FINAL REGISTRATION REPORT

**Part B**

**Section 7**

**Metabolism and Residues**

Detailed summary of the risk assessment

Product code: GLOB2007bF

Product name: Observer Pro

Chemical active substances:

Zoxamide, 67.5 g/L
Propamocarb-HCl, 450 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Globachem NV

Submission date: November 2023

Update: July 2024

MS Finalisation date: 31/10/2024

# Version history

| When | What |
|---|---|
| November 2023 | Initial dossier submission by applicant for approval of new product |
| March 2024 | Dossier sent for evaluation |
| July 2024 | Applicant update 01 following zRMS request for implementation of Appendix 1 |
| July 2024 | zRMS finalised evaluation |
| October 2024 | zRMS finalised evaluation after commenting period |
| | |

# Table of Contents

zRMS comments:
This report has been completed by the Applicant. The text highlighted in grey was provided by the zRMS.
~~The text highlighted in grey was provided by the zRMS.~~

# 7 Metabolism and residue data (KCA section 6)

## 7.1 Summary and zRMS Conclusion

Comparison of intended and critical EU GAPs
Propamocarb

| Type of GAP | Crop | Max number of applications | Method of application | Growth stage at last application | Max appl. rate per treatment (g a.s./ha) | PHI (days) |
|---|---|---|---|---|---|---|
| critical NEU GAP (EFSA Journal 2013;11(4):3214) | Potatoes | 4 | Foliar treatment-spraying | BBCH 20-95 | 840 | 7 |
| Critical NEU and SEU GAP (SANCO/10057/2006 final, 25 April 2007) | Potatoes | 6 | Foliar spray | As 1st symptoms occur | 1083 | 14 |
| Intended GAP | Potatoes | 3 | Downward spraying | BBCH 21-79 | 900 | 7 |

The proposed uses of propamocarb-HCl in the formulation GLOB2007bF do not represent unacceptable acute and chronic risks for the consumer.

Zoxamide

| Type of GAP | Crop | Max number of applications | Method of application | Growth stage at last application | Max appl. rate per treatment (g a.s./ha) | PHI (days) |
|---|---|---|---|---|---|---|
| critical NEU GAP, RAR (RMS LV, 2017) | Potatoes | 5 | Foliar treatment-spraying | BBCH 20-80 | 180 | 7 |
| Critical NEU GAP (EFSA Journal. 2023;21:e8427) | Potatoes | 5 | Foliar treatment-spraying | BBCH 31-93 | 180 | 7 |
| Intended GAP | Potatoes | 3 | Downward spraying | BBCH 21-79 | 135 | 7 |

The proposed uses of zoxamide in the formulation GLOB2007bF do not represent unacceptable acute and chronic risks for the consumer.

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

### 7.1.1 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 GLOB2007bF are presented in Table 7.1-1. They have been selected from the individual GAPs in the NEU for potato. A list of all intended uses within the NEU is given in Part B, Section 0.

**Overall conclusion**

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of 0.3 mg/kg for propamocarb-HCl and 0.02* mg/kg for zoxamide in potato as laid down in Reg. (EU) 396/2005 is not expected.
The chronic and the short-term intakes of propamocarb-HCl and zoxamide residues are unlikely to present a public health concern.
As far as consumer health protection is concerned, PL, zRMS agrees with the authorization of the intended use.

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

**Data gaps**

None in the framework of this application.

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

| | | | |
|---|---|---|---|
| PPP (product name/code): | GLOB2007bF | Formulation type: | SC [a, b] |
| Active substance 1: | zoxamide | Conc. of as 1: | 67.5 g/L [c] |
| Active substance 2: | propamocarb | Conc. of as 2: | 450 g/L [c] |
| Applicant: | Globachem NV | Professional use: | ☒ |
| Zone(s): | Central | Non professional use: | ☐ |
| Verified by MS: | yes | | |
| Field of use: | Fungicide | | |

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Use-No.** [e] | **Member state(s)** | **Crop and/ or situation**<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] | **Conclusion** |
| | | | | | Method / Kind | Timing / Growth stage of crop & season | Max. number<br>a) per use<br>b) per crop/ season | Min. interval between applications (days) | kg or L product / ha<br>a) max. rate per appl.<br>b) max. total rate per crop/season | g or kg as/ha<br><br>a) max. rate per appl.<br>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 | CZ, HU, IE, PL, RO, SK, DE, BE, NL | Seed, ware and starch potato (SOLTU)<br>code: 0211000 | F | *Phytophthora infestans* (PHYTIN) | Downwards spraying | BBCH 21-79 | a) 3<br>b) 3 | 7 | a) 2<br>b) 6 | a) 135 Zoxamide + 900 Propamocarb-HCl<br>b) 405 Zoxamide + 2700 Propamocarb-HCl | 150-300 | 7 | / | A |

Explanation for Column 11 "Conclusion"

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

### 7.1.2 Summary of the evaluation

The preparation GLOB2007bF is composed of zoxamide and propamocarb-HCl.

**Table 7.1-2: Toxicological reference values for the dietary risk assessment of zoxamide and propamocarb-HCl**

| Reference value | Source | Year | Value | Study relied upon | Safety factor |
|---|---|---|---|---|---|
| zoxamide | | | | | |
| ADI | SANTE/10052/2018 Rev 2 | 2018 | 0.5 mg/kg bw per day | 1-year dog | 100 |
| ARfD | SANTE/10052/2018 Rev 2 | 2018 | not allocated – not necessary | | |
| RH-150721, zoxamide metabolite in processed commodities | | | | | |
| ADI | EFSA | 2023 | 0.04 mg/kg bw per day | 90-day rats | 1000 |
| ARfD | EFSA | 2023 | 0.22 mg/kg bw | 14-day rats | 300 |
| Propamocarb-HCl | | | | | |
| ADI | EFSA | 2006 | 0.29 mg as/kg bw/day | 52-week dietary study in rats | 100 |
| ARfD | EFSA | 2006 | 1 mg as/kg bw~~/day~~ | 28-day rat study | 100 |

#### 7.1.2.1 Summary for propamocarb-HCl

**Table 7.1-3: Summary for propamocarb-HCl**

| 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 | Potato | Yes | Yes | Yes | Yes | Yes | No | No |

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

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

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

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 zoxamide

**Table 7.1-4: Summary for zoxamide**

| 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 | Potato | Yes | Yes | Yes | Yes | Yes | No | No |

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

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

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

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

### 7.1.2.3 Summary for GLOB2007bF

**Table 7.1-5: Information on GLOB2007bF (KCA 6.8)**

| Crop | PHI for GLOB2007bF proposed by applicant | PHI/ Withholding period* sufficiently supported for | | PHI for GLOB2007bF proposed by zRMS | zRMS Comments (if different PHI proposed) |
|---|---|---|---|---|---|
| | | Propamocarb-HCl | Zoxamide | | |
| Potato | 7 days | Yes | Yes | 7 days | - |

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).

**Waiting periods before planting succeeding crops**

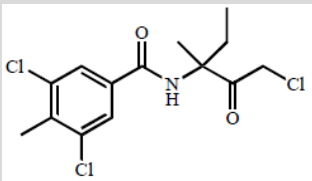
Not relevant.

**Assessment**

## 7.2 Zoxamide

General data on zoxamide are summarized in the table below.

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

| | |
|---|---|
| Active substance (ISO Common Name) | Zoxamide |
| IUPAC | *(RS)*-3,5-dichloro-*N*-(3-chloro-1-ethyl-1-methyl-2-oxopropyl)-*p*- toluamide. |
| Chemical structure | 3,5-dichloro-*N*-(3-chloro-1-ethyl-1-methyl-2-oxo[rp[ul)-4-methylbenzamide  |
| Molecular formula | $C_{14}H_{16}NO_2Cl_3$ |
| Molar mass | 336.65 g/mol |
| Chemical group | benzamides |
| Mode of action (if available) | Zoxamide belongs to the chemical group of the toluamides (FRAC code group 22), which affect tubulin polymerization (B3). It is a contact compound that has protective as well as curative activity against oomycetes. |
| Systemic | No |
| Company (ies) | Gowan Crop Protection Ltd |
| Rapporteur Member State (RMS) | Latvia |
| Approval status | Approved (01/07/2018)<br><br>Reg. (EU) No 540/2011 as amended by Reg. (EU) 2018/84 and Reg. (EU) 2018/692 |
| Restriction | ~~Only useσ as a fungicide may be authorized.~~ None |
| Review Report | SANTE/10052/2018 Rev 2 (23 March 2018) |
| Current MRL regulation | Regulation (EC) No 2017/171 |
| Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed | ~~Pending~~<br>Yes, EFSA Journal. 2023;21:e8427 |
| EFSA Journal: Conclusion on the peer review | Yes<br>EFSA Journal 2017; 15 (9):4980 |
| EFSA Journal: conclusion on article 12 | ~~Pending~~<br>EFSA Journal. 2023;21:e8427 |
| Current MRL applications on intended uses | Not applicable |

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

** If yes: EFSA, YYYY - see list of references

## 7.2.1 Stability of Residues (KCA 6.1)

### 7.2.1.1 Stability of residues during storage of samples

**Available data**

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

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

| Matrix | Characteristics of the matrix | Acceptable Maximum Storage duration | Reference |
|---|---|---|---|
| **Data relied on in EU** | | | |
| **Plant products** | | | |
| Potato | High starch content | 24 months | EFSA, 2017 |
| **New data** | | | |
| **Plant products** | | | |
| Potato | High starch content | 13 months | Gustloff, C. & Mohaupt, R., 2023, S21-07041 |

**Conclusion on stability of residues during storage**

Storage stability studies of zoxamide assessed in this section cover the requested use on potatoes for GLOB2007bF.

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

Not relevant.

zRMS comments:
Not relevant. The Applicant did not provide any new studies in this dossier.

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

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

**Available data**

No new data submitted in the framework of this application.

**Table 7.2-3: Summary of plant metabolism studies in root and tuber vegetables (potato)**

| Crop Group | Crop | Label position | Application and sampling details | | | | | Reference |
|---|---|---|---|---|---|---|---|---|
| | | | Method, F or G (a) | Rate (kg a.s./ha) | No | Sampling (DAT) | Remarks | |
| **EU data** | | | | | | | | |
| **Root and tuber vegetables** | potato | Uniformly isotopically labelled in the phenyl ring | Foliar application | 0.9 | 3 | 14 | No parent zoxamide was found on potato tubers. The main components of the residue in potato tubers were the metabolites RH-141452 and RH-141455. | EFSA, 2017 |

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

The metabolism in primary crops was investigated after foliar spray application in root crops (potato) using zoxamide $^{14}$C-labelled in the phenyl ring. In potatoes in contrast to the rest of the crops where metabolism was investigated ( grape, tomato, cucumber and pea) two major metabolites RH-141452 and RH-141455 were observed at 21% and 39% , respectively. Parent zoxamide was not found in potato tubers.
The metabolic pathways in the four primary crop groups were adequately elucidated but a comparable pathway could not be confirmed yet. Because of outstanding toxicological issues on the metabolites RH-141452 and RH-141455, an overall residue definition (RD) for plants cannot be set. For risk assessment (RA) it is therefore proposed to set provisional residue definitions for root crops the sum of metabolites RH-141452 and RH-141455. The residue definition for monitoring for the root crops is proposed as the sum of metabolites RH-141455 and RH-141452.

**Conclusion on metabolism in primary crops**

For risk assessment (RA) it was proposed to set provisional residue definitions for root crops the sum of metabolites RH-141452 and RH-141455. The residue definition for monitoring for the root crops was proposed as the sum of metabolites RH-141455 and RH-141452.

zRMS comments:
According to EFSA Journal. 2023;21:e8427:
"In the framework of the peer review, the metabolism in primary crops was investigated after foliar spray application in fruits (grape, tomato, cucumber), pulses and oilseeds (pea) and root crops (potato) using zoxamide $^{14}$C-labelled in the phenyl ring.
In fruits, zoxamide was the main component of the total radioactive residue (TRR) in grape (98%). The remaining TRR was extensively metabolised to a range of metabolites representing less than 10% TRR in these commodities.
In potatoes, two major metabolites RH-141452 and RH-141455 were observed at 21% TRR(0.037 mg/kg)

and 39% TRR (0.067 mg/kg), respectively. Parent zoxamide was not found in potato tubers.”
The metabolism of zoxamide in potatoes following foliar application is sufficiently addressed to support the proposed uses of GLOB2007bF.

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

**Available data**

No new data submitted in the framework of this application.

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

| Crop group | Crop | Label position | Application and sampling details | | | | | Reference |
|---|---|---|---|---|---|---|---|---|
| | | | Method, F or G * | Rate (kg a.s./ha) | Sowing intervals (DAT) | Harvest Intervals (DAT) | Remarks | |
| **EU data** | | | | | | | | |
| **Root and tuber vegetables** | Radish, turnip | Uniformly isotopically labelled in the phenyl ring | F | 4 x 0.5 | 30;137;210;365 | 137 | The 210 and 365 mature mustard and radish samples lost due to freezer failure. | EFSA, 2017 |
| **Leafy vegetables** | Mustard | | F | | 30;145;210;365 | 145 | | |
| **Cereals (small grain)** | Sorghum | | F | | 30;137;210;365 | 137 | | |
| **Pulses and oilseeds** | Soybean | | F | | 30;137;210;365 | 137 | | |

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

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

In a rotational crop study, 14C-labelled zoxamide was applied directly to bare soil at a rate of 4 × 0.50 kg/ha equivalent to 2.2N rate for potatoes. Zoxamide was not detected in any of the analysed plant parts, instead several metabolites were observed amongst which RH-141452 was identified mainly in the immature parts of the crops (12% TRR in immature mustard leaves, 15% TRR in immature radish tops, 23.5% TRR in immature soybean forage) and to a lower extend in mature crops (3% TRR in mustard leaf, 7% TRR in radish tops, not detected in soybean seeds). However, it remains unclear whether degradation of zoxamide occurred in soil with the preferential plant uptake of metabolites or whether the degradation of zoxamide is part of the metabolism in plants. In view of the representative uses, it can be concluded that significant individual residue compounds are unlikely to be present in rotational crops while for a more critical use pattern in terms of application rate the issue may have to be reconsidered for future uses.

**Conclusion on metabolism in rotational crops**

Rotation crop and primary crop metabolisms seems to be similar. Very little uptake of residues from soil. Parent zoxamide not detected in following crops. The crops metabolite RH-141452 was found at trace levels in following crops. No detectable residues of zoxamide or related metabolites are expected in rotational crops.

zRMS comments:
Metabolism in primary and rotational crops was found to be similar and a specific residue definition for rotational crops is not deemed necessary. In addition according to EFSA Journal. 2023;21:e8427: the geometric mean $DT_{50}$ in soil of zoxamide is 5.5 days, while the $DT_{50}$ of soil metabolites are less than 60 days (EFSA, 2017). Therefore, in principle further investigation on residues in rotational crops are not required.

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

**Available data**

No new data submitted in the framework of this application.
Processing studies are not required for potato as residues of zoxamide (and the metabolites RH-141455 and RH-141452) are <0.02 mg/kg (<LOQ).

zRMS comments:
The Applicant did not provide any new studies on nature of residues in processed commodities. According to the Commission Regulation (EU) No 283/2013: studies on the nature of residues in processing shall be provided where residues in products of plant or animal origin subject to processing may occur at a level of or higher than 0.01 mg/kg (based on the residue definition for risk assessment for the raw commodity). As quantifiable residues of zoxamide are not expected in the potato (when used in accordance with the proposed GAP) additional studies are not required in the framework of this registration.

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

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

| **Endpoints** | |
|---|---|
| Plant groups covered | Root and tuber vegetables (Potatoes) |
| Rotational crops covered | Yes<br>EFSA Journal 2017;15(9):4980:<br>Root/tuber crops -radish, turnip<br>Leafy crops – mustard<br>Cereals – sorghum<br>Other - soybean |
| Metabolism in rotational crops similar to metabolism in primary crops? | Yes |
| Processed commodities | Not required<br>radiolabelled vinification study showed that the major residue in wine is metabolite RH-150721, EFSA Journal 2017;15(9):4980<br>zoxamide is not stable under processing conditions leading to the formation of several degradates upon processing |

| | |
|---|---|
| Residue pattern in processed commodities similar to pattern in raw commodities? | Not required<br>No, EFSA Journal. 2023;21:e8427 |
| Plant residue definition for monitoring | Root crops: metabolites RH-141455 and RH-141452 (EFSA,2017)<br>Proposed in EFSA Journal. 2023;21:e8427: zoxamide (sum of constituent isomers)<br>Current: Zoxamide, Reg. (EU) 2017/171 |
| Plant residue definition for risk assessment | Metabolites RH-141455 and RH-141452 for root crops<br>Pending data for RH-141455 and RH-141452 (EFSA, 2017)<br>EFSA Journal. 2023;21:e8427:<br>Raw commodities:<br>sum of zoxamide and RH-141452, expressed as zoxamide<br>Processed commodities:<br>RD-1: sum of zoxamide and RH-141452, expressed as zoxamide;<br>RD-2 metabolite RH-150721 |
| Conversion factor from enforcement to RA | 1 (EFSA, 2017 and EFSA Journal. 2023;21:e8427) |

* If residue pattern in processed commodities is not similar to that in raw commodities
** A more recent proposal by EFSA may be provided as additional information (EFSA RO XXXX).
*** If no EFSA proposal is available, a proposal should be made by the applicant/zRMS.

zRMS comments:
According to EFSA Journal. 2023;21:e8427:
“The metabolism of zoxamide in all primary crops was similar in the three crop groups whereas additional metabolites were identified in potatoes. The metabolism in rotational crops is similar to the metabolism observed in primary crops and the processing of zoxamide leads to the generation of several degradates. As the parent compound was found to be a sufficient marker in fruits, roots and pulses and oilseeds, rotational crops and processed commodities, the residue definition for enforcement is proposed as zoxamide only (sum of constituent isomers) (for primary, rotational crops, honey and processed commodities).
In available trials supporting the existing uses and the MRL application, residues of metabolite RH-141452 in fruits occurred at levels above the LOQ in grapes, cucumbers and onions, while metabolite RH-141455 was observed always below the LOQ in all plant commodities. Furthermore, an extensive data set of more than 20 overdosed trials on potatoes reported in the RAR and its addenda (Latvia, 2016, 2017) demonstrate that metabolites RH-141452 and RH-141455 are not expected to occur at levels above the LOQ in potatoes. Metabolite RH-150721 was never found at levels above the LOQ in the raw commodities.
For risk assessment, parent and metabolite RH-141452 are toxicologically relevant and thus should be considered in the consumer exposure. Metabolite RH-141452 encountered in the rat metabolism and was considered covered by the toxicological profile of the parent compound. Therefore, the residue for risk assessment in raw commodities from primary and rotational crops and for honey is proposed as the sum of zoxamide and RH-141452, expressed as zoxamide.
The only metabolite consistently found at levels above the LOQ in processed commodities was RH-150721 (e.g. grape juice, must, wine, raisins, and tomato juice, puree, canned). For metabolite RH-150721 an ADI lower than the parent was set; also, an ARfD was derived for this metabolite while for parent was considered not necessary. Therefore, for processed commodities, two separated residue definitions for risk assessment are proposed: sum of zoxamide andRH-141452, expressed as zoxamide; metabolite RH-150721.”

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

**Available data**

No new data submitted in the framework of this application.

**Table 7.2-6: Summary of animal metabolism studies**

| Group | Species | Label position | No of animal | Application details | | Sample details | | Reference |
|---|---|---|---|---|---|---|---|---|
| | | | | Rate (mg/kg bw/d) | Duration (days) | Commodity | Time of samp-ling | |
| **EU data** | | | | | | | | |
| **Lactating ruminants** | Goat | Uniformly isotopically labelled in the phenyl ring | 1 | 2.82 | 7 | Milk | twice daily | EFSA, 2017 |
| | | | | | | Urine and faeces | twice daily | |

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

Calculation of the livestock dietary burden considering residues in potato triggered poultry and ruminants metabolism studies. This calculation should be considered as provisional based on the outstanding data on the toxicity of these compounds (RH-141452 and RH-141455) and the nature of residues in processed commodities. However, a poultry metabolism study was not presented (data gap) but triggered consequent to a provisional dietary intake calculations. Only a goat metabolism study with $^{14}$C-labelled zoxamide is available. Zoxamide was not detected in the goat study and the metabolites RH-141452 and RH-141455 were observed as terminal compound of a minor metabolic pathway. It should be noted that from the potato metabolism study it is evident that animals will be mainly exposed to RH-141452 and RH-141455, and therefore the metabolic picture depicted with zoxamide cannot be quantitatively representative for the fate of RH-141452 and RH-1414555 in ruminants. The metabolites RH-141288 (sum of isomers) and RH-127450 (sum of isomers) were found in high concentrations in fat than in muscle leading to the assumption that zoxamide residues can be considered as fat soluble. In order to finally conclude on the fat-solubility of zoxamide residues, log $P_{ow}$ for RH-141288 and RH-127450, and an assessment regarding their potential fat-solubility according to FAO (2009) should be provided (data gap). For ruminants, metabolism is addressed and can be considered consistent with rat. For the time being and considering the outstanding toxicological data on the metabolites RH-141452 and RH-141455 and the open question on the fat solubility of the residues, the derivation of the RD for ruminant matrices is not possible.

**Conclusion on metabolism in livestock**

Only goat metabolism study was submitted. Poultry metabolism study is required according to provisional dietary burden calculation.

zRMS comments:
According to EFSA Journal. 2023;21:e8427:
"Zoxamide is authorised for use on potatoes that might be fed to livestock. Livestock dietary burden calculations were therefore performed for different groups of livestock according to OECD guidance (OECD, 2013), which has now also been agreed upon at European level. Since the calculated dietary burdens for all groups of livestock were found to be below the trigger value of 0.004 mg/kg bw per day further investigation of residues as well as the setting of MRLs in commodities of animal origin is unnecessary. Although not needed for the current MRL review, the metabolism of zoxamide residues in livestock was investigated in lactating goats (Latvia, 2017) and assessed in the framework of the peer review (EFSA, 2017). In this study, zoxamide radiolabelled in the phenyl ring of the molecule was administered

orally to a lactating goat once a day for 7 consecutive days. The test material was dosed at levels equivalent to a dietary concentration of 60.7 mg/kg (equivalent to 2.82 mg/kgbw per day). Zoxamide was not detected in the goat study and the metabolites RH-141452 and RH-141455 were observed as terminal compounds of a minor metabolic pathway (EFSA, 2017). It was also noted in the peer review that from the potato metabolism study it was evident that animals will be mainly exposed to RH-141452 and RH-141455, and therefore, the metabolic picture depicted with zoxamide cannot be quantitatively representative for the fate of RH-141452 and RH-141455in ruminants (EFSA, 2017)."

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

**Table 7.2-7: Summary on the nature of residues in commodities of animal origin**

| | **Endpoints** |
|---|---|
| Animals covered | Lactating goats |
| Time needed to reach a plateau concentration | 4 days in milk |
| Animal residue definition for monitoring | Pending (data gap (EFSA, 2017)<br>Not triggered, EFSA Journal. 2023;21:e8427 |
| Animal residue definition for risk assessment | Pending (data gap (EFSA, 2017)<br>Not triggered, EFSA Journal. 2023;21:e8427 |
| Conversion factor | - |
| Metabolism in rat and ruminant similar | Yes |
| Fat soluble residue | Yes, log $P_{ow}$ 3.76 for zoxamide (data gap for RH-141288 and RH-127450) (EFSA,2017) |

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

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

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

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

**Table 7.2-8: Summary of EU reported and new data supporting the intended uses of GLOB2007bF and conformity to existing MRL**

| Commodity | Source | Residue zone (N-EU, S-EU, EU, outside EU) | 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) * | MRL compliance |
|---|---|---|---|---|---|---|---|---|
| Potato | DAR<br>Wais, A. (1999):<br>KCA 6.3.1/05,<br>KCA 6.3.1/10,<br>Grolleau, G. (1999):<br>KCA 6.3.1/07<br>Wais, A. (2000):<br>KCA 6.3.1/14 | N-EU | GAP on which MRL is based: 5 x 0.180 kg as/ha, BBCH 20-80, PHI 7d, outdoor<br>RH-7281 (zoxamide) ~~All~~ 4 x < LOQ 0.02 mg/kg<br>RH-141452 ~~All~~ 4 x < LOQ 0.02 mg/kg<br>RH-141455 ~~All~~ 4 x < LOQ 0.02 mg/kg | N/A | | | | |
| | Overall supporting data for cGAP | N-EU | 4 x < LOQ 0.02 mg/kg | 0.02 | 0.02 | 0.02 | 0.02* | Yes |

* Source of EU MRL: Reg (EU) 2017/171

### 7.2.3.2 Effects on the residue level in pollen and bee products

In Regulation (EU) No. 283/2013 for active substances, the residue level in pollen and bee products for human consumption resulting from residues taken up by honeybees needs to be determined. As this determination of residues level in pollen and bee products is an active substance requirement rather than a plant protection product requirement, such active substance studies should be addressed during the annex I renewal of the active substance. Furthermore, the uses of zoxamide in GLOB2007bF are on potatoes which are not considered to be a melliferous crop.

zRMS comments:
According to the Appendix II of SANTE/11956/2016 rev. 9 potato is a crop which it is not possible to produce honey therefore residues in honey are not expected. Additional studies are not required.

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

According to the available data, the intended use on potato is considered acceptable, for outdoor uses.
The data submitted show that no exceedance of the MRL will occur.
The uses are considered acceptable.
The residue data for potatoes evaluated in the RAR of zoxamide and the GAP taken into account in the trials in terms of application time, frequency and total rate of applied zoxamide was considered to be more critical to the proposed GAP for GLOB2007bF. At the proposed GAP in this dossier residues of zoxamide and metabolites RH-141452 , RH-141455, will be < 0.02 mg/kg and below the current EU MRL for zoxamide of 0.02 mg/kg.

Potato

The indicated results come from studies evaluated in RAR (RMS LV, 2017);
zoxamide: 4 x < 0.02 mg/kg
RH-141452: 4 x < 0.02 mg/kg
RH-141455: 4 x < 0.02 mg/kg

The GAP assessed in the RAR is more critical than that proposed for GLOB2007bF:
EU cGAP (RMS LV, 2017, EFSA 2017):
Max 5 appl. in BBCH 20-80, interval between appl. 8 days, max appl. rate per treatment 180 g a.s./ha, PHI 7 days
GAP proposed for GLOB2007bF:
Max 3 appl. in BBCH 21-79, interval between appl. 7 days, max appl. rate per treatment 135 g a.s./ha, PHI 7 days

As assessed by RMS (LV, 2017) in RAR:
"Total 4 residue trials in North zone and 5 residue trials in South zone are valid to support proposed GAP on potatoes. Residues of RH-141452 and RH-141455 were always below LOQ 0.02 mg/kg.
According to Commission Regulation (EU) No 283/2013 the number of studies to be performed may be reduced if residue trials show that residues in plant or plant products are lower than the LOQ. Minimum of four trials per zone shall be presented for major crop."
According to EFSA Journal 2017;15(9):4980:
"The available residue trials on potato were only partly supported by sufficient storage stability data. In order to judge the validity of the remaining trials, a consistent reporting of the application timing according to growth stages of mono- and dicotyledonous plants (BBCH) scale for the potato plant in accordance with

the requested GAPs (BBCH 20–80) is necessary (data gap). Furthermore, sufficient field trials in potatoes in northern Europe (NEU) and southern Europe (SEU) supporting the critical GAP for the full RD for RA are required (data gap).”
However, in Final Renewal report for the active substance zoxamide, SANTE/10052/2018 Rev 2., the use on potatoes assessed in the RAR was indicated as supported by available data.
According to EFSA Journal. 2023;21:e8427:
“Potatoes: The number of residue trials supporting the southern outdoor/indoor GAP is not compliant with the data requirements for this crop. However, it is noted that an extensive data set of more than 20 overdosed trials performed with 10–7 applications reported in the RAR and its addenda (Latvia, 2016, 2017) demonstrate that residues of parent and metabolites RH-141452 are not expected to occur at levels above the LOQ when zoxamide is applied according to the authorised uses. Therefore, the reduced number of residue trials is considered acceptable in this case because all results were below the LOQ and residues above the LOQ are not expected to occur. Further residue trials are therefore not required.”

The data submitted show that no exceedance of the MRL (0.02 mg/kg, Reg. (EU) 2017/171) will occur.

## 7.2.4 Magnitude of residues in livestock

### 7.2.4.1 Dietary burden calculation

Zoxamide RAR: *Potatoes may be fed to livestock, however residues of zoxamide and metabolites RH-141452 and RH-141455 in potatoes were <0.02 mg/kg in all trials and therefore will not result in significant residues occurring in the diets of livestock. The proposed residue definition in root crops is sum of RH-141452 and RH-141455, therefore the dietary burden calculations have been performed using the residue levels of both metabolites (sum of RH-141452 and RH-141455)*

**Table 7.2-9: Input values for the dietary burden calculation (considering the uses under consideration)**

| Feed Commodity | Median dietary burden | | Maximum dietary burden | |
|---|---|---|---|---|
| | Input value (mg/kg) | Comment | Input value (mg/kg) | Comment |
| Residue definition for root crops: sum of RH-141452 and RH-141455 | | | | |
| Potato | 0.04 | STMR (<0.04 mg/kg) | 0.11 | HR 0.11 |

*EFSA (2017)

**Table 7.2-10: 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 1 (sum of RH-141452 and RH-141455) | | | | | |
| Beef cattle* | 0.004 | | | 0.17 | Y |
| Dairy cattle* | 0.006 | | | 0.17 | Y |

| 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) |
|---|---|---|---|---|---|
| Ram/ewe | 0.006 | | | 0.17 | Y |
| Lamb | 0.006 | | | 0.11 | Y |
| Breeding swine | 0.006 | | | 0.28 | N |
| Finishing swine* | 0.008 | | | 0.28 | N |
| Broiler poultry | 0.004 | | | 0.06 | Y |
| Layer poultry* | 0.004 | | | 0.06 | Y |
| Turkey | 0.008 | | | 0.11 | Y |

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

EFSA, 2017: *Calculation of the livestock dietary burden considering residues in potato triggered poultry and ruminants metabolism studies. This calculation should be considered as provisional based on the outstanding data on the toxicity of these compounds (RH-141452 and RH-141455) and the nature of residues in processed commodities. However, a poultry metabolism study was not presented (data gap) but triggered consequent to a provisional dietary intake calculation. Only a goat metabolism study with 14C–labelled zoxamide is available. Zoxamide was not detected in the goat study and the metabolites RH-141452 and RH-141455 were observed as terminal compounds of a minor metabolic pathway. It should be noted that from the potato metabolism study it is evident that animals will be mainly exposed to RH-141452 and RH-141455, and therefore, the metabolic picture depicted with zoxamide cannot be quantitatively representative for the fate of RH-141452 and RH-141455 in ruminants. The metabolites RH-141288 (sum of isomers) and RH-127450 (sum of isomers) were found in higher concentrations in fat than in muscle leading to the assumption that zoxamide residues can be considered as fat soluble. In order to finally conclude on the fat-solubility of zoxamide residues, log Po/w for RH-141288 and RH-127450, and an assessment regarding their potential fat-solubility according to FAO (2009) should be provided (data gap). For ruminants, metabolism is addressed and can be considered consistent with rat. For the time being and considering the outstanding toxicological data on the metabolites RH-141452 and RH-141455 and the open question on the fat solubility of the residues, the derivation of the RD for ruminant matrices is not possible.*

Open points relevant to active substance data to be addressed by Notifier at next renewal.

zRMS comments:
According to EFSA Journal. 2023;21:e8427:
"Zoxamide is authorised for use on potatoes that might be fed to livestock. Livestock dietary burden calculations were therefore performed for different groups of livestock according to OECD guidance (OECD, 2013), which has now also been agreed upon at European level. The input values for all relevant commodities are summarised in Appendix D. Since the calculated dietary burdens for all groups of livestock were found to be below the trigger value of 0.004 mg/kg bw per day further investigation of residues as well as the setting of MRLs in commodities of animal origin is unnecessary."

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

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

### 7.2.5 Magnitude of residues in processed commodities (Industrial Processing and/or

### Household Preparation) (KCA 6.5.2-6.5.3)

No new data were submitted in the framework of this application.
Processing studies are not required for potato as residues of zoxamide (and the metabolites RH-141452, RH-141455) are <0.02 mg/kg (LOQ).

zRMS comments:
According to the Reg. (EU) No 283/2013:
“If the level of residues is less than 0.1 mg/kg, processing studies shall be carried out if the contribution of the commodity under consideration to the theoretical maximum daily intake (TMDI) is ≥ 10 % of the ADI or if the estimated daily intake is ≥ 10 % of the ARfD for any European consumer group diet.”
Residues of zoxamide and the metabolites RH-141452, RH-141455 are below LOQ. The contribution of the commodity under consideration (potato) to the TMDI is < 10 % of the ADI.
Additional studies are not required.

## 7.2.6 Magnitude of residues in representative succeeding crops

No new data submitted in the framework of this application.
As mentioned in the RAR of zoxamide:
*No supervised field trials were conducted to investigate residues in succeeding crops. However , in the confined rotational crop metabolism study, the only crops to contain total radioactive residues greater than 0.1 mg/kg were immature radish (0.127 mg/kg) and soybean hay (0.189 mg/kg). Both corps were planted 30 days after bare soil was treated (4 applications at 18 day intervals) at a rate of 500 g/ha. Therefore residues in succeeding crops are not considered to be of concern.*

zRMS comments:
According to EFSA Journal 2017;15(9):4980:
“In a rotational crop study, $^{14}C$-labelled zoxamide was applied directly to bare soil at a rate of 4 x 0.50 kg/ha equivalent to 2.2 N rate for potatoes. Zoxamide was not detected in any of the analysed plant parts, instead several metabolites were observed amongst which RH-141452 was identified mainly in the immature parts of the crops (12% TRR in immature mustard leaves, 15% TRR in immature radish tops, 23.5% TRR in immature soybean forage) and to a lower extent in mature crops (3% TRR in mustard leaf, 7% TRR in radish tops, not detected in soybean seeds). However, it remains unclear whether degradation of zoxamide occurred in soil with the preferential plant uptake of metabolites or whether the degradation of zoxamide is part of the metabolism in plants. **In view of the representative uses, it can be concluded that significant individual residue compounds are unlikely to be present in rotational crops** while for a more critical use pattern in terms of application rate the issue may have to be reconsidered for future uses.”
According to EFSA Journal. 2023;21:e8427:
“Low residue levels were found in the rotational crop metabolism study using an exaggerated application rate (2.2 N). Residues in crops grown in rotation are not expected if zoxamide is applied according to the GAPs.”

The proposed use of zoxamide under the GAP for GLOB2007bF is less critical than assessed in EFSA Journal 2017;15(9):4980 and EFSA Journal. 2023;21:e8427.
Residues in crops grown in rotation are not expected if zoxamide is applied according to the GAP proposed for GLOB2007bF.

### 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 GLOB2007bF. Therefore, other special studies are not needed.

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

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

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

**Table 7.2-11: Input values for the consumer risk assessment**

| Commodity | Chronic risk assessment | |
|---|---|---|
| | Input value (mg/kg) | Comment |
| Risk assessment residue definition (root crops): Metabolites RH-141452 and RH-141455 | | |
| Potato | 0.02* | EU MRL<br>Reg (EU) 2017/171 |
| All other commodities | EU MRLs | Reg (EU) 2017/171 |

* Indicates lower limit of analytical determination

#### 7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

**Table 7.2-12: Consumer risk assessment**

| | |
|---|---|
| TMDI (% ADI) according to EFSA PRIMo (rev.3.1) | 8% (based on NL toddler) |
| IEDI (% ADI) according to EFSA PRIMo (rev.3.1) | No IEDI calculations were performed as the TMDI calculations using the MRLs were already acceptable. No refinement of the chronic risk assessment is required. |
| IESTI (% ARfD) according to EFSA PRIMo*(rev.3.1) | No ARfD value available |
| NTMDI (% ADI) ** | - |
| NEDI (% ADI)** | - |
| NESTI (% ARfD) ** | - |

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

The proposed uses of zoxamide in the formulation GLOB2007bF do not represent unacceptable acute and chronic risks for the consumer.

zRMS comments:

For information purposes, the risk assessment performed during the review of the MRL values, EFSA Journal. 2023;21:e8427:

zoxamide

| | |
|---|---|
| ADI | 0.5 mg/kg bw per day (Reg. (EU) 2018/692) |
| TMDI (% ADI) according to EFSA PRIMo | Not assessed |
| IEDI (% ADI) according to EFSA PRIMo (rev. 3.1) | 0.5% ADI (PT general population)Major contributors among crops assessed:<br>Wine grapes: 0.4% of ADI<br>Tomatoes: 0.1% of ADI |
| Assumptions made for the calculations | The calculation is based on the median residue levels derived for raw agricultural commodities, according to the residue definition for enforcement, multiplied by the relevant conversion factors (CFs) for risk assessment. A peeling factor (PeF = 0.17) was applied to cucurbits with inedible peel. The contributions of commodities where no GAP was reported in the framework of the MRL review were not included in the calculation. |

metabolite RH-150721 in processed commodities

| | |
|---|---|
| ARfD | 0.22 mg/kg bw (EFSA, 2023) |
| Highest IESTI, according to EFSA PRIMo (rev.3.1) | Scenario CX metabolite RH-150721:<br>Pumpkins (boiled): 49% of ARfD |
| NESTI (% ARfD) | Not assessed |
| Assumptions made for the calculations | Scenario CX metabolite RH-150721:The calculation is based on the highest residue levels expected in raw agricultural commodities, considering a full conversion of the parent to the metabolite and a correction factor of 0.95 from the MW metabolite150721/MW parent. |

"The exposure values calculated were compared with the toxicological reference value for zoxamide, derived by EFSA (EFSA, 2017). The highest chronic exposure was calculated for PT general representing 0.5% of the acceptable daily intake (ADI). These calculations indicate that the uses assessed under this review result in a consumer exposure lower than the toxicological reference values. For honey residue trials were analysed for parent only, however, since there is a wide margin of safety and the contribution of honey to the overall exposure is minimal (0.0002%), this is not deemed to have an impact on the consumer risk assessment. These calculations indicate that the uses assessed under this review result in a consumer exposure lower than the toxicological reference values."

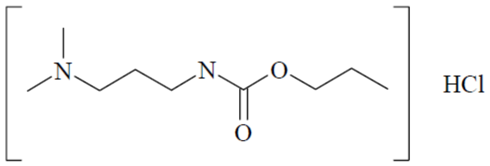
"Since metabolite RH-150721 was proposed for separate residue definition for processing commodities, a consumer risk assessment was performed for the potential exposure to this metabolite in processed commodities. Considering the large margin of safety for the chronic exposure of raw commodities respect to the ADI of 0.5 mg/kg bw per day set for parent, exceedances of the ADI of 0.04 mg/kg bw per day set for metabolite RH-150721, are not expected. Therefore, only acute exposures were calculated for metabolite RH-150721. As a worst-case scenario, it was assumed a full conversion of the parent to the metabolite considering a correction factor based on the MW of metabolite RH-150721 and the MW of parent (318.19/336.6 = 0.95). The exposure values calculated were compared with the toxicological reference value for RH-150721, derived in Section 1. The highest acute exposure was calculated for pumpkin (boiled), representing 49% of the ARfD. These calculations indicate that, even in the unlikely event that all commodities are consumed processed, the uses assessed under this review and the existing CXLs result in a consumer exposure lower than the toxicological reference values for metabolite RH-150721."

The short-term and long-term intake of residues resulting from the use of zoxamide according to the proposed use on potato are unlikely to present a risk to consumer health.

## 7.3 Propamocarb-HCl

General data on Propamocarb-HCl are summarized in the table below.

**Table 7.3-1: General information on Propamocarb-HCl**

| | |
|---|---|
| Active substance (ISO Common Name) | Propamocarb (unless otherwise stated, the following data relate to the variant propamocarb hydrochloride) |
| IUPAC | Propyl 3-(dimethylamino)propylcarbamate (propamocarb)<br>Propyl 3-(dimethylamino) propylcarbamate hydrochloride |
| Chemical structure |  |
| Molecular formula | $C_9H_{21}ClN_2O_2$ |
| Molar mass | 224.7 |
| Chemical group | Carbamate |
| Mode of action (if available) | Propamocarb-HCl is a systemic fungicide with protectant, curative and anti-sporulant activity against oomycetes, belonging in the chemical group of the carbamates (FRAC code group 28), which affect the cell membrane permeability (F4). |
| Systemic | Yes |
| Company (ies) | Arysta LifeScience<br>Bayer CropScience |
| Rapporteur Member State (RMS) | First approval: Ireland<br>Renewal: Portugal |
| Approval status | Approved<br>01/10/2007<br>Commission Directive 2007/25/EC of 23 April 2007<br>Regulation (EU) No 540/2011 |
| Restriction | Only uses as fungicide may be authorised. |
| Review Report | SANCO/10057/2006 final<br>25 April 2007 |
| Current MRL regulation | ~~Reg. (EU) 2020/856~~ Reg. (EU) 2024/1439 |
| Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed | Yes |
| EFSA Journal : Conclusion on the peer review | Yes<br>EFSA Scientific Report (2006) 78, 1-80 |
| EFSA Journal: conclusion on article 12 | Yes<br>EFSA Journal 2013;11(4):3214 |

| | |
|---|---|
| Current MRL applications on intended uses | - |

* Notifier in the EU process to whom the a.s. belong(s)
** If yes: EFSA, YYYY - see list of references

## 7.3.1 Stability of Residues (KCA 6.1)

### 7.3.1.1 Stability of residues during storage of samples

**Available data**

No new data submitted in the framework of this application.

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

| Matrix | Characteristics of the matrix | Acceptable Maximum Storage duration | Reference |
|---|---|---|---|
| **Data relied on in EU** | | | |
| **Plant products** | | | |
| Potato | High starch content | 26 months | RAR of Propamocarb Everitt, S.L; Charter, G.E., 1998 (data out of protection) |
| Tomato | High water content | 26 months | EFSA, 2006 |
| Lettuce | High water content | 24 months | EFSA, 2006 |
| Cucumber | High water content | 12 months | EFSA, 2006 |
| Brussels sprouts | High water content | 12 months | EFSA, 2006 |
| **Animal Products** | | | |
| | Muscle | No study available | |
| | Liver | No study available | |
| | Kidney | No study available | |
| | Milk | No study available | |
| | Egg | No study available | |

**Conclusion on stability of residues during storage**

Storage stability studies of Propamocarb-HCl assessed in this section cover the requested use on potato belonging to high starch content commodities for GLOB2007bF.

zRMS comments:
The Applicant did not provide any new storage stability studies. The data presented by the Applicant, assessed at EU level, are sufficient and appropriate. Additional studies are not required.

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

Not relevant.

zRMS comments:
The Applicant did not provide any new studies in this dossier.

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

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

**Available data**

No new data submitted in the framework of this application.
The data evaluated during the EU Review of Propamocarb-HCl are out of protection and are sufficient to describe the behaviour of the formulated product, so no further studies are required.
Plant metabolism studies had been conducted with tomato, cucumber, spinach, lettuce and potato. The results of the metabolism studies are consistent as they demonstrate that parent Propamocarb is always detected in the treated samples. The studies also suggest that parent Propamocarb is the only residue definition which is suitable for the control of the use of this active substance.

**Table 7.3-3: Summary of plant metabolism studies**

| Crop Group | Crop | Label position | Application and sampling details | | | | | Reference |
|---|---|---|---|---|---|---|---|---|
| | | | Method, F or G (a) | Rate (kg a.s./ha) | No | Sampling (DAT) | Remarks | |
| **EU data** | | | | | | | | |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Fruits and fruiting vegetable | Tomatoes | Not reported. | Soil, G | 7.22 g a.s./$m^2$ | 4 | 14, 21, 28, 25 | - | EFSA Journal 2013;11(4): 3214 |
| | | | | 36.1 g a.s./ $m^2$ | 4 | | | |
| | | | Foliar, G | 2.166 | 1 | 7, 14, 21, 28 | - | EFSA, 2006 |
| | Cucumbers | Not reported. | Foliar (b) | 2.9 | 1 | 30 | - | |
| | | | Soil (hydroponic) (b) | 53.4 mg/plant (aqueous) | 1 | 21 | - | |
| Leafy vegetables | Spinach | [$^{14}$C-carbamate] | Foliar, F | 2.53 | 2 | after the 1st appl: 0 after the 2nd appl.: 3 | - | |
| | Lettuce | Not reported. | Soil, G | drench: 7.22 g a.s./$m^2$ | 3 | 38 | - | |
| | | | Foliar, G | foliar spray: 1.083 | 3 | 21 | - | |
| Root and tuber vegetables | Potatoes | [$^{14}$C-propyl] | Foliar, F | 2.45 | 3 | 42 | - | |
| | | | Foliar, F | 2.166 | 6 | 7 | After the 6th application the foliage had died and the spray was sprayed on soil | |
| | | | | 10.83 | 6 | | | |

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

The metabolism of Propamocarb hydrochloride in plants has been investigated in spinach, potatoes, cucumbers, lettuce and tomatoes. Studies were submitted by both notifiers and as they agreed in conducting a task-force, the entire information was used independently of its source to understand the behaviour in plants of the compound when applied according to the representative uses supported by both notifiers. The information provided is sufficient with regard to all representative uses. The metabolic pattern found in plants is strongly influenced by the mode of application of the product.

In lettuce, after foliar applications, residues are highly extractable (90% of the Total Radioactive Residues – TRR) and consist essentially in Propamocarb. Two minor metabolites, accounting for less than 5% of the TRR were also identified, hydroxypropyl-propamocarb and propamocarb-N-oxyde, indicating that the degradation of propamocarb hydrochloride proceeds through hydroxylation and oxidation. Similar pattern was observed in spinach after foliar treatment, with 2 further metabolites identified, resulting from N-demethylation and cyclization of the hydroxy metabolite identified in lettuce. Foliar treatment of tomato plants also resulted in Propamocarb being the major constituent in tomato fruits (75% of the TRR).

Propamocarb hydrochloride applied hydroponically or as soil treatment in tomatoes or lettuce results in a quite different metabolic pattern in harvested lettuce and tomatoes. The amounts of unchanged parent and of its structurally related metabolites are low when present, but the TRR are essentially constituted of polar material rather similar for the 2 plants and indicating the reincorporation in endogenous material of $CO_2$ resulting from the degradation of Propamocarb hydrochloride by the plant or in the soil. In contrast to the observations made in lettuce and tomatoes, cucumbers grown hydroponically and treated with Propamocarb hydrochloride applied in the nutrient solution showed an important level of parent Propamocarb (50% of the TRR).

Two metabolism studies on potatoes were submitted. Unchanged Propamocarb-anion was present in tubers at 15% of the TRR in one study and at 2% of the TRR in the second study. In both cases, the vast majority of the radioactivity present could be allocated to natural plant constituents (mainly starch), demonstrating the incorporation in plant material of $CO_2$ produced by the degradation of Propamocarb hydrochloride.
The residue definition in plant commodities for monitoring and risk assessment is proposed to be restricted to Propamocarb and its salts, the sum being expressed as Propamocarb, as no metabolite structurally related to Propamocarb is present at level suggesting a significant contribution to the toxicological burden, whatever the plant or the type of treatment. In addition to this, no metabolite has been identified in plant which was not present in rat metabolism.

**Summary of new plant metabolism studies**

No new data is required.

**Conclusion on metabolism in primary crops**

The metabolism of Propamocarb hydrochloride in plants has been fully elucidated. Applied by foliar treatment of plants, the compound is degraded through hydroxylation, oxidation, N-demethylation and cyclisation, but however remains the major compound of the residue pattern. Applied by soil treatment or hydroponically with nutritive solution, its levels, as well as those of its structurally related metabolites, resulting from uptake and translocation into edible parts of the plants are low. In this case, the major part of the radioactivity present in plants is due to the incorporation in the plant of the $CO_2$ produced by complete degradation of the compound. Similar residue pattern is found in potato tubers after foliar treatment of the aerial parts of the plant. The residue definition proposed consists therefore in the sum of Propamocarb and its salts.

zRMS comments:
The Applicant did not provide any new metabolism studies. The data presented by the Applicant, assessed at EU level, are sufficient and appropriate. According to the EFSA Journal 2013;11(4):3214: the metabolism of propamocarb hydrochloride in the crops under consideration is sufficiently addressed and **the residue definition for enforcement purposes and risk assessment in all plant commodities is defined as the sum of propamocarb and its salts, expressed as propamocarb** since the identified metabolites in all crops were recovered at a low proportion (<10% TRR) and no significant contribution to the toxicological burden is expected.
Additional studies are not required.

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

**Available data**

No new data submitted in the framework of this application.

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

| Crop group | Crop | Label position | Application and sampling details | | | | | Reference |
|---|---|---|---|---|---|---|---|---|
| | | | Method, F or G * | Rate (kg a.s./ha) | Sowing intervals (DAT) | Harvest Intervals (DAT) | Remarks | |
| **EU data** | | | | | | | | |
| **Leafy** | Lettuce | $^{14}C$- | | 5.96 - 6.16 | 30, 120, | n.r. | - | Ireland, 2004 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **vegetables** | | aminopropyl | Bare soil, G | | 365 | | | EFSA, 2006 |
| **Root and tuber vegetables** | Radish | | | | | | | |
| **Cereals** | Wheat | | | | | | | |

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

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

In crops planted in the 30 day aged soil, total residues ranged from 0.36 (radish roots) to 2.33 mg/kg (wheat straw), and declined rapidly in crops planted in soil aged 120 days and 365 days to a maximum of 0.09 mg eq/kg. Propamocarb was found in all acidic methanol sample extracts from the 30 day aged soil and was the major component (15.4 % TRR (0.36 mg/kg) in wheat straw to 67.4 % TRR (0.91 mg/kg) in radish tops), except in wheat grain, where the main compound was the oxazolidine metabolite representing 19.9 % TRR (0.13 mg/kg). 2-hydroxy propamocarb, N-oxide and desmethyl propamocarb (wheat only) were not present in any sample at levels exceeding 10 % TRR. The remaining residue was a complex mixture of highly polar components. Residues released after acid and base hydrolysis (< 10 % TRR) indicated a similar pattern of metabolites.

**Summary of new plant metabolism studies**

No new data submitted in the framework of this application.

**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. Although the oxazolidine metabolite was recovered in significant amounts in wheat straw, this metabolism study was carried out with plants grown in pots with an overdosed application rate. Consequently, it is expected that this metabolite will not be present in significant amounts following realistic application conditions (<0.01 mg eq/kg).

zRMS comments:
The Applicant did not provide any new metabolism studies. The data presented by the Applicant, assessed at EU level, are sufficient and appropriate. According to the EFSA Journal 2013;11(4):3214 metabolism in primary and rotational crops was found to be similar and a specific residue definition for rotational crops is not deemed necessary. Based on data from metabolism studies, the presence of propamocarb residues in rotational crops planted 30 days after treatment cannot be excluded.

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

**Available data**

Residues in processed commodities resulting from the representative uses are not expected (EFSA, 2006).

**Conclusion on nature of residues in processed commodities**

No new data submitted in the framework of this application.

zRMS comments:
The Applicant did not provide any new studies on nature of residues in processed commodities. In addition, the effect of processing on the nature of propamocarb was not investigated in the framework of the peer review. According to the Commission Regulation (EU) No 283/2013: studies on the nature of residues in

processing shall be provided where residues in products of plant or animal origin subject to processing may occur at a level of or higher than 0.01 mg/kg (based on the residue definition for risk assessment for the raw commodity). As quantifiable residues of propamocarb are not expected in the potato (when used in accordance with the proposed GAP) additional studies are not required in the framework of this registration.

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

**Table 7.3-5: Summary of the nature of residues in commodities of plant origin**

| **Endpoints** | |
|---|---|
| Plant groups covered | Root and tuber vegetables (Potatoes)<br>Fruits and fruiting vegetables (Tomatoes, cucumbers)<br>Leafy vegetables (Spinach, lettuce) |
| Rotational crops covered | Leafy vegetables (lettuce)<br>Root and tuber vegetables (radish)<br>Cereals (wheat) |
| Metabolism in rotational crops similar to metabolism in primary crops? | Yes. New metabolite oxazolidine observed but not present in significant amount to be taken into consideration in the residue definition. |
| Processed commodities | - The residues of Propamocarb are not expected above 0.1 mg/kg in potatoes and tomatoes therefore processing studies are not required. |
| Residue pattern in processed commodities similar to pattern in raw commodities? | ~~- The residues of Propamocarb are not expected above 0.1 mg/kg in potatoes and tomatoes therefore processing studies are~~ not required. |
| Plant residue definition for monitoring | Sum of Propamocarb and its salts, expressed as Propamocarb<br>EFSA Scientific Report (2006) 78, 1-80; ~~Reg. (EU) 2020/856~~ Reg. (EU) 2024/1439 |
| Plant residue definition for risk assessment | Sum of Propamocarb and its salts, expressed as Propamocarb<br>EFSA Scientific Report (2006) 78, 1-80<br>EFSA Journal 2013;11(4):3214 |
| Conversion factor from enforcement to RA | Not applicable |

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

#### Available data

No new data submitted in the framework of this application.

**Table 7.3-6: Summary of animal metabolism studies**

| Group | Species | Label position | No of animal | Application details | | Sample details | | Reference |
|---|---|---|---|---|---|---|---|---|
| | | | | Rate (mg/kg bw/d) | Duration (days) | Commodity | Time of sampling | |
| **EU data** | | | | | | | | |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Lactating ruminants** | Cow | $^{14}$C-carbon | 1 | 2 | 7 | Milk | twice daily | Ireland, 2004; EFSA, 2006 |
| | | | | | | Urine and faeces | twice daily | |
| | | | | | | Tissues | at sacrifice | |
| **Laying poultry** | Hens | | 12 | 1.02 | 14 | Eggs | Once daily | EFSA, 2013 (data under protection) |
| | | | | | | Excreta | n.r. | |
| | | | | | | Tisues | at sacrifice | |

n.r.: Not reported

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

**DAR (Ireland, 2004)**

Ruminants:

Based on the representative uses supported by the notifiers in the DAR (Ireland, 2004), potatoes is the only feed item which may contain residues of Propamocarb. Given the residue levels to expect in practice, the actual exposure of animals is however very low (less than 0.02 and 0.007 mg/kg bw/d for beef and dairy cattle respectively) and no transfer of residues resulting in measurable amounts in animal commodities is expected. However a metabolism study in lactating cow has been submitted. This study was conducted with an exposure rate of animals 3.2 orders of magnitude higher than the expected level of exposure of animals and showed limited transfer of residues to animal commodities. Liver contained the highest levels of TRR (0.4 mg/kg). The metabolic pattern was similar to that observed in rats and plants, and no sign of potential accumulation was identified.

**Article 12 EFSA Reasoned Opinion (2013)**

Ruminants:

*"In cow, over 80 % of the administered dose was excreted in urine and faeces while only 0.7% and 0.46% of the AR remained in tissues and milk, respectively. No quantifiable residues (<0.01 mg/kg) were recovered in fat and no further metabolites identification was attempted. The highest total radioactive residues were found in liver (0.415 mg eq/kg) and in kidney (0.107 mg eq/kg) and to a minor extent in muscle (0.02 mg eq/kg) and in milk (0.057 mg eq/kg). Propamocarb accounted for 24.6 % TRR in muscle (0.005 mg/kg), 23.5 % TRR in kidney (0.025 mg/kg), 6.2 % TRR in liver (0.026 mg/kg) and 6.0 % TRR in milk (0.003 mg/kg). Parent compound was either oxidized to form N-oxide propamocarb, or hydroxylated at the propyl side chain to form the 2-hydroxy-propamocarb followed by a cyclisation to form the oxazolidine-2-one propamocarb metabolite. Another route of degradation consisted of demethylation of the parent molecule into the N-desmethyl propamocarb. Metabolite N-oxide propamocarb was the predominant metabolite of the total residues found in kidney (41 % TRR – 0.044 mg/kg), liver (49 % TRR – 0.203 mg/kg), muscle (40.5 % TRR – 0.008 mg/kg) and also in milk (21 % TRR – 0.012 mg/kg). Oxazolidine-2-one propamocarb occurred in significant amounts in kidney, liver and milk (14 – 23 % TRR; 0.014 – 0.09 mg/kg). 2-hydroxy propamocarb was the major metabolite of the total residues in milk (37.5 % TRR – 0.022 mg/kg) but was also identified at a lower level in liver (5 % TRR) and kidney (13 % TRR). N-desmethyl propamocarb was either not detected (kidney, liver) or identified at a trace level in milk and muscle (up to 0.002 mg/kg)."*

Hens:

The study was conducted with an exposure rate of animals 3.8 orders of magnitude higher than the expected level of exposure of poultry.

*"In hens, the majority of the residues (92 to 99 % TRR) in the egg and tissues was extractable. The*

*total radioactive residues accounted for 0.254 mg/kg in eggs, 0.492 mg/kg in liver, 0.117 – 0.135 mg/kg in muscle and 0.042 – 0.065 mg/kg in fat. The predominant compound of the total residues was the N-desmethyl propamocarb in eggs (45 % TRR), liver (22 % TRR), muscle (29 % TRR) and to a minor extend in fat (6 % TRR) whilst the parent compound occurred at a lower level in all matrices (2 – 12 % TRR). Bis desmethyl propamocarb and N-oxide propamocarb accounted for less than 10% TRR. It is noted that a significant fraction of the radioactive residues remained uncharacterized in liver and muscle (32 % and 41 % TRR, respectively)."*

*"Based on these studies, EFSA proposes to limit the residue definition to the best marker compound and to define the residue for enforcement in pig and ruminant tissues and milk as N-oxide propamocarb only and in poultry tissues and eggs as N-desmethyl propamocarb. For risk assessment, EFSA proposes to define the residue in milk, pig and ruminant tissues as the sum of propamocarb, N-oxide propamocarb, oxazolidine-2-one propamocarb and 2-hydroxypropamocarb expressed as propamocarb. For poultry tissues, EFSA proposes to define the residue as the sum of propamocarb and N-desmethyl propamocarb, expressed as propamocarb."*

**Summary of new animal metabolism studies**

No new data submitted in the framework of this application.

**Conclusion on metabolism in livestock**

**DAR (Ireland, 2004)**

Taking into account the practical low level of exposure of livestock, there is no need to establish any residue definition nor MRLs for animal commodities.

**Article 12 EFSA Reasoned Opinion (2013)**

*"With an additional route of degradation of propamocarb through hydroxylation of the parent molecule at the propyl side chain with further cyclisation of the side chain, the metabolic degradation of propamocarb in cows appears to be more extensive compared to the metabolism depicted in hens. All the major metabolites identified in cow and hens were also observed in the rat metabolism and are therefore assumed to have similar toxicological properties as the parent compound. The general metabolic pathways of propamocarb in rodents and ruminants were found to be comparable; the findings in ruminants can therefore be extrapolated to pigs.*

*Based on these studies, EFSA proposes to limit the residue definition to the best marker compound and to define the residue for enforcement in pig and ruminant tissues and milk as N-oxide propamocarb only and in poultry tissues and eggs as N-desmethyl propamocarb.*

*For risk assessment, EFSA proposes to define the residue in milk, pig and ruminant tissues as the sum of propamocarb, Noxide propamocarb, oxazolidine-2-one propamocarb and 2-hydroxypropamocarb expressed as propamocarb. For poultry tissues, EFSA proposes to define the residue as the sum of propamocarb and N-desmethyl propamocarb, expressed as propamocarb.*

*Theoretical conversion factors could also be derived as follow: 1.3 for all poultry tissues and eggs, 4.25 for milk, 2.2 for ruminant kidney, 1.7 for ruminant liver and muscle, 1 for ruminant fat. Analytical methods for enforcement of the proposed residue definition are not available (see also section 1.2). The conclusions reached by EFSA are not in line with those of the JMPR (FAO, 2006a) who set a residue definition by default as propamocarb (free base) because the dietary burden was not triggered."*

zRMS comments:
According to the information indicated by the Applicant, data on metabolism evaluated during the review of the MRL values under Article 12 (EFSA Journal 2013;11(4):3214) are still protected and the Applicant has no access to them. Therefore, zRMS recognizes that they have been summarized only as an indication that additional data in this area is available at EU level. In the opinion of zRMS, these data cannot support the dossier. However, considering that the results of field studies indicate the lack of residues of propamocarb in potatoes above the LOQ (for N-EU) and the intended use do not modify the dietary burden calculations completed at EU level, zRMS found that in the framework of this application the lack of access to poultry metabolism study is not critical area of concern and no additional studies are required.

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

**Table 7.3-7: Summary on the nature of residues in commodities of animal origin**

| | **Endpoints** |
|---|---|
| Animals covered | A metabolism study was not required. Metabolism studies in the cow and hens were however submitted. |
| Animal residue definition for monitoring | EFSA Journal 2013;11(4):3214<br>Reg. (EU) 2024/1439<br>In milk, pig and ruminant tissues:<br>N-oxide propamocarb<br>In poultry tissues and eggs:<br>N-desmethyl propamocarb |
| Animal residue definition for risk assessment | EFSA Journal 2013;11(4):3214<br>In milk, pig and ruminant tissues:<br>the sum of propamocarb, N-oxide propamocarb, oxazolidine-2-one propamocarb and 2-hydroxyPropamocarb expressed as propamocarb<br>In poultry tissues and eggs:<br>the sum of propamocarb and N-desmethyl propamocarb, expressed as propamocarb |
| Conversion factor | EFSA Journal 2013;11(4):3214<br>Theoretical conversion factors could be derived as follow :<br>1.3 for all poultry tissues and eggs<br>4.25 for milk<br>2.2 for ruminant kidney<br>1.7 for ruminant liver and muscle<br>1 for ruminant fat |
| Metabolism in rat and ruminant similar | Yes |
| Fat soluble residue | Non fat soluble. |

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

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

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

**Table 7.3-8: Summary of EU reported and new data supporting the intended uses of propamocarb-HCl and conformity to existing MRL**

| Commodity | Source | Residue zone (N-EU, S-EU, EU, outside EU) | 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) * | MRL compliance |
|---|---|---|---|---|---|---|---|---|
| Potatoes | DAR of propamocarb-HCl (Ireland, 2004)<br><br>EFSA Scientific Report (2006) 78, 1-80 | N-EU | 6 x 1083g/ha, PHI 14d, outdoor<br>E: 8x<0.1<br>RA: 8x<0.1 | 0.1 | 0.1 | 0.1 | 0.3 | Yes |
| | | S-EU | 6 x 1083g/ha, PHI 14d, outdoor<br>E :4x<0.1<br>RA: 4x<0.1 | 0.1 | 0.1 | 0.1 | | Yes |
| | Infinito (France, AMM in France. No. 2090136, unprotected data at MS level) | N-EU | 4 x 1000g/ha, PHI 7d, outdoor<br>E: 4x<0.01<br>RA: 4x<0.01 | 0.01 | 0.01 | 0.01 | | Yes |
| | | S-EU | 4 x 1000g/ha, PHI 7d, outdoor<br>E :4x<0.01<br>RA: 4x<0.01 | 0.01 | 0.01 | 0.01 | | Yes |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | EFSA review of all MRLs (2013) data under protection | NEU | 4 x 840 g as/ha, PHI 7d, outdoor<br>E: 8x<0.01<br>RA: 8x<0.01 | 0.01 | 0.01 | 0.01 | | Yes |
| | | SEU | 4 x 840 g as/ha, PHI 7d, outdoor<br>E: 2x<0.01, 0.01, 0.03<br>RA: 2x<0.01, 0.01, 0.03 | 0.01 | 0.03 | 0.07 | | Yes |

*Source of EU MRL: Reg. (EU) ~~No 2020/856~~ No2024/1439

### 7.3.3.2 Effects on the residue level in pollen and bee products

~~In Regulation (EU) No. 283/2013 for active substances, the residue level in pollen and bee products for human consumption resulting from residues taken up by honeybees needs to be determined. As this determination of residues level in pollen and bee products is an active substance requirement rather than a plant protection product requirement, such active substance studies should be addressed during the annex I renewal of the active substance. Furthermore, the~~ The uses of propamocarb-HCl in GLOB2007bF are on potatoes which is not considered to be a melliferous crop.

zRMS comments:
According to the Appendix II of SANTE/11956/2016 rev. 9 potato is a crop which it is not possible to produce honey therefore residues in honey are not expected. Additional studies are not required.

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

There are numerous trials available across EU territory with variable GAPs in different years showing practically no difference between North and South EU and absence of significant residue amounts.

According to the available data, the intended uses on potato are considered acceptable as residues found are considerably lower than the existing EU MRL (aligned to the global Codex MRL).

The data submitted show that no exceedance of the MRL will occur when GLOB2007bF is used according to the intended GAP.

zRMS comments:
The Applicant did not provide any new studies.
Comparison of intended and critical EU GAPs

| Type of GAP | Crop | Max number of applications | Method of application | Growth stage at last application | Max appl. rate per treatment (g a.s./ha) | PHI (days) |
|---|---|---|---|---|---|---|
| critical NEU GAP (EFSA Journal 2013;11(4):3214) | Potatoes | 4 | Foliar treatment-spraying | BBCH 20-95 | 840 | 7 |
| Critical NEU and SEU GAP (SANCO/10057/2006 final, 25 April 2007) | Potatoes | 6 | Foliar spray | As 1st symptoms occur | 1083 | 14 |
| Intended GAP | Potatoes | 3 | Downward spraying | BBCH 21-79 | 900 | 7 |

EU GAP covers GAP proposed for GLOB2007bF.
The field studies evaluated at EU level and presented by the Applicant in this dossier are appropriate and sufficient to conclude that after application of GLOB2007bF, in accordance with the proposed GAP, no residues above the applicable MRL are expected in potatoes.

## 7.3.4 Magnitude of residues in livestock

### 7.3.4.1 Dietary burden calculation

Propamocarb-HCl is already authorised for use on several crops that might be fed to livestock. A dietary burden calculation, including the requested use on potato, has already been made by EFSA in the framework of the Art. 12 evaluation of Propamocarb-HCl (EFSA Journal 2013;11(4):3214).
EU-MRLs on potato were set accordingly and a change of MRL is not needed for this application.

**Table 7.3-9: 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**: sum of propamocarb and its salts, expressed as propamocarb | | | | |
| Cabbage | 0.2 | Median residue (EFSA, 2013) | 0.36 | Highest residue (EFSA, 2013) |
| Kale | 4 | Median residue (EFSA, 2013) | 11.8 | Highest residue (EFSA, 2013) |
| Potatoes | 0.01 | Median residue (EFSA, 2013) | 0.03 | Highest residue (EFSA, 2013) |
| Potato processed waste | 0.2 | Median residue (EFSA, 2013) x EFSA default PF (20) | 0.2 | Median residue (EFSA, 2013) x EFSA default PF (20) |
| Potato dried pulp | 0.38 | Median residue (EFSA, 2013) x EFSA default PF (38) | 0.38 | Median residue (EFSA, 2013) x EFSA default PF (38) |

**Table 7.3-10: Results of the dietary burden calculation**

| 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 | | | | | 0.10 |
| | Median | Maximum | Median | Maximum | | | | mg/kg DM |
| Cattle (all diets) | 0,225 | 0,626 | 6,02 | 16,45 | Dairy cattle | Kale | leaves | Yes |
| Cattle (dairy only) | 0,225 | 0,626 | 5,85 | 16,28 | Dairy cattle | Kale | leaves | Yes |
| Sheep (all diets) | 0,128 | 0,350 | 3,35 | 8,58 | Lamb | Kale | leaves | Yes |
| Sheep (ewe only) | 0,112 | 0,286 | 3,35 | 8,58 | Ram/Ewe | Kale | leaves | Yes |
| Swine (all diets) | 0,070 | 0,191 | 3,03 | 8,28 | Swine (breeding) | Kale | leaves | Yes |
| Poultry (all diets) | 0,009 | 0,014 | 0,14 | 0,20 | Poultry layer | Cabbage, heads | leaves | Yes |
| Poultry (layer only) | 0,009 | 0,014 | 0,14 | 0,20 | Poultry layer | Cabbage, heads | leaves | Yes |

(a): When several diets are relevant (e.g. cattle, sheep and poultry "all diets"), the most critical diet is identified from the maximum dietary burdens expressed as "mg/kg bw per day"
(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as "mg/kg bw per day".

The intended uses of GLOB2007bF are covered by the uses assessed during the review of all existing MRLs for Propamocarb-HCl (EFSA, 2013). The intended uses do not modify the dietary burden calculations completed at European level.

zRMS comments:

The calculations presented by the Applicant in Table 7.2-10 were made using an Animal model 2017. The intended use do not modify the dietary burden calculations completed at EU level.

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

**Available data**

No new data were submitted in the framework of this application.
The uses of GLOB2007bF are adequately covered by the animal dietary burden calculations previously presented in the Article 12 Reasoned Opinion (EFSA, 2013); as a consequence, the existing EU MRLs for propamocarb-HCl in livestock products remain valid for the proposed uses.

The available data presented in Article 12 Reasoned Opinion (EFSA,2013) are considered sufficient for deriving MRLs in hens matrices.
*"Considering that an analytical method is required for enforcement purposes and that further clarification on the individual results for propamocarb and its metabolite in the hen metabolism study are still necessary, the MRL proposals should be regarded as tentative only.*
*Regarding ruminants and pigs, tentative MRLs and risk assessment values were derived from the metabolism study and are summarised in [Table 7.2-10]. A representative ruminants feeding study supported by storage stability data is required in order to derive robust MRLs and risk assessment values."*

zRMS comments:
Additional studies are not required.

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

The effect of processing on the nature of Propamocarb-HCl was not investigated during the peer review and no new studies have been submitted in the framework of this application. Therefore, no data on the effect of processing on Propamocarb-HCl are available.

### 7.3.4.4 Available data for all crops under consideration

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

### 7.3.4.5 Conclusion on processing studies

During EU review, both notifiers indicated that of the representative crops used in the peer-review, lettuce is not processed and residues of Propamocarb will not exceed 0.1 mg/kg in either potatoes or tomatoes. Consequently processing studies are not required for these crops.

zRMS comments:
Additional studies are not required.

### 7.3.5 Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation.

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

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

**Available data**

No new data submitted in the framework of this application.

Rotational crop field trials were evaluated in the framework of the peer review (Ireland, 2004). Propamocarb was applied on bare soil at 4 x 1.68 kg a.s./ha (1 N) and the magnitude of residues was investigated on several succeeding crops (wheat, soybean, sugar beet, table beet and dry beans) sown at three different plant-back intervals (30, 60 and 365 days) following application of the active substance. Wheat was the only crop grown on 30 days aged soils which contained parent residues at or above LOQ. Further rotational crop field trials were submitted where Propamocarb was applied on white cabbage with 2 drench applications at a dose rate of 72.2 kg a.s./ha followed by 2 foliar applications at 3.61 kg a.s./ha (1 N) and the magnitude of residues was investigated on wheat and lamb's lettuce sown at two different plant-back intervals (81 – 102 days for wheat and 52 – 59 days for lamb's lettuce) (Ireland, 2012). No residue was detected (<LOQ of the method) in any of the following crops. In a third set of rotational crop field trials, Propamocarb was sprayed on lettuce as the primary crop at 3 x 1.33 kg a.s./ha (1.8 N) and the magnitude of Propamocarb residues was investigated in lettuce, carrot, winter wheat and barley sown at the 30 day plant-back interval. Residues were < 0.01 mg/kg in all the edible parts of the rotated crops and < 0.05 mg/kg for straw.

Furthermore, we make reference to the following statement (RAR of Propamocarb-HCl, 2017, unprotected data):

| | |
|---|---|
| Report: | KCA 6.6/01; Gateaud, L.; 2010; M - 359448 - 02 - 1 |
| Title: | Statement concerning the reduction of the plant back interval for products containing propamocarb |
| Report No.: | M - 359448 - 02 - 1 |
| Document No.: | M - 359448 - 02 - 1 |
| Guideline(s): | not specified |
| Guideline deviation(s): | not specified |
| GLP/GEP: | no |

Since Annex I Inclusion, no new study has been performed to investigate the metabolism of Propamocarb in rotational crops. Only the magnitude of the residues in the rotational crops has been investigated with new studies:

| | |
|---|---|
| Report: | KCA 6.6.2/02; Klein, E. H. J.; 2004; M-226597-01-1 |
| Title: | Decline of residues in white cabbage, lamb's lettuce and wheat Field Rotation Crop Study European Union (Northern zone) 2002 propamocarb hydrochloride, AE B066752 Water soluble concentrate (SL); 66.5 percent w/w (= 722 g/L) |
| Report No.: | C039190 |
| Document No.: | M-226597-01-1 |
| Guideline(s): | Not specified but complies with EU Commission Working Document 7029/VI/95 rev. 5 22/07/97 |
| Guideline deviation(s): | none |

| | |
|---|---|
| GLP/GEP: | yes |

| | |
|---|---|
| Report: | KCA 6.6.2/03; Melrose, I.; Portet, M.; 2010; M-349882-02-1 |
| Title: | Determination of the residues of fosetyl and propamocarb in/on carrot, lettuce and wheat, winter after spraying of fosetyl & propamocarb SL 840 in the field in Netherlands -Rotational crop study |
| Report No.: | 08-2504 |
| Document No.: | M-349882-02-1 |
| Guideline(s): | EU-Ref: Council Directive 91/414/EEC of July 15, 1991,Annex II, part A, section 6 and AnnexIII, part A, section 8Residues in or on Treated Products, Food and FeedEC guidance working document 7029/VI/95 rev. 5 (1997-07-22)EC guidance working document 7524/VI/95 rev. 2 (1997-07-22)OECD Guideline for testing of Chemicals; Residues in rotational crops(limited field studies), No. 504, 8 Jan. 2007 |
| Guideline deviation(s): | none |
| GLP/GEP: | yes |

| | |
|---|---|
| Report: | KCA 6.6.2/04; Melrose, I.; Portet, M.; 2010; M-349137-02-1 |
| Title: | Determination of the residues of fosetyl and propamocarb in/on carrot, lettuce and barley, winter after spraying of fosetyl & propamocarb SL 840 in the field in France (North) -Rotational crop study |
| Report No.: | 08-2505 |
| Document No.: | M-349137-02-1 |
| Guideline(s): | EU-Ref: Council Directive 91/414/EEC of July 15, 1991,Annex II, part A, section 6 and Annex III, part A, section 8Residues in or on Treated Products, Food and FeedEC guidance working document 7029/VI/95 rev. 5 (1997-07-22)EC guidance working document 7524/VI/95 rev. 2 (1997-07-22)OECD Guideline for testing of Chemicals;Residues in rotational crops(limited field studies), No. 504, 8 Jan. 2007 |
| Guideline deviation(s): | none |
| GLP/GEP: | yes |

| | |
|---|---|
| Report: | KCA 6.6.2/05; Melrose, I.; Portet, M.; 2010; M-361470-01-1 |
| Title: | Determination of the residues of fosetyl and propamocarb in/on carrot, lettuce and wheat, winter after spraying of fosetyl & propamocarb SL 840 in the field in Spain |
| Report No.: | 08-2506 |
| Document No.: | M-361470-01-1 |
| Guideline(s): | EU-Ref: Council Directive 91/414/EEC of July 15, 1991,Annex II, part A, section 6and Annex III, part A, section 8Residues in or on Treated Products, Food and FeedEC guidance working document 7029/VI/95 rev. 5 (1997-07-22)EC guidance working document 7524/VI/95 rev. 2 (1997-07-22)OECD Guideline for testing of Chemicals; Residues inrotational crops(limited field studies), No. 504, 8 Jan. 2007 |
| Guideline deviation(s): | none |

| | |
|---|---|
| GLP/GEP: | yes |

| | |
|---|---|
| Report: | KCA 6.6.2/06; Melrose, I.; Portet, M.; 2010; M-349147-02-1 |
| Title: | Determination of the residues of fosetyl and propamocarb in/on carrot,lettuce and wheat, winter after spraying of fosetyl & propamocarb SL 840 in the field in Italy |
| Report No.: | 08-2507 |
| Document No.: | M-349147-02-1 |
| Guideline(s): | EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8 Residues in or on Treated Products, Food and Feed EC guidance working document 7029/VI/95 rev. 5 (1997-07-22) OECD Guideline for testing of Chemicals; Residues in rotational crops (limited field studies), No. 504, 8 Jan. 2007 |
| Guideline deviation(s): | yes, but acceptable, see report |
| GLP/GEP: | yes |

These 5 studies have already been provided to the MS for the re-authorization (Step 2) of Propamocarb-based products as a result of the first Annex I inclusion in 2007 (Step 2 submission: October 2009, Step 2 re-authorization: October 2011 - varying according to each Member State).
Please refer to re-authorization dossier of Propamocarb-based products as those data should also have been used - such as Proplant (Reg. No.: 9500199), Proxanil (Reg. No.: 2080114) and Previcur Energy (Reg. No.: 2070107) attracting no data protection.
Alternatively, those data should have also been used for new registrations obtained after Annex I inclusion of Propamocarb like Infinito (Reg. No.: 2090136) and for which data protection is over.

All of them have been evaluated and peer reviewed within EFSA Journal 2013; 11 (4): 3214 leading to the conclusion that Propamocarb residue levels in rotational commodities are not expected to exceed 0.01 mg/kg, provided that Propamocarb is applied in compliance with the supported GAP. A statement was submitted to support the proposal of a Plant Back Interval of 30 days (M-359448-02-1). EFSA was therefore of the opinion that the label restriction proposed during the peer review (EFSA Scientific Report (2006) 78, 1 - 80) can be cancelled.

**Table 7.3-11: Summary of available studies in field rotational crops**

| Primary crop | Rate (kg a.s./ha) (GS at application or PHI) | Residue levels in succeeding crops | | | |
|---|---|---|---|---|---|
| | | Succeeding crop group | Succeeding crop | Sowing intervals (DAT) | Reference / Remarks |
| **EU data** | | | | | |
| Bare soil | 6.7 (4x1.68) | Leafy vegetables | Soy bean grain | 30<br>60<br>365 | Ireland, 2004<br>EFSA, 2006 |
| | | | Soy bean forage | | |
| | | | Soy bean hay | | |
| | | Root and tuber vegetables | Sugar & table beet top | | |
| | | | Sugar & table beet root | | |
| | | Cereals | Wheat forage | | |
| | | | Wheat grain | | |
| | | | Wheat straw | | |
| | | Pulses and oilseed | Dry bean grain | | |
| **Data from EFSA Journal 2013;11(4):3214** | | | | | |
| Lettuce | 3.975 (1.325x3) | Leafy vegetables | Lettuce | 30 | Melrose I., Portet, M., 2010, report N°08-2504 |
| | | Root and tuber vegetables | Carrot top | 30 | |
| | | | Carrot root | | |
| | | Cereals | Wheat forage | 30 | |
| | | | Wheat grain | | |
| | | | Wheat straw | | |
| Lettuce | 3.975 (1.325x3) | Leafy vegetables | Lettuce | 35 | Melrose I., Portet, M., 2010, report N°08-2505 |
| | | Root and tuber vegetables | Carrot top | 36 | |
| | | | Carrot root | | |
| | | Cereals | Barley forage | 41 | |
| | | | Barley grain | | |
| | | | Barley straw | | |

<table>
<tr><th rowspan="2">Primary crop</th><th rowspan="2">Rate (kg a.s./ha)<br>(GS at application or PHI)</th><th colspan="4">Residue levels in succeeding crops</th></tr>
<tr><th>Succeeding crop group</th><th>Succeeding crop</th><th>Sowing intervals (DAT)</th><th>Reference / Remarks</th></tr>
<tr><td rowspan="6">Lettuce</td><td rowspan="6">3.975 (1.325x3)</td><td>Leafy vegetables</td><td>Lettuce</td><td>98</td><td rowspan="6">Melrose I., Portet, M., 2010, report N°08-2506</td></tr>
<tr><td rowspan="2">Root and tuber vegetables</td><td>Carrot top</td><td rowspan="2">90</td></tr>
<tr><td>Carrot root</td></tr>
<tr><td rowspan="3">Cereals</td><td>Wheat forage</td><td rowspan="3">93</td></tr>
<tr><td>Wheat grain</td></tr>
<tr><td>Wheat straw</td></tr>
<tr><td rowspan="6">Lettuce</td><td rowspan="6">3.975 (1.325x3)</td><td>Leafy vegetables</td><td>Lettuce</td><td>40</td><td rowspan="6">Melrose I., Portet, M., 2010, report N°08-2507</td></tr>
<tr><td rowspan="2">Root and tuber vegetables</td><td>Carrot top</td><td rowspan="2">40</td></tr>
<tr><td>Carrot root</td></tr>
<tr><td rowspan="3">Cereals</td><td>Wheat forage</td><td rowspan="3">43</td></tr>
<tr><td>Wheat grain</td></tr>
<tr><td>Wheat straw</td></tr>
<tr><td rowspan="4">Cabbage</td><td rowspan="4">115.42 (cabbage drench treatment BBCH 00-11 at 72.2 kg as/ha + drench treatment BBCH 10-13 at 36 kg as/ha + 2x3.61 kg as/ha as foliar treatment)</td><td>Leafy vegetables</td><td>Lettuce</td><td>52-59</td><td rowspan="4">Klein E. H-J., 2004, report N° C039190</td></tr>
<tr><td rowspan="3">Cereals</td><td>Wheat forage</td><td rowspan="3">81-102</td></tr>
<tr><td>Wheat grain</td></tr>
<tr><td>Wheat straw</td></tr>
</table>

**Conclusion on rotational crops studies**

As European data are out of protection, the results of the above rotational crop study can be used by the applicant and are sufficient to support the intended use of GLOB2007bF as fungicide in potato. No residue above 0.01 mg/kg is expected in rotational crops.

zRMS comments:
zRMS agrees with the data presented by the Applicant. The rotational crop studies evaluated at EU level in the framework of the review of MRLs for propamocarb and presented by the Applicant in the dossier are out of protection. No residue above 0.01 mg/kg is expected in rotational crops. EFSA was of the opinion that the label restriction proposed during the peer review (EFSA Scientific Report (2006) 78, 1 - 80) can be cancelled.
Additional studies are not required.

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

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of GLOB2007bF. Therefore, other special studies are not needed.

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

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

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

Consumer risk assessment calculations were performed taking into account all the crops for which an MRL has been set for Propamocarb-HCl under Reg. (EU) ~~No 289/2014~~ No 2024/1439. Where the MRL for a particular crop is below the LOQ, calculations have been made with the LOQ for that crop.

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

| Commodity | Chronic risk assessment | | Acute risk assessment | |
|---|---|---|---|---|
| | **Input value (mg/kg)** | **Comment** | **Input value (mg/kg)** | **Comment** |
| **Risk assessment residue definition:** sum of propamocarb and its salts, expressed as propamocarb | | | | |
| Potato | MRL<br>0.3 | Reg. (EU) No 2020/856<br>Reg. (EU) No 2024/1439 | 0.01 | HR (EFSA, 2006) |
| Other crops | MRL | Reg. (EU) No 2020/856 | Crops not applicable to this submission | |
| Honey and other apiculture products | ~~0.05~~ MRL<br>15 | ~~MRL (Reg. (EU) No 2020/856)~~<br>Reg. (EU) No 2024/1439 | Commodities not applicable to this submission | |
| Potatoes / chips | NA | | 0.01 | STMR (EFSA, 2006) |
| Potatoes / dried (flakes) | NA | | 0.046 | STMR (EFSA, 2006) x default PF (4.6, OECD, 2008) |
| Potatoes / fried | NA | | 0.01 | HR (EFSA, 2006) |
| **Risk assessment residue definition:**<br>the sum of propamocarb, N-oxide propamocarb, oxazolidine-2-one propamocarb and 2-hydroxyPropamocarb expressed as propamocarb | | | | |
| Swine Muscle/meat | 0.017 | MRL (Reg. (EU) No 2020/856) x CF(1.7) (EFSA, 2013) | 0.02 | HR × CF (1.7) (EFSA, 2013) |
| Swine Fat | 0.01 | MRL (Reg. (EU) No 2020/856) x CF(1) (EFSA, 2013) | 0.01 | HR × CF (1) (EFSA, 2013) |

| Commodity | Chronic risk assessment | | Acute risk assessment | |
|---|---|---|---|---|
| | **Input value (mg/kg)** | **Comment** | **Input value (mg/kg)** | **Comment** |
| Swine Liver | 0.17 | MRL (Reg. (EU) No 2020/856) x CF(1.7) (EFSA, 2013) | 0.09 | HR × CF (1.7) (EFSA, 2013) |
| Swine Kidney | 0.044 | MRL (Reg. (EU) No 2020/856) x CF(2.2) (EFSA, 2013) | 0.02 | HR × CF (2.2) (EFSA, 2013) |
| Swine edible offals | 0.1 | MRL (Reg. (EU) No 2020/856) | 0.1 | MRL (Reg. (EU) No 2020/856) |
| Swine Other animal products | 0.01 | MRL (Reg. (EU) No 2020/856) | 0.01 | MRL (Reg. (EU) No 2020/856) |
| Ruminant Muscle/meat | 0.017 | MRL (Reg. (EU) No 2020/856) x CF(1.7) (EFSA, 2013) | 0.02 | HR × CF (1.7) (EFSA, 2013) |
| Ruminant Fat | 0.01 | MRL (Reg. (EU) No 2020/856) x CF(1) (EFSA, 2013) | 0.01 | HR × CF (1) (EFSA, 2013) |
| Ruminant Liver | 0.34 | MRL (Reg. (EU) No 2020/856) x CF(1.7) (EFSA, 2013) | 0.22 | HR × CF (1.7) (EFSA, 2013) |
| Ruminant Kidney | 0.11 | MRL (Reg. (EU) No 2020/856) x CF(2.2) (EFSA, 2013) | 0.06 | HR × CF (2.2) (EFSA, 2013) |
| Ruminant edible offals | 0.2 | MRL (Reg. (EU) No 2020/856) | 0.2 | MRL (Reg. (EU) No 2020/856) |
| Ruminant Milk | 0.0425 | MRL (Reg. (EU) No 2020/856) x CF(4.25) (EFSA, 2013) | 0.04 | STMR × CF (4.25) (EFSA, 2013) |
| Ruminant Other animal products | 0.01 | MRL (Reg. (EU) No 2020/856) | 0.01 | MRL (Reg. (EU) No 2020/856) |
| Other animal product | MRL (Reg. (EU) No 2020/856) | | MRL (Reg. (EU) No 2020/856) | |
| **Risk assessment residue definition:** the sum of propamocarb and N-desmethyl propamocarb, expressed as propamocarb | | | | |
| Poultry Muscle/meat | 0.026 | MRL (Reg. (EU) No 2020/856) x CF(1.3) (EFSA, 2013) | 0.03 | HR × CF (1.3) (EFSA, 2013) |
| Poultry Fat | 0.013 | MRL (Reg. (EU) No 2020/856) x CF(1.3) (EFSA, 2013) | 0.013 | HR × CF (1.3) (EFSA, 2013) |
| Poultry Liver | 0.065 | MRL (Reg. (EU) No 2020/856) x CF(1.3) (EFSA, 2013) | 0.04 | HR × CF (1.3) (EFSA, 2013) |

| Commodity | Chronic risk assessment | | Acute risk assessment | |
|---|---|---|---|---|
| | **Input value (mg/kg)** | **Comment** | **Input value (mg/kg)** | **Comment** |
| Poultry Kidney | 0.01* | MRL (Reg. (EU) No 2020/856) | 0.01* | <LOQ MRL |
| Poultry Edible offals | 0.065 | MRL (Reg. (EU) No 2020/856) x CF(1.3) | 0.065 | MRL (Reg. (EU) No 2020/856) x CF(1.3) |
| Poultry Eggs | 0.065 | MRL (Reg. (EU) No 2020/856) x CF(1.3) (EFSA, 2013) | 0.05 | HR × CF (1.3) (EFSA, 2013) |
| Poultry Other animal products | 0.013 | MRL (Reg. (EU) No 2020/856) x CF(1.3) | 0.013 | MRL (Reg. (EU) No 2020/856) x CF(1.3) |

zRMS comments:
All MRL values in Reg. (EU) No 2020/856 are the same as in the current Reg. (EU) 2024/1439, except for honey, for which the MRL value has been increased from 0.05 mg/kg to 15 mg/kg.

### 7.3.7.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

**Table 7.3-13: Consumer risk assessment**

| | |
|---|---|
| TMDI (% ADI) according to EFSA PRIMo (rev. 3.1) | 21% (based on NL toddler) |
| IEDI (% ADI) according to EFSA PRIMo (rev. 3.1) | No IEDI calculations were performed as the TMDI calculations using the MRLs were already acceptable. No refinement of the chronic risk assessment is required. |
| IESTI (% ARfD) according to EFSA PRIMo*(rev. 3.1) | **Raw commodities:**<br>Potato: 0.2 % for children<br>Milk (Cattle): 0.5% for children<br>**Processed commodities**:<br>Potatoes, fried: 0.1%, Potatoes, dried (flakes): 0.1%, for children |
| NTMDI (% ADI) ** | - |
| NEDI (% ADI)** | - |
| NESTI (% ARfD) ** | - |

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

The proposed uses of Propamocarb-HCl in the formulation GLOB2007bF do not represent unacceptable acute and chronic risks for the consumer.

zRMS comments:
Changing the MRL value for honey does not modify the chronic and acute risk assessment for the consumer. The proposed uses of Propamocarb-HCl in the formulation GLOB2007bF do not represent unacceptable acute and chronic risks for the consumer.

## 7.4 Combined exposure and risk assessment

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

## 7.5 References

EFSA (European Food Safety Authority), Bellisai, G., Bernasconi, G., Carrasco Cabrera, L.,Castellan, I., del Aguila, M., Ferreira, L., Santonja, G. G., Greco, L., Jarrah, S., Leuschner, R., Perez, J. M., Miron, I., Nave, S., Pedersen, R., Reich, H., Ruocco, S., Santos, M., Scarlato, A. P., … Verani, A. (2023). Review of the existing maximum residue levels for zoxamide according to Article 12 of Regulation (EC) No 396/2005 and setting of an import tolerance for onions, garlic and shallots. EFSA Journal, 21(12), e8427. https://doi.org/10.2903/j.efsa.2023.8427

EFSA (European Food Safety Authority), 2017. Peer review of the pesticide risk of the active substance zoxamide. EFSA Journal (2017) 15(9): 4980.

European Food Safety Authority, 2013. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for propamocarb according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2013;11(4):3214, 72 pp. doi:10.2903/j.efsa.2013.3214

Commission Regulation (EU) 2020/856 of 9 June 2020 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for cyantraniliprole, cyazofamid, cyprodinil, fenpyroximate, fludioxonil, fluxapyroxad, imazalil, isofetamid, kresoxim-methyl, lufenuron, mandipropamid, propamocarb, pyraclostrobin, pyriofenone, pyriproxyfen and spinetoram in or on certain products (Text with EEA relevance)

EFSA (European Food Safety Authority), 2006. Conclusion on the peer review of the pesticide risk assessment of the active substance propamocarb. EFSA Journal 2006;4(7):78r, 80 pp. https://doi.org/10.2903/j.efsa.2006.78r

Ireland, 2004. Draft assessment report on the active substance propamocarb prepared by the rapporteur Member State Ireland in the framework of Council Directive 91/414/EEC, October 2004. Available online: www.efsa.europa.eu

EC (European Commission), 2007. Review report for the active substance propamocarb finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 24 November 2006 in view of the inclusion of propamocarb in Annex I of Directive 91/414/EEC

# 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 |
|---|---|---|---|---|---|
| KCA 6.1 | Gustloff, C. | 2023 | Storage stability of Residues of Zoxamide and its Metabolites in/on Grape and Potato Matrices, Eurofins Agroscience Services Chem Gmbh, Report No.: S21-07041, GLP, Unpublished | N | Globachem NV |

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

| Data point | Author(s) | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not | Vertebrate study Y/N | Owner |
|---|---|---|---|---|---|
| CA, 6.1/01 | Ross, JR | 1998a | Ross, J.R., Storage Stability of RH-117281 Residues in Grapes, Grape Juice, Raisins and Potatoes under Conditions of Frozen Storage, Rohm and Haas Technical Report No. 34-98-161, December 15, 1998, GLP, unpublished. ER ref. no. R 61.1 | N | Gowan |
| CA, 6.1/02 | Ross, JR | 1998b | Ross, J.R., Stability of RH-141455 and RH-141452 Residues in Potatoes, Potato Chips, and Potato Flakes under Conditions of Frozen Storage, Rohm and Haas Technical Report No. 34-98-162, December 15, 1998, GLP, unpublished. ER ref. no. R 61.2 | N | Gowan |
| CA, 6.1/03 | Reibach, P.H. | 2000 | Storage Stability of RH-117,281 Residue in Potato Samples under Conditions of Frozen Storage:Supplement to TR34-98-161 (ER 61.1) Rohm and Haas unpublished Technical Report No. 34-00-80 September 2, 2000 ER ref. no. R 77.11 (submitted with 44.7) | N | Gowan |
| CA, 6.2.1/02 | Reibach, PH, Spencer, WO | 1998b | Reibach, PH and Spencer, WO, 14C-RH-117,281: Nature of the Residue in Potato, Rohm and Haas Technical Report No. 34- 98-50, September 17, 1998, GLP, unpublished. ER ref. no. 14.3 | N | Gowan |
| CA, 6.2.3/01 | - | 1998 | xxxxxxxxxxxx, Metabolism of 14C-RH-117,281 in lactating goats, Technical Report No. 34-97-166, September 10, 1998, GLP, unpublished. ER ref. no. 16.1 | Y | Gowan |
| CA, 6.3.1/01 | Wais, A. | 1999a | Determination of residues of RH-117281 and mancozeb in/on potatoes (RAC tubers) following treatment with RH-7281 2F and Dithane /RH-117,281 75 DG Blend from field trials in Germany; 1996 Report no. 553002/649776, April 12, 1999 GLP, unpublished ER ref. no. R 66.4/R 66.5 | N | Gowan |
| CA, 6.3.1/02 | Wais, A. | 1999b | Determination of residues of RH-117281 and mancozeb in/on potatoes (RAC tubers) following treatment with RH-7281 2F and Dithane /RH-117,281 75 DG Blend from field trials in the United Kingdom; 1996 Report no. 553300/649811, April 16, 1999 GLP, unpublished ER ref. no. R 70.3/R 70.4 | N | Gowan |
| CA, 6.3.1/03 | Grolleau, G. | 1999a | Magnitude of the residue of RH-7281 and its metabolites RH-1452 and RH-1455 in Potato Raw Agricultural Commodity. Northern and Southern France, 1996 Report no. EA960112, April 6, 1999 GLP, unpublished ER ref. no. R 63.3 | N | Gowan |
| CA, 6.3.1/04 | Wais, A. | 1999c | Determination of residues of RH-117281 and mancozeb in/on potato (RAC tubers) following treatment with RH-7281 2F and Dithane /RH-117,281 75 DG Blend from field trials in Italy; 1996 Report no. 553103/649800, April 13, 1999 GLP, unpublished ER ref. no. R 67.5/R 67.6 | N | Gowan |

| | | | | | |
|---|---|---|---|---|---|
| CA, 6.3.1/05 | Wais, A. | 1999d | Determination of residues of RH-117281 and mancozeb in/on potatoes (RAC tubers) following treatment with RH-7281 2F and Dithane /RH-117,281 75 DG Blend from field trials in Germany; 1997 Report no. 652252, March 18, 1999 GLP, unpublished ER ref. no. R 64.4/R 64.5 | N | Gowan |
| CA, 6.3.1/06 | Wais, A. | 1999e | Determination of residues of RH-117281 and mancozeb in/on potatoes (RAC tubers) following treatment with RH-7281 2F and Dithane /RH-117,281 75 DG Blend from field trials in UK; 1997 Report no. 652263, March 23, 1999 GLP, unpublished ER ref. no. R 65.5/R 65.6 | N | Gowan |
| CA, 6.3.1/07 | Wais, A. | 1999f | Magnitude of the residue of RH-7281 and its metabolites RH-1452 and RH-1455 in Potato Raw Agricultural Commodity. Northern and Southern France, 1997 Report no. EA970131, April 6, 1999 GLP, unpublished ER ref. no. R 64.1 | N | Gowan |
| CA, 6.3.1/08 | Wais, A. | 1999g | Determination of residues of RH-117281 and mancozeb in/on potatoes (RAC tubers) following treatment with RH-7281 2F and Dithane /RH-117,281 75 DG Blend from field trials in Italy; 1997 Report no. 652285, March 25, 1999 GLP, unpublished ER ref. no. R 65.3/R 65.4 | N | Gowan |
| CA, 6.3.1/09 | Wais, A. | 1999h | Determination of residues of RH-117281 and mancozeb in/on potatoes (RAC tubers) following treatment with RH-7281 2F and Dithane/RH-117,281 75 DG Blend from field trials in Greece; 1997 Report no. 652307, March 17, 1999 GLP, unpublished ER ref. no. R 64.2/R 64.3 | N | Gowan |
| CA, 6.3.1/10 | Wais, A. | 1999i | Determination of residues of RH-117,281 and mancozeb in/on potato (RAC tubers) following treatment with Dithane/RH-117,281 75 DG Blend (8:1) and Dithane/RH-117,281 75 WP Blend (8:1) from two field trials in Germany; 1998 Report no. 688904, April 13, 1999 GLP, unpublished,ER ref. no. R 68.1/R 68.2 | N | Gowan |
| CA, 6.3.1/11 | Wais, A. | 1999j | Determination of residues of RH-117,281 and mancozeb in/on potato (RAC tubers) following treatment with Dithane/RH-117,281 75 DG Blend (8:1) and Dithane/RH-117,281 75 WP Blend (8:1) from two field trials in UK; 1998 Report no. 688937, April 13, 1999 GLP, unpublished,ER ref. no. R 68.3/R 68.4 | N | Gowan |
| CA, 6.3.1/12 | Wais, A. | 1999k | Determination of residues of RH-117,281 and mancozeb in/on potato (RAC tubers) following treatment with Dithane/RH-117,281 75 DG Blend (8:1) and Dithane/RH-117,281 75 WP Blend (8:1) from four field trials in Spain; 1998 Report no. 688926, April 13, 1999 GLP, unpublished ER ref. no. R 66.6/R 66.7 | N | Gowan |
| CA, 6.3.1/14 | Wais, A. | 2000 | Determination of residues of RH-117,281 and its metabolites RH-141,452 and RH-141,455 in/on potatoes (RAC tubers) following treatment with RH-7281/mancozeb 75WG from a field trial (semi residue decline study) in the Netherlands; 1999 Report no. 734567, January 2000 GLP, unpublished ER ref. no. R 72.5 | N | Gowan |

| | | | | | |
|---|---|---|---|---|---|
| CA, 6.3.1/15 | Wais, A. | 2000 | Determination of residues of RH-117,281 and its metabolites RH-141,452 and RH-141,455 in/on potatoes (RAC tubers and processing products) following treatment with RH-7281/mancozeb 75WG from a field trial (semi residue decline study) in Northern France; 1999 Report no. 734556, February 2000 GLP, unpublished ER ref. no. R 72.9 | N | Gowan |
| CA, 6.3.1/16 | Wais, A. | 2000 | Determination of residues of RH-117,281 and its metabolites RH-141,452 and RH-141,455 in/on potatoes (RAC tubers) following treatment with RH-7281/mancozeb 75WP from a field trial (semi residue decline study) in Northern France; 1999 Report no. 739001, March 2000 GLP, unpublished ER ref. no. R 72.4 | N | Gowan |
| CA, 6.3.1/17 | Wais, A. | 2000 | Determination of residues of RH-117,281 and its metabolites RH-141,452 and RH-141,455 in/on potatoes (RAC tubers and processing products) following treatment with RH-7281/mancozeb 75WG from a field trial (semi residue decline study) in Italy; 1999 Report no. 734545, March 2000 GLP, unpublished, ER ref. no. R 73.2 | N | Gowan |
| IIA, 6.6.1/01 | Kim-Kang, H | 1998 | Kim-Kang, H., 14C-RH-117,281: Confined Rotational Crop Study, XenoBiotic Laboratories, Inc., Rohm and Haas Technical Report No. 34-98-144, December 4, 1998, GLP, unpublished. ER ref. no. R 60.2 | N | Gowan |
| KCA 6.2.2-6.2.5 | xxxxxxxxxxxxx | 2010 | Metabolism of [14c]-propamocarb hydrochloride in the laying hen<br>xxxxxxxxxxxxxxxxxxxx,<br>Report No.: MEPRX029,<br>Edition Number: M-366633-01-1<br>Date: 2010-04-08<br>GLP, unpublished | Y | Bayer CropScience |
| KCA 6.6.2 /02 | Klein, E. H. J. | 2004 | Decline of residues in white cabbage, lamb's lettuce and wheat Field Rotation Crop Study European Union (Northern zone) 2002 Propamocarb hydrochloride, AE B066752 Water soluble concentrate (SL); 66.5 percent w/w (= 722 g/L)<br>Bayer CropScience GmbH, Frankfurt am Main, Germany<br>TF-BCS-Arysta LifeScience,<br>Report No.: C039190,<br>Edition Number: M-226597-01-1<br>Date: 2004-03-04<br>GLP/GEP: yes, unpublished | N | TF-BCS-Arysta LifeScience |

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|---|---|---|---|---|---|
| KCA 6.6.2 /03 | Melrose, I.; Portet, M. | 2009 | Determination of the residues of fosetyl and propamocarb in/on carrot, lettuce and wheat, winter after spraying of fosetyl & propamocarb SL 840 in the field in Netherlands - Rotational crop study<br>Bayer S.A.S., Bayer CropScience, Lyon, France<br>TF-BCS-Arysta LifeScience,<br>Report No.: 08-2504,<br>Report includes Trial Nos.:<br>08-2504-01<br>08-2504-02<br>08-2504-03<br>Edition Number: M-349882-02-1<br>Date: 2009-06-22<br>**...Amended: 2010-01-13**<br>GLP/GEP: yes, unpublished | N | TF-BCS-Arysta LifeScience |
| KCA 6.6.2 /04 | Melrose, I.; Portet, M. | 2009 | Determination of the residues of fosetyl and propamocarb in/on carrot, lettuce and barley, winter after spraying of fosetyl & propamocarb SL 840 in the field in France (North) - Rotational crop study<br>Bayer S.A.S., Bayer CropScience, Lyon, France<br>TF-BCS-Arysta LifeScience,<br>Report No.: 08-2505,<br>Report includes Trial Nos.:<br>08-2505-01<br>08-2505-02<br>08-2505-03<br>Edition Number: M-349137-02-1<br>Date: 2009-06-12<br>**...Amended: 2010-01-12**<br>GLP/GEP: yes, unpublished | N | TF-BCS-Arysta LifeScience |

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|---|---|---|---|---|---|
| KCA 6.6.2 /05 | Melrose, I.; Portet, M. | 2010 | Determination of the residues of fosetyl and propamocarb in/on carrot, lettuce and wheat, winter after spraying of fosetyl & propamocarb SL 840 in the field in Spain<br>Bayer S.A.S., Bayer CropScience, Lyon, France<br>TF-BCS-Arysta LifeScience,<br>Report No.: 08-2506,<br>Report includes Trial Nos.:<br>08-2506-01<br>08-2506-02<br>08-2506-03<br>Edition Number: M-361470-01-1<br>Date: 2010-01-14<br>GLP/GEP: yes, unpublished | N | TF-BCS-Arysta LifeScience |
| KCA 6.6.2 /06 | Melrose, I.; Portet, M. | 2009 | Determination of the residues of fosetyl and propamocarb in/on carrot, lettuce and wheat, winter after spraying of fosetyl & propamocarb SL 840 in the field in Italy<br>Bayer S.A.S., Bayer CropScience, Lyon, France<br>TF-BCS-Arysta LifeScience,<br>Report No.: 08-2507,<br>Report includes Trial Nos.:<br>08-2507-01<br>08-2507-02<br>08-2507-03<br>Edition Number: M-349147-02-1<br>Date: 2009-06-12<br>Amended: 2010-01-15<br>GLP/GEP: yes, unpublished | N | TF-BCS-Arysta LifeScience |
| KCA 6.6.2 | Gateaud, L. | 2010 | Statement concerning the reduction of the plant back interval for products containing propamocarb<br>Bayer S.A.S., Bayer CropScience, Lyon, France<br>TF-BCS-Arysta LifeScience,<br>Report No.: M-359448-02-1,<br>Edition Number: M-359448-02-1<br>Date: 2010-01-18<br>GLP/GEP: n.a., unpublished | N | TF-BCS-Arysta LifeScience |

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|---|---|---|---|---|---|
| KCA 6.1 | Everitt, S. L.; Charter, G. E | 1998 | Potatoes tubers: Stability during deep freeze storage up to 26 months propamocarb hydrochloride active substance, Code: AE B066752 AgrEvo UK Crop Protection Ltd., Chesterford Park, United Kingdom TF-BCS-Arysta LifeScience, Report No.: C003683, Report includes Trial Nos.: 067/02/004 Edition Number: M-167991-02-1 EPA MRID No.: 45090807 Date: 1998-07-15 ...Amended: 1999-04-29 GLP/GEP: yes, unpublished | N | TF-BCS-Arysta LifeScience |
| KCA 6.1 | Everitt, S. L.; Charter, G. E | 2000 | Cabbage: Stability during deep freeze storage up to 39 months active substance Propamocarb hydrochloride Code: AE B066752 Aventis CropScience UK Limited, Residues & Human Exposure, Chesterford Park, United Kingdom TF-BCS-Arysta LifeScience, Report No.: C009293, Report includes Trial Nos.: 067/02/005 Edition Number: M-198306-01-1 Date: 2000-11-06 GLP/GEP: yes, unpublished | N | TF-BCS-Arysta LifeScience |
| KCA 6.1 | Moede J. | 1990 | Stability of propamocarb x HCl in tomatoes during deep freeze storage Generated by: Schering AG, Berlin, Germany Document No: A85300 GLP / GEP No un-published | N | Bayer CropScience |
| KCA 6.1 | Sutton A.L., Charter G.E. | 1999 | Tomatoes: Stability during deep freeze storage up to 26 months Propamocarb hydrochloirde Active substance Generated by: AgrEvo UK Limited; Chesterford Park, England Document No: C003740 GLP / GEP Yes un-published | N | Bayer CropScience |
| KCA 6.1 | Wrede-Rücker A. | 1990 | Stability of propamocarb x HCl in lettuce during deep freeze storage Generated by: Schering AG, Berlin, Germany Document No: A85303 GLP / GEP No un-published | N | Bayer CropScience |
| KCA 6.2.1 | Rupprecht K. J., Daniel L. E. | 2000 | Metabolism of [14C]-Propamocarb Hydrochloride in Spinach (Amended Report Replacing Report AV97E519, Document A89868) Generated by: Aventis CropScience Environmental Chemistry Department Pikeville, NorthCarolina, USA Document No: B002936 GLP / GEP Yes un-published | N | Bayer CropScience |
| KCA 6.2.1 | Foertsch A. | 1991 | The fate of Propamocarb x HCl in potato tubers Generated by: Schering AG, Ecochemistry Berlin, Germany Document No: A85140 GLP / GEP Yes un-published | N | Bayer CropScience |
| KCA 6.2.1 | Foertsch A. | 1994 | The fate of Propamocarb hydrochloride in potato tubers addendum to report UPSR 14/91 Generated by: Schering AG, Ecochemistry Berlin, Germany Document No: A85141 GLP / GEP Yes un-published | N | Bayer CropScience |
| KCA 6.2.1 | Rupprecht K.J., Feyerabend M. | 1998 | Metabolism of propamocarb HCL in cucumber grown in soil and hydroculture propamocarb hydrochloride Generated by: Hoechst Schering AgrEvo GmbH; Ecochemistry Frankfurt Germany Document No: A85149 GLP / GEP Yes un-published | N | Bayer CropScience |
| KCA 6.2.1 | Goodyear, A. | 2001 | (14C)-Propamocarb: Metabolism in tomatoes; Covance Labs. study # 1669/3-D2149, GLP, unpublished | N | Chimac Agriphar |

| | | | | | |
|---|---|---|---|---|---|
| KCA 6.2.1 | Goodyear, A. | 2002 | (14C)-Propamocarb: Metabolism in lettuce; Covance Labs. study # 1669/6-D2149, GLP, unpublished | N | Chimac Agriphar |
| KCA 6.2.1 | Goodyear, A. | 2002 | (14C)-Propamocarb: Metabolism in potatoes; Covance Labs. study # 1669/5-D2149, GLP, unpublished | N | Chimac Agriphar |
| KCA 6.2.1 | Cooke J. | 2002 | (14C)-Propamocarb: Identification of metabolites in Tomato, Potato and lettuce plant extracts; Covance Labs. study # 1669/10-D2149, GLP, unpublished | N | Chimac Agriphar |
| KCA 6.2.2-6.2.5 | Rupprecht K. J., Daniel L.E. | 2000 | Propamocarb: Ruminant (Cow) - Metabolism, Distribution and Nature of the Residues in Milk and Edible Tissues (Amended Report Replacing Report AV97E521, Document A91204) Generated by: Aventis CropScience Environmental Chemistry Department Pikeville, NorthCarolina, USA Document No: B002935 GLP / GEP Yes un-published | N | Bayer CropScience |
| KCA 6.1 | Moede J. | 1990 | Stability of propamocarb x HCl in tomatoes during deep freeze storage Generated by: Schering AG, Berlin, Germany Document No: A85300 GLP / GEP No un-published | N | Bayer CropScience |
| KCA 6.3 | Pigeon, O. | 2000 | Determination of residues of propamocarb in potatoes after treatment with Proplant. Dep. de phytopharmacie, centre de recherche agronomiques de Gembloux, study # 11992; GLP, unpublished (season 1999); final report. | N | Chimac Agriphar |
| KCA 6.3 | Pigeon, O. | 2002 | Determination of residues of propamocarb in potatoes after treatments with Proplant (in mixture with DITHANE M 45 WP); Dep. de phytopharmacie, centre de recherche agronomiques de Gembloux, study # 20237; GLP, unpublished (season 2001); final report. | N | Chimac Agriphar |
| KCA 6.3 | Pigeon, O. | 2002 | Determination of residues of propamocarb in potatoes after treatment with Proplant (in mixture with mancozeb); Dep. de phytopharmacie, centre de recherche agronomiques de Gembloux, study # 20284; GLP, unpublished (season 2001); final report. | N | Chimac Agriphar |
| KCA 6.6.1 | Meyer B.N. | 2000 | Uptake of [14C]-Propamocarb Hydrochloride Residues in Soil by Rotational Crops Under Confined Conditions (Amended Report Replacing Report AV96E518, Document A91264) Generated by: Aventis CropScience Environmental Chemistry Department Pikeville, NorthCarolina, USA Document No: B002934 GLP / GEP Yes un-published | N | Bayer CropScience |
| KCA 6.6.2 | Singer S.S. | 1999 | AT HARVEST PROPAMOCARB HYDROCHLORIDE DERIVED RESIDUES IN ROTATIONAL CROPS FOLLOWING SEQUENTIAL APPLICATIONS OF BANOL® TO BARE SOIL AT THE MAXIMUM PROPOSED RATE AND THE SHORTEST ROTATIONAL INTERVAL, USA, 1997 Generated by: Schering AG, Ecochemistry Berlin, Germany Document No: C003451 GLP / GEP Yes un-published | N | Bayer CropScience |

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|---|---|---|---|---|---|
| KCA 6.3 | Sonder K.H. | 2003 | Residue behaviour in potatoes European Union (Northern zone) 2002 Propamocarb hydrochloride + AE C638206 water miscible suspension concentrate (SC) 625 g/L + 62.5 g/L Code: AE B066752 04 SC61 A102 Bayer CropScience GmbH, Frankfurt, DEU;Residues and Human Exposure, Frankfurt Bayer CropScience AG, Report No.: 02R286 (**C032828**), Edition Number: M-232144-01-1 Pages: 1-90 Date: 02.09.2003 GLP, unpublished | N | TF-BCS-Arysta LifeScience |
| KCA 6.3 | Sonder K.-H. | 2003 | Residue behaviour in potatoes European Union (Southern zone) 2002 Propamocarb hydrochloride + AE C638206 water miscible suspension concentrate (SC) 625 g/L + 62.5 g/L Code: AE B066752 04 SC61 A102 Bayer CropScience GmbH, Frankfurt, DEU; Bayer CropScience AG, Report No.: 02R287 (**C032829**), Edition Number: M-232146-01-1 Pages: 1-100 Date: 04.09.2003 GLP, unpublished | N | TF-BCS-Arysta LifeScience |
| KCA 6.3 | Sonder K.-H. | 2003 | Residue behaviour in potatoes European Union (Southern zone) 2002 Propamocarb hydrochloride + AE C638206 water miscible suspension concentrate (SC) 625 g/L + 62.5 g/L Code: AE B066752 04 SC61 A102 Bayer CropScience GmbH, Frankfurt, DEU; Bayer CropScience AG, Report No.: 02R287 (**C032829**), Edition Number: M-232146-01-1 Pages: 1-100 Date: 04.09.2003 GLP, unpublished | N | TF-BCS-Arysta LifeScience |
| KCA 6.3 | Sonder K.-H. | 2003 | Residue behaviour in potatoes European Union (Southern zone) 2002 Propamocarb hydrochloride + AE C638206 water miscible suspension concentrate (SC) 625 g/L + 62.5 g/L Code: AE B066752 04 SC61 A102 Bayer CropScience GmbH, Frankfurt, DEU; Bayer CropScience AG, Report No.: 02R287 (**C032829**), Edition Number: M-232146-01-1 Pages: 1-100 Date: 04.09.2003 GLP, unpublished | N | TF-BCS-Arysta LifeScience |

**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<br>Y/N | Owner |
|---|---|---|---|---|---|
| KCP XX | Author | YYYY | Title<br>Company Report No<br>Source<br>GLP/non GLP/GEP/non GEP<br>Published/Unpublished | Y/N | Owner |
| | | | | | |

**List of data relied on and not submitted by the applicant but necessary for evaluation**

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

# Appendix 2 Detailed evaluation of the additional studies relied upon

## A 2.1 Zoxamide

### 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

| | |
|---|---|
| Comments of zRMS: | The study is accepted and adequate to confirm the stability of zoxamide and its metabolites RH-1452 and RH 1455 in homogenates of potato (tuber) and of zoxamide and its metabolite RH-1452 in grape (bunches, juice, raisin) upon storage at ≤ 18 °C for 13 months.<br>The results, in accordance with OECD 506, should be presented as absolute values in mg/kg and not adjusted by recovery, as well as % of nominal spike value. The presented results are not given in mg/kg, but such data are included in the study report. |

| | |
|---|---|
| Reference: | KCA 6.1 |
| Report | Storage stability of Residues of Zoxamide and its Metabolites RH-1452 and RH-1455 in Plant Matrices under Deep Frozen Conditions in/on Grape and Potato Matrices, Gustloff, C., 2023, Eurofins Agroscience Services Chem Gmbh, Report No.: S21-07041, GLP, Unpublished |
| Guideline(s): | OECD 506 |
| Deviations: | No |
| GLP: | Yes |
| Acceptability: | Yes |

**Materials and methods**

*Study Objective*

The objective of the study was to obtain data about the storage stability of zoxamide and its metabolites RH-1452 and RH-1455 in potato (tuber) and grape (bunches, juice, raisin) under deep frozen conditions in the dark over a storage period up to 13 months in accordance to OECD Guideline 506.

*Study Setup*

The fortification level for storage samples was at ten times the limit of quantification (LOQ) of the method (0.1 mg/kg) with all analytes fortified separately on aliquots of homogenised control sample material.

Storage samples were kept at ≤ -18 °C with no exceedance.
The day 0 testing was accompanied by analysis of a control sample while the testing after each storage interval was accompanied by analysis of a control sample and concurrent recovery samples.
Storage samples allow assessment of storage stability, while concurrent recoveries demonstrate the performance of the analytical method.

*Analytical Method*

For zoxamide, sample extraction and determination of analyte levels was performed according to the multi-residue QuEChERS as validated in study no. S21-07039.
In brief, for zoxamide samples of potato (tuber) and grape (bunches, juice, raisin) are extracted with acetonitrile and if necessary, after addition of water. The ratio was 10 mL of extraction solvent per 10 g of potato tuber and grape (bunches, juice) or 5 g of grape (raisin). Quantification was performed by use of LC-MS/MS.
For RH-1452 and RH-1455, sample extraction and determination of analyte levels was performed based on Podhorniak, L. V. (2014) as validated in study no. S21-07040.
In brief, for RH-1452 and RH-1455 samples of potato (tuber) and grape (bunches, juice, raisin) were extracted with glycine buffer. Liquid-liquid partition was performed twice with acetonitrile. Clean-up of the extract was performed with an ENVI-Carb SPE cartridge. Quantification was performed by use of LC-MS/MS.
The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for each analyte and each matrix with a limit of detection (LOD) set at 0.003 mg/kg (30 % of the LOQ).

*Accuracy and Precision*

For zoxamide the mean recovery for samples extracted without any storage (i.e. day 0 storage samples) was 98 % for potato (tuber), 103 % for grape (bunches), 103 % for grape (juice) and 108 % for grape (raisin).

For RH-1452 the mean recovery for samples extracted without any storage (i.e. day 0 storage samples) was 96 % for potato (tuber), 94 % for grape (bunches), 102 % for grape (juice) and 91 % for grape (raisin).

For RH-1455 the mean recovery for samples extracted without any storage (i.e. day 0 storage samples) was 93 % for potato (tuber).

Relative standard deviations were ≤ 20 % for all analytes and matrices.

For duplicate analysis of storage samples from the same time point the difference between the highest and lowest recovery did not exceed 20 %. For triplicate analysis the relative standard deviation of the recoveries obtained for storage samples from the same time point did not exceed 20 %.

These values demonstrate satisfying analytical performance for all analytes and matrices while analysing the storage samples.

**Results and discussions**

*Analysis of Storage Samples*

The analyte levels detected in the storage samples allow the monitoring of the stability of the analytes upon storage. The values were as follows:

| Storage Period | Concurrent Recoveries | Storage Samples |
|---|---|---|

| | Single Values (%) | Percentage of analyte found relative to the nominal fortification level (%) | | Percentage recovered corrected for the (mean) concurrent recovery of the individual date of extraction [a] | Percentage recovered relative to the mean percentage recovered at Day 0[a] |
|---|---|---|---|---|---|
| | | Single Values (%) [b] | Mean [a] in brackets: rel. std. deviation (%) | | |
| Analyte: Zoxamide Matrix Type: Potato (tuber) Nominal Fortification Level: 0.1 mg/kg (10xLOQ) | | | | | |
| 0 days | - | 98, 99, 99 | 98 (0.5) | - | - |
| 6 months (181 days) | 94 | 94, 91 | 92 | 98 | 94 |
| 13 months (393 days) | 88 | 90, 95 | 93 | 105 | 94 |
| Analyte: Zoxamide Test System: Grape (bunches) Nominal Fortification Level: 0.1 mg/kg (10xLOQ) | | | | | |
| 0 days | - | 101, 106, 102 | 103 (2.4) | - | - |
| 6 months (181 days) | 94 | 99, 99 | 99 | 105 | 96 |
| 13 months (393 days) | 115 | 115, 110 | 112 | 98 | 109 |
| Analyte: Zoxamide Test System: Grape (juice) Nominal Fortification Level: 0.1 mg/kg (10xLOQ) | | | | | |
| 0 days | - | 105, 103, 100 | 103 (2.5) | - | - |
| 6 months (181 days) | 99 | 99, 101 | 100 | 101 | 97 |
| 13 months (393 days) | 100 | 101, 104 | 102 | 102 | 99 |
| Analyte: Zoxamide Test System: Grape (raisin) Nominal Fortification Level: 0.1 mg/kg (10xLOQ) | | | | | |
| 0 days | - | 110, 110, 103 | 108 (3.7) | - | - |
| 6 months (181 days) | 111 | 108, 104 | 106 | 96 | 98 |
| 13 months (393 days) | 111 | 99, 97 | 98 | 88 | 91 |

[a] calculated from unrounded values; [b] not corrected for concurrent recoveries

| **Storage Period** | **Concurrent Recoveries** | **Storage Samples** | | | |
|---|---|---|---|---|---|
| | Single Values (%) | Percentage of analyte found relative to the nominal fortification level (%) | | Percentage recovered corrected for the (mean) concurrent recovery of the individual date of extraction [a] | Percentage recovered relative to the mean percentage recovered at Day 0[a] |
| | | Single Values (%) [b] | Mean [a] in brackets: rel. std. deviation (%) | | |
| Analyte: RH-1452 Test System: Potato (tuber) Nominal Fortification Level: 0.1 mg/kg (10xLOQ) | | | | | |
| 0 days | - | 93, 95, 99 | 96 (3.3) | - | - |
| 6 months (180 days) | 89 | 80, 80 | 80 | 90 | 84 |
| 13 months | 91 | 88, 85 | 86 | 95 | 90 |

| | | | | | |
|---|---|---|---|---|---|
| (392 days) | | | | | |
| Analyte: RH-1452 Test System: Grape (bunches) Nominal Fortification Level: 0.1 mg/kg (10xLOQ) | | | | | |
| 0 days | - | 96, 89, 96 | 94 (4.6) | - | - |
| 6 months (182 days) | 96 | 89, 91 | 90 | 93 | 96 |
| 13 months (392 days) | 117 | 102, 99 | 101 | 86 | 107 |
| Analyte: RH-1452 Test System: Grape (juice) Nominal Fortification Level: 0.1 mg/kg (10xLOQ) | | | | | |
| 0 days | - | 102, 99, 106 | 102 (3.5) | - | - |
| 6 months (183 days) | 103 | 98, 88 | 93 | 91 | 91 |
| 13 months (393 days) | 108 | 99, 103 | 101 | 93 | 99 |
| Analyte: RH-1452 Test System: Grape (raisin) Nominal Fortification Level: 0.1 mg/kg (10xLOQ) | | | | | |
| 0 days | - | 94, 88, 92 | 91 (3.2) | - | - |
| 6 months (181 days) | 92 | 88, 86 | 87 | 94 | 95 |
| 13 months (393 days) | 98 | 102, 95 | 98 | 100 | 108 |
| Analyte: RH-1455 Test System: Potato (tuber) Nominal Fortification Level: 0.1 mg/kg (10xLOQ) | | | | | |
| 0 days | - | 96, 93, 89 | 93 (3.7) | - | - |
| 6 months (180 days) | 84 | 79, 80 | 80 | 95 | 86 |
| 13 months (392 days) | 96 | 89, 88 | 88 | 92 | 95 |

[a] calculated from unrounded values; [b] not corrected for concurrent recoveries

For all combinations of analytes and matrices the average amount of analyte recovered relative to the initial mean recovery at day 0 was ≥ 70 % at any testing interval.

**Conclusion**

The study is deemed sufficient for assessing the stability of zoxamide and its metabolites RH-1452 and RH-1455 in homogenates of potato (tuber) and of zoxamide and its metabolite RH-1452 in grape (bunches, juice, raisin) upon storage at ≤ -18 °C for 13 months.

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

No new study submitted.

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

No new study submitted.

### A 2.1.3 Magnitude of residues in plants

No new study submitted.

### A 2.1.4 Magnitude of residues in livestock

No new study submitted.

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

No new study submitted.

### A 2.1.6 Magnitude of residues in representative succeeding crops

No new study submitted.

### A 2.1.7 Other/Special Studies

No new study submitted.

## A 2.2 Propamocarb-HCl

No additional studies submitted.

# Appendix 3 Pesticide Residue Intake Model (PRIMo)

## A 3.1 TMDI calculations

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

# Zoxamide

| | | | |
|---|---|---|---|
| LOQs (mg/kg) range from: | | to: | |
| **Toxicological reference values** | | | |
| ADI (mg/kg bw/day): | 0.5 | ARfD (mg/kg bw): | insert valid entry |
| Source of ADI: | EFSA | Source of ARfD: | |
| Year of evaluation: | 2017 | Year of evaluation: | |

Input values

Details - chronic risk assessment

Supplementary results - chronic risk assessment

Details - acute risk assessment/children

Details - acute risk assessment/adults

Comments:

**Normal mode**

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

No of diets exceeding the ADI : ---

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

| Calculated exposure (% of ADI) | MS Diet | 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) |
|---|---|---|---|---|---|---|---|---|---|---|
| 8% | NL toddler | 40.02 | 4% | Spinaches | 2% | Table grapes | 1% | Escaroles/broad-leaved endives | | |
| 5% | IT adult | 26.51 | 2% | Lettuces | 0.9% | Other lettuce and other salad plants | 0.6% | Spinaches | | |
| 5% | ES adult | 24.68 | 3% | Lettuces | 0.5% | Chards/beet leaves | 0.4% | Spinaches | | |
| 5% | DE child | 23.64 | 1% | Table grapes | 1% | Spinaches | 0.5% | Lettuces | | |
| 4% | GEMS/Food G10 | 21.98 | 2% | Lettuces | 0.4% | Wine grapes | 0.4% | Cress and other sprouts and shoo | | |
| 4% | GEMS/Food G07 | 21.62 | 1% | Wine grapes | 1% | Lettuces | 0.3% | Table grapes | | |
| 4% | FR adult | 20.73 | 2% | Wine grapes | 0.9% | Other lettuce and other salad plants | 0.3% | Spinaches | | |
| 4% | GEMS/Food G06 | 20.66 | 1% | Table grapes | 0.6% | Lettuces | 0.4% | Watermelons | | |
| 4% | IT toddler | 20.46 | 2% | Lettuces | 0.7% | Other lettuce and other salad plants | 0.4% | Chards/beet leaves | | |
| 4% | NL child | 20.19 | 2% | Spinaches | 1% | Table grapes | 0.6% | Escaroles/broad-leaved endives | | |
| 4% | GEMS/Food G08 | 20.13 | 1% | Lettuces | 1% | Wine grapes | 0.4% | Lamb's lettuce/corn salads | | |
| 4% | ES child | 19.71 | 3% | Lettuces | 0.5% | Spinaches | 0.5% | Chards/beet leaves | | |
| 4% | GEMS/Food G11 | 18.61 | 1% | Wine grapes | 0.6% | Spinaches | 0.5% | Lamb's lettuce/corn salads | | |
| 4% | PT general | 18.17 | 2% | Wine grapes | 0.6% | Lettuces | 0.3% | Table grapes | | |
| 4% | IE adult | 18.15 | 1% | Wine grapes | 0.8% | Spinaches | 0.5% | Lettuces | | |
| 4% | SE general | 17.64 | 2% | Lettuces | 0.4% | Spinaches | 0.1% | Cucumbers | | |
| 3% | NL general | 15.95 | 0.9% | Spinaches | 0.6% | Escaroles/broad-leaved endives | 0.6% | Wine grapes | | |
| 3% | GEMS/Food G15 | 14.70 | 1% | Wine grapes | 0.7% | Lettuces | 0.3% | Table grapes | | |
| 3% | FR child 3 15 yr | 13.67 | 0.7% | Other lettuce and other salad plants | 0.6% | Spinaches | 0.4% | Wine grapes | | |
| 3% | DE women 14-50 yr | 13.56 | 0.8% | Wine grapes | 0.7% | Lettuces | 0.3% | Table grapes | | |
| 2% | RO general | 12.32 | 2% | Wine grapes | 0.2% | Tomatoes | 0.2% | Watermelons | | |
| 2% | DE general | 12.29 | 0.8% | Wine grapes | 0.6% | Lettuces | 0.3% | Spinaches | | |
| 2% | FR infant | 11.24 | 2% | Spinaches | 0.2% | Chards/beet leaves | 0.2% | Courgettes | | |
| 2% | UK vegetarian | 10.87 | 0.8% | Lettuces | 0.8% | Wine grapes | 0.2% | Spinaches | | |
| 2% | UK adult | 10.42 | 1% | Wine grapes | 0.7% | Lettuces | 0.1% | Spinaches | | |
| 2% | DK adult | 10.07 | 1.0% | Wine grapes | 0.5% | Lettuces | 0.2% | Table grapes | | |
| 2% | DK child | 9.97 | 0.8% | Lettuces | 0.7% | Cucumbers | 0.2% | Table grapes | | |
| 2% | FR toddler 2 3 yr | 9.55 | 0.9% | Spinaches | 0.2% | Wine grapes | 0.2% | Other lettuce and other salad plan | | |
| 2% | FI adult | 8.08 | 0.8% | Lettuces | 0.3% | Wine grapes | 0.1% | Cucumbers | | |
| 2% | FI 6 yr | 7.50 | 0.5% | Lettuces | 0.3% | Spinaches | 0.3% | Cucumbers | | |
| 1% | FI 3 yr | 7.39 | 0.4% | Cucumbers | 0.4% | Spinaches | 0.2% | Table grapes | | |
| 0.8% | UK toddler | 4.11 | 0.2% | Table grapes | 0.2% | Spinaches | 0.1% | Lettuces | | |
| 0.7% | PL general | 3.44 | 0.3% | Table grapes | 0.1% | Tomatoes | 0.1% | Lettuces | | |
| 0.7% | LT adult | 3.39 | 0.4% | Lettuces | 0.2% | Cucumbers | 0.1% | Tomatoes | | |
| 0.3% | UK infant | 1.59 | 0.1% | Milk: Cattle | 0.1% | Spinaches | 0.0% | Tomatoes | | |
| 0.2% | IE child | 0.86 | 0.1% | Table grapes | 0.0% | Lettuces | 0.0% | Spinaches | | |

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

European Food Safety Authority
EFSA PRIMo revision 3.1; 2019/03/19

## Propamocarb-HCl

| | | | |
|---|---|---|---|
| LOQs (mg/kg) range from: | 0.01 | to: | 0.05 |
| **Toxicological reference values** | | | |
| ADI (mg/kg bw/day): | 0.29 | ARfD (mg/kg bw): | 1 |
| Source of ADI: | EFSA | Source of ARfD: | EFSA |
| Year of evaluation: | 2006 | Year of evaluation: | 2006 |

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) |
|---|---|---|---|---|---|---|---|---|---|---|
| 21% | NL toddler | 60.43 | 10% | Spinaches | 2% | Cauliflowers | 2% | Escaroles/broad-leaved endives | 0.1% | |
| 15% | GEMS/Food G06 | 44.79 | 5% | Tomatoes | 2% | Watermelons | 1% | Lettuces | 0.0% | |
| 14% | SE general | 39.18 | 6% | Lettuces | 1% | Chinese cabbages/pe-tsai | 1% | Tomatoes | 0.0% | |
| 13% | GEMS/Food G10 | 37.41 | 4% | Lettuces | 2% | Tomatoes | 1% | Chinese cabbages/pe-tsai | 0.0% | |
| 12% | ES adult | 35.81 | 7% | Lettuces | 1% | Chards/beet leaves | 1% | Tomatoes | 0.0% | |
| 12% | IT adult | 34.19 | 5% | Lettuces | 2% | Tomatoes | 1% | Spinaches | 0.0% | |
| 11% | ES child | 32.95 | 6% | Lettuces | 1% | Tomatoes | 1% | Spinaches | 0.0% | |
| 11% | DE child | 32.05 | 3% | Spinaches | 1% | Tomatoes | 1% | Lettuces | 0.1% | |
| 10% | IT toddler | 28.98 | 4% | Lettuces | 2% | Tomatoes | 0.8% | Chards/beet leaves | 0.0% | |
| 10% | NL child | 27.97 | 3% | Spinaches | 1% | Lettuces | 0.8% | Tomatoes | 0.1% | |
| 10% | GEMS/Food G08 | 27.59 | 3% | Lettuces | 2% | Tomatoes | 0.5% | Leeks | 0.0% | |
| 9% | IE adult | 26.23 | 2% | Spinaches | 1% | Melons | 1% | Lettuces | 0.1% | |
| 9% | FR infant | 25.89 | 4% | Spinaches | 2% | Leeks | 0.9% | Cauliflowers | 0.0% | |
| 9% | GEMS/Food G07 | 25.71 | 3% | Lettuces | 1% | Tomatoes | 0.5% | Spinaches | 0.0% | |
| 9% | NL general | 25.23 | 2% | Spinaches | 1% | Lettuces | 0.9% | Leeks | 0.0% | |
| 9% | GEMS/Food G11 | 25.04 | 2% | Leeks | 1% | Spinaches | 1% | Tomatoes | 0.1% | |
| 8% | FR toddler 2 3 yr | 22.78 | 2% | Spinaches | 2% | Leeks | 0.8% | Cauliflowers | 0.0% | |
| 8% | GEMS/Food G15 | 22.20 | 2% | Tomatoes | 2% | Lettuces | 0.8% | Watermelons | 0.0% | |
| 8% | DK child | 22.17 | 3% | Cucumbers | 2% | Lettuces | 0.7% | Tomatoes | 0.0% | |
| 7% | FR child 3 15 yr | 21.73 | 1% | Spinaches | 1% | Leeks | 1% | Tomatoes | 0.0% | |
| 7% | RO general | 18.95 | 3% | Tomatoes | 0.8% | Watermelons | 0.5% | Onions | 0.0% | |
| 6% | DE women 14-50 yr | 18.19 | 2% | Lettuces | 1% | Tomatoes | 0.7% | Spinaches | 0.0% | |
| 6% | FI 3 yr | 17.75 | 2% | Cucumbers | 0.9% | Spinaches | 0.8% | Tomatoes | 0.0% | |
| 6% | DE general | 16.55 | 1% | Lettuces | 0.9% | Tomatoes | 0.6% | Spinaches | 0.0% | |
| 6% | FI 6 yr | 16.10 | 1% | Cucumbers | 1% | Lettuces | 0.8% | Spinaches | 0.0% | |
| 5% | PT general | 15.47 | 1% | Lettuces | 1% | Kales | 1% | Tomatoes | 0.0% | |
| 5% | UK vegetarian | 15.02 | 2% | Lettuces | 0.9% | Tomatoes | 0.5% | Spinaches | 0.0% | |
| 5% | FR adult | 13.18 | 0.9% | Leeks | 0.7% | Spinaches | 0.6% | Tomatoes | 0.0% | |
| 4% | FI adult | 12.80 | 2% | Lettuces | 0.8% | Tomatoes | 0.6% | Cucumbers | 0.1% | |
| 4% | DK adult | 10.93 | 1% | Lettuces | 0.7% | Tomatoes | 0.4% | Cucumbers | 0.0% | |
| 4% | UK adult | 10.53 | 2% | Lettuces | 0.6% | Tomatoes | 0.3% | Spinaches | 0.0% | |
| 3% | PL general | 9.97 | 1% | Tomatoes | 0.4% | Potatoes | 0.3% | Cauliflowers | 0.0% | |
| 3% | UK toddler | 9.62 | 0.8% | Tomatoes | 0.4% | Cauliflowers | 0.4% | Cauliflowers | 0.0% | |
| 3% | LT adult | 8.97 | 0.9% | Lettuces | 0.9% | Tomatoes | 0.7% | Cucumbers | 0.0% | |
| 3% | UK infant | 8.45 | 0.9% | Cauliflowers | 0.6% | Milk: Cattle | 0.5% | Tomatoes | 0.0% | |
| 0.7% | IE child | 1.96 | 0.1% | Lettuces | 0.1% | Cauliflowers | 0.1% | Tomatoes | 0.0% | |

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

## A 3.2 IEDI calculations

Not required as TMDI does not exceed ADI.

## A 3.3 IESTI calculations - Raw commodities

Zoxamide: No ARfD value available.

Propamocarb-HCl:

**Unprocessed commodities**

| Results for children | | | | Results for adults | | | |
|---|---|---|---|---|---|---|---|
| No. of commodities for which ARfD/ADI is exceeded (IESTI): | | | --- | No. of commodities for which ARfD/ADI is exceeded (IESTI): | | | --- |
| **IESTI** | | | | **IESTI** | | | |
| Highest % of ARfD/ADI | Commodities | MRL / input for RA (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI | Commodities | MRL / input for RA (mg/kg) | Exposure (µg/kg bw) |
| 0.5% | Milk: Cattle | 0.01 / 0.04 | 5.3 | 0.2% | Milk: Cattle | 0.01 / 0.04 | 1.6 |
| 0.2% | Bovine: Liver | 0.2 / 0.22 | 1.8 | 0.09% | Bovine: Liver | 0.2 / 0.22 | 0.88 |
| 0.2% | Potatoes | 0.3 / 0.01 | 1.5 | 0.07% | Bovine: Edible offals (other | 0.2 / 0.2 | 0.66 |
| 0.1% | Bovine: Edible offals (other | 0.2 / 0.2 | 1.5 | 0.06% | Sheep: Liver | 0.2 / 0.2 | 0.56 |
| 0.06% | Eggs: Chicken | 0.05 / 0.05 | 0.62 | 0.04% | Swine: Kidney | 0.02 / 0.2 | 0.44 |
| 0.05% | Poultry: Muscle/meat | 0.02 / 0.03 | 0.51 | 0.04% | Poultry: Muscle | 0.02 / 0.03 | 0.35 |
| 0.03% | Swine: Edible offals (other | 0.1 / 0.1 | 0.30 | 0.03% | Potatoes | 0.3 / 0.01 | 0.30 |
| 0.03% | Swine: Kidney | 0.02 / 0.2 | 0.25 | 0.03% | Swine: Edible offals (other | 0.1 / 0.1 | 0.26 |
| 0.02% | Swine: Muscle/meat | 0.01 / 0.02 | 0.24 | 0.02% | Eggs: Chicken | 0.05 / 0.05 | 0.21 |
| 0.02% | Milk: Goat | 0.01 / 0.01 | 0.24 | 0.02% | Poultry: Liver | 0.05 / 0.04 | 0.19 |
| 0.02% | Bovine: Kidney | 0.05 / 0.06 | 0.23 | 0.02% | Milk: Goat | 0.01 / 0.01 | 0.18 |
| 0.02% | Honey and other apiculture | 0.05 / 0.05 | 0.18 | 0.02% | Milk: Sheep | 0.01 / 0.01 | 0.15 |
| 0.01% | Swine: Liver | 0.1 / 0.09 | 0.11 | 0.01% | Sheep: Edible offals (other | 0.2 / 0.2 | 0.14 |
| 0.01% | Bovine: Muscle/meat | 0.01 / 0.01 | 0.07 | 0.01% | Swine: Liver | 0.1 / 0.09 | 0.13 |
| 0.01% | Other farmed animals: | 0.01 / 0.01 | 0.07 | 0.01% | Bovine: Kidney | 0.05 / 0.06 | 0.13 |
| Expand/collapse list | | | | | | | |
| **Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)** | | | | | | | |

## A 3.4 IESTI calculations - Processed commodities

Zoxamide: No ARfD value available.

Propamocarb-HCl:

| Processed commodities | **Results for children** No of processed commodities for which ARfD/ADI is exceeded (IESTI): | | | --- | **Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI): | | | --- |
|---|---|---|---|---|---|---|---|---|
| | **IESTI** | | | | **IESTI** | | | |
| | Highest % of ARfD/ADI | Processed commodities | MRL / input for RA (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI | Processed commodities | MRL / input for RA (mg/kg) | Exposure (µg/kg bw) |
| | 0.1% | Potatoes / fried | 0.3 / 0.01 | 0.93 | 0.0% | Potatoes / chips | 0.3 / 0.01 | 0.08 |
| | 0.1% | Potatoes / dried (flakes) | 0.3 / 0.05 | 0.59 | 0.01% | Potatoes / dried (flakes) | 0.3 / 0.05 | 0.06 |
| | #GETAL! | #GETAL! | #GETAL! | #GETAL! | #GETAL! | #GETAL! | #GETAL! | #GETAL! |
| | #GETAL! | #GETAL! | #GETAL! | #GETAL! | #GETAL! | #GETAL! | #GETAL! | #GETAL! |
| | #GETAL! | #GETAL! | #GETAL! | #GETAL! | #GETAL! | #GETAL! | #GETAL! | #GETAL! |
| | #GETAL! | #GETAL! | #GETAL! | #GETAL! | #GETAL! | #GETAL! | #GETAL! | #GETAL! |
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| | #GETAL! | #GETAL! | #GETAL! | #GETAL! | #GETAL! | #GETAL! | #GETAL! | #GETAL! |
| | Expand/collapse list | | | | | | | |