REGISTRATION REPORT

# Part B

# Section 7

# Metabolism and Residues

Detailed summary of the risk assessment

Product code: AG-E1-500 SC1

Product name(s): see Part A

Chemical active substance:

Ethofumesate, 500 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

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

Submission date: March 2021

MS Finalisation date: January 2022 (initial core Assessment)

June 2022 (final Core Assessment)

# Version history

| When | What |
|---|---|
| March 2021 | dRR version 1 submitted by the Applicant. |
| January 2022 | dRR version 1.1 submitted by the Applicant – inclusion of interim results of storage stability of residues in lettuce and cereal grains and inclusion of explanation regarding residue trials. |
| January 2022 | Initial ZRMS assessment.<br><br>The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are ~~struck through and shaded for transparency~~. |
| June 2022 | Final report (Core Assessment updated following the commenting period).<br><br>No additional information or assessments after the commenting period. |

## DATA PROTECTION CLAIM

Under Article 59, Regulation 1107/2009/EC, on behalf of the Sponsor Company the applicant claims data protection for these studies. The data protection status and corresponding justification as valid for the respective country will be confirmed in the respective PART A

## STATEMENT FOR OWNERSHIP

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## 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 AG-E1-500 SC1 are presented in Table 7.1-1. They have been selected from the individual GAPs in the Central zone for sugar beet and fodder beet. A list of all intended uses within the Central zone is given in Part B, Section 0.

The critical GAP corresponds to the highest application rate per application, with 2 applications of 0.5 kg a.s./ha at 5-day intervals up to BBCH 18. The maximum annual rate must not exceed 1 kg a.s./ha every 3 years.

**Overall conclusion**

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of 0.2 mg/kg for ethofumesate as laid down in Reg. (EU) 396/2005 is not expected.

The chronic and the short-term intakes of ethofumesate residues are unlikely to present a public health concern.

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

According to available data, specific mitigation measures should apply:

- Do not grow root vegetables (except sugar or fodder beet) in case of crop failure.

**Data gaps**

Noticed data gaps are:

- Final report for the storage stability study of residues of ethofumesate and its metabolite ethofumesate-2-keto in lettuce and cereal grain stored frozen for up to two years (Watson, 2021). Interim results of the ongoing study after six month of freezer storage is included in this submission.

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

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 15 | 11 | 12 | 13 | 14 | 15 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Use-No.** (e) | **Member state(s)** | **Crop and/ or situation**<br><br>**(crop destination / purpose of crop)** | **F, Fn, Fpn G, Gn, Gpn or I** | **Pests or Group of pests controlled**<br><br>(additionally: developmental stages of the pest or pest group) | **Application** | | | | **Application rate** | | | **PHI** (days) | **Remarks:**<br><br>e.g. g safener/synergist per ha (f) | **zRMS Conclusion** |
| | | | | | Method / Kind | Timing / Growth stage of crop & season | Max. number a) per use b) per crop/ season | Min. interval between applications (days) | kg or L AG-E1-500 SC1 / ha a) max. rate per appl. b) max. total rate per crop/season | g or kg ethofumesate/ha<br><br>a) max. rate per appl. b) max. total rate per crop/season | Water L/ha<br><br>min / max | | | |
| **Zonal uses (field or outdoor uses, certain types of protected crops)** | | | | | | | | | | | | | | |
| 1 | HU | Sugar beet BEAVA<br>Fodder beet BEAVC | F | annual dicot weeds and annual grass weeds | foliar spraying, overall | BBCH 10-18/ spring | a) 2<br>b) 2 | a) 5<br>b) 5 | a) 1 L/ha<br>b) 2 L/ha | a) 500<br>b) 1000 | 100-400 | n.a. | Max. rate of active must not exceed 1.0 kg/ha every 3 years. | A |
| 2 | SK | Sugar beet BEAVA<br>Fodder beet BEAVC | F | annual dicot weeds and annual grass weeds | foliar spraying, overall | BBCH 10-18/ spring | a) 2<br>b) 2 | a) 5<br>b) 5 | a) 1 L/ha<br>b) 2 L/ha | a) 500<br>b) 1000 | 100-400 | n.a. | Max. rate of active must not exceed 1.0 kg/ha every 3 years. | A |
| 3 | PL | Sugar beet BEAVA<br>Fodder beet BEAVC | F | annual dicot weeds and annual grass weeds | foliar spraying, overall | BBCH 10-18/ spring | a) 3<br>b) 3 | a) 5<br>b) 5 | a) 0.6 L/ha<br>b) 1.8 L/ha | a) 300<br>b) 900 | 100-400 | n.a. | Max. rate of active must not exceed 1.0 kg/ha every 3 years.<br>At each time can be applied in tankmix: AG-E1-50 SC 0.5 L/ha + Goltix Titan 565 SC 1.5 L/ha + Atpolan BIO 80 EC 1.0 L/ha | A |

**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

(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.

Explanation for Column 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 AG-E1-500 SC1 is composed of ethofumesate.

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

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

### 7.1.2.1 Summary for ethofumesate

**Table 7.1-3: Summary for ethofumesate**

| Use-No.* | Crop | Plant metabolism covered? | Sufficient residue trials? | PHI sufficiently supported? | Sample storage covered by stability data? | MRL compliance | Chronic risk for consumers identified? | Acute risk for consumers identified? |
|---|---|---|---|---|---|---|---|---|
| 1, 2, 3 | Sugar beet | Yes | Yes (36 trials) | N/A (determined by growth stage at last application) | Yes | Yes | No | N/A (no ARfD set) |
| 1, 2, 3 | Fodder beet | Yes | Yes (extrapolated from sugar beet) | N/A (determined by growth stage at last application) | Yes | N/A (no MRL set) | | N/A (no ARfD set) |

N/A: Not applicable
* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

The effects of processing on the nature of ethofumesate residues have been investigated. Processing studies on the magnitude of residues have been submitted but are not required to support the proposed uses of ethofumesate in this submission, as the trigger for requiring such studies is not met by the envisaged uses for AG-E1-500 SC1.

Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP use and following mitigation measure has been proposed: Do not grow root vegetables in case of crop failure.

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

### 7.1.2.2 Summary for AG-E1-500 SC1

**Table 7.1-4: Information on AG-E1-500 SC1 (KCA 6.8)**

| Crop | PHI for AG-E1-500 SC1 proposed by applicant | PHI/ Withholding period* sufficiently supported for | PHI for AG-E1-500 SC1 proposed by zRMS | zRMS Comments (if different PHI proposed) |
|---|---|---|---|---|
| | | Ethofumesate | | |
| Sugar beet | F** | NR | F | - |

| Crop | PHI for AG-E1-500 SC1 proposed by applicant | PHI/ Withholding period* sufficiently supported for | PHI for AG-E1-500 SC1 proposed by zRMS | zRMS Comments (if different PHI proposed) |
|---|---|---|---|---|
| | | Ethofumesate | | |
| Fodder beet | F** | NR | F | - |

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

**Table 7.1-5: Waiting periods before planting succeeding crops**

| Waiting period before planting succeeding crops | | Overall waiting period proposed by zRMS for AG-E1-500 SC1 |
|---|---|---|
| Crop group | Led by ethofumesate | |
| Leafy vegetables | None | None |
| Root vegetables | ~~None~~ | Do not grow root vegetables (except sugar or fodder beet) in case of crop failure |
| Cereals | None | None |

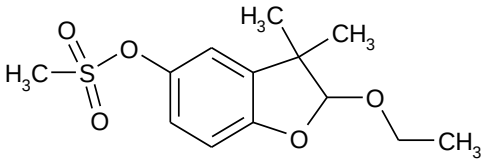
NR: not relevant

**Assessment**

## 7.2 Ethofumesate

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

**Table 7.2-1: General information on ethofumesate**

| | |
|---|---|
| Active substance (ISO Common Name) | Ethofumesate |
| IUPAC | (*RS*)-2-ethoxy-2,3-dihydro-3,3-dimethylbenzofuran-5-yl methanesulfonate |
| Chemical structure |  |
| Molecular formula | $C_{13}H_{18}O_5S$ |
| Molar mass | 286.3 u |
| Chemical group | Benzofurane |
| Mode of action (if available) | Inhibitor of lipid synthesis and cell division in susceptible weeds by a reduction of photosynthesis and respiration |
| Systemic | Yes |
| Company (ies) | Task Force Ethofumesate (representing Bayer CropScience and Adama Deutschland GmbH (former Feinchemie Schwebda GmbH)) and United Phosphorus Limited |
| Rapporteur Member State (RMS) | Austria<br>DAR: Sweden<br>RAR-RMS: Austria<br>Co-RMS: Denmark |
| Approval status | Approved (01/11/2016)<br>Commission Implementing Regulation (EU) 2016/1426 of 25 August 2016 |
| Restriction<br>(e.g. is restricted to use as "...") | Only uses as herbicide may be authorised |
| Review Report | SANTE/10119/2016 Rev. 3<br>12 July 2016 |
| Current MRL regulation | Commission Regulation (EU) 2017/1016 of 14 June 2017 |
| Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed | Yes |
| EFSA Journal : Conclusion on the peer review | Yes. EFSA, 2016 |
| EFSA Journal: conclusion on article 12 | Yes. EFSA, 2012 |
| Current MRL applications on intended uses | EFSA-Q-2019-00468 (EMS Germany, 10/10/2019)<br>Caraway, fresh herbs, edible flowers<br>Status: Additional data request |

### 7.2.1 Stability of Residues (KCA 6.1)

#### 7.2.1.1 Stability of residues during storage of samples

## Available data

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

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

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

**Table 7.2-2: Summary of stability data achieved at ≤ - 18°C for ethofumesate and metabolites**

| Matrix | Characteristics of the matrix | Acceptable Maximum Storage duration [months] | | | | Reference |
|---|---|---|---|---|---|---|
| **Data relied on in EU** | | | | | | |
| **Plant products** | | | | | | |
| | | **Ethofumesate** | **NC 20645, as NC 9607** | | **NC 8493[(b)]** | |
| Sugar beet (roots) | High starch content | 12 | 6[(a)] | | - | Austria, 2015a,b EFSA, 2016 |
| Sugar beet (leaves) | High water content | 12 | 6[(a)] | | - | Austria, 2015a,b EFSA, 2016 |
| Rape seed | High oil content | - | 6[(a)] | | - | Austria, 2015a,b EFSA, 2016 |
| Dry bean | High protein content | - | 6[(a)] | | - | Austria, 2015a,b EFSA, 2016 |
| Orange fruits | High acid content | - | 6[(a)] | | - | Austria, 2015a,b EFSA, 2016 |
| **Animal Products** | | | | | | |
| | | **Ethofumesate** | **NC 9607** | **NC 20645** | **NC8493[(b)]** | |
| not specified in the study | Muscle | 6 | 6 | 1 | 6 | Austria, 2015a,b EFSA, 2016 |
| not specified in the study | Liver | 6 | 6 | 6 | 6 | Austria, 2015a,b EFSA, 2016 |
| not specified in the study | Kidney | 6 | 6 | 6 | 3 | Austria, 2015a,b EFSA, 2016 |
| not specified in the study | Fat | 6 | 6 | <1 | 6 | Austria, 2015a,b EFSA, 2016 |
| Bovine | Milk | 6 | 6 | 6 | 6 | Austria, 2015a,b EFSA, 2016 |
| **New data** | | | | | | |
| **Plant products** | | | | | | |
| | | **Ethofumesate** | **NC 20645, as NC 9607** | | **NC 8493[(b)]** | |
| Sugar beet (roots) | High starch content | - | 24 | | - | Schulte, 2015, Report no. MR-12/058 (KCA 6.1/01; KCP 8/12) |
| Sugar beet (leaves) | High water content | - | 24 | | - | |
| Rape seed | High oil content | - | 24 | | - | |
| Dry bean | High protein content | - | 24 | | - | |
| Orange fruits | High acid content | - | 24 | | - | |
| Lettuce | High water content | 6[(c)] | 6[(c)] | | - | Watson, 2021 |

| Matrix | Characteristics of the matrix | Acceptable Maximum Storage duration [months] | | | Reference |
|---|---|---|---|---|---|
| Cereal grain | High starch content | 6[(c)] | 6[(c)] | - | Report no. RES-00278 (KCA 6.1/02; KCP 8/02) |

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

**Summary on stability of residues during storage reported in the EU**

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

**Conclusion on stability of residues during storage**

Conclusion for plant products

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

Storage stability studies for the metabolite NC 8493 are not required based on the intended uses because NC 8493 is not part of the residue definition. Since major amounts of metabolite NC 8493 were only detected in intermediate growth stages it was not necessary to include this metabolite in the residue definition for mature crops, as well as its conjugate which was always a minor metabolite. Furthermore, the metabolite NC 8493 was not determined in the sugar beet residue trials relevant for the intended uses and in the rotation crop field trials. Thus, storage stability data is not needed for NC 8493 for the product AG-E1-500 SC1.

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

Storage stability data are also available in additional crops that are not relevant to the crop categories to be addressed while the number of commodities per group studied is not in line with current requirements according to OECD Guidance (data gap). Therefore, with regard to the rotational lettuce and cereals crop, storage stability is not appropriately addressed. However, the applicant conducted a new storage stability study of residues of ethofumesate and its metabolite ethofumesate-lactone (NC 9607) in lettuce and cereal grain stored frozen for up to two years. Interim results show stability of both compounds in lettuce and grain after 6 month of freezer stor-age (details see Appendix 2)

Conclusion for animal products

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

Thus, further data is not needed for the product AG-E1-500 SC1.

**zRMS comments:**
zRMS agrees with information provided by the Applicant above.
Sugar/fodder beet roots belong to high starch content matrices, sugar/fodder beet leaves belong to high water content matrices.
The potential degradation of residues during storage of the residue trials samples was assessed in the framework of the peer review. Applicant submitted new storage stability study.
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.
Additional data submitted showed the stability of the metabolite NC 20645 for 24 months in sugar beet roots and leaves, in rape seed, dry bean seed and orange fruit (i.e. high starch, high water, high oil, high protein, high acid containing commodities).
The residue data are valid with regard to storage stability.

Applicant submitted the new storage stability study of residues of ethofumesate and its metabolite ethofumesate-2-keto in lettuce and cereal grain stored frozen for up to two years (Watson, 2021). Submitted interim report contains data up to the 6-month timepoint.
The analytes ethofumesate and ethofumesate-2-keto can be considered stable in the investigated matrices of lettuce and cereal grain under deep-freezer storage conditions (≤-18°C) for 6 months.

Regarding animal products, ethofumesate and its metabolites NC 9607, NC8493 and NC 20645 were found to be stable under frozen storage for up to 6 months (see Table 7.2-2) except for metabolite NC 20645 in muscle (1 month) and for metabolite NC8493 in kidney (3 months).
However, these data are not required since a comparison of expected intakes and residue levels found in the metabolism studies in livestock showed that residues < LOQ are expected.

No additional data are required.

#### 7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

As residue samples in trials with ethofumesate were routinely stored frozen for longer periods of time prior to their analysis, the stability of residues during storage of samples and effects of frozen storage on the residue levels were investigated.
The storage stability of ethofumesate residues in sample extracts is routinely tested during method development. Since the validity of the methods is based on and confirmed by factors such as reproducibility for interruption during the work-up process, it can be concluded that the stability of residues in extracts is always guaranteed. In addition, when conducting analyses of "normal" samples, the entire analytical procedure is monitored by conducting concurrent recoveries with each sample set.

**zRMS comments:**
Information given by the Applicant is sufficient.
No further data are required.

### 7.2.2 Nature of residues in plants, livestock and processed commodities

#### 7.2.2.1 Nature of residue in primary crops (KCA 6.2.1)

**Available data**
*Reference: Austria, 2015a, b; EFSA, 2016*
The metabolism of ethofumesate was investigated for foliar application on root and tuber vegetables (sugar beet, onion), cereals (ryegrass) and leafy vegetables (tobacco) using [$^{14}$C-benzene] and/or [$^{14}$C-mesyl]-labelled ethofumesate. These studies are summarised in the table below.
No new plant metabolism data have been submitted by the applicant in the framework of this application.

**Table 7.2-3: Summary of plant metabolism studies**

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

(a) Outdoor/field application (F) or glasshouse/protected/indoor application (G)
(b) F or G not reported
(c) DAFA = days after first application

**Summary of plant metabolism studies reported in the EU**

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

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

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

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

above 97% and confirmed that the compound would be detected, if present." (*Austria, 2015a, b)*
"Primary crop metabolism of $^{14}$C ethofumesate was investigated following pre-emergence application and post-emergence foliar application to sugar beet, post-emergence foliar application to ryegrass and tobacco (non GLP), and pre-emergence application to onions (non GLP). In addition, rotational crop metabolism was studied in radish, carrots, cabbage, spinach, wheat, ryegrass, and French beans, investigating different plant-back intervals upon soil application of $^{14}$C ethofumesate. Metabolic patterns in the different studies were similar, metabolism of ethofumesate leading to the metabolites ethofumesate-2-hydroxy (NC 8493), ethofumesate lactone (NC 9607) and ethofumesate carboxylic acid (NC 20645), recovered also in their conjugated form. NC 20645 is the open ring form of NC9607. Intra-molecular ring closure appeared to be conditioned by the pH i.e. primarily when acidic conditions are applied to release the aglycon of conjugated residues. The proportions observed of parent and metabolites and their conjugates varied depending on the time, mode and rate of application as well as on the crop studied. Commonly, until harvest of the mature primary crop, parent had been degraded to a significant extent, if not completely, into its metabolites, majorly present as conjugated compounds. The pertinent residue was identified as NC 20645, free and conjugated.[…] In view of the metabolic pathway in mammals EFSA considered that the plant metabolites NC 20645, NC 9607 and NC 8493 are covered by the toxicological endpoints of parent compound." (*EFSA, 2016)*

**Conclusion on metabolism in primary crops**
The metabolism of ethofumesate in crops following foliar and soil application is sufficiently addressed to support the proposed uses of product AG-E1-500 SC1.

**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 AG-E1-500 SC1..

### 7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

**Available data**
*Reference: Sweden, 2000; Austria, 2015a, b; EFSA, 2012, 2016*
The metabolism of ethofumesate in rotational crops was investigated in leafy vegetables (cabbage, spinach), root and tuber vegetables (radish, carrot), cereals (wheat, ryegrass) and pulses and oilseeds (French beans) using [$^{14}$C-benzene]-labelled ethofumesate. These studies are summarised in the table below.
No new data submitted in the framework of this application.

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

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

(a) Outdoor/field application (F) or glasshouse/protected/indoor application (G)
(b) F or G not reported

**Summary of metabolism studies on rotational crops reported in the EU**

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

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

"In a confined rotational crop study, parent ethofumesate was recovered in almost all commodities tested. Upon hydrolysis significant portions of conjugated residues were identified as NC9607 in most of the

commodities, and in root crops also of NC 8493. The observation of residues of unchanged ethofumesate in rotational crops was presumably caused by the high persistence and low leaching potential of ethofumesate in some soils and likely increased availability in the root zone upon breaking up of the soil at planting of the following crop." (*EFSA, 2016)*

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

**zRMS comments:**
Information given by the Applicant is sufficient. The metabolism of ethofumesate in rotational crops was sufficiently investigated during the renewal of approval of the active substance. Rotational crop metabolism was studied in radish, carrots, cabbage, spinach, wheat, ryegrass and French beans, investigating different plant-back intervals upon soil application of $^{14}C$ ethofumesate. Based on these studies, it was concluded that metabolism in primary and rotational crops is similar (EFSA, 2016).
No further data are required.

### 7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

**Available data**
*Reference: Austria, 2015a, b; EFSA, 2016*
The nature of residues under representative processing conditions (pasteurisation, baking/boiling/brewing, sterilisation) and during sugar beet purification was assessed. The results are shown in the table below.
No new data are submitted in the framework of this application.

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

| Conditions (Duration, Temperature, pH) | Identified compound(s) (%) | Reference |
|---|---|---|
| **EU data** | | |
| **Pasteurisation** (20 minutes, 90°C, pH 4) | Parent (98.6%) | Austria, 2015a,b<br>EFSA, 2016 |
| **Baking, boiling, brewing**<br>(60 minutes, 100°C, pH 5) | Parent (99.3%) | Austria, 2015a,b<br>EFSA, 2016 |
| **Sterilisation** (20 minutes, 120°C, pH 6) | Parent (100%) | Austria, 2015a,b<br>EFSA, 2016 |
| **Other conditions** | | |
| **Purification process sugar beet** (30 minutes, 90°C, pH 11) | Parent (97.6%) | Austria, 2015a,b<br>EFSA, 2016 |

**Conclusion on nature of residues in processed commodities**
"Hydrolysis products were detected in a range between 0.7 and 2.1%. They were not further investigated, due to their low amount in the test solutions." (*Austria, 2015a, b)*
"A study investigating the nature of residues under conditions simulating industrial and household common processes indicated ethofumesate was stable. No data is available that investigated the metabolites included in the residue definition NC 9607 and NC 20645, it is however known from analytical methods that acidic conditions lead to rearrangement of NC 20645 and formation of NC 9607. Whether or not NC 9607 will remain entirely stable when processing conditions are applied is currently not addressed, however residues of NC 9607 in food commodities for processing were <LOQ in the trials supporting the representative GAP." (*EFSA, 2016).*

**zRMS comments:**
Information given by the Applicant is sufficient. It can be concluded that ethofumesate is stable during processing.
No further data are required.

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

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

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

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

**Available data**

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

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

No new data submitted in the framework of this application.

**Table 7.2-7: Summary of animal metabolism studies**

| **Group** | **Species** | **Label position** | **No of animal** | **Application details** | | **Sample details** | | **Remarks** | **Reference** |
|---|---|---|---|---|---|---|---|---|---|
| | | | | **Rate (mg/kg bw/d)[(a)]** | **Duration (days)** | **Commodity** | **Time of sampling** | | |
| **EU reviewed data** | | | | | | | | | |
| **Lactating ruminants** | Cow | [$^{14}$ C-benzene] | 1 | 0.3-0.36 | 7 | Milk | Twice daily | Dean, G.M. *et al*., 1992 Report A82968 | Sweden, 2000 Austria, 2015a,b EFSA, 2012, 2016 |
| | | | | | | Urine & faeces | Day -1, 1, 7 | | |
| | | | | | | Tissues | After sacrifice | | |
| | Cow | [$^{14}$ C-benzene] | 1 | 5 | 4 | Milk | Twice daily | Reynolds, C.M.M., 1999 | Sweden, 2000 Austria, 2015a,b |
| | | | | | | Urine & faeces | Daily | | |

| Group | Species | Label position | No of animal | Application details | | Sample details | | Remarks | Reference |
|---|---|---|---|---|---|---|---|---|---|
| | | | | Rate (mg/kg bw/d)[(a)] | Duration (days) | Commodity | Time of sampling | | |
| | | | | | | Blood | 0.5, 1, 2, 3, 4, 6, 8h after initial dosing, then twice daily after milking | Report C003362 | EFSA, 2012 |
| | | | | | | Tissues | After sacri-fice | | |
| | Sheep | [$^{14}$C-benzene] | 1 | 0.2 | 1 | Milk | Not analysed | Warner, P.A., 1976 Report A82958 | Sweden, 2000 Austria, 2015a,b EFSA, 2012 |
| | | | | | | Urine and faeces | Daily | | |
| | | | | | | Tissue | After sacrifice (4 days after dosing) | | |
| **Laying poultry** | Hens | [$^{14}$C-benzene] | 6 | 0.6 | 14 | Eggs | Daily | Hawkins, D.R. *et al*., 1992 Report A82969 | Sweden, 2000 EFSA, 2012 Austria, 2015a,b |
| | | | | | | Excreta | Daily | | |
| | | | | | | Tissues | After sacrifice | | |
| | | [$^{14}$C-benzene] | 3 | 0.78 | 10 | Eggs | Twice daily | Moss, T., Reynolds, C.M.M., 1999 Report C002998 | Sweden, 2000 Austria, 2015a,b EFSA, 2012, 2016 |
| | | | | | | Excreta | Daily | | |
| | | | | | | Tissues | After sacrifice | | |

**Summary of animal metabolism studies reported in the EU**

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

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

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

For poultry there is in principle no necessity to establish a residue definition because the calculated dietary burden of poultry to ethofumesate residues amounted to less than 0.1 mg/kg DM. Nevertheless, two metabolism studies in laying hens are reported (Sweden, 1998, 2002). These studies demonstrate that metabolic pathways of ethofumesate in ruminants and poultry are very similar. It is therefore concluded that the relevant residues in poultry could also be defined as the sum of 2-keto-ethofumesate and open-ring-2-keto-ethofumesate, expressed as ethofumesate, provided that the use of ethofumesate is supported on additional crops resulting in a higher exposure of poultry to ethofumesate residues. In the meantime, a residue definition for poultry products is not required.
In the framework of the peer review, ethofumesate was considered to be not fat soluble based on the fact that its log Po/w is lower than 3 (Sweden, 2002)." (*EFSA, 2012)*
"Significant intakes were calculated for livestock. Metabolism in poultry and lactating ruminants was sufficiently investigated with $^{14}C$ ethofumesate. The relevant residue definition for both enforcement and risk assessment in livestock was derived as the sum of ethofumesate, NC 9607, NC 20645, expressed as ethofumesate. Based on the metabolism studies, it is also concluded that significant residues in animal commodities are not expected, considering livestock exposure linked to the representative uses." (*EFSA, 2016)*

**Conclusion on metabolism in livestock**
The metabolism of ethofumesate in livestock animals is sufficiently addressed to support the proposed uses of product AG-E1-500 SC1.

**zRMS comments:**
Information given by the Applicant is sufficient. The metabolism of ethofumesate in livestock (poultry and lactating ruminants) was sufficiently investigated during the renewal of approval of the active substance.

**Residue definition:**
The residue definition for enforcement: the sum of ethofumesate, NC 9607, NC 20645, expressed as ethofumesate
The residue definition for risk assessment: the sum of ethofumesate, NC 9607, NC 20645, expressed as ethofumesate.
Conversion factor (monitoring to risk assessment): 1.

In EFSA Journal 2016;14(1):4374 it is stated that based on the metabolism studies, it is also concluded that significant residues in animal commodities are not expected, considering livestock exposure linked to the representative uses.
No further data are required.

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

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

| | **Endpoints** |
|---|---|
| Animals covered | Lactating cows/sheep |
| | Laying hens |
| Time needed to reach a plateau concentration | 32 h in milk |
| | 9 days in eggs |
| Animal residue definition for monitoring | Ethofumesate (Sum of ethofumesate, 2-keto-ethofumesate (NC 9607), open-ring-2-keto-ethofumesate (NC 20645) and its conjugate, expressed as ethofumesate) (Regulation (EU) n°2017/1016) |
| Animal residue definition for risk assessment | Ethofumesate (Sum of ethofumesate, 2-keto-ethofumesate (NC 9607), open-ring-2-keto-ethofumesate (NC 20645) ~~and its conjugate~~, expressed as ethofumesate) (EFSA, 2016) |
| Conversion factor | 1 (Austria, 2015a, b) |
| Metabolism in rat and ruminant similar | Yes |

| | **Endpoints** |
|---|---|
| Fat soluble residue | No |

## 7.2.3 Magnitude of residues in plants (KCA 6.3)

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

The intended cGAP for AG-E1-500 SC1 in sugar beet and fodder beet corresponds to or is less critical than the EU cGAP as shown in the table below.
No new studies on the magnitude of residue are submitted by the applicant in the framework of this application. All available data are summarized Table 7.2-10 below.

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

| Type of GAP | Region | Crop | Number of applications | Application rate per treatment (kg a.s./ha) | Interval between applications [min. days] | Growth stage at last application | PHI (days) | Remark |
|---|---|---|---|---|---|---|---|---|
| cGAP EU (Austria, 2015a; EFSA, 2016) | EU | Sugar beet, fodder beet | 3 | 0.33 | 5 | Post-emergence up to BBCH 18 | n.a. | max. 1.0 kg a.s./ha every three years |
| | EU | Sugar beet, fodder beet | 1 | 1.0 | - | Pre-emergence | n.a. | |
| cGAP EU (Art. 12, EFSA, 2012) | EU | Sugar beet | 1 | 1.0 | - | BBCH 12-14 | 90 | - |
| | N-EU | Fodder beet | 1 | 1.0 | - | BBCH 10-18 | n.a. | - |
| Intended cGAP (number 1, 2) | N-EU | Sugar beet, fodder beet | 2 | 0.5 | 5 | BBCH 10-18 | n.a. | max. 1.0 kg a.s./ha every three years |

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

**Table 7.2-10: Summary of EU reported and new data supporting the intended uses of AG-E1-500 SC1 and conformity to existing MRL**

| Commodity | Source | Residue zone | Evaluation<br>GAP<br>Residue levels (mg/kg)<br>E = according to enforcement residue definition<br>RA = according to risk assessment residue definition | STMR (mg/kg) | HR (mg/kg) | Unrounded OECD calculator MRL (mg/kg) | Current EU MRL (mg/kg)[a] | MRL compliance |
|---|---|---|---|---|---|---|---|---|
| Residue definition for enforcement(E) and risk assessment(RA):<br>Sum of ethofumesate, ethofumesate-lactone (NC 9607), ethofumesate carboxylic acid (NC 20645), and its conjugate expressed as ethofumesate | | | | | | | | |
| Sugar beet roots | EFSA, 2016 | N-EU | GAP on which MRL/EU a.s. assessment is based: 3x 0.33 kg a.s./ha (max. 1.0 kg a.s./ha every 3 years), post-emergence up to BBCH 18, outdoor<br><br>E/RA[b]: 8x<0.02, 15x<0.06, 0.06, 0.09, 11x<0.1 | E: <0.06<br>RA: <0.06 | E: <0.1<br>RA: <0.1 | 0.18 | 0.2 | Yes |
| | Overall supporting data for cGAP | N-EU | E/RA[b]: 8x<0.02, 15x<0.06, 0.06, 0.09, 11x<0.1 | E: <0.06<br>RA: <0.06 | E: <0.1<br>RA: <0.1 | 0.18 | 0.2 | Yes |
| Sugar beet tops | EFSA, 2016 | N-EU | GAP on which MRL/EU a.s. assessment is based: 3x 0.33 kg a.s./ha (max. 1.0 kg a.s./ha every 3 years), post-emergence up to BBCH 18, outdoor<br><br>RA: 8x<0.02, 11x<0.06, 0.06, 0.07, 9x<0.1, <0.12, 0.18 | <0.06 | 0.18 | N/A | N/A | N/A |
| | Overall supporting data for cGAP | N-EU | RA: 8x<0.02, 11x<0.06, 0.06, 0.07, 9x<0.1, <0.12, 0.18 | <0.06 | 0.18 | N/A | N/A | N/A |

(a) Source of EU MRL: Commission Regulation (EU) 2017/1016 of 14 June 2017

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

### 7.2.3.2 Conclusion on the magnitude of residues in plants

EFSA (2016) concluded that "The total number of available residue trials in the primary sugar beet crop, which were deemed appropriate to address the residue definition, was sufficient to support the cGAP."
The intended cGAP for AG-E1-500 SC1 corresponds to or is less critical than the EU cGAP evaluated by EFSA (2016), therefore, according to the available data, the intended uses on sugar beet are considered acceptable for outdoor uses.
Data on sugar beet (0900010) can be extrapolated to fodder beet according to EC guidance document SANCO 7525/VI/95 Rev. 10.3 (13 June 2017).
Thus, according to the available data, the intended uses on sugar beet and fodder beet are considered acceptable. The data submitted show that no exceedance of the MRL will occur.

**zRMS comments:**
Information given by the Applicant is sufficient.
Sugar beet is the major crop in northern Europe (EU Technical Guidelines Document SANTE/2019/12752). A minimum of eight trials are required. Residue data on sugar beet (0900010) can be extrapolated to fodder beet.
The intended GAP for ethofumesate for sugar and fodder beets in northern Europe is 2x0.50 kg a.i./ha or 3x0.30 kg a.i./ha with interval between applications of 5 days at BBCH 10-18 with PHI as not applicable, the PHI is covered by the time remaining between application and harvest with remark: max. rate of active must not exceed 1.0 kg/ha every 3 years.

No new studies on the magnitude of residue have been submitted by the Applicant in the framework of this application.
Sufficient trials are available to support the proposed use in sugar beet (EFSA, 2016).
In EFSA Journal 2016;14(1):4374 it is stated that "*In residue trials in the primary crop and in rotational crops residues of ethofumesate and by turns of free NC 9607, free and conjugated NC 20645 and NC 8493 were determined. When the occurrence of residues in the primary or rotational crop (food and feed items) at harvesting stage is considered, the residue definition for risk assessment is appropriately defined as the sum of ethofumesate, NC 9607, NC20645 and its conjugate, expressed as ethofumesate. The same residue definition was proposed for monitoring purposes and MRL setting*."
Sufficient residue trials were conducted in NEU. According to the RMS-Austria conclusion (DRAR for Ethofumesate, 2015): "*Between 1972 and 2012, numerous residue trials were conducted to support the presented "representative use" (pre-emergence and post-emergence use) of ethofumesate in Beta vulgaris, the trials were conducted in different growing areas in the northern and southern European residue region. The vegetation period in sugar and fodder beet ranges between 5 and 9 months and the studies indicate that the variation within the vegetation period is much higher than the time period between pre- and post-emergent treatment. The final residues were at or slightly above the LOQ levels."*

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

The trials are supported by valid storage stability data for sugar beet and validated analytical methods.
The residues arising from the proposed uses will not exceed the MRL established for ethofumesate (as Sum of ethofumesate, 2-keto–ethofumesate, open-ring-2-keto-ethofumesate and its conjugate, expressed as ethofumesate) for sugar beet roots (0.2 mg/kg) in Reg. (EC) No 2017/1016.

In GAP for Poland Applicant proposes that "At each time can be applied in tankmix: AG-E1-50 SC 0.5 L/ha + Goltix Titan 565 SC 1.5 L/ha + Atpolan BIO 80 EC 1.0 L/ha."
The residue studies were conducted without the addition of adjuvant. Applicant submitted the following statement (January 2022):
"*A field trials for the active substance ethofumesate were not conducted with the addition of an oil adjuvant. However, due to the early application (BBCH < 18) of product Ethosat 500 SC in tank mix with adjuvant, it is not expected to have any negative impact on residues or exceedance of currently applicable MRLs. In addition, the adjuvant Atpolan BIO 80 EC has been widely used in Poland with a wide range of herbicides for many years and no impact on residue levels of these plant protection products has been observed.*

*However, taking into account that a guideline introducing the obligation to submit for new registrations or extensions of existing authorizations residue studies of the mixture with the adjuvant was published on November 4,*

*2021, and the application for Ethosat 500 SC was submitted to Authorities on April 16, 2021, we believe that the above guideline should not apply in the evaluation of Ethosat 500 SC, as the Applicant was not able to comply with the new requirements."*
zRMS-PL agrees with Applicant position. Due to early application (BBCH < 18) of product Ethosat 500 SC in tank mix with oil adjuvant, no significant increase in residue level in/on harvested sugar beet roots is expected. No additional data are required.

## 7.2.4 Magnitude of residues in livestock

### 7.2.4.1 Dietary burden calculation

According to the OECD guidance document on residues in livestock (ENV/JM/MONO(2013)8), fodder beets, sugar beet tops, dried pulp of beets, ensiled pulp of beets and molasses are the beet matrices fed to livestock. In addition, rotational crops, planted directly after crop failure (within 30 days after treatment of the failed beet crop) can show small ethofumesate related residues. These rotational crops can also contribute to the animal diet. The dietary burdens were calculated for different groups of livestock using the EFSA calculator[1].
The dietary burden calculation made by EFSA (2012) in the framework of the Art. 12 evaluation is available for ethofumesate. Evaluation was done for use on several crops that might be fed to livestock using the agreed European methodology (European Commission, 1996). As no data were reported on magnitude of residues in sugar/fodder beet tops and grass, these commodities were not taken into account and consequently the intake was underestimated. Data for sugar and fodder beet, and additional relevant data, are now included in the table below as given in the EFSA peer review for the active substance renewal (EFSA, 2016).

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

| Feed Commodity | Median dietary burden | | Maximum dietary burden | |
|---|---|---|---|---|
| | Input value (mg/kg) | Comment | Input value (mg/kg) | Comment |
| Risk assessment residue definition: Ethofumesate (Sum of ethofumesate, 2-keto-ethofumesate (NC 9607), open-ring-2-keto-ethofumesate (NC 20645) and its conjugate, expressed as ethofumesate) | | | | |
| **1-Forages** | | | | |
| Barley (forage) | 0.03 | Median residue, rotational crops (EFSA; 2016) | 0.03 | Median residue, rotational crops (EFSA; 2016) |
| Beet, mangel (fodder) | ~~0.10~~ 0.06 | Median residue primary crop (see Table 7.2-10) ~~+ rotational crop: root crops, root (0.06 + 0.04)~~ | ~~0.15~~ 0.1 | Highest residue primary crop (see Table 7.2-10) ~~+ rotational crop: root crops, root (0.1 + 0.05)~~ |
| Sugar/fodder beet (tops) | ~~0.10~~ 0.06 | Median residue primary crop (see Table 7.2-10) ~~+ rotational crops: root crops, leaves (0.06 + 0.04)~~ | ~~0.22~~ 0.18 | Highest residue primary crop (see Table 7.2-10) ~~+ rotational crops: root crops, leaves (0.18 + 0.04)~~ |
| Corn, field (forage, silage) | 0.03 | Median residue, rotational crops (EFSA; 2016) | 0.03 | Median residue, rotational crops (EFSA; 2016) |
| Millet (forage) | 0.03 | Median residue, rotational crops (EFSA; 2016) | 0.03 | Median residue, rotational crops (EFSA; 2016) |
| Oats (forage) | 0.03 | Median residue, rotational crops (EFSA; 2016) | 0.03 | Median residue, rotational crops (EFSA; 2016) |

[1] http://ec.europa.eu/food/plant/docs/pesticides_mrl_guidelines_animal_model_2016.xls

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

DM = Dry matter
PF = Processing factor

**Table 7.2-12: Results of the dietary burden calculation**

| ~~Animal species~~ | ~~Median dietary burden (mg/kg bw/d)~~ | ~~Maximum dietary burden (mg/kg bw/d)~~ | ~~Highest contributing commodity~~ | | ~~Max dietary burden (mg/kg DM)~~ | ~~Trigger exceeded (Y/N)~~ |
|---|---|---|---|---|---|---|
| ~~Risk assessment residue definition: Sum of ethofumesate, ethofumesate-lactone (NC 9607), ethofumesate carboxylic acid (NC 20645), and its conjugate expressed as ethofumesate~~ | | | | | | |
| ~~Beef cattle*~~ | ~~0.011~~ | ~~0.015~~ | ~~Bett, sugar~~ | ~~molasses~~ | ~~0.61~~ | ~~Yes~~ |

| 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) |
|---|---|---|---|---|---|---|
| Dairy cattle* | 0.016 | 0.021 | Beet, sugar | tops | 0.55 | Yes |
| Ram/ewe | 0.013 | 0.017 | Beet, sugar | tops | 0.50 | Yes |
| Lamb | 0.016 | 0.021 | Beet, sugar | tops | 0.51 | Yes |
| Breeding swine | 0.008 | 0.010 | Beet, mangel | fodder | 0.44 | Yes |
| Finishing swine* | 0.008 | 0.009 | Swede | roots | 0.29 | Yes |
| Broiler poultry | 0.004 | 0.004 | Swede | roots | 0.06 | Yes |
| Layer poultry* | 0.005 | 0.007 | Beet, sugar | tops | 0.11 | Yes |
| Turkey | 0.004 | 0.004 | Swede | roots | 0.06 | Yes |

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

**zRMS comments:**
Taking into account the inputs for animal burden calculations presented in EFSA Journal 2016;14(1):4374 (several values have been corrected in the Table 7.2-11), the median and maximum dietary burdens has been calculated for different groups of livestock using the EFSA Animal model 2017 and the results are presented below:

**Table 7.2-12: Results of the dietary burden calculation (Animal Model 2017)**

| Relevant groups | Dietary burden expressed in | | | | Most critical diet (a) | Most critical commodity (b) | | Trigger exceeded (Yes/No) |
|---|---|---|---|---|---|---|---|---|
| | mg/kg bw per day | | mg/kg DM | | | | | 0.004 |
| | Median | Maximum | Median | Maximum | | | | mg/kg bw |
| Cattle (all diets) | 0,013 | 0,017 | 0,39 | 0,51 | Dairy cattle | Beet, mangel | fodder | Yes |
| Cattle (dairy only) | 0,013 | 0,017 | 0,35 | 0,44 | Dairy cattle | Beet, mangel | fodder | Yes |
| Sheep (all diets) | 0,014 | 0,017 | 0,34 | 0,40 | Lamb | Swede | roots | Yes |
| Sheep (ewe only) | 0,011 | 0,013 | 0,34 | 0,40 | Ram/Ewe | Swede | roots | Yes |
| Swine (all diets) | 0,008 | 0,009 | 0,31 | 0,39 | Swine (breeding) | Beet, mangel | fodder | Yes |
| Poultry (all diets) | 0,004 | 0,006 | 0,06 | 0,08 | Poultry layer | Swede | roots | Yes |
| Poultry (layer only) | 0,004 | 0,006 | 0,06 | 0,08 | Poultry layer | Swede | roots | Yes |

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

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

**Available data**
*Reference: Austria, 2015a; EFSA, 2016*
Significant intakes (>0.004 mg/kg bw/day) were calculated for livestock. Metabolism studies in cow, sheep and hens were presented in the RAR (Austria, 2015a). No feeding study in pigs is required because metabolic pathways in the rat, in ruminants and in poultry are similar (*Austria, 2015a*).
No new data are submitted in the framework of this application.

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

livestock metabolism studies, and the corresponding maximum dietary burden of the animal, it can be concluded that the residues in all animal matrices will not exceed 0.01 mg/kg and therefore no feeding studies have to be conducted, neither in ruminants nor in poultry.
Nevertheless, in the scope of the original Annex II submission in 1996, a feeding study in poultry and two feeding studies in lactating cow were submitted and evaluated. All feeding studies were conducted in the US and did not completely follow the EU guidelines, however confirmed the low transfer of the ethofumesate related residues in edible matrices." (*Austria, 2015a)*
No residues above 0.01 mg/kg are expected in animal tissues." (*EFSA, 2016*)
Details of transfer factors calculated are shown in the tables below:

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

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

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

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

**Conclusion on feeding studies**
Considering the transfer factors for the total radioactive residue in an animal matrix, as estimated in the livestock metabolism studies (Table 7.2-13 and Table 7.2-14), and the calculated corresponding maximum dietary burden of the animals (see Table 7.2-12), it can be concluded that the ethofumesate residues in all animal matrices will not exceed 0.01 mg/kg.
The conclusions drawn in EFSA (2012, 2016) and Austria (2015a) on existing MRLs are considered to be still valid and no further data are considered necessary.

**zRMS comments:**
Data presented by Applicant in point 7.2.4.2 have been accepted and are sufficient to support the proposed uses. It should be noted that the dietary intakes of ruminants and poultry are low and therefore residue levels are expected to remain below the LOQ when AG-E1-500 SC1 is applied according to the intended GAPs.
The intended uses of ethofumesate in the product AG-E1-500 SC1 (Ethosat 500 SC) do not lead to an exceedance of the existing EU MRLs for animal commodities.

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

### 7.2.5.1 Available data for all crops under consideration

*References*: *Sweden, 1998; EFSA, 2016*
Processing studies for ethofumesate have been conducted on sugar beet (sugar, molasses, wet pulp, thick juice and thin raw juice).

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

**Table 7.2-15: Overview of the available processing studies**

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

N/A = Not applicable

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

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

**Summary of processing studies reported in the EU**

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

### 7.2.5.2 Conclusion on processing studies

Processing studies have been submitted but are not required to support the proposed uses of ethofumesate in this submission, as the trigger for requiring such studies is not met by the envisaged uses for AG-E1-500 SC1.

**zRMS comments:**
Information given by the Applicant is sufficient. 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 AG-E1-500 SC1.

## 7.2.6 Magnitude of residues in representative succeeding crops

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

### 7.2.6.1 Field rotational crop studies (KCA 6.6.2)

**Available data**

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

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

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

**Table 7.2-16: Summary of available studies in field rotational crops**

| Primary crop | Rate (kg a.s./ha) (GS at application or PHI) | Residue levels in succeeding crops | | | | |
|---|---|---|---|---|---|---|
| | | Succeeding crop group | Succeeding crop | Sowing intervals (DAT) | Remarks | Reference |
| **EU data** | | | | | | |
| Sugar beet | 6-8 (no data) | Cereals | Wheat, maize | Not reported in the monograph, but are expected to be almost one year. | Castro, L. E., 1994 Report A83117<br><br>Crofts, M.; Whiteoak, R. J., 1974a Report A82995<br><br>Crofts, M.; Whiteoak, R. J., 1974b Report A82994<br><br>Peatman, M. H.; Snowdon, P. J., 1991 Report A83376 | Sweden, 1998 EFSA, 2012 Austria, 2015a, b |
| Sugar beet | 3.45 and 5.58 (12 months only) | Leafy vegetables | Spinach, cabbage | 6 months<br>12 months | | |
| | | Root and tuber vegetables | Carrot, potato, red beet | 6 months<br>12 months | | |
| | | Cereals | Barley, sorghum, oats | 6 months<br>12 months | | |
| Sugar beet | 1.5 | Leafy vegetables | Spinach | 30<br>70 | | |
| | | Cereals | Maize | 30<br>70 | | |
| Sugar beet | 1.0 (to soil or sugar beet at BBCH 16 or 18) | Leafy vegetables | Lettuce | 25-29<br>57-259<br>320-354 | Schulte, G., Diehl, P., 2013 Report 10-2501 | Austria, 2015a, b EFSA, 2016 |
| | | Root and tuber vegetables | Carrot | 25-29<br>54-259<br>320-354 | | |
| | | Cereals | Barley | 25-33<br>131-259<br>284-330 | | |
| Sugar beet | 1.0 (to soil or at BBCH 14-16) | Leafy vegetables | Spinach | 30-41<br>90-103<br>335 | Spence, C., 2014 Report 34890 | Austria, 2015a, b EFSA, 2016 |
| | | Root and tuber vegetables | Carrot or radish | 30-40<br>90-103<br>335 | | |
| | | Cereals | Spring barley or winter wheat | 30-31<br>176-180<br>335 | | |

**Conclusion on rotational crops studies**

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

- 0.05 mg/kg in root crops
- 0.03 mg/kg in leafy crops
- 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 were always below the LOQ of 0.01 mg/kg." (*EFSA, 2016)*

**Risk mitigation measures**

Pre-harvest interval for each relevant crop

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

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

AG-E1-500 SC1 for root crops is not intended for use in areas to be grazed by livestock. Therefore, a re-entry period does not need to be established.

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

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

b) Buildings: Not relevant.

c) Spaces: Not relevant

Withholding period (in days) for animal feedingstuffs

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

Waiting period between last application and sowing or planting

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

Waiting period between application and handling treated products

The last application of ethofumesate-containing products is intended in root crops at an early growth stage (BBCH 18), thus significant time prior to harvest. There is no need to handle treated crops before harvest.

Waiting period before sowing/planting succeeding crops

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

**zRMS comments:**

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

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

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

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

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

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

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

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

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

*No residues of Ethofumesate and its metabolites included in the proposed residue definition need to be expected in rotational crops after application of Ethofumesate according to the intended GAP.*
*Summarising the above, it can be concluded that ethofumesate related residues are only expected at or slightly above the LOQ. The highest residues in mature crops were detected as ethofumesate in root crops up to 0.03 mg/kg where ethofumesate was applied as pre-emergence application on bare soil."*

It can concluded that residue of ethofumesate in rotational root crops ranged from <0.02 to 0.05 mg/kg (mature and immature crops) after a plant-back interval of 25-33 days. Residues of ethofumesate for any other plant-back interval were always below LOQ.
In lettuce, cereals grain and straw no residues of ethofumesate and NC 9607 above the LOQ of 0.01 mg/kg were detected.
To avoid MRL exceedance in root crops (the MRL value for the group of Root and tuber vegetables equals 0.03 mg/kg, excluding beetroots (0.2 mg/kg), the MRL value for sugar beet roots equals 0.2 mg/kg), the following mitigation measures should apply: **Do not grow root vegetables (except sugar or fodder beet) in case of crop failure**.

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

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

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of AG-E1-500 SC1. Therefore, other special studies are not needed.

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

Additionally to the full bee toxicity package with ethofumesate, further acute oral laboratory studies with the ethofumesate plant metabolites NC 20645, NC 8493 and NC 9607 were conducted. Comparing the endpoints of the acute studies, there is no indication that the metabolites are more toxic than the active substance. Therefore, it can be concluded that the risk from the metabolites will be covered by the assessment of the parent compound.
However, additional information such as residue data, attractiveness of agricultural crops and their typical cultivation practices are considered in the following to support this conclusion.

**Residues of ethofumesate in beet and rotational crops**

Beet (Beta vulgaris)

*Beta vulgaris* is mainly wind-pollinated and bees do only occasionally visit the crops (e.g. nectar collection). Beets are considered of low attraction to bees for pollen, but their collection cannot be excluded. However, exposure of bees can be considered as negligible given that sugar beets, fodder beets and beetroots are generally harvested in the first year, i.e. before flowering.
Bolting of sugar beets (starting of shoot elongation) during the first year of vegetation is only observed in rare cases (due to frost in late spring). In these cases, the respective shoots/plants are removed manually before flowering to avoid any seed spreading to the soil (and thus prevent seeds from uncontrolled germination and growing in the following years) in order to facilitate mechanical harvest. The removal of bolting sugar beets is common practice in agriculture. Thus, in the first vegetation year, no flowers of sugar beet are available for bees.
Flowers of *Beta vulgaris* are only present if crops are grown for seed production. The area used for seed production is very limited and represents less than 1% of the whole cultivation area of *Beta vulgaris* in Europe (ca. 8500 ha for sugar beets). For seed production the failure is extremely rare, as they are not sowing but planting small beets coming from nurseries.
However, even intense foraging of bees would not lead to any ethofumesate residues in bee bread and nectar. The half-life of total ethofumesate residues in sugar beet roots and leaves was estimated based on the total radioactive residues (TRR) determined in the sugar beet metabolism study (Caley *et al.*, 1994, A87553 (M-161455-01); RAR, Vol. 3, B7) at four different points in time (day 0, 7, 28 and 150 = maturity). Assuming first order kinetics, the DT50 of the TRR is approx. 21 days in shoots and approx. 22 days in roots. After application of 1.5 kg a.s./ha, the total ethofumesate residues in sugar beet shoots

declined from 126 mg/kg at the day of the last application (day 0) to 76.2 mg/kg at day 7 and to 0.75 mg/kg at day 150 (maturity), indicating a decline of 39.5% 7 days after application and 99.4% 150 days after application. Residues in shoots will be below 0.01 mg/kg after approx. 280 days (9-10 months). For roots, ethofumesate residues declined from 1.9 mg/kg at day 0 to 0.01 mg/kg at day 150 and a residue level of 0.01 mg/kg was reached after 145 days (approx. 5 months). For details please refer to RAR, Vol. 3, B7). As the metabolism study has been conducted in a protected area (glasshouse), even faster degradation can be assumed under field conditions, which was confirmed by a huge number of field residue trials.

Since *Beta vulgaris* are biennial crops, the flowers are formed in the second year and thus at a time when ethofumesate-related residues are generally <0.01 mg/kg in roots and in most cases also in leaves. Although ethofumesate-related residues cannot be completely excluded in leaves, a translocation of the residues into flowers and pollen is not very plausible. Eshel *et al.*[1] detected that acropetal translocation of radiolabelled ethofumesate-related residues was rapid, but there was no translocation out of the leaves. Furthermore, ethofumesate or its metabolites were not translocated basipetally after foliar application. Thus, even metabolite NC 20645, which should be phloem mobile according to its physicochemical properties (pka1 = 4.8 at pH = 4-5 and pKa2 = 11.7 at pH = 10-13 and log $P_{ow}$ = 0.4 at pH = 5 and log $P_{ow}$ = -2.4 at pH = 9) and which should be present in the samples under investigation, was only transported in the xylem. An explanation could be that the metabolite was already conjugated and thus its mobility properties were changed. Based on this publication, the residues in the leaves cannot be re-translocated in the roots before the leaves die during winter. As a consequence the residues are no longer available for transport in the new shoots and the flowers in the second year.

The low incidence of residues of ethofumesate in bees, pollen and honey is also indicated in a review by Johnson *et al.*[2], which collated residues data in the United States from more than 150 different pesticides over the past 20 years. Under field conditions, residues of ethofumesate were found to be always below detection in bees, pollen and honey. Only wax contained residues of up to 0.56 mg/kg ethofumesate.

Rotational crops

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

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

**Table 7.2-17: Highest residues in crops of the 1st rotation**

| **Commodity** | **Highest residue in 1st rotation [mg a.s. equiv./kg]** | | |
|---|---|---|---|
| | **Ethofumesate** | **NC 9607** | **Total** |
| Carrot, leaf | 0.03 | <0.01 | 0.04 |
| Carrot, root | 0.04 | <0.01 | 0.05 |
| Lettuce (BBCH 41) | 0.02 | 0.01 | 0.03 |
| Lettuce (BBCH 49) | <0.01 | <0.01 | <0.02 |

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

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

| | | | |
|---|---|---|---|
| Barley/wheat, green material (BBCH 30) | <0.01 | 0.02 | 0.03 |

LOQ = 0.01 mg/kg

Carrots (representative crop for root crops)
Generally, bees are not foraging in root crops. However, visits by bees during pollen and nectar collection cannot be excluded.
Considering that carrots are usually harvested before flowering they would not represent a route of exposure based on typical cultivation practices. Additionally, as for the primary crop (sugar beet), no ethofumesate residues (<0.01 mg/kg) will be available in the roots when the flowers are formed in the second vegetation year. Even after late sowing (June-July), residues in roots will be below 0.01 mg/kg before forming the flowers in early summer.

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

Barley/wheat (representative crop for cereals)
Generally, bees are not foraging in cereals as they low attractive to bees. However, it is known that bees can collect some pollen of cereals when they forage close to fields.
In Europe, it is very common to grow sugar beets and winter cereals in rotation, however winter cereals cannot be sown before September. Considering agricultural practice, the interval between the treatment of the sugar/fodder beet with ethofumesate (April/May) and sowing of cereals due to crop failure cannot be shorter than 4-5 months. Flowering of the winter cereals will be in May in the following year at the earliest (barley) and thus approx. 1 year after application of ethofumesate. Checking the residue values of green material in the field rotational crop study, it can be shown that ethofumesate-related residues were <0.01 mg/kg in all sample materials (green material, grain and straw) when collected approx. 300 days after application of ethofumesate. Thus, translocation of residues in pollen of cereals can be excluded.
Due to the early application of ethofumesate in the season and the rather short half-life of ethofumesate-related residues in crops, translocation of these residues in flowers and therefore in nectar and pollen is not very plausible.
Generally, the residues will be <0.05 mg/kg in the aerial plant matrix before formation of flowers. Moreover a translocation or even selective enrichment of ethofumesate-related residues in nectar and in pollen was excluded in a study conducted with radiolabelled ethofumesate. In this study no phloem mobile component was detected within 15 days following foliar application. Apparently, ethofumesate and its metabolites (which should be formed at this time) are unable to enter the phloem. Moreover, a selective enrichment of ethofumesate traces in nectar can be excluded due to the hydrophobic character of ethofumesate-related residues.
Based on these results, residues in pollen and nectar can be excluded in *Beta vulgaris*, weeds and in all succeeding crops (e.g. maize, sunflower) in the central zone.
Thus a risk for the consumer can be excluded –especially when considering that ethofumesate residues up to 10,000 mg/kg in honey would be still safe for the consumer (EFSA PRIMo rev. 2.0), even when calculating with all MRLs.

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

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

Toxicological reference values relevant for dietary risk assessment are reported in the summary of the

evaluation (see 7.1.2).
As an ARfD was not deemed necessary, acute risk assessment is not relevant.

#### 7.2.8.1 Input values for the consumer risk assessment

The input values for the consumer risk assessment (TMDI calculation) are given in Appendix 3 (A 3.1). Current EU MRLs (Reg. (EU) 2017/1016) were used for all commodities.

**Table 7.2-18: Input values for the consumer risk assessment**

| Commodity | Chronic risk assessment | | Acute risk assessment | |
|---|---|---|---|---|
| | Input value (mg/kg) | Comment | Input value (mg/kg) | Comment |
| Risk assessment residue definition : Sum of ethofumesate, ethofumesate-lactone (NC 9607), ethofumesate carboxylic acid (NC 20645), and its conjugate expressed as ethofumesate | | | | |
| Sugar beet (root) | 0.2 | MRL (Reg. (EU) 2017/1016) | Not relevant | |
| All other commodities | MRL | | | |

#### 7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 4.

**Table 7.2-19: Consumer risk assessment**

| | |
|---|---|
| TMDI (% ADI) according to EFSA PRIMo 3.1 | 0.5 % (based on NL toddler) |
| IEDI (% ADI) according to EFSA PRIMo | -- |
| NTMDI (% ADI) ** | -- |
| NEDI (% ADI)** | -- |

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

The proposed uses of ethofumesate in the formulation AG-E1-500 SC1 do not represent unacceptable chronic risks for the consumer.

**zRMS comments:**
The consumer risk assessments were performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo). The calculation of the TMDI using EFSA model (version 3.1) and MRLs according to Reg. (EU) 2017/1016 led to a utilisation of the ADI of 0.5% with the NL toddler being the population group with the highest value. For this diet, the highest contributor is Milk: Cattle with 0.2% of the ADI.
The intended uses will not result in a consumer chronic exposure exceeding the ADI.
As no ARfD has been set for ethofumesate, an acute risk assessment was not conducted.

### 7.3 Combined exposure and risk assessment

Not relevant. The product contains only one active substance.

## 7.4 References

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

Austria, 2015b. Revised renewal assessment report (RAR) on ethofumesate, compiled by EFSA, December 2015. Available online: www.efsa.europa.eu

EFSA (European Food Safety Authority), 2012. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for ethofumesate according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2012;10(11):2959 [43 pp.] doi:10.2903/j.efsa.2012.2959. Available online: www.efsa.europa.eu/efsajournal

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

Sweden, 1998. Draft assessment report (DAR) on the active substance ethofumesate prepared by the rapporteur Member State, Sweden, in the framework of Council Directive 91/414 (EEC). Available online: www.efsa.europa.eu

Sweden, 2000. Addendum to the draft assessment report on the active substance ethofumesate prepared by the rapporteur Member State Sweden in the framework of Council Directive 91/414/EEC, December 2000

# 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**<br>**Company Report No.**<br>**Source (where different from company)**<br>**GLP or GEP status**<br>**Published or not** | Vertebrate study Y/N | Owner |
|---|---|---|---|---|---|
| KCP 8/01 (KCA 6.1/01) | Schulte, G. | 2015 | Storage Stability of open-ring-2-keto ethofumesate (AE C520645) in Plant Matrices for 24 Months<br>Bayer CropScience AG, 40789 Monheim, Germany<br>Report No. MR-12/058<br>Study ID P642120507<br>GLP<br>Unpublished | N | TFE |
| KCP 8/02 (KCA 6.1/02) (and KCP 5.1.2/01) | Watson, G. | 2021 | Ethofumesate: Storage Stability of Residues of Ethofumesate and its Metabolite in Lettuce and Cereal Grain Stored Frozen for up to Two Years; Interim Report 1.<br>Report No. RES-00278<br>Study ID 000106576<br>GLP<br>Unpublished | N | ADAMA |

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

The list below was not validated by the zRMS since majority of the active substance data have been taken from the EU review of Ethofumesate and the complete list of studies evaluated at the EU level is provided in Vol. 2 of the RAR (2015).

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

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

| Data point | Author(s) | Year | **Title**<br>**Company Report No.**<br>**Source (where different from company)**<br>**GLP or GEP status**<br>**Published or not** | Vertebrate study Y/N | Owner |
|---|---|---|---|---|---|
| KCA 6.1 | Whiteoak, R. J. | 1975 | STABILITY OF RESIDUES DURING STORAGE OF CROP AND SOIL SAMPLES FROM TRIALS WITH NORTRON<br>Fisons plc, United Kingdom<br>Bayer Crop Science, Report No.: A83296,<br>Edition Number: M-155565-01-1 Date: 1975-08-01 | N | Bayer CropScience |

| Data point | Author(s) | Year | **Title**<br>**Company Report No.**<br>**Source (where different from company)**<br>**GLP or GEP status**<br>**Published or not** | **Vertebrate study Y/N** | **Owner** |
|---|---|---|---|---|---|
| | | | No GLP<br>Unpublished | | |
| KCA 6.1 | Bright, J. H. M. | 1991 | STABILITY OF ETHOFUMESATE AND NC 9607 RESIDUES IN SUGARBEET ROOTS AND TOPS DURING DEEP FREEZE STORAGE<br>Schering AG, Berlin, Germany<br>Bayer CropScience, Report No.: A83111, Report includes Trial Nos.: 041/02/001<br>Edition Number: M-155386-01-1 Date: 1991-03-08<br>GLP<br>Unpublished | N | Bayer CropScience |
| KCA 6.1 | Schulte, G. | 2013 | Storage stability of open-ring-2-keto ethofumesate (AE C520645) in plant matrices for 24 months - Phase report after 6 months<br>Bayer CropScience, Report No.: MR-13/086,<br>Edition Number: M-459806-01-1 Date: 2013-07-11<br>GLP<br>Unpublished | N | Task Force Ethofumesate |
| KCA 6.1 | Hamberger, R. | 2013 | Determination of the storage stability of Ethofumesate and its metabolite NC20645 in sugar beet matrices during storage at < or = to - 18°C for a period of 12 months AgriChem B.V., 12A04042-01-SSSB<br>CIP Chemisches Institut Pforzheim GmbH<br>GLP<br>Unpublished | N | ACM* |
| KCA 6.1 | Schlewitz, P. | 2014 | Frozen storage stability of residues of ethofumesate metabolite NC 20645 in sugar beet (roots and tops with leaves)<br>United Phosphorus Ltd., R B1312 ANADIAG<br>GLP<br>Unpublished | N | UPL |
| KCA 6.1 | Perez, R.; Schmitt, J. L.; Patel, D. | 2014 | Freezer storage stability of ethofumesate in animal matrix samples - interim report<br>ADPEN Laboratories, Inc.,<br>Jacksonville, FL, USA<br>Bayer CropScience, Report No.: RAADP031,<br>Edition Number: M-467206-02-1<br>Date: 2013-09-26<br>GLP<br>Unpublished | N | Task Force Ethofumesate |
| KCA 6.2 /01 | Miller, C. | 1999 | Summary of the metabolism of ethofumesate in plants Ethofumesate AE B049913 AgrEvo UK Crop Protection Ltd., Chesterford Park, United Kingdom Bayer CropScience, Report No.: C003349,<br>Edition Number: M-185979-01-1<br>No GLP<br>Unpublished | N | Bayer CropScience |
| KCA 6.2.1 | Adcock, J. W.; | 1976 | The metabolism of $^{14}C$- ethofumesate in the onion | N | Bayer |

| Data point | Author(s) | Year | **Title**<br>**Company Report No.**<br>**Source (where different from company)**<br>**GLP or GEP status**<br>**Published or not** | **Vertebrate study Y/N** | **Owner** |
|---|---|---|---|---|---|
| /01 | Warner, P. A., Challis, I. R. | | Fisons plc, United Kingdom<br>Bayer Crop Science, Report No.: A82959,<br>Edition Number: M-155236-01-1 Date: 1976-10-01<br>No GLP<br>Unpublished | | CropScience |
| KCA 6.2.1 /02 | Warner, P. A.; Adcock, J. W. | 1977 | Metabolism of ethofumesate in tobacco<br>Fisons plc, united kingdom<br>Bayer Crop Science, Report no.: A82963,<br>Edition number: m-155240-01-1 date: 1977-12-01<br>No GLP<br>Unpublished | N | Bayer CropScience |
| KCA 6.2.1 /03 | Lines, D. S.; Adcock, J. W. | 1978 | The metabolism of ethofumesate by sugar beet under greenhouse conditions<br>Fisons plc, United Kingdom<br>Bayer Crop Science, Report No.: A82964,<br>Edition Number: M-155241-01-1 Date: 1978-12-01<br>No GLP<br>Unpublished | N | Bayer CropScience |
| KCA 6.2.1 /04 | Lines, D. S.; Adcock, J. W. | 1979 | The metabolism of ethofumesate (98% pure $^{14}C$ - ethofumesate) by sugar beet under field conditions<br>Fisons plc, United Kingdom<br>Bayer Crop Science, Report No.: A82965,<br>Edition Number: M-155242-01-1 Date: 1979-01-01<br>No GLP<br>Unpublished | N | Bayer CropScience |
| KCA 6.2.1 /05 | Chapleo, S. | 1992 | The metabolism of [$^{14}C$]- ethofumesate in sugar beet - a glasshouse study<br>Inveresk Research Int. Ltd., Tranent, Scotland<br>Bayer CropScience, Report No.: A82970, Report includes Trial Nos.: 381174<br>ENVIR 84B<br>Edition Number: M-155247-01-1 Date: 1992-09-22<br>GLP<br>Unpublished | N | Bayer CropScience |
| KCA 6.2.1 /06 | Caley, C. Y.; Chapleo, S.; Haswell, A. | 1994 | The metabolism of $^{14}C$- ethofumesate in sugar beet<br>Inveresk Research Int. Ltd., Tranent, Scotland<br>Bayer CropScience, Report No.: A87553,<br>Report includes Trial Nos.: 382445<br>Edition Number: M-161455-01-1 Date: 1994-06-01<br>GLP<br>Unpublished | N | Bayer CropScience |
| KCA 6.2.1 /07 | Chapleo, S. | 1992 | The metabolism of [$^{14}C$]- ethofumesate in annual ryegrass - a glasshouse study<br>Inveresk Research Int. Ltd., Tranent, | N | Bayer CropScience |

| Data point | Author(s) | Year | **Title**<br>**Company Report No.**<br>**Source (where different from company)**<br>**GLP or GEP status**<br>**Published or not** | Vertebrate study Y/N | Owner |
|---|---|---|---|---|---|
| | | | Scotland<br>Bayer CropScience, Report No.: A82971,<br>Report includes Trial Nos.: 381169<br>ENVIR 85B<br>Edition Number: M-155248-01-1 Date: 1992-09-17<br>GLP<br>Unpublished | | |
| KCA 6.2.1 /08 | Mellet, M. | 1993 | Determination of the residues of ethofumesate, ethofumesate-2- keto and the conjugates in sugar beets after application of Ethosat 500 SC in France, 1992<br>ANADIAG S.A., Haguenau, France Feinchemie Schwebda,<br>Report No.: M-468491-01-1,<br>Report includes Trial Nos.: 92HBEBI01, 92HBEBI06<br>Edition Number: M-468491-01-1 Date: 1993-06-07<br>GLP<br>Unpublished | N | Adama (former Feinchemie Schwebda) |
| KCA 6.2.1/01 (KCA 6.2.1/09) | Hennecke, D. | 2003 | Metabolism of Ethofumesate in sugar beets<br>United Phosphorus Ltd., GAB-002/7-08<br>Fraunhofer Institute for Molecular Biology and Applied Ecology (IME), Schmallenberg, Germany<br>GLP<br>Unpublished | N | UPL |
| KCA 6.2.2 /01 | Hawkins, D. R.; Elsom, L. F.; Dighton, M. H.; Cameron, D. M. | 1992 | THE METABOLISM OF $^{14}$C ETHOFUMESATE IN LAYING HENS<br>Huntingdon Research Centre Ltd., Huntingdon, United Kingdom<br>Bayer CropScience, Report No.: A82969,<br>Report includes Trial Nos.: SMS 297/920431<br>TOX 90542<br>Edition Number: M-155246-01-1<br>Date: 1992-06-09<br>GLP<br>Unpublished | Y | Bayer CropScience |
| KCA 6.2.2 /02 | Moss, T.; Reynolds, C. M. M. | 1999 | Poultry - Metabolism, Distribution and nature of the residues in eggs and edible tissues Code AE B049913<br>AgrEvo UK Crop Protection Ltd.,<br>Chesterford Park, United Kingdom<br>Bayer CropScience, Report No.: C002998,<br>Report includes Trial Nos.: Tox97227<br>Edition Number: M-185380-01-1<br>Date: 1999-06-01<br>GLP<br>Unpublished | Y | Bayer CropScience |

| Data point | Author(s) | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not | Vertebrate study Y/N | Owner |
|---|---|---|---|---|---|
| KCA 6.2.3 /01 | Warner, P. A. | 1976 | THE METABOLISM OF $^{14}$CETHOFUMESATE IN THE SHEEP<br>Fisons plc, United Kingdom<br>Bayer CropScience, Report No.: A82958,<br>Edition Number: M-155235-01-1<br>Date: 1976-09-01<br>No GLP<br>Unpublished | Y | Bayer CropScience |
| KCA 6.2.3 /02 | Dean, G. M.; Aikens, P. J.; Saxton, J. E.; Cheng, K. N.; Cameron, D. M.; Kirkpatrick, D. | 1992 | THE METABOLISM OF $^{14}$C-ETHOFUMESATE IN THE COW<br>Huntingdon Research Centre Ltd.,<br>Huntingdon, United Kingdom<br>Bayer CropScience, Report No.: A82968,<br>Report includes Trial Nos.:<br>SMS 296/920441<br>TOX 90541<br>Edition Number: M-155245-01-1<br>Date: 1992-06-04<br>GLP<br>Unpublished | Y | Bayer CropScience |
| KCA 6.2.3 /03 | Reynolds, C. M. M. | 1999 | Metabolism, distribution and nature of the residues in milk and edible tissues Ethofumesate ruminant<br>Code: AE B049913<br>AgrEvo UK Crop Protection Ltd.,<br>Chesterford Park, United Kingdom<br>Bayer CropScience, Report No.: C003362,<br>Report includes Trial Nos.:<br>TOX97226<br>Edition Number: M-185993-01-1<br>Date: 1999-04-07<br>No GLP<br>Unpublished | Y | Bayer CropScience |
| KCA 6.3.5 /01 | Crofts, M. | 1975 | RESIDUES IN FODDER BEET AND RED BEET FROM 1974 APPLICATIONS OF NORTRON IN THE UK<br>Fisons plc, United Kingdom<br>Bayer CropScience, Report No.: A83007,<br>Edition Number: M-155284-01-1 EPA MRID No.: 41214220<br>Date: 1975-05-01<br>No GLP<br>Unpublished | N | Bayer CropScience |
| KCA 6.3.5 /02 | Crofts, M.; Whiteoak, R. J. | 1976 | RESIDUES IN MANGOLDS, FODDER BEET AND RED BEET FROM 1975 AND 1976 APPLICATIONS OF NORTRON IN THE UK (AND 1 RED BEET TRIAL IN SWEDEN)<br>Fisons plc, United Kingdom | N | Bayer CropScience |

| Data point | Author(s) | Year | **Title**<br>**Company Report No.**<br>**Source (where different from company)**<br>**GLP or GEP status**<br>**Published or not** | **Vertebrate study Y/N** | **Owner** |
|---|---|---|---|---|---|
| | | | Bayer CropScience, Report No.: A83020,<br>Edition Number: M-155297-01-1 EPA MRID No.: 41214219<br>Date: 1976-09-01<br>No GLP<br>Unpublished | | |
| KCA 6.3.5 /03 | Crofts, M.; Whiteoak, R. J. | 1977 | RESIDUES IN RED BEET ROOTS FROM 1976 TRIALS WITH NORTRON IN AUSTRALIA<br>Fisons plc, United Kingdom<br>Bayer CropScience, Report No.: A83022,<br>Edition Number: M-155299-01-1 EPA MRID No.: 41214220<br>Date: 1977-02-01<br>No GLP<br>Unpublished | N | Bayer CropScience |
| KCA 6.3.5 /04 | Crofts, M. | 1978 | HARVEST RESIDUES IN RED BEET FROM NORTRON TRIALS IN THE USA (NEW YORK, TEXAS AND WISCONSIN) IN 1976/77<br>Fisons plc, United Kingdom<br>Bayer CropScience, Report No.: A83036,<br>Edition Number: M-155313-01-1<br>EPA MRID No.: 41214219 Date: 1978-01-31<br>No GLP<br>Unpublished | N | Bayer CropScience |
| KCA 6.3.5 /05 | Crofts, M. | 1978 | HARVEST RESIDUES IN RED BEET FROM A NORTRON TRIAL IN CANADA IN 1977<br>Fisons plc, United Kingdom<br>Bayer CropScience, Report No.: A83039,<br>Edition Number: M-155316-01-1 EPA MRID No.: 41214233<br>Date: 1978-11-02<br>No GLP<br>Unpublished | N | Bayer CropScience |
| KCA 6.3.5 /06 | Wrede, A. | 1995 | Residues in red beet after application of Betanal progress in France 1993<br>Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany<br>Bayer CropScience, Report No.: A83118, Report includes Trial Nos.:<br>PF-R 93 098<br>Edition Number: M-155393-01-1 Date: 1995-04-04<br>GLP<br>Unpublished | N | Bayer CropScience |
| KCA 6.3.5 /07 | Crofts, M.; Whiteoak, R. J. | 1973 | HARVEST RESIDUES IN SUGAR BEET (ROOTS AND LEAVES) FROM 1972 TRIALS WITH NORTRON IN THE UK<br>Fisons plc, United Kingdom<br>Bayer CropScience, Report No.: A82975,<br>Edition Number: M-155252-01-1 EPA MRID No.: acc.36374 | N | Bayer CropScience |

| Data point | Author(s) | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not | Vertebrate study Y/N | Owner |
|---|---|---|---|---|---|
| | | | Date: 1973-07-01<br>No GLP<br>Unpublished | | |
| KCA 6.3.5 /08 | Crofts, M.; Whiteoak, R. J. | 1973 | HARVEST RESIDUES IN SUGAR BEET (ROOTS AND LEAVES) FROM FRENCH TRIALS WITH NORTRON IN 1972<br>Fisons plc, United Kingdom<br>Bayer CropScience, Report No.: A82976,<br>Edition Number: M-155253-01-1 EPA MRID No.: 41214219<br>Date: 1973-07-01<br>No GLP<br>Unpublished | N | Bayer CropScience |
| KCA 6.3.5 /09 | Crofts, M.; Whiteoak, R. J. | 1973 | HARVEST RESIDUES IN SUGAR BEET (ROOTS AND LEAVES) FROM DANISH TRIALS WITH NORTRON IN 1972<br>Fisons plc, United Kingdom<br>Bayer CropScience, Report No.: A82977,<br>Edition Number: M-155254-01-1 EPA MRID No.: 41214219<br>Date: 1973-08-01<br>No GLP<br>Unpublished | N | Bayer CropScience |
| KCA 6.3.5 /10 | Crofts, M.; Whiteoak, R. J. | 1973 | HARVEST RESIDUES IN SUGAR BEET (ROOTS AND LEAVES) FROM AUSTRIAN TRIALS WITH NORTRON IN 1972<br>Fisons plc, United Kingdom<br>Bayer CropScience, Report No.: A82978,<br>Edition Number: M-155255-01-1<br>Date: 1973-08-01<br>No GLP<br>Unpublished | N | Bayer CropScience |
| KCA 6.3.5 /11 | Crofts, M.; Whiteoak, R. J. | 1973 | HARVEST RESIDUES IN SUGAR BEET (ROOTS AND LEAVES) FROM 1972 TRIALS WITH NORTRON IN YUGOSLAVIA<br>Fisons plc, United Kingdom<br>Bayer CropScience, Report No.: A82979,<br>Edition Number: M-155256-01-1 EPA MRID No.: 41414219<br>Date: 1973-08-01<br>No GLP<br>Unpublished | N | Bayer CropScience |
| KCA 6.3.5 /12 | Whiteoak, R. J.; Crofts, M.; Harris, R. J. | 1973 | RESIDUES IN SUGAR BEET (ROOTS AND LEAVES) FROM 1972 TRIALS WITH NORTRON IN W. GERMANY (UPDATED)<br>Fisons plc, United Kingdom<br>Bayer Crop Science, Report No.: A82980, | N | Bayer CropScience |

| Data point | Author(s) | Year | **Title**<br>**Company Report No.**<br>**Source (where different from company)**<br>**GLP or GEP status**<br>**Published or not** | **Vertebrate study Y/N** | **Owner** |
|---|---|---|---|---|---|
| | | | Edition Number: M-155257-01-1 EPA MRID No.: 41214220<br>Date: 1973-10-01<br>No GLP<br>Unpublished | | |
| KCA 6.3.5 /13 | Whiteoak, R. J. | 1973 | RESIDUE DECLINE STUDIES IN COLORADO (USA) WITH SUGAR BEET TREATED PRE-EMERGENCE WITH NORTRON IN 1972<br>Fisons plc, United Kingdom<br>Bayer Crop Science, Report No.: A82982,<br>Edition Number: M-155259-01-1 EPA MRID No.: acc.36365<br>Date: 1973-12-01<br>No GLP<br>Unpublished | N | Bayer CropScience |
| KCA 6.3.5 /14 | Whiteoak, R. J.; Crofts, M. | 1974 | RESIDUE DECLINE STUDIES IN MICHIGAN (USA) WITH SUGAR BEET TREATED PRE-EMERGENCE WITH NORTRON IN 1972<br>Fisons plc, United Kingdom<br>Bayer Crop Science, Report No.: A82983,<br>Edition Number: M-155260-01-1 EPA MRID No.: acc.37839<br>Date: 1974-02-01<br>No GLP<br>Unpublished | N | Bayer CropScience |
| KCA 6.3.5 /15 | Crofts, M.; Whiteoak, R. J. | 1974 | NORTRON RESIDUE IN HARVEST SUGAR BEET FROM NINE REGIONS OF THE USA IN 1972<br>Fisons plc, United Kingdom<br>Bayer Crop Science, Report No.: A82986,<br>Edition Number: M-155263-01-1 EPA MRID No.: acc.36366<br>Date: 1974-03-01<br>No GLP<br>Unpublished | N | Bayer CropScience |
| KCA 6.3.5 /16 | Crofts, M.; Whiteoak, R. J. | 1974 | HARVEST RESIDUES IN SUGAR BEET FROM 1973 PRE-EMERGENCE APPLICATIONS OF NORTRON (TRAMAT) IN ITALY<br>Fisons plc, United Kingdom<br>Bayer Crop Science, Report No.: A82990,<br>Edition Number: M-155267-01-1<br>Date: 1974-06-01<br>No GLP<br>Unpublished | N | Bayer CropScience |

| Data point | Author(s) | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not | Vertebrate study Y/N | Owner |
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| KCA 6.3.1/10 | Anspach, T. | 2001 | Magnitude of the residue of Phenmedipham, Desmedipham, Ethofumesate and its metabolite 2- oxo-Ethofumesate in sugar beets (roots and leaves/tops) after the application of Betasana Trio under filed conditions in Germany, 2000 United Phosphorus Ltd., ADN-0004 Dr. Specht Partner, Chemische Laboratorien GmbH, Germany<br>GLP<br>Unpublished | N | UPL |
| KCA 6.3.1/11 | Tandy, R. | 2013 | Determination of residues of ETHOFUMSATE and ETHOFUMESATE-2-KETO, after one or three applications of ETHOFOL 500SC, or three application of BETASANA TRIO SC in sugar beet (outdoor) at 5 sites in Northern europe and 5 stes in Southern Europe 2010<br>United Phosphorus Ltd., S10-00258<br>Eurofins Agroscience Services LTD,<br>UK<br>GLP<br>Unpublished | N | UPL |
| KCA 6.3.1/12 | Waalkens, W.M.<br>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<br>AgriChem B.V., R03-16-SP-06<br>Res.Comp. for Plant Protec. "De Bredelaar" B.V., Elst, NL<br>GLP<br>Unpublished | N | ACM* |
| KCA 6.3.1/13 | Waalkens, W.M.,<br>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<br>AgriChem B.V., R03-16-FR-07<br>Res.Comp. for Plant Protec. "De Bredelaar" B.V., Elst, NL<br>GLP<br>Unpublished | N | ACM* |
| KCA 6.3.1/14 | Huaulmé, 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<br>AgriChem B.V., BPL12/435/GC<br>BIOTEK Agriculture<br>GLP | N | ACM* |

| Data point | Author(s) | Year | **Title**<br>**Company Report No.**<br>**Source (where different from company)**<br>**GLP or GEP status**<br>**Published or not** | **Vertebrate study Y/N** | **Owner** |
|---|---|---|---|---|---|
| | | | Unpublished | | |
| KCA 6.3.1/15 | Tandy, R. | 2012b | Validation of the analytical method A0019 to confirm the conversion of NC 20645 to NC 9607 in sugar beet roots and tops and wheat grain and straw<br>United Phosphorus Ltd., S11-03715<br>Eurofins Agroscience Service GmbH<br>No GLP<br>Unpublished | N | UPL |
| KCA 6.3.1/16 | Weir, A. | 2014 | METHOD MODIFICATION AND VALIDATION OF AN ANALYTICAL METHOD FOR THE DETERMINATION OF ETHOFUMESATE AND ITS METABOLITES NC 20645 AND NC 9607 IN SUGARBEET ROOTS AND TOPS<br>United Phosphorus Ltd., S13-03837 Eurofins Agroscience Services LTD, UK<br>GLP<br>Unpublished | N | UPL |
| KCA 6.4.1/01 | xxxxxxxxxxxxx | 1975 | INVESTIGATION OF TISSUE AND EGG - RESIDUES FROM HENS FOLLOWING DIETARY INTAKE OF NC 8438 FOR 21 DAYS<br>x, Report No.: A83011,<br>Edition Number: M-155288-01-1 Date: 1975-09-01<br>No GLP<br>Unpublished<br>...also filed: KCA 4.1.2 /27 | Y | Bayer CropScience |
| KCA 6.4.1/02 | xxxxxxxxxxxxxx | 1999 | Review of animal metabolism data; maximum estimated dietary concentration for poultry and cattle; rebuttal for further animal feeding studies Ethofumesate Code: AE B049913<br>xxxxxxxxxxxxxxxxxxxx, Report No.: C003329,<br>Edition Number: M-185950-01-1<br>No GLP<br>Unpublished<br>...also filed: KCA 6.4.2 /04 | Y | Bayer CropScience |
| KCA 6.4.2/01 | xxxxxxxxxx | 1977 | RESIDUES IN MILK AND TISSUES FOLLOWING A 28-DAY FEEDING STUDY WITH ETHOFUMESATE IN DAIRY COWS - PART 1<br>xxxxxxxxxxxxxxx, Report No.: A83024,<br>Edition Number: M-155301-01-1<br>EPA MRID No.: 41214208<br>Date: 1977-06-01<br>No GLP<br>Unpublished<br>...also filed: KCA 4.1.2 /25 | Y | Bayer CropScience |
| KCA 6.4.2/02 | Whiteoak, R. J. | 1977 | RESIDUES IN MILK AND TISSUES FOLLOWING A 28-DAY FEEDING STUDY WITH ETHOFUMESATE IN DAIRY COWS - PART 2<br>Fisons plc, United Kingdom | Y | Bayer CropScience |

| Data point | Author(s) | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not | Vertebrate study Y/N | Owner |
|---|---|---|---|---|---|
| | | | Bayer CropScience, Report No.: A89223,<br>Edition Number: M-164398-01-1<br>Date: 1977-06-01<br>No GLP<br>Unpublished | | |
| KCA 6.4.2/03 | xxxxxxxxxxxxxxx | 1994 | Ethofumesate-derived residues in the meat and milk of dairy cows: resulting from oral ingestion of ethofumesate<br>xxxxxxxxxxxxxxxxxxxxxxxxx, Report No.: B002201,<br>Report includes Trial Nos.:<br>B93R04/05<br>Edition Number: M-237976-01-1<br>EPA MRID No.: 43458701<br>Date: 1994-10-12<br>No GLP<br>Unpublished<br>...also filed: KCA 4.1.2 /29 | Y | Bayer CropScience |
| KCA 6.4.2 /04 | xxxxxxxxxxxx. | 1999 | Review of animal metabolism data; maximum estimated dietary concentration for poultry and cattle; rebuttal for further animal feeding studies Ethofumesate Code: AE B049913<br>Xxxxxxxxxxxxxxxxxxx<br>, Report No.: C003329,<br>Edition Number: M-185950-01-1<br>No GLP<br>Unpublished<br>...also filed: KCA 6.4.1 /02 | Y | Bayer CropScience |
| KCA 6.5.1 /01 | Miebach, D.; Bongartz, R. | 2010 | Nature of the residues of ethofumesate in processed commodities - High temperature hydrolysis<br>Bayer CropScience, Report No.: MEF-10/803,<br>Edition Number: M-397800-01-1 Date: 2010-12-09<br>GLP<br>Unpublished | N | Bayer CropScience |
| KCA 6.5.3 /01 | Whiteoak, R. J.; Crofts, M. | 1973 | CONJUGATED RESIDUES IN FRACTIONS PROCESSED FROM SUGAR BEET TREATED WITH NORTRON<br>Fisons plc, United Kingdom<br>Bayer Crop Science, Report No.: A82973,<br>Edition Number: M-155250-01-1 EPA MRID No.: acc.36368<br>Date: 1973-05-01<br>No GLP<br>Unpublished | N | Bayer CropScience |
| KCA 6.5.3 /02 | Crofts, M.; Whiteoak, R. J. | 1974 | FATE OF THE METABOLITE CONJUGATED NC 9607 DURING PRODUCTION OF SUGAR FROM NORTRON TREATED SUGAR BEET<br>Fisons plc, United Kingdom | N | Bayer CropScience |

| Data point | Author(s) | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not | Vertebrate study Y/N | Owner |
|---|---|---|---|---|---|
| | | | Bayer Crop Science, Report No.: A82985,<br>Edition Number: M-155262-01-1 EPA MRID No.: acc.36369<br>Date: 1974-03-01<br>No GLP<br>Unpublished<br>...also filed: KCA 4.1.2 /10 | | |
| KCA 6.5.3 /03 | Crofts, M.; Whiteoak, R. J. | 1975 | FATE OF THE METABOLITE CONJUGATED NC 9607 DURING PRODUCTION OF SUGAR FROM NORTRON TREATED SUGAR BEET - ARTIFICIALLY HIGH RESIDUES IN BEET GROWN AND PROCESSED IN THE UNITED KINGDOM<br>Fisons plc, United Kingdom<br>Bayer CropScience, Report No.: A83002,<br>Edition Number: M-155279-01-1 Date: 1975-03-01<br>No GLP<br>Unpublished | N | Bayer CropScience |
| KCA 6.5.3 /04 | Crofts, M.; Whiteoak, R. J. | 1975 | FATE OF THE METABOLITE CONJUGATED NC 9607 DURING PRODUCTION OF SUGAR FROM NORTRON TREATED SUGAR BEET - ARTIFICIALLY HIGH RESIDUE IN BEET GROWN AND PROCESSED IN W. GERMANY<br>Fisons plc, United Kingdom<br>Bayer Crop Science, Report No.: A83003,<br>Edition Number: M-155280-01-1 Date: 1975-03-01<br>No GLP<br>Unpublished | N | Bayer CropScience |
| KCA 6.6.1 /01 | Carlton, R.; Cordell, P. | 1993 | THE UPTAKE AND METABOLISM OF ETHOFUMESATE AND ITS SOIL METABOLITES IN A CONFINED ROTATIONAL CROP STUDY<br>Schering AG, Berlin, Germany<br>Bayer Crop Science, Report No.: A83396, Report includes Trial Nos.:<br>90B<br>Edition Number: M-155664-01-1 Date: 1993-06-18<br>GLP<br>Unpublished | N | Bayer CropScience |
| KCA 6.6.1 /02 | Schneider, E. | 1994 | PR94/025 - Ethofumesate - Determination of ethofumesate residues in soil of a long time field study after the application of Ethosat (FSG031894) to sugar beet plants<br>Dr. G. Krebs Analytik, Köln, Germany Feinchemie Schwebda,<br>Report No.: M-468487-01-1,<br>Edition Number: M-468487-01-1 Date: 1994-08-12<br>GLP<br>Unpublished | N | Adama (former Feinchemie Schwebda) |

| Data point | Author(s) | Year | **Title**<br>**Company Report No.**<br>**Source (where different from company)**<br>**GLP or GEP status**<br>**Published or not** | Vertebrate study Y/N | Owner |
|---|---|---|---|---|---|
| KCA 6.6.1/01 | Chapleo, S. | 2003 | The uptake of [$^{14}$C]-Ethofumesate residues in soil by rotational crops under confined conditions AgriChem B.V., Inveresk Research International, Tranent, Scotland<br>Report No.: 22558<br>GLP<br>Unpublished | N | ACM* |
| KCA 6.6.2 /01 | Castro, L. E. | 1994 | ETHOFUMESATE EMULSIFIABLE CONCENTRATE 200 g/l CR 13768: AT-HARVEST RESIDUES OF ETHOFUMESATE AND METABOLITES IN ROTATIONAL CROPS AND SOIL FOLLOWING APPLICATIONS OF NORTRON EC TO SUGARBEETS, USA, 1990<br>Nor-Am Chemical Company, Pikeville, NC, USA<br>Bayer CropScience, Report No.: A83117,<br>Edition Number: M-155392-01-1 EPA MRID No.: 43298104<br>Date: 1994-05-05<br>GLP/GEP: yes, unpublished | N | Bayer CropScience |
| KCA 6.6.2 /02 | Crofts, M.; Whiteoak, R. J. | 1974a | RESIDUE ANALYSIS OF WHEAT GROWN IN THE UK AS A FOLLOWING CROP AFTER SUGAR BEET TREATED WITH NORTRON (1973)<br>Fisons plc, United Kingdom<br>Bayer Crop Science, Report No.: A82995,<br>Edition Number: M-155272-01-1 Date: 1974-11-01<br>No GLP<br>Unpublished | N | Bayer CropScience |
| KCA 6.6.2 /03 | Crofts, M.; Whiteoak, R. J. | 1974b | RESIDUE ANALYSIS OF WHEAT AND CORN (MAIZE) GROWN AS FOLLOWING CROPS AFTER SUGAR BEET TREATED WITH NORTRON (1973)<br>Fisons plc, United Kingdom<br>Bayer Crop Science, Report No.: A82994,<br>Edition Number: M-155271-01-1 Date: 1974-09-01<br>No GLP<br>Unpublished | N | Bayer CropScience |
| KCA 6.6.2 /04 | Peatman, M. H.; Snowdon, P. J. | 1991 | RESIDUES OF SOIL AND EMERGENCY CROPS FOLLOWING APPLICATION OF ETHOFUMESATE AS A 50 SC FORMULATION IN THE UK 1990/91<br>Schering AG, Berlin, Germany<br>Bayer Crop Science, Report No.: A83376, Report includes Trial Nos.:<br>041/04/057<br>Edition Number: M-155644-01-1 Date: 1991-12-20<br>GLP<br>Unpublished | N | Bayer CropScience |
| KCA 6.6.2 /05 | Schulte, G.; Diehl, P. | 2013 | Amendment No. 1 to Report No: 10- 2501 - Determination of the residues of ethofumesate in/on the field rotational crop barley, carrot, lettuce and wheat after spray application of ethofumesate SC 500 on sugar beet and soil in the field, in the Netherlands, Italy, Spain and Germany<br>Bayer CropScience, Report No.: 10-2501, Report includes Trial Nos.: | N | Task Force Ethofumesate |

| Data point | Author(s) | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not | Vertebrate study Y/N | Owner |
|---|---|---|---|---|---|
| | | | 10-2501-02<br>10-2501-03<br>10-2501-04<br>10-2501-05<br>Edition Number: M-463906-02-1 Date: 2013-08-22<br>...Amended: 2013-09-13<br>GLP<br>Unpublished | | |
| KCA 6.6.2/01 | Spence, C. | 2014 | Evaluation of Ethofumesate Herbicide Residues Crop Rotation Study, Cereal, Root and Leafy Vegetable Crops Following Sugar Beet - One Application to Two Trials Initiated in 2012 - NEU (the United Kingdom) and SEU (Italy)<br>AgriChem B.V., 697614, 34890<br>Charles River Laboratories ,<br>Edinburgh, UK<br>GLP<br>Unpublished | N | ACM* |
| KCA 6.10 /01 | Wang, P.; Wang, Q.; Jiang, S.; Qiu, J.; Wang, P.; Zhou, Z. | 2005 | Stereoselective degradation of ethofumesate in turfgrass and soil. Journal:Pestic. Biochem. Physiol., Volume:82, Issue:3, Pages:197-204, Year:2005,<br>Report No.: M-458577-01-1,<br>Edition Number: M-458577-01-1 Date: 2005-12-31<br>No GLP<br>Published<br>...also filed: KCA 7.1.2.1.1 /14 | N | published |
| KCA 6.10.1/01 | Lückmann, J. | 2013 | Ethofumesate - exposure of honeybees to residues in nectar, pollen and guttation fluid in sugar and fodder beets<br>United Phosphorus Ltd., P13096 RIFCon GmbH, Hirschberg, Germany<br>No GLP<br>Unpublished | N | UPL |

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

**List of data submitted by the applicant and not relied on**

| Data point | Author(s) | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>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<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not | Vertebrate study Y/N | Owner |
|---|---|---|---|---|---|
| - | - | - | - | - | - |

# Appendix 2 Detailed evaluation of the additional studies relied upon

## A 2.1 Ethofumesate

### A 2.1.1 Stability of residues
### A 2.1.1.1 Stability of residues during storage of samples
### A 2.1.1.1.1 Storage stability of residues in plant products

#### A 2.1.1.1.1.1 Study 1: Report MR-12/058

| | |
|---|---|
| Comments of zRMS: | A storage stability study was conducted with AE C520645 (open-ring-2-keto-ethofumesate; NC 20645) in plant commodities (sugar beet leaf, sugar beet body, rape seed, bean dry seed and orange fruit) to determine the stability of the residues while stored frozen for up to approximately 24 months using Method 01343.<br>The fortification level was 0.10 mg/kg.<br>The fortified samples were stored frozen and analyzed for analyte NC 20645 at nominal intervals of 30, 90, 180, 360, 540 and 720 days.<br>All method validation data are within the acceptable criteria: mean recovery range of 70-120% and relative standard deviation ≤ 20%.<br><br>The analyte NC 20645 can be considered stable in the investigated matrices: of sugar beet leaf (high water content), sugar beet body (high starch content), rape seed (high oil content), dry bean seed (high protein content) and orange fruit (high acid content) under deep-freezer storage conditions (≤-18°C) for at least 24 months.<br>The study is acceptable. |

| | |
|---|---|
| Reference: | KCP 8/01 (KCA 6.1/01) |
| Report | Storage Stability of open-ring-2-keto ethofumesate (AE C520645) in Plant Matrices for 24 Months, Schulte, G., 2015, Report No. MR-12/058, Study ID P642120507 |
| Guideline(s): | Yes.<br>Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 Concerning the Placing of Plant Protection Products on the Market and Repealing Council Directives 79/117/EEC and 91/414/EEC<br>OECD Guidelines for the Testing of Chemicals. Stability of Pesticide Residues in Stored Commodities. 506. 2007-10-16<br>US EPA OCSPP 860.1380, Storage Stability Data |
| Deviations: | No |
| GLP: | Yes |
| Acceptability: | Yes |

**Materials and methods**

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

Except for the day-0 analysis, samples were stored in glass containers in a freezer at ≤ -18°C for later use. For day-0 analysis, five treated samples of each material were chosen, as well as two control sample of each. In addition, two recoveries spiked at the respective LOQ level and two recoveries spiked at the 10-fold LOQ level were analysed. After nominally 30, 90, 180, 360, 540 and 720 days, three fortified and

three control samples of each plant material were removed from the deep-freezer and allowed to reach room temperature. Subsequently, two of the control samples of each plant material were fortified with the test items to determine the concurrent recoveries (the fortification level was at 0.01 mg/kg as the spiked storage samples). The samples were extracted and analyzed concurrently with the third control sample and the spiked storage samples.
NC 20645 was determined using analytical method 01343 (cf. study MR-12/056, Schulte, G.; 2013; M-448288- 01; KCA 4.1.2/36), which was validated prior to and parallel to the analysis of the stored samples.
Method 01343 was developed for the determination of open-ring-2-keto-ethofumesate (NC 20645) in/on plant materials. Open-ring-2-keto-ethofumesate (NC 20645) was extracted from sugar beet leaf, sugar beet body, rape seed, dry bean and orange fruit, with acetonitrile/water (4/1, v/v) using a shaker. After filtration of the extract, the stable isotopically labelled internal standard was added. The internal standard is hydrolysed during analysis to the corresponding phenyl-$^{13}$C6 open-ring-2-keto-ethofumesate. The solution was made up to volume, filtered and subjected to reversed phase HPLC-MS/MS in negative ion mode without further clean-up. Residues were quantified using internal stable labelled standards.
The LOQ was 0.01 mg/kg for NC 20645 (expressed in analyte equivalents).

**Results and discussions**
In the control samples used for fortification the residues were always below 30% of the LOQ, except for rape seed at the storage intervals of 185 and 543 days with approx. 88% and 33% of the LOQ respectively.
After a deep-freezer storage period of about 24 months, the mean recovery rates from the stored samples ranged between 73% and 101% for open-ring-2-keto-ethofumesate. The concurrent recoveries determined from freshly fortified samples were in a range of 70% - 110%.
Altogether, the study results demonstrate that the residues of open- ring-2-keto-ethofumesate are stable in the tested plant commodities for 24 months (718 days for rape seed, bean dry seed, orange fruit and 719 days for sugar beet leaf and body) under deep-freezer storage conditions.

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

| Commodity | Storage period (days) | Residue level in stored samples | | | Day-0 normalized recovery[a] | Average % of fresh concurrent recoveries | Average corrected % recovery[b] |
|---|---|---|---|---|---|---|---|
| | | mg/kg (mg/kg) | % of nominal spiking level | Average % recovery | | | |
| Sugar beet leaf | NC 20645 | | | | | | |
| | 0 | 0.0966<br>0.0918<br>0.0881<br>0.0869<br>0.0911 | 97<br>92<br>88<br>87<br>91 | 91 | 100 | 87 | 105 |
| | 30 | 0.0952<br>0.0962<br>0.0937 | 95<br>96<br>94 | 95 | 104 | 95 | 101 |
| | 89 | 0.0898<br>0.0900<br>0.0897 | 90<br>90<br>90 | 90 | 99 | 89 | 102 |
| | 187 | 0.0781<br>0.0830<br>0.0851 | 78<br>83<br>85 | 82 | 90 | 90 | 92 |
| | 362 | 0.0793<br>0.0841<br>0.0748 | 79<br>84<br>75 | 79 | 87 | 82 | 97 |
| | 544 | 0.0893<br>0.0951<br>0.0881 | 89<br>95<br>88 | 91 | 100 | 88 | 104 |
| | 719 | 0.0711<br>0.0748<br>0.0736 | 71<br>75<br>74 | 73 | 81 | 76 | 96 |

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

b Corrected percent recovery = (average % recovery (stored) / Average of fresh concurrent recoveries) x 100%
Mean values were calculated with unrounded values. Therefore minor deviations may occur when the values given in the table are used.

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

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

a Normalized Recovery = (average recovery / average recovery at day 0) x 100%
b Corrected percent recovery = (average % recovery (stored) / Average of fresh concurrent recoveries) x 100%
Mean values were calculated with unrounded values. Therefore minor deviations may occur when the values given in the table are used.

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

| Commodity | Storage period (days) | Residue level in stored samples | | | Day-0 normalized recovery[a] | Average % of fresh concurrent recoveries | Average corrected % recovery[b] |
|---|---|---|---|---|---|---|---|
| | | mg/kg (mg/kg) | % of nominal spiking level | Average % recovery | | | |
| Rape seed | NC 20645 | | | | | | |
| | 0 | 0.0977<br>0.0952<br>0.0964<br>0.0978<br>0.0987 | 98<br>95<br>96<br>98<br>99 | 97 | 100 | 92 | 106 |
| | 31 | 0.0922<br>0.0911<br>0.0887 | 92<br>91<br>89 | 91 | 93 | 98 | 93 |
| | 89 | 0.0747<br>0.0757<br>0.0702 | 75<br>76<br>70 | 74 | 76 | 97 | 76 |
| | 185 | 0.0826<br>0.0781<br>0.0849 | 83<br>78<br>85 | 82 | 84 | 97 | 85 |
| | 360 | 0.775 | 78 | 80 | 82 | 81 | 99 |

| Commodity | Storage period (days) | Residue level in stored samples | | | Day-0 normalized recovery[a] | Average % of fresh concurrent recoveries | Average corrected % recovery[b] |
|---|---|---|---|---|---|---|---|
| | | mg/kg (mg/kg) | % of nominal spiking level | Average % recovery | | | |
| | | 0.0789<br>0.0849 | 79<br>83 | | | | |
| | 543 | 0.0878<br>0.0799<br>0.0840 | 88<br>80<br>84 | 84 | 86 | 93 | 91 |
| | 718 | 0.0780<br>0.0758<br>0.0797 | 78<br>76<br>80 | 78 | 80 | 81 | 96 |

a Normalized Recovery = (average recovery / average recovery at day 0) x 100%
b Corrected percent recovery = (average % recovery (stored) / Average of fresh concurrent recoveries) x 100%
Mean values were calculated with unrounded values. Therefore minor deviations may occur when the values given in the table are used.

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

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

a Normalized Recovery = (average recovery / average recovery at day 0) x 100%
b Corrected percent recovery = (average % recovery (stored) / Average of fresh concurrent recoveries) x 100%
Mean values were calculated with unrounded values. Therefore minor deviations may occur when the values given in the table are used.

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

| Commodity | Storage period (days) | Residue level in stored samples | | | Day-0 normalized recovery[a] | Average % of fresh concurrent recoveries | Average corrected % recovery[b] |
|---|---|---|---|---|---|---|---|
| | | mg/kg (mg/kg) | % of nominal spiking level | Average % recovery | | | |
| Orange fruit | NC 20645 | | | | | | |
| | 0 | 0.0980<br>0.1009<br>0.0953 | 98<br>101<br>95 | 101 | 100 | 99 | 102 |

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

a Normalized Recovery = (average recovery / average recovery at day 0) x 100%
b Corrected percent recovery = (average % recovery (stored) / Average of fresh concurrent recoveries) x 100%
Mean values were calculated with unrounded values. Therefore minor deviations may occur when the values given in the table are used.

**Conclusion**
After a deep freezer storage period at -18°C of about 24 months, the mean recovery rates of metabolite NC 20645 in stored samples of sugar beet leaf, sugar beet body, rape seed, dry bean and orange fruit, representing a wide array of plant-based sample materials (i.e. high water, high oil, high starch, high protein, high acid containing commodities), ranged between 73% and 88%.
Furthermore the concurrent recoveries determined from freshly fortified samples were in a range of 76% to 84% (mean values). Altogether, the study results demonstrate that the residues of NC 20645 are stable in the tested plant commodities for at least 24 months under deep-freezer storage conditions.
Altogether, the study results demonstrate that the residues of open- ring-2-keto-ethofumesate are stable in the tested plant commodities for 24 months (718 days for rape seed, bean dry seed, orange fruit and 719 days for sugar beet leaf and body) under deep-freezer storage conditions.

### A 2.1.1.1.1.1 Study 2: Report RES-00278

| | |
|---|---|
| Comments of zRMS: | A storage stability study was conducted with ethofumesate and ethofumesate-2-keto in plant commodities (lettuce and cereal grain) to determine the stability of the residues while stored frozen for up to approximately 24 months using analytical method OHG 00955/M002. This interim report contains data up to the 6-month timepoint.<br><br>The fortification level was 0.10 mg/kg.<br>The analytes ethofumesate and ethofumesate-2-keto can be considered stable in the investigated matrices of lettuce and cereal grain under deep-freezer storage conditions (≤-18°C) for 6 months. All method validation data are within the acceptable criteria: mean recovery range of 70-110% and relative standard deviation ≤ 20%.<br>The study is acceptable. |

Reference: KCP 8/02 (KCA 6.1/02) (and KCP 5.1.2/01)

Report: Ethofumesate: Storage Stability of Residues of Ethofumesate and its Metabolite in Lettuce and Cereal Grain Stored Frozen for up to Two Years;

| | |
|---|---|
| | Interim Report 1, Watson, G., 2021, Report No. RES-00278, Study ID 000106576 |
| Guideline(s): | Yes.<br>Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 Concerning the Placing of Plant Protection Products on the Market and Repealing Council Directives 79/117/EEC and 91/414/EEC<br>OECD Guidelines for the Testing of Chemicals. Stability of Pesticide Residues in Stored Commodities. 506. 2007-10-16<br>OECD ENV/JM/MONO(2007)17<br>SANCO/3029/99 rev.4 |
| Deviations: | No |
| GLP: | Yes |
| Acceptability: | Yes |

An ongoing objective of this study is to determine the stability of residue levels of ethofumesate and ethofumesate-2-keto in lettuce and cereal grain following frozen storage for up to 24 months. This interim report contains data up to the 6-month timepoint.

**Materials and methods**
To determine the freezer stability of the ethofumesate and the ethofumesate-2-keto metabolite (NC 9607) in lettuce and cereal grain, individual 10-g control samples were spiked to a fortification level of 0.1 mg/kg.
Prior to fortification, sample sets were removed from the freezer. Each sample set included three control sub-samples and two sub-samples individually fortified with ethofumesate or ethofumesate-2-keto at 0.1 mg/kg by addition of an aliquot of a 10 µg/mL fortification standard (100 µL). Sample sets were returned to the freezer after fortification. Sample sets were prepared for each timepoint (6, 12 and 24 months) and spare sample sets were prepared for any potential repeat analyses. Samples were kept deep frozen at -18°C or below. The samples analysed so far remained frozen throughout the storage. Each analysis timepoint included one control, two controls freshly fortified with ethofumesate or ethofumesate-2-keto at 0.1 mg/kg and two stored fortified samples. The freshly fortified samples served as procedural recovery samples to evaluate method performance. Prior to extraction, the samples were transferred to 250 mL round bottomed flasks using the extraction solvent (100 mL) to rinse the centrifuge tubes.
Ethofumesate and ethofumesate-2-keto were determined using analytical method OHG 00955/M002 (cf. study RE-00278; Watson, G., 2021.; KCP 5.1.2/01), which was validated prior to and parallel to the analysis of the stored samples.
The method involves extraction by reflux using ethyl acetate / n-hexane (1/1, v/v). Extracts are concentrated and the retained matrix is then refluxed under acidic conditions before filtration and concentration. Extracts from both reflux steps are combined and concentrated to dryness. Extracts are re-dissolved in n-hexane and passed through a silica gel and C18 cartridge before reducing to dryness and re-dissolving in ethyl acetate. Quantification of ethofumesate and ethofumesate-2-keto is achieved by GC-MS monitoring of three fragment ions for each analyte.
The LOQ was 0.01 mg/kg for both, ethofumesate and ethofumesate-2-keto.

**Results and discussions**
Control lettuce and cereal grain was sourced and homogenised by ResChem Analytical. Aliquots of each matrix type were weighed, arranged into sample sets and the relevant specimens were fortified. Each set included a control, two procedural recoveries and two fortified stored specimens. Each set was stored at ≤ –18 ˚C and relevant samples analysed after 6 months. The 0.1 mg/kg procedural recoveries from the method validation aspect of the study also served as the 0-day timepoint for the storage stability aspect of the study.
Ethofumesate and ethofumesate-2-keto residues were determined using the analytical method validated in this study. No residues above 30% of the LOQ were found in any of the reagent blanks or untreated spec-

imens.
Procedural recoveries were extracted, stored and quantified concurrently with stored specimens; all mean batch procedural recoveries were within the acceptable range of 70 – 110%. Procedural recovery results are detailed in Table A 6 to Table A 9.
The specificity for ethofumesate and ethofumesate-2-keto was demonstrated by GC-MS where no significant interferences were detected in any of the reagent blank or control specimens.
Instrument carryover was assessed on a run-by-run basis by injection of a solvent blank immediately after injection of the top calibration standard. Instrumental carryover was found to be less than 1% which is in accordance with ResChem Analytical standard operating procedures.
The linearity of the detector was checked on a run-by-run basis by single injection of matrix-matched calibration standards at 6 concentration levels covering a range equivalent to 30% of the LOQ up to 120% of the upper fortification level. The calibration curves obtained for ethofumesate and ethofumesate-2-keto were linear with correlation coefficients (r) greater than 0.995. Example linearity plots can be found in Section 10 along with representative chromatograms.
There was no significant decrease in the observed residue levels of ethofumesate and ethofumesate-2-keto in the fortified lettuce and cereal grain specimens stored frozen at ≤ –18 ˚C for a period of six months. The recovery values for the 6-month stored fortified samples (mean of three replicates) were between 70 – 110% for all three matrices. Storage stability results are detailed in are detailed in Table A 6 to Table A 9.

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

| Storage Interval | | Specimen Ref. | Fort. Level. (mg/kg) | Procedural Recovery Residue (mg/kg) | Mean Procedural Recovery (%) | Stored Sample Residue (mg/kg) | Mean Stored Sample Residue (mg/kg) | Mean stored sample recovery (%) |
|---|---|---|---|---|---|---|---|---|
| Months | Days (Actual) | | | | | | | |
| 0 | 0 | 12439 | 0.1 | 0.092486 | 92 | N/A | N/A | N/A |
| | | 12440 | 0.1 | 0.092066 | | | | |
| | | 12441 | 0.1 | 0.091284 | | | | |
| | | 12442 | 0.1 | 0.090976 | | | | |
| | | 12443 | 0.1 | 0.092002 | | | | |
| 6 | 183 | 12445 | 0.1 | 0.092110 | 94 | - | - | - |
| | | 12446 | 0.1 | 0.095283 | | - | | |
| | | 12447 | 0.1 | - | - | 0.093330 | 0.09358 | 94 |
| | | 12448 | 0.1 | - | | 0.093838 | | |

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

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

| Storage Interval | | Specimen Ref. | Fort. Level. (mg/kg) | Procedural Recovery Residue (mg/kg) | Mean Procedural Recovery (%) | Stored Sample Residue (mg/kg) | Mean Stored Sample Residue (mg/kg) | Mean stored sample recovery (%) |
|---|---|---|---|---|---|---|---|---|
| Months | Days (Actual) | | | | | | | |
| 0 | 0 | 12523 | 0.1 | 0.091615 | 91 | N/A | N/A | N/A |
| | | 12524 | 0.1 | 0.094003 | | | | |
| | | 12525 | 0.1 | 0.091964 | | | | |
| | | 12526 | 0.1 | 0.089637 | | | | |
| | | 12527 | 0.1 | 0.089704 | | | | |
| 6 | 181 | 12529 | 0.1 | 0.090003 | 92 | - | - | - |

| Storage Interval | | Specimen Ref. | Fort. Level. (mg/kg) | Procedural Recovery Residue (mg/kg) | Mean Procedural Recovery (%) | Stored Sample Residue (mg/kg) | Mean Stored Sample Residue (mg/kg) | Mean stored sample recovery (%) |
|---|---|---|---|---|---|---|---|---|
| Months | Days (Actual) | | | | | | | |
| | | 12530 | 0.1 | 0.094039 | | - | | |
| | | 12531 | 0.1 | - | - | 0.090683 | 0.08990 | 90 |
| | | 12523 | 0.1 | - | | 0.089114 | | |

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

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

| Storage Interval | | Specimen Ref. | Fort. Level. (mg/kg) | Procedural Recovery Residue (mg/kg) | Mean Procedural Recovery (%) | Stored Sample Residue (mg/kg) | Mean Stored Sample Residue (mg/kg) | Mean stored sample recovery (%) |
|---|---|---|---|---|---|---|---|---|
| Months | Days (Actual) | | | | | | | |
| 0 | 0 | 12481 | 0.1 | 0.095543 | 97 | N/A | N/A | N/A |
| | | 12482 | 0.1 | 0.097512 | | | | |
| | | 12483 | 0.1 | 0.098586 | | | | |
| | | 12484 | 0.1 | 0.096903 | | | | |
| | | 12485 | 0.1 | 0.095938 | | | | |
| 6 | 185 | 12487 | 0.1 | 0.096191 | 99 | - | - | - |
| | | 12488 | 0.1 | 0.101272 | | - | | |
| | | 12489 | 0.1 | - | - | 0.095716 | 0.09701 | 97 |
| | | 12490 | 0.1 | - | | 0.098311 | | |

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

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

| Storage Interval | | Specimen Ref. | Fort. Level. (mg/kg) | Procedural Recovery Residue (mg/kg) | Mean Procedural Recovery (%) | Stored Sample Residue (mg/kg) | Mean Stored Sample Residue (mg/kg) | Mean stored sample recovery (%) |
|---|---|---|---|---|---|---|---|---|
| Months | Days (Actual) | | | | | | | |
| 0 | 0 | 12565 | 0.1 | 0.089529 | 92 | N/A | N/A | N/A |
| | | 12566 | 0.1 | 0.091486 | | | | |
| | | 12567 | 0.1 | 0.091602 | | | | |
| | | 12568 | 0.1 | 0.091519 | | | | |
| | | 12569 | 0.1 | 0.093721 | | | | |
| 6 | 183 | 12571 | 0.1 | 0.092093 | 89 | - | - | - |
| | | 12572 | 0.1 | 0.086068 | | - | | |
| | | 12573 | 0.1 | - | - | 0.091994 | 0.08926 | 89 |
| | | 12574 | 0.1 | - | | 0.086526 | | |

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

## Conclusion

The results of this 6-months interim study showed that residue levels of ethofumesate and ethofumesate-2-keto were stable in fortified samples of lettuce and cereal grain specimens stored frozen at ≤–18 ˚C for a period of six months. The recovery values for the 6-month stored fortified samples (mean of two repli-

cates) was between 70 – 110% for the matrices tested.

### A 2.1.1.1.2 Storage stability of residues in animal products

No new or additional studies have been submitted.

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

### A 2.1.2.1 Nature of residue in plants

### A 2.1.2.1.1 Nature of residue in primary crops

No new or additional studies have been submitted.

### A 2.1.2.1.2 Nature of residue in rotational crops

No new or additional studies have been submitted.

### A 2.1.2.1.3 Nature of residues in processed commodities

No new or additional studies have been submitted.

### A 2.1.2.2 Nature of residues in livestock

No new or additional studies have been submitted.

## A 2.1.3 Magnitude of residues in plants

No new or additional studies have been submitted.

# Appendix 3 Pesticide Residue Intake Model (PRIMo) – Input tables

## A 3.1 EFSA PRIMo input values for ethofumesate

| Code number | Commodity | Input value | Comment |
|---|---|---|---|
| 0100000 | . FRUITS, FRESH or FROZEN; TREE NUTS | 0.03* | EU MRL[a] |
| 0110000 | . Citrus fruits | 0.03* | EU MRL[a] |
| 0110010 | . Grapefruits | 0.03* | EU MRL[a] |
| 0110020 | . Oranges | 0.03* | EU MRL[a] |
| 0110030 | . Lemons | 0.03* | EU MRL[a] |
| 0110040 | . Limes | 0.03* | EU MRL[a] |
| 0110050 | . Mandarins | 0.03* | EU MRL[a] |
| 0110990 | . Others (2) | 0.03* | EU MRL[a] |
| 0120000 | . Tree nuts | 0.03* | EU MRL[a] |
| 0120010 | . Almonds | 0.03* | EU MRL[a] |
| 0120020 | . Brazil nuts | 0.03* | EU MRL[a] |
| 0120030 | . Cashew nuts | 0.03* | EU MRL[a] |
| 0120040 | . Chestnuts | 0.03* | EU MRL[a] |
| 0120050 | . Coconuts | 0.03* | EU MRL[a] |
| 0120060 | . Hazelnuts/cobnuts | 0.03* | EU MRL[a] |
| 0120070 | . Macadamias | 0.03* | EU MRL[a] |
| 0120080 | . Pecans | 0.03* | EU MRL[a] |
| 0120090 | . Pine nut kernels | 0.03* | EU MRL[a] |
| 0120100 | . Pistachios | 0.03* | EU MRL[a] |
| 0120110 | . Walnuts | 0.03* | EU MRL[a] |
| 0120990 | . Others (2) | 0.03* | EU MRL[a] |
| 0130000 | . Pome fruits | 0.03* | EU MRL[a] |
| 0130010 | . Apples | 0.03* | EU MRL[a] |
| 0130020 | . Pears | 0.03* | EU MRL[a] |
| 0130030 | . Quinces | 0.03* | EU MRL[a] |
| 0130040 | . Medlars | 0.03* | EU MRL[a] |
| 0130050 | . Loquats/Japanese medlars | 0.03* | EU MRL[a] |
| 0130990 | . Others (2) | 0.03* | EU MRL[a] |
| 0140000 | . Stone fruits | 0.03* | EU MRL[a] |
| 0140010 | . Apricots | 0.03* | EU MRL[a] |
| 0140020 | . Cherries (sweet) | 0.03* | EU MRL[a] |
| 0140030 | . Peaches | 0.03* | EU MRL[a] |
| 0140040 | . Plums | 0.03* | EU MRL[a] |
| 0140990 | . Others (2) | 0.03* | EU MRL[a] |
| 0150000 | . Berries and small fruits | 0.03* | EU MRL[a] |
| 0151000 | . (a) grapes | 0.03* | EU MRL[a] |
| 0151010 | . Table grapes | 0.03* | EU MRL[a] |
| 0151020 | . Wine grapes | 0.03* | EU MRL[a] |
| 0152000 | . (b) strawberries | 0.03* | EU MRL[a] |
| 0153000 | . (c) cane fruits | 0.03* | EU MRL[a] |
| 0153010 | . Blackberries | 0.03* | EU MRL[a] |
| 0153020 | . Dewberries | 0.03* | EU MRL[a] |
| 0153030 | . Raspberries (red and yellow) | 0.03* | EU MRL[a] |
| 0153990 | . Others (2) | 0.03* | EU MRL[a] |
| 0154000 | . (d) other small fruits and berries | 0.03* | EU MRL[a] |
| 0154010 | . Blueberries | 0.03* | EU MRL[a] |
| 0154020 | . Cranberries | 0.03* | EU MRL[a] |

| Code number | Commodity | Input value | Comment |
|---|---|---|---|
| 0154030 | . Currants (black, red and white) | 0.03* | EU MRL[a] |
| 0154040 | . Gooseberries (green, red and yellow) | 0.03* | EU MRL[a] |
| 0154050 | . Rose hips | 0.03* | EU MRL[a] |
| 0154060 | . Mulberries (black and white) | 0.03* | EU MRL[a] |
| 0154070 | . Azaroles/Mediterranean medlars | 0.03* | EU MRL[a] |
| 0154080 | . Elderberries | 0.03* | EU MRL[a] |
| 0154990 | . Others (2) | 0.03* | EU MRL[a] |
| 0160000 | . Miscellaneous fruits with | 0.03* | EU MRL[a] |
| 0161000 | . (a) edible peel | 0.03* | EU MRL[a] |
| 0161010 | . Dates | 0.03* | EU MRL[a] |
| 0161020 | . Figs | 0.03* | EU MRL[a] |
| 0161030 | . Table olives | 0.03* | EU MRL[a] |
| 0161040 | . Kumquats | 0.03* | EU MRL[a] |
| 0161050 | . Carambolas | 0.03* | EU MRL[a] |
| 0161060 | . Kaki/Japanese persimmons | 0.03* | EU MRL[a] |
| 0161070 | . Jambuls/jambolans | 0.03* | EU MRL[a] |
| 0161990 | . Others (2) | 0.03* | EU MRL[a] |
| 0162000 | . (b) inedible peel, small | 0.03* | EU MRL[a] |
| 0162010 | . Kiwi fruits (green, red, yellow) | 0.03* | EU MRL[a] |
| 0162020 | . Litchis/lychees | 0.03* | EU MRL[a] |
| 0162030 | . Passionfruits/maracujas | 0.03* | EU MRL[a] |
| 0162040 | . Prickly pears/cactus fruits | 0.03* | EU MRL[a] |
| 0162050 | . Star apples/cainitos | 0.03* | EU MRL[a] |
| 0162060 | . American persimmons/Virginia kaki | 0.03* | EU MRL[a] |
| 0162990 | . Others (2) | 0.03* | EU MRL[a] |
| 0163000 | . (c) inedible peel, large | 0.03* | EU MRL[a] |
| 0163010 | . Avocados | 0.03* | EU MRL[a] |
| 0163020 | . Bananas | 0.03* | EU MRL[a] |
| 0163030 | . Mangoes | 0.03* | EU MRL[a] |
| 0163040 | . Papayas | 0.03* | EU MRL[a] |
| 0163050 | . Granate apples/pomegranates | 0.03* | EU MRL[a] |
| 0163060 | . Cherimoyas | 0.03* | EU MRL[a] |
| 0163070 | . Guavas | 0.03* | EU MRL[a] |
| 0163080 | . Pineapples | 0.03* | EU MRL[a] |
| 0163090 | . Breadfruits | 0.03* | EU MRL[a] |
| 0163100 | . Durians | 0.03* | EU MRL[a] |
| 0163110 | . Soursops/guanabanas | 0.03* | EU MRL[a] |
| 0163990 | . Others (2) | 0.03* | EU MRL[a] |
| 0200000 | . VEGETABLES, FRESH or FROZEN | | |
| 0210000 | . Root and tuber vegetables | | |
| 0211000 | . (a) potatoes | 0.03* | EU MRL[a] |
| 0212000 | . (b) tropical root and tuber vegetables | 0.03* | EU MRL[a] |
| 0212010 | . Cassava roots/manioc | 0.03* | EU MRL[a] |
| 0212020 | . Sweet potatoes | 0.03* | EU MRL[a] |
| 0212030 | . Yams | 0.03* | EU MRL[a] |
| 0212040 | . Arrowroots | 0.03* | EU MRL[a] |
| 0212990 | . Others (2) | 0.03* | EU MRL[a] |
| 0213000 | . (c) other root and tuber vegetables except sugar beets | | |
| 0213010 | . Beetroots | 0.2 | EU MRL[a] |
| 0213020 | . Carrots | 0.03* | EU MRL[a] |

| Code number | Commodity | Input value | Comment |
|---|---|---|---|
| 0213030 | . Celeriacs/turnip rooted celeries | 0.03* | EU MRL[(a)] |
| 0213040 | . Horseradishes | 0.03* | EU MRL[(a)] |
| 0213050 | . Jerusalem artichokes | 0.03* | EU MRL[(a)] |
| 0213060 | . Parsnips | 0.03* | EU MRL[(a)] |
| 0213070 | . Parsley roots/Hamburg roots parsley | 0.03* | EU MRL[(a)] |
| 0213080 | . Radishes | 0.03* | EU MRL[(a)] |
| 0213090 | . Salsifies | 0.03* | EU MRL[(a)] |
| 0213100 | . Swedes/rutabagas | 0.03* | EU MRL[(a)] |
| 0213110 | . Turnips | 0.03* | EU MRL[(a)] |
| 0213990 | . Others (2) | 0.03* | EU MRL[(a)] |
| 0220000 | . Bulb vegetables | 0.03* | EU MRL[(a)] |
| 0220010 | . Garlic | 0.03* | EU MRL[(a)] |
| 0220020 | . Onions | 0.03* | EU MRL[(a)] |
| 0220030 | . Shallots | 0.03* | EU MRL[(a)] |
| 0220040 | . Spring onions/green onions and Welsh onions | 0.03* | EU MRL[(a)] |
| 0220990 | . Others (2) | 0.03* | EU MRL[(a)] |
| 0230000 | . Fruiting vegetables | 0.03* | EU MRL[(a)] |
| 0231000 | . (a) Solanaceae and Malvaceae | 0.03* | EU MRL[(a)] |
| 0231010 | . Tomatoes | 0.03* | EU MRL[(a)] |
| 0231020 | . Sweet peppers/bell peppers | 0.03* | EU MRL[(a)] |
| 0231030 | . Aubergines/eggplants | 0.03* | EU MRL[(a)] |
| 0231040 | . Okra/lady's fingers | 0.03* | EU MRL[(a)] |
| 0231990 | . Others (2) | 0.03* | EU MRL[(a)] |
| 0232000 | . (b) cucurbits with edible peel | 0.03* | EU MRL[(a)] |
| 0232010 | . Cucumbers | 0.03* | EU MRL[(a)] |
| 0232020 | . Gherkins | 0.03* | EU MRL[(a)] |
| 0232030 | . Courgettes | 0.03* | EU MRL[(a)] |
| 0232990 | . Others (2) | 0.03* | EU MRL[(a)] |
| 0233000 | . (c) cucurbits with inedible peel | 0.03* | EU MRL[(a)] |
| 0233010 | . Melons | 0.03* | EU MRL[(a)] |
| 0233020 | . Pumpkins | 0.03* | EU MRL[(a)] |
| 0233030 | . Watermelons | 0.03* | EU MRL[(a)] |
| 0233990 | . Others (2) | 0.03* | EU MRL[(a)] |
| 0234000 | . (d) sweet corn | 0.03* | EU MRL[(a)] |
| 0239000 | . (e) other fruiting vegetables | 0.03* | EU MRL[(a)] |
| 0240000 | . Brassica vegetables (excluding brassica roots and brassica baby leaf crops) | 0.03* | EU MRL[(a)] |
| 0241000 | . (a) flowering brassica | 0.03* | EU MRL[(a)] |
| 0241010 | . Broccoli | 0.03* | EU MRL[(a)] |
| 0241020 | . Cauliflowers | 0.03* | EU MRL[(a)] |
| 0241990 | . Others (2) | 0.03* | EU MRL[(a)] |
| 0242000 | . (b) head brassica | 0.03* | EU MRL[(a)] |
| 0242010 | . Brussels sprouts | 0.03* | EU MRL[(a)] |
| 0242020 | . Head cabbages | 0.03* | EU MRL[(a)] |
| 0242990 | . Others (2) | 0.03* | EU MRL[(a)] |
| 0243000 | . (c) leafy brassica | 0.03* | EU MRL[(a)] |
| 0243010 | . Chinese cabbages/pe-tsai | 0.03* | EU MRL[(a)] |
| 0243020 | . Kales | 0.03* | EU MRL[(a)] |
| 0243990 | . Others (2) | 0.03* | EU MRL[(a)] |
| 0244000 | . (d) kohlrabies | 0.03* | EU MRL[(a)] |
| 0250000 | . Leaf vegetables, herbs and edible flowers | | |

| Code number | Commodity | Input value | Comment |
|---|---|---|---|
| 0251000 | . (a) lettuces and salad plants | 0.03* | EU MRL[(a)] |
| 0251010 | . Lamb's lettuces/corn salads | 0.03* | EU MRL[(a)] |
| 0251020 | . Lettuces | 0.03* | EU MRL[(a)] |
| 0251030 | . Escaroles/broad-leaved endives | 0.03* | EU MRL[(a)] |
| 0251040 | . Cresses and other sprouts and shoots | 0.03* | EU MRL[(a)] |
| 0251050 | . Land cresses | 0.03* | EU MRL[(a)] |
| 0251060 | . Roman rocket/rucola | 0.03* | EU MRL[(a)] |
| 0251070 | . Red mustards | 0.03* | EU MRL[(a)] |
| 0251080 | . Baby leaf crops (including brassica species) | 0.03* | EU MRL[(a)] |
| 0251990 | . Others (2) | 0.03* | EU MRL[(a)] |
| 0252000 | . (b) spinaches and similar leaves | | |
| 0252010 | . Spinaches | 0.1* | EU MRL[(a)] |
| 0252020 | . Purslanes | 0.03* | EU MRL[(a)] |
| 0252030 | . Chards/beet leaves | 0.3 | EU MRL[(a)] |
| 0252990 | . Others (2) | 0.03* | EU MRL[(a)] |
| 0253000 | . (c) grape leaves and similar species | 0.03* | EU MRL[(a)] |
| 0254000 | . (d) watercresses | 0.03* | EU MRL[(a)] |
| 0255000 | . (e) witloofs/Belgian endives | 0.03* | EU MRL[(a)] |
| 0256000 | . (f) herbs and edible flowers | | |
| 0256010 | . Chervil | 0.05* | EU MRL[(a)] |
| 0256020 | . Chives | 0.05* | EU MRL[(a)] |
| 0256030 | . Celery leaves | 0.05* | EU MRL[(a)] |
| 0256040 | . Parsley | 1.5 | EU MRL[(a)] |
| 0256050 | . Sage | 1.5 | EU MRL[(a)] |
| 0256060 | . Rosemary | 1.5 | EU MRL[(a)] |
| 0256070 | . Thyme | 1.5 | EU MRL[(a)] |
| 0256080 | . Basil and edible flowers | 1 | EU MRL[(a)] |
| 0256090 | . Laurel/bay leaves | 0.05* | EU MRL[(a)] |
| 0256100 | . Tarragon | 0.05* | EU MRL[(a)] |
| 0256990 | . Others (2) | 0.05* | EU MRL[(a)] |
| 0260000 | . Legume vegetables | | |
| 0260010 | . Beans (with pods) | 0.1* | EU MRL[(a)] |
| 0260020 | . Beans (without pods) | 0.03* | EU MRL[(a)] |
| 0260030 | . Peas (with pods) | 0.1* | EU MRL[(a)] |
| 0260040 | . Peas (without pods) | 0.03* | EU MRL[(a)] |
| 0260050 | . Lentils | 0.03* | EU MRL[(a)] |
| 0260990 | . Others (2) | 0.03* | EU MRL[(a)] |
| 0270000 | . Stem vegetables | 0.03* | EU MRL[(a)] |
| 0270010 | . Asparagus | 0.03* | EU MRL[(a)] |
| 0270020 | . Cardoons | 0.03* | EU MRL[(a)] |
| 0270030 | . Celeries | 0.03* | EU MRL[(a)] |
| 0270040 | . Florence fennels | 0.03* | EU MRL[(a)] |
| 0270050 | . Globe artichokes | 0.03* | EU MRL[(a)] |
| 0270060 | . Leeks | 0.03* | EU MRL[(a)] |
| 0270070 | . Rhubarbs | 0.03* | EU MRL[(a)] |
| 0270080 | . Bamboo shoots | 0.03* | EU MRL[(a)] |
| 0270090 | . Palm hearts | 0.03* | EU MRL[(a)] |
| 0270990 | . Others (2) | 0.03* | EU MRL[(a)] |
| 0280000 | . Fungi, mosses and lichens | 0.03* | EU MRL[(a)] |
| 0280010 | . Cultivated fungi | 0.03* | EU MRL[(a)] |

| Code number | Commodity | Input value | Comment |
|---|---|---|---|
| 0280020 | . Wild fungi | 0.03* | EU MRL[(a)] |
| 0280990 | . Mosses and lichens | 0.03* | EU MRL[(a)] |
| 0290000 | . Algae and prokaryotes organisms | 0.03* | EU MRL[(a)] |
| 0300000 | . PULSES | | |
| 0300010 | . Beans | 0.03* | EU MRL[(a)] |
| 0300020 | . Lentils | 0.03* | EU MRL[(a)] |
| 0300030 | . Peas | 0.1* | EU MRL[(a)] |
| 0300040 | . Lupins/lupini beans | 0.03* | EU MRL[(a)] |
| 0300990 | . Others (2) | 0.03* | EU MRL[(a)] |
| 0400000 | . OILSEEDS AND OIL FRUITS | 0.03* | EU MRL[(a)] |
| 0401000 | . Oilseeds | 0.03* | EU MRL[(a)] |
| 0401010 | . Linseeds | 0.03* | EU MRL[(a)] |
| 0401020 | . Peanuts/groundnuts | 0.03* | EU MRL[(a)] |
| 0401030 | . Poppy seeds | 0.03* | EU MRL[(a)] |
| 0401040 | . Sesame seeds | 0.03* | EU MRL[(a)] |
| 0401050 | . Sunflower seeds | 0.03* | EU MRL[(a)] |
| 0401060 | . Rapeseeds/canola seeds | 0.03* | EU MRL[(a)] |
| 0401070 | . Soyabeans | 0.03* | EU MRL[(a)] |
| 0401080 | . Mustard seeds | 0.03* | EU MRL[(a)] |
| 0401090 | . Cotton seeds | 0.03* | EU MRL[(a)] |
| 0401100 | . Pumpkin seeds | 0.03* | EU MRL[(a)] |
| 0401110 | . Safflower seeds | 0.03* | EU MRL[(a)] |
| 0401120 | . Borage seeds | 0.03* | EU MRL[(a)] |
| 0401130 | . Gold of pleasure seeds | 0.03* | EU MRL[(a)] |
| 0401140 | . Hemp seeds | 0.03* | EU MRL[(a)] |
| 0401150 | . Castor beans | 0.03* | EU MRL[(a)] |
| 0401990 | . Others (2) | 0.03* | EU MRL[(a)] |
| 0402000 | . Oil fruits | 0.03* | EU MRL[(a)] |
| 0402010 | . Olives for oil production | 0.03* | EU MRL[(a)] |
| 0402020 | . Oil palms kernels | 0.03* | EU MRL[(a)] |
| 0402030 | . Oil palms fruits | 0.03* | EU MRL[(a)] |
| 0402040 | . Kapok | 0.03* | EU MRL[(a)] |
| 0402990 | . Others (2) | 0.03* | EU MRL[(a)] |
| 0500000 | . CEREALS | 0.03* | EU MRL[(a)] |
| 0500010 | . Barley | 0.03* | EU MRL[(a)] |
| 0500020 | . Buckwheat and other pseudocereals | 0.03* | EU MRL[(a)] |
| 0500030 | . Maize/corn | 0.03* | EU MRL[(a)] |
| 0500040 | . Common millet/proso millet | 0.03* | EU MRL[(a)] |
| 0500050 | . Oat | 0.03* | EU MRL[(a)] |
| 0500060 | . Rice | 0.03* | EU MRL[(a)] |
| 0500070 | . Rye | 0.03* | EU MRL[(a)] |
| 0500080 | . Sorghum | 0.03* | EU MRL[(a)] |
| 0500090 | . Wheat | 0.03* | EU MRL[(a)] |
| 0500990 | . Others (2) | 0.03* | EU MRL[(a)] |
| 0600000 | . TEAS, COFFEE, HERBAL INFUSIONS, COCOA AND CAROBS | | |
| 0610000 | . Teas | 0.1* | EU MRL[(a)] |
| 0620000 | . Coffee beans | 0.1* | EU MRL[(a)] |
| 0630000 | . Herbal infusions from | | EU MRL[(a)] |
| 0631000 | . (a) flowers | 15 | EU MRL[(a)] |
| 0631010 | . Chamomile | 15 | EU MRL[(a)] |

| Code number | Commodity | Input value | Comment |
|---|---|---|---|
| 0631020 | . Hibiscus/roselle | 15 | EU MRL[a] |
| 0631030 | . Rose | 15 | EU MRL[a] |
| 0631040 | . Jasmine | 15 | EU MRL[a] |
| 0631050 | . Lime/linden | 15 | EU MRL[a] |
| 0631990 | . Others (2) | 15 | EU MRL[a] |
| 0632000 | . (b) leaves and herbs | 15 | EU MRL[a] |
| 0632010 | . Strawberry | 15 | EU MRL[a] |
| 0632020 | . Rooibos | 15 | EU MRL[a] |
| 0632030 | . Mate/maté | 15 | EU MRL[a] |
| 0632990 | . Others (2) | 15 | EU MRL[a] |
| 0633000 | . (c) roots | 0.1* | EU MRL[a] |
| 0633010 | . Valerian | 0.1* | EU MRL[a] |
| 0633020 | . Ginseng | 0.1* | EU MRL[a] |
| 0633990 | . Others (2) | 0.1* | EU MRL[a] |
| 0639000 | . (d) any other parts of the plant | 0.1* | EU MRL[a] |
| 0640000 | . Cocoa beans | 0.1* | EU MRL[a] |
| 0650000 | . Carobs/Saint John's breads | 0.1* | EU MRL[a] |
| 0700000 | . HOPS | 0.1* | EU MRL[a] |
| 0800000 | . SPICES | | |
| 0810000 | . Seed spices | 0.6 | EU MRL[a] |
| 0810010 | . Anise/aniseed | 0.6 | EU MRL[a] |
| 0810020 | . Black caraway/black cumin | 0.6 | EU MRL[a] |
| 0810030 | . Celery | 0.6 | EU MRL[a] |
| 0810040 | . Coriander | 0.6 | EU MRL[a] |
| 0810050 | . Cumin | 0.6 | EU MRL[a] |
| 0810060 | . Dill | 0.6 | EU MRL[a] |
| 0810070 | . Fennel | 0.6 | EU MRL[a] |
| 0810080 | . Fenugreek | 0.6 | EU MRL[a] |
| 0810090 | . Nutmeg | 0.6 | EU MRL[a] |
| 0810990 | . Others (2) | 0.6 | EU MRL[a] |
| 0820000 | . Fruit spices | 0.1* | EU MRL[a] |
| 0820010 | . Allspice/pimento | 0.1* | EU MRL[a] |
| 0820020 | . Sichuan pepper | 0.1* | EU MRL[a] |
| 0820030 | . Caraway | 0.1* | EU MRL[a] |
| 0820040 | . Cardamom | 0.1* | EU MRL[a] |
| 0820050 | . Juniper berry | 0.1* | EU MRL[a] |
| 0820060 | . Peppercorn (black, green and white) | 0.1* | EU MRL[a] |
| 0820070 | . Vanilla | 0.1* | EU MRL[a] |
| 0820080 | . Tamarind | 0.1* | EU MRL[a] |
| 0820990 | . Others (2) | 0.1* | EU MRL[a] |
| 0830000 | . Bark spices | 0.1* | EU MRL[a] |
| 0830010 | . Cinnamon | 0.1* | EU MRL[a] |
| 0830990 | . Others (2) | 0.1* | EU MRL[a] |
| 0840000 | . Root and rhizome spices | 0.1* | EU MRL[a] |
| 0840010 | . Liquorice | 0.1* | EU MRL[a] |
| 0840020 | . Ginger (10) | 0.1* | EU MRL[a] |
| 0840030 | . Turmeric/curcuma | 0.1* | EU MRL[a] |
| 0840040 | . Horseradish (11) | 0.1* | EU MRL[a] |
| 0840990 | . Others (2) | 0.1* | EU MRL[a] |
| 0850000 | . Bud spices | 0.1* | EU MRL[a] |

| Code number | Commodity | Input value | Comment |
|---|---|---|---|
| 0850010 | . Cloves | 0.1* | EU MRL[(a)] |
| 0850020 | . Capers | 0.1* | EU MRL[(a)] |
| 0850990 | . Others (2) | 0.1* | EU MRL[(a)] |
| 0860000 | . Flower pistil spices | 0.1* | EU MRL[(a)] |
| 0860010 | . Saffron | 0.1* | EU MRL[(a)] |
| 0860990 | . Others (2) | 0.1* | EU MRL[(a)] |
| 0870000 | . Aril spices | 0.1* | EU MRL[(a)] |
| 0870010 | . Mace | 0.1* | EU MRL[(a)] |
| 0870990 | . Others (2) | 0.1* | EU MRL[(a)] |
| 0900000 | . SUGAR PLANTS | | |
| 0900010 | . Sugar beet roots | 0.2 | EU MRL[(a)] |
| 0900020 | . Sugar canes | 0.03* | EU MRL[(a)] |
| 0900030 | . Chicory roots | 0.1* | EU MRL[(a)] |
| 0900990 | . Others (2) | 0.03* | EU MRL[(a)] |
| 1000000 | . PRODUCTS OF ANIMAL ORIGIN -TERRESTRIAL ANIMALS | | |
| 1010000 | . Commodities from | 0.03* | EU MRL[(a)] |
| 1011000 | . (a) swine | 0.03* | EU MRL[(a)] |
| 1011010 | . Muscle | 0.03* | EU MRL[(a)] |
| 1011020 | . Fat | 0.03* | EU MRL[(a)] |
| 1011030 | . Liver | 0.03* | EU MRL[(a)] |
| 1011040 | . Kidney | 0.03* | EU MRL[(a)] |
| 1011050 | . Edible offals (other than liver and kidney) | 0.03* | EU MRL[(a)] |
| 1011990 | . Others (2) | 0.03* | EU MRL[(a)] |
| 1012000 | . (b) bovine | 0.03* | EU MRL[(a)] |
| 1012010 | . Muscle | 0.03* | EU MRL[(a)] |
| 1012020 | . Fat | 0.03* | EU MRL[(a)] |
| 1012030 | . Liver | 0.03* | EU MRL[(a)] |
| 1012040 | . Kidney | 0.03* | EU MRL[(a)] |
| 1012050 | . Edible offals (other than liver and kidney) | 0.03* | EU MRL[(a)] |
| 1012990 | . Others (2) | 0.03* | EU MRL[(a)] |
| 1013000 | . (c) sheep | 0.03* | EU MRL[(a)] |
| 1013010 | . Muscle | 0.03* | EU MRL[(a)] |
| 1013020 | . Fat | 0.03* | EU MRL[(a)] |
| 1013030 | . Liver | 0.03* | EU MRL[(a)] |
| 1013040 | . Kidney | 0.03* | EU MRL[(a)] |
| 1013050 | . Edible offals (other than liver and kidney) | 0.03* | EU MRL[(a)] |
| 1013990 | . Others (2) | 0.03* | EU MRL[(a)] |
| 1014000 | . d) goat | 0.03* | EU MRL[(a)] |
| 1014010 | . Muscle | 0.03* | EU MRL[(a)] |
| 1014020 | . Fat | 0.03* | EU MRL[(a)] |
| 1014030 | . Liver | 0.03* | EU MRL[(a)] |
| 1014040 | . Kidney | 0.03* | EU MRL[(a)] |
| 1014050 | . Edible offals (other than liver and kidney) | 0.03* | EU MRL[(a)] |
| 1014990 | . Others (2) | 0.03* | EU MRL[(a)] |
| 1015000 | . (e) equine | 0.03* | EU MRL[(a)] |
| 1015010 | . Muscle | 0.03* | EU MRL[(a)] |
| 1015020 | . Fat | 0.03* | EU MRL[(a)] |
| 1015030 | . Liver | 0.03* | EU MRL[(a)] |
| 1015040 | . Kidney | 0.03* | EU MRL[(a)] |
| 1015050 | . Edible offals (other than liver and kidney) | 0.03* | EU MRL[(a)] |

| Code number | Commodity | Input value | Comment |
|---|---|---|---|
| 1015990 | . Others (2) | 0.03* | EU MRL[(a)] |
| 1016000 | . (f) poultry | 0.03* | EU MRL[(a)] |
| 1016010 | . Muscle | 0.03* | EU MRL[(a)] |
| 1016020 | . Fat | 0.03* | EU MRL[(a)] |
| 1016030 | . Liver | 0.03* | EU MRL[(a)] |
| 1016040 | . Kidney | 0.03* | EU MRL[(a)] |
| 1016050 | . Edible offals (other than liver and kidney) | 0.03* | EU MRL[(a)] |
| 1016990 | . Others (2) | 0.03* | EU MRL[(a)] |
| 1017000 | . (g) other farmed terrestrial animals | 0.03* | EU MRL[(a)] |
| 1017010 | . Muscle | 0.03* | EU MRL[(a)] |
| 1017020 | . Fat | 0.03* | EU MRL[(a)] |
| 1017030 | . Liver | 0.03* | EU MRL[(a)] |
| 1017040 | . Kidney | 0.03* | EU MRL[(a)] |
| 1017050 | . Edible offals (other than liver and kidney) | 0.03* | EU MRL[(a)] |
| 1017990 | . Others (2) | 0.03* | EU MRL[(a)] |
| 1020000 | . Milk | 0.03* | EU MRL[(a)] |
| 1020010 | . Cattle | 0.03* | EU MRL[(a)] |
| 1020020 | . Sheep | 0.03* | EU MRL[(a)] |
| 1020030 | . Goat | 0.03* | EU MRL[(a)] |
| 1020040 | . Horse | 0.03* | EU MRL[(a)] |
| 1020990 | . Others (2) | 0.03* | EU MRL[(a)] |
| 1030000 | . Birds eggs | 0.03* | EU MRL[(a)] |
| 1030010 | . Chicken | 0.03* | EU MRL[(a)] |
| 1030020 | . Duck | 0.03* | EU MRL[(a)] |
| 1030030 | . Geese | 0.03* | EU MRL[(a)] |
| 1030040 | . Quail | 0.03* | EU MRL[(a)] |
| 1030990 | . Others (2) | 0.03* | EU MRL[(a)] |
| 1040000 | . Honey and other apiculture products (7) | 0.05* | EU MRL[(a)] |
| 1050000 | . Amphibians and Reptiles | 0.03* | EU MRL[(a)] |
| 1060000 | . Terrestrial invertebrate animals | 0.03* | EU MRL[(a)] |
| 1070000 | . Wild terrestrial vertebrate animals | 0.03* | EU MRL[(a)] |

* MRL at Limit of Quantitation (LOQ)
(a) Source of EU MRL: Commission Regulation (EU) 2017/1016 of 14 June 2017

# Appendix 4 Pesticide Residue Intake Model (PRIMo 3.1)

## A 4.1 TMDI calculations

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

**Ethofumesate**

LOQs (mg/kg) range from: 0.03 to: 0.10

**Toxicological reference values**

| | | | |
|---|---|---|---|
| ADI (mg/kg bw/day): | 1 | ARfD (mg/kg bw): | not necessary |
| Source of ADI: | EFSA | Source of ARfD: | EFSA |
| Year of evaluation: | 2016 | Year of evaluation: | 2016 |

Input values

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

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

Comments:

**Normal mode**

**Chronic risk assessment: JMPR methodology (IEDI/TMDI)**

No of diets exceeding the ADI : ---

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

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

# Appendix 5 Additional information provided by the applicant

None.