FINAL REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: CHR/H/FDF 574 SC

Product name(s): Cezaro 574 SC/ Huron 574 SC

Chemical active substance(s):

Florasulam, 12 g/L
Diflufenican, 250 g/L
Flufenacet, 312 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Innvigo Sp. z o.o.

Submission date: November 2021

MS Finalisation date: 21/11/2022

Version history

When	What
March 2022	Dossier sent for evaluation
September 2022	zRMS evaluation of dRR
November 2022	Final version prepared by zRMS after Commenting period

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7 Metabolism and residue data (KCA section 6)

In the following document, data for active substances - diflufenican and flufenacet - was described during its inclusion on Annex 1 process in respectively 2009 and 2004 . Were reference to active substance data in the current risk assessment has been made, it was based on the data which protection for expired 10 years from date of inclusion of active substances on Annex I.
Data matching studies for florasulam have been evaluated by Poland. As a result of the assessment all reports were accepted and considered as equivalent to protected studies. Therefore, to support the authorization of CHR/H/FDF 574 SC INNVIGO is allowed to refer to EU approved reports

7.1 Summary and zRMS Conclusion

The document was not rewritten by the evaluator. The evaluator text is on grey background.

7.1.1 Critical GAP(s) and overall conclusion

Selection of critical uses and justification

The critical GAPs with respect to consumer intake and risk assessment for the preparation CHR/H/FDF 574 SC are presented in Table 7.1-1. They have been selected from the individual GAPs in the zone for winter cereals. A list of all intended uses within the CEU is given in Part B, Section 0.
In the representative GAPs for winter cereals the critical rates of flufenacet and diflufenican are 0,24 kg as/ha thus they are much more critical than those proposed by the applicant for cereals within the intended GAP.
The proposed amount of florasulam is 28% higher than in the representative GAP for winter cereals, however in the trials presented by the applicant with such florasulam rate level the residues of interest are not detectable.

Overall conclusion

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of 0.01 mg/kg for florasulam (Reg. (EU) No 1317/2013), 0.02 mg/kg for diflufenican, 0.1 (0,05) mg/kg for flufenacet as laid down in Reg. (EU) 396/2005 is not expected.
The chronic and the short-term intakes of florasulam, diflufenican and flufenacet residues are unlikely to present a public health concern.
As far as consumer health protection is concerned, zRMS agrees with the authorization of the intended uses.
According to available data, no specific mitigation measures should apply.

Data gaps

Noticed data gaps are: none

Table 7.1-1: Acceptability of critical GAPs (and respective fall-back GAPs, if applicable)

1	2	3	4	5	6	7	8	9	15	11	12	13	14	15
Use-No. (e)	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha (f)	ZRMs Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	PL	Winter wheat (TRZAW), Winter triticale (TTLWI), Winter barley (HORVW), Winter rye (SECCW)	F	dicotyledonous weeds	Spray, medium sprayer	autumn BBCH 11-25	a)1 b)1	n/a	a) 0.4 l/ha b) 0.4 l/ha	a) 0.2296 kg a.s./ha (0.1248 FLU + 0.1 D + 0.0048 FLO) b) 0.2296 kg a.s./ha (0.1248 FLU + 0.1 D + 0.0048 FLO)	200-400	n/a		

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
** Use also code numbers according to Annex I of Regulation (EU) No 396/2005
*** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

Explanation for Column 11 "Conclusion"

A	Exposure acceptable without risk mitigation measures, safe use
R	Further refinement and/or risk mitigation measures required
N	Exposure not acceptable, no safe use

7.1.2 Summary of the evaluation

The preparation CHR/H/FDF 574 SC is composed of florasulam, diflufenican and flufenacet.

Table 7.1-2: Toxicological reference values for the dietary risk assessment of florasulam, diflufenican and flufenacet

Reference value	Source	Year	Value	Study relied upon	Safety factor
Florasulam - Parent compound					
ADI	EFSA Journal 2015;13(1):3984 Reg. (EU) 2015/1397	2015	0.05 mg/kg bw per day	1 year dog	100
ARfD	Not applicable				
Diflufenican - Parent compound					
ADI	EFSA	2007	0.2 mg/kg bw/day	2-year rat study	100
ARfD	Not applicable				
Flufenacet - Parent compound					
ADI	SANCO 7469/VI/98-Final 3 July 2003	2003	0.005 mg/kg bw/day	rat: 2y study (LOEL)	250
ARfD	SANCO 7469/VI/98-Final 3 July 2003	2003	0.017 mg/kg bw/day	dog: 90d and 1y study	100

7.1.2.1 Summary for florasulam

Table 7.1-3: Summary for florasulam

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
	Winter cereals	Yes	Yes	Yes	Yes	Yes	No	No

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

As residues of florasulam do not exceed the trigger values defined in Reg (EU) No 283/2013, there is no need to investigate the effect of industrial and/or household processing.

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 pre-sent in succeeding crops.
Considering dietary burden and based on the intended uses, no significant modification of the in-take was calculated for livestock. Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary.

7.1.2.2 Summary for diflufenican

Table 7.1-4: Summary for diflufenican

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
	Winter cereals	Yes	Yes	Yes	Yes	Yes	~~Yes~~ No	~~Yes~~ No

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

For winter cereals, no additional data are required in post-registration to confirm that a "no-residue" situation occurs in the worst case application: 1 application of 0.1 g/ha at growth stage BBCH 11-25.
Based on the intakes calculated above and the animal metabolism studies, residues in animal products are not expected to be above the limit of determination (0.01 mg/kg milk, 0.02 mg/kg in muscle, eggs, fat, kidney and liver).

As residues of diflufenican do not exceed the trigger values defined in Reg (EU) No 283/2013, there is no need to investigate the effect of industrial and/or household processing.

7.1.2.3 Summary for flufenacet

Table 7.1-5: Summary for flufenacet

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
	Winter cereals	Yes	Yes	Yes	Yes	Yes	~~Yes~~ No	~~Yes~~ No

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

For winter cereals, no additional data are required in post-registration to confirm that a "no-residue" situation occurs in the worst case application: 1 application of 0.1248 g/ha at growth stage BBCH 11-25.
Since the trigger value was not acceded no livestock feeding studies are necessary.

As residues of flufenacet do not exceed the trigger values defined in Reg (EU) No 283/2013, there is no need to investigate the effect of industrial and/or household processing.

7.1.2.4 Summary for CHR/H/FDF 574 SC

Table 7.1-6: Information on CHR/H/FDF 574 SC (KCA 6.8)

Crop	PHI for CHR/H/FDF 574 SC proposed by applicant	PHI/ Withholding period* sufficiently supported for			PHI for CHR/H/FDF 574 SC proposed by zRMS	zRMS Comments (if different PHI proposed)
		Florasulam	Diflufenican	Flufenacet		
Winter	NR	NR	NR	NR	n/a	n/a

Crop	PHI for CHR/H/FDF 574 SC proposed by applicant	PHI/ Withholding period* sufficiently supported for			PHI for CHR/H/FDF 574 SC proposed by zRMS	zRMS Comments (if different PHI proposed)
		Florasulam	Diflufenican	Flufenacet		
cereals						

NR: not relevant
* Purpose of withholding period to be specified
** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

Table 7.1-7: Waiting periods before planting succeeding crops

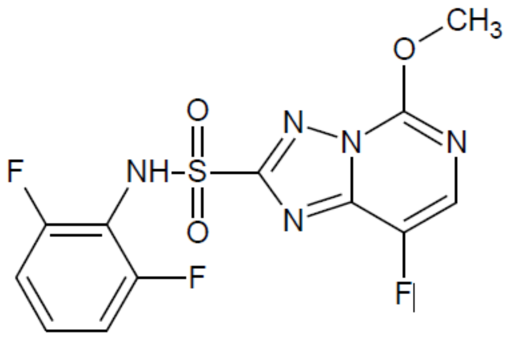
Waiting period before planting succeeding crops				Overall waiting period proposed by zRMS for CHR/H/FDF 574 SC
Crop group	**Led by Florasulam**	**Led by Diflufenican**	**Led by Flufenacet**	
Leafy vegetables	NR	NR	NR	n/a
Root vegetables	NR	NR	NR	
Cereals	NR	NR	NR	

NR: not relevant

7.2 Florasulam

General data on Florasulam are summarized in the table below (last updated 2016/01/01)

Table 7.4-1: General information on Florasulam

Active substance (ISO Common Name)	Florasulam
IUPAC	2′,6′,8-trifluoro-5-methoxy[1,2,4]triazolo[1,5-c] pyrimidine-2-sulfonanilide
Chemical structure	
Molecular formula	C12H8O3N5F3S
Molar mass	359.3 g/mol
Chemical group	1,5c triazolopyrimidine sulfonanilides
Mode of action (if available)	ALS inhibitor
Systemic	Yes
Company (ies)	Dow AgroScienes
Rapporteur Member State (RMS)	POLAND
Approval status	Approved Date of (01/01/2016) and reference to decision (COM-MISSION DIRECTIVE 91/414/EEC - REGULATION (EU) No 2015/1397)
Restriction	Commission Implementing Regulation (EU) 2015/1397 of 14 August 2015
Review Report	SANTE/10542/2015 Rev 1 14/07/2015
Current MRL regulation	Reg. (EU) No 1317/2013
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Pending
EFSA Journal : Conclusion on the peer review	EFSA Journal 2015;13(1):3984
EFSA Journal: conclusion on article 12	EFSA Journal 2012;10(3):2626
Current MRL applications on intended uses	EFSA-Q-2008-545 (EMS) Review of all existing MRLs Status: Evaluation ongoing

7.2.1 Stability of Residues (KCA 6.1) - florasulam

7.2.1.1 Stability of residues during storage of samples - florasulam

Available data

No new data submitted in the framework of this application.

Table 7.4-2: Summary of stability data achieved at ≤ - 18°C (unless stated otherwise)

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products			
Cereal (cereal grain, straw and immature cereal plants	High starch content	18 – 24 months	RAR, Florasulam - Volume 3, Annex B.7, 2013

Conclusion on stability of residues during storage

The storage stability evaluated during Annex I inclusion covers plant matrices for use CHR/H/FDF 574 SC according to the GAP, therefore no new studies are necessary.

7.2.1.2 Stability of residues in sample extracts (KCA 6.1) - florasulam

Not relevant for this application, in supervised studies evaluated during Annex I inclusion and presented in RAR Florasulam - Volume 3, Annex B.7 2013, analysis time were less than 24 hours between extraction and analysis.

7.2.2 Nature of residues in plants, livestock and processed commodities - florasulam

7.2.2.1 Nature of residue in primary crops (KCA 6.2.1) - florasulam

Available data

No new data submitted in the framework of this application.

Table 7.4-3: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (g a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Cereals	Winter wheat	[14C-phenyl]-florasulam	F	50 g as/ha	10	0, 30, 65 and 129 days	none	RMS, 1999 DAR, 1999. Florasulam – Annex B.6: Residue data EFSA Journal 2015; 13(1):3984
Cereals	Winter	[14C-	F	50 g as/ha	10	0, 30, 65	none	RMS, 1999

	wheat	triazolopy-rimidine]-florasulam.				and 129 days		DAR, 1999. Florasulam – Annex B.6: Residue data EFSA Journal 2015; 13(1):3984

Summary of plant metabolism studies reported in the EU

The metabolism of florasulam was investigated in winter wheat after foliar application of [^{14}C-phenyl]-florasulam and [^{14}C-triazolopyrimidine]-florasulam. At the immature plant stage (forage), florasulam (28-33% TRR) and metabolite 4-OH-phenyl-florasulam plus glucose-conjugate (19-42% TRR) were the major residues. In the mature wheat plants (straw), parent florasulam was only recovered in one of the two experimental subsets with later application (7-14% TRR). Metabolite 4-OH-phenyl-florasulam plus glucose-conjugate was major (up to 36% TRR). Residues in wheat grain were too low to permit any identification. The presence of increasing proportions of metabolite ASTP with time (up to 19% TRR at harvest) indicated that a cleavage of the molecule occurred with progressing metabolism.

Conclusion on metabolism in primary crops

The metabolism in primary crops presented during Annex I inclusion, covers use of CHR/H/FDF 574 SC on cereals. No new studies were necessary.

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1) - florasulam

Available data

The nature of residues in rotational crops were evaluated during Annex I inclusion, and presented in RAR Florasulam - Volume 3, Annex B.7 2013.

No new data submitted in the framework of this application.

Table 7.4-4: Summary of metabolism studies in rotational crops

Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G *	**Rate (g a.s./ha)**	**Sowing intervals (DAT)**	**Harvest Intervals (DAT)**	**Remarks**	
EU data								
Leafy vegetables	cabbage	[14C-phenyl]-florasulam [14C-triazolopyrimidine]-florasulam.	F	7.5	30 days	195 days	none	RMS 2013, RAR, Florasulam - Volume 3, Annex B.7
Root and tuber vegetables	carrots	[14C-phenyl]-florasulam [14C-	F	7.5	30 days	156 days	none	RMS 2013, RAR, Florasulam - Volume 3, Annex B.7

		tria-zolopy-rimidine]-florasu-lam.						
Pulses and oilseeds	sunflower	[14C-phe-nyl]-flo-rasulam	F	7.5	30 days	168 days	none	RMS 2013, RAR, Florasulam - Volume 3, Annex B.7
		[14C-tria-zolopy-rimidine]-florasu-lam.						
Cereals	Spring wheat	[14C-phe-nyl]-flo-rasulam	F	7.5	30 days	168 days	none	RMS 2013, RAR, Florasulam - Volume 3, Annex B.7
		[14C-tria-zolopy-rimidine]-florasu-lam.						

Summary of plant metabolism studies reported in the EU

The following total radioactive residues (TRR expressed in mg Florasulam equiv./kg) were determined :
-soil, after treatment (day 0): 0.019-0.043 mg/kg.
-soil, after ageing (day 30) : 0.011-0.033 mg/kg.
-soil at maturity (harvest time) : 0.002-0.007 mg/kg.
Florasulam and metabolite 5-hydroxy were detected in soil at concentrations ranging from 0.003 to 0.008 mg/kg at sowing date (day 30). These were the main components for potential uptake into the crops.

Crop	Fraction	Phenyl labeled Florasulam	Triazolopyrimidine labeled Florasulam
Spring wheat (168 days after soil treatment)	Ears	nd	0.001
	Straw	0.003	0.004
Sunflowers (168 days after soil treatment)	Heads	nd	nd
	Stems	0.002	0.001
Cabbage (195 days after soil treatment)	Heads	nd	0.002
Carrots (156 days after soil treatment)	Leaves	0.004	0.006
	Roots	0.001	0.001

nd : Not radiodetected

The investigation of rotational crops was considered insufficient with regard to the potential for uptake of significant levels in plant commodities, particularly in terms of the persistent metabolites TSA and ASTCA (both with triazole sulfone moiety), since the available data did not address a plant back interval of 365 days and the application rate in the study seems insufficient considering repeated/multiannual applications, information that may be necessary when persistent soil residues occur.

Conclusion on metabolism in rotational crops

The metabolism in rotational crops covers use of CHR/H/FDF 574 SC according to the label/GAP.

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1) - florasulam

Available data

No significant residues, i.e. >0.1 mg/kg, were found in cereals and therefore processing studies are not required. No new studies are necessary for CHR/H/FDF 574 SC, since all residues are expected to be below 0.1 mg/kg.

7.2.2.4 Conclusion on the nature of residues in commodities of plant origin (KCA 6.7.1) - florasulam

Table 7.2-5: Summary of the nature of residues in commodities of plant origin

Endpoints	
Plant groups covered	Cereals (Wheat)
Rotational crops covered	Spring wheat, cabbage, sunflowers and carrots
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Not provided and not required
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes
Plant residue definition for monitoring	Reg. (EU) No 1317/2013 of 16 December 2013
Plant residue definition for risk assessment	EFSA Journal 2015; 13(1):3984
Conversion factor from enforcement to RA	Not necessary (all residue data <LOQ)

7.2.2.5 Nature of residues in livestock (KCA 6.2.2-6.2.5) - florasulam

Available data

The metabolism in livestock was evaluated during Annex I inclusion, and presented in RAR Florasulam - Volume 3, Annex B.7 2013 and EFSA Journal 2015; 13(1):3984

No new data submitted in the framework of this application.

Table 7.4-6: Summary of animal metabolism studies

Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling	
EU data								
Lactating ruminants	Goat	[14C-phenyl]-florasulam	1 control, 2 doses animal	11	5	Milk	twice daily	RMS 2013, RAR, Florasulam - Volume
						Urine and faeces	daily	
		[14C-				Tissues	at	

		triazolopyrimi-dine]-florasulam.					sacrifice	3, Annex B.7; EFSA Journal 2015; 13(1):3984
Laying poultry	Hens	[14C-phenyl]-florasulam	10 control, 10 doses animal	11	5	Eggs	twice daily	RMS 2013, RAR, Florasulam - Volume 3, Annex B.7; EFSA Journal 2015; 13(1):3984
						Excreta	twice daily	
		[14C-triazolopyrimi-dine]-florasulam.				Tissues	at sacrifice	

Summary of plant metabolism studies reported in the EU

The metabolism of florasulam was investigated in goat and hen with [14C-phenyl]-florasulam and [14C-triazolopyrimidine]-florasulam. Metabolism of florasulam was not extensive, resulting in florasulam being the pertinent residue (80% up to 99% TRR) in the different goat and hen matrices with the exception of goat liver (15% TRR with 82-87% TRR not extracted).

The majority of the applied radioactivity for lactating goat was recovered as unchanged florasulam in excreta. The amount of radioactivity recovered in milk and in edible tissues was only 0.15% of the total dose and the major constituent of the total radioactive residue was the parent molecule, florasulam, in urine, milk and kidney. When the total recovered radioactivity in mil and edible tissues was expressed as florasulam equivalents, the following levels were calculated (based on results from the two goats): milk – (0.016 – 0.033 mg/kg), muscle – (0.0009 – 0.0016 mg/kg), fat – (0.0016 – 0.0017 mg/kg), liver – (0.023 – 0.033 mg/kg), kidney – (0.039 – 0.069 mg/kg). Therefore, of these edible tissues matrices, the highest residue level were found in liver and kidney.

	^{14}C"A" treated goat I		^{14}C"TP" treated goat II	
Tissues	**mg/kg**	**% of total dose**	**mg/kg**	**% of total dose**
Urine	4.61	72.6	3.52	70.9
Cage washing	0.265	0.072	0.587	0.122
Faeces	2.33	15.8	2.34	12.1
Total excretion	*7.205*	*88.472*	*6.447*	*83.122*
Milk	0.016	0.052	0.033	0.085
Liver	0.033	0.0275	0.023	0.023
Kidney	0.069	0.0096	0.039	0.0073
Muscle	0.0016	0.024	0.0009	0.0153
Fat	0.0016	0.0079	0.0017	0.0092
Blood	0.007	0.0135	0.00528	0.0109
Total recovery	7.33	88.60	6.54	83.27

The studies for laying hen demonstrated that the majority of the applied radioactivity was recovered as unchanged florasulam in excreta (91.3 to 96.9% of the total dose in laying hen). In hen eggs, 0.01% of the applied radioactivity was recovered (0.004 mg/kg florasulam equivalent) and the parent compound florasulam was found to be the major constituent (95% TRR).

	^{14}C"A" Hens I		^{14}C"TP" Hens II	
Tissues	**TRR (mg a.s. equiv./kg)**	**% of total dose**	**TRR (mg a.s. equiv./kg)**	**% of total dose**
Excreta	10	91.3	11.5	96.9
Eggs	0.0038	0.013	0.0043	0.013
Skin	0.0066	0.002	0.0050	0.002
Liver	<0.0014*	<0.001	<0.00097*	<0.001
Composite fat	<0.00043*	<0.001	<0.00059*	<0.001
Composite muscle	<0.00048*	<0.001	<0.00078*	<0.001
TOTAL	10.010	91.31	11.50	96.91

* : Tissue residue levels below the experimental minimum quantifiable amount.

Conclusion on metabolism in livestock

Available metabolism studies demonstrated the residues of florasulam are not expected in significant amount since they are very polar and extensively excreted. The metabolic patterns identified in lactating goats and laying hens is consistent with the rat metabolism and a specific metabolism study in pigs is not considered necessary.

7.2.2.6 Conclusion on the nature of residues in commodities of animal origin (KCA 6.7.1)

Table 7.4-7: Summary on the nature of residues in commodities of animal origin

	Endpoints
Animals covered	Lactating goats
	Laying hens
Time needed to reach a plateau concentration	within 24 hours
	within 24 hours
Animal residue definition for monitoring	Florasulam
Animal residue definition for risk assessment	Florasulam pending assessment with regard to 4-OH-phenyl-florasulam *EFSA Journal 2015; 13(1):3984*
Conversion factor	For milk, liver, kidney and eggs: 1 *EFSA Journal 2015; 13(1):3984*
Metabolism in rat and ruminant similar	Yes *EFSA Journal 2015; 13(1):3984*
Fat soluble residue	No *EFSA Journal 2015; 13(1):3984*

7.2.3 Magnitude of residues in plants (KCA 6.3) - florasulam

7.2.3.1 Summary of European data and new data supporting the intended uses - florasulam

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application, which cGAP for CHR/H/FLO 100 SC. Please refer to the *Final Report: Determination of residues of iodosulfuron-methyl, tribenuron-methyl, florasulam and mefenpyr-diethyl after one application of IDS 100 OD or FLOT 150 WG and Adjuwant Super in wheat at 4 sites in Northern Europe 2016*, J. Semrau, 2017. These studies are summarized in the Table below.

Table 7.4-8: Summary of EU reported and new data supporting the intended uses of CHR/H/FLO 100 SC and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Cereals (grain)	J. Semrau, Final Report, S16-02449, 2017	N-EU	GAP on which Florasulam a.s. assessment is based: 5 g as/ha, BBCH 32, PHI n/a, outdoor E: 4x <0.003 RA: 4x <0.003	N/A				
Cereals (straw)	J. Semrau, Final Report, S16-02449, 2017	N-EU	GAP on which Florasulam a.s. assessment is based: 5 g as/ha, BBCH 32, PHI n/a, outdoor E: 4x <0.003 RA: 4x <0.003	N/A				
Cereals (whole plant)	J. Semrau, Final Report, S16-02449, 2017	N-EU	GAP on which Florasulam a.s. assessment is based: 5 g as/ha, BBCH 32, PHI n/a, outdoor E: 4x <0.003 RA: 4x <0.003	N/A				
Cereals	Overall supporting data for cGAP	N-EU	GAP on which Florasulam a.s. assessment is based: 5 g as/ha, BBCH 32, PHI n/a, outdoor E: 4x <0.003 RA: 4x <0.003	<0.003	<0.003	-	0.01	Yes

7.2.3.2 Conclusion on the magnitude of residues in plants - florasulam

According to the available data, the intended uses on cereals are considered acceptable.

The data for CHR/H/FDF 574 SC submitted show that no exceedance of the MRL will occur.

The uses are considered acceptable.

7.2.4 Magnitude of residues in livestock - florasulam

7.2.4.1 Dietary burden calculation - florasulam

According to the *Final Report: Determination of residues of iodosulfuron-methyl, tribenuron-methyl, florasulam and mefenpyr-diethyl after one application of IDS 100 OD or FLOT 150 WG and Adjuwant Super in wheat at 4 sites in Northern Europe 2016, J. Semrau, 2017, Germany* all residues in cereals (grain, straw and whole plant) are below the LOD (0.003 mg/kg). Therefore, it does not cause any risk for livestock and new data is not required on this application.

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3) - florasulam

According to the *Final Report: Determination of residues of iodosulfuron-methyl, tribenuron-methyl, florasulam and mefenpyr-diethyl after one application of IDS 100 OD or FLOT 150 WG and Adjuwant Super in wheat at 4 sites in Northern Europe 2016, J. Semrau, 2017, Germany* all residues in cereals (grain, straw and whole plant) are below LOD (0.003 mg/kg). Therefore, it does not cause any risk for livestock from intakes of florasulam and new data is not required on this application.

7.2.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation) (KCA 6.5.2-6.5.3) - florasulam

No significant residues, i.e. >0.1 mg/kg, were found in cereals and therefore processing studies are not required. No new studies are necessary for CHR/H/FDF 574 SC, since all residues are below 0.003 mg/kg.

7.2.5.1 Available data for all crops under consideration - florasulam

No new data were submitted in the framework of this application.

7.2.5.2 Conclusion on processing studies - florasulam

Due to the residues from supervised trials for representative use in cereals, all residues are below LOD (0.003 mg/kg) therefore no processing studies are necessary.

7.2.6 Magnitude of residues in representative succeeding crops - florasulam

According to the *EFSA Journal 2015; 13(1):3984* residues of parent florasulam in succeeding crops are not sufficient to reach measurable levels in monitoring (<0.01 mg/kg) and no specific plant-back restrictions related to florasulam are required. Therefore, new data is not required on this application.

7.2.6.1 Field rotational crop studies (KCA 6.6.2) - florasulam

Available data

No new data submitted in the framework of this application.

Conclusion on rotational crops studies

According to the *EFSA Journal 2015; 13(1):3984* residues of parent florasulam in succeeding crops are not sufficient to reach measurable levels in monitoring (<0.01 mg/kg) and no specific plant-back restrictions related to florasulam are required.

7.2.7 Other / special studies (KCA6.10, 6.10.1) - florasulam

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of CHR/H/FDF 574 SC. Therefore, other special studies are not needed.

7.2.8 Estimation of exposure through diet and other means (KCA 6.9)

As ARfD was not deemed necessary, acute risk assessment is not relevant.

7.2.8.1 Input values for the consumer risk assessment - florasulam

Table 7.4-10: Input values for the consumer risk assessment

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Risk assessment residue definition : florasulam		
Barley	0.01	Reg. (EU) No 1317/2013
Buckwheat and other pseudo-cereals	0.01	Reg. (EU) No 1317/2013
Maize/corn	0.01	Reg. (EU) No 1317/2013
Common millet/proso millet	0.01	Reg. (EU) No 1317/2013
Oat	0.01	Reg. (EU) No 1317/2013
Rice	0.01	Reg. (EU) No 1317/2013
Rye	0.01	Reg. (EU) No 1317/2013
Sorghum	0.01	Reg. (EU) No 1317/2013
Wheat	0.01	Reg. (EU) No 1317/2013
Other cereals	0.01.	Reg. (EU) No 1317/2013

7.2.8.2 Conclusion on consumer risk assessment - florasulam

Extensive calculation sheets are presented in Appendix 3.

Table 7.4-11: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo	0.3 % (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo	0.3 % (based on NL toddler)

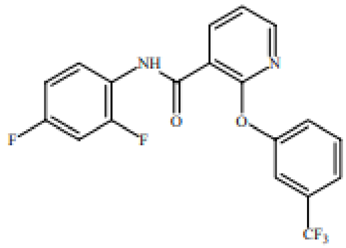
The proposed uses of florasulam in the formulation CHR/H/FDF 574 SC do not represent unacceptable acute and chronic risks for the consumer.

7.3 Diflufenican

General data on diflufenican are summarized in the table below (last updated 2008/03/14)

Table 7.3-1: General information on Difluflenican

Active substance (ISO Common Name)	Diflufenican
IUPAC	2′,4′-difluoro-2-(α,α,α-trifluoro-m-tolyloxy)nicotinani-lide

Chemical structure	
Molecular formula	C19H11F5N2O2
Molar mass	394
Chemical group	herbicide
Mode of action (if available)	
Systemic	Yes
Company (ies)	Bayer Crop Science
Rapporteur Member State (RMS)	CZ
Approval status	COMMISSION DIRECTIVE 2008/66/EC of 30 June 2008
Restriction	diflufenican SANCO/3782/08 – rev. 1 14 March 2008
Review Report	diflufenican SANCO/3782/08 – rev. 1 14 March 2008
Current MRL regulation	Reg. (EU) 2017/623
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes
EFSA Journal : Conclusion on the peer review	EFSA Scientific Report (2007) 122, 1-84
EFSA Journal: conclusion on article 12	EFSA Journal 2013; 11(6):3281
Current MRL applications on intended uses	Reg. (EU) 2017/623

* Notifier in the EU process to whom the a.s. belong(s)
** If yes: EFSA, YYYY - see list of references

7.3.1 Stability of Residues (KCA 6.1)

7.3.1.1 Stability of residues during storage of samples

Available data

No new data submitted in the framework of this application.

Table 7.3-2: Summary of stability data achieved at ≤ - 18°C (unless stated otherwise)

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products			
Wheat	High starch content	24 months	Class T., 2003

Conclusion on stability of residues during storage

Samples of wheat (forage, grain and straw) were fortified at 0.1 mg/kg grain and 0.5 mg/kg forage and straw with diflufenican and were stored in a freezer (at -18°C) for 24 months.

7.3.1.2 Stability of residues in sample extracts (KCA 6.1)

Not relevant for this application, in supervised studies evaluated during Annex I inclusion.

7.3.2 Nature of residues in plants, livestock and processed commodities

7.3.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

No new data submitted in the framework of this application.

Table 7.3-3: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	**Rate (kg a.s./ha)**	**No**	**Sampling (DAT)**	**Remarks**	
EU data								
Cereals	Wheat	Pyridine Difluoro-phenyl Trifluoro-methylphenyl	F	0.19, 0.4 0.94	1	0 and maturity		Oddy A.M., Lowden (2003a) three rings; Williams C.M., Savage E.A. (1984a) England D.A., Savage E.A. (1987a) Oddy A.M., Hatcher G. (2000b) Oddy A., Lowden P. (2003b) Williams C.M., Savage E.A. (1984b)

Summary of plant metabolism studies reported in the EU

Studies were carried out in the UK in 1999/2000. Pyridine, difluorophenyl and trifluromethylphenyl ring labelled [14C] diflufenican (radiochemical purity >98%) were applied (formulated as a suspension concentrate) to field grown wheat, as either a pre-emergence or a post emergence (GS13/14-3/4 leaves- which is in-line with the existing use) application, at a rate of either 0.19 (1.6N) or 0.4 (3N) or 0.94 (8N) kg as/ha. Samples were taken of the immature (forage) and maturity crop. All the samples were analysed by LSC following combustion. Selected samples were also extracted with methanol/water (grain only-pre-emergence only), sodium chloride solution (grain only), acetonitrile/water (all except grain), methanol (all except grain) and acetone (pyridine label post emergence straw only). The resulting extracts were analysed by LSC, TLC and HPLC. The remaining unextractable material was combusted and analysed by LSC. The total [14C] residues at harvest in the grain and straw for the pre and post emergence applications (1.6N) were less than 0.01 mg/kg, with the exception of straw from the pre and post-emergence pyridine study and the post emergence trifluromethylphenyl study (0.01 mg/kg). On characterisation (1.6N studies) of the extractable radioactivity) one major component was identified in the straw at harvest as parent diflufenican, which accounted for 2-16% of the total radioactivity in the straw for the pre and post-emergence treatments (parent was also identified in the grain but the amount present was not quantified due to the low levels of radioactivity in the grain). One other metabolite was identified, plus several unknowns which individually did not represent more than 10% (<0.01 mg/kg) of the total radioactivity in the straw, with the exception of one unknown polar metabolite, which accounted for up to 70% (<0.01 mg/kg) of the total radioactivity in the straw. The remaining unextractable radioactivity in the straw accounted for less than 0.01 mg/kg

Conclusion on metabolism in primary crops

The metabolism of diflufenican was investigated in wheat, by applying pyridine, difluorophenyl and trifluromethylphenyl ring labelled [14C] diflufenican as either a pre or a post-emergence foliar application, at rate of 1 x 0.19 kg as/ha (1.6N). At harvest the total [14C] residues (expressed as parent equivalent) in grain and straw were less than 0.01 mg/kg, with the exception of straw from the pre and post-emergence pyridine study and the post emergence trifluromethylphenyl study (0.01 mg/kg). On characterisation of the extractable radioactivity one major component was identified in the straw at harvest as parent diflufenican, which accounted for 2-16% of the total radioactivity in the straw for the pre and post-emergence treatments (parent was also identified in the grain but the amount present was not quantified). One other metabolite was identified, plus several unknowns which individually did not represent more than 10% (<0.01 mg/kg) of the total radioactivity in the straw, with the exception of one unknown polar metabolite, which accounted for up to 70% (<0.01 mg/kg) of the total radioactivity in the straw. The remaining unextractable radioactivity in the straw accounted for less than 0.01 mg/kg. Based on the plant metabolism data submitted for wheat, residues in cereals should be defined as diflufenican.

7.3.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

No new data submitted in the framework of this application.

Table 7.3-4: Summary of metabolism studies in rotational crops

Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G *	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks	
EU data								
Leafy vegetables	Cabbage	Pyridyl, amiline and phenyl ring	Soil, F	0.36	12 weeks	At maturity		Oddy A 2003c.; Oddy A., Do-ble M. 2003a; Lowden P., Oddy A.M.,
Root and tuber vegetables	Sugar beet	Pyridyl, amiline and phenyl ring	Soil, F	0.36	12 weeks	At maturity		

								Parsons R.G., Summerfield M. 1999a;
Cereals	Wheat	Pyridyl, amiline and phenyl ring	Soil, F	0.36	12 weeks	At maturity		

* Outdoor/field application (F) or glasshouse/protected/indoor application (G)

Summary of plant metabolism studies reported in the EU

Field trials were conducted in 2002 in the UK, growing wheat, cabbage, sugar beet in soil treated (bare ground application) with pyridine, difluorophenyl and trifluromethylphenyl ring labelled [14C] diflufenican (dissolved in acetone; radiochemical purity >99%), at a rate of 0.36 kg as/ha (represents an accumulation pleateau for several years application of diflufenican at 0.19 kg as/ha [max application rate applied]). The crops were planted 12 weeks after application (in a crop failure situation following crops [according to the label] must not be planted until 12 weeks after the initial application of diflufenican). All samples were analysed by LSC, following combustion. Samples were also sequentially extracted with sodium chloride solution (grain only), acetonitrile (cabbage and sugar beet only) and acetonitrile/water.The resulting extracts were analysed by LSC, TLC, HPLC-UV and LC-MS/MS. The remaining unextractable material (wheat grain and straw) was further extracted by enzyme (cellulose and mecielase) and acid hydrolysis, before being combusted and analysed by LSC. The total [14C] residues in the mature crops at harvest (expressed as parent equivalent) were less than 0.06 mg/kg, with the exception of straw (0.08 – 0.17 mg/kg). On characterisation of the extractable radioactivity three components were identified in the crops at harvest as parent diflufenican and its metabolites 2-(3-trifluoromethyl-phenoxy)-nicotinamide and 2-(3-trifluoromethylphenoxy)-nicotinic acid. For cabbage the three components accounted for up to 47% of the total radioactivity in the crop at harvest. One other unknown metabolite was present at a level of less than 0.01 mg/kg. The remaining unextractable radioactivity in the crop accounted for less than 0.01 mg/kg.
For sugar beet tops the three components accounted for up to 69% of the total radioactivity in the crop at harvest. One other unknown metabolite was present at a level of less than 0.01 mg/kg. The remaining unextractable radioactivity in the crop accounted for less than 0.01 mg/kg. For sugar beet root the three components accounted for up to 88% of the total radioactivity in the crop at harvest. Two other unknown metabolites were present at levels of less than 0.01 mg/kg. The remaining unextractable radioactivity in the crop accounted for less than 0.01 mg/kg. For wheat grain the three components accounted for up to 5% of the total radioactivity in the crop at harvest, with the majority of the radioactivity (up to 87% [0.03 mg/kg] being associated with polar material resulting from the fragmentation of the compound in the plant or in the soil prior to uptake). The remaining unextractable radioactivity in the crop accounted for 0.01 mg/kg. For wheat straw the three components accounted for up to 13% of the total radioactivity in the crop at harvest, with the majority of the radioactivity (up to 60% [0.08 mg/kg] being associated with polar material resulting from the fragmentation of the compound in the plant or soil prior to uptake). One other unknown metabolite was present at a level of less than 0.01 mg/kg. The remaining unextractable radioactivity in the crop accounted for less than 0.07 mg/kg and was probably associated with the fragmentation of

Conclusion on metabolism in rotational crops

On characterisation of the extractable radioactivity three components were identified in the crops at harvest as parent diflufenican and its metabolites 2-(3-trifluoromethylphenoxy)-nicotinamide and 2-(3-trifluoromethyl-phenoxy)-nicotinic acid. For cabbage the three components accounted for up to 47% of the total radioactivity in the crop at harvest. One other unknown metabolite was present at a level of less than 0.01 mg/kg. The remaining unextractable radioactivity in the crop accounted for less than 0.01 mg/kg. For sugar beet tops the three components accounted for up to 69% of the total radioactivity in the crop at harvest. One other unknown metabolite was present at a level of less than 0.01 mg/kg. The remaining unextractable radioactivity in the crop accounted for less than 0.01 mg/kg. For sugar beet root the three components accounted for up to 88% of the total radioactivity in the crop at harvest. Two other unknown metabolites

were present at levels of less than 0.01 mg/kg. The remaining unextractable radioactivity in the crop accounted for less than 0.01 mg/kg. For wheat grain the three components accounted for up to 5% of the total radioactivity in the crop at harvest, with the majority of the radioactivity (up to 87% [0.03 mg/kg] being associated with polar material resulting from the fragmentation of the compound
in the plant or in the soil prior to uptake). The remaining unextractable radioactivity in the crop accounted for 0.01 mg/kg. For wheat straw the three components accounted for up to 13% of the total radioactivity in the crop at harvest, with the majority of the radioactivity (up to 60% [0.08 mg/kg] being associated with polar material resulting from the fragmentation of the compound in the plant or soil prior to uptake). One other unknown metabolite was present at a level of less than 0.01 mg/kg. The remaining unextractable radioactivity in the crop accounted for less than 0.07 mg/kg and was probably associated with the fragmentation of the compound and the natural incorporation of these fragments into the plant tissue.

7.3.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

No new data submitted in the framework of this application.
No investigation or the behaviour and the level of residues under processing conditions is necessary due to the insignificant level of residues in wheat grain. Straw is usually not processed.
Residues in cereal grain were less than 0.01 mg/kg
Conclusion on nature of residues in processed commodities

As residues of diflufenican exceeding 0.1 mg/kg are not expected in the treated crops and since the chronic exposure does not exceed 10% of the ADI, there is no need to investigate the effect of industrial and/or household processing.

7.3.2.4 Conclusion on the nature of residues in commodities of plant origin (KCA 6.7.1)

Table 7.3-5: Summary of the nature of residues in commodities of plant origin

Endpoints	
Plant groups covered	Cereals (Wheat)
Rotational crops covered	Leafy vegetable, roo and tuber vegetables, cereals
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	a.s. is stable
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes
Plant residue definition for monitoring	Diflufenican (Regulation n° 2017/623) **
Plant residue definition for risk assessment	Diflufenican (EFSA 2013)***
Conversion factor from enforcement to RA	none

* If residue pattern in processed commodities is not similar to that in raw commodities
** A more recent proposal by EFSA may be provided as additional information (EFSA RO XXXX).
*** If no EFSA proposal is available, a proposal should be made by the applicant/zRMS.

7.3.2.5 Nature of residues in livestock (KCA 6.2.2-6.2.5)

Available data

No new data submitted in the framework of this application.

Table 7.3-6: Summary of animal metabolism studies

Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling	
EU data								
Lactating ruminants	Cow	Pyridyl ring	1	0.2 or 2	7	Milk	twice daily	xxxxx. 1989a;
						Urine and faeces	daily	
						Tissues	at sacrifice	
Lactating ruminants	Cow	Aniline ring	1	0.035 or 0.717	7	Milk	twice daily	xxxxx . 2000a;
						Urine and faeces	daily	
						Tissues	at sacrifice	
Laying poultry	Hens	Aniline ring	5	0.17 or 1.92	14	Eggs	Daily	xxxxx. 20001
						Excreta	Daily	
						Tissues	At sacrifice	

Summary of plant metabolism studies reported in the EU

The metabolism and distribution in animals was investigated in lactating cows and chickens, using difluorophenyl and pyridine ring labelled [^{14}C] diflufenican. For lactating cows dosed at rates of 1 (2N for dairy cattle; 0.8N for beef cattle based on the highest residues in cereal grain and straw) and 20 mg/kg (40N for dairy cattle; 15N for beef cattle) in feed in the case of the difluorophenyl study and 5 (10N for dairy cattle; 4N for beef cattle) and 50 mg/kg (100N for dairy cattle; 40N for beef cattle) in feed in the case of the pyridine study, overall recovery of radioactivity was 70-86% (the remaining 14-30% was assumed to be present in the gastrointestinal tract), the bulk of the radioactivity was excreted (70-86%), with less than 0.1% in the milk and less than 0.2% in the tissues. On characterisation of the extractable radioactivity one major component was identified in the milk as parent diflufenican which representing 48-52% of the total radioactivity in the milk. Two other metabolites were identified, plus several unknowns which individually were present at levels of less than 0.01 mg/kg. The remaining unextractable radioactivity, accounted for 22-26% (<0.01 mg/kg) of the total radioactivity in the milk. On characterisation of the extractable radioactivity in the tissues one major component was identified in the fat as parent diflufenican, representing 82-91% of the total radioactivity in the fat. The remaining unextractable radioactivity, accounted for less than 0.03 mg/kg of the total radioactivity in the fat. For liver, several metabolites were tentatively identified as diflufenican, hydroxylated diflufenican and hydroxylated anilines/deflouorinated hydroxylated analines, however none were present at a detectable level, with the exception of 2-(3-trifluoromethylphenoxy)-nicotinamide (M&B38181) [0.02 mg/kg]. The remaining unextractable radioactivity, accounted for 0.09 (difluorophenyl study) and 0.26 (pyridine study) mg/kg of the total radioactivity in the liver. For kidney (difluorophenyl only), several metabolites were tentatively identified as hydroxylated anilines/deflouorinated hydroxylated analines, however none were present at a detectable level. The remaining unextractable radioactivity, accounted for 38% (0.01 mg/kg) of the total radioactivity in the kidney. For chickens dosed at a rate of 1 and 20 mg/kg in feed (100 and 2000N based on the highest residue in grain), the overall recovery of radioactivity was 85-89%, the bulk of which was excreted (85-89%), with less than 0.3% in the eggs and less than 0.1% in the tissues. On characterisation of the extractable radioactivity one major component was identified in the eggs as parent diflufenican, which representing 66-75% of the total radioactivity in the egg yolk. One other unknown metabolite was isolated was present at level of less than 0.02 mg/kg in the 20 mg/kg study. The remaining unextractable radioactivity, accounted for less than 0.08 mg/kg (20 mg/kg study). On characterisation of the extractable radioactivity in the tissues one major component was identified in the fat as parent diflufenican, representing 88-90% of the total radioactivity in the fat. One unknown metabolite was isolated which was at a level of less than 0.01 mg/kg. The remaining unextractable radioactivity, accounted for less than 0.06 mg/kg (20 mg/kg study) of the total radioactivity in the fat. For muscle, one major component was identified as parent diflufenican, representing 42-97% of the total radioactivity in the muscle. One unknown metabolites was isolated which was at a level of less than 0.01 mg/kg. The remaining unextractable radioactivity, accounted for less than 0.01 mg/kg of the total radioactivity in the muscle. For liver, one major component was identified as parent diflufenican, representing 36% of the total radioactivity in the liver. The remaining unextractable radioactivity, accounted for less than 0.2 mg/kg (20 mg/kg study) of the total radioactivity in the liver. For kidney, no component was present at a level greater than 0.01 mg/kg. The remaining unextractable radioactivity, accounted for less than 0.05 mg/kg (20 mg/kg study) of the total radioactivity in the kidney

Conclusion on metabolism in livestock

Based on the metabolism data submitted for domestic animals, residues in products of ruminant origin should be defined as parent diflufenican.

7.3.2.6 Conclusion on the nature of residues in commodities of animal origin (KCA 6.7.1)

Table 7.3-7: Summary on the nature of residues in commodities of animal origin

	Endpoints
Animals covered	Lactating goats
	Laying hens
Time needed to reach a plateau concentration	3 days in milk
	8days in eggs
Animal residue definition for monitoring	Diflufenican (Regulation n° 2017/623)
Animal residue definition for risk assessment	Diflufenican (EFSA 2013)
Conversion factor	None
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	Yes

* A more recent proposal by EFSA may be provided as additional information (EFSA RO XXXX)
** If no EFSA proposal is available, a proposal should be made by the applicant/zRMS.
*** If metabolism in rat and ruminant are not similar

7.3.3 Magnitude of residues in plants (KCA 6.3)

7.3.3.1 Summary of European data and new data supporting the intended uses

No new data are submitted in the framework of this application.

Table 7.3-8: Summary of EU reported and new data supporting the intended uses of CHR/H/FDF 574 SC and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Cereals	EFSA Scientific Report (2007) 122, 1-84	N-EU	GAP on which EU a.s. assessment is based: 0.19 kg as/ha, BBCH 30, PHI 14d, outdoor E: 9x <0.01 for grain E: 7x <0.05, 0.14, 0.17 for straw RA: 9x <0.01 for grain	N/A				
	Overall supporting data for cGAP	N-EU	RA: 9x <0.01 for grain	E: 0.01 for grain	E: 0.01 for grain		0.02	Yes

* Source of EU MRL: Reg. (EU) 2017/623

7.3.3.2 Conclusion on the magnitude of residues in plants

According to the available data, the intended uses on cereals are considered acceptable, for both outdoor uses.

The data submitted show that no exceedance of the MRL will occur.

The uses are considered acceptable.

7.3.4 Magnitude of residues in livestock

7.3.4.1 Dietary burden calculation

According to Dar Diflufeican – Volume 3, annex B.7: Residues An assessment of the theoretical maximum and the mean daily intakes by domestic animals from the consumption of cereal grain and cereal straw has been made. The following assumptions have been made:
i) the highest likely inclusion rate of all crops which may have been treated has been used with the proviso that the aggregate does not exceed 100% diet.
ii) all crops which may have been treated, have been treated and contain residues at the following mg/kg levels:

	Highest	Median
Cereal grain:	0.01 mg/kg	0.01 mg/kg
Cereal straw:	2.5 mg/kg	0.69 mg/kg

iii) no loss of residue occurs during transport, storage, processing or preparation of feed prior to consumption.

Table B.7.25 Theoretical maximum daily intakes of diflufenican by domestic animals

	mg/kg diet DM	mg/kg diet AR	mg/animal /day	mg/kg bw/day
Dairy cattle	0.6	0.5	12	0.02
Beef cattle	1.5	1.3	22	0.06
Sheep	1.5	1.3	4.4	0.06
Goat	0.6	0.5	1.8	0.03
Pig	0.01	0.01	<0.1	<0.001
Chicken	0.01	0.01	<0.1	0.001
Turkey	0.01	0.01	<0.1	<0.001

Table B.7.26 Theoretical mean daily intakes of diflufenican by domestic animals

	mg/kg diet DM	mg/kg diet AR	mg/animal /day	mg/kg bw/day
Dairy cattle	0.2	0.1	3.3	0.006
Beef cattle	0.4	0.4	6.1	0.02
Sheep	0.4	0.4	1.2	0.02
Goat	0.2	0.1	0.5	0.007
Pig	0.01	0.01	<0.1	<0.001
Chicken	0.01	0.01	<0.1	0.001
Turkey	0.01	0.01	<0.1	<0.001

Based on the intakes calculated above and the animal metabolism studies, residues in animal products would be not be expected to be above the limit of determination (0.01 mg/kg milk, 0.02 mg/kg in muscle, eggs, fat, kidney and liver).

7.3.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

No new data were submitted in the framework of this application.
According to the mentioned metabolism studies, it is concluded that, after exposure to maximum dietary burden, residue levels in ruminant commodities are expected to remain below the enforcement LOQ. Hence, no livestock feeding study is needed.

Pigs and poultry are not expected to be exposed to significant levels of diflufenican residues.
No data were submitted or required as no residues of diflufenican above the limit of quantification are likely to occur in edible animal matrices according to the diflufenican residue levels found in the metabolism study

7.3.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation) (KCA 6.5.2-6.5.3)

As residues of diflufenican exceeding 0.1 mg/kg are not expected in the treated crops and since the chronic exposure does not exceed 10% of the ADI, there is no need to investigate the effect of industrial and/or household processing.

7.3.6 Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation.

Considering available data dealing with nature of residues (see **Błąd! Nie można odnaleźć źródła odwołania.**), no study dealing with magnitude of residues in succeeding crops is needed.

7.3.6.1 Field rotational crop studies (KCA 6.6.2)

Available data

No new data submitted in the framework of this application.

Table 7.3-9: Summary of available studies in field rotational crops

Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G *	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks	
EU data								
Leafy vegetables	Cabbage	Pyridyl, amiline and phe-nyl ring	Soil, F	0.36	12 weeks	At maturity		Oddy A 2003c.; Oddy A., Do-ble M. 2003a; Lowden P., Oddy A.M., Parsons R.G., Sum-merfield M. 1999a;
Root and tuber vegetables	Sugar beet	Pyridyl, amiline and phe-nyl ring	Soil, F	0.36	12 weeks	At maturity		
Cereals	Wheat	Pyridyl, amiline	Soil, F	0.36	12 weeks	At maturity		

		and phe-nyl ring						

Conclusion on rotational crops studies

During the peer-review, it was concluded that no residues above 0.01 mg/kg were expected in succeeding crops because in the representative use on cereals, the critical dose rate was only 0.12 kg a.s./ha.

7.3.7 Other / special studies (KCA6.10, 6.10.1)

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of CHR/H/FDF 574 SC. Therefore, other special studies are not needed.

7.3.8 Estimation of exposure through diet and other means (KCA 6.9)

Toxicological reference values relevant for dietary risk assessment are reported in the summary of the evaluation (see 7.1.2).

As ARfD was not deemed necessary, acute risk assessment is not relevant.

7.3.8.1 Input values for the consumer risk assessment

Table 7.3-10: Input values for the consumer risk assessment

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Wheat	0.02	Reg. (EU) 2017/623
Barley	0.02	Reg. (EU) 2017/623
Rye	0.02	Reg. (EU) 2017/623
Other	0.01	Reg. (EU) 2017/623

7.3.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.3-11: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo	0.1 % (based on DK child)
IEDI (% ADI) according to EFSA PRIMo	0.1 % (based on DK child)

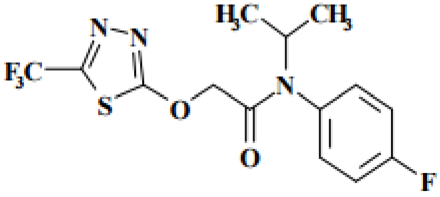
* include raw and processed commodities if both values are required for PRIMo
** if national model is available

The proposed uses of diflufenican in the formulation CHR/H/FDF 574 SC do not represent unacceptable chronic risks for the consumer

7.4 Flufenacet

General data on Flufenacet are summarized in the table below (last updated 2016/12/08):

Table 7.4-1: General information on Flufenacet

Active substance (ISO Common Name)	**Flufenacet**
IUPAC	4'-fluoro-N-isopropyl-2-[5-(trifluoromethyl)-1,3,4 thiadi-azol-2-yloxy]acetanilide
Chemical structure	
Molecular formula	$C_{14}H_{13}F_4N_3O_2S$
Molar mass	363.34 g/mol
Chemical group	oxyacetanilide herbicide
Mode of action (if available)	group K3 HRAC inhibition of the biosynthesis of very long chain fatty acids (VLCFAs) resulting in inhibition of cell division and cell growth
Systemic	Systemic, with apoplastic transport and distribution
Company (ies)	Bayer Crop Science
Rapporteur Member State (RMS)	UK
Approval status	Approved 01/01/2004 Commission Directive 2003/84/EC of 25 September 2003
Restriction	See Commission Directive 2003/84/EC of 25 September 2003
Review Report	SANCO/7469/VI/98-Final 3 July 2003
Current MRL regulation	Commission Regulation (EU) No 1127/2014 of 20 October 2014
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	EFSA Journal 2012;10(4):2689
EFSA Journal : Conclusion on the peer review	N/A
EFSA Journal: conclusion on article 12	EFSA Journal 2012;10(4):2689
Current MRL applications on intended uses	Commission Regulation (EU) No 1127/2014 of 20 October 2014

7.4.1 Stability of Residues (KCP 6.1)

7.4.1.1 Stability of residues during storage of samples

Available data

Storage stability data was reported in Annex I inclusion (Bosnak, L. L.; 1997). The freezer storage stability of flufenacet (FOE 5043) and 5 of its metabolites (FOEoxalate, FOE sulfonic acid, FOE thioglycolate sulfoxide, FOE methylsulfoxide, and FOE methylsulfone) was examined in commodities of three different

crops, representing oil-, starch- and water containing materials. Field grown corn grain, forages, and fodder; soybean seeds, forage, and hay; and turnip roots and tops were fortified at a nominal rate of 1 mg/kg with the radiolabeled compounds. The first study covers a storage period of 11 months for all commodities. In the addendum, freezer storage stability data for turnips up to 20 months and for corn and soybean commodities up to 28 months were reported. The results show that residues of flufenacet and its metabolites are stable in all tested matrices under frozen conditions for at least as long as the storage stability studies lasted. Storage stability data were considered appropriate in the Monograph (Annex B6)
No new data submitted in the framework of this application.

Table 7.4-2: Summary of stability data achieved at ≤ - 21°C (unless stated otherwise)

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products			
Corn grain	High starch content	28 months	Monograph Annex B 6 Bosnak, L. L.; 1997
Corn forage	High starch content	28 months	Monograph Annex B 6 Bosnak, L. L.; 1997
Corn fodder	High starch content	28 months	Monograph Annex B 6 Bosnak, L. L.; 1997
Soybean seed	High lipid content	28 months	Monograph Annex B 6 Bosnak, L. L.; 1997
Soybean forage	High lipid content	28 months	Monograph Annex B 6 Bosnak, L. L.; 1997
Soybean hay	High lipid content	28 months	Monograph Annex B 6 Bosnak, L. L.; 1997
Turnip roots	High water content	20 months	Monograph Annex B 6 Bosnak, L. L.; 1997
Turnip tops	High water content	20 months	Monograph Annex B 6 Bosnak, L. L.; 1997
Animal Products - not required			

Conclusion on stability of residues during storage

The storage stability evaluated during Annex I inclusion covers plant matrices for use CHR/H/FDF 574 SC according to the label, therefore no new studies are necessary.

7.4.1.2 Stability of residues in sample extracts (KCP 6.1)

Not relevant for this application, in supervised studies evaluated during Annex I inclusion and presented in Monograph Flufenacet Annex B 6 -Residues 1997 , analysis time were less than 24 hours between extraction and analysis.

7.4.2 Nature of residues in plants, livestock and processed commodities

7.4.2.1 Nature of residue in primary crops (KCP 6.2.1)

Available data

The nature of residues in primary crops were evaluated during Annex I inclusion, and presented in Monograph Flufenacet Annex B 6 -Residues 1997.

No new data submitted in the framework of this application.

Table 7.4-3: Summary of plant metabolism studies

Crop Group	**Crop**	**Label position**	**Application and sampling details**					**Reference**
			Method, F or G (a)	**Rate (kg a.s./ha)**	**No**	**Sampling (DAT)**	**Remarks**	
EU data								
Cereals	Corn (maize)	[Fluorophenyl-UL-^{14}C]	F	1.37	1	96 days (forage and fresh kernels) And 110 d (fodder and dry kernels)	-	Baird, J. H.; 1994;
Oilseeds	Soybean	[Fluorophenyl-UL-^{14}C] [Thiadiazole-2-^{14}C]	F F	1.485 1.38	1 1	20 d, 42d, 66 d, 80 d. 21 d, 48d, 91d and 105d	-	Krolski, M. E.; Bosnak, L. L.; 1995
	Cotton	[Fluorophenyl-UL-^{14}C]	F	1.778	1	21 d, 43 d and 156 d		Krolski, M. E.; Bosnak, L. L.; 1995
Plant cell suspension cultures	Soybean, wheat, peanut, corn, cotton	[Fluorophenyl-UL-^{14}C] [Thiadiazole-2-^{14}C]	Lab	-	-	-	-	Koester, J.; Brauner, A.; 1995

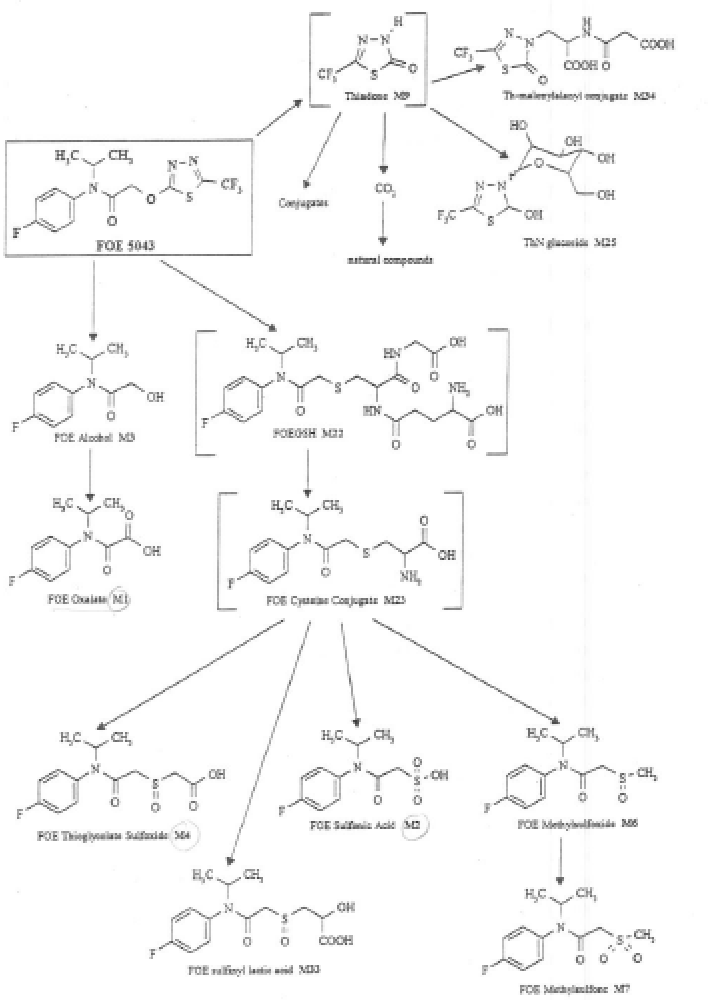
Summary of plant metabolism studies reported in the EU

Most of the plant metabolism studies were conducted with [fluorophenyl-UL-14C]flufenacet. These studies included maize/corn, soybeans and cotton (all pre-planting treatment) as well as the rotated crops kale, turnip and wheat with different plant back intervals. For soybeans (pre-planting treatment) and the rotated crops the [thiadiazole-2-14C] label was used additionally. These studies were submitted with the dossier for Annex I listing of flufenacet according to EU directive 91/414/EEC and reported.

A summary of the results of these studies were evaluated during Annex I application. The initial metabolic reaction is cleavage of the molecule into the thiadone and acetamide moiety. While the resulting thiadone (M09) itself was not observed, various conjugates were formed, the most important being the corresponding N-glucoside (M25). In soybeans, the malonylalanine conjugate (M34) predominated.
The fluorophenyl-acetamide portion is directly conjugated with glutathione (GSH) or homoglutathione (hGSH) and further metabolized yielding the transient FOE cysteine conjugate (M23). All subsequent metabolites can be considered as hydrolysis, oxidation and conjugation products of the glutathione pathway. However, the FOE oxalate (M01) most likely arose through direct oxidation of the transient hydrolysis product of flufenacet, the primary alcohol (FOE alc, M03).
From these studies a conclusion on the residue definition in food of plant origin was made: “The metabolism of the flufenacet results in a number of metabolites, which all have the common moiety Nisopropyl- 4-fluorophenyl. Although no parent compound was found in any study and only three

metabolites were of quantitative significance (M01: FOE oxalate; M02: FOE sulfonic acid, M04: FOE thioglycolate sulfoxide) a **“total residue“ approach is proposed, based on the total amount of Nfluor-ophenyl- N-isopropyl derived residues**.” (Monograph on FOE 5043 (flufenacet), Annex B.6, Section B.6.3.

Proposed metabolic pathway of Flufenacet (FOE 5043) in plants:



Conclusion on metabolism in primary crops

The metabolism in primary crops presented during Annex I inclusion, covers use of CHR/H/FDF 574 SC. No new studies were necessary.

7.4.2.2 Nature of residue in rotational crops (KCP 6.6.1)

Available data

The nature of residues in rotational crops were evaluated during Annex I inclusion, and presented in Monograph Flufenacet Annex B 6 -Residues 1997.

No new data submitted in the framework of this application.

Table 7.4-4: Summary of metabolism studies in rotational crops

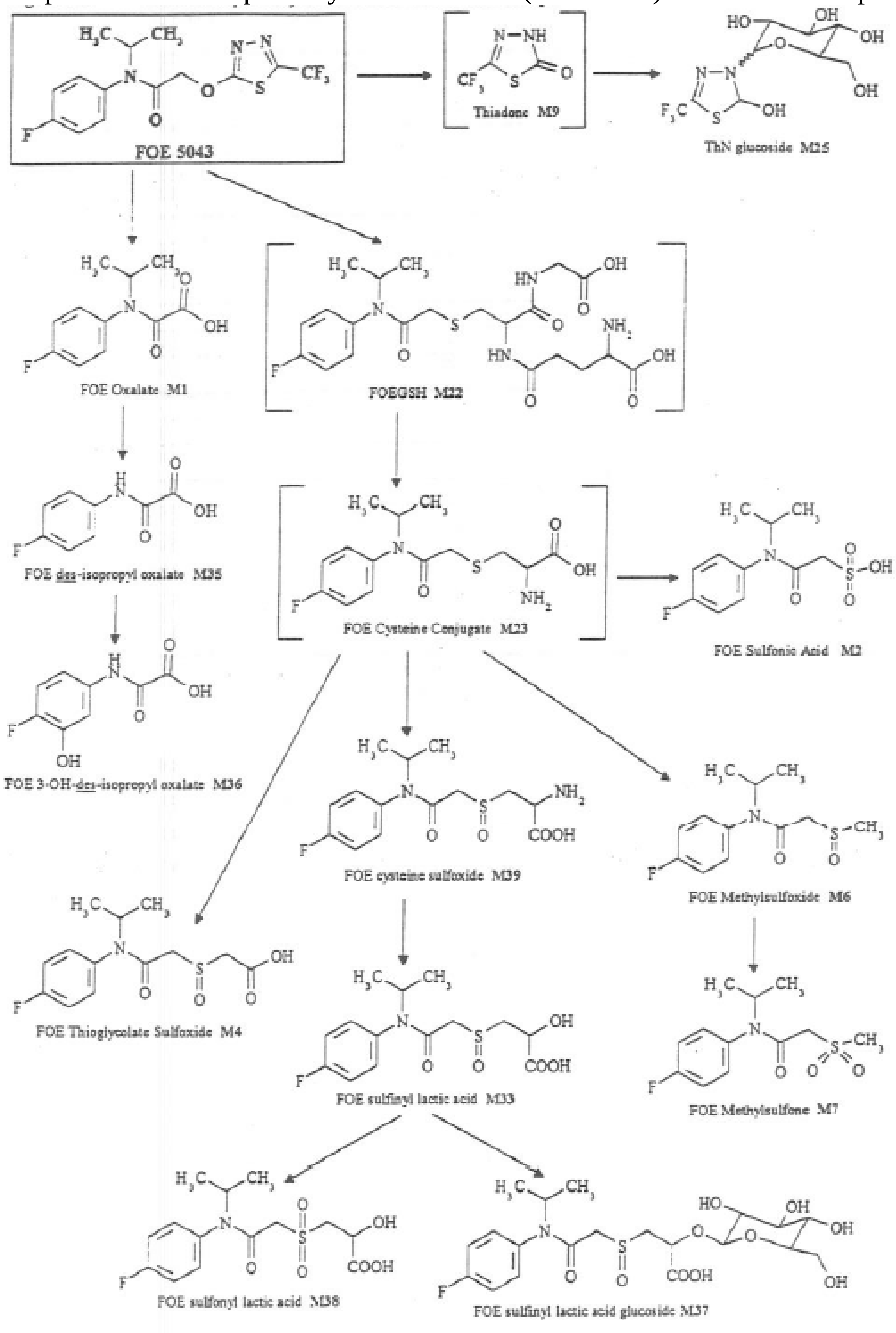
Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G *	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks	
EU data Syngenta studies on Annex I								
Leafy vegetables	Kale	[Fluorophenyl-UL-14C] [Thiadiazole-2-14C]	F	0.9 kg a.s./ha	1 month 4-5 months 12 months	33d,157d,361d 30d,120d,365d	none	Lenz, M.F. McKinney, M.K. (1994) Harlarnkar, P.P., Mennicke, E.J. (1995)
Root and tuber vegetables	Turnips	[Fluorophenyl-UL-14C] [Thiadiazole-2-14C]	F	0.9 kg a.s./ha	1 month 4-5 months 12 months	33d,157d,361d 30d,120d,365d	none	Lenz, M.F. McKinney, M.K. (1994) Harlarnkar, P.P., Mennicke, E.J. (1995)
Cereals	Wheat	[Fluorophenyl-UL-14C] [Thiadiazole-2-14C]	F	0.9 kg a.s./ha	1 month 4-5 months 12 months	33d,157d,361d 30d,120d,365d	none	Lenz, M.F. McKinney, M.K. (1994) Harlarnkar, P.P., Mennicke, E.J. (1995)

Summary of plant metabolism studies reported in the EU

The results of the confined rotational crop studies demonstrate that the metabolic pattern after application of FOE 5043 (flufenacet) is similar in target crops and crops grown in rotation. No active ingredient was found and all metabolites are derived by the same metabolic pathway via glutathione and homoglutathione, which is common to all plant species. Although several additional compounds were only observed in rotational crops, they are considered as products of further metabolism of known metabolites. Most of them should be detectable with the total residue method developed for plant residue analysis and/or are considered of being of no relevance because they are not expected to appear in significant amounts.
After normal agricultural use of FOE 5043 no significant residues are to be expected in leafy or root crops grown in rotation with the target crops, even at rates which are considerably higher than the highest recommended field application in Europe. According to the above mentioned studies the only exception would be wheat (which at the same time is also a target crop).Therefore, it is concluded, that the high residue levels in the confined rotational crop study are a consequence of the experimental design and do not reflect normal practice relevant conditions. Consequently, a field rotational crop study is considered as not being necessary.

Evaluation in EFSA Reasoned Opinion on existing MRLs (EFSA Journal 2012;10(4):2689)
In the DAR it was concluded that after use of flufenacet according to the GAPs, no significant residues are expected in leafy or root crops grown in rotation with the primary crops. According to the confined rotational crop metabolism studies the only exception to this would be wheat. However an assessment of the results from field trials in cereals and maize shows that no residues are detected in any trial, except in green material sampled within 40 days of application and therefore it was concluded in the DAR that the high residue levels seen in wheat were a consequence of the experimental design and do not reflect normal practice. Considering, also, that the application rate of flufenacet within the EU ranges between 0.15-0.6 kg a.s./ha it can be concluded that flufenacet residue levels in rotational commodities are not expected to exceed 0.01 mg/kg, provided flufenacet is applied in compliance with the GAPs reported in Appendix A.

Proposed metabolic pathway for Flufenacet (FOE 5043) in rotational crops:



Conclusion on metabolism in rotational crops

A similar profile as in primary crops is observed in the rotational crops.
The metabolism in rotational crops covers use of CHR/H/FDF 574 SC according to the label

7.4.2.3 Nature of residues in processed commodities (KCP 6.5.1)

No significant residues, i.e. >0.1 mg/kg, were found in grain and therefore processing studies are not required. No new studies are necessary for CHR/H/FDF 574 SC, since all residues are expected to be below 0.1 mg/kg.

7.4.2.4 Conclusion on the nature of residues in commodities of plant origin (KCP 6.7.1)

Table 7.4-5: Summary of the nature of residues in commodities of plant origin

Endpoints	
Plant groups covered	Cereals (maize) and oilseeds (soybean and cotton)
Rotational crops covered	Kale, Turnips, Wheat
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Not provided and not required
Residue pattern in processed commodities similar to pattern in raw commodities?	Not required
Plant residue definition for monitoring	Sum of all compounds containing the N fluorophenyl-N-isopropyl moiety expressed as flufenacet equivalent Commission Regulation (EU) No 1127/2014 of 20 October 2014
Plant residue definition for risk assessment	Flufenacet including all metabolites containing the Nfluorophenyl- N-isopropyl moiety, expressed as flufenacet 7469/VI/98-Final – 3rd July 2003
Conversion factor from enforcement to RA	Not necessary

7.4.2.5 Nature of residues in livestock (KCP 6.2.2-6.2.5)

Available data

The metabolism in livestock was evaluated during Annex I inclusion, and presented in Monograph Flufenacet Annex B 6 -Residues 1997:

No new data submitted in the framework of this application.

Table 7.4-5: Summary of animal metabolism studies

Group	**Species**	**Label position**	**No of animal**	**Application details**		**Sample details**		**Reference**
				Rate (mg/kg bw/d)	**Duration (days)**	**Commodity**	**Time of sampling**	
EU data								
Poultry	laying	[Fluorophenyl-	10	5	3 days	Milk	daily	xxxxxxxxx

	hen	UL-14C] FOE 5043				Urine and faeces	daily	1995;
						Tissues	daily	
Poultry	laying hen	[Thiadiazole-2-14C] FOE 5043	10	5	3 days	Milk	daily	xxxxxxxxxxx; et al.; 1995;
						Urine and faeces	daily	
						Tissues	daily	
Poultry	laying hen	[Fluorophenyl-UL-14C] FOE oxalate	10	5	3 days	Milk	daily	xxxxxx; et al.; 1995;
						Urine and faeces	daily	
						Tissues	daily	
Lactating ruminants	goat	[Fluorophenyl-UL-14C] FOE 5043	1	5	3 days	Milk	Twice daily	xxxxxxxx 1995;
						Urine and faeces	daily	
						Tissues	daily	
Lactating ruminants	goat	[Thiadiazole-2-14C] FOE 5043	1	5	3 days	Milk	Twice daily	xxxxxxxxxx.; 1995;
						Urine and faeces	daily	
						Tissues	daily	
Lactating ruminants	goat	[Fluorophenyl-UL-14C] FOE oxalate	1	5.12	3 days	Milk	daily	xxxxxxx; et al.; 1995;
						Urine and faeces	daily	
						Tissues	daily	
Rat	rats	[Fluorophenyl-UL-14C] FOE Oxalate [Thiadiazole-2-14C] FOE 5043 [Thiadiazole-5-14C] FOE 5043	10	1.0 and 150	4days	Urine and faeces	daily	xxxxxxxxxxxxx. 1995;
						Tissues	daily	

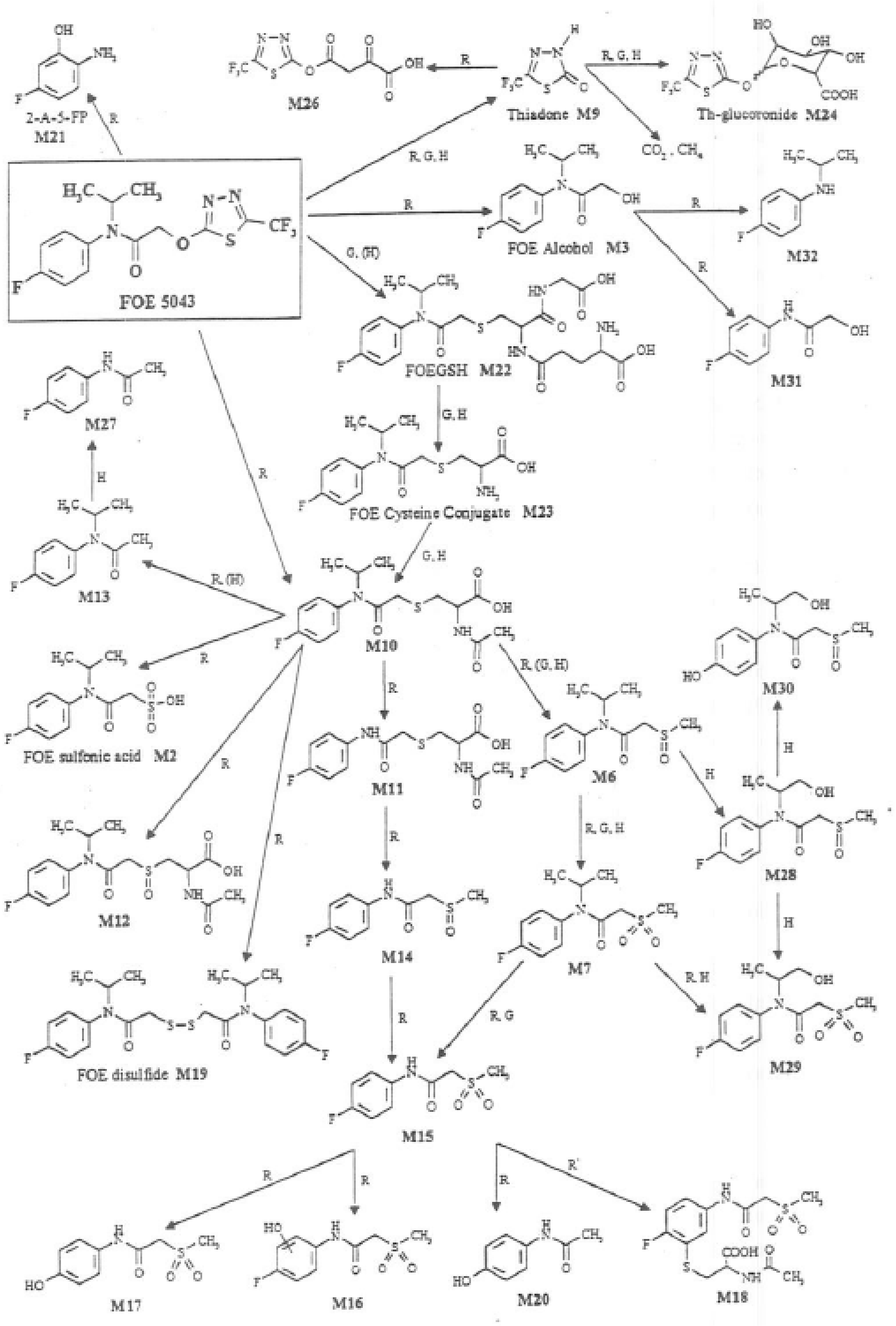
Summary of plant metabolism studies reported in the EU

The nature of flufenacet resides in laying hen was investigated in the framework of Directive 91/414/EEC. The studies used [fluorophenyl-UL-^{14}C]flufenacet , [thiadiazole-2-^{14}C]flufenacet and [fluorophenyl-UL-^{14}C]flufenacet oxalate, the latter one being the main plant metabolite in poultry and ruminant feed. The studies were reviewed in the Monograph (1997).

Since the parent compound degrades rapidly in plants and is not detectable in animal feeding items the metabolism study using [fluorophenyl-UL-^{14}C] FOE oxalate provides the most relevant information. Oral administration of [fluorophenyl-U-^{14}C]flufenacet oxalate to ruminant and poultry showed its metabolic stability. Flufenacet oxalate is essentially not metabolised by the animal. The low residue levels in tissue, milk and eggs suggest that flufenacet oxalate is minimally absorbed and rapidly excreted. This metabolic

stability was confirmed by a bio-availability study of flufenacet oxalate in rats. Following oral administration of radiolabeled flufenacet oxalate to three rats at a dose rate of approx. 1 mg/kg bw 19 – 37% of thedose was excreted with urine and 61 – 80% was excreted with faeces as unchanged flufenacet oxalate. The metabolism studies performed with flufenacet indicate a wide range of metabolites are formed containing the N-fluorophenyl-N-isopropyl moiety.
In the goat Flufenacet is extensively metabolised. The first metabolisation step is conjugation with glutathione. Further biodegradation follows the mercapturic acid pathway, with additional formation of cysteine- or mercapturic acid conjugates.

Proposed metabolic pathway of Flufenacet (FOE 5043) in animals:



Conclusion on metabolism in livestock

All studies presented during Annex I inclusion covers use of CHR/H/FDF 574 SC, therefore no new studies are necessary.

7.4.2.6 Conclusion on the nature of residues in commodities of animal origin

(KCP 6.7.1)

Table 7.4-6: Summary on the nature of residues in commodities of animal origin

	Endpoints
Animals covered	Poultry (hen), Rats, Goat
Animal residue definition for monitoring	sum of all compounds containing the N-fluorophenyl-N-isopropyl moiety expressed as flufenacet *EFSA Journal 2012;10(4):2689*
Animal residue definition for risk assessment	sum of all compounds containing the N-fluorophenyl-N-isopropyl moiety expressed as flufenacet *EFSA Journal 2012;10(4):2689*
Conversion factor	Not available
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	Not available

7.4.3 Magnitude of residues in plants (KCP 6.3)

7.4.3.1 Summary of European data and new data supporting the intended uses

Applicant provide supervised residues studies for Annex I inclusion , which covers critical GAP for Annex I inclusion and cGAP for CHR/H/FDF 574 SC containing Fludioxonil.
Please refer to the Monograph DAR Flufenacet - Volume 3, Annex B.6: Residues. Summary of available studies is presented in Table 7.2.-9.
No new data are submitted in the framework of this application.

Table 7.4-7: Summary of EU reported and new data supporting the intended uses of CHR/H/FDF 574 SC and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Wheat	Monograph DAR 1997 (Flufenacet) Vol3. B6-Residues.	N-EU	GAP on which MRL/EU a.s. assessment is based:1 x 0.24 kg as/ha, BBCH 11-25 , PHI is not relevant, outdoor **Grain:** 17x<0.05 **Straw:** 17x<0.1 **Green material:** 18x<0.05	N/A				
	New trials	N-EU	Now new trials submitted					
	Overall supporting data for cGAP	N-EU	**Grain:** 17x<0.05 **Straw:** 17x<0.1 **Green material:** 18x<0.05	E: 0.05 RA: 0.05	E: 0.05 RA: 0.05	-	0.1 mg/kg	Yes

* Source of EU MRL: No 1127/2014 of 20 October 2014

7.4.3.2 Conclusion on the magnitude of residues in plants

According to the available data, the intended uses on wheat are considered acceptable, for both outdoor use.

All available data presented in EU conclusion is sufficient to support use of CHR/H/FDF 574 SC containing flufenacet, therefore no new studies are necessary.

The data submitted show that no exceedance of the MRL will occur.

The uses are considered acceptable.

7.4.4 Magnitude of residues in livestock

7.4.4.1 Dietary burden calculation

Dietary Burden calculations were performed during Annex I inclusion. New calculations were presented below with MRL-Calculator.

Table 7.4-8: Input values for the dietary burden calculation

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition : Flufenacet				
wheat grain (small)	0.05	Median residue (DAR 1997)	0.05	Highest residue (DAR 1997)
wheat straw	0.1	Median residue (DAR 1997)	0.1	Highest residue (DAR 1997)

Table 7.4-9: Results of the dietary burden calculation

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Risk assessment residue definition: Flufenacet					
Beef cattle*	0.0011	-	grain	0.05	N
Dairy cattle*	0.0017	-	grain	0.05	N
Ram/ewe	0.0023	-	grain/straw	0.07	N
Lamb	0.0034	-	grain	0.08	N
Breeding swine	0.001	-	grain	0.04	N
Finishing swine*	0.000	-	grain	0.04	N
Broiler poultry	0.003	-	grain	0.04	N
Layer poultry*	0.003		grain	0.05	N
Turkey	0.002	-	grain	0.03	N

<u>As no residues were quantified in feed stuff, the values of the LOQ of the analytical plant residue method were used in the calculations. Because of this, the results do not describe a</u>

realistic, but „worst case" situation, according to the results presented in table 7.2-11, no livestock feeding studies are necessary. See Appendix 2 for calculations.

7.4.4.2 Livestock feeding studies (KCP 6.4.1-6.4.3)

According Monograph DAR Flufenacet - Volume 3, Annex B.6: Residues (1997):

As no residues were quantified in feed stuff, the values of the LOQ of the analytical plant residue method were used in the calculations. Because of this, the results do not describe a reali-stic, but „worst case" situation, according to the results presented in table 7.2-11, no livestock feeding studies are necessary.

Livestock feeding studies with Flufenacet are not triggered because firstly the trigger value of 0.1 mg/kg residues in feedstuff is not reached, and because secondly the data from metabolism studies do not indicate a possible transfer from residues in feedstuff to foofstuff. Accordingly, such a study was not conducted in Europe. As however a feeding study from the USA was available, it was submitted by the applicant. In this study, cows were administrated highly exaggerated doses of FOE oxalate, which constitutes a representative metabolite. The results show, that even of a dietary burden of 0.555 ppm (US) would be assumed, no detectable residues of Flufenacet are to be expected in tissues or products of animals, which have been fed crops grown, on FOE 5043-treated soil.

No new data were submitted in the framework of this application.

Withholding period for animal feedingstuffs
According to EU guidance document 7031/VI/95 rev.4 the cereal commodities fed to livestock consist of grain and straw harvested at normal maturity. According to the OECD guidance document on residues in livestock relevant feeding items are grain, straw and cereal forages and silage. The highest levels of flufenacet residues likely to be present in these commodities were taken into account, as appropriate, to evaluate the dietary burden of livestock and when considering the need for MRLs in food of animal origin .It is not necessary to define a withholding period for animal feeding stuff.

7.4.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation) (KCP 6.5.2-6.5.3)

No significant residues, i.e. >0.1 mg/kg, were found in grain and therefore processing studies are not required. No further studies have been performed

7.4.5.1 Available data for all crops under consideration

No new data were submitted in the framework of this application.

7.4.5.2 Conclusion on processing studies

Due to the residues from supervised trials for representative use in winter wheat, all residues are below LOQ, therefore no processing studies are necessary.

7.4.6 Magnitude of residues in representative succeeding crops

Confined rotational crop studies with flufenacet were conducted using the $_{14}$C-labelled test substance, the radiolabel being in the [fluorophenyl-UL-$_{14}$C] and in the [thiadiazole-2-$_{14}$C] -position. These studies were already included in the submission for Annex I inclusion.

The results of the confined rotational crop studies demonstrate that the metabolic pattern after application of FOE 5043 (flufenacet) is similar in target crops and crops grown in rotation. No active ingredient was found and all metabolites are derived by the same metabolic pathway via glutathione and homoglutathione, which is common to all plant species. Although several additional compounds were only observed in rotational crops, they are considered as products of further metabolism of known metabolites. Most of them should be detectable with the total residue method developed for plant residue analysis and/or are considered of being of no relevance because they are not expected to appear in significant amounts.

After normal agricultural use of FOE 5043 no significant residues are to be expected in leafy or root crops grown in rotation with the target crops, even at rates which are considerably higher than the highest recommended field application in Europe. According to the above mentioned studies the only exception would be wheat (which at the same time is also a target crop). However, a comparison with the results from field trials in cereals and maize at recommended application rates of 240 ai/ha and 600 g a.i./ha reveals that no residues were detected. Therefore, it is concluded, that the high residue levels in the confined rotational crop study are a consequence of the experimental design and do not reflect normal practice relevant conditions. Consequently, a field rotational crop study is considered as not being necessary.

7.4.6.1 Field rotational crop studies (KCP 6.6.2)

Field rotational studies are not required.

7.4.7 Other / special studies (KCP6.10, 6.10.1)

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of CHR/H/FDF 574 SC containing Flufenacet. Therefore, other special studies are not needed.

7.4.8 Estimation of exposure through diet and other means (KCA 6.9)

Toxicological reference values relevant for dietary risk assessment are reported in the summary of the evaluation (see 7.1.2).
As ARfD was not deemed necessary, acute risk assessment is not relevant.

7.4.8.1 Input values for the consumer risk assessment

Table 7.4-10: Input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition 1 (if applicable)				
Wheat	0.1	Reg. (EU) No 1127/2014	0.1	Reg. (EU) No 1127/2014
Barley	0.1	Reg. (EU) No 1127/2014	0.1	Reg. (EU) No 1127/2014
Rye	0.05	Reg. (EU) No 1127/2014	0.05	Reg. (EU) No 1127/2014
Other	0.01	Reg. (EU) No 1127/2014	0.01	Reg. (EU) No 1127/2014

7.4.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.4-11: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo	15 % (based on GEMS/Food G06)
IEDI (% ADI) according to EFSA PRIMo	15 % (based on GEMS/Food G06)
IESTI (% ARfD) according to EFSA PRIMo*	Wheat:8 % (based on children/unprocessed) Wheat:5 % (based on adult/unprocessed) Wheat/milling: 7% (based on children/processed) Barley/beer: 4% (based on adult/processed)

* include raw and processed commodities if both values are required for PRIMo
** if national model is available

The proposed uses of flufenacet in the formulation CHR/H/FDF 574 SC do not represent unacceptable acute and chronic risks for the consumer.

7.5 Combined exposure and risk assessment

From a scientific point of view it is regarded necessary to take into account potential combination effects. However, the evaluation of cumulative or synergistic effects as requested by Art. 4 (3b) of Regulation (EC) No. 1107/2009 should only be performed when harmonised "scientific methods accepted by the Authority to assess such effects are available."
Currently, no EU-harmonized guidance is available on the risk assessment of combined exposure to multiple active substances; this approach is not mandatory at EU level.

The following paragraphs are to be considered as proposals, based on "standard" criteria.

The product is a mixture of three active substances, but for only one of them has an acute reference dose been allocated

7.5.1 Acute consumer risk assessment from combined exposure

The product is a mixture of three active substances, but for only one of them has an acute refer-ence dose been allocated. Therefore, the acute consumer risk assessment from combined exposure could not be calculated.

7.5.2 Chronic consumer risk assessment from combined exposure

The uses under consideration provide only a minor contribution to the overall chronic exposure of consumers to pesticide residues. The issue requires a more universal consideration and possibly the generic usage of monitoring data. A harmonised approach is not yet available, and currently no specific consideration is warranted in the scope of this evaluation.

Crop	Active Ingredient	HQ (based on IESTI according to EFSA PRIMo)
Winter cereals	Florasulam	0.003
	Diflufeniacn	0.001
	Flufenacet	0.15
	Cumulative risk Crop 1 (HI)	**0.154**

The Hazard Index is <1. Thus combined exposure to all active substances in product code is not expected to present a consumer risk. No further refinement of the assessment is required.

7.6 References

DAR Florasulam, Volume 3, Annex B, B7
DAR Diflufeniacn, Volume 3, Annex B, B7
SANCO/7469/VI/98-Final 3 July 2003

EFSA Scientific Report (2009) 343, 1-90
EFSA Scientific Report (2007) 122
EFSA Journal 2012;10(4):2689

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Owner
KCP 6.3/01	J. Semrau	2016	Final Report Determination of residues of iodosulfuron-methyl, tribenuron-methyl, florasulam and mefenpyr-diethyl after one application of IDS 100 OD or FLOT 150 WG and Adjuwant Super in wheat at 4 sites in Northern Europe 2016 EAS Study Code S16-02449 Eurofins Agroscience Services GmbH, Stade, Germany GLP yes Unpublished	N	PUH Chemirol Sp. z o.o.

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.1/01	Butler, RE, Gambie, A,	1997	The Stability of DE-570 in Wheat Under Frozen Storage Conditions over 18 months (Interim Report) ST96-001 DowElanco Europe, Letcombe Regis, Oxon, UK GLP yes Unpublished	N	DAS
KCP 6.1/02	Gambie, A, Teas-dale R	1999	The Stability of DE-570 in Wheat Under Frozen Storage Conditions over 18 months (Final Report) ST96-001 DowElanco Europe, Letcombe Regis, Oxon, UK GLP yes Unpublished	N	DAS

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.2.1	Pillar, F.	1997	The Metabolism of XDE-570 in Winter Wheat - Final Report 5U DowElanco Europe, Letcombe Regis, Oxon, UK GLP yes Unpublished	N	DAS
KCP 6.2.2/01	xxxxxxxxxx	1994	Nature of the Residue of [14C]XDE-570 in Lactating Goats MET94017 xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx GLP yes Unpublished	Y	DAS
KCP 6.2.2/02	xxxxxxxxxx	1994	Nature of the Residue of [14C]XDE-570 in Laying Hens MET94018 xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx GLP yes Unpublished	Y	DAS
KCP 6.6.1/01	MacDonald, A.	1997	The Uptake of XDE-570 into Four Succeeding Crops 7U DowElanco Europe, Letcombe Regis, Oxon, UK GLP yes Unpublished	N	DAS
KCP 6.1/02	Adams A.M., Maycey P.A., Savage E.A.	1989	Herbicides: Diflufenican – Storage stability study on cereals Generated by: Rhone-Poulenc; Rhone-Poulenc Ltd. Agriculture, Ongar, Essex, GBR; Analytical Chemistry Department Document No: R008135 GLP / GEP Yes unpublished	N	BCS
KCP 6.1/03	Class T.	2003	Freezer storage stability of diflufenican in cereal (wheat grain, straw and green plant) over 24 months Generated by: BCS, Monheim, Germany; PTRL Europe, Ulm, Germany; Document No: C036072	N	BCS

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GLP / GEP Yes unpublished		
KCP 6.2.1/02	Oddy A.M., Lowden P.	2003	Metabolism, distribution and expression of residues in winter wheat, with compound labelled in each of the three rings; following pre-emergence application (14C)-Diflufenican Generated by: BCS S.A., FRA; Environmental Chemistry, Lyon Battelle AgriFood Ltd., Essex, GBR; Document No: C030791 GLP / GEP Yes	N	BCS
KCP 6.2.1/03	Williams C.M., Savage E.A.	1984	Diflufenican: Metabolism in wheat following pre-emergence application. Generated by: Rhone-Poulenc; May & Baker Ltd., England; Environmental Chemistry Department Document No: R008068 GLP / GEP Yes unpublished	N	BCS
KCP 6.2.1/04	England D.A., Savage E.A.	1987	Diflufenican - Metabolites in wheat grain at harvest following pre-emergence application Generated by: Rhone-Poulenc; May & Baker Ltd., Ongar, Essex, GBR; Environmental Chemistry Document No: R008186 GLP / GEP Yes unpublished	N	BCS
KCP 6.2.1/05	Oddy A.M., Hatcher G.	2000	(14C)-Pyridine labelled diflufenican: metabolism in post emergence treated wheat Generated by: Aventis CropScience UK Limited, GBR; Aventis CropScience UK Limited, GBR; Document No: C010437 GLP / GEP Yes unpublished	N	BCS

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.2.1/06	Oddy A., Lowden P.	2003	(14C)-Diflufenican: Metabolism, distribution and expression of residues in winter wheat, with 2,4-difluorophenyl-ring- labelled and 3- trifluoromethylphenyl-ring-labelled compound following post-emergence treatment Generated by: BCS S.A., FRA; Environmental Chemistry, Lyon Battelle AgriFood Ltd., Essex, GBR; Document No: C030790 GLP / GEP Yes unpublished	N	BCS
KCP 6.2.1./07	Williams C.M., Savage E.A.	1984	Diflufenican: Metabolism in wheat following post-emergence application. Generated by: Rhone-Poulenc; May & Baker Ltd., Ongar, Essex, GBR; Environmental Chemistry Department Document No: R008190 GLP / GEP Yes unpublished	N	BCS
KCP 6.2.2./03	xxxxxxxxxxxxx	1989	(14C)-diflufenican - Absorption, tissue retention, metabolism and execretion in lactating cow. xxxxxxxxxxxxxxxxxxxxxxx Document No: R008143 GLP / GEP Yes unpublished	Y	BCS
KCP 6.2.2./04	xxxxxxxxxxxxxxxx	2000	The distribution and metabolism of (14C)-diflufenican in the lactating cow xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx Document No: C010651 GLP / GEP Yes unpublished	Y	BCS
KCP 6.2.2/05	xxxxxxxxxxxxxxxx	2000	The distribution and metabolism of (14C)-diflufenican in the laying hen xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx Document No: C010650 GLP / GEP Yes unpublished	Y	BCS

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	Vertebrate study Y/N	Owner
KCP 6.3/01	Maycey P.A., Outram J.R.	1988	Herbicides: Diflufenican: Residue studies on cereals, West Germany, 1984/85 Generated by: Rhone-Poulenc Agriculture, UK; Rhone-Poulenc Agriculture, UK; Document No: C022247 GLP / GEP unpublished	N	BCS
KCP 6.3/02	Holmgaard M.	1998	Determination of the residues of flurtamone and diflufenican in winter wheat after a spring application of Bacara - Season 1995, Denmark Generated by: Rhone-Poulenc; Agrolab A/S, Middelfart, Denmark; Grappa, Avignon, France; Rhone-Poulenc Secteur Agro, Lyon, France; Document No: R008241 GLP / GEP Yes unpublished	N	BCS
KCP 6.3/03	Holmgaard M.	1998	Flurtamone and diflufenican Formulation EXP30930A Trials / Denmark / 1995 Residue in winter rye Generated by: Rhone-Poulenc; Agrolab A/S, Middelfart, Denmark; GRAPPA, Avignon, France; Rhone-Poulenc Secteur Agro, Lyon, France; Document No: R008257 GLP / GEP Yes unpublished	N	BCS
KCP 6.3/04	Gloeckner M.	2002	Decline of residues in wheat European Union (northern zone) 2001 Isoproturon + Diflufenican water miscible suspension concentrate (SC), 500 g/L + 62.5 g/L Code: AE F016410 42 SC51 A301 (EXP04072E) Generated by: BCS GmbH, DEU; Residues & Human Exposure, Frankfurt BCS S.A., FRANCE; Centre de la Recherche de la Dargoire, Lyon	N	BCS

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Document No: C025399 GLP / GEP Yes unpublished		
KCP 6.3/04	Gloeckner M.	2002	Residues at harvest in barley European Union (northern zone 2001) isoproturon + diflufenican water miscible suspension concentrate (SC) 500 g/L + 62.5 g/L Code: AE F016410 42 SC51 A301 Generated by: BCS GmbH, DEU; Residues and Human Exposure, Frankfurt BCS S.A., FRANCE; Regulatory Affairs Europe, Lyon Document No: C025428 GLP / GEP Yes unpublished	N	BCS
KCP 6.3/05	Klein E.H.-J.	2003	Residues at harvest in wheat European Union (Northern zone) 2002 Isoproturon + diflufenican, AE F016410 + AE F088657 water miscible suspension concentrate (SC) 45.05% w/w + 5.63% w/w (= 500 g/L + 62.5 g/L) Code: AE F016410 42 SC51 A302 Generated by: BCS GmbH, DEU; Residues and Human Exposure, Frankfurt BCS S.A., FRA; Regulatory Affairs Europe, Lyon Document No: C029587 GLP / GEP Yes unpublished	N	BCS
KCP 6.3/06	Klein E.H.-J.	2003	Decline of residues in wheat European Union (Northern and Southern zone) 2002 Iodosulfuron-methyl-sodium + mesosulfuron-methyl (as sodium salt) + diflufenican + mefenpyr-diethyl water dispersible granule (WG) 0.9 + 2.81 + 45 + 8.1 % w/w Code: AE F1150 Generated by: BCS GmbH, DEU; Residues and Human Exposure, Frankfurt BCS S.A., FRANCE; Regulatory Affairs Europe, Lyon Document No: C031018 GLP / GEP Yes unpublished	N	BCS

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.3/07	Klein E.H.-J.	2003	Decline of residues in wheat European Union (Northern and Southern zone) 2002 Iodosulfuron-methyl-sodium + mesosulfuron-methyl (as sodium salt) + diflufenican + mefenpyr-diethyl water dispersible granule (WG) 0.9 + 2.81 + 45 + 8.1 % w/w Code: AE F1150 Generated by: BCS GmbH, DEU; Residues and Human Exposure, Frankfurt BCS S.A., FRANCE; Regulatory Affairs Europe, Lyon Document No: C031018 GLP / GEP Yes unpublished	N	BCS
KCP 6.2.2/06	Laporte F.	2003	Diflufenican: Rationale for not performing livestock feeding studies Code: AE F088657 Generated by: BCS GmbH, DEU; Residues, Operator and Consumer Safety, Frankfurt Document No: C031485 GLP / GEP unpublished	N	BCS
KCP 6.6.1/01	Lowden P., Oddy A.M., Parsons R.G., Sumerfield M.	1999	(14C)-diflufenican: A confined rotational crop study Generated by: Rhone-Poulenc; Rhone-Poulenc Agriculture Ltd., Essex; Document No: R006362 GLP / GEP Yes unpublished	N	BCS
KCP 6.6.1/02	Oddy A., Doble M.	2003	(14C)-Diflufenican: Confined rotational crop: Characterisation and identification of the residue in wheat straw Generated by: Battelle AgriFood ltd., Essex, GBR; BCS S.A., FRA; Environmental Chemistry, Lyon Document No: C030792 GLP / GEP Yes unpublished	N	BCS

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.6.1/03	Oddy A.	2003	(C-14) Diflufenican: metabolism in crops following planting in soil treated to simulate accumulation. Generated by: Battelle Agrifoodv Ltd. Ongar, UK; Bayer Crop Science, Lyon FRA; Environmental Chemistry Document No: C030793 GLP / GEP Yes unpublished	N	BCS
KCP 6.1/04	Bosnak, L. L.	1995	The storage stability of FOE 5043 and metabolites in corn, soybean, and turpin raw agricultural commodities - Addendum 1 - The storage stability of FOE 5043 and metabolites in corn, soybean, and turnip raw agricultural commodities- 20-month and 28-month data Bayer Corporation, Stilwell, KS, USA Bayer CropScience, Report No.: 106971, GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 6.2.1/08	Baird, J. H.	1994	Metabolism of [fluorophenyl-UL-14C] FOE 5043 in corn Miles Inc., Agriculture Division, Stilwell, KS, USA Bayer CropScience, Report No.: MR105027, Edition Number: M-002270-01-1 Date: 1994-12-19 GLP/GEP: yes, unpublished published: no	N	Bayer CropScience
KCP 6.2.1/09	Krolski, M. E.; Bosnak, L. L.	1995	The metabolism of FOE 5043 in soybeans Bayer CropScience, Report No.: MR105187, GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 6.2.1/10	Krolski, M. E.; Bosnak, L. L.	1995	The metabolism of [Fluorophenyl-UL-14C] FOE 5043 in cotton Bayer Corporation, Stilwell, KS, USA Bayer CropScience, Report No.: MR106666, Edition Number: M-002277-01-1 Date: 1995-12-01 GLP/GEP: yes, unpublished	N	Bayer CropScience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.2.1/11	Koester, J.; Brauner, A.	1995	Degradation of [Fluorophenyl-UL-14C]FOE 5043 and [Thiadiazole-2-14C]FOE 5043 by heterotrophic plant cel suspension cultures (supplemental study in support of biodegradation in plants) Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: PF4049, GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 6.2.2/07	xxxxxxxxx	1995	Metabolism of [Fluorophenyl-UL-14C] FOE 5043 in laying hens xxxxxxxxxxxxxxxxxx Report No.: MR103946, Edition Number: M-002251-01-1 Date: 1995-03-24 GLP/GEP: yes, unpublished	Y	Bayer CropScience
KCP 6.2.2/08	xxxxxxxxx	1995	Metabolism of [Thiadiazole-2-14C] FOE 5043 in laying hens xxxxxxxxxxxxxxxxxxx Report No.: MR106785, GLP/GEP: yes, unpublished	Y	Bayer CropScience
KCP 6.2.2/09	xxxxxxxxx	1995	Metabolism of [phenyl-UL-14C] FOE oxalate in laying hens xxxxxxxxxxxxxxxxxx Report No.: MR106787, Date: 1995-04-11 GLP/GEP: yes, unpublished	Y	Bayer CropScience
KCP 6.2.2/10	xxxxxxxxxxx	1995	Metabolism of [Fluorophenyl-UL-14C] FOE 5043 in a lactating goat xxxxxxxxxxxxxxxxx Report No.: MR105184, Date: 1995-03-03 GLP/GEP: yes, unpublished	Y	Bayer CropScience
KCP 6.2.2/11	xxxxxxxxxx	1995	Metabolism of [thiadiazole-2-14C] FOE 5043 in a lactating goat xxxxxxxxxxxxxxxxxxx Report No.: MR105184, Date: 1995-03-03 GLP/GEP: yes, unpublished		

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.2.2/12	xxxxxxxxxxxxx	1995	The metabolism of FOE 5043 in rats. xxxxxxxxxxxxxxxxxxxxx Report No MR106665 GLP/GEP: yes, unpublished	Y	Bayer CropScience
KCP 6.3/08	Seym, M.	1996	Determination of residues of FOE 5043 60 WG in/on winter barley, winter rye and winter wheat following early postemergence spray application in Germany and France Bayer AG, Leverkusen, Germany Bayer CropScience, Report includes Trial Nos.: 400351 400378 400386 400394 401528 401544 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 6.3/09	Jersch-Schmitz, S.; Seym, M.	1995	Determination of residues of FOE 5043 60 WG in/on winter wheat and winter barley following early post-emergence spray application in Germany, France and the Netherlands Bayer AG, Leverkusen, Germany Bayer CropScience, Report includes Trial Nos.: 300489 301655 301663 301671 302554 302562 305030 305049 305057 305065 305138	N	Bayer CropScience

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	Vertebrate study Y/N	Owner
			305146 GLP/GEP: yes, unpublished		
KCP 6.2.2/13	-	1995	FOE Oxalate - a 29-day dairy cattle feeding study xxxxxxxxxxxxxxxxxxxxxxxx Report No.: MR106945, Edition Number: M-002268-01-1 Date: 1995-09-27 GLP/GEP: yes, unpublished	Y	Bayer CropScience
KCP 6.6.1/04	Halarnkar, P. P.; Mennicke, E. J.	1995	Accumulation of [Thiadiazole-2-14C]FOE 5043 residues in confined rotational crops Bayer Corporation, Stilwell, KS, USA Bayer CropScience, GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 6.6.1/05	Lenz, M. F.; McKinney, M. K.	1994	Accumulation of [Phenyl-14C] FOE 5043 residues in confined rotational crops Miles Inc., Agriculture Division, Stilwell, KS, USA Bayer CropScience, GLP/GEP: yes, unpublished	N	Bayer CropScience

Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1 Florasulam

A 2.1.1 Stability of residues

A 2.1.1.1 Stability of residues during storage of samples

A 2.1.1.1.1 Storage stability of residues in plant products

Not required.

A 2.1.1.1.2 Storage stability of residues in animal products

Not required

A 2.1.2 Nature of residues in plants, livestock and processed commodities

A 2.1.2.1 Nature of residue in plants

A 2.1.2.1.1 Nature of residue in primary crops

Not required

A 2.1.2.1.2 Nature of residue in rotational crops

Not required

A 2.1.2.1.3 Nature of residues in processed commodities

Not required

A 2.1.2.2 Nature of residues in livestock

Not required

A 2.1.3 Magnitude of residues in plants

Comments of zRMS:	The study has been accepted.

Reference:	KCA 6.3
Report	Final Report Determination of residues of iodosulfuron-methyl, tribenuron-methyl, florasulam and mefenpyr-diethyl after one application of IDS 100 OD or FLOT 150 WG and Adjuwant Super in wheat at 4 sites in Northern Europe 2016, J. Semrau, EAS Study Code S16-02449,
Guideline(s):	SANCO/3029/99, rev. 4
Deviations:	No
GLP:	Yes
Acceptability:	Yes

The objective of the study was to determine residue levels of iodosulfuron-methyl, tribenuron-methyl, florasulam and mefenpyr-diethyl in the raw agricultural commodity wheat after application of the products IDS 100 OD or FLOT 150 WG.
Four trials were conducted in wheat during 2016 in Poland (S16-02449-01 and S16-02449-03), Northern France (S16-02449-02) and Germany (S16-02449-04).
The trials comprised three plots, one untreated, one treated with IDS 100 OD (containing 100 g/L iodosulfuron-methyl-sodium, nominal content), and one treated with FLOT 150 WG (containing 25 g/kg florasulam, 75 g/kg tribenuron-methyl, 50 g/kg iodosulfuron-methyl-sodium, nominal content). One application of IDS 100 OD was performed at growth stage BBCH 32 at a nominal rate of 0.1 L product /ha. The

adjuvant Adjuwant Super 209/2016 was added to this application at a nominal rate of 0.1 L/ha. The product and adjuvant were diluted with water immediately prior to application to a spray volume of 200-300 L/ha (nominal).

One application of FLOT 150 WG was performed at growth stage BBCH 32 at a nominal rate of 0.2 kg product /ha. The adjuvant Adjuwant Super 965/2015 was added to this application at a nominal rate of 0.1 L/ha. The product and adjuvant were diluted with water immediately prior to application to a spray volume of 200-300 L/ha (nominal).

At trials S16-0229-01 and -02 specimens of the crop from the untreated and treated plots were taken at growth stage BBCH 89 (normal commercial harvest). At trials S16-02249-03 and -04 specimens of the crop from the untreated and treated plots were taken at the day of application and at growth stages BBCH 45-55, 65-69, 75-77 and 89 (normal commercial harvest). Specimens of wheat (whole plant, grain, straw) were analysed for residues of iodosulfuron-methyl,

tribenuron-methyl, florasulam and mefenpyr-diethyl. Specimen extraction and determination of residues of iodosulfuron and tribenuron-methyl were performed according to the EAS Chem Method M01-021 [1] and the residues of florasulam and mefenpyr-diethyl were performed according to the multi-residue QuEChERS [2].

Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical methods was 0.01 mg/kg for each analyte and each matrix with a limit of detection (LOD) set at each 0.003 mg/kg (30 % of the LOQ).

The analytical methods EAS Chem Method M01-021 for the determination of residues of iodosulfuron and tribenuron-methyl and the multi-residue QuEChERS for the determination of residues of florasulam and mefenpyr-diethyl in wheat (whole plant, grain and straw) were validated according to SANCO/3029/99, rev. 4

within this analytical phase of this study.

The accuracy and precision of the method during specimen analysis were considered to be acceptable since single recoveries were in the range of 60 - 120 % and the mean recoveries at each fortification level were in the range of 70 - 110 % with relative standard deviation(s) below 20 % for all combinations of matrices and

analytes.

No residues of tribenuron-methyl, iodosulfuron-methyl, florasulam and mefenpyr-diethyl were detected at or above the LOQ in any of the untreated specimens. The following residues were detected in the treated specimens.

Sampling Code	Timing	Plot No.	Sample Code (5 of trial code replaced by L)	Sample Type	Residue of Tribenuron-methyl mg/kg	Residue of Iodosulfuron-methyl mg/kg	Residue of Florasulam mg/kg	Residue of Mefenpyr-diethyl mg/kg
Trial S16-02449-01 (Poland)								
S1	BBCH 89 (NCH)	U1	-001A	Grain	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.
			-002A	Straw	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.
		2	-003A	Grain	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.
			-004A	Straw	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.
		3	-005A	Grain	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.
			-006A	Straw	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.
Trial S16-02449-02 (Northern France)								
S1	BBCH 89 (NCH)	U1	-001A	Grain	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.
			-002A	Straw	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.
		2	-003A	Grain	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.
			-004A	Straw	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.
		3	-005A	Grain	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.
			-006A	Straw	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.
Trial S16-02449-03 (Poland)								
S1	0 DBA1	U1	-001A	Whole Plant	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.
S2	0 DAA1	2	-002A	Whole Plant	< 0.003 n.d.	0.19	< 0.003 n.d.	0.91
		3	-003A	Whole Plant	0.32	0.18	0.19	1.2
S3	BBCH 45-55	U1	-004A	Whole Plant	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.
		2	-005A	Whole Plant	< 0.003 n.d.	< 0.01	< 0.003 n.d.	< 0.003 n.d.
		3	-006A	Whole Plant	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.
S4	BBCH 65-69	U1	-007A	Whole Plant	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.
		2	-008A	Whole Plant	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.
		3	-009A	Whole Plant	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.
S5	BBCH 75-77	U1	-010A	Whole Plant	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.
		2	-011A	Whole Plant	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.
		3	-012A	Whole Plant	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.
S6	BBCH 89 (NCH)	U1	-013A	Grain	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.
		U1	-014A	Straw	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.
		2	-015A	Grain	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.
		2	-016A	Straw	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.
		3	-017A	Grain	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.
		3	-018A	Straw	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.

Sampling Code	Timing	Plot No.	Sample Code (5 of trial code replaced by L)	Sample Type	Residue of Tribenuron-methyl mg/kg	Residue of Iodosulfuron-methyl mg/kg	Residue of Florasulam mg/kg	Residue of Mefenpyr-diethyl mg/kg
Trial S16-02449-04 (Germany)								
S1	0 DBA1	U1	-001A	Whole Plant	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.
S2	0 DAA1	2	-002A	Whole Plant	< 0.003 n.d.	0.35	< 0.003 n.d.	0.73
		3	-003A	Whole Plant	0.39	0.36	0.13	0.80
S3	BBCH 45-55	U1	-004A	Whole Plant	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.
		2	-005A	Whole Plant	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.
		3	-006A	Whole Plant	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.
S4	BBCH 65-69	U1	-007A	Whole Plant	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.
		2	-008A	Whole Plant	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.
		3	-009A	Whole Plant	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.
S5	BBCH 75-77	U1	-010A	Whole Plant	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.
		2	-011A	Whole Plant	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.
		3	-012A	Whole Plant	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.
S6	BBCH 89 (NCH)	U1	-013A	Grain	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.
		U1	-014A	Straw	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.
		2	-015A	Grain	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.
		2	-016A	Straw	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.
		3	-017A	Grain	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.
		3	-018A	Straw	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.

DBA = Days before application, DAA = days after application, NCH = Normal commercial harvest

Field Site(s) and Plot Design

The trials were carried out at four locations in Poland, Northern France and Germany. Regions, varieties and cultivation were typical for the cultivation of wheat. The trials comprised three plots (one untreated, one treated with IDS 100 OD + Adjuvant Super 209/2016, and one treated with FLOT 150 WG + Adjuvant Super 965/2015).

Weather data were taken from the regions' relevant weather stations of official weather services or from Eurofins Agroscience Services own weather stations and are shown summarized in Appendix A 1 of the report. During application and sampling the climatic conditions were measured with portable equipment at the trial sites.

The proposed application schedule is given in the table below. Care was taken that the spray solution was prepared and well homogenized by mixing before application. The nozzle type and pressure were chosen before the application, after considering the amount of water required and the calibration results. The actual applied amount was calculated by measuring the remaining spray solution after application.

Proposed Application Schedule

All trials				
Appl' code	**Plot**	**Timing**	**Application rate**	**Water volume**
-	U1	-	-	-
A1	2	BBCH 32	0.1 L **IDS 100 OD** / ha and adjuvant 0.1 L **Adjuwant Super 209/2016** / ha	200-300 L/ha
	3	BBCH 32	0.2 kg **FLOT 150 WG** / ha and adjuvant 0.1 L **Adjuwant Super 965/2015** / ha	200-300 L/ha

Sampling Method

For wheat whole plant samplings specimens were taken manually from at least 12 plants distributed over the entire plot. Samples of wheat grain and straw were taken mechanically by taking a minimum of 12 random samples from the combine harvester at equal intervals through the plot, or mature plants were cut at the field and taken to the test site where they were threshed mechanically. Other than this scissors were also used and in trial S16-02449-02 there was a use of cut hedge. Sampling equipment was cleaned before use, and between treated plots. No diseased or damaged crop was collected. Duplicate specimens were taken as cover. After sampling the control specimens and treated specimens were kept separated by an adequate space at all times. Residue specimens were deep frozen immediately after arrival at the test sites.

Material and Methods

Specifications essential for correct identification of the test item for use under GLP are based on the certificate of analysis as provided by the sponsor/supplier. They have not been verified by the test facility and might have not been generated under GLP, except where this is explicitly claimed on the certificate of analysis. Additional specifications for test item characterisation may originate from (non-GLP) sources other than the sponsor/supplier.

Test Item 1			
Name	IDS 100 OD Synonyms: CHR/H/IDS 100 OD, Jodosulfuron-Methyl-Sodium 100 OD	Batch number*	159/2016
EAS Material Code	M-00003135	Appearance / colour	liquid / brown
Formulation type	OD	Intended usage	herbicide
Active ingredient 1	iodosulfuron-methyl sodium	Content of ai nominal	100 g/L (10% w/w)
CAS number	144550-36-7	Content of ai analysed	100.7 g/L
Density (20 °C) nominal analysed	1.10 g/cm³ 1.10 g/cm³	Risk symbol(s)	Environment (very toxic to aquatic life)
Certificate of analysis date	22 Feb 2016	Expiry date	22 Feb 2018 (Not given by sponsor but assumed to be stable for two years after analysis)
Stability and homogeneity in application solution	sufficient for the test purpose (at least 1h; if formulation has thoroughly dispersed)	Storage conditions	dark and dry at room temperature (14.5°C, 26.4 °C)

Test Item 2 (Adjuvant for use with test item 1 only)			
Name	Adjuwant Super Synonyms: Adjusafner	Batch number	209/2016
EAS Material Code	M-00003405	Appearance / colour	liquid / not available
Formulation type	not available	Intended usage	plant safener
Active ingredient 1	mefenpyr-diethyl	Content of ai nominal	300 g/L
CAS number	135590-91-9	Content of ai analysed	297.4 g/L
Density (20 °C) nominal analysed	1.01 g/cm³ 1.0181 g/cm³	Risk symbol(s)	Environment (very toxic to aquatic life)
Certificate of analysis date	03 Mar 2016	Expiry date	03 Mar 2018 (Not given by sponsor but assumed to be stable for two years after analysis)
Stability and homogeneity in application solution	sufficient for the test purpose (at least 1h; if formulation has thoroughly dispersed)	Storage conditions	dark and dry at room temperature (14.5°C, 26.4 °C)

Selectivity

The analytes were determined in the final specimen extracts by use of LC-MS/MS detection.
For each analyte, one (1) mass transition was evaluated. A second mass transition was monitored for confirmation of peak identity but was not used for quantification of specimens
Untreated samples for accompanying control sample work up, for determination of (procedural) recoveries and, if needed, for preparation of matrix-matched standards originated from the current study.
At least one (1) control sample per each matrix type and analytical set was analysed to investigate the residue level of the analytes and to check for any background interferences at the expected retention times of the analytes.
Correction for blank values was not performed.

Matrix Effects

The effect of wheat (whole, plant, grain and straw) on the LC-MS/MS response was assessed by comparing peak areas of matrix-matched standards with solvent standards at identical concentrations. Matrix effects were calculated as follows:

Matrix effect (%)	$= [(100 \cdot A_{Matrix\text{-}Std} \cdot C_{Solv\text{-}Std}) / (A_{Solv\text{-}Std} \cdot C_{Matrix\text{-}Std})] - 100$
$A_{Solv\text{-}Std}$	Peak area of solvent standard
$A_{Matrix\text{-}Std}$	Peak area of matrix-matched standard
$C_{Solv\text{-}Std}$	Concentration of solvent standard in ng/mL
$C_{Matrix\text{-}Std}$	Concentration of matrix-matched standard in ng/mL

During validation of the methods following matrix effects were determined:

Matrix / Commodity	**Standard Concen-tration (ng/mL)**	**Matrix Effect for Iodosulfuron-methyl (%)**		**Matrix Effect for Tribenuron-methyl (%)**	
		Quantification (508→167 m/z)	**Confirmation (508→141 m/z)**	**Quantification (396→155 m/z)**	**Confirmation (396→181 m/z)**
Wheat (whole plant)	1 - 50	(-) 12	(+) 26	(-) 89	(-) 87
Wheat (grain)	1 - 50	(-) 10	(-) 31	(-) 3.2	(-) 34
Wheat (straw)	1 - 50	(-) 43	(-) 53	(-) 50	(-) 40

Matrix / Commodity	**Standard Concen-tration (ng/mL)**	**Matrix Effect for Florasulam (%)**		**Matrix Effect for Mefenpyr-diethyl (%)**	
		Quantification (358→167 m/z)	**Confirmation (358→152 m/z)**	**Quantification (373→327 m/z)**	**Confirmation (373→160 m/z)**
Wheat (whole plant)	1 - 50	(+) 4.6	(+) 6.1	(-) 3.9	(-) 1.2
Wheat (grain)	1 - 50	(+) 2.1	(+) 1.7	(-) 1.5	(+) 1.3
Wheat (straw)	1 - 50	(-) 7.4	(-) 3.8	(-) 27	(-) 25

(+) matrix enhancement; (-) matrix suppression
Matrix effects were ≥ 20 % for Tribenuron-methyl and Iodosulfuron-methyl in wheat (whole plant, grain and straw) and for Mefenpyr-diethyl in wheat (straw), the matrix effect were deemed significant. Therefore matrix-matched standards were used for quantification.
Matrix effects were < 20 %, for Florasulam in wheat (whole plant, grain and straw) and Mefenpyr-diethyl in wheat (whole plant and grain), the matrix effect were deemed insignificant. Therefore solvent standards were used for quantification.

Matrix effects were once again tested during the analysis of the field samples to determine the actually conditions of mass spectrometer system. Matrix effects were < 20 % for Florasulam and Mefenpyr-diethyl in wheat (whole plant) and thus deemed to be insignificant. However, matrix-matched standards were used for quantification of field samples.

Linearity

The linearity of the detector response was demonstrated by single determination of matrix-matched and solvent calibration standards at a minimum of five (5) concentration levels ranging from 0.30 ng/mL to 100 ng/mL for determination of all analytes in wheat (whole plant) and for the determination of florasulam and Mefenpyr-diethyl in wheat (grain).

For the determination of Iodosulfuron-methyl and Tribenuron-methyl in wheat (straw) the concentration levels range was from 0.15 ng/mL to 50 ng/mL and for the determination of Florasulam and Mefenpyr-diethyl in wheat (grain and straw) from 0.3 ng/mL to 50 ng/mL.

This range corresponds to a fortification level of 0.003 mg/kg to 1.0 mg/kg and thus covers the range from no more than 30 % of the LOQ and at least + 20 % of the highest analyte concentration detected in any (diluted) specimen extract.

The calibration curves obtained for both mass transitions for each analyte were linear with coefficients of determination (R^2) ≥ 0.980. Linear regression was performed without any weighting.

Quantification

Quantification was performed using a calibration curve that fulfilled the above given criteria. The injection of standard solutions was spread evenly over the whole analytical sequence. The average response factor was used for calculation of the analyte concentrations. The relative standard deviation of the average response factor was lower or equal to 20 %.

If necessary, specimen extracts and extracts from high level recovery samples were diluted with solvent to be within the calibration range. Diluted sample extracts (at least by a factor of 10) were quantified using solvent calibration standards instead of matrix-matched calibration standards.

Method Validation

Apart from the determination of procedural recoveries during analysis of specimens, a sole validation set in accordance to SANCO/3029/99 rev. 4. was conducted for each analytical method in wheat (whole plant, grain and straw).

Procedural recoveries that were conducted during specimen analysis represent validation sets for wheat (whole plant, grain and straw) in accordance to SANCO/3029/99 rev. 4.

Five (5) recovery determinations at 0.01 mg/kg (LOQ) and five (5) recovery determinations at 0.1 mg/kg (10x LOQ) were performed.

The analytes were fortified jointly (depending of the used method) and quantified separately.

At least one (1) control sample were analysed per matrix and method.

Only for the purpose of validation, two (2) mass transitions were evaluated and representative ion chromatograms are in the appendix of the report. One of the two mass transitions is proposed as quantification transition but both selected mass transitions proofed to be interchangeably applicable for quantification and confirmation.

The following recoveries were obtained:

Matrix	Fortification level (mg/kg)	Recovery (%)					Mean Recovery (%)	Rel. Std. Dev. (%)	Replicates	Overall Mean Recovery (%)	Overall Rel. Std. Dev. (%)
Florasulam - Ion Mass Transition 358/167 *m/z* (Quantification)											
Wheat (Whole Plant)	0.01 (LOQ)	88	83	85	95	101	90	2.8	5	89	4.7
	0.1	92	92	93	92	96	93	0.6	5		
Florasulam - Ion Mass Transition 358/152*m/z* (Confirmation)											
Wheat (Whole Plant)	0.01 (LOQ)	89	92	83	109	107	96	4.8	5	89	3.5
	0.1	88	91	89	93	96	91	1.7	5		
Mefenpyr-diethyl - Ion Mass Transition 373/327 *m/z* (Quantification)											
Wheat (Whole Plant)	0.01 (LOQ)	101	102	90	104	118	103	6.5	5	100	5.2
	0.1	102	99	105	106	107	104	2.9	5		
Mefenpyr-diethyl - Ion Mass Transition 373/160 *m/z* (Confirmation)											
Wheat (Whole Plant)	0.01 (LOQ)	101	89	94	109	117	102	5.9	5	98	6.3
	0.1	97	99	107	102	110	103	5.1	5		
Tribenuron-methyl - Ion Mass Transition 396/155 *m/z* (Quantification)											
Wheat (Whole Plant)	0.01 (LOQ)	116	99	95	107	115	106	10	5	102	13
	0.1	110	110	80	80	87	93	19	5		
Tribenuron-methyl - Ion Mass Transition 396/181 *m/z* (Confirmation)											
Wheat (Whole Plant)	0.01 (LOQ)	110	126	103	104	103	109	11	5	107	14
	0.1	96	121	85	83	82	93	20	5		
Iodosulfuron-methyl - Ion Mass Transition 508/167 *m/z* (Quantification)											
Wheat (Whole Plant)	0.01 (LOQ)	75	70	91	88	78	80	14	5	79	13
	0.1	73	72	93	92	72	80	15	5		
Iodosulfuron-methyl - Ion Mass Transition 508/141 *m/z* (Confirmation)											

Wheat (Whole Plant)	0.01 (LOQ)	80	77	95	89	77	84	12	5	81	12
	0.1	73	70	91	89	72	79	14	5		

Matrix	**Fortification level (mg/kg)**	**Procedural Recovery (%)**					**Mean Recovery (%)**	**Rel. Std. Dev. (%)**	**Replicates**	**Overall Mean Recovery (%)**	**Overall Rel. Std. Dev. (%)**
Florasulam - Ion Mass Transition 358/167 *m/z* (Quantification)											
Wheat (Grain)	0.01 (LOQ)	96	95	100	99	94	97	2.7	5	100	4.2
	0.1	101	103	106	102	101	103	2.5	5		
Florasulam - Ion Mass Transition 358/152*m/z* (Confirmation)											
Wheat (Grain)	0.01 (LOQ)	88	106	100	101	94	98	9.4	5	99	6.8
	0.1	101	95	105	100	100	100	5.0	5		
Mefenpyr-diethyl - Ion Mass Transition 373/327 *m/z* (Quantification)											
Wheat (Grain)	0.01 (LOQ)	100	106	109	108	109	106	4.3	5	106	3.1
	0.1	108	107	108	108	107	108	0.5	5		
Mefenpyr-diethyl - Ion Mass Transition 373/160 *m/z* (Confirmation)											
Wheat (Grain)	0.01 (LOQ)	108	107	106	108	108	107	0.9	5	108	2.4
	0.1	108	106	113	109	108	109	3.3	5		
Tribenuron-methyl - Ion Mass Transition 396/155 *m/z* (Quantification)											
Wheat (Grain)	0.01 (LOQ)	95	81	84	84	86	86	8.6	5	88	6.2
	0.1	87	93	85	76	79	84	5.0	5		
Tribenuron-methyl - Ion Mass Transition 396/181 *m/z* (Confirmation)											
Wheat (Grain)	0.01 (LOQ)	106	98	103	108	89	101	4.0	5	96	8.2
	0.1	87	91	89	74	82	85	2.4	5		

Iodosulfuron-methyl - Ion Mass Transition 508/167 *m/z* (Quantification)											
Wheat (Grain)	0.01 (LOQ)	87	92	93	95	85	90	3.6	5	88	4.3
	0.1	83	89	86	79	82	84	3.6	5		
Iodosulfuron-methyl - Ion Mass Transition 508/141 *m/z* (Confirmation)											
Wheat (Grain)	0.01 (LOQ)	89	80	98	97	79	89	10	5	91	7.8
	0.1	86	98	93	85	94	91	6.6	5		

Matrix	Fortification level (mg/kg)	Procedural Recovery (%)					Mean Recovery (%)	Rel. Std. Dev. (%)	Replicates	Overall Mean Recovery (%)	Overall Rel. Std. Dev. (%)
Florasulam - Ion Mass Transition 358/167 *m/z* (Quantification)											
Wheat (Straw)	0.01 (LOQ)	88	83	85	95	101	90	2.8	5	89	4.7
	0.1	92	92	93	92	96	93	0.6	5		
Florasulam - Ion Mass Transition 358/152*m/z* (Confirmation)											
Wheat (Straw)	0.01 (LOQ)	89	92	83	109	107	96	4.8	5	89	3.5
	0.1	88	91	89	93	96	91	1.7	5		
Mefenpyr-diethyl - Ion Mass Transition 373/327 *m/z* (Quantification)											
Wheat (Straw)	0.01 (LOQ)	101	102	90	104	118	103	6.5	5	100	5.2
	0.1	102	99	105	106	107	104	2.9	5		
Mefenpyr-diethyl - Ion Mass Transition 373/160 *m/z* (Confirmation)											
Wheat (Straw)	0.01 (LOQ)	101	89	94	109	117	102	5.9	5	98	6.3
	0.1	97	99	107	102	110	103	5.1	5		
Tribenuron-methyl - Ion Mass Transition 396/155 *m/z* (Quantification)											
Wheat (Straw)	0.01 (LOQ)	99	99	90	97	97	96	5.4	5	97	7.8
	0.1	87	100	108	99	83	95	11	5		

Tribenuron-methyl - Ion Mass Transition 396/181 *m/z* (Confirmation)											
Wheat (Straw)	0.01 (LOQ)	88	84	86	79	61	80	2.5	5	92	10
	0.1	110	93	92	110	86	98	10	5		
Iodosulfuron-methyl - Ion Mass Transition 508/167 *m/z* (Quantification)											
Wheat (Straw)	0.01 (LOQ)	77	97	91	95	90	90	11	5	87	7.7
	0.1	87	84	87	94	86	88	2.0	5		
Iodosulfuron-methyl - Ion Mass Transition 508/141 *m/z* (Confirmation)											
Wheat (Straw)	0.01 (LOQ)	94	94	106	102	105	100	6.9	5	91	10
	0.1	86	82	83	99	80	86	2.4	5		

The mean recovery at each fortification level was in the range of 70 - 110 % with a relative standard deviation of ≤ 20 % for both mass transitions of all analytes in all tested matrices and thus comply with the standard acceptance criteria of the guidance document SANCO/3029/99 rev 4.

Procedural Recoveries

The method's applicability in terms of accuracy and repeatability was assessed for each analytical set by fortification of control (untreated) test portions of the respective matrix and subsequent determination of the procedural recoveries upon applying the test method.

The analytes were fortified jointly (depending the used method) and quantified separately.

Procedural recoveries were handled and stored in the same way and for the same time period as the analytical specimen extracts that were prepared within the same analytical set.

At least one (1) procedural recovery was performed at the level of LOQ and one (1) at the level of 10x LOQ per analytical set of each respective matrix.

Higher residues were confirmed by at least one (1) recovery determination in the range of the level or higher than the level of the highest residues found in a sample.

The following procedural recoveries were obtained:

Matrix	**Fortification level (mg/kg)**	**Procedural Recovery (%)**	**Replicates**
Iodosulfuron-methyl Mass Transition 508→167 *m/z* (Quantification)			
Wheat (whole plant)	0.01 (LOQ)	95	1
	0.1 (10xLOQ)	92	1

Matrix	**Fortification level (mg/kg)**	**Procedural Recovery (%)**	**Replicates**
	0.4 (40xLOQ)	75	1
Tribenuron-methyl Mass Transition 396→155 *m/z* (Quantification)			
Wheat (whole plant)	0.01 (LOQ)	110	1
	0.1 (10xLOQ)	80	1
	0.4 (40xLOQ)	76	1
Florasulam Mass Transition 508→167 *m/z* (Quantification)			
Wheat (whole plant)	0.01 (LOQ)	97	1
	0.1 (10xLOQ)	102	1
	0.2 (20xLOQ)	98	1
Mefenpyr-diethyl Mass Transition 396→155 *m/z* (Quantification)			
Wheat (whole plant)	0.01 (LOQ)	104	1
	0.1 (10xLOQ)	108	1
	1.2 (1200xLOQ)	99	1

No observable peak was detected in any control sample extract
Recoveries are without any blank correction

All recoveries were in the range of 70 - 110 % each.

Conclusion

The method was successfully validated for determination of all analytes in all matrices with an LOQ of 0.01 mg/kg according to the guidance document(s) SANCO/3029/99 rev. 4.
With regard to selectivity, accuracy and precision, the analytical methods were applied successfully for each analytical set when analysing the specimens of the study

A 2.1.4 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)

Not required

A 2.1.5 Magnitude of residues in representative succeeding crops

Not required

A 2.1.6 Other/Special Studies

Not required

A 2.2 Diflufenican

Not required

A 2.3 Flufenacet

Not required

Appendix 3 Pesticide Residue Intake Model (PRIMo)

A 3.1 TMDI calculations – Florasulam

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Florasulam (F)

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	**0.05**	ARfD (mg/kg bw):	**calculation with ADI (no ARfD was inserted)**
Source of ADI:	**EFSA**	Source of ARfD:	
Year of evaluation:	**2015**	Year of evaluation:	

Input values

Details - chronic risk assessment | Supplementary results - chronic risk assessment

Details - acute risk assessment/children | Details - acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
0.3%	NL toddler	0.13	0.1%	Maize/corn	0.1%	Wheat	0.0%	Rice		
0.2%	DK child	0.11	0.1%	Rye	0.1%	Wheat	0.0%	Oat		
0.2%	GEMS/Food G06	0.10	0.1%	Wheat	0.0%	Rice	0.0%	Maize/corn		
0.2%	IT toddler	0.08	0.1%	Wheat	0.0%	Other cereals	0.0%	Rice		
0.1%	GEMS/Food G10	0.07	0.1%	Wheat	0.0%	Rice	0.0%	Maize/corn		
0.1%	GEMS/Food G15	0.07	0.1%	Wheat	0.0%	Barley	0.0%	Maize/corn		
0.1%	GEMS/Food G08	0.06	0.1%	Wheat	0.0%	Barley	0.0%	Rye		
0.1%	RO general	0.06	0.1%	Wheat	0.0%	Maize/corn	0.0%	Rice		
0.1%	DE child	0.06	0.1%	Wheat	0.0%	Rye	0.0%	Rice		
0.1%	GEMS/Food G07	0.06	0.1%	Wheat	0.0%	Barley	0.0%	Rice		
0.1%	FR child 3 15 yr	0.06	0.1%	Wheat	0.0%	Rice	0.0%	Maize/corn		
0.1%	PT general	0.05	0.1%	Wheat	0.0%	Rice	0.0%	Maize/corn		
0.1%	ES child	0.05	0.1%	Wheat	0.0%	Rice	0.0%	Maize/corn		
0.1%	IT adult	0.05	0.1%	Wheat	0.0%	Other cereals	0.0%	Rice		
0.1%	GEMS/Food G11	0.05	0.1%	Wheat	0.0%	Barley	0.0%	Rice		
0.1%	NL child	0.05	0.1%	Wheat	0.0%	Maize/corn	0.0%	Rye		
0.1%	UK toddler	0.05	0.1%	Wheat	0.0%	Rice	0.0%	Oat		
0.1%	UK infant	0.05	0.1%	Wheat	0.0%	Maize/corn	0.0%	Rice		
0.1%	SE general	0.04	0.1%	Wheat	0.0%	Rice	0.0%	Rye		
0.1%	FR toddler 2 3 yr	0.04	0.1%	Wheat	0.0%	Rice	0.0%	Maize/corn		
0.1%	IE adult	0.03	0.0%	Wheat	0.0%	Buckwheat and other pseudo-cereals	0.0%	Rice		
0.1%	ES adult	0.03	0.0%	Wheat	0.0%	Barley	0.0%	Rice		
0.1%	DE general	0.03	0.0%	Wheat	0.0%	Rye	0.0%	Barley		
0.1%	FI 3 yr	0.03	0.0%	Wheat	0.0%	Rye	0.0%	Oat		
0.1%	DE women 14-50 yr	0.03	0.0%	Wheat	0.0%	Rye	0.0%	Barley		
0.1%	LT adult	0.03	0.0%	Rye	0.0%	Wheat	0.0%	Rice		
0.1%	NL general	0.03	0.0%	Wheat	0.0%	Barley	0.0%	Rice		
0.1%	UK vegetarian	0.03	0.0%	Wheat	0.0%	Rice	0.0%	Oat		
0.0%	FR adult	0.02	0.0%	Wheat	0.0%	Rice	0.0%	Maize/corn		
0.0%	FI 6 yr	0.02	0.0%	Wheat	0.0%	Rye	0.0%	Rice		
0.0%	UK adult	0.02	0.0%	Wheat	0.0%	Rice	0.0%	Barley		
0.0%	DK adult	0.02	0.0%	Wheat	0.0%	Rye	0.0%	Rice		
0.0%	IE child	0.01	0.0%	Wheat	0.0%	Rice	0.0%	Oat		
0.0%	FI adult	0.01	0.0%	Rye	0.0%	Wheat	0.0%	Oat		
0.0%	FR infant	0.01	0.0%	Wheat	0.0%	Rice	0.0%	Maize/corn		
0.0%	PL general	0.00	0.0%	Maize/corn		Grapefruits				

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Florasulam (F) is unlikely to present a public health concern.

A 3.2 TMDI calculations – Diflufenican

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Diflufenican

LOQs (mg/kg) range from:		to:	
Toxicological reference values			
ADI (mg/kg bw/day):	**0.2**	ARfD (mg/kg bw):	**not necessary**
Source of ADI:	**EFSA**	Source of ARfD:	
Year of evaluation:	**2007**	Year of evaluation:	

Input values | Details - chronic risk assessment | Supplementary results - chronic risk assessment | Details - acute risk assessment/children | Details - acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
0.1%	DK child	0.20	0.1%	Rye	0.0%	Wheat				
0.1%	IT toddler	0.15	0.1%	Wheat	0.0%	Other cereals	0.0%	Barley		
0.1%	GEMS/Food G06	0.15	0.1%	Wheat	0.0%	Barley	0.0%	Rye		
0.1%	GEMS/Food G08	0.11	0.0%	Wheat	0.0%	Barley	0.0%	Rye		
0.1%	GEMS/Food G15	0.11	0.0%	Wheat	0.0%	Barley	0.0%	Rye		
0.1%	RO general	0.10	0.1%	Wheat		Grapefruits				
0.1%	DE child	0.10	0.0%	Wheat	0.0%	Rye	0.0%	Barley		
0.0%	GEMS/Food G07	0.10	0.0%	Wheat	0.0%	Barley	0.0%	Rye		
0.0%	GEMS/Food G10	0.09	0.0%	Wheat	0.0%	Barley	0.0%	Rye		
0.0%	FR child 3 15 yr	0.09	0.0%	Wheat	0.0%	Rye	0.0%	Barley		
0.0%	NL toddler	0.09	0.0%	Wheat	0.0%	Rye	0.0%	Barley		
0.0%	IT adult	0.09	0.0%	Wheat	0.0%	Other cereals	0.0%	Barley		
0.0%	ES child	0.09	0.0%	Wheat	0.0%	Barley				
0.0%	GEMS/Food G11	0.09	0.0%	Wheat	0.0%	Barley	0.0%	Rye		
0.0%	NL child	0.09	0.0%	Wheat	0.0%	Rye	0.0%	Barley		
0.0%	PT general	0.08	0.0%	Wheat	0.0%	Rye	0.0%	Barley		
0.0%	UK toddler	0.08	0.0%	Wheat	0.0%	Barley	0.0%	Rye		
0.0%	SE general	0.07	0.0%	Wheat	0.0%	Rye				
0.0%	FR toddler 2 3 yr	0.06	0.0%	Wheat	0.0%	Rye	0.0%	Barley		
0.0%	DE general	0.06	0.0%	Wheat	0.0%	Rye	0.0%	Barley		
0.0%	ES adult	0.06	0.0%	Wheat	0.0%	Barley				
0.0%	DE women 14-50 yr	0.06	0.0%	Wheat	0.0%	Rye	0.0%	Barley		
0.0%	UK infant	0.05	0.0%	Wheat		Grapefruits				
0.0%	IE adult	0.05	0.0%	Wheat	0.0%	Rye	0.0%	Barley		
0.0%	NL general	0.05	0.0%	Wheat	0.0%	Barley	0.0%	Rye		
0.0%	FR adult	0.04	0.0%	Wheat	0.0%	Rye	0.0%	Barley		
0.0%	LT adult	0.04	0.0%	Rye	0.0%	Wheat	0.0%	Barley		
0.0%	UK vegetarian	0.04	0.0%	Wheat	0.0%	Barley	0.0%	Barley		
0.0%	FI 3 yr	0.04	0.0%	Wheat	0.0%	Rye	0.0%	Barley		
0.0%	UK adult	0.03	0.0%	Wheat	0.0%	Barley	0.0%	Rye		
0.0%	DK adult	0.03	0.0%	Wheat	0.0%	Rye				
0.0%	FI 6 yr	0.03	0.0%	Wheat	0.0%	Rye	0.0%	Barley		
0.0%	IE child	0.02	0.0%	Wheat	0.0%	Barley				
0.0%	FI adult	0.02	0.0%	Rye	0.0%	Wheat	0.0%	Barley		
0.0%	FR infant	0.02	0.0%	Wheat	0.0%	Rye	0.0%	Barley		
	Column7			Grapefruits		Grapefruits				

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Diflufenican is unlikely to present a public health concern.

A 3.3 TMDI calculations – Flufenacet

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Flufenacet

LOQs (mg/kg) range from:		to:	
Toxicological reference values			
ADI (mg/kg bw/day):	**0.005**	ARfD (mg/kg bw):	**0.017**
Source of ADI:	**Sanco**	Source of ARfD:	**Sanco**
Year of evaluation:	**2003**	Year of evaluation:	**2003**

Input values

Details - chronic risk assessment

Supplementary results - chronic risk assessment

Details - acute risk assessment/children

Details - acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
15%	GEMS/Food G06	0.73	14%	Wheat	0.1%	Barley	0.0%	Rye		
14%	DK child	0.72	9%	Wheat	6%	Rye				
14%	IT toddler	0.68	13%	Wheat	0.3%	Other cereals	0.0%	Barley		
11%	GEMS/Food G15	0.54	9%	Wheat	2%	Barley	0.2%	Rye		
11%	GEMS/Food G08	0.53	8%	Wheat	2%	Barley	0.6%	Rye		
10%	RO general	0.51	10%	Wheat		Grapefruits				
10%	GEMS/Food G07	0.48	8%	Wheat	1%	Barley	0.1%	Rye		
9%	DE child	0.46	8%	Wheat	0.8%	Rye	0.0%	Barley		
9%	FR child 3 15 yr	0.46	9%	Wheat	0.0%	Barley	0.0%	Rye		
9%	GEMS/Food G10	0.46	8%	Wheat	1%	Barley	0.1%	Rye		
9%	ES child	0.44	9%	Wheat	0.0%	Barley				
9%	GEMS/Food G11	0.44	7%	Wheat	2%	Barley	0.0%	Rye		
9%	NL toddler	0.43	8%	Wheat	0.4%	Rye	0.3%	Barley		
8%	IT adult	0.42	8%	Wheat	0.1%	Other cereals	0.0%	Barley		
8%	NL child	0.42	8%	Wheat	0.2%	Rye	0.0%	Barley		
8%	PT general	0.40	8%	Wheat	0.1%	Rye	0.1%	Barley		
8%	UK toddler	0.39	8%	Wheat	0.0%	Barley	0.0%	Rye		
7%	SE general	0.33	6%	Wheat	0.3%	Rye				
6%	FR toddler 2 3 yr	0.31	6%	Wheat	0.0%	Barley	0.0%	Rye		
6%	ES adult	0.28	5%	Wheat	1.0%	Barley				
5%	DE general	0.27	4%	Wheat	1%	Barley	0.6%	Rye		
5%	UK infant	0.26	5%	Wheat		Grapefruits				
5%	DE women 14-50 yr	0.26	4%	Wheat	0.5%	Rye	0.4%	Barley		
5%	IE adult	0.24	5%	Wheat	0.1%	Rye	0.0%	Barley		
5%	NL general	0.23	4%	Wheat	0.6%	Barley	0.1%	Rye		
4%	FR adult	0.22	4%	Wheat	0.0%	Barley	0.0%	Rye		
4%	UK vegetarian	0.21	4%	Wheat	0.0%	Barley	0.0%	Rye		
3%	UK adult	0.17	3%	Wheat	0.1%	Barley	0.0%	Rye		
3%	LT adult	0.17	2%	Wheat	1%	Rye	0.1%	Barley		
3%	FI 3 yr	0.16	2%	Wheat	0.7%	Rye	0.1%	Barley		
3%	DK adult	0.14	2%	Wheat	0.5%	Rye				
3%	FI 6 yr	0.13	2%	Wheat	0.6%	Rye	0.1%	Barley		
2%	IE child	0.12	2%	Wheat	0.0%	Barley				
2%	FR infant	0.08	2%	Wheat	0.0%	Rye	0.0%	Barley		
1%	FI adult	0.07	0.7%	Rye	0.6%	Wheat	0.0%	Barley		
	Column7			Grapefruits		Grapefruits				

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Flufenacet is unlikely to present a public health concern.

A 3.4 IESTI calculations - Raw commodities – only Flufenacet

Acute risk assessment /children	Acute risk assessment / adults / general population
Details - acute risk assessment /children	Details - acute risk assessment/adults

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

Unprocessed commodities

Results for children				Results for adults			
No. of commodities for which ARfD/ADI is exceeded (IESTI):			---	No. of commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				**IESTI**			
Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
8%	Wheat	0.1 / 0.1	1.4	5%	Wheat	0.1 / 0.1	0.84
3%	Barley	0.1 / 0.1	0.56	3%	Barley	0.1 / 0.1	0.48
2%	Rye	0.05 / 0.05	0.32	1%	Rye	0.05 / 0.05	0.24
Expand/collapse list							
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)							

Processed commodities

Results for children				Results for adults			
No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---	No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				**IESTI**			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
7%	Wheat / milling (flour)	0.1 / 0.1	1.2	4%	Barley / beer	0.1 / 0.02	0.72
3%	Wheat / milling (wholemea	0.1 / 0.1	0.55	3%	Wheat / bread/pizza	0.1 / 0.1	0.44
2%	Barley / cooked	0.1 / 0.1	0.36	2%	Wheat / pasta	0.1 / 0.1	0.38
1%	Rye / boiled	0.05 / 0.05	0.18	2%	Wheat / bread	0.1 / 0.1	0.35
1%	Barley / milling (flour)	0.1 / 0.1	0.18	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
1%	Rye / milling (wholemeal)-l	0.05 / 0.05	0.18	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
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Expand/collapse list							

A 3.5 IESTI calculations - Processed commodities

Acute risk assessment /children | **Acute risk assessment / adults / general population**

Details - acute risk assessment /children | Details - acute risk assessment/adults

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
8%	Wheat	0.1 / 0.1	1.4	5%	Wheat	0.1 / 0.1	0.84
3%	Barley	0.1 / 0.1	0.56	3%	Barley	0.1 / 0.1	0.48
2%	Rye	0.05 / 0.05	0.32	1%	Rye	0.05 / 0.05	0.24

Expand/collapse list

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)

Processed commodities

Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
7%	Wheat / milling (flour)	0.1 / 0.1	1.2	4%	Barley / beer	0.1 / 0.02	0.72
3%	Wheat / milling (wholemea	0.1 / 0.1	0.55	3%	Wheat / bread/pizza	0.1 / 0.1	0.44
2%	Barley / cooked	0.1 / 0.1	0.36	2%	Wheat / pasta	0.1 / 0.1	0.38
1%	Rye / boiled	0.05 / 0.05	0.18	2%	Wheat / bread	0.1 / 0.1	0.35
1%	Barley / milling (flour)	0.1 / 0.1	0.18	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
1%	Rye / milling (wholemeal)-l	0.05 / 0.05	0.18	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
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Expand/collapse list

Appendix 4 Additional information provided by the applicant

Not required