FINAL REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: CHR/H/PENDIF 599.5 SC

Product name(s): Cevino Trio 599.5 SC/ Trivino 599.5 SC

Chemical active substance(s):

Penoxsulam, 37.5 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: October 2021

MS Finalisation date: 24/08/2022

Version history

When	What
February 2022	Dossier sent for evaluation
April 2022	zRMS evaluation of dRR
August 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 - penoxsulam, diflufenican and flufenacet - was described during its inclusion on Annex 1 process in respectively 2010, 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

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/PENDIF 599.5 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.

Among the actives selected to contain in the subject formulation the only not EU GAP supported is penoxsulam (see the source documents: SANCO/11082/09, EC 7469/VI/98 and SANCO/3782/08). Therefore, new studies on the magnitude of penoxsulam residues have been submitted by the applicant in the framework of this application. The detailed assessment of these studies is presented in Appendix 2. All residues for formulation CHR/H/PENDIF 599.5 SC containing penoxsulam in cereals are nd. Also, therefore the reduced number of trials is acceptable for major crops.

In the representative GAPs 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.

Overall conclusion

The data available are considered sufficient for risk assessment. An exceedance of the current MRLs of 0.01 mg/kg for penoxsulam, 0.02 mg/kg for diflufenican, 0.1 mg/kg for flufenacet as laid down in Reg. (EU) 396/2005 is not expected.

The chronic and the short-term intakes of penoxsulam, 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	10	11	12	13	14	15
Use-No. *	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	**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),	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) 0.2398 kg a.s./ha (0.1248 FLU + 0.1 D + 0.015 P) b) 0.2398 kg a.s./ha (0.1248 FLU + 0.1 D + 0.015 P)	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 15 "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/PENDIF 599.5 SC is composed of penoxsulam, diflufenican and flufenacet.

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

Reference value	Source	Year	Value	Study relied upon	Safety factor
Penoxsulam - Parent compound					
ADI	EFSA	2009	0.05 mg/kg bw/day	2-year rat	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 penoxsulam

Table 7.1-3: Summary for penoxsulam

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~~ Wheat, triticale	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 0.015 g/ha at growth stage BBCH 11-25.
As residues of penoxsulam 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.
Since all residues for formulation CHR/H/PENDIF 599.5 SC containing penoxsulam in cereals are below LOD (0.003 mg/kg) there is no need to perform risk assessment for dietary burden.

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~~ Wheat, triticale	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~~ Wheat, triticale	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/PENDIF 599.5 SC

Table 7.1-6: Information on CHR/H/PENDIF 599.5 SC (KCA 6.8)

Crop	PHI for CHR/H/PEN-DIF 599.5 SC proposed by applicant	PHI/ Withholding period* sufficiently supported for			PHI for CHR/H/PEN-DIF 599.5 SC proposed by zRMS	zRMS Comments (if different PHI proposed)
		Penoxsulam	Diflufenican	Flufenacet		
Winter cereals	NR	NR	NR	NR	N/A	N/A

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

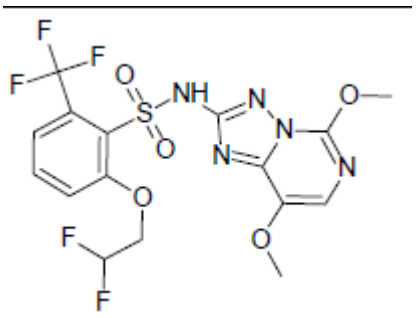
Waiting period before planting succeeding crops				Overall waiting period proposed by zRMS for CHR/H/PENDIF 599.5 SC
Crop group	Led by Penoxsulam	Led by Diflufenican	Led by Flufenacet	
Leafy vegetables	NR	NR	NR	N/A
Root vegetables	NR	NR	NR	N/A
Cereals	NR	NR	NR	N/A

NR: not relevant

7.2 Penoxsulam

General data on penoxsulam are summarized in the table below (last updated 2010/01/22)

Table 7.2-1: General information on Penoxsulam

Active substance (ISO Common Name)	Penoxsulam
IUPAC	3-(2,2-difluoroethoxy)-N-(5,8-dimethoxy[1,2,4]triazolo[1,5-c]pyrimidin-2-yl)-α,α,α-trifluorotoluene-2-sulfonamide
Chemical structure	
Molecular formula	C16 H14 F5 N5 O5S
Molar mass	483.37 g/mol
Chemical group	herbicide

Mode of action (if available)	
Systemic	No
Company (ies)	Dow AgroScience
Rapporteur Member State (RMS)	IT
Approval status	COMMISSION DIRECTIVE 2010/25/EU of 18 March 2010
Restriction (e.g. is restricted to use as "...")	COMMISSION DIRECTIVE 2010/25/EU of 18 March 2010
Review Report	Penoxsulam SANCO/11082/09 - final 22 January 2010
Current MRL regulation	Reg. (EU) 2018/1516
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 (2009) 343, 53-90
EFSA Journal: conclusion on article 12	EFSA Journal 2017;15(4):4753
Current MRL applications on intended uses	Reg. (EU) 2018/1516

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

7.2.1 Stability of Residues (KCA 6.1)

7.2.1.1 Stability of residues during storage of samples

Available data

No new data submitted in the framework of this application.

Table 7.2-2: 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			
Rice	High starch content	210 days	Miller, A. M., Thomas, A. D., and Lindsay, D. A. (2002)
Animal Products			
Not required			

Conclusion on stability of residues during storage

Residues of DE-638 are stable in rice grain, straw, and immature forage when stored frozen at -20°C for up to 210 days. Residues of DE-638 are stable in rice bran, hulls and polished rice when stored frozen at -20oC

for up to 197 days.

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

Not required since analysis time were less than 24 hours between extraction and analysis or it was shown that study extracts are stable.

7.2.2 Nature of residues in plants, livestock and processed commodities

7.2.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

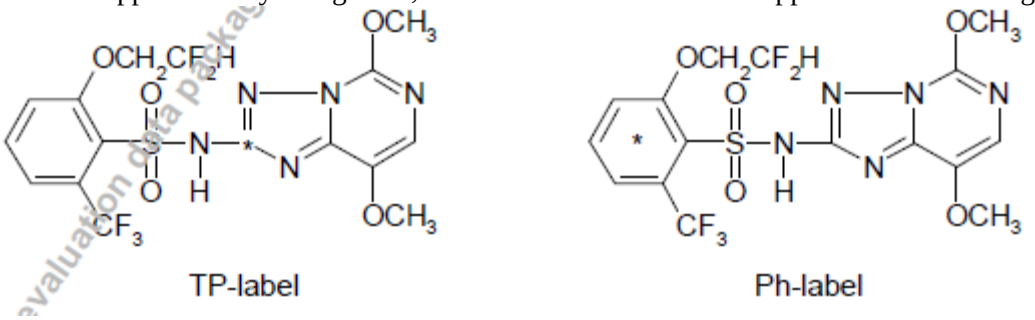
No new data submitted in the framework of this application.

Table 7.2-3: 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	Rice	TP	Foliar	0.1	1	0, 3, 7, 14, 30, 134		Yoder, R. N. and Embrey, S. K. (2001)
				0.05	2			
		Ph	Foliar	0.1	1	0, 3, 7, 14, 30, 134		
				0.05	2			

Summary of plant metabolism studies reported in the EU

14C-DE-638 formulated as a suspension concentrate (SC) was applied to both the paddy water and the rice foliage of Japonica rice at the 5- to 6-leaf stage of development. DE-638 radiolabelled in the 2-position on the sulphonamide ring (TP) or uniformly labelled in the phenyl ring (Ph) was applied in a single application at a rate of approximately 100 g ai/ha, or twice the maximum label application rate of 50 g as/ha.



The radiochemical purity of the TP-labelled formulated test substance was 99% as determined by HPLC and the specific activity was 43255 dpm/ìg (720.9 Bq/ìg). The Ph-labelled formulated test material had a radiochemical purity of 98.2% by HPLC and the specific activity was 30375 dpm/ìg (506.3 Bq/ìg). The test materials were formulated as the SC (North American Formulation 567) and the final concentration of DE-638 was approximately 10% (w:w). The formulated test substances were diluted to 5 mL with HPLC-grade water and stored at room temperature prior to shipment to the field site. The test system crop was rice (Oryza sativa L.). The variety used, M-202, is representative of commercially grown Japonica rice. The field

portion of the study was conducted by Plant Sciences, Inc., Watsonville, CA, USA (PSI). Rice was grown in bins of two different sizes. Each bin consisted of a galvanised steel tank lined with plastic sheeting. Rice was planted in two large bins of 120 cm2, one bin was treated with Ph-labelled and one with TP-labelled DE- 638. Additionally, a second small bin (90 cm2) was treated with TP-labelled XDE 638. The control rice was planted in a separate 90 cm2 bin. After planting, the bins were flooded to a depth of about 6 cm. Separate screenhouses were maintained for each radiolabel and the control. The screenhouses consisted of wood frames with mesh-screened sides and chickenwire tops and were located in the PSI San Joaquin County Facility in Manteca, California, USA. The formulated test material for each radiolabel was quantitatively transferred to a 200-mL volumetric flask, diluted to volume with HPLC-grade water, and mixed. An even, foliar spray application was made to the rice plants at 5-6 leaf growth stage on 8-June-1999 by using a series of broadcast passes over the bin until the total volume of dose solution was dispensed. The entire Ph-labelled solution was applied to one large bin for a total application rate of 107 g ai/ha. The TP-labelled solution was divided between a large and a small bin so the total application rate to each bin was 93g ai/ha. Immature rice samples were harvested from both treated bins and from the untreated control bin at 0, 3, 7, 14 and 30 days after treatment (DAT). Mature samples were harvested 134 DAT. All Ph-labelled samples were harvested from the large bin. TP -labelled immature samples were harvested from the small bin. The entire TP-treated large bin was harvested at maturity. At maturity, panicles were cut from the straw with clean shears. The remaining straw was harvested. The panicle samples were dried on racks containing portable heaters in a process similar to commercial practices. After drying, the unhulled grain was removed from the panicle stem (chaff) by hand stripping. The chaff was combined with the straw. A portion of the hulled grain was further processed into brown rice and hulls using hand-operated ricehusking machine. All tissue samples were shipped frozen to the Indianapolis laboratory. The method of grinding tissue varied depending upon the mass and nature (dry, mature plants vs. immature plants) of tissue extracted. Samples for 0 DAT and 3 DAT, where only a very small amount of tissue was available, were minced with a Polytron homogeniser and extraction solvent as the first extraction step. Liquid nitrogen was used to freeze the 7 DAT, 14 DAT, 30 DAT and mature rice grain samples. A mortar and pestle were then used to grind the frozen tissue prior to sample analysis. The mature straw was milled with dry ice using a Willey Mill. Total Radioactive Residue (TRR) values for 7, 14, 30 DAT tissue and mature rice and straw were generated by oxidative combustion of a small amount of wet (non-extracted) tissue. Due to the small amount of tissue harvested at 0 DAT and 3 DAT, the entire sample was simultaneously ground using a Polytron homogeniser and extracted with acetonitrile:water (80:20). A portion of the post-extracted air-dried tissue was combusted to obtain nonextractable residue (NER) information. TRR values for 0 DAT and 3 DAT samples included the extractable radioactivity plus the radioactivity recovered by post-extraction combustion. After addition of the extraction solvent, the samples were shaken and the extraction liquid was recovered by vacuum filtration. The extraction procedure was repeated a total of three times, pooling the extracts and the total extract volume was recorded. The total radioactivity extracted was determined by LSC. Several clean-up steps, including filtration and extraction with hexane to remove colour, were used to prepare the samples for HPLC analysis. A portion of the post-extracted tissue for samples 14 DAT and later was subjected to acid hydrolysis to characterise the non-extractable residues (NER). Each sample was hydrolysed with 1 N HCl and refluxed for four hours. The sample was vacuum filtered and shaken with fresh 1 N HCl. The sample was again vacuum-filtered and the extraction solvents were pooled. Aliquots of the acid hydrolysate were counted by LSC. Due to the low amounts of radioactivity found in the hydrolysates, they were not subjected to further analysis. Each sample was then air-dried prior to oxidative combustion to determine radioactivity remaining in the tissue.

Conclusion on metabolism in primary crops

Levels of penoxsulam in rice decreased rapidly following foliar application, probably due to a combination of metabolism and biological growth dilution. Radioactive residues were readily extractable using neutral solvents and were multi-component in nature. Immature samples contained primarily penoxsulam. Residues in both the grain and straw consisted of penoxsulam, the 5-OH analog of penoxsulam, and two unidentified metabolites. One of these unknown metabolites was very polar in nature and may represent conjugates of the 5-OH metabolite and other metabolites. At normal use rates, each of these components should

be present at levels less than 0.01 mg/kg. Low residues were detected in the mature straw and rice grain samples after foliar application at 100 g as/ha. Final residues in the mature tissues were approximately 0.022 mg penoxsulam equivalents per kg in the straw and 0.003 mg penoxsulam equivalents per kg in the grain. Since the 100 g as/ha application rate is 2.5X the maximum application rate of 50 g as/ha and 3-5 times the typical application rate of 17-35 g as/ha, anticipated residue levels in crops treated under actual field conditions should be even lower than reported here. Based on the above results, the residue definition in rice commodities is penoxsulam.

According to study the main way of treatment was following foliar application of penoxsulam on rice, it was concluded that metabolism of penoxsulam in cereals is the same pathway like in rice. Specially that the rice belong to the same metabolism plant group like cereals – cereals/grass hop. The presented data are sufficient to support the intended uses of CHR/H/PENDIF 599.5 SC on cereals. No further data are required.

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

No new data submitted in the framework of this application.

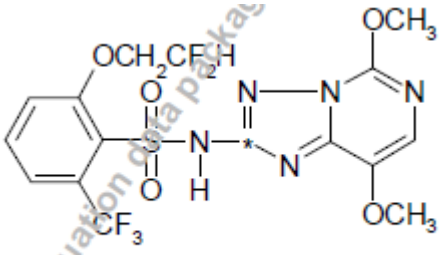
Table 7.2-4: Summary of metabolism studies in rotational crops

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	Kale	TP and PH	F	0.05 and 0.1	90	238, 291		Graper, L. K. (2002)
Root and tuber vegetables	Potato	TP and PH	F	0.05 and 0.1	90	298, 305		
Cereals	Wheat	TP and PH	F	0.05 and 0.1	90	187, 252, 294		

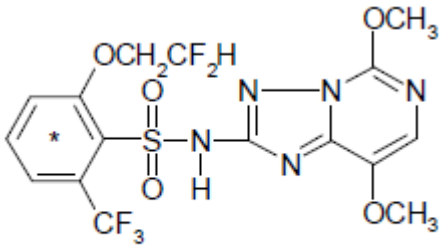
* Outdoor/field application (F) or glasshouse/protected/indoor application (G)

Summary of plant metabolism studies reported in the EU

The test material was labelled either universally in the phenyl ring (Ph-label) of the molecule or at the 2-position in the triazolopyrimidine ring (TP-label). The phenyl label had a radiopurity of 96.9% and a specific activity when applied of 40,900 dpm/ìg (681.7 Bq/ìg). The triazolopyrimidine label had a radiopurity of 98.1% and a specific activity when applied
of 40,700 dpm/ìg (678.3 Bq/ìg).



TP-label



Ph-label

* denotes position of 14C

The phenyl-labeled (PH) 14C-DE-638 used in the study was prepared by diluting 0.0269 g of 14C-test material with 0.0491 g of unlabeled test material. The triazolopyrimidine-labeled (PH) 14C-DE-638 used in the study was prepared by diluting 0.0229 g of 14C-test material with 0.0529 g of unlabeled test material. Prior to application, the test materials were dissolved in acetonitrile. The 14C -test material was delivered to each treated plot in 450 ml solution of acetonitrile. The control plots received 450 ml of acetonitrile. Each plot (box) used in this study was 5 feet x 3 feet x 18 inches (152.4 cm x 91.44 cm x 45.72 cm, l x w x h) and was lined with 6 mil (0.015 cm) plastic. The boxes were filled with sandy loam soil to within approximately 2 inches (5.08 cm) from the top. The treatment area for each of the treated boxes was 15 square feet (13,935 cm2 or 1.39 x 10-4 ha). Fifteen boxes were prepared. Applications were made to bare soil. Three boxes were controls. Three boxes were treated with phenyl-labeled 14C-DE-638 (14C-DE-638-PH) at a rate of 51.1 g a.s./ha (1X). Three boxes were treated with 14C-DE-638-PH at a rate of 101.3 g a.s./ha (2X). Three boxes were treated with triazolopyrimidine-labeled 14C-DE-638 (14C-DE-638-TP) at a target rate of 50.9 g a.s./ha (1X). Three boxes were treated with 14C-DE-638-TP at a target rate of 104.1 g a.s./ha (2X). Test substance was applied 20-Jul-00. On 18-Oct-00, ninety (90) days after treatment (DAT), small grains, leafy vegetables, and root crops were planted into the treated and control boxes. One crop type was planted per box. Crops of wheat, kale, and potatoes, were grown to maturity outdoors. Wheat forage (187 DAT), hay (252 DAT), straw (294 DAT) and grain (294 DAT) were collected. At maturity, potato foliage (298 DAT) and potato tubers (305 DAT) were collected. Mature kale was harvested from all plots at 238 DAT except for the TP-2X plot which was harvested at 291 DAT due to delayed maturity. Soil samples were collected at 88, 200, 266, and 305 DAT. Filter disks, which had been placed in each plot prior to application of test material, were collected at 0 DAT shortly after application and served as a 0 DAT soil sample.

Conclusion on metabolism in rotational crops

Wheat, kale, and potatoes planted into soil 90 days after treatment with PH or TP-labeled penoxsulam at target rates of 50 and 100 g a.i./ha contained total radioactive residues ranging from less than the LOD to 0.062 mg/kg in penoxsulam equivalents. Although residues were generally lower for plant samples from the TP label treated plots than for samples from the PH label treated plots, no significant conclusions were made for this difference. Because of the low residues in wheat forage and grain and potato tubers from the 1.25X and 2.5X treatments and in kale from the 1.25X treatment, no attempt was made to characterize any of the residues for these samples. Because of higher residues in wheat hay and straw and potato foliage from the 1.25X and 2.5X treatments and in kale from the 2.5X treatment, these samples were subjected to extraction and partitioning procedures. Radioactivity that could be extracted using acetonitrile/water 80/20 ranged from 0.006 to 0.060 mg/kg, with no greater than 0.009 mg/kg remaining in the extracted tissues (non-extractable). When partitioned, from 0.001 to 0.017 mg/kg of the radioactive residues partitioned into organic solvent (organosoluble) and from 0.005 to 0.042 mg/kg remained in the extracted aqueous (aqueous soluble). The only extracts that possessed sufficient concentrations of radioactivity to warrant analysis by HPLC were the organic phases and one of the extracted aqueous phases from potato samples that had been taken from plots treated with the PH labeled penoxsulam. When analyzed by HPLC, the residues in all three fractions were shown to be multi-component, with no single component present at a level greater than 0.015 mg/kg. The results from this study indicated that no residues of concern would be present in raw agricultural

commodities from small grains, leafy vegetables, or root crops planted 90 days after treatment with penoxsulam at either 50 or 100 g a.i./ha (1.25X or 2.5X of the maximum seasonal rate, respectively).

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Since no residues were detected in rice grain, investigation into the effect of industrial processing on the nature of residue is not required.

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

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

Endpoints	
Plant groups covered	Cereals (Wheat)
Rotational crops covered	Wheat, Kale, Potato
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	Penoxsulam
Plant residue definition for risk assessment	Penoxsulam
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.

7.2.2.5 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 7.2-6: 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	TP and Ph	2	11	5	Milk	twice daily	XXXX (2002)
						Urine and faeces	daily	
						Tissues	at sacrifice	
Laying poultry	Hens	TP and Ph	30	11	7	Eggs	Twice daily	XXXX (2002)
						Excreta	Daily	
						Tissues	At scrifice	

Summary of plant metabolism studies reported in the EU

Goat:

Two lactating goats (Capra hircus) were given a daily oral dose of either N-((1-(2,2-difluoroethoxy)-3-trifluoromethyl-2-benzene-Ph-UL-14C)sulfonyl)-2-amino-5,8-dimethoxy-1,2,4-triazolo-[1,5-c]pyrimidine [PH label] or N-((1-(2,2-difluoroethoxy)-3-trifluoromethyl-2-benzene)sulfonyl)-2-amino-5,8-dimethoxy-1,2,4-triazolo-[1,5-c]pyrimidine-2-14C [TP label] for 5 consecutive days. The radiochemical purity of each test substance was >98.4%. The specific activity of the PH and TP label was 910 MBq/mmole and 1070 MBq/mmole, respectively. Oral administration was chosen, as oral ingestion is the most likely route of exposure. Each animal received a dietary equivalent of approximately 11 mg/kg/day of test material. Residues from rice grain are <0.01 mg/kg ; the dose in this study was 1000X greater than the theoretical maximum potential exposure in the diet. Each goat was milked once in the morning and once in the evening. Urine and feces were collected at 24-hour intervals. Each goat was sacrificed within 24 hours of the last dose and the liver, kidneys, along with samples of fat, muscle, gastrointestinal contents and urine from the bladder were collected. Total radioactive residue (TRR) levels in tissue, milk, urine and faeces were determined by combustion and/or direct liquid scintillation counting. Radioactive
residues in liver and kidney were further characterised by neutral and acidic solvent extraction followed by chromatographic analysis using HPLC and HPLC/MS.

For both labels greater than 99% of the total dose administered was recovered in the samples collected. The test substance was rapidly excreted by the animals, with >99% of the recovered radioactivity residing in the urine (6.24 – 10.95 % radioactivity recovered as percent of daily dose) and faeces (6.92 – 15.40 % Radioactivity recovered as percent of daily dose). For milk, residues never exceeded 0.008 mg/kg of parent equivalents and appeared to plateau within 12 hours after the initial dose. For the tissues, 14C residues exceeded 0.01 mg/kg of penoxsulam only in liver and kidney samples. Residues in both muscle and fat were less than the limit of detection of 0.0065 mg/kg and 0.0044 mg/kg, respectively. Liver and kidney were extracted in various solvents and fractionated.
For kidney, over 75% of the recovered radioactivity for either label was accounted for in the neutral and acidic extracts, while for liver only 40-50% of the sample radioactivity was accounted for in these same two extracts.
Kidney residue neutral extract was further characterized by HPLC. This extract contained 0.024 mg/kg and 0.045 mg/kg as parent in the TP and PH labelled samples, respectively. The neutral extract of the TP label also contained 0.001 mg/kg as an unknown. Acid extract of the TP and PH label contained 0.004 mg/kg and 0.007 mg/kg, respectively. It was not analysed further due to the low levels. NER of the TP and PH labelled samples contained 0.005 mg/kg and 0.007 mg/Kg, respectively. NER remaining in kidney samples post extraction was not further characterized due to the low levels. Liver residue neutral extract was further characterized by HPLC. This extract contained 0.005 mg/kg and 0.007 mg/kg as parent in the TP and PH labelled samples, respectively. The neutral extract also contained unknowns at 0.0005 mg/kg and 0.001 mg/kg in the TP and PH labels, respectively. Acid extract of the TP and PH label was not analyzed further due to the low levels. Base hydrolysis was used to release the non extractable residues (NER) in liver. This procedure released 64.1% (0.026 mg/kg) and 68.6% (0.021 mg/kg) of the NER from the TP and PH liver samples, respectively. Subsequent partitioning of these base hydrolysate solutions at both alkaline and acidic pH with dichloromethane or dichloromethane:acetonitrile (50:50) did not remove any radioactivity. Confirmation of penoxsulam in liver PH neutral extract was performed by LC/MS. Both and penoxsulam standard and the sample were analyzed by positive electrospray (ESI) using single and tandem liquid chromatograph-mass spectrometry (LC/MS and LC/MS/MS). The mass spectra of the major component observed with the sample is consistent with that of the reference standard of penoxsulam.

Hens:
Two groups of ten laying hens per group were given a daily oral dose of either N-((1-(2,2- difluoroethoxy)-3-trifluoromethyl-2-benzene-Ph-UL-14C)sulfonyl)-2-amino-5,8-dimethoxy-1,2,4-triazolo-[1,5-c]pyrimidine [PH label] or N-((1-(2,2-difluoroethoxy)-3-trifluoromethyl-2-benzene)sulfonyl)-2-amino-5,8-dimethoxy-1,2,4-triazolo-[1,5-c]pyrimidine-2-14C [TP label], and a third group received empty capsules, for

seven consecutive days. Radiochemical purity of each test substance was >99%. The specific activity of the TP and PH label was 1070 MBq/mmole and 1040 MBq/mmole, respectively. Oral administration was chosen, as oral ingestion is the most likely route of exposure. Each animal received a dietary equivalent of approximately 11 mg/kg/day of test material. As residues from rice grain are <0.01 mg/kg; the dose in this study was 1000X greater than the maximum theoretical exposure in the diet. Beginning on the day before the first dose, egg samples were collected twice daily, and excreta samples were collected daily. Each animal was sacrificed within 22 ± 2 hours of the last dose, and the liver, samples of fat, muscle, and the skin were collected. All of these samples were analysed for 14C content by combustion and/or liquid scintillation counting. Residues in liver were further characterised by neutral and acidic solvent extraction followed by chromatographic analysis using HPLC. For both labels greater than 92% of the total dose administered was accounted for in the samples collected. The test substance was rapidly excreted by the animals, with >92% of the recovered radioactivity residing in the excreta. With the exception of the Day 6 TP eggs, no detectable residues were observed in any of the eggs collected over the 7-day dosing period (LOD was 0.002 mg/kg). Likewise for the edible tissues, only liver contained residues in excess of the LOD. Extraction of the liver samples showed as much as 45-50% of the total recovered sample radioactivity to be accounted for in the neutral and acidic solvent extracts. Liver residue neutral extract was further characterized by HPLC. This extract contained 0.004 mg/kg as parent in the TP labeled sample. The neutral extract also contained unknown at 0.002 mg/kg in the TP labels. The neutral extract of the PH label was not analyzed further dueto the low levels. The acid extract of the TP and PH label was not analyzed due to the lowlevels. The NER remaining in liver samples post-extraction was not characterized further due to the low concentrations

Conclusion on metabolism in livestock

Goat:

14C-TP or 14C-PH DE-638 orally fed to lactating goats at the equivalent of approximately 11 mg/kg in the diet for five consecutive days, was rapidly and completely excreted by the animals. Radiochemical analysis of the edible tissues demonstrated the presence of very low residues, with the highest concentration of 0.0712 and 0.0581 mg/kg TRR in the TP and PH treated liver, respectively. Kidney samples contained concentrations of 0.0375 and 0.0512 mg/kg for the TP and PH treated tissues, respectively. Fat and muscle tissue concentrations were below the limit of detection. Milk samples contained peak concentrations of 0.0083 and 0.0070 mg/kg for the TP and PH treated animals. The very low residue levels in the milk and edible tissues, combined with the rapid excretion of the test substance, demonstrates that the residues of DE-638 do not bioconcentrate in the ruminants.
DE-638 was identified in kidney tissue at 76.6% (0.024 mg/kg) and 91.5% (0.045 mg/kg) of the TRR and in the liver at 24.3% (0.005 mg/kg) and 30.6% (0.007 mg/kg) of the TRR for the TP and PH labels, respectively (Tables 7.2.1-3 and 7.2.1-4). Two very low level, more polar metabolites were seen in the extracts from kidney and liver, one of which had a retention time similar to that of 5-OH DE-638. Attempts to further identify this residue and the unknown peak were not performed due to the low concentrations at which they were present. Acid extract was not further characterized due to the low concentration. The behavior of DE-638 residue in lactating goat tissues during extraction, fractionation and chromatographic analysis demonstrated no significant differences between the TP and PH labels. Therefore, sulfonamide bridge cleavage did not occur to any significant extent as a result of animal metabolism. The highly exaggerated exposure level (approximately 1000X levels seen in the MOR in rice) and the resulting low tissue residues demonstrate that a ruminant feeding study should not be required.

Hens:

14C-TP or 14C-PH penoxsulam orally fed to laying hens at the equivalent of approximately 11 mg/kg (dry weight) in the diet for seven consecutive days, was rapidly and completely excreted by the animals. Radiochemical analysis of the edible tissues demonstrated the presence of very low residues, with the highest concentration of 0.017 and 0.006 mg/kg penoxsulam equivalents in the TP and PH treated liver, respectively. Fat, skin, egg and muscle tissue concentrations were below the limit of detection. The absence of

detectable residues in eggs and in all tissues except liver, combined with the rapid excretion of the test substance, demonstrates that the residues of penoxsulam do not bioconcentrate in the poultry. Penoxsulam was identified in liver tissue at 22.9% (0.004 mg/kg) of the TRR for the TP label. One very low level, more polar metabolite was seen in the extracts from liver. Attempts to further identify the unknown peak were not performed due to the low concentrations at which it was present. The behavior of penoxsulam residue in laying hen tissues during extraction, fractionation and chromatographic analysis demonstrated no significant differences between the TP and PH labels. Therefore, sulfonamide bridge cleavage did not occur to any significant extent as a result of animal metabolism. The highly exaggerated exposure levels (approximately 1000X levels detected in residue studies) and the resulting low tissue residues demonstrate that a poultry feeding study is not required

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

Table 7.2-7: 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	5 days in milk
	7 days in eggs
Animal residue definition for monitoring	Penoxsulam
Animal residue definition for risk assessment	Penoxsulam
Conversion factor	None
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	No

* 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

7.2.3 Magnitude of residues in plants (KCA 6.3)

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

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application. These studies are summarized in the Table below. The detailed assessment of these studies is presented in Appendix 2.

Table 7.2-8: Summary of EU reported and new data supporting the intended uses of CHR/H/PENDIF 599.5 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
Winter cereals	S. Niewelt, Study code: DPL/203/2020, S. Niewelt: Study code: DPL/204/2020 G. Paszek, Study code: DPL/205/2020, G. Paszek: DPL/206/2020	N-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 0.015 kg as/ha, BBCH 25, PHI 14d, outdoor E: 4 x <LOD RA: 4 x <LOD	N/A				
	Overall supporting data for cGAP	N-EU	E: 4 x <LOD RA: 4 x <LOD	<LOD	<LOD		0.01	Yes

* Source of EU MRL: Reg. (EU) 2018/1516

7.2.3.2 Conclusion on the magnitude of residues in plants

According to the available data, the intended uses on winter 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.

7.2.4 Magnitude of residues in livestock

Since all residues for formulation CHR/H/PENDIF 599.5 SC containing penoxsulam in cereals are below LOD (0.003 mg/kg) there is no need to perform risk assessment for dietary burden. There will no risk for domestic animals feeding grains and green material in accord to the label.

7.2.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation) (KCA 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.

7.2.5.1 Available data for all crops under consideration

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

7.2.6 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 7.2.2.2), no study dealing with magnitude of residues in succeeding crops is needed.

7.2.6.1 Field rotational crop studies (KCA 6.6.2)

Available data

No new data submitted in the framework of this application. According to EFSA Scientific Report (2009) 343, 53-90 the succeeding study are available. Therefore, new study is not required:

Residues in succeeding crops (Annex IIA, point 6.6, Annex IIIA, point 8.5)

.....	Wheat, kale, and potatoes planted into soil 90 days after treatment with PH or TP-labeled penoxsulam at target rates of 50 and 100 g a.i./ha contained total radioactive residues ranging from less than the LOD to 0.062 mg/kg penoxsulam equivalents. A metabolite BSTCA (not occurring in the primary crop and in rat metabolism) was identified in significant amounts. Further data to address residues in rotational crops are required.

Conclusion on rotational crops studies

Wheat, kale, and potatoes planted into soil 90 days after treatment with PH or TP-labeled penoxsulam at target rates of 50 and 100 g a.i./ha contained total radioactive residues ranging from less than the LOD to 0.062 mg/kg in penoxsulam equivalents. Although residues were generally lower for plant samples from the TP label treated plots than for samples from the PH label treated plots, no significant conclusions were made for this difference. Because of the low residues in wheat forage and grain and potato tubers from the

1.25X and 2.5X treatments and in kale from the 1.25X treatment, no attempt was made to characterize any of the residues for these samples. Because of higher residues in wheat hay and straw and potato foliage from the 1.25X and 2.5X treatments and in kale from the 2.5X treatment, these samples were subjected to extraction and partitioning procedures. Radioactivity that could be extracted using acetonitrile/water 80/20 ranged from 0.006 to 0.060 mg/kg, with no greater than 0.009 mg/kg remaining in the extracted tissues (non-extractable). When partitioned, from 0.001 to 0.017 mg/kg of the radioactive residues partitioned into organic solvent (organosoluble) and from 0.005 to 0.042 mg/kg remained in the extracted aqueous (aqueous soluble). The only extracts that possessed sufficient concentrations of radioactivity to warrant analysis by HPLC were the organic phases and one of the extracted aqueous phases from potato samples that had been taken from plots treated with the PH labeled penoxsulam. When analyzed by HPLC, the residues in all three fractions were shown to be multi-component, with no single component present at a level greater than 0.015 mg/kg. The results from this study indicated that no residues of concern would be present in raw agricultural commodities from small grains, leafy vegetables, or root crops planted 90 days after treatment with penoxsulam at either 50 or 100 g a.i./ha (1.25X or 2.5X of the maximum seasonal rate, respectively).

7.2.7 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/PENDIF 599.5 SC. Therefore, other special studies are not needed.

7.2.8 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.

7.2.8.1 Input values for the consumer risk assessment

Table 7.2-9: Input values for the consumer risk assessment

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Wheat	0.01	Reg. (EU) 2018/1516
Barley	0.01	Reg. (EU) 2018/1516
Rye	0.01	Reg. (EU) 2018/1516
Other	0.01	Reg. (EU) 2018/1516

7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.2-10: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo	0.2 % (based on DK Child)
IEDI (% ADI) according to EFSA PRIMo	0.2 % (based on DK Child)

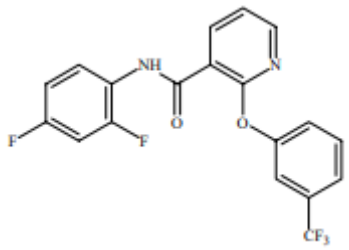
* include raw and processed commodities if both values are required for PRIMo
** if national model is available

The proposed uses of penoxsulam in the formulation CHR/H/PENDIF 599.5 SC do not represent unacceptable 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)nicotinanilide
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 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 and phe-nyl 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/PENDIF 599.5 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 7.2.2.2), 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 phenyl 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., Summerfield M. 1999a;
Root and tuber vegetables	Sugar beet	Pyridyl, amiline and phenyl ring	Soil, F	0.36	12 weeks	At maturity		
Cereals	Wheat	Pyridyl, amiline	Soil, F	0.36	12 weeks	At maturity		

		and phenyl 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/PENDIF 599.5 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)

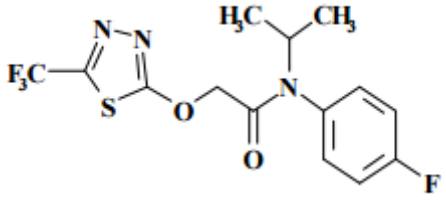
* include raw and processed commodities if both values are required for PRIMo
** if national model is available

The proposed uses of diflufenican in the formulation CHR/H/PENDIF 599.5 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 thiadiazol-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/PENDIF 599.5 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	-	XXXX 1995
	Cotton	[Fluorophenyl-UL-^{14}C]	F	1.778	1	21 d, 43 d and 156 d		XXXX 1995
Plant cell suspension cultures	Soybean, wheat, peanut, corn, cotton	[Fluorophenyl-UL-^{14}C] [Thiadiazole-2-^{14}C]	Lab	-	-	-	-	Koester, J.; Brauner, A.; 1995

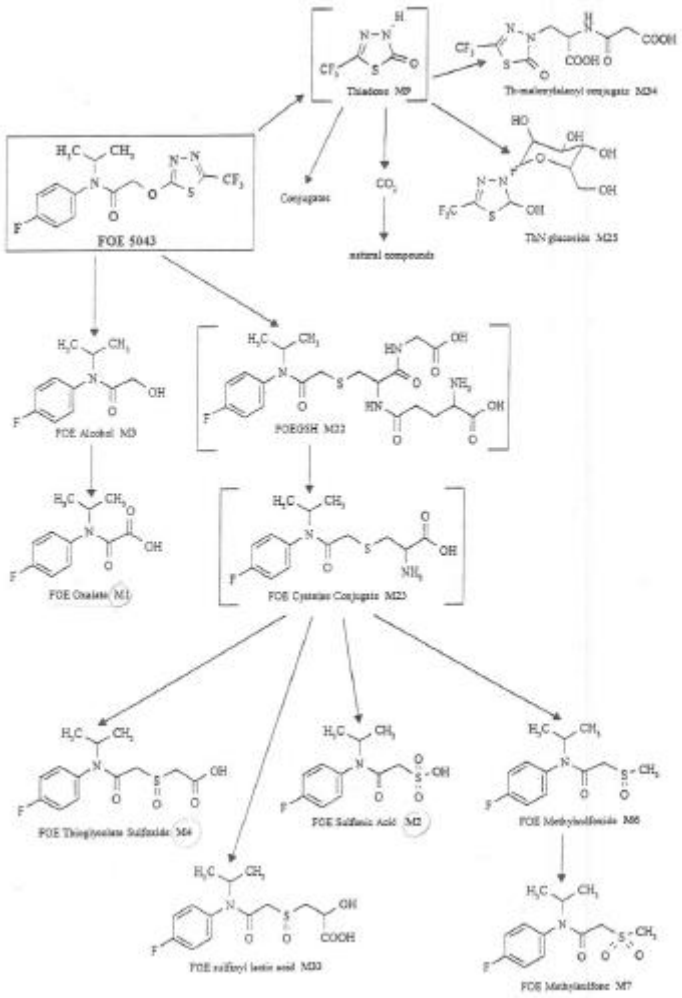
Summary of plant metabolism studies reported in the EU

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 Nfluorophenyl- 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/PENDIF 599.5 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

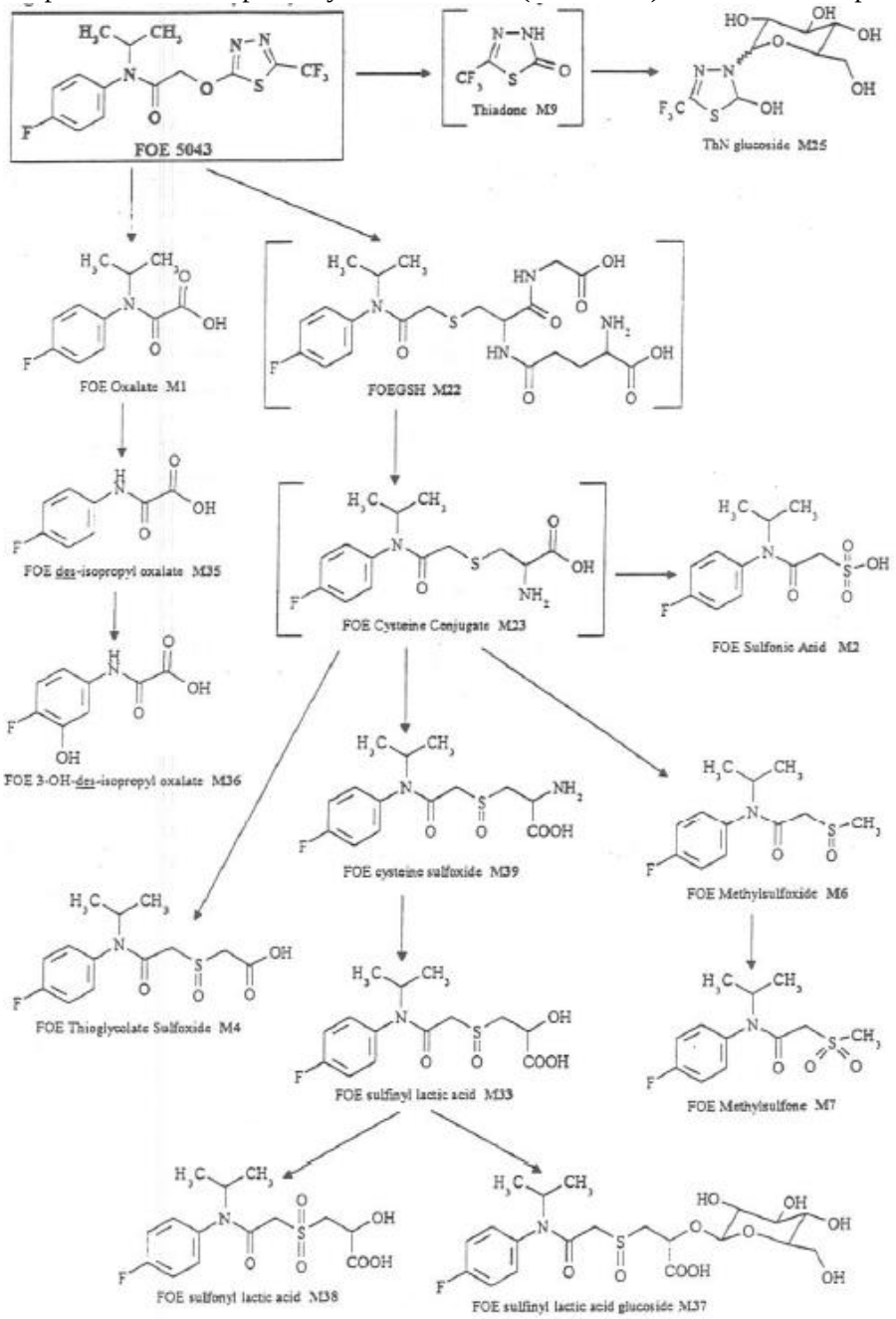
Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G *	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks	
EU data Syngenta studies on Annex I								
Leafy vegetables	Kale	[Fluorophenyl-UL-14C] [Thiadiazole-2-14C]	F	0.9 kg a.s./ha	1 month 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/PENDIF 599.5 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/PENDIF 599.5 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	XXXX;

	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	XXXX; 1995;
						Urine and faeces	daily	
						Tissues	daily	
Poultry	laying hen	[Fluorophenyl-UL-14C] FOE oxalate	10	5	3 days	Milk	daily	XXXX; 1995;
						Urine and faeces	daily	
						Tissues	daily	
Lactating ruminants	goat	[Fluorophenyl-UL-14C] FOE 5043	1	5	3 days	Milk	Twice daily	XXXX; 1995;
						Urine and faeces	daily	
						Tissues	daily	
Lactating ruminants	goat	[Thiadiazole-2-14C] FOE 5043	1	5	3 days	Milk	Twice daily	XXXX; 1995;
						Urine and faeces	daily	
						Tissues	daily	
Lactating ruminants	goat	[Fluorophenyl-UL-14C] FOE oxalate	1	5.12	3 days	Milk	daily	XXXX;
						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	XXXX 1995;
						Tissues	daily	

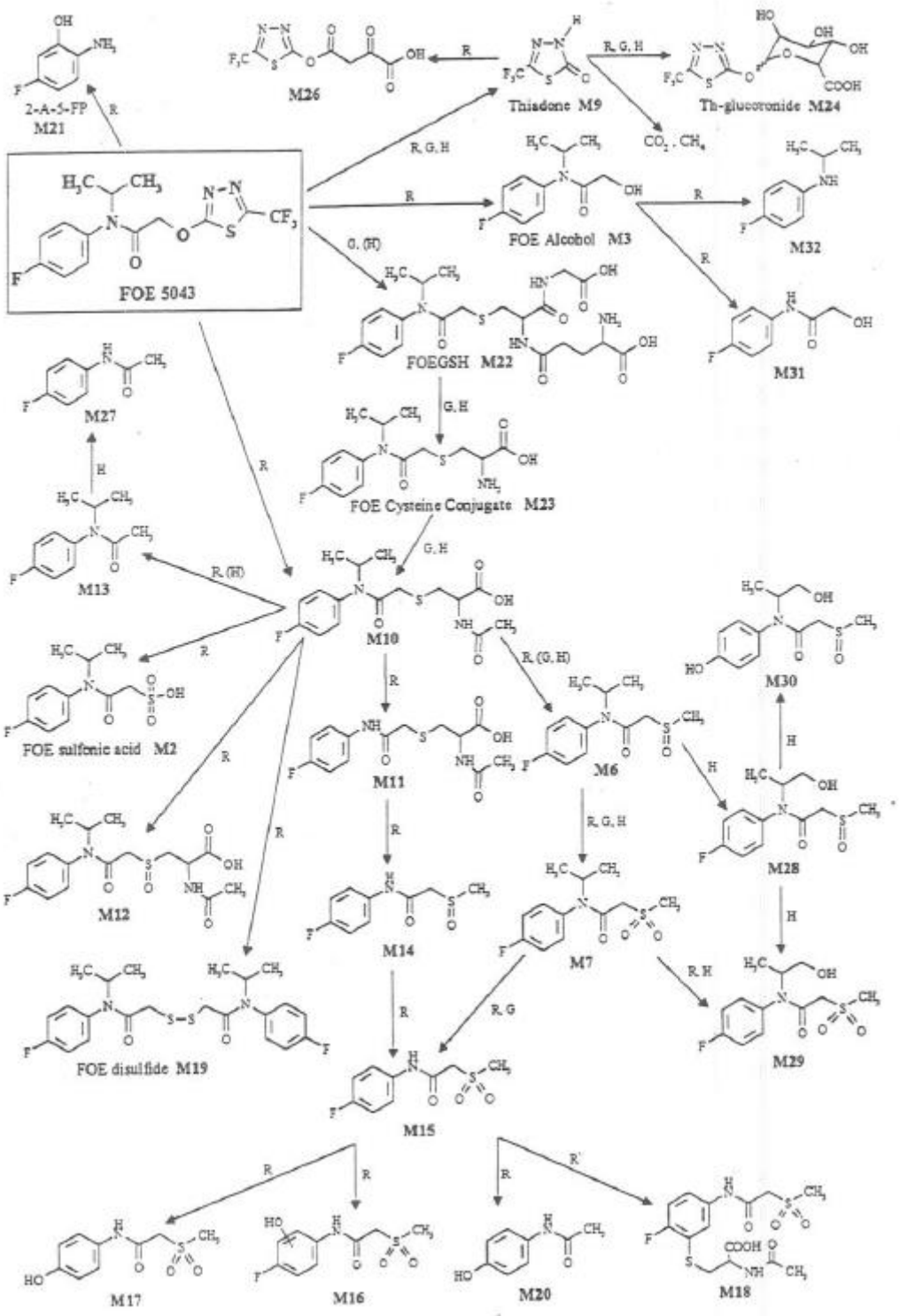
Summary of plant metabolism studies reported in the EU

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/PENDIF 599.5 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/PENDIF 599.5 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/PENDIF 599.5 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/PENDIF 599.5 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

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 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 realistic, 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/PENDIF 599.5 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/PENDIF 599.5 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)
Crop 1	Penoxsulam	0.002
	Diflufeniacn	0.001
	Flufenacet	0.15
	Cumulative risk Crop 1 (HI)	**0.153**

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 Penoxsulam, 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	T. Peda	2021	Magnitude of the residue of penoxsulam in Winter Wheat (Raw Agricultural Commodity) after one application of CHR/H/PENDIF 599.5 SC – one harvest trial in Poland – 2020 20SGS37 SGS Polska Sp. z o. o., Ul. Jana Kazimierza 3, 01-248 Warszawa, Poland GLP Unpublished	N	Chemirol Sp. z o.o.
KCP 6.3/02	S. Niewelt	2021	Magnitude of the residue of penoxsulam in Winter Wheat (Raw Agricultural Commodity) after one application of CHR/H/PENDIF 599.5 SC – one harvest trial in Poland – 2020 DPL/203/2020 SGS Polska Sp. z o. o., Ul. Jana Kazimierza 3, 01-248 Warszawa, Poland GLP Unpublished	N	Chemirol Sp. z o.o.
KCP 6.3/03	T. Peda	2021	Magnitude of the residue of penoxsulam in Winter Wheat (Raw Agricultural Commodity) after one application of CHR/H/PENDIF 599.5 SC – one decline curve trial in Poland – 2020 20SGS38 SGS Polska Sp. z o. o., Ul. Jana Kazimierza 3, 01-248 Warszawa, Poland GLP Unpublished	N	Chemirol Sp. z o.o.
KCP 6.3/04	S. Niewelt	2021	Magnitude of the residue of penoxsulam in Winter Wheat (Raw Agricultural Commodity) after one application of CHR/H/PENDIF 599.5 SC – one harvest trial in Poland – 2020 DPL/204/2020 SGS Polska Sp. z o. o., Ul. Jana Kazimierza 3, 01-248 Warszawa, Poland GLP Unpublished	N	Chemirol Sp. z o.o.

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 6.3/05	T. Peda	2021	Magnitude of the residue of penoxsulam in Winter Wheat (Raw Agricultural Commodity) after one application of CHR/H/PENDIF 599.5 SC – one harvest trial in Germany – 2020 20SGS39 SGS Polska Sp. z o. o., Ul. Jana Kazimierza 3, 01-248 Warszawa, Poland GLP Unpublished	N	Chemirol Sp. z o.o.
KCP 6.3/06	G. Paszek	2021	Magnitude of the residue of penoxsulam in Winter Wheat (Raw Agricultural Commodity) after one application of CHR/H/PENDIF 599.5 SC – one harvest trial in Germany – 2020 DPL/205/2020 SGS Polska Sp. z o. o., Ul. Jana Kazimierza 3, 01-248 Warszawa, Poland GLP Unpublished	N	Chemirol Sp. z o.o.
KCP 6.3/07	T. Peda	2021	Magnitude of the residue of penoxsulam in Winter Wheat (Raw Agricultural Commodity) after one application of CHR/H/PENDIF 599.5 SC – one decline curve trial in Germany – 2020 20SGS40 SGS Polska Sp. z o. o., Ul. Jana Kazimierza 3, 01-248 Warszawa, Poland GLP Unpublished	N	Chemirol Sp. z o.o.
KCP 6.3/08	G. Paszek	2021	Magnitude of the residue of penoxsulam in Winter Wheat (Raw Agricultural Commodity) after one application of CHR/H/PENDIF 599.5 SC – one decline curve trial in Germany – 2020 DPL/206/2020 SGS Polska Sp. z o. o., Ul. Jana Kazimierza 3, 01-248 Warszawa, Poland GLP Unpublished	N	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	Verte-brate study Y/N	Owner
KCP 6.1/01	A M Miller A D Thomas D A Lindsay	2002	Frozen Storage Stability of XDE-638 in Rice (Raw Agricultural Commodities: Grain, Straw, Immature Forage) and its Processed Products (Bran, Hills, Polished rice) – Interim Report GH-C-5485 Dow AgroSciences LLC Indianapolis, Indiana, USA GLP Unpublished	N	Dow AgroSciences
KCP 6.2.1/01	Yoder, R.N., Embrey, S.K.	2001	Nature of Residue of XDE-638 in Rice following Postemergent, Foliar Application 990028 Dow AgroSciences LLC Indianapolis, Indiana, USA GLP Unpublished	N	Dow AgroSciences
KCP 6.2.2/01	XXXXX	2002	Nature of Residue in the Lactating Goat Using 14C-XDE-638 000277 Dow AgroSciences LLC Indianapolis, Indiana, 46268 USA GLP Unpublished	Y	Dow AgroSciences
KCP 6.2.2./02	XXXXX	2002	Nature of Residue in the Laying Hen Using 14C-XDE-638 000371 Dow AgroSciences LLC Indianapolis, Indiana, 46268 USA GLP Unpublished	Y	Dow AgroSciences
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	N	BCS

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
			unpublished		
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 GLP / GEP Yes unpublished	N	BCS
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

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 6.2.1/05	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
KCP 6.2.1/06	Oddy A., Lowden P.	2003	(14C)-Diflufenican: Metabolism, distribution and expression of residues in winter wheat, with 2,4-difluorophenylring- 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	XXXXX	1989	(14C)-diflufenican - Absorption, tissue retention, metabolism and execretion in lactating cow. Generated by: Rhone-Poulenc; Inveresk Research International Ltd; Rhone-Poulenc Agriculture; Document No: R008143 GLP / GEP Yes	Y	BCS

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
			unpublished		
KCP 6.2.2./04	XXXXX	2000	The distribution and metabolism of (14C)-diflufenican in the lactating cow Generated by: Aventis CropScience UK Limited, GBR; Inveresk Research International Ltd, GBR; Document No: C010651 GLP / GEP Yes unpublished	Y	BCS
KCP 6.2.2/05	XXXXXX	2000	The distribution and metabolism of (14C)-diflufenican in the laying hen Generated by: Aventis CropScience UK Limited, GBR; Inveresk Research International Ltd, GBR; Document No: C010650 GLP / GEP Yes unpublished	Y	BCS
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,	N	BCS

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
			France; Document No: R008241 GLP / GEP Yes unpublished		
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 Document No: C025399 GLP / GEP Yes unpublished	N	BCS
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	N	BCS

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
			Document No: C025428 GLP / GEP Yes unpublished		
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
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	N	BCS

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
			Europe, Lyon Document No: C031018 GLP / GEP Yes unpublished		
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
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	N	BCS

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
			Document No: C030793 GLP / GEP Yes unpublished		
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	N	Bayer CropScience

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
			GLP/GEP: yes, unpublished		
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	XXXXX	1995	Metabolism of [Fluorophenyl-UL-14C] FOE 5043 in laying hens Bayer CropScience, 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	XXXX	1995	Metabolism of [Thiadiazole-2-14C] FOE 5043 in laying hens Bayer CropScience, Report No.: MR106785, GLP/GEP: yes, unpublished	Y	Bayer CropScience
KCP 6.2.2/09	XXXXX	1995	Metabolism of [phenyl-UL-14C] FOE oxalate in laying hens Bayer CropScience, Report No.: MR106787, Date: 1995-04-11 GLP/GEP: yes, unpublished	Y	Bayer CropScience
KCP 6.2.2/10	XXXXX	1995	Metabolism of [Fluorophenyl-UL-14C] FOE 5043 in a lactating goat Bayer CropScience, Report No.: MR105184, Date: 1995-03-03 GLP/GEP: yes, unpublished	Y	Bayer CropScience

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 6.2.2/11	XXXXX	1995	Metabolism of [thiadiazole-2-14C] FOE 5043 in a lactating goat Bayer CropScience, Report No.: MR105184, Date: 1995-03-03 GLP/GEP: yes, unpublished		
KCP 6.2.2/12	XXXXX.	1995	The metabolism of FOE 5043 in rats. Bayer AG, 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	N	Bayer CropScience

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
			301663 301671 302554 302562 305030 305049 305057 305065 305138 305146 GLP/GEP: yes, unpublished		
KCP 6.2.2/13	-	1995	FOE Oxalate - a 29-day dairy cattle feeding study Bayer CropScience, 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 Penoxsulam

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

A 2.1.3.1.1 Study 1

a) Field Phase:

Comments of zRMS:	The study has been accepted. The field phase of the study is acceptable. The objective of the study 1 harvest trial was to determine the residues of Penoxsulam in winter wheat RAC following one application of the formulated product CHR/H/PENDIF 599.5 SC. The collected samples were suitable for the purpose of the study and the residue values can therefore be considered as representative of the crop and of the application timing and rate of 15 g a.s./ha. SANCO/825/00, rev. 8.1; 16/11/2010 and SANCO/3029/99, rev. 4; 11/07/2000 are analytical guidelines. See for the analytical phase on next pages.

Reference:	KCP 6.3/01
Report	Magnitude of the residue of penoxsulam in Winter Wheat (Raw Agricultural Commodity) after one application of CHR/H/PENDIF 599.5 SC – one harvest trial in Poland – 2020, T. Peda, 2021, Study code: 20SGS37
Guideline(s):	Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009

	concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997 OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published in September 2009) SANCO/825/00, rev. 8.1; 16/11/2010 SANCO/3029/99, rev. 4; 11/07/2000
Deviations:	No
GLP:	Yes
Acceptability:	Yes

INTRODUCTION
Test item is a mixture of penoxsulam, diflufenican and flufenacet. It is an effective herbicide currently registered in winter wheat. The trial site chosen was representative for commercial production areas of winter wheat in Poland.

OBJECTIVE(S) OF THE STUDY

The objective of the study was conducted to determine the residue level of Penoxsulam in winter wheat RAC specimens in one harvest study trial following one application of the formulated product CHR/H/PENDIF 599.5 SC under cultural practice typical for winter wheat production.

MATERIAL AND METHODS

		CHR/H/PENDIF 599.5 SC
Batch No.:		032020
Active substance (a.s.):		Penoxsulam
		Diflufenican
		Flufenacet
CAS Number Penoxsulam:		219714-96-2
CAS Number Diflufenican:		83164-33-4
CAS Number Flufenacet:		142459-58-3
Formulation Name:		SC
Formulation Type:		Suspension Concentrate
Main uses:		Herbicide
Content of Penoxsulam	nominal:	3,1% w/w
	analysed:	3,97% w/w
Content of Diflufenican	nominal:	20,4% w/w
	analysed:	26,14% w/w

Content of Flufenacet	nominal:	25,4% w/w
	analysed:	32,55% w/w
Certificate of Analysis dated:		24/11/2020

The test item was stored at the test facility, in its original container and in an appropriate pesticide storage room at 0-30°C as defined in MSDS.

TRIAL SITE

One field trial was established on winter wheat. Trial number and location are summarised in table below

Trial number	Study type	Zone	Country (region)	Trial site	Postal code
20SGS37-01	HS	Central Europe	Poland (Warmińsko-Mazurskie)	Janowiec Kościelny	13-111

APPLICATION OF TEST ITEM

Application equipment

The application equipment consisted of boom sprayer. The foliar application closely simulated commercial-type treatments.

Calibration

Calibration of the spray equipment at the trial site was accomplished by using the volume/time method for liquid applications. Before application, the spray equipment and the sprayer speed were calibrated to deliver an average volume of spray mixture per unit time at a given pressure resulting in the desired spray volume per hectare.

Target application of the test item

CHR/H/PENDIF 599.5 SC was mixed only with water. The target dose rate of the test item according to study plan was 0,4 l/ha, equivalent to 15 g a.s./ha and target water volume 200-400 l/ha according to Good Agricultural Practice.

Actual application date	Application timing (BBCH)	Actual rate (l/ha)	Actual rate (g a. s./ha)	Percent of deviation (%)	Spray volume applied (l/ha)	Treated area (m^2)	Total spray mixture (ml)	Test item added to spray mixture (g)	Spray mixture remaining (ml)	Spray mixture applied to plot area (ml)
26/11/2020	22	0,412	15,5	+3,0	308,7	30	1400	2,260	474	926

Conditions at application

Application was carry out within one hour after mixing the spray solution and performed under conditions typical for the crop. The environmental conditions at the time of application were recorded in the Field Trial Notebook. These data include: air temperature, wind speed and direction, percentage of relative humidity, percentage of cloud cover, soil temperature, rainfall within 3 hours after application and soil surface and foliage moisture.

RAC SPECIMEN COLLECTION

Specimen collection

RAC specimens were collected following the target schedule below:

Sampling Timing	Sampling Event	Plot	Timing*	Commodity	**Minimum** sample size
	S1	U/T	**CH**	Grain	1 kg
				Straw	0,5 kg

*CH – Commercial Harvest;

Actual sampling details

Sampling date	**Specimen type**	**Plot**	**Specimen ID**	**Specimen weight [g]**
27/07/2021	Grain	U	20SGS37-01 1	1015
		U	20SGS37-01 1R	1034
		T	20SGS37-01 2	1012
		T	20SGS37-01 2R	1061
	Straw	U	20SGS37-01 3	598
		U	20SGS37-01 3R	533
		T	20SGS37-01 4	661
		T	20SGS37-01 4R	531

RAC specimen handling, storage and shipment

Quality control measures taken to maintain specimen integrity and to avoid contamination at the trial sites were recorded in the Field Trial Notebooks and included the following:

- Locating untreated plot at least 10 m away from treated plot.
- Collecting specimens from the inner part of each plot.
- Harvesting untreated plot before treated plot and/or different people sampled untreated and treated plots.
- Wearing disposable gloves.
- Transporting and storing untreated and treated specimens separately.

RAC specimens were shipped deep frozen at a target temperature below -18°C to the following analytical laboratory.

Table A 1: Summary of the study 1 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Grain	Straw		
20SGS37/Janowiec Kościelny, Poland/ Central Zone/ 2021	Winter Wheat/Mondia	1) 20.09.2020 2) – 3) 27.07.2021	15.5	308.7	5.02	26.11.2020	22	5 g for grain 2 g for straw	<LOD		NR	

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

b) Analytical Phase

Comments of zRMS:	The analytical phase of the study has been accepted. The method for determination of penoxsulam in winter wheat was validated for grain, plant and straw according to SANCO/3029/99, rev. 4 guidelines and SANCO/825/00 rev. 8.1.

Reference:	KCP 6.3/02
Report	Magnitude of the residue of penoxsulam in Winter Wheat (Raw Agricultural Commodity) after one application of CHR/H/PENDIF 599.5 SC – one harvest trial in Poland – 2020, S.Niewelt, 2021, Study code: DPL/203/2020
Guideline(s):	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC Commission Regulation (EU) no 283/2013 setting out the data requirements for active substances, in accordance with Regulation (EC) no 1107/2009
Deviations:	No
GLP:	Yes

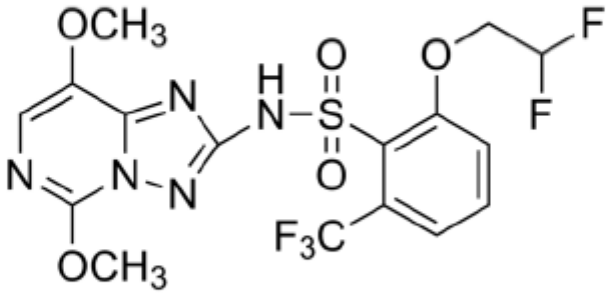
Specimen extraction and determination of residues of penoxsulam were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg.

MATERIALS AND METHODS

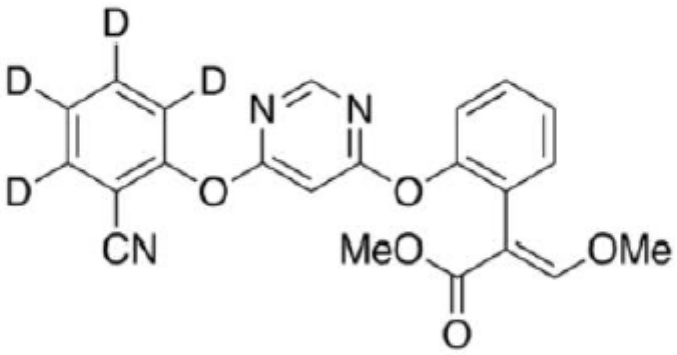
REFERENCE ITEMS

Penoxsulam

This reference item will be used for calibration and fortification purposes.
This reference item has been provided by HPC Standards, with certified information concerning identity, purity, and expiration date.

Common Name:	Penoxsulam
IUPAC Name:	3-(2,2-difluoroethoxy)-N-(5,8-dimethoxy[1,2,4]triazolo[1,5-c]pyrimidin-2-yl)-α,α,α-trifluorotoluene-2-sulfonamide
CAS –No:	219714-96-2
Molecular formula:	$C_{16}H_{14}F_5N_5O_5S$
Chemical structure: 	
Molecular weight:	483.37 g/mol
Purity:	99.9%
Lot:	793485
Expiry date:	01.02.2026

Azoxystrobin D4
This reference item will be used as internal standard for calibration and fortification purposes.
This reference item has been provided by HPC Standards, with certified information concerning identity, purity, and expiration date.

Common Name:	Azoxystrobin D4
IUPAC Name:	Methyl €-2-[2-[6-(2-cyano-3,4,5,6-tetradeuteriophenoxy) pyrimidin-4-yl]oxyphenyl]-3-methoxyprop-2-enoate
CAS –No:	1346606-39-0
Molecular formula:	$C_{22}H_{13}D_4N_3O_5$
Chemical structure: 	
Molecular weight:	407.41 g/mol
Purity:	99.9%
Lot:	789114
Expiry date:	01.02.2024

DETAILED DESCRIPTION OF THE ANALYTICAL PROCEDURE
INITIAL SAMPLE PREPARATION AND HOMOGENISATION

The field specimens arrived at the Test Site in good conditions, frozen and were stored in a freezer at ≤ -18oC before analysis. After removal from the freezer the samples were homogenized with dry ice at Test Site, using a knife grinder. The homogenized samples were divided into few portions: one portion was used as test sample in this study (DPL/203/2020), other portions were prepared as archival samples and the rest of the homogenized material was kept for use as a reference matrix, e.g. for method validation studies or freezer storage stability studies. The homogenized specimens were further stored at ≤ -18oC until beginning of analysis.

Information about specimen reception, extraction and analysis date

No.	Study sample code	Sample type	Laboratory sample code	Specimen Reception	Extraction Date/ Analysis Date
1	20SGS37-01 1	wheat (grain)	DPL/203/2020/01U	13.08.2021	20.08.2021
2	20SGS37-01 2	wheat (grain)	DPL/203/2020/02T	13.08.2021	20.08.2021
3	20SGS37-01 3	wheat (straw)	DPL/203/2020/03U	13.08.2021	20.08.2021
4	20SGS37-01 4	wheat (straw)	DPL/203/2020/04T	13.08.2021	20.08.2021

EXTRACTION
5 g (grain) / 2 g (straw) of the homogenized sample was weighed into a 50 mL centrifuge tube. 10 mL of deionized water and 10 mL of acetonitrile was added. Next to the sample was added 50 µL (grain) / 20 µL (straw) of internal standard solution (1.3), and the mixture was shaken vigorously by hand for one minute. After addition of buffering salts (4 g anhydrous magnesium sulfate, 1 g sodium chloride, 1 g trisodium citrate dehydrate, 0.5 g disodium hydrogencitrate sesquihydrate), the mixture was shaken again intensively for 1 min, then centrifuged at 4700 rpm for 5 min for phase separation and finally subjected to a freezing process at ≤ -18 oC for 1.5 h.. After that, the extract (organic phase) was filtered through a membrane filter and the final extract was directly employed for LC-MS/MS analysis. Quantification was performed using an internal standard, which was added to the extract after the initial addition of acetonitrile.

FORTIFICATION AND CONTROL SAMPLES
For analytical sequence one sample blank matrix and two procedural recoveries at the level of LOQ and two at the level 10 x LOQ were prepared together with the study samples. 5 g (grain) / 2 g (straw) of the homogenized untreated sample were weighed into a 50 mL centrifuge tube.
Preparation of fortification and control samples for grain

Fortification level	Amount of added standard solution [1.1] [µL]	Amount of added standard solution [1.2] [µL]	Amount of added internal standard solution [1.3] [µL]
Matrix blank	-	-	50.0
PK 0.010 mg/kg (LOQ)	-	50.0	50.0
PK 0.10 mg/kg (10 x LOQ)	50.0	-	50.0

Preparation of fortification and control samples for straw

Fortification level	Amount of added standard solution [1.1] [µL]	Amount of added standard solution [1.2] [µL]	Amount of added internal standard solution [1.3] [µL]
Matrix blank	-	-	20.0
PK 0.010 mg/kg (LOQ)	-	20.0	20.0
PK 0.10 mg/kg (10 x LOQ)	20.0	-	20.0

Extraction of field samples, as well as control and fortified samples was performed on 20.08.2021 and after that the samples were directly employed for LC-MS/MS analysis, that was started on the same day.

THE RESULTS FOR TREATED AND UNTREATED SAMPLES
The following residues concentration was determined in the field samples analyzed on 20.08.2021:

Residue concentrations of penoxsulam detected in analyzed field samples (Study No.: 20SGS37, Trial No.: 20SGS37-01 Harvest Study)

No	Timing	Study sample code	Type of commodity	Sample number given by the laboratory	Result [mg/kg]
1	S1	20SGS37-01 1	wheat (grain)	DPL/203/2020/01U	< LOD
2		20SGS37-01 2	wheat (grain)	DPL/203/2020/02T	< LOD
3		20SGS37-01 3	wheat (straw)	DPL/203/2020/03U	< LOD
4		20SGS37-01 4	wheat (straw)	DPL/203/2020/04T	< LOD

Residues are not corrected for procedural recoveries;
Calculation based on unrounded values, LOD = 0.003 mg/kg, LOQ = 0.01 mg/kg

CONCLUSIONS
The method was validated according to SANCO/3029/99, rev. 4 guidelines and SANCO/825/00 rev. 8.1., 16/11/2010 guidelines. The results acquired during validation of the analytical method (accuracy and repeatability) were in the range of 70 – 120% and RSD ≤ 20% for average recovery. The limit of quantification of the method was established at 0.010 mg/kg for grain and straw. There were no interfering signals at retention time of analyzed compound in examined control matrix. The analytical method for determining the residues of penoxsulam in wheat (grain, straw) meets the criteria of SANCO/3029/99, rev. 4 guidelines, SANCO/825/00 rev. 8.1., 16/11/2010 and SANTE/2020/12830, Rev.1 guidelines in terms of precision, accuracy and uncertainty.

A 2.1.3.1.2 Study 2

c) Field Phase:

Comments of zRMS:	The study has been accepted. The field phase of the study is acceptable. The objective of the study 1 decline trial was the determination of the residues of penoxsulam in winter wheat after one application of CHR/H/PENDIF 599.5 SC. The collected samples were suitable for the purpose of the study and the residue values can therefore be considered as representative of the crop and of the application timing and rate. The target rate of the test item according to study plan was 0,4 l/ha, equivalent to 15 g a.s./ha. SANCO/825/00, rev. 8.1; 16/11/2010 and SANCO/3029/99, rev. 4; 11/07/2000 are analytical guidelines. See for the analytical phase on next pages.

Reference:	KCP 6.3/03
Report	Magnitude of the residue of penoxsulam in Winter Wheat (Raw Agricultural Commodity) after one application of CHR/H/PENDIF 599.5 SC – one decline curve trial in Poland – 2020, T. Peda, 2021, Study code: 20SGS38
Guideline(s):	Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

	Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997 OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published in September 2009) SANCO/825/00, rev. 8.1; 16/11/2010 SANCO/3029/99, rev. 4; 11/07/2000
Deviations:	No
GLP:	Yes
Acceptability:	Yes

INTRODUCTION
Test item is a mixture of penoxsulam, diflufenican and flufenacet. It is an effective herbicide currently registered in winter wheat. The trial site chosen was representative for commercial production areas of winter wheat in Poland.

OBJECTIVE(S) OF THE STUDY

The objective of the study was conducted to determine the residue level of Penoxsulam in winter wheat RAC specimens in one harvest study trial following one application of the formulated product CHR/H/PENDIF 599.5 SC under cultural practice typical for winter wheat production.

MATERIAL AND METHODS

		CHR/H/PENDIF 599.5 SC
Batch No.:		032020
Active substance (a.s.):		Penoxsulam
		Diflufenican
		Flufenacet
CAS Number Penoxsulam:		219714-96-2
CAS Number Diflufenican:		83164-33-4
CAS Number Flufenacet:		142459-58-3
Formulation Name:		SC
Formulation Type:		Suspension Concentrate
Main uses:		Herbicide
Content of Penoxsulam	nominal:	3,1% w/w
	analysed:	3,97% w/w
Content of Diflufenican	nominal:	20,4% w/w
	analysed:	26,14% w/w
Content of Flufenacet	nominal:	25,4% w/w

	analysed:	32,55% w/w
Certificate of Analysis dated:		24/11/2020

The test item was stored at the test facility, in its original container and in an appropriate pesticide storage room at 0-30°C as defined in MSDS.

TRIAL SITE

One field trial was established on winter wheat. Trial number and location are summarised in table below

Trial number	**Study type**	**Zone**	**Country (region)**	**Trial site**	**Postal code**
20SGS38-01	DCS	Central Europe	Poland (Kujawsko-Pomorskie)	Kamień Krajeński	89-430

APPLICATION OF TEST ITEM

Application equipment

The application equipment consisted of boom sprayer. The foliar application closely simulated commercial-type treatments.

Calibration

Calibration of the spray equipment at the trial site was accomplished by using the volume/time method for liquid applications. Before application, the spray equipment and the sprayer speed were calibrated to deliver an average volume of spray mixture per unit time at a given pressure resulting in the desired spray volume per hectare.

Target application of the test item

CHR/H/PENDIF 599.5 SC was mixed only with water. The target dose rate of the test item according to study plan was 0,4 l/ha, equivalent to 15 g a.s./ha and target water volume 200-400 l/ha according to Good Agricultural Practice.

Actual application date	**Application timing (BBCH)**	**Actual rate (l/ha)**	**Actual rate (g a.s./ha)**	**Percent of deviation (%)**	**Spray volume applied (l/ha)**	**Treated area (m²)**	**Total spray mixture (ml)**	**Test item added to spray mixture (g)**	**Spray mixture remaining (ml)**	**Spray mixture applied to plot area (ml)**
24/11/2020	22	0,411	15,4	+2,7	205,3	45	1400	3,389	476	924

Conditions at application

Application was carry out within one hour after mixing the spray solution and performed under conditions typical for the crop. The environmental conditions at the time of application were recorded in the Field Trial Notebook. These data include: air temperature, wind speed and direction, percentage of relative humidity, percentage of cloud cover, soil temperature, rainfall within 3 hours after application and soil surface and foliage moisture.

RAC SPECIMEN COLLECTION

Specimen collection

RAC specimens were collected following the target schedule below:

Sampling Timing	Sampling Event	Plot	Timing*	Commodity	**Minimum** sample size
	S1	U/T	**0 DALA**	Whole plant without root	0,1 kg
	S2	T	**BBCH 37**	Whole plant without root	0,5 kg
	S3	T	**BBCH 71**	Whole plant without root	0,5 kg
	S4	U/T	**CH**	Grain	1 kg
				Straw	0,5 kg

*CH – Commercial Harvest;

Actual sampling details

Sampling date	**Specimen type**	**Plot**	**Specimen ID**	**Specimen weight [g]**
24/11/2020	Whole plant without root	U	20SGS38-01 1	310
		U	20SGS38-01 1R	305
		T	20SGS38-01 2	303
		T	20SGS38-01 2R	301
25/05/2021	Whole plant without root	T	20SGS38-01 3	621
		T	20SGS38-01 3R	531
28/06/2021	Whole plant without root	T	20SGS38-01 4	836
		T	20SGS38-01 4R	958
10/08/2021	Grain	U	20SGS38-01 5	1207
		U	20SGS38-01 5R	1210
		T	20SGS38-01 6	1377
		T	20SGS38-01 6R	1077
	Straw	U	20SGS38-01 7	716

		U	20SGS38-01	7R	588
		T	20SGS38-01	8	603
		T	20SGS38-01	8R	501

RAC specimen handling, storage and shipment

Quality control measures taken to maintain specimen integrity and to avoid contamination at the trial sites were recorded in the Field Trial Notebooks and included the following:

- Locating untreated plot at least 10 m away from treated plot.
- Collecting specimens from the inner part of each plot.
- Harvesting untreated plot before treated plot and/or different people sampled untreated and treated plots.
- Wearing disposable gloves.
- Transporting and storing untreated and treated specimens separately.

RAC specimens were shipped deep frozen at a target temperature below -18°C to the following analytical laboratory.

Table A 2: Summary of the study 2 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)			PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Grain	Straw	Whole Plant		
	(a)	(b)				(c)						(d)	(e)
20SGS38/Kamień Krajeński, Poland/ Central Zone/ 2021	Winter Wheat/Admont	1) 02.10.2020 2) – 3) 10.09.2021	15.4	205.3	7.5	24.11.2020	22	5 g for grain and plant 2 g for straw	<LOD			NR	

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

d) Analytical Phase

Comments of zRMS:	The analytical phase of the study has been accepted. The method was validated according to SANCO/3029/99. The results acquired during validation of the analytical method (accuracy and repeatability) were in the range of 70 - 120% and RSD s < 20% for average recovery. The LOQ of the method was established at 0.010 mg/kg for each of matrix.

Reference:	KCP 6.3/04
Report	Magnitude of the residue of Penoxsulam in Winter Wheat (Raw Agricultural Commodity) after one application of CHR/H/PENDIF 599.5 SC – one decline curve trial in Poland – 2020, S.Niewelt, 2021, Study code: DPL/204/2020
Guideline(s):	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC Commission Regulation (EU) no 283/2013 setting out the data requirements for active substances, in accordance with Regulation (EC) no 1107/2009
Deviations:	No
GLP:	Yes

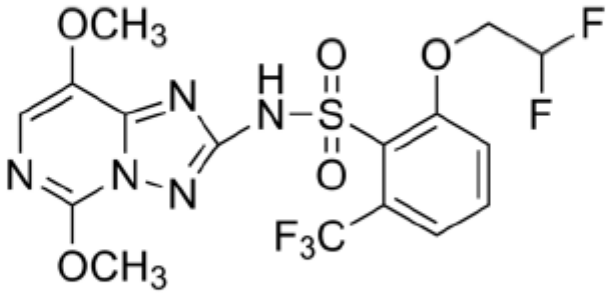
Specimen extraction and determination of residues of penoxsulam were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg.

MATERIALS AND METHODS

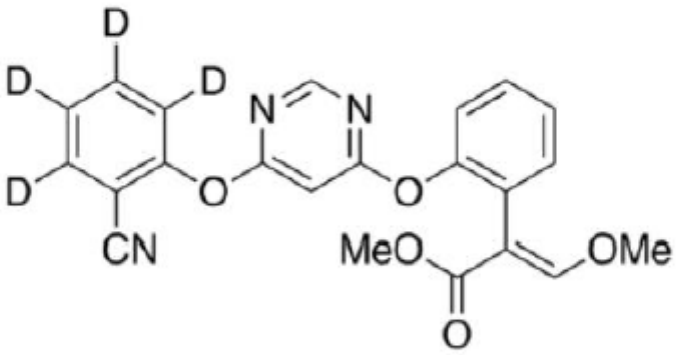
REFERENCE ITEMS

Penoxsulam

This reference item will be used for calibration and fortification purposes.
This reference item has been provided by HPC Standards, with certified information concerning identity, purity, and expiration date.

Common Name:	Penoxsulam
IUPAC Name:	3-(2,2-difluoroethoxy)-N-(5,8-dimethoxy[1,2,4]triazolo[1,5-c]pyrimidin-2-yl)-α,α,α-trifluorotoluene-2-sulfonamide
CAS –No:	219714-96-2
Molecular formula:	$C_{16}H_{14}F_5N_5O_5S$
Chemical structure: 	
Molecular weight:	483.37 g/mol
Purity:	99.9%
Lot:	793485
Expiry date:	01.02.2026

Azoxystrobin D4
This reference item will be used as internal standard for calibration and fortification purposes.
This reference item has been provided by HPC Standards, with certified information concerning identity, purity, and expiration date.

Common Name:	Azoxystrobin D4
IUPAC Name:	Methyl €-2-[2-[6-(2-cyano-3,4,5,6-tetradeuteriophenoxy) pyrimidin-4-yl]oxyphenyl]-3-methoxyprop-2-enoate
CAS –No:	1346606-39-0
Molecular formula:	$C_{22}H_{13}D_4N_3O_5$
Chemical structure: 	
Molecular weight:	407.41 g/mol
Purity:	99.9%
Lot:	789114
Expiry date:	01.02.2024

DETAILED DESCRIPTION OF THE ANALYTICAL PROCEDURE
INITIAL SAMPLE PREPARATION AND HOMOGENISATION

The field specimens arrived at the Test Site in good conditions, frozen and were stored in a freezer at ≤ -18oC before analysis. After removal from the freezer the samples were homogenized with dry ice at Test Site, using a knife grinder. The homogenized samples were divided into few portions: one portion was used as test sample in this study (DPL/204/2020), other portions were prepared as archival samples and the rest of the homogenized material was kept for use as a reference matrix, e.g. for method validation studies or freezer storage stability studies. The homogenized specimens were further stored at ≤ -18oC until beginning of analysis..

Information about specimen reception, extraction and analysis date

No.	Study sample code	Sample type	Laboratory sample code	Specimen Reception	Extraction Date/ Analysis Date
1	20SGS37-01 1	wheat (grain)	DPL/203/2020/01U	13.08.2021	20.08.2021
2	20SGS37-01 2	wheat (grain)	DPL/203/2020/02T	13.08.2021	20.08.2021
3	20SGS37-01 3	wheat (straw)	DPL/203/2020/03U	13.08.2021	20.08.2021
4	20SGS37-01 4	wheat (straw)	DPL/203/2020/04T	13.08.2021	20.08.2021

EXTRACTION
5 g (plant, grain) / 2 g (straw) of the homogenized sample was weighed into a 50 mL centrifuge tube. 10 mL of deionized water and 10 mL of acetonitrile was added. Next to the sample was added 50 µL (plant, grain) / 20 µL (straw) of internal standard solution (1.3), and the mixture was shaken vigorously by hand for one minute. After addition of buffering salts (4 g anhydrous magnesium sulfate, 1 g sodium chloride, 1 g trisodium citrate dehydrate, 0.5 g disodium hydrogencitrate sesquihydrate), the mixture was shaken again intensively for 1 min, then centrifuged at 4700 rpm for 5 min for phase separation and finally subjected to a freezing process at ≤ -18 oC for 1.5 h.. After that, the extract (organic phase) was filtered through a membrane filter and the final extract was directly employed for LC-MS/MS analysis. Quantification was performed using an internal standard, which was added to the extract after the initial addition of acetonitrile.

FORTIFICATION AND CONTROL SAMPLES
For analytical sequence one sample blank matrix and two procedural recoveries at the level of LOQ and two at the level 10 x LOQ were prepared together with the study samples. 5 g (plant, grain) / 2 g (straw) of the homogenized untreated sample were weighed into a 50 mL centrifuge tube.
Preparation of fortification and control samples for plant and grain

Fortification level	Amount of added standard solution [1.1] [µL]	Amount of added standard solution [1.2] [µL]	Amount of added internal standard solution [1.3] [µL]
Matrix blank	-	-	50.0
PK 0.010 mg/kg (LOQ)	-	50.0	50.0
PK 0.10 mg/kg (10 x LOQ)	50.0	-	50.0

Preparation of fortification and control samples for straw

Fortification level	Amount of added standard solution [1.1] [µL]	Amount of added standard solution [1.2] [µL]	Amount of added internal standard solution [1.3] [µL]
Matrix blank	-	-	20.0
PK 0.010 mg/kg (LOQ)	-	20.0	20.0
PK 0.10 mg/kg (10 x LOQ)	20.0	-	20.0

Extraction of field samples, as well as control and fortified samples was performed on:
- 23.12.2020 (DPL/204/2020/01U, /02T)

- 28.05.2021 (DPL/204/2020/03T)
- 05.07.2021 (DPL/204/2020/04T)
- 20.08.2021 (DPL/204/2020/05U, /06T, /07U, /08T)

and after that the samples were directly employed for LC-MS/MS analysis, that was started on the same day.

THE RESULTS FOR TREATED AND UNTREATED SAMPLES

The following residues concentration was determined in the field samples analyzed on 23.12.2020, 28.05.2021, 05.07.2021 and 20.08.2021:

Residue concentrations of penoxsulam detected in analyzed field samples (Study No.: 20SGS38, Trial No.: 20SGS38-01 Decline Study)

No	Timing	Study sample code	Type of commodity	Sample number given by the laboratory	Result [mg/kg]
1	S1	20SGS38-01 1	wheat (whole plant without root)	DPL/204/2020/01U	< LOD
2		20SGS38-01 2	wheat (whole plant without root)	DPL/204/2020/02T	1.67
3	S2	20SGS38-01 3	wheat (whole plant without root)	DPL/204/2020/03T	< LOD
4	S3	20SGS38-01 4	wheat (whole plant without root)	DPL/204/2020/04T	< LOD
5	S4	20SGS38-01 5	wheat (grain)	DPL/204/2020/05U	< LOD
6		20SGS38-01 6	wheat (grain)	DPL/204/2020/06T	< LOD
7		20SGS38-01 7	wheat (straw)	DPL/204/2020/07U	< LOD
8		20SGS38-01 8	wheat (straw)	DPL/204/2020/08T	< LOD

Residues are not corrected for procedural recoveries;
Calculation based on unrounded values, LOD = 0.003 mg/kg, LOQ = 0.01 mg/kg

All recovery values at fortification levels of 0.010 mg/g and 0.10 mg/kg comply with the standard acceptance criteria of the guidance documents to SANCO/3029/99, SANCO/825/00 rev. 8.1, 16/11/2010 and SANTE/2020/12830, Rev.1.

The stability of the analytes in the final extracts was proven by the corresponding procedural recovery samples, which were stored under the same conditions together with the extracts of the specimens for residue analysis. The recovery values for PK2 0.010 mg/kg and PK2 0.10 mg/kg (in the range of 70 – 120%) confirms the active substance stability during the analytical procedure. The duration of the extraction and chromatographic analysis:

1) 23.12.2020 (wheat plant) – duration of the extraction process was about 3 h and duration of the chromatographic analysis was 260 min (4.3 h), the total analytical procedure was performed and completed within 1 day (less than 8 h)

2) 28.05.2021 (wheat plant) - duration of the extraction process was about 3 h and duration of the chromatographic analysis was 208 min (3.5 h), the total analytical procedure was performed and completed within 1 day (about 6.5 h)

3) 05.07.2021 (wheat plant) - duration of the extraction process was about 3 h and duration of the

chromatographic analysis was 208 min (3.5 h), the total analytical procedure was performed and completed within 1 day (about 6.5 h)
4) 20.08.2021 (wheat grain) - duration of the extraction process was about 3 h and duration of the chromatographic analysis was 286 min (4.8 h), the total analytical procedure was performed and completed within 1 day (about 8 h)
5) 20.08.2021 (wheat straw) - duration of the extraction process was about 3 h and duration of the chromatographic analysis was 273 min (4.6 h), the total analytical procedure was performed and completed within 1 day (less than 8 h)
Extract stability is not considered to be an issue, since working standard that were used for quantification were always prepared on the same day as the work up of the specimen for residue analysis took place.

CONCLUSIONS
The method was validated according to SANCO/3029/99, rev. 4 guidelines and SANCO/825/00 rev. 8.1., 16/11/2010 guidelines. The results acquired during validation of the analytical method (accuracy and repeatability) were in the range of 70 – 120% and RSD ≤ 20% for average recovery. The limit of quantification of the method was established at 0.010 mg/kg for grain, plant and straw. There were no interfering signals at retention time of analyzed compound in examined control matrix. The analytical method for determining the residues of penoxsulam in wheat (grain, plant, straw) meets the criteria of SANCO/3029/99, rev. 4 guidelines, SANCO/825/00 rev. 8.1., 16/11/2010 and SANTE/2020/12830, Rev.1 guidelines in terms of precision, accuracy and uncertainty.

A 2.1.3.1.3 Study 3

e) Field Phase:

Comments of zRMS:	The study has been accepted. The field phase of the study is acceptable. The objective of the study 1 decline trial was the determination of the residues of penoxsulam in winter wheat after one application of CHR/H/PENDIF 599.5 SC. The collected samples were suitable for the purpose of the study and the residue values can therefore be considered as representative of the crop and of the application timing and rate. The target rate of the test item according to study plan was 0,4 l/ha, equivalent to 15 g a.s./ha. SANCO/825/00, rev. 8.1; 16/11/2010 and SANCO/3029/99, rev. 4; 11/07/2000 are analytical guidelines. See for the analytical phase on next pages.

Reference:	KCP 6.3/05
Report	Magnitude of the residue of penoxsulam in Winter Wheat (Raw Agricultural Commodity) after one application of CHR/H/PENDIF 599.5 SC – one harvest trial in Germany – 2020, T. Peda, 2021, Study code: 20SGS39
Guideline(s):	Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997 OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published in September 2009) SANCO/825/00, rev. 8.1; 16/11/2010

	SANCO/3029/99, rev. 4; 11/07/2000
Deviations:	Yes, deviations has no impact on the study.
GLP:	Yes
Acceptability:	Yes

INTRODUCTION
Test item is a mixture of penoxsulam, diflufenican and flufenacet. It is an effective herbicide currently registered in winter wheat. The trial site chosen was representative for commercial production areas of winter wheat in Germany.

OBJECTIVE(S) OF THE STUDY

The objective of the study was conducted to determine the residue level of Penoxsulam in winter wheat RAC specimens in one harvest study trial following one application of the formulated product CHR/H/PENDIF 599.5 SC under cultural practice typical for winter wheat production.

MATERIAL AND METHODS

		CHR/H/PENDIF 599.5 SC
Batch No.:		032020
Active substance (a.s.):		Penoxsulam
		Diflufenican
		Flufenacet
CAS Number Penoxsulam:		219714-96-2
CAS Number Diflufenican:		83164-33-4
CAS Number Flufenacet:		142459-58-3
Formulation Name:		SC
Formulation Type:		Suspension Concentrate
Main uses:		Herbicide
Content of Penoxsulam	nominal:	3,1% w/w
	analysed:	3,97% w/w
Content of Diflufenican	nominal:	20,4% w/w
	analysed:	26,14% w/w
Content of Flufenacet	nominal:	25,4% w/w
	analysed:	32,55% w/w
Certificate of Analysis dated:		24/11/2020

The test item was stored at the test facility, in its original container and in an appropriate pesticide storage room at 0-30°C as defined in MSDS.

TRIAL SITE

One field trial was established on winter wheat. Trial number and location are summarised in table below

Trial number	Study type	Zone	Country (region)	Trial site	Postal code
20SGS39-01	HS	Central Europe	Germany (Brandenburg)	Neuruppin	16816

APPLICATION OF TEST ITEM

Application equipment

The application equipment consisted of boom sprayer. The foliar application closely simulated commercial-type treatments.

Calibration

Calibration of the spray equipment at the trial site was accomplished by using the volume/time method for liquid applications. Before application, the spray equipment and the sprayer speed were calibrated to deliver an average volume of spray mixture per unit time at a given pressure resulting in the desired spray volume per hectare.

Target application of the test item

CHR/H/PENDIF 599.5 SC was mixed only with water. The target dose rate of the test item according to study plan was 0,4 l/ha, equivalent to 15 g a.s./ha and target water volume 200-400 l/ha according to Good Agricultural Practice.

Actual application date	Application timing (BBCH)	Actual rate (l/ha)	Actual rate (g a.s./ha)	Percent of deviation (%)	Spray volume applied (l/ha)	Treated area (m²)	Total spray mixture (ml)	Test item added to spray mixture (g)	Spray mixture remaining (ml)	Spray mixture applied to plot area (ml)
08/12/2020	22	0,387	14,5	-3,3	193,3	30	2000	4,842	1420	580

Conditions at application

Application was carry out within one hour after mixing the spray solution and performed under conditions typical for the crop. The environmental conditions at the time of application were recorded in the Field Trial Notebook. These data include: air temperature, wind speed and direction, percentage of relative humidity, percentage of cloud cover, soil temperature, rainfall within 3 hours after application and soil surface and foliage moisture.

RAC SPECIMEN COLLECTION

Specimen collection

RAC specimens were collected following the target schedule below:

Sampling Timing	Sampling Event	Plot	Timing*	Commodity	**Minimum** sample size
	S1	U/T	**CH**	Grain	1 kg
				Straw	0,5 kg

*CH – Commercial Harvest;

Actual sampling details

Sampling date	**Specimen type**	**Plot**	**Specimen ID**	**Specimen weight [g]**
21/07/2021	Grain	U	20SGS39-01 1	1415,4
		U	20SGS39-01 1R	1072
		T	20SGS39-01 2	1019
		T	20SGS39-01 2R	1026,2
	Straw	U	20SGS39-01 3	933
		U	20SGS39-01 3R	915,2
		T	20SGS39-01 4	834
		T	20SGS39-01 4R	889,8

RAC specimen handling, storage and shipment

Quality control measures taken to maintain specimen integrity and to avoid contamination at the trial sites were recorded in the Field Trial Notebooks and included the following:

- Locating untreated plot at least 10 m away from treated plot.
- Collecting specimens from the inner part of each plot.
- Harvesting untreated plot before treated plot and/or different people sampled untreated and treated plots.
- Wearing disposable gloves.
- Transporting and storing untreated and treated specimens separately.

RAC specimens were shipped deep frozen at a target temperature below -18°C to the following analytical laboratory.

Table A 3: Summary of the study 3 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Grain	Straw		
20SGS39/Neuruppin, Germany, Brandenburg/ 2021	Winter Wheat/RGT Reform	1) 01.20.2020 2) – 3) 19.07.2021-25.07.2021	14.5	193.3	7.5	08.12.2020	22	5 g	<LOD		NR	

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

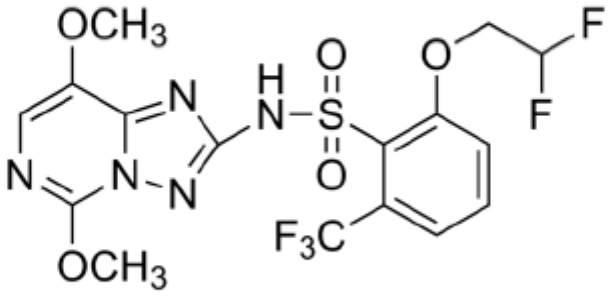
f) Analytical Phase

Comments of zRMS:	The analytical phase of the study has been accepted. The method was validated according to SANCO/3029/99. The results acquired during validation of the analytical method (accuracy and repeatability) were in the range of 70 - 110% and RSD s < 20% for average recovery. The LOQ of the method was established at 0.010 mg/kg.

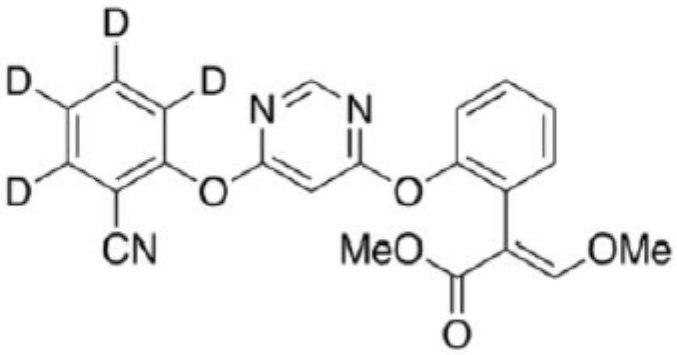
Reference:	KCP 6.3/06
Report	Magnitude of the residue of Penoxsulam in Winter Wheat (Raw Agricultural Commodity) after one application of CHR/H/PENDIF 599.5 SC – one harvest trial in Germany – 2020, G. Paszek, 2021, Study code: DPL/205/2020
Guideline(s):	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC Commission Regulation (EU) no 283/2013 setting out the data requirements for active substances, in accordance with Regulation (EC) no 1107/2009
Deviations:	No
GLP:	Yes

The method for determination of penoxsulam in winter wheat (independent for grains, plant and straw) was validated at Test Site SGS Polska Sp. z o.o., ul. Cieszyńska 52A, Pszczyna, according to SANCO/3029/99, rev. 4 guidelines and SANCO/825/00 rev. 8.1. Validation criteria and results will be summarized in study DPL/206/2020 (20SGS40), entitled: "Magnitude of the residue of Penoxsulam in Winter Wheat (Raw Agricultural Commodity) after one application of CHR/H/PENDIF 599.5 SC – one decline curve trial in Germany – 2020". ANALYTICAL PROCEDURE DPL-29 Determination of residues of penoxsulam in plant material using the QuEChERS technique and LC-MSMS detection based on:
EN 15662:2018 Foods of plant origin. Multimethod for the determination of pesticide residues using GC- and LC-based analysis following acetonitrile extraction/partitioning and clean-up by dispersive SPE. Modular QuEChERS-method.

MATERIALS AND METHODS
REFERENCE ITEMS
Penoxsulam
This reference item will be used for calibration and fortification purposes.
This reference item has been provided by HPC Standards, with certified information concerning identity, purity, and expiration date.

Common Name:	Penoxsulam
IUPAC Name:	3-(2,2-difluoroethoxy)-N-(5,8-dimethoxy[1,2,4]triazolo[1,5-c]pyrimidin-2-yl)-α,α,α-trifluorotoluene-2-sulfonamide
CAS –No:	219714-96-2
Molecular formula:	$C_{16}H_{14}F_5N_5O_5S$
Chemical structure: 	
Molecular weight:	483.37 g/mol
Purity:	99.9%
Lot:	793485
Expiry date:	01.02.2026

Azoxystrobin D4
This reference item will be used as internal standard for calibration and fortification purposes.
This reference item has been provided by HPC Standards, with certified information concerning identity, purity, and expiration date.

Common Name:	Azoxystrobin D4
IUPAC Name:	Methyl €-2-[2-[6-(2-cyano-3,4,5,6-tetradeuteriophenoxy) pyrimidin-4-yl]oxyphenyl]-3-methoxyprop-2-enoate
CAS –No:	1346606-39-0
Molecular formula:	$C_{22}H_{13}D_4N_3O_5$
Chemical structure: 	
Molecular weight:	407.41 g/mol
Purity:	99.9%
Lot:	789114
Expiry date:	01.02.2024

DETAILED DESCRIPTION OF THE ANALYTICAL PROCEDURE
INITIAL SAMPLE PREPARATION AND HOMOGENISATION

The field specimens arrived at the Test Site in good conditions, frozen and were stored in a freezer at ≤ -18oC before analysis. After removal from the freezer the samples were homogenized with dry ice at Test Site, using a knife grinder. The homogenized samples were divided into few portions: one portion was used as test sample in this study (DPL/205/2020), other portions were prepared as archival samples and the rest of the homogenized material was kept for use as a reference matrix, e.g. for method validation studies or freezer storage stability studies. The homogenized specimens were further stored at ≤ -18oC until beginning of analysis.

Information about specimen reception, extraction and analysis date

No.	Study sample code	Sample type	Laboratory sample code	Specimen Reception	Extraction Date/ Analysis Date
1	20SGS39-01 1	wheat (grain)	DPL/205/2020/01U	13.08.2021	20.08.2021
2	20SGS39-01 2	wheat (grain)	DPL/205/2020/02T	13.08.2021	20.08.2021
3	20SGS39-01 3	wheat (straw)	DPL/205/2020/03U	13.08.2021	20.08.2021
4	20SGS39-01 4	wheat (straw)	DPL/205/2020/04T	13.08.2021	20.08.2021

EXTRACTION
5 g of the homogenized sample was weighed into a 50 mL centrifuge tube. 10 mL of acetonitrile was added together with 50 µL of internal standard solution (1.3), and the mixture was shaken vigorously by hand for one minute. After addition of buffering salts (4 g anhydrous magnesium sulfate, 1 g sodium chloride, 1 g trisodium citrate dehydrate, 0.5 g disodium hydrogencitrate sesquihydrate), the mixture was shaken again intensively for 1 min, then centrifuged at 4700 rpm. After that, the extract (organic phase) was filtered through a membrane filter and the final extract was directly employed for LC-MS/MS analysis. Quantification was performed using an internal standard, which was added to the extract after the initial addition of acetonitrile..

FORTIFICATION AND CONTROL SAMPLES
For analytical sequence one sample blank matrix and two procedural recoveries at the level of LOQ and two at the level 10 x LOQ were prepared together with the study samples.5 g of the homogenized untreated sample were weighed into a 50 mL centrifuge tube.
Preparation of fortification and control samples

Fortification level	Amount of standard solution 1.1 added [µL]	Amount of standard solution 1.2 added [µL]
Matrix blank	-	-
PK 0.01 mg/kg (LOQ)	-	50.0
PK 0.10 mg/kg (10xLOQ)	50.0	-

Extraction of all field samples (treated and untreated), as well as control and fortified samples was performed on 20.08.2021 and after that the samples were directly employed for LC-MS/MS analysis, that was started on the same day.

THE RESULTS FOR TREATED AND UNTREATED SAMPLES
The following residues concentration was determined in the field samples analyzed on 20.08.2021:
Residue concentrations of penoxsulam detected in analyzed field samples (Study No.: 20SGS39, Trial No.: 20SGS39-01 Harvest Study)

No	Timing	Study sample code	Type of commodity	Sample number given by the laboratory	Result [mg/kg]
1	S1	20SGS39-01 1	wheat (grain)	DPL/205/2020/01U	< LOD
2		20SGS39-01 2	wheat (grain)	DPL/205/2020/02T	< LOD
3		20SGS39-01 3	wheat (straw)	DPL/205/2020/03U	< LOD
4		20SGS39-01 4	wheat (straw)	DPL/205/2020/04T	< LOD

Residues are not corrected for procedural recoveries;
Calculation based on unrounded values, **LOD = 0.003 mg/kg, LOQ = 0.01 mg/kg**

All recovery values at fortification levels of 0.010 mg/g and 0.10 mg/kg comply with the standard acceptance criteria of the guidance documents to SANTE/2020/12830, Rev.1. The stability of the analytes in the final extracts was proven by the corresponding procedural recovery samples, which were stored under the same conditions together with the extracts of the specimens for residue analysis. The recovery values for PK2 0.01 mg/kg and PK2 0.10 mg/kg (in the range of 70 – 110%) confirms the active substance stability during the analytical procedure. The duration of the extraction process was about 4 hours, the duration of the chromatographic analysis was 559 minutes (9.3 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day (less than 10 h). Working standard that were used for quantification were always prepared on the same day as the work up of the specimen for residue analysis took place and samples were analyzed within 24 hours of extraction. Then extract stability is not considered to be an issue.

CONCLUSIONS
The method was validated according to SANCO/3029/99, rev. 4 guideline..
The results acquired during validation of the analytical method (accuracy and repeatability) were in the range of 70 – 110% and RSD ≤ 20% for average recovery.
The limit of quantification of the method was established at 0.01 mg/kg.
There were no interfering signals at retention time of analyzed compound in examined control matrix.

A 2.1.3.1.4 Study 4

g) Field Phase:

Comments of zRMS:	The study has been accepted. The field phase of the study is acceptable. The objective of the study 1 decline trial was the determination of the residues of penoxsulam in winter wheat after one application of CHR/H/PENDIF 599.5 SC. The collected samples were suitable for the purpose of the study and the residue values can therefore be considered as representative of the crop and of the application timing and rate. The target rate of the test item according to study plan was 0,4 l/ha, equivalent to 15 g a.s./ha. SANCO/825/00, rev. 8.1; 16/11/2010 and SANCO/3029/99, rev. 4; 11/07/2000 are analytical guidelines. See for the analytical phase on next pages.

Reference: KCP 6.3/07

Report	Magnitude of the residue of penoxsulam in Winter Wheat (Raw Agricultural Commodity) after one application of CHR/H/PENDIF 599.5 SC – one decline curve trial in Germany – 2020, T. Peda, 2021, Study code: 20SGS40
Guideline(s):	Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997 OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published in September 2009) SANCO/825/00, rev. 8.1; 16/11/2010 SANCO/3029/99, rev. 4; 11/07/2000
Deviations:	No
GLP:	Yes
Acceptability:	Yes

INTRODUCTION
Test item is a mixture of penoxsulam, diflufenican and flufenacet. It is an effective herbicide currently registered in winter wheat. The trial site chosen was representative for commercial production areas of winter wheat in Germany.

OBJECTIVE(S) OF THE STUDY

The objective of the study was conducted to determine the residue level of Penoxsulam in winter wheat RAC specimens in one harvest study trial following one application of the formulated product CHR/H/PENDIF 599.5 SC under cultural practice typical for winter wheat production.

MATERIAL AND METHODS

		CHR/H/PENDIF 599.5 SC
Batch No.:		032020
Active substance (a.s.):		Penoxsulam
		Diflufenican
		Flufenacet
CAS Number Penoxsulam:		219714-96-2
CAS Number Diflufenican:		83164-33-4
CAS Number Flufenacet:		142459-58-3
Formulation Name:		SC
Formulation Type:		Suspension Concentrate
Main uses:		Herbicide
Content of Penoxsulam	nominal:	3,1% w/w

	analysed:	3,97% w/w
Content of Diflufenican	nominal:	20,4% w/w
	analysed:	26,14% w/w
Content of Flufenacet	nominal:	25,4% w/w
	analysed:	32,55% w/w
Certificate of Analysis dated:		24/11/2020

The test item was stored at the test facility, in its original container and in an appropriate pesticide storage room at 0-30°C as defined in MSDS.

TRIAL SITE

One field trial was established on winter wheat. Trial number and location are summarised in table below

Trial number	Study type	Zone	Country (region)	Trial site	Postal code
20SGS40-01	DCS	Central Europe	Germany (Schleswig Holstein)	Wallsbüll	24980

APPLICATION OF TEST ITEM

Application equipment

The application equipment consisted of boom sprayer. The foliar application closely simulated commercial-type treatments.

Calibration

Calibration of the spray equipment at the trial site was accomplished by using the volume/time method for liquid applications. Before application, the spray equipment and the sprayer speed were calibrated to deliver an average volume of spray mixture per unit time at a given pressure resulting in the desired spray volume per hectare.

Target application of the test item

CHR/H/PENDIF 599.5 SC was mixed only with water. The target dose rate of the test item according to study plan was 0,4 l/ha, equivalent to 15 g a.s./ha and target water volume 200-400 l/ha according to Good Agricultural Practice.

Actual application date	Application timing (BBCH)	Actual rate (l/ha)	Actual rate (g a.s./ha)	Percent of deviation (%)	Spray volume applied (l/ha)	Treated area (m^2)	Total spray mixture (ml)	Test item added to spray mixture (g)	Spray mixture remaining (ml)	Spray mixture applied to plot area (ml)

01/12/2020	12	0,405	15,19	+1,3	253,3	60	2500	4,842	980	1520

Conditions at application

Application was carry out within one hour after mixing the spray solution and performed under conditions typical for the crop. The environmental conditions at the time of application were recorded in the Field Trial Notebook. These data include: air temperature, wind speed and direction, percentage of relative humidity, percentage of cloud cover, soil temperature, rainfall within 3 hours after application and soil surface and foliage moisture.

RAC SPECIMEN COLLECTION

Specimen collection

RAC specimens were collected following the target schedule below:

Sampling Timing	Sampling Event	Plot	Timing*	Commodity	**Minimum** sample size
	S1	U/T	**0 DALA**	Whole plant without root	0,1 kg
	S2	T	**BBCH 37**	Whole plant without root	0,5 kg
	S3	T	**BBCH 71**	Whole plant without root	0,5 kg
	S4	U/T	**CH**	Grain	1 kg
				Straw	0,5 kg

*CH – Commercial Harvest;

Actual sampling details

Sampling date	**Specimen type**	**Plot**	**Specimen ID**	**Specimen weight [g]**
01/12/2020	Whole plant without root	U	20SGS40-01 1	105,2
		U	20SGS40-01 1R	101,4
		T	20SGS40-01 2	102,6
		T	20SGS40-01 2R	100,2
20/05/2021	Whole plant without root	T	20SGS40-01 3	575
		T	20SGS40-01 3R	546,4
25/06/2021	Whole plant without root	T	20SGS40-01 4	1410,8
		T	20SGS40-01 4R	13,70,2
05/08/2021	Grain	U	20SGS40-01 5	1963
		U	20SGS40-01 5R	2108,2

		T	20SGS40-01	6	2491,6
		T	20SGS40-01	6R	1897,2
	Straw	U	20SGS40-01	7	524
		U	20SGS40-01	7R	507,4
		T	20SGS40-01	8	584,4
		T	20SGS40-01	8R	549,4

RAC specimen handling, storage and shipment

Quality control measures taken to maintain specimen integrity and to avoid contamination at the trial sites were recorded in the Field Trial Notebooks and included the following:

- Locating untreated plot at least 10 m away from treated plot.
- Collecting specimens from the inner part of each plot.
- Harvesting untreated plot before treated plot and/or different people sampled untreated and treated plots.
- Wearing disposable gloves.
- Transporting and storing untreated and treated specimens separately.

RAC specimens were shipped deep frozen at a target temperature below -18°C to the following analytical laboratory.

Table A 4: Summary of the study 4 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)			PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Grain	Straw	Whole Plant		
	(a)	(b)				(c)						(d)	(e)
20SGS40/Wallsbull, Schleswig Holstein, Germany, Central Zone/ 2021	Winter Wheat/DCS	1) 28.10.2020 2) – 3) 5.08.2021	15.19	254.4	5.97	1.12.2020	12	5 g	<LOD			NR	

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

h) Analytical Phase

Comments of zRMS:	The analytical phase of the study has been accepted. The method was validated according to SANCO/3029/99. The results acquired during validation of the analytical method (accuracy and repeatability) were in the range of 70 - 120% and RSD s < 20% for average recovery. The LOQ of the method was established at 0.010 mg/kg for each matrix.

Reference:	KCP 6.3/08
Report	Magnitude of the residue of Penoxsulam in Winter Wheat (Raw Agricultural Commodity) after one application of CHR/H/PENDIF 599.5 SC – one decline curve trial in Germany – 2020, G. Paszek, 2021, Study code: DPL/206/2020
Guideline(s):	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC Commission Regulation (EU) no 283/2013 setting out the data requirements for active substances, in accordance with Regulation (EC) no 1107/2009
Deviations:	No
GLP:	Yes

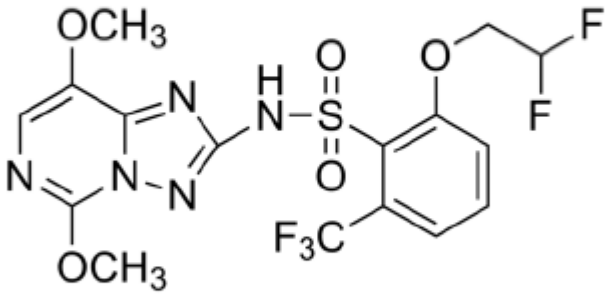
Specimen extraction and determination of residues of penoxsulam were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg.

MATERIALS AND METHODS

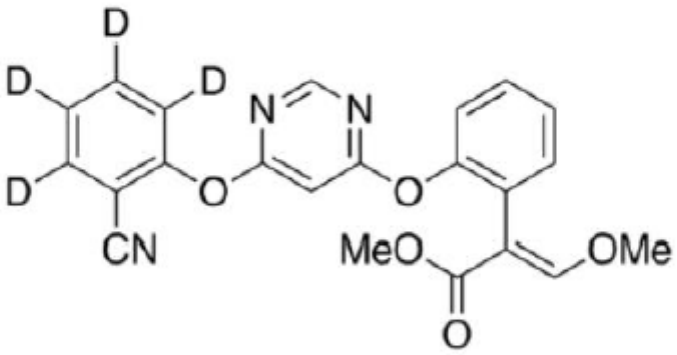
REFERENCE ITEMS

Penoxsulam

This reference item will be used for calibration and fortification purposes.
This reference item has been provided by HPC Standards, with certified information concerning identity, purity, and expiration date.

Common Name:	Penoxsulam
IUPAC Name:	3-(2,2-difluoroethoxy)-N-(5,8-dimethoxy[1,2,4]triazolo[1,5-c]pyrimidin-2-yl)-α,α,α-trifluorotoluene-2-sulfonamide
CAS –No:	219714-96-2
Molecular formula:	$C_{16}H_{14}F_5N_5O_5S$
Chemical structure: 	
Molecular weight:	483.37 g/mol
Purity:	99.9%
Lot:	793485
Expiry date:	01.02.2026

Azoxystrobin D4
This reference item will be used as internal standard for calibration and fortification purposes.
This reference item has been provided by HPC Standards, with certified information concerning identity, purity, and expiration date.

Common Name:	Azoxystrobin D4
IUPAC Name:	Methyl €-2-[2-[6-(2-cyano-3,4,5,6-tetradeuteriophenoxy) pyrimidin-4-yl]oxyphenyl]-3-methoxyprop-2-enoate
CAS –No:	1346606-39-0
Molecular formula:	$C_{22}H_{13}D_4N_3O_5$
Chemical structure: 	
Molecular weight:	407.41 g/mol
Purity:	99.9%
Lot:	789114
Expiry date:	01.02.2024

DETAILED DESCRIPTION OF THE ANALYTICAL PROCEDURE
INITIAL SAMPLE PREPARATION AND HOMOGENISATION

The field specimens arrived at the Test Site in good conditions, frozen and were stored in a freezer at ≤ -18oC before analysis. After removal from the freezer the samples were homogenized with dry ice at Test Site, using a knife grinder. The homogenized samples were divided into few portions: one portion was used as test sample in this study (DPL/206/2020), other portions were prepared as archival samples and the rest of the homogenized material was kept for use as a reference matrix, e.g. for method validation studies or freezer storage stability studies. The homogenized specimens were further stored at ≤ -18oC until beginning of analysis..

Information about specimen reception, extraction and analysis date

No.	Field sample code	Sample type	Specimen Reception	Extraction Date	Analysis Date
1	20SGS40-01 1	wheat (whole plant without root)	03.12.2020	23.12.2020	23.12.2020
2	20SGS40-01 2	wheat (whole plant without root)	03.12.2020	23.12.2020	23.12.2020
3	20SGS40-01 3	wheat (whole plant without root)	27.05.2021	28.05.2021	28.05.2021
4	20SGS40-01 4	wheat (whole plant without root)	02.07.2021	05.07.2021	05.07.2021
5	20SGS40-01 5	wheat (grain)	13.08.2021	20.08.2021	20.08.2021
6	20SGS40-01 6	wheat (grain)	13.08.2021	20.08.2021	20.08.2021
7	20SGS40-01 7	wheat (straw)	13.08.2021	20.08.2021	20.08.2021
8	20SGS40-01 8	wheat (straw)	13.08.2021	20.08.2021	20.08.2021

EXTRACTION
5 g of the homogenized sample were weighed into a 50 mL centrifuge tube. 10 mL of acetonitrile was added together with 50 µL of internal standard solution (1.3), and the mixture was shaken vigorously by hand for one minute. After addition of buffering salts (4 g anhydrous magnesium sulfate, 1 g sodium chloride, 1 g trisodium citrate dehydrate, 0.5 g disodium hydrogencitrate sesquihydrate), the mixture was shaken again intensively for 1 min, then centrifuged at 4700 rpm for 5 min for phase separation. After that, 5 mL of the clean extract (organic phase) was transferred to a 10 ml vial. Following clean-up the extract was filtered through a membrane filter and the final extract was directly employed for LC-MS/MS analysis. Quantification was performed using an internal standard, which was added to the extract after the initial addition of acetonitrile.

FORTIFICATION AND CONTROL SAMPLES
For analytical sequence one sample blank matrix and two procedural recoveries at the level of LOQ and two at the level 10 x LOQ were prepared together with the study samples. 5 g of the homogenized untreated sample were weighed into a 50 mL centrifuge tube.
Preparation of fortification and control samples

Fortification level	Amount of standard solution 1.1 added [µL]	Amount of standard solution 1.2 added [µL]
Matrix blank	-	-
PK 0.003 mg/kg (LOD) *- only in case of validation*	-	15.0
PK 0.01 mg/kg (LOQ)	-	50.0
PK 0.10 mg/kg (10xLOQ)	50.0	-

THE RESULTS FOR TREATED AND UNTREATED SAMPLES
The following residues concentration was determined in the field samples:
Residue concentrations of penoxsulam detected in analyzed field samples (Study Number 20SGS40, Trial No.: 20SGS40-01 Decline Study)

No	Timing	Study sample code	Type of commodity	Sample number given by the laboratory	Result [mg/kg]
1	S1	20SGS40-01 1	wheat (whole plant without root)	DPL/206/2020/01U	< LOD
2		20SGS40-01 2	wheat (whole plant without root)	DPL/206/2020/02T	1.03
3	S2	20SGS40-01 3	wheat (whole plant without root)	DPL/206/2020/03T	< LOD
4	S3	20SGS40-01 4	wheat (whole plant without root)	DPL/206/2020/04T	< LOD
5	S4	20SGS40-01 5	wheat (grain)	DPL/206/2020/05U	< LOD
6		20SGS40-01 6	wheat (grain)	DPL/206/2020/06T	< LOD
7		20SGS40-01 7	wheat (straw)	DPL/206/2020/07U	< LOD
8		20SGS40-01 8	wheat (straw)	DPL/206/2020/08T	< LOD

Residues are not corrected for procedural recoveries;
Calculation based on unrounded values, **LOD = 0.003 mg/kg, LOQ = 0.010 mg/kg**

The stability of the analytes in the final extracts was proven by the corresponding procedural recovery samples, which were stored under the same conditions together with the extracts of the specimens for residue analysis. The recovery values for PK2 0.010 mg/kg and PK2 0.10 mg/kg (in the range of 70 – 120%) confirms the active substance stability during the analytical procedure. The duration of the extraction process was about 4 hours, the duration of the chromatographic analysis was 430 minutes (7.2 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day (about 11.2 h). Working standard that were used for quantification were always prepared on the same day as the work up of the specimen for residue analysis took place and samples were analyzed within 24 hours of extraction. Then extract stability is not considered to be an issue.

CONCLUSIONS
The method was validated according to SANCO/3029/99, rev. 4 guidelines.The results acquired during validation of the analytical method (accuracy and repeatability) were in the range of 70 – 120% and RSD ≤ 20% for average recovery. The limit of quantification of the method was established at 0.010 mg/kg for each of matrix.
There were no interfering signals at retention time of analyzed compound in examined control matrix.

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 – Penoxsulam

European Food Safety Authority
EFSA PRIMo revision 3.1; 2019/03/19

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	**0.05**	ARfD (mg/kg bw):	**not necessary**
Source of ADI:	**EFSA**	Source of ARfD:	
Year of evaluation:	**2009**	Year of evaluation:	

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 : ---

	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)
TMDI/NEDI/IEDI calculation (based on average food consumption)	0.2%	DK child	0.10	0.1%	Rye	0.1%	Wheat				
	0.2%	IT toddler	0.08	0.1%	Wheat	0.0%	Other cereals	0.0%	Barley		
	0.1%	GEMS/Food G06	0.07	0.1%	Wheat	0.0%	Barley	0.0%	Rye		
	0.1%	GEMS/Food G08	0.06	0.1%	Wheat	0.0%	Barley	0.0%	Rye		
	0.1%	GEMS/Food G15	0.06	0.1%	Wheat	0.0%	Barley	0.0%	Rye		
	0.1%	RO general	0.05	0.1%	Wheat		Grapefruits				
	0.1%	DE child	0.05	0.1%	Wheat	0.0%	Rye	0.0%	Barley		
	0.1%	GEMS/Food G07	0.05	0.1%	Wheat	0.0%	Barley	0.0%	Rye		
	0.1%	IT adult	0.05	0.1%	Wheat	0.0%	Other cereals	0.0%	Barley		
	0.1%	GEMS/Food G10	0.05	0.1%	Wheat	0.0%	Barley	0.0%	Rye		
	0.1%	FR child 3 15 yr	0.05	0.1%	Wheat	0.0%	Rye	0.0%	Barley		
	0.1%	NL toddler	0.05	0.1%	Wheat	0.0%	Rye	0.0%	Barley		
	0.1%	ES child	0.04	0.1%	Wheat	0.0%	Barley				
	0.1%	GEMS/Food G11	0.04	0.1%	Wheat	0.0%	Barley	0.0%	Rye		
	0.1%	NL child	0.04	0.1%	Wheat	0.0%	Rye	0.0%	Barley		
	0.1%	PT general	0.04	0.1%	Wheat	0.0%	Rye	0.0%	Barley		
	0.1%	UK toddler	0.04	0.1%	Wheat	0.0%	Barley	0.0%	Rye		
	0.1%	SE general	0.03	0.1%	Wheat	0.0%	Rye				
	0.1%	FR toddler 2 3 yr	0.03	0.1%	Wheat	0.0%	Rye	0.0%	Barley		
	0.1%	DE general	0.03	0.0%	Wheat	0.0%	Rye	0.0%	Barley		
	0.1%	ES adult	0.03	0.0%	Wheat	0.0%	Barley				
	0.1%	DE women 14-50 yr	0.03	0.0%	Wheat	0.0%	Rye	0.0%	Barley		
	0.1%	UK infant	0.03	0.1%	Wheat		Grapefruits				
	0.0%	IE adult	0.02	0.0%	Wheat	0.0%	Rye	0.0%	Barley		
	0.0%	NL general	0.02	0.0%	Wheat	0.0%	Barley	0.0%	Rye		
	0.0%	FR adult	0.02	0.0%	Wheat	0.0%	Rye	0.0%	Barley		
	0.0%	LT adult	0.02	0.0%	Rye	0.0%	Wheat	0.0%	Barley		
	0.0%	UK vegetarian	0.02	0.0%	Wheat	0.0%	Barley	0.0%	Barley		
	0.0%	FI 3 yr	0.02	0.0%	Wheat	0.0%	Rye	0.0%	Barley		
	0.0%	UK adult	0.02	0.0%	Wheat	0.0%	Barley	0.0%	Rye		
	0.0%	DK adult	0.02	0.0%	Wheat	0.0%	Rye				
	0.0%	FI 6 yr	0.02	0.0%	Wheat	0.0%	Rye	0.0%	Barley		
	0.0%	IE child	0.01	0.0%	Wheat	0.0%	Barley				
	0.0%	FI adult	0.01	0.0%	Rye	0.0%	Wheat	0.0%	Barley		
	0.0%	FR infant	0.01	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 Penoxsulam 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 — Details - acute risk assessment /children

Acute risk assessment / adults / general population — 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!
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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 (children)

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

IESTI (adults)

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
5%	Wheat	0.1 / 0.1	0.84
3%	Barley	0.1 / 0.1	0.48
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 (children)

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
3%	Wheat / milling (wholemea	0.1 / 0.1	0.55
2%	Barley / cooked	0.1 / 0.1	0.36
1%	Rye / boiled	0.05 / 0.05	0.18
1%	Barley / milling (flour)	0.1 / 0.1	0.18
1%	Rye / milling (wholemeal)-l	0.05 / 0.05	0.18
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IESTI (adults)

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
4%	Barley / beer	0.1 / 0.02	0.72
3%	Wheat / bread/pizza	0.1 / 0.1	0.44
2%	Wheat / pasta	0.1 / 0.1	0.38
2%	Wheat / bread	0.1 / 0.1	0.35
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Appendix 4 Additional information provided by the applicant

Not required