

REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: GLOB1912H

Product name: **Jura Max**

Chemical active substances:

Prosulfocarb, 667 g/L

Diflufenican, 14 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Globachem NV

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Version history

When	What
November 2021	Initial submission by the applicant for approval of new product.
June 2022	Initial RR
December 2022	RR finalization after comments by zRMS

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7 Metabolism and residue data (KCA section 6)

7.1 Summary and zRMS Conclusion

The applicant's dRR text was not rewritten. All zRMS comments/corrections within the report are on grey background.

7.1.1 Critical GAP(s) and overall conclusion

The critical GAPs with respect to consumer intake and risk assessment for the preparation Jura Max are presented in Table 7.1-1. They have been selected from the individual GAPs in the CEU. For prosulfocarb based on Appendix II of SANCO/2824/07 rev3, for diflufenican on Appendix II of SANCO/3782/08 – rev. 1. The seasonal maximum total rates for the proposed in the present authorization request GAP in cereals are lowered as follows: for prosulfocarb from ~4 kg /ha to ~2 kg /ha, for diflufenican from 120 g /ha to 42 g /ha. Also, in potatoes for prosulfocarb from ~4 kg /ha to ~2 kg /ha. Both actives are not EU supported in sunflower and diflufenican also in potato.

However, in EFSA Journal 2011;9(8):2346 sunflower seed GAP is reported for prosulfocarb (again the intended rate is lowered from ~4 kg /ha to ~2 kg /ha).

A list of all intended uses within the CEU is given in Part B, Section 0.

Overall conclusion

The data available are considered sufficient for risk assessment. An exceedance of the current MRLs for prosulfocarb and diflufenican as laid down in Reg. (EU) 396/2005 is not expected:

Code number	products to which the MRLs apply (a)	Prosulfocarb Reg. (EU) No 777/2013	Diflufenican Reg. (EU) 2017/623
0500010	Barley	0.01*	0,02
0500070	Rye	0.01*	0,02
0500090	Wheat	0.01*	0,02
0211000	Potatos	0.01*	0.01*
0401050	Sunflower seeds	0.02*	0.01*

zRMS agrees with the applicant that no exceedance of the default MRL in honey is expected based on the intended uses.

All analytical methods are active substance data and were provided in the EU review of prosulfocarb and diflufenican. The residue definition for diflufenican (the parent, EFSA 2007) can be maintain for the purpose of the approval request (see the relevant metabolism paragraph of the present section).

No waiting period before planting succeeding crops is deemed necessary.

The chronic and the short-term intakes of prosulfocarb and diflufenican, residues are unlikely to present a public health concern. As far as consumer health protection is concerned, zRMS agrees with the authorization of the intended uses.

According to available data, no specific mitigation measures should apply. However, although for prosulfocarb the trigger DT90 value was not exceeded, the risk mitigation measures issue especially in case of crop failure should be considered individually on the level of each cMS (DE comment, EFSA Journal 2011;9(8):2346).

Data gaps

Noticed data gaps are: none

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

1	2	3	4	5	6	7		8				9			10	11
GAP number (see part B.0)*	Crop and/or situation **	Zone	Product code	F, Fn, Fpn G, Gn, Gpn or I***	Pests or Group of pests controlled	Formulation		Application				Application rate per treatment			PHI (days)	Conclusion
						Type	Conc. of as	method kind	growth stage & season	number min max	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max		
1	Winter wheat (TRZAW), Winter barley (HORVW), Winter rye (SECCW), Triticale (TTLWI), Winter durum wheat (TRZDW), Spelt (TRZSP)	Central	GLOB1912H	F	Annual broad leaved weeds (BBBAN) & grasses (GGGAN)	EC	Prosulfocarb: 667 g/L Diflufenican: 14 g/L	Downward spraying	Pre-emergence (BBCH 0-09)	1	-	Prosulfocarb: 0.711-1.33 Diflufenican: 0.015-0.028	160-300	Prosulfocarb: 2.134 Diflufenican: 0.0448	NR	
2	Winter wheat (TRZAW), Winter barley (HORVW), Winter rye (SECCW), Triticale (TTLWI), Winter durum wheat (TRZDW), Spelt (TRZSP)	Central	GLOB1912H	F	Annual broad leaved weeds (BBBAN) & grasses (GGGAN)	EC	Prosulfocarb: 667 g/L Diflufenican: 14 g/L	Downward spraying	Pre-emergence (BBCH 0-09)	1	-	Prosulfocarb: 0.667-1.25 Diflufenican: 0.014-0.026	160-300	Prosulfocarb: 2.001 Diflufenican: 0.042	NR	
3	Winter wheat (TRZAW), Winter barley (HORVW), Winter rye	Central	GLOB1912H	F	Annual broad leaved weeds (BBBAN) & grasses (GGGAN)	EC	Prosulfocarb: 667 g/L Diflufenican: 14 g/L	Downward spraying	BBCH10-21	1	-	Prosulfocarb: 0.711-1.33 Diflufenican: 0.015-0.028	160-300	Prosulfocarb: 2.134 Diflufenican: 0.0448	NR	

	(SECCW), Triticale (TTLWI), Winter durum wheat (TRZDW), Spelt (TRZSP)															
4	Winter wheat (TRZAW), Winter barley (HORVW), Winter rye (SECCW), Triticale (TTLWI), Winter durum wheat (TRZDW), Spelt (TRZSP)	Central	GLOB1912H	F	Annual broad leaved weeds (BBAN) & grasses (GGAN)	EC	Prosul- focarb: 667 g/L Diflufenican: 14 g/L	Down- ward spraying	BBCH10- 21	1	-	Prosul- focarb: 0.667-1.25 Diflufenican: 0.014-0.026	160-300	Prosulfocarb: 2.001 Diflufenican: 0.042	NR	
5	Potato (SOLTU)	Central	GLOB1912H	F	Annual broad leaved weeds (BBAN) & grasses (GGAN)	EC	Prosul- focarb: 667 g/L Diflufenican: 14 g/L	Down- ward spraying	Pre-emer- gence (BBCH 0- 09)	1	-	Prosul- focarb: 0.711-1.33 Diflufenican: 0.015-0.028	160-300	Prosulfocarb: 2.134 Diflufenican: 0.0448	NR	
6	Potato (SOLTU)	Central	GLOB1912H	F	Annual broad leaved weeds (BBAN) & grasses (GGAN)	EC	Prosul- focarb: 667 g/L Diflufenican: 14 g/L	Down- ward spraying	Pre-emer- gence (BBCH 0- 09)	1	-	Prosul- focarb: 0.667-1.25 Diflufenican: 0.014-0.026	160-300	Prosulfocarb: 2.001 Diflufenican: 0.042	NR	
7	Sunflower (HELAN)	Central	GLOB1912H	F	Annual broad leaved weeds (BBAN) & grasses (GGAN)	EC	Prosul- focarb: 667 g/L Diflufenican: 14 g/L	Down- ward spraying	Pre-emer- gence (BBCH 0- 09)	1	-	Prosul- focarb: 0.711-1.33 Diflufenican: 0.015-0.028	160-300	Prosulfocarb: 2.134 Diflufenican: 0.0448	NR	
8	Sunflower (HELAN)	Central	GLOB1912H	F	Annual broad leaved weeds (BBAN) & grasses (GGAN)	EC	Prosul- focarb: 667 g/L Diflufenican: 14 g/L	Down- ward spraying	Pre-emer- gence (BBCH 0- 09)	1	-	Prosul- focarb: 0.667-1.25 Diflufenican: 0.014-0.026	160-300	Prosulfocarb: 2.001 Diflufenican: 0.042	NR	

* 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 GLOB1912H is composed of the active substances prosulfocarb and diflufenican.

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

Reference value	Source	Year	Value	Study relied upon	Safety factor
Prosulfocarb					
ADI	EFSA	2007	0.005 mg/kg bw/d	2-year rat oral toxicity, supported by multi-generation study	100
ARfD	EFSA	2007	0.1 mg/kg	Rat, developmental toxicity	100
Diflufenican					
ADI	EFSA	2007	0.2 mg/kg bw/d	2-year rat and 13-week rat	100
ARfD	EFSA	2007	-	Not necessary	

7.1.2.1 Summary for prosulfocarb

Table 7.1-3: Summary for prosulfocarb

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+2 1-4	Winter cereals	Yes	Yes (36)	N/A	Yes	Yes	No	No
3 5,6	Potato	Yes	Yes (16)	N/A	Yes	Yes	No	No
4 7,8	Sun-flower	Yes	Yes (14)	N/A	Yes	Yes	No	No

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

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

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

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

7.1.2.2 Summary for diflufenican

Table 7.1-4: Summary for diflufenican

Use- No.*	Crop	Plant metab- olism cov- ered?	Sufficient residue tri- als?	PHI suffi- ciently sup- ported?	Sample storage covered by stabil- ity data?	MRL com- pliance	Chronic risk for consumers identified?	Acute risk for con- sumers identified?
1+2 1-4	Winter cereals	Yes	Yes (17)	N/A	Yes	Yes	No	No
3 5,6	Potato	Yes	Yes (8)	N/A	Yes	Yes	No	No
4 7,8	Sun- flower	Yes	Yes (9)	N/A	Yes	Yes	No	No

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

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

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.

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

7.1.2.3 Summary for GLOB1912H

Table 7.1-5: Information on GLOB1912H (KCA 6.8)

Crop	PHI for GLOB1912H proposed by applicant	PHI/ Withholding period* sufficiently supported for		PHI for GLOB1912H proposed by zRMS	zRMS Comments (if different PHI pro- posed)
		Prosulfocarb	Diflufenican		
Cereals	NR	NR	NR	n/a	
Potato	NR	NR	NR		
Sun- flower	NR	NR	NR		

NR: not relevant

* Purpose of withholding period to be specified

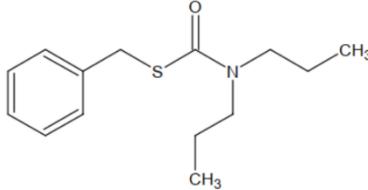
** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

Assessment

7.2 Prosulfocarb

General data on prosulfocarb are summarized in the table below (last updated 2021/04/19)

Table 7.2-1: General information on prosulfocarb

Active substance (ISO Common Name)	Prosulfocarb
IUPAC	S-benzyl dipropyl(thiocarbamate)
Chemical structure	
Molecular formula	C ₁₄ H ₂₁ NOS
Molar mass	251.4
Chemical group	Thiocarbamate
Mode of action (if available)	Inhibition of lipid synthesis in the meristem
Systemic	Yes
Company (ies)	Syngenta*
Rapporteur Member State (RMS)	Sweden
Approval status	Approved Reg. (EU) 2022/1480 Date of 01/11/2009 and reference to decision COMMISSION DIRECTIVE 2007/76/EC REGULATION (EU) No 2019/1589 REGULATION (EU) No 540/2011.
Restriction	Restricted to use as herbicide
Review Report	SANCO/2824/07 – rev. 3 10/09/2007
Current MRL regulation	Regulation (EU) No 777/2013
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 2007
EFSA Journal: conclusion on article 12	Yes, EFSA 2011
Current MRL applications on intended uses	-

* 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

Several storage stability studies are available in the DAR of prosulfocarb (Sweden, 2006). A new stability study on sunflower seeds has been submitted by the applicant in the framework of this application. Results are summarized in the Table below. The detailed assessment of these studies is presented in Appendix 2.

Table 7.2-2: Summary of stability data achieved at $\leq -18^{\circ}\text{C}$ (unless stated otherwise)

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products			
Pea	High water content	18 months	Sweden, 2006
Wheat forage		25 months	Sweden, 2006
Dry bean	High protein content	18 months	Sweden, 2006
Potato	High starch content	18 months	Sweden, 2006
Wheat grain		25 months	Sweden, 2006
Wheat straw	-	25 months	Sweden, 2006
New data			
Plant products			
Sunflower seeds	High oil content	180 days	Jonchère F., 2010a

Conclusion on stability of residues during storage

Storage stability studies of prosulfocarb in this section cover the requested uses for GLOB1912H.

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

Procedural recoveries obtained during residue analysis demonstrate the stability of residues of prosulfocarb in sample extracts and fully support the residue data presented in this submission.

7.2.2 Nature of residues in plants, livestock and processed commodities

7.2.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

No new data submitted in the framework of this application.

Table 7.2-3: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Root and tuber vegetables	Potatoes	[¹⁴ C]phenyl	Soil spraying, F	3.42	1	Tubers: 105	-	Sweden, 2006
Pulses and oilseeds	Peas		Soil spraying, G	4.05	1	Shelled peas: maturity	-	Sweden, 2006
Cereals	Winter wheat		Soil spraying, F	3.64	1	Grain, straw: 283	-	Sweden, 2006
	Winter barley			4.00	1	Immature plant: 7, 14, 161 Grain, straw: 237	-	Sweden, 2007

Summary of plant metabolism studies reported in the EU

Metabolism studies conducted with crops representative of three different crop groups (cereal/grass: winter barley; spring barley and wheat; root vegetables: potato and carrot; pulses and oilseed: peas) have provided a detailed understanding of the metabolism of prosulfocarb in food and feed commodities. The metabolic pathways in the studies are similar and consequently the available crop metabolism studies fully support the current proposed uses of **prosulfocarb** on crops. The metabolism of ¹⁴C-prosulfocarb in plants is extensive.

Levels of organosoluble radioactivity are low in potatoes and contain a multi-component residue with only benzoic acid (3.1% TRR in potato tubers) identified as a prosulfocarb related metabolite. The nature of the residue is dominated by natural incorporation of the radiolabelled carbon. In potatoes, incorporation is associated mainly with starch, with over 70% of the radioactive residue present in this fraction. A similar pattern of metabolism is assumed to occur in wheat grain and straw where high levels (>50%) of radioactive residue are present in aqueous soluble and bound fractions after acid hydrolysis.

The metabolism of **prosulfocarb** following application to winter barley is complex and extensive. No prosulfocarb or related metabolites were detected in mature grain or straw. All observed chromatographic peaks in the grain and straw were <10% TRR and <0.05 mg/kg. The winter barley study confirms the rapid and extensive metabolism of parent to natural products resulting in neither prosulfocarb nor structurally related metabolites being present in detectable quantities in mature crop commodities. Characterisation of the residues in immature barley foliage has allowed the identification of a number of prosulfocarb plant metabolites. In peas, incorporation is associated with proteins and carbohydrates, which account for *ca* 78% and *ca* 17% of the radioactive residue, respectively. The incorporation of radioactivity into the plant structure is assumed to be through assimilation of ¹⁴CO₂ produced from the extensive mineralisation of prosulfocarb in the soil. Soil studies have shown that up to 43% of prosulfocarb is mineralised within two months of application.

Conclusion on metabolism in primary crops

The data reported above are sufficient to support the intended uses of GLOB1912H.

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

The metabolism of prosulfocarb in rotational crops was not investigated in the framework of the peer review because the DT₉₀ of prosulfocarb and its relevant soil metabolites were below the trigger of 100 days.

Therefore, no residues are expected in rotational crops and no further study is deemed necessary.

Conclusion on metabolism in rotational crops

The data reported above are sufficient to support the intended uses of GLOB1912H.

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

As residues of prosulfocarb exceeding 0.1 mg/kg are not expected in treated cereals, the contribution of this crop to the TMDI is < 10% and the estimated daily intake is < 10% of the ARfD, investigation of the magnitude of residues in processed commodities is not needed.

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	Foliar treatment (early post-emergence application): cereals (wheat, barley) Soil treatment: root vegetables (potato) and pulses (pea)
Rotational crops covered	Not required given the low to moderate persistence of prosulfocarb in soil
Metabolism in rotational crops similar to metabolism in primary crops?	Assessment not required
Processed commodities	Not required as no residues are present in raw commodities
Residue pattern in processed commodities similar to pattern in raw commodities?	Assessment not required*
Plant residue definition for monitoring	Prosulfocarb (Regulation (EU) No 777/2013)**
Plant residue definition for risk assessment	Prosulfocarb (EFSA 2007)***
Conversion factor from enforcement to RA	None (EFSA 2007)

* If residue pattern in processed commodities is not similar to that in raw commodities

** A more recent proposal by EFSA may be provided as additional information (EFSA RO XXXX).

*** If no EFSA proposal is available, a proposal should be made by the applicant/zRMS.

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

Available data

No new data submitted in the framework of this application.

Summary of animal metabolism studies reported in the EU

An animal metabolism study is not required due to the extremely low exposure of livestock.

Conclusion on metabolism in livestock

The data reported above are sufficient to support the intended uses of GLOB1912H.

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

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

	Endpoints
Animals covered	No required due to the extremely low exposure of livestock.
Time needed to reach a plateau concentration	Assessment not required.
Animal residue definition for monitoring	Assessment not required.
Animal residue definition for risk assessment	Assessment not required.
Conversion factor	Assessment not required.
Metabolism in rat and ruminant similar	Assessment not required.
Fat soluble residue	Assessment not required.

* A more recent proposal by EFSA may be provided as additional information (EFSA RO XXXX)

** If no EFSA proposal is available, a proposal should be made by the applicant/zRMS.

*** If metabolism in rat and ruminant are not similar

7.2.3 Magnitude of residues in plants (KCA 6.3)

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

Residue trials on cereals were already evaluated in the context of the peer review process. All trials compliant with the intended GAP as well as trials with a GAP that is worst case compared to the intended GAP have been selected from the DAR of prosulfocarb (Sweden, 2006).

Residue trials on potato were already evaluated in the context of the peer review process. Two additional trials have been conducted by the applicant.

New studies on the magnitude of residues in sunflower have been submitted by the applicant. Four additional trials in S-EU were conducted by the applicant in order to confirm the < LOQ residue situation.

Table 7.2-6: Summary of EU reported and new data supporting the intended uses of GLOB1912H 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 grain (winter wheat, winter barley, winter rye)	EFSA, 2007 Sweden, 2006	N-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 3.0-8.0 kg as/ha, BBCH 11-25, PHI 96-311 d, outdoor 32 x < 0.01 mg/kg	N/A				
	Sweden, 2006	S-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 3.375-6.75 kg as/ha, BBCH 12-13, PHI 132-211 d, outdoor 4 x < 0.01 mg/kg					
	Overall supporting data for cGAP	N-EU + S-EU	36 x < 0.01 mg/kg	0.01	0.01	0.01	0.01	Yes
Cereal straw (winter wheat, winter barley, winter rye)	EFSA, 2007 Sweden, 2006	N-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 3.0-8.0 kg as/ha, BBCH 11-25, PHI 96-302 d, outdoor 17 x < 0.01 mg/kg	N/A				
	Sweden, 2006	S-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 3.375-6.75 kg as/ha, BBCH 12-13, PHI 132-211 d, outdoor					

			4 x < 0.01 mg/kg					
	Overall supporting data for cGAP	N-EU + S-EU	21 x < 0.01 mg/kg	0.01	0.01	-	-	-
Potato	EFSA, 2007 Sweden, 2006	N-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 3.6-4.0 kg as/ha, BBCH 00-11, outdoor 10 x < 0.01 mg/kg	N/A				
	EFSA, 2007 Sweden, 2006	S-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 4.0-4.8 kg as/ha, BBCH 00-10 and BBCH 39-40 (1 trial) , outdoor 4 x < 0.01 mg/kg					
	New	S-EU	GAP: 1 x 4.0 kg a.s./ha; BBCH 00, outdoor 2 x < 0.01 mg/kg					
	Overall supporting data for cGAP	N-EU + S-EU	16 x < 0.01 mg/kg	0.01	0.01	0.01	0.01	Yes
Sunflower seeds	New	N-EU	GAP: 1 x 4.0 kg a.s./ha; BBCH 00-03, outdoor 8 x < 0.01 mg/kg	N/A				
	EFSA, 2011	S-EU	GAP: 1 x 4.0 kg a.s./ha; BBCH 00-09, outdoor 2 x < 0.01 mg/kg					
	New	S-EU	GAP: 1 x 2.8681 kg a.s./ha; BBCH 00-08, outdoor 4 x < 0.01 mg/kg					
	Overall supporting data for cGAP	N-EU + S-EU	14 x < 0.01 mg/kg	0.01	0.01	0.01	0.02	Yes

* Source of EU MRL: Reg. (EU) No 777/2013

7.2.3.2 Effects on the residue level in pollen and bee products

Prosulfocarb is a ~~non~~ systemic herbicide applied in winter cereals, potatoes and sunflower at early growth stages. Winter cereals and potatoes are considered a non-melliferous crop, while sunflower is considered a melliferous crop. In all three crops, the application of GLOB1912H is before the flowering stage. Therefore, only the exposure of non-target plants (in-field weeds and adjacent plants) is relevant.

Referring to a recent publication (Maynard *et al.* (2015)¹), it was shown that less than 2% of all weeds recorded in arable crops (wheat, oilseed rape, sugarbeet, sunflower, potatoes, maize, peas and beans) are at flowering growth stage when herbicides are applied. It can therefore be considered that the exposure of bees to in-field flowering weeds resulting shortly after application of an herbicide is not a realistic scenario as flowering weeds are not present in the field in significant quantities in realistic conditions. Similarly, in arable crops, the weeds present during application of the herbicide and which are not yet at the flowering growth stage (< BBCH 60) will not survive cultural practices aimed at eliminating them (i.e. herbicidal treatments themselves) so that exposure will also not occur at significant level.

Therefore, only off field flowering weeds and plants should still be considered, which will only be exposed to a drift rate (and not to the full rate).

It was shown in the plant metabolism studies that the parent prosulfocarb is rapidly and extensively metabolized. Since the residue definition for food of plant origin only includes prosulfocarb, no exceedance of the default MRL in honey is to expected

Moreover, considering that for GLOB1912H only autumn to winter use is intended in winter cereals, the application timing will not coincide with the flowering period of weeds and non-target plants.

The application in sunflower and potatoes will be made between February and early May, so it also does not coincided for the largest part with the flowering period of non-target plants.

In conclusion, no exceedance of the default MRL in honey is expected based on the intended uses.

7.2.3.3 Conclusion on the magnitude of residues in plants

Cereals are a major crop in both northern and southern Europe, so normally 8 trials are required in each region. However, as the primary crop metabolism study on cereals showed that the residues of prosulfocarb were not detected in grain or straw, only 3 trials per region are needed.

According to the EU guideline SANTE/2019/12752, extrapolation from any one of the following barley / oats / rye / triticale / wheats to the remaining four crops is possible as long as the last application is done before consumable parts of the crops have started to form (BBCH 51). Considering the intended uses, the extrapolation is possible.

Potato is a major crop in both northern and southern Europe, so normally 8 trials are required in each region. However, as residues were all below the LOQ in the tubers, only 4 trials per region are needed.

Sunflower is a major crop in both northern and southern Europe, so normally 8 trials are required in each region. However, as residues were all below the LOQ in seeds, only 4 trials per region are needed. Due to the < LOQ residue situation in all trials on sunflower, it is considered acceptable to extrapolate the results of northern Europe also to southern Europe in order to obtain a sufficient number of trials in each zone. Moreover, four additional trials in S-EU are performed by the applicant in order to confirm the < LOQ

¹ Maynard S.K., Albuquerque R., Weber C., von Mérey G., Geiger M.F., Becker R., Keppler J., Masche J., Brougham K, Coulson M., 1.8 Weeds in the treated field – a realistic scenario for pollinator risk assessment? Hazards of pesticides to bees – 12th International Symposium of the ICP-PR Bee Protection Group, Ghent (Belgium, September 15-17, 2014, Julius-Kühn-Archiv, 450, 2015.

residue situation.

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

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

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

The input values for the dietary burden calculation are summarised in the following table. Considering the available residue trials and the crop metabolism studies (EFSA Journal 2011;9(8):2346), as well as the application early in the growing season, no significant residues are anticipated in cereals, potato and sunflower seeds. Therefore, no default processing factor was applied to processed products of these commodities.

Table 7.2-7: 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
Risk assessment residue definition: Prosulfocarb				
Cereal grain	0.01	Median residue (EFSA, 2011)	0.01	Median residue (EFSA, 2011)
Cereal straw	0.01	Median residue (EFSA, 2011)	0.10	Highest residue (EFSA, 2011)
Peas (dry)	0.01	Median residue (EFSA, 2011)	0.01	Median residue (EFSA, 2011)
Beans (dry)	0.01	Median residue (EFSA, 2011)	0.01	Median residue (EFSA, 2011)
Potatoes	0.01	Median residue (EFSA, 2011)	0.01	Highest residue (EFSA, 2011)
Brewer's grain	0.01	Median residue (EFSA, 2011)	-	-
Distiller's grain	0.01	Median residue (EFSA, 2011)	-	-
Potato process waste	0.01	Median residue (EFSA, 2011)	-	-
Potato dried pulp	0.01	Median residue (EFSA, 2011)	-	-
Sunflower meal	0.01	Median residue (EFSA, 2011)	-	-
Wheat gluten meal	0.01	Median residue (EFSA, 2011)	-	-

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Wheat milled by-products	0.01	Median residue (EFSA, 2011)	-	-

Table 7.2-8: Results of the dietary burden calculation

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Risk assessment residue definition: prosulfocarb					
Beef cattle*	0.0012	0.002	Barley (straw)	0.08	N
Dairy cattle*	0.0017	0.003	Barley (straw)	0.07	N
Ram/ewe	0.0017	0.003	Barley (straw)	0.1	N
Lamb	0.0014	0.004	Barley (straw)	0.09	N
Breeding swine	0.001	0.001	Potato (process waste)	0.05	N
Finishing swine*	0.001	0.001	Potato (culls)	0.03	N
Broiler poultry	0.001	0.001	Potato (culls)	0.02	N
Layer poultry*	0.001	0.002	Wheat (straw)	0.03	N
Turkey	0.001	0.001	Potato (culls)	0.02	N

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

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

The calculated dietary burden is not exceeding the trigger. Further investigations of residues is therefore not required.

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

As residues of prosulfocarb exceeding 0.1 mg/kg are not expected in treated cereals, the contribution of this crop to the TMDI is < 10% and the estimated daily intake is < 10% of the ARfD, investigation of the magnitude of residues in processed commodities is not needed.

7.2.6 Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation.

Considering available data dealing with nature of residues (see 7.2.2.2), no study dealing with magnitude of residues in succeeding crops is needed.

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

Five decline curve residue studies were performed to determine the degradation rate of prosulfocarb residue in cereal plants. The purpose of these studies was to refine the risk assessment to mammals. These studies are summarized in Appendix 2.

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 7.2-9: Input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: Prosulfocarb				
All commodities	MRL	Reg. (EU) No 777/2013	MRL	Reg. (EU) No 777/2013

7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.2-10: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo	47% (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo	No IEDI calculations were performed as the TMDI calculations using the MRLs were already acceptable. No refinement of the chronic risk assessment is required.
IESTI (% ARfD) according to EFSA PRIMo*	Carrots: 63% (based on UK infant) Celeries: 56% (based on BE toddlers) 51% for Celeries/boiled Carrots/juice: 36% (based on DE child)
NTMDI (% ADI) **	-
NEDI (% ADI)**	-
NESTI (% ARfD) **	-

* include raw and processed commodities if both values are required for PRIMo

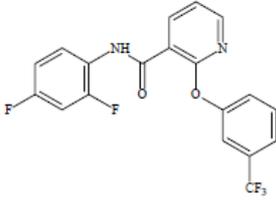
** if national model is available

The proposed uses of prosulfocarb in the formulation GLOB1912H do not represent unacceptable acute and chronic risks for the consumer.

7.3 Diflufenican

General data on diflufenican are summarized in the table below (last updated 2021/04/19)

Table 7.3-1: General information on diflufenican

Active substance (ISO Common Name)	Diflufenican
IUPAC	2',4'-difluoro-2-(α,α,α -trifluoro-mtolyloxy)nicotinamide
Chemical structure	
Molecular formula	C ₁₉ H ₁₁ F ₅ N ₂ O ₂
Molar mass	394 g/mol
Chemical group	Carboxamide
Mode of action (if available)	Inhibitor of phytoene dehydrogenase, a key enzyme of carotenoid biosynthesis
Systemic	Yes
Company (ies)	Bayer CropScience*
Rapporteur Member State (RMS)	UK
Approval status	Approved Reg. (EU) 2022/1480 <small>Date of (01/01/2009) and reference to decision (COMMISSION DIRECTIVE 2008/66 – REGULATION (EU) No 2019/1589 and REGULATION (EU) No 540/2011).</small>
Restriction (e.g. is restricted to use as "...")	Restricted to use as herbicide
Review Report	SANCO/3782/08 – rev. 1 14/03/2008
Current MRL regulation	Regulation (EU) 2017/623
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes
EFSA Journal : Conclusion on the peer review	Yes, EFSA, 2007**
EFSA Journal: conclusion on article 12	Yes, EFSA, 2013**
Current MRL applications on intended uses	-

* 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

A storage stability study on wheat is available in the DAR of diflufenican (UK, 2005).

A new stability study on oilseed rape has been submitted by the applicant in the framework of this application. Results are summarized in the Table below. The detailed assessment of this study is presented in Appendix 2.

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

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products			
Wheat grain Wheat straw	High starch content	24 months	UK, 2005
Wheat grain	High starch content	24 months	UK, 2005
Wheat forage Wheat grain Wheat straw	High water content High starch content	24 months	UK, 2005
New data			
Plant products			
Oilseed rape	High oil content	540 days	Jonchère F., 2012

Conclusion on stability of residues during storage

Storage stability studies of diflufenican in this section cover the requested use for GLOB1912H.

7.3.1.2 Stability of residues in sample extracts (KCA 6.1)

Procedural recoveries obtained during residue analysis demonstrate the stability of residues of diflufenican in sample extracts and fully support the residue data presented in this submission.

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

Metabolism studies on wheat and olives are available in the DAR of diflufenican (UK, 2005). New metabolism studies on potatoes and oilseed rape 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 7.3-3: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Fruits and fruiting vegetable	Olives	Pyridyl, aniline and phenyl ring	Soil spraying, F	0.75	1	Ground harvest: 7, 21, 35 DAT Tree	-	EFSA, 2012

						harvest: 7, 35 DAT		
Cereals	Wheat	Pyridyl, aniline and phenyl ring	Soil (pre- emer- gence) and foliar (BBCH 13-14) spraying, F	0.19 or 0.40 or 0.94	1	Forage: at BBCH 41- 65 Grain, straw: at BBCH 92 (maturity)	-	UK, 2005
	Wheat	Pyridyl, aniline and phenyl ring	Foliar spraying (BBCH 29), F	0.38	1	Forage: 6 DAT (BBCH 45) Grain, straw: 58 DAT (at maturity)	-	France, 2013
New data								
Pulses and oilseeds	Oilseed rape	Trifluoro- methyl phenyl, pyridine, difluoro- phenyl	Foliar spraying (BBCH 16), F	0.080	1	Whole plant: 30 DAT Forage: at BBCH 61- 69 Seeds: at maturity	-	Quistad G.B., Bronner K. and Ko- vatchev A., 2010
Root and tuber vegetables	Potato	Trifluoro- methyl phenyl, pyridine, difluoro- phenyl	Soil spray- ing (BBCH 09), F	0.1	1	As soon as sufficient material available BBCH 12- 14: foliage Immature: before BBCH 40: foliage Early har- vest BBCH 43-46: foli- age, tuber Main har- vest BBCH 47-49: foli- age, tuber	-	Corden M., 2014

Summary of plant metabolism studies reported in the EU

Following an application of 0.19 kg a.s./ha, the TRR in grain and straw represented less than 0.01 mg eq./kg at harvest, with the exception of straw from the pre- and post-emergence pyridine study and the post-emergence trifluoromethylphenyl study (0.01 mg eq./kg). Radioactivity levels were significantly higher after a foliar application at 0.38 kg a.s./ha performed at the later growth stage of BBCH 29 where it ranged between 0.02-0.06 mg eq./kg in grain and up to 3.68-5.70 mg eq./kg in straw. Further analysis in wheat grain could only be obtained from the study investigating foliar spraying at BBCH 29. Diflufenican was identified in grains but only in very low amounts (0.002 mg/kg; 1.8-9.1 % TRR). Two metabolites, AE 0542291₁₁ (max. 8.9 % TRR; 0.005 mg eq./kg) and AE B107137 (max. 5.4 % TRR; 0.003 mg eq./kg) were also identified in grain. In straw, parent diflufenican accounted for 2-16% TRR following both pre and early post-emergence treatments. It represented 67.1-73.5 % (2.47-4.12 mg/kg) of the TRR after later foliar spraying at

BBCH 29. Other metabolites were also identified in straw. After pre and early post-emergence treatments, several unknown metabolites were found but they did not individually represent more than 10 % (<0.01 mg eq./kg) of the total radioactivity, with the exception of one unknown polar metabolite, which accounted for up to 70 % (<0.01 mg/kg) of the total radioactivity. The remaining unextractable radioactivity accounted for less than 0.01 mg/kg. In straw from the wheat study investigating foliar spraying at BBCH 29, the metabolites encountered in grain were also identified and represented a very small part of the residue (<6 % TRR). Metabolite AE 0542291 was about 5.9 % TRR (0.17 mg eq./kg) and metabolite AE B107137 about 3.6 % TRR (0.21 mg eq./kg).

The situation in olives from the *ground harvest* study was significantly different. In samples taken 7 DAT the highest radioactivity was identified in samples from the phenyl study (0.83 mg eq/kg), followed by samples from the pyridyl study (0.31 mg eq/kg) with the lowest radioactivity identified in samples from the aniline study (0.14 mg eq/kg). Over time the TRR decreased from 0.14-0.33 mg eq/kg in samples taken 21 DAT to 0.085-0.132 mg eq./kg in samples taken 35 DAT. The majority of the radioactivity could be rinsed off (86-100 % TRR). The characterisation of TRR in samples from the phenyl study indicated that diflufenican was the main component of the identified radioactivity accounting for 0.81 mg/kg (98 %), 0.38 mg/kg (99.9 %) and 0.13 mg/kg (100 %) at the PHI intervals of 7, 21 and 35 days, respectively. The same situation was observed in samples from the pyridyl and aniline study where parent diflufenican accounted for 0.61-0.14 mg/kg (100 % TRR) in samples taken 7 DAT, 0.33-0.15 mg/kg (99.5-100 % TRR) in samples taken 21 DAT and for 0.11-0.085 mg/kg (100 % TRR) in samples taken 35 DAT. The characterisation of the TRR revealed that more than 99 % of the TRR was parent diflufenican in samples from all treatment groups, indicating no extensive metabolism of the active substance in olives which got into contact with the parent compound on the treated soil.

Parent diflufenican is the most important compound in olives and cereals straw. In cereals grain, no predominant component was identified because residues levels were very low. The metabolism of diflufenican in plants involves cleavage on both sides of the nitrogen and amide bonds. This degradation is very limited for the investigated crops, as indicated by the very low levels of metabolites metabolites AE 0542291 and AE B107137. The metabolite AE 0542291 was not found in the rat but was shown to be an intermediate of metabolite AE B107137, which directly results from the hydroxylation of metabolite AE 0542291. The metabolite AE B107137 was identified in the rat metabolism studies and is not expected to be more toxic than diflufenican. Due to their very low levels compared to the parent compound in cereals straw (approximately 20 times lower), and also considering that neither parent compound nor any of these metabolites did occur in relevant amounts in cereal grain, these metabolites are not expected to be of concern for enforcement or risk assessment. Consequently, the residue for both enforcement and risk assessment in fruit and fruiting vegetables, cereals (grain and straw) and grass is defined as diflufenican only. EFSA is of the opinion that only two crop categories have been covered (fruit and fruiting vegetable, cereals) which is insufficient to propose a general residue definition for all commodities of plant origin. Diflufenican is also authorised for other crops such as peas for which no representative metabolism study is available. In order to extend the proposed residue definition to pulses and oilseeds, a representative metabolism study for this crop group is required. Meanwhile, it is proposed on a tentative basis to also define the residue for enforcement and risk assessment in pulses and oilseeds as diflufenican.

Summary of new plant metabolism studies

Oilseed rape

A metabolism study was conducted with radiolabeled diflufenican labeled in three positions (trifluoromethylphenyl, pyridine and difluorophenyl rings). The [¹⁴C]diflufenican was formulated to simulate a 50% SC preparation used for commercial field applications. It was diluted with water and applied by spraying on oilseed rape plants (31 days before whole-plant harvest, 94 days before forage harvest, and 179 days before harvest for mature seed). The target application rate was 80 g a.i./ha (8 mg/m²) (normal field rate). The actual application rates were 111% for the TFP label, 104% for the pyridine label and 109 % of target for the DFP label.

The Total Radioactive Residue (TRR) in extracts and the PES was 0.252 ppm for the whole plant, 0.002 ppm for the forage and 0.012 ppm for mature seeds with the TFP radiolabel. The TRR was 0.305 ppm for the whole plant, 0.003 ppm for the forage and 0.017 ppm for the mature seeds with the pyridine radiolabel.

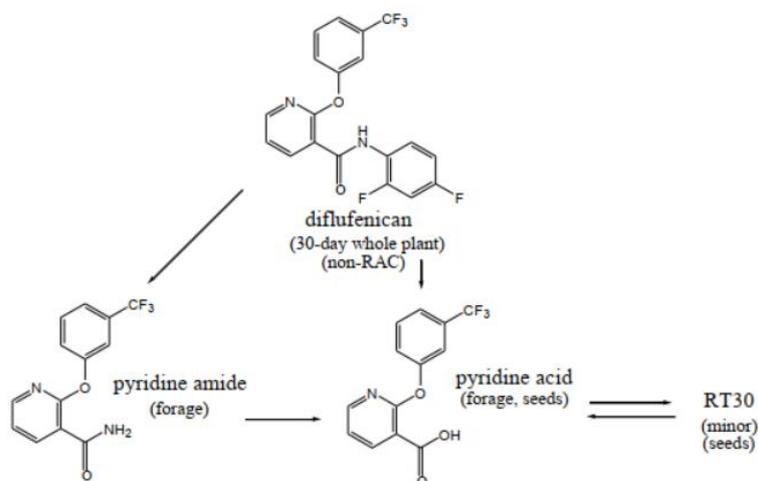
For the DFP radiolabel, TRR was 0.253 ppm for the whole plant, 0.001 ppm for the forage and 0.001 ppm for the mature seeds. Generally, the TRR data based on sum of fractions agreed with data based on combustion.

Typically, acetonitrile and acetonitrile:water (1:1) extractions were effective in extracting about 92-100% of the radiolabel from whole plant and forage. Additional extraction with 0.1 M KOH released 1-2% of the radiolabel from whole plant. Strong base released 3-5% of the radiolabel from whole plant.

The major radiolabeled residue in whole plant (31 days after treatment) was diflufenican. Pyridine acid and pyridine amide were major residues in forage (TFP and pyridine label). These metabolites were not detected in the DFP label matrices (as expected).

A metabolic pathway is proposed in the figure below based on the metabolites detected. The predominant pathways include cleavage on both sides of the nitrogen of the amide bond, liberating pyridine acid, pyridine amide, and 2,4-difluoroaniline.

Metabolism in oilseed rape is similar to that in wheat.



Potato

The TRR was low (<0.01 mg/kg) for all samples except early harvest foliage, main harvest foliage and main harvest tuber peel. Samples of early harvest tuber and main harvest tuber flesh had TRR values of 0.006 - 0.008 mg/kg therefore were not investigated further.

In the early harvest foliage samples characterised further the major components identified from the chromatograms were diflufenican, DFF amide and DFF acid. Unidentified polar components accounted for up to 0.004 mg/kg of the residue. Unextractable residue accounted for no more than 0.007 mg/kg. In the main harvest foliage samples the major components identified were also diflufenican, DFF amide and DFF acid. These were present in comparable amounts. The remainder of the residue was unidentified polar components and the unextractable residue accounted for no more than 0.003 mg/kg.

In the early harvest tuber samples the main components of the residue were diflufenican and DFF acid. The remainder of the residue was composed of other non-discrete radioactivity and unextractable residues, each accounting for 0.001 mg/kg of the residue respectively. Main harvest tuber peel samples were composed of diflufenican and DFF acid. The remainder of the residue was unidentified polar components, non-discrete radioactivity and unextractable residues, none of which exceeded 0.001 mg/kg. In the main harvest tuber flesh samples the major component of the residue was DFF acid (0.003 mg/kg, 46 % TRR). The remainder of the residue was unidentified polar components, non-discrete radioactivity and unextractable residues, none of which exceeded 0.001 mg/kg. The main harvest whole tuber sample residues were calculated from the individual tuber peel and tuber flesh data. The major components identified were diflufenican and DFF acid (<0.001 mg/kg, 6.3 % TRR and 0.003 mg/kg, 42.6% TRR). The remainder of the residue was unidentified polar components, non-discrete radioactivity and unextractable residues, none of which exceeded 0.001 mg/kg.

None of the metabolites, known or unknown, were present at levels greater than 0.01 mg/kg (all <0.008 mg/kg). The parent diflufenican was also only present at a maximum of 0.008 mg/kg in main harvest peel. The metabolism of diflufenican in potato, and by extrapolation, in the root and tuber crop group is considered sufficiently enough well-elucidated.

Conclusion on metabolism in primary crops

Since two crop categories covered (fruit and fruiting vegetable, cereals) is insufficient to confirm residue definition for all intended by the applicant crops, a representative metabolism study at least in a third primary crop group (e.g. oilseeds) was required (EFSA (EJ 2013;11(6):3281)). The applicant submitted metabolism data for OSR and potato, thus covering all intended uses. Although metabolism should not be evaluated during PPP registration but on the active renewal by the RMS on EU level, due to the need to confirm the tentative residue definition and finalize the risk assessment for the product the submitted data were here exceptionally evaluated and accepted by the zRMS. It can be considered that in all cases the metabolism of diflufenican in plants involves cleavage on both sides of the nitrogen and amide bonds and the parent is the only predominant compound (except that in cereals grain no predominant component). The metabolism data for evaluated crops groups (fruit/fruiting vegetable, cereals, oilseeds and root and tuber vegetables) allows to maintain the adopted residue definition for the purpose of the authorisation request. The data reported above are sufficient to support the intended uses of GLOB1912H.

7.3.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

No new data submitted in the framework of this application.

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

Crop group	Crop	Label position	Application and sampling details				Reference	
			Method, F or G *	Rate (kg a.s./ha)	Sowing intervals (weeks)	Harvest Intervals (DAT)		Remarks
EU data								
Leafy vegetables	Cabbage	Pyridyl, aniline and phenyl ring	Soil, F	0.36	12	At maturity	-	UK, 2005
Root and tuber vegetables	Sugar beet							
Cereals	Wheat							

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

Summary of plant metabolism studies reported in the EU

At harvest, TRR in all crops represented less than 0.06 mg eq/kg, with the exception of straw (0.08 – 0.17 mg eq/kg). Three components were identified in the crops as diflufenican and its metabolites AE 0542291 and AE B107137¹⁴, free and conjugated. These components accounted for up to 47% of the TRR in cabbage, for up to 69 % of the TRR in sugar beet tops and for up to 88% of the TRR in sugar beet root. Other residues of unknown or unextractable nature were present each at less than 0.01 mg eq/kg. In wheat grain, the three identified components accounted for up to 6% of the TRR at harvest and in wheat straw for up to 13% of the TRR, with the majority of the radioactivity (up to 87% (0.03 mg/kg) in grain and up to 60% (0.08 mg/kg) in straw), being associated with polar material resulting from the fragmentation of the compound in the plant or in the soil prior to uptake. One other unknown metabolite was present at level inferior to 0.01 mg/kg. The remaining unextractable radioactivity in grain accounted for 0.01 mg/kg and in straw less than 0.07 mg/kg and was probably associated with the fragmentation of the compound and the natural

incorporation of these fragments into the plant tissue. The metabolite AE 0542291 was not found in the rat but was not considered to be of concern at the levels found in the study (<0.01 mg/kg). The metabolite AE B107137 was identified in the rat metabolism studies and is not expected to be more toxic than diflufenican. The highest residue for metabolite AE B107137 found in this study was 0.04 mg/kg in sugar beets after 120 days. Metabolite AE B107137 is therefore the only compound of concern in succeeding crops.

Conclusion on metabolism in rotational crops

The data reported above are sufficient to support the intended uses of GLOB1912H.

7.3.2.3 Nature of residues in processed commodities (KCA 6.5.1)

No data submitted or required as residues in cereal grains were less than 0.01 mg/kg.

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

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

Endpoints	
Plant groups covered	Cereals (Wheat), oilseed rape, potato
Rotational crops covered	Cabbage, wheat, sugar beet
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	No data submitted or required as residues in cereal grains were less than 0.01 mg/kg
Residue pattern in processed commodities similar to pattern in raw commodities?	-
Plant residue definition for monitoring	Diflufenican (Regulation (EU) 2017/623) **
Plant residue definition for risk assessment	Diflufenican (EFSA, 2007)***
Conversion factor from enforcement to RA	None (EFSA, 2007)

* If residue pattern in processed commodities is not similar to that in raw commodities

** A more recent proposal by EFSA may be provided as additional information (EFSA RO XXXX).

*** If no EFSA proposal is available, a proposal should be made by the applicant/zRMS.

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

Available data

No new data submitted in the framework of this application.

Table 7.3-6: Summary of animal metabolism studies

Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling	
EU data								
Lactating ruminants	Cow	Pyridyl ring	1	0.2 or 2	7	Milk	twice daily	UK, 2005
						Urine and faeces	daily	
						Tissues	at sacrifice	
	Cow	Aniline ring	1	0.035 or 0.717	7	Milk	twice daily	
						Urine and faeces	daily	
						Tissues	at sacrifice	
Laying poultry	Hens	Aniline ring	5	0.17 or 1.92	14	Eggs	daily	UK, 2005
						Excreta	daily	
						Tissues	at sacrifice	

Summary of livestock metabolism studies reported in the EU

Lactating cows were dosed with 0.2-2 mg/kg bw per d of ¹⁴C-pyridyl-diflufenican and 0.035-0.717 mg/kg bw per d of ¹⁴C-aniline-diflufenican, corresponding to approximately 2-23 and 0.4-8 times the exposure of meat ruminant, respectively. These studies demonstrate that the majority of the AR was excreted (70-86 %) and that transfer of residues to milk and tissues was relatively low (0.1 and 0.2 % AR, respectively). In milk, a plateau level was reached after 3 days of exposure and in the lowest doses studies residues did not exceed 0.01 mg/kg. In milk, the major component was identified as diflufenican (48-52 % AR). Two other metabolites were identified, plus several unknowns, which individually were present at less than 0.01 mg/kg. In fat, the major component was identified as diflufenican (82-91 % AR – 0.02-0.07 mg/kg). In liver and kidney, metabolites were detected and tentatively identified as diflufenican, hydroxylated diflufenican¹⁵ and several hydroxylated/defluorinated anilines. However none were present at a quantifiable level, with the exception of AE B107137 in liver (0.02 mg/kg).

Laying hens were dosed with 0.17-1.92 mg/kg bw per d of ¹⁴C-aniline-diflufenican, corresponding to more than 17000 times the exposure of poultry. This study demonstrates that transfer of residues to eggs and tissues is relatively low. The majority of the AR was excreted (85-89 %) and less than 0.3 % and 0.1 % were found in the eggs and tissues, respectively. Diflufenican was identified as the main component in eggs (66-75 % AR in yolk) and in tissues (88-90 % AR in fat, 42-97 % AR in muscles, 36 % AR in liver). One unknown metabolite was represented less than 0.02 mg/kg in eggs and less than 0.01 mg/kg in fat and muscle in the high dose study. In kidney, no component was present above 0.01 mg/kg. The general metabolic pathways in rodents and ruminants were found to be comparable; the findings in ruminants can therefore be extrapolated to pigs.

Conclusion on metabolism in livestock

The data reported above are sufficient to support the intended uses of GLOB1912H.

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

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

	Endpoints
Animals covered	Dairy cattle
	Laying hens
Time needed to reach a plateau concentration	3 days in milk
	8 days in eggs
Animal residue definition for monitoring	Diflufenican (Regulation (EU) 2017/623) *
Animal residue definition for risk assessment	Diflufenican (EFSA, 2007)**
Conversion factor	None (EFSA, 2007)
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	Yes

* A more recent proposal by EFSA may be provided as additional information (EFSA RO XXXX)

** If no EFSA proposal is available, a proposal should be made by the applicant/zRMS.

*** If metabolism in rat and ruminant are not similar

7.3.3 Magnitude of residues in plants (KCA 6.3)

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

No new data are submitted in the framework of this application with regard to the use in cereals.

New studies on the magnitude of residues in potato in N-EU have been submitted by the applicant. Four additional trials in S-EU were conducted by the applicant in order to confirm the < LOQ residue situation.

New studies on the magnitude of residues in oilseed rape have been submitted by the applicant, which can be extrapolated to sunflower. Four additional trials in S-EU on sunflower were conducted by the applicant in order to confirm the < LOQ residue situation.

Table 7.3-8: Summary of EU reported and new data supporting the intended uses of GLOB1912H and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Wheat, barley, rye grain	UK, 2005 and UK, 2007	S-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 0.15 kg as/ha, BBCH 30, outdoor 8 x < 0.01 mg/kg	N/A				
	UK, 2005 and UK, 2007	N-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 0.15 kg as/ha, BBCH 30, outdoor 9 x < 0.01 mg/kg					
	Overall supporting data for cGAP	N-EU + S-EU	17 x < 0.01 mg/kg	0.01	0.01	0.01	0.02	Yes
Wheat, barley, rye straw	UK, 2005 and UK, 2007	S-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 0.15 kg as/ha, BBCH 30, outdoor 0.06; 0.07; 6 x < 0.05 mg/kg	N/A				
	UK, 2005 and UK, 2007	N-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 0.15 kg as/ha, BBCH 30, outdoor					

			0.14; 0.17; 7 x < 0.05					
	Overall supporting data for cGAP	N-EU + S-EU	0.06; 0.07; 13 x < 0.05; 0.14; 0.17 mg/kg	0.05	0.17	-	-	-
Potato	New	N-EU	GAP: 1 x 125 g a.s./ha, BBCH 00-08, outdoor 2 x < 0.01 mg/kg	N/A				
	New	N-EU	GAP: 1 x 60.2 g a.s./ha; BBCH 00-08, outdoor 2 x < 0.01 mg/kg					
	New	S-EU	GAP: 1 x 60.2 g a.s./ha; BBCH 00-08, outdoor 4 x < 0.01 mg/kg					
	Overall supporting data for cGAP	N-EU + S-EU	8 x < 0.01 mg/kg	0.01	0.01	0.01	0.01	yes
Sunflower seeds	New	N-EU	GAP: 1 x 70-80 g a.s./ha, BBCH 16, outdoor 4 x < 0.01 mg/kg	N/A				
	New	S-EU	GAP: 1 x 80 g a.s./ha, BBCH 16, outdoor 1 x < 0.01 mg/kg					
	New	S-EU	GAP: 1 x 60.2 g a.s./ha; BBCH 00-08, outdoor 4 x < 0.01 mg/kg					
	Overall supporting data for cGAP	N-EU + S-EU	9 x < 0.01 mg/kg	0.01	0.01	0.01	0.01	yes

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

7.3.3.2 Effects on the residue level in pollen and bee products

Diflufenican is a systemic herbicide applied in winter cereals, potatoes and sunflower at early growth stages. Winter cereals and potatoes are considered a non-melliferous crop, while sunflower is considered a melliferous crop. In all three crops, the application of GLOB1912H is before the flowering stage. Therefore, only the exposure through sunflower, non-target plants (in-field weeds and adjacent plants) and succeeding crops is relevant.

Referring to a recent publication (Maynard *et al.* (2015)²), it was shown that less than 2% of all weeds recorded in arable crops (wheat, oilseed rape, sugarbeet, sunflower, potatoes, maize, peas and beans) are at flowering growth stage when herbicides are applied. It can therefore be considered that the exposure of bees to in-field flowering weeds resulting shortly after application of an herbicide is not a realistic scenario as flowering weeds are not present in the field in significant quantities in realistic conditions. Similarly, in arable crops, the weeds present during application of the herbicide and which are not yet at the flowering growth stage (< BBCH 60) will not survive cultural practices aimed at eliminating them (i.e. herbicidal treatments themselves) so that exposure will also not occur at significant level.

Therefore, only sunflower, succeeding crops and off field flowering weeds and plants should still be considered.

Sunflower:

According to the metabolism study in oilseed rape, only very low levels of diflufenican (< 0.001 mg/kg) are detected in forage samples harvested 94 days after application. Harvesting for forage is done before flowering of the crop, so this value can be used as a worst-case surrogate for the residue level found in aerial parts. According to the recent technical guidance on honey MRL (11956), if the highest residue (HR) found in aerial parts are below 0.05 mg/kg, no further residue studies in honey are necessary and the default MRL of 0.05 mg/kg can be set.

Succeeding crops:

Based on the metabolism study in rotational crops with diflufenican, the only compound of concern was the metabolite AE B107137. This metabolite is not included in the residue definition for food of plant origin and therefore no further consideration is needed.

Off-field flowering weeds and plants:

According to the recent technical guidance on honey MRL (11956), if the highest residue (HR) found in aerial parts are below 0.05 mg/kg, no further residue studies in honey are necessary and the default MRL of 0.05 mg/kg can be set. If the HR value is found to be above 0.05 mg/kg but below 0.5 mg/kg in the aerial parts, the MRL could be based on the HR value considering a transfer factor of 1 from aerial parts to honey. If the HR value is found to be above 0.5 mg/kg in the aerial parts, further specific data would be needed to set the MRL.

To estimate the residue level in aerial parts, reference is made to Appendix F of the EFSA bee guidance from 2013 which mentions RUD values in pollen/nectar for approx. 35 substances based on HR values analysed after spray applications during flowering. For pollen, the **95th percentile** and the highest RUD are given at **82.1** and 149.8 mg a.s./kg respectively. For nectar, the 95th percentile and the highest RUD are given at 12.0 and 20.7 mg a.s./kg respectively. Considering the 95th percentile RUD for aerial parts (i.e. pollen) of 82.1 mg a.s./kg, such an RUD would cover a MRL setting without the need of specific additional data up to a dose rate of 6.09 g a.s./ha (with such an application rate, the calculated MRL would be $82.1 * 0.00609 = 0.499$ mg as/kg pollen, thus below the threshold value of 0.5 mg/kg). On the other hand, the default MRL of 0.05 mg/kg would be supported for dose rate < 0.6 g a.s./ha. In case the dose rate is higher than 6.09 g a.s./ha, further residue studies would be necessary.

² Maynard S.K., Albuquerque R., Weber C., von Mérey G., Geiger M.F., Becker R., Keppler J., Masche J., Brougham K, Coulson M., 1.8 Weeds in the treated field – a realistic scenario for pollinator risk assessment? Hazards of pesticides to bees – 12th International Symposium of the ICP-PR Bee Protection Group, Ghent (Belgium, September 15-17, 2014, Julius-Kühn-Archiv, 450, 2015.

Since off-field flowering weeds and plants are only exposed to the drift rate (2.77% of the full rate), the dose rate to be taken into account for diflufenican would be 1.24 g a.s./ha. This is below 6.09 g a.s./ha and thus no further studies are needed.

Moreover, considering that for GLOB1912H only autumn to winter use is intended in winter cereals, the application timing will not coincide with the flowering period of non-target plants. Therefore, no further studies are needed.

The application in sunflower and potatoes will be made between February and early May, so it also does not coincided for the largest part with the flowering period of non-target plants.

In conclusion, no exceedance of the default MRL in honey is expected based on the intended uses.

7.3.3.3 Conclusion on the magnitude of residues in plants

Cereals are a major crop in both northern and southern Europe, so 8 trials are required in each region. The representative use on cereals for diflufenican in the DAR is more critical than the intended GAP of GLOB1912H. Therefore, the residue trials presented in the DAR of diflufenican can be used to support the intended use of GLOB1912H.

According to the EU guideline SANTE/2019/12752, extrapolation from any one of the following barley / oats / rye / triticale / wheats to the remaining four crops is possible as long as the last application is done before consumable parts of the crops have started to form (BBCH 51). Considering the intended uses, the extrapolation is possible.

Potato is a major crop in both northern and southern Europe, so normally 8 trials are required in each region. However, as residues were all below the LOQ in the tubers, only 4 trials per region are needed. Due to the < LOQ residue situation in all trials on potato, it is considered acceptable to extrapolate the results of northern Europe also to southern Europe. Moreover, four additional trials in S-EU were conducted by the applicant in order to confirm the < LOQ residue situation.

Sunflower is a major crop in both northern and southern Europe, so normally 8 trials are required in each region. However, as residues were all below the LOQ in seeds, only 4 trials per region are needed. Due to the < LOQ residue situation in all trials, it is considered acceptable to extrapolate the results of northern Europe also to southern Europe in order to obtain a sufficient number of trials in each zone.

According to the EU guideline SANTE/2019/12752, extrapolation from oilseed rape seeds to sunflower seeds is possible as long as the last application is done before consumable parts of the crops have started to form (BBCH 65). Considering the intended uses, the extrapolation is possible.

Four additional trials in S-EU are conducted by the applicant in order to confirm the < LOQ residue situation.

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

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

7.3.4 Magnitude of residues in livestock

7.3.4.1 Dietary burden calculation

The input values for the dietary burden calculation are summarised in the following table.

In accordance with the MRL review of diflufenican (EFSA Journal 2013; 11(6):3281) no default processing factor was applied for apple and citrus by-products, because diflufenican is applied early in the growing season and residues are expected to be below the LOQ. Concentration of residues in these commodities is therefore not expected.

Also for potatoes and sunflower by-products, no default processing factor was applied, because diflufenican is applied early in the growing season and residues are below the LOQ. Concentration of residues in these commodities is therefore not expected.

Cereals have a LOQ STMR, residues are not typically expected and positive residues are very rare, hence it is not needed to apply a processing factor.

Table 7.3-9: 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
Risk assessment residue definition: Diflufenican				
Small cereal grain	0.01	Median residue (EFSA, 2013)	0.01	Median residue (EFSA, 2007)
Small cereal straw	0.05	Median residue (UK, 2005 and UK, 2007)	0.17	Highest residue (UK, 2005 and UK, 2007)
Brewer's grain	0.01	Median residue (UK, 2005 and UK, 2007)	-	-
Distiller's grain	0.01	Median residue (UK, 2005 and UK, 2007)	-	-
Wheat gluten meal	0.01	Median residue (UK, 2005 and UK, 2007)	-	-
Wheat milled by-products	0.01	Median residue (UK, 2005 and UK, 2007)	-	-
Apple pomace, wet	0.01	Median residue (EFSA, 2013)	-	-
Citrus dried pulp	0.01	Median residue (EFSA, 2013)	-	-
Potato, culls	0.01	Median residue (new data)	0.01	Highest residue (new data)
Potato, process waste	0.01	Median residue (new data)	-	-
Potato, dried pulp	0.01	Median residue (new data)	-	-
Sunflower, meal	0.01	Median residue (new data)	-	-

Table 7.3-10: Results of the dietary burden calculation

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Risk assessment residue definition: Diflufenican					
Beef cattle*	0.0016	0.003	Rye straw	0.11	N

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)
Dairy cattle*	0.0022	0.004	Rye straw	0.10	N
Ram/ewe	0.0022	0.005	Rye straw	0.15	Y
Lamb	0.0026	0.006	Rye straw	0.14	Y
Breeding swine	0.0010	0.001	Barley grain	0.05	N
Finishing swine*	0.0009	0.0009	Barley grain	0.03	N
Broiler poultry	0.0011	0.001	Wheat gluten meal	0.02	N
Layer poultry*	0.0014	0.002	Wheat straw	0.03	N
Turkey	0.0014	0.001	Wheat gluten meal	0.02	N

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

7.3.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

The trigger values are not exceeded in the dietary burden calculations, except for ram/ewe and lamb. However, based on the metabolism studies, it can be concluded that, after exposure to the maximum dietary burden, residue levels are expected to remain below 0.01 mg/kg. Hence, no livestock feeding studies are required.

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

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

7.3.6 Magnitude of residues in representative succeeding crops

During the peer-review, it was concluded that no residues above 0.01 mg/kg were expected in succeeding crops because, in the representative use on cereals, the critical dose rate was only 0.12 kg a.s./ha. It was also highlighted that if uses with higher application rates and/or a later time of application were requested in the future, Member States should pay attention to the residues in rotational crops. Considering the GAPs reported in Appendix A of the MRL review (highest dose rate of 0.25 kg a.s./ha authorised on cereals), the overdosing factor of the rotational crop metabolism study is only 1.4. Therefore, the presence of metabolite AE B107137 at levels above 0.01 mg/kg in root crops (planted after 120 days) cannot be excluded. Consequently, EFSA is of the opinion that further investigation on the levels of diflufenican and its metabolite AE B107137 in succeeding crops (particularly in root crops) is required. Meanwhile, Member States granting authorisations for diflufenican should take the appropriate risk mitigation measures (e.g. definition of pre-plant intervals, limitation of rate of application) in order to avoid the presence of diflufenican and metabolite AE B107137 residues in rotational crops. Based on the rotational crop metabolism study, a waiting period of 150 days before planting root crops seems the most appropriate. However, due to the early application timing of GLOB1912H, a long interval before planting subsequent crops can be expected. Therefore, no waiting period before planting succeeding crops is deemed necessary.

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

The available data for diflufenican sufficiently address aspects of the residue situation that might arise from the use of GLOB1912H. Therefore, other special studies are not needed.

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

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

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

7.3.8.1 Input values for the consumer risk assessment

Table 7.3-11: Input values for the consumer risk assessment

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Risk assessment residue definition: Diflufenican		
All commodities	MRL	Reg. (EU) 2017/623

7.3.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.3-12: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo	0.7% (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo	No IEDI calculations were performed as the TMDI calculations using the MRLs were already acceptable. No refinement of the chronic risk assessment is required.
NTMDI (% ADI) **	-
NEDI (% ADI)**	-

* include raw and processed commodities if both values are required for PRIMo

** if national model is available

The proposed uses of diflufenican in the formulation GLOB1912H do not represent unacceptable chronic risks for the consumer.

7.4 Combined exposure and risk assessment

From a scientific point of view it is regarded necessary to take into account potential combination effects. However, the evaluation of cumulative or synergistic effects as requested by Art. 4 (3b) of Regulation (EC) No. 1107/2009 should only be performed when harmonised “scientific methods accepted by the Authority to assess such effects are available.”

Currently, no EU-harmonized guidance is available on the risk assessment of combined exposure to multiple active substances; this approach is not mandatory at EU level.

7.4.1 Acute consumer risk assessment from combined exposure

Not required.

7.4.2 Chronic consumer risk assessment from combined exposure

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

7.5 **References**

EFSA (European Food Safety Authority), 2007. Conclusions regarding the peer review of the pesticide risk assessment of the active substance prosulfocarb. EFSA Scientific Report (2007) 111, 1-81.

EFSA (European Food Safety Authority), 2011. Review of the existing maximum residue levels (MRLs) for prosulfocarb according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2011;9(8):2346. [39 pp.] doi:10.2903/j.efsa.2011.2346.

EFSA (European Food Safety Authority), 2007. Conclusions regarding the peer review of the pesticide risk assessment of the active substance diflufenican. EFSA Scientific Report (2007) 122, 1-84.

EFSA (European Food Safety Authority), 2011. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for diflufenican according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2013;11(6):3281. [42 pp.] doi:10.2903/j.efsa.2013.3281.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.1	Jonchère F.	2010a	Frozen storage stability of residues of prosulfocarb in sunflower seeds A9086 Anadiag GLP Unpublished	N	Globachem NV
KCA 6.1	Jonchère F.	2012	Frozen storage stability of diflufenican residues in oilseed rape seeds A9260 Anadiag GLP Unpublished	N	Globachem NV
KCA 6.1	Quistad G.B., Bronner K, and Kovatchev A.	2010	A metabolism study with [14C]Diflufenican (3 radiolabels) using oilseed rape 1984W PTRL West, Inc. GLP Unpublished	N	Globachem NV
KCA 6.3	Jonchère F.	2010b	Determination of prosulfocarb residues in potato following treatment with Prosulfocarb 800 g/L EC under field conditions in southern Europe in 2009 A9050 Anadiag GLP Unpublished	N	Globachem NV
KCA 6.3	Jonchère F.	2010c	Determination of prosulfocarb residues in sunflower following treatment with Prosulfocarb 800 g/L EC under field conditions in norther Europe in 2009 A9049 Anadiag GLP	N	Globachem NV

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
			Unpublished		
KCA 6.3	Jonchère F.	2010d	Determination of diflufenican residues in potato following treatment with Diflufenican 500 SC under fields conditions in Northern Europe in 2010 B0132 Anadiag GLP Unpublished	N	Globachem NV
KCA 6.3	Ertus C.	2021a	Determination of diflufenican and its metabolites and conjugates residues in potatoes following soil application with GLOB1912H under field conditions in Northern Europe in 2021 C1238 Anadiag GLP Unpublished	N	Globachem NV
KCA 6.3	Ertus C.	2021b	Determination of diflufenican and its metabolites and conjugates residues in potatoes following soil application with GLOB1912H under field conditions in Southern Europe in 2021 C1082 Anadiag GLP Unpublished	N	Globachem NV
KCA 6.3	Jonchère F.	2011	Determination of diflufenican residues in winter oilseed rape following treatment with Diflufenican 500 SC under field conditions in northern and southern Europe in 2009-2010. A9258 Anadiag GLP Unpublished	N	Globachem NV
KCA 6.3	Ertus C.	2021c	Determination of diflufenican (and its metabolites and conjugates) and prosulfocarb residues in sunflower following soil application with GLOB1912H under field conditions in Southern Europe in 2021. C1081 Anadiag	N	Globachem NV

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GLP Unpublished		
KCA 6.10	Jonchère F.	2010d	Determination of Prosulfocarb Residues In Winter Wheat RAC Following Treatment with Prosulfocarb 800 g/l EC under Field Conditions in Northern Europe in 2009-2010. A9051 Anadiag GLP Unpublished	N	Globachem NV
KCA 6.10	Perny A.	2010	Determination of Prosulfocarb Residues In Winter Wheat RAC Following Treatment with Prosulfocarb 800 g/l EC under Field Conditions in Northern Europe in 2011-2012. R B1234 Anadiag GLP Unpublished	N	Globachem NV

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
None					

Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1 Prosulfocarb

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

Comments of zRMS:	The study has been accepted. The study was conducted to determine the frozen storage stability of prosulfocarb in sunflower seeds. QuEChERS followed by a method based on LC with MS/MS detection were applied. The LOQ of the method was 0.01 mg/kg for sunflower seeds (see validation study A9085 evaluated in PL already - on 2 validated levels a mean recovery is within the range 70-110 % with a RSD less than 20 %).
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Reference:	KCA 6.1
Report	Frozen storage stability of residues of prosulfocarb in sunflower seeds, Jonchère F., 2010a, A9086.
Guideline(s):	Yes, ENV/JM/MONO(2007)17, Working document 7032/VI/95 rev. 5 (appendix H), SANCO/825/00 rev. 7, SANCO/3029/99 rev.4
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

Samples were blended under dry ice and placed for at least 12 hours at < -18°C. The amount required by the analytical method was weighed from this homogenous matrix and placed into individual vessels. An aliquot of a solution of prosulfocarb in acetonitrile was added to each vessel to obtain a target initial concentration of 0.1 mg/kg. Thereafter, the samples were rehomogenised by mixing.

Residues are extracted with acetonitrile/acetic acid 99.9:0.1% in the presence of magnesium sulfate and sodium chloride. After centrifugation the extract is purified with magnesium sulfate and PSA. The internal standard (triphenylphosphate in acetonitrile) and formic acid are added to the extract before analysis by liquid chromatography using a MS/MS detector. The validation of this method was performed by ANADIAG in the study A9085 “Validation of the Analytical Method for the Determination of Prosulfocarb residues in Potato Tubers, Sunflower Seeds and Winter Wheat Whole Plant”; Report No. R A9085; GLP study; 07/01/2010” which is summarized in dRR Section B5 and submitted as study KCP 5.1.2.

The limit of quantification is 0.01 mg/kg.

Results and discussions

Table A 1: Summary of concurrent recoveries of prosulfocarb from sunflower seeds.

Matrix	Spike level (µg/kg)	Storage Interval (days)	Sample size (n)	Individual procedural recoveries (%)
Prosulfocarb				
Sunflower seeds	100.2	0	1	92.6
		60	1	100.8
		180	1	86.2

Table A 2: Stability of prosulfocarb residues in sunflower seeds following storage at -18°C

Matrix	Spike level (mg/kg)	Storage interval (days)	Individual recovered residues (mg/kg)	Average amount found (mg/kg)	% of initial value ⁽¹⁾	% recovery ⁽²⁾	Residues corrected for the recovery (mg/kg) ⁽³⁾	% of initial value corrected for the recovery (%) ⁽⁴⁾
Prosulfocarb								
Sunflower seeds	0.1	0	0.093	0.098	-	92.6	0.106	-
			0.107					
			0.094					
		60	0.095	0.097	99.0	100.8	0.096	90.6
			0.098					
		180	0.099	0.101	103.1	0.117	0.117	110.4
0.103								

(1) (Value from column 2 divided by the initial value) x 100

(2) Taken from table A1

(3) (Value of column 2 divided by value of column 4) x 100

(4) (Value of column 5 divided by the initial value corrected) x 100

Conclusion

The results show a good stability of prosulfocarb residues in sunflower seeds for up to 180 days of frozen storage.

A 2.1.1.1.2 Storage stability of residues in animal products

No new studies were submitted.

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 studies were submitted.

A 2.1.2.1.2 Nature of residue in rotational crops

No new studies were submitted.

A 2.1.2.1.3 Nature of residues in processed commodities

No new studies were submitted.

A 2.1.2.2 Nature of residues in livestock

Now new studies were submitted.

A 2.1.3 Magnitude of residues in plants

A 2.1.3.1 Potatoes

Table A 3: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (DAR, Sweden, 2006)	1	4.00 kg prosulfocarb/ha	NA	BBCH 11	NR
cGAP EU (Art. 12, EFSA, 2011)	1	4.00 kg prosulfocarb/ha	NA	BBCH 11	NR
Intended cGAP (3-5-6*)	1	2.134 kg prosulfocarb/ha	NA	BBCH 09	NR

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

A 2.1.3.1.1 Study 1

Comments of zRMS:	The study has been accepted, however was not relevant (SEU). The objective of the study was to determine the levels of prosulfocarb in potato after one foliar application of the formulated product PROSULFOCARB 800 g/L EC (800 g/L prosulfocarb) on the crop. The samples were taken at harvest. A LOQ was set at 0,01. The residues found in 2 performed trials by the validated analytical method were undetectable.
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Reference:	KCA 6.3
Report	Determination of prosulfocarb residues in potato following treatment with Prosulfocarb 800 g/L EC under field conditions in southern Europe in 2009, Jonchère F., 2010b, A9050.
Guideline(s):	Yes, 7029/VI/95 rev. 5, SANCO 7525/VI/95 rev. 8, SANCO/825/00 rev. 7, SANCO/3029/99 rev.4
Deviations:	No
GLP:	Yes
Acceptability:	Supplementary

A 2.1.3.2 Sunflower

Table A 5: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (DAR, Sweden, 2006)	-	-	-	-	-
cGAP EU (Art. 12, EFSA, 2011)	1	4.00 kg prosulfocarb/ha	NA	BBCH 09	NR
Intended cGAP (4 7-8*)	1	2.134 kg prosulfocarb/ha	NA	BBCH 09	NR

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

A 2.1.3.2.1 Study 1

Comments of zRMS:	<p>The study has been accepted.</p> <p>The objective of the study was to determine the residue levels of prosulfocarb in sunflower after one application (4.00 kg prosulfocarb/ha) of the formulated product PROSULFOCARB 800 g/L EC. The study was conducted at 8 NEU independent sites. The seed samples were taken at harvest.</p> <p>The residues were determined by means of QuEChERS followed by LC-MS/MS. The LOQ of the method was 0.01 mg/kg for sunflower seeds (see also validation study <u>A9085</u> evaluated in PL already - on 2 validated levels a mean recovery is within the range 70-110 % with a RSD less than 20 %).</p> <p>The analytical method used validation parameters were consistent with the requirements. The residues determined were undetectable.</p>
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Reference:	KCA 6.3
Report	Determination of prosulfocarb residues in sunflower following treatment with Prosulfocarb 800 g/L EC under field conditions in northern Europe in 2009, Jonchère F., 2010c, A9049.
Guideline(s):	Yes, 7029/VI/95 rev. 5, SANCO 7525/VI/95 rev. 8, SANCO/825/00 rev. 7, SANCO/3029/99 rev.4
Deviations:	Yes; 4 deviations in field phase were recorded however with no substantial impact on the study.
GLP:	Yes
Acceptability:	Yes

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treat- ment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion an- alyzed	Resi- dues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Analyte 1		
R A9049 A9049 BP1 Attray 45170 Northern France	Sunflower/Pegasol	1) 06/04/2009 2) 27/06/2009 to 05/07/2009 3) 31/08/2009	3933	295	1333	14/04/2009	03	Seeds	<u>≤ 0.01</u>	-	Prosulfocarb 800 EC Analytical method consisted in extrac- tion with acetoni- trile/acetic acid. Detection with LC- MS/MS. Method fully vali- dated in A9085. LOQ: 0.01 mg/kg Untreated specimens were all < LOQ. Max. storage interval between sampling and analysis: 105 days

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Analyte 1		
R A9049 A9049 BM1 Thorée les Pins 72800 Northern France	Sunflower/Gulliver	1) 21/04/2009 2) 07/07/2009 to 18/07/2009 3) 07/09/2009	4227	317	1333	22/04/2009	00	Seeds	< 0.01	-	Prosulfocarb 800 EC Analytical method consisted in extraction with acetonitrile/acetic acid. Detection with LC-MS/MS. Method fully validated in A9085. LOQ: 0.01 mg/kg Untreated specimens were all < LOQ. Max. storage interval between sampling and analysis: 98 days
R A9049 A9049 GE1 Eichstetten 79356 Northern Germany	Sunflower/Es Biba	1) 23/06/2009 2) 30/08/2009 to 20/09/2009 3) 15/10/2009 to 25/10/2009	3840	288	1333	25/06/2009	00	Seeds	< 0.01	-	Prosulfocarb 800 EC Analytical method consisted in extraction with acetonitrile/acetic acid. Detection with LC-MS/MS. Method fully validated in A9085. LOQ: 0.01 mg/kg Untreated specimens were all < LOQ. Max. storage interval between sampling and analysis: 56 days

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treat- ment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion an- alyzed	Resi- dues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Analyte 1		
R A9049 A9049 HA1 Landringhausen 30890 Northern Germany	Sunflower/Perceval	1) 11/07/2009 2) 14/09/2009 to 07/10/2009 3) 23/10/2009	4093	307	1333	14/07/2009	00	Seeds	< 0.01	-	Prosulfocarb 800 EC Analytical method consisted in extrac- tion with acetoni- trile/acetic acid. Detection with LC- MS/MS. Method fully vali- dated in A9085. LOQ: 0.01 mg/kg Untreated specimens were all < LOQ. Max. storage interval between sampling and analysis: 52 days
R A9049 A9049 CZ1 Vsestary 50312 Northern Czech Republic	Sunflower/Alexan- dra	1) 17/04/2009 2) 03/07/2009 to 20/07/2009 3) 24/09/2009	4040	303	1333	20/04/2209	00	Seeds	< 0.01	-	Prosulfocarb 800 EC Analytical method consisted in extrac- tion with acetoni- trile/acetic acid. Detection with LC- MS/MS. Method fully vali- dated in A9085. LOQ: 0.01 mg/kg Untreated specimens were all < LOQ. Max. storage interval between sampling and analysis: 81 days

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treat- ment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion an- alyzed	Resi- dues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Analyte 1		
R A9049 A9049 HU1 Komárom 2900 Northern Hungary	Sunflower/Picasol	1) 08/04/2009 2) 30/04/2009 to 15/07/2009 3) 29/08/2009	3827	287	1333	10/04/2009	00	Seeds	≤ 0.01	-	Prosulfocarb 800 EC Analytical method consisted in extrac- tion with acetoni- trile/acetic acid. Detection with LC- MS/MS. Method fully vali- dated in A9085. LOQ: 0.01 mg/kg Untreated specimens were all < LOQ. Max. storage interval between sampling and analysis: 107 days

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Analyte 1		
R A9049 A9049 PL1 Góra Swietej Malgorzaty 99-122 Northern Poland	Sun-flower/Stonecznik ogrodowy	1) 18/04/2009 2) 05/07/2009 to 20/07/2009 3) 10/08/2009 to 11/08/2009	3893	292	1333	20/04/2009	00	Seeds	<u>≤ 0.01</u>	-	Prosulfocarb 800 EC Analytical method consisted in extraction with acetone-trile/acetic acid. Detection with LC-MS/MS. Method fully validated in A9085. LOQ: 0.01 mg/kg Untreated specimens were all < LOQ. Max. storage interval between sampling and analysis: 95 days

(a) According to CODEX Classification / Guide

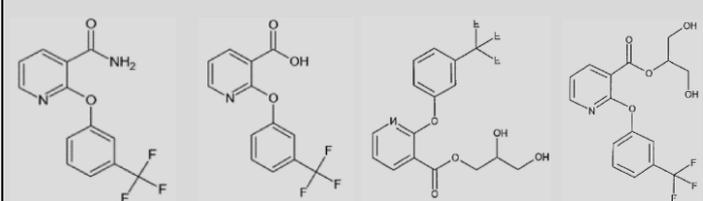
(b) Only if relevant

(c) Year must be indicated

(d) Days after last application (Label pre-harvest interval, PHI, underline)

(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

A 2.1.3.2.2 Study 2

Comments of zRMS:	<p>The study has been accepted. This is SEU study.</p> <p>The objective of the study was to determine the residues of Diflufenican (and its metabolites and conjugates) and Prosulfocarb in sunflower after one application of GLOB1912H (667 g Prosulfocarb/L, 14 g Diflufenican/L), at the rate of 4.3 L/ha (2868.1 g Prosulfocarb/ha, 60.2 g Diflufenican/ha) at preemergence of the crop. The study was conducted at 4 sites in Southern Europe. Sampling was performed at maturity of the crop (NCH) in both plots (treated and untreated) and all trials.</p> <p>The purpose of the method employed in the study (Analytical phase report No. E21025) was to determine the residues levels of Diflufenican, Diflufenican Amide (AE 0542291), total Diflufenican Acid (AE B107137) and glycerol conjugates of AE B107137 (BCS-CO86433 and BCS-CO86434) and Prosulfocarb in sunflower seeds. The relevant structures are as follows:</p> <div style="text-align: center;">  <p>Diflufenican amide Diflufenican acid BCS-CO86433 BCS-CO86434</p> </div> <p>The methods MET/DIFLUFENICAN/03 and MET/PROSULFOCARB/01 were used. MET/DIFLUFENICAN/03 was successfully validated for the analysis of Diflufenican and its metabolites in sunflower seeds during study E21023. The LOQ is 0.01 mg/kg expressed as Diflufenican equivalent for Diflufenican and its metabolites. In summary, residues are extracted with acetonitrile and acetonitrile/water (1:1 ratio, v/v) through solid- liquid extraction. Glycerol conjugates of AE B107137 are hydrolysed into Diflufenican Acid with sodium hydroxide solution. After filtration, final solution is concentrated, filtered again through 0.2µm pore size filter and analysed by LC-MS/MS.</p> <p>MET/PROSULFOCARB/01 was successfully validated for the analysis of Prosulfocarb in sunflower seeds during the study E21024. The LOQ is 0.01 mg/kg and it is a QuEChERS-based method.</p> <p>Matrix-matched standards were used in this study for calibration and quantification for both methods. The R² value for each calibration curve is higher than 0.99. The recovery and RSD results included in the study report for all analytes of both actives and all metabolites in both mass transitions were consistent with the validation requirements.</p> <p>Residues determined in control samples were below the LOQ. The residue results obtained for Diflufenican, Diflufenican amide, Diflufenican acid (as sum of residues of Diflufenican acid and Diflufenican glycerol conjugates BCS-CO86433 and BCS-CO86434 after hydrolysis into Diflufenican acid) and Prosulfocarb in the treated specimens are summarised below in the table:</p> <table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <thead> <tr> <th colspan="6">Normal Harvest BBCH 89 (132-147 DAA)</th> </tr> <tr> <th>Trial No.</th> <th>Matrix</th> <th>Diflufenican residues (mg/kg)</th> <th>Diflufenican Amide residues (mg/kg)</th> <th>Diflufenican Acid* residues (mg/kg)</th> <th>Prosulfocarb residues (mg/kg)</th> </tr> </thead> <tbody> <tr> <td>C1081 TL1</td> <td>Seeds</td> <td>< LOQ</td> <td>< LOQ</td> <td>< LOQ</td> <td>< LOQ</td> </tr> <tr> <td>C1081 ES1</td> <td>Seeds</td> <td>< LOQ</td> <td>< LOQ</td> <td>< LOQ</td> <td>< LOQ</td> </tr> <tr> <td>C1081 GR1</td> <td>Seeds</td> <td>< LOQ</td> <td>< LOQ</td> <td>< LOQ</td> <td>< LOQ</td> </tr> <tr> <td>C1081 IT1</td> <td>Seeds</td> <td>< LOQ</td> <td>< LOQ</td> <td>< LOQ</td> <td>< LOQ</td> </tr> </tbody> </table>	Normal Harvest BBCH 89 (132-147 DAA)						Trial No.	Matrix	Diflufenican residues (mg/kg)	Diflufenican Amide residues (mg/kg)	Diflufenican Acid* residues (mg/kg)	Prosulfocarb residues (mg/kg)	C1081 TL1	Seeds	< LOQ	< LOQ	< LOQ	< LOQ	C1081 ES1	Seeds	< LOQ	< LOQ	< LOQ	< LOQ	C1081 GR1	Seeds	< LOQ	< LOQ	< LOQ	< LOQ	C1081 IT1	Seeds	< LOQ	< LOQ	< LOQ	< LOQ
Normal Harvest BBCH 89 (132-147 DAA)																																					
Trial No.	Matrix	Diflufenican residues (mg/kg)	Diflufenican Amide residues (mg/kg)	Diflufenican Acid* residues (mg/kg)	Prosulfocarb residues (mg/kg)																																
C1081 TL1	Seeds	< LOQ	< LOQ	< LOQ	< LOQ																																
C1081 ES1	Seeds	< LOQ	< LOQ	< LOQ	< LOQ																																
C1081 GR1	Seeds	< LOQ	< LOQ	< LOQ	< LOQ																																
C1081 IT1	Seeds	< LOQ	< LOQ	< LOQ	< LOQ																																

	DAA: Days after application LOD is equivalent to less than 0.003 mg/kg LOQ = 0.01 mg/kg (expressed as Diflufenican equivalent for Diflufenican and its metabolites) and 0.01 mg/kg for Prosulfocarb * Sum of residues of Diflufenican acid and Diflufenican glycerol conjugates BCS-C086434) after hydrolysis into Diflufenican acid.
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Reference:	KCA 6.3
Report	Determination of diflufenican (and its metabolites and conjugates) and prosulfocarb residues in sunflower following soil application with GLOB1912H under field conditions in Southern Europe in 2021, Ertus C., 2021c, C1081. With 3 amendments
Guideline(s):	Yes, OECD TG 509, SANTE/2019/12752, SANTE/2020/12830 Rev. 1, ENV/JM/MONO(2007)17
Deviations:	Yes: Storage temperature of reference items was not -20°C +/- 5°C as indicated in the analytical phase plan. Storage temperature was done as described in the SDS of each reference item.
GLP:	Yes
Acceptability:	Supplementary

For the summary table, please refer to A 2.2.3.2.2.

A 2.1.4 Magnitude of residues in livestock

A 2.1.4.1 Livestock feeding studies

No new studies were 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 studies were submitted.

A 2.1.5.2 Processing studies on a core set of representative processes

No new studies were submitted.

A 2.1.6 Magnitude of residues in representative succeeding crops

No new studies were submitted.

A 2.1.7 Other/Special Studies

A 2.1.7.1 Study 1

Comments of zRMS:	<p>The studies have been accepted.</p> <p>Two studies with numbers R A9051 and R B1234 were evaluated with total of 5 trials conducted in NEU. The objective was prosulfocarb decline determination in wheat whole plant after nominal 1x4kg prosulfocarb /ha at BBCH 12. Also, for each trial the period of time (DT₅₀) it took for prosulfocarb undergoing decay to decrease by half was calculated. The LC-MS/MS technique was applied.</p> <p>The limit of quantification has been validated by fortifications at 0.01 mg/kg. The recoveries were all in the range of 70 – 110 % and relative standard deviations (RSD) were < 20 %. Average DT₅₀ calculated is 1,8 day.</p> <p>These studies were already evaluated in PL.</p>
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Reference: KCA 6.10

Report: Determination of Prosulfocarb Residues In Winter Wheat RAC Following Treatment with Prosulfocarb 800 g/l EC under Field Conditions in Northern Europe in 2009-2010, Jonchère F., 2010d, A9051.

Guideline(s): Yes, 7029/VI/95 rev. 5, SANCO 7525/VI/95 rev. 8, SANCO/825/00 rev. 7, SANCO/3029/99 rev.4

Deviations: No

GLP: Yes

Acceptability: **Yes**

Reference: KCA 6.10

Report: Determination of Prosulfocarb Residues In Winter Wheat RAC Following Treatment with Prosulfocarb 800 g/l EC under Field Conditions in Northern Europe in 2011-2012, Perny A., 2012, R B1234.

Guideline(s): Yes, 7029/VI/95 rev. 5, SANCO 7525/VI/95 rev. 8, SANCO/825/00 rev. 8.1, SANCO/3029/99 rev.4

Deviations: No

GLP: Yes

Acceptability: **Yes**

Materials and methods

The objective of the studies was to determine the residue levels of prosulfocarb in winter wheat raw agricultural commodity after one foliar application of the formulated product PROSULFOCARB 800 g/L EC on the crop. The study was composed of two phases: the field phase and the analytical phase.

The study was conducted at 5 sites in Northern Europe (Northern France and Germany).

One plot was treated once with PROSULFOCARB 800 g/L EC at the application rate of 5 L/ha with a spray volume of 300 L water/ha at BBCH growth stage 12. A second plot remained untreated.

Wheat samples (whole plants) were taken at 0, 1, 2, 4, 7 (± 1) and 14 (± 1) days after the last application. Prosulfocarb residues were analysed in samples harvested during the field phase using the method developed and validated by ANADIAG in the study A9085 “Validation of the Analytical Method for the Determination of Prosulfocarb residues in Potato Tubers, Sunflower Seeds and Winter Wheat Whole Plant”; Report No. R A9085; GLP study; 07/01/2010” which is summarized in dRR Section B5 and submitted as study KCP 5.1.2.

The results are based on samples sizes of minimum 100 grams of plant material. At this immature stage, 100 gram of immature plants corresponds to the sampling of up to 200 whole plants. This is in accordance with the Guidance Document Sanco7029/VI/95 rev5 that reads on page 56: if immature samples are to be taken, cut no less than 12 short lengths from rows over the entire plot. As can be seen in the final report of the study, this was respected. As the product was applied at BBCH 12 and samplings were taken starting at BBCH 12 up to BBCH 13 (14 days after the last application), a sample size of 1 kg of plant material was not possible however this is accepted by the above guidance.

Although this study was conducted in Northern Europe, the results are valid in Southern Europe too as the study is a higher Tier study used for refinement of the risk assessment to determine the DT_{50} value of the active ingredient in plants. Conditions in Northern Europe can be colder than in Southern Europe meaning that the study is worst case: under colder conditions, the plants will grow slower and degradation can be slower. Therefore the obtained DT_{50} value is worst case and thus acceptable.

Results and discussions

Table A 7: Tier 1 tables of the residue studies used for the refinement of the DT₅₀ of prosulfocarb in winter wheat plants

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active ingredient : **Prosulfocarb** Producer of commercial product : GLOBACHEM NV
 Crop/crop group : Wheat / Cereals
 Responsible body for reporting : ANADIAG, 16 rue Ampère Page : /12
 (name, address) : 67500 HAGUENAU, France
 Country : Northern France Indoor/Glasshouse/Outdoor : Outdoor
 Content of active substance (g/kg or g/l) : prosulfocarb 800 g/L Other a.i. in formulation : -
 Formulation (e.g. WP) : EC (common name and content) :
 Commercial product (name) : **PROSULFOCARB 800 g/L** Residues calculated as : mg/kg prosulfocarb

1 Report-No ; Location including Postal code	2 Commodity /Variety (a)	3 Date of (b) 1) Sowing 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment (actual)			6 Dates of treatment or n°. of treatm. and last date (d)	7 Growth stage at last treatm. or date(e)	8 Portion analysed (a)	9 Residues (mg/kg)	10 PHI (days) (f)	11 Remarks (g)
				g a.i./ha (h)	Water (l/ha)	g a.i./hl (h)						
A9051 AN1 Seebach (67160) Northern France	Wheat / Apache	1) 14/10/09 2) - 3) -	Foliar spray	4093	307	1333	13/11/09	12	Whole plant Whole plant Whole plant Whole plant Whole plant	454.41 316.95 92.47 20.85 10.72 1.59	0 1 2 4 7 13	LOQ prosulfocarb 0.01 mg/kg
A9051 GE1 Neuershausen (79232) Germany	Wheat / Apache	1) 28/10/09 2) - 3) -	Foliar spray	4013	301	1333	01/12/09	12	Whole plant Whole plant Whole plant Whole plant Whole plant	714.54 452.58 327.90 123.23 38.85 5.70	0 1 2 4 6 13	LOQ prosulfocarb 0.01 mg/kg

Remarks: (a) According to EEC and Codex Classification (both) should be used?
 (b) Only if relevant
 (c) High or low volume spraying, spreading, dusting etc
 (d) Year must be indicated
 (e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4
 (f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)
 (g) Remarks may include: Climatic conditions; Reference to analytical method and information on which metabolites are included

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

Active ingredient : **Prosulfocarb** Producer of commercial product : GLOBACHEM NV
 Crop/crop group : Wheat / Cereals
 Responsible body for reporting (name, address) : ANADIAG, 16 rue Ampère 67500 HAGUENAU, France Page : 61/3
 Country : Northern France Indoor/Glasshouse/Outdoor : Outdoor
 Content of active substance (g/kg or g/l) : prosulfocarb 800 g/L Other a.i. in formulation : -
 Formulation (e.g. WP) : EC (common name and content) :
 Commercial product (name) : **PROSULFOCARB 800 g/L** Residues calculated as : mg/kg prosulfocarb

1 Report-No ; Location including Postal code	2 Commodity /Variety (a)	3 Date of (b) 1) Sowing 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment (actual)			6 Dates of treatment or n°. of treatm. and last date (d)	7 Growth stage at last treatm. or date(e)	8 Portion analysed (a)	9 Residues (mg/kg)	10 PHI (days) (f)	11 Remarks (g)
				g a.i./ha (h)	Water (l/ha)	g a.i./hl (h)						
B1234 AN1 Seebach (67160) Northern France	Wheat / Premio	1) 11/10/11 2) - 3) -	Foliar spray	3840	288	1333	10/11/11	12	Whole plant Whole plant Whole plant Whole plant Whole plant Whole plant	286.5 233.9 135.6 42.5 29.4 4.4	0 1 2 4 7 14	LOQ prosulfocarb 0.01 mg/kg

Remarks:

- (a) According to EEC and Codex Classification (both) should be used⁷
- (b) Only if relevant
- (c) High or low volume spraying, spreading, dusting *etc*
- (d) Year must be indicated
- (e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4
- (f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)
- (g) Remarks may include: Climatic conditions; Reference to analytical method and information on which metabolites are included

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active ingredient : **Prosulfocarb** Producer of commercial product : GLOBACHEM NV
 Crop/crop group : Wheat / Cereals
 Responsible body for reporting (name, address) : ANADIAG, 16 rue Ampère Page : 62/2
 Country : Northern France Indoor/Glasshouse/Outdoor : Outdoor
 Content of active substance (g/kg or g/l) : prosulfocarb 800 g/L Other a.i. in formulation : -
 Formulation (e.g. WP) : EC (common name and content) :
 Commercial product (name) : **PROSULFOCARB 800 g/L** Residues calculated as : mg/kg prosulfocarb

1 Report-No ; Location including Postal code	2 Commodity /Variety (a)	3 Date of (b) 1) Sowing 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment (actual)			6 Dates of treatment or n°. of treatm. and last date (d)	7 Growth stage at last treatm. or date(e)	8 Portion analysed (a)	9 Residues (mg/kg)	10 PHI (days) (f)	11 Remarks (g)
				g a.i./ha (h)	Water (l/ha)	g a.i./hl (h)						
B1234 BM1 Thorée les Pins (72800) Northern France	Wheat / Premio	1) 18/10/11 2) - 3) -	Foliar spray	4227	317	1333	17/11/11	12	Whole plant Whole plant Whole plant Whole plant Whole plant	443.6 280.2 158.3 59.8 28.0 4.1	0 1 2 4 7 14	LOQ prosulfocarb 0.01 mg/kg

Remarks:

- (a) According to EEC and Codex Classification (both) should be used⁷
- (b) Only if relevant
- (c) High or low volume spraying, spreading, dusting *etc*
- (d) Year must be indicated
- (e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4
- (f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)
- (g) Remarks may include: Climatic conditions; Reference to analytical method and information on which metabolites are included

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active ingredient : **Prosulfocarb** Producer of commercial product : GLOBACHEM NV
 Crop/crop group : Wheat / Cereals
 Responsible body for reporting (name, address) : ANADIAG, 16 rue Ampère Page : 63/2
 Country : Northern France Indoor/Glasshouse/Outdoor : Outdoor
 Content of active substance (g/kg or g/l) : prosulfocarb 800 g/L Other a.i. in formulation : -
 Formulation (e.g. WP) : EC (common name and content) :
 Commercial product (name) : **PROSULFOCARB 800 g/L** Residues calculated as : mg/kg prosulfocarb

1 Report-No ; Location including Postal code	2 Commodity /Variety (a)	3 Date of (b) 1) Sowing 2) Flowering 3) Harvest (b)	4 Method of treatment (c)	5 Application rate per treatment (actual)			6 Dates of treatment or n°. of treatm. and last date (d)	7 Growth stage at last treatm. or date(e)	8 Portion analysed (a)	9 Residues (mg/kg)	10 PHI (days) (f)	11 Remarks (g)
				g a.i./ha (h)	Water (l/ha)	g a.i./hl (h)						
B1234 BP1 Engenville (45300) Northern France	Wheat / Premio	1) 22/10/11 2) - 3) -	Foliar spray	3827	287	1333	14/11/11	12	Whole plant Whole plant Whole plant Whole plant Whole plant Whole plant	278.3 122.4 74.2 57.5 13.7 2.7	0 1 2 4 7 14	LOQ prosulfocarb 0.01 mg/kg

Remarks:

- (a) According to EEC and Codex Classification (both) should be used⁷
- (f) Only if relevant
- (g) High or low volume spraying, spreading, dusting *etc*
- (h) Year must be indicated
- (i) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4
- (f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)
- (g) Remarks may include: Climatic conditions; Reference to analytical method and information on which metabolites are included

Table A 8: Summary tables of the residue studies used for the refinement of the DT₅₀ of prosulfocarb in winter wheat plants (including weather data)

Country Year Trial No.	Application					Average T	Rainfall	Residues (prosulfocarb)			DT50
	Formu-lation	N°	kg a.i./ha	L/ha	Growth stage (BBCH)			Commodity and growth stage (BBCH)	PHI (days)	mg/kg	
North France 2009 A9051 AN1	800 EC	1	4.093	307	12	9.6°C	0 mm	Whole plant (12)	0	454.41	1.43 days
						9.9°C	1.1 mm	Whole plant (12)	1	316.95	
						8.5°C	12.9 mm	Whole plant (12)	2	92.47	
						11.9°C	4.3 mm	Whole plant (12)	4	20.85	
						9°C	0 mm	Whole plant (12/13)	7	10.72	
						11.9°C	0 mm	Whole plant (13)	13	1.59	
Germany 2009 A9051 GE1	800 EC	1	4.013	301	12	5°C	0 mm	Whole plant (12)	0	714.54	1.75 days
						4.6°C	0 mm	Whole plant (12)	1	452.58	
						6.2°C	2 mm	Whole plant (12)	2	327.9	
						3.8°C	0 mm	Whole plant (12)	4	123.23	
						8.1°C	0 mm	Whole plant (12)	6	38.85	
						-0.7°C	0 mm	Whole plant (12-13)	13	5.7	
North France 2011 B1234 AN1	800 EC	1	3.84	288	12	6.2°C	0 mm	Whole plant (12)	0	286.5	2.2 days
						7.1°C	0 mm	Whole plant (12)	1	233.9	
						8°C	0 mm	Whole plant (12-13)	2	135.6	
						3.1°C	0.3 mm	Whole plant (12-13)	4	42.5	
						4.4°C	0 mm	Whole plant (12-13)	7	29.4	
						0.2°C	0.3 mm	Whole plant (12-13)	14	4.4	
North France 2011 B1234 BM1	800 EC	1	4.227	317	12	13.5°C	0.3 mm	Whole plant (12)	0	443.6	1.93 days
						10.8°C	0.1 mm	Whole plant (12)	1	280.2	
						11°C	0.3 mm	Whole plant (12)	2	158.3	
						11.5°C	0.1 mm	Whole plant (12)	4	59.8	
						8.8°C	0 mm	Whole plant (12-13)	7	28	

						9.5°C	1.8 mm	Whole plant (12-13)	14	4.1	
North France	800 EC	1	3.827	287	12	8.3°C	0.3 mm	Whole plant (12)	0	278.3	1.92 days
2011						6.8°C	0.2 mm	Whole plant (12)	1	122.4	
B1234 BP1						6°C	0.1 mm	Whole plant (12)	2	74.2	
						11°C	0.2 mm	Whole plant (12)	4	57.5	
						12.3°C	0.1 mm	Whole plant (13)	7	13.7	
						8.3°C	0.2 mm	Whole plant (13)	14	2.7	

Based on these results, the half-life of prosulfocarb in the five trials was calculated in the table below.

Table A 9: DT₅₀ of prosulfocarb in winter wheat plants

Trial No.	Half-life (days)	Coefficient of determination R²
A9051 AN1	1.43	0.9042
A9051 GE1	1.75	0.9745
B1234 AN1	2.20	0.9592
B1234 BM1	1.93	0.9595
B1234 BP1	1.92	0.9293
Geometric mean	1.83	
Arithmetic mean	1.85	

Conclusion

The DT₅₀ of prosulfocarb ranged from 1.43 to 2.2 days in five residue trials conducted in winter wheat, with arithmetic and geometric means of 1.85 and 1.83 days respectively.

A 2.2 **Diflufenican**

A 2.2.1 **Stability of residues**

A 2.2.1.1 **Stability of residues during storage of samples**

A 2.2.1.1.1 **Storage stability of residues in plant products**

Comments of zRMS:	The study and the applicant conclusion have been accepted. The analytical method validation is in report No. R A9259 which is summarized in the present Section B5 of the registration report and submitted as study KCP 5.1.2.
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Reference:	KCA 6.1
Report	Frozen storage stability of diflufenican residues in oilseed rape seeds, Jonchère F., 2012, A9260.
Guideline(s):	Yes, ENV/JM/MONO(2007)17, Working document 7032/VI/95 rev. 5 (appendix H), SANCO/825/00 rev. 7, SANCO/3029/99 rev.4
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

Oilseed rape seeds were homogenized by mixing. Samples were blended under dry ice and placed for at least 12 hours at < -18°C. The amount required by the analytical method was weighed from this homogeneous matrix and placed into individual vessels. An aliquot of a solution of diflufenican in acetonitrile was added to each vessel to obtain a target initial concentration of 0.1 mg/kg. Thereafter, the samples were rehomogenised by mixing.

Residues are extracted with acetonitrile/acetic acid 99.9:0.1% in the presence of magnesium sulfate and sodium chloride. After centrifugation the extract is purified with magnesium sulfate and PSA. The internal standard (triphenylphosphate in acetonitrile) and formic acid are added to the extract before analysis by liquid chromatography using a MS/MS detector. The validation of this method was performed by ANADIAG in the study A9259 “Validation of the Analytical Method for the Determination of Diflufenican residues in Oilseed rape seeds”; Report No. R A9259” which is summarized in dRR Section B5 and submitted as study KCP 5.1.2.

The limit of quantification is 0.01 mg/kg.

Results and discussions

Table A 10: Summary of concurrent recoveries of diflufenican from sunflower seeds.

Matrix	Spike level (µg/kg)	Storage Interval (days)	Sample size (n)	Individual procedural recoveries (%)
Diflufenican				
Oilseed rape seeds	101.60	0	1	81.9
		30	1	101.0
		90	1	72.1
		180	1	89.8
		365	1	70.8
		450	1	101.3

Table A 11: Stability of diflufenican residues in sunflower seeds following storage at -18°C

Matrix	Spike level (mg/kg)	Storage interval (days)	Individual recovered residues (mg/kg)	Average amount found (mg/kg)	% of initial value ⁽¹⁾	% recovery ⁽²⁾	Residues corrected for the recovery (mg/kg) ⁽³⁾	% of initial value corrected for the recovery (%) ⁽⁴⁾
Diflufenican								
Oilseed rape seeds	0.1	0	0.102	0.089	-	81.9	0.109	-
			0.075					
			0.089					
		30	0.102	0.097	109.0	101.0	0.096	88.1
			0.91					
		90	0.080	0.081	91.0	72.1	0.112	102.8
			0.081					
		180	0.080	0.076	85.4	89.8	0.085	78.0
			0.072					
		365	0.082	0.091	102.2	70.8	0.129	118.3
			0.100					
		540	0.106	0.104	116.9	101.3	0.103	94.5
			0.101					

(1) (Value from column 2 divided by the initial value) x 100

(2) Taken from table A1

(3) (Value of column 2 divided by value of column 4) x 100

(4) (Value of column 5 divided by the initial value corrected) x 100

Conclusion

The results show a good stability of diflufenican residues in oilseed rape seeds for up to 540 days of frozen storage.

A 2.2.1.1.2 Storage stability of residues in animal products

No new studies were submitted.

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

A 2.2.2.1 Nature of residue in plants

A 2.2.2.1.1 Nature of residue in primary crops

A 2.2.2.1.1.1 Study 1

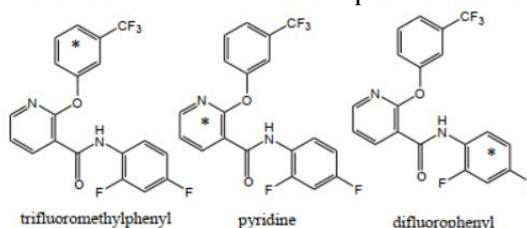
Comments of zRMS:	The study has been accepted for the purpose of this authorisation request. Diflufenican was found the major radiolabeled residue in the whole plant. Radio-labeled metabolites result from cleavage near the amide bond, resulting in pyridine amide and pyridine acid as major metabolites. Hydrolysis of the amide bond in diflufenican gave pyridine acid and presumably 2,4-difluoroaniline. Cleavage of the ether linkage in diflufenican was not found.
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Reference:	KCA 6.1
Report	A metabolism study with [¹⁴ C]Diflufenican (3 radiolabels) using oilseed rape, Quistad G.B., Bronner K and Kovatchev A., 2010, 1984W
Guideline(s):	Yes, US EPA OPPTS 860.1300, OECD 501
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

A metabolism study was conducted with radiolabeled diflufenican sprayed on oilseed rape. The study design consisted of 4 test plots: 3 treated (one for each of three radiolabel positions) and one control plot. Each of the treated plots received one application at the 6-leaf stage. The [¹⁴C]diflufenican was formulated to mimic a 50% SC. It was diluted in water and applied evenly by spraying directly onto the oilseed rape in the plot.

The chemical structures of the test substance and radiolabel positions are shown below.



Pre- and post-application radiochemical purities averaged 99.9-100%. The target rate was 80 g a.i./ha for each application. The actual application rate averaged 104-111% of target.

At 30 days (\pm 2 days) after treatment, about 10% of the whole plants (excluding roots) were harvested. These samples were analyzed due to low residues in the forage samples. At the appropriate harvest time (BBCH code 61-69, flowering), a forage sample was collected. About 25% of the crop was taken as forage. Mature seeds were collected separately at maturity (total = 3 fractions each for analysis of 31-day whole plant, forage and seeds). At mature harvest, the remaining plants (stalks, leaves) were harvested together for possible use in metabolite analysis. The harvested samples were processed and the total radioactive residue in each sample determined by combustion analysis and liquid scintillation counting.

Samples of oilseed rape (whole plants, forage, and seeds) were processed in the presence of dry ice using a Waring Blender or a K-25 food processor. The dry ice was allowed to sublime overnight in a freezer. Approximately 30 to 40 grams of each processed matrix was weighed into a centrifuge bottle. Samples were extracted twice using acetonitrile:water (1:1) each time and once using 100% acetonitrile. For each extraction, the solvent was added, the bottles were tightly capped, and shaken on a wrist-action shaker for 30 min. After centrifugation, the supernatants were combined, volume was measured, and aliquoted for LSC. Samples were then further extracted using 0.1M KOH. The solvent was added, and shaken on a wrist-action shaker for 1 hr. After centrifugation the supernatant volume was measured and aliquotted for LSC. Samples were extracted further with 24% KOH in water overnight to release hemicellulose. Some samples were then further extracted using 100% MeOH. The solvent was added, and shaken on a wrist-action shaker for 1 hr. After centrifugation, the supernatant volume was measured and aliquotted for LSC. A portion of the post-extraction solids (PES) was combusted to determine the remaining residual radiocarbon levels.

HPLC analyses were performed using Agilent series 1100 HPLC pumps with UV/VIS detectors, and Rheodyne manual injectors. Radiolabel was monitored by collection of fractions in vials followed by liquid scintillation counting. Radiocarbon chromatograms were generated using the PTRL West Radiochromatogram Program. A Chemstation data system was used to collect UV signals. All gradients were linear.

Thin layer chromatography was conducted using 20 cm x 20 cm plates containing silica gel 60, 0.25 mm thick, with fluorescent marker (254 nm). The following solvent systems were used: Method 1: ethyl acetate:hexane:acetic acid, 3:1:0.1 Developed TLC plates were exposed to phosphor screens then scanned with a Storm 820 phosphor imager system to detect radiocarbon.

Results and discussion

Table A 12: Total Radioactive Residues (TRRs) in oilseed rape matrices.

Matrix	TRR (ppm)		
	Trifluoromethyl phenyl label	Pyridine label	Difluorophenyl label
Whole plant	0.252	0.305	0.253
Forage	0.002	0.003	0.001
Mature seeds	0.012	0.017	0.001

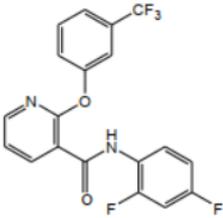
Table A 13: Summary of characterization and identification of Radioactive Residues in plant matrices following application of radiolabeled diflufenican at 80 g a.i./ha.

Compound	Whole plant		Forage		Mature seeds	
	% TRR	ppm	% TRR	ppm	% TRR	ppm
TFP label (TRR)	-	0.252	-	0.002	-	0.012
Diflufenican	46.0	0.116	< 50	< 0.001	NA	ND
Pyridine acid	6.3	0.016	< 50	< 0.001	33	0.004
Pyridine amide	11.9	0.030	50	0.001	NA	ND
Max. other single (ACN/water extractable)	17.5	0.044	< 50	< 0.001	33	0.004 ⁽¹⁾
Total identified	64.2					
Total extractable	100	-	100	-	92	-
Unextractable (PES)*	-	< 0.001	-	< 0.001	8	0.001
Pyridine label (TRR)	-	0.305	-	0.003	-	0.017
Diflufenican	79.0	0.241	< 33	< 0.001	NA	ND
Pyridine acid	1.6	0.005	33	0.001	35	0.006
Pyridine amide	4.3	0.013	33	0.001	NA	ND
Max. other single (ACN/water extractable)	3.0	0.009	< 33	< 0.001	41 ⁽¹⁾	0.007
Total identified	84.9					
Total extractable	99.7	-	100	-	94	-
Unextractable (PES)*	0.3	0.001	-	< 0.001	6	0.001
DFP label (TRR)	-	0.253	-	0.001	-	0.001
Diflufenican	77.5	0.196	NA	< 0.001	Not extracted	
Max. other single (ACN/water extractable)	4.3	0.011	NA	< 0.001		
Total identified	77.5					
Total extractable	99.6	-	100	-	NA	-
Unextractable (PES)*	0.4	0.001	-	< 0.001	-	NA

* Residues remaining after exhaustive extractions.

⁽¹⁾ 50-70% converts to pyridinic acid upon concentration and TLC analysis

Table A 14: Identification of compounds from metabolism study

Common name/code	Chemical name	Chemical structure
Diflufenican	2'4'-difluoro-2-(α,α,α -trifluoro- <i>m</i> -tolylxy)nicotinamide	

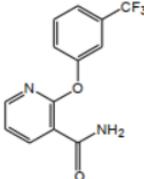
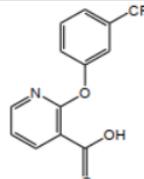
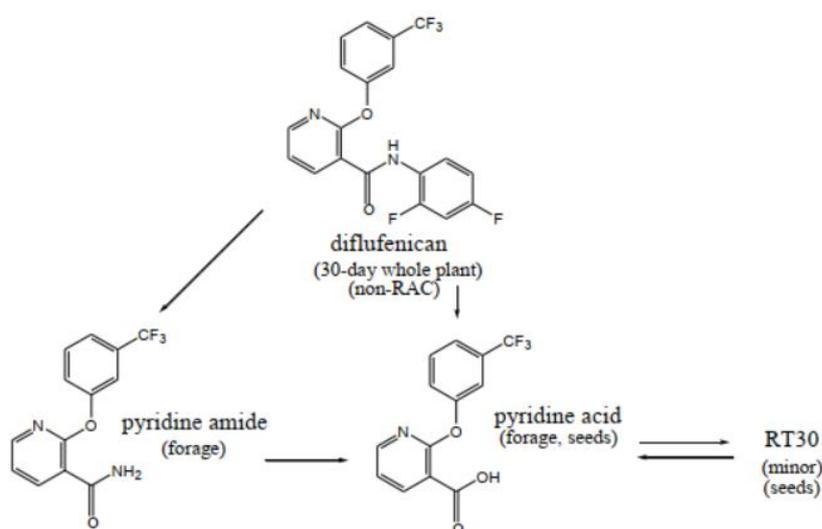
Common name/code	Chemical name	Chemical structure
Pyridine amide	2-[3-(trifluoromethyl)phenoxy]nicotinamide	
Pyridine acid	2-[3-(trifluoromethyl)phenoxy]nicotinic acid	

Figure A 1: Proposed Metabolic Profile of diflufenican in oilseed rape



Conclusions

The major radiolabeled residue in whole plant (31 days after treatment) was diflufenican. Pyridine acid and pyridine amide were major residues in forage (TFP and pyridine label). These metabolites were not detected in the DFP label matrices (as expected).

Comments of zRMS:	The data provided has been accepted for the purpose of the present authorisation request. However, the original study was not provided as well as the relevant LoA. These gaps should be completed by the applicant asap for formal reasons.
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Globachem NV has obtained access from Adama Ltd. for the following study. A letter of access will be provided.

Reference:	KCA 6.1
Report	[14C]-Diflufenican: metabolism in potatoes, Corden M., 2014, ACM/01
Guideline(s):	Yes, OECD 501
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

Test material:

Chemical name	[Trifluoromethylphenyl ring ¹⁴ C(U)]diflufenican	[Pyridine ring- ¹⁴ C]diflufenican	[Difluorophenyl- ¹⁴ C(U)]diflufenican
Specific radioactivity	2.22 GBq/mmol, 5.60 MBq/mg	2.07 GBq/mmol, 5.23 MBq/mg	2.44 GBq/mmol, 6.16 MBq/mg
Radiochemical purity by HPLC (%)	99.6	99.7	99.4

A typical commercial variety of potato was used, *Solanum tuberosum*, SOLTU, cv Cara. The test compounds were applied to the soils as a pre-emergent application (before growth stage BBCH 09) at a rate of 100 g a.i./ha.

Crop samples were taken as follows:

Sample	Growth stage	Plant part sampled
As soon as sufficient material available (36 days after planting)	BBCH 12-15	Foliage
Immature (52 days after planting)	Before BBCH 40	Foliage
Early harvest (93 days after planting)	BBCH 43-46	Foliage, Tuber
Main harvest (105-125 days after planting)	BBCH 47-49	Foliage, Tuber

Samples were stored frozen (approximately -20°C). Prior to TRR determination, samples were defrosted and homogenised in a food processor. Samples were weighed for radioassay by combustion and LSC to allow determination of the TRR. For the main harvest foliage, total radioactive residues were determined by summing the radioactivity in the extracts and unextractable residue. Main harvest tubers were peeled to provide tuber flesh and tuber peel samples which were homogenised and analysed separately.

Foliage, Tuber (early harvest), Tuber flesh and peel (main harvest): 50 g of homogenised plant sample were weighed into centrifuge pots and were extracted with acetonitrile using a homogeniser. The samples were centrifuged and the extract decanted. The residue was sequentially extracted in the same way using acetonitrile (twice) and acetonitrile:water 1:1 (twice). 2 x 1 mL aliquots of extracts were taken for LSC. The radioactivity remaining in the unextractable residue, following drying, was determined by combustion and LSC.

Radioactivity in liquid samples was quantified by LSC using a Perkin Elmer Packard liquid scintillation counter with automatic external standard quench correction. Radioactivity in plant samples was determined after combustion in oxygen using an automatic sample oxidiser (Perkin Elmer 307). The combustion products were absorbed into CarboSorb E and mixed with the scintillation cocktail PermaFluor E+.

Thin layer chromatography was carried out using pre-layered, glass backed silica gel plates with fluorescent indicator (SilG25 UV 254). Chromatographic correspondence of the test substance to radioactive components was determined following co-elution of sample with the non-labelled test substance. The reference compounds used were diflufenican, DFF acid and DFF amide only.

Results and discussion

Table A 15: Total Radioactive Residues (TRRs) in potato matrices.

Matrix	PHI (days)	TRR (ppm)		
		¹⁴ C Trifluoro-methylphenyl label	¹⁴ C Pyridine label	¹⁴ C Difluorophenyl label
As soon as sufficient material is available, foliage	36	0.003	0.004	0.002
Immature sample, foliage	52	0.002	0.002	0.001
Early harvest, foliage	93	0.017	0.017	0.006
Early harvest, tuber	93	0.008	0.008	0.001
Main harvest, foliage	105	0.017	0.016	0.004
Main harvest, tuber peel	125	0.016	0.017	0.007
Main harvest, tuber flesh	125	0.003	0.006	< 0.001
Main harvest, whole tuber	125	0.004	0.007	0.001

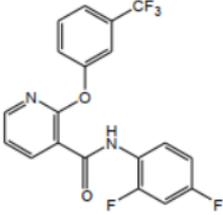
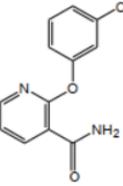
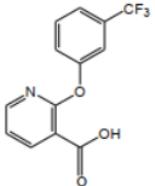
Table A 16: Summary of characterization and identification of Radioactive Residues in plant matrices following application of radiolabeled diflufenican at 100 g a.i./ha.

Compound	Early harvest foliage samples		Early harvest tuber samples		Main harvest foliage samples		Main harvest tuber peel samples		Main harvest tuber flesh samples		Main harvest whole tuber samples	
	% TRR	ppm	% TRR	ppm	% TRR	ppm	% TRR	ppm	% TRR	ppm	% TRR	ppm
¹⁴C Trifluoromethylphenyl label												
Diflufenican	14.3	0.002	3.5	< 0.001	17.7	0.003	54.6	0.008	-	-	-	-
DFF amide	29.8	0.005	< 0.1	< 0.001	26.5	0.004	< 0.1	< 0.001	-	-	-	-
DFF acid	6.3	0.001	75.4	0.006	10.9	0.002	31.3	0.005	-	-	-	-
Unidentified polar	24.3	0.004	< 0.1	< 0.001	18.8	0.003	3.8	0.001	-	-	-	-
Others	8.0	0.001	7.1	0.001	7.2	0.001	0.7	< 0.001	-	-	-	-
Unextractable (PES)*	17.2	0.003	14.0	0.001	18.9	0.003	6.4	0.001	-	-	-	-
Unanalysed extracts	-	-	-	-	-	-	3.3	0.001	-	-	-	-
¹⁴C Pyridine label												
Diflufenican	12.0	0.002	10.6	0.001	18.2	0.003	36.8	0.006	< 0.1	< 0.001	6.3	< 0.001
DFF amide	11.7	0.002	< 0.1	< 0.001	33.9	0.005	< 0.1	< 0.001	< 0.1	< 0.001	< 0.1	< 0.001
DFF acid	14.6	0.002	66.5	0.005	11.1	0.002	46.1	0.008	46.2	0.003	46.2	0.003
Unidentified polar	15.5	0.003	< 0.1	< 0.001	14.8	0.002	3.8	0.001	21.5	0.001	18.4	0.001
Others	4.2	0.001	11.5	0.001	5.1	0.001	4.3	0.001	19.6	0.001	17.0	0.001
Unextractable (PES)*	42.1	0.007	11.3	0.001	17.0	0.003	5.7	0.001	12.8	0.001	11.6	0.001
Unanalysed extracts	-	-	-	-	-	-	3.4	< 0.001	-	-	0.6	< 0.001
¹⁴C Difluorophenyl label												
Diflufenican	-	-	-	-	46.3	0.002	81.7	0.006	-	-	-	-
DFF amide	-	-	-	-	-	-	-	-	-	-	-	-
DFF acid	-	-	-	-	-	-	-	-	-	-	-	-
Unidentified polar	-	-	-	-	15.9	0.001	2.6	< 0.001	-	-	-	-

Compound	Early harvest foliage samples		Early harvest tuber samples		Main harvest foliage samples		Main harvest tuber peel samples		Main harvest tuber flesh samples		Main harvest whole tuber samples	
	% TRR	ppm	% TRR	ppm	% TRR	ppm	% TRR	ppm	% TRR	ppm	% TRR	ppm
Others	-	-	-	-	14.9	0.001	1.5	< 0.001	-	-	-	-
Unextractable (PES)*	-	-	-	-	23.0	0.001	11.2	0.001	-	-	-	-
Unanalysed extracts	-	-	-	-	-	-	2.9	< 0.001	-	-	-	-

* Residues remaining after exhaustive extractions.

Table A 17: Identification of compounds from metabolism study

Common name/code	Chemical name	Chemical structure
Diflufenican	2'4'-difluoro-2-(α,α,α -trifluoro- <i>m</i> -tolxyloxy)nicotinamide	
Pyridine amide	2-[3-(trifluoromethyl)phenoxy]nicotinamide	
Pyridine acid	2-[3-(trifluoromethyl)phenoxy]nicotinic acid	

Conclusions

The TRR was low (<0.01 mg/kg) for all samples except early harvest foliage, main harvest foliage and main harvest tuber peel. Samples of early harvest tuber and main harvest tuber flesh had TRR values of 0.006 - 0.008 mg/kg therefore were not investigated further.

In the early harvest foliage samples characterised further the major components identified from the chromatograms were diflufenican, DFF amide and DFF acid. Unidentified polar components accounted for up to 0.004 mg/kg of the residue. Unextractable residue accounted for no more than 0.007 mg/kg. In the main harvest foliage samples the major components identified were also diflufenican, DFF amide and DFF acid. These were present in comparable amounts. The remainder of the residue was unidentified polar components and the unextractable residue accounted for no more than 0.003 mg/kg.

In the early harvest tuber samples the main components of the residue were diflufenican and DFF acid. The remainder of the residue was composed of other non-discrete radioactivity and unextractable residues, each accounting for 0.001 mg/kg of the residue respectively. Main harvest tuber peel samples were composed of diflufenican and DFF acid. The remainder of the residue was unidentified polar components, non-discrete radioactivity and unextractable residues, none of which exceed 0.001 mg/kg. In the main harvest tuber flesh samples the major component of the residue was DFF acid (0.003 mg/kg, 46 % TRR). The remainder of the residue was unidentified polar components, non-discrete radioactivity and unextractable residues, none of which exceeded 0.001 mg/kg. The main harvest whole tuber sample residues were calculated from the individual tuber peel and tuber flesh data. The major components identified were diflufenican and DFF acid (<0.001 mg/kg, 6.3 % TRR and 0.003 mg/kg, 42.6% TRR). The remainder of the residue was unidentified polar components, non-discrete radioactivity and unextractable residues, none of which exceed 0.001 mg/kg.

None of the metabolites, known or unknown, were present at levels greater than 0.01 mg/kg (all <0.008 mg/kg). The parent diflufenican was also only present at a maximum of 0.008 mg/kg in main harvest peel. The metabolism of diflufenican in potato, and by extrapolation, in the root and tuber crop group is considered sufficiently enough well-elucidated.

A 2.2.2.1.2 Nature of residue in rotational crops

No new studies were submitted.

A 2.2.2.1.3 Nature of residues in processed commodities

No new studies were submitted.

A 2.2.2.2 Nature of residues in livestock

Now new studies were submitted.

A 2.2.3 Magnitude of residues in plants

A 2.2.3.1 Potato

Table A 18: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (DAR, Sweden, 2006)	-	-	-	-	-
cGAP EU (Art. 12, EFSA, 2013)	-	-	-	-	-
Intended cGAP (§ 5-6*)	1	0.0448 kg diflufenican/ha	NA	BBCH 09	NR

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

A 2.2.3.1.1 Study 1

Comments of zRMS:	<p>The study has been accepted.</p> <p>The objective of the study was to determine the residue levels of diflufenican in potato after a single application at pre-emergence stage of DIFLUFENICAN 500 SC (500 g as/L). The study was conducted at 2 sites in Northern Europe.</p> <p>In each trial one plot was treated once with DIFLUFENICAN 500 SC at the application rate of 0.25 L/ha (125 g/ha as diflufenican). The application was performed at pre-emergence stage. One plot remained untreated. In each trial sampling of tubers was performed at maturity of the crop (BBCH 49).</p> <p>Samples were analysed for diflufenican according to the method validated in ANA-DIAG study No. B0133 and based on the method NF EN 15662 for determination of pesticide residues using GC-MS and/or LC-MS/MS following acetonitrile extraction/partitioning and clean-up by dispersive SPE - QuEChERS-method. LC-MS/MS here was used. The validation parameters were consistent with requirements.</p>
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Reference:	KCA 6.3
Report	Determination of diflufenican residues in potato following treatment with Diflufenican 500 SC under field conditions in Northern Europe in 2010, Jonchère F., 2010d, B0132.
Guideline(s):	Yes, 7029/VI/95 rev. 5, SANCO 7525/VI/95 rev. 8, SANCO/825/00 rev. 7, SANCO/3029/99 rev.4, ENV/JM/MONO(2007)17
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Table A 19: Summary of the study 1 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treat- ment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion an- alyzed	Resi- dues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Analyte 1		
B0132 AN1 Handschuheim 67117 France Northern zone 2010	Potato/Safrane	1) 24/04/2010 2) N.r. 3) 15/07/2010 to 23/07/2010	119.2	286	41.7	12/05/2010	Pre-emer- gence	Tubers	<u>NDR</u>	-	Diflufenican 500 SC Analytical method consisted in extrac- tion with acetoni- trile/ acetic acid. Detection with UPLC MS/MS. Method fully vali- dated on oilseed rape in study B0133. LOQ: 0.01 mg/kg Untreated specimens were all <LOQ Max. storage Interval between sampling and analysis: 9 days Max. storage Interval between extraction and analysis: 1 days

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Analyte 1		
B0132 CZ1 Kostelec And Orlici 51741 Czech Republic Northern zone 2010	Potato/Agata	1) 29/04/2010 2) N.r. 3) 20/07/2010	135.0	324	41.7	15/05/2010	Pre-emergence	Tubers	<u><0.01</u>	-	Diflufenican 500 SC Analytical method consisted in extraction with acetonitrile/ acetic acid. Detection with UPLC MS/MS. Method fully validated on oilseed rape in study B0133. LOQ: 0.01 mg/kg Untreated specimens were all <LOQ Max. storage Interval between sampling and analysis: 9 days Max. storage Interval between extraction and analysis: 1 days

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

A 2.2.3.1.2 Study 2

Comments of zRMS:	<p>The study has been accepted.</p> <p>The objective of the study was to determine the residue levels of Diflufenican and its metabolites and conjugates in potatoes after one soil application of the formulated product GLOB1912H (667 g Prosulfocarb/L, 14 g Diflufenican/L), at pre-emergence of the crop at the application rate of 4.3 L/ha (2868.1 g Prosulfocarb/ha, 60.2 g Diflufenican/ha). The study was conducted under field conditions at 2 sites in Northern Europe. Both trials were sampled at normal commercial harvest.</p> <p>The analytical method MET/DIFLUFENICAN/02 was used for the analyses. This method was successfully validated for the analysis of Diflufenican and its metabolites in potato tubers within the study E21003. The LOQ was 0.01 mg/kg expressed as Diflufenican equivalent for Diflufenican and its metabolites. In summary, residues were extracted with acetonitrile and acetonitrile/water (1:1 ratio, v/v) through solid-liquid extraction. Glycerol conjugates of AE B107137 were hydrolysed in Diflufenican Acid with sodium hydroxide solution. After filtration, the final solution was concentrated, filtered and analysed by LC-MS/MS. The validation parameters were consistent with requirements.</p> <p>Residues in control samples were below the limit of quantification. The residue results for Diflufenican, Diflufenican amide and Diflufenican acid* in the treated specimens are summarised below:</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th colspan="5" style="text-align: center;">NCH (83-95 DAA)</th> </tr> <tr> <th style="width: 15%;">Trial No.</th> <th style="width: 15%;">Matrix</th> <th style="width: 20%;">Diflufenican residues (mg/kg)</th> <th style="width: 20%;">Diflufenican Amide residues (mg/kg)</th> <th style="width: 30%;">Diflufenican Acid * residues (mg/kg)</th> </tr> </thead> <tbody> <tr> <td>C1238 MA1</td> <td>Tuber</td> <td style="text-align: center;">< LOQ</td> <td style="text-align: center;">< LOQ</td> <td style="text-align: center;">< LOQ</td> </tr> <tr> <td>C1238 CZ1</td> <td>Tuber</td> <td style="text-align: center;">< LOQ</td> <td style="text-align: center;">< LOQ</td> <td style="text-align: center;">< LOQ</td> </tr> </tbody> </table> <p>DAA: Days after application NCH: Normal commercial harvest LOD □ 0.003 mg/kg (equivalent to less than 0.003 mg/kg) LOQ = 0.01 mg/kg (expressed as Diflufenican equivalent for Diflufenican and its metabolites) * Sum of residues of Diflufenican acid and Diflufenican glycerol conjugates (BCS-C086433 and BCS-C086434) after hydrolysis into Diflufenican acid.</p>	NCH (83-95 DAA)					Trial No.	Matrix	Diflufenican residues (mg/kg)	Diflufenican Amide residues (mg/kg)	Diflufenican Acid * residues (mg/kg)	C1238 MA1	Tuber	< LOQ	< LOQ	< LOQ	C1238 CZ1	Tuber	< LOQ	< LOQ	< LOQ
NCH (83-95 DAA)																					
Trial No.	Matrix	Diflufenican residues (mg/kg)	Diflufenican Amide residues (mg/kg)	Diflufenican Acid * residues (mg/kg)																	
C1238 MA1	Tuber	< LOQ	< LOQ	< LOQ																	
C1238 CZ1	Tuber	< LOQ	< LOQ	< LOQ																	

Reference:	KCA 6.3
Report	Determination of diflufenican and its metabolites and conjugates residues in potatoes following soil application with GLOB1912H under field conditions in Northern Europe in 2021, Ertus C., 2021a, C1238. (with 2 amendments)
Guideline(s):	Yes, OECD TG 509, SANTE/2019/12752, SANTE/2020/12830 Rev. 1, ENV/JM/MONO(2007)17
Deviations:	Yes, two with no impact on the study
GLP:	Yes
Acceptability:	Yes

Table A 20: Summary of the study 2 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Va- riety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treat- ment or no. of treatments and last date (c)	Growth stage at last treat- ment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Di- flufeni- can		
C1238 MA1 58710 Donnelay France Northern zone 2021	Potato Colomba	1) 14/06/2021 2) 20/07/2021- 02/08/2021 3) 07/09/2021	Prosul- focarb: 3004.7 Di- flufeni- can: 63.1	314	Prosul- focarb: 956.9 Di- flufeni- can: 20.1	16/06/2021	BBCH08	Tubers	<LOQ	-	GLOB1912H Analytical method con- sisted in extraction with acetonitrile and acetonitrile water and hydrolysis with aque- ous NaOH. Detection with HPLC- MS/MS. Method fully validated in E21003. LOQ: 0.01 mg/kg Untreated specimens were all <LOQ Max. storage interval between sampling and analysis: 28 days Max. storage interval between extraction and analysis: 1 days

Trial No./ Location/ EU zone/ Year	Commodity/ Va- riety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treat- ment or no. of treatments and last date (c)	Growth stage at last treat- ment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Di- flufeni- can		
C1238 CZ1 51745 Chleny Czech Republic Northern zone 2021	Potato Laura	1) 24/06/2021 2) N.r. 3) 02/10/2021	Prosul- focarb: 3004.7 Di- flufeni- can: 63.1	314	Prosul- focarb: 956.9 Di- flufeni- can: 20.1	29/06/2021	BBCH05	Tubers	<LOQ	-	GLOB1912H Analytical method con- sisted in extraction with acetonitrile and acetonitrile water and hydrolysis with aque- ous NaOH. Detection with HPLC- MS/MS. Method fully validated in E21003. LOQ: 0.01 mg/kg Untreated specimens were all <LOQ Max. storage interval between sampling and analysis: 9 days Max. storage interval between extraction and analysis: 1 days

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

A 2.2.3.1.3 Study 3

Comments of zRMS:	<p>The study has been accepted. This is SEU study – not relevant.</p> <p>The objective of the study was to determine the residue levels of Diflufenican and its metabolites and conjugates in potatoes after one soil application of the formulated product GLOB1912H (667 g Prosulfocarb/L, 14 g Diflufenican/L), at pre-emergence of the crop at the rate of 4.3 L/ha (2868.1 g Prosulfocarb/ha, 60.2 g Diflufenican/ha). The study was conducted under field conditions at 4 sites in Southern Europe. All the trials were sampled at normal commercial harvest.</p> <p>The analytical method MET/DIFLUFENICAN/02 was used for the analyses. This method was successfully validated for the analysis of Diflufenican and its metabolites in potato tubers during the study E21003. The LOQ was 0.01 mg/kg expressed as Diflufenican equivalent for Diflufenican and its metabolites. In summary residues were extracted with acetonitrile and acetonitrile/water (1:1 ratio, v/v) through solid-liquid extraction. Glycerol conjugates of AE B107137 were hydrolysed in Diflufenican Acid with sodium hydroxide solution. After filtration, the final solution is concentrated, filtered again and analysed by LC-MS/MS. The validation parameters were consistent with requirements.</p> <p>Residues in control samples were below the limit of quantification. The residue results for Diflufenican, Diflufenican amide, Diflufenican acid (as sum of residues of Diflufenican acid and glycerol conjugates BCS-C086433 and BCS-C086434 after hydrolysis into Diflufenican acid) in the treated specimens are summarised below:</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th colspan="5" style="text-align: center;">NCH (97-126 DAA)</th> </tr> <tr> <th style="width: 10%;">Trial No.</th> <th style="width: 10%;">Matrix</th> <th style="width: 20%;">Diflufenican residues (mg/kg)</th> <th style="width: 20%;">Diflufenican Amide residues (mg/kg)</th> <th style="width: 20%;">Diflufenican Acid * residues (mg/kg)</th> </tr> </thead> <tbody> <tr> <td>C1082 TL1</td> <td>Tuber</td> <td>< LOQ</td> <td>< LOQ</td> <td>< LOQ</td> </tr> <tr> <td>C1082 ES1</td> <td>Tuber</td> <td>< LOQ</td> <td>< LOQ</td> <td>< LOQ</td> </tr> <tr> <td>C1082 GR1</td> <td>Tuber</td> <td>< LOQ</td> <td>< LOQ</td> <td>< LOQ</td> </tr> <tr> <td>C1082 IT1</td> <td>Tuber</td> <td>< LOQ</td> <td>< LOQ</td> <td>< LOQ</td> </tr> </tbody> </table> <p>DAA: Days after application NCH: Normal commercial harvest LOD \square 0.003 mg/kg (equivalent to less than 0.003 mg/kg) LOQ = 0.01 mg/kg (expressed as Diflufenican equivalent for Diflufenican and its metabolites) * Sum of residues of Diflufenican acid and glycerol conjugates BCS-C086433 and BCS-C086434 after hydrolysis into Diflufenican acid.</p>	NCH (97-126 DAA)					Trial No.	Matrix	Diflufenican residues (mg/kg)	Diflufenican Amide residues (mg/kg)	Diflufenican Acid * residues (mg/kg)	C1082 TL1	Tuber	< LOQ	< LOQ	< LOQ	C1082 ES1	Tuber	< LOQ	< LOQ	< LOQ	C1082 GR1	Tuber	< LOQ	< LOQ	< LOQ	C1082 IT1	Tuber	< LOQ	< LOQ	< LOQ
NCH (97-126 DAA)																															
Trial No.	Matrix	Diflufenican residues (mg/kg)	Diflufenican Amide residues (mg/kg)	Diflufenican Acid * residues (mg/kg)																											
C1082 TL1	Tuber	< LOQ	< LOQ	< LOQ																											
C1082 ES1	Tuber	< LOQ	< LOQ	< LOQ																											
C1082 GR1	Tuber	< LOQ	< LOQ	< LOQ																											
C1082 IT1	Tuber	< LOQ	< LOQ	< LOQ																											

Reference:	KCA 6.3
Report	Determination of diflufenican and its metabolites and conjugates residues in potatoes following soil application with GLOB1912H under field conditions in Southern Europe in 2021, Ertus C., 2021b, C1082.
Guideline(s):	Yes, OECD TG 509, SANTE/2019/12752, SANTE/2020/12830 Rev. 1, ENV/JM/MONO(2007)17
Deviations:	No
GLP:	Yes
Acceptability:	Supplementary

Table A 21: Summary of the study 3 trials

Trial No./ Location/ EU zone/ Year	Com- modity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treat- ment or date	Por- tion ana- lyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Diflufeni- can		
C1082 TL1 Grenade sur Garonne 31330 France Southern zone 2021	Potato Agata	1) 02/04/2021 2) 22/06/2021- 29/06/2021 3) 14/07/2021- 15/07/2021	Prosul- focarb: 3059.3 Diflufeni- can: 64.2	320	Prosul- focarb: 956.0 Diflufeni- can: 20.1	06/04/2021	BBCH00	Tubers	≤ LOQ	-	GLOB1912H Analytical method consisted in ex- traction with acetonitrile and ace- tonitrile water and hydrolysis with aqueous NaOH. Detection with HPLC-MS/MS. Method fully in E21003. LOQ: 0.01 mg/kg Untreated specimens were all < LOQ. Max. storage interval between sampling and analysis: 23 days Max. storage Interval between ex- traction and analysis: 1 days
C1082 ES1 Vilamalla 17469 Spain Southern zone 2021	Potato Red Pon- tiac	1) 31/03/2021 2) 25/05/2021- 02/07/2021 3) 27/07/2021- 30/07/2021	Prosul- focarb: 2772.5 Diflufeni- can: 58.2	193	Prosul- focarb: 1436.5 Diflufeni- can: 30.2	01/04/2021	BBCH05	Tubers	≤ LOQ	-	GLOB1912H Analytical method consisted in ex- traction with acetonitrile and ace- tonitrile water and hydrolysis with aqueous NaOH. Detection with HPLC-MS/MS. Method fully validated in E21003. LOQ: 0.01 mg/kg Untreated specimens were all < LOQ. Max. storage interval between sampling and analysis: 15 days Max. storage Interval between

											extraction and analysis: 4 days
C1082 GR1 Drepano 50100 Greece Southern zone 2021	Potato Spunta	1) 11/04/2021 2) 05/06/2021- 26/06/2021 3) 08/08/2021	Prosul- focarb: 3059.3 Di flufeni- can: 64.2	320	Prosul- focarb: 956.0 Di flufeni- can: 20.1	12/04/2021	BBCH00	Tubers	< LOQ	-	GLOB1912H Analytical method consisted in ex- traction with acetonitrile and ace- tonitrile water and hydrolysis with aqueous NaOH. Detection with HPLC-MS/MS. Method fully validated in E21003. LOQ: 0.01 mg/kg Untreated specimens were all < LOQ. Max. storage interval between sampling and analysis: 7 days Max. storage Interval between ex- traction and analysis: 4 days
C1082 IT1 Casei Ger- ola 27050 Italy Southern zone 2021	Potato Hermes	1) 15/03/2021 2) N.r. 3) 20/08/2021- 22/08/2021	Prosul- focarb: 2868.1 Di flufeni- can: 60.2	300	Prosul- focarb: 956.0 Di flufeni- can: 20.1	31/03/2021	BBCH05	Tubers	< LOQ	-	GLOB1912H Analytical method consisted in ex- traction with acetonitrile and ace- tonitrile water and hydrolysis with aqueous NaOH. Detection with HPLC-MS/MS. Method fully validated in E21003. LOQ: 0.01 mg/kg Untreated specimens were all < LOQ. Max. storage interval between sampling and analysis: 9 days Max. storage Interval between ex- traction and analysis: 4 days

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

A 2.2.3.2 Sunflower

Table A 22: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (DAR, Sweden, 2006)	-	-	-	-	-
cGAP EU (Art. 12, EFSA, 2013)	-	-	-	-	-
Intended cGAP (4 7-8*)	1	0.0448 kg diflufenican/ha	NA	BBCH 09	NR

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

A 2.2.3.2.1 Study 1

Comments of zRMS:	<p>The study has been accepted.</p> <p>The objective of the study was to determine the residue levels of diflufenican in winter oilseed rape raw agricultural commodity after one application of the formulated product DIFLUFENICAN 500 SC (Diflufenican 500 g/L).</p> <p>The study was conducted at five sites in Northern and Southern Europe (UK, Germany, Northern France and Southern France). In two trials in Northern Europe (A9258 AN1 and A9258 HA1) and in one trial in Southern Europe (A9258 TL1) one plot was treated once with DIFLUFENICAN 500 SC (Diflufenican 500 g/L) at the rate of 160 mL/ha (80 g a.i./ha) at BBCH stage 16. In two trials in Northern Europe (A9258 GE1 and A9258 UK1) one plot was treated once with DIFLUFENICAN 500 SC (Diflufenican 500 g/L) at the rate of 140 mL/ha (70 g a.i./ha) at BBCH stage 16. In all trials, one plot remained untreated. The sampling was performed at maturity of the crop (BBCH 89) in all plots.</p> <p>The samples were analysed using a method validated in ANADIAG Study No. A9259 and adapted from NF EN 15662 method for determination of pesticide residues using LC-MS/MS following acetonitrile extraction/partitioning and clean-up by dispersive SPE - QuEChERS-method. Extracts were analysed using an ANADIAG in-house method based on LC-MS/MS. The LOQ was set at 0.01 mg/kg. The validation parameters were consistent with requirements. The residues determined were <LOQ.</p>
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Reference:	KCA 6.3
Report	Determination of diflufenican residue in winter oilseed rape following treatment with Diflufenican 500 SC under field conditions in northern and southern Europe in 2009-2010, Jonchère F., 2011, A9258.
Guideline(s):	Yes, 7029/VI/95 rev. 5, SANCO 7525/VI/95 rev. 8, SANCO/825/00 rev. 7, SANCO/3029/99 rev.4
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Table A 23: Summary of the study 1 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Va- riety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treat- ment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Analyte 1		
A9258 A9258 AN1 Seebach 67160 Northern France	Oilseed rape/Grizzly	4) 01/09/2009 5) 05/04/2010 to 30/04/2010 6) 12/07/2010	83.5	313	26.7	29/09/20 09	16	Seeds	<u>≤ 0.01</u>	286	Diflufenican 500 SC Analytical method con- sisted in extraction with acetonitrile/ acetic acid. Detection with LC MS/MS. Method fully validated on oilseed rape in study A9259. LOQ: 0.01 mg/kg Untreated specimens were all <LOQ Max. Storage Interval between sampling and analysis: 63 days Max. Storage Interval between extraction and analysis: 16 days
A9258 A9258 GE1 Neuenburg 79395 Northern Germany	Oilseed rape/NK Petrol	7) 19/09/2009 8) 20/04/2010 to 01/05/2010 9) 12/07/2010	67.2	288	23.3	21/10/20 09	16	Seeds	<u>≤ 0.01</u>	264	Diflufenican 500 SC Analytical method con- sisted in extraction with acetonitrile/ acetic acid. Detection with LC MS/MS. Method fully validated on oilseed rape in study A9259. LOQ: 0.01 mg/kg

Trial No./ Location/ EU zone/ Year	Commodity/ Va- riety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treat- ment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Analyte 1		
											Untreated specimens were all <LOQ Max. Storage Interval between sampling and analysis: 63 days Max. Storage Interval between extraction and analysis: 16 days
A9258 A9258 HA1 Wunstorf 31515 Northern Germany	Oilseed rape/NK Petrol	1) 28/08/2009 2) n.r. 3) 31/07/2010	77.3	290	26.7	06/11/20 09	16	Seeds	<0.01	267	Diflufenican 500 SC Analytical method con- sisted in extraction with acetonitrile/ acetic acid. Detection with LC MS/MS. Method fully validated on oilseed rape in study A9259. LOQ: 0.01 mg/kg Untreated specimens were all <LOQ Max. Storage Interval between sampling and analysis: 44 days Max. Storage Interval between extraction and analysis: 16 days

Trial No./ Location/ EU zone/ Year	Commodity/ Va- riety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treat- ment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Analyte 1		
A9258 A9258 UK1 Abingdon OX13 6 NZ Northern UK	Oilseed rape/Cas- tille	1) 27/08/2009 2) 05/05/2010 to 26/05/2010 3) 26/07/2010	66.0	283	23.3	22/10/20 09	16	Seeds	<u>≤ 0.01</u>	272	Diflufenican 500 SC Analytical method con- sisted in extraction with acetonitrile/ acetic acid. Detection with LC MS/MS. Method fully validated on oilseed rape in study A9259. LOQ: 0.01 mg/kg Untreated specimens were all <LOQ Max. Storage Interval between sampling and analysis: 63 days Max. Storage Interval between extraction and analysis: 7 days
A9258 A9258 TL1 Castelnau d'Estréte- fonds 31620 Southern France	Oilseed rape/Bil- bao	1) 03/09/2009 2) 01/04/2010 to 25/04/2010 3) 02/07/2010	84.5	317	26.7	29/10/20 09	16	Seeds	<u>≤ 0.01</u>	246	Diflufenican 500 SC Analytical method con- sisted in extraction with acetonitrile/ acetic acid. Detection with LC MS/MS. Method fully validated on oilseed rape in study A9259. LOQ: 0.01 mg/kg Untreated specimens were all <LOQ

A 2.2.3.2.2 Study 2

Comments of zRMS:	<p>The study has been accepted. This is SEU study – not relevant. See also prosulfocarb part of the present Appendix 2 – the study is also there.</p> <p>The objective of the study was to determine the residue levels of Diflufenican, Diflufenican Amide (AE 0542291), total Diflufenican Acid (AE B107137) and glycerol conjugates of AE B107137 (BCS-CO86433 and BCS-CO86434) and Prosulfocarb in sunflower seeds after one soil application of GLOB1912H (667 g Prosulfocarb/L, 14 g Diflufenican/L) at pre-emergence of the crop at the rate of 4.3 L/ha (2868.1 g Prosulfocarb/ha, 60.2 g Diflufenican/ha). The study was conducted under field conditions at 4 sites in Southern Europe. All the trials were sampled at normal commercial harvest.</p> <p>The analytical methods MET/DIFLUFENICAN/03 and MET/PROSULFOCARB/01 were used for the analyses.</p> <p>MET/DIFLUFENICAN/03 was successfully validated for the analysis of Diflufenican and its metabolites in sunflower seeds during study E21023. The LOQ was 0.01 mg/kg expressed as Diflufenican equivalent for Diflufenican and its metabolites. In summary, residues were extracted with acetonitrile and acetonitrile/water (1:1 ratio, v/v) through solid- liquid extraction. Glycerol conjugates of AE B107137 were hydrolysed into Diflufenican Acid with sodium hydroxide solution. After filtration, final solution was concentrated, filtered, and analysed by LC-MS/MS.</p> <p>MET/PROSULFOCARB/01 was successfully validated for the analysis of Prosulfocarb in sunflower seeds during the study E21024. The LOQ was 0.01 mg/kg and it is a QuEChERS-based method.</p> <p>No residues were found at or above the LOQ in untreated specimens for Diflufenican and its metabolites or Prosulfocarb.</p> <p>Residue determination in treated sunflower seeds specimens:</p> <table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <thead> <tr> <th style="width: 25%;">Specimen ID</th> <th style="width: 15%;">Diflufenican Detected (mg/kg)</th> <th style="width: 15%;">Diflufenican Amide Detected (mg/kg)</th> <th style="width: 15%;">Diflufenican Acid¹ Detected (mg/kg)</th> <th style="width: 15%;">Prosulfocarb Detected (mg/kg)</th> </tr> </thead> <tbody> <tr> <td>C1081 TL1 / TH / A</td> <td>< LOQ</td> <td><LOQ</td> <td>< LOQ</td> <td>< LOQ</td> </tr> <tr> <td>C1081 ES1 / TH / A</td> <td>< LOQ</td> <td><LOQ</td> <td>< LOQ</td> <td>< LOQ</td> </tr> <tr> <td>C1081 GR1 / TH / A</td> <td>< LOQ</td> <td><LOQ</td> <td>< LOQ</td> <td>< LOQ</td> </tr> <tr> <td>C1081 IT1 / TH / A</td> <td>< LOQ</td> <td><LOQ</td> <td>< LOQ</td> <td>< LOQ</td> </tr> </tbody> </table>	Specimen ID	Diflufenican Detected (mg/kg)	Diflufenican Amide Detected (mg/kg)	Diflufenican Acid ¹ Detected (mg/kg)	Prosulfocarb Detected (mg/kg)	C1081 TL1 / TH / A	< LOQ	<LOQ	< LOQ	< LOQ	C1081 ES1 / TH / A	< LOQ	<LOQ	< LOQ	< LOQ	C1081 GR1 / TH / A	< LOQ	<LOQ	< LOQ	< LOQ	C1081 IT1 / TH / A	< LOQ	<LOQ	< LOQ	< LOQ
Specimen ID	Diflufenican Detected (mg/kg)	Diflufenican Amide Detected (mg/kg)	Diflufenican Acid ¹ Detected (mg/kg)	Prosulfocarb Detected (mg/kg)																						
C1081 TL1 / TH / A	< LOQ	<LOQ	< LOQ	< LOQ																						
C1081 ES1 / TH / A	< LOQ	<LOQ	< LOQ	< LOQ																						
C1081 GR1 / TH / A	< LOQ	<LOQ	< LOQ	< LOQ																						
C1081 IT1 / TH / A	< LOQ	<LOQ	< LOQ	< LOQ																						

Reference:	KCA 6.3
Report	Determination of diflufenican (and its metabolites and conjugates) and prosulfocarb residues in sunflower following soil application with GLOB1912H under field conditions in Southern Europe in 2021, Ertus C., 2021c, C1081. (with amendments)
Guideline(s):	Yes, OECD TG 509, SANTE/2019/12752, SANTE/2020/12830 Rev. 1, ENV/JM/MONO(2007)17
Deviations:	Yes
GLP:	Yes
Acceptability:	Supplementary

Table A 24: Summary of the study 2 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treat- ments and last date (c)	Growth stage at last treat- ment or date	Portion ana- lyzed	Residues (mg/kg)		PHI (day s) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Prosul- focarb	Diflufeni- can		
C1081 TL1 Castelnaud d'Estrétefond s 3162 France Southern zone 2021	Sunflower Talento	1) 19/04/2021 2) 19/07/2021 – 31/07/2021 3) 14/09/2021	Prosul- focarb: 2995.6 Diflufeni- can: 62.9	313	Prosul- focarb: 956.0 Diflufeni- can: 20.1	20/04/ 2021	BBCH00	Seeds	< LOQ	< LOQ	-	GLOB1912H Analytical method consisted in extraction with acetonitrile for prosulfocarb and extraction with acetonitrile and hydrolysis with aqueous NaOH for diflufenican. Detection with LC-MS/MS. Method fully validated in E21023 and E21024. LOQ: 0.01 mg/kg Untreated specimens were all <LOQ Max. Storage Interval between sampling and analysis: 9 days Max. Storage Interval between extraction and analysis: 1 day

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treat- ments and last date (c)	Growth stage at last treat- ment or date	Portion ana- lyzed	Residues (mg/kg)		PHI (day s) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Prosul- focarb	Diflufeni- can		
C1081 GR1 Thimaria 50100 Greece Southern zone 2021	Sunflower ES Electric CLP	1) 09/04/2021 2) 21/06/2021 – 10/07/2021 3) 02/09/2021	Prosul- focarb: 2884.0 Diflufeni- can: 60.5	302	Prosul- focarb: 956.0 Diflufeni- can: 20.1	12/04/ 2021	BBCH00	Seeds	<LOQ	<LOQ	-	GLOB1912H Analytical method con- sisted in extraction with acetonitrile for prosul- focarb and extraction with acetonitrile and acetonitrile water and hydrolysis with aqueous NaOH for diflufenican. Detection with LC- MS/MS. Method fully validated in E21023 and E21024. LOQ: 0.01 mg/kg Untreated specimens were all <LOQ Max. Storage Interval between sampling and analysis: 21 days Max. Storage Interval between extraction and analysis: 1 day

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treat- ments and last date (c)	Growth stage at last treat- ment or date	Portion ana- lyzed	Residues (mg/kg)		PHI (day s) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Prosul- focarb	Diflufeni- can		
C1081 IT1 Silvano Pietra 27050 Italy Southern zone 2021	Sunflower MAS 84.02	1) 31/03/2021 2) 10/06/2021 – 05/07/2021 3) 25/08/2021	Prosul- focarb: 3059.3 Diflufeni- can: 64.2	320	Prosul- focarb: 956.0 Diflufeni- can: 20.1	09/04/ 2021	BBCH05	Seeds	< LOQ	< LOQ	-	GLOB1912H Analytical method con- sisted in extraction with acetonitrile for prosul- focarb and extraction with acetonitrile and acetonitrile water and hydrolysis with aqueous NaOH for diflufenican. Detection with LC- MS/MS. Method fully validated in E21023 and E21024. LOQ: 0.01 mg/kg Untreated specimens were all <LOQ Max. Storage Interval between sampling and analysis: 29 days Max. Storage Interval between extraction and analysis: 1 day

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

A 2.2.4 Magnitude of residues in livestock

A 2.2.4.1 Livestock feeding studies

No new studies were submitted.

A 2.2.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)

A 2.2.5.1 Distribution of the residue in peel/pulp

No new studies were submitted.

A 2.2.5.2 Processing studies on a core set of representative processes

No new studies were submitted.

A 2.2.6 Magnitude of residues in representative succeeding crops

No new studies were submitted.

A 2.2.7 Other/Special Studies

No new studies were submitted.

Appendix 3 Pesticide Residue Intake Model (PRIMO)

A 3.1 TMDI calculations



Prosulfocarb			
LOQs (mg/kg) range from:	0.01	to:	0.16
Toxicological reference values			
ADI (mg/kg bw/day):	0.005	ARfD (mg/kg bw):	0.1
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2007	Year of evaluation:	2007

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)

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	No of diets exceeding the ADI : ...			3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from	
			Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)			Commodity / group of commodities	MRLs set at the LOQ (in % of ADI)
47%	NL toddler	2.37	21%	Carrots	12%	Milk: Cattle	2%	Apples	25%
39%	UK infant	1.97	26%	Carrots	8%	Milk: Cattle	0.7%	Celeries	12%
38%	DK child	1.80	27%	Carrots	3%	Milk: Cattle	1%	Flye	8%
36%	DE child	1.79	21%	Carrots	4%	Milk: Cattle	2%	Apples	12%
33%	GEMS/Food G11	1.66	15%	Carrots	8%	Celeries	2%	Milk: Cattle	3%
29%	FR infant	1.46	22%	Carrots	3%	Milk: Cattle	1.0%	Celeries	6%
26%	FR toddler 2-3 yr	1.29	14%	Carrots	6%	Milk: Cattle	0.6%	Apples	11%
25%	SE general	1.27	17%	Carrots	2%	Milk: Cattle	0.3%	Bovine: Muscle/meat	7%
23%	FR child 3-15 yr	1.13	10%	Carrots	5%	Milk: Cattle	1%	Celeries	11%
22%	NL child	1.09	8%	Carrots	5%	Milk: Cattle	2%	Sugar beet roots	14%
22%	GEMS/Food G07	1.08	9%	Carrots	4%	Celeries	1%	Milk: Cattle	8%
21%	UK toddler	1.04	10%	Carrots	4%	Milk: Cattle	1%	Celeries	9%
21%	FI 3 yr	1.04	17%	Carrots	0.9%	Potatoes	0.4%	Strawberries	3%
20%	GEMS/Food G15	0.99	8%	Carrots	2%	Celeries	1%	Milk: Cattle	8%
19%	GEMS/Food G08	0.96	9%	Carrots	1%	Celeries	1%	Milk: Cattle	8%
18%	PT general	0.89	13%	Carrots	1%	Potatoes	0.8%	Wheat	4%
18%	IE adult	0.88	6%	Carrots	4%	Celeries	0.9%	Milk: Cattle	7%
17%	RO general	0.85	9%	Carrots	2%	Milk: Cattle	1%	Wheat	7%
16%	GEMS/Food G10	0.79	5%	Carrots	2%	Celeries	1%	Sogabeans	8%
15%	FI 6 yr	0.76	12%	Carrots	0.8%	Potatoes	0.3%	Strawberries	3%
15%	DE women 14-50 yr	0.73	6%	Carrots	2%	Milk: Cattle	0.9%	Sugar beet roots	7%
14%	FI adult	0.69	7%	Carrots	6%	Coffee beans	0.2%	Potatoes	7%
13%	DK adult	0.67	10%	Carrots	1%	Milk: Cattle	0.3%	Potatoes	3%
13%	DE general	0.66	5%	Carrots	2%	Milk: Cattle	0.8%	Sugar beet roots	7%
12%	GEMS/Food G06	0.61	2%	Carrots	1%	Wheat	1%	Celeries	8%
12%	ES child	0.58	4%	Carrots	2%	Milk: Cattle	0.9%	Wheat	8%
11%	NL general	0.55	4%	Carrots	2%	Milk: Cattle	0.6%	Sugar beet roots	6%
9%	FR adult	0.46	4%	Carrots	0.9%	Milk: Cattle	0.6%	Celeries	4%
9%	UK vegetarian	0.43	5%	Carrots	1%	Celeries	0.7%	Milk: Cattle	3%
8%	PL general	0.41	6%	Carrots	0.7%	Potatoes	0.4%	Apples	2%
8%	IT toddler	0.39	4%	Carrots	1%	Wheat	0.8%	Celeries	3%
7%	ES adult	0.37	3%	Carrots	1.0%	Milk: Cattle	0.5%	Wheat	4%
7%	UK adult	0.34	4%	Carrots	0.6%	Milk: Cattle	0.4%	Celeries	3%
7%	LT adult	0.34	3%	Carrots	0.8%	Milk: Cattle	0.6%	Potatoes	3%
6%	IT adult	0.30	3%	Carrots	0.8%	Wheat	0.6%	Celeries	2%
5%	IE child	0.26	3%	Carrots	0.7%	Milk: Cattle	0.2%	Wheat	2%

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



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

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

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)

Calculated exposure (% of ADI)		MS Diet		Exposure (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		MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
0.1%		NL toddler		1.35	0.3%		Milk: Cattle		0.1%		Apples	0.0%				
0.5%		GEMS/Food G08		0.35	0.2%		Olives for oil production		0.0%		Wheat	0.0%		Milk: Cattle		
0.5%		ES child		0.30	0.2%		Olives for oil production		0.1%		Milk: Cattle	0.0%		Wheat		
0.4%		NL child		0.77	0.1%		Milk: Cattle		0.0%		Sugar beet roots	0.0%		Wheat		
0.4%		DE child		0.74	0.1%		Milk: Cattle		0.1%		Apples	0.0%		Wheat		
0.4%		FR child 3-15 yr		0.72	0.1%		Milk: Cattle		0.0%		Wheat	0.0%		Olives for oil production		
0.3%		GEMS/Food G06		0.68	0.1%		Olives for oil production		0.1%		Wheat	0.0%		Tomatoes		
0.3%		GEMS/Food G10		0.67	0.1%		Olives for oil production		0.0%		Wheat	0.0%		Milk: Cattle		
0.3%		UK infant		0.67	0.2%		Milk: Cattle		0.0%		Wheat	0.0%		Potatoes		
0.3%		FR toddler 2-3 yr		0.65	0.1%		Milk: Cattle		0.0%		Wheat	0.0%		Apples		
0.3%		GEMS/Food G07		0.65	0.1%		Olives for oil production		0.0%		Wheat	0.0%		Milk: Cattle		
0.3%		GEMS/Food G11		0.63	0.1%		Olives for oil production		0.0%		Milk: Cattle	0.0%		Wheat		
0.3%		GEMS/Food G15		0.58	0.1%		Olives for oil production		0.0%		Wheat	0.0%		Milk: Cattle		
0.3%		DK child		0.56	0.1%		Milk: Cattle		0.1%		Rye	0.0%		Wheat		
0.3%		UK toddler		0.52	0.1%		Milk: Cattle		0.0%		Wheat	0.0%		Potatoes		
0.3%		ES adult		0.51	0.1%		Olives for oil production		0.0%		Milk: Cattle	0.0%		Wheat		
0.2%		DE women 14-50 yr		0.47	0.1%		Milk: Cattle		0.0%		Olives for oil production	0.0%		Sugar beet roots		
0.2%		DE general		0.47	0.1%		Milk: Cattle		0.0%		Olives for oil production	0.0%		Sugar beet roots		
0.2%		SE general		0.46	0.1%		Milk: Cattle		0.0%		Bovine: Muscle/meat	0.0%		Wheat		
0.2%		RO general		0.46	0.1%		Milk: Cattle		0.1%		Wheat	0.0%		Potatoes		
0.2%		PT general		0.40	0.1%		Olives for oil production		0.0%		Wheat	0.0%		Potatoes		
0.2%		IE adult		0.38	0.0%		Wheat		0.0%		Milk: Cattle	0.0%		Sweet potatoes		
0.2%		FI adult		0.36	0.1%		Coffee beans		0.0%		Rye	0.0%		Potatoes		
0.2%		NL general		0.36	0.0%		Milk: Cattle		0.0%		Wheat	0.0%		Sugar beet roots		
0.2%		FR infant		0.32	0.1%		Milk: Cattle		0.0%		Potatoes	0.0%		Apples		
0.2%		FR adult		0.31	0.0%		Milk: Cattle		0.0%		Wheat	0.0%		Olives for oil production		
0.1%		IT toddler		0.23	0.1%		Wheat		0.0%		Other cereals	0.0%		Tomatoes		
0.1%		FI 3 yr		0.21	0.0%		Potatoes		0.0%		Wheat	0.0%		Bananas		
0.1%		LT adult		0.21	0.0%		Milk: Cattle		0.0%		Potatoes	0.0%		Rye		
0.1%		DK adult		0.20	0.0%		Milk: Cattle		0.0%		Wheat	0.0%		Swine: Muscle/meat		
0.1%		UK vegetarian		0.17	0.0%		Wheat		0.0%		Milk: Cattle	0.0%		Potatoes		
0.1%		UK adult		0.17	0.0%		Wheat		0.0%		Milk: Cattle	0.0%		Potatoes		
0.1%		FI 6 yr		0.17	0.0%		Potatoes		0.0%		Wheat	0.0%		Rye		
0.1%		IT adult		0.16	0.0%		Wheat		0.0%		Tomatoes	0.0%		Apples		
0.0%		IE child		0.10	0.0%		Milk: Cattle		0.0%		Wheat	0.0%		Potatoes		
0.0%		PL general		0.10	0.0%		Potatoes		0.0%		Apples	0.0%		Tomatoes		

Conclusion:

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

A 3.2 IESTI calculations - Raw commodities

Prosulfocarb

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							
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):	
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IESTI		IESTI		IESTI new		IESTI new	
Highest % of ARfD/ADI	Commodities	MRL /input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL /input for RA (mg/kg)	Exposure (µg/kg bw)
63%	Carrots	1/1	63	24%	Celeries	15/15	24
56%	Celeries	1.5/1.5	56	20%	Carrots	1/1	20
4%	Celeriacs/turnip rooted	0.08/0.08	4.4	1%	Chamomille	2/2	1.2
3%	Parsnips	0.08/0.08	2.9	1%	Chamomille	2/2	1.2
2%	Salsifis	0.08/0.08	2.5	1%	Chamomille	2/2	1.2
2%	Potatoes	0.01/0.01	1.5	1%	Chamomille	2/2	1.2
2%	Melons	0.01/0.01	1.5	1%	Chamomille	2/2	1.2
1%	Pears	0.01/0.01	1.4	1%	Parsnips	0.08/0.08	1.1
1%	Oranges	0.01/0.01	1.3	0.9%	Celeriacs/turnip rooted	0.08/0.08	0.95
1%	Milk: Cattle	0.01/0.01	1.2	0.9%	Salsifis	0.08/0.08	0.86
1%	Watermelons	0.01/0.01	1.2	0.8%	Parsley roots/Hamburg	0.08/0.08	0.82
1%	Apples	0.01/0.01	1.1	0.8%	Rooibos	2/2	0.80
1%	Pineapples	0.01/0.01	1.0	0.8%	Rooibos	2/2	0.80
1.0%	Bananas	0.01/0.01	0.97	0.6%	Hybiscus/roselle	2/2	0.60
1.0%	Peaches	0.01/0.01	0.95	0.6%	Horseradishes	0.08/0.08	0.58
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)			

A 3.3 IESTI calculations - Processed commodities

Prosulfocarb

Processed commodities	Results for children				Results for adults				Results for children				Results for adults			
	No of processed commodities for which ARfD/ADI is exceeded (IESTI):				No of processed commodities for which ARfD/ADI is exceeded (IESTI):				No of processed commodities for which ARfD/ADI is exceeded (IESTI new):				No of processed commodities for which ARfD/ADI is exceeded (IESTI new):			
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IESTI				IESTI				IESTI new				IESTI new				
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	
36%	Carrots / juice	1/1	36	51%	Celeriacs / boiled	1.5/1.5	51	36%	Carrots / juice	1/1	36	30%	Celeriacs / boiled	1.5/1.5	30	
4%	Parsnips / boiled	0.08/0.08	4.1	8%	Carrots / canned	1/1	8.2	2%	Salsifias / boiled	0.08/0.08	1.7	8%	Carrots / canned	1/1	8.2	
2%	Salsifias / boiled	0.08/0.08	2.1	2%	Parsnips / boiled	0.08/0.08	1.7	2%	Parsnips / boiled	0.08/0.08	1.7	0.9%	Celeriacs / boiled	0.08/0.08	0.87	
1%	Celeriacs / juice	0.08/0.08	1.2	1%	Celeriacs / boiled	0.08/0.08	1.5	1%	Celeriacs / juice	0.08/0.08	1.2	0.7%	Parsnips / boiled	0.08/0.08	0.73	
1%	Sugar beets (root) / sugar	0.01/0.12	1.1	0.7%	Salsifias / boiled	0.08/0.08	0.66	1%	Sugar beets (root) /	0.01/0.12	1.1	0.7%	Salsifias / boiled	0.08/0.08	0.73	
0.9%	Potatoes / fried	0.01/0.01	0.93	0.6%	Pumpkins / boiled	0.01/0.01	0.55	0.6%	Potatoes / dried (flakes)	0.01/0.05	0.59	0.4%	Sugar beets (root) / sugar	0.01/0.12	0.44	
0.9%	Pumpkins / boiled	0.01/0.01	0.89	0.4%	Sugar beets (root) / sugar	0.01/0.12	0.44	0.5%	Apples / juice	0.01/0.01	0.54	0.4%	Pumpkins / boiled	0.01/0.01	0.40	
0.9%	Witloofs / boiled	0.01/0.01	0.89	0.4%	Cauliflowers / boiled	0.01/0.01	0.42	0.5%	Pumpkins / boiled	0.01/0.01	0.53	0.3%	Apples / juice	0.01/0.01	0.33	
0.8%	Broccoli / boiled	0.01/0.01	0.79	0.4%	Beetroots / boiled	0.01/0.01	0.39	0.5%	Oranges / juice	0.01/0.01	0.53	0.2%	Cauliflowers / boiled	0.01/0.01	0.25	
0.7%	Cauliflowers / boiled	0.01/0.01	0.70	0.3%	Apples / juice	0.01/0.01	0.33	0.5%	Broccoli / boiled	0.01/0.01	0.47	0.2%	Coffee beans / extraction	0.05/0.01	0.24	
0.7%	Escaroles/broad-leaved	0.01/0.01	0.66	0.3%	Onions / boiled	0.03/0.03	0.28	0.5%	Witloofs / boiled	0.01/0.01	0.47	0.2%	Witloofs / boiled	0.01/0.01	0.22	
0.6%	Potatoes / dried (flakes)	0.01/0.05	0.59	0.2%	Broccoli / boiled	0.01/0.01	0.24	0.4%	Potatoes / fried	0.01/0.01	0.44	0.2%	Onions / boiled	0.03/0.03	0.22	
0.6%	Leeks / boiled	0.01/0.01	0.57	0.2%	Coffee beans / extraction	0.05/0.01	0.24	0.4%	Wine grapes / juice	0.01/0.01	0.44	0.2%	Shallots / boiled	0.03/0.03	0.21	
0.5%	Apples / juice	0.01/0.01	0.54	0.2%	Courgettes / boiled	0.01/0.01	0.23	0.4%	Cauliflowers / boiled	0.01/0.01	0.42	0.2%	Wine grapes / juice	0.01/0.01	0.21	
0.5%	Oranges / juice	0.01/0.01	0.53	0.2%	Kohlrabies / boiled	0.01/0.01	0.21	0.4%	Escaroles/broad-leaved	0.01/0.01	0.40	0.2%	Broccoli / boiled	0.01/0.01	0.20	
Expand/collapse list																
<p>Conclusion: No exceedance of the toxicological reference value was identified for any unprocessed commodity. A short term intake of residues of Prosulfocarb is unlikely to present a public health risk. For processed commodities, no exceedance of the ARfD/ADI was identified.</p>																