulfoxaflor are below the trigger value of 5 indicating a potential long-term risk to earthworms from the proposed protected uses of GF-2626.

Based on the results of field studies on earthworms and soil micro-arthropods (Collembola, Acari) it was concluded that all proposed uses of GF-2626 posed an acceptable risk to soil macro-organisms in permanent covered crops.

Effects on soil micro-organisms

The risk to soil micro-organisms was assessed in line with the Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002). When applying GF-2626 according to the proposed representative GAPs on protected fruiting vegetables and ornamentals, no negative effects on microbial activities were to be expected.

Effects on non-target plants

The uses of GF-2626 on fruiting vegetables and ornamentals grown under protection will not lead to significant exposure of non-target plants, thus the risk to this wildlife group is considered to be negligible.

IIIA 10.11.3 Short and long term risks for non-target species, populations, communities and processes

There are no additional European requirements for formulated products.

IIIA 10.11.4 Risk of fish kills and fatalities in large vertebrates or terrestrial predators

There are no additional European requirements for formulated products.

IIIA 10.11.5 Precautions necessary to avoid/minimise environmental contamination and to protect non-target species

Protected uses of GF-2626 at the proposed label rates without mitigation measures for fruiting vegetables and ornamentals pose an acceptable risk to all non-target species.

It is recommended thata re-introduction of pollinator's colonies in permanent covered crops must be realised at least 6 days after spray dried. To protect the wild pollinators, structure covering the crops should be closed during the application and during a period of 6 days after application.

Following application of sulfoxaflor in greenhouses, wait for a period of 2 months before introducing beneficial organisms as biological control agents.

Appendix 1: List of data submitted in support of the evaluation

The submitted studies are reported in the DAR of the Sulfoxaflor (2013)

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)
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
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)
Poland	Aubergines (incl. Pepinos), Bulbs, Ornamentals, Flowers, Cucurbits (Cucumber, Water Melon, Zuccini, Melon), Pepper (incl. Chilli pepper), Tomatoes
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	Interval between applications (min)	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	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		
	NL, PT, RO, ES, UK, PL)														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	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	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,	GF-2626	G	Aphids, Whiteflies	SC	120 g/L	Ground applied foliar spray,	BBCH 20-87	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.

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		
	DE, EL, IE, IT, MA, NL, PT, RO, ES, UK, PL)						broadcast	All year							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.
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	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.

(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