REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: GLOB1817H

Product name: **Eledura**

Chemical active substances:

Prosulfocarb, 667 g/L
Diflufenican, 14 g/L
Halauxifen-methyl, 1.33 g/L
Cloquintocet-mexyl, 1.33 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Globachem NV

Submission date: May 2021

MS Finalisation date: January 2022

Revision date: April 2022

Version history

When	What
May 2021	Initial submission by the applicant for approval of new product.
January 2022	Initial zRMS RR
April 2022	Version modified to take into account comments of cMS and the applicant

Table of Contents

7 Metabolism and residue data (KCA section 6)

7.1 Summary and zRMS Conclusion

Chapter 7.1 is filled in by the zRMS. 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 Eledura are presented in Table 7.1-2. They have been selected from the individual GAPs in the CEU for cereals. For prosulfocarb based on Appendix II of SANCO/2824/07 rev3, for diflufenican on Appendix II of SANCO/3782/08 – rev. 1 and for halauxifen-methyl on Appendix II of SANTE/10406 /2015 rev. 1. The seasonal maximum total rates for the proposed in the present authorization request GAP are lowered as follows: for prosulfocarb from ~4 kg /ha to ~2 kg /ha, for diflufenican from 120 g /ha to 42 g /ha and for halauxifen-methyl from 14 g /ha to 4 g /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, diflufenican and halauxifen-methyl 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	Halauxifen-methyl (sum of halauxifen-methyl and halauxifen expressed as halauxifen-methyl) Reg. (EU) 2016/67
0500010	Barley	0.01*	0,02	0.02*
0500070	Rye	0.01*	0,02	0.02*
0500090	Wheat	0.01*	0,02	0.02*

All analytical methods are active substance data and were provided in the EU review of prosulfocarb, diflufenican and halauxifen-methyl.
Cloquintocet-mexyl is not an active substance and has not been reviewed under Directive 91/414/EEC or under Regulation (EC) No 1107/2009. The data for the cloquintocet-mexyl evaluation is not required according to the current legal framework.

Processing: As residues of prosulfocarb, diflufenican and halauxifen-methyl exceeding 0.1 mg/kg are not expected in treated cereals, cereals contribution to TMDIs is < 10% and the estimated daily intake is < 10% of the ARfD, investigation of the magnitude of residues in processed commodities is not needed.

Livestock dietary burdens: In the context of livestock dietary burdens for prosulfocarb, diflufenican and halauxifen-methyl and considering the results of available residues trials and primary crops metabolism studies as well as the intended GAP with the early application, the presence of residues in cereal grain is unlikely. Furthermore, for prosulfocarb and halauxifen-methyl no triggers were exceeded in burden calculations. For diflufenican, although EFSA reports trigger exceedance (EJ 2013; 11(6):3281), regarding the rate of diflufenican in the intended GAP and 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.
Thus, it can be concluded that due to the low exposure of livestock the MRLs of animal products are not expected to be exceeded after feeding when the product will be applied consistently with the intended GAP.

Chronic and acute exposure calculations were performed using the EFSA PRIMO (rev. 3.1) model. For prosulfocarb, the maximum calculated exposure values accounted for 47% of ADI (NL toddler). The results of the IESTI calculations demonstrate that in no case the IESTI is above the acute reference dose (ARfD) of 0.1 mg/kg bw/day (max. 63% for carrots for UK infant).
For diflufenican, the maximum calculated exposure values accounted for 0.7% of ADI (NL toddler). IESTI calculations were not performed since no ARfD is set.
For halauxifen-methyl, the maximum calculated exposure values accounted for 4% of ADI (NL toddler). The results of the IESTI calculations demonstrate that in no case the IESTI is above the acute reference dose (ARfD) of 0.058 mg/kg bw/day (max. 5% for potatoes for UK infant).
Thus, it can be concluded that the chronic and the short-term intakes of prosulfocarb, diflufenican and halauxifen-methyl residues are unlikely to present a public health concern when the product applied according to the recommendations.

Crops rotation: It is very unlikely that residues will be present in succeeding crops when the product will be applied consistently with the intended GAP.

Honey: winter cereals are considered a non-melliferous crop. Therefore, only the exposure through non-target plants (in-field weeds and adjacent plants) and succeeding crops are relevant.

As far as consumer health protection is concerned, zRMS agrees with the authorization of the intended uses (see Table 7.1-1).

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

Data gaps

Noticed data gaps are:
no data gaps were identified in the context of the present authorisation request.

Table 7.1-2: 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 be-tween ap-plications (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)	Central	GLOB1817H	F	Annual broad leaved weeds (BBBAN) & grasses (GGGAN)	EC	Prosulfocarb: 667 g/L Diflufenican: 14 g/L Halauxifen-methyl: 1.33 g/L	Downward spraying	BBCH10-14, (sept)oct-dec	1	-	Prosulfocarb: 0.667-2.001 Diflufenican: 0.014-0.042 Halauxifen-methyl: 0.00133-0.00399	200-300	Prosulfocarb: 2.001 Diflufenican: 0.042 Halauxifen-methyl: 0.00399	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 GLOB1817H is composed of the active substances prosulfocarb, diflufenican, halauxifen-methyl and the safener cloquintocet-mexyl.

Table 7.1-3: Toxicological reference values for the dietary risk assessment of prosulfocarb, diflufenican, halauxifen-methyl and the safener cloquintocet-mexyl

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	
Halauxifen-methyl					
ADI	EFSA	2014	0.058 mg/kg bw/d	Dietary rabbit developmental toxicity study	100
ARfD	EFSA	2014	0.058 mg/kg bw/d	Dietary rabbit developmental toxicity study	100
Cloquintocet-mexyl					
ADI	Monograph of clodinafop-propargyl	2003	0.04 mg/kg bw	24 months oral toxicity study on rats	100
ARfD	Monograph of clodinafop-propargyl	2003	1 mg/kg bw	Increased incidence of foetal anomaly on rats	100

7.1.2.1 Summary for prosulfocarb

Table 7.1-4: 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	Winter cereals	Yes	Yes (36)	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 7.1-5: Summary for diflufenican

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
1	Winter cereals	Yes	Yes (17)	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 halauxifen-methyl

Table 7.1-6: Summary for halauxifen-methyl

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	Winter cereals	Yes	Yes (43)	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 halauxifen-methyl 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.

7.1.2.4 Summary for cloquintocet-mexyl

Table 7.1-7: Summary for cloquintocet-mexyl

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance (French MRL)	Chronic risk for consumers identified?	Acute risk for consumers identified?
1	Cereals	Yes	Yes (43)	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

Cloquintocet-mexyl (safener) status under Reg. (EC) No 1107/2009 is not yet assessed at EU level. Maximum Residue Levels are not set. No toxicological information.

As residues of cloquintocet-mexyl 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 not been investigated but 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.~~
No requirement to conclude residues in succeeding crops.

7.1.2.5 Summary for GLOB1817H

Table 7.1-8: Information on GLOB1817H (KCA 6.8)

Crop	PHI for GLOB1817H proposed by applicant	PHI/ Withholding period* sufficiently supported for			PHI for GLOB1817H proposed by zRMS	zRMS Comments (if different PHI proposed)
		Prosulfocarb	Diflufenican	Halauxifen-methyl		
Cereals	NR	NR	NR	NR		

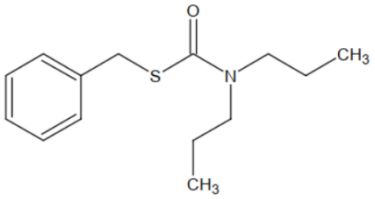
NR: not relevant
* Purpose of withholding period to be specified
** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

Assessment

7.2 Prosulfocarb

General data on prosulfocarb are summarized in the table below (last updated 2020/09/14)

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) 2021/1449. 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

No new data submitted in the framework of this application.

Table 7.2-2: Summary of stability data achieved at ≤ - 18°C (unless stated otherwise)

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products			
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

Conclusion on stability of residues during storage

Storage stability studies of prosulfocarb in this section cover the requested use on cereals for GLOB1817H.

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 ^{14}C-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 $^{14}CO_2$ 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 use of GLOB1817H on cereals.

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 DT_{90} of prosulfocarb and its relevant soil metabolites were below the trigger of 100 days. Moreover, taking into account the early application timing of GLOB1817H, a long interval before planting subsequent crops can be expected. Even in the case of crop failure, planting of subsequent crops is expected to occur with spring sown crops.

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 use of GLOB1817H on cereals.

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 use of GLOB1817H on cereals.

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).

Table 7.2-6: Summary of EU reported and new data supporting the intended uses of GLOB1817H 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	N-EU +	21 x < 0.01 mg/kg	0.01	0.01	-	-	-

	supporting data for cGAP	S-EU						

* 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 at early growth stages. Winter cereals are considered a non-melliferous crop. Therefore, only the exposure of non-target plants (in-field weeds and adjacent plants) is relevant.
Considering that for GLOB1817H only autumn use (October-December) is intended, the application timing will not coincide with the flowering period of non-target plants. Therefore, no further studies are needed.

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.

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

According to the available data, the intended uses on cereals 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)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
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)	-	-
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) Carrots/juice: 36% (based on DE child)
NTMDI (% ADI) **	-
NEDI (% ADI)**	-
NESTI (% ARfD) **	-

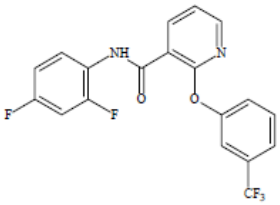
* include raw and processed commodities if both values are required for PRIMo
** if national model is available

The proposed uses of prosulfocarb in the formulation GLOB1817H 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 2020/09/18)

Table 7.3-1: General information on diflufenican

Active substance (ISO Common Name)	Diflufenican
IUPAC	2′,4′-difluoro-2-(*α*,*α*,*α*-trifluoro-*m*tolyloxy)nicotinanilide
Chemical structure	
Molecular formula	$C_{19}H_{11}F_5N_2O_2$
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) 2021/1449 Date of (01/01/2009) and reference to decision (COMMISSION DIRECTIVE 2008/66 - REGULATION (EU) No 2019/1589 and REGULATION (EU) No 540/2011).
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

No new data submitted in the framework of this application.

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

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products			
Wheat 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

Conclusion on stability of residues during storage

Storage stability studies of diflufenican in this section cover the requested use on cereals for GLOB1817H.

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

No new data submitted in the framework of this application.

Table 7.3-3: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								

Fruits and fruiting vegetable	Olives	Pyridyl, aniline and phenyl ring	Soil spraying, F	0.75	1	Ground harvest: 7, 21, 35 DAT Tree harvest: 7, 35 DAT	-	EFSA, 2012
Cereals	Wheat	Pyridyl, aniline and phenyl ring	Soil (pre-emergence) 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

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 0542291$_{11}$ (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 unknowns 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.

Conclusion on metabolism in primary crops

The data reported above are sufficient to support the intended use of GLOB1817H on cereals.

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 $B107137_{14}$, 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 use of GLOB1817H on cereals.

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)
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	UK, 2005
						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 ^{14}C-pyridyl-diflufenican and 0.035-0.717 mg/kg bw per d of ^{14}C-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 diflufenican[15] 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 ^{14}C-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 use of GLOB1817H on cereals.

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.

Table 7.3-8: Summary of EU reported and new data supporting the intended uses of GLOB1817H 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	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					
	Overall supporting data for cGAP	N-EU + S-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 0.15 kg as/ha, BBCH 30, outdoor 17 x < 0.01	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	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	N-EU + S-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 0.15 kg as/ha, BBCH 30, outdoor	0.05	0.17	-	-	-

	data for cGAP		0.06; 0.07; 13 x < 0.05; 0.14; 0.17					

* 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 at early growth stages. Winter cereals are considered a non-melliferous crop. Therefore, only the exposure through non-target plants (in-field weeds and adjacent plants) and succeeding crops are relevant.

Non-target plants:
Considering that for GLOB1817H only autumn use (October-December) is intended, the application timing will not coincide with the flowering period of non-target plants. Therefore, no further studies are needed.

Succeeding crops:
According to the rotational crop studies, no residues above 0.01 mg/kg are expected in succeeding crops for low dose rates and early application timings in cereals.
Moreover, taking into account the intended use, a long interval before planting subsequent crops can be expected because even in the case of crop failure, planting of subsequent crops is expected to occur with spring sown crops. Therefore, residues in honey are not expected and no further consideration is needed.

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

The representative uses for diflufenican in the DAR are more critical than the intended GAP of GLOB1817H. Therefore, the residue trials presented in the DAR of diflufenican can be used to support the intended use of GLOB1817H.

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.

The data submitted show that no exceedance of the MRL will occur.
According to the available data, the intended uses on cereals 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.
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)	-	-

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: Dilufenican					
Beef cattle*	0.0006	0.001	Rye straw	0.05	N
Dairy cattle*	0.0008	0.002	Rye straw	0.05	N
Ram/ewe	0.0011	0.003	Rye straw	0.1	N
Lamb	0.0014	0.004	Rye straw	0.09	N
Breeding swine	0.0003	0.0003	Barley grain	0.01	N
Finishing swine*	0.0003	0.0003	Barley grain	0.01	N
Broiler poultry	0.001	0.001	Wheat gluten meal	0.01	N
Layer poultry*	0.001	0.002	Wheat straw	0.03	N
Turkey	0.001	0.001	Wheat gluten meal	0.01	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.
Moreover, 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.
However, for the completeness it should be added that in EFSA Journal 2013; 11(6):3281 results of the dietary burden calculation reported showing the triggers exceeded for ruminants.
On the other hand, according to the metabolism studies, it is concluded that, after exposure to the maximum dietary burden (lower than the dose level of the metabolism studies), residue levels in ruminant commodities are expected to remain below the enforcement LOQ. Hence, no livestock feeding study is needed; MRLs and risk assessment values for the relevant commodities in ruminants can be established at the LOQ level.

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 GLOB1817H, a long interval before planting subsequent crops can be expected. Even in the case of crop failure, planting of subsequent crops is expected to occur with spring sown crops. So taking into account this long interval as well as the intended use in cereals, 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 GLOB1817H. 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)**	-

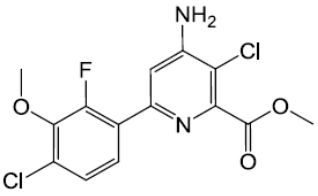
* include raw and processed commodities if both values are required for PRIMo
** if national model is available

The proposed uses of diflufenican in the formulation GLOB1817H do not represent unacceptable chronic risks for the consumer.

7.4 Halauxifen-methyl

General data on halauxifen-methyl are summarized in the table below (last updated 2020/09/22)

Table 7.4-1: General information on halauxifen-methyl

Active substance (ISO Common Name)	Halauxifen-methyl
IUPAC	methyl 4-amino-3-chloro-6-(4-chloro-2-fluoro-3- meth-oxyphenyl)pyridine-2-carboxylate
Chemical structure	
Molecular formula	~~$C_{14}H_{13}Cl_2FN_2O_3$~~ $C_{14}H_{11}Cl_2FN_2O_3$
Molar mass	~~347.17 g/mol~~ 345.16 g/mol
Chemical group	Picolinic acid
Mode of action (if available)	Synthetic auxin
Systemic	Yes
Company (ies)	Dow AgroSciences Limited*
Rapporteur Member State (RMS)	UK
Approval status	Approved Date of (05/08/2015) and reference to decision (REGU-LATION (EU) No 2015/1165 and REGULATION (EU) No 540/2011).
Restriction (e.g. is restricted to use as "...")	Restricted to use as a herbicide
Review Report	SANTE/10406/2015– rev. 1 26/01/2018
Current MRL regulation	Regulation (EU) No 2016/67
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	No
EFSA Journal : Conclusion on the peer review	Yes, EFSA, 2014**
EFSA Journal: conclusion on article 12	No**
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

7.4.1 Stability of Residues (KCA 6.1)

7.4.1.1 Stability of residues during storage of samples

Available data

No new data submitted in the framework of this application.

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

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products			
Lettuce	High water content	16 months	UK, 2013
Wheat grain	High starch content	16 months	UK, 2013
Oilseed rape	High lipid content	16 months	UK, 2013
Oranges	High acid content	16 months	UK, 2013
Animal Products			
Ruminant	Muscle, Milk	12 months (halauxifen-methyl and metabolite XDE 729); 6 months (metabolite X11449757)	UK, 2013
Poultry	Liver, Eggs	12 months (halauxifen-methyl and metabolite XDE 729); 6 months (metabolite X11449757)	UK, 2013

Conclusion on stability of residues during storage

Storage stability studies of halauxifen-methyl in this section cover the requested use on cereals for GLOB1817H.

7.4.1.2 Stability of residues in sample extracts (KCA 6.1)

Available data

From the DAR (UK, 2013):

In the multiresidue method (Annex B5 Section B.5.2.1), final sample extracts containing XDE 729 methyl ester and XDE 729 acid were evaluated for storage periods ranging from 6 to 12 days. In general, the mean recoveries of the second injection of sample extracts were within 20% of the mean recoveries obtained from the first injection. Exceptions were observed for the determination of XDE 729 methyl ester in barley grain at the 0.01 mg/kg level where the recovery of the second injection (after 9 days) decreased 22% and for the determination of XDE 729 methyl ester in kale leaves at the 0.01 mg/kg level where the recovery of the second injection (after 10 days) decreased 25%.
In the enforcement method (Annex B5 Section B.5.2.3), final sample extracts containing XDE 729 methyl ester and XDE 729 acid were evaluated for a storage period of 11 days. For XDE 729 methyl ester, on Day 0 the recoveries ranged from 81-99%, while on Day 11, the recoveries ranged from 82-98%. For XDE 729 acid, on Day 0 the recoveries ranged from 76-95%, while on Day 11, the recoveries ranged from 82-97%.
In the data generation method (Annex B7, Section B.7.6.2), final sample extracts containing XDE 729 methyl ester and XDE 729 acid were evaluated for a storage period of 4 days. For XDE 729 methyl ester, on Day 0 the recoveries ranged from 97-103%, while on Day 4, the recoveries ranged from 96-102%. For XDE 729 acid, on Day 0 the recoveries ranged from 92-105%, while on Day 4, the recoveries ranged from 90-112%.

Conclusion on stability of residues in sample extracts

The data reported above are sufficient to support the intended use of GLOB1817H on cereals.

7.4.2 Nature of residues in plants, livestock and processed commodities

7.4.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

No new data submitted in the framework of this application.

Table 7.4-3: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Root and tuber vegetables	Turnip	[^{14}C]phenyl and [^{14}C]pyridine	foliar treatment, F	10 g as/ha	1	14, 28	-	UK, 2013
Cereals	Wheat	[^{14}C]phenyl and [^{14}C]pyridine	foliar treatment, F	10 g as/ha	1	7 and 24 (immature forage and hay), 84 (mature straw and grain)	-	UK, 2013

Summary of plant metabolism studies reported in the EU

Wheat:
A single application of XDE-729 methyl with and without the safener cloquintocet-mexyl at an application rate of 10 g as/ha resulted in immature forage, hay and mature straw and grain that contained 0.09-0.20, 0.24-0.41, 0.07-0.35, and ≤ 0.004 mg/kg XR-729 methyl equivalents of the TRR, respectively.
The majority of the residues were found to be readily extractable with a mild procedure, and minimal additional residues were extractable with stronger procedures. Typically 62-77% of the residue was extracted from forage, hay and straw samples and was further characterized by HPLC.
The neutral ASE extract of immature forage consisted of multiple components, including parent XR-729 methyl (4-9% of the TRR), X11449757 (approx. 5% of the TRR), X11393729 (0.6-2.0 % of the TRR), X11861662 (4-5% of TRR), X11406790 (3-4% of TRR), X11406790 glucose conjugate (2-3% of the TRR), and X11406790 glucose-malonyl conjugate (X12245409, 6-10% of the TRR). The neutral ASE extract of hay and straw showed a similar HPLC profile to the forage extract. No other single component accounted for more than 4% of the TRR.
Overall, the average of the TRR identified in forage, hay and straw was 30%, 20% and 16% respectively. Whilst the level of TRR characterized (extractable radioactivity that was multi-component and did not co-elute with any known reference compound or identified conjugate) was on average 26%, 28% and 31%. It is stated in the study report that the characterised residue is multi-component; however, given that levels in hay and straw are between 0.072-0.113 mg/kg XDE-729 methyl equivalents, the notifier was requested to address whether any single component may exceed the trigger <0.05 mg/kg for animal feed. The notifier responded stating that “No other single component accounted for more than 4% of the TRR or 0.01 mg eq/kg”.
The samples from four different plots showed similar metabolite levels, which indicates there is no significant effect of the safener CQC on the transformation of XR-729 methyl in wheat.

No characterization of radioactivity was performed for the grain samples due to low TRR levels (≤ 0.004 mg/kg XR-729 methyl equivalents).
The amount of non-extractable, or bound radioactivity, was 24-29% (0.03-0.05 mg/kg XR-729 methyl equivalents), 27-30% (0.07-0.12 mg/kg XR-729 methyl equivalents), and 25-31% of the TRR (0.05-0.11 mg/kg XR-729 methyl equivalents) in forage, hay and straw, respectively.
The bound residues of forage, hay and straw were evaluated, and the results demonstrated broadly similar levels of incorporation or encapsulation of radioactivity into pectin, ADF soluble and ADF of forage, hay and straw tissue. There is slightly more radioactivity associated with lignin in the straw, which is to be expected as the plant grows. The residues in the pectin, lignin, ADF soluble and ADF fractions are below the 0.05 mg/kg trigger value for animal feed, therefore further characterisation of the metabolites is not required.
Metabolism of XDE-729 methyl in wheat proceeds through dissociation to produce the XDE-729 acid or demethylation of the methoxy group on the phenyl ring to produce the metabolite X11406790. X11406790 is then conjugated with glucose followed by further conjugation with malonic acid. Metabolism continues through natural incorporation of the radiolabelled carbon into natural plant constituents, such as pectin and lignin. Low levels of the X11861662 are proposed to be as a result of absorption of the photodegradation product by the plant.

Turnip:
Individual metabolite levels were low, with the majority of the radioactive residues identified as the parent XDE-729 methyl, primarily conjugated through nitrogen. Additionally, de-methylation metabolites X11393729 and X11406790, and glucose or malonyl-glucose conjugates of these metabolites were also observed. The higher amounts of conjugates to primary metabolites indicates that conjugation is a preferential route of metabolism. The overall metabolic pathway is consistent with the metabolic pathway in wheat.

Conclusion on metabolism in primary crops

The data reported above are sufficient to support the intended use of GLOB1817H on cereals.

7.4.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

No new data submitted in the framework of this application.

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

Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G *	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks	
EU data								
Leafy vegetables	Lettuce	[^{14}C]phenyl and [^{14}C]pyridine	F	10 g as/ha	14, 90, 270	BBCH 41-43 (immature); BBCH 49 (mature)	-	UK, 2013
Root and tuber vegetables	Radish					BBCH 49 (mature tops and roots)	-	UK, 2013

Cereals	Wheat					BBCH 25 (forage); BBCH 61-85 (hay); BBCH 89 (straw & grain)	-	UK, 2013

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

Summary of plant metabolism studies reported in the EU

It is unlikely that crops rotated into wheat fields treated with XDE-729 at 10 g a.e./ha would result in detectible levels of XDE-729 methyl or metabolites in any Raw Agricultural Commodity. Because of the low residue levels in all crops at all plant-back intervals, a metabolic pathway has not been proposed, and a succeeding residue trials crop study and tolerance/MRL are not necessary for succeeding crops.

Conclusion on metabolism in rotational crops

The data reported above are sufficient to support the intended use of GLOB1817H on cereals.

7.4.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

No new data submitted in the framework of this application.

Table 7.4-5: Nature of the residues in processed commodities

Conditions (Duration, Temperature, pH)	Identified compound(s) (%)	Reference
EU data		
Pasteurisation (20 minutes, 90°C, pH 4)	Parent XDE-729 methyl (99%), metabolite X11393729 (1.6%) X11393729 (halauxifen) (98.5%)	UK, 2013
Baking, boiling, brewing (60 minutes, 100°C, pH 5)	Parent XDE-729 methyl (93%), metabolite X11393729 (6.3%) X11393729 (halauxifen) (100.7%)	UK, 2013
Sterilisation (20 minutes, 120°C, pH 6)	Parent XDE-729 methyl (69.2%), metabolite X11393729 (29.6%) X11393729 (halauxifen) (100%)	UK, 2013

Under conditions representative of processing operations, ^{14}C-XDE-729 methyl is degraded with increased pH and temperature, with formation of one degradate, X11393729, accounting for up to 29.6% of the total radioactivity. ^{14}C-X11393729 can be regarded as stable to hydrolysis.

Conclusion on nature of residues in processed commodities

The data reported above are sufficient to support the intended use of GLOB1817H on cereals.

7.4.2.4 Conclusion on the nature of residues in commodities of plant origin

(KCA 6.7.1)

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

Endpoints	
Plant groups covered	Wheat and turnip, representing cereal and root/tuber crops
Rotational crops covered	Wheat, radish and lettuce, representing cereal, root and leafy vegetable crops
Metabolism in rotational crops similar to metabolism in primary crops?	Due to the low residue levels in all crops fractions (TRR < 0.01 mg eq/kg) at all plant-back intervals, a metabolic pathway has not been proposed.
Processed commodities	Halauxifen-methyl is degraded to X11393729 (halauxifen) under standard hydrolysis conditions. X11393729 (halauxifen) can be regarded as stable to hydrolysis.
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes, residues present in both, RAC and processed commodities defined as halauxifen-methyl and X11393729 (halauxifen).
Plant residue definition for monitoring	Sum halauxifen-methyl and X11393729 (halauxifen), expressed as halauxifen-methyl ~~(restricted to cereals)~~.**
Plant residue definition for risk assessment	Sum halauxifen-methyl and X11393729 (halauxifen), expressed as halauxifen-methyl ~~(restricted to cereals)~~.***
Conversion factor from enforcement to RA	None

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

7.4.2.5 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 7.4-7: Summary of animal metabolism studies

Group	**Species**	**Label position**	**No of animal**	**Application details**		**Sample details**		**Reference**
				Rate (mg/kg bw/d)	**Duration (days)**	**Commodity**	**Time of sampling**	
EU data								
Lactating ruminants	Goat	[^{14}C]phenyl and [^{14}C]pyridine	2	10 mg/kg feed	5	Milk	twice daily	UK, 2013
						Urine and faeces	daily	
						Tissues	at sacrifice	
Laying poultry	Hens	[^{14}C]phenyl and [^{14}C]pyridine	10	10 mg/kg feed	7	Eggs	twice daily	UK, 2013
						Excreta	daily	

						Tissues	at sacrifice	

Summary of plant metabolism studies reported in the EU

Metabolism of XDE-729 has been studied in both lactating goats and laying hens. The results show no difference in behaviour of XDE-729 residue when using the two radiolabelled test items: 14C-PH-label-XDE-729 methyl and 14C-PY-label-XDE-729 methyl in the tissues and edible products of lactating goats and laying hens.
Metabolism in lactating goats and laying hens is essentially the same. Similar metabolism is seen in the lactating goat and the rat and therefore additional studies in pigs are not required.
The lactating goat metabolism studies were conducted at a rate equivalent to 476 times the maximum theoretical dietary burden to dairy cattle. In edible matrices, metabolite X11449757 was observed at the highest level, 0.048 mg/kg XDE-729 methyl equivalents, in PH-labelled liver. When normalised to reflect the dietary burden (estimated as 0.021 mg/kg dry feed weight for dairy cattle), neither parent nor metabolites would be predicted at levels greater than the analytical method proposed LOQ (0.01 mg/kg).
The hen metabolism studies were conducted at a rate equivalent to 625 times the maximum theoretical dietary burden to hens. In the edible matrices analysed, metabolite X11449757 was typically observed at the highest level. When normalised to reflect the dietary burden (estimated as 0.016 mg/kg dry feed weight), parent or metabolites would be predicted at levels much less than the analytical method proposed LOQ, (0.01 mg/kg).

Conclusion on metabolism in livestock

The data reported above are sufficient to support the intended use of GLOB1817H on cereals.

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

Table 7.4-8: Summary on the nature of residues in commodities of animal origin

	Endpoints
Animals covered	Lactating goats (ruminant)
	Laying hens (poultry)
Time needed to reach a plateau concentration	3 days in milk
	Eggs: a definite plateau was not reached
Animal residue definition for monitoring	~~Not required, not proposed*~~ Animal residue definition for monitoring according to Reg. (EU) 2016/67: Halauxifen-methyl (sum of halauxifen-methyl and X11393729 (halauxifen), expressed as halauxifen-methyl)
Animal residue definition for risk assessment	~~Not required, not proposed **~~ Animal residue definition for monitoring according to Reg. (EU) 2016/67: Halauxifen-methyl (sum of halauxifen-methyl and X11393729 (halauxifen), expressed as halauxifen-methyl)
Conversion factor	Not applicable
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	Not concluded on

* 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

7.4.3 Magnitude of residues in plants (KCA 6.3)

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

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

Table 7.4-9: Summary of EU reported and new data supporting the intended uses of GLOB1817H and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Winter wheat	EFSA, 2014	N-EU	GAP on which MRL/EU a.s. assessment is based: 2 x 5.5 to 8.4 g as/ha, BBCH 13-29 and BBCH45, outdoor Grain: 11 x < 0.02 Straw: 11 x < 0.02	0.02 (grain) 0.02 (straw)	0.02 (grain) 0.02 (straw)	0.02	0.02	Y
	EFSA, 2014	S-EU	GAP on which MRL/EU a.s. assessment is based: 2 x 5.5 to 8.4 g as/ha, BBCH 13-29 and BBCH45, outdoor Grain: 11 x < 0.02 Straw: 11 x < 0.02					
Winter barley	EFSA, 2014	N-EU	GAP on which MRL/EU a.s. assessment is based: 2 x 5.4 to 8.6 g as/ha, BBCH 13-29 and BBCH45, outdoor Grain: 10 x < 0.02 Straw: 10 x < 0.02	0.02 (grain) 0.02 (straw)	0.02 (grain) 0.05 (straw)	0.02	0.02	Y
	EFSA, 2014	S-EU	GAP on which MRL/EU a.s. assessment is based: 2 x 5.4 to 8.6 g as/ha, BBCH 13-29 and BBCH45, outdoor Grain: 11 x < 0.02 Straw: 9 x < 0.02, 0.05					

* Source of EU MRL: Reg. (EU) 2016/67

7.4.3.2 Effects on the residue level in pollen and bee products

Halauxifen-methyl is a systemic herbicide applied in winter cereals at early growth stages. Winter cereals are considered a non-melliferous crop. Therefore, only the exposure of non-target plants (in-field weeds and adjacent plants) and succeeding crops are relevant.

Non-target plants:
Considering that for GLOB1817H only autumn use (October-December) is intended, the application timing will not coincide with the flowering period of non-target plants. Therefore, no further studies are needed.

Succeeding crops:
According to the rotational crop studies, low residue levels are expected in all crops at all plant-back intervals. Moreover, taking into account the intended use, a long interval before planting subsequent crops can be expected because even in the case of crop failure, planting of subsequent crops is expected to occur with spring sown crops. Therefore, residues in honey are not expected and no further consideration is needed.

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

7.4.3.3 Conclusion on the magnitude of residues in plants

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

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.
The data submitted show that no exceedance of the MRL will occur.
The uses are considered acceptable.

7.4.4 Magnitude of residues in livestock

7.4.4.1 Dietary burden calculation

Table 7.4-10: Input values for the dietary burden calculation (considering the uses authorized within the zone 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: Halauxifen-methyl (sum of halauxifen-methyl and X11393729 (halauxifen), expressed as halauxifen-methyl				
Wheat grain	0.02	Median residue (EFSA, 2014)	0.02	Highest residue (EFSA, 2014)
Wheat straw	0.02	Median residue (EFSA, 2014)	0.03	Highest residue (EFSA, 2014)
Barley grain	0.02	Median residue (EFSA, 2014)	0.02	Highest residue (EFSA, 2014)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Barley straw	0.02	Median residue (EFSA, 2014)	0.05	Highest residue (EFSA, 2014)
Rye grain	0.02	Median residue (EFSA, 2014)	0.02	Highest residue (EFSA, 2014)
Rye straw	0.02	Median residue (EFSA, 2014)	0.05	Highest residue (EFSA, 2014)
Triticale grain	0.02	Median residue (EFSA, 2014)	0.02	Highest residue (EFSA, 2014)
Triticale straw	0.02	Median residue (EFSA, 2014)	0.05	Highest residue (EFSA, 2014)
Brewer's grain dried	0.07	Median residue x PF (EFSA, 2014)	-	-
Distiller's grain dried	0.07	Median residue x PF (EFSA, 2014)	-	-
Wheat gluten meal	0.04	Median residue x PF (EFSA, 2014)	-	-
Wheat milled by-products	0.14	Median residue x PF (EFSA, 2014)	-	-

Table 7.4-11: Results of the dietary burden calculation

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Risk assessment residue definition: Halauxifen-methyl (sum of halauxifen-methyl and X11393729 (halauxifen), expressed as halauxifen-methyl					
Beef cattle*	0.0015	0.002	Wheat milled by-products	0.07	N
Dairy cattle*	0.0024	0.003	Wheat milled by-products	0.07	N
Ram/ewe	0.0026	0.003	Wheat milled by-products	0.1	N
Lamb	0.0039	0.005	Wheat milled by-products	0.11	Y
Breeding swine	0.002	0.002	Wheat milled by-products	0.09	N
Finishing swine*	0.003	0.003	Wheat milled by-products	0.09	N
Broiler poultry	0.003	0.003	Wheat milled by-products	0.05	N
Layer poultry*	0.003	0.003	Wheat milled by-products	0.05	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)
Turkey	0.003	0.003	Wheat milled by-products	0.05	N

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

7.4.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

The calculated dietary burden for lamb is exceeding the trigger values.
Based on the metabolism studies, it can be concluded that, after exposure to the maximum dietary burden, residue levels in lamb are expected to remain below 0.01 mg/kg. Hence, no livestock feeding studies are required.

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

Although the levels of residues in grain from supervised residue trials do not trigger a requirement for processing studies, studies with both wheat and grain were carried out in the DAR to evaluate the residues in processed products.

7.4.5.1 Available data for all crops under consideration

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

Table 7.4-12: Overview of the available processing studies

Processed commodity	Number of studies	Median PF *	Median CF **	Comments	Reference
EU data					
Enforcement residue definition: Halauxifen-methyl (sum of halauxifen-methyl and X11393729 (halauxifen), expressed as halauxifen-methyl					
Wheat/ cleaned grain, middlings, wheat germ, fine bran, coarse bran, total bran, refined flour, white bread, wholemeal bread and wholemeal flour.	3	Residues of halauxifen-methyl and X11393729 (halauxifen) <LOD (<0.003 mg/kg) in RAC (grain) and all processed. Halauxifen-methyl residues are not expected to concentrate in processed fractions of grain.		No comments	EFSA, 2014
Barley/ cleaned grain, pot barley, barley bran, barley flour, brewing malt, malt sprouts, spent grain, flocs, brewer's yeast and beer.	3			No comments	EFSA, 2014

* The median processing factor is obtained by calculating the median of the individual processing factors of each processing study.
** The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors of each processing study.

7.4.5.2 Conclusion on processing studies

The data reported above are sufficient to support the intended use of GLOB1817H on cereals.

7.4.6 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.

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

The available data for halauxifen-methyl sufficiently address aspects of the residue situation that might arise from the use of GLOB1817H. Therefore, other special studies are not needed.

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

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

7.4.8.1 Input values for the consumer risk assessment

Table 7.4-13: 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: Halauxifen-methyl (sum of halauxifen-methyl and X11393729 (halauxifen), expressed as halauxifen-methyl				
All commodities	MRL	Reg. (EU) 2016/67	MRL	Reg. (EU) 2016/67

7.4.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.4-14: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo	4% (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*	Potatoes: 5% (based on UK infant) Sugar beets (roots)/sugar: 4% (based on NL 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 halauxifen-methyl in the formulation GLOB1817H do not represent unacceptable acute and chronic risks for the consumer.

7.5 Cloquintocet-mexyl

Cloquintocet-mexyl is not an active substance and has not been reviewed under Directive 91/414/EEC or under Regulation (EC) No 1107/2009.
Although in agreement with the Reg. 1107/2009 the safener should be evaluated. In the Regulation, it is stated "*In addition to active substance, plant protection products may contain safeners or synergists for which similar rules should be provided. The technical rules necessary for the evaluation of such substances should be established. Substances currently on the market should only be evaluated after those rules have been established.*"
In addition, Article 26 is referred to safeners and synergists already on the market, and states: "*By 14 December 2014, a Regulation shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 79(4) establishing a work programme for the gradual review of synergists and safeners on the market when that Regulation enters into force. The Regulation shall include the establishment of data requirements, including measures to minimise animal testing, notification, evaluation, assessment and decision-making procedures. It shall require interested parties to submit all the necessary data to the Member States, the Commission and the Authority within a specified period.*"
This means that at this date, when evaluating a dossier which includes a safener, Member States should apply national rules. Being a zonal dossier, no particular evaluation of cloquintocet-mexyl is made in this dossier. Nevertheless, we highlight that since cloquintocet-mexyl is already included in the formulated product, its plant residue impacts are already accounted for in the studies.

The applicant is aware that a national MRL is established in France for cloquintocet-mexyl in cereals, laid down in the « Arrêté du 8 novembre 1996 modifiant l'arrêté du 10 février 1989 relatif aux teneurs maximales en résidus de pesticides admissibles dans et sur les céréales destinées à la consommation humaine » (Journal Officiel de la République Française (JORF), 6 décembre 1996). For the rest of countries to which this application is intended, technical rules necessary for the evaluation of safeners are not established yet. Hence, data for the cloquintocet-mexyl evaluation is not required according to the current legal framework of these countries.

The safener cloquintocet-mexyl has already been considered in the EU as part of the review of clodinafop (see DAR on clodinafop-propargyl prepared by the Netherlands, dated October 2003). It is known that cloquintocet-mexyl acts as a safener by inducing plant metabolism in wheat and increasing the rate of degradation of herbicides as a detoxification mechanism.

Indication mentioned in part Vol.3 B.7.16.1 of the monograph of clodinafop-propargyl about the assessment of cloquintocet-mexyl:

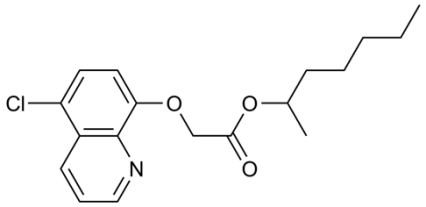
"Certain of the submitted reports contained data for the safener cloquintocet-mexyl (CGA 185072) and its metabolite(s). Data on the safener have not been evaluated. The assessment is based upon the applicant's summary of the data on the safener, which was included in doc I of the registration dossier."

Studies investigating the interaction of cloquintocet-mexyl with clodinafop-propargyl have shown that cloquintocet-mexyl increases the rate of pyridinyl ring hydroxylation, ether cleavage and glucosylation of the herbicide. Cloquintocet-mexyl has also been shown to increase the expression of energy-dependent vacuolar transporters which can mediate the removal of glucosylated metabolites from the cytoplasm.

In Germany, national MRLs for safeners are laid down in the Regulation „Verordnung über Höchstmengen an Rückständen von Pflanzenschutz- und Schädlingsbekämpfungsmitteln in oder auf Lebensmitteln (Rückstands-Höchstmengenverordnung - RHmV)", last amended on 16. Juli 2020 (BGBl. I S. 1699). Cloquintocet-mexyl is not listed in the regulation, therefore default MRL of 0.01 mg/kg cloquintocet-mexyl is set for commodities listed in the appendix of the national regulation.
TMDI (EFSA PRIMO 3.1, default MRL 0.01 mg/kg): 3 % of ADI (NL toddler) IESTI (EFSA PRIMO 3.1, default MRL 0.01 mg/kg): < <0.1 % for commodities under assessment.

General data on cloquintocet-mexyl are summarized in the table below (last updated 2020/09/24)

Table 7.5-1: General information on cloquintocet-mexyl

Active substance (ISO Common Name)	Cloquintocet-mexyl
IUPAC	(RS)-1-methylhexyl (5-chloroquinolin-8-yloxy)acetate
Chemical structure	
Molecular formula	$C_{18}H_{22}ClNO_3$
Molar mass	335.8 g/mol
Chemical group	Unclassified
Mode of action (if available)	Accelerates the herbicide detoxification process
Systemic	Yes
Company (ies)	Not required
Rapporteur Member State (RMS)	Not required
Approval status	Approved
Restriction (e.g. is restricted to use as "...")	Herbicide safener
Review Report	-
Current MRL regulation	-
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	No
EFSA Journal : Conclusion on the peer review	No**
EFSA Journal: conclusion on article 12	No**
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

7.5.1 Stability of Residues (KCA 6.1)

7.5.1.1 Stability of residues during storage of samples

Available data

Cloquintocet-mexyl studies and reports about its stability were submitted for approval of Halauxifen-Methyl.
The frozen storage stability of the safener cloquintocet-mexyl and its major metabolite cloquintocet acid have been determined in crops representing four crop groupings as part of an ongoing 24 month study. The crops included lettuce (a high-water crop), wheat grain (a dry crop), oilseed rape seed (an oily crop), and oranges (a high-acid crop). Data has been collected to 338 days (approximately 11 months) and indicates that residues of cloquintocet-mexyl and cloquintocet acid are stable, with no observable degradation.

Moreover, cloquintocet-mexyl studies and reports about its stability were submitted for approval of clodinafop-propargyl. Cloquintocet-mexyl residues are stable for 2 years for grain and straw.

Table 7.5-2: 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			
Lettuce	High water content	11 months (both)	Halauxifen-methyl UK, 2014 (Devine H.C., 2012*)
Wheat grain	High starch content	11 months (both)	
Oilseed rape	High lipid content	11 months (both)	
Oranges	High acid content	11 months (both)	
Lettuce	High water content	24 months (both)	Devine H.C., 2013*
Wheat grain	High starch content	24 months (both)	
Oilseed rape	High lipid content	24 months (both)	
Oranges	High acid content	24 months (both)	
Wheat grain	High starch	24 months (cloquintocet-mexyl) 9 months (cloquintocet-acid)	Clodinafop-propargyl NL, 2003
Wheat straw	No group	24 months (cloquintocet-mexyl) 9 months (cloquintocet-acid)	

*An interim report of frozen storage stability studies was submitted at the time of the Halauxifen-Methyl DAR. The final frozen storage stability report is now available. Final data was collected to 738 days (approximately 24 months) and indicates that residues of cloquintocet-mexyl and cloquintocet acid are stable, with no observable degradation. The final report of storage stability study of plant matrices with cloquintocet-mexyl and cloquintocet acid is submitted.

Report:	IIIA 8.1.1/02; Devine, H. C. (2013)
Title:	Cloquintocet-mexyl and Cloquintocet acid: Residue Stability Study in Crops under Frozen Storage Conditions **Final Report: 24 Months Stability Data**
Document No:	Dow AgroSciences LLC Study Number 110564 CEMAS Study Number CEMS-4958
Guidelines:	EC Guideline 1607/VI/97 rev.2, Appendix H 7032/VI/95 rev.5 U.S. EPA OPPTS 860.1380
GLP	Yes

Summary

Separate samples of agricultural commodities (lettuce, wheat grain, oilseed rape seed, and whole orange) were fortified with cloquintocet-mexyl and cloquintocet acid at 0.10 mg/kg and were stored in polyethylene containers at ≤ 18°C. The crop selection for frozen storage stability residues was chosen to represent the four European Union crop groupings (high-water content, dry, high-fat content, and high-acid content). These conditions are consistent with the storage of actual field samples. The results of this study indicate

that cloquintocet-mexyl and cloquintocet acid in crop samples from field studies can be stored frozen for at least 24 months with no observable degradation of residues.

Test Procedure
Five-gram aliquots of the specimens were placed in separate, labelled, polypropylene screw-top bottles. The recovery samples for storage stability analysis were fortified at the beginning of the study with a mixed fortification solution containing both cloquintocet-mexyl and cloquintocet acid to achieve the fortification level of 0.10 mg/kg for each analyte. An additional six spare sets of fortified specimens for each matrix were prepared at the start of the study to allow for any required repeat analyses.
The stored fortified samples were stored in a freezer set to maintain a specimen temperature of ≤18°C. The bulk unfortified control specimens were also stored at ≤18°C.

Analytical Method (Scope)
The analytical method used for the determination of cloquintocet-mexyl and cloquintocet acid was Enviro-Test Laboratories Method M313, "Determination of Residues of Cloquintocet-mexyl and its Acid Metabolite in Crop Samples by Liquid Chromatography with Tandem Mass Spectrometry Detection". This method is applicable for the quantitative determination of residues of cloquintocet-mexyl and cloquintocet acid in agricultural commodities representative of the high water content and dry European crop groupings. The method was validated over the concentration range of 0.01-0.10 mg/kg with a validated limit of quantitation of 0.01 mg/kg.

Method Performance
The efficiency of the analytical method was determined at the time of analysis for each sampling event by creating two procedural recovery (freshly fortified) samples at the initial time point and at each of the following time points; 93 days, 184 days, 338 days, 469 days, and 738 days and analysing them according to the above method.
For cloquintocet-mexyl, the average for the procedural recovery samples was within the range of 69-112% with standard deviations within the range of 6.3-14.7%.
For cloquintocet acid, the average for the procedural recovery samples was within the range 91-109% with standard deviations within the range of 3.7-6.4%.
The storage stability sample concentrations were corrected for the mean recovery values of the procedural samples.

Results of procedural recoveries and frozen Storage Stability in Wheat Grain

Actual storage time (days)	Amount Fortified mg/kg	Cloquintocet-mexyl			
		Mean Procedural Recovery %	Uncorrected Amount found (mg/kg)	Mean (mg/kg)	% Remaining
Zero	0.1 0.1 0.1	69 *(ind.: 74; 63)*	0.0724 0.0599 0.0703	0.099 (corrected because of low procedural recovery)	100%
93	0.1 0.1 0.1	112 *(ind. : 120 ; 103)*	0.1066 0.1039 0.1121	0.108	109%
184	0.1 0.1 0.1	100 *(ind.: 100 ; 100)*	0.0990 0.1010 0.0982	0.099	100%
338	0.1 0.1 0.1	104 *(ind.: 103 ; 104)*	0.1034 0.0887 0.0926	0.095	96%
469	0.1 0.1 0.1	101 *(ind.:100 ; 102)*	0.0975 0.0988 0.0961	0.097	98%

738	0.1 0.1 0.1	98 *(ind.: 97 ; 99)*	0.0947 0.0908 0.0902	0.092	93%

Results of Frozen Storage Stability in Lettuce

Actual storage time (days)	Amount Fortified mg/kg	Cloquintocet-mexyl			
		Mean Procedural Recovery %	Uncorrected Amount found (mg/kg)	Mean (mg/kg)	% Remaining
Zero	0.1 0.1 0.1	78 *(ind.: 77; 78)*	0.0831 0.0758 0.0849	0.104 corrected due to big differences between recoveries at t0 and others)	100%
93	0.1 0.1 0.1	102 *(ind.: 99; 104)*	0.1128 0.0889 0.1051	0.102	98%
184	0.1 0.1 0.1	100 *(ind.: 100; 100)*	0.1114 0.1108 0.1099	0.111	107%
338	0.1 0.1 0.1	102 *(ind.: 101; 102)*	0.0991 0.0993 0.1033	0.101	97%
469	0.1 0.1 0.1	95 *(ind.: 95; 95)*	0.1027 0.1015 0.1021	0.102	98%
738	0.1 0.1 0.1	96 *(ind.: 95; 97)*	0.0912 0.0942 0.0957	0.094	90%

Results of Frozen Storage Stability in Rape Seed

Actual storage time (days)	Amount Fortified mg/kg	Cloquintocet-mexyl			
		Mean Procedural Recovery %	Uncorrected Amount found (mg/kg)	Mean (mg/kg)	% Remaining
Zero	0.1 0.1 0.1	109 *(ind.: 108; 109)*	0.1036 0.1091 0.1100	0.108	100%
93	0.1 0.1 0.1	110 *(ind.: 112; 107)*	0.1138 0.1171 0.1108	0.114	105%
184	0.1 0.1 0.1	99 *(ind.: 99; 98)*	0.1163 0.1108 0.1113	0.113	104%
338	0.1 0.1 0.1	97 *(ind.: 97; 96)*	0.1042 0.0967 0.0962	0.099	92%
469	0.1 0.1 0.1	96 *(ind.: 99; 93)*	0.1048 0.1051 0.1022	0.104	96%
738	0.1 0.1 0.1	97 *(ind.: 98; 95)*	0.1057 0.0988 0.1023	0.102	95%

Results of Frozen Storage Stability in Whole Oranges

Actual storage time (days)	Amount Fortified mg/kg	Cloquintocet-mexyl			
		Mean Procedural Recovery %	Uncorrected Amount found (mg/kg)	Mean (mg/kg)	% Remaining
Zero	0.1 0.1 0.1	112 *(ind.:109; 114)*	0.1087 0.1128 0.1114	0.111	100%
93	0.1 0.1 0.1	85 *(ind.: 88; 82)*	0.0925 0.1000 0.0979	0.097	87%
184	0.1 0.1 0.1	103 *(ind.: 100; 106)*	0.1190 0.1214 0.1227	0.121	109%
338	0.1 0.1 0.1	99 *(ind.: 99; 98)*	0.0944 0.0970 0.0952	0.096	86%
469	0.1 0.1 0.1	95 *(ind.: 94; 95)*	0.1029 0.1000 0.1009	0.101	91%
738	0.1 0.1 0.1	98 *(ind.: 96; 99)*	0.0997 0.0999 0.1005	0.100	90%

Conclusion
The results of this study indicate that Cloquintocet-mexyl and Cloquintocet-acid in crop samples from field studies can be stored frozen for 24 months with no significant degradation of residues.

Conclusion on stability of residues during storage

The data reported above are sufficient to support the intended use of GLOB1817H on cereals.

7.5.1.2 Stability of residues in sample extracts (KCA 6.1)

Available data

In residue studies for the safener Cloquintocet-mexyl and its acid metabolite Cloquintocet, batch recoveries were carried out in parallel with the analytical batches for the residue studies and acceptable recoveries were achieved, indicating acceptable stability of residue in extracts.

Conclusion on stability of residues in sample extracts

The data reported above are sufficient to support the intended use of GLOB1817H on cereals.

7.5.2 Nature of residues in plants, livestock and processed commodities

7.5.2.1 Nature of residue in primary crops (KCA 6.2.1)

From the DAR of clodinafop (the Netherlands, 2003):

The safener CGA 185072 (cloquintocet-mexyl) is rapidly degraded to CGA 153433 in plants. At maturity, very low residues were found which did not allow for further metabolite identification. Because the safener

is applied at a 4-fold lower dose (15 g/ha versus 60 g sa/ha) compared to the active substance (clodinafop), total residues are expected never to exceed residues of clodinafop-propargyl. Given the rapid degradation of CGA 185072, no CGA 185072 is expected to be part of the terminal residues in wheat grain and straw. A limited greenhouse experiment (14 days) indicated that the safener has no significant effect on the metabolism pathway of clodinafop-propargyl in wheat.

The wheat metabolism study in the DAR of halauxifen-methyl (UK, 2013) was performed with and without cloquintocet-mexyl. There was no significant effect detected of the safener cloquinocet-mexyl on the metabolism of halauxifen-methyl.

No new data is required or submitted in the framework of this application.

7.5.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Residues in rotational crops have not been investigated but taking into account the intended use being considered here, it is very unlikely that residues will be present in rotational crops.

No new data is required or submitted in the framework of this application.

7.5.2.3 Nature of residues in processed commodities (KCA 6.5.1)

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

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

Table 7.5-3: Summary of the nature of residues in commodities of plant origin

Endpoints	
Plant groups covered	Cereals (Wheat)
Rotational crops covered	-
Metabolism in rotational crops similar to metabolism in primary crops?	-
Processed commodities	Not required
Residue pattern in processed commodities similar to pattern in raw commodities?	Not required*
Plant residue definition for monitoring	-
Plant residue definition for risk assessment	-
Conversion factor from enforcement to RA	-

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

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

From the DAR of clodinafop (the Netherlands, 2003):

Feeding studies with the safener CGA 185072 (cloquintocet-mexyl) were conducted in goat and hen at concentrations in the diet at least 100x higher than can be expected under worst-case scenarios. In both

species, radioactivity was rapidly excreted. No accumulation in edible tissues was observed. Total resides in milk and eggs were marginal (if detectable at all).

No new data is required or submitted in the framework of this application.

7.5.3 Magnitude of residues in plants (KCA 6.3)

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

For cloquintocet-mexyl, reference is made to the residue trials of halauxifen-methyl described in Section 7.4.3 above. These trials were conducted with a formulation containing the herbicide safener cloquintocet-mexyl at a nominal concentration of 7.5 g/L. No residues of cloquintocet-mexyl and cloquintocet acid were detected (< 0.005 mg/kg) in the grain or straw from any of the residue trials.

7.5.3.2 Conclusion on the magnitude of residues in plants

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

7.5.4 Magnitude of residues in livestock

Not required.

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

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

7.5.6 Magnitude of residues in representative succeeding crops

Residues in rotational crops have not been investigated but taking into account the intended use being considered here, it is very unlikely that residues will be present in rotational crops.

No new data is required or submitted in the framework of this application.

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

The available data for cloquintocet-mexyl sufficiently address aspects of the residue situation that might arise from the use of GLOB1817H. Therefore, other special studies are not needed.

7.5.8 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).

According with the European information available, cloquintocet-mexyl is not an active substance and has not been reviewed under Directive 91/414/EEC or under Regulation (EC) No 1107/2009.

Furthermore, there is no data available for the applicant indicating in which crops cloquintocet-mexyl is authorised. Hence, a risk assessment cannot be properly carried out.

However, no values above the LOQ have been found in any of the trials performed in grain. Taking this into account, it can be considered that the proposed uses of cloquintocet-mexyl in the formulation GLOB1817H do not represent unacceptable chronic and acute risks for the consumer.

7.6 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.

7.6.1 Acute consumer risk assessment from combined exposure

Not required.

7.6.2 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.

7.7 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.

EFSA (European Food Safety Authority), 2014. Conclusions on the peer review of the pesticide risk assessment of the active substance halauxifen-methyl (XDE-729 methyl). EFSA Journal (2014); 12(12):3913, 93pp. doi:10.2903/j.efsa.2014.3913.

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

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

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.10	XXXX F.	2010	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. R A9051 Anadiag GLP Unpublished	N	Globachem NV
KCA 6.10	XXXX 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					

The following tables are to be completed by MS.

List of data submitted by the applicant and not relied on

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

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

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

Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1 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

No new studies were submitted.

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

No new studies were submitted.

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:	The studies have been accepted. 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 (DT_{50}) it took for prosulfocarb undergoing decay to decrease by half was calculated. The LC-MS/MS technique was applied. 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 DT_{50} calculated is 1,8 day.

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, XXXX F., 2010, R 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, XXXX 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 1: Tier 1 tables of the residue studies used for the refinement of the DT_{50} 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 (name, address)	: ANADIAG, 16 rue Ampère 67500 HAGUENAU, France	Page	: 1/2
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	2	3	4	5			6	7	8	9	10	11
Report-No ; Location including Postal code	Commodity /Variety	Date of (b) 1) Sowing 2) Flowering 3) Harvest	Method of treatment	Application rate per treatment (actual)			Dates of treatment	Growth stage	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
				g a.i./ha	Water (l/ha)	g a.i./hl	or n°. of treatm. and last date (d)	at last treatm. or date(e)				
	(a)	(b)	(c)	(h)		(h)			(a)		(f)	(g)
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 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

Report-No ; Location including Postal code	Commodity /Variety	Date of (b) 1) Sowing 2) Flowering 3) Harvest	Method of treatment	Application rate per treatment (actual)			Dates of treatment	Growth stage	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
				g a.i./ha	Water (l/ha)	g a.i./hl	or n°. of treatm. and last date (d)	at last treatm. or date(e)				
	(a)	(b)	(c)	(h)		(h)			(a)		(f)	(g)
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 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 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 67500 HAGUENAU, France	Page	: 65/3
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	2	3	4	5			6	7	8	9	10	11
Report-No ; Location including Postal code	Commodity /Variety (a)	Date of (b) 1) Sowing 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment (actual) g a.i./ha (h)	Water (l/ha)	g a.i./hl (h)	Dates of treatment or n°. of treatm. and last date (d)	Growth stage at last treatm. or date(e)	Portion analysed (a)	Residues (mg/kg)	PHI (days) (f)	Remarks (g)
B1234 AN1	Wheat	1) 11/10/11	Foliar	3840	288	1333	10/11/11	12	Whole plant	**286.5**	0	LOQ
Seebach	/ Premio	2) -	spray						Whole plant	**233.9**	1	prosulfocarb
(67160)		3) -							Whole plant	**135.6**	2	0.01 mg/kg
Northern									Whole plant	**42.5**	4	
France									Whole plant	**29.4**	7	
									Whole plant	**4.4**	14	

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 67500 HAGUENAU, France	Page	: 66/2
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	2	3	4	5			6	7	8	9	10	11
Report-No ; Location including Postal code	Commodity /Variety (a)	Date of (b) 1) Sowing 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment (actual) g a.i./ha (h)	Water (l/ha)	g a.i./hl (h)	Dates of treatment or n°. of treatm. and last date (d)	Growth stage at last treatm. or date(e)	Portion analysed (a)	Residues (mg/kg)	PHI (days) (f)	Remarks (g)
B1234 BM1	Wheat	1) 18/10/11	Foliar	4227	317	1333	17/11/11	12	Whole plant	**443.6**	0	LOQ
Thorée les Pins	/ Premio	2) -	spray						Whole plant	**280.2**	1	prosulfocarb
(72800)		3) -							Whole plant	**158.3**	2	0.01 mg/kg
Northern France									Whole plant	**59.8**	4	
									Whole plant	**28.0**	7	
									Whole plant	**4.1**	14	

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 67500 HAGUENAU, France	Page	: 67/2
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	2	3	4	5			6	7	8	9	10	11
Report-No ; Location including Postal code	Commodity /Variety (a)	Date of (b) 1) Sowing 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment (actual) g a.i./ha (h)	Water (l/ha)	g a.i./hl (h)	Dates of treatment or n°. of treatm. and last date (d)	Growth stage at last treatm. or date(e)	Portion analysed (a)	Residues (mg/kg)	PHI (days) (f)	Remarks (g)
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 2: Summary tables of the residue studies used for the refinement of the DT_{50} of prosulfocarb in winter wheat plants (including weather data)

Country Year Trial No.	Application					Average T	Rainfall	Residues (prosulfocarb)			DT50
	Formu-la-tion	N°	kg a.i./ha	L/ha	Growth stage (BBCH)			Commodity and growth stage (BBCH)	PHI (days)	mg/kg	
North France	800 EC	1	4.093	307	12	9.6°C	0 mm	Whole plant (12)	0	454.41	1.43 days
2009						9.9°C	1.1 mm	Whole plant (12)	1	316.95	
A9051 AN1						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	800 EC	1	4.013	301	12	5°C	0 mm	Whole plant (12)	0	714.54	1.75 days
2009						4.6°C	0 mm	Whole plant (12)	1	452.58	
A9051 GE1						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	800 EC	1	3.84	288	12	6.2°C	0 mm	Whole plant (12)	0	286.5	2.2 days
2011						7.1°C	0 mm	Whole plant (12)	1	233.9	
B1234 AN1						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	800 EC	1	4.227	317	12	13.5°C	0.3 mm	Whole plant (12)	0	443.6	1.93 days
2011						10.8°C	0.1 mm	Whole plant (12)	1	280.2	
B1234 BM1						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 3: DT_{50} of prosulfocarb in winter wheat plants

Trial No.	Half-life (days)	Coefficient of determination R^2
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 DT_{50} 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

No new studies were submitted.

A 2.3 Halauxifen-methyl

No new studies were submitted.

A 2.4 Cloquintocet-mexyl

No new studies were submitted.

Appendix 3 Pesticide Residue Intake Model (PRIMo)

A 3.1 TMDI calculations

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

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)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
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%	
36%	DK child	1.80	27%	Carrots	3%	Milk: Cattle	1%	Rye	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	9%	
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	0.9%	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%	Soyabeans	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/NEDI/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)

No of diets exceeding the ADI : ---

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

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	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
0.7%	NL toddler	1.35	0.3%	Milk: Cattle	0.1%	Apples	0.0%	Wheat		
0.5%	GEMS/Food G08	0.95	0.2%	Olives for oil production	0.0%	Wheat	0.0%	Milk: Cattle		
0.5%	ES child	0.90	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/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Diflufenican (F) (F) is unlikely to present a public health concern.

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

Halauxifen-methyl

LOQs (mg/kg) range from:	0.02	to:	0.10

Toxicological reference values

ADI (mg/kg bw/day):	0.058	ARfD (mg/kg bw):	0.058
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2014	Year of evaluation:	2014

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
4%	NL toddler	2.58	2%	Milk: Cattle	0.4%	Apples	0.2%	Maize/corn	4%	
2%	NL child	1.41	0.8%	Milk: Cattle	0.3%	Sugar beet roots	0.2%	Apples	2%	
2%	DE child	1.28	0.7%	Milk: Cattle	0.4%	Apples	0.1%	Wheat	2%	
2%	UK infant	1.22	1%	Milk: Cattle	0.1%	Potatoes	0.1%	Wheat	2%	
2%	FR toddler 2 3 yr	1.13	1%	Milk: Cattle	0.1%	Apples	0.1%	Wheat	2%	
2%	FR child 3 15 yr	1.13	0.8%	Milk: Cattle	0.2%	Wheat	0.1%	Sugar beet roots	2%	
2%	GEMS/Food G11	0.98	0.3%	Soybeans	0.3%	Milk: Cattle	0.1%	Potatoes	2%	
2%	UK toddler	0.90	0.7%	Milk: Cattle	0.1%	Wheat	0.1%	Potatoes	2%	
2%	GEMS/Food G10	0.88	0.3%	Soybeans	0.2%	Milk: Cattle	0.1%	Wheat	2%	
2%	GEMS/Food G08	0.88	0.2%	Milk: Cattle	0.2%	Soybeans	0.1%	Wheat	2%	
2%	GEMS/Food G07	0.88	0.2%	Milk: Cattle	0.2%	Soybeans	0.1%	Wheat	2%	
1%	GEMS/Food G15	0.85	0.2%	Milk: Cattle	0.2%	Wheat	0.1%	Soybeans	1%	
1%	GEMS/Food G06	0.84	0.2%	Wheat	0.1%	Tomatoes	0.1%	Soybeans	1%	
1%	DK child	0.82	0.4%	Milk: Cattle	0.2%	Rye	0.2%	Wheat	1%	
1%	ES child	0.78	0.4%	Milk: Cattle	0.2%	Wheat	0.1%	Cocoa beans	1%	
1%	RO general	0.78	0.4%	Milk: Cattle	0.2%	Wheat	0.1%	Potatoes	1%	
1%	DE women 14-50 yr	0.75	0.4%	Milk: Cattle	0.2%	Sugar beet roots	0.1%	Apples	1%	
1%	SE general	0.75	0.4%	Milk: Cattle	0.2%	Bovine: Muscle/meat	0.1%	Potatoes	1%	
1%	DE general	0.73	0.4%	Milk: Cattle	0.1%	Sugar beet roots	0.1%	Apples	1%	
1%	FI adult	0.71	1.0%	Coffee beans	0.0%	Potatoes	0.0%	Rye	1%	
1%	IE adult	0.69	0.2%	Milk: Cattle	0.1%	Sweet potatoes	0.1%	Wheat	1%	
1%	NL general	0.65	0.3%	Milk: Cattle	0.1%	Sugar beet roots	0.1%	Potatoes	1%	
1%	FR infant	0.59	0.6%	Milk: Cattle	0.1%	Potatoes	0.1%	Apples	1%	
0.8%	FR adult	0.45	0.2%	Milk: Cattle	0.1%	Wine grapes	0.1%	Wheat	0.8%	
0.8%	PT general	0.44	0.2%	Potatoes	0.1%	Wheat	0.1%	Wine grapes	0.8%	
0.7%	ES adult	0.43	0.2%	Milk: Cattle	0.1%	Wheat	0.0%	Oranges	0.7%	
0.6%	FI 3 yr	0.36	0.2%	Potatoes	0.0%	Bananas	0.0%	Wheat	0.6%	
0.6%	IT toddler	0.33	0.2%	Wheat	0.1%	Other cereals	0.0%	Tomatoes	0.6%	
0.6%	DK adult	0.33	0.2%	Milk: Cattle	0.0%	Potatoes	0.0%	Wheat	0.6%	
0.6%	LT adult	0.33	0.1%	Milk: Cattle	0.1%	Potatoes	0.1%	Apples	0.6%	
0.5%	UK vegetarian	0.30	0.1%	Milk: Cattle	0.1%	Wheat	0.0%	Potatoes	0.5%	
0.5%	FI 6 yr	0.29	0.1%	Potatoes	0.0%	Cocoa beans	0.0%	Wheat	0.5%	
0.5%	UK adult	0.28	0.1%	Milk: Cattle	0.1%	Wheat	0.0%	Potatoes	0.5%	
0.4%	IT adult	0.25	0.1%	Wheat	0.0%	Tomatoes	0.0%	Apples	0.4%	
0.3%	PL general	0.20	0.1%	Potatoes	0.1%	Apples	0.0%	Tomatoes	0.3%	
0.3%	IE child	0.16	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes	0.3%	

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Halauxifen-methyl 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

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
63%	Carrots	1 / 1	63
56%	Celeries	1.5 / 1.5	56
4%	Celeriacs/turnip rooted	0.08 / 0.08	4.4
3%	Parsnips	0.08 / 0.08	2.9
2%	Salsifies	0.08 / 0.08	2.5
2%	Potatoes	0.01 / 0.01	1.5
2%	Melons	0.01 / 0.01	1.5
1%	Pears	0.01 / 0.01	1.4
1%	Oranges	0.01 / 0.01	1.3
1%	Milk: Cattle	0.01 / 0.01	1.2
1%	Watermelons	0.01 / 0.01	1.2
1%	Apples	0.01 / 0.01	1.1
1%	Pineapples	0.01 / 0.01	1.0
1.0%	Bananas	0.01 / 0.01	0.97
1.0%	Peaches	0.01 / 0.01	0.95

Expand/collapse list

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

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
24%	Celeries	1.5 / 1.5	24
20%	Carrots	1 / 1	20
1%	Chamomille	2 / 2	1.2
1%	Chamomille	2 / 2	1.2
1%	Chamomille	2 / 2	1.2
1%	Chamomille	2 / 2	1.2
1%	Chamomille	2 / 2	1.2
1%	Parsnips	0.08 / 0.08	1.1
0.9%	Celeriacs/turnip rooted	0.08 / 0.08	0.95
0.9%	Salsifies	0.08 / 0.08	0.86
0.8%	Parsley roots/Hamburg	0.08 / 0.08	0.82
0.8%	Rooibos	2 / 2	0.80
0.8%	Rooibos	2 / 2	0.80
0.6%	Hybiscus/roselle	2 / 2	0.60
0.6%	Horseradishes	0.08 / 0.08	0.58

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

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
34%	Celeries	1.5 / 1.5	34
27%	Carrots	1 / 1	27
3%	Celeriacs/turnip rooted	0.08 / 0.08	2.7
1%	Salsifies	0.08 / 0.08	1.3
1%	Milk: Cattle	0.01 / 0.01	1.2
1%	Parsnips	0.08 / 0.08	1.2
0.9%	Melons	0.01 / 0.01	0.91
0.8%	Strawberries	0.05 / 0.05	0.82
0.7%	Watermelons	0.01 / 0.01	0.73
0.7%	Oranges	0.01 / 0.01	0.67
0.7%	Potatoes	0.01 / 0.01	0.66
0.6%	Apples	0.01 / 0.01	0.62
0.6%	Bananas	0.01 / 0.01	0.61
0.6%	Pineapples	0.01 / 0.01	0.61
0.6%	Pears	0.01 / 0.01	0.59

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

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

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
14%	Celeries	1.5 / 1.5	14
12%	Carrots	1 / 1	12
1%	Chamomille	2 / 2	1.2
1%	Chamomille	2 / 2	1.2
1%	Chamomille	2 / 2	1.2
1%	Chamomille	2 / 2	1.2
1%	Chamomille	2 / 2	1.2
0.8%	Rooibos	2 / 2	0.80
0.8%	Rooibos	2 / 2	0.80
0.7%	Parsnips	0.08 / 0.08	0.68
0.6%	Hybiscus/roselle	2 / 2	0.60
0.6%	Celeriacs/turnip rooted celeries	0.08 / 0.08	0.57
0.5%	Oranges	0.01 / 0.01	0.47
0.5%	Strawberries	0.05 / 0.05	0.47
0.4%	Plums	0.01 / 0.01	0.39

Halauxifen-methyl

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

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

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

Show results for all crops

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
5%	Potatoes	0.02 / 0.02	3.1
5%	Melons	0.02 / 0.02	3.0
5%	Pears	0.02 / 0.02	2.8
5%	Oranges	0.02 / 0.02	2.7
4%	Milk: Cattle	0.02 / 0.02	2.5
4%	Watermelons	0.02 / 0.02	2.4
4%	Apples	0.02 / 0.02	2.2
3%	Pineapples	0.02 / 0.02	2.0
3%	Bananas	0.02 / 0.02	1.9
3%	Peaches	0.02 / 0.02	1.9
3%	Mangoes	0.02 / 0.02	1.6
3%	Grapefruits	0.02 / 0.02	1.6
3%	Table grapes	0.02 / 0.02	1.5
2%	Cucumbers	0.02 / 0.02	1.3
2%	Carrots	0.02 / 0.02	1.3

Expand/collapse list

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

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
1%	Head cabbages	0.02 / 0.02	0.84
1%	Watermelons	0.02 / 0.02	0.81
1%	Melons	0.02 / 0.02	0.78
1%	Milk: Cattle	0.02 / 0.02	0.77
1%	Swedes/rutabagas	0.02 / 0.02	0.68
1%	Table grapes	0.02 / 0.02	0.68
1%	Oranges	0.02 / 0.02	0.61
1%	Pears	0.02 / 0.02	0.61
1%	Potatoes	0.02 / 0.02	0.60
1%	Pineapples	0.02 / 0.02	0.59
1.0%	Yams	0.02 / 0.02	0.57
1.0%	Apples	0.02 / 0.02	0.56
1.0%	Cucumbers	0.02 / 0.02	0.56
0.9%	Aubergines/egg plants	0.02 / 0.02	0.54
0.9%	Mangoes	0.02 / 0.02	0.52

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

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
4%	Milk: Cattle	0.02 / 0.02	2.5
3%	Melons	0.02 / 0.02	1.8
3%	Watermelons	0.02 / 0.02	1.5
2%	Oranges	0.02 / 0.02	1.3
2%	Potatoes	0.02 / 0.02	1.3
2%	Apples	0.02 / 0.02	1.2
2%	Bananas	0.02 / 0.02	1.2
2%	Pineapples	0.02 / 0.02	1.2
2%	Pears	0.02 / 0.02	1.2
2%	Peaches	0.02 / 0.02	1.1
2%	Apricots	0.02 / 0.02	0.98
2%	Mangoes	0.02 / 0.02	0.94
2%	Grapefruits	0.02 / 0.02	0.94
2%	Table grapes	0.02 / 0.02	0.88
1%	Kiwi fruits (green, red,	0.02 / 0.02	0.80

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

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

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
2%	Oranges	0.02 / 0.02	0.94
1%	Plums	0.02 / 0.02	0.78
1%	Milk: Cattle	0.02 / 0.02	0.77
1%	Pears	0.02 / 0.02	0.71
1%	Mandarins	0.02 / 0.02	0.66
1%	Potatoes	0.02 / 0.02	0.62
1%	Apples	0.02 / 0.02	0.60
1.0%	Bananas	0.02 / 0.02	0.56
0.9%	Yams	0.02 / 0.02	0.55
0.9%	Kaki/Japanese persimmons	0.02 / 0.02	0.54
0.9%	Head cabbages	0.02 / 0.02	0.50
0.8%	Watermelons	0.02 / 0.02	0.49
0.8%	Wine grapes	0.02 / 0.02	0.47
0.8%	Melons	0.02 / 0.02	0.47
0.8%	Mangoes	0.02 / 0.02	0.47

A 3.3 IESTI calculations - Processed commodities

Prosulfocarb

Processed commodities

Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---				**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---				**Results for children** No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---				**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---			
IESTI				**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%	Celeries / boiled	1.5 / 1.5	51	36%	Carrots / juice	1 / 1	36	30%	Celeries / boiled	1.5 / 1.5	30
4%	Parsnips / boiled	0.08 / 0.08	4.1	8%	Carrots / canned	1 / 1	8.2	2%	Salsifies / boiled	0.08 / 0.08	1.7	8%	Carrots / canned	1 / 1	8.2
2%	Salsifies / 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%	Salsifies / boiled	0.08 / 0.08	0.66	1%	Sugar beets (root) /	0.01 / 0.12	1.1	0.7%	Salsifies / 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															

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.

Halauxifen-methyl

Processed commodities

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
4%	Sugar beets (root) / sugar	0.02 / 0.24	2.2
3%	Potatoes / fried	0.02 / 0.02	1.9
3%	Pumpkins / boiled	0.02 / 0.02	1.8
3%	Witloofs / boiled	0.02 / 0.02	1.8
3%	Broccoli / boiled	0.02 / 0.02	1.6
2%	Cauliflowers / boiled	0.02 / 0.02	1.4
2%	Escaroles/broad-leaved endives / boiled	0.02 / 0.02	1.3
2%	Potatoes / dried (flakes)	0.02 / 0.09	1.2
2%	Leeks / boiled	0.02 / 0.02	1.1
2%	Apples / juice	0.02 / 0.02	1.1
2%	Oranges / juice	0.02 / 0.02	1.1
2%	Turnips / boiled	0.02 / 0.02	1.0
2%	Parsnips / boiled	0.02 / 0.02	1.0
2%	Sweet potatoes / boiled	0.02 / 0.02	1.0
2%	Florence fennels / boiled	0.02 / 0.02	0.91

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
2%	Pumpkins / boiled	0.02 / 0.02	1.1
2%	Sugar beets (root) / sugar	0.02 / 0.24	0.88
1%	Cauliflowers / boiled	0.02 / 0.02	0.83
1%	Beetroots / boiled	0.02 / 0.02	0.78
1%	Celeries / boiled	0.02 / 0.02	0.68
1%	Apples / juice	0.02 / 0.02	0.67
0.8%	Broccoli / boiled	0.02 / 0.02	0.48
0.8%	Coffee beans / extraction	0.1 / 0.02	0.48
0.8%	Courgettes / boiled	0.02 / 0.02	0.46
0.7%	Parsnips / boiled	0.02 / 0.02	0.43
0.7%	Kohlrabies / boiled	0.02 / 0.02	0.43
0.7%	Wine grapes / juice	0.02 / 0.02	0.42
0.7%	Florence fennels / boiled	0.02 / 0.02	0.39
0.7%	Escaroles/broad-leaved	0.02 / 0.02	0.41
0.7%	Turnips / boiled	0.02 / 0.02	0.38

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

IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
4%	Sugar beets (root) /	0.02 / 0.24	2.2
2%	Potatoes / dried (flakes)	0.02 / 0.09	1.2
2%	Apples / juice	0.02 / 0.02	1.1
2%	Pumpkins / boiled	0.02 / 0.02	1.1
2%	Oranges / juice	0.02 / 0.02	1.1
2%	Broccoli / boiled	0.02 / 0.02	0.95
2%	Witloofs / boiled	0.02 / 0.02	0.95
2%	Potatoes / fried	0.02 / 0.02	0.87
2%	Wine grapes / juice	0.02 / 0.02	0.87
1%	Cauliflowers / boiled	0.02 / 0.02	0.84
1%	Escaroles/broad-leaved	0.02 / 0.02	0.80
1%	Carrots / juice	0.02 / 0.02	0.72
1%	Leeks / boiled	0.02 / 0.02	0.66
1%	Pears / juice	0.02 / 0.02	0.65
1.0%	Currants (red, black and	0.02 / 0.02	0.57

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

IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
2%	Sugar beets (root) / sugar	0.02 / 0.24	0.88
1%	Pumpkins / boiled	0.02 / 0.02	0.80
1%	Apples / juice	0.02 / 0.02	0.67
0.9%	Cauliflowers / boiled	0.02 / 0.02	0.50
0.8%	Coffee beans / extraction	0.1 / 0.02	0.48
0.7%	Witloofs / boiled	0.02 / 0.02	0.43
0.7%	Wine grapes / juice	0.02 / 0.02	0.42
0.7%	Celeries / boiled	0.02 / 0.02	0.41
0.7%	Broccoli / boiled	0.02 / 0.02	0.40
0.7%	Rhubarbs / sauce/puree	0.02 / 0.02	0.39
0.6%	Beetroots / boiled	0.02 / 0.02	0.33
0.5%	Courgettes / boiled	0.02 / 0.02	0.32
0.5%	Escaroles/broad-leaved	0.02 / 0.02	0.31
0.5%	Oranges / juice	0.02 / 0.02	0.30
0.5%	Leeks / boiled	0.02 / 0.02	0.27

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