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REASONED OPINION

Modification of the existing maximum residue level for propamocarb in honey

European Food Safety Authority (EFSA) | Giulia Bellisai | Giovanni Bernasconi | Luis Carrasco Cabrera | Irene Castellan | Monica del Aguila | Lucien Ferreira | German Giner Santonja | Luna Greco | Samira Jarrah | Renata Leuschner | Javier Martinez Perez | Ileana Miron | Stefanie Nave | Ragnor Pedersen | Hermine Reich | Silvia Ruocco | Miguel Santos | Alessia Pia Scarlato | Anne Theobald | Manuela Tiramani | Alessia Verani

Correspondence: pesticides.mrl@efsa.europa.eu

Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Bayer AG Crop Science Division submitted a request to the competent national authority in Greece to modify the existing maximum residue level (MRL) for the active substance propamocarb in honey. The data submitted in support of the request were found to be sufficient to derive MRL proposals for honey. Adequate analytical methods for enforcement are available to control the residues of propamocarb on the commodity under consideration at the validated limit of quantification (LOQ) of 0.01 mg/kg. 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 reported agricultural practice is unlikely to present a risk to consumer health.

KEYWORDS

consumer risk assessment, honey, MRL, pesticide, propamocarb, propamocarb hydrochloride

CONTENTS

SUMMARY

In accordance with Article 6 of Regulation (EC) No 396/2005, Bayer AG Crop Science Division submitted an application to the competent national authority in Greece (evaluating Member State, EMS) to modify the existing maximum residue level (MRL) for the active substance propamocarb in honey.

The application, alongside the dossier containing the supporting data in IUCLID format, was submitted through the European Food Safety Authority (EFSA) Central Submission System on 7 December 2021. The appointed EMS Greece assessed the dossier and declared its admissibility on 28 June 2022. Subsequently, following the implementation of the EFSA's confidentiality decision, the non-confidential version of the dossier was published by EFSA, and a public consultation launched on the dossier. The consultation aimed to consult stakeholders and the public on the scientific data, studies and other information part of, or supporting, the submitted application, in order to identify whether other relevant scientific data or studies are available. The consultation run from 20 April 2023 to 11 May 2023. No additional data nor comments were submitted in the framework of the consultation.

At the end of the commenting period, the EMS proceeded drafting the evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the EFSA on 31 May 2023. To accommodate for the intended use of propamocarb, the EMS proposed to raise the existing MRL from the limit of quantification (LOQ) of 0.05 to 15 mg/kg.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified points which needed further clarification and requested the EMS to address them. The additional information was duly considered by the EMS who submitted a revised evaluation report to EFSA on 21 August 2023 (Greece, 2023), which replaced the previously submitted evaluation report. On 25 September 2023, the applicant updated IUCLID dossier with the requested information.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC, the data evaluated under previous MRL assessments, and the additional data provided by the EMS in the framework of this application, the following conclusions are derived.

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 (hydrolysis studies) demonstrated that the active substance is stable under processing conditions.

In rotational crops, the confined study did not indicate that a different metabolism is expected in rotational crops.

Based on the metabolic pattern identified in metabolism studies, hydrolysis studies, the toxicological relevance 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, processed products and honey.

Sufficiently validated analytical methods based on high performance liquid chromatography (HPLC) with tandem mass spectrometry (MS/MS) detection are available to quantify residues in honey according to the enforcement residue definition. The methods enable quantification of residues at or above 0.01 mg/kg in honey (LOQ).

The applicant provided four independent residue trials for honey, where propamocarb was applied to phacelia under semi-field conditions in tunnels. One beehive was set up per tunnel for the control and treated plot each. Colony assessments were performed before set up of the hives in the tunnels and after sampling of the honey. Honey was collected once mature at the end of flowering or if the water content was < 20% or after comb closure for subsequent residue analysis. The available residue trials are sufficient and were deemed appropriate to derive an MRL proposal of 15 mg/kg for honey.

Specific studies investigating the magnitude of propamocarb residues in processed honey are not required.

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 nature and 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 authorised Good Agricultural Practices (GAP) assessed in the framework of the MRL review. Therefore, residues in honey are not expected to occur from rotational crops.

Residues of propamocarb in commodities of animal origin were not assessed since the honey, the commodity 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 acceptable daily intake (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 toxicological reference values were recalculated based on the molecular weight (MW) conversion factor of 0.83 (MW[Propamocarb]/MW[Propamocarb hydrochloride]) to express ADI and ARfD.

The consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo). The estimated short-term exposure for honey was 2.46% of the ARfD while the estimated long-term dietary intake accounted for a maximum of 6% of ADI (Dutch toddler diet). The contribution of residues expected in honey to the overall long-term exposure accounted for less than 0.07% of the ADI.

EFSA concluded that the proposed MRL on honey will not results in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumer's health.

The peer review of the active substance in accordance with Regulation (EC) No 1107/2009 is ongoing and therefore the conclusions reported in this reasoned opinion might need to be reconsidered in the light of the outcome of the peer review.

EFSA proposes to amend the existing MRL as reported in the summary table below.

Full details of all end points and the consumer risk assessment can be found in Appendices B–D.

Code[a]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Propamocarb (Sum of propamocarb and its salts, expressed as propamocarb)				
1040000	Honey and other apiculture products[b]	0.05[c]	15	The MRL proposal reflects residues in honey from trials performed on semi-field conditions with propamocarb. The submitted data are sufficient to derive an MRL proposal for indoor use. Risk for consumers unlikely

Abbreviations: MRL, maximum residue level; NEU, northern Europe; SEU, southern Europe.

[a]Commodity code number according to Annex I of Regulation (EC) No 396/2005.

[b]According to Regulation (EC) No 396/2005 MRLs are not applicable to other apiculture products until individual products have been identified and listed within this group.

[c]Indicates that the MRL is set at the limit of analytical quantification (LOQ).

ASSESSMENT

The European Food Safety Authority (EFSA) received an application to modify the existing MRL for propamocarb in honey. The current MRL application is not linked to one specific good agricultural practice (GAP) but is related to the existing uses in crops that might be attractive to bees and that are a potential source for residues of propamocarb in honey. The worst-case GAP was identified by the applicant (Greece, 2023).

Propamocarb is the ISO common name for propyl 3-(dimethylamino)propylcarbamate (IUPAC). The chemical structures of the active substance and its main metabolites are reported in Appendix E.

Propamocarb was evaluated in the framework of Directive 91/414/EEC[1] 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 (EFSA, 2006). Propamocarb was approved[2] for the use as fungicide on 1 October 2007. The process of renewal of the first approval is currently ongoing.

The EU MRLs for propamocarb are established in Annexes II of Regulation (EC) No 396/2005[3]. 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 several reasoned opinions on the modification of MRLs for propamocarb. The proposals from these reasoned opinions have been considered in recent MRL regulations.[4] Certain codex maximum residue limits (CXLs) have been taken over in the EU MRL legislation.[5]

In accordance with Article 6 of Regulation (EC) No 396/2005 and following the provisions set by the 'Transparency Regulation' (EU) 2019/1381[6], the applicant Bayer AG Crop Science Division submitted on 7 December 2021 an application to the competent national authority in Greece, alongside the dossier containing the supporting data using the IUCLID format.

The appointed EMS Greece assessed the dossier and declared its admissibility on 28 June 2022. Subsequently, following the implementation of the EFSA's confidentiality decision, the non-confidential version of the dossier was published by EFSA, and a public consultation launched on the dossier. The consultation aimed to consult stakeholders and the public on the scientific data, studies and other information part of, or supporting, the submitted application, in order to identify whether other relevant scientific data or studies are available. The consultation run from 20 April 2023 to 11 May 2023. No additional data nor comments were submitted in the framework of the consultation.

At the end of the commenting period, the EMS proceeded drafting the evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the EFSA on 31 May 2023. To accommodate for the intended use of propamocarb, the EMS proposed to raise the existing MRL from the LOQ of 0.05 to 15 mg/kg.

EFSA based its assessment on the evaluation report submitted by the EMS (Greece, 2023), the draft assessment report (DAR) and its final addendum prepared under Council Directive 91/414/EEC (Ireland, 2004, 2006), the 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 (EFSA, 2014, 2015a, 2015c, 2017), including the reasoned opinion on the MRL review according to Article 12 of Regulation No 396/2005 (EFSA, 2013) and two scientific reports of EFSA in support to the preparation of the EU position for 47th and 51st session of the Codex Committee on Pesticide Residues (EFSA, 2015b, 2019).

For this application, the data requirements established in Regulation (EU) No 544/2011[7] and the guidance documents applicable at the date of submission of the IUCLID application are applicable (European Commission, 1997a–g, 2010, 2018, 2020, 2021, 2023; 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[8].

As the EU pesticides peer review of the active substance in accordance with Regulation (EC) No 1107/2009 is not yet finalised, the conclusions reported in this reasoned opinion may need to be reconsidered in the light of the outcome of the peer review.

[1]Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1–32.

[2]Commission 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.

[3]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.

[4]For an overview of all MRL Regulations on this active substance, please consult: https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/start/screen/mrls

[5]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. C/2020/3608. OJ L 195, 19.6.2020, p. 9–51.

[6]Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC, PE/41/2019/REV/1. OJ L 231, 6.9.2019, p. 1–28.

[7]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.

[8]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.

A selected list of end points of the studies assessed by EFSA in the framework of this MRL application including the end points of relevant studies assessed previously, is presented in Appendix B.

The evaluation report submitted by the EMS (Greece, 2023) 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.[9]

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 in primary crops belonging to the group of fruit crops, root crops and leafy crops, has been investigated in the framework of the EU pesticides peer review (EFSA, 2006). Information on the nature of residues in primary crops is relevant to support the present MRL application in honey (see Section 3.1). Details of the studies are presented in Appendix B.

In the crops tested (cucumber, tomato, potato, spinach and lettuce), after foliar applications residues are highly extractable, representing more than 90% of the total radioactive residues (TRR) with parent compound being the main residue. Two minor metabolites, accounting for less than 5% of the TRR were also identified, 2-hydroxypropamocarb and N-oxide propamocarb, indicating that the degradation of propamocarb hydrochloride proceeds through hydroxylation and oxidation. A similar pattern was observed in spinach after foliar treatment, with two further metabolites identified (< 4% TRR), i.e. N-desmethyl propamocarb resulting from N-demethylation and oxazolidine-2-one propamocarb resulting from the cyclisation of the 2-hydroxypropamocarb. Foliar treatment of tomato plants also resulted in propamocarb being the major constituent in tomato fruits (75% TRR). In lettuce, no information was provided on the amount of the total residues that could remain on the surface of the leaves at harvest. The metabolic behaviour in primary crops following foliar treatment is deemed sufficiently addressed.

In the studies where propamocarb hydrochloride was applied hydroponically or as a soil treatment in tomatoes or lettuce a number of unidentified compounds were found, none of them exceeding 10% of the TRR. Therefore, in the peer review of 2006 it was concluded that no significant metabolite was to be expected in the tested crops after soil treatment (EFSA, 2006). However, this conclusion may be updated in the framework of the renewal assessment of propamocarb.

1.1.2 | Nature of residues in rotational crops

Although not required since the DT90 field value of propamocarb hydrochloride ranged from 57 to 78 days, the possible transfer of propamocarb residues to crops that are grown in crop rotation has been assessed in EU pesticides peer review (EFSA, 2006) and in the MRL review (EFSA, 2013). Details of the study are presented in Appendix B. It was concluded that the metabolism in primary and rotational crops was similar and that a specific residue definition for rotational crops was not necessary.

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 of pasteurisation, baking/brewing/boiling and sterilisation.

1.1.4 | Analytical methods for enforcement purposes in plant commodities

As the current MRL application is on honey, evaluation of analytical methods for enforcement of residues in primary crops is not required.

1.1.5 | Storage stability of residues in plants

As the current MRL application is on honey though, investigations of storage stability in primary crops are not required.

[9]Background documents to this reasoned opinion are published on OpenEFSA portal and are available at the following link:

https://open.efsa.europa.eu/study-inventory/EFSA-Q-2022-00427

1.1.6 | Proposed residue definitions

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

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

The same residue definitions are applicable to rotational crops and processed products. The residue definition for enforcement set in Regulation (EC) No 396/2005 is identical with the above-mentioned residue definition. 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

As the current MRL application is on honey, investigations of residues in primary crops are not required.

1.2.2 | Magnitude of residues in rotational crops

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 authorised uses assessed in the framework of the MRL review.

Therefore, residues in honey are not expected to occur from rotational crops.

1.2.3 | Magnitude of residues in processed commodities

As the current MRL application is on honey, investigations on the magnitude of residues in processed crops are not required.

1.2.4 | Proposed MRLs

As the current MRL application is on honey, there are no proposed MRLs for plant commodities. In Section 3, EFSA assessed the MRL proposal for honey.

2 | RESIDUES IN LIVESTOCK

Not relevant as honey is not used for feed purposes.

3 | RESIDUES IN HONEY

3.1 | Nature of residues in honey

Honey is produced by bees from sugary secretions of plants (floral nectar mainly) through regurgitation, enzymatic conversion and water evaporation and followed by storage in the beehives for a certain time period.

In the absence of specific metabolism studies with honeybees, studies investigating the nature of residues in primary crops and rotational crops and studies investigating the degradation during pasteurisation should be considered to determine the nature of residues in honey (European Commission, 2018). It is likely that the nature of residues in pollen and nectar collected from primary and rotational crops, as well as in honey (resulting from the residues in floral nectar), is the same as in primary and rotational crops.

Considering that sufficient data investigating the metabolic profile in primary and rotational crops and the degradation of the active substance under standard hydrolysis conditions are available (see Sections 1.1.1, 1.1.2 and 1.1.3, respectively), no further information is required for the current application according to the guidelines. However, it would be desirable to further investigate whether enzymatic processes involved in the production of honey occurring in the bee gut or during the storage in the beehive have an impact on the nature of residues in honey.

3.1.1 | Analytical methods for enforcement in honey

In the framework of the present assessment, the applicant submitted the validation results of an analytical method for enforcement developed to determine propamocarb residues in honey (Greece, 2023). The method, based on high performance liquid chromatography with tandem mass spectrometry (HPLC–MS/MS) detection is sufficiently validated according to SANTE/2020/12830 rev. 1 for the determination (quantification and simultaneous confirmation) of propamocarb according to the residue definition for enforcement, at or above the LOQ of 0.01 mg/kg. The method proposed is supported by a validated independent laboratory validation (ILV) (Greece, 2023).

Information on extraction efficiency of the analytical methods applied for enforcement of residues in honey is not available. However, since the existing guidance document on extraction efficiency (European Commission, 2023[10]) cannot be applied to the honey matrix and since no other guidance on how to investigate extraction efficiency in honey is available, demonstration of extraction efficiency in honey matrix is not required for the present assessment.

3.1.2 | Storage stability of residues in honey

The storage stability of residues of propamocarb in honey samples stored under frozen conditions was investigated in the current MRL application (Greece, 2023).

It was demonstrated that residues of propamocarb were stable for at least 6 months when stored at ≤ −18°C (deep-freezer storage conditions) in honey.

3.1.3 | Proposed residue definitions

In the absence of specific metabolism studies on honey, the studies investigating the nature of residues in primary and rotational crops and studies investigating the degradation of the active substance during pasteurisation are considered to derive the residue definitions for honey; the same residue definitions as mentioned for plant commodities are therefore proposed.

3.2 | Magnitude of residues in honey

Studies investigating the magnitude of residues in honey were submitted in the current application. In 2020 a total of four trials were performed in Germany (2) and Spain (2) under semi-field conditions in order to determine the magnitude of residues of propamocarb in bee honey. On each trial site one tunnel confining the bees was established on the control and the treated plot. One beehive was set up per tunnel for the control and treated plot each (Greece, 2023).

A suspension concentrate formulation was applied to plots with *Phacelia tanacetifolia* by spraying foliage four times with spray intervals of 5–7 days. The application rate of propamocarb hydrochloride was 3000 g a.s./ha for the first application and 900–1100 g a.s./ha for the second, third and fourth applications. For all trials, the first application was performed 14 ± 2 days before growth stage BBCH 61–63. The second application was performed 7 ± 2 days before growth stage BBCH 61–63, while the third application was performed at growth stage BBCH 61–63 in the morning until noon. The fourth application was performed 7 ± 2 days after the third application during full flowering, in the morning until noon.

Honey samples were collected from initially empty combs, which were introduced in the hive shortly before the third application. Honey was collected 3–11 days after the last application once mature at the end of flowering (BBCH 67–69), either when the water content was < 20% or after comb closure – whatever occurred first, for subsequent residue analysis. The sampled honey amount ranged from 35.96 to 171.26 g. The samples of these residue trials were stored under conditions for which integrity of the samples has been demonstrated and were analysed for the parent compound.

The method used in the analysis of samples in the context of the residue trials is based on HPLC–MS/MS detection and enables the quantification of residues of parent propamocarb at or above the LOQ of 0.01 mg/kg in the commodity assessed. According to the assessment of the EMS, the methods used are sufficiently validated for the quantification of residues of propamocarb and are fit for purpose (Greece, 2023). Information on extraction efficiency of the analytical method used for data generation from honey samples is not available. However, since the existing guidance document on extraction efficiency (European Commission, 2023) cannot be applied for the honey matrix and since no other guidance on how to investigate extraction efficiency in honey is available, demonstration of extraction efficiency in honey matrix is not required for the present assessment.

The four residue trials are considered valid and independent. The residue levels in honey, measured as propamocarb (four independent results), ranged from 0.14 to 5.77 mg/kg. The available four residue trials are sufficient to derive an MRL

[10]The previous revision 4 of SANTE/2017/10632, the technical guidance on extraction efficiency, was applicable at the date of submission of the IUCLID application (European Commission, 2022). Since then, further precisions on its applicability were addressed in the revised version 5, applicable from 23 May 2023. Since the revision 5 does not contain any new elements or obligations, EFSA took into consideration this newly released version directly.

proposal of 15 mg/kg for honey. It should be noted that currently, MRLs set for honey are not applicable to other apicultural products following Commission Regulation (EU) 2018/62[11].

The GAP parameters tested in the residue trials reported above were then compared to a critical GAP on melliferous crops identified among the GAPs notified in the context of the EU MRL review to verify whether the proposed MRL is in line with the critical agricultural practices. With respect to residues in honey, the critical GAP identified by the EMS was the following:

- SEU GAP on cucumbers and courgettes: 4 × 2166 g propamocarb hydrochloride/ha, 10-day interval between applications, BBCH from 14 to 89, PHI of 4 days (EFSA, 2013).

The application pattern performed in the trials on *P. tanacetifolia* and the application pattern defined in the SEU GAP on cucumbers/courgettes are different considering the single application rates. The first application of propamocarb hydrochloride on *P. tanacetifolia* (3000 g a.s./ha) is higher compared to the GAP on cucumbers/courgettes. However, as propamocarb is considered a systemic substance, all applications performed before and during flowering are expected to affect the total residue in honey. This rationale has been submitted by the EMS (Greece, 2023) and is acceptable. Therefore, a comparison based on the total rate applied around flowering is deemed relevant.

The seasonal rate applied with the critical GAP on cucumber/courgettes is 8664 g propamocarb hydrochloride/ha. However, as the last application is likely to be done after the formation of the fruits (PHI 4 days), only the first three applications are expected to affect the residue in honey in a worst-case scenario where they would all be done around flowering (total 6498 g propamocarb hydrochloride/ha). The total application rate applied in the tunnel trials with phacelia is 6000 g propamocarb hydrochloride/ha. As in the trials all applications were performed before or around flowering, the four applications performed in the trials (total 6000 g a.s./ha) are expected to affect the total residue in honey. Consequently, the total of applications that are expected to affect the residues in honey in the tunnel trials and in the SEU GAP on cucumbers and courgettes are in the same range (within the 25% margin of tolerance).

It is concluded that the available tunnel trials are sufficiently representative for the critical GAP considered on melliferous crops (SEU GAP on cucumbers/courgettes). Therefore, these trials are appropriate to derive an MRL proposal and risk assessment values for honey.

4 | CONSUMER RISK ASSESSMENT

EFSA performed a dietary risk assessment using revision 3.1 of the EFSA PRIMo (EFSA, 2018, EFSA et al., 2019). 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 derived in the framework of the EU pesticides peer review (EFSA, 2006). The toxicological reference values were recalculated to express the ADI and ARfD as propamocarb equivalents (ADI of 0.24 mg/kg bw per day and ARfD of 0.84 mg/kg bw).

Short-term (acute) dietary risk assessment. The short-term exposure assessment was performed for the commodities assessed in this application in accordance with the internationally agreed methodology (FAO, 2016). The calculations were based on the highest residue (HR) according to the residue definition for risk assessment expected in the raw agricultural commodity derived from supervised field trials. The complete list of input values can be found in Appendix D.1.

The short-term exposure did not exceed the ARfD for honey. The estimated short-term exposure for honey was 2.46% of the ARfD (see Appendix B.4).

However, EFSA identified an exceedance of the ARfD for two commodities that are not part of the present MRL application: lettuce and leek, accounting for 113% and 105% of the ARfD, respectively. For lettuces, it should be noted that exceedances of the ARfD were not previously identified with PRIMo rev.2 (EFSA, 2015c) while the present calculation was updated with PRIMo rev 3.1. For leeks, this exceedance of the ARfD was already identified and discussed in a previous EFSA assessment (EFSA, 2015a).

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). After the MRL review, EFSA issued several opinions assessing new MRLs on propamocarb (EFSA, 2014, 2015a, 2015c; EFSA et al., 2017). EFSA updated the chronic exposure assessment performed in 2017, adding the STMR on honey submitted in support of the present MRL application and using the last version of PRIMo (3.1) and adding the CXLs that have been implemented in the meantime (FAO, 2006, 2014, 2019). The input values used in the exposure calculations are summarised in Appendix D.1.

The estimated long-term dietary intake accounted for a maximum of 6% of the ADI (NL toddler diet). The contribution of residues expected in honey to the overall long-term exposure was estimated to be less than 0.07% (DE child diet) (see Appendix B.4).

[11]Commission Regulation (EU) 2018/62 of 17 January 2018 replacing Annex I to Regulation (EC) No 396/2005 of the European Parliament and of the Council. C/2018/0138. OJ L 18, 23.1.2018, p. 1–73.

EFSA concluded that the long-term intake of residues resulting from the use of propamocarb under consideration is unlikely to present a risk to consumer health.

For further details on the exposure calculations, a screenshot of the Report sheet of the PRIMo is presented in Appendix C.

5 | CONCLUSION AND RECOMMENDATIONS

The data submitted in support of this MRL application were found to be sufficient to derive an MRL proposal of 15 mg/kg for honey.

Based on the results of the risk assessment, EFSA concluded that the short-term and long-term intake of residues resulting from the potential transfer of residues into honey and the existing uses of propamocarb assessed in the present MRL application in honey of propamocarb is unlikely to present a risk to consumer health. EFSA concluded that the proposed use of propamocarb will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers' health.

It should be highlighted that EFSA identified an exceedance of the ARfD for lettuce (which is not part of the present MRL application), accounting for 113% of the ARfD. Such an exceedance of the ARfD was not previously identified with PRIMo rev.2 (EFSA, 2015c) while the present calculation was updated with PRIMo rev 3.1.

The MRL recommendations are summarised in Appendix B.5.

ABBREVIATIONS

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CF	conversion factor for enforcement to risk assessment residue definition
cGAP	critical GAP
CXL	Codex maximum residue limit
DALA	days after last application
DAR	draft assessment report
DT_{90}	period required for 90% dissipation (define method of estimation)
EMS	evaluating Member State
eq	residue expressed as a.s. equivalent
EURL	EU Reference Laboratory (former Community Reference Laboratory (CRL))
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
IPCS	International Programme of Chemical Safety
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
MW	molecular weight
NEU	northern Europe
OECD	Organisation for Economic Co-operation and Development
PBI	plant back interval
PHI	pre-harvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
RA	risk assessment
RAC	raw agricultural commodity
RD	residue definition
RMS	rapporteur Member State
SEU	southern Europe
STMR	supervised trials median residue
TRR	total radioactive residue
WHO	World Health Organization

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CONFLICT OF INTEREST

If you wish to access the declaration of interests of any expert contributing to an EFSA scientific assessment, please contact interestmanagement@efsa.europa.eu.

REQUESTOR

European Commission

QUESTION NUMBER

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APPENDIX A

Summary of intended GAP triggering the amendment of existing EU MRLs

In the framework of the review of existing MRLs according to Art. 12 of EU Regulation 396/2005 (EFSA, 2013), numerous GAPs were reported for crops that might be attractive to bees for food foraging and that might contribute to the final residues of propamocarb in honey. However, since the MRL application is not linked to one specific GAP and applies to honey as food item for consumers, this Appendix is not relevant for the given application.[12]

[12]The use pattern of propamocarb in *Phacelia tanacetifolia*, which was tested in the residue trials, was reported in the GAP table in the MRL application and in the evaluation report (Greece, 2023). However, the applicant clarified that a use in *P. tanacetifolia* is not intended for propamocarb.

APPENDIX B

List of end points

B.1 | RESIDUES IN PLANTS

B.1.1 | Nature of residues and analytical methods for enforcement purposes in plant commodities

B.1.1.1 | Metabolism studies, analytical methods and residue definitions in plants

Primary crops (available studies)	Crop groups	Crop(s)	Application(s)	Sampling[a]	Comment/Source
	Fruit crops	Tomato	Foliar, 1 × 2.17 kg propamocarb HCl/ha	7, 14, 21, 28 DALA	Radiolabel position not reported (tomato, cucumber, lettuce) (EFSA, 2006)
			Soil, 4 × 7.22 or 36.1 g propamocarb HCl/m^2	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	Radiolabelled active substance: [propyl-^{14}C] propamocarb hydrochloride (EFSA, 2006)
			Foliar, 6 × 2.17 or 10.83 kg propamocarb HCl/ha	7 DALA	Death of foliage by the 6th application with drift to soil (EFSA, 2015a)
	Leafy crops	Lettuce	Foliar, 3 × 1.08 kg propamocarb HCl/ha, interval 10 days	21 DALA	Radiolabel position not reported (EFSA, 2006)
			Soil: 3 × 7.22 g/m^2	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 (EFSA, 2006)
Rotational crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**PBI (DAT)**	**Comment/Source**
	Root/tuber crops	Radish	1 × 6 kg propamocarb HCl/ha to bare soil	30, 120, 365	Radiolabelled active substance: [aminopropyl-^{14}C]- propamocarb hydrochloride (EFSA, 2006)
	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	
	Other	–	–	–	–
Processed commodities (hydrolysis study)	**Conditions**			**Stable?**	**Comment/Source**
	Pasteurisation (20 min, 90°C, pH 4)			Yes	Propamocarb hydrochloride, the tested material, was stable under standard processing conditions (EFSA, 2015a)
	Baking, brewing and boiling (60 min, 100°C, pH 5)			Yes	
	Sterilisation (20 min, 120°C, pH 6)			Yes	
	Other processing conditions			–	–

Can a general residue definition be proposed for primary crops?	Yes	EFSA (2006, 2013)
Rotational crop and primary crop metabolism similar?	Yes	EFSA (2006, 2013)
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes	EFSA (2006, 2013)
Plant residue definition for monitoring (RD-Mo)	Propamocarb (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	
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)	Matrices with high water content: HPLC–MS/MS, LOQ 0.01 mg/kg Confirmatory method available ILV available (EFSA, 2013)	

DAT: days after treatment; DAT_1: days after first treatment; DALA: days after last application; PBI: plant-back interval; HPLC–MS/MS: high-performance liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; ILV: independent laboratory validation.

B.1.1.2 | Stability of residues in plants

Plant products (available studies)	Category	Commodity	Stability period T (°C)	Value	Unit	Compounds covered	Comment/Source
	High-water content	Tomato	–18	26	Months	Propamocarb	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 (EFSA, 2006)
		Lettuce	–18	24	Months	Propamocarb	
		Cucumber, Brussels sprout	–18	12	Months	Propamocarb	

B.1.2 | Magnitude of residues in plants

Not relevant for honey.

B.1.2.1 | Residues in rotational crops

Residues in rotational and succeeding crops expected based on confined rotational crop study?	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. A major part of the residues was identified as parent compound, except in wheat grain, where the main compound was the oxazolidine-2-one propamocarb metabolite (19.9% of TRR).
Residues in rotational and succeeding crops expected based on 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-day aged soil treated with 6.7 kg/ha. However residues above LOQ are not expected under the authorised uses assessed in the framework of the MRL review (EFSA, 2013).

B.1.2.2 | Processing factors

No processing studies were submitted in the framework of the present MRL application as not applicable to honey.

B.2 | RESIDUES IN LIVESTOCK

Not relevant as not applicable to honey.

B.3 | RESIDUES IN HONEY

B.3.1 | Nature of residues and analytical methods for enforcement purposes in honey

B.3.1.1 | Metabolism studies, analytical methods and residue definitions in honey

Metabolism studies in honey	In the absence of specific metabolism studies investigating the nature of propamocarb during formation of honey, data on the nature of residues in primary crops and processed commodities (a.s. is hydrolytically stable) were considered to determine the nature of residues in honey.
Honey residue definition for monitoring (RD-Mo)	Propamocarb (Sum of propamocarb and its salts, expressed as propamocarb).
Honey residue definition for risk assessment (RD-RA)	Sum of propamocarb and its salts, expressed as propamocarb.
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)	HPLC-MS/MS, LOQ 0.01 mg/kg. Confirmatory method not needed (SANTE/11956/2016 rev. 9). ILV available (Greece, 2023).

HPLC–MS/MS: high-performance liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; ILV: independent laboratory validation.

B.3.1.2 | Storage stability of residues in honey

Products of animal origin (available studies)	Category	Commodity	T (°C)	Stability period		Compounds covered	Comment/ Source
				Value	Unit		
	Bee products	Honey	–18	6	Months	Propamocarb	Greece (2023)

B.3.2 | Magnitude of residues in honey

B.3.2.1 | Summary of residues data from the supervised residue trials

Commodity	Region[a]	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR[b] (mg/kg)	STMR[c] (mg/kg)	CF[d]
Honey	Indoor	0.14; 1.5; 1.73; 5.77	Four trails under semi-field (tunnel) conditions were carried out in NEU (2) and SEU (2) on *Phacelia tanacetifolia* Residues expressed as propamocarb (Greece, 2023)	**15**	5.77	1.62	1.0

Abbreviations: CF, conversion factor for enforcement to risk assessment residue definition; HR, highest residue; MRL, maximum residue level; NEU, northern European Union; SEU, southern European Union; STMR, supervised trials median residue.

*Indicates that the MRL is proposed at the limit of quantification.

[a]NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe; EU: indoor EU trials or Country code: if non-EU trials.

[b]Highest residue. The highest residue for risk assessment refers to the whole commodity and not to the edible portion.

[c]Supervised trials median residue. The median residue for risk assessment refers to the whole commodity and not to the edible portion.

[d]Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.

B.4 | CONSUMER RISK ASSESSMENT

ARfD	0.84 mg/kg bw (EFSA, 2006)[1]
Highest IESTI, according to EFSA PRIMo	Honey: 2.46% of ARfD
Assumptions made for the calculations	The calculation is based on the highest residue levels in honey derived from the residue trials according to the residue definition for risk assessment: Sum of propamocarb and its salts, expressed as propamocarb. For commodities not included in the present MRL application the short-term exposure assessment was performed using the risk assessment values derived in previous EFSA reasoned opinions (HR values), which indicated exceedance of the ARfD for lettuces and leeks. For what concerns lettuce, accounting for 113% of the ARfD, such exceedance of the ARfD was not previously identified with PRIMo rev.2 (EFSA, 2015c) while the present calculation was updated with PRIMo rev 3.1. All calculations performed with PRIMo revision 3.1

ADI	0.24 mg/kg bw per day (EFSA, 2006)[1]
Highest IEDI, according to EFSA PRIMo	6% ADI (NL toddler diet) Contribution of crops assessed: Honey: 0.068% of ADI (DE child diet)
Assumptions made for the calculations	The calculation is based on: • the median residue levels derived from the residue trials supporting the MRL application in honey; • 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). The crops on which no uses have been reported in the EU pesticides peer review or in subsequent EFSA outputs were not included in the exposure calculation. The CXLs reported by EFSA within the issued scientific reports in support of preparing the EU position in the Sessions of the Codex Committee on Pesticide Residues (CCPR), were included in the exposure calculation (EFSA, 2015b, 2019). Calculations performed with PRIMo revision 3.1

ARfD: acute reference dose; bw: body weight; IESTI: international estimated short-term intake; PRIMo: (EFSA) Pesticide Residues Intake Model; ADI: acceptable daily intake; IEDI: international estimated daily intake; MRL: maximum residue level; CXL: codex maximum residue limit.

[1] Expressed as propamocarb Using the MW conversion factor of 0.83 (MW[Propamocarb] / MW[Propamocarb hydrochloride])

B.5 | RECOMMENDED MRLS

Code[a]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Propamocarb (Sum of propamocarb and its salts, expressed as propamocarb)				
1040000	Honey and other apiculture products[b]	0.05*	15	The MRL proposal reflects residues in honey from trials performed on semi-field conditions with propamocarb. The submitted data are sufficient to derive an MRL proposal for indoor use. Risk for consumers unlikely

Abbreviations: MRL, maximum residue level; NEU, northern Europe; SEU, southern Europe.

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

[a]Commodity code number according to Annex I of Regulation (EC) No 396/2005.

[b]According to Regulation (EC) No 396/2005 MRLs are not applicable to other apiculture products until individual products have been identified and listed within this group.

APPENDIX C

Pesticide Residue Intake Model (PRIMo)

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Propamocarb

LOQs (mg/kg) range from: 0.01 to: 0.05

Toxicological reference values

ADI (mg/kg bw per day):	0.24	ARfD (mg/kg bw):	0.84
Source of ADI:	EFSA, 2006(a)	Source of ARfD:	EFSA, 2006(a)
Year of evaluation:		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:

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : —

	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	6%	NL toddler	14.61	3%	Spinaches	1%	Milk: Cattle	0.4%	Escaroles/broad-leaved endives		6%
	3%	DE child	7.34	0.9%	Spinaches	0.4%	Cucumbers	0.3%	Milk: Cattle		3%
	3%	NL child	6.43	1%	Spinaches	0.4%	Milk: Cattle	0.2%	Cucumbers		3%
	3%	SE general	6.29	0.6%	Lettuces	0.3%	Chinese cabbages/pe-tsai	0.3%	Spinaches		3%
	3%	FR infant	6.06	1%	Spinaches	0.3%	Milk: Cattle	0.3%	Courgettes		3%
	2%	GEMS/Food G06	5.91	0.8%	Tomatoes	0.4%	Cucumbers	0.2%	Spinaches		2%
	2%	GEMS/Food G10	5.51	0.5%	Lettuces	0.3%	Tomatoes	0.3%	Chinese cabbages/pe-tsai		2%
	2%	FR toddler 2 3 yr	5.37	0.7%	Spinaches	0.5%	Milk: Cattle	0.3%	Leeks		2%
	2%	IT adult	5.05	0.6%	Lettuces	0.4%	Spinaches	0.3%	Other spinach and similar		2%
	2%	ES child	4.63	0.7%	Lettuces	0.4%	Spinaches	0.2%	Tomatoes		2%
	2%	NL general	4.57	0.7%	Spinaches	0.2%	Escaroles/broad-leaved endives	0.2%	Milk: Cattle		2%
	2%	DK child	4.53	1%	Cucumbers	0.2%	Milk: Cattle	0.2%	Lettuces		2%
	2%	ES adult	4.50	0.8%	Lettuces	0.3%	Spinaches	0.2%	Tomatoes		2%
	2%	FR child 3 15 yr	4.46	0.5%	Spinaches	0.4%	Milk: Cattle	0.2%	Leeks	0.0%	2%
	2%	IT toddler	4.24	0.5%	Lettuces	0.3%	Tomatoes	0.3%	Spinaches		2%
	2%	GEMS/Food G11	4.22	0.4%	Spinaches	0.3%	Leeks	0.2%	Tomatoes		2%
	2%	IE adult	4.20	0.6%	Spinaches	0.1%	Lettuces	0.1%	Basil and edible flowers		2%
	2%	GEMS/Food G08	4.01	0.3%	Lettuces	0.3%	Tomatoes	0.1%	Parsley		2%
	2%	GEMS/Food G07	3.68	0.4%	Lettuces	0.2%	Tomatoes	0.2%	Spinaches		2%
	1%	FI 3 yr	3.48	0.7%	Cucumbers	0.3%	Spinaches	0.1%	Tomatoes		1%
	1%	DE women 14-50 yr	3.32	0.2%	Spinaches	0.2%	Milk: Cattle	0.2%	Lettuces		1%
	1%	GEMS/Food G15	3.12	0.3%	Tomatoes	0.2%	Lettuces	0.1%	Parsley		1%
	1%	DE general	3.10	0.2%	Milk: Cattle	0.2%	Spinaches	0.2%	Lettuces		1%
	1%	FI 6 yr	2.88	0.5%	Cucumbers	0.3%	Spinaches	0.1%	Lettuces		1%
	1%	RO general	2.84	0.4%	Tomatoes	0.2%	Milk: Cattle	0.2%	Cucumbers		1%
	1%	UK infant	2.74	0.7%	Milk: Cattle	0.1%	Cauliflowers	0.1%	Tomatoes		1%
	1.0%	UK toddler	2.31	0.4%	Milk: Cattle	0.1%	Tomatoes	0.1%	Spinaches		1.0%
	0.9%	FR adult	2.22	0.2%	Spinaches	0.1%	Leeks	0.1%	Tomatoes	0.0%	0.9%
	0.9%	UK vegetarian	2.18	0.2%	Lettuces	0.2%	Spinaches	0.1%	Tomatoes		0.9%
	0.9%	PT general	2.09	0.3%	Kales	0.2%	Tomatoes	0.2%	Lettuces		0.9%
	0.8%	FI adult	1.88	0.2%	Cucumbers	0.2%	Lettuces	0.1%	Tomatoes		0.8%
	0.7%	DK adult	1.71	0.1%	Cucumbers	0.1%	Lettuces	0.1%	Tomatoes		0.7%
	0.7%	LT adult	1.71	0.3%	Cucumbers	0.1%	Tomatoes	0.1%	Lettuces		0.7%
	0.6%	UK adult	1.49	0.2%	Lettuces	0.1%	Tomatoes	0.1%	Spinaches		0.6%
	0.6%	PL general	1.46	0.2%	Tomatoes	0.1%	Potatoes	0.0%	Cauliflowers		0.6%
	0.2%	IE child	0.41	0.1%	Milk: Cattle	0.0%	Spinaches	0.0%	Cauliflowers		0.2%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of propamocarb 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.

Acute risk assessment /children	Acute risk assessment / adults / general population
Details - acute risk assessment /children	Details - acute risk assessment/adults

The acute risk assessment is based on the ARfD. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.
The calculation is based on the large portion of the most critical consumer group.

Show results of IESTI calculation for all crops

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): 2

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
113%	Lettuces	40 / 25	952
105%	Leeks	20 / 15	884
78%	Spinaches	40 / 29	655
62%	Kales	20 / 11.8	519
46%	Chards/beet leaves	40 / 25	390
45%	Chinese cabbages/pe-tsai	20 / 11.8	379
39%	Escaroles/broad-leaved endives	20 / 8.1	325
38%	Witloofs/Belgian endives	15 / 8	317
28%	Spring onions/green onions and Welsh onions	30 / 15	235
25%	Cauliflowers	10 / 3.67	213
22%	Cucumbers	5 / 2.8	184
15%	Courgettes	5 / 2.8	130
15%	Pumpkins	5 / 4.8	128
15%	Tomatoes	4 / 2.18	127
13%	Sweet peppers/bell peppers	3 / 1.8	107

Expand/collapse list

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
56%	Chards/beet leaves	40 / 25	472
36%	Lettuces	40 / 25	304
36%	Chinese cabbages/pe-tsai	20 / 11.8	299
27%	Kales	20 / 11.8	227
23%	Leeks	20 / 15	197
19%	Escaroles/broad-leaved	20 / 8.1	163
18%	Witloofs/Belgian endives	15 / 8	147
14%	Spinaches	40 / 29	116
10%	Cauliflowers	10 / 3.67	85
9%	Cucumbers	5 / 2.8	78
8%	Pumpkins	5 / 4.8	71
8%	Spring onions/green onions	30 / 15	67
8%	Courgettes	5 / 2.8	65
7%	Aubergines/egg plants	4 / 2.18	59
5%	Red mustards	20 / 8.1	43

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation) 2

Processed commodities

Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI): 1

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
102%	Leeks / boiled	20 / 15	859
93%	Chards/beet leaves / boiled	40 / 25	778
84%	Witloofs / boiled	15 / 8	710
64%	Escaroles/broad-leaved endives / boiled	20 / 8.1	537
51%	Pumpkins / boiled	5 / 4.8	426
48%	Spinaches / frozen; boiled	40 / 29	403
39%	Kales / boiled	20 / 11.8	325
30%	Cauliflowers / boiled	10 / 3.67	255
16%	Broccoli / boiled	3 / 1.7	134
13%	Gherkins / pickled	5 / 4.8	110
12%	Courgettes / boiled	5 / 2.8	99
3%	Shallots / boiled	2 / 1.3	21
2%	Potatoes / fried	0.3 / 0.17	16
2%	Brussels sprouts / boiled	2 / 1.3	13
1%	Tomatoes / juice	4 / 0.55	10

Expand/collapse list

Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
37%	Chards/beet leaves / boiled	40 / 25	313
32%	Pumpkins / boiled	5 / 4.8	265
31%	Leeks / boiled	20 / 15	262
29%	Spinaches / frozen; boiled	40 / 29	240
20%	Escaroles/broad-leaved	20 / 8.1	166
18%	Cauliflowers / boiled	10 / 3.67	153
18%	Witloofs / boiled	15 / 8	148
10%	Purslanes / boiled	40 / 21	87
8%	Courgettes / boiled	5 / 2.8	64
5%	Broccoli / boiled	3 / 1.7	41
1%	Onions / boiled	2 / 1.3	12
1.0%	Shallots / boiled	2 / 1.3	8.1
0.5%	Tomatoes / sauce/puree	4 / 0.55	4.5
0.3%	Kohlrabies / boiled	0.3 / 0.13	2.8
0.2%	Head cabbages / canned	1 / 0.2	1.9

Expand/collapse list

Conclusion:
The estimated short-term intake (IESTI) exceeded the toxicological reference value for 2 commodities.
For processed commodities, the toxicological reference value was exceeded in one or several cases.

APPENDIX D

Input values for the exposure calculations

D.1 | Consumer risk assessment

Commodity	Existing/ Proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value[a] (mg/kg)	Comment	Input value[a] (mg/kg)	Comment[b]
Residue definition for risk assessment: Sum of propamocarb and its salts, expressed as propamocarb						
Potatoes	0.3	EFSA (2013)	0.05	STMR-RAC	0.17	HR-RAC
Celeriacs/turnip rooted celeries	0.09	EFSA (2015c)	0.01	STMR-RAC	0.042	HR-RAC
Radishes	3	EFSA (2013)	0.61	STMR-RAC	1.2	HR-RAC
Garlic	2	EFSA (2015a)	0.05	STMR-RAC	1.3	HR-RAC
Onions	2	EFSA (2015a)	0.05	STMR-RAC	1.3	HR-RAC
Shallots	2	EFSA (2015a)	0.05	STMR-RAC	1.3	HR-RAC
Spring onions/green onions and Welsh onions	30	EFSA (2014)	2.5	STMR-RAC	15	HR-RAC
Tomatoes	4	EFSA (2013)	0.55	STMR-RAC	2.18	HR-RAC
Sweet peppers/bell peppers	3	EFSA (2013)	0.27	STMR-RAC	1.80	HR-RAC
Aubergines/egg plants	4	EFSA (2013)	0.55	STMR-RAC	2.18	HR-RAC
Cucumbers	5	EFSA (2013)	1.6	STMR-RAC	2.8	HR-RAC
Gherkins	5	EFSA (2013)	0.59	STMR-RAC	4.8	HR-RAC
Courgettes	5	EFSA (2013)	1.6	STMR-RAC	2.8	HR-RAC
Other cucurbits - edible peel	5	FAO (2006)	5	MRL		
Melons	5	EFSA (2013)	0.06	STMR-RAC × PeF	0.40	HR-RAC × PeF
Pumpkins	5	EFSA (2013)	0.59	STMR-RAC	4.8	HR-RAC
Watermelons	5	EFSA (2013)	0.06	STMR-RAC × PeF	0.40	HR-RAC × PeF
Other cucurbits - inedible peel	5	FAO (2006)	0.51	STMR-RAC		
Broccoli	3	FAO (2014)	0.29	STMR-RAC	1.7	HR-RAC
Cauliflowers	10	EFSA (2013)	1.24	STMR-RAC	3.67	HR-RAC
Brussels sprouts	2	FAO (2014)	0.47	STMR-RAC	1.3	HR-RAC
Head cabbages	1	EFSA (2019)	0.2	STMR-RAC	0.36	HR-RAC
Chinese cabbages/pe-tsai	20	EFSA (2014)	4	STMR-RAC	11.8	HR-RAC
Kales	20	EFSA (2019)	4	STMR-RAC	11.8	HR-RAC
Kohlrabies	0.3	EFSA (2013)	0.04	STMR-RAC	0.13	HR-RAC
Lamb's lettuce/corn salads	20	EFSA (2013)	4	STMR-RAC	8.1	HR-RAC
Lettuces	40	EFSA (2015c)	3.8	STMR-RAC	25	HR-RAC
Escaroles/broad-leaved endives	20	EFSA (2013)	4	STMR-RAC	8.1	HR-RAC
Cress and other sprouts and shoots	20	EFSA (2013)	4	STMR-RAC	8.1	HR-RAC
Land cress	20	EFSA (2013)	4	STMR-RAC	8.1	HR-RAC
Roman rocket/rucola	30	EFSA (2014)	3.39	STMR-RAC	18	HR-RAC
Red mustards	20	EFSA (2013)	4	STMR-RAC	8.1	HR-RAC
Baby leaf crops (including brassica species)	20	EFSA (2013)	4	STMR-RAC	8.1	HR-RAC
Spinaches	40	EFSA (2013)	11.2	STMR-RAC	29	HR-RAC
Purslanes	40	EFSA (2015c)	3.8	STMR-RAC	21	HR-RAC

Commodity	Existing/ Proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value[a] (mg/kg)	Comment	Input value[a] (mg/kg)	Comment[b]
Chards/beet leaves	40	EFSA et al. (2017)	4.5	STMR-RAC	25	HR-RAC
Other spinach and similar	40	EFSA (2013)	11.2	STMR-RAC		
Witloofs/Belgian endives	15	EFSA (2013)	0.30	STMR-RAC	8	HR-RAC
Chervil	30	EFSA (2013)	9.7	STMR-RAC	15.1	HR-RAC
Chives	30	EFSA (2013)	9.7	STMR-RAC	15.1	HR-RAC
Celery leaves	30	EFSA (2015c)	9.7	STMR-RAC	15.1	HR-RAC
Parsley	30	EFSA (2013)	9.7	STMR-RAC	15.1	HR-RAC
Sage	30	EFSA (2013)	9.7	STMR-RAC	15.1	HR-RAC
Rosemary	30	EFSA (2013)	9.7	STMR-RAC	15.1	HR-RAC
Thyme	30	EFSA (2013)	9.7	STMR-RAC	15.1	HR-RAC
Basil and edible flowers	30	EFSA (2013)	9.7	STMR-RAC	15.1	HR-RAC
Laurel/bay leaves	30	EFSA (2013)	9.7	STMR-RAC	15.1	HR-RAC
Tarragon	30	EFSA (2013)	9.7	STMR-RAC	15.1	HR-RAC
Other herbs	30	EFSA (2013)	9.7	STMR-RAC		
Beans (with pods)	0.1	EFSA (2013)	0.1	STMR-RAC	0.1	HR-RAC
Celeries	0.01	EFSA (2015c)	0.01	STMR-RAC	0.042	HR-RAC
Florence fennels	0.01	EFSA (2015c)	0.01	STMR-RAC	0.01	HR-RAC
Leeks	20	EFSA (2015a)	2.5	STMR-RAC	15	HR-RAC
Honey and other apiculture products	15	Proposed MRL	1.62	STMR-RAC	5.77	HR-RAC
Residue definition for products of animal origin 1: Sum of propamocarb, N-oxide propamocarb, oxazolidine-2-one propamocarb and 2-hydroxypropamocarb expressed as propamocarb						
Swine: Muscle/meat[c]	0.01	EFSA (2013)	0.02	STMR-RAC × CF[d]	0.02	HR-RAC × CF[d]
Swine: Fat tissue	0.01	EFSA (2013)	0.01	STMR-RAC × CF[d]	0.01	HR-RAC × CF[d]
Swine: Liver	0.1	EFSA (2013)	0.03	STMR-RAC × CF[d]	0.09	HR-RAC × CF[d]
Swine: Kidney	0.02	EFSA (2013)	0.02	STMR-RAC × CF[d]	0.02	HR-RAC × CF[d]
Swine: Edible offals (other than liver and kidney)[e]	0.1	EFSA (2013)	0.03	STMR-RAC × CF	0.09	HR-RAC × CF
Bovine: Muscle/meat[c]	0.01	EFSA (2013)	0.02	STMR-RAC × CF[d]	0.02	HR-RAC × CF[d]
Bovine: Fat tissue	0.01	EFSA (2013)	0.01	STMR-RAC × CF[d]	0.01	HR-RAC × CF[d]
Bovine: Liver	0.2	EFSA (2013)	0.07	STMR-RAC × CF[d]	0.22	HR-RAC × CF[d]
Bovine: Kidney	0.05	EFSA (2013)	0.02	STMR-RAC × CF[d]	0.06	HR-RAC × CF[d]
Bovine: Edible offals (other than liver and kidney)[e]	0.2	EFSA (2013)	0.07	STMR-RAC × CF	0.22	HR-RAC × CF
Sheep: Muscle/meat[c]	0.01	EFSA (2013)	0.02	STMR-RAC × CF[d]	0.02	HR-RAC × CF[d]
Sheep: Fat tissue	0.01	EFSA (2013)	0.01	STMR-RAC × CF[d]	0.01	HR-RAC × CF[d]
Sheep: Liver	0.2	EFSA (2013)	0.07	STMR-RAC × CF[d]	0.22	HR-RAC × CF[d]
Sheep: Kidney	0.05	EFSA (2013)	0.02	STMR-RAC × CF[d]	0.06	HR-RAC × CF[d]
Sheep: Edible offals (other than liver and kidney)[e]	0.2	EFSA (2013)	0.07	STMR-RAC × CF	0.22	HR-RAC × CF
Goat: Muscle/meat[c]	0.01	EFSA (2013)	0.02	STMR-RAC × CF[d]	0.02	HR-RAC × CF[d]
Goat: Fat tissue	0.01	EFSA (2013)	0.01	STMR-RAC × CF[d]	0.01	HR-RAC × CF[d]
Goat: Liver	0.2	EFSA (2013)	0.07	STMR-RAC × CF[d]	0.22	HR-RAC × CF[d]
Goat: Kidney	0.05	EFSA (2013)	0.02	STMR-RAC × CF[d]	0.06	HR-RAC × CF[d]
Goat: Edible offals (other than liver and kidney)[e]	0.2	EFSA (2013)	0.07	STMR-RAC × CF	0.22	HR-RAC × CF
Equine: Muscle/meat[c]	0.01	EFSA (2013)	0.02	STMR-RAC × CF[d]	0.02	HR-RAC × CF[d]
Equine: Fat tissue	0.01	EFSA (2013)	0.01	STMR-RAC × CF[d]	0.01	HR-RAC × CF[d]

Commodity	Existing/ Proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value[a] (mg/kg)	Comment	Input value[a] (mg/kg)	Comment[b]
Equine: Liver	0.2	EFSA (2013)	0.07	STMR-RAC × CF[d]	0.22	HR-RAC × CF[d]
Equine: Kidney	0.05	EFSA (2013)	0.02	STMR-RAC × CF[d]	0.06	HR-RAC × CF[d]
Equine: Edible offals (other than liver and kidney)[e]	0.2	EFSA (2013)	0.07	STMR-RAC × CF	0.22	HR-RAC × CF
Residue definition for products of animal origin 2: Sum of propamocarb and N-desmethyl propamocarb, expressed as propamocarb						
Poultry: Muscle/meat[c]	0.02	EFSA (2013)	0.01	STMR-RAC × CF[d]	0.03	HR-RAC × CF[d]
Poultry: Fat tissue	0.01	FAO (2014)	0.01	STMR-RAC × CF[d]	0.01	HR-RAC × CF[d]
Poultry: Liver	0.05	EFSA (2013)	0.01	STMR-RAC × CF[d]	0.04	HR-RAC × CF[d]
Poultry: Kidney	0.01	EFSA (2013)	0.01	LOQ[d]	0.01	LOQ[d]
Poultry: Edible offals (other than liver and kidney)[e]	0.05	EFSA (2013)	0.01	STMR-RAC × CF	0.04	HR-RAC × CF
Other farmed animals: Muscle/meat[c]	0.01	EFSA (2013)	0.02	STMR-RAC[d]	0.02	HR-RAC[d]
Other farmed animals: Fat tissue	0.01	EFSA (2013)	0.01	STMR-RAC[d]	0.01	HR-RAC[d]
Other farmed animals: Liver	0.2	EFSA (2013)	0.07	STMR-RAC[d]	0.22	HR-RAC[d]
Other farmed animals: Kidney	0.05	EFSA (2013)	0.02	STMR-RAC[d]	0.06	HR-RAC[d]
Other farmed animals: Edible offals (other than liver and kidney)[e]	0.2	EFSA (2013)	0.07	STMR-RAC	0.22	HR-RAC
Milk	0.01	FAO (2019)	0.04	STMR-RAC × CF[d]	0.04	HR-RAC × CF[d]
Birds' eggs	0.05	EFSA (2013)	0.02	STMR-RAC × CF[d]	0.05	HR-RAC × CF[d]

Abbreviations: HR-RAC, highest residue in raw agricultural commodity; MRL, maximum residue level; STMR-RAC, supervised trials median residue in raw agricultural commodity.

[a]Figures in the table are rounded to two digits, but the calculations are normally performed with the calculated values (which may contain more digits). To reproduce dietary burden calculations, the unrounded values need to be used.

[b]Input values for the commodities which are not under consideration for the acute risk assessment are reported in grey.

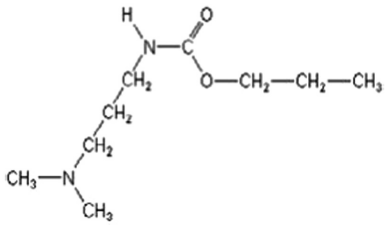
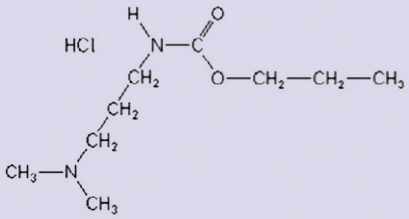
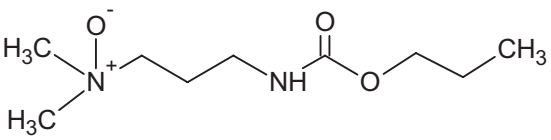
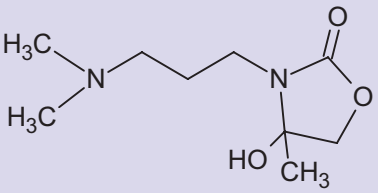
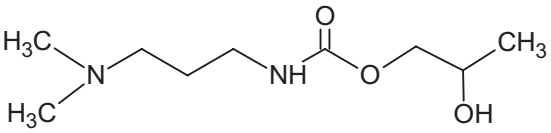
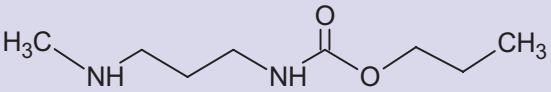
[c]Consumption figures in the EFSA PRIMo are expressed as meat. STMR and HR for meat residue values were calculated considering an 80%/90% muscle and 20%/10% fat content for mammal/poultry meat respectively (FAO, 2016).

[d]Tentative conversion factors (CF) from enforcement to risk assessment were proposed in the framework of the MRL review based on metabolism studies.

[e] 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[a]	IUPAC name/SMILES notation/InChiKey[b]	Structural formula[c]
Propamocarb	propyl 3-(dimethylamino)propylcarbamate (IUPAC)	
Propamocarb hydrochloride	propyl 3-(dimethylamino) propylcarbamate hydrochloride (IUPAC)	
N-oxide propamocarb	propyl [3-(dimethylnitroryl)propyl]carbamate	
Oxazolidine-2-one propamocarb (oxazolidine-one, AE B132679)	3-[3-(dimethylamino) propyl]-4-hydroxy-4-methyl-1,3-oxazolidin-2-one	
2-hydroxypropamocarb	2-hydroxypropyl [3-(dimethylamino)propyl] carbamate	
N-desmethyl propamocarb	propyl [3-(methylamino)propyl]carbamate	

Abbreviations: ACD/ChemSketch, Advanced Chemistry Development, Inc., ACD/Labs Release, 12.00 Product version: 12.00 (Build 29305, 25 Nov 2008); IUPAC, International Union of Pure and Applied Chemistry; SMILES, simplified molecular-input line-entry system; InChiKey, International Chemical Identifier Key.

[a]The metabolite name in bold is the name used in the conclusion.

[b]ACD/Name 2020.2.1 ACD/Labs 2020 Release (File version N15E41, Build 116563, 15 June 2020).

[c]ACD/ChemSketch 2020.2.1 ACD/Labs 2020 Release (File version C25H41, Build 121153, 22 March 2021).