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## Modification of the existing MRLs for propamocarb in various crops

European Food Safety Authority (EFSA)

### Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the evaluating Member States (EMS), Germany and Belgium, sent an application to change the existing maximum residue levels (MRLs) for the active substance propamocarb in celeriacs, Florence fennel, purslanes and chards, and to maintain the MRL in celery leaves. Germany and Belgium drafted the evaluation reports in accordance with Article 8 of Regulation (EC) No 396/2005, which were submitted to the European Commission and forwarded to EFSA. According to EFSA the data are sufficient to derive an MRL proposal at the limit of quantification LOQ of 0.01 mg/kg for Florence fennel, 0.09 mg/kg for the celeriacs, 30 mg/kg for chards, 40 mg/kg for purslanes and to maintain the MRL of 30 mg/kg for celery leaves. Adequate analytical enforcement methods are available to control the residues of propamocarb on the commodities under consideration at the validated LOQ of 0.01 mg/kg. Based on the risk assessment results, EFSA concludes that the proposed use of propamocarb on celeriacs, celery leaves, Florence fennel, purslanes and chards 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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**Keywords:** propamocarb, various crops, MRL application, consumer risk assessment, propamocarb hydrochloride

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## Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, the evaluating Member State (EMS) Germany, received an application from Landwirtschaftskammer Nordrhein-Westfalen to change the existing maximum residue levels (MRLs) for the active substance propamocarb in celeriacs, celery leaves and Florence fennel. In addition the EMS Belgium, compiled an application to modify the existing MRLs for propamocarb in purslanes and chards. The EMS (Germany and Belgium) drafted two evaluation reports in accordance with Article 8 of Regulation (EC) No 396/2005, which were submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 19 December 2014 and 7 June 2015 respectively.

EFSA bases its assessment on the evaluation report submitted by the EMS, the draft assessment report (DAR) (and its addendum) prepared under Council Directive 91/414/EEC, the Commission review report on propamocarb, the conclusion on the peer review of the pesticide risk assessment of the active substance propamocarb, 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 and 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 following foliar applications on fruit, root and leafy crop groups and following soil application on fruit and leafy crop groups. From these studies the peer review concluded to establish the residue definitions for enforcement and for risk assessment as the sum of propamocarb and its salts expressed as propamocarb. For the use on the crops under consideration, EFSA concludes that the metabolism of propamocarb in primary crops is sufficiently addressed and the residue definitions are applicable.

EFSA concludes that the submitted supervised residue trials are sufficient to derive an MRL proposal of 0.01 mg/kg for Florence fennels, 0.09 mg/kg on celeriacs, 30 mg/kg on chards, 40 mg/kg on purslanes and to maintain the current MRL value of 30 mg/kg on celery leaves. Adequate analytical enforcement methods are available to monitor the residues of propamocarb in the commodities under consideration at the validated LOQ of 0.01 mg/kg.

Studies investigating the nature of propamocarb hydrochloride residues under standard hydrolysis conditions were assessed in the framework of the previous Article 10 application and showed the active substance to be hydrolytically stable under standard processing conditions. Consequently, the same residue definition as for raw commodities (RAC) is applicable. Several processing factors were derived for tomatoes, spinaches and head cabbages during the Article 12 MRL review. Additional studies were not submitted and are not requested.

Since the  $DT_{90}$  value of propamocarb is lower than 100 days, data on residues in succeeding crops were not provided and are not requested.

Residues of propamocarb in commodities of animal origin were not assessed, 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). No long-term or acute consumer intake risks were identified. For propamocarb the highest estimated chronic intake accounted for 5% of the ADI (FR toddler) and the highest acute exposure was calculated to be 38% for chards and purslanes.

EFSA concludes that the proposed use of propamocarb on celeriacs, celery leaves, Florence fennel, purslanes and chards will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a health risk to consumers.

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

Code <sup>(a)</sup>	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/Justification
<b>Enforcement residue definition:</b> propamocarb and its salts expressed as propamocarb				
0213030	Celeriacs/turnip rooted celeries	0.01*	0.09	Supported by indoor trials
0252020	Purslanes	0.01*	40	Extrapolation from indoor residue trials on lettuce (open leaf varieties)
0252030	Chards/beet leaves	0.01*	30	Extrapolation from NEU outdoor residue trials on spinaches
0256030	Celery leaves	30	30 (no change)	No change proposed, since the use by drench applications results in much lower residue levels than the use by foliar applications assessed under the Article 12 MRL review.
0270040	Florence fennels	0.01*	0.01*	Supported by indoor trials

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

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

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## Background

Regulation (EC) No 396/2005<sup>1</sup> establishes the rules governing the setting of pesticide maximum residue levels (MRLs) at European Union (EU) level. Article 6 of the 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/EEC,<sup>2</sup> repealed by Regulation (EC) No 1107/2009,<sup>3</sup> shall submit to a Member State, when appropriate, an application to modify a MRL in accordance with the provisions of Article 7 of the Regulation.

Germany, hereafter referred to as the evaluating Member State (EMS-DE), received an application from the company Landwirtschaftskammer Nordrhein-Westfalen<sup>4</sup> to change the existing MRL for celeriacs, to set an MRL for Florence fennel and to maintain the existing MRL for celery leaves. In addition, Belgium, hereafter referred to as the evaluating Member State (EMS-BE), compiled an application to modify the existing MRLs for propamocarb in purslanes and chards. These applications were notified to the European Commission and the European Food Safety Authority (EFSA) and were subsequently evaluated by the EMS in accordance with Article 8 of the Regulation. After completion, the evaluation reports were submitted to the European Commission and to EFSA on 19 December 2014 and on 7 July 2015 respectively.

The applications were included in the EFSA Register of Questions with the following reference numbers and the following subject:

EFSA-Q- 2014-00932 *Propamocarb- Modification of the existing MRLs in celeriac, celery leaves and fennel.*

EFSA-Q- 2015-00421 *Propamocarb- Modification of the existing MRLs in purslanes and chards.*

For reasons of efficiency EFSA combined both applications in a single reasoned opinion.

Germany proposed to raise the existing MRL for celeriacs from the limit of quantification of 0.01 mg/kg to 0.08 mg/kg, to set the MRL at 0.01 mg/kg for Florence fennel and to maintain the existing MRL values of 30 mg/kg for celery leaves. Belgium proposed to raise the MRL from the limit of quantification of 0.01 mg/kg to 30 mg/kg for chards and to 40 mg/kg for purslanes.

Further clarifications/information were requested on 21 January 2015 to Germany (Annex 1 of the application form, and information on the GAP) which were submitted on 3 September 2015 together with an updated evaluation report. Clarification on the GAPs was also requested to Belgium on 22 July 2015 which were submitted to EFSA in the form of an updated evaluation report on 4 September 2015.

EFSA proceeded with the assessment of the applications and the evaluation reports as required by Article 10 of the Regulation.

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

In accordance with Article 11 of the 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 if more detailed evaluations need to be carried out) from the date of receipt of the application. If EFSA requests supplementary information, the time limit laid down shall be suspended until that information has been provided.

<sup>1</sup> 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.

<sup>2</sup> 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.

<sup>3</sup> 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.

<sup>4</sup> Landwirtschaftskammer Nordrhein-Westfalen Siebengebirgsstraße 200, 53229 Bonn, Germany

## 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 the active substance and its main metabolite are reported in Appendix C.

Propamocarb was included in Annex I of this Directive by Commission Directive 2007/25/EC<sup>5</sup> which entered into force on 01 October 2007 for use as fungicide only. In accordance with Commission Implementing Regulation (EU) No 540/2011<sup>6</sup> propamocarb is approved under Regulation (EC) No 1107/2009, repealing Council Directive 91/414/EEC.

The EU MRLs for propamocarb are established in Annex II of Regulation (EC) No 396/2005. The revision of the existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (hereafter Article 12 MRL review) has been finalised by EFSA in 2013 (EFSA, 2013a). The recommendations have already been implemented into the EU legislation by the Regulation (EU) No 289/2014. Since then EFSA issued several reasoned opinions on the modification of MRLs for propamocarb (EFSA 2013b, 2014, 2015), and they are summarised in Table 1

**Table 1:** Overview of the MRL changes/proposals after the Article 12 MRL review.

Procedure <sup>(a)</sup>	Considered by Regulation	Remarks
Art. 12 (EFSA, 2013a)	(EU) No 289/2014	Review of the existing MRLs
Art. 10 (EFSA, 2013b)	(EU) No 2014/36	Rocket and leek
Art. 10 (EFSA, 2014)	(EU) No 2015/846	Spring onions and Chinese cabbage
Art. 10 (EFSA, 2015a)	Not yet legally implemented	Onions, garlic, shallots and leeks
Art. 43 (EFSA, 2015b)	Not yet legally implemented	Various crops

(a): Art. 10: Assessment of MRL application according to Article 6 to 10 of Regulation (EC) No 396/2005

Art. 12: Review of the existing MRLs according to Article 12 of Regulation (EC) No 396/2005

Art. 43: EFSA scientific opinion according to Article 43 of Regulation (EC) No 396/2005

Codex Alimentarius has established maximum residue limits (CXL) for a wide range of commodities, including spinach for which the CXL is set at 40 mg/kg. For the other crops considered under the current application there are no CXL in place.

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

## Assessment

EFSA bases its assessment on the evaluation report submitted by the EMS (Germany, Belgium 2015), the DAR prepared under Directive 91/414/EEC (Ireland, 2004), the Commission review report on propamocarb (European Commission, 2006), the conclusion on the peer review of the pesticide risk assessment of the active substance propamocarb (EFSA, 2006), the JMPR Evaluation report (FAO, 2006) as well as the conclusions from previous EFSA opinions on propamocarb, including the review of the existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (EFSA 2013a, 2013b 2014, 2015a, 2015b). 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<sup>7</sup> and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (European Commission, 1996, 1997a–g, 2000, 2010a, b, 2011; OECD, 2011).

<sup>5</sup> 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.

<sup>6</sup> 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

<sup>7</sup> 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.

## 1. Method of analysis

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

Analytical methods for determination of propamocarb residues in plant matrices were evaluated during the peer review and in the framework of Article 12 MRL review. The methods, based on HPLC-MS/MS quantification, were concluded to be validated at the LOQ of 0.01 mg/kg in high water, acidic and high oil content commodities.

As the commodities under consideration belong to high water content group, EFSA concluded that sufficient validated analytical methods are available to monitor the residues of propamocarb at the validated LOQ level of 0.01 mg/kg.

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

Analytical methods for the determination of residues in food of animal origin are not assessed in the current application, since the crops under consideration are normally 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 (MW) conversion factor of 0.84.<sup>8</sup> These toxicological reference values are summarised in Table 2.

**Table 2:** Overview of the toxicological reference values

	Source	Year	Value	Study	Safety factor
<b>Propamocarb hydrochloride</b>					
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
<b>Propamocarb</b>					
ADI	EFSA	2006	0.244 mg/kg bw per day <sup>(a)</sup>	-	-
ARfD	EFSA	2006	0.84 mg/kg bw <sup>(a)</sup>	-	-

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

It is noted that JMPR established an ADI of 0.2 mg/kg bw per day and the ARfD is 2 mg/kg bw for propamocarb (FAO, 2006).

## 3. Residues

### 3.1. Nature and magnitude of residues in plant

#### 3.1.1. Primary crops

##### Nature of residues

The metabolism of propamocarb was investigated during the peer review on fruit (cucumber, tomato), leafy (spinach, lettuce) and root (potato) crop groups with propamocarb hydrochloride after soil and foliar applications. An overview of the available metabolism studies is presented in Table 3.

<sup>8</sup> MW propamocarb/MW propamocarb hydrochloride 188.3/224.7=0.84

**Table 3:** Summary of available metabolism studies in plants

Crop group	Crops	Application	Sampling <sup>(a)</sup> (day, DAT)	Comments
Fruit	Tomato	Foliar: 2170 g/ha	28 DAT <sub>4</sub>	
		Soil: 4x 7.22 or 36.1 g/m <sup>2</sup>	25 DAT <sub>4</sub>	
	Cucumber	Foliar: 2900 g/ha	30 DAT <sub>1</sub>	
		Soil: 53.4 mg/plant	21 DAT <sub>1</sub>	
Root	Potato	Foliar: 3x 2450 g/ha	42 DAT <sub>1</sub>	
		Foliar: 6 x 2170 or 10900g/ha	7 DAT <sub>1</sub>	Death of foliage by the 6th application with drift to soil.
Leafy	Lettuce	Foliar: 3x 11080 g/ha	21 DAT <sub>1</sub>	
		Soil: 3x 7.22 or 36.1 g/m <sup>2</sup>	38 DAT <sub>1</sub>	
	Spinach	Foliar 2x 2530 g/ha	3 DAT <sub>1</sub>	

(a) DAT<sub>x</sub>, days after treatment x, e.g. DAT<sub>2</sub>: day after 2nd treatment.

Based on these metabolism studies the residue definition for monitoring and risk assessment derived during the peer review and confirmed in the framework of the Article 12 MRL review was set as the sum of propamocarb and its salts, expressed as propamocarb (EFSA, 2006, 2013b). 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 crops under consideration, EFSA concludes that the metabolism of propamocarb is sufficiently addressed and the residue definitions for enforcement and risk assessment are applicable.

### Magnitude of residues

#### a. Celeriac & celery leaves: *Indoor GAP; 2 drench applications at 15900 g/ha at BBCH 0 to 10*

In support of the MRL proposal, Germany submitted five residue trials on celeriac conducted during the growing seasons 2010 and 2011 and using two drench applications at 16000 g/ha; the first at sowing and the second 7 to 9 days after, at growth stage BBCH 03 to 10. Leave samples and root samples were collected 79 to 80 days and 100 to 102 days after the last application to derive MRL values for celery leaves and celeriac respectively. Residues of propamocarb were in the range of <0.01 to 0.02 mg/kg in leaves and in the range of <0.01 to 0.042 mg/kg in roots, resulting in an MRL proposal of 0.04 mg/kg for celery leaves and 0.09 mg/kg for celeriac.

However, during the Article 12 MRL review, based on foliar applications (2x 1330 g/ha, PHI 14) and residue trials conducted on lettuce open leaf varieties, an MRL of 30 mg/kg was extrapolated to the whole group 'herbs and edible flowers' including celery leaves. Therefore, no change is proposed for the MRL on celery leaves, as the use by drench applications supported in the current MRL application is already covered by the MRL of 30 mg/kg proposed in the framework of the Article 12 MRL review.

#### b. Purslanes: *Indoor GAP; 2x 1000 g/ha, PHI 14 days*

The EMS-BE submitted eight indoor residue trials on lettuce (open leaf varieties) to support the extrapolation of the MRL to purslanes. According to European Commission, 2011 the extrapolation is possible. Residue levels ranged from 1.9 mg/kg to 25 mg/kg resulting in an MRL proposal of 40 mg/kg, extrapolated to purslanes.

It is noted that under Article 12 review, an MRL of 40 mg/kg has already been derived for lettuce grown indoor, but based on a different GAP defined as 3 applications at 1080 g/ha and a 21 days PHI.

#### c. Purslanes and chards: *NEU GAP; 3x 1000 g/ha propamocarb, PHI 14 days*

The EMS-BE refers to the eight residue trials submitted during the Article 12 MRL review to support the MRL extrapolation to purslanes and chards (EFSA, 2013a). The residue trials were conducted according to similar GAPs and an MRL of 30 mg/kg was proposed for NEU derived from residues in the range of 1.0 to 18 mg/kg. According to European Commission, 2011 the extrapolation to purslanes and chards is possible.

However for purslanes the outdoor use of propamocarb (3x 1000 g/ha, PHI 14 days) is already covered by the MRL of 40 mg/kg derived from the indoor trials conducted according to a GAP defined with 2 applications at 1000g/ha and a PHI of 14 days.

**d. Florence fennel:** *Indoor GAP; 2 drench applications at 15900 g/ha at BBCH 0 to 10*

In support of the MRL proposal, the EMS-DE submitted four residue trials conducted in Germany during the growing seasons 2010 and 2011 and using two drench applications at 16000 g/ha at growth stages BBCH 00 and BBCH 3 to 11. Residues in the fennel samples collected 79 to 83 days after the second application were all below the LOQ of 0.01 mg/kg, leading to an MRL proposal of 0.01\* mg/kg.

The results of the residue trials, the related risk assessment input values (highest residue, median residue) and the MRL proposals are summarised in Table 4.

The stability of propamocarb residues in plant matrices under storage conditions prior to analysis was assessed during the peer review. Residues of propamocarb were found to be stable at  $\leq -18^{\circ}\text{C}$  for 26 months in high water content (tomatoes and lettuce). As the 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.

According to the EMS, the analytical methods used to analyse the residue trial samples have been sufficiently validated and were proven to be fit for purpose (Germany and Belgium, 2015).

EFSA concludes that the data are sufficient to propose the following MRL values:

- 0.09 mg/kg Celeriac (indoor use)
- 40 mg/kg Purslanes by extrapolation from indoor trials on lettuce (open leaf varieties). It covers also the NEU outdoor uses on purslanes
- 30 mg/kg Chards by extrapolation from outdoor trials on spinach,
- 0.01 mg/kg Florence fennels (indoor use)

No change is proposed to the current MRL of 30 mg/kg set on celery leaves under Regulation (EU) 2015/846, since the use of propamocarb by drench applications supported in the framework of this MRL application results in a lower residues levels than the use by foliar applications assessed in the framework of the Article 12 MRL review.

**Table 4:** Overview of the available residues trials data

Crop (Trials GAPs)	Region/ Indoor <sup>(a)</sup>	Residue levels observed in the supervised residue trials <sup>(b)</sup> (mg/kg)	Recommendations/comments <sup>(c)</sup>	MRL proposal (mg/kg)	HR <sup>(d)</sup> (mg/kg)	STMR <sup>(e)</sup> (mg/kg)
<b>Celery</b> (2x 16000 g/ha, PHI 100 days)	Indoor	<u>Roots</u> : 3x <0.01; 0.042	First drench application at sowing, second 7 to 9 days after BBCH 3 to 10. Roots: MRL <sub>OECD</sub> 0.08/0.09 Leaves: MRL <sub>OECD</sub> 0.03/0.04	0.09	0.042	0.01
	Indoor	<u>Whole plant</u> : <0.01;		No change	0.02	0.01
		<u>Leaves</u> : 2x <0.01; 0.02				
		<u>Whole plant</u> : <0.01				
<b>Florence fennel</b> (2x 16000 g/ha, PHI ca 80 days)	Indoor	4x <0.01	First drench application at sowing, second 7 to 9 days after at BBCH 3 to 11.	0.01*	0.01	0.01
<b>Lettuce</b> (2x 1000 g/ha, PHI 14 days)	Indoor	1.9; 2.1; 2.8; 3.0; 4.5; 10; 13; 25	Trials conducted on lettuce open leaf varieties and used for MRL extrapolation to purslanes. MRL <sub>OECD</sub> : 35/40	40	25	3.8
<b>Spinach</b> (3x 1000g/ha, PHI 14 days)	NEU	1.0; 1.6; 2.9; 3.3; 3.5; 7.6; 10; 18	MRL proposal of 30 mg/kg derived from trials on spinach extrapolated to chards. MRL <sub>OECD</sub> : 28.9/30	30	18	3.4

(\*): Indicates that the MRL is proposed at the limit of analytical quantification (LOQ).

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

(b): Individual residue levels considered for MRL calculation are reported in ascending order; the residue trials are reported as propamocarb, except for lettuce where were presented for both

(c): Any information/comment supporting the decision and OECD MRL calculation (unrounded/rounded values)

(d): HR: Highest residue level according to the residue definition for risk assessment.

(e): STMR: Median residue level according to residue definition for risk assessment.

## Effect of industrial processing and/or household preparation

The effect of processing on the nature of propamocarb under standard hydrolysis conditions was investigated in a previous Article 10 application. The Netherlands submitted standard hydrolysis studies performed with propamocarb hydrochloride which shows no degradation of the active substance (Netherlands, 2014). Since propamocarb is hydrolytically stable under the representative processing conditions, the same residue definition as for RAC is applicable.

Additionally, during the Article 12 MRL review were proposed several processing factors for tomatoes, head cabbages and spinaches based on the studies reported by the RMS and JMPR (EFSA, 2013a).

### 3.1.2. Rotational crops

The crops under consideration can be grown in rotation with other plants, therefore the possible occurrence of residues in succeeding crops resulting from the proposed uses of propamocarb have to be examined (European Commission, 1997c).

The soil degradation studies demonstrated that the degradation rate of propamocarb hydrochloride is moderate; the maximum  $DT_{90}$  from field studies was 58-78 days (EFSA, 2006), which is below the trigger value of 100 days. Therefore, no further studies investigating the nature and magnitude of the compound uptake in rotational crops are required (European Commission, 1997c).

### 3.2. Nature and magnitude of residues in livestock

As crops under consideration and their products are not normally fed to livestock, the nature and magnitude of propamocarb residues in livestock is not assessed in the framework of this application (European Commission, 1996).

## 4. Consumer risk assessment

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 population<sup>9</sup> (EFSA, 2007).

In the framework of the Article 12 MRL review, a comprehensive long-term exposure assessment was performed taking into account the existing uses of propamocarb at the EU level and the acceptable CXLs (EFSA, 2013a). EFSA now updated this risk assessment taking into account the STMR values derived from the residue trials conducted on the crops in this MRL application (see Table 4). The STMR derived for rockets, spring onions and Chinese cabbage, bulb vegetables and leeks derived in previous EFSA opinions (EFSA, 2013b, 2014, 2015) following the Article 12 MRL review were also considered. The remaining commodities of plant and animal origin were excluded from the exposure calculation, assuming that there is no use on these crops.

The acute exposure assessment was performed only with regard to the commodities under consideration 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 residue level (HR) as observed in supervised field trials (see Table 4). A variability factor accounting for the inhomogeneous distribution on the individual items consumed was included in the calculation, when required (EFSA, 2007).

The input values used for the dietary exposure calculation are summarised in Table 5.

<sup>9</sup> The calculation of the long-term exposure (chronic exposure) is based on the mean consumption data representative for 22 national diets collected from Member States 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 is used. The complete list of diets incorporated in EFSA PRIMo is given in its reference section (EFSA, 2007).

**Table 5:** Input values for the consumer dietary exposure assessment

Commodity	Chronic exposure assessment		Acute exposure assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
<b>Risk assessment residue definition:</b> sum of propamocarb and its salts, expressed as propamocarb				
Celeriacs	0.01	STMR	0.042	HR
Florence fennel	0.01	STMR	0.01	HR
Purslanes	3.8	STMR	21	HR
Chards/beet leaves	3.4	STMR	18	HR
Onions, garlic, shallots	0.05	STMR (EFSA, 2015)	Acute risk assessment undertaken only with regard to the crops under consideration	
Leek	2.5	STMR (EFSA, 2015)		
Chinese cabbage	4.0	STMR (EFSA, 2014)		
Spring onions	2.5	STMR (EFSA, 2014)		
Rockets	3.4	STMR (EFSA, 2013b)		
Other plant and animal commodities	Input values listed in Table 4-1 of the reasoned opinion issued under Art 10 of Regulation (EC) 396/2005 (EFSA, 2015)			

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

No long-term consumer intake concern was identified for any of the European diets incorporated in the EFSA PRIMo model. The total chronic intake calculated accounted for up to 5 % of the ADI (FR, Toddler), the maximum contribution for the crops under consideration was 0.1 % of the ADI for chards (ES, child).

No acute consumer risk was identified in relation to the MRL proposals for the crop under consideration. The highest acute consumer exposure was calculated to be 38 % of the ARfD for chards and purslanes.

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 concern for public health.

## Conclusions and recommendations

Code	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/Justification
<b>Enforcement residue definition:</b> propamocarb and its salts expressed as propamocarb				
0213030	Celeriacs/turnip rooted celeries	0.01*	0.09	Supported by indoor trials
0252020	Purslanes	0.01*	40	Extrapolation from indoor residue trials on lettuce (open leaf varieties)
0252030	Chards/beet leaves	0.01*	30	Extrapolation from NEU outdoor residue trials on spinaches
0256030	Celery leaves	30	30 (no change)	No change proposed, since the use by drench applications results in much lower residue levels that the use by foliar applications assessed under the Article 12 MRL review.
0270040	Florence fennels	0.01*	0.01*	Supported by indoor trials

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## Abbreviations

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
bw	body weight
CXL	Codex maximum residue limit (Codex MRL)
DAR	draft assessment report
DAT	days after treatment
DT90	period required for 90 % dissipation (define method of estimation)
EFSA	European Food Safety Authority
EMS	evaluating Member State
EURL	EU Reference Laboratory (former Community Reference Laboratory (CRL))
FAO	Food and Agriculture Organization of the United Nations
GAP	good agricultural practice
GC	gas chromatography
GCPF	Global Crop Protection Federation (formerly International Group of National Associations of Manufacturers of Agrochemical Products (GIFAP))
GS	growth stage
HPLC	high performance liquid chromatography
HR	highest residue
IPCS	International Programme of Chemical Safety
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LOQ	limit of quantification
MRL	maximum residue level
MS/MS	tandem mass spectrometry detector
MW	molecular weight
NEU	northern Europe
OECD	Organisation for Economic Co-operation and Development
PHI	pre-harvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
RAC	raw agricultural commodity
RMS	rappporteur Member State
SANCO	Directorate-General for Health and Consumers
SC	soluble concentrate
STMR	supervised trials median residue

## Appendix A – Good Agricultural Practice (GAPs)

Crop and/or situation <sup>(a)</sup>	MS or NEU/SEU or Country	F G or I <sup>(b)</sup>	Pest or group of pests controlled <sup>(c)</sup>	Formulation		Application				Application rate per treatment			PHI (days) <sup>(l)</sup>	Remarks <sup>(m)</sup>
				type	conc.	Method kind <sup>(f-h)</sup>	Growth stage & season <sup>(j)</sup>	Number min-max <sup>(k)</sup>	Interval min-max	g/hL min-max	Water L/ha min-max	g/ha min-max		
Fennel	Indoor (Germany)	G	<i>Pythium sp.</i>	SC		drench	BBCH 0-10	1-2	7		30 L/ha	15900	n.a	
Celeriac	Indoor (Germany)	G	<i>Pythium sp.</i>	SC		drench	BBCH 0-10	1-2	7		30 L/ha	15900	n.a	
Celery leaves	Indoor (Germany)	G	<i>Pythium sp.</i>	SC		drench	BBCH 0-10	1-2	7		30 L/ha	15900	n.a	
Purslane	Indoor (Belgium)	G	mildew	SC		spraying	BBCH 14-47	1-2				1000	14	
Purslane & chards	NEU (Belgium)	F	mildew	SC		spraying	BBCH 14-47	1-3				1000	14	

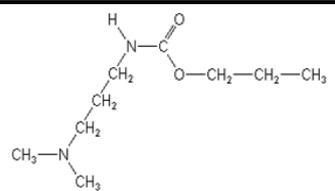
### Remarks:

- (a) For crops, EU or other classifications, e.g. Codex, should be used; where relevant, the usage 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), water soluble granule (WG)
- (e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
- (f) all abbreviations must be explained
- (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
- (h) Kind, eg. overall, broadcast, aerial spraying, row, individual plant, between the plants. type of equipment used must be indicated
- (i) g/kg or µg/L
- (j) Growth stage at last treatment (Meier U, 2001. Growth Stages of mono- and dicotyledonous plants. BBCH Monograph, 2nd Ed., Federal Biological Research Centre of Agriculture and Forestry, Braunschweig, Germany, 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
- (m) Remarks may include: Extent of use/economic importance/restrictions

## Appendix B – Pesticide Residue Intake Model (PRIMO)

<b>Propamocarb (free base)</b>																		
Status of the active substance:		approved		Code no.:														
LOQ (mg/kg bw):				proposed LOQ:														
<b>Toxicological end points</b>																		
ADI (mg/kg bw/day):		0.244		ARfD (mg/kg bw):		0.84												
Source of ADI:		EFSA		Source of ARfD:		EFSA												
Year of evaluation:		2011		Year of evaluation:		2011												
Toxicological endpoints derived for propamocarb hydrochloride (ADI 0.29 mg/kg bw per day and ARfD 1 mg/kg bw) recalculated by applying a MW conversion factor of 0.84.																		
<b>Chronic risk assessment - refined calculations</b>																		
				TMDI (range) in % of ADI minimum - maximum														
				0 - 5														
<b>No of diets exceeding ADI:</b> ---																		
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	pTMRLs at LOQ (in % of ADI)										
4.9	FR toddler	3.2	Spinach	0.6	Leek	0.3	Courgettes											
4.2	NL child	1.7	Spinach	0.5	Milk and milk products: Cattle	0.3	Scarole (broad-leaf endive)											
3.6	FR infant	2.0	Spinach	0.4	Milk and milk products: Cattle	0.4	Courgettes											
3.3	WHO Cluster diet B	1.0	Lettuce	0.7	Tomatoes	0.4	Spinach											
2.6	DE child	0.9	Spinach	0.4	Cucumbers	0.2	Milk and milk products: Cattle											
2.4	ES adult	1.5	Lettuce	0.3	Spinach	0.2	Tomatoes											
2.3	ES child	1.1	Lettuce	0.4	Spinach	0.2	Tomatoes											
2.3	WHO regional European diet	1.0	Lettuce	0.2	Tomatoes	0.2	Spinach											
2.1	NL general	0.7	Spinach	0.3	Lettuce	0.2	Scarole (broad-leaf endive)											
2.1	IT adult	1.0	Lettuce	0.4	Spinach	0.3	Tomatoes											
2.0	IE adult	0.6	Spinach	0.3	Leek	0.2	Lettuce											
1.8	SE general population 90th percentile	0.3	Chinese cabbage	0.3	Spinach	0.2	Milk and milk products: Cattle											
1.8	DK child	1.1	Cucumbers	0.4	Lettuce	0.1	Tomatoes											
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											
1.3	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											
0.9	FR all population	0.2	Lettuce	0.1	Leek	0.1	Tomatoes											
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	PL general population	0.2	Tomatoes	0.1	Potatoes	0.0	Cauliflower											
0.6	UK Toddler	0.1	Tomatoes	0.1	Spinach	0.1	Cucumbers											
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											
<b>Conclusion:</b>																		
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI. A long-term intake of residues of Propamocarb (free base) is unlikely to present a public health concern.																		
<b>Acute risk assessment /children - refined calculations</b>					<b>Acute risk assessment / adults / general population - refined calculations</b>													
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.																		
<b>Threshold MRL</b> 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):		---			
	IESTI 1	*)	**)	IESTI 2	*)	**)	IESTI 1	*)	**)	IESTI 2	*)	**)	IESTI 1	*)	**)	IESTI 2	*)	**)
	Highest % of ARfD/ADI		pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI		pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI		pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI		pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI		pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI		pTMRL/ threshold MRL (mg/kg)
	37.8	Purslane	21 / -	28.6	Purslane	21 / -	25.8	Purslane	21 / -	23.5	Purslane	21 / -	37.8	Purslane	21 / -	28.6	Purslane	21 / -
	37.6	Beet leaves (chard)	18 / -	28.5	Beet leaves (chard)	18 / -	15.9	Beet leaves (chard)	18 / -	13.4	Beet leaves (chard)	18 / -	37.6	Beet leaves (chard)	18 / -	28.5	Beet leaves (chard)	18 / -
0.2	Celery	0.042 / -	0.2	Celery	0.042 / -	0.1	Celery	0.042 / -	0.1	Celery	0.042 / -	0.2	Celery	0.042 / -	0.2	Celery	0.042 / -	
0.02	Fennel	0.01 / -	0.02	Fennel	0.01 / -	0.03	Fennel	0.01 / -	0.02	Fennel	0.01 / -	0.02	Fennel	0.01 / -	0.02	Fennel	0.01 / -	

## Appendix C – Used compound codes

Code/Trivial name	Chemical name	Structural formula
Propamocarb	propyl 3-(dimethylamino)propylcarbamate (IUPAC) MW=188.3 g/mol	
Propamocarb hydrochloride	propyl 3-(dimethylamino) propylcarbamate hydrochloride (IUPAC) MW=224.7 g/mol	