

REGISTRATION REPORT

Part B

Section 4: Metabolism and Residues

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

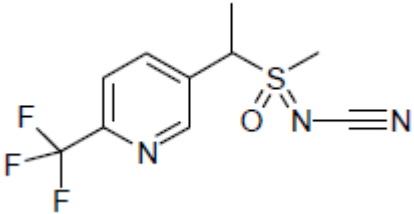
IIIA 8	METABOLISM AND RESIDUES DATA	4
Sulfoxaflor	4	
IIIA 8.1	Stability of Residues.....	6
IIIA 8.1.1	Stability of residues during storage of samples	6
IIIA 8.1.2	Stability of residues in sample extracts	7
IIIA 8.2	Studies on metabolism in plants or livestock	8
IIIA 8.2.1	Metabolism in plants	8
IIIA 8.2.2	Metabolism in livestock	10
IIIA 8.3	Residue trials (supervised field trials)	11
IIIA 8.3.1	Tomatoes & aubergines.....	11
IIIA 8.3.2	Peppers	20
IIIA 8.3.3	Cucurbits with edible peel (cucumber).....	27
IIIA 8.3.4	Cucurbits with inedible peel	34
IIIA 8.3.5	Conversion factors calculation	44
IIIA 8.4	Livestock Feeding Studies	45
IIIA 8.5	Studies on Industrial Processing and/or Household Preparation.....	45
IIIA 8.5.1	Nature of residues.....	45
IIIA 8.5.2	Distribution of the residue in peel/pulp	46
IIIA 8.5.3	Balance studies on a core set of representative processes	47
IIIA 8.6	Studies for Residues in Representative Succeeding Crops	48
IIIA 8.6.1	Preliminary consideration.....	48
IIIA 8.6.2	Summary of European data	48
IIIA 8.6.3	New data.....	49
IIIA 8.6.4	Conclusion on succeeding crops studies	49
IIIA 8.7	Proposed Residue Definition and Maximum Residue Levels.....	49
IIIA 8.7.1	Proposed residue definition	49
IIIA 8.7.2	Proposed maximum residue levels (MRLs)	50
IIIA 8.8	Proposed Pre-Harvest Intervals, Re-Entry or Withholding Periods	50
IIIA 8.8.1	Pre-harvest interval (in days) for each relevant crop.....	50
IIIA 8.8.2	Re-entry period (in days) for livestock, to areas to be grazed	50
IIIA 8.8.3	Re-entry period for man to crops, buildings or spaces treated	50
IIIA 8.8.4	Withholding period (in days) for animal feedingstuffs	50
IIIA 8.8.5	Waiting period before sowing or planting crop to be protected	50
IIIA 8.8.6	Waiting period between application and handling treated products.....	50
IIIA 8.8.7	Waiting period (in days) before sowing or planting succeeding crops	50
IIIA 8.9	Other/Special Studies	50
IIIA 8.10	Estimation of Exposure Through Diet and Other Means	51
IIIA 8.10.1	TMDI calculations.....	53
IIIA 8.10.2	IEDI calculations	54
IIIA 8.10.3	IESTI calculations	56
IIIA 8.10.4	Consumer risk assessment conclusion.....	57
IIIA 8.11	Summary and Evaluation of Residue Behaviour for sulfoxaflor	57
Overall conclusion	58	
Summary of the evaluation.....	58	
References :	60	
Appendix 1: List of data submitted in support of the evaluation	62	

Appendix 2: Acceptable critical Uses –GAP tables.....	64
--	-----------

IIIA 8 METABOLISM AND RESIDUES DATA

Sulfoxaflor

General data on sulfoxaflor are summarized in the table thereafter

Active substance (ISO Common Name)	Sulfoxaflor
Company (ies)	Dow AgroSciences
Function (e.g. fungicide)	Insecticide
Rapporteur Member State	Ireland (MRL/Import tolerance proposal, CLH, Residues data, Toxicology & Metabolism, Coordination)
Co-rapporteur Member State	France (Identity, Application data, Phys.Chem, Methods of Analysis & Efficacy) Czech Republic (Eco-tox) Poland (E-Fate & Behaviour)
Approval Status (pending/approved/ not approved)	Approved
Approval Date (DD Month YYYY)	18/08/2015
Directive/Regulation number (AAAA/X/EC or EU)	Reg. (EU) 2015/1295
Residue definition for monitoring (as defined in current regulation)	Sulfoxaflor (sum of isomers)
Legislation footnotes	/
EFSA Journal Conclusions on the peer-review	EFSA (European Food Safety Authority), 2014a. Conclusion on the peer review of the pesticide risk assessment of the active substance sulfoxaflor. EFSA Journal 2014;12(5):3692, [172 pp.] doi:10.2903/j.efsa.2014.3692. Available online: www.efsa.europa.eu/efsajournal.htm
Inclusion Directive Reference/ Approval Regulation Reference	Reg. (EU) 2015/1295 of 27 July 2015, OJEU L199, 29.7.2015, p. 8-11 Reg. (EU) No 540/2011 of 25 May 2011, OJEU L153, 11.6.2011, p. 1-186
Restriction (is restricted to use as "...")	None
Chemical structure	
Molecular formula	C ₁₀ H ₁₀ F ₃ N ₃ O S
Molecular mass	277.3 g/mol
Log POW	pH 5: Log Pow= 0.806 pH 7: Log Pow= 0.802 pH 9: Log Pow= 0.799
Chemical group	sulfoximine
Main Pest Target	sap-feeding insects such as aphids, woolly aphids, plant bugs and hoppers, whiteflies and mealybugs, scales, thrips and psyllids
Mode of action (if available)	Acts through a unique interaction with the nicotinic

	acetylcholine receptor (nAChR) in insects. Relative to neonicotinoids, Sulfoxaflor is a highly efficacious agonist of the nicotinic receptor with low binding affinity for the imidacloprid binding site.
Representative uses (The uses supported were "...")	The supported uses were as an insecticide on fruiting vegetables (field use and glasshouse application; tomato, cherry tomato, pepper (bell and non bell), aubergine), cucurbits (field use and glasshouse application; cucumber, water melon, courgette), spring and winter cereals (wheat, rye, barley, oats, triticale) and cotton.
Systemic	Yes: Sulfoxaflor is a xylem mobile systemic insecticide with translaminar movement which enters the insect primarily through contact and ingestion. Contact occurs by direct application. Ingestion occurs in aphids through the stylet (feeding tube) from within the vascular system of the plant. Following entry to the insect, sulfoxaflor acts on the insect nicotinic-acetylcholine site at a unique target receptor. Symptoms appear almost immediately and complete mortality occurs within a few hours.
IUPAC	[methyl(oxo){1-[6-(trifluoromethyl)-3-pyridyl]ethyl}-λ6-sulfanylidene]cyanamide
12(1) or 12(2)	In progress (EFSA-Q-2015-00485)

Toxicological reference values relevant for dietary risk assessment

Overview of the toxicological reference values for sulfoxaflor

	Source	Year	Value	Study relied upon	Safety factor
Sulfoxaflor					
ADI	EC	2015	0.04 mg/kg bw/day	2-year Rat	x100
ARfD	EC	2015	0.25 mg/kg bw	Rat acute neurotoxicity study	x100

Considerations about established MRL for active substance

Today, the MRLs for active substance are published in Regulation (EU) N° 2016/1. **New MRLs have been proposed in document SANTE/11442/2016.** It should be noted that an MRL modification request has been applied for in Ireland. The request concerns various commodities. The assessment of the dossier is currently ongoing.

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

Appendix 2 of this document presents the acceptable critical uses for the risk assessment of GF-2626 (CLOSER) in this section.

IIIA 8.1 Stability of Residues

IIIA 8.1.1 STABILITY OF RESIDUES DURING STORAGE OF SAMPLES

IIIA 8.1.1.1 European data (Ireland 2012)

Data on the stability of sulfoxaflor and metabolite X11719474 has been evaluated in the framework of EU evaluation. The findings of frozen storage stability studies from the DAR (Vol. 3, B.7.6.4 and B.7.8) are briefly summarised thereafter.

Plant matrices:

The frozen storage stability of sulfoxaflor and its metabolite X11719474 was investigated in orange (whole fruit), peach (whole fruit), wheat grain and soybean seed that are representative of high acid content, high water content, high starch content (dry) and high oil content commodities respectively. In all commodities, residues were found to be stable for at least 680 days (22 months) when stored at -20 °C.

Animal matrices:

Stability of residues in products of animal origin was considered as part of the livestock feeding studies that were evaluated in the DAR. The frozen storage stability of sulfoxaflor and its metabolite X11719474 was investigated in egg, poultry muscle, liver and fat matrices, and in whole and skim milk, cream and bovine muscle, liver, kidney and fat.

Residues were found to be stable for up to 64 days in poultry tissues and eggs, 56 days in bovine tissues and 42 days in milk at < -18 °C.

Table IIIA 8.1.1-1: Summary of stability data for sulfoxaflor

Plant products		
Crop	Characteristics of the crop group	Acceptable Maximum Storage duration
Orange whole fruit	High acid content	680 days (22 months)
Peach whole fruit	High water content	680 days (22 months)
Wheat Grain	Dry	680 days (22 months)
Soybean seeds	High oil content	680 days (22 months)
Animal Products		
Hen	Eggs	64 days
	Muscle	
	Liver	
	Fat	
Cow	Milk	42 days
	Skim Milk	
	Cream	
	Muscle	56 days
	Liver	
	Kidney	
	Fat	

Table IIIA 8.1.1-2: Summary of stability data for metabolite X11719474

Plant products		
Crop	Characteristics of the crop group	Acceptable Maximum Storage duration
Orange whole fruit	High acid content	680 days (22 months)
Peach whole fruit	High water content	680 days (22 months)
Wheat Grain	Dry	680 days (22 months)
Soybean seeds	High oil content	680 days (22 months)
Animal Products		
Hen	Eggs	64 days
	Muscle	
	Liver	
	Fat	
Cow	Milk	42 days
	Skim Milk	
	Cream	
	Muscle	56 days
	Liver	
	Kidney	
	Fat	

IIIA 8.1.1.2 New data

No new data submitted. Moreover, the data provided in support of the EU Approval submission for sulfoxaflor and evaluated in the DAR are sufficient to describe the stability of the residues in crops under consideration. Therefore, no new data are required.

IIIA 8.1.1.3 Conclusion on stability of residues during storage

Considering the intended use in the framework of the present dossier (tomatoes, peppers, aubergines, cucurbits with edible and inedible peel), it can be concluded that sulfoxaflor and its metabolite X11719474 are stable in high water commodities for 680 days.

IIIA 8.1.2 STABILITY OF RESIDUES IN SAMPLE EXTRACTS

No specific new data have been submitted. However, relevant information on the stability of residues in the final or any intermediate extracts can be derived from the fortification experiments performed during sample analysis. Every analytical batch performed in the submitted studies does contain at least one freshly fortified sample for concurrent recovery determination. The extracts from fortified and study samples have been handled and stored in parallel. As the recoveries in the fortified samples are within the acceptable range of 70%-110%, the stability of the sample extracts is considered as sufficiently proven.

IIIA 8.2 Studies on metabolism in plants or livestock**IIIA 8.2.1 METABOLISM IN PLANTS****IIIA 8.2.1.1 European data (Ireland 2012, EFSA 2014a)**

Plant metabolism was studied in tomato, snap peas, lettuce, and rice with sulfoxaflor labelled in the [14C-pyridine] ring in the framework of approbation of active substance. For each metabolism study, foliar and soil applications were studied separately. Characteristics of the studies are summarised in table below.

Table IIIA 8.2.1-1: Summary of plant metabolism studies

Group	Crop	Label position	Formulation	Type of treatment (foliar, seed, ...)/(F) or (G) or (I) ⁽¹⁾	Application details				Reference
					Growth stage at application	Rate	No	Sampling	
Fruits and fruiting vegetable	Tomato	[14C-pyridine] ring	N.R.	Foliar application F	N.R.	600 g as/ha split in 4 applications (200 + 200 +125+75)		Immature plants:14 DA1A, 14DA2A Tomatoes: 1, 7, 14 DALA Vines 14 DALA	Ireland, 2012
			N.R.	Soil application F	N.R.	225g as./ha	2	Immature plants:14 DA1A Tomatoes: 14, 21, 28 DALA Vines : 28 DALA	
Leafy vegetables	Lettuce	[14C-pyridine] ring	N.R.	Foliar application F	N.R.	200 g as/ha	3	Immature plants:14 DA1A Mature plants: 7 DALA	Ireland, 2012
			N.R.	Soil application F	N.R.	225 g as/ha	2	Immature plants:14 DA1A Mature plants: 7 DALA	
Pulses and oilseeds	Snap Peas	[14C-pyridine] ring	N.R.	Foliar application F	N.R.	200 g as/kg	3	Immature plants: 14 DA1A, 14 DA2A, At maturity: pods, vines	Ireland, 2012
			N.R.	Soil application F	N.R.	450 g as/ha	1	Immature plants: 14 DA1A, At maturity: pods, vines	
Cereals	Rice	[14C-pyridine] ring	N.R.	Foliar application F	N.R.	600 g as/ha split in 3 applications at 225, 225 &		Immature plants:14 DA1A At maturity :	Ireland, 2012

Group	Crop	Label position	Formulation	Type of treatment (foliar, seed, ...)/(F) or (G) or (I) ⁽¹⁾	Application details				Reference
					Growth stage at application	Rate	No	Sampling	
						150 g as/ha		straw, hulls, grain	
			Rice plant were transplanted at BBCH 13-14	Soil application F	N.R.	400 g as/ha	1	Immature plants 14 and 28 DAT At maturity : straw, hulls, grain	

(1) Outdoor or field use (F), glasshouse application (G), Indoor Application (I)

N.R.: Not Reported in the DAR

DA1A: Day After 1st Application

DA2A : Day After 2nd Application

DAT: Day After Treatment

DALA : Day After Last Application

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

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

Overall, compounds X11719474 and X11721061 (conjugated form) were the pertinent metabolites in mature tomato fruit (20 – 29 % and 13 – 22 % TRR, respectively), foliage (16 % and 14 % TRR), pods of snap pea (both 13 % TRR) and vines (12 % and 7 % TRR), lettuce (30 % and 8 % TRR), rice grain (8 % and 11 % TRR) and straw (10 % and 8 % TRR). Only low proportions of free X11721061 were observed in the mature crops (≤ 4 % TRR). Other metabolites were not significant.

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

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

Based on the available metabolism data in primary and rotational crops, the metabolite X11719474 was considered quantitatively relevant. With regard to the toxicological profile of metabolite X11719474, the available acute and short term toxicity data show a lower toxicity than sulfoxaflor, however, the lack of a long term toxicity and carcinogenicity study and the fact that it consists of four isomers did not allow to

reach consensus that the potential for chronic toxicity of the metabolite X11719474 is significantly lower than of parent. For the time being it will be assumed for the consumer risk assessment that this metabolite is as toxic as the parent compound, and the residue definition for risk assessment was therefore agreed as sum of sulfoxaflor and X11719474, expressed as sulfoxaflor. If this metabolite were to be demonstrated as being significantly less toxic than sulfoxaflor, only the parent compound might be considered in the residue definition for risk assessment. For monitoring the plant residue definition is proposed as sulfoxaflor only.

IIIA 8.2.1.2 New data

No new data submitted

IIIA 8.2.1.3 Conclusion on metabolism in plants

The data evaluated during the approval of the active substance sulfoxaflor, and published in the DAR (Feb 2012) are sufficient to describe the behaviour of the active substance, and no further studies are required. It should be noted that the metabolism studies evaluated in the DAR are in accordance with the intended cGAPs of the uses under consideration and thus cover those uses.

IIIA 8.2.2 METABOLISM IN LIVESTOCK

As the crops under consideration are not fed to animals, livestock considerations are not required.

IIIA 8.3 Residue trials (supervised field trials)

For all intended crops, details on the analytical methods used in residue trials are available in Section 2 of this dRR (Section 2: Methods of analysis).

IIIA 8.3.1 TOMATOES & AUBERGINES

Table IIIA 8.3.1-1: Comparison of intended and critical EU GAPs

Crop	Type of GAP	Number of applications	Application rate per treatment (g as/ha)	Interval between application (days)	Growth stage at last application	PHI (days)
Tomatoes & Aubergines	EU (DAR) ⁽¹⁾	1	24	-	BBCH 20 – 39 BBCH 40 - 89	≥1
	MRL application (Australia)	4	96	7	Up to BBCH 89	1
	Intended EU	1	48	7	BBCH 20-87	1

(1). Representative use

IIIA 8.3.1.1 Summary of B.7.6 Data (Ireland 2012 & 2014; EFSA, 2014a)

The use of sulfoxaflor on tomatoes has already been assessed in the framework of Annex I inclusion process. In the monograph of sulfoxaflor, two residue studies performed on indoor tomatoes had been provided; 4 trials were performed in each study. In the first study, sulfoxaflor was only applied once at 24 g a.s./ha. This application rate corresponds to the representative use but does not match the critical GAP intended for GF-2626 (CLOSER) on indoor tomatoes. Therefore, results of this study are not presented thereafter. On the other hand, in the second monograph study, sulfoxaflor was applied once at 24 g a.s./ha or 48 g a.s./ha with a 1-day PHI. While in the DAR, data from the 24 g a.s./ha plots were selected to support the representative use, results from the 48 g a.s./ha plots were retained in the framework of this dossier to cope with the higher intended application rate.

The application characteristics of all trials comply with the agricultural practices intended for tomatoes. Residue levels of sulfoxaflor and its metabolites X11719474 have been measured. Total residues in tomatoes range from 0.021 mg/kg to 0.067 mg/kg. Results of the trials are summarised in Table IIIA 8.3.1-2.

Table IIIA 8.3.1-2 : Residue trials on indoor tomatoes performed with sulfoxaflor and submitted in the monograph

GLP and Trial Details	Crop	Country	Application Details									Residues found		
Trial ID Study ID Report No. GLP(Y/N) Trial Year	Crop Variety	Country Zone Location	Form No.	No. of Appls	Appl Rate (g ai/ha)	Spray Vol (L/ha)	Appl Conc (g ai/hL)	Appl Date	GS at Last Appl	PHI (days)	Portion Analysed	XDE-208 (mg/kg)	X11719474 (mg/kg)	Total* (mg/kg)
CEMS-4698A CEMS-4698 DAS Report #:101457 Y 2010	tomato Sartigys	France SZ Glasshouse or plastic tunnel or protected	GF-2626	1	48.5	770	6.3	02-Aug-2010	BBCH.88 to 89	0 1 3 7 10	Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit	<0.01 <0.01 0.012 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	<0.019 <0.019 0.021 <0.019 <0.019
CEMS-4698B CEMS-4698 DAS Report #:101457 Y 2010	tomato Rally	Greece SZ Glasshouse or plastic tunnel or protected	GF-2626	1	45.3	943	4.8	08-Jun-2010	BBCH.83	0 1 3 7 10	Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit	0.017 0.018 0.011 <0.01 0.014	<0.01 <0.01 <0.01 <0.01 <0.01	0.026 0.027 0.020 <0.019 0.023
CEMS-4698C CEMS-4698 DAS Report #:101457 Y 2010	cherry tomato Carminio	Italy SZ Glasshouse or plastic tunnel or protected	GF-2626	1	51	498	10.2	13-Jul-2010	BBCH.87	0 1 3 7 10	Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit	0.048 0.040 0.058 0.055 0.041	<0.01 <0.01 <0.01 <0.01 <0.01	0.057 0.049 0.067 0.064 0.050
CEMS-4698D CEMS-4698 DAS Report #:101457 Y 2010	cherry tomato Granillon	Spain SZ Glasshouse or plastic tunnel or protected	GF-2626	1	49.4	1029	4.8	17-Aug-2010	BBCH.84	0 1 3 7 10	Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit	0.056 0.052 0.040 0.045 0.038	<0.01 <0.01 <0.01 <0.01 <0.01	0.065 0.061 0.049 0.054 0.047

* - Sum of sulfoxaflor and X11719474 expressed as sulfoxaflor. A conversion factor of 0.939 has been applied to residues of X11719474

IIIA 8.3.1.2 New data**IIIA 8.3.1.2.1 Study 1 – CEMS-5009**

Report:	IIIA 8.3.5.1/06, Rawle, N. W., 2012
Title:	Residues of sulfaxoflor in indoor tomatoes at intervals and harvest following a single application of GF-2626 – Europe - 2011
Document No:	Study ID : CEMS-5009, Report ID : CEMR-5009 Dow AgroSciences Reference : GHE-P-12705
Guidelines:	-Commission Directive 96/68/EC amending Council Directive 91/414/EEC concerning the placing of plant protection products on the market, Oct.21, 1996, -"Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realisation of Residue Trials, July 22, 1997", and -OECD Guidelines for the Testing of Chemicals, No. 509: Crop Field Trial, 2009.
GLP	Yes

Acceptability	Deviations
Yes	<p>CEMS-5009A: A farmer agreement was not in place. At the first sampling event, untreated samples were taken before, instead of after, application.</p> <p>CEMS-5009C: Sample temperatures rose above -18°C during shipment, but samples remained frozen at all times. One retain sample was less than 2 kg (1.36 kg / ≥ 12 units).</p> <p>CEMS-5009D: The final sampling event did not take place because the farmer had already destroyed the crop. Plot size was less than 30 m². One sample weight was below 2 kg.</p> <p>None of the deviations had major impacts on the study.</p>

Table IIIA 8.3.1-3: Summary of global information on study 1

Comparative trials (between formulations, with and adjuvant/safener/synergist)	No, SC formulation containing 120 g/L Sulfoxaflor
Number of applications	1
Dose (g as/ha)	48 g a.s./ha
Mode of application	Foliar broadcast
PHI (days) and/or growth stage (BBCH)	1, 3, 7, 10, 21 & 28 days
Analytical method (Code +Type)	091031 Liquid Chromatography/Mass Spectrometry
LoQ (mg/kg)	0.01mg/kg

Table IIIA 8.3.1-4: Summary of the study 1 trials

N° Trial	CEMS-5010A	CEMS-5010B	CEMS-5010C	CEMS-5010D
North/South/Indoor	I	I	I	I
Decline (D)/Harvest (H) trial?	D	D	D	D
Formulation	SC	SC	SC	SC
Equivalence between formulations	Y	Y	Y	Y
Accordance with intended GAP	Y	Y	Y	Y
Correct sampling	Y	Y	Y	Y
Samples frozen within 24h	Y	Y	Y	Y
Storage period (in days)	Sample	141	105	99
	Extract	1	1	1
Storage T° <-18°C	Y	Y	Y	Y
Validated analytical method	Y	Y	Y	Y
Negative controls	Y	Y	Y	Y
Considered trial	Y	Y	Y	Y
Remarks	-	-	-	-

Table IIIA 8.3.1-5: Summary of data from residue trials for study 1

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Notifier: Dow AgroSciences, European Development Centre

address 1 2nd Floor – 3 Milton Park, Abingdon

address 2 Oxon OX14 4RN, UK

address 3

Content of a.i. (g/kg or g/l) : 120 g/L

Formulation (e.g. WP) : SC

Commercial (name) : GF-2626

product

Applicant : Eurofins AgroScience Services GmbH

Active ingredient : Sulfoxaflor

Crop / crop group : Fruiting Vegetables : Tomatoes

Submission date :

Page :

Indoors / outdoors : Indoor

Other a. s. in formulation

(common name and content) : None

Residues calculated as : XDE-208 + X11719474

GLP and Trial Details	Crop	Country	Application Details									Residues found			Remarks
Trial ID Study ID Report No. GLP(Y/N) Trial Year	Crop Variety	Country (Zone) Location incl. postal code	Form No.	No. of Appls	Appl Rate (g ai/ha)	Spray Vol (L/ha)	Appl Conc (g ai/hL)	Appl Date	GS at Last Appl	PHI (days)	Portion Analysed	XDE-208 (mg/kg)	X11719474 (mg/kg)	Total* (mg/kg)	
	(a)							(c)		(d)	(a)				
CEMS-5009A CEMS-5009 GHE-P-12705 Y 2011	tomato Losna	Italy (SZ) 04022 Fondi, Latina Glasshouse or plastic tunnel or protected	GF-2626	1	47.6	993	4.8	11-Jul-2011	BBCH.89	0 1 3 7 10 21 28	Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit	0.025 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.034 <0.019 <0.019 <0.019 <0.019 <0.019 <0.019 <0.019	

GLP and Trial Details	Crop	Country	Application Details									Residues found			Remarks
Trial ID Study ID Report No. GLP(Y/N) Trial Year	Crop Variety	Country (Zone) Location incl. postal code	Form No.	No. of Appls	Appl Rate (g ai/ha)	Spray Vol (L/ha)	Appl Conc (g ai/hL)	Appl Date	GS at Last Appl	PHI (days)	Portion Analysed	XDE-208 (mg/kg)	X11719474 (mg/kg)	Total* (mg/kg)	
(a)	(a)							(c)		(d)	(a)				
CEMS-5009B CEMS-5009 GHE-P-12705 Y 2011	tomato Caramba	Spain (SZ) 50669 Santa Engracia, Aragon Glasshouse or plastic tunnel or protected	GF- 2626	1	49.6	723	6.9	16-Aug- 2011	BBCH.87 to 89	0 1 3 7 10 21 28	Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit	0.015 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.024 <0.019 <0.019 <0.019 <0.019 <0.019 <0.019 <0.019	
CEMS-5009C CEMS-5009 GHE-P-12705 Y 2011	tomato Vanessa	Germany (NZ) 03226 Vetschau, Brandenburg Glasshouse or plastic tunnel or protected	GF- 2626	1	46.8	975	4.8	22-Aug- 2011	BBCH.77	0 1 3 7 10 21 28	Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit	0.010 <0.01 <0.01 <0.01 0.010 0.010 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.019 <0.019 <0.019 <0.019 0.019 0.019 <0.019	
CEMS-5009D CEMS-5009 GHE-P-12705 Y 2011	tomato Roma	France (NZ) 56620 Plouhinec, Britanny Glasshouse or plastic tunnel or protected	GF- 2626	1	47.4	493	9.6	30-Aug- 2011	BBCH.83 to 88	0 1 3 8 11 21	Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit	0.011 <0.01 <0.01 <0.01 0.010 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.020 <0.019 <0.019 <0.019 0.019 <0.019	

Remarks:

(a) According to CODEX Classification / Guide

(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

(b) Only if relevant

(c) Year must be indicated

(d) Days after last application (Label pre-harvest interval, PHI, underline)

* - Sum of sulfoxaflor and X11719474 expressed as sulfoxaflor. A conversion factor of 0.939 has been applied to residues of X11719474

IIIA 8.3.1.3 Summary of monograph and new data supporting the intended use on tomatoes and aubergines and conformity to existing MRL

Table IIIA 8.3.1-6: Summary of monograph and new data supporting the intended use on tomatoes and aubergines and conformity to existing MRL

Commodity	Source	EU zone	Evaluation GAP Residue levels (mg/kg)	STMR (mg/kg)	HR (mg/kg)	Rber (mg/kg)	Rmax (mg/kg)	OECD calculator MRL (mg/kg)	In force EU MRL (mg/kg) (1)	MRL compliance resulting / in force
Tomatoes → Aubergines	Monograph	Indoor (4)	Trials GAP: 1 x 48 g a.s./ha, PHI 1d Mo: 0.012; 0.018; 0.052; 0.058 RA: 0.021; 0.027; 0.051; 0.067	Mo: 0.035 RA: 0.039	Mo: 0.058 RA: 0.067	Mo: 0.113	Mo: 0.155	Mo: 0.15	Reg (EU) 2016/1 & Doc SANTE/11 442/2016: 0.3	Yes
	New trials	Indoor (4)	Trials GAP: 1 x 48 g a.s./ha, PHI 1d Mo: 2x <0.01; 2x 0.01 RA: 2x <0.019; 2x 0.019	Mo: 0.010 RA: 0.019	Mo: 0.010 RA: 0.019	Mo: 0.020	Mo: 0.010	Mo: 0.02		
	Overall supporting data for EU GAP	Indoor (8)	Mo: 2x <0.01; 2x 0.01; 0.012; 0.018; 0.052; 0.058 RA: 2x <0.019; 2x 0.019; 0.021; 0.027; 0.051; 0.067	Mo: 0.011 RA: 0.020	Mo: 0.058 RA: 0.067	Mo: 0.087	Mo: 0.087	Mo: 0.1		

Mo = residue levels expressed according to residue definition for enforcement (sulfoxaflor)

RA = residue levels expressed according to residue definition for risk assessment (sum of sulfoxaflor and metabolite X11719474, expressed as sulfoxaflor)

(1) source of EU MRL : EU MRL data base: http://ec.europa.eu/sanco_pesticides/public/index.cfm

IIIA 8.3.1.4 Conclusion for tomatoes and aubergines

Tomatoes are a major crop in Southern and Northern Europe. Thus, a minimum of eight trials are required to support the use of GF-2626 on indoor tomatoes.

The 8 indoor trials presented above are sufficient to support the use of sulfoxaflor on indoor tomatoes. They confirm that the residues arising from the proposed use on tomatoes will not exceed the current EU MRL.

According to EU Guideline Document SANCO 7525/VI/95- rev. 9, March 2011, results from tomatoes trials can be extrapolated to aubergines. As both commodities share the same MRL, the extrapolation is possible. The use of sulfoxaflor on aubergines should not lead to an MRL exceedance.

The use of GF-2626 (CLOSER) on indoor tomatoes and aubergines is fully supported in Europe.

IIIA 8.3.2 PEPPERS**Table IIIA 8.3.2-1: Comparison of intended and critical EU GAPs**

Crop	Type of GAP	Number of applications	Application rate per treatment (g a.s./ha)	Interval between application (days)	Growth stage at last application	PHI (days)
Peppers	EU (DAR) ⁽¹⁾	1	24	-	BBCH 20 – 39 BBCH 40 - 89	≥1
	MRL application (Australia)	4	96	7	Up to BBCH 89	1
	Intended EU	1	48	7	BBCH 20-87	1

(1). Representative use

IIIA 8.3.2.1 Summary of B.7.6 Data (Ireland 2012 & 2014; EFSA, 2014a)

The use of sulfoxaflor on peppers has already been assessed in the framework of Annex I inclusion process. Two residue studies performed on indoor peppers were provided in the frame of sulfoxaflor monograph. In the first study, sulfoxaflor was only applied once at 24 g a.s./ha. As this application rate does not match the critical GAP intended for GF-2626 (CLOSER) on indoor peppers, results of this study are not presented thereafter. On the other hand, in the second monograph study, sulfoxaflor was applied once at 24 g a.s./ha or 48 g a.s./ha with a 1-day PHI. While in the DAR, data from the 24 g a.s./ha plots were selected to support the representative use, results from the 48 g a.s./ha plots were retained in the frame of this dossier to cope with the higher intended application rate. Residue levels of sulfoxaflor and its metabolites X11719474 have been measured in all trials: total residues in peppers range from 0.029 mg/kg to 0.044 mg/kg.

Results of the trials are summarised in Table IIIA 8.3.2-2.

Table IIIA 8.3.2-2: Residue trials on indoor peppers performed with sulfoxaflor and submitted in the monograph

GLP and Trial Details	Crop	Country	Application Details									Residues found		
Trial ID Study ID Report No. GLP(Y/N) Trial Year	Crop Variety	Country Zone Location	Form No.	No. of Appls	Appl Rate (g ai/ha)	Spray Vol (L/ha)	Appl Conc (g ai/hL)	Appl Date	GS at Last Appl	PHI (days)	Portion Analysed	XDE-208 (mg/kg)	X11719474 (mg/kg)	Total * (mg/kg)
CEMS-4702A CEMS-4702 DAS Report #:101463 Y 2010	pepper Joselito	France SZ Glasshouse or plastic tunnel or protected	GF-2626	1	49.1	815	6.0	29-Jun-10	BBCH.89	0 1 3 7 10	Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit	0.037 0.035 0.027 0.022 0.017	<0.01 <0.01 <0.01 <0.01 <0.01	0.046 0.044 0.036 0.031 0.026
CEMS-4702B CEMS-4702 DAS Report #:101463 Y 2010	pepper Navarro	Italy SZ Glasshouse or plastic tunnel or protected	GF-2626	1	51.2	1000	5.1	17-Aug-10	BBCH.89	0 1 3 7 10	Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit	0.048 0.028 0.035 0.017 0.030	<0.01 <0.01 <0.01 <0.01 <0.01	0.057 0.037 0.044 0.026 0.039
CEMS-4702C CEMS-4702 DAS Report #:101463 Y 2010	pepper Raico	Greece SZ Glasshouse or plastic tunnel or protected	GF-2626	1	50.1	1044	4.8	13-Jul-10	BBCH.74	0 1 3 7 10	Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit	0.019 0.018 0.013 0.020 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	0.028 0.027 0.022 0.029 <0.019
CEMS-4702D CEMS-4702 DAS Report #:101463 Y 2010	pepper Morron	Spain SZ Glasshouse or plastic tunnel or protected	GF-2626	1	54.1	844	6.4	27-Sep-10	BBCH.87-89	0 1 3 7 10	Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit	0.019 0.013 0.020 0.011 0.019	<0.01 <0.01 <0.01 <0.01 <0.01	0.028 0.022 0.029 0.020 0.028

* - Sum of sulfoxaflor and X11719474 expressed as sulfoxaflor. A conversion factor of 0.939 has been applied to residues of X11719474

IIIA 8.3.2.2 New data**IIIA 8.3.2.2.1 Study 1 – CEMS-5012**

Report:	IIIA 8.3.5.2/04, Rawle, N. W., 2011
Title:	Residues of sulfaxoflor in indoor bell peppers at intervals and harvest following a single application of GF-2626 – Europe - 2011
Document No:	Study ID : CEMS-5012, Report ID : CEMR-5012 Dow AgroSciences Reference : GHE-P-12708
Guidelines:	-Commission Regulations (EC) No. 544/2011 and 545/2011, implementing Regulation (EC) No.1107/2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC -"Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997"
GLP	Yes

Acceptability	Deviations
Yes	None with impact on the study

Table IIIA 8.3.2-3: Summary of global information on study 1

Comparative trials (between formulations, with and adjuvant/safener/synergist)	No, SC formulation containing 120 g/L Sulfoxafloor
Number of applications	1
Dose (g as/ha)	48 g a.s./ha
Mode of application	Foliar broadcast
PHI (days) and/or growth stage (BBCH)	0, 1, 3, 7, 10, 21 & 28 days
Analytical method (Code +Type)	Method N°091031 LC-MS/MS
LoQ (mg/kg)	0.01 mg/kg

Table IIIA 8.3.2-4: Summary of the study 1 trials

N° Trial	CEMS-5012A	CEMS-5012B	CEMS-5012C	CEMS-5012D
North/South/Indoor	I	I	I	I
Decline (D)/Harvest (H) trial?	D	D	D	D
Formulation	SC	SC	SC	SC
Equivalence between formulations	Y	Y	Y	Y
Accordance with intended GAP	Y	Y	Y	Y
Correct sampling	Y	Y	Y	Y
Samples frozen within 24h	Y	Y	Y	Y
Storage period (in days)	191	205	187	268
Sample Extract	1	1	1	1
Storage T° <-18°C	Y	Y	Y	Y
Validated analytical method	Y	Y	Y	Y
Negative controls	Y	Y	Y	Y
Considered trial	Y	Y	Y	Y
Remarks	-	-	-	-

Table IIIA 8.3.2-5: Summary of data from residue trials for study 1

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Notifier: Dow AgroSciences, European Development Centre

address 1 2nd Floor – 3 Milton Park, Abingdon

address 2 Oxon OX14 4RN, UK

address 3

Active ingredient : Sulfoxaflor

Crop / crop group : Fruiting Vegetables : Bell peppers

Submission date :

Page :

Content of a.i. (g/kg or g/l) : 120 g/L

Formulation (e.g. WP) : SC

Commercial (name) : GF-2626

product

Applicant : Eurofins AgroScience Services GmbH

Indoors / outdoors : Indoor

Other a. s. in formulation

(common name and content) : None

Residues calculated as : XDE-208 + X11719474

GLP and Trial Details	Crop	Country	Application Details									Residues found			Remarks
Trial ID Study ID Report No. GLP(Y/N) Trial Year	Crop Variety (a)	Country (Zone) Location incl. postal code	Form No.	No. of Appls	Appl Rate (g ai/ha)	Spray Vol (L/ha)	Appl Conc (g ai/hL)	Appl Date (c)	GS at Last Appl	PHI (days) (d)	Portion Analysed (a)	XDE-208 (mg/kg)	X11719474 (mg/kg)	Total * (mg/kg)	
CEMS-5012A CEMS-5012 GHE-P-12708 Y 2011	pepper Lamuyo	Spain (SZ) 50669 Santa Engarcia, Aragon Glasshouse or plastic tunnel or protected	GF- 2626	1	49.3	1027	4.8	05-Sep-11	BBCH 75- 85	0 1 3 7 10 21 28	Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit	0.017 <0.01 <0.01 <u>0.017</u> <0.01 0.015 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.026 <0.019 <u>0.026</u> <0.019 0.024 <0.019 <0.019	
CEMS-5012B CEMS-5012 GHE-P-12708 Y 2011	pepper Corrado	Italy (SZ) Glasshouse 04020 M.S. BAgio, Latina Glasshouse or plastic tunnel or protected	GF- 2626	1	51.0	1062	4.8	22-Aug-11	BBCH 87	0 1 3 7 10 21 28	Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit	0.021 <u>0.017</u> 0.013 <0.01 0.013 0.011 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.030 <u>0.026</u> 0.022 <0.019 0.022 0.020 <0.019	

GLP and Trial Details	Crop	Country	Application Details									Residues found			Remarks
Trial ID Study ID Report No. GLP(Y/N) Trial Year	Crop Variety (a)	Country (Zone) Location incl. postal code	Form No.	No. of Appls	Appl Rate (g ai/ha)	Spray Vol (L/ha)	Appl Conc (g ai/hL)	Appl Date (c)	GS at Last Appl	PHI (days) (d)	Portion Analysed (a)	XDE-208 (mg/kg)	X11719474 (mg/kg)	Total * (mg/kg)	
CEMS-5012C CEMS-5012 GHE-P-12708 Y 2011	pepper Kapirex F1	Hungary (NZ) 2347 Bugyi, Pest Glasshouse or plastic tunnel or protected	GF- 2626	1	46.3	483	9.6	09-Sep-11	BBCH 88	0 1 3 7 10 21 28	Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit	0.030 0.016 <u>0.021</u> 0.012 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.039 0.025 <u>0.030</u> 0.021 <0.019 <0.019 <0.019	
CEMS-5012D CEMS-5012 GHE-P-12708 Y 2011	pepper Vaso	Greece (SZ) 57008 Nea Magnisia, Thessaloniki Glasshouse or plastic tunnel or protected	GF- 2626	1	47.8	997	4.8	20-Jun-2011	BBCH 73	0 1 3 7 10 21 28	Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit	0.017 <u>0.017</u> 0.016 0.012 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.026 <u>0.026</u> 0.025 0.021 <0.019 <0.019 <0.019	

Remarks:

- (a) According to CODEX Classification / Guide
- (b) Only if relevant
- (c) Year must be indicated
- (d) Days after last application (Label pre-harvest interval, PHI, underline)

(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

* - Sum of sulfoxaflor and X11719474 expressed as sulfoxaflor. A conversion factor of 0.939 has been applied to residues of X11719474

IIIA 8.3.2.3 Summary of monograph and new data supporting the intended use on peppers and conformity to existing MRL

Table IIIA 8.3.2-6: Summary of monograph and new data supporting the intended use on peppers and conformity to existing MRL

Commodity	Source	EU zone	Evaluation GAP Residue levels (mg/kg)	STMR (mg/kg)	HR (mg/kg)	Rber (mg/kg)	Rmax (mg/kg)	OECD calculator MRL (mg/kg)	In force EU MRL (mg/kg) (1)	MRL compliance resulting / in force
Pepper	Monograph	Indoor (4)	Trials GAP: 1 x 48 g a.s./ha, PHI 1d Mo: 2x 0.020; 2x 0.035 RA: 2x 0.029; 2x 0.044	Mo: 0.028 RA: 0.037	Mo: 0.035 RA: 0.044	Mo: 0.070	Mo: 0.072	Mo: 0.09	Reg (EU) 2016/1 & Doc SANTE/11 442/2016; 0.4	Yes
	New trials	Indoor (4)	Trials GAP: 1 x 48 g a.s./ha, PHI 1d Mo : 3x 0.017; 0.021 RA : 3x 0.026; 0.030	Mo: 0.017 RA: 0.026	Mo: 0.021 RA: 0.030	Mo: 0.040	Mo: 0.028	Mo: 0.06		
	Overall supporting data for EU GAP	Indoor (8)	Mo : 3x 0.017; 2x 0.020; 0.021; 2x 0.035 RA : 3x 0.026; 2x 0.029; 0.030; 2x 0.044	Mo: 0.020 RA: 0.029	Mo: 0.035 RA: 0.044	Mo: 0.063	Mo: 0.047	Mo: 0.07		

Mo = residue levels expressed according to residue definition for enforcement (sulfoxaflor)

RA = residue levels expressed according to residue definition for risk assessment (sum of sulfoxaflor and metabolite X11719474, expressed as sulfoxaflor)

(1) source of EU MRL : EU MRL data base: http://ec.europa.eu/sanco_pesticides/public/index.cfm

IIIA 8.3.2.4 Conclusion for peppers

Peppers are a major crop in Southern and Northern Europe. Thus, a minimum of eight trials are required to support the use of GF-2626 on indoor peppers.

The 8 indoor trials presented above are sufficient to support the use of sulfoxaflor on indoor peppers. They confirm that the residues arising from the proposed use on peppers will not exceed the current EU MRL.

The use of GF-2626 (CLOSER) on indoor peppers is fully supported in Southern Europe.

IIIA 8.3.3 CUCURBITS WITH EDIBLE PEEL (CUCUMBER)**Table IIIA 8.3.3-1: Comparison of intended and critical EU GAPs**

Crop	Type of GAP	Number of applications	Application rate per treatment (g a.s./ha)	Interval between application (days)	Growth stage at last application	PHI (days)
Cucurbits with edible peel (cucumber)	EU (DAR) ⁽¹⁾	1	24	-	BBCH 20–39 BBCH 40–89	≥1
	Intended EU	1	48	-	BBCH 20–87	1

(1). Representative use

IIIA 8.3.3.1 Summary of B.7.6 Data (Ireland 2012 & 2014; EFSA, 2014a)

The use of sulfoxaflor on cucurbits with edible peel has already been assessed in the framework of Annex I inclusion process. In the monograph of sulfoxaflor, two residue studies performed on indoor cucumbers have been provided. In the first study, sulfoxaflor was only applied once at 24 g a.s./ha. Although this application rate corresponds to the representative use, it does not match the critical GAP intended for GF-2626 (CLOSER) on indoor cucurbits. Therefore, results of this study are not presented thereafter. On the other hand, in the second monograph study, sulfoxaflor was applied once at 24 g a.s./ha or 48 g a.s./ha with a 1-day PHI. While in the DAR, data from the 24 g a.s./ha plots were selected to support the representative use, results from the 48 g a.s./ha plots were retained in the frame of this dossier to cope with the higher intended application rate.

The application characteristics of all trials comply with the agricultural practices intended for cucurbits with inedible peel. Residue levels of sulfoxaflor and its metabolites X11719474 have been measured: total residues in cucumbers range from 0.023 mg/kg to 0.048 mg/kg.

Results of the trials are summarised in Table IIIA 8.3.3-2.

Table IIIA 8.3.3-2: Residue trials on indoor cucumbers performed with sulfoxaflor and submitted in the monograph

GLP and Trial Details	Crop	Country	Application Details									Residues found		
Trial ID Study ID Report No. GLP(Y/N) Trial Year	Crop Variety	Country Zone Location	Form No.	No. of Appls	Appl Rate (g ai/ha)	Spray Vol (L/ha)	Appl Conc (g ai/hL)	Appl Date	GS at Last Appl	PHI (days)	Portion Analysed	XDE-208 (mg/kg)	X11719474 (mg/kg)	Total * (mg/kg)
CEMS-4705A CEMS-4705 DAS Report #:101629 Y 2010	cucumber Loustic	France SZ Glasshouse or plastic tunnel or protected	GF-2626	1	53.1	828	6.4	16-Aug-10	BBCH.84	0 1 3 7 10	Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit	0.046 0.039 0.023 0.013 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	0.055 0.048 0.032 0.022 <0.019
CEMS-4705B CEMS-4705 DAS Report #:101629 Y 2010	cucumber Illas	Greece SZ Glasshouse or plastic tunnel or protected	GF-2626	1	49.4	1029	4.8	08-Jun-10	BBCH.75	0 1 3 7 10	Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit	0.039 0.027 0.022 0.015 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	0.048 0.036 0.031 0.024 <0.019
CEMS-4705C CEMS-4705 DAS Report #:101629 Y 2010	cucumber Ekron	Italy SZ Glasshouse or plastic tunnel or protected	GF-2626	1	53.7	1048	5.1	12-Jul-10	BBCH.74	0 1 3 7 10	Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit	<0.01 0.014 0.013 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	<0.019 0.023 0.022 <0.019 <0.019
CEMS-4705D CEMS-4705 DAS Report #:101629 Y 2010	cucumber Llamo Verde	Spain SZ Glasshouse or plastic tunnel or protected	GF-2626	1	46.7	973	4.8	10-Aug-10	BBCH.83	0 1 3 7 10	Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit	0.023 0.017 0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	0.032 0.026 0.019 <0.019 <0.019

* - Sum of sulfoxaflor and X11719474 expressed as sulfoxaflor. A conversion factor of 0.939 has been applied to residues of X11719474

IIIA 8.3.3.2 New data**IIIA 8.3.3.2.1 Study 1 – CEMS-5014**

Report:	IIIA 8.3.6.1/04, Rawle, N. W., 2012
Title:	Residues of sulfaxoflor in indoor cucumbers at intervals and harvest following a single application of GF-2626 – Europe - 2011
Document No:	Study ID : CEMS-5014, Report ID : CEMR-5014, Dow AgroSciences Reference : GHE-P-12710
Guidelines:	-Commission Regulations (EC) No. 544/2011 and 545/2011, implementing Regulation (EC) No. 1107/2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC -"Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997"
GLP	Yes

Acceptability	Deviations
Yes	None with impact on the study

Table IIIA 8.3.3-3: Summary of global information on study 1

Comparative trials (between formulations, with and adjuvant/safener/synergist)	No, SC formulation containing 120 g/L Sulfoxafloor
Number of applications	1
Dose (g as/ha)	48 g a.s./ha
Mode of application	Foliar broadcast
PHI (days) and/or growth stage (BBCH)	0, 1, 3, 7, 10, 21 & 28 days
Analytical method (Code +Type)	Method N°091031 LC-MS/MS
LoQ (mg/kg)	0.01 mg/kg

Table IIIA 8.3.3-4: Summary of the study 1 trials

N° Trial	CEMS-5014A	CEMS-5014B	CEMS-5014C	CEMS-5014D
North/South/Indoor	I	I	I	I
Decline (D)/Harvest (H) trial?	D	D	D	D
Formulation	SC	SC	SC	SC
Equivalence between formulations	Y	Y	Y	Y
Accordance with intended GAP	Y	Y	Y	Y
Correct sampling	Y ⁽¹⁾	Y	Y	Y
Samples frozen within 24h	Y	Y	Y	Y
Storage period (in days)	294	204	322	260
Sample Extract	12 ⁽²⁾	12 ⁽²⁾	12 ⁽²⁾	12 ⁽²⁾
Storage T° <-18°C	Y	Y	Y	Y
Validated analytical method	Y	Y	Y	Y
Negative controls	Y	Y	Y	Y
Considered trial	Y	Y	Y	Y
Remarks	(1), (2)	(2)	(2)	(2)

(1). One retain sample was not taken.

(2). The procedural recoveries demonstrate the stability of the analyte during this storage (up to 12 days)." (CEMR-5014, p.18)

Table IIIA 8.3.3-5: Summary of data from residue trials for study 1

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Notifier: Dow AgroSciences, European Development Centre

address 1 2nd Floor – 3 Milton Park, Abingdon

address 2 Oxon OX14 4RN, UK

address 3

Active ingredient : Sulfoxaflor

Crop / crop group : Fruiting Vegetables : Cucumbers

Submission date :

Page :

Content of a.i. (g/kg or : 120 g/L
g/l)

Indoors / outdoors : Indoor

Formulation (e.g. WP) : SC

Other a. s. in formulation
(common name and content) : None

Commercial product (name) : GF-2626

Residues calculated as : XDE-208 + X11719474

Applicant : Eurofins AgroScience Services GmbH

GLP and Trial Details	Crop	Country	Application Details									Residues found			Remarks (e)
Trial ID Study ID Report No. GLP(Y/N) Trial Year	Crop Variety (a)	Country (Zone) Location incl. postal code	Form No.	No. of Appls	Appl Rate (g ai/ha)	Spray Vol (L/ha)	Appl Conc (g ai/hL)	Appl Date (c)	GS at Last Appl	PHI (days) (d)	Portion Analysed (a)	XDE-208 (mg/kg)	X11719474 (mg/kg)	Total * (mg/kg)	
CEMS-5014A CEMS-5014 GHE-P-12710 Y 2011	Cucumber Ozon	France (SZ) 66200 Elne, Pyrénées- Orientales Glasshouse or plastic tunnel or protected	GF- 2626	1	48.8	1020	4.8	07-Jun-11	BBCH.71	0 1 3 7 10 21 28	Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit	0.034 0.027 0.015 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.043 0.036 0.024 <0.019 <0.019 <0.019 <0.019	
CEMS-5014B CEMS-5014 GHE-P-12710 Y 2011	Cucumber Tigre	Spain (SZ) 46800 Xativa, Valencia Glasshouse or plastic tunnel or protected	GF- 2626	1	48.3	1007	4.8	05-Sep-11	BBCH.73	0 1 3 7 10 21 28	Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit	<0.01 <0.01 0.011 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	<0.019 <0.019 0.020 <0.019 <0.019 <0.019 <0.019	

GLP and Trial Details	Crop	Country	Application Details									Residues found			Remarks (e)
Trial ID Study ID Report No. GLP(Y/N) Trial Year	Crop Variety (a)	Country (Zone) Location incl. postal code	Form No.	No. of Appls	Appl Rate (g ai/ha)	Spray Vol (L/ha)	Appl Conc (g ai/hL)	Appl Date (c)	GS at Last Appl	PHI (days) (d)	Portion Analysed (a)	XDE-208 (mg/kg)	X11719474 (mg/kg)	Total * (mg/kg)	
CEMS-5014C CEMS-5014 GHE-P-12710 Y 2011	Cucumber Okron	Italy (SZ) 04020 M.S. Bagio, Latina Glasshouse or plastic tunnel or protected	GF- 2626	1	46.8	983	4.8	10-May-11	BBCH.81	0 1 3 7 10	Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit	<0.01 <u><0.01</u> <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	<0.019 <u><0.019</u> <0.019 <0.019 <0.019	
CEMS-5014D CEMS-5014 GHE-P-12710 Y 2011	Cucumber Cassib	Greece (SZ) 57008 Nea Magnisia, Thessaloniki Glasshouse or plastic tunnel or protected	GF- 2626	1	46.9	976	4.8	11-Jul-11	BBCH.74	0 1 3 7 10 21 28	Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit	<0.01 <u><0.01</u> <0.01 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	<0.019 <u><0.019</u> <0.019 <0.019 <0.019 <0.019 <0.019	

Remarks:

(a) According to CODEX Classification / Guide

(b) Only if relevant

(c) Year must be indicated

(d) Days after last application (Label pre-harvest interval, PHI, underline)

(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

* - Sum of sulfoxaflor and X11719474 expressed as sulfoxaflor. A conversion factor of 0.939 has been applied to residues of X11719474

IIIA 8.3.3.3 Summary of monograph and new data supporting the intended use on cucurbits with edible peel and conformity to existing MRL

Table IIIA 8.3.3-6: Summary of monograph and new data supporting the intended use on cucurbits with edible peel and conformity to existing MRL

Commodity	Source	EU zone	Evaluation GAP Residue levels (mg/kg)	STMR (mg/kg)	HR (mg/kg)	Rber (mg/kg)	Rmax (mg/kg)	OECD calculator MRL (mg/kg)	In force EU MRL (mg/kg) (1)	MRL compliance resulting / in force
Cucumbers → Cucurbits with edible peel	Monograph	Indoor (4)	Trials GAP: 1 x 48 g a.s./ha, PHI 1d Mo: 0.014; 0.017; 0.027; 0.039 RA: 0.023; 0.026; 0.036; 0.048	Mo: 0.022 RA: 0.031	Mo: 0.039 RA: 0.048	Mo: 0.072	Mo: 0.082	Mo: 0.08	Reg (EU) 2016/1: 0.03 on cucumbers and courgettes 0.01* on gherkins and others Doc SANTE/11 442/2016: 0.5 on cucurbits with edible peel	Yes
	New trials	Indoor (4)	Trials GAP: 1 x 48 g a.s./ha, PHI 1d Mo: 2x <0.01; 0.011; 0.027 RA: 2x <0.019; 0.020; 0.036	Mo: 0.011 RA: 0.020	Mo: 0.027 RA: 0.036	Mo: 0.046	Mo: 0.057	Mo: 0.05		
	Overall supporting data for EU GAP	Indoor (8)	Mo: 2x <0.01; 0.011; 0.014; 0.017; 2x 0.027; 0.039 RA: 2x <0.019; 0.020; 0.023; 0.026; 2x 0.036; 0.048	Mo: 0.016 RA: 0.025	Mo: 0.039 RA: 0.048	Mo: 0.054	Mo: 0.053	Mo: 0.07		

Mo = residue levels expressed according to residue definition for enforcement (sulfoxaflor)

RA = residue levels expressed according to residue definition for risk assessment (sum of sulfoxaflor and metabolite X11719474, expressed as sulfoxaflor)

(1) source of EU MRL : EU MRL data base: http://ec.europa.eu/sanco_pesticides/public/index.cfm

IIIA 8.3.3.4 Conclusion for cucurbits with edible peel

Cucumbers are a major crop in Northern Europe and a minor crop in Southern Europe. Thus, eight indoor trials are required to support the indoor use of sulfoxaflor on cucumbers. Moreover, according to EU Guideline Document SANCO 7525/VI/95- rev. 9, March 2011, data from cucumbers trials can be extrapolated to the whole “cucurbits with edible peel” group.

The 8 trials presented above have been performed according to the intended GAP. Therefore enough residue data are available to support the intended uses.

On the basis of the available supporting residue data it is possible to conclude that the proposed MRLs of 0.5mg/kg on cucurbits with edible peel (document SANTE/1142/2016) will not be exceeding according to the intended GAP in EU.

IIIA 8.3.4 CUCURBITS WITH INEDIBLE PEEL**Table IIIA 8.3.4-1: Comparison of intended and critical EU GAPs**

Crop	Type of GAP	Number of applications	Application rate per treatment (g a.s./ha)	Interval between application (days)	Growth stage at last application	PHI (days)
Cucurbits with inedible peel - melons	EU (DAR)	1	24	-	BBCH 20-39 BBCH 40-89 through the year	≥1
	Intended EU	1	48	-	BBCH 20-87	1

IIIA 8.3.4.1 Summary of B.7.6 Data (Ireland 2012 & 2014; EFSA, 2014a)

The use of sulfoxaflor on cucurbits with inedible peel has already been assessed in the framework of Annex I inclusion process. Two residue studies performed on indoor melons were provided in the frame of sulfoxaflor monograph. In the first study, sulfoxaflor was only applied once at 24 g a.s./ha. As this application rate does not match the critical GAP intended for GF-2626 (CLOSER) on indoor cucurbits, results of this study are not presented thereafter. On the other hand, in the second monograph study, sulfoxaflor was applied once at 24 g a.s./ha or 48 g a.s./ha with a 1-day PHI. While in the DAR, only data from the 24 g a.s./ha plots were reported and selected to support the representative use, results from the 48 g a.s./ha plots were retained in the frame of this dossier to cope with the higher intended application rate. Residue levels of sulfoxaflor and its metabolites X11719474 have been measured in all trials: total residues in whole melons ranged from 0.019 mg/kg to 0.034 mg/kg. Results of the trials are summarised in Table IIIA 8.3.4-2.

Table IIIA 8.3.4-2: Summary of residues data for sulfoxaflor in melons

GLP and Trial Details	Crop	Country	Application Details									Residues found		
Trial ID Study ID Report No. GLP(Y/N) Trial Year	Crop Variety	Country Zone Location	Form No.	No. of Appls	Appl Rate (g ai/ha)	Spray Vol (L/ha)	Appl Conc (g ai/hL)	Appl Date	GS at Last Appl	PHI (days)	Portion Analysed	XDE-208 (mg/kg)	X11719474 (mg/kg)	Total * (mg/kg)
CEMS-4708B CEMS-4708 DAS Ref. ID 101469 Y 2010	Melon Galia	Greece SZ Glasshouse or plastic tunnel or protected	GF- 2626	1	48.2	1004	4.8	04-Aug-10	BBCH.83	0 1 3 7 10 0 1 3 7 10 0 1 3 7 10 0 1 3 7 10	Peel Peel Peel Peel Peel Pulp Pulp Pulp Pulp Pulp Whole Fruit Whole Fruit Whole Fruit Whole Fruit Whole Fruit Whole Fruit Whole Fruit Whole Fruit Whole Fruit Whole Fruit Whole Fruit	0.053 0.039 0.012 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 0.036 0.025 0.011 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.062 0.048 0.021 <0.019 <0.019 <0.019 <0.019 <0.019 <0.019 <0.019 0.045 0.034 0.020 <0.019 <0.019 <0.019 <0.019 0.048 <0.019 <0.019 <0.019 <0.019 <0.019
CEMS-4708C CEMS-4708 DAS Ref. ID 101469 Y 2010	Melon Proteo	Italy SZ Glasshouse or plastic tunnel or protected	GF- 2626	1	49.4	965	5.1	21-Jun-10	BBCH.89	0 1 3 7 10 0 1 3 7 10 0 1 3 7 10 0 1 3 7 10	Peel Peel Peel Peel Peel Pulp Pulp Pulp Pulp Pulp Whole Fruit Whole Fruit Whole Fruit Whole Fruit Whole Fruit Whole Fruit Whole Fruit Whole Fruit Whole Fruit Whole Fruit Whole Fruit	0.059 0.013 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 0.039 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.068 0.022 <0.019 <0.019 <0.019 <0.019 <0.019 <0.019 <0.019 <0.019 0.048 <0.019 <0.019 <0.019 <0.019 <0.019 0.048 <0.019 <0.019 <0.019 <0.019 <0.019

GLP and Trial Details	Crop	Country	Application Details									Residues found		
Trial ID Study ID Report No. GLP(Y/N) Trial Year	Crop Variety	Country Zone Location	Form No.	No. of Appls	Appl Rate (g ai/ha)	Spray Vol (L/ha)	Appl Conc (g ai/hL)	Appl Date	GS at Last Appl	PHI (days)	Portion Analysed	XDE-208 (mg/kg)	X11719474 (mg/kg)	Total * (mg/kg)
CEMS-4708D CEMS-4708 DAS Ref. ID 101469 Y 2010	Melon Jucar	Spain SZ Glasshouse or plastic tunnel or protected	GF- 2626	1	51.3	1069	4.8	11-May-10	BBCH.83	0 1 3 7 9 0 1 3 7 9 0 1 3 7 9	Peel Peel Peel Peel Peel Pulp Pulp Pulp Pulp Pulp Whole Fruit Whole Fruit Whole Fruit Whole Fruit Whole Fruit	0.012 0.012 0.010 0.013 0.015 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.021 0.021 0.020 0.022 0.024 <0.019 <0.019 <0.019 <0.019 <0.019 <0.019 <0.019 <0.019 <0.019 <0.019 <0.019 <0.019
CEMS-4708E CEMS-4708 DAS Ref. ID 101469 Y 2010	Melon Edgar	France SZ Glasshouse or plastic tunnel or protected	GF- 2626	1	43	717	6.0	20-Jul-10	BBCH.88 to 89	0 1 3 7 10 0 1 3 7 10 0 1 3 7 10	Peel Peel Peel Peel Peel Pulp Pulp Pulp Pulp Pulp Whole Fruit Whole Fruit Whole Fruit Whole Fruit Whole Fruit	<0.01 0.017 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 0.011 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	<0.019 0.026 <0.019 <0.019 <0.019 <0.019 <0.019 <0.019 <0.019 <0.019 <0.019 <0.019 0.020 <0.019 <0.019 <0.019 <0.019

* - Sum of sulfoxaflor and X11719474 expressed as sulfoxaflor. A conversion factor of 0.939 has been applied to residues of X11719474

IIIA 8.3.4.2 New data**IIIA 8.3.4.2.1 Study 1 –CEMS-5016**

Report:	IIIA 8.3.6.2/04, Rawle, N. W., 2012
Title:	Residues of sulfoxaflor in indoor melons at intervals and harvest following a single application of GF-2626 – Europe - 2011
Document No:	Study ID : CEMS-5016, Report ID : CEMR-5016 Dow AgroSciences Reference : GHE-P-12712
Guidelines:	-Commission Regulations (EC) No. 544/2011 and 545/2011, implementing Regulation (EC) No.1107/2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC -"Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997"
GLP	Yes

Acceptability	Deviations
Yes	<p>CEMS-5016B: Triangulation measurements were not taken. Sample temperatures rose above -18°C during storage, but samples remained frozen at all times.</p> <p>CEMS-5016A and C: The two trials were less than 15 km apart and used the same melon variety.</p> <p>Analysis: The stable isotope internal standard used for the alcohol (X11721061) metabolite was a 13C D3 isotope (X11963606) instead of a D3 stable isotope (X11922457), because of availability.</p>

Table IIIA 8.3.4-3: Summary of global information on study 1

Comparative trials (between formulations, with and adjuvant/safener/synergist)	No, SC formulation containing 120 g/L Sulfoxaflor
Number of applications	1
Dose (g as/ha)	48 g a.s./ha
Mode of application	Foliar broadcast
PHI (days) and/or growth stage (BBCH)	0, 1, 3, 7 & 10 days
Analytical method (Code +Type)	091031 Liquid Chromatography/Mass Spectrometry
LoQ (mg/kg)	0.01 mg/kg

Table IIIA 8.3.4-4: Summary of the study 1 trials

N° Trial	CEMS-5016A	CEMS-5016B	CEMS-5016C	CEMS-5016D
North/South/Indoor	I	I	I	I
Decline (D)/Harvest (H) trial?	D	D	D	D
Formulation	SC	SC	SC	SC
Equivalence between formulations	Y	Y	Y	Y
Accordance with intended GAP	Y	Y	Y	Y
Correct sampling	Y	Y	Y	Y
Samples frozen within 24h	Y	Y	Y	Y
Storage period (in days)	279	342	279	315
Sample Extract	Max 4d ⁽¹⁾	Max 4d ⁽¹⁾	Max 4d ⁽¹⁾	Max 4d ⁽¹⁾
Storage T° <-18°C	Y	Y	Y	Y
Validated analytical method	Y	Y	Y	Y
Negative controls	Y	Y	Y	Y
Considered trial	Y	Y	Y	Y
Remarks	1	1	1	1

(1). The procedural recoveries demonstrate the stability of the analyte during this storage period (up to 4 days).” (CEMR-5016, p.19)

Table IIIA 8.3.4-5: Summary of data from residue trials for study 1

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Notifier: Dow AgroSciences, European Development Centre

address 1 2nd Floor – 3 Milton Park, Abingdon

address 2 Oxon OX14 4RN, UK

address 3

Active ingredient : Sulfoxaflor

Crop / crop group : Fruiting Vegetables : Melons

Submission date :

Page :

Content of a.i. (g/kg or g/l) : 120 g/L

Formulation (e.g. WP) : SC

Commercial product (name) : GF-2626

Indoors / outdoors : Indoor

Other a. s. in formulation
(common name and content) : None

Residues calculated as : XDE-208 + X11719474

Applicant : Eurofins AgroScience Services GmbH

GLP and Trial Details	Crop	Country	Application Details									Residues found			Remarks
Trial ID Study ID Report No. GLP(Y/N) Trial Year	Crop Variety (a)	Country (Zone) Location incl. postal code	Form No.	No. of Appls	Appl Rate (g ai/ha)	Spray Vol (L/ha)	Appl Conc (g ai/hL)	Appl Date (c)	GS at Last Appl	PHI (days) (d)	Portion Analysed (a)	XDE-208 (mg/kg)	X11719474 (mg/kg)	Total * (mg/kg)	
CEMS-5016A CEMS-5016 GHE-P-12712 Y 2011	Melon Honeymoon	Italy (SZ) 46028 Sermide, Ferrara Glasshouse or plastic tunnel or protected	GF- 2626	1	50.1	731	6.9	16-Aug-11	BBCH.83 to 87	0 1 3 7 10 0 1 3 7 10 0 1 3 7 10	Peel Peel Peel Peel Peel Pulp Pulp Pulp Pulp Pulp Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	<0.019 <0.019 <0.019 <0.019 <0.019 <0.019 <u><0.019</u> <0.019 <0.019 <0.019 <0.019 <0.019 <u><0.019</u> <0.019 <0.019 <0.019 <0.019	

GLP and Trial Details	Crop	Country	Application Details									Residues found			Remarks
Trial ID Study ID Report No. GLP(Y/N) Trial Year	Crop Variety (a)	Country (Zone) Location incl. postal code	Form No.	No. of Appls	Appl Rate (g ai/ha)	Spray Vol (L/ha)	Appl Conc (g ai/hL)	Appl Date (c)	GS at Last Appl	PHI (days) (d)	Portion Analysed (a)	XDE-208 (mg/kg)	X11719474 (mg/kg)	Total * (mg/kg)	
CEMS-5016B CEMS-5016 GHE-P-12712 Y 2011	Melon Jucar	Spain (SZ) 11150 Vejer de la Frontera, Cadiz Glasshouse or plastic tunnel or protected	GF-2626	1	49.6	1033	4.8	14-Jun-11	BBCH.82	0 1 3 7 10 0 1 3 7 10 0 1 3 7 10	Peel Peel Peel Peel Peel Pulp Pulp Pulp Pulp Pulp Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	<0.019 <0.019 <0.019 <0.019 <0.019 <0.019 <0.019 <0.019 <0.019 <0.019 <0.019 <0.019 <0.019 <0.019 <0.019	
CEMS-5016C CEMS-5016 GHE-P-12712 Y 2011	Melon Honey-moon	Italy (SZ) 46028 Sermide, Ferrara Glasshouse or plastic tunnel or protected	GF-2626	1	46.7	686	6.8	16-Aug-11	BBCH.83 to 87	0 1 3 7 10 0 1 3 7 10 0 1 3 7 10	Peel Peel Peel Peel Peel Pulp Pulp Pulp Pulp Pulp Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	<0.019 <0.019 <0.019 <0.019 <0.019 <0.019 <0.019 <0.019 <0.019 <0.019 <0.019 <0.019 <0.019 <0.019 <0.019	

GLP and Trial Details	Crop	Country	Application Details									Residues found			Remarks
Trial ID Study ID Report No. GLP(Y/N) Trial Year	Crop Variety (a)	Country (Zone) Location incl. postal code	Form No.	No. of Appls	Appl Rate (g ai/ha)	Spray Vol (L/ha)	Appl Conc (g ai/hL)	Appl Date (c)	GS at Last Appl	PHI (days) (d)	Portion Analysed (a)	XDE-208 (mg/kg)	X11719474 (mg/kg)	Total * (mg/kg)	
CEMS-5016D CEMS-5016 GHE-P-12712 Y 2011	Melon Galia F1	Greece (SZ) 57008 Nea Magnisia, Thessaloniki Glasshouse or plastic tunnel or protected	GF- 2626	1	49.1	716	6.9	11-Jul-11	BBCH.82	0 1 3 7 10 0 1 3 7 10 0 1 3 7 10	Peel Peel Peel Peel Peel Pulp Pulp Pulp Pulp Pulp Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit	0.022 0.016 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 0.013 <u>0.011</u> <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.031 0.025 <0.019 <0.019 <0.019 <0.019 <0.019 <u><0.019</u> <0.019 <0.019 <0.019 0.022 <u>0.020</u> <0.019 <0.019 <0.019	

Remarks:

(a) According to CODEX Classification / Guide

(b) Only if relevant

(c) Year must be indicated

(d) Days after last application (Label pre-harvest interval, PHI, underline)

(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

* - Sum of sulfoxaflor and X11719474 expressed as sulfoxaflor. A conversion factor of 0.939 has been applied to residues of X11719474

IIIA 8.3.4.3 Summary of monograph and new data supporting the intended use on cucurbits with inedible peel and conformity to existing MRL

Table IIIA 8.3.4-6: Summary of monograph and new data supporting the intended use on cucurbits with inedible peel and conformity to existing MRL

Commodity	Source	EU zone	Evaluation GAP Residue levels (mg/kg)	STMR (mg/kg)	HR (mg/kg)	Rber (mg/kg)	Rmax (mg/kg)	OECD calculator MRL (mg/kg)	In force EU MRL (mg/kg) (1)	MRL compliance resulting / in force
Melons → Cucurbits with inedible peel	Monograph	Indoor (4)	Trials GAP: 1 x 48 g a.s./ha, PHI 1d Mo Whole Fruit: 2x <0.01; 0.011; 0.025 RA Whole Fruit: 2x <0.019; 0.020; 0.034 RA pulp: 4x <0.019	Mo WF: 0.011 RA WF: 0.020 RA pulp: 0.019	Mo WF: 0.025 RA WF: 0.034 RA pulp: 0.019	Mo WF: 0.043	Mo WF: 0.052	Mo WF: 0.05	Reg (EU) 2016/1: 0.02 on melons and watermelon 0.01* on pumpkins and others Doc SANTE/11 442/2016: 0.5 on cucurbits with inedible peel	Yes
	New trials	Indoor (4)	Trials GAP: 1 x 48 g a.s./ha, PHI 1d Mo Whole Fruit: 3x <0.01; 0.011 RA Whole Fruit: 3 <0.019; 0.020 RA pulp: 4x <0.019	Mo WF: 0.010 RA WF: 0.019 RA pulp: 0.019	Mo WF: 0.011 RA WF: 0.020 RA pulp: 0.019	Mo WF: 0.022	Mo WF: 0.013	Mo WF: 0.015		
	Overall supporting data for EU GAP	Indoor (8)	Mo Whole Fruit: 5 <0.01; 2x 0.011; 0.025 RA Whole Fruit: 5<0.019; 2x 0.020; 0.034 RA pulp: 8x <0.019	Mo WF: 0.010 RA WF: 0.019 RA pulp: 0.019	Mo WF: 0.025 RA WF: 0.034 RA pulp: 0.019	Mo WF: 0.022	Mo WF: 0.029	Mo WF: 0.04		

Enf = residue levels expressed according to residue definition for enforcement (sulfoxaflor)

RA = residue levels expressed according to residue definition for risk assessment (sum of sulfoxaflor and metabolite X11719474, expressed as sulfoxaflor)

(1) source of EU MRL : EU MRL data base: http://ec.europa.eu/sanco_pesticides/public/index.cfm

IIIA 8.3.4.4 Conclusion for cucurbits with inedible peel

Melons are a major crop in Southern Europe and a minor crop in Northern Europe. Thus, eight indoor trials are required to support the indoor use of sulfoxaflor on melons. Moreover, according to EU Guideline Document SANCO 7525/VI/95- rev. 9, March 2011, data from melons trials can be extrapolated to the whole “cucurbits with inedible peel” group.

The 8 indoor trials presented above have been performed according to the intended GAP. Therefore enough residue data are available to support the intended uses.

On the basis of the available supporting residue data it is possible to conclude that the proposed MRLs of 0.5 mg/kg on cucurbits with inedible peel (document SANTE/1142/2016) will not be exceeding according to the intended GAP in EU.

IIIA 8.3.5 CONVERSION FACTORS CALCULATION

For sulfoxaflor, the residue definition for risk assessment (RD-RA) differs from the residue definition for monitoring (RD-Mo). Thus, a conversion factor should be proposed. Since the ratio "level according RD-RA/level according RD-Mo" might be time dependant, possible changes in the ratio at the various PHI time points should be considered. The evolution of CF values at the different available PHIs is presented in Table IIIA 8.3.5-1

Table IIIA 8.3.5-1: Median CF estimated at the different PHIs in the supervised residue trials^(a)

PHI ^(b) (days)	0+	1	3	7	10	21	28	Comments
Tomatoes → Eggplants	1.5 (NC; 2x 1.2; 1.4; 1.5; 1.6; 1.8; 1.9)	<u>1.2</u> (5x NC; 2x 1.2; 1.5)	1.5 (4x NC; 2x 1.2; 2x 1.8)	1.2 (6x NC; 2x 1.2)	1.6 (3x NC; 2x 1.2; 1.6; 2x 1.9)	1.9 (3x NC; 1.9)	NC (3x NC)	Levels of metabolite X11719474 were below LoQ (0.01 mg/kg) in all trials.
Peppers	1.45 (2x 1.2; 1.3; 1.4; 4x 1.5)	1.5 (NC; 2x 1.3; 3x 1.5; 1.6; 1.7)	1.5 (2x 1.3; 1.4; 2x 1.5; 1.6; 2x 1.7)	1.65 (2x NC; 1.4; 2x 1.5; 3x 1.8)	1.5 (3x NC; 1.3; 2x 1.5; 1.6; 1.7)	1.8 (3x NC; 1.8)	NC (4x NC)	Levels of metabolite X11719474 were below LoQ (0.01 mg/kg) in all trials.
Cucumbers → Cucurbits with edible peel	1.25 (4x NC; 2x 1.2; 1.3; 1.4)	1.3 (3x NC; 1.2; 2x 1.3; 1.5; 1.6)	1.65 (2x NC; 2x 1.4; 1.6; 1.7; 1.8; 1.9)	1.65 (6x NC; 1.6; 1.7)	NC (8x NC)	NC (3x NC)	NC (3x NC)	Levels of metabolite X11719474 were below LoQ (0.01 mg/kg) in all trials.
Melons – → whole fruit → Cucurbits with inedible peel	1.3 (5x NC; 1.2; 1.3; 1.7)	1.8 (5x NC; 1.4; 2x 1.8)	1.8 (7x NC; 1.8)	NC (8x NC)	NC (8x NC)	N/A -	N/A -	Levels of metabolite X11719474 were below LoQ (0.01 mg/kg) in all trials.
An overall CF of 1 is proposed for all crop commodities investigated.								

(a): CFs calculated at the supported PHI are underlined.

(b): 0-/0+ for samples collected just before/after the last application

NC: Not Calculated – residue levels according to both residue definitions are < LoQ.

N/A: Not Applicable

Median CFs could be derived for 6 different PHIs. However, in all trials, levels of metabolite X11719474 were always below LoQ (<0.01 mg/kg) at all time points. Thus, the reliability of the derived CFs is questioned by zRMS (France) and an overall CF of 1 is proposed for this crop.

IIIA 8.4 Livestock Feeding Studies

As the crops under consideration are not fed to animals, the intended uses of GF-2626 (CLOSER) will not result in a modification of the animal intake.

Then, the use of GF-2626 (CLOSER) will not lead to an exceeding of the MRLs set in products of animal origin.

IIIA 8.5 Studies on Industrial Processing and/or Household Preparation

IIIA 8.5.1 NATURE OF RESIDUES

IIIA 8.5.1.1 Summary of European data (Ireland 2012, EFSA 2014a)

A hydrolysis study investigating the effect of typical processing conditions on the nature of the residues of sulfoxaflor and its metabolites X11719474 and X11721061 was evaluated and summarised in the DAR (Vol. 3, B.7.7.1). A summary of the conditions and results is given in the Table IIIA 8.5.1-1.

Table IIIA 8.5.1-1: Summary of EU available data on the nature of sulfoxaflor residue in processed commodities

Test Substance	Test conditions ⁽¹⁾	% Material balance	% sulfoxaflor after treatment	% X11719474 after treatment	% X11721061 after treatment	% X11579457 after treatment
¹⁴ C-Sulfoxaflor	Pasteurisation	100.5	99.6	-	-	-
	Baking, brewing, boiling	100.2	100.0	-	-	-
	Sterilisation	99.1	100.4	-	-	-
¹⁴ C-X11719474	Pasteurisation	100.6	-	99.0	-	0.4
	Baking, brewing, boiling	100.6	-	96.9	-	3.8
	Sterilisation	99.4	-	89.1	-	11.6
¹⁴ C-X11721061	Pasteurisation	101.2	-	-	100.0	-
	Baking, brewing, boiling	97.4	-	-	99.9	-
	Sterilisation	95.4	-	-	99.7	-

(1). Pasteurisation: pH 4, 90°C, 20 min / Baking, brewing, boiling: pH 5, 100 °C, 60 min / Sterilisation: pH 6, 120 °C, 20 min

Under conditions simulating industrial and household food processes (pasteurisation, baking, brewing, boiling and sterilisation), ¹⁴C-sulfoxaflor and ¹⁴C-X11721061 were found to be stable, whereas ¹⁴C-X11719474 was hydrolysed at the isocyanate moiety to form compound X11579457 (0.4-11.6 %).

It was considered during the peer review that the existing residue definition for plants (sum of parent compound and X11719474, expressed as sulfoxaflor) covered residues arising in processed plant commodities.

IIIA 8.5.1.2 New data

No new data submitted

IIIA 8.5.1.3 Conclusion on nature of residues

Uses under considerations are covered by processing studies on the nature of residues. Furthermore considering the intended uses the metabolite X11579457 is not expected to be formed in significant quantity. Indeed at the intended GAP residue levels of metabolite X11719474 are below the LOQ (<0.01 mg/kg) in tomatoes, peppers, cucumbers and melons (cf. IIIA 8.3).

Therefore, the residue definition for plants (sum of parent compound and X11719474, expressed as sulfoxaflor) is deemed to cover residues arising in processed plant commodities.

IIIA 8.5.2 DISTRIBUTION OF THE RESIDUE IN PEEL/PULP

IIIA 8.5.2.1 Summary of European data

Although cucurbits with inedible peel are one of the representative use of sulfoxaflor, the distribution of the residue in peel and pulp has not been assessed during Annex I inclusion.

IIIA 8.5.2.2 New data

For cucurbits (inedible peel) the distribution of the residues in the peel and pulp was investigated in the available residue trials conducted on indoor melons. In each of these trials, residues were measured in peel, pulp and whole fruit. Details of the residues in the separate peel and pulp fractions are included under section IIIA 8.1.1. Results of the trials are summarised in Table IIIA 8.5.1-1.

For the purpose of process factor calculations, all residues below the LoQ have been assumed to be at the LoQ (0.01 mg/kg). In the event of residues in both peel and pulp being below the LoQ, no calculation was performed. Processing factors calculated for peel and pulp are presented in Table IIIA 8.5.2-2.

Table IIIA 8.5.2-1: A summary of the peel and pulp distribution data for melons

Trial	PHI	XDE-208 residues (mg/kg)			X11719474 residues (mg/kg)		
		Whole fruit	Peel	Pulp	Whole fruit	Peel	Pulp
CEMS-4708B	1	0.025	0.039	<0.01	<0.01	<0.01	<0.01
CEMS-4708C	1	<0.01	0.013	<0.01	<0.01	<0.01	<0.01
CEMS-4708D	1	<0.01	0.012	<0.01	<0.01	<0.01	<0.01
CEMS-4708E	1	0.011	0.017	<0.01	<0.01	<0.01	<0.01
CEMS-5016A	1	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
CEMS-5016B	1	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
CEMS-5016C	1	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
CEMS-5016D	1	0.011	0.016	<0.01	<0.01	<0.01	<0.01

Table IIIA 8.5.2-2: Transfer Factors for XDE-208 and X11719474 into melon peel and pulp

Melon	Individual transfer factors	Median Transfer factors (mean/median)
XDE-208		
Peel ⁽¹⁾	3x ND; 1.2; 1.3; 1.5; 2x 1.6	1.5
Pulp ⁽²⁾	5x ND; 0.4; 2x 0.9	0.9
X11719474		
Peel ⁽¹⁾	8x ND	ND
Pulp ⁽²⁾	8x ND	ND

(1) residue in peel / residue in whole fruit

(2) residue in pulp / residue in whole fruit

ND – not determined (the ratio could not be calculated from the data)

Residue trials on melons show that residue levels of parent sulfoxaflor (XDE-208) were always below the LOQ in pulp while in half of the trials, they exceeded the LOQ in peel.

Overall median transfer factors of 1.5 and 0.9 were derived for melon peel and pulp, respectively. According to those factors, parent sulfoxaflor tends to concentrate in melon peel but is reduced in melon pulp. However, it should be noted that, due to the “no residue” situation in melon pulp, the liability of the transfer factor derived for melon pulp is questioned by zRMS (France): the derived peeling factor should be considered as informative only.

On the other hand, residues of X11719474 were not quantifiable in either melon peel or pulp. No transfer factor could be derived for metabolite X11719474.

IIIA 8.5.2.3 Conclusion on distribution of the residue in peel/pulp

Residues of parent sulfoxaflor tend to concentrate into peel. However, as residues levels in melon pulp were always below the LOQ, no robust peeling factors could be derived.

No residues of X11719474 above 0.01 mg/kg were found in either peel or pulp of any sample. Thus, no overall trend about residue concentration or dilution could be detected for metabolite X11719474 in melon.

IIIA 8.5.3 BALANCE STUDIES ON A CORE SET OF REPRESENTATIVE PROCESSES**IIIA 8.5.3.1 Summary of European data**

Processing studies on barley, wheat, cotton and tomato were assessed during sulfoxaflor Annex I inclusion process (EFSA, 2014a). Tomato processing data are summarised thereafter. In the EFSA conclusion, data were presented for parent sulfoxaflor only. However, for completeness, data for parent sulfoxaflor and metabolite X11719474 expressed as sulfoxaflor were added to the summary table.

Table IIIA 8.5.3-1: A summary of the processing factors from the DAR (tomato)

Crop/process/processed product	Number of studies	Processing Factor (PF)			
		Parent Sulfoxaflor only		Parent Sulfoxaflor + X11719474, expressed as sulfoxaflor	
		Individual values	Median PF	Individual values	Median PF
Washed and peeled tomatoes	2 (3 trials)	0.5, 0.8, 1.2	0.8	0.5; 0.8; 1.2	0.8
Tomato juice		0.6, 1.0, 1.0	1.0	0.7; 1.0; 1.0	1.0
Canned tomatoes		0.2, 0.4, 0.8	0.4	0.2; 0.4; 0.8	0.4
Ketchup		1.4, 2.1; 2.2	2.1	1.3; 2.1; 2.2	2.1
Tomato puree		1.0, 1.6, 2.0	1.6	1.0; 1.5; 2.0	1.5
Tomato paste		2.7, 4.4, 4.9	4.4	2.6; 4.4; 4.9	4.4

IIIA 8.5.3.2 New data

No new data submitted.

FR Comments:	No new data required.
--------------	-----------------------

IIIA 8.5.3.3 Conclusion on balance studies

Residues in the raw agricultural commodities (RAC) are below 0.1 mg/kg (based on the total residue definition for risk assessment). Moreover, based on the residues arising from the proposed uses, the contribution of the crops to the estimated daily intake (IEDI) and the estimated short-term intake (IESTI) are below 10 % of the ADI and ARfD (respectively) for every European consumer group diet. Thus, considering the low individual contributions of solanaceae and cucurbits to the total dietary intake, processing studies are not required and none were submitted.

IIIA 8.5.3.4 Follow-up studies; potable waters; irrigated crops

This is not an EC data requirement/ not required.

IIIA 8.6 Studies for Residues in Representative Succeeding Crops

IIIA 8.6.1 PRELIMINARY CONSIDERATION

The proposed uses are for fruiting vegetables grown in glasshouses. There is the potential for re-use of treated compost or for the spreading of spent compost on agricultural land. Therefore consideration of the potential for residues to arise in following crops is considered below, taking into account, as a worst case, the total maximum seasonal application rate.

During the peer review required by Regulation (EC) No 1107/2009, it was demonstrated that although sulfoxaflor DT90 never overcame 25 days in the field studies, the DT90 values of metabolite X11719474 and X11519540 exceeded the trigger value of 100 days in most of those studies. A detailed assessment of the nature and magnitude of sulfoxaflor residues was therefore considered relevant.

IIIA 8.6.2 SUMMARY OF EUROPEAN DATA

IIIA 8.6.2.1 Nature of residues in succeeding crops

A confined rotational crop study conducted in California, USA was assessed and summarised in sulfoxaflor DAR (Vol.3, B7.9.1.). In this study, ¹⁴C-Sulfoxaflor was applied to bare confined plots of sandy loam soil at a nominal rate of 600 g a.i./ha. This corresponds to 12.5X the maximum seasonal rate intended on the crops under consideration. Following aging for plant back intervals (PBIs) of 30, 120, and 365 days, radishes (root and tuber vegetable), lettuce (leafy vegetable), and wheat (cereal) were planted and grown outdoors to maturity. Plot maintenance simulated typical cultural practices.

Table 8.6.2-1: Summary of the available rotational crop metabolism studies

Crop groups	Crop(s)	PBI (days)	Comments
Root crops	Radish	30, 120 & 365	Trials conducted with an application at 600 g a.s./ha on bare soil (12.5N intended GAP).
Leafy crops	Lettuce	30, 120 & 365	
Cereal (small grain)	Wheat	30, 120 & 365	
<i>Comments: Results of rotational crops studies are consistent with those of the primary crop metabolism studies. X11719474 was the most abundant metabolite observed in all crops at all three plant-back intervals (up to 88% of TRR in mature radish roots). There is strong indication that X11719474 may be preferentially taken up by the roots of the plants from the soil.</i>			

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

Results of rotational crops studies are consistent with those of the primary crop metabolism studies. Indeed, the identified metabolic pathways in the four primary crops and rotational crops were qualitatively similar. Therefore, no specific residue definitions need to be derived for rotational crops.

IIIA 8.6.2.2 Magnitude of residues in succeeding crops

To assess the potential for accumulation of X11719474 in succeeding crops at various plant back intervals, field rotational crop residue trials were conducted in radish, lettuce, spring onions and barley (rates of 24 g a.s./ha or 48 g a.s./ha) in Northern and Southern Europe. Sulfoxaflor was applied to bare soil and the tested crops were planted 30, 75, 120 and 270 days after treatment.

Analysis of crop samples showed that residues of sulfoxaflor and X11579457 were below the LOQ (<0.01 mg/kg) in all crops at all plant-back intervals (PBI) at all trial sites for both application rates. In some instances residues of X11719474 or X11519540 were found in rotational crops at levels above the LOQ of 0.01 mg/kg, mostly in leafy parts of the crops in rotation that are used as feeds (radish leaves, spring onions, straw) and in the trials with the higher application rate. Indeed, at the 48 g a.s./ha rate,

X11519540 was only detected at the 30-day PBI in radish leaves (0.0165 mg/kg) and spring onion (0.011 mg/kg). Metabolite X11719474 was found at a maximum level of 0.017 mg/kg in spring onion (30-day and 270-day PBI) and in barley straw (30-day PBI). The maximum residue seen for X11719474 overall was found in the radish leaves sample at the 30 day PBI: 0.065 mg/kg. However, no residue levels above the LoQ of 0.01 mg/kg were seen in radish roots, lettuce or barley grain at any PBI at all four trial sites (Ireland 2012 & 2014).

During sulfoxaflor peer-review, the residue levels of X11719474 in rotational crops were considered in the livestock dietary burden estimates where appropriate. However no MRLs were proposed in relation to rotational cropping since residues in commodities for human consumption were expected to be insignificant under EU critical GAP conditions (EFSA, 2014a).

IIIA 8.6.3 NEW DATA

No new data submitted

FR Comments:	No new data required
---------------------	----------------------

IIIA 8.6.4 CONCLUSION ON SUCCEEDING CROPS STUDIES

Since a maximum seasonal rate of 48 g a.s./ha is proposed for fruiting vegetables, the rotational studies evaluated during sulfoxaflor peer review cover the intended GAP. Moreover, RMS agrees with the applicant that the results of the study represent a worst-case as the application was made directly to the bare soil. Therefore, no further considerations about rotational crops are required in this evaluation: significant residues of sulfoxaflor and its metabolites are not expected in rotational crops, provided that the active substance is applied according to the proposed GAPs.

IIIA 8.7 Proposed Residue Definition and Maximum Residue Levels

IIIA 8.7.1 PROPOSED RESIDUE DEFINITION

Table IIIA 8.7.1-1: Residue definitions

	Definition	Conversion factor for enforcement to risk assessment	Source
Plant residue definition for monitoring	Sulfoxaflor (sum of isomers)	N/A	Reg. (EU) 2016/1
	<i>Parent sulfoxaflor (sulfoxaflor) only</i>	N/A	EFSA, 2014a
Plant residue definition for risk assessment	Sum of parent sulfoxaflor and metabolite X11719474, expressed as sulfoxaflor ⁽¹⁾	None	EFSA, 2014a
Animal residue definition for monitoring	Sulfoxaflor (sum of isomers)	N/A	Reg. (EU) 2016/1
	<i>Parent sulfoxaflor (sulfoxaflor) only</i>	N/A	EFSA, 2014a
Animal residue definition for risk assessment	Sum of parent sulfoxaflor and metabolite X11719474, expressed as sulfoxaflor ⁽¹⁾	None	EFSA, 2014a
Other residue definitions (in processed commodities, ...)	-	-	-

(1). It was agreed that if metabolite X11719474 is shown to be significantly less toxic than Sulfoxaflor then the residue definition for risk assessment will become parent Sulfoxaflor only.

N/A: Not applicable

IIIA 8.7.2 PROPOSED MAXIMUM RESIDUE LEVELS (MRLS)

Not relevant

IIIA 8.8 Proposed Pre-Harvest Intervals, Re-Entry or Withholding Periods

IIIA 8.8.1 PRE-HARVEST INTERVAL (IN DAYS) FOR EACH RELEVANT CROP

Table IIIA 8.8.1-1: Pre-harvest interval by crop

Crop (intended GAP)	PHI (days) or later application growth stage (BBCH)
Tomatoes & Aubergines (1 x 48 g a.s./ha)	1 day
Peppers (1 x 48 g a.s./ha)	1 day
Cucurbits with edible peel (1 x 48 g a.s./ha)	1 day
Cucurbits with inedible peel (1 x 48 g a.s./ha)	1 day

IIIA 8.8.2 RE-ENTRY PERIOD (IN DAYS) FOR LIVESTOCK, TO AREAS TO BE GRAZED

The proposed uses are for crops grown within glasshouses and therefore there is no potential for the crops to be grazed by livestock.

IIIA 8.8.3 RE-ENTRY PERIOD FOR MAN TO CROPS, BUILDINGS OR SPACES TREATED

This is not an EC data requirement/ not required for the residue section.
Please refer to IIIA 7.5 part of Mammalian Toxicology Section.

IIIA 8.8.4 WITHHOLDING PERIOD (IN DAYS) FOR ANIMAL FEEDINGSTUFFS

The proposed uses are for crops that are not considered animal feed items. No withholding period is therefore necessary.

IIIA 8.8.5 WAITING PERIOD BEFORE SOWING OR PLANTING CROP TO BE PROTECTED

Not relevant – crops to be protected have already been planted before application of GF-2626 (CLOSER).

IIIA 8.8.6 WAITING PERIOD BETWEEN APPLICATION AND HANDLING TREATED PRODUCTS

This is not an EC data requirement/ not required for the residue section.

IIIA 8.8.7 WAITING PERIOD (IN DAYS) BEFORE SOWING OR PLANTING SUCCEEDING CROPS

No specific plant-back restriction is required following the proposed uses of GF-2626 (CLOSER).

IIIA 8.9 Other/Special Studies

The Annex II summaries for sulfoxaflor sufficiently address aspects of the residue situation that might arise from the use of GF-2626 (CLOSER). Therefore, other special studies are not needed.

IIIA 8.10 Estimation of Exposure Through Diet and Other Means

Toxicological reference values relevant for dietary risk assessment are reported at the beginning of the active substance assessment.

Consumer chronic and acute risk assessments were performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). In order to estimate consumer chronic exposure, IEDI calculations have been performed with the following input values:

- for the uses under evaluation in this dossier: STMR value as derived from the residue trials
- for commodities of plant and animal origin that have already been evaluated at European level: STMRs proposed under previous assessments (EFSA, 2014a)
- for commodities of plant and animal origin for which a CXL has been adopted: STMRs proposed by the JMPR (JMPR, 2011, 2013 & 2014)
- for the remaining commodities: the existing MRLs, as established under Document SANCO/11442/2016. No conversion factors were applied to those commodities as they correspond to commodities for which no use has yet been reported.

When multiple refined values were available for a given crop, the highest STMR was used to perform the IEDI calculations.

It should be noted that the JMPR's risk assessment residue definition for sulfoxaflor is parent sulfoxaflor only. However, results on the concentration of metabolite X11719474 were reported in JMPR evaluations (JMPR 2011, 2013 & 2014) and in all cases except cherries the residues were below 0.01 mg/kg. Additionally, for cherries the concentration of the metabolite would not significantly alter the risk assessment. Thus, the differences regarding the risk assessment residue definitions are of low relevance for the crops under discussion (EFSA, 2015) and JMPR's STMRs were used without applying conversion factors.

The acute exposure assessment was performed only with regard to the commodities under consideration in this application, that is, tomatoes, peppers, aubergines and cucurbits.

The input values for the PRIMo are reported in Table IIIA 8.10-1.

Table IIIA 8.10-1: Input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: Sum of parent sulfoxaflor and metabolite X11719474, expressed as sulfoxaflor.				
Products of plant origin				
Grapefruits	0.021	STMR GF-2626 – SEU use	Acute risk assessment was performed on the intended use only.	
Oranges	0.26	STMR (JMPR, 2014)		
Lemons	0.038	STMR (JMPR, 2014)		
Mandarins	0.31	STMR (JMPR, 2011 & 2014)		
Almonds	0.019	STMR (EFSA, 2014a)		
Pecans	0.019	STMR (EFSA, 2014a)		
Pome fruits	0.185	STMR GF-2626 – SEU use		
Apricots	0.155	STMR (JMPR, 2014)		

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Cherries	0.34	STMR (JMPR, 2014)		
Peaches	0.227	STMR GF-2626 – SEU use		
Plums	0.038	STMR (JMPR, 2014)		
Table grapes	0.165	STMR (EFSA, 2014a)		
Wine grapes	0.14	STMR (JMPR, 2011)		
Strawberries	0.20	STMR (EFSA, 2014a)		
Potatoes	0.019	STMR (EFSA, 2014a)		
Root and tuber vegetables (except potatoes)	0.01	STMR (JMPR, 2011)		
Garlic	0.01	STMR (JMPR, 2011)		
Spring onions/green	0.11	STMR (JMPR, 2011)		
Tomatoes	0.11	STMR (JMPR, 2011)	0.067	HR
Peppers	0.11	STMR (JMPR, 2011)	0.044	HR
Aubergines	0.11	STMR (JMPR, 2011)	0.067	HR
Cucumbers	0.033	STMR GF-2626 – outdoor use	0.048	HR
Gherkins	0.033	STMR GF-2626 – Outdoor use	0.048	HR
Courgettes	0.033	STMR GF-2626 – Outdoor use	0.048	HR
Other cucurbits with edible peel	0.033	STMR GF-2626 – Outdoor use	0.048	HR
Melons	0.029	STMR (JMPR, 2011)	0.034	HR
Pumpkins	0.029	STMR (JMPR, 2011)	0.034	HR
Watermelons	0.029	STMR (JMPR, 2011)	0.034	HR
Other cucurbits with inedible peel	0.029	STMR (JMPR, 2011)	0.034	HR
Broccoli	0.074	STMR (JMPR, 2011)	Acute risk assessment was performed on the intended use only.	
Cauliflowers	0.019	STMR GF-2626 – Outdoor use		
Head cabbages	0.099	STMR (JMPR, 2011)		
Chinese cabbage	1.00	STMR (EFSA, 2014a)		
Lettuce	0.585	STMR (EFSA, 2014a)		
Spinach	1.34	STMR (EFSA, 2014a)		
Celery leaves	0.255	STMR (EFSA, 2014a)		
Celeries	0.19	STMR (JMPR, 2011)		
Beans (dry)	0.075	STMR (JMPR, 2013)		

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Rape seed	0.068	STMR (EFSA, 2014a)		
Soya been	0.023	STMR (EFSA, 2014a)		
Cotton seed	0.02	STMR (JMPR, 2011)		
Barley	0.063	STMR (JMPR, 2011)		
Oats	0.020	STMR (EFSA, 2014a)		
Rye	0.019	STMR (EFSA, 2014a)		
Wheat	0.025	STMR (JMPR, 2011)		
All other crops	EU MRL	SANTE/11442/2016		
Products of animal origin				
Mammalian ^(a) meat	0.045	STMR (JMPR, 2011)	Acute risk assessment was performed on the intended use only.	
Mammalian fat	0.03	STMR (JMPR, 2011)		
Mammalian liver	0.13	STMR (JMPR, 2011)		
Mammalian kidney	0.13	STMR (JMPR, 2011)		
Mammalian edible offals (other than liver and kidney)	0.13	STMR (JMPR, 2011)		
Poultry meat	0.015	STMR (JMPR, 2011)		
Poultry fat	0.01	STMR (EFSA, 2014a)		
Poultry liver	0.046	STMR (JMPR, 2011)		
Poultry kidney	0.046	STMR (JMPR, 2011)		
Poultry edible offals (other than liver and kidney)	0.046	STMR (JMPR, 2011)		
Milk	0.05	STMR (JMPR, 2011)		
Eggs	0.013	STMR (JMPR, 2011)		
All other commodities	EU MRL	SANTE/11442/2016		

(a): Mammalian = Swine, bovine, sheep, goat, equine and other farmed terrestrial animals

IIIA 8.10.1 TMDI CALCULATIONS

As no conversion factors are available at European Level, TMDI calculations were not performed in this dossier.

IIIA 8.10.2 IEDI CALCULATIONS

Sulfoxaflor		Prepare workbook for refined calculations						
Status of the active substance:	Approved	Code no.						
LOQ (mg/kg bw):	0,01	proposed LOQ:						
Toxicological end points								
ADI (mg/kg bw/day):	0,04	ARfD (mg/kg bw):	0,25					
Source of ADI:	EC	Source of ARfD:	EC					
Year of evaluation:	2015	Year of evaluation:	2015					
<p>Explain choice of toxicological reference values.</p> <p>The risk assessment has been performed on the basis of the MRLs collected from Member States in April 2006. For each pesticide/commodity the highest national MRL was identified (proposed temporary MRL = pTMRL). The pTMRLs have been submitted to EFSA in September 2006.</p>								
Chronic risk assessment - refined calculations								
TMDI (range) in % of ADI minimum - maximum 2 14								
No of diets exceeding ADI: ---								
Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	pTMRLs at LOQ (in % of ADI)
13,9	DE child	5,6	Apples	2,5	Oranges	1,8	Milk and milk products: Cattle	0,1
13,1	NL child	3,7	Milk and milk products: Cattle	2,9	Apples	2,0	Oranges	0,2
7,7	FR infant	3,2	Milk and milk products: Cattle	1,5	Spinach	1,2	Apples	0,1
7,0	WHO Cluster diet B	0,8	Tomatoes	0,6	Wine grapes	0,6	Oranges	0,3
6,9	FR toddler	2,4	Spinach	1,3	Oranges	1,2	Apples	0,2
6,4	ES child	1,6	Milk and milk products: Cattle	1,4	Oranges	0,6	Lettuce	0,1
5,5	IE adult	0,7	Oranges	0,4	Mandarins	0,4	Wine grapes	0,4
5,1	SE general population 90th percentile	1,5	Milk and milk products: Cattle	0,5	Chinese cabbage	0,5	Apples	0,1
4,6	NL general	1,0	Oranges	0,8	Milk and milk products: Cattle	0,5	Apples	0,1
4,4	ES adult	0,8	Oranges	0,8	Lettuce	0,6	Milk and milk products: Cattle	0,1
4,3	UK Toddler	1,3	Oranges	0,8	Apples	0,6	Sugar beet (root)	0,7
4,0	WHO regional European diet	0,6	Milk and milk products: Cattle	0,6	Lettuce	0,3	Oranges	0,1
3,9	WHO cluster diet E	0,6	Wine grapes	0,4	Apples	0,4	Milk and milk products: Cattle	0,1
3,9	WHO Cluster diet F	0,6	Oranges	0,5	Milk and milk products: Cattle	0,4	Lettuce	0,1
3,6	WHO cluster diet D	0,6	Milk and milk products: Cattle	0,5	Chinese cabbage	0,4	Wheat	0,1
3,4	FR all population	1,4	Wine grapes	0,3	Milk and milk products: Cattle	0,2	Apples	0,0
3,4	PT General population	0,9	Wine grapes	0,5	Apples	0,4	Oranges	0,1
3,2	DK child	1,1	Apples	0,3	Wheat	0,3	Pears	0,1
3,1	IT kids/toddler	0,4	Lettuce	0,4	Wheat	0,4	Apples	0,1
3,0	UK Infant	0,8	Oranges	0,7	Apples	0,3	Sugar beet (root)	0,4
2,9	IT adult	0,6	Lettuce	0,4	Apples	0,3	Tomatoes	0,1
2,4	LT adult	0,9	Apples	0,5	Milk and milk products: Cattle	0,2	Tomatoes	0,0
2,4	UK vegetarian	0,6	Oranges	0,3	Wine grapes	0,3	Apples	0,1
2,1	PL general population	0,9	Apples	0,2	Tomatoes	0,2	Potatoes	0,0
1,9	UK Adult	0,4	Wine grapes	0,4	Oranges	0,2	Apples	0,1
1,8	DK adult	0,5	Wine grapes	0,4	Apples	0,1	Wheat	0,0
1,7	FI adult	0,6	Oranges	0,2	Apples	0,1	Tomatoes	0,0
<p>Conclusion:</p> <p>The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.</p> <p>A long-term intake of residues of Sulfoxaflor is unlikely to present a public health concern.</p>								

IIIA 8.10.3 IESTI CALCULATIONS

Acute risk assessment /children - refined calculations							Acute risk assessment / adults / general population - refined calculations																																	
<p>The acute risk assessment is based on the ARfD.</p> <p>For each commodity the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS an average European unit weight was used for the IESTI calculation.</p> <p>In the IESTI 1 calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002), for lettuce a variability factor of 5 was used.</p> <p>In the IESTI 2 calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce the calculation was performed with a variability factor of 3.</p> <p>Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100 % of the ARfD.</p>																																								
Unprocessed commodities	No of commodities for which ARfD/ADI is exceeded (IESTI 1):				---			No of commodities for which ARfD/ADI is exceeded (IESTI 2):				---			No of commodities for which ARfD/ADI is exceeded (IESTI 1):				---			No of commodities for which ARfD/ADI is exceeded (IESTI 2):				---														
	IESTI 1				*)			**)			IESTI 2				*)			**)			IESTI 1				*)			**)			IESTI 2				*)			**)		
	Highest % of ARfD/ADI		Commodities		pTMRL/ threshold MRL (mg/kg)				Highest % of ARfD/ADI		Commodities		pTMRL/ threshold MRL (mg/kg)				Highest % of ARfD/ADI		Commodities		pTMRL/ threshold MRL (mg/kg)				Highest % of ARfD/ADI		Commodities		pTMRL/ threshold MRL (mg/kg)											
	2,1		Melons		0,034 / -				2,1		Melons		0,034 / -				0,7		Pumpkins		0,034 / -				0,7		Pumpkins		0,034 / -											
	1,7		Watermelons		0,034 / -				1,7		Watermelons		0,034 / -				0,7		Aubergines (egg)		0,067 / -				0,7		Aubergines (egg plants)		0,067 / -											
	1,6		Tomatoes		0,067 / -				1,1		Tomatoes		0,067 / -				0,6		Watermelons		0,034 / -				0,6		Watermelons		0,034 / -											
	1,1		Cucumbers		0,048 / -				1,1		Cucumbers		0,048 / -				0,5		Melons		0,034 / -				0,5		Melons		0,034 / -											
1,1		Peppers		0,044 / -				0,8		Peppers		0,044 / -				0,5		Courgettes		0,048 / -				0,4		Courgettes		0,048 / -												
No of critical MRLs (IESTI 1)							---							No of critical MRLs (IESTI 2)							---																			
Processed commodities	No of commodities for which ARfD/ADI is exceeded:				---			No of commodities for which ARfD/ADI is exceeded:				---																												
	***)							***)																																
	Highest % of ARfD/ADI		Processed commodities		pTMRL/ threshold MRL (mg/kg)				Highest % of ARfD/ADI		Processed commodities		pTMRL/ threshold MRL (mg/kg)																											
	0,8		Tomato juice		0,11 / -				0,1		Tomato (preserved-		0,11 / -																											
*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.																																								
**) pTMRL: provisional temporary MRL																																								
***) pTMRL: provisional temporary MRL for unprocessed commodity																																								
<p>Conclusion:</p> <p>For Sulfoxaflor IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.</p> <p>No exceedance of the ARfD/ADI was identified for any unprocessed commodity.</p> <p>For processed commodities, no exceedance of the ARfD/ADI was identified.</p>																																								

IIIA 8.10.4 CONSUMER RISK ASSESSMENT CONCLUSION

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo model. The total calculated intake values ranged from 1.7 to 13.9 % of the ADI (DE child). The three highest contributors to the critical diet (DE child), expressed in percent of the ADI, were apples (5.6%), oranges (2.5%) and milk and milk products from cattle (1.8%). Therefore, no chronic (long-term) consumer risk was identified for the intended uses on tomatoes, peppers, aubergines and cucurbits.

No acute consumer risk was identified in relation to the intended uses. The maximum calculated exposure was 2.1 % of the ARfD for melons.

According to EFSA, a theoretical factor of 2 may be applied to these estimates, in order to take into account for the uncertainty concerning the unknown ratio of enantiomers present in the individual diastereomers of sulfoxaflor and of X11719474, respectively (EFSA, 2014a). Even considering this factor, the toxicological reference values would not be exceeded.

Therefore, the intended uses of sulfoxaflor on tomatoes, peppers, aubergines, melons, watermelons, cucurbits do not represent unacceptable acute and chronic risks for the consumer.

IIIA 8.11 Summary and Evaluation of Residue Behaviour for sulfoxaflor

See overall conclusion.

Overall conclusion

Overall conclusion

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of for sulfoxaflor as laid down in Reg. (EU) 396/2005 is not expected according to the intended uses for tomatoes, peppers, aubergines and cucurbits with edible and inedible peel.

The chronic and the short-term intakes of sulfoxaflor residues are unlikely to present a public health concern.

As far as consumer health protection is concerned, zRMS France agrees with the authorization of the intended and proposed uses on tomatoes, peppers, aubergines and cucurbits with edible and inedible peel.

According to available data, no specific mitigation measures should apply.

Data gaps

No data gaps have been noticed in the framework of this evaluation.

SUMMARY OF THE EVALUATION

The preparation GF-2626 (CLOSER) is composed of sulfoxaflor.

Table 0-1: Summary for sulfoxaflor

Use- No.*	Crop	Plant metabolis m covered?	Sufficien t residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance SANTE/11 442/2016	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
/	Tomatoes → Aubergines	Yes	Yes	Yes	Yes	Yes	No	No	Acceptable use
/	Peppers	Yes	Yes	Yes	Yes	Yes		No	Acceptable use
/	Cucurbits with edible peel	Yes	Yes	Yes	Yes	Yes		No	Acceptable use
/	Cucurbits with inedible peel	Yes	Yes	Yes	Yes	Yes		No	Acceptable use

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

N/A: Not Applicable

The effects of processing on the nature of sulfoxaflor residues have been investigated. Data on effects of processing on the amount of residue have been submitted. These data were not considered for risk assessment.

Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. It is very unlikely that residues will be present in succeeding crops.

The crops under evaluation are not fed to animals. Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary.

Summary for GF-2626 (CLOSER)

Table 0-2: Information on GF-2626 (CLOSER) (KCA 6.8)

Crop	PHI for GF-2626 (CLOSER) proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for GF-2626 (CLOSER) proposed by zRMS	zRMS Comments (if different PHI proposed)
		Sulfoxaflor		
Tomatoes → Aubergines	1 day	Yes	1 day	-
Peppers	1 day	Yes	1 day	-
Cucurbits with edible peel	1 day	Yes	1 day	-
Cucurbits with inedible peel	1 day	Yes	1 day	-

* Purpose of withholding period to be specified

Waiting periods before planting succeeding crops

Not relevant

References :

Sulfoxaflor

EC (European Commission), 2015. Final review report for the active substance sulfoxaflor. Finalised in the Standing Committee on Plants, Animals, Food and Feed at its meeting on 29 May 2015 in view of the approval of sulfoxaflor as active substance in accordance with Regulation (EC) No 1107/2009. SANCO/10665/2015-rev 2, 29 May 2015. Available online: http://ec.europa.eu/sanco_pesticides/public/index.cfm?event=activesubstance.selection

EFSA (European Food Safety Authority), 2012. Scientific support for preparing an EU position in the 44th Session of the Codex Committee on Pesticide Residues (CCPR). EFSA Journal 2012;10(7):2859. [155 pp.] doi:10.2903/j.efsa.2012.2859. Available online: www.efsa.europa.eu/efsajournal

EFSA (European Food Safety Authority), 2014a. Conclusion on the peer review of the pesticide risk assessment of the active substance sulfoxaflor, EFSA Journal 2014;12(5):3962, [170 pp.] doi:10.2903/j.efsa.2014.3962. Available online: www.efsa.europa.eu/efsajournal.htm

EFSA (European Food Safety Authority), 2014b. Scientific support for preparing an EU position in the 46th Session of the Codex Committee on Pesticide Residues (CCPR). EFSA Journal 2014;12(7):3737, 182 pp. doi:10.2903/j.efsa.2014.3737 Available online: www.efsa.europa.eu/efsajournal

EFSA (European Food Safety Authority), 2015. Scientific support for preparing an EU position in the 47th Session of the Codex Committee on Pesticide Residues (CCPR). EFSA Journal 2015;13(7):4208. 178 pp. doi:10.2903/j.efsa.2015 Available online: www.efsa.europa.eu/efsajournal

FAO (Food and Agriculture Organisation of the United Nations), 2011. Sulfoxaflor in: Pesticide residues in food – 2011. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues. Geneva, Switzerland, 20-29 September 2011. FAO Plant Production and Protection Paper 211. Available online: <http://www.fao.org/agriculture/crops/core-themes/theme/pests/pm/jmpr/jmpr-rep/en/>

FAO (Food and Agriculture Organisation of the United Nations), 2011. Sulfoxaflor in: Pesticide residues in food – 2011. Evaluations. Part I. Residues. FAO Plant Production and Protection Paper 212. Available online: <http://www.fao.org/agriculture/crops/core-themes/theme/pests/pm/jmpr/jmpr-rep/en/>

FAO (Food and Agriculture Organisation of the United Nations), 2013. Sulfoxaflor in: Pesticide residues in food – 2013. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues. Geneva, Switzerland, 17 to 26 September 2013. FAO Plant Production and Protection Paper 219. Available online: <http://www.fao.org/agriculture/crops/core-themes/theme/pests/pm/jmpr/jmpr-rep/en/>

FAO (Food and Agriculture Organisation of the United Nations), 2014. Sulfoxaflor in: Pesticide residues in food – 2014. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues. Rome, Italy, 16-25 September 2014. FAO Plant Production and Protection Paper 221. Available online: <http://www.fao.org/agriculture/crops/core-themes/theme/pests/pm/jmpr/jmpr-rep/en/>

France 2016. Evaluation Report prepared under Article 8 of Regulation (EC) No 396/2005 Modification on the setting of MRL in globe artichokes.

Ireland, 2012. Draft assessment report on the active substance sulfoxaflor prepared by the rapporteur Member State Ireland in the framework of Council Directive 1107/2009/EC, Month 2012.

Ireland, 2014. Final Addendum to the Draft Assessment Report (DAR) on sulfoxaflor, compiled by EFSA, January 2014. Available at www.efsa.europa.eu

General documents:

- EC (European Commission), 1996.** Appendix G. Livestock Feeding Studies. 7031/VI/95 rev.4. Available online: http://ec.europa.eu/food/plant/protection/resources/publications_en.htm
- EC (European Commission), 1997a.** Appendix A. Metabolism and distribution in plants. 7028/IV/95-rev.3. Available online: http://ec.europa.eu/food/plant/protection/resources/publications_en.htm
- EC (European Commission), 1997b.** Appendix B. General recommendations for the design, preparation and realization of residue trials. Annex 2. Classification of (minor) crops not listed in the Appendix of Council Directive 90/642/EEC. 7029/VI/95-rev.6. Available online: http://ec.europa.eu/food/plant/protection/resources/publications_en.htm
- EC (European Commission), 1997c.** Appendix C. Testing of plant protection products in rotational crops. 7524/VI/95-rev.2. Available online: http://ec.europa.eu/food/plant/protection/resources/publications_en.htm
- EC (European Commission), 1997d.** Appendix E. Processing studies. 7035/VI/95-rev.5. Available online: http://ec.europa.eu/food/plant/protection/resources/publications_en.htm
- EC (European Commission), 1997e.** Appendix F. Metabolism and distribution in domestic animals. 7030/VI/95-rev.3. Available online: http://ec.europa.eu/food/plant/protection/resources/publications_en.htm
- EC (European Commission), 1997f.** Appendix H. Storage stability of residue samples. 7032/VI/95-rev.5. Available online: http://ec.europa.eu/food/plant/protection/resources/publications_en.htm
- EC (European Commission), 1997g.** Appendix I. Calculation of maximum residue level and safety intervals. 7039/VI/95. As amended by the document: classes to be used for the setting of EU pesticide maximum residue levels (MRLs). SANCO 10634/2010. Available online: http://ec.europa.eu/food/plant/protection/resources/publications_en.htm
- EC (European Commission), 2000.** Residue analytical methods. For pre-registration data requirement for Annex II (part A, section 4) and Annex III (part A, section 5 of Directive 91/414. SANCO/3029/99-rev.4. Available online: http://ec.europa.eu/food/plant/protection/resources/publications_en.htm
- EC (European Commission), 2004.** Residue analytical methods. For post-registration control. SANCO/825/00-rev.7. Available online: http://ec.europa.eu/food/plant/protection/resources/publications_en.htm
- EC (European Commission), 2010.** Classes to be used for the setting of EU pesticide Maximum Residue Levels (MRLs). SANCO 10634/2010 Rev. 0, finalized in the Standing Committee on the Food Chain and Animal Health at its meeting of 23-24 March 2010. Available online: http://ec.europa.eu/food/plant/protection/resources/publications_en.htm
- EC (European Commission), 2011.** Appendix D. Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. 7525/VI/95-rev.9. Available online: http://ec.europa.eu/food/plant/protection/resources/publications_en.htm
- FAO (Food and Agriculture Organization of the United Nations), 2009.** Submission and evaluation of pesticide residues data for the estimation of Maximum Residue Levels in food and feed. Pesticide Residues. 2nd Ed. FAO Plant Production and Protection Paper 197, 264 pp.

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

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner	Relied on Y/N
IIIA 8.3.1.1/0 1	Rawle, N. W.	2011a	Residues of XDE-208 in indoor tomatoes at intervals and harvest Following a single application of GF-2626 – Europe – 2010 Dow AgroSciences DAS report CEMR-4698 Y Unpublished	Y	DAS	Y
IIIA 8.3.1.1/0 2	Rawle, N. W.	2012a	Residues of sulfoxaflor in indoor tomatoes at intervals and harvest following a single application of GF-2626 – Europe – 2011 Dow AgroSciences DAS report CEMR-5009 Y Unpublished	Y	DAS	Y
IIIA 8.3.1.2/0 1	Rawle, N. W.	2011b	Residues of XDE-208 in indoor peppers at intervals and harvest following a single application of GF-2626 – Europe – 2010 Dow AgroSciences DAS report CEMR-4702 Y Unpublished	Y	DAS	Y
IIIA 8.3.1.2/0 2	Rawle, N. W.	2011c	Residues of sulfoxaflor in indoor bell peppers at intervals and harvest following a single application of GF-2626 – Europe – 2011 Dow AgroSciences DAS report CEMR-5012 Y Unpublished	Y	DAS	Y
IIIA 8.3.2.1/0 1	Rawle, N. W.	2011d	Residues of XDE-208 in indoor cucumbers at intervals and harvest following a single application of GF-2626 – Europe – 2010 Dow AgroSciences DAS report CEMR-4705 Y Unpublished	Y	DAS	Y

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner	Relied on Y/N
IIIA 8.3.2.1/02	Rawle, N. W.	2012b	Residues of sulfoxaflor in indoor cucumbers at intervals and harvest following a single application of GF-2626 – Europe – 2011 Dow AgroSciences DAS report CEMR-5014 Y Unpublished	Y	DAS	Y
IIIA 8.3.2.2/01	Rawle, N. W.	2011e	Residues of XDE-208 in indoor melons at intervals and harvest following a single application of GF-2626 – Europe – 2010 Dow AgroSciences DAS report CEMR-4708 Y Unpublished	Y	DAS	Y
IIIA 8.3.2.2/02	Rawle, N. W.	2012c	Residues of sulfoxaflor in indoor melons at intervals and harvest following a single application of GF-2626 – Europe – 2011 Dow AgroSciences DAS report CEMR-5016 Y Unpublished	Y	DAS	Y
IIIA 8.6.2/01	Semrau, J.	2013	Determination of residues of XDE-208 after one application of GF-2626 on bare soil in rotational crops (radish, leaf lettuce, spring onion and barley) at 2 sites in Northern Europe and 2 sites in Southern Europe 2011 / 2012 Dow AgroSciences DAS report 110385 Y Unpublished	Y	DAS	Y

Appendix 2: Acceptable critical Uses –GAP tables

Crop and/ or situation (a)	Zone	Product code	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min) (l)	kg as/hL min max	water L/ha min max	kg as/ha min max		
Tomatoes → aubergines (including pepinos)	BG, CY, EL, ES, FR, HR, IT, MT, PT AT, BE, DE, IE, NL, RO, UK, PL	GF- 2626	G	Aphids, Whiteflies	SC	120 g/L	Ground applied foliar spray, broadcast	BBCH 20- 87	1-2	7 days	0.0016- 0.0096	500- 1500	0.024- 0.048	1	<u>Aphids:</u> One or two applications of 24 g a.s./ha. Two applications would be minimum 7 days interval. <u>Whiteflies:</u> Either two applications of 24 g a.s./ha with a minimum 7 days interval or only one application of 48 g a.s./ha.

<i>Crop and/ or situation</i>	<i>Zone</i>	<i>Product code</i>	<i>F G or I</i>	<i>Pests or Group of pests controlled</i>	<i>Formulation</i>		<i>Application</i>				<i>Application rate per treatment</i>			<i>PHI (days)</i>	<i>Remarks:</i>
					<i>Type</i>	<i>Conc. of as</i>	<i>method kind</i>	<i>growth stage & season</i>	<i>number min max</i>	<i>interval between applications (min)</i>	<i>kg as/hL</i> <i>min max</i>	<i>water L/ha</i> <i>min max</i>	<i>kg as/ha</i> <i>min max</i>		
<i>(a)</i>			<i>(b)</i>	<i>(c)</i>	<i>(d-f)</i>	<i>(i)</i>	<i>(f-h)</i>	<i>(j)</i>	<i>(k)</i>					<i>(l)</i>	<i>(m)</i>
Peppers (including chilli peppers)	BG, CY, EL, ES, FR, HR, IT, MT, PT AT, BE, DE, IE, NL, RO, UK, PL	GF- 2626	G	Aphids, Whiteflies	SC	120 g/L	Ground applied foliar spray, broadcast	BBCH 20- 87	1-2	7 days	0.0016- 0.0096	500- 1500	0.024- 0.048	1	<u>Aphids:</u> One or two applications of 24 g a.s./ha. Two applications would be minimum 7 days interval. <u>Whiteflies:</u> Either two applications of 24 g a.s./ha with a minimum 7 days interval or only one application of 48 g a.s./ha.

<i>Crop and/ or situation</i>	<i>Zone</i>	<i>Product code</i>	<i>F G or I</i>	<i>Pests or Group of pests controlled</i>	<i>Formulation</i>		<i>Application</i>				<i>Application rate per treatment</i>			<i>PHI (days)</i>	<i>Remarks:</i>
					<i>Type</i>	<i>Conc. of as</i>	<i>method kind</i>	<i>growth stage & season</i>	<i>number min max</i>	<i>interval between applications (min)</i>	<i>kg as/hL</i> <i>min max</i>	<i>water L/ha</i> <i>min max</i>	<i>kg as/ha</i> <i>min max</i>		
<i>(a)</i>			<i>(b)</i>	<i>(c)</i>	<i>(d-f)</i>	<i>(i)</i>	<i>(f-h)</i>	<i>(j)</i>	<i>(k)</i>					<i>(l)</i>	<i>(m)</i>
Cucurbits (edible peel – cucumbers, courgettes, gherkins)	BG, EL, ES, FR, IT, PT AT, BE, DE, IE, NL, UK	GF- 2626	G	Aphids, Whiteflies	SC	120 g/L	Ground applied foliar spray, broadcast	BBCH 20- 87	1-2	7 days	0.0016- 0.0096	500- 1500	0.024- 0.048	1	<u>Aphids:</u> One or two applications of 24 g a.s./ha. Two applications would be minimum 7 days interval. <u>Whiteflies:</u> Either two applications of 24 g a.s./ha with a minimum 7 days interval or only one application of 48 g a.s./ha.

<i>Crop and/ or situation</i>	<i>Zone</i>	<i>Product code</i>	<i>F G or I</i>	<i>Pests or Group of pests controlled</i>	<i>Formulation</i>		<i>Application</i>				<i>Application rate per treatment</i>			<i>PHI (days)</i>	<i>Remarks:</i>
					<i>Type</i>	<i>Conc. of as</i>	<i>method kind</i>	<i>growth stage & season</i>	<i>number min max</i>	<i>interval between applications (min)</i>	<i>kg as/hL</i> <i>min max</i>	<i>water L/ha</i> <i>min max</i>	<i>kg as/ha</i> <i>min max</i>		
<i>(a)</i>			<i>(b)</i>	<i>(c)</i>	<i>(d-f)</i>	<i>(i)</i>	<i>(f-h)</i>	<i>(j)</i>	<i>(k)</i>					<i>(l)</i>	<i>(m)</i>
Cucurbits (inedible peel – melons, pumpkins/ squash, watermelons)	BG, EL, ES, FR, IT, PT AT, BE, DE, IE, NL, UK, PL	GF- 2626	G	Aphids, Whiteflies	SC	120 g/L	Ground applied foliar spray, broadcast	BBCH 20- 87	1-2	7 days	0.0016- 0.0096	500- 1500	0.024- 0.048	1	<u>Aphids:</u> One or two applications of 24 g a.s./ha. Two applications would be minimum 7 days interval. <u>Whiteflies:</u> Either two applications of 24 g a.s./ha with a minimum 7 days interval or only one application of 48 g a.s./ha.

Remarks:

(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 plants - 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) The minimum and maximum number of application possible under practical conditions of use must be provided

(l) PHI - minimum pre-harvest interval

(m) Remarks may include: Extent of use/economic importance/restrictions

