FINAL REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: PP-113H

Product name(s): BARILOCHE

Chemical active substance:

Clopyralid 100 g/L (10% w/v) SL

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: PROPLAN Plant Protection Company, S.L.U.

Submission date: December 2021

MS Finalization date: July 2022; April 2023; November 2023; January 2024

Version history

When	What
February 2019	Initial version
December 2021	Version 2, Update for the renewal.
July 2022	Assessment by the expert
April 2023	The final version of RR after commenting period.
November 2023	Verification of the Report in accordance with the Polish National Authority's (Ministry of Agriculture and Rural Development) arrangements regarding the assessment of plant protection products containing the active substance clopyralid.
January 2024	Verification of the Report in accordance with the 3rd round of commenting

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The product PP-113H (Clopyralid 10% w/v SL), is registered in several European countries under the brands Bariloche and Bariloche 100.

The product BARILOCHE is currently registered in south (16096), Spain (ES-00493), UK (Re. No. 17577), Poland (Reg. No. R-26/2018wu), Germany (Reg. No. 008865-00), Czech Republic (Reg. No. 5583-0) and Romania (Reg. No. 466PC) in Sugar beet.
Bariloche 100 is registered in France (Reg. No. 2150085) and Spain (Reg. No. 25.909) for sugar beet and oilseed rape.

This new dossier has been carried out to support the renewal of the approval of the active substance Clopyralid.

All the changes that have been made in this section, with respect to the original dossier, have been highlighted in yellow. It must be taken into account that the format of the dossier has changed.

7 Metabolism and residue data (KCA section 6)

7.1 Summary and zRMS Conclusion

November 2023 Verification of the Report in accordance with the Polish National Authority's (Ministry of Agriculture and Rural Development) arrangements, from the meeting regarding the assessment of plant protection products containing the active substance 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)

10 months in olive (fruit and oil) (high oil content matrix)

10 months in orange / orange peel (high acid content matrix)

Metabolism in plants and animals

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

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.

EFSA Journal 2021;19(1):6389:

Based on the metabolic pattern identified in metabolism studies with cereals, rotational crops and the results of hydrolysis studies, the residue definitions were proposed as clopyralid common moiety (sum of clopyralid, its salts and conjugates expressed as clopyralid) both, for enforcement and risk assessment. These residue definitions are applicable to cereals/grass crop group, rotational crops and processed products.

Since the clarification of the unknown polar metabolite (called 'polar clopyralid') in mature sugar beet and oilseeds identified by the EU pesticides peer review was not sufficiently addressed under the current assessment, EFSA concludes that the proposed residue definitions are applicable only to cereals/grass crop group for which a new metabolism study was submitted under the current assessment and for which the data gap identified by the peer review is not relevant. For remaining crop groups, the data gap as identified by the EU pesticides peer review remains open.

According to EFSA, the residue definition should be limited to cereals/grass only. Taking this into account, application on winter rape and sugar beet are not acceptable until the data gap is filled.

Authority's arrangements:

- in the case of clopyralid, assessment of residue data for the uses proposed by the Applicants, including, among others, on oilseeds, roots or tubers (crops other than representative crops assessed in RAR (2019) for the substance clopyralid) should be carried out in accordance with the general residue definition for clopyralid proposed by EFSA in the document EFSA Journal 2018;16(8):5389 - applies all administrative proceedings conducted by the Ministry of Agriculture and Rural Development (Article 33, Article 43, Article 40, Article 45, Article 51).

Plant residue definition for monitoring: Clopyralid (Reg. (EU) 2021/1807)

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).

The intended use on sugar beet is ~~not~~ supported by the evaluated plant metabolism studies.

Magnitude of residues in plants

Sugar beet

~~According to EFSA, the residue definitions should be limited to cereals/grass only. Taking this into account, application on sugar beet are not acceptable (until the data gap is filled).~~

Proposed use: 1 application, BBCH ~~12-14 (Spring)~~ 10-39, 120 g as/ha, PHI: not required

Applicant refers to unprotected EU data:

Trials GAP (sugar beets): 1 x 0.1 kg as/ha + 1x 0.2 kg/ha latest timing of BBCH 39

Residues: 0.12, 0.17, 0.21, 0.29, 0.34, 0.35, 0.36, 0.41, 0.56, 0.80 mg/kg

Trials are overdosed. Sufficient data are available to support the proposed uses. The residues arising from the proposed uses will not exceed the MRLs established for sugar beet roots (Reg. (EU) 2021/1807).

Livestock feeding studies, Magnitude of residues in processed commodities, Rotational study

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

New Dietary Burden calculations were performed by the zRMS, taking into account STMR and HR values from residues trials (only proposed use). These data fall within the data used for the calculations presented in EFSA Journal 2021;19(1):6389. Calculations were presented below in Animal model 2017. No additional calculation is needed.

The intended use on sugar beet is ~~not~~ supported by the evaluated plant metabolism studies.

Magnitude of residues in representative succeeding crops

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

A study to determine the residues of Clopyralid in honey has been submitted. The objective of the study was to determine residues of clopyralid, its salts and conjugates (expressed as clopyralid) in honey from *Phacelia tanacetifolia* after one application of PP-113H (Clopyralid 100 g/L SL) under semi-field conditions.

The study is acceptable ~~but not taken into account until a definition for the risk assessment of sugar beet has been established.~~

Current MRL for clopyralid in honey is 0.05 mg/kg, and according to the provided study on magnitude of

residues in honey, the MRL is potentially exceeded when Bariloche is applied to melliferous plants. Until the new MRL has been set for honey, use on melliferous target crops during flowering cannot be authorized.

As sugar beet is not melliferous plants according to SANTE/11956/2016 rev. 9, proposed use is accepted.

Estimation of exposure through diet and other means

~~The intended use on sugar beet is not supported by the evaluated plant metabolism studies~~.

The proposed uses of clopyralid in the formulation PP-113H do not represent unacceptable acute and chronic risks for the consumer.

7.1.1 Critical GAP(s) and overall conclusion

Selection of critical uses and justification

The critical GAPs with respect to consumer intake and risk assessment for the preparation PP-113H are presented in Table 7.1-1. They have been selected from the individual GAPs in the central zone of EU for sugar beet. A list of all intended uses within the central zone is given in Part B, Section 0.

Overall conclusion

The data available are considered ~~not~~ sufficient for risk assessment. An exceedance of the current MRL of 1 mg/kg for Clopyralid as laid down in Reg. (EU) 396/2005 is not expected.
The chronic and the short-term intakes of Clopyralid residues are unlikely to present a public health concern.
As far as consumer health protection is concerned, zRMS Poland 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).

Data gaps

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

Noticed data gaps are:
~~The intended use on sugar beet is not supported by the evaluated plant metabolism studies.~~
none

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

1	2	3	4	5	6	7		8				9			10	11
GAP number (see part B.0)*	**Crop and/ or situation ****	**Zone**	**Product code**	**F, Fn, Fpn G, Gn, Gpn or I*****	**Pests or Group of pests controlled**	**Formulation**		**Application**				**Application rate per treatment**			**PHI (days)**	**Conclusion**
						Type	**Conc. of as**	**method kind**	**growth stage & season**	**number min max**	**interval between applications (min)**	**L product / ha min max**	**water L/ha min max**	**kg as/ha min max**		
1	Sugar beet	C. EU (CZ, GE, PL, RO)	PP-113H	F	CIRAR and COMPOSITAE	SL	10	Tractor boom sprayer	BBCH 10-39	1	-	1.2	80-400	0.12	None	Do not use between the 31st August and 1st March A

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

Explanation for Column 11 “Conclusion”

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

7.1.2 Summary of the evaluation

The preparation PP-113H is composed of Clopyralid.

Table 7.1-2: Toxicological reference values for the dietary risk assessment of Clopyralid.

Reference value	Source	Year	Value	Study relied upon	Safety factor
Clopyralid					
ADI	EFSA	2018	0.15 mg/kg bw/day	rat, 2-year chronic toxicity and oncogenicity study	100
ARfD	EFSA	2018	0.17 mg/kg bw/day	rabbit, developmental toxicity	100

7.1.2.1 Summary for Clopyralid

Table 7.1-3: 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?
1	Sugar beet	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

7.1.2.2 Summary for active substance 2

Not required. The product only has one active substance.

7.1.2.3 Summary for PP-113H

Table 7.1-4: Information on PP-113H (KCA 6.8)

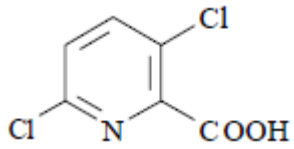
Crop	PHI for PP-113H proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for PP-113H proposed by zRMS	zRMS Comments (if different PHI proposed)
		Clopyralid		
Sugar beet	NR	NR	NR	-

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).

7.2 Clopyralid

General data on Clopyralid are summarized in the table below (last updated 2018/07/06)

Table 7.2-1: 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	Pyridinecarboxylic acid
Mode of action (if available)	Selective systemic herbicide, absorbed by the leaves and roots, with translocation both acropetally and basipetally, and accumulation in meristematic tissue. Exhibits an auxin-type reaction. Acts on cell elongation and respiration.
Systemic	Yes
Company (ies)	Dow Agrosciences
Rapporteur Member State (RMS)	FI
Approval status	Approved. Date of (19/07/2019) and reference to decision *(COMMISSION IMPLEMENTING REGULATION (EU) 2021/1191):* https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32021R1191&from=EN
Restriction	Only uses as herbicide may be authorised.
Review Report	SANTE/10206/2021 Rev 1 20 May 2021
Current MRL regulation	Reg. (EU) 2021/1807
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	No
EFSA Journal : Conclusion on the peer review	Peer review of the pesticide risk assessment of the active substance clopyralid EFSA Journal 2018;16(8):5389
EFSA Journal: conclusion on article 12	No
Current MRL applications on intended uses	~~Reg. (EU) 2021/1807~~ none

7.2.1 Stability of Residues (KCA 6.1)

7.2.1.1 Stability of residues during storage of samples

The stability of residues for the active substance was reviewed during the Annex I inclusion process (An-

nex II Section 4 Point 6.1) and no further data is required.

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

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products			
Pasture grass	High water content	17 months	SANTE/10206/2021 Rev 1 (Clements, B, Bolton, A. 1996)
Maize fodder/forage	High water content	13 months	SANTE/10206/2021 Rev 1 (Foster, D.R., Blakeslee, B.A., Rutherford, B.S. 1996)
Oilseed rape	High oil content	3 months	SANTE/10206/2021 Rev 1 (Day SR. 1987)
Olive (fruit and oil)	High oil content	10 months	SANTE/10206/2021 Rev 1 (Day SR. 1987)
Maize	High starch content	13 months	SANTE/10206/2021 Rev 1 (Foster, D.R., Blakeslee, B.A., Rutherford, B.S. 1996)
Orange / orange peel	High acid content	10 months	SANTE/10206/2021 Rev 1
Animal Products			
Bovine	Muscle	19 months	SANTE/10206/2021 Rev 1 (Kuper AW. 1975)
Bovine	Liver	19 months	
Bovine	Kidney	19 months	
Bovine	Milk	19 months	
Hen	Egg	19 months	
Bovine	Fat	24 months	

Conclusion on stability of residues during storage

Storage stability studies indicated that clopyralid was stable at least 12 months (382 days) in maize grain, forage and fodder and 18 months (520 days) in pasture. These studies cover starch as well as water containing materials. Indeed, no data of freezer storage of clopyralid in oil containing materials was introduced although the use of clopyralid is intended to oilseed rape. However, clopyralid is relatively stable within plant tissues and the studies of plant metabolism have indicated that radioactively labelled residues of clopyralid mainly distributed to straw than in seeds in oilseed rape. Therefore, the presented data is considered acceptable for evaluation of storage stability of clopyralid. However, need for a new study on freezer storage stability of clopyralid in oil containing crops should be considered.
(DAR Clopyralid. Vol 3. Annex B7. Point B.7.6.1.)

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

Not evaluated by RMS, availability unknown. No information available in Peer review of the pesticide risk assessment of the active substance clopyralid EFSA Journal 2018;16(8):5389 nor in Draft renewal assessment report Volume 3-B7, Finland, 2017.

7.2.2 Nature of residues in plants, livestock and processed commodities

7.2.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

No new data submitted in the framework of this application.

Table 7.2-3: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Leafy vegetables	Cabbage		Foliar	420 g s/ha, BBCH 31 (at the 8 – 10 leaf stage)		0, 5 and 38d		SANTE/10206/2021 Rev 1 (Guo, C. 1996)
Root and tuber vegetables	Sugar beet		Foliar	300 g as/ha, BBCH 36,		0, 28 and 105 d (maturity)		SANTE/10206/2021 Rev 1 (Chapelo, S.; Caley C. Y. 2002)
Pulses and oilseeds	Oilseed rape		Foliar	300 g as/ha, BBCH 36,		0, 28 and 77 d (maturity)		SANTE/10206/2021 Rev 1 (Chapelo, S.; Caley, C. Y., White, D.E. 2002)

Summary of plant metabolism studies reported in the EU

The metabolism of clopyralid residues in primary crops was investigated in leafy vegetables, root and tuber vegetables, pulses and oilseeds. In the framework of the peer review EFSA proposed to establish the risk assessment and enforcement residue definition in plants as "clopyralid, including its salts and conjugates, expressed as clopyralid". This residue definition is not in line with the existing enforcement residue definition in Regulation (EC) No 396/2005, which is set for parent clopyralid only. The need to modify the enforcement residue definition according to the conclusions of the peer review as well as the impact of this change on the MRL levels needs to be discussed in the framework of Article 12 of Regulation (EC) No 396/2005. According to the metabolism study results, in brassica vegetables, turnips and swedes clopyralid will be the main residue, whereas in linseed clopyralid conjugates might significantly contribute to the final residue levels. The submitted residue data on the crops under consideration include parent clopyralid and its conjugates. EFSA concludes that the metabolism of clopyralid in the crops under consideration is sufficiently addressed and the residue definitions agreed in the peer review are applicable. Adequate analytical methods are available to monitor all compounds given in the proposed enforcement residue definition (clopyralid, its salts and conjugates, expressed as clopyralid) in the crops under consideration.

The plant metabolism of clopyralid has been studied in three plant groups covering oilseeds (rapeseed), root and tuber vegetables (sugar beet) and leaf vegetables and fresh herbs (cabbage). These studies were evaluated in the DAR.

Although the metabolism studies are not performed with crop groups covering the representative uses in cereals and grass, they are sufficient to derive a general residue definition for primary and rotational crops for risk assessment and monitoring as 'clopyralid common moiety (sum of clopyralid, its salts and conjugates expressed as clopyralid)' – pending the outstanding clarification on the nature of 'polar clopyralid'. *[Peer review of the pesticide risk assessment of the active substance clopyralid EFSA Journal 2018;16(8):5389]*.

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

No new data submitted in the framework of this application.

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

Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G *	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks	
EU data								
Leafy vegetables	Lettuce, Cabbage					125, 319 30 days	The 30 DAT mature cabbage was harvested at 128 days (9+ leafs/head; heads failed to fully close due to heat, BBCH 53).	SANTE/10206/2021 Rev 1 (Wright, JP. 1996)
Root and tuber vegetables	Turnip Radish					125, 319 30 days		SANTE/10206/2021 Rev 1 (Rawle, N.W. Khoshab, A. 2002)
Cereals	Wheat					30, 125, 319 days		SANTE/10206/2021 Rev 1 (Rawle,N.W., Khoshab, A. 2002)
Other	Soybean (green plant and beans)					125, 319 days		SANTE/10206/2021 Rev 1

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

Summary of plant metabolism studies reported in the EU

Three nature of residues studies in three rotational crops covering the plant-back interval (PBI) of ca 30, 120 and 365 days are available. Only in the most recent study covering PBI of 30 days, identification of residues was performed and besides the parent only conjugated clopyralid is found in wheat, cabbage and

radish. Although the metabolism studies are not performed with crop groups covering the representative uses in cereals and grass, they are sufficient to derive a general residue definition for primary and rotational crops for risk assessment and monitoring as 'clopyralid common moiety (sum of clopyralid, its salts and conjugates expressed as clopyralid)' – pending the outstanding clarification on the nature of 'polar clopyralid'. *[Peer review of the pesticide risk assessment of the active substance clopyralid EFSA Journal 2018;16(8):5389]*.

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

No new data submitted in the framework of this application.

Table 7.2-5: Nature of the residues in processed commodities

Conditions (Duration, Temperature, pH)	Identified compound(s) (%)	Reference
EU data		
Pasteurisation (20 minutes, 90°C, pH 4)	Parent (99.3%)	SANTE/10206/2021 Rev 1 (Osborne KA. 1988)
Baking, boiling, brewing (60 minutes, 100°C, pH 5)	Parent (96.9%)	
Sterilisation (20 minutes, 120°C, pH 6)	Parent (97.1%)	

Conclusion on nature of residues in processed commodities

Considering the low contribution of residues in the crops under consideration to the total dietary intake, it is concluded that currently the studies investigating effects of processing on the nature and magnitude of clopyralid residues are not required. However, processing studies have been conducted with rapeseed and commercial sugar beet process fractions have been monitored (Draft renewal assessment report Volume 3-B7, Finland, 2017).

Clopyralid proved to be stable under pasteurisation, baking, brewing, boiling and sterilisation conditions. Processing factors have been established. *[Peer review of the pesticide risk assessment of the active substance clopyralid EFSA Journal 2018;16(8):5389]*.

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

Table 7.2-6: Summary of the nature of residues in commodities of plant origin

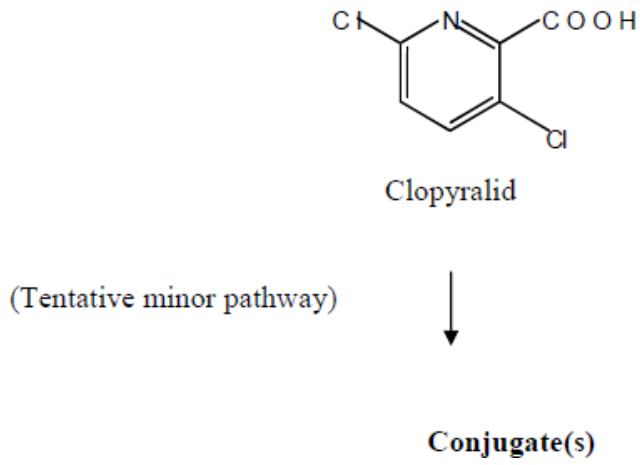
Endpoints	
Plant groups covered	Root crops (sugarbeet) Leafy crops (cabbage) Pulses/oilseeds (oilseed rape)
Rotational crops covered	Yes
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	a.s. is stable under standard hydrolysis conditions
Residue pattern 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)~~ Reg. (EU) 2021/1807
Plant residue definition for risk assessment	Clopyralid common moiety (sum of clopyralid, its salts and conjugates expressed as clopyralid) SAN-TE/10206/2021 Rev 1 limited to cereals/grass only (EFSA Journal 2021;19(1):6389)
Conversion factor from enforcement to RA	~~Residue definitions are the same, i.e. conversion factor is not needed. SAN-TE/10206/2021 Rev 1~~

* 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.

The metabolism of clopyralid was studied in four different crops: sugar beet, oilseed rape, cabbage, and pasture. Pasture study was not done in compliance with GLP and thus it can be regarded only as additional information. The metabolism of clopyralid was similar in all studied crop groups, thus the metabolic behaviour of clopyralid in plants can be regarded sufficiently studied. Clopyralid was found to be the major component of the residue, thus the residue definition in plants is clopyralid.
Most of the recovered radioactivity was removed from the sugar beets and rape plants by surface washing on the day of application. At maturity most of the radioactivity was taken up into plants. At maturity the major radioactive compound was unchanged parent compound and polar and conjugated forms of parent, together these fractions accounted for 89 – 97 % of TRR. No other significant metabolites were detected. In sugar beets clopyralid accounted for 0.36 –0.38 mg/kg in both beets and shoots. In oilseed rape clopyralid accounted for 0.71mg/kg in straw and 0.059 mg/kg in seeds. In cabbage plants unchanged clopyralid was found to be the major component of the residue, accounting for 0.321 mg/kg in cabbage heads and 1.21 mg/kg in wrapper leaves. It was stated that the presence of residues in the cabbage hearts indicates translocation from the immature leaves with the residue level being diluted by growth. The metabolism of clopyralid in grass is also very limited and the reduction of residue levels (from 13.1 mg/kg to 0.16 mg/kg) is due to the growth dilution.

Figure 1: Proposed metabolic pathway of tolylfluanid in plants.



zRMS: According to EFSA (EFSA Journal 2021;19(1):6389), the residue definition should be limited to cereals/grass only. Taking this into account, application on winter rape and sugar beet are not acceptable until the data gap is filled.

~~The intended use on sugar beet is not supported by the evaluated plant metabolism studies.~~

Authority's arrangements:

- in the case of clopyralid, assessment of residue data for the uses proposed by the Applicants, including,

among others, on oilseeds, roots or tubers (crops other than representative crops assessed in RAR (2019) for the substance clopyralid) should be carried out in accordance with the general residue definition for clopyralid proposed by EFSA in the document EFSA Journal 2018;16(8):5389 - applies all administrative proceedings conducted by the Ministry of Agriculture and Rural Development (Article 33, Article 43, Article 40, Article 45, Article 51).

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

Available data

No new data submitted in the framework of this application.

Table 7.2-7: Summary of animal metabolism studies

Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling	
EU data								
Lactating ruminants	Cow /Goat			50.9 mg a.s./kg dry feed/day equivalent to 0.484 mg/kg bw per day	5			SANTE/ 10206/2021 Rev 1 (Kutschinski AH. 1974)
Laying poultry	Hens			11.4 mg a.s./kg feed per day, equivalent to 0.56-0.65 mg/kg bw per day	7			
								SANTE/ 10206/2021 Rev 1 (Kuper AW. 1975)

Reference:	**KCA 6.2.2-01: Bauriedel, 1983**
Source:	**Clopyralid DAR, B.7. Residues. Point B.7.2.1.**
Title:	The metabolic fate of 14C-3,6-dichloropicolinic acid (Dowco 290) fed to lactating goats
Guideline(s):	No
Deviations:	-
GLP:	-
Acceptability:	Yes

Materials and methods

Two lactating goats were fed 14C-ring labelled 3,6-dichloropicolinic acid (Dowco 290), labelled in the 2,6- position, at the rate of 230 and 69 ppm in the feed for 7 days. The radiochemical purity of the test substance was > 99% with a specific activity of 1.32 Ci/mole. Each goat was milked twice daily. Milk was analysed whole and following separation by centrifugation into milk fat and skimmed milk phases. Blood samples were taken immediately prior the evening milking. These were assayed as whole and after centrifugation as plasma and red cell fractions. Urine and faeces were also collected on a daily basis. Radioactivity in expired air was monitored in one goat in an indirect calorimetric chamber. Animals were sacrificed within 15 hours of the last dose and tissue samples (comprising blood, liver, kidney, heart, skeletal muscle and composite fat samples (visceral and subcutaneous)) were taken. Gastrointestinal contents (GI-tract) were also collected.
Total ^{14}C-residue levels in liquid samples were determined by liquid scintillation counting (LSC). Solid samples were analysed by oxidative combustion followed by liquid scintillation counting. To quantify and characterise the nature of the radioactive residue, samples of milk, liver, kidney, muscle and urine were processed and extracted into an appropriate solvent, prior to chromatographic analysis by HPLC or GC-MS. Confirmation of identity was obtained by comparison with known reference compounds and GC-MS. The lower limit of detection was determined to be 0.015 mg/kg.

Results
Recovery of administered radioactivity is presented in Table 7.3-2. More than 95% of the administered radioactivity was recovered, with the majority being found in urine (>93%, of the recovered radioactivity). Most of the balance was recovered from faeces or gastrointestinal tract.
Daily average levels in milk reached a plateau of clopyralid in 4 to 5 days. Radioactivity in milk fat was below the limit of detection, indicating no tendency to accumulate in milk fat. Blood levels indicated that the rate of assimilation was essentially equivalent to the rate of elimination, and no radioactivity was determined in the expired carbon dioxide, indicating no total degradation of the active substance.
HPLC examination of the urine samples indicated the major component (>97%) as unchanged clopyralid. The remainder of the radioactivity was determined to be a glycine conjugate of clopyralid. 14C residues in milk consisted of two components, unchanged clopyralid and the same glycine conjugate observed in urine. In milk, the two residues were present in about equal amounts. Under alkaline hydrolysis, the conjugate in milk was hydrolysed to clopyralid. Residues in liver and kidney comprised unchanged clopyralid only.

Table 7.2-8 Total recovered radioactivity from lactating goats fed with clopyralid

SAMPLE	% TOTAL RADIOACTIVITY	
	Animal 3 (230 ppm)	Animal 4 (69 ppm)
Total	95.5	107.8
Urine	93.3	96.1
Faeces	0.7	9.4
GI Tract	1.4	2.2
Muscle	0.09	0.03
Liver		
Kidney		
Fat		
Milk	0.03	0.04

Conclusions
Orally administered clopyralid was rapidly excreted in the urine, primarily unchanged. Milk and tissue residues are low and consist of about equal amounts of clopyralid and the glycine conjugate of clopyralid. The study is acceptable.

Reference:	**KCA 6.2.2-02: Bauriedel, Bidlack and Yackovich, 1974**
Source:	**Clopyralud DAR, B.7. Residues. Point B.7.2.1.**

Title:	The Fate of ^{14}C-labelled DOWCO 290 Fed as a single oral dose to broiler chickens.
Guideline(s):	The study was not performed using any official guideline or test method, and it was not done under GLP. The study was performed in 1974 before the existence of OECD test guidelines or GLP guidelines.
Deviations:	-
GLP:	-
Acceptability:	Yes

Materials and methods
^{14}C-labelled DOWCO 290 was fed as a single oral dose as both the free compound (4 birds) and as "grown in" residue in wheat (2 birds) to broiler chickens. These birds had received feed containing 100 ppm added Dowco 290 (purity not stated) for over two weeks before test. After dosing, all birds were returned to the diet containing unlabelled clopyralid. Droppings were collected for 24 hours after, and thereafter the birds were killed and tissue samples were taken.
Total ^{14}C-residue levels in liquid samples were determined by liquid scintillation counting (LSC). Solid samples were analysed by oxidative combustion followed by liquid scintillation counting. To quantify and characterise the nature of the radioactive residue, samples were processed and extracted into an appropriate solvent, prior to chromatographic analysis by HPLC or GC-MS. Confirmation of identity was obtained by comparison with known reference compounds and TLC or GC-MS.

Results
The droppings of all treated birds, whether they were given direct doses of radioactive clopyralid or 'grown-in' residues, were found to contain all of the administered 14C-activity (recovery 95 – 102%). This activity was identified as unchanged clopyralid by thin layer chromatography, gas chromatography and gas chromatography-mass spectrometry. No detectable 14C-activity was found in the tissues. The study is acceptable.

Results
Clopyralid is not metabolised by the chicken and the compound passes rapidly through the bird without accumulation in the tissues. The study is acceptable.

Reference:	**KCA 6.2.2-03: Yachovich and Bauriedel, 1974**
Source:	**Clopyralud DAR, B.7. Residues. Point B.7.2.2.**
Title:	Fate of ^{14}C-DOWCO 290 in laying hens
Guideline(s):	The study was not performed using any official guideline or test method, and it was not done under GLP. The study was performed in 1974 before the existence of OECD test guidelines or GLP guidelines.
Deviations:	-
GLP:	-
Acceptability:	Yes

Materials and methods
^{14}C-labelled DOWCO 290 was fed as a single oral dose as both the free compound (4 birds) and as "grown in" residue in wheat (2 birds) to broiler chickens. These birds had received feed containing 100 ppm added Dowco 290 (purity not stated) for over two weeks before test. After dosing, all birds were returned to the diet containing unlabelled clopyralid. Droppings were collected for 24 hours after, and thereafter the birds were killed and tissue samples were taken.
Total ^{14}C-residue levels in liquid samples were determined by liquid scintillation counting (LSC). Solid samples were analysed by oxidative combustion followed by liquid scintillation counting. To quantify and characterise the nature of the radioactive residue, samples were processed and extracted into an ap-

propriate solvent, prior to chromatographic analysis by HPLC or GC-MS. Confirmation of identity was obtained by comparison with known reference compounds and TLC or GC-MS.

Results
The droppings of all treated birds, whether they were given direct doses of radioactive clopyralid or 'grown-in' residues, were found to contain all of the administered 14C-activity (recovery 95 – 102%). This activity was identified as unchanged clopyralid by thin layer chromatography, gas chromatography and gas chromatography-mass spectrometry. No detectable 14C-activity was found in the tissues. The study is acceptable.

Conclusion
Clopyralid is not metabolised by the chicken and the compound passes rapidly through the bird without accumulation in the tissues. The study is acceptable.

Reference:	**KCA 6.2.2-04: Yachovich and Bauriedel, 1974**
Source:	**Clopyralud DAR, B.7. Residues. Point B.7.2.3.**
Title:	Fate of ^{14}C-DOWCO 290 in laying hens
Guideline(s):	The study was not performed using any official guideline or test method, and it was not done under GLP. The study was performed in 1974 before the existence of OECD test guidelines or GLP guidelines.
Deviations:	-
GLP:	-
Acceptability:	Yes

Material and methods
Two laying hens (Leghorn) were given a daily oral dose of 14C-clopyralid, labelled in the 2,6- position, for five and six consecutive days. The radiochemical purity was 98%, with a specific activity of 10.6 Ci/mole. Oral administration was chosen since oral ingestion is the most likely route of exposure. The animals received daily 100 ppm of test material in the feed. Eggs and excreta were collected daily. The hens were sacrificed after the last dose and tissue samples and gastrointestinal contents were collected. Eggs were divided into yolks, whites and shells.
Total ^{14}C-residue levels in samples were determined by combustion radioanalysis and/or liquid scintillation counting (LSC). To quantify and characterise the nature of the radioactive residue, samples of eggs, liver, kidney, muscle and excreta were processed and extracted into an appropriate solvent, prior to chromatographic analysis by TLC or GC. Confirmation of identity was obtained by comparison with known reference compounds and GC-MS.

Results
Analysis of the eggs showed that residues rapidly reached a concentration of approximately 0.15 ppm clopyralid equivalents in egg white and 0.02 ppm in the yolk and shell. The egg white residues were identified as unchanged clopyralid by mass spectroscopy, thin layer chromatography and gas chromatography. Residue levels in the tissues ranged from 0.02 ppm in the fat to 1.1 ppm in the kidney. Breast and leg muscle contained residues of 0.03 and 0.10 ppm, respectively. Analysis of the bird droppings collected daily accounted for approximately 90% of the administered 14C-activity. The residues in the droppings, liver, kidney and leg muscle were identified as unchanged clopyralid by gas chromatography-mass spectroscopy and thin layer chromatography.

Conclusion
Clopyralid can occur as residue in eggs and body tissue of laying hens, when fed at dose levels of 100

ppm in the diet (100 mg/kg). Approximately 90% of the dose passed through the birds and was not metabolised. The residues detected in the eggs and tissues were unchanged clopyralid. The study is supportive.

Reference:	**KCA 6.2.2-05: Yackovich, Bauriedel and Templeton, 1974**
Source:	**Clopyralud DAR, B.7. Residues. Point B.7.2.4.**
Title:	Fate of DOWCO 290 in sheep
Guideline(s):	The study was not performed using any official guideline or test method, and it was not done under GLP. The study was performed in 1974 before the existence of OECD test guidelines or GLP guidelines.
Deviations:	-
GLP:	-
Acceptability:	Yes

Material and methods

Four young lambs were given Dowco 290/clopyralid (purity not stated) at a dietary concentration of 100 ppm for 8 weeks. A two-part study of the fate of the compound was then conducted. In the first part, 14C-labelled clopyralid was added to freshly drawn rumen fluid at 1 ppm and fermented in vitro in the laboratory. No metabolic or chemical degradation occurred during fermentation for six hours. In the second part, after ten weeks on the diet containing 100 ppm of unlabelled clopyralid, one male lamb was administered a single 2.072 mg oral dose (equivalent to 1 ppm daily intake) of the labelled clopyralid.

Results

Analysis of the collected urine and faeces showed only unchanged clopyralid to be present. Recovery data indicated that the herbicide was excreted rapidly and quantitatively by sheep primarily via the urine. Over 90% were excreted in the urine within 24 hours. Practically the entire dose was excreted within 36 hours with only 3.3% found in the faeces. At the end of the 72-hour collection period, 98.2% had been detected in the urine and 4.2% in the faeces.

Conclusion

Clopyralid is excreted rapidly and quantitatively by sheep via urine. The study is acceptable.

Conclusion on metabolism in livestock

Metabolism studies both for ruminants and poultry are submitted indicating that conjugation is the major pathway; however, significant amounts of glycine conjugates were only found in milk. The conversion factor of 1.3 for monitoring to risk assessment is only relevant for milk and is based on the new ruminant metabolism study.

The residue definition in products of animal origin for risk assessment is proposed as ‘clopyralid common moiety (sum of clopyralid, its salts and glycine conjugates expressed as clopyralid)’ and ‘clopyralid and its salts’ for monitoring. The plateau in eggs was reached at ca 7 days and in milk at day 1.

GLP- and guideline-compliant feeding studies with poultry and cattle analysing for all compounds covered by the residue definition for risk assessment and within a time period covered by storage stability data were presented. Residues in poultry matrices at the highest dose group at sampling day 28 were highest in eggs (up to 0.046 mg/kg), followed by liver (up to 0.034 mg/kg) and muscle (up to 0.017 mg/kg), whereas very little residue were quantified in fat (0.005 mg/kg). Residues in cow´s milk were in the highest dosing group already at day 2 (up to 0.0175 mg/kg) and remained at this level.

Residue levels at the highest dose group were observed also in all other organs (up to 0.484 mg/kg in muscle, up to 1.962 mg/kg in liver, up to 25.3 mg/kg in kidney and up to 2.131 mg/kg in average fat). *[Peer review of the pesticide risk assessment of the active substance clopyralid EFSA Journal 2018;16(8):5389]*.

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

Table 7.2-8: Summary on the nature of residues in commodities of animal origin

	Endpoints
Animals covered	Lactating goats
	Laying hens
Time needed to reach a plateau concentration	1 days in milk
	7 days in eggs
Animal residue definition for monitoring	Clopyralid and its salts SANTE/10206/2021 Rev 1
Animal residue definition for risk assessment	Clopyralid common moiety (sum of clopyralid, its salts and glycine conjugates expressed as clopyralid). SANTE/10206/2021 Rev 1
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. SANTE/10206/2021 Rev 1
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	No

* A more recent proposal by EFSA may be provided as additional information (EFSA RO XXXX)
** If no EFSA proposal is available, a proposal should be made by the applicant/zRMS.
*** If metabolism in rat and ruminant are not similar

7.2.3 Magnitude of residues in plants (KCA 6.3)

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

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

Table 7.2-9: Summary of EU reported and new data supporting the intended uses of PP-113H 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
Sugar beet roots	EFSA (2005)	NEU (10)	GAP on which MRL/EU a.s. assessment is based: 1 x 0.1 kg as/ha + 1x 0.2 kg/ha latest timing of BBCH 39 **E: 0.12; 0.17; 0.21; 0.29; 0.34; 0.35; 0.36; 0.41; 0.56; 0.8 RA: 0.12; 0.17; 0.21; 0.29; 0.34; 0.35; 0.36; 0.41; 0.56; 0.8 CF: -	E: 0.35 RA: 0.35	E: 0.8 RA: 0.8	1.0	1.0	Yes. The MRL proposal derived in the framework of the peer review was 1 mg/kg (EFSA, 2005). The use of the OECD calculatorf results in an MRL proposal of 1.5 mg/kg. Rber= 0.90 Rmax=0.94
	New trials	NEU	no data	-	-	-		
	Overall supporting data for cGAP	NEU (10)	GAP on which MRL/EU a.s. assessment is based: 1 x 0.1 kg as/ha + 1x 0.2 kg/ha latest timing of BBCH 39 **E: 0.12; 0.17; 0.21; 0.29; 0.34; 0.35; 0.36; 0.41; 0.56; 0.8 RA: 0.12; 0.17; 0.21; 0.29; 0.34; 0.35; 0.36; 0.41; 0.56; 0.8 CF: -	E: 0.35 RA: 0.35	E: 0.8 RA: 0.8	1.0		
Sugar beet tops	EFSA (2005)	NEU (7)	GAP on which MRL/EU a.s. assessment is based: 1 x 0.1 kg as/ha + 1x 0.2 kg/ha latest timing of BBCH 39 RA: 0.13, 0.14, 0.23, 0.36, 0.47, 0.62, 1.05	RA: ~~0.42~~ 0.36	RA: 1.05		N/A (MRLs are not currently set for animal feed commodities)	-
	New trials	NEU	no data	-	-	-		
	Overall	NEU (7)	GAP on which MRL/EU a.s. assessment is based: 1 x 0.1 kg as/ha	RA: ~~0.42~~	RA: 1.05			

	supporting data for cGAP		+ 1x 0.2 kg/ha latest timing of BBCH 39 RA: 0.13, 0.14, 0.23, 0.36, 0.47, 0.62, 1.05	0.36				

* Source of EU MRL: Reg. (EU) 2021/1807

**Residues in the trials were determined as clopyralid. In most instances a hydrolysis step was included in the used analytical methods. Residues above the LOQ were found in all studied crops. In few trials from the 1970's on oilseed rape and sugar beets residues have been analysed with a method without a hydrolysis step. No significant differences in residue levels observed in those trials compared to the more recent residue trials in oilseed rape and sugar beets were observed. Hence those trials were included in the evaluation.

7.2.3.2 Conclusion on the magnitude of residues in plants

A total of 28 supervised residue trials with Clopyralid have been carried out on Sugar beet crops in open field conditions in Northern and Southern Europe. The trials have been conducted by using EF-1136 formulation containing 100 g/L Clopyralid. The trials have been carried out at critical GAP (± 25 %) in order to propose an MRL for raw commodities for human consumption and a maximum excepted residue following application to pasture. Most of the trials have been carried out in 2000 and 2001 to reflect current labels, but some older studies were also included, where these reflect critical GAP. Therefore, supplementary residue trials are not considered to be necessary. (DAR Clopyralid 2005. Vol.3.Annex B7. Point B.7.6.).

See point 7.1

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

The calculated dietary burdens and the results of livestock feeding studies were used to assess the potential carry-over of clopyralid residues in commodities of animal origin. Results indicate that for the calculated dietary burdens residues above the LOQ are expected in meat, liver, kidney of ruminants and milk. The analytical enforcement method is available to monitor all compounds given in the proposed enforcement residue definition in kidney, fat and eggs at the LOQ of 0.01 mg/kg (EFSA Journal 2018;16(8):5389).
zRMS: New Dietary Burden calculations were performed, taking into account STMR and HR values from residues trials (only proposed use). These data fall within the data used for the calculations presented in EFSA Journal 2021;19(1):6389. Calculations were presented below in Animal model 2017. No additional calculation is needed.

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)	0,125	0,148	3,26	3,84	Dairy cattle	Beet, sugar	ensiled pulp	Yes
Cattle (dairy only)	0,125	0,148	3,26	3,84	Dairy cattle	Beet, sugar	ensiled pulp	Yes
Sheep (all diets)	0,135	0,151	3,17	3,56	Lamb	Beet, sugar	dried pulp	Yes
Sheep (ewe only)	0,015	0,119	0,46	3,56	Ram/Ewe	Beet, sugar	dried pulp	Yes
Swine (all diets)	0,043	0,043	1,58	1,78	Swine (finishing)	Beet, sugar	dried pulp	Yes
Poultry (all diets)	0,005	0,012	0,08	0,17	Poultry layer	Beet, sugar	tops	Yes
Poultry (layer only)	0,005	0,012	0,08	0,17	Poultry layer	Beet, sugar	tops	Yes

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Livestock feeding studies were carried out with lactating goats, calves, laying hens and pigs (Finland, 2003, 2005). The feeding study with pigs, however, was not peer reviewed as it was not required and is considered only as additional information.
Results indicate that for the calculated dietary burdens no residues above the LOQ of 0.05 mg/kg are expected to occur in meat, fat, liver and kidney of poultry and swine, eggs and ruminant fat. Clopyralid residues may occur above the LOQ in ruminant meat (0.08 mg/kg), ruminant liver (0.06 mg/kg) and ruminant kidney (0.4 mg/kg). Residues at 0.015 mg/kg are estimated in milk. Study results also confirm that clopyralid is not fat soluble. (EFSA Journal 2011;9(10):2418).

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

Clopyralid DAR, Vol.3, Annex B, B7, Point B.7.7:

Sugar beet
A number of studies were conducted during 1984-1987 to determine the residues of clopyralid present in commercial samples of the process fractions of sugar beet as a result of treating the crop with clopyralid.
Samples of sugar beet molasses and/or massecuite (massecuite is a green syrup from which molasses is prepared) were collected from different factories. No special procedures were set up for a study and samples were taken from normally production runs. Clopyralid were then extracted from the molasses and/or massecuite and analysed by using a gas chromatographic method.
The data indicated that clopyralid was concentrated during the processing from massecuite to molasses. Since no data for the water content of samples were available, it was not possible to draw conclusion whether this increase was in parallel to the concentration of the sugar content of the syrup. However, despite the fact that clopyralid residues were concentrated during processing of sugar beet, the residues were below the limit of detection in refined sugar. The low levels of residues indicate that changes to the quality to the fresh or processed products are unlikely.

EFSA Scientific Report (2005) 50, 1–65, Conclusion on the peer review of clopyralid:

Processing factors (Annex IIA, point 6.5, Annex IIIA, point 8.4)

Crop/processed crop	Number of studies	Transfer factor	% Transference *
Rapeseed oil	15	0.1	-
Sugar beet	>1	0.01	-

* Calculated on the basis of distribution in the different portions, parts or products as determined through balance studies

Processing studies were performed with rapeseed, and commercial sugar beet processing fractions have been monitored. No concentration of clopyralid was observed in oil samples. Clopyralid residues were concentrated during processing of sugar beet, but residue levels were below the limit of detection in refined sugar. For cereals no processing study was submitted. Therefore the experts' meeting for residues agreed on that such study has to be provided.

EFSA Journal 2018;16(8):5389
Clopyralid proved to be stable under pasteurisation, baking, brewing, boiling and sterilisation conditions. Processing factors have been established. Validity is pending the evaluation of the underlying residue field trials.

7.2.5.1 Available data for all crops under consideration

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

7.2.5.2 Conclusion on processing studies

See previous point 7.2.5.

7.2.6 Magnitude of residues in representative succeeding crops

7.2.6.1 Field rotational crop studies (KCA 6.6.2)

All crops under consideration can be grown in rotation with other plants and therefore the possible occurrence of clopyralid residues in succeeding crops resulting from the use on primary crops has to be assessed. The available soil degradation laboratory studies demonstrate that the degradation rate of clopyralid is slow with the maximum DT90lab of 217 days which exceeds the trigger value of 100 days (EFSA, 2005). The field degradation studies, however, demonstrate faster degradation of clopyralid in soil with a maximum DT90f of 79 days.
The metabolism of clopyralid residues in rotational crops has not been assessed in the framework of the peer review under Directive 91/414/EEC (Finland, 2003) as the need for the studies was not triggered by the relevant soil degradation field studies. However, during the evaluation meetings the RMS and EFSA decided that occurrence of clopyralid residues in rotational crops has to be further assessed given the results of soil degradation laboratory studies as well as systemic behavior of clopyralid in plants.
Consequently, the nature and magnitude of the clopyralid uptake in rotational crops has to be further investigated. (EFSA Journal 2011;9(10):2418).
Cereals, pasture, oilseed rape and sugar beet can be planting as succeeding crops because all of them are crops intended for use of clopyralid.
However, although clopyralid is readily degraded in soil it is relatively stable within plant tissue, leguminous and solenaceous crops are sensitive to clopyralid in soil, therefore ensure that all residues of the treated crop have completely decayed before planting such a crop.
(EFSA Scientific Report (2005) 50, 1–65, Conclusion on the peer review of Clopyralid).

Nevertheless, in case of damage to the crop treated, only sowing or planting authorized crops (sugar beet, cereals, pasture and oilseed rape).

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).

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

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of PP-113H. A study to determine the residues of Clopyralid in honey has been submitted.

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

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

7.2.8.1 Input values for the consumer risk assessment

Since 2007, the EFSA PRIMo (Pesticide Residue Intake Model), an Excel-based calculation spreadsheet, is the standard tool used at EU level to perform the dietary risk assessment for pesticide residues in the framework of setting and reviewing of maximum residue levels for pesticides under Regulation (EC) No 396/2005 and in the peer review of pesticides under Regulation (EU) No 1107/2009. The model was now updated *(EFSA PRIMO revision 3, according to EFSA Journal 2019;16(1):5147)* with regard to food consumption data derived from some recent dietary food surveys. In addition, new functionalities were included in the calculation spread sheet to make the tool more user-friendly and to allow automatic integration of the EFSA PRIMo in the workflows where dietary risk assessments are performed.

In a first step, the calculation of the TMDI was performed taking into account all the crops to which the Clopyralid may be applied. Using the new value of ARfD of 0.17 mg/kg bw/day, established in the Efsa Journal 2018, children have problems with the short-term intake (IESTI) because it exceeds the toxicological reference value for one commodity (cauliflower). For this reason, the refined mode of the model was used, including only crops susceptible to being treated with Clopyralid (sugar beet and sugar beet roots).

The summary of the calculation using the EFSA model rev 3.1 is presented in Appendix 3.

The MRLs used are summarized in Appendix 4.

7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.2-10: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo	6 % (NL Child)
IESTI (% ARfD) according to EFSA PRIMo	Sugar beet:0.01% (children)

The proposed uses of clopyralid in the formulation PP-113H do not represent unacceptable acute and chronic risks for the consumer.

7.3 Active substance 2

Not required. The product only has one active substance.

7.4 Combined exposure and risk assessment

Not relevant. The product contains only one active substance.

7.4.1 Acute consumer risk assessment from combined exposure

Not relevant. The product contains only one active substance.

7.4.2 Chronic consumer risk assessment from combined exposure

Not relevant. The product contains only one active substance.

7.5 References

Conclusion regarding the peer review of the pesticide risk assessment of the active substance clopyralid. EFSA Scientific Report (2005) 50, 1–65, Conclusion on the peer review of clopyralid. December 2005.
Outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment of confirmatory data for the active substance clopyralid. EFSA supporting publication 2014: EN-624.
Modification of the existing MRLs for clopyralid in various commodities. EFSA Journal 2011;9(10):2418.
Peer review of the pesticide risk assessment of the active substance clopyralid. EFSA Journal 2018;16(8):5389. July 2018.
Scientific support for preparing an EU position for the 45th Session of the Codex Committee on Pesticide Residues (CCPR). EFSA Journal 2013;11(7):3312.
Pesticide residues in food 2012. REPORT 2012. Joint FAO/WHO Meeting on Pesticide Residues.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 5.3	Antón, B.	2020	Determination of Residues of Clopyralid (Common Moiety Method- Sum of Clopyralid, its Salts and Conjugates Expressed as Clopyralid) in Honey, after One Application of PP-113H (Clopyralid 100 g/L SL) in Phacelia tanacetifolia under semi- field conditions, at 4 Sites in Central and Southern Europe in 2020. Analytical phase report. Eurofins. Report No: S20-01463 GLP, Unpublished	N	PROPLAN

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

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

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

Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1 Clopyralid

A 2.1.1 Other/Special Studies

A 2.1.1.1 Study 1

Comments of zRMS:	The study is acceptable ~~but not taken into account until a definition for the risk assessment of sugar beet has been established~~

Report:	**KCA 6.10-01, Antón, B. (2020)**
Title:	Determination of Residues of Clopyralid (Common Moiety Method- Sum of Clopyralid, its Salts and Conjugates Expressed as Clopyralid) in Honey, after One Application of PP-113H (Clopyralid 100 g/L SL) in Phacelia tanacetifolia under semi- field conditions, at 4 Sites in Central and Southern Europe in 2020.
Document Nº	S20-01463
Guidelines	Guideline 7029/VI/95 (rev. 5) to Directive 91/414/EEC and Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009, SANTE/11956/2016 rev. 9, SANCO/3029/99 rev. 4
GLP	Yes

Summary

A study was performed in order to determine the residues of clopyralid in honey from Phacelia tanacetifolia following one application of PP-113H (Clopyralid 100 g/L SL), at the equivalent amount to 125 g active ingredient/ha, under semi-field conditions.

The study comprised of four residue trials in phacelia plants in 2020. Two trials (S20-01463-01 and -02) were conducted in Spain and two trials (S20-01463-03 and -04) were conducted in Germany. The study was carried out under GLP conditions and according to OECD Good Laboratory Practice Standards. Trial sites were separated by at least 10 km and under different cultivation conditions.

Each trial consisted of one untreated and one treated tunnel with 200 m2 plot size. One healthy queen-right honeybee colony was placed in each tunnel. One foliar application was performed at BBCH-63-65 in the treated plots. The application equipment consisted in a boom sprayer with a hand held boom. The equipment was calibrated/verified before application.

Sampling was carried out in both, control and treated plots at honey maturity (between 7 to 26 days after application). Samples were frozen on dry ice shortly after the sampling, and they were maintained deep frozen (≤ -18ºC) until analysis. Maximum storage period of the samples until analysis was 23 days.

The analytical methodology for residues analysis (quantification by UPLC-MS/MS) was adjusted and validated according to SANCO/3029/99 rev. 4 and SANCO/825/00 rev. 8.1 for the quantification of clopyralid in honey matrix.

The limit of quantification (LOQ) of the analytical method for clopyralid residues determination in honey was 0.01 mg/kg, with a limit of detection (LOD) set at 0.003 mg/kg (30 % of the LOQ).

No residues of clopyralid were detected at or above the limit of quantification in any of the control samples. Residues of clopyralid in treated samples ranged from 0.02 mg/kg to 0.34 mg/kg.

Summary of Residues in Honey

Trial code	Sample timing	Plot	Sample	Clopyralid Residue Level (mg/kg)
S20-01463-01	15DAA	Control	L20-01463-01-C-S1-HO-A1	< LOQ
		Treated	L20-01463-01-T-S1-HO-A1	0.02
S20-01463-02	8DAA	Control	L20-01463-02-C-S1-HO-A1	< LOQ
		Treated	L20-01463-02-T-S1-HO-A1	0.12
S20-01463-03	7DAA	Control	L20-01463-03-C-S1-HO-A1	< LOQ
		Treated	L20-01463-03-T-S1-HO-A1	0.15
S20-01463-04	11DAA	Control	L20-01463-04-C-S1-HO-A1	< LOQ
	26DAA	Control	L20-01463-04-C-S1-3-HO-A	< LOQ
	11DAA	Treated	L20-01463-04-T-S1-HO-R1	0.34

DAA: days after application LOQ: Limit of quantification: 0.01 mg/kg

Study Objective

The objective of the study was to determine residues of clopyralid, its salts and conjugates (expressed as clopyralid) in honey from Phacelia tanacetifolia after one application of PP-113H (Clopyralid 100 g/L SL) under semi-field conditions. The study was conducted as four separate field trials in Spain and Germany in 2020.

Amendments and Deviations

The study was performed according to the Study Plan S20-01463 and the Study Plan Amendments No. 1, 2, & 3.

The following amendments were added to the Study Plan:

- Correction of the active ingredient CAS number, cancellation of the spray solution sampling, and extension of the timing for initial and final colony assessments.
- Inclusion of the PI, the Analytical Phase Plan and update of the proposed study schedule.
- Inclusion of the analytical phase amendment M01, to include the analysis of an extra control sample.

The following relevant deviations to the Study Plan occurred during the test performance:

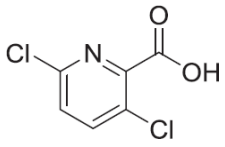
- Minimum distance between Field Sites corresponding to trials -01 & -02 was > 10 km, as required in SANTE/11956/2016 rev. 9, but not > 20 km as required in the Study Plan.
- Honey samples corresponding to trial -03 and control sample corresponding to trial -04

were sampled from a single comb since other combs had no honey storages.

- The hives set up in trial -03 was performed one day earlier, since the scheduled application was postponed one day due to a bad weather forecast. However, the introduction of the new empty combs was performed on the application day.
- A-Samples corresponding to trial -04 arrived thawed to the analytical Test Site due to a delay in their delivery. The corresponding treated R-sample was sent for analysis. An extra control sample was taken from the control hive in the monitoring site and was additionally analysed together with the control A-sample, since no control R-sample could be sampled.
- The transfer of the audited field raw data corresponding to trials -03 and -04 was not performed within 4 weeks after last sampling.

The reported deviations had no impact on the outcome of the study.

Material and Methods

Test item:	
Test item name/code	PP-113H (Clopyralid 100 g/L SL)
Other name	BARILOCHE 100
Warning word / Symbol	None
Formulation	SL (Soluble concentrate)
Intended use	Herbicide
Appearance	Faint yellow liquid
Stability	Stable mixture under normal conditions.
Storage	Store in cool dry place. Avoid extreme temperatures (< 5ºC; >40 ºC) and sun light
Batch code	20190506
Manufacturing date	06 May 2019
Date of analysis	17 – 20 May 2019
Date of analytical certificate	06 June 2019
Expiry date	06 May 2021
Density [g/cm^3]	1.0470 at 20ºC
Solubility	Non applicable; it is a aqueous solution
Vapour pressure	Not available
pH	6.3 (1%)
Active ingredient	**Clopyralid**
Chemical name (IUPAC)	3,6-dichloropyridine-2-carboxylic acid or 3,6-dichloropicolinic acid
CAS number	1702-17-6
Empirical formula	$C_6H_3Cl_2NO_2$
Structural formula	
Molecular weight [g/mol]	191.96

Content of a.i. (nominal) [g/L]	100
Content of a.i. (analytical) [g/L]	102 ± 1

Location		**Test Facility**	**Test Site**
Test item Storage		Stored under controlled temperature, protected from sunlight, heat and humidity. Storage in original container and in dark conditions.	
Date of receipt		27 Mar 2020	24 Apr 2020
Storage Temperature during study period [°C]	**Maximum**	18.27	25.12
	Minimum	12.51	17.58

Specifications essential for correct identification of the test item for use under GLP are based on the Certificate of Analysis as provided by the Sponsor / supplier. They have not been verified by the Test Facility and might be not generated under GLP, except where this is explicitly claimed on the Certificate of Analysis. Additional specifications for test item characterisation may originate from (non-GLP) sources other than the Sponsor / supplier.

Field Sites and Plot Design

Two residue trials were carried out in Spain and two residue trials were conducted in Germany. Minimum distance between the different test fields was ≥ 10 km to each other. Two tunnels per trial with 200 m2 plot space (dimensions 5 x 40 x 3.5 m) were set up for control and treated plots. The covering gauze used had a mesh size of approximately 1.5 mm. Summaries of field sites information are given in Appendix A.
One colony in healthy condition was placed into each tunnel. The hives were placed into the tunnels in the evening before application for trials -01 (BBCH 63-65), -02 (BBCH 63) and -04 (BBCH 63). Between 3 and 4 empty but built combs were marked and placed in the brood body. For trial -03, the hives were placed in the evening two days before the application (BBCH 62-63). For this trial, the empty combs were placed in the brood body on the application day.
A water source for the honeybees was also placed in each tunnel, with floatable material.
The design of the plot, dimensions of the tunnels and location of honeybee hives are given in Figure 1.

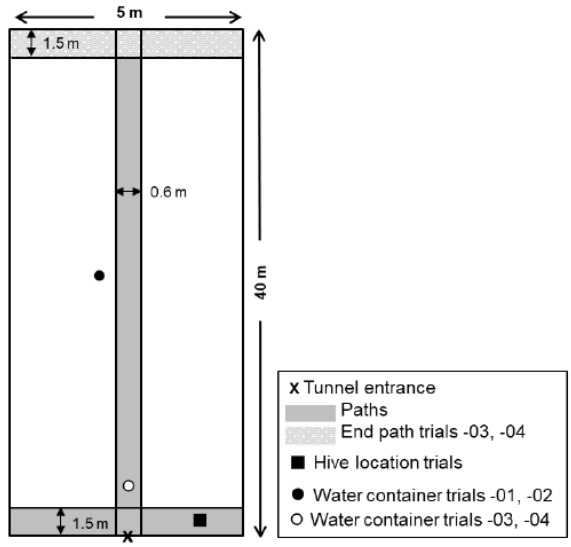


Figure 1. Tunnels design

Environmental conditions in the tunnels

Environmental conditions (temperature, humidity and rainfall) from the applications until the end of the trials were continuously registered by means of data-loggers and rain gauges located in each field site. Long-term monthly average weather data (temperature and rainfall) corresponding to the previous 4-5 years, were obtained for each trial and test period from external nearby relevant weather stations of an official weather service.

Application

The test item was tested in a program of one application at the maximum field rate, according to the product GAP. The nominal application schedule according to the GAP is given in the table below.

Application code	Trial	Timing	Plot	Application rate		Water volume
				Formulated product (FP)	Active ingredient (a.i.)	
A	-01 -02 -03 -04	BBCH 63 - 65 In the morning until noon	T	1.250L product /ha	125 g clopyralid/ha	400 L/ha

For the application solutions preparation, the appropriate amount of test item was weighted in the Test Facility/Site and transported to the Field Site. Temperatures during transport ranged from 12.8 ºC to 21.7 ºC. The test item was diluted with tap water. The spray solutions were prepared at the trial site just before each application.

Calibrated equipment was used for applications. Calibration was performed by using the volume/time method for liquid applications. Calibration runs (three independent runs) verified that the system was operating consistently, uniformly and as expected. Deviation among nozzles regarding delivery volume was in the ± 5 % range. Deviation among runs regarding delivery volume was in the ± 5 % range. On each application day, the application equipment was verified/calibrated before use. Thus, the application times per plot were determined after considering the verification/calibration results.

The application was performed by spraying the test item solution with a boom sprayer with a hand held boom, in the absence of wind (≤ 0.3 m/s) and at a distance of 40-50 cm from the crop. Care was taken that the spray solution was prepared and well homogenized by mixing before application. The actual applied active ingredient was calculated by measuring the remaining spray solution in the drum after the application, considering the prepared amount of formulated product for the corresponding spray solution, and the active ingredient content in the formulated product according to the certificate of analysis. The deviation from the target active ingredient to be applied per plot ranged between - 1.98 % to +2.90 %.

During applications, the water containers were taken out of the tunnels and the honeybee colonies were covered with a plastic sheet until the end of the application to avoid direct contamination.

Samplings

Honey samples from control and treated plots were collected at honey maturity (between 7 and 15 days after application). Sample amounts between 15.5 and 110.5 g of honey were collected from treated plots. Sample amounts between 2.4 and 110.0 g of honey were collected from untreated plots. An extra sample of control for trial -03 was taken from the monitoring site (26 DAA) since no R-sample was collected on the corresponding sampling day, due to the low amount of available honey.
Sampling was performed on the marked combs inserted to the hives prior to set-up, and from several spots within a comb. Honey was sampled by gently pushing a spoon into the walls of storage cells, allowing the honey to flow onto the spoon. Honey from capped and non-capped honey cells was collected, since its water content was determined at the field with a digital refractometer as < 20 % (based on º Brix values) for both, control and treated honey.
Treated and untreated specimens were chilled on dry ice directly after sampling, and were transported to the Test Site/Facility within a period < 7 h from the sampling start.

Storage and Shipment

Treated and untreated specimens were directly chilled on dry ice after sampling and stored deep frozen, until their shipment to the Analytical Test Site. Samples were shipped in thermo-boxes with dry ice. Treated and untreated samples were transported in separate containers to avoid contamination. Treated R-sample and an extra control corresponding to trial -03 were shipped to the Analyical Test Site since the corresponding A-samples arrived thawed. The samples' maximum storage interval from sampling to analysis was 23 days.
Remaining R-samples are kept deep frozen at the Test Site/Facility. They will be disposed of after 4 weeks from the Final Report issuance, unless the Sponsor's Representative requests for further storage.

Specimen Residue Analysis

Clopyralid content (sum of clopyralid, its salts and conjugates expressed as clopyralid) in samples was determined by UPLC-MS/MS under the delegated phase with code E20053.
The method was successfully validated for the determination of clopyralid, its salts and conjugates in honey matrix samples according to the guidance documents SANCO/825/00 rev.8.1 and SANCO/3029/99 rev. 4. The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg. With regard to selectivity, accuracy and precision, the analytical method was applied successfully when analysing the samples of the study.

Results

The test item was applied; specimens were generated and analysed according to the study objectives. Results of residue analysis may therefore be used in order to predict the residue behaviour of clopyralid after usage of PP-113H (Clopyralid 100 g/L SL) when applied as per the study.
No residues of clopyralid were detected at or above the limit of quantification in any of the control samples. Residues of clopyralid in treated samples ranged from 0.02 mg/kg to 0.34 mg/kg.

Trial code	Sampling code	Sample timing	Plot	Sample	Clopyralid Residue Level (mg/kg)
S20-01463-01	S1	15DAA	Control	L20-01463-01-C-S1-HO-A1	< LOQ
	S1		Treated	L20-01463-01-T-S1-HO-A1	0.02
S20-01463-02	S1	8DAA	Control	L20-01463-02-C-S1-HO-A1	< LOQ
	S1		Treated	L20-01463-02-T-S1-HO-A1	0.12
S20-01463-03	S1	7DAA	Control	L20-01463-03-C-S1-HO-A1	< LOQ
	S1		Treated	L20-01463-03-T-S1-HO-A1	0.15
S20-01463-04	S1	11DAA	Control	L20-01463-04-C-S1-HO-A1	< LOQ
	S1_3	26DAA	Control	L20-01463-04-C-S1-3-HO-A1	< LOQ
	S1	11DAA	Treated	L20-01463-04-T-S1-HO-R1	0.34

DAA: days after application; LOQ: Limit of quantification: 0.01 mg/kg

Conclusion

The test item was applied according to the product GAP; specimens were generated and analysed according to the study objectives. Results of residue analysis may therefore be used in order to predict the residue behaviour of clopyralid after usage of PP-113H (Clopyralid 100 g/L SL) when applied as per the study.
No residues above the limit of quantification were found in any control sample.
Residues of clopyralid in honey, after one application of PP-113H (Clopyralid 100 g/L SL) at a rate equivalent to 125 g active ingredient/ha, ranged from 0.02 mg/kg to 0.34 mg/kg mg/kg at honey maturity.

Appendix 3 Pesticide Residue Intake Model (EFSA PRIMO revision 3, according to EFSA Journal 2019;16(1):5147)

A 3.1 TMDI calculations

Clopyralid: Normal mode

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Clopyralid
Reg. (EU) 2021/1807

LOQs (mg/kg) range from:	0.05	to:	0.05
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:	2005	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	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	42%	NL toddler	63.38	9%	Maize/corn	8%	Wheat	4%	Apples	2%	
	33%	DK child	50.03	18%	Rye	9%	Wheat	0.8%	Potatoes	0.5%	
	27%	GEMS/Food G06	40.60	14%	Wheat	2%	Rice	2%	Maize/corn	0.2%	
	25%	NL child	37.29	8%	Wheat	6%	Sugar beet roots	2%	Apples	0.9%	
	25%	DE child	36.95	8%	Wheat	4%	Apples	3%	Rye	0.7%	
	21%	RO general	31.13	10%	Wheat	3%	Head cabbages	1%	Maize/corn	0.5%	
	21%	GEMS/Food G15	30.78	9%	Wheat	2%	Head cabbages	1%	Potatoes	0.4%	
	20%	GEMS/Food G08	30.74	8%	Wheat	2%	Rye	1%	Potatoes	0.3%	
	20%	FR child 3 15 yr	29.78	9%	Wheat	2%	Sugar beet roots	1%	Oranges	0.9%	
	20%	GEMS/Food G10	29.28	8%	Wheat	2%	Rice	1%	Soyabeans	0.3%	
	18%	IT toddler	27.67	13%	Wheat	2%	Other cereals	0.5%	Tomatoes		
	18%	IE adult	27.37	5%	Wheat	2%	Sweet potatoes	2%	Linseeds	0.2%	
	18%	GEMS/Food G07	27.26	8%	Wheat	1%	Potatoes	0.8%	Barley	0.4%	
	17%	GEMS/Food G11	25.66	7%	Wheat	1%	Potatoes	1%	Soyabeans	0.4%	
	17%	UK toddler	24.87	8%	Wheat	2%	Sugar beet roots	1%	Potatoes	0.7%	
	16%	FR toddler 2 3 yr	23.56	6%	Wheat	2%	Sugar beet roots	1%	Apples	1%	
	15%	SE general	23.08	6%	Wheat	1%	Potatoes	1%	Head cabbages	0.4%	
	15%	PT general	23.04	8%	Wheat	2%	Potatoes	1%	Rice		
	15%	UK infant	22.89	5%	Wheat	1%	Maize/corn	1%	Milk: Cattle	1%	
	15%	ES child	22.49	9%	Wheat	0.7%	Oranges	0.6%	Rice	0.5%	
	15%	DE women 14-50 yr	22.09	4%	Wheat	3%	Sugar beet roots	2%	Rye	0.5%	
	14%	DE general	21.74	4%	Wheat	3%	Sugar beet roots	2%	Rye	0.5%	
	12%	IT adult	18.12	8%	Wheat	0.9%	Other cereals	0.4%	Tomatoes		
	12%	NL general	17.90	4%	Wheat	2%	Sugar beet roots	0.8%	Potatoes	0.3%	
	12%	FI 3 yr	17.37	2%	Wheat	2%	Rye	2%	Potatoes	0.0%	
	10%	LT adult	14.91	4%	Rye	2%	Wheat	1%	Potatoes	0.2%	
	9%	ES adult	13.99	5%	Wheat	0.7%	Barley	0.4%	Oranges	0.2%	
	9%	FI 6 yr	13.78	2%	Rye	2%	Wheat	1%	Potatoes	0.0%	
	9%	FR adult	13.58	4%	Wheat	0.8%	Wine grapes	0.5%	Sugar beet roots	0.2%	
	8%	UK vegetarian	12.50	4%	Wheat	0.5%	Rice	0.5%	Potatoes	0.1%	
	8%	FI adult	11.39	2%	Rye	2%	Coffee beans	0.6%	Wheat		
	7%	FR infant	10.44	2%	Wheat	0.9%	Sugar beet roots	0.6%	Potatoes	0.6%	
	7%	DK adult	10.43	2%	Wheat	2%	Rye	0.4%	Potatoes	0.2%	
	7%	UK adult	10.37	3%	Wheat	0.5%	Rice	0.5%	Potatoes	0.1%	
	4%	PL general	6.17	1%	Potatoes	0.7%	Head cabbages	0.7%	Apples		
	4%	IE child	5.64	2%	Wheat	0.4%	Rice	0.2%	Potatoes	0.1%	

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Clopyralid
Reg. (EU) 2021/1807
Annex IIIA is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

Clopyralid: Refined mode

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Clopyralid
Reg. (EU) 2021/1807

LOQs (mg/kg) range from:	0.05	to:	0.05
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:	2005	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:

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
6%	NL child	8.44	6%	Sugar beet roots						6%
3%	NL toddler	5.25	3%	Sugar beet roots		FRUIT AND TREE NUTS				3%
3%	DE women 14-50 yr	4.59	3%	Sugar beet roots	0.0%	Sugar canes			0.0%	3%
3%	DE general	4.22	3%	Sugar beet roots	0.0%	Sugar canes			0.0%	3%
2%	FR child 3 15 yr	3.67	2%	Sugar beet roots	0.0%	Sugar canes			0.0%	2%
2%	UK toddler	3.20	2%	Sugar beet roots		FRUIT AND TREE NUTS				2%
2%	NL general	2.87	2%	Sugar beet roots		FRUIT AND TREE NUTS				2%
2%	FR toddler 2 3 yr	2.84	2%	Sugar beet roots	0.0%	Sugar canes			0.0%	2%
1%	GEMS/Food G06	1.56	1.0%	Sugar beet roots	0.1%	Sugar canes			0.1%	1%
0.9%	UK infant	1.41	0.9%	Sugar beet roots		FRUIT AND TREE NUTS				0.9%
0.9%	FR infant	1.35	0.9%	Sugar beet roots	0.0%	Sugar canes			0.0%	0.9%
0.9%	RO general	1.32	0.9%	Sugar beet roots		FRUIT AND TREE NUTS				0.9%
0.5%	FR adult	0.80	0.5%	Sugar beet roots	0.0%	Sugar canes			0.0%	0.5%
0.4%	UK adult	0.56	0.4%	Sugar beet roots		FRUIT AND TREE NUTS				0.4%
0.4%	UK vegetarian	0.53	0.4%	Sugar beet roots		FRUIT AND TREE NUTS				0.4%
0.1%	ES child	0.18	0.1%	Sugar beet roots		FRUIT AND TREE NUTS				0.1%
0.1%	ES adult	0.13	0.1%	Sugar beet roots		FRUIT AND TREE NUTS				0.1%
0.1%	GEMS/Food G11	0.10	0.1%	Sugar canes		FRUIT AND TREE NUTS			0.1%	0.1%
0.1%	GEMS/Food G08	0.08	0.1%	Sugar canes		FRUIT AND TREE NUTS			0.1%	0.1%
0.1%	GEMS/Food G07	0.08	0.1%	Sugar canes	0.0%	Sugar beet roots			0.1%	0.1%
0.0%	GEMS/Food G10	0.07	0.0%	Sugar canes	0.0%	Sugar beet roots			0.0%	0.0%
0.0%	GEMS/Food G15	0.07	0.0%	Sugar canes		FRUIT AND TREE NUTS			0.0%	0.0%
	DE child			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	DE child			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	DE child			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	DE child			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	DE child			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	DE child			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
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	DE child			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	DE child			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	DE child			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Clopyralid
Reg. (EU) 2021/1807
Annex IIIA is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

A 3.2 IEDI calculations

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

A 3.3 IESTI calculations - Processed commodities

Clopyralid: Normal mode

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. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union

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	Results for adults	IESTI new Results for children	IESTI new Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): 1	No. of commodities for which ARfD/ADI is exceeded (IESTI): ---	No. of commodities for which ARfD/ADI is exceeded (IESTI new): ---	No. of commodities for which ARfD/ADI is exceeded (IESTI new): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
102%	Cauliflowers	3 / 3	174
78%	Head cabbages	3 / 3	133
46%	Swedes/rutabagas	1.5 / 1.5	78
45%	Potatoes	0.5 / 0.5	77
45%	Melons	0.5 / 0.5	76
41%	Pears	0.5 / 0.5	69
39%	Oranges	0.5 / 0.5	66
37%	Broccoli	1.5 / 1.5	62
36%	Watermelons	0.5 / 0.5	61
34%	Beetroots	1 / 1	57
32%	Apples	0.5 / 0.5	54
32%	Turnips	1.5 / 1.5	54
30%	Pineapples	0.5 / 0.5	51
29%	Bananas	0.5 / 0.5	49
28%	Peaches	0.5 / 0.5	48

Expand/collapse list

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
74%	Head cabbages	3 / 3	126
41%	Cauliflowers	3 / 3	70
30%	Swedes/rutabagas	1.5 / 1.5	51
21%	Broccoli	1.5 / 1.5	36
17%	Yams	1 / 1	28
15%	Chinese cabbages/pe-tsai	1 / 1	25
15%	Wheat	3 / 3	25
14%	Rye	5 / 5	24
14%	Beetroots	1 / 1	23
12%	Sweet potatoes	1 / 1	21
12%	Watermelons	0.5 / 0.5	20
12%	Melons	0.5 / 0.5	20
11%	Kales	1 / 1	19
11%	Chards/beet leaves	1 / 1	19
10%	Rice	2 / 2	17

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
61%	Cauliflowers	3 / 3	104
47%	Head cabbages	3 / 3	80
27%	Swedes/rutabagas	1.5 / 1.5	47
27%	Melons	0.5 / 0.5	46
25%	Wheat	3 / 3	43
22%	Broccoli	1.5 / 1.5	37
22%	Watermelons	0.5 / 0.5	37
20%	Oranges	0.5 / 0.5	33
19%	Potatoes	0.5 / 0.5	33
19%	Rye	5 / 5	32
18%	Apples	0.5 / 0.5	31
18%	Bananas	0.5 / 0.5	31
18%	Pineapples	0.5 / 0.5	30
17%	Pears	0.5 / 0.5	30
16%	Peaches	0.5 / 0.5	27

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
45%	Head cabbages	3 / 3	76
25%	Cauliflowers	3 / 3	42
18%	Swedes/rutabagas	1.5 / 1.5	31
17%	Broccoli	1.5 / 1.5	29
16%	Yams	1 / 1	27
15%	Wheat	3 / 3	25
14%	Rye	5 / 5	24
14%	Oranges	0.5 / 0.5	23
11%	Plums	0.5 / 0.5	20
10%	Pears	0.5 / 0.5	18
10%	Rice	2 / 2	17
10%	Mandarins	0.5 / 0.5	16
9%	Potatoes	0.5 / 0.5	16
9%	Chinese cabbages/pe-tsai	1 / 1	15
9%	Apples	0.5 / 0.5	15

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)	Total number of commodities found exceeding the ARfD/ADI in children and adult diets (IESTI new calculation)
1	

Processed commodities

Results for children	Results for adults	IESTI new Results for children	IESTI new Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): 1	No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---	No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---	No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
123%	Cauliflowers / boiled	3 / 3	209
70%	Broccoli / boiled	1.5 / 1.5	118
65%	Sugar beets (root) / sugar	1 / 12	110
45%	Turnips / boiled	1.5 / 1.5	76
30%	Sweet potatoes / boiled	1 / 1	50
27%	Potatoes / fried	0.5 / 0.5	47
27%	Maize / oil	2 / 50	47
26%	Pumpkins / boiled	0.5 / 0.5	44
26%	Witloofs / boiled	0.5 / 0.5	44
26%	Beetroots / boiled	1 / 1	44
24%	Leeks / boiled	0.7 / 0.7	40
21%	Wheat / milling (flour)	3 / 3	36
19%	Escaroles/broad-leaved endi	0.5 / 0.5	33
18%	Chards/beet leaves / boiled	1 / 1	31
17%	Potatoes / dried (flakes)	0.5 / 2.3	30

Expand/collapse list

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
74%	Cauliflowers / boiled	3 / 3	125
26%	Sugar beets (root) / sugar	1 / 12	44
23%	Beetroots / boiled	1 / 1	39
21%	Broccoli / boiled	1.5 / 1.5	36
17%	Turnips / boiled	1.5 / 1.5	29
17%	Head cabbages / canned	3 / 3	28
16%	Pumpkins / boiled	0.5 / 0.5	28
15%	Maize / oil	2 / 50	25
11%	Cassava roots / boiled	1 / 1	19
10%	Celeries / boiled	0.5 / 0.5	17
10%	Apples / juice	0.5 / 0.5	17
9%	Sweet potatoes / boiled	1 / 1	15
8%	Barley / beer	2 / 0.4	14
8%	Wheat / bread/pizza	3 / 3	13
7%	Chards/beet leaves / boiled	1 / 1	13

IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
74%	Cauliflowers / boiled	3 / 3	125
65%	Sugar beets (root) / sugar	1 / 12	110
42%	Broccoli / boiled	1.5 / 1.5	71
27%	Maize / oil	2 / 50	47
21%	Wheat / milling (flour)	3 / 3	36
19%	Turnips / boiled	1.5 / 1.5	33
17%	Potatoes / dried (flakes)	0.5 / 2.3	30
16%	Sweet potatoes / boiled	1 / 1	28
16%	Apples / juice	0.5 / 0.5	27
16%	Pumpkins / boiled	0.5 / 0.5	27
16%	Oranges / juice	0.5 / 0.5	26
14%	Witloofs / boiled	0.5 / 0.5	24
14%	Cranberries / juice	4 / 4	23
14%	Leeks / boiled	0.7 / 0.7	23
13%	Potatoes / fried	0.5 / 0.5	22

IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
44%	Cauliflowers / boiled	3 / 3	75
26%	Sugar beets (root) / sugar	1 / 12	44
18%	Broccoli / boiled	1.5 / 1.5	30
17%	Head cabbages / canned	3 / 3	28
15%	Maize / oil	2 / 50	25
12%	Pumpkins / boiled	0.5 / 0.5	20
10%	Beetroots / boiled	1 / 1	17
10%	Apples / juice	0.5 / 0.5	17
8%	Barley / beer	2 / 0.4	14
8%	Turnips / boiled	1.5 / 1.5	14
8%	Wheat / bread/pizza	3 / 3	13
7%	Sweet potatoes / boiled	1 / 1	12
7%	Wheat / pasta	3 / 3	11
7%	Cassava roots / boiled	1 / 1	11
6%	Witloofs / boiled	0.5 / 0.5	11

Conclusion:
The estimated short term intake (IESTI) exceeded the toxicological reference value for 1 commodities.

For processed commodities, the toxicological reference value was exceeded in one or several cases.

Clopyralid: Refined mode

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. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union

The calculation is based on the large portion of the most critical consumer group.

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

Show results for all crops

Unprocessed commodities

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

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

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

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

IESTI (children)

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.01%	Sugar canes	0.05 / 0.05	0.01

IESTI (adults)

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)

IESTI new (children)

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.01%	Sugar canes	0.05 / 0.05	0.01

IESTI new (adults)

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)

Expand/collapse list

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

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

Processed commodities

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

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

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

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

IESTI (children)

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
65%	Sugar beets (root) / sugar	1 / 12	110
0.3%	Sugar canes / sugar	0.05 / 0.05	0.46
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!

IESTI (adults)

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
26%	Sugar beets (root) / sugar	1 / 12	44
0.2%	Sugar canes / sugar	0.05 / 0.05	0.28
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!

IESTI new (children)

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
65%	Sugar beets (root) / sugar	1 / 12	110
0.3%	Sugar canes / sugar	0.05 / 0.05	0.46
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!

IESTI new (adults)

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
26%	Sugar beets (root) / sugar	1 / 12	44
0.2%	Sugar canes / sugar	0.05 / 0.05	0.28
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!

Expand/collapse list

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short term intake of residues of Clopyralid
For processed commodities, no exceedance of the ARfD/ADI was identified.

A 3.4 IESTI calculations - Raw commodities

No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short-term intake of residues of Clopyralid 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

MRL Clopyralid Reg. (EU) No 2021/1807

		Clopyralid Reg. (EU) 2021/1807 Annex IIIA
Code number	**Groups and examples of individual products to which the MRLs apply (a)**	**Current**
0100000	FRUITS, FRESH or FROZEN; TREE NUTS	
0110000	Citrus fruits	0.5
0110010	Grapefruits	0.5
0110020	Oranges	0.5
0110030	Lemons	0.5
0110040	Limes	0.5
0110050	Mandarins	0.5
0110990	Others (2)	0.5
0120000	Tree nuts	0.5
0120010	Almonds	0.5
0120020	Brazil nuts	0.5
0120030	Cashew nuts	0.5
0120040	Chestnuts	0.5
0120050	Coconuts	0.5
0120060	Hazelnuts/cobnuts	0.5
0120070	Macadamias	0.5
0120080	Pecans	0.5
0120090	Pine nut kernels	0.5
0120100	Pistachios	0.5
0120110	Walnuts	0.5
0120990	Others (2)	0.5
0130000	Pome fruits	0.5
0130010	Apples	0.5
0130020	Pears	0.5
0130030	Quinces	0.5
0130040	Medlars	0.5
0130050	Loquats/Japanese medlars	0.5
0130990	Others (2)	0.5
0140000	Stone fruits	0.5
0140010	Apricots	0.5
0140020	Cherries (sweet)	0.5
0140030	Peaches	0.5
0140040	Plums	0.5
0140990	Others (2)	0.5
0150000	Berries and small fruits	
0151000	(a) grapes	0.5

0151010	Table grapes	0.5
0151020	Wine grapes	0.5
0152000	(b) strawberries	0.5
0153000	(c) cane fruits	0.5
0153010	Blackberries	0.5
0153020	Dewberries	0.5
0153030	Raspberries (red and yellow)	0.5
0153990	Others (2)	0.5
0154000	(d) other small fruits and berries	
0154010	Blueberries	0.5
0154020	Cranberries	4
0154030	Currants (black, red and white)	0.5
0154040	Gooseberries (green, red and yellow)	0.5
0154050	Rose hips	0.5
0154060	Mulberries (black and white)	0.5
0154070	Azaroles/Mediterranean medlars	0.5
0154080	Elderberries	0.5
0154990	Others (2)	0.5
0160000	Miscellaneous fruitswith	0.5
0161000	(a) edible peel	0.5
0161010	Dates	0.5
0161020	Figs	0.5
0161030	Table olives	0.5
0161040	Kumquats	0.5
0161050	Carambolas	0.5
0161060	Kaki/Japanese persimmons	0.5
0161070	Jambuls/jambolans	0.5
0161990	Others (2)	0.5
0162000	(b) inedible peel, small	0.5
0162010	Kiwi fruits (green, red, yellow)	0.5
0162020	Litchis/lychees	0.5
0162030	Passionfruits/maracujas	0.5
0162040	Prickly pears/cactus fruits	0.5
0162050	Star apples/cainitos	0.5
0162060	American persimmons/Virginia kaki	0.5
0162990	Others (2)	0.5
0163000	(c) inedible peel, large	0.5
0163010	Avocados	0.5
0163020	Bananas	0.5
0163030	Mangoes	0.5
0163040	Papayas	0.5
0163050	Granate apples/pomegranates	0.5
0163060	Cherimoyas	0.5
0163070	Guavas	0.5
0163080	Pineapples	0.5
0163090	Breadfruits	0.5
0163100	Durians	0.5

0163110	Soursops/guanabanas	0.5
0163990	Others (2)	0.5
0200000	VEGETABLES, FRESH or FROZEN	
0210000	Root and tuber vegetables	
0211000	(a) potatoes	0.5
0212000	(b) tropical root and tuber vegetables	1
0212010	Cassava roots/manioc	1
0212020	Sweet potatoes	1
0212030	Yams	1
0212040	Arrowroots	1
0212990	Others (2)	1
0213000	(c) other root and tuber vegetables except sugar beets	
0213010	Beetroots	1
0213020	Carrots	0.5
0213030	Celeriacs/turnip rooted celeries	0.5
0213040	Horseradishes	0.5
0213050	Jerusalem artichokes	0.5
0213060	Parsnips	0.5
0213070	Parsley roots/Hamburg roots parsley	0.5
0213080	Radishes	0.5
0213090	Salsifies	0.5
0213100	Swedes/rutabagas	1.5
0213110	Turnips	1.5
0213990	Others (2)	0.5
0220000	Bulb vegetables	
0220010	Garlic	0.5
0220020	Onions	0.5
0220030	Shallots	0.5
0220040	Spring onions/green onions and Welsh onions	0.7
0220990	Others (2)	0.5
0230000	Fruiting vegetables	0.5
0231000	(a) Solanaceae and Malvaceae	0.5
0231010	Tomatoes	0.5
0231020	Sweet peppers/bell peppers	0.5
0231030	Aubergines/eggplants	0.5
0231040	Okra/lady's fingers	0.5
0231990	Others (2)	0.5
0232000	(b) cucurbits with edible peel	0.5
0232010	Cucumbers	0.5
0232020	Gherkins	0.5
0232030	Courgettes	0.5
0232990	Others (2)	0.5
0233000	(c) cucurbits with inedible peel	0.5
0233010	Melons	0.5
0233020	Pumpkins	0.5
0233030	Watermelons	0.5
0233990	Others (2)	0.5

0234000	(d) sweet corn	0.5
0239000	(e) other fruiting vegetables	0.5
0240000	Brassica vegetables(excluding brassica roots and brassica baby leaf crops)	
0241000	(a) flowering brassica	
0241010	Broccoli	1.5
0241020	Cauliflowers	3
0241990	Others (2)	0.5
0242000	(b) head brassica	
0242010	Brussels sprouts	0.5
0242020	Head cabbages	3
0242990	Others (2)	0.5
0243000	(c) leafy brassica	
0243010	Chinese cabbages/pe-tsai	1
0243020	Kales	1
0243990	Others (2)	0.5
0244000	(d) kohlrabies	0.5
0250000	Leaf vegetables, herbs and edible flowers	
0251000	(a) lettuces and salad plants	0.5
0251010	Lamb's lettuces/corn salads	0.5
0251020	Lettuces	0.5
0251030	Escaroles/broad-leaved endives	0.5
0251040	Cresses and other sprouts and shoots	0.5
0251050	Land cresses	0.5
0251060	Roman rocket/rucola	0.5
0251070	Red mustards	0.5
0251080	Baby leaf crops (including brassica species)	0.5
0251990	Others (2)	0.5
0252000	(b) spinaches and similar leaves	
0252010	Spinaches	1
0252020	Purslanes	0.5
0252030	Chards/beet leaves	1
0252990	Others (2)	0.5
0253000	(c) grape leaves and similar species	0.5
0254000	(d) watercresses	0.5
0255000	(e) witloofs/Belgian endives	0.5
0256000	(f) herbs and edible flowers	3
0256010	Chervil	3
0256020	Chives	3
0256030	Celery leaves	3
0256040	Parsley	3
0256050	Sage	3
0256060	Rosemary	3
0256070	Thyme	3
0256080	Basil and edible flowers	3
0256090	Laurel/bay leaves	3
0256100	Tarragon	3
0256990	Others (2)	3

0260000	Legume vegetables	0.5
0260010	Beans (with pods)	0.5
0260020	Beans (without pods)	0.5
0260030	Peas (with pods)	0.5
0260040	Peas (without pods)	0.5
0260050	Lentils	0.5
0260990	Others (2)	0.5
0270000	Stem vegetables	
0270010	Asparagus	0.5
0270020	Cardoons	0.5
0270030	Celeries	0.5
0270040	Florence fennels	0.5
0270050	Globe artichokes	0.5
0270060	Leeks	0.7
0270070	Rhubarbs	0.5
0270080	Bamboo shoots	0.5
0270090	Palm hearts	0.5
0270990	Others (2)	0.5
0280000	Fungi, mosses and lichens	0.5
0280010	Cultivated fungi	0.5
0280020	Wild fungi	0.5
0280990	Mosses and lichens	0.5
0290000	Algae and prokaryotes organisms	0.5
0300000	PULSES	0.5
0300010	Beans	0.5
0300020	Lentils	0.5
0300030	Peas	0.5
0300040	Lupins/lupini beans	0.5
0300990	Others (2)	0.5
0400000	OILSEEDS AND OIL FRUITS	
0401000	Oilseeds	
0401010	Linseeds	20
0401020	Peanuts/groundnuts	0.5
0401030	Poppy seeds	0.5
0401040	Sesame seeds	0.5
0401050	Sunflower seeds	0.5
0401060	Rapeseeds/canola seeds	0.5
0401070	Soyabeans	0.5
0401080	Mustard seeds	0.5
0401090	Cotton seeds	0.5
0401100	Pumpkin seeds	0.5
0401110	Safflower seeds	0.5
0401120	Borage seeds	0.5
0401130	Gold of pleasure seeds	0.5
0401140	Hemp seeds	0.5
0401150	Castor beans	0.5
0401990	Others (2)	0.5

0402000	Oil fruits	0.5
0402010	Olives for oil production	0.5
0402020	Oil palms kernels	0.5
0402030	Oil palms fruits	0.5
0402040	Kapok	0.5
0402990	Others (2)	0.5
0500000	CEREALS	
0500010	Barley	2
0500020	Buckwheat and other pseudocereals	2
0500030	Maize/corn	2
0500040	Common millet/proso millet	2
0500050	Oat	3
0500060	Rice	2
0500070	Rye	5
0500080	Sorghum	2
0500090	Wheat	3
0500990	Others (2)	2
0600000	TEAS, COFFEE, HERBAL INFUSIONS, COCOA AND CAROBS	
0610000	Teas	0.5
0620000	Coffee beans	0.5
0630000	Herbal infusions from	5
0631000	(a) flowers	5
0631010	Chamomile	5
0631020	Hibiscus/roselle	5
0631030	Rose	5
0631040	Jasmine	5
0631050	Lime/linden	5
0631990	Others (2)	5
0632000	(b) leaves and herbs	5
0632010	Strawberry	5
0632020	Rooibos	5
0632030	Mate/maté	5
0632990	Others (2)	5
0633000	(c) roots	5
0633010	Valerian	5
0633020	Ginseng	5
0633990	Others (2)	5
0639000	(d) any other parts of the plant	5
0640000	Cocoa beans	0.5
0650000	Carobs/Saint John's breads	0.5
0700000	HOPS	5
0800000	SPICES	
0810000	Seed spices	0.5
0810010	Anise/aniseed	0.5
0810020	Black caraway/black cumin	0.5
0810030	Celery	0.5
0810040	Coriander	0.5

0810050	Cumin	0.5
0810060	Dill	0.5
0810070	Fennel	0.5
0810080	Fenugreek	0.5
0810090	Nutmeg	0.5
0810990	Others (2)	0.5
0820000	Fruit spices	0.5
0820010	Allspice/pimento	0.5
0820020	Sichuan pepper	0.5
0820030	Caraway	0.5
0820040	Cardamom	0.5
0820050	Juniper berry	0.5
0820060	Peppercorn (black, green and white)	0.5
0820070	Vanilla	0.5
0820080	Tamarind	0.5
0820990	Others (2)	0.5
0830000	Bark spices	0.5
0830010	Cinnamon	0.5
0830990	Others (2)	0.5
0840000	Root and rhizome spices	
0840010	Liquorice	0.5
0840020	Ginger (10)	
0840030	Turmeric/curcuma	0.5
0840040	Horseradish (11)	
0840990	Others (2)	0.5
0850000	Bud spices	0.5
0850010	Cloves	0.5
0850020	Capers	0.5
0850990	Others (2)	0.5
0860000	Flower pistil spices	0.5
0860010	Saffron	0.5
0860990	Others (2)	0.5
0870000	Aril spices	0.5
0870010	Mace	0.5
0870990	Others (2)	0.5
0900000	SUGAR PLANTS	
0900010	Sugar beet roots	1
0900020	Sugar canes	0.05*
0900030	Chicory roots	0.05*
0900990	Others (2)	0.05*
1000000	PRODUCTS OF ANIMAL ORIGIN -TERRESTRIAL ANIMALS	
1010000	Commodities from	
1011000	(a) swine	
1011010	Muscle	0.05*
1011020	Fat	0.05*
1011030	Liver	0.05*
1011040	Kidney	0.6

1011050	Edible offals (other than liver and kidney)	0.05*
1011990	Others (2)	0.05*
1012000	(b) bovine	
1012010	Muscle	0.08
1012020	Fat	0.15
1012030	Liver	0.15
1012040	Kidney	1.5
1012050	Edible offals (other than liver and kidney)	0.05*
1012990	Others (2)	0.05*
1013000	(c) sheep	
1013010	Muscle	0.08
1013020	Fat	0.2
1013030	Liver	0.2
1013040	Kidney	2
1013050	Edible offals (other than liver and kidney)	0.05*
1013990	Others (2)	0.05*
1014000	d) goat	
1014010	Muscle	0.08
1014020	Fat	0.2
1014030	Liver	0.2
1014040	Kidney	2
1014050	Edible offals (other than liver and kidney)	0.05*
1014990	Others (2)	0.05*
1015000	(e) equine	0.05*
1015010	Muscle	0.05*
1015020	Fat	0.05*
1015030	Liver	0.05*
1015040	Kidney	0.05*
1015050	Edible offals (other than liver and kidney)	0.05*
1015990	Others (2)	0.05*
1016000	(f) poultry	0.05*
1016010	Muscle	0.05*
1016020	Fat	0.05*
1016030	Liver	0.05*
1016040	Kidney	0.05*
1016050	Edible offals (other than liver and kidney)	0.05*
1016990	Others (2)	0.05*
1017000	(g) other farmed terrestrial animals	0.05*
1017010	Muscle	0.05*
1017020	Fat	0.05*
1017030	Liver	0.05*
1017040	Kidney	0.05*
1017050	Edible offals (other than liver and kidney)	0.05*
1017990	Others (2)	0.05*
1020000	Milk	0.05*
1020010	Cattle	0.05*
1020020	Sheep	0.05*

1020030	Goat	0.05*
1020040	Horse	0.05*
1020990	Others (2)	0.05*
1030000	Birds eggs	0.05*
1030010	Chicken	0.05*
1030020	Duck	0.05*
1030030	Geese	0.05*
1030040	Quail	0.05*
1030990	Others (2)	0.05*
1040000	Honey and other apiculture products (7)	0.05*
1050000	Amphibians and Reptiles	0.05*
1060000	Terrestrial invertebrate animals	0.05*
1070000	Wild terrestrial vertebrate animals	0.05*
1100000	PRODUCTS OF ANIMAL ORIGIN - FISH, FISHPRODUCTS AND ANY OTHER MARINE AND FRESHWATER FOOD PRODUCTS (8)	
1200000	PRODUCTS OR PART OF PRODUCTS EXCLUSIVELY USED FOR ANIMAL FEED PRODUCTION (8)	
1300000	PROCESSED FOOD PRODUCTS (9)	