FINAL REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: CHR/H/CFF 250 EC

Product name(s): Hapi 250 EC/ Turango 250 EC

Chemical active substance(s):

Clopyralid, 120 g/L
Fluroxypyr-acid, 120 g/L (as fluroxypyr-meptyl, 172.9 g/L)
Florasulam, 10 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Innvigo Sp. z o.o.

Submission date: March 2023

MS Finalisation date: January 2024; November 2024

Version history

When	What
November 2023	New data provided by the Applicant
January 2024	ZRMs evaluated submitted by Applicant dRR
November 2024	The final Registration Report

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7 Metabolism and residue data (KCA section 6)

In the following document, data for active substances - Fluroxypyr - was described during its inclusion on Annex 1 process in respectively 2009. Were reference to active substance data in the current risk assessment has been made, it was based on the data which protection for expired 10 years from date of inclusion of active substances on Annex I.
Data matching studies for florasulam have been evaluated by Poland. As a result of the assessment all reports were accepted and considered as equivalent to protected studies. Therefore, to support the authorization of CHR/H/CFF 250 EC INNVIGO is allowed to refer to EU approved reports
Data matching studies for clopyralid have been evaluated by RMS - Finland. As a result of the assessment all re-ports were accepted and considered as equivalent to protected studies. Therefore, to support the renewal of authorization of CHR/H/CFF 250 EC INNVIGO is allowed to refer to EU approved reports

7.1 Summary and zRMS Conclusion

Florasulam

Stability of residues during storage of samples

No new data submitted in the framework of this application.

Storage stability of florasulam was demonstrated in cereal grain, cereal straw and immature cereal plants for a period of 18 to 23 month at temperature ranging from -18°C to -25°C.

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

No further data are required to support the proposed uses.

Metabolism in plants and animals

The data evaluated during the Annex I inclusion and renewal process of the active substance are sufficient to describe the behaviour of the formulated product, and no further studies are required.

Plant and animal residue definitions for monitoring: Florasulam (Reg. (EU) 2022/1363)

Plant residue definition for risk assessment (EFSA Journal 2015;13(1): 3984): Florasulam and provisionally 4-OH- phenyl-florasulam (data gap)

Animal residue definition for risk assessment (EFSA Journal 2015;13(1): 3984): Florasulam pending assessment with regard to 4-OH-phenyl-florasulam

Conversion factor (monitoring to risk assessment): For milk, liver, kidney and eggs: 1

The data gap concerns the further toxicological evaluation of the plant metabolite 4-OH- phenyl-florasulam.

Magnitude of residues in plants

Winter wheat, spelt, emmer wheat, einkorn wheat, durum wheat, spring rye

Proposed GAP: 1 application, BBCH 21-33 (Spring), 0.004 – 0.005 kg as/ha

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application.

Trials GAP: 5 g as/ha, BBCH 32, PHI n/a, outdoor

Residues (winter wheat): 4x <0.003 mg/kg (LOD)

According to SANTE/2019/12752 rev.1 extrapolation from wheat to spelt and rye is possible.

Sufficient trials on cereals are available to support the proposed uses.

The residues arising from the proposed uses will not exceed the MRLs established for cereals (0.01 mg/kg; Reg. (EU) 2022/1363)

Magnitude of residues in livestock

According to the new study all residues in cereals (grain, straw and whole plant) are below the LOD (0.003 mg/kg). Therefore, it does not cause any risk for livestock and supplementary livestock feeding studies are not required.

zRMS calculation (input values - proposed uses, see point 7.2.4): trigger values are not exceeded

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

As quantifiable residues of florasulam are not expected in edible part of crops based on available residue data, there is no need to investigate the effect of industrial and/or household processing.

Magnitude of residues in representative succeeding crops

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

EFSA Journal 2015; 13(1):*3984: In the section on residues data gaps were identified with regard to residues in animal commodities and rotational crops. Nonetheless, the margin of safety in the consumer risk assessment is considered big even if the potentially relevant toxicological burden for consumers via their diet might have been underestimated in the current assessment.*

Residues of parent florasulam in succeeding crops are not sufficient to reach measurable levels in monitoring (<0.01 mg/kg) and no specific plant-back restrictions related to florasulam are required.

Other / special studies

Studies are not required. Cereals are not a melliferous crop foraged by bees.

Estimation of exposure through diet and other means

The proposed uses of Florasulam in the formulation CHR/H/CFF 250 EC do not represent unacceptable chronic risks for the consumer.

Clopyralid

Stability of residues during storage of samples

Stability of residues during storage of samples was provided during the EU review of clopyralid.

Residues of clopyralid were found to be stable at ≤ -18°C for up to:

13 months in maize fodder and forage (high water content matrix)

13 months in maize grain (high starch content matrix)

17 months in pasture grass (high water content matrix)

24 months in rape seed (high oil content matrix)

Metabolism in plants and animals

Residue definition for monitoring (Commission Regulation (EU) 2021/1807 of 13 October 2021): clopyralid (plants and animals)

Proposed residue definition for monitoring (EFSA Journal 2021;19(1):6389): clopyralid common moiety (sum of clopyralid, its salts and conjugates expressed as clopyralid) (applicable only for cereals/grass).

The proposed change will not have an impact on the existing MRLs, as the analytical methods used to generate data for risk assessment and for enforcement include a hydrolysis step which is capable to cover the common moiety.

Residue definition for risk assessment:

Clopyralid common moiety (sum of clopyralid, its salts and conjugates expressed as clopyralid) – pending the outstanding clarification on the nature of "polar clopyralid" (EFSA Journal 2018;16(7):5389)

During the peer review, the data gap related to the identification of an unknown compound observed in sugar beet and oilseed rape metabolism studies was identified.

The intended uses on cereals are supported by the evaluated plant metabolism studies.

One new hydrolysis study was evaluated as equivalent to protected hydrolysis study and was accepted in data matching (Finland 2022): K. Hamnett; 2019; Study no: FR/001648 which is equivalent to Adusumilli, H. 2014; study no: 140574. The test compound clopyralid was stable under all conditions of high temperature hydrolysis for simulation of food processing.

New metabolism study in rotational crops was evaluated as equivalent to protected study and was accepted in data matching (Finland 2022): Hall, L. R.; 2015; DAS Study No. 130733 to which is equivalent Rooney P., 2021, [14C]-Clopyralid Metabolism in Rotational Crops FR/001647. The requirement for alternative tests has been met.

NOTE: the new alternative studies have not been assessed in this application.

Magnitude of residues in plants

Winter wheat, spelt, emmer wheat, einkorn wheat, durum wheat, spring rye

Proposed uses: 1 application, BBCH 21-33 (Spring), 0.048 – 0.060 kg as/ha, PHI: not required.

Applicant refers to the unprotected EU data. GAP on which EU a.s. assessment is based: 1 x 0.150 kg as/ha, BBCH 39.

Presented data are still valid and meet criteria of current guidelines.

Additionally, new magnitude of residues in plant studies (bridging studies for studies assessed on EU level) have been submitted by the applicant in the framework of this application.

Trials GAP: 1x 0.060 kg clopyralid/ha, BBCH 33, outdoor

Residues: wheat grain: 0.18, 0.29, 0.37, 0.63 mg/kg

Residues: wheat straw: 0.17, 0.33, 0.52, 1.77 mg/kg

According to SANTE/2019/12752 rev.1 extrapolation from wheat to spelt and rye is possible.

Sufficient trials are available to support the proposed use. The residues arising from the proposed uses will not exceed the MRLs established for wheat (Reg. (EU) 2021/1807).

Livestock feeding studies

New Dietary Burden calculations were performed, taking into account STMR and HR values from residues trials on CHR/H/CFF 250 EC (using Animal model 2017 and EU data). The new animal model calculation (Excel spreadsheet Animal model 2017) modify the theoretical maximum daily intake for animals, but regarding available feeding data, there is no risk for animal MRL to be exceeded.

According to EFSA Journal 2018;16(7):5389 livestock feeding studies are performed during Annex I inclusion and renewal. No new livestock studies feeding studies are necessary.

Magnitude of residues in processed commodities

New, alternative to the protected study was provided by the applicant (White T., 2021, S19-01810; White T., 2021, S20-04397) and was accepted in data matching (Finland 2022). No further data is required.

NOTE: new alternative study has not been assessed in this application.

Processing factors have been established at EU level. Validity is pending the evaluation of the underlying residue field trials.

Rotational study

According to the available data following label restriction is proposed: not to use clopyralid on the same field for 125 days after the initial application regardless of the crop grown (see EFSA Journal 2021;19(1):6389).

Other / special studies

Cereals have not melliferous capacity. No further data is required.

Estimation of exposure through diet and other means

The proposed use of clopyralid in the formulation CHR/H/CFF 250 EC do not represent unacceptable acute and chronic risks for the consumer (EFSA PRIMo rev 3.1)

Fluroxypyr

Stability of Residues

Fluroxypyr residues stable in wheat matrices (whole plant, straw and grain) over the period of 24 months, when stored frozen at -18°C. Additional studies are not required.

Metabolism in plants and animals

Residue definition for monitoring (plants and animals): Fluroxypyr (sum of fluroxypyr, its salts, its esters, and its conjugates, expressed as fluroxypyr) (Reg. (EU) 2022/1363)

Residue definition for risk assessment (plants and animals): Fluroxypyr, its esters, salts and its conjugates expressed as fluroxypyr (EFSA Journal 2011;9(3):2091)

The residue definition for risk assessment set for the primary crops may also apply to the rotational crops on a tentative basis but in view of the high persistence of the metabolite fluroxypyr methoxypyridine and the absence of toxicological data on this metabolite, rotational crops field trials covering the maximum plateau concentration of this metabolite are required. EFSA recommends avoiding rotation with root and tuber crops.

EFSA Journal 2019;17(9):5816 (*Animal residue definition for risk assessment*):

Residue definition for risk assessment (tentatively derived in the MRL review)
Ruminants: sum of fluroxypyr and its salts, expressed as fluroxypyr (tentative) (EFSA, 2013)Poultry: in the context of the MRL review a metabolism study in poultry was submitted but not triggered and therefore no residue definition was proposed for poultry matrices (EFSA, 2013)

Residue definition for risk assessment (evaluation of confirmatory data following the MRL review)
The tentative residue definition for risk assessment (ruminants) could not be confirmed and should be reconsidered, pending on the data gap for toxicological information on the metabolite fluroxypyr pyridinol and its conjugates.

Magnitude of residues in plants

Winter wheat, spelt, emmer wheat, einkorn wheat, durum wheat, spring rye

Proposed uses: 1 application, BBCH 21-33, 0.048 – 0.060 kg as/ha, PHI: not required

New magnitude of residues in plant studies have been submitted by the applicant in the framework of this application.

Trials GAP: 1x 0.060 kg fluroxypyr/ha, BBCH 33, outdoor

Residues: 4 x < 0.01 mg/kg

Sufficient data are available to support the proposed use. The residues arising from the proposed uses will not exceed the MRLs established for cereals (Reg. (EU) 2022/1363)

According to the SANTE/2019/12752 rev.1 extrapolation from wheat to spelt and rye is possible.

Uses are accepted.

Livestock feeding studies

The requested uses do not modify the theoretical maximum daily intake for animals, and there is no risk for animal MRLs to be exceeded.

Magnitude of residues in processed commodities

Residues of Fluroxypyr exceeding 0.1 mg/kg are not expected in the treated crops. Additionally the chronic exposure does not exceed 10 % of the ADI. No further data is required.

Rotational study

Confined studies conducted with 14C-fluroxypyr-MHE at a dose rate of 594 to 676 g a.s./ha (c.a. 3N) indicate that significant residues are not expected to be present in rotational crops.

Nevertheless, EFSA recommends avoiding rotation with root and tuber crops (in view of the high persistence of the metabolite fluroxypyr methoxypyridine and the absence of toxicological data on this metabolite).

Other / special studies

Cereals have not melliferous capacity. No further data is required.

Estimation of exposure through diet and other means

The proposed uses of Fluroxypyr in the formulation CHR/H/CFF 250 EC EW do not represent unacceptable chronic risks for the consumer.

7.1.1 Critical GAP(s) and overall conclusion

Selection of critical uses and justification

The critical GAPs with respect to consumer intake and risk assessment for the preparation CHR/H/CFF 250 EC are presented in Table 7.1-1. They have been selected from the individual GAPs in the zone for winter cereals. A list of all intended uses within the zone/EU is given in Part B, Section 0.
Justification for the selection of the critical GAP

Overall conclusion

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of 0.01 mg/kg for florasulam, 3 mg/kg for clopyralid, 0.1 mg/kg for fluroxypyr as laid down in Reg. (EU) 396/2005 is not expected.
The chronic and the short-term intakes of florasulam, clopyralid and fluroxypyr residues are unlikely to present a public health concern.
As far as consumer health protection is concerned, authority, zRMS agrees with the authorization of the intended use(s).

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

- According to the available data following label restriction is proposed: not to use clopyralid on the same field for 125 days after the initial application regardless of the crop grown (see EFSA Journal 2021;19(1):6389).
- EFSA recommends avoiding rotation with root and tuber crops (in view of the high persistence of the metabolite fluroxypyr methoxypyridine and the absence of toxicological data on this metabolite).

Data gaps

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

Noticed data gaps are:

- none

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

GAP rev. , date: 2021-01-13

PPP product name:		Formulation type:	EC [a, b]
product code:	CHR/H/CFF		
Active substance 1:	clopyralid	Conc. of as 1:	120 g/l [c]
Active substance 2:	fluroxypyr	Conc. of as 2:	120 g/l [c]
Active substance 3:	florasulam	Conc. of as 3:	10 g/l (c)
Safener:	-	Conc. of safener:	- [c]
Synergist:	-	Conc. of synergist:	- [c]
Applicant:	Innvigo Sp. z o.o.	Professional use:	☒
Zone(s):	Central [d]	Non professional use:	☐
Verified by MS:	no		

Field of use: herbicide

1	2	3	4	5	6	7	8	9	15	11	12	13	14	15
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:**	ZRMs Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		e.g. g safener/synergist per ha [f]	

Zonal uses (field or outdoor uses, certain types of protected crops)														
1	PL	Winter wheat (TRZAW), Winter triticale (TTLWI)	F	dicotyle-donous weeds	Spray, medium sprayer	spring BBCH 21-33	a)1 b)1	n/a	a) 0.4 - 0.5 l/ha b) 0.4 - 0.5 l/ha	a) 0.1 - 0.125 kg a.s./ha (0.048 CLO + 0.048 FLUROX + 0.004 FLO) –(0.06 CLO + 0.06 FLUROX + 0.005 FLO) b) 0.1 - 0.125 kg a.s./ha (0.048 CLO + 0.048 FLUROX + 0.004 FLO) –(0.06 CLO + 0.06 FLUROX + 0.005 FLO)	200-400	n/a		A
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)														
2														
3														
Minor uses according to Article 51 (zonal uses)														
4	PL	Spelt *Triticum spelta* (3SPWC) Emmer wheat *Triticum dicoccum* (TRZDI) Einkorn wheat *Triticum monococcum (TRZMO)* Durum wheat *Triticum durum* (TRZDW) Spring Rye *Secale cereale* (SECCS)	F	Monaocots and dicots weeds	Spray, medium sprayer	BBCH 21-33	a)1 b)1	n/a	a) 0.4 - 0.5 l/ha b) 0.4 - 0.5 l/ha	a) 0.1 - 0.125 kg a.s./ha (0.048 CLO + 0.048 FLUROX + 0.004 FLO) –(0.06 CLO + 0.06 FLUROX + 0.005 FLO) b) 0.1 - 0.125 kg a.s./ha (0.048 CLO + 0.048 FLUROX + 0.004 FLO) –(0.06 CLO + 0.06 FLUROX + 0.005 FLO)	200-400		.	A
5														

Minor uses according to Article 51 (interzonal uses)														
6														
7														

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

Explanation for Column 11 “Conclusion”

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

7.1.2 Summary of the evaluation

The preparation CHR/H/CFF 250 EC is composed of florasulam, clopyralid and fluroxypyr.

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

Reference value	Source	Year	Value	Study relied upon	Safety factor
Florasulam - Parent compound					
ADI	EFSA Journal 2015;13(1):3984 Reg. (EU) 2015/1397	2015	0.05 mg/kg bw per day	1 year dog	100
ARfD	Not applicable				
Clopyralid - Parent compound					
ADI	*EFSA Journal 2018;16(7):5389*	2018	0.15 mg/kg bw per day	rat, 2-year chronic toxicity and oncogenicity study	100
ARfD	*EFSA Journal 2018;16(7):5389*	2018	0.17 mg/kg bw	rabbit, developmental toxicity	300
Fluroxypyr - Parent compound					
ADI	SANCO 7469/VI/98-Final 3 July 2003	2003	0.8 mg/kg bw/day	rat: 2y study (LOEL)	250
ARfD					

7.1.2.1 Summary for florasulam

Table 7.1-3: Summary for florasulam

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

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

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

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

7.1.2.2 Summary for clopyralid

Table 7.1-4: Summary for clopyralid

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

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

For winter cereals, no additional data are required in post-registration to confirm that a "no-residue" situation occurs in the worst case application: 1 application of 0.06 g/ha at growth stage BBCH 21-33.

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

7.1.2.3 Summary for fluroxypyr

Table 7.1-5: Summary for fluroxypyr

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

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

For winter cereals, no additional data are required in post-registration to confirm that a "no-residue" situation occurs in the worst case application: 1 application of 0.06 g/ha at growth stage BBCH 21-33

As residues of fluroxypyr 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.

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7.1.2.4 Summary for CHR/H/CFF 250 EC

Table 7.1-6: Information on CHR/H/CFF 250 EC (KCA 6.8)

Crop	PHI for CHR/H/CFF 250 EC proposed by applicant	PHI/ Withholding period* sufficiently supported for			PHI for CHR/H/CFF 250 EC proposed by zRMS	zRMS Comments (if different PHI proposed)
		Florasulam	Clopyralid	Fluroxypyr		
Winter 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).

Table 7.1-7: Waiting periods before planting succeeding crops

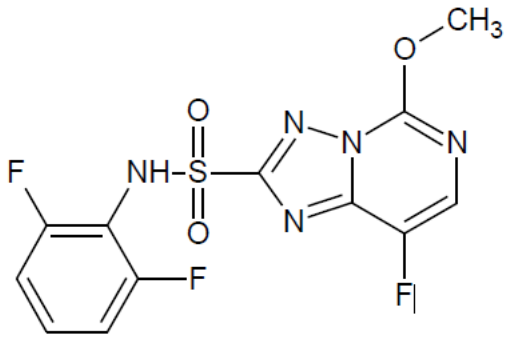
Waiting period before planting succeeding crops				Overall waiting period proposed by zRMS for CHR/H/CFF 250 EC
Crop group	Led by Florasulam	Led by Clopyralid	Led by Fluroxypyr	
Leafy vegetables	NR	NR	NR	According to the available data following label restriction is proposed: not to use clopyralid on the same field for 125 days after the initial application regardless of the crop grown (see EFSA Journal 2021;19(1):6389).
Root vegetables	NR	NR	NR	EFSA recommends avoiding rotation with root and tuber crops (in view of the high persistence of the metabolite fluroxypyr methoxypyridine and the absence of toxicological data on this metabolite). According to the available data following label restriction is proposed: not to use clopyralid on the same field for 125 days after the initial application regardless of the crop grown (see EFSA Journal 2021;19(1):6389).
Cereals	NR	NR	NR	According to the available data following label restriction is proposed: not to use clopyralid on the same field for 125 days after the initial application regardless of the crop grown (see EFSA Journal 2021;19(1):6389).

NR: not relevant

7.2 Florasulam

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

Table 7.4-1: General information on Florasulam

Active substance (ISO Common Name)	Florasulam
IUPAC	2′,6′,8-trifluoro-5-methoxy[1,2,4]triazolo[1,5-c] pyrimidine-2-sulfonanilide
Chemical structure	
Molecular formula	C12H8O3N5F3S
Molar mass	359.3 g/mol
Chemical group	1,5c triazolopyrimidine sulfonanilides
Mode of action (if available)	ALS inhibitor
Systemic	Yes
Company (ies)	Dow AgroScienes
Rapporteur Member State (RMS)	POLAND
Approval status	Approved Date of (01/01/2016) and reference to decision (COM-MISSION DIRECTIVE 91/414/EEC - REGULATION (EU) No 2015/1397)
Restriction	Commission Implementing Regulation (EU) 2015/1397 of 14 August 2015
Review Report	SANTE/10542/2015 Rev 1 14/07/2015
Current MRL regulation	~~Reg. (EU) No 1317/2013~~ Reg. (EU) 2022/1363
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Pending
EFSA Journal : Conclusion on the peer review	EFSA Journal 2015;13(1):3984
EFSA Journal: conclusion on article 12	EFSA Journal 2012;10(3):2626
Current MRL applications on intended uses	EFSA-Q-2008-545 (EMS) Review of all existing MRLs Status: Evaluation ongoing

7.2.1 Stability of Residues (KCA 6.1) - florasulam

7.2.1.1 Stability of residues during storage of samples - florasulam

Available data

No new data submitted in the framework of this application.

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

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

Conclusion on stability of residues during storage

The storage stability evaluated during Annex I inclusion covers plant matrices for use CHR/H/CFF 250 EC according to the GAP, therefore no new studies are necessary.

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

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

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

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

Available data

No new data submitted in the framework of this application.

Table 7.4-3: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (g a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Cereals	Winter wheat	[14C-phenyl]-florasulam	F	50 g as/ha	10	0, 30, 65 and 129 days	none	RMS, 1999 DAR, 1999.

								Florasulam – Annex B.6: Residue data EFSA Journal 2015; 13(1):3984
Cereals	Winter wheat	[14C-triazolopyrimidine]-florasulam.	F	50 g as/ha	10	0, 30, 65 and 129 days	none	RMS, 1999 DAR, 1999. Florasulam – Annex B.6: Residue data EFSA Journal 2015; 13(1):3984

Summary of plant metabolism studies reported in the EU

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

Conclusion on metabolism in primary crops

The metabolism in primary crops presented during Annex I inclusion, covers use of CHR/H/CFF 250 EC on cereals. No new studies were necessary.

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

Available data

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

No new data submitted in the framework of this application.

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

Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G *	Rate (g a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks	
EU data								

Leafy vegetables	cabbage	[14C-phenyl]-florasulam [14C-triazolopyrimidine]-florasulam.	F	7.5	30 days	195 days	none	RMS 2013, RAR, Florasulam - Volume 3, Annex B.7
Root and tuber vegetables	carrots	[14C-phenyl]-florasulam [14C-triazolopyrimidine]-florasulam.	F	7.5	30 days	156 days	none	RMS 2013, RAR, Florasulam - Volume 3, Annex B.7
Pulses and oilseeds	sunflower	[14C-phenyl]-florasulam [14C-triazolopyrimidine]-florasulam.	F	7.5	30 days	168 days	none	RMS 2013, RAR, Florasulam - Volume 3, Annex B.7
Cereals	Spring wheat	[14C-phenyl]-florasulam [14C-triazolopyrimidine]-florasulam.	F	7.5	30 days	168 days	none	RMS 2013, RAR, Florasulam - Volume 3, Annex B.7

Summary of plant metabolism studies reported in the EU

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

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

nd : Not radiodetected

The investigation of rotational crops was considered insufficient with regard to the potential for uptake of significant levels in plant commodities, particularly in terms of the persistent metabolites TSA and ASTCA (both with triazole sulfone moiety), since the available data did not address a plant back interval

of 365 days and the application rate in the study seems insufficient considering repeated/multiannual applications, information that may be necessary when persistent soil residues occur.

Conclusion on metabolism in rotational crops

The metabolism in rotational crops covers use of CHR/H/CFF 250 EC according to the label/GAP.

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

Available data

No significant residues, i.e. >0.1 mg/kg, were found in cereals and therefore processing studies are not required. No new studies are necessary for CHR/H/CFF 250 EC, since all residues are expected to be below 0.1 mg/kg.

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

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

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

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

Available data

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

No new data submitted in the framework of this application.

Table 7.4-6: Summary of animal metabolism studies

Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling	
EU data								
Lactating ruminants	Goat	[14C-phenyl]-florasulam	1 control, 2 doses animal	11	5	Milk	twice daily	RMS 2013, RAR, Florasulam - Volume 3, Annex B.7; EFSA Journal 2015; 13(1):3984
						Urine and faeces	daily	
		[14C-triazolopyrimidine]-florasulam.				Tissues	at sacrifice	
Laying poultry	Hens	[14C-phenyl]-florasulam	10 control, 10 doses animal	11	5	Eggs	twice daily	RMS 2013, RAR, Florasulam - Volume 3, Annex B.7; EFSA Journal 2015; 13(1):3984
						Excreta	twice daily	
		[14C-triazolopyrimidine]-florasulam.				Tissues	at sacrifice	

Summary of plant metabolism studies reported in the EU

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

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

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

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

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

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

Conclusion on metabolism in livestock

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

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

(KCA 6.7.1)

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

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

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

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

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

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

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

7.2.3.2 Conclusion on the magnitude of residues in plants - florasulam

According to the available data, the intended uses on cereals are considered acceptable.
The data for CHR/H/CFF 250 EC submitted show that no exceedance of the MRL will occur.
The uses are considered acceptable.
All storage stability for samples are cover by stability studies presented at point 7.2.1

7.2.4 Magnitude of residues in livestock - florasulam

7.2.4.1 Dietary burden calculation - florasulam

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

zRMS: trigger values are not exceeded
Input values: proposed uses

Relevant groups	Dietary burden expressed in				Most critical diet (a)	Most critical commodity (b)		Trigger exceeded (Yes/No)
	mg/kg bw per day		mg/kg DM					0.004
	Median	Maximum	Median	Maximum				mg/kg bw
Cattle (all diets)	0,001	0,001	0,03	0,03	Dairy cattle	Wheat	milled bypdts	No
Cattle (dairy only)	0,001	0,001	0,03	0,03	Dairy cattle	Wheat	milled bypdts	No
Sheep (all diets)	0,002	0,002	0,05	0,05	Lamb	Wheat	milled bypdts	No
Sheep (ewe only)	0,001	0,001	0,04	0,04	Ram/Ewe	Wheat	milled bypdts	No
Swine (all diets)	0,001	0,001	0,05	0,05	Swine (finishing)	Wheat	milled bypdts	No
Poultry (all diets)	0,002	0,002	0,02	0,02	Poultry layer	Wheat	milled bypdts	No
Poultry (layer only)	0,002	0,002	0,02	0,02	Poultry layer	Wheat	milled bypdts	No

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

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

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

No significant residues, i.e. >0.1 mg/kg, were found in cereals and therefore processing studies are not required. No new studies are necessary for CHR/H/CFF 250 EC, since all residues are below 0.003 mg/kg.

7.2.5.1 Available data for all crops under consideration - florasulam

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

7.2.5.2 Conclusion on processing studies - florasulam

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

7.2.6 Magnitude of residues in representative succeeding crops - florasulam

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

7.2.6.1 Field rotational crop studies (KCA 6.6.2) - florasulam

Available data

No new data submitted in the framework of this application.

Conclusion on rotational crops studies

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

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

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of CHR/H/CFF 250 EC. Therefore, other special studies are not needed.

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

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

7.2.8.1 Input values for the consumer risk assessment - florasulam

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

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Wheat/bread (wholemeal); Wheat/bread/pizza Wheat/pasta; Wheat/ milling (flour); Wheat/ milling(wholemeal) -baking	0.01	Reg. (EU) 2022/1363	0.01	Reg. (EU) 2022/1363
Swine, Bovine, Sheep, Goat, Equine, Poultry and other farmed terrestrial animals" muslce, fat, liver, kidney, dible offals, milk and other	0.05	Reg. (EU) 2022/1363	0.05	Reg. (EU) 2022/1363
Birds egg	0.05	Reg. (EU) 2022/1363	0.05	Reg. (EU) 2022/1363

7.2.8.2 Conclusion on consumer risk assessment - florasulam

Extensive calculation sheets are presented in A 2.3.1.

Table 7.4-11: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo rev.3.1	1 % (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo	~~1 % (based on NL toddler)~~ n.r.

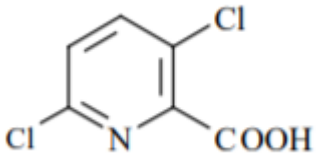
The proposed uses of florasulam in the formulation CHR/H/CFF 250 EC do not represent unacceptable acute and chronic risks for the consumer.

7.3 Clopyralid

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

Table 7.3-1: General information on clopyralid

Active substance (ISO Common Name)	Clopyralid
IUPAC	3,6-dichloropyridine-2-carboxylic acid

Chemical structure	
Molecular formula	$C_6H_3Cl_2NO_2$
Molar mass	191.96
Chemical group	3,6-dichloro-2-pyridinecarboxylic acid
Systemic	Yes
Company (ies)	Dow AgroSciences
Rapporteur Member State (RMS)	RMS - Finland Co-RMS - Poland
Approval status	Approved Date of approval (01/05/2007) (COMMISSION DIRECTIVE 2006/74//EC - REGULATION (EU) No 540/2011) The renewal of approval Date of approval 1 October 2021 COMMISSION IMPLEMENTING REGULATION (EU) 2021/1191 of 19 July 2021
Restriction	COMMISSION IMPLEMENTING REGULATION (EU) 2021/1191 of 19 July 2021 Member States shall pay particular attention to: - the specification of the technical material as commercially manufactured; - the protection of operators, ensuring that conditions of use for operators include the application of adequate personal protective equipment; - possible presence of clopyralid residues in rotational crops; - the possible transfer of clopyralid residues via compost or manure of animals whose feed originates from treated areas, to avoid damage to susceptible crops; - the protection of groundwater under vulnerable conditions.
Review Report	SANTE/10206/2021 Rev 1 20 May 2021
Current MRL regulation	COMMISSION REGULATION (EU) 2021/1807 of 13 October 2021
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 Journal 2018;16(7):5389*
EFSA Journal: conclusion on article 12	No
Current MRL applications on intended uses	N/A – MRL already set

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.

IIIA 8.1 Stability of Residues

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products			
Maize forage/fodder	High water content	13 months	EFSA Journal 2018;16(7):5389 Clements, B, Bolton, A , (1996) RES93050.01; Foster, D.R., Blakeslee, B.A., Rutherford, B.S. DAS Study No. RES93050.01;1996
Pasture grass	High water content	17 months	EFSA Journal 2018;16(7):5389 Clements, B, Bolton, A , (1996) RES93050.01; Foster, D.R., Blakeslee, B.A., Rutherford, B.S. DAS Study No. RES93050.01;1996
Maize (corn grain)	High starch content	13 months	EFSA Journal 2018;16(7):5389 Clements, B, Bolton, A , (1996) RES93050.01; Foster, D.R., Blakeslee, B.A., Rutherford, B.S. DAS Study No. RES93050.01;1996
Oilseed rape (seed)	High oil content	24 months	EFSA Journal 2018;16(7):5389 Dial, E., Lindsay, D. 2006 DAS Study No. 020122.02
Animal products			
Bovine	Muscle	19 months	EFSA Journal 2018;16(7):5389 DAS Study No. 020120.01
Bovine	Liver Kidney Milk	19 months	EFSA Journal 2018;16(7):5389 DAS Study No. 020120.01

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Hen	Eggs	19 months	EFSA Journal 2018;16(7):5389 DAS Study No. 020120.01
Bovine	Fat	24 months	EFSA Journal 2018;16(7):5389 DAS Study No. 120602;

According to EFSA Journal 2018;16(7):5389 stability of conjugates has not been tested, though clopyralid conjugates are major metabolites comprising up to 50 % of TRR depending on crop studied. It is assumed that conjugated clopyralid will be also stable.

7.3.1.2 Stability of residues in sample extracts (KCA 6.1)

~~No further data is required.~~
Not relevant for this application, in supervised studies evaluated during Annex I inclusion and presented in RAR Clopyralid - Volume 3, Annex B.7 and new studies, analysis time were less than 24 hours between extraction and analysis.

7.3.1.3 Nature of residue in primary crops (KCA 6.2.1)

The metabolism in primary crops presented during Annex I inclusion and renewal, covers use of CHR/H/CFF 250 EC. No new studies were necessary.
(Clopyralid RAR Volume 3 B7 Chapelo S., Caley 2002a; Chapelo S., Caley 2002b; Guo 1996)
Plant metabolism of clopyralid was studied in three crops: sugarbeet, oilseed rape, cabbage.
The extraction with caustic methanol employed in the cabbage study has led to cleavage of the conjugates and resulted in the presence of free clopyralid at maturity up to 92% and 99% total radioactive residue (TRR) in head and wrapper leaves, respectively. In the studies with oilseed rape and sugar beet, a first extraction was performed with acetonitrile/water and followed with a caustic extraction allowing for investigation of the presence of eventual conjugates. In sugar beet, clopyralid was initially the major residue in the plant (97% TRR at day 0 and 85% TRR at day 28). At maturity, it decreased to 51% TRR in the shoot and to 58% TRR in the root. A ‘polar form of clopyralid’ was observed in shoots and roots up to 37% TRR and 39% TRR, respectively, but only in the mature plant parts. In oilseed rape clopyralid was present at 63% TRR in immature plant and at 32% and 43% TRR in mature straw and seed, respectively. A ‘polar form of clopyralid’ was reported to 32% and 28% TRR in mature straw and seed, respectively and an unknown metabolite B also referred to as ‘clopyralid conjugates’ to 29% and 18% TRR in mature straw and seed, respectively.

7.3.1.4 Nature of residue in rotational crops (KCA 6.6.1)

Available data

No new data submitted in the framework of this application.

Table 7.3-2: Summary of metabolism studies in rotational crops

Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G *	Rate (g a.s./ha)	Sowing intervals (DAT)	Harvest (BBCH)	Remarks	
EU data								
Leafy vegetables	Lettuce, Cabbage	pyridine	Spray, G	1 x 0.3 kg/ha to bare soil (30 days) 1 x 0.28 kg/ ha to bare soil (125 and 319 days)	125, 319 30	Immature BBCH 53 Mature BBCH 53		Yackovich, P. R. ; Lardie, T. S. ; Brink, D. L. , 1993, Study number: GH-C 2992; Yackovich, P.R.; Lardie T.S.; Miller J.H., 1989, Study number: GH-C 2277; Hall, L. R.; 2015; DAS Study No. 130733 to which is equivalent Rooney P., 2021, [14C]-Clopyralid Metabolism in Rotational Crops FR/001647
Root and tuber vegetables	Turnip, Radish	pyridine	Spray, G	1 x 0.3 kg/ha to bare soil (30 days) 1 x 0.28 kg/ ha to bare soil (125 and 319 days)	125, 319 30	53		
Cereals	Wheat	pyridine	Spray, G	1 x 0.3 kg/ha to bare soil (30 days) 1 x 0.28 kg/ ha to bare soil (125 and 319 days)	30, 125, 319	Forage BBCH 43 Hay BBCH 71 Straw and grain BBCH 97		

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

Summary of plant metabolism studies reported in the EU

In plants, clopyralid is converted to at least one major conjugate that was readily hydrolysed in base to clopyralid. This result suggested that the conjugate was probably an ester formed by reaction with the carboxylic acid group in clopyralid. The nature of this residue, other than its hydrolysis to clopyralid, was not further investigated.

Another, usually minor pathway noted primarily in straw was binding to plant matrix. The majority of the bound residues in straw were solubilized by heating in 1 N NaOH, and this yielded several minor products that were characterized on the basis of distinctly different solubilities in MTBE, acid, and base.

Conclusion on metabolism in rotational crops

The metabolism in rotational crops presented in Clopyralid, RAR, annex B, B.7 Residue, covers use of CHR/H/CFF 250 EC. No further studies are necessary.

7.3.1.5 Nature of residues in processed commodities (KCA 6.5.1)

No new data submitted in the framework of this application.

Table 7.3-4: Nature of the residues in processed commodities

Conditions (Duration, Temperature, pH)	Identified compound(s) (%)	Reference
EU data		
Pasteurisation (20 minutes, 90°C, pH 4)	99.3 % of the initial clopyralid concentration	K. Hamnett; 2019; Study no: FR/001648 which is equivalent to Adusumilli, H. 2014; study no: 140574
Baking, boiling, brewing (60 minutes, 100°C, pH 5)	96.9 % of the initial clopyralid concentration	
Sterilisation (20 minutes, 120°C, pH 6)	97.1 % of the initial clopyralid concentration	

Conclusion on nature of residues in processed commodities

The test compound clopyralid was stable under all conditions of high temperature hydrolysis for simulation of food processing. No changes proposed in residue definition on basis of hydrolysis test.

7.3.1.6 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	Root crops(sugar beet), leafy crops(cabbage), Pulses/oilseeds(oilseed rape), cereals(wheat)
Rotational crops covered	Root/tuber crops(turnip, radish), leafy crops(lettuce, cabbage), Cereal(wheat),
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	a.s. is stable
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes
Plant residue definition for monitoring	clopyralid common moiety (sum of clopyralid, its salts and conjugates expressed as clopyralid) – pending the outstanding clarification on the nature of "polar clopyralid" EFSA Journal 2018;16(7):5389

Plant residue definition for risk assessment	clopyralid common moiety (sum of clopyralid, its salts and conjugates expressed as clopyralid) – pending the outstanding clarification on the nature of "polar clopyralid" EFSA Journal 2018;16(7):5389
Conversion factor from enforcement to RA	N/A

* 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.

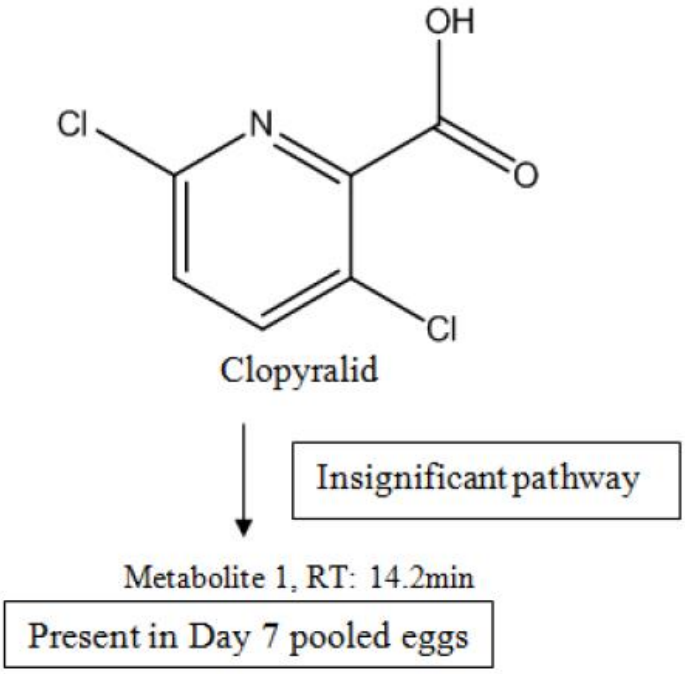
7.3.1.7 Nature of residues in livestock (KCA 6.2.2-6.2.5)

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

Table 7.3-6: Summary of animal metabolism studies

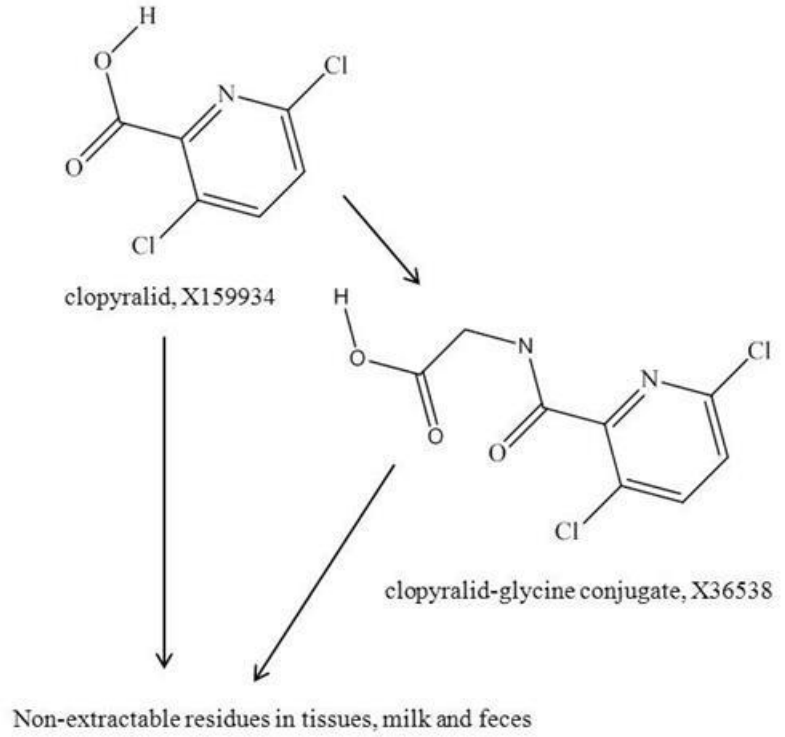
Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling	
EU data								
Ruminants	Caprine (goat)	[14C]Clopyralid labelled at two sites of the molecule	14	50.9 mg a.s./kg dry feed/day equivalent to 0.484 mg/kg bw per day	5	Milk	twice daily	A Nature of the Residue Study in the Ruminant with [14C]Clopyralid; .; Study No. 130202; 16 January 2015;
						Urine and faeces	daily	
						Tissues	at sacrifice	
Laying hen	Gallus domesticus	[14C]Clopyralid labelled at two sites of the molecule	N/A	11.4 mg a.s./kg feed per day, equivalent to 0.56-0.65 mg/kg bw per day	7	eggs	Once a day	Nature of the Residue Study in the Laying Hen with [14C]-Clopyralid; Study No. 130906; 20 November 2014;

Conclusion on metabolism in livestock
- <u>poultry</u>
It is concluded on basis of the laying hen study by (2014) that clopyralid metabolism is limited in laying hens. The majority of clopyralid is excreted unchanged.
Identification rate in eggs varied from 52 to 72 %TRR on day 7, which is the last dosing day of the study. A deficiency of the study is 7 days was not long period enough to reach steady state. It is clear that on day 7 the levels of total radioactivity in eggs was still increasing.
Positive identification by HPLC tandem mass spectrometry was used for identification.
The study fulfils its objectives.
While a diminutive amount, 2.0% TRR and 0.0002 mg eq./kg is metabolized in eggs to an unidentified Metabolite 1.
A metabolic pathway is proposed below:



Clopyralid is minimally metabolized in laying hens.
Identification rate in eggs varied from 52 to 72 %TRR on day 7, which is the last dosing day of the study. A deficiency of the study is 7 days was not long period enough to reach steady state. It is clear that on day 7 the levels of total radioactivity in eggs was still increasing

-<u>Lactating ruminnats</u>
In milk over 21% of TRR (corresponding to 0.002 mg eq/kg) was found as clopyralid-glycine conjugate (X36538).
Clopyralid comprised from 54% to over 70% of the TRR in milk, urine and faeces.
In the tissues unchanged clopyralid was the major residue along with minor amounts of conjugate X36538.
Proposed metabolic profile of active substance in domestic animals.



7.3.1.8 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	Goat, laying hen
Time needed to reach a plateau concentration	- For clopyralid residues in milk dosing was once a day and the residues had already declined to low levels within one day. Any accumulating potential could not be demonstrated. Plateau was reached at day 1. - For eggs residue levels are still slightly increasing at the end of the experiment, i.e. after 7 days of dosing, but a plateau can be assumed at day 7.
Animal residue definition for monitoring	clopyralid and its salts (EFSA Journal 2018;16(7):5389)
Animal residue definition for risk assessment	clopyralid common moiety (sum of clopyralid, its salts and glycine conjugates expressed as clopyralid) (EFSA Journal 2018;16(7):5389)
Conversion factor	The conversion factor monitoring / risk assessment is only relevant for milk and is based on the new ruminant metabolism study as 1.3.(EFSA Journal 2018;16(7):5389)
Metabolism in rat and ruminant similar	Yes (EFSA Journal 2018;16(7):5389)
Fat soluble residue	No (EFSA Journal 2018;16(7):5389)

* 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

7.3.2 Magnitude of residues in plants (KCA 6.3)

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

New magnitude of residues in plant studies have not been submitted by the applicant in the framework of this application. These studies are summarized in the table below. The detailed assessment of these

studies was presented and evaluated during the registration process. Taking into account that no changes in GAP has been implemented, studies were conducted in compliance with Good Laboratory Practice, method validation includes hydrolysis and current residue definition is pending, no new studies are required and data can be used to support the authorization of CHR/H/CFF 250 EC.

Table 7.3-8: Summary of EU reported and new data supporting the intended uses of CHR/H/~~ePD 300 SL CFF 250 EC~~ 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		Substrate	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg)	MRL compliance
Cereals	*DAR_05_vol 3_B7*	N-EU	Trials GAP: clopyralid 0.150kg/ha, outdoor BBCH 39	1x0.93, 1x0.73, 1x0.23, 1x0.07, 1x0.79, 1x1.11, 1x1.06, 1x1.26, 1x0.38, 1x0.24, 1x0.82, 1x0.95, 1x0.14, 1x0.37, 1x0.61, 1x0.34, 1x0.47	Grain	0.61	1.26	-	3mg/kg	Yes
				1x0.12, 1x0.32, 1x0.63, 1x0.43, 1x0.33, 1x0.58, 1x0.81, 1x0.17, 1x0.32, 1x0.28, 1x0.50,	Straw	0.415	1.08	-		N/A

				1x0.40, 1x1.08, 1x1.05, 1x0.87, 1x0.31						
				1x1.16, 1x1.06, 1x1.62, 1x1.15, 1x0.31, 1x1.57, 1x0.46, 1x0.89	Whole plant	1.105	1.62	-		N/A
	New trials only for bridging studies for studies assessed on EU level *C. Ertus, Study code: R C2107-C2110*	N-EU	GAP: 1x ~~0.048~~ 0.060 clopyralid/ha , BBCH 33, outdo0r Wheat Grain: 0.18, 0.29, 0.37, 0.63 Wheat Straw: 0.17, 0.33, 0.52, 1.77			Grain: 0.33 Straw: 0.425	Grain: 0.63 Straw: 1.77	-		Yes

* Source of EU MRL: COMMISSION REGULATION (EU) 2021/1807

Conclusions
According to the available data, the intended use and winter wheat is considered acceptable. The data submitted show that no exceedance of the MRL will occur.
All storage stability for samples are cover by stability studies presented at point 7.3.1

7.3.3 Magnitude of residues in livestock

7.3.3.1 Dietary burden calculation

Table 7.3-9: 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
Residues expressed as Clopyralid				
Wheat, grain	0.61	STMR (please refer to Table 7.2-8)	1.26	HR (please refer to Table 7.2-8)
Wheat, straw	0.415	STMR (please refer to Table 7.2-8)	1.08	HR (please refer to Table 7.2-8)
Canola, meal	0.05	STMRx default PF	N/A	N/A
Rape, meal	0.05	STMRx default PF	N/A	N/A
Distiller's grain, dried	2.01	STMRxdefault PF	N/A	N/A
Wheat gluten, meal	1.10	STMRxdefault PF	N/A	N/A
Wheat, milled by-pdts	4.27	STMRxdefault PF	N/A	N/A

New Dietary Burden calculations were performed, taking into account STMR and HR values from residues trials on CHR/H/CFF 250 EC. New calculations were presented below in Animal model 2017.

Table 7.3-10: Results of the dietary burden calculation

Animal burden calculation — Clopyralid

According to: "OECD Guidance Document, Series on testing and assessment No 64 and Series on pesticides No 32" and "OECD Guidance Document on Residues in livestock, Series on Pesticides No 73"

Maximum Intake	Cattle						Sheep					
	Beef (500 kg / 12 kg)			Dairy (650 kg / 25 kg)			Ram/Ewe (75 kg / 2.5 kg)			Lamb (40 kg / 1.7 kg)		
(mg/kg bw/d)	0.047	mg/kg bw/d	%	0.076	mg/kg bw/d	%	0.086	mg/kg bw/d	%	0.127	mg/kg bw/d	%
Contributor 1	Wheat	milled bypdts	30	Wheat	milled bypdts	30	Wheat	milled bypdts	40	Wheat	milled bypdts	50
Contributor 2	Wheat	straw	20	Wheat	straw	20	Wheat	straw	40	Wheat	straw	40
Contributor 3	Wheat	grain	40	Wheat	grain	40	Wheat	grain	20	Wheat	grain	10
Contributor 4												
Median intake	0.0438	mg/kg bw/d		0.0702	mg/kg bw/d		0.0770	mg/kg bw/d		0.1177	mg/kg bw/d	

Maximum Intake	Swine					
	Breeding (260 kg / 6 kg)			Finishing (100 kg / 3 kg)		
(mg/kg bw/d)	0.064	mg/kg bw/d	%	0.083	mg/kg bw/d	%
Contributor 1	Wheat	milled bypdts	50	Wheat	milled bypdts	50
Contributor 2	Wheat	grain	50	Wheat	grain	50
Contributor 3						
Contributor 4						
Median intake	0.064	mg/kg bw/d		0.083	mg/kg bw/d	

Intakes >0.004 mg/kg bw/d are highlighted

Maximum Intake	Poultry								
	Broiler (1.7 kg / 0.12 kg)			Layer (1.9 kg / 0.13 kg)			Turkey (7 kg / 0.5 kg)		
(mg/kg bw/d)	0.102	mg/kg bw/d	%	0.108	mg/kg bw/d	%	0.094	mg/kg bw/d	%
Contributor 1	Wheat	milled bypdts	20	Wheat	milled bypdts	20	Wheat	milled bypdts	20
Contributor 2	Wheat	grain	70	Wheat	straw	10	Wheat	grain	50
Contributor 3				Wheat	grain	70			
Contributor 4									
Median intake	0.102	mg/kg bw		0.102	mg/kg bw		0.094	mg/kg bw	

Intakes expressed on the dry mater basis (mg/kg DM)

mg/kg DM	Cattle		Sheep		Swine	
	Beef	Dairy	Ram/Ewe	Lamb	Breeding	Finishing
Maximum	1.98	1.98	2.6	2.99	2.77	2.77
Median	1.82	1.82	2.31	2.77	2.77	2.77

	Poultry		
	Broiler	Layer	Turkey
Maximum	1.45	1.57	1.31
Median	1.45	1.50	1.31

Intake >0.1 mg/kg DM in red characters

Livestock feeding studies (KCA 6.4.1-6.4.3)

According to EFSA Journal 2018;16(7):5389 new livestock feeding studies are performed during Annex I inclusion and renewal. No new livestock studies feeding studies are necessary.

OECD Guideline 503 and SANCO/11187/2013 rev. 3 (fish)	Animal	Dose (mg/kg bw/d)	Duration (days)	N rate/comment
Animals covered	Laying hen	11.4 mg a.s./kg feed per day, equivalent to 0.56-0.65 mg/kg bw per day	7	N rates can be established only once HR and STMR for cereal straw and grass from valid residue trials are available.
	Goat/Cow	50.9 mg a.s./kg dry feed/day equivalent to 0.484 mg/kg bw per day	5	N rates can be established only once HR and STMR for cereal straw and grass from valid residue trials are available.
	Pig			Not considered necessary.
	Fish			No studies submitted.
	In milk over 21% of TRR (corresponding to 0.002 mg eq/kg) was found as clopyralid-glycine conjugate (X36538). Clopyralid comprised from 54% to over 70% of the TRR in milk, urine and faeces. In the tissues unchanged clopyralid was the major residue along with minor amounts of conjugate X36538.			

Time needed to reach a plateau concentration in milk and eggs (days)	For clopyralid residues in milk dosing was once a day and the residues had already declined to low levels within one day. Any accumulating potential could not be demonstrated. Plateau was reached at day 1. For eggs residue levels are still slightly increasing at the end of the experiment, i.e. after 7 days of dosing, but a plateau can be assumed at day 7.

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

Data/information on processing studies on wheat was reviewed during the renewal of approval of active substance(s) and were considered acceptable. No new study is necessary.

Data/information on processing studies on sugar beet were reviewed during the Annex I inclusion process and was considered to be acceptable and no further studies have been generated.

7.3.4.1 Available data for all crops under consideration

Please refer to Clopyralid RAR (Section B.7) (Devine, H.C., 2006, Study report no. GHE-P-11274 to which are equivalent Tim White, 2021, study codes: S19-01810, S20-04937)

Crop (RAC)/Edible part or Crop (RAC)/Processed product	Number of studies[a]	Processing Factor (PF)		Conversion Factor (CF_P) for RA[b]
		Individual values	Median PF	
Representative uses (row to be deleted if not relevant)				
Wheat / bran	4	3.5, 4.3, 6.1, 10.4	6.1 / 5.2	N/A
Wheat / white flour	4	0.1, 0.2, 0.3, 0.6	0.3 / 0.3	N/A
Wheat / wholemeal flour	2	0.8, 1.2	1 / 1	N/A
Wheat / germ	2	2.3, 4.3	3.3	N/A
Wheat / white bread	2	0.1, 0.1	0.1 / 0.1	N/A
Wheat / wholemeal bread	2	0.5, 0.6	0.6 / 0.6	N/A
Barley / malt sprouts	2	0.2, 0.2	0.2 / 0.2	N/A
Barley / brewing malt	2	0.6, 0.7	0.7 /0.7	N/A
Barley / spent grains and flocs	2	0.1, 0.2	0.2 / 0.2	N/A
Barley / brewer's yeast	2	0.1, 0.1	0.1 / 0.1	N/A
Barley / beer	2	0.1, 0.1	0.1 / 0.1	N/A

[a]: Studies with residues in the RAC at or close to the LOQ should be disregarded (unless concentration)
[b]: When the residue definition for risk assessment differs from the residue definition for monitoring

7.3.4.2 Conclusion on processing studies

Results of residue in processed commodities may therefore be used in order to predict the residue behaviour of clopyralid after usage of CHR/H/CFF 250 EC

7.3.5 Magnitude of residues in representative succeeding crops

According to EFSA Journal 2018;16(7):5389 residues in succeeding crops were reviewed during the Annex I inclusion and renewal process and were considered to be acceptable and no further data have been generated.
Crops under evaluation are expected to be grown in rotation.

Residues in succeeding crops (Regulation (EU) N° 283/2013, Annex Part A, point 6.6.2)	
Confined rotational crop study (Quantitative aspect) OECD Guideline 502	In rotational crop intervals majority of the residue identified was clopyralid conjugates (up to 81%TRR) most abundant residue at all PBIs. Unconjugated clopyralid correspond from 10 to 50 %TRR. Clopyralid taken up by the plants as glucose conjugate of clopyralid
Field rotational crop study OECD Guideline 504	Data gap: Rotational crop field trials according to current guidelines should be submitted as residues of free and conjugated parent were found in all plant parts at PHI 30.

zRMS: According to the available data following label restriction is proposed: not to use clopyralid on the same field for 125 days after the initial application regardless of the crop grown (see EFSA Journal 2021;19(1):6389).

7.3.5.1 Field rotational crop studies (KCA 6.6.2)

No new data submitted in the framework of this application.

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

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of CHR/H/CFF 250 EC. Therefore, other special studies are not needed.

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

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

7.3.7.1 Input values for the consumer risk assessment

Table 7.3-12: Input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Wheat/bread (wholemeal); Wheat/bread/pizza Wheat/pasta; Wheat/ milling (flour); Wheat/ milling(wholemeal) -baking	3	COMMISSION REGULATION (EU) 2021/1807	3	COMMISSION REGULATION (EU) 2021/1807
Sheep, Goat, Equine, Poultry and other farmed terrestrial animals" muslce, fat, liver, kidney, dible offals, milk and other	0.05	COMMISSION REGULATION (EU) 2021/1807	0.05	COMMISSION REGULATION (EU) 2021/1807
Birds egg	0.05	COMMISSION REGULATION (EU) 2021/1807	0.05	COMMISSION REGULATION (EU) 2021/1807

7.3.7.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in A 2.3.1.

Table 7.3-13: Consumer risk assessment

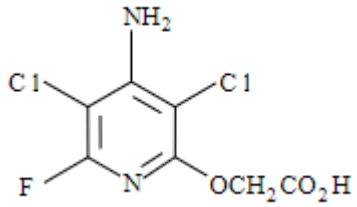
Clopyralid		
ADI	0.15 mg/kg bw per day	
TMDI (% ADI) according to EFSA PRIMo rev. 3.1	15% (based on GEMS/Food)	
ARfD	0.17 mg/kg bw per day	
IESTI (% ARfD) according to EFSA PRIMo rev. 3.1	Processed	21% (wheat for children – worst case)
	unprocessed	25% (wheat for children – worst case)

The proposed use of clopyralid in the formulation CHR/H/CFF 250 EC do not represent unacceptable acute and chronic risks for the consumer.

7.4 Fluroxypyr

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

Table 7.4-1: General information on Fluroxypyr

Active substance (ISO Common Name)	**Fluroxypyr**
IUPAC	4-amino-3,5-dichloro-6-fluoro-2-pyridyloxyacetic acid
Chemical structure	
Molecular formula	C7H5Cl2FN2O3
Molar mass	255 g/mol
Chemical group	Pyridine class
Mode of action (if available)	In susceptible plant species the product induces an epinastic response (ie. stimulation of cell elongation and premature senescence, particularly in meristematic tissue) leading to cessation of normal growth and death
Systemic	Systemic
Company (ies)	DOW
Rapporteur Member State (RMS)	DE
Approval status	Approved 01/01/2012 Commission Directive 2003/84/EC of 25 September 2003
Restriction	SANCO/11019/2011 rev 5 17 June 2011 23 March 2017
Review Report	Fluroxypyr SANCO/11019/2011 rev 5 17 June 2011 23 March 2017
Current MRL regulation	Reg. (EU) 2022/1363
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	EFSA Journal 2019;17(9):5816
EFSA Journal : Conclusion on the peer review	EFSA Journal 2011;9(3):2091
EFSA Journal: conclusion on article 12	EFSA Journal 2019;17(9):5816
Current MRL applications on intended uses	Reg. (EU) 2022/1363

7.4.1 Stability of Residues (KCP 6.1)

7.4.1.1 Stability of residues during storage of samples

Available data

Storage stability data was reported in Annex I inclusion . No new data submitted in the framework of this application.

Table 7.4-2: Summary of stability data achieved at ≤ - 18°C

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products			
Wheat (whole plant, straw and grain)	High starch content	24 months	Monograph Annex B 6 Bosnak, L. L.; 1997
Animal Products - not required			

Conclusion on stability of residues during storage

The storage stability evaluated during Annex I inclusion covers plant matrices for use CHR/H/CFF 250 EC according to the label, therefore no new studies are necessary.

7.4.1.2 Stability of residues in sample extracts (KCP 6.1)

Not relevant for this application, in supervised studies ~~evaluated during Annex I inclusion and presented in DAR Fluroxypy, Volume 3, Section b7~~ , analysis time were less than 24 hours between extraction and analysis.

7.4.2 Nature of residues in plants, livestock and processed commodities

7.4.2.1 Nature of residue in primary crops (KCP 6.2.1)

Available data

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

No new data submitted in the framework of this application.

Table 7.4-3: Summary of plant metabolism studies

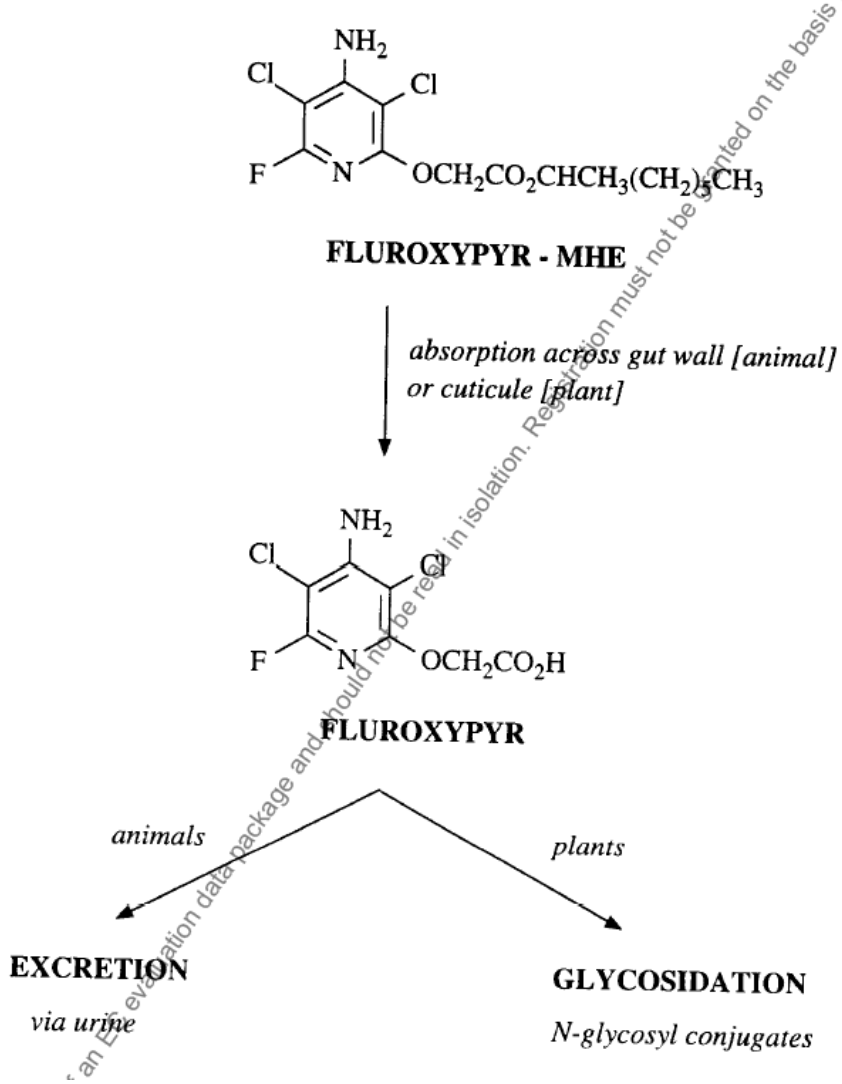
Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Cereals	Wheat	14C-fluroxypyr-MHE (4-amino-3,5-dichloro-6-fluoro-2,6-[14C]-2-pyridinyloxyacetic acid 1-methylheptylester	F	Exaggerated rates	1	harvest	-	Hawkins, 1981 Puvanesarajah, 1991)

Summary of plant metabolism studies reported in the EU

Two wheat metabolism studies (Hawkins, 1981 and Puvanesarajah, 1991) were submitted and accepted for the foliar application of fluroxypyr under the original EU evaluation. The studies were conducted with [14C-fluroxypyr-MHE (4-amino-3,5-dichloro-6-fluoro-2,6-[14C]-2-pyridinyloxyacetic acid 1-methylheptylester) applied at exaggerated rates. Both studiesdemonstrated that fluroxypyr-MHE was shown to be partially absorbed from a foliarapplication. Fluroxypyr-MHE appeared to be mainly resident

on the plant surface where it was either lost by "weathering" or absorbed and translocated into the cuticula where hydrolysis took place to form the parent acid. These residues are translocated within the plant to the vegetation tips. At harvest levels were generally low in grain (<0.1 mg/kg) from applications up to 150 % the maximum recommended rate, whilst in straw a range of 3.0 - 7.9 mg/kg were present. The bulk of the residue was shown to be either fluroxypyr acid or a fluroxypyr conjugate and was readily extractable with a methanolic alkalia procedure.
Two further metabolism studies were accepted under the original EU evaluation. The two studies conducted on broad leaved weeds were designed primarily to investigate the herbicidal mode of action of fluroxypyr 1-methylheptyl ester. Studies undertaken to measure uptake and behaviour within broad-leaved weed species indicated a similar fate to that in grass species.
These results confirm the findings of the studies in the wheat metabolism studies in that following hydrolysis of the applied ester no other degradative step occurs in plants, with conjugation believed to be the route of detoxification. The metabolic pathway in plants is shown below
It was concluded that on the basis of the studies presented that the most appropriate residue definition for fluroxypyr is “fluroxypyr and its ester fluroxypyr 1-MHE expressed as fluroxypyr”. It should also be noted that the notifier provided an additional wheat metabolism study (Caley, 1995) as part of the re-review process. The additional wheat metabolism study merely provides additional data and does not alter any of the End Points from the original plant metabolism evaluation. A full evaluation of the additional wheat metabolism study has not been reported here because plant metabolism has been adequately addressed under the original EU evaluation

Proposed metabolic pathway of Fluroxypyr in plants:



Conclusion on metabolism in primary crops

The metabolism in primary crops presented during Annex I inclusion, covers use of CHR/H/CFF 250 EC. No new studies were necessary.

7.4.2.2 Nature of residue in rotational crops (KCP 6.6.1)

Available data

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

No new data submitted in the framework of this application.

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

Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G *	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks	
EU data Syngenta studies on Annex I								
Leafy vege-tables	lettuce	14C-fluroxypyr-MHE (4-amino-3,5-dichloro-6-fluoro-2,6-[14C]-2-pyridinyloxyacetic acid 1-methylheptylester	F	0.594 kg a.e./ha).	30, 120 and 360 DAA	At maturity	none	Lickly, L.S., 1990
Root and tuber vege-tables	Turnips	14C-fluroxypyr-MHE (4-amino-3,5-dichloro-6-fluoro-2,6-[14C]-2-pyridinyloxyacetic acid 1-methylheptylester	F	0.594 kg a.e./ha).	30, 120 and 360 DAA	At maturity	none	Lickly, L.S., 199
Cereals	Wheat	14C-fluroxypyr-MHE (4-amino-3,5-dichloro-6-fluoro-2,6-[14C]-2-pyridinyloxyacetic acid 1-methylheptylester	F	0.594 kg a.e./ha).	30, 120 and 360 DAA	At maturity	none	Lickly, L.S., 1990
Oilseeds	Soya	14C-fluroxypyr-MHE (4-amino-3,5-dichloro-6-fluoro-2,6-[14C]-2-pyridinyloxyacetic acid 1-methylheptylester	F	0.594 kg a.e./ha).	30, 120 and 360 DAA	At maturity	None	Lickly, L.S., 1990
Legumes	Broad bean	14C-fluroxypyr-MHE (4-amino-3,5-dichloro-6-	F	0.594 kg a.e./ha).	30, 120 and 360 DAA	At maturity	none	Lickly, L.S., 199

		fluoro-2,6-[14C]-2-pyridinyloxyacetic acid 1-methylheptylester						

Summary of plant metabolism studies reported in the EU

Under the original EU evaluation, a confined rotational crop study (Lickly, L.S., 1990) was conducted to determine residues in crops grown in soil previously treated with Fluroxypyr-MHE, either in the normal rotation or after crop failure (the study used an application rate of 0.594 kg a.e./ha). The rotational crops were planted 30, 120 and 360 days after application (DAA) to soil. Under the original EU evaluation, rotational crop studies conducted with radiolabelled fluroxypyr on lettuce, turnips, broad beans, soya beans and wheat were evaluated and accepted. The analyses of succeeding crops indicated that all residues were below the LOD (0.02 mg/kg).
The notifier also provided an additional rotational crop study (Yaskovich, P.R., 1996) as part of the rereview process. The additional rotational crop study was conducted on wheat, lettuce and turnip.
The rotational crop study results from the new study are in agreement with residue results from the older rotational crop study. It was not considered necessary to provide a report for the new study considering the new rotational crop study is viewed as additional data. The new rotational crop study does not change the End Points from the original EU evaluation..

Conclusion on metabolism in rotational crops

A similar profile as in primary crops is observed in the rotational crops.
The metabolism in rotational crops covers use of CHR/H/CFF 250 EC according to the label

7.4.2.3 Nature of residues in processed commodities (KCP 6.5.1)

No significant residues, i.e. >0.1 mg/kg, were found in grain and therefore processing studies are not required. No new studies are necessary for CHR/H/CFF 250 EC, since all residues are expected to be below 0.1 mg/kg.
According to DAR Fluroxypyr , Volume 3, B7 The conclusion from the original EU evaluation remains acceptable. It is not considered necessary to determine the effects of any preparation procedures on the RAW Agricultural Commodity (RAC) because of the low levels of fluroxypr residues found in cereal grain and maize kernel/cob. The highest residue (HR) found in cereal grain was 0.09 mg/kg.

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

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

Endpoints	
Plant groups covered	Cereals
Rotational crops covered	Wheat, lettuce, turnip, broad beans, soya beans
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Not provided and not required
Residue pattern in processed commodities similar to pattern in raw commodities?	Not required

Plant residue definition for monitoring	Fluroxypyr, its esters, salts and its conjugates expressed as fluroxypyr
Plant residue definition for risk assessment	Fluroxypyr, its esters, salts and its conjugates expressed as fluroxypyr
Conversion factor from enforcement to RA	Not applicable

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

Available data

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

No new data submitted in the framework of this application.

Table 7.4-5: Summary of animal metabolism studies

Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling	
EU data								
Poultry	laying hen	^{14}C-Fluroxypyr acid	10	0.663	10 days	Milk	daily	[redacted], 1989
						Urine and faeces	daily	
						Tissues	At sacrifice	
Lactating ruminants	goat	^{14}C-Fluroxypyr acid	2	100	4 days	Milk	Twice daily	[redacted]., 1990
						Urine and faeces	daily	
						Tissues	At sacrifice	
Cow	cow	[1]	10	20	4 days	Urine and faeces	daily	[redacted]., 1985
						Tissues	At sacrifice	

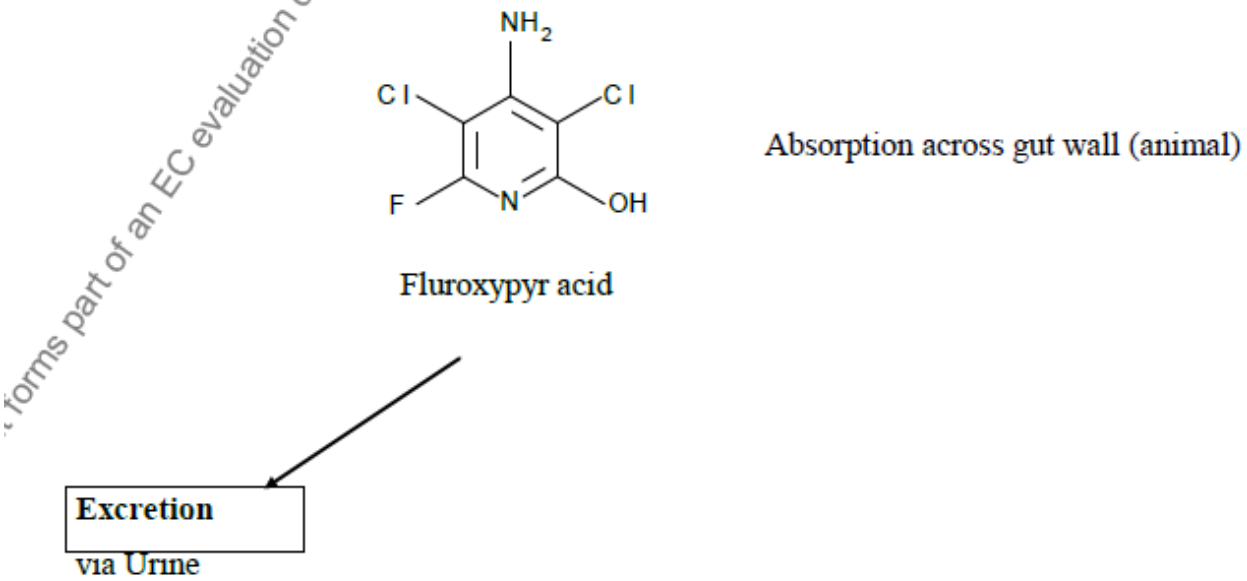
Summary of plant metabolism studies reported in the EU

Three animal metabolism studies (hen, cow and goat) were evaluated under the original EU evaluation. The test material in these experiments was Fluroxypyr acid. Administration of Fluroxypyr acid is justified because this is the most relevant residue in plants used for animal nutrition. In addition, investigations in rats have shown that the ester (Fluroxypyr 1-MHE) is metabolised to the acid and that both are pharmacokinetically equivalent. Laying hens were exposed orally to 14C-Fluroxypyr acid (9.77 mg/kg in the diet or 0.663 mg/kg bw/day) for 10 days. In a dairy cow, the excretion of radioactivity was studied after a single oral dose of 14C-Fluroxypyr acid (approx. 20 g). In a goat metabolism study, two lactating goats received orally administered 14C Fluroxypyr acid at a level equivalent to 100 mg/kg in feed for four consecutive days. A third goat was similarly dosed at the equivalent of 344 mg/kg in feed. A fourth goat was given placebo doses containing no chemical and served as a control.
It was accepted under the original EU evaluation that the three metabolism studies indicated that Fluroxypyr acid was the major residue detected in all animal matrices tested. The three metabolism studies also noted that unchanged Fluroxypyr acid is rapidly excreted. The highest residue level of fluroxypyr found

in poultry was in the liver with an average level of 0.005 mg/kg and gizzard with an average level of 0.01 mg/kg. Residues were below 0.01 mg/kg in all other poultry tissues. No measurable level of fluroxypyr appeared in eggs. In the ruminant metabolism studies the vast majority of the recovered activity was found in the urine and faeces, while only 0.05% was found in tissues or milk. Fluroxypyr was the major residue detected in urine, faeces, milk, liver and kidney tissue samples.
On the basis of the information provied, it was agreed that the animal residue definition should be "fluroxypyr acid" only. No additional animal metabolism studies were provided for the re-review.

Under the original evaluation, a comparison of the animal and rat metabolism studies indicated that both animal and rats provide the same metabolic profile. On the basis of this information it was decided that it was not necessary to conduct a metabolism study for pigs.

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



Conclusion on metabolism in livestock

All studies presented during Annex I inclusion covers use of CHR/H/CFF 250 EC, therefore no new studies are necessary.

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

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

	Endpoints
Animals covered	Goat (using fluroxypyr) (Poultry and cow studies informative only; no characterisation of the nature of the residues)
Animal residue definition for monitoring	Fluroxypyr and its salts expressed as fluroxypyr
Animal residue definition for risk assessment	Fluroxypyr and its salts expressed as fluroxypyr
Conversion factor	Not applicable

Metabolism in rat and ruminant similar	Yes
Fat soluble residue	Fluroxypyr-MHE – Yes Fluroxypyr - No

7.4.3 Magnitude of residues in plants (KCP 6.3)

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

Applicant provide supervised residues studies for Annex I inclusion , which covers critical GAP for Annex I inclusion and cGAP for CHR/H/CFF 250 EC containing ~~Fludioxonil~~ Fluroxypyr..

Please refer to the DAR Fluroxypyr - Volume 3, Annex B.7: Residues. Summary of available studies is presented in Table 7.2.-9.

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

Table 7.4-7: Summary of EU reported and new data supporting the intended uses of CHR/H/CFF 250 EC 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	~~DAR Fluroxypyr - Volume 3, Annex B.7: Residues.~~	~~N-EU~~	~~GAP on which MRL/EU a.s. assessment is based:1 x 0.25 kg as/ha, BBCH 35-47 , PHI from 58 to 97, outdoor~~ ~~Wheat grain: 10x <0.05, 0.06~~ ~~Wheat straw: <0.2, 0.53, 0.90, 0.97, 1.21, 1.30, 1.38, 1.50, 2.97, 4.91~~	N				
	New trials *C. Ertus, Study code: R C2107-C2110*	N-EU	~~Now new trials submitted~~ GAP on which new data assessment is base – ~~1x 0.048 g~~ 1 x 0.060 kg as/ha, BBCH 33, outdoor Wheat grain: 2x <LOD, 2x <LOQ Wheat straw: 0.21, 0.23, 0.79, 0.89					
	Overall supporting data for cGAP	N-EU	Wheat grain: 2x LOD, 2x <LOQ ~~10x <0.05, 0.06~~ Wheat straw: 0.21, 0.23, 0.79, 0.89 ~~<0.2, 0.53, 0.90, 0.97, 1.21, 1.30, 1.38, 1.50, 2.97, 4.91~~	E: ~~0.05~~<LOQ RA: ~~0.05~~ 0.51	E: ~~0.05~~ <LOQ RA:~~0.05~~ 0.89	-	0.1 mg/kg	Yes

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

7.4.3.2 Conclusion on the magnitude of residues in plants

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

All available data ~~presented in EU conclusion~~ is sufficient to support use of CHR/H/CFF 250 EC containing fluroxypyr. All storage stability for samples are cover by stability studies presented at point 7.4.1

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

The uses are considered acceptable.

7.4.4 Magnitude of residues in livestock

7.4.4.1 Dietary burden calculation

Dietary Burden calculations were performed during Annex I inclusion. No new studies are required for this application. However new calculation is provided below:

Animal burden calculation — **Fluroxypyr**

According to: "OECD Guidance Document, Series on testing and assessment No 64 and Series on pesticides No 32" and "OECD Guidance Document on Residues in livestock, Series on Pesticides No 73"

Maximum Intake	Cattle						Sheep					
	Beef (500 kg / 12 kg)			Dairy (650 kg / 25 kg)			Ram/Ewe (75 kg / 2.5 kg)			Lamb (40 kg / 1.7 kg)		
(mg/kg bw/d)	0.006	mg/kg bw/d	%	0.009	mg/kg bw/d	%	0.015	mg/kg bw/d	%	0.019	mg/kg bw/d	%
Contributor 1	Rye	straw	20	Rye	straw	20	Rye	straw	40	Rye	straw	40
Contributor 2	Wheat	milled bypdts	30	Wheat	milled bypdts	30	Wheat	milled bypdts	40	Wheat	milled bypdts	50
Contributor 3	Rye	grain	40	Rye	grain	40	Rye	grain	20	Rye	grain	10
Contributor 4												
Median intake	0.0035	mg/kg bw/d		0.0056	mg/kg bw/d		0.0089	mg/kg bw/d		0.0116	mg/kg bw/d	

Intakes >0.004 mg/kg bw/d are highlighted

Maximum Intake	Swine					
	Breeding (260 kg / 6 kg)			Finishing (100 kg / 3 kg)		
(mg/kg bw/d)	0.001	mg/kg bw/d	%	0.001	mg/kg bw/d	%
Contributor 1	Wheat	milled bypdts	50	Wheat	milled bypdts	50
Contributor 2	Rye	grain	50	Rye	grain	50
Contributor 3						
Contributor 4						
Median intake	0.001	mg/kg bw/d		0.001	mg/kg bw/d	

Maximum Intake	Poultry								
	Broiler (1.7 kg / 0.12 kg)			Layer (1.9 kg / 0.13 kg)			Turkey (7 kg / 0.5 kg)		
(mg/kg bw/d)	0.002	mg/kg bw/d	%	0.009	mg/kg bw/d	%	0.002	mg/kg bw/d	%
Contributor 1	Wheat	milled bypdts	20	Wheat	straw	10	Wheat	milled bypdts	20
Contributor 2	Rye	grain	70	Wheat	milled bypdts	20	Rye	grain	60
Contributor 3				Wheat	grain	70			
Contributor 4									
Median intake	0.002	mg/kg bw		0.006	mg/kg bw		0.002	mg/kg bw	

Intakes expressed on the dry mater basis (mg/kg DM)

mg/kg DM	Cattle		Sheep		Swine	
	Beef	Dairy	Ram/Ewe	Lamb	Breeding	Finishing
Maximum	0.23	0.23	0.4	0.45	0.05	0.05
Median	0.14	0.14	0.27	0.27	0.05	0.05

	Poultry		
	Broiler	Layer	Turkey
Maximum	0.02	0.12	0.02
Median	0.02	0.08	0.02

Intake >0.1 mg/kg DM in red characters

7.4.4.2 Livestock feeding studies (KCP 6.4.1-6.4.3)

According DAR Fluroxypyr - Volume 3, Annex B.7: Residues:

The conclusion from the original EU evaluation remains acceptable. No new feeding studies were provided for the purposes of the re-review. The original EU evaluation contained acceptable poultry and ruminant feeding studies.

Three animal metabolism studies (hen, cow and goat) were evaluated under the original EU evaluation. The test material in these experiments was Fluroxypyr acid. Administration of Fluroxypyr acid is justified because this is the most relevant residue in plants used for animal nutrition. In addition, investigations in rats have shown that the ester (Fluroxypyr 1-MHE) is metabolised to the acid and that both are pharmacokinetically equivalent. Laying hens were exposed orally to ^{14}C-Fluroxypyr acid (9.77 mg/kg in the diet or 0.663 mg/kg bw/day) for 10 days. In a dairy cow, the excretion of radioactivity was studied after a single oral dose of ^{14}C-Fluroxypyr acid (approx. 20 g). In a goat metabolism study, two lactating goats received orally administered ^{14}C Fluroxypyr acid at a level equivalent to 100 mg/kg in feed for four consecutive days. A third goat was similarly dosed at the equivalent of 344 mg/kg in feed. A fourth goat was given placebo doses containing no chemical and served as a control. It was accepted under the original EU evaluation that the three metabolism studies indicated that Fluroxypyr acid was the major residue detected in all animal matrices tested. The three metabolism studies also noted that unchanged Fluroxypyr acid is rapidly excreted. The highest residue level of fluroxypyr found in poultry was in the liver with an average level of 0.005 mg/kg and gizzard with an average level of 0.01 mg/kg. Residues were below 0.01 mg/kg in all other poultry tissues. No measurable level of fluroxypyr appeared in eggs. In the ruminant metabolism studies the vast majority of the recovered activity was found in the urine and faeces, while only 0.05% was found in tissues or milk. Fluroxypyr was the major residue detected in urine, faeces, milk, liver and kidney tissue samples. On the basis of the information provided, it was agreed that the animal residue definition should be “fluroxypyr acid” only. No additional animal metabolism studies were provided for the re-review.

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

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

7.4.5.1 Available data for all crops under consideration

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

7.4.5.2 Conclusion on processing studies

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

7.4.6 Magnitude of residues in representative succeeding crops

According DAR Fluroxypyr - Volume 3, Annex B.7: Residues:

Acceptable rotational crop studies were conducted under the original EU evaluation. On the basis of the results of the supervised residues trials it is clear that residues in cereal grain less than 0.10 mg/kg, however, significant residues are to be found in cereal straw. A confined rotational crop study (Lickly, L.S., 1990) was therefore conducted to determine residues in crops grown in soil previously treated with Fluroxypyr-MHE, either in the normal rotation or after crop failure the study used an application rate of 0.594 kg a.e./ha). The rotational crops were planted 30, 120 and 360 days after application (DAA) to soil. Under the original EU evaluation, rotational crop studies conducted with radiolabelled fluroxypyr on lettuce, turnips, broad beans, soya beans and wheat were evaluated and accepted. The analyses of succeeding crops indicated that all residues were below the LOD (0.02 mg/kg). The notifier also provided an additional rotational crop study (Yaskovich, P.R., 1996) as part of the re-review process. The additional rotational crop study was conducted on wheat, lettuce and turnip. The highest residues were found in the crops 30 day after the last application (DAA) and ranged from 0.02 mg/kg in turnip foliage to 0.59 mg/kg in wheat straw. The 120 DAA and 365 DAA crops contained lower radioactive residues with the highest

residue level being approximately 0.06 mg/kg in 120 DAA wheat straw. Residues in edible crop parts were always below 0.10 mg/kg despite the fact that an exaggerated dose rate was used in the study. The rotational crop study results from the new study are in agreement with residue results from the older rotational crop study. It was not considered necessary to provide a full report for the new study considering the new rotational crop study is viewed as additional data. The new rotational crop study does not change the End Points from the original EU evaluation..

zRMS: EFSA recommends avoiding rotation with root and tuber crops (in view of the high persistence of the metabolite fluroxypyr methoxypyridine and the absence of toxicological data on this metabolite).

7.4.6.1 Field rotational crop studies (KCP 6.6.2)

Field rotational studies are not required.

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

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of CHR/H/CFF 250 EC containing Fluroxypyr. Therefore, other special studies are not needed.

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

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

7.4.8.1 Input values for the consumer risk assessment

Table 7.4-8: Input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Wheat/bread (wholemeal); Wheat/bread/pizza Wheat/pasta; Wheat/ milling (flour); Wheat/ milling(wholemeal) -baking	0.1	Reg. (EU) 2022/1363	0.1	Reg. (EU) 2022/1363
Sheep, Goat: muslce, fat, liver, kidney, dible offals, milk and other	0.06	Reg. (EU) 2022/1363	0.06	Reg. (EU) 2022/1363
Poultry: muslce, fat, liver, kidney, dible offals, milk and other	0.01	Reg. (EU) 2022/1363	0.01	Reg. (EU) 2022/1363
Birds egg	0.01	Reg. (EU)	0.01	Reg. (EU) 2022/1363

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
		2022/1363		

7.4.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in A 2.3.1.

Table 7.4-9: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo rev.3.1	0.5% (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo	~~0.5% (based on NL toddler)~~ n.r.
IESTI (% ARfD) according to EFSA PRIMo*	ARfD is not applicable

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

The proposed uses of fluroxypyr in the formulation CHR/H/CFF 250 EC do not represent unacceptable acute and chronic risks for the consumer.

7.5 Combined exposure and risk assessment

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

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

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

7.5.1 Acute consumer risk assessment from combined exposure

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

7.5.2 Chronic consumer risk assessment from combined exposure

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

ation is warranted in the scope of this evaluation.

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

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

7.6 References

DAR Florasulam, Volume 3, Annex B, B7
DAR Fluroxypyr, Volume 3, Annex B, B7
DAR Clopyralid, Volume 3, Annex B, B7

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

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

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.3/01	J. Semrau	2016	Final Report Determination of residues of iodosulfuron-methyl, tribenuron-methyl, florasulam and mefenpyr-diethyl after one application of IDS 100 OD or FLOT 150 WG and Adjuwant Super in wheat at 4 sites in Northern Europe 2016 EAS Study Code S16-02449 Eurofins Agroscience Services GmbH, Stade, Germany GLP yes Unpublished	N	PUH Chemirol Sp. z o.o.
KCP 6.3/2	C. Ertus	2023	Determination of Clopyralid and Fluroxypyr Residues in Winter Wheat Following Foliar Application with CHR/H/CFF 250 EC under Field Conditions in Northern Europe in 2022 Study code: R C 2107 ANADIAG, 16, rue Ampère, 67500 HAGUENAU, France GLP Unpublished	N	PUH Chemirol Sp. z o.o.
KCP 6.3/3	C. Ertus	2023	Determination of Clopyralid and Fluroxypyr Residues in Winter Wheat Following Foliar Application with CHR/H/CFF 250 EC under Field Conditions in Northern Europe in 2022 Study code: R C 2108 ANADIAG, 16, rue Ampère, 67500 HAGUENAU, France GLP Unpublished	N	PUH Chemirol Sp. z o.o.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.3/4	C. Ertus	2023	Determination of Clopyralid and Fluroxypyr Residues in Winter Wheat Following Foliar Application with CHR/H/CFF 250 EC under Field Conditions in Northern Europe in 2022 Study code: R C 2109 ANADIAG, 16, rue Ampère, 67500 HAGUENAU, France GLP Unpublished	N	PUH Chemirol Sp. z o.o.
KCP 6.3/5	C. Ertus	2023	Determination of Clopyralid and Fluroxypyr Residues in Winter Wheat Following Foliar Application with CHR/H/CFF 250 EC under Field Conditions in Northern Europe in 2022 Study code: R C 2110 ANADIAG, 16, rue Ampère, 67500 HAGUENAU, France GLP Unpublished	N	PUH Chemirol Sp. z o.o.

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

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Unpublished		
KCA 6.2.1	Pillar, F.	1997	The Metabolism of XDE-570 in Winter Wheat - Final Report 5U DowElanco Europe, Letcombe Regis, Oxon, UK GLP yes Unpublished	N	DAS
KCP 6.2.2	[redacted].	1994	Nature of the Residue of [14C]XDE-570 in Lactating Goats MET94017 [redacted]. GLP yes Unpublished	Y	DAS
KCP 6.2.2	[redacted].	1994	Nature of the Residue of [14C]XDE-570 in Laying Hens MET94018 [redacted]. GLP yes Unpublished	Y	DAS
KCP 6.6.1	MacDonald, A.	1997	The Uptake of XDE-570 into Four Succeeding Crops 7U DowElanco Europe, Letcombe Regis, Oxon, UK GLP yes Unpublished	N	DAS
KCA 6.1	Dial, E., Lindsay, D.	2006	Frozen Storage Stability of Clopyralid in Oilseed Rape DAS Study No. 020122.02 CEM Analytical Services (CEMAS), North Ascot, Berkshire, UK GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS
KCA 6.1	Foster, D.R., Blakeslee, B.A., Rutherford, B.S.	1996	Frozen Storage Stability of Clopyralid, 2,4-D in Corn Grain, Straw and Fodder DAS Study No. RES93050.01 Dow Elanco, Indianapolis, Indiana, US GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.1	Clements, B, Bolton, A	1996	Determination of the Stability of Clopyralid Residues in Pasture under Frozen Storage Conditions DAS Study No. GHE-P-5350 CEM Analytical Services (CEMAS), North Ascot, Berkshire, UK GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS
KCA 6.1		2004	Frozen Storage Stability of Clopyralid in Beef Muscle, Liver, Kidney, Milk and Chicken Egg Study No. 020120.01 GLP/GEP (Y/N): Yes Published (Y/N): No LoA	N	DAS
KCA 6.1		2015	Frozen Storage Stability of Clopyralid in Bovine Fat Study No. 120602 GLP/GEP (Y/N): Yes Published (Y/N): No LoA	N	DAS
KCA 6.2.1	Chapleo So. Caley C.Y.	2002	The metabolism of [14C]-Clopyralid in Sugar Beet DAS Study No. GHE-P-9939 Inveresk Research International, Tranent, East Lothian, United Kingdom GLP: Y Unpublished	N	DAS
KCA 6.2.1	Guo C.	1996	Metabolism of 14C-Clopyralid in Cabbage DAS Study No. GH-C-4289 ABC Laboratories Inc., Columbia, Missouri, USA GLP: Y Unpublished	N	DAS
KCA 6.2.1	Chapleo So. Caley C.Y.	2002	The metabolism of (14C)-Clopyralid in Oilseed Rape DAS Study No. GHE-P-9938 Inveresk Research International, Tranent, East Lothian, United Kingdom GLP: Y Unpublished	N	DAS
KCA 6.2.2-		2015	A Nature of the Residue Study in the Ruminant with [14C]Clopyralid Study No. 130202	N	DAS

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
6.2.5			GLP/GEP (Y/N): Yes Published (Y/N): No LoA		
KCA 6.2.2-6.2.5		2014	A Nature of the Residue Study in the Laying Hen with [14C]-Clopyralid Study No. 130906 GLP/GEP (Y/N): Yes Published (Y/N): No Dow AgroSciences LLC, Indianapolis, Indiana, USA LoA	Y	DAS
KCA 6.4.1-6.4.3		1974	Dowco 290 and 2,4-D Chicken Feeding Study DAS Study No. TA-517 GLP: Y Unpublished	Y	DAS
KCA 6.4.1-6.4.3		1975	Residues of Dowco 290 (3,6-dichloropicolinic acid) in Tissues of Chicken Fed the Herbicide DAS Study No. GH-C 819 GLP: N Unpublished	Y	DAS
KCA 6.4.1-6.4.3		2015	Summary of Clopyralid Livestock Feeding Study: Magnitude of Residue in Eggs, Muscle, Liver and Fat of Laying Hens DAS Study No. 150031 Lab Study No. CEMS-6921 GLP: Y Unpublished	Y	DAS
KCA 6.4.1-6.4.3		1974	Milk Residue Study with Dairy Cows Fed Lontrel Herbicide, Nellite Nematocide and 2,4-D Herbicide: Animal Care, Sampling and Production Records DAS Study No. GH-A 579 GLP: N Unpublished	Y	DAS
KCA 6.4.1-6.4.3		1974	Residues of Dowco 290 (3,6-dichloropicolini acid) in Milk and Cream from Cows Fed the Herbicide DAS Study No. GH-C 745 GLP: N Unpublished	Y	DAS

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.4.1-6.4.3		1975	Residues of Dowco 290 (3,6-dichloropicolini acid) in Bovine Tissues from Calves Fed the Herbicide DAS Study No. GH-C 811 GLP: N Unpublished	Y	DAS
KCA 6.4.1-6.4.3		2015	Summary of Clopyralid Livestock Feeding Study: Magnitude of Residue in Milk, Muscle, Liver and Fat of Lactating Dairy Cattle DAS Study No. 150030 Lab Study No. CEMS-6968 GLP: Y Unpublished	Y	DAS
KCA 6.5.1	Adusumili H.	2014	Processing Study to Determine the Nature of Residues of 14C -Clopyralid Following the Industrial or Household Preparation DAS Study No. 140574 Dow AgroSciences LLC, Indianapolis, Indiana, USA GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS
KCA 6.5.1	Devine, H.C.	2006	Residues of clopyralid in wheat and process fractions at harvest following a single application of EF-1498, Northern France - 2005 DAS Study No. GHE-P-11274 CEM Analytical Services - UK GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS
KCA 6.6.1	Hall, L. R.	2015	14C -Clopyralid: Metabolism in Confined Rotational Crops with a 30-Day Plant-back Interval DAS Study No. 130733 ABC Laboratories, Inc., Columbia, Missouri 65202, USA GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS
KCA 6.6.1	Yackovich P.R., Lardie T.S. Brink D.L.	1993	A 10-1/2 Month Rotational Crops Study With 14C-Labeled Clopyralid – MET90080 DAS Study Np. GH-C-2992 Dow AgroSciences LLC, Indianapolis, Indiana, United States GLP: Y Unpublished	N	DAS
KCA 6.6.1	Yackovich P.R., Lardie T.S.	1989	A 125-Day Rotational Crops Study With 14C-Labelled Clopyralid DAS Study Np. GH-C-2277	N	DAS

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
	Miller J.H.		DowElanco, Midland, Michigan, USA GLP: Y Unpublished		
KCA 6.3	Jones, EM Yuill, MM	1976a	Determination of Residues of 3,6-dichloropicolinic Acid (DOWCO 290) in Rape Seed Oil and Cake from 1975 Trials Carried Out by the Boots Company Limited Dow Chemical Company DAS Report No.: GHE-P-325 GLP:N Unpublished	N	DAS
KCA 6.3	Jones, EM Yuill, MM	1976b	Determination of Residues of 3,6-dichloropicolinic Acid (DOWCO 290) in Rape Seed, Cake, Oil and Straw from a Trial Carried Out in 1975 in Sweden by BT KEMI Dow Chemical Company DAS Report No.: GHE-P-337 GLP:N Unpublished	N	DAS
KCA 6.3	Rawle N.W. Khoshab A.	2002	Residues of Clopyralid in Oilseed Rape at Intervals and at Harvest Following Multiple Applications of Lontrel 100 (EF-1136), EU Northern Zone – 2001. DAS Report No.: GHE-P-9380 GLP: Y Unpublished	N	DAS
KCA 6.3	Freeman JMH Walker SM	1980	Determination of Residues of 3,6-dichloropicolinic Acid (DOWCO* 290) in Sugar Beet, Roots and Tops, Treated with FORMAT** - UK 1980 Dow Chemical Company DAS Report No.: GHE-P-803 GLP:N Unpublished	N	DAS
KCA 6.3	Rawle N.W. Khoshab A.	2002	Residues of Clopyralid in Sugarbeet at Intervals Under Open Field Conditions Following Multiple Applications of Lontrel 100 (EF-1136), Northern France and UK – 2000. DAS Report No.: GHE-P-9356 GLP: Y Unpublished	N	DAS
KCA 6.3	Rawle N.W.	2002	Residues of Clopyralid in Sugar Beet at Harvest Under Open Field Conditions Following Multiple Applications of	N	DAS

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
	Khoshab A.		Lontrel 100 (EF-1136), Northern France and UK – 2000. DAS Report No.: GHE-P-9357 GLP: Y Unpublished		
KCA 6.3	Rawle N.W. Khoshab A.	2002	Residues of Clopyralid in Sugar Beet at Intervals and at Harvest Following Multiple Applications of Lontrel (EF-1136), Northern Zone – 2001. DAS Report No.: GHE-P-9381 GLP: Y Unpublished	N	DAS
KCA 6.3	Freeman, JMH at al	1982	Effect of Length of Period Between Application of CYRONAL* and Harvest on Residues of 3,6-dichoropicolinic Acid (DOWCO 290**) in Winter Wheat, Winter Barley and Maize – Belgium 1981 Dow Chemical Company DAS Report No.: GHE-P-943 GLP:N Unpublished	N	DAS
KCA 6.3	Freeman, JMH	1984	Clopyralid Residues in Wheat Grain and Straw Treated with Either LONPAR* or LONTREL* 100 from French Trials, 1983 Dow Chemical Company DAS Report No.: GHE-P-1258 GLP:N Unpublished	N	DAS
KCA 6.3	Rawle N.W. Khoshab A.	2002	Residues of Clopyralid in Wheat at Intervals Under Open Field Conditions Following a Single Application of Lontrel (EF-1136), UK and Germany – 2000. DAS Report No.: GHE-P-9358 GLP:Y Unpublished	N	DAS
KCA 6.3	Rawle N.W. Khoshab A.	2002	Residues of Clopyralid in Wheat at Intervals Under Open Field Conditions Following a Single Application of Lontrel 100 (EF-1136), EU Northern Zone – 2001. DAS Report No.: GHE-P-9385 GLP:Y Unpublished	N	DAS
KCA 6.3	Freeman, JMH	1982	Effect of Length of Period Between Application of CYRONAL* and Harvest on Residues of 3,6-dichoropicolinic	N	DAS

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Acid (DOWCO 290**) in Winter Wheat, Winter Barley and Maize – Belgium 1981 Dow Chemical Company DAS Report No.: GHE-P-943 GLP:N Unpublished		
KCA 6.3	Rawle N.W. Khoshab A.	2002	Residues of Clopyralid in Barley at Intervals and at Harvest Following a Single Application of Lontrel 100 (EF-1136), EU Northern Zone – 2001. DAS Report No.: GHE-P-9383 GLP:Y Unpublished	N	DAS
KCA 6.3	Rawle N.W. Khoshab A.	2002	Residues of Clopyralid in Barley at Intervals Under Open Field Conditions Following a Single Application of Lontrel (EF-1136), UK – 2000. DAS Report No.: GHE-P-9360 GLP:Y Unpublished	N	DAS
KCA 6.3	Rawle N.W. Khoshab A.	2002	Residues of Clopyralid in Barley at Harvest in Open Field Conditions Following a Single Application of Lontrel 100 (EF-1136), UK – 2000. DAS Report No.: GHE-P-9359 GLP:Y Unpublished	N	DAS
KCA 6.1	Teasdale, R.	1996	Frozen storage stability of Fluroxypyr in winter wheat immature plant, grain and straw Dow Elanco, CEM Analytical Services, Oxon, UK GHE-P-4830 (O32C) 1996-06-19 GLP: yes not published	N	DOW
KCA 6.1	Woods, J.S.	1990	Determination of residues of Fluroxypyr in eggs, muscle, liver and fat tissues from chickens administered Fluroxypyr herbicide Formulations and Environmental Chemistry Dow Elanco, Michigan, Midland, USA	N	DOW

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
			GH-C 2327 (N86) 1990-04-24 GLP: yes not published Also filed under IIA: 6.4.1/01		
KCA 6.2.1	Hawkins D.R., Kirkpatrick, D., Conway, B., Finn, C.M., Powell, G.P.	1981	The metabolism of 14C-DOWCO MHE in spring wheat and soil after field application Dow Chemical, Huntingdon Research Centre, Huntingdon, Cambridgeshire, UK GHE-P-895 (L1) 1982-01-07 GLP: no not published	N	DOW
KCa 6.2.1	Puvanesarajah V., Stewart, R.C.	1991	Metabolism of 14C-Fluroxypyr in wheat Dow Elanco, ABC Lab., Inc., Columbia, Missouri, USA GHE-C-2650 (L2) 1991-10-25 GLP: yes not published	N	DOW
KCA 6.2.1	Caley C. Y., O'Boyle, F	1995	Comparative Metabolism of [14C]-Fluroxypyr butoxypropyl ester and [14C]-Fluroxypyr methylheptyl ester in winter wheat DowElanco, Inveresk Research International, Tranent, Scotland GHE-P-4236 1995-04-27 GLP: yes not published	N	DOW
KCA 6.2.1	Baloch R.I., Brumhard, B., Fuhr, F.	1993	Behaviour of [2,6-14C] Fluroxypyr 1-methylheptyl ester in a sandy Pseudogley Braunerde after post-emerge application to spring barley DowElanco Europe, Institute	N	DOW

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
			Radioagronomie, Jülich, Germany GHE-P-2803 (K17B) 1993-05-11 GLP: yes not published		
KCA 6.2.2	[redacted]	1989	The fate of 14C labelled Fluroxypyr fed to laying hens [redacted] GH-C-2148 (N87) 1989-01-20 GLP: yes not published	Y	DOW
KCa 6.4.1	[redacted]..	1985	The excretion and tissue levels of radioactivity in a dairy cow after oral administration of 14C-DOWCO 433 acid [redacted]. DET 602 (H3) 1985-06-27 GLP: yes not published	Y	DOW
KCA 6.2.2	[redacted].	1990	The fate of 14C labelled Fluroxypyr fed to lactating goats [redacted]. GH-C 2297 1990-02-12 GLP: yes not published	Y	DOW
KCA 6.3	Butler, R.E.	1999	Residues of Fluroxypyr and florasulam in winter wheat at harvest following a single application of Fluroxypyr BPE / Florasulam SE (EF-1466), Northern France - 1998 Dow AgroSciences Europe, Letcombe Lab., Oxon, UK	N	DOW

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
			GHE-P-7814 (N100) 1999-05-28 GLP: yes not published		
KCA 6.3	Teasdale, R.	1995	Residues of Fluroxypyr in winter wheat at intervals following a single application of Starane 400 EW (EF-1312), UK - 1994 DowElanco, CEM Analytical Services, Oxon, UK GHE-P-4651 (N27E) 1995-12-18 GLP: yes not published	N	DOW
KCA 6.3	Teasdale, R.	1995	Residues of Fluroxypyr in winter wheat and soil at harvest following application of novel Starane formulations, UK - 1993 DowElanco, CEM Analytical Services, Oxon, UK GHE-P-4297 (N27) 1995-07-17 GLP: yes not published	N	DOW
KCA 6.3	Clements, B.	1997	Residues of Fluroxypyr-BPE, Clopyralid and MCPA in cereals at harvest following a single application of Bofix (new) (EF-1403), France (North and South) - 1996 Dow Elanco, Letcombe Lab., Oxon, UK GHE-P-6502 (N29A) 1997-10-29 GLP: yes not published	N	DOW
KCA 6.4	Nicholas, L., Cameron, D.M., Macdonald, I.A.,	1986	DOWCO 433 (Fluroxypyr) residues in milk and tissue, UK trial Dow Chemical, Huntingdon Research Centre,	N	DOW

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
	Brown, D.		Huntingdon, Cambridgeshire, UK DWC 422/8693 (N85) 1986-03-27 GLP: yes not published Also filed under IIA 4.8/01		
KCA 6.5.1 KCA 6.6.2	Lickly, L.S., Lardie, T.S., Miller, J.H., Baldwin, W.S.	1990	14C Fluroxypyr-MHE: Confined accumulation study on rotational crops planted at 30, 120 and 366 days after soil treatment Environmental Chemistry Lab. DowElanco, Midland, Michigan, USA GH-C 2410, (N38) 1990-09-17 GLP: yes not published	N	DOW
KCA 6.5.1 KCA 6.6.2	Yackovich, P. R., McCracken, M., O`Neal, S.	1996	A confined rotational crop study with 14CFluroxypyr Methylheptyl Ester PTRL East, Inc. Richmond, Kentucky and Global Environmental Chemistry Laboratory – Indianapolis Lab, DowElanco, Indianapolis, Indiana GH-C 3988 1996-05-08 GLP: yes not published`	N	DOW

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 Florasulam

A 2.1.1 Stability of residues

A 2.1.1.1 Stability of residues during storage of samples

A 2.1.1.1.1 Storage stability of residues in plant products

Not required.

A 2.1.1.1.2 Storage stability of residues in animal products

Not required

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

A 2.1.2.1 Nature of residue in plants

A 2.1.2.1.1 Nature of residue in primary crops

Not required

A 2.1.2.1.2 Nature of residue in rotational crops

Not required

A 2.1.2.1.3 Nature of residues in processed commodities

Not required

A 2.1.2.2 Nature of residues in livestock

Not required

A 2.1.3 Magnitude of residues in plants

Comments of zRMS:	Study is accepted.

Reference:	KCA 6.3/01
Report	Final Report Determination of residues of iodosulfuron-methyl, tribenuron-methyl, florasulam and mefenpyr-diethyl after one application of IDS 100 OD or FLOT 150 WG and Adjuwant Super in wheat at 4 sites in Northern Europe 2016, J. Semrau, EAS Study Code S16-02449,
Guideline(s):	SANCO/3029/99, rev. 4
Deviations:	No
GLP:	Yes
Acceptability:	Yes

The objective of the study was to determine residue levels of florasulam in the raw agricultural commodity wheat after application of the products FLOT 150 WG.
Four trials were conducted in wheat during 2016 in Poland (S16-02449-01 and S16-02449-03), Northern France (S16-02449-02) and Germany (S16-02449-04). The trials comprised three plots, one treated with FLOT 150 WG (containing 25 g/kg florasulam, 75 g/kg tribenuron-methyl, 50 g/kg iodosulfuron-methyl-sodium, nominal content). One application of FLOT 150 WG was performed at growth stage BBCH 32 at a nominal rate of 0.2 kg product /ha. The adjuvant Adjuwant Super 965/2015 was added to this application at a nominal rate of 0.1 L/ha. The product and adjuvant were diluted with water immediately prior to application to a spray volume of 200-300 L/ha (nominal). At trials S16-0229-01 and -02 specimens of the crop from the untreated and treated plots were taken at growth stage BBCH 89 (normal commercial harvest). At trials S16-02249-03 and -04 specimens of the crop from the untreated and treated plots were taken at the day of application and at growth stages BBCH 45-55, 65-69, 75-77 and 89 (normal commercial harvest). Samples of wheat grain and straw were taken mechanically by taking a minimum of 12 random samples from the combine harvester at equal intervals through the plot, or mature plants were cut at the field and taken to the test site where they were threshed mechanically. Other than this scissors were also used and in trial S16-02449-02 there was a use of cut hedge. Sampling equipment was cleaned before use, and between treated plots. No diseased or damaged crop was collected. Duplicate specimens were taken as cover. After sampling the control specimens and treated specimens were kept separated by an adequate space at all times. Residue specimens were deep frozen immediately after arrival at the test sites. Specimens of wheat (whole plant, grain, straw) were analysed for residues of florasulam. Specimen extraction and determination of residues of florasulam was performed according to the multi-residue QuEChERS.

Method validation

The analytical methods multi-residue QuEChERS for the determination of residues of florasulam in wheat (whole plant, grain and straw) was validated according to SANCO/3029/99, rev. 4 within this analytical phase of this study. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical methods was 0.01 mg/kg for each analyte and each matrix with a limit of detection (LOD) set at each 0.003 mg/kg (30 % of the LOQ). No residues above 30% of the LOQ were detected in the control (untreated) test portions used for recovery determination. All mean recovery values at fortification levels of 0.01 mg/kg (LOQ) and 0.1 mg/kg (10x LOQ) comply with the standard acceptance criteria of the guidance document SANCO/3029/99 rev 4, with the evaluation od two mass transitions.

Selectivity

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

Matrix Effects

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

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

During validation of the methods following matrix effects were determined:

Matrix / Commodity	**Standard Concentration (ng/mL)**	**Matrix Effect for Florasulam (%)**	
		Quantification (358→167 m/z)	**Confirmation (358→152 m/z)**
Wheat (whole plant)	1 - 50	(+) 4.6	(+) 6.1
Wheat (grain)	1 - 50	(+) 2.1	(+) 1.7
Wheat (straw)	1 - 50	(-) 7.4	(-) 3.8

(+) matrix enhancement; (-) matrix suppression

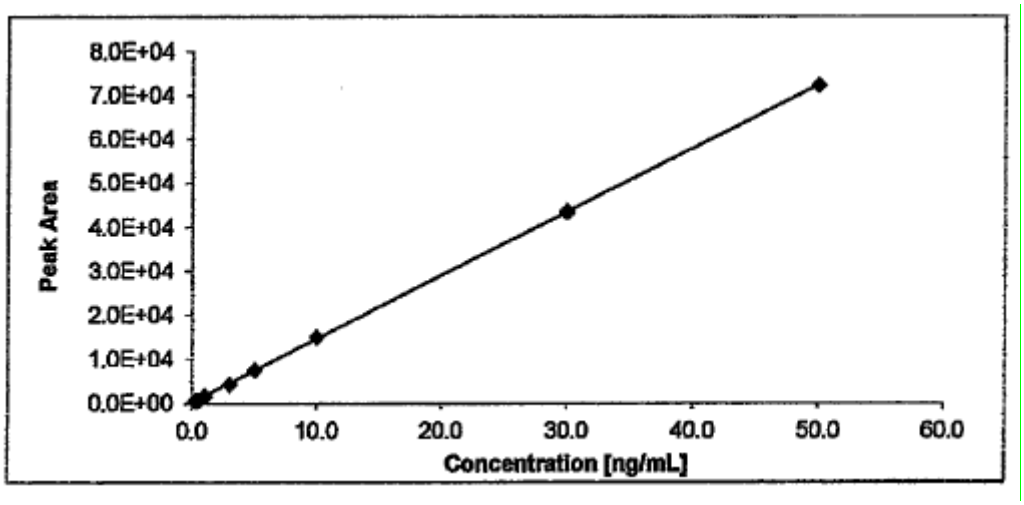
Matrix effects were < 20 % for Florasulam in wheat (whole plant, grain and straw), the matrix effect were deemed insignificant. Therefore solvent standards were used for quantification.

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

Linearity

The linearity of the detector response was demonstrated by single determination of matrix-matched and solvent calibration standards at a minimum of five (5) concentration levels ranging from 0.30 ng/mL to 100 ng/mL for determination of all analyte in wheat (whole plant) and for the determination of florasulam in wheat (grain) and the determination of florasulam in wheat (grain and straw) from 0.3 ng/mL to 50 ng/mL.

This range corresponds to a fortification level of 0.003 mg/kg to 1.0 mg/kg and thus covers the range from no more than 30 % of the LOQ and at least + 20 % of the highest analyte concentration detected in any (diluted) specimen extract.
The calibration curves obtained for both mass transitions for each analyte were linear with coefficients of determination (R^2) ≥ 0.980. Linear regression was performed without any weighting. Representative linear regression curve(s) are below.



Quantification

Quantification was performed using a calibration curve that fulfilled the above given criteria. The injection of standard solutions was spread evenly over the whole analytical sequence. The average response factor was used for calculation of the analyte concentrations. The relative standard deviation of the average response factor was lower or equal to 20 %.
If necessary, specimen extracts and extracts from high level recovery samples were diluted with solvent to be within the calibration range. Diluted sample extracts (at least by a factor of 10) were quantified using solvent calibration standards instead of matrix-matched calibration standards.

Procedural Recoveries

The method's applicability in terms of accuracy and repeatability was assessed for forasulam by fortification of control (untreated) test portions of the respective matrix and subsequent determination of the procedural recoveries upon applying the test method.
The analytee was fortified jointly (depending the used method) and quantified separately.
Procedural recoveries was handled and stored in the same way and for the same time period as the analytical specimen extract that was prepared within the same analytical set.
At least one (1) procedural recovery was performed at the level of LOQ and one (1) at the level of 10x LOQ per analytical set of each respective matrix.
Higher residues were confirmed by at least one (1) recovery determination in the range of the level or higher than the level of the highest residues found in a sample.

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

Summary of the study

1 Report No. Location (region)	2 Commodity/Variety (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date (d)	7 Growth stage at last treatment or date (e) BBCH	8 Portion analysed (a)	9 Residues (mg/kg) (*)	10 PHI (days) (f)	11 Remarks: (g)
				kg as/hL	Water (L/ha)	kg as/ha						
S16-02449-04 27449, Mulsum, Lower Saxony, Germany	Wheat / KWS Chamsin	1) 24 Mar 2016 2) 14 Jun to 21 Jun 2016 3) 16 Aug 2016	Foliar spray with boom sprayer with DG110 02, Teejet nozzles	0.002	315	0.0053	25 May 2016	32	whole plant whole plant whole plant whole plant grain straw	0.13 n/d n/d n/d n/d n/d	0 12 23 49 83 83	Plot 3: Adjuvant added at 0.1 L/ha (nominal)

1 Report No. Location (region)	2 Commodity/Variety (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date (d)	7 Growth stage at last treatment or date (e) BBCH	8 Portion analysed (a)	9 Residues (mg/kg) (*)	10 PHI (days) (f)	11 Remarks: (g)
				kg as/hL	Water (L/ha)	kg as/ha						
S16-02449-03 64-520, Gaj Maly, Wielkopolska, Poland	Wheat / Bamberka	1) 15 Oct 2015 2) 08 to 15 Jun 2016 3) 29 Jul 2016	Foliar spray with boom sprayer with IDK 120-04 Lechler nozzles	0.002	324	0.0054	07 May 2016	32	whole plant whole plant whole plant whole plant grain straw	0.19 n/d n/d n/d n/d n/d	0 17 22 45 80 80	Plot 3: Adjuvant added at 0.1 L/ha (nominal)

1 Report No. Location (region)	2 Commodity/Variety (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date (d)	7 Growth stage at last treatment or date (e) BBCH	8 Portion analysed (a)	9 Residues (mg/kg) (*)	10 PHI (days) (f)	11 Remarks: (g)
				kg as/hL	Water (L/ha)	kg as/ha						
S16-02449-02 45300, Sermaises (Merobes), Loiret, France	Wheat / Sensas	1) 23 Mar 2016 2) 15 Jun to 30 Jun 2016 3) 10 Aug 2016	Foliar spray with boom sprayer with TT 110 015, Teejet nozzles	0.003	199	0.005	27 May 2016	32	grain straw	n/d n/d	75 75	Plot 3: Adjuvant added at 0.1 L/ha (nominal)

1 Report No. Location (region)	2 Commodity/Variety (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date (d)	7 Growth stage at last treatment or date (e) BBCH	8 Portion analysed (a)	9 Residues (mg/kg) (*)	10 PHI (days) (f)	11 Remarks: (g)
				kg as/hL	Water (L/ha)	kg as/ha						
S16-02449-01 88-400 Murczyn, Kujawsko-Pomorskie, Poland	Wheat / Suagen	1) 03 Oct 2015 2) 09-16 Jun 2016 3) 28 Jul 2016	Foliar spray with boom sprayer with IDK 120-04 Lechler nozzles	0.002	317	0.0053	07 May 2016	32	grain straw	n/d n/d	82 82	Plot 3: Adjuvant added at 0.1 L/ha (nominal)

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

Not required

A 2.1.5 Magnitude of residues in representative succeeding crops

Not required

A 2.1.6 Other/Special Studies

Not required

A 2.2 Clopyralid

A 2.2.1 Stability of residues

A 2.2.1.1 Stability of residues during storage of samples

A 2.2.1.1.1 Storage stability of residues in plant products

Not required.

A 2.2.1.1.2 Storage stability of residues in animal products

Not required

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

A 2.2.2.1 Nature of residue in plants

A 2.2.2.1.1 Nature of residue in primary crops

Not required

A 2.2.2.1.2 Nature of residue in rotational crops

Not required

A 2.2.2.1.3 Nature of residues in processed commodities

Not required

A 2.2.2.2 Nature of residues in livestock

Not required

A 2.2.3 Magnitude of residues in plants

Table 2.2.3 Summary of the study in winter wheat

Trial No./ Location/ EU zone/ Year (a)	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment: g a.s./ ha	Application rate per treatment: Water (l/ha)	Application rate per treatment: g a.s./hl	Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg): Clopyralid	Residues (mg/kg): Fluroxypyr	PHI (days) (d)	Details on trial (e)
C2107 AN1/ Seebach 67160 France/ N-EU/ 2022	Winter wheat/ FILON	1) 20.11.2021 2) 18.05.2022 to 25.05.2022 3) 05.07.2022	58 clopyralid 58 fluroxypyr	193	30 g clopyralid 30 g fluroxypyr	21.04.2022	BBCH 33	Whole Plant Whole Plant Whole Plant Ears Rest of plants Grain Straw	1.91 0.47 0.39 0.50 0.18 0.29 0.33	1.94 0.50 0.37 < LOQ 0.32 < LOQ 0.23	0 18 25 53 53 75 75	LOQ = 0.01 mg/kg
C2108 HU1/ Acs H-2941 Hungary/N-EU/ 2022	Winter wheat/ Midas	1) 22.10.2021 2) 20.05.2022 to 25.05.2022 3) 07.07.2022	65 g clopyralid 65 g fluroxypyr	325	20 g clopyralid 20 g fluroxypyr	10.05.2022	BBCH 33	Whole Plant Whole Plant Whole Plant Ears Rest of plants Grain Straw	1.42 1.11 0.73 2.04 0.32 0.63 1.77	2.31 2.29 1.46 0.02 1.27 < LOQ 0.89	0 2 8 28 28 50 50	LOQ = 0.01 mg/kg
C2109 PL1/ Gora Swietej Malgorzaty 99-122 Poland/ N-EU/2022	Winter Wheat/ Euforia	1) 09.10.2021 2) 04.06.2022 to 17.06.2022 3) 23.07.2022	63 g clopyralid 63 g fluroxypyr	420	15 g clopyralid 15 g fluroxypyr	20.05.2022	BBCH 33	Grain Straw	0.37 0.17	< LOD 0.79	63 63	LOQ = 0.01 mg/kg LOD = 0.002 mg/kg
C2110 CZ1/ Chleny 51745 Czech Republic/N-EU/2022	Winter wheat/Calgary	1) 08.10.2021 2) 25.05.2022 to 06.06.2022 3) 30.07.2022	61.3 g clopyralid 61.3 g fluroxypyr	307	20 g clopyralid 20 g fluroxypyr	06.05.2022	BBCH 33	Grain Straw	0.18 0.52	< LOD 0.21	84 84	LOQ = 0.01 mg/kg LOD = 0.002 mg/kg

A 2.2.3.1.1 Study 1

Comments of zRMS:	Study is accepted.

Reference:	KCP 6.3/2
Report	Determination of Clopyralid and Fluroxypyr Residues in Winter Wheat Following Foliar Application with CHR/H/CFF 250 EC under Field Conditions in Northern Europe in 2022, C. Ertus, 2023, Study code: R C2107
Guideline(s):	Regulation (EC) No. 1107/2009
Deviations:	No
GLP:	Yes
Acceptability:	Yes

The objective of the study was to determine the residue levels of clopyralid (its salts and conjugates expressed as clopyralid) and fluroxypyr (its salts, its esters and its conjugates, expressed as fluroxypyr) in winter wheat raw agricultural commodity (RAC) after one foliar application of the formulated product CHR/H/CFF 250 EC (120 g clopyralid/L, 120 g fluroxypyr/L and 10 g florasulam /L), at the rate of 0.5 L/ha.
The study consisted of two phases: the field phase and the analytical phase.
The study was conducted under field conditions at one site in Northern Europe.
One plot was treated once with CHR/H/CFF 250 EC at the application rate of 0.5 L/ha (60 g clopyralid/ha, 60 g fluroxypyr/ha and 5 g florasulam/ha). The application was made at BBCH 33.
One plot remained untreated.
Samplings were performed just before application in the untreated plot, just after application in the treated plot, then at BBCH 39, BBCH 59 and BBCH 77 in the treated plot, and finally at BBCH 89 (at maturity of the crop) in both plots.
Clopyralid (its salts and conjugates expressed as clopyralid) and fluroxypyr (its salts, its esters and its conjugates, expressed as fluroxypyr) residues was analysed in samples harvested during the field phase.

SUMMARIZED RESULTS
Residues in control samples were non-detectable. The residue results for clopyralid and fluroxypyr in the treated specimens are summarized below:

	Clopyralid (its salts and conjugates expressed as clopyralid) residues (mg/kg)					
Trial No.	**Matrix**	**0 DAA, BBCH 33**	**BBCH 39**	**BBCH 59**	**BBCH 77**	**NCH, BBCH 89**
C2107 AN1	Whole plant	1.91	0.47	0.39	-	-
	Ears	-	-	-	0.50	-
	Rest of plant	-	-	-	0.18	-
	Grain	-	-	-	-	0.29
	Straw	-	-	-	-	0.33

DAA: Days after application
NCH: Normal commercial harvest
LOD = 0.002 mg/kg
LOQ = 0.01 mg/kg

	Fluroxypyr (its salts, its esters and its conjugates, expressed as fluroxypyr) residues (mg/kg)					
Trial No.	**Matrix**	**0 DAA, BBCH 33**	**BBCH 39**	**BBCH 59**	**BBCH 77**	**NCH, BBCH 89**
C2107 AN1	Whole plant	1.94	0.50	0.37	-	-
	Ears	-	-	-	< LOQ	-
	Rest of plant	-	-	-	0.32	-
	Grain	-	-	-	-	< LOQ
	Straw	-	-	-	-	0.23

DAA: Days after application
NCH: Normal commercial harvest
< LOQ: Residues between LOD and LOQ
LOD = 0.002 mg/kg
LOQ = 0.01 mg/kg

TRIAL No. C2107 AN1 – Clopyralid analysis

Analytical Sample No.	Field Sample No.	Harvest / Sampling Date	Extraction Date	Storage time of samples*	Analysis date	Storage time of extracts**
C2107 01 01	C2107 AN1 / U1 / A	21/04/2022	02/03/2023	315	04/03/2023	2
C2107 01 02	C2107 AN1 / T1 / A	21/04/2022	02/03/2023	315	10/03/2023	8
C2107 01 03	C2107 AN1 / T2 / A	09/05/2022	02/03/2023	297	10/03/2023	8
C2107 01 04	C2107 AN1 / T3 / A	16/05/2022	02/03/2023	290	10/03/2023	8
C2107 01 05	C2107 AN1 / T4e / A	13/06/2022	16/05/2023	337	17/05/2023	1
C2107 01 06	C2107 AN1 / T4r / A	13/06/2022	19/04/2023	310	20/04/2023	1
C2107 01 07	C2107 AN1 / UHg / A	05/07/2022	08/03/2023	246	09/03/2023	1
C2107 01 08	C2107 AN1 / UHs / A	05/07/2022	09/03/2023	247	10/03/2023	1
C2107 01 09	C2107 AN1 / THg / A	05/07/2022	08/03/2023	246	16/03/2023	8
C2107 01 10	C2107 AN1 / THs / A	05/07/2022	09/03/2023	247	16/03/2023	7

*Frozen storage time of samples from sampling to extraction (days)

** Refrigerated storage time of final extracts, from extraction to analysis (days)

TRIAL No. C2107 AN1 – Fluroxypyr analysis

Analytical Sample No.	Field Sample No.	Harvest / Sampling Date	Extraction Date	Storage time of samples*	Analysis date	Storage time of extracts**
C2107 02 01	C2107 AN1 / U1 / A	21/04/2022	12/07/2023	447	13/07/2023	1
C2107 02 02	C2107 AN1 / T1 / A	21/04/2022	12/07/2023	447	13/07/2023	1
C2107 02 03	C2107 AN1 / T2 / A	09/05/2022	12/07/2023	429	13/07/2023	1
C2107 02 04	C2107 AN1 / T3 / A	16/05/2022	12/07/2023	422	13/07/2023	1
C2107 02 11	C2107 AN1 / T4e / R	13/06/2022	21/07/2023	403	22/07/2023	1
C2107 02 06	C2107 AN1 / T4r / A	13/06/2022	13/07/2023	395	19/07/2023	6
C2107 02 07	C2107 AN1 / UHg / A	05/07/2022	11/07/2023	371	13/07/2023	2
C2107 02 08	C2107 AN1 / UHs / A	05/07/2022	26/07/2023	386	27/07/2023	1
C2107 02 09	C2107 AN1 / THg / A	05/07/2022	11/07/2023	371	13/07/2023	2
C2107 02 10	C2107 AN1 / THs / A	05/07/2022	26/07/2023	386	27/07/2023	1

*Frozen storage time of samples from sampling to extraction (days)

** Frozen storage time of final extracts, from extraction to analysis (days)

A 2.2.3.1.2 Study 2

Comments of zRMS:	Study is accepted.

Reference:	KCP 6.3/3
Report	Determination of Clopyralid and Fluroxypyr Residues in Winter Wheat Following Foliar Application with CHR/H/CFF 250 EC under Field Conditions in Northern Europe in 2022, C. Ertus, 2023, Study code: R C2108
Guideline(s):	Regulation (EC) No. 1107/2009
Deviations:	No
GLP:	Yes
Acceptability:	yes

The objective of the study was to determine the residue levels of clopyralid (its salts and conjugates expressed as clopyralid) and fluroxypyr (its salts, its esters and its conjugates, expressed as fluroxypyr) in winter wheat raw agricultural commodity (RAC) after one foliar application of the formulated product CHR/H/CFF 250 EC (120 g clopyralid/L, 120 g fluroxypyr/L and 10 g florasulam /L), at the rate of 0.5 L/ha.
The study consisted of two phases: the field phase and the analytical phase.
The study was conducted under field conditions at one site in Northern Europe.
One plot was treated once with CHR/H/CFF 250 EC at the application rate of 0.5 L/ha (60 g clopyralid/ha, 60 g fluroxypyr/ha and 5 g florasulam/ha). The application was made at BBCH 33.
One plot remained untreated.
Sampling was performed just before application in the untreated plot, just after application in the treated plot, then at BBCH 39 in the treated plot, BBCH 59 in the treated plot, BBCH 77 in the treated plot and BBCH 89 (at maturity of the crop) in both plots.
Clopyralid (its salts and conjugates expressed as clopyralid) and fluroxypyr (its salts, its esters and its conjugates, expressed as fluroxypyr) residues were analysed in samples harvested during the field phase.
SUMMARIZED RESULTS
Residues in control samples were non-detectable except for whole plant and straw analysed for fluroxypyr which showed residues at or above the limit of quantification*. The residue results for clopyralid and fluroxypyr in the treated specimens are summarized below:

	Clopyralid (its salts and conjugates expressed as clopyralid) residues (mg/kg)					
Trial No.	**Matrix**	**0 DAA, BBCH 33**	**BBCH 39**	**BBCH 59**	**BBCH 77**	**NCH, BBCH 89**
C2108 HU1	Whole plant	1.42	1.11	0.73	-	-
	Ears	-	-	-	2.04	-
	Rest of plant	-	-	-	0.32	-
	Grain	-	-	-	-	0.63
	Straw	-	-	-	-	1.77

	Fluroxypyr (its salts, its esters and its conjugates, expressed as fluroxypyr) residues (mg/kg)					
Trial No.	**Matrix**	**0 DAA, BBCH 33**	**BBCH 39**	**BBCH 59**	**BBCH 77**	**NCH, BBCH 89**
C2108 HU1	Whole plant	2.31	2.29	1.46	-	-
	Ears	-	-	-	0.02	-
	Rest of plant	-	-	-	1.27	-
	Grain	-	-	-	-	< LOQ
	Straw	-	-	-	-	0.89

DAA: Days after application
NCH: Normal commercial harvest
< LOQ: Residues between LOD and LOQ
LOD = 0.002 mg/kg / LOQ = 0.01 mg/kg

TRIAL No. C2108 HU1 – Clopyralid analysis

Analytical Sample No.	Field Sample No.	Harvest / Sampling Date	Extraction Date	Storage time of samples*	Analysis date	Storage time of extracts**
C2108 01 01	C2108 HU1 / U1 / A	10/05/2022	02/03/2023	296	04/03/2023	2
C2108 01 02	C2108 HU1 / T1 / A	10/05/2022	02/03/2023	296	10/03/2023	8
C2108 01 03	C2108 HU1 / T2 / A	12/05/2022	02/03/2023	294	10/03/2023	8
C2108 01 04	C2108 HU1 / T3 / A	18/05/2022	02/03/2023	288	10/03/2023	8
C2108 01 05	C2108 HU1 / T4e / A	07/06/2022	16/05/2023	343	25/05/2023	9
C2108 01 06	C2108 HU1 / T4r / A	07/06/2022	19/04/2023	316	20/04/2023	1
C2108 01 07	C2108 HU1 / UHg / A	29/06/2022	08/03/2023	252	09/03/2023	1
C2108 01 08	C2108 HU1 / UHs / A	29/06/2022	09/03/2023	253	10/03/2023	1
C2108 01 09	C2108 HU1 / THg / A	29/06/2022	08/03/2023	252	16/03/2023	8
C2108 01 10	C2108 HU1 / THs / A	29/06/2022	09/03/2023	253	16/03/2023	7

*Frozen storage time of samples from sampling to extraction (days)

** Refrigerated storage time of final extracts, from extraction to analysis (days)

TRIAL No. C2108 HU1 – Fluroxypyr analysis

Analytical Sample No.	Field Sample No.	Harvest / Sampling Date	Extraction Date	Storage time of samples*	Analysis date	Storage time of extracts**
C2108 02 01	C2108 HU1 / U1 / A	10/05/2022	12/07/2023	428	13/07/2023	1
C2108 02 02	C2108 HU1 / T1 / A	10/05/2022	12/07/2023	428	13/07/2023	1
C2108 02 03	C2108 HU1 / T2 / A	12/05/2022	12/07/2023	426	13/07/2023	1
C2108 02 04	C2108 HU1 / T3 / A	18/05/2022	12/07/2023	420	13/07/2023	1
C2108 02 11	C2108 HU1 / T4e / R	07/06/2022	21/07/2023	409	22/07/2023	1
C2108 02 06	C2108 HU1 / T4r / A	07/06/2022	13/07/2023	401	19/07/2023	6
C2108 02 07	C2108 HU1 / UHg / A	29/06/2022	11/07/2023	377	13/07/2023	2
C2108 02 12	C2108 HU1 / UHs / R	29/06/2022	26/07/2023	392	27/07/2023	1
C2108 02 09	C2108 HU1 / THg / A	29/06/2022	11/07/2023	377	13/07/2023	2
C2108 02 13	C2108 HU1 / THs / R	29/06/2022	26/07/2023	392	27/07/2023	1

*Frozen storage time of samples from sampling to extraction (days)

** Frozen storage time of final extracts, from extraction to analysis (days)

A 2.2.3.1.3 Study 3

Comments of zRMS:	Study is accepted.

Reference:	KCP 6.3/4
Report	Determination of Clopyralid and Fluroxypyr Residues in Winter Wheat Following Foliar Application with CHR/H/CFF 250 EC under Field Conditions in Northern Europe in 2022, C. Ertus, 2023, Study code: R C2109
Guideline(s):	Regulation (EC) No. 1107/2009
Deviations:	No
GLP:	Yes
Acceptability:	Yes

The objective of the study was to determine the residue levels of clopyralid (its salts and conjugates expressed as clopyralid) and fluroxypyr (its salts, its esters and its conjugates, expressed as fluroxypyr) in winter wheat raw agricultural commodity (RAC) after one foliar application of the formulated product CHR/H/CFF 250 EC (120 g clopyralid/L, 120 g fluroxypyr/L and 10 g florasulam /L), at the rate of 0.5 L/ha.
The study consisted of two phases: the field phase and the analytical phase. The study was conducted under field conditions at one site in Northern Europe.
One plot was treated once with CHR/H/CFF 250 EC at the application rate of 0.5 L/ha (60 g clopyralid/ha, 60 g fluroxypyr/ha and 5 g florasulam/ha). The application was made at BBCH 33.
One plot remained untreated.
Sampling was performed at BBCH 89 (at maturity of the crop) in both plots.
Clopyralid (its salts and conjugates expressed as clopyralid) and fluroxypyr (its salts, its esters and its conjugates, expressed as fluroxypyr) residues were analysed in samples harvested during the field phase.
SUMMARIZED RESULTS
Residues in control samples were non-detectable. The residue results for clopyralid and fluroxypyr in the treated specimens are summarized below:

	Clopyralid (its salts and conjugates expressed as clopyralid) residues (mg/kg)	
Trial No.	**Matrix**	**NCH, BBCH 89**
C2109 PL1	Grain	0.37
	Straw	0.17

NCH: Normal commercial harvest
LOD = 0.002 mg/kg
LOQ = 0.01 mg/kg

	Fluroxypyr (its salts, its esters and its conjugates, expressed as fluroxypyr) residues (mg/kg)	
Trial No.	**Matrix**	**NCH, BBCH 89**
C2109 PL1	Grain	NDR
	Straw	0.79

NCH: Normal commercial harvest
NDR: No detectable residues (residues below the limit of detection)
LOD = 0.002 mg/kg
LOQ = 0.01 mg/kg

TRIAL No. C2109 PL1 – Clopyralid analysis

Analytical Sample No.	Field Sample No.	Harvest / Sampling Date	Extraction Date	Storage time of samples*	Analysis date	Storage time of extracts**
C2109 01 01	C2109 PL1 / UHg / A	22/07/2022	08/03/2023	229	09/03/2023	1
C2109 01 02	C2109 PL1 / UHs / A	22/07/2022	09/03/2023	230	10/03/2023	1
C2109 01 03	C2109 PL1 / THg / A	22/07/2022	08/03/2023	229	16/03/2023	8
C2109 01 04	C2109 PL1 / THs / A	22/07/2022	09/03/2023	230	16/03/2023	7

*Frozen storage time of samples from sampling to extraction (days)
** Refrigerated storage time of final extracts, from extraction to analysis (days)

TRIAL No. C2109 PL1 – Fluroxypyr analysis

Analytical Sample No.	Field Sample No.	Harvest / Sampling Date	Extraction Date	Storage time of samples*	Analysis date	Storage time of extracts**
C2109 02 01	C2109 PL1 / UHg / A	22/07/2022	11/07/2023	354	13/07/2023	2
C2109 02 05	C2109 PL1 / UHs / R	22/07/2022	26/07/2023	369	27/07/2023	1
C2109 02 03	C2109 PL1 / THg / A	22/07/2022	11/07/2023	354	13/07/2023	2
C2109 02 06	C2109 PL1 / THs / R	22/07/2022	26/07/2023	369	27/07/2023	1

*Frozen storage time of samples from sampling to extraction (days)
** Frozen storage time of final extracts, from extraction to analysis (days)

A 2.2.3.1.4 Study 4

Comments of zRMS:	Study is accepted.

Reference:	KCP 6.3/5
Report	Determination of Clopyralid and Fluroxypyr Residues in Winter Wheat Following Foliar Application with CHR/H/CFF 250 EC under Field Conditions in Northern Europe in 2022, C. Ertus, 2023, Study code: R C2110
Guideline(s):	Regulation (EC) No. 1107/2009
Deviations:	No
GLP:	Yes

Acceptability: Yes

The objective of the study was to determine the residue levels of clopyralid (its salts and conjugates expressed as clopyralid) and fluroxypyr (its salts, its esters and its conjugates, expressed as fluroxypyr) in winter wheat raw agricultural commodity (RAC) after one foliar application of the formulated product CHR/H/CFF 250 EC (120 g clopyralid/L, 120 g fluroxypyr/L and 10 g florasulam /L), at the rate of 0.5 L/ha.
The study consisted of two phases: the field phase and the analytical phase.
The study was conducted under field conditions at one site in Northern Europe.
One plot was treated once with CHR/H/CFF 250 EC at the application rate of 0.5 L/ha (60 g clopyralid/ha, 60 g fluroxypyr/ha and 5 g florasulam/ha). The application was made at BBCH 33.
One plot remained untreated.
Sampling was performed at BBCH 89 (at maturity of the crop) in both plots.
Clopyralid (its salts and conjugates expressed as clopyralid) and fluroxypyr (its salts, its esters and its conjugates, expressed as fluroxypyr) residues were analysed in samples harvested during the field phase
SUMMARIZED RESULTS
Residues in control samples were non-detectable. The residue results for clopyralid and fluroxypyr in the treated specimens are summarized below:

	Clopyralid (its salts and conjugates expressed as clopyralid) residues (mg/kg)	
Trial No.	**Matrix**	**NCH, BBCH 89**
C2110 CZ1	Grain	0.18
	Straw	0.52

	Fluroxypyr (its salts, its esters and its conjugates, expressed as fluroxypyr) residues (mg/kg)	
Trial No.	**Matrix**	**NCH, BBCH 89**
C2110 CZ1	Grain	NDR
	Straw	0.21

NCH: Normal commercial harvest
NDR: No detectable residues (residues below the limit of detection)
LOD = 0.002 mg/kg
LOQ = 0.01 mg/kg

TRIAL No. C2110 CZ1 – Clopyralid analysis

Analytical Sample No.	Field Sample No.	Harvest / Sampling Date	Extraction Date	Storage time of samples*	Analysis date	Storage time of extracts**
C2110 01 01	C2110 CZ1 / UHg / A	29/07/2022	08/03/2023	222	09/03/2023	1
C2110 01 02	C2110 CZ1 / UHs / A	29/07/2022	09/03/2023	223	10/03/2023	1
C2110 01 03	C2110 CZ1 / THg / A	29/07/2022	08/03/2023	222	16/03/2023	8
C2110 01 04	C2110 CZ1 / THs / A	29/07/2022	09/03/2023	223	16/03/2023	7

*Frozen storage time of samples from sampling to extraction (days)

** Refrigerated storage time of final extracts, from extraction to analysis (days)

TRIAL No. C2110 CZ1 – Fluroxypyr analysis

Analytical Sample No.	Field Sample No.	Harvest / Sampling Date	Extraction Date	Storage time of samples*	Analysis date	Storage time of extracts**
C2110 02 01	C2110 CZ1 / UHg / A	29/07/2022	11/07/2023	347	13/07/2023	2
C2110 02 02	C2110 CZ1 / UHs / A	29/07/2022	26/07/2023	362	27/07/2023	1
C2110 02 03	C2110 CZ1 / THg / A	29/07/2022	11/07/2023	347	13/07/2023	2
C2110 02 04	C2110 CZ1 / THs / A	29/07/2022	26/07/2023	362	27/07/2023	1

*Frozen storage time of samples from sampling to extraction (days)

** Frozen storage time of final extracts, from extraction to analysis (days)

A 2.2.4 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)

Not required

A 2.2.5 Magnitude of residues in representative succeeding crops

Not required

A 2.2.6 Other/Special Studies

Not required

A 2.3 Fluroxypyr

A 2.3.1 Stability of residues

A 2.3.1.1 Stability of residues during storage of samples

A 2.3.1.1.1 Storage stability of residues in plant products

Not required.

A 2.3.1.1.2 Storage stability of residues in animal products

Not required

A 2.3.2 Nature of residues in plants, livestock and processed commodities

A 2.3.2.1 Nature of residue in plants

A 2.3.2.1.1 Nature of residue in primary crops

Not required

A 2.3.2.1.2 Nature of residue in rotational crops

Not required

A 2.3.2.1.3 Nature of residues in processed commodities

Not required

A 2.3.2.2 Nature of residues in livestock

Not required

A 2.3.3 Magnitude of residues in plants

Please see point A 2.2.3.

A 2.3.4 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)

Not required

A 2.3.5 Magnitude of residues in representative succeeding crops

Not required

A 2.3.6 Other/Special Studies

Not required

Appendix 3 Pesticide Residue Intake Model (PRIMo)

A 3.1 TMDI calculations – Florasulam

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Florasulam (F)

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	**0.05**	ARfD (mg/kg bw):	**not necessary**
Source of ADI:	**EFSA**	Source of ARfD:	
Year of evaluation:	**2015**	Year of evaluation:	

Input values

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

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

	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)
TMDI/NEDI/IEDI calculation (based on average food consumption)	1%	NL toddler	0.67	1%	Milk: Cattle	0.1%	Wheat	0.0%	Bovine: Muscle/meat		
	0.9%	UK infant	0.45	0.8%	Milk: Cattle	0.1%	Wheat	0.0%	Eggs: Chicken		
	0.7%	FR toddler 2 3 yr	0.37	0.6%	Milk: Cattle	0.1%	Wheat	0.0%	Bovine: Muscle/meat		
	0.7%	FR child 3 15 yr	0.33	0.5%	Milk: Cattle	0.1%	Wheat	0.0%	Bovine: Muscle/meat		
	0.6%	NL child	0.32	0.5%	Milk: Cattle	0.1%	Wheat	0.0%	Swine: Muscle/meat		
	0.5%	UK toddler	0.27	0.4%	Milk: Cattle	0.1%	Wheat	0.0%	Bovine: Muscle/meat		
	0.5%	DE child	0.27	0.4%	Milk: Cattle	0.1%	Wheat	0.0%	Eggs: Chicken		
	0.4%	DK child	0.22	0.3%	Milk: Cattle	0.1%	Wheat	0.0%	Swine: Muscle/meat		
	0.4%	ES child	0.22	0.2%	Milk: Cattle	0.1%	Wheat	0.0%	Bovine: Muscle/meat		
	0.4%	SE general	0.21	0.2%	Milk: Cattle	0.1%	Bovine: Muscle/meat	0.1%	Wheat		
	0.4%	RO general	0.20	0.2%	Milk: Cattle	0.1%	Wheat	0.0%	Swine: Muscle/meat		
	0.4%	FR infant	0.19	0.3%	Milk: Cattle	0.0%	Wheat	0.0%	Swine: Muscle/meat		
	0.3%	DE women 14-50 yr	0.17	0.2%	Milk: Cattle	0.0%	Wheat	0.0%	Swine: Muscle/meat		
	0.3%	DE general	0.17	0.2%	Milk: Cattle	0.0%	Wheat	0.0%	Swine: Muscle/meat		
	0.3%	GEMS/Food G15	0.15	0.1%	Milk: Cattle	0.1%	Wheat	0.0%	Swine: Muscle/meat		
	0.3%	GEMS/Food G11	0.15	0.2%	Milk: Cattle	0.1%	Wheat	0.0%	Swine: Muscle/meat		
	0.3%	GEMS/Food G07	0.15	0.1%	Milk: Cattle	0.1%	Wheat	0.0%	Poultry: Muscle/meat		
	0.3%	GEMS/Food G08	0.13	0.1%	Milk: Cattle	0.1%	Wheat	0.0%	Swine: Muscle/meat		
	0.3%	GEMS/Food G10	0.13	0.1%	Milk: Cattle	0.1%	Wheat	0.0%	Poultry: Muscle/meat		
	0.3%	NL general	0.13	0.2%	Milk: Cattle	0.0%	Wheat	0.0%	Swine: Muscle/meat		
	0.2%	GEMS/Food G06	0.11	0.1%	Wheat	0.0%	Milk: Cattle	0.0%	Poultry: Muscle/meat		
	0.2%	ES adult	0.10	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Bovine: Muscle/meat		
	0.2%	FR adult	0.09	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Swine: Muscle/meat		
	0.2%	IE adult	0.09	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Bovine: Muscle/meat		
	0.2%	DK adult	0.09	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Swine: Muscle/meat		
	0.1%	LT adult	0.07	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Swine: Muscle/meat		
	0.1%	IT toddler	0.07	0.1%	Wheat		Grapefruits				
	0.1%	UK adult	0.06	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Bovine: Muscle/meat		
	0.1%	UK vegetarian	0.06	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Eggs: Chicken		
	0.1%	IE child	0.05	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Swine: Muscle/meat		
	0.1%	IT adult	0.04	0.1%	Wheat		Grapefruits				
	0.1%	PT general	0.04	0.1%	Wheat		Grapefruits				
	0.0%	FI 3 yr	0.01	0.0%	Wheat		Grapefruits				
	0.0%	FI 6 yr	0.01	0.0%	Wheat		Grapefruits				
	0.0%	FI adult	0.00	0.0%	Wheat		Grapefruits				
		Column7			Grapefruits		Grapefruits				

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

A 3.2 TMDI calculations – Clopyralid

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Clopyralid (F)

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	**0.15**	ARfD (mg/kg bw):	**0.17**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2018**	Year of evaluation:	**2018**

Input values

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

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

	Calculated exposure (% of ADI)	MS Diet	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)
TMDI/NEDI/IEDI calculation (based on average food consumption)	15%	GEMS/Food G06	21.89	14%	Wheat	0.1%	Milk: Cattle	0.0%	Poultry: Muscle/meat		
	13%	IT toddler	19.94	13%	Wheat		Grapefruits				
	11%	RO general	15.86	10%	Wheat	0.4%	Milk: Cattle	0.0%	Poultry: Muscle/meat		
	10%	FR child 3 15 yr	15.04	9%	Wheat	0.8%	Milk: Cattle	0.0%	Eggs: Chicken		
	10%	NL toddler	14.86	8%	Wheat	2%	Milk: Cattle	0.0%	Poultry: Muscle/meat		
	9%	GEMS/Food G15	14.05	9%	Wheat	0.2%	Milk: Cattle	0.0%	Poultry: Muscle/meat		
	9%	ES child	14.05	9%	Wheat	0.4%	Milk: Cattle	0.0%	Poultry: Muscle/meat		
	9%	DK child	13.96	9%	Wheat	0.4%	Milk: Cattle	0.0%	Eggs: Chicken		
	9%	DE child	13.68	8%	Wheat	0.7%	Milk: Cattle	0.0%	Eggs: Chicken		
	9%	NL child	13.62	8%	Wheat	0.8%	Milk: Cattle	0.0%	Poultry: Muscle/meat		
	9%	GEMS/Food G07	13.06	8%	Wheat	0.2%	Milk: Cattle	0.0%	Poultry: Muscle/meat		
	9%	UK toddler	12.85	8%	Wheat	0.7%	Milk: Cattle	0.0%	Eggs: Chicken		
	8%	GEMS/Food G08	12.58	8%	Wheat	0.2%	Milk: Cattle	0.0%	Poultry: Muscle/meat		
	8%	IT adult	12.41	8%	Wheat		Grapefruits				
	8%	GEMS/Food G10	12.11	8%	Wheat	0.2%	Milk: Cattle	0.0%	Poultry: Muscle/meat		
	8%	PT general	11.76	8%	Wheat		Grapefruits				
	8%	GEMS/Food G11	11.26	7%	Wheat	0.3%	Milk: Cattle	0.0%	Poultry: Muscle/meat		
	7%	FR toddler 2 3 yr	10.78	6%	Wheat	1.0%	Milk: Cattle	0.0%	Eggs: Chicken		
	7%	SE general	10.27	6%	Wheat	0.4%	Milk: Cattle	0.0%	Eggs: Chicken		
	7%	UK infant	9.88	5%	Wheat	1%	Milk: Cattle	0.0%	Eggs: Chicken		
	5%	ES adult	7.36	5%	Wheat	0.2%	Milk: Cattle	0.0%	Poultry: Muscle/meat		
	5%	IE adult	7.18	5%	Wheat	0.1%	Milk: Cattle	0.0%	Sheep: Muscle/meat		
	5%	DE women 14-50 yr	7.10	4%	Wheat	0.4%	Milk: Cattle	0.0%	Eggs: Chicken		
	5%	FR adult	6.95	4%	Wheat	0.1%	Milk: Cattle	0.0%	Eggs: Chicken		
	4%	UK vegetarian	6.33	4%	Wheat	0.1%	Milk: Cattle	0.0%	Eggs: Chicken		
	4%	DE general	6.31	4%	Wheat	0.4%	Milk: Cattle	0.0%	Eggs: Chicken		
	4%	NL general	6.26	4%	Wheat	0.3%	Milk: Cattle	0.0%	Poultry: Muscle/meat		
	3%	UK adult	5.22	3%	Wheat	0.1%	Milk: Cattle	0.0%	Poultry: Muscle/meat		
	2%	IE child	3.69	2%	Wheat	0.1%	Milk: Cattle	0.0%	Eggs: Chicken		
	2%	DK adult	3.67	2%	Wheat	0.2%	Milk: Cattle	0.0%	Eggs: Chicken		
	2%	FI 3 yr	3.58	2%	Wheat		Grapefruits				
	2%	LT adult	3.39	2%	Wheat	0.1%	Milk: Cattle	0.0%	Eggs: Chicken		
	2%	FR infant	3.22	2%	Wheat	0.6%	Milk: Cattle	0.0%	Poultry: Muscle/meat		
	2%	FI 6 yr	2.92	2%	Wheat		Grapefruits				
	0.6%	FI adult	0.96	0.6%	Wheat		Grapefruits				
		Column7			Grapefruits		Grapefruits				

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

A 3.3 TMDI calculations – Fluroxypyr

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Fluroxypyr (F)

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	0.8	ARfD (mg/kg bw):	calculation with ADI (no ARfD was inserted)
Source of ADI:	EFSA	Source of ARfD:	
Year of evaluation:	2018	Year of evaluation:	

Input values

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

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)	Calculated exposure (% of ADI)	MS Diet	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)
	0.5%	NL toddler	3.99	0.4%	Milk: Cattle	0.0%	Wheat	0.0%	Poultry: Muscle/meat		
	0.3%	UK infant	2.60	0.3%	Milk: Cattle	0.0%	Wheat	0.0%	Eggs: Chicken		
	0.3%	FR toddler 2 3 yr	2.10	0.2%	Milk: Cattle	0.0%	Wheat	0.0%	Milk: Goat		
	0.2%	NL child	1.89	0.2%	Milk: Cattle	0.1%	Wheat	0.0%	Poultry: Muscle/meat		
	0.2%	FR child 3 15 yr	1.87	0.2%	Milk: Cattle	0.1%	Wheat	0.0%	Eggs: Chicken		
	0.2%	UK toddler	1.64	0.2%	Milk: Cattle	0.0%	Wheat	0.0%	Eggs: Chicken		
	0.2%	DE child	1.63	0.1%	Milk: Cattle	0.1%	Wheat	0.0%	Eggs: Chicken		
	0.2%	ES child	1.23	0.1%	Milk: Cattle	0.1%	Wheat	0.0%	Poultry: Muscle/meat		
	0.2%	RO general	1.22	0.1%	Milk: Cattle	0.1%	Wheat	0.0%	Poultry: Muscle/meat		
	0.2%	DK child	1.22	0.1%	Milk: Cattle	0.1%	Wheat	0.0%	Eggs: Chicken		
	0.1%	FR infant	1.09	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Poultry: Muscle/meat		
	0.1%	SE general	1.07	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Eggs: Chicken		
	0.1%	DE women 14-50 yr	0.98	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Milk: Sheep		
	0.1%	DE general	0.94	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Milk: Sheep		
	0.1%	GEMS/Food G06	0.91	0.1%	Wheat	0.0%	Milk: Cattle	0.0%	Milk: Sheep		
	0.1%	GEMS/Food G15	0.91	0.1%	Wheat	0.1%	Milk: Cattle	0.0%	Milk: Sheep		
	0.1%	GEMS/Food G11	0.84	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Poultry: Muscle/meat		
	0.1%	GEMS/Food G07	0.84	0.1%	Wheat	0.0%	Milk: Cattle	0.0%	Sheep: Muscle/meat		
	0.1%	GEMS/Food G08	0.76	0.1%	Wheat	0.0%	Milk: Cattle	0.0%	Poultry: Muscle/meat		
	0.1%	GEMS/Food G10	0.74	0.0%	Wheat	0.0%	Milk: Cattle	0.0%	Poultry: Muscle/meat		
	0.1%	NL general	0.71	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Poultry: Muscle/meat		
	0.1%	IT toddler	0.66	0.1%	Wheat		Grapefruits				
	0.1%	ES adult	0.55	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Sheep: Muscle/meat		
	0.1%	IE adult	0.54	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Sheep: Muscle/meat		
	0.1%	FR adult	0.51	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Sheep: Muscle/meat		
	0.1%	DK adult	0.44	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Eggs: Chicken		
	0.1%	IT adult	0.41	0.1%	Wheat		Grapefruits				
	0.1%	UK vegetarian	0.40	0.0%	Wheat	0.0%	Milk: Cattle	0.0%	Eggs: Chicken		
	0.0%	PT general	0.39	0.0%	Wheat		Grapefruits				
	0.0%	UK adult	0.35	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Poultry: Muscle/meat		
	0.0%	LT adult	0.35	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Eggs: Chicken		
	0.0%	IE child	0.34	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Eggs: Chicken		
	0.0%	FI 3 yr	0.12	0.0%	Wheat		Grapefruits				
	0.0%	FI 6 yr	0.10	0.0%	Wheat		Grapefruits				
	0.0%	FI adult	0.03	0.0%	Wheat		Grapefruits				
		Column7			Grapefruits		Grapefruits				

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

A 3.4 IESTI calculations - Raw commodities and processed commodities – only clopyralid

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)
25%	Wheat	3 / 3	43
4%	Milk: Cattle	0.05 / 0.05	6.2
0.7%	Milk: Goat	0.05 / 0.05	1.2
0.5%	Poultry: Muscle/meat	0.05 / 0.05	0.85
0.4%	Eggs: Chicken	0.05 / 0.05	0.62
0.2%	Other farmed animals:	0.05 / 0.05	0.35
0.2%	Equine: Muscle/meat	0.05 / 0.05	0.30
0.2%	Sheep: Muscle/meat	0.05 / 0.05	0.27
0.1%	Milk: Sheep	0.05 / 0.05	0.18
0.03%	Poultry: Liver	0.05 / 0.05	0.06
0.00%	Poultry: Fat tissue	0.05 / 0.05	0.01

Expand/collapse list

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)
15%	Wheat	3 / 3	25
1%	Milk: Cattle	0.05 / 0.05	1.9
0.5%	Milk: Goat	0.05 / 0.05	0.92
0.4%	Milk: Sheep	0.05 / 0.05	0.76
0.3%	Poultry: Muscle	0.05 / 0.05	0.59
0.2%	Other farmed animals:	0.05 / 0.05	0.28
0.1%	Equine: Muscle/meat	0.05 / 0.05	0.24
0.1%	Sheep: Muscle/meat	0.05 / 0.05	0.24
0.1%	Poultry: Liver	0.05 / 0.05	0.24
0.1%	Eggs: Chicken	0.05 / 0.05	0.21
0.08%	Sheep: Liver	0.05 / 0.05	0.14
0.05%	Goat: Muscle	0.05 / 0.05	0.08
0.04%	Eggs: Quail	0.05 / 0.05	0.07
0.04%	Poultry: Kidney	0.05 / 0.05	0.06
0.02%	Sheep: Edible offals (other	0.05 / 0.05	0.03

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

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)
25%	Wheat	3 / 3	43
4%	Milk: Cattle	0.05 / 0.05	6.2
0.7%	Milk: Goat	0.05 / 0.05	1.2
0.5%	Poultry: Muscle/meat	0.05 / 0.05	0.85
0.4%	Eggs: Chicken	0.05 / 0.05	0.62
0.2%	Other farmed animals:	0.05 / 0.05	0.35
0.2%	Equine: Muscle/meat	0.05 / 0.05	0.30
0.2%	Sheep: Muscle/meat	0.05 / 0.05	0.27
0.1%	Milk: Sheep	0.05 / 0.05	0.18
0.03%	Poultry: Liver	0.05 / 0.05	0.06
0.00%	Poultry: Fat tissue	0.05 / 0.05	0.01

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)
15%	Wheat	3 / 3	25
1%	Milk: Cattle	0.05 / 0.05	1.9
0.5%	Milk: Goat	0.05 / 0.05	0.92
0.4%	Milk: Sheep	0.05 / 0.05	0.76
0.3%	Poultry: Muscle	0.05 / 0.05	0.59
0.2%	Other farmed animals:	0.05 / 0.05	0.28
0.1%	Equine: Muscle/meat	0.05 / 0.05	0.24
0.1%	Sheep: Muscle/meat	0.05 / 0.05	0.24
0.1%	Poultry: Liver	0.05 / 0.05	0.24
0.1%	Eggs: Chicken	0.05 / 0.05	0.21
0.08%	Sheep: Liver	0.05 / 0.05	0.14
0.05%	Goat: Muscle	0.05 / 0.05	0.08
0.04%	Eggs: Quail	0.05 / 0.05	0.07
0.04%	Poultry: Kidney	0.05 / 0.05	0.06
0.02%	Sheep: Edible offals (other than	0.05 / 0.05	0.03

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

Processed commodities

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
21%	Wheat / milling (flour)	3 / 3	36
10%	Wheat / milling (wholemea	3 / 3	17
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
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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)
8%	Wheat / bread/pizza	3 / 3	13
7%	Wheat / pasta	3 / 3	11
6%	Wheat / bread	3 / 3	10
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
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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)
21%	Wheat / milling (flour)	3 / 3	36
10%	Wheat / milling	3 / 3	17
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
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#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!

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)
8%	Wheat / bread/pizza	3 / 3	13
7%	Wheat / pasta	3 / 3	11
6%	Wheat / bread (wholemeal)	3 / 3	10
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
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Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short term intake of residues of Clopyralid (F) is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

Appendix 4 Additional information provided by the applicant

Not required