FINAL REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: SHA 2619 A

Product name: KONARK

Chemical active substance:

Flufenacet, 60 g/L

Pendimethalin, 300 g/L

Central

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

Submission date: March 2021

MS Finalisation date: 11/2021; 05/2023

Version history

When	What
September 2021	Updated by Applicant
October 2021	Updated by Applicant
01.2023	Draft assessment prepared by zRMS
05.2023	zRMS revision after commenting phase – final version of the RR

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7 Metabolism and residue data (KCA section 6)

7.1 Summary and zRMS Conclusion

Storage stability

Flufenacet

Storage stability is demonstrated for 2 high starch commodities (corn and turnip - root) and there-fore stability can be supported for the entire high starch category in accordance with OECD guideline 506. This covers the stability of the residues in winter cereals.

Pendimethalin

Pendimethalin and metabolite CL 202347 are stable in commodities with high water, high acid, high protein, high starch and in high lipid commodity for at least a period of 12-43 months.

In addition, applicant provided study of residue storage stability of pendimethalin in high water content matrix. Study is accepted. The results of this study showed that pendimethalin is stable in apple when stored at ≤-18ºC for a period at least up to 24 months.

Sufficient stability has been demonstrated to support the residue data presented in this submission.

No further data are required.

Metabolism in plants and animals

Flufenacet

The metabolism in plants and livestock for the active substance was reviewed during the Annex I inclusion process.

Plant residue definition for monitoring and risk assessment Sum of all compounds containing the N fluorophenyl-N-isopropyl moiety expressed as flufenacet (EFSA, 2012, Regulation n°1127/2014)

Pendimethalin

The metabolism in plants and livestock for the active substance was reviewed during the Annex I inclusion and renewal process.

Plant residue definitions for monitoring and risk assessment: Pendimethalin (Reg. (EU) 2019/1791,

EFSA, 2016)

Animal residue definitions for monitoring and risk assessment: Pendimethalin (Reg. (EU) 2019/1791,

EFSA, 2016)

Additionally applicant submitted alternative to the protected high temperature hydrolysis of

14C-Pendimethalin under cooking, baking and pasteurization conditions study. Study is accepted.

The data evaluated are sufficient to support the proposed uses.

Magnitude of residues in plants

Winter cereals (wheat, barley, rye, oats, triticale)

Proposed uses:

1 x 0.24 kg as/ha flufenacet + 1.2 kg as/ha pendimethanil; BBCH 00-09 and 11-25; PHI: not required

Flufenacet

GAP on which N-EU assessment is based: 1 x 240 g as/ha, early post emergence

According to the available unprotected N-EU data, the intended uses on wheat and barley are considered acceptable.

According to SANTE/2019/12752, when the application is before forming of the edible part (in the case of cereals before stage BBCH 51), it is possible to extrapolate from barley and/or wheat to oat, rye.

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

Uses are accepted.

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application. These studies were not included in the evaluation because they were performed in the south of Europe.

Pendimethalin

EU GAP (SANTE/11656/2016, 18 May, 2017, rev.2): 1 x 1.600 kg as/ha, BBCH: 00-29 autumn, PHI: not required

Proposed uses are less critical than uses in the EU GAP.

New acceptable studies on the magnitude of residue have been submitted by the applicant in the framework of this application (harvest and decline in Poland and in Germany).

Trials GAP:

Trials GAP: 1 x 1.5-1.7 kg as/ha, BBCH 25-30, PHI 54-94 days, outdoor

Application rate is more critical compared to the proposed one. However, these trials are acceptable as worst case situation.

Residues: 5x <0.01 mg/kg (wheat), 5x<0.01 mg/kg (barley)

New studies performed in the south of Europe were not included in the evaluation.

The number of trials is sufficient as to support the use of Pendimethalin in winter cereals according to the proposed GAP in Central Zone.

The residues arising from the proposed use will not exceed the MRLs for cereals set at 0.05 mg/kg (Reg. (EU) 2019/1791).

According to SANTE/2019/12752 extrapolation from wheat and barley to rye, oats and triticale is possible.

Uses are accepted.

Note: Some of the studies presented were carried out on spring crops instead of winter. Application timing in spring is considered more critical due to the shorter interval between application and harvest. Therefore, these trials are accepted.

Magnitude of residues in livestock

There is no risk for animal MRLs to be exceeded.

Magnitude of residues in processed commodities

As quantifiable residues of flufenacet and pendimethalin are not expected in the edible parts of most crops under consideration, and as consumer exposure is far below 10 % of the ADI, there is no need to investigate the effect of industrial and/or household processing.

Magnitude of residues in representative succeeding crops

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."

Pendimethalin

EFSA Journal 2016;14(3):4420:

The radioactive residues were characterised as polar fractions further incorporated into the natural compounds of the plant tissues (16% of TRR in wheat straw, up to 81% of TRR in wheat grain). The parent compound was identified at lower proportions (<1% TRR in wheat grain to 19% TRR in immature lettuce) whilst metabolite M455H030 was identified in radish root only (13% TRR-0.011 mg/kg) at 30 d plant back interval.

Field rotational crop study are not required.

Waiting periods for avoiding residues in succeeding crops are not required.

Estimation of exposure through diet and other means

The proposed uses of pendimethalin in the formulation PENSHUI do not represent unacceptable acute and chronic risks for the consumer.

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 KONARK are presented in Table 7.1-1. A list of all intended uses within the Central zone is given in Part B, Section 0.

Overall conclusion

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of 0.1 mg/kg on barley, wheat, for flufenacet, and MRL of 0.05 mg/kg on barley, wheat, for pendimethalin, as laid down in Reg. (EU) 396/2005 is not expected.
The chronic and the short-term intakes of flufenacet and pendimethalin residues are unlikely to present a public health concern.

As far as consumer health protection is concerned, authority, zRMS agrees with the authorization of the intended use(s).

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

Data gaps

Data gaps should be listed in the summary to give an overview (especially for cMS).

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: develop-mental stages of the pest or pest group)	**Application**				**Application rate**			PHI (days)	Remarks: e.g. g saf-ener/ 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			Groundwater
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	CEU	**Winter wheat**	F	Broadleaved and grass weeds	Foliar Spray	Pre emer-gence BBCH 00-09	a) 1 b) 1	NA	a) 4 b) 4	a) 0.24 flufe-nacet + 1.2 pendimethanil b) 0.24 flufe-nacet + 1.2 pendimethanil	200-400	-	Weeds at early stages	A
2	CEU	**Winter wheat**	F	Broadleaved and grass weeds	Foliar Spray	Post emer-gence BBCH 11-25	a) 1 b) 1	NA	a) 4 b) 4	a) 0.24 flufe-nacet + 1.2 pendimethanil b) 0.24 flufe-nacet + 1.2 pendimethanil	200-400	-	Weeds at early stages	A
3	CEU	**Winter barley**	F	Broadleaved and grass weeds	Foliar Spray	Pre emer-gence BBCH 00-09	a) 1 b) 1	NA	a) 4 b) 4	a) 0.24 flufe-nacet + 1.2 pendimethanil b) 0.24 flufe-nacet + 1.2 pendimethanil	200-400	-	Weeds at early stages	A
4	CEU	**Winter barley**	F	Broadleaved and grass weeds	Foliar Spray	Post emer-gence BBCH 11-25	a) 1 b) 1	NA	a) 4 b) 4	a) 0.24 flufe-nacet + 1.2 pendimethanil b) 0.24 flufe-nacet + 1.2 pendimethanil	200-400	-	Weeds at early stages	A
5	CEU	**Winter rye**	F	Broadleaved and grass weeds	Foliar Spray	Pre emer-gence BBCH 00-09	a) 1 b) 1	NA	a) 4 b) 4	a) 0.24 flufe-nacet + 1.2 pendimethanil b) 0.24 flufe-	200-400	-	Weeds at early stages	A

										nacet + 1.2 pendimethanil				
6	CEU	**Winter rye**	F	Broadleaved and grass weeds	Foliar Spray	Post emergence BBCH 11-25	a) 1 b) 1	NA	a) 4 b) 4	a) 0.24 flufenacet + 1.2 pendimethanil b) 0.24 flufenacet + 1.2 pendimethanil	200-400	-	Weeds at early stages	A
7	CEU	**Winter triticale**	F	Broadleaved and grass weeds	Foliar Spray	Pre emergence BBCH 00-09	a) 1 b) 1	NA	a) 4 b) 4	a) 0.24 flufenacet + 1.2 pendimethanil b) 0.24 flufenacet + 1.2 pendimethanil	200-400	-	Weeds at early stages	A
8	CEU	**Winter triticale**	F	Broadleaved and grass weeds	Foliar Spray	Post emergence BBCH 11-25	a) 1 b) 1	NA	a) 4 b) 4	a) 0.24 flufenacet + 1.2 pendimethanil b) 0.24 flufenacet + 1.2 pendimethanil	200-400	-	Weeds at early stages	A

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

Explanation for Column 11 “Conclusion”

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

7.1.2 Summary of the evaluation

The preparation KONARK is composed of flufenacet and pendimethalin.

Table 7.1-2-1: Toxicological reference values for the dietary risk assessment of flufenacet

Reference value	Source	Year	Value	Study relied upon	Safety factor
Flufenacet					
ADI	7469/VI/98-Final	2003	0.005 mg/kg bw/d	rat: 2y study	250
ARfD	7469/VI/98-Final	2003	0.017 mg/kg bw/d	dog: 90d and 1y study	100

Table 7.1-3-2: Toxicological reference values for the dietary risk assessment of pendimethalin

Reference value	Source	Year	Value	Study relied upon	Safety factor
Pendimethalin					
ADI	SANTE/11656/2016 18 May 2017 rev 2	2017	0.125 mg/kg bw/d	2-year toxicity study in dogs	100
ARfD	SANTE/11656/2016 18 May 2017 rev 2	2017	0.3 mg/kg bw/d	rabbit, developmental toxicity	100

7.1.2.1 Summary for flufenacet

Table 7.1-2-3: 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?
1	Wheat	Yes	Yes	Yes	Yes	Yes	No	No
2	Barley	Yes	Yes	Yes	Yes	Yes		No
3	Rye	Yes	Yes	Yes	Yes	Yes		No
4	Triticale	Yes	Yes	Yes	Yes	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

Table 7.1-2-4: Summary for pendimethalin

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?
1	Wheat	Yes	Yes	Yes	Yes	Yes	No	No
2	Barley	Yes	Yes	Yes	Yes	Yes		No
3	Rye	Yes	Yes	Yes	Yes	Yes		No
4	Triticale	Yes	Yes	Yes	Yes	Yes		No

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

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

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

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

7.1.2.2 Summary for KONARK

Table 7.1-2-5: Information on KONARK (KCA 6.8)

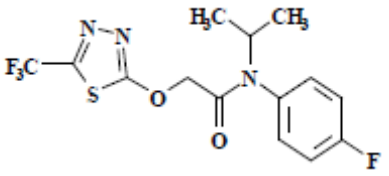
Crop	PHI for KONARK proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for KONARK proposed by zRMS	zRMS Comments (if different PHI proposed)
		flufenacet		
Wheat	NR	NR		
Barley	NR	NR		
Rye	NR	NR		
Triticale	NR	NR		

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).

7.2 Flufenacet

General data on flufenacet are summarized in the table below (last updated 2020/11/30)

Table 7.2-1: 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
Chemical group	Herbicide
Mode of action (if available)	Flufenacet is transported and distributed through the cell walls and acts by inhibiting cell division and cell growth in meristematic tissues.
Systemic	Yes
Company (ies)	Bayer
Rapporteur Member State (RMS)	France
Approval status	Approved the 01/01/2004 (COMMISSION DIRECTIVE 2006/85/EC- COMMISSION IMPLEMENTING REGULATION (EU) 540/2011 and COMMISSION IMPLEMENTING REGULATION 823/2012 (EU))
Restriction	Restricted to use as herbicide
Review Report	SANCO/7469/VI/98 – 03/07/2004
Current MRL regulation	Regulation (EU) No 1127/2014
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes
EFSA Journal : Conclusion on the peer review	No
EFSA Journal: conclusion on article 12	Yes, EFSA 2012
Current MRL applications on intended uses	EFSA-Q-2008-546 (EMS) Commodities Reasoned opinion available (EFSA Journal 2012;10(4):2689)

* 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 7.2-1: 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			
Corn	High dry/protein content	28 months	France, 1997

Conclusion on stability of residues during storage

The stability of residues during storage for the active substance was reviewed during the Annex I inclusion process on corn. Further data with KONARK is not required. .

Samples of corn were spiked with flufenacet and were stored in a freezer (at -26 ± 5°C) for either 6, 11, 20 and 28 months. Recoveries show that residues of flufenacet are stable under frozen conditions for at least 20 – 28 months (please refer to the *DAR of Flufenacet - Annex B.6, 1997*).

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

Not relevant, residue stability in sample extract was not investigated during the EU review of flufenacet.

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 7.2-2: 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								

Pulses and oilseeds	Soybean	Fluorophenyl-UL-^{14}C	Soil treatment, greenhouse	1.485	1	Whole plant: 20; forage, 66: 42; beans: 42, 66, 80; hay: 80	Pre-emergence application	France, 1997
		Thiadiazole-2-^{14}C	Soil treatment, greenhouse	1.380	1	Forage: 21, 48, 90; Beans: 48, 91; hay: 105	Pre-emergence application	
	Cotton	Fluorophenyl-UL-^{14}C	Soil treatment, greenhouse	1.778	1	Forage: 21,43; mature plant: 156; seeds: 156	Pre-emergence application	France, 1997
Cereals	Corn	Fluorophenyl-UL-^{14}C	Soil treatment, greenhouse	1.370	1	Forage: 96; fresh kernels: 96; fodder 110; dry kernels: 110	Pre-emergence application	France, 1997
Root and tuber vegetables	Potatoes	Fluoro-phenyl-U-^{14}C	Soil, F/G	2.6	1	40, 109 days after planting	Seed potatoes were cultivated in a greenhouse for six weeks then the containers were moved outside where the crop remained until harvest	France, 2012
			Foliar, F	3.0	1	67		

Summary of plant metabolism studies reported in the EU

The initial metabolic reaction is cleavage of the molecule into the thiadone and acetamide moiety. While the resulting thiadone itself was not observed, various conjugates were formed, the quantitatively most important being the corresponding N-glucoside (M 25). The flourophenylacetamide portion is directly conjugated with glutathione (GHS) or (homoglutathione, hGSH) and further metabolised yielding the FOE cysteine conjugate. All further metabolites can be considered as hydrolysis, oxidation and conjugation products of the glutathione pathway (DAR of Flufenacet - Annex B.6, 1997).

Summary of new plant metabolism studies

No new plant metabolism studies.

Conclusion on metabolism in primary crops

The current residue definition for enforcement and risk assessment is defined as sum of all compounds containing the N fluorophenyl-N-isopropyl moiety expressed as flufenacet

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 7.2-3: 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	Fluorophenyl-UL-^{14}C	Soil application	0.9	33, 157 and 361	n.r.		France, 1997
		Thiadiazole-2-^{14}C	Soil application	0.9	120 and 365	n.r.		
Root and tuber vegetables	turnip-bulbs and tops	Fluorophenyl-UL-^{14}C	Soil application	0.9	33, 157 and 361	n.r.		France, 1997
		Thiadiazole-2-^{14}C	Soil application	0.9	120 and 365	n.r.		
Cereals	Wheat immature	Fluorophenyl-UL-^{14}C	Soil application	0.9	33, 157 and 361	n.r.		France, 1997
		Thiadiazole-2-^{14}C	Soil application	0.9	120 and 365	n.r.		
	Wheat straw	Fluorophenyl-UL-^{14}C	Soil application	0.9	33, 157 and 361	n.r.		
		Thiadiazole-2-^{14}C	Soil application	0.9	120 and 365	n.r.		
	Wheat grain	Fluorophenyl-UL-^{14}C	Soil application	0.9	33, 157 and 361	n.r.		
		Thiadiazole-2-^{14}C	Soil application	0.9	120 and 365	n.r.		

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

Summary of plant metabolism studies reported in the EU

Fluorophenyl-UL-^{14}C
During the experiment the amount of radioactivity in the soil decreased from 0.59 mg/kg total radioactive residue at day 0 to 0.56 mg/kg at day 33 and 0.15 mg/kg at day 361. Analyses of soil samples revealed that the metabolic pattern was the same like in the soil metabolism studies.

The highest total radioactive residue (TRR) was usually found in the 33-day planting interval, the only exception being kale, where the highest TRR was measured at the 157-day replant. Generally the TRR in kale and turnip was very low. The maximum radioactive residue in the turnip tops and bulb was 0.08 and 0.06 mg/kg, respectively, and in kale 0.14 mg/kg. The only crop containing significant residues was wheat. At the 33-day, 157-day and 361-day planting the TRR in immature wheat was 1.97, 0.41 and 0.19 mg/kg, in wheat straw 7.82, 1.50 and 0.61 mg/kg and in wheat grain 6.94, 0.32 and 0.17 mg/kg parent compound equivalents, respectively (DAR of Flufenacet - Annex B.6, 1997).

Thiadiazole-2-^{14}C
During the experiment the amount of radioactivity in the soil decreased from 0.52 mg/kg total radioactive residue at day 0 to 0.23 mg/kg at day 30 and 0.055 mg/kg at day 365. Analyses of soil samples revealed that all of the radioactivity found was the parent compound.. The highest total radioactive residue (TRR) was usually found in the 120-day planting interval, the only exception being turnip tops, where the highest TRR was measured at the 365-day replant. But generally, like in the study with phenyl labelled active ingredient, the TRR in kale and turnip was very low. The maximum radioactive residue in the turnip tops and bulbs was 0.082 and 0.041 mg/kg, respectively, and in kale 0.1 mg/kg. The highest residues were measured in wheat. However, compared to the study using Fluorophenyl-UL-14C the residues at the 120-day and 365-day replant were significantly lower. The only exception was wheat grain, where maximum radioactive residues of 0.319 mg/kg (day-120 replant) were measured (DAR of Flufenacet - Annex B.6, 1997).

Summary of new plant metabolism studies

No new plant metabolism have been submitted

Conclusion on metabolism in rotational crops

After normal agricultural use of flufenacet no significant residues are to be expected in leafy or root crops grown in rotation with the target crops. A comparison with the results from trials in cereals and maize at recommended application rates of 240 g a.i./ha and 600 g a.i./ha reveals that no residues were detected in any trial, except in green material sampled within 40 days after application. Therefore, it is concluded, that the 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 (DAR of Flufenacet - Annex B.6, 1997).

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

No new data submitted in the framework of this application.

Conclusion on nature of residues in processed commodities

The effect of processing on the nature of flufenacet was investigated in the framework of the peer review. Studies on the hydrolytic degradation of flufenacet at pH 5, 7 and 9 and incubated for 30 days in the dark at 25°C (relevant to environmental conditions) showed that the parent compound is not significantly affected by this process (France, 1997).

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

Table 7.2-4: Summary of the nature of residues in commodities of plant origin

Endpoints	
Plant groups covered	Pulses and oilseeds (soybean, cotton), Cereals (corn)
Rotational crops covered	Leafy vegetables (kale), root and tuber vegetables (turnips), cereals (wheat)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	stable under standard hydrolysis conditions
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes
Plant residue definition for monitoring	Sum of all compounds containing the N fluorophenyl-N-isopropyl moiety expressed as flufenacet (Regulation n°1127/2014)
Plant residue definition for risk assessment	Sum of all compounds containing the N-fluorophenyl-N-isopropyl moiety expressed as flufenacet equivalent (EFSA 2012)
Conversion factor from enforcement to RA	1 (barley grain, wheat grain, rye grain, barley straw, wheat straw and rye straw) (EFSA 2012)

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 7.2-5: 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								
Lactating ruminants	Goat	[Fluorophenyl-UL-^{14}C] FOE5043	1	5	3	Milk	twice daily	France 1997
						Urine and faeces	n.r.	
						Tissues	at sacrifice	
		[Thiadiazole-2-^{14}C] FOE5043	1	5	3	Milk	twice daily	France 1997
						Urine and faeces	n.r.	
						Tissues	at sacrifice	
		[phenyl-UL-	1	5.12	3	Milk	twice	France

		[^{14}C] FOE5043 oxalate					daily	1997
						Urine and faeces	n.r.	
						Tissues	at sacrifice	
Laying poultry	Hens	[Fluorophenyl-UL-^{14}C] FOE5043	10	5	3	Eggs	2 days after first dose	France 1997
						Excreta	n.r.	
						Tissues	at sacrifice	
		[Thiadiazole-2-^{14}C] FOE5043	10	5	3	Eggs	2 days after first dose	France 1997
						Excreta	n.r.	
						Tissues	at sacrifice	
		[phenyl-UL-^{14}C] FOE5043 oxalate		5	3	Eggs	daily	France 1997
						Excreta	n.r.	
						Tissues	at sacrifice	

n.r.: Not reported

Summary of plant metabolism studies reported in the EU

After administration of 5 mg/kg bw of [fluorophenyl-UL-^{14}C]flufenacet to a lactating goat on three consecutive days the total radioactive residue of flufenacet in tissues, organs and milk was relatively low due to the fast elimination kinetics. Highest levels were found in kidney followed by that in liver as the main excretory and the main metabolizing organ. Very low amounts of the total dose was secreted with the milk. The identification rate ranged from 81% (muscle and kidney) to 89% (fat). Flufenacet is extensively metabolized in the goat (fluorophenyl label). The first metabolisation step is conjugation with glutathione as already observed in the rat metabolism study. Further biodegradation follows the mercapturic acid pathway, with additional formation of cysteine- or mercapturic acid conjugates. Due to the fact that the thiadiazole portion of flufenacet remained undefined, [thiadiazole-2-^{14}C]flufenacet was administered to a lactating goat to investigate the metabolism and distribution of the thiadiazole portion of the molecule. The identification rate ranged from 53% (milk) to 98% (kidney). Flufenacet (thiadiazole label) was rapidly cleaved at the ether bond yielding thiadone (M9) as the major metabolite which was primarily conjugated to glucuronic acid (M24). Unchanged parent compound was not present in any tissue, organ or milk (DAR of Flufenacet - Annex B.6, 1997).

After administration of 5 mg/kg bw of [fluorophenyl-UL-^{14}C]flufenacet to laying hens the total radioactive residues of flufenacet in tissues, organs and eggs was relatively low due to the fast elimination kinetics. The identification rate varied from 7% (eggs) to 83% (fat). Flufenacet (fluorophenyl label) in poultry appeared to involve the mercapturic acid pathway resulting in a wide range of methylsulfinyl and methylsulfonyl containing metabolites produced from further metabolisation of the cysteine or mercapturic acid conjugates. Application of [thiadiazole-2-^{14}C]flufenacet resulted in residue levels in the same order of magnitude compared to the levels observed in fluorophenyl study. The identification rate ranged from 86% (muscle and eggs) to 95% (fat). FOE 5043 (thiadiazole label) was rapidly cleaved at the ether bond yielding thiadone (M9) (DAR of Flufenacet - Annex B.6, 1997).

Due to the fact no parent compound was found as residue in feed items additional lifestock studies were performed using one representative plant residue, i.e. FOE oxalate, which accounted for 77 to 99% of the total radioactive residue. In the laying hen study FOE oxalate was also unmetabolised. The residue in the tissues ranged from 85% (liver) to 96% (fat) (DAR of Flufenacet - Annex B.6, 1997).

Conclusion on metabolism in livestock

The general metabolic pathways in rodents and ruminants were found to be comparable therefore the findings in ruminants can be extrapolated to pigs. Due to the fact that in animals almost all metabolites are glutathione related compounds, the residue definition is based on the total amount of N-fluorophenyl-N-isopropyl.

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

Table 7.2-6: 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	-
	-
Animal residue definition for monitoring	Sum of all compounds containing the N fluorophenyl-N-isopropyl moiety expressed as flufenacet (Regulation n°1127/2014)
Animal residue definition for risk assessment	Sum of all compounds containing the N-fluorophenyl-N-isopropyl moiety expressed as flufenacet equivalent (EFSA 2012)
Conversion factor	-
Metabolism in rat and ruminant similar	Yes Studies of metabolism in pig is unnecessary since rat and ruminant studies have similar results.
Fat soluble residue	No

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 7.2-7: Summary of EU reported and new data supporting the intended uses of SHA 2600 A 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
Cereal (Wheat, barley, rye, triticale)	DAR 1997/EFSA 2012 (Jersch-Schmitz, S. and Seym, M., 1995; Seym, M., 1996)	N-EU	GAP on which assessment is based: 1 x 240 g as/ha, early post emergence, PHI 120-271 days E/RA: 15x<0.05 (LOQ)	N/A				
	~~Submitted trials (KCP 8.3.1/01; KCP 8.3.1/02, Appendix A.2.2.3)~~	~~S-EU~~	~~GAP on which assessment is based: 1 x 250 g as/ha, BBCH 25, PHI 75-85 days (wheat) 73-99 (barley), outdoor~~ ~~E/RA: 2<0.002 (LOD), 1x<0.01 (LOQ), 0.03 (wheat), 4x<0.002 (barley)~~						
	Overall supporting data for cGAP	N-EU	15x<0.05 (LOQ)	0.05	0.05	0.05	0.1 (wheat, barley, triticale) 0.05 (rye)	Yes

	~~Overall supporting data for cGAP~~	~~S EU~~	~~6x<0.002, <0.01, 0.03~~	0.002	0.03	0.05	0.1 (wheat, barley, triticale) 0.05 (rye)	Yes

* Source of EU MRL: Reg. (EU) 2014/1127

7.2.3.2 Conclusion on the magnitude of residues in plants

According to the available data and guideline SANTE/2019/12752, the intended uses of SHA2619A, at one application on wheat, barley, rye and triticale before forming the edible part, are considered acceptable.

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

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

Table 7.2-8: Input values for the dietary burden calculation (considering the uses evaluated in Art. 12 procedure and the uses under consideration)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Sum of all compounds containing the N-fluorophenyl-N-isopropyl moiety expressed as flufenacet equivalent				
Cereal grain (small)	0.05	Median residue (EFSA Journal 2012;10(4):2689)	0.05	Median residue (EFSA Journal 2012;10(4):2689)
Maize grain	0.05	Median residue (EFSA Journal 2012;10(4):2689)	0.05	Median residue (EFSA Journal 2012;10(4):2689)
Cereal bran	0.4	Median residue × 8 (EFSA Journal 2012;10(4):2689)	0.4	Median residue × 8 (EFSA Journal 2012;10(4):2689)
Cereal straw	0.1	Median residue (EFSA Journal 2012;10(4):2689)	0.11	Highest residue (EFSA Journal 2012;10(4):2689)
Potatoes	0.05	Median residue (EFSA Journal 2012;10(4):2689)	0.11	Highest residue (EFSA Journal 2012;10(4):2689)
Sunflower seed	0.05	Median residue (EFSA Journal 2012;10(4):2689)	0.05	Median residue (EFSA Journal 2012;10(4):2689)
Sunflower seed meal	0.1	Median residue × 2 (EFSA Journal 2012;10(4):2689)	0.1	Median residue × 2 (EFSA Journal 2012;10(4):2689)
Soya bean	0.05	Median residue (EFSA Journal 2012;10(4):2689)	0.05	Median residue (EFSA Journal 2012;10(4):2689)
Soya bean meal	0.05	Median residue (EFSA Journal 2012;10(4):2689)	0.05	Median residue (EFSA Journal 2012;10(4):2689)

Table 7.2-09: 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)
Sum of all compounds containing the N-fluorophenyl-N-isopropyl moiety expressed as flufenacet equivalent					
Beef cattle	0.0134	0.0238	Potatoes	0.5555	Y
Dairy cattle	0.0090	0.0135	Potatoes	0.3704	Y
Pig	0.0125	0.0221	Potatoes	0.5531	Y
Poultry	0.0092	0.0143	Wheat bran	0.2257	Y

zRMS comment:

Input values for the dietary burden calculation (proposed uses, animal model 2017)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: sum of all compounds containing the N-fluorophenyl-N-isopropyl moiety expressed as flufenacet equivalent				
Cereal grain (wheat, barley, rye, oats, triticale)	0.05	Median residue (EFSA, 2012)	0.05	Median residue (EFSA, 2012)
Cereal straw	0.1	Median residue (EFSA, 2012)	0.11	Median residue (EFSA, 2012)

Results of the dietary burden calculation (proposed uses, animal model 2017)

Relevant groups	Dietary burden expressed in				Most critical diet (a)	Most critical commodity (b)		Trigger exceeded (Yes/No)
	mg/kg bw per day		mg/kg DM					0.004
	Median	Maximum	Median	Maximum				mg/kg bw
Cattle (all diets)	0,007	0,007	0,18	0,18	Dairy cattle	Wheat	milled bypdts	Yes
Cattle (dairy only)	0,007	0,007	0,18	0,18	Dairy cattle	Wheat	milled bypdts	Yes
Sheep (all diets)	0,011	0,011	0,26	0,26	Lamb	Wheat	milled bypdts	Yes
Sheep (ewe only)	0,008	0,008	0,23	0,23	Ram/Ewe	Wheat	milled bypdts	Yes
Swine (all diets)	0,007	0,007	0,23	0,23	Swine (finishing)	Wheat	milled bypdts	Yes
Poultry (all diets)	0,009	0,009	0,13	0,13	Poultry layer	Wheat	milled bypdts	Yes
Poultry (layer only)	0,009	0,009	0,13	0,13	Poultry layer	Wheat	milled bypdts	Yes

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

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

Conclusion
Livestock feeding data were provided for the EU review of Flufenacet.

On the basis of the animal metabolism studies it is concluded that residue levels in livestock commodities are expected to remain below the enforcement LOQ of 0.01 mg/kg in milk, 0.02 mg/kg in liver and 0.05 mg/kg in fat, eggs, kidney and muscle. Hence, no livestock feeding study is needed; MRLs and risk assessment values for the relevant commodities in ruminants, pigs and poultry can be established at the LOQ level (EFSA, 2012).

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

7.2.5.1 Available data for all crops under consideration

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

7.2.5.2 Conclusion on processing studies

Further processing studies are anyhow not required in this case as they are not expected residue to affect the outcome of the risk assessment.

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 the 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.

Conclusion on rotational crops studies

No risk mitigation measures are necessary after the use of KONARK in respect of the GAP.

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 KONARK. 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).

7.2.8.1 Input values for the consumer risk assessment

Table 7.2-20: Input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Sum of all compounds containing the N-fluorophenyl-N-isopropyl moiety expressed as flufenacet equivalent				
Barley, Wheat (triticale)	0.1	Current EU MRL - Reg. (EU) 1127/2014	0.1	Current EU MRL - Reg. (EU) 1127/2014
Rye	0.05	Current EU MRL - Reg. (EU) 1127/2014	0.05	Current EU MRL - Reg. (EU) 1127/2014
Other plant and animal commodities	Reg. (EU) 1127/2014			

7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.2-31: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo 3.1	88% (based on NL Toddler)
IESTI (% ARfD) according to EFSA PRIMo 3.1	Unprocessed commodities Results for children: 136% potato Results for adults: 26% potato Results after refinement: Children: 8% wheat, 3% barley, 2% rye Adults: 5% wheat, 3% barley, 1% rye Processed commodities Results for children: 82% potato/fried Results for adults: 16% pumpkins/boiled Results after refinement: Children: ~~8~~ 7% wheat/flour Adults: ~~7~~ 4% barley/beer

The calculation of the TMDI was performed taking into account all the crops ~~to which flufenacet may be applied~~. The summary of the calculation using the EFSA model rev 3.1 is presented in Appendix 3. With the current EFSA model the chronic risk assessment reaches a maximum of 88% of ADI. The diet with the highest TMDI is "NL toddler". For this diet, the highest contributor is potatoes with 13% of ADI.

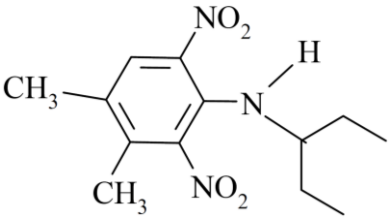
Acute dietary exposure was performed taking into account all the crops with corresponding MRL values. Due to unacceptable results obtained for unprocessed commoditites for children, refinement was considered by using MRL for intended uses wheat and barley crops. Final values resulted to be acceptable for acute exposure for processed and unprocessed commodities.

Based on the above calculation, it can be concluded that the proposed uses of flufenacet in the formulation SHA 2619A do not represent unacceptable chronic or acute risk for the consumer.

7.3 Pendimethalin

General data on pendimethalin are summarized in the table below (last updated 2020/11/30)

Table 7.33-1: General information on pendimethalin

Active substance (ISO Common Name)	pendimethalin
IUPAC	N-(1-ethylpropyl)-3,4-dimethyl-2,6- dinitrobenzenamine
Chemical structure	
Molecular formula	$C_{13}H_{19}N_3O_4$
Molar mass	281.3
Chemical group	Dinitroaniline
Mode of action (if available)	Microtubule assembly inhibition
Systemic	Yes
Company (ies)	ADAMA Agriculture B.V. and BASF SE
Rapporteur Member State (RMS)	Netherlands
Approval status	Approved on 01/09/2017 by Reg. (EU) 2017/1114
Restriction	Not restricted
Review Report	SANTE/11656/2016
Current MRL regulation	~~Reg. (EU) 2018/687~~ Reg. (EU) 2019/1791
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes
EFSA Journal : Conclusion on the peer review	Yes
EFSA Journal: conclusion on article 12	Yes
Current MRL applications on intended uses	EFSA Journal 2012;10(4):2683

* 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 7.33-2: 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~~			
~~Alfalfa hay~~	~~High dry/protein content~~	~~43 months~~	~~EFSA 2016, Netherlands, 2017~~

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products			
Alfalfa forage	High water content	43 months	EFSA 2016, Netherlands, 2017 (Witkonton, S., 1996; ~~Afzal, 2006~~)
Alfalfa hay	High protein content	43 months	
Alfalfa seed	High starch content	43 months	
~~Corn grain~~	~~High starch content~~	~~24 months~~	
Apple	High water content	24 months	Kicinska, J., 2019 (KCP 7.3.1.1/01)

Conclusion on stability of residues during storage

Studies of storage stability (freezer stability) for pendimethalin were carried out as a result of the EU evaluation process for the inclusion of Pendimethalin in Annex I and during renewal process. The results of unprotected data (Witkonton, 1996) reviewed during renewal, showed that residues of pendimethalin are stable in frozen samples for up to 43 months in matrices representative of high water content (alfalfa forage), high protein conent (alfalfa hay) and high starch content (alfalfa seed), which could be relevant to support residue data for intended use ~~water, protein and starch matrices~~.
In addition, applicant is submitting study of residue storage stability of pendimethalin in high water content matrix (apple) and summary in Appendix 2.

7.3.1.2 Stability of residues in sample extracts (KCA 6.1)

Not relevant.

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 7.33-3: 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								
Root and tuber vegetables	Potatoes	4-^{14}C-methyl pendimethalin	Soil treatment	2.20	1	120 DAT		DAR Addendum 1998 /RAR 2015
			Soil treatment, G and F	1.10	1	93, 106 DAT		
		U-^{14}C-phenyl pendimethalin	Foliar treatment	1.68	1	0, 109 DAT		
	Onions	U-^{14}C-phenyl pendimethalin	Foliar treatment	3.00	2	77 DAT		DAR Addendum 1998 / RAR 2015
Pulses and oilseeds	Soybean	position unknown	Soil treatment	1.68	1	4, 8, 14 weeks after treatment		DAR Addendum 1998 / RAR 2015
		3,4-^{14}C-dimethyl pendimethalin	Soil treatment	1.65	1	1, 2, 4 months after treatment		
Cereals	Sweet corn	^{14}C-ethylpropyl and 4-^{14}C-methyl pendimethalin	Soil treatment, G	1.60	1	30, 60, 80 DAT		DAR Addendum 1998 /RAR 2015
		3,4-^{14}C-dimethyl pendimethalin	Foliar treatment, G	1.65	1	2, 6, 12 weeks after treatment		
		U-^{14}C-phenyl pendimethalin	Foliar treatment, F	2.24	1	14, 30, 60, 81 DAT		
	Wheat	^{14}C-ethylpropyl and 4-^{14}C-methyl	Soil treatment, F	1.54-1.65	1	30, 60, 120 days after breaking		DAR Addendum 1998 /RAR 2015

		pendimethalin				winter dormancy		

Summary of plant metabolism studies reported in the EU

The metabolism of radiolabeled pendimethalin has been examined in a variety of crops including sweet corn, soybeans, potatoes, wheat and onions. Studies were conducted outdoors in small contained field plots, or in pots under greenhouse conditions. Application rates of the 14C-pendimethalin to the test crop plants were in the range 1-2 lb ai/A (~1.1-2.2 kg/ha). Most of the applications were at 1.5 lb ai/A (~1.7 kg/ha) with the exception of the onion study in which the total application rate was 6.0 kg/ha. The early studies utilized 14C-CL pendimethalin radiolabeled in one of three positions: the 4-methyl group, the 3,4-dimethyl groups, or the N-1-(ethyl-1-14C-propyl) group. The more recent studies were conducted with 14C-CL pendimethalin that was uniformly ring-labeled. Typically, the 14C-pendimethalin that was uniformly ring-labeled. No significant differences in plant metabolite profiles have been observed for the differently labeled pendimethalin tracers utilized in the studies. Total radioactive residues (TRR) present in the harvest crop commodities were low. Extraction and analysis (radio-TLC and/or radio-HPLC) showed that only trace amounts of parent pendimethalin, the 4-hydroxymethyl metabolite CL 202,347, and the 4-carboxylic acid metabolite CL 99,900 were detectable in the TRR of crop samples. Of the TRR that was extractable with organic solvents, the vast majority was found to be a mixture of several water-soluble, polar metabolites, each present in trace (<0.01 ppm) amounts. The residue remaining in the tissue marc following extraction with organic solvents was found to be associated with natural, endogenous cell constituents such as protein (soybean), cellulose, hemicellulose, and lignin (RAR 2015).

The metabolism of pendimethalin was investigated for soil pre-emergence and foliar post-emergence applications in cereals (wheat), root and tuber vegetables (carrot) and leafy crops (lettuce) using respectively 14C-phenyl and 13C-4-methyl group labelled pendimethalin. The metabolism of pendimethalin was found to be similar in all investigated crops with the formation of numerous minor metabolites and unidentified polar compounds (RAR 2015, EFSA

Conclusion on metabolism in primary crops

The residue definition for risk assessment and monitoring purposes is set as pendimethalin.

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 7.33-4: 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)	PBI (DAT)	Harvest Intervals (DAT)	
EU data							
Leafy vegetables	Lettuce	3,4-^{14}C-dimethyl pendimethalin	Soil treatment	2.20	30, 90	90, 120, 150	DAR Addendum 1998 / RAR 2015
					365	Maturity and half maturity	

Root and tuber vegetables	Red beet	4-^{14}C-methyl pendimethalin	Soil treatment	1.68	180	210, 270, 330	
	Carrot	3,4-^{14}C-dimethyl pendimethalin		2.20	30, 120	140	
					365	Half mature size and maturity	
	Radishes				30, 90	-	
					365	Half mature size and maturity	
Pulses and oilseeds	Cotton	4-^{14}C-methyl pendimethalin	Soil treatment	1.10	± 120	138, 154, 184, 254	
	Soybean						
	Snap bean	3,4-^{14}C-dimethyl pendimethalin	Soil treatment	2.20	30, 90	90, 120, 150	
					365	Half maturity and maturity	
Cereals	Wheat	3,4-^{14}C-dimethyl pendimethalin	Soil treatment	2.20	30, 120	-	
					365	Maturity and half maturity	

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

Summary of plant metabolism studies reported in the EU

The nature of pendimethalin residues in rotational crops was investigated using 14C-labelled pendimethalin. Four metabolism studies were submitted on cotton seed, soya bean, red beets, lettuce, winter and spring wheat, snap beans, carrots and radishes. These studies were used also for assessing the magnitude of pendimethalin residues in rotational crops (RAR 2015).

In general, studies show that rotational crops, planted back at various intervals after pendimethalin applications up to 2.2 kg a.s./ha contain low TRR levels in the harvested crop commodities. Most of the residue is attributable to incorporation into naturally occurring structural cell components and/or metabolism to water-soluble degradates. Pendimethalin is extensively metabolised to a complex mixture of water-soluble components and other minor components, some of which incorporate into macromolecular plant material such as cellulose and lignin (RAR 2015).

Conclusion on metabolism in rotational crops

The metabolic pathway of pendimethalin in rotational crops is similar to that in primary crops and no formation of new metabolites was observed. Hence the same residue definition of as for primary crops applies to the rotational crops (RAR 2015, EFSA 2016).

7.3.2.3 Nature of residues in processed commodities (KCA 6.5.1)

No new data submitted in the framework of this application.

Available data

Table 7.33-5: Nature of the residues in processed commodities

Conditions (Duration, Temperature, pH)	Identified compound(s) (%)	Reference
EU data		
Pasteurisation (20 minutes, 90°C, pH 4)	Pendimethalin (102.0 %)	Netherlands, 2017

Conditions (Duration, Temperature, pH)	Identified compound(s) (%)	Reference
Baking, boiling, brewing (60 minutes, 100°C, pH 5)	Pendimethalin (102.0 %)	(EFSA 2016); Mohama-Krishna, R.Ch., 2018 (KCP 7.3.2.3-01)
Sterilisation (20 minutes, 120°C, pH 6)	Pendimethalin (94.0 %)	

Conclusion on nature of residues in processed commodities

Pendimethalin is stable under all conditions of high temperature hydrolysis for simulation of food processing (EFSA 2016). Additionally applicant is submitting alternative study, data matching document, which is summarized in Appendix 2.

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

Table 7.33-6: Summary of the nature of residues in commodities of plant origin

Endpoints	
Plant groups covered	Root and tuber vegetables (potatoes, onions) Cereals (wheat, sweet corn) Pulses and oilseeds (soybean)
Rotational crops covered	Leafy vegeables (lettuce) Root and tuber vegetables (red beet, carrot, radishes) Cereals (wheat) Pulses and oilseeds (cotton, soybean, snap bean)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Pendimethalin is stable under hydrolysis process.
Residue pattern in processed commodities similar to pattern in raw commodities?	Residue pattern in raw and processed commodities is similar
Plant residue definition for monitoring	Pendimethalin (EFSA, 2016)
Plant residue definition for risk assessment	Pendimethalin (EFSA, 2016)
Conversion factor from enforcement to RA	Not relevant

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 7.3-7: Summary of animal metabolism studies

Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate (mg/kg DM)	Duration (days)	Commodity	Time of sampling	
EU data								
Lactating ruminants	Goat	U-^{14}C-phenyl pendimethalin	3	2.1 and 6.3	7	Urine and faeces	Daily	DAR Addendum 1998 / RAR 2015
						Tissues	At sacrifice	
						Milk	Daily	
		Position unknown	4	0.5, 1.5 and 20	10	Urine and faeces	Daily	
						Tissues	At sacrifice	
						Milk	Daily	
		4-^{14}C-methyl pendimethalin	3	6.5	7	Urine and faeces	Daily	
						Tissues	At sacrifice	
Laying poultry	Hens	U-^{14}C-phenyl pendimethalin	-	0.5 and 10	7	Eggs	Twice daily	DAR Addendum 1998 / RAR 2015
						Excreta	Once daily	
						Tissues	After sacrifice	

Summary of animal metabolism studies reported in the EU

Metabolism studies in laying hens and lactating goats were submitted and demonstrated that pendimethalin was recovered at trace amounts in all matrices and was degraded into very minor polar components. Based on the estimated livestock dietary burden and the representative uses only, the total residues in livestock matrices are expected to be < 0.01 mg/kg. The agreed residue definition for enforcement and risk assessment were set by default as pendimethalin. MRLs for products of animal origin are not requested (EFSA 2016).

Conclusion on metabolism in livestock

The residue definition for risk assessment and monitoring purposes is set as pendimethalin.

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

Table 7.3-8: 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	1 day
Animal residue definition for monitoring	Pendimethalin (EFSA, 2016)
Animal residue definition for risk assessment	Pendimethalin (EFSA, 2016)
Conversion factor	Not relevant
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	Yes

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

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 7.33-9: Summary of EU reported and new data supporting the intended uses of SHA 2600 A 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
Cereal (Wheat, barley, rye, triticale)	Submitted trials (Peda, T., 2018 – Rubino, M., 2018a,b,c; Romero S., 2018a,b; Roehl, T., 2018a,b)	N-EU	GAP on which assessment is based: 1 x 1.5~~10.7~~ 1.7 kg as/ha, BBCH 25-30, PHI 54-94 days, outdoor 5x <0.01 (wheat), 5x<0.01 (barley)	N/A				
	~~Submitted trials (Zazetta, P., 2019a,b; Orrico Marín, A., 2018a,b; Kicinska, J., 2017; Orrico Marín, A., 2019; Rubino, M., 2018d)~~	~~S-EU~~	~~GAP on which assessment is based: 1 x 1.6-1.8 kg as/ha, BBCH 25-30, PHI 49-114 days, outdoor~~ ~~3x<0.01, 0.01 (wheat), 5x<0.01 barley~~					

	Overall supporting data for cGAP	EU	~~18x<0.01, 0.01~~ 10 x < 0.01	0.01	0.01		0.05	Yes

* Source of EU MRL: Reg. (EU) 2018/687

7.3.3.2 Conclusion on the magnitude of residues in plants

According to the available data, the intended uses of SHA2619A, at one application on wheat, barley, rye and triticale before forming the edible part, are considered acceptable according to guideline SANTE/2019/12752.

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

7.3.4 Magnitude of residues in livestock

7.3.4.1 Dietary burden calculation

Table 7.33-10: Input values for the dietary burden calculation (considering the uses authorized in the country of the zRMS/authorized within the zone/evaluated in Art. 12 procedure and the uses under consideration)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: pendimethalin				
Cabbage	0.05	Median residue	0.05	Highest residue
Kale	0.05	Median residue	0.25	Highest residue
Maize silage	0.05	Median residue	0.05	Highest residue
Apple pomace	0.05	Median residue x PF (1.0)	0.05	Median residue x PF (1.0)
Cereal grain	0.05	Median residue	0.05	Median residue
Brewer's grain, dried	0.05	Median residue x PF (1.0)	0.05	Median residue x PF (1.0)
Distiller's grain dried	0.05	Median residue x PF (1.0)	0.05	Median residue x PF (1.0)
Wheat gluten, meal	0.05	Median residue x PF (1.0)	0.05	Median residue x PF (1.0)
Wheat, milled by-pdts	0.05	Median residue x PF (1.0)	0.05	Median residue x PF (1.0)
Cereal straw	0.07	Median residue	0.14	Highest residue
Bean, pea seed (dry)	0.06	Median residue	0.06	Median residue

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Poatoes	0.05	Median residue	0.05	Highest residue
Potato, process waste	0.05	Median residue x PF (1.0)	0.05	Median residue x PF (1.0)
Potato, dried pulp	0.05	Median residue x PF (1.0)	0.05	Median residue x PF (1.0)
Cotton seed	0.05	Median residue	0.05	Median residue
Cotton meal	0.05	Median residue x PF (1.0)	0.05	Median residue x PF (1.0)
Sunflower seed (meal)	0.05	Median residue x PF (1.0)	0.05	Median residue x PF (1.0)
Soya bean seed	0.05	Median residue	0.05	Median residue
Soybean meal	0.05	Median residue x PF (1.0)	0.05	Median residue x PF (1.0)
Soybean hulls	0.05	Median residue x PF (1.0)	0.05	Median residue x PF (1.0)
Peanuts (meal)	0.05	Median residue x PF (1.0)	0.05	Median residue x PF (1.0)

Table 7.33-11: 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)
Pendimethalin					
Cattle (all diets)	0.011	0.021	Kale leaves	0.58	Yes
Cattle (dairy only)	0.011	0.021	Kale leaves	0.55	Yes
Sheep (all diets)	0.010	0.014	Kale leaves	0.42	Yes
Sheep (ewe only)	0.010	0.014	Kale leaves	0.42	Yes
Swine (all diets)	0.006	0.009	Kale leaves	0.39	Yes
Poultry (all diets)	0.007	0.007	Potato culls	0.10	Yes
Poultry (layer only)	0.006	0.006	Cabbage, heads leaves	0.09	Yes

* These categories correspond to those (formerly) assessed at EU level.

zRMS comment:

Input values for the dietary burden calculation (proposed uses, animal model 2017)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: sum of all compounds containing the N-fluorophenyl-N-isopropyl moiety expressed as flufenacet equivalent				
Cereal grain (wheat, barley, rye, oats, triticale)	0.05	Median residue	0.05	Median residue
Cereal straw	0.7	Median residue	0.14	Median residue

Results of the dietary burden calculation (proposed uses, animal model 2017)

Relevant groups	Dietary burden expressed in				Most critical diet (a)	Most critical commodity (b)		Trigger exceeded (Yes/No)
	mg/kg bw per day		mg/kg DM					0.004
	Median	Maximum	Median	Maximum				mg/kg bw
Cattle (all diets)	0,007	0,015	0,19	0,38	Dairy cattle	Barley	straw	Yes
Cattle (dairy only)	0,007	0,015	0,19	0,38	Dairy cattle	Barley	straw	Yes
Sheep (all diets)	0,012	0,027	0,28	0,63	Lamb	Barley	straw	Yes
Sheep (ewe only)	0,008	0,021	0,25	0,63	Ram/Ewe	Barley	straw	Yes
Swine (all diets)	0,007	0,007	0,23	0,23	Swine (finishing)	Wheat	milled bypdts	Yes
Poultry (all diets)	0,009	0,014	0,14	0,20	Poultry layer	Wheat	straw	Yes
Poultry (layer only)	0,009	0,014	0,14	0,20	Poultry layer	Wheat	straw	Yes

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.

Based on the estimated livestock dietary burden considering respectively the authorised European uses that were revised under Article 12 of Regulation (EC) No. 396/20056 and the representative uses only (wheat and barley), the total residues in livestock matrices are expected to be < 0.01 mg/kg. MRLs for products of animal origin are not requested (EFSA 2016).

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

As quantifiable residues of pendimethalin are not expected in the edible parts of most crops under consideration, and as consumer exposure is far below 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

Taking into account the results obtained in residue tirals in addition to the fact that the confined rotational crop metabolism study represents the worst case, a field rotational crop study is not considered necessary for pendimethalin (RAR 2015).

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 SHA 2600 A. 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).

7.3.8.1 Input values for the consumer risk assessment

Current MRL values are considered. No refinement of the chronic assessment is required.

7.3.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.33-122: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo 3.1	4% (based on NL Toddler)
IESTI (% ARfD) according to EFSA PRIMo 3.1	Unprocessed commodities Results for children: 51% lettuce Results for adults: 16% lettuce Processed commodities Results for children: 12% parsnips/boiled Results for adults: 5% parnips/boiled

The calculation of the TMDI was performed taking into account all the crops to which pendimethalin may be applied. The summary of the calculation using the EFSA model rev 3.1 is presented in Appendix 3. With the current EFSA model the chronic risk assessment reaches a maximum of 4% of ADI. The diet with the highest TMDI is “NL toddler”. For this diet, the highest contributor is milk with 1% of ADI.

Acute dietary exposure was performed taking into account all the crops with corresponding MRL values. Final values resulted to be acceptable for acute exposure for processed and unprocessed commodities.

Based on the above calculation, it can be concluded that the proposed uses of pendimethalin in the formulation SHA 2619A do not represent unacceptable chronic or acute risk for the consumer.

7.4 Combined exposure and risk assessment

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.

7.5 References

1. EFSA 2012. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for flufenacet according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2012;10(4):2689
2. France, 1997. Monograph. (DAR 1997)
3. Review report for the active substance flufenacet.7469/VI/98, 03.07.2003
4. EFSA 2016. Peer review of the pesticide risk assessment of the active substance pendimethalin. EFSA Journal 2016;14(3):4420
5. Netherlands, 2017. Monograph pendimethalin. (RAR 2015).
6. DAR Addendum pendimthalin, 1998.

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

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	Vertebrate study Y/N	Owner
~~KCP 8.3.1/01~~	~~Casalinuovo, L.~~	~~2020~~	~~Determination of flufenacet residues in raw agricultural commodities barley and winter wheat following one application of flufenacet 50%SC. (South Europe 2 harvest trials and 1 multi harvest trial year 2018).~~ ~~Biotecnologie BT report No BIU 004 18.~~ ~~GLP~~ ~~Unpublished~~	~~N~~	~~Sharda~~
~~KCP 8.3.1/02~~	~~Gotsis, G.~~	~~2020~~	~~Generation of Specimens for the Determination of Magnitude of Residue of Flufenacet in/on Winter Wheat at Fixed Intervals and at Harvest, following One application of Flufenacet 50% SC herbicide. Greece – 2018.~~ ~~Agriscience, report No S18 0084R.~~ ~~GLP~~ ~~Unpublished~~	~~N~~	~~Sharda~~
~~KCP 8.3.1/03~~	~~Pardo Martínez, M.~~	~~2020~~	~~Determination of Flufenacet and Its metabolites in/on Winter Wheat and Barley at Fixed intervals and at Harvest, following One application of Flufenacet 50% SC herbicide. Greece – 2018.~~ ~~Chemservice, report No CH 0040/2020 (Analytical phase study report).~~ ~~GLP~~ ~~Unpublished~~	~~N~~	~~Sharda~~

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
~~KCP 8.3.1/04~~	~~Gotsis, G.~~	~~2020~~	~~Generation of Specimens for the Determination of Magnitude of Residue of Flufenacet in/on Winter Barley at Fixed Intervals and at Harvest, following One application of Flufenacet 50% SC herbicide. Greece - 2018.~~ ~~Agriscience, report No S18-0083R.~~ ~~GLP~~ ~~Unpublished~~	~~N~~	~~Sharda~~
~~KCP 8.3.1/05~~	~~Orrico Marín, A.~~	~~2020~~	~~Decline residue study with Flufenacet 50% EC (CAS No. 142459-58-3) in barley cultivated in open field after one application. GLP study in Spain. Year 2017.~~ ~~SICOP, report No SI17HR003ES01.~~ ~~GLP~~ ~~Unpublished~~	~~N~~	~~Sharda~~
~~KCP 8.3.1/06~~	~~Pardo Martínez, M.~~	~~2020~~	~~Determination of flufenacet and its metabolites decline residues in barley cultivated in open field after one application of Flufenacet 50% SC.~~ ~~Chemservice, report No CH-0039/2020 (Analytical phase study report).~~ ~~GLP~~ ~~Unpublished~~	~~N~~	~~Sharda~~
KCP 8.3.1/07	Peda, T.	2018	Magnitude of the residue of Pendimethalin in wheat (Raw Agricultural Commodity) after one application of Pendimethalin 33% EC – one decline curve trial in Poland -2017. Report No. 17SGS011 SGS Polska Sp. z o.o. GLP Unpublished	N	Sharda
KCP 8.3.1/08	Rubino, M.	2018a	Determination of pendimethalin (CAS: 40487-42-1) in wheat by LC-MS according to SOPa-288-LABCHI-REV.0 and SOPa-289-LABCHI-REV.0. Report No. 18.618093.0002 CHELAB S.R.L. GLP Unpublished	N	Sharda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 8.3.1/09	Romero, S.	2018a	Magnitude of residue of Pendimethalin in wheat Raw Agricultural Commodity after one application of Pendimethalin 33% EC under field conditions – 1 harvest trial and 1 decline trial and 1 refinement decline trial. Report No. BPL17-010 BIOTEK Agriculture España SL GLP Unpublished	N	Sharda
KCP 8.3.1/10	Roehl, T.	2018a	Residue study (Decline) in wheat following one post emergence application with Pendimethalin 33% EC in Germany 2017. Report No. CT17-1-47 CropTrials GmbH GLP Unpublished	N	Sharda
KCP 8.3.1/11	Rubino, M.	2018b	Determination of Pendimethalin (CAS: 40487-42-1) in wheat by LC-MS according to SOPa-288-LABCHI-REV.0 and SOPa-2289-LABCHI-REV.0 Report No 18.618095.0005 CHELAB S.R.L. GLP Unpublished	N	Sharda
~~KCP 8.3.1/12~~	~~Zazzetta, P.~~	~~2019~~	~~Determination of pendimethalin residues in Raw Agricultural Commodity wheat (seeds) following one applications of Pendimethalin (F) 33% EC~~ ~~Report No. RA 17 097 BPL SH~~ ~~Research Centre RES AGRARIA~~ ~~GLP~~ ~~Unpublished~~	~~N~~	~~Sharda~~
~~KCP 8.3.1/13~~	~~Orrico Marin, A.~~	~~2019~~	~~Decline residue study with Pendimethalin 33% EC 9CAS No. 40487 42 1) in wheat cultivated in open field after one application. GLP study in Spain. Year 2017~~ ~~Report No SI17HR07ES~~ ~~Sistemas de Control de Producción SL (SICOP)~~ ~~GLP~~ ~~Unpublished~~	~~N~~	~~Sharda~~

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
~~KCP 8.3.1/14~~	~~M.Rubino~~	~~2018d~~	~~Determination of pendimethalin (CAS: 40487-42-1) in wheat by LC-MS according to SOPa-288-LABCHI-REV.0 and SOPa-289-LABCHI-REV.0.~~ ~~Report No 18.638294.0002~~ ~~CHELAB S.R.L.~~ ~~GLP~~ ~~Unpublished~~	~~N~~	~~Sharda~~
~~KCP 8.3.1/15~~	~~P. Zazzetta~~	~~2019b~~	~~Determination of pendimethalin residues in raw agricultural commodity barley (seeds) following one application of Pendimethalin (F) 33%, Italy 2018~~ ~~Report No RA 17 052 BPL SH~~ ~~Research Centre RES AGRARIA S.r.l.~~ ~~GLP~~ ~~Unpublished~~	~~N~~	~~Sharda~~
~~KCP 8.3.1/16~~	~~A. O. Marin~~	~~2018a~~	~~Harvest residue study with Pendimethalin 33% EC (CAS No. 40487-42-1) in cereal cultivated in open field after one application. GLP study in Spain, 2016.~~ ~~Report No. SI16HR009ES~~ ~~Sistemas de Control de Producción SL (SICOP)~~ ~~GLP~~ ~~Unpublished~~	~~N~~	~~Sharda~~
~~KCP 8.3.1/17~~	~~A. O. Marin~~	~~2018b~~	~~Decline residue study with Pendimethalin 33% EC (CAS No. 40487-42-1) in cereal cultivated in open field after one application. GLP study in Spain, 2016.~~ ~~Report No. SI16HR010ES~~ ~~Sistemas de Control de Producción SL (SICOP)~~ ~~GLP~~ ~~Unpublished~~	~~N~~	~~Sharda~~
~~KCP 8.3.1/18~~	~~J. Kicińska~~	~~2017~~	~~Determination of the residues of pendimethalin applied as "Pendimethalin 330 g/L" in barley at one site in Spain, 2016~~ ~~Report No. ZBBZ-2016/69/DPL/1ES~~ ~~Food Safety Laboratory~~ ~~GLP~~ ~~Unpublished~~	~~N~~	~~Sharda~~

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 8.3.1/19	S. Romero	2018b	Magnitude of residue of Pendimethalin in barley Raw Agricultural Commodity after one application of Pendimethalin 33% EC under field conditions – 1 harvest trial and 1 decline trial Report No. BPL17-009 BIOTEK Agriculture España SL GLP Unpublished	N	Sharda
KCP 8.3.1/20	T. Roehl	2018b	Residue study (Harvest and decline) in barley following one post emergence application with Pendimethalin 33% EC in Germany 2017 – field part Report No. CT17-1-45 CropTrials GmbH GLP Unpublished	N	Sharda
KCP 8.3.1/21	M.Rubino	2018c	Determination of pendimethalin (CAS: 40487-42-1) in barley by LC-MS according to SOPa-288-LABCHI-Rev. 0 and SOPa-289-LABCHI-Rev. 0 Report No. 18.618095.0004 CHELAB S.R.L. GLP Unpublished	N	Sharda
KCP 7.3.1.1/01	Kicinska, J.	2019	Stability study of pendimethalin residues in apple samples during 2 years of storage. Inhort Report No ZBBZ-2017/2. GLP Unpublished	N	Sharda
KCP 7.3.2.3/01	Mohama-Krishna, R.C.	2018	High temperature hydrolysis of 14C-Pendimethalin under cooking, baking and pasteurization conditions. Eurofins Advinus Report No G16100. GLP Unpublished	N	Sharda

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

The following tables are to be completed by MS.

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

List of data relied on and not submitted by the applicant but necessary for evaluation

Data point	**Author(s)**	**Year**	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	**Vertebrate study** **Y/N**	**Owner**
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1 Flufenacet

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

No new additional studies were performed.

A 2.1.1.1.2 Storage stability of residues in animal products

No new additional studies were performed.

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

No new additional studies were performed.

A 2.1.2.1.2 Nature of residue in rotational crops

No new additional studies were performed.

A 2.1.2.2 Nature of residues in livestock

No new additional studies were performed.

A 2.1.3 Magnitude of residues in plants

A 2.1.3.1 Cereals (wheat and barley).

New studies on the magnitude of residues are submitted.

A 2.1.3.1.1 Study 1

Comments of zRMS:	Study was not included in the evaluation because it was performed in the south of Europe

Reference:	KCP 8.3.1/01
Report	Determination of flufenacet residues in raw agricultural commodities barley and winter wheat following one application of flufenacet 50%SC. (South Europe-2 harvest trials and 1 multi harvest trial year 2018). Casalinuovo, L., 2020. Report No BIU-004-18.
Guideline(s):	Commission Regulation (EU) No 283/2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 EU Guidance documents on residue analytical methods SANCO/825/00 rev. 8.1 (16/11/2010) and SANCO/3029/99, rev. 4 (11/07/2000) EC guidance document 1607/VI/97 rev.2, 10/6/1999
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials:
Test material: Flufenacet 50% SC
Crop: wheat, barley

Study design and methods:

Three trials, one harvest in wheat, one decline in wheat and one harvest in barley were conducted to determine residue of flufenacet in that crops.
The formulated product was applied once at BBCH 25 at a nominal rate of 480 mL/ha, corresponding to 240.0 g flufenacet/ha.
The application water volume, for all trails, was selected according to Good Agricultural Practices in the respective production areas (nominal 200-400 L/ha).
Field samples were stored frozen at about T<-18°C from reception time to extraction date.

The Analytical Phase was conducted to determine the residues of flufenacet in cereals, by determining all compounds containing the N fluorophenyl-N-isopropyl moiety expressed as flufenacet equivalent. Analytical method was validated according to SANCO/3029/99 and SANCO/825/00 to determine flufenacet

and metabolites flufenacet cysteine conjugate, flufenacet oxalate, flufenacet sulfonic acid and flufenacet thioglycolate sulfoxide in cereal (Report No. CH -0753/2019).

The samples were extracted using methanol, filtered and analysed into the UHPLC. LOQ was 0.01 mg/kg, being LOD 0.002 mg/kg.

Table A 1: Summary of the study 3 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				Flufenacet (mg/kg)	Flufenacet CC (mg/kg)	Flufenacet SA (mg/kg)	Flufenacet OA (mg/kg)	Flufenacet TGS (mg/kg)	SUM as Flufenacet equivalent (mg/kg)		
	(a)	(b)				(c)									(d)	(e)
I/FL18/WW01 /Italy/S-EU/2018	Wheat/Levante	1. 06/11/2017 3. 26/06/2018	251	418	60.05	12/04/2018	BBCH 25	Grain Straw	<0.002 <0.002	<0.002 <0.002	<0.002 <0.002	<0.002 0.02	<0.002 <0.002	<0.002 0.02	75 75	Frozen storage 20 months LOQ 0.01 mg/kg LOD 0.002 mg/kg
I/FL18/WW02 /Italy/S-EU/2018	Wheat/Bologna	1. 05/12/2017 3. 03/07/2018	245	409	59.90	10/04/2018	BBCH 25	Whole plant Whole plant Whole plant Straw Panicle Grain Straw	<0.002 <0.002 <0.002 <0.002 <0.002 <0.002 <0.002	<0.002 <0.002 <0.002 <0.002 <0.002 <0.002 <0.002	<0.002 <0.002 <0.01 <0.01 <0.002 <0.002 <0.01	0.03 0.04 0.05 0.03 0.03 0.03 0.03	<0.01 <0.002 0.01 <0.01 <0.01 <0.002 <0.01	0.03 0.04 0.07 0.04 0.04 0.03 0.05	18 34 59 66 66 84 84	Max frozen storage 22 months LOQ 0.01 mg/kg LOD 0.002 mg/kg
I/FL18/BA01 /Italy/S-EU/2018	Barley/Pilastro	1. 05/10/2017 3. 29/06/2018	246	410	60.00	23/03/2018	BBCH 25	Grain Straw	<0.002 <0.002	<0.002 <0.002	<0.002 0.02	<0.002 <0.002	<0.002 <0.002	<0.002 0.02	98 98	Frozen 20 months LOQ 0.01 mg/kg LOD 0.002 mg/kg

A 2.1.3.1.2 Study 2

Comments of zRMS:	Study was not included in the evaluation because it was performed in the south of Europe

Reference:	KCP 8.3.1/02
Report	Generation of Specimens for the Determination of Magnitude of Residue of Flufenacet in/on Winter Wheat at Fixed Intervals and at Harvest, following One application of Flufenacet 50% SC herbicide. Greece - 2018. Gotsis, G., 2020. Report No S18-0084R.
Guideline(s):	Commission Regulation (EU) No 283/2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 EU Guidance documents on residue analytical methods SANCO/825/00 rev. 8.1 (16/11/2010) and SANCO/3029/99, rev. 4 (11/07/2000) EC guidance document 1607/VI/97 rev.2, 10/6/1999
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Reference:	KCP 8.3.1/03
Report	Determination of Flufenacet and Its metabolites in/on Winter Wheat and Barley at Fixed intervals and at Harvest, following One application of Flufenacet 50% SC herbicide. Greece – 2018. Pardo-Martínez, M., 2020. Study report No CH-0040/2020 (Analytical phase study report).
Guideline(s):	Regulation (EC) No 1107/2009 EU Guidance Document SANCO/3029/99 rev. 4 EU Guidance Document SANCO/825/00 rev. 8.1
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials:
Test material: Flufenacet 50% SC
Crop: wheat

Study design and methods:

Two trials, one harvest and one decline, were conducted to determine residue of flufenacet in wheat.
The formulated product was applied once at BBCH 25 at a nominal rate of 480 mL/ha, corresponding to 240.0 g flufenacet/ha.

The application water volume, for all trails, was selected according to Good Agricultural Practices in the respective production areas (nominal 200-400 L/ha).
Field samples were stored frozen at about T<-18°C from reception time to extraction date.

The analytical phase was conducted in study report No. CH-0040/2020. Analysis was carried out to determine the residues of flufenacet in wheat, by determining all compounds containing the N fluorophenyl-N-isopropyl moiety expressed as flufenacet equivalent. Analytical method was validated according to SANCO/3029/99 and SANCO/825/00 to determine flufenacet and metabolites flufenacet cysteine conjugate, flufenacet oxalate, flufenacet sulfonic acid and flufenacet thioglycolate sulfoxide in cereal (Report No. CH -0753/2019).

The samples were extracted using methanol, filtered and analysed into the UHPLC. LOQ was 0.01 mg/kg, being LOD 0.002 mg/kg.

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 treat-ments 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				Flufenacet (mg/kg)	Flufenacet CC (mg/kg)	Flufenacet SA (mg/kg)	Flufenacet OA (mg/kg)	Flufenacet TGS (mg/kg)	SUM as Flufenacet equivalent (mg/kg)		
	(a)	(b)				(c)									(d)	(e)
S18-0084R01 /Greece/S-EU/2018	Wheat/Odisseo	1. 09/12/2017 3. 06/06/2018	243	303	80.20	13/03/2018	BBCH 25	Grain Straw	<0.002 <0.002	<0.002 <0.002	<0.002 <0.01	<0.01 0.01	<0.002 0.01	<0.01 0.03	85 85	21 months LOQ 0.01 mg/kg LOD 0.002 mg/kg
S18-0084R02 /Greece/S-EU/2018	Wheat/Odisseo	1. 08/12/2017 3. 12/06/2018	246	308	79.87	13/03/2018	BBCH 25	Whole plant Whole plant Whole plant Grain Straw	0.13 0.01 <0.002 <0.002 <0.002	<0.002 <0.002 <0.002 <0.002 <0.002	<0.002 0.02 <0.01 <0.002 0.01	<0.01 0.02 0.02 <0.01 0.03	<0.002 <0.01 <0.01 <0.002 0.02	0.13 0.07 0.03 <0.002 0.09	16 33 66 85 85	24 months LOQ 0.01 mg/kg LOD 0.002 mg/kg

A 2.1.3.1.3 Study 3

Comments of zRMS:	Study was not included in the evaluation because it was performed in the south of Europe

Reference:	KCP 8.3.1/04
Report	Generation of Specimens for the Determination of Magnitude of Residue of Flufenacet in/on Winter Barley at Fixed Intervals and at Harvest, following One application of Flufenacet 50% SC herbicide. Greece - 2018. Gotsis, G., 2020. Report No S18-0083R.
Guideline(s):	Commission Regulation (EU) No 283/2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 EU Guidance documents on residue analytical methods SANCO/825/00 rev. 8.1 (16/11/2010) and SANCO/3029/99, rev. 4 (11/07/2000) EC guidance document 1607/VI/97 rev.2, 10/6/1999
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Reference:	KCP 8.3.1/03
Report	Determination of Flufenacet and Its metabolites in/on Winter Wheat and Barley at Fixed intervals and at Harvest, following One application of Flufenacet 50% SC herbicide. Greece – 2018. Pardo-Martínez, M., 2020. Study report No CH-0040/2020 (Analytical phase study report).
Guideline(s):	Regulation (EC) No 1107/2009 EU Guidance Document SANCO/3029/99 rev. 4 EU Guidance Document SANCO/825/00 rev. 8.1
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials:
Test material: Flufenacet 50% SC
Crop: barley

Study design and methods:

Two trials, one harvest and one decline, were conducted to determine residue of flufenacet in barley.

The formulated product was applied once at BBCH 25 at a nominal rate of 480 mL/ha, corresponding to 240.0 g flufenacet/ha.
The application water volume, for all trails, was selected according to Good Agricultural Practices in the respective production areas (nominal 200-400 L/ha).
Field samples were stored frozen at about T<-18°C from reception time to extraction date.

The analytical phase was conducted in study report No. CH-0040/2020. Analysis was carried out to determine the residues of flufenacet in barley, by determining all compounds containing the N fluorophenyl-N-isopropyl moiety expressed as flufenacet equivalent. Analytical method was validated according to SANCO/3029/99 and SANCO/825/00 to determine flufenacet and metabolites flufenacet cysteine conjugate, flufenacet oxalate, flufenacet sulfonic acid and flufenacet thioglycolate sulfoxide in cereal (Report No. CH -0753/2019).

The samples were extracted using methanol, filtered and analysed into the UHPLC. LOQ was 0.01mg/kg, LOD 0.002 mg/kg.

Table A 3: 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 treat-ments 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				Flufenacet (mg/kg)	Flufenacet CC (mg/kg)	Flufenacet SA (mg/kg)	Flufenacet OA (mg/kg)	Flufenacet TGS (mg/kg)	SUM as Flufenacet equivalent (mg/kg)		
	(a)	(b)				(c)									(d)	(e)
S18-0083R01 /Greece/S-EU/2018	Barley /Olympic	1. 07/12/2017 3. 12/06/2018	246	308	79.87	09/03/2018	BBCH 25	Grain Straw	<0.002 <0.002	<0.002 <0.002	<0.002 0.01	<0.002 <0.01	<0.002 <0.01	<0.002 0.01	95 95	21 months LOQ 0.01 mg/kg LOD 0.002 mg/kg
S18-0083R02 /Greece/S-EU/2018	Barley /Zhana	1. 10/12/2017 3. 14/06/2018	244	304	80.26	07/03/2018	BBCH 25	Whole plant Whole plant Whole plant Grain Straw	0.04 <0.01 <0.002 <0.002 <0.01	<0.002 <0.002 <0.002 <0.002 <0.002	<0.01 0.01 0.01 <0.01 0.02	<0.002 0.01 0.02 <0.002 0.01	<0.002 0.02 0.01 <0.002 0.01	0.04 0.05 0.06 <0.002 0.05	16 33 66 99 99	24 months LOQ 0.01 mg/kg LOD 0.002 mg/kg

A 2.1.3.1.4 Study 4

Comments of zRMS:	Study was not included in the evaluation because it was performed in the south of Europe

Reference:	KCP 8.3.1/05
Report	Decline residue study with Flufenacet 50% EC (CAS No. 142459-58-3) in barley cultivated in open field after one application. GLP study in Spain. Year 2017. Orrico-Marín, A., 2020. Report No SI17HR003ES01.
Guideline(s):	Commission Regulation (EU) No 283/2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 EU Guidance documents on residue analytical methods SANCO/825/00 rev. 8.1 (16/11/2010) and SANCO/3029/99, rev. 4 (11/07/2000) EC guidance document 1607/VI/97 rev.2, 10/6/1999
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Reference:	KCP 8.3.1/06
Report	Determination of flufenacet and its metabolites decline residues in barley cultivated in open field after one application of Flufenacet 50% SC. Pardo-Martínez, M., 2020. Study report No CH-0039/2020 (Analytical phase study report).
Guideline(s):	Regulation (EC) No 1107/2009 EU Guidance Document SANCO/3029/99 rev. 4 EU Guidance Document SANCO/825/00 rev. 8.1
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials:
Test material: Flufenacet 50% SC
Crop: barley

Study design and methods:

One decline trial was conducted to determine residue of flufenacet in barley.

The formulated product was applied once at BBCH 25 at a nominal rate of 480 mL/ha, corresponding to 240.0 g flufenacet/ha.
The application water volume, for all trails, was selected according to Good Agricultural Practices in the respective production areas (nominal 200-400 L/ha).
Field samples were stored frozen at about T<-18°C from reception time to extraction date.

The analytical phase was conducted in study report No. CH-0039/2020. Analysis was carried out to determine the residues of flufenacet in barley, by determining all compounds containing the N fluorophenyl-N-isopropyl moiety expressed as flufenacet equivalent. Analytical method was validated according to SANCO/3029/99 and SANCO/825/00 to determine flufenacet and metabolites flufenacet cysteine conjugate, flufenacet oxalate, flufenacet sulfonic acid and flufenacet thioglycolate sulfoxide in cereal (Report No. CH -0753/2019).

The samples were extracted using methanol, filtered and analysed into the UHPLC. LOQ was 0.01mg/kg, LOD 0.002 mg/kg.

Table A 4: 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 treat-ments 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				Flufenacet (mg/kg)	Flufenacet CC (mg/kg)	Flufenacet SA (mg/kg)	Flufenacet OA (mg/kg)	Flufenacet TGS (mg/kg)	SUM as Flufenacet equivalent (mg/kg)		
	(a)	(b)				(c)									(d)	(e)
SI17HR003ES01 /Spain/S-EU/2018	Barley/Pewters	1. 29/01/2018 3. 29/06/2018	253	418	60.53	17/04/2018	BBCH 25	Whole plant Whole plant Whole plant Grain Straw	0.41 0.06 0.02 <0.002 0.01	0.03 0.04 0.22 <0.002 <0.002	<0.01 0.02 0.07 <0.002 0.02	<0.01 0.01 0.18 <0.002 <0.01	0.01 0.01 0.35 <0.002 <0.01	0.46 0.16 1.08 <0.002 0.04	18 33 66 73 73	Frozen storage 22 months LOQ 0.01 mg/kg LOD 0.002 mg/kg

A 2.1.4 Magnitude of residues in livestock

A 2.1.4.1 Livestock feeding studies

No new additional studies have been submitted.

A 2.1.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)

A 2.1.5.1 Distribution of the residue in peel/pulp

No new additional studies have been submitted.

A 2.1.5.2 Processing studies on a core set of representative processes

No new additional studies have been submitted.

A 2.1.6 Magnitude of residues in representative succeeding crops

No new additional studies have been submitted.

A 2.1.7 Other/Special Studies

No new additional studies have been submitted.

A 2.2 Pendimethalin

A 2.2.1 Stability of residues

A 2.2.1.1.1 Storage stability of residues in plant products

Comments of zRMS:	Study is accepted

New data were submitted in the framework of this application

Reference:	KCP 7.3.1.1/01
Report	Stability study of pendimethalin residues in apple samples during 2 years of storage. Kicinska, J., 2019. Report No ZBBZ-2017/2.
Guideline(s):	Commission Regulation (EU) No 283/2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 EU Guidance documents on residue analytical methods SANCO/825/00 rev. 8.1 (16/11/2010) and SANCO/3029/99, rev. 4 (11/07/2000) EC Guideline No 7032/VI/95 rev 5. OECD Test Guidance No 506/2007.
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials:
Test material: Pendimethalin
Crop: apple

Study design and methods:

The storage stability study was performed to evaluate the stability of pendimethalin in apple as representative of high water content, when stored under frozen conditions at 0, 3, 6, 12, 18 and 24 months. Apple samples spiked at 0.1 mg/kg were stored at ≤-18ºC.

Samples were extracted with acidified acetonitrile and water. After addition of a buffer-salt mixture containing magnesium sulfate and sodium acetate the extract was shaken. After centrifugation, an aliquot of the upper acetonitrile phase was cleaned by primary secondary amine (PSA) and dehydrated by magnesium sulfate addition. Quantification was performed by use of highly selective liquid chromatography coupled with tandem mass spectrometry (LC-MS/MS), following the validated methods described in same study No ZBBZ-2016/69/DPL/1ES, validated according to guidelines SANCO/3029/99 and SANCO/825/00

The LOQ of the method was LOQ of 0.01 mg/kg. The LOD was set at 0.003 mg/k

Table 1 Summarized results of Pendimethalin residues in stored samples

Matrix	Time of analyses [months]	n*	Pendimethalin		
			Mean Residues [mg/kg]	Mean Recovery [%]	RSD** (%)
Apple	0	3	0.087	87	11.8
	3	3	0.095	95	3.5
	6	3	0.090	90	2.0
	12	3	0.096	96	4.5
	18	3	0.079	79	2.6
	24	3	0.086	86	10.6

n* - number of replicates;
RSD** - relative standard deviation

The results of this study showed that pendimethalin is stable in apple when stored at ≤-18ºC for a period at least up to 24 months.

A 2.2.2 Nature of residues in plants, livestock and processed commodities

New data were submitted in the framework of this application.

Comments of zRMS:	Study is accepted

Reference: KCP 7.3.2.3/01

Report: High temperature hydrolysis of 14C-Pendimethalin under cooking, baking and pasteurization conditions. Mohama-Krishna, R.Ch., 2018. Study report G16100.

Guideline(s): Commission Regulation (EU) No 283/2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009

OECD Test Guideline for the Testint of Chemicals 507. Nature of the pesticide residues in processed commodities-High temperature hydrolysis (16 October 2007)

Deviations: No

GLP: Yes

Acceptability: Yes

Materials:
Test material: [phenyl-U-14C]-pendimethalin 98.9% (radiochemical purity)

Study design and methods:

The hydrolytic stability of 14C-pendimethalin was studied in sterile buffer solutions of pH 4, 5 and 6 to simulate representative processing conditions: pasteurization at 90ºC for 20 min pH4, boil-

ing/backing/brewing at 100ºC 60 min pH5, and sterilization at 120ºC 20 min at pH 6. A citrate buffer 0.01 M was selected and a nominal concentration of 0.03 ug/ml using 1% acetonitrile as co-solvent. Samples were analyzed for total radioactivity and identification of parent compound and hydrolysis products. Test item was identify by retention time and quantified with reference standard pendimethalin by LC-DAD/radiochemical detection. The test solution was characterized by LC-MS/MS.

Results

	Incubation		Mass balance (%AR)	
pH	T ºC	Time (min)	Average	Range
4	90	20	96.2	95.2-97.2
5	100	60	90.9	87.1-94.6
6	120	20	88.9	83.2-95.0

Average radioactivity recovered from buffer solutions treated with 14C-pendimethalin (as percentage of applied radioactivity)

	Compound	Time 0 min	After incubation
pH 4	Pendimethalin	96.9	95.4
	Others	--	--
pH 5	Pendimethalin	94.3	87.4
	Others	--	--
pH 6	Pendimethalin	92.6	83.3
	Others	1.8	--

The mean amount of 14C-pendimethalin in the sterile pH 4, pH5 and pH 6 samples is showed above Table. Pendimethalin in the hydrolysis samples was identified as major component and confirmed by LC-MS/MS. There were no metabolites at the end of incubation period. Therefore pendimethalin resulted to be stable under high temperature hydrolysis in processing conditions.

A 2.2.3 Magnitude of residues in plants

A 2.2.3.1 Cereal (Wheat and barley)

A 2.2.3.1.1 Study 1

Comments of zRMS:	Study is accepted

Reference:	KCP 8.3.1/07
Report	Magnitude of the residue of Pendimethalin in wheat (Raw Agricultural Commodity) after one application of Pendimethalin 33% EC – one decline curve trial in Poland -2017. T. Peda, 2018. Report No. 17SGS011 (Field phase)
Guideline(s):	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

Acceptability:	Yes

Reference:	KCP 8.3.1/08
Report	Determination of pendimethalin (CAS: 40487-42-1) in wheat by LC-MS according to SOPa-288-LABCHI-REV.0 and SOPa-289-LABCHI-REV.0. M.Rubino, 2018a, Report No. 18.618093.0002 (Analytical phase)
Guideline(s):	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21-Oct-2009 concerning the placing of plant protection products on the market and repealing council Directives 79/117/EEC and 91/414/EC Guideline 7029/VI/95 (rev. 5) to Directive 91/414/EEC and Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 EU Guidance Document SANCO/3029/99 rev. 4 EU Guidance Document SANCO/825/00 rev. 8.1
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL
Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

Crop: Wheat

STUDY DESIGN
The objective of this Study was to determinate Pendimethalin residues in wheat in open field. With this purpose one decline trial was subjected to a residue programme which included 1 foliar application of Pendimethalin 33% EC at BBCH 27 in Poland.

The formulated product was applied at a rate of 1.5 kg a.i./ha.
The application water volume was 472 L/ha.

The analytical phase of the study 18.618093.0002 was conducted to determine the residual level of Pendimethalin in wheat by LC-MS, following the validated method described in study No 16.566423.0005 and No 16.566423.0006 on the matrix cereal grains and straw according to guideline SANCO/3029/99 and SANCO/825/00.

Field samples were stored frozen at about T<-18°C from reception time to extraction date. Homogenized sample was extracted with water and acidified acetonitrile. Thereafter magnesium sulphate anhydrous and sodium acetate were added to the sample and vortexed again. Further purification by PSA and magnesium sulphate was performed. An aliquot of the extract was analysed by LC-MS/MS.

The LOQ of the method was LOQ of 0.01 mg/kg. The LOD was set at 0.003 mg/kg.

Table A 5: Summary of the study 1 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				Pendimethalin		
	(a)	(b)				(c)				(d)	(e)
17SGS011 PL01/Poland/N-EU/2017	Wheat/Tybalt	11/04/2017 13-28/06/2017 14-15/08/2017	1523	472	323	29/05/2017	BBCH 27	Whole plants Whole plants Straw Grain Straw	2.90 0.12 0.03 <0.01 0.04	0 44 77 77 77	Frozen storage 12 months Analytical report: 18.618093.0002

A 2.2.3.1.2 Study 2

Comments of zRMS:	Study is accepted

Reference:	KCP 8.3.1/09
Report	Magnitude of residue of Pendimethalin in wheat Raw Agricultural Commodity after one application of Pendimethalin 33% EC under field conditions – 1 harvest trial and 1 decline trial and 1 refinement decline trial. S. Romero, 2018a, Report No. BPL17-010. (Field phase)
Guideline(s):	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
Acceptability:	Yes

MATERIAL
Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

Crop: Wheat

STUDY DESIGN
The objective of this Study was to determinate Pendimethalin residues in wheat in open field. With this purpose two decline trials and one trial at harvest were subjected to a residue programme which included 1 foliar application of Pendimethalin 33% EC at BBCH 25-30 in Poland.

The formulated product was applied at a rate of 1.5 kg a.i./ha.
The application water volume was approx.. 300 L/ha.

The analytical phase was conducted to determine the residual level of Pendimethalin in wheat by LC-MS, following the validated methods described in study No 16.566423.0005 and No 16.566423.0006 on the matrix cereal grains and straw according to guidelines SANCO/3029/99 and SANCO/825/00.

Field samples were stored frozen at about T<-18°C from reception time to extraction date. Homogenized sample was extracted with water and acidified acetonitrile. Thereafter magnesium sulphate anhydrous and sodium acetate were added to the sample and vortexed again. Further purification by PSA and magnesium sulphate was performed. An aliquot of the extract was analysed by LC-MS/MS.

The LOQ of the method was LOQ of 0.01 mg/kg. The LOD was set at 0.003 mg/kg.

Table A 61: Summary of the study 2

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				Pendimethalin		
	(a)	(b)				(c)				(d)	(e)
BPL17-010-01/Poland/N-EU/2017	Spring wheat/Arabella	29/03/17 19-28/06/17 3-4/08/18	1574	306	510	18/05/17	BBCH 25-30	Grain	<0.01	78	Frozen storage 7 months
BPL17-010-02/Poland/N-EU/2017	Spring wheat/Harenda	14/03/17 12-28/06/17 07/08/17	1510	294	510	08/05/17	BBCH 25-30	Whole plant Whole plant Grain Straw	6.23 0.13 <0.01 0.04	0 30 91 91	Frozen storage 13 months
BPL17-010-03/Poland/N-EU/2017	Spring wheat/Rospuda	30/03/17 19-26/06/17 07/08/17	1498	291	510	16/05/17	BBCH 25-30	Whole plant Whole plant Whole plant Whole plant Whole plant Whole plant Whole plant Whole plant Whole plant Whole plant Whole plant Whole plant Whole plant Grain Straw	6.79 2.80 3.19 2.68 1.19 1.16 1.15 1.22 1.34 1.49 1.46 0.68 0.78 <0.01 0.04	+0 1 2 3 4 5 6 7 8 9 10 13 14 83 83	Frozen storage 13 months

A 2.2.3.1.3 Study 3

Comments of zRMS:	Study is accepted

Reference:	KCP 8.3.1/10
Report	Residue study (Decline) in wheat following one post emergence application with Pendimethalin 33% EC in Germany 2017. T. Roehl (Field phase). Report No. CT17-1-47
Guideline(s):	- EEC document 7029/V1/95 rev. 5, 1997, Appendix B working document 1607/V1/97, rev. 2, 1999: General recommendation for the design, preparation and realisation of residue trials - Rückstandsversuche, Teil 1 Prüfungen an Pflanzen, A: Allgemeiner Teil, B: Spezieller Teil, IVA-Guideline, Industrieverband Agrar e. V. 1992
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Reference:	KCP 8.3.1/11
Report	Determination of Pendimethalin (CAS: 40487-42-1) in wheat by LC-MS according to SOPa-288-LABCHI-REV.0 and SOPa-2289-LABCHI-REV.0, M. Rubino, 2018b, Report No 18.618095.0005(Analytical phase)
Guideline(s):	Guideline 7029/VI/95 (rev. 5) to Directive 91/414/EEC and Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 EU Guidance Document SANCO/3029/99 rev. 4 EU Guidance Document SANCO/825/00 rev. 8.1
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL
Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

Crop: Wheat

STUDY DESIGN
The objective of this Study was to determinate Pendimethalin residues in wheat in open field. With this purpose one decline trial was subjected to a residue programme which included 1 foliar application of Pendimethalin 33% EC at BBCH 30 in Germany.

The formulated product was applied at a rate of 1.5 kg a.i./ha.
The application water volume was 300 L/ha.

The analytical phase of the study 18.618095.0005 was conducted to determine the residual level of Pendimethalin in wheat by LC-MS, following the validated methods described in study No 16.566423.0005 and No 16.566423.0006 on the matrix cereal grains and straw according to guidelines SANCO/3029/99 and SANCO/825/00.

Field samples were stored frozen at about T<-18°C from reception time to extraction date. Homogenized sample was extracted with water and acidified acetonitrile. Thereafter magnesium sulphate anhydrous and sodium acetate were added to the sample and vortexed again. Further purification by PSA and magnesium sulphate was performed. An aliquot of the extract was analysed by LC-MS/MS.

The LOQ of the method was LOQ of 0.01 mg/kg. The LOD was set at 0.003 mg/kg.

Table A 72: Summary of the study 3

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				Pendimethalin		
	(a)	(b)				(c)				(d)	(e)
CT17-1-47DE1/Germany/N-EU/2018	Spring wheat/Dino	25/03/2017 - -	1498.6	300	500	26/05/2017	BBCH 30	Whole plant Whole plant Whole plant Whole plant Whole plant Whole plant Whole plant Whole plant Whole plant Whole plant Whole plant Whole plant Whole plant Grain Straw	5.81 3.69 3.42 1.39 1.19 1.21 0.31 0.34 0.21 0.03 0.19 0.07 0.12 <0.01 0.01	0 1 2 3 4 5 6 7 8 9 10 12 14 73 73	Frozen storage 12 months Analytical report: 18.618095.0005

A 2.2.3.1.4 Study 4

Comments of zRMS:	Study was not included in the evaluation because it was performed in the south of Europe

Reference:	KCP 8.3.1/12
Report	Determination of pendimethalin residues in Raw Agricultural Commodity wheat (seeds) following one applications of Pendimethalin (F) 33% EC. P. Zazzetta, 2019, Report No. RA 17 097 BPL SH
Guideline(s):	EU Guidance documents on residue analytical methods SANCO/825/00 rev. 8.1 (16/11/2010) and SANCO/3029/99, rev. 4 (11/07/2000). EC guidance document 1607/VI/97 rev.2, 10/6/1999. Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009.
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL
Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

Crop: wheat

STUDY DESIGN
The objective of this Study was to determinate Pendimethalin residues in wheat in open field. With this purpose 2 harvest trials were subjected to a residue programme which included 1 foliar application of Pendimethalin 33% EC in Italy.

The formulated product was applied at a rate of 1.65 kg a.i./ha.
The application water volume was 800 L/ha.

The analytical phase was conducted to determine the residual level of Pendimethalin in wheat by LC-MS, following the validated method described in study No RAU-039-17 validated on the matrix cereal grains and straw according to guidelines SANCO/3029/99 and SANCO/825/00.

Field samples were stored frozen at about T<-18°C from reception time to extraction date. Homogenized sample was extracted with water and acidified acetonitrile. After addition of magnesium sulphate anhydrous, sodium chloride, dibasic sodium citrate sesquihydrate and tribasic sodium citrate dihydrate, the mixture was shaken and centrifuged. The extract was purified with PSA and magnesium sulfate. An aliquot of the extract was analysed by LC-MS/MS.

The LOQ of the method was LOQ of 0.01 mg/kg. The LOD was set at 0.003 mg/kg.

Table A 83: Summary of the study 4

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				Pendimethalin		
(a)		(b)				(c)				(d)	(e)
RA 17 097 BPL IT 01/Italy/ S-EU/2018	Wheat	18/02/2017	1640	800	220	20/03/2018	BBCH 27	Grain	<0.01	111	Frozen storage 3 months
RA 17 097 BPL IT 02/Italy/ S-EU/2018	Wheat	10/11/2017	1640	800	220	20/03/2018	BBCH 26	Grain	<0.01	113	Frozen storage 3 months

A 2.2.3.1.5 Study 5

Comments of zRMS:	Study was not included in the evaluation because it was performed in the south of Europe

Reference:	KCP 8.3.1./13
Report	Decline residue study with Pendimethalin 33% EC 9CAS No. 40487-42-1) in wheat cultivated in open field after one application. GLP study in Spain. Year 2017, Orrico-Marín, A., 2019, Report No SI17HR07ES (Field phase)
Guideline(s):	Directive 91/414/EEC
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Reference:	KCP 8.3.1/14
Report	Determination of pendimethalin (CAS: 40487-42-1) in wheat by LC-MS according to SOPa-288-LABCHI-REV.0 and SOPa-289-LABCHI-REV.0, M. Rubino, 2018d, Report No 18.638294.0002 (Analytical phase)
Guideline(s):	Guideline 7029/VI/95 (rev. 5) to Directive 91/414/EEC and Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 EU Guidance Document SANCO/3029/99 rev. 4 EU Guidance Document SANCO/825/00 rev. 8.1
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL
Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

Crop: Wheat

STUDY DESIGN
The objective of this Study was to determinate Pendimethalin residues in wheat in open field. With this purpose two decline trials were subjected to a residue programme which included 1 foliar application of Pendimethalin 33% EC at BBCH 30 in Spain.

The formulated product was applied at a rate of 1.65 kg a.i./ha.
The application water volume was approx.. 600 L/ha.

The analytical phase of the study 18.638294.0002 was conducted to determine the residual level of Pendimethalin in wheat by LC-MS, following the validated methods described in study No 16.566423.0005 and No 16.566423.0006 on the matrix cereal grains and straw according to guidelines SANCO/3029/99 and SANCO/825/00.

Field samples were stored frozen at about T<-18°C from reception time to extraction date. Homogenized sample was extracted with water and acidified acetonitrile. Thereafter magnesium sulphate anhydrous and sodium acetate were added to the sample and vortexed again. Further purification by PSA and magnesium sulphate was performed. An aliquot of the extract was analysed by LC-MS/MS.

The LOQ of the method was LOQ of 0.01 mg/kg. The LOD was set at 0.003 mg/kg.

Table A 94: Summary of the study 5

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				Pendimethalin		
	(a)	(b)				(c)				(d)	(e)
SI17HR007ES01/Spain/S-EU/2017	Wheat/Artur	29/01/2018	1648	595	277	17/04/2018	BBCH 30	Whole plants	2.49	0	Frozen storage 5 months
								Whole plants	1.32	1	
								Whole plants	0.49	2	Analytical report:
								Whole plants	0.45	3	18.638294.0002
								Whole plants	0.44	4	
								Whole plants	32.35	5	
								Whole plants	52.49	6	
								Whole plants	3.81	7	
								Whole plants	37.55	8	
								Whole plants	56.92	9	
								Whole plants	31.86	10	
								Whole plants	11.72	12	
								Whole plants	13.53	14	
								Grain	<0.01	73	
								Straw	0.02	73	
SI17HR007ES02/Spain/S-EU/2017	Wheat/Berdun	02/02/2018	1616	584	277	17/04/2018	BBCH 30	Whole plants	62.39	0	Frozen storage 5 months
								Whole plants	0.01	1	
								Whole plants	0.78	2	Analytical report:
								Whole plants	0.32	3	18.638294.0002
								Whole plants	0.34	4	
								Whole plants	55.37	5	
								Whole plants	5.94	6	
								Whole plants	4.16	7	
								Whole plants	28.14	8	
								Whole plants	30.24	9	
								Whole plants	9.52	10	
								Whole plants	18.59	12	
								Whole plants	8.00	14	
								Grain	0.01	64	
								Straw	0.03	64	

A 2.2.3.1.6 Study 6

Comments of zRMS:	Study was not included in the evaluation because it was performed in the south of Europe

Reference:	KCP 8.3.1/18
Report	Determination of pendimethalin residues in raw agricultural commodity barley (seeds) following one application of Pendimethalin (F) 33%, Italy 2018, P. Zazzetta, 2019b. Report No RA 17 052 BPL SH (Field and analytical phase)
Guideline(s):	The EC guidance working document SANCO/7029/VI/95 rev. 5 (22/07/1997). OECD/OCDE 509 Adopted: 7 September 2009, OECD guidelines for the testing of chemicals, Crop Field Trial. Document SANCO 3029/99, rev. 4 of 11/07/00 of the European Commission. OECD (2007). Guidance document on pesticide residue analytical methods. Document ENV/JM/MONO(2007)17.
Deviations:	No
GLP:	Yes
Acceptability:	Yes

The objective of this Study was to determinate Pendimethalin residues in barley in open field. With this purpose one at harvest trial was subjected to a residue programme which included 1 foliar application of Pendimethalin 33% EC at BBCH 27 in Italy.

The formulated product was applied at a rate of 1.6 kg a.i./ha.
The application water volume was 800 L/ha.

The analytical phase was conducted to determine the residual level of Pendimethalin in barley by LC-MS according to the validated methods described in study No RAU-039-17 validated on the matrix cereal grains and straw according to guidelines SANCO/3029/99 and SANCO/825/00.

Field samples were stored frozen at about T<-18°C from reception time to extraction date. Homogenized sample was extracted with water and acidified acetonitrile. After addition of magnesium sulphate anhydrous, sodium chloride, dibasic sodium citrate sesquihydrate and tribasic sodium citrate dihydrate, the mixture was shaken and centrifuged. The extract was purified with PSA and magnesium sulfate. An aliquot of the extract was analysed by LC-MS/MS.

The LOQ of the method was LOQ of 0.01 mg/kg. The LOD was set at 0.003 mg/kg.

Table A 105: Summary of the study 6

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				Pendimethalin		
	(a)	(b)				(c)				(d)	(e)
RA 17 052 BPL IT 01/Italy/S-EU/2018	Barley	-	1562	800	205	20/03/2018	BBCH 27	Grain	<0.01	114	Frozen storage 11 months

A 2.2.3.1.7 Study 7

Comments of zRMS:	Study was not included in the evaluation because it was performed in the south of Europe

Reference:	KCP 8.3.1/19
Report	Harvest residue study with Pendimethalin 33% EC (CAS No. 40487-42-1) in cereal cultivated in open field after one application. GLP study in Spain, 2016. A. Orrico-Marin A., 2018a, Report No. SI16HR009ES (Field phase)
Guideline(s):	Directive 91/414/EEC
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Reference:	KCP 8.3.1/20
Report	Determination of the residues of pendimethalin applied as "Pendimethalin 330 g/L" in barley at one site in Spain, 2016, J. Kicińska 2017, Report No. ZBBZ-2016/69/DPL/1ES (Analytical phase)
Guideline(s):	Guideline 7029/VI/95 (rev. 5) to Directive 91/414/EEC and Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 EU Guidance Document SANCO/3029/99 rev. 4 EU Guidance Document SANCO/825/00 rev. 8.1
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL
Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

Crop: Barley

STUDY DESIGN
The objective of this Study was to determinate Pendimethalin residues in barley in open field. With this purpose two at harvest trials were subjected to a residue programme which included 1 foliar application of Pendimethalin 33% EC at BBCH 30 in Spain.

The formulated product was applied at a rate of 1.65 kg a.i./ha.
The application water volume was approx.. approx.. 240 L/ha.

The analytical phase of the study ZBBZ-2016/69/DPL/1ES was conducted to determine the residual level of Pendimethalin in barley by LC-MS, following the validated methods described in same study No ZBBZ-2016/69/DPL/1ES, validated on the matrix grain and straw cereal according to guidelines SANCO/3029/99 and SANCO/825/00.

Field samples were stored frozen at about T<-18°C from reception time to extraction date. Homogenized sample was extracted with acidified acetonitrile and water. After addition of a buffer-salt mixture contain-

ing magnesium sulfate and sodium acetate the extract was shaken. After centrifugation, an aliquot of the upper acetonitrile phase was cleaned by primary secondary amine (PSA) and dehydrated by magnesium sulfate addition. Quantification was performed by use of highly selective liquid chromatography coupled with tandem mass spectrometry (LC-MS/MS)

The LOQ of the method was LOQ of 0.01 mg/kg. The LOD was set at 0.003 mg/kg.

Table A 116: Summary of the study 7

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				Pendimethalin		
	(a)	(b)				(c)				(d)	(e)
SI16HR009ES01/S-EU/Spain/2016	Barley/Pewter	15/12/2015 - 26/07/2016	1723	240	718	08/06/2018	BBCH 30	Grain	<0.01	49	Frozen storage 15 months Analytical report: ZBBZ-2016/69/DPL/1ES
SI16HR009ES02/S-EU/Spain/2016	Barley/Pewter	15/12/2015 - 26/07/2016	1650	230	717	08/06/2018	BBCH 30	Grain	<0.01	49	Frozen storage 15 months Analytical report: ZBBZ-2016/69/DPL/1ES

A 2.2.3.1.8 Study 8

Comments of zRMS:	Study was not included in the evaluation because it was performed in the south of Europe

Reference:	KCP 8.3.1/21
Report	Decline residue study with Pendimethalin 33% EC (CAS No. 40487-42-1) in cereal cultivated in open field after one application. GLP study in Spain, 2016. Orrico-Marin A. 2018b, Report No. SI16HR010ES (Field phase)
Guideline(s):	Directive 91/414/EEC
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Reference:	KCP 8.3.1/20
Report	Determination of the residues of pendimethalin applied as "Pendimethalin 330 g/L" in barley at one site in Spain, 2016, J. Kicińska, Report No. ZBBZ-2016/69/DPL/1ES (Analytical phase)
Guideline(s):	Guideline 7029/VI/95 (rev. 5) to Directive 91/414/EEC and Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 EU Guidance Document SANCO/3029/99 rev. 4 EU Guidance Document SANCO/825/00 rev. 8.1
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL
Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

Crop: Barley

STUDY DESIGN
The objective of this Study was to determinate Pendimethalin residues in barley in open field. With this purpose two decline trials were subjected to a residue programme which included 1 foliar application of Pendimethalin 33% EC at BBCH 30 in Spain.

The formulated product was applied at a rate of 1.6-1.8 kg a.i./ha.
The application water volume was approx.. 250 L/ha.

The analytical phase of the study ZBBZ-2016/69/DPL/1ES was conducted to determine the residual level of Pendimethalin in barley by LC-MS according to the validated method described in same study No ZBBZ-2016/69/DPL/1ES, validated on the matrix grain and straw cereal in accordance to the guidance documents SANCO/825/00, rev. 8.1. and SANCO/3029/99, rev. 4.

Field samples were stored frozen at about T<-18°C from reception time to extraction date. Homogenized sample was extracted with acidified acetonitrile and water. After addition of a buffer-salt mixture containing magnesium sulfate and sodium acetate the extract was shaken. After centrifugation, an aliquot of the upper acetonitrile phase was cleaned by primary secondary amine (PSA) and dehydrated by magnesium sulfate addition. Quantification was performed by use of highly selective liquid chromatography coupled with tandem mass spectrometry (LC-MS/MS)

The LOQ of the method was LOQ of 0.01 mg/kg. The LOD was set at 0.003 mg/kg.

Table A 127: Summary of the study 8

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				Pendimethalin		
	(a)	(b)				(c)				(d)	(e)
SI16HR010ES01/S-EU/Spain/2016	Barley/Pewter	15/12/2015 - 26/07/2016	1791	250	716	08/06/2018	BBCH 30	Whole plants Whole plants Straw Grain	44.0 1.25 1.41 <0.01	0 31 49 49	Frozen storage 15 months Analytical report: ZBBZ-2016/69/DPL/1ES
SI16HR010ES02/S-EU/Spain/2016	Barley/Pewter	15/12/2015 - 26/07/2016	1650	230	717	08/06/2018	BBCH 30	Whole plants Whole plants Straw Grain	67.2 0.130 0.261 <0.01	0 31 49 49	Frozen storage 15 months Analytical report: ZBBZ-2016/69/DPL/1ES

A 2.2.3.1.9 Study 9

Comments of zRMS:	Study is accepted

Reference:	KCP 8.3.1/22
Report	Magnitude of residue of Pendimethalin in barley Raw Agricultural Commodity after one application of Pendimethalin 33% EC under field conditions – 1 harvest trial and 1 decline trial, S. Romero, 2018b, Report No. BPL17-009 (Field and analytical phase)
Guideline(s):	The EC guidance working document SANCO/7029/VI/95 rev. 5 (22/07/1997). OECD/OCDE 509 Adopted: 7 September 2009, OECD guidelines for the testing of chemicals, Crop Field Trial. Document SANCO 3029/99, rev. 4 of 11/07/00 of the European Commission. OECD (2007). Guidance document on pesticide residue analytical methods. Document ENV/JM/MONO(2007)17.
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL
Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

Crop: Barley

STUDY DESIGN
The objective of this Study was to determinate Pendimethalin residues in barley in open field. With this purpose two trials (one decline and one at harvest) were subjected to a residue programme which included 1 foliar application of Pendimethalin 33% EC at BBCH 25-30 in Poland.

The formulated product was applied at a rate of 1.5-1.6 kg a.i./ha.
The application water volume was approx. 300 L/ha.

The analytical phase was conducted to determine the residual level of Pendimethalin in barley by LC-MS following the methods described in study No 16.566423.0005 and No 16.566423.0006, validated on the matrix cereal grains and straw according to guidelines SANCO/3029/99 and SANCO/825/00.

Field samples were stored frozen at about T<-18°C from reception time to extraction date. Homogenized sample was extracted with water and acidified acetonitrile. Thereafter magnesium sulphate anhydrous and sodium acetate were added to the sample and vortexed again. Further purification by PSA and magnesium sulphate was performed. An aliquot of the extract was analysed by LC-MS/MS.

The LOQ of the method was LOQ of 0.01 mg/kg. The LOD was set at 0.003 mg/kg.

Table A 138: Summary of the study 9

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				Pendimethalin		
	(a)	(b)				(c)				(d)	(e)
BPL17-009-01/Poland/N-EU/2017	Spring barley/Propino	13/03/17 14-30/06/17 31/07/17	1510	294	510	11/05/17	BBCH 25-27	Grain	<0.01	81	Frozen storage 12 months
BPL17-009-02/Poland/N-EU/2017	Spring barley/Propino	16/03/17 10-19/06/17 10/08/17	1582	308	514	08/05/17	BBCH 26-30	Whole plants Whole plants Grain Straw	3.94 0.35 <0.01 <0.01	+0 30 94 94	Frozen storage 12 months

A 2.2.3.1.10 Study 10

Comments of zRMS:	Study is accepted

Reference:	KCP 8.3.1/23
Report	Residue study (Harvest and decline) in barley following one post emergence application with Pendimethalin 33% EC in Germany 2017 – field part, T. Roehl, 2018b, Report No. CT17-1-45 (Field phase)
Guideline(s):	Directive 91/414/EEC
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Reference:	KCP 8.3.1/24
Report	Determination of pendimethalin (CAS: 40487-42-1) in barley by LC-MS according to SOPa-288-LABCHI-Rev. 0 and SOPa-289-LABCHI-Rev. 0, M.Rubino, 2018c, Report No. 18.618095.0004 (Analytical phase)
Guideline(s):	Guideline 7029/VI/95 (rev. 5) to Directive 91/414/EEC and Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 EU Guidance Document SANCO/3029/99 rev. 4 EU Guidance Document SANCO/825/00 rev. 8.1
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL
Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

Crop: barley

STUDY DESIGN
The objective of this Study was to determinate Pendimethalin residues in barley in open field. With this purpose two harvest trials and one decline were subjected to a residue programme which included 1 foliar application of Pendimethalin 33% EC at BBCH 25-30 in Germany.

The formulated product was applied at a rate of 1.6-1.7 kg a.i./ha.
The application water volume was 300 L/ha.

The analytical phase of the study 18/618095.0004 was conducted to determine the residual level of Pendimethalin in barley by LC-MS following the methods described in study No 16.566423.0005 and No 16.566423.0006, validated on the matrix cereal grains and straw according to guidelines SANCO/3029/99 and SANCO/825/00.

Field samples were stored frozen at about T<-18°C from reception time to extraction date. Homogenized sample was extracted with water and acidified acetonitrile. Thereafter magnesium sulphate anhydrous and

sodium acetate were added to the sample and vortexed again. Further purification by PSA and magnesium sulphate was performed. An aliquot of the extract was analysed by LC-MS/MS.

The LOQ of the method was LOQ of 0.01 mg/kg. The LOD was set at 0.003 mg/kg.

Table A 149: Summary of the study 10

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				Pendimethalin		
	(a)	(b)				(c)				(d)	(e)
CT17-1-45-DE1/Germany/N-EU/2017	Spring barley/Quench	25/03/2017 01/04/2017 06/08/2017	1723	300	574	26/05/2017	BBCH 30	Grain	0.01	73	Frozen storage 3 months Analytical report: 18.618095.0004
CT17-1-45-DE2/Germany/N-EU/2017	Spring barley/Avalon	16/03/2017 01/04/2017 02/08/2017	1752	300	584	10/05/2017	BBCH 25-28	Grain	<0.01	83	Frozen storage 3 months Analytical report: 18.618095.0004
CT17-1-45-DE3/Germany/N-EU/2017	Spring barley/Avalon	13/03/2017 28/03/2017 13/07/2017	1623	300	541	26/05/2017	BBCH 30	Whole plant Whole plant Grain Straw	5.66 0.08 <0.01 0.10	0 40 54 54	Frozen storage 3 months Analytical report: 18.618095.0004

Appendix 3 Pesticide Residue Intake Model (PRIMo)

A 3.1 Flufenacet TMDI calculations

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:	**Review**	Source of ARfD:	**Review Report**
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 : ---

	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)	88%	NL toddler	4,41	13%	Potatoes	12%	Milk: Cattle	11%	Apples		8%
	57%	NL child	2,83	10%	Potatoes	8%	Sugar beet roots	8%	Wheat		8%
	55%	DE child	2,73	12%	Apples	8%	Wheat	8%	Potatoes		8%
	47%	GEMS/Food G06	2,33	14%	Wheat	6%	Potatoes	4%	Tomatoes		15%
	45%	GEMS/Food G11	2,27	12%	Potatoes	7%	Wheat	4%	Soyabeans		9%
	45%	GEMS/Food G08	2,24	12%	Potatoes	8%	Wheat	2%	Soyabeans		10%
	44%	GEMS/Food G07	2,19	11%	Potatoes	8%	Wheat	2%	Soyabeans		10%
	43%	GEMS/Food G15	2,16	11%	Potatoes	9%	Wheat	2%	Soyabeans		11%
	43%	FR child 3 15 yr	2,13	9%	Wheat	5%	Milk: Cattle	5%	Potatoes		9%
	42%	GEMS/Food G10	2,08	9%	Potatoes	8%	Wheat	3%	Soyabeans		9%
	41%	RO general	2,05	11%	Potatoes	10%	Wheat	2%	Milk: Cattle		10%
	40%	DK child	2,00	9%	Wheat	7%	Potatoes	6%	Rye		9%
	39%	SE general	1,95	13%	Potatoes	6%	Wheat	4%	Bovine: Muscle/meat		6%
	39%	UK toddler	1,95	10%	Potatoes	8%	Wheat	4%	Milk: Cattle		8%
	39%	UK infant	1,94	10%	Potatoes	8%	Milk: Cattle	5%	Wheat		5%
	37%	FR toddler 2 3 yr	1,87	6%	Wheat	6%	Milk: Cattle	6%	Potatoes		6%
	36%	IE adult	1,78	7%	Potatoes	5%	Wheat	4%	Sweet potatoes		5%
	35%	PT general	1,77	16%	Potatoes	8%	Wheat	2%	Wine grapes		8%
	33%	ES child	1,67	9%	Wheat	6%	Potatoes	2%	Milk: Cattle		9%
	29%	DE women 14-50 yr	1,45	5%	Sugar beet roots	4%	Wheat	3%	Potatoes		5%
	29%	NL general	1,43	7%	Potatoes	4%	Wheat	3%	Sugar beet roots		4%
	28%	DE general	1,42	4%	Sugar beet roots	4%	Wheat	4%	Potatoes		5%
	27%	FI 3 yr	1,37	14%	Potatoes	2%	Wheat	1%	Bananas		3%
	25%	IT toddler	1,24	13%	Wheat	3%	Potatoes	2%	Other cereals		13%
	22%	FI 6 yr	1,10	12%	Potatoes	2%	Wheat	0,8%	Bananas		2%
	21%	ES adult	1,04	5%	Wheat	3%	Potatoes	1%	Oranges		6%
	20%	LT adult	1,02	10%	Potatoes	2%	Wheat	2%	Apples		2%
	20%	FR infant	1,01	6%	Potatoes	3%	Milk: Cattle	2%	Apples		2%
	19%	FR adult	0,97	4%	Wheat	2%	Wine grapes	2%	Potatoes		4%
	17%	IT adult	0,87	8%	Wheat	2%	Potatoes	1%	Tomatoes		8%
	17%	UK vegetarian	0,83	4%	Potatoes	4%	Wheat	0,9%	Oranges		4%
	17%	PL general	0,83	10%	Potatoes	2%	Apples	0,9%	Tomatoes		
	16%	DK adult	0,79	4%	Potatoes	2%	Wheat	1%	Milk: Cattle		2%
	16%	UK adult	0,78	4%	Potatoes	3%	Wheat	1%	Wine grapes		3%
	15%	FI adult	0,77	6%	Coffee beans	4%	Potatoes	0,7%	Rye		0,7%
	7%	IE child	0,37	2%	Wheat	2%	Potatoes	0,7%	Milk: Cattle		2%

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 3.2 Flufenacet IESTI calculations - Raw and processed commodities

Acute risk assessment /children	Acute risk assessment / adults / general population	Acute risk assessment /children	Acute risk assessment / adults / general population
Details - acute risk assessment /children	Details - acute risk assessment/adults	Hide IESTI new calculations	Show IESTI new calculations

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

IESTI new calculations:
The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.
Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.

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

IESTI

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

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

IESTI new

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 new

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)		**Total number of commodities found exceeding the ARfD/ADI in children and adult diets (IESTI new 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): ---	**Results for children** No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---	**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---

IESTI

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 (wholemeal)-l	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)-bal	0,05 / 0,05	0,18
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!

IESTI

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 (wholemeal)	0,1 / 0,1	0,35
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!

IESTI new

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 (wholemeal)-	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)-	0,05 / 0,05	0,18
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!

IESTI new

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 (wholemeal)	0,1 / 0,1	0,35
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!

Expand/collapse list

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short term intake of residues of Flufenacet is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

A 3.3 Pendimethalin TMDI calculations

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Pendimethalin

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	**0,125**	ARfD (mg/kg bw):	**0,3**
Source of ADI:	**SANTE/11656**	Source of ARfD:	**SANTE/11656/2016**
Year of evaluation:	**2017**	Year of evaluation:	**2017**

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 : ---

	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)	4%	NL toddler	5,07	1,0%	Milk: Cattle	0,6%	Carrots	0,4%	Apples		
	3%	SE general	3,72	1%	Lettuces	0,5%	Carrots	0,2%	Milk: Cattle		
	3%	DE child	3,49	0,6%	Carrots	0,5%	Apples	0,3%	Milk: Cattle		
	3%	GEMS/Food G10	3,24	1%	Lettuces	0,2%	Wheat	0,2%	Carrots		
	2%	ES child	3,03	1%	Lettuces	0,2%	Milk: Cattle	0,2%	Wheat		
	2%	GEMS/Food G07	3,01	0,8%	Lettuces	0,2%	Carrots	0,2%	Wheat		
	2%	NL child	2,99	0,4%	Milk: Cattle	0,3%	Sugar beet roots	0,2%	Lettuces		
	2%	ES adult	2,98	2%	Lettuces	0,1%	Wheat	0,1%	Carrots		
	2%	DK child	2,93	0,8%	Carrots	0,5%	Lettuces	0,2%	Rye		
	2%	GEMS/Food G08	2,89	0,6%	Lettuces	0,3%	Carrots	0,2%	Wheat		
	2%	GEMS/Food G11	2,75	0,4%	Carrots	0,3%	Lettuces	0,2%	Potatoes		
	2%	UK infant	2,73	0,7%	Carrots	0,6%	Milk: Cattle	0,1%	Potatoes		
	2%	GEMS/Food G15	2,55	0,4%	Lettuces	0,2%	Carrots	0,2%	Wheat		
	2%	IE adult	2,42	0,3%	Lettuces	0,2%	Carrots	0,1%	Sweet potatoes		
	2%	GEMS/Food G06	2,41	0,3%	Lettuces	0,3%	Wheat	0,1%	Tomatoes		
	2%	FR toddler 2 3 yr	2,27	0,5%	Milk: Cattle	0,4%	Carrots	0,1%	Apples		
	2%	FR child 3 15 yr	2,26	0,4%	Milk: Cattle	0,3%	Carrots	0,2%	Wheat		
	2%	IT adult	2,25	1%	Lettuces	0,2%	Wheat	0,1%	Carrots		
	2%	IT toddler	2,15	0,9%	Lettuces	0,3%	Wheat	0,1%	Carrots		
	2%	UK toddler	2,05	0,3%	Milk: Cattle	0,3%	Carrots	0,2%	Wheat		
	2%	PT general	2,01	0,4%	Carrots	0,3%	Lettuces	0,2%	Potatoes		
	2%	DE women 14-50 yr	1,99	0,4%	Lettuces	0,2%	Milk: Cattle	0,2%	Sugar beet roots		
	1%	DE general	1,84	0,3%	Lettuces	0,2%	Milk: Cattle	0,2%	Sugar beet roots		
	1%	FR infant	1,74	0,6%	Carrots	0,3%	Milk: Cattle	0,1%	Potatoes		
	1%	RO general	1,73	0,3%	Carrots	0,2%	Wheat	0,2%	Milk: Cattle		
	1%	NL general	1,63	0,3%	Lettuces	0,1%	Milk: Cattle	0,1%	Carrots		
	1%	FI 3 yr	1,57	0,5%	Carrots	0,2%	Potatoes	0,1%	Lettuces		
	1%	FI adult	1,43	0,5%	Lettuces	0,2%	Coffee beans	0,2%	Carrots		
	1%	FI 6 yr	1,42	0,3%	Carrots	0,3%	Lettuces	0,2%	Potatoes		
	1%	UK vegetarian	1,39	0,5%	Lettuces	0,1%	Carrots	0,1%	Wheat		
	1%	DK adult	1,31	0,3%	Lettuces	0,3%	Carrots	0,1%	Milk: Cattle		
	0,9%	UK adult	1,16	0,4%	Lettuces	0,1%	Carrots	0,1%	Wheat		
	0,8%	LT adult	1,00	0,2%	Lettuces	0,1%	Potatoes	0,1%	Carrots		
	0,8%	FR adult	1,00	0,1%	Carrots	0,1%	Wine grapes	0,1%	Wheat		
	0,6%	PL general	0,80	0,2%	Carrots	0,1%	Potatoes	0,1%	Apples		
	0,4%	IE child	0,45	0,1%	Carrots	0,1%	Milk: Cattle	0,0%	Wheat		

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

A 3.4 Pendimethalin IESTI calculations - Raw and processed commodities

Acute risk assessment /children	Acute risk assessment / adults / general population	Acute risk assessment /children	Acute risk assessment / adults / general population
Details - acute risk assessment /children	Details - acute risk assessment/adults	Hide IESTI new calculations	Show IESTI new calculations

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

IESTI new calculations:
The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.
Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.

Show results for all crops

Unprocessed commodities

Results for children
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)
51%	Lettuces	4 / 4	152
15%	Carrots	0,7 / 0,7	44
8%	Parsnips	0,7 / 0,7	25
7%	Kales	0,5 / 0,5	22
7%	Salsifies	0,7 / 0,7	22
7%	Swedes/rutabagas	0,4 / 0,4	21
5%	Chinese cabbages/pe-tsai	0,5 / 0,5	16
5%	Kohlrabies	0,3 / 0,3	16
5%	Turnips	0,4 / 0,4	14
4%	Celeriacs/turnip rooted	0,2 / 0,2	11
3%	Potatoes	0,05 / 0,05	7,7
3%	Melons	0,05 / 0,05	7,6
2%	Pears	0,05 / 0,05	6,9
2%	Oranges	0,05 / 0,05	6,6
2%	Watermelons	0,05 / 0,05	6,1

Expand/collapse list

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

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)
16%	Lettuces	4 / 4	49
5%	Carrots	0,7 / 0,7	14
5%	Swedes/rutabagas	0,4 / 0,4	14
4%	Chinese cabbages/pe-tsai	0,5 / 0,5	13
3%	Parsnips	0,7 / 0,7	9,8
3%	Kales	0,5 / 0,5	9,6
2%	Salsifies	0,7 / 0,7	7,5
2%	Parsley roots/Hamburg roots	0,7 / 0,7	7,2
2%	Horseradishes	0,7 / 0,7	5,1
1%	Turnips	0,4 / 0,4	4,5
1%	Kohlrabies	0,3 / 0,3	4,2
0,8%	Parsley	2 / 2	2,4
0,8%	Celeriacs/turnip rooted	0,2 / 0,2	2,4
0,7%	Head cabbages	0,05 / 0,05	2,1
0,7%	Watermelons	0,05 / 0,05	2,0

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

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
30%	Lettuces	4 / 4	91
6%	Carrots	0,7 / 0,7	19
4%	Kales	0,5 / 0,5	13
4%	Swedes/rutabagas	0,4 / 0,4	12
4%	Salsifies	0,7 / 0,7	12
4%	Parsnips	0,7 / 0,7	11
3%	Chinese cabbages/pe-tsai	0,5 / 0,5	9,6
3%	Kohlrabies	0,3 / 0,3	9,4
2%	Celeriacs/turnip rooted	0,2 / 0,2	6,6
2%	Turnips	0,4 / 0,4	6,2
2%	Melons	0,05 / 0,05	4,6
1%	Watermelons	0,05 / 0,05	3,7
1%	Oranges	0,05 / 0,05	3,3
1%	Potatoes	0,05 / 0,05	3,3
1%	Apples	0,05 / 0,05	3,1

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

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

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
10%	Lettuces	4 / 4	29
3%	Carrots	0,7 / 0,7	8,3
3%	Swedes/rutabagas	0,4 / 0,4	8,2
3%	Chinese cabbages/pe-tsai	0,5 / 0,5	7,6
2%	Parsnips	0,7 / 0,7	5,9
2%	Kales	0,5 / 0,5	5,8
1%	Salsifies	0,7 / 0,7	3,4
1%	Parsley roots/Hamburg roots parsley	0,7 / 0,7	3,1
0,8%	Kohlrabies	0,3 / 0,3	2,5
0,8%	Parsley	2 / 2	2,4
0,8%	Oranges	0,05 / 0,05	2,3
0,7%	Horseradishes	0,7 / 0,7	2,2
0,7%	Turnips	0,4 / 0,4	2,2
0,7%	Plums	0,05 / 0,05	2,0
0,6%	Pears	0,05 / 0,05	1,8

Processed commodities

Results for children
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)
12%	Parsnips / boiled	0,7 / 0,7	35
8%	Carrots / juice	0,7 / 0,7	25
7%	Turnips / boiled	0,4 / 0,4	20
6%	Salsifies / boiled	0,7 / 0,7	18
5%	Kales / boiled	0,5 / 0,5	14
2%	Sugar beets (root) / sugar	0,05 / 0,6	5,5
2%	Potatoes / fried	0,05 / 0,05	4,7
2%	Florence fennels / boiled	0,1 / 0,1	4,5
1%	Pumpkins / boiled	0,05 / 0,05	4,4
1%	Witloofs / boiled	0,05 / 0,05	4,4
1%	Broccoli / boiled	0,05 / 0,05	3,9
1%	Cauliflowers / boiled	0,05 / 0,05	3,5
1%	Escaroles/broad-leaved endi	0,05 / 0,05	3,3
1,0%	Potatoes / dried (flakes)	0,05 / 0,23	3,0
1,0%	Celeriacs / juice	0,2 / 0,2	2,9

Expand/collapse list

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)
5%	Parsnips / boiled	0,7 / 0,7	15
3%	Turnips / boiled	0,4 / 0,4	7,6
2%	Kohlrabies / boiled	0,3 / 0,3	6,4
2%	Salsifies / boiled	0,7 / 0,7	5,8
2%	Carrots / canned	0,7 / 0,7	5,7
1%	Celeriacs / boiled	0,2 / 0,2	3,6
1%	Celeries / boiled	0,1 / 0,1	3,4
0,9%	Pumpkins / boiled	0,05 / 0,05	2,8
0,7%	Sugar beets (root) / sugar	0,05 / 0,6	2,2
0,7%	Cauliflowers / boiled	0,05 / 0,05	2,1
0,6%	Beetroots / boiled	0,05 / 0,05	1,9
0,6%	Florence fennels / boiled	0,1 / 0,1	1,9
0,6%	Apples / juice	0,05 / 0,05	1,7
0,4%	Broccoli / boiled	0,05 / 0,05	1,2
0,4%	Courgettes / boiled	0,05 / 0,05	1,1

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

IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
8%	Carrots / juice	0,7 / 0,7	25
5%	Salsifies / boiled	0,7 / 0,7	15
5%	Parsnips / boiled	0,7 / 0,7	15
3%	Turnips / boiled	0,4 / 0,4	8,7
3%	Kales / boiled	0,5 / 0,5	8,3
2%	Sugar beets (root) / sugar	0,05 / 0,6	5,5
1,0%	Potatoes / dried (flakes)	0,05 / 0,23	3,0
1,0%	Celeriacs / juice	0,2 / 0,2	2,9
0,9%	Florence fennels / boiled	0,1 / 0,1	2,7
0,9%	Apples / juice	0,05 / 0,05	2,7
0,9%	Pumpkins / boiled	0,05 / 0,05	2,7
0,9%	Oranges / juice	0,05 / 0,05	2,6
0,8%	Broccoli / boiled	0,05 / 0,05	2,4
0,8%	Witloofs / boiled	0,05 / 0,05	2,4
0,7%	Potatoes / fried	0,05 / 0,05	2,2

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

IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
2%	Parsnips / boiled	0,7 / 0,7	6,4
2%	Salsifies / boiled	0,7 / 0,7	6,4
2%	Carrots / canned	0,7 / 0,7	5,7
1%	Turnips / boiled	0,4 / 0,4	3,6
0,9%	Kohlrabies / boiled	0,3 / 0,3	2,7
0,7%	Sugar beets (root) / sugar	0,05 / 0,6	2,2
0,7%	Celeriacs / boiled	0,2 / 0,2	2,2
0,7%	Celeries / boiled	0,1 / 0,1	2,0
0,7%	Pumpkins / boiled	0,05 / 0,05	2,0
0,6%	Apples / juice	0,05 / 0,05	1,7
0,4%	Cauliflowers / boiled	0,05 / 0,05	1,2
0,4%	Florence fennels / boiled	0,1 / 0,1	1,2
0,4%	Witloofs / boiled	0,05 / 0,05	1,1
0,4%	Beans / canned	0,15 / 0,15	1,1
0,3%	Wine grapes / juice	0,05 / 0,05	1,0

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short term intake of residues of Pendimethalin is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

A 3.5

Appendix 4 Additional information provided by the applicant

No additional information was provided by the applicant.