

# **REGISTRATION REPORT**

## **Part B**

### **Section 4: Metabolism and Residues**

#### **Detailed summary of the risk assessment**

**TRANSFORM (GF-2372)**

**500 g/Kg Sulfoxaflor**

**Southern Zone**

**Zonal Rapporteur Member State: France**

## **CORE ASSESSMENT**

**Applicant: DOW AgroSciences**

**Date: October 2017**

## Table of Contents

<b>IIIA 8</b>	<b>METABOLISM AND RESIDUES DATA .....</b>	<b>4</b>
<b>Sulfoxaflor</b>	<b>4</b>	
IIIA 8.1	Stability of Residues.....	6
IIIA 8.1.1	Stability of residues during storage of samples .....	6
IIIA 8.1.2	Stability of residues in sample extracts .....	7
IIIA 8.2	Studies on metabolism in plants or livestock .....	8
IIIA 8.2.1	Metabolism in plants .....	8
IIIA 8.2.2	Metabolism in livestock .....	10
IIIA 8.3	Residue trials (supervised field trials) .....	12
IIIA 8.3.1	RAPE SEED.....	12
IIIA 8.3.2	COTTON SEED.....	24
IIIA 8.3.3	CEREALS (BARLEY, OATS) .....	33
IIIA 8.3.4	WHEAT, RYE, SPELT, TRITICALE .....	52
IIIA 8.4	Livestock Feeding Studies .....	67
IIIA 8.4.1	Dietary burden calculation .....	67
IIIA 8.4.2	Nature of residue in fish .....	67
IIIA 8.5	Studies on Industrial Processing and/or Household Preparation.....	70
IIIA 8.5.1	Nature of residues.....	70
IIIA 8.5.2	Distribution of the residue in peel/pulp .....	71
IIIA 8.5.3	Balance studies on a core set of representative processes .....	71
IIIA 8.6	Studies for Residues in Representative Succeeding Crops .....	73
IIIA 8.6.1	Preliminary consideration.....	73
IIIA 8.6.2	Summary of European data .....	73
IIIA 8.6.3	New data.....	74
IIIA 8.6.4	Conclusion on succeeding crops studies .....	74
IIIA 8.7	Proposed Residue Definition and Maximum Residue Levels.....	74
IIIA 8.7.1	Proposed residue definition .....	74
IIIA 8.7.2	Proposed maximum residue levels (MRLs) .....	76
IIIA 8.8	Proposed Pre-Harvest Intervals, Re-Entry or Withholding Periods.....	76
IIIA 8.8.1	Pre-harvest interval (in days) for each relevant crop.....	76
IIIA 8.8.2	Re-entry period (in days) for livestock, to areas to be grazed.....	76
IIIA 8.8.3	Re-entry period for man to crops, buildings or spaces treated .....	76
IIIA 8.8.4	Withholding period (in days) for animal feedingstuffs .....	77
IIIA 8.8.5	Waiting period before sowing or planting crop to be protected .....	77
IIIA 8.8.6	Waiting period between application and handling treated products.....	77
IIIA 8.8.7	Waiting period (in days) before sowing or planting succeeding crops .....	77
IIIA 8.9	Other/Special Studies .....	77
IIIA 8.10	Estimation of Exposure Through Diet and Other Means .....	77
IIIA 8.10.1	TMDI calculations.....	79
IIIA 8.10.2	IEDI calculations .....	80
IIIA 8.10.3	IESTI calculations .....	82
IIIA 8.10.4	Consumer risk assessment conclusion.....	83
IIIA 8.11	Summary and Evaluation of Residue Behaviour for active substance 1 .....	83
<b>Conclusion</b>	<b>84</b>	
	Summary of the evaluation.....	84
<b>References :</b>	<b>86</b>	
<b>Appendix 1:</b>	<b>List of data submitted in support of the evaluation .....</b>	<b>88</b>

<b>Appendix 2: Acceptable critical Uses –GAP tables .....</b>	<b>90</b>
---	-----------

## 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)	DowAgroSciences
Function (e.g. fungicide)	Insecticide
Rapporteur Member State	<b>Ireland</b> (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
First Approval Date (DD Month YYYY)	18/08/2015
Inclusion Directive Reference	Reg. (EU) 2015/1295
<b>Residue definition for monitoring</b> (as defined in current regulation)	Sulfaxoflor (sum of isomers)
<b>Legislation footnotes</b>	/
<b>EFSA Journal</b> 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: <a href="http://www.efsa.europa.eu/efsajournal.htm">www.efsa.europa.eu/efsajournal.htm</a>
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
<b>Restriction</b> (is restricted to use as "...")	None
<b>Molecular mass</b>	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 supported uses were as an insecticide on

(The uses supported were "...")	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
MRL codex?	Yes

### 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					
<b>ADI</b>	EFSA	2014	0.04 mg/kg bw per day	2-year Rat	x100
<b>ARfD</b>	EFSA	2014	0.25 mg/kg bw	Rat acute neurotoxicity study	x100

### Considerations about established MRL for active substance

Today, the MRLs for sulfoxaflor are published in Reg (EU) 2016/1. New MRL have been voted at EU level (SCoPAFF 28-29 November 2016) and are proposed 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-2372 (TRANSFORM) 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 (IE 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**

<b>Plant products</b>		
<b>Crop</b>	<b>Characteristics of the crop group</b>	<b>Acceptable Maximum Storage duration</b>
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)
<b>Animal Products</b>		
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 sulfoxaflo 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 [<sup>14</sup>C-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) <sup>1</sup>	Application details				Reference
					Growth stage at application	Rate	No	Sampling	
Fruits and fruiting vegetable	Tomato	[ <sup>14</sup> C-pyridine] ring	NR <sup>2</sup>	Foliar application F	NM <sup>2</sup>	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 <sup>2</sup>	Soil application F	NM <sup>2</sup>	225g as./ha	2	Immature plants:14 DA1A Tomatoes:14, 21, 28 DALA Vines : 28 DALA	
Leafy vegetables	Lettuce	[ <sup>14</sup> C-pyridine] ring	NR <sup>2</sup>	Foliar application F	NM <sup>2</sup>	200 g as/ha	3	Immature plants:14 DA1A Mature plants: 7 DALA	Ireland, 2012
			NR <sup>2</sup>	Soil application F	NM <sup>2</sup>	225 g as/ha	2	Immature plants:14 DA1A Mature plants: 7 DALA	
Pulses and oilseeds	Snap Peas	[ <sup>14</sup> C-pyridine] ring	NR <sup>2</sup>	Foliar application F	NM <sup>2</sup>	200 g as/kg	3	Immature plants: 14 DA1A, 14 DA2A, At maturity: pods, vines	Ireland, 2012
			NR <sup>2</sup>	Soil application F	NM <sup>2</sup>	450 g as/ha	1	Immature plants: 14 DA1A, At maturity: pods, vines	
Cereals	Rice	[ <sup>14</sup> C-pyridine] ring	NR <sup>2</sup>	Foliar application F	NM <sup>2</sup>	600 g as/ha split in 3 applications at 225, 225 &		Immature plants:14 DA1A At maturity :	Ireland, 2012



Group	Crop	Label position	Formulation	Type of treatment (foliar, seed, ...)/(F) or (G) or (I) <sup>1</sup>	Application details				Reference
					Growth stage at application	Rate	No	Sampling	
						150 g as/ha		straw, hulls, grain	
			Rice plant were transplanted at BBCH 13-14	Soil application F	NM <sup>2</sup>	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 1<sup>st</sup> Application  
**DA2A** : Day After 2<sup>nd</sup> Application  
**DAT**: Day After Treatment  
**DALA** : Day After Last Application

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

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

Overall, compounds X11719474 and X11721061 (conjugated form) were the pertinent metabolites in mature tomato fruit (20 – 29 % and 13 – 22 % TRR, respectively), foliage (16 % and 14 % TRR), pods of snap pea (both 13 % TRR) and vines (12 % and 7 % TRR), lettuce (30 % and 8 % TRR), rice grain (8 % and 11 % TRR) and straw (10 % and 8 % TRR). Only low proportions of free X11721061 were observed in the mature crops ( $\leq 4$  % 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	[ <sup>14</sup> 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)	Ireland 2012
					Urine	Twice a day	
					Faeces	Daily	
					<ul style="list-style-type: none"> <li>• Liver</li> <li>• Kidney</li> <li>• Muscle (loin &amp; flank)</li> <li>• fat(subcutaneous, omental &amp; renal)</li> <li>• small and large intestine</li> <li>• Stomach</li> <li>• Contents of the gastrointestinal tract</li> </ul>	At sacrifice, 6 hours after the final dose	
Hen	[ <sup>14</sup> 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)	Ireland 2012
					Excreta	Daily	
					<ul style="list-style-type: none"> <li>• Cage rinse</li> <li>• muscle (beast, leg)</li> <li>• liver</li> <li>• fat</li> <li>• skin with</li> </ul>	At sacrifice, 6 h after final dose	

Species	Label position	Number of specimen	Application details		Sampling		Reference
			Duration	Rate	Commodity	Time	
					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	[ <sup>14</sup> 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)	Ireland 2012
					Urine	Daily	
					Faeces	Daily	
					<ul style="list-style-type: none"> <li>• Liver</li> <li>• Kidney</li> <li>• muscle (loin &amp; flank)</li> <li>• fat(subcutaneous, omental &amp; renal)</li> <li>• gastrointestinal tract and its content</li> </ul>	At sacrifice, 6 hours after the final dose	
Hen	[ <sup>14</sup> 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)	Ireland 2012
					Excreta	Daily	
					<ul style="list-style-type: none"> <li>• Cage rinse</li> <li>• muscle (beast, leg)</li> <li>• liver</li> <li>• fat</li> <li>• skin with subcutaneous fat</li> </ul>	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 diastereomers 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)****IIIA 8.3.1 RAPE SEED****Table IIIA 8.3.1-1: Comparison of intended and critical EU GAPs**

Crop	Type of GAP	Number of applications	Application rate per treatment (g a.s./ha)	Interval between application (days)	Growth stage at last application	PHI (days)
Rape seed	DAR - MRL Application (CAN) <sup>(1)</sup>	2	50	14	Up to BBCH 87/89	14
	Intended FR	2	24	21	BBCH 10-87	28

(1). MRL Application – import tolerance, MRL estimated from trials conducted according to the Canadian cGAPs.

**IIIA 8.3.1.1 Summary of B.7.6 Data**

Use on rape seed 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 Canadian GAP and supporting residue trials have been performed outside EU (Canada, USA and Australia). Therefore they cannot be used to support the intended GAP.

Based on the supporting residue data an MRL of 0.1 mg/kg based on Canadian GAP was proposed by EFSA and then adopted at EU level in Regulation 2016/1.

Later the existing CXL of 0.15 mg/kg was voted at EU level and proposed in document SANTE/11442/2016.

In evaluation report EU trials are also summarized, but they were performed according to a more critical GAP than intended one (2 application at ca 50 g as/ha) involving residue level in seed at intended PHI which are higher than the in force MRL.

Therefore trials available in evaluation report and submitted to support the MRL application cannot be considered to support the intended EU use of GF-2372 on rape seed.

**IIIA 8.3.1.2 New data****IIIA 8.3.1.2.1 Study 1 – CEMS-3927**

<b>Report:</b>	KIIIA 8.3.1/01, Rawle, N.W., 2012
<b>Title:</b>	Residues of XDE-208 in oil seed rape at intervals and harvest following a single application of GF-2032 – Northern and Southern Europe - 2008 and 2009
<b>Document No:</b>	Study ID : CEMS-3927, Report ID : CEMR-3927 Dow AgroSciences Reference ID 080052-01
<b>Guidelines:</b>	-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.
<b>GLP</b>	Yes

<b>Acceptability</b>	<b>Deviations</b>
Yes	None with impact on the study

**Table IIIA 8.3.1-2: Summary of global information on study 1**

<b>Comparative trials (between formulations, with and adjuvant/safener/synergist)</b>	No, formulation SC containing 240 g sulfoxaflor/L
<b>Number of applications</b>	1
<b>Dose (g as/ha)</b>	24 g a.s./ha
<b>Mode of application</b>	foliar broadcast
<b>PHI (days) and/or growth stage (BBCH)</b>	0,7,21,28,35 days
<b>Analytical method (Code +Type)</b>	Method 091031 LC-MS/MS
<b>LoQ (mg/kg)</b>	0.01 mg/kg

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

N° Trial	CEMS-3927A	CEMS-3927B	CEMS-3927C	CEMS-3927D	CEMS-3927E	CEMS-3927F	CEMS-3927G
North/South/Indoor	N	N	N	N	S	S	S
Decline (D)/Harvest (H) trial?	D	D	H	H	D	H	D
Formulation	SC	SC	SC	SC	SC	SC	SC
Equivalence between formulations	Y	Y	Y	Y	Y	Y	Y
Accordance with intended GAP	N <sup>(1)</sup>	N <sup>(1)</sup>	N <sup>(1)</sup>	N <sup>(1)</sup>	N <sup>(1)</sup>	N <sup>(1)</sup>	N <sup>(1)</sup>
Correct sampling	Y	Y	Y	Y	Y	Y	Y
Samples frozen within 24h	Y	Y	Y	Y	Y	Y	Y
Storage period (in days)	244	252	224	215	255	191	260
Sample Extract <sup>(2)</sup>	12	12	12	12	12	12	12
Storage T° <-18°C	Y	Y	Y	Y	Y	Y	Y
Validated analytical method	Y	Y	Y	Y	Y	Y	Y
Negative controls	Y	Y	Y	Y	Y	Y	Y
Considered trial	N	N	N	N	N	N	N
Remarks	1, 2	1, 2	1, 2	1, 2	1, 2	1, 2	1, 2

(1). Only one application at 24 g a.s./ha instead of 2

(2). The procedural recoveries which were within 70-110% demonstrate the stability of the analytes during storage (up to 12 days)

**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 2<sup>nd</sup> Floor – 3 Milton Park, Abington

Content of a.i. (g/kg or g/l) : 240 g/L

Formulation (e.g. WP) : SC

Commercial product (name) : GF-2032

Applicant : Eurofins

Active ingredient : Sulfoxaflor (XDE-208)

Crop / crop group : Oil Seed Rape

Indoors / outdoors : Outdoor

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

Residues calculated as : XDE 208 +X11719474

GLP and Trial Details	Crop Variety	Country (Zone) Location incl. postal code	Application Details									Residues found			Remarks
Trial ID Study ID Report No. GLP(Y/N) Trial Year			Form No.	No. of Appls	Appl Rate (g ai/ha)	Spray Vol (L/ha)	Appl Conc (g ai/hL)	Appl Date	GS at Last Appl	PHI (days)	Portion Analysed	XDE-208 (mg/kg)	X11719474 (mg/kg)	Total* (mg/kg)	
	(a)							(c)		(d)	(a)				(e)
CEMS-3927A	Rape seed Taurus	Germany NZ Outdoor (field)	GF-2032	1	25.2	420	6	24-Jun-2008	BBCH 78	0	Whole plant	0.273	<0.01	0.282	
CEMS-3927										6	Whole plant	0.069	<0.01	0.078	
DAS Ref#										21	Seed	0.012	<0.01	0.021	
080052-01										29	Seed	<b>0.015</b>	<0.01	<b>0.024</b>	
Y										29	Rest of plant	<0.01	<0.01	<0.019	
2008									35	Seed	0.011	<0.01	0.020		
CEMS-3927B	Rape seed Grizzly	N France NZ Outdoor (field)	GF-2032	1	23.2	290	8	16-Jun-2008	BBCH 80	0	Whole plant	0.287	<0.01	0.296	
CEMS-3927										7	Whole plant	0.055	<0.01	0.064	
DAS Ref#										21	Seed	<0.01	<0.01	<0.019	
080052-01										28	Seed	<b>&lt;0.01</b>	<0.01	<b>&lt;0.019</b>	
Y										28	Rest of plant	0.031	<0.01	0.040	
2008									35	Seed	<0.01	<0.01	<0.019		

GLP and Trial Details	Crop Variety	Country (Zone) Location incl. postal code	Application Details									Residues found			Remarks
			Form No.	No. of Appls	Appl Rate (g ai/ha)	Spray Vol (L/ha)	Appl Conc (g ai/hL)	Appl Date	GS at Last Appl	PHI (days)	Portion Analysed	XDE-208 (mg/kg)	X11719474 (mg/kg)	Total* (mg/kg)	
	(a)							(c)		(d)	(a)				(e)
CEMS-3927C CEMS-3927 DAS Ref# 080052-01 Y 2008	Rape seed Californium	Poland NZ Outdoor (field)	GF-2032	1	26.0	433	6	18-Jun-2008	BBCH 83	28 28	Seed Rest of plant	<b>0.020</b> 0.028	<0.01 <0.01	<b>0.029</b> 0.037	
CEMS-3927D CEMS-3927 DAS Ref# 080052-01 Y 2008	Rape seed Astrid	UK NZ Outdoor (field)	GF-2032	1	24.4	407	6	27-Jun-2008	BBCH 80	28 28	Seed Rest of plant	<b>0.030</b> <0.01	<b>&lt;0.01</b> <0.01	<b>0.039</b> <0.019	
CEMS-3927E CEMS-3927 DAS Ref# 080052-01 Y 2008	Rape seed Es Artist	Spain SZ Outdoor (field)	GF-2032	1	24.9	617	4	13-Jun-2008	BBCH 79	0 21 28 28 35	Whole plant Whole plant Pods Rest of plant Seed	0.130 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	0.139 <0.019 <b>&lt;0.019</b> <0.019 <0.019	
CEMS-3927F CEMS-3927 DAS Ref# 080052-01 Y 2008	Rape seed Olindigo	S France SZ Outdoor (field)	GF-2032	1	21.8	272	8	20-Jul-2008	BBCH 83	29 29	Seed Rest of plant	<b>&lt;0.01</b> 0.080	<0.01 <0.01	<b>&lt;0.019</b> 0.089	



GLP and Trial Details	Crop Variety	Country (Zone) Location incl. postal code	Application Details									Residues found			Remarks
Trial ID Study ID Report No. GLP(Y/N) Trial Year			Form No.	No. of Appls	Appl Rate (g ai/ha)	Spray Vol (L/ha)	Appl Conc (g ai/hL)	Appl Date	GS at Last Appl	PHI (days)	Portion Analysed	XDE-208 (mg/kg)	X11719474 (mg/kg)	Total* (mg/kg)	
	(a)							(c)		(d)	(a)				(e)
CEMS-3927G	Rape seed	Spain	GF-	1	22.7	283	8	17-Jun-	BBCH 80	0	Whole plant	0.192	0.012	0.203	
CEMS-3927	CF 605	SZ	2032					2009		7	Whole plant	0.059	<0.01	0.068	
DAS Ref#		Outdoor								21	Seed	0.030	<0.01	0.039	
080052-01		(field)								27	Seed	0.011	<0.01	0.020	
Y										27	Rest of plant	0.016	<0.01	0.025	
2009										35	Seed	<b>0.012</b>	<0.01	<b>0.021</b>	

\* 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 – CEMS-5945

<b>Report:</b>	KIIIA 8.3.1/02, Rawle, N.W., 2014
<b>Title:</b>	Residues of sulfoxaflor in oil seed rape at intervals and harvest following multiple application of GF-2372 – Southern Europe - 2013
<b>Document No:</b>	Study ID : CEMS-5945, Report ID : CEMR-5945 Dow AgroSciences Reference 130158
<b>Guidelines:</b>	-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"
<b>GLP</b>	Yes

<b>Acceptability</b>	<b>Deviations</b>
Yes	None with impact on the study

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

<b>Comparative trials (between formulations, with and adjuvant/safener/synergist)</b>	No, formulation WG containing 500 g sulfoxaflor/kg
<b>Number of applications</b>	2
<b>Dose (g as/ha)</b>	24 g a.s./ha
<b>Mode of application</b>	foliar broadcast
<b>PHI (days) and/or growth stage (BBCH)</b>	0,7,14, 21,28,35 days
<b>Analytical method (Code +Type)</b>	Method 091031 LC-MS/MS
<b>LoQ (mg/kg)</b>	0.01 mg/kg

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

N° Trial		CEMS-5945A	CEMS-5945B	CEMS-5945C	CEMS-5945D	CEMS-5945E	CEMS-5945F
North/South/Indoor		S	S	S	S	S	S
Decline (D)/Harvest (H) trial?		D	D	D	H	H	H
Formulation		WG	WG	WG	WG	WG	WG
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	275	273	268	250	238	244
	Extract	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	1	1	1	1	1

(1). The procedural recoveries which were within 70-110% demonstrate the stability of the analytes during storage

**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 3B Park Square, Milton Park, Abingdon  
Content of a.i. (g/kg or g/l) : 500 g/kg  
Formulation (e.g. WP) : WG  
Commercial product (name) : GF-2372  
Applicant :

Active ingredient : Sulfoxaflor (XDE-208)  
Crop / crop group : Oil Seed Rape

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
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-5945A CEMS-5945 DAS Ref# 130158 Y 2013	Rape seed Exquisite	Spain SZ Outdoor (field)	GF- 2372	2	23.6 22.8	390 380	6 6	06-May- 2013 27-May- 2013	BBCH 75- 79	0 7 14 21 29 29 35	Whole plant Whole plant Whole plant Seed Seed Rest of plant Seed	0.289 0.028 0.023 0.019 <0.01 <0.01 <b>&lt;0.01</b>	0.01 0.01 0.02 0.016 <0.01 <0.01 0.013	0.298 0.037 0.042 0.034 <0.019 <0.019 <b>0.022</b>	
CEMS-5945B CEMS-5945 DAS Ref# 130158 Y 2013	Rape seed Hybrid Star	Italy SZ Outdoor (field)	GF- 2372	2	24.0 23.6	504 495	4.8 4.8	08-May- 2013 29-May- 2013	BBCH 80	0 7 15 21 28 28 34	Whole plant Whole plant Whole plant Seed Seed Rest of plant Seed	0.300 0.079 0.038 0.027 <b>0.020</b> <0.01 0.016	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.309 0.088 0.047 0.036 <b>0.029</b> <0.019 0.025	

GLP and Trial Details	Crop	Country	Application Details									Residues found			Remarks
Trial ID Study ID Report No. GLP(Y/N) Trial Year	Crop Variety	Country (Zone) Location incl. postal code	Form No.	No. of Appls	Appl Rate (g ai/ha)	Spray Vol (L/ha)	Appl Conc (g ai/hL)	Appl Date	GS at Last Appl	PHI (days)	Portion Analysed	XDE-208 (mg/kg)	X11719474 (mg/kg)	Total* (mg/kg)	
(a)								(c)		(d)	(a)				
CEMS-5945C CEMS-5945 DAS Ref# 130158 Y 2013	Rape seed Albatros	S France SZ Outdoor (field)	GF-2372	2	23.0 21.7	335 317	6.9 6.9	10-May-2013 03-Jun-2013	BBCH 79-80	0 7 14 21 28 28 35	Whole plant Whole plant Whole plant Seed Seed Rest of plant Seed	0.319 0.116 0.059 0.030 <b>0.028</b> 0.068 0.023	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.328 0.125 0.068 0.039 <b>0.037</b> 0.077 0.032	
CEMS-5945D CEMS-5945 DAS Ref# 130158 Y 2013	Rape seed SY Carlo	S France SZ Outdoor (field)	GF-2372	2	24.0 25.0	500 520	4.8 4.8	02-May-2013 21-May-2013	BBCH 80	30 30	Seed Rest of plant	<b>0.020</b> 0.016	<0.01 <0.01	<b>0.029</b> 0.025	
CEMS-5945E CEMS-5945 DAS Ref# 130158 Y 2013	Rape seed Grizzlie	S France SZ Outdoor (field)	GF-2372	2	22.6 23.2	377 368	6.0 6.0	14-May-2013 04-Jun-2013	BBCH 73-74	28 28	Seed Rest of plant	<b>&lt;0.01</b> <0.01	<0.01 <0.01	<b>&lt;0.019</b> <0.019	
CEMS-5945F CEMS-5945 DAS Ref# 130158 Y 2013	Rape seed Hybrid Lord	Italy SZ Outdoor (field)	GF-2372	2	24.3 23.7	511 499	4.8 4.8	08-May-2013 29-May-2013	BBCH 79-80	28 28	Seed Rest of plant	<b>0.023</b> 0.010	<0.01 <0.01	<b>0.032</b> 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 rape seed and conformity to existing MRL

Table IIIA 8.3.1-8: Summary of monograph and new data supporting the intended use on rape seed 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
Rape seed	New trials	South (6)	<b>Trials GAP: 2x0.024 kg/ha ; Interval 21 days ; PHI 28 days</b> <b>Mo</b> : 2x <0.01, 2x 0.020, 0.023, 0.028 <b>RA</b> : <0.019, 0.022, 2x 0.029, 0.032, 0.037	0.020	0.028	0.049	0.045	0.047 (0.05)	0.10	Yes
	Overall supporting data for FR GAP	North (0)	No data available	-	-	-	-	-		
		South (6)	<b>Mo</b> : 2x <0.01, 2x 0.020, 0.023, 0.028 <b>RA</b> : <0.019, 0.022, 2x 0.029, 0.032, 0.037	0.020	0.028	0.049	0.045	0.047 (0.05)		
	Overall supporting data for SEU GAP	South (6)	<b>Mo</b> : 2x <0.01, 2x 0.020, 0.023, 0.028 <b>RA</b> : <0.019, 0.022, 2x 0.029, 0.032, 0.037	0.020	0.028	0.049	0.045	0.047 (0.05)		

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

**Mo**: Monitoring residue data (sulfoxaflor only)

**RA**: Risk assessment residue data (Sulfoxaflor + metabolite X11719474 expressed as sulfoxaflor)

### IIIA 8.3.1.4 Conclusion for rape seeds

Rape seed is a major crop in Southern and Northern Europe. Moreover, in France, rapeseed is cultivated in Northern and Southern regions of the country. Thus, 8 trials from each zone are required to support the use of sulfoxaflor on rapeseed in France.

According to the applicant trials of study CEMS-3927 could be considered to support the intended. In this registration report the applicant provided the following argumentation: *“Although the 2008 trials made a single application instead of two, this was not found to be a critical factor. Sulfoxaflor residues decline rapidly; by 21 days after application, which is the proposed spray interval, residues of sulfoxaflor were typically low in the seed. Since the residues immediately after application are at least an order of magnitude higher, it can be concluded that the first application will not contribute significantly to the residue in the seed at harvest. Furthermore, all residue values following the proposed PHI were within the same range, confirming that the number of applications is not a critical factor in influencing the residue levels in the treated seed.”*

FR as zRMS did not consider this argumentation as acceptable. Indeed for study CEMS-3927 in 3 among 4 Northern residue trials and in 1 among 4 Southern residue trials, residues of sulfoxaflor above 0.01 mg (0.011 to 0.03 mg/kg) were found in grain 28 days after application. Therefore it cannot be concluded that the number of applications is not a critical factor in influencing the residue levels in the treated seed. Therefore FR consider that trials of study CEMS-3927 have been performed at a less critical GAP than intended one and are not considered acceptable to support the intended use of GF-2372 in France and SEU.

In conclusion no NEU and 6 SEU trials are suitable to support the intended use on rapeseed. Therefore, the provided trials are not sufficient to support the use of GF-2372 on rapeseed in France.

**The use of GF-2372 (TRANSFORM) on rape seeds is not supported in France and then is not considered as acceptable.**

### IIIA 8.3.2 COTTON SEED

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

Crop	Type of GAP	Number of applications	Application rate per treatment (g a.s./ha)	Interval between application (days)	Growth stage at last application	PHI (days)
Cotton seed	EU DAR	1	24	-	BBCH 20-39 BBCH 40-89 May-Sept	14
	Intended EL	2	24	7	BBCH 20-87	14

(1) Representative use

#### IIIA 8.3.2.1 Summary of B.7.6 Data

The intended GAP is more critical than the representative EU use of sulfoxaflor in cotton 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 one application at ca 50 g a.s./ha, PHI of 14 days. As the application rate is equivalent to the maximum intended seasonal rate of 2 applications at 24 g a.s./ha, these trials are considered suitable to support the intended GAP.



Results of the supported trials are summarized below.

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

Table IIIA 8.3.2-2: Summary of cotton trials from monograph

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-4712 (Study no: 101473) Trial 1: CEMS-4712A	Cotton	58100 Giannitsa, Pella, Greece. 2010 SEU	1 x 25.0 GF-2032	84	NA	0	Seeds	Seeds	Seeds
						7	ND	ND	ND
						14	ND	ND	(0.004)
						22	ND	ND	(0.003)
						27	ND	ND	(0.005)
			1 x 25.1 GF-2372	84	NA	0	ND	ND	ND
						7	ND	ND	ND
						14	ND	ND	ND
						22	ND	ND	(0.003)
Doc ID: CEMR-4712 (Study no: 101473) Trial 2: CEMS-4712B	Cotton	41440 Lora del Rio, Sevilla, Spain. 2010 SEU	1 x 24.4 GF-2032	86	NA	27	ND	ND	(0.006)
						0	Seeds	Seeds	Seeds
						7	ND	ND	ND
						14	ND	ND	ND
						21	ND	ND	ND
			1 x 50.2 GF-2372	84	NA	22	ND	ND	(0.003)
						27	ND	ND	(0.005)
						0	Seeds	Seeds	Seeds
						7	ND	ND	(0.003)
Doc ID: CEMR-4712 (Study no: 101473) Trial 2: CEMS-4712B	Cotton	41440 Lora del Rio, Sevilla, Spain. 2010 SEU	1 x 24.2 GF-2372	86	NA	14	ND	ND	(0.004)
						21	ND	ND	(0.004)
						28	ND	ND	(0.004)
						0	Seeds	Seeds	Seeds
						7	ND	ND	(0.004)
						14	ND	ND	(0.004)
						21	ND	ND	(0.004)
						28	ND	ND	(0.004)
						0	Seeds	Seeds	Seeds

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
			1 x 47.0 <b>GF-2372</b>	86	NA	0 7 <u>14</u> 21 28	Seeds (0.005) ND <u>ND</u> ND ND	Seeds ND ND <u>ND</u> ND ND	Seeds (0.004) (0.006) (0.004) (0.004) (0.008)
<b>Doc ID: CEMR-4712</b> (Study no: 101473) Trial 3: CEMS-4712C	Cotton	58100 Giannitsa, Pella, Greece. 2010 SEU	1 x 25.0 <b>GF-2032</b>	85	NA	14	Seeds ND	Seeds ND	Seeds (0.004)
			1 x 25.1 <b>GF-2372</b>	85	NA	14	Seeds ND	Seeds ND	Seeds (0.004)
			1 x 49.8 <b>GF-2372</b>	85	NA	<u>14</u>	<u>Seeds</u> <u>ND</u>	<u>Seeds</u> <u>ND</u>	<u>Seeds</u> (0.006)
<b>Doc ID: CEMR-4712</b> (Study no: 101473) Trial 4 : CEMS-4712D	Cotton	41220 Burguillos , Sevilla, Spain. 2010 SEU	1 x 24.8 <b>GF-2032</b>	87	NA	14	Seeds ND	Seeds ND	Seeds (0.005)
			1 x 25.1 <b>GF-2372</b>	87	NA	14	Seeds ND	Seeds ND	Seeds (0.006)
			1 x 50.9 <b>GF-2372</b>	87	NA	<u>14</u>	<u>Seeds</u> <u>ND</u>	<u>Seeds</u> <u>ND</u>	<u>Seeds</u> (0.005)

ND : not detected <0.003 mg/kg

LOQ : 0.01 mg/kg

**IIIA 8.3.2.2 New data****IIIA 8.3.2.2.1 Study 1 – CEMS-5007**

<b>Report:</b>	KIIIA 8.3.2/02, Rawle, N.W. , 2012
<b>Title:</b>	Residues of sulfoxaflor in cotton at intervals and harvest following a single application of GF-2372 – Southern Europe – 2011
<b>Document No:</b>	Study ID : CEMS-5007, Report ID : CEMR-5007 Dow AgroSciences Reference : GHE-P-12703
<b>Guidelines:</b>	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"
<b>GLP</b>	yes

<b>Acceptability</b>	<b>Deviations</b>
Yes	None with impact on the study

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

<b>Comparative trials (between formulations, with and adjuvant/safener/synergist)</b>	No, formulation WG containing 500 g sulfoxaflor/kg
<b>Number of applications</b>	1
<b>Dose (g as/ha)</b>	48 g a.i./ha
<b>Mode of application</b>	foliar broadcast
<b>PHI (days) and/or growth stage (BBCH)</b>	1, 3, 7 & 14 days
<b>Analytical method (Code +Type)</b>	091031 Liquid Chromatography/ Mass Spectrometry
<b>LoQ (mg/kg)</b>	0.01 mg/kg

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

<b>N° Trial</b>	<b>CEMS-5007A</b>	<b>CEMS-5007B</b>	<b>CEMS-5007C</b>	<b>CEMS-5007D</b>
<b>North/South/Indoor</b>	S	S	S	S
<b>Decline (D)/Harvest (H) trial?</b>	D	H	D	H
<b>Formulation</b>	WG	WG	WG	WG
<b>Equivalence between formulations</b>	Y	Y	Y	Y
<b>Accordance with intended GAP</b>	More critical <sup>(1)</sup>	More critical <sup>(1)</sup>	More critical <sup>(1)</sup>	More critical <sup>(1)</sup>
<b>Correct sampling</b>	Y	Y	Y	Y
<b>Samples frozen within 24h</b>	Y	Y	Y	Y
<b>Storage period (in days)</b>	<b>Sample</b>	259	259	270
	<b>Extract</b>	36 <sup>(2)</sup>	36 <sup>(2)</sup>	36 <sup>(2)</sup>
<b>Storage T° &lt;-18°C</b>	Y	Y	Y	Y
<b>Validated analytical method</b>	Y	Y	Y	Y
<b>Negative controls</b>	Y	Y	Y	Y
<b>Considered trial</b>	Y	Y	Y	Y
<b>Remarks</b>	1, 2	1, 2	1, 2	1, 2

- (1). Residue trials were performed with a single application at 48 g a.s./ha which is equivalent to the maximum intended seasonal rate of 2 applications at 24 g a.s./ha. The residue trials are considered to represent a more critical residues situation.
- (2). The procedural recoveries which were within 70-110 % demonstrate the stability of the analyte during this storage (up to 36 days).

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

**RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)**

(Application on agricultural and horticultural crops)

Notifier: Dow AgroSciences, European Development Centre  
address 1 2<sup>nd</sup> Floor – 3 Milton Park, Abington  
address 2 Oxon OX14 4RN  
address 3 UK

Content of a.i. (g/kg or g/l) : 500 g/kg  
Formulation (e.g. WP) : WG  
Commercial product (name) : GF-2372  
Applicant :

Active ingredient : Sulfoxaflor (XDE-208)  
Crop / crop group : Cotton

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
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-5007A CEMS-5007 DAS Ref# GHE-P-12703 Y 2012	Cotton Campo	Spain SZ Outdoor (field)	GF- 2372	1	50.5	631	8.0	26-Sep- 2011	BBCH 85	0 1 3 7 14 14	Whole plant Whole plant Whole plant Whole plant Non-delinted seed Gin by- products	1.530 0.462 0.269 0.142 <b>&lt;0.01</b> 0.101	0.017 0.012 0.010 0.010 <0.01 0.013	1.546 0.473 0.278 0.151 <b>&lt;0.019</b> 0.113	
CEMS-5007B CEMS-5007 DAS Ref# GHE-P-12703 Y 2012	Cotton Coronita	Spain SZ Outdoor (field)	GF- 2372	1	51.8	647	8.0	13-Sep- 2011	BBCH 87	13 13	Non-delinted seed Gin by- products	<b>&lt;0.01</b> 0.095	<0.01 <0.01	<b>&lt;0.019</b> 0.104	

GLP and Trial Details	Crop	Country	Application Details									Residues found			Remarks
Trial ID Study ID Report No. GLP(Y/N) Trial Year	Crop Variety (a)	Country (Zone) Location incl. postal code	Form No.	No. of Appls	Appl Rate (g ai/ha)	Spray Vol (L/ha)	Appl Conc (g ai/hL)	Appl Date (c)	GS at Last Appl	PHI (days) (d)	Portion Analysed (a)	XDE-208 (mg/kg)	X11719474 (mg/kg)	Total* (mg/kg)	
CEMS-5007C CEMS-5007 DAS Ref# GHE-P-12703 Y 2012	Cotton Celia	Greece SZ Outdoor (field)	GF- 2372	1	49.6	517	9.6	15-Sep- 2011	BBCH 85	0 1 3 7 14	Whole plant Whole plant Whole plant Whole plant Non-delinted seed	2.378 1.117 0.280 0.249 <u>&lt;0.01</u>	0.031 0.024 <0.01 <0.01 <0.01	2.407 1.140 0.289 0.258 <u>&lt;0.019</u>	
CEMS-5007D CEMS-5007 DAS Ref# GHE-P-12703 Y 2012	Cotton DP 419	Greece SZ Outdoor (field)	GF- 2372	1	49.0	510	9.6	15-Sep- 2011	BBCH 85	14	Non-delinted seed	<u>&lt;0.01</u>	<0.01	<u>&lt;0.019</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 8.3.2.3 Summary of monograph and new data supporting the intended use on cotton and conformity to existing MRL

Table IIIA 8.3.2-6: Summary of monograph and new data supporting the intended use on cotton 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
Cotton seed	Monograph	South (4)	<b>Trials GAP:</b> 1x0.050 kg/ha ; PHI 14 days <b>Mo</b> : 4x <0.01 <b>Ro</b> : 4x <0.019	<b>Mo:</b> 0.01* <b>RA:</b> 0.019	<b>Mo:</b> 0.01* <b>RA:</b> 0.019	-	-	0.01	Reg EU 2016/1: 0.02* SANTE/1 1442/2016 ; 0.4	Yes
	New trials	South (4)	<b>Trials GAP:</b> 1x0.048 kg/ha ; PHI 14 days <b>Mo</b> : 4x <0.01 <b>Ro</b> : 4x <0.019	<b>Mo:</b> 0.01* <b>RA:</b> 0.019	<b>Mo:</b> 0.01* <b>RA:</b> 0.019	-	-	0.01		
	Overall supporting data for EL GAP	South (8)	<b>Mo</b> : 8 x <0.01 <b>RA</b> : 8 x <0.019	<b>Mo:</b> 0.01* <b>RA:</b> 0.019	<b>Mo:</b> 0.01* <b>RA:</b> 0.019	-	-	0.01		
	Overall supporting data for SEU GAP	South (8)	<b>Mo</b> : 4x ND ; 4x <0.01 <b>RA</b> : 4x ND ; 4x <0.019	<b>Mo:</b> 0.01* <b>RA:</b> 0.019	<b>Mo:</b> 0.01* <b>RA:</b> 0.019	-	-	0.01		

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

**Mo:** Monitoring residue data (sulfoxaflor only)

**RA:** Risk assessment residue data (Sulfoxaflor + metabolite X11719474 expressed as sulfoxaflor)



#### IIIA 8.3.2.4 Conclusion for cotton seeds

Cotton is a major crop in Southern Europe. Thus a minimum of eight trials are required to support the use of sulfoxaflor in Southern European countries.

A total of 8 SEU cotton trials are available.

Based on SEU residue data it is possible to conclude that the current MRL of 0.02\* mg/kg (Reg EU 2016/1) and the proposed MRL of 0.4 mg/kg (SANTE/11442/2016) on cotton seed will not be exceed according to the intended GAP in EU.

The use of GF-2372 (TRANSFORM) on cotton seeds is fully supported in Greece.

#### IIIA 8.3.3 CEREALS (BARLEY, OATS)

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

Crop	Type of GAP	Number of applications	Application rate per treatment (g a.s./ha)	Interval between application (days)	Growth stage at last application	PHI (days)
Barley Oats	EU DAR <sup>1</sup>	1	24	-	BBCH 40-89 April-July	21
	Intended FR, IT	2	24	21	BBCH 12-87	21

(1). Representative use

##### IIIA 8.3.3.1 Summary of B.7.6 Data

The intended GAP is more critical than the representative EU uses of sulfoxaflor in barley and oats 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 EU with 2 applications at ca 24-25 g a.s./ha, PHI of 21 days.

Results of the supported trials are summarized below.

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

Table IIIA 8.3.3-2: Summary of barley trials submitted in sulfoxaflor monograph

GLP and Trial Details	Crop	Country	Application Details						Residues found					
Trial ID Study ID Report No. GLP(Y/N) Trial Year	Crop Variety	Country Zone Location	Form No.	No. of Appls	Appl Rate (g ai/ha)	Spray Vol (L/ha)	Appl Conc (g ai/hL)	Appl Date	GS at Last Appl	PHI (days)	Portion Analysed	XDE-208 (mg/kg)	X11719474 (mg/kg)	Total* (mg/kg)
CEMS-3922A CEMS-3922 DAS Ref. ID 080050-01 Y 2008	Spring barley Simba	Germany NZ Outdoor (field)	GF- 2032	1	24.1	302	8	30-Jun- 2008	BBCH 69	15	Grain	0.011	<0.01	0.020
										22	Grain	<0.01	<0.01	<0.019
										28	Grain	<0.01	<0.01	<0.019
										15	Straw	<0.01	<0.01	<0.019
										22	Straw	<0.01	<0.01	<0.019
										28	Straw	<0.01	<0.01	<0.019
										0	Whole plant	0.988	0.013	1.000
										8	Whole plant	0.014	<0.01	0.023
	Spring barley Simba		GF- 2032	2	25.1 24.3	313 303	8 8	16-Jun- 2008 30-Jun- 2008	BBCH 69	15	Grain	0.014	<0.01	0.023
										22	Grain	0.012	<0.01	0.021
										28	Grain	<b>0.014</b>	<0.01	<b>0.023</b>
										15	Straw	<0.01	<0.01	<0.019
										22	Straw	<b>&lt;0.01</b>	<0.01	<0.019
										28	Straw	<0.01	0.011	<b>0.020</b>
										<0	Whole plant	0.011	<0.01	0.020
										0	Whole plant	0.497	0.012	0.508
										8	Whole plant	0.016	<0.01	0.025
CEMS-3922B CEMS-3922 DAS Ref. ID 080050-01 Y 2008	Winter barley Nelly	Hungary NZ Outdoor (field)	GF- 2032	1	24.2	323	7.5	09-Jun- 2008	BBCH 71	21	Grain	<b>0.011</b>	<0.01	<b>0.020</b>
										21	Straw	<0.01	<0.01	<0.019
	Winter barley Nelly		GF- 2032	2	22.3 23.0	307 317	7.3 7.3	26-May- 2008 09-Jun- 2008	BBCH 71	21	Grain	<0.01	<0.01	<0.019
										21	Straw	<b>&lt;0.01</b>	<0.01	<b>&lt;0.019</b>
CEMS-3922C CEMS-3922 DAS Ref. ID	Spring barley Laila	Poland NZ Outdoor	GF- 2032	1	25.4	317	8	08-Jul- 2008	BBCH 75	21	Grain	<0.01	<0.01	<0.019
										21	Straw	<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)
080050-01 Y 2008	Spring barley Lailla	(field)	GF- 2032	2	23.5 23.9	294 299	8 8	23-Jun- 2008 08-Jul- 2008	BBCH 75	21 21	Grain Straw	<u><b>0.011</b></u> <u><b>0.013</b></u>	<u><b>&lt;0.01</b></u> <u><b>&lt;0.01</b></u>	<u><b>0.020</b></u> <u><b>0.022</b></u>
CEMS-3922D CEMS-3922 DAS Ref. ID 080050-01 Y 2008	Winter barley Antilope	United Kingdom NZ Outdoor (field)	GF- 2032	1	24.2	200	12.1	10-Jul- 2008	BBCH 83 to 85	7	Grain	0.031	<0.01	0.040
										14	Grain	0.027	<0.01	0.036
										21	Grain	0.022	<0.01	0.031
										28	Grain	<0.01	<0.01	<0.019
										7	Straw	0.224	0.041	0.262
										14	Straw	0.057	0.020	0.076
										21	Straw	0.038	0.012	0.049
										28	Straw	0.019	<0.01	0.028
										0	Whole plant	0.644	0.035	0.677
	Winter barley Antilope		GF- 2032	2	24.2 24.1	200 199	12.1 12.1	26-Jun- 2008 10-Jul- 2008	BBCH 83 to 85	7	Grain	0.052	<0.01	0.061
										14	Grain	0.029	<0.01	0.038
										21	Grain	<u><b>0.024</b></u>	<u><b>&lt;0.01</b></u>	<u><b>0.033</b></u>
										28	Grain	0.011	<0.01	0.020
										7	Straw	0.152	0.033	0.183
										14	Straw	0.087	0.028	0.113
										21	Straw	<u><b>0.037</b></u>	<u><b>0.015</b></u>	<u><b>0.051</b></u>
										28	Straw	0.021	<0.01	0.030
										<0	Whole plant	0.012	<0.01	0.021
										0	Whole plant	0.646	0.030	0.674

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-3922E CEMS-3922 DAS Ref. ID 080050-01 Y 2008	Spring barley Sebastian	France SZ Outdoor (field)	GF-2032	1	24.8	413	6	16-Jun-2008	BBCH 85	22 22	Grain Straw	<0.01 <b>0.061</b>	<0.01 <b>&lt;0.01</b>	<0.019 <b>0.070</b>
	Spring barley Sebastian		GF-2032	2	27.4 26.2	457 437	6 6	02-Jun-2008 16-Jun-2008	BBCH 85	22 22	Grain Straw	<b>0.023</b> <0.01	<b>&lt;0.01</b> <0.01	<b>0.032</b> <0.019
CEMS-3922F CEMS-3922 DAS Ref. ID 080050-01 Y 2008	Winter barley Bolley	Spain SZ Outdoor (field)	GF-2032	1	24.3	299	8.1	03-Jun-2008	BBCH 75	22	Grain	<0.01	<0.01	<0.019
										29	Grain	<0.01	<0.01	<0.019
										22	Straw	<0.01	0.019	0.028
										29	Straw	<0.01	0.024	0.033
										0	Whole plant	0.402	<0.01	0.411
										8	Whole plant	0.034	<0.01	0.043
										14	Whole plant	<0.01	<0.01	<0.019
	Winter barley Bolley		GF-2032	2	23.7 23.8	291 293	8.1 8.1	21-May-2008 03-Jun-2008	BBCH 75	22	Grain	<b>&lt;0.01</b>	<b>&lt;0.01</b>	<b>&lt;0.019</b>
										29	Grain	<0.01	<0.01	<0.019
										22	Straw	<b>&lt;0.01</b>	0.031	0.039
									29	Straw	<0.01	<b>0.034</b>	<b>0.042</b>	
									<0	Whole plant	<0.01	<0.01	<0.019	
									0	Whole plant	1.242	0.033	1.273	
									8	Whole plant	0.025	<0.01	0.034	
									14	Whole plant	<0.01	0.011	0.020	
CEMS-3922G CEMS-3922 DAS Ref. ID 080050-01 Y 2008	Spring barley Sibema	Italy SZ Outdoor (field)	GF-2032	1	24.1	397	6.1	27-May-2008	BBCH 69 to 71	28	Grain	<0.01	<0.01	<0.019
										28	Straw	<0.01	<0.01	<0.019
										0	Whole plant	0.894	<0.01	0.903
										8	Whole plant	0.015	<0.01	0.024
										14	Whole plant	<0.01	<0.01	<0.019
									21	Whole plant	<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)
	Spring barley Sibema		GF- 2032	2	24.3 24.5	401 404	6.1 6.1	13-May- 2008 27-May- 2008	BBCH 69 to 71	28 28 <0 0 8 14 21	Grain Straw Whole plant Whole plant Whole plant Whole plant	<0.01 <0.01 <0.01 0.519 0.010 <0.01 0.026	<0.01 0.013 <0.01 <0.01 <0.01 <0.01	<0.019 0.022 <0.019 0.528 0.019 <0.019 0.035
CEMS-3922H CEMS-3922 DAS Ref. ID 080050-01 Y 2008	Winter barley Everest R2	Greece SZ Outdoor	GF- 2032	1	24.0	200	12	03-Jun- 2008	BBCH 87	21 21	Grain Straw	<0.01 0.011	<0.01 <0.01	<0.019 0.020
	Winter barley Everest R2	(field)	GF- 2032	2	23.0 23.6	192 197	12 12	20-May- 2008 03-Jun- 2008	BBCH 87	21 21	Grain Straw	<b><u>0.012</u></b> <b><u>0.019</u></b>	<b><u>&lt;0.01</u></b> <b><u>&lt;0.01</u></b>	<b><u>0.021</u></b> <b><u>0.028</u></b>
CEMS-3922I CEMS-3922 DAS Ref. ID 080050-01 Y 2009	Winter barley Volley	Spain SZ Outdoor (field)	GF- 2032	1	24.8	310	8	22-Jun- 2009	BBCH 83 to 85	7 14 21 28 7 14 21 28 0	Grain Grain Grain Grain Straw Straw Straw Straw Whole plant	0.038 0.015 0.019 0.010 0.357 0.143 0.070 0.126 1.400	<0.01 <0.01 <0.01 <0.01 0.024 0.014 <0.01 0.014 0.071	0.047 0.024 0.028 0.019 0.380 0.156 0.079 0.139 1.467

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)
	Winter barley Volley		GF- 2032	2	22.7 24.4	283 305	8 8	05-Jun- 2009 22-Jun- 2009	BBCH 83 to 85	7 14 21 28 7 14 21 28 <0 0	Grain Grain Grain Grain Straw Straw Straw Straw Whole plant Whole plant	0.058 0.023 <b>0.032</b> 0.018 0.380 0.249 0.178 <b>0.202</b> 0.107 1.372	<0.01 <0.01 <b>&lt;0.01</b> <0.01 0.032 0.020 0.018 <b>0.020</b> 0.012 0.070	0.067 0.032 <b>0.041</b> 0.027 0.410 0.268 0.195 <b>0.221</b> 0.118 1.438
CEMS-3922J CEMS-3922 DAS Ref. ID 080050-01 Y 2009	Winter barley Otis	Italy SZ Outdoor (field)	GF- 2032	1	25.3	426	5.9	11-Jun- 2009	BBCH 81 to 83	8 15 20 29 8 15 20 29 0	Grain Grain Grain Grain Straw Straw Straw Straw Whole plant	0.020 0.026 <b>0.025</b> 0.010 0.086 0.029 0.014 <0.01 0.452	<0.01 <0.01 <b>&lt;0.01</b> <0.01 <0.01 <0.01 <0.01 <0.01 0.018	0.029 0.035 <b>0.034</b> 0.019 0.095 0.038 0.023 <0.019 0.469
	Winter barley Otis		GF- 2032	2	21.6 25.1	367 422	5.9 5.9	29-May- 2009 11-Jun- 2009	BBCH 81 to 83	8 15 20 29 8 15 20 29 <0 0	Grain Grain Grain Grain Straw Straw Straw Straw Whole plant Whole plant	0.018 0.024 0.024 0.011 0.094 0.020 <b>0.024</b> <0.01 0.445 0.480	<0.01 <0.01 <0.01 <0.01 0.011 <0.01 <b>&lt;0.01</b> <0.01 0.020 0.019	0.027 0.033 0.033 0.020 0.104 0.029 <b>0.033</b> <0.019 0.464 0.498



### IIIA 8.3.3.2 New data

#### IIIA 8.3.3.2.1 Study 1 – CEMS-5006

<b>Report:</b>	KIIIA 8.3.3/02, Rawle, N.W., 2012
<b>Title:</b>	Residues of sulfoxaflor in barley at intervals and harvest following multiple applications of GF-2372 – Northern and Southern Europe – 2011
<b>Document No:</b>	Study ID : CEMS-5006, Report ID : CEMR-5006 Dow AgroSciences Reference : GHE-P-12702
<b>Guidelines:</b>	-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.
<b>GLP</b>	Yes

Acceptability	Deviations
Yes	None with impact on the study

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

<b>Comparative trials (between formulations, with and adjuvant/safener/synergist)</b>	No, formulation WG containing 500 g sulfoxaflor/kg
<b>Number of applications</b>	2
<b>Dose (g as/ha)</b>	24 g a.i./ha
<b>Mode of application</b>	foliar broadcast
<b>PHI (days) and/or growth stage (BBCH)</b>	0, 1, 3, 7, 10, 14 & 21 days
<b>Analytical method (Code +Type)</b>	091031 Liquid Chromatography/ Mass Spectrometry
<b>LoQ (mg/kg)</b>	0.01 mg/kg



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

N° Trial		CEMS-5006A	CEMS-5006B	CEMS-5006C	CEMS-5006D	CEMS-5006E	CEMS-5006F	CEMS-5006G	CEMS-5006H
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		WG	WG	WG	WG	WG	WG	WG	WG
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 <sup>1</sup>	Y	Y	Y	Y	Y <sup>1</sup>
Samples frozen within 24h		Y	Y	Y	Y	Y	Y	Y	Y
Storage period (in days)	Sample	240	246	231	260	260	249	240	246
	Extract <sup>(1)</sup>	7	7	7	7	7	7	7	7
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 7 days). (CEMR-5006, p.25)

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

**RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)**

(Application on agricultural and horticultural crops)

Notifier: Dow AgroSciences, European Development Centre  
address 1 2<sup>nd</sup> Floor – 3 Milton Park, Abington  
address 2 Oxon OX14 4RN  
address 3 UK

Content of a.i. (g/kg or g/l) : 500 g/kg  
Formulation (e.g. WP) : WG  
Commercial product (name) : GF-2372  
Applicant :

Active ingredient : Sulfoxaflor (XDE-208)  
Crop / crop group : Barley/ cereals

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
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-5006A CEMS-5006 GHE-P-12702 Y 2011	Winter barley Estrella	Spain (SZ) 49150 Fonfria, Aragon Outdoor (field)	GF- 2372	2	24.2 22.3	302 279	8 8	13-Jun- 2011 04-Jul- 2011	BBCH 87 to 89	22 22 <0 0 1 3 7 14	Grain Straw Whole plant Whole plant Whole plant Whole plant Whole plant	<u><b>0.031</b></u> <u><b>0.067</b></u> 0.055 0.735 0.733 0.823 0.313 0.222	<0.01 0.011 <0.01 0.015 0.021 0.010 0.021 0.012	<u><b>0.040</b></u> <u><b>0.077</b></u> 0.064 0.749 0.753 0.832 0.333 0.233	

GLP and Trial Details	Crop	Country	Application Details									Residues found			Remarks
Trial ID Study ID Report No. GLP(Y/N) Trial Year	Crop Variety	Country (Zone) Location incl. postal code	Form No.	No. of Appls	Appl Rate (g ai/ha)	Spray Vol (L/ha)	Appl Conc (g ai/hL)	Appl Date	GS at Last Appl	PHI (days)	Portion Analysed	XDE-208 (mg/kg)	X11719474 (mg/kg)	Total* (mg/kg)	
	(a)							(c)		(d)	(a)				
CEMS-5006B CEMS-5006 GHE-P-12702 Y 2011	Spring barley Violeta	Bulgaria (SZ) 7290 Loznitsa, Razgrad Outdoor (field)	GF- 2372	2	23.8 24.4	298 306	8 8	07-Jun- 2011 28-Jun- 2011	BBCH 77	21 21 <0 0 1 3 7 10 14	Grain Straw Whole plant Whole plant Whole plant Whole plant Whole plant Whole plant	<u>&lt;0.01</u> <u>0.021</u> <0.01 0.666 0.426 0.130 0.058 0.033 0.039	<0.01 <0.01 <0.01 <0.01 0.011 <0.01 <0.01 <0.01	<u>&lt;0.019</u> <u>0.030</u> <0.019 0.675 0.436 0.139 0.067 0.042 0.048	
CEMS-5006C CEMS-5006 GHE-P-12702 Y 2011	Spring barley Sunshine	France (SZ) 86200 Loudun, Vienne Outdoor (field)	GF- 2372	2	23.1 24.5	288 307	8 8	07-Jun- 2011 28-Jun- 2011	BBCH 83	22 22	Grain Straw	<u>0.023</u> <u>0.014</u>	<0.01 <0.01	<u>0.032</u> <u>0.023</u>	
CEMS-5006D CEMS-5006 GHE-P-12702 Y 2011	Spring barley Rondo	Italy (SZ) 40057 Quarto Inferiore, Bologna Outdoor (field)	GF- 2372	2	25.1 26.1	313 327	8 8	10-May- 2011 31-May- 2011	BBCH 73 to 75	21 21	Grain Straw	<u>&lt;0.01</u> <u>&lt;0.01</u>	<0.01 0.018	<u>&lt;0.019</u> <u>0.027</u>	

GLP and Trial Details	Crop	Country	Application Details									Residues found			Remarks
Trial ID Study ID Report No. GLP(Y/N) Trial Year	Crop Variety	Country (Zone) Location incl. postal code	Form No.	No. of Appls	Appl Rate (g ai/ha)	Spray Vol (L/ha)	Appl Conc (g ai/hL)	Appl Date	GS at Last Appl	PHI (days)	Portion Analysed	XDE-208 (mg/kg)	X11719474 (mg/kg)	Total* (mg/kg)	
	(a)							(c)		(d)	(a)				
CEMS-5006E CEMS-5006 GHE-P-12702 Y 2011	Winter barley Highlight	Germany (NZ) 16321 Bernau, Brandenburg Outdoor (field)	GF-2372	2	24.6 24.8	256 258	9.6 9.6	24-May-2011 14-Jun-2011	BBCH 83 to 85	21 21 <0 0 1 3 7 10 15	Grain Straw Whole plant Whole plant Whole plant Whole plant Whole plant Whole plant	<u>0.010</u> <u>0.011</u> <0.01 0.942 0.372 0.347 0.041 0.025 0.020	<0.01 0.011 <0.01 0.011 <0.01 <0.01 <0.01 <0.01	<u>0.019</u> <u>0.021</u> <0.019 0.952 0.381 0.356 0.050 0.034 0.029	
CEMS-5006F CEMS-5006 GHE-P-12702 Y 2011	Spring barley Jubilant	Hungary (NZ) 2456 Besnyő, Fejér Outdoor (field)	GF-2372	2	24.6 23.1	410 386	6 6	02-Jun-2011 25-Jun-2011	BBCH 75	21 21 <0 0 1 3 7 10 14	Grain Straw Whole plant Whole plant Whole plant Whole plant Whole plant Whole plant	<u>0.010</u> <u>0.017</u> 0.010 0.346 0.236 0.143 0.036 0.019 0.020	<0.01 0.010 <0.01 0.013 0.011 <0.01 <0.01 <0.01 <0.01	<u>0.019</u> <u>0.026</u> 0.019 0.358 0.246 0.152 0.045 0.028 0.029	
CEMS-5006G CEMS-5006 GHE-P-12702 Y 2011	Spring barley Sebastian	France (NZ) 45300 Rouvres St Jean, Loiret Outdoor (field)	GF-2372	2	25.2 24.2	210 202	12 12	30-May-2011 20-Jun-2011	BBCH 77 to 83	21 21	Grain Straw	<u>&lt;0.01</u> <u>0.014</u>	<0.01 <0.01	<u>&lt;0.019</u> <u>0.023</u>	

GLP and Trial Details	Crop	Country	Application Details						Residues found						Remarks
Trial ID Study ID Report No. GLP(Y/N) Trial Year	Crop Variety (a)	Country (Zone) Location incl. postal code	Form No.	No. of Appls	Appl Rate (g ai/ha)	Spray Vol (L/ha)	Appl Conc (g ai/hL)	Appl Date (c)	GS at Last Appl	PHI (days) (d)	Portion Analysed (a)	XDE-208 (mg/kg)	X11719474 (mg/kg)	Total* (mg/kg)	
CEMS-5006H CEMS-5006 GHE-P-12702 Y 2011	Winter barley Canpanila	Poland (NZ) 64-960 Kluczewo, Wielkopols ka Outdoor (field)	GF- 2372	2	26.0 24.2	323 302	8 8	24-May- 2011 14-Jun- 2011	BBCH 77	21 21	Grain Straw	<u>&lt;0.01</u> <u>&lt;0.01</u>	<0.01 <0.01	<u>&lt;0.019</u> <u>&lt;0.019</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 8.3.3.2.2 Study 2 – CEMS-5034

<b>Report:</b>	KIIIA 8.3.3/03, Rawle, N.W., 2014
<b>Title:</b>	Residues of sulfoxaflor in barley grain and process fractions at harvest following multiple applications of GF-2372 – 2011
<b>Document No:</b>	Study ID : CEMS-5034, Report ID : CEMR-5034 Dow AgroSciences Reference GHE-P-12729
<b>Guidelines:</b>	-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", -"Commission Working Document 7035/VI/95 Rev. 5, Processing Studies, July 22, 1997", -EPA Residue Chemistry Test Guidelines, OPPTS 860.1520, Processed Food/Feed, August 1996, -OECD Guideline for the Testing of Chemicals, Magnitude of the Pesticide Residues in Processed Commodities, testing Guideline 508, 3 October 2008 -OECD Residue Chemistry Studies, Series on Pesticides No.32.
<b>GLP</b>	Yes

Acceptability	Deviations
Yes	None with impact on the study

Table IIIA 8.3.3-6: Summary of global information on study 2

<b>Comparative trials (between formulations, with and adjuvant/safener/synergist)</b>	No, formulation WG containing 500 g sulfoxaflor/kg
<b>Number of applications</b>	2
<b>Dose (g as/ha)</b>	24 g a.s./ha
<b>Mode of application</b>	foliar broadcast
<b>PHI (days) and/or growth stage (BBCH)</b>	21 days
<b>Analytical method (Code +Type)</b>	091031 Liquid Chromatography/ Mass Spectrometry
<b>LoQ (mg/kg)</b>	0.01 mg/kg

Table IIIA 8.3.3-7: Summary of the study 2 trials

N° Trial	CEMS-5034A	CEMS-5034B
North/South/Indoor	N	S
Decline (D)/Harvest (H) trial?	H	H
Formulation	WG	WG
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)	391	391
	Max 51 days	Max 51 days
Storage T° <-18°C	Y	Y
Validated analytical method	Y	Y
Negative controls	Y	Y
Considered trial	Y	Y
Remarks	(1)	(1)

(1). The procedural recoveries demonstrate the stability of the analyte during this storage (up to 51 days)

**Table IIIA 8.3.3-8: 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) : 500 g/kg  
Formulation (e.g. WP) : WF  
Commercial product (name) : GF-2372  
Applicant : Eurofins

Active ingredient : Sulfoxaflor (XDE-208)  
Crop / crop group : Barley

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
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-5034A CEMS-5034 GHE-P-12729 Y 2011	Spring barley Quench	Germany (NZ) 75428 Illingen, Baden- Württemberg Outdoor (field)	GF- 2372	2	24.0 24.1	300 301	8 8	30-May- 2011 21-Jun- 2011	BBCH 77 to 83	21	Grain (RAC)	<u>&lt;0.01</u>	<0.01	<u>&lt;0.019</u>	



GLP and Trial Details	Crop	Country	Application Details						Residues found						Remarks
Trial ID Study ID Report No. GLP(Y/N) Trial Year	Crop Variety (a)	Country (Zone) Location incl. postal code	Form No.	No. of Appls	Appl Rate (g ai/ha)	Spray Vol (L/ha)	Appl Conc (g ai/hL)	Appl Date (c)	GS at Last Appl	PHI (days) (d)	Portion Analysed (a)	XDE-208 (mg/kg)	X11719474 (mg/kg)	Total* (mg/kg)	
CEMS-5034B CEMS-5034 GHE-P-12729 Y 2011	Winter barley Azurel	France (SZ) 82700 Bourret, Tarn-et- Garonne Outdoor (field)	GF- 2372	2	24.0 23.2	305 296	7.9 7.8	19-May- 2011 09-Jun- 2011	BBCH 85	20	Grain (RAC)	<u>0.025</u>	<0.01	<u>0.034</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 8.3.3.3 Summary of monograph and new data supporting the intended use on barley and oat and conformity to existing MRL

Table IIIA 8.3.3-9 Summary of monograph and new data supporting the intended use on barley and oat 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
Barley grain → Oats grain	Monograph	North (4)	Trials GAP: 2x 24 g/ha ; Interval 14d ; PHI 21d Mo : 2 x 0.011, 0.014, 0.024 RA: 2 x 0.02, 0.023, 0.033	Mo: 0.013	Mo: 0.024	-	-	-	Reg EU 2016/1): Barley and oats grain: 0.04  SANTE/11 442/2016 Barley: 0.6 Oat: 0.04	Barley : yes according doc SANTE/11442/ 2016 Oat: No
		South (5)	Trials GAP: 2x 24 g/ha ; Interval 14d ; PHI 21d Mo: <0.01, 0.012, 0.023, 0.025, 0.032 RA: <0.019, 0.021, 0.032, 0.034, 0.041	Mo: 0.023 RA: 0.032	Mo: 0.032 RA: 0.041	-	-	-		
	New trials	North (5)	Trials GAP: 2 x 24 g as/ha, Interval 21d, PHI 21d Mo: 3x <0.01 ; 2x 0.01 RA: 3x <0.019 ; 2x 0.019	Mo : 0.01 RA: 0.019	Mo: 0.01 RA: 0.019	-	-	-		
		South (5)	Trials GAP: 2 x 24 g as/ha, Interval 21d, PHI 21d Mo : 2x <0.01 ; 0.023 ; 0.025 ; 0.031 RA : 2x <0.019 ; 0.032 ; 0.034 ; 0.040	Mo: 0.023 RA: 0.032	Mo: 0.031 RA: 0.040	-	-	-		
	Overall supporting data for FR GAP and SEU GAP	North (9)	Mo : 3x <0.01, 2x 0.01, 2x0.011, 0.014, 0.024 RA : 3x <0.019, 2x 0.019, 2 x0.02, 0.023, 0.033	Mo: 0.01 RA: 0.019	Mo: 0.024 RA: 0.033	0.025	0.026	0.03 (0.031)		
		South (10)	Mo : 3 x <0.01, 0.012, 2 x 0.023, 2 x 0.025, 0.031, 0.032 RA : 3 x <0.019, 0.021, 2 x 0.032, 2 x 0.034, 0.040, 0.041	Mo: 0.023 RA: 0.032	Mo: 0.032 RA: 0.041	0.053	0.046	0.06 (0.055)		

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
Barley straw → Oats straw	Monograph	North (4)	<b>Trials GAP: 2x 24 g/ha ; Interval 14d ; PHI 21d</b> <b>Mo</b> : 2 x <0.01, 0.013, 0.037 <b>RA</b> : <0.02, 0.02, 0.022, 0.051	<b>Mo</b> : 0.012 <b>RA</b> : 0.021	<b>Mo</b> : 0.038 <b>RA</b> : 0.051	N/A	N/A	N/A	Feedstuffs - No MRL	N/A
		South (5)	<b>Trials GAP: 2x 24 g/ha ; Interval 14d ; PHI 21d</b> <b>Mo</b> : <0.01, 0.019, 0.024, 0.061, 0.202 <b>RA</b> : 0.028, 0.033, 0.042, 0.07, 0.221	<b>Mo</b> : 0.024 <b>RA</b> : 0.042	<b>Mo</b> : 0.202 <b>RA</b> : 0.221	N/A	N/A	N/A		
	New trials	North (4)	<b>Trials GAP: 2 x 24 g as/ha, Interval 21d, PHI 21d</b> <b>Mo</b> : <0.01 ; 0.011 ; 0.014 ; 0.017 <b>RA</b> : <0.019 ; 0.021 ; 0.023 ; 0.026	<b>Mo</b> : 0.013 <b>RA</b> : 0.022	<b>Mo</b> : 0.017 <b>RA</b> : 0.026	N/A	N/A	N/A		
		South (4)	<b>Trials GAP: 2 x 24 g as/ha, Interval 21d, PHI 21d</b> <b>Mo</b> : <0.01 ; 0.014 ; 0.021 ; 0.067 <b>RA</b> : 0.023 ; 0.027; 0.030 ; 0.077	<b>Mo</b> : 0.018 <b>RA</b> : 0.029	<b>Mo</b> : 0.067 <b>RA</b> : 0.077	N/A	N/A	N/A		
	Overall supporting data for FR GAP	North (8)	<b>Mo</b> : 3 x <0.01; 0.011 ; 0.013 ; 0.014 ; 0.017 ; 0.037 <b>RA</b> : <0.019, <0.02, 0.02, 0.021, 0.022, 0.023, 0.026, 0.051	<b>Mo</b> : 0.012 <b>RA</b> : 0.022	<b>Mo</b> : 0.037 <b>RA</b> : 0.051	N/A	N/A	N/A		
		South (9)	<b>Mo</b> : 2 x <0.01, 0.014, 0.019, 0.021, 0.024, 0.061, 0.067, 0.202 <b>RA</b> : 0.023, 0.027, 0.028, 0.03, 0.033, 0.042, 0.07, 0.078, 0.221	<b>Mo</b> : 0.021 <b>RA</b> : 0.033	<b>Mo</b> : 0.202 <b>RA</b> : 0.221	N/A	N/A	N/A		
	Overall supporting data for SEU GAP	South (9)	<b>Mo</b> : 2 x <0.01, 0.014, 0.019, 0.021, 0.024, 0.061, 0.067, 0.202 <b>RA</b> : 0.023, 0.027, 0.028, 0.03, 0.033, 0.042, 0.07, 0.078, 0.221	<b>Mo</b> : 0.021 <b>RA</b> : 0.033	<b>Mo</b> : 0.202 <b>RA</b> : 0.221	N/A	N/A	N/A		

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

**Mo**: Monitoring residue data (sulfoxaflor only)

**RA**: Risk assessment residue data (Sulfoxaflor + metabolite X11719474 expressed as sulfoxaflor)

#### IIIA 8.3.3.4 Conclusion for cereals (barley, oats)

Barley and Oats are major crops in both Northern and Southern Europe. Moreover, in France, they are cultivated in Northern and Southern regions of the country. Thus, a minimum of eight residues trials performed in each zone are required to support the use of sulfoxaflor on those crops in France.

According to EU Guideline Document SANCO 7525/VI/95- rev. 10, extrapolation from barley data to oats is possible.

9 NEU and 10 SEU barley trials are available to support the use of sulfoxaflor on barley and oat.

Therefore sufficient residue trials have been submitted.

On the basis of the available supporting residue data it is possible to conclude that current MRL (Reg EU 2016/1) of 0.04 mg/kg on barley will be exceeded according to the intended GAP in SEU. Nevertheless on the basis of the available supporting residue data it is possible to conclude that the MRL proposed in document SANTE/11442/2016 of 0.6 mg/kg on barley will not be exceeded according to the intended GAP in SEU

On the basis of the available supporting residue data it is possible to conclude that current MRL of 0.04 mg/kg on oat (Reg EU 2016/1 and SANTE/11442/2016) will be exceeded according to the intended GAP in SEU. Therefore intended use of GF-2372 on oat in FR and SEU is not considered acceptable.

It should be noted that according to the applicant an application to modify the in force MRL on oat from 0.04 to 0.6 mg/kg has been submitted to the EMS Ireland.

#### IIIA 8.3.4 WHEAT, RYE, SPELT, TRITICALE

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

Crop	Type of GAP	Number of applications	Application rate per treatment (g a.s./ha)	Interval between application (days)	Growth stage at last application	PHI (days)
Wheat, Rye & Triticale	EU DAR <sup>(1)</sup>	1	24	-	BBCH 40-89 April-July	21
	Intended FR & IT	2	24	21	BBCH 12-87	21

(1). Representative use

##### IIIA 8.3.4.1 Summary of B.7.6 Data (wheat, rye, spelt, triticale))

The intended GAP is more critical than the representative EU uses of sulfoxaflor in wheat which were assessed in the framework of the approbation of the 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 2 applications at ca 24-25 g a.s./ha, PHI of 21 days.

Results of the supported trials are summarized in Table IIIA 8.3.4-2. Residue levels of sulfoxaflor and metabolite X11719474 in grain and straw from trials considered suitable to support the intended GAP are underlined.

Table IIIA 8.3.4-2: Summary of Wheat trials available in sulfoxaflor monograph

GLP and Trial Details	Crop	Country	Application Details									Residues found			Remarks
Trial ID Study ID Report No. GLP(Y/N) Trial Year	Crop Variety (a)	Country (Zone) Location incl. postal code	Form No.	No. of Appls	Appl Rate (g ai/ha)	Spray Vol (L/ha)	Appl Conc (g ai/hL)	Appl Date (c)	GS at Last Appl	PHI (days) (d)	Portion Analysed (a)	XDE-208 (mg/kg)	X11719474 (mg/kg)	Total* (mg/kg)	(e)
CEMS-3920A CEMS-3920 DAS Ref. ID 080049-01 Y 2008	Winter wheat Bussard	Germany NZ 16356 Blumberg, Brandenburg Outdoor (field)	GF- 2032	1	25.1	262	9.6	08-Jul- 2008	BBCH 77	0	Whole plant	0.443	<0.01	0.452	
										7	Grain	0.014	<0.01	0.023	
										7	Straw	0.067	<0.01	0.076	
										14	Grain	<0.01	<0.01	<0.019	
										14	Straw	0.027	<0.01	0.036	
										21	Grain	<0.01	<0.01	<0.019	
										21	Straw	0.035	<0.01	0.044	
										28	Grain	<0.01	<0.01	<0.019	
										28	Straw	0.028	<0.01	0.037	
			GF- 2032	2	25.3 25.0	263 261	9.6 9.6	25-Jun- 2008 08-Jul- 2008	BBCH 77	-0	Whole plant	0.088	<0.01	0.097	
										0	Whole plant	0.969	0.012	0.980	
										7	Grain	0.020	<0.01	0.029	
										7	Straw	0.096	<0.01	0.105	
										14	Grain	<0.01	<0.01	<0.019	
										14	Straw	0.058	<0.01	0.067	
										21	Grain	<u>&lt;0.01</u>	<0.01	<u>&lt;0.019</u>	
										21	Straw	0.048	<0.01	0.057	
										28	Grain	<0.01	<0.01	<0.019	
										28	Straw	<u>0.064</u>	<0.01	<u>0.073</u>	
CEMS-3920B CEMS-3920 DAS Ref. ID 080049-01 Y 2008	Winter wheat Courtot	N France (NZ) 45300 Rouvres St- Jean, Centre Outdoor (field)	GF- 2032	1	24.6	202	12.2	26-Jun- 2008	BBCH 85	21	Grain	<0.01	<0.01	<0.019	Higher residues in straw sampled in the plot treated with a single application
			GF- 2032	2	24.5 24.2	201 199	12.2 12.2	12-Jun- 2008 26-Jun- 2008	BBCH 85	21	Straw	<u>0.052</u>	<0.01	<u>0.061</u>	
										21	Grain	<u>&lt;0.01</u>	<0.01	<u>&lt;0.019</u>	
										21	Straw	0.051	0.010	0.060	
CEMS-3920C CEMS-3920	Spring wheat	Poland (NZ) 64560	GF- 2032	1	24.7	308	8.0	15-Jul- 2008	BBCH 77	21 21	Grain Straw	<0.01 0.050	<0.01 <0.01	<0.019 0.059	

GLP and Trial Details	Crop	Country	Application Details									Residues found			Remarks
Trial ID Study ID Report No. GLP(Y/N) Trial Year	Crop Variety (a)	Country (Zone) Location incl. postal code	Form No.	No. of Appls	Appl Rate (g ai/ha)	Spray Vol (L/ha)	Appl Conc (g ai/hL)	Appl Date (c)	GS at Last Appl	PHI (days) (d)	Portion Analysed (a)	XDE-208 (mg/kg)	X11719474 (mg/kg)	Total* (mg/kg)	(e)
DAS Ref. ID 080049-01 Y 2008	Bomboma	Szczepankowo Huby, Wielkopolska Outdoor (field)	GF- 2032	2	23.3 25.7	292 322	8.0 8.0	02-Jul- 2008 15-Jul- 2008	BBCH 77	21 21	Grain Straw	<u>&lt;0.01</u> <u>0.078</u>	<0.01 0.014	<u>&lt;0.019</u> <u>0.091</u>	
CEMS-3920D CEMS-3920 DAS Ref. ID 080049-01 Y 2008	Winter wheat Hereward	UK (NZ) Southam, Warwickshire CV47 9QB Outdoor (field)	GF- 2032	1	24.3	201	12.1	17-Jul- 2008	BBCH 83- 85	0 7 7 14 14 21 21 28 28	Whole plant Grain Straw Grain Straw Grain Straw Grain Straw	0.354 0.035 0.361 <0.01 0.115 <0.01 <u>0.086</u> <0.01 0.038	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.363 0.044 0.370 <0.019 0.124 <0.019 <u>0.095</u> <0.019 0.047	Higher residues in straw sampled in the plot treated with a single application
			GF- 2032	2	24.2 24.5	200 202	12.1 12.1	04-Jul- 2008 17-Jul- 2008	BBCH 83- 85	-0 0 7 7 14 14 21 21 28 28	Whole plant Whole plant Grain Straw Grain Straw Grain Straw Grain Straw	0.019 0.445 0.029 0.494 <0.01 0.190 <u>&lt;0.01</u> 0.079 <0.01 0.048	<0.01 <0.01 <0.01 0.015 <0.01 0.014 <0.01 0.012 <0.01 <0.01	0.028 0.454 0.038 0.508 <0.019 0.203 <u>&lt;0.019</u> 0.090 <0.019 0.057	

GLP and Trial Details	Crop	Country	Application Details									Residues found			Remarks
Trial ID Study ID Report No. GLP(Y/N) Trial Year	Crop Variety (a)	Country (Zone) Location incl. postal code	Form No.	No. of Appls	Appl Rate (g ai/ha)	Spray Vol (L/ha)	Appl Conc (g ai/hL)	Appl Date (c)	GS at Last Appl	PHI (days) (d)	Portion Analysed (a)	XDE-208 (mg/kg)	X11719474 (mg/kg)	Total* (mg/kg)	(e)
CEMS-3920E CEMS-3920 DAS Ref. ID 080049-01 Y 2008	Durum wheat Joyocer	S France (SZ) 66200 Latour- Bas-Elne, Languedoc- Roussillon Outdoor (field)	GF- 2032	1	23.2	387	6.0	29-May- 2008	BBCH 79	0	Whole plant	0.500	<0.01	0.509	Higher residues in straw and grain sampled in the plot treated with a single application
										8	Grain	0.027	<0.01	0.036	
										8	Straw	0.120	<0.01	0.129	
										14	Grain	0.018	<0.01	0.027	
										14	Straw	0.133	<0.01	0.142	
										21	Grain	<b>0.013</b>	<0.01	<b>0.022</b>	
										21	Straw	0.029	<0.01	0.038	
										28	Grain	<0.01	<0.01	<0.019	
										28	Straw	<b>0.109</b>	<0.01	<b>0.118</b>	
			GF- 2032	2	25.4 25.2	423 420	6.0 6.0	15-May- 2008 29-May- 2008	BBCH 79	-0	Whole plant	0.016	<0.01	0.025	
										0	Whole plant	0.544	<0.01	0.553	
										8	Grain	0.028	<0.01	0.037	
										8	Straw	0.101	<0.01	0.110	
										14	Grain	<0.01	<0.01	<0.019	
										14	Straw	0.103	<0.01	0.112	
										21	Grain	0.012	<0.01	0.021	
										21	Straw	0.100	<0.01	0.109	
										28	Grain	<0.01	<0.01	<0.019	
										28	Straw	0.089	<0.01	0.098	

GLP and Trial Details	Crop	Country	Application Details									Residues found			Remarks
Trial ID Study ID Report No. GLP(Y/N) Trial Year	Crop Variety (a)	Country (Zone) Location incl. postal code	Form No.	No. of Appls	Appl Rate (g ai/ha)	Spray Vol (L/ha)	Appl Conc (g ai/hL)	Appl Date (c)	GS at Last Appl	PHI (days) (d)	Portion Analysed (a)	XDE-208 (mg/kg)	X11719474 (mg/kg)	Total* (mg/kg)	(e)
CEMS-3920F CEMS-3920 DAS Ref. ID 080049-01 Y 2008	Durum wheat Anza	Spain (SZ) 50490 Villareal de Huerva, Aragón Outdoor (field)	GF- 2032	1	24.2	299	8.1	16-Jun- 2008	BBCH 65	0 7 14 21 28 28	Whole plant	0.721	<0.01	0.730	
											Whole plant	0.043	<0.01	0.052	
											Whole plant	0.014	<0.01	0.023	
											Whole plant	0.012	<0.01	0.021	
											Ears	0.010	<0.01	0.019	
			Straw	0.025	<0.01	0.034									
			GF- 2032	2	24.5 24.3	302 301	8.1 8.1	03-Jun- 2008 16-Jun- 2008	BBCH 65	-0 0 7 14 21 28 28	Whole plant	0.024	<0.01	0.033	
											Whole plant	0.680	0.012	0.691	
											Whole plant	0.029	0.015	0.043	
											Whole plant	0.032	0.015	0.046	
Whole plant	0.025	0.014									0.038				
Ears	0.015	<0.01	0.024												
Straw	0.016	0.012	0.027												
CEMS-3920G CEMS-3920 DAS Ref. ID 080049-01 Y 2008/9	Durum wheat Duilio	Italy (SZ) 40062 Santa Maria Codifume, Emilia Romagna Outdoor (field)	GF- 2032	1	23.7	396	6.0	05-Jun- 2008	BBCH 75	21 21	Grain Straw	<0.01 <b>0.025</b>	<0.01 <0.01	0.019 <b>0.034</b>	Higher residues in straw sampled in the plot treated with a single application
			GF- 2032	2	23.3 24.2	292 403	8.0 6.0	22-May- 2008 05-Jun- 2008	BBCH 75	21 21	Grain Straw	<b>&lt;0.01</b>	<0.01	<b>&lt;0.019</b>	
												0.017	<0.01	0.026	
CEMS-3920H CEMS-3920 DAS Ref. ID 080049-01 Y 2008/9	Durum wheat Simeto	Greece (SZ) Epanomi, Thessaloniki Outdoor (field)	GF- 2032	1	24.0	200	12.0	03-Jun- 2008	BBCH 87	21 21	Grain Straw	<0.01 0.074	<0.01 <0.01	<0.019 0.083	
			GF- 2032	2	23.2 24.0	193 200	12.0 12.0	20-May- 2008 03-Jun- 2008	BBCH 87	21 21	Grain Straw	<b>&lt;0.01</b>	<0.01	<b>&lt;0.019</b>	
												<b>0.134</b>	<0.01	<b>0.143</b>	



GLP and Trial Details	Crop	Country	Application Details									Residues found			Remarks
Trial ID Study ID Report No. GLP(Y/N) Trial Year	Crop Variety (a)	Country (Zone) Location incl. postal code	Form No.	No. of Appls	Appl Rate (g ai/ha)	Spray Vol (L/ha)	Appl Conc (g ai/hL)	Appl Date (c)	GS at Last Appl	PHI (days) (d)	Portion Analysed (a)	XDE-208 (mg/kg)	X11719474 (mg/kg)	Total* (mg/kg)	(e)
CEMS-3920I CEMS-3920 DAS Ref. ID 080049-01 Y 2009	Durum wheat Amarok	Spain (SZ) 50368 Mainar, Aragón Outdoor (field)	GF- 2032	1	26.2	327	8.0	03-Jul- 2009	BBCH 83	0	Whole plant	0.932	0.024	0.955	
										7	Whole plant	0.288	0.012	0.299	
										14	Grain	0.014	<0.01	0.023	
										14	Straw	0.328	0.020	0.347	
										21	Grain	<0.01	<0.01	<0.019	
										21	Straw	0.214	0.012	0.225	
										28	Grain	<0.01	<0.01	<0.019	
										28	Straw	0.139	0.016	0.154	
			GF- 2032	2	23.5 26.4	294 329	8.0 8.0	19-Jun- 2009 03-Jul- 2009	BBCH 83	-0	Whole plant	0.114	<0.01	0.123	
										0	Whole plant	1.409	0.035	1.442	
										7	Whole plant	0.368	0.018	0.385	
										14	Grain	<0.01	<0.01	0.019	
										14	Straw	0.320	0.021	0.340	
										21	Grain	<u>&lt;0.01</u>	<0.01	<u>&lt;0.019</u>	
										21	Straw	<u>0.334</u>	0.021	<u>0.354</u>	
										28	Grain	<0.01	<0.01	<0.019	
										28	Straw	0.262	0.028	0.288	

### IIIA 8.3.4.2 New data

#### IIIA 8.3.4.2.1 Study 1 – CEMS-5005

<b>Report:</b>	KIIIA 8.3.4/02, Rawle N.W., 2012
<b>Title:</b>	Residues of sulfoxaflor in wheat at intervals and harvest Following multiple applications of GF-2372 – Northern and Southern Europe – 2011
<b>Document No:</b>	Study ID : CEMS-5005, Report ID : CEMR-5005 Dow AgroSciences Reference : ID GHE-P-12701
<b>Guidelines:</b>	-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"
<b>GLP</b>	Yes

<b>Acceptability</b>	<b>Deviations</b>
Yes	None with impact on the study

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

<b>Comparative trials (between formulations, with and adjuvant/safener/synergist)</b>	No, formulation WG containing 500 g sulfoxaflor/kg
<b>Number of applications</b>	2
<b>Dose (g as/ha)</b>	24 g a.s./ha
<b>Mode of application</b>	Broadcast
<b>PHI (days) and/or growth stage (BBCH)</b>	0, 1, 3, 7, 10, 14 & 21 days
<b>Analytical method (Code +Type)</b>	Method N° 091031 LC-MS/MS
<b>LoQ (mg/kg)</b>	0.01 mg/kg

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

N° Trial	CEMS-5005A	CEMS-5005B	CEMS-5005C	CEMS-5005D	CEMS-5005E	CEMS-5005F	CEMS-5005G	CEMS-5005H
North/South/Indoor	N	N	N	N	S	S	S	S
Decline (D)/Harvest (H) trial?	D	D	H	H	D	D	H	H
Formulation	WG	WG	WG	WG	WG	WG	WG	WG
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)	224	231	208	229	237	265	259	243
Sample Extract <sup>(1)</sup>	Max 6 days	Max 6 days	Max 6 days	Max 6 days	Max 6 days	Max 6 days	Max 6 days	Max 6 days
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 6 days).” (CEMR-5005, p.20)

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

**RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)**

(Application on agricultural and horticultural crops)

Notifier: Dow AgroSciences, European Development Centre

address 1 2<sup>nd</sup> Floor – 3 Milton Park, Abington

Content of a.i. (g/kg or g/l) : 500 g/kg

Formulation (e.g. WP) : WF

Commercial product (name) : GF-2372

Applicant : Eurofins

Active ingredient : Sulfoxaflor (XDE-208)

Crop / crop group : Wheat / cereals

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
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-5005A CEMS-5005 DAS Ref. ID GHE-P-12071 Y 2011	Winter wheat Potenzial	Germany (NZ) 16321, Bernau, Brandenbur g Outdoor (field)	GF- 2372	2	24.9 23.9	259 249	9.6 9.6	14-Jun- 2011 05-Jul- 2011	BBCH 85	-0 0 1 3 7 10 14 22 22	Whole plant Whole plant Whole plant Whole plant Whole plant Whole plant Grain Straw	<0.01 0.207 0.203 0.095 0.036 0.046 0.024 <u>&lt;0.01</u> <u>&lt;0.01</u>	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 0.011	<0.019 0.216 0.212 0.104 0.045 0.055 0.033 <u>&lt;0.019</u> <u>0.020</u>	

GLP and Trial Details	Crop	Country	Application Details									Residues found			Remarks
Trial ID Study ID Report No. GLP(Y/N) Trial Year	Crop Variety (a)	Country (Zone) Location incl. postal code	Form No.	No. of Appls	Appl Rate (g ai/ha)	Spray Vol (L/ha)	Appl Conc (g ai/hL)	Appl Date (c)	GS at Last Appl	PHI (days) (d)	Portion Analysed (a)	XDE-208 (mg/kg)	X11719474 (mg/kg)	Total* (mg/kg)	
CEMS-5005B CEMS-5005 DAS Ref. ID GHE-P-12071 Y 2011	Winter wheat Courtot	N France (NZ) 45480 Leouville, Loiret Outdoor (field)	GF- 2372	2	23.0 24.8	287 308	8.0 8.0	08-Jun- 2011 29-Jun- 2011	BBCH 87	-0 0 1 3 7 10 14 21 21	Whole plant Whole plant Whole plant Whole plant Whole plant Whole plant Grain Straw	0.013 0.530 0.410 0.246 0.336 0.274 0.156 <u>&lt;0.01</u> <u>0.032</u>	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.022 0.539 0.419 0.255 0.345 0.283 0.165 <u>&lt;0.019</u> <u>0.041</u>	
CEMS-5005C CEMS-5005 DAS Ref. ID GHE-P-12071 Y 2011	Spring wheat Ina	Poland (NZ) 64-606, Wychowani ec, Wiekopolsk a Outdoor (field)	GF- 2372	2	25.8 25.7	323 321	8.0 8.0	30-Jun- 2011 23-Jul- 2011	BBCH 85	20 20	Grain Straw	<u>0.019</u> <u>0.157</u>	<0.01 0.022	<u>0.028</u> <u>0.178</u>	
CEMS-5005D CEMS-5005 DAS Ref. ID GHE-P-12071 Y 2011	Winter wheat Palotas	Hungary (NZ) 8127, Alba, Fejer Outdoor (field)	GF- 2372	2	23.2 25.0	387 417	6.0 6.0	08-Jun- 2011 01-Jul- 2011	BBCH 81	21 21	Grain Straw	<u>&lt;0.01</u> <u>0.028</u>	<0.01 <0.01	<u>&lt;0.019</u> <u>0.037</u>	

GLP and Trial Details	Crop	Country	Application Details									Residues found			Remarks
Trial ID Study ID Report No. GLP(Y/N) Trial Year	Crop Variety (a)	Country (Zone) Location incl. postal code	Form No.	No. of Appls	Appl Rate (g ai/ha)	Spray Vol (L/ha)	Appl Conc (g ai/hL)	Appl Date (c)	GS at Last Appl	PHI (days) (d)	Portion Analysed (a)	XDE-208 (mg/kg)	X11719474 (mg/kg)	Total* (mg/kg)	
CEMS-5005E CEMS-5005 DAS Ref. ID GHE-P-12071 Y 2011	Winter wheat Boticelli	Spain (SZ) 50490 Villarreal, Aragon Outdoor (field)	GF- 2372	2	25.3 24.6	313 304	8.1 8.1	02-Jun- 2011 24-Jun- 2011	BBCH 86- 87	-0 0 1 3 6 10 13 20 20	Whole plant Whole plant Whole plant Whole plant Whole plant Whole plant Grain Straw	0.018 0.834 0.642 0.417 0.200 0.221 0.194 <u>&lt;0.01</u> <u>0.216</u>	<0.01 0.016 0.020 0.019 0.010 0.015 0.014 <0.01 0.023	0.027 0.849 0.661 0.435 0.209 0.235 0.207 <u>&lt;0.019</u> <u>0.238</u>	
CEMS-5005F CEMS-5005 DAS Ref. ID GHE-P-12071 Y 2011	Spring wheat Gekora	Greece (SZ) 58100, Achlocho ri, Pella Outdoor (field)	GF- 2372	2	24.3 24.7	404 411	6.0 6.0	06-May- 2011 27-May- 2011	BBCH 73	-0 0 1 3 7 10 14 20 20	Whole plant Whole plant Whole plant Whole plant Whole plant Whole plant Grain Straw	<0.01 0.443 0.429 0.058 0.047 0.031 0.026 <u>&lt;0.01</u> <u>0.016</u>	<0.01 <0.01 <0.01 <0.01 <0.01 0.010 0.013 <0.01 <0.01	<0.019 0.452 0.438 0.067 0.056 0.040 0.038 <u>&lt;0.019</u> <u>0.025</u>	
CEMS-5005G CEMS-5005 DAS Ref. ID GHE-P-12071 Y 2011	Winter wheat Blasco	Italy (SZ) 40057, Granarolo, Bologna Outdoor (field)	GF- 2372	2	23.5 25.3	293 317	8.0 8.0	11-May- 2011 01-Jun- 2011	BBCH 77	21 21	Grain Straw	<u>&lt;0.01</u> <u>0.077</u>	<0.01 <0.01	<u>&lt;0.019</u> <u>0.086</u>	

GLP and Trial Details	Crop	Country	Application Details						Residues found						Remarks
Trial ID Study ID Report No. GLP(Y/N) Trial Year	Crop Variety (a)	Country (Zone) Location incl. postal code	Form No.	No. of Appls	Appl Rate (g ai/ha)	Spray Vol (L/ha)	Appl Conc (g ai/hL)	Appl Date (c)	GS at Last Appl	PHI (days) (d)	Portion Analysed (a)	XDE-208 (mg/kg)	X11719474 (mg/kg)	Total* (mg/kg)	
CEMS-5005H CEMS-5005 DAS Ref. ID GHE-P-12071 Y 2011	Winter wheat Ingenio	S France (SZ) 82700, Finhan, Tarn-et- Garonne Outdoor (field)	GF- 2372	2	24.8 21.6	310 270	8.0 8.0	26-May- 2011 17-Jun- 2011	BBCH 87	21 21	Grain Straw	<u>&lt;0.01</u> <u>0.095</u>	<0.01 <0.01	<u>&lt;0.019</u> <u>0.104</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 8.3.4.3 Summary of monograph and new data supporting the intended use on wheat and conformity to existing MRL

Table IIIA 8.3.4-6: Summary of monograph and new data supporting the intended use on Wheat 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
Wheat → Spelt Triticale Rye	Monograph	North (4)	<b>Trials GAP: 2*24g as/ha; Interval 14d , PHI 21d</b> <b>Grain :</b> <b>Mo :</b> 4x <0.01 <b>RA :</b> 4x <0.019	<b>Mo:</b> 0.010 <b>RA:</b> 0.019	<b>Mo:</b> 0.010 <b>RA:</b> 0.019	-	-		-	-
			<b>Straw :</b> <b>Mo :</b> 0.052, 0.064 , 0.078 , 0.086 <b>RA :</b> 0.061 , 0.073 , 0.091 , 0.095	<b>Mo:</b> 0.071 <b>RA:</b> 0.082	<b>Mo:</b> 0.086 <b>RA:</b> 0.095	NA	NA	NA	NA	NA
		South (4)	<b>Trials GAP: 2*24g as/ha, Interval 14d , PHI 21d</b> <b>Grain :</b> <b>Mo :</b> 3x <0.01 , 0.013 , <b>RA :</b> 3x <0.019 , 0.022 ,	<b>Mo:</b> 0.010 <b>RA:</b> 0.019	<b>Mo:</b> 0.013 <b>RA:</b> 0.022	-	-	-	-	-
			<b>Straw :</b> <b>Mo :</b> 0.025 , 0.109 , 0.134 , 0.334 <b>RA :</b> 0.034 , 0.118 , 0.143 , 0.354	<b>Mo:</b> 0.122 <b>RA:</b> 0.131	<b>Mo:</b> 0.334 <b>RA:</b> 0.354	NA	NA	NA	NA	NA
	New trials	North (4)	<b>Trials GAP: 2 x 0.024 kg as/ha, Interval 21d, PHI 21d</b> <b>Grain :</b> <b>Mo :</b> 3x <0.01, 0.019 <b>RA :</b> 3x <0.019, 0.028	<b>Mo:</b> 0.010 <b>RA:</b> 0.019	<b>Mo:</b> 0.019 <b>RA:</b> 0.028	-	-	-		
			<b>Straw</b> <b>Mo :</b> <0.01, 0.028, 0.032, 0.157 <b>RA :</b> 0.020, 0.037, 0.041, 0.178	<b>Mo:</b> 0.030 <b>RA:</b> 0.039	<b>Mo:</b> 0.157 <b>RA:</b> 0.178	NA	NA	NA	NA	NA



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
		South (4)	Trials GAP: 2 x 0.024 kg as/ha, Interval 21d, PHI 21d <b>Grain :</b> <b>Mo :</b> 4x <0.01 <b>RA :</b> 4x <0.019	<b>Mo:</b> 0.010 <b>RA:</b> 0.019	<b>Mo:</b> 0.010 <b>RA:</b> 0.019	0.020	0.010	0.010		
			<b>Straw</b> <b>Mo :</b> 0.016, 0.077; 0.095, 0.216 <b>RA :</b> 0.025, 0.086, 0.104, 0.238	<b>Mo:</b> 0.086 <b>RA:</b> 0.095	<b>Mo:</b> 0.216 <b>RA:</b> 0.238	NA	NA	NA	NA	NA
	Overall supporting data for FR GAP and SEU GAP	North (8)	<b>Grain :</b> <b>Mo :</b> 7x <0.01, 0.019 <b>RA :</b> 7x <0.019, 0.028,	<b>Mo:</b> 0.010 <b>RA:</b> 0.019	<b>Mo:</b> 0.019 <b>RA:</b> 0.028	0.020	0.021	0.024 (0.03)	Wheat grain: Reg EU 2016/1; 0.09 SANTE/114 42/2016: 0.2	Wheat : Yes  Rye : No
			<b>Straw :</b> <b>Mo :</b> <0.01, 0.028, 0.032, 0.052, 0.064 , 0.078, 0.086, 0.157 <b>RA :</b> 0.020, 0.037, 0.041, 0.061, 0.073, 0.091, 0.095, 0.178	<b>Mo:</b> 0.058 <b>RA:</b> 0.067	<b>Mo:</b> 0.157 <b>RA:</b> 0.178	NA	NA	NA		
		South (8)	<b>Grain:</b> <b>Mo :</b> 7x <0.01, 0.013 <b>RA :</b> 7x <0.019, 0.022	<b>Mo:</b> 0.010 <b>RA:</b> 0.019	<b>Mo:</b> 0.013 <b>RA:</b> 0.022	0.20	0.014	0.015	Rye grain: Reg EU 2016/1 and SANTE/114 42/2016 : 0.015  Straw: no MRL	
			<b>Straw</b> <b>Mo :</b> 0.016, 0.025, 0.077, 0.095, 0.109 , 0.134, 0.216, 0.334 <b>RA :</b> 0.025, 0.034, 0.086, 0.104, 0.118, 0.143, 0.238, 0.354	<b>Mo:</b> 0.102 <b>RA:</b> 0.111	<b>Mo:</b> 0.334 <b>RA:</b> 0.354	NA	NA	NA		

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

**Mo:** Monitoring residue data (sulfoxaflor only), **RA:** Risk assessment residue data (Sulfoxaflor + metabolite X11719474 expressed as sulfoxaflor)

\* Calculations have been performed only for monitoring residue data

#### **IIIA 8.3.4.4 Conclusion for cereals (wheat, rye, spelt, triticale)**

Wheat and rye are major crops in Northern and Southern zones of Europe whereas spelt and triticale are minor crops in both zones. Additionally, in France, wheat, spelt and triticale are cultivated in Northern and Southern regions of the country while rye is predominantly grown in Northern regions of the country. Thus, a minimum of eight trials of each zone are required to support the intended use on wheat whereas eight NEU trials are sufficient to support the use on rye.

8 NEU and 8 SEU trials are available to support the use of sulfoxaflor on wheat. Those trials confirm that the in force MRL of 0.09 mg/kg (Reg EU 2016/1) and the proposed MRL of 0.2 mg/kg (SANTE/11442/2016) on wheat should not be exceeded. The intended use on wheat covers the uses on spelt and triticale.

Additionally, according to EU Guideline Document SANCO 7525/VI/95- rev. 10, data from wheat trials can be extrapolated to rye. Nevertheless, wheat residue data demonstrate that MRL of 0.015 mg/kg on rye might be exceeded (Reg EU 2016/1 and SANTE/11442/2016).

**The use of GF-2372 (TRANSFORM) is fully supported on wheat, spelt and triticale. However, there is some evidence that the in-force MRL on rye might be exceeded. Consequently the intended use on rye is not considered acceptable.**

It should be noted that according to the applicant an application to modify the in force MRL on rye grain from 0.015 to 0.09 mg/kg has been submitted to the EMS Ireland.

## 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 overestimated 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					Dairy Cattle					Beef Cattle					Pig				
			1,9	kg bw		0,12	kg MS	550	kg bw		20	kg MS	350	kg bw		15	kg MS	75	kg bw		3	kg MS
			% intake	to 100%	total	fresh	residue	% intake	to 100%	total	fresh	residue	% intake	to 100%	total	fresh	residue	% intake	to 100%	total	fresh	residue
			intake	to 100%	MS (%)	weight	intake	intake	to 100%	MS (%)	weight	intake	intake	to 100%	MS (%)	weight	intake	intake	to 100%	MS (%)	weight	intake
<b>I - Green Forage (Incl. Hay)</b>																						
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		-	-	-
<b>II - Grains</b>																						
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
<b>III - Straws (cereals)</b>																						
	86	0,354			-	-	-	20		20	4,7	1,6	50		50	8,7	3,1			-	-	-
<b>IV - Pulses</b>																						
	86		30		-	-	-	20		-	-	-	20		-	-	-	40		-	-	-
<b>V - Root and Tubers</b>																						
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		-	-	-
<b>VI - Oil seed (Meal Cake)</b>																						
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 <sup>(1)</sup>	% Material balance	% sulfoxaflor after treatment	% X11719474 after treatment	% X11721061 after treatment	% X11579457 after treatment
<sup>14</sup> C-Sulfoxaflor	Pasteurisation	100.5	99.6	-	-	-
	Baking, brewing, boiling	100.2	100.0	-	-	-
	Sterilisation	99.1	100.4	-	-	-
<sup>14</sup> 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
<sup>14</sup> 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), <sup>14</sup>C-sulfoxaflor and <sup>14</sup>C-X11721061 were found to be stable, whereas <sup>14</sup>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**

Not relevant for the uses under consideration.

**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 cotton seed, barley and wheat have been submitted in the framework of the EU evaluation of active substance. These studies are briefly summarised below.

**Cotton seed**

One study was evaluated in the DAR which investigated the residues in cotton seed and its processed commodities following simulated commercial processing procedures. Cotton was treated at an exaggerated rate and grown under field conditions in a single trial (12.6 N compared to the proposed GAP). At harvest samples were processed into delinted seed, hulls, meal, crude oil, refined oil and meal presscake. Processing factors derived from these studies are summarised in table below.

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

Crop/process/processed product	Number of studies	Processing Factor (PF) Sulfoxaflor		Processing Factor (PF) X11719474	
		Individual values	Median PF	Individual values	Median PF
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	-

NC: Not calculated

**Barley**

Two studies were evaluated in the DAR which investigated the residues in barley and its processed commodities following simulated commercial processing procedures. Barley was treated at an exaggerated rate and grown under field conditions in two separate trials (6.25-12.5 N compared to the proposed GAP). At harvest, samples were processed into pearl barley, pot barley, bran, flour, cleaned barley, brewing malt, malt sprouts, beer, spent grains and brewer's yeast. Samples were stored for within the demonstrated period of stability and were analysed according to the validated analytical method 091031. Processing factors derived from these studies are summarised in table below.

**Table IIIA 8.5.3-2: A summary of the processing factors from the DAR (barley)**

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,	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

Crop/ process/ processed product	Number of studies	Processing Factor (PF) Sulfoxaflo		Processing Factor (PF) X11719474	
		Individual values	Median PF	Individual values	Median PF
cleaned barley, brewing malt, malt sprouts, beer, spent grains and brewer's yeast		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

### Wheat

Two studies were evaluated in the DAR which investigated the residues in wheat and its processed commodities following simulated commercial processing procedures. Wheat was treated at an exaggerated rate (10.4 N compared to the proposed GAP) and grown under field conditions in three separate trials. At harvest, samples were processed into cleaned grain, coarse bran, fine bran, total bran, germ, middlings, shorts, whole meal flour, refined flour, whole grain bread and white bread. Samples were stored for within the demonstrated period of stability and were analysed according to the validated analytical method 091031. A summary of the processing factors derived from these studies is given in Table IIIA 8.5.3-3 below.

**Table IIIA 8.5.3-3: A summary of the processing factors from the DAR (wheat)**

Crop/ process/ processed product	Number of studies	Processing Factor (PF) Sulfoxaflo		Processing Factor (PF) X11719474	
		Individual values	Median PF	Individual values	Median PF
Wheat grain → cleaned grain, coarse bran, fine bran, total bran (combined coarse and fine bran), germ, middlings, shorts, whole meal flour, refined flour, whole grain bread and white bread from refined flour.	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
		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



Crop/ process/ processed product	Number of studies	Processing Factor (PF) Sulfoxaflor		Processing Factor (PF) X11719474	
		Individual values	Median PF	Individual values	Median PF
		<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

**IIIA 8.5.3.2 New data**

No new data submitted.

**IIIA 8.5.3.3 Conclusion on balance studies**

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

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

This is not an EC data requirement/ not required.

**IIIA 8.6 Studies for Residues in Representative Succeeding Crops****IIIA 8.6.1 PRELIMINARY CONSIDERATION**

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**

A confined rotational crop study conducted in California, USA was assessed and summarised in sulfoxaflor DAR (Vol.3, B7.9.1.). In this study, <sup>14</sup>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**

Table 6/12- 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	
<b>Comments:</b> 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 8.6.2.1 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 use 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	EFSA 2014

	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.	
<b>Residue pattern in processed commodities similar to pattern in raw commodities?</b>	Yes	EFSA 2014
<b>Plant residue definition for monitoring</b>	Parent sulfoxaflo (sulfoxaflo) only	EFSA 2014, Reg. (EU) 2016/1
<b>Plant residue definition for risk assessment</b>	Sum of parent sulfoxaflo and metabolite X11719474, expressed as sulfoxaflo. However, it was agreed that if metabolite X11719474 is shown to be significantly less toxic than Sulfoxaflo then the residue definition for risk assessment will become parent Sulfoxaflo only.	EFSA 2014
<b>Conversion factor</b>	None	EFSA 2014

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

	<b>Endpoints</b>	<b>Reference</b>
<b>Animals covered</b>	Goat	EFSA 2014
	Hen	EFSA 2014
<b>Time needed to reach a plateau concentration</b>	<b>Milk:</b> A plateau was reached in milk matrices over the course of the 5 day dosing period ( <i>ca.</i> 0.2 – 0.3 mg/kg).	EFSA 2014
	<b>Eggs:</b> A steady plateau was observed in egg matrices after six days dosing ( <i>ca.</i> 0.06 mg/kg).	EFSA 2014
<b>Animal residue definition for monitoring</b>	Parent sulfoxaflo (sulfoxaflo) only <sup>(a)</sup>	EFSA 2014 Reg. (EU) 2016/1
<b>Animal residue definition for risk assessment</b>	Sum of parent sulfoxaflo and metabolite X11719474, expressed as sulfoxaflo. However, it was agreed that if metabolite X11719474 is shown to be significantly less toxic than Sulfoxaflo then the residue definition for risk assessment will become parent Sulfoxaflo only	EFSA 2014
<b>Conversion factor</b>	None	EFSA 2014
<b>Metabolism in rat and ruminant similar</b>	Yes. Metabolism of parent sulfoxaflo in the ruminant (goat) and rodent are similar, therefore there is no need to request a swine (pig) metabolism study.	EFSA 2014
<b>Fat soluble residue</b>	No. Parent sulfoxaflo is not fat soluble as log Po/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):	EFSA 2014

	Log Pow = 0.806 at pH5 Log Pow = 0.802 at pH 7 Log Pow = 0.799 at pH 9	
--	--	--

### 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: Existing EU MRLs for sulfoxaflor (for crops in this submission)

Crop	EU MRL (mg/kg) Proposed in document SANTE/11442/2016	EU MRL (mg/kg) (Required for the GAP in the current submission)	Proposed MRL in MRL application
Rape seed	0.15 (CXL)	No change	No change
Cotton seed	0.4 (CXL)	No change	No change
Barley	0.6 (CXL)	0.06 (SEU data)	No change
Oats	0.04 (EU GAP)	0.06 (extrapolated from barley)	0.6
Wheat (spelt, triticale)	0.2 (CXL)	No change	0.4
Rye	0.015 (EU GAP)	0.03 (extrapolated from wheat)	0.09

Pending the modification of in force MRL intended uses on oat and rye are not considered acceptable.

### 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)
Cotton seed (2 x 24 g a.s/ha)	14
Barley (2 x 24 g a.s/ha)	21
Wheat, spelt, triticale (2 x 24 g a.s/ha)	21

#### 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. However, the general approach of avoiding handling until the spray solution has dried is recommended.

#### **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-2372.

#### **IIIA 8.9 Other/Special Studies**

The Annex II summaries for the active substance(s) sufficiently address aspects of the residue situation that might arise from the use of GF-2372. 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 in the table below.

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 MRLs, as proposed in document SANTE/1142/2016 .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 and for which sufficient supporting residue data were provided.

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

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

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
<b>Risk assessment residue definition:</b> Sum of parent sulfoxaflor and metabolite X11719474, expressed as sulfoxaflor.				
<b>Products of plant origin</b>				
Cotton seed	0.02	STMR (JMPR, 2011)	0.019	STMR SEU (8.3.2)
Wheat	0.025	STMR (JMPR, 2011)	0.019	STMR NEU/SEU (8.3.4)
Barley	0.06	STMR (JMPR, 2011)	0.03	STMR SEU (8.3.3)
Oats	0.020	STMR (EFSA, 2014)	Use not acceptable due to an MRL exceedance	
Rye	0.019	STMR (EFSA, 2014)		
Rape seed	0.068	STMR (EFSA, 2014)	Use not considered acceptable as no Northern supporting residue data were provided	
Grapefruits,	0.021	STMR GF-2626		
Oranges	0.26	STMR JMPR 2014	Acute risk assessment was performed on the intended use only	
Lemons,	0.038	STMR JMPR 2014		
Mandarins	0.31	STMR JMPR 2011-2014		
Pome fruits	0.185	STMR SEU (8.3.2)		
Peaches	0.227	STMR SEU (8.3.3)		
Cherries	0.34	STMR (JMPR, 2014)		
Potatoes	0.019	STMR (EFSA, 2014)		
Tomatoes	0.11	STMR (JMPR 2011)		
Peppers	0.11	STMR (JMPR 2011)		
Aubergines	0.11	STMR (JMPR 2011)		
Broccoli	0.074	STMR (JMPR, 2011)		
Cauliflower	0.019	STMR (GF-2626)		
Brussels sprout	0.019	STMR (see 8.3.12)		
Head cabbage	0.099	STMR (JMPR, 2011)		
Chinese cabbage	1.00	STMR (EFSA, 2014)		
Lettuce	0.585	STMR (EFSA, 2014)		
Spinach	1.34	STMR (EFSA, 2014)		
Cucurbits with edible peel	0.033	STMR SEU (GF-2626)		
Cucurbits with inedible peel	0.029	STMR (JMPR, 2011)		
Almonds	0.019	STMR (EFSA, 2014)		

Commodity	Chronic risk assessment		Acute risk assessment			
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment		
Pecans	0.019	STMR (EFSA, 2014)				
Apricots	0.155	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)				
Soya been	0.023	STMR (EFSA, 2014)				
All other crops	EU MRL	Reg. (EU) 2016/1				
Products of animal origin						
Mammalian <sup>(a)</sup> 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)				
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

### **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 above table.



**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 variability 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		*)
			**) pTMRL/ threshold MRL (mg/kg)			**) pTMRL/ threshold MRL (mg/kg)			**) pTMRL/ threshold MRL (mg/kg)			**) pTMRL/ threshold MRL (mg/kg)
	Highest % of ARfD/ADI	Commodities		Highest % of ARfD/ADI	Commodities		Highest % of ARfD/ADI	Commodities		Highest % of ARfD/ADI	Commodities	
	0,1	Wheat	0,019 / -	0,1	Wheat	0,019 / -	0,1	Barley	0,03 / -	0,1	Barley	0,03 / -
	0,0	Barley	0,03 / -	0,0	Barley	0,03 / -	0,1	Wheat	0,019 / -	0,1	Wheat	0,019 / -

#### **IIIA 8.10.4 CONSUMER RISK ASSESSMENT CONCLUSION**

The proposed 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 for cotton seed, barley and wheat, spelt and triticale. However, exceedance of the current MRL of sulfoxaflor is expected for oat and rye. Furthermore concerning the intended use on rape seed, in absence of supporting Northern residue data it is not possible to conclude on the MRL compliance.

It should be noted that according to the applicant an application to modify the in force MRLs on several crops has been submitted to the EMS Ireland. The assessment of these MRL proposals by EMS Ireland is currently ongoing.

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 for cotton seed, barley and wheat, spelt, triticale but disagrees with the authorization of the intended uses for rape seed, oat and rye.

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

## SUMMARY OF THE EVALUATION

The preparation GF-2372 (TRANSFORM) 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 SANTÉ/11 442/2016	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
	Rape seed	Yes	No (0 NEU/6SEU)	-	Yes	Yes	No	N/A	Use not acceptable No Northern residue trials
	Cotton seed	Yes	Yes (8 SEU)	Yes	Yes	Yes		No	Use acceptable
	Barley	Yes	Yes (9NEU/10 SEU)	Yes	Yes	Yes		No	Use acceptable
	Oat	Yes	Yes (9NEU/10 SEU)	Yes	Yes	No		N/A	Use not acceptable MRL exceedance
	Wheat,	Yes	Yes (8	Yes	Yes	Yes		No	Use

Use- No. *	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance SANTE/11 442/2016	Chronic risk for consumers identified ?	Acute risk for consumers identified?	Comments
	spelt, triticale		NEU/8 SEU)						acceptable
	Rye	Yes	Yes (8 NEU/8 SEU)	Yes	Yes	No		N/A	Use not acceptable MRL exceedance

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-2372 (TRANSFORM)

**Table 0-2: Information on GF-2372 (TRANSFORM) (KCA 6.8)**

Crop	PHI for GF- 2372 (TRANSFORM) proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for GF- 2372(TRANSFORM) proposed by zRMS	zRMS Comments (if different PHI proposed)
		Sulfoxaflor		
Cotton seed	14	Y	14	-
Wheat, spelt, triticale	21	Y	21	-
Barley	21	Y	21	-

## References :

### Sulfoxaflor:

- EC (European Commission), 2015.** Final review report for the active substance sulfoxaflor. Finalised in the Standing Committee on Plants, Animals, Food and Feed at its meeting on 29 May 2015 in view of the approval of sulfoxaflor as active substance in accordance with Regulation (EC) No 1107/2009. SANCO/10665/2015-rev 2, 29 May 2015. Available online: [http://ec.europa.eu/sanco\\_pesticides/public/index.cfm?event=activesubstance.selection](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](http://www.efsa.europa.eu)
- 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](http://www.efsa.europa.eu/efsajournal.htm)
- 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/>
- France 2016.** Evaluation Report prepared under Article 8 of Regulation (EC) No 396/2005 Modification on the setting of MRL in globe artichokes.

### 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](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](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](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](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](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](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](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](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](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](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](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](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. 2<sup>nd</sup> 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 (Y/N) Published or unpublished	Data protection claimed (Y/N)	Owner	Relied on Y/N
IIIA 8.3.1/01	Rawle, N. W.	2012a	Residues of XDE-208 in oil seed rape at intervals and harvest following a single application of GF-2032– Northern and Southern Europe – 2008 and 2009 Dow AgroSciences CEMR-3927 GLP: Y Unpublished	Y	DAS	Y
IIIA 8.3.1/02	Rawle, N. W.	2014	Residues of sulfoxaflor in oil seed rape at intervals and harvest following multiple application of GF-2372 – Southern Europe – 2013 Dow AgroSciences CEMR-5945 GLP: Y Unpublished	Y	DAS	Y
IIIA 8.3.2/01	Rawle, N. W.	2011a	Residues of XDE-208 in cotton at intervals and harvest following a single application of GF-2032 or GF-2372 – Southern Europe – 2010 Dow AgroSciences CEMR-4712 GLP: Y Unpublished	Y	DAS	Y
IIIA 8.3.2/02	Rawle, N. W.	2012b	Residues of sulfoxaflor in cotton at intervals and harvest following a single application of GF-2372 – Southern Europe – 2011 Dow AgroSciences CEMR-5007 GLP: Y Unpublished	Y	DAS	Y
IIIA 8.3.3/01	Rawle, N. W.	2011b	Residues of XDE-208 in barley at intervals and harvest following single or multiple applications of GF-2032 – Northern and Southern Europe – 2008 and 2009 Dow AgroSciences CEMR-3922 GLP: Y Unpublished	Y	DAS	Y



<b>Annex Point</b>	<b>Author</b>	<b>Year</b>	<b>Title Source (where different from company) Company Report No. GLP or GEP status (Y/N) Published or unpublished</b>	<b>Data protection claimed (Y/N)</b>	<b>Owner</b>	<b>Relied on Y/N</b>
IIIA 8.3.3/02	Rawle, N. W.	2012c	Residues of sulfoxaflor in barley at intervals and harvest following multiple applications of GF-2372 – Northern and Southern Europe – 2011 Dow AgroSciences CEMR-5006 GLP: Y Unpublished	Y	DAS	Y
IIIA 8.3.3/03	Rawle, N. W.	2012d	Residues of sulfoxaflor in barley grain and process fractions at harvest following multiple applications of GF-2372 – 2011 Dow AgroSciences CEMR-5034 GLP: Y Unpublished	Y	DAS	Y
IIIA 8.3.4/01	Rawle, N. W.	2011c	Residues of XDE-208 in wheat at intervals and harvest following single or multiple applications of GF-2032 – Northern and Southern Europe – 2008 and 2009 Dow AgroSciences CEMR-3920 GLP: Y Unpublished	Y	DAS	Y
IIIA 8.3.4/02	Rawle, N. W.	2012e	Residues of sulfoxaflor in wheat at intervals and harvest following multiple applications of GF-2372 – Northern and Southern Europe – 2011 Dow AgroSciences CEMR-5005 GLP: Y Unpublished	Y	DAS	Y

## Appendix 2: Acceptable critical Uses –GAP tables

Crop and/ or situation  (a)	Zone	Product code	F G or I  (b)	Pests or Group of pests controlled  (c)	Formulation		Application				Application rate per treatment			PHI (days )  (l)	Remarks:  (m)
					Type  (d-f)	Conc. of a.s.  (i)	method kind  (f-h)	growth stage & season  (j)	numbe r min max (k)	interval between applications (min)	kg as/hL  min max	water L/ha  min max	kg as/ha  min max		
Rape seed	SEU FR	GF-2372	F	Aphids	W G	500 g/kg	Ground applied foliar spray, broadcast	BBCH 10-87	1-2	21 days	0.004- 0.016	100-600	0.024	28	Two applications would be minimum 21 days interval. Only 1 application is allowed in the Sep-Dec interval followed by 1 application in the April-June Period. If no autumn application, 2 spring applications are possible.  <b>Use not acceptable : No supporting northern residue data</b>

Crop and/ or situation  (a)	Zone	Product code	F G or I  (b)	Pests or Group of pests controlled  (c)	Formulation		Application				Application rate per treatment			PHI (days )  (l)	Remarks:  (m)
					Type  (d-f)	Conc. of a.s.  (i)	method kind  (f-h)	growth stage & season  (j)	numbe r min max (k)	interval between applications (min)	kg as/hL  min max	water L/ha  min max	kg as/ha  min max		
Cotton seed	SEU EL	GF-2372	F	Aphids	W G	500 g/kg	Ground applied foliar spray, broadcast	BBCH 20-87	1-2	7 days	0.004- 0.016	300-1000	0.024	14	<u>Aphids</u> : One or two applications of 24 g a.s./ha. Two applications would be minimum 7 days interval.
Cereals (Barley, <del>Oats</del> ) [w, s]	SEU FR, IT	GF-2372	F	Aphids	W G	500 g/kg	Ground applied foliar spray, broadcast	BBCH 12-87	1-2	21 days	0.004- 0.016	100-600	0.024	21	Two applications would be minimum 21 days interval. Only 1 application is allowed in the Sep-Dec interval followed by 1 application in the March-July Period. If no autumn application, 2 spring applications are possible

Crop and/or situation (a)	Zone	Product code	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of a.s. (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max		
Cereals (Oats) [w, s]	SEU FR, IT	GF-2372	F	Aphids	WG	500 g/kg	Ground applied foliar spray, broadcast	BBCH 12-87	1-2	21 days	0.004-0.016	100-600	0.024	21	Two applications would be minimum 21 days interval. Only 1 application is allowed in the Sep-Dec interval followed by 1 application in the March-July Period. If no autumn application, 2 spring applications are possible  <b>Use on oat not acceptable: MRL exceedance</b>

Crop and/or situation  (a)	Zone	Product code	F G or I  (b)	Pests or Group of pests controlled  (c)	Formulation		Application				Application rate per treatment			PHI (days)  (l)	Remarks:  (m)
					Type  (d-f)	Conc. of a.s.  (i)	method kind  (f-h)	growth stage & season  (j)	number min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max		
Cereals (Wheat, Rye, Spelt, Triticale) [w, s]	SEU FR, IT	GF-2372	F	Aphids	W G	500 g/kg	Ground applied foliar spray, broadcast	BBCH 12-87	1-2	21 days	0.004-0.016	100-600	0.024	21	Two applications would be minimum 21 days interval. Only 1 application is allowed in the Sep-Dec interval followed by 1 application in the March-July Period. If no autumn application, 2 spring applications are possible

Crop and/or situation (a)	Zone	Product code	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of a.s. (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max		
Rye [w, s]	SEU FR, IT	GF-2372	F	Aphids	W G	500 g/kg	Ground applied foliar spray, broadcast	BBCH 12-87	1-2	21 days	0.004-0.016	100-600	0.024	21	Two applications would be minimum 21 days interval. Only 1 application is allowed in the Sep-Dec interval followed by 1 application in the March-July Period. If no autumn application, 2 spring applications are possible  <b>Use not acceptable: MRL exceedance</b>

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