

REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: HBZ10

Product name: Wizard/Beetup Pro/Betasana Max

Chemical active substances:

Phenmedipham, 125 g/L

Ethofumesate, 125 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(Authorisation - Art. 33 application)

Applicant: UPL Holdings Coöperatief U.A.

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Version history

When	What
October 2021	Part B - Section - Core Assessment - Central Zone, version 1
December 2022	<p>Initial zRMS assessment.</p> <p>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.</p>
March 2023	<p>Final report (Core Assessment updated following the commenting period)</p> <p>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. Information no longer relevant is struck through and shaded.</p>

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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 HBZ10 are presented in **Table 7.1.1-1**. They have been selected from the individual GAPs in central Europe (C-EU) for beet crops (sugar beet, red beet, yellow beet, fodder beet and chard). A list of all intended uses within the C-EU is given in Part B, Section 0.

Overall conclusion

The data available are considered sufficient for risk assessment. An exceedance of the current MRLs for Phenmedipham of 0.05 mg/kg in crop sugar beet and 0.15 mg/kg in crop beetroot, and for Ethofumesate of 0.2 mg/kg in crop beetroot and sugar beet as laid down in Reg. (EU) No 396/2005 is not expected.

According to the SANTE/2019/12752, extrapolation from sugar beet tops to tops of red beet, yellow beet and chard is not possible. Considering the above, in our opinion, the proposed uses of HBZ10 on beet leaves and chard are not acceptable.

The chronic and the short-term intakes of Phenmedipham and 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) **without beet leaves and chard**.

According to available data, specific mitigation measures should apply:

- 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.

Data gaps

Noticed data gaps are: none.

Table 7.1.1-1 Acceptability of critical GAPs (and respective fall-back GAPs, if applicable)

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No. (e)	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha (f)	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number per use a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha max. rate per appl. a) max. rate per appl. b) max. total rate per crop/season	kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
1, 6, 11, 16, 21	NL	Beet crops (sugar beet (0900010), red beet (0213010), yellow beet (0213010), fodder beet, ehard)	F	Broadleaf weeds	Spraying	Spring- summer BBCH 10-39	a) 6 b) 6	5	a) 1.2 b) 7.2	a) Etho: 0.150 Phen: 0.150 b) Etho: 0.900 Phen: 0.900	80-400	-	Max. 7.2 L/ha per year	A
2, 7, 12, 17, 22	NL		F	Broadleaf weeds	Spraying	Spring- summer BBCH 10-39	a) 3 b) 3	6	a) 2.4 b) 7.2	a) Etho: 0.300 Phen: 0.300 b) Etho: 0.900 Phen: 0.900	80-400	-	Max. 7.2 L/ha per year	A
3, 8, 13, 18, 23	BE CZ PL AT		F	Broadleaf weeds	Spraying	Spring- summer BBCH 10-39	a) 5 b) 5	7	a) 1.2 b) 6	a) Etho: 0.150 Phen: 0.150 b) Etho: 0.750 Phen: 0.750	80-400	-	Max. 6.0 L/ha per year	A
4, 9, 14, 19, 24	NL BE CZ PL AT		F	Broadleaf weeds	Spraying	Spring- summer BBCH 10-39	a) 3 b) 3	6	a) 1.8 b) 5.4	a) Etho: 0.225 Phen: 0.225 b) Etho: 0.675 Phen: 0.675	80-400	-	Max. 5.4 L/ha per year	A
5, 10, 15, 20, 25	BE CZ PL AT		F	Broadleaf weeds	Spraying	Spring- summer BBCH 10-39	a) 3 b) 3	9	a) 2.4 b) 7.2	a) Etho: 0.300 Phen: 0.300 b) Etho: 0.900 Phen: 0.900	80-400	-	Max. 7.2 L/ha per year	A
21	NL	Chard (0252030)	F	Broadleaf weeds	Spraying	Spring-sum- mer BBCH 10-39	a) 6 b) 6	5	a) 1.2 b) 7.2	a) Etho: 0.150 Phen: 0.150 b) Etho: 0.900 Phen: 0.900	80-400	-	Max. 7.2 L/ha per year	N
22	NL	Chard (0252030)	F	Broadleaf weeds	Spraying	Spring-sum- mer BBCH 10-39	a) 3 b) 3	6	a) 2.4 b) 7.2	a) Etho: 0.300 Phen: 0.300 b) Etho: 0.900 Phen: 0.900	80-400	-	Max. 7.2 L/ha per year	N
23	BE CZ PL AT	Chard (0252030)	F	Broadleaf weeds	Spraying	Spring- summer BBCH 10-39	a) 5 b) 5	7	a) 1.2 b) 6.0	a) Etho: 0.150 Phen: 0.150 b) Etho: 0.750 Phen: 0.750	80-400	-	Max. 6.0 L/ha per year	N

24	NL BE CZ PL AT	Chard (0252030)	F	Broadleaf weeds	Spraying	Spring-summer BBCH 10-39	a) 3 b) 3	6	a) 1.8 b) 5.4	a) Etho: 0.225 Phen: 0.225 b) Etho: 0.675 Phen: 0.675	80-400	-	Max. 5.4 L/ha per year	N
25	BE CZ PL AT	Chard (0252030)	F	Broadleaf weeds	Spraying	Spring-summer BBCH 10-39	a) 3 b) 3	9	a) 2.4 b) 7.2	a) Etho: 0.300 Phen: 0.300 b) Etho: 0.900 Phen: 0.900	80-400	-	Max. 7.2 L/ha per year	N

Remarks table heading:

- (a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
- (b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
- (c) g/kg or g/l

Remarks columns:

- 1 Numeration necessary to allow references
- 2 Use official codes/nomenclatures of EU Member States
- 3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
- 4 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
- 5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
- 6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.

- (d) Select relevant
- (e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
- (f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

- 7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
- 8 The maximum number of application possible under practical conditions of use must be provided.
- 9 Minimum interval (in days) between applications of the same product
- 10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
- 11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
- 12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
- 13 PHI - minimum pre-harvest interval
- 14 Remarks may include: Extent of use/economic importance/restrictions
- 15 **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 HBZ10 is composed of Phenmedipham (125 g/L) and Ethofumesate (125 g/L).

Table 7.1.2-1 Toxicological reference values for the dietary risk assessment of Ethofumesate and Phenmedipham

Reference value	Source	Year	Value	Study relied upon	Safety factor
Phenmedipham					
ADI	SANCO/4060/2001	2004	0.03 mg/kg bw/day	2-year rat	100
ARfD	SANCO/4060/2001	2004	Not necessary		
Ethofumesate					
ADI	EFSA Journal 2016;14(1):4374	2016	1 mg/kg bw/day	2-year rat	100
ARfD	EFSA Journal 2016;14(1):4374	2016	Not Applicable	-	-

7.1.2.1 Summary for Phenmedipham

Table 7.1.2.1-1 Summary for Phenmedipham

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 to 20	Beet crops	Yes	Yes (4 trials)	Yes	Yes	Yes	No	N/A**
21-25	Chards	No	No	No	No	No	-	-

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

** Not applicable since no ARfD is deemed necessary

7.1.2.2 Summary for Ethofumesate

Table 7.1.2.2-1 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 to 20	Beet crops	Yes	Yes (51 trials)	Yes	Yes	Yes	No	N/A**
21-25	Chards	Yes	No	No	No	No	-	-

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

** Not applicable since no ARfD is deemed necessary

7.1.2.3 Summary for HBZ10

Table 7.1.2.3-1 Information on HBZ10 (KCA 6.8)

Crop	PHI for HBZ10 proposed by applicant	PHI/ Withholding period* sufficiently supported for		PHI for HBZ10 proposed by zRMS	zRMS Comments (if different PHI proposed)
		Phenmedipham	Ethofumesate		
Beet crops (sugar beet, red beet, yellow beet, fodder beet, chard)	Not required (latest application at BBCH 39)	Yes	Yes	Yes, the PHI is covered by the time remaining between application and harvest.	-

* Purpose of withholding period to be specified

Table 7.1.2.3-2 Waiting periods before planting succeeding crops

Waiting period before planting succeeding crops			Overall waiting period proposed by zRMS for HBZ10
Crop group	Led by Phenmedipham	Led by Ethofumesate	
Root and tuber vegetables	Not required	Not required PHI covered by the vegetation period, max. 1 kg a.s./ha every three years	Do not grow root vegetables (except sugar beet roots, beetroots or fodder beet) in case of crop failure.

Assessment

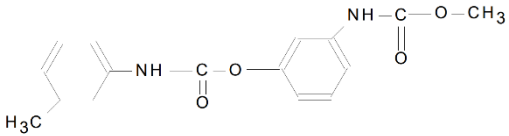
7.2 Phenmedipham

zRMS comments:

The current Wizard/Beetup Pro/Betasana Max (product code HBZ10) application was submitted before the renewal of the approval of phenmedipham. The date of approval expiration is 31/07/2023. It should be noted that the EU peer review on the renewal of the approval of phenmedipham is available: EFSA Journal 2018;16(1):5151 – “*Peer review of the pesticide risk assessment of the active substance phenmedipham*”.

General data on Phenmedipham are summarized in the table below (last updated 16.06.2021)

Table 7.2-1 General information on Phenmedipham

Active substance (ISO Common Name)	Phenmedipham
IUPAC	methyl 3-(3-methylcarbaniloxy)carbanilate; 3-methoxycarbonylamino phenyl 3-methylcarbanilate
Chemical structure	
Molecular formula	C ₁₆ H ₁₆ N ₂ O ₄
Molar mass	300.3 g/mol
Chemical group	Phenylcarbamates
Mode of action (if available)	Inhibition of photosynthesis at PS II
Systemic	No
Companies*	Original notifiers: Task Force Phenmedipham TOP 2 (comprising AgrEvo GmbH, KVK STEFES AGRO A/S, and United Phosphorus Ltd.), Barclay Chemicals, Phytorus S.A. Renewal: Task Force Phenmedipham (comprising Bayer CropScience AG and UPL Europe Ltd)
Rapporteur Member State (RMS)	FI
Approval status	Approved
Restriction	No restrictions
Review Report	SANCO/4060/2001 - final 13 February 2004
Current MRL regulation	Reg. (EU) 2015/2075
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes
EFSA Journal: Conclusion on the peer review	Yes, for ongoing renewal (EFSA, 2018)
EFSA Journal: conclusion on article 12	Yes (EFSA, 2014)
Current MRL applications on intended uses	None

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

7.2.1 Stability of Residues (KCA 6.1)

7.2.1.1 Stability of residues during storage of samples

Available data

No new data submitted in the framework of this application. The stability of residues for the active substance Phenmedipham was already addressed during the EU Review process. Regarding uses intended with this submission, the active substance was shown to be stable under frozen storage conditions for 24 months (up to 749 days) at -20°C in commodities with high water content (sugar beet) (Finland, 1999). No further data is required.

Table 7.2.1.1-1 Summary of stability data achieved at $\leq -18^{\circ}\text{C}$

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products			
Beet (leaves)	High water content	24 months	Finland, 1999
Beet (roots)	High starch content	24 months	Finland, 1999

Livestock feeding studies are not required, therefore no data on storage stability of residues in animal products are provided.

Conclusion on stability of residues during storage

The stability of residues for the active substance Phenmedipham was already addressed during the EU Review process. Regarding uses intended with this submission, the active substance was shown to be stable under frozen storage for 24 months at -20°C in commodities with high water content (sugar beet leaves) and high starch content (sugar beet roots). No further data is required.

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

A new study on supervised residue trials is presented with this dossier. In this study, sample extracts were stored frozen for maximum 2 days for analysis of the free form of Phenmedipham and MHPC for leaves with tops and 1 day for roots. Sample extracts treated for the analysis of the sum of conjugated and free Phenmedipham and MHPC were stored for maximum 14 days (tops) or 6 days (roots).

Stored sample extracts were shown to be stable for at least 17 days (extracts for analysis of Phenmedipham free form) and 12 or 11 days (extracts for analysis of free form of MHPC, for tops and roots, respectively) after step No 1. Stored sample extracts for analysis of MHPC (free form) after step No. 2 were shown to be stable for at least 16 days in leaves with tops extracts and 17 days in roots extracts.

zRMS comments:

zRMS agrees with information provided by the Applicant in point 7.2.1.1 and 7.2.1.2.

According to OECD 506 sugar, fodder, red and yellow beet roots belong to high starch content matrices, sugar, fodder, red and yellow beet leaves and chard belong to high water content matrices.

Applicant did not submit a new storage stability study.

In EFSA Journal 2014;12(8):3807 it is stated that in the framework of the peer review, storage stability of phenmedipham was demonstrated for a period of 24 months at -20°C in commodities with high water content (sugar beet) (Finland, 1999).

Additionally, the potential degradation of residues during storage of the residue trials samples was assessed in the framework of the peer review (EFSA, 2018). According to the EFSA Journal 2018;16(1):5151 – „Peer review of the pesticide risk assessment of the active substance phenmedipham“: „Storage stability data demonstrated that phenmedipham and MHPC residues are stable up to 24 months in high water-, high oil-, high protein-, high starch- and high acid-content commodities when stored at -20°C .“

The residue data are valid with regard to storage stability.

No additional 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

Studies on metabolism of Phenmedipham in plants were already addressed during the EU Review process and were considered acceptable.

Uptake, translocation, and metabolism of Phenmedipham were evaluated in 1999 (Finland, 1999). Information on crops tested, application and sampling details are given in **Table 7.2.2.1-1** below.

No new data submitted in the framework of this application.

Table 7.2.2.1-1 Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G ^(a)	Rate [kg a.s./ha]	No	Sampling (DAT)	Remarks	
EU data								
Root and tuber vegetables	Sugar beet	PC ring ^(b) or MPC ring ^(c)	Not mentioned, G ^(d)	1 and 5	1	5, 10, 20, 30 and 40	-	Finland, 1999
		Not mentioned ^(e)	Foliar spraying, G ^(f)	2.2	1	0, 3, 7, 14, 21 and 28		
		PC ring ^(b)	Foliar spraying, G	Not mentioned	1	7, 15, 30, 60		

DAT: Days after treatment

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

(b): phenyl ring-labelled Phenmedipham.

(c): methylphenyl ring-labelled Phenmedipham.

(d): Plant growth stage at application: “14-day old plants of cotyledonous stage” (BBCH 09).

(e): The only information provided is that the parent was ¹⁴C or ³H labelled.

(f): Plant growth stage at application: “cotyledons to 2-leaf stage of development” (BBCH 09-12).

Summary of plant metabolism studies reported in the EU

From the data evaluated during the EU Review, it was concluded that Phenmedipham and metabolite MHPC (methyl 3-hydroxyphenylcarbanate) were the main compounds identified. Both are also conjugated to glucose or glucose-2 sulphate. Furthermore, metabolite 3-aminophenol was found.

Conclusion on metabolism in primary crops

Based on the available information the residue definition for enforcement and risk assessment was proposed as Phenmedipham only in the EU Review.

zRMS comments:

Metabolism of phenmedipham was investigated for foliar application on fruits and fruiting vegetables (strawberries) and root and tuber vegetables (sugar beet), using phenyl-labelled or methylphenyl-labelled phenmedipham (Finland, 1999, 2010).

In EFSA Journal 2014;12(8):3807 it is stated that EFSA is of the opinion that no conclusion can be derived on the basis of the available metabolism data on sugar beets, as both studies showed several deficiencies. None of them was performed according to the GLP principles. Moreover, as samples were not harvested at maturity, studies do not give information about the metabolism of phenmedipham in mature crop parts. Consequently, EFSA cannot rely on the available metabolism data to define the residue in root and tuber vegetables and leafy vegetables. As a consequence, new metabolism data covering the currently authorised European uses and performed on crops representative for root and tuber vegetables and leafy vegetables metabolism groups, are required. According to the RMS, a new metabolism study on sugar beet will be submitted in the framework of the renewal of the approval of the active substance under Regulation (EC) No 1107/2009 (January 2015). Meanwhile, a **tentative residue definition for enforcement and risk assessment in plant commodities is defined as phenmedipham only**. Validated analytical methods for enforcement of the proposed residue definition are available.

Additionally, according to the EFSA Journal 2018;16(1):5151 *Metabolism of phenmedipham in primary crops was investigated upon foliar application in roots/tuber crops (sugar beet) with both [amino-phenyl-UL-¹⁴C] and [phenyl-methyl-UL-¹⁴C] phenmedipham at max. 1,066 g/ha application rate, and in fruits (strawberries) only with [amino-phenyl-UL-¹⁴C] radiolabelled phenmedipham at max. 2,880 g/ha application rate.*

Phenmedipham and its conjugates were the predominant compounds of the total residues in sugar beet in immature and mature leaves (95% total radioactive residue (TRR) and 51% TRR, respectively). In sugar beet root, phenmedipham and its conjugates were detected at a low level (6.6% TRR) while a major unknown fraction accounted for ca. 26% TRR in roots and 14% TRR in maturity leaves. This fraction was generated only from the amino phenol moiety and constituted of several polar minor metabolite fractions. The metabolism data in sugar beet were considered sufficient to support the representative uses on sugar beet, except one MS who considered that a new metabolism study in root crops should be provided in view of the authorised uses on other root crops. (...) Based on these metabolism studies, the residue definition for monitoring was derived as phenmedipham restricted to roots and fruit crops only. For risk assessment residue definition, the experts were of the opinion, that in addition to phenmedipham also, glucoside conjugates should be included and the residue definition should be restricted to sugar beet only.

It should be noted that currently the genotoxic potential of phenmedipham cannot be concluded (see data gap in Section 2). Provisional conversion factors (CFs) for risk assessment in sugar beet of 1.4 (root) and 1.2 (leaves) were derived from the metabolism studies.

Summary:

The EU pesticides peer review in the framework of the renewal of approval of the active substance, based on the metabolic pattern identified in primary and rotational crop metabolism studies, the results of hydrolysis studies, the toxicological significance of metabolites and degradation products, the capabilities of enforcement analytical methods, proposed the following residue definitions (EFSA, 2018):

- residue for risk assessment:
 - ‘phenmedipham (free and glucoside conjugates)’ (RAC: restricted to sugar beet),
 - ‘sum of phenmedipham and MHPC, and their conjugates, expressed as phenmedipham’ (RAC: rotational crops),
 - ‘sum of phenmedipham and MHPC, expressed as phenmedipham’ and ‘m-toluidine’ (provisional, processed commodities).
- residue definition for enforcement:
 - ‘phenmedipham’ (RAC: root and fruit crops),
 - ‘sum of phenmedipham and MHPC, expressed as phenmedipham’ (processed commodities).

Provisional conversion factors (CFs) for risk assessment of 1.4 (root) and 1.2 (leaves) were derived from the metabolism studies; these data would still need to be confirmed by residue trials (EFSA, 2018).

According to the EFSA Journal 2021;19(3):6482:

Metabolism studies, methods of analysis and residue definitions in plants

Metabolism studies, methods of analysis and residue definitions in plants					
Primary crops (available studies)	Crop groups	Crop(s)	Application(s)	Sampling (DAT)	Comment/Source
	Fruit crops	Strawberries	Foliar BBCH 42; 1 x 0.96 kg/ha (1 x 2.88 kg/ha; supporting trial)	49	Radiolabelled active substance: [¹⁴ C-amino-phenyl]- phenmedipham (Finland, 2016; EFSA, 2014, 2018b)
	Root crops	Sugar beet	1 x 1 kg/ha, and 1 x 5 kg/ha (old study)	5, 10, 20, 30, and 40	Radiolabelled active substance: [¹⁴ C-amino-phenyl]- phenmedipham or [¹⁴ C- phenylmethyl]-phenmedipham (Finland, 2016; EFSA, 2018b; old studies: Finland, 1999; EFSA, 2014)
			1 x 2.2 kg/ha (old study)	0, 3, 7, 14, 21, and 28	
			Foliar: 1 x 1.066 kg/ha (BBCH 14)	19, and 137	
			Foliar: 1 x 1.044 kg/ha (BBCH 14)		
	Leafy crops	-	-	-	-
	Cereals/grass	-	-	-	-
	Pulses / oilseeds	-	-	-	-
Miscellaneous	-	-	-	-	

Can a general residue definition be proposed for primary crops?

No Root and fruit crops only (EFSA, 2018b).

Rotational crop and primary crop metabolism similar?

No In rotational crops, besides phenmedipham, MHPC (soil metabolite) occurs in significant level (25% TRRs in straw) (EFSA, 2018b).

Residue pattern in processed commodities similar to residue pattern in raw commodities?

No Under standard condition simulating pasteurisation phenmedipham is considered stable, while for other processing conditions phenmedipham degrades completely into m-toluidine and/or MHPC (EFSA, 2018b).

Plant residue definition for monitoring (RD-Mo)

MRL review (EFSA, 2014), Regulation (EC) No 396/2005: phenmedipham (tentative)
EU pesticides peer review (EFSA, 2018b):
Root and fruit crops: phenmedipham.
Processed commodities: sum of phenmedipham and MHPC, expressed as phenmedipham.

Plant residue definition for Risk assessment (RD-RA)

MRL review (EFSA, 2014): phenmedipham (fruits and fruiting crops; tentative for other crops).
EU pesticides peer review (EFSA, 2018b):
Primary crops: phenmedipham (free and glucoside conjugates) restricted to sugar beet.
Rotational crops: sum of phenmedipham and MHPC, and their conjugates, expressed as phenmedipham.
Processed commodities (provisional):
1) sum of phenmedipham and MHPC expressed as phenmedipham.
2) m-toluidine, pending upon confirmation of the toxicity of m-toluidine.

Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)	Matrices with high water content, high oil content, high acid content and dry matrices: DFG S19 (extended revision) LC–MS/MS, LOQ: 0.01 mg/kg (phenmedipham) QuEChERS GC–MS and/or LC–MS/MS, LOQ: 0.01-0.05 mg/kg (phenmedipham) ILV available. (EFSA, 2018b)
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DAT: days after treatment; BBCH: growth stages of mono- and dicotyledonous plants; PBI: plant-back interval; a.s.: active substance; AR: applied radioactivity; TRR: total radioactive residue; MRL: maximum residue level; LOQ: limit of quantification; LC-MS/MS: liquid chromatography with tandem mass spectrometry; GC-MS: gas chromatography with mass spectrometry; QuEChERS: Quick, Easy, Cheap, Effective, Rugged, and Safe; ILV: independent laboratory validation.

Conclusions:
Metabolism on root and fruit crops is available only. No general residue definition has been proposed for primary crops (root and fruit crops only). So, taking into the above account, proposed uses of Wizard/Beetup Pro/Betasana Max (product code HBZ10) on sugar, fodder, red and yellow beet roots belonging to root and tuber vegetables are possible.

Beet leaves and chard belong to the group of leafy vegetables and the metabolism of phenmedipham has not been investigated on this crop group. Whilst investigations on the nature of residues in leafy crops or a general residue definition are lacking, in our opinion the proposed uses of Wizard/Beetup Pro/Betasana Max (product code HBZ10) on beet leaves and chard are not possible.

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

Studies on residues in succeeding crops were evaluated during the EU Review process of Phenmedipham and were considered to be acceptable. Studies are summarised in **Table 7.2.2.2-1** below.

No new data submitted in the framework of this application.

Table 7.2.2.2-1 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	Lettuce	PC ring ^(b)	bare soil, G	1.1	30, 120, 365	Mature	-	Finland, 2002 (DAR Addendum 2)
Root and tuber vegetables	Sugar beet	PC ring ^(b)	bare soil, G	1.1	30, 120, 365	Mature	-	
Cereals	Wheat	PC ring ^(b)	bare soil, G	1.1	30, 120, 365	Immature, Mature	-	

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

(b): phenyl ring-labelled Phenmedipham

Summary of rotational crops studies reported in the EU

In the studies evaluated during the EU Review, radiolabelled Phenmedipham was applied to bare soil at 1.1 kg a.s./ha. Succeeding crops were sown 30, 120 and 365 days after application. Total radioactive residues in mature succeeding crops ranged at harvest of succeeding crops from <0.004 mg/kg in mature edible Sugar beet roots and tops of the 365-d plant back interval to 0.2 mg/kg in wheat straw of the 30-day plant back interval. Maximum TRR values in mature food commodities were up to 0.05 mg/kg for the 30 days plant back interval (lettuce), up to 0.01 mg/kg in the 120 days plant back interval (grain), and 0.02 mg/kg in the 365 days plant back interval (grain). Main identified residues were Phenmedipham and MHPC. Residues of single substances were all < 0.01 mg/kg in edible commodities.

Conclusion on metabolism in rotational crops

On the basis of the available data no residues above the MRL are expected even if succeeding crops are sown after crop failure directly after application of HBZ10. Moreover, metabolism in rotational crops can be considered as similar as for primary crops.

zRMS comments:

The metabolism of phenmedipham in rotational crops: lettuce, sugar beet, wheat has been evaluated (Finland, 2002). Confined rotational crop studies investigating the nature of residues following different plant-back intervals are available.

EFSA is of the opinion that no robust conclusion on the metabolism of phenmedipham and its expected residue levels in rotational crops can be derived from the available study; therefore new rotational crops metabolism data are required. According to the RMS, a new rotational crop metabolism study will be submitted in the framework of the renewal of the approval of the active substance under Regulation (EC) No 1107/2009 (January 2015). Meanwhile, Member States granting authorisations for phenmedipham should take the appropriate risk mitigation measures (e.g. plant back intervals) in order to avoid significant phenmedipham residues in crops grown in rotation (EFSA, 2014).

According to the EFSA Journal 2021;19(3):6482: *The nature of phenmedipham in rotational crops was investigated in the MRL review and in the EU pesticides peer review (EFSA, 2014, 2018). A study was conducted with the amino-phenyl-UL-¹⁴C phenmedipham (1.1 kg/ha) on lettuce, sugar beet and wheat at 30, 120 and 365 plant-back intervals (PBIs). The metabolic pattern was consistent throughout all PBIs with phenmedipham and MHPC being the only identified metabolite in rotational crops. In wheat straw, phenmedipham (20% TRR) and MHPC (25% TRR) were the major compounds of the TRR (0.95 mg eq./kg). The same metabolic pattern was observed in cereal forage. A significant decline of the total residues from the first to the third rotation interval was observed.*

In the framework of the EU pesticides peer review (EFSA, 2018), a new confined rotational crop study was conducted on wheat, turnip and chard with an application of 1.28 kg phenyl-methyl-UL-¹⁴C phenmedipham/ha at 30, 164 and 305 days PBIs. Although some deficiency was noted (low rate of identification) as in the first study, the metabolism pattern was considered sufficiently addressed because of the expected low residue levels in all edible parts.

The EU pesticides peer review concluded that the metabolism of phenmedipham in rotational crops proceeds in a different pathway than in primary crops, with phenmedipham and MHPC being the relevant residues (EFSA, 2018).

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Based in the supervised residue data summarised below, residue levels of > 0.01 mg/kg are not expected in raw commodities of the intended crops. Furthermore, the contribution of the intended crops amounts to far less than 10% of the ADI to the TMDI. Therefore, a study on the nature of the residue in processed commodities is not required.

No new data submitted in the framework of this application.

zRMS comments:

Information given by the Applicant is sufficient.

Not required since residues in intended crops are < 0.1 mg/kg and the chronic exposure does not exceed 10% of the ADI.

No further data are required to support the proposed uses.

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

Table 7.2.2.4-1 Summary of the nature of residues in commodities of plant origin

Endpoints	
Plant groups covered	Root and tuber vegetables (sugar beet)
Rotational crops covered	Leafy vegetables (lettuce) Root and tuber vegetables (sugar beet) Cereals (wheat)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Not relevant
Residue pattern in processed commodities similar to pattern in raw commodities?	Not applicable
Plant residue definition for monitoring	Phenmedipham (EFSA, 2014; Reg. (EU) 2015/2075)
Plant residue definition for risk assessment	Phenmedipham (EFSA, 2014)
Conversion factor from enforcement to RA	Not applicable

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

Available data

Studies on the metabolism of Phenmedipham in livestock were already evaluated during the EU Review process and were considered acceptable (Finland, 1999). Studies are summarised in **Table 7.2.2.5-1** below. Further data on the metabolism of Phenmedipham in livestock are therefore not required.

Table 7.2.2.5-1 Summary of animal metabolism studies

Table 7.2.2.3-1 Summary of animal metabolism studies								
Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate [mg/kg bw/d]	Duration [days]	Commodity	Time of sampling	
EU data								
Lactating ruminants	Cow	PC ring ^(a)	1	0.1	3	Milk	twice daily	Finland, 1999 EFSA, 2014
						Urine and faeces	on days 2, 3, 4	
						Tissues	at sacrifice	
		MPC ring ^(b)	1	0.1	3	Milk	twice daily	
						Urine and faeces	on day 3	
						Tissues	at sacrifice	
Laying poultry	Hens	PC ring ^(a)	6	0.79	14	Eggs	daily	
						Excreta	daily	
						Tissues	at sacrifice	

(a): phenyl ring labelled Phenmedipham

(b): methylphenyl ring labelled Phenmedipham

Summary of animal metabolism studies reported in the EU

The nature of Phenmedipham residues in commodities of animal origin was investigated in the framework of Directive 91/414/EEC (Finland, 1999). Reported metabolism studies include one study in lactating cows and one study in laying hens using phenyl-labelled Phenmedipham or methylphenyl-labelled Phenmedipham.

In the study in lactating ruminants evaluated in the EU Review, lactating cows were dosed with radiolabelled Phenmedipham at 0.1 mg/kg bw/day. Results demonstrate that the transfer of residues to milk and tissues is relatively low. In kidney, total residue levels amounted to 0.14 mg eq./kg and 0.15 mg eq./kg, for MPC- and PC-labels, respectively. In liver, residue levels amounted to 0.112 mg eq./kg and 0.015 mg eq./kg, for MPC- and PC-labels, respectively. Finally, in milk, residue levels reached plateau levels of 0.008 mg eq./L and 0.018 mg eq./L, for MPC- and PC-labels, respectively. Total residues in animal tissues ranged between 0.008 mg eq./L in milk for MPC-labels and 0.15 mg eq./kg in kidney for PC-labels. No parent compound was found in any of the analysed samples. Major components were metabolites MHPC, 3-aminophenol, 3-acetamidophenol, 4-amino-*o*-cresol, 4-acetamido-*o*-cresol, 3-aminobenzoic acid, and 3-acetamidobenzoic acid.

In the study in poultry, laying hens were dosed with 1.5 mg/animal/days (about 0.79 mg/kg bw/day). Studies demonstrate that transfer of residues to tissues and eggs is insignificant. Highest residue levels were found

in liver, with only 0.011 – 0.027 mg eq./kg, and in egg yolk, with a plateau of 0.031 – 0.043 mg eq./kg reached on day 6. Identification of metabolites was attempted but failed due to the low levels of radioactivity. Components of the residue could not be identified in the poultry study.

Conclusion on metabolism in livestock

Based on the metabolism study in cow, it can be concluded that Phenmedipham is extensively metabolised. Metabolism involved the cleavage of the two phenyl rings to form MHPC. Successive hydrolysis and acetylation reaction subsequently occur forming numerous metabolites.

Considering the intended use rates of Phenmedipham with HBZ10, no residues of Phenmedipham are expected in animal tissues of lactating ruminants, pigs or poultry.

zRMS comments:

The nature of phenmedipham residues in commodities of animal origin was investigated in the framework of Directive 91/414/EEC (Finland, 1999).

In EFSA Journal 2014;12(8):3807 it is stated that: *In the ruminant metabolism study, the absence of parent phenmedipham indicates extensive metabolism. No information was given about the percentages of residues extracted and not identified and no information was given about residues in muscle and fat. Nevertheless, it can be concluded that the metabolism of phenmedipham in ruminants involves the cleavage of the two phenyl rings to form two compounds, one of which being MHPC. Successive hydrolysis and acetylation reaction subsequently occur, forming numerous metabolites. The general metabolic pathways in rodents and ruminants were found to be comparable; the findings in ruminants can therefore be extrapolated to pigs. EFSA notes that the toxicology of the metabolites was not particularly studied in the DAR. As the same metabolites were formed in rats and ruminants, it was concluded that they are probably covered by a full range of toxicological studies conducted with the parent compound. According to the results of the study, metabolites MHPC, 3-aminophenol and 3-acetamidophenol seem to be the major components of the residue in ruminant and pig tissues. Nevertheless, available data are not sufficient to define the residue in ruminant and pig matrices. Therefore, a new ruminant metabolism study is required. Meanwhile, a tentative residue definition for enforcement and risk assessment in ruminant and pig matrices is proposed as parent phenmedipham only. Validated analytical methods for enforcement of the proposed residue definition are available.*

On the basis of the poultry metabolism study, after exposure to the maximum dietary burden (about 125 times lower than the application dose rate of the metabolism studies; see also Section 3.2.1), residue levels in poultry commodities are expected to remain below the enforcement LOQ of 0.05 mg/kg. Therefore, a default residue definition for enforcement and risk assessment in poultry matrices can be proposed as parent phenmedipham only.

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

Table 7.2.2.6-1 Summary on the nature of residues in commodities of animal origin

	Endpoints
Animals covered	Lactating cow
	Laying hens
Time needed to reach a plateau concentration	3 days in milk
	6 days in eggs
Animal residue definition for monitoring	Phenmedipham (EFSA, 2014; Reg. (EU) 2015/2075)
Animal residue definition for risk assessment	Phenmedipham (EFSA, 2014)
Conversion factor	Not applicable
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	No

The general metabolic pathways in rodents and ruminants were found to be comparable; the findings in ruminants can therefore be extrapolated to pigs, therefore no pig metabolism study was deemed necessary. No metabolism studies on fish are considered as necessary, since Phenmedipham should be considered as root and tuber crops (the major intended use in beets) are not considered as a significant part of the fish diet.

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

Since the residue data presented in the DAR were performed with varying application rates and residue levels were not reported in a detailed way, new residue data are presented in the following table for the intended uses of HBZ10. Samples were analysed for free Phenmedipham, free MHPC and the sum of free and conjugated Phenmedipham and MHPC.

Table 7.2.3.1-1 Summary of new residues data supporting the intended uses of HBZ10 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 (root) Ò extrapolated to red beet, yellow beet, fodder beet (root)	New data	N-EU	GAP: total 900 g/ha (3 x 300 g a.s./ha), up to BBCH 39, outdoor E/RA: 4 x < 0.01	E/RA: 0.01	E/RA: 0.01	0.01	0.05 (sugar beet), 0.15 (beetroot)	Yes
			GAP: total 900 g/ha (6 x 150 g a.s./ha), up to BBCH 39, outdoor E/RA: 4x < 0.01	E/RA: 0.01	E/RA: 0.01	0.01		Yes
Sugar beet (tops) Ò extrapolated to red beet, yellow beet, fodder beet and chard (tops)	New data	N-EU	GAP: total 900 g/ha (3 x 300 g a.s./ha), up to BBCH 39, outdoor E/RA: 3 x < 0.01, 0.02	E/RA: 0.01	E/RA: 0.02	0.03	0.3	Yes
			GAP: total 900 g/ha (6 x 150 g a.s./ha), up to BBCH 39, outdoor E/RA: 4x < 0.01	E/RA: 0.01	E/RA: 0.01	0.01		Yes

N/A: Not applicable

* Source of EU MRL: Reg. (EU) 2015/2075

7.2.3.2 Conclusion on the magnitude of residues in plants

According to the available data, the intended uses on beet crops (sugar beet, red beet, yellow beet, fodder beet and chard) are considered acceptable, for outdoor uses.

According to SANTE/2019/12752, sugar beet and fodder beet are major crops. Therefore, a total of 8 supervised residue trials would normally be required for the intended uses. However, the number of required trials can be reduced to 4 trials if all residues are below the LOQ. Since this is the case for beet roots, no further data are required.

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

The uses are considered acceptable.

zRMS comments:

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 beetroots (0213040) and fodder beet.

The intended GAP for phenmedipham for beet crops (sugar beet, red beet, yellow beet, fodder beet, chard) in Central Europe is 6x0.15 kg a.i./ha, 5x0.15 kg/ha or 3x0.30 kg a.i./ha with interval between applications of 5-9 days at BBCH 10-39 with PHI as not applicable, the PHI is covered by the time remaining between application and harvest.

1. Roots

New studies on the magnitude of residue have been submitted by the Applicant in the framework of this application. The trials are supported by valid storage stability data for sugar beet and validated analytical methods.

A total of 4 supervised residue trials were performed in Northern Europe. The tested application rates and timings, corresponded to the intended GAPs for HBZ10.

Trials were performed with 3 plots, each: an untreated control, a plot treated with HBZ10 with 3 applications of 300 g/ha Ethofumesate and 300 g/ha Phenmedipham at an interval of 5-7 days up to BBCH 37-39, and another plot with 6 applications of 150 g/ha Ethofumesate and 150 g/ha Phenmedipham at an interval of 4-6 days up to BBCH 37-39.

For phenmedipham, parent phenmedipham and its metabolite MHPC were analysed in their free form. Furthermore, a second analysis was done, hydrolysing the residues in order to analyse the sum of phenmedipham and MHPC in their free and conjugated forms. Furthermore, 3-methylaniline was analysed.

Residues in roots:

GAP: 3 x 300 g a.s./ha, up to BBCH 39

E/RA: 4x < 0.01 mg/kg

GAP: 6 x 150 g a.s./ha, up to BBCH 39

E/RA: 4 x < 0.01 mg/kg

Residues in tops:

GAP: 3 x 300 g a.s./ha, up to BBCH 39

E/RA: 3 x < 0.01, 0.02 mg/kg

GAP: 6 x 150 g a.s./ha, up to BBCH 39

E/RA: 4 x < 0.01 mg/kg

The trials confirmed that no residues above the LOQ of 0.01 mg/kg are expected in sugar beet roots. The number of trials presented is therefore considered sufficient.

The residues arising from the proposed uses will not exceed the MRLs established for phenmedipham for root of sugar beet of 0.05 mg/kg, beetroots of 0.15 mg/kg in Reg. (EC) No 2015/2075.

The proposed uses on roots of sugar beet, red beet, yellow beet, fodder beet are considered acceptable.

2. Leaves (tops)

Beet leaves and chard belong to the group of leafy vegetables and the metabolism of phenmedipham has not been investigated on this crop group. No general residue definition has been proposed for primary crops (root and fruit crops only). Additionally, according to the SANTE/2019/12752, extrapolation from sugar beet tops to tops of red beet, yellow beet and chard is not possible.

Considering the above, in our opinion, the proposed uses of Wizard/Beetup Pro/Betasana Max (product code HBZ10) on beet leaves and chard are not acceptable.

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

A dietary burden calculation was performed with the EFSA animal burden calculator (2017) using the results of the new supervised residue trials with HBZ10. Since the analytical method used does not allow to distinguish between Phenmedipham and MHPC when analysing the sum of free and conjugated residues, the sum of Phenmedipham and MHPC, expressed as Phenmedipham was used in the risk assessment below as a worst case. Input values are given in **Table 7.2.4.1-1**, results are summarised in **Table 7.2.4.1-2**.

Table 7.2.4.1-1 Input values for the dietary burden calculation (considering as a worst case the sum of free and conjugated Phenmedipham and MHPC)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value [mg/kg]	Comment	Input value [mg/kg]	Comment
Risk assessment residue definition: sum of Phenmedipham and MHPC, free and conjugated forms (worst-case)				
Sugar beet tops	0.025	Median residue (see Table 7.2.3.1-1)	0.25	Highest residue (see Table 7.2.3.1-1)
Fodder beet	0.025	Median residue for beet tops (see Table 7.2.3.1-1)	0.25	Highest residue for beet tops (see Table 7.2.3.1-1)
Sugar beets, dried pulp	0.01	Median residue (see Table 7.2.3.1-1)*	0.01	Highest residue (see Table 7.2.3.1-1)*
Sugar beets, molasses	0.01	Median residue (see Table 7.2.3.1-1)*	0.01	Highest residue (see Table 7.2.3.1-1)*

* no processing factors were applied since residues were < LOQ

Table 7.2.4.1-2 Results of the dietary burden calculation (considering as a worst case the sum of free and conjugated Phenmedipham and MHPC)

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 Phenmedipham and MHPC, free and conjugated forms (worst-case)					
Beef cattle	0.0016	0.012	Beet, mangel (fodder)	0.52	Y
Dairy cattle	0.0026	0.017	Beet, mangel (fodder)	0.44	Y
Ram/ewe	0.0009	0.007	Beet, sugar (tops)	0.2	Y
Lamb	0.0011	0.009	Beet, sugar (tops)	0.22	Y
Breeding swine	0.001	0.006	Beet, mangel (fodder)	0.25	Y
Finishing swine	0.000	0.000	Beet, sugar (dried pulp)	0.00	n.a.
Broiler poultry	n.a.	n.a.	n.a.	n.a.	n.a.
Layer poultry	0.000	0.004	Beet, sugar (tops)	0.05	N
Turkey	n.a.	n.a.	n.a.	n.a.	n.a.

n.a. Not applicable – no intake

Table 7.2.4.1-3 Input values for the dietary burden calculation (considering Phenmedipham only)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value [mg/kg]	Comment	Input value [mg/kg]	Comment
Risk assessment residue definition: Phenmedipham				
Sugar beet tops	0.01	Median residue (see Table 7.2.3.1-1)	0.02	Highest residue (see Table 7.2.3.1-1)
Fodder beet	0.01	Median residue for beet tops (see Table 7.2.3.1-1)	0.02	Highest residue for beet tops (see Table 7.2.3.1-1)
Sugar beets, dried pulp	0.01	Median residue (see Table 7.2.3.1-1)*	0.01	Highest residue (see Table 7.2.3.1-1)*
Sugar beets, molasses	0.01	Median residue (see Table 7.2.3.1-1)*	0.01	Highest residue (see Table 7.2.3.1-1)*

* no processing factors were applied since residues were < LOQ

Table 7.2.4.1-4 Results of the dietary burden calculation (considering free Phenmedipham only)

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: Phenmedipham					
Beef cattle	0.0009	0.001	Beet, mangel (fodder)	0.06	N
Dairy cattle	0.0017	0.002	Beet, mangel (fodder)	0.06	N
Ram/ewe	0.0004	0.001	Beet, sugar (tops)	0.0	N
Lamb	0.0006	0.001	Beet, sugar (tops)	0.02	N
Breeding swine	0.001	0.001	Beet, mangel (fodder)	0.02	N
Finishing swine	0.000	0.000	Beet, sugar (dried pulp)	0.00	n.a.
Broiler poultry	n.a.	n.a.	n.a.	n.a.	n.a.
Layer poultry	0.000	0.000	Beet, sugar (tops)	0.00	N
Turkey	n.a.	n.a.	n.a.	n.a.	n.a.

n.a. Not applicable – no intake

The results show that the trigger value of 0.004 mg/kg bw/day is exceeded for cattle, sheep and breeding swine, when the dietary burden assessment is calculated with the sum of free and conjugated Phenmedipham and MHPC as a worst case. When the dietary burden assessment is calculated only considering Phenmedipham, the trigger is not exceeded for any of the animal species.

The expected maximum dietary intakes are much lower than the dose rates tested in the cow metabolism study (0.1 mg/kg bw/day) which resulted in low residue levels in tissues (TRR max. 0.15 mg eq/kg). It is therefore not expected that relevant residue levels will occur in commodities of animal origin and livestock feeding studies are therefore not required.

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 burden for phenmedipham only was not 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. Therefore, no further investigation of residues is required.

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Available data

Considering the low dietary intake, no feeding studies are considered to be required.

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

Conclusion on feeding studies

Based on the expected dietary intake, no feeding studies are required and no exceedance of the current MRLs for animal commodities is expected.

zRMS comments:

Data presented by Applicant in point 7.2.4.2 have been accepted and are sufficient to support the proposed uses.

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

Residue levels in beet crops (sugar beet, red beet, yellow beet, fodder beet and chard) are not expected to be > 0.1 mg/kg (see Point 7.2.3 above). Furthermore, the contribution of sugar beet and red beet to the theoretical maximum daily intake (TMDI) is well below 10% of the ADI. A short-term risk assessment is not required since no ARfD was set. Therefore, no processing studies are required for these crops.

7.2.5.1 Available data for all crops under consideration

As the residue levels are low in beet roots, processing studies are not required.

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

7.2.5.2 Conclusion on processing studies

The trigger for requiring new studies is not met by the intended uses. No further studies are deemed necessary.

zRMS comments:

Information given by the Applicant is sufficient.

Not required since residues in intended crops are < 0.1 mg/kg and the chronic exposure does not exceed 10% of the ADI.

No further data are required to support the proposed uses.

7.2.6 Magnitude of residues in representative succeeding crops

7.2.6.1 Field rotational crop studies (KCA 6.6.2)

Available data

Considering the low residue levels found in the confined rotational crops study (maximum TRR values in mature food commodities up to 0.05 mg/kg for the 30 days plant back interval and residues of single substances all < 0.01 mg/kg in edible commodities), data in field rotational crops studies are not considered to be required.

No new data submitted in the framework of this application.

Conclusion on rotational crops studies

Field studies on rotational crops are not considered to be required.

zRMS comments:

Information given by the Applicant is sufficient.

Additionally, in EFSA Journal 2021;19(3):6482 it is stated that: *The magnitude of phenmedipham in rotational crops was investigated in the framework of the EU pesticides peer review (EFSA, 2018b). Phenmedipham was applied either on a bare soil or target crop sugar beet at an application rate of 0.96 kg/ha, followed by planting of rotational crops lettuce, carrots, turnips, wheat and barley. The results confirm the conclusions of the confined study, that residues of phenmedipham and MHPC do not occur above the level of 0.01 mg/kg in the rotational crops studied.*

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 (KCA 6.10, 6.10.1)

In accordance with Appendix II to the Technical guidelines for determining the magnitude of pesticide residues in honey (SANTE/11956/2016 rev 9), sugar beet, fodder beet and red beet are not melliferous crops.

Beets for consumption are harvested by the end of the first year, while flowering of these crops occurs in the second year. Also, beets for seed production are not attractive to honeybees since beet flowers are wind pollinated. Regarding guttation droplets as source of water, the beet structure does not allow formation of water reservoirs in leaf axils and therefore the risk of taking up residues with guttation water is low. Therefore, bees are not exposed to the active substance and information on residue data in honey is not required.

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 beet, fodder beet, yellow beet and red beet and rotational crops. Regarding uses on sugar beet, fodder beet, yellow beet and red 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 Point 7.1.2). The calculation of the TMDI was performed using the EFSA PRIMo Model 3.1 taking into account all EU-MRLs set for Phenmedipham as given in Regulation (EU) 2015/2075. As an ARfD was not deemed necessary, acute risk assessment is not relevant.

7.2.8.1 Input values for the consumer risk assessment

A first-tier chronic consumer risk assessment was performed using all currently set MRLs and the EFSA PRIMo 3.1. Input values are given in **Table 7.2.8.1-1** below.

Table 7.2.8.1-1 Input values for the consumer risk assessment

Commodity	Chronic risk assessment	
	Input value [mg/kg]	Comment
Risk assessment residue definition: Phenmedipham		
Strawberries	0.3	EU MRL
Beetroots	0.15	EU MRL
Spinaches	0.3	EU MRL
Chards/beet leaves	0.3	EU MRL
Chervil, chives, celery leaves, parsley, sage, rosemary, thyme, basil and edible flowers, laurel/bay leaves	7	EU MRL
Tarragon	0.3	EU MRL
Other herbs and edible flowers	0.02	EU MRL
Teas, coffee, herbal infusions, cocoa and carob	0.05*	EU MRL
Hobs	0.05*	EU MRL
Spices	0.05*	EU MRL
Sugar beet roots	0.05*	EU MRL
All other commodities of plant origin	0.01*	EU MRL
Products of animal origin – terrestrial animals	0.05*	EU MRL

7.2.8.2 Conclusion on consumer risk assessment

A chronic consumer risk assessment was performed using all currently set EU MRLs. The risk assessment was calculated using EFSA PRIMo 3.1. The highest chronic exposure for Phenmedipham was calculated for NL toddler, representing 14% of the ADI.

The proposed uses of Phenmedipham in the formulation HBZ10, therefore, do not represent unacceptable risks for the consumer. Extensive calculation sheets are presented in Appendix 3.

Table 7.2.8.2-1 Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo	14% (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo	Not performed, since TMDI was well below ADI
IENTI (% ARfD) according to EFSA PRIMo*	Not applicable
NTMDI (% ADI) **	Not relevant
NEDI (% ADI)**	Not relevant
NESTI (% ARfD) **	Not applicable

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

** If national model is available

zRMS comments:

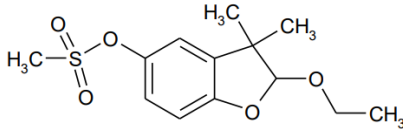
The consumer risk assessments for phenmedipham were performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMO rev. 3.1). The calculation of the TMDI using EFSA model PRIMo rev. 3.1 and MRLs according to Reg. (EU) 2015/2075 led to a utilisation of the ADI of 14% with the NL toddler being the population group with the highest value. For this diet, the highest contributor is Milk: Cattle with 10% of the ADI. The intended uses will not result in a consumer chronic exposure exceeding the ADI.

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

7.3 Ethofumesate

General data on Ethofumesate are summarized in the table below (last updated 07.06.2021)

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 g/mol
Chemical group	Benzofurane
Mode of action (if available)	Inhibition of lipid synthesis - not ACCase inhibition (15)
Systemic	Yes
Companies	UPL Europe Ltd. Task Force comprising Bayer CropScience and ADAMA
Rapporteur Member State (RMS)	Austria DAR: Sweden RAR-RMS: Austria Co-RMS: Denmark
Approval status	Approved (renewal of approval) 01.11.2016 (2016/1426) ¹ .
Restriction	None Only uses as herbicide may be authorised
Review Report	SANTE/10119/2016 Rev. 3 12.07.2016
Current MRL regulation	Regulation (EU) No 2017/1016
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	None

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

7.3.1 Stability of Residues (KCA 6.1)

7.3.1.1 Stability of residues during storage of samples

Available data

According to the EFSA Conclusion of the EU Review of Ethofumesate, the residue definition for monitoring and risk assessment in plants was set to the sum of Ethofumesate, ethofumesate-lactone (NC 9607), ethofumesate-carboxylic acid (NC 20645) and its conjugate, expressed as Ethofumesate; the residue definition in animal commodities was set to the sum of Ethofumesate, ethofumesate-lactone (NC 9607), ethofumesate-carboxylic acid (NC 20645, free form only), expressed as Ethofumesate.

Sufficient data to show the stability of residues during storage of samples to cover this residue definition were already submitted during the EU Review and can be found in the DAR (Sweden, 1998) and RAR (Austria 2015).

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

¹ OJ L 231, 28.06.2016, p. 34–38

Table 7.3.1.1-1: Summary of stability data achieved at ≤ -18°C (plant commodities) and at -21 °C (animal commodities)

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Plant products			
Data relied on in EU (Ethofumesate)			
Sugar beet (roots)	High starch content	24 months	Sweden, 1998
Sugar beet (leaves)	High water content	24 months	Sweden, 1998
Grass	High water content	18 months	Austria, 2015
Data relied on in EU (NC 9607, NC 20645 and conjugated NC 20645)			
Sugar beet (roots)	High starch content	24 months	Sweden, 1998, Austria, 2015
Sugar beet (leaves)	High water content	24 months	Sweden, 1998, Austria, 2015
Rape seed	High oil content	6 months	Austria, 2015
Dry bean seed	High protein content	6 months	Austria, 2015
Orange fruit	High acid content	6 months	Austria, 2015
Animal products			
Data relied on in EU (Ethofumesate and its metabolites NC 9607, NC8493 and NC 20645)			
Ruminant	Muscle	6 months*	Austria, 2015
Ruminant	Liver	6 months	Austria, 2015
Ruminant	Kidney	6 months**	Austria, 2015
Ruminant	Fat	6 months***	Austria, 2015
Ruminant	Milk	6 months	Austria, 2015

* 1 month for NC 20645

** 3 months for NC 8493

*** <1 month for NC 20645

Conclusion on stability of residues during storage

The stability of residues for the active substance Ethofumesate was already addressed during the original EU Review process. Regarding uses intended with this submission, the active substance and its metabolite NC 9607 were shown to be stable under frozen storage for 24 months in sugar beet roots (high starch content matrix), and up to 24 months for sugar beet leaves (high water content matrix), and at least 18 months in grass (high water content matrix). Additional data submitted for the renewal of approval of Ethofumesate showed the stability of the metabolite NC 20645 (free and conjugated) in sugar beet roots and leaves for 24 months and in rape seed, dry bean seed and orange fruit for at least 6 months (Austria 2015).

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 7.3.1.1-1** above).

zRMS comments:

zRMS agrees with information provided by the Applicant above.

According to OECD 506 sugar, fodder, red and yellow beet roots belong to high starch content matrices, sugar, fodder, red and yellow beet leaves and chard belong to high water content matrices.

Applicant did not submit a new storage stability study. The potential degradation of residues during storage of the residue trials samples was assessed in the framework of the peer review.

According to the EFSA Journal 2016;14(1):4374:

Stability of residues (Regulation (EU) N° 283/2013, Annex Part A, point 6.1)

OECD Guideline 506

Plant products (Category)	Commodity	T (°C)	Stability (Month/Year)		
			ethofumesate	NC 20645, as NC 9607	NC 8493
High water content	sugar beet (leaves)	< -18	1 year	2 years	Not available*
High oil content	rape seed	< -18		6 months	
High protein content	dry bean	< -18		6 months	
High starch content	sugar beet (roots)	< -18	1 year	2 years	Not available *
High acid content	orange fruits	< -18		6 months	

* In a couple of residue trials, sugar beets were analysed for NC 8493, however storage stability data to validate the results were not included. NC 8493 is currently not included in the residue definition for insignificant occurrence in sugar beet. This might be acceptable provided NC 8493 residues were indeed stable until analysis.

Animal	Animal Commodity	T (°C)	Stability (Month/Year)			
			ethofumesate	NC 9607	NC 20645	NC 8493
not specified in the study	Muscle	-21	6	6	1	6
not specified in the study	Liver	-21	6	6	6	6
not specified in the study	Kidney	-21	6	6	6	3
not specified in the study	Fat	-21	6	6	<1	6
bovine	Milk	-21	6	6	6	6

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

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.

The residue data are valid with regard to storage stability.

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 except for metabolite NC 20645 in muscle (1 month) and for metabolite NC8493 in kidney (3 months).

No additional data are required.

7.3.1.2 Stability of residues in sample extracts (KCA 6.1)

A new study on supervised residue trials is presented with this dossier. In this study, sample extracts were stored frozen for maximum 9 days for leaves with tops and 8 days for roots for the analysis of free forms of Ethofumesate and its metabolites. Sample extracts treated for the analysis of the conjugated form were stored for maximum 9 days (tops) or 7 days (roots).

Stored sample extracts were shown to be stable for at least 15 days in high water content extracts under frozen conditions (extracts for analysis of free forms). Stored sample extracts for analysis of conjugated form were shown to be stable for at least 15 days in high water content extracts under frozen conditions.

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 sample extracts is always guaranteed. In addition, when conducting analyses of residue samples, the entire analytical procedure is monitored by conducting concurrent recoveries with each sample set.

Conclusion on stability of residues in sample extracts

Stability of extracts of residue samples of Ethofumesate is confirmed by procedural recoveries.

zRMS comments:

Information given by the Applicant is sufficient.

No further data are 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

Studies on metabolism of Ethofumesate in plants were already addressed during the EU Review process and were considered acceptable.

Uptake, translocation, and metabolism of Ethofumesate were evaluated in the DAR on Ethofumesate (Sweden, 1998, Volume 3, B6) and re-evaluated in the RAR (Austria, 2015, Volume 3, B7) and in the EFSA Conclusion (EFSA, 2016). Information on crops tested, application and sampling details are given in **Table 7.3.2.1-1** below.

No new data submitted in the framework of this application.

Table 7.3.2.1-1: 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	Tobacco	[¹⁴ C- benzene]	Soil, G	2.00	1	7, 15, 30, 60, 90 and 120	Warner and Adcock, 1977 Non-GLP	Sweden, 1998 Austria, 2015
			Foliar, G	2 mg/ plant				
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	Sweden, 1998
		[¹⁴ C- benzene]	Foliar, G	1.50 or 7.5	1	0, 7, 28 and at maturity	Caley, et al. 1994	Austria, 2015
		[¹⁴ C- benzene]	Foliar, F	1.5	1	1, 10, 50, 90, 137	Hennecke, 2003	Austria, 2015
		[¹⁴ C- benzene]	Soil, G	2.00	1	10, 20, 30, 40 and 50	Lines and Adcock, 1978; Non-GLP	Sweden, 1998 Austria, 2015
			Foliar, G					
		[¹⁴ C- mesyl]	Soil, F	2.00	1	50, 75, 125 and 175	Lines and Adcock, 1979; Non-GLP	
	Foliar, F		50, 75 and 125					
	Onion	Not reported	Soil ^(b)	2.00	1	22, 30, 40, 50, 60, 70, 80, 90, 100, 110, 120 and 162	Adcock et al., 1976 Non-GLP	Sweden, 1998 Austria, 2015
Cereals	Ryegrass	[¹⁴ C- benzene]	Foliar, G	2.09 or ~10.45	1	0+, 7, 28, (silage) and 112 (maturity)	Chapleo, 1992	Sweden, 1998 Austria, 2015

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

(b) F or G not reported

Summary of plant metabolism studies reported in the EU

From the data evaluated during the EU Review, it was concluded that the metabolism pattern of Ethofumesate is similar among the different crops investigated, leading to the metabolites ethofumesate-2-hydroxy (NC 8493), ethofumesate-lactone (NC 9607) and ethofumesate-carboxylic acid (NC 20645), recovered also in their conjugate form. NC 20645 is the open ring form of NC 9607. When conjugated NC 20645 is treated under acidic hydrolytic conditions, the conjugation is cleaved, and metabolite NC 20645 is converted to metabolite NC 9607 by an intramolecular ring closure. This same conversion into NC 9607 can happen to the free form of NC 20645 either when it undergoes acidic hydrolysis or when it is analysed by GC-MS. Since major amounts of metabolite NC 8493 were only detected in intermediate growth stages it is not necessary to include this metabolite in the residue definition for mature crops, as well as its conjugate which was always a minor metabolite.

Comparison of pre-and post-emergence treatments revealed that Ethofumesate is taken-up via roots and leaves. The metabolism in the plants is independent from the route of uptake.

Since the parent has been degraded to a significant extent, if not completely, into its metabolites at harvest, EFSA proposed a new residue definition for risk assessment and enforcement as the *sum of Ethofumesate, NC 9607, NC 20645 and its conjugate, expressed as Ethofumesate* (EFSA, 2016).

Summary of new plant metabolism studies

No new data submitted in the framework of this application.

Conclusion on metabolism in primary crops

Based on the available information the residue definition is proposed as the sum of Ethofumesate, NC 9607, NC 20645 and its conjugate, expressed as Ethofumesate in the EU Review (EFSA, 2016).

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 Wizard/Beetup Pro/Betasana Max (product code HBZ10).

7.3.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

Studies on residues in succeeding crops were evaluated during the EU Review process of Ethofumesate and were considered to be acceptable. Studies are summarised in **Table 7.3.2.2-1** below.

No new data submitted in the framework of this application.

Table 7.3.2.2-1 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]	Bare soil, G	4.6 4.5	96, 276, 367	Immature plants: 145, 334 and 404 Mature plants: 292, 418 and 473	Carlton, Cordell, 1993	Sweden, 1998 Austria, 2015
	Spinach		Bare soil, G	1	30	98	Chapleo, 2003	Austria, 2015
Root and tuber vegetables	Radish	[¹⁴ C-benzene]	Bare soil, G	4.6 4.5	96, 276, 367	Immature plants: 130, 314 and 397 Mature plants: 139, 347 and 411	Carlton, Cordell, 1993	Sweden, 1998 Austria, 2015
	Carrots		Bare soil, G	1	30	133	Chapleo, 2003	Austria, 2015
Pulses and oilseeds	French beans	[¹⁴ C-benzene]	Bare soil, G	1	30	109	Chapleo, 2003	Austria, 2015
Cereals	Wheat	[¹⁴ C-benzene]	Bare soil, G	4.6 4.5	157, 276, 367	Immature plants: 229, 383 and 432 Mature plants: 486, 535 and 508	Carlton, Cordell, 1993	Sweden, 1998 Austria, 2015
	Ryegrass		Bare soil, G	1	30	132	Chapleo, 2003	Austria, 2015

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

Summary of the metabolism in rotational crops reported in the EU

In the studies evaluated during the EU Review, radiolabelled Ethofumesate was applied to bare soil from 1 to 4.6 4.5 kg a.s./ha. Succeeding crops were sown 1, 3, 5, 9 and 12 months after application, covering plant-back interval of crop failure. The metabolism in rotational crops was shown to be similar to the metabolism in primary crops.

Conclusion on metabolism in rotational crops

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 Ethofumesate in confined rotational crops follows the same metabolic pathway as in primary crops.

On the basis of the available data, residues in succeeding crops were found to be significant and therefore field studies were carried out (see point 7.3.6).

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.

7.3.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Studies on the nature of residues in processing are only necessary where residues in products to be processed occur at a level of or higher than 0.01 mg/kg (based on the residue definition for risk assessment for the raw commodity). As no relevant residues are expected from the data submitted by UPL Europe Ltd. for the EU Review, such a study is not required. Furthermore, the theoretical maximum daily intake of Ethofumesate residues is below 10% of the ADI using the highest residues of Ethofumesate. Hence, no studies on the effects of processing are considered to be required.

Nevertheless, a study on the nature of residues under conditions simulating industrial and household common processes was evaluated during the EU Review of Ethofumesate and considered acceptable (EFSA, 2016).

Available data

A study on the nature of residues in processed commodities was already evaluated during the EU Review of Ethofumesate and was considered acceptable (EFSA, 2016). The study is summarised in **Table 7.3.2.3-1** below.

No new data submitted in the framework of this application.

Table 7.3.2.3-1 Nature of the residues in processed commodities

Conditions (Duration, Temperature, pH)	Ethofumesate [%]*	Reference
EU data		
Pasteurisation (20 min, 90°C, pH 4)	98.6	Austria, 2015
Baking, boiling, brewing (60 min, 100°C, pH 5)	99.3	Austria, 2015
Sterilisation (20 min, 120°C, pH 6)	100	Austria, 2015
Other conditions		
Industrial process of sugar production (30 min, 90°C, pH 11)**	97.6	Austria, 2015

* Metabolites not analysed

** Sugar beets purification process

The test compound Ethofumesate was stable under all conditions of high temperature hydrolysis for simulation of food processing. No significant hydrolysis products of Ethofumesate ($\leq 2.1\%$) were detected above an estimated LOD of 0.7% of the total radioactivity.

Conclusion on nature of residues in processed commodities

Based on the available data it can be concluded that Ethofumesate is stable during processing. The behaviour of the major metabolites NC 9607 and NC 20645 was not analysed. Nevertheless, since both metabolites are interconvertible depending on the pH, and the residue levels are expected to be below the LOQ under practical conditions, no additional studies are deemed necessary (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.

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

Table 7.3.2.4-1 Summary of the nature of residues in commodities of plant origin

Endpoints	
Plant groups covered	Root and tuber vegetables (sugar beet and onion) Cereals and grass crops (ryegrass) Leafy vegetables (tobacco)
Rotational crops covered	Root and tuber vegetables (radish, carrots) Leafy crops (cabbage, spinach) Small cereal grains (wheat, ryegrass) Other (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, opening-2-keto-ethofumesate and its conjugate, expressed as ethofumesate). (Reg. (EU) 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	Sum of Ethofumesate, ethofumesate-lactone (NC 9607), ethofumesate-carboxylic acid (NC 20645), expressed as ethofumesate). (EFSA, 2016)
Conversion factor from enforcement to RA	1 (EFSA, 2016)

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

Available data

Studies on metabolism of Ethofumesate in livestock were already evaluated during the EU Review process and were considered acceptable (see RAR on Ethofumesate, Austria 2015, and EFSA conclusion, EFSA, 2016). Studies are summarised in **Table 7.3.2.5-1** below. Further data on the metabolism of Ethofumesate in livestock are therefore not required.

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

Table 7.3.2.5-1 Summary of animal metabolism studies

Table 7.3.2.3-1 Summary of animal metabolism studies									
Group	Species	Label position	No of animal	Application details		Sample details		Reference	
				Rate [mg/kg bw/d]	Duration [days]	Commodity	Time of sampling		
EU data									
Lactating ruminants	Cow	[¹⁴ C-benzene]	1	0.3 - 0.36	7	Milk	Twice daily	Sweden, 1998 Austria, 2015	
						Urine and faeces	Day -1, 1 and 7		
						Tissues	After sacrifice		
				1	5	4	Milk	Twice daily	Sweden, 1998 Austria, 2015
							Urine and faeces	Daily	
							Tissues	After sacrifice	
	Sheep	[¹⁴ C-benzene]	1	0.2	1	Milk	Not analysed	Sweden, 1998 Austria, 2015	
						Urine and faeces	Daily		
						Tissues	After sacrifice (4 days after dosing)		
Laying poultry	Hens	[¹⁴ C-benzene]	6	0.6	14	Eggs	Daily	Sweden, 1998 Austria, 2015	
						Excreta	Daily		
						Tissues	After sacrifice		
			3	0.78	10	Eggs	Twice daily	Sweden, 1998 Austria, 2015	
						Excreta	Daily		
						Tissues	After sacrifice		

Since the metabolism in the rat and in the cow was very similar, no pig metabolism study was deemed necessary. No metabolism studies on fish are considered as necessary, since Ethofumesate should be considered as not fat soluble due to a log P_{ow} of 2.7, i.e. <3 ; besides, root and tuber crops (the major intended use in beets) are not considered as a significant part of the fish diet.

Summary of animal metabolism studies reported in the EU

In the studies in lactating ruminants evaluated in the EU Review, two cows and a sheep were dosed with radio labelled Ethofumesate at 0.2-2.94 g/cow/day (corresponding to 0.3-5.0 mg/kg bw/day) and at 8.54 mg/sheep/day (corresponding to 0.2 mg/kg bw/day), respectively. Since the sheep was dosed only once, the study does not fulfil the current requirements as outlined in the OECD Guideline 503 and was not considered. Daily oral administration of Ethofumesate to lactating cows was performed for 7 or 4 consecutive days. Total radioactive residues in milk ranged between 0.003 and 0.591 mg/L. Highest residues in milk were found on day 5 and 3, respectively. Total residues in animal tissues ranged between 0.033 mg/kg in muscle and 0.122-1.863 mg/kg in kidney. Major components were parent compound, NC 9607 and NC 20645. The metabolite NC 20645 was the main component in kidney. NC 8493 was detected at low levels in milk, fat, kidney, and muscle. Urine was the most important elimination pathway. The metabolic pattern identified for cows was consistent with the rat metabolism and very similar to that in poultry (see below).

In the 2 studies in poultry evaluated in the EU Review, a total of 6 and 3 laying hens were dosed with radiolabelled Ethofumesate at 1.0-1.5 g/bird/day (corresponding to 0.60-0.78 mg/kg bw/day) during 10-14 consecutive days. Total radioactive residues in eggs ranged between 0.003 and 0.01 mg/kg. Highest residues in eggs were found on day 2 and 8, respectively. Total residues in animal tissues ranged between 0.007 mg/kg in muscle and 0.160-0.362 mg/kg in the gastrointestinal tract, indicating that ^{14}C -Ethofumesate was to a large extent eliminated by the excreta. Major components were parent compound, NC 9607 and NC 20645. The metabolite NC 20645 was the main component in the muscle and liver. NC 9607 was present in all tissues and NC 8493 was present at low levels in the muscle.

Conclusion on metabolism in livestock

Considering the intended use rates of Ethofumesate with HBZ10, no residues of Ethofumesate are expected in animal tissues of lactating ruminants, pigs or poultry.

Based on the available data, the residue definition of Ethofumesate in animal tissues for both enforcement and risk assessment should be the *sum of Ethofumesate, NC 9607 and NC 20645 expressed as Ethofumesate* (EFSA, 2016).

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.

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

Table 7.3.2.6-1 Summary on the nature of residues in commodities of animal origin

	Endpoints
Animals covered	Lactating cows
	Laying hens
Time needed to reach a plateau concentration	32 hours in milk
	9 days in eggs
Animal residue definition for monitoring	Sum of Ethofumesate, -2-keto ethofumesate, open ring 2-keto ethofumesate and its conjugate, expressed as ethofumesate (Regulation 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	Sum of Ethofumesate, ethofumesate-lactone (NC 9607), ethofumesate-carboxylic acid (NC 20645), expressed as ethofumesate). (EFSA 2016)
Conversion factor	1 (EFSA 2016)
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	No (FAO, 2009)

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: Beet crops (sugar beets, fodder beets and red beets)

The use in beet crops (sugar beets, fodder beets, chard, yellow beets, and red beets) was already evaluated in the EU Review of Ethofumesate (AIR 3). A full data package in compliance with the intended GAP was presented by the main notifier UPL Europe Ltd. to support the use of Ethofumesate on beet crops.

A sufficient number of residue data in beets was already evaluated during the original EU Review of Ethofumesate (Sweden, 1998). The additional data package of UPL Europe Ltd. evaluated in the RAR consisted of a total of 37 trials in Northern Europe and 9 trials in Southern Europe conducted from 2000 to 2012. While for post-emergence mainly split applications are foreseen for Ethofumesate 500 SC, the EFSA Conclusion only considered trials with one application of the maximum total dose of 1 kg a.s./ha in the overall summary of results (see **Table 7.3.3.1-1** below). With only few exceptions, residues were found to be < LOQ in beet roots, while residues in leaves were < 0.1 mg/kg in most trials.

Table 7.3.3.1-1 Summary of EU reported and new data supporting the intended uses of HBZ10 in beets and conformity to existing MRLs

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] ²	MRL compliance
Post-emergence use								
Sugar beet (root) Ò extrapolated to red beet, yellow beet, fodder beet (root)	EFSA, 2016	N-EU	GAP on which EU a.s. assessment is based: post-emergence, 1 kg a.s./ha, outdoor ¹ E/RA: 8x < 0.02, 15x < 0.06, 0.06, 0.09, 11x < 0.1	E/RA: 0.06	E/RA: < 0.1	-	-	-
		S-EU	GAP on which EU a.s. assessment is based: post-emergence, 1 kg a.s./ha, outdoor ¹ E/RA: 8x < 0.02, 3x < 0.06	E/RA: 0.02	E/RA: 0.06	-	-	-
	New studies	N-EU	GAP: total 900 g/ha (3 x 300 g a.s./ha), up to BBCH 39, outdoor E/RA: < 0.01, 2x 0.01, 0.02	E/RA: 0.01	E/RA: 0.02	0.03	-	-
			GAP: total 900 g/ha (6 x 150 g a.s./ha), up to BBCH 39, outdoor E/RA: 4 x < 0.01	E/RA: 0.01	E/RA: 0.01	0.01	-	-
	Overall	N-EU	E/RA: 5x < 0.01, 2x 0.01, 8x < 0.02, 0.02, 15x < 0.06, 0.06, 0.09, 11x < 0.1	E/RA: 0.06	E/RA: < 0.1	0.190	0.2	Yes
		S-EU	E/RA: 8x < 0.02, 3x < 0.06	E/RA: 0.02	E/RA: 0.06	0.06	0.2	Yes
Sugar beet (tops) Ò extrapolated to red beet, yellow beet, fodder beet and chard (tops)	EFSA, 2016	N-EU	GAP on which EU a.s. assessment is based: post-emergence, 1 kg a.s./ha, outdoor ¹ E/RA: 8x < 0.02, 11x < 0.06, 0.06, 0.07, 9x < 0.1, < 0.12, 0.18	E/RA: 0.06	E/RA: 0.18	-	-	-
		S-EU	GAP on which EU a.s. assessment is based: post-emergence, 1 kg a.s./ha, outdoor ¹ E/RA: 6x < 0.02, 0.04, 0.06, 0.14	E/RA: 0.02	E/RA: 0.14	-	-	-
	New studies	N-EU	GAP: total 900 g/ha (3 x 300 g a.s./ha), up to BBCH 39, outdoor E/RA: 0.03, 0.05, 0.13, 0.45 ³	E/RA: 0.05	E/RA: 0.13 ⁴	0.28	-	-
			GAP: total 900 g/ha (6 x 150 g a.s./ha), up to BBCH 39, outdoor E/RA: < 0.01, 0.02, 0.08, 0.16	E/RA: 0.05	E/RA: 0.16	0.34	-	-
	Overall	N-EU	E/RA: < 0.01, 8x < 0.02, 0.02, 0.03, 0.05, 0.08, 11x < 0.06, 0.06, 0.07, 9x < 0.1, < 0.12, 0.13, 0.16, 0.18, 0.45 ³	E/RA: 0.06	E/RA: 0.18 ⁴	0.231	0.3	Yes
		S-EU	E/RA: 6x < 0.02, 0.04, 0.06, 0.14	E/RA: 0.02	E/RA: 0.14	0.2	0.3	Yes

1) Worst case of 1 application at 1 kg a.s./ha also covers all split applications with a maximum total rate of 1 kg a.s./ha per season.

2) Source of EU MRL: Reg. (EU) No 2017/1016

3) Outlier according to Dixon's Q test (see below)

4) Excluding outlier

7.3.3.2 Conclusion on the magnitude of residues in plants

According the table above, the new dataset obtained from the new residue trials submitted in the framework of this application range from < 0.01 to 0.45 mg/kg in sugar beet leaves.

Ethofumesate is a well know active substance, for which several residue trials have been performed since its approval and leading to low residue levels. Such a highest residue level of 0.45 mg/kg seems not realistic and thus, a Dixon's Q test has been performed to check if such a residue level should be considered as an outlier or not.

The considered data set refers to the eight residue levels determined in sugar beet leaves (at two different application rates) in the four trials performed in 2020, as follows:

< 0.01, 0.02, 0.03, 0.05, 0.08, 0.13, 0.16, 0.45

The following formula is used to check if the value of 0.45 mg/kg is an outlier or not:

$Q = \text{gap} / \text{range}$

Where:

gap: absolute value of the hypothetic outlier minus its nearest value of the dataset

range: the highest value of the data set minus the lowest value of the dataset

This gives the following equation:

$Q = (|0.45 - 0.16|) / (0.45 - 0.01)$

$Q = 0.659$

According to Qtable, determining the limit values of the two-tailed Dixon's Q test, and considering a total of eight values in the dataset and a 99% confidence, the limit value is of 0.634

Since, $Q > Q_{\text{table}}$, we can conclude that the value of 0.45 mg/kg is an outlier when considering the study dataset.

In this context, this value is excluded and not considered in the unrounded MRL calculations. Due to the significant amount of residue trials performed over the years and relied on in this dossier, the required minimum data package of 8 residue trials is not affected.

According to the available data, the intended uses on beet crops (sugar beets, fodder beets, chards, yellow beets and red beets) are considered acceptable.

The uses are considered acceptable.

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 beetroots (0213040) and fodder beet.

According to the EFSA Journal 2016;14(1):4374 – „Peer review of the pesticide risk assessment of the active substance ethofumesate“: 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.

“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.”

In DRAR for Ethofumesate, Vol. 1 (RMS:Austria, 09.2015) it is stated that:

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.

However, considering the later application timing and also considering that some positive results from pre-emergence uses are originated from residue trials where residues were found in the control samples, the post emergence use (treatment around BBCH 14-18) with single application rate at approximately 1 kg a.s./ha was considered as the worst-case use regarding the magnitude of residues in mature sugar-, and fodder beet roots. In the northern European climatic zone 34 post-emergence trials and for the southern European region 11 post-emergence trials were used for MRL calculation. The residue values for the post-emergence use as well as the residue values considering all residue trials (pre- and post-emergence trials) are summarised in the following table. No significant differences could be observed between these two datasets and there was no difference in the input values for consumer risk assessment.

Table 2.7-1 Summary on data from the supervised residue trials northern and southern Europe

Crop	Region	Residue levels (mg/kg) observed in the supervised residue trials relevant to the supported GAPs	HR (mg/kg)	STMR (mg/kg)
Beetroots		extrapolation from sugar beets		
post-emergence use				
sugar beet leaves Chard/beet leaves	NEU	8x<0.02, 11x<0.06, 2x 0.06, 2x 0.07, 9x<0.1, <0.12, 0.18	0.18	0.06
	SEU	6x<0.02, 0.04, 0.06, 0.14	0.14	0.02
sugar beet roots	NEU	8x<0.02, 15x<0.06, 0.06, 0.09, 11x<0.1	0.1	0.06
	SEU	8x<0.02, 3x<0.06	0.06	0.02
pre- and post-emergence use				
sugar beet leaves Chard/beet leaves	NEU	8x<0.02, 19x<0.06, 5x 0.06, 2x 0.07, 2x 0.08, 0.09, 9x<0.1, <0.12, 0.18	0.18	0.06
	SEU	6x<0.02, 0.04, 3x <0.06, 0.06, 8x <0.1, 0.14	0.14	0.06
sugar beet roots	NEU	8x<0.02, 30x<0.06, 0.6, 0.07, 0.09, 11x<0.1	0.1	0.06
	SEU	8x<0.02, 6x<0.06, 8x<0.01	0.06	0.02

The results of all trials conducted in the southern European residue region demonstrate that:

- The data set is considered as sufficient to cover the intended use.
- Following one early application (either pre- or early post emergence), residue levels of “total ethofumesate” in sugar beets declined significantly with time and residue levels were at or below the limit of quantification in mature sugar beet roots and leaves at harvest.

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 intended GAP for ethofumesate for beet crops (sugar beet, red beet, yellow beet, fodder beet, chard) in Central Europe is 6x0.15 kg a.i./ha or 3x0.30 kg a.i./ha with interval between applications of 5-7 days at BBCH 10-39 with PHI as not applicable, the PHI is covered by the time remaining between application and harvest.

New studies on the magnitude of residue have been submitted by the Applicant in the framework of this application. The trials are supported by valid storage stability data for sugar beet and validated analytical methods.

A total of 4 supervised residue trials were performed in Northern Europe. The tested application rates and timings, corresponded to the intended GAPs for HBZ10.

Trials were performed with 3 plots, each: an untreated control, a plot treated with HBZ10 with 3 applications of 300 g/ha Ethofumesate and 300 g/ha Phenmedipham at an interval of 5-7 days up to BBCH 37-39, and another plot with 6 applications of 150 g/ha Ethofumesate and 150 g/ha Phenmedipham at an interval of 4-6 days up to BBCH 37-39.

For residues of Ethofumesate, the following components were analysed: parent Ethofumesate, metabolites NC 9607, and NC 20645 (free and conjugated).

Residues in roots:

GAP: 3 x 300 g a.s./ha, up to BBCH 39

E/RA: < 0.01, 2x 0.01, 0.02 mg/kg

GAP: 6 x 150 g a.s./ha, up to BBCH 39

E/RA: 4 x < 0.01mg/kg

Residues in tops:

GAP: 3 x 300 g a.s./ha, up to BBCH 39

E/RA: 0.03, 0.05, 0.13, 0.45 mg/kg

GAP: 6 x 150 g a.s./ha, up to BBCH 39
E/RA: < 0.01, 0.02, 0.08, 0.16 mg/kg

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

The proposed uses on roots of sugar beet, red beet, yellow beet, fodder beet are considered acceptable.

According to the SANTE/2019/12752, extrapolation from sugar beet tops to tops of red beet, yellow beet and chard is not possible.

Considering the above, in our opinion, the proposed uses of Wizard/Beetup Pro/Betasana Max (product code HBZ10) on beet leaves and chard are not acceptable.

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.

7.3.4 Magnitude of residues in livestock

7.3.4.1 Dietary burden calculation

The livestock dietary burden calculation was calculated for the intended use following the recommendations of the Joint Meeting on Pesticide Residues (JMPR) on livestock burden calculations (JMPR, 2004, 2007), and according to the OECD guidance document on residues in livestock published on July 10th, 2013 (ENV/JM/MONO(2013)8) using the EFSA animal model 2017.

A livestock dietary burden calculation according to current guidelines and using the EFSA model 2015 was already calculated during the EU Review for the renewal of approval of Ethofumesate. It considered the use in sugar and fodder beets, and thus also covers the critical GAP of HBZ10. EFSA concluded that while the trigger value of 0.004 mg/kg bw was exceeded (maximum intakes for ruminants and poultry: 0.02 mg/kg bw for lamb, 0.006 mg/kg bw for poultry layer, respectively), no feeding studies were required since metabolism studies in ruminants and poultry showed that no residues above 0.01 mg/kg are expected in animal tissues (EFSA, 2016). The use of HBZ10 on beet crops is hereby covered.

The input values for a livestock burden calculation using the EFSA model 2017 listed in **Tables 7.3.4.1-1** and **7.3.4.1-2** below, excluding or including the outlier found for beet leaves, respectively. Results are given in **Tables 7.3.4.1-3** and **7.3.4.1-4** below.

Table 7.3.4.1-1: Input values for the dietary burden calculation (excluding outlier)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value [mg/kg]	Comment	Input value [mg/kg]	Comment
Risk assessment residue definition: Sum of Ethofumesate, NC 9607 and NC 20645, expressed as Ethofumesate				
Beet, mangel fodder	0.06	See Table 7.3.3.1-1 above	0.18	See Table 7.3.3.1-1 above
Beet, sugar, tops	0.06	See Table 7.3.3.1-1 above	0.18	See Table 7.3.3.1-1 above
Sugar beet, dried pulp	0.35	Value estimated based on the residue in sugar beet root (dry matter (DM) = 15) and the DM of 88 for dried pulp (see EFSA, 2016)	-	-
Sugar beet, ensiled pulp	0.06	Value estimated based on the residue in sugar beet root (dry matter (DM) = 15) and the DM 15 for ensiled pulp (see EFSA, 2016)	-	-
Molasses	0.76	Median processing factor of 12.7 for molasses was applied (see EFSA, 2016)	-	-
Cereal, forage, hay	0.03	Rotational crops (see EFSA, 2016)	0.03	Rotational crops (see EFSA, 2016)
Root crops, root	0.04	Rotational crops (see EFSA, 2016)	0.05	Rotational crops (see EFSA, 2016)

Table 7.3.4.1-2: Input values for the dietary burden calculation (including outlier)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value [mg/kg]	Comment	Input value [mg/kg]	Comment
Risk assessment residue definition: Sum of Ethofumesate, NC 9607 and NC 20645, expressed as Ethofumesate				
Beet, mangel fodder	0.06	See Table 7.3.3.1-1 above	0.45	See Table 7.3.3.1-1 above
Beet, sugar, tops	0.06	See Table 7.3.3.1-1 above	0.45	See Table 7.3.3.1-1 above
Sugar beet, dried pulp	0.35	Value estimated based on the residue in sugar beet root (dry matter (DM) = 15) and the DM of 88 for dried pulp (see EFSA, 2016)	-	-
Sugar beet, ensiled pulp	0.06	Value estimated based on the residue in sugar beet root (dry matter (DM) = 15) and the DM 15 for ensiled pulp (see EFSA, 2016)	-	-
Molasses	0.76	Median processing factor of 12.7 for molasses was applied (see EFSA, 2016)	-	-
Cereal, forage, hay	0.03	Rotational crops (see EFSA, 2016)	0.03	Rotational crops (see EFSA, 2016)
Root crops, root	0.04	Rotational crops (see EFSA, 2016)	0.05	Rotational crops (see EFSA, 2016)

Table 7.3.4.1-3: Results of the dietary burden calculation (excluding outlier)

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, NC 9607 and NC 20645, expressed as Ethofumesate					
Beef cattle	0.009	0.016	Beet, mangel fodder	0.66	Yes
Dairy cattle	0.013	0.022	Beet, mangel fodder	0.56	Yes
Ram/ewe	0.011	0.016	Beet, sugar tops	0.47	Yes
Lamb	0.014	0.020	Beet, sugar tops	0.47	Yes
Breeding swine	0.007	0.011	Beet, mangel fodder	0.46	Yes
Finishing swine	0.007	0.016	Swede (roots)	0.28	Yes
Broiler poultry	0.003	0.004	Swede (roots)	0.05	No
Layer poultry	0.004	0.010	Beet, sugar (tops)	0.15	Yes
Turkey	0.003	0.004	Potato (culls)	0.05	No

Table 7.3.4.1-4: Results of the dietary burden calculation (including outlier)

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, NC 9607 and NC 20645, expressed as Ethofumesate					
Beef cattle	0.009	0.029	Beet, mangel fodder	1.20	Yes
Dairy cattle	0.013	0.039	Beet, mangel fodder	1.01	Yes
Ram/ewe	0.011	0.023	Beet, sugar tops	0.70	Yes
Lamb	0.014	0.030	Beet, sugar tops	0.73	Yes
Breeding swine	0.007	0.017	Beet, mangel fodder	0.28	Yes
Finishing swine	0.007	0.008	Swede (roots)	0.28	Yes
Broiler poultry	0.003	0.004	Swede (roots)	0.05	No
Layer poultry	0.004	0.010	Beet, sugar (tops)	0.15	Yes
Turkey	0.003	0.004	Potato (culls)	0.05	No

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 except Broiler poultry and Turkey. Further investigation of residues is therefore required (see point 7.3.4.2).

7.3.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Livestock dietary intake calculations for the intended worst case uses showed an exceedance of the trigger value of 0.004 mg/kg bw/day for ruminants, pigs, and laying poultry. Thus, further considerations are required.

Available data

The metabolism studies in poultry evaluated in the DAR (Sweden, 1998) and RAR (Austria, 2015) were performed with dose rates of 0.6 and 0.78 mg/kg bw/day. Highest residue levels according to the residue definition in poultry ranged between 0.007 mg/kg in muscle and maximum 0.362 mg/kg in the gastro-intestinal tract at a dosing rate of approximately 0.8 mg/kg bw/day. Considering the low dietary intake of poultry (max. 0.01 mg/kg bw/day), no residues > 0.01 mg/kg are expected. Therefore, feeding studies in poultry are not required.

According to the metabolism studies in lactating cows evaluated in the DAR (Sweden, 1998) and RAR (Austria, 2015), highest residues according to the residue definition were found in kidney: TRR of 1.86 mg/kg at a dosing rate of 5 mg/kg bw/day, corresponding to 1.699 mg/kg for the sum of Ethofumesate, NC 9607 and NC 20645 (see **Table 7.3.4.2-1**).

Table 7.3.4.2-1: Residue levels of Ethofumesate, NC 9607 and NC 20645 in cows dosed with 5 mg/kg bw/day (i.e. 274 mg/kg feed, data from the metabolism study in ruminants see RAR, Volume 3, B7, Tables 7.2.2-22 to 7.2.2-28)

	TRR [mg/kg]	Ethofumesate [mg/kg]	NC 9607 [mg/kg]	NC 20645 [mg/kg]	Sum of Ethofumesate, NC 9607 and NC 20645 [mg/kg]
Milk (max)	0.134	0.074	0.012	0.019	0.105
Subcutaneous fat	0.548	0.477	0.013	0.012	0.502
Omental fat	0.539	0.456	-	0.020	0.476
Renal fat	0.528	0.043 + 0.428	0.008	0.006	0.485
Kidney	1.863	0.040 + 0.003	0.158 + 0.012	1.427 + 0.059	1.699
Psoas muscle	0.033	0.015	0.005	0.002	0.022
Liver	0.661	0.006 + 0.251	0.017 + 0.054	0.024 + 0.046	0.398

Considering the maximum dietary intake calculated for ruminants (0.039 mg/kg bw/day or 0.022 mg/kg bw/day, respectively, for dairy cattle, when including or excluding the outlier), residues well below the LOQ of 0.03 mg/kg (current MRL) would be expected for the sum of Ethofumesate, NC 9607, and NC 20645 in all animal commodities.

Nevertheless, a feeding study in lactating cows was submitted and evaluated in the scope of the original EU Review of Ethofumesate. It was conducted in the USA and did not completely follow the EU guidelines; however, the study confirmed the low transfer of the Ethofumesate related residues in edible matrices.

Groups of 2 or 3 lactating Friesian dairy cows were fed for 28 days on a diet containing Ethofumesate. The cows received 0, 1.0, 3.0 or 10.0 g of technical grade Ethofumesate per day. This is approximately equivalent to 0, 65, 195, and 650 ppm in the diet, when assuming a feed intake of 15 kg/day. Milk was sampled twice daily. Samples of kidney, liver, muscle, and fat were taken at slaughter. All samples were analysed by GC-FPD for Ethofumesate and its metabolite NC 9607 (Sweden, 1998). The LOQ varied between 0.02 mg/kg for NC 9607 in milk and 0.1 mg/kg for Ethofumesate and NC 9607 in fat.

In the low dose group, residues in muscle, fat, and milk were < LOQ, while residues in liver were < 0.15 mg/kg and residues in kidney were highest with 1.25 mg/kg for the sum of Ethofumesate and its metabolite NC 9607. Comparing the tested dose rate of 65 mg/kg feed with the expected maximum intakes of 1.2 mg/kg feed in ruminants and 0.73 mg/kg feed in pigs, it is not expected that residues > LOQ could occur in animal commodities.

Conclusion on feeding studies

The requested uses (or the new mode of calculation) modify the theoretical maximum daily intake for animals, but regarding available feeding data, there is no risk for animal MRL to be exceeded.

zRMS comments:

Data presented by Applicant in point 7.3.4.2 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 HBZ10 is applied according to the intended GAPs. The intended uses of ethofumesate in the product Wizard/Beetup Pro/Betasana Max (product code HBZ10) do not lead to an exceedance of the existing EU MRLs for animal commodities.

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

Processing studies were already evaluated during Annex I inclusion of Ethofumesate.

Residue levels in sugar and fodder beets were all < 0.1 mg/kg (see Point 7.3.3 above) and the contribution of these commodities to the theoretical maximum daily intake (TMDI) is < 10% of the ADI. Therefore, no processing studies are required for these crops.

7.3.5.1 Available data for all crops under consideration

Processing studies were already evaluated during Annex I inclusion and are considered acceptable (EFSA, 2016). They are summarised in **Table 7.3.5.1-1** below.

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

Table 7.3.5.1-1 Overview of the available processing studies (EFSA, 2016)

Processed commodity	Number of studies	Median PF *	Median CF **	Comments	Reference
EU data					
Sugarbeet / Sugar	4	0.2	-	-	Sweden, 1998
Sugarbeet / Molasses	4	12.7	-	-	Sweden, 1998
Sugarbeet / Wet pulp	3	0.2	-	-	Sweden, 1998
Sugarbeet / Thick juice	5	4.7	-	-	Sweden, 1998
Sugarbeet / Thin (raw) juice	5	1.1	-	-	Sweden, 1998

* 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

Robust processing factors were derived during the EU review and were considered acceptable. The trigger for requiring new studies is not met by the intended uses. No further studies are deemed necessary.

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 Wizard/Beetup Pro/Betasana Max (product code HBZ10).

7.3.6 Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation.

From the already evaluated confined rotational crop studies (see Point 7.3.2.2), it was concluded that the metabolic patterns in primary and succeeding crops are similar, but residues in succeeding crops could not be excluded.

Data dealing with the magnitude of residues in succeeding crops are available and are summarized hereafter.

7.3.6.1 Field rotational crop studies (KCA 6.6.2)

Available data

Rotational crop studies were already evaluated in the original EU Review of Ethofumesate and were considered acceptable. Since the application rates used in these studies were too high, additional studies were conducted for the renewal process of Ethofumesate. They are summarised in **Table 7.3.6.1-1** below.

Table 7.3.6.1-1 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)	Reference/Remarks	
EU data						
Sugar beet	6.0 (pre-emergence)	Cereal	Wheat	Not stated	Sweden, 1998	
Sugar beet	2.17 (pre-emergence) 1.29 (PHI 90 – 113 d)	Small grain	Not stated	6 and 12 months	Sweden, 1998	
		Leafy vegetables	Spinach			
		Root and tuber vegetables	Carrots, red beets			
	4.29 (pre-emergence) 1.29 (PHI 90 – 113 d)	Small grain	Not stated	12 months	Sweden, 1998	
		Leafy vegetables	Spinach			
		Root and tuber vegetables	Carrots / red beets			
Bare soil	1.5	Leafy vegetables	Spinach	30 and 70 days	Sweden, 1998	
		Cereals	Maize	30 days		
		Root and tuber vegetables	Carrots	70 days		
Bare soil	1.5	Leafy vegetables	Spinach	30 days	Sweden, 1998	
		Cereals	Maize	30 days		
Bare soil	1.0	Root and tuber vegetables	Carrot	25-33 days	Austria, 2015	
		Leafy vegetables	Lettuce	25-33 days		
		Cereals	Barley / wheat	25-33 days		
Sugar beet	1.0 (BBCH 16 or 18)	Root and tuber vegetables	Carrot	54-259 days 284-354 days		
		Leafy vegetables	Lettuce	54-259 days 284-354 days		
		Cereals	Barley/ wheat	54-259 days 284-354 days		
Sugar beet	0.96 – 1.13 (BBCH 14 – 16)	Root and tuber vegetables	Radish / carrot	30-40, 90-103 and 335 days	Austria, 2015	
		Leafy vegetables	Spinach	30-41, 90-103 and 335 days		
		Cereals	Winter barley / wheat	30-31, 176-180 and 335 days		
Bare soil	0.96 – 1.13 (pre-emergence)	Cereals	Spring barley	30-31 days		

No significant residue levels 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 GAP evaluated during the Annex I inclusion or the renewal procedure of Ethofumesate.

In the studies evaluated by Austria (2015), residues of Ethofumesate were only detected in the first rotation. Highest total residues accounted for 0.05 mg/kg in root crops, 0.03 mg/kg in leafy crops and 0.03 mg/kg in cereal forage. The only residue detected above the LOQ of 0.01 mg/kg was Ethofumesate; the residues of the common moiety NC 9607 (analysed after an acidic hydrolysis step in order to quantify the sum of NC 9607, NC 20645 and its conjugate) were always below the LOQ of 0.01 mg/kg. Older studies submitted for the original EU review of Ethofumesate (Sweden, 1998), were done with exaggerated application rates. Still, residue levels of Ethofumesate and its metabolites were low. In case the older studies included an acidic hydrolysis step and analysis was done by GC-MS, the results for NC 9607 will also have included the free and conjugated NC 20645.

Conclusion on rotational crops studies

Only very low residues of Ethofumesate were observed in rotational crops. The almost negligible highest residue levels obtained in the rotational roots and cereals crops were used to estimate the burden calculation to livestock feed. Adequate MRLs are in force to cover residues that might occur in rotational crops.

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 be 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 beet roots, beetroots 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.

7.3.7 Other / special studies (KCA 6.10, 6.10.1)

In accordance with Appendix II to the Technical guidelines for determining the magnitude of pesticide residues in honey (SANTE/11956/2016 rev 9), sugar beet, fodder beet, chard, yellow beet and red beet are not melliferous crops.

Beets for consumption are harvested by the end of the first year, while flowering of these crops occurs in the second year. Also, beets for seed production are not attractive to honeybees since beet flowers are wind pollinated. Regarding guttation droplets as source of water, the beet structure does not allow formation of water reservoirs in leaf axils and therefore the risk of taking up residues with guttation water is low.

Therefore, bees are not exposed to the active substance and information on residue data in honey is not required.

zRMS comments:

Information given by the Applicant is sufficient. A statement was provided by the applicant UPL within RAR for Ethofumesate, Vol 1, 2015, which outlines the situation for honeybees in detail:

„The risk for honeybees to get in contact with contaminated nectar and pollen is negligible as sugar and fodder beets do not build flowers within the first year. Sugar and fodder beets are harvested by the end of the first year. In the rare case that shoots with flowers are produced in the first year or beets are flowering in the second year (if beets are grown for seed production) no risk for honeybees is expected as beet flowers are wind pollinated. Sugar and fodder beet flowers are not mentioned in any standard or handbook on honey bee foraging plants.“

The non-relevance of residues in pollen and bee products was mainly justified with the overall low residue levels in sugar beet, fodder beet, chard, yellow beet and red beet and rotational crops. Regarding uses on sugar beet, fodder beet, chard, yellow beet and red beet, no additional data are needed in the frame of this registration.

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 point 9 7.1.2). The calculation of the TMDI was performed using the EFSA PRIMo Model 3.1 taking into account all commodities for which EU-MRLs for Ethofumesate have been set as input parameters, and are detailed in the table below:

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

7.3.8.1 Input values for the consumer risk assessment

Table 7.3.8.1-1: Input values for the consumer risk assessment (taken from Regulation 2017/1016)

Commodity	Chronic risk assessment	
	Input value [mg/kg]	Comment
Sum of ethofumesate, 2-keto-ethofumesate, open-ring-2-keto-ethofumesate and its conjugate, expressed as ethofumesate		
1. FRUIT FRESH OR FROZEN; NUTS	0.03*	EU-MRL
2. VEGETABLES FRESH OR FROZEN		
(i) Root and tuber vegetables		
(a) potatoes	0.03*	EU-MRL
(b) tropical root and tuber vegetables	0.03*	EU-MRL
(c) other root and tuber vegetables except sugar beets		
Beetroots	0.2	EU-MRL
Carrots	0.03*	EU-MRL
Celeriacs/turnip rooted celeries	0.03*	EU-MRL
Horseradishes	0.03*	EU-MRL
Jerusalem artichokes	0.03*	EU-MRL
Parsnips	0.03*	EU-MRL
Parsley roots/Hamburg roots parsley	0.03*	EU-MRL
Radishes	0.03*	EU-MRL
Salsifies	0.03*	EU-MRL
Swedes/rutabagas	0.03*	EU-MRL
Turnips	0.03*	EU-MRL
Others	0.03*	EU-MRL
(ii) Bulb vegetables	0.03*	EU-MRL
(iii) Fruiting vegetables	0.03*	EU-MRL

Commodity	Chronic risk assessment	
	Input value [mg/kg]	Comment
Sum of ethofumesate, 2-keto-ethofumesate, open-ring-2-keto-ethofumesate and its conjugate, expressed as ethofumesate		
(iv) Brassica vegetables	0.03*	EU-MRL
(v) Leaf vegetables & fresh herbs		
(a) Lettuce and salad plants	0.03*	EU-MRL
(b) Spinach & similar (leaves)		
Spinach (New Zealand spinach, turnip greens (turnip tops))	0.1	EU-MRL
Purslane	0.03*	EU-MRL
Chards/beet leaves	0.3	EU-MRL
Others	0.03*	EU-MRL
(c) grape leaves and similar species	0.03*	EU-MRL
(d) watercresses	0.03*	EU-MRL
(e) witloofs/Belgian endives	0.03*	EU-MRL
(f) herbs and edible flowers		
Chervil	0.05*	EU-MRL
Chives	0.05*	EU-MRL
Celery leaves	0.05*	EU-MRL
Parsley	1.5	EU-MRL
Sage	1.5	EU-MRL
Rosemary	1.5	EU-MRL
Thyme	1.5	EU-MRL
Basil and edible flowers	1.0	EU-MRL
Laurel/bay leave	0.05*	EU-MRL
Tarragon	0.05*	EU-MRL
Others	0.05*	EU-MRL
(vi) Legume vegetables (fresh)		
Beans (fresh, with pods)	0.1*	EU-MRL
Beans (without pods)	0.03*	EU-MRL
Peas (fresh, with pods)	0.1*	EU-MRL
Peas (without pods)	0.03*	EU-MRL
Lentils	0.03*	EU-MRL
Others	0.03*	EU-MRL
(vii) Stem vegetables (fresh)	0.03*	EU-MRL
(viii) Fungi	0.03*	EU-MRL
(ix) Algae and prokaryotes organisms	0.03*	EU-MRL
3. PULSES, DRY		
Beans	0.03*	EU-MRL
Lentils	0.03*	EU-MRL
Peas	0.1*	EU-MRL
Lupins	0.03*	EU-MRL
Others	0.03*	EU-MRL
4. OILSEEDS AND OILFRUITS	0.03*	EU-MRL
5. CEREALS	0.03*	EU-MRL
6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA		

Commodity	Chronic risk assessment	
	Input value [mg/kg]	Comment
Sum of ethofumesate, 2-keto-ethofumesate, open-ring-2-keto-ethofumesate and its conjugate, expressed as ethofumesate		
(i) Tea	0.1 *	EU-MRL
(ii) Coffee beans	0.1 *	EU-MRL
(iii) Herbal infusions		
a) Flowers	15	EU-MRL
b) Leaves	15	EU-MRL
c) Roots	0.1 *	EU-MRL
(d) any other parts of the plant	0.1 *	EU-MRL
(iv) Cocoa beans	0.1 *	EU-MRL
(v) Carobs/Saint John's breads	0.1 *	EU-MRL
7. HOPS (dried), including hop pellets and unconcentrated powder	0.1 *	EU-MRL
8. SPICES		
(i) Seeds	0.6	EU-MRL
(ii) Fruits and berries	0.1 *	EU-MRL
(iii) Bark	0.1 *	EU-MRL
(iv) Roots or rhizome	0.1 *	EU-MRL
(v) Buds	0.1 *	EU-MRL
(vi) Flower stigma	0.1 *	EU-MRL
(vii) Aril	0.1 *	EU-MRL
9. SUGAR PLANTS		
Sugar beet roots	0.2	EU-MRL
Sugar canes	0.03*	EU-MRL
Chicory roots	0.1 *	EU-MRL
Others	0.03*	EU-MRL
10. PRODUCTS OF ANIMAL ORIGIN-TERRESTRIAL ANIMALS	0.03*	EU-MRL

7.3.8.2 Conclusion on consumer risk assessment

A chronic consumer risk assessment was performed using all currently set EU MRLs. The risk assessment was calculated using EFSA PRIMo 3.1. The highest chronic exposure for Ethofumesate was calculated for NL toddler, representing 0.5% of the ADI.

The proposed uses of Ethofumesate in the formulation HBZ10, therefore, do not represent unacceptable risks for the consumer. Extensive calculation sheets are presented in Appendix 3.

Table 7.3.8.2-1: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo	0.5% (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo	Not performed, since TMDI was well below ADI
IESTI (% ARfD) according to EFSA PRIMo*	Not applicable
NTMDI (% ADI) **	Not relevant
NEDI (% ADI)**	Not relevant
NESTI (% ARfD) **	Not applicable

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

** If national model is available

zRMS comments:

The consumer risk assessments were performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo rev.3.1). 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.

7.4 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 none of them an acute reference dose has been allocated. Therefore, the calculation of a combined exposure is not required.

7.4.2 Chronic consumer risk assessment from combined exposure

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

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

Austria (2015). Draft Renewal Assessment Report prepared according to the Commission Regulation (EC) No 1107/2009: Ethofumesate.

EFSA, 2014. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for phenmedipham according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2014;12(8):3807, 38 pp. doi:10.2903/j.efsa.2014.3807

EFSA, 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

EFSA, 2018. Conclusion on the peer review of the pesticide risk assessment of the active substance phenmedipham. EFSA Journal 2018;16(1):5151, 25 pp. <https://doi.org/10.2903/j.efsa.2018.5151>ISSN: 1831-4732

FAO (Food and Agriculture Organization of the United Nations), 2009. Submission and evaluation of pesticide residues data for the estimation of Maximum Residue Levels in food and feed. Pesticide Residues. 2nd Ed. FAO Plant Production and Protection Paper 197, 264 pp.

Finland (1999). EU Review Programme for Existing Active Substances (Article 8.2 of Council Directive 91/414/EEC): Phenmedipham.

Sweden (1998). EU Review programme on active substances in Plant Protection Products: Ethofumesate.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.3/01	Schneider, E.	2021	DETERMINATION OF ETHOFUMESATE AND PHENMEDIPHAM RESIDUES IN SUGAR BEETS FOLLOWING FOLIAR APPLICATION WITH HBZ10 (ETHOFUMESATE/PHENMEDIPHAM 125/125 G/L EC) UNDER FIELD CONDITIONS IN NORTHERN EUROPE IN 2020 Report No. R C0252 Anadiag S.A., Haguenau, France GLP Unpublished	N	UPL

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

Peer reviewed data on Phenmedipham (cited only)

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
CA 6.1	Scheuermann, H.-J.	1988	STABILITY OF TOTAL RESIDUES OF PHENMEDIPHAM IN BEET ROOTS AND LEAVES DURING DEEP FREEZE STORAGE Report No. R148, A.62014 Hoechst Schering AgrEvo GmbH, Berlin non GLP/GEP Unpublished	N	TFP
CA 6.2.1	Boerner, H.	1969	DECOMPOSITION AND TRANSLOCATION OF PHENMEDIPHAM IN BEETS Report No. M4 not available non GLP/GEP Unpublished	N	TFP
CA 6.2.1	Johnson, B.G.	1969	DISTRIBUTION OF PHENMEDIPHAM FOLLOWING FOLIAR APPLICATIONS TO SUGAR BEETS (BETA VULGARIS L.) ADDENDUM: METABOLISM OF PHENMEDIPHAM FOLLOWING FOLIAR APPLICATIONS TO SUGAR BEETS (BETA VULGARIS L.) Report No. M5, A61823 Industrial Bio-test Laboratories, Inc. non GLP/GEP Unpublished	N	TFP

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
CA 6.2.1	Bruehl, R., Celorio, J.	1981	ESTIMATION OF METHYL-N-(3-HYDROXYPHENYL) CARBAMATE RESIDUES IN SUGAR BEETS Report No. M15, A61835 Schering AG, Berlin, Germany non GLP/GEP Unpublished	N	TFP
CA 6.2.1	Celorio, J.-I.	1983	METABOLISMUS VON PHENMEDIPHAM IN DER ZUCKERRÜBE (BETA VULGARIS L.) Report No. M16, A61836 Schering AG, Berlin, Germany non GLP/GEP Unpublished	N	TFP
CA 6.2.1	Celorio, J.I., Hoyer, G.A., Iwan, J., Baltes, W.	1984	METABOLISM OF PHENMEDIPHAM IN SUGAR BEET (BETA VULGARIS L.) Report No. M17 Lebensmittelchem. Gerichtl. Chem., 38, 73 non GLP/GEP Published	N	-
CA 6.2.1	Celorio, J.I., Hoyer, G.A., Iwan, J., Koelsch, L.	1987	METABOLISM OF PHENMEDIPHAM IN SUGAR BEET (BETA VULGARIS L.) Report No. M22 Pesticide Science and Biotechnology, 1987, 495-498 non GLP/GEP Published	N	-
CA 6.2.2	██████	1991	THE DISPOSITION OF [14C]-PHENMEDIPHAM FOLLOWING REPEATED ORAL ADMINISTRATION TO LAYING HENS ██████ GLP Unpublished	⚡Y	TFP
CA 6.2.3	██████	1989	INDICATION OF THE METABOLITES OF PHENMEDIPHAM IN THE MILK AND MEAT OF A COW FOLLOWING ORAL DOSING FOR 3 DAYS ██████ GLP Unpublished	⚡Y	TFP
CA 6.6.1	Downey, S.S.	1993	UPTAKE OF [14C]-PHENMEDIPHAM RESIDUES IN SOIL BY ROTATIONAL CROPS UNDER CONFINED CONDITIONS Report No. W267 NOR-AM Chemical Company; USA GLP Unpublished	N	TFP

TFP: Taskforce Phenmedipham

Peer reviewed data on Ethofumesate (cited only)

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
CA 6.1	Whiteoak, R.J.	1975	STABILITY OF RESIDUES DURING STORAGE OF CROP AND SOIL SAMPLES FROM TRIALS WITH NORTON Report No. NC 8438/ R52=W40 not stated non GLP/GEP Unpublished	N	BCS
CA 6.1	Cole, M.G.	1995	ETHOFUMESATE: STABILITY OF ETHOFUMESATE, NC 9607 AND NC 8493 IN GRASS DURING FROZEN STORAGE, USA, 1993 Report No. A54281 not available GLP Unpublished	N	BCS
CA 6.1	Bright, J.H.M.	1991	STABILITY OF ETHOFUMESATE AND NC 9607 RESIDUES IN SUGAR BEET ROOTS AND TOPS DURING DEEP FREEZE STORAGE Report No. NC 8438 / R171 not stated GLP Unpublished	N	BCS
CA 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 Report No. 12A04042-01-SSSB CIP Chemisches Institut Pforzheim GmbH GLP Unpublished	N	UPL
CA 6.1	Schlewitz, P.	2014	FROZEN STORAGE STABILITY OF RESIDUES OF ETHOFUMESATE METABOLITE NC 20645 IN SUGAR BEET (ROOTS AND TOPS WITH LEAVES) Report No. B1312 Anadiag S.A., Haguenau, France GLP Unpublished	N	UPL
CA 6.2	Miller, C.A.	1999	SUMMARY OF THE METABOLISM OF ETHOFUMESATE IN PLANTS Report No. C003349 AgrEvo UK Ltd. non GLP/GEP Unpublished	N	BCS
CA 6.2.1	Adcock, J.W., Warner, P.A., Challis, I.R.	1976	THE METABOLISM OF 14C-ETHOFUMESATE IN THE ONION Report No.META/76/22 AgrEvo	N	BCS

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
			non GLP/GEP Unpublished		
CA 6.2.1	Adcock, J.W., Lines, D.	1978	THE METABOLISM OF ETHOFUMESATE BY SUGAR BEET UNDER GLASSHOUSE CONDITIONS Report No. META/78/57 AgrEvo non GLP/GEP Unpublished	N	BCS
CA 6.2.1	Warner, P.A., Adcock, J.W.	1977	THE METABOLISM OF 14C-ETHOFUMESATE IN TOBACCO Report No. META/77/38 AgrEvo UK Ltd. non GLP/GEP Unpublished	N	BCS
CA 6.2.1	Lines, D., Adcock, J.W.	1979	THE METABOLISM OF ETHOFUMESATE (98% PURE 14C-ETHOFUMESATE) BY SUGAR BEET UNDER FIELD CONDITIONS Report No. NC 8438/M43 AgrEvo non GLP/GEP Unpublished	N	BCS
CA 6.2.1	Chapleo, S.	1992a	THE METABOLISM OF 14C-ETHOFUMESATE IN SUGAR BEET - A GLASSHOUSE STUDY Report No. IRI 381174 AgrEvo GLP Unpublished	N	BCS
CA 6.2.1	Caley, C.Y., Chapleo, S., Haswell, A.	1994	THE METABOLISM OF 14C-ETHOFUMESATE IN SUGAR BEET Report No. 10056 AgrEvo GLP Unpublished	N	BCS
CA 6.2.1	Chapleo, S.	1992b	THE METABOLISM OF 14C-ETHOFUMESATE IN ANNUAL RYEGRASS - A GLASSHOUSE STUDY Report No. IRI 381169 AgrEvo GLP Unpublished	N	BCS
CA 6.2.1	Mellet, M.	1993	DETERMINATION OF THE RESIDUE OF ETHOFUMESATE, ETHOFUMESATE-2-KETO AND THE CONJUGATES IN SUGAR BEETS AFTER APPLICATION OF ETHOSAT 500 SC IN FRANCE, 1992 Report No. RF 2102-1 not stated GLP Unpublished	N	FCS

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
CA 6.2.1	Hennecke, D.	2003	METABOLISM OF ETHOFUMESATE IN SUGAR BEETS Report No. GAB-002/7-08 Fraunhofer Institute for Molecular Biology and Applied Ecology (IME), Schmallenberg, Germany GLP Unpublished	N	UPL
CA 6.2.2	[REDACTED]	1992	THE METABOLISM OF 14C-ETHOFUMESATE IN LAYING HENS [REDACTED] GLP Unpublished	N Y	BCS
CA 6.2.2	[REDACTED]	1999	POULTRY METABOLISM, DISTRIBUTION AND NATURE OF THE RESIDUES IN EGGS AND EDIBLE TISSUES. CODE AE B 049913 [REDACTED] GLP Unpublished	N Y	BCS
CA 6.2.3	[REDACTED]	1976	THE METABOLISM OF 14C-ETHOFUMESATE IN THE SHEEP [REDACTED] non GLP/GEP Unpublished	N Y	BCS
CA 6.2.3	[REDACTED]	1992	THE METABOLISM OF 14C-ETHOFUMESATE IN THE COW [REDACTED] GLP Unpublished	N Y	BCS
CA 6.2.3	[REDACTED]	1999	ETHOFUMESATE RUMIANT: METABOLISM, DISTRIBUTION AND NATURE OF THE RESIDUES IN MILK AND EDIBLE TISSUES. CODE AE B 049913 [REDACTED] GLP Unpublished	N Y	BCS
CA 6.3	Tandy, R.	2012	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 Report No. S11-03715 Eurofins Agrosience Services GmbH 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
CA 6.3	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 Report No. R A0015 Anadiag S.A., Haguenau, France GLP Unpublished	N	UPL
CA 6.3	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 Report No. R A1114 Anadiag S.A., Haguenau, France GLP Unpublished	N	UPL
CA 6.3	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 NETHERLANDS, BELGIUM) - 2012 Report No. BPL12/436/GC BIOTEK Agriculture GLP Unpublished	N	UPL
CA 6.3	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 Report No. BPL11/380/GC BIOTEK Agriculture GLP Unpublished	N	UPL
CA 6.3	Waalkens, W.M., Hamberger, R.	2005a	DETERMINATION OF THE DECLINE OF THE RESIDES 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 Report No. R03-16-NF-08 Res.Comp. for Plant Protec. "De Bredelaar" B.V., Elst, NL 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
CA 6.3	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 / PHENMEDIPAHM / DESMEDIPHAM 128/62/21 G/L EC TO SUGAR BEETS IN THE NETHERLANDS AND NORTHERN FRANCE, 2003 Report No. R03-16-NF-09 Res.Comp. for Plant Protec. "De Bredelaar" B.V., Elst, NL GLP Unpublished	N	UPL
CA 6.3	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 Report No. R04-16-NF-08 Res.Comp. for Plant Protec. "De Bredelaar" B.V., Elst, NL GLP Unpublished	N	UPL
CA 6.3	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 Report No. R04-16-NF-09 Res.Comp. for Plant Protec. "De Bredelaar" B.V., Elst, NL GLP Unpublished	N	UPL
CA 6.3	Anspach T.	2001	MAGNITUDE OF THE RESIDUES OF PHENMEDIPHAM, DESMEDIPHAM, ETHOFUMESATE AND ITS METABOLITE 2-OXO-ETHOFUMESATE IN SUGAR BEETS (ROOTS AND LEAVES/TOPS) AFTER THE APPLICATION OF BETASANA TRIO UNDER FIELD CONDITIONS IN GERMANY, 2000 Report No. AND-0004 Dr. Specht Partner, Chemische Laboratorien GmbH, Germany GLP Unpublished	N	UPL
CA 6.3	Tandy, R.	2013	DETERMINATION OF RESIDUES OF ETHOFUMESATE AND ETHOFUMESATE-2-KETO, AFTER ONE OR THREE APPLICATIONS OF ETHOFOL 500SC, OR THREE APPLICATIONS OF BETASANA TRIO SC IN SUGAR BEET (OUTDOOR) AT 5 SITES IN NORTHERN EUROPE AND 5 SITES IN SOUTHERN EUROPE 2010 Report No. S10-00258	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
			Eurofins Agroscience Services LTD, UK GLP Unpublished		
CA 6.3	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 Report No. R03-16-SP-06 Res.Comp. for Plant Protec. "De Bredelaar" B.V., Elst, NL GLP Unpublished	N	UPL
CA 6.3	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 Report No. R03-16-FR-07 Res.Comp. for Plant Protec. "De Bredelaar" B.V., Elst, NL GLP Unpublished	N	UPL
CA 6.3	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 Report No. BPL12/435/GC BIOTEK Agriculture GLP Unpublished	N	UPL
CA 6.3	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 Report No. S13-03837 Eurofins Agroscience Services LTD, UK GLP Unpublished	N	UPL
CA 6.4.1	Harris, R.J.	1975	INVESTIGATION OF TISSUE AND EGG RESIDUES FROM HENS FOLLOWING DIETARY INTAKE OF NC 8438 FOR 21 DAYS Report No. NC 8438/ R57	N	BCS

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, UK non GLP/GEP Unpublished		
CA 6.4.2	Roberts, N.L., Ross, D.B.	1977	RESIDUES IN MILK AND TISSUES FOLLOWING A 28 DAY FEEDING STUDY WITH ETHOFUMESATE IN DAIRY COWS. PART I; FEEDING STUDY AND PREPARATION OF SAMPLES Report No. RESID/77/R28 NC 8438/R29 Huntingdon Research Centre, Huntingdon, UK non GLP/GEP Unpublished	N	BCS
CA 6.4.2	Harris, R.J., Whiteoak, R.J.	1977	RESIDUES IN MILK AND TISSUES FOLLOWING A 28 DAY FEEDING STUDY WITH EHTOFUMESATE IN DAIRY COWS. PART II ANALYSIS FOR ETHOFUMESATE AND ITS METABOLITES Report No. RESID/77/28 NC 8438/R 78 Fisons plc, UK non GLP/GEP Unpublished	N	BCS
CA 6.4.2	Castro, L.E.	1994a	ETHOFUMESATE-DERIVED RESIDUES IN THE MEAT AND MILK OF DAIRY COWS; RESULTING FROM ORAL INGESTION OF ETHOFUMESATE Report No. B002201 AgrEvo non GLP/GEP Unpublished	N	BCS
CA 6.5.3	Crofts, M., Whiteoak, R.J.	1973a	CONJUGATED RESIDUES IN FRACTIONS PROCESSED FROM SUGAR BEET TREATED WITH NORTRON Report No. NC 8438/R 5 Fisons plc, UK non GLP/GEP Unpublished	N	BCS
CA 6.5.3	Crofts, M., Whiteoak, R.J.	1974a	FATE OF THE METABOLITE CONJUGATED NC 9607 DURING PRODUCTION OF SUGAR FROM NORTRON-TREATED SUGARBEET Report No. NC 8438/R 19 Fisons plc, UK non GLP/GEP Unpublished	N	BCS
CA 6.5.3	Crofts M., Whiteoak R.J.	1975a	FATE OF THE METABOLITE CONJUGATED NC 9607 DURING PRODUCTION OF SUGAR FROM NORTRON- TREATED SUGARBEET - ARTIFICIALLY HIGH RESIDUES IN BEET GROWN AND PROCESSED IN THE UNITED KINGDOM Report No. NC 8438 / R40 Fisons plc, UK non GLP/GEP Unpublished	N	BCS

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
CA 6.5.3	Crofts M., Whiteoak R.J.	1975b	FATE OF THE METABOLITE CONJUGATED NC 9607 DURING PRODUCTION OF SUGAR FROM NORTON- TREATED SUGARBEET - ARTIFICIALLY HIGH RESIDUES IN BEET GROWN AND PROCESSED IN WEST GERMANY Report No. NC 8438 / R41 Fisons plc, UK non GLP/GEP Unpublished	N	BCS
CA 6.6.1	Chapleo, S.	2003	THE UPTAKE OF [14C]-ETHOFUMESATE RESIDUES IN SOIL BY ROTATIONAL CROPS UNDER CONFINED CONDITIONS Report No. 22558 Inveresk Research International, Tranent, Scotland GLP Unpublished	N	UPL
CA 6.6.1	Carlton, R., Cordell, P.	1993	THE UPTAKE AND METABOLISM OF ETHOFUMESATE AND ITS SOIL METABOLITES IN A CONFINED ROTATIONAL CROP STUDY Report No. A83396/W153-1 AgrEvo UK Ltd. GLP Unpublished	N	BCS
CA 6.6.2	Spence, Ch.	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) Report No. 34890 Charles River Laboratories , Edinburgh, UK GLP Unpublished	N	UPL
CA 6.6.2	Castro, L.E.	1994b	ETHOFUMESATE EMULSIFIABLE CONCENTRATE 200G/L CR13678: AT HARVEST RESIDUES OF ETHOFUMESATE AND METABOLITES IN ROTATIONAL CROPS AND SOIL FOLLOWING APPLICATIONS OF NORTON EC TO SUGAR BEETS, USA,1990 Report No. A83117/R178-1 NOR-AM Chemical Company; USA GLP Unpublished	N	BCS
CA 6.6.2	Crofts, M., Whiteoak, R.J.	1974b	RESIDUE ANALYSIS OF WHEAT GROWN IN THE UK AS A FOLLOWING CROPS AFTER SUGAR BEET TREATED WITH NORTON Report No. NC 8438/R30 Fisons plc, UK non GLP/GEP Unpublished	N	BCS

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
CA 6.6.2	Crofts, M., Whiteoak, R.J.	1973b	RESIDUE ANALYSIS OF WHEAT AND CORN (MAIZE) GROWN AS FOLLOWING CROPS AFTER SUGAR BEET TREATED WITH NORTON Report No. NC 8438/R29 Fisons plc, UK non GLP/GEP Unpublished	N	BCS
CA 6.6.2	Peatman, M.H., Snowdon, P.J.	1991	RESIDUES OF SOIL AND EMERGENCY CROPS FOLLOWING APPLICATIONS OF ETHOFUMESATE AS A 50 SC FORMULATION IN THE UK 1990/91 Report No. NC 8438/W119 = R174 AgrEvo GLP Unpublished	N	BCS
CA 6.10.1	Lückmann, J.	2013	ETHOFUMESATE - EXPOSURE OF HONEYBEES TO RESIDUES IN NECTAR, POLLEN AND GUTTATION FLUID IN SUGAR AND FODDER BEETS Report No. P13096 RIFCon GmbH, Hirschberg, Germany non GLP/GEP Unpublished	N	UPL

BCS: Bayer CropScience, FCS: Feinchemie Schwebda, UPL: UPL Europe Ltd.

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 Phenmedipham

A 2.1.1 Stability of residues

No new studies submitted.

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

No new studies submitted.

A 2.1.3 Magnitude of residues in plants

A 2.1.3.1 Beets

Table A 2.1.3.1-1 Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment [kg a.s./ha]	Interval between application	Growth stage at last application	PHI [days]
cGAP EU (DAR, RMS, year)	1	0.96	-	-	-
cGAP EU (Art. 12, EFSA, year)	1	0.96	-	BBCH 33	90
Intended cGAP (number*) 1-20	6	0.15	5	BBCH 39	F
	3	0.3	6	BBCH 39	F

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

One new study, consisting of 4 new trials for sugar beet are summarised in the following.

A 2.1.3.1.1 Study 1

Comments of zRMS:

The study was conducted under field conditions at 4 sites in Northern Europe. All the trials were sampled at harvest. In each trial there were 3 plots.

One plot B was treated three times with HBZ10 (Ethofumesate/Phenmedipham 125/125 g/L EC) at the application rate of 2.4 L/ha (300 g ethofumesate /ha, 300 g phenmedipham /ha). The applications were made at 5-7 days interval and the last application was performed at BBCH 37-39.

One plot C was treated six times with HBZ10 (Ethofumesate/Phenmedipham 125/125 g/L EC) at the application rate of 1.2 L/ha (150 g ethofumesate /ha, 150 g phenmedipham /ha). The applications were made at 4-6 days interval (7 days between applications No.2 and No.3 for trial C0252 CZ1, see deviation No.29/06/2020) and the last application was performed at BBCH 37-39.

No application was performed after BBCH 39.

One plot remained untreated.

In all trials sampling was performed at maturity of the crop.

Residues of ethofumesate, phenmedipham and their metabolites were analysed in samples harvested during the field phase.

The analytical methods were validated according to guideline SANCO/3029/99 rev. 4.

Limit of quantification: LOQ was 0.01 mg/kg for all matrices and analytes.

Limit of detection: LOD is defined as 30% of the LOQ (i.e. 0.003 mg/kg).

Storage of samples: max 280 days.

Residues in control samples were below the limit of quantification.

The residue results for phenmedipham in the treated specimens are summarized below:

Trial No.	Matrix	Plot	Phenmedipham and metabolites – Residue found (mg/kg)						
			3-methylaniline	Phenmedipham Free form Step No. 1	MHPC Free form Step No. 1	Phenmedipham and MHPC Sum free forms* Step No. 1	Phenmedipham and MHPC Sum free + Conj. forms* Step No. 2	Phenmedipham and MHPC Sum Conj. Forms*	
C0252 DE1	Leaves with tops	B	NDR	NDR	NDR	NDR	<LOQ	<LOQ	
		C	NDR	NDR	NDR	NDR	NDR	NDR	
	Roots	B	NDR	NDR	NDR	NDR	NDR	NDR	
		C	NDR	NDR	NDR	NDR	NDR	NDR	
	C0252 NL1	Leaves with tops	B	NDR	0.02	NDR	0.02	0.25	0.23
			C	NDR	< LOQ	NDR	< LOQ	0.12	0.12
Roots		B	NDR	NDR	NDR	NDR	<LOQ	<LOQ	
		C	NDR	NDR	NDR	NDR	NDR	NDR	
C0252 CZ1	Leaves with tops	B	NDR	NDR	NDR	NDR	0.02	0.02	
		C	NDR	NDR	NDR	NDR	<LOQ	<LOQ	
	Roots	B	NDR	NDR	NDR	NDR	<LOQ	<LOQ	
		C	NDR	NDR	NDR	NDR	NDR	NDR	
	C0252 PL1	Leaves with tops	B	NDR	< LOQ	NDR	< LOQ	0.03	0.03
			C	NDR	NDR	NDR	NDR	0.01	0.01
Roots		B	NDR	NDR	NDR	NDR	<LOQ	<LOQ	
		C	NDR	NDR	NDR	NDR	NDR	NDR	

* Expressed as phenmedipham (the step No. 2 was analyzed as MHPC)

DALA: Days after last application

NDR: No detectable residues (residues below the limit of detection)

<LOQ: residues between LOD and LOQ

LOD = 0.003 mg/kg for 3-methylaniline, phenmedipham and MHPC (Step No. 1).

LOD = 0.002 mg/kg for phenmedipham as MHPC (step No. 2)

LOQ = 0.01 mg/kg.

The study is acceptable.

Reference:	KCA 6.3/01
Report	Determination of Ethofumesate and Phenmedipham Residues in Sugar beets Following Foliar application with HBZ10 (Ethofumesate/Phenmedipham 125/125 g/L EC) under Field Conditions in Northern Europe in 2020, Schneider, E. (2021), report No R C0252,
Guideline(s):	Yes (OECD 509, SANCO 7525/VI/95 rev. 10.3, SANCO 3029/99 rev. 4, SANTE/202012830 rev. 1, OECD ENV/JM/MONO(2007)17)
Deviations:	No deviation with impact on quality and integrity of the study.
GLP:	Yes
Acceptability:	Yes

Materials and Methods

A total of 4 supervised residue trials were performed in Northern Europe (Germany, The Netherlands, the Czech Republic, and Poland). Trials were performed with 3 plots, each: an untreated control, a plot treated with HBZ10 with 3 applications of 2.4 L/ha (corresponding to 300 g/ha Ethofumesate and 300 g/ha Phenmedipham) at an interval of 5-7 days up to BBCH 37-39, and another plot with 6 applications of 1.2 L/ha (corresponding to 150 g/ha Ethofumesate and 150 g/ha Phenmedipham) at an interval of 4-6 days up to BBCH 37-39. The tested application rates and timings, thus, corresponded to the intended GAPs for HBZ10.

Trials were sampled only once, at normal commercial harvest, which was between 64 and 95 days after the last application. Samples were separated into roots and leaves with tops.

Samples were analysed for residues of Ethofumesate and Phenmedipham.

For Phenmedipham, parent Phenmedipham and its metabolite MHPC were analysed in their free form. Furthermore, a second analysis was done, hydrolysing the residues in order to analyse the sum of Phenmedipham and MHPC in their free and conjugated forms. Furthermore, 3-methylaniline was analysed. The method for the analysis of Phenmedipham residues was validated in study C0327 and consisted of an extraction with acidified acetonitrile/water mixture, of which an aliquot was analysed for free Phenmedipham and free MHPC by LC-MS/MS. Another aliquot was hydrolysed to transform Phenmedipham (free or conjugated) and conjugated MHPC into free MHPC, so that the sum of free and conjugated Phenmedipham and MHPC could be quantified by LC-MS/MS. The LOQ for each analyte (free Phenmedipham, free MHPC, and sum of residues) was 0.01 mg/kg.

Samples for the analysis of residues of Phenmedipham were stored for a maximum of 280 days before analysis. Sample extracts for analysis of the free forms of Phenmedipham and MHPC were stored for a maximum of 1 day for roots and 2 days for leaves with tops under frozen conditions before analysis, while the method validation study C0327 showed that Phenmedipham (free form) is stable for at least 17 days in extracts of leaves with tops and roots. Free MHPC was shown to be stable for at least 12 days in leaves with tops and 11 days in roots.

Sample extracts for the analysis of the sum of free and conjugated residues were stored for a maximum of 14 days for leaves and tops and 6 days for roots, which is also covered by storage stability experiments in the validation study C0327 (stable for at least 16 days in extracts of leaves with tops and 17 days in extracts of roots).

Mean concurrent recoveries were all in the range of 70-120% with a relative standard deviation < 20%.

Table A 2.1.3.1.1-1 Summary of the study 1 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1. Sowing or planting 2. Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analysed	Residues [mg/kg]			PHI [days] (d)	Details on trial (e)
			[g a.s./ ha]	Water [L/ha]	[g a.s./hL]				Phen- medi- pham free form	MHPC free form	Sum free and conjuga- ted		
C252 DE1 46342 Velen- Ramsdorf, North-Rhine Westphalia, Germany, N-EU, 2020	Sugar beet / Hannibal	1. 05.05.20	326.7	327	100	25.06.2020	BBCH 35	Roots	<u>n.d.</u>	n.d.	n.d.	64	Method of analysis: LC-MS/MS, fully validated in report No. C0327 LOQ: 0.01 mg/kg Formulation type used: EC, Storage of samples: max 280 days
		2. n.a.	313.3	313	100	02.07.2020	BBCH 37	Leaves	<u>n.d.</u>	n.d.	< 0.01	64	
		3. 09.09.20	316.7	317	100	07.07.2020	BBCH 39	with tops					
			153.3	307	50	12.06.2020	BBCH 16	Roots	n.d.	n.d.	n.d.	64	
			160	320	50	17.06.2020	BBCH 31	Leaves	n.d.	n.d.	n.d.	64	
			156.7	313	50	22.06.2020	BBCH 34	with tops					
			158.3	317	50	27.06.2020	BBCH 35						
			155	310	50	02.07.2020	BBCH 37						
			155	310	50	07.07.2020	BBCH 39						
C0252 NL2 6599 AV Ven- zelderheide, Limburg, The Netherlands N-EU, 2020	Sugar beet / Marsley	1. 07.05.20	313.3	313	100	25.06.2020	BBCH 34	Roots	n.d.	n.d.	n.d.	64	Method of analysis: LC-MS/MS, fully validated in report No. C0327 LOQ: 0.01 mg/kg Formulation type used: EC, Storage of samples: max 280 days
		2. n.a.	296.7	297	100	02.07.2020	BBCH 37	Leaves	0.02	n.d.	0.25	64	
		3. 09.09.20	303.3	303	100	07.07.2020	BBCH 39	with tops					
			158.3	317	50	12.06.2020	BBCH 18	Roots	n.d.	n.d.	n.d.	64	
			158.3	317	50	17.06.2020	BBCH 31	Leaves	< 0.01	n.d.	0.12.	64	
			141.7	283	50	22.06.2020	BBCH 33	with tops					
			146.7	293	50	26.06.2020	BBCH 35						
			156.7	313	50	02.07.2020	BBCH 37						
			153.3	307	50	07.07.2020	BBCH 39						

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1. Sowing or planting 2. Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analysed	Residues [mg/kg]			PHI [days] (d)	Details on trial (e)
			[g a.s./ ha]	Water [L/ha]	[g a.s./hL]				Phen- medi- pham free form	MHPC free form	Sum free and conjuga- ted		
C0252 CZ3, 56601 Tisova, Pardubice, Czech Republic N-EU, 2020	Sugar beet / Conuisio	1. 15.03.20 2. n.a. 3. 12.10.20	293.3	293	100	27.06.2020	BBCH 34	Roots	n.d.	n.d.	< 0.01	95	Method of analysis: LC-MS/MS, fully validated in report No. C0327 LOQ: 0.01 mg/kg Formulation type used: EC, Storage of samples: max 247 days
			286.7	287	100	03.07.2020	BBCH 35-37	Leaves	n.d.	n.d.	n.d.	95	
			313.3	313	100	09.07.2020	BBCH 37-39	with tops	n.d.	n.d.	n.d.	95	
			160	320	50	09.06.2020	BBCH 32	Roots	n.d.	n.d.	n.d.	95	
			163.3	327	50	15.06.2020	BBCH 33	Leaves	n.d.	n.d.	< 0.01	95	
			170	340	50	22.06.2020	BBCH 33-34	with tops	n.d.	n.d.	n.d.	95	
			150	300	50	27.06.2020	BBCH 34		n.d.	n.d.	n.d.	95	
			140	280	50	03.07.2020	BBCH 35-37		n.d.	n.d.	n.d.	95	
C0252 PL4, 99-122 Góra Świętej Małgorzaty, Łódzkie, Poland N-EU, 2020	Sugar beet / Ozon	1. 11.04.20 2. n.a. 3. 22.09.20	321.3	428	75	09.06.2020	BBCH 35-36	Roots	n.d.	n.d.	< 0.01	92	Method of analysis: LC-MS/MS, fully validated in report No. C0327 LOQ: 0.01 mg/kg Formulation type used: EC, Storage of samples: max 267 days
			313.8	418	75	15.06.2020	BBCH 37-38	Leaves	< 0.01	n.d.	0.03	92	
			307.5	410	75	22.06.2020	BBCH 39	with tops	n.d.	n.d.	n.d.	92	
			164.4	438	38	27.05.2020	BBCH 16	Roots	n.d.	n.d.	n.d.	92	
			158.1	422	37	02.06.2020	BBCH 31	Leaves	n.d.	n.d.	0.01	92	
			158.8	423	38	07.06.2020	BBCH 32-33	with tops	n.d.	n.d.	n.d.	92	
			154.4	412	37	12.06.2020	BBCH 36-37		n.d.	n.d.	n.d.	92	
			162.5	433	38	17.06.2020	BBCH 38		n.d.	n.d.	n.d.	92	
C0252 PL4, 99-122 Góra Świętej Małgorzaty, Łódzkie, Poland N-EU, 2020	Sugar beet / Ozon	1. 11.04.20 2. n.a. 3. 22.09.20	156.9	418	38	22.06.2020	BBCH 39		n.d.	n.d.	n.d.	92	

(a) According to CODEX Classification / Guide

(b) Only if relevant

(c) Year must be indicated

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

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

A 2.1.4 Magnitude of residues in livestock

No new studies submitted.

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

No new studies submitted.

A 2.1.6 Magnitude of residues in representative succeeding crops

No new studies submitted.

A 2.1.7 Other/Special Studies

No new studies submitted.

A 2.2 Ethofumesate

A 2.2.1 Stability of residues

No new studies submitted.

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

No new studies submitted.

A 2.2.3 Magnitude of residues in plants

A 2.2.3.1 Beets

Table A 2.2.3.1-1 Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment [kg a.s./ha]	Interval between application	Growth stage at last application	PHI [days]
cGAP EU (DAR, RMS, year)	1	0.96	-	-	-
cGAP EU (Art. 12, EFSA, year)	1	0.96	-	BBCH 33	90
Intended cGAP (number 1-20)	6	0.15	5	BBCH 39	F
	3	0.3	6	BBCH 39	F

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

One new study, consisting of 4 new trials in the northern zone for sugar beet are summarised in the following.

A 2.2.3.1.1 Study 1

Comments of zRMS:	<p>The study was conducted under field conditions at 4 sites in Northern Europe. All the trials were sampled at harvest. In each trial there were 3 plots.</p> <p>One plot B was treated three times with HBZ10 (Ethofumesate/Phenmedipham 125/125 g/L EC) at the application rate of 2.4 L/ha (300 g ethofumesate /ha, 300 g phenmedipham /ha). The applications were made at 5-7 days interval and the last application was performed at BBCH 37-39.</p> <p>One plot C was treated six times with HBZ10 (Ethofumesate/Phenmedipham 125/125 g/L EC) at the application rate of 1.2 L/ha (150 g ethofumesate /ha, 150 g phenmedipham /ha). The applications were made at 4-6 days interval (7 days between applications No.2 and No.3 for trial C0252 CZ1, see deviation No.29/06/2020) and the last application was performed at BBCH 37-39.</p> <p>No application was performed after BBCH 39.</p> <p>One plot remained untreated.</p> <p>In all trials sampling was performed at maturity of the crop.</p> <p>Residues of ethofumesate, phenmedipham and their metabolites were analysed in samples harvested during the field phase.</p> <p>The analytical methods were validated according to guideline SANCO/3029/99 rev. 4.</p> <p>Limit of quantification: LOQ was 0.01 mg/kg for all matrices and analytes.</p> <p>Limit of detection: LOD is defined as 30% of the LOQ (i.e. 0.003 mg/kg).</p> <p>Storage of samples: max 140 days.</p> <p>Residues in control samples were below the limit of quantification.</p> <p>The residue results for ethofumesate in the treated specimens are summarized below:</p> <table><tr><th rowspan="3">Trial No.</th><th rowspan="3">Matrix</th><th rowspan="3">Plot</th><th colspan="4">Ethofumesate and metabolites – Residue found (mg/kg)</th></tr><tr><th>Ethofumesate</th><th>NC 9607</th><th>NC 20645 Free form</th><th>NC 20645 Conj. form</th></tr><tr><th colspan="4">BBCH 49 (64-95 DALA)</th></tr><tr><td rowspan="4">C0252 DE1</td><td rowspan="2">Leaves with tops</td><td>B</td><td>NDR</td><td>NDR</td><td>< LOQ</td><td>0.03</td></tr><tr><td>C</td><td>NDR</td><td>NDR</td><td>NDR</td><td>< LOQ</td></tr><tr><td rowspan="2">Roots</td><td>B</td><td>NDR</td><td>NDR</td><td>NDR</td><td>NDR</td></tr><tr><td>C</td><td>NDR</td><td>NDR</td><td>NDR</td><td>NDR</td></tr><tr><td rowspan="4">C0252 NL1</td><td rowspan="2">Leaves with tops</td><td>B</td><td>NDR</td><td>NDR</td><td>NDR</td><td>0.45</td></tr><tr><td>C</td><td>NDR</td><td>NDR</td><td>NDR</td><td>0.16</td></tr><tr><td rowspan="2">Roots</td><td>B</td><td>NDR</td><td>NDR</td><td>NDR</td><td>0.01</td></tr><tr><td>C</td><td>NDR</td><td>NDR</td><td>NDR</td><td>< LOQ</td></tr><tr><td rowspan="4">C0252 CZ1</td><td rowspan="2">Leaves with tops</td><td>B</td><td>NDR</td><td>NDR</td><td>< LOQ</td><td>0.05</td></tr><tr><td>C</td><td>NDR</td><td>NDR</td><td>NDR</td><td>0.02</td></tr><tr><td rowspan="2">Roots</td><td>B</td><td>NDR</td><td>NDR</td><td>NDR</td><td>0.02</td></tr><tr><td>C</td><td>NDR</td><td>NDR</td><td>NDR</td><td>< LOQ</td></tr><tr><td rowspan="4">C0252 PL1</td><td rowspan="2">Leaves with tops</td><td>B</td><td>NDR</td><td>NDR</td><td>NDR</td><td>0.13</td></tr><tr><td>C</td><td>NDR</td><td>NDR</td><td>NDR</td><td>0.08</td></tr><tr><td rowspan="2">Roots</td><td>B</td><td>NDR</td><td>NDR</td><td>NDR</td><td>0.01</td></tr><tr><td>C</td><td>NDR</td><td>NDR</td><td>NDR</td><td>< LOQ</td></tr></table> <p>DALA: Days after last application</p> <p>NDR: No detectable residues (residues below the limit of detection)</p> <p><LOQ: residues between LOD and LOQ</p> <p>LOD = 0.003 mg/kg</p> <p>LOQ = 0.01 mg/kg</p> <p>The study is acceptable.</p>	Trial No.	Matrix	Plot	Ethofumesate and metabolites – Residue found (mg/kg)				Ethofumesate	NC 9607	NC 20645 Free form	NC 20645 Conj. form	BBCH 49 (64-95 DALA)				C0252 DE1	Leaves with tops	B	NDR	NDR	< LOQ	0.03	C	NDR	NDR	NDR	< LOQ	Roots	B	NDR	NDR	NDR	NDR	C	NDR	NDR	NDR	NDR	C0252 NL1	Leaves with tops	B	NDR	NDR	NDR	0.45	C	NDR	NDR	NDR	0.16	Roots	B	NDR	NDR	NDR	0.01	C	NDR	NDR	NDR	< LOQ	C0252 CZ1	Leaves with tops	B	NDR	NDR	< LOQ	0.05	C	NDR	NDR	NDR	0.02	Roots	B	NDR	NDR	NDR	0.02	C	NDR	NDR	NDR	< LOQ	C0252 PL1	Leaves with tops	B	NDR	NDR	NDR	0.13	C	NDR	NDR	NDR	0.08	Roots	B	NDR	NDR	NDR	0.01	C	NDR	NDR	NDR	< LOQ
Trial No.	Matrix				Plot	Ethofumesate and metabolites – Residue found (mg/kg)																																																																																																						
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C0252 DE1	Leaves with tops	B	NDR	NDR	< LOQ	0.03																																																																																																						
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	Roots	B	NDR	NDR	NDR	NDR																																																																																																						
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	Roots	B	NDR	NDR	NDR	0.01																																																																																																						
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		C	NDR	NDR	NDR	< LOQ																																																																																																						

Reference:	KCA 6.3/01
Report	Determination of Ethofumesate and Phenmedipham Residues in Sugar beets Following Foliar application with HBZ10 (Ethofumesate/Phenmedipham 125/125 g/L EC) under Field Conditions in Northern Europe in 2020, Schneider, E. (2021), report No R C0252,
Guideline(s):	Yes (OECD 509, SANCO 7525/VI/95 rev. 10.3, SANCO 3029/99 rev. 4, SANTE/202012830 rev. 1, OECD ENV/JM/MONO(2007)17)
Deviations:	No deviation with impact on quality and integrity of the study.
GLP:	Yes
Acceptability:	Yes

Materials and Methods

A total of 4 supervised residue trials were performed in Northern Europe (Germany, The Netherlands, Czech Republic, and Poland). Trials were performed with 3 plots, each: an untreated control, a plot treated with HBZ10 with 3 applications of 2.4 L/ha (corresponding to 300 g/ha Ethofumesate and 300 g/ha Phenmedipham) at an interval of 5-7 days up to BBCH 37-39, and another plot with 6 applications of 1.2 L/ha (corresponding to 150 g/ha Ethofumesate and 150 g/ha Phenmedipham) at an interval of 4-6 days up to BBCH 37-39. The tested application rates and timings, thus, corresponded to the intended GAPs for HBZ10.

Trials were sampled only once, at normal commercial harvest, which was between 64 and 95 days after the last application. Samples were separated into roots and leaves with tops.

Samples were analysed for residues of Ethofumesate and Phenmedipham. For residues of Ethofumesate, the following components were analysed: parent Ethofumesate, metabolites NC 9607, and NC 20645 (free and conjugated).

The method for the analysis of Ethofumesate residues was validated in study B3016 and consisted of an extraction with acetonitrile in the presence of citrate buffer and sodium chloride, of which an aliquot was purified on a charcoal cartridge and analysed for free Ethofumesate, free NC 9607 and free NC 20645 by LC-MS/MS. Conjugated residues were extracted from the aqueous phase and the remains of the sample by acidic hydrolysis to release conjugated NC 20645 in its free form for analysis by LC-MS/MS. The LOQ for each analyte (free Ethofumesate, free NC 9607, free NC 20645 and conjugated NC 20645) was 0.01 mg/kg.

Samples for the analysis of residues of Ethofumesate were stored for a maximum of 140 days before analysis. Sample extracts for analysis of the free forms of Ethofumesate and its metabolites were stored for a maximum of 8 days for roots and 9 days for leaves with tops under frozen conditions before analysis, while the method validation study B3016 showed that Ethofumesate (free form) was stable for at least 15 days in extracts.

Samples extracts for the analysis of conjugated residues were stored for a maximum of 9 days for leaves and tops and 7 days for roots, which is also covered by storage stability experiments in the validation study B3016 (stable for at least 15 days in sample extracts).

Mean concurrent recoveries were all in the range of 70-120% with a relative standard deviation < 20%.

Table A 2.2.3.1.1-1 Summary of the study 1 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1. Sowing or planting 2. Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analysed	Residues [mg/kg]				PHI [days] (d)	Details on trial (e)
			[g a.s./ ha]	Water [L/ha]	[g a.s./hL]				Ethofumesate	NC 9607	NC 20645 free	NC 20645 conj.		
C252 DE1 46342 Velen-Ramsdorf, North-Rhine Westphalia, Germany, N-EU, 2020	Sugar beet / Hannibal	1. 05.05.20 2. n.a. 3. 09.09.20	326.7	327	100	25.06.2020	BBCH 35	Roots	n.d.	n.d.	n.d.	n.d.	64	Method of analysis: LC-MS/MS, fully validated in report No. B3016 LOQ: 0.01 mg/kg Formulation type used: EC, Storage of samples: max 140 days
			313.3	313	100	02.07.2020	BBCH 37	Leaves	n.d.	n.d.	< LOQ	0.03	64	
			316.7	317	100	07.07.2020	BBCH 39	with tops	n.d.	n.d.	n.d.	n.d.	64	
			153.3	307	50	12.06.2020	BBCH 16	Roots	n.d.	n.d.	n.d.	n.d.	64	
			160	320	50	17.06.2020	BBCH 31	Leaves	n.d.	n.d.	n.d.	< LOQ	64	
			156.7	313	50	22.06.2020	BBCH 34	with tops	n.d.	n.d.	n.d.	n.d.	64	
			158.3	317	50	27.06.2020	BBCH 35		n.d.	n.d.	n.d.	n.d.	64	
			155	310	50	02.07.2020	BBCH 37		n.d.	n.d.	n.d.	n.d.	64	
C0252 NL2 6599 AV Ven-zelderheide, Limburg, The Netherlands N-EU, 2020	Sugar beet / Marsley	1. 07.05.20 2. n.a. 3. 09.09.20	313.3	313	100	25.06.2020	BBCH 34	Roots	n.d.	n.d.	n.d.	0.01	64	Method of analysis: LC-MS/MS, fully validated in report No. B3016 LOQ: 0.01 mg/kg Formulation type used: EC, Storage of samples: max 140 days
			296.7	297	100	02.07.2020	BBCH 37	Leaves	0.02	n.d.	n.d.	0.45	64	
			303.3	303	100	07.07.2020	BBCH 39	with tops	n.d.	n.d.	n.d.	< LOQ	64	
			158.3	317	50	12.06.2020	BBCH 18	Roots	n.d.	n.d.	n.d.	< LOQ	64	
			158.3	317	50	17.06.2020	BBCH 31	Leaves	< 0.01	n.d.	n.d.	0.16	64	
			141.7	283	50	22.06.2020	BBCH 33	with tops	n.d.	n.d.	n.d.	n.d.	64	
			146.7	293	50	26.06.2020	BBCH 35		n.d.	n.d.	n.d.	n.d.	64	
			156.7	313	50	02.07.2020	BBCH 37		n.d.	n.d.	n.d.	n.d.	64	
			153.3	307	50	07.07.2020	BBCH 39		n.d.	n.d.	n.d.	n.d.	64	

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1. Sowing or planting 2. Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analysed	Residues [mg/kg]				PHI [days] (d)	Details on trial (e)
			[g a.s./ ha]	Water [L/ha]	[g a.s./hL]				Ethofumesate	NC 9607	NC 20645 free	NC 20645 conj.		
C0252 CZ3, 56601 Tisova, Pardubice, Czech Republic N-EU, 2020	Sugar beet / Conuisio	1. 15.03.20 2. n.a. 3. 12.10.20	293.3	293	100	27.06.2020	BBCH 34	Roots	n.d.	n.d.	n.d.	0.02	95	Method of analysis: LC-MS/MS, fully validated in report No. B3016 LOQ: 0.01 mg/kg Formulation type used: EC, Storage of samples: max 107 days
			286.7	287	100	03.07.2020	BBCH 35-37	Leaves	n.d.	n.d.	< LOQ	0.05	95	
			313.3	313	100	09.07.2020	BBCH 37-39	with tops	n.d.	n.d.	n.d.	< LOQ	95	
			160	320	50	09.06.2020	BBCH 32	Roots	n.d.	n.d.	n.d.	< LOQ	95	
			163.3	327	50	15.06.2020	BBCH 33	Leaves	n.d.	n.d.	n.d.	0.02	95	
			170	340	50	22.06.2020	BBCH 33-34	with tops						
			150	300	50	27.06.2020	BBCH 34							
			140	280	50	03.07.2020	BBCH 35-37							
C0252 PL4, 99-122 Góra Świętej Małgorzaty, Łódzkie, Poland N-EU, 2020	Sugar beet / Ozon	1. 11.04.20 2. n.a. 3. 22.09.20	321.3	428	75	09.06.2020	BBCH 35-36	Roots	n.d.	n.d.	n.d.	0.01	92	Method of analysis: LC-MS/MS, fully validated in report No. B3016 LOQ: 0.01 mg/kg Formulation type used: EC, Storage of samples: max 127 days
			313.8	418	75	15.06.2020	BBCH 37-38	Leaves	n.d.	n.d.	n.d.	0.13	92	
			307.5	410	75	22.06.2020	BBCH 39	with tops	n.d.	n.d.	n.d.	< 0.01	92	
			164.4	438	38	27.05.2020	BBCH 16	Roots	n.d.	n.d.	n.d.	0.08	92	
			158.1	422	37	02.06.2020	BBCH 31	Leaves	n.d.	n.d.	n.d.			
			158.8	423	38	07.06.2020	BBCH 32-33	with tops						
			154.4	412	37	12.06.2020	BBCH 36-37							
			162.5	433	38	17.06.2020	BBCH 38							
			156.9	418	38	22.06.2020	BBCH 39							

(a) According to CODEX Classification / Guide

(b) Only if relevant

(c) Year must be indicated

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

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

A 2.2.4 Magnitude of residues in livestock

No new studies submitted.

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

No new studies submitted.

A 2.2.6 Magnitude of residues in representative succeeding crops

No new studies submitted.

A 2.2.7 Other/Special Studies

No new studies submitted.

Appendix 3 Pesticide Residue Intake Model (PRIMo)

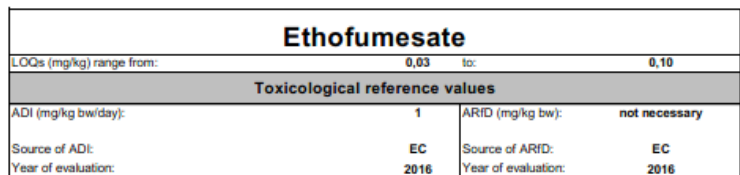
A 3.1 TMDI calculations



Phenmedipham				Input values			
LOQs (mg/kg) range from:		0.01	to:	0.05			
Toxicological reference values							
ADI (mg/kg bw/day):		0.03	ARID (mg/kg bw):		not necessary		
Source of ADI:		Dir 04/58	Source of ARID:		Dir 04/58		
Year of evaluation:			Year of evaluation:				
Normal mode							
Chronic risk assessment: JMPR methodology (IEDI/TMDI)							
No of diets exceeding the ADI : ---			Exposure resulting from				
Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	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)
10%	Milk: Cattle	0.9%	Sugar beet roots	0.7%	Spinaches	13%	0.9%
6%	Milk: Cattle	0.2%	Sugar beet roots	0.2%	Eggs: Chicken	8%	0.2%
3%	Milk: Cattle	0.5%	Strawberries	0.4%	Apples	5%	0.0%
4%	Milk: Cattle	1%	Sugar beet roots	0.3%	Strawberries	7%	1%
5%	Milk: Cattle	0.5%	Sugar beet roots	0.3%	Parsley	7%	0.5%
4%	Milk: Cattle	0.6%	Sugar beet roots	0.2%	Bovine: Muscle/meat	6%	0.6%
3%	Milk: Cattle	0.5%	Sugar beet roots	0.2%	Bovine: Muscle/meat	5%	0.5%
2%	Milk: Cattle	0.8%	Sugar beet roots	0.2%	Parsley	4%	0.8%
3%	Milk: Cattle	0.3%	Spinaches	0.2%	Sugar beet roots	4%	0.2%
2%	Milk: Cattle	0.7%	Bovine: Muscle/meat	0.4%	Parsley	4%	0.0%
2%	Milk: Cattle	0.7%	Sugar beet roots	0.2%	Swine: Muscle/meat	4%	0.7%
2%	Milk: Cattle	0.4%	Swine: Muscle/meat	0.2%	Bovine: Muscle/meat	4%	0.0%
2%	Milk: Cattle	0.2%	Bovine: Muscle/meat	0.2%	Poultry: Muscle/meat	4%	0.0%
1.0%	Parsley	0.9%	Milk: Cattle	0.2%	Poultry: Muscle/meat	2%	0.1%
1%	Milk: Cattle	0.6%	Parsley	0.2%	Poultry: Muscle/meat	3%	0.1%
1%	Milk: Cattle	0.7%	Parsley	0.2%	Swine: Muscle/meat	3%	0.1%
0.9%	Milk: Cattle	0.8%	Parsley	0.3%	Swine: Muscle/meat	2%	0.1%
1%	Milk: Cattle	0.3%	Parsley	0.2%	Swine: Muscle/meat	3%	0.2%
2%	Milk: Cattle	0.2%	Sugar beet roots	0.2%	Swine: Muscle/meat	3%	0.2%
0.8%	Basil and edible flowers	0.7%	Milk: Cattle	0.2%	Strawberries	2%	0.1%
1%	Milk: Cattle	0.5%	Sugar beet roots	0.2%	Swine: Muscle/meat	3%	0.5%
0.4%	Milk: Cattle	0.3%	Parsley	0.2%	Sugar beet roots	2%	0.3%
0.7%	Milk: Cattle	0.1%	Sugar beet roots	0.1%	Parsley	2%	0.1%
0.8%	Milk: Cattle	0.1%	Bovine: Muscle/meat	0.1%	Swine: Muscle/meat	2%	0.0%
0.9%	Milk: Cattle	0.1%	Swine: Muscle/meat	0.1%	Bovine: Muscle/meat	2%	
0.7%	Milk: Cattle	0.2%	Swine: Muscle/meat	0.1%	Potatoes	1%	0.1%
0.9%	Coffee beans	0.1%	Strawberries	0.0%	Potatoes	1%	0.0%
0.5%	Milk: Cattle	0.1%	Sugar beet roots	0.1%	Strawberries	1%	0.1%
0.5%	Milk: Cattle	0.1%	Bovine: Muscle/meat	0.1%	Sugar beet roots	1%	0.1%
0.4%	Strawberries	0.2%	Potatoes	0.1%	Spinaches	0.6%	0.0%
0.2%	Wheat	0.2%	Parsley	0.1%	Strawberries	0.5%	
0.6%	Milk: Cattle	0.0%	Wheat	0.0%	Sage	0.8%	0.0%
0.3%	Strawberries	0.1%	Potatoes	0.1%	Spinaches	0.5%	0.1%
0.2%	Parsley	0.1%	Wheat	0.1%	Spinaches	0.4%	0.0%
0.2%	Potatoes	0.1%	Wheat	0.1%	Parsley	0.7%	
0.2%	Celery leaves	0.1%	Potatoes	0.1%	Beetroots	0.3%	0.1%

health concern.

was a member of the European Union.



Supplementary results - chronic risk assessment

Details - acute risk assessment/adults

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)
	MS Diet										
TMD/MEDVEDI 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%	

The estimated long-term dietary intake (TMDI/NEDI/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.