European Food Safety Authority

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REASONED OPINION

Reasoned opinion on the review of the existing maximum residue levels (MRLs) for propamocarb according to Article 12 of Regulation (EC) No 396/2005[1]

European Food Safety Authority[2, 3]

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ABSTRACT

According to Article 12 of Regulation (EC) No 396/2005, the European Food Safety Authority (EFSA) has reviewed the Maximum Residue Levels (MRLs) currently established at European level for the pesticide active substance propamocarb. In order to assess the occurrence of propamocarb residues in plants, processed commodities, rotational crops and livestock, EFSA considered the conclusions derived in the framework of Directive 91/414/EEC, the MRLs established by the Codex Alimentarius Commission as well as the European authorisations reported by Member States (incl. the supporting residues data). Based on the assessment of the available data, MRL proposals were derived and a consumer risk assessment was carried out. Some information required by the regulatory framework was found to be missing and a possible acute risk to consumers was identified. Hence, the consumer risk assessment is considered indicative only, some MRL proposals derived by EFSA still require further consideration by risk managers and measures for reduction of the consumer exposure should also be considered.

KEY WORDS

propamocarb, MRL review, Regulation (EC) No 396/2005, consumer risk assessment, carbamate, fungicide, propamocarb hydrochloride

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SUMMARY

Propamocarb was included in Annex I to Directive 91/414/EEC on 01 October 2007, which is before the entry into force of Regulation (EC) No 396/2005 on 02 September 2008. EFSA is therefore required to provide a reasoned opinion on the review of the existing MRLs for that active substance in compliance with Article 12(2) of the aforementioned regulation. In order to collect the relevant pesticide residues data, EFSA asked Ireland, as the designated rapporteur Member State (RMS), to complete the Pesticide Residues Overview File (PROFile). The requested information was submitted to EFSA on 20 April 2010 and, after having considered several comments made by EFSA, the RMS provided on 12 June 2012 a revised PROFile as well as an evaluation Report.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC, the MRLs established by the Codex Alimentarius Commission and the additional information provided by the RMS, EFSA issued on 17 October 2012 a draft reasoned opinion that was circulated to Member States' experts for consultation. Comments received by 21 December 2012 were considered in the finalisation of this reasoned opinion. The following conclusions are derived.

The toxicological profile of propamocarb was evaluated in the framework of Directive 91/414/EEC, which resulted in an ADI and an ARfD being established at 0.244 mg/kg bw per d and 0.84 mg/kg bw, respectively.

Primary crop metabolism of propamocarb was investigated in three different crop groups following foliar or soil applications. Based on these studies, EFSA proposes to define the residue for enforcement and risk assessment in all plant commodities as the sum of propamocarb and its salts, expressed as propamocarb. Validated analytical methods for enforcement of this residue definition are available with an LOQ of 0.01 mg/kg in high water content commodities.

Regarding the magnitude of residues in primary crops, at least one GAP is fully supported by data for most of the crops reported and the available residue data are considered acceptable to derive MRL proposals as well as risk assessment values for all commodities under evaluation, except for potatoes, peppers, cauliflower, salad plants (except lettuce) and fresh herbs where only tentative MRLs can be derived.

The nature of residues of propamocarb in processed commodities was not investigated. Studies investigating the magnitude of residues in several processed products of tomatoes and head cabbage, and for cooked spinach are available, which allowed EFSA to derive processing factors. Pending further investigation on the nature of the residues in processed commodities however, processing factors are indicative only and it cannot be excluded that additional processing studies may be required in order to derive robust processing factors for enforcement purposes.

The potential incorporation of soil residues into succeeding and rotational crops was investigated in lettuce, radish and wheat during the peer review. This study showed comparable metabolic patterns in primary and succeeding crops. Additional field trials also demonstrated that significant residues of parent propamocarb in rotational crops are not expected, provided that propamocarb is applied according to the GAPs supported in the framework of this review.

Based on the uses reported by the RMS, significant intakes were calculated for ruminants, poultry and pigs. Metabolism in lactating ruminants and poultry was sufficiently investigated and findings in ruminants can be extrapolated to pigs. The relevant residue definition for enforcement was defined as N-oxide propamocarb in milk, pig and ruminants tissues and as N-desmethyl propamocarb in poultry products. For risk assessment, the residue is defined in milk, pig and ruminant tissues as the sum of propamocarb, N-oxide propamocarb, oxazolidine-2-one propamocarb and 2-hydroxypropamocarb expressed as propamocarb; for poultry tissues, the residue is defined as the sum of propamocarb and

N-desmethyl propamocarb, expressed as propamocarb. Fully validated analytical methods for enforcement of both residue definitions are not available and therefore still required.

The RMS also reported a livestock feeding study on lactating cows which was underdosed; no reliable conclusion can be drawn on the magnitude of residues in ruminants and pigs. A representative feeding study for ruminants is therefore required and tentative MRLs and risk assessment values were derived from the available metabolism study on cows. Regarding poultry, a feeding study in hens demonstrated that significant residues of propamocarb in edible matrices of poultry are expected but separate results for propamocarb and N-desmethyl propamocarb are still required; tentative MRLs and risk assessment values were derived.

Chronic and acute consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 2 of the EFSA PRIMo. For spinach, lettuce and leek, an exceedance of the ARfD was identified representing 121, 119 and 105 % of the ARfD, respectively. Considering fall-back MRLs for spinach and for lettuce and excluding leek (no fall-back MRL available), the highest chronic exposure represented 2.9 % of the ADI (WHO Cluster Diet B) and the highest acute exposure amounted to 95 % of the ARfD (kale).

Apart from the MRLs evaluated in the framework of this review, internationally recommended CXLs have also been established for propamocarb. Additional calculations of the consumer exposure, considering these CXLs, were therefore carried out and an exceedance of the ARfD was identified for the existing CXL in lettuce (275 %). Excluding this CXL from the calculation, the highest chronic exposure represented 4.3 % of the ADI (French toddlers) and the highest acute exposure amounted to 95 % of the ARfD (kale).

Based on the above assessment, EFSA does not recommend inclusion of this active substance in Annex IV to Regulation (EC) No 396/2005. MRL recommendations were derived in compliance with the decision tree reported in Appendix D of the reasoned opinion (see summary table). All MRL values listed as 'Recommended' in the table are sufficiently supported by data and are therefore proposed for inclusion in Annex II to the Regulation. The remaining MRL values listed in the table are not recommended for inclusion in Annex II because they require further consideration by risk managers (see summary table footnotes for details). In particular, some tentative MRLs need to be confirmed by the following data:

- a fully validated analytical method, with its ILV and a confirmatory method, for enforcement of N-oxide propamocarb in milk, pig and ruminant tissues;
- a fully validated analytical method, with its ILV and a confirmatory method, for enforcement of N-desmethyl propamocarb in poultry products;
- 4 additional residue trials supporting the indoor GAP on cauliflower;
- 8 residue trials on lettuce (open leaves varieties) supporting the northern outdoor GAP on lamb's lettuce, scarole and rocket;
- 8 residue trials on lettuce (open leaves varieties) supporting the southern outdoor GAP and 8 residue trials on lettuce (open leaves varieties) supporting the indoor GAP on salad plants (except lettuce);
- trials on fresh herbs or on any crop allowing extrapolation to fresh herbs supporting the indoor GAP;
- separate results for propamocarb and N-desmethyl propamocarb in the hen feeding study;

- a representative feeding study on ruminants supported by storage stability data.

Additionally, some of the MRLs derived result from a CXL or from a GAP in one climatic zone only, while other GAPs reported by the RMS were not fully supported by data. EFSA therefore identified the following data gaps which are not expected to impact on the validity of the MRLs derived but which might have an impact on national authorisations:

- 4 additional residue trials supporting the southern outdoor GAP on potato;
- 8 residue trials supporting the southern outdoor GAP and 8 residue trials supporting the indoor GAP on pepper;
- 4 residue trials supporting the southern outdoor GAP on cucumber;
- 4 residue trials supporting the indoor GAP on gherkin;
- 4 residue trials supporting the northern outdoor GAP and 4 residue trials supporting the southern outdoor GAP on Chinese cabbage;

If the above reported data gaps are not addressed in the future, Member States are recommended to withdraw or modify the relevant authorisations at national level. It is also highlighted that an exceedance of the ARfD was identified for the GAPs authorised on spinach and lettuce in the southern outdoor area and on leek in the northern outdoor area. Therefore, MSs concerned are in any case, regardless of the data gaps listed above, recommended to withdraw or modify those authorisations at national level. Moreover, as the indoor GAP reported by the Netherlands for lettuce may lead to an exceedance of the proposed MRL (based on the supported indoor GAP), the Netherlands are strongly recommended to reconsider their indoor GAPs as well in order not to have exceedances of the proposed MRL.

Minor deficiencies were also identified in the assessment but these deficiencies are not expected to impact either on the validity of the MRLs derived or on the national authorisations. The following data are therefore considered desirable but not essential:

- residues trials supporting the indoor GAP on fresh beans with pods carried out with analytical methods achieving a LOQ of 0.01 mg/kg;
- a hydrolysis study investigating the effect of processing on the nature of the residues.

SUMMARY TABLE

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
Enforcement residue definition: sum of propamocarb and its salts, expressed as propamocarb					
211000	Potatoes	0.5	0.3	0.3	Recommended [(a)]
213080	Radishes	10	1	3	Recommended [(b)]
220020	Onions	10	-	2	Recommended [(c)]
231010	Tomatoes	10	2	4	Recommended [(b)]

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
231020	Peppers	10	3	3	Recommended [a]
231030	Aubergines (egg plants)	10	0.3	4	Recommended [b]
232010	Cucumbers	10	5	5	Recommended [b]
232020	Gherkins	10	5	5	Recommended [d]
232030	Courgettes	10	5	5	Recommended [b]
233010	Melons	5	5	5	Recommended [d]
233020	Pumpkins	10	5	5	Recommended [d]
233030	Watermelons	5	5	5	Recommended [d]
241010	Broccoli	10	-	3	Recommended [c]
241020	Cauliflower	10	0.2	10	Further consideration needed [e]
242010	Brussels sprouts	10	-	2	Recommended [c]
242020	Head cabbage	10	-	0.7	Recommended [c]
243010	Chinese cabbage	10	-	0.01*	Recommended [c]
243020	Kale	20	-	20	Recommended [c]
244000	Kohlrabi	10	-	0.3	Recommended [c]
251010	Lamb's lettuce	30	-	20	Further consideration needed [f]
251020	Lettuce	50	100	40	Recommended [g]
251030	Scarole	10	-	20	Further consideration needed [f]
251040	Cress	30	-	20	Further consideration needed [f]
251050	Land cress	20	-	20	Further consideration needed [f]
251060	Rocket, Rucola	20	-	20	Further consideration needed [f]
251070	Red mustard	20	-	20	Further consideration needed [f]
251080	Leaves and sprouts of *Brassica* spp	20	-	20	Further consideration needed [f]
252010	Spinach	30	40	40	Recommended [d]
255000	Witloof	10	2	15	Recommended [b]
256000	Fresh herbs	30	-	30	Further consideration needed [f]
260010	Beans (fresh, with pods)	0.1*	-	0.1	Recommended [c]
270060	Leek	10	-	-	Further consideration needed [h]
-	Other products of plant origin	See App. C.1	-	-	Further consideration needed [i]
Enforcement residue definition (existing): sum of propamocarb and its salts, expressed as propamocarb **Enforcement residue definition (proposed):** N-oxide propamocarb					
1011010	Swine meat	0.1*	0.01*	0.01	Further consideration needed [j]
1011020	Swine fat (free of lean meat)	0.1*	0.01*	0.01	Further consideration needed [j]
1011030	Swine liver	0.1*	0.01*	0.1	Further consideration needed [j]

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
1011040	Swine kidney	0.1*	0.01*	0.02	Further consideration needed (j)
1012010	Bovine meat	0.1*	0.01*	0.01	Further consideration needed (j)
1012020	Bovine fat	0.1*	0.01*	0.01	Further consideration needed (j)
1012030	Bovine liver	0.1*	0.01*	0.2	Further consideration needed (j)
1012040	Bovine kidney	0.1*	0.01*	0.05	Further consideration needed (j)
1013010	Sheep meat	0.1*	0.01*	0.01	Further consideration needed (j)
1013020	Sheep fat	0.1*	0.01*	0.01	Further consideration needed (j)
1013030	Sheep liver	0.1*	0.01*	0.2	Further consideration needed (j)
1013040	Sheep kidney	0.1*	0.01*	0.05	Further consideration needed (j)
1014010	Goat meat	0.1*	0.01*	0.01	Further consideration needed (j)
1014020	Goat fat	0.1*	0.01*	0.01	Further consideration needed (j)
1014030	Goat liver	0.1*	0.01*	0.2	Further consideration needed (j)
1014040	Goat kidney	0.1*	0.01*	0.05	Further consideration needed (j)
1020010	Cattle milk	0.1*	0.01*	0.01	Further consideration needed (j)
1020020	Sheep milk	0.1*	0.01*	0.01	Further consideration needed (j)
1020030	Goat milk	0.1*	0.01*	0.01	Further consideration needed (j)
Enforcement residue definition (existing): sum of propamocarb and its salts, expressed as propamocarb **Enforcement residue definition (proposed):** N-desmethyl propamocarb					
1016010	Poultry meat	0.1*	0.01*	0.02	Further consideration needed (j)
1016020	Poultry fat	0.1*	0.01*	0.01	Further consideration needed (j)
1016030	Poultry liver	0.1*	0.01*	0.05	Further consideration needed (j)
1030000	Birds' eggs	0.1*	0.01*	0.05	Further consideration needed (j)
-	Other product of animal origin	See App. C.1	-	-	Further consideration needed (i)

(*): Indicates that the MRL is set at the limit of analytical quantification.
(a): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level, which is not fully supported by data, leads to a lower tentative MRL (combination E-VII in Appendix D).
(b): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; existing CXL is covered by the recommended MRL (combination G-III in Appendix D).
(c): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; no CXL is available (combination G-I in Appendix D).
(d): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level, which is also fully supported by data, leads to a lower MRL (combination G-VII in Appendix D).
(e): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified; existing CXL is covered by the tentative MRL (combination E-III in Appendix D).
(f): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified; no CXL is available (combination E-I in Appendix D).
(g): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; CXL is higher, supported by data but a risk to consumers cannot be excluded (combination G-VI in Appendix D).
(h): GAP evaluated at EU level is fully supported by data but a risk to consumers cannot be excluded; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination F-I in Appendix D).

(i): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix D).
(j): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified; CXL is not compatible with EU residue definitions (combination E-II in Appendix D).

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BACKGROUND

Regulation (EC) No 396/2005[4] establishes the rules governing the setting and the review of pesticide MRLs at European level. Article 12(2) of that regulation stipulates that EFSA shall provide by 01 September 2009 a reasoned opinion on the review of the existing MRLs for all active substances included in Annex I to Directive 91/414/EEC[5] before 02 September 2008. As propamocarb was included in Annex I to the above mentioned directive on 01 October 2007, EFSA initiated the review of all existing MRLs for that active substance and a task with the reference number EFSA-Q-2008-611 was included in the EFSA Register of Questions.

According to the legal provisions, EFSA shall base its reasoned opinion in particular on the relevant assessment report prepared under Directive 91/414/EEC. It should be noted, however, that in the framework of Directive 91/414/EEC only a few representative uses are evaluated, while MRLs set out in Regulation (EC) No 396/2005 should accommodate all uses authorised within the EU, and uses authorised in third countries that have a significant impact on international trade. The information included in the assessment report prepared under Directive 91/414/EEC is therefore insufficient for the assessment of all existing MRLs for a given active substance.

In order to gain an overview of the pesticide residues data that have been considered for the setting of the existing MRLs, EFSA developed the Pesticide Residues Overview File (PROFile). The PROFile is an inventory of all pesticide residues data relevant to the risk assessment and MRL setting for a given active substance. This includes data on:

- the nature and magnitude of residues in primary crops;
- the nature and magnitude of residues in processed commodities;
- the nature and magnitude of residues in rotational crops;
- the nature and magnitude of residues in livestock commodities and;
- the analytical methods for enforcement of the proposed MRLs.

Ireland, the designated rapporteur Member State (RMS) in the framework of Directive 91/414/EEC, was asked to complete the PROFile for propamocarb. The requested information was submitted to EFSA on 20 April 2010 and subsequently checked for completeness. On 12 June 2012, after having clarified some issues with EFSA, the RMS provided a revised PROFile.

A draft reasoned opinion was issued by EFSA on 17 October 2012 and submitted to Member States (MS) for commenting. All MS comments received by 21 December 2012 were considered by EFSA in the finalisation of the reasoned opinion.

[4] Commission Regulation (EC) No 396/2005 of 23 February 2005. OJ L 70, 16.3.2005, p. 1-16.
[5] Council Directive 91/414/EEC of 15 July 1991, OJ L 230, 19.8.1991, p. 1-32.

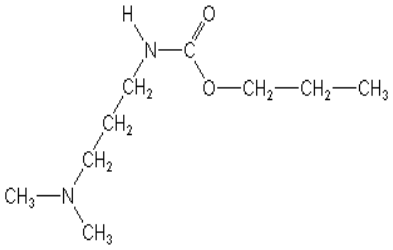
TERMS OF REFERENCE

According to Article 12 of Regulation (EC) No 396/2005, EFSA shall provide a reasoned opinion on:

- the inclusion of the active substance in Annex IV to the Regulation, when appropriate;
- the necessity of setting new MRLs for the active substance or deleting/modifying existing MRLs set out in Annex II or III of the Regulation;
- the inclusion of the recommended MRLs in Annex II or III to the Regulation;
- the setting of specific processing factors as referred to in Article 20(2) of the Regulation.

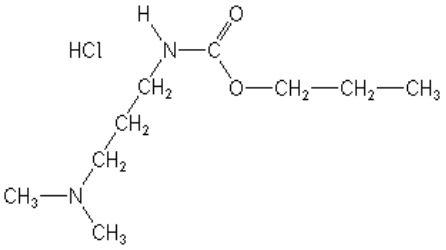
THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Propamocarb is the ISO common name for propyl 3-(dimethylamino)propylcarbamate (IUPAC). Propamocarb are 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 use supported for the peer review process were foliar spraying, drenching or dip irrigation to control a broad spectrum of plant diseases in lettuce, potato, tomato (grown in soil and rock wool). The active substance in the formulation was propamocarb hydrochloride. Following the peer review, which was carried out by EFSA, 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/EC[6], which entered into force on 01 October 2007. According to Regulation (EU) No 540/2011[7], propamocarb is deemed to have been approved under Regulation (EC) No 1107/2009[8]. 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, regardless whether propamocarb or propamocarb hydrochloride is applied as an active substance.

[6] Directive 2007/25/EC of 23 April 2007, OJ L 106, 24.4.2007, p. 34-42.
[7] Regulation (EU) No 540/2011 of 25 May 2011, OJ L 153, 11.6.2011, p. 1-186.
[8] Regulation (EC) No 1107/2009 of 21 October 2009, OJ 309, 24.11.2009, p. 1–50.

Since the entry into force of that regulation, EFSA recommended the modification of the existing MRLs for witloof, radish and kale (EFSA, 2011, 2012) which was legally implemented in Regulations (EU) No 978/2011[9] and No 34/2013[10]. All existing EU MRLs, which are established for the sum of propamocarb and its salts expressed as propamocarb, are summarised in Appendix C.1 to this document. CXLs for propamocarb were also established by the Codex Alimentarius Commission and are reported in Appendix C.2 to this reasoned opinion. These CXLs refer to propamocarb only.

For the purpose of this MRL review, the critical uses of propamocarb currently authorised within the EU, have been collected by the RMS and reported in the PROFile. The additional GAPs reported during the consultation of Member States were also considered. The reported dose rates of application were expressed as propamocarb (free base) equivalents (see Appendix A). Propamocarb is authorised in northern and southern Europe for foliar or local application in a wide range of crops, both under outdoor and indoor conditions. The PHI may vary from 1 to 21 days. The RMS did not report any use authorised in third countries that might have a significant impact on international trade.

ASSESSMENT

EFSA bases its assessment on the PROFile submitted by the RMS, the evaluation report accompanying the PROFile (Ireland, 2012), 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, 2006a, 2006b), the previous reasoned opinions on propamocarb (EFSA, 2011, 2012) as well as the evaluation reports submitted during the consultation of Member States (Belgium, 2012; France, 2012; Germany, 2012; Italy, 2012; Netherlands, 2013; United Kingdom, 2010). The assessment is performed in accordance with the legal provisions of the Uniform Principles for Evaluation and Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011[11] and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (EC, 1996, 1997a, 1997b, 1997c, 1997d, 1997e, 1997f, 1997g, 2000, 2010a, 2010b, 2011; OECD, 2011).

1. Methods of analysis

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

During the peer review under Directive 91/414/EEC, an analytical method using HPLC-MS/MS and its ILV were evaluated and validated for the determination of propamocarb in plant matrices with an LOQ of 0.01 mg/kg in high water content commodities (cabbage, cucumber, melon, sweet pepper, potato, tomato and lettuce) (Ireland, 2004). Nevertheless, as validation data were provided for one transition only, a confirmatory method is missing.

However, an HPLC-MS/MS method was evaluated and validated for the determination of propamocarb with an LOQ of 0.01 mg/kg in high water content (lettuce, chicory, pepper, potato, spinach, leek, onion, cabbage, cauliflower, Brussels sprout, broccoli and cucumber), high oil content (avocado), and dry commodities (wheat grain) (FAO, 2006b). This method can be used as a confirmatory method.

The multi-residue QuEChERS method and a multi-residue method using diatomaceous earth in combination with HPLC-MS/MS, as described by CEN (2008a, 2008b), are reported for analysis of

[9] Regulation (EU) 978/2011 of 3 October 2011, OJ L 258, 4.10.2011, p. 12–69.
[10] Regulation (EU) 34/2013 of 16 January 2013, OJ L 25, 26.1.2013, p. 1–48.
[11] Regulation (EU) No 546/2011 of 10 June 2011. OJ L 155, 11.06.2011, p. 127-175.

propamocarb only but validation data were not evaluated in detail because a validated analytical method is reported above.

Hence it is concluded that the sum of propamocarb and its salts expressed as propamocarb can be enforced in food of plant origin with an LOQ of 0.01mg/kg in high water content commodities.

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

During the peer review under Directive 91/414/EEC, an analytical method using HPLC-MS/MS and its ILV was reported for the determination of propamocarb in food of animal origin with an LOQ of 0.01mg/kg in milk, meat, liver, kidney and eggs (Ireland, 2004; FAO, 2006b).

In addition, after Annex I inclusion, the RMS also reported an HPLC-MS/MS method for the determination of propamocarb with an LOQ of 0.01 mg/kg in meat, fat, liver, kidney, milk and eggs (Ireland, 2012).

Nevertheless, as the residue for enforcement is defined as N-oxide propamocarb in ruminant and pig matrices and N-desmethyl propamocarb in poultry matrices (see also section 3.2.2), a fully validated analytical method, with its ILV and a confirmatory method for the determination of each analyte are required.

2. Mammalian toxicology

The toxicological assessment of propamocarb was peer reviewed under Directive 91/414/EEC and toxicological reference values were established by 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 0.84[12]. 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 d	52 week rat study	100
ARfD	EFSA	2006	1 mg/kg bw	28 d gavage study in rats	100
Propamocarb					
ADI	EFSA	2006	0.244 mg/kg bw per d [(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.

[12] 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 investigated for foliar application on fruits and fruiting vegetables (cucumber, tomato), root and tuber vegetables (potato), and leafy vegetables (spinach, lettuce); and for soil application on fruits and fruiting vegetables (tomato) and leafy vegetables (lettuce), using ^{14}C-labelled propamocarb (Ireland, 2004). The characteristics of these studies are summarised in Table 3-1.

Table 3-1: Summary of available metabolism studies in plants

Group	Crop	Label position	Application and sampling details				
			Method, F or G [(a)]	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks
Fruits and fruiting vegetable	Tomatoes	Not reported.	Soil, G	7.22 g a.s./m^2	4	14, 21, 28, 25	-
				36.1 g a.s./ m^2	4		
			Foliar, G	2.166	1	7, 14, 21, 28	-
	Cucumbers	Not reported.	Foliar [(b)]	2.9	1	30	-
			Soil (hydroponic) [(b)]	53.4 mg/plant (aqueous)	1	21	-
Leafy vegetables	Spinach	[^{14}C-carbamate]	Foliar, F	2.53	2	after the 1st appl: 0 after the 2nd appl.: 3	-
	Lettuce	Not reported.	Soil, G	drench: 7.22 g a.s./m^2	3	38	-
			Foliar, G	foliar spray: 1.083	3	21	-
Root and tuber vegetables	Potatoes	[^{14}C-propyl]	Foliar, F	2.45	3	42	-
			Foliar, F	2.166	6	7	After the 6th application the foliage had died and the spray was sprayed on soil
				10.83	6		

(a): Outdoor/field application (F) or glasshouse/protected/indoor application (G)
(b): F or G not stated

The metabolic pattern of propamocarb depicted in plants is strongly influenced by the mode of application of the product.

In lettuce, no information was provided on the amount of the total residues that could remain on the surface of the leaves at harvest. After foliar applications, residues are highly extractable (90 % TRR) and consist essentially of propamocarb. Two minor metabolites, accounting for less than 5 % of the TRR were also identified, hydroxypropyl-propamocarb[13] and N-oxide propamocarb[14], 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[15] resulting from N-demethylation and oxazolidine[16] resulting from the cyclization of the hydroxypropyl-propamocarb. Foliar treatment of tomato plants also resulted in propamocarb being the major constituent in tomato fruits (75 % TRR).

Propamocarb hydrochloride applied hydroponically or as soil treatment in tomatoes or lettuce results in a quite different metabolic pattern in harvested lettuce and tomatoes. The amounts of unchanged parent and of its structurally related metabolites are low, demonstrating a high rate of degradation in plants and in the soil. The total residues are essentially constituted of polar material rather similar for both crops, indicating the incorporation of labelled carbon in the endogenous material. In contrast to the observations made in lettuce and tomatoes, cucumbers grown hydroponically and treated with propamocarb hydrochloride applied in the nutrient solution showed significantly higher levels of parent propamocarb (50 % TRR).

In potato tubers, unchanged propamocarb was present at 2-15 % of the TRR. The vast majority of the radioactivity could be allocated to natural plant constituents (mainly starch), demonstrating the incorporation in plant material of CO_2 produced by the degradation of propamocarb hydrochloride.

EFSA concludes that the metabolism of propamocarb hydrochloride in the crops under consideration is sufficiently addressed and the residue definition for enforcement purposes and risk assessment in all plant commodities is defined as the sum of propamocarb and its salts, expressed as propamocarb since the identified metabolites in all crops were recovered at a low proportion (<10% TRR) and no significant contribution to the toxicological burden is expected. Validated analytical methods for enforcement of the proposed residue definition are available (see also section 1.1). The conclusions reached by EFSA reflect the views of the RMS and are also in line with those of the JMPR (FAO, 2006a) even if the wording used by JMPR is slightly different (the residue is defined as propamocarb (free base)).

3.1.1.2. Magnitude of residues

According to the RMS, the active substance propamocarb is authorised in northern and southern Europe for foliar or local application in a wide range of crops, both under outdoor and indoor conditions (see Appendix A). To assess the magnitude of propamocarb residues resulting from these GAPs, EFSA considered all residue trials reported in the PROFile, including residue trials evaluated in the framework of the peer review (EFSA, 2006) or in the framework of previous MRL applications (EFSA, 2011, 2012) and additional data submitted during the consultation of Member States (Belgium, 2012; France, 2012; Germany, 2012; Italy, 2012; Netherlands, 2013; United Kingdom, 2010). All available residue trials that, according to the RMS, comply with the authorised GAPs, are summarised in Table 3-2 and expressed as propamocarb. When residues were reported in the studies

[13] 2-hydroxypropyl [3-(dimethylamino)propyl]carbamate. See Appendix E.
[14] propyl [3-(dimethylnitroryl)propyl]carbamate. See Appendix E.
[15] Propyl [3-(methylamino)propyl]carbamate. See Appendix E.
[16] 3-[3-(dimethylamino)propyl]-4-hydroxy-4-methyl-1,3-oxazolidin-2-one. See Appendix E.

as propamocarb hydrochloride, the values were multiplied by 0.84 to obtain the results expressed as propamocarb.

The number of residue trials and extrapolations were evaluated in accordance with the European guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs (EC, 2011). A sufficient number of trials complying with the GAP was reported by the RMS for all crops under assessment, except in the following cases:

- Potato: the number of residue trials supporting the northern outdoor GAP on potatoes is compliant with the data requirements but a different GAP, authorised in Belgium by mutual recognition from the United Kingdom, was notified during the consultation of Member States. On the basis of three residue trials, this GAP was deemed to be not more critical than the one considered above (United Kingdom, 2010). However, the number of residues trials supporting the southern outdoor GAP is not compliant with the data requirements for this crop (4 trials instead of 8). Although tentative MRL and risk assessment values can be derived from this GAP, 4 additional trials complying with the southern GAP are still required.

- Peppers: the number of residue trials supporting the indoor GAP is compliant with the data requirements but trials were carried out with a slightly more critical GAP than the one authorised (including two drench treatments conducted in nursery). This is considered relevant as residue trials in other commodities have demonstrated that early drench treatments may have an impact on the final residue. Hence, although tentative MRL and risk assessment values can be derived from these trials, 8 trials on peppers complying with the indoor GAP are still required. Moreover, no residue trials are available to support the southern outdoor use. Considering that it is a major crop in Europe, 8 residue trials complying with the southern outdoor GAP are also required.

- Cucumbers: no residue trials are available to support the southern outdoor use. Although MRL and risk assessment values can be derived from the indoor GAP, 4 residue trials complying with the southern outdoor GAP are still required.

- Gherkins: no residue trials are available to support the indoor use and extrapolation from cucumbers is not possible as GAPs are significantly different. Although MRL and risk assessment values can be derived from the northern outdoor GAP, 4 residue trials complying with the indoor GAP are still required.

- Cauliflower: the number of residues trials supporting the indoor GAP is not compliant with the data requirements for this crop (4 trials instead of 8). Although tentative MRL and risk assessment values can be derived, 4 additional trials complying with the indoor GAP are still required.

- Chinese cabbage: as a no residue situation is expected from the indoor use and as trials for an identical GAP are available on head cabbage and cauliflower to demonstrate a no residue situation in brassica (Netherlands, 2013), EFSA considers that results from trials on head cabbage and cauliflower can be also extrapolated to chinese cabbage and no further data is required to support the indoor use. However, no residue trials are available to support the northern and southern outdoor uses. Considering that it is a minor crop in northern and southern Europe, 4 residue trials complying with the GAP are required for both areas. Meanwhile, MRL and risk assessment values are derived on the basis of the indoor GAP.

- Kale: as a no residue situation is expected from the indoor use on kale and as trials for an identical GAP are available on head cabbage and cauliflower to demonstrate a no residue situation in brassica (Netherlands, 2013), EFSA considers that results from trials on head

cabbage and cauliflower can be also extrapolated to kale and no further data is required to support the indoor use. No residue trials are available to support the French southern outdoor use. Nevertheless, according to the European guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs (EC, 2011), trials in only one area are necessary to cover both areas. Consequently, the absence of residue trials in the southern zone is considered acceptable and further residue trials are not required.

- Lettuce: the assessment of the indoor use is based on a GAP reported by Belgium, Germany and France (Belgium, 2012; France, 2012; Germany, 2012) which is supported by residue trials compliant with the GAP. A more critical indoor GAP was reported by the Netherlands during the consultation of Member States but residue trials compliant with the GAP were not available. Also considering that higher residue levels may be of concern for consumers, this use is considered as the critical one in this review. Member States are strongly recommended to reconsider any indoor GAP more critical than the one considered in this review in order not to have exceedances of the proposed MRL.

- Salad plants including *Brassica* spp (except lettuce): the number of residue trials on lettuce (open leaf varieties) supporting the indoor GAP for other salad plants is compliant with the data requirements but trials were carried out with a slightly more critical GAP than the one authorised (including two drench treatments conducted in nursery). This is considered relevant as residue trials in other commodities have demonstrated that early drench treatments may have an impact on the final residue. Hence, although tentative MRL and risk assessment values can be derived from these trials, 8 additional trials on lettuce (open leaves varieties) complying with the indoor GAP are still required. Moreover, no residue trials are available to support the northern and southern outdoor uses. Consequently, 8 trials on lettuce (open leaf varieties) complying with the GAPs are required for both areas.

- Fresh herbs: the number of residue trials on lettuce (open leaf varieties) supporting the indoor GAP for herbs is compliant with the data requirements but trials were carried out with a slightly more critical GAP than the one authorised (including two drench treatments conducted in nursery). This is considered relevant as residue trials in other commodities have demonstrated that early drench treatments may have an on the final residue. Hence, although tentative MRL and risk assessment values can be derived from these trials, trials on fresh herbs or on any crop allowing extrapolation to fresh herbs complying with the indoor GAP are still required.

- Beans, fresh with pods: 8 residue trials complying with the indoor GAP are available, but the method used was only validated for an LOQ of 0.1 mg/kg, which is not compliant with the LOQ validated for enforcement purpose (see section 1.1). Consequently, 8 trials on beans (fresh, with pods) in which samples were analysed with an LOQ of 0.01 mg/kg are still desirable (minor deficiency).

The potential degradation of residues during storage of the residue trials samples was also assessed. In the framework of the peer review, storage stability of propamocarb was demonstrated at -18°C for a period of 26 months in commodities with high water content (tomato, lettuce) (Ireland, 2004). According to the RMS, all residues trial samples reported in the PROFile were stored in compliance with the storage conditions reported above. Degradation of residues during storage of the trial samples is therefore not expected.

Consequently, the available residues data are considered sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation, except for potatoes, peppers, cauliflower, salad plants (except lettuce) and fresh herbs where only tentative MRLs can be derived (see also Table 3-2). Where several uses are authorised for one commodity, the final MRL proposal was derived from the most critical use and indicated in bold in Table 3-2.

Table 3-2: Overview of the available residues trials data

Commodity	Residue region [a]	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [b]	Highest residue (mg/kg) [c]	MRL proposal (mg/kg)	Median CF [d]	Comments
			Enforcement (sum of propamocarb and its salts, expressed as propamocarb)	Risk assessment (sum of propamocarb and its salts, expressed as propamocarb)					
Potatoes	NEU	Outdoor	8x<0.01	8x<0.01	0.01	0.01	0.01	1.00	Trials compliant with GAP.
	SEU	Outdoor	2x<0.01;0.01; 0.03	2x<0.01;0.01; 0.03	**0.01**	**0.03**	**0.07 (tentative)**	1.00	Trials compliant with GAP (Italy, 2012). Rber = 0.05 Rmax = 0.07 OECD = 0.06
Radishes	NEU	Outdoor	0.14; 0.47; 0.61; 0.92; 1.2	0.14; 0.47; 0.61; 0.92; 1.2	**0.61**	**1.20**	**3**	1.00	Trials compliant with GAP (EFSA, 2012). Rber = 2.12 Rmax = 2.39 OECD = 2.30
	EU	Indoor	0.27; 0.30; 0.36; 0.38	0.27; 0.30; 0.36; 0.38	0.33	0.38	1	1.00	Trials compliant with GAP (EFSA, 2012). Rber = 0.75 Rmax = 0.59 OECD = 0.98

Commodity	Residue region [a]	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [b]	Highest residue (mg/kg) [c]	MRL proposal (mg/kg)	Median CF [d]	Comments
			Enforcement (sum of propamocarb and its salts, expressed as propamocarb)	Risk assessment (sum of propamocarb and its salts, expressed as propamocarb)					
Onions	NEU	Outdoor	<0.01; 0.01; 2x0.02; 3x0.05; 0.21; 0.41; 1.3	<0.01; 0.01; 2x0.02; 3x0.05; 0.21; 0.41; 1.3	**0.05**	**1.30**	**2**	1.00	Trials compliant with GAP. Rber = 0.52 Rmax = 1.38 OECD = 1.82
	SEU	Outdoor	0.07; 0.05; 0.02; 0.03; 0.04; 0.02; 0.05; <0.01	0.07; 0.05; 0.02; 0.03; 0.04; 0.02; 0.05; <0.01	0.04	0.07	0.15	1.00	Trials compliant with GAP. Rber = 0.1 Rmax = 0.1 OECD = 0.12
Tomatoes Aubergines	NEU	Outdoor	0.06; 0.59; 1.93; 1.84; 0.45; 0.92; 0.11; 0.5	0.06; 0.59; 1.93; 1.84; 0.45; 0.92; 0.11; 0.5	**0.55**	1.93	**4**	1.00	Trials compliant with GAP. Rber = 3.22 Rmax = 3.1 OECD = 3.69
	SEU	Outdoor	0.16; 0.24; 1.26; 0.42; 0.09; 0.19; 0.14; 0.12	0.16; 0.24; 1.26; 0.42; 0.09; 0.19; 0.14; 0.12	0.18	1.26	2	1.00	Trials compliant with GAP. Rber = 0.75 Rmax = 1.57 OECD = 1.89
	EU	Indoor	0.32; 0.44; 0.46; 0.48; 0.52; 0.59; 0.74; 2.18	0.32; 0.44; 0.46; 0.48; 0.52; 0.59; 0.74; 2.18	0.50	**2.18**	4	1.00	Trials compliant with GAP. Rber = 1.4 Rmax = 2.64 OECD = 3.13

Commodity	Residue region [a]	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [b]	Highest residue (mg/kg) [c]	MRL proposal (mg/kg)	Median CF [d]	Comments
			Enforcement (sum of propamocarb and its salts, expressed as propamocarb)	Risk assessment (sum of propamocarb and its salts, expressed as propamocarb)					
Peppers	SEU	Outdoor	-	-	-	-	-	1.00	No residue trials available.
	EU	Indoor	2x<0.008; 0.02; 0.025; 0.08; 0.11; 0.11; 0.14; 0.15; 0.16; 0.22; 1.0	2x<0.008; 0.02; 0.025; 0.08; 0.11; 0.11; 0.14; 0.15; 0.16; 0.22; 1.0	0.11	1.00	1.5 (tentative)	1.00	Trials include two additional drench treatments compared to the critical GAP reported (Netherlands, 2013). Rber = 0.32 Rmax = 0.91 OECD = 1.25
Cucumbers Courgettes	NEU	Outdoor	0.9; 0.6; 1.3; 1.0; 0.7; 0.9; 0.68; 0.9; 1.6; 2.2; 2.5; 1.7	0.9; 0.6; 1.3; 1.0; 0.7; 0.9; 0.68; 0.9; 1.6; 2.2; 2.5; 1.7	0.95	2.50	4	1.00	Trials on cucumbers compliant with GAP. Not authorised on courgettes. Rber = 3.35 Rmax = 2.95 OECD = 3.75
	SEU	Outdoor	-	-	-	-	-	1.00	No residue trials available. Not authorised on courgettes.
	EU	Indoor	2.8; 1.8; 2.1; 1.6; 2.2; 0.9; 1.1; 1.0; 1.2	2.8; 1.8; 2.1; 1.6; 2.2; 0.9; 1.1; 1.0; 1.2	**1.60**	**2.80**	**5**	1.00	Trials on cucumber compliant with GAP. Rber = 4.3 Rmax = 3.59 OECD = 4.90

Commodity	Residue region [a]	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [b]	Highest residue (mg/kg) [c]	MRL proposal (mg/kg)	Median CF [d]	Comments
			Enforcement (sum of propamocarb and its salts, expressed as propamocarb)	Risk assessment (sum of propamocarb and its salts, expressed as propamocarb)					
Gherkins	NEU	Outdoor	0.9; 0.6; 1.3; 1.0; 0.7; 0.9; 0.68; 0.9; 1.6; 2.2; 2.5; 1.7	0.9; 0.6; 1.3; 1.0; 0.7; 0.9; 0.68; 0.9; 1.6; 2.2; 2.5; 1.7	0.95	2.50	4	1.00	Extrapolation from the northern outdoor GAP on cucumbers.
	EU	Indoor	-	-	-	-	-	1.00	No residue trials available. Extrapolation from the indoor GAP on cucumbers is not possible as GAPs are different.
Cucurbits with inedible peel	SEU	Outdoor	0.1; 0.28; 0.38; 0.4; 0.44; 0.57; 0.6; 0.65; 0.92; 1.1	0.1; 0.28; 0.38; 0.4; 0.44; 0.57; 0.6; 0.65; 0.92; 1.1	**0.51**	**1.10**	**2**	1.00	Trials on melon compliant with GAP. Rber = 1.44 Rmax = 1.41 OECD = 1.73
	EU	Indoor	0.03; 0.03; 0.05; 0.07; 0.07; 0.13; 0.14; 0.15; 0.23; 0.25; 0.34; 0.83	0.03; 0.03; 0.05; 0.07; 0.07; 0.13; 0.14; 0.15; 0.23; 0.25; 0.34; 0.83	0.14	0.83	1.5	1.00	Trials on melon compliant with GAP on cucurbits with inedible peel. Rber = 0.49 Rmax = 0.8 OECD = 1.08

Commodity	Residue region [a]	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [b]	Highest residue (mg/kg) [c]	MRL proposal (mg/kg)	Median CF [d]	Comments
			Enforcement (sum of propamocarb and its salts, expressed as propamocarb)	Risk assessment (sum of propamocarb and its salts, expressed as propamocarb)					
Broccoli	NEU	Outdoor	Broccoli: 0.16; 0.17; 0.29; 0.29 Cauliflower: <0.01; 0.01; 0.03; 0.04; 0.08	Broccoli: 0.16; 0.17; 0.29; 0.29 Cauliflower: <0.01; 0.01; 0.03; 0.04; 0.08	0.08	0.29	0.6	1.00	Combined trials on broccoli and cauliflower compliant with GAP. Rber = 0.46 Rmax = 0.46 OECD = 0.57
	SEU	Outdoor	Broccoli: 0.20; 0.32; 0.52; 0.97; 1.7 Cauliflower: 0.01; 0.05; 0.20; 0.82	0.20; 0.97; 0.32; 0.52; 0.05; 0.01; 0.20; 1.7; 0.82	**0.32**	**1.70**	**3**	1.00	Combined trials on broccoli and cauliflower compliant with GAP. Rber = 1.79 Rmax = 2.2 OECD = 2.73
	EU	Indoor	12 x <0.01	12 x <0.01	0.01	0.01	0.01*	1.00	Combined trials on cauliflower (8) and head cabbage (4) compliant with GAP (Netherlands, 2013).

Commodity	Residue region [a]	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [b]	Highest residue (mg/kg) [c]	MRL proposal (mg/kg)	Median CF [d]	Comments
			Enforcement (sum of propamocarb and its salts, expressed as propamocarb)	Risk assessment (sum of propamocarb and its salts, expressed as propamocarb)					
Cauliflower	NEU	Outdoor	Broccoli: 0.16; 0.17; 0.29; 0.29 Cauliflower: <0.01; 0.01; 0.03; 0.04; 0.08	Broccoli: 0.16; 0.17; 0.29; 0.29 Cauliflower: <0.01; 0.01; 0.03; 0.04; 0.08	0.08	0.29	0.6	1.00	Combined trials on broccoli and cauliflower compliant with GAP. Rber = 0.46 Rmax = 0.46 OECD = 0.57
	SEU	Outdoor	Broccoli: 0.20; 0.32; 0.52; 0.97; 1.7 Cauliflower: 0.01; 0.05; 0.20; 0.82	Broccoli: 0.20; 0.32; 0.52; 0.97; 1.7 Cauliflower: 0.01; 0.05; 0.20; 0.82	0.32	1.70	3	1.00	Combined trials on broccoli and cauliflower compliant with GAP. Rber = 1.79 Rmax = 2.2 OECD = 2.73
	EU	Indoor	2x<0.1; 2.38; 3.67	2x<0.1; 2.38; 3.67	**1.24**	**3.67**	**10 (tentative)**	1.00	Trials compliant with the GAP (Belgium, 2013). Rber = 6.70 Rmax = 10.66 OECD = 8.64
Brussels sprouts	NEU	Outdoor	0.2; 0.24; 0.25; 0.46; 0.48; 0.49; 0.64; 1.3	0.2; 0.24; 0.25; 0.46; 0.48; 0.49; 0.64; 1.3	**0.47**	**1.30**	**2**	1.00	Trials compliant with GAP. Rber = 1.21 Rmax = 1.64 OECD = 1.93
	EU	Indoor	12 x <0.01	12 x <0.01	0.01	0.01	0.01*	1.00	Combined trials on cauliflower (8) and head cabbage (4) compliant with GAP (Netherlands, 2013).

Commodity	Residue region [a]	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [b]	Highest residue (mg/kg) [c]	MRL proposal (mg/kg)	Median CF [d]	Comments
			Enforcement (sum of propamocarb and its salts, expressed as propamocarb)	Risk assessment (sum of propamocarb and its salts, expressed as propamocarb)					
Head cabbage	NEU	Outdoor	0.03; 0.08; 0.36; 0.13; 0.32; 0.21; 0.18; 0.24	0.03; 0.08; 0.36; 0.13; 0.32; 0.21; 0.18; 0.24	**0.20**	**0.36**	**0.7**	1.00	Trials compliant with GAP. Rber = 0.6 Rmax = 0.56 OECD = 0.65
	SEU	Outdoor	0.1; 0.06; 0.23; 0.28	0.1; 0.06; 0.23; 0.28	0.17	0.28	0.6	1.00	Trials compliant with GAP. Rber = 0.54 Rmax = 0.7 OECD = 0.58
	EU	Indoor	12 x <0.01	12 x <0.01	0.01	0.01	0.01*	1.00	Combined trials on cauliflower (8) and head cabbage (4) compliant with GAP (Netherlands, 2013).
Chinese cabbage	NEU	Outdoor	-	-	-	-	-	1.00	No residue trials available.
	SEU	Outdoor	-	-	-	-	-	1.00	No residue trials available.
	EU	Indoor	12 x <0.01	12 x <0.01	0.01	0.01	0.01*	1.00	Although not foreseen in the current guidance documents, extrapolation from the indoor GAPs on head and flowering brassica is acceptable to demonstrate a no residue situation.

Commodity	Residue region [a]	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [b]	Highest residue (mg/kg) [c]	MRL proposal (mg/kg)	Median CF [d]	Comments
			Enforcement (sum of propamocarb and its salts, expressed as propamocarb)	Risk assessment (sum of propamocarb and its salts, expressed as propamocarb)					
Kale	NEU	Outdoor	0.33; 0.39; 0.46; 3.9; 4.0; 4.0; 5.2; 10.7; 11.8	0.33; 0.39; 0.46; 3.9; 4.0; 4.0; 5.2; 10.7; 11.8	**4.00**	**11.80**	**20**	1.00	Trials compliant with GAP (EFSA, 2012). Rber = 15.9 Rmax = 17.38 OECD = 21.48
	SEU	Outdoor	-	-	-	-	-	1.00	The southern use is only authorised in France. NEU trials are sufficient to cover the SEU GAP.
	EU	Indoor	12 x <0.01	12 x <0.01	0.01	0.01	0.01*	1.00	Although not foreseen in the current guidance documents, extrapolation from the indoor GAPs on head and flowering brassica is acceptable to demonstrate a no residue situation.
Kohlrabi	NEU	Outdoor	0.03; 0.03; 0.04; 0.13	0.03; 0.03; 0.04; 0.13	0.04	0.13	0.3	1.00	Trials compliant with GAP. Rber = 0.22 Rmax = 0.31 OECD = 0.25

Commodity	Residue region [a]	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [b]	Highest residue (mg/kg) [c]	MRL proposal (mg/kg)	Median CF [d]	Comments
			Enforcement (sum of propamocarb and its salts, expressed as propamocarb)	Risk assessment (sum of propamocarb and its salts, expressed as propamocarb)					
Lettuce	NEU	Outdoor	1.2; 3.4; 5.2; 6.4; 6.9; 7.0; 7.5; 12	1.2; 3.4; 5.2; 6.4; 6.9; 7.0; 7.5; 12	**6.65**	12.00	20	1.00	Trials conducted with open leaf varieties compliant with GAP. Rber = 14.75 Rmax = 16.31 OECD = 18.88
	SEU	Outdoor	2.9; 3.7; 4.1; 4.11; 4.4; 5; 7.1; 9.1; 13.4; 37	2.9; 3.7; 4.1; 4.11; 4.4; 5; 7.1; 9.1; 13.4; 37	4.70	**37.00**	**50**	1.00	Trials compliant with GAP on lettuce. Rber = 20.35 Rmax = 39.10 OECD = 50.34
	EU	Indoor	<0.008; 1.6; 1.8; 2.1; 2.4; 3; 4.1; 4.6; 4.7; 5.1; 5.2; 7; 7.3; 7.6; 10.1; 13.4; 14.5; 16; 25.3; 26.9; 29.3	<0.008; 1.6; 1.8; 2.1; 2.4; 3; 4.1; 4.6; 4.7; 5.1; 5.2; 7; 7.3; 7.6; 10.1; 13.4; 14.5; 16; 25.3; 26.9; 29.3	5.20	29.30	40	1.00	Trials compliant with GAP on lettuce (Germany, 2012, also reported by France, Italy and the Netherlands). A more critical GAP is reported by the Netherlands but is not sufficiently supported by data (see also body text). Rber = 27.9 Rmax = 29.76 OECD = 43.93

Commodity	Residue region [a]	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [b]	Highest residue (mg/kg) [c]	MRL proposal (mg/kg)	Median CF [d]	Comments
			Enforcement (sum of propamocarb and its salts, expressed as propamocarb)	Risk assessment (sum of propamocarb and its salts, expressed as propamocarb)					
Lamb's lettuce Scarole (broad-leaf endive) Cress Land cress Rocket, rucola Red mustard Leaves and sprouts of Brassica spp	NEU	Outdoor	-	-	-	-	-	1.00	No GAP on cress, land cress, red mustard and leaves and sprouts of Brassica spp. No GAP compliant residue trials available for the other crops and extrapolation for lettuce is not possible as GAPs are different.
	SEU	Outdoor	-	-	-	-	-	1.00	No GAP compliant residue trials available and extrapolation for lettuce is not possible as GAPs are different.
	EU	Indoor	0.01; 0.65; 0.71; 2.9; 4; 4.2; 5.5; 7.6; 8.1	0.01; 0.65; 0.71; 2.9; 4; 4.2; 5.5; 7.6; 8.1	4.00	8.10	20 (tentative)	1.00	Trials on lettuce (open leaves varieties) include two additional drench treatments compared to the critical GAP reported (Netherlands, 2013). Rber = 12.75 Rmax = 13.10 OECD = 15.63

Commodity	Residue region [a]	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [b]	Highest residue (mg/kg) [c]	MRL proposal (mg/kg)	Median CF [d]	Comments
			Enforcement (sum of propamocarb and its salts, expressed as propamocarb)	Risk assessment (sum of propamocarb and its salts, expressed as propamocarb)					
Fresh herbs	NEU	Outdoor	1.2; 3.4; 5.2; 6.4; 6.9; 7.0; 7.5; 12	1.2; 3.4; 5.2; 6.4; 6.9; 7.0; 7.5; 12	6.65	12.00	20	1.00	Extrapolation from the northern outdoor GAP on lettuce is possible.
	EU	Indoor	0.92; 3.11; 3.95; 9.24; 10.08; 10.92; 12.6; 15.12	0.92; 3.11; 3.95; 9.24; 10.08; 10.92; 12.6; 15.12	**9.66**	**15.12**	**30 (tentative)**	1.00	Trials on lettuce (open leaves varieties) include two additional drench treatments compared to the critical GAP reported (Netherlands, 2013). Rber = 24.36 Rmax = 24.24 OECD = 28.31
Spinach	NEU	Outdoor	2.9; 10; 1.6; 18; 3.27; 1.0; 3.5; 7.6	2.9; 10; 1.6; 18; 3.27; 1.0; 3.5; 7.6	3.39	18.00	30	1.00	Trials compliant with GAP. Rber = 18.8 Rmax = 24.27 OECD = 28.92
	SEU	Outdoor	6.2; 8.4; 16; 35; 45	6.2; 8.4; 16; 35; 45	**16**	**45**	**100**	1.00	Trials compliant with GAP. There is a high uncertainty due to the small dataset. Rber = 80 Rmax = 94.08 OECD = 90.49
Witloof	EU	Indoor	0.03; 0.09; 0.1; 0.1; 0.13; 0.18; 0.25; 0.34; 0.35; 0.37; 1.8; 5.3; 7.7; 8	0.03; 0.09; 0.1; 0.1; 0.13; 0.18; 0.25; 0.34; 0.35; 0.37; 1.8; 5.3; 7.7; 8	0.30	8.00	15	1.00	Trials compliant with GAP. Rber = 5.35 Rmax = 9.42 OECD = 13.48
Beans, fresh with pods	EU	Indoor	8 x <0.1	8 x <0.1	0.10	0.10	0.1	1.00	Trials compliant with GAP (Belgium, 2012).

Commodity	Residue region [a]	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [b]	Highest residue (mg/kg) [c]	MRL proposal (mg/kg)	Median CF [d]	Comments
			Enforcement (sum of propamocarb and its salts, expressed as propamocarb)	Risk assessment (sum of propamocarb and its salts, expressed as propamocarb)					
Leek	NEU	Outdoor	0.2; 0.7; 0.9; 2.4; 2.6; 4.0; 5.5; 15	0.2; 0.7; 0.9; 2.4; 2.6; 4.0; 5.5; 15	2.50	15.00	30	1.00	Trials compliant with GAP. Rber = 10.21 Rmax = 19.25 OECD = 23.19

(a): NEU (Northern and Central Europe), SEU (Southern Europe and Mediterranean), EU (i.e outdoor 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 residues trial.
(*): Indicates that the MRL is set at the limit of analytical quantification.

3.1.1.3. Effect of industrial processing and/or household preparation

The effect of processing on the nature of propamocarb was not investigated in the framework of the peer review. As quantifiable residues of propamocarb are expected in the treated crops, a hydrolysis study investigating the effect of processing on the nature of the residues would be desirable.

Studies investigating the magnitude of residues in processed commodities of tomatoes, cabbage and spinach were assessed by the RMS after Annex I inclusion or by JMPR (2006a). An overview of all available processing studies is available in Table 3-3. Processing factors for enforcement and risk assessment were derived for several processed products of tomatoes and head cabbage, and for cooked spinach. Based on the available balance studies, residues of propamocarb are expected to be removed by washing and when cooking, only 10 % of parent propamocarb were degraded.

Pending the nature of the residues in processed commodities, all processing factors are considered on a tentative basis and it cannot be excluded that additional processing studies may be required in order to derive robust processing factors for enforcement purposes.

Table 3-3: Overview of the available processing studies

Processed commodity	Number of studies	Median PF [(a)]	Median CF [(b)]	Comments
Enforcement residue definition: sum of propamocarb and its salts, expressed as propamocarb				
Indicative processing factors (nature of residues not investigated)				
Tomatoes, peeled and canned	4	0.30	1.00	PROFile
Tomatoes, paste	4	3.10	1.00	
Tomatoes, ketchup	4	0.70	1.00	
Tomatoes, juice	4	0.45	1.00	
Head cabbage, cooked	4	0.17	1.00	JMPR, 2006.
Head cabbage, sauerkraut	4	0.19	1.00	
Head cabbage, sauerkraut juice	4	0.39	1.00	
Spinach, cooked	4	0.88	1.00	Trials on cooked spinach leaves may be extrapolated to other cooked leafy vegetables (PROFile).

(a): The median processing factor is obtained by calculating the median of the individual processing factors of each processing study.
(b): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors of each processing study.

3.1.2. Rotational crops

3.1.2.1. Preliminary considerations

All crops under consideration may be grown in rotation. According to the laboratory soil degradation studies evaluated in the framework of the peer review, DT_{90} value of propamocarb hydrochloride is expected to range between 57 – 78 days which is lower than the trigger value of 100 days (EFSA, 2006). According to the European guidelines on rotational crops (EC, 1997b), further investigation of

residues in rotational crops is in principle not required and relevant residues in rotational crops are not expected.

3.1.2.2. Nature of residues

Although not required, the metabolism of propamocarb in rotational crops – lettuce, radish, wheat – has been evaluated (Ireland, 2004). A confined rotational crop study investigating the nature of residues following different plant-back intervals is available. The characteristics of this study are summarised in Table 3-4.

Table 3-4: Summary of available metabolism studies in rotational crops

Crop group	Crop	Label position	Application and sampling details				
			Method, F or G [(a)]	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks
Leafy vegetables	Lettuce	^{14}C-aminopropyl	Bare soil, G	5.96 – 6.16	30, 120, 365	n.r.	-
Root and tuber vegetables	Radish						
Cereals	Wheat						

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

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

Consequently, metabolism in primary and rotational crops was found to be similar and a specific residue definition for rotational crops is not deemed necessary. Although the oxazolidine metabolite was recovered in significant amounts in wheat straw, this metabolism study was carried out with plants grown in pots with an overdosed application rate. Consequently, it is expected that this metabolite will not be present in significant amounts following realistic application conditions (<0.01 mg eq/kg).

3.1.2.3. Magnitude of residues

Rotational crop field trials were evaluated in the framework of the peer review (Ireland, 2004). Propamocarb was applied on bare soil at 4 x 1.68 kg a.s./ha (1 N) and the magnitude of residues was investigated on several succeeding crops (wheat, soybean, sugar beet, table beet and dry beans) sown at three different plant-back intervals (30, 60 and 365 days) following application of the active substance. Wheat was the only crop grown on 30 days aged soils which contained parent residues at or above LOQ. Further rotational crop field trials were submitted where propamocarb was applied on white cabbage with 2 drench applications at a dose rate of 72.2 kg a.s./ha followed by 2 foliar applications at 3.61 kg a.s./ha (1 N) and the magnitude of residues was investigated on wheat and

lamb's lettuce sown at two different plant-back intervals (81 – 102 days for wheat and 52 – 59 days for lamb's lettuce) (Ireland, 2012). No residue was detected (<LOQ of the method) in any of the following crops. In a third set of rotational crop field trials, propamocarb was sprayed on lettuce as the primary crop at 3 x 1.33 kg a.s./ha (1.8 N) and the magnitude of propamocarb residues was investigated in lettuce, carrot, winter wheat and barley sown at the 30 day plant-back interval. Residues were < 0.01 mg/kg in all the edible parts of the rotated crops and < 0.05 mg/kg for straw.

Based on the rotational crop field studies and considering that the application rate of propamocarb within the EU ranges between 0.84 – 1.85 kg a.s./ha and the fact that propamocarb was applied to a bare soil (interception of propamocarb by the plants is expected in practice), it can be concluded that propamocarb residue levels in rotational commodities are not expected to exceed 0.01 mg/kg, provided that propamocarb is applied in compliance with the GAPs reported in Appendix A. EFSA is of the opinion that the label restriction proposed during the peer review (EFSA, 2006) can be cancelled.

3.2. Nature and magnitude of residues in livestock

3.2.1. Dietary burden of livestock

Propamocarb is authorised for use on several crops that might be fed to livestock. The median and maximum dietary burdens were therefore calculated for different groups of livestock using the agreed European methodology (EC, 1996). The input values for all relevant commodities have been selected according to the recommendations of JMPR (FAO, 2009) and are summarised in Table 3-5.

Table 3-5: Input values for the dietary burden calculation

Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: sum of propamocarb and its salts, expressed as propamocarb				
Cabbage	0.20	Median residue	0.36	Highest residue
Kale	4.00	Median residue	11.80	Highest residue
Potatoes	0.01	Median residue	0.03	Highest residue

The results of the calculations are reported in Table 3-6. The calculated dietary burdens for all groups of livestock were found to exceed the trigger value of 0.1 mg/kg DM. Further investigation of residues is therefore required in all commodities of animal origin.

Table 3-6: Results of the dietary burden calculation

	Median dietary burden (mg/kg bw per d)	Maximum dietary burden (mg/kg bw per d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Risk assessment residue definition: sum of propamocarb and its salts, expressed as propamocarb					
Dairy ruminants	0.364	1.075	Kale	29.86	Y
Meat ruminants	0.430	1.269	Kale	29.52	Y
Poultry	0.091	0.269	Kale	4.27	Y
Pigs	0.173	0.510	Kale	12.76	Y

3.2.2. Nature of residues

The nature of propamocarb residues in commodities of animal origin was investigated in the framework of Directive 91/414/EEC (Ireland, 2004) or after Annex I inclusion (Ireland, 2012). Reported metabolism studies include one study in lactating cows and one study in laying hens using ^{14}C-labelled propamocarb. The characteristics of these studies are summarised in Table 3-7.

Table 3-7: Summary of available metabolism studies in livestock

Group	Species	Label position	No of animal	Application details		Sample details	
				Rate (mg/kg bw per d)	Duration (days)	Commodity	Time
Lactating ruminants	Cow	^{14}C-carbon	1	2	7	Milk	Twice daily
						Urine and faeces	Twice daily
						Tissues	At sacrifice
Laying poultry	Hens		12	1.02	14	Eggs	Once daily
						Excreta	n.r.
						Tissues	At sacrifice

n.r.: Not reported

Lactating cows and laying hens were dosed with 2 and 1.02 mg/kg bw per d of propamocarb hydrochloride respectively, corresponding to approximately 1.6 and 3.8 times the exposure of meat ruminant and poultry, respectively.

In cow, over 80 % of the administered dose was excreted in urine and faeces while only 0.7% and 0.46% of the AR remained in tissues and milk, respectively. No quantifiable residues (<0.01 mg/kg) were recovered in fat and no furher metabolites identification was attempted. The highest total radioactive residues were found in liver (0.415 mg eq/kg) and in kidney (0.107 mg eq/kg) and to a minor extent in muscle (0.02 mg eq/kg) and in milk (0.057 mg eq/kg). Propamocarb accounted for 24.6 % TRR in muscle (0.005 mg/kg), 23.5 % TRR in kidney (0.025 mg/kg), 6.2 % TRR in liver (0.026 mg/kg) and 6.0 % TRR in milk (0.003 mg/kg). Parent compound was either oxidized to form

N-oxide propamocarb, or hydroxylated at the propyl side chain to form the 2-hydroxy-propamocarb[17] followed by a cyclisation to form the oxazolidine-2-one propamocarb metabolite. Another route of degradation consisted of demethylation of the parent molecule into the N-desmethyl propamocarb. Metabolite N-oxide propamocarb was the predominant metabolite of the total residues found in kidney (41 % TRR – 0.044 mg/kg), liver (49 % TRR – 0.203 mg/kg), muscle (40.5 % TRR – 0.008 mg/kg) and also in milk (21 % TRR – 0.012 mg/kg). Oxazolidine-2-one propamocarb occurred in significant amounts in kidney, liver and milk (14 – 23 % TRR; 0.014 – 0.09 mg/kg). 2-hydroxy propamocarb was the major metabolite of the total residues in milk (37.5 % TRR – 0.022 mg/kg) but was also identified at a lower level in liver (5 % TRR) and kidney (13 % TRR). N-desmethyl propamocarb was either not detected (kidney, liver) or identified at a trace level in milk and muscle (up to 0.002 mg/kg).

In hens, the majority of the residues (92 to 99 % TRR) in the egg and tissues was extractable. The total radioactive residues accounted for 0.254 mg/kg in eggs, 0.492 mg/kg in liver, 0.117 – 0.135 mg/kg in muscle and 0.042 – 0.065 mg/kg in fat. The predominant compound of the total residues was the N-desmethyl propamocarb in eggs (45 % TRR), liver (22 % TRR), muscle (29 % TRR) and to a minor extend in fat (6 % TRR) whilst the parent compound occurred at a lower level in all matrices (2 – 12 % TRR). Bis desmethyl propamocarb[18] and N-oxide propamocarb accounted for less than 10% TRR. It is noted that a significant fraction of the radioactive residues remained uncharacterized in liver and muscle (32 % and 41 % TRR, respectively).

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

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

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

3.2.3. Magnitude of residues

The magnitude of propamocarb residues in ruminants and poultry was investigated in two feeding studies with lactating cows and laying hens provided after Annex I inclusion (Ireland, 2012).

[17] 2-hydroxypropyl [3-(dimethylamino)propyl]carbamate (also hydroxypropylpropamocarb). See Appendix E.
[18] propyl [3-(amino)propyl]carbamate. See Appendix E.

The feeding study on ruminants is not considered acceptable as it was underdosed and therefore no reliable conclusion can be drawn on the magnitude of residues in ruminants and pigs. The feeding study on poultry however was considered as acceptable. Four groups of laying hens, each consisting of twelve animals were dosed for 36 consecutive days with propamocarb at levels of 1.2, 4.1, 12.3 and 41.1 mg/kg in the diet (equivalent to 0.076, 0.259, 0.777 and 2.596 mg/kg bw, *i.e.* 0.28X, 1X, 2.9 X and 9.7X). The samples were analysed for both parent propamocarb and N-desmethyl propamocarb and results of the poultry feeding study are summarised in Table 3-8. In the 9.7X eggs, a plateau level was reached after 28 days of exposure.

EFSA highlights that results of the hen feeding study were only reported for the sum of compounds which did not allow deriving separate results for enforcement and risk assessment. EFSA has used on a tentative basis the conversion factor for risk assessment derived from the metabolism study in order to estimate the residue levels according to the enforcement residue definition. However, the individual results for propamocarb and its metabolite are still considered necessary by EFSA in order to ensure derving more robust MRLs and risk assessment values.

No storage stability data for the residues of propamocarb and its relevant metabolites in milk and ruminant tissues were reported. A storage stability study in milk and tissues is therefore required for all the relevant compounds included in the risk assessment residue definition and covering the maximum storage period of the residue samples of the requested feeding study. Samples from the poultry feeding study were stored for less than 1 month under frozen conditions and a storage stability study is therefore not required for those commodities (EC, 1997f).

Consequently, the available data are considered as sufficient for deriving MRLs in hens matrices. These MRLs were derived in compliance with the latest recommendations on this matter (FAO, 2009) and are summarised in Table 3-8. Considering that an analytical method is required for enforcement purposes and that further clarification on the individual results for propamocarb and its metabolite in the hen metabolism study are still necessary, the MRL proposals should be regarded as tentative only.

Regarding ruminants and pigs, tentative MRLs and risk assessment values were derived from the metabolism study and are summarised in Table 3-8. A representative ruminants feeding study supported by storage stability data is required in order to derive robust MRLs and risk assessment values.

Table 3-8: Overview of the values derived from the ruminant metabolism and poultry feeding studies

Commodity	Dietary burden		Results of the livestock feeding study						Median residue (mg/kg)[b]	Highest residue (mg/kg)[c]	MRL proposal (mg/kg)	CF for RA [d]
	Med. (mg/kg bw per d)	Max. (mg/kg bw per d)	Dose Level (mg/kg bw per d)[a]	No	Result for enf.		Result for RA					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
Enforcement residue definition: N-oxide propamocarb **Risk assessment residue definition:** sum of propamocarb, N-oxide propamocarb, oxazolidin-2-one propamocarb and 2-hydroxypropamocarb expressed as propamocarb												
Pig muscle/meat [e]	0.173	0.510	2	1	n.r.	0.01	n.r.	0.01	0.01	0.01	0.01 (tentative)	1.7
Pig fat			2	1	n.r.	0.01	n.r.	0.01	0.01	0.01	0.01 (tentative)	1.0
Pig liver			2	1	n.r.	0.20	n.r.	0.34	0.02	0.05	0.1 (tentative)	1.7
Pig kidney			2	1	n.r.	0.04	n.r.	0.10	0.01	0.01	0.02 (tentative)	2.2
Ruminant muscle/meat [e]	0.430	1.269	2	1	n.r.	0.01	n.r.	0.01	0.01	0.01	0.01 (tentative)	1.7
Ruminant fat			2	1	n.r.	0.01	n.r.	0.01	0.01	0.01	0.01 (tentative)	1.0
Ruminant liver			2	1	n.r.	0.20	n.r.	0.34	0.04	0.13	0.2 (tentative)	1.7
Ruminant kidney			2	1	n.r.	0.04	n.r.	0.10	0.01	0.03	0.05 (tentative)	2.2
Milk	0.364	1.075	2	1	n.r.	0.01	n.r.	0.05	0.01	0.01	0.01 (tentative)	4.25

Commodity	Dietary burden		Results of the livestock feeding study						Median residue (mg/kg)[b]	Highest residue (mg/kg)[c]	MRL proposal (mg/kg)	CF for RA [d]
	Med. (mg/kg bw per d)	Max. (mg/kg bw per d)	Dose Level (mg/kg bw per d)[a]	No	Result for enf.		Result for RA					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
Enforcement residue definition: N-desmethyl propamocarb **Risk assessment residue definition:** sum of propamocarb and N-desmethyl propamocarb, expressed as propamocarb												
Poultry muscle/meat [e]	0.091	0.269	0.26	12	n.r.	0.02 [f]	n.r.	0.02	0.01	0.02	0.02 (tentative)	1.3
			0.78	12	n.r.	0.04 [f]	n.r.	0.04				
			2.60	12	n.r.	0.10 [f]	n.r.	0.12				
Poultry fat			0.26	12	n.r.	0.005 [f]	n.r.	0.01	0.01	0.01	0.01 (tentative)	1.3
			0.78	12	n.r.	0.01 [f]	n.r.	0.02				
			2.60	12	n.r.	0.13 [f]	n.r.	0.17				
Poultry liver			0.26	12	n.r.	0.03 [f]	n.r.	0.04	0.01	0.03	0.05 (tentative)	1.3
			0.78	12	n.r.	0.06 [f]	n.r.	0.08				
			2.60	12	n.r.	0.11 [f]	n.r.	0.16				
Eggs			0.26	144	n.r.	0.04 [f]	n.r.	0.05	0.01	0.04	0.05 (tentative)	1.3
			0.78	144	n.r.	0.09 [f]	n.r.	0.12				
			2.60	288	n.r.	0.37 [f]	n.r.	0.47				

n.r.: Not reported
(a): Based on a 1.9 kg body weight; animal consuming 0.12 kg feed DM/day.
(b): Median residue value according to the enforcement residue definition, derived by interpolation/extrapolation from the feeding study for the median dietary burden (FAO, 2009).
(c): Highest residue value (tissues, eggs) or mean residue value (milk) according to the enforcement residue definition, derived by interpolation/extrapolation of the maximum dietary burden between the relevant feeding groups of the study (FAO, 2009).
(d): The median conversion factor for enforcement to risk assessment.
(e): While the results of the livestock feeding study refer to the muscle, the MRL proposal and risk assessment values are applicable to the meat.
(f): Results for enforcement were tentatively calculated using the risk assessment values and the conversion factors derived from the metabolism study.
(*): Indicates that the MRL is set at the limit of analytical quantification.

4. Consumer risk assessment

In the framework of this review, only the uses of propamocarb reported by the RMS in Appendix A were considered, however the use of propamocarb was previously also assessed by the JMPR (FAO, 2006a). The CXLs, resulting from this assessment by JMPR and adopted by the CAC, are now international recommendations that need to be considered by European risk managers when establishing MRLs. In order to facilitate consideration of these CXLs by risk managers, the consumer exposure was calculated both with and without consideration of the existing CXLs (see Appendix C.2).

4.1. Consumer risk assessment without consideration of the existing CXLs

Chronic and acute exposure calculations for all crops reported in the framework of this review were performed using revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo) (EFSA, 2007). Input values for the exposure calculations were derived in compliance with Appendix D and are summarised in Table 4-1. The (tentative) median and highest residue values selected for chronic and acute intake calculations are based on the residue levels in the raw agricultural commodities reported in section 3. The contributions of other commodities, for which no GAP was reported in the framework of this review, were not included in the calculation. For products of animal origin, the conversion factors derived under section 3.2 have been included in the calculation on a tentative basis.

Table 4-1: Input values for the consumer risk assessment (without consideration of CXLs)

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: sum of propamocarb and its salts, expressed as propamocarb				
Potatoes	0.01	Median residue (tentative) [a]	0.03	Highest residue (tentative) [a]
Radishes	0.61	Median residue [b]	1.20	Highest residue [b]
Onions	0.05	Median residue [b]	1.30	Highest residue [b]
Tomatoes	0.55	Median residue [b]	2.18	Highest residue [b]
Peppers	0.11	Median residue (tentative) [a]	1.00	Highest residue (tentative) [a]
Aubergines (egg plants)	0.55	Median residue [b]	2.18	Highest residue [b]
Cucumbers	1.60	Median residue [b]	2.80	Highest residue [b]
Gherkins	0.95	Median residue [b]	2.50	Highest residue [b]
Courgettes	1.60	Median residue [b]	2.80	Highest residue [b]
Cucurbits with inedible peel	0.51	Median residue [b]	1.10	Highest residue [b]
Broccoli	0.32	Median residue [b]	1.70	Highest residue [b]
Cauliflower	1.24	Median residue (tentative) [a]	3.67	Highest residue (tentative) [a]
Brussels sprouts	0.47	Median residue [b]	1.30	Highest residue [b]
Head cabbage	0.20	Median residue [b]	0.36	Highest residue [b]

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Chinese cabbage	0.01*	Median residue [b]	0.01*	Highest residue [b]
Kale	4.00	Median residue [b]	11.80	Highest residue [b]
Kohlrabi	0.04	Median residue [b]	0.13	Highest residue [b]
Salad plants (except lettuce)	4.00	Median residue (tentative) [a]	8.10	Highest residue (tentative) [a]
Lettuce	6.65	Median residue [b]	37.00	Highest residue [b]
Spinach	16.00	Median residue [b]	45.00	Highest residue [b]
Witloof	0.30	Median residue [b]	8.00	Highest residue [b]
Fresh herbs	9.67	Median residue (tentative) [a]	15.12	Highest residue (tentative) [a]
Beans (fresh, with pods)	0.10	Median residue [b]	0.10	Highest residue [b]
Leek	2.50	Median residue [b]	15.00	Highest residue [b]
Risk assessment residue definition: sum of propamocarb, N-oxide propamocarb, oxazolidin-2-one propamocarb and 2-hydroxypropamocarb expressed as propamocarb				
Swine meat	0.02	Median residue x CF (tentative) [c]	0.02	Highest residue x CF (tentative) [c]
Swine fat (free of lean meat)	0.01	Median residue (tentative) [c]	0.01	Highest residue (tentative) [c]
Swine liver	0.03	Median residue x CF (tentative) [c]	0.09	Highest residue x CF (tentative) [c]
Swine kidney	0.02	Median residue x CF (tentative) [c]	0.02	Highest residue x CF (tentative) [c]
Ruminant meat	0.02	Median residue x CF (tentative) [c]	0.02	Highest residue x CF (tentative) [c]
Ruminant fat	0.01	Median residue (tentative) [c]	0.01	Highest residue (tentative) [c]
Ruminant liver	0.07	Median residue x CF (tentative) [c]	0.22	Highest residue x CF (tentative) [c]
Ruminant kidney	0.02	Median residue x CF (tentative) [c]	0.06	Highest residue x CF (tentative) [c]
Ruminant milk	0.04	Median residue x CF (tentative) [c]	0.04	Highest residue x CF (tentative) [c]
Risk assessment residue definition: sum of propamocarb and N-desmethyl propamocarb, expressed as propamocarb				
Poultry meat	0.01	Median residue x CF (tentative) [c]	0.03	Highest residue x CF (tentative) [c]
Poultry fat	0.01	Median residue x CF (tentative) [c]	0.01	Highest residue x CF (tentative) [c]
Poultry liver	0.01	Median residue x CF (tentative) [c]	0.04	Highest residue x CF (tentative) [c]

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Birds' eggs	0.02	Median residue x CF (tentative) (c)	0.05	Highest residue x CF (tentative) (c)

(*): Indicates that the input value is proposed at the limit of analytical quantification.
(a): Use reported by the RMS is not fully supported by data but the risk assessment values derived in section 3 are used for indicative exposure calculations.
(b): At least one relevant GAP reported by the RMS is fully supported by data for this commodity; the risk assessment values derived in section 3 are used for the exposure calculations.
(c): Dietary burden relevant to this commodity of animal origin, resulting from the GAPs reported by the RMS, is not fully supported by data; the risk assessment values derived in section 3 are used for indicative exposure calculations.

The calculated exposures were compared with the toxicological reference values derived for propamocarb (see Table 2-1); detailed results of the calculations are presented as EU scenario 1 in Appendix B.1. The highest chronic exposure was calculated for French toddlers, representing 6.3 % of the ADI. With regard to the acute exposure, however, an exceedance of the ARfD was identified for spinach, lettuce and leek, representing 121 %, 119 % and 105 % of the ARfD, respectively. A second exposure calculation was therefore performed, considering fall-back MRLs of 30 mg/kg for spinach based on the use of propamocarb in northern Europe and of 40 mg/kg for lettuce based on the use of propamocarb indoor, and excluding leek (no fall-back MRL available). According to the results of this second calculation (see Appendix B.2 – EU scenario 2), the highest chronic exposure declined to 2.9 % of the ADI for WHO Cluster Diet B; the highest acute exposure is then calculated for kale, representing 95 % of the ARfD.

Based on the above calculations, EFSA concludes that the use of propamocarb on crops fully supported by data (footnote b in Table 4-1) is acceptable with regard to consumer exposure, except for lettuce, spinach and leek where an exceedance of the ARfD was identified. For the other crops, major uncertainties remain due to the data gaps identified in section 3 but considering tentative MRLs in the exposure calculation did not indicate a risk to consumers. It is noted that for lettuce and spinach, EFSA was able to identify a fall-back GAP that is fully supported by data and for which no risk to consumers is identified. For leek, no fall-back GAP could be identified.

4.2. Consumer risk assessment with consideration of the existing CXLs

In order to include the CXLs in the calculations of the consumer exposure, all data relevant to the consumer exposure assessment have been collected from JMPR evaluations and reported in Appendix C.2 to this document. The CXLs were compared with the EU MRL proposals in compliance with Appendix D and input values resulting from this comparison are summarised in Table 4-2. It is noted however that CXLs for propamocarb on products of animal origin have been established by default for parent compound only while the residue definition derived at EU level is more complex. Also considering that the CXLs for plant commodities are not expected to significantly impact on the livestock dietary burden already calculated for the European authorisations, CXLs in animal commodities were not further considered. For melon and watermelon, the peeling factors derived by JMPR have been included in the calculation.

Table 4-2: Input values for the consumer risk assessment (with consideration of CXLs)

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	**Comment**	**Input value (mg/kg)**	**Comment**
Risk assessment residue definition: sum of propamocarb and its salts, expressed as propamocarb				
Potatoes	0.05	Median residue (CXL) [(a)]	0.17	Highest residue (CXL) [(a)]
Radishes	0.61	Median residue [(b)]	1.20	Highest residue [(b)]
Onions	0.05	Median residue [(b)]	1.30	Highest residue [(b)]
Tomatoes	0.55	Median residue [(b)]	2.18	Highest residue [(b)]
Peppers	0.27	Median residue (CXL) [(a)]	1.80	Highest residue (CXL) [(a)]
Aubergines (egg plants)	0.55	Median residue [(b)]	2.18	Highest residue [(b)]
Cucumbers	1.60	Median residue [(b)]	2.80	Highest residue [(b)]
Gherkins	0.59	Median residue (CXL) [(a)]	4.80	Highest residue (CXL) [(a)]
Courgettes	1.60	Median residue [(b)]	2.80	Highest residue [(b)]
Melons	0.06	Median residue x 0.18 (CXL) [(a)]	0.40	Highest residue x 0.18 (CXL) [(a)]
Pumpkins	0.59	Median residue (CXL) [(a)]	4.80	Highest residue (CXL) [(a)]
Watermelons	0.06	Median residue x 0.18 (CXL) [(a)]	0.40	Highest residue x 0.18 (CXL) [(a)]
Broccoli	0.32	Median residue [(b)]	1.70	Highest residue [(b)]
Cauliflower	1.24	Median residue (tentative) [(c)]	3.67	Highest residue (tentative) [(c)]
Brussels sprouts	0.47	Median residue [(b)]	1.30	Highest residue [(b)]
Head cabbage	0.20	Median residue [(b)]	0.36	Highest residue [(b)]
Chinese cabbage	0.01*	Median residue [(b)]	0.01*	Highest residue [(b)]
Kale	4.00	Median residue [(b)]	11.80	Highest residue [(b)]
Kohlrabi	0.04	Median residue [(b)]	0.13	Highest residue [(b)]
Salads (except lettuce)	4.00	Median residue (tentative) [(c)]	8.10	Highest residue (tentative) [(c)]
Lettuce	9.90	Median residue (CXL) [(a)]	86.00	Highest residue (CXL) [(a)]
Spinach	11.20	Median residue (CXL) [(a)]	29.00	Highest residue (CXL) [(a)]
Witloof	0.30	Median residue [(b)]	8.00	Highest residue [(b)]
Fresh herbs	9.67	Median residue (tentative) [(c)]	15.12	Highest residue (tentative) [(c)]
Beans (fresh, with pods)	0.10	Median residue [(b)]	0.10	Highest residue [(b)]
Risk assessment residue definition: sum of propamocarb, N-oxide propamocarb, oxazolidin-2-one propamocarb and 2-hydroxypropamocarb expressed as propamocarb				
Swine meat	0.02	Median residue x CF (tentative) [(d)]	0.02	Highest residue x CF (tentative) [(d)]

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Swine fat (free of lean meat)	0.01	Median residue (tentative) (d)	0.01	Highest residue (tentative) (d)
Swine liver	0.03	Median residue x CF (tentative) (d)	0.09	Highest residue x CF (tentative) (d)
Swine kidney	0.02	Median residue x CF (tentative) (d)	0.02	Highest residue x CF (tentative) (d)
Ruminant meat	0.02	Median residue x CF (tentative) (d)	0.02	Highest residue x CF (tentative) (d)
Ruminant fat	0.01	Median residue (tentative) (d)	0.01	Highest residue (tentative) (d)
Ruminant liver	0.07	Median residue x CF (tentative) (d)	0.22	Highest residue x CF (tentative) (d)
Ruminant kidney	0.02	Median residue x CF (tentative) (d)	0.06	Highest residue x CF (tentative) (d)
Ruminant milk	0.04	Median residue x CF (tentative) (d)	0.04	Highest residue x CF (tentative) (d)
Risk assessment residue definition: sum of propamocarb and N-desmethyl propamocarb, expressed as propamocarb				
Poultry meat	0.01	Median residue x CF (tentative) (d)	0.03	Highest residue x CF (tentative) (d)
Poultry fat	0.01	Median residue x CF (tentative) (d)	0.01	Highest residue x CF (tentative) (d)
Poultry liver	0.01	Median residue x CF (tentative) (d)	0.04	Highest residue x CF (tentative) (d)
Birds' eggs	0.02	Median residue x CF (tentative) (d)	0.05	Highest residue x CF (tentative) (d)

(a): CXL is supported by data; the corresponding risk assessment values are used for the exposure calculations.
(b): At least one relevant GAP reported by the RMS is fully supported by data for this commodity; the risk assessment values derived in section 3 are used for the exposure calculations.
(c): Use reported by the RMS is not fully supported by data but the risk assessment values derived in section 3 are used for indicative exposure calculations.
(d): Dietary burden relevant to this commodity of animal origin, resulting from the GAPs reported by the RMS, is not fully supported by data; the risk assessment values derived in section 3 are used for indicative exposure calculations.

Chronic and acute exposure calculations were also performed using revision 2 of the EFSA PRIMo and calculated exposures were compared with the toxicological reference values derived for propamocarb (see Table 2-1); detailed results of the calculations are presented as EU/Codex scenario 1, in Appendix B.3. The highest chronic exposure was calculated for French toddlers, representing 4.3 % of the ADI. With regard to the acute exposure, however, an exceedance of the ARfD was identified for lettuce, representing 275 % of the ARfD. A second exposure calculation was therefore performed, excluding this crop. According to the results of this second calculation (see Appendix B.4 – EU/Codex scenario 2), the highest chronic exposure remained unchanged; the highest acute exposure is then calculated for kale, representing 95% of the ARfD.

Based on the above calculations, EFSA concludes that all CXLs are supported by data (footnote a in Table 4-2) and not expected to be of concern for European consumers, except for lettuce where an exceedance of the ARfD was identified.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The toxicological profile of propamocarb was evaluated in the framework of Directive 91/414/EEC, which resulted in an ADI and an ARfD being established at 0.244 mg/kg bw per d and 0.84 mg/kg bw, respectively.

Primary crop metabolism of propamocarb was investigated in three different crop groups following foliar or soil applications. Based on these studies, EFSA proposes to define the residue for enforcement and risk assessment in all plant commodities as the sum of propamocarb and its salts, expressed as propamocarb. Validated analytical methods for enforcement of this residue definition are available with an LOQ of 0.01 mg/kg in high water content commodities.

Regarding the magnitude of residues in primary crops, at least one GAP is fully supported by data for most of the crops reported and the available residue data are considered acceptable to derive MRL proposals as well as risk assessment values for all commodities under evaluation, except for potatoes, peppers, cauliflower, salad plants (except lettuce) and fresh herbs where only tentative MRLs can be derived.

The nature of residues of propamocarb in processed commodities was not investigated. Studies investigating the magnitude of residues in several processed products of tomatoes and head cabbage, and for cooked spinach are available, which allowed EFSA to derive processing factors. Pending further investigation on the nature of the residues in processed commodities however, processing factors are indicative only and it cannot be excluded that additional processing studies may be required in order to derive robust processing factors for enforcement purposes.

The potential incorporation of soil residues into succeeding and rotational crops was investigated in lettuce, radish and wheat during the peer review. This study showed comparable metabolic patterns in primary and succeeding crops. Additional field trials also demonstrated that significant residues of parent propamocarb in rotational crops are not expected, provided that propamocarb is applied according to the GAPs supported in the framework of this review.

Based on the uses reported by the RMS, significant intakes were calculated for ruminants, poultry and pigs. Metabolism in lactating ruminants and poultry was sufficiently investigated and findings in ruminants can be extrapolated to pigs. The relevant residue definition for enforcement was defined as N-oxide propamocarb in milk, pig and ruminants tissues and as N-desmethyl propamocarb in poultry products. For risk assessment, the residue is defined in milk, pig and ruminant tissues as the sum of propamocarb, N-oxide propamocarb, oxazolidine-2-one propamocarb and 2-hydroxypropamocarb expressed as propamocarb; for poultry tissues, the residue is defined as the sum of propamocarb and N-desmethyl propamocarb, expressed as propamocarb. Fully validated analytical methods for enforcement of both residue definitions are not available and therefore still required.

The RMS also reported a livestock feeding study on lactating cows which was underdosed; no reliable conclusion can be drawn on the magnitude of residues in ruminants and pigs. A representative feeding study for ruminants is therefore required and tentative MRLs and risk assessment values were derived from the available metabolism study on cows. Regarding poultry, a feeding study in hens demonstrated that significant residues of propamocarb in edible matrices of poultry are expected but

separate results for propamocarb and N-desmethyl propamocarb are still required; tentative MRLs and risk assessment values were derived.

Chronic and acute consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 2 of the EFSA PRIMo. For spinach, lettuce and leek, an exceedance of the ARfD was identified representing 121, 119 and 105 % of the ARfD, respectively. Considering fall-back MRLs for spinach and for lettuce and excluding leek (no fall-back MRL available), the highest chronic exposure represented 2.9 % of the ADI (WHO Cluster Diet B) and the highest acute exposure amounted to 95 % of the ARfD (kale).

Apart from the MRLs evaluated in the framework of this review, internationally recommended CXLs have also been established for propamocarb. Additional calculations of the consumer exposure, considering these CXLs, were therefore carried out and an exceedance of the ARfD was identified for the existing CXL in lettuce (275 %). Excluding this CXL from the calculation, the highest chronic exposure represented 4.3 % of the ADI (French toddlers) and the highest acute exposure amounted to 95 % of the ARfD (kale).

RECOMMENDATIONS

Based on the above assessment, EFSA does not recommend inclusion of this active substance in Annex IV to Regulation (EC) No 396/2005. MRL recommendations were derived in compliance with the decision tree reported in Appendix D of the reasoned opinion (see summary table). All MRL values listed as 'Recommended' in the table are sufficiently supported by data and are therefore proposed for inclusion in Annex II to the Regulation. The remaining MRL values listed in the table are not recommended for inclusion in Annex II because they require further consideration by risk managers (see summary table footnotes for details). In particular, some tentative MRLs need to be confirmed by the following data:

- a fully validated analytical method, with its ILV and a confirmatory method, for enforcement of N-oxide propamocarb in milk, pig and ruminant tissues;
- a fully validated analytical method, with its ILV and a confirmatory method, for enforcement of N-desmethyl propamocarb in poultry products;
- 4 additional residue trials supporting the indoor GAP on cauliflower;
- 8 residue trials on lettuce (open leaves varieties) supporting the northern outdoor GAP on lamb's lettuce, scarole and rocket;
- 8 residue trials on lettuce (open leaves varieties) supporting the southern outdoor GAP and 8 residue trials on lettuce (open leaves varieties) supporting the indoor GAP on salad plants (except lettuce);
- trials on fresh herbs or on any crop allowing extrapolation to fresh herbs supporting the indoor GAP;
- separate results for propamocarb and N-desmethyl propamocarb in the hen feeding study;
- a representative feeding study on ruminants supported by storage stability data.

Additionally, some of the MRLs derived result from a CXL or from a GAP in one climatic zone only, while other GAPs reported by the RMS were not fully supported by data. EFSA therefore identified the following data gaps which are not expected to impact on the validity of the MRLs derived but which might have an impact on national authorisations:

- 4 additional residue trials supporting the southern outdoor GAP on potato;
- 8 residue trials supporting the southern outdoor GAP and 8 residue trials supporting the indoor GAP on pepper;
- 4 residue trials supporting the southern outdoor GAP on cucumber;
- 4 residue trials supporting the indoor GAP on gherkin;
- 4 residue trials supporting the northern outdoor GAP and 4 residue trials supporting the southern outdoor GAP on Chinese cabbage;

If the above reported data gaps are not addressed in the future, Member States are recommended to withdraw or modify the relevant authorisations at national level. It is also highlighted that an exceedance of the ARfD was identified for the GAPs authorised on spinach and lettuce in the southern outdoor area and on leek in the northern outdoor area. Therefore, MSs concerned are in any case, regardless of the data gaps listed above, recommended to withdraw or modify those authorisations at national level. Moreover, as the indoor GAP reported by the Netherlands for lettuce may lead to an exceedance of the proposed MRL (based on the supported indoor GAP), the Netherlands are strongly recommended to reconsider their indoor GAPs as well in order not to have exceedances of the proposed MRL.

Minor deficiencies were also identified in the assessment but these deficiencies are not expected to impact either on the validity of the MRLs derived or on the national authorisations. The following data are therefore considered desirable but not essential:

- residues trials supporting the indoor GAP on fresh beans with pods carried out with analytical methods achieving a LOQ of 0.01 mg/kg;
- a hydrolysis study investigating the effect of processing on the nature of the residues.

SUMMARY TABLE

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
Enforcement residue definition: sum of propamocarb and its salts, expressed as propamocarb					
211000	Potatoes	0.5	0.3	0.3	Recommended [a]
213080	Radishes	10	1	3	Recommended [b]
220020	Onions	10	-	2	Recommended [c]
231010	Tomatoes	10	2	4	Recommended [b]
231020	Peppers	10	3	3	Recommended [a]
231030	Aubergines (egg plants)	10	0.3	4	Recommended [b]
232010	Cucumbers	10	5	5	Recommended [b]

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
232020	Gherkins	10	5	5	Recommended [d]
232030	Courgettes	10	5	5	Recommended [b]
233010	Melons	5	5	5	Recommended [d]
233020	Pumpkins	10	5	5	Recommended [d]
233030	Watermelons	5	5	5	Recommended [d]
241010	Broccoli	10	-	3	Recommended [c]
241020	Cauliflower	10	0.2	10	Further consideration needed [e]
242010	Brussels sprouts	10	-	2	Recommended [c]
242020	Head cabbage	10	-	0.7	Recommended [c]
243010	Chinese cabbage	10	-	0.01*	Recommended [c]
243020	Kale	20	-	20	Recommended [c]
244000	Kohlrabi	10	-	0.3	Recommended [c]
251010	Lamb's lettuce	30	-	20	Further consideration needed [f]
251020	Lettuce	50	100	40	Recommended [g]
251030	Scarole	10	-	20	Further consideration needed [f]
251040	Cress	30	-	20	Further consideration needed [f]
251050	Land cress	20	-	20	Further consideration needed [f]
251060	Rocket, Rucola	20	-	20	Further consideration needed [f]
251070	Red mustard	20	-	20	Further consideration needed [f]
251080	Leaves and sprouts of *Brassica* spp	20	-	20	Further consideration needed [f]
252010	Spinach	30	40	40	Recommended [d]
255000	Witloof	10	2	15	Recommended [b]
256000	Fresh herbs	30	-	30	Further consideration needed [f]
260010	Beans (fresh, with pods)	0.1*	-	0.1	Recommended [c]
270060	Leek	10	-	-	Further consideration needed [h]
-	Other products of plant origin	See App. C.1	-	-	Further consideration needed [i]
Enforcement residue definition (existing): sum of propamocarb and its salts, expressed as propamocarb **Enforcement residue definition (proposed):** N-oxide propamocarb					
1011010	Swine meat	0.1*	0.01*	0.01	Further consideration needed [j]
1011020	Swine fat (free of lean meat)	0.1*	0.01*	0.01	Further consideration needed [j]
1011030	Swine liver	0.1*	0.01*	0.1	Further consideration needed [j]
1011040	Swine kidney	0.1*	0.01*	0.02	Further consideration needed [j]
1012010	Bovine meat	0.1*	0.01*	0.01	Further consideration needed [j]
1012020	Bovine fat	0.1*	0.01*	0.01	Further consideration needed [j]

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
1012030	Bovine liver	0.1*	0.01*	0.2	Further consideration needed (j)
1012040	Bovine kidney	0.1*	0.01*	0.05	Further consideration needed (j)
1013010	Sheep meat	0.1*	0.01*	0.01	Further consideration needed (j)
1013020	Sheep fat	0.1*	0.01*	0.01	Further consideration needed (j)
1013030	Sheep liver	0.1*	0.01*	0.2	Further consideration needed (j)
1013040	Sheep kidney	0.1*	0.01*	0.05	Further consideration needed (j)
1014010	Goat meat	0.1*	0.01*	0.01	Further consideration needed (j)
1014020	Goat fat	0.1*	0.01*	0.01	Further consideration needed (j)
1014030	Goat liver	0.1*	0.01*	0.2	Further consideration needed (j)
1014040	Goat kidney	0.1*	0.01*	0.05	Further consideration needed (j)
1020010	Cattle milk	0.1*	0.01*	0.01	Further consideration needed (j)
1020020	Sheep milk	0.1*	0.01*	0.01	Further consideration needed (j)
1020030	Goat milk	0.1*	0.01*	0.01	Further consideration needed (j)
Enforcement residue definition (existing): sum of propamocarb and its salts, expressed as propamocarb **Enforcement residue definition (proposed):** N-desmethyl propamocarb					
1016010	Poultry meat	0.1*	0.01*	0.02	Further consideration needed (j)
1016020	Poultry fat	0.1*	0.01*	0.01	Further consideration needed (j)
1016030	Poultry liver	0.1*	0.01*	0.05	Further consideration needed (j)
1030000	Birds' eggs	0.1*	0.01*	0.05	Further consideration needed (j)
-	Other product of animal origin	See App. C.1	-	-	Further consideration needed (i)

(*): Indicates that the MRL is set at the limit of analytical quantification.
(a): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level, which is not fully supported by data, leads to a lower tentative MRL (combination E-VII in Appendix D).
(b): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; existing CXL is covered by the recommended MRL (combination G-III in Appendix D).
(c): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; no CXL is available (combination G-I in Appendix D).
(d): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level, which is also fully supported by data, leads to a lower MRL (combination G-VII in Appendix D).
(e): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified; existing CXL is covered by the tentative MRL (combination E-III in Appendix D).
(f): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified; no CXL is available (combination E-I in Appendix D).
(g): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; CXL is higher, supported by data but a risk to consumers cannot be excluded (combination G-VI in Appendix D).
(h): GAP evaluated at EU level is fully supported by data but a risk to consumers cannot be excluded; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination F-I in Appendix D).
(i): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix D).
(j): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified; CXL is not compatible with EU residue definitions (combination E-II in Appendix D).

DOCUMENTATION PROVIDED TO EFSA

1. Pesticide Residues Overview File (PROFile) on propamocarb prepared by the rapporteur Member State Ireland in the framework of Article 12 of Regulation (EC) No 396/2005. Submitted to EFSA on 20 April 2010. Last updated on 12 June 2012.

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APPENDIX A – GOOD AGRICULTURAL PRACTICES (GAPS)

Critical Outdoor GAPs for Northern Europe																				
Crop		Region	Outdoor/ Indoor	Member state or Country	Pests controlled	Formulation			Application							Application rate			PHI or wiaiting period (days)	Comments (max. 250 charachters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Min. rate	Max. rate	Rate Unit		
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.					
Potatoes	*Tuber form Solanum Spp*	NEU	Outdoor	AT, BE, DE, UK, IE	Phytin	SC	375.0	g/L	Foliar treatment - spraying	20	95	2	4				0.84	kg a.i./ha	7	cGAP BE notified during MSC : 6x750g/ha, PHI=7d. Deemed to be not more critical that the initial cGAP on the basis of 3 NEU trials.
Radishes	*Raphanus sativus var. saitvus*	NEU	Outdoor	DE, CH	Phytophthora	SC	625.0	g/L	Foliar treatment - spraying	13	47	1	2				0.84	kg a.i./ha	14	
Onions	*Allium cepa*	NEU	Outdoor	PL, FR, EE, LT, LV	PSPECU	SC	625.0	g/L	Foliar treatment - spraying	13	49	2	3				0.84	kg a.i./ha	7	
Tomatoes	*Lycopersicum esculentum*	NEU	Outdoor	EE,LT,LV	Phytin	SC	625.0	g/L	Foliar treatment - spraying	20	89	1	3				1.05	kg a.i./ha	3	
Aubergines (egg plants)	*Solanum melongena*	NEU	Outdoor	EE,LT,LV	Phytin	SC	625.0	g/L	Foliar treatment - spraying	20	89	1	3				1.05	kg a.i./ha	3	
Cucumbers	*Cucumis sativus*	NEU	Outdoor	EE,DE,FR,LV,NL	PSPECU, PYTHSP	SL	722.0	g/L	Foliar treatment - general (see also comment field)	20	95	1	4				1.85	kg a.i./ha	3	GAP includes drench at BBCH 00-10 at up to 72.2 Kg a.a/ha (2 applications) followed by foliar applications at BBCH 20 -95
Gherkins	*Cucumis sativus*	NEU	Outdoor	EE,DE,FR,LV,NL	PSPECU, PYTHSP	SL	722.0	g/L	Foliar treatment - general (see also comment field)	20	95	1	4				1.85	kg a.i./ha	3	GAP includes drench at BBCH 00-10 at up to 72.2 Kg a.a/ha (2 applications) followed by foliar applications at BBCH 20 -95
Broccoli	*Brassica oleracea var. italica*	NEU	Outdoor	DE, EE, LT, LV	PEROBR	SC	625.0	g/L	Foliar treatment - spraying	21	49	1	3				0.84	kg a.i./ha	14	
Cauliflower	*Brassica oleracea var. botrytis*	NEU	Outdoor	BE, DE, NL, EE, LT, LV	PEROBR	SC	625.0	g/L	Foliar treatment - spraying	13	51	1	3				0.84	kg a.i./ha	14	
Brussels sprouts	*Brassica oleracea var. gemmifera*	NEU	Outdoor	BE, NL	PEROBR	SC	625.0	g/L	Foliar treatment - spraying	13	51	1	3				0.84	kg a.i./ha	14	
Head cabbage	*Brassica oleracea convar capitata*	NEU	Outdoor	BE, NL, EE, LT, LV	PEROBR	SC	625.0	g/L	Foliar treatment - spraying	13	49	1	3				0.84	kg a.i./ha	14	
Chinese cabbage	*Brassica pekinensis*	NEU	Outdoor	DE	PHYTSP, PYTHSP	SL	722.0	g/L	Local treatment - drenching	0	10	1	1				60.65	kg a.i./ha	n.a.	Drenching only
Kale	*Brassica oleracea convar. Acephalea*	NEU	Outdoor	NL	P brassicae	SC	625.0	g/L	Foliar treatment - spraying	13	49	1	3				0.84	kg a.i./ha	14	
Kohlrabi	*Brassica oleracea convar. acephala, var. gongylodes*	NEU	Outdoor	CH	PEROBR	SC	625.0	g/L	Foliar treatment - spraying	20	49	1	3				0.84	kg a.i./ha	14	
Lamb's lettuce	*Valerianella locusta*	NEU	Outdoor	BE					Foliar treatment - spraying			1	3				1.08	kg a.i./ha	21	
Lettuce	*Lactuca sativa*	NEU	Outdoor	NL	PHYTSP, PYTHSP	SC	625.0	g/L	Foliar treatment - spraying	10	49	1	3				0.91	kg a.i./ha	7	
Scarole (broad-leaf endive)	*Cichorium endiva*	NEU	Outdoor	BE					Foliar treatment - spraying			1	3				1.08	kg a.i./ha	21	
Rocket, Rucola	*Eruca sativa (Diplotaxis spec.)*	NEU	Outdoor	DE	Downy mildew	SL	605.0	g/L	Foliar treatment - spraying		49	1	3	7	14		1.15	kg a.i./ha	21	
Spinach	*Spinacia oleracea*	NEU	Outdoor	UK, IE	PHYTSP	SL	530.0	g/L	Foliar treatment - spraying	12	49	1	3				1.33	kg a.i./ha	14	
Chervil	*Anthriscus cerefolium*	NEU	Outdoor	BE	PHYTSP, PYTHSP				Foliar treatment - spraying			1	3				1.08	kg a.i./ha	7	
Chives	*Allium schoenoprasum*	NEU	Outdoor	BE	PHYTSP, PYTHSP				Foliar treatment - spraying			1	3				1.08	kg a.i./ha	7	
Celery leaves	*Apium graveolens var. seccalinum*	NEU	Outdoor	BE	PHYTSP, PYTHSP				Foliar treatment - spraying			1	3				1.08	kg a.i./ha	7	
Parsley	*Petroselinum crispum*	NEU	Outdoor	BE	PHYTSP, PYTHSP				Foliar treatment - spraying			1	3				1.08	kg a.i./ha	7	
Sage	*Salvia officinalis*	NEU	Outdoor	BE	PHYTSP, PYTHSP				Foliar treatment - spraying			1	3				1.08	kg a.i./ha	7	
Rosemary	*Rosmarinus officinalis*	NEU	Outdoor	BE	PHYTSP, PYTHSP				Foliar treatment - spraying			1	3				1.08	kg a.i./ha	7	
Thyme	*Thymus spp.*	NEU	Outdoor	BE	PHYTSP, PYTHSP				Foliar treatment - spraying			1	3				1.08	kg a.i./ha	7	
Basil	*Ocimum basilicum*	NEU	Outdoor	BE	PHYTSP, PYTHSP				Foliar treatment - spraying			1	3				1.08	kg a.i./ha	7	
Bay leaves (laurel)	*Laurus nobilis*	NEU	Outdoor	BE	PHYTSP, PYTHSP				Foliar treatment - spraying			1	3				1.08	kg a.i./ha	7	
Tarragon	*Artemisia dracunculus*	NEU	Outdoor	BE	PHYTSP, PYTHSP				Foliar treatment - spraying			1	3				1.08	kg a.i./ha	7	
Leek	*Allium porrum*	NEU	Outdoor	BE, EE, DE, LT, LV, NL, PL	PHYTSP	SC	625.0	g/L	Foliar treatment - spraying	20	49	1	3				0.84	kg a.i./ha	14	

Critical Outdoor GAPs for Southern Europe																				
Crop		Region	Outdoor/ Indoor	Member state or Country	Pests controlled	Formulation			Application							Application rate			PHI or wiaiting period (days)	Comments (max. 250 charachters)
							Content			Growth stage		Number		Interval (days)						
Common name	Scientific name					Type	Conc.	Unit	Method	From BBCH	Until BBCH	Min.	Max.	Min.	Max.	Min. rate	Max. rate	Rate Unit		
Potatoes	*Tuber form Solanum Spp*	SEU	Outdoor	IT	Psytin	SC	375.0	g/L	Foliar treatment - spraying	19	89	1	4	7	10	0.63	0.84	kg a.i./ha	7	
Onions	*Allium cepa*	SEU	Outdoor	PT, RO, ES	PSPECU	SC	625.0	g/L	Foliar treatment - spraying	13	49	2	3				0.84	kg a.i./ha	7	
Tomatoes	*Lycopersicum esculentum*	SEU	Outdoor	IT, ES, PT	Psytin	SC	625.0	g/L	Foliar treatment - spraying	20	89	1	3				1.05	kg a.i./ha	3	
Peppers	*Capsicum annuum, var grossum and var. longum*	SEU	Outdoor	IT	PYTHSP	SL	530.0	g/L	Local treatment - general (see also comment field)		19		2	10	15	1.06	1.59	kg a.i./ha	n.a.	GAP includes drench at BBCH 00-13 at up to 47,7 Kg a.a/ha (splitted in 2 applications, 31,8+15,9). Drip/drench irrigation
Aubergines (egg plants)	*Solanum melongena*	SEU	Outdoor	IT, ES, PT	Psytin	SC	625.0	g/L	Foliar treatment - spraying	20	89	1	3				1.05	kg a.i./ha	3	
Cucumbers	*Cucumis sativus*	SEU	Outdoor	CY,EE,IT	PSPECU, PYTHSP	SL	722.0	g/L	Foliar treatment - general (see also comment field)	20	95	1	4				1.85	kg a.i./ha	3	GAP includes drench at BBCH 00-10 at up tp 72.2 Kg a.a/ha (2 applications) followed by foliar applications at BBCH 20 -95
Melons	*Cucumis melo*	SEU	Outdoor	FR, ES, IT, EL	PSPECU	SL	722.0	g/L	Foliar treatment - spraying	20	89	1	3				1.85	kg a.i./ha	3	
Pumpkins	*Cucurbita maxima*	SEU	Outdoor	IT	PSPECU	SC	722.0	g/L	Foliar treatment - spraying	20	89	1	3				1.85	kg a.i./ha	3	
Watermelons	*Citrullus lanatus*	SEU	Outdoor	IT	PSPECU	SC	722.0	g/L	Foliar treatment - spraying	20	89	1	3				1.85	kg a.i./ha	3	
Broccoli	*Brassica oleracea var. italica*	SEU	Outdoor	ES	PEROBR	SC	625.0	g/L	Foliar treatment - spraying	13	51	1	3				0.84	kg a.i./ha	14	
Cauliflower	*Brassica oleracea var. botrytis*	SEU	Outdoor	ES	PEROBR	SC	625.0	g/L	Foliar treatment - spraying	13	51	1	3				0.84	kg a.i./ha	14	
Head cabbage	*Brassica oleracea convar capitata*	SEU	Outdoor	ES	PEROBR	SC	625.0	g/L	Foliar treatment - spraying	13	51	1	3				0.84	kg a.i./ha	14	
Chinese cabbage	*Brassica pekinensis*	SEU	Outdoor	ES, IT	PHYTSP, PYTHSP	SL	722.0	g/L	Local treatment - drenching	0	10		1				60.65	kg a.i./ha	n.a.	Drenching only
Kale	*Brassica oleracea convar. Acephalea*	SEU	Outdoor	FR	P brassicae	SC	625.0	g/L	Foliar treatment - spraying	13	49	1	2				0.84	kg a.i./ha	14	
Lamb's lettuce	*Valerianella locusta*	SEU	Outdoor	IT	Bremia	SL	530.0	g/L	Foliar treatment - spraying		47	1	2				1.59	kg a.i./ha	20	
Lettuce	*Lactuca sativa*	SEU	Outdoor	FR, EL, IT, ES, PT,RO,EE	PHYTSP, PYTHSP	SC	625.0	g/L	Foliar treatment - general (see also comment field)	12	49	1	3				0.84	kg a.i./ha	7	
Scarole (broad-leaf endive)	*Cichorium endiva*	SEU	Outdoor	IT	Bremia	SL	530.0	g/L	Foliar treatment - spraying		47	1	2				1.59	kg a.i./ha	20	
Cress	*Lepidium sativum*	SEU	Outdoor	IT	Bremia	SL	530.0	g/L	Foliar treatment - spraying		47	1	2				1.59	kg a.i./ha	20	
Land cress	*Barbarea verna*	SEU	Outdoor	IT	Bremia	SL	530.0	g/L	Foliar treatment - spraying		47	1	2				1.59	kg a.i./ha	20	
Rocket, Rucola	*Eruca sativa (Diplotaxis spec.)*	SEU	Outdoor	IT	Bremia	SL	530.0	g/L	Foliar treatment - spraying		47	1	2				1.59	kg a.i./ha	20	
Red mustard	*Brassica juncea var. rugosa*	SEU	Outdoor	IT	Bremia	SL	530.0	g/L	Foliar treatment - spraying		47	1	2				1.59	kg a.i./ha	20	
Leaves and sprouts of Brassica spp	*Brassica spp*	SEU	Outdoor	IT	Bremia	SL	530.0	g/L	Foliar treatment - spraying		47	1	2				1.59	kg a.i./ha	20	
Spinach	*Spinacia oleracea*	SEU	Outdoor	IT	PHYTSP	SL	530.0	g/L	Foliar treatment - spraying	12	49	1	2				1.33	kg a.i./ha	14	

Critical Indoor GAPs for Northern and Southern Europe (incl. post-harvest treatments)																				
Crop		Region	Outdoor/ Indoor	Member state or Country	Pests controlled	Formulation			Application							Application rate			PHI or wiaiting period (days)	Comments (max. 250 charachters)
							Content			Growth stage		Number		Interval (days)						
Common name	Scientific name					Type	Conc.	Unit	Method	From BBCH	Until BBCH	Min.	Max.	Min.	Max.	Min. rate	Max. rate	Rate Unit		
Radishes	*Raphanus sativus var. saitvus*	NEU/SEU	Indoor	FR, NL, UK	PSPECU	SL	530.0	g/L	Foliar treatment - spraying	12	49	1	2				1.33	kg a.i./ha	14	
Tomatoes	*Lycopersicum esculentum*	NEU/SEU	Indoor	EE, HU, IE, ES, LV, LT, EL	Psytin	SC	625.0	g/L	Foliar treatment - spraying	20	89	1	3				1.05	kg a.i./ha	1	
Peppers	*Capsicum annuum, var grossum and var. longum*	NEU/SEU	Indoor	BE	PSYPSP,PYTHSP	SL	530.0	g/L	Local treatment - general (see also comment field)			1	4				1.59	kg a.i./ha	3	Drip application
Aubergines (egg plants)	*Solanum melongena*	NEU/SEU	Indoor	EE, HU, IE, ES, LV, LT, EL	Phytin	SC	625.0	g/L	Foliar treatment - spraying	20	89	1	3				1.05	kg a.i./ha	1	
Cucumbers	*Cucumis sativus*	NEU/SEU	Indoor	ES, IT, FR, EL	PSPECU, PYTHSP	SL	722.0	g/L	Foliar treatment - general (see also comment field)	20	95	1	4				1.85	kg a.i./ha	3	GAP includes drench at BBCH 00-10 at up tp 72.2 Kg a.a/ha (2 applications) followed by foliar applications at BBCH 20 -95
Gherkins	*Cucumis sativus*	NEU/SEU	Indoor	BE	PSYPSP,PYTHSP	SL	530.0	g/L	Local treatment - general (see also comment field)			1	4				1.59	kg a.i./ha	3	Drip application
Courgettes	*Cucurbita pepo var. melopepo*	NEU/SEU	Indoor	NL,ES	PSPECU	SL	722.0	g/kg	Foliar treatment - general (see also comment field)	20	95	1	4				1.85	kg a.i./ha	3	GAP include drench at BBCH 00-10 at up tp 72.2 Kg a.a/ha (2 applications) followed by foliar applications at BBCH 20 -95
Melons	*Cucumis melo*	NEU/SEU	Indoor	ES,IT	PSPECU	SL	530.0	g/kg	Foliar treatment - general (see also comment field)	20	89	1	4				1.59	kg a.i./ha	3	
Pumpkins	*Cucurbita maxima*	NEU/SEU	Indoor	IT	PSPECU	SL	530.0	g/kg	Foliar treatment - general (see also comment field)	20	89	1	4				1.59	kg a.i./ha	3	
Watermelons	*Citrullus lanatus*	NEU/SEU	Indoor	IT	PSPECU	SL	530.0	g/kg	Foliar treatment - general (see also comment field)	20	89	1	4				1.59	kg a.i./ha	3	
Broccoli	*Brassica oleracea var. italica*	NEU/SEU	Indoor	BE	PHYTSP, PYTHSP	SC	530.0	g/L	Local treatment - drenching	0	12	1	2	7	10		15.90	kg a.i./ha	n.a.	
Cauliflower	*Brassica oleracea var. botrytis*	NEU/SEU	Indoor	BE	PHYTSP, PYTHSP	SC	530.0	g/L	Foliar treatment - spraying	19	45	1	2	14			2.17	kg a.i./ha	n.a.	
Brussels sprouts	*Brassica oleracea var. gemmifera*	NEU/SEU	Indoor	BE	PHYTSP, PYTHSP	SC	530.0	g/L	Local treatment - drenching	0	12	1	2	7	10		15.90	kg a.i./ha	n.a.	
Head cabbage	*Brassica oleracea convar capitata*	NEU/SEU	Indoor	BE	PHYTSP, PYTHSP	SC	530.0	g/L	Local treatment - drenching	0	12	1	2	7	10		15.90	kg a.i./ha	n.a.	
Chinese cabbage	*Brassica pekinensis*	NEU/SEU	Indoor	BE	PHYTSP, PYTHSP	SC	530.0	g/L	Local treatment - drenching	0	12	1	2	7	10		15.90	kg a.i./ha	n.a.	
Kale	*Brassica oleracea convar. Acephalea*	NEU/SEU	Indoor	BE	PHYTSP, PYTHSP	SC	530.0	g/L	Local treatment - drenching	0	12	1	2	7	10		15.90	kg a.i./ha	n.a.	
Lamb's lettuce	*Valerianella locusta*	NEU/SEU	Indoor	IT	Bremia	SL	530.0	g/L	Foliar treatment - spraying		47	1	2				1.59	kg a.i./ha	20	
Lettuce	*Lactuca sativa*	NEU/SEU	Indoor	BE, DE, FR	PYTHSP				Foliar treatment - general (see also comment field)			1	3		10		1.08	kg a.i./ha	21	More critical GAP were reported during MSC, but were disregarded as no residue trials compliant with the GAP were available and available trials loosely covering the GAP show evidence of a potential acute risk for these uses.
Scarole (broad-leaf endive)	*Cichorium endiva*	NEU/SEU	Indoor	IT	Bremia	SL	530.0	g/L	Foliar treatment - spraying		47	1	2				1.59	kg a.i./ha	20	
Cress	*Lepidium sativum*	NEU/SEU	Indoor	IT	Bremia	SL	530.0	g/L	Foliar treatment - spraying		47	1	2				1.59	kg a.i./ha	20	
Land cress	*Barbarea verna*	NEU/SEU	Indoor	IT	Bremia	SL	530.0	g/L	Foliar treatment - spraying		47	1	2				1.59	kg a.i./ha	20	
Rocket, Rucola	*Eruca sativa (Diplotaxis spec.)*	NEU/SEU	Indoor	IT	Bremia	SL	530.0	g/L	Foliar treatment - spraying		47	1	2				1.59	kg a.i./ha	20	DE : 3x1,15kg/ha, PHI:21d
Red mustard	*Brassica juncea var. rugosa*	NEU/SEU	Indoor	IT	Bremia	SL	530.0	g/L	Foliar treatment - spraying		47	1	2				1.59	kg a.i./ha	20	
Leaves and sprouts of Brassica spp	*Brassica spp*	NEU/SEU	Indoor	IT	Bremia	SL	530.0	g/L	Foliar treatment - spraying		47	1	2				1.59	kg a.i./ha	20	
Witloof	*Cichorium intybus. var. Foliosum*	NEU/SEU	Indoor	FR,NL	PYTHSP	SL	530.0	g/L	Local treatment - general (see also comment field)				1				20.00	g a.i./hL	21	Carried out in special forcing room
Chervil	*Anthriscus cerefolium*	NEU/SEU	Indoor	NL	PYTHSP	SC	530.0	g/L	Foliar treatment - spraying			1	2				1.33	kg a.i./ha	14	
Chives	*Allium schoenoprasum*	NEU/SEU	Indoor	NL	PYTHSP	SC	530.0	g/L	Foliar treatment - spraying			1	2				1.33	kg a.i./ha	14	
Celery leaves	*Apium graveolens var. seccalinum*	NEU/SEU	Indoor	NL	PYTHSP	SC	530.0	g/L	Foliar treatment - spraying			1	2				1.33	kg a.i./ha	14	
Parsley	*Petroselinum crispum*	NEU/SEU	Indoor	NL	PYTHSP	SC	530.0	g/L	Foliar treatment - spraying			1	2				1.33	kg a.i./ha	14	
Sage	*Salvia officinalis*	NEU/SEU	Indoor	NL	PYTHSP	SC	530.0	g/L	Foliar treatment - spraying			1	2				1.33	kg a.i./ha	14	
Rosemary	*Rosmarinus officinalis*	NEU/SEU	Indoor	NL	PYTHSP	SC	530.0	g/L	Foliar treatment - spraying			1	2				1.33	kg a.i./ha	14	
Thyme	*Thymus spp.*	NEU/SEU	Indoor	NL	PYTHSP	SC	530.0	g/L	Foliar treatment - spraying			1	2				1.33	kg a.i./ha	14	

Critical Indoor GAPs for Northern and Southern Europe (incl. post-harvest treatments)																				
Crop		Region	Outdoor/ Indoor	Member state or Country	Pests controlled	Formulation			Application							Application rate			PHI or wiaiting period (days)	Comments (max. 250 charachters)
							Content			Growth stage		Number		Interval (days)						
Common name	Scientific name					Type	Conc.	Unit	Method	From BBCH	Until BBCH	Min.	Max.	Min.	Max.	Min. rate	Max. rate	Rate Unit		
Basil	*Ocimum basilicum*	NEU/SEU	Indoor	NL	PYTHSP	SC	530.0	g/L	Foliar treatment - spraying			1	2				1.33	kg a.i./ha	14	
Bay leaves (laurel)	*Laurus nobilis*	NEU/SEU	Indoor	NL	PYTHSP	SC	530.0	g/L	Foliar treatment - spraying			1	2				1.33	kg a.i./ha	14	
Tarragon	*Artemisia dracunculus*	NEU/SEU	Indoor	NL	PYTHSP	SC	530.0	g/L	Foliar treatment - spraying			1	2				1.33	kg a.i./ha	14	
Beans (with pods)	*Phaseolus vulgaris,*	NEU/SEU	Indoor	BE	PHYTSP	SL	722.0	g/L	Local treatment - drenching	0	0	1	1				36.10	kg a.i./ha	n.a.	Drenching at sowing

APPENDIX B – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

Appendix B.1 – EU scenario 1 including all EU MRL proposals resulting from the GAPs reported by the RMS

Appendix B.2 – EU scenario 2 including demonstrated safe EU MRL proposals resulting from the GAPs reported by the RMS

Appendix B.3 – EU/Codex scenario 1 including demonstrated safe EU MRL proposals and all CXLs

Appendix B.4 – EU/Codex scenario 2 including demonstrated safe EU MRL proposals and demonstrated safe CXLs

APPENDIX B.1 – PRIMO INCLUDING ALL EC MRL PROPOSALS RESULTING FROM THE GAPS REPORTED BY THE RMS

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**	Source of ARfD:	**EFSA**
Year of evaluation:	**2011**	Year of evaluation:	**2011**

Chronic risk assessment - refined calculations

	TMDI (range) in % of ADI minimum - maximum
	0 6
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	pTMRLs at LOQ (in % of ADI)
6.3	FR toddler	4.6	Spinach	0.7	Leek	0.3	Courgettes	
4.8	NL child	2.4	Spinach	0.5	Milk and milk products: Cattle	0.3	Scarole (broad-leaf endive)	
4.4	FR infant	2.9	Spinach	0.4	Milk and milk products: Cattle	0.4	Courgettes	
3.4	WHO Cluster diet B	1.0	Lettuce	0.7	Tomatoes	0.5	Spinach	
2.9	DE child	1.3	Spinach	0.4	Cucumbers	0.2	Milk and milk products: Cattle	
2.4	ES adult	1.5	Lettuce	0.5	Spinach	0.2	Tomatoes	
2.4	NL general	0.9	Spinach	0.3	Lettuce	0.2	Leek	
2.4	ES child	1.1	Lettuce	0.5	Spinach	0.2	Tomatoes	
2.3	WHO regional European diet	1.0	Lettuce	0.2	Tomatoes	0.2	Spinach	
2.3	IE adult	0.8	Spinach	0.3	Leek	0.2	Lettuce	
2.3	IT adult	1.0	Lettuce	0.6	Spinach	0.3	Tomatoes	
1.8	IT kids/toddler	0.8	Lettuce	0.4	Spinach	0.3	Tomatoes	
1.8	DK child	1.1	Cucumbers	0.4	Lettuce	0.1	Tomatoes	
1.6	SE general population 90th percentile	0.4	Spinach	0.2	Milk and milk products: Cattle	0.2	Cucumbers	
1.4	WHO Cluster diet F	0.8	Lettuce	0.2	Tomatoes	0.1	Cucumbers	
1.4	WHO cluster diet E	0.3	Spinach	0.2	Lettuce	0.2	Parsley	
1.3	WHO cluster diet D	0.2	Tomatoes	0.2	Kale	0.1	Celery leaves	
1.0	UK vegetarian	0.4	Lettuce	0.2	Spinach	0.1	Tomatoes	
1.0	FR all population	0.2	Lettuce	0.1	Leek	0.1	Tomatoes	
0.7	LT adult	0.3	Cucumbers	0.2	Lettuce	0.1	Tomatoes	
0.7	UK Adult	0.3	Lettuce	0.1	Spinach	0.1	Tomatoes	
0.6	UK Toddler	0.2	Spinach	0.1	Tomatoes	0.1	Cucumbers	
0.6	FI adult	0.2	Lettuce	0.2	Cucumbers	0.1	Tomatoes	
0.5	PL general population	0.2	Tomatoes	0.0	Cauliflower	0.0	Cucumbers	
0.4	DK adult	0.2	Cucumbers	0.1	Tomatoes	0.0	Leek	
0.4	UK Infant	0.1	Cauliflower	0.1	Tomatoes	0.1	Spinach	
0.3	PT General population	0.2	Tomatoes	0.0	Potatoes	0.0	Parsley	

Conclusion:
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.

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 variabilty 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): 3			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** 1			**No of commodities for which ARfD/ADI is exceeded (IESTI 1):** ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** ---		
IESTI 1	***)**	****)**	**IESTI 2**	***)**	****)**	**IESTI 1**	***)**	****)**	**IESTI 2**	***)**	**)
Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
121.1	Spinach	45 / 37.16	121.1	Spinach	45 / 37.16	48.4	Lettuce	37 / -	47.9	Spinach	45 / -
118.5	Lettuce	37 / 31.22	84.3	Scarole (broad-leaf	8.1 / -	47.9	Spinach	45 / -	29.0	Lettuce	37 / -
105.3	Leek	15 / 14.24	75.2	Leek	15 / -	34.1	Leek	15 / -	25.8	Leek	15 / -
95.0	Kale	11.8 / -	71.1	Lettuce	37 / -	28.6	Kale	11.8 / -	21.3	Kale	11.8 / -
84.3	Scarole (broad-leaf	8.1 / -	67.9	Kale	11.8 / -	15.7	Witloof	8 / -	13.9	Cauliflower	3.67 / -

No of critical MRLs (IESTI 1) 3 **No of critical MRLs (IESTI 2)** 1

Processed commodities

No of commodities for which ARfD/ADI is exceeded: ---				**No of commodities for which ARfD/ADI is exceeded:** ---			
		*****)**				*****)**	
Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)		Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	
4.5	Tomato juice	2.18 / -		0.5	Tomato (preserved-	2.18 / -	
0.0	Potato puree (flakes)	0.03 / -		0.0	Potato uree (flakes)	0.03 / -	
0.0	Fried potatoes	0.03 / -		0.0	Fried potatoes	0.03 / -	

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

Conclusion:

For Propamocarb (free base) IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.
The estimated short term intake (IESTI 1) exceeded the ARfD/ADI for 3 commodities.
Also the IESTI 2 calculation, using less conservative variability factors, resulted in exceedances of the ARfD/ADI for 1 commodities.
For processed commodities, no exceedance of the ARfD/ADI was identified.

APPENDIX B.2 – PRIMO INCLUDING SAFE EC MRL PROPOSALS RESULTING FROM THE GAPS REPORTED BY THE RMS

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**	Source of ARfD:	**EFSA**
Year of evaluation:	**2011**	Year of evaluation:	**2011**

Chronic risk assessment - refined calculations

	TMDI (range) in % of ADI minimum - maximum
	0 3
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	pTMRLs at LOQ (in % of ADI)
2.9	WHO Cluster diet B	1.0	Lettuce	0.7	Tomatoes	0.2	Parsley	
2.7	NL child	0.5	Spinach	0.5	Milk and milk products: Cattle	0.3	Scarole (broad-leaf endive)	
2.1	WHO regional European diet	1.0	Lettuce	0.2	Tomatoes	0.1	Celery leaves	
2.0	ES adult	1.5	Lettuce	0.2	Tomatoes	0.1	Spinach	
1.9	FR toddler	1.0	Spinach	0.3	Courgettes	0.2	Cauliflower	
1.9	ES child	1.1	Lettuce	0.2	Tomatoes	0.2	Milk and milk products: Cattle	
1.8	DE child	0.4	Cucumbers	0.3	Spinach	0.2	Milk and milk products: Cattle	
1.8	IT adult	1.0	Lettuce	0.3	Tomatoes	0.1	Spinach	
1.7	FR infant	0.6	Spinach	0.4	Milk and milk products: Cattle	0.4	Courgettes	
1.7	DK child	1.1	Cucumbers	0.4	Lettuce	0.1	Tomatoes	
1.5	IT kids/toddler	0.8	Lettuce	0.3	Tomatoes	0.1	Courgettes	
1.4	NL general	0.3	Lettuce	0.2	Spinach	0.2	Scarole (broad-leaf endive)	
1.3	WHO Cluster diet F	0.8	Lettuce	0.2	Tomatoes	0.1	Cucumbers	
1.3	IE adult	0.2	Lettuce	0.2	Spinach	0.2	Melons	
1.3	WHO cluster diet D	0.2	Tomatoes	0.2	Kale	0.1	Celery leaves	
1.2	SE general population 90th percentile	0.2	Milk and milk products: Cattle	0.2	Cucumbers	0.2	Tomatoes	
1.1	WHO cluster diet E	0.2	Lettuce	0.2	Parsley	0.1	Tomatoes	
0.8	UK vegetarian	0.4	Lettuce	0.1	Tomatoes	0.1	Cucumbers	
0.8	FR all population	0.2	Lettuce	0.1	Tomatoes	0.1	Courgettes	
0.7	LT adult	0.3	Cucumbers	0.2	Lettuce	0.1	Tomatoes	
0.6	UK Adult	0.3	Lettuce	0.1	Tomatoes	0.0	Cucumbers	
0.5	FI adult	0.2	Lettuce	0.2	Cucumbers	0.1	Tomatoes	
0.5	PL general population	0.2	Tomatoes	0.0	Cauliflower	0.0	Cucumbers	
0.4	UK Toddler	0.1	Tomatoes	0.1	Cucumbers	0.1	Lettuce	
0.4	DK adult	0.2	Cucumbers	0.1	Tomatoes	0.0	Melons	
0.3	UK Infant	0.1	Cauliflower	0.1	Tomatoes	0.0	Brussels sprouts	
0.3	PT General population	0.2	Tomatoes	0.0	Potatoes	0.0	Parsley	

Conclusion:
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.

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 variabilty 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):** ---		
IESTI 1	***)**	****)**	**IESTI 2**	***)**	****)**	**IESTI 1**	***)**	****)**	**IESTI 2**	***)**	**)
Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
95.0	Kale	11.8 / -	84.3	Scarole (broad-leaf	8.1 / -	38.3	Lettuce	29.3 / -	23.0	Lettuce	29.3 / -
93.8	Lettuce	29.3 / -	67.9	Kale	11.8 / -	28.6	Kale	11.8 / -	21.3	Kale	11.8 / -
84.3	Scarole (broad-leaf	8.1 / -	56.3	Lettuce	29.3 / -	19.1	Spinach	18 / -	19.1	Spinach	18 / -
48.4	Spinach	18 / -	48.4	Spinach	18 / -	15.7	Witloof	8 / -	13.9	Cauliflower	3.67 / -
44.2	Witloof	8 / -	33.6	Witloof	8 / -	13.9	Cauliflower	3.67 / -	12.9	Witloof	8 / -
No of critical MRLs (IESTI 1) ---						**No of critical MRLs (IESTI 2)** ---					

Processed commodities

No of commodities for which ARfD/ADI is exceeded: ---				**No of commodities for which ARfD/ADI is exceeded:** ---			
		*****)**				*****)**	
Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)		Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	
4.5	Tomato juice	2.18 / -		0.5	Tomato (preserved-	2.18 / -	
0.0	Potato puree (flakes)	0.03 / -		0.0	Potato uree (flakes)	0.03 / -	
0.0	Fried potatoes	0.03 / -		0.0	Fried potatoes	0.03 / -	

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

Conclusion:

For Propamocarb (free base) IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.
No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

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

APPENDIX B.3 – PRIMO INCLUDING SAFE EC MRL PROPOSALS AND ALL CXLS

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**	Source of ARfD:	**EFSA**
Year of evaluation:	**2011**	Year of evaluation:	**2011**

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	pTMRLs at LOQ (in % of ADI)
4.3	FR toddler	3.2	Spinach	0.3	Courgettes	0.2	Cauliflower	
4.1	NL child	1.7	Spinach	0.5	Milk and milk products: Cattle	0.4	Lettuce	
3.4	WHO Cluster diet B	1.5	Lettuce	0.7	Tomatoes	0.4	Spinach	
3.2	FR infant	2.0	Spinach	0.4	Milk and milk products: Cattle	0.4	Courgettes	
2.9	ES adult	2.2	Lettuce	0.3	Spinach	0.2	Tomatoes	
2.7	WHO regional European diet	1.5	Lettuce	0.2	Tomatoes	0.2	Spinach	
2.7	ES child	1.7	Lettuce	0.4	Spinach	0.2	Tomatoes	
2.6	DE child	0.9	Spinach	0.4	Cucumbers	0.3	Lettuce	
2.5	IT adult	1.5	Lettuce	0.4	Spinach	0.3	Tomatoes	
2.1	NL general	0.7	Spinach	0.5	Lettuce	0.2	Scarole (broad-leaf endive)	
2.0	IT kids/toddler	1.2	Lettuce	0.3	Tomatoes	0.3	Spinach	
1.9	DK child	1.1	Cucumbers	0.6	Lettuce	0.1	Tomatoes	
1.8	WHO Cluster diet F	1.2	Lettuce	0.2	Tomatoes	0.1	Cucumbers	
1.7	IE adult	0.6	Spinach	0.3	Lettuce	0.1	Basil	
1.4	SE general population 90th percentile	0.3	Spinach	0.2	Milk and milk products: Cattle	0.2	Cucumbers	
1.3	WHO cluster diet E	0.4	Lettuce	0.2	Spinach	0.2	Parsley	
1.3	WHO cluster diet D	0.2	Tomatoes	0.2	Kale	0.1	Celery leaves	
1.1	UK vegetarian	0.6	Lettuce	0.2	Spinach	0.1	Tomatoes	
0.9	FR all population	0.4	Lettuce	0.1	Tomatoes	0.1	Courgettes	
0.9	LT adult	0.3	Lettuce	0.3	Cucumbers	0.1	Tomatoes	
0.8	UK Adult	0.5	Lettuce	0.1	Tomatoes	0.1	Spinach	
0.7	FI adult	0.3	Lettuce	0.2	Cucumbers	0.1	Tomatoes	
0.6	UK Toddler	0.1	Tomatoes	0.1	Spinach	0.1	Lettuce	
0.5	PL general population	0.2	Tomatoes	0.1	Potatoes	0.1	Lettuce	
0.4	UK Infant	0.1	Cauliflower	0.1	Tomatoes	0.1	Potatoes	
0.4	DK adult	0.2	Cucumbers	0.1	Tomatoes	0.0	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 pTMRLs 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 variabilty 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):		**1**	**No of commodities for which ARfD/ADI is exceeded (IESTI 2):**		**1**	**No of commodities for which ARfD/ADI is exceeded (IESTI 1):**		**1**	**No of commodities for which ARfD/ADI is exceeded (IESTI 2):**		**---**
IESTI 1	***)**	****)**	**IESTI 2**	***)**	****)**	**IESTI 1**	***)**	****)**	**IESTI 2**	***)**	**)
Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
275.4	Lettuce	86 / 31.22	165.3	Lettuce	86 / 52.03	112.5	Lettuce	86 / 76.43	67.5	Lettuce	86 / -
95.0	Kale	11.8 / -	84.3	Scarole (broad-leaf	8.1 / -	30.9	Spinach	29 / -	30.9	Spinach	29 / -
84.3	Scarole (broad-leaf	8.1 / -	78.0	Spinach	29 / -	30.2	Pumpkins	4.8 / -	30.2	Pumpkins	4.8 / -
78.0	Spinach	29 / -	67.9	Kale	11.8 / -	28.6	Kale	11.8 / -	21.3	Kale	11.8 / -
44.2	Witloof	8 / -	33.6	Witloof	8 / -	15.7	Witloof	8 / -	13.9	Cauliflower	3.67 / -
No of critical MRLs (IESTI 1)		1				**No of critical MRLs (IESTI 2)**		1			

Processed commodities

No of commodities for which ARfD/ADI is exceeded:		**---**				**No of commodities for which ARfD/ADI is exceeded:**		**---**			
		*****)**						*****)**			
Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)				Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)			
4.5	Tomato juice	2.18 / -				0.5	Tomato (preserved-	2.18 / -			
0.3	Potato puree (flakes)	0.17 / -				0.0	Potato uree (flakes)	0.17 / -			
0.0	Fried potatoes	0.17 / -				0.0	Fried potatoes	0.17 / -			

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

Conclusion:

For Propamocarb (free base) IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.
The estimated short term intake (IESTI 1) exceeded the ARfD/ADI for 1 commodities.
Also the IESTI 2 calculation, using less conservative variability factors, resulted in exceedances of the ARfD/ADI for 1 commodities.
For processed commodities, no exceedance of the ARfD/ADI was identified.

APPENDIX B.4 – PRIMO INCLUDING SAFE EC MRL PROPOSALS AND SAFE CXLS

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**	Source of ARfD:	**EFSA**
Year of evaluation:	**2011**	Year of evaluation:	**2011**

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	pTMRLs at LOQ (in % of ADI)
4.3	FR toddler	3.2	Spinach	0.3	Courgettes	0.2	Cauliflower	
3.9	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	
3.0	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	
1.9	NL general	0.7	Spinach	0.3	Lettuce	0.2	Scarole (broad-leaf endive)	
1.7	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	IE adult	0.6	Spinach	0.2	Lettuce	0.1	Basil	
1.4	SE general population 90th percentile	0.3	Spinach	0.2	Milk and milk products: Cattle	0.2	Cucumbers	
1.4	WHO Cluster diet F	0.8	Lettuce	0.2	Tomatoes	0.1	Cucumbers	
1.2	WHO cluster diet D	0.2	Tomatoes	0.2	Kale	0.1	Celery leaves	
1.2	WHO cluster diet E	0.2	Lettuce	0.2	Spinach	0.2	Parsley	
0.9	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	UK Toddler	0.1	Tomatoes	0.1	Spinach	0.1	Cucumbers	
0.6	FI adult	0.2	Lettuce	0.2	Cucumbers	0.1	Tomatoes	
0.5	PL general population	0.2	Tomatoes	0.1	Potatoes	0.0	Cauliflower	
0.4	UK Infant	0.1	Cauliflower	0.1	Tomatoes	0.1	Potatoes	
0.4	DK adult	0.2	Cucumbers	0.1	Tomatoes	0.0	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 pTMRLs 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 variabilty 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):** ---		
IESTI 1	***)**	****)**	**IESTI 2**	***)**	****)**	**IESTI 1**	***)**	****)**	**IESTI 2**	***)**	**)
Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
95.0	Kale	11.8 / -	84.3	Scarole (broad-leaf	8.1 / -	38.3	Lettuce	29.3 / -	30.9	Spinach	29 / -
93.8	Lettuce	29.3 / -	78.0	Spinach	29 / -	30.9	Spinach	29 / -	30.2	Pumpkins	4.8 / -
84.3	Scarole (broad-leaf	8.1 / -	67.9	Kale	11.8 / -	30.2	Pumpkins	4.8 / -	23.0	Lettuce	29.3 / -
78.0	Spinach	29 / -	56.3	Lettuce	29.3 / -	28.6	Kale	11.8 / -	21.3	Kale	11.8 / -
44.2	Witloof	8 / -	33.6	Witloof	8 / -	15.7	Witloof	8 / -	13.9	Cauliflower	3.67 / -
No of critical MRLs (IESTI 1) ---						**No of critical MRLs (IESTI 2)** ---					

Processed commodities

No of commodities for which ARfD/ADI is exceeded: ---				**No of commodities for which ARfD/ADI is exceeded:** ---			
		*****)**				*****)**	
Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)		Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	
4.5	Tomato juice	2.18 / -		0.5	Tomato (preserved-	2.18 / -	
0.3	Potato puree (flakes)	0.17 / -		0.0	Potato uree (flakes)	0.17 / -	
0.0	Fried potatoes	0.17 / -		0.0	Fried potatoes	0.17 / -	

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

Conclusion:

For Propamocarb (free base) IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.
No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

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

APPENDIX C – EXISTING EU MAXIMUM RESIDUE LIMITS (MRLS) AND CODEX LIMITS (CXLS)

Appendix C.1 – Existing EU MRLs

Appendix C.2 – Existing CXLs

APPENDIX C.1 – EXISTING EU MRLS

(Pesticides - Web Version - EU MRLs (File created on 07/03/2013 13:37)

Code number	Groups and examples of individual products to which the MRLs apply (a)	Propamocarb (Sum of propamocarb and its salt expressed as propamocarb)
100000	1. FRUIT FRESH OR FROZEN; NUTS	
110000	(i) Citrus fruit	
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids)	10
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0,1*
110030	Lemons (Citron, lemon)	10
110040	Limes	10
110050	Mandarins (Clementine, tangerine and other hybrids)	10
110990	Others	10
120000	(ii) Tree nuts (shelled or unshelled)	0,1*
120010	Almonds	0,1*
120020	Brazil nuts	0,1*
120030	Cashew nuts	0,1*
120040	Chestnuts	0,1*
120050	Coconuts	0,1*
120060	Hazelnuts (Filbert)	0,1*
120070	Macadamia	0,1*
120080	Pecans	0,1*
120090	Pine nuts	0,1*
120100	Pistachios	0,1*
120110	Walnuts	0,1*
120990	Others	0,1*
130000	(iii) Pome fruit	
130010	Apples (Crab apple)	10
130020	Pears (Oriental pear)	10
130030	Quinces	0,1*
130040	Medlar	0,1*
130050	Loquat	0,1*
130990	Others	0,1*
140000	(iv) Stone fruit	0,1*
140010	Apricots	0,1*
140020	Cherries (sweet cherries, sour cherries)	0,1*
140030	Peaches (Nectarines and similar hybrids)	0,1*
140040	Plums (Damson, greengage, mirabelle)	0,1*
140990	Others	0,1*
150000	(v) Berries & small fruit	
151000	(a) Table and wine grapes	0,1*
151010	Table grapes	0,1*
151020	Wine grapes	0,1*
152000	(b) Strawberries	10
153000	(c) Cane fruit	0,1*
153010	Blackberries	0,1*
153020	Dewberries (Loganberries, Boysenberries, and cloudberries)	0,1*
153030	Raspberries (Wineberries)	0,1*
153990	Others	0,1*
154000	(d) Other small fruit & berries	0,1*
154010	Blueberries (Bilberries cowberries (red bilberries))	0,1*
154020	Cranberries	0,1*
154030	Currants (red, black and white)	0,1*
154040	Gooseberries (Including hybrids with other ribes species)	0,1*
154050	Rose hips	0,1*
154060	Mulberries (arbutus berry)	0,1*
154070	Azarole (mediteranean medlar)	0,1*
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea sallowthorn), hawthorn, service berries, and other treeberries)	0,1*
154990	Others	0,1*
160000	(vi) Miscellaneous fruit	0,1*
161000	(a) Edible peel	0,1*
161010	Dates	0,1*
161020	Figs	0,1*
161030	Table olives	0,1*
161040	Kumquats (Marumi kumquats, nagami kumquats)	0,1*
161050	Carambola (Bilimbi)	0,1*
161060	Persimmon	0,1*
161070	Jambolan (java plum) (Java apple (water apple), pomerac, rose apple, Brazilean cherry (grumichama), Surinam cherry)	0,1*
161990	Others	0,1*
162000	(b) Inedible peel, small	0,1*
162010	Kiwi	0,1*
162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	0,1*
162030	Passion fruit	0,1*
162040	Prickly pear (cactus fruit)	0,1*
162050	Star apple	0,1*
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammey sapote)	0,1*
162990	Others	0,1*
163000	(c) Inedible peel, large	0,1*
163010	Avocados	0,1*
163020	Bananas (Dwarf banana, plantain, apple banana)	0,1*
163030	Mangoes	0,1*
163040	Papaya	0,1*
163050	Pomegranate	0,1*
163060	Cherimoya (Custard apple, sugar apple (sweetsop) , llama and other medium sized Annonaceae)	0,1*
163070	Guava	0,1*
163080	Pineapples	0,1*
163090	Bread fruit (Jackfruit)	0,1*
163100	Durian	0,1*
163110	Soursop (guanabana)	0,1*
163990	Others	0,1*
200000	2. VEGETABLES FRESH OR FROZEN	
210000	(i) Root and tuber vegetables	
211000	(a) Potatoes	0,5
212000	(b) Tropical root and tuber vegetables	
212010	Cassava (Dasheen, eddoe (Japanese taro), tannia)	0,5
212020	Sweet potatoes	0,5
212030	Yams (Potato bean (yam bean), Mexican yam bean)	0,5
212040	Arrowroot	10
212990	Others	10
213000	(c) Other root and tuber vegetables except sugar beet	
213010	Beetroot	0,1*
213020	Carrots	10
213030	Celeriac	0,2
213040	Horseradish	0,5
213050	Jerusalem artichokes	0,1*
213060	Parsnips	0,1*
213070	Parsley root	0,5
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	10
213090	Salsify (Scorzonera, Spanish salsify (Spanish oysterplant))	0,1*
213100	Swedes	0,1*
213110	Turnips	10
213990	Others	0,1*
220000	(ii) Bulb vegetables	
220010	Garlic	10
220020	Onions (Silverskin onions)	10
220030	Shallots	2
220040	Spring onions (Welsh onion and similar varieties)	0,1*
220990	Others	0,1*
230000	(iii) Fruiting vegetables	
231000	(a) Solanacea	10
231010	Tomatoes (Cherry tomatoes,)	10
231020	Peppers (Chilli peppers)	10
231030	Aubergines (egg plants) (Pepino)	10
231040	Okra, lady's fingers	10

Code number	Groups and examples of individual products to which the MRLs apply (a)	Propamocarb (Sum of propamocarb and its salt expressed as propamocarb)
231990	Others	10
232000	(b) Cucurbits - edible peel	10
232010	Cucumbers	10
232020	Gherkins	10
232030	Courgettes (Summer squash, marrow (patisson))	10
232990	Others	10
233000	(c) Cucurbits-inedible peel	
233010	Melons (Kiwano)	5
233020	Pumpkins (Winter squash)	10
233030	Watermelons	5
233990	Others	10
234000	(d) Sweet corn	2
239000	(e) Other fruiting vegetables	10
240000	(iv) Brassica vegetables	
241000	(a) Flowering brassica	10
241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	10
241020	Cauliflower	10
241990	Others	10
242000	(b) Head brassica	10
242010	Brussels sprouts	10
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	10
242990	Others	10
243000	(c) Leafy brassica	
243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	10
243020	Kale (Borecole (curly kale), collards)	20
243990	Others	10
244000	(d) Kohlrabi	10
250000	(v) Leaf vegetables & fresh herbs	
251000	(a) Lettuce and other salad plants including Brassicacea	
251010	Lamb´s lettuce (Italian cornsalad)	30
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	50
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curld leave endive,	10
	sugar loaf)	
251040	Cress	30
251050	Land cress	20
251060	Rocket, Rucola (Wild rocket)	20
251070	Red mustard	20
251080	Leaves and sprouts of Brassica spp (Mizuna)	20
251990	Others	20
252000	(b) Spinach & similar (leaves)	
252010	Spinach (New Zealand spinach, turnip greens (turnip tops))	30
252020	Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glassworth)	20
252030	Beet leaves (chard) (Leaves of beetroot)	10
252990	Others	10
253000	(c) Vine leaves (grape leaves)	30
254000	(d) Water cress	5
255000	(e) Witloof	10
256000	(f) Herbs	30
256010	Chervil	30
256020	Chives	30
256030	Celery leaves (fennel leaves , Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cisely and other Apiacea)	30
256040	Parsley	30
256050	Sage (Winter savory, summer savory,)	30
256060	Rosemary	30
256070	Thyme (marjoram, oregano)	30
256080	Basil (Balm leaves, mint, peppermint)	30
256090	Bay leaves (laurel)	30
256100	Tarragon (Hyssop)	30
256990	Others	30
260000	(vi) Legume vegetables (fresh)	0,1*
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	0,1*
260020	Beans (without pods) (Broad beans, Flageolets, jack bean, lima	0,1*
	bean, cowpea)	
260030	Peas (with pods) (Mangetout (sugar peas))	0,1*
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0,1*
260050	Lentils	0,1*
260990	Others	0,1*
270000	(vii) Stem vegetables (fresh)	
270010	Asparagus	0,1*
270020	Cardoons	0,1*
270030	Celery	10
270040	Fennel	0,1*
270050	Globe artichokes	0,1*
270060	Leek	10
270070	Rhubarb	0,1*
270080	Bamboo shoots	0,1*
270090	Palm hearts	0,1*
270990	Others	0,1*
280000	(viii) Fungi	0,1*
280010	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	0,1*
280020	Wild (Chanterelle, Truffle, Morel ,)	0,1*
280990	Others	0,1*
290000	(ix) Sea weeds	0,1*
300000	3. PULSES, DRY	0,1*
300010	Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas)	0,1*
300020	Lentils	0,1*
300030	Peas (Chickpeas, field peas, chickling vetch)	0,1*
300040	Lupins	0,1*
300990	Others	0,1*
400000	4. OILSEEDS AND OILFRUITS	0,1*
401000	(i) Oilseeds	0,1*
401010	Linseed	0,1*
401020	Peanuts	0,1*
401030	Poppy seed	0,1*
401040	Sesame seed	0,1*
401050	Sunflower seed	0,1*
401060	Rape seed (Bird rapeseed, turnip rape)	0,1*
401070	Soya bean	0,1*
401080	Mustard seed	0,1*
401090	Cotton seed	0,1*
401100	Pumpkin seeds	0,1*
401110	Safflower	0,1*
401120	Borage	0,1*
401130	Gold of pleasure	0,1*
401140	Hempseed	0,1*
401150	Castor bean	0,1*
401990	Others	0,1*
402000	(ii) Oilfruits	0,1*
402010	Olives for oil production	0,1*
402020	Palm nuts (palmoil kernels)	0,1*
402030	Palmfruit	0,1*
402040	Kapok	0,1*
402990	Others	0,1*
500000	5. CEREALS	0,1*
500010	Barley	0,1*
500020	Buckwheat	0,1*
500030	Maize	0,1*
500040	Millet (Foxtail millet, teff)	0,1*
500050	Oats	0,1*
500060	Rice	0,1*
500070	Rye	0,1*
500080	Sorghum	0,1*
500090	Wheat (Spelt Triticale)	0,1*
500990	Others	0,1*
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	0,2*
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	0,2*
620000	(ii) Coffee beans	0,2*
630000	(iii) Herbal infusions (dried)	0,2*
631000	(a) Flowers	0,2*
631010	Camomille flowers	0,2*
631020	Hybiscus flowers	0,2*
631030	Rose petals	0,2*
631040	Jasmine flowers	0,2*
631050	Lime (linden)	0,2*
631990	Others	0,2*
632000	(b) Leaves	0,2*
632010	Strawberry leaves	0,2*
632020	Rooibos leaves	0,2*
632030	Maté	0,2*
632990	Others	0,2*
633000	(c) Roots	0,2*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Propamocarb (Sum of propamocarb and its salt expressed as propamocarb)
633010	Valerian root	0,2*
633020	Ginseng root	0,2*
633990	Others	0,2*
639000	(d) Other herbal infusions	0,2*
640000	(iv) Cocoa (fermented beans)	0,2*
650000	(v) Carob (st johns bread)	0,2*
700000	7. HOPS (dried) , including hop pellets and unconcentrated powder	0,2*
800000	8. SPICES	0,2*
810000	(i) Seeds	0,2*
810010	Anise	0,2*
810020	Black caraway	0,2*
810030	Celery seed (Lovage seed)	0,2*
810040	Coriander seed	0,2*
810050	Cumin seed	0,2*
810060	Dill seed	0,2*
810070	Fennel seed	0,2*
810080	Fenugreek	0,2*
810090	Nutmeg	0,2*
810990	Others	0,2*
820000	(ii) Fruits and berries	0,2*
820010	Allspice	0,2*
820020	Anise pepper (Japan pepper)	0,2*
820030	Caraway	0,2*
820040	Cardamom	0,2*
820050	Juniper berries	0,2*
820060	Pepper, black and white (Long pepper, pink pepper)	0,2*
820070	Vanilla pods	0,2*
820080	Tamarind	0,2*
820990	Others	0,2*
830000	(iii) Bark	0,2*
830010	Cinnamon (Cassia)	0,2*
830990	Others	0,2*
840000	(iv) Roots or rhizome	0,2*
840010	Liquorice	0,2*
840020	Ginger	0,2*
840030	Turmeric (Curcuma)	0,2*
840040	Horseradish	0,2*
840990	Others	0,2*
850000	(v) Buds	0,2*
850010	Cloves	0,2*
850020	Capers	0,2*
850990	Others	0,2*
860000	(vi) Flower stigma	0,2*
860010	Saffron	0,2*
860990	Others	0,2*
870000	(vii) Aril	0,2*
870010	Mace	0,2*
870990	Others	0,2*
900000	9. SUGAR PLANTS	0,1*
900010	Sugar beet (root)	0,1*
900020	Sugar cane	0,1*
900030	Chicory roots	0,1*
900990	Others	0,1*
1000000	10. PRODUCTS OF ANIMAL ORIGIN-TERRESTRIAL ANIMALS	0,1*
1010000	(i) Meat, preparations of meat, offals, blood, animal fats fresh chilled or frozen, salted, in brine, dried or smoked or processed as flours or meals other processed products such as sausages and food preparations based on these	0,1*
1011000	(a) Swine	0,1*
1011010	Meat	0,1*
1011020	Fat free of lean meat	0,1*
1011030	Liver	0,1*
1011040	Kidney	0,1*
1011050	Edible offal	0,1*
1011990	Others	0,1*
1012000	(b) Bovine	0,1*
1012010	Meat	0,1*
1012020	Fat	0,1*
1012030	Liver	0,1*
1012040	Kidney	0,1*
1012050	Edible offal	0,1*
1012990	Others	0,1*
1013000	(c) Sheep	0,1*
1013010	Meat	0,1*
1013020	Fat	0,1*
1013030	Liver	0,1*
1013040	Kidney	0,1*
1013050	Edible offal	0,1*
1013990	Others	0,1*
1014000	(d) Goat	0,1*
1014010	Meat	0,1*
1014020	Fat	0,1*
1014030	Liver	0,1*
1014040	Kidney	0,1*
1014050	Edible offal	0,1*
1014990	Others	0,1*
1015000	(e) Horses, asses, mules or hinnies	0,1*
1015010	Meat	0,1*
1015020	Fat	0,1*
1015030	Liver	0,1*
1015040	Kidney	0,1*
1015050	Edible offal	0,1*
1015990	Others	0,1*
1016000	(f) Poultry -chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	0,1*
1016010	Meat	0,1*
1016020	Fat	0,1*
1016030	Liver	0,1*
1016040	Kidney	0,1*
1016050	Edible offal	0,1*
1016990	Others	0,1*
1017000	(g) Other farm animals (Rabbit, Kangaroo)	0,1*
1017010	Meat	0,1*
1017020	Fat	0,1*
1017030	Liver	0,1*
1017040	Kidney	0,1*
1017050	Edible offal	0,1*
1017990	Others	0,1*
1020000	(ii) Milk and cream, not concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curd	0,1*
1020010	Cattle	0,1*
1020020	Sheep	0,1*
1020030	Goat	0,1*
1020040	Horse	0,1*
1020990	Others	0,1*
1030000	(iii) Birds' eggs, fresh preserved or cooked Shelled eggs and egg yolks fresh, dried, cooked by steaming or boiling in water, moulded, frozen or otherwise preserved whether or not containing added sugar or sweetening matter	0,1*
1030010	Chicken	0,1*
1030020	Duck	0,1*
1030030	Goose	0,1*
1030040	Quail	0,1*
1030990	Others	0,1*
1040000	(iv) Honey (Royal jelly, pollen)	0,1*
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	0,1*
1060000	(vi) Snails	0,1*
1070000	(vii) Other terrestrial animal products	0,1*

(*) Indicates lower limit of analytical determination

APPENDIX C.2 – EXISTING CXLS

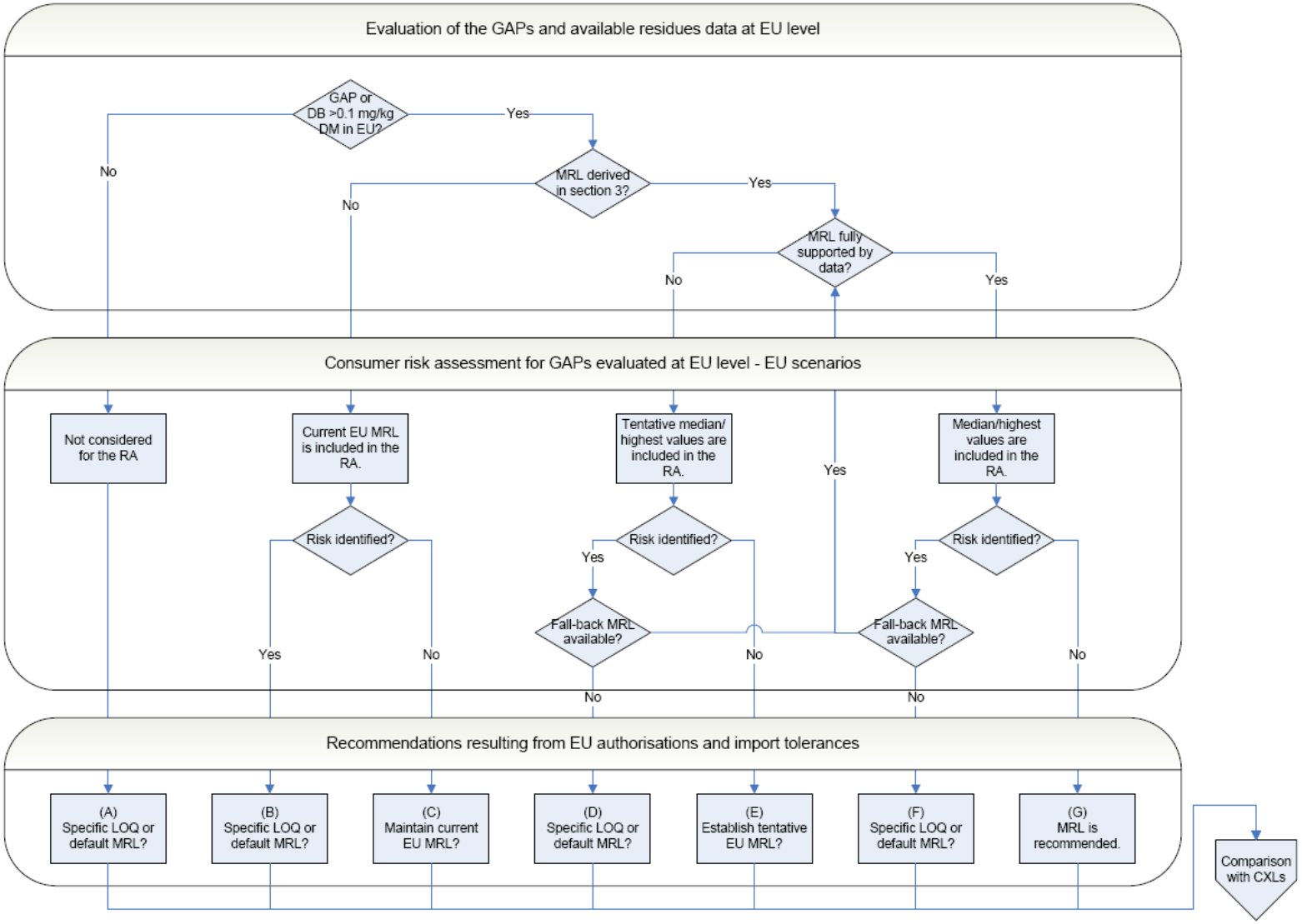
Summary of CXLs for propamocarb in plant commodities															
Commodity code	Commodity name	Values adopted by the CCPR		Critical values of the JMPR evaluation					Risk assessment values as calculated by EFSA				Comments on the JMPR evaluation		
		Residue definition	CXL (mg/kg)	Residue definition	STMR (-P) (mg/kg)	HR (-P) (mg/kg)	Default variability factor	Reduced variability factor	STMR (mg/kg)	HR (mg/kg)	Median peeling factor	Median conversion factor	Year	Based on EU GAP only?	Other comments
211000	Potatoes	Propamocarb	0.3	Propamocarb	0.05	0.17	3	n.c.	0.05	0.17	n.a.	1	2006	No	Trials were conducted in the USA and EU according to GAP.
213080	Radishes	Propamocarb	1	Propamocarb	0.33	0.42	1	n.c.	0.33	0.42	n.a.	1	2006	Yes	All trials were conducted in the EU according to appropriate GAP.
231010	Tomatoes	Propamocarb	2	Propamocarb	0.515	1.4	3	n.c.	0.515	1.4	n.a.	1	2006	No	Trials were conducted in the USA according to appropriate GAP.
231020	Peppers	Propamocarb	3	Propamocarb	0.265	1.8	3	n.c.	0.265	1.8	n.a.	1	2006	No	Trials were conducted in the USA according to appropriate GAP.
231030	Aubergines (egg plants)	Propamocarb	0.3	Propamocarb	0.008	0.16	3	n.c.	0.008	0.16	n.a.	1	2006	Yes	Based on EU sweet pepper trials.
232010	Cucumbers	Propamocarb	5	Propamocarb	0.59	4.8	3	n.c.	0.59	4.8	n.a.	1	2006	No	Data for cucumber and courgette were combined to estimate a CXL for cucurbits (except melon). Trials were conducted according to EU and USA GAP.
232020	Gherkins	Propamocarb	5	Propamocarb	0.59	4.8	3	n.c.	0.59	4.8	n.a.	1	2006	No	
232030	Courgettes	Propamocarb	5	Propamocarb	0.59	4.8	3	n.c.	0.59	4.8	n.a.	1	2006	No	
233010	Melons	Propamocarb	5	Propamocarb	0.04	0.53	3	n.c.	0.315	2.2	0.18	1	2006	No	Trials were conducted in the USA and EU according to GAP.
233020	Pumpkins	Propamocarb	5	Propamocarb	0.59	4.8	3	n.c.	0.59	4.8	n.a.	1	2006	No	See comments for cucumber
233030	Watermelons	Propamocarb	5	Propamocarb	0.04	0.53	3	n.c.	0.315	2.2	0.18	1	2006	No	See comments for melon.
241020	Cauliflower	Propamocarb	0.2	Propamocarb	0.035	0.09	3	n.c.	0.035	0.09	n.a.	1	2006	Yes	All trials were conducted in the EU according to appropriate GAP.
251020	Lettuce	Propamocarb	100	Propamocarb	9.9	86	3	n.c.	9.9	86	n.a.	1	2006	No	Trials were conducted in the USA and EU according to GAP.
252010	Spinach	Propamocarb	40	Propamocarb	11.2	29	3	n.c.	11.2	29	n.a.	1	2006	Yes	All trials were conducted in the EU according to appropriate GAP.
255000	Witloof	Propamocarb	2	Propamocarb	0.6	0.9	3	n.c.	0.6	0.9	n.a.	1	2006	Yes	All trials were conducted in the EU according to appropriate GAP.

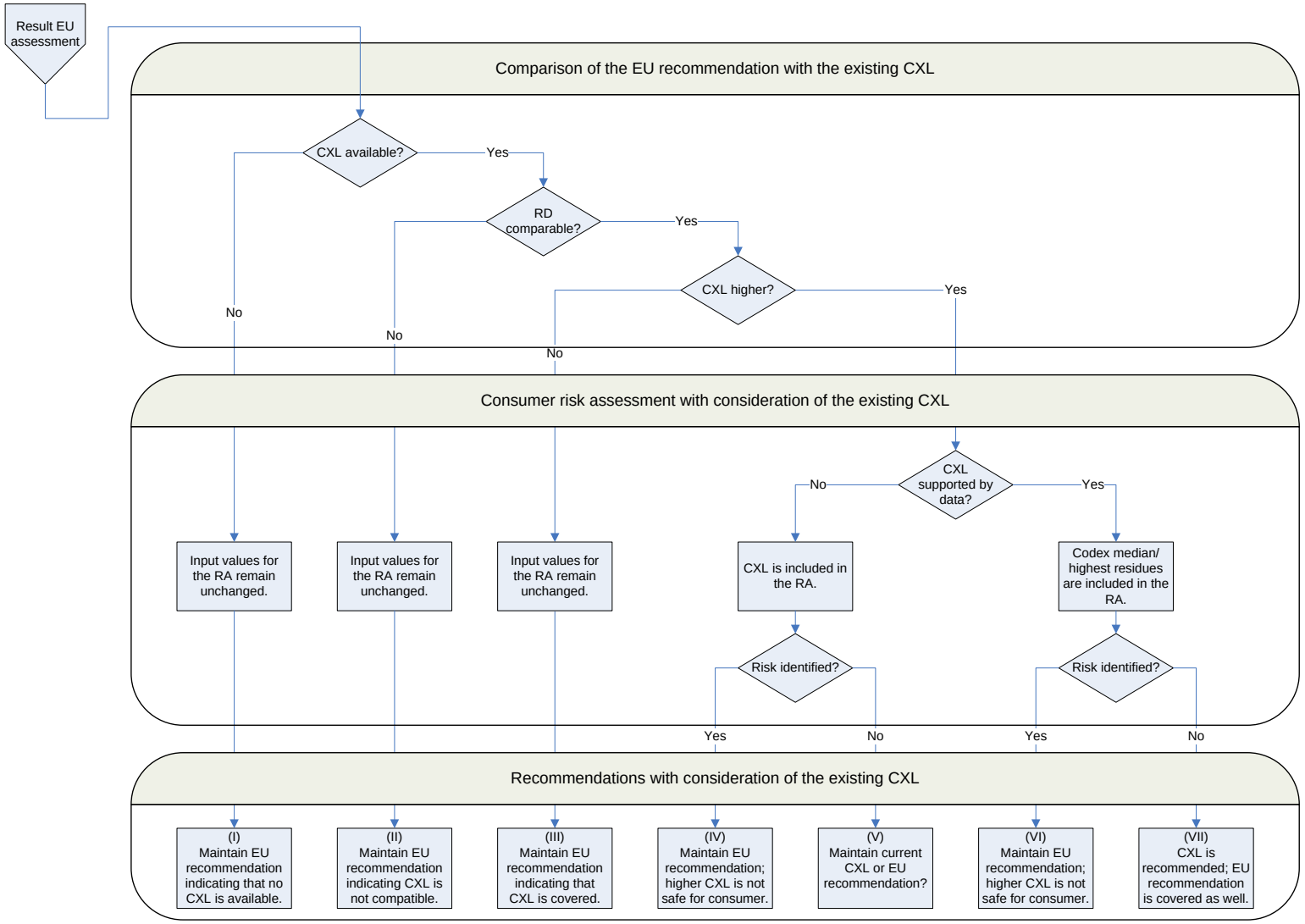
(*) Indicates the lower limit of analytical quantification.
n.a.: not applicable
n.c.: not considered
n.k.: not known

Summary of CXLs for propamocarb in livestock commodities										
Commodity code	Commodity name	Values adopted by the CCPR			Critical values of the JMPR evaluation			Comment on the JMPR evaluation		
		Residue definition	Expressed as fat?	CXL (mg/kg)	Residue definition	STMR (mg/kg)	HR (mg/kg)	Year	Based on EU GAP only?	Other comments
1011010	Swine meat	Propamocarb	no	0.01 *	Propamocarb	0	0.01	2006	no	No dietary burden is expected for propamocarb as a result of potato consumption.
1011030	Swine liver	Propamocarb	n.a.	0.01 *	Propamocarb	0	0.01	2006	no	
1011040	Swine kidney	Propamocarb	n.a.	0.01 *	Propamocarb	0	0.01	2006	no	
1011050	Swine edible offal	Propamocarb	n.a.	0.01 *	Propamocarb	0	0.01	2006	no	
1012010	Bovine meat	Propamocarb	no	0.01 *	Propamocarb	0	0.01	2006	no	No dietary burden is expected for propamocarb as a result of potato consumption.
1012030	Bovine liver	Propamocarb	n.a.	0.01 *	Propamocarb	0	0.01	2006	no	
1012040	Bovine kidney	Propamocarb	n.a.	0.01 *	Propamocarb	0	0.01	2006	no	
1012050	Bovine edible offal	Propamocarb	n.a.	0.01 *	Propamocarb	0	0.01	2006	no	
1013010	Sheep meat	Propamocarb	no	0.01 *	Propamocarb	0	0.01	2006	no	No dietary burden is expected for propamocarb as a result of potato consumption.
1013030	Sheep liver	Propamocarb	n.a.	0.01 *	Propamocarb	0	0.01	2006	no	
1013040	Sheep kidney	Propamocarb	n.a.	0.01 *	Propamocarb	0	0.01	2006	no	
1013050	Sheep edible offal	Propamocarb	n.a.	0.01 *	Propamocarb	0	0.01	2006	no	
1014010	Goat meat	Propamocarb	no	0.01 *	Propamocarb	0	0.01	2006	no	No dietary burden is expected for propamocarb as a result of potato consumption.
1014030	Goat liver	Propamocarb	n.a.	0.01 *	Propamocarb	0	0.01	2006	no	
1014040	Goat kidney	Propamocarb	n.a.	0.01 *	Propamocarb	0	0.01	2006	no	
1014050	Goat edible offal	Propamocarb	n.a.	0.01 *	Propamocarb	0	0.01	2006	no	
1015010	Horses, asses, mules or hinnies meat	Propamocarb	no	0.01 *	Propamocarb	0	0.01	2006	no	No dietary burden is expected for propamocarb as a result of potato consumption.
1015030	Horses, asses, mules or hinnies liver	Propamocarb	n.a.	0.01 *	Propamocarb	0	0.01	2006	no	
1015040	Horses, asses, mules or hinnies kidney	Propamocarb	n.a.	0.01 *	Propamocarb	0	0.01	2006	no	
1015050	Horses, asses, mules or hinnies edible offal	Propamocarb	n.a.	0.01 *	Propamocarb	0	0.01	2006	no	
1016010	Poultry meat	Propamocarb	no	0.01 *	Propamocarb	0	0.01	2006	no	No dietary burden is expected for propamocarb as a result of potato consumption.
1016030	Poultry liver	Propamocarb	n.a.	0.01 *	Propamocarb	0	0.01	2006	no	
1016040	Poultry kidney	Propamocarb	n.a.	0.01 *	Propamocarb	0	0.01	2006	no	
1016050	Poultry edible offal	Propamocarb	n.a.	0.01 *	Propamocarb	0	0.01	2006	no	
1017010	Other farm animals meat	Propamocarb	no	0.01 *	Propamocarb	0	0.01	2006	no	No dietary burden is expected for propamocarb as a result of potato consumption.
1017030	Other farm animals liver	Propamocarb	n.a.	0.01 *	Propamocarb	0	0.01	2006	no	
1017040	Other farm animals kidney	Propamocarb	n.a.	0.01 *	Propamocarb	0	0.01	2006	no	
1017050	Other farm animals edible offal	Propamocarb	n.a.	0.01 *	Propamocarb	0	0.01	2006	no	
1020010	Cattle milk	Propamocarb	n.a.	0.01 *	Propamocarb	0	n.c.	2006	no	No dietary burden is expected for propamocarb as a result of potato consumption.
1020020	Sheep milk	Propamocarb	n.a.	0.01 *	Propamocarb	0	n.c.	2006	no	
1020030	Goat milk	Propamocarb	n.a.	0.01 *	Propamocarb	0	n.c.	2006	no	
1020040	Horse milk	Propamocarb	n.a.	0.01 *	Propamocarb	0	n.c.	2006	no	
1030000	Birds' eggs	Propamocarb	n.a.	0.01 *	Propamocarb	0	0.01	2006	no	No dietary burden is expected for propamocarb as a result of potato consumption.

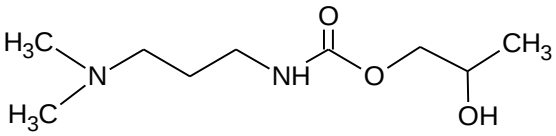
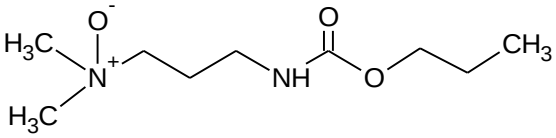
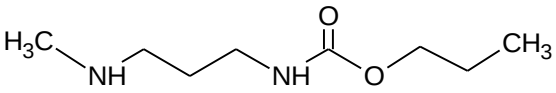
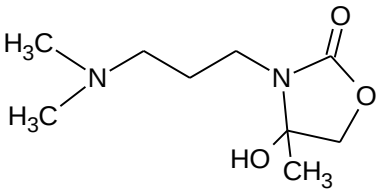
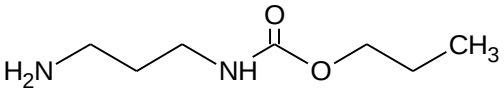
(*) Indicates the lower limit of analytical quantification.
n.a.: not applicable
n.c.: not considered
n.k.: not known

APPENDIX D – DECISION TREE FOR DERIVING MRL RECOMMENDATIONS




Result EU assessment
Comparison of the EU recommendation with the existing CXL
CXL available?
Yes
No
RD comparable?
Yes
No
CXL higher?
Yes
No
Consumer risk assessment with consideration of the existing CXL
CXL supported by data?
No
Yes
Input values for the RA remain unchanged.
Input values for the RA remain unchanged.
Input values for the RA remain unchanged.
CXL is included in the RA.
Codex median/ highest residues are included in the RA.
Risk identified?
Risk identified?
Yes
No
Yes
No
Recommendations with consideration of the existing CXL
(I) Maintain EU recommendation indicating that no CXL is available.
(II) Maintain EU recommendation indicating CXL is not compatible.
(III) Maintain EU recommendation indicating that CXL is covered.
(IV) Maintain EU recommendation; higher CXL is not safe for consumer.
(V) Maintain current CXL or EU recommendation?
(VI) Maintain EU recommendation; higher CXL is not safe for consumer.
(VII) CXL is recommended; EU recommendation is covered as well.

APPENDIX E – LIST OF METABOLITES AND RELATED STRUCTURAL FORMULA

Common name	IUPAC name	Structural formula
hydroxypropyl-propamocarb (also 2-hydroxy-propamocarb)	2-hydroxypropyl [3-(dimethylamino)propyl]carbamate	
propamocarb-N-oxide	propyl [3-(dimethylnitroryl)propyl]carbamate	
N-desmethyl-propamocarb	propyl [3-(methylamino)propyl]carbamate	
Oxazolidine-2-one propamocarb	3-[3-(dimethylamino)propyl]-4-hydroxy-4-methyl-1,3-oxazolidin-2-one	
Bis desmethyl-propamocarb	propyl [3-(amino)propyl]carbamate	

ABBREVIATIONS

a.s.	active substance
ADI	acceptable daily intake
AR	applied radioactivity
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CAC	Codex Alimentarius Commission
CEN	European Committee for Standardisation (Comité Européen de Normalisation)
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CXL	codex maximum residue limit
d	day
DAR	Draft Assessment Report (prepared under Council Directive 91/414/EEC)
DAT	days after treatment
DM	dry matter
DT_{90}	period required for 90 percent dissipation (define method of estimation)
EC	European Commission
EFSA	European Food Safety Authority
eq	residue expressed as a.s. equivalent
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
GAP	good agricultural practice
ha	hectare
HPLC-MS/MS	high performance liquid chromatography with tandem mass spectrometry
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
LOQ	limit of quantification
MRL	maximum residue limit
MS	Member States
MW	molecular weight
NEU	northern European Union
OECD	Organisation for Economic Co-operation and Development
PF	processing factor
PHI	pre-harvest interval
PROFile	(EFSA) Pesticide Residue Overview File
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
RA	risk assessment
RMS	rapporteur Member State
SC	suspension concentrate
SEU	Southern European Union
SL	soluble concentrate
TRR	total radioactive residue
WHO	World Health Organisation