REGISTRATION REPORT

Part B
Section 4: Metabolism and Residues

Detailed summary of the risk assessment

CLOSER (GF-2626)

120 g/L Sulfoxaflor

Southern Zone

Zonal Rapporteur Member State: France

(Field F)

CORE ASSESSMENT

Applicant: DOW AgroSciences

Date: October 2017

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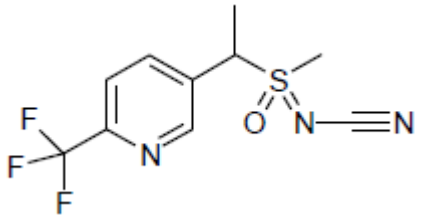
IIIA 8 METABOLISM AND RESIDUES DATA

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)	Sulfaxoflor (sum of isomers)
Legislation footnotes	/
EFSA Journal Conclusions on the peer-review	EFSA (European Food Safety Authority), 2014. 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	C10 H10 F3 N3 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	EFSA	2014	0.04 mg/kg bw/d	2-year Rat	x100
ARfD	EFSA	2014	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 MRL have been proposed at EU level in document SANTE/11442/2016. Furthermore it should be noted that an MRL modification request has been applied for in Ireland. The request concerns various commodities including ones under evaluation. 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, EFSA 2014)

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

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

Uses under consideration are covered by available storage stability data.

IIIA 8.1.2 STABILITY OF RESIDUES IN SAMPLE EXTRACTS

Procedural recoveries were conducted in parallel with the sample analysis in the residue studies submitted. Acceptable recoveries were achieved, demonstrating the stability of residues in sample extracts.

IIIA 8.2 Studies on metabolism in plants or livestock

IIIA 8.2.1 METABOLISM IN PLANTS

IIIA 8.2.1.1 European data (IE 2012, EFSA 2014)

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	NR[2]	Foliar application F	NM[2]	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
			NR[2]	Soil application F	NM[2]	225g as./ha	2	Immature plants:14 DA1A Tomatoes:14, 21, 28 DALA Vines : 28 DALA	
Leafy vegetables	Lettuce	[14C-pyridine] ring	NR[2]	Foliar application F	NM[2]	200 g as/ha	3	Immature plants:14 DA1A Mature plants: 7 DALA	Ireland, 2012
			NR[2]	Soil application F	NM[2]	225 g as/ha	2	Immature plants:14 DA1A Mature plants: 7 DALA	
Pulses and oilseeds	Snap Peas	[^{14}C-pyridine] ring	NR[2]	Foliar application F	NM[2]	200 g as/kg	3	Immature plants: 14 DA1A, 14 DA2A, At maturity: pods, vines	Ireland, 2012
			NR[2]	Soil application F	NM[2]	450 g as/ha	1	Immature plants: 14 DA1A, At maturity: pods, vines	
Cereals	Rice	[^{14}C-	NR[2]	Foliar	NM[2]	600 g as/ha		Immature	Ireland,

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	
		pyridine] ring		application F		split in 3 applications at 225, 225 & 150 g as/ha		plants:14 DA1A At maturity : straw, hulls, grain	2012
			Rice plant were transplanted at BBCH 13-14	Soil application F	NM[2]	400 g as/ha	1	Immature plants 14 and 28 DAT DAT At maturity : straw, hulls, grain	

[1] Outdoor or field use (F), glasshouse application (G), Indoor Application (I)
[2]**NR**: 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 diasteromers observed. However the residues of the metabolite X11719474 could not be resolved into its two diastereomeric pairs of enantiomers in plant matrices, while in a buffer solution no epimerisation was observed. No information is available in terms of the ratios of enantiomers present in the individual diastereomers of sulfoxaflor and of X11719474, respectively. All data reported here below refer to the sum of the four isomers of sulfoxaflor and X11719474, respectively.

Upon foliar treatment, parent sulfoxaflor was a major residue in the mature tomato fruit (26 – 35 % TRR) and foliage (28 % TRR), pods of snap pea (59 %TRR) and vines (71 % TRR), lettuce (16 % TRR), rice grain (35 % TRR) and straw (44 % TRR).
Overall, compounds X11719474 and X11721061 (conjugated form) were the pertinent metabolites in mature tomato fruit (20 – 29 % and 13 – 22 %TRR, respectively), foliage (16 % and 14 % TRR), pods of snap pea (both 13 % TRR) and vines (12 % and 7 % TRR), lettuce (30 % and 8 % TRR), rice grain (8 % and 11 %TRR) and straw (10 % and 8 % TRR). Only low proportions of free X11721061 were observed in the mature crops (≤ 4 % TRR). Other metabolites were not significant.

Upon soil treatment - as for the rapid degradation of 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

Uses under consideration are covered by available metabolism studies.

IIIA 8.2.2 METABOLISM IN LIVESTOCK

IIIA 8.2.2.1 European data (IE 2012, EFSA 2014)

Metabolism of sulfoxaflor and metabolism of metabolite X11719474 in commodities of animal origin was investigated in the framework of European Evaluation. The basic characteristics of the metabolism studies design are summarised in table below.

Table IIIA 8.2.2-1: Summary of animal metabolism studies performed with sulfoxaflor

Species	Label position	Number of specimen	Application details		Sampling		Reference
			Duration	Rate	Commodity	Time	
Goat	[^{14}C-pyridine] ring	2 (1 test, 1 control)	5 days (+12 days of acclimation)	12.2 mg/kg in the diet	Milk	Twice a day (morning and afternoon)	IE 2012 EFSA 2014
					Urine	Twice a day	
					Faeces	Daily	
					Liver Kidney Muscle (loin & flank) fat(subcutaneous, omental & renal) small and large intestine Stomach Contents of the gastrointestinal tract	At sacrifice, 6 hours after the final dose	
Hen	[^{14}C-pyridine] ring	20 (10 tests, 10 controls)	7 days (+ 21 days of acclimation)	12.2 mg/kg dry feed	Eggs	Twice a day (morning and afternoon)	IE 2012 EFSA 2014
					Excreta	Daily	
					Cage rinse muscle (beast, leg) liver	At sacrifice, 6 h after final dose	

Species	Label position	Number of specimen	Application details		Sampling		Reference
			Duration	Rate	Commodity	Time	
					fat skin with subcutaneous fat		

Table IIIA 8.2.2-2: Summary of animal metabolism studies performed with metabolite X11719474

Species	Label position	Number of specimen	Application details		Sampling		Reference
			Duration	Rate	Commodity	Time	
Goat	[^{14}C-pyridine] ring	2 (1 test, 1 control)	5 days (+8 days of acclimation)	11.4 mg/kg in the diet	Milk	Twice a day (morning and afternoon)	IE 2012 EFSA 2014
					Urine	Daily	
					Faeces	Daily	
					Liver Kidney muscle (loin & flank) fat(subcutaneous, omental & renal) gastrointestinal tract and its content	At sacrifice, 6 hours after the final dose	
Hen	[^{14}C-pyridine] ring	20 (10 test, 10 controls)	7 days (+ 17 days of acclimation)	13.3 mg/kg dry feed	Eggs	Twice a day (morning and afternoon)	IE 2012 EFSA 2014
					Excreta	Daily	
					Cage rinse muscle (beast, leg) liver fat skin with subcutaneous fat	At sacrifice, 6 h after final dose	

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

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

The peer review concluded that for livestock commodities the residue definition for risk assessment should be sulfoxaflor and X11719474, with the possibility for revision in future. Indeed if in the future it is agreed that the metabolite X11719474 is shown to be significantly less toxic than sulfoxaflor then the

residue definition for risk assessment will become parent Sulfoxaflor only. For monitoring the animal residue definition was proposed as sulfoxaflor only.

IIIA 8.2.2.2 New data

No new data submitted.

IIIA 8.2.2.3 Conclusion on metabolism in livestock

Uses under consideration are covered by available livestock metabolism studies.

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 CITRUS FRUITS

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

Crop	Type of GAP	Number of applications	Application rate per treatment	Interval between application	Growth stage at last application	PHI (days)
Citrus (grapefruits, oranges, lemons, mandarins)	DAR MRL Application (AUS)[1]	1-2	192 g as/ha	14	BBCH 89	1
	DAR MRL Application (US)[1]	1-3	100 g as/h	14	BBCH 89	1
	Intended FR and SEU	1	48 g/ha	-	BBCH 30-85	7
		2	24 g/ha	7	BBCH 30-85	7

[1] MRL Application

IIIA 8.3.1.1 Summary of EU Data

Use on citrus has been assessed in the meantime of the EU evaluation of sulfoxaflor, in the framework of MRL application for an import tolerance.
However this MRL application is based on Australian and US GAP and residue trials supporting the import tolerance have been performed outside EU (US and Aus) and then they cannot be considered to support the intended use of GF-2626 on citrus fruits in EU.

IIIA 8.3.1.2 New data

IIIA 8.3.1.2.1 Study 1

Report:	IIIA 8.3.1/01, Rawle, N. W., 2012
Title:	Residues of sulfoxaflor in oranges and mandarins at intervals and harvest following a single application of GF-2626 – Southern Europe –2011
Document No:	CEMR-5031 Version 2 (Report ID); GHE-P-12727 (Dow AgroSciences Reference)
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 and are designed to comply with the "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 8.3.1-2: Summary of global information on study 1

Comparative trials (between formulations, with and adjuvant/safener/synergist)	No, formulation SC containing 120 g sulfoxaflor/L
Number of applications	1
Dose (g as/ha)	24 or 48 g/ha
Mode of application	Foliar broadcast application
PHI (days) and/or growth stage (BBCH)	0, 1, 3, 7, 10, 42 and 56
Analytical method (Code +Type)	Method N° 091031 LC-MS/MS
LoQ (mg/kg)	0.01 mg/kg

Table IIIA 8.3.1-3: Summary of the study 1 trials

N° Trial		CEMS-5031A		CEMS-5031B		CEMS-5031C		CEMS-5031D		CEMS-5031E	
		2	3	2	3	2	3	2	3	2	3
North/South/Indoor		S		S		S		S		S	
Decline (D)/Harvest (H) trial?		D		D		D		D		D	
Formulation		SC		SC		SC		SC		SC	
Equivalence between formulations		Y		Y		Y		Y		Y	
Accordance with intended GAP		N[1]	Y	N[1]	Y	N[1]	Y	N[1]	Y	N[1]	Y
Correct sampling		Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Samples frozen within 24h		Y		Y		Y		Y		Y	
Storage period (in days)	Sample	456	456	214	214	415	415	415	415	223	223
	Extract[2]	62		62		62		62		62	
Storage T° <-18°C		Y		Y		Y		Y		Y	
Validated analytical method		Y		Y		Y		Y		Y	
Negative controls		Y		Y		Y		Y		Y	
Considered trial		N	Y	N	Y	N	Y	N	Y	N	Y
Remarks		1		1		1		1		1	

[1] Single application at 24 g a.s./ha instead of 48 g a.s./ha

[2] The procedural recoveries demonstrate the stability of the analyte during the storage (up to 62 days)." (GHE-P-12727, p.33)

N° Trial		CEMS-5031F		CEMS-5031G		CEMS-5031H	
		2	3	2	3	2	3
North/South/Indoor		S		S		S	
Decline (D)/Harvest (H) trial?		D		D		D	
Formulation		SC		SC		SC	
Equivalence between formulations		Y		Y		Y	
Accordance with intended GAP		N[1]	Y	N[1]	Y	N[1]	Y
Correct sampling		Y	Y	Y	Y	Y	Y
Samples frozen within 24h		Y		Y		Y	
Storage period (in days)	Sample	231	231	228	228	238	238
	Extract[2]	62		62		62	
Storage T° <-18°C		Y		Y		Y	
Validated analytical method		Y		Y		Y	
Negative controls		Y		Y		Y	
Considered trial		N	Y	N	Y	N	Y
Remarks		1		1		1	

[1] Single application at 24 g a.s./ha instead of 48 g a.s./ha

[2] The procedural recoveries demonstrate the stability of the analyte during the storage (up to 62 days).” (GHE-P-12727, p.33)

Table IIIA 8.3.1-4: 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

Active ingredient : Sulfoxaflor
Crop / crop group : Citrus Fruit
-Oranges
-Mandarins

Content of a.i. (g/kg or g/l) : 120 g/L
Formulation (e.g. WP) : SC
Commercial product (name) : GF-2626
Applicant : Eurofins

Indoors / outdoors : Outdoor
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**			
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)	**Remarks (e)**

GLP and Trial Details	Crop	Country	Application Details									Residues found			
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)**	**Remarks (e)**
CEMS-5031A CEMS-5031 GHE-P-12727 Y 2011	Orange Navelina	Spain (SZ) 46650 Canals, Valencia Outdoor (field)	GF-2626	1	47.6	2479	1.92	25-Oct-2011	BBCH.81	0	Peel	0.058	<0.01	0.067	
										1	Peel	0.036	<0.01	0.045	
										3	Peel	0.026	<0.01	0.035	
										7	Peel	0.011	<0.01	0.020	
										10	Peel	0.012	<0.01	0.021	
										42	Peel	0.017	<0.01	0.026	
										56	Peel	<0.01	<0.01	<0.019	
										0	Pulp	<0.01	<0.01	<0.019	
										1	Pulp	<0.01	<0.01	<0.019	
										3	Pulp	<0.01	<0.01	<0.019	
										7	Pulp	<0.01	<0.01	<0.019	
										10	Pulp	<0.01	<0.01	<0.019	
										42	Pulp	<0.01	<0.01	<0.019	
										56	Pulp	<0.01	<0.01	<0.019	
										0	Whole Fruit	0.035	<0.01	0.044	
										1	Whole Fruit	0.023	<0.01	0.032	
										3	Whole Fruit	0.016	<0.01	0.025	
										7	Whole Fruit	<0.01	<0.01	<0.019	
										10	Whole Fruit	<0.01	<0.01	<0.019	
										42	Whole Fruit	**0.011**	<0.01	**0.020**	
										56	Whole Fruit	<0.01	<0.01	<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 (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)	**Remarks (e)**
CEMS-5031B CEMS-5031 GHE-P-12727 Y 2011	Orange Navelino	Spain (SZ) 41520 El Viso Del Arcor, Sevilla Outdoor (field)	GF-2626	1	48.9	1529	3.2	31-Oct-2011	BBCH.81	0	Peel	0.048	<0.01	0.057	
										1	Peel	0.061	<0.01	0.070	
										3	Peel	0.028	<0.01	0.037	
										7	Peel	0.023	<0.01	0.032	
										10	Peel	0.023	<0.01	0.032	
										42	Peel	0.019	<0.01	0.028	
										57	Peel	0.017	<0.01	0.026	
										0	Pulp	<0.01	<0.01	<0.019	
										1	Pulp	<0.01	<0.01	<0.019	
										3	Pulp	<0.01	<0.01	<0.019	
										7	Pulp	<0.01	<0.01	<0.019	
										10	Pulp	<0.01	<0.01	<0.019	
										42	Pulp	<0.01	<0.01	<0.019	
										57	Pulp	<0.01	<0.01	<0.019	
										0	Whole Fruit	0.028	<0.01	0.037	
										1	Whole Fruit	0.040	<0.01	0.049	
										3	Whole Fruit	0.018	<0.01	0.027	
										7	Whole Fruit	0.013	<0.01	0.022	
										10	Whole Fruit	**0.014**	<0.01	**0.023**	
										42	Whole Fruit	0.011	<0.01	0.020	
										57	Whole Fruit	<0.01	<0.01	<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 (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)**	**Remarks (e)**
CEMS-5031C CEMS-5031 GHE-P-12727 Y 2011	Orange Kyno	Greece(SZ) 24009 Mikroliman i, Messinia Outdoor (field)	GF- 2626	1	47.2	1968	2.4	05-Dec- 2011	BBCH.85	0 1 3 7 10 42 56 0 1 3 7 10 42 56 0 1 3 7 10 42 56	Peel Peel Peel Peel Peel Peel Peel Pulp Pulp Pulp Pulp Pulp Pulp Pulp Whole Fruit Whole Fruit Whole Fruit Whole Fruit Whole Fruit Whole Fruit Whole Fruit	0.076 0.019 0.017 0.015 0.014 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 0.051 0.012 0.012 **<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	0.085 0.028 0.026 0.024 0.023 <0.019 <0.019 <0.019 <0.019 <0.019 <0.019 <0.019 <0.019 <0.019 <0.019 0.060 0.021 0.021 **<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 (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)	**Remarks (e)**
CEMS-5031D CEMS-5031 GHE-P-12727 Y 2011	Orange Botsato	Greece (SZ) 24100 Kalamata, Messinia Outdoor (field)	GF-2626	1	47.0	1956	2.4	05-Dec-2011	BBCH.85	0 1 3 7 10 42 56 0 1 3 7 10 42 56 0 1 3 7 10 42 56	Peel Peel Peel Peel Peel Peel Peel Pulp Pulp Pulp Pulp Pulp Pulp Pulp Whole Fruit Whole Fruit Whole Fruit Whole Fruit Whole Fruit Whole Fruit Whole Fruit	0.016 0.025 0.016 0.026 <0.01 <0.01 0.02 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 0.011 0.017 0.011 **0.018** <0.01 <0.01 0.014	<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	0.025 0.034 0.025 0.035 <0.019 <0.019 0.029 <0.019 <0.019 <0.019 <0.019 <0.019 <0.019 <0.019 0.020 0.026 0.020 **0.027** <0.019 <0.019 0.023	

GLP and Trial Details	Crop	Country	Application Details									Residues found			
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)**	**Remarks (e)**
CEMS-5031E CEMS-5031 GHE-P-12727 Y 2011	Mandarin Orogrande	Spain (SZ) 46220 Picassent, Valencia Outdoor (field)	GF-2626	1	47.8	996	4.8	08-Nov-2011	BBCH.81 to 83	0	Peel	0.110	<0.01	0.119	
										1	Peel	0.078	<0.01	0.087	
										3	Peel	0.068	<0.01	0.077	
										7	Peel	0.054	<0.01	0.063	
										10	Peel	0.050	<0.01	0.059	
										42	Peel	0.031	<0.01	0.040	
										56	Peel	0.032	<0.01	0.041	
										0	Pulp	<0.01	<0.01	<0.019	
										1	Pulp	<0.01	<0.01	<0.019	
										3	Pulp	<0.01	<0.01	<0.019	
										7	Pulp	<0.01	<0.01	<0.019	
										10	Pulp	<0.01	<0.01	<0.019	
										42	Pulp	0.010	<0.01	0.019	
										56	Pulp	<0.01	<0.01	<0.019	
										0	Whole Fruit	0.070	<0.01	0.079	
										1	Whole Fruit	0.051	<0.01	0.060	
										3	Whole Fruit	0.043	<0.01	0.052	
										7	Whole Fruit	**0.035**	<0.01	**0.044**	
										10	Whole Fruit	0.031	<0.01	0.040	
										42	Whole Fruit	0.025	<0.01	0.034	
										56	Whole Fruit	0.022	<0.01	0.031	

GLP and Trial Details	Crop	Country	Application Details									Residues found			
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)	**Remarks (e)**
CEMS-5031F CEMS-5031 GHE-P-12727 Y 2011	Mandarin Clementine	Spain (SZ) 41520 El Viso Del Arcor, Sevilla Outdoor (field)	GF-2626	1	48.4	1008	4.8	31-Oct-2011	BBCH.81	0	Peel	0.122	<0.01	0.131	
										1	Peel	0.064	<0.01	0.073	
										3	Peel	0.071	<0.01	0.080	
										7	Peel	0.059	<0.01	0.068	
										10	Peel	0.043	<0.01	0.052	
										42	Peel	0.034	<0.01	0.043	
										57	Peel	0.019	<0.01	0.028	
										0	Pulp	<0.01	<0.01	<0.019	
										1	Pulp	<0.01	<0.01	<0.019	
										3	Pulp	<0.01	<0.01	<0.019	
										7	Pulp	<0.01	<0.01	<0.019	
										10	Pulp	<0.01	<0.01	<0.019	
										42	Pulp	<0.01	<0.01	<0.019	
										57	Pulp	<0.01	<0.01	<0.019	
										0	Whole Fruit	0.082	<0.01	0.091	
										1	Whole Fruit	0.045	<0.01	0.054	
										3	Whole Fruit	0.047	<0.01	0.056	
										7	Whole Fruit	**0.042**	<0.01	**0.051**	
										10	Whole Fruit	0.032	<0.01	0.041	
										42	Whole Fruit	0.024	<0.01	0.033	
										57	Whole Fruit	0.013	<0.01	0.022	

GLP and Trial Details	Crop	Country	Application Details									Residues found			
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)**	**Remarks (e)**
CEMS-5031G CEMS-5031 GHE-P-12727 Y 2011	Mandarin Clementinas	Greece (SZ) 24009 Aris, Messinia Outdoor (field)	GF-2626	1	47.0	1956	2.4	05-Dec-2011	BBCH.85	0	Peel	0.027	<0.01	0.036	
										1	Peel	0.017	<0.01	0.026	
										3	Peel	0.018	<0.01	0.027	
										7	Peel	0.011	<0.01	0.020	
										10	Peel	<0.01	<0.01	<0.019	
										42	Peel	<0.01	<0.01	<0.019	
										56	Peel	<0.01	<0.01	<0.019	
										0	Pulp	<0.01	<0.01	<0.019	
										1	Pulp	<0.01	<0.01	<0.019	
										3	Pulp	<0.01	<0.01	<0.019	
										7	Pulp	<0.01	<0.01	<0.019	
										10	Pulp	<0.01	<0.01	<0.019	
										42	Pulp	<0.01	<0.01	<0.019	
										56	Pulp	<0.01	<0.01	<0.019	
										0	Whole Fruit	0.020	<0.01	0.029	
										1	Whole Fruit	0.011	<0.01	0.020	
										3	Whole Fruit	0.013	<0.01	0.022	
										7	Whole Fruit	**<u><0.01</u>**	<0.01	**<u><0.019</u>**	
										10	Whole Fruit	<0.01	<0.01	<0.019	
										42	Whole Fruit	<0.01	<0.01	<0.019	
										56	Whole Fruit	<0.01	<0.01	<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 (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)	**Remarks (e)**
CEMS-5031H CEMS-5031 GHE-P-12727 Y 2011	Mandarin Nova	Greece (SZ) 24200 Velike, Messinia Outdoor (field)	GF-2626	1	47.5	1980	2.4	05-Dec-2011	BBCH.85	0	Peel	0.061	<0.01	0.070	
										1	Peel	0.012	<0.01	0.021	
										3	Peel	<0.01	<0.01	<0.019	
										7	Peel	<0.01	<0.01	<0.019	
										10	Peel	<0.01	<0.01	<0.019	
										42	Peel	<0.01	<0.01	<0.019	
										56	Peel	<0.01	<0.01	<0.019	
										0	Pulp	<0.01	<0.01	<0.019	
										1	Pulp	<0.01	<0.01	<0.019	
										3	Pulp	<0.01	<0.01	<0.019	
										7	Pulp	<0.01	<0.01	<0.019	
										10	Pulp	<0.01	<0.01	<0.019	
										42	Pulp	<0.01	<0.01	<0.019	
										56	Pulp	<0.01	<0.01	<0.019	
										0	Whole Fruit	0.048	<0.01	0.057	
										1	Whole Fruit	<0.01	<0.01	<0.019	
										3	Whole Fruit	<0.01	<0.01	<0.019	
										7	Whole Fruit	**<u><0.01</u>**	<0.01	**<u><0.019</u>**	
										10	Whole Fruit	<0.01	<0.01	<0.019	
										42	Whole Fruit	<0.01	<0.01	<0.019	
										56	Whole Fruit	<0.01	<0.01	<0.019	

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

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

IIIA 8.3.1.2.2 Study 2

Report:	IIIA1 8.3.1/02; Rawle, N.W.; 2012a
GRF	Residues of sulfoxaflor in oranges and process fractions following a single application of GF-2626 – Southern Europe – 2011
Document No:	CEMS-5033 (Study ID); GHE-P-12728 (Dow AgroSciences Reference)
Guidelines:	Commission Regulations (EU) 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", "Commission Working Document 7035/VI/95 Rev. 5, Processing Studies, July 22, 1997", OECD Guideline for the Testing of Chemicals, Magnitude of the Residues in Processed Commodities, Testing Guideline 508, 3 October 2008, EPA Residue Chemistry Test Guidelines, OPPTS 860.1520, Processed Food/Feed, August, 1996.
GLP	Y

Acceptability	Deviations
Yes	None with impact on the study

Table IIIA 8.3.1-5: Summary of global information on study 2

Comparative trials (between formulations, with and adjuvant/safener/synergist)	No
Number of applications	1
Dose (g as/ha)	48 g as/ha
Mode of application	Foliar Broadcast application
PHI (days) and/or growth stage (BBCH)	7 days
Analytical method (Code +Type)	091031 Liquid Chromatography/ Mass Spectrometry
LoQ (mg/kg)	0.01 mg/kg

Table IIIA 8.3.1-6: Summary of the study 2 trials

N° Trial		CEMS-5033A	CEMS-5033B	CEMS-5033C
North/South/Indoor		S		
Decline (D)/Harvest (H) trial?		H		
Formulation		SC		
Equivalence between formulations		Y		
Accordance with intended GAP		Y		
Correct sampling		Y	Y	Y
Samples frozen within 24h		Y	Y	Y
Storage period (in days)	Sample	273	273	261
	Extract	47[1]	47[1]	47[1]
Storage T° <-18°C		Y	Y	Y
Validated analytical method		Y	Y	Y
Negative controls		Y	Y	Y
Considered trial		Y	Y	Y
Remarks				

[1] The procedural recoveries demonstrate the stability of the analyte during the storage (up to 47 days)." (GHE-P-12728, p.20)

Table IIIA 8.3.1-7: Summary of data from residue trials for study 2

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, Abington

Active ingredient : Sulfoxaflor
Crop / crop group : Citrus Fruit (Oranges)

Content of a.i. (g/kg or g/l) : 120 g/L
Formulation (e.g. WP) : SC
Commercial product (name) : GF – 2626
Applicant :

Indoors / outdoors : Outdoor
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 (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-5033A CEMS-5033 GHE-P-12728 Y 2011	Oranges New Hall	Spain (SZ) 41410 Carmona, Sevilla Outdoor (field)	GF-2626	1	47.2	983	4.8	02-Nov-2011	BBCH.83	7 7 7 7 7 7 7 7 7 7	Juice Oil Peel Peel (Processing) Pomace, dry Pomace, wet Pulp Raw juice Whole Fruit Whole fruit (processing)	<0.01 0.0125 0.011 0.0575 <0.01 <0.01 <0.01 <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	<0.019 0.022 0.020 0.067 <0.019 <0.019 <0.019 <0.019 **<u><0.019</u>** <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-5033B CEMS-5033 GHE-P-12728 Y 2011	Oranges Navelino	Spain (SZ) 41980 La Algaba, Sevilla Outdoor (field)	GF-2626	1	50.9	1273	4.0	02-Nov-2011	BBCH.81	7 7 7 7 7 7 7 7 7 7	Juice Oil Peel Peel (Processing) Pomace, dry Pomace, wet Pulp Raw juice Whole Fruit Whole fruit (processing)	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <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	<0.019 <0.019 <0.019 <0.019 <0.019 <0.019 <0.019 <0.019 **<u><0.019</u>** <0.019	
CEMS-5033C CEMS-5033 GHE-P-12728 Y 2011	Oranges Navelina	Spain (SZ) 46260 Alberic, Valencia Outdoor (field)	GF-2626	1	45.9	1434	3.2	14-Nov-2011	BBCH.83 to 85	7 7 7 7 7 7 7 7 7 7	Juice Oil Peel Peel (Processing) Pomace, dry Pomace, wet Pulp Raw juice Whole Fruit Whole fruit (processing)	<0.01 <0.01 <0.01 0.025 <0.01 <0.01 <0.01 <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	<0.019 <0.019 <0.019 0.034 <0.019 <0.019 <0.019 <0.019 **<u><0.019</u>** <0.019	

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

Remarks:

(a) According to CODEX Classification / Guide

(b) Only if relevant

(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

(c) Year must be indicated

IIIA 8.3.1.2.3 Study 3

Report:	IIIA 8.3.1/03; Rawle, N.W.; 2014
Title:	Residues of Sulfoxaflor in oranges and mandarins at intervals and harvest following a single application of GF-2032 – Southern Europe - 2013
Document No:	CEMS-5948 (Study ID); 130192 (Dow AgroSciences Reference)
Guidelines:	Commission Regulations (EU) No. 283/2013 and 284/2013, 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

Table IIIA 8.3.1-8: Summary of global information on study 3

Comparative trials (between formulations, with and adjuvant/safener/synergist)	No
Number of applications	1
Dose (g as/ha)	96 g as/ha
Mode of application	Foliar Broadcast application
PHI (days) and/or growth stage (BBCH)	7, 42, 90, 120 ,150
Analytical method (Code +Type)	091031 Liquid Chromatography/ Mass Spectrometry
LoQ (mg/kg)	0.01 mg/kg

Table IIIA 8.3.1-9: Summary of the study 3 trials

N° Trial		CEMS- 5948A					CEMS- 5948B					CEMS- 5948C					CEMS- 5948D				
N° Treatment		2	3	4	5	6	2	3	4	5	6	2	3	4	5	6	2	3	4	5	6
North/South/Indoor		S					S					S					S				
Decline (D)/Harvest (H) trial?		REVERSE DECLINE					REVERSE DECLINE					REVERSE DECLINE					REVERSE DECLINE				
Formulation		SC					SC					SC					SC				
Equivalence between formulations		Y					Y					Y					Y				
Accordance with intended GAP		W[1]	N[2]	N[2]	N[2]	N[2]	W[1]	N[2]	N[2]	N[2]	N[2]	W[1]	N[2]	N[2]	N[2]	N[2]	W[1]	N[2]	N[2]	N[2]	N[2]
Correct sampling		Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Samples frozen within 24h		Y					Y					Y					Y				
Storage period (in days)	Sample	69	69	69	69	69	48	48	48	48	48	62	62	62	62	62	63	63	63	63	63
	Extract[3]	2					2					2					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	N	N	N	N	Y	N	N	N	N	Y	N	N	N	N	Y	N	N	N	N
Remarks		1,2					2					2					2				

[1]W for Worse (96 g a.i./L instead of 48 g a.i./L with the same PHI)
[2] PHI of 42, 90, 120 and 150 days instead of 7 days
[3] The procedural recoveries demonstrate the stability of the analyte during the storage (up to 2 days).” (CEMR-5948, p.18)

Table IIIA 8.3.1-10: Summary of data from residue trials for study 3

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)
Notifier: Dow AgroSciences Ltd.
Content of a.i. (g/kg or g/l) : 240 g/L
Formulation (e.g. WP) : SC
Commercial product (name) : GF-2032
Applicant :

Active ingredient : Sulfoxaflor
Crop / crop group : Citrus fruit : -Orange, CIDSI
Indoors / outdoors : Outdoor
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 (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-5948A CEMS-5948 CEMR-5948 Y 2013	Oranges Navel Fukumoto	Spain (SZ) 46389 Turís, Valencia Outdoor (field)	GF-2032	1	95.1	1485	6.4	24-Oct-13	BBCH 81-83	7	Whole fruit	**0.102**	<0.01	**0.111**	
					94.0	1469	6.4	19-Sep-13	BBCH 74-79	42	Whole fruit	0.054	<0.01	0.063	
					94.0	1467	6.4	02-Aug-13	BBCH 74	90	Whole fruit	0.051	<0.01	0.060	
					97.4	1521	6.4	04-Jul-13	BBCH 73-74	119	Whole fruit	0.014	<0.01	0.023	
					97.2	1519	6.4	03-Jun-13	BBCH 73-74	150	Whole fruit	<0.01	<0.01	<0.019	
CEMS-5948B CEMS-5948 CEMR-5948 Y 2013	Oranges Navelina	Spain (SZ) 46661 L'Enova, Valencia Outdoor (field)	GF-2032	1	94.2	1962	4.8	14-Nov-13	BBCH 83-85	7	Whole fruit	0.021	<0.01	0.030	
					99.2	2066	4.8	11-Oct-13	BBCH 81	41	Whole fruit	**0.023**	<0.01	**0.032**	
					96.4	2007	4.8	23-Aug-13	BBCH 75-76	90	Whole fruit	0.020	<0.01	0.029	
					95.0	1980	4.8	24-Jul-13	BBCH 74-75	120	Whole fruit	<0.01	<0.01	<0.019	
					94.6	1973	4.8	24-Jun-13	BBCH 74	150	Whole fruit	<0.01	<0.01	<0.019	
CEMS-5948C CEMS-5948	Mandarin Clemenule	Spain (SZ) 46163	GF-2032	1	96.8	2015	4.8	31-Oct-13	BBCH 81	7	Whole fruit	**0.071**	<0.01	**0.080**	
					93.5	1955	4.8	26-Sep-13	BBCH 76	42	Whole fruit	0.031	<0.01	0.040	

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)	
CEMR-5948 Y 2013	s	Marines, Valencia Outdoor (field)			96.8	2020	4.8	09-Aug-13	BBCH 73	90	Whole fruit	<0.01	<0.01	<0.019	
					93.5	1950	4.8	10-Jul-13	BBCH 73	120	Whole fruit	<0.01	<0.01	<0.019	
					96.8	2015	4.8	10-Jun-13	BBCH 73	150	Whole fruit	<0.01	<0.01	<0.019	
CEMS-5948D CEMS-5948 CEMR-5948 Y 2013	Mandarin Clemenules	Spain (SZ) 12001 Castellón de la Plana, Castellón Outdoor (field)	GF-2032	1	95.9	1999	4.8	30-Oct-13	BBCH 81	7	Whole fruit	**0.126**	<0.01	**0.135**	
					96.5	2014	4.8	26-Sep-13	BBCH 76	41	Whole fruit	0.046	<0.01	0.055	
					94.8	1979	4.8	08-Aug-13	BBCH 73-74	90	Whole fruit	0.019	<0.01	0.028	
					92.9	1937	4.8	08-Jul-13	BBCH 73	121	Whole fruit	<0.01	<0.01	<0.019	
					96.5	2011	4.8	10-Jun-13	BBCH 73	149	Whole fruit	<0.01	<0.01	<0.019	

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

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

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

Table IIIA 8.3.1-11: Summary of monograph and new data supporting the intended use on citrus 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
Citrus Fruits	Monograph MRL Application	No EU trials available								
	New trials Orange	South (9)	Trials GAP: 1 x 48 g s/ha, PHI 7 Mo: 4 x <0.01, 0.011, 0.014, 0.018 Ra: 4 x <0.019, 0.02, 0.023, 0.027							
			Trials GAP: 1 x 96 g s/ha, PHI 7 Mo: 0.023, 0.102 Ra: 0.032, 0.111							
			Scale residue data* Mo: 0.012, 0.051 Ra: 0.021, 0.06							
	New trials Mandarins	South (6)	Trials GAP: 1 x 48 g s/ha, PHI 7 Mo: 2 x <0.01, 0.035, 0.042 Ra: 2 x <0.019, 0.044, 0.051							
			Trials GAP: 1 x 96 g s/ha, PHI 7 Mo: 0.071, 0.126 Ra: 0.080, 0.135							
			Scale residue data Mo: 0.036, 0.063 Ra: 0.045, 0.072							
	Overall supporting	South (15)	Mo: 6 x <0.01, 0.011, 0.012, 0.014, 0.018, 0.035, 0.036, 0.042, 0.051, 0.063	0.012	0.063	0.072	0.069	0.092→ 0.1	Reg EU 2016/1:	

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
	data for SEU GAP		Ra: 6 x <0.019, 0.02, 0.021, 0.023, 0.027, 0.044, 0.045, 0.051, 0.06, 0.072	0.021	0.072				Citrus : 0.01* SANTE/11442/2016 Grape fruits: 0.15 Oranges, mandarins : 0.8 Lemons : 0.4 Lime : 0.01*	Grape fruits, Oranges, mandarins, Lemons : Yes Lime : No

(1) Source of EU MRL: EU MRL data base: http://ec.europa.eu/sanco_pesticides/public/index.cfm
* residue data have been scaled according to the recommendations and the conclusions described in the OECD draft guidance document on crop field trials (Series on pesticides No. 66 and series on testing assessment No. 164 ENV/JM/MONO(2011)50/REV1 sept 2016). Scale residue data: (intended dose rate x residue at harvest in residue trial)/ application dose rate in the residue trial

IIIA 8.3.1.4 Conclusion for citrus fruit

According to the EU guidelines 8 trials performed on oranges and 8 trials performed on mandarins or/and lemon are required to extrapolate to the whole group of citrus fruits.
A total of 9 southern residues trials on orange and 6 southern trials on mandarin are available to support the intended use on citrus in EU.
Therefore 2 further SEU trials on mandarin should be required to support the intended uses of GF 2626 on citrus.
On the basis of the available supporting residue data it is possible to conclude that the MRLs proposed in document SANTE/11442/2016 of 0.15 mg/kg on grape fruits, of 0.8 mg/kg on orange and mandarin and of 0.4 mg/kg on lemons will not be exceeded according to the intended GAP in SEU

Nevertheless a minimum of 2 trials performed on mandarin and/or lemon according to the intended GAP are required in post authorization to complete the data set.

On the basis of the available supporting residue data it is possible to conclude that the MRL proposed in document SANTE/11442/2016 of of 0.01* mg/kg on limes will be exceed according to the intended GAP in EU. Consequently the intended use on lime is not acceptable.

IIIA 8.3.2 POME FRUITS (APPLE AND PEAR)

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

Crop	Type of GAP	Number of applications	Application rate per treatment	Interval between application	Growth stage at last application	PHI (days)
Apple and pear	DAR MRL Application (AUS)[1]	1-2	192 g a.s./ha	14	Up to BBCH 85-87	7
	Intended FR and SEU	1	48 g/ha	-	BBCH 51-59 (pre-flowering) BBCH 69-85	7
		2	24 g/ha	7		7

[1] MRL Application – import tolerance, MRL estimated from trials according to Australian cGAPs.

IIIA 8.3.2.1 Summary of EU Data

Use on apple and pear has been assessed in the meantime of the EU evaluation of sulfoxaflor, in the framework of MRL application for an import tolerance.
However this MRL application is based on Australian and New Zealand GAP and residue trials supporting the import tolerance have been performed outside EU (NZ and Aus).
Based on the supporting residue data an MRL of 0.4 mg/kg was proposed on apple and pear by EFSA and then adopted at EU level in Regulation 2016/1.
Later the existing CXL of 0.3 mg/kg on quince, medlar and loquat was voted at EU level and proposed in document SANTE/11442/2016.

Nevertheless, in evaluation report EU trials are also summarized. These trials were also submitted by the applicant to support the intended use of GF-2626. They were performed according to a more critical GAP than intended one (2 applications at ca 200 g as/ha). As these EU trials involved residue levels in fruits which are in accordance with the in force MRL, they can be used to support the intended uses of GF-2626.
These trials are summarized in tables below.

Residue levels of sulfoxaflor and metabolite X11719474 in fruits from trials considered suitable to support the intended GAP are underlined.

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-3968C CEMS-3968 080045-02 Y 2008	Apple Golden	Spain SZ Outdoor (field)	GF-2032	2	210 210	1041 1041	20.2 20.2	19-Aug-08 26-Aug-08	BBCH 78 BBCH 79	3 7 14 28	Whole fruit Whole fruit Whole fruit Whole fruit	0.270 0.266 0.196 0.178	<0.01 <0.01 <0.01 <0.01	0.279 0.275 0.205 0.187
CEMS-3968D CEMS-3968 080045-02 Y 2008	Apple Mutsu	Greece SZ Outdoor (field)	GF-2032	2	200 200	1000 1000	20.0 20.0	16-Jul-08 23-Jul-08	BBCH 81 BBCH 85	7	Whole fruit	0.074	<0.01	0.083
CEMS-3971D CEMS-3971 080046-02 Y 2008	Pear Williams	Greece SZ Outdoor (field)	GF-2032	2	200 200	1000 1000	20.0 20.0	23-Jul-08 30-Jul-08	BBCH 81 BBCH 85	7	Whole fruit	0.184	<0.01	0.193
CEMS-3971E CEMS-3971 080046-02 Y 2008	Pear Flor de invierno	Spain SZ Outdoor (field)	GF-2032	2	212 214	1578 1594	13.4 13.4	15-Sep-08 23-Sep-08	BBCH 85 BBCH 87	3 7 14 28	Whole fruit Whole fruit Whole fruit Whole fruit	0.074 0.097 0.099 0.097	<0.01 <0.01 <0.01 <0.01	0.083 0.106 0.108 0.106
CEMS-4714B CEMS-4714 101474 Y 2010	Pear Abate	Italy SZ Outdoor (field)	GF-2032	2	203 208	970 994	20.9 20.9	31-Aug-10 07-Sep-10	BBCH 87-88 BBCH 87-89	7	Whole fruit	0.176	<0.01	0.185

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-3968A CEMS-3968 080045-02 Y 2008	Apple Jonagold	Germany NZ Outdoor (field)	GF- 2032	2	201 204	1007 1020	20.0 20.0	11-Sep-08 17-Sep-08	BBCH 83 BBCH 85	3 7 14 27	Whole fruit Whole fruit Whole fruit Whole fruit	0.240 0.185 0.177 0.101	<0.01 <0.01 <0.01 <0.01	0.249 0.193 0.186 0.110
CEMS-3968B CEMS-3968 080045-02 Y 2008	Apple Idared	Poland NZ Outdoor (field)	GF- 2032	2	208 195	1041 977	20.0 20.0	16-Sep-08 23-Sep-08	BBCH 85 BBCH 87	7	Whole fruit	0.079	<0.01	0.105
CEMS-3971A CEMS-3971 080046-02 Y 2008	Pear Williams Christ	Germany NZ Outdoor (field)	GF- 2032	2	181 203	903 1013	20.0 20.0	01-Aug-08 08-Aug-08	BBCH 81 BBCH 85	3 7 14 28	Whole fruit Whole fruit Whole fruit Whole fruit	0.102 0.058 0.055 0.025	<0.01 <0.01 <0.01 <0.01	0.111 0.067 0.064 0.034
CEMS-3971B CEMS-3971 080046-02 Y 2008	Pear Pap korte	Hungary NZ Outdoor (field)	GF- 2032	2	201 209	1004 1043	20.0 20.0	26-Sep-08 03-Oct-08	BBCH 85 BBCH 89	7	Whole fruit	0.052	<0.01	0.061
CEMS-4714A CEMS-4714 101474 Y 2010	Pear Condo	Germany NZ Outdoor (field)	GF- 2032	2	181 206	902 1031	20.1 20.0	06-Sep-10 13-Sep-10	BBCH 81 BBCH 85	0 3 7 14 21	Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit	0.381 0.128 0.105 0.104 0.084	<0.01 <0.01 <0.01 <0.01 <0.01	0.390 0.137 0.114 0.113 0.093

IIIA 8.3.2.2 New data

IIIA 8.3.2.2.1 Study 1

Report:	IIIA 8.3.2/01, Rawle, N. W., 2012
Title:	Residues of sulfoxaflor in apples and pears at intervals and harvest following a single application of GF-2626 – Northern and Southern Europe – 2011
Document No:	Study ID : CEMS-5027, Report ID : CEMR-5027 Dow AgroSciences Reference : GHE-P-12723
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	None with impact on the study

Table IIIA 8.3.2-2: 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)	24 or 48 g a.s./ha
Mode of application	Foliar broadcast
PHI (days) and/or growth stage (BBCH)	0,7,14,21,28 & 42 days
Analytical method (Code +Type)	Method N° 091031 LC-MS/MS
LoQ (mg/kg)	0.01 mg/kg

Table IIIA 8.3.2-3: Summary of the study 1 trials

N° Trial		CEMS-5027A		CEMS-5027B		CEMS-5027C		CEMS-5027D		CEMS-5027E		CEMS-5027F		CEMS-5027G		CEMS-5027H	
N° Treatment		2	3	2	3	2	3	3	2	3	2	2	3	2	3	2	3
North/South/Indoor		S		S		S		S		N		N		N		N	
Decline (D)/Harvest (H) trial?		D		D		H		H		D		D		H		H	
Formulation		SC		SC		SC		SC		SC		SC		SC		SC	
Equivalence between formulations		Y		Y		Y		Y		Y		Y		Y		Y	
Accordance with intended GAP		N[1]	Y	N[1]	Y	N[1]		N[2]	N[1]	N[2]	N[1]	N[1]	Y	N[1]	N[2]	N[1]	N[2]
Correct sampling		Y	Y	Y	Y	Y		Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Samples frozen within 24h		Y		Y		Y		Y		Y		Y		Y		Y	
Storage period (in days)	Sample	152	152	194	194		171	171	159	159	160	206	206	143	143	132	132
	Extract[3]	Max 2		Max 2		Max 2		Max 2		Max 2		Max 2		Max 2		Max 2	
Storage T° <-18°C		Y		Y		Y		Y		Y		N[4]		Y		Y	
Validated analytical method		Y		Y		Y		Y		Y		Y		Y		Y	
Negative controls		Y		Y		Y		Y		Y		Y		Y		Y	
Considered trial		N	Y	N	Y	N		N	N	N	N	N	Y	N	N	N	N
Remarks																	

(1) Trials carried out at a less critical GAP than intended one: Single application at 24 g a.s./ha instead of 48 g a.s./ha
(2) Trials carried out at a less critical GAP than intended one: PHI of 28 days instead of 7 days
(3) The procedural recoveries demonstrate the stability of the analyte during this storage (up to 2 days)." (GHE-P-12723, p.20)

Table IIIA 8.3.2-4: 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

Content of a.i. (g/kg or g/l) : 120 g/L
Formulation (e.g. WP) : SC
Commercial product (name) : GF-2626
Applicant : Eurofins AgroScience Services GmbH

Active ingredient : Sulfoxaflor
Crop / crop group : Pome Fruits : -Apples Pears
Indoors / outdoors : Outdoor
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 (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-5027A CEMS-5027 GHE-P-12723 Y 2011	Apple Firiki	Greece (SZ) 58100 Drosero, Pella Outdoor (field)	GF-2626	1	48.8	1322	3.7	24-Aug-11	BBCH.81	0 7 14 21 28 42	Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit	0.036 <0.01 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.045 <0.019 <0.019 <0.019 <0.019 <0.019	
				1	24.3	1314	1.8			0 7 14 21 28 42	Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit	0.040 **0.011** <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.049 **0.02** <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-5027B CEMS-5027 GHE-P-12723 Y 2011	Pear Confer-ence	Italy (SZ) 41034 Finale Emilia, Emilia Romagna Outdoor (field)	GF-2626	1	52.5	1094	4.8	13-Jul-11	BBCH 77-79	0 7 14 21 29 42	Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit	0.084 **<u>0.012</u>** 0.010 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.093 **<u>0.021</u>** <0.019 <0.019 <0.019 <0.019	
				1	26	1083	2.4			0 7 14 21 29 42	Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit	0.044 <0.01 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.053 <0.019 <0.019 <0.019 <0.019 <0.019	
CEMS-5027C	Apples/ Gala	France (SZ) 82100 Castelsarrasin Tarn et Garonne Outdoor (field)	GF-2626	1	24.2	1014	2.4	8- Jul-11	BBCH 79	28	Whole fruit	<0.01	<0.01	<0.019	
				1	46.1	966	4.8			28	Whole fruit	<0.01	<0.01	<0.019	
CEMS-5027D	Pears Blanquilla	Spain (SZ) 50280 Colatorao, Aragonien Outdoor (field)	GF-2626	1	22.3	1117	2.0	21-Jul-11	BBCH 85	27	Whole fruit	0.013	<0.01	0.022	
				1	44.6	1114	4.0			27	Whole fruit	0.017	<0.01	0.026	

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-5027E CEMS-5027 GHE-P-12723Y 2011	Apple Idared	Germany (NZ) 15345, Atlandsberg, Brandenburg Outdoor (field)	GF-2626	1	48	1250	3.8	16-Aug-11	BBCH.79-81	0	Whole fruit	0.013	<0.01	0.022	
										7	Whole fruit	**<u><0.01</u>**	<0.01	**<u><0.019</u>**	
										14	Whole fruit	<0.01	<0.01	<0.019	
										21	Whole fruit	<0.01	<0.01	<0.019	
										28	Whole fruit	<0.01	<0.01	<0.019	
										41	Whole fruit	<0.01	<0.01	<0.019	
				1	24.2	1260	1.9			0	Whole fruit	<0.01	<0.01	<0.019	
										7	Whole fruit	<0.01	<0.01	<0.019	
										14	Whole fruit	<0.01	<0.01	<0.019	
										21	Whole fruit	<0.01	<0.01	<0.019	
										28	Whole fruit	<0.01	<0.01	<0.019	
										41	Whole fruit	<0.01	<0.01	<0.019	
CEMS-5027F CEMS-5027 GHE-P-12723Y 2011	Pear Williams	N France (NZ) 37190, Vallers, Indre et Loire Outdoor (field)	GF-2626	1	48.2	602	8.0	01-Jul-11	BBCH 75	0	Whole fruit	0.065	<0.01	0.074	
										7	Whole fruit	**<u><0.01</u>**	<0.01	**<u><0.019</u>**	
										14	Whole fruit	<0.01	<0.01	<0.019	
										21	Whole fruit	<0.01	<0.01	<0.019	
										28	Whole fruit	<0.01	<0.01	<0.019	
										42	Whole fruit	<0.01	<0.01	<0.019	
				1	24.4	611	4			0	Whole fruit	0.034	<0.01	0.043	
										7	Whole fruit	<0.01	<0.01	<0.019	
										14	Whole fruit	<0.01	<0.01	<0.019	
										21	Whole fruit	<0.01	<0.01	<0.019	
										28	Whole fruit	<0.01	<0.01	<0.019	
										42	Whole fruit	<0.01	<0.01	<0.019	

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

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

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

Table IIIA 8.3.2-5: Summary of monograph and new data supporting the intended use on pome fruits 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
Pome Fruits	Monograph									
	MRL Application	North (2 apple, 3 pear)	Trials GAP : 2 x 200 g a.s./ha, PHI 7d Mo: 0.052, 0.058, 0.079, 0.105, 0.185 Ra: 0.061 0.067, 0.105, 0.114, 0.193						Reg EU 2016/1: Apple and pear :0.4 Quince, medlar, loquat: 0.01* Doc SANTE/11442/2016: Apple and pear :0.4 Quince, medlar, loquat: 0.3	Yes according to HR and considering that most of trials have been performed at a more critical GAP
		South (2 apple, 3 pear)	Trials GAP : 2 x 200 g a.s./ha, PHI 7d Mo: 0.074 ; 0.099; 0.176, 0.184, 0.266 Ra: 0.083, 0.108, 0.185, 0.193, 0.275,							
	New trials	North (1 apple/1 pear)	Trials GAP: 1 x 48 g a.s./ha, PHI 7d Mo: 2 x <0.01 Ra: 2 x <0.019							
		South (1 apple/1 pear)	Trials GAP: 1x48 g a.s./ha, PHI 7d Mo: 0.011, 0.012 Ra: 0.02, 0.021							
	Overall supporting data for FR	North (5)	Trials GAP : 2 x 200 g a.s./ha, PHI 7d Mo: 0.052, 0.058, 0.079, 0.105, 0.185	0.079	0.185	0.290	0.323	0.312 →0.4		
			Ra: 0.061 0.067, 0.105, 0.114, 0.193	0.105	0.193					

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
	GAP	North (2)	Trials GAP: 1 x 48 g a.s./ha, PHI 7d Mo: 2 x <0.01	0.01	0.01	NA	NA	NA		
			Ra: 2 x <0.019	0.019	0.019					
		South (5)	Trials GAP : 2 x 200 g a.s./ha, PHI 7d Mo: 0.074 ; 0.099; 0.176, 0.184, 0.266	0.176	0.266	0.450	0.482	0.478 → 0.5		
			Ra: 0.083, 0.108, 0.185, 0.193, 0.275	0.185	0.275					
		South (2)	Trials GAP: 1x48 g a.s./ha, PHI 7d Mo: 0.011, 0.012	0.011	0.012	NA	NA	NA		
			Ra: 0.02, 0.021	0.02	0.021					
	Overall supporting data for SEU GAP	South (5)	Trials GAP : 2 x 200 g a.s./ha, PHI 7d Mo: 0.074 ; 0.099; 0.176, 0.184, 0.266	0.176	0.266	0.450	0.482	0.478 → 0.5		
			Ra: 0.083, 0.108, 0.185, 0.193, 0.275	0.185	0.275					
		South (2)	Trials GAP: 1x48 g a.s./ha, PHI 7d Mo: 0.011, 0.012	0.011	0.012	NA	NA	NA		
			Ra: 0.02, 0.021	0.02	0.021					

(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 apple and pear

According to the EU guidelines 8 trials performed on apples and/or pears with a minimum of 4 apples trials is required to extrapolate to the whole group of pome fruits.
A total of 7 SEU and the 7 NEU residues trials performed on apples (3 N + 3S) and on pears (4N + 4 S) are available to support the intended uses on apple and pears.
Therefore 1 NEU trial and 1 SEU trial performed on apple should be submitted in post authorization to complete the data set.

On the basis of the available supporting residue data and considering that most of the residue trials have been carried out at a more critical GAP than intended one it is possible to conclude that MRL of 0.4 mg/kg on apple and pear (Regulation 2016/1, SANTE/11442/2016) will not be exceed according to the intended GAP in EU.

On the basis of the available supporting residue data and considering that most of the residue trials have been carried out at a more critical GAP than intended one it is possible to conclude that the MRL proposed in document SANTE/11442/2016 of 0.3 mg/kg on quince and medlar will not be exceed according to the intended GAP in EU.

Nevertheless 1 NEU trial and 1 SEU trial performed according to the intended GAP are required in post authorization to complete the data set.

IIIA 8.3.3 PEACH

Table IIIA 8.3.3-1: Comparison of intended and critical EU GAPs

Crop	Type of GAP	Number of applications	Application rate per treatment	Interval between application	Growth stage at last application	PHI (days)
Peach	DAR MRL Application (AUS)[1]	1-2	144 g a.s./ha	14	Up to BBCH 85-87	7
	Intended FR et SEU	1	48 g/ha	-	BBCH 51-59 (pre-flowering) BBCH 69-85	7
		2	24 g/ha	7		7

[1] MRL Application – import tolerance, MRL proposed according to Australian cGAPs.

IIIA 8.3.3.1 Summary of EU Data

Uses on peach and apricots have been assessed in the meantime of the EU evaluation of sulfoxaflor, in the framework of MRL application for an import tolerance.
However this MRL application is based on Australian and New Zealand GAP and residue trials supporting the MRL application have been performed outside EU (NZ and Aus).
Based on the supporting residue data an MRL of 0.5 mg/kg was proposed by EFSA and then adopted at EU level in Regulation 2016/1.

Nevertheless, in evaluation report (IE, 2012) EU trials are also summarized. These trials were also submitted by the applicant to support the intended use of GF-2626. They were performed according to a more critical GAP than intended one (2 applications at ca 200 g as/ha). The highest residue level measured in these trials is below the in force MRL they can be used as indicative data to support the intended uses of GF-2626.
These trials are summarized in tables below.

Residue levels of sulfoxaflor and metabolite X11719474 in fruits from trials considered suitable to support the intended GAP are underlined.

Summary of MRL application data (IE 2012)

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-4069C CEMS-4069 # 080047-02 Y 2008	Peach Corindon	S France SZ Outdoor (field)	GF-2032	2	206 200	1031 1002	20.0 20.0	04-Aug-08 11-Aug-08	BBCH 81 BBCH 85	7 7	Whole fruit Flesh	**0.483** 0.541	<0.01 <0.01	**0.492** 0.550
CEMS-4069D CEMS-4069 # 080047-02 Y 2008	Peach Federica	Spain SZ Outdoor (field)	GF-2032	2	203 201	2031 2013	10.0 10.0	16-Jun-08 23-Jun-08	BBCH 77 BBCH 81	3 7 14 21 3 7 14 21	Whole fruit Whole fruit Whole fruit Whole fruit Flesh Flesh Flesh Flesh	0.455 **0.248** 0.231 0.109 0.491 0.266 0.246 0.118	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.464 **0.257** 0.240 0.118 0.500 0.275 0.255 0.127
CEMS-4069E CEMS-4069 # 080047-02 Y 2008	Peach Sweet Red	Italy SZ Outdoor (field)	GF-2032	2	186 209	1395 1566	13.3 13.3	28-Jul-08 04-Aug-08	BBCH 83-85 BBCH 85	7 7	Whole fruit Flesh	**0.188** 0.204	<0.01 <0.01	**0.197** 0.213
CEMS-4069G CEMS-4069 # 080047-02 Y 2008	Peach Andross	Greece SZ Outdoor (field)	GF-2032	2	217 202	1627 1512	13.3 13.4	28-Jul-09 04-Aug-09	BBCH 76 BBCH 85	7 7	Whole fruit Flesh	**0.072** 0.083	<0.01 <0.01	**0.081** 0.092

IIIA 8.3.3.2 New data

IIIA 8.3.3.2.1 Study 1

Report:	IIIA 8.3.3.2/01, Rawle, N. W., 2012
Title:	Residues of XDE-208 in peaches at intervals and harvest following a single application of GF-2032 – Northern and Southern Europe - 2008
Document No:	Study ID : CEMS-4068, Report ID : CEMR-4068 Dow AgroSciences Reference : ID 080047-01
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	None with impact on the study

Table IIIA 8.3.3-2: Summary of global information on study 1

Comparative trials (between formulations, with and adjuvant/safener/synergist)	No, SC formulation containing 240 g/L Sulfoxaflor
Number of applications	1
Dose (g as/ha)	24 g a.s./ha
Mode of application	Foliar broadcast
PHI (days) and/or growth stage (BBCH)	0, 3, 7, 14, 21 & 28 days
Analytical method (Code +Type)	Method N° 091031 LC-MS/MS
LoQ (mg/kg)	0.01mg/kg

Table IIIA 8.3.3-3: Summary of the study 1 trials

N° Trial		CEMS-4068C	CEMS-4068D	CEMS-4068E	CEMS-4068F
North/South/Indoor		S	S	S	S
Decline (D)/Harvest (H) trial?		H	D	H	D
Formulation		SC	SC	SC	SC
Equivalence between formulations		Y	Y	Y	Y
Accordance with intended GAP		N[1]	N[1]	N[1]	N[1]
Correct sampling		Y	Y	Y	Y
Samples frozen within 24h		Y	Y	Y	Y
Storage period (in days)	Sample	246	267	253	256
	Extract[2]	3	3	3	3
Storage T° <-18°C		Y	Y	Y	Y
Validated analytical method		Y	Y	Y	Y
Negative controls		Y	Y	Y	Y
Considered trial[3]		Y	Y	Y	Y
Remarks		1, 2, 3	1, 2, 3	1, 2, 3	1, 2, 3

[1] Only one application at 24 g/ha instead of 48 g/ha

[2] The procedural recoveries demonstrate the stability of the analyte during this storage (up to 3 days).” (CEMR-4068, p.20)

[3] Results of corresponding trials can be considered applying the proportionality. Indeed according to OECD draft guidance document on crop field trials (Series on pesticides No. 66 and series on testing assessment No. 164 ENV/JM/MONO(2011)50/REV1 sept 2016) proportionality can be applied to results of residue trials when the application rate is the only factor to vary from 0.3 to 4 times the intended GAP.

Table IIIA 8.3.3-4: 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

Active ingredient : Sulfoxaflor
Crop / crop group : Stone Fruits : Peach

Content of a.i. (g/kg or g/l) : 240 g/L
Formulation (e.g. WP) : SC
Commercial product (name) : GF-2032
Applicant : Eurofins AgroScience Services GmbH

Indoors / outdoors : Outdoor
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 (e)
Trial ID Study ID Report No. GLP(Y/N) Trial Year	**Crop Variety (a)**	**Country (Zone) Location**	**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-4068C CEMS-4068 # 080047-01 Y 2008	Peach Corindon	S France (SZ) 66130, Corbère, Languedoc-Roussillon Outdoor (field)	GF-2032	1	23.5	981	2.4	04-Aug-08	BBCH 83	7 21 7 21	Whole fruit Whole fruit Flesh Flesh	0.013 **0.386** 0.014 0.447	<0.01 0.013 <0.01 0.015	0.022 **0.398** 0.023 0.461	

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**	**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-4068D CEMS-4068 # 080047-01 Y 2008	Peach Royal Gladys	Spain (SZ) 46837 Quatretonda, Valencia Outdoor (field)	GF-2032	1	23.6	983	2.4	21-Jul-08	BBCH 81	0 3 7 14 21 28 0 3 7 14 21 28	Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit Flesh Flesh Flesh Flesh Flesh Flesh	0.038 0.030 **0.018** 0.011 0.010 <0.01 0.042 0.032 0.019 0.012 0.010 <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	0.047 0.039 **0.027** 0.020 0.019 <0.019 0.053 0.041 0.028 0.021 0.019 <0.019	
CEMS-4068E CEMS-4068 # 080047-01 Y 2008	Peach Stark Red Gold	Italy (SZ) 48010 Barbiano, Emilia Romagna Outdoor (field)	GF-2032	1	22.8	1435	1.6	28-Jul-08	BBCH 85-87	7 21 7 21	Whole fruit Whole fruit Flesh Flesh	0.012 **0.018** 0.013 0.019	<0.01 <0.01 <0.01 <0.01	0.021 **0.027** 0.022 0.028	

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**	**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-4068F CEMS-4068 # 080047-01 Y 2008	Peach Andross	Greece (SZ) 58100 Gypsochori, Pella Outdoor (field)	GF-2032	1	24.1	1505	1.6	01-Aug-08	BBCH 87	0 3 7 14 21 28 0 3 7 14 21 28	Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit Flesh Flesh Flesh Flesh Flesh Flesh	0.037 0.025 **<u>0.020</u>** 0.020 <0.01 <0.01 0.039 0.026 0.021 0.021 <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	0.046 0.034 **<u>0.029</u>** 0.029 <0.019 <0.019 0.048 0.035 0.030 0.030 <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

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

IIIA 8.3.3.2.2 Study 2

Report:	IIIA 8.3.3.2/02, Rawle, N. W., 2012
Title:	Residues of sulfaxoflor in peaches at intervals and harvest following a single application of GF-2626 – Northern and Southern Europe - 2011
Document No:	Study ID : CEMS-5030, Report ID : CEMR-5030 ; Dow AgroSciences Reference : GHP-P-12726
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	None with impact on the study

Table IIIA 8.3.3-5: Summary of global information on study 2

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)	24 or 48 g a.s./ha
Mode of application	Foliar broadcast
PHI (days) and/or growth stage (BBCH)	0, 7, 14, 21 & 28 days
Analytical method (Code +Type)	Method N° 091031 LC-MS/MS
LoQ (mg/kg)	0.01mg/kg

Table IIIA 8.3.3-6: Summary of the study 2 trials

N° Trial		CEMS-5030C		CEMS-5030D		CEMS-5030E		CEMS-5030F	
N° Treatment		2	3	2	3	2	3	2	3
North/South/Indoor		S		S		S		S	
Decline (D)/Harvest (H) trial?		D		D		H		H	
Formulation		SC		SC		SC		SC	
Equivalence between formulations		Y		Y		Y		Y	
Accordance with intended GAP		N[1]	Y	N[1]	Y	N[1,2]	N[2]	N[1,2]	N[2]
Correct sampling		Y	Y	Y	Y	Y	Y	Y	Y
Samples frozen within 24h		Y		Y		Y		Y	
Storage period (in days)	Sample	230	230	239	239	175	175	195	195
	Extract	6	6	6	6	6	6	6	6
Storage T° <-18°C		Y		Y		Y		Y	
Validated analytical method		Y		Y		Y		Y	
Negative controls		Y		Y		Y		Y	
Considered trial		N	Y	N	Y	N	N	N	N
Remarks		1, 3		1, 3		1, 3		1, 3	

[1] Trial carried out at a less critical GAP than intended one: 1 application at 24 g/ha (instead of 48 g/ha)
[2] Trial carried out at a less critical GAP than intended one: PHI of 28 days instead of 7 days
[3] The procedural recoveries demonstrate the stability of the analyte up to 6 days. (CEMR-5030, p.20)

Only trials performed according to the intended GAP are summarised in the table below.

Table IIIA 8.3.3-7: Summary of data from residue trials for study 2

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 product (name) : GF-2626
Applicant : Eurofins AgroScience Services GmbH

Active ingredient : Sulfoxaflor
Crop / crop group : Stone Fruits : Peach
Submission date :
Page :
Indoors / outdoors : Outdoor
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 (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-5030C CEMS-5030 # GHE-P-12726 Y 2011	Peach Fortuna	Greece (SZ) 58500 Lakka, Pella Outdoor (field)	GF-2626	1	48.6	1316	3.7	14-Jul-11	BBCH 76	0 7 14 21 28 0 7 14 21 28	Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit Flesh Flesh Flesh Flesh Flesh	0.026 0.011 **0.014** <0.01 <0.01 0.031 0.013 0.016 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.035 0.020 **0.023** <0.019 <0.019 0.040 0.022 0.025 <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-5030D CEMS-5030 # GHE-P-12726 Y 2011	Peach Stark Red Gold	Italy (SZ) 48010 Cotignola, Emilia Romagna Outdoor (field)	GF-2626	1	48.1	1211	4.0	05-Jul-11	BBCH 79-81	0 7 14 21 28 0 7 14 21 28	Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit Flesh Flesh Flesh Flesh Flesh	0.023 **0.024** <0.01 <0.01 <0.01 0.027 0.029 <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	0.032 0.033 <0.019 <0.019 <0.019 0.036 **0.038** <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

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

IIIA 8.3.3.3 Summary of monograph and new data supporting the intended use on peach and conformity to existing MRL

Table IIIA 8.3.3-1: Summary of monograph and new data supporting the intended use on peach 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
Peach	MRL Application	South (4)	Trials GAP: 2 x 200 g a.s./ha – PHI 7 days Mo: 0.072, 0.188, 0.248, 0.483 Ra : 0.081, 0.197, 0.257, 0.492						0.5	Yes According to the global residue data set
	New trials	South (2)	Trials GAP: 1x48 g a.s./ha - PHI 7days Mo: 0.014, 0.024, Ra: 0.025, 0.038	0.019	0.024	N/A	N/A	N/A		
		South (4)	Trials GAP: 1 x 24 g a.s./ha - PHI 7days Mo: 0.013, 2 x 0.018, 0.020 Ra: 0.022 ; 0.027 ; 0.028 ; 0.029							
			Scale residue data *: Mo: 0.027, 0.037, 0.038, 0.04 Ra: 0.045, 0.055, 0.057, 0.058							
	Overall supporting data for FR and SEU GAP	South (4)	2 x 200 g a.s./ha – PHI 7 days Mo: 0.072, 0.188, 0.248, 0.483	0.218	0.483	0.849	1.138	0.94 → 1		
			Ra : 0.081, 0.197, 0.257, 0.492	0.227	0.492					
		South (6)	1x48 g a.s./ha - PHI 7days Mo: 0.014, 0.024, 0.027, 0.037, 0.038, 0.04	0.032	0.04	0.077	0.068	0.09 → 0.09		
			Ra: 0.025, 0.038, 0.045, 0.055, 0.057, 0.058	0.05	0.058					

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

* residue data have been scaled according to the recommendations and the conclusions described in the OECD draft guidance document on crop field trials (Series on pesticides No. 66 and series on testing assessment No. 164 ENV/JM/MONO(2011)50/REV1 sept 2016). Scale residue data = (intended dose rate X residue at harvest in residue trial)/ application dose rate in the residue trial

IIIA 8.3.3.4 Conclusion for peach

Among the 10 available peaches southern residue trials:
- 2 trials were performed at the intended GAP
- 4 trials were performed at a less intended. A single application at ca 24 g as/ha instead of 48 g as/ha. These trials have been considered after application of proportionality to residue data

4 trials were performed at a more critical GAP than intended one (2 x 200 g as/ha). For these trials the proportionality cannot be applied as the application rate vary for more than 4X the intended dose rate. Nevertheless as the highest residue level at harvest is below the in force MRL on peach they can be considered as indicative supporting residue data

In one trial (4068C) a significantly higher residue of sulfoxaflor (0.386 mg/kg) was measured 21 days after the last application. In all other trials residues, measured at the same interval, ranged from below the LOQ to 0.018 mg/kg. In the same trial the residue measured at 7 days was 0.013 mg/kg. Although there is no apparent explanation for the high value in this trial it is approximately 20 to 40 times higher than the other corresponding samples and is inconsistent with the observed decline of sulfoxaflor residues. Furthermore, as this value was a statistical outlier the reported residue value was not considered.

On the basis of the available supporting residue data and considering that half of the residue trials have been carried out at a more critical GAP than intended one it is possible to conclude that current MRL of 0.5 mg/kg on peach (Regulation 2016/1, SANTE/11442/2016) will not be exceed according to the intended GAP in EU.

Nevertheless 2 SEU trials performed according to the intended GAP are required in post authorization to complete the data set. Indeed FR considers that proportionality can be used to complete a residue data set but can represent at maximum 50% of the supporting data set.

IIIA 8.3.4 CHERRY

Table IIIA 8.3.4-1: Comparison of intended and critical EU GAPs

Crop	Type of GAP	Number of applications	Application rate per treatment	Interval between application	Growth stage at last application	PHI (days)
Cherries	MRL Application[1] (USA)	3	100 g a.s./ha		BBCH 87	7
	MRL Application[1] (Australia, New Zealand)	2	96 g a.s./ha		BBCH 87	7
	Intended FR et SEU	1	36-48 g/ha	-	BBCH 51-59 (pre-flowering) BBCH 69-85	7
		2	24 g/ha	7		7

[1] MRL Application – import tolerance

IIIA 8.3.4.1 Summary of EU Data

Use on cherry has been assessed in the framework of MRL application.
However this MRL application is based on US GAP and Australian-NZ GAP and residue trials submitted to the support the import tolerance have been performed outside EU (US and Canadian) and then they cannot be considered to support the intended use of GF2626 on cherries in EU
Furthermore as trials were not in compliance with the authorised GAP or were not sufficient to calculate an MRL based on the authorized GAP in US, Australia or New Zealand no MRL was proposed by EFSA and then a default MRL of 0.01* mg/kg was set for cherries at EU level in Regulation 2016/1.
Later the existing CXL of 1.5 mg/kg on cherries was voted at EU level and proposed in document SANTE/11442/2016.

It should be noted that in the evaluation report EU trials are also summarized (IE, 2012). They were performed according to a more critical GAP than intended one (2 applications at ca 200 g as/ha).

As these EU trials involved residue levels in fruits which are in accordance with the MRL proposed in document SANTE/11442/2016, they could be used to support the intended uses of GF-2626.
However as sufficient new trials have been submitted by the applicant they are only presented as indicative data.
These trials are summarized in tables below.

Residue trial number	Crop	Country and year	Application rate (g as/ha)	Growth stage at last treatment	DALA	Application No.	Residues found (mg/kg)	Remarks
CEMS-4072D	Cherries (Sour cherries)	50290 Epila, Zaragoza, Spain. 2009 EU Southern Zone	1 x 199.0 + 1 x 202.1 (Foliar application)	BBCH 77	7	2	**XDE-208:** 7 DALA: 0.504, 0.465 (**X11719474:** 7 DALA: (0.009), (0.008) **X11721061:** 7 DALA: 0.026, 0.020	
CEMS-4072E	Cherries (Sweet cherries)	58002 Panagitsa, Pella, Greece. 2008 EU Southern Zone	1 x 201.8 + 1 x 201.5 (Foliar application) Decline study	BBCH 87-89	-	2	**XDE-208:** 3 DALA: 0.886, 0.724 7 DALA: 0.809, 0.850 14 DALA: 0.654, 0.660 21 DALA: 0.506, 0.670 **X11719474:** 3 DALA: (0.010), (0.008) 7 DALA: 0.011, 0.013 14 DALA: 0.016, 0.015 21 DALA: 0.015, 0.019 **X11721061:** 3 DALA: 0.011, 0.010 7 DALA: 0.013, 0.015 14 DALA: 0.018, 0.017 21 DALA: 0.017, 0.018	
CEMS-4072F	Cherries (Sweet cherries)	66360 Sahorre, Languedoc-Roussillon, France. 2008 EU Southern Zone	1 x 202.9 + 1 x 194.1 (Foliar application)	BBCH 81	7	2	**XDE-208:** 7 DALA: 0.773, 0.632 **X11719474:** 7 DALA: (0.009), (0.007) **X11721061:** 7 DALA: 0.041, 0.036	

IIIA 8.3.4.1 New data

IIIA 8.3.4.1.1 Study 1

Report:	IIIA 8.3.3.1/01, Rawle, N. W., 2012c
Title:	Residues of XDE-208 in cherries at intervals and harvest following a single application of GF-2032 – Northern and Southern Europe - 2008
Document No:	CEMR-4071
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	None with impact on the study

In this study 2 trials were performed in NEU. They were not assessed in the framework of current application as only SEU residue trials are needed to support the use on cherries in France and SEU.

Table IIIA 8.3.4-2: Summary of global information on study 1

Comparative trials (between formulations, with and adjuvant/safener/synergist)	GF-2032 formulation (a SC formulation containing of 240 g sulfoxaflor/L).
Number of applications	1
Dose (g as/ha)	24
Mode of application	Foliar broadcast application
PHI (days) and/or growth stage (BBCH)	0, 3, 7, 14, 21
Analytical method (Code +Type)	Method N° 091031 LC-MS/MS
LoQ (mg/kg)	0.01mg/kg

Table IIIA 8.3.4-3: Summary of the study 1 trials

N° Trial		CEMS-4071C	CEMS-4071D
North/South/Indoor		S	S
Decline (D)/Harvest (H) trial?		H	D
Formulation		SC	SC
Equivalence between formulations		Y	Y
Accordance with intended GAP		N(1)	N(1)
Correct sampling		Y	Y
Samples frozen within 24h		Y	Y
Storage period (in days)	Sample	281	292
	Extract	1	1
Storage T° <-18°C		Y	Y
Validated analytical method		Y	Y
Negative controls		Y	Y
Considered trial		Y	Y
Remarks		(2)	(2)

(1):Trials were carried out at a less critical GAP than intended one (1 x 24 gas/ha instead of 1 x48 g as/ha or 2 x 24 g as/ha)

(2): Results of corresponding trials can be considered applying the proportionality. Indeed according to OECD draft guidance document on crop field trials (Series on pesticides No. 66 and series on testing assessment No. 164 ENV/JM/MONO(2011)50/REV1 sept 2016) proportionality can be applied to results of residue trials when the application rate is the only factor to vary from 0.3 to 4 times the intended GAP.

Table IIIA 8.3.4-4: Summary of data from residue trials for study 1

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-4071C CEMS-4071 DAS#: 080048-01 Y 2008	Sour cherry Blanca	Spain SZ Outdoor (field)	GF-2032	1	24.3	1005	2.4	24-Jun-2008	BBCH.77	7 7	Flesh Whole Fruit	0.026 **0.023**	<0.01 <0.01	0.035 **0.032**
CEMS-4071D CEMS-4071 DAS#: 080048-01 Y 2008	Sweet Cherries Mpakirtzeika	Greece SZ Outdoor (field)	GF-2032	1	24.1	1203	2.0	20-Jun-2008	BBCH.87 to 89	0 3 7 14 21 0 3 7 14 21	Flesh Flesh Flesh Flesh Flesh Whole Fruit Whole Fruit Whole Fruit Whole Fruit Whole Fruit	0.122 0.074 0.062 0.067 0.046 0.106 0.065 0.054 **0.057** 0.042	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.131 0.083 0.071 0.076 0.055 0.115 0.074 0.063 **0.066** 0.051

IIIA 8.3.4.1.2 Study 2

Report:	IIIA 8.3.3.1/02, Rawle, N. W. 2012d
Title:	Residues of sulfoxaflor in cherries at intervals and harvest following a single application of GF-2626 – Northern and Southern Europe - 2011
Document No:	CEMR-5028
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	None

In this study 2 trials were performed in NEU. They were not assessed in the framework of current application as only SEU residue trials are needed to support the use on cherries in France and SEU.

Table IIIA 8.3.4-5: Summary of global information on study 2

Comparative trials (between formulations, with and adjuvant/safener/synergist)	GF-2626 formulation (a SC formulation containing 120 g sulfoxaflor/L).
Number of applications	1
Dose (g as/ha)	Plot 2 :24 Plot 3: 48
Mode of application	Foliar broadcast application
PHI (days) and/or growth stage (BBCH)	0, 1, 3, 7 and 10
Analytical method (Code +Type)	Method N° 091031 LC-MS/MS
LoQ (mg/kg)	0.01mg/kg

Table IIIA 8.3.4-6: Summary of the study 2 trials

N° Trial		CEMS-5028E (plot 3)	CEMS-5028F (plot 3)
North/South/Indoor		S	S
Decline (D)/Harvest (H) trial?		D	H
Formulation		SC	SC
Equivalence between formulations		Y	Y
Accordance with intended GAP		Y	Y
Correct sampling		Y	Y
Samples frozen within 24h		Y	Y
Storage period (in days)	Sample	176	163
	Extract	1	1
Storage T° <-18°C		Y	Y
Validated analytical method		Y	Y
Negative controls		Y	Y
Considered trial		Y	Y

Remarks		

Table IIIA 8.3.4-7: Summary of data from residue trials for study 1

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-5028E CEMS-5028 GHE-P-12724 Y 2011	Sweet cherry Bigarreu	Italy SZ Outdoor (field)	GF-2626	1	43.2	1362	3.2	17-May-2011	BBCH.87 to 89	0 1 3 7 10 0 1 3 7 10	Flesh Flesh Flesh Flesh Flesh Whole Fruit Whole Fruit Whole Fruit Whole Fruit Whole Fruit	0.068 0.047 0.042 0.040 0.027 0.064 0.044 0.039 **0.036** 0.025	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.077 0.056 0.051 0.049 0.036 0.073 0.053 0.048 **0.045** 0.034
CEMS-5028F CEMS-5028 GHE-P-12724 Y 2011	Sour Cherry Dwarf Meteor	Greece SZ Outdoor (field)	GF-2626	1	49.0	816	6.0	23-May-2011	BBCH 85	7 7	Flesh Whole fruit	0.032 **0.028**	<0.01 <0.01	0.041 **0.037**

IIIA 8.3.4.2 Summary of monograph and new data supporting the intended use on cherries and conformity to existing MRL

Table IIIA 8.3.4-8: Summary of monograph and new data supporting the intended use on cherries 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
Cherries	New trials	South (2)	Trials GAP: 1 x 48 g as/ha, PHI 7d Mo: 0.028, 0.036 Ra: 0.037, 0.045						Reg EU 2016/1 :0.01* SANTE/11 442/2016: 1.5	Yes
		South (2)	Trials GAP: 1 x 24 g as/ha, PHI 7d Mo: 0.023, 0.057 Ra: 0.032, 0.066 Scale up residue data: Mo: 0.046, 0.11 Ra: 0.064, 0.132							
	Overall supporting data for FR and SEU GAP	South (4)	Mo: 0.028, 0.036, 0.046, 0.11	0.04	0.11	0.22	0.31	0.25→0.3		
			Ra: 0.037, 0.045, 0.064, 0.132	0.05	0.132					

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

* residue data have been scaled according to the recommendations and the conclusions described in the OECD draft guidance document on crop field trials (Series on pesticides No. 66 and series on testing assessment No. 164 ENV/JM/MONO(2011)50/REV1 sept 2016). Scale residue data: (intended dose rate x residue at harvest in residue trial)/ application dose rate in the residue trial

IIIA 8.3.4.3 Conclusion for cherries

Among the 4 available cherries southern residue trials:
- 2 trials were performed at the intended GAP
- 2 trials were performed at a less intended. A single application at ca 24 g as/ha instead of 48 g as/ha. These trials have been considered after application of proportionality to residue data

A total of 4 southern residue trails is therefore available to support the intended use on cherries. Therefore sufficient residue trials is available and no further trials is required.

On the basis of the available supporting residue data it is possible to conclude that the proposed MRL of 1.5 mg/kg on cherries (document SANTE/11442/2016) will not be exceeded according to the intended GAP in SEU.

IIIA 8.3.5 PLUM

Table IIIA 8.3.5-1: Comparison of intended and critical EU GAPs

Crop	Type of GAP	Number of applications	Application rate per treatment	Interval between application	Growth stage at last application	PHI (days)
Plums	MRL Application[1] (USA)	3	100 g a.s./ha		BBCH 87	7
	MRL Application[1] (AUS)	2	144 g a.s./ha		BBCH 87	7
	Intended FR et SEU	1	36-48 g/ha	-	BBCH 51-59 (pre-flowering) BBCH 69-85	7
		2	24 g/ha	7		7

[1] MRL Application – import tolerance

IIIA 8.3.5.1 Summary of EU Data

Use on plums has been assessed in the framework of MRL application for an import tolerance.
However this MRL application is based on US GAP and Australian GAP and residue trials submitted to the support the import tolerance have been performed outside EU (US and Canadian) and then they cannot be considered to support the intended use of GF-2626 on plums in EU.
Furthermore as trials were not in compliance with the authorised GAP or were not sufficient to calculate an MRL based on the authorized GAP in US or Australia no MRL was proposed by EFSA and then a default MRL of 0.01* mg/kg was set for plums at EU level in Regulation 2016/1.
Later the existing CXL of 0.5 mg/kg on plum was voted at EU level and proposed in document SANTE/11442/2016.

IIIA 8.3.5.1 New data

IIIA 8.3.5.1.1 Study 1

Report:	IIIA 8.3.3.3/01, Rawle, N. W. 2012g
Title:	Residues of XDE-208 in plums at intervals and harvest following a single application of GF-2032 – Northern and Southern Europe - 2008
Document No:	CEMR-4070
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	None with impact on the study

Table IIIA 8.3.5-2: Summary of global information on study 1

Comparative trials (between formulations, with and adjuvant/safener/synergist)	GF-2032 (a SC formulation containing 240 g sulfoxaflor/L).
Number of applications	1
Dose (g as/ha)	24
Mode of application	Foliar broadcast application
PHI (days) and/or growth stage (BBCH)	0, 7,15, 22, 28, 36
Analytical method (Code +Type)	Method N° 091031 LC-MS/MS
LoQ (mg/kg)	0.01mg/kg

In this study 4 trials were performed in NEU. They were not assessed in the framework of current application as only SEU residue trials are needed to support the use on plum in France and SEU.

Table IIIA 8.3.5-3: Summary of the study 1 trials

N° Trial		CEMS-4070E	CEMS-4070F
North/South/Indoor		S	S
Decline (D)/Harvest (H) trial?		D	D
Formulation		SC	SC
Equivalence between formulations		Y	Y
Accordance with intended GAP		N(1)	N(2)
Correct sampling		Y	Y
Samples frozen within 24h		Y	Y
Storage period (in days)	Sample	238	181
	Extract(3)	6	6
Storage T° <-18°C		Y	Y
Validated analytical method		Y	Y
Negative controls		Y	Y
Considered trial		N	N
Remarks			

(1):Trial was carried out at a less critical GAP than intended one (1 x 24 gas/ha instead of 1 x48 g as/ha or 2 x 24 g as/ha)
(2): Trial was carried out at a less critical GAP than intended one (1 x 24 gas/ha, PHI 21d instead of 1 x48 g as/ha or 2 x 24 g as/ha, PHI 7d)
(3): The procedural recoveries demonstrate the stability of the analyte up to 6 days

Proportionality cannot be applied to these trials as residues were below the LOQ and it is not possible to scale up residue below the LOQ according to the recommendations and the conclusions described in the OECD draft guidance document on crop field trials (Series on pesticides No. 66 and series on testing assessment No. 164 ENV/JM/MONO(2011)50/REV1 sept 2016)

Table IIIA 8.3.5-4: Summary of data from residue trials for study 1

Summary of residues data for sulfoxaflor in plums

GLP and Trial Details	Crop	Country	Application Details									Residues found			Remark
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-4070E CEMS-4070 DAS #: 080151 Y 2008	Plum Presideur	France SZ Outdoor (field)	GF-2032	1	24.5	1022	2.4	08-Aug-2008	BBCH.81	0 7 15 22 28 36 0 7 15 22 28 36	Flesh Flesh Flesh Flesh Flesh Flesh Whole Fruit Whole Fruit Whole Fruit Whole Fruit Whole Fruit Whole Fruit (calculated)	<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	
CEMS-4070F CEMS-4070 DAS #: 080151 Y 2008	Plums/ Presideur	France SZ Outdoor (field)	GF-2032	1	22.7	948	2.4	13 Sep 08	BBCH 87	21	Whole fruit	<0.01	<0.01	<0.019	

IIIA 8.3.5.1.2 Study 2

Report:	IIIA 8.3.3.3/02, Rawle, N. W., 2012h
Title:	Residues of sulfoxaflor in plums at intervals and harvest following a single application of GF-2626 – Northern and Southern Europe - 2011
Document No:	CEMR-5029
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	None with impact on the study

Table IIIA 8.3.5-5: Summary of global information on study 2

Comparative trials (between formulations, with and adjuvant/safener/synergist)	GF-2626 (SC formulation containing 120 g sulfoxaflor/L)
Number of applications	1
Dose (g as/ha)	Plot 2 :24 Plot 3: 48
Mode of application	Foliar broadcast application
PHI (days) and/or growth stage (BBCH)	0, 7, 14, 21, 28
Analytical method (Code +Type)	Method N° 091031 LC-MS/MS
LoQ (mg/kg)	0.01mg/kg

Table IIIA 8.3.5-6: Summary of the study 2 trials

N° Trial		CEMS-5029A (Plot 3)	CEMS-5029B (Plot 3)	CEMS-5029C (Plot 3)	CEMS-5029D (Plot 3)
North/South/Indoor		S	S	S	S
Decline (D)/Harvest (H) trial?		D	D	H	H
Formulation		SC	SC	SC	SC
Equivalence between formulations		Y	Y	Y	Y
Accordance with intended GAP		Y	Y	N(1)	N(1)
Correct sampling		Y	Y	Y	Y
Samples frozen within 24h		Y	Y	Y	Y
Storage period (in days)	Sample	204	288	240	184
	Extract	2	2	2	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	N(1)	N(1)
Remarks					

(1): Trial was carried out at a less critical GAP than intended one (PHI 28d instead of 7 days)
(2): The procedural recoveries demonstrate the stability of the analyte up to 2 days

Table IIIA 8.3.5-7: Summary of data from residue trials for study 2

Summary of residues data for sulfoxaflor in plums

GLP and Trial Details	Crop	Country	Application Details									Residues found			Remark
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-5029A CEMS-5029 GHE-P-12725 Y 2011	Plum Angelino	Italy SZ Outdoor (field)	GF-2626	1	48.9	1018	4.8	26-Jul-2011	BBCH.81	0 7 14 21 28 0 7 14 21 28	Flesh Flesh Flesh Flesh Flesh Whole Fruit Whole Fruit Whole Fruit Whole Fruit Whole Fruit (calculated)	<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	
CEMS-5029B CEMS-5029 GHE-P-12725 Y 2011	Plum Red Beauty	Spain SZ Outdoor (field)	GF-2626	1	47.7	1998	2.4	03-May-2011	BBCH.77	0 7 14 21 28 0 7 14 21 28	Flesh Flesh Flesh Flesh Flesh Whole Fruit Whole Fruit Whole Fruit Whole Fruit Whole Fruit (calculated)	0.021 0.014 <0.01 <0.01 <0.01 0.019 **0.013** <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	0.030 0.023 <0.019 <0.019 <0.019 0.028 **0.022** <0.019 <0.019 <0.019	

Summary of residues data for sulfoxaflor in plums

GLP and Trial Details	Crop	Country	Application Details									Residues found			Remark
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-5029C CEMS-5029 GHE-P-12725 Y 2011	Plums / Black Diamond	Greece SZ Outdoor (field)	GF-2626	1	48.8	812	6	23 May 11	BBCH 75	28	Whole fruit	<0.01	<0.01	<0.019	
CEMS-5029D CEMS-5029 GHE-P-12725 Y 2011	Plums / Stenley	Bulgaria SZ Outdoor (field	GF-2626	1	44.13	784	5.7	18 Jul 11	BBCH 78	28	Whole fruit	<0.01	<0.01	<0.019	

IIIA 8.3.5.2 Summary of monograph and new data supporting the intended use on plum and conformity to existing MRL

Table IIIA 8.3.5-8: Summary of monograph and new data supporting the intended use on plum 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
Plums	New trials = Overall supporting data	South (2)	Trials GAP: 1 x 48 g as/ha, PHI 7d Mo: <0.01, 0.013	0.01	0.013	-	-	-	Reg EU 2016/1 : 0.01* SANTE/11 442/2016: 0.5	Yes
			Ra: <0.019, 0.022	0.02	0.022					

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

IIIA 8.3.5.3 Conclusion for plum

Among the available Southern residue trials only 2 are considered suitable to support the intended use on plum.
Consequently insufficient residue trials are available to support and to consider acceptable the intended use on plum.

It should be noted that some of the trials (CEMS-4070E and CEMS-4070F) performed at a less critical GAP (1x24 g as/ha instead of 1 x 48 g as/ha) were considered by the notifiant after scaling up the residue level at harvest. However as for the corresponding residue trials residues were below the LOQ it is not possible to scale up according to the recommendations and the conclusions described in the OECD draft guidance document on crop field trials (Series on pesticides No. 66 and series on testing assessment No. 164 ENV/JM/MONO(2011)50/REV1 sept 2016).

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IIIA 8.3.6 POTATO

Table IIIA 8.3.6-1: Comparison of intended and critical EU GAPs

Crop	Type of GAP	Number of applications	Application rate per treatment	Interval between application	Growth stage at last application	PHI (days)
Potatoes	DAR MRL Application (USA)[1]	1-4	71-80 g a.s./ha	14	N/A	7
	Intended FR and SEU	2	24 g/ha	21		7

[1] MRL Application – import tolerance, MRL proposed according to USA cGAPs.

IIIA 8.3.6.1 Summary of EU Data

Use on potatoes has been assessed in the meantime of the EU evaluation of sulfoxaflor, in the framework of MRL application for an import tolerance.
However this MRL application is based on US GAP and residue trials supporting the import tolerance have been performed outside EU (USA). Therefore they cannot be used to support the intended GAP.
Based on the supporting residue data an MRL of 0.01* mg/kg was proposed by EFSA and then adopted at EU level in Regulation 2016/1.
Later the existing CXL of 0.03 mg/kg on potato was voted at EU level and proposed in document SANTE/11442/2016.

In the evaluation report EU trials (4 NEU and 4 SEU) are also summarized. They were performed according to a more critical GAP than intended one (4 applications at ca 100 g as/ha). These trials were not submitted by the applicant to support the intended use of GF-2626 as residue trials performed according to the intended GAP were provided.

IIIA 8.3.6.2 New data

IIIA 8.3.6.2.1 Study 1

Report:	IIIA 8.3.4/01, Rawle, N. W., 2012
Title:	Residues of sulfoxaflor in potatoes at intervals and harvest following multiple applications of GF-2626 – Northern and Southern Europe - 2011
Document No:	Study ID : CEMS-5026, Report ID : CEMR-5026 Dow AgroSciences Reference : GHE-P-12722
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	None with impact on the study

Table IIIA 8.3.6-2: 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	2
Dose (g as/ha)	24 g a.s./ha
Mode of application	Foliar broadcast
PHI (days) and/or growth stage (BBCH)	0, 7, 14, 21 & 28 days
Analytical method (Code +Type)	Method N° 091031 LC-MS/MS
LoQ (mg/kg)	0.01mg/kg

Table IIIA 8.3.6-3: Summary of the study 1 trials

N° Trial		CEMS-5026A	CEMS-5026B	CEMS-5026C	CEMS-5026D	CEMS-5026E	CEMS-5026F	CEMS-5026G	CEMS-5026H
North/South/Indoor		S	S	S	S	N	N	N	N
Decline (D)/Harvest (H) trial?		D	D	H	H	D	D	H	H
Formulation		SC	SC	SC	SC	SC	SC	SC	SC
Equivalence between formulations		Y	Y	Y	Y	Y	Y	Y	Y
Accordance with intended GAP		Y	Y	N[1]	N[1]	Y	Y	N[1]	N[1]
Correct sampling		Y	Y	Y	Y	Y	Y	Y	Y
Samples frozen within 24h		Y	Y	Y	Y	Y	Y	Y	Y
Storage period (in days)	Sample	105	96	171	133	128	91	99	55
	Extract	1	1	1	1	1	1	1	1
Storage T° <-18°C		Y	Y	Y	Y	Y	Y	Y	Y
Validated analytical method		Y	Y	Y	Y	Y	Y	Y	Y
Negative controls		Y	Y	Y	Y	Y	Y	Y	Y
Considered trial		Y	Y	N	N	Y	Y	N	N
Remarks				1	1			1	1

[1] Trials carried out at a less critical GAP than intended one: PHI of 28 days instead of 7 days

Only trials performed according to the intended GAP are summarised in table below.

Table IIIA 8.3.6-4: 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

Content of a.i. (g/kg or g/l) : 120 g/L
Formulation (e.g. WP) : SC
Commercial product (name) : GF-2626
Applicant : Eurofins AgroScience Services GmbH

Active ingredient : Sulfoxaflor
Crop / crop group : Roots and Tuber vegetables : Potatoes
Indoors / outdoors : Outdoor
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 (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-5026A CEMS-5026 GHE-P-12722 Y 2011	Potato Agria	Spain(SZ) 50591 Alcala de Moncayo, Aragon Outdoor (field)	GF-2626	2	26.1 26.1	435 435	6.0 6.0	21-Jul-11 11-Aug-11	BBCH.91	<0 0 7 14 21 27	Tuber Tuber Tuber Tuber Tuber Tuber	<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	
CEMS-5026B CEMS-5026 GHE-P-12722 Y 2011	Potato Agria	Bulgaria (SZ) 4644 Kostandovo, Pazardjik Outdoor (field)	GF-2626	2	24.2 24.4	403 407	6.0 6.0	30-Jul-11 20-Aug-11	BBCH.42	<0 0 7 14 21 28	Tuber Tuber Tuber Tuber Tuber Tuber	<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	

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-5026E CEMS-5026 GHE-P-12722 Y 2011	Potato Karlena	Germany(NZ) 16356 Blumberg, Brandenburg Outdoor (field)	GF-2626	2	24.4 24.0	508 500	4.8 4.8	29-Jun-11 19-Jul-11	BBCH.79	<0 0 7 14 21 28	Tuber Tuber Tuber Tuber Tuber Tuber	<0.01 **<u><0.01</u>** <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01	<0.019 <0.019 **<u><0.019</u>** <0.019 <0.019 <0.019	
CEMS-5026F CEMS-5026 GHE-P-12722 Y 2011	Potato Rudawa	Poland (NZ) 64-600 Uscikowo, Wielkopolska Outdoor (field)	GF-2626	2	23.3 23.9	388 399	6.0 6.0	05-Aug-11 25-Aug-11	BBCH.89	<0 0 7 14 21 28	Tuber Tuber Tuber Tuber Tuber Tuber	<0.01 <0.01 **<u><0.01</u>** <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01	<0.019 <0.019 **<u><0.019</u>** <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

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

IIIA 8.3.6.3 Summary of monograph and new data supporting the intended use on potato and conformity to existing MRL

Table IIIA 8.3.6-1: Summary of monograph and new data supporting the intended use on potato 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
Potato	MRL Application Monograph/	North (4)	Trials GAP: 4 x 100 g a.s/ha, PHI 7d Mo 4 x <0.01 Ra : <0.019, 0.020, 0.032, 0.038						Reg EU 2016/1: 0.01* SANTE/11442/2016: 0.03	Yes
		South (4)	Trials GAP: 4 x 100 g a.s/ha, PHI 7d Mo 4 x <0.01 Ra : 4 x < 0.019							
	New trials	North (2)	Trials GAP: 2 x 24 g a.s/ha, PHI 7d Mo 2 x <0.01 Ra : 2 x < 0.019							
		South (2)	Trials GAP: 2 x 24 g a.s/ha, PHI 7d Mo 2 x <0.01 Ra : 2 x < 0.019							
	Overall supporting data for FR GAP	North (2)	Mo 2 x <0.01	0.01	0.01	-	-	-		
			Ra : 2 x < 0.019	0.019	0.019					
		South (2)	Mo 2 x <0.01	0.01	0.01	-	-	-		
			Ra : 2 x < 0.019	0.019	0.019					
	Overall supporting data for SEU GAP	South (2)	Mo 2 x <0.01	0.01	0.01	-	-	-		
			Ra : 2 x < 0.019	0.019	0.019					

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

IIIA 8.3.6.4 Conclusion for potato

2 southern residue trials and 2 northern residue trials are available to support the intended GAP.
Furthermore in the 4 SEU and NEU trials available in the evaluation report and performed according to a more critical GAP than intended one (4 applications at ca 100 g as/ha) no residue of sulfoxaflor at or above 0.01 mg/kg were observed in tubers at harvest.

As a no residue situation is observed at harvest the reduce data set is considered acceptable.

On the basis of the available supporting residue data it is possible to conclude that current MRL of 0.01* mg/kg (Regulation 2016/1) on potatoes will not be exceed according to the intended GAP in EU.

IIIA 8.3.7 TOMATO, AUBERGINE

Table IIIA 8.3.7-1: Comparison of intended and critical EU GAPs

Crop	Type of GAP	Number of applications	Application rate per treatment	Interval between application	Growth stage at last application	PHI (days)
Tomatoes Aubergines	EU (DAR)[1]	1	24 g a.s./ha	-	BBCH 20 – 39 BBCH 40 - 89 Apr - Nov	≥1
	MRL application (USA)[2]	4	78 g a.s./ha	7	BBCH 89	1
	Intended FR and SEU	1	48 g a.s./ha	-	BBCH 20-87	1
		2	24 g a.s./ha	7		1

[1] Representative use
[2] MRL Application

IIIA 8.3.7.1 Summary of B.7.6 Data

Uses on tomatoes and aubergines have been assessed in the framework of the approbation of the active substance as a representative use. Furthermore they have also been assessed in the meantime of the EU evaluation of sulfoxaflor, in the framework of MRL application based on an import tolerance from USA.
The in force MRL of 0.3 mg/kg on tomatoes and aubergine was set based on this import tolerance. However this MRL application is based on US GAP and residue trials supporting the import tolerance have been performed outside EU (USA). Therefore they cannot be used to support the intended GAP.

The intended GAP is more critical than the representative EU uses of sulfoxaflor on tomato and aubergine which were assessed in the framework of the approbation of active substance.
However among the trials reported in the monograph of active substance some are considered suitable to support the intended GAP. They were performed in southern EU with 1 application at ca 48 g a.s/ha, PHI of 0 to 10 days.

Characteristics and results of the supported trials are summarized below.
Residue levels of sulfoxaflor and metabolite X11719474 in tomato from trials considered suitable to support the intended GAP are underlined.

Summary of EU data for tomatoes (IE, 2012)

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-4694E CEMS-4694 DAS Report #:101458 Y 2010	tomato Ondina	France SZ Outdoor (field)	GF-2626	1	51.0	498	10.2	24-Aug-2010	BBCH.86	0 1 3 7 10	Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit	0.040 **0.045** 0.019 0.014 0.011	<0.01 <0.01 <0.01 <0.01 <0.01	0.049 **0.054** 0.028 0.023 0.020
CEMS-4694F CEMS-4694 DAS Report #:101458 Y 2010	tomato Meteor	Greece SZ Outdoor (field)	GF-2626	1	47.3	984	4.8	27-Jul-2010	BBCH.81	0 1 3 7 10	Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit	0.018 0.020 <0.01 <0.01 **0.034**	<0.01 <0.01 <0.01 <0.01 <0.01	0.027 0.029 <0.019 <0.019 **0.043**
CEMS-4694G CEMS-4694 DAS Report #:101458 Y 2010	tomato Caramba	Italy SZ Outdoor (field)	GF-2626	1	46.9	733	6.4	27-Jul-2010	BBCH.82	0 1 3 7 10	Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit	0.013 **0.027** <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	0.022 **0.036** <0.019 <0.019 <0.019
CEMS-4694H CEMS-4694 DAS Report #:101458 Y 2010	tomato Trinity	Spain SZ Outdoor (field)	GF-2626	1	45.4	945	4.8	18-Oct-2010	BBCH.87	0 1 3 7 10	Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit	0.014 **0.013** <0.01 <0.01 0.010	<0.01 <0.01 <0.01 <0.01 <0.01	0.023 **0.022** <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-4696E CEMS-4696 DAS Report #:101459 Y 2010	cherry tomato Katalina F1	France SZ Outdoor (field)	GF-2626	1	51.1	800	6.4	20-Sep-2010	BBCH.89	0 1 3 7 10	Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit	0.077 0.019 **0.022** 0.015 0.013	<0.01 <0.01 <0.01 <0.01 <0.01	0.086 0.028 **0.031** 0.024 0.022
CEMS-4696F CEMS-4696 DAS Report #:101459 Y 2010	cherry tomato Genio	Greece SZ Outdoor (field)	GF-2626	1	48.4	1008	4.8	23-Jun-2010	BBCH.83	0 1 3 7 9	Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit	0.042 **0.040** 0.035 0.021 0.031	<0.01 <0.01 <0.01 <0.01 <0.01	0.051 **0.049** 0.044 0.030 0.040
CEMS-4696G CEMS-4696 DAS Report #:101459 Y 2010	cherry tomato Carminio	Italy SZ Outdoor (field)	GF-2626	1	51	697	7.3	26-Jul-2010	BBCH.83	0 1 3 7 10	Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit	0.040 **0.033** 0.028 0.031 0.015	<0.01 <0.01 <0.01 <0.01 <0.01	0.049 **0.042** 0.037 0.040 0.024
CEMS-4696H CEMS-4696 DAS Report #:101459 Y 2010	cherry tomato Granillon	Spain SZ Outdoor (field)	GF-2626	1	51.4	1071	4.8	03-Aug-2010	BBCH.81	0 1 3 7 10	Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit	0.033 0.024 **0.025** 0.024 0.023	<0.01 <0.01 <0.01 <0.01 <0.01	0.042 0.033 **0.034** 0.033 0.032

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

IIIA 8.3.7.2 New data

IIIA 8.3.7.2.1 Study 1

Report:	IIIA 8.3.5.1/03, Rawle, N. W., 2012
Title:	Residues of sulfoxaflor in tomatoes at intervals and harvest following a single application of GF-2626 – Northern and Southern Europe - 2011
Document No:	Study ID : CEMS-5008, Report ID : CEMR-5008 Dow AgroSciences Reference : GHE-P-12704
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	None with impact on the study

Table IIIA 8.3.7-2: 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)	0.01mg/kg

Table IIIA 8.3.7-3: Summary of the study 1 trials

N° Trial		CEMS-5008A	CEMS-5008B	CEMS-5008C	CEMS-5008D
North/South/Indoor		S	S	S	S
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	99	74	99	119
	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 8.3.7-4: 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
Content of a.i. (g/kg or g/l) : 120 g/L
Formulation (e.g. WP) : SC
Commercial product (name) : GF-2626
Applicant : Eurofins AgroScience Services GmbH

Active ingredient : Sulfoxaflor
Crop / crop group : Fruiting Vegetables : Tomatoes
Indoors / outdoors : Outdoor
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 (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-5008A CEMS-5008 GHE-P-12704 Y 2011	tomato H-9036	Spain (SZ) 50637 Remolinos, Aragon Outdoor (field)	GF-2626	1	51.2	1067	4.8	05-Sep-2011	BBCH.87 to 89	0 1 3 7 10	Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit	0.016 0.010 **0.011** <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	0.025 0.019 **0.020** <0.019 <0.019	
CEMS-5008B CEMS-5008 GHE-P-12704 Y 2011	tomato Nikolima	Bulgaria (SZ) 4417 Ognianovo, Pazardjik Outdoor (field)	GF-2626	1	46.3	482	9.6	30-Sep-2011	BBCH.88	0 1 3 7 10	Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit	0.018 **0.014** <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	0.027 **0.023** <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-5008C CEMS-5008 GHE-P-12704 Y 2011	tomato Beef master	France (SZ) 66700 Argeles sur Mer, Pyrénées Orientales Outdoor (field)	GF- 2626	1	50.4	1050	4.8	05-Sep- 2011	BBCH.88 to 89	0 1 3 7 10	Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit	0.038 0.010 **0.015** <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	0.047 0.019 **0.024** <0.019 <0.019	
CEMS-5008D CEMS-5008 GHE-P-12704 Y 2011	tomato H3402	Italy (SZ) Conselice, Ravenna Outdoor (field)	GF- 2626	1	51.8	756	6.9	16-Aug- 2011	BBCH.75 to 89	0 1 3 7 10	Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit	0.020 **<0.01** <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	<0.029 **<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

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

IIIA 8.3.7.2.2 Study 2

Report:	IIIA 8.3.5.1/04, Rawle, N. W., 2012
Title:	Residues of sulfoxaflor in cherry tomatoes at intervals and harvest following a single application of GF-2626 – Northern and Southern Europe - 2011
Document No:	Study ID : CEMS-5010, Report ID : CEMR-5010 Dow AgroSciences Reference : GHE-P-12706
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	None with impact on the study

Table IIIA 8.3.7-5: Summary of global information on study 2

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)	Method N° 091031 LC-MS/MS
LoQ (mg/kg)	0.01 mg/kg

Table IIIA 8.3.7-6: Summary of the study 2 trials

N° Trial		CEMS-5010E	CEMS-5010F	CEMS-5010G	CEMS-5010H
North/South/Indoor		S	S	S	S
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	147	110	133	78
	Extract[1]	2	2	2	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] The procedural recoveries demonstrate the stability of the analyte up to up to 2 days (CEMR-5010, p.19)

Table IIIA 8.3.7-7: Summary of data from residue trials for study 2

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)
Notifier: Dow AgroSciences, European Development Centre

Active ingredient : Sulfoxaflor
Crop / crop group : Fruiting Vegetables : Cherry Tomatoes

Content of a.i. (g/kg or g/l) : 120 g/L
Formulation (e.g. WP) : SC
Commercial product (name) : GF-2626
Applicant : Eurofins AgroScience Services GmbH

Indoors / outdoors : Outdoor
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 (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-5010E CEMS-5010 GHE-P-12706 Y 2011	cherry tomatoes Paime	Spain (SZ) 11140 Conil de la Frontera, Cadiz Outdoor (field)	GF-2626	1	49.3	1028	4.8	12-Jul-2011	BBCH.82 to 83	0 1 3 7 10	Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit	0.091 **0.055** 0.042 0.037 0.034	<0.01 <0.01 <0.01 <0.01 <0.01	0.100 **0.064** 0.051 0.046 0.043	
CEMS-5010F CEMS-5010 GHE-P-12706 Y 2011	cherry tomatoes Tomito	Greece (SZ) 57008 Nea Magnisia, Thessaloniki Outdoor (field)	GF-2626	1	49.9	831	6.0	18-Aug-2011	BBCH.82	0 1 3 7 10	Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit	0.030 **0.025** 0.018 0.019 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	0.039 **0.034** 0.027 0.028 <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-5010G CEMS-5010 GHE-P-12706 Y 2011	cherry tomatoes Tropical	Italy (SZ) 04022 Fondi, Latina Outdoor (field)	GF-2626	1	44.9	936	4.8	26-Jul-2011	BBCH.87	0 1 3 7 10	Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit	0.014 **0.010** <0.01 <0.01 0.010	<0.01 <0.01 <0.01 <0.01 <0.01	0.023 **0.019** <0.019 <0.019 0.019	
CEMS-5010H CEMS-5010 GHE-P-12706 Y 2011	cherry tomatoes Quorun	Greece (SZ) 57008 Nea Magnisia, Thessaloniki Outdoor (field)	GF-2626	1	45.8	764	6.0	19-Sep-2011	BBCH.85	0 1 3 7 10	Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit	0.064 **0.019** <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	0.073 **0.028** <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

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

IIIA 8.3.7.3 Summary of monograph and new data supporting the intended use on tomatoes and aubergines and conformity to existing MRL

Table IIIA 8.3.7-8: 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
Tomato and aubergine	Monograph	South (8)	Trials GAP: 1x48 g a.s./ha – PHI 1 day **MO** : 0.013, 0.022, 0.025, 0.027, 0.033, 0.034, 0.04, 0.045, **RA** : 0.022, 0.031, 0.034, 0.036, 0.042, 0.043, 0.049, 0.054						0.3 mg/kg for tomato and aubergine	Yes
	New trials	South (8)	Trials GAP: 1x48 g a.s./ha – PHI 1 day **MO** : <0.01, 0.01, 0.011, 0.014, 0.015, 0.019, 0.025, 0.055 **RA** : 2 x 0.019, 0.020, 0.023, 0.024, 0.028, 0.034, 0.064							
	Overall supporting data for FR, IT, SP & SEU GAP	South (16)	**MO** : <0.01, 0.01, 0.011, 0.013, 0.014, 0.015, 0.019, 0.022, 2 x 0.025, 0.027, 0.033, 0.034, 0.04, 0.045, 0.055	MO: 0.024	MO: 0.055	0.068	0.059	0.079→0.08		
			RA : 2 x 0.019, 0.020, 0.022, 0.023, 0.024, 0.028, 0.031, 2 x 0.034, 0.036, 0.042, 0.043, 0.049, 0.054, 0.064	RA: 0.033	RA: 0.064					

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

IIIA 8.3.7.4 Conclusion for tomato

According to EU guideline 7525/VI/95-rev.10, Appendix D « Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs», extrapolation of residue data from tomatoes to aubergines is possible when the application is performed close to harvest.

A total of 16 trials are considered suitable to support the intended SEU GAPs of GF-2626 in tomatoes.

Therefore enough relevant residue data are available to support the intended uses on tomato and aubergine in SEU and no further residue data are required.

On the basis of the available supporting residue data it is possible to conclude that the in force MRL of 0.3 mg/kg on tomato and aubergine (Regulation 2016/1) will not be exceeded according to the intended GAP in SEU.

IIIA 8.3.8 PEPPER

Table IIIA 8.3.8-1: Comparison of intended and critical EU GAPs

Crop	Type of GAP	Number of applications	Application rate per treatment	Interval between application	Growth stage at last application	PHI (days)
Pepper	EU (DAR)[1]	1	24 g a.s./ha	-	BBCH 20 – 39 BBCH 40 - 89 Apr - Nov	≥1
	MRL application (USA)[2]	4	78 g a.s./ha	7	BBCH 89	1
	Intended FR and SEU	1	48 g a.s./ha	-	BBCH 20-87	1
		2	24 g a.s./ha	7		1

[1] Representative Use
[2] MRL Application – import tolerance, MRL assessed according to USA authorised cGAPs

IIIA 8.3.8.1 Summary of EU data

Use on pepper has been assessed in the framework of the approbation of the active substance as a representative use. Furthermore use on pepper has also been assessed in the meantime of the EU evaluation of sulfoxaflor, in the framework of MRL application based on an import tolerance from USA.
The in force MRL of 0.4 mg/kg on peppers was set based on this import tolerance. However this MRL application is based on US GAP and residue trials supporting the import tolerance have been performed outside EU (USA). Therefore they cannot be used to support the intended GAP.

The intended GAP is more critical than the representative EU use of sulfoxaflor on pepper which was assessed in the framework of the approbation of active substance.
However among the trials reported in the monograph of active substance some are considered suitable to support the intended GAP. They were performed in southern EU with 1 application at ca 48 g a.s/ha, PHI of 0 to 10 days.

Characteristics and results of the supported trials are summarized below.
Residue levels of sulfoxaflor and metabolite X11719474 in pepper from trials considered suitable to support the intended GAP are underlined.

Summary of EU data for pepper

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-4700A CEMS-4700 DAS Report #:101462 Y 2010	pepper Kalifornij-sko tchudo	Bulgaria SZ Outdoor (field)	GF-2626	1	48.9	611	8.0	04-Oct-10	BBCH 89	0 1 3 7 10	Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit	0.073 **0.048** 0.026 0.011 0.011	<0.01 <0.01 <0.01 <0.01 <0.01	0.082 **0.057** 0.035 0.020 0.020
CEMS-4700B CEMS-4700 DAS Report #:101462 Y 2010	pepper Joselito	France SZ Outdoor (field)	GF-2626	1	54.0	857	6.3	18-Aug-10	BBCH 88-89	0 1 3 7 10	Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit	0.179 0.108 **0.138** 0.064 0.052	<0.01 <0.01 <0.01 <0.01 <0.01	0.188 0.117 **0.147** 0.073 0.061
CEMS-4700C CEMS-4700 DAS Report #:101462 Y 2010	pepper Raiko	Greece SZ Outdoor (field)	GF-2626	1	47.8	997	4.8	08-Sep-10	BBCH 81	0 1 3 7 10	Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit	0.053 0.027 **0.030** 0.024 0.022	<0.01 <0.01 <0.01 <0.01 <0.01	0.062 0.036 **0.039** 0.033 0.031
CEMS-4700D CEMS-4700 DAS Report #:101462 Y 2010	pepper Italiano	Spain SZ Outdoor (field)	GF-2626	1	49.4	1030	4.8	26-Jul-10	BBCH 88	0 1 3 7 10	Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit	0.035 **0.029** 0.022 0.018 0.021	<0.01 <0.01 <0.01 <0.01 <0.01	0.044 **0.038** 0.031 0.027 0.030

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

IIIA 8.3.8.2 New data

IIIA 8.3.8.2.1 Study 1

Report:	IIIA 8.3.5.2/02, Rawle, N. W., 2011
Title:	Residues of sulfaxoflor in bell peppers at intervals and harvest following a single application of GF-2626 – Northern and Southern Europe - 2011
Document No:	Study ID : CEMS-5011, Report ID : CEMR-5011 Dow AgroSciences Reference : GHE-P-12707
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	None with impact on the study

Table IIIA 8.3.8-2: 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)	0.01mg/kg

Table IIIA 8.3.8-3: Summary of the study 1 trials

N° Trial		CEMS-5011E	CEMS-5011F	CEMS-5011G	CEMS-5011H
North/South/Indoor		S	S	S	S
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	148	227	242	241
	Extract[1]	3	3	3	3
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] The procedural recoveries demonstrate the stability of the analyte up to up to 3 days

Table IIIA 8.3.8-4: 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
Content of a.i. (g/kg or g/l) : 120 g/L
Formulation (e.g. WP) : SC
Commercial product (name) : GF-2626
Applicant : Eurofins AgroScience Services GmbH

Active ingredient : Sulfoxaflor
Crop / crop group : Fruiting Vegetables : Bell peppers
Indoors / outdoors : Outdoor
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 (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-5011E CEMS-5011 GHE-P-12707 Y 2011	pepper Kalifornij- suo tchudo	Bulgaria (SZ) 5570 Letnitsa, Letnitsa Outdoor (field)	GF- 2626	1	46.5	484	9.6	20-Oct-11	BBCH 88	0 1 3 7 10	Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit	0.027 **0.020** 0.010 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	0.036 **0.029** 0.019 <0.019 <0.019	
CEMS-5011F CEMS-5011 GHE-P-12707 Y 2011	pepper Joselito	France (SZ) 66380 pia, Pyrénées- Orientales Outdoor (field)	GF- 2626	1	50.3	1048	4.8	02-Aug-11	BBCH 89	0 1 3 7 10	Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit	0.103 0.090 **0.115** 0.057 0.040	<0.01 <0.01 <0.01 <0.01 <0.01	0.112 0.099 **0.124** 0.066 0.049	

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-5011G CEMS-5011 GHE-P-12707 Y 2011	pepper Teseo	Italy (SZ) 04022 Fondi, Latina Outdoor (field)	GF-2626	1	46.0	960	4.8	18-Jul-11	BBCH 87	0 1 3 7 10	Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit	0.067 **0.030** <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	0.076 **0.039** <0.019 <0.019 <0.019	
CEMS-5011H CEMS-5011 GHE-P-12707 Y 2011	pepper Raico	Greece (SZ) 57008 Nea Magnisia, Thessaloniki Outdoor (field)	GF-2626	1	48.2	803	6.0	19-Jul-11	BBCH 73	0 1 3 7 10	Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit	0.059 **0.048** 0.028 0.034 0.024	<0.01 <0.01 <0.01 <0.01 <0.01	0.068 **0.057** 0.037 0.043 0.033	

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

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

IIIA 8.3.8.3 Summary of monograph and new data supporting the intended use on pepper and conformity to existing MRL

Table IIIA 8.3.8-5: Summary of monograph and new data supporting the intended use on pepper 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	South (4)	Trials GAP: 1x48 g a.s./ha – PHI 1 day MO : 0.029, 0.030, 0.048, 0.138 RA : 0.038, 0.039, 0.057, 0.147						0.4	Yes
	New trials	South (4)	Trials GAP: 1x48 g a.s./ha – PHI 1 day MO : 0.020, 0.030, 0.048, 0.115 RA : 0.029, 0.039, 0.057, 0.124							
	Overall supporting data for FR, IT, SP & SEU GAP	South (8)	Mo : 0.020, 0.029, 2 x 0.030, 2 x 0.048, 0.115, 0.138	MO: 0.039	MO: 0.138	0.197	0.198	0.234 → 0.3		
			Ra : 0.029, 0.038, 2 x 0.039, 2 x 0.057, 0.124, 0.147	RA: 0.048	RA: 0.147					

(1): Source of EU MRL: http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=homepage&language=EN

IIIA 8.3.8.4 Conclusion for pepper

A total of 8 Southern trials are considered suitable to support the intended SEU GAPs of GF-2626 on peppers.
So enough relevant residue data are available to support the intended uses on pepper in SEU and no further residue data are required.

On the basis of the available supporting residue data it is possible to conclude that the MRL of 0.4 mg/kg on pepper in Regulation 2016/1 will not be exceeded according to the intended GAP in SEU.

IIIA 8.3.9 CUCUMBER, COURGETTE, GERKIN

Table IIIA 8.3.9-1: Comparison of intended and critical EU GAPs

Crop	Type of GAP	Number of applications	Application rate per treatment	Interval between application	Growth stage at last application	PHI (days)
Cucumber Courgette	EU (DAR)[1]	1	24 g a.s./ha	-	BBCH 20 – 39 BBCH 40 - 89 Apr - Nov	≥1
	MRL application (USA)[2]	4	78 g a.s./ha	7	BBCH 89	1
Cucumber Courgette Gherkin	Intended FR and SEU	1	48 g a.s./ha	-	BBCH 20-87	1
		2	24 g a.s./ha	7		1

[1] Representative use
[2] MRL Application – import tolerance, MRL assessed according to USA authorised cGAP

IIIA 8.3.9.1 Summary of B.7.6 Data

Uses on cucumber and courgette have been assessed in the framework of the approbation of the active substance as a representative use.
Furthermore these uses have also been assessed in the meantime of the EU evaluation of sulfoxaflor, in the framework of MRL application based on an import tolerance from USA. Nevertheless as trials were not in compliance with the authorised GAP or were not sufficient to calculate an MRL based on the authorized GAP in US, no MRL import tolerance was proposed by EFSA.
So, in force MRL of 0.03 mg/kg (Reg EU 2016/1 was derived from EU representative uses.
Later the existing CXL of 0.5 mg/kg on cucurbits with edible peel was voted at EU level and proposed in document SANTE/11442/2016.

The intended GAP is more critical than the representative EU uses of sulfoxaflor on cucumber and courgette which were assessed in the framework of the approbation of active substance.
However from the available trials reported in the monograph of active substance some are considered suitable to support the intended GAP. They were performed in southern and Northern EU with 1 application at ca 48 g a.s./ha, PHI of 0 to 10 days.

Characteristics and results of the supported trials are summarized below.
Residue levels of sulfoxaflor and metabolite X11719474 in cucumber from trials considered suitable to support the intended GAP are underlined.

Summary of NEU data

Residue trial number	Crop	Country and year	Application rate (g as/ha)	Growth stage at last treatment	Interval between applications (days)	PHI days	Residues found (mg/kg)		
							Sulfoxaflor	Metabolite X11719474	Metabolite X11721061
Doc ID: CEMR-4703 (Study no: 101464) Trial 1: CEMS-4703A	Cucumber Outdoor	49650 Allonnes, Main et Loire, France. 2010 NEU	1 x 25.6 **GF-2626**	71-75	NA		Fruit	Fruit	Fruit
						0	0.011	ND	ND
						1	(0.006)	ND	(0.003)
						3	ND	ND	ND
						7	ND	ND	(0.004)
						10	ND	ND	ND
			1 x 51.8 **GF-2626**	71-75	NA		Fruit	Fruit	Fruit
						0	0.018	ND	(0.006)
						1	0.023	ND	ND
						3	(0.008)	ND	(0.007)
						7	(0.003)	ND	(0.004)
						10	ND	(0.005)	(0.007)
Doc ID: CEMR-4703 (Study no: 101464) Trial 2: CEMS-4703B	Cucumber Outdoor	74613 Büttelbrom, Baden-Württemberg, Germany. 2010 NEU	1 x 25.6 **GF-2626**	89	NA		Fruit	Fruit	Fruit
						0	(0.004)	ND	(0.004)
						1	ND	ND	ND
						3	ND	ND	ND
						7	ND	ND	ND
						10	ND	ND	(0.004)
			1 x 50.1 **GF-2626**	89	NA		Fruit	Fruit	Fruit
						0	(0.008)	ND	ND
						1	(0.007)	ND	(0.006)
						3	ND	ND	ND
						7	ND	ND	(0.005)
						10	ND	ND	(0.003)
Doc ID: CEMR-4703 (Study no:	Cucumber Outdoor	2225 Üllö, Pest, Hungary.	1 x 24.7 **GF-2626**	79-81	NA		Fruit	Fruit	Fruit
						0	0.039	ND	ND

Residue trial number	Crop	Country and year	Application rate (g as/ha)	Growth stage at last treatment	Interval between applications (days)	PHI days	Residues found (mg/kg)		
							Sulfoxaflor	Metabolite X11719474	Metabolite X11721061
101464) Trial 3: CEMS-4703C		2010 NEU				1 3 8 10	0.020 0.015 (0.006) ND	ND ND ND ND	(0.004) (0.005) (0.005) ND
			1 x 47.7 **GF-2626**	79-81	NA		Fruit 	Fruit 	Fruit
						0 1 3 8 10	0.064 0.059 0.019 (0.008) 0.012	ND (0.003) ND ND ND	(0.005) (0.005) ND (0.005) (0.005)
Doc ID: CEMR-4703 (Study no: 101464) Trial 4: CEMS-4703D	Cucumber Outdoor	15938 Schöneiche, Brandenburg, Germany. 2010 NEU	1 x 25.9 **GF-2626**	88	NA		Fruit 	Fruit 	Fruit
						0 1 3 7 10	0.053 0.020 (0.009) (0.006) (0.008)	ND ND ND ND ND	(0.004) (0.005) (0.004) (0.003) (0.005)
			1 x 51.2 **GF-2626**	88	NA		Fruit 	Fruit 	Fruit
						0 1 3 7 10	0.074 0.052 0.015 0.016 0.011	ND ND ND ND ND	(0.005) (0.004) (0.005) (0.005) (0.005)

Summary of SEU data

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-4703E CEMS-4703 DAS Report #:101464 Y 2010	cucumber Raider	France SZ Outdoor (field)	GF-2626	1	55.9	546	10.2	20-Sep-10	BBCH.65 to 85	0 1 3 7 10	Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit	0.086 **0.042** 0.023 <0.01 0.010	<0.01 <0.01 <0.01 <0.01 <0.01	0.095 **0.051** 0.032 <0.019 0.019
CEMS-4703F CEMS-4703 DAS Report #:101464 Y 2010	cucumber Kassip	Greece SZ Outdoor (field)	GF-2626	1	48.2	1004	4.8	10-Aug-10	BBCH.75	0 1 3 7 10	Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit	0.018 **0.014** <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	0.027 **0.023** <0.019 <0.019 <0.019
CEMS-4703G CEMS-4703 DAS Report #:101464 Y 2010	cucumber Canan	Italy SZ Outdoor (field)	GF-2626	1	50.2	982	5.1	05-Jul-10	BBCH.87	0 1 3 7 10	Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit	0.027 **0.025** 0.013 0.013 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	0.036 **0.034** 0.022 0.022 <0.019
CEMS-4703H CEMS-4703 DAS Report #:101464 Y 2010	cucumber Serena	Spain SZ Outdoor (field)	GF-2626	1	49.9	832	6.0	21-Jun-10	BBCH.85	0 1 3 7 10	Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit	0.017 **0.010** <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	0.026 **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 8.3.9.2 New data

IIIA 8.3.9.2.1 Study 1

Report:	IIIA 8.3.6.1/02, Rawle, N. W., 2012
Title:	Residues of sulfoxaflor in cucumbers at intervals and harvest following a single application of GF-2626 – Northern and Southern Europe - 2011
Document No:	Study ID : CEMS-5013, Report ID : CEMR-5013 Dow AgroSciences Reference : GHE-P-12709
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	None with impact on the study

Table IIIA 8.3.9-2: 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)	Method N°091031 LC-MS/MS
LoQ (mg/kg)	0.01mg/kg

Table IIIA 8.3.9-3: Summary of the study 1 trials

N° Trial		CEMS-5013A	CEMS-5013B	CEMS-5013C	CEMS-5013D	CEMS-5013E	CEMS-5013F	CEMS-5013G	CEMS-5013H
North/South/Indoor		N	N	N	N	S	S	S	S
Decline (D)/Harvest (H) trial?		D	D	D	D	D	D	D	D
Formulation		SC	SC	SC	SC	SC	SC	SC	SC
Equivalence between formulations		Y	Y	Y	Y	Y	Y	Y	Y
Accordance with intended GAP		Y	Y	Y	Y	Y	Y	Y	Y
Correct sampling		Y	Y	Y	Y	Y	Y	Y	Y
Samples frozen within 24h		Y	Y	Y	Y	Y	Y	Y	Y
Storage period (in days)	Sample	220	231	210	256	258	237	273	231
	Extract[1]	5	5	5	5	5	5	5	5
Storage T° <-18°C		Y	Y	Y	Y	Y	Y	Y	Y
Validated analytical method		Y	Y	Y	Y	Y	Y	Y	Y
Negative controls		Y	Y	Y	Y	Y	Y	Y	Y
Considered trial		Y	Y	Y	Y	Y	Y	Y	Y
Remarks									

[1] The procedural recoveries demonstrate the stability of the analyte during this storage period (up to 5 days)." (CEMR-5013, p.20)

Table IIIA 8.3.9-4: Summary of data from residue trials for study 1

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Active ingredient : Sulfoxaflor
Crop / crop group : Fruiting Vegetables : Cucumbers

Notifier: Dow AgroSciences, European Development Centre

Content of a.i. (g/kg or g/l) : 120 g/L
Formulation (e.g. WP) : SC
Commercial product (name) : GF-2626
Applicant : Eurofins AgroScience Services GmbH

Indoors / outdoors : Outdoor
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 (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-5013A CEMS-5013 GHE-P-12709 Y 2011	Cucumbers Raider	France (NZ) 49650 Allones Maine et Loire Outdoor (field)	GF-2626	1	48.3	1006	4.8	16-Aug-11	85	0 1 3 7 10	Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit	0.024 **0.024** <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	0.033 **0.033** <0.019 <0.019 <0.019	
CEMS-5013B CEMS-5013 GHE-P-12709 Y 2011	Cucumber Travito	Germany 74626 Bretzfeld Baden- Württemberg Outdoor (field)	GF-2626	1	48.7	710	6.9	05-Aug-11	87-89	0 1 3 7 10	Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit	0.019 **0.01** <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	0.028 **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-5013C CEMS-5013 GHE-P-12709 Y 2011	Cucumbers Trilogy F1	Hungary 4821 Opalyi Szabalcs- Szaemar- Bereg Outdoor (field)	GF- 2626	1	47.7	795	6.0	26-Aug- 2011	83	0 1 3 7 10	Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit	0.062 **0.023** 0.022 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	0.071 **0.032** 0.031 <0.019 <0.019	
CEMS-5013D CEMS-5013 GHE-P-12709 Y 2011	Cucumbers Lothar F1	Germany 69124 Kirchheim Baden- Württemberg Outdoor (field)	GF- 2626	1	51.4	643	8.0	11-Jul-11	79	0 1 3 7 10	Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit	0.010 **<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	
CEMS-5013E CEMS-5013 GHE-P-12709 Y 2011	Cucumber Bowing	France (SZ) 30128 Garons, Gard Outdoor (field)	GF- 2626	1	49.9	945	5.3	05-Jul-11	BBCH.89	0 1 3 7 10	Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit	<0.01 **0.014** <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	<0.019 **0.023** <0.019 <0.019 <0.019	
CEMS-5013F CEMS-5013 GHE-P-12709 Y 2011	Cucumber Illas	Greece (SZ) 57008, Nea Magnisia, Thessaloniki Outdoor (field)	GF- 2626	1	47.3	985	4.8	26-Jul-11	BBCH.73	0 1 3 7 10	Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit	0.017 **<0.01** <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	0.026 **<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-5013G CEMS-5013 GHE-P-12709 Y 2011	Cucumber Okron	Italy (SZ) 04022, Fondi, Latina Outdoor (field)	GF-2626	1	45.6	958	4.8	20-Jun-11	BBCH.87	0 1 3 7 10	Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit	0.028 **0.021** 0.014 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	0.037 **0.030** 0.023 <0.019 <0.019	
CEMS-5013H CEMS-5013 GHE-P-12709 Y 2011	Cucumber Basher	Spain (SZ) 41520, El Viso del Arcor, Andalucia Outdoor (field)	GF-2626	1	54.1	1127	4.8	01-Aug-11	BBCH.85	0 1 3 7 10	Whole fruit Whole fruit Whole fruit Whole fruit Whole fruit	0.012 **≤0.01** <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	0.021 **≤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

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

IIIA 8.3.9.3 Summary of monograph and new data supporting the intended use on cucumber and conformity to existing MRL

Table IIIA 8.3.9-5: Summary of monograph and new data supporting the intended use on crop 1 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
Cucumber Courgette Gerkins	Monograph	North (4)	Trials GAP: 1x48 g a.s./ha – PHI 1 day Mo : <0.01, 0.023, 0.052, 0.059 Ra : <0.019, 0.032, 0.061, 0.068	0.038	0.059				Reg EU 2016/1: 0.03 on cucumbers and courgettes 0.01* on gherkins and others SANTE/11442/2016: 0.5 on cucurbits with edible peel	Yes
		South (4)	Trials GAP: 1x48 g a.s./ha – PHI 1 day Mo : <0.01, 0.014, 0.025, 0.042 Ra : <0.019, 0.023, 0.034, 0.051	0.020	0.042					
	New trials	North (4)	Trials GAP: 1x48 g a.s./ha – PHI 1 day Mo : <0.01, 0.01, 0.023, 0.024 Ra : <0.0.19, 0.019, 0.032, 0.033	0.017	0.024					
		South (4)	Trials GAP: 1x48 g a.s./ha – PHI 1 day Mo : 2 x <0.01, 0.014 ; 0.021 Ra : 2 x <0.019, 0.023, 0.030	0.012	0.021					
	Overall supporting data for FR, IT, SP & SEU GAP	North (8)	Trials GAP: 1x48 g a.s./ha – PHI 1 day Mo : 2 x <0.01, 0.01, 2 x 0.023, 0.024, 0.052, 0.059	0.023	0.059	0.090	0.087	0.103 →0.1		
			Ra : 2 x <0.019, 0.019, 2x 0.032, 0.033, 0.061, 0.068	0.033	0.068					
		South (8)	Trials GAP: 1x48 g a.s./ha – PHI 1 day Mo : 3 x <0.01, 2 x 0.014, 0.021, 0.025, 0.042	0.014	0.042	0.037	0.054	0.063 →0.07		
			Ra :3 x <0.019, 0.032, 2 x 0.033, 0.034, 0.051	0.033	0.051					

Source of EU MRL: EU MRL data base: http://ec.europa.eu/sanco_pesticides/public/index.cfm

IIIA 8.3.9.4 Conclusion for cucumber, courgette and gherkin

According to EU guideline 7525/VI/95-rev.10, Appendix D « Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs», extrapolation of residue data from courgette and or cucumber to the whole group of cucurbit with edible peel is possible when the application is performed close to harvest.

A total of 8 southern residues trials and 8 northern residue trials are available to support 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 current MRLs of 0.03 mg/kg on cucumber and courgette and of 0.01* mg/kg on gherkin will be exceed according to the intended GAP in EU.
Nevertheless on the basis of the available supporting residue data it is possible to conclude that the proposed MRL of 0.5 mg/kg on cucurbits with edible peel (document SANTE/1142/2016) will not be exceeded according to the intended GAP.

IIIA 8.3.10 MELON, WATER MELON, PUMPKIN

Table IIIA 8.3.10-1: Comparison of intended and critical EU GAPs

Crop	Type of GAP	Number of applications	Application rate per treatment	Interval between application	Growth stage at last application	PHI (days)
Melon Watermelon	EU (DAR)[1]	1	24 g a.s./ha	-	BBCH 20 – 39 BBCH 40 - 89 Apr - Nov	≥1
	MRL application (USA)[2]	4	78 g a.s./ha	7	BBCH 89	1
Melon Watermelon pumpkin	Intended FR and SEU	1	48 g a.s./ha	-	BBCH 20-87	1
		2	24 g a.s./ha	7		1

[1] Representative Use
[2]MRL Application – import tolerance, MRL assessed according to USA authorised cGAPs

IIIA 8.3.10.1 Summary of B.7.6 Data

Uses on melon and water melon have been assessed in the framework of the approbation of the active substance as a representative use.
Furthermore these uses have also been assessed in the meantime of the EU evaluation of sulfoxaflor, in the framework of MRL application based on an import tolerance from USA. Nevertheless as trials were not in compliance with the authorised GAP or were not sufficient to calculate an MRL based on the authorized GAP in US, no MRL import tolerance was proposed by EFSA.
So, in force MRL of 0.02 mg/kg (Reg EU 2016/1) was derived from EU representative uses.
Later the existing CXL of 0.5 mg/kg on cucurbits with inedible peel was voted at EU level and proposed in document SANTE/11442/2016.

The intended GAP is more critical than the representative EU uses of sulfoxaflor which was assessed in the framework of the approbation of active substance.
However from the available trials reported in the monograph of active substance some are considered suitable to support the intended GAP. They were performed in southern EU with 1 applications at ca 48 g a.s./ha, PHI of 0 to 10 days.

Characteristics and results of the supported trials are summarized below.
Residue levels of sulfoxaflor and metabolite X11719474 in melon from trials considered suitable to support the intended GAP are underlined.

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-4706A CEMS-4706 DAS Ref. ID 101467 Y 2010	Melon Anasta	France SZ Outdoor (field)	GF-2626	1	53.5	622	8.6	23-Aug-10	BBCH.85	0	Peel	0.033	<0.01	0.042
										1	Peel	0.017	<0.01	0.026
										3	Peel	0.015	<0.01	<0.019
										7	Peel	<0.01	<0.01	<0.019
										10	Peel	<0.01	<0.01	<0.019
										0	Pulp	<0.01	<0.01	<0.019
										1	Pulp	<0.01	<0.01	<0.019
										3	Pulp	<0.01	<0.01	<0.019
										7	Pulp	<0.01	<0.01	<0.019
										10	Pulp	<0.01	<0.01	<0.019
										0	Whole Fruit	0.018	<0.01	0.027
										1	Whole Fruit	0.010	<0.01	0.019
										3	Whole Fruit	**0.011**	<0.01	**0.020**
										7	Whole Fruit	<0.01	<0.01	<0.019
										10	Whole Fruit	<0.01	<0.01	<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-4706B CEMS-4706 DAS Ref. ID 101467 Y 2010	Melon Galia F1	Greece SZ Outdoor (field)	GF-2626	1	47.5	990	4.8	04-Aug-10	BBCH.84	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	0.045 0.035 0.048 0.017 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 0.030 0.024 **0.034** 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	0.054 0.044 0.057 0.026 <0.019 <0.019 <0.019 <0.019 <0.019 <0.019 0.039 0.033 **0.043** 0.020 <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-4706C CEMS-4706 DAS Ref. ID 101467 Y 2010	Melon Bacir	Italy SZ Outdoor (field)	GF-2626	1	52.3	511	10.2	13-Jul-10	BBCH.87 to 89	0	Peel	<0.01	<0.01	<0.019
										1	Peel	<0.01	<0.01	<0.019
										3	Peel	<0.01	<0.01	<0.019
										7	Peel	<0.01	<0.01	<0.019
										9	Peel	<0.01	<0.01	<0.019
										0	Pulp	<0.01	<0.01	<0.019
										1	Pulp	<0.01	<0.01	<0.019
										3	Pulp	<0.01	<0.01	<0.019
										7	Pulp	<0.01	<0.01	<0.019
										9	Pulp	<0.01	<0.01	<0.019
										0	Whole Fruit	<0.01	<0.01	<0.019
										1	Whole Fruit	**<0.01**	<0.01	**<0.019**
										3	Whole Fruit	<0.01	<0.01	<0.019
										7	Whole Fruit	<0.01	<0.01	<0.019
										9	Whole Fruit	<0.01	<0.01	<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-4706D CEMS-4706 DAS Ref. ID 101467 Y 2010	Melon Nicolas	Spain SZ Outdoor (field)	GF-2626	1	50.7	845	6.0	13-Jul-10	BBCH.82 to 84	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	0.010 <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

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

IIIA 8.3.10.2 New data

IIIA 8.3.10.2.1 Study 1

Report:	IIIA 8.3.6.2/02, Rawle, N. W., 2012
Title:	Residues of sulfaxoflor in outdoor melons at intervals and harvest following a single application of GF-2626 – Northern and Southern Europe - 2011
Document No:	Study ID : CEMS-5015, Report ID : CEMR-5015 Dow AgroSciences Reference : GHE-P-12711
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 8.3.10-2: 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)	Method N°091031 LC-MS/MS
LoQ (mg/kg)	0.01 mg/kg

Table IIIA 8.3.10-3: Summary of the study 1 trials

N° Trial		CEMS-5015E	CEMS-5015F	CEMS-5015G	CEMS-5015H
North/South/Indoor		S	S	S	S
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	289	253	274	338
	Extract[1]	7	7	7	7
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] The procedural recoveries demonstrate the stability of the analyte during this storage period (up to 7 days) (CEMR-5015, p.24)

Table IIIA 8.3.10-4: 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

Content of a.i. (g/kg or g/l) : 120 g/L
Formulation (e.g. WP) : SC
Commercial product (name) : GF-2626
Applicant : Eurofins AgroScience Services GmbH

Active ingredient : Sulfoxaflor
Crop / crop group : Fruiting Vegetables : Melons

Indoors / outdoors : Outdoor
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 (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-5015E CEMS-5015 GHE-P-12711 Y 2011	Melon Stellio	France (SZ) 66670 Bages, Pyrénées- Orientales Outdoor (field)	GF-2626	1	49.4	1021	4.8	25-Jul-11	BBCH.85 to 86	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 0.012 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 0.015 **<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 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.031 0.021 <0.019 <0.019 <0.019 <0.019 <0.019 <0.019 <0.019 <0.019 0.024 **<u>≤0.019</u>** <0.019 <0.019 <0.019	Formula for whole fruit residue rate calculation missing

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-5015F CEMS-5015 GHE-P-12711 Y 2011	Melon Orestiados	Greece (SZ) 57011 Prochoma, Thessaloniki Outdoor (field)	GF-2626	1	48.3	603	8.0	30-Aug-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	0.025 0.021 0.011 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 0.016 **0.013** <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	0.034 0.030 0.020 <0.019 <0.019 <0.019 <0.019 <0.019 <0.019 <0.019 0.025 **0.022** <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-5015G CEMS-5015 GHE-P-12711 Y 2011	Melon Bacir	Italy (SZ) 40054 Budrio, Emilia Romagna Outdoor (field)	GF-2626	1	49.4	518	9.5	09-Aug-11	BBCH.85 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 <0.01 <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 (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-5015H CEMS-5015 GHE-P-12711 Y 2011	Melon Albero	Spain (SZ) 41720, Los Palacios y Villafranca, Sevilla Outdoor (field)	GF-2626	1	49.7	1035	4.8	06-Jun-11	BBCH.85	0	Peel	0.016	<0.01	0.025	
										1	Peel	0.012	<0.01	0.021	
										3	Peel	<0.01	<0.01	<0.019	
										7	Peel	<0.01	<0.01	<0.019	
										10	Peel	<0.01	<0.01	<0.019	
										0	Pulp	<0.01	<0.01	<0.019	
										1	Pulp	<0.01	<0.01	<0.019	
										3	Pulp	<0.01	<0.01	<0.019	
										7	Pulp	<0.01	<0.01	<0.019	
										10	Pulp	<0.01	<0.01	<0.019	
										0	Whole Fruit	<0.01	<0.01	<0.019	
										1	Whole Fruit	**<0.01**	<0.01	**<0.019**	
										3	Whole Fruit	<0.01	<0.01	<0.019	
										7	Whole Fruit	<0.01	<0.01	<0.019	
										10	Whole Fruit	<0.01	<0.01	<0.019	

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

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

IIIA 8.3.10.3 Summary of monograph and new data supporting the intended use on Crop 1 and conformity to existing MRL

Table IIIA 8.3.10-5: Summary of monograph and new data supporting the intended use on crop 1 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
Melon	Monograph	South (4)	Trials GAP: 1x48 g a.s./ha – PHI 1 day MO : 2 x <0.01, 0.011 ; 0.034 RA: 2 x <0.019, 0.02, 0.043 RA pulp : 4 x <0.019	0.011	0.034				Reg EU 2016/1: 0.02 Melon and watermelon 0.01*pumpkins SANTE/11442/2016 0.5 for cucurbit with inedible peel	Yes
	New trials	South (4)	Trials GAP: 1x48 g a.s./ha – PHI 1 day MO : 3 x <0.01 ; 0.013 RA: 3 x <0.019, 0.022 RA pulp: 4 x <0.019	0.010	0.013					
	Overall supporting data for FR, IT, SP & SEU GAP	South (8)	Trials GAP: 1x48 g a.s./ha – PHI 1 day MO : 5 x <0.01, 0.011, 0.013, 0.034	0.010	0.034	0.025	0.040	0.047 (0.05)		
			RA: 5 x <0.019, 0.02, 0.022, 0.043 RA pulp: 8 x <0.019	0.019	0.043					

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

IIIA 8.3.10.4 Conclusion for melon

According to EU guideline 7525/VI/95-rev.10, Appendix D « Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs», extrapolation of residue data from melon to the whole group of cucurbit with inedible peel is possible when the application is performed close to harvest.

A total of 8 southern residues trials are available to support 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 current MRLs of 0.02 mg/kg on melon and watermelon and of 0.01* mg/kg on pumpkins will be exceed according to the intended GAP in EU.
Nevertheless on the basis of the available supporting residue data it is possible to conclude that the proposed MRL of 0.5 mg/kg on cucurbits with inedible peel (document SANTE/11442/2016) will not be exceeded according to the intended GAP.

IIIA 8.3.11 FLOWERING BRASSICA

Table IIIA 8.3.11-1: Comparison of intended and critical EU GAPs

Crop	Type of GAP	Number of applications	Application rate per treatment	Interval between application	Growth stage at last application	PHI (days)
Broccoli	DAR MRL Application (USA)[1]	1-3	100 g a.s./ha	7	Up to BBCH 49	3
	DAR MRL Application (AUS)[1]	1-4	96 a.s./ha	7	Up to BBCH 49	3
	Intended FR and SEU	1	24 g a.s./ha	-	BBCH 20-49	7
Cauliflower	DAR MRL Application (AUS)[1]	1-4	96 a.s./ha	7	Up to BBCH 49	3
	Intended FR and SEU	1	24 g a.s./ha	-	BBCH 20-49	7

[1] MRL Application – import tolerance

IIIA 8.3.11.1 Summary of B.7.6 Data

Use on broccoli has been assessed in the meantime of the EU evaluation of sulfoxaflor, in the framework of MRL application for an import tolerance.
However this MRL application is based on US and Australian GAP and residue trials supporting the import tolerance have been performed outside EU (USA). Therefore they cannot be used to support the intended GAP.
Based on the supporting residue data an MRL of 0.7 mg/kg based on US GAP was proposed by EFSA and then adopted at EU level in Regulation 2016/1. (No MRL was derived based on the Australian GAP as insufficient residue trial performed according to the authorized GAP was available).
It should be noted that in the evaluation report EU trials are also summarized (IE, 2012). They were performed according to a more critical GAP than intended one (4 applications at ca 100 g as/ha).
Later the existing CXL of 3 mg/kg on broccoli was voted at EU level and proposed in document SANTE/11442/2016.

Use on cauliflower has been assessed in the meantime of the EU evaluation of sulfoxaflor, in the framework of MRL application for an import tolerance.
However this MRL application is based on an Australian GAP and residue trials submitted to the support the import tolerance have been performed outside EU (US and Canadian) and then they cannot be considered to support the intended use of GF-2626 on cauliflower in EU
Furthermore as trials were not in compliance with the authorised GAP or were not sufficient to calculate an MRL based on the authorized GAP in Australia no MRL was proposed by EFSA and then a default MRL of 0.01* mg/kg was set for cauliflower at EU level in Regulation 2016/1.
Later the existing CXL of 0.04 mg/kg on cauliflower was voted at EU level and proposed in document SANTE/11442/2016.

It should be noted that in the evaluation report EU trials are also summarized (IE, 2012). They were performed according to a more critical GAP than intended one (4 applications at ca 100 g as/ha).

IIIA 8.3.11.2 New data

IIIA 8.3.11.2.1 Study 1

Report:	IIIA 8.3.7.1/01, Rawle, N. W., 2012
Title:	Residues of XDE-208 in broccoli at intervals and harvest following a single application of GF-2032 – Northern and Southern Europe - 2008
Document No:	Study ID : CEMS-3944, Report ID : CEMR-3944 Dow AgroSciences Reference ID 080033-01
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" - OECD Guidelines for the Testing of Chemicals, No. 509: Crop Field Trial, 2009.
GLP	Yes

Acceptability	**Deviations**
Yes	None with impact on the study

Table IIIA 8.3.11-2: Summary of global information on study 1

Comparative trials (between formulations, with and adjuvant/safener/synergist)	No, SC formulation containing 240 g/L XDE-208
Number of applications	1
Dose (g as/ha)	24 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)	Method N° 091031 LC-MS/MS
LoQ (mg/kg)	0.01mg/kg

Table IIIA 8.3.11-3: Summary of the study 1 trials

N° Trial		CEMS-3944A	CEMS-3944B	CEMS-3944C	CEMS-3944D
North/South/Indoor		N	N	S	S
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	168	282	241	248
	Extract[1]	Max 22	Max 22	Max 22	Max 22
Storage T° <-18°C		Y	Y	Y	Y
Validated analytical method		Y	Y	Y	Y

Negative controls	N[2]	Y	Y	Y
Considered trial	N	Y	Y	Y
Remarks	2			

[1] The procedural recoveries demonstrate the stability of the analyte during the storage period (up to 22 days).” (CEMR-3944, p.17)
[2] One control sample was not negative (XDE-208 = 0.141 mg/ kg, PHI 7d)

Table IIIA 8.3.11-4: 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
Content of a.i. (g/kg or g/l) : 240 g/L
Formulation (e.g. WP) : SC
Commercial product (name) : GF-2032
Applicant : Eurofins AgroScience Services GmbH

Active ingredient : Sulfoxaflor
Crop / crop group : Brassicas : Broccoli
Indoors / outdoors : Outdoor
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 (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-3944A CEMS-3944 DAS Ref# 080033-01 Y 2009	Broccoli Parthenon	United Kingdom (NZ) PR4-6XT Sealand, Clwyd Outdoor (field)	GF-2032	1	24.1	499	4.8	08-Jan-2009	BBCH.45 to 46	0 1 3 7 10	Inflorescence Inflorescence Inflorescence Inflorescence Inflorescence	0.115 0.114 0.102 0.070 0.077	<0.01 <0.01 <0.01 <0.01 <0.01	0.124 0.123 0.111 0.079 0.086	Residue in control samples XDE-208 = 0.141 mg/kg, PHI 7d
CEMS-3944B CEMS-3944 DAS Ref# 080033-01 Y 2008	Broccoli Ironman	Germany (NZ) 25348 Blomesche Wildnis, Schleswig-Holstein Outdoor (field)	GF-2032	1	25.3	527	4.8	16-Sep-2008	BBCH.49	0 1 3 7 10	Inflorescence Inflorescence Inflorescence Inflorescence Inflorescence	0.045 0.019 0.011 **<0.01** <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	0.054 0.028 0.020 **<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-3944C CEMS-3944 DAS Ref# 080033-01 Y 2008	Broccoli Emecouet e	France (SZ) 66700 Angelès- sur-Mer Languedoc- Roussillon Outdoor (field)	GF- 2032	1	24	800	3.0	27-Oct- 2008	BBCH.49	0 1 3 7 10	Inflorescence Inflorescence Inflorescence Inflorescence Inflorescence	0.061 0.025 0.012 **<u><0.01</u>** <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	0.070 0.034 0.021 **<u><0.019</u>** <0.019	
CEMS-3944D CEMS-3944 DAS Ref# 080033-01 Y 2008	Broccoli Marathon	Greece(SZ) 55133 Ionia Thessalonik i Outdoor (field)	GF- 2032	1	23.3	485	4.8	20-Oct- 2008	BBCH.47	0 1 3 7 10	Inflorescence Inflorescence Inflorescence Inflorescence Inflorescence	0.031 0.039 0.018 **<u>0.010</u>** <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	0.040 0.048 0.027 **<u>0.019</u>** <0.019	

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

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
Note: All entries to be filled in as appropriate

IIIA 8.3.11.2.2 Study 2

Report:	IIIA 8.3.7.1/02, Rawle, N. W., 2012
Title:	Residues of sulfoxaflor in broccoli at intervals and harvest following a single application of GF-2626 – Northern and Southern Europe - 2011
Document No:	Study ID : CEMS-5018, Report ID : CEMR-5018 Dow AgroSciences Reference GHE-P-12714
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 8.3.11-5: Summary of global information on study 2

Comparative trials (between formulations, with and adjuvant/safener/synergist)	No, SC formulation containing 240 g/L XDE-208
Number of applications	1
Dose (g as/ha)	24 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)	Method N°091031 Liquid Chromatography/Mass Spectrometry
LoQ (mg/kg)	0.01mg/kg

Table IIIA 8.3.11-6: Summary of the study 2 trials

N° Trial		CEMS-5018A	CEMS-5018B	CEMS-5018C	CEMS-5018D	CEMS-5018E	CEMS-5018F	CEMS-5018G	CEMS-5018H
North/South/Indoor		N	N	N	N	S	S	S	S
Decline (D)/Harvest (H) trial?		D	D	D	D	D	D	D	D
Formulation		SC	SC	SC	SC	SC	SC	SC	SC
Equivalence between formulations		Y	Y	Y	Y	Y	Y	Y	Y
Accordance with intended GAP		Y	Y	Y	Y	Y	Y	Y	Y
Correct sampling		Y	Y	Y	Y	Y	Y	Y	Y
Samples frozen within 24h		Y	Y	Y	Y	Y	Y	Y	Y
Storage period (in days)	Sample	204	210	274	160	229	217	350	240
	Extract	1	[1]	1	1	1	1	1	1
Storage T° <-18°C		Y	Y	Y	Y	Y	Y	Y	Y
Validated analytical method		Y	Y	Y	Y	Y	Y	Y	Y
Negative controls		Y	Y	Y	Y	Y	Y	Y	Y
Considered trial		Y	Y	Y	Y	Y	Y	Y	Y
Remarks									

Table IIIA 8.3.11-7: Summary of data from residue trials for study 2

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

Content of a.i. (g/kg or g/l) : 120 g/L
Formulation (e.g. WP) : SC
Commercial product (name) : GF-2626
Applicant : Eurofins AgroScience Services GmbH

Active ingredient : Sulfoxaflor
Crop / crop group : Brassicas : Broccoli

Indoors / outdoors : Outdoor
Other a. s. in formulation : None
(common name and content) : -
Residues calculated as : XDE-208 + X11719474

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)**	**X1171947 4 (mg/kg)**	**Total * (mg/kg)**	
CEMS-5018A CEMS-5018 GHE-P-12714 Y 2011	Broccoli Steel	United Kingdom (NZ) PR4 6XS, Hesketh Bank, Lancashire Outdoor (field)	GF-2626	1	25.0	420	6.0	31-Oct-2011	BBCH.43 to 45	0 1 3 7 10	Inflorescence Inflorescence Inflorescence Inflorescence Inflorescence	0.060 0.017 0.011 **<u>≤0.01</u>** <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	0.069 0.026 0.020 **<u>≤0.019</u>** <0.019	
CEMS-5018B CEMS-5018 GHE-P-12714 Y 2011	Broccoli Lord	Poland (NZ) 62-001 Wargowo, Wielkopolska Outdoor (field)	GF-2626	1	25.9	432	6.0	25-Oct-2011	BBCH.47	0 1 3 7 10	Inflorescence Inflorescence Inflorescence Inflorescence Inflorescence	0.046 0.038 0.018 **<u>≤0.01</u>** <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	0.055 0.047 0.027 **<u>≤0.019</u>** <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)**	**X1171947 4 (mg/kg)**	**Total * (mg/kg)**	
CEMS-5018C CEMS-5018 GHE-P-12714 Y 2011	Broccoli Ironman	Germany (NZ) 71277 Perousse, Baden- Württemberg Outdoor (field)	GF- 2626	1	23.8	298	8.0	22-Aug- 2011	BBCH.4 7	0 1 3 7 10	Inflorescence Inflorescence Inflorescence Inflorescence Inflorescence	0.074 0.068 0.045 0.015 **0.020**	<0.01 <0.01 <0.01 <0.01 <0.01	0.083 0.077 0.054 0.024 **0.029**	
CEMS-5018D CEMS-5018 GHE-P-12714 Y 2011	Broccoli Panteon	Hungary (NZ) 5900, Oroshaza, Bekes Outdoor (field)	GF- 2626	1	24.4	509	4.8	14-Dec- 2011	BBCH.4 9	0 1 3 7 10	Inflorescence Inflorescence Inflorescence Inflorescence Inflorescence	0.044 <0.01 <0.01 **<0.01** <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	0.053 <0.019 <0.019 **<0.019** <0.019	
CEMS-5018E CEMS-5018 GHE-P-12714 Y 2011	Broccoli Marathon	Greece (SZ) 57008 Nea Magnisia, Thessaloniki Outdoor (field)	GF- 2626	1	23.4	585	4.0	07-Oct- 2011	BBCH.4 6	0 1 3 7 10	Inflorescence Inflorescence Inflorescence Inflorescence Inflorescence	0.013 0.020 0.013 **<0.01** <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	0.022 0.029 0.022 **<0.019** <0.019	
CEMS-5018F CEMS-5018 GHE-P-12714 Y 2011	Broccoli Faros	Bulgaria (SZ) 4488 Zvanichevo, Pazardjik Outdoor (field)	GF- 2626	1	23.8	397	6.0	19-Oct- 2011	BBCH.4 8	0 1 3 7 10	Inflorescence Inflorescence Inflorescence Inflorescence Inflorescence	0.043 0.035 0.017 **0.016** 0.014	<0.01 <0.01 <0.01 <0.01 <0.01	0.052 0.044 0.026 **0.025** 0.024	

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**)**	**X1171947 4 (**mg/kg**)**	**Total * (**mg/kg**)**	
CEMS-5018G CEMS-5018 GHE-P-12714 Y 2011	Broccoli Heracleon	Italy (SZ) 40057 Granarolo, Emilia Romagna Outdoor (field)	GF- 2626	1	24.8	313	8.0	08-Jun- 2011	BBCH.4 5 to 47	0 1 3 7 9	Inflorescence Inflorescence Inflorescence Inflorescence Inflorescence	0.044 0.064 0.016 **<u>0.01</u>** <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	0.053 0.073 0.025 **<u>0.019</u>** <0.019	
CEMS-5018H CEMS-5018 GHE-P-12714 Y 2011	Broccoli Ironman	France (SZ) 31330 Merville, Midi Pyrénées Outdoor (field)	GF- 2626	1	23.6	393	6.0	26-Sep- 2011	BBCH.4 5 to 49	0 1 3 7 10	Inflorescence Inflorescence Inflorescence Inflorescence Inflorescence	0.057 0.036 0.011 **<u>0.01</u>** <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	0.066 0.045 0.020 **<u>0.019</u>** <0.019	

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

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

IIIA 8.3.11.2.3 Study 3

Report:	IIIA 8.3.7.1/03, Rawle, N. W., 2012s
Title:	Residues of XDE-208 in cauliflower at intervals and harvest following a single application of GF-2032 – Northern and Southern Europe - 2008
Document No:	CEMR-3946
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 WorkingDocument 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation andRealisation of Residue Trials, July 22, 1997", OECD Guidelines for the Testing ofChemicals, No. 509: Crop Field Trial, 2009.
GLP	Yes

Acceptability	**Deviations**
Yes	None with impact on the study

Table IIIA 8.3.11-8: Summary of global information on study 3

Comparative trials (between formulations, with and adjuvant/safener/synergist)	No
Number of applications	1
Dose (g as/ha)	24 g as/ha
Mode of application	Foliar application
PHI (days) and/or growth stage (BBCH)	0, 1, 3, 7 and 10
Analytical method (Code +Type)	Method N°091031 LC-MS/MS
LoQ (mg/kg)	0.01

Table IIIA 8.3.11-9: Summary of the study 3 trials

N° Trial		CEMR-3946A	CEMR-3946B	CEMR-3946C	CEMR-3946D
North/South/Indoor		N	N	S	S
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	265	265	265	265
	Extract[1]	19	19	19	19
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]The procedural recoveries demonstrate the stability of the analyte during the storage period (up to 19 days)

Table IIIA 8.3.11-10: Summary of data from residue trials for study 3

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)
Notifier: Dow AgroSciences
Content of a.i. (g/kg or g/l) : 240 g/l
Formulation (e.g. WP) : SC
Commercial product (name) : GF-2032
Applicant :

Active ingredient : Sulfoxaflor
Crop / crop group : Cauliflower
Indoors / outdoors : Outdoor
Other a. s. in formulation : None
(common name and content) :
Residues calculated as : XDE-208 + X11719474

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 ()**	**Appl Date**	**GS at Last Appl**	**PHI (days)**	**Portion Analysed**	**XDE-208 (**mg/kg**)**	**X11719474 (**mg/kg**)**	**Total * (**mg/kg**)**
CEMS-3946A CEMS-3946 DAS Ref. ID 080033-03 Y 2008	Cauli-flower Clarify	Germany NZ Outdoor (field)	GF-2032	1	24.3	507	4.8	14-Oct-2008	BBCH.49	0 1 3 7 10	Inflorescence Inflorescence Inflorescence Inflorescence Inflorescence	<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
CEMS-3946B CEMS-3946 DAS Ref. ID 080033-03 Y 2008	Cauli-flower Glacier	United Kingdom NZ Outdoor (field)	GF-2032	1	24.3	501	4.9	24-Nov-2008	BBCH.47	0 1 3 7 10	Inflorescence Inflorescence Inflorescence Inflorescence Inflorescence	0.021 0.045 0.022 <0.01 **0.028**	<0.01 <0.01 <0.01 <0.01 <0.01	0.030 0.054 0.031 <0.019 **0.037**
CEMS-3946C CEMS-3946 DAS Ref. ID 080033-03 Y 2009	Cauli-flower Optimist	France SZ Outdoor (field)	GF-2032	1	24.1	805	3.0	02-Feb-2009	BBCH.49	0 1 3 7 10	Inflorescence Inflorescence Inflorescence Inflorescence Inflorescence	0.046 <0.01 <0.01 **<0.01** <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	0.055 <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 ()**	**Appl Date**	**GS at Last Appl**	**PHI (days)**	**Portion Analysed**	**XDE-208 (**mg/kg**)**	**X11719474 (**mg/kg**)**	**Total * (**mg/kg**)**
CEMS-3946D CEMS-3946 DAS Ref. ID 080033-03 Y 2008	Cauli- flower Americo	Greece SZ Outdoor (field)	GF- 2032	1	24.4	508	4.8	11-Nov-2008	BBCH.46	0 1 3 7 10	Inflorescence Inflorescence Inflorescence Inflorescence Inflorescence	<0.01 <0.01 <0.01 **<u><0.01</u>** <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	<0.019 <0.019 <0.019 **<u><0.019</u>** <0.019

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

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

IIIA 8.3.11.2.4 Study 4

Report:	IIIA 8.3.7.1/04, Rawle, N. W., 2012t
Title:	Residues of sulfoxaflor in cauliflower at intervals and harvest following a single application of GF-2626 – Northern and Southern Europe – 2011
Document No:	CEMR 5017
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", OECD Guidelines for the Testing of Chemicals, No. 509: Crop Field Trial, 2009.
GLP	Yes

Acceptability	Deviations
Yes	None

Table IIIA 8.3.11-11: Summary of global information on study 4

Comparative trials (between formulations, with and adjuvant/safener/synergist)	No, SC formulation containing 120 g sulfoxaflor/l
Number of applications	1
Dose (g as/ha)	24 g a.s./ha
Mode of application	Foliar application
PHI (days) and/or growth stage (BBCH)	0, 1, 3, 7, 10
Analytical method (Code +Type)	Method N°091031 LC-MS/MS
LoQ (mg/kg)	0.01

Table IIIA 8.3.11-12: Summary of the study 4 trials

N° Trial		CEMR-5017A	CEMR-5017B	CEMR-5017C	CEMR-5017D	CEMR-5017E	CEMR-5017F	CEMR-5017G	CEMR-5017H
North/South/Indoor		S	S	S	S	N	N	N	N
Decline (D)/Harvest (H) trial?		D	D	D	D	D	D	D	D
Formulation		SC	SC	SC	SC	SC	SC	SC	SC
Equivalence between formulations		Y	Y	Y	Y	Y	Y	Y	Y
Accordance with intended GAP		Y	Y	Y	Y	Y	Y	Y	Y
Correct sampling		Y	Y	Y	Y	Y	Y	Y	Y
Samples frozen within 24h		Y	Y	Y	Y	Y	Y	Y	Y
Storage period (in days)	Sample	212	212	212	212	212	212	212	212
	Extract[1]	5	5	5	5	5	5	5	5
Storage T° <-18°C		Y	Y	Y	Y	Y	Y	Y	Y
Validated analytical method		Y	Y	Y	Y	Y	Y	Y	Y
Negative controls		Y	Y	Y	Y	Y	Y	Y	Y
Considered trial		Y	Y	Y	Y	Y	Y	Y	Y
Remarks									

[1]The procedural recoveries demonstrate the stability of the analyte during the storage period (up to 19 days)

Table IIIA 8.3.11-13: Summary of data from residue trials for study 4

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)
Notifier: Dow Agrosciences
address 1
Content of a.i. (g/kg or g/l) : 120 g/l
Formulation (e.g. WP) : SC
Commercial product (name) : GF-2626
Applicant :

Active ingredient : Sulfoxaflor
Crop / crop group : Cauliflower

Indoors / outdoors : Outdoor
Other a. s. in formulation None
(common name and content) : -
Residues calculated as : XDE-208 + X11719474

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 ()**	**Appl Date**	**GS at Last Appl**	**PHI (days)**	**Portion Analysed**	**XDE-208 (**mg/kg**)**	**X11719474 (**mg/kg**)**	**Total * (**mg/kg**)**
CEMS-5017A CEMS-5017 GHE-P-12713 Y 2011	Cauli-flower Jerez	Spain SZ Outdoor (field)	GF-2626	1	25.9	432	6.0	21-Nov-2011	BBCH.45 to 47	0 1 3 7 10	Inflorescence Inflorescence Inflorescence Inflorescence Inflorescence	<0.01 0.013 0.010 **<u><0.01</u>** <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	<0.019 0.022 0.019 **<u><0.019</u>** <0.019
CEMS-5017B CEMS-5017 GHE-P-12713 Y 2011	Cauli-flower Snowboul	Bulgaria SZ Outdoor (field)	GF-2626	1	24.2	504	4.8	27-Sep-2011	BBCH.48	0 1 3 7 10	Inflorescence Inflorescence Inflorescence Inflorescence Inflorescence	0.031 0.036 0.019 **<u><0.01</u>** <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	0.040 0.045 0.028 **<u><0.019</u>** <0.019
CEMS-5017C CEMS-5017 GHE-P-12713 Y 2011	Cauli-flower Appia	France SZ Outdoor (field)	GF-2626	1	25.0	417	6.0	04-Oct-2011	BBCH.41 to 49	0 1 3 7 10	Inflorescence Inflorescence Inflorescence Inflorescence Inflorescence	0.035 <0.01 <0.01 **<u><0.01</u>** <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	0.044 <0.019 <0.019 **<u><0.019</u>** <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 ()**	**Appl Date**	**GS at Last Appl**	**PHI (days)**	**Portion Analysed**	**XDE-208 (mg/kg)**	**X11719474 (mg/kg)**	**Total * (mg/kg)**
CEMS-5017D CEMS-5017 GHE-P-12713 Y 2011	Cauli-flower Oceano	Italy SZ Outdoor (field)	GF-2626	1	25.0	416	6.0	24-Oct-2011	BBCH.47 to 49	0 1 3 7 11	Inflorescence Inflorescence Inflorescence Inflorescence Inflorescence	<0.01 <0.01 <0.01 **<u><0.01</u>** <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	<0.019 <0.019 <0.019 **<u><0.019</u>** <0.019
CEMS-5017E CEMS-5017 GHE-P-12713 Y 2011	Cauli-flower Lecanu	Germany NZ Outdoor (field)	GF-2626	1	24.0	400	6.0	12-Jul-2011	BBCH.47 to 49	0 1 3 7 9	Inflorescence Inflorescence Inflorescence Inflorescence Inflorescence	<0.01 <0.01 <0.01 **<u><0.01</u>** <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	<0.019 <0.019 <0.019 **<u><0.019</u>** <0.019
CEMS-5017F CEMS-5017 GHE-P-12713 Y 2011	Cauli-flower Cartes F1	Hungary NZ Outdoor (field)	GF-2626	1	24.4	509	4.8	06-Dec-2011	BBCH.49	0 1 3 7 10	Inflorescence Inflorescence Inflorescence Inflorescence Inflorescence	<0.01 <0.01 <0.01 **<u><0.01</u>** <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	<0.019 <0.019 <0.019 **<u><0.019</u>** <0.019
CEMS-5017G CEMS-5017 GHE-P-12713 Y 2011	Cauli-flower Naruto	United Kingdom NZ Outdoor (field)	GF-2626	1	22.3	376	5.9	22-Nov-2011	BBCH.48 to 49	0 1 3 7 10	Inflorescence Inflorescence Inflorescence Inflorescence Inflorescence	0.012 <0.01 <0.01 **<u><0.01</u>** <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	0.021 <0.019 <0.019 **<u><0.019</u>** <0.019
CEMS-5017H CEMS-5017 GHE-P-12713 Y 2011	Cauli-flower Aviso	Poland NZ Outdoor (field)	GF-2626	1	25.6	427	6.0	04-Oct-2011	BBCH.48	0 1 3 7 10	Inflorescence Inflorescence Inflorescence Inflorescence Inflorescence	0.026 0.026 <0.01 **<u><0.01</u>** <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	0.035 0.035 <0.019 **<u><0.019</u>** <0.019

IIIA 8.3.11.3 Summary of monograph and new data supporting the intended use on Flowering brassica and conformity to existing MRL

Table IIIA 8.3.11-14: Summary of monograph and new data supporting the intended use on flowering brassica 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
Broccoli cauliflower	New trials Broccoli	North (5)	Trials GAP: 1x24 g a.s./ha – PHI 7 days MO : 4 x <0.01, 0.020 RA : 4 x <0.019, 0.029						Reg EU 2016/1: 0.7 broccoli 0.01* cauliflower SANTE/11442/2016: 3 Broccoli 0.04 Cauliflower	Yes
		South (6)	Trials GAP: 1x24 g a.s./ha – PHI 7 days MO: 4 x <0.01, 0.01, 0.016 RA: 4 x <0.019, 0.019, 0.025							
	New trials Cauliflower	North (6)	Trials GAP: 1x24 g a.s./ha – PHI 7 days MO : 5 x <0.01, 0.028 RA : 5 x <0.019, 0.037							
		South (6)	Trials GAP: 1x24 g a.s./ha – PHI 7 days MO: 6 x <0.01 RA: 6 x <0.019							
	Overall supporting data for FR, IT, SP & SEU GAP	North (11)	MO : 9 x <0.01, 0.02, 0.028	0.010	0.028	0.02	0.029	0.036 (0.04)		
			RA : 9 x <0.019, 0.029, 0.037	0.019	0.037					
		South (12)	MO : 10 x <0.01, 0.01, 0.016	0.010	0.016	0.020	0.015	0.017 (0.02)		
			RA : 10 x <0.019, 0.019, 0.025	0.019	0.025					

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

IIIA 8.3.11.4 Conclusion for flowering brassica

According to EU guideline 7525/VI/95-rev.10, Appendix D « Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs», extrapolation of residue data from broccoli and cauliflower to the whole group of flowering brassica is possible when the application is performed close to harvest.

A total of 12 southern residues trials and 11 northern residue trials are available to support 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 in force MRL of 0.7 mg/kg (Reg EU 2016/1) as well as the proposed MRLof 3 mg/kg (SANTE/11442/2016) on broccoli will not be exceed according to the intended GAP in EU.

On the basis of the available supporting residue data it is possible to conclude that current MRLs of 0.01* mg/kg on cauliflower (Reg EU 2016/1) will be exceed according to the intended GAP in EU.
Nevertheless on the basis of the available supporting residue data it is possible to conclude that in force the proposed MRLof 0.04 mg/kg on cauliflower (SANTE/11442/2016) will not be exceed according to the intended GAP in EU.

IIIA 8.3.12 BRUSSELS SPROUT

Table IIIA 8.3.12-1: Comparison of intended and critical EU GAPs

Crop	Type of GAP	Number of applications	Application rate per treatment	Interval between application	Growth stage at last application	PHI (days)
Brussels sprout	Intended FR and SEU	1	24 g a.s./ha	-	BBCH 20-49	7

IIIA 8.3.12.1 Summary of B.7.6 Data

Use on Brussel sprout has not been assessed in the framework of EU evaluation, neither as representative use nor as an import tolerance. Consequently the in force MRL on Brussels sprout is set at 0.01* mg/kg in Regulation 2016/1.

IIIA 8.3.12.2 New data

IIIA 8.3.12.2.1 Study 1

Report:	IIIA 8.3.7.2/01, Rawle, N.W., 2008
Title:	Residues of XDE-208 in Brussels sprouts at intervals and harvest following a single application of GF-2032 – Northern and southern Europe – 2008
Document No:	DAS report CEMR-3925
Guidelines:	
GLP	Y

Acceptability	Deviations
Yes	None with impact on the study

Table IIIA 8.3.12-2: Summary of global information on study 1

Comparative trials (between formulations, with and adjuvant/safener/synergist)	No GF-2032 SC containing 240 g sulfoxaflor /L).
Number of applications	1
Dose (g as/ha)	24 g a.s./ha
Mode of application	Foliar broadcast application
PHI (days) and/or growth stage (BBCH)	0, 1, 3, 7, 10
Analytical method (Code +Type)	Method N° 091031 LC-MS/MS
LoQ (mg/kg)	0.01

Table IIIA 8.3.12-3: Summary of the study 1 trials

N° Trial		CEMS-3925A	CEMS-3925B	CEMS-3925C	CEMS-3925D	CEMS-3925E	CEMS-3925F
North/South/Indoor		N	N	N	N	S	S
Decline (D)/Harvest (H) trial?		D	D	D	D	D	D
Formulation		SC	SC	SC	SC	SC	SC
Equivalence between formulations		Y	Y	Y	Y	Y	Y
Accordance with intended GAP		Y	Y	Y	Y	Y	Y
Correct sampling		Y	Y	Y	Y	Y	Y
Samples frozen within 24h		Y	Y	Y	Y	Y	Y
Storage period (in days)	Sample	210	210	210	210	210	210
	Extract[1]	4	4	4	4	4	4
Storage T° <-18°C		Y	Y	Y	Y	Y	Y
Validated analytical method		Y	Y	Y	Y	Y	Y
Negative controls		Y	Y	Y	Y	Y	Y
Considered trial		Y	Y	Y	Y	Y	Y
Remarks							

[1] The procedural recoveries demonstrate the stability of the analyte during the storage period (up to 4 days).

Table IIIA 8.3.12-4: Summary of data from residue trials for study 1

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)
Notifier:

Active ingredient : Sulfoxaflor
Crop / crop group : Brussels sprouts

Content of a.i. (g/kg or g/l) : 240 g/l
Formulation (e.g. WP) : SC
Commercial product (name) : GF-2032
Applicant : Dow Agrosciences

Indoors / outdoors : outdoor
Other a. s. in formulation : none
(common name and content) :
Residues calculated as : XDE-208 + X11719474

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 ()**	**Appl Date**	**GS at Last Appl**	**PHI (days)**	**Portion Analysed**	**XDE-208 (**mg/Kg**)**	**X11719474 (**mg/Kg**)**	**Total* (**mg/Kg**)**
CEMS-3925A CEMS-3925 DAS Ref. ID 080035 Y 2008	Brussels sprouts Kilaherb	Germany NZ Outdoor (field)	GF-2032	1	24.6	1027	2.4	13-Oct-2008	BBCH.46	0 1 3 7 10	Sprouts Sprouts Sprouts Sprouts Sprouts	0.035 0.014 0.010 **<u><0.01</u>** <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	0.044 0.023 0.019 **<u><0.019</u>** <0.019
CEMS-3925B CEMS-3925 DAS Ref. ID 080035 Y 2009	Brussels sprouts Cirus	United Kingdom NZ Outdoor (field)	GF-2032	1	24.2	590	4.1	09-Feb-2009	BBCH.47	0 1 3 7 9	Sprouts Sprouts Sprouts Sprouts Sprouts	0.017 <0.01 <0.01 **<u><0.01</u>** <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	0.026 <0.019 <0.019 **<u><0.019</u>** <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 ()**	**Appl Date**	**GS at Last Appl**	**PHI (days)**	**Portion Analysed**	**XDE-208 (mg/Kg)**	**X11719474 (mg/Kg)**	**Total* (mg/Kg)**
CEMS-3925C CEMS-3925 DAS Ref. ID 080035 Y 2008	Brussels sprouts Bruxelles 1/2 nano	Hungary NZ Outdoor (field)	GF-2032	1	24.8	825	3.0	18-Nov-2008	BBCH.47	0 1 3 7 10	Sprouts Sprouts Sprouts Sprouts Sprouts	0.030 0.026 0.019 **<0.01** <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	0.039 0.035 0.028 **<0.019** <0.019
CEMS-3925D CEMS-3925 DAS Ref. ID 080035 Y 2008	Brussels sprouts Cyrilus	France NZ Outdoor (field)	GF-2032	1	26.6	621	4.3	04-Nov-2008	BBCH.48 to 49	0 1 3 7 10	Sprouts Sprouts Sprouts Sprouts Sprouts	0.023 <0.01 <0.01 **<0.01** <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	0.032 <0.019 <0.019 **<0.019** <0.019
CEMS-3925E CEMS-3925 DAS Ref. ID 080035 Y 2009	Brussels sprouts Jade Cross	Spain SZ Outdoor (field)	GF-2032	1	24.1	795	3.0	12-Jan-2009	BBCH.48	0 1 3 7 10	Sprouts Sprouts Sprouts Sprouts Sprouts	0.019 0.016 0.019 **<0.01** <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	0.028 0.025 0.028 **<0.019** <0.019
CEMS-3925F CEMS-3925 DAS Ref. ID 080035 Y 2009	Brussels sprouts Masterlime	France SZ Outdoor (field)	GF-2032	1	25.3	844	3.0	05-Jan-2009	BBCH.49	0 1 3 7 10	Sprouts Sprouts Sprouts Sprouts Sprouts	0.01 <0.01 <0.01 **<0.01** <0.01	<0.01 <0.01 <0.01 0.011 <0.01	0.019 <0.019 <0.019 **0.020** <0.019

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

IIIA 8.3.12.2.2 Study 2

Report:	IIIA 8.3.7.2/02, Rawle, N.W., 2012
Title:	Residues of sulfoxaflor in Brussels sprouts at intervals and harvest following a single application of GF-2626 – Northern and Southern Europe – 2011
Document No:	DAS report CEMR-5019
Guidelines:	
GLP	Yes

Acceptability	**Deviations**
Yes	None

Table IIIA 8.3.12-5: Summary of global information on study 2

Comparative trials (between formulations, with and adjuvant/safener/synergist)	No GF-2626 SC formulation containing 120 g sulfoxaflor/l
Number of applications	1
Dose (g as/ha)	24
Mode of application	24 g a.s./ha
PHI (days) and/or growth stage (BBCH)	Foliar broadcast application
Analytical method (Code +Type)	0, 1, 3, 7, 10
LoQ (mg/kg)	Method N° 091031 LC-MS/MS
	0.01

Table IIIA 8.3.12-6: Summary of the study 2 trials

N° Trial		CEMS-5019A	CEMS-5019B	CEMS-5019C	CEMS-5019D
North/South/Indoor		N	N	S	S
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	100	100	100	100
	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 8.3.12-7: Summary of data from residue trials for study 1

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)
Content of a.i. (g/kg or g/l) : 120 g/l
Formulation (e.g. WP) : SC
Commercial product (name) : GF-2626
Applicant : Dow agrosciences

Active ingredient : Sulfoxaflor
Crop / crop group : Brussels sprout
Indoors / outdoors : Outdoor
Other a. s. in formulation (common name and content) : None
Residues calculated as :

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 ()**	**Appl Date**	**GS at Last Appl**	**PHI (days)**	**Portion Analysed**	**XDE-208 (**mg/Kg**)**	**X11719474 (**mg/Kg**)**	**Total* (**mg/Kg**)**
CEMS-5019A CEMS-5019 GHE-P-12715 Y 2011	Brussels sprouts Genius	Germany NZ Outdoor (field)	GF-2626	1	22.6	377	6.0	25-Oct-2011	BBCH.44 to 49	0 1 3 7 10	Sprouts Sprouts Sprouts Sprouts Sprouts	<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
CEMS-5019B CEMS-5019 GHE-P-12715 Y 2011	Brussels sprouts Botaurus	United Kingdom NZ Outdoor (field)	GF-2626	1	21.7	367	5.9	31-Oct-2011	BBCH.47	0 1 3 7 10	Sprouts Sprouts Sprouts Sprouts Sprouts	<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
CEMS-5019C CEMS-5019 GHE-P-12715 Y 2011	Brussels sprouts Gustus	Spain SZ Outdoor (field)	GF-2626	1	24.5	612	4.0	15-Nov-2011	BBCH.48	0 1 3 7 10	Sprouts Sprouts Sprouts Sprouts Sprouts	0.021 <0.01 **<0.01** <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	0.030 <0.019 <0.019 **<0.019** <0.019
CEMS-5019D CEMS-5019 GHE-P-12715 Y 2011	Brussels sprouts Sigmund	Italy SZ Outdoor (field)	GF-2626	1	23.7	394	6.0	21-Nov-2011	BBCH.47	0 1 3 7 10	Sprouts Sprouts Sprouts Sprouts Sprouts	0.054 0.026 0.011 **0.011** <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	0.063 0.035 0.020 **0.020** <0.019

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

IIIA 8.3.12.3 Summary of monograph and new data supporting the intended use on Brussels sprouts and conformity to existing MRL

Table IIIA 8.3.12-8: Summary of monograph and new data supporting the intended use on Brussels sprouts 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
Brussels sprouts	New trials	North (6)	Trials GAP: 1 x 24 g a.s./ha, PHI 7d Mo: 6 x <0.01 Ra: 6 x <0.019							
		South (4)	Trials GAP: 1 x 24 g a.s./ha, PHI 7d Mo: 3 x <0.01, 0.011 Ra: 2 x <0.019, 2 x 0.02							
	Overall supporting data for FR GAP	North (6)	Mo: 6 x <0.01	0.01	0.01	-	-	0.01	0.01*	Yes
			Ra: 6 x <0.019	0.019	0.019					
	Overall supporting data for BG, EL, ES, IT GAP	South (4)	Mo: 3 x <0.01, 0.011	0.01	0.011	0.022	0.013	0.015 → 0.015		No
			Ra: 2 x <0.019, 2 x 0.02	0.019	0.02					

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

IIIA 8.3.12.4 Conclusion for Brussels sprouts

A total of 4 southern residues trials and 6 northern residue trials are available to support the intended GAP on Brussels sprout in France and SEU. Therefore enough residue data are available to support the intended use.

According to EU guideline 7525/VI/95-rev.10, Appendix D « Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs», only NEU data are needed to support the use on Brussels sprout in France.
On the basis of the available supporting northern residue data it is possible to conclude that in force MRL of 0.01* mg/kg on Brussels sprout will not be exceeded according to the intended GAP in France.

However on the basis of the available southern supporting residue data it is possible to conclude that current MRLs of 0.01* mg/kg on Brussels sprout will be exceed according to the intended GAP in SEU.
Nevertheless It should be noted that according to the applicant an application to modify the in force MRL on Brussels sprout from 0.01* to 2 mg/kg has been requested to the EMS Ireland
Consequently pending the modification of the in force MRL the intended uses of GF-2626 on Brussels sprout should not be considered acceptable in BG, EL, ES, IT.

IIIA 8.3.13 HEAD CABBAGE

Table IIIA 8.3.13-1: Comparison of intended and critical EU GAPs

Crop	Type of GAP	Number of applications	Application rate per treatment	Interval between application	Growth stage at last application	PHI (days)
Head cabbage	DAR MRL Application (USA)[1]	1-3	100 g a.s./ha	7	Up to BBCH 49	3
	DAR MRL Application (AUS)[1]	1-4	96 a.s./ha	7	Up to BBCH 49	3
	Intended FR and SEU	1	24 g a.s./ha	-	BBCH 20-49	7

[1] MRL Application.

IIIA 8.3.13.1 Summary of B.7.6 Data

Use on head cabbage has been assessed in the meantime of the EU evaluation of sulfoxaflor, in the framework of MRL application for an import tolerance.
However this MRL application is based on an Australian and US GAP and residue trials submitted to e support the import tolerance have been performed outside EU (US and Australia) and then they cannot be considered to support the intended use of GF-2626 on head cabbage in EU
Furthermore as trials were not in compliance with the authorised GAP or were not sufficient to calculate an MRL based on the authorized GAP in Australia and USA no MRL was proposed by EFSA and then a default MRL of 0.01* mg/kg was set for head cabbage at EU level in Regulation 2016/1.
Later the existing CXL of 0.4 mg/kg on head cabbage was voted at EU level and proposed in document SANTE/11442/2016.

It should be noted that in the evaluation report EU trials are also summarized (IE, 2012). They were performed according to a more critical GAP than intended one (4 applications at ca 100 g as/ha). As these EU trials involved residue levels which are not in accordance with the in force MRL, they cannot be used to support the intended uses of GF-2626 on head cabbage.

Characteristics and results of the supported trials are summarized below.

Table IIIA 8.3.13-2: Residue Trial Results For Cabbage

Residue trial number	Crop	Country and year	Application rate (g as/ha)	Growth stage at last treatment	PHI (days)	Residues found (mg/kg)		
						Sulfoxaflor	Metabolite X11719474	Metabolite X11721061
Doc ID: DAS Study ID 080034-02 Trial CEMS-3949A	Cabbage (head with leaves)	N EU, Altenbruch, Germany, 2008	1 x 102 1 x 100 1 x 98 1 x 100 (Total application rate = 400 g as/ha)	BBCH 44-45 BBCH 45 BBCH 45-47 BBCH 49	1 3 7 11	0.317, 0.230 0.400, 0.354 0.262, 0.205 0.159, 0.152	0.022, 0.020 0.039, 0.044 0.049, 0.026 0.045, 0.032	0.018, 0.013 0.031, 0.044 0.046, 0.031 0.028, 0.026
Doc ID: DAS Study ID 080034-02 Trial CEMS-3949B	Cabbage (head with leaves)	N EU, Mere Brow, United Kingdom, 2008	1 x 105 1 x 104 1 x 101 1 x 106 (Total application rate = 416 g as/ha)	BBCH 45 BBCH 45 BBCH 45-47 BBCH 49	3	0.109, 0.053	(0.006), (0.006)	ND, ND
Doc ID: DAS Study ID 080034-02 Trial CEMS-3949C	Cabbage (head with leaves)	N EU, Limersheim, France, 2008	1 x 107 1 x 110 1 x 108 1 x 105 (Total application rate = 430 g as/ha)	BBCH 48 BBCH 48 BBCH 48 BBCH 49	3	0.034, 0.033	0.014, 0.011	(0.007), (0.007)

Residue trial number	Crop	Country and year	Application rate (g as/ha)	Growth stage at last treatment	PHI (days)	Residues found (mg/kg)		
						Sulfoxaflor	Metabolite X11719474	Metabolite X11721061
Doc ID: DAS Study ID 080034-02 Trial CEMS-3949D	Cabbage (head with leaves)	N EU, Seregelyes, Hungary, 2008	1 x 103 1 x 109 1 x 106 1 x 110 (Total application rate = 428 g as/ha)	BBCH 45 BBCH 45 BBCH 49 BBCH 49	3	0.021, 0.011	(0.008), (0.008)	ND, ND
Doc ID: DAS Study ID 080034-02 Trial CEMS-3949E	Cabbage (head with leaves)	S EU, Brouilla, France, 2008	1 x 101 1 x 110 1 x 104 1 x 102 (Total application rate = 417 g as/ha)	BBCH 47 BBCH 48 BBCH 49 BBCH 49	1 3 7 10	0.120, 0.129 0.076, 0.056 0.016, 0.054 (0.007), 0.022	0.019, 0.017 0.014, (0.009) 0.012, 0.028 (0.007), (0.010)	(0.009), 0.011 (0.005), ND 0.017, ND ND, ND
Doc ID: DAS Study ID 080034-02 Trial 3949F	Cabbage (head with leaves)	S EU, Nea Magnisia Ionia, Greece, 2008	1 x 103 1 x 99 1 x 99 1 x 97 (Total application rate = 398 g as/ha)	BBCH 45 BBCH 47 BBCH 47 BBCH 49	3	0.024, 0.014	0.015, 0.018	(0.006), (0.010)

IIIA 8.3.13.2 New data

IIIA 8.3.13.2.1 Study 1

Report:	IIIA 8.3.7.3/01, Rawle, N.W., 2012v
Title:	Residues of XDE-208 in head cabbage at intervals and harvest following a single application of GF-2032 – Northern and Southern Europe – 2008
Document No:	DAS report CEMR-3948
Guidelines:	
GLP	Yes

Acceptability	**Deviations**
Yes	None with impact on the study

Table IIIA 8.3.13-3: Summary of global information on study 1

Comparative trials (between formulations, with and adjuvant/safener/synergist)	GF-2032 (a SC formulation containing of 240 g sulfoxaflor/L)
Number of applications	1
Dose (g as/ha)	24 g as/ha
Mode of application	Foliar broadcast application
PHI (days) and/or growth stage (BBCH)	0, 1, 3, 7 and 10
Analytical method (Code +Type)	Method N° 091031 LC-MS/MS
LoQ (mg/kg)	0.01mg/kg

Table IIIA 8.3.13-4: Summary of the study 1 trials

N° Trial		CEMS-3948A	CEMS-3948B	CEMS-3948C	CEMS-3948D	CEMS-3948F	CEMS-3948G
North/South/Indoor		N	N	N	N	S	S
Decline (D)/Harvest (H) trial?		D	D	D	D	D	D
Formulation		SC	SC	SC	SC	SC	SC
Equivalence between formulations		Y	Y	Y	Y	Y	Y
Accordance with intended GAP		Y	Y	Y	Y	Y	Y
Correct sampling		Y	Y	Y	Y	Y	Y
Samples frozen within 24h		Y	Y	Y	Y	Y	Y
Storage period (in days)	Sample	236	246	218	211	231	134
	Extract[1]	2	2	2	2	2	2
Storage T° <-18°C		Y	Y	Y	Y	Y	Y
Validated analytical method		Y	Y	Y	Y	Y	Y
Negative controls		Y	Y	Y	Y	Y	Y
Considered trial		Y	Y	Y	Y	Y	Y
Remarks							

[1] The procedural recoveries demonstrate the stability of the analyte during this storage (up to 2 days)

Table IIIA 8.3.13-5: Summary of data from residue trials for study 1

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Notifier:
Content of a.i. (g/kg or g/l) : 240
Formulation (e.g. WP) : SC
Commercial product (name) : GF-2032
Applicant : Dow

Active ingredient : Sulfoxaflor
Crop / crop group : Head cabbage
Indoors / outdoors : outdoor
Other a. s. in formulation : none
(common name and content) : -
Residues calculated as : XDE-208 and X11719474

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-3948A CEMS-3948 DAS Ref# 080034-01 Y 2008	Head cabbage Lennox	Germany NZ Outdoor (field)	GF-2032	1	23.2	677	3.4	25-Sep-08	BBCH.48 to 49	0 1 3 7 11	Head Head Head Head Head	0.109 0.029 0.020 **0.017** <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	0.118 0.038 0.029 **0.026** <0.019
CEMS-3948B CEMS-3948 DAS Ref# 080034-01 Y 2008	Head cabbage Clarissa F1	United Kingdom NZ Outdoor (field)	GF-2032	1	24.7	611	4.0	15-Sep-08	BBCH.47 to 49	0 1 3 7 10	Head Head Head Head Head	0.029 0.045 0.060 **0.021** 0.011	<0.01 <0.01 <0.01 **<0.01** <0.01	0.038 0.054 0.069 **0.030** 0.020
CEMS-3948C CEMS-3948 DAS Ref# 080034-01 Y 2008	Head cabbage Atria	France NZ Outdoor (field)	GF-2032	1	25.6	640	4.0	13-Oct-08	BBCH.49	0 1 3 7 10	Head Head Head Head Head	<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

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-3948D CEMS-3948 DAS Ref# 080034-01 Y 2008	Head cabbage Szentesi tartós	Hungary NZ Outdoor (field)	GF-2032	1	25.6	533	4.8	20-Oct-08	BBCH.49	0 1 3 7 11	Head Head Head Head Head	<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
CEMS-3948F CEMS-3948 DAS Ref# 080034-01 Y 2008	Head cabbage Grand Slam	Greece SZ Outdoor (field)	GF-2032	1	23.8	497	4.8	30-Sep-08	BBCH.48	0 1 3 7 10	Head Head Head Head Head	0.027 <0.01 <0.01 **<0.01** <0.01	<0.01 <0.01 <0.01 **<0.01** <0.01	0.036 <0.019 <0.019 **<0.019** <0.019
CEMS-3948G CEMS-3948 DAS Ref# 080034-01 Y 2009	Head cabbage Milan	France SZ Outdoor (field)	GF-2032	1	24.0	800	3.0	05-Jan-09	BBCH.49	0 1 3 7 10	Head Head Head Head Head	0.097 0.100 0.174 **0.015** 0.014	<0.01 <0.01 <0.01 **<0.01** <0.01	0.106 0.109 0.183 **0.024** 0.023

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

IIIA 8.3.13.2.2 Study 2

Report:	IIIA 8.3.7.3/02, Rawle, N.W., 2012w
Title:	Residues of sulfoxaflor in head cabbage at intervals and harvest following a single application of GF-2626 – Northern and Southern Europe – 2011
Document No:	DAS report CEMR-5020
Guidelines:	
GLP	Yes

Acceptability	**Deviations**
Yes	None with impact on the study

Table IIIA 8.3.13-6: Summary of global information on study 2

Comparative trials (between formulations, with and adjuvant/safener/synergist)	GF-2626 (a SC formulation containing 120 g sulfoxaflor/L).
Number of applications	1
Dose (g as/ha)	24 g as/ha
Mode of application	Foliar broadcast application
PHI (days) and/or growth stage (BBCH)	0, 1, 3, 7, 10, 14, 21
Analytical method (Code +Type)	Method N° 091031 LC-MS/MS
LoQ (mg/kg)	0.01mg/kg

Table IIIA 8.3.13-7: Summary of the study 2 trials

N° Trial		CEMS-5020A	CEMS-5020B	CEMS-5020C	CEMS-5020D	CEMS-5020E	CEMS-5020F
North/South/Indoor		N	N	N	N	S	S
Decline (D)/Harvest (H) trial?		D	D	D	D	D	D
Formulation		SC	SC	SC	SC	SC	SC
Equivalence between formulations		Y	Y	Y	Y	Y	Y
Accordance with intended GAP		Y	Y	Y	Y	Y	Y
Correct sampling		Y	Y	Y	Y	Y	Y
Samples frozen within 24h		Y	Y	Y	Y	Y	Y
Storage period (in days)	Sample	247	224	240	296	203	255
	Extract[(1)]	3	3	3	3	3	3
Storage T° <-18°C		Y	Y	Y	Y	Y	Y
Validated analytical method		Y	Y	Y	Y	Y	Y
Negative controls		Y	Y	Y	Y	Y	Y
Considered trial		Y	Y	Y	Y	Y	Y
Remarks							

[1] The procedural recoveries demonstrate the stability of the analyte during this storage (up to 2 days)

Table IIIA 8.3.13-8: Summary of data from residue trials for study 1

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Notifier: Dow

Content of a.i.	(g/kg or g/l)	:	120 g/l	Indoors / outdoors	: Outdoor
Formulation	(e.g. WP)	:	SC	Other a. s. in formulation	None
Commercial product	(name)	:	GF-2626	(common name and content)	: -
Applicant		:		Residues calculated as	: XDE-208 and X11719474
Active ingredient		:	Sulfoxaflor		
Crop / crop group		:	Head cabbage		

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-5020A CEMS-5020 GHE-P-12716 Y 2011	Head cabbage Jubilee	France NZ Outdoor (field)	GF-2626	1	24.3	303	8.0	20-Sep-11	BBCH.47	0 1 3 7 10 14 20	Head Head Head Head Head Head Head	<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
CEMS-5020B CEMS-5020 GHE-P-12716 Y 2011	Head cabbage Stallion	United Kingdom NZ Outdoor (field)	GF-2626	1	24.7	415	6.0	13-Oct-11	BBCH.47	0 1 3 8 11 15 22	Head Head Head Head Head Head Head	<0.01 0.012 <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 0.021 <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-5020C CEMS-5020 GHE-P-12716 Y 2011	Head cabbage Selma	Germany NZ Outdoor (field)	GF-2626	1	23.4	389	6.0	27-Sep-11	BBCH.48	0 1 3 7 10 15 20	Head Head Head Head Head Head Head	0.010 <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
CEMS-5020D CEMS-5020 GHE-P-12716 Y 2011	Head cabbage Kilaherb	Poland NZ Outdoor (field)	GF-2626	1	23.6	393	6.0	02-Aug-11	BBCH.47 to 48	0 1 3 7 9 14 20	Head Head Head Head Head Head Head	0.020 <0.01 0.013 **<0.01** <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.029 <0.019 0.022 **<0.019** <0.019 <0.019 <0.019
CEMS-5020E CEMS-5020 GHE-P-12716 Y 2011	Head cabbage Kyose	Bulgaria SZ Outdoor (field)	GF-2626	1	24.0	400	6.0	03-Nov-11	BBCH.48	0 1 3 7 10 14 21	Head Head Head Head Head Head Head	0.017 0.033 0.010 **0.015** <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.026 0.042 0.019 **0.024** <0.019 <0.019 <0.019
CEMS-5020F CEMS-5020 GHE-P-12716 Y 2011	Head cabbage Banner	Greece SZ Outdoor (field)	GF-2626	1	24.9	415	6.0	12-Sep-11	BBCH.47	0 1 3 7 11 14 22	Head Head Head Head Head Head Head	0.010 <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

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-5020G CEMS-5020 GHE-P-12716 Y 2011	Head cabbage Artost	Italy SZ Outdoor (field)	GF-2626	1	25.5	535	4.8	04-Jul-11	BBCH.43 to 45	0 1 3 7 10 14 21	Head Head Head Head Head Head Head	0.010 <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
CEMS-5020H CEMS-5020 GHE-P-12716 Y 2011	Head cabbage Lenox	France SZ Outdoor (field)	GF-2626	1	24.0	400	6.0	12-Sep-11	BBCH.47	0 1 3 7 10 14 21	Head Head Head Head Head Head Head	0.056 0.012 <0.01 **<0.01** <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.065 0.021 <0.019 **<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 8.3.13.3 Summary of monograph and new data supporting the intended use on head cabbage and conformity to existing MRL

Table IIIA 8.3.13-9: Summary of monograph and new data supporting the intended use on head cabbage 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
Head cabbage	MRL application	North (4)	Trials GAP: 4 x 100 g as/ha, PHI 3-7d Mo: 0.021, 0.034, 0.109, 0.262	0.071	0.262				Reg EU 2016/1: 0.01* SANTE/11442/2016: 0.4	Yes
			Ra: 0.03, 0.047, 0.12, 0.31,	0.083	0.31					
		South (2)	Trials GAP: 4 x 100 g as/ha, PHI 3-7d Mo: 0.024, 0.054	0.039	0.054	-	-	-		
			Ra: 0.041, 0.08	0.06	0.08	-	-	-		
	New trials = Overall supporting data for	North (8)	Trials GAP: 1 x 24 g as/ha, PHI 7d Mo: 6 x <0.01, 0.017, 0.021,	0.01	0.021	0.031	0.026	0.029→ 0.03		
			Ra:6 x <0.019, 0.026, 0.03,	0.019	0.03					
		South (6)	Trials GAP: 1 x 24 g as/ha, PHI 7d Mo: 4 x <0.01, 2 x 0.015,	0.01	0.015	0.03	0.021	0.022→0.03		
			Ra: 4 x <0.019, 2x 0.024	0.019	0.024					

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

IIIA 8.3.13.4 Conclusion for head cabbage

A total of 8 NEU and 6 SEU residue trials performed according to the intended GAP are considered suitable to support the intended use on head cabbage.
Furthermore 4 NEU and 2 SEU performed according to a more critical GAP can also be considered to support 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 MRL of 0.4 mg/kg on head cabbage (document SANTE/11442/2016) will not be exceeded according to the intended GAP.

IIIA 8.3.14 LEAFY BRASSICA

Table IIIA 8.3.14-1: Comparison of intended and critical EU GAPs

Crop	Type of GAP	Number of applications	Application rate per treatment	Interval between application	Growth stage at last application	PHI (days)
Chinese cabbage	DAR MRL Application (USA)[1]	1-3	100 g a.s./ha	7	Up to BBCH 49	3
Leafy brassica	Intended FR and SEU	1	24 g a.s./ha	-	BBCH 20-49	7

[1] MRL Application – import tolerance

IIIA 8.3.14.1 Summary of EU Data

Use on Chinese cabbage (mustard greens) has been assessed in the meantime of the EU evaluation of sulfoxaflor, in the framework of MRL application for an import tolerance.
However this MRL application is based on an US GAP and residue trials submitted to the support the import tolerance have been performed outside EU (US) and then they cannot be considered to support the intended use of GF-2626 on leafy brassica in EU
Based on the supporting residue data an MRL of 2 mg/kg based on US GAP was proposed by EFSA and then adopted at EU level in Regulation 2016/1.

IIIA 8.3.14.2 New data

IIIA 8.3.14.2.1 Study 1

Report:	IIIA 8.3.7.4/01, Rawle, N.W., 2012x
Title:	Residues of XDE-208 in kale at intervals and harvest following a single application of GF-2032 – Northern and Southern Europe – 2008
Document No:	CEMR-3951
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", OECD Guidelines for the Testing of Chemicals, No. 509: Crop Field Trial, 2009.
GLP	Y

Acceptability	Deviations
Yes	None

Table IIIA 8.3.14-2: Summary of global information on study 1

Comparative trials (between formulations, with and adjuvant/safener/synergist)	No, SC formulation containing 240 g sulfoxaflor/l
Number of applications	1
Dose (g as/ha)	24 g a.s./ha
Mode of application	Foliar application
PHI (days) and/or growth stage (BBCH)	0, 1, 3, 7 and 10 days
Analytical method (Code +Type)	Method N° 091031 LC-MS/MS
LoQ (mg/kg)	0.01

Table IIIA 8.3.14-3: Summary of the study 1 trials

N° Trial		CEMS-3915A	CEMS-3915B	CEMS-3915C	CEMS-3915D
North/South/Indoor		N	N	S	S
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	254	254	254	254
	Extract[1]	5	5	5	5
Storage T° <-18°C		Y	Y	Y	Y
Validated analytical method		Y	Y	Y	Y
Negative controls		Y	N[2]	Y	Y
Considered trial		Y	Y	Y	Y
Remarks					

[1:] The procedural recoveries demonstrate the stability of the analyte during this storage (up to 5 days).
[2:] Residue of sulfoxaflor was found in control sample harvest at 1 day PHI only and it is supposed to not impact the validity of the results at the intended PHI.

Table IIIA 8.3.14-4: Summary of data from residue trials for study 1

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)
Notifier:
Content of a.i. (g/kg or g/l) : 240 g/l
Formulation (e.g. WP) : SC
Commercial product (name) : GF-2032
Applicant : Dow Agrosciences

Active ingredient : Sulfoxaflor
Crop / crop group : Kale
Indoors / outdoors : Outdoor
Other a. s. in formulation : None
(common name and content) :
Residues calculated as : XDE-208 and X11719474

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-3951A CEMS-3951 DAS Ref# 080069 Y 2008	Kale Winterbor	Germany NZ Outdoor (field)	GF-2032	1	24.5	713	3.4	01-Sep-08	BBCH 48-49	0 1 3 7 10	Foliage Foliage Foliage Foliage Foliage	0.186 0.198 0.022 **<0.01** <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	0.195 0.207 0.031 **<0.019** <0.019
CEMS-3951B CEMS-3951 DAS Ref# 080069 Y 2008	Kale Winatou	UK NZ Outdoor (field)	GF-2032	1	24.3	602	4.0	10-Dec-08	BBCH 47	0 1 3 7 10	Foliage Foliage Foliage Foliage Foliage	0.593 0.657 0.351 0.352 **0.421**	<0.01 <0.01 <0.01 <0.01 0.013	0.602 0.666 0.360 0.361 **0.433**
CEMS-3951C CEMS-3951 DAS Ref# 080069 Y 2008	Kale Palmibo	Italy SZ Outdoor (field)	GF-2032	1	24.7	514	4.8	16-Oct-08	BBCH 48-49	0 1 3 7 10	Foliage Foliage Foliage Foliage Foliage	0.346 0.131 0.025 **0.014** <0.01	<0.01 0.017 <0.01 <0.01 <0.01	0.355 0.147 0.034 **0.023** <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-3951D CEMS-3951 DAS Ref# 080069 Y 2008	Kale Nero Toscana	Italy SZ Outdoor (field)	GF-2032	1	25.2	525	4.8	28-Oct-08	BBCH 48	0 1 3 7 10	Foliage Foliage Foliage Foliage Foliage	0.281 <0.01 <0.01 **<u><0.01</u>** <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	0.290 <0.019 <0.019 **<u><0.019</u>** <0.019

IIIA 8.3.14.2.2 Study 2

Report:	IIIA 8.3.7.4/02, Rawle, N. W., 2012y
Title:	Residues of sulfoxaflor in indoor bell peppers at intervals and harvest following a single application of GF-2626 – Europe – 2011
Document No:	CEMR-5021
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 WorkingDocument 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation andRealisation of Residue Trials, July 22, 1997", OECD Guidelines for the Testing ofChemicals, No. 509: Crop Field Trial, 2009.
GLP	Y

Acceptability	**Deviations**
Yes	None with impact on the study

Table IIIA 8.3.14-5: Summary of global information on study 2

Comparative trials (between formulations, with and adjuvant/safener/synergist)	No, SC formulation containing 120 g sulfoxaflor/l
Number of applications	1
Dose (g as/ha)	24 g a.s./ha
Mode of application	Foliar application
PHI (days) and/or growth stage (BBCH)	0, 1, 3, 7 and 10 days
Analytical method (Code +Type)	Method N° 091031 LC-MS/MS
LoQ (mg/kg)	0.01

Table IIIA 8.3.14-6: Summary of the study 2 trials

N° Trial		CEMR-5021A	CEMR-5021B	CEMR-5021C	CEMR-5021D
North/South/Indoor		N	N	S	S
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	120	120	120	120
	Extract[1]	3	3	3	3
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:] The procedural recoveries demonstrate the stability of the analyte during this storage (up to 3 days).

Table IIIA 8.3.14-7: Summary of data from residue trials for study 2

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Notifier:
Content of a.i. (g/kg or g/l) : 120 g/l
Formulation (e.g. WP) : SC
Commercial product (name) : GF-2626
Applicant : Dow Agrosciences

Active ingredient : Sulfoxaflor
Crop / crop group : Kale

Indoors / outdoors : Outdoor
Other a. s. in formulation (common name and content) :
Residues calculated as :

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-5021A	Kale	Germany	GF-	1	21.7	361	6.0	25-Oct-11	BBCH 49	0	Foliage	0.576	<0.01	0.585
CEMS-5021	Winterbor	NZ	2626							1	Foliage	0.491	<0.01	0.500
GHE-P-12717		Outdoor								3	Foliage	0.301	<0.01	0.310
Y		(field)								7	Foliage	0.251	0.011	0.260
2011										10	Foliage	**0.327**	0.019	**0.345**
CEMS-5021B	Kale	UK	GF-	1	24.8	418	5.9	21-Nov-11	BBCH 49	0	Foliage	0.166	<0.01	0.175
CEMS-5021	Winnetou 2	NZ	2626							1	Foliage	0.115	<0.01	0.124
GHE-P-12717		Outdoor								3	Foliage	0.167	<0.01	0.176
Y		(field)								7	Foliage	**0.038**	<0.01	**0.047**
2011										10	Foliage	0.025	<0.01	0.034
CEMS-5021C	Kale	Italy	GF-	1	24.5	409	6.0	03-Oct-11	BBCH 47	0	Foliage	0.362	<0.01	0.371
CEMS-5021	Palmizio	SZ	2626							1	Foliage	0.142	<0.01	0.151
GHE-P-12717		Outdoor								3	Foliage	0.026	<0.01	0.035
Y		(field)								7	Foliage	**<0.01**	<0.01	**<0.019**
2011										10	Foliage	<0.01	<0.01	<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-5021D	Kale	France	GF-	1	22.7	400	5.7	14-Nov-11	BBCH 48-	0	Foliage	0.814	<0.01	0.823
CEMS-5021	Reflex	SZ	2626						49	1	Foliage	0.243	<0.01	0.252
GHE-P-12717		Outdoor								3	Foliage	0.090	<0.01	0.099
Y		(field)								7	Foliage	**0.023**	<0.01	**0.032**
2011										10	Foliage	0.021	0.012	0.032

IIIA 8.3.14.3 Summary of monograph and new data supporting the intended use on leafy brassica and conformity to existing MRL

Table IIIA 8.3.14-8: Summary of monograph and new data supporting the intended use on leafy brassica 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
Leafy brassica	New trials	North (4)	Trials GAP: 1x24 g a.s./ha – PHI 7 days MO : <0.01, 0.038, 0.327, 0.421 RA : <0.019, 0.047, 0.345, 0.433						0.01* mg/kg for kale 2 mg/kg for Chinese cabbage	Yes for Chinese cabbage No for Kale
		South (4)	Trials GAP: 1x24 g a.s./ha – PHI 7 days MO: 2 x <0.01, 0.014, 0.023 RA: 2 x <0.019, 0.023, 0.032							
	Overall supporting data for FR GAP	North (4)	MO : <0.01, 0.038, 0.327, 0.421	0.18	0.421	0.79	1.26	1.023 → 1		
			RA : <0.019, 0.047, 0.345, 0.433	0.392	0.433					
		South (4)	MO: 2 x <0.01, 0.014, 0.023	0.012	0.023	0.04	0.05	0.039 → 0.04		
			RA: 2 x <0.019, 0.023, 0.032	0.021	0.032					
	Overall supporting data for SEU GAP	South (4)	MO: 2 x <0.01, 0.014, 0.023	0.012	0.023	0.04	0.05	0.039 → 0.04		
			RA: 2 x <0.019, 0.023, 0.032	0.021	0.032					

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

IIIA 8.3.14.4 Conclusion for leafy brassica

According to EU guideline 7525/VI/95-rev.10, Appendix D « Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs», extrapolation of residue data from kale to the whole group of leafy brassica is possible when the application is performed close to harvest.

A total of 4 southern residues trials and 4 northern residue trials are available to support 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 current MRL of 2 mg/kg on Chinese cabbage will not be exceed according to the intended GAP in EU.

However on the basis of the available supporting residue data it is possible to conclude that current MRLs of 0.01* mg/kg on kale will be exceed according to the intended GAP in EU.
It should be noted that according to the applicant an application to modify the in force MRL on kale from 0.01* to 1 mg/kg has been submitted to the EMS Ireland
Consequently pending the modification of the in force MRL the intended uses of GF-2626 on kale is not considered acceptable.

IIIA 8.3.15 LETTUCE AND OTHER SALADS PLANTS

Table IIIA 8.3.15-1: Comparison of intended and critical EU GAPs

Crop	Type of GAP	Number of applications	Application rate per treatment	Interval between application	Growth stage at last application	PHI (days)
Lettuce	DAR MRL Application (USA)[1]	1-3	100 g a.s./ha	7	Up to BBCH 49	3
	DAR MRL Application (Australia)[1]	1-4	96 g a.s./ha	7	Up to BBCH 49	3
	Intended FR and SEU	1	24 g a.s./ha	-	BBCH 20-49	7

[1] MRL Application – import tolerance

IIIA 8.3.15.1 Summary of B.7.6 Data

Use on lettuce has been assessed in the meantime of the EU evaluation of sulfoxaflor, in the framework of MRL application for an import tolerance.
However this MRL application is based on an US GAP and residue trials submitted to the support the import tolerance have been performed outside EU (US and Australia) and then they cannot be considered to support the intended use of GF-2626 on lettuce in EU
Based on the supporting residue data an MRL of 4 mg/kg based on US GAP was proposed by EFSA and then adopted at EU level in Regulation 2016/1.

In the evaluation report EU trials are also summarized (IE, 2012). They were performed according to a more critical GAP than intended one (4 applications at ca 100 g as/ha). These trials were not submitted by the applicant to support the intended use of GF-2626 and are not summarized in the framework of current registration as sufficient residue trials performed according to the intended GAP have been provided.

Use on other salad plants has not been assessed in the framework of EU evaluation neither as representative use nor as an import tolerance. Consequently the in force MRLs on other salad plants are set at 0.01* mg/kg in Regulation 2016/1.

IIIA 8.3.15.2 New data

IIIA 8.3.15.2.1 Study 1

Report:	IIIA 8.3.8/01, Rawle, N. W., 2012
Title:	Residues of XDE-208 in leaf lettuce at intervals and harvest following a single application of GF-2032 – Northern and Southern Europe - 2008
Document No:	Study ID : CEMS-3938, Report ID : CEMR-3938 Dow AgroSciences Reference ID 080032-03
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"

	- OECD Guidelines for the Testing of Chemicals, No. 509: Crop Field Trial, 2009.
GLP	Yes

Acceptability	**Deviations**
Yes	None with impact on the study

Table IIIA 8.3.15-2: Summary of global information on study 1

Comparative trials (between formulations, with and adjuvant/safener/synergist)	No, SC formulation containing 240 g/L XDE-208
Number of applications	1
Dose (g as/ha)	24 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)	Method N°091031 LC-MS/MS
LoQ (mg/kg)	0.01mg/kg

Table IIIA 8.3.15-3: Summary of the study 1 trials

N° Trial		CEMS-3938A	CEMS-3938B	CEMS-3938C	CEMS-3938D	CEMS-3938E	CEMS-3938F	CEMS-3938G	CEMS-3938H
North/South/Indoor		N	N	N	N	S	S	S	S
Decline (D)/Harvest (H) trial?		D	D	D	D	D	D	D	D
Formulation		SC	SC	SC	SC	SC	SC	SC	SC
Equivalence between formulations		Y	Y	Y	Y	Y	Y	Y	Y
Accordance with intended GAP		Y	Y	Y	Y	Y	Y	Y	Y
Correct sampling		Y	Y	Y	Y	Y	Y	Y	Y
Samples frozen within 24h		Y	Y	Y	Y	Y	Y	Y	Y
Storage period (in days)	Sample	219	268	240	322	184	274	205	191
	Extract	1	1	1	1	1	1	1	1
Storage T° <-18°C		Y	Y	Y	Y	Y	Y	Y	Y
Validated analytical method		Y	Y	Y	Y	Y	Y	Y	Y
Negative controls		Y	Y	Y	Y	Y	Y	Y	Y
Considered trial		Y	Y	Y	Y	Y	Y	Y	Y
Remarks									

Table IIIA 8.3.15-4: 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

Content of a.i. (g/kg or g/l) : 240 g/L
Formulation (e.g. WP) : SC
Commercial product (name) : GF-2032
Applicant : Eurofins AgroScience Services GmbH

Active ingredient : XDE-208
Crop / crop group : Leaf vegetables : Leaf Lettuce

Indoors / outdoors : Outdoor
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 (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-3938A CEMS-3938 DAS Ref# 080032-03 Y 2008	Leaf lettuce Murai	Germany (NZ) 74229 Degmarn/Oedheim, Baden-Württemberg Outdoor (field)	GF-2032	1	24	600	4.0	29-Sep-08	BBCH.48	0 1 3 7 10	Leaves Leaves Leaves Leaves Leaves	0.808 0.556 0.143 **0.062** 0.045	0.016 0.011 <0.01 <0.01 <0.01	0.823 0.566 0.152 **0.071** 0.054	

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-3938B CEMS-3938 DAS Ref# 080032-03 Y 2008	Leaf lettuce Lollo Rossa	United Kingdom (NZ) WR118RE Harvington, Evesham, Worcestershire Outdoor (field)	GF-2032	1	24.5	603	4.1	11-Aug-08	BBCH.47	0 1 3 7 9	Leaves Leaves Leaves Leaves Leaves	0.554 0.094 0.051 0.014 **0.017**	<0.01 <0.01 <0.01 <0.01 <0.01	0.563 0.103 0.060 0.023 **0.026**	
CEMS-3938C CEMS-3938 DAS Ref# 080032-03 Y 2008	Leaf lettuce Batavia / Piticie Vilmoun	France (NZ) 56680 Plouhinec, Bretagne Outdoor (field)	GF-2032	1	24.4	508	4.8	08-Sep-08	BBCH.48	0 1 3 7 10	Leaves Leaves Leaves Leaves Leaves	0.476 0.137 0.093 **0.024** 0.019	<0.01 <0.01 <0.01 <0.01 <0.01	0.485 0.146 0.102 **0.033** 0.028	
CEMS-3938D CEMS-3938 DAS Ref# 080032-03 Y 2008	Leaf lettuce Krolowa Majowych	Poland (NZ) 64500 Smilowo, Wielkopolska Outdoor (field)	GF-2032	1	24.4	815	3.0	18-Jun-08	BBCH.49	0 1 3 7 10	Leaves Leaves Leaves Leaves Leaves	0.485 0.453 0.037 <0.01 **0.011**	<0.01 <0.01 <0.01 <0.01 <0.01	0.494 0.462 0.046 <0.019 **0.020**	
CEMS-3938E CEMS-3938 DAS Ref# 080032-03 Y 2008	Leaf lettuce Attraktion	Greece (SZ) 57019 Aggelochori, Thessaloniki Outdoor (field)	GF-2032	1	23.2	483	4.8	03-Nov-08	BBCH.49	0 1 3 7 10	Leaves Leaves Leaves Leaves Leaves	0.736 0.242 0.079 **0.056** 0.013	0.011 <0.01 <0.01 <0.01 <0.01	0.746 0.251 0.088 **0.065** 0.022	

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-3938F CEMS-3938 DAS Ref# 080032-03 Y 2008	Leaf lettuce Lolo Rosso	Spain (SZ) 46820 Anna, Valencia Outdoor (field)	GF-2032	1	24.2	807	3.0	05-Aug-08	BBCH.48	0 1 3 7 10	Leaves Leaves Leaves Leaves Leaves	0.525 0.250 0.091 0.020 **0.022**	<0.01 <0.01 <0.01 <0.01 <0.01	0.534 0.259 0.100 0.029 **0.031**	
CEMS-3938G CEMS-3938 DAS Ref# 080032-03 Y 2008	Leaf lettuce Exquese	Italy (SZ) 40057 Granarolo dell'Emilia, Bologna Outdoor (field)	GF-2032	1	24.0	599	4.0	13-Oct-08	BBCH.47 to 48	0 1 3 7 10	Leaves Leaves Leaves Leaves Leaves	0.451 0.281 0.126 0.024 **0.041**	<0.01 <0.01 <0.01 <0.01 <0.01	0.460 0.290 0.135 0.033 **0.050**	
CEMS-3938H CEMS-3938 DAS Ref# 080032-03 Y 2008	Leaf lettuce Scarolle	France (SZ) 66200 Latour-Bas- Elne Outdoor (field)	GF-2032	1	25.6	853	3.0	27-Oct-08	BBCH.47	0 1 3 7 10	Leaves Leaves Leaves Leaves Leaves	0.266 0.082 0.039 **0.018** 0.018	<0.01 <0.01 <0.01 <0.01 <0.01	0.275 0.091 0.048 **0.027** 0.027	

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

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

IIIA 8.3.15.2.2 Study 2

Report:	IIIA 8.3.8/02, Rawle, N. W., 2012
Title:	Residues of sulfoxaflor in leaf lettuce at intervals and harvest following a single application of GF-2626 – Northern and Southern Europe - 2011
Document No:	Study ID : CEMS-5022, Report ID : CEMR-5022 Dow AgroSciences ReferenceGHE-P-12718
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 8.3.15-5: Summary of global information on study 2

Comparative trials (between formulations, with and adjuvant/safener/synergist)	No, SC formulation containing 120 g/L XDE-208
Number of applications	1
Dose (g as/ha)	24 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)	Method N°091031 LC-MS/MS
LoQ (mg/kg)	0.01mg/kg

Table IIIA 8.3.15-6: Summary of the study 2 trials

N° Trial		CEMS-5022A	CEMS-5022B	CEMS-5022C	CEMS-5022D	CEMS-5022E	CEMS-5022F	CEMS-5022G	CEMS-5022H
North/South/Indoor		S	S	S	S	N	N	N	N
Decline (D)/Harvest (H) trial?		D	D	D	D	D	D	D	D
Formulation		SC	SC	SC	SC	SC	SC	SC	SC
Equivalence between formulations		Y	Y	Y	Y	Y	Y	Y	Y
Accordance with intended GAP		Y	Y	Y	Y	Y	Y	Y	Y
Correct sampling		Y	Y	Y	Y	Y	Y	Y	Y
Samples frozen within 24h		Y	Y	Y	Y	Y	Y	Y	Y
Storage period (in days)	Sample	112	243	97	223	281	135	232	145
	Extract[1]	4	4	4	4	4	4	4	4
Storage T° <-18°C		Y	Y	Y	Y	Y	Y	Y	Y
Validated analytical method		Y	Y	Y	Y	Y	Y	Y	Y
Negative controls		Y	Y	Y	Y	Y	Y	Y	Y
Considered trial		Y	Y	Y	Y	Y	Y	Y	Y
Remarks		1	1	1,	1	1	1	1	1

[1] The procedural recoveries demonstrate the stability of the analyte during this storage (up to 4 days).

Table IIIA 8.3.15-7: Summary of data from residue trials for study 2

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)
Notifier: Dow AgroSciences, European Development Centre
Content of a.i. (g/kg or g/l) : 120 g/L
Formulation (e.g. WP) : SC
Commercial product (name) : GF-2626
Applicant : Eurofins AgroScience Services GmbH

Active ingredient : Sulfoxaflor
Crop / crop group : Leaf vegetables : Leaf Lettuce
Indoors / outdoors : Outdoor
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 (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-5022A CEMS-5022 GHE-P-12718 Y 2011	Leaf Lettuce Mancheste r	Greece (SZ) 57008 Nea Magnisia, Thessalonik i Outdoor (field)	GF-2626	1	26.0	433	6.0	31-Oct-11	BBCH.48	0 1 3 7 10	Leaves Leaves Leaves Leaves Leaves	0.561 0.189 0.135 **0.105** 0.058	<0.01 <0.01 <0.01 <0.01 <0.01	0.570 0.197 0.144 **0.114** 0.067	
CEMS-5022B CEMS-5022 GHE-P-12718 Y 2011	Leaf Lettuce Mancheste r M.T.	Bulgaria (SZ) 5570 Letnitsa, Lovetch Outdoor (field)	GF-2626	1	25.9	407	6.4	22-Jun-11	BBCH.45	0 1 3 7 10	Leaves Leaves Leaves Leaves Leaves	1.274 0.209 0.034 **<0.01** <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	1.283 0.218 0.043 **<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-5022C CEMS-5022 GHE-P-12718 Y 2011	Leaf Lettuce Kitare	France (SZ) 66200 Elne, Pyrénées-Orientales Outdoor (field)	GF-2626	1	25.3	422	6.0	15-Nov-11	BBCH.47	0 1 3 7 10	Leaves Leaves Leaves Leaves Leaves	0.233 0.040 0.023 **<u><0.01</u>** <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	0.242 0.049 0.032 **<u><0.019</u>** <0.019	
CEMS-5022D CEMS-5022 GHE-P-12718 Y 2011	Leaf Lettuce Gentilina	Italy (SZ) 40057 Granarolo, Bologna Outdoor (field)	GF-2626	1	22.5	378	6.0	12-Jul-11	BBCH.45 to 46	0 1 3 7 10	Leaves Leaves Leaves Leaves Leaves	0.689 0.088 0.023 **<u><0.01</u>** <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	0.698 0.097 0.032 **<u><0.019</u>** <0.019	
CEMS-5022E CEMS-5022 GHE-P-12718 Y 2011	Leaf Lettuce Crispa	Germany (NZ) 71706 Unterriexingen, Baden-Württemberg Outdoor (field)	GF-2626	1	26.1	327	8.0	10-May-11	BBCH.47	0 1 3 7 10	Leaves Leaves Leaves Leaves Leaves	0.694 0.473 0.071 **<u>0.015</u>** <0.01	0.012 <0.01 <0.01 <0.01 <0.01	0.705 0.482 0.080 **<u>0.024</u>** <0.019	
CEMS-5022F CEMS-5022 GHE-P-12718 Y 2011	Leaf Lettuce Jolito	Hungary (NZ) 6760 Kistelek, Csongrad Outdoor (field)	GF-2626	1	26.1	544	4.8	03-Oct-11	BBCH.43	0 1 3 7 10	Leaves Leaves Leaves Leaves Leaves	0.634 0.461 0.128 0.031 **<u>0.042</u>**	<0.01 <0.01 <0.01 <0.01 <0.01	0.643 0.470 0.137 0.040 **<u>0.051</u>**	

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-5022G CEMS-5022 GHE-P-12718 Y 2011	Leaf Lettuce Abago	France (NZ) 56330 Pluvigner, Bretagne Outdoor (field)	GF-2626	1	25.3	211	12.0	28-Jun-11	BBCH.47	0 1 3 7 10	Leaves Leaves Leaves Leaves Leaves	0.482 0.074 0.042 **<u><0.01</u>** <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	0.491 0.083 0.051 **<u><0.019</u>** <0.019	
CEMS-5022H CEMS-5022 GHE-P-12718 Y 2011	Leaf Lettuce Oak Leaf Red	United Kingdom (NZ) CO7-7RU Colchester, East Anglia Outdoor (field)	GF-2626	1	23.8	402	6.0	23-Sep-11	BBCH.48 to 49	0 1 3 7 10	Leaves Leaves Leaves Leaves Leaves	0.498 0.081 0.034 **<u>0.016</u>** 0.011	<0.01 <0.01 <0.01 <0.01 <0.01	0.507 0.090 0.043 **<u>0.025</u>** 0.020	

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

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

IIIA 8.3.15.2.3 Study 3

Report:	IIIA 8.3.8/03, Rawle, N. W., 2012
Title:	Residues of XDE-208 in head lettuce at intervals and harvest following a single application of GF-2032 – Northern and Southern Europe - 2008
Document No:	Study ID : CEMS-3941, Report ID : CEMR-3938 Dow AgroSciences Reference ID 080032-01
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" - OECD Guidelines for the Testing of Chemicals, No. 509: Crop Field Trial, 2009.
GLP	Yes

Acceptability	**Deviations**
Yes	None with impact on the study

Table IIIA 8.3.15-8: Summary of global information on study 3

Comparative trials (between formulations, with and adjuvant/safener/synergist)	No, SC formulation containing 240 g/L XDE-208
Number of applications	1
Dose (g as/ha)	24 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)	Method N°091031 LC-MS/MS
LoQ (mg/kg)	0.01mg/kg

Table IIIA 8.3.15-9: Summary of the study 3 trials

N° Trial		CEMS-3941A	CEMS-3941B	CEMS-3941C	CEMS-3941D	CEMS-3941E	CEMS-3941F	CEMS-3941G	CEMS-3941H
North/South/Indoor		N	N	N	N	S	S	S	S
Decline (D)/Harvest (H) trial?		D	D	D	D	D	D	D	D
Formulation		SC	SC	SC	SC	SC	SC	SC	SC
Equivalence between formulations		Y	Y	Y	Y	Y	Y	Y	Y
Accordance with intended GAP		Y	Y	Y	Y	Y	Y	Y	Y
Correct sampling		Y	Y	Y	Y	Y	Y	Y	Y
Samples frozen within 24h		Y	Y	Y	Y	Y	Y	Y	Y
Storage period (in days)	Sample	220	278	199	233	185	317	206	155
	Extract[1]	4	4	4	4	4	4	4	4
Storage T° <-18°C		Y	Y	Y	Y	Y	Y	Y	Y
Validated analytical method		Y	Y	Y	Y	Y	Y	Y	Y
Negative controls		Y	Y	Y	Y	Y	Y	Y	Y
Considered trial		Y	Y	Y	Y	Y	Y	Y	Y
Remarks									

[1] The procedural recoveries demonstrate the stability of the analyte during this storage (up to 4 days)

Table IIIA 8.3.15-10: Summary of data from residue trials for study 3

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Notifier: Dow AgroSciences, European Development Centre

Content of a.i. (g/kg or g/l) : 240 g/L
Formulation (e.g. WP) : SC
Commercial product (name) : GF-2032
Applicant : Eurofins AgroScience Services GmbH

Active ingredient : XDE-208
Crop / crop group : Leafy vegetables : Head Lettuce

Indoors / outdoors : Outdoor
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 (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-3941A CEMS-3941 DAS Ref# 080032-01 Y 2008	Head lettuce Lucan	Germany (NZ) 74177 Bad Friedrichshall, Baden-Württemberg Outdoor (field)	GF-2032	1	24.1	603	4.0	29-Sep-08	BBCH.48	0 1 3 7 10	Head Head Head Head Head	0.244 0.253 0.041 **0.021** 0.014	<0.01 <0.01 <0.01 <0.01 <0.01	0.253 0.262 0.050 **0.030** 0.023	
CEMS-3941B CEMS-3941 DAS Ref# 080032-01 Y 2008	Head lettuce Talia	United Kingdom (NZ) PR9-8EB Banks/Southport, Merseyside Outdoor (field)	GF-2032	1	24.4	600	4.1	02-Aug-08	BBCH.47	0 1 3 6 10	Head Head Head Head Head	0.308 <0.01 0.054 **<0.01** <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	0.317 <0.019 0.063 **<0.019** <0.019	
CEMS-3941C CEMS-3941 DAS Ref# 080032-01 Y 2008	Head lettuce Estrella	Germany (NZ) 71706 Unterriexingen, Baden-Württemberg Outdoor (field)	GF-2032	1	24.8	619	4.0	20-Oct-08	BBCH.48	0 1 3 8 10	Head Head Head Head Head	0.128 0.224 0.035 **0.022** <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	0.137 0.233 0.044 **0.031** <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-3941D CEMS-3941 DAS Ref# 080032-01 Y 2008	Head lettuce Grenada	Poland (NZ) 62090 Rokietnica, Wielkopolska Outdoor (field)	GF-2032	1	23.5	587	4.0	16-Sep-08	BBCH.48	0 1 3 7 10	Head Head Head Head Head	<0.01 <0.01 <0.01 **<u><0.01</u>** <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	<0.019 <0.019 <0.019 **<u><0.019</u>** <0.019	
CEMS-3941E CEMS-3941 DAS Ref# 080032-01 Y 2008	Head lettuce Iceberg	Greece (SZ) 57019 Aggelochori, Thessaloniki Outdoor (field)	GF-2032	1	22.9	477	4.8	03-Nov-08	BBCH.49	0 1 3 7 10	Head Head Head Head Head	0.451 0.198 0.094 0.027 **<u>0.034</u>**	<0.01 <0.01 <0.01 <0.01 <0.01	0.460 0.207 0.103 0.036 **<u>0.043</u>**	
CEMS-3941F CEMS-3941 DAS Ref# 080032-01 Y 2008	Head lettuce Iceberg	Spain (SZ) 46820 Anna, Valencia Outdoor (field)	GF-2032	1	23.6	788	3.0	24-Jun-08	BBCH.46	0 1 3 7 10	Head Head Head Head Head	0.238 0.106 0.021 **<u>0.019</u>** <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	0.247 0.115 0.030 **<u>0.028</u>** <0.019	
CEMS-3941G CEMS-3941 DAS Ref# 080032-01 Y 2008	Head lettuce Impulsion	Italy (SZ) 40057 Granarolo, Emilia Romagna Outdoor (field)	GF-2032	1	22.5	563	4.0	13-Oct-08	BBCH.47 to 48	0 1 3 7 10	Head Head Head Head Head	0.184 0.043 0.024 **<u><0.01</u>** <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	0.193 0.052 0.033 **<u><0.019</u>** <0.019	
CEMS-3941H CEMS-3941 DAS Ref# 080032-01 Y 2008	Head lettuce Maral	France (SZ) 66600 Rivesaltes, Languedoc-Roussillon Outdoor (field)	GF-2032	1	24.5	816	3.0	03-Dec-08	BBCH.49	0 1 3 7 9	Head Head Head Head Head	0.258 0.105 0.108 0.037 **<u>0.049</u>**	<0.01 <0.01 <0.01 <0.01 <0.01	0.267 0.114 0.117 0.046 **<u>0.058</u>**	

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

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

IIIA 8.3.15.2.4 Study 4

Report:	IIIA 8.3.8/04, Rawle, N. W., 2012
Title:	Residues of sulfoxaflor in head lettuce at intervals and harvest following a single application of GF-2626 – Northern and Southern Europe - 2011
Document No:	Study ID : CEMS-5023, Report ID : CEMR-5023 Dow AgroSciences Reference : GHE-P-12719
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 8.3.15-11: Summary of global information on study 4

Comparative trials (between formulations, with and adjuvant/safener/synergist)	No, SC formulation containing 120 g/L XDE-208
Number of applications	1
Dose (g as/ha)	24 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)	Method N°091031 LC-MS/MS
LoQ (mg/kg)	0.01mg/kg

Table IIIA 8.3.15-12: Summary of the study 4 trials

N° Trial		CEMS-5023A	CEMS-5023B	CEMS-5023C	CEMS-5023D	CEMS-5023E	CEMS-5023F	CEMS-5023G	CEMS-5023H
North/South/Indoor		N	N	N	N	S	S	S	S
Decline (D)/Harvest (H) trial?		D	D	D	D	D	D	D	D
Formulation		SC	SC	SC	SC	SC	SC	SC	SC
Equivalence between formulations		Y	Y	Y	Y	Y	Y	Y	Y
Accordance with intended GAP		Y	Y	Y	Y	Y	Y	Y	Y
Correct sampling		Y	Y	Y	Y	Y	Y	Y	Y
Samples frozen within 24h		Y	Y	Y	Y	Y	Y	Y	Y
Storage period (in days)	Sample	145	247	169	239	241	143	171	128
	Extract[1]	5	5	5	5	5	5	5	5
Storage T° <-18°C		Y	Y	Y	Y	Y	Y	Y	Y
Validated analytical method		Y	Y	Y	Y	Y	Y	Y	Y
Negative controls		Y	Y	Y	Y	Y	Y	Y	Y
Considered trial		Y	Y	Y	Y	Y	Y	Y	Y
Remarks									

[1] The procedural recoveries demonstrate the stability of the analyte during this storage (up to 5 days).

Table IIIA 8.3.15-13: Summary of data from residue trials for study 4

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Notifier: Dow AgroSciences, European Development Centre
Content of a.i. (g/kg or g/l) : 120 g/L
Formulation (e.g. WP) : SC
Commercial product (name) : GF-2626
Applicant : Eurofins AgroScience Services GmbH

Active ingredient : Sulfoxaflor
Crop / crop group : Leafy vegetables : Head Lettuce
Indoors / outdoors : Outdoor
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 (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-5023A CEMS-5023 GHE-P-12719 Y 2011	Head Lettuce Little Green	United Kingdom (NZ) CO7 7RU Colchester, Essex Outdoor (field)	GF-2626	1	24.2	409	5.9	23-Sep-11	BBCH.48	0 1 3 7 10	Head Head Head Head Head	0.034 0.019 <0.01 **<u><0.01</u>** <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	0.043 0.028 <0.019 **<u><0.019</u>** <0.019	
CEMS-5023B CEMS-5023 GHE-P-12719 Y 2011	Head Lettuce Analena	Poland (NZ) 64514 Przeclaw, Wielkopolska Outdoor (field)	GF-2626	1	24.5	383	6.4	13-Jun-11	BBCH.47	0 1 3 7 10	Head Head Head Head Head	0.305 0.029 0.023 **<u><0.01</u>** <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	0.314 0.038 0.032 **<u><0.019</u>** <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-5023C CEMS-5023 GHE-P-12719 Y 2011	Head Lettuce Forlina	Germany (NZ) 69124 Heidelberg-Neurott, Baden-Württemberg Outdoor (field)	GF-2626	1	27.3	344	7.9	30-Aug-11	BBCH.43	0 1 3 7 10	Head Head Head Head Head	0.211 0.146 0.118 **0.017** <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	0.220 0.155 0.127 **0.026** <0.019	
CEMS-5023D CEMS-5023 GHE-P-12719 Y 2011	Head Lettuce Guetary	France (NZ) 56680 Plouhinec, Morbihan Outdoor (field)	GF-2626	1	24.7	206	12.0	21-Jun-11	BBCH.46	0 1 3 7 10	Head Head Head Head Head	0.178 0.153 0.027 **0.015** <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	0.187 0.162 0.036 **0.024** <0.019	
CEMS-5023E CEMS-5023 GHE-P-12719 Y 2011	Head Lettuce Cervantes	Spain (SZ) 46820, Anna, Valencia Outdoor (field)	GF-2626	1	25.6	533	4.8	25-Jul-11	BBCH.46	0 1 3 7 10	Head Head Head Head Head	0.219 0.122 0.058 **<0.01** <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	0.228 0.131 0.067 **<0.019** <0.019	
CEMS-5023F CEMS-5023 GHE-P-12719 Y 2011	Head Lettuce Justin	Greece (SZ) 57008 Nea Magnisia, Thessaloniki Outdoor (field)	GF-2626	1	24.9	415	6.0	31-Oct-11	BBCH.47	0 1 3 7 10	Head Head Head Head Head	0.035 0.050 0.021 **<0.01** <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	0.044 0.059 0.030 **<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-5023G CEMS-5023 GHE-P-12719 Y 2011	Head Lettuce Iceberg	Italy (SZ) 40057 Granarolo, Bologna Outdoor (field)	GF- 2626	1	24.4	410	6.0	03-Oct-11	BBCH.45 to 47	0 1 3 7 10	Head Head Head Head Head	<0.01 <0.01 <0.01 **<u><0.01</u>** <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	<0.019 <0.019 <0.019 **<u><0.019</u>** <0.019	
CEMS-5023H CEMS-5023 GHE-P-12719 Y 2011	Head Lettuce Forlina	France (SZ) 66200 Elne, Pyrénées- Orientales Outdoor (field)	GF- 2626	1	24.3	404	6.0	15-Nov-11	BBCH.47	0 1 3 7 10	Head Head Head Head Head	0.251 0.018 0.016 **<u><0.01</u>** <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	0.260 0.027 0.025 **<u><0.019</u>** <0.019	

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

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

IIIA 8.3.15.3 Summary of monograph and new data supporting the intended use on lettuce and conformity to existing MRL

Table IIIA 8.3.15-14: Summary of monograph and new data supporting the intended use on 1ettuce 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
Lettuce	New trials	North (8 open leaves lettuce)	Trials GAP: 1x24 g a.s./ha – PHI 7 days MO : <0.01, 0.011, 0.015, 0.016, 0.017, 0.024, 0.042, 0.062 RA : <0.019, 0.020, 0.024, 0.025, 0.026, 0.033, 0.051, 0.071							
		North (8 head lettuce)	Trials GAP: 1x24 g a.s./ha – PHI 7 days MO : 4 x <0.01, 0.015, 0.017, 0.021, 0.022 RA : 4 x <0.019, 0.024, 0.026, 0.030, 0.031							
		South (8 open leaves lettuce)	Trials GAP: 1x24 g a.s./ha – PHI 7 days MO : 3 x <0.01, 0.018, 0.022, 0.041, 0.056, 0.105 RA : 3 x <0.019, 0.027, 0.031, 0.050, 0.065, 0.114							
		South (8 head lettuce)	Trials GAP: 1x24 g a.s./ha – PHI 7 days MO : 5 x <0.01, 0.019, 0.034, 0.049 RA : 5 x <0.019, 0.028, 0.043, 0.058							
	Overall supporting data for FR, IT, SP & SEU	North (8 open lettuce)	MO : <0.01, 0.011, 0.015, 0.016, 0.017, 0.024, 0.042, 0.062	0.017	0.062	0.08	0.08	0.098 → 0.1	4.0	Yes
			RA : <0.019, 0.020, 0.024, 0.025, 0.026, 0.033, 0.051, 0.071	0.026	0.071					

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
	GAP	North (8 head lettuce)	MO : 4 x <0.01, 0.015, 0.017, 0.021, 0.022	0.013	0.022	0.04	0.03	0.035 → 0.04		
			RA : 4 x <0.019, 0.024, 0.026, 0.030, 0.031	0.022	0.031					
		North (16)	MO : 5 x <0.01, 0.011, 2 x 0.015, 0.016, 2 x 0.017, 0.021, 0.022, 0.024, 0.042, 0.062	0.016	0.062	0.04	0.06	0.075 → 0.08		
			RA : 5 x <0.019, 0.020, 2 x 0.024, 0.025, 2 x 0.026, 0.030, 0.031, 0.033, 0.051, 0.071	0.025	0.071					
		South (8 open lettuce)	MO : 3 x <0.01, 0.018, 0.022, 0.041, 0.056, 0.105	0.02	0.105	0.11	0.14	0.167 → 0.2		
			RA : 3 x <0.019, 0.027, 0.031, 0.050, 0.065, 0.114	0.029	0.114					
		South (8 head lettuce	MO : 5 x <0.01, 0.019, 0.034, 0.049	0.01	0.049	0.06	0.07	0.078 → 0.08		
			RA : 5 x <0.019, 0.028, 0.043, 0.058	0.019	0.058					
		South (16)	MO : 8 x <0.01, 0.018, 0.019, 0.022, 0.034, 0.041, 0.049, 0.056, 0.105	0.01	0.105	0.08	0.09	0.13 → 0.15		
			RA : 8 x <0.019, 0.027, 0.028, 0.031, 0.043, 0.050, 0.058, 0.065, 0.114	0.023	0.114					

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

IIIA 8.3.15.4 Conclusion for lettuce

A total of 16 SEU and the 16 NEU residues trials are available to support the intended uses on lettuce. Among these trials 8 SEU and 8 NEU residues trials were performed on open leaves lettuce varieties. Therefore enough residue data are available to support the intended uses and no further data are required.

On the basis of the available supporting residue data it is possible to conclude that the in force MRL of 4 mg/kg on lettuce will not be exceed according to the intended GAP in EU.

According to EU guideline 7525/VI/95-rev.10, Appendix D « Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs», extrapolation of residue data from open leaves lettuce to the whole group of lettuce and other salad plants group is possible when the application is performed close to harvest.
Nevertheless in force MRLs on other salad plants are set at 0.01* mg/kg in Regulation 2016/1. Therefore on the basis of the available supporting residue data it is possible to conclude that the current MRL of 0.01* mg/kg on other salads plant will be exceed according to the intended GAP in EU.
Consequently uses on lamb lettuce, escarole, cress, ruccola, red mustard and baby leaf crops are not considered acceptable.

IIIA 8.3.16 SPINACH AND SIMILAR LEAVES

Table IIIA 8.3.16-1: Comparison of intended and critical EU GAPs

Crop	Type of GAP	Number of applications	Application rate per treatment	Interval between application	Growth stage at last application	PHI (days)
Spinach	DAR MRL Application (USA)[1]	1-3	100 g a.s./ha	7	Up to BBCH 49	3
	DAR MRL Application (Australia)[1]	1-4	96 g a.s./ha	7	Up to BBCH 49	3
	Intended FR and SEU	1	24 g a.s./ha	-	BBCH 20-49	7

[1] MRL Application

Use on spinach has been assessed in the meantime of the EU evaluation of sulfoxaflor, in the framework of MRL application for an import tolerance.
However this MRL application is based on an US and Australian GAP and residue trials submitted to the support the import tolerance have been performed outside EU (US and Australia) and then they cannot be considered to support the intended use of GF-2626 on spinach in EU
Based on the supporting residue data an MRL of 6 mg/kg based on US GAP was proposed by EFSA and then adopted at EU level in Regulation 2016/1.

Uses on purslane and chards have not been assessed in the framework of EU evaluation neither as representative use nor as an import tolerance. Consequently the in force MRLs on purslane and chards are set at 0.01* mg/kg in Regulation 2016/1.

According to EU guideline 7525/VI/95-rev.10, Appendix D « Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs», extrapolation of residue data from open leaves lettuce to the whole group of spinach similar leaves is possible when the application is performed close to harvest.
On the basis of the available supporting residue data on open leaves lettuce it is possible to conclude that current MRL of 6 mg/kg on spinach will not be exceed according to the intended GAP in EU.
Nevertheless in force MRLs on purslane and chard are set at 0.01* mg/kg in Regulation 2016/1. Therefore on the basis of the available supporting residue data it is possible to conclude that the current MRL of 0.01* mg/kg on purslane and chard will be exceed according to the intended GAP in EU.
Consequently uses on purslane and chard are not considered acceptable.

IIIA 8.3.17 LEGUMES VEGETABLES (FRESH PEAS AND BEANS WITH PODS)

Table IIIA 8.3.17-1: Comparison of intended and critical EU GAPs

Crop	Type of GAP	Number of applications	Application rate per treatment	Interval between application	Growth stage at last application	PHI (days)
Succulent bean	DAR MRL Application (USA)[1]	1-4	80 g a.s./ha	14	-	7
Beans and peas with pods	Intended BG, EL, ES, FR, IT, PT	2	24 g a.s./ha	21		14

[1] MRL Application

Use on fresh beans has been assessed in the framework of MRL application for an import tolerance.
This MRL application is based on US GAP and residue trials submitted to the support the import tolerance were performed in EU. Consequently EU trials were not considered valid by EFSA and no MRL was proposed and then a default MRL of 0.01* mg/kg was set for fresh beans at EU level in Regulation 2016/1.

Use on fresh peas has not been assessed in the framework of EU evaluation neither as representative use nor as an import tolerance. Consequently the in force MRLs on these crops are set at 0.01* mg/kg in Regulation 2016/1.

It should be noted that EU trials summarized in the evaluation report were performed according to a more critical GAP than intended one (4 applications at ca 100 g as/ha). As these EU trials involved residue levels which are not in accordance with the in force MRL, they cannot be used to support the intended uses of GF-2626 on fresh vegetables.

According to EU guideline 7525/VI/95-rev.10, Appendix D « Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs», extrapolation of residue data between fresh beans with pods and fresh peas with pods is possible when the application is performed close to harvest.

The applicant provided 12 SEU and 8 NEU residue trials to support the intended uses on fresh beans with pods and fresh peas with pods.
Nevertheless these trials have not been assessed as it appears that the intended GAP involved an MRL exceedance (see table below). Furthermore some of the trials were performed at a less critical GAP.

The submitted trials are then only summarized below on information basis.
According to the applicant an application to modify the in force MRL from 0.01* to 0.15 mg/kg on fresh beans with pods and fresh peas with pods has been submitted to the EMS Ireland.

Pending the modification of the in force MRL the intended GAPs on fresh beans with pods and fresh peas with pods are not considered acceptable.

Table IIIA 8.3.17-2: Summary of residues data for sulfoxaflor in beans and peas (fresh, with pods) at the GAP for GF-2626

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-3974A CEMS-3974 DAS Ref# 080113-01 Y 2008	Beans Contender	France SZ Outdoor (field)	GF-2032	1	25.5	213	12.0	07-Jul-08	BBCH.79	0 1 3 7 10	Whole pods Whole pods Whole pods Whole pods Whole pods	0.032 0.019 0.015 <0.01 **<u><0.01</u>**	<0.01 <0.01 <0.01 <0.01 <0.01	0.041 0.028 0.024 <0.019 **<u><0.019</u>**
CEMS-3974B CEMS-3974 DAS Ref# 080113-01 Y 2008	Beans Cleo	Spain SZ Outdoor (field)	GF-2032	1	23.2	387	6.0	28-Jul-08	BBCH.78	0 1 3 7 10	Whole pods Whole pods Whole pods Whole pods Whole pods	0.042 0.020 0.010 <0.01 **<u><0.01</u>**	<0.01 <0.01 <0.01 <0.01 <0.01	0.051 0.029 0.019 <0.019 **<u><0.019</u>**
CEMS-3974C CEMS-3974 DAS Ref# 080113-01 Y 2008	Beans Polo	Italy SZ Outdoor (field)	GF-2032	1	23.9	399	6.0	10-Jun-08	BBCH.78 to 79	0 1 3 7 10	Whole pods Whole pods Whole pods Whole pods Whole pods	0.107 0.098 0.047 <0.01 **<u>0.029</u>**	<0.01 <0.01 <0.01 <0.01 <0.01	0.116 0.107 0.056 <0.019 **<u>0.038</u>**
CEMS-3974D CEMS-3974 DAS Ref# 080113-01 Y 2008	Beans Roco	Greece SZ Outdoor (field)	GF-2032	1	24.8	517	4.8	06-Oct-08	BBCH.79	0 1 3 7 10	Whole pods Whole pods Whole pods Whole pods Whole pods	0.041 0.022 0.022 0.012 **<u><0.01</u>**	<0.01 <0.01 <0.01 <0.01 <0.01	0.050 0.031 0.031 0.021 **<u><0.019</u>**

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-5024A CEMS-5024 GHE-P-12720 Y 2011	Green beans Tabella	Spain SZ Outdoor (field)	GF-2626	2	25.1 26.0	521 541	4.8 4.8	29-Aug-11 19-Sep-11	BBCH.77	21 <0 0 1 3 7 9 14 21 <0 0 1 3 7 9 14	Beans, Dried Rest of plant Rest of plant Rest of plant Rest of plant Rest of plant Rest of plant Rest of plant Straw Whole pods Whole pods Whole pods Whole pods Whole pods Whole pods Whole pods	<0.01 <0.01 1.265 0.984 0.428 0.084 0.030 0.013 0.032 <0.01 0.036 0.050 0.028 <0.01 <0.01 **<u><0.01</u>**	<0.01 <0.01 0.018 0.017 0.017 <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 1.282 1.000 0.444 0.093 0.039 0.022 0.041 <0.019 0.045 0.059 0.037 <0.019 <0.019 **<u><0.019</u>**

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-5024B CEMS-5024 GHE-P-12720 Y 2011	Green beans Corela	Bulgaria SZ Outdoor (field)	GF-2626	2	25.2 24.3	525 506	4.8 4.8	08-Sep-11 29-Sep-11	BBCH.78	35 <0 0 1 3 7 10 14 35 <0 0 1 3 7 10 14	Beans, Dried Rest of plant Rest of plant Rest of plant Rest of plant Rest of plant Rest of plant Rest of plant Straw Whole pods Whole pods Whole pods Whole pods Whole pods Whole pods Whole pods	<0.01 0.010 0.952 0.876 0.306 0.242 0.045 0.029 <0.01 <0.01 0.044 0.020 0.017 0.014 <0.01 **<0.01**	<0.01 <0.01 <0.01 0.014 <0.01 0.011 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	<0.019 <0.019 0.961 0.889 0.315 0.252 0.054 0.038 <0.019 <0.019 0.053 0.029 0.026 0.023 <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-5024D CEMS-5024 GHE-P-12720 Y 2011	Green beans Vesuvio	Italy SZ Outdoor (field)	GF-2626	2	25.2 24.4	212 205	11.9 11.9	16-May-11 06-Jun-11	BBCH.83 to 85	<0 0 1 3 7 10 14 <0 0 1 3 7 10 14	Rest of plant Rest of plant Rest of plant Rest of plant Rest of plant Rest of plant Rest of plant Whole pods Whole pods Whole pods Whole pods Whole pods Whole pods Whole pods	0.012 0.596 0.266 0.170 0.349 0.244 0.205 <0.01 0.134 0.069 0.043 0.082 0.095 **0.088**	<0.01 0.016 <0.01 <0.01 0.030 0.027 0.039 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.021 0.611 0.275 0.179 0.377 0.269 0.242 <0.019 0.143 0.078 0.052 0.091 0.104 **0.097**

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-5024I CEMS-5024 GHE-P-12720 Y 2011	Green beans Linek	France SZ Outdoor (field)	GF-2626	2	23.7 24.3	397 407	6.0 6.0	01-Aug-11 22-Aug-11	BBCH.87	21 <0 0 1 3 7 10 14 21 <0 0 1 3 7 10 14	Beans, Dried Rest of plant Rest of plant Rest of plant Rest of plant Rest of plant Rest of plant Rest of plant Straw Whole pods Whole pods Whole pods Whole pods Whole pods Whole pods Whole pods	<0.01 0.010 1.233 0.789 0.525 0.053 0.053 <0.01 <0.01 <0.01 0.036 0.029 0.026 <0.01 <0.01 **<u><0.01</u>**	<0.01 0.062 0.105 0.088 0.078 0.058 0.020 <0.01 0.016 0.010 0.011 <0.01 0.012 0.010 <0.01 0.011	<0.019 0.068 1.332 0.872 0.598 0.107 0.072 <0.019 0.025 <0.019 0.046 0.038 0.037 <0.019 <0.019 **0.020**
CEMS-5951A CEMS-5951 # 130193 Y 2013	Green beans Emili	Spain SZ Outdoor (field)	GF-2032	2	22.7 23.5	673 697	3.4 3.4	04-Jul-13 18-Jul-13	BBCH 65 BBCH 71	14	Whole pods	**<u><0.01</u>**	<0.01	**<u><0.019</u>**
CEMS-5951B CEMS-5951 # 130193 Y 2013	Green beans Contender	Spain SZ Outdoor (field)	GF-2032	2	23.5 23.5	693 680	3.4 3.5	04-Jul-13 18-Jul-13	BBCH 65 BBCH 71	15	Whole pods	**<u><0.01</u>**	<0.01	**<u><0.019</u>**

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-5951C CEMS-5951 # 130193 Y 2013	Green beans Cueto	Spain SZ Outdoor (field)	GF-2032	2	23.5 24.9	593 737	4.0 3.4	19-Jun-13 03-Jul-13	BBCH 65-69 BBCH 69-71	14	Whole pods	**0.011**	<0.01	**0.020**
CEMS-5951D CEMS-5951 # 130193 Y 2013	Green beans Contender	Spain SZ Outdoor (field)	GF-2032	2	25.7 24.2	753 717	3.4 3.4	16-Jul-13 31-Jul-13	BBCH 71 BBCH 75	14	Whole pods	**<0.01**	<0.01	**<0.019**
CEMS-3974E CEMS-3974 DAS Ref# 080113-01 Y 2008	Beans Janka	Hungary NZ Outdoor (field)	GF-2032	1	24.1	502	4.8	09-Sep-2008	BBCH.77	0 1 3 8 10	Whole pods Whole pods Whole pods Whole pods Whole pods	0.088 0.043 0.019 <0.01 **<0.01**	<0.01 <0.01 <0.01 <0.01 <0.01	0.097 0.052 0.028 <0.019 **<0.019**
CEMS-3974F CEMS-3974 DAS Ref# 080113-01 Y 2008	Beans Sonesta	Poland NZ Outdoor (field)	GF-2032	1	22.6	377	6.0	07-Jul-2008	BBCH.72	0 1 3 7 10	Whole pods Whole pods Whole pods Whole pods Whole pods	0.046 0.014 0.013 <0.01 **<0.01**	<0.01 <0.01 <0.01 <0.01 <0.01	0.055 0.023 0.022 <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-3974G CEMS-3974 DAS Ref# 080113-01 Y 2008	Beans Spectra	Germany NZ Outdoor (field)	GF-2032	1	26.4	440	6.0	21-Sep-2008	BBCH.78	0 1 3 7 10	Whole pods Whole pods Whole pods Whole pods Whole pods	0.022 0.029 0.013 0.012 **<u><0.01</u>**	<0.01 <0.01 <0.01 <0.01 <0.01	0.031 0.038 0.022 0.021 **<u><0.019</u>**
CEMS-3974I CEMS-3974 DAS Ref# 080113-01 Y 2008	Beans Flauet	France NZ Outdoor (field)	GF-2032	1	24.3	303	8.0	29-Sep-2008	BBCH.79	0 1 3 7 10	Whole pods Whole pods Whole pods Whole pods Whole pods	0.077 0.061 0.045 <0.01 **<u><0.01</u>**	<0.01 <0.01 <0.01 <0.01 <0.01	0.086 0.070 0.054 <0.019 **<u><0.019</u>**

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-5024E CEMS-5024 GHE-P-12720 Y 2011	Field beans Niele	Germany NZ Outdoor (field)	GF-2626	2	23.7 23.8	297 297	8.0 8.0	27-Jun-2011 19-Jul-2011	BBCH.78	59 <0 0 1 3 7 9 14 59 <0 0 1 3 7 9 14	Beans, Dry Rest of plant Rest of plant Rest of plant Rest of plant Rest of plant Rest of plant Rest of plant Straw Whole pods Whole pods Whole pods Whole pods Whole pods Whole pods Whole pods	<0.01 0.105 0.746 0.413 0.358 0.161 0.208 0.165 <0.01 <0.01 0.011 0.023 0.015 0.015 <0.01 **<0.01**	<0.01 0.017 0.036 0.024 0.024 0.013 0.022 0.016 0.010 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	<0.019 0.121 0.780 0.436 0.381 0.173 0.229 0.180 <0.019 <0.019 0.020 0.032 0.024 0.024 <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-5024F	Green	Hungary	GF-	2	23.7	496	4.8	17-Sep-2011	BBCH.78	<0	Rest of plant	<0.01	<0.01	<0.019
CEMS-5024	beans	NZ	2626		23.9	500	4.8	07-Oct-2011		0	Rest of plant	1.133	0.026	1.157
GHE-P-12720	Trento	Outdoor								1	Rest of plant	0.334	0.026	0.358
Y		(field)								3	Rest of plant	0.274	0.039	0.311
2011										6	Rest of plant	0.087	0.028	0.113
										9	Rest of plant	0.098	0.030	0.126
										14	Rest of plant	0.069	0.030	0.097
										21	Straw	0.038	<0.01	0.047
										<0	Whole pods	<0.01	<0.01	<0.019
										0	Whole pods	0.034	<0.01	0.043
										1	Whole pods	0.043	<0.01	0.052
										3	Whole pods	0.020	<0.01	0.029
										6	Whole pods	0.011	<0.01	0.020
										9	Whole pods	0.013	<0.01	0.022
										14	Whole pods	**0.016**	<0.01	**0.025**

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-5024G CEMS-5024 GHE-P-12720 Y 2011	Green beans Coco de Painpol	France NZ Outdoor (field)	GF-2626	2	22.1 26.4	138 165	16.0 16.0	18-Aug-2011 09-Sep-2011	BBCH.78	20 <0 0 1 3 6 10 13 20 <0 0 1 3 6 10 13	Beans, Dried Rest of plant Rest of plant Rest of plant Rest of plant Rest of plant Rest of plant Rest of plant Straw Whole pods Whole pods Whole pods Whole pods Whole pods Whole pods Whole pods	<0.01 0.012 0.883 0.573 0.127 0.046 0.022 0.028 <0.01 <0.01 0.018 0.023 0.012 <0.01 <0.01 **<0.01**	<0.01 <0.01 0.010 <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 0.021 0.892 0.582 0.136 0.055 0.031 0.037 <0.019 <0.019 0.027 0.032 0.021 <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-5024H CEMS-5024 GHE-P-12720 Y 2011	Green beans Unidor	Poland NZ Outdoor (field)	GF-2626	2	25.2 25.5	420 424	6.0 6.0	26-Jul-2011 18-Aug-2011	BBCH.75 to 76	49 <0 0 1 3 7 11 15 49 <0 0 1 3 7 11 15	Beans, Dried Rest of plant Rest of plant Rest of plant Rest of plant Rest of plant Rest of plant Rest of plant Straw Whole pods Whole pods Whole pods Whole pods Whole pods Whole pods Whole pods	<0.01 0.021 0.934 0.760 0.098 0.066 0.012 <0.01 <0.01 <0.01 0.026 0.028 <0.01 <0.01 <0.01 <0.01 **<0.01**	<0.01 0.027 0.045 0.042 0.020 0.024 0.022 0.024 0.019 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	<0.019 0.046 0.976 0.799 0.117 0.089 0.033 0.033 0.028 <0.019 0.035 0.037 <0.019 <0.019 <0.019 <0.019 **<0.019**

IIIA 8.3.18 LEGUMES VEGETABLES (FRESH PEAS AND BEANS WITHOUT PODS)

Table IIIA 8.3.18-1: Comparison of intended and critical EU GAPs

Crop	Type of GAP	Number of applications	Application rate per treatment	Interval between application	Growth stage at last application	PHI (days)
Beans and peas without pods	Intended BG, EL, ES, FR, IT, PT	2	24 g a.s./ha	21	?	14

Use on fresh bean without pods and fresh peas without pods have not been assessed in the framework of EU evaluation, neither as representative use nor as an import tolerance. Consequently the in force MRL on these crops is set at 0.01* mg/kg in Regulation 2016/1.

According to EU guideline 7525/VI/95-rev.10, Appendix D « Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs», extrapolation of residue data between fresh beans with pods and fresh peas without pods is possible when the application is performed close to harvest.

The applicant provided 6 SEU and 8 NEU bean residue trials to support the intended uses on fresh beans without pods and fresh peas without pods.
Nevertheless these trials have not been assessed as it appears that the intended GAP and even less critical one (1application instead of 2) involved an MRL exceedance (see table below). Furthermore some of the trials were performed at a less critical GAP.

The submitted trials are then only summarized below on information basis.
According to the applicant an application to modify the in force MRL from 0.01* to 0.1 mg/kg on fresh beans with pods and fresh peas without pods has been submitted to the EMS Ireland.

Pending the modification of the in force MRL the intended GAPs on fresh beans with pods and fresh peas without pods are not considered acceptable.

Table 8.3.9.2-4: Summary of residues data for sulfoxaflor in beans and peas (fresh, without pods) at the GAP for GF-2626

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-3976E CEMS-3976 DAS Ref# 080114-01 Y 2008	Pea Telephone	S France SZ Outdoor (field)	GF-2032	1	24.9	207	12.0	21-Jun-08	BBCH 65	0 3 7 14 22 29	Whole pod Seed Seed Seed Seed Dry peas	0.032 <0.01 <0.01 **<0.01** <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.041 <0.019 <0.019 **<0.019** <0.019 <0.019
CEMS-3974F CEMS-3974 DAS Ref# 080113-01 Y 2008	Pea Televisia	Spain SZ Outdoor (field)	GF-2032	1	24.1	402	6.0	17-Jun-08	BBCH 73	0 3 7 13 21 28	Whole pod Seed Seed Seed Seed Dry peas	0.114 0.021 <0.01 0.020 **0.024** 0.032	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.123 0.030 <0.019 0.029 **0.033** 0.041

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-5025F CEMS-5025 DAS Ref# GHE-P-12721 Y 2011	Pea Progress	Greece SZ Outdoor (field)	GF-2626	2	24.5 25.2	306 315	8.0 8.0	10-May-11 31-May-11	BBCH 65 BBCH 71-72	-0 0 1 3 7 9 14 -0 0 1 3 7 9 14 21 21	Rest of plant Rest of plant Rest of plant Rest of plant Rest of plant Rest of plant Rest of plant Seed Seed Seed Seed Seed Seed Seed Dry peas Straw	<0.01 0.297 0.160 0.050 0.054 0.028 0.019 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 **<u><0.01</u>** <0.01 0.065	0.011 0.011 0.012 <0.01 0.028 0.017 0.034 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 0.011 0.038	0.020 0.307 0.171 0.059 0.080 0.044 0.051 <0.019 <0.019 <0.019 <0.019 <0.019 <0.019 **<u><0.019</u>** 0.020 0.101

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-5025H	Pea	Spain	GF-	2	28.3	530	5.3	07-Jun-11	BBCH 39	-0	Rest of plant	<0.01	0.219	0.216
CEMS-5025	Resal	SZ	2626		26.5	497	5.3	28-Jun-11	BBCH 75	0	Rest of plant	0.701	0.196	0.885
DAS Ref# GHE-P-12721		Outdoor (field)								1	Rest of plant	0.233	0.215	0.435
Y										3	Rest of plant	0.146	0.189	0.323
2011										7	Rest of plant	0.108	0.280	0.371
										10	Rest of plant	0.041	0.092	0.127
										14	Rest of plant	0.238	0.352	0.569
										-0	Seed	<0.01	0.017	0.026
										0	Seed	<0.01	0.017	0.026
										1	Seed	<0.01	0.020	0.029
										3	Seed	<0.01	0.021	0.030
										7	Seed	<0.01	0.040	0.048
										10	Seed	<0.01	0.028	0.036
										14	Seed	**0.017**	0.078	**0.090**
										20	Dry peas	0.017	0.096	0.107
										20	Straw	0.224	0.436	0.633
CEMS-5506B	Pea	Italy	GF-	2	23.4	391	6.0	14-May-12	BBCH 35-37	-0	Whole plant	<0.01	<0.01	<0.019
CEMS-5506	Wavarex	SZ	2626							0	Whole plant	0.283	0.013	0.295
DAS Ref# GHE-P-12839		Outdoor (field)			23.9	399	6.0	05-Jun-12	BBCH 65-71	1	Whole plant	0.209	0.017	0.225
Y										3	Whole plant	0.132	0.017	0.148
2012										7	Whole plant	0.172	0.023	0.194
										10	Fresh peas	<0.01	<0.01	<0.019
										10	Rest of plant	0.137	0.019	0.155
										14	Fresh peas	**<0.01**	<0.01	**<0.019**
										14	Rest of plant	0.236	0.043	0.276
										21	Dry peas	0.012	<0.01	0.021
										21	Straw	0.573	0.080	0.648

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-5506C	Pea	Spain	GF-	2	24.9	415	6.0	15-May-12	BBCH 33	-0	Rest of plant	<0.01	<0.01	<0.019
CEMS-5506	Tristar	SZ	2626		24.0	400	6.0	05-Jun-12	BBCH 72	0	Rest of plant	0.745	0.025	0.768
DAS Ref# GHE-P-12839		Outdoor (field)								1	Rest of plant	0.328	0.019	0.346
Y										3	Rest of plant	0.104	0.014	0.117
2012										7	Rest of plant	0.050	0.015	0.064
										9	Rest of plant	0.063	0.036	0.097
										14	Rest of plant	0.055	0.057	0.109
										-0	Fresh peas	<0.01	<0.01	<0.019
										0	Fresh peas	<0.01	<0.01	<0.019
										1	Fresh peas	<0.01	<0.01	<0.019
										3	Fresh peas	<0.01	<0.01	<0.019
										7	Fresh peas	<0.01	<0.01	<0.019
										9	Fresh peas	<0.01	<0.01	<0.019
										14	Fresh peas	**<0.01**	<0.01	**<0.019**
										21	Dry peas	0.022	0.010	0.031
										21	Straw	0.099	0.058	0.153
CEMS-3976A	Pea	Germany	GF-	1	24.9	415	6.0	16-Jun-08	BBCH 77	0	Seed	0.016	<0.01	0.025
CEMS-3976	Hardy	NZ	2032							3	Seed	<0.01	<0.01	<0.019
DAS Ref# 080114-01		Outdoor (field)								7	Seed	<0.01	<0.01	<0.019
										14	Seed	<0.01	<0.01	<0.019
Y										21	Seed	**0.014**	<0.01	**0.023**
2008										28	Dry peas	<0.01	<0.01	<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-3974B CEMS-3974 DAS Ref# 080113-01 Y 2008	Pea Bacara	N France NZ Outdoor (field)	GF-2032	1	24.7	309	8.0	11-Jun-08	BBCH 73	0 3 7 14 21 36	Whole pod Whole pod Whole pod Seed Seed Dry peas	0.048 0.018 <0.01 **<u><0.01</u>** <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.057 0.027 <0.019 **<u><0.019</u>** <0.019 <0.019
CEMS-3976C CEMS-3976 DAS Ref# 080114-01 Y 2008	Pea Grana	Hungary NZ Outdoor (field)	GF-2032	1	20.8	283	7.3	07-Jun-08	BBCH 76	0 3 7 14 21 26	Seed Seed Seed Seed Seed Dry peas	<0.01 <0.01 <0.01 **<u><0.01</u>** <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01	<0.019 <0.019 <0.019 **<u><0.019</u>** <0.019 <0.019
CEMS-3974D CEMS-3974 DAS Ref# 080113-01 Y 2008	Pea Einstein	UK NZ Outdoor (field)	GF-2032	1	24.5	203	12.1	11-Jun-08	BBCH 67-75	0 3 7 14 21 31	Seed Seed Seed Seed Seed Dry peas	<0.01 <0.01 <0.01 **<u><0.01</u>** <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01	<0.019 <0.019 <0.019 **<u><0.019</u>** <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-5025A	Pea	N France	GF-	2	22.7	190	11.9	18-May-11	BBCH 61	-0	Rest of plant	0.015	<0.01	0.024
CEMS-5025	Kayanne	NZ	2626		23.1	192	12.0	08-Jun-11	BBCH 77	0	Rest of plant	0.263	<0.01	0.272
DAS Ref# GHE-P-12721		Outdoor (field)								1	Rest of plant	0.134	<0.01	0.143
Y										3	Rest of plant	0.140	<0.01	0.149
2011										7	Rest of plant	0.049	<0.01	0.058
										9	Rest of plant	0.043	<0.01	0.052
										14	Rest of plant	0.030	<0.01	0.039
										-0	Seed	<0.01	<0.01	<0.019
										0	Seed	<0.01	<0.01	<0.019
										1	Seed	<0.01	<0.01	<0.019
										3	Seed	<0.01	<0.01	<0.019
										7	Seed	<0.01	<0.01	<0.019
										9	Seed	<0.01	<0.01	<0.019
										14	Seed	**<0.01**	<0.01	**<0.019**
										22	Dry peas	<0.01	<0.01	<0.019
										22	Straw	0.015	0.010	0.024

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-5025B	Pea	Poland	GF-	2	27.3	428	6.4	01-Jun-11	BBCH 51	-0	Rest of plant	0.014	<0.01	0.023
CEMS-5025	Medal	NZ	2626		27.1	425	6.4	22-Jun-11	BBCH 72	0	Rest of plant	0.317	<0.01	0.326
DAS Ref# GHE-P-12721		Outdoor (field)								1	Rest of plant	0.036	<0.01	0.045
										3	Rest of plant	0.038	<0.01	0.047
Y										7	Rest of plant	0.029	0.012	0.040
2011										9	Rest of plant	0.019	<0.01	0.028
										14	Rest of plant	<0.01	0.019	0.028
										-0	Whole pods	<0.01	<0.01	<0.019
										0	Whole pods	0.031	<0.01	0.040
										1	Whole pods	<0.01	<0.01	<0.019
										3	Whole pods	<0.01	<0.01	<0.019
										7	Seed	<0.01	<0.01	<0.019
										9	Seed	<0.01	<0.01	<0.019
										14	Seed	**<0.01**	<0.01	**<0.019**
										42	Dry peas	<0.01	<0.01	<0.019
										42	Straw	<0.01	0.019	0.028

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-5025C CEMS-5025 DAS Ref# GHE-P-12721 Y 2011	Pea Alvesta	Germany NZ Outdoor (field)	GF-2626	2	25.9 25.7	323 322	8.0 8.0	25-May-11 15-Jun-11	BBCH 65 BBCH 78	-0 0 1 3 7 9 14 -0 0 1 3 7 9 14 20 20	Rest of plant Rest of plant Rest of plant Rest of plant Rest of plant Rest of plant Rest of plant Seed Seed Seed Seed Seed Seed Seed Dry peas Straw	<0.01 0.298 0.145 0.056 0.034 0.024 0.018 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 **<u><0.01</u>** <0.01 0.020	0.012 0.019 0.026 0.022 0.024 0.019 0.037 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 0.069	0.021 0.316 0.169 0.077 0.057 0.042 0.053 <0.019 <0.019 <0.019 <0.019 <0.019 <0.019 **<u><0.019</u>** <0.019 0.085

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-5506E	Pea	Germany	GF-	2	24.5	296	8.3	04-Jul-13	BBCH 63	-0	Rest of plant	0.031	<0.01	0.040
CEMS-5506	Alvesta	NZ	2626		25.8	311	8.3	25-Jul-14	BBCH 79	0	Rest of plant	0.452	0.016	0.467
DAS Ref# GHE-P-12839		Outdoor (field)								1	Rest of plant	0.285	0.018	0.302
Y										3	Rest of plant	0.087	0.010	0.096
2013										7	Rest of plant	0.145	<0.01	0.154
										9	Rest of plant	0.169	0.013	0.181
										13	Rest of plant	0.165	0.016	0.180
										-0	Seed	<0.01	<0.01	<0.019
										0	Seed	<0.01	<0.01	<0.019
										1	Seed	<0.01	<0.01	<0.019
										3	Seed	<0.01	<0.01	<0.019
										7	Seed	<0.01	<0.01	<0.019
										9	Seed	<0.01	<0.01	<0.019
										13	Seed	**<0.01**	<0.01	**<0.019**
										20	Dry peas	<0.01	<0.01	<0.019
										20	Straw	0.101	0.021	0.121

IIIA 8.3.19 PULSES

Table IIIA 8.3.19-1: Comparison of intended and critical EU GAPs

Crop	Type of GAP	Number of applications	Application rate per treatment	Interval between application	Growth stage at last application	PHI (days)
Pulses	Intended FR	2	24 g a.s./ha	21		14

Use on pulses has not been assessed in the framework of EU evaluation, neither as representative use nor as an import tolerance. Consequently the in force MRL on these crops is set at 0.01* mg/kg in Regulation 2016/1.
Later the existing CXL of 0.3 mg/kg on dry beans was voted at EU level and proposed in document SANTE/11442/2016.

According to EU guideline 7525/VI/95-rev.10, Appendix D « Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs», extrapolation of residue data from dry peas to the whole group of pulses is possible when the application is performed close to harvest.

The applicant provided 6 SEU and 8 NEU pea residue trials to support the intended uses on pulses.
Nevertheless these trials have not been assessed as none of the residue trials were performed at the intended GAP (higher PHI than intended one).

Consequently the intended GAPs on pulses are not considered acceptable.

Table 8.3.9.2-4: Summary of residues data for sulfoxaflor in beans and peas (fresh, without pods) at the GAP for GF-2626

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-3976E CEMS-3976 DAS Ref# 080114-01 Y 2008	Pea Telephone	S France SZ Outdoor (field)	GF-2032	1	24.9	207	12.0	21-Jun-08	BBCH 65	0 3 7 14 22 29	Whole pod Seed Seed Seed Seed Dry peas	0.032 <0.01 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.041 <0.019 <0.019 <0.019 <0.019 <0.019
CEMS-3974F CEMS-3974 DAS Ref# 080113-01 Y 2008	Pea Televisia	Spain SZ Outdoor (field)	GF-2032	1	24.1	402	6.0	17-Jun-08	BBCH 73	0 3 7 13 21 28	Whole pod Seed Seed Seed Seed Dry peas	0.114 0.021 <0.01 0.020 0.024 **0.032**	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.123 0.030 <0.019 0.029 0.033 0.041

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-5025F CEMS-5025 DAS Ref# GHE-P-12721 Y 2011	Pea Progress	Greece SZ Outdoor (field)	GF-2626	2	24.5 25.2	306 315	8.0 8.0	10-May-11 31-May-11	BBCH 65 BBCH 71-72	-0 0 1 3 7 9 14 -0 0 1 3 7 9 14 21 21	Rest of plant Rest of plant Rest of plant Rest of plant Rest of plant Rest of plant Rest of plant Seed Seed Seed Seed Seed Seed Seed Dry peas Straw	<0.01 0.297 0.160 0.050 0.054 0.028 0.019 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 0.065	0.011 0.011 0.012 <0.01 0.028 0.017 0.034 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 0.011 0.038	0.020 0.307 0.171 0.059 0.080 0.044 0.051 <0.019 <0.019 <0.019 <0.019 <0.019 <0.019 <0.019 0.020 0.101

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-5025H CEMS-5025 DAS Ref# GHE-P-12721 Y 2011	Pea Resal	Spain SZ Outdoor (field)	GF-2626	2	28.3 26.5	530 497	5.3 5.3	07-Jun-11 28-Jun-11	BBCH 39 BBCH 75	-0 0 1 3 7 10 14 -0 0 1 3 7 10 14 20 20	Rest of plant Rest of plant Rest of plant Rest of plant Rest of plant Rest of plant Rest of plant Seed Seed Seed Seed Seed Seed Seed Dry peas Straw	<0.01 0.701 0.233 0.146 0.108 0.041 0.238 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 0.017 **0.017** 0.224	0.219 0.196 0.215 0.189 0.280 0.092 0.352 0.017 0.017 0.020 0.021 0.040 0.028 0.078 0.096 0.436	0.216 0.885 0.435 0.323 0.371 0.127 0.569 0.026 0.026 0.029 0.030 0.048 0.036 0.090 0.107 0.633
CEMS-5506B CEMS-5506 DAS Ref# GHE-P-12839 Y 2012	Pea Wavarex	Italy SZ Outdoor (field)	GF-2626	2	23.4 23.9	391 399	6.0 6.0	14-May-12 05-Jun-12	BBCH 35-37 BBCH 65-71	-0 0 1 3 7 10 10 14 14 21 21	Whole plant Whole plant Whole plant Whole plant Whole plant Fresh peas Rest of plant Fresh peas Rest of plant Dry peas Straw	<0.01 0.283 0.209 0.132 0.172 <0.01 0.137 <0.01 0.236 **0.012** 0.573	<0.01 0.013 0.017 0.017 0.023 <0.01 0.019 <0.01 0.043 <0.01 0.080	<0.019 0.295 0.225 0.148 0.194 <0.019 0.155 <0.019 0.276 0.021 0.648

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-5506C CEMS-5506 DAS Ref# GHE-P-12839 Y 2012	Pea Tristar	Spain SZ Outdoor (field)	GF-2626	2	24.9 24.0	415 400	6.0 6.0	15-May-12 05-Jun-12	BBCH 33 BBCH 72	-0 0 1 3 7 9 14 -0 0 1 3 7 9 14 21 21	Rest of plant Rest of plant Rest of plant Rest of plant Rest of plant Rest of plant Rest of plant Fresh peas Fresh peas Fresh peas Fresh peas Fresh peas Fresh peas Fresh peas Dry peas Straw	<0.01 0.745 0.328 0.104 0.050 0.063 0.055 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 0.022 0.099	<0.01 0.025 0.019 0.014 0.015 0.036 0.057 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 0.010 0.058	<0.019 0.768 0.346 0.117 0.064 0.097 0.109 <0.019 <0.019 <0.019 <0.019 <0.019 <0.019 <0.019 0.031 0.153
CEMS-3976A CEMS-3976 DAS Ref# 080114-01 Y 2008	Pea Hardy	Germany NZ Outdoor (field)	GF-2032	1	24.9	415	6.0	16-Jun-08	BBCH 77	0 3 7 14 21 28	Seed Seed Seed Seed Seed Dry peas	0.016 <0.01 <0.01 <0.01 0.014 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.025 <0.019 <0.019 <0.019 0.023 <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-3974B CEMS-3974 DAS Ref# 080113-01 Y 2008	Pea Bacara	N France NZ Outdoor (field)	GF-2032	1	24.7	309	8.0	11-Jun-08	BBCH 73	0 3 7 14 21 36	Whole pod Whole pod Whole pod Seed Seed Dry peas	0.048 0.018 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.057 0.027 <0.019 <0.019 <0.019 <0.019
CEMS-3976C CEMS-3976 DAS Ref# 080114-01 Y 2008	Pea Grana	Hungary NZ Outdoor (field)	GF-2032	1	20.8	283	7.3	07-Jun-08	BBCH 76	0 3 7 14 21 26	Seed Seed Seed Seed Seed Dry peas	<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
CEMS-3974D CEMS-3974 DAS Ref# 080113-01 Y 2008	Pea Einstein	UK NZ Outdoor (field)	GF-2032	1	24.5	203	12.1	11-Jun-08	BBCH 67-75	0 3 7 14 21 31	Seed Seed Seed Seed Seed Dry peas	<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

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-5025A	Pea	N France	GF-	2	22.7	190	11.9	18-May-11	BBCH 61	-0	Rest of plant	0.015	<0.01	0.024
CEMS-5025	Kayanne	NZ	2626		23.1	192	12.0	08-Jun-11	BBCH 77	0	Rest of plant	0.263	<0.01	0.272
DAS Ref# GHE-P-12721		Outdoor (field)								1	Rest of plant	0.134	<0.01	0.143
Y										3	Rest of plant	0.140	<0.01	0.149
2011										7	Rest of plant	0.049	<0.01	0.058
										9	Rest of plant	0.043	<0.01	0.052
										14	Rest of plant	0.030	<0.01	0.039
										-0	Seed	<0.01	<0.01	<0.019
										0	Seed	<0.01	<0.01	<0.019
										1	Seed	<0.01	<0.01	<0.019
										3	Seed	<0.01	<0.01	<0.019
										7	Seed	<0.01	<0.01	<0.019
										9	Seed	<0.01	<0.01	<0.019
										14	Seed	<0.01	<0.01	<0.019
										22	Dry peas	<0.01	<0.01	<0.019
										22	Straw	0.015	0.010	0.024

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-5025B	Pea	Poland	GF-	2	27.3	428	6.4	01-Jun-11	BBCH 51	-0	Rest of plant	0.014	<0.01	0.023
CEMS-5025	Medal	NZ	2626		27.1	425	6.4	22-Jun-11	BBCH 72	0	Rest of plant	0.317	<0.01	0.326
DAS Ref# GHE-P-12721		Outdoor (field)								1	Rest of plant	0.036	<0.01	0.045
Y										3	Rest of plant	0.038	<0.01	0.047
2011										7	Rest of plant	0.029	0.012	0.040
										9	Rest of plant	0.019	<0.01	0.028
										14	Rest of plant	<0.01	0.019	0.028
										-0	Whole pods	<0.01	<0.01	<0.019
										0	Whole pods	0.031	<0.01	0.040
										1	Whole pods	<0.01	<0.01	<0.019
										3	Whole pods	<0.01	<0.01	<0.019
										7	Seed	<0.01	<0.01	<0.019
										9	Seed	<0.01	<0.01	<0.019
										14	Seed	<0.01	<0.01	<0.019
										42	Dry peas	<0.01	<0.01	<0.019
										42	Straw	<0.01	0.019	0.028

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-5025C CEMS-5025 DAS Ref# GHE-P-12721 Y 2011	Pea Alvesta	Germany NZ Outdoor (field)	GF-2626	2	25.9 25.7	323 322	8.0 8.0	25-May-11 15-Jun-11	BBCH 65 BBCH 78	-0 0 1 3 7 9 14 -0 0 1 3 7 9 14 20 20	Rest of plant Rest of plant Rest of plant Rest of plant Rest of plant Rest of plant Rest of plant Seed Seed Seed Seed Seed Seed Seed Dry peas Straw	<0.01 0.298 0.145 0.056 0.034 0.024 0.018 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 0.020	0.012 0.019 0.026 0.022 0.024 0.019 0.037 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 0.069	0.021 0.316 0.169 0.077 0.057 0.042 0.053 <0.019 <0.019 <0.019 <0.019 <0.019 <0.019 <0.019 <0.019 0.085

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-5506E	Pea	Germany	GF-	2	24.5	296	8.3	04-Jul-13	BBCH 63	-0	Rest of plant	0.031	<0.01	0.040
CEMS-5506	Alvesta	NZ	2626		25.8	311	8.3	25-Jul-14	BBCH 79	0	Rest of plant	0.452	0.016	0.467
DAS Ref# GHE-P-12839		Outdoor (field)								1	Rest of plant	0.285	0.018	0.302
Y										3	Rest of plant	0.087	0.010	0.096
2013										7	Rest of plant	0.145	<0.01	0.154
										9	Rest of plant	0.169	0.013	0.181
										13	Rest of plant	0.165	0.016	0.180
										-0	Seed	<0.01	<0.01	<0.019
										0	Seed	<0.01	<0.01	<0.019
										1	Seed	<0.01	<0.01	<0.019
										3	Seed	<0.01	<0.01	<0.019
										7	Seed	<0.01	<0.01	<0.019
										9	Seed	<0.01	<0.01	<0.019
										13	Seed	<0.01	<0.01	<0.019
										20	Dry peas	<0.01	<0.01	<0.019
										20	Straw	0.101	0.021	0.121

IIIA 8.4 Livestock Feeding Studies

IIIA 8.4.1 DIETARY BURDEN CALCULATION

Input values use for dietary burden calculations are summarised in the table below.

Table IIIA 8.4.1-1: Input values for the dietary burden calculation

Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Residue definition : sum of sulfoxaflor and metabolite X11719474				
Wheat and rye grain	0.019	STMR (EFSA 2014)	0.019	STMR (EFSA 2014)
Barley and oat grain	0.02	STMR (EFSA 2014)	0.02	STMR (EFSA 2014)
Wheat and rye bran	0.04	STMR x 2.1 (PF) (EFSA 2014)	0.04	STMR x 2.1 (PF) (EFSA 2014)
Wheat and rye straw	0.111	STMR SEU (residue data GF-2372)	0.354	HR SEU (residue data GF-2372)
Barley and oat straw	0.022	STMR (EFSA 2014)	0.147	HR (EFSA 2014)
Potato	0.019	STMR, EFSA 2015	0.019	HR (EFSA 2014)
Cotton seed meal	0.015	STMR (EU) x 0.8 (PF) (EFSA 2014)	0.015	STMR (EU) x 0.8 (PF), (EFSA 2014)
Soya meal	0.03	STMR x 1.3 (PF), EFSA 2014	0.03	STMR x 1.3 (PF), (EFSA 2014)
Rape seed meal	0.136	STMR x 2 (PF), (EFSA 2014)	0.136	STMR x 2 (PF), (EFSA 2014)
Kale - Cabbage	0.01	STMR (rotational crop residue trials) (EFSA 2014)	0.01	HR (rotational crop residue trials) (EFSA 2014)
Fodder/sugar beet tops	0.014	STMR (radish leaves – rotational crop field trial- PBI 30 days)	0.065	HR (radish leaves – rotational crop field trial- PBI 30 days)
Apple (wet pomace)	0.123	STMR x 1.1 (PF), (EFSA 2014)	0.123	STMR x 1.1 (PF) (EFSA 2014)

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

Except for sugar beet - fodder beet tops and wheat straw the same input values than the ones uses by EFSA were considered in the framework of the current application.
For sugar/fodder beet tops in the framework of EU evaluation the highest application rate was of 24 g as/ha and in the framework of this current application is of 48 g a.s./ha .According to available rotational crop studies the highest residue expected in sugar beet top is of 0.065 mg/kg and not of 0.018 mg/kg.

Furthermore for wheat straw, EFSA has considered wheat straw data corresponding to import tolerance (HR of 1.648 mg/kg). Whereas for import tolerances use cereal straw should be disregarded from animal

burden calculations, as these are not expected to be imported within EU (Estimation of animal intakes and HR, STMR and MRL calculations for products of animal origin, EFSA 2015).

Considering input value of 0.354 mg/kg for cereal straw (HR wheat straw considering intended uses of preparation GF-2372) and 0.065 mg/kg for sugar/fodder beet tops the dietary burden remain unchanged for poultry, is reduced for beef cattle (from 1.15 to 0.40 mg/kg dm/d) and for dairy cattle (from 0.52 to 0.26 mg/kg dm/d) and is slightly increased for pig (from 0.13 mg/kg DM/D to 0.20 mg/kg) compared to EFSA calculations (see results of dietary burden calculation in table below)

Consequently as in force MRL on animal commodities were set based on the EU evaluation there is no risk for poultry and bovine MRL to be overcome and no further studies are required for these kind of livestock.

However for pig the estimated dietary burden is slightly increased due to the higher input considered for fodder/sugar beet tops.
Nevertheless it should be noted that the field rotational crop study has been performed with direct bare soil application whereas the preparation GF-2626 is intended to be used close to harvest (PHI ranging from 1 to 7 days). Therefore the residue level measured in rotational crops at harvest is clearly over estimated and consequently the estimated dietary burden is also overestimated.

Consequently it is assumed that the intended uses would have no effect on the pig dietary burden and that no MRL exceedance is intended in pig commodities.

Table IIIA 8.4.1-2: Dietary burden calculation results

Crop/Commodity	% dry matter	Residue mg/kg (STMR or HR)	Chicken 1,9 kg bw % intake	intake to 100%	total MS (%)	0,12 fresh weight	kg MS residue intake	Dairy Cattle 550 kg bw % intake	intake to 100%	total MS (%)	20 fresh weight	kg MS residue intake	Beef Cattle 350 kg bw % intake	intake to 100%	total MS (%)	15 fresh weight	kg MS residue intake	Pig 75 kg bw % intake	intake to 100%	total MS (%)	3 fresh weight	kg MS residue intake
I - Green Forage (Incl. Hay)																						
Grasses	20				-	-	-	100		-	-	-	100		-	-	-			-	-	-
Alfalfa/Clover	20				-	-	-	40		-	-	-	40		-	-	-	15		-	-	-
Forage Rape	14				-	-	-			-	-	-	35		-	-	-	15		-	-	-
Kale/Cabbage	14	0,01	5	0	0	0,000	0,000	35	0	0	0,0	0,00	35	0	0	0,0	0,0	15	0	0	0,0	0,00
Sugar Beet Leaves/Tops	16	0,065			-	-	-	30		30	37,5	2,4	30	0	0	0,0	0,0	25		25	4,7	0,3
Silage (Clover, Grasses)	20				-	-	-	100		-	-	-	100		-	-	-	15		-	-	-
Silage (Maize)*	20				-	-	-	100		-	-	-	100		-	-	-			-	-	-
Fruit Pomace (Apple, Citrus)	23	0,123			-	-	-	10	0	0	0,0	0,0	30		30	19,6	2,4			-	-	-
Hay	85				-	-	-	100		-	-	-	100		-	-	-	15		-	-	-
II - Grains																						
Grains (except maize)	86	0,02	70		70	0,098	0,002	40	0	0	0,0	0,0	80	0	0	0,0	0,0	80	0	0	0,0	0,00
Maize	86		70		-	-	-	30		-	-	-	30		-	-	-	40		-	-	-
Bran (Wheat and Rye)	89	0,04	15	0	0	0,000	0,000	20		20	4,5	0,2	20	0	0	0,0	0,0	20	0	0	0,0	0,00
III - Straws (cereals)	86	0,354			-	-	-	20		20	4,7	1,6	50		50	8,7	3,1			-	-	-
IV - Pulses	86		30		-	-	-	20		-	-	-	20		-	-	-	40		-	-	-
V - Root and Tubers																						
Potatoes	15	0,019	20		20	0,160	0,003	30	0	0	0,0	0,0	60	0	0	0,0	0,0	60	55	55	11,0	0,2
Swede/turnips	10		20		-	-	-	30		-	-	-	60		-	-	-	60		-	-	-
Sugar and Fodder beet	20		20		-	-	-	30		-	-	-	60		-	-	-	60		-	-	-
VI - Oil seed (Meal Cake)																						
Soya,Peanut,Rape,sunflower	86	0,136	10		10	0,014	0,002	30		30	7,0	0,9	30	20	20	3,5	0,5	20		20	0,7	0,1
% total MS intake (must be <100%)					100					100					100					100		
	mg/animal/day						0,007					5,2					6,0					0,6
	mg/kg bw/day				**Chicken**		0,004			**Dairy Cattle**		0,009			**Beef Cattle**		0,017			**Pig**		0,008
	mg/kg DM/day						0,06					0,26					0,40					0,20

IIIA 8.4.2 NATURE OF RESIDUE IN FISH

This is not an EC data requirement/ not required.

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 (IE 2012, EFSA, 2014)

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), ^{14}C-sulfoxaflor and ^{14}C-X11721061 were found to be stable, whereas ^{14}C-X11719474 was hydrolysed at the isocyanate moiety to form compound X11579457 (0.4-11.6 %).
According to the toxicology section the toxicological reference value of sulfoxaflor can be applied to this metabolite. Furthermore considering the representative uses and to the uses of MRL application FR is of the opinion that metabolite X11579457 is not expected to be formed in significant quantity. Indeed at the intended GAP residue levels of metabolite X11719474 are almost below the LOQ (<0.01 mg/kg) or quite above the LOQ.
It was therefore 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.

IIIA 8.5.2 DISTRIBUTION OF THE RESIDUE IN PEEL/PULP

IIIA 8.5.2.1 Summary of European data

No EU data are available

IIIA 8.5.2.2 New data

IIIA 8.5.2.2.1 Citrus

Eleven of the available residues trials on oranges and mandarins (see Section 8.3.1) reported the distribution of residues in the peel and pulp of the fruit.
Residues of sulfoxaflor were found to concentrate in the citrus peel (median transfer factor (TF) of 1.5), whilst no quantifiable residues were measured in the citrus pulp (median TF of 0.6). Residues of X11719474 where found to be below the LOQ in whole fruit, peel and pulp samples.
A summary of the data from these trials (at the PHI selected for estimation of the STMR, HR and MRL values) are presented in table below.

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

Trial	PHI	Sulfoxaflor residues (mg/kg)			X11719474 (mg/kg)		
		Whole fruit	Peel	Pulp	Whole fruit	Peel	Pulp
CEMS-5031A	42*	0.011	0.017	<0.01	<0.01	<0.01	<0.01
CEMS-5031B	10*	0.014	0.023	<0.01	<0.01	<0.01	<0.01
CEMS-5031C	7	<0.01	0.015	<0.01	<0.01	<0.01	<0.01
CEMS-5031D	7	0.018	0.026	<0.01	<0.01	<0.01	<0.01
CEMS-5031E	7	0.035	0.054	<0.01	<0.01	<0.01	<0.01
CEMS-5031F	7	0.042	0.059	<0.01	<0.01	<0.01	<0.01
CEMS-5031G	7	<0.01	0.011	<0.01	<0.01	<0.01	<0.01
CEMS-5031H	7	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
CEMS-5033A	7	<0.01	0.0575	<0.01	<0.01	<0.01	<0.01
CEMS-5033B	7	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
CEMS-5033C	7	<0.01	0.025	<0.01	<0.01	<0.01	<0.01

* Higher residue measured at a later PHI

Individual and median peeling factor for sulfoxaflor are estimated in table below considering only trials where residues in whole fruits were above the LOQ.
No peeling factor can be derived for X11719474 since residues in the whole fruit are below the limit of quantification.

Table IIIA 8.5.2-2: Transfer Factors for sulfoxaflor into citrus peel and pulp

Melon	Individual transfer factors	Median Transfer factors (mean/median)
Sulfoxaflor		
Peel(1)	2 x 1.4, 2x1.5, 1.6	1.5
Pulp(2)	0.2, 0.3, 0.6, 0.7, 0.9	0.6

(1) residue in peel / residue in whole fruit
(2) residue in pulp / residue in whole fruit

IIIA 8.5.2.2.2 Cucurbits inedible peel

All of the available SEU and indoor residues trials on melons (see Section 8.3) reported the distribution of residues in the peel and pulp portions of the fruit.

Residues of sulfoxaflor were found to concentrate in the peel (median TF 1.5), whilst no quantifiable residues were measured in the melon pulp (median TF 0.8). Residues of X11719474 where found to be below the LOQ in whole fruit, peel and pulp samples.
A summary of the data from these trials (at the PHI selected for estimation of the STMR, HR and MRL values) are presented in table below.

Table IIIA 8.5.2-3: A summary of the peel and pulp distribution data for melons

Trial	PHI	Sulfoxaflor residues (mg/kg)			X11719474 (mg/kg)		
		Whole fruit	Peel	Pulp	Whole fruit	Peel	Pulp
CEMS-4706A	3*	0.011	0.015	<0.01	<0.01	<0.01	<0.01
CEMS-4706B	3*	0.034	0.048	<0.01	<0.01	<0.01	<0.01
CEMS-4706C	1	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
CEMS-4706D	1	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
CEMS-5015E	1	<0.01	0.012	<0.01	<0.01	<0.01	<0.01
CEMS-5015F	1	0.013	0.021	<0.01	<0.01	<0.01	<0.01
CEMS-5015G	1	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
CEMS-5015H	1	<0.01	0.012	<0.01	<0.01	<0.01	<0.01
CEMS-4708B[1]	1	0.025	0.039	<0.01	<0.01	<0.01	<0.01
CEMS-4708C[1]	1	<0.01	0.013	<0.01	<0.01	<0.01	<0.01
CEMS-4708D[1]	1	<0.01	0.012	<0.01	<0.01	<0.01	<0.01
CEMS-4708E[1]	1	0.011	0.017	<0.01	<0.01	<0.01	<0.01
CEMS-5016A[1]	1	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
CEMS-5016B[1]	1	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
CEMS-5016C[1]	1	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
CEMS-5016D[1]	1	0.011	0.016	<0.01	<0.01	<0.01	<0.01

* Higher residue measured at a later PHI
(1): Indoor trials (see drr for indoor uses)

Individual and median peeling factor for sulfoxaflor are estimated in table below considering only trials where residues in whole fruits were above the LOQ.
No peeling factor can be derived for X11719474 since residues in the whole fruit are below the limit of quantification.

Table IIIA 8.5.2-4: Transfer Factors for sulfoxaflor into melon peel and pulp

Melon	Individual transfer factors	Median Transfer factors (mean/median)
Sulfoxaflor		
Peel(1)	2 x 1.4, 2 x 1.5, 2 x 1.6	1.5
Pulp(2)	0.3, 0.4, 0.8, 3 x 0.9	0.8

(1) residue in peel / residue in whole fruit
(2) residue in pulp / residue in whole fruit

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

Residues of parent sulfoxaflor tend to concentrate into citrus and cucurbits peel (median TF of 1.5) and to dilute into citrus and melon pulp (median TF of 0.6 and 0.8 respectively). However, as residues levels in pulp were always below the LOQ, derived peeling factors cannot be considered as fully reliable.
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 citrus and 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, 2014). Processing data are summarised thereafter. In the EFSA conclusion, data were presented for parent sulfoxaflor only. For completeness processing factor for metabolite X11719474 are also summarised (IE, 2012).

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

Crop/ process/ processed product	**Number of studies**	**Processing Factor** (PF) **Sulfoxaflor**		**Processing Factor** (PF) **X11719474**	
		Individual values	Median PF	Individual values	Median PF
Barley grain → pearl barley, pot barley, bran, flour, cleaned barley, brewing malt, malt sprouts, beer, spent grains and brewer's yeast	2	1.0,0.7 (pearl barley)	0.85	0.7, 0.9	0.8
		1.0, 0.9 (pot barley)	0.95	0.8, 0.9	0.9
		2.5, 1.0 (bran)	1.75	1.3, 1.9	1.6
		0.9, 0.8 (flour)	0.85	0.7, 0.7	0.7
		1.3, 0.9 (cleaned barley)	1.1	1.2, 1.4	1.3
		0.9, 0.9 (brewing malt)	0.9	1.1, 1.5	1.3
		1.3, 1.3 (malt sprouts)	1.3	2.1, 3.7	2.9
		0.1, 0.2 (beer)	0.15	0.8, 0.7	0.8
		0.1, 0.2 (spent grain)	0.15	0.7, 0.7	0.7
		0.2, 0.1 (brewer's yeast)	0.15	0.7, 0.7	0.7
Cotton seed → aspirated seed fractions, delinted seed, hulls, meal, meal presscake, crude oil, and refined oil	1	23 (aspirated seed fractions)	23	12	12
		1.0 (delinted seed)	1.0	NC	-
		1.8 (hulls)	1.8	NC	-
		0.8 (meal)	0.8	NC	-
		0.8 (meal presscake)	0.8	NC	-
		<0.1 (crude oil)	<0.1	NC	-
		<0.1 (refined oil)	<0.1	NC	-
Tomatoes → washed and peeled tomatoes, juice, canned tomatoes, puree, paste, and ketchup (Parent sulfoxaflor results only)	2	0.5, 0.8, 1.2 (fruit washed and peeled)	0.8	1.0, 1.2, NC	1.1
		0.6, 1.0, 1.0 (juice)	1.0	1.0, 1.3, NC	1.2
		0.2, 0.4, 0.8 (canned)	0.4	1.0, 1.3, NC	1.2
		1.4, 2.2, 2.1 (ketchup)	2.1	2.4, 2.7, NC	2.6
		1.0, 1.6, 2.0 (puree)	1.6	1.0, 1.8, NC	1.4
		2.7, 4.9, 4.4 (paste)	4.4	5.0, 5.4, NC	5.2
Wheat grain → cleaned grain, coarse bran, fine bran, total bran (combined coarse and fine bran), germ,	2 (3 trials)	21 (aspirated grain fraction)	21	22	22
		0.3, 1.0 (clean grain)	0.65	<0.8, 1.0	0.9
		1.0, 3.1 (coarse bran)	2.1	<0.8, 1.1	<1

Crop/ process/ processed product	Number of studies	Processing Factor (PF) Sulfoxaflor		Processing Factor (PF) X11719474	
		Individual values	Median PF	Individual values	Median PF
middlings, shorts, whole meal flour, refined flour, whole grain bread and white bread from refined flour.		0.3, 1.0 (fine bran)	0.65	<0.8, 1.0	<0.9
		0.4, 1.0, 3.1 (total bran)	1.0	0.7, <0.8, 1.0	<0.8
		0.5, 0.8, 2.8 (germ)	0.8	0.6, <0.8, 1.0	<0.8
		0.08, 0.2, 0.3 (middlings)	0.2	0.4, <0.8, 1.0	<0.8
		0.2, 0.6, 1.2 (shorts)	0.6	0.5, <0.8, 1.0	<0.8
		0.2, 0.4, 1.0 (whole meal flour)	0.4	0.4, <0.8, 1.0	<0.8
		0.05, <0.2, 0.2 (refined flour)	0.2	0.4, <0.8, 1.0	<0.8
		<0.2, 0.2, 0.6 (whole grain bread)	0.2	0.4, <0.8, 1.0	<0.8
		0.04, 0.1, <0.2, (white bread)	0.1	0.4, <0.8, 1.0	<0.8
		<0.2 (gluten)	<0.2	<0.8	<0.8
		<0.2 (gluten feed meal)	<0.2	<0.8	<0.8
		<0.2 (starch)	<0.2	<0.8	<0.8

NC: Not calculated; residues were below the LOQ in both the RAC and processed fractions.

Furthermore a number of processing studies were considered in the MRL evaluation report which was prepared by the RMS as part of the DAR (2012). Summaries of the previously assessed data are given below for pome fruit (relevant to the livestock dietary burden), and cherries and kale (extrapolated from cabbage).

Orange

The following processing factors for sulfoxaflor in citrus processed commodities were derived by the RMS in the context of the MRL section of the DAR (Ireland, 2012):

Crop	Processed Commodity	Processing Factor Sulfoxaflor
Orange	Juice	<0.2
	Wet pomace (pulp)	2.5
	Dry pomace (pulp)	8.3
(Parent Sulfoxaflor results only)	Peel	9.1
	Oil	<0.2
	Marmalade	<0.2
	Canned slices	<0.2

No process factors are presented for the metabolite X11719474 as residues were below the limit of quantification in the RAC. However residue of metabolite were observed in peel and dried peel (tentative PFs of 1.6 and 2.3 were derived in the evaluation report respectively for peel and dried peel)

Apple

The following processing factors for apple processed commodities were derived by the RMS in the context of the MRL section of the DAR (Ireland, 2012):

Crop	Processed Commodity	Processing Factor sulfoxaflor	Processing factor X11719474
Apple	Washed apples	0.7	0.6
	Apple sauce	0.6	0.7
	Juice	0.4	0.3
	Wet pomace	1.1	1.1
	Dry pomace	4.2	4.8
	Canned apples	0.03	0.3
	Dried apples	0.3	0.3

The processing factors for wet pomace given in the table above have been used for the estimation of residues in apple pomace, relevant to the dietary burden calculation.

Cherries

The following processing factors for cherry processed commodities were derived by the RMS in the context of the MRL section of the DAR (Ireland, 2012):

Crop	Processed Commodity	Processing Factor sulfoxaflor	Processing factor X11719474
Cherry	Washed cherries	0.8	1.1
	Canned cherries	1.0	1.9
	Juice	0.9	1.0
	Jam	1.1	1.3
	Dried cherries	5.2	68

Cabbage

The following processing factors for cabbage processed commodities (relevant for kale) were derived by the RMS in the context of the MRL section of the DAR (Ireland, 2012):

Crop	Processed Commodity	Processing Factor sulfoxaflor	Processing factor X11719474
Cabbage (Parent Sulfoxaflor results only)	Inner leaves	0.1	0.4
	Outer (wrapper) leaves	1.8	1.9
	Cooked head	0.1	0.6
	Cooking liquid	0.1	0.6

IIIA 8.5.3.2 Conclusion on balance studies

Uses under consideration are covered by sufficient processing studies and no further data are required.

IIIA 8.5.3.3 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

Some of the crops under consideration can grow in rotation.
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, ^{14}C-Sulfoxaflor was applied to bare confined plots of sandy loam soil at a nominal rate of 600 g a.s./ha. This corresponds to 12.5X the maximum seasonal rate. 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 outdoor 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 the intended GAP).
Leafy crops	Lettuce	30, 120 & 365	
Cereal (small grain)	Wheat	30, 120 & 365	
***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.*			

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, 2014).

IIIA 8.6.3 NEW DATA

No new data submitted

IIIA 8.6.4 CONCLUSION ON SUCCEEDING CROPS STUDIES

Since a maximum seasonal rate of 48 g a.s./ha is proposed for uses under consideration, 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 food 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: Summary of residue definitions in plants

Endpoints		**Source**
Plant groups covered	Tomatoes, peas, lettuce and rice	EFSA 2014
Rotational crops covered	Radish, lettuce, wheat (grain, forage, straw, hay)	EFSA 2014
Metabolism in rotational crops similar to metabolism in primary crops?	Results of rotational crops studies are consistent with those of the primary crop metabolism studies.	EFSA 2014
Processed commodities	Parent sulfoxaflor and metabolite X11721061 are stable under hydrolysis conditions. The metabolite X11719474 can be considered stable to hydrolysis at pH4 and 90°C for 20 minutes but is degraded slightly with increase pH and temperature, with the formation of one degradate, X11579457, accounting for up to 11.6% of the total radioactivity.	EFSA 2014
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes	EFSA 2014
Plant residue definition for monitoring	Parent sulfoxaflor (sulfoxaflor) only	EFSA 2014 Reg. (EU) 2016/1
Plant residue definition for risk assessment	Sum of parent sulfoxaflor and metabolite X11719474, expressed as sulfoxaflor. However, it was agreed that if	EFSA 2014

	metabolite X11719474 is shown to be significantly less toxic than Sulfoxaflor then the residue definition for risk assessment will become parent Sulfoxaflor only.	
Conversion factor	None	EFSA 2014

Table IIIA 8.7.1-2: Summary of residue definitions in livestock

	Endpoints	**Reference**
Animals covered	Goat	EFSA 2014
	Hen	EFSA 2014
Time needed to reach a plateau concentration	**Milk**: A plateau was reached in milk matrices over the course of the 5 day dosing period (*ca.* 0.2 – 0.3 mg/kg).	EFSA 2014
	Eggs: A steady plateau was observed in egg matrices after six days dosing (*ca.* 0.06 mg/kg).	EFSA 2014
Animal residue definition for monitoring	Parent sulfoxaflor (sulfoxaflor) only [(a)]	EFSA 2014 Reg. (EU) 2016/1
Animal residue definition for risk assessment	Sum of parent sulfoxaflor and metabolite X11719474, expressed as sulfoxaflor. However, it was agreed that if metabolite X11719474 is shown to be significantly less toxic than Sulfoxaflor then the residue definition for risk assessment will become parent Sulfoxaflor only	EFSA 2014
Conversion factor	None	EFSA 2014
Metabolism in rat and ruminant similar	Yes. Metabolism of parent sulfoxaflor in the ruminant (goat) and rodent are similar, therefore there is no need to request a swine (pig) metabolism study.	EFSA 2014
Fat soluble residue	No. Parent sulfoxaflor is not fat soluble as log $P_{o/w}$ <3. Log Pow is 0.78 for X11546257 (diastereoisomer 1) Log Pow is 0.87 for X11546258 (diastereoisomer 2) And for the PAI (both distereoisomers): Log Pow = 0.806 at pH5 Log Pow = 0.802 at pH 7 Log Pow = 0.799 at pH 9	EFSA 2014

IIIA 8.7.2 PROPOSED MAXIMUM RESIDUE LEVELS (MRLS)

Modifications of MRLs on several crops under consideration are currently under evaluation at EU level according to the applicant.

A summary of current and proposed MRLs is presented in table below.

Table IIIA 8.7.2-1: Summary of MRL modification request

Code[(a)]	Commodity	Current MRL	Proposed MRL
0110040	Limes	0.01*	0.8
0242010	Brussels sprouts	0.01*	2.0
0243020	Kales	0.01*	1
0243990	Others	0.01*	1
0251000	Salad plants (lettuce group)	0.01*	4
0252000	Similar leaves (Spinach group)	0.01*	6
0256000	Herbs and edible flowers	0.01*	6
0260000	Legume vegetables	0.01*	0.15
0300000	Pulses	0.01*	0.15

(a). Food commodity code as reported in Annex I of Regulation (EC) No 396/2005.

Pending the modification of in force MRL intended uses on limekale, lamb lettuce, escarole, cress, rucola, red mustard and baby leaf crops (lettuce group), purslane, chard, legume vegetables (with and without pods) and pulses are not considered acceptable in SEU and France.
Pending the modification of in force MRL intended uses on Brussels sprout is not considered acceptable in SEU.

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)
Grapefruits, oranges, lemons, mandarins (1 x 48 g a.s/ha or 2 x 24 g a.s./ha)	7
Pome fruits (1 x 48 g a.s/ha or 2 x 24 g a.s./ha)	7
Peach (1 x 48 g a.s/ha or 2 x 24 g a.s./ha)	7
Cherry (1 x 48 g a.s/ha or 2 x 24 g a.s./ha)	7
Potato (2 x 24 g a.s./ha)	7
Tomato, aubergine (1 x 48 g a.s/ha or 2 x 24 g a.s./ha)	1
Pepper (1 x 48 g a.s/ha or 2 x 24 g a.s./ha)	1
Cucurbits with edible peel (1 x 48 g a.s/ha or 2 x 24 g a.s./ha)	1
Cucurbits with inedible peel (1 x 48 g a.s/ha or 2 x 24 g a.s./ha)	1
Broccoli (1 x 24 g a.s./ha)	7
Brussels sprout (1 x 24 g a.s./ha)	7
Cauliflower (1 x 24 g a.s./ha)	7
Head cabbage (1 x 24 g a.s./ha)	7
Chinese cabbage (1 x 24 g a.s./ha)	7
Lettuce (1 x 24 g a.s./ha)	7
Spinach (1 x 24 g a.s./ha)	7

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

Not applicable considering intended uses

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

This period is covered by the PHI.

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

Not applicable considering intended uses.

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.

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. 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.

Chronic and acute Consumer 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 in section 8.3 or STMR proposed under previous assessment if higher (EFSA,2014 or JMPR 2011, 2013 and 2014).
- For commodities of plant and animal origin that have already been evaluated at European level: STMRs proposed under previous assessments (EFSA, 2014)
- 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 SANTE/11442/2016.No conversion factors were applied to those commodities as they correspond to commodities for which no use has yet been reported.

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 considering the crops under evaluation which not lead to an MRL exceedance.
The input values for the PRIMo are reported in Table IIIA 8.10-1.

Table IIIA 8.10-1-1: 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	0.072	HR SEU (8.3.1)
Oranges	0.26	STMR JMPR 2014	0.072	HR SEU (8.3.1)
Lemons,	0.038	STMR JMPR 2014	0.072	HR SEU (8.3.1)
Mandarins	0.31	STMR JMPR 2011-2014	0.072	HR SEU (8.3.1)
Pome fruits	0.185	STMR SEU (8.3.2)	0.275	HR SEU (8.3.2)
Peaches	0.227	STMR SEU (8.3.3)	0.058	HR SEU (8.3.3)
Cherries	0.34	STMR (JMPR, 2014)	0.132	HR SEU (8.3.4)
Potatoes	0.019	STMR (EFSA, 2014)	0.019	HR SEU/NEU (8.3.6)
Tomatoes	0.11	STMR (JMPR 2011)	0.064	HR SEU (8.3.7)
Peppers	0.11	STMR (JMPR 2011)	0.147	HR SEU (8.3.8)
Aubergines	0.11	STMR (JMPR 2011)	0.064	HR SEU (8.3.7)
Cucumbers, gerkins	0.033	STMR SEU (8.3.9)	0.068	HR NEU (8.3.9)
Courgettes	0.033	STMR SEU (8.3.9)	0.051	HR SEU (8.3.9)
Cucurbits with inedible peel	0.029	STMR (JMPR, 2011)	0.043	HR SEU (8.3.10)
Broccoli	0.074	STMR (JMPR, 2011)	0.037	HR NEU (8.3.11)
Cauliflower	0.019	STMR (8.3.11)	0.037	HR NEU (8.3.11)
Brussels sprout	0.019	STMR (see 8.3.12)	0.019	HR NEU (8.3.12)
Head cabbage	0.099	STMR (JMPR, 2011)	0.03	HR NEU (8.3.13)
Chinese cabbage	1.00	STMR (EFSA, 2014)	0.433	HR NEU (8.3.14)
Lettuce	0.585	STMR (EFSA, 2014)	0.114	HR SEU (8.3.15)

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Spinach	1.34	STMR (EFSA, 2014)	0.114	HR Lettuce SEU (8.3.15)
Almonds	0.019	STMR (EFSA, 2014)	Acute risk assessment was performed on the intended use only	
Pecans	0.019	STMR (EFSA, 2014)		
Apricots	0.155	STMR (JMPR, 2014)		
Plums	0.038	STMR (JMPR, 2014)		
Table grapes	0.165	STMR (EFSA, 2014)		
Wine grapes	0.14	STMR (JMPR, 2011)		
Strawberries	0.2	STMR (EFSA, 2014)		
Tropical roots and tuber vegetables Other roots and tuber vegetables	0.01	STMR (JMPR, 2011)		
Spring onions	0.11	STMR (JMPR, 2011)		
Celery leaves	0.255	STMR (EFSA, 2014)		
Celery	0.19	STMR (JMPR, 2011)		
Beans	0.075	STMR (JMPR, 2013)		
Rape seed	0.068	STMR (EFSA, 2014)		
Soya been	0.023	STMR (EFSA, 2014)		
Cotton seed	0.02	STMR (JMPR, 2011)		
Barley	0.06	STMR (JMPR, 2011)		
Oats	0.020	STMR (EFSA, 2014)		
Rye	0.019	STMR (EFSA, 2014)		
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 other edible offals	0.13	STMR (JMPR, 2011)		
Poultry meat	0.015	STMR (JMPR, 2011)		

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Poultry fat	0.01	STMR (EFSA, 2014)		
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

It should be noted that for uses on tomato, pepper and aubergine the preparation GF-2626 is also intended to be use under indoor conditions. Even if uses under indoor conditions lead to higher HR (see DRR indoor for GF-2626), acute consumer risk assessment in this registration report has been performed only considering field uses. Please refer to RR concerning indoor uses to know acute risk corresponding to the indoor intended uses.

IIIA 8.10.1 TMDI CALCULATIONS

As no conversion factors are available at European Level, TMDI calculations, considering all plant and animal commodities, were not performed in this dossier.

IIIA 8.10.2 IEDI CALCULATIONS

IEDI calculations were performed considering input values reported in table below.

Table IIIA 8.10.2-1: Results of refined chronic risk assessment according to EFSA model

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
13,9	DE child	5,6	Apples	2,5	Oranges		1,8	Milk and milk products: Cattle
13,1	NL child	3,7	Milk and milk products: Cattle	2,9	Apples		2,0	Oranges
7,7	FR infant	3,2	Milk and milk products: Cattle	1,5	Spinach		1,2	Apples
7,0	WHO Cluster diet B	0,8	Tomatoes	0,6	Wine grapes		0,6	Oranges
6,9	FR toddler	2,4	Spinach	1,3	Oranges		1,2	Apples
6,4	ES child	1,6	Milk and milk products: Cattle	1,4	Oranges		0,6	Lettuce
5,5	IE adult	0,7	Oranges	0,4	Mandarins		0,4	Wine grapes
5,1	SE general population 90th percentile	1,5	Milk and milk products: Cattle	0,5	Chinese cabbage		0,5	Apples
4,6	NL general	1,0	Oranges	0,8	Milk and milk products: Cattle		0,5	Apples
4,4	ES adult	0,8	Oranges	0,8	Lettuce		0,6	Milk and milk products: Cattle
4,3	UK Toddler	1,3	Oranges	0,8	Apples		0,6	Sugar beet (root)
4,0	WHO regional European diet	0,6	Milk and milk products: Cattle	0,6	Lettuce		0,3	Oranges
3,9	WHO cluster diet E	0,6	Wine grapes	0,4	Apples		0,4	Milk and milk products: Cattle
3,9	WHO Cluster diet F	0,6	Oranges	0,5	Milk and milk products: Cattle		0,4	Lettuce
3,6	WHO cluster diet D	0,6	Milk and milk products: Cattle	0,5	Chinese cabbage		0,4	Wheat
3,4	FR all population	1,4	Wine grapes	0,3	Milk and milk products: Cattle		0,2	Apples
3,4	PT General population	0,9	Wine grapes	0,5	Apples		0,4	Oranges
3,2	DK child	1,1	Apples	0,3	Wheat		0,3	Pears
3,1	IT kids/toddler	0,4	Lettuce	0,4	Wheat		0,4	Apples
3,0	UK Infant	0,8	Oranges	0,7	Apples		0,3	Sugar beet (root)
2,9	IT adult	0,6	Lettuce	0,4	Apples		0,3	Tomatoes
2,4	LT adult	0,9	Apples	0,5	Milk and milk products: Cattle		0,2	Tomatoes
2,4	UK vegetarian	0,6	Oranges	0,3	Wine grapes		0,3	Apples
2,1	PL general population	0,9	Apples	0,2	Tomatoes		0,2	Potatoes
1,9	UK Adult	0,4	Wine grapes	0,4	Oranges		0,2	Apples
1,8	DK adult	0,5	Wine grapes	0,4	Apples		0,1	Wheat
1,7	FI adult	0,6	Oranges	0,2	Apples		0,1	Tomatoes

IIIA 8.10.3 IESTI CALCULATIONS

IIIA 8.10.3-1: Results of acute risk assessment according to EFSA model

	Acute risk assessment /children - refined calculations						Acute risk assessment / adults / general population - refined calculations					
	The acute risk assessment is based on the ARfD.											
	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.											
	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. In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce the calculation was performed with a variabilty factor of 3.											
	Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100 % of the ARfD.											
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)
	10,8	Apples	0,275 / -	7,9	Apples	0,275 / -	6,2	Chinese cabbage	0,433 / -	6,2	Chinese cabbage	0,433 / -
	10,0	Pears	0,275 / -	7,2	Pears	0,275 / -	2,5	Apples	0,275 / -	2,1	Apples	0,275 / -
	6,4	Chinese cabbage	0,433 / -	6,4	Chinese cabbage	0,433 / -	2,4	Pears	0,275 / -	1,8	Pears	0,275 / -
	3,8	Oranges	0,072 / -	2,8	Oranges	0,072 / -	1,0	Peppers	0,147 / -	0,9	Pumpkins	0,043 / -
	3,7	Peppers	0,147 / -	2,6	Peppers	0,147 / -	0,9	Pumpkins	0,043 / -	0,7	Watermelons	0,043 / -
	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)			
	15,9	Orange juice	0,8 / -				3,2	Orange juice	0,8 / -			
	8,2	Apple juice	0,4 / -				1,1	Apple juice	0,4 / -			
	3,6	Peach juice	0,5 / -				0,4	Peach preserved with	0,5 / -			
	2,8	Pear juice	0,4 / -				0,4	Bread/pizza	0,2 / -			
	2,1	Tomato juice	0,3 / -				0,2	Tomato (preserved-	0,3 / -			
	*) 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											

IIIA 8.10.4 CONSUMER RISK ASSESSMENT CONCLUSION

The intended uses of sulfoxaflor do not represent unacceptable acute and chronic risks for the consumer.

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, 2014). Even considering this factor, the toxicological reference values would not be exceeded.

IIIA 8.11 Summary and Evaluation of Residue Behaviour for sulfoxaflor

See overall conclusion.

Conclusion

Overall conclusion

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of sulfoxaflor as laid down in Reg. (EU) 396/2005 is not expected according to the intended uses in SEU and France for grapefruits, oranges, lemons, mandarins, pome fruits, peach, cherry, potato, tomatoes, peppers, aubergines, cucurbits with edible peel, cucurbits with inedible peel, cauliflower, broccoli, head cabbage, Chinese cabbage, lettuce, spinach, and for Brussels sprout in France. However, exceedance of the current MRL of sulfoxaflor is expected in SEU and France for limes, kale, lamb lettuce, escarole, cress, rucola, red mustard and baby leaf crops (lettuce group), purslane, chard, legume vegetables (with and without pods), and for Brussels sprout in SEU.
Furthermore residue data are insufficient to support the intended use on plum and pulses.

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 uses in SEU and France for grapefruits, oranges, lemons, mandarins, pome fruits, peach, cherry, potato, tomatoes, peppers, aubergines, cucurbits with edible peel, cucurbits with inedible peel, cauliflower, broccoli, head cabbage, Chinese cabbage, lettuce, spinach, and for Brussels sprout in France but disagrees with the authorization of the intended uses in SEU and France for limes, , plums, , kale, lamb lettuce, escarole, cress, rucola, red mustard and baby leaf crops (lettuce group), purslane, chard, legume vegetables (with and without pods), pulses and for Brussels sprout in SEU.

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

Data gaps

/

Data required in post-authorization

Noticed data required in post-authorization are:

- 1 supplementary Southern and 1 supplementary Northern apple residues trials are required in post registration to complete the dataset for apple and pear
- 2 Supplementary Southern residues trials are required in post registration on peach to complete the dataset.
- 2 Supplementary Southern residues trials are required in post registration on mandarin and/or lemon to complete the dataset for citrus.

SUMMARY OF THE EVALUATION

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

Table 0-1: Summary for sulfoxaflor

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance SANTE/ 11442/ 2016	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
	Grapefruits, oranges, lemons, mandarins)	Yes	Yes (9 SEU on orange, 6 SEU on mandarin)	Yes	Yes	Yes	No	No	Acceptable use Additional trials required in post authorisation
	Limes	Yes	Yes (9 SEU on orange, 6 SEU on mandarin)	Yes	Yes	No		N/A	Unacceptable use (MRL exceedance)
	Pome fruits	Yes	Yes (7 NEU, 7 SEU)	Yes	Yes	Yes		No	Acceptable use Additional trials required in post authorisation
	Cherries	Yes	Yes (4 SEU)	Yes	Yes	Yes		No	Acceptable use
	Peaches	Yes	Yes (6 SEU at the GAP and 4 SEU at more critical GAP)	Yes	Yes	Yes		No	Acceptable use Additional trials required in post authorisation
	Plums	Yes	No (3SEU)	No	Yes	Yes		N/A	Unacceptable use (Insufficient residue trials)
	Potato	Yes	Yes (2 NEU, 2 SEU)	Yes	Yes	Yes		No	Acceptable use
	Tomatoes Aubergines	Yes	Yes (16 SEU)	Yes	Yes	Yes		No	Acceptable use
	Peppers	Yes	Yes (8 SEU)	Yes	Yes	Yes		No	Acceptable use
	Cucurbits	Yes	Yes (8	Yes	Yes	**Yes**		No	Acceptable

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance SANTE/ 11442/ 2016	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
	with edible peel		NEU, 8 SEU)						use
	Cucurbits with inedible peel	Yes	Yes (8 SEU)	Yes	Yes	**Yes**		No	Acceptable use
	Broccoli	Yes	Yes (11 NEU, 12 SEU)	Yes	Yes	Yes		No	Acceptable use
	Cauliflower	Yes	Yes (11 NEU, 12 SEU)	Yes	Yes	**Yes**		No	Acceptable use
	Brussels sprout	Yes	Yes (6 NEU, 4 SEU)	Yes	Yes	**Yes for France No for SEU**		No	Acceptable use in France Unacceptable use in BG, EL, ES FR, IT
	Head cabbage	Yes	Yes (8 NEU, 6 SEU)	Yes	Yes	**Yes**		No	Acceptable use
	Kale	Yes	Yes (4NEU, 4 SEU)	Yes	Yes	**No**		N/A	Unacceptable use (MRL exceedance)
	Chinese cabbage	Yes	Yes (4NEU, 4 SEU)	Yes	Yes	**Yes**		No	Acceptable use
	Lettuce	Yes	Yes (8 NEU, 8 SEU)	Yes	Yes	**Yes**		No	Acceptable use
	Spinach	Yes	Yes (8 NEU, 8 SEU)	Yes	Yes	**Yes**		No	Acceptable use
	lamb lettuce, escarole, cress, rucola, red mustard and baby leaf crops	Yes	Yes (8 NEU, 8 SEU)	Yes	Yes	**No**		N/A	Unacceptable use (MRL exceedance)
	Purslane, chard	Yes	Yes (8 NEU, 8 SEU)	Yes	Yes	**No**		N/A	Unacceptable use (MRL exceedance)

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance SANTE/ 11442/ 2016	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
	Beans (fresh, with pods) Peas (fresh with pods)	Yes	Yes (8 NEU, 12 SEU)	Yes	Yes	**No**		N/A	Unacceptable use (MRL exceedance)
	Beans (fresh, without pods), peas (fresh without pods)	Yes	Yes (8 NEU, 6 SEU)	Yes	Yes	**No**		N/A	Unacceptable use (MRL exceedance)
	Pulses	Yes	NO (0 NEU, 0 SEU)	No	Yes	N/A		N/A	Unacceptable use (No residue trials performed at intended GAP)
	Ornamentals	Use not assessed in residue section							

* 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

For apple and pear, 1 southern residue trial and 1 northern residue trial performed on apple are required in post registration to complete the s residue package for the following critical GAP: 1 application at 48 g a.s./ha, PHI of 7 days.
For peach, 2 southern residue trials are required in post registration to complete the residue package for the following critical GAP: 1 application at 48 g a.s./ha, PHI of 7 days.
For citrus 2 southern residue trials performed on mandarin and/or lemon are required in post registration to complete the residue package for the following critical GAP: 1 application at 48 g a.s./ha, PHI of 7 days.

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 food crops.

Considering dietary burden and based on the intended uses, no significant modification of the intake was calculated for livestock. 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		
Pome fruits	7	Yes	7	-
Grapefruits, oranges, lemons, mandarins	7	Yes	7	-
Peaches	7	Yes	7	-
Cherries	7	Yes	7	-
Potato	7	Yes	7	-
Tomatoes Aubergines	1	Yes	1	-
Peppers	1	Yes	1	-
Cucurbit with edible peel	1	Yes	1	
Cucurbit with inedible peel	1	Yes	1	
Broccoli	7	Yes	7	-
Cauliflower	7	Yes	7	
Head cabbage	7	Yes	7	
Brussels sprout	7	Yes	7	Only applicable for FR Use on Brussel Sprout is not considered acceptable in BG, EL, ES, IT
Chinese cabbage	7	Yes	7	-
Lettuce	7	Yes	7	-
Spinach	7	Yes	7	-

* Purpose of withholding period to be specified

Waiting periods before planting succeeding crops

Not relevant

References :

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 5EC) 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

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

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), 2014. 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/

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 8.3.1/01	Rawle, N. W.	2013a	Residues of sulfoxaflor in oranges and mandarins at intervals and harvest following a single application of GF-2626 – Southern Europe – 2011 Dow AgroSciences CEMR-5031 Y Unpublished	Y	DAS	Y
IIIA 8.3.1/02	Rawle, N. W.	2012a	Residues of sulfoxaflor in oranges and process fractions following a single application of GF-2626 – Southern Europe – 2011 Dow AgroSciences CEMR-5033 Y Unpublished	Y	DAS	Y
IIIA 8.3.1/03	Rawle, N. W.	2014a	Residues of sulfoxaflor in oranges and mandarins at intervals and harvest following a single application of GF-2032 – Southern Europe – 2013 Dow AgroSciences CEMR-5948 Y Unpublished	Y	DAS	Y
IIIA 8.3.2/01	Rawle, N. W.	2012b	Residues of sulfoxaflor in apples and pears at intervals and harvest following a single application of GF-2626 – Northern and Southern Europe – 2011 Dow AgroSciences CEMR-5027 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 8.3.2/02	Rawle, N. W.	2010b	Residues of XDE-208 in apples at intervals and harvest following multiple applications of GF-2032 – Northern and Southern Europe - 2008 Dow AgroSciences CEMR-3968 Y Unpublished	Y	DAS	Y
IIIA 8.3.2/03	Rawle, N. W.	2010c	Residues of XDE-208 in pears at intervals and harvest following multiple applications of GF-2032 – Northern and Southern Europe - 2008 Dow AgroSciences CEMR-3971 Y Unpublished	Y	DAS	Y
IIIA 8.3.2/04	Rawle, N. W.	2010d	Residues of XDE-208 in pears at intervals and harvest following multiple applications of GF-2032 – Northern and Southern Europe - 2010 Dow AgroSciences CEMR-4714 Y Unpublished	Y	DAS	Y
IIIA 8.3.3.1/01	Rawle, N. W.	2012c	Residues of XDE-208 in cherries at intervals and harvest following a single application of GF-2032 – Northern and Southern Europe - 2008 Dow AgroSciences CEMR-4071 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 8.3.3.1/02	Rawle, N. W.	2012d	Residues of sulfoxaflor in cherries at intervals and harvest following a single application of GF-2626 – Northern and Southern Europe - 2011 Dow AgroSciences CEMR-5028 Y Unpublished	Y	DAS	Y
IIIA 8.3.3.2/01	Rawle, N. W.	2012e	Residues of XDE-208 in peaches at intervals and harvest following a single application of gf-2032 – Northern and Southern Europe - 2008 Dow AgroSciences CEMR-4068 Y Unpublished	Y	DAS	Y
IIIA 8.3.3.2/02	Rawle, N. W.	2012f	Residues of sulfoxaflor in peaches at intervals and harvest following a single application of gf-2626 – Northern and Southern Europe – 2011 Dow AgroSciences CEMR-5030 Y Unpublished	Y	DAS	Y
IIIA 8.3.3.2/03	Rawle, N. W.	2010e	Residues of XDE-208 in peaches at intervals and harvest following multiple applications of GF-2032 – Northern and Southern Europe –2008 and 2009 Dow AgroSciences CEMR-4069 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 8.3.3.3/01	Rawle, N. W.	2012g	Residues of XDE-208 in plums at intervals and harvest following a single application of GF-2032 – Northern and Southern Europe - 2008 Dow AgroSciences CEMR-4070 Y Unpublished	Y	DAS	Y
IIIA 8.3.3.3/02	Rawle, N. W.	2012h	Residues of sulfoxaflor in plums at intervals and harvest following a single application of GF-2626 – Northern and Southern Europe - 2011 Dow AgroSciences CEMR-5029 Y Unpublished	Y	DAS	Y
IIIA 8.3.4/01	Rawle, N. W.	2012i	Residues of sulfoxaflor in potatoes at intervals and harvest following multiple applications of GF-2626 – Northern and southern Europe – 2011 Dow AgroSciences DAS report CEMR-5026 Y Unpublished	Y	DAS	Y
IIIA 8.3.5.1/01	Rawle, N. W.	2011a	Residues of XDE-208 in tomatoes at intervals and harvest following a single application of GF-2626 – Northern and Southern Europe – 2010 Dow AgroSciences DAS report CEMR-4694 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 8.3.5.1/02	Rawle, N. W.	2011b	Residues of XDE-208 in cherry tomatoes at intervals and harvest following a single application of GF-2626 – Northern and Southern Europe – 2010 Dow AgroSciences DAS report CEMR-4696 Y Unpublished	Y	DAS	Y
IIIA 8.3.5.1/03	Rawle, N. W.	2012j	Residues of sulfoxaflor in tomatoes at intervals and harvest following a single application of GF-2626 – Northern and southern Europe – 2011 Dow AgroSciences DAS report CEMR-5008 Y Unpublished	Y	DAS	Y
IIIA 8.3.5.1/04	Rawle, N. W.	2012k	Residues of sulfoxaflor in cherry tomatoes at intervals and harvest following a single application of GF-2626 – Northern and Southern Europe – 2011 Dow AgroSciences DAS report CEMR-5010 Y Unpublished	Y	DAS	Y
IIIA 8.3.5.2/01	Rawle, N. W.	2011d	Residues of XDE-208 in bell peppers at intervals and harvest following a single application of GF-2626 – Southern Europe – 2010 Dow AgroSciences DAS report CEMR-4700 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 8.3.5.2/02	Rawle, N. W.	2011e	Residues of sulfoxaflor in bell peppers at intervals and harvest following a single application of GF-2626 – Northern and Southern Europe – 2011 Dow AgroSciences DAS report CEMR-5011 Y Unpublished	Y	DAS	Y
IIIA 8.3.6.1/01	Rawle, N. W.	2011h	Residues of XDE-208 in cucumbers at intervals and harvest following a single application of GF-2626 – Northern and Southern Europe – 2010 Dow AgroSciences DAS report CEMR-4703 Y Unpublished	Y	DAS	Y
IIIA 8.3.6.1/02	Rawle, N. W.	2012m	Residues of sulfoxaflor in cucumbers at intervals and harvest following a single application of GF-2626 – Northern and Southern Europe – 2011 Dow AgroSciences DAS report CEMR-5013 Y Unpublished	Y	DAS	Y
IIIA 8.3.6.2/01	Rawle, N. W.	2011j	Residues of XDE-208 in outdoor melons at intervals and harvest following a single application of GF-2626 – Southern Europe – 2010 Dow AgroSciences DAS report CEMR-4706 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 8.3.6.2/02	Rawle, N. W.	2012(o)	Residues of sulfoxaflor in outdoor melons at intervals and harvest following a single application of GF-2626 – Northern and Southern Europe – 2011 Dow AgroSciences DAS report CEMR-5015 Y Unpublished	Y	DAS	Y
IIIA 8.3.7.1/01	Rawle, N. W.	2012q	Residues of XDE-208 in broccoli at intervals and harvest following a single application of GF-2032 – Northern and Southern Europe - 2008 Dow AgroSciences DAS report CEMR-3944 Y Unpublished	Y	DAS	Y
IIIA 8.3.7.1/02	Rawle, N. W.	2012r	Residues of sulfoxaflor in broccoli at intervals and harvest following a single application of GF-2626 – Northern and Southern Europe – 2011 Dow AgroSciences DAS report CEMR-5018 Y Unpublished	Y	DAS	Y
IIIA 8.3.7.1/03	Rawle, N. W.	2012s	Residues of XDE-208 in cauliflower at intervals and harvest following a single application of GF-2032 – Northern and Southern Europe - 2008 Dow AgroSciences DAS report CEMR-3946 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 8.3.7.1/04	Rawle, N. W.	2012t	Residues of sulfoxaflor in cauliflower at intervals and harvest following a single application of GF-2626 – Northern and Southern Europe – 2011 Dow AgroSciences DAS report CEMR-5017 Y Unpublished	Y	DAS	Y
IIIA 8.3.7.2/01	Rawle, N.W.	2010h	Residues of XDE-208 in Brussels sprouts at intervals and harvest following a single application of GF-2032 – Northern and southern Europe – 2008 Dow AgroSciences DAS report CEMR-3925 Y Unpublished	Y	DAS	Y
IIIA 8.3.7.2/02	Rawle, N.W.	2012u	Residues of sulfoxaflor in Brussels sprouts at intervals and harvest following a single application of GF-2626 – Northern and Southern Europe – 2011 Dow AgroSciences DAS report CEMR-5019 Y Unpublished	Y	DAS	Y
IIIA 8.3.7.3/01	Rawle, N.W.	2012v	Residues of XDE-208 in head cabbage at intervals and harvest following a single application of GF-2032 – Northern and Southern Europe – 2008 Dow AgroSciences DAS report CEMR-3948 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 8.3.7.3/02	Rawle, N.W.	2012w	Residues of sulfoxaflor in head cabbage at intervals and harvest following a single application of GF-2626 – Northern and Southern Europe – 2011 Dow AgroSciences DAS report CEMR-5020 Y Unpublished	Y	DAS	Y
IIIA 8.3.7.4/01	Rawle, N.W.	2012x	Residues of XDE-208 in kale at intervals and harvest following a single application of GF-2032 – Northern and Southern Europe – 2008 Dow AgroSciences DAS report CEMR-3951 Y Unpublished	Y	DAS	Y
IIIA 8.3.7.4/02	Rawle, N.W.	2012y	Residues of sulfoxaflor in kale at intervals and harvest following a single application of GF-262 – Northern and Southern Europe – 2011 Dow AgroSciences DAS report CEMR-5021 Y Unpublished	Y	DAS	Y
IIIA 8.3.8/01	Rawle, N.W.	2012z	Residues of XDE-208 in leaf lettuce at intervals and harvest following a single application of GF-2032 – Northern and Southern Europe – 2008 Dow AgroSciences DAS report CEMR-3938 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 8.3.8/02	Rawle, N.W.	2012aa	Residues of sulfoxaflor in leaf lettuce at intervals and harvest following a single application of GF-262 – Northern and Southern Europe – 2011 Dow AgroSciences DAS report CEMR-5022 Y Unpublished	Y	DAS	Y
IIIA 8.3.8/03	Rawle, N.W.	2012bb	Residues of XDE-208 in head lettuce at intervals and harvest following a single application of GF-2032 – Northern and Southern Europe – 2008 Dow AgroSciences DAS report CEMR-3941 Y Unpublished	Y	DAS	Y
IIIA 8.3.8/04	Rawle, N.W.	2012cc	Residues of sulfoxaflor in head lettuce at intervals and harvest following a single application of GF-2626 – Northern and Southern Europe – 2011 Dow AgroSciences DAS report CEMR-5023 Y Unpublished	Y	DAS	Y
IIIA 8.3.9.1/01	Rawle, N.W.	2012dd	Residues of XDE-208 in beans at intervals and harvest following a single application of GF-2032 – Northern and Southern Europe – 2008 Dow AgroSciences DAS report CEMR-3974 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 8.3.9.1/02	Rawle, N.W.	2012ee	Residues of sulfoxaflor in beans at intervals and harvest following multiple applications of GF-2626 – Northern and Southern Europe – 2011 Dow AgroSciences DAS report CEMR-5024 Y Unpublished	Y	DAS	Y
IIIA 8.3.9.1/03	Rawle, N.W.	2014b	Residues of sulfoxaflor in green beans at harvest following multiple applications of GF-2032 – Southern Europe – 2013 Dow AgroSciences DAS report CEMR-5951 Y Unpublished	Y	DAS	Y
IIIA 8.3.9.2/01	Rawle, N.W.	2012ff	Residues of XDE-208 in peas at intervals and harvest following a single application of GF-2032 – Northern and Southern Europe – 2008 Dow AgroSciences DAS report CEMR-3976 Y Unpublished	Y	DAS	Y
IIIA 8.3.9.2/02	Rawle, N.W.	2012gg	Residues of sulfoxaflor in peas at intervals and harvest following multiple applications of GF-2626 – Northern and Southern Europe – 2011 Dow AgroSciences DAS report CEMR-5025 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 8.3.9.3/03	Rawle, N.W.	2014c	Residues of sulfoxaflor in peas at intervals and harvest following multiple applications of GF-2626 – Northern and Southern Europe – 2012 and 2013 Dow AgroSciences DAS report CEMR-5506 Y Unpublished	Y	DAS	Y
IIIA 8.6.1/01	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	EU data

Appendix 2: Acceptable critical Uses –GAP tables

Crop and/or situation (a)	Member State or Country	Product Name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days)	Remarks
					Type (d-f)	Conc. of a.s. (i)	Method Kind (f-h)	Growth stage & season (j)	Number min max (k)	Interval between apps. (min)	kg a.s./hL min max	water (L/ha) min max	kg a.s./ha min max	(l)	(m)
Citrus fruit (grapefruits, oranges, lemons, mandarins) *[pomelos, bergamot, clementine, tangerine]*	EL, ES, FR, IT, PT *[IT only]*	GF-2626	F	Aphids, Mealybugs, Scales	SC	120 g/L	Ground applied foliar spray, broadcast	BBCH 30-85	1-2	7 days	0.00096-0.0096	500-2500	0.024-0.048	7	Two applications of 0.024 kg a.s./ha would be minimum 7 days interval. If higher rate than 24 g/ha is applied, only one application is possible in a year. Use not acceptable on lime due to an MRL exceedance
Pome fruit (apples, pears) *[quinces, medlar]*	BG, EL, ES, FR, HR, IT, PT *[IT only]*	GF-2626	F	Aphids, Scales	SC	120 g/L	Ground applied foliar spray, broadcast	BBCH 51-59 (pre-flowering) BBCH 69-85	1-2	7 days	0.0016-0.016	300-1500	0.024-0.048	7	Two applications of 24 g/ha rate would be minimum 7 days interval. If higher rate than 24 g/ha is applied, only one application is possible either pre or post flowering. No spray is allowed during the flowering

Crop and/or situation (a)	Member State or Country	Product Name	F 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 a.s. (i)	Method Kind (f-h)	Growth stage & season (j)	Number min max (k)	Interval between apps. (min)	kg a.s./hL min max	water (L/ha) min max	kg a.s./ha min max		
Cherries	BG, ES, EL, FR, HR, IT, PT	GF-2626	F	Aphids, Scales	SC	120 g/L	Ground applied foliar spray, broadcast	BBCH 51-59 (pre-flowering) BBCH 69-85	1-2	7 days	0.0016-0.016	300-1500	0.024-0.048	7	Two applications of 24 g/ha rate would be minimum 7 days interval. If higher rate than 24 g/ha is applied, only one application is possible either pre or post flowering. No spray is allowed during the flowering
Peaches, nectarines	BG, CY, EL, ES, FR, HR, IT, PT	GF-2626	F	Aphids, Scales	SC	120 g/L	Ground applied foliar spray, broadcast	BBCH 51-59 (pre-flowering) BBCH 69-85	1-2	7 days	0.0016-0.016	300-1500	0.024-0.048	7	Two applications of 24 g/ha rate would be minimum 7 days interval. If higher rate than 24 g/ha is applied, only one application is possible either pre or post flowering. No spray is allowed during the flowering

Crop and/or situation (a)	Member State or Country	Product Name	F 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 a.s. (i)	Method Kind (f-h)	Growth stage & season (j)	Number min max (k)	Interval between apps. (min)	kg a.s./hL min max	water (L/ha) min max	kg a.s./ha min max		
Plums	BG, EL, ES, FR, HR, IT, PT	GF-2626	F	Aphids, Scales	SC	120 g/L	Ground applied foliar spray, broadcast	BBCH 51-59 (pre-flowering) BBCH 69-85	1-2	7 days	0.0016-0.016	300-1500	0.024-0.048	7	Two applications of 24 g/ha rate would be minimum 7 days interval. If higher rate than 24 g/ha is applied, only one application is possible either pre or post flowering. No spray is allowed during the flowering **Use not acceptable as insufficient residue trial is available to support the intended use**
Tomatoes → aubergines (including pepinos)	BG, CY, EL, ES, FR, HR, IT, MT, PT	GF-2626	F/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	Aphids: One or two applications of 24 g a.s./ha. Two applications would be minimum 7 days interval. Whiteflies: 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.

Crop and/or situation (a)	Member State or Country	Product Name	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 a.s. (i)	Method Kind (f-h)	Growth stage & season (j)	Number min max (k)	Interval between apps. (min)	kg a.s./hL min max	water (L/ha) min max	kg a.s./ha min max		
Peppers (including chilli peppers)	BG, CY, EL, ES, FR, HR, IT, MT, PT	GF-2626	F/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	Aphids: One or two applications of 24 g a.s./ha. Two applications would be minimum 7 days interval. Whiteflies: 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.
Cucurbits (edible peel – cucumbers, courgettes, gherkins)	BG, EL, ES, FR, IT, PT	GF-2626	F/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	Aphids: One or two applications of 24 g a.s./ha. Two applications would be minimum 7 days interval. Whiteflies: 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

Crop and/or situation (a)	Member State or Country	Product Name	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 a.s. (i)	Method Kind (f-h)	Growth stage & season (j)	Number min max (k)	Interval between apps. (min)	kg a.s./hL min max	water (L/ha) min max	kg a.s./ha min max		
Cucurbits (inedible peel – melons, pumpkins/ squash, watermelons)	BG, EL, ES, FR, IT, PT	GF-2626	F/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	Aphids: One or two applications of 24 g a.s./ha. Two applications would be minimum 7 days interval. Whiteflies: 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.
Flowering brassica (broccoli, cauliflower)	BG, EL, ES, FR, IT	GF-2626	F	Aphids	SC	120 g/L	Ground applied foliar spray, broadcast	BBCH 20-49	1	n/a	0.004-0.012	200-1000	0.024	7	
Brussels sprouts	BG, EL, ES, IT	GF-2626	F	Aphids	SC	120 g/L	Ground applied foliar spray, broadcast	BBCH 20-49	1	n/a	0.004-0.012	200-1000	0.024	7	**Use not acceptable in BG, EL, ES, IT due to an MRL exceedance**
Brussels sprouts	FR	GF-2626	F	Aphids	SC	120 g/L	Ground applied foliar spray, broadcast	BBCH 20-49	1	n/a	0.004-0.012	200-1000	0.024	7	
Head cabbage	BG, EL, ES, FR, IT	GF-2626	F	Aphids	SC	120 g/L	Ground applied foliar spray, broadcast	BBCH 20-49	1	n/a	0.004-0.012	200-1000	0.024	7	

Crop and/or situation (a)	Member State or Country	Product Name	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 a.s. (i)	Method Kind (f-h)	Growth stage & season (j)	Number min max (k)	Interval between apps. (min)	kg a.s./hL min max	water (L/ha) min max	kg a.s./ha min max		
Leafy brassica	BG, EL, ES, FR, IT	GF-2626	F	Aphids	SC	120 g/L	Ground applied foliar spray, broadcast	BBCH 20-49	1	n/a	0.004-0.012	200-1000	0.024	7	**Use not acceptable on the whole group due to an MRL exceedance on some crops**
Kale	BG, EL, ES, FR, IT	GF-2626	F	Aphids	SC	120 g/L	Ground applied foliar spray, broadcast	BBCH 20-49	1	n/a	0.004-0.012	200-1000	0.024	7	**Use not acceptable due to an MRL exceedance**
Chinese cabbage	BG, EL, ES, FR, IT	GF-2626	F	Aphids	SC	120 g/L	Ground applied foliar spray, broadcast	BBCH 20-49	1	n/a	0.004-0.012	200-1000	0.024	7	
Lettuce and other salad plants including Brassicacea, spinach and similar (leaves), herbs	BG, EL, ES, FR, IT	GF-2626	F	Aphids	SC	120 g/L	Ground applied foliar spray, broadcast	BBCH 20-49	1	n/a	0.004-0.012	200-1000	0.024	7	**Use not acceptable on the whole groups due to due to an MRL exceedance on some crops**
Lettuce	BG, EL, ES, FR, IT	GF-2626	F	Aphids	SC	120 g/L	Ground applied foliar spray, broadcast	BBCH 20-49	1	n/a	0.004-0.012	200-1000	0.024	7	
Spinach	BG, EL, ES, FR, IT	GF-2626	F	Aphids	SC	120 g/L	Ground applied foliar spray, broadcast	BBCH 20-49	1	n/a	0.004-0.012	200-1000	0.024	7	

Crop and/or situation (a)	Member State or Country	Product Name	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 a.s. (i)	Method Kind (f-h)	Growth stage & season (j)	Number min max (k)	Interval between apps. (min)	kg a.s./hL min max	water (L/ha) min max	kg a.s./ha min max		
lamb lettuce, escarole, cress, rucola, red mustard and baby leaf crops	BG, EL, ES, FR, IT	GF-2626	F	Aphids	SC	120 g/L	Ground applied foliar spray, broadcast	BBCH 20-49	1	n/a	0.004-0.012	200-1000	0.024	7	**Use not acceptable due to an MRL exceedance**
Purslane, chard	BG, EL, ES, FR, IT	GF-2626	F	Aphids	SC	120 g/L	Ground applied foliar spray, broadcast	BBCH 20-49	1	n/a	0.004-0.012	200-1000	0.024	7	**Use not acceptable due to an MRL exceedance**
Potato	BG, EL, ES, FR, IT, PT	GF-2626	F	Aphids	SC	120 g/L	Ground applied foliar spray, broadcast	BBCH 20-95	2	21	0.004-0.012	200-600	0.024	7	
Beans (fresh, without pods), beans (fresh, with pods) peas (fresh without pods), peas (fresh with pods)	BG, EL, ES, FR, IT, PT	GF-2626	F	Aphids	SC	120 g/L	Ground applied foliar spray, broadcast	BBCH 40-85	1-2	21	0.004-0.016	150-1000	0.024	14	**Use not acceptable due to an MRL exceedance**
Pulses	BG, EL, ES, FR, IT, PT	GF-2626	F	Aphids	SC	120 g/L	Ground applied foliar spray, broadcast	BBCH 40-85	1-2	21	0.004-0.016	150-1000	0.024	14	**Use not acceptable on dry peas and dry lentils due to an MRL exceedance** **Use not acceptable on dry beans as insufficient residue trial is available**

Crop and/or situation (a)	Member State or Country	Product Name	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 a.s. (i)	Method Kind (f-h)	Growth stage & season (j)	Number min max (k)	Interval between apps. (min)	kg a.s./hL min max	water (L/ha) min max	kg a.s./ha min max		
Ornamentals	BG, EL, ES, IT, PT	GF-2626	F/G	Aphids, Whiteflies	SC	120 g/L	Ground applied foliar spray, broadcast	BBCH 12-59	1-2	7	0.0012-0.024	200-2000	0.024-0.048	1	Aphids: One or two applications of 24 g a.s./ha. Two applications would be minimum 7 days interval. Whiteflies: 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. **Use not assessed in the residue section**

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