Modification of the existing maximum residue level for propamocarb in chards/beet leaves

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the competent national authority in Belgium sent an application to modify the existing maximum residue level (MRL) for the active substance propamocarb in chards. The data submitted in support of the request were found to be sufficient to derive a MRL proposal for chards/beet leaves. An adequate analytical method for enforcement is available to control the residues of propamocarb on the commodity under consideration. Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of residues resulting from the use of propamocarb according to the intended agricultural practice is unlikely to present a risk to consumer health.

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, the competent national authority in Belgium compiled an application to modify the existing maximum residue level (MRL) for the active substance propamocarb in chards. Belgium drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005 which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA). To accommodate for the intended use of propamocarb, the evaluating Member State (EMS) proposed to raise the existing MRL from 30 to 40 mg/kg.

EFSA based its assessment on the evaluation report submitted by the EMS, the draft assessment report (DAR) prepared under Directive 91/414/EEC, the Commission review report on propamocarb, the conclusion on the peer review of the pesticide risk assessment of the active substance propamocarb as well as the conclusions from previous EFSA opinions and a scientific report on propamocarb.

The metabolism of propamocarb following foliar and soil applications was investigated in crops belonging to the groups of fruit crops, root crops and leafy crops. Studies investigating the effect of processing on the nature of propamocarb hydrochloride (hydrolysis studies) demonstrated that the active substance is stable under processing conditions. In rotational crops, the major residue identified was the parent compound, except in wheat grain. However, the metabolites identified in grain were not expected to occur in significant amounts at the investigated uses.

Based on the metabolic pattern identified in metabolism studies, hydrolysis studies and the toxicological significance of metabolites, the residue definitions for plant products were proposed as 'sum of propamocarb and its salts expressed as propamocarb' for enforcement and risk assessment. These residue definitions are applicable to primary crops, rotational crops and processed products.

EFSA concluded that for the crop assessed in this application, metabolism of propamocarb in primary crops, rotational crops and the possible degradation in processed products has been sufficiently addressed and that the previously derived residue definitions are applicable.

A sufficiently validated analytical method is available to quantify residues on chards/beet leaves according to the enforcement residue definition. The method enables quantification of residues of propamocarb at or above 0.01 mg/kg in the crop assessed.

The available residue trials are sufficient to derive a MRL proposal for chards/beet leaves by extrapolation from lettuces. A risk manager decision has to be taken whether to set the MRL at the value of 50 mg/kg or 40 mg/kg on this crop.

Specific studies investigating the magnitude of propamocarb residues in processed commodities are not required, as the total theoretical maximum daily intake (TMDI) is expected to be below the trigger value of 10% of the acceptable daily intake (ADI).

Although not required due to the low persistency, the occurrence of propamocarb residues in rotational crops was investigated in the framework of the EU pesticides peer review and the MRL review. Based on the available information on the magnitude of residues, it was concluded that significant residue levels are unlikely to occur in rotational crops, provided that the active substance is used according to the proposed good agricultural practice (GAP).

Residues of propamocarb in commodities of animal origin were not assessed since the crop under consideration in this MRL application is normally not fed to livestock.

The toxicological profile of propamocarb was assessed in the framework of the EU pesticides peer review under Directive 91/414/EEC and the data were sufficient to derive an ADI and an acute reference dose (ARfD) for propamocarb hydrochloride. The toxicological reference values were recalculated to express the ADI and ARfD as propamocarb equivalents (ADI of 0.24 mg/kg body weight (bw) per day and ARfD of 0.84 mg/kg bw).

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). For the long-term exposure, the intended use under assessment, the authorised uses and Codex maximum residue limits previously assessed by EFSA were considered. The short-term risk assessment was performed only with regard to chards/beet leaves.

EFSA concluded that the proposed indoor use of propamocarb on chards/beets leaves will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers’ health.

EFSA proposes to amend the existing MRL as reported in the summary table below.
| Code\(^{(a)}\) | Commodity                  | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|--------------|----------------------------|-------------------------|-------------------------|-----------------------|
| 0252030      | Chards/beet leaves         | 30                      | 50 or 40                | The indoor use is sufficiently supported by data. Using the OECD calculator, a MRL proposal of 50 mg/kg is derived. According to EFSA, a MRL of 40 mg/kg would be sufficient to cover the intended use. The proposed MRL of 40 mg/kg is in line with the proposal of the applicant and the RMS. A consumer health concern was not identified. |

**Enforcement residue definition:** Propamocarb (sum of propamocarb and its salts, expressed as propamocarb)

MRL: maximum residue level; OECD: Organisation for Economic Co-operation and Development; RMS: rapporteur Member State.

\(^{(a)}\): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
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Background

Regulation (EC) No 396/2005¹ (hereinafter referred to as 'the MRL regulation') establishes the rules governing the setting of pesticide maximum residue levels (MRLs) at European Union (EU) level. In accordance with Article 6(3) of the MRL regulation, the competent authority in Belgium, hereafter referred to as the evaluating Member State (EMS), compiled an application to modify the existing MRL for the propamocarb in chards.

The EMS submitted an evaluation report to the European Commission which was forwarded to the European Food Safety Authority (EFSA) on 8 March 2017. The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2017-00227 and the following subject:

Propamocarb: MRL in chards

Belgium proposed to raise the existing MRL of propamocarb in chards from 30 to 40 mg/kg.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation.

Terms of Reference

In accordance with Article 10 of Regulation (EC) No 396/2005, EFSA shall assess the application and the evaluation report and give a reasoned opinion on the risks to the consumer and where relevant to animals associated with the setting of the requested MRLs. The opinion shall include:

- an assessment of whether the analytical method for routine monitoring proposed in the application is appropriate for the intended control purposes;
- the anticipated limit of quantification (LOQ) for the pesticide/product combination;
- an assessment of the risks of the acceptable daily intake (ADI) and acute reference dose (ARfD) being exceeded as a result of the modification of the MRL;
- the contribution to the intake due to the residues in the product for which the MRLs was requested;
- any other element relevant to the risk assessment.

In accordance with Article 11 of the MRL regulation, EFSA shall give its reasoned opinion as soon as possible and at the latest within 3 months from the date of receipt of the application.

The evaluation report submitted by the EMS (Belgium, 2017) and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available as background documents to this reasoned opinion.

The active substance and its use pattern

The detailed description of the intended use of propamocarb which is the basis for the current MRL application is reported in Appendix A.

Propamocarb is the ISO common name for propyl 3-(dimethylamino)propylcarbamate (IUPAC). Propamocarb is often used in plant protection product formulations in form of a salt, i.e. propamocarb hydrochloride, which is the ISO common name for propyl 3-(dimethylamino) propylcarbamate hydrochloride (IUPAC). The chemical structures of the active substances and the main metabolites are reported in Appendix E.

Propamocarb was evaluated in the framework of Directive 91/414/EEC with Ireland designated as rapporteur Member State (RMS) for the representative uses as a foliar spraying, drenching or drip irrigation on lettuces, potatoes, tomatoes. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by EFSA (2006). It should be noted that the data evaluated in the framework of the EU pesticides peer review referred to the variant hydrochloride, unless otherwise specified in the conclusion. The peer review of the renewal of the first approval is currently ongoing.

Propamocarb was approved² for the use as fungicide only on 1 October 2007.

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¹ Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1–16.

² Directive 2007/25/EC of 23 April 2007 amending Council Directive 91/414/EEC to include dimethoate, dimethomorph, glufosinate, metribuzin, phosmet and propamocarb as active substances. OJ L 106, 24.4.2007, p. 34–42.
The EU MRLs for propamocarb are established in Annexes II of Regulation (EC) No 396/2005, regardless whether propamocarb or propamocarb hydrochloride is applied as active substance. The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has been performed (EFSA, 2013) and the proposed modifications have been implemented in the MRL legislation. After completion of the MRL review, EFSA has issued a number of reasoned opinions on the modification of MRLs for propamocarb. The proposals from these reasoned opinions have been considered in regulations, for EU MRL legislation.

Assessment

EFSA has based its assessment on the evaluation report submitted by the EMS (Belgium, 2017), the DAR and its final addendum prepared under Directive 91/414/EEC (Ireland, 2004, 2006), the European Commission review report on propamocarb (European Commission, 2007), the conclusion on the peer review of the pesticide risk assessment of the active substance propamocarb (EFSA, 2006) as well as the conclusions from previous EFSA opinions on propamocarb, including the MRL review (EFSA, 2013, 2014, 2015a,c) and a scientific report of EFSA in support to the preparation of the EU position for 47th session of the Codex Committee on Pesticide Residues (EFSA, 2015b).

For this application, the data requirements established in Regulation (EU) No 544/2011 and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 1997a-g, 2000, 2010a,b, 2017; OECD, 2011). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011.

A selected list of end points of the studies assessed by EFSA in the framework of the MRL review, including the end points of studies submitted in support of the current MRL application, are presented in Appendix B.

1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

The metabolism of propamocarb hydrochloride in primary crops has been investigated with the hydrochloride salt after foliar and soil application on the groups of fruit crops and leafy crops and after foliar applications on root crops in the framework of the EU pesticides peer review (EFSA, 2006). Details of the studies are presented in Appendix B.

For the intended use, the metabolic behaviour in primary crops is sufficiently addressed.

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3 Commission Regulation (EU) No 289/2014 of 21 March 2014 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for foramsulfuron, azimsulfuron, iodosulfuron, oxasulfuron, mesosulfuron, flazasulfuron, imazosulfuron, propamocarb, bifenthrane, chlorpropham and thienobencarb in or on certain products. OJ L 87, 22.3.2014, p. 49–83.
4 Commission Regulation (EU) No 36/2014 of 16 January 2014 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 aminopyralid, chlorantraniliprole, cyflufenamid, mepipquat, metalaxyl-M, propamocarb, pyraclostrobin and quinoxystine in or on certain products OJ L 17, 21.1.2014, p. 1–41.
5 Commission Regulation (EU) 2015/846 of 28 May 2015 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 acetamiprid, amacetradin, amusibrom, bubipirinate, clodenzenthe, ethephon, ethirimol, fluopicolide, imazapic, propamocarb, pyraclostrobin and tau-fluvalinate in or on certain products. OJ L 140, 5.6.2015, p. 1–49.
6 Commission Regulation (EU) 2016/1 of 3 December 2016 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 bifenthrane, boscalid, cyazofamid, cyromazine, dazomet, dithiocarbamates, fluazifop-P, mepanipyrim, metrafenone, picloram, propamocarb, pyridaben, pyridifenonene, sulfoxaflor, tebuconazole, tebufenpyrad and thiram in or on certain products. OJ L 2, 5.1.2016, p. 1–62.
7 Commission Regulation (EU) 2016/1003 of 17 June 2016 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 abamectin, acequinocyl, acetamiprid, benzinidfluipry, bromoxynil, fludioxonil, flupicolaide, fosetyl, mepipquat, proquinazid, propamocarb, prohexadione and tebuconazole in or on certain products. OJ L 167, 24.6.2016, p. 46–103.
8 Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances. OJ L 155, 11.6.2011, p. 1–66.
9 Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.
1.1.2. Nature of residues in rotational crops

Propamocarb is proposed to be used on a crop that can be grown in rotation with other crops. According to the soil degradation studies evaluated in the framework of the EU pesticides peer review, the DT<sub>90</sub> field value of propamocarb hydrochloride ranged from 57 to 78 days (EFSA, 2006). The trigger value of 100 days was not exceeded and therefore further studies investigating the nature and magnitude of residues in rotational crops are in principle not required.

Although not required, a rotational crop metabolism study was submitted and assessed (EFSA, 2006). Details of the study are presented in Appendix B.

1.1.3. Nature of residues in processed commodities

The effect of processing on the nature of propamocarb was investigated in the framework of a previous MRL application (EFSA, 2015a). The study showed that propamocarb hydrochloride is hydrolytically stable under standard processing conditions.

1.1.4. Methods of analysis in plants

An analytical method for the determination of propamocarb residues was assessed during the MRL review and considered to be fully validated in high water content commodities. The method allows quantifying residues at or above the LOQ of 0.01 mg/kg (EFSA, 2013).

1.1.5. Stability of residues in plants

The storage stability of the active substance in plants stored under frozen conditions was investigated in the framework of the EU pesticides peer review (EFSA, 2006). It was demonstrated that in the crop assessed in the framework of this application, residues were stable for at least 26 months when stored at −18°C.

1.1.6. Proposed residue definitions

Based on the metabolic pattern identified in metabolism studies, the results of hydrolysis studies, the toxicological significance of metabolites and the capability of enforcement analytical method, the following residue definitions were proposed

- residue for risk assessment and enforcement: Sum of propamocarb and its salts, expressed as propamocarb.

The same residue definitions are applicable to rotational crops and processed products.

EFSA concluded that these residue definitions are appropriate and no further information is required.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

In support of the MRL application, eight Good Agricultural Practice (GAP)-compliant supervised residue trials on lettuces (open leaf varieties) were submitted. According to the assessment of the EMS, the analytical method used was sufficiently validated and trial samples were stored under conditions for which integrity was demonstrated.

Since two trials were conducted in the same location with the same experimental conditions (variety, dose rate, planting, application and harvest time), the mean value of the two results was selected for the MRL calculation. Furthermore, residues above the LOQ were reported in three untreated control samples (up to 0.06 mg/kg). The EMS could not find any explanation linked to these findings. However, the highest concentration was extremely low, about 430 times lower than the residue in the corresponding sample from the treated plot. Therefore, these amounts are not expected to impact on the validity of the MRL proposal.

According to the EU guidance document (European Commission, 2017), seven trials on lettuce (open leaf varieties) are sufficient to derive a MRL proposal for chards by extrapolation.
1.2.2. Magnitude of residues in rotational crops

Although not required, the possible transfer of propamocarb residues to crops that are grown in crop rotation has been assessed in EU pesticides peer review and the MRL review (EFSA, 2006, 2013). The available studies, confirmed that no significant residues (residues above 0.01 mg/kg) are expected in succeeding crops, provided that the active substance is applied according to the proposed GAP.

1.2.3. Magnitude of residues in processed commodities

Specific processing studies for the crop under assessment are not available and not required taking into account the limited contribution of chard/beet leaves to the chronic dietary intake.

1.2.4. Proposed MRLs

The available data are considered sufficient to derive a MRL proposal as well as risk assessment values for chards/beet leaves (see Appendix B.1.2.1). According to the OECD calculator, a MRL proposal of 50 mg/kg is derived. However, EFSA is of the opinion that an MRL of 40 mg/kg would be sufficient to accommodate for the intended use on chards/beet leaves. This lower MRL would be in line with the MRL suggested by the applicant, the RMS proposal\(^\text{10}\) and the current MRL for purslane which is based on the same GAP. In Section 3, EFSA assessed whether residues on this crop resulting from the intended use is likely to pose a consumer health risk.

2. Residues in livestock

Not relevant as chards/beet leaves are not used for feed purposes.

3. Consumer risk assessment

EFSA performed a dietary risk assessment using revision 2 of the EFSA PRIMo (EFSA, 2007). This exposure assessment model contains food consumption data for different sub-groups of the EU population and allows the acute and chronic exposure assessment to be performed in accordance with the internationally agreed methodology for pesticide residues (FAO, 2016).

The toxicological reference values for propamocarb used in the risk assessment (i.e. ADI and ARfD values) were recalculated to free base from the values derived in the framework of the EU pesticides peer review for propamocarb hydrochloride (European Commission, 2007).

3.1. Short-term (acute) dietary risk assessment

The short-term exposure assessment was performed for the commodity assessed in this application, taking into account the HR value derived from supervised residue trials. The input value can be found in Appendix D.2.

The short-term exposure did not exceed the ARfD for chards/beet leaves (see Appendix B.3).

3.2. Long-term (chronic) dietary risk assessment

In the framework of the MRL review, a comprehensive long-term exposure assessment was performed, taking into account the existing uses at EU level and the acceptable CXLs (EFSA, 2013). EFSA updated the calculation with the relevant STMR value derived from the residue trials submitted in support of this MRL application for chards/beet leaves. In addition, STMRs derived in EFSA opinions published after the MRL review (EFSA, 2014, 2015a,c) were used. The input values used in the exposure calculations are summarised in Appendix D.2.

The estimated long-term dietary intake was in the range of 0–5% of the ADI. The contribution of residues expected in the chards/beet leaves to the overall long-term exposure is presented in more detail in Appendix C.

EFSA concluded that the long-term intake of residues of propamocarb resulting from the existing uses and the intended use on propamocarb is unlikely to present a risk to consumer health.

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\(^{10}\) The EMS proposed a MRL of 40 mg/kg based on the results of the eight trials submitted (Belgium, 2017).
Conclusions and recommendations

The data submitted in support of this MRL application were found to be sufficient to derive a MRL proposal for chards/beet leaves. An adequate analytical method for enforcement is available to control the residues of propamocarb in the commodity under consideration.

Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of residues resulting from the use of propamocarb according to the intended agricultural practice is unlikely to present a risk to consumer health.

The MRL recommendation is summarised in Appendix B.4.

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**Abbreviations**

- **a.s.** active substance
- **ADI** acceptable daily intake
- **AR** applied radioactivity
- **ARfD** acute reference dose
- **BBCH** growth stages of mono- and dicotyledonous plants
- **bw** body weight
- **CCPR** Codex Committee on Pesticide Residues
- **CF** conversion factor for enforcement to risk assessment residue definition
- **DALA** days after last application
- **DAR** draft assessment report
- **DAT** days after treatment
- **DT90** period required for 90% dissipation (define method of estimation)
- **EMS** evaluating Member State
- **eq** residue expressed as a.s. equivalent
- **FAO** Food and Agriculture Organization of the United Nations
- **GAP** Good Agricultural Practice
- **HPLC-MS/MS** high-performance liquid chromatography with tandem mass spectrometry
- **HR** highest residue
- **IEDI** international estimated daily intake
- **IESTI** international estimated short-term intake
- **ILV** independent laboratory validation
- **ISO** International Organisation for Standardisation
- **IUPAC** International Union of Pure and Applied Chemistry
- **LOQ** limit of quantification
- **MRL** maximum residue level
- **MS** Member States
- **MS/MS** tandem mass spectrometry detector
- **NEU** northern Europe
- **OECD** Organisation for Economic Co-operation and Development
- **PBI** plant back interval
- **PHI** preharvest interval
- **PRIMO** (EFSA) Pesticide Residues Intake Model
- **Rber** statistical calculation of the MRL by using a non-parametric method
- **Rmax** statistical calculation of the MRL by using a parametric method
- **RA** risk assessment
- **RD** residue definition
- **RMS** rapporteur Member State
- **SANCO** Directorate-General for Health and Consumers
- **SC** suspension concentrate
- **SEU** southern Europe
- **SMILES** simplified molecular-input line-entry system
- **STMR** supervised trials median residue
- **TMDI** theoretical maximum daily intake
- **TRR** total radioactive residue
### Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs

| Crop and/or situation | NEU, SEU, MS or country | F G or I(a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|-------------------------|------------|-----------------------------------|-------------|-------------|--------------------------------|----------------|---------|
| Chards/beet leaves    | EU (Belgium)            | G          | Mildew                            | SC          | Foliar spraying BBCH 14-47 | 0.84 (1 kg propamocarb HCl/ha) | 14              | Interval between applications in the residue trials was 7 days |

NEU: northern European Union; SEU: southern European Union; MS: Member State; a.s.: active substance; SC: suspension concentrate.

(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide formulation types and international coding system.
(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.
(d): PHI: minimum preharvest interval.
(e): Concentration expressed as propamocarb hydrochloride HCl; equivalent to 525 g/L as propamocarb.
Appendix B – List of end points

B.1. Residues in plants

B.1.1. Nature of residues and methods of analysis in plants

B.1.1.1. Metabolism studies, methods of analysis and residue definitions in plants

| Primary crops (available studies) | Crop groups | Crop(s) | Application(s) | Sampling\(^{(a)}\) |
|----------------------------------|-------------|---------|----------------|------------------|
| Fruit crops                      | Tomato      | Foliar, 1 × 2.17 kg propamocarb HCl/ha | 7, 14, 21, 28 DALA |
|                                  |             | Soil, 4 × 7.22 or 36.1 g propamocarb HCl/m² | 14, 21, 28, 35 DALA |
| Cucumber                         | Foliar, 1 × 2.90 kg propamocarb HCl/ha | 30 DAT |
|                                  | Soil (to hydroponic solution), 1 × 0.53 g/plant | 21 DAT |
| Root crops                       | Potato      | Foliar, 3 × 2.45 kg propamocarb HCl/ha, interval about 20 days | 42 DALA |
|                                  | Foliar, 6 × 2.17 or 10.83 kg propamocarb HCl/ha | 7 DALA |
| Leafy crops                      | Lettuce     | Foliar: 3 × 1.08 kg propamocarb HCl/ha, interval 10 days | 21 DALA |
|                                  | Soil: 3 × 7.22 g/m² | 38 DALA |
| Spinach                          | Foliar 2 × 2.53 kg/ha, interval 20 days | 0, 20 DAT\(_1\), 3 DALA |

Radiolabelled active substance: [carbamate-\(^{14}\)C] propamocarb hydrochloride (spinach); [propyl-\(^{14}\)C] propamocarb hydrochloride (potato); radiolabel position not reported (tomato, cucumber, lettuce).

Reference: EFSA (2006)

| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s) | PBI (days) |
|-------------------------------------|-------------|---------|----------------|------------|
| Root/tuber crops                    | Radish      | 1 × 6 kg propamocarb HCl/ha to bare soil | 30, 120, 365 |
| Leafy crops                         | Lettuce     | 1 × 6 kg propamocarb HCl/ha to bare soil | 30, 120, 365 |
| Cereal (small grain)                | Wheat       | 1 × 6 kg propamocarb HCl/ha to bare soil | 30, 120, 365 |

Radiolabelled active substance: [aminopropyl-\(^{14}\)C]- propamocarb hydrochloride

Comments: Not triggered (DT\(_{90}\) propamocarb hydrochloride: 57–78 days).

Reference: EFSA (2006)

| Processed commodities (hydrolysis study) | Conditions                                             | Investigated? |
|-----------------------------------------|--------------------------------------------------------|---------------|
|                                        | Pasteurisation (20 min, 90°C, pH 4)                    | Yes           |
|                                        | Baking, brewing and boiling (60 min, 100°C, pH 5)      | Yes           |
|                                        | Sterilisation (20 min, 120°C, pH 6)                    | Yes           |

Comment: Propamocarb hydrochloride, the tested material, was stable under standard processing conditions. Reference: EFSA (2015a)

\(^{(a)}\): DAT: days after treatment; DAT\(_1\): days after first treatment; DALA: days after last application.
Can a general residue definition be proposed for primary crops? | Yes
---|---
Rotational crop and primary crop metabolism similar? | Yes
Residue pattern in processed commodities similar to residue pattern in raw commodities? | Yes
Plant residue definition for monitoring (RD-Mo) | Sum of propamocarb and its salts, expressed as propamocarb
Plant residue definition for risk assessment (RD-RA) | Sum of propamocarb and its salts, expressed as propamocarb
Conversion factor (monitoring to risk assessment) | Not applicable
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs) | Matrices with high water content: HPLC–MS/MS, LOQ 0.01mg/kg Confirmatory method available ILV available (EFSA, 2013)

### B.1.1.2. Stability of residues in plants

| Plant products (available studies) | Category | Commodity | T (°C) | Stability |
|---|---|---|---|---|
| High water content | Tomato | –18 | 26 months |
| | Lettuce | –18 | 24 months |
| | Cucumber, Brussels sprout | –18 | 12 months |

Comment: Samples were analysed at day zero, after 4, 8, 17 and 26 months (tomatoes), after 1 year (cucumbers, Brussels sprouts, lettuces) and 2 years (lettuces) of storage.

Reference: EFSA (2006)
B.1.2. Magnitude of residues in plants

B.1.2.1. Summary of residues data from the supervised residue trials

| Crop       | Region/indoor(a) | Residue levels observed in the supervised residue trials (mg/kg) | Comments (OECD calculations)                                                                 | MRL proposals (mg/kg) | HR(b) (mg/kg) | STMR(c) (mg/kg) |
|------------|------------------|------------------------------------------------------------------|--------------------------------------------------------------------------------------------|-----------------------|--------------|----------------|
| Lettuces   | Indoor           | 1.9, 2.1, 2.9(b); 4.5, 10, 13, 25                                  | Open leaf lettuces<br>OECUnrounded: 42.22<br>Rber/Rmax: 40.00<br>A MRL proposal of 40 mg/kg is considered sufficient<br><b>Extrapolation to chards/beet leaves</b> | 50 or 40             | 25           | 4.5           |

MRL: maximum residue level; OECD: Organisation for Economic Co-operation and Development; Rber: statistical calculation of the MRL by using a non-parametric method; Rmax: statistical calculation of the MRL by using a parametric method.

(a): NEU: Outdoor trials conducted in northern Europe; SEU: Outdoor trials conducted in southern Europe; Indoor: indoor EU trials or Country code: if non-EU trials.

(b): Highest residue.

(c): Supervised trials median residue.

(d): Mean of two values (2.8 and 3.0 mg/kg) from replicate plots which applied the same experimental conditions.
B.1.2.2. Residues in succeeding crops

Confined rotational crop study
(quantitative aspect)

Not triggered
Study available. Residues in succeeding crops at 30 days PBI ranged from 0.36 to 2.33 mg eq/kg and declined over the following PBIs. The major part of the residues was identified as parent compound, except in wheat grain, where the main compound was the oxazolidine-one metabolite (19.9% of TRR). The dose rate in the confined rotational crop study was 3N the intended application rate for chards/beets leaves.

Field rotational crop study

Not triggered
Rotational crop field trials available. Range of total dose rate from 3.99 to 7.22 kg/ha tested in several succeeding crops (wheat, soybean, sugar beets, beet roots, dry beans, lamb's lettuces, lettuces, carrots and barley) sown at different PBIs. Residues at or above the LOQ were observed only in wheat grown on a 30 days aged soil treated with 6.7 kg/ha (> 3N intended application rate for chards/beets leaves)
Reference: EFSA (2006, 2013)

B.1.2.3. Processing factors

Not triggered (TMDI for chards/beet leaves expected to be < 10% ADI).

B.2. Residues in livestock

Not relevant (crop not used as feed item).
B.3. Consumer risk assessment

| ARfD | 0.84 mg propamocarb/kg bw<sup>(a)</sup> (EFSA, 2006) |
|------|-----------------------------------------------------|
| Highest IESTI, according to EFSA PRIMo | Chards/beet leaves: 52.2% ARfD |
| Assumptions made for the calculations | The calculation is based on the highest residue level observed in the supporting residue trials |

| ADI | 0.24 mg propamocarb/kg bw per day<sup>(a)</sup> (EFSA, 2006) |
|-----|-------------------------------------------------------------|
| Highest IEDI, according to EFSA PRIMo | 5.1% of ADI (FR toddler) |
| Contribution of crop assessed: | Chards/beet leaves: 0.15% of ADI |
| Assumptions made for the calculations | The calculation is based on  
• the median residue levels derived from the residue trials supporting the MRL application in chards;  
• the expected median residues expected according to the currently authorised uses in other crops and the Codex MRL included in the EU legislation  
In addition, the following factors were considered:  
• the peeling factor of 0.18 for melons and watermelons;  
• the conversion factors of 1.7 (mammalian meat, liver), 1 (mammalian fat), 2.2 (mammalian kidney), 4.25 (milk), 1.3 (poultry) |

(a): Recalculated by EFSA applying a molecular weight conversion factor of 0.84 to the toxicological reference values derived during the peer review for propamocarb hydrochloride (ARfD: 1 mg/kg bw; ADI: 0.29 mg/kg bw per day).

B.4. Recommended MRLs

| Code<sup>(a)</sup> | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|---------------------|-----------|------------------------|-------------------------|-----------------------|
| 0252030             | Chards/beet leaves | 30                     | 50 or 40                | The indoor use is sufficiently supported by data.  
Using the OECD calculator, a MRL proposal of 50 mg/kg is derived. According to EFSA a MRL of 40 mg/kg would be sufficient to cover the intended use. The proposed MRL of 40 mg/kg is in line with the proposal of the applicant and the RMS.  
A consumer health concern was not identified |

MRL: maximum residue level; OECD: Organisation for Economic Co-operation and Development; RMS: rapporteur Member State.  
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
## Propamocarb

**Status of the active substance:** Approved

**Code no.: Proposed LOQ:**

### Toxicological end points

| ADI (mg/kg bw per day): | ARfD (mg/kg bw): |
|------------------------|------------------|
| 0.24                   | 0.84             |

- **Source of ADI:** EFSA
- **Year of evaluation:** 2006
- **Source of ARfD:** EFSA
- **Year of evaluation:** 2006

### No of diets exceeding ADI:

| Highest calculated TMDI values in % of ADI | MS Diet |
|-------------------------------------------|---------|
| 5.1 FR toddler                            | 3.3 Spinach |
| 4.2 NL child                              | 1.7 Spinach |
| 3.7 FR infant                             | 2.1 Spinach |
| 3.2 WHO Cluster diet B                    | 0.8 Lettuce |
| 2.6 DE child                              | 1.0 Spinach |
| 2.1 NL general                            | 0.7 Spinach |
| 2.1 ES adult                              | 1.2 Lettuce |
| 2.1 ES child                              | 0.9 Lettuce |
| 2.1 WHO regional European diet            | 0.8 Lettuce |
| 2.0 IT adult                              | 0.8 Lettuce |
| 2.0 IE adult                              | 0.6 Spinach |
| 1.9 SE general population 90th percentile | 0.3 Chinese cabbage |
| 1.7 DK child                              | 1.1 Cucumbers |
| 1.7 WHO cluster diet D                    | 0.3 Chinese cabbage |
| 1.7 IT lactofluid                        | 0.6 Lettuce |
| 1.4 WHO cluster diet F                    | 0.7 Lettuce |
| 1.3 WHO cluster diet E                    | 0.2 Spinach |
| 0.9 UK vegetarian                        | 0.3 Lettuce |
| 0.9 FR all population                     | 0.2 Lettuce |
| 0.7 LT adult                             | 0.3 Cucumbers |
| 0.6 UK Adult                             | 0.3 Lettuce |
| 0.6 PL general population                | 0.2 Tomatoes |
| 0.6 FI adult                             | 0.2 Cucumbers |
| 0.6 UK Toddler                           | 0.1 Tomatoes |
| 0.4 DK adult                             | 0.2 Cucumbers |
| 0.4 UK Infant                            | 0.1 Cauliflower |
| 0.4 PT General population                | 0.2 Tomatoes |

### Highest contributor to MS diet (in % of ADI)

| Commodity/ group of commodities |
|----------------------------------|
| Spinach                          |
| Spinach                          |
| Spinach                          |
| Spinach                          |
| Spinach                          |
| Spinach                          |
| Spinach                          |
| Spinach                          |
| Spinach                          |
| Spinach                          |
| Spinach                          |

### 2nd contributor to MS diet (in % of ADI)

| Commodity/ group of commodities |
|----------------------------------|
| Milk and milk products: Cattle   |
| Milk and milk products: Cattle   |
| Milk and milk products: Cattle   |
| Milk and milk products: Cattle   |
| Milk and milk products: Cattle   |
| Spinach                          |
| Spinach                          |
| Spinach                          |
| Spinach                          |
| Spinach                          |
| Spinach                          |
| Spinach                          |

### 3rd contributor to MS diet (in % of ADI)

| Commodity/ group of commodities |
|----------------------------------|
| Leek                            |
| Leek                            |
| Leek                            |
| Leek                            |
| Leek                            |
| Spinach                         |
| Spinach                         |
| Spinach                         |
| Spinach                         |
| Spinach                         |
| Spinach                         |
| Spinach                         |

### pTMRLs at LOQ (in % of ADI)

| Commodity/ group of commodities |
|----------------------------------|
| Courgettes                      |
| Scarole (broad-leaf endive)      |
| Leek                            |
| Lettuce                         |
| Spinach                         |
| Spinach                         |
| Spinach                         |
| Spinach                         |
| Spinach                         |
| Spinach                         |
| Spinach                         |

### Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI. A long-term intake of residues of Propamocarb is unlikely to present a public health concern.
The acute risk assessment is based on the ARfD.

For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS, an average European unit weight was used for the IESTI calculation.

In the IESTI 1 calculation, the variability factors were 10, 7, or 5 (according to JMPR manual 2002); for lettuce, a variability factor of 5 was used.

In the IESTI 2 calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variability factor of 3.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

### Unprocessed commodities

| No of commodities for which ARfD/ADI is exceeded (IESTI 1): | No of commodities for which ARfD/ADI is exceeded (IESTI 2): | No of commodities for which ARfD/ADI is exceeded (IESTI 1): | No of commodities for which ARfD/ADI is exceeded (IESTI 2): |
|------------------------------------------------------------|------------------------------------------------------------|------------------------------------------------------------|------------------------------------------------------------|
| IESTI 1 | **(*)** | IESTI 2 | **(*)** | IESTI 1 | **(*)** | IESTI 2 | **(*)** |
| Highest % of ARfD/ADI Commodities | pTMRL/ threshold MRL (mg/kg) | Highest % of ARfD/ADI Commodities | pTMRL/ threshold MRL (mg/kg) | Highest % of ARfD/ADI Commodities | pTMRL/ threshold MRL (mg/kg) | Highest % of ARfD/ADI Commodities | pTMRL/ threshold MRL (mg/kg) |
| 52.2 Beet leaves (chard) | 25/- | 39.6 Beet leaves | 25/- | 22.1 Beet leaves (chard) | 25/- | 18.7 Beet leaves (chard) | 25/- |

No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

### Processed commodities

For processed commodities, no exceedance of the ARfD/ADI was identified.

**No of critical MRLs (IESTI 1):**

**No of critical MRLs (IESTI 2):**

- **No exceedance of the ARfD/ADI was identified for any processed commodity.**

**Conclusion:**

- The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD were reported.
- **(*)** pTMRL: provisional temporary MRL.
- **(*)** pTMRL: provisional temporary MRL for unprocessed commodity.

- No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

For processed commodities, no exceedance of the ARfD/ADI was identified.
Appendix D – Input values for the exposure calculations

D.1. Livestock dietary burden calculations

Not applicable.

D.2. Consumer risk assessment

| Commodity                                                  | Chronic risk assessment | Acute risk assessment |
|------------------------------------------------------------|-------------------------|-----------------------|
|                                                             | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment |
| Residue definition for risk assessment: Sum of propamocarb and its salts, expressed as propamocarb |
| Potatoes                                                   | 0.05                    | STMR (EFSA, 2013)     |                      |         |
| Celeriacs/turnip rooted celeries                          | 0.01                    | STMR (EFSA, 2015c)    |                      |         |
| Radishes                                                   | 0.61                    | STMR (EFSA, 2013)     |                      |         |
| Garlic, Onions, Shallots                                  | 0.05                    | STMR (EFSA, 2015a)    |                      |         |
| Spring onions/green onions and Welsh onions               | 2.5                     | STMR (EFSA, 2014)     |                      |         |
| Tomatoes                                                   | 0.55                    | STMR (EFSA, 2013)     |                      |         |
| Peppers                                                    | 0.27                    | STMR (EFSA, 2013)     |                      |         |
| Aubergines                                                 | 0.55                    | STMR (EFSA, 2013)     |                      |         |
| Cucumbers                                                  | 1.60                    | STMR (EFSA, 2013)     |                      |         |
| Gherkins                                                   | 0.95                    | STMR (EFSA, 2013)     |                      |         |
| Courgettes                                                 | 1.60                    | STMR (EFSA, 2013)     |                      |         |
| Other cucurbits, edible peel                              | 5                       | Existing MRL          |                      |         |
| Melons                                                     | 0.06                    | STMR-PeelF (EFSA, 2013)|                      |         |
| Pumpkins                                                   | 0.59                    | STMR (EFSA, 2013)     |                      |         |
| Watermelons                                                | 0.06                    | STMR-PeelF (EFSA, 2013)|                      |         |
| Other cucurbits, inedible peel                            | 5                       | Existing MRL          |                      |         |
| Broccoli                                                   | 0.32                    | STMR (EFSA, 2013)     |                      |         |
| Cauliflower                                                | 1.24                    | STMR (EFSA, 2013)     |                      |         |
| Brussels sprouts                                           | 0.47                    | STMR (EFSA, 2013)     |                      |         |
| Head cabbage                                               | 0.20                    | STMR (EFSA, 2013)     |                      |         |
| Chinese cabbage/pe-tsai                                   | 4.00                    | STMR (EFSA, 2014)     |                      |         |
| Kale                                                       | 4.00                    | STMR (EFSA, 2013)     |                      |         |
| Kohlrabi                                                   | 0.04                    | STMR (EFSA, 2013)     |                      |         |
| Salad plants (except lettuces and rucola)                 | 4.00                    | STMR (EFSA, 2013)     |                      |         |
| Lettuces                                                   | 5.20                    | STMR (EFSA, 2013)     |                      |         |
| Roman rocket/rucola                                        | 3.39                    | STMR (EFSA, 2014)     |                      |         |
| Spinaches                                                  | 11.2                    | STMR (EFSA, 2013)     |                      |         |
| Purslanes                                                  | 3.80                    | STMR (EFSA, 2015c)    |                      |         |
| Chards/beet leaves                                         | 4.50                    | STMR                  | 25                   | HR      |
| Witloofs/Belgian endives                                   | 0.30                    | STMR (EFSA, 2013)     |                      |         |
| Herbs and edible flowers                                  | 9.67                    | STMR (EFSA, 2013)     |                      |         |
| Beans, with pods                                           | 0.10                    | STMR (EFSA, 2013)     |                      |         |
| Celeries                                                   | 0.01                    | STMR (EFSA, 2015c)    |                      |         |
| Florence fennels                                           | 0.01                    | STMR (EFSA, 2015c)    |                      |         |
| Leeks                                                      | 2.50                    | STMR (EFSA, 2015a)    |                      |         |
Residue definition for risk assessment: Sum of propamocarb, N-oxide propamocarb, oxazolidine-2-one propamocarb and 2-hydroxypropamocarb expressed as propamocarb

| Commodity | Chronic risk assessment | Acute risk assessment |
|-----------|-------------------------|-----------------------|
|           | Input value (mg/kg)     | Comment               | Input value (mg/kg)     | Comment               |
| Swine, muscle (a) | 0.02 | STMR × CF (EFSA, 2013) |                      |                       |
| Swine, fat tissue (a) | 0.01 | STMR × CF (EFSA, 2013) |                      |                       |
| Swine, liver (a) | 0.03 | STMR × CF (EFSA, 2013) |                      |                       |
| Swine, kidney (a) | 0.02 | STMR × CF (EFSA, 2013) |                      |                       |
| Swine, edible offal (a) | 0.03 | STMR (liver) × CF (b) |                      |                       |
| Bovine, sheep, goat, equine, other farmed terrestrial animals, muscle (a) | 0.02 | STMR × CF (EFSA, 2013) |                      |                       |
| Bovine, sheep, goat, equine, other farmed terrestrial animals, fat tissue (a) | 0.01 | STMR × CF (EFSA, 2013) |                      |                       |
| Bovine, sheep, goat, equine, other farmed terrestrial animals, liver (a) | 0.07 | STMR × CF (EFSA, 2013) |                      |                       |
| Bovine, sheep, goat, equine, other farmed terrestrial animals, kidney (a) | 0.02 | STMR × CF (EFSA, 2013) |                      |                       |
| Bovine, sheep, goat, equine, other farmed terrestrial animals, edible offal (a) | 0.07 | STMR (liver) × CF (b) |                      |                       |
| Milk (a) | 0.04 | STMR × CF (EFSA, 2013) |                      |                       |

Residue definition for risk assessment: Sum of propamocarb and N-desmethyl propamocarb, expressed as propamocarb

| Commodity | Chronic risk assessment | Acute risk assessment |
|-----------|-------------------------|-----------------------|
|           | Input value (mg/kg)     | Comment               | Input value (mg/kg)     | Comment               |
| Poultry, muscle (a) | 0.01 | STMR × CF (EFSA, 2013) |                      |                       |
| Poultry, fat tissue (a) | 0.01 | STMR × CF (EFSA, 2013) |                      |                       |
| Poultry, liver (a) | 0.01 | STMR × CF (EFSA, 2013) |                      |                       |
| Poultry, edible offal (a) | 0.01 | STMR (liver) × CF (b) |                      |                       |
| Birds eggs (a) | 0.02 | STMR × CF (EFSA, 2013) |                      |                       |

PeelF: peeling factor; STMR: supervised trials median residue; MRL: maximum residue level; HR: highest residue.
(a): Tentative conversion factors (CF) from enforcement to risk assessment were proposed in the framework of the MRL review based on metabolism studies.
(b): The STMR and tentative CF derived for liver (EFSA, 2013) were used to refine the risk assessment for offal of animal origin since the same MRL as for liver was set in the MRL regulation.
### Appendix E – Used compound codes

| Code/trivial name                  | Chemical name/SMILES notation                              | Structural formula |
|-----------------------------------|------------------------------------------------------------|--------------------|
| Propamocarb                        | Propyl 3-(dimethylamino) propylcarbamate (IUPAC)           | ![Propamocarb](image1) |
| Propamocarb hydrochloride         | Propyl 3-(dimethylamino) propylcarbamate hydrochloride (IUPAC) | ![Propamocarb hydrochloride](image2) |
| N-oxide propamocarb               | Propyl [3-(dimethylnitroyl) propyl]carbamate                | ![N-oxide propamocarb](image3) |
| Oxazolidine-2-one propamocarb     | 3-[3-(dimethylamino)propyl]-4-hydroxy-4-methyl-1,3-oxazolidin-2-one | ![Oxazolidine-2-one propamocarb](image4) |
| 2-hydroxypropamocarb              | 2-hydroxypropyl [3-(dimethylamino) propyl]carbamate         | ![2-hydroxypropamocarb](image5) |
| N-desmethyl propamocarb           | Propyl [3-(methylamino)propyl] carbamate                    | ![N-desmethyl propamocarb](image6) |

SMILES: simplified molecular-input line-entry system; IUPAC: International Union of Pure and Applied Chemistry.

(ACD/ChemSketch, Advanced Chemistry Development, Inc., ACD/Labs Release: 12.00 Product version: 12.00 (Build 29305, 25 Nov 2008).