

REASONED OPINION

Reasoned opinion on the modification of the existing MRLs for propamocarb in spring onions and Chinese cabbage¹

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ABSTRACT

In accordance with Article 6 of Regulation (EC) No 396/2005, Belgium, hereafter referred to as the evaluating Member State (EMS), compiled an application to modify the existing MRLs for the active substance propamocarb in spring onions and Chinese cabbage. In order to accommodate for the intended uses of propamocarb, Belgium proposed to raise the existing MRLs from the value of 0.1* mg/kg to 30 mg/kg for spring onions and from 10 mg/kg to 20 mg/kg for Chinese cabbage. 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 EFSA. According to EFSA, the data are sufficient to derive MRL proposal of 30 mg/kg for the proposed uses on spring onions and of 20 mg/kg for Chinese cabbage. Adequate analytical enforcement methods are available to control the residues of propamocarb in the commodities under consideration. Based on the risk assessment results, EFSA concludes that the proposed uses of propamocarb on spring onions and Chinese cabbage will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a consumer health risk.

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KEY WORDS

Propamocarb, spring onions and Chinese cabbage, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, carbamate fungicides, propamocarb hydrochloride

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SUMMARY

In accordance with Article 6 of Regulation (EC) No 396/2005, Belgium, hereafter referred to as the evaluating Member State (EMS), compiled an application to modify the existing MRLs for the active substance propamocarb in spring onions and Chinese cabbage. In order to accommodate for the intended uses of propamocarb, Belgium proposed to raise the existing MRLs from the value of 0.1* mg/kg to 30 mg/kg for spring onions and from 10 mg/kg to 20 mg/kg for Chinese cabbage. 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 EFSA on 27 February 2014.

EFSA bases its assessment on the evaluation report submitted by EMS, the draft Assessment Report (DAR) prepared under Council Directive 91/414/EEC, the Review Report on propamocarb, the conclusion on the peer review of the pesticide risk assessment of the active substance propamocarb, the JMPR evaluation report as well as the conclusions from the previous EFSA reasoned opinions on the modification of MRLs on certain crops and the review of the existing MRLs according to Article 12 of Regulation (EC) No 396/2005.

The toxicological profile of propamocarb was assessed in the framework of the peer review under Directive 91/414/EEC. For propamocarb hydrochloride, the data were sufficient to derive an ADI of 0.29 mg/kg bw per day and an ARfD of 1 mg/kg bw.

The metabolism was investigated on fruit crops, root/tuber crops and leafy crops following foliar applications and on fruit crops and leafy crops following soil application. From these studies the peer review concluded to establish the residue definition for enforcement and for risk assessment as the sum of propamocarb and its salts expressed as propamocarb. For the use on spring onions and Chinese cabbage, EFSA concludes that the metabolism of propamocarb in primary crops is sufficiently addressed and that the residue definitions are applicable.

EFSA concludes that the residue trials conducted on leeks and kale are sufficient to support the MRL proposals of 30 mg/kg for spring onions and of 20 mg/kg for Chinese cabbage for the intended uses on these crops. Adequate analytical enforcement methods are available to control the residues of propamocarb in the commodities under consideration at the validated LOQ of 0.01 mg/kg.

Studies investigating the nature of propamocarb residues in processed commodities are not available and were not submitted in the framework of MRL review. EFSA is of the opinion that standard hydrolysis study investigating the effect of processing on the nature of the residues would be desirable.

As the DT₉₀ value of propamocarb is lower than 100 days, the occurrence of residues in succeeding crops is unlikely, provided that the compound is used according to the proposed GAP (Good Agricultural Practice).

Residues of propamocarb in commodities of animal origin were not assessed in the framework of this application, since the crops under consideration are normally not fed to livestock.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). In the framework of the review of the existing MRLs for propamocarb according to Article 12 of Regulation (EC) No 396/2005, a comprehensive long term exposure assessment was performed taking into account the existing uses of propamocarb at the EU level and CXLs set for some commodities at Codex level. EFSA now updates this risk assessment with median residue values on spring onions and Chinese cabbage derived from the supervised residue trials and the proposals for rocket and rucola from the previous application under art 10 of the Regulation (EU) 396/2005.

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake accounted for up to 4 % of the ADI (FR toddler). The contribution of residues in Chinese cabbage to the total consumer exposure accounted for a maximum

of 0.3 % of the ADI (SE general population) and for spring onions the contribution was lower than 0.1 % of the ADI.

No acute consumer risk was identified in relation to the MRL proposals for crops under consideration. The calculated maximum exposure in percentage of the ARfD was 55 % for Chinese cabbage and 8 % for spring onions.

EFSA concludes that the proposed uses of propamocarb on spring onions and Chinese cabbage will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a consumer health risk.

Thus EFSA proposes to amend the existing MRLs as reported in the summary table.

SUMMARY TABLE

Code number ^(a)	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: sum of propamocarb and its salts expressed as propamocarb				
220040	Spring onions	0.1*	30	The MRL proposals of 30 mg/kg for spring onions and 20 mg/kg for Chinese cabbage are sufficiently supported. No consumer health risk was identified for the intended uses on these crops in NEU.
243010	Chinese cabbage	10	20	

(a): According to Annex I of Regulation (EC) No 396/2005.

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

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BACKGROUND

Regulation (EC) No 396/2005³ establishes the rules governing the setting of pesticide MRLs at European Union level. Article 6 of that Regulation lays down that any party having a legitimate interest or requesting an authorisation for the use of a plant protection product in accordance with Council Directive 91/414/EEC⁴, repealed by Regulation (EC) No 1107/2009⁵, shall submit to a Member State, when appropriate, an application to modify a MRL in accordance with the provisions of Article 7 of that Regulation.

Belgium hereafter referred to as the evaluating Member State (EMS), compiled an application to modify the existing MRLs for the propamocarb in spring onions and Chinese cabbage. This application was notified to the European Commission and EFSA, and was subsequently evaluated in accordance with Article 8 of the Regulation.

After completion, the evaluation report was submitted to the European Commission who forwarded the application, the evaluation report and the supporting dossier to EFSA on 27 February 2014.

The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2014-00135 and the following subject:

Propamocarb - Modification of existing MRLs in spring onions and Chinese cabbage

Belgium proposed to raise the existing MRLs of propamocarb and head cabbage from the 0.1* mg/kg to 30 mg/kg in spring onions and from 10 mg/kg to 20 mg/kg for Chinese cabbage.

EFSA proceeded with the assessment of the application and the evaluation report as required by Article 10 of the Regulation.

TERMS OF REFERENCE

In accordance with Article 10 of Regulation (EC) No 396/2005, EFSA shall, based on the evaluation report provided by the evaluating Member State, provide a reasoned opinion on the risks to the consumer associated with the application.

In accordance with Article 11 of that Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within three months (which may be extended to six months where more detailed evaluations need to be carried out) from the date of receipt of the application. Where EFSA requests supplementary information, the time limit laid down shall be suspended until that information has been provided.

In this particular case the deadline for providing the reasoned opinion is 27 May 2014.

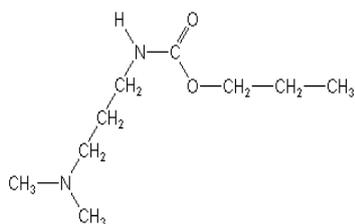
³ Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.03.2005, p. 1-16.

⁴ Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.08.1991, p. 1-32.

⁵ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1-50.

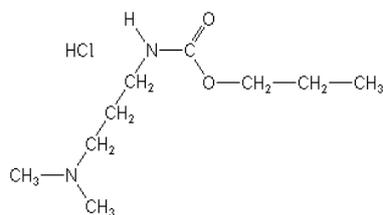
THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Propamocarb is the ISO common name for propyl 3-(dimethylamino)propylcarbamate (IUPAC). Propamocarb is often used in plant protection product formulations under the form of the salt propamocarb hydrochloride, which is the ISO common name for propyl 3-(dimethylamino)propylcarbamate hydrochloride (IUPAC). The chemical structures of both compounds are herewith reported:



MW=188.3 g/mol

Propamocarb



MW=224.7 g/mol

Propamocarb hydrochloride

Propamocarb and propamocarb hydrochloride belong to the chemical group of carbamate fungicides. The active substances are systemic and are taken up via leaves and roots and act as multi-site inhibitors with protective action which specifically controls phycomycetous diseases.

Propamocarb was evaluated in the framework of Directive 91/414/EEC with Ireland, being the designated rapporteur Member State (RMS). The representative uses supported during the peer review were foliar spray applications and drench or drip irrigation to control a broad spectrum of plant diseases in lettuce, potato, tomato (grown in soil and on rock wool). The active substance was peer reviewed by EFSA and therefore, an EFSA conclusion is available (EFSA, 2006). A decision on inclusion of the active substance in Annex I to Directive 91/414/EEC was published by means of Commission Directive 2007/25/EC⁶, which entered into force on 01 October 2007. According to Regulation (EU) No 540/2011⁷, propamocarb is deemed to be approved under Regulation (EC) No 1107/2009⁸. This approval is restricted to uses as fungicide only.

The EU MRLs for propamocarb are established in Annex IIIA of Regulation (EC) No 396/2005. Since the entry into force of this Regulation, EFSA has issued several reasoned opinions on the modification of MRLs on certain crops (EFSA, 2011, 2012, 2013b), and the proposals of the last EFSA opinion were considered by Regulation (EC) 36/2014⁹. In addition, the revision of the existing MRLs according to Article 12 of Regulation (EC) No 396/2005 has been finalised by EFSA in 2013 (EFSA, 2013a). The recommendations have already been discussed in the SCoFCAH, but have not yet been transposed in the EU legislation.

Codex Alimentarius has established CXLs for a wide range of commodities, but not for the spring onions and Chinese cabbage.

The details of the intended GAPs for propamocarb are given in Appendix A.

⁶ 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.

⁷ Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances, OJ L 153, 11.6.2011, p. 1-186.

⁸ Regulation (EC) No 1107/2009 of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, OJ 309, 24.11.2009, p. 1-50.

⁹ 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, chlorantranilprole, cyflufenamid, mepiquat, metalaxyl-M, propamocarb, pyriofenone and quinoxyfen in or on certain products; OJ L 17, 21/01/2014, p. 1-41.

ASSESSMENT

EFSA bases its assessment on the evaluation report submitted by EMS (Belgium, 2014), the draft Assessment Report (DAR) prepared under Council Directive 91/414/EEC (Ireland, 2004), the Review Report on propamocarb (EC, 2007), the conclusion on the peer review of the pesticide risk assessment of the active substance propamocarb (EFSA, 2006), the JMPR evaluation reports (FAO, 2006) as well as the conclusions from previous EFSA reasoned opinions on the modification of MRL on certain crops (EFSA, 2011, 2012 and 2013b) and the review of the existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (EFSA, 2013a). 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 546/2011¹⁰ and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (EC, 1996, 1997a-g, 2000, 2010a,b, 2011; OECD, 2011).

1. Method of analysis

1.1. Methods for enforcement of residues in food of plant origin

Analytical method using HPLC-MS/MS and its ILV for determination of propamocarb in plants with an LOQ of 0.01 mg/kg in high water content commodities (cabbage, cucumber, melon, sweet pepper, potato, tomato and lettuce) was assessed during the peer review under Directive 91/414/EEC. Additional multi-residue methods for determination of propamocarb from plant matrices based on HPLC-MS/MS with an LOQ of 0.01 mg/kg were evaluated during the MRL review (EFSA 2013b).

Since the crops under consideration belong to the group of high water content commodities, EFSA concludes that sufficiently validated analytical methods for enforcing the proposed MRLs for propamocarb on the crops under consideration are available.

1.2. Methods for enforcement of residues in food of animal origin

The analytical methods for the determination of residues in food of animal origin are not assessed in the current application, since spring onions and Chinese cabbage are not fed to livestock.

2. Mammalian toxicology

The toxicological assessment of propamocarb was peer reviewed under Directive 91/414/EEC and toxicological reference values were established by EFSA (EFSA, 2006). As the residue definition for risk assessment is expressed as propamocarb, whilst the toxicological reference values have been derived for propamocarb hydrochloride, the toxicological reference values for propamocarb were recalculated by applying the molecular weight conversion factor of 0.84¹¹. These toxicological reference values are summarised in Table 2-1.

Table 2-1: Overview of the toxicological reference values

	Source	Year	Value	Study relied upon	Safety factor
Propamocarb hydrochloride					
ADI	EFSA	2006	0.29 mg/kg bw per day	52 week rat study	100
ARfD	EFSA	2006	1 mg/kg bw	28 days gavage study in rats	100
Propamocarb					
ADI	EFSA	2006	0.244 mg/kg bw per day ^(a)	-	-
ARfD	EFSA	2006	0.84 mg/kg bw ^(a)	-	-

(a): Recalculated by applying a molecular weight conversion factor of 0.84 to the toxicological reference values derived for propamocarb hydrochloride.

¹⁰ 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, 11.06.2011, p. 127-175.

¹¹ MW propamocarb/MW propamocarb hydrochloride $188.3/224.7=0.84$.

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

Metabolism of propamocarb hydrochloride was evaluated during the MRL review under Article 12 (EFSA, 2013a). The metabolism was investigated on fruit crop (cucumber, tomato), root/tuber crops (potato) and leafy crop (spinach, lettuce) following foliar applications and on fruit crop (tomato) and leafy crop (lettuce) following soil application. Based on these studies, the residue definition for enforcement and risk assessment was proposed as sum of propamocarb and its salts, expressed as propamocarb. The current residue definition set in Regulation (EC) No 396/2005 is identical to the residue definition for enforcement derived in the peer review.

For the uses on spring onion and Chinese cabbage, EFSA concludes that the metabolism of propamocarb is sufficiently addressed and the proposed residue definitions are applicable.

3.1.1.2. Magnitude of residues

The EMS refers to residue trials conducted on leek and kale, already evaluated under a previous MRL application (EFSA 2012), and during the review of the existing MRLs under Article 12 (EFSA 2013a).

a. Spring onions

The applicant refers to the eight trials performed on leek assessed already by EFSA (EFSA, 2012, 2013a), to support the extrapolation to spring onions as proposed by the guidance document SANCO 7525/VI/95. The trials were slightly overdosed ($3 \times 1100 \text{ g/ha}$) but within the $\pm 25 \%$ tolerance, as the intended GAPs on spring onion are defined as ($3 \times 1000 \text{ g/ha}$). Based on these data, an MRL of 30 mg/kg was derived for leek, but not recommended by EFSA and not transposed in the EU legislation by Regulation (EC) 36/2014, since resulting in an ARfD exceedance, considering the consumption figures for leek included in the EFSA PRIMo model (EFSA, 2013a,b). Since no acute consumer intake concerns were identified for the spring onions (see section 4) EFSA, would recommend the setting of the MRL value of 30 mg/kg on spring onions.

b. Chinese cabbage

The applicant refers to nine trials performed on kale, evaluated during the MRL review under Article 12 (EFSA, 2013a), to support the extrapolation to Chinese cabbage as proposed by the SANCO 7525/VI/95 guideline. These trials were performed with propamocarb chloride in NEU according to the proposed GAP ($3 \times 1000 \text{ g/ha}$; PHI 14 days). Residue levels were in the range of 0.33 to 11.8 mg/kg. Based on this dataset, the MRL proposal of 20 mg/kg derived for kale is extrapolated to Chinese cabbages.

The results of the residue trials, the related risk assessment input values (highest residue, median residue) and the MRL proposals are summarised in Table 3-2.

The storage stability of propamocarb in primary crops was investigated in the framework of the peer review. Stability of propamocarb residues was demonstrated at $-18 \text{ }^\circ\text{C}$ for a period of 26 months in commodities with high water content (tomato, lettuce). As the supervised residue trial samples were stored under conditions for which integrity of the samples was demonstrated, it is concluded that the residue data are valid with regard to storage stability.

EFSA concludes that the data are sufficient to derive MRL proposals of 30 mg/kg on spring onions and of 20 mg/kg on Chinese cabbage for the intended uses in NEU.

Table 3-1: Overview of the available residues trials data

Commodity	Region (a)	Outdoor /Indoor	Individual trial results (mg/kg)	Median residue (mg/kg) (b)	Highest residue (mg/kg) (c)	MRL proposal (mg/kg)	CF (d)	Comments (e)
			Residue definition for enforcement and risk assessment (sum of propamocarb and its salts, expressed as propamocarb)					
Leek→ spring onions	NEU	Outdoor	0.24; 0.74; 0.92; 2.40; 2.60; 4.03; 5.46; 15.0	2.5	15	30	-	R _{ber} = 10.2 R _{max} = 19.2 MRL _{OECD} = 23/30
Kale→ Chinese cabbage	NEU	Outdoor	0.33; 0.39; 0.46; 3.9; 4.0; 4.0; 5.2; 10.7; 11.8	4.0	11.8	20	-	R _{ber} =15.9 R _{max} =17.4 MRL _{OECD} = 21/30

(a): NEU (Northern and Central Europe), SEU (Southern Europe and Mediterranean), EU (i.e. indoor use) or Import (country code) (EC, 2011).

(b): Median value of the individual trial results according to the enforcement residue definition.

(c): Highest value of the individual trial results according to the enforcement residue definition.

(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residue trial.

(e): Statistical estimation of MRLs according to the EU methodology (R_{ber}, R_{max}; EC, 1997g) and unrounded/rounded values according to the OECD methodology (OECD, 2011).

3.1.1.3. Effect of industrial processing and/or household preparation

The effect of processing on the nature of propamocarb was not investigated during the peer review. As significant residues of propamocarb are expected in treated crops, EFSA concluded that a hydrolysis studies investigating the effect of processing on the nature of propamocarb would be desirable (EFSA, 2013a).

Studies investigating the magnitude of residues in processed commodities of tomatoes, cabbage and spinach were evaluated during MRL review under Article 12 and several processing factors were derived. Considering the low estimated intakes (see section 4), processing studies on green onions and Chinese cabbage are not requested.

3.1.2. Rotational crops

Spring onions and Chinese cabbage can be grown in rotation with other plants and therefore the possible occurrence of residues in succeeding crops has to be assessed. The soil degradation studies were evaluated during the peer review. DT₉₀ value of propamocarb hydrochloride is expected to be in the range of 57 to 78 days which is lower the trigger value of 100 days, therefore no additional investigation is needed (EFSA 2013a).

3.2. Nature and magnitude of residues in livestock

Since the crops under consideration are not normally fed to livestock, the nature and magnitude of propamocarb residues in livestock is not assessed in the framework of this application (EC, 1996).

4. Consumer risk assessment

In the framework of the MRL review under Article 12 of Regulation (EC) No 396/2005 a comprehensive dietary exposure assessment was performed, taking into account the existing uses for propamocarb (EFSA, 2013). The long-term consumer exposure assessment was now updated including the median residue concentration for spring onions and Chinese cabbage.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). This exposure assessment model contains the relevant European food consumption data for different sub-groups of the EU population¹² (EFSA, 2007).

For the calculation of chronic exposure, EFSA used the STMR values as derived from the residue trials on leek and kale (see Table 3-1), the STMR derived for rocket in a previous EFSA opinion (EFSA, 2013b) and the STMRs reported in the framework of the review of existing MRLs under Article 12 to Regulation (EC) No 396/2005 (EFSA, 2013a), where CXLs were also considered.

The model assumptions for the long-term exposure assessment are considered to be sufficiently conservative for a first tier exposure assessment, assuming that all food items consumed have been treated with the active substance under consideration. In reality, it is not likely that all food consumed will contain residues at the MRL or at levels of the median residue values identified in supervised field trials. However, if this first tier exposure assessment does not exceed the toxicological reference value for long-term exposure (i.e. the ADI), a consumer health risk can be excluded with a high probability.

The acute exposure assessment was performed only with regard to the commodities under consideration in this MRL application, assuming the consumption of a large portion of the food items as reported in the national food surveys and that these items contained residues at the highest level as observed in supervised field trials. A variability factor accounting for the inhomogeneous distribution on the individual items consumed was included in the calculation, when required (EFSA, 2007).

¹² The calculation of the long-term exposure (chronic exposure) is based on the mean consumption data representative for 22 national diets collected from MS surveys plus 1 regional and 4 cluster diets from the WHO GEMS Food database; for the acute exposure assessment the most critical large portion consumption data from 19 national diets collected from MS surveys are used. The complete list of diets incorporated in EFSA PRIMo is given in its reference section (EFSA, 2007).

The input values used for the dietary exposure calculation are summarised in Table 4-1.

Table 4-1: Input values for the consumer dietary exposure assessment

Commodity	Chronic exposure assessment		Acute exposure assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: (sum of propamocarb and its salts, expressed as propamocarb)				
Chinese cabbage	4.0	STMR	11.8	HR
Spring onions	2.5	STMR	15.0	HR
Rocket, Rucola	3.39	STMR (EFSA, 2013b)	-	
Other commodities assessed during the MRL review	See Table 4.2 in EFSA Reasoned Opinion on the review of the existing MRLs under article 12 of Regulation (EC) 396/2005 (EFSA, 2013a)			

The estimated exposure was then compared with the toxicological reference values derived for propamocarb (see Table 2-1). The results of the intake calculation are presented in Appendix B to this reasoned opinion.

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake accounted for up to 4 % of the ADI (FR toddler). The contribution of residues in Chinese cabbage to the total consumer exposure accounted for a maximum of 0.3 % of the ADI (SE, general population) and lower than 0.1 % of the ADI for spring onions.

No acute consumer risk was identified in relation to the MRL proposals for crops under consideration. The calculated maximum exposure in percentage of the ARfD was 55 % for Chinese cabbage and 8 % for spring onions.

EFSA concludes that the intended use of propamocarb on crops under consideration will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a public health concern.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The toxicological profile of propamocarb was assessed in the framework of the peer review under Directive 91/414/EEC. For propamocarb hydrochloride, the data were sufficient to derive an ADI of 0.29 mg/kg bw per day and an ARfD of 1 mg/kg bw.

The metabolism was investigated on fruit crops, root/tuber crops and leafy crops following foliar applications and on fruit crops and leafy crops following soil application. From these studies the peer review concluded to establish the residue definition for enforcement and for risk assessment as the sum of propamocarb and its salts expressed as propamocarb. For the use on spring onions and Chinese cabbage, EFSA concludes that the metabolism of propamocarb in primary crops is sufficiently addressed and that the residue definitions are applicable.

EFSA concludes that the residue trials conducted on leeks and kale are sufficient to support the MRL proposals of 30 mg/kg for spring onions and of 20 mg/kg for Chinese cabbage for the intended uses on these crops. Adequate analytical enforcement methods are available to control the residues of propamocarb in the commodities under consideration at the validated LOQ of 0.01 mg/kg.

Studies investigating the nature of propamocarb residues in processed commodities are not available and were not submitted in the framework of MRL review. EFSA is of the opinion that standard hydrolysis study investigating the effect of processing on the nature of the residues would be desirable.

As the DT90 value of propamocarb is lower than 100 days, the occurrence of residues in succeeding crops is unlikely, provided that the compound is used according to the proposed GAP (Good Agricultural Practice).

Residues of propamocarb in commodities of animal origin were not assessed in the framework of this application, since the crops under consideration are normally not fed to livestock.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMO). In the framework of the review of the existing MRLs for propamocarb according to Article 12 of Regulation (EC) No 396/2005, a comprehensive long term exposure assessment was performed taking into account the existing uses of propamocarb at the EU level and CXLs set for some commodities at Codex level. EFSA now updates this risk assessment with median residue values on spring onions and Chinese cabbage derived from the supervised residue trials and the proposals for rocket and rucola from the previous application under art 10 of the Regulation (EU) 396/2005.

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMO. The total calculated intake accounted for up to 4 % of the ADI (FR toddler). The contribution of residues in Chinese cabbage to the total consumer exposure accounted for a maximum of 0.3 % of the ADI (SE general population) and for spring onions the contribution was lower than 0.1 % of the ADI.

No acute consumer risk was identified in relation to the MRL proposals for crops under consideration. The calculated maximum exposure in percentage of the ARfD was 55 % for Chinese cabbage and 8 % for spring onions.

EFSA concludes that the proposed uses of propamocarb on spring onions and Chinese cabbage will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a consumer health risk.

RECOMMENDATIONS

Code number ^(a)	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: sum of propamocarb and its salts expressed as propamocarb				
220040	Spring onions	0.1*	30	The MRL proposals of 30 mg/kg for spring onions and 20 mg/kg for Chinese cabbage are sufficiently supported. No consumer health risk was identified for the intended uses on these crops in NEU.
243010	Chinese cabbage	10	20	

(a): According to Annex I of Regulation (EC) No 396/2005.

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

REFERENCES

Belgium 2014, Evaluation report on the modification of MRLs for propamocarb in spring onions and Chinese cabbage prepared by the evaluating Member State Belgium under Article 8 of Regulation (EC) No 396/2005, 23 January 2014, 9 pp.

EC (European Commission), 1996. Appendix G. Livestock Feeding Studies. 7031/VI/95-rev.4.

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APPENDICES

Appendix A. Good Agricultural Practice (GAPs)

Crop and/or situation (a)	Member State or Country	F G or I (b)	Pest or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)
				type (d- f)	conc. of a.s. (i)	method kind (f - h)	Growth stage & season (j)	number min-max (k)	interval min-max	kg as/hL min-max	Water L/ha min-max	kg a.s./ha min-max	
Spring onion	BELGIUM NEU	G	downey mildew	SC	625g/l	Spraying	-	1-3	-	-	-	1	14
Chinese cabbage	BELGIUM NEU	G	downey mildew; white blister	SC	625g/l	Spraying	BBCH 41-49	1-3	-	-	-	1	14

- Remarks:
- (a) For crops, EU or other classifications, e.g. Codex, should be used; where relevant, the use situation should be described (e.g. fumigation of a structure).
 - (b) Outdoor or field use (F), glasshouse application (G) or indoor application (I).
 - (c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds.
 - (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR).
 - (e) GCPF Technical Monograph No 2, 4th Ed., 1999 or other codes, e.g. OECD/CIPAC, should be used.
 - (f) All abbreviations used must be explained.
 - (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench.
 - (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.
 - (i) g/kg or g/l
 - (j) Growth stage at last treatment (Growth stages of mono-and dicotyledonous plants. BBCH Monograph, 2nd Ed., 2001), including where relevant, information on season at time of application.
 - (k) The minimum and maximum number of application possible under practical conditions of use must be provided.
 - (l) PHI - minimum pre-harvest interval.

Appendix B. Pesticide Residue Intake Model (PRIMO)

Propamocarb (free base)												
Status of the active substance:			Included			Code no.:						
LOQ (mg/kg bw):						proposed LOQ:						
Toxicological end points												
ADI (mg/kg bw/day):			0.244			ARfD (mg/kg bw):			0.84			
Source of ADI:			EFSA 2011			Source of ARfD:			EFSA 2011			
Year of evaluation:						Year of evaluation:						
Chronic risk assessment - refined calculations												
TMDI (range) in % of ADI minimum - maximum												
0 4												
No of diets exceeding ADI:												

	Highest calculated TMDI values in % of ADI	MS Diet	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	pTMRs at LOQ (in % of ADI)			
	4.3	FR toddler	3.2	Spinach	0.3	Courgettes	0.2	Cauliflower				
	4.0	NL child	1.7	Spinach	0.5	Milk and milk products: Cattle	0.3	Scarole (broad-leaf endive)				
	3.2	FR infant	2.0	Spinach	0.4	Milk and milk products: Cattle	0.4	Courgettes				
	3.1	WHO Cluster diet B	1.0	Lettuce	0.7	Tomatoes	0.4	Spinach				
	2.5	DE child	0.9	Spinach	0.4	Cucumbers	0.2	Milk and milk products: Cattle				
	2.2	ES adult	1.5	Lettuce	0.3	Spinach	0.2	Tomatoes				
	2.2	WHO regional European diet	1.0	Lettuce	0.2	Tomatoes	0.2	Spinach				
	2.1	ES child	1.1	Lettuce	0.4	Spinach	0.2	Tomatoes				
	2.0	IT adult	1.0	Lettuce	0.4	Spinach	0.3	Tomatoes				
	2.0	NL general	0.7	Spinach	0.3	Lettuce	0.2	Scarole (broad-leaf endive)				
	1.7	SE general population 90th percentile	0.3	Chinese cabbage	0.3	Spinach	0.2	Milk and milk products: Cattle				
	1.7	DK child	1.1	Cucumbers	0.4	Lettuce	0.1	Tomatoes				
	1.7	IE adult	0.6	Spinach	0.2	Lettuce	0.1	Basil				
	1.7	IT kids/toddler	0.8	Lettuce	0.3	Tomatoes	0.3	Spinach				
	1.6	WHO cluster diet D	0.3	Chinese cabbage	0.2	Tomatoes	0.2	Kale				
	1.5	WHO Cluster diet F	0.8	Lettuce	0.2	Tomatoes	0.1	Chinese cabbage				
	1.2	WHO cluster diet E	0.2	Lettuce	0.2	Spinach	0.2	Parsley				
	1.0	UK vegetarian	0.4	Lettuce	0.2	Spinach	0.1	Tomatoes				
	0.8	FR all population	0.2	Lettuce	0.1	Tomatoes	0.1	Courgettes				
	0.8	LT adult	0.3	Cucumbers	0.2	Lettuce	0.1	Tomatoes				
	0.7	UK Adult	0.3	Lettuce	0.1	Tomatoes	0.1	Spinach				
	0.6	FI adult	0.2	Lettuce	0.2	Cucumbers	0.1	Tomatoes				
	0.6	UK Toddler	0.1	Tomatoes	0.1	Spinach	0.1	Cucumbers				
	0.6	PL general population	0.2	Tomatoes	0.1	Potatoes	0.0	Cauliflower				
	0.4	DK adult	0.2	Cucumbers	0.1	Tomatoes	0.0	Potatoes				
	0.4	UK Infant	0.1	Cauliflower	0.1	Tomatoes	0.1	Potatoes				
	0.4	PT General population	0.2	Tomatoes	0.1	Potatoes	0.0	Peppers				
Conclusion:												
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRs were below the ADI. A long-term intake of residues of Propamocarb (free base) is unlikely to present a public health concern.												
Acute risk assessment / children - refined calculations						Acute risk assessment / adults / general population - refined calculations						
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 leads 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):		
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	IESTI 1	*)	**)	IESTI 2	*)	**)	IESTI 1	*)	**)	IESTI 2	*)	**)
	Highest % of ARfD/ADI	Commodities	pTMR/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMR/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMR/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMR/ threshold MRL (mg/kg)
52.2	Chinese cabbage	11.8 / -	52.2	Chinese cabbage	11.8 / -	50.2	Chinese cabbage	11.8 / -	50.2	Chinese cabbage	11.8 / -	
8.2	Spring onions	15 / -	8.2	Spring onions	15 / -	1.7	Spring onions	15 / -	1.7	Spring onions	15 / -	

Prepare workbook for refined calculations

Undo refined calculations

ABBREVIATIONS

ADI	acceptable daily intake
ARfD	acute reference dose
a.s.	active substance
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CXL	Codex Maximum Residue Limit (Codex MRL)
DAR	Draft Assessment Report
DT ₉₀	period required for 90 % dissipation (define method of estimation)
EC	European Community
EFSA	European Food Safety Authority
EMS	evaluating Member State
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
GAP	good agricultural practice
GCPF	Global Crop Protection Federation (former GIFAP)
GS	growth stage
ha	hectare
hL	hectolitre
HPLC	high performance liquid chromatography
HR	highest residue
ILV	independent laboratory validation
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
kg	kilogram
L	litre
LOQ	limit of quantification
MRL	maximum residue level
MS/MS	tandem mass spectrometry
MW	molecular weight
NEU	northern European Union
OECD	Organisation for Economic Co-operation and Development
PHI	pre-harvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model

R _{ber}	statistical calculation of the MRL by using a non-parametric method
R _{max}	statistical calculation of the MRL by using a parametric method
RAC	raw agricultural commodity
RD	residue definition
RMS	rappporteur Member State
SANCO	Directorate-General for Health and Consumers
SC	suspension concentrate
STMR	supervised trials median residue
WHO	World Health Organization
wk	week