

REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: ADM.01851.H.1.A

Product name(s): see Part A

Chemical active substances:

Ethofumesate, 500 g/L

Clopyralid, 75 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Country organisation / representative of ADAMA,
as given in Part A.

Submission date: July 2024

MS Finalisation date: March 2025 (initial Core Assessment)
June 2025 (final Core Assessment)

Version history

When	What
July 2024	dRR version 1 submitted by the Applicant.
March 2025	Initial zRMS assessment The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are ~~struck through~~ and shaded for transparency.
June 2025	Final report (Core Assessment updated following the commenting period) Additional information/assessments included by the zRMS in the report in response to comments received from the CMS and the Applicant are highlighted in yellow. Not agreed or not relevant information are ~~struck through~~ and shaded for transparency.

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7 Metabolism and residue data (KCA section 6)

7.1 Summary and zRMS Conclusion

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 ADM.01851.H.1.A are presented in Table 7.1-1. They have been selected from the individual GAPs in the Central zone for sugar beet and fodder beet. A list of all intended uses within the Central zone is given in Part B, Section 0.

The critical GAP corresponds to the highest application rate per application, with 3 applications of 0.66 L product/ha (corresponding to 330 g ethofumesate/ha and 49.5 g clopyralid/ha) at 5-day intervals up to BBCH 19.

Overall conclusion

The data available are considered sufficient for risk assessment. An exceedance of the current MRLs of 0.2 mg/kg for ethofumesate and 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 and chronic intakes for ethofumesate residues are unlikely to present a public health concern.

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

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

Ethofumesate:

- Do not grow root vegetables (except sugar or fodder beet) in case of crop failure;
- According to the EFSA Journal 2016;14(1):4374 for ethofumesate the maximum annual rate must not exceed 1 kg a.s./ha every 3 years.

Clopyralid:

- a 30-day PBI is supported for leafy and brassica vegetables, oilseeds and for all other food and feed commodities except sugar canes;
- sugar canes not be planted for 125 days after application of clopyralid.

Data gaps

Noticed data gaps are: none.

Remark for clopyralid:

- In accordance with national harmonization arrangements, for products containing clopyralid, after completing the procedure under Article 12 of Regulation No 396/2005, it will be necessary to verify the assessment performed in terms of the established residues definition for the accepted uses.

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

1	2	3	4	5	6	7		8				9			10	11	12
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)	Remarks	Conclusion
						Type	Conc. of as	method kind	growth stage & season	number min max	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max			
1	Sugar beet BEAVA Fodder beet BEAVC	Central Zone (Poland)	ADM.01851.H.1.A	F	Annual dicot weeds and annual grass weeds	SC	Ethofumesate: 500 g/L Clopyralid: 75 g/L	Foliar, spraying, overall	BBCH 10-19 / Mar-Jun	3	5 days	Ethofumesate: 0.0825-0.330 Clopyralid: 0.0124-0.0495	100-400	Ethofumesate: 0.330 Clopyralid: 0.0495	-	Total rate per season 2 L/ha Max rate of ethofumesate should not exceed 1.0 kg/ha every 3 years	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 ADM.01851.H.1.A is composed of ethofumesate and clopyralid.

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

Reference value	Source	Year	Value	Study relied upon	Safety factor
Ethofumesate - Parent compound					
ADI	EFSA	2016	1.0 mg/kg bw/day	Rat, 2-year	100
ARfD	EFSA	2016	-	Not necessary	
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	rabbit, developmental toxicity	300

7.1.2.1 Summary for ethofumesate

Table 7.1-3: Summary for ethofumesate

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
1, 2	Sugar beet	Yes	Yes (36 trials)	n.a.	Yes	Yes	No	Not relevant, no ARfD set
1, 2	Fodder beet	Yes	Yes (extrapolated from sugar beet)	n.a.	Yes	no MRL required		

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
n.a.: not applicable, the PHI is covered by the time remaining between application and harvest.

The effects of processing on the nature of ethofumesate residues have been investigated. Data on effects of processing on the amount of residue have been submitted.
These data were considered for dietary burden calculation, but not for consumer risk assessment.

Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. It is very unlikely that residues will be present in succeeding crops above the default LOQ EU MRLs. Any low residues that could occur, below the MRL, are taken into account for the livestock dietary burden and dietary exposure estimates.

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

7.1.2.2 Summary for clopyralid

Table 7.1-4: Summary for clopyralid

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
1, 2	Sugar beet	Yes	Yes (10 trials)	n.a.	Yes	Yes	No	No
1, 2	Fodder beet	Yes	Yes (extrapolated from sugar beet)	n.a.	Yes	no MRL required		Not relevant, only for animal feed

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

n.a.: not applicable, the PHI is covered by the time remaining between application and harvest.

The effects of processing on the nature of clopyralid residues have been investigated. Data on effects of processing on the amount of residue have been submitted.

These data were not considered for risk assessment.

Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. It is very unlikely that residues will be present in succeeding crops above the EU MRLs. Any low residues that could occur, below the MRL, are taken into account for the livestock dietary burden and dietary exposure estimates.

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

7.1.2.3 Summary for ADM.01851.H.1.A

Table 7.1-5: Information on ADM.01851.H.1.A (KCA 6.8)

Crop	PHI for ADM.01851.H.1.A proposed by applicant	PHI/ Withholding period* sufficiently supported for		PHI for ADM.01851.H.1.A proposed by zRMS	zRMS Comments (if different PHI proposed)
		Ethofumesate	Clopyralid		
Sugar beet	F**	NR	NR	F	-
Fodder beet	F**	NR	NR	F	-

NR: not relevant

* Purpose of withholding period to be specified

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

Table 7.1-6: Waiting periods before planting succeeding crops

Waiting period before planting succeeding crops			Overall waiting period proposed by zRMS for ADM.01851.H.1.A
Crop group	Led by ethofumesate	Led by clopyralid	
Leafy vegetables Oilseeds	None	None 30 days	None 30 days
Root vegetables	None PHI covered by the	None	None Do not grow root vegetables (except

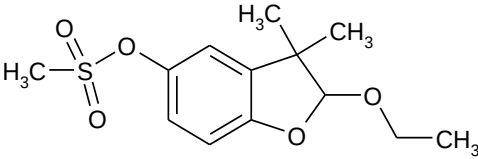
	vegetation period, max. 1 kg a.s./ha every three years		sugar beet roots, beetroots or fodder beet) in case of crop failure.
All other food and feed crops not specified	None	None ~~30 days~~	None ~~30 days~~
Cereals Sugar canes	None	None 125 days	None 125 days

Assessment

7.2 Ethofumesate

General data on ethofumesate are summarized in the table below (last updated 2020/08/31)

Table 7.2-1: General information on ethofumesate

Active substance (ISO Common Name)	Ethofumesate
IUPAC	(<i>RS</i>)-2-ethoxy-2,3-dihydro-3,3-dimethylbenzofuran-5-yl methanesulfonate
Chemical structure	
Molecular formula	C ₁₃ H ₁₈ O ₅ S
Molar mass	286.3 u
Chemical group	Benzofurane
Mode of action (if available)	Inhibitor of lipid synthesis and cell division in susceptible weeds by a reduction of photosynthesis and respiration
Systemic	Yes
Company (ies)*	Task Force Ethofumesate (representing Bayer CropScience and Adama Deutschland GmbH (former Feinchemie Schwebda GmbH)) and United Phosphorus Limited
Rapporteur Member State (RMS)	Austria DAR: Sweden RAR-RMS: Austria Co-RMS: Denmark
Approval status	Approved Commission Implementing Regulation (EU) 2016/1426 of 25 August 2016
Restriction (e.g. is restricted to use as "...")	Only uses as herbicide may be authorised
Review Report	SANTE/10119/2016 Rev. 3 12 July 2016
Current MRL regulation	Commission Regulation (EU) 2017/1016 of 14 June 2017
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes
EFSA Journal : Conclusion on the peer review	Yes. EFSA, 2016
EFSA Journal: conclusion on article 12	Yes. EFSA, 2012
Current MRL applications on intended uses	No

* Notifier in the EU process to whom the a.s. belong(s)

7.2.1 Stability of Residues (KCA 6.1)

7.2.1.1 Stability of residues during storage of samples

Available data

Reference: Austria, 2015a, b; EFSA, 2016

The potential for degradation of residues during storage has been previously assessed in the framework of the peer review for ethofumesate. Storage stability of ethofumesate, NC 9607, NC 20645 and NC 8493 when frozen (approximately <-18°C) was demonstrated for the following periods in the commodities listed in the table below.

One new stability study has been submitted by the applicant in the framework of this application. Results are summarized in the table below. The detailed assessment of this study is presented in Appendix 2.

Table 7.2-2: Summary of stability data achieved at $\leq -18^{\circ}\text{C}$ for ethofumesate and metabolites

Table A2.1: Summary of toxicity data derived from 10 000 Ethofumesate and Metolachlor						
Matrix		Characteristics of the matrix	Acceptable Maximum Storage duration [months]			Reference
Data relied on in EU						
Plant products						
		Ethofumesate	NC 20645, as NC 9607		NC 8493 ^(b)	
Sugar beet (roots)	High starch content	12	6 ^(a)		-	Austria, 2015a,b EFSA, 2016
Sugar beet (leaves)	High water content	12	6 ^(a)		-	Austria, 2015a,b EFSA, 2016
Rape seed	High oil content	-	6 ^(a)		-	Austria, 2015a,b EFSA, 2016
Dry bean	High protein content	-	6 ^(a)		-	Austria, 2015a,b EFSA, 2016
Orange fruits	High acid content	-	6 ^(a)		-	Austria, 2015a,b EFSA, 2016
Animal Products						
		Ethofumesate	NC 9607	NC 20645	NC8493 ^(b)	
not specified in the study	Muscle	6	6	1	6	Austria, 2015a,b EFSA, 2016
not specified in the study	Liver	6	6	6	6	Austria, 2015a,b EFSA, 2016
not specified in the study	Kidney	6	6	6	3	Austria, 2015a,b EFSA, 2016
not specified in the study	Fat	6	6	<1	6	Austria, 2015a,b EFSA, 2016
Bovine	Milk	6	6	6	6	Austria, 2015a,b EFSA, 2016
New data						
Plant products						
		Ethofumesate	NC 20645, as NC 9607		NC 8493 ^(b)	
Sugar beet (roots)	High starch content	-	24		-	Schulte, 2015, Report no. MR-12/058 (KCA 6.1/01)
Sugar beet (leaves)	High water content	-	24		-	
Rape seed	High oil content	-	24		-	
Dry bean	High protein content	-	24		-	
Orange fruits	High acid content	-	24		-	
Lettuce	High water content	24	24		-	Watson, 2022 Report no. RES-00278 (KCA 6.1/02)
Cereal grain	High starch content	24	24		-	

- (a) According to RAR, study was still ongoing (Austria, 2015 a,b). In the final report (NEW data; Schulte, 2015) 24 month storage stability has been confirmed.
- (b) Not required because NC 8493 is not part of the residue definition.

Summary on stability of residues during storage reported in the EU

“In the DAR, the storage stability of ethofumesate and its metabolite ethofumesate-lactone (NC 9607) was assessed for sugar beets. The results of the respective studies indicated that ethofumesate and its metabolite are stable in deep-frozen samples ($\leq -18^{\circ}\text{C}$) of the tested plant commodities (roots and leaves) for at least 1 or 2 years, respectively.[...] The storage stability study addressed the compounds included in the residue definition; the longest storage period in the feeding study was 153 days for kidney; the study is suitable to cover the storage periods in the animal feeding study, as the metabolite NC 8493 is not included in the residue definition.” (Austria, 2015a, b).

Conclusion on stability of residues during storage

Conclusion for plant products

Freezer storage stability data indicated that ethofumesate was stable for at least 12 months, and NC 20645 and conjugated NC 20645, analysed as NC 9607 were stable for at least 24 months in sugar beet roots and leaves. The maximal storage period in the residue trials for sugar beet and fodder beet used for risk assessment is covered.

Storage stability studies for the metabolite NC 8493 are not required based on the intended uses because NC 8493 is not part of the residue definition. Since major amounts of metabolite NC 8493 were only detected in intermediate growth stages it was not necessary to include this metabolite in the residue definition for mature crops, as well as its conjugate which was always a minor metabolite. Furthermore, the metabolite NC 8493 was not determined in the sugar beet residue trials relevant for the intended uses and in the rotation crop field trials. Thus, storage stability data is not needed for NC 8493 for the product ADM.01851.H.1.A.

During a storage period of 24 months under deep-freezer conditions, metabolite NC 20645 was stable in sugar beet leaf, sugar beet root, rape seed, dry bean and orange fruit, representing all major plant matrices. Together with the results from the storage stability studies conducted for parent compound and metabolite NC 9607 (see studies submitted for the first Annex I inclusion), these results validate the residue values reported in all supervised field trials and processing studies with respect to storage stability of samples frozen prior to analysis.

Storage stability data are also available in additional crops that are not relevant to the crop categories to be addressed, while the number of commodities per group studied is not in line with current requirements according to OECD Guidance (data gap). Therefore, with regard to the rotational lettuce and cereals crop, storage stability is not appropriately addressed. Therefore, the applicant conducted a new storage stability study of residues of ethofumesate and its metabolite ethofumesate-lactone (NC 9607 or ethofumesate-2-keto) in lettuce and cereal grain stored frozen for up to two years. The results of this study show stability of both compounds in lettuce and grain after 24 months of freezer storage (details see Appendix 2)

Conclusion for animal products

Sufficient data are available to demonstrate the storage stability of ethofumesate and all compounds included in the residue definition in deep frozen animal matrix samples (EFSA, 2016). The longest storage period in the feeding study evaluated in the RAR was 153 days for kidney.

Thus, further data is not needed for the product ADM.01851.H.1.A.

zRMS comments:

zRMS agrees with information provided by the Applicant above.

Sugar and fodder beet roots belong to high starch content matrices, sugar and fodder beet leaves belong to high water content matrices.

The potential degradation of residues during storage of the residue trials samples was assessed in the framework of the peer review. Applicant submitted additional storage stability studies.

Storage stability of ethofumesate was demonstrated for a period of 12 months at below -18°C in sugar beet roots and

leaves. Freezer storage stability data indicated that NC 20645 and conjugated NC 20645, analysed as NC 9607 were stable for at least 24 months in sugar beet roots and leaves.

In addition, submitted data showed the stability of the metabolite NC 20645 for 24 months in sugar beet roots and leaves, in rape seed, dry bean seed and orange fruit (i.e. high starch, high water, high oil, high protein, high acid containing commodities).

The residue data are valid with regard to storage stability.

Applicant submitted additional storage stability study of residues of ethofumesate and its metabolite ethofumesate-2-keto in lettuce and cereal grain stored frozen for up to two years (Watson, 2021).

The analytes ethofumesate and ethofumesate-2-keto can be considered stable in the investigated matrices of lettuce and cereal grain under deep-freezer storage conditions ($\leq -18^{\circ}\text{C}$) for 24 months.

Regarding animal products, ethofumesate and its metabolites NC 9607, NC8493 and NC 20645 were found to be stable under frozen storage for up to 6 months (see Table 7.2-2) except for metabolite NC 20645 in muscle (1 month) and for metabolite NC8493 in kidney (3 months).

However, these data are not required since a comparison of expected intakes and residue levels found in the metabolism studies in livestock showed that residues $< \text{LOQ}$ are expected.

No additional data are required.

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

As residue samples from trials with ethofumesate were routinely stored frozen for long periods of time prior to their analysis, the stability of residues during storage of samples and effects of frozen storage on the residue levels were investigated.

The storage stability of ethofumesate residues in sample extracts is routinely tested during method development. Since the validity of the methods is based on and confirmed by factors such as reproducibility for interruption during the work-up process, it can be concluded that the stability of residues in extracts is always guaranteed. In addition, when conducting analyses of "normal" samples, the entire analytical procedure is monitored by conducting concurrent recoveries with each sample set.

zRMS comments:

Information given by the Applicant is sufficient.

No further data are required.

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

Reference: Austria, 2015a, b; EFSA, 2016

The metabolism of ethofumesate was investigated for foliar application on root and tuber vegetables (sugar beet, onion), cereals (ryegrass) and leafy vegetables (tobacco) using [^{14}C -benzene] and/or [^{14}C -mesyl]-labelled ethofumesate. These studies are summarised in the table below.

No new plant metabolism data have been submitted by the applicant in the framework of this application.

Table 7.2-3: Summary of plant metabolism studies

Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Root and tuber vegetables	Sugar beet	[¹⁴ C-benzene]	Foliar, G	1.27 or 6.37	1	0+, 10, 30 and 81 and at maturity	Chapleo, 1992 Report A82970	Austria, 2015a, b EFSA, 2012, 2016
		[¹⁴ C-benzene]	Foliar, G BBCH 14	1.50 or 7.5	1	0, 7, 28 and at maturity	Caley, C. Y.; Chapleo, S.; Haswell, A.; 1994; Report A87553	Austria, 2015a, b EFSA, 2012, 2016
		[¹⁴ C-benzene]	Foliar, F 4-6 leaf growth stage	1.5	1	1, 10, 50, 90, 137	Hennecke, D. 2003 Report GAB-002/7-08	Austria, 2015a, b EFSA, 2012, 2016
		[¹⁴ C-benzene]	Soil, G Pre-emergence	2.00	1	10, 20, 30, 40 and 50	Lines, D. S.; Adcock, J. W.; 1978; Report A82964	Austria, 2015a, b EFSA, 2012, 2016
			Foliar, G BBCH 14					
		[¹⁴ C-mesyl]	Soil, F Pre-emergence	2.00	1	50, 75, 125 and 175	Lines, D. S.; Adcock, J. W.; 1979; Report A82965	Austria, 2015a, b EFSA, 2012, 2016
	Foliar, F BBCH 12	2.00	1	50, 75 and 125				
Root and tuber vegetables	Onion	Not reported	Soil ^(b) Pre-emergence	2.00	1	22, 30, 40, 50, 60, 70, 80, 90, 100, 110, 120 and 162	Adcock, J.W. <i>et al.</i> , 1976 Report A82959	Austria, 2015a, b EFSA, 2012, 2016
Cereals	Ryegrass	[¹⁴ C-benzene]	Foliar, G BBCH 12-13	2.09 or ~10.45	1	0+, 7, 28 (silage) and 112 (maturity)	Chapleo, S., 1992 Report A82971	Austria, 2015a, b EFSA, 2012, 2016
Leavy vegetables	Tobacco	[¹⁴ C-benzene]	Soil, G Pre-emergence	2.00	1	7, 15, 30, 60, 90 and 120	Warner, P.A., Adcock, J.W., 1977 Report A82963	Austria, 2015a, b EFSA, 2012, 2016
			Foliar, G BBCH 14-16	2 mg/plant	1			

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

(b) F or G not reported

(c) DAFA = days after first application

Summary of plant metabolism studies reported in the EU

“The major metabolic pathway for ethofumesate in plants was identified as follows:

- Cleavage of the ethoxy side chain, with hydroxylation at the 2 position to give metabolite NC 8493 (ethofumesate-2-hydroxy = 2,3-dihydro-2-hydroxy-3,3-dimethylbenzofuran-5-yl methane-sulfonate).
- This metabolite can either undergo conjugation to give polar metabolites or oxidation to the lactone NC 9607 (ethofumesate-lactone = 2,3-dihydro-3,3-dimethyl-2-oxobenzofluran-5-yl methanesulfonate).
- The lactone ring opens to the carboxylic acid NC 20645 (ethofumesate-carboxylic acid = 2-(2-hydroxy- 5-methanesulfoxyphenyl)-2-methyl propionic acid) which can also undergo conjugation to give polar metabolites.

The lactone NC 9607 and the carboxy analogue NC 20645 are inter-convertible and depending on the ambient conditions, either one or the other metabolite will predominate. Under acidic conditions, metabolite NC 20645 is converted to metabolite NC 9607 by an intramolecular ring closure.

Cleavage of the molecule under release of methansulphonic acid was excluded in two sugar beet studies using two different chromatographic systems (TLC and TLE). The extraction and analysis processes were validated beforehand with a radiolabelled reference compound (¹⁴C-MSA). Recoveries of MSA were

above 97% and confirmed that the compound would be detected, if present.” (Austria, 2015a, b)

“Primary crop metabolism of ^{14}C ethofumesate was investigated following pre-emergence application and post-emergence foliar application to sugar beet, post-emergence foliar application to ryegrass and tobacco (non GLP), and pre-emergence application to onions (non GLP). In addition, rotational crop metabolism was studied in radish, carrots, cabbage, spinach, wheat, ryegrass, and French beans, investigating different plant-back intervals upon soil application of ^{14}C ethofumesate. Metabolic patterns in the different studies were similar, metabolism of ethofumesate leading to the metabolites ethofumesate-2-hydroxy (NC 8493), ethofumesate lactone (NC 9607) and ethofumesate carboxylic acid (NC 20645), recovered also in their conjugated form. NC 20645 is the open ring form of NC9607. Intra-molecular ring closure appeared to be conditioned by the pH i.e. primarily when acidic conditions are applied to release the aglycon of conjugated residues. The proportions observed of parent and metabolites and their conjugates varied depending on the time, mode and rate of application as well as on the crop studied. Commonly, until harvest of the mature primary crop, parent had been degraded to a significant extent, if not completely, into its metabolites, majorly present as conjugated compounds. The pertinent residue was identified as NC 20645, free and conjugated.[...] In view of the metabolic pathway in mammals EFSA considered that the plant metabolites NC 20645, NC 9607 and NC 8493 are covered by the toxicological endpoints of parent compound.” (EFSA, 2016)

Conclusion on metabolism in primary crops

The metabolism of ethofumesate in crops following foliar and soil application is sufficiently addressed to support the proposed uses of product ADM.01851.H.1.A.

zRMS comments:

Information given by the Applicant is sufficient.

Metabolism pattern of ethofumesate is sufficiently elucidated in the frame of this registration.

Additionally, in EFSA Journal 2016;14(1):4374 it is stated that the metabolism studies on tobacco and onion are for supporting information only. The metabolism performed for cereal crops was conducted on ryegrass and therefore no information on cereal grains is available.

Residue definition:

The residue definition for enforcement: Sum of ethofumesate, ethofumesate-lactone (NC 9607), ethofumesate-carboxylic acid (NC 20645) and its conjugate, expressed as ethofumesate.

The residue definition for risk assessment: Sum of ethofumesate, ethofumesate-lactone (NC 9607), ethofumesate-carboxylic acid (NC 20645) and its conjugate, expressed as ethofumesate.

Conversion factor (monitoring to risk assessment): 1.

The current residue definition for plants and for products of animal origin set in Regulation (EC) No 396/2005 (Reg. (EU) 2017/1016) is identical to the residue definition for enforcement derived in the peer review for Ethofumesate.

No further data are required to support the proposed uses of product ADM.01851.H.1.A.

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

Reference: Sweden, 2000; Austria, 2015a, b; EFSA, 2012, 2016

The metabolism of ethofumesate in rotational crops was investigated in leafy vegetables (cabbage, spinach), root and tuber vegetables (radish, carrot), cereals (wheat, ryegrass) and pulses and oilseeds (French beans) using [^{14}C -benzene]-labelled ethofumesate. These studies are summarised in the table below.

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 ^(a)	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks	
EU data								
Leafy vegetables	Cabbage	[¹⁴ C-benzene]	Soil ^(b)	4.6 4.5	96, 276 and 367	<u>Immature plants:</u> 145, 334 and 404 <u>Mature plants:</u> 292, 418 and 473	Carlton, R., Cordell, P., 1993 Report A83396	Sweden, 2000 EFSA, 2012 EFSA, 2016
	Spinach	[¹⁴ C-benzene]	Soil ^(b)	1	30	<u>Immature plants:</u> 77 <u>Mature plants:</u> 98	Chapleo, S., 2003 Report 22558	Austria, 2015a, b
Root and tuber vegetables	Radish	[¹⁴ C-benzene]	Soil ^(b)	4.6 4.5	96, 276 and 367	<u>Immature plants:</u> 130, 314 and 397 <u>Mature plants:</u> 139, 347 and 411	Carlton, R., Cordell, P., 1993 Report A83396	Sweden, 2000 EFSA, 2012 EFSA, 2016
	Carrot	[¹⁴ C-benzene]	Soil ^(b)	1	30	<u>Immature plants:</u> 95 <u>Mature plants:</u> 133	Chapleo, S., 2003 Report 22558	Austria, 2015a,b EFSA, 2016
Cereals	Wheat	[¹⁴ C-benzene]	Soil ^(b)	4.6 4.5	96, 276 and 367	<u>Immature plants:</u> 229, 383 and 432 <u>Mature plants:</u> 486, 535 and 508	Carlton, R., Cordell, P., 1993 Report A83396	Sweden, 2000 EFSA, 2012 EFSA, 2016
	Ryegrass	[¹⁴ C-benzene]	Soil ^(b)	1	30	<u>Immature plants:</u> 84 <u>Mature plants:</u> 132	Chapleo, S., 2003 Report 22558	Austria, 2015a,b EFSA, 2016
Pulses and oilseeds	French beans	[¹⁴ C-benzene]	Soil ^(b)	1	30	<u>Immature plants:</u> 77 <u>Mature plants:</u> 109	Chapleo, S., 2003 Report 22558	Austria, 2015a, b

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

(b) F or G not reported

Summary of metabolism studies on rotational crops reported in the EU

“The metabolic routes detected are in line with those observed in primary crops. On the basis of these results it can be concluded that the metabolism of [¹⁴C]-ethofumesate in confined rotational crops follows the same metabolic path as primary crops:

The proposed residue definition for plants for monitoring and risk assessment is therefore still: the sum of Ethofumesate, 2-keto-ethofumesate (NC 9607), open-ring-2-keto-ethofumesate (NC 20645) and its conjugate.” (Austria, 2015a, b)

“In a confined rotational crop study, parent ethofumesate was recovered in almost all commodities tested. Upon hydrolysis significant portions of conjugated residues were identified as NC9607 in most of the commodities, and in root crops also of NC 8493. The observation of residues of unchanged ethofumesate in rotational crops was presumably caused by the high persistence and low leaching potential of ethofumesate in some soils and likely increased availability in the root zone upon breaking up of the soil at planting of the following crop.” (EFSA, 2016)

Conclusion on metabolism in rotational crops

Metabolism in primary and rotational crops was found to be similar and a specific residue definition for rotational crops is not deemed necessary.

zRMS comments:

Information given by the Applicant is sufficient.

The metabolism of ethofumesate in rotational crops was sufficiently investigated during the renewal of approval of the active substance. Rotational crop metabolism was studied in radish, carrots, cabbage, spinach, wheat, ryegrass and French beans, investigating different plant-back intervals upon soil application of ¹⁴C ethofumesate. Based on these studies, it was concluded that metabolism in primary and rotational crops is similar (EFSA, 2016).

No further data are required.

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

Reference: Austria, 2015a, b; EFSA, 2016

The nature of residues under representative processing conditions (pasteurisation, baking/boiling/brewing, sterilisation) and during sugar beet purification was assessed. The results are shown in the table below.

No new data are 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 (98.6%)	Austria, 2015a,b EFSA, 2016
Baking, boiling, brewing (60 minutes, 100°C, pH 5)	Parent (99.3%)	Austria, 2015a,b EFSA, 2016
Sterilisation (20 minutes, 120°C, pH 6)	Parent (100%)	Austria, 2015a,b EFSA, 2016
Other conditions		
Purification process sugar beet (30 minutes, 90°C, pH 11)	Parent (97.6%)	Austria, 2015a,b EFSA, 2016

Conclusion on nature of residues in processed commodities

“Hydrolysis products were detected in a range between 0.7 and 2.1%. They were not further investigated, due to their low amount in the test solutions.” (Austria, 2015a, b)

“A study investigating the nature of residues under conditions simulating industrial and household common processes indicated ethofumesate was stable. No data is available that investigated the metabolites included in the residue definition NC 9607 and NC 20645, it is however known from analytical methods that acidic conditions lead to rearrangement of NC 20645 and formation of NC 9607. Whether or not NC 9607 will remain entirely stable when processing conditions are applied is currently not addressed, however residues of NC 9607 in food commodities for processing were <LOQ in the trials supporting the representative GAP.” (EFSA, 2016).

zRMS comments:

Information given by the Applicant is sufficient.

It can be concluded that ethofumesate is stable during processing.

No further data are required.

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 and tuber vegetables (Sugar beets, onion) Leafy crops (Tobacco) Cereal/grass crops (Ryegrass)
Rotational crops covered	Leafy vegetables (Cabbage, spinach) Root and tuber vegetables (Radish, carrot) Cereals (Wheat, ryegrass) Pulses and oilseeds (French beans)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Ethofumesate is stable under standard hydrolysis conditions
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes Hydrolysis products were detected in a range between 0.7 and 2.1%. They were not further investigated, due to their low amount in the test solutions.
Plant residue definition for monitoring	Ethofumesate (Sum of ethofumesate, 2-keto-ethofumesate (NC 9607), open-ring-2-keto-ethofumesate (NC 20645) and its conjugate, expressed as ethofumesate) (Regulation (EU) n°2017/1016) Sum of Ethofumesate, ethofumesate-lactone (NC 9607), ethofumesate-carboxylic acid (NC 20645), expressed as ethofumesate). (EFSA, 2016)
Plant residue definition for risk assessment	~~Ethofumesate (Sum of ethofumesate, 2-keto-ethofumesate (NC 9607), open-ring-2-keto-ethofumesate (NC 20645) and its conjugate, expressed as ethofumesate) (EFSA, 2016)~~ Sum of Ethofumesate, ethofumesate-lactone (NC 9607), ethofumesate-carboxylic acid (NC 20645), expressed as ethofumesate). (EFSA, 2016)
Conversion factor from enforcement to RA	1 (Austria, 2015a, b, EFSA, 2016)

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

Available data

Reference: Sweden, 2000; Austria, 2015a, b; EFSA, 2012, 2016

The metabolism of ethofumesate in livestock animals was investigated in lactating ruminants (cow, sheep) and laying poultry (hen) using [¹⁴C-benzene]-labelled ethofumesate.

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		Remarks	Reference
				Rate (mg/kg bw/d) ^(a)	Duration (days)	Commodity	Time of sampling		
EU reviewed data									
Lactating ruminants	Cow	[¹⁴ C-benzene]	1	0.3-0.36	7	Milk	Twice daily	██████ 1992 Report A82968	Sweden, 2000 Austria, 2015a,b EFSA, 2012, 2016
						Urine & faeces	Day -1, 1, 7		
						Tissues	After sacrifice		
	Cow	[¹⁴ C-benzene]	1	5	4	Milk	Twice daily	██████ 1999 Report C003362	Sweden, 2000 Austria, 2015a,b
Urine & faeces						Daily			

Group	Species	Label position	No of animal	Application details		Sample details		Remarks	Reference
				Rate (mg/kg bw/d) ^(a)	Duration (days)	Commodity	Time of sampling		
						Blood	0.5, 1, 2, 3, 4, 6, 8h after initial dosing, then twice daily after milking		
	Sheep	[¹⁴ C-benzene]	1	0.2	1	Tissues	After sacrifice	1976 Report A82958	EFSA, 2012 Sweden, 2000 Austria, 2015a,b EFSA, 2012
						Milk	Not analysed		
						Urine and faeces	Daily		
						Tissue	After sacrifice (4 days after dosing)		
Laying poultry	Hens	[¹⁴ C-benzene]	6	0.6	14	Eggs	Daily	1992 Report A82969	Sweden, 2000 EFSA, 2012 Austria, 2015a,b
						Excreta	Daily		
						Tissues	After sacrifice		
		[¹⁴ C-benzene]	3	0.78	10	Eggs	Twice daily	1999 Report C002998	Sweden, 2000 Austria, 2015a,b EFSA, 2012, 2016
						Excreta	Daily		
						Tissues	After sacrifice		

Summary of animal metabolism studies reported in the EU

“According to the results of the cow metabolism study (Sweden, 2000), urine was the most important pathway in the elimination of ethofumesate. The water-soluble metabolite open-ring-2-keto-ethofumesate was the single component found in urine. Residues in milk, blood/plasma and urine reached peaks at 32 hrs after the initial dose, with a peak residue in milk of 0.134 mg/kg. After sacrifice, the TRR accounted for 1.86 mg eq/kg in kidney, 0.66 mg eq/kg in liver, ca. 0.540 mg eq/kg in fat (omental, renal and subcutaneous), 0.134 mg eq/kg in milk and 0.033 mg eq/kg in muscle. According to the current guidance on metabolism studies in livestock (EC, 1997e), extraction was efficient enough, as at least 75 % of the TRR was extracted. Characterisation and identification were sufficient in milk and organs, but not in liver in which only 54.6 % of the TRR were characterised, due to loss of radioactivity during analytical. Similar losses were observed in the second study in cow (Sweden, 1998), but this has not been identified as an open point during peer-review.

Residues in fat mainly consist of parent compound (81.1 to 91.2 % of the TRR) and of small amounts of open-ring-2-keto-ethofumesate, 2-hydroxy-ethofumesate and 2-keto-ethofumesate. Similar repartitions are observed in muscle (52.2 % of the TRR as ethofumesate, 16.05 % as open-ring-2-keto-ethofumesate, free form), in milk (51.2 % of the TRR as ethofumesate, 13 % as open-ring-2-keto-ethofumesate) and in liver (33.9 % of the TRR as ethofumesate, <10 % for others compounds). Residues in kidney mainly consist of open-ring-2-keto-ethofumesate (70.5 % of the TRR) and of small amounts of 2-keto-ethofumesate (8.02 % of the TRR) and parent compound (2.05 % of the TRR).

The metabolic patterns identified for cows were consistent with the rat metabolism and ethofumesate, 2-keto-ethofumesate and open-ring-2-keto-ethofumesate are considered as the major indicator compounds in commodities of ruminant origin. Moreover, livestock is expected to be only exposed to the metabolites 2-keto-ethofumesate and open-ring-2-keto-ethofumesate rather than to the parent compound. An even higher contribution of these metabolites in livestock is therefore to be expected, clearly highlighting the need to include them not only in the residue definition for risk assessment but also for enforcement, and also highlighting the need not to include the parent compound ethofumesate. Hence the relevant residue for enforcement and risk assessment in commodities of ruminants and pigs is defined as the sum of 2-

keto-ethofumesate and open-ring-2-keto-ethofumesate (free form only), expressed as ethofumesate [...]
For poultry there is in principle no necessity to establish a residue definition because the calculated dietary burden of poultry to ethofumesate residues amounted to less than 0.1 mg/kg DM. Nevertheless, two metabolism studies in laying hens are reported (Sweden, 1998, 2002). These studies demonstrate that metabolic pathways of ethofumesate in ruminants and poultry are very similar. It is therefore concluded that the relevant residues in poultry could also be defined as the sum of 2-keto-ethofumesate and open-ring-2-keto-ethofumesate, expressed as ethofumesate, provided that the use of ethofumesate is supported on additional crops resulting in a higher exposure of poultry to ethofumesate residues. In the meantime, a residue definition for poultry products is not required.

In the framework of the peer review, ethofumesate was considered to be not fat soluble based on the fact that its log Po/w is lower than 3 (Sweden, 2002).” (EFSA, 2012)

“Significant intakes were calculated for livestock. Metabolism in poultry and lactating ruminants was sufficiently investigated with ¹⁴C ethofumesate. The relevant residue definition for both enforcement and risk assessment in livestock was derived as the sum of ethofumesate, NC 9607, NC 20645, expressed as ethofumesate. Based on the metabolism studies, it is also concluded that significant residues in animal commodities are not expected, considering livestock exposure linked to the representative uses.” (EFSA, 2016)

Conclusion on metabolism in livestock

The metabolism of ethofumesate in livestock animals is sufficiently addressed to support the proposed uses of product ADM.01851.H.1.A.

zRMS comments:

Information given by the Applicant is sufficient.

The metabolism of ethofumesate in livestock (poultry and lactating ruminants) was sufficiently investigated during the renewal of approval of the active substance.

Residue definition:

The residue definition for enforcement: the sum of ethofumesate, NC 9607, NC 20645, expressed as ethofumesate

The residue definition for risk assessment: the sum of ethofumesate, NC 9607, NC 20645, expressed as ethofumesate.

Conversion factor (monitoring to risk assessment): 1.

In EFSA Journal 2016;14(1):4374 it is stated that based on the metabolism studies, it is also concluded that significant residues in animal commodities are not expected, considering livestock exposure linked to the representative uses.

No further data are required.

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 cows/sheep
	Laying hens
Time needed to reach a plateau concentration	32 h in milk
	9 days in eggs
Animal residue definition for monitoring	Ethofumesate (Sum of ethofumesate, 2-keto-ethofumesate (NC 9607), open-ring-2-keto-ethofumesate (NC 20645) and its conjugate, expressed as ethofumesate) (Regulation (EU) n°2017/1016) Sum of Ethofumesate, ethofumesate-lactone (NC 9607), ethofumesate-carboxylic acid (NC 20645), expressed as ethofumesate). (EFSA, 2016)

Animal residue definition for risk assessment	~~Ethofumesate (Sum of ethofumesate, 2 keto-ethofumesate (NC 9607), opening 2 keto-ethofumesate (NC 20645), expressed as ethofumesate) (EFSA, 2016)~~ Sum of Ethofumesate, ethofumesate-lactone (NC 9607), ethofumesate-carboxylic acid (NC 20645), expressed as ethofumesate). (EFSA 2016)
Conversion factor	1 (Austria, 2015a, b)
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	No

7.2.3 Magnitude of residues in plants (KCA 6.3)

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

The intended cGAP for ADM.01851.H.1.A in sugar beet and fodder beet corresponds to the EU cGAP as shown in the table below.

No new studies on the magnitude of residue are submitted by the applicant in the framework of this application. All available data are summarized Table 7.2-10 below.

Table 7.2-9: Comparison of intended and critical EU GAPs

Type of GAP	Region	Crop	Number of applications	Application rate per treatment (kg a.s./ha)	Interval between applications [min. days]	Growth stage at last application	PHI (days)	Remark
cGAP EU (Austria, 2015a; EFSA, 2016)	EU	Sugar beet, fodder beet	3	0.33	5	Post-emergence up to BBCH 18	n.a.	max. 1.0 kg a.s./ha every three years
	EU	Sugar beet, fodder beet	1	1.0	-	Pre-emergence	n.a.	
cGAP EU (Art. 12, EFSA, 2012)	EU	Sugar beet	1	1.0	-	BBCH 12-14	90	-
	N-EU	Fodder beet	1	1.0	-	BBCH 10-18	n.a.	-
Intended cGAP (number 1)	N-EU	Sugar beet, fodder beet	3	0.330	5	BBCH 10-19	n.a.	Total rate per season 2 L/ha. Max rate of ethofumesate should not exceed 1.0 kg/ha every 3 years

n.a.: not applicable, the PHI is covered by the time remaining between application and harvest

Table 7.2-10: Summary of EU reported data supporting the intended uses of ADM.01851.H.1.A and conformity to existing MRL

Commodity	Source	Residue zone	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) ^(a)	MRL compliance
Residue definition for enforcement (E) and risk assessment (RA): Sum of ethofumesate, ethofumesate-lactone (NC 9607), ethofumesate carboxylic acid (NC 20645), and its conjugate expressed as ethofumesate								
Sugar beet roots	EFSA, 2016	N-EU	GAP on which MRL/EU a.s. assessment is based: 3x 0.33 kg a.s./ha (max. 1.0 kg a.s./ha every 3 years), post-emergence up to BBCH 18, outdoor E/RA ^(b) : 8x<0.02, 15x<0.06, 0.06, 0.09, 11x<0.1	<0.06	<0.1	0.18	0.2	Yes
	Overall supporting data for cGAP (3 x 0.330 kg as/ha, 5d interval, BBCH 10-19)	N-EU	E/RA ^(b) : 8x<0.02, 15x<0.06, 0.06, 0.09, 11x<0.1	<0.06	<0.1	0.18	0.2	Yes
Sugar beet tops	EFSA, 2016	N-EU	GAP on which MRL/EU a.s. assessment is based: 3x 0.33 kg a.s./ha (max. 1.0 kg a.s./ha every 3 years), post-emergence up to BBCH 18, outdoor E/RA ^(b) : 8x<0.02, 11x<0.06, 0.06, 0.07, 9x<0.1, <0.12, 0.18	<0.06	0.18	N/A	N/A	N/A
	Overall supporting data for cGAP (3 x 0.330 kg as/ha, 5d interval, BBCH 10-19)	N-EU	E/RA ^(b) : 8x<0.02, 11x<0.06, 0.06, 0.07, 9x<0.1, <0.12, 0.18	<0.06	0.18	N/A	N/A	N/A

(a) Source of EU MRL: [Commission Regulation \(EU\) 2017/1016 of 14 June 2017](#)

(b) Residue definitions for risk assessment and monitoring are the same: Sum of ethofumesate, ethofumesate-lactone (NC 9607), ethofumesate-carboxylic acid (NC 20645) and its conjugate, expressed as ethofumesate.

7.2.3.2 Conclusion on the magnitude of residues in plants

EFSA (2016) concluded that “The total number of available residue trials in the primary sugar beet crop, which were deemed appropriate to address the residue definition, was sufficient to support the cGAP.” The intended cGAP for ADM.01851.H.1.A corresponds to the EU cGAP evaluated by EFSA (2016), therefore, according to the available data, the intended uses on sugar beet are considered acceptable for outdoor uses.

Residue data for sugar beet covers also application on fodder beet and thus the residues are taken into account for the livestock dietary burden calculation.

Thus, according to the available data, the intended uses on sugar beet and fodder beet are considered acceptable. The data submitted show that no exceedance of the MRL will occur.

zRMS comments:

Information given by the Applicant is sufficient.

Sugar beet is the major crop in northern Europe (EU Technical Guidelines Document SANTE/2019/12752). A minimum of eight trials are required. Residue data on sugar beet (0900010) can be extrapolated to fodder beet. The intended GAP for ethofumesate (ADM.01851.H.1.A) for sugar and fodder beets in northern Europe is 3 x 0.33 kg a.i./ha with interval between applications of 5 days at BBCH 10-19 with PHI as not applicable, the PHI is covered by the time remaining between application and harvest with remark: max. rate of active must not exceed 1.0 kg/ha every 3 years.

No new studies on the magnitude of residue have been submitted by the Applicant in the framework of this application.

Sufficient trials are available to support the proposed use in sugar beet (EFSA, 2016).

In EFSA Journal 2016;14(1):4374 it is stated that “*In residue trials in the primary crop and in rotational crops residues of ethofumesate and by turns of free NC 9607, free and conjugated NC 20645 and NC 8493 were determined. When the occurrence of residues in the primary or rotational crop (food and feed items) at harvesting stage is considered, the residue definition for risk assessment is appropriately defined as the sum of ethofumesate, NC 9607, NC20645 and its conjugate, expressed as ethofumesate. The same residue definition was proposed for monitoring purposes and MRL setting.*”

Sufficient residue trials were conducted in NEU. According to the RMS-Austria conclusion (DRAR for Ethofumesate, 2015): “*Between 1972 and 2012, numerous residue trials were conducted to support the presented “representative use” (pre-emergence and post-emergence use) of ethofumesate in Beta vulgaris, the trials were conducted in different growing areas in the northern and southern European residue region. The vegetation period in sugar and fodder beet ranges between 5 and 9 months and the studies indicate that the variation within the vegetation period is much higher than the time period between pre- and post-emergent treatment. The final residues were at or slightly above the LOQ levels.*”

Residues of ethofumesate (Sum of ethofumesate, ethofumesate-lactone (NC 9607), ethofumesate carboxylic acid (NC 20645), and its conjugate expressed as ethofumesate) in samples of sugar beet roots (applications post-emergence up to BBCH 18) were 8x<0.02, 15x<0.06, 0.06, 0.09, 11x<0.1 mg/kg.

The trials are supported by valid storage stability data for sugar beet and validated analytical methods.

The residues arising from the proposed uses will not exceed the MRL established for ethofumesate (as Sum of ethofumesate, 2-keto-ethofumesate, open-ring-2-keto-ethofumesate and its conjugate, expressed as ethofumesate) for sugar beet roots (0.2 mg/kg) in Reg. (EC) No 2017/1016.

No additional data are required.

Remark:

In EFSA Journal 2016;14(1):4374 it is highlighted that the maximum amount of active substance must not exceed 1.0 kg/ha every 3 years.

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

According to the OECD guidance document on residues in livestock (ENV/JM/MONO(2013)8), fodder

beets, sugar beet tops, dried pulp of beets, ensiled pulp of beets and molasses are the beet matrices fed to livestock. In addition, rotational crops, planted directly after crop failure (within 30 days after treatment of the failed beet crop) can show small ethofumesate related residues. These rotational crops can also contribute to the animal diet. The dietary burdens were calculated for different groups of livestock using the EFSA calculator¹.

The dietary burden calculation made by EFSA (2012) in the framework of the Art. 12 evaluation is available for ethofumesate. Evaluation was done for use on several crops that might be fed to livestock using the agreed European methodology (European Commission, 1996). As no data were reported on magnitude of residues in sugar/fodder beet tops and grass, these commodities were not taken into account and consequently the intake was underestimated. Data for sugar and fodder beet, and additional relevant data, are now included in the table below as given in the EFSA peer review for the active substance renewal (EFSA, 2016).

Table 7.2-11: Input values for the dietary burden calculation (considering the uses evaluated in Art. 12 procedure and the uses under consideration)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: Ethofumesate (Sum of ethofumesate, 2-keto-ethofumesate (NC 9607), open-ring-2-keto-ethofumesate (NC 20645) and its conjugate, expressed as ethofumesate)				
1-Forages				
Barley (forage)	0.03	Median residue, rotational crops (EFSA; 2016)	0.03	Median residue, rotational crops (EFSA; 2016)
Barley silage	0.04	Median residue, rotational crops (EFSA; 2016) x default PF 1.3	0.04	Median residue, rotational crops (EFSA; 2016) x default PF 1.3
Beet, mangel (fodder)	0.06	Median residue primary crop (see Table 7.2-10)	0.1	Highest residue primary crop (see Table 7.2-10)
Sugar/fodder beet (tops)	0.06	Median residue primary crop (see Table 7.2-10)	0.18	Highest residue primary crop (see Table 7.2-10)
Corn, field (forage, silage)	0.03	Median residue, rotational crops (EFSA; 2016)	0.03	Median residue, rotational crops (EFSA; 2016)
Millet (forage)	0.03	Median residue, rotational crops (EFSA; 2016)	0.03	Median residue, rotational crops (EFSA; 2016)
Oats (forage)	0.03	Median residue, rotational crops (EFSA; 2016)	0.03	Median residue, rotational crops (EFSA; 2016)
Oat (hay)	0.09	Median residue, rotational crops (EFSA; 2016) x default PF 3	0.09	Median residue, rotational crops (EFSA; 2016) x default PF 3
Rye (forage)	0.03	Median residue, rotational crops (EFSA; 2016)	0.03	Median residue, rotational crops (EFSA; 2016)
Sorghum (forage)	0.03	Median residue, rotational crops (EFSA; 2016)	0.03	Median residue, rotational crops (EFSA; 2016)

¹ [pesticides_mrl_guidelines_animal_model_2017.xls](#)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Sorghum silage	0.02	Median residue, rotational crops (EFSA; 2016) x default PF 0.6	0.02	Median residue, rotational crops (EFSA; 2016) x default PF 0.6
Triticale (forage)	0.03	Median residue, rotational crops (EFSA; 2016)	0.03	Median residue, rotational crops (EFSA; 2016)
Triticale (hay)	0.09	Median residue, rotational crops (EFSA; 2016) x default PF 2.9	0.09	Median residue, rotational crops (EFSA; 2016) x default PF 2.9
Wheat (forage)	0.03	Median residue, rotational crops (EFSA; 2016)	0.03	Median residue, rotational crops (EFSA; 2016)
Wheat (hay)	0.11	Median residue, rotational crops (EFSA; 2016) x default PF 3.5	0.11	Median residue, rotational crops (EFSA; 2016) x default PF 3.5
2-Roots and tubers				
Carrot (culls)	0.04	Median residue, rotational crops (EFSA, 2016)	0.05	Highest residue, rotational crops (EFSA, 2016)
Cassava/tapioca (roots)	0.04	Median residue, rotational crops (EFSA, 2016)	0.05	Highest residue, rotational crops (EFSA, 2016)
Swede (roots)	0.04	Median residue, rotational crops (EFSA, 2016)	0.05	Highest residue, rotational crops (EFSA, 2016)
Turnip (roots)	0.04	Median residue, rotational crops (EFSA, 2016)	0.05	Highest residue, rotational crops (EFSA, 2016)
3-Cereal grains / crop seeds				
Pea, field (dry seed)	0.05	Median residue (EFSA, 2012)	0.05	Median residue (EFSA, 2012)
4-By-products				
Sugar beet (dried pulp)	0.35	Median residue sugar beet root (DM 15%) calculated for sugar beet dried pulp DM 88% (EFSA, 2016)	0.35	Median residue sugar beet root (DM 15%) calculated for sugar beet dried pulp DM 88% (EFSA, 2016)
Sugar beet (ensiled pulp)	0.06	Median residue sugar beet root (DM 15%) calculated for sugar beet ensiled pulp DM 15% (EFSA, 2016)	0.06	Median residue sugar beet root (DM 15%) calculated for sugar beet ensiled pulp DM 15% (EFSA, 2016)
Molasses	0.76	Median residue x PF 12.7 (EFSA; 2016)	0.76	Median residue x PF 12.7 (EFSA; 2016)

DM = Dry matter
PF = Processing factor

Table 7.2-12: Results of the dietary burden calculation

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Risk assessment residue definition: Sum of ethofumesate, ethofumesate-lactone (NC 9607), ethofumesate carboxylic acid (NC					

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
20645), and its conjugate expressed as ethofumesate					
Beef cattle*	0.0094	0.012	Beet, sugar, molasses	0.51	Yes
Dairy cattle*	0.0134	0.019	Beet, sugar, tops	0.50	Yes
Ram/ewe	0.0112	0.016	Beet, sugar, tops	0.5	Yes
Lamb	0.0143	0.020	Beet, sugar, tops	0.47	Yes
Breeding swine	0.007	0.009	Beet, mangel, fodder	0.39	Yes
Finishing swine*	0.008	0.009	Swede, roots	0.29	Yes
Broiler poultry	0.004	0.004	Swede, roots	0.06	Yes
Layer poultry*	0.004	0.007	Beet, sugar, tops	0.10	Yes
Turkey	0.004	0.004	Swede, roots	0.06	Yes

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

zRMS comments:

The median and maximum dietary burdens has been calculated for different groups of livestock using the EFSA Animal model 2017.

The calculated dietary burdens for ethofumesate were found to exceed the trigger value of 0.1 mg/kg DM (or 0.004 mg/kg bw/d, respectively) for all groups of livestock. Further investigation of residues is therefore required (see point 7.2.4.2).

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Available data

Reference: Austria, 2015a; EFSA, 2016

Significant intakes (>0.004 mg/kg bw/day) were calculated for livestock. Metabolism studies in cow, sheep and hens were presented in the RAR (Austria, 2015a). No feeding study in pigs is required because metabolic pathways in the rat, in ruminants and in poultry are similar (*Austria, 2015a*).

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

Summary of animal feeding studies reported in the EU

“According to the [...] metabolism studies in lactating cows, highest residues according to the residue definition were found in kidney: 1.50 mg/kg at a 833N dosing rate and 0.11 mg/kg at a 60N dosing rate. It is therefore concluded that significant residues in edible matrices of ruminants and pigs are not expected. [...] MRLs for poultry products are not required because they are not exposed to significant levels of ethofumesate. These conclusions may however need to be revised if it cannot be confirmed that open-ring-2-keto-ethofumesate is covered by the residue trials reported.” (*EFSA, 2012*)

“Considering the transfer factors for the total radioactive residue in an animal matrix, as estimated in the livestock metabolism studies, and the corresponding maximum dietary burden of the animal, it can be concluded that the residues in all animal matrices will not exceed 0.01 mg/kg and therefore no feeding studies have to be conducted, neither in ruminants nor in poultry.

Nevertheless, in the scope of the original Annex II submission in 1996, a feeding study in poultry and two feeding studies in lactating cow were submitted and evaluated. All feeding studies were conducted in the US and did not completely follow the EU guidelines, however confirmed the low transfer of the ethofumesate related residues in edible matrices.” (*Austria, 2015a*)

No residues above 0.01 mg/kg are expected in animal tissues.” (*EFSA, 2016*)

Details of transfer factors calculated are shown in the tables below:

Table 7.2-13: Transfer factors determined in the cow metabolism study (Austria, 2015a) (dietary burden in the metabolism study ~ 5 mg/kg bw)

Sample	Transfer of total residue
Milk (□ 8-95 h samples)	0.002
Subcutaneous fat	0.002
Omental fat	0.002
Renal fat	0.002
Kidney	0.007
Hind quarters muscle	<0.001
Psoas muscle	<0.001
Loin muscle	<0.001
Heart muscle	<0.001
Liver	0.002

Table 7.2-14: Transfer factors determined in the poultry metabolism study (Austria, 2015a) (dietary burden in the metabolism study ~ 0.8 mg/kg bw)

Sample	Transfer of total residues
Egg yolk (steady state: day 8)	0.002
Egg white (steady state: day 6)	<0.001
Muscle	<0.001
Skin	0.002
Fat, abdominal	0.002
Fat, subcutaneous	0.001
Liver	0.008

Table 7.2-15: Overview of the values derived from livestock feeding studies

Table A2-10: Overview of the values derived from livestock feeding studies

Commodity	Dietary burden		Results of the livestock metabolism study						Median residue (mg/kg) ^(b)	Highest residue (mg/kg) ^(c)	Calculated MRL (mg/kg)	CF for RA ^(d)
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level (mg/kg bw/d) ^(a)	No	Result for enforcement		Result for RA					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
EU data (Austria, 2015a; EFSA, 2016)												
Enforcement residue definition: Ethofumesate (Sum of ethofumesate, 2-keto-ethofumesate (NC 9607), open-ring-2-keto-ethofumesate (NC 20645) and its conjugate, expressed as ethofumesate (Regulation (EU) n°2017/1016)												
Sum of Ethofumesate, ethofumesate-lactone (NC 9607), ethofumesate-carboxylic acid (NC 20645), expressed as ethofumesate (EFSA, 2016)												
Risk assessment residue definition: Sum of Ethofumesate, ethofumesate-lactone (NC 9607), ethofumesate-carboxylic acid (NC 20645), expressed as ethofumesate (EFSA, 2016)												
Pig meat	0.008	0.009	5	1	0.021	0.021	0.021	0.021	<0.01	<0.01	0.01*	1
Pig fat	0.008	0.009	5	1	0.502	0.502	0.502	0.502	<0.01	<0.01	0.01*	1
Pig liver	0.008	0.009	5	1	0.398	0.398	0.398	0.398	<0.01	<0.01	0.01*	1
Pig kidney	0.008	0.009	5	1	1.7	1.7	1.7	1.7	<0.01	<0.01	0.01*	1
Ruminant meat	0.0143	0.020	5	1	0.021	0.021	0.021	0.021	<0.01	<0.01	0.01*	1
Ruminant fat	0.0143	0.020	5	1	0.502	0.502	0.502	0.502	<0.01	<0.01	0.01*	1
Ruminant liver	0.0143	0.020	5	1	0.398	0.398	0.398	0.398	<0.01	<0.01	0.01*	1
Ruminant kidney	0.0143	0.020	5	1	1.7	1.7	1.7	1.7	<0.01	<0.01	0.01*	1
Poultry meat	0.004	0.007	0.78	3	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0.01*	1
Poultry fat	0.004	0.007	0.78	3	0.013	0.013	0.013	0.013	<0.01	<0.01	0.01*	1
Poultry liver	0.004	0.007	0.78	3	0.028	0.028	0.028	0.028	<0.01	<0.01	0.01*	1
Milk	0.0134	0.019	5	1	0.105	N/A	0.105	N/A	<0.01	<0.01	0.01*	1
Eggs	0.004	0.007	0.78	3	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0.01*	1

N/A: Not applicable – only the mean values are considered for calculating MRLs in milk.

(*): Indicates that the MRL is set at the limit of analytical quantification.

(a): Based on livestock metabolism studies reported in RAR (Austria, 2015a).

(b): Median residue value according to the enforcement residue definition, derived by interpolation/extrapolation from the feeding study for the median dietary burden (FAO, 2009).

(c): Highest residue value (tissues, eggs) or mean residue value (milk) according to the enforcement residue definition, derived by interpolation/extrapolation of the maximum dietary burden between the relevant feeding groups of the study (FAO, 2009).

(d): The median conversion factor for enforcement to risk assessment.

Conclusion on feeding studies

Considering the transfer factors for the total radioactive residue in an animal matrix, as estimated in the livestock metabolism studies, and the calculated corresponding maximum dietary burden of the animals, it can be concluded that the ethofumesate residues in all animal matrices will not exceed 0.01 mg/kg.

The conclusions drawn in EFSA (2012, 2016) and Austria (2015a) on existing MRLs are considered to be still valid and no further data are considered necessary.

zRMS comments:

Data presented by Applicant in point 7.2.4.2 have been accepted and are sufficient to support the proposed uses. It should be noted that the dietary intakes of ruminants and poultry are low and therefore residue levels are expected to remain below the LOQ when ADM.01851.H.1.A is applied according to the intended GAP.

The intended uses of ethofumesate in the product ADM.01851.H.1.A do not lead to an exceedance of the existing EU MRLs for animal commodities.

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

7.2.5.1 Available data for all crops under consideration

References: Sweden, 1998; EFSA, 2016

Processing studies for ethofumesate have been conducted on sugar beet (sugar, molasses, wet pulp, thick juice and thin raw juice).

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

Table 7.2-16: Overview of the available processing studies

Processed commodity	Number of studies	Median PF *	Median CF **	Comments	Reference
EU data					
Enforcement residue definition: Ethofumesate (Sum of ethofumesate, 2-keto-ethofumesate (NC 9607), open-ring-2-keto-ethofumesate (NC 20645) and its conjugate, expressed as ethofumesate)					
Sugar beet (sugar)	4	0.20	N/A		Sweden, 1998 EFSA, 2016
Sugar beet (molasses)	4	12.7	N/A		
Sugar beet (wet pulp)	3	0.2	N/A		
Sugar beet (thick juice)	5	4.7	N/A		
Sugar beet (thin (raw) juice)	5	1.1	N/A		

N/A = Not applicable

* The median processing factor is obtained by calculating the median of the individual processing factors of each processing study.

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

Summary of processing studies reported in the EU

“Studies on the magnitude of residues in processed sugar beet commodities, previously submitted under Dir. 91/41/EEC, were not included the RAR, barring an overview table with the derived processing factors from these trials. Therefore, the details of processing trials on the magnitude of residues and their acceptability in the view of current guidance were not subject to peer review during the renewal procedure. As the trigger for requiring such studies is not met by the representative uses assessed, this will not be identified as a data gap.” (EFSA, 2016)

7.2.5.2 Conclusion on processing studies

Processing studies have been submitted but are not required to support the proposed uses of ethofumesate

in this submission, as the trigger for requiring such studies is not met by the envisaged uses for ADM.01851.H.1.A.

zRMS comments:

Information given by the Applicant is sufficient.

Processing studies are required if the level of residue in the plant or plant product to be processed exceeds >0.1 mg/kg (OECD Test Guideline 508: Magnitude of the pesticide residues in processed commodities). Total residues of ethofumesate not exceeded 0.1 mg/kg in the RAC for intended crops in supervised residue trials for representative use, so processing studies are not required to support the proposed uses in this submission.

Processing studies for ethofumesate have been conducted on sugar beet and are available in the frame of this registration. Robust processing factors were derived during the EU review and were considered acceptable. No further data are required for support of uses for ADM.01851.H.1.A.

7.2.6 Magnitude of residues in representative succeeding crops

Data dealing with magnitude of residues in succeeding crops have been submitted and are summarized hereafter.

7.2.6.1 Field rotational crop studies (KCA 6.6.2)

Available data

References: Sweden, 1998; Austria, 2015a, b; EFSA, 2012, 2016

Field rotational crop studies have been conducted with ethofumesate applied either to soil or sugar beet. The residues of ethofumesate and metabolites were investigated in leafy vegetables, root/tuber vegetables and cereals grown at various plant-back intervals after application.

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

Table 7.2-17: Summary of available studies in field rotational crops

Summary of available studies in field rotational crops						
Primary crop	Rate (kg a.s./ha) (GS at application or PHI)	Residue levels in succeeding crops				
		Succeeding crop group	Succeeding crop	Sowing intervals (DAT)	Remarks	Reference
EU data						
Sugar beet	6-8 (no data)	Cereals	Wheat, maize	Not reported in the monograph, but are expected to be almost one year.	Castro, L. E., 1994 Report A83117	Sweden, 1998 EFSA, 2012 Austria, 2015a, b
Sugar beet	3.45 and 5.58 (12 months only)	Leafy vegetables	Spinach, cabbage	6 months 12 months	Crofts, M.; Whiteoak, R. J., 1974a Report A82995	
		Root and tuber vegetables	Carrot, potato, red beet	6 months 12 months	Crofts, M.; Whiteoak, R. J., 1974b Report A82994	
		Cereals	Barley, sorghum, oats	6 months 12 months	Peatman, M. H.; Snowdon, P. J., 1991 Report A83376	
Sugar beet	1.5	Leafy vegetables	Spinach	30 70		
		Cereals	Maize	30 70		
Sugar beet	1.0 (to soil or sugar beet at BBCH 16 or 18)	Leafy vegetables	Lettuce	25-29 57-259 320-354	Schulte, G., Diehl, P., 2013 Report 10-2501	Austria, 2015a, b EFSA, 2016

Primary crop	Rate (kg a.s./ha) (GS at application or PHI)	Residue levels in succeeding crops				
		Succeeding crop group	Succeeding crop	Sowing intervals (DAT)	Remarks	Reference
Sugar beet	1.0 (to soil or at BBCH 14-16)	Root and tuber vegetables	Carrot	25-29 54-259 320-354	Spence, C., 2014 Report 34890	Austria, 2015a, b EFSA, 2016
		Cereals	Barley	25-33 131-259 284-330		
		Leafy vegetables	Spinach	30-41 90-103 335		
		Root and tuber vegetables	Carrot or radish	30-40 90-103 335		
		Cereals	Spring barley or winter wheat	30-31 176-180 335		

Conclusion on rotational crops studies

“Additionally, to the already submitted studies [i.e. with the original DAR], two rotational crop field studies were submitted. The highest total residues of ethofumesate in rotational root crops; detectable residues were only found as ethofumesate; Residues of ethofumesate were only detected in root crops, leafy crops and cereal forage of the first rotation. Highest total residues accounted for

- 0.03 mg/kg in mature root crops (NEU)
- 0.03 and 0.02 mg/kg in immature and mature leafy crops respectively (NEU)
- 0.03 mg/kg in cereal forage (NEU)

The only residue detected above the LOQ of 0.01 mg/kg in NEU mature root and leafy crops was ethofumesate (max 0.02 mg/kg), with residues of the common moiety NC 9607 below the LOQ of 0.01 mg/kg at all plant-back intervals.. NC 9607 was detected up to 0.02 mg/kg in cereal forage only, with the corresponding ethofumesate residues being <0.01 mg/kg at all plant-back intervals.

No residues above existing default LOQ MRL of 0.03* mg/kg for all crops would be expected in crops following rotation with sugar/fodder beet treated according to the proposed GAP. Maximum residue levels have nevertheless been taken into account for the livestock dietary burden (and dietary risk assessment via inclusion of MRLs for all crops not under consideration).

Risk mitigation measures

Pre-harvest interval for each relevant crop

The envisaged pre-harvest intervals for EU uses are covered by the normal vegetation period which remains between last treatment and harvest of the crops. A pre-harvest interval (in days) is not deemed necessary.

Re-entry period (in days) for livestock, to areas to be grazed

ADM.01851.H.1.A for root crops is not intended for use in areas to be grazed by livestock. Therefore, a re-entry period does not need to be established.

Re-entry period for man to crops, buildings or spaces treated

Re-entry exposure was evaluated based on conservative model assumptions. Exposure was estimated to be within acceptable levels and no unacceptable risk is anticipated for workers entering the treated crop and performing re-entry activities when standard work clothing is worn (shoes, socks, long pants, and long sleeves). Therefore, setting a specific re-entry period is not indicated.

b) Buildings: Not relevant.

c) Spaces: Not relevant

Withholding period (in days) for animal feedstuffs

Due to the time between last treatment and harvest, as defined by the intended GAPs, it is not necessary to set a withholding period for use of treated plants as animal feedstuffs.

Waiting period between last application and sowing or planting

Not applicable since the intended GAP uses involve an application after sowing or planting of the crop to be protected.

Waiting period between application and handling treated products

The last application of ethofumesate-containing products is intended in root crops at an early growth stage (BBCH 19), thus significant time prior to harvest. There is no need to handle treated crops before harvest.

Waiting period before sowing/planting succeeding crops

For the setting of waiting periods, is not necessary. No residues of ethofumesate (acc. to residue definition) at or above the LOQ were detected at normal crop rotation.

zRMS comments:

Information given by the Applicant is sufficient. RMS-Austria concluded in DRAR for Ethofumesate, 2015:

“Several field rotational crop studies – either as “multi-crop” study (containing data for two rotations with three crop groups: leafy, root, and cereal crops) or as “limited” study (containing data for one rotation with one crop) were conducted during the first approval process. The studies were conducted with exaggerated field rates, either in Europe or the US. Since none of the study was conducted with the current application rate of 1.0 kg as./ha, an additional field rotational crop study was submitted in addition.

In the framework of this evaluation process 2 additional studies were submitted.

In the first study four rotational crop field trials were conducted in Europe (2 each in the northern and southern residue regions). Ethofumesate was applied once either to bare soil or to a target crop (sugar beet) at an active substance rate of 1.0 kg/ha, the target crop was then harvested, and crops representing 3 different botanical groups (roots, leafy veg., cereals) were planted on the plots at 3 intervals thereafter.

Residues of ethofumesate in all rotational crops were only detected in the first rotation, i.e. grown after a plant-back interval (PBI) of 25-33 days.

The highest total residues of ethofumesate in rotational root crops (immature carrot roots sampled approx. 14 days prior to the mature crop) ranged from <0.02-0.05 mg/kg. Residues in the mature roots ranged from <0.02-0.04 mg/kg. Residues were also determined in the leaves and ranged from <0.02-0.04 mg/kg, independent if harvested from the immature or the mature crop. Detectable residues were only found as ethofumesate; residues of the common moiety NC 9607 were always below the LOQ of 0.01 mg/kg in carrot roots and leaves.

In lettuce, cereals grain and straw no residues of ethofumesate and NC 9607 above the LOQ of 0.01 mg/kg were detected.

In green material taken earlier in the rotation, ethofumesate residues were below the LOQ of 0.01 mg/kg and the residues of the common moiety NC 9607 ranged from <0.01-0.02 mg/kg. Thus the total residue ranged from <0.02-0.03 mg/kg in green material of the first rotation.

In the second study two field rotation trials were carried out. At both trials, ethofumesate was applied once at 1 kg as/ha to sugar beets. The application was carried out at a BBCH 14-16 except for the plot with a plant-back interval of 30-31 days and the rotation with spring barley. Three different crop groups (leafy vegetables, root vegetables and cereal) were planted at three different plant back intervals (30-41 days, 90-176 days and 335 days. No residues of Ethofumesate and the sum of its metabolites NC9607 + NC20645 above the LOQ (0.01 mg/kg for each analyte for root and leafy vegetable matrices and 0.05 mg/kg for each analyte for cereal matrices) were found in any of the control and treated specimens.

No residues of Ethofumesate and its metabolites included in the proposed residue definition need to be expected in rotational crops after application of Ethofumesate according to the intended GAP.

Summarising the above, it can be concluded that ethofumesate related residues are only expected at or slightly above the LOQ. The highest residues in mature crops were detected as ethofumesate in root crops up to 0.03 mg/kg where ethofumesate was applied as pre-emergence application on bare soil.”

It can concluded that residue of ethofumesate in rotational root crops ranged from <0.02 to 0.05 mg/kg (mature and immature crops) after a plant-back interval of 25-33 days. Residues of ethofumesate for any other plant-back interval were always below LOQ.

In lettuce, cereals grain and straw no residues of ethofumesate and NC 9607 above the LOQ of 0.01 mg/kg were

detected.

To avoid MRL exceedance in root crops (the MRL value for the group of Root and tuber vegetables equals 0.03 mg/kg, excluding beetroots (0.2 mg/kg), the MRL value for sugar beet roots equals 0.2 mg/kg), the following mitigation measures should apply: **Do not grow root vegetables (except sugar or fodder beet) in case of crop failure.**

No waiting periods beyond normal agricultural practice are proposed for succeeding crops to be planted.

No further data are required.

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 ADM.01851.H.1.A. Therefore, other special studies are not needed.

Precautionary consideration of ethofumesate residues in pollen and nectar and their potential risk for bees

Additionally to the full bee toxicity package with ethofumesate, further acute oral laboratory studies with the ethofumesate plant metabolites NC 20645, NC 8493 and NC 9607 were conducted. Comparing the endpoints of the acute studies, there is no indication that the metabolites are more toxic than the active substance. Therefore, it can be concluded that the risk from the metabolites will be covered by the assessment of the parent compound.

However, additional information such as residue data, attractiveness of agricultural crops and their typical cultivation practices are considered in the following to support this conclusion.

Residues of ethofumesate in beet and rotational crops

Beet (*Beta vulgaris*)

Beta vulgaris is mainly wind-pollinated and bees do only occasionally visit the crops (e.g. nectar collection). Beets are considered of low attraction to bees for pollen, but their collection cannot be excluded. However, exposure of bees can be considered as negligible given that sugar beets, fodder beets and beetroots are generally harvested in the first year, i.e. before flowering.

Bolting of sugar beets (starting of shoot elongation) during the first year of vegetation is only observed in rare cases (due to frost in late spring). In these cases, the respective shoots/plants are removed manually before flowering to avoid any seed spreading to the soil (and thus prevent seeds from uncontrolled germination and growing in the following years) in order to facilitate mechanical harvest. The removal of bolting sugar beets is common practice in agriculture. Thus, in the first vegetation year, no flowers of sugar beet are available for bees.

Flowers of *Beta vulgaris* are only present if crops are grown for seed production. The area used for seed production is very limited and represents less than 1% of the whole cultivation area of *Beta vulgaris* in Europe (ca. 8500 ha for sugar beets). For seed production the failure is extremely rare, as they are not sowing but planting small beets coming from nurseries.

However, even intense foraging of bees would not lead to any ethofumesate residues in bee bread and nectar. The half-life of total ethofumesate residues in sugar beet roots and leaves was estimated based on the total radioactive residues (TRR) determined in the sugar beet metabolism study (Caley *et al.*, 1994, A87553 (M-161455-01); RAR, Vol. 3, B7) at four different points in time (day 0, 7, 28 and 150 = maturity). Assuming first order kinetics, the DT50 of the TRR is approx. 21 days in shoots and approx. 22 days in roots. After application of 1.5 kg a.s./ha, the total ethofumesate residues in sugar beet shoots declined from 126 mg/kg at the day of the last application (day 0) to 76.2 mg/kg at day 7 and to 0.75 mg/kg at day 150 (maturity), indicating a decline of 39.5% 7 days after application and 99.4% 150 days after application. Residues in shoots will be below 0.01 mg/kg after approx. 280 days (9-10 months). For roots, ethofumesate residues declined from 1.9 mg/kg at day 0 to 0.01 mg/kg at day 150 and a residue level of 0.01 mg/kg was reached after 145 days (approx. 5 months). For details please refer to RAR, Vol. 3, B7). As the metabolism study has been conducted in a protected area (glasshouse), even faster degradation can be assumed under field conditions, which was confirmed by a huge number of field

residue trials.

Since *Beta vulgaris* are biennial crops, the flowers are formed in the second year and thus at a time when ethofumesate-related residues are generally <0.01 mg/kg in roots and in most cases also in leaves. Although ethofumesate-related residues cannot be completely excluded in leaves, a translocation of the residues into flowers and pollen is not very plausible. Eshel *et al.*² detected that acropetal translocation of radiolabelled ethofumesate-related residues was rapid, but there was no translocation out of the leaves. Furthermore, ethofumesate or its metabolites were not translocated basipetally after foliar application. Thus, even metabolite NC 20645, which should be phloem mobile according to its physicochemical properties ($pK_{a1} = 4.8$ at pH = 4-5 and $pK_{a2} = 11.7$ at pH = 10-13 and $\log P_{ow} = 0.4$ at pH = 5 and $\log P_{ow} = -2.4$ at pH = 9) and which should be present in the samples under investigation, was only transported in the xylem. An explanation could be that the metabolite was already conjugated and thus its mobility properties were changed. Based on this publication, the residues in the leaves cannot be re-translocated in the roots before the leaves die during winter. As a consequence the residues are no longer available for transport in the new shoots and the flowers in the second year.

The low incidence of residues of ethofumesate in bees, pollen and honey is also indicated in a review by Johnson *et al.*³, which collated residues data in the United States from more than 150 different pesticides over the past 20 years. Under field conditions, residues of ethofumesate were found to be always below detection in bees, pollen and honey. Only wax contained residues of up to 0.56 mg/kg ethofumesate.

Rotational crops

A metabolism study in the confined rotational crops radish (root crop), cabbage (leafy crop) and wheat (cereals) indicated that ethofumesate residues can arise in succeeding crops (Carlton and Cordell, 1993, report A83396 (M-155664-01)). For details please refer to RAR, Vol. 3, B7. Since the metabolism study was conducted at an exaggerated rate (4.1 kg a.s./ha), additional field rotational crop studies were initiated at the registered application rate of 1.0 kg a.s./ha. These field residue data are used as a basis for estimating ethofumesate-related residues in rotational crops since they represent a realistic scenario.

Field rotational crop studies (Schulte and Diehl, 2013, report 10-2501 (M-463906-02); RAR, Vol. 3, B7) conducted with carrots (root crop), lettuce (leafy crop) and with barley and wheat (cereals) showed only ethofumesate-related residues in crops of the first rotation (sowing or re-planting 25-33 days after the application). This rotation is representative for re-sowing/planting of crops after the rare case of a complete crop failure. For details please refer to RAR, Vol. 3, B7. In the crops of all other rotations, the ethofumesate-related residues were below 0.01 mg/kg. Moreover, in two additional field rotational crop studies (Spence, 2014, report 34890, RAR, Vol. 3, B7), conducted with carrots or radish (root crops), spinach (leafy crop) and barley (cereals) no ethofumesate-related residues were detected above the LOQ in all rotations. For details please refer to RAR, Vol. 3, B7.

Table 7.2-18: Highest residues in crops of the 1st rotation

Commodity	Highest residue in 1 st rotation [mg a.s. equiv./kg]		
	Ethofumesate	NC 9607	Total
Carrot, leaf	0.03	<0.01	0.04
Carrot, root	0.02	<0.01	0.03
Lettuce (BBCH 41)	0.02	0.01	0.03
Lettuce (BBCH 49)	<0.01	<0.01	<0.02
Barley/wheat, green material (BBCH 30)	<0.01	0.02	0.03

LOQ = 0.01 mg/kg

² Eshel, J.; Zimdahl, R. L.; Schweizer, E.E.: Uptake and Translocation of ethofumesate in sugar beet plants, Pestic. Sci., 9, 301-304, 1978.

³ Johnson, R.M., Ellis, M.D., Mullin, C.A., Frazier, M.: Pesticides and honey bee toxicity in the United States. In: Sammataro, D., Yoder, J.A. (eds): Honey bee colony and health. Challenges and sustainable solutions. CRC Press, pp. 145-160, 2012.

Carrots (representative crop for root crops)

Generally, bees are not foraging in root crops. However, visits by bees during pollen and nectar collection cannot be excluded.

Considering that carrots are usually harvested before flowering they would not represent a route of exposure based on typical cultivation practices. Additionally, as for the primary crop (sugar beet), no ethofumesate residues (<0.01 mg/kg) will be available in the roots when the flowers are formed in the second vegetation year. Even after late sowing (June-July), residues in roots will be below 0.01 mg/kg before forming the flowers in early summer.

Lettuce (representative crop for leafy vegetables and brassica)

Generally, bees are not foraging in lettuce or Brassica crops (also these crops are wind- pollinated). Considering that lettuce is usually harvested before flowering it also would not represent a route of exposure based on typical cultivation practices. Moreover, ethofumesate-related residues detected in immature plants (BBCH 41-45) decreased rather quickly and were below 0.01 mg/kg at harvest (BBCH 49). Therefore, no residues are expected even if flowers are formed (BBCH 53).

Barley/wheat (representative crop for cereals)

Generally, bees are not foraging in cereals as they are low attractive to bees. However, it is known that bees can collect some pollen of cereals when they forage close to fields.

In Europe, it is very common to grow sugar beets and winter cereals in rotation, however winter cereals cannot be sown before September. Considering agricultural practice, the interval between the treatment of the sugar/fodder beet with ethofumesate (April/May) and sowing of cereals due to crop failure cannot be shorter than 4-5 months. Flowering of the winter cereals will be in May in the following year at the earliest (barley) and thus approx. 1 year after application of ethofumesate. Checking the residue values of green material in the field rotational crop study, it can be shown that ethofumesate-related residues were <0.01 mg/kg in all sample materials (green material, grain and straw) when collected approx. 300 days after application of ethofumesate. Thus, translocation of residues in pollen of cereals can be excluded.

Due to the early application of ethofumesate in the season and the rather short half-life of ethofumesate-related residues in crops, translocation of these residues in flowers and therefore in nectar and pollen is not very plausible.

Generally, the residues will be <0.05 mg/kg in the aerial plant matrix before formation of flowers. Moreover a translocation or even selective enrichment of ethofumesate-related residues in nectar and in pollen was excluded in a study conducted with radiolabelled ethofumesate. In this study no phloem mobile component was detected within 15 days following foliar application. Apparently, ethofumesate and its metabolites (which should be formed at this time) are unable to enter the phloem. Moreover, a selective enrichment of ethofumesate traces in nectar can be excluded due to the hydrophobic character of ethofumesate-related residues.

Based on these results, residues in pollen and nectar can be excluded in *Beta vulgaris*, weeds and in all succeeding crops (e.g. maize, sunflower) in the central zone.

Thus a risk for the consumer can be excluded –especially when considering that ethofumesate residues up to 10,000 mg/kg in honey would be still safe for the consumer (EFSA PRIMo rev. 3.1), even when calculating with all MRLs.

zRMS comments:

Information given by the Applicant is sufficient. The non-relevance of residues in pollen and bee products was mainly justified with the overall low residue levels in sugar beets and rotational crops. Regarding uses on sugar beet and fodder beet, no additional data are needed in the frame of this registration.

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).

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

7.2.8.1 Input values for the consumer risk assessment

Table 7.2-19: Input values for the consumer risk assessment

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Risk assessment residue definition: Ethofumesate (Sum of ethofumesate, 2-keto-ethofumesate (NC 9607), open-ring-2-keto-ethofumesate (NC 20645) and its conjugate, expressed as ethofumesate)		
Sugar beet (root)	0.2	MRL (Regulation (EU) 2017/1016)
All other commodities	MRL	Regulation (EU) 2017/1016

7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.2-20: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo rev 3.1	0.5 % (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo rev. 3.1	Not necessary, because the TMDI is well below 100% of ADI
IESTI (% ARfD) according to EFSA PRIMo rev. 3.1	Not relevant, because ARfD not necessary

The proposed uses of ethofumesate in the formulation ADM.01851.H.1.A do not represent unacceptable chronic risks for the consumer.

zRMS comments:

The consumer risk assessments were performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo). The calculation of the TMDI using EFSA model (version 3.1) and MRLs according to Reg. (EU) 2017/1016 led to a utilisation of the ADI of 0.5% with the NL toddler being the population group with the highest value. For this diet, the highest contributor is Milk: Cattle with 0.2% of the ADI.

The intended uses will not result in a consumer chronic exposure exceeding the ADI.

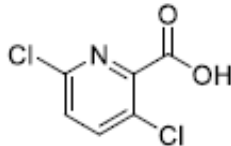
As no ARfD has been set for ethofumesate, an acute risk assessment was not conducted.

7.3 Clopyralid

General data on clopyralid are summarized in the table below (last updated 2024/01/29)

Applicant provided LoA from Dow AgroSciences for clopyralid: access to Dow AgroSciences data on active substance clopyralid for registration of pesticide ADM.01851.H.1A.

Table 7.3-1: General information on clopyralid

Active substance (ISO Common Name)	Clopyralid
IUPAC	3,6-dichloropyridine-2-carboxylic acid or 3,6-dichloropicolinic acid
Chemical structure	
Molecular formula	C ₆ H ₃ Cl ₂ NO ₂
Molar mass	191.96 g/mol
Chemical group	Pyridines
Mode of action (if available)	Clopyralid is pyridinecarboxylic acid herbicide, with a synthetic auxin mode of action.
Systemic	Yes
Company (ies)	Dow AgroSciences S.A.S., now Corteva Agriscience*
Rapporteur Member State (RMS)	Finland co-RMS: Poland
Approval status	Approved Commission Implementing Regulation (EU) 2021/1191 of 19 July 2021
Restriction (e.g. is restricted to use as "...")	Only uses as herbicide may be authorised
Review Report	SANTE/10206/2021 Rev 1 20 May 2021
Current MRL regulation	~~Commission Regulation (EU) 2021/1807 of 13 October 2021~~ Commission Regulation (EU) 2024/2612
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Pending
EFSA Journal : Conclusion on the peer review	Yes. EFSA, 2018
EFSA Journal: conclusion on article 12	No
Current MRL applications on intended uses	No

7.3.1 Stability of Residues (KCA 6.1)

7.3.1.1 Stability of residues during storage of samples

Available data

No new data submitted in the framework of this application. Studies not reviewed in EFSA 2018 are referenced via a letter of access from Corteva.

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

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

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Plant products			
Pasture grass	High water content	17 months	EFSA, 2018 Corteva Report No.: GHE-P-5350
Maize fodder/forage	High water content	13 months	EFSA, 2018 Corteva Report No.: GH-C 3779
Maize	High starch content	13 months	
Olive (fruit and oil)	High oil content	10 months	EFSA, 2018 Corteva Study No. 120939
Oilseed Rape	High oil content	24 months	EFSA, 2018 Corteva Study 020122.02
Orange	High acid content	10 months	EFSA, 2018 Corteva Study No. 120939
Orange peel	Other	10 months	EFSA, 2018 Corteva Study 120939
Dried Bean	High protein content	13 months	Skaggs, C.S., Penning, B.N. 2021 Corteva Study No. 191728
Strawberries	High acid content	18 months	Teasdale, R., 1996 Corteva Study No. GHE-P-4832
Animal Products			
Ruminant	Muscle	19 months	EFSA, 2018 Corteva Study 020120.01
Ruminant	Liver	19 months	EFSA, 2018 Corteva Study 020120.01
Ruminant	Kidney	19 months	EFSA, 2018 Corteva Study 020120.01
Ruminant	Milk	19 months	EFSA, 2018 Corteva Study 020120.01
Ruminant	Fat	24 months	EFSA, 2018 Corteva Study No. 120602
Poultry	Eggs	19 months	EFSA, 2018 Corteva Study 020120.01

Conclusion on stability of residues during storage

Clopyralid (free and conjugated) is stable for at least 17 months in high water commodities, 24 months in high oil commodities, 13 months in high starch commodities and 10 months in high acid commodities when stored under frozen ($\leq -18^{\circ}\text{C}$) conditions.

Clopyralid (free and conjugated) is stable for at least 19 months in tissues, milk and eggs and up to 24 months in fat when stored under frozen ($\leq -18^{\circ}\text{C}$) conditions.

zRMS comments:

According to the EFSA Journal 2021;19(1):6389: “The storage stability of clopyralid in plants stored under frozen conditions was investigated in the framework of the EU pesticides peer review (EFSA, 2018d). It was demonstrated that clopyralid was stable for at least 10 months when stored at -18°C in commodities with high water, high oil, high acid and dry/high starch content (details see Appendix B). In pasture stability was demonstrated up to 17 months, in maize grain and forage/fodder up to 13 months when stored at -20°C .”

The storage stability studies indicated that clopyralid is stable for at least 19 months in animal tissues, milk and eggs and up to 24 months in fat when stored under frozen ($\leq -18^{\circ}\text{C}$) conditions.

Two studies on storage stability of clopyralid in plant products, in dried navy beans (Skaggs, C. S., Penning, B. N; 2021) and in strawberries (Teasdale, R.; 1996) have been evaluated and accepted by zRMS-PL in RR – Part B7 for EF-243/ Lontrel 300 (February 2023, Applicant: Corteva Agriscience).

Storage stability of clopyralid was demonstrated for a period of 13 months under frozen ($\leq -18^{\circ}\text{C}$) conditions in dried navy beans (commodity with high protein content) and for a period of 18 months in strawberries (commodities with high protein acid content).

It can be concluded that residues of clopyralid are stable for at least 13 months in all crop commodities when stored under frozen (-18°C) conditions.

The studies on the magnitude of residues are valid with regard to storage stability. The stability of residues during storage of clopyralid in plants and animal products is sufficiently addressed to support the proposed uses of the product ADM.01851.H.1.A. No additional study is required.

7.3.1.2 Stability of residues in sample extracts (KCA 6.1)

As residue samples in trials with clopyralid were routinely stored frozen for longer periods of time prior to their analysis the stability of residues during storage of samples and effects of frozen storage on the residue levels were investigated.

The storage stability of clopyralid residues in sample extracts is routinely tested during method development. Since the validity of the methods is based on and confirmed by factors such as reproducibility for interruption during the work-up process, it can be concluded that the stability of residues in extracts is always guaranteed. In addition, when conducting analyses of "normal" samples, the entire analytical procedure is monitored by conducting concurrent recoveries with each sample set.

zRMS comments:

Procedural recoveries obtained during residue analysis demonstrate the stability of residues of clopyralid in sample extracts. No additional study is required.

7.3.2 Nature of residues in plants, livestock and processed commodities

7.3.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

In addition to the existing EU data, new metabolism studies have been submitted by the data owner Corteva Agriscience (letter of access provided). These studies are summarized in the table below.

Table 7.3-3: Summary of plant metabolism studies

Table 7.5.5. 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	¹⁴ C-clopyralid	G, foliar	0.42	1	0, 5, 38	Application at BBCH 31 (8-10 leaf stage)	Finland, 2018a
Root and tuber vegetables	Sugar beet	¹⁴ C-clopyralid	F, foliar	0.30	1	0, 28, 105 (maturity)	Application at BBCH 36	EFSA, 2018a and Finland, 2018a Finland 2018b†
Pulses and oilseeds	Oilseed rape	¹⁴ C-clopyralid	F, foliar	0.30	1	0, 28 (60% final size), 77 (maturity)	Application at BBCH 36	EFSA, 2018a and Finland, 2018a Finland 2018b†

Cereals/grass crops	Pasture grass	¹⁴ C-clopyralid	F, foliar	1.12	1	1, 2, 4, 8, 18 weeks	Non-GLP, non-guideline compliant. Supporting information only.	Finland, 2018a
Cereals and oilseeds	Oilseed rape and wheat	¹⁴ C-clopyralid	G, Hydroponic	75 µg/L	-	-	Non-guideline compliant. No metabolism data available, only biodistribution. Supporting information only.	Finland, 2018a
New data								
Cereals/grass crops	Cereals	¹⁴ C-clopyralid	F, foliar (last 3 weeks indoors, G)	125 g ae/ha	1	3 (forage), 23 (hay), and maturity (92 for straw and grain)	Application at BBCH 39,	EFSA RO: EFSA Journal 2021;19(1): 6389 Corteva study No. 191200
Pulses and oilseeds	Oilseed rape	¹⁴ C-clopyralid	F	200 g ae/ha	1	23 (forage) and maturity (94) (seeds & trash); pollen (between 9 and 31)	Application at BBCH 30 Trash is not a RAC	EFSA RO: j.efsa.2024.8546 Corteva study No. 200928
Root and tuber vegetables	Sugar beet	¹⁴ C-clopyralid	F	314 g ae/ha	1	21 (immature), 110 (roots & foliage)	Application at BBCH 19	EFSA RO: j.efsa.2024.8546 Corteva Study No. 210071

Summary of plant metabolism studies reported in the EU

Reference: EFSA, 2018a

“Three Good Laboratory Practice (GLP) and guideline-compliant metabolism studies with foliar application of ¹⁴C-clopyralid are available for root crop, leafy vegetable and pulses/oilseeds.

The extraction with caustic methanol employed in the cabbage study has led to cleavage of the conjugates and resulted in the presence of free clopyralid at maturity up to 92% and 99% total radioactive residue (TRR) in head and wrapper leaves, respectively. In the studies with oilseed rape and sugar beet, a first extraction was performed with acetonitrile/water and followed with a caustic extraction allowing for investigation of the presence of eventual conjugates. In sugar beet, clopyralid was initially the major residue in the plant (97% TRR at day 0 and 85% TRR at day 28). At maturity, it decreased to 51% TRR in the shoot and to 58% TRR in the root. A ‘polar form of clopyralid’ was observed in shoots and roots up to 37% TRR and 39% TRR, respectively, but only in the mature plant parts. In oilseed rape clopyralid was present at 63% TRR in immature plant and at 32% and 43% TRR in mature straw and seed, respectively. A ‘polar form of clopyralid’ was reported to 32% and 28% TRR in mature straw and seed, respectively and an unknown metabolite B also referred to as ‘clopyralid conjugates’ to 29% and 18% TRR in mature straw and seed, respectively. From the analytical protocol it can be assumed that the ‘polar clopyralid’ refers to the protonated form (clopyralid acid). However, a confirmation that the observed results in the different metabolism studies are consistent with the analytical conditions (pH) used and an explanation why in mature samples of sugar beet and oilseed rape ‘polar clopyralid’ and clopyralid were observed while ‘polar clopyralid’ was not observed in immature samples as the analytical procedure used was always the same within one study is outstanding (data gap). A clarification is also needed whether the term ‘polar clopyralid’ is referring always to a single structure (and not different polar compounds) and that this structure of ‘polar clopyralid’ is identical across all metabolism studies where it has been identified (data gap).”

Summary of new plant metabolism studies

A GLP metabolism study covering the group of cereals (wheat) was assessed in MRL application (EFSA, 2021). Free clopyralid was the only identified residue in straw and grain, ranging between 20% and 28% TRR. A multitude of less polar compounds were reported accounting for 30% to 45% TRR. These less polar fractions were not identified. However, when the plant extracts were subjected to a base treatment, these compounds were found to release free clopyralid. Therefore, these compounds were characterised as base labile. Because of this lack of further identification, it was concluded that the study did not fulfil the requirements of OECD Guideline 501 (OECD, 2007a).

In the framework of the Honey MRL application, the data owner Corteva Agriscience submitted two new GLP and guidelines-compliant Metabolism studies: one on oilseed rape and one on sugar beet (Finland, 2023). Both studies are performed with application patterns similar to the studies assessed in the peer review (foliar application at an early growth stage at the rate of 200 or 300 g a.s./ha).

The results of the new study on oilseed rape showed similar results compared to the previously assessed study on wheat, with a significant part of the TRR corresponding to compounds less polar than clopyralid, not properly identified, but which are readily converted to free parent after basic hydrolysis. In both cases, an impact on the magnitude of residues in samples analysed in the residue trials and in monitoring is not expected, provided that the analytical methods used to generate the data also apply basic hydrolysis in order to convert all the relevant residues to clopyralid (EFSA, 2021). Information on the nature of residues in primary crops is relevant to support the present MRL application in honey. EFSA concludes that the nature of residues in plants (and in plant parts foraged by bees) has been sufficiently depicted to support the present MRL request for honey. The available studies submitted after the EU peer review indicate that clopyralid (free, conjugated or any forms readily converted to free clopyralid after basic hydrolysis) is the only relevant compound found in oilseed rape, wheat and sugar beet. However, a conclusion on the metabolism of clopyralid in plants shall be taken in the MRL review according to Article 12 of Regulation (EC) No 396/2005 where all available plant metabolism studies will be reassessed.

Conclusion on metabolism in primary crops

EFSA RO, 2024:

A general residue definition for primary and rotational crops was derived in the EU assessment of the renewal of clopyralid as follows (EFSA, 2018c):

- Residue definition for risk assessment: clopyralid common moiety (sum of clopyralid, its salts and conjugates expressed as clopyralid).
- Residue definition for enforcement: clopyralid common moiety (sum of clopyralid, its salts and conjugates expressed as clopyralid).

Data gaps were identified in the EFSA conclusion on the peer review of clopyralid regarding the nature of polar residues found in sugar beet and oilseed rape metabolism studies. Furthermore, it was also noted that the characterisation of metabolism in leafy crops was limited because of a direct extraction performed with caustic methanol. However, the above residue definition was confirmed for cereal crops after the evaluation of a new metabolism study performed on wheat and submitted in a previous MRL assessment (EFSA, 2021).

It should be noted that the residue definition for enforcement currently set in Regulation (EC) No 396/2005 is ‘clopyralid’ alone. However, provided the analytical method used for enforcement and for generating data for risk assessment includes a hydrolysis step comparable to the one applied in the metabolism studies, it is expected that free clopyralid and clopyralid moiety released from its different conjugated forms would be analysed. A change of the wording of the existing enforcement residue definition might need to be proposed in the framework of the MRL review (art 12 of Reg (EU) 396/2005) to better reflect these aspects of the nature of clopyralid residues in plants.

Furthermore, whether this residue definition is also applicable to crops other than cereals also need to be concluded in the framework of the MRL review. The two new studies submitted and assessed in the

framework of the Honey MRL application indicate that clopyralid (free, conjugated or any forms readily converted to free clopyralid after basic hydrolysis) is the only relevant compound found in oilseed rape and sugar beet. No further metabolites were identified, thus a different degradation of the parent compound in these crops is not expected compared to wheat. In the new sugar beet study, the presence of clopyralid conjugates could be demonstrated. In the new oilseed rape study, however, the authors could only formulate the hypothesis that clopyralid may undergo interaction with endogenous plant matrix, in the form of weak chelation effects or electrostatic interactions. Nevertheless, in both cases, an impact on the magnitude of residues in samples analysed in monitoring, or in the residue trials, is not expected provided that the analytical methods used to generate the data also apply basic hydrolysis to convert all the relevant residues to clopyralid.

Evaluator comments:

The metabolism of clopyralid following foliar application was investigated in the EU pesticides peer review in crops belonging to the groups of root crops, leafy crops and pulses/oilseeds. In the framework of the assessment in accordance with Article 6 of Regulation (EC) No 396/2005, a new metabolism study in wheat, representing cereals/grass crop group was submitted. 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 and, although the applicant and EMS provided further clarifications under the current assessment, EFSA still considers this data gap as not addressed. In addition, the EU pesticides peer review noted that the extraction conditions in metabolism study with leafy crops were not suitable to allow an elucidation of the metabolism of clopyralid. EFSA concludes that for the intended uses in grass and cereals, the metabolic behaviour of clopyralid in these crops is addressed with the new metabolism study in wheat (EFSA, 2021).

The EU pesticides peer review concluded that, based on the metabolic pattern identified in leafy crops, root crops and cereals/oilseeds crop groups, the results of hydrolysis and rotational crop studies, the data are sufficient to derive the following general residue definitions in primary and rotational crops, pending the outstanding clarification on the nature of ‘polar clopyralid’ in oilseed rape and sugar beet metabolism:

Residue definition for risk assessment: clopyralid common moiety (sum of clopyralid, its salts and conjugates expressed as clopyralid)

Residue definition for enforcement: clopyralid common moiety (sum of clopyralid, its salts and conjugates expressed as clopyralid)
(EFSA, 2018)

The residue definition for enforcement set in Regulation (EC) No 396/2005 is currently ‘clopyralid’ alone. EFSA proposes to change the existing enforcement residue definition by including clopyralid salts and conjugates. The proposed change will not have an impact on the existing MRLs, as the analytical methods used to generate data for risk assessment and for enforcement include a hydrolysis step which is capable to cover the common moiety.

Additionally, EFSA concluded in EFSA Journal 2021;19(1):6389 that *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.*

The residue definition for enforcement set in Regulation (EC) No 396/2005 is currently ‘clopyralid’ alone. EFSA proposes to change the existing enforcement residue definition by including clopyralid salts and conjugates. The proposed change will not have an impact on the existing MRLs, as the analytical methods used to generate data for risk assessment and for enforcement include a hydrolysis step which is capable to cover the common moiety. The residue definitions are applicable to processed products.

In the framework of the new MRL application in honey (EFSA, 2024 – „Modification of the existing maximum residue level for clopyralid in honey”), the applicant submitted two new GLP and guidelines - compliant metabolism studies: one on oilseed rape and one on sugar beet (Finland, 2023). Both studies are performed with application patterns similar to the studies assessed in the peer review (foliar application at an early growth stage at the rate of 200 or 300 g a.s./ha).

EFSA, 2024: *The two new studies submitted and assessed in the framework of the present application indicate that clopyralid (free, conjugated or any forms readily converted to free clopyralid after basic hydrolysis) is the only relevant compound found in oilseed rape and sugar beet. No further metabolites were identified, thus a different degradation of the parent compound in these crops is not expected compared to wheat. In the new sugar beet study, the presence of clopyralid conjugates could be demonstrated. In the new oilseed rape study, however, the authors could only formulate the hypothesis that clopyralid may undergo interaction with endogenous plant matrix, in the*

form of weak chelation effects or electrostatic interactions. Nevertheless, in both cases, an impact on the magnitude of residues in samples analysed in monitoring, or in the residue trials, is not expected provided that the analytical methods used to generate the data also apply basic hydrolysis to convert all the relevant residues to clopyralid.

The results of a new study on oilseed rape showed similar results compared to the previously assessed study on wheat, with a significant part of the TRR corresponding to compounds less polar than clopyralid, not properly identified, but which are readily converted to free parent after basic hydrolysis. In both cases, an impact on the magnitude of residues in samples analysed in the residue trials and in monitoring is not expected, provided that the analytical methods used to generate the data also apply basic hydrolysis in order to convert all the relevant residues to clopyralid (EFSA, 2021).

(...) The available studies submitted after the EU peer review indicate that clopyralid (free, conjugated or any forms readily converted to free clopyralid after basic hydrolysis) is the only relevant compound found in oilseed rape, wheat and sugar beet. However, **a conclusion on the metabolism of clopyralid in plants shall be taken in the MRL review according to Article 12 of Regulation (EC) No 396/2005 where all available plant metabolism studies will be reassessed.**

(...) A change of the wording of the existing enforcement residue definition might need to be proposed in the framework of the MRL review (art 12 of Reg (EU) 396/2005) to better reflect these aspects of the nature of clopyralid residues in plants.

Furthermore, whether this residue definition is also applicable to crops other than cereals also needs to be concluded in the framework of the MRL review.

Conclusion:

Taking into account EFSA conclusion presented in EFSA Journal 2018;16(8):5389 for clopyralid, a general residue definition for primary and rotational crops for risk assessment and monitoring has been derived.

At present, no additional data are required to support the proposed uses on sugar and fodder beet.

Taking the above into account and in accordance with national harmonization arrangements (<https://www.gov.pl/web/rolnictwo/ustalenia-dotyczace-sporzadzania-oceny-lub-uwag-w-zakresie-srodkow-ochrony-roslin-przez-podmioty-upowaznione>; 17.12.2024), for products containing clopyralid, after completing the procedure under Article 12 of Regulation No 396/2005, it will be necessary to verify the assessment performed in terms of the established residues definition for the accepted uses.

7.3.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

Reference: Finland, 2005 and 2017; EFSA, 2018

Metabolism studies in rotational crops have been conducted with four crop groups and three plant back intervals. The results are shown in the table below.

No new data submitted in the framework of this application.

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

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								
Root and tuber vegetables	Turnip	¹⁴ C-clopyralid ^a	Soil	0.280	125, 319 days	Not reported		Finland, 2005 and 2017 EFSA, 2018
	Radish	¹⁴ C-clopyralid ^a	Soil	0.300	30 days	78 days (tops and roots)		Finland, 2017 EFSA, 2018
Leafy vegetables	Lettuce	¹⁴ C-clopyralid ^a	Soil	0.280	125, 319 days	Not reported		Finland, 2005 and 2017 EFSA, 2018
	Cabbage	¹⁴ C-clopyralid ^a	Soil	0.300	30 days	78 days (immature cabbage), 128 days (mature)	Mature cabbage: 9+ leaves/head; heads failed to fully	Finland, 2017 EFSA, 2018

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	
						cabbage)	close due to heat, BBCH 53	
Cereal (small grain)	Wheat	¹⁴ C-clopyralid ^a	Soil	0.280	125, 319 days	Not reported		Finland, 2005 and 2017 EFSA, 2018
				0.300	30 days	62 days (forage), 78 days (hay), 107 days (straw and grain)		Finland, 2017 EFSA, 2018
Other	Soybean (green plant and beans)	¹⁴ C-clopyralid ^a	Soil	0.280	125, 319 days	Not reported		Finland, 2005 and 2017 EFSA, 2018

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

a: 3,6-dichloro-2-6-¹⁴C-2-pyridinecarboxylic acid.

Summary of metabolism studies on rotational crops 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. As residues in rotational crops cannot be excluded based on the available data, rotational crop field trials according to current guidelines should be submitted (data gap).” (EFSA, 2018)

In the rotational crop metabolism study conducted at PBI of 30 days (application rate 300 g as/ha), the following residues of total clopyralid (including conjugates) were found: wheat forage – 0.367 mg/kg, wheat straw – 0.625 mg/kg, wheat hay – 0.729 mg/kg, wheat grain – 0.549 mg/kg, immature cabbage – 0.212 mg/kg, mature cabbage – 0.085 mg/kg, radish tops - <0.01 mg/kg. (Finland, 2017)

“The metabolism of clopyralid was shown to proceed in rotational crops in a similar fashion as in the primary crops. Consequently, the same definition of residue can be maintained.

In rotational crop intervals majority of the residue identified was clopyralid. Free and conjugated clopyralid were the most abundant residue species at all PBIs. Clopyralid taken up by the plants possibly as a glucose conjugate of clopyralid.” (Finland, 2017)

“From the rotational crop metabolism studies which were assessed in the framework of the EU pesticides peer review, it was concluded that the same metabolic pattern is observed across all rotational crops and that this corresponds with the findings in primary crops with clopyralid and conjugated clopyralid being the major residues (EFSA, 2018d). The studies covered three plant back intervals (PBI), with quantifiable amounts reported at PBI of 30 days (except for radish roots) and identification performed in all plant parts. Low amounts of radioactive residues were still detected at PBI of 125 days in soybeans (0.013 mg eq/kg), soybean plant (0.015 mg eq/kg) and wheat straw (0.015 mg eq/kg).” (EFSA, 2021)

Conclusion on metabolism in rotational crops

Metabolism in primary and rotational crops was found to be similar and a specific residue definition for rotational crops is not deemed necessary.

zRMS comments:

Information presented by Applicant is sufficient and acceptable.

zRMS-PL agrees that the same general residue definition set for primary crops can be applied to rotational crop.

The residue definition for monitoring and risk assessment for rotational crops: clopyralid common moiety (sum of clopyralid, its salts and conjugates expressed as clopyralid) – pending the outstanding clarification on the nature of ‘polar clopyralid.

EFSA concluded in EFSA Journal 2021;19(1):6389 that *Clopyralid is proposed to be used on crops that can be grown in rotation with other crops. It is considered to be low to medium persistent, forming no metabolites at levels triggering identification or further assessment; it does not accumulate in soil (EFSA, 2018d).*

From the rotational crop metabolism studies which were assessed in the framework of the EU pesticides peer review, it was concluded that the same metabolic pattern is observed across all rotational crops and that this corresponds with the findings in primary crops with clopyralid and conjugated clopyralid being the major residues (EFSA, 2018d). The studies covered three plant back intervals (PBI), with quantifiable amounts reported at PBI of 30 days (except for radish roots) and identification performed in all plant parts. Low amounts of radioactive residues were still detected at PBI of 125 days in soybeans (0.013 mg eq/kg), soybean plant (0.015 mg eq/kg) and wheat straw (0.015 mg eq/kg).

As residues in rotational crops cannot be excluded based on these findings, the peer review recommended that rotational crop field trials according to current guidelines should be submitted (EFSA, 2018d).

The EU pesticides peer review identified a data gap for the submission of rotational crop field trials according to current guidelines, since in the metabolism studies the residues of free and conjugated parent were found in all plant parts at PHI 30 days (except in radish roots) in soybean plant and wheat straw up to 0.015 mg eq/kg at PHI 120 days (EFSA, 2018).

In the absence of rotational crop field trials the applicant and EMS proposed to apply risk mitigation measures and to restrict the use for succeeding crops.

EFSA re-iterates the data gap from the EU pesticides peer review, to request rotational crop field studies to address this data requirement. Until these studies become available EFSA suggests, to risk managers, to label clopyralid containing products with the restriction not to use clopyralid on the same field for 125 days after the initial application, regardless of the crop grown, as the risk mitigation measure (EFSA Journal 2021;19(1):6389; Clopyralid-SANTE/10206/2021, Rev. 1, 20 May 2021).

Specific mitigation measures are recommended before planting succeeding crops – see point 7.3.6.1.
No additional data are required.

7.3.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

Reference: Finland, 2017; EFSA, 2018

The nature of residues under representative processing conditions (pasteurisation, baking/boiling/brewing, sterilisation) has been assessed. The results are shown in the table below.

No new data submitted in the framework of this application.

Table 7.3-5: 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%)	Finland, 2017 EFSA, 2018
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

“Clopyralid proved to be stable under pasteurisation, baking, brewing, boiling and sterilisation conditions.” (EFSA, 2018)

“Clopyralid is stable to processing hydrolysis under all conditions tested. Therefore, the nature of the residue is not expected to be altered during processing.” (Finland, 2017).

zRMS comments:

The effect of processing on the nature of clopyralid was investigated in the framework of the EU pesticides peer review (EFSA, 2018). The study showed that clopyralid is hydrolytically stable under standard processing

conditions.
No further data are required.

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

Table 7.3-6: Summary of the nature of residues in commodities of plant origin

Endpoints	
Plant groups covered	Root and tuber vegetables (Sugar beet) Leafy crops (Cabbage) Pulses and oilseeds (Oilseed rape)
Rotational crops covered	Root and tuber vegetables (Turnip, radish) Leafy vegetables (Lettuce, cabbage) Cereals (Wheat) Other (Soybean)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes (EFSA, 2018a)
Processed commodities	Clopyralid is stable under standard hydrolysis conditions
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes
Plant residue definition for monitoring	Existing residue definition of Regulation (EC) No 396/2005 : Clopyralid (Regulation (EU) ~~#2021/1807~~ 2024/2612) Clopyralid common moiety (sum of clopyralid, its salts and conjugates expressed as clopyralid) – pending the outstanding clarification on the nature of “polar clopyralid” (EFSA, 2018) EFSA, 2024: Cereals: Clopyralid common moiety (sum of clopyralid, its salts and conjugates expressed as clopyralid) (EFSA, 2021) [Wording of the existing residue definition and extension to other crop groups to be assessed in the MRL review].
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, 2018) EFSA, 2024: Cereals: Clopyralid common moiety (sum of clopyralid, its salts and conjugates expressed as clopyralid) (EFSA, 2021) [Wording of the existing residue definition and extension to other crop groups to be assessed in the MRL review].
Conversion factor from enforcement to RA	Residue definitions are the same, i.e. conversion factor is not needed. (Finland, 2017, EFSA, 2018)

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

Available data

Reference: Finland, 2017; EFSA, 2018

The metabolism of clopyralid in livestock animals was investigated in lactating ruminants (goat/cow) and laying poultry (hen) using ¹⁴C-clopyralid.

No new data submitted in the framework of this application.

Table 7.3-7: Summary of animal metabolism studies

Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling	
EU data								
Lactating ruminants	Goat/Cow	¹⁴ C-clopyra-lid	1	0.484	5	Milk	twice daily	Finland, 2017 EFSA, 2018
						Urine and faeces	daily	
						Tissues	at sacrifice	
Laying poultry	Hens	¹⁴ C-clopyra-lid	Not reported	0.56–0.65	7	Eggs	twice daily	Finland, 2017 EFSA, 2018
						Excreta	daily	
						Tissues	at sacrifice	

Summary of animal metabolism studies reported in the EU

“A new poultry nature of residue (NOR) study was conducted according to the current guideline requirements and also performed complete characterization on the tissues. Findings in this study for the tissue residues and the excretion and metabolite profiles were consistent with findings in a prior goat nature of residue study. Unchanged clopyralid was the major residue with a minor amount of X36538 in both studies.

In eggs plateau was not reached at the end of the experiment, and consequently the studies should be continued. Results indicate that clopyralid is minimally metabolized in laying hens. The majority of clopyralid is excreted unchanged. While a diminutive amount, 2.0% TRR and 0.0002 mg eq./kg is metabolized in eggs to the unidentified Metabolite 1.” (*Finland, 2017*)

“In a new submitted metabolism study by and (2015) clopyralid and its glycine conjugate were present as the primary residue in milk, in all tissues, in feces and in urine corresponding from 54 to over 112% of the TRR. X36538 was present only in subcutaneous fat, urine and feces at less than 2% of the TRR and in milk at from 11 to 22% of the TRR.

Clopyralid was identified by co-chromatography with a reference standard by HPLC and confirmed by LC/MS. There was no reference standard for X36538, and its identity was tentatively assigned by results obtained from LC/MS analysis and by reference to an earlier study in which it was observed.

Clopyralid is not metabolized in the goat, except for formation of small amounts of clopyralid glycine conjugate, X36538. Non-extractable or bound radioactivity in kidney was liberated as only clopyralid after treatment using base and acid treatment. While the non-extractable radioactivity from no samples other than kidney was treated with base and acid to release clopyralid, it was proposed that those non-extractable residues were likely to contain clopyralid and/or X36538.” (*Finland, 2017*)

“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.” (*EFSA, 2018*)

Conclusion on metabolism in livestock

The metabolism of clopyralid in livestock animals is sufficiently addressed to support the proposed uses

of product ADM.01851.H.1.A.

zRMS comments:

The information provided by the Applicant is sufficient and acceptable.

The residue definition for monitoring for animal: clopyralid (Reg. (EU) 2024/2612);
clopyralid and its salts (EFSA, 2018)
The residue definition for risk assessment for animal: clopyralid common moiety (sum of clopyralid, its
salts and glycine conjugates expressed as clopyralid)
(EFSA, 2018)

The metabolism of clopyralid in livestock is sufficiently addressed to support the proposed uses of
ADM.01851.H.1.A.

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

Table 7.3-8: Summary on the nature of residues in commodities of animal origin

	Endpoints
Animals covered	Lactating goats
	Laying hens
Time needed to reach a plateau concentration	1 days in milk
	7 days in eggs
Animal residue definition for monitoring	Clopyralid (Regulation (EU) ~~2021/1807~~ 2024/2612)
Animal residue definition for risk assessment	Sum of clopyralid, its salts and glycine conjugates expressed as clopyralid (EFSA 2018)
Conversion factor	1.3 only relevant for milk (EFSA, 2018)
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	No

7.3.3 Magnitude of residues in plants (KCA 6.3)

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

The intended cGAP for ADM.01851.H.1.A in sugar beet and fodder beet is less critical than the EU cGAP as shown in the table below.

All studies summarised in the Table 7.3-10 have been evaluated during the first approval of clopyralid and were considered acceptable. No new studies are submitted.

Table 7.3-9: Comparison of intended and critical EU GAPs

Type of GAP	Region	Crop	Number of applications	Application rate per treatment (kg a.s./ha)	Interval between applications [min. days]	Growth stage at last application	PHI (days)	Remark
cGAP EU (Finland, 2005)	N-EU (UK, Ireland)	Sugar beet	2	0.100 + 0.200	21	BBCH 10	n.a.	
	N-EU	Sugar beet	2	0.100 + 0.200	21	BBCH 10-39	n.a.	
Intended cGAP (number 1)	N-EU	Sugar beet, fodder beet	3	0.0495	5	BBCH 10-19	n.a.	Total rate per season 2 L/ha. Max rate of ethofumesate should not exceed 1.0 kg/ha every 3 years

n.a.; the PHI is covered by the time remaining between application and harvest

Table 7.3-10: Summary of EU reported data supporting the intended uses of ADM.01851.H.1.A and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Sugar beet → extrapolated to fodder beet	Finland, 2005	N-EU	GAP on which EU a.s. assessment is based: 1 x 0.1 + 1 x 0.2 kg as/ha, 21 days interval, BBCH 10-39, outdoor Roots: RA: 0.12 0.17, 0.21, 0.29, 0.34, 0.35, 0.36, 0.41, 0.56, 0.80 Tops: RA: 0.13, 0.14, 0.23, 0.36, 0.46, 2 x 0.47, 0.57, 0.62, 1.05	N/A				
	Overall supporting data for cGAP (3 x 0.0495 kg as/ha, 5d interval, BBCH 10-19)	N-EU	Roots: 0.12, 0.17, 0.21, 0.29, 0.34, 0.35, 0.36, 0.41, 0.56, 0.80 Tops: 0.13, 0.14, 0.23, 36, 0.46, 2 x 0.47, 0.57, 0.62, 1.05	Roots: 0.345 Tops: 0.465	Roots: 0.80 Tops: 1.05	1.158**	1	Yes**

* Source of EU MRL: Reg. (EU) ~~2021/1807~~ 2024/2612

** The MRL was recalculated in this dossier with the OECD MRL Calculator from 2020 which was not applicable at the time of first approval of clopyralid. The current MRL of 1 mg/kg for sugar beet was set based on the residue trials summarised in this table and the Rber/Rmax calculation approach and therefore does not need to be increased. All residues of clopyralid in sugar beet roots were below the MRL. Thus, MRL compliance is concluded.

E Enforcement residue definition according to Reg. (EU) ~~2021/1807~~ 2024/2612 is clopyralid

RA Clopyralid common moiety (sum of clopyralid, its salts and conjugates expressed as clopyralid) (EFSA, 2018). This residue definition was proposed by EFSA 2018 also as enforcement residue definition.

7.3.3.2 Conclusion on the magnitude of residues in plants

Ten EU reviewed residue trials on sugar beet are available to support the intended cGAP (3 x 0.0495 kg as/ha, 5d interval between applications, BBCH 10-19), four of these trials were decline trials. The intended cGAP is within the risk envelope of the trials GAP (the last application with 0.2 kg as/ha was four times more than a single application in the intended cGAP and 35% higher than the total rate of the intended GAP, and was conducted at a later growth stage than intended, therefore this is considered to represent a worst-case), the data from which were used as the basis of the EU MRL. Since the trials were performed with a higher overall application rate and a later timing of application they can be considered to be more critical than the intended cGAP and no further data are required. The trials are overdosed and clearly show an acceptable risk assessment and no exceedance of the MRL – and therefore the same conclusion can be made for the intended GAP.

The residue trials were conducted with an SL formulation whereas the product under consideration in this dossier is an SC formulation. According to SANTE/2019/12752 Rev.1 and the OECD Guidance Document on Crop Field Trials, 2016 as well as OECD Test Guideline No. 509, 2021, these formulations are diluted in water and can be considered comparable.

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

Residue data for sugar beet covers also application on fodder beet and thus the residues are taken into account for the livestock dietary burden calculation.

The current MRL of 1 mg/kg for sugar beet was set based on the residue trials summarised in the table above. All residues of clopyralid in sugar beet roots were below the MRL. Thus, MRL compliance is concluded.

zRMS comments:

Sugar beet is the major crops in northern Europe (SANTE/2019/12752). A minimum of eight independent trials representative of the proposed growing area for outdoor are required.

The intended cGAP for ADM.01851.H.1.A in sugar beet and fodder beet is less critical than the EU cGAP GAP on which EU a.s. assessment is based: 1 x 0.1 + 1 x 0.2 kg as/ha, 21 days interval, BBCH 10-39, outdoor; intended cGAP for ADM.01851.H.1.A is: 3 x 0.0495 kg as/ha, 5d interval, BBCH 10-19.

No new studies are submitted by the Applicant. All studies have been evaluated during the first approval of clopyralid and were considered acceptable.

A total of 10 supervised residue trials with clopyralid have been carried out on sugar beet in open field conditions in Northern. The majority of trials have been conducted by using EF-1136 formulation containing 100 g/L clopyralid. The trials are overdosed and are considered to represent a worst-case.

Residues of clopyralid found in the treated sugar beet roots samples ranged from 0.12 to 0.80 mg/kg (10 NEU trials: 0.12, 0.17, 0.21, 0.29, 0.34, 0.35, 0.36, 0.41, 0.56, 0.80 mg/kg).

Residues of clopyralid found in the treated sugar beet tops samples ranged from 0.13 to 1.05 mg/kg (10 NEU trials: 0.13, 0.14, 0.23, 0.36, 0.46, 2 x 0.47, 0.57, 0.62, 1.05 mg/kg).

According to the SANTE/2019/12752 the residue trials on sugar beets (0900010) may be extrapolated to fodder beets.

It should be noted that the MRL value was recalculated in this dossier with the OECD MRL Calculator from 2020 which was not applicable at the time of first approval of clopyralid. The current MRL of 1 mg/kg for sugar beet was set based on the residue trials summarised in this table and the Rber/Rmax calculation approach and therefore does not need to be increased. All residues of clopyralid in sugar beet roots were below the MRL. Thus, MRL compliance is concluded.

Conclusion:

Available results show that the in force MRL of clopyralid on sugar beets of 1 mg/kg (Reg. (EU) 2024/2612) will not be exceeded. The current EU MRLs for clopyralid are sufficient to support the proposed use.

Therefore, sufficient residue trials are available to support the intended GAP uses on sugar beets and fodder beets.

7.3.4 Magnitude of residues in livestock

7.3.4.1 Dietary burden calculation

The peer review of MRLs according to Article 12 of Reg No 396/2005 EC is still pending. The input values for the dietary burden calculation have been taken from the most recent EFSA Reasoned Opinion (Modification of the existing MRLs for clopyralid in various commodities, EFSA, 2021). The uses under consideration in this dossier are covered with this calculation, because sugar beet and fodder beet input values were based on the magnitude of residue trials presented in this dossier. Also, residue values from the new rotational crop study from EFSA 2024 MRL evaluation (see Section 7.3.6.1) were included in this calculation. The addition of residues arising from rotational crops and based on the GAP under consideration, does not modify the livestock dietary burden from that calculated in EFSA, 2021 and no further consideration of residues in products of animal origin is required.

Table 7.3-11: Input values for the dietary burden calculation (considering the uses evaluated during MRL setting procedure in EU and the uses under consideration)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: Clopyralid common moiety (sum of clopyralid, its salts and glycine conjugates expressed as clopyralid)				
Alfalfa, forage	0.01	STMR (rotated pulse/oilseed whole plant – current evaluation)	0.21	HR (rotated pulse/oilseed whole plant – current evaluation)
Alfalfa hay, meal	0.025	STMR (rotated pulse/oilseed whole plant – current evaluation) x default PF	0.53	HR (rotated pulse/oilseed whole plant – current evaluation) x default PF
Alfalfa, silage	0.011	STMR (rotated pulse/oilseed whole plant – current evaluation) x default PF	0.23	HR (rotated pulse/oilseed whole plant – current evaluation) x default PF
Barley, forage	0.12	STMR (rotated cereal whole plant – current evaluation)	0.58	HR (rotated cereal whole plant – current evaluation)
Barley, straw	0.91	STMR (EFSA, 2021)	1.86	HR (EFSA, 2021)
Barley, silage	0.16	STMR (rotated cereal whole plant – current evaluation) x default PF	0.75	HR (rotated cereal whole plant – current evaluation) x default PF
Bean, vines	0.01	STMR (rotated pulse/oilseed whole plant – current evaluation)	0.21	HR (rotated pulse/oilseed whole plant – current evaluation)
Beet mangel, fodder	0.47	STMR (EFSA, 2005)	1.05	HR (EFSA, 2005)
Beet, sugar (tops)	0.47	STMR (EFSA, 2005)	1.05	HR (EFSA, 2005)
Cabbage, heads (leaves)	0.23	STMR (EFSA, 2011)	1.52	HR (EFSA, 2011)
Clover, forage, silage	0.01	STMR (rotated pulse/oilseed whole plant – current evaluation)	0.21	HR (rotated pulse/oilseed whole plant – current evaluation)
Clover, hay	0.03	STMR (rotated pulse/oilseed whole plant – current evaluation) x default PF	0.63	HR (rotated pulse/oilseed whole plant – current evaluation) x default PF
Corn, field (forage/silage)	0.12	STMR (rotated cereal whole plant – current evaluation)	0.58	HR (rotated cereal whole plant – current evaluation)
Corn,field (stover)	0.46	STMR (Finland, 2018b)	0.88	HR (Finland, 2018b)
Corn, pop (stover)	0.46	STMR (Finland, 2018b)	0.88	HR (Finland, 2018b)
Cowpea, forage	0.01	STMR (rotated pulse/oilseed	0.21	HR (rotated pulse/oilseed

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
		whole plant – current evaluation)		whole plant – current evaluation)
Cowpea, hay	0.029	STMR (rotated pulse/oilseed whole plant – current evaluation) x default PF	0.61	HR (rotated pulse/oilseed whole plant – current evaluation) x default PF
Grass, forage (fresh)	7.08	STMR (EFSA, 2021)	15.16	HR (EFSA, 2021)
Grass, hay	24.78	STMR (EFSA, 2021) x default PF	53.2	HR (EFSA, 2021) x default PF
Grass, silage	11.33	STMR (EFSA, 2021) x default PF	24.32	HR (EFSA, 2021) x default PF
Kale	1	MRL	1	MRL
Lespedeza, forage	0.01	STMR (rotated pulse/oilseed whole plant – current evaluation)	0.21	HR (rotated pulse/oilseed whole plant – current evaluation)
Lespedeza, hay	0.04	STMR (rotated pulse/oilseed whole plant – current evaluation) x default PF	0.84	HR (rotated pulse/oilseed whole plant – current evaluation) x default PF
Millet, forage	0.12	STMR (rotated cereal whole plant – current evaluation)	0.58	HR (rotated cereal whole plant – current evaluation)
Millet, straw	0.13	STMR (rotated cereal straw – current evaluation)	0.28	HR (rotated cereal straw – current evaluation)
Oat, forage	0.12	STMR (rotated cereal whole plant – current evaluation)	0.58	HR (rotated cereal whole plant – current evaluation)
Oat, hay	0.36	STMR (rotated cereal whole plant – current evaluation) x default PF	1.74	HR (rotated cereal whole plant – current evaluation) x default PF
Oat, straw	0.58	STMR (EFSA, 2021)	2.17	HR (EFSA, 2021)
Pea, vines (green)	0.01	STMR (rotated pulse/oilseed whole plant – current evaluation)	0.21	HR (rotated pulse/oilseed whole plant – current evaluation)
Pea, hay (fodder)	0.035	STMR (rotated pulse/oilseed whole plant – current evaluation) x default PF	0.74	HR (rotated pulse/oilseed whole plant – current evaluation) x default PF
Pea, silage	0.016	STMR (rotated pulse/oilseed whole plant – current evaluation) x default PF	0.34	HR (rotated pulse/oilseed whole plant – current evaluation) x default PF
Rape, forage	0.01	STMR (rotated pulse/oilseed whole plant – current evaluation)	0.21	HR (rotated pulse/oilseed whole plant – current evaluation)
Rye, forage	0.12	STMR (rotated cereal whole plant – current evaluation)	0.58	HR (rotated cereal whole plant – current evaluation)
Rye, straw	0.58	STMR (EFSA, 2021)	2.17	HR (EFSA, 2021)
Sorghum, forage	0.12	STMR (rotated cereal whole plant – current evaluation)	0.58	HR (rotated cereal whole plant – current evaluation)
Sorghum, stover	0.13	STMR (rotated cereal straw – current evaluation)	0.28	HR (rotated cereal straw – current evaluation)
Sorghum, silage	0.072	STMR (rotated cereal whole plant – current evaluation) x default PF	0.35	HR (rotated cereal whole plant – current evaluation) x default PF
Soybean, forage (green)	0.01	STMR (rotated pulse/oilseed	0.21	HR (rotated pulse/oilseed

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
		whole plant – current evaluation)		whole plant – current evaluation)
Soybean, hay (fodder)	0.015	STMR (rotated pulse/oilseed whole plant – current evaluation) x default PF	0.32	HR (rotated pulse/oilseed whole plant – current evaluation) x default PF
Soybean, silage	0.005	STMR (rotated pulse/oilseed whole plant – current evaluation) x default PF	0.11	HR (rotated pulse/oilseed whole plant – current evaluation) x default PF
Trefoil, forage	0.01	STMR (rotated pulse/oilseed whole plant – current evaluation)	0.21	HR (rotated pulse/oilseed whole plant – current evaluation)
Trefoil, hay	0.028	STMR (rotated pulse/oilseed whole plant – current evaluation) x default PF	0.59	HR (rotated pulse/oilseed whole plant – current evaluation) x default PF
Triticale, forage	0.12	STMR (rotated cereal whole plant – current evaluation)	0.58	HR (rotated cereal whole plant – current evaluation)
Triticale, hay	0.35	STMR (rotated cereal whole plant – current evaluation) x default PF	1.68	HR (rotated cereal whole plant – current evaluation) x default PF
Triticale, straw	0.58	STMR (EFSA, 2021)	2.17	HR (EFSA, 2021)
Turnip, tops (leaves)	0.47	STMR (EFSA, 2005)	1.05	HR (EFSA, 2005)
Vetch, forage	0.01	STMR (rotated pulse/oilseed whole plant – current evaluation)	0.21	HR (rotated pulse/oilseed whole plant – current evaluation)
Vetch, hay	0.028	STMR (rotated pulse/oilseed whole plant – current evaluation) x default PF	0.59	HR (rotated pulse/oilseed whole plant – current evaluation) x default PF
Wheat, forage	0.12	STMR (rotated cereal whole plant – current evaluation)	0.58	HR (rotated cereal whole plant – current evaluation)
Wheat, hay	0.42	STMR (rotated cereal whole plant – current evaluation) x default PF	2.03	HR (rotated cereal whole plant – current evaluation) x default PF
Wheat, straw	0.58	STMR (EFSA, 2021)	2.17	HR (EFSA, 2021)
Carrot, culls	0.01	STMR (rotated root and tuber, roots – current evaluation)	0.042	HR (rotated root and tuber, roots – current evaluation)
Cassava/tapioca, roots	0.01	STMR (rotated root and tuber, roots – current evaluation)	0.042	HR (rotated root and tuber, roots – current evaluation)
Potato, culls	0.01	STMR (rotated root and tuber, roots – current evaluation)	0.042	HR (rotated root and tuber, roots – current evaluation)
Swede, roots	0.35	STMR (EFSA, 2011)	0.80	HR (EFSA, 2011)
Turnip, roots	0.35	STMR (EFSA, 2011)	0.80	HR (EFSA, 2011)
Barley, grain	0.33	STMR (EFSA, 2021)	0.33	STMR (EFSA, 2021)
Maize,field (grain)	0.06	STMR (Finland, 2018b)	0.06	STMR (Finland, 2018b)
Maize, pop (grain)	0.06	STMR (Finland, 2018b)	0.06	STMR (Finland, 2018b)
Cotton	0.5	MRL	0.5	MRL
Millet, grain	0.044	STMR (rotated cereal grain –	0.044	STMR (rotated cereal grain

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
		current evaluation)		– current evaluation)
Oat, grain	0.72	STMR (EFSA, 2021)	0.72	STMR (EFSA, 2021)
Pea, seed (dry)	0.5	MRL	0.5	MRL
Rye, grain	0.72	STMR (EFSA, 2021)	0.72	STMR (EFSA, 2021)
Sorghum, grain	0.044	STMR (rotated cereal grain – current evaluation)	0.044	STMR (rotated cereal grain – current evaluation)
Soybean seed	0.5	MRL	0.5	MRL
Triticale, grain	0.72	STMR (EFSA, 2021)	0.72	STMR (EFSA, 2021)
Wheat, grain	0.72	STMR (EFSA, 2021)	0.72	STMR (EFSA, 2021)
Apple, pomace (wet)	0.05	STMR (EFSA, 2005) x default PF	0.05	STMR (EFSA, 2005) x default PF
Beet, sugar (dried pulp)	6.30	STMR (EFSA, 2005) x default PF	6.30	STMR (EFSA, 2005) x default PF
Beet, sugar (ensiled pulp)	1.05	STMR (EFSA, 2005) x default PF	1.05	STMR (EFSA, 2005) x default PF
Beet, sugar (molasses)	9.80	STMR (EFSA, 2005) x default PF	9.80	STMR (EFSA, 2005) x default PF
Brewer's grain,dried	1.09	STMR (EFSA, 2021) x default PF	1.09	HR (EFSA, 2021) x default PF
Canola (rapeseed), meal	0.06	STMR (Finland, 2018b) x default PF	0.06	STMR (Finland, 2018b) x default PF
Citrus, dried pulp	5	MRL x default PF	5	MRL x default PF
Corn, field (milled by-products)	0.06	STMR (Finland, 2018b) x default PF	0.06	STMR (Finland, 2018b) x default PF
Corn, field (hominy meal)	0.36	STMR (Finland, 2018b) x default PF	0.36	STMR (Finland, 2018b) x default PF
Corn, field (gluten feed)	0.15	STMR (Finland, 2018b) x default PF	0.15	STMR (Finland, 2018b) x default PF
Corn, field (gluten meal)	0.06	STMR (Finland, 2018b) x default PF	0.06	STMR (Finland, 2018b) x default PF
Cotton, meal	0.65	MRL x default PF	0.65	MRL x default PF
Distiller grain, dried	2.38	STMR (EFSA, 2021) x default PF	2.38	HR (EFSA, 2021) x default PF)
Flaxseed/Linseed, meal	8.92	STMR (EFSA, 2011) x default PF	8.92	STMR (EFSA, 2011) x default PF
Peanut, meal	1	MRL x default PF	1	MRL x default PF
Potato, process waste	0.20	STMR (rotated root and tuber, roots – current evaluation) x default PF	0.20	STMR (rotated root and tuber, roots – current evaluation) x default PF
Potato, dried pulp	0.38	STMR (rotated root and tuber, roots – current evaluation) x default PF	0.38	STMR (rotated root and tuber, roots – current evaluation) x default PF
Rape meal	0.06	MRL x default PF	0.06	MRL x default PF
Soybean, meal	0.65	MRL x default PF	0.65	MRL x default PF
Soybean, hulls	6.50	MRL x default PF	6.50	MRL x default PF
Sunflower meal	1	MRL x default PF	1	MRL x default PF

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Wheat gluten, meal	1.3	STMR (EFSA, 2021) x default PF	1.3	HR (EFSA, 2021) x default PF
Wheat, milled byproducts	5.04	STMR (EFSA, 2021) x default PF	5.04	HR (EFSA, 2021) x default PF

Table 7.3-12: Results of the dietary burden calculation

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Risk assessment residue definition: Clopyralid common moiety (sum of clopyralid, its salts and glycine conjugates expressed as clopyralid)					
Beef cattle*	0.4028	0.836	Grass forage (fresh)	34.83	Y
Dairy cattle*	0.7612	1.521	Grass forage (fresh)	39.55	Y
Ram/ewe	0.9137	1.934	Grass forage (fresh)	58.0	Y
Lamb	0.7384	1.452	Grass forage (fresh)	34.16	Y
Breeding swine	0.221	0.407	Grass forage (fresh)	17.62	Y
Finishing swine*	0.130	0.185	Swede roots	6.16	Y
Broiler poultry	0.146	0.178	Swede roots	2.52	Y
Layer poultry*	0.145	0.204	Cabbage heads, leaves	2.98	Y
Turkey	0.142	0.174	Swede roots	2.47	Y

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

zRMS comments:

Calculations presented by Applicant are sufficient and acceptable.

The calculated dietary burdens for all groups of livestock were found to exceed the trigger value of 0.004 mg/kg bw/day. Further investigation of clopyralid residues is therefore required in all commodities of animal origin.

7.3.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Available data

Reference: Finland, 2017; EFSA, 2018

Significant intakes (>0.004 mg/kg bw/day) were calculated for livestock. Metabolism and feeding studies in poultry and ruminants were presented in the RAR (*Finland, 2017*). No feeding study in pigs is required because metabolic pathways in the rat, in ruminants and in poultry are similar (*Finland, 2017*).

Reference: EFSA, 2021

For modification of the existing MRLs for clopyralid in various commodities, an updated dietary burden calculation was performed with the currently applicable calculator, Animal model 2017. New MRLs in animal commodities were proposed based on the new calculation and the feeding studies evaluated during the renewal of clopyralid. (*EFSA, 2021*) Sugar beet and fodder beet input values are based on the magnitude of residue trials presented in the DAR (*Finland, 2005*).

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

Summary of animal feeding studies reported in the EU

“The feeding studies with lactating cows and laying hens were assessed in the framework of the EU pesticides peer review (EFSA, 2018d). The analytical method used in the two studies was sufficiently validated. It employs a hydrolysis step with sodium hydroxide converting all eventually present conjugates into clopyralid. Higher values are not expected as conjugates are only found in milk.

Hens were dosed orally with clopyralid at 0, 4.90 (19), 10.26 (29) 19.82 (49) and 50.5 (109) mg/kg DM feed/day for 28 or 29 consecutive days, corresponding to approximately 0, 0.280, 0.571, 1.086 and 2.779 mg/kg bw per day, respectively. Plateau in eggs was reached after 7 days.

Residues of clopyralid in muscle, liver and eggs increased from the lowest to highest dose groups, with residues in the liver present above LOQ in all treatment groups. No residues of clopyralid above the LOQ were found in the fat in any treatment group. Residues of clopyralid in the tissues and eggs of the depuration animals fell to below the LOQ 3 days after withdrawal of the test item from the hens' diet.

Lactating cows were dosed orally with clopyralid at 0, 16.70, 56.60, 309.80 and 1,019.5 mg ai/kg DM feed/day for 28 or 29 consecutive days, corresponding to approximately 0, 0.451, 1.670, 8.517 and 30.538 mg/kg bw per day, respectively. Residues above the LOQ were found in liver and kidney at the lowest dose group, in milk, fat and muscle from the second dose group onwards. A plateau was reached in milk within 1 day. Residues of clopyralid declined rapidly following withdrawal of the test item from the cows' diet.

The dietary burdens calculated in the framework of the current assessment were compared with the feeding levels of available feeding studies in order to estimate whether the existing animal commodity MRLs would need to be modified.” (EFSA, 2021)

An increase of MRL was proposed for swine kidney as well as bovine, sheep and goat fat, liver and kidney (EFSA, 2021). These proposals were implemented in the currently applicable MRL Regulation (Reg. (EU) ~~2021/1807~~ 2024/2612).

Table 7.3-13: Overview of the values derived from livestock feeding studies

Commodity	Dietary burden		Results of the livestock feeding study						Median residue (mg/kg) ^(b)	Highest residue (mg/kg) ^(c)	Calculated MRL (mg/kg)	CF for RA ^(d)
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level (mg/kg bw/d)	No	Result for enforcement		Result for RA					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
EU data (Finland, 2017; EFSA, 2018)												
Enforcement residue definition: Clopyralid (Regulation (EU) °2024/2612)												
Clopyralid and its salts OR clopyralid common moiety (sum of clopyralid, its salts and glycine conjugates expressed as clopyralid) (EFSA, 2018d)												
Risk assessment residue definition: Sum of clopyralid, its salts and glycine conjugates expressed as clopyralid (EFSA 2018)												
Pig meat	0.221	0.407	0.451	4	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0.01*	-
			1.670	4	0.023	0.029	0.023	0.029				
			8.517	4	0.104	0.113	0.104	0.113				
Pig fat	0.221	0.407	0.451	4	0.013	0.020	0.013	0.020	0.01	0.05	0.05	-
			1.670	4	0.062	0.149	0.062	0.149				
			8.517	4	0.320	0.635	0.320	0.635				
Pig liver	0.221	0.407	0.451	4	0.032	0.036	0.032	0.036	0.02	0.05	0.05	-
			1.670	4	0.112	0.145	0.112	0.145				
			8.517	4	0.502	0.560	0.502	0.560				
Pig kidney	0.221	0.407	0.451	4	0.429	0.606	0.429	0.606	0.21	0.55	0.6	-
			1.670	4	1.460	1.559	1.460	1.559				
			8.517	4	5.100	6.030	5.100	6.030				
Ruminant meat	0.9137	1.934	0.451	4	<0.01	<0.01	<0.01	<0.01	0.02	0.03	0.04	-
			1.670	4	0.023	0.029	0.023	0.029				
			8.517	4	0.104	0.113	0.104	0.113				
Ruminant fat	0.9137	1.934	0.451	4	0.013	0.020	0.013	0.020	0.06	0.17	0.2	-
			1.670	4	0.062	0.149	0.062	0.149				
			8.517	4	0.320	0.635	0.320	0.635				
Ruminant liver	0.9137	1.934	0.451	4	0.032	0.036	0.032	0.036	0.06	0.17	0.2	-
			1.670	4	0.112	0.145	0.112	0.145				

Commodity	Dietary burden		Results of the livestock feeding study						Median residue (mg/kg) ^(b)	Highest residue (mg/kg) ^(c)	Calculated MRL (mg/kg)	CF for RA ^(d)
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level (mg/kg bw/d)	No	Result for enforcement		Result for RA					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
			8.517	4	0.502	0.560	0.502	0.560				
Ruminant kidney	0.9137	1.934	0.451	4	0.429	0.606	0.429	0.606	0.87	1.81	2	-
			1.670	4	1.460	1.559	1.460	1.559				
			8.517	4	5.100	6.030	5.100	6.030				
Poultry meat	0.146	0.204	0.280	3	<0.01	0.011	<0.01	0.011	<0.01	<0.01	0.01*	-
			0.571	3	<0.01	0.011	<0.01	0.011				
			1.086	3	<0.01	<0.01	<0.01	<0.01				
Poultry fat	0.146	0.204	0.280	3	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0.01*	-
			0.571	3	<0.01	<0.01	<0.01	<0.01				
			1.086	3	<0.01	<0.01	<0.01	<0.01				
Poultry liver	0.146	0.204	0.280	3	0.019	0.032	0.019	0.032	0.01	0.02	0.03	-
			0.571	3	0.023	0.033	0.023	0.033				
			1.086	3	0.017	0.027	0.017	0.027				
Milk	0.9137	1.934	0.451	36	<0.01 ^(e)	N/A	<0.01 ^(e)	N/A	<0.01	0.01	0.015	-
			1.670	36	<0.01 ^(e)	N/A	<0.01 ^(e)	N/A				
			8.517	36	0.040 ^(e)	N/A	0.040 ^(e)	N/A				
Eggs	0.145	0.204	0.280	30	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0.01*	-
			0.571	30	<0.01	0.011	<0.01	0.011				
			1.086	30	0.011	0.018	0.011	0.018				

N/A: Not applicable – only the mean values are considered for calculating MRLs in milk.

(*): Indicates that the MRL is set at the limit of analytical quantification.

(b): Median residue value according to the enforcement residue definition, derived by interpolation/extrapolation from the feeding study for the median dietary burden (FAO, 2009).

(c): Highest residue value (tissues, eggs) or mean residue value (milk) according to the enforcement residue definition, derived by interpolation/extrapolation of the maximum dietary burden between the relevant feeding groups of the study (FAO, 2009).

(d): The median conversion factor for enforcement to risk assessment.

(e): Mean residue level from day 2 until day 28/29 (4 cows, 9 sampling days).

Conclusion on feeding studies

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

zRMS comments:

Information presented by Applicant are sufficient.

The requested uses and the new mode of calculation do not modify the theoretical maximum daily intake for animals. Regarding available feeding data, there is no risk for animal MRL to be exceeded (Commission Regulation (EU) 2024/2612).

No additional data are required.

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

7.3.5.1 Available data for all crops under consideration

Clopyralid is stable under pasteurisation, baking, brewing, boiling and sterilisation conditions (EFSA, 2018a).

New processing studies have been submitted by the Data owner Corteva Agriscience (letter of access provided). These studies are summarized in the table below.

Table 7.3-14: Overview of the available processing studies

Processed commodity	Number of studies	Median PF *	Median CF **	Comments	Reference
EU data					
Sum of clopyralid, its salts and conjugates, expressed as clopyralid					
Wheat / bran	4	5.7	N/A	-	EFSA, 2021
Wheat / white flour	4	0.25	N/A	-	EFSA, 2021
Wheat / wholemeal flour	2	1	N/A	-	EFSA, 2021
Wheat / germ	2	3.3	N/A	-	EFSA, 2021
Wheat / white bread	2	0.1	N/A	-	EFSA, 2021
Wheat / wholemeal bread	2	0.6	N/A	-	EFSA, 2021
Barley / malt sprouts	2	0.2	N/A	-	EFSA, 2021
Barley / brewing malt	2	0.7	N/A	-	EFSA, 2021
Barley / spent grains and flocs	2	0.2	N/A	-	EFSA, 2021
Barley / brewer's yeast	2	0.1	N/A	-	EFSA, 2021
Barley / beer	2	0.1	N/A	-	EFSA, 2021
Oilseed rape / oil	15	0.1	NA	-	EFSA, 2005
New data					
Sugar beet / pulp	3	0.7	N/A	-	Report GH-C 3305 and Report No. 181493
Sugar beet / molasses	3	4.4	N/A	-	
Sugar beet / brown sugar	2	0.9	N/A	-	
Sugar beet / sugar juice	2	0.5	N/A	-	
Sugar beet / non-refined sugar	2	4.1	N/A	-	
Sugar beet / white sugar	3	0.3	N/A	-	

* The median processing factor is obtained by calculating the median of the individual processing factors of each processing study.

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

7.3.5.2 Conclusion on processing studies

Clopyralid residues in sugar beet root are above 0.1 mg/kg, thus processing studies are required. Data on sugar beet and wheat processed commodities summarised above can be used to refine dietary burden and consumer intakes where necessary. Default processing factors can be used for all other commodities.

zRMS comments:

Processing data were evaluated in the EU review for clopyralid for wheat and barley (EFSA, 2018). Processing studies are normally required if the supervised residue trials reveal that the total residues in commodities exceed the trigger value of 0.1 mg/kg, or if the total Theoretical Maximum Daily Intake (TMDI) is more than 10% of the ADI.

Based on these data requirements, processing studies are required for sugar beet.

Sugar beet (new data)

Two processing studies have been evaluated and accepted by zRMS-PL in RR – Part B7 for EF-243/ Lontrel 300 (February 2023, Applicant: Corteva Agriscience).

The studies demonstrate that clopyralid residues concentrate in sugar beet /molasses and sugar beet /non-refined sugar whereas a reduction is observed in other processed commodities of sugar beet.

No additional data are required.

Remark:

Processing factors (PF) derived for sugar beet were not used neither in the dietary burden calculation nor in the consumer risk assessment calculation. More critical default PF were used instead.

7.3.6 Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation.

Considering available data dealing with nature of residues (see 7.2.2.2), a study dealing with magnitude of residues in succeeding crops is needed.

7.3.6.1 Field rotational crop studies (KCA 6.6.2)

Available data (EFSA 2024)

No new data were submitted in the framework of this application. A study submitted to EU (EFSA, 2024) by Corteva Agriscience (letter of access is provided) is summarised in the table below.

Table 7.3-15: Summary of available studies in field rotational crops

Table 7.5.15: Summary of available studies in field rotational crops					
Primary crop	Rate (g ae/ha) (GS at application or PHI)	Residue levels in succeeding crops			
		Succeeding crop group	Succeeding crop	Sowing intervals (DAT)	Reference / Remarks
EU data					
Bare soil	3 rates: 60, 80, 125 (1 application to achieve targeted plantback intervals)	Leafy and Brassica vegetables	Head cabbage	30, 90, 125, 270- 365	Devine, C., 2021, Study No. 190557
		Root and tuber vegetables	Radish		
		Oilseeds	Oilseed rape, Sunflower		
		Cereals	Barley, Wheat		

EFSA conclusion, 2024

“A new field study investigating the magnitude of clopyralid residues in rotational crops was submitted in the framework of the present application and the EMS assessed this study in its evaluation report

(Finland, 2023).

In all trials, the protocol started with one application of clopyralid on bare soil. In each trial, different application rates were tested (60, 80 or 125 g a.s./ha). The application on bare soil was followed by planting crops (radish, cabbage, oilseed rape, wheat, barley and sunflower) at different plant back intervals (30, 90, 125 and 270–365 days).

It is noted that the highest application rate tested (125 g a.s./ha) corresponds to the critical GAP on oilseed rape, identified by the applicant as the worst-case authorised GAP with respect to residues in honey. Overall, residue uptakes were found in cereals (grain and straw) at all investigated PBIs, as well as in root crops (roots and tops) and in aerial parts of oilseed plants (only at short PBIs). Regarding leafy crops or oilseed (seed parts), the available results indicate that no residues uptakes are expected, even at the shortest PBI (30 days) and highest investigated application rate (125 g a.s./ha on bare soil).

Regarding the potential residue uptakes in cereals and root crops, the need for deriving MRLs or implementing risk mitigation measures (as proposed by EMS) should be assessed in the framework of the MRL review to be carried out under Article 12 of Reg (EU) 396/2005.”

A summary of the residues from this study is given below:

Table 7.3-16: Summary of residue values in the field rotational crops study

Crop Group/Representative Crop matrix	Rate g as/ha	Clopyralid residues (mg/kg) per Plant-back interval (days) ^(a)			
		30	90	125	270-365
Leafy and Brassica Vegetables / Head Cabbage	60	6 x <0.01	6 x <0.01	6 x <0.01	6 x <0.01
	80	6 x <0.01	6 x <0.01	6 x <0.01	6 x <0.01
	125	6 x <0.01	6 x <0.01	6 x <0.01	6 x <0.01
Root and Tuber vegetables / Radish root	60	5 x <0.01*, 0.041 (STMR 0.010)	6 x <0.01 †	6 x <0.01	6 x <0.01
	80	6 x <0.01*	6 x <0.01 †	6 x <0.01	6 x <0.01
	125	4 x <0.01*, 0.027, 0.042 (STMR 0.010)	6 x <0.01 †	6 x <0.01	6 x <0.01
Tops of Root and Tuber vegetables / Radish tops with leaves	60	4 x <0.01*, 0.17, 0.38 (STMR 0.010)	6 x <0.01 †	6 x <0.01	6 x <0.01
	80	4 x <0.01*, 0.17, 0.52 (STMR 0.010)	5 x <0.01 †, 0.025 (STMR 0.010)	6 x <0.01	6 x <0.01
	125	3 x <0.01, 0.017**, 0.54, 0.63 (STMR 0.010)	6 x <0.01 †	6 x <0.01	6 x <0.01
Oilseeds / Oilseed rape and Sunflower whole plant	60	4 x <0.01, 0.086, 0.15 (STMR 0.010)	6 x <0.01	6 x <0.01	6 x <0.01
	80	4 x <0.01, 0.11, 0.21 (STMR 0.010)	6 x <0.01	6 x <0.01	6 x <0.01
	125	4 x <0.01, 0.097, 0.11 (STMR 0.010)	6 x <0.01	6 x <0.01	6 x <0.01
Oilseeds / Oilseed rape and Sunflower seed	60	6 x <0.01	6 x <0.01	5 x <0.01	6 x <0.01
	80	6 x <0.01	6 x <0.01	6 x <0.01	6 x <0.01
	125	6 x <0.01	6 x <0.01	6 x <0.01	6 x <0.01
Oilseeds / Oilseed rape and Sunflower rest of plant	60	4 x <0.01, 0.022, 0.023 (STMR 0.010)	6 x <0.01	5 x <0.01	6 x <0.01
	80	4 x <0.01, 0.024, 0.075 (STMR 0.010)	6 x <0.01	6 x <0.01	6 x <0.01
	125	3 x <0.01, 0.015, 0.027, 0.089 (STMR 0.013)	6 x <0.01	6 x <0.01	6 x <0.01
Cereals / Barley and Wheat whole plant	60	3 x <0.01, 0.018, 0.083, 0.21 (STMR 0.014)	4 x <0.01, 0.012, 0.028 (STMR 0.010)	6 x <0.01	6 x <0.01
	80	3 x <0.01, 0.029, 0.14, 0.56 (STMR 0.020)	6 x <0.01	6 x <0.01	5 x <0.01, 0.017 (STMR 0.010)
	125	2 x <0.01, 0.034, 0.20, 0.52, 0.58 (STMR 0.117)	5 x <0.01, 0.084 (STMR 0.010)	6 x <0.01	6 x <0.01
Cereals / Barley and	60	6 x <0.01	6 x <0.01	6 x <0.01	6 x <0.01

Crop Group/Representative Crop matrix	Rate g as/ha	Clopyralid residues (mg/kg) per Plant-back interval (days) ^(a)			
		30	90	125	270-365
Wheat grain	80	4 x <0.01, 0.14, 0.15 (STMR 0.010)	6 x <0.01	5 x <0.01, 0.015 (STMR 0.010)	5 x <0.01, 0.037 (STMR 0.010)
	125	2 x <0.01, 0.035, 0.053, 0.13, 0.17 (STMR 0.044)	5 x <0.01, 0.011 (STMR 0.010)	5 x <0.01, 0.012 (STMR 0.010)	5 x <0.01, 0.025 (STMR 0.010)
Cereals / Barley and Wheat straw	60	2 x <0.01, 0.018, 0.024, 0.040, 0.12 (STMR 0.021)	6 x <0.01	6 x <0.01	4 x <0.01, <0.01, 0.012 (STMR 0.010)
	80	2 x <0.01, 0.015, 0.027, 0.12, 0.27 (STMR 0.021)	6 x <0.01	6 x <0.01	4 x <0.01, 0.012, 0.015 (STMR 0.010)
	125	2 x <0.01, 0.10, 0.16, 0.18, 0.28 (STMR 0.130)	6 x <0.01	6 x <0.01	4 x <0.01, 0.016, 0.036 (STMR 0.010)

(a) STMRs are given in brackets for those datasets where residues at or above 0.01 mg/kg were found. The most critical STMRs and HRs used for dietary burden calculation are marked in bold.

* Residue value of <0.01 mg/kg is excluded from the evaluation due to exceedance of frozen storage stability.

† Two residue values of <0.01 mg/kg are excluded from the evaluation due to exceedance of frozen storage stability.

** Residue value of 0.017 mg/kg is excluded from the evaluation due to exceedance of frozen storage stability.

Conclusion on rotational crops studies

The application rate of up to 125 g a.s./ha in the new Corteva study is within ± 25 of the acceptance range of the intended cGAP for ADM.01851.H.1.A.

Residues of clopyralid in rotational crop food commodities are anticipated to be less than the established EU MRLs. No significant residues are expected in leafy vegetables and oilseed seeds at any of the plant back intervals or in root and tuber vegetables from PBI 90 days onwards. Any residue levels found in the rotational crops, at any of the PBIs, were either lower than the input values used in the most recent EFSA dietary burden calculation or were included in the livestock dietary burden calculation. There is no impact on the MRLs in animal commodities. As MRLs were used for the consumer risk assessment, which are higher than the residues measured in rotated crops, the dietary exposure to any residues arising in rotated crop is also covered in this assessment.

It is concluded that sufficient data is available to support the uses under consideration in this dossier.

Since any residues do not modify the livestock dietary burden, and residues are taken into account in the consumer risk assessment and are compliant with the current EU MRLs, no restrictions regarding a plant-back interval are needed.

zRMS comments:

The EU pesticides peer review identified a data gap for the submission of rotational crop field trials according to current guidelines, since in the metabolism studies the residues of free and conjugated parent were found in all plant parts at PHI 30 days (except in radish roots) in soybean plant and wheat straw up to 0.015 mg eq/kg at PHI 120 days (EFSA, 2018d).

In the absence of rotational crop field trials the applicant and EMS proposed to apply risk mitigation measures and to restrict the use for succeeding crops.

EFSA re-iterates the data gap from the EU pesticides peer review, to request rotational crop field studies to address this data requirement. Until these studies become available EFSA suggests, to risk managers, to label clopyralid containing products with the restriction not to use clopyralid on the same field for 125 days after the initial application, regardless of the crop grown, as the risk mitigation measure (EFSA Journal 2021;19(1):6389; Clopyralid-SANTE/10206/2021, Rev. 1, 20 May 2021).

To address this data requirement and consequent risk mitigation, the Applicant provided access to a new study (Devine, C., 2021; CEMS-9009/190557). This study has been previously submitted to Poland for a clopyralid product by Corteva (PPP of EF-243) in December 2021 as part of their art. 43 dossier, and to EMS – Finland in the framework of the application of modification of the existing maximum residue levels (MRLs) for the active substance clopyralid in honey and the EMS assessed this study in its evaluation report (Finland, 2023; DOI: 10.2903/j.efsa.2024.8546).

Six crop rotational trials were conducted in northern Europe (three trials) and Southern Europe (three trials) to determine residues of clopyralid in rotational crops at harvest, following one application to bare soil. GF-1966 (720 g ae/kg clopyralid) was applied once at a nominal rate of 60, 80, or 125 g ae/ha with an application volume of 200-400 L/ha. Following plant back intervals (PBI) of approximately 30, 125 and 270-365 days the plots were planted with a root crop, leafy crop, cereal, or oilseed.

The application was made on bare soil and the highest dose of 125 g as/ha is in accordance (within 25% deviation) with the intended annual critical dose for all crops.

Residue above 0.01 mg/kg is expected in rotational crops at 30-day PBI at 125 g ae/ha treatment rate. However the residue levels coming from rotational crops are not expected to lead to MRL exceedances except for sugar cane (Reg. (EU) 2024/2612).

During the commenting period Applicant submitted additional explanations:

“EFSA 2024 (EFSA Journal 2024.8546) concluded: “Regarding the potential residue uptakes in cereals and root crops, the need for deriving MRLs or implementing risk mitigation measures (as proposed by EMS) should be assessed in the framework of the MRL review to be carried out under Article 12 of Reg (EU) 396/2005”

New rotational crop residue trials have been submitted in this dossier. In leafy vegetables and oilseeds, residues of clopyralid were <0.01 mg/kg in all food commodities, thus there is no impact on the existing MRLs for these commodities. In root and tuber vegetables, the HR of clopyralid was 0.042 mg/kg in radish root. This value is only 8.4% of the lowest MRL for root and tuber vegetables (0.5 mg/kg), thus no exceedance of the MRL is expected and no PBI is needed. The HR in cereal grain was 0.17 mg/kg that is only 8.5% of the lowest MRL for cereals (2 mg/kg), thus no exceedance of the MRL is expected and no PBI is needed. Furthermore, residues found in rotational crop feed commodities were considered in dietary burden calculation. The calculated dietary burden for livestock did not increase compared to the most recent EFSA calculation. Thus, there is no impact on MRLs for animal commodities. Therefore, no plant-back restriction is needed to manage residues and no planting prior to 30 days in a crop failure situation is feasible in any case. The exception to this is sugarcane where the MRL is set at the default LOQ and therefore the applicant agrees with the 125-day restriction in this instance.”

According to available data and taking into account the Applicant’s explanations, the following specific mitigation measures are recommended before planting succeeding crops:

- ~~a 30 day PBI is supported for leafy and brassica vegetables, oilseeds and for all other food and feed commodities except sugar canes;~~
- sugar canes not be planted for 125 days after application of clopyralid.

No additional data are required.

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

According to the EU guideline SANTE/11956/2016 rev. 9, sugar beet and fodder beet do not have melliferous capacity (except seed production uses for sugar beet which is not under consideration in this dossier), therefore no data on residues on honey are required.

From the uses under consideration in this dossier for ADM.01851.H.1.A, no clopyralid residues are expected in rotational crops after normal crop maturity and harvest.

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of ADM.01851.H.1.A. Therefore, other special studies are not needed.

zRMS comments:

Information given by the Applicant is sufficient.
No additional data are required.

Additional information:

Applicant has access to honey study (Study Code: S20-00871) with the LoA. The data on honey has been submitted to EMS - Finland in the framework of an MRL application (EFSA Journal. 2024;22:e8546; DOI: 10.2903/j.efsa.2024.8546 – “Modification of the existing maximum residue level for clopyralid in honey”).

The study was conducted as six field trials in Germany, Romania, The Netherlands, Southern France and Spain. The rate used in the study: foliar application 1 × 125 g a.s./ha; BBCH 30–51. The residues in honey were 3x <0.01, 0.0179, 0.0274, 0.0695 mg/kg.

The MRL for clopyralid in honey now is 0.15 mg/kg (Commission Regulation (EU) 2024/2612), and according to the study on magnitudes of residues in honey, the MRL is not potentially exceeded.

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

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

7.3.8.1 Input values for the consumer risk assessment

Table 7.3-17: Input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: Clopyralid common moiety (sum of clopyralid, its salts and glycine conjugates expressed as clopyralid)				
Sugar beet (root)	1	MRL (Regulation (EU) 2021/1807 2024/2612)	0.8	HR sugar beet roots (for sugar, the default PF of 12 was used)
All other commodities	MRL	Regulation (EU) 2021/1807 2024/2612	MRL	Regulation (EU) 2021/1807 2024/2612
Milk	0.05 x CF (1.3)	Milk	0.05 x CF (1.3)	
Animal commodities	MRL	Animal commodities	MRL	

7.3.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.3-18: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo rev 3.1	42.43% (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo rev 3.1	Not necessary, because the TMDI is well below 100% of ADI
IESTI (% ARfD) according to EFSA PRIMo rev 3.1	Sugar beet: 65.62% from sugar (based on children)

The proposed uses of clopyralid in the formulation ADM.01851.H.1.A do not represent unacceptable acute and chronic risks for the consumer.

zRMS comments:

Table 7.3-16 has been corrected by the zRMS-PL and is highlighted in grey. As no refinement of the chronic risk assessment is required (TMDI < 100% ADI), STMR values do not need to be presented.

 European Food Safety Authority EFSA PRIMo revision 3.1; 2019/03/19		clopyralid		Input values							
LOQs (mg/kg) range from:		to:		Details - chronic risk assessment							
		Toxicological reference values		Supplementary results - chronic risk assessment							
ADI (mg/kg bw/day):		0.15	ARfD (mg/kg bw):	0.17							
Source of ADI:		EFSA 2018	Source of ARfD:	EFSA 2018							
Year of evaluation:		Year of evaluation:		Details - acute risk assessment/children							
				Details - acute risk assessment/adults							
Comments:											
Normal mode											
Chronic risk assessment: JMPR methodology (IED/TMDI)											
		No of diets exceeding the ADI:									

TMDI/NIED/IED calculation (based on average food consumption)	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
	43%	NL toddler	64.28	9%	Maize/corn	8%	Wheat	4%	Apples		
	33%	DK child	50.22	18%	Rye	9%	Wheat	0.8%	Potatoes		
	27%	GEMS/Food G06	40.64	14%	Wheat	2%	Rice	2%	Maize/corn		
	25%	NL child	37.66	8%	Wheat	6%	Sugar beet roots	2%	Apples		
	25%	DE child	37.25	8%	Wheat	4%	Apples	3%	Rye		
	21%	RO general	31.30	10%	Wheat	3%	Head cabbages	1%	Maize/corn		
	21%	GEMS/Food G15	30.89	9%	Wheat	2%	Head cabbages	1%	Potatoes		
	21%	GEMS/Food G08	30.82	8%	Wheat	2%	Rye	1%	Potatoes		
	20%	FR child 3 15 y	30.12	9%	Wheat	2%	Sugar beet roots	1%	Oranges		
	20%	GEMS/Food G10	29.37	8%	Wheat	2%	Rice	1%	Soyabeans		
	18%	IT toddler	27.67	13%	Wheat	2%	Other cereals	0.5%	Tomatoes		
	18%	IE adult	27.44	5%	Wheat	2%	Sweet potatoes	2%	Linseds		
	18%	GEMS/Food G07	27.36	8%	Wheat	1%	Potatoes	0.8%	Barley		
	17%	GEMS/Food G11	25.78	7%	Wheat	1%	Potatoes	1%	Soyabeans		
	17%	UK toddler	25.18	8%	Wheat	2%	Sugar beet roots	1%	Potatoes		
	16%	FR toddler 2 3 y	24.00	6%	Wheat	2%	Sugar beet roots	1%	Milk: Cattle		
	16%	UK infant	23.47	5%	Wheat	2%	Milk: Cattle	1%	Maize/corn		
	16%	SE general	23.26	6%	Wheat	1%	Potatoes	1%	Head cabbages		
	15%	PT general	23.04	8%	Wheat	2%	Potatoes	1%	Rice		
	15%	ES child	22.68	9%	Wheat	0.7%	Oranges	0.6%	Rice		
	15%	DE women 14-50 y	22.28	4%	Wheat	3%	Sugar beet roots	2%	Rye		
	15%	DE general	21.93	4%	Wheat	3%	Sugar beet roots	2%	Rye		
	12%	IT adult	18.12	8%	Wheat	0.9%	Other cereals	0.4%	Tomatoes		
	12%	NL general	18.02	4%	Wheat	2%	Sugar beet roots	0.8%	Potatoes		
	12%	FI 3 y	17.37	2%	Wheat	2%	Rye	2%	Potatoes		
	10%	LT adult	14.97	4%	Rye	2%	Wheat	1%	Potatoes		
	9%	ES adult	14.07	5%	Wheat	0.7%	Barley	0.4%	Oranges		
	9%	FI 6 y	13.78	2%	Rye	2%	Wheat	1%	Potatoes		
	8%	FR adult	13.65	4%	Wheat	0.8%	Wine grapes	0.5%	Sugar beet roots		
	8%	UK vegetarian	12.55	4%	Wheat	0.5%	Rice	0.5%	Potatoes		
	8%	FI adult	11.39	2%	Rye	2%	Coffee beans	0.6%	Wheat		
	7%	FR infant	10.69	2%	Wheat	0.9%	Sugar beet roots	0.7%	Milk: Cattle		
	7%	DK adult	10.51	2%	Wheat	2%	Rye	0.4%	Potatoes		
	7%	UK adult	10.41	3%	Wheat	0.5%	Rice	0.5%	Potatoes		
	4%	PL general	6.17	1%	Potatoes	0.7%	Head cabbages	0.7%	Apples		
4%	IE child	5.69	2%	Wheat	0.4%	Rice	0.2%	Potatoes			
Conclusion: The estimated long-term dietary intake (TMDI/NIED/IED) was below the ADI. The long-term intake of residues of clopyralid is unlikely to present a public health concern.											

The calculation of the TMDI using EFSA model (PRIMo ver. 3.1) and MRLs values for all plant and animals commodities according to Regulation (EU) 2024/2612 led to a utilisation of the ADI of 43% for NL toddler diet with the highest value. For this diet, the highest contributor is Maize/corn with 9% of the ADI.

Additionally, the evaluator performed an acute consumer risk assessment using MRLs for intended uses and MRLs for animal commodities and using a value of ARfD of 0.17 mg/kg bw.

Acute risk assessment /children				Acute risk assessment / adults / general population				Acute risk assessment /children				Acute risk assessment / adults / general population				
Details - acute risk assessment /children				Details - acute risk assessment/adults				Hide IESTI new calculations				Show IESTI new calculations				
The acute risk assessment is based on the ARfD. The calculation is based on the large portion of the most critical consumer group.																
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				IESTI				IESTI new				IESTI new			
	Highest % of ARfD/ADI		Commodities		MRL / input for RA (mg/kg)		Exposure (µg/kg bw)		Highest % of ARfD/ADI		Commodities		MRL / input for RA (mg/kg)		Exposure (µg/kg bw)	
	5%	Milk: Cattle	0.05 / 0.07	8.1	2%	Bovine: Kidney	1.5 / 1.5	3.2	5%	Milk: Cattle	0.05 / 0.07	8.1	2%	Bovine: Kidney	1.5 / 1.5	3.2
	3%	Bovine: Kidney	1.5 / 1.5	5.6	1%	Milk: Cattle	0.05 / 0.07	2.5	3%	Bovine: Kidney	1.5 / 1.5	5.6	1%	Milk: Cattle	0.05 / 0.07	2.5
	0.9%	Milk: Goat	0.05 / 0.07	1.6	0.8%	Swine: Kidney	0.05 / 0.07	1.3	0.9%	Milk: Goat	0.05 / 0.07	1.6	0.8%	Swine: Kidney	0.05 / 0.07	1.3
	0.7%	Bovine: Liver	0.15 / 0.15	1.2	0.7%	Milk: Goat	0.05 / 0.07	1.2	0.7%	Bovine: Liver	0.15 / 0.15	1.2	0.7%	Milk: Goat	0.05 / 0.07	1.2
	0.5%	Poultry: Musclemeat	0.05 / 0.05	0.85	0.6%	Milk: Sheep	0.05 / 0.07	0.98	0.5%	Poultry: Musclemeat	0.05 / 0.05	0.85	0.6%	Milk: Sheep	0.05 / 0.07	0.98
	0.4%	Swine: Kidney	0.6 / 0.6	0.76	0.4%	Bovine: Liver	0.15 / 0.15	0.60	0.4%	Swine: Kidney	0.6 / 0.6	0.76	0.4%	Bovine: Liver	0.15 / 0.15	0.60
	0.4%	Eggs: Chicken	0.05 / 0.05	0.62	0.3%	Poultry: Muscle	0.05 / 0.05	0.59	0.4%	Eggs: Chicken	0.05 / 0.05	0.62	0.3%	Poultry: Muscle	0.05 / 0.05	0.59
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):				IESTI new Results for children No. of processed commodities for which ARfD/ADI is exceeded (IESTI new):				IESTI new Results for adults No. of processed commodities for which ARfD/ADI is exceeded (IESTI new):			
	IESTI				IESTI				IESTI new				IESTI new			
	Highest % of ARfD/ADI		Processed commodities		MRL / input for RA (mg/kg)		Exposure (µg/kg bw)		Highest % of ARfD/ADI		Processed commodities		MRL / input for RA (mg/kg)		Exposure (µg/kg bw)	
	62%	Sugar beets (root) / sugar	0.96 / 11.52	106	25%	Sugar beets (root) / sugar	0.96 / 11.52	42	62%	Sugar beets (root) / sugar	0.96 / 11.52	106	25%	Sugar beets (root) / sugar	0.96 / 11.52	42
	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA
	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA
	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA
	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA
	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA
	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA	ILICZBA
Expand/collapse list																
Conclusion: No exceedance of the toxicological reference value was identified for any unprocessed commodity. A short term intake of residues of Pilease insert here the MRLs of COM database (use 'base values' function) is unlikely to present a public health risk. For processed commodities, no exceedance of the ARfD/ADI was identified.																

The highest International Estimated Short-Term Intake (IESTI) is at 5% and 2% of the ARfD for the consumption of Milk:Cattle by children and Bovine: Kidney by adults respectively and for processed commodities at 62% and 25% of the ARfD from the consumption of sugar beets (root)/sugar by children and by adults, respectively. The proposed uses of clopyralid in the product ADM.01851.H.1.A do not represent unacceptable acute and chronic risks for the consumer.

7.4 Combined exposure and risk assessment

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

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

7.4.1 Acute consumer risk assessment from combined exposure

The product is a mixture of two active substances, but for only one of them has an acute reference dose been allocated. Therefore, combined acute exposure can not be considered.

7.4.2 Chronic consumer risk assessment from combined exposure

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

zRMS comments:

Information given by the Applicant is sufficient.

We agree with Applicant that the uses under consideration provide only a minor contribution to the overall chronic exposure of consumers to pesticide residues. A harmonised approach is not yet available, and currently no specific consideration is warranted in the scope of this evaluation.

7.5 References

Ethofumesate

Austria, 2015a. Renewal assessment report (RAR) on the active substance ethofumesate prepared by the rapporteur Member State, Austria, in the framework of Commission Implementing Regulation (EU) No 844/2012, January 2015. Available online: www.efsa.europa.eu

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EFSA (European Food Safety Authority), 2016. Conclusion on the peer review of the pesticide risk assessment of the active substance ethofumesate. EFSA Journal 2016;14(1):4374, 141 pp. doi:10.2903/j.efsa.2016.4374

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Clopyralid

EFSA (European Food Safety Authority), 2005. Conclusion regarding the peer review of the pesticide risk assessment of the active substance clopyralid. EFSA Journal 2005;3(12):50r, 65 pp. <https://doi.org/10.2903/j.efsa.2005.50r>

EFSA (European Food Safety Authority), 2011. Modification of the existing MRLs for clopyralid in various commodities. EFSA Journal 2011;9(10):2418, 40 pp. <https://doi.org/10.2903/j.efsa.2011.2418>

EFSA (European Food Safety Authority), 2018. Conclusion on the peer review of the pesticide risk assessment of the active substance clopyralid. EFSA Journal 2018;16(8):5389, 21 pp. <https://doi.org/10.2903/j.efsa.2018.5389>

European Food Safety Authority (EFSA), 2021. Reasoned Opinion on the modification of the existing maximum residue levels for clopyralid in various commodities. EFSA Journal 2021;19(1):6389, 46 pp. <https://doi.org/10.2903/j.efsa.2021.6389>

EFSA (European Food Safety Authority), 2024. Modification of the existing maximum residue level for clopyralid in honey. EFSA Journal, 22(1), e8546. <https://doi.org/10.2903/j.efsa.2024.8546>

Finland, 2017. Renewal Assessment Report (RAR) on the active substance clopyralid prepared by the rapporteur Member State Finland, in the framework of Commission Implementing Regulation (EU) No 844/2012, May 2017. Available online: www.efsa.europa.eu

Finland, 2018a. Revised Renewal Assessment Report (RAR) on clopyralid prepared by the rapporteur Member State Finland in the framework of Commission Implementing Regulation (EU) No 844/2012, May 2018. Available online: www.efsa.europa.eu

Finland, 2018b. Evaluation report on the modification of MRLs for clopyralid in various commodities. May 2018, revised in August 2020, 212 pp.

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
Ethofumesate					
KCA 6.1/01	Schulte, G.	2015	Storage Stability of open-ring-2-keto ethofumesate (AE C520645) in Plant Matrices for 24 Months Bayer CropScience AG, 40789 Monheim, Germany Report No. MR-12/058 Study ID P642120507 GLP Unpublished	N	TFE
KCA 6.1/02	Watson, G.	2022	Ethofumesate: Storage Stability of Residues of Ethofumesate and its Metabolite in Lettuce and Cereal Grain Stored Frozen for up to Two Years Report No. RES-00278 Study ID 000106576 GLP Unpublished	N	ADAMA
Clopyralid (studies are referenced via a letter of access from Corteva Agriscience)					
KCA 6.1/01	Skaggs, C.S., Penning, B.N.	2021	Storage Stability of Clopyralid for One Year in Dried Beans Corteva Report No. 191728 Study No. SGS-19-01-08 SGS North America, Inc GLP Unpublished	N	Corteva Agriscience
KCA 6.1/02	Teasdale, R.	1996	Frozen Storage Stability of Clopyralid Residues in Strawberries Corteva Report No. GHE-P-4832 Study No. CEMS-235 CEM Analytical Services Ltd. GLP Unpublished	N	Corteva Agriscience
KCA 6.2.1/01	Morton Lloyd, G.	2020	The Metabolism of [14C]-Clopyralid in Wheat Corteva Study No. 191200 Study No. 229882 Charles River Laboratories	N	Corteva Agriscience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GLP Unpublished		
KCA 6.2.1/02	MacKenzie, A.	2021	The Metabolism of [14C]-Clopyralid in Spring Oilseed Rape Corteva Study No. 200928 Study No. 231101 Charles River Laboratories GLP Unpublished	N	Corteva Agriscience
KCA 6.2.1/03	Tuffnail, W.	2022	[14C]-Clopyralid: A Nature of Residue in Sugar Beet (2020); Corteva Study No. 210071 Lab Study No. DWA/10 Pharmaron-UK Ltd, Rushden, Northamptonshire, United Kingdom GLP Unpublished	N	Corteva Agriscience
KCA 6.5.3/01	Phillips, A.M.	1994	Determination of residues of clopyralid in sugar beet processed fractions CORTEVA Report No. GH-C 3305 North American Environmental Chemistry Laboratory GLP Unpublished	N	Corteva Agriscience
KCA 6.5.3/02	Devine, C.	2020	Residues of Clopyralid in Sugar Beet and Process Fractions Following Multiple Applications of GF-1966 – Northern Europe – 2019 CORTEVA Report No. 181493 Study No. CEMS-8908 CEM Analytical Services Ltd (CEMAS) GLP Unpublished	N	Corteva Agriscience
KCA 6.6.2/01	Devine, C.	2021	Determination of Residues of Clopyralid after One Application of GF-1966 (EC Formulation) on Bare Soil in Rotational Crops at 3 Sites in Northern Europe and 3 Sites in Southern Europe 2019-2020 Corteva Study No. 190557 Study No. CEMS-9009 CEM Analytical Services Ltd (CEMAS) GLP Unpublished	N	Corteva Agriscience

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

The lists below were not validated by the zRMS since majority of the active substances data have been taken from the EU review of Ethofumesate and Clopyralid. The complete lists of studies evaluated at the EU level are provided in Vol. 2 of the RARs.

Ethofumesate: For studies owned by Bayer the applicant has a Letter of Co-ownership. For studies owned by the TFE (TaskForce Ethofumesate), ADAMA Agricultural Solutions and all its affiliates has also access as ADAMA is member of the TFE. For studies owned by UPL or ACM the TFE has either equivalent studies or a Letter of Access.

List of information, tests and studies which are considered as relied upon by the RMS for the evaluation with a view to the approval of the active substance Ethofumesate.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.1	Whiteoak, R. J.	1975	STABILITY OF RESIDUES DURING STORAGE OF CROP AND SOIL SAMPLES FROM TRIALS WITH NORTON Fisons plc, United Kingdom Bayer Crop Science, Report No.: A83296, Edition Number: M-155565-01-1 Date: 1975-08-01 No GLP Unpublished	N	Bayer CropScience
KCA 6.1	Bright, J. H. M.	1991	STABILITY OF ETHOFUMESATE AND NC 9607 RESIDUES IN SUGARBEET ROOTS AND TOPS DURING DEEP FREEZE STORAGE Schering AG, Berlin, Germany Bayer CropScience, Report No.: A83111, Report includes Trial Nos.: 041/02/001 Edition Number: M-155386-01-1 Date: 1991-03-08 GLP Unpublished	N	Bayer CropScience
KCA 6.1	Schulte, G.	2013	Storage stability of open-ring-2-keto ethofumesate (AE C520645) in plant matrices for 24 months - Phase report after 6 months Bayer CropScience, Report No.: MR-13/086, Edition Number: M-459806-01-1 Date: 2013-07-11 GLP Unpublished	N	Task Force Ethofumesate
KCA 6.1	Hamberger, R.	2013	Determination of the storage stability of Ethofumesate and its metabolite NC20645 in sugar beet matrices during storage at < or = to - 18°C for a period of 12 months AgriChem B.V., 12A04042-01-SSSB CIP Chemisches Institut Pforzheim GmbH GLP Unpublished	N	ACM*
KCA 6.1	Schlewitz, P.	2014	Frozen storage stability of residues of ethofumesate metabolite NC 20645 in sugar beet (roots and tops with leaves) United Phosphorus Ltd., R B1312 ANADIAG GLP Unpublished	N	UPL

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.1	Perez, R.; Schmitt, J. L.; Patel, D.	2014	Freezer storage stability of ethofumesate in animal matrix samples - interim report ADPEN Laboratories, Inc., Jacksonville, FL, USA Bayer CropScience, Report No.: RAADP031, Edition Number: M-467206-02-1 Date: 2013-09-26 GLP Unpublished	N	Task Force Ethofumesate
KCA 6.2 /01	Miller, C.	1999	Summary of the metabolism of ethofumesate in plants Ethofumesate AE B049913 AgrEvo UK Crop Protection Ltd., Chesterford Park, United Kingdom Bayer CropScience, Report No.: C003349, Edition Number: M-185979-01-1 No GLP Unpublished	N	Bayer CropScience
KCA 6.2.1 /01	Adcock, J. W.; Warner, P. A., Challis, I. R.	1976	The metabolism of ¹⁴ C- ethofumesate in the onion Fisons plc, United Kingdom Bayer Crop Science, Report No.: A82959, Edition Number: M-155236-01-1 Date: 1976-10-01 No GLP Unpublished	N	Bayer CropScience
KCA 6.2.1 /02	Warner, P. A.; Adcock, J. W.	1977	Metabolism of ethofumesate in tobacco Fisons plc, united kingdom Bayer Crop Science, Report no.: A82963, Edition number: m-155240-01-1 date: 1977-12-01 No GLP Unpublished	N	Bayer CropScience
KCA 6.2.1 /03	Lines, D. S.; Adcock, J. W.	1978	The metabolism of ethofumesate by sugar beet under greenhouse conditions Fisons plc, United Kingdom Bayer Crop Science, Report No.: A82964, Edition Number: M-155241-01-1 Date: 1978-12-01 No GLP Unpublished	N	Bayer CropScience
KCA 6.2.1 /04	Lines, D. S.; Adcock, J. W.	1979	The metabolism of ethofumesate (98% pure ¹⁴ C - ethofumesate) by sugar beet under field conditions Fisons plc, United Kingdom Bayer Crop Science, Report No.: A82965, Edition Number: M-155242-01-1 Date: 1979-01-01 No GLP Unpublished	N	Bayer CropScience
KCA 6.2.1 /05	Chapleo, S.	1992	The metabolism of [¹⁴ C]- ethofumesate in sugar beet - a glasshouse study Inveresk Research Int. Ltd., Tranent, Scotland	N	Bayer CropScience

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
			Bayer CropScience, Report No.: A82970, Report includes Trial Nos.: 381174 ENVIR 84B Edition Number: M-155247-01-1 Date: 1992-09-22 GLP Unpublished		
KCA 6.2.1 /06	Caley, C. Y.; Chapleo, S.; Haswell, A.	1994	The metabolism of ¹⁴ C- ethofumesate in sugar beet Inveresk Research Int. Ltd., Tranent, Scotland Bayer CropScience, Report No.: A87553, Report includes Trial Nos.: 382445 Edition Number: M-161455-01-1 Date: 1994-06-01 GLP Unpublished	N	Bayer CropScience
KCA 6.2.1 /07	Chapleo, S.	1992	The metabolism of [¹⁴ C]- ethofumesate in annual ryegrass - a glasshouse study Inveresk Research Int. Ltd., Tranent, Scotland Bayer CropScience, Report No.: A82971, Report includes Trial Nos.: 381169 ENVIR 85B Edition Number: M-155248-01-1 Date: 1992-09-17 GLP Unpublished	N	Bayer CropScience
KCA 6.2.1 /08	Mellet, M.	1993	Determination of the residues of ethofumesate, ethofumesate-2- keto and the conjugates in sugar beets after application of Ethosat 500 SC in France, 1992 ANADIAG S.A., Haguenau, France Feinchemie Schwebda, Report No.: M-468491-01-1, Report includes Trial Nos.: 92HBEBI01, 92HBEBI06 Edition Number: M-468491-01-1 Date: 1993-06-07 GLP Unpublished	N	Adama (former Feinchemie Schwebda)
KCA 6.2.1/01 (KCA 6.2.1/09)	Hennecke, D.	2003	Metabolism of Ethofumesate in sugar beets United Phosphorus Ltd., GAB-002/7-08 Fraunhofer Institute for Molecular Biology and Applied Ecology (IME), Schmallingenberg, Germany GLP Unpublished	N	UPL
KCA 6.2.2 /01		1992	THE METABOLISM OF ¹⁴ C ETHOFUMESATE IN LAYING HENS Bayer CropScience, Report No.: A82969, Report includes Trial Nos.: SMS 297/920431 TOX 90542	Y	Bayer CropScience

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
			Edition Number: M-155246-01-1 Date: 1992-06-09 GLP Unpublished		
KCA 6.2.2 /02	██████	1999	Poultry - Metabolism, Distribution and nature of the residues in eggs and edible tissues Code AE B049913 ██████ Bayer CropScience, Report No.: C002998, Report includes Trial Nos.: Tox97227 Edition Number: M-185380-01-1 Date: 1999-06-01 GLP Unpublished	Y	Bayer CropScience
KCA 6.2.3 /01	██████	1976	THE METABOLISM OF ¹⁴ CETHOFUMESATE IN THE SHEEP ██████ Bayer CropScience, Report No.: A82958, Edition Number: M-155235-01-1 Date: 1976-09-01 No GLP Unpublished	Y	Bayer CropScience
KCA 6.2.3 /02	██████	1992	THE METABOLISM OF ¹⁴ C-ETHOFUMESATE IN THE COW ██████ Bayer CropScience, Report No.: A82968, Report includes Trial Nos.: SMS 296/920441 TOX 90541 Edition Number: M-155245-01-1 Date: 1992-06-04 GLP Unpublished	Y	Bayer CropScience
KCA 6.2.3 /03	██████	1999	Metabolism, distribution and nature of the residues in milk and edible tissues Ethofumesate ruminant Code: AE B049913 ██████ Bayer CropScience, Report No.: C003362, Report includes Trial Nos.: TOX97226 Edition Number: M-185993-01-1 Date: 1999-04-07 No GLP Unpublished	Y	Bayer CropScience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.3.5 /01	Crofts, M.	1975	RESIDUES IN FODDER BEET AND RED BEET FROM 1974 APPLICATIONS OF NORTRON IN THE UK Fisons plc, United Kingdom Bayer CropScience, Report No.: A83007, Edition Number: M-155284-01-1 EPA MRID No.: 41214220 Date: 1975-05-01 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /02	Crofts, M.; Whiteoak, R. J.	1976	RESIDUES IN MANGOLDS, FODDER BEET AND RED BEET FROM 1975 AND 1976 APPLICATIONS OF NORTRON IN THE UK (AND 1 RED BEET TRIAL IN SWEDEN) Fisons plc, United Kingdom Bayer CropScience, Report No.: A83020, Edition Number: M-155297-01-1 EPA MRID No.: 41214219 Date: 1976-09-01 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /03	Crofts, M.; Whiteoak, R. J.	1977	RESIDUES IN RED BEET ROOTS FROM 1976 TRIALS WITH NORTRON IN AUSTRALIA Fisons plc, United Kingdom Bayer CropScience, Report No.: A83022, Edition Number: M-155299-01-1 EPA MRID No.: 41214220 Date: 1977-02-01 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /04	Crofts, M.	1978	HARVEST RESIDUES IN RED BEET FROM NORTRON TRIALS IN THE USA (NEW YORK, TEXAS AND WISCONSIN) IN 1976/77 Fisons plc, United Kingdom Bayer CropScience, Report No.: A83036, Edition Number: M-155313-01-1 EPA MRID No.: 41214219 Date: 1978-01-31 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /05	Crofts, M.	1978	HARVEST RESIDUES IN RED BEET FROM A NORTRON TRIAL IN CANADA IN 1977 Fisons plc, United Kingdom Bayer CropScience, Report No.: A83039, Edition Number: M-155316-01-1 EPA MRID No.: 41214233 Date: 1978-11-02 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /06	Wrede, A.	1995	Residues in red beet after application of Betanal progress in France 1993 Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany	N	Bayer CropScience

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
			Bayer CropScience, Report No.: A83118, Report includes Trial Nos.: PF-R 93 098 Edition Number: M-155393-01-1 Date: 1995-04-04 GLP Unpublished		
KCA 6.3.5 /07	Crofts, M.; Whiteoak, R. J.	1973	HARVEST RESIDUES IN SUGAR BEET (ROOTS AND LEAVES) FROM 1972 TRIALS WITH NORTRON IN THE UK Fisons plc, United Kingdom Bayer CropScience, Report No.: A82975, Edition Number: M-155252-01-1 EPA MRID No.: acc.36374 Date: 1973-07-01 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /08	Crofts, M.; Whiteoak, R. J.	1973	HARVEST RESIDUES IN SUGAR BEET (ROOTS AND LEAVES) FROM FRENCH TRIALS WITH NORTRON IN 1972 Fisons plc, United Kingdom Bayer CropScience, Report No.: A82976, Edition Number: M-155253-01-1 EPA MRID No.: 41214219 Date: 1973-07-01 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /09	Crofts, M.; Whiteoak, R. J.	1973	HARVEST RESIDUES IN SUGAR BEET (ROOTS AND LEAVES) FROM DANISH TRIALS WITH NORTRON IN 1972 Fisons plc, United Kingdom Bayer CropScience, Report No.: A82977, Edition Number: M-155254-01-1 EPA MRID No.: 41214219 Date: 1973-08-01 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /10	Crofts, M.; Whiteoak, R. J.	1973	HARVEST RESIDUES IN SUGAR BEET (ROOTS AND LEAVES) FROM AUSTRIAN TRIALS WITH NORTRON IN 1972 Fisons plc, United Kingdom Bayer CropScience, Report No.: A82978, Edition Number: M-155255-01-1 Date: 1973-08-01 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /11	Crofts, M.; Whiteoak, R. J.	1973	HARVEST RESIDUES IN SUGAR BEET (ROOTS AND LEAVES) FROM 1972 TRIALS WITH NORTRON IN YUGOSLAVIA	N	Bayer CropScience

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
			Fisons plc, United Kingdom Bayer CropScience, Report No.: A82979, Edition Number: M-155256-01-1 EPA MRID No.: 41414219 Date: 1973-08-01 No GLP Unpublished		
KCA 6.3.5 /12	Whiteoak, R. J.; Crofts, M.; Harris, R. J.	1973	RESIDUES IN SUGAR BEET (ROOTS AND LEAVES) FROM 1972 TRIALS WITH NORTRON IN W. GERMANY (UPDATED) Fisons plc, United Kingdom Bayer Crop Science, Report No.: A82980, Edition Number: M-155257-01-1 EPA MRID No.: 41214220 Date: 1973-10-01 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /13	Whiteoak, R. J.	1973	RESIDUE DECLINE STUDIES IN COLORADO (USA) WITH SUGAR BEET TREATED PRE-EMERGENCE WITH NORTRON IN 1972 Fisons plc, United Kingdom Bayer Crop Science, Report No.: A82982, Edition Number: M-155259-01-1 EPA MRID No.: acc.36365 Date: 1973-12-01 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /14	Whiteoak, R. J.; Crofts, M.	1974	RESIDUE DECLINE STUDIES IN MICHIGAN (USA) WITH SUGAR BEET TREATED PRE-EMERGENCE WITH NORTRON IN 1972 Fisons plc, United Kingdom Bayer Crop Science, Report No.: A82983, Edition Number: M-155260-01-1 EPA MRID No.: acc.37839 Date: 1974-02-01 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /15	Crofts, M.; Whiteoak, R. J.	1974	NORTRON RESIDUE IN HARVEST SUGAR BEET FROM NINE REGIONS OF THE USA IN 1972 Fisons plc, United Kingdom Bayer Crop Science, Report No.: A82986, Edition Number: M-155263-01-1 EPA MRID No.: acc.36366 Date: 1974-03-01 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /16	Crofts, M.; Whiteoak, R. J.	1974	HARVEST RESIDUES IN SUGAR BEET FROM 1973 PRE-EMERGENCE APPLICATIONS OF NORTRON (TRAMAT) IN ITALY	N	Bayer CropScience

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
			Fisons plc, United Kingdom Bayer Crop Science, Report No.: A82990, Edition Number: M-155267-01-1 Date: 1974-06-01 No GLP Unpublished		
KCA 6.3.5 /17	Crofts, M.; Whiteoak, R. J.	1974	RESIDUE DECLINE STUDY IN THE UK (1973) WITH SUGAR BEET TREATED PRE-EMERGENCE WITH NORTRON Fisons plc, United Kingdom Bayer Crop Science, Report No.: A82992, Edition Number: M-155269-01-1 Date: 1974-07-01 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /18	Crofts, M.; Whiteoak, R. J.	1974	HARVEST RESIDUES IN FODDER BEET FROM 1973 PRE-EMERGENCE APPLICATION OF NORTRON (TRAMAT) IN W. GERMANY Fisons plc, United Kingdom Bayer Crop Science, Report No.: A82993, Edition Number: M-155270-01-1 Date: 1974-11-01 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /19	Crofts, M.; Whiteoak, R. J.	1974	HARVEST RESIDUES IN FODDER BEET FROM 1972 AND 1973 POST- EMERGENCE APPLICATIONS OF NORTRON (TRAMAT) IN W. GERMANY Fisons plc, United Kingdom Bayer Crop Science, Report No.: A82996, Edition Number: M-155273-01-1 Date: 1974-11-01 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /20	Crofts, M.; Whiteoak, R. J.	1974	RESIDUE DECLINE STUDY IN THE UK (1973) WITH SUGAR BEET TREATED POST-EMERGENCE WITH NORTRON Fisons plc, United Kingdom Bayer Crop Science, Report No.: A82997, Edition Number: M-155274-01-1 Date: 1974-11-01 No GLP Unpublished	N	Bayer CropScience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.3.5 /21	Crofts, M.; Whiteoak, R. J.	1974	HARVEST RESIDUES IN SUGAR BEET FROM 1973 PRE-EMERGENCE APPLICATIONS OF NORTRON (TRAMAT) IN W. GERMANY Fisons plc, United Kingdom Bayer Crop Science, Report No.: A82998, Edition Number: M-155275-01-1 Date: 1974-12-01 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /22	Crofts, M.; Whiteoak, R. J.	1974	HARVEST RESIDUES IN SUGAR BEET AND SOIL FROM 1973 POST- EMERGENCE APPLICATIONS OF NORTRON (TRAMAT) IN ITALY Fisons plc, United Kingdom Bayer Crop Science, Report No.: A83290, Edition Number: M-155559-01-1 Date: 1974-12-01 No GLP Unpublished...also filed: KCA 7.1.2.2.1 /10	N	Bayer CropScience
KCA 6.3.5 /23	Crofts, M.; Whiteoak, R. J.	1974	HARVEST RESIDUES IN SUGAR BEET FROM 1973 POST-EMERGENCE APPLICATIONS OF NORTRON IN THE UK Fisons plc, United Kingdom Bayer Crop Science, Report No.: A82999, Edition Number: M-155276-01-1 Date: 1974-12-01 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /24	Crofts, M.	1975	HARVEST RESIDUES IN SUGAR BEET FROM 1974 PRE-EMERGENCE APPLICATIONS OF NORTRON IN CANADA Fisons plc, United Kingdom Bayer Crop Science, Report No.: A83004, Edition Number: M-155281-01-1 EPA MRID No.: 41214220 Date: 1975-03-01 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /25	Crofts, M.	1975	DECLINE IN RESIDUES IN SUGAR BEET TREATED PRE-EMERGENCE WITH NORTRON (TRAMAT) IN ITALY (1974) Fisons plc, United Kingdom Bayer Crop Science, Report No.: A83005, Edition Number: M-155282-01-1 Date: 1975-04-01 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /26	Crofts, M.	1975	DECLINE OF RESIDUES IN SUGAR BEET TREATED POST-EMERGENCE WITH NORTRON (TRAMAT) IN ITALY (1974) Fisons plc, United Kingdom	N	Bayer CropScience

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
			Bayer Crop Science, Report No.: A83006, Edition Number: M-155283-01-1 Date: 1975-04-01 No GLP Unpublished		
KCA 6.3.5 /27	Crofts, M.; Whiteoak, R. J.	1976	NORTRON RESIDUES IN MATURE SUGAR BEET FOLLOWING POST- EMERGENCE APPLICATIONS AS A TANK MIX WITH DESMEDIPHAM IN THE USA Fisons plc, United Kingdom Bayer Crop Science, Report No.: A83012, Edition Number: M-155289-01-1 Date: 1976-02-01 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /28	Crofts, M.; Harris, R. J.; Wilkie, P. M.	1976	COMPARISON OF RESIDUES IN MATURE SUGAR BEET TREATED PRE- EMERGENCE WITH NORTRON 20 EC OR TCA OR A TANK MIX OF BOTH COMPONENTS IN THE USA Fisons plc, United Kingdom Bayer Crop Science, Report No.: A83013, Edition Number: M-155290-01-1 Date: 1976-03-01 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /29	Crofts, M.; Harris, R. J.; Wilkie, P. M.	1976	COMPARISON OF RESIDUES IN MATURE SUGAR BEET TREATED PRE- EMERGENCE WITH NORTRON OR PYRAMIN OR A TANK MIX OR BOTH COMPONENTS IN THE USA IN 1975 Fisons plc, United Kingdom Bayer Crop Science, Report No.: A83016, Edition Number: M-155293-01-1 Date: 1976-05-01 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /30	Crofts, M.	1976	NORTRON AND RO-NEET RESIDUES IN MATURE SUGAR BEET FOLLOWING PRE-EMERGENCE APPLICATION AND TANK MIX IN THE USA IN 1974 Fisons plc, United Kingdom Bayer Crop Science, Report No.: A83017, Edition Number: M-155294-01-1 Date: 1976-05-01 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /31	Crofts, M.	1976	COMPARISON OF RESIDUES IN MATURE SUGAR BEET TREATED WITH AN SC OR AN EC FORMULATION OF NORTRON IN UK, 1975 Fisons plc, United Kingdom Bayer Crop Science, Report No.: A83019, Edition Number: M-155296-01-1 Date: 1976-06-01	N	Bayer CropScience

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			No GLP Unpublished		
KCA 6.3.5 /32	Crofts, M.	1978	HARVEST RESIDUES IN SUGAR BEET FROM PRE- EMERGENCE APPLICATIONS OF TRAMAT (NORTRON) SC FORMULATION IN W. GERMANY IN 1976. Fisons plc, United Kingdom Bayer Crop Science, Report No.: A83034, Edition Number: M-155311-01-1 Date: 1978-01-23 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /33	Crofts, M.	1978	HARVEST RESIDUES IN SUGAR BEET FROM 1977 TRIALS WITH TRAMAT (NORTRON) SC AND EC FORMULATIONS IN W. GERMANY Fisons plc, United Kingdom Bayer Crop Science, Report No.: A83035, Edition Number: M-155312-01-1 Date: 1978-01-23 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /34	Harris, R. J.; Reary, J. B.	1979	RESIDUES IN MATURE SUGAR BEET FOLLOWING PRE-EMERGENCE APPLICATIONS OF SEPARATE OR TANK-MIX FORMULATIONS OF ETHOFUMESATE AND CHLORIDAZON IN MICHIGAN AND OHIO 1978 Fisons plc, United Kingdom Bayer Crop Science, Report No.: A83045, Edition Number: M-155322-01-1 Date: 1979-09-13 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /35	Browne, P. M.; Reary, J. B.	1979	ETHOFUMESATE RESIDUES IN MATURE SUGAR BEET TREATED POST EMERGENCE IN MIXTURES WITH PHENMEDIPHAM AND/OR DESMEDIPHAM IN USA 1977 Fisons plc, United Kingdom Bayer Crop Science, Report No.: A83046, Edition Number: M-155323-01-1 EPA MRID No.: 41214220 Date: 1979-08-30 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /36	Reary, J. B.	1980	RESIDUES IN MATURE SUGAR BEET TREATED POST-EMERGENCE WITH MIXTURES OF ETHOFUMESATE AND/OR PHENMEDIPHAM AND DESMEDIPHAM (COMMERCIAL EC FORMULATIONS) IN USA 1979 Fisons plc, United Kingdom Bayer Crop Science, Report No.: A83049, Edition Number: M-155326-01-1 EPA MRID No.: 41214219	N	Bayer CropScience

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			Date: 1980-05-23 No GLP Unpublished		
KCA 6.3.5 /37	Reary, J. B.	1980	RESIDUES IN MATURE SUGAR BEET FOLLOWING PRE AND POST- EMERGENCE APPLICATION OF ETHOFUMESATE (20 EC) IN CALIFORNIA 1977 Fisons plc, United Kingdom Bayer Crop Science, Report No.: A83050, Edition Number: M-155327-01-1 EPA MRID No.: 41214220 Date: 1980-06-20 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /38	Browne, P. M.; Reary, J. B.	1980	RESIDUES IN SUGAR BEET TREATED PRE- EMERGENCE WITH A SUSPENSION CONCENTRATE FORMULATION (50 SC) OF ETHOFUMESATE IN WEST GERMANY Fisons plc, United Kingdom Bayer Crop Science, Report No.: A83053, Edition Number: M-155330-01-1 Date: 1980-09-12 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /39	Reary, J. B.	1980	RESIDUES IN MATURE SUGAR BEET TREATED PRE-EMERGENCE WITH MIXTURES OF ETHOFUMESATE AND/OR PEBULATE OR CYCLOATE (COMMERCIAL EC FORMULATIONS) IN CALIFORNIA 1979 Fisons plc, United Kingdom Bayer Crop Science, Report No.: A83051, Edition Number: M-155328-01-1 EPA MRID No.: 41214220 Date: 1980-08-14 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /40	Housden, M. C.; Reary, J. B.	1981	Residues of Ethofumestae and metabolites in sugar beet treated pre--emergence with a one-pack mixture of Ethofumestae and Lenacil in West Germany 1980 Fisons plc, United Kingdom Bayer Crop Science, Report No.: A83057, Edition Number: M-155334-01-1 Date: 1981-01-14 No GLP Unpublished	N	Bayer CropScience

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KCA 6.3.5 /41	Reary, J. B.	1981	Residues of Ethofumesate and metabolites in sugar beet treated pre-emergence with a one-pack mixture of Ethofumesate and Chloridazon in West Germany 1980 Fisons plc, United Kingdom Bayer CropScience, Report No.: A83058, Edition Number: M-155335-01-1 Date: 1981-01-15 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /42	Reary, J. B.	1981	Residues in sugar beet treated post- emergence with a suspension concentrate formulation (50 SC) of Ethofumesate in West Germany 1980 Fisons plc, United Kingdom Bayer Crop Science, Report No.: A83059, Edition Number: M-155336-01-1 Date: 1981-01-15 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /43	Haldeman, J. K.; Ford, J. J.	1982	ANTOR AND NORTON HERBICIDE RESIDUES IN SUGAR BEETS FROM TREATED PLOTS FBC Limited, Chesterford Park, United Kingdom Bayer CropScience, Report No.: A89134, Edition Number: M-164269-01-1 Date: 1982-02-22 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /44	Cron, J. H.	1982	Residues of Ethofumesate and metabolites in sugar beet treated pre-emergence with a one-pack mixture of Ethofumesate and Chloridazon in West Germany 1981 FBC Limited, Chesterford Park, United Kingdom Bayer CropScience, Report No.: A83064, Edition Number: M-155341-01-1 Date: 1982-02-11 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /45	Haldeman, J. K.	1982	NORTON HERBICIDE RESIDUES IN SUGAR BEETS TREATED PRE- AND POST-PLANTING Hercules Inc.; Bayer Crop Science, Report No.: A83066, Edition Number: M-155343-01-1 Date: 1982-04-29 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /46	Cron, J. H.	1982	Residues of Ethofumesate and metaboiltes in sugar/fodder beet treated post-emergence with Ethofumesate (50 SC) in West Germany 1981 FBC Limited, Chesterford Park, United Kingdom Bayer CropScience, Report No.: A83065, Edition Number: M-155342-01-1 Date: 1982-04-02 No GLP	N	Bayer CropScience

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			Unpublished		
KCA 6.3.5 /47	Haldeman, J. K.	1982	ETHOFUMESATE RESIDUES IN SUGAR BEETS FROM TWO CALIFORNIA LOCATIONS FBC Limited, Chesterford Park, United Kingdom Bayer CropScience, Report No.: A83067, Edition Number: M-155344-01-1 Date: 1982-05-07 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /48	Ford, J. J.	1983	DIETHATYL ETHYL (ANTOR HERBICIDE) AND ETHOFUMESATE (NORTRON HERBICIDE) RESIDUES IN 6-MONTH SUGAR BEETS FROM CALIFORNIA FBC Limited, Chesterford Park, United Kingdom Bayer CropScience, Report No.: A89135, Report includes Trial Nos.: H41/3/81 H79/3/3 Edition Number: M-164271-01-1 EPA MRID No.: 41214220 Date: 1983-07-13 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /49	Lee, G. E.; Weishedel, B. C.	1984	ETHOFUMESATE (NORTRON HERBICIDE) RESIDUES IN SUGAR BEETS FROM QUEBEC AND MANITOBA FBC Limited, Chesterford Park, United Kingdom Bayer CropScience, Report No.: A83069, Edition Number: M-155346-01-1 Date: 1984-04-16 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /50	Manley, J. D.; Snowdon, P. J.	1984	Residues of Ethofumesate and major metabolites in sugarbeet treated in West Germany 1982 and 1983, with a Co-formulation of Ethofumesate and Phenmedipham FBC Limited, Chesterford Park, United Kingdom Bayer CropScience, Report No.: A83072, Report includes Trial Nos.: 041/03/080 Edition Number: M-155349-01-1 Date: 1984-09-20 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /51	Snowdon, P. J.	1985	Residues of Ethofumesate and major metabolites in sugarbeet treated in France 1984 with Ethofumesate and Phenmedipham as either a Co-formulation of a Tank-mix FBC Limited, Chesterford Park, United Kingdom Bayer CropScience, Report No.: A83071, Report includes Trial Nos.: 041/03/082 Edition Number: M-155348-01-1 Date: 1985-04-18 No GLP	N	Bayer CropScience

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			Unpublished		
KCA 6.3.5 /52	Manley, J. D.; Snowdon, P. J.	1986	Residues of Ethofumesate and major metabolites in sugar beet treated in the ederal Republic of Germany, 1983 with a Co-formulation of Ethofumesate and Phenmedipham FBC Limited, Chesterford Park, United Kingdom Bayer CropScience, Report No.: A83077, Report includes Trial Nos.: 041/03/080 Edition Number: M-155353-01-1 Date: 1986-08-04 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /53	Manley, J. D.; Snowdon, P. J.	1986	Residues of Ethofumesate and major metabolites in sugarbeet tretaed in the Federal Republic of Germany 1985 with a Co-formulation of Ethofumesate and Phenmedipham FBC Limited, Chesterford Park, United Kingdom Bayer CropScience, Report No.: A83078, Report includes Trial Nos.: 041/03/085 Edition Number: M-155354-01-1 EPA MRID No.: 41214220 Date: 1986-09-16 No GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /54	Banwell, M.; Bright, J. H. M.	1990	Residues of Ethofumesate and its major metabolites in sugar beet following multiple post-emergence application of an EC Co-formulation with Penmedipham and Desmedipham in Denmark 1989 (2nd Edition) Schering AG, Berlin, Germany Bayer Crop Science, Report No.: A83095, Report includes Trial Nos.: 041/03/116 Edition Number: M-155764-02-1 Date: 1990-07-11 ...Amended: 1990-11-01 GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /55	Straszewski, A.	1993	Ethofumesate: SC (CQ 1273/01): Residues of Ethofumesate and its major metabolite in sugar beets France 1992 Schering AG, Berlin, Germany Bayer Crop Science, Report No.: A83115, Edition Number: M-155390-01-1 Date: 1993-09-23 GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /56	Wrede, A.	1995	Residues in sugar beet after application of Betanal progress of in France 1993 Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer Crop Science, Report No.: A62042, Edition Number: M-145562-01-1 Date: 1995-04-04 GLP Unpublished	N	Bayer CropScience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.3.5 /57	Helgers, A.	1997	Ethofumesate and lenacil suspension concentrate 300 + 120 g/l AE B049913 02 SC 37 A101 and AE B049913 02 WP42 A101 Ethofumesate and lenacil SC compared with a WP formulation in sugar beet; determination of residues in sugar beet roots and Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: A89772, Edition Number: M-165366-02-1 Date: 1997-01-27 ...Amended: 1997-02-27 GLP Unpublished	N	Bayer CropScience
KCA 6.3.5 /58	Schulte, G.	2013	Amendment no. 1 to report no: 10- 2109 - Determination of the residues of ethofumesate in/on sugar beet after spray application of ethofumesate SC 500 in the field in Spain, Italy and Greece Bayer CropScience, Report No.: 10-2109, Report includes Trial Nos.: 10-2109-01 10-2109-02 10-2109-03 10-2109-04 Edition Number: M-444836-02-1 Date: 2013-01-15 ...Amended: 2013-07-09 GLP Unpublished	N	Bayer CropScience
KCA 6.3.1/01	Tandy, R.	2012a	Determination of residues of Ethofumesate, Phenmedipham and Desmedipham after one application of Ethofol 500SC or three applications of Betasana Trio SC in sugar beet (outdoor) at 4 sites in Northern Europe 2009 United Phosphorus Ltd., S09-01656 Eurofins Agroscience Services LTD, UK GLP Unpublished	N	UPL
KCA 6.3.1/02	Perny, A.	2002	Residue study in sugar beets following treatments with a formulated product containing Ethofumesate 128 g/l, Phenmedipham 62 g/l and Desmedipham 16 g/l on sugar beet fields under field conditions in France and in the Netherlands in 2000 AgriChem B.V., R A0015 Anadiag S.A., Haguenau, France GLP Unpublished	N	ACM*
KCA 6.3.1/03	Perny, A.	2003	Residue study in sugar beets following treatments with a formulated product containing Ethofumesate 128 g/l, Phenmedipham 62 g/l and Desmedipham 16 g/l on sugar beet fields under field conditions in France and in The Netherlands in 2001 AgriChem B.V., R A1114 Anadiag S.A., Haguenau, France GLP Unpublished	N	ACM*
KCA 6.3.1/04	Huauilmé, J.-M.	2013a	Magnitude of residue of Ethofumesate and metabolites in sugar beet raw agricultural commodities after one foliar application of Ethofumesate 500 g/L SC - 4 trials (2 harvest trials and 2 decline curve trials) Northern Europe (The	N	ACM*

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
			Netherlands, Belgium) - 2012 AgriChem B.V., BPL12/436/GC BIOTEK Agriculture GLP Unpublished		
KCA 6.3.1/05	Chevallier, E.	2012	Magnitude of residue of Ethofumesate and metabolites in sugar beet raw agricultural commodities after one foliar application of Ethofumesate 500 g/L SC - 4 trials (2 harvest trials and 2 decline curve trials) Northern Europe (The Netherlands, Belgium) - 2011 AgriChem B.V., BPL11/380/GC BIOTEK Agriculture GLP Unpublished	N	ACM*
KCA 6.3.1/06	Waalkens, W.M., Hamberger, R.	2005a	Determination of the decline of the residues of Phenmedipham, MHPC, Methylaniline, Desmedipham, EHPC, Aniline, Ethofumesate, 2-Keto- Ethofumesate in/on sugar beet plants and roots after foliar applications of Phenmedipham 157 g/l EC, Phenmedipham 157 g/l SE and Ethofumesate / Phenmedipham / Desmedipham 128/62/21 g/l EC to sugar beets in the Netherlands and northern France, 2003 AgriChem B.V., R03-16-NF-08 Res.Comp. for Plant Protec. "De Bredelaar" B.V., Elst, NL GLP Unpublished	N	ACM*
KCA 6.3.1/07	Waalkens, W.M., Hamberger, R.	2005b	Determination of the magnitude of the residues of Phenmedipham, MHPC, Methylaniline, Desmedipham, EHPC, Aniline, Ethofumesate, 2-Keto- Ethofumesate in/on sugar beet plants and roots after foliar applications of Phenmedipham 157 g/l EC, Phenmedipham 157 g/l SE and Ethofumesate / Phenmedipham / Desmedipham 128/62/21 g/l EC to sugar beets in the Netherlands and northern France, 2003 AgriChem B.V., R03-16-NF-09 Res.Comp. for Plant Protec. "De Bredelaar" B.V., Elst, NL GLP Unpublished	N	ACM*
KCA 6.3.1/08	Waalkens, W.M., Hamberger, R.	2005c	Determination of the decline of the residues of Phenmedipham, MHCP, Methylaniline, Desmedipham, EHPC, Aniline, Ethofumesate, 2-Keto- Ethofumesate in/on sugar beet plants and roots after foliar applications of Phenmedipham 157 g/l SE and Ethofumesate / Phenmedipham / Desmedipham 128/62/21 g/l EC to sugar beets in the Netherlands and northern France, 2004 AgriChem B.V., R04-16-NF-08 Res.Comp. for Plant Protec. "De Bredelaar" B.V., Elst, NL GLP Unpublished	N	ACM*
KCA 6.3.1/09	Waalkens, W.M., Hamberger, R.	2005d	Determination of the magnitude of the residues of Phenmedipham, MHPC, Methylaniline, Desmedipham, EHPC, Aniline, Ethofumesate, 2-Keto-Ethofumesate in / on sugar beet plants and roots after foliar applications of Phenmedipham 157 g/l SE and Ethofumesate / Phenmedipham / Desmedipham 128/62/21 g/l EC to sugar beets in the Netherlands and northern France, 2004	N	ACM*

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			AgriChem B.V., R04-16-NF-09 Res.Comp. for Plant Protec. "De Bredelaar" B.V., Elst, NL GLP Unpublished		
KCA 6.3.1/10	Anspach, T.	2001	Magnitude of the residue of Phenmedipham, Desmedipham, Ethofumesate and its metabolite 2- oxo-Ethofumesate in sugar beets (roots and leaves/tops) after the application of Betasana Trio under filed conditions in Germany, 2000 United Phosphorus Ltd., ADN-0004 Dr. Specht Partner, Chemische Laboratorien GmbH, Germany GLP Unpublished	N	UPL
KCA 6.3.1/11	Tandy, R.	2013	Determination of residues of ETHOFUMSATE and ETHOFUMESATE-2-KETO, after one or three applications of ETHOFOL 500SC, or three application of BETASANA TRIO SC in sugar beet (outdoor) at 5 sites in Northern europe and 5 stes in Southern Europe 2010 United Phosphorus Ltd., S10-00258 Eurofins Agrosience Services LTD, UK GLP Unpublished	N	UPL
KCA 6.3.1/12	Waalkens, W.M. Hamberger, R.,	2005e	Determination of the magnitude of the residues of Phenmedipham, MHPC, Methylaniline, Desmedipham, EHPC, aniline, Ethofumesate, 2-Keto-Ethofumesate in/on sugar beet plants and roots after foliar applications of Phenmedipham 157 g/l SE and Ethofumesate / Phenmedipham / Desmedipham 128/62/21 g/l EC to sugar beets in northern Spain, 2003 AgriChem B.V., R03-16-SP-06 Res.Comp. for Plant Protec. "De Bredelaar" B.V., Elst, NL GLP Unpublished	N	ACM*
KCA 6.3.1/13	Waalkens, W.M., Hamberger, R.	2005f	Determination of the decline of the residues of Phenmedipham, MHPC, Methylaniline, Desmedipham, EHPC, Aniline, Ethofumesate, 2-Keto- Ethofumesate in/on fodder beet plants and roots after foliar applications of Phenmedipham 157 g/l SE and Ethofumesate / Phenmedipham / Desmedipham 128/62/21 g/l EC to fodder beets in southern France, 2003 AgriChem B.V., R03-16-FR-07 Res.Comp. for Plant Protec. "De Bredelaar" B.V., Elst, NL GLP Unpublished	N	ACM*
KCA 6.3.1/14	Huauilmé, J.-M.	2013b	Magnitude of residue of Ethofumesate and metabolites in sugar beet raw agricultural commodities after one foliar application of Ethofumesate 500 g/L SC - 4 trials (2 harvest trials and 2 decline curve trials) Southern Europe (Italy, Spain)-2012 AgriChem B.V., BPL12/435/GC BIOTEK Agriculture GLP	N	ACM*

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			Unpublished		
KCA 6.3.1/15	Tandy, R.	2012b	Validation of the analytical method A0019 to confirm the conversion of NC 20645 to NC 9607 in sugar beet roots and tops and wheat grain and straw United Phosphorus Ltd., S11-03715 Eurofins Agrosience Service GmbH No GLP Unpublished	N	UPL
KCA 6.3.1/16	Weir, A.	2014	METHOD MODIFICATION AND VALIDATION OF AN ANALYTICAL METHOD FOR THE DETERMINATION OF ETHOFUMESATE AND ITS METABOLITES NC 20645 AND NC 9607 IN SUGARBEET ROOTS AND TOPS United Phosphorus Ltd., S13-03837 Eurofins Agrosience Services LTD, UK GLP Unpublished	N	UPL
KCA 6.4.1/01	██████	1975	INVESTIGATION OF TISSUE AND EGG - RESIDUES FROM HENS FOLLOWING DIETARY INTAKE OF NC 8438 FOR 21 DAYS Bayer CropScience, Report No.: A83011, Edition Number: M-155288-01-1 Date: 1975-09-01 No GLP Unpublished ...also filed: KCA 4.1.2 /27	Y	Bayer CropScience
KCA 6.4.1/02	██████	1999	Review of animal metabolism data; maximum estimated dietary concentration for poultry and cattle; rebuttal for further animal feeding studies Ethofumesate Code: AE B049913 ██████ Bayer CropScience, Report No.: C003329, Edition Number: M-185950-01-1 No GLP Unpublished ...also filed: KCA 6.4.2 /04	Y	Bayer CropScience
KCA 6.4.2/01	██████	1977	RESIDUES IN MILK AND TISSUES FOLLOWING A 28-DAY FEEDING STUDY WITH ETHOFUMESATE IN DAIRY COWS - PART 1 ██████ Bayer CropScience, Report No.: A83024, Edition Number: M-155301-01-1 EPA MRID No.: 41214208 Date: 1977-06-01 No GLP Unpublished ...also filed: KCA 4.1.2 /25	Y	Bayer CropScience
KCA 6.4.2/02	██████	1977	RESIDUES IN MILK AND TISSUES FOLLOWING A 28-DAY FEEDING STUDY WITH ETHOFUMESATE	Y	Bayer

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
			IN DAIRY COWS - PART 2 Bayer CropScience, Report No.: A89223, Edition Number: M-164398-01-1 Date: 1977-06-01 No GLP Unpublished		CropScience
KCA 6.4.2/03		1994	Ethofumesate-derived residues in the meat and milk of dairy cows: resulting from oral ingestion of ethofumesate Bayer Crop Science, Report No.: B002201, Report includes Trial Nos.: B93R04/05 Edition Number: M-237976-01-1 EPA MRID No.: 43458701 Date: 1994-10-12 No GLP Unpublished ...also filed: KCA 4.1.2 /29	Y	Bayer CropScience
KCA 6.4.2 /04		1999	Review of animal metabolism data; maximum estimated dietary concentration for poultry and cattle; rebuttal for further animal feeding studies Ethofumesate Code: AE B049913 Bayer Crop Science, Report No.: C003329, Edition Number: M-185950-01-1 No GLP Unpublished ...also filed: KCA 6.4.1 /02	Y	Bayer CropScience
KCA 6.5.1 /01	Miebach, D.; Bongartz, R.	2010	Nature of the residues of ethofumesate in processed commodities - High temperature hydrolysis Bayer CropScience, Report No.: MEF-10/803, Edition Number: M-397800-01-1 Date: 2010-12-09 GLP Unpublished	N	Bayer CropScience
KCA 6.5.3 /01	Whiteoak, R. J.; Crofts, M.	1973	CONJUGATED RESIDUES IN FRACTIONS PROCESSED FROM SUGAR BEET TREATED WITH NORTRON Fisons plc, United Kingdom Bayer Crop Science, Report No.: A82973, Edition Number: M-155250-01-1 EPA MRID No.: acc.36368 Date: 1973-05-01 No GLP Unpublished	N	Bayer CropScience

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KCA 6.5.3 /02	Crofts, M.; Whiteoak, R. J.	1974	FATE OF THE METABOLITE CONJUGATED NC 9607 DURING PRODUCTION OF SUGAR FROM NORTRON TREATED SUGAR BEET Fisons plc, United Kingdom Bayer Crop Science, Report No.: A82985, Edition Number: M-155262-01-1 EPA MRID No.: acc.36369 Date: 1974-03-01 No GLP Unpublished ...also filed: KCA 4.1.2 /10	N	Bayer CropScience
KCA 6.5.3 /03	Crofts, M.; Whiteoak, R. J.	1975	FATE OF THE METABOLITE CONJUGATED NC 9607 DURING PRODUCTION OF SUGAR FROM NORTRON TREATED SUGAR BEET - ARTIFICIALLY HIGH RESIDUES IN BEET GROWN AND PROCESSED IN THE UNITED KINGDOM Fisons plc, United Kingdom Bayer CropScience, Report No.: A83002, Edition Number: M-155279-01-1 Date: 1975-03-01 No GLP Unpublished	N	Bayer CropScience
KCA 6.5.3 /04	Crofts, M.; Whiteoak, R. J.	1975	FATE OF THE METABOLITE CONJUGATED NC 9607 DURING PRODUCTION OF SUGAR FROM NORTRON TREATED SUGAR BEET - ARTIFICIALLY HIGH RESIDUE IN BEET GROWN AND PROCESSED IN W. GERMANY Fisons plc, United Kingdom Bayer Crop Science, Report No.: A83003, Edition Number: M-155280-01-1 Date: 1975-03-01 No GLP Unpublished	N	Bayer CropScience
KCA 6.6.1 /01	Carlton, R.; Cordell, P.	1993	THE UPTAKE AND METABOLISM OF ETHOFUMESATE AND ITS SOIL METABOLITES IN A CONFINED ROTATIONAL CROP STUDY Schering AG, Berlin, Germany Bayer Crop Science, Report No.: A83396, Report includes Trial Nos.: 90B Edition Number: M-155664-01-1 Date: 1993-06-18 GLP Unpublished	N	Bayer CropScience
KCA 6.6.1 /02	Schneider, E.	1994	PR94/025 - Ethofumesate - Determination of ethofumesate residues in soil of a long time field study after the application of Ethosat (FSG031894) to sugar beet plants Dr. G. Krebs Analytik, Köln, Germany Feinchemie Schwebda, Report No.: M-468487-01-1, Edition Number: M-468487-01-1 Date: 1994-08-12 GLP	N	Adama (former Feinchemie Schwebda)

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			Unpublished		
KCA 6.6.1/01	Chapleo, S.	2003	The uptake of [¹⁴ C]-Ethofumesate residues in soil by rotational crops under confined conditions AgriChem B.V., Inveresk Research International, Tranent, Scotland Report No.: 22558 GLP Unpublished	N	ACM*
KCA 6.6.2 /01	Castro, L. E.	1994	ETHOFUMESATE EMULSIFIABLE CONCENTRATE 200 g/l CR 13768: AT-HARVEST RESIDUES OF ETHOFUMESATE AND METABOLITES IN ROTATIONAL CROPS AND SOIL FOLLOWING APPLICATIONS OF NORTRON EC TO SUGARBEETS, USA, 1990 Nor-Am Chemical Company, Pikeville, NC, USA Bayer CropScience, Report No.: A83117, Edition Number: M-155392-01-1 EPA MRID No.: 43298104 Date: 1994-05-05 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCA 6.6.2 /02	Crofts, M.; Whiteoak, R. J.	1974a	RESIDUE ANALYSIS OF WHEAT GROWN IN THE UK AS A FOLLOWING CROP AFTER SUGAR BEET TREATED WITH NORTRON (1973) Fisons plc, United Kingdom Bayer Crop Science, Report No.: A82995, Edition Number: M-155272-01-1 Date: 1974-11-01 No GLP Unpublished	N	Bayer CropScience
KCA 6.6.2 /03	Crofts, M.; Whiteoak, R. J.	1974b	RESIDUE ANALYSIS OF WHEAT AND CORN (MAIZE) GROWN AS FOLLOWING CROPS AFTER SUGAR BEET TREATED WITH NORTRON (1973) Fisons plc, United Kingdom Bayer Crop Science, Report No.: A82994, Edition Number: M-155271-01-1 Date: 1974-09-01 No GLP Unpublished	N	Bayer CropScience
KCA 6.6.2 /04	Peatman, M. H.; Snowdon, P. J.	1991	RESIDUES OF SOIL AND EMERGENCY CROPS FOLLOWING APPLICATION OF ETHOFUMESATE AS A 50 SC FORMULATION IN THE UK 1990/91 Schering AG, Berlin, Germany Bayer Crop Science, Report No.: A83376, Report includes Trial Nos.: 041/04/057 Edition Number: M-155644-01-1 Date: 1991-12-20 GLP Unpublished	N	Bayer CropScience
KCA 6.6.2 /05	Schulte, G.; Diehl, P.	2013	Amendment No. 1 to Report No: 10- 2501 - Determination of the residues of ethofumesate in/on the field rotational crop barley, carrot, lettuce and wheat after spray application of ethofumesate SC 500 on sugar beet and soil in the field, in the Netherlands, Italy, Spain and Germany	N	Task Force Ethofumesate

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
			Bayer CropScience, Report No.: 10-2501, Report includes Trial Nos.: 10-2501-02 10-2501-03 10-2501-04 10-2501-05 Edition Number: M-463906-02-1 Date: 2013-08-22 ...Amended: 2013-09-13 GLP Unpublished		
KCA 6.6.2/01	Spence, C.	2014	Evaluation of Ethofumesate Herbicide Residues Crop Rotation Study, Cereal, Root and Leafy Vegetable Crops Following Sugar Beet - One Application to Two Trials Initiated in 2012 - NEU (the United Kingdom) and SEU (Italy) AgriChem B.V., 697614, 34890 Charles River Laboratories , Edinburgh, UK GLP Unpublished	N	ACM*
KCA 6.10 /01	Wang, P.; Wang, Q.; Jiang, S.; Qiu, J.; Wang, P.; Zhou, Z.	2005	Stereoselective degradation of ethofumesate in turfgrass and soil. Journal:Pestic. Biochem. Physiol., Volume:82, Issue:3, Pages:197-204, Year:2005, Report No.: M-458577-01-1, Edition Number: M-458577-01-1 Date: 2005-12-31 No GLP Published ...also filed: KCA 7.1.2.1.1 /14	N	published
KCA 6.10.1/01	Lückmann, J.	2013	Ethofumesate - exposure of honeybees to residues in nectar, pollen and guttation fluid in sugar and fodder beets United Phosphorus Ltd., P13096 RIFCon GmbH, Hirschberg, Germany No GLP Unpublished	N	UPL

* AgriChem B.V. is part of United Phosphorus Ltd since 2012. Studies performed for Agichem B.V. are therefore now fully owned by United Phosphorus Ltd

Clopyralid

For studies owned by Corteva (previously Dow AgroSciences S.A.S.) and submitted for the renewal of clopyralid the applicant has a Letter of Access. Studies from the initial clopyralid approval (DAR, 2005) are not data protected.

List of information, tests and studies which are considered as relied upon by the RMS for the evaluation with a view to the approval or renewal of the active substance Clopyralid.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.1	Foster, D.R., Blakeslee, B.A., Rutherford, B.S.	1996	Frozen Storage Stability of Clopyralid, 2,4-D in Corn Grain, Straw and Fodder DAS Report No. GH-C 3779, File No. N136 DowElanco, Indianapolis, Indiana, US GLP Unpublished	N	Corteva (Study from DAR, 2005)
KCA 6.1	Clements, B., Bolton, A.	1996	Determination of the Stability of Clopyralid Residues in Pasture under Frozen Storage Conditions DAS Report No. GHE-P-5350, File No. N138 CEM Analytical Services (CEMAS), North Ascot, Berkshire, UK GLP Unpublished	N	Corteva (Study from DAR, 2005)
KCA 6.1	Anon.	2015	Frozen Storage Stability of Clopyralid in Bovine Fat DAS Study No. 120602 GLP Unpublished	N	Corteva (new study submitted for renewal)
KCA 6.1	Anon.	2004	Frozen Storage Stability of Clopyralid in Beef Muscle, Liver, Kidney, Milk and Chicken Egg DAS Study No. 020120.01 GLP Unpublished	N	Corteva (new study submitted for renewal)
KCA 6.2.1	Chapleo, S. ; Caley, C. Y.	2002	The Metabolism of [14C]-Clopyralid in Sugar Beet DAS Report No. GHE-P-9939, File No. L10 Inveresk Research International, Tranent, East Lothian, United Kingdom GLP Unpublished	N	Corteva (Study from DAR, 2005)
KCA 6.2.1	Guo, C.	1996	Metabolism of 14C -Clopyralid in Cabbage DAS Report No. GH-C-4289, File No. L06 ABC Laboratories Inc, Columbia, Missouri, USA GLP Unpublished	N	Corteva (Study from DAR, 2005)

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.2.1	Chapleo, S., Caley, C. Y., White, D. E.	2002	The Metabolism of (14C)-Clopyralid in Oilseed Rape DAS Report No. GHE-P 9938, File No. L09 Inveresk Research International, Tranent, East Lothian, UK GLP Unpublished	N	Corteva (Study from DAR, 2005)
KCA 6.2.2	██████	2014	A Nature of the Residue Study in the Laying Hen with [14C]-Clopyralid DAS Study No. 130906 ██████ GLP Unpublished	Y	Corteva (new study submitted for renewal)
KCA 6.2.3	██████	2015	A Nature of the Residue Study in the Ruminant with [14C]Clopyralid DAS Study No. 130202 GLP Unpublished	Y	Corteva (new study submitted for renewal)
KCA 6.3	Freeman J.M.H., Walker, S.M.	1980	Determination of residues of 3,6-dichloropicolinic acid (DOWCO* 290) in sugar beet, roots and tops, treated with FORMAT** - UK 1980 Dow Chemical Company DAS Report No. GHE-P-803, File No. N76 No GLP Unpublished	N	Corteva (Study from DAR, 2005)
KCA 6.3	Rawle, N.W., Khoshab, A.	2002	Residues of clopyralid in sugar beet at intervals under open field conditions following multiple applications of Lontrel 100 (EF-1136), Northern France and UK – 2000 DAS Report No. GHE-P-9356, File No. N195 GLP Unpublished	N	Corteva (Study from DAR, 2005)
KCA 6.3	Rawle, N.W., Khoshab, A.	2002	Residues of clopyralid in sugar beet at harvest under open field conditions following multiple applications of Lontrel 100 (EF-1136), Northern France and UK – 2000 DAS Report No. GHE-P-9357, File No. N198 GLP Unpublished	N	Corteva (Study from DAR, 2005)
KCA 6.3	Rawle, N.W., Khoshab, A.	2002	Residues of clopyralid in sugar beet at intervals and at harvest following multiple applications of Lontrel (EF-1136), EU Northern Zone – 2001 DAS Report No. GHE-P-9381, File No. N199 GLP	N	Corteva (Study from DAR, 2005)

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Unpublished		
KCA 6.4.1	████	1974	Dowco 290 and 2,4-D Chicken Feeding Study DAS Study No. TA-517 No GLP Unpublished	Y	Corteva (new study submitted for renewal)
KCA 6.4.1	████	1975	Residues of Dowco 290 (3,6-dichloropicolinic acid) in Tissues of Chickens Fed the Herbicide DAS Study No. GH-C 819 No GLP Unpublished	Y	Corteva (Study from DAR, 2005)
KCA 6.4.1	████	2015	Summary of Clopyralid Livestock Feeding Study: Magnitude of Residue in Eggs, Muscle, Liver and Fat of Laying Hens DAS Study No. 150031 ████ GLP Unpublished	Y	Corteva (new study submitted for renewal)
KCA 6.4.2	████	1974	Milk Residue Study with Dairy Cows Fed Lontrel Herbicide, Nellite Nematocide and 2,4-D Herbicide: Animal Care, Sampling and Production Records DAS Study No. GH-A 579 No GLP Unpublished	Y	Corteva (Study from DAR, 2005)
KCA 6.4.2	████	1974	Residues of Dowco 290 (3,6-dichloropicolini acid) in Milk and Cream from Cows Fed the Herbicide DAS Study No. GH-C 745 No GLP Unpublished	Y	Corteva (Study from DAR, 2005)
KCA 6.4.2	████	1975	Residues of Dowco 290 (3,6-dichloropicolinic acid) in Bovine Tissues from Calves Fed the Herbicide DAS Study No. GH-C 811 No GLP Unpublished	Y	Corteva (Study from DAR, 2005)
KCA 6.4.2	████	2015	Summary of Clopyralid Livestock Feeding Study: Magnitude of Residue in Milk, Muscle, Liver, Kidney and Fat of Lactating Dairy Cattle DAS Study No. 150030 ████ GLP Unpublished	Y	Corteva (new study submitted for renewal)

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.4.3	██████	1975	Residues of Dowco 290 (3,6-dichloropicolinic acid) in Tissues of Swine Fed the Herbicide DAS Study No. GH-C 874 No GLP Unpublished	Y	Corteva (Study from DAR, 2005)
KCA 6.5.1	Adusumilli, H.	2014	Processing Study to Determine the Nature of Residues of 14C -Clopyralid Following the Industrial or Household Preparation DAS Study No. 140574 Dow AgroSciences LLC, Indianapolis, Indiana, USA GLP Unpublished	N	Corteva (new study submitted for renewal)
KCA 6.5.3	Almond, R.H.	1985	Determination of residues of clopyralid in sugar beet molasses Dow Chemical Company DAS Report No. GHE-P-1334, File No. N79 No GLP Unpublished	N	Corteva (Study from DAR, 2005)
KCA 6.5.3	Day, S.R., Osborne, K.A.	1988a	Clopyralid residues in sugar N beet molasses produced by British S N ugar beet factories in the UK – 1986/87 sugar processing campaign Dow Chemical Company DAS Report No. GHE-P-1802, File No. N80 No GLP Unpublished	N	Corteva (Study from DAR, 2005)
KCA 6.5.3	Day, S.R., Osborne, K.A.	1988b	Clopyralid residues in sugarbeet molasses produced by two factories in the UK – 1986/7 sugarbeet processing campaign Dow Chemical Company DAS Report No. GHE-P-1803, File No. N81 No GLP Unpublished	N	Corteva (Study from DAR, 2005)
KCA 6.5.3	Osborne, K.A.	1988	Clopyralid in refined white sugar produced by British sugar factories in the UK – 1986/7 sugar beet processing campaign Dow Chemical Company DAS Report No. GHE-P-1804, File No. N82 No GLP Unpublished	N	Corteva (Study from DAR, 2005)
KCA 6.5.3	Osborne, K.A.,	1989	Clopyralid residues in sugarbeet molasses and massecuite prepared from sugarbeet treated with DOW SHIELD – UK	N	Corteva

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
	Walker, S.M.		1988 Dow Chemical Company DAS Report No. GHE-P-1954, File No. N84 No GLP Unpublished		(Study from DAR, 2005)
KCA 6.6.1	Yackovich, P. R. ; Lardie, T. S. ; Brink, D. L.	1993	A 10-1/2 Month Rotational Crops Study With 14C -Labeled Clopyralid - MET90080 DAS Study No. GH-C 2992 Dow AgroSciences LLC, Indianapolis, Indiana, United States GLP Unpublished	N	Corteva (Study from DAR, 2005)
KCA 6.6.1	Yackovich, P.R.; Lardie T.S.; Miller J.H.	1989	A 125-Day Rotational Crops Study with 14C Labelled Clopyralid DAS Study No. GH-C 2277 DowElanco, Midland, Michigan, USA Unpublished	N	Corteva (Study from DAR, 2005)
KCA 6.6.1	Hall, L. R.	2015	14C -Clopyralid: Metabolism in Confined Rotational Crops with a 30-Day Plant-back Interval DAS Study No. 130733 ABC Laboratories, Inc., Columbia, Missouri 65202, USA GLP Unpublished	N	Corteva (new study submitted for renewal)

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 Ethofumesate

A 2.1.1 Stability of residues

A 2.1.1.1 Stability of residues during storage of samples

A 2.1.1.1.1 Storage stability of residues in plant products

A 2.1.1.1.1.1 Study 1: Report MR-12/058

Comments of zRMS:	The study has been evaluated and accepted by zRMS-PL in RR – Part B7 for AG-E1-500 SC1/ Ethosat 500 SC (January 2022). This study has not been reassessed in the framework of this application. The conclusions of the assessment are presented below: <i>A storage stability study was conducted with AE C520645 (open-ring-2-keto-ethofumesate; NC 20645) in plant commodities (sugar beet leaf, sugar beet body, rape seed, bean dry seed and orange fruit) to determine the stability of the residues while stored frozen for up to approximately 24 months using Method 01343.</i> <i>The fortification level was 0.10 mg/kg.</i> <i>The fortified samples were stored frozen and analyzed for analyte NC 20645 at nominal intervals of 30, 90, 180, 360, 540 and 720 days.</i> <i>All method validation data are within the acceptable criteria: mean recovery range of 70-120% and relative standard deviation $\leq$ 20%.</i> <i>The analyte NC 20645 can be considered stable in the investigated matrices: of sugar beet leaf (high water content), sugar beet body (high starch content), rape seed (high oil content), dry bean seed (high protein content) and orange fruit (high acid content) under deep-freezer storage conditions ($\leq -18^{\circ}\text{C}$) for at least 24 months.</i> <i>The study is acceptable.</i>
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Reference: KCA 6.1/01

Report Storage Stability of open-ring-2-keto ethofumesate (AE C520645) in Plant Matrices for 24 Months, Schulte, G., 2015, Report No. MR-12/058, Study ID P642120507

Guideline(s): Yes.
Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 Concerning the Placing of Plant Protection Products on the Market and Repealing Council Directives 79/117/EEC and 91/414/EEC
OECD Guidelines for the Testing of Chemicals. Stability of Pesticide Residues in Stored Commodities. 506. 2007-10-16
US EPA OCSPP 860.1380, Storage Stability Data

Deviations: No

GLP: Yes

Acceptability: Yes

Materials and methods

To determine the freezer stability of the analyte NC 20645 in plant materials, individual 10 g control samples of sugar beet leaf (high water content), sugar beet body (high starch content), rape seed (high oil content), dry bean seed (high protein content) and orange fruit (high acid content) were spiked with 1 μg NC 20645, resulting in a fortification level of 0.1 mg/kg.

Except for the day-0 analysis, samples were stored in glass containers in a freezer at $\leq -18^{\circ}\text{C}$ for later use.

For day-0 analysis, five treated samples of each material were chosen, as well as two control sample of each. In addition, two recoveries spiked at the respective LOQ level and two recoveries spiked at the 10-fold LOQ level were analysed. After nominally 30, 90, 180, 360, 540 and 720 days, three fortified and three control samples of each plant material were removed from the deep-freezer and allowed to reach room temperature. Subsequently, two of the control samples of each plant material were fortified with the test items to determine the concurrent recoveries (the fortification level was at 0.01 mg/kg as the spiked storage samples). The samples were extracted and analyzed concurrently with the third control sample and the spiked storage samples.

NC 20645 was determined using analytical method 01343, which was validated prior to and parallel to the analysis of the stored samples.

Method 01343 was developed for the determination of open-ring-2-keto-ethofumesate (NC 20645) in/on plant materials. Open-ring-2-keto-ethofumesate (NC 20645) was extracted from sugar beet leaf, sugar beet body, rape seed, dry bean and orange fruit, with acetonitrile/water (4/1, v/v) using a shaker. After filtration of the extract, the stable isotopically labelled internal standard was added. The internal standard is hydrolysed during analysis to the corresponding phenyl-¹³C6 open-ring-2-keto-ethofumesate. The solution was made up to volume, filtered and subjected to reversed phase HPLC-MS/MS in negative ion mode without further clean-up. Residues were quantified using internal stable labelled standards.

The LOQ was 0.01 mg/kg for NC 20645 (expressed in analyte equivalents).

Results and discussions

In the control samples used for fortification the residues were always below 30% of the LOQ, except for rape seed at the storage intervals of 185 and 543 days with approx. 88% and 33% of the LOQ respectively.

After a deep-freezer storage period of about 24 months, the mean recovery rates from the stored samples ranged between 73% and 101% for open-ring-2-keto-ethofumesate. The concurrent recoveries determined from freshly fortified samples were in a range of 70% - 110%.

Altogether, the study results demonstrate that the residues of open- ring-2-keto-ethofumesate are stable in the tested plant commodities for 24 months (718 days for rape seed, bean dry seed, orange fruit and 719 days for sugar beet leaf and body) under deep-freezer storage conditions.

Table A 1: Summary of concurrent recoveries and storage stability data of NC 20645 from sugar beet leaves

Commodity	Storage period (days)	Residue level in stored samples			Day-0 normalized recovery ^a	Average % of fresh concurrent recoveries	Average corrected % recovery ^b
		mg/kg (mg/kg)	% of nominal spiking level	Average % recovery			
Sugar beet leaf	NC 20645						
	0	0.0966	97	91	100	87	105
		0.0918	92				
		0.0881	88				
		0.0869	87				
		0.0911	91				
	30	0.0952	95	95	104	95	101
		0.0962	96				
		0.0937	94				
	89	0.0898	90	90	99	89	102
		0.0900	90				
		0.0897	90				
	187	0.0781	78	82	90	90	92
		0.0830	83				
		0.0851	85				
	362	0.0793	79	79	87	82	97
0.0841		84					
0.0748		75					
544	0.0893	89	91	100	88	104	
	0.0951	95					
	0.0881	88					
719	0.0711	71	73	81	76	96	

Commodity	Storage period (days)	Residue level in stored samples			Day-0 normalized recovery ^a	Average % of fresh concurrent recoveries	Average corrected % recovery ^b
		mg/kg (mg/kg)	% of nominal spiking level	Average % recovery			
		0.0748 0.0736	75 74				

a Normalized Recovery = (average recovery / average recovery at day 0) x 100%

b Corrected percent recovery = (average % recovery (stored) / Average of fresh concurrent recoveries) x 100%

Mean values were calculated with unrounded values. Therefore minor deviations may occur when the values given in the table are used.

Table A 2: Summary of concurrent recoveries and storage stability data of NC 20645 from sugar beet root

Commodity	Storage period (days)	Residue level in stored samples			Day-0 normalized recovery ^a	Average % of fresh concurrent recoveries	Average corrected % recovery ^b
		mg/kg (mg/kg)	% of nominal spiking level	Average % recovery			
Sugar beet root	NC 20645						
	0	0.0922	92	94	100	102	92
		0.0910	91				
		0.0940	94				
		0.0951	95				
		0.0966	97				
	30	0.0873	87	87	92	86	101
		0.0846	85				
		0.0879	88				
	89	0.0952	95	96	102	92	104
		0.0976	98				
		0.0955	95				
	187	0.0933	93	94	100	97	97
		0.0927	93				
		0.0956	96				
	362	0.0927	93	94	100	85	110
0.0946		95					
0.0934		93					
544	0.0760	76	78	84	83	95	
	0.0774	77					
	0.0818	82					
719	0.0860	86	88	94	78	114	
	0.0905	91					
	0.0872	87					

a Normalized Recovery = (average recovery / average recovery at day 0) x 100%

b Corrected percent recovery = (average % recovery (stored) / Average of fresh concurrent recoveries) x 100%

Mean values were calculated with unrounded values. Therefore minor deviations may occur when the values given in the table are used.

Table A 3: Summary of concurrent recoveries and storage stability data of NC 20645 from rape seed

Commodity	Storage period (days)	Residue level in stored samples			Day-0 normalized recovery ^a	Average % of fresh concurrent recoveries	Average corrected % recovery ^b
		mg/kg (mg/kg)	% of nominal spiking level	Average % recovery			
Rape seed	NC 20645						
	0	0.0977	98	97	100	92	106
		0.0952	95				
		0.0964	96				
		0.0978	98				
		0.0987	99				
	31	0.0922	92	91	93	98	93
		0.0911	91				
		0.0887	89				

Commodity	Storage period (days)	Residue level in stored samples			Day-0 normalized recovery ^a	Average % of fresh concurrent recoveries	Average corrected % recovery ^b
		mg/kg (mg/kg)	% of nominal spiking level	Average % recovery			
	89	0.0747 0.0757 0.0702	75 76 70	74	76	97	76
	185	0.0826 0.0781 0.0849	83 78 85	82	84	97	85
	360	0.775 0.0789 0.0849	78 79 83	80	82	81	99
	543	0.0878 0.0799 0.0840	88 80 84	84	86	93	91
	718	0.0780 0.0758 0.0797	78 76 80	78	80	81	96

a Normalized Recovery = (average recovery / average recovery at day 0) x 100%

b Corrected percent recovery = (average % recovery (stored) / Average of fresh concurrent recoveries) x 100%

Mean values were calculated with unrounded values. Therefore minor deviations may occur when the values given in the table are used.

Table A 4: Summary of concurrent recoveries and storage stability data of NC 20645 from dry bean seed

Commodity	Storage period (days)	Residue level in stored samples			Day-0 normalized recovery ^a	Average % of fresh concurrent recoveries	Average corrected % recovery ^b
		mg/kg (mg/kg)	% of nominal spiking level	Average % recovery			
Bean dry seed	NC 20645						
	0	0.1014 0.1046 0.0965 0.0948 0.0991	101 105 97 95 99	99	100	94	106
	31	0.0979 0.0929 0.0915	98 93 92	94	95	99	95
	89	0.0832 0.0865 0.0851	83 86 85	85	85	95	90
	185	0.0890 0.0868 0.0860	89 87 86	87	88	93	94
	360	0.0874 0.0913 0.0858	87 91 86	88	89	83	106
	543	0.0860 0.0808 0.0819	86 81 82	83	84	86	97
	718	0.0787 0.0778 0.0781	79 78 78	78	79	84	94

a Normalized Recovery = (average recovery / average recovery at day 0) x 100%

b Corrected percent recovery = (average % recovery (stored) / Average of fresh concurrent recoveries) x 100%

Mean values were calculated with unrounded values. Therefore minor deviations may occur when the values given in the table are used.

Table A 5: Summary of concurrent recoveries and storage stability data of NC 20645 from orange fruit

Commodity	Storage period (days)	Residue level in stored samples			Day-0 normalized recovery ^a	Average % of fresh concurrent recoveries	Average corrected % recovery ^b
		mg/kg (mg/kg)	% of nominal spiking level	Average % recovery			
Orange fruit	NC 20645						
	0	0.0980	98	101	100	99	102
		0.1009	101				
		0.0953	95				
		0.1112	111				
		0.0993	99				
	31	0.0979	98	96	95	97	99
		0.0948	95				
		0.0940	94				
	89	0.0997	100	98	97	99	99
		0.0992	99				
		0.0953	95				
	185	0.0878	88	88	88	89	99
		0.0897	90				
		0.0867	87				
	360	0.0866	87	87	86	84	104
		0.0827	83				
		0.0896	90				
	543	0.0916	92	88	88	84	106
		0.0878	88				
		0.0855	86				
	718	0.0772	77	83	82	81	102
		0.0864	86				
		0.0857	86				

^a Normalized Recovery = (average recovery / average recovery at day 0) x 100%

^b Corrected percent recovery = (average % recovery (stored) / Average of fresh concurrent recoveries) x 100%

Mean values were calculated with unrounded values. Therefore minor deviations may occur when the values given in the table are used.

Conclusion

After a deep freezer storage period at -18°C of about 24 months, the mean recovery rates of metabolite NC 20645 in stored samples of sugar beet leaf, sugar beet body, rape seed, dry bean and orange fruit, representing a wide array of plant-based sample materials (i.e. high water, high oil, high starch, high protein, high acid containing commodities), ranged between 73% and 88%.

Furthermore the concurrent recoveries determined from freshly fortified samples were in a range of 76% to 84% (mean values). Altogether, the study results demonstrate that the residues of NC 20645 are stable in the tested plant commodities for at least 24 months under deep-freezer storage conditions.

Altogether, the study results demonstrate that the residues of open- ring-2-keto-ethofumesate are stable in the tested plant commodities for 24 months (718 days for rape seed, bean dry seed, orange fruit and 719 days for sugar beet leaf and body) under deep-freezer storage conditions.

A 2.1.1.1.2 Study 2: Report RES-00278

Comments of zRMS:	The study (interim report) has been evaluated and accepted by zRMS-PL in RR – Part B7 for AG-E1-500 SC1/ Ethosat 500 SC (January 2022). The conclusions of the assessment are presented below: <i>A storage stability study was conducted with ethofumesate and ethofumesate-2-keto in plant commodities (lettuce and cereal grain) to determine the stability of the residues while stored frozen for up to approximately 24 months using analytical method OHG 00955/M002. This interim report contains data up to the 6-month timepoint.</i> <i>The fortification level was 0.10 mg/kg.</i> <i>The analytes ethofumesate and ethofumesate-2-keto can be considered stable in the investigated matrices of lettuce and cereal grain under deep-freezer storage conditions (≤</i>
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	18°C) for 6 months. All method validation data are within the acceptable criteria: mean recovery range of 70-110% and relative standard deviation $\leq$ 20%. The study is acceptable. Final report is provided by Applicant and this study is reassessed in the framework of this application. The analytes ethofumesate and ethofumesate-2-keto can be considered stable in the investigated matrices of lettuce and cereal grain under deep-freezer storage conditions ($\leq$ -18°C) for 24 months. The final report is acceptable.
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Reference:	KCA 6.1/02
Report	Ethofumesate: Storage Stability of Residues of Ethofumesate and its Metabolite in Lettuce and Cereal Grain Stored Frozen for up to Two Years, Watson, G., 2022, Report No. RES-00278, Study ID 000106576
Guideline(s):	Yes. Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 Concerning the Placing of Plant Protection Products on the Market and Repealing Council Directives 79/117/EEC and 91/414/EEC OECD Guidelines for the Testing of Chemicals. Stability of Pesticide Residues in Stored Commodities. 506. 2007-10-16 OECD ENV/JM/MONO(2007)17 SANCO/3029/99 rev.4
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

To determine the freezer stability of the ethofumesate and the ethofumesate-2-keto metabolite (NC 9607) in lettuce and cereal grain, individual 10-g control samples were spiked to a fortification level of 0.1 mg/kg.

Prior to fortification, sample sets were removed from the freezer. Each sample set included three control sub-samples and two sub-samples individually fortified with ethofumesate or ethofumesate-2-keto at 0.1 mg/kg by addition of an aliquot of a 10 µg/mL fortification standard (100 µL). Sample sets were returned to the freezer after fortification. Sample sets were prepared for each timepoint (6, 12 and 24 months) and spare sample sets were prepared for any potential repeat analyses. Samples were kept deep frozen at -18°C or below. The samples analysed so far remained frozen throughout the storage. Each analysis timepoint included one control, two controls freshly fortified with ethofumesate or ethofumesate-2-keto at 0.1 mg/kg and two stored fortified samples. The freshly fortified samples served as procedural recovery samples to evaluate method performance. Prior to extraction, the samples were transferred to 250 mL round bottomed flasks using the extraction solvent (100 mL) to rinse the centrifuge tubes.

Ethofumesate and ethofumesate-2-keto were determined using analytical method OHG 00955/M002 which was validated prior to and parallel to the analysis of the stored samples.

The method involves extraction by reflux using ethyl acetate / n-hexane (1/1, v/v). Extracts are concentrated and the retained matrix is then refluxed under acidic conditions before filtration and concentration. Extracts from both reflux steps are combined and concentrated to dryness. Extracts are re-dissolved in n-hexane and passed through a silica gel and C18 cartridge before reducing to dryness and re-dissolving in ethyl acetate. Quantification of ethofumesate and ethofumesate-2-keto is achieved by GC-MS monitoring of three fragment ions for each analyte.

The LOQ was 0.01 mg/kg for both, ethofumesate and ethofumesate-2-keto.

Results and discussions

Control lettuce and cereal grain was sourced and homogenised by ResChem Analytical. Aliquots of each

matrix type were weighed, arranged into sample sets and the relevant specimens were fortified. Each set included a control, two procedural recoveries and two fortified stored specimens. Each set was stored at $\leq -18^{\circ}\text{C}$ and relevant samples analysed after 6 months. The 0.1 mg/kg procedural recoveries from the method validation aspect of the study also served as the 0-day timepoint for the storage stability aspect of the study.

Ethofumesate and ethofumesate-2-keto residues were determined using the analytical method validated in this study. No residues above 30% of the LOQ were found in any of the reagent blanks or untreated specimens.

Procedural recoveries were extracted, stored and quantified concurrently with stored specimens; all mean batch procedural recoveries were within the acceptable range of 70 – 110%. Procedural recovery results are detailed in the tables below.

The specificity for ethofumesate and ethofumesate-2-keto was demonstrated by GC-MS where no significant interferences were detected in any of the reagent blank or control specimens.

Instrument carryover was assessed on a run-by-run basis by injection of a solvent blank immediately after injection of the top calibration standard. Instrumental carryover was found to be less than 1 % which is in accordance with ResChem Analytical standard operating procedures.

The linearity of the detector was checked on a run-by-run basis by single injection of matrix-matched calibration standards at 6 concentration levels covering a range equivalent to 30% of the LOQ up to 120% of the upper fortification level. The calibration curves obtained for ethofumesate and ethofumesate-2-keto were linear with correlation coefficients (r) greater than 0.995.

There was no significant decrease in the observed residue levels of ethofumesate and ethofumesate-2-keto in the fortified lettuce and cereal grain specimens stored frozen at $\leq -18^{\circ}\text{C}$ for a period of 24 months. The recovery values for the 24-month stored fortified samples (mean of three replicates) were between 70 – 110% for both matrices. Storage stability results are detailed in the tables below.

Table A 6: Summary of concurrent recoveries and storage stability data of ethofumesate in lettuce (primary ion 286 m/z)

Storage Interval		Specimen Ref.	Fort. Level. (mg/kg)	Procedural Recovery Residue (mg/kg)	Mean Procedural Recovery (%)	Stored Sample Residue (mg/kg)	Mean Stored Sample Residue (mg/kg)	Mean stored sample recovery (%)
Months	Days (Actual)							
0	0	12439	0.1	0.092486	92	N/A	N/A	N/A
		12440	0.1	0.092066				
		12441	0.1	0.091284				
		12442	0.1	0.090976				
		12443	0.1	0.092002				
6	183	12445	0.1	0.092110	94	-	-	-
		12446	0.1	0.095283		-		
		12447	0.1	-	-	0.093330	0.09358	94
		12448	0.1	-		0.093838		
12	365	12450	0.1	0.096344	97	-	-	-
		12451	0.1	0.097398		-		
		12452	0.1	-	-	0.097988	0.09750	98
		12453	0.1	-		0.097021		
24	744	12455	0.1	0.099853	98	-	-	-
		12456	0.1	0.095295		-		
		12457	0.1	-	-	0.095210	0.09471	95
		12458	0.1	-		0.094204		

Note: Residues in the control sample and reagent blank were less than 30% of the LOQ.

Table A 7: Summary of concurrent recoveries and storage stability data of ethofumesate in cereal grain (primary ion 286 m/z)

Storage Interval		Specimen Ref.	Fort. Level. (mg/kg)	Procedural Recovery Residue (mg/kg)	Mean Procedural Recovery (%)	Stored Sample Residue (mg/kg)	Mean Stored Sample Residue (mg/kg)	Mean stored sample recovery (%)
Months	Days (Actual)							
0	0	12523	0.1	0.091615	91	N/A	N/A	N/A
		12524	0.1	0.094003				
		12525	0.1	0.091964				
		12526	0.1	0.089637				
		12527	0.1	0.089704				
6	181	12529	0.1	0.090003	92	-	-	-
		12530	0.1	0.094039		-		
		12531	0.1	-	-	0.090683	0.08990	90
		12523	0.1	-		0.089114		
12	363	12534	0.1	0.086428	90	-	-	-
		12535	0.1	0.093391		-		
		12536	0.1	-	-	0.089499	0.08796	88
		12537	0.1	-		0.086414		
24	742	12539	0.1	0.094528	94	-	-	-
		12540	0.1	0.092929		-		
		12541	0.1	-	-	0.088402	0.08960	90
		12542	0.1	-		0.090807		

Note: Residues in the control sample and reagent blank were less than 30% of the LOQ.

Table A 8: Summary of concurrent recoveries and storage stability data of ethofumesate-2-keto in lettuce (primary ion 256 m/z)

Storage Interval		Specimen Ref.	Fort. Level. (mg/kg)	Procedural Recovery Residue (mg/kg)	Mean Procedural Recovery (%)	Stored Sample Residue (mg/kg)	Mean Stored Sample Residue (mg/kg)	Mean stored sample recovery (%)
Months	Days (Actual)							
0	0	12481	0.1	0.095543	97	N/A	N/A	N/A
		12482	0.1	0.097512				
		12483	0.1	0.098586				
		12484	0.1	0.096903				
		12485	0.1	0.095938				
6	185	12487	0.1	0.096191	99	-	-	-
		12488	0.1	0.101272		-		
		12489	0.1	-	-	0.095716	0.09701	97
		12490	0.1	-		0.098311		
12	367	12492	0.1	0.097227	97	-	-	-
		12493	0.1	0.096383		-		
		12494	0.1	-	-	0.092224	0.09372	94
		12495	0.1	-		0.095208		
24	735	12497	0.1	0.094958	95	-	-	-
		12498	0.1	0.094757		-		

Storage Interval		Specimen Ref.	Fort. Level. (mg/kg)	Procedural Recovery Residue (mg/kg)	Mean Procedural Recovery (%)	Stored Sample Residue (mg/kg)	Mean Stored Sample Residue (mg/kg)	Mean stored sample recovery (%)
Months	Days (Actual)							
		12499	0.1	-	-	0.094337	0.09319	93
		12500	0.1	-		0.092035		

Note: Residues in the control sample and reagent blank were less than 30% of the LOQ.

Table A 9: Summary of concurrent recoveries and storage stability data of ethofumesate-2-keto in cereal grain (primary ion 256 m/z)

Storage Interval		Specimen Ref.	Fort. Level. (mg/kg)	Procedural Recovery Residue (mg/kg)	Mean Procedural Recovery (%)	Stored Sample Residue (mg/kg)	Mean Stored Sample Residue (mg/kg)	Mean stored sample recovery (%)
Months	Days (Actual)							
0	0	12565	0.1	0.089529	92	N/A	N/A	N/A
		12566	0.1	0.091486				
		12567	0.1	0.091602				
		12568	0.1	0.091519				
		12569	0.1	0.093721				
6	183	12571	0.1	0.092093	89	-	-	-
		12572	0.1	0.086068		-		
		12573	0.1	-	-	0.091994	0.08926	89
		12574	0.1	-		0.086526		
12	365	12576	0.1	0.090755	92	-	-	-
		12577	0.1	0.092913		-		
		12578	0.1	-	-	0.080256	0.07932	79
		12579	0.1	-		0.078383		
24	733	12617	0.1	0.094058	98	-	-	-
		12618	0.1	0.102571		-		
		12619	0.1	-	-	0.071240	0.07223	72
		12620	0.1	-		0.073225		

Note: Residues in the control sample and reagent blank were less than 30% of the LOQ.

Conclusion

The results of this 24-months study showed that residue levels of ethofumesate and ethofumesate-2-keto were stable in fortified samples of lettuce and cereal grain specimens stored frozen at $\leq -18^{\circ}\text{C}$ for a period of 24 months. The recovery values for the 24-month stored fortified samples (mean of two replicates) was between 70 – 110% for the matrices tested.

A 2.1.1.1.2 Storage stability of residues in animal products

No new or additional studies have been submitted.

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

A 2.1.2.1 Nature of residue in plants

A 2.1.2.1.1 Nature of residue in primary crops

No new or additional studies have been submitted.

A 2.1.2.1.2 Nature of residue in rotational crops

No new or additional studies have been submitted.

A 2.1.2.1.3 Nature of residues in processed commodities

No new or additional studies have been submitted.

A 2.1.2.2 Nature of residues in livestock

No new or additional studies have been submitted.

A 2.1.3 Magnitude of residues in plants

No new or additional studies have been submitted.

A 2.1.4 Magnitude of residues in livestock

A 2.1.4.1 Livestock feeding studies

No new or additional studies have been submitted.

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

A 2.1.5.1 Distribution of the residue in peel/pulp

No new or additional studies have been submitted.

A 2.1.5.2 Processing studies on a core set of representative processes

No new or additional studies have been submitted.

A 2.1.6 Magnitude of residues in representative succeeding crops

No new or additional studies have been submitted.

A 2.1.7 Other/Special Studies

No new or additional studies have been submitted.

A 2.2 Clopyralid

No new or additional studies have been submitted.

Appendix 3 Pesticide Residue Intake Model (PRIMo)

A 3.1 TMDI calculations

Ethofumesate:



European Food Safety Authority
EFSA PRIMo revision 3.1; 2021/01/06

Ethofumesate

LOQs (mg/kg) range from: 0,03 to: 0,10

Toxicological reference values

ADI (mg/kg bw/day): 1 ARID (mg/kg bw): insert valid entry

Source of ADI: EFSA Source of ARID:

Year of evaluation: 2016 Year of evaluation:

Input values

Details - chronic risk assessment

Supplementary results - chronic risk assessment

Details - acute risk assessment/children

Details - acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

Calculated exposure (in % of ADI)		Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
TMDI(NED)/IEDI calculation (based on average food consumption)	0.5%	NL toddler	4.74	0.2%	Milk: Cattle	0.1%	Sugar beet roots	0.0%	Apples	0.4%
	0.3%	NL child	3.46	0.2%	Sugar beet roots	0.1%	Milk: Cattle	0.0%	Apples	0.2%
	0.2%	FR child 3 15 yr	2.32	0.1%	Sugar beet roots	0.1%	Milk: Cattle	0.0%	Wheat	0.2%
	0.2%	DE child	2.29	0.1%	Milk: Cattle	0.0%	Apples	0.0%	Mate/maté	0.2%
	0.2%	FR toddler 2 3 yr	2.23	0.1%	Milk: Cattle	0.1%	Sugar beet roots	0.0%	Apples	0.2%
	0.2%	DE women 14-50 yr	2.13	0.1%	Sugar beet roots	0.0%	Milk: Cattle	0.0%	Hybiscus/roselle	0.1%
	0.2%	UK infant	2.07	0.1%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Potatoes	0.2%
	0.2%	DE general	1.97	0.1%	Sugar beet roots	0.0%	Milk: Cattle	0.0%	Hybiscus/roselle	0.1%
	0.2%	UK toddler	1.89	0.1%	Sugar beet roots	0.1%	Milk: Cattle	0.0%	Wheat	0.1%
	0.1%	GEMS/Food G06	1.48	0.0%	Sugar beet roots	0.0%	Wheat	0.0%	Tomatoes	0.1%
	0.1%	NL general	1.41	0.1%	Sugar beet roots	0.0%	Milk: Cattle	0.0%	Potatoes	0.1%
	0.1%	GEMS/Food G11	1.37	0.0%	Milk: Cattle	0.0%	Potatoes	0.0%	Soyabeans	0.1%
	0.1%	RO general	1.37	0.0%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Wheat	0.1%
	0.1%	GEMS/Food G07	1.35	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Mate/maté	0.1%
	0.1%	GEMS/Food G15	1.25	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes	0.1%
	0.1%	GEMS/Food G08	1.23	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes	0.1%
	0.1%	GEMS/Food G10	1.23	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Soyabeans	0.1%
	0.1%	DK child	1.23	0.0%	Milk: Cattle	0.0%	Rye	0.0%	Wheat	0.1%
	0.1%	ES child	1.18	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Oranges	0.1%
	0.1%	SE general	1.18	0.0%	Milk: Cattle	0.0%	Bovine: Muscle/meat	0.0%	Potatoes	0.1%
	0.1%	FR infant	1.18	0.1%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Potatoes	0.1%
	0.1%	IE adult	1.09	0.0%	Milk: Cattle	0.0%	Sweet potatoes	0.0%	Wheat	0.1%
	0.1%	FR adult	0.80	0.0%	Sugar beet roots	0.0%	Milk: Cattle	0.0%	Wine grapes	0.1%
	0.1%	FI adult	0.78	0.1%	Coffee beans	0.0%	Potatoes	0.0%	Rye	0.1%
	0.1%	ES adult	0.68	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Oranges	0.1%
	0.1%	PT general	0.63	0.0%	Potatoes	0.0%	Wheat	0.0%	Wine grapes	0.1%
	0.1%	FI 3 yr	0.55	0.0%	Potatoes	0.0%	Bananas	0.0%	Wheat	0.1%
	0.1%	UK vegetarian	0.54	0.0%	Sugar beet roots	0.0%	Milk: Cattle	0.0%	Wheat	0.0%
	0.1%	IT toddler	0.53	0.0%	Wheat	0.0%	Other cereals	0.0%	Tomatoes	0.1%
	0.1%	UK adult	0.51	0.0%	Sugar beet roots	0.0%	Milk: Cattle	0.0%	Wheat	0.0%
	0.1%	LT adult	0.51	0.0%	Milk: Cattle	0.0%	Potatoes	0.0%	Apples	0.0%
	0.0%	DK adult	0.50	0.0%	Milk: Cattle	0.0%	Potatoes	0.0%	Wheat	0.0%
	0.0%	FI 6 yr	0.44	0.0%	Potatoes	0.0%	Wheat	0.0%	Bananas	0.0%
0.0%	IT adult	0.42	0.0%	Wheat	0.0%	Tomatoes	0.0%	Apples	0.0%	
0.0%	PL general	0.33	0.0%	Potatoes	0.0%	Apples	0.0%	Beetroots	0.0%	
0.0%	IE child	0.24	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes	0.0%	

Conclusion:

The estimated long-term dietary intake (TMDI(NED)/IEDI) was below the ADI.
The long-term intake of residues of Ethofumesate 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.

 **efsa** 
European Food Safety Authority
EFSA PRIMo revision 3.1; 2021/01/06

Clopyralid			
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:	2018	Year of evaluation:	2018

Details - chronic risk assessment

Supplementary results - chronic risk assessment

Details - acute risk assessment/children

Details - acute risk assessment/adults

Comments:										
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Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

				No of diets exceeding the ADI : ---								Exposure resulting from	
	Calculated exposure (% of ADI)		Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)		
TMDINED/IEDI calculation (based on average food consumption)	42%	NL toddler	63,38	9%	Maize/corn	8%	Wheat	4%	Apples	2%	3%		
	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%	1,0%		
	25%	NL child	37,29	8%	Wheat	6%	Sugar beet roots	2%	Apples	0,9%	6%		
	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%	0,9%		
	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%	2%		
	20%	GEMS/Food G10	29,29	8%	Wheat	2%	Rice	1%	Soyabeans	0,3%	0,0%		
	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	27,27	8%	Wheat	1%	Potatoes	0,8%	Barley	0,4%	0,0%		
	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%	2%		
	16%	FR toddler 2 3 yr	23,56	6%	Wheat	2%	Sugar beet roots	1%	Apples	1%	2%		
	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%	0,9%		
	15%	ES child	22,49	9%	Wheat	0,7%	Oranges	0,6%	Rice	0,5%	0,1%		
	15%	DE women 14-50 yr	22,09	4%	Wheat	3%	Sugar beet roots	2%	Rye	0,5%	3%		
	14%	DE general	21,74	4%	Wheat	3%	Sugar beet roots	2%	Rye	0,5%	3%		
	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%	2%		
	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%	0,1%		
	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%	0,5%		
	8%	UK vegetarian	12,50	4%	Wheat	0,5%	Rice	0,5%	Potatoes	0,1%	0,4%		
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%	0,9%			
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%	0,4%			
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/NED/IEDI) was below the ADI.
The long-term intake of residues of Clopyralid 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.

 European Food Safety Authority EFSA PRIMo revision 3.1; 2019/03/19		clopyralid				Input values					
		LOQs (mg/kg) range from: _____ to: _____									
		Toxicological reference values									
		ADI (mg/kg bw/day): 0,15		ARfD (mg/kg bw): 0,17		Details - chronic risk assessment		Supplementary results - chronic risk assessment			
Source of ADI: EFSA 2018		Source of ARfD: EFSA		Details - acute risk assessment/children		Details - acute risk assessment/adults					
Year of evaluation: 2018		Year of evaluation: 2018									
Comments:											
Normal mode											
Chronic risk assessment: JMPR methodology (IEDI/TMDI)											
		No of diets exceeding the ADI : _____								Exposure resulting from	
	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	43%	NL toddler	64,28	9%	Maize/corn	8%	Wheat	4%	Apples		
	33%	DK child	50,22	18%	Rye	9%	Wheat	0,8%	Potatoes		
	27%	GEMS/Food G06	40,64	14%	Wheat	2%	Rice	2%	Maize/corn		
	25%	NL child	37,66	8%	Wheat	6%	Sugar beet roots	2%	Apples		
	25%	DE child	37,25	8%	Wheat	4%	Apples	3%	Rye		
	21%	RO general	31,30	10%	Wheat	3%	Head cabbages	1%	Maize/corn		
	21%	GEMS/Food G15	30,89	9%	Wheat	2%	Head cabbages	1%	Potatoes		
	21%	GEMS/Food G08	30,82	8%	Wheat	2%	Rye	1%	Potatoes		
	20%	FR child 3 15 yr	30,12	9%	Wheat	2%	Sugar beet roots	1%	Oranges		
	20%	GEMS/Food G10	29,37	8%	Wheat	2%	Rice	1%	Soyabeans		
	18%	IT toddler	27,67	13%	Wheat	2%	Other cereals	0,5%	Tomatoes		
	18%	IE adult	27,44	5%	Wheat	2%	Sweet potatoes	2%	Linseeds		
	18%	GEMS/Food G07	27,36	8%	Wheat	1%	Potatoes	0,8%	Barley		
	17%	GEMS/Food G11	25,78	7%	Wheat	1%	Potatoes	1%	Soyabeans		
	17%	UK toddler	25,18	8%	Wheat	2%	Sugar beet roots	1%	Potatoes		
	16%	FR toddler 2 3 yr	24,00	6%	Wheat	2%	Sugar beet roots	1%	Milk: Cattle		
	16%	UK infant	23,47	5%	Wheat	2%	Milk: Cattle	1%	Maize/corn		
	16%	SE general	23,26	6%	Wheat	1%	Potatoes	1%	Head cabbages		
	15%	PT general	23,04	8%	Wheat	2%	Potatoes	1%	Rice		
	15%	ES child	22,68	9%	Wheat	0,7%	Oranges	0,6%	Rice		
	15%	DE women 14-50 yr	22,28	4%	Wheat	3%	Sugar beet roots	2%	Rye		
	15%	DE general	21,93	4%	Wheat	3%	Sugar beet roots	2%	Rye		
	12%	IT adult	18,12	8%	Wheat	0,9%	Other cereals	0,4%	Tomatoes		
	12%	NL general	18,02	4%	Wheat	2%	Sugar beet roots	0,8%	Potatoes		
	12%	FI 3 yr	17,37	2%	Wheat	2%	Rye	2%	Potatoes		
	10%	LT adult	14,97	4%	Rye	2%	Wheat	1%	Potatoes		
	9%	ES adult	14,07	5%	Wheat	0,7%	Barley	0,4%	Oranges		
	9%	FI 6 yr	13,78	2%	Rye	2%	Wheat	1%	Potatoes		
	9%	FR adult	13,65	4%	Wheat	0,8%	Wine grapes	0,5%	Sugar beet roots		
	8%	UK vegetarian	12,55	4%	Wheat	0,5%	Rice	0,5%	Potatoes		
	8%	FI adult	11,39	2%	Rye	2%	Coffee beans	0,6%	Wheat		
	7%	FR infant	10,69	2%	Wheat	0,9%	Sugar beet roots	0,7%	Milk: Cattle		
7%	DK adult	10,51	2%	Wheat	2%	Rye	0,4%	Potatoes			
7%	UK adult	10,41	3%	Wheat	0,5%	Rice	0,5%	Potatoes			
4%	PL general	6,17	1%	Potatoes	0,7%	Head cabbages	0,7%	Apples			
4%	IE child	5,69	2%	Wheat	0,4%	Rice	0,2%	Potatoes			
Conclusion: 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 3.2 IEDI calculations

Not necessary, because the TMDI is well below 100% of ADI for both ethofumesate and clopyralid.

A 3.3 IESTI calculations - Raw commodities

Ethofumesate: Not relevant, because ARfD not necessary

Clopyralid:

Acute risk assessment /children					Acute risk assessment / adults / general population					Acute risk assessment /children					Acute risk assessment / adults / general population				
Details - acute risk assessment /children					Details - acute risk assessment/adults					Hide IESTI new calculations					Show IESTI new calculations				
The acute risk assessment is based on the ARfD. 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):						
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	IESTI				IESTI				IESTI new				IESTI new						
	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)			
	4%	Milk: Cattle	0,05 / 0,05	6,2	2%	Bovine: Kidney	1,5 / 1,5	3,2	4%	Milk: Cattle	0,05 / 0,05	6,2	2%	Bovine: Kidney	1,5 / 1,5	3,2			
	3%	Bovine: Kidney	1,5 / 1,5	5,6	1%	Milk: Cattle	0,05 / 0,05	1,9	3%	Bovine: Kidney	1,5 / 1,5	5,6	1%	Milk: Cattle	0,05 / 0,05	1,9			
	0,7%	Bovine: Liver	0,15 / 0,15	1,2	0,8%	Swine: Kidney	0,6 / 0,6	1,3	0,7%	Bovine: Liver	0,15 / 0,15	1,2	0,8%	Swine: Kidney	0,6 / 0,6	1,3			
	0,7%	Milk: Goat	0,05 / 0,05	1,2	0,5%	Milk: Goat	0,05 / 0,05	0,92	0,7%	Milk: Goat	0,05 / 0,05	1,2	0,5%	Milk: Goat	0,05 / 0,05	0,92			
	0,5%	Poultry: Muscle/meat	0,05 / 0,05	0,85	0,4%	Milk: Sheep	0,05 / 0,05	0,76	0,5%	Poultry: Muscle/meat	0,05 / 0,05	0,85	0,4%	Milk: Sheep	0,05 / 0,05	0,76			
	0,4%	Swine: Kidney	0,6 / 0,6	0,76	0,4%	Bovine: Liver	0,15 / 0,15	0,60	0,4%	Swine: Kidney	0,6 / 0,6	0,76	0,4%	Bovine: Liver	0,15 / 0,15	0,60			
0,4%	Eggs: Chicken	0,05 / 0,05	0,62	0,3%	Poultry: Muscle	0,05 / 0,05	0,59	0,4%	Eggs: Chicken	0,05 / 0,05	0,62	0,3%	Poultry: Muscle	0,05 / 0,05	0,59				
0,4%	Swine: Muscle/meat	0,05 / 0,05	0,61	0,3%	Sheep: Liver	0,2 / 0,2	0,56	0,4%	Swine: Muscle/meat	0,05 / 0,05	0,61	0,3%	Sheep: Liver	0,2 / 0,2	0,56				
0,3%	Bovine: Muscle/meat	0,08 / 0,08	0,58	0,3%	Bovine: Muscle	0,08 / 0,08	0,46	0,3%	Bovine: Muscle/meat	0,08 / 0,08	0,58	0,3%	Bovine: Muscle	0,08 / 0,08	0,46				
0,3%	Sheep: Muscle/meat	0,08 / 0,08	0,43	0,2%	Sheep: Muscle/meat	0,08 / 0,08	0,38	0,3%	Sheep: Muscle/meat	0,08 / 0,08	0,43	0,2%	Sheep: Muscle/meat	0,08 / 0,08	0,38				
0,2%	Bovine: Edible offals (other	0,05 / 0,05	0,36	0,2%	Other farmed animals:	0,05 / 0,05	0,28	0,2%	Bovine: Edible offals (other	0,05 / 0,05	0,36	0,2%	Other farmed animals: Muscle/meat	0,05 / 0,05	0,28				
0,2%	Other farmed animals:	0,05 / 0,05	0,35	0,1%	Swine: Muscle/meat	0,05 / 0,05	0,24	0,2%	Other farmed animals:	0,05 / 0,05	0,35	0,1%	Swine: Muscle/meat	0,05 / 0,05	0,24				
0,2%	Bovine: Fat tissue	0,15 / 0,15	0,31	0,1%	Equine: Muscle/meat	0,05 / 0,05	0,24	0,2%	Bovine: Fat tissue	0,15 / 0,15	0,31	0,1%	Equine: Muscle/meat	0,05 / 0,05	0,24				
0,2%	Equine: Muscle/meat	0,05 / 0,05	0,30	0,1%	Poultry: Liver	0,05 / 0,05	0,24	0,2%	Equine: Muscle/meat	0,05 / 0,05	0,30	0,1%	Poultry: Liver	0,05 / 0,05	0,24				
0,1%	Honey and other apiculture	0,05 / 0,05	0,18	0,1%	Eggs: Chicken	0,05 / 0,05	0,21	0,1%	Honey and other apiculture	0,05 / 0,05	0,18	0,1%	Eggs: Chicken	0,05 / 0,05	0,21				
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)											

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 ARID. 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 ARID/ADI is exceeded (IESTI): ---				Results for adults No. of commodities for which ARID/ADI is exceeded (IESTI): ---				IESTI new Results for children No. of commodities for which ARID/ADI is exceeded (IESTI new): ---				IESTI new Results for adults No. of commodities for which ARID/ADI is exceeded (IESTI new): ---			
	IESTI				IESTI				IESTI new				IESTI new			
	Highest % of ARID/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARID/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARID/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARID/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
	5%	Milk: Cattle	0,05 / 0,07	8,1	2%	Bovine: Kidney	1,5 / 1,5	3,2	5%	Milk: Cattle	0,05 / 0,07	8,1	2%	Bovine: Kidney	1,5 / 1,5	3,2
	3%	Bovine: Kidney	1,5 / 1,5	5,6	1%	Milk: Cattle	0,05 / 0,07	2,5	3%	Bovine: Kidney	1,5 / 1,5	5,6	1%	Milk: Cattle	0,05 / 0,07	2,5
0,9%	Milk: Goat	0,05 / 0,07	1,6	0,8%	Swine: Kidney	0,6 / 0,6	1,3	0,9%	Milk: Goat	0,05 / 0,07	1,6	0,8%	Swine: Kidney	0,6 / 0,6	1,3	
0,7%	Bovine: Liver	0,15 / 0,15	1,2	0,7%	Milk: Goat	0,05 / 0,07	1,2	0,7%	Bovine: Liver	0,15 / 0,15	1,2	0,7%	Milk: Goat	0,05 / 0,07	1,2	
0,5%	Poultry: Muscle/meat	0,05 / 0,05	0,85	0,6%	Milk: Sheep	0,05 / 0,07	0,98	0,5%	Poultry: Muscle/meat	0,05 / 0,05	0,85	0,6%	Milk: Sheep	0,05 / 0,07	0,98	
0,4%	Swine: Kidney	0,6 / 0,6	0,76	0,4%	Bovine: Liver	0,15 / 0,15	0,60	0,4%	Swine: Kidney	0,6 / 0,6	0,76	0,4%	Bovine: Liver	0,15 / 0,15	0,60	
0,4%	Eggs: Chicken	0,05 / 0,05	0,62	0,3%	Poultry: Muscle	0,05 / 0,05	0,59	0,4%	Eggs: Chicken	0,05 / 0,05	0,62	0,3%	Poultry: Muscle	0,05 / 0,05	0,59	
0,4%	Swine: Muscle/meat	0,05 / 0,05	0,61	0,3%	Sheep: Liver	0,2 / 0,2	0,56	0,4%	Swine: Muscle/meat	0,05 / 0,05	0,61	0,3%	Sheep: Liver	0,2 / 0,2	0,56	
0,3%	Bovine: Muscle/meat	0,08 / 0,08	0,58	0,3%	Bovine: Muscle	0,08 / 0,08	0,46	0,3%	Bovine: Muscle/meat	0,08 / 0,08	0,58	0,3%	Bovine: Muscle	0,08 / 0,08	0,46	
0,3%	Honey and other	0,15 / 0,15	0,54	0,2%	Sheep: Muscle/meat	0,08 / 0,08	0,38	0,3%	Honey and other	0,15 / 0,15	0,54	0,2%	Sheep: Muscle/meat	0,08 / 0,08	0,38	
0,3%	Sheep: Muscle/meat	0,08 / 0,08	0,43	0,2%	Other farmed animals:	0,05 / 0,05	0,28	0,3%	Sheep: Muscle/meat	0,08 / 0,08	0,43	0,2%	Other farmed animals:	0,05 / 0,05	0,28	
0,2%	Bovine: Edible offals	0,05 / 0,05	0,36	0,1%	Swine: Muscle/meat	0,05 / 0,05	0,24	0,2%	Bovine: Edible offals	0,05 / 0,05	0,36	0,1%	Swine: Muscle/meat	0,05 / 0,05	0,24	
0,2%	Other farmed animals:	0,05 / 0,05	0,35	0,1%	Equine: Muscle/meat	0,05 / 0,05	0,24	0,2%	Other farmed animals:	0,05 / 0,05	0,35	0,1%	Equine: Muscle/meat	0,05 / 0,05	0,24	
0,2%	Bovine: Fat tissue	0,15 / 0,15	0,31	0,1%	Poultry: Liver	0,05 / 0,05	0,24	0,2%	Bovine: Fat tissue	0,15 / 0,15	0,31	0,1%	Poultry: Liver	0,05 / 0,05	0,24	
0,2%	Equine: Muscle/meat	0,05 / 0,05	0,30	0,1%	Eggs: Chicken	0,05 / 0,05	0,21	0,2%	Equine: Muscle/meat	0,05 / 0,05	0,30	0,1%	Eggs: Chicken	0,05 / 0,05	0,21	
Expand/collapse list																
Total number of commodities exceeding the ARID/ADI in children and adult diets (IESTI calculation)								Total number of commodities found exceeding the ARID/ADI in children and adult diets (IESTI new calculation)								

Clopyralid:

[illegible]

[illegible]

Appendix 4 Additional information provided by the applicant

None.