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Review of the existing maximum residue levels for methomyl according to Article 12 of Regulation (EC) No 396/2005

European Food Safety Authority (EFSA)

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 methomyl. In order to assess the occurrence of methomyl 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 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.

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Keywords: methomyl, MRL review, Regulation (EC) No 396/2005, consumer risk assessment, oxime carbamate, insecticide, thiodicarb

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Summary

Methomyl was included in Annex I to Directive 91/414/EEC on 1 September 2009 by Commission Directive 2009/115/EC, and has been deemed to be approved under Regulation (EC) No 1107/2009, in accordance with Commission Implementing Regulation (EU) No 540/2011, as amended by Commission Implementing Regulation (EU) No 541/2011. As the active substance was approved after the entry into force of Regulation (EC) No 396/2005 on 2 September 2008, EFSA is required to provide a reasoned opinion on the review of the existing maximum residue levels (MRLs) for that active substance in compliance with Article 12(1) of the aforementioned regulation. In order to collect the relevant pesticide residues data, EFSA asked the United Kingdom, as the designated rapporteur Member State (RMS), to complete the Pesticide Residues Overview File (PROFile) and to prepare a supporting evaluation report. However, as neither registered good agricultural practices (GAPs) nor import tolerances from any Member State had been provided, the RMS was not able to submit these documents. Nevertheless, a PROFile was prepared by EFSA in order to compile all the information relative to methomyl, by default including the representative uses evaluated during the peer review.

A request for additional information was addressed to the Member States in the framework of a completeness check period which was initiated by EFSA on 6 March 2015 and finalised on 6 May 2015. This completeness check was seen as the opportunity for Member States to provide to EFSA an updated view on their authorised GAPs for methomyl. After having considered all the information provided, EFSA prepared a completeness check report which was made available to Member States on 11 June 2015.

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 and Member States, EFSA prepared in August 2015 a draft reasoned opinion, which was circulated to Member States for consultation via a written procedure. Comments received by 11 September 2015 were considered during the finalisation of this reasoned opinion. The following conclusions are derived.

The metabolism of methomyl has been properly investigated in grapes. The other submitted metabolism studies were not deemed acceptable. Methomyl remained the major component of the residue in grapes and the three identified metabolites are not expected to significantly contribute to the global toxicological burden. Consequently, a residue definition for monitoring and risk assessment including methomyl only can be proposed but is restricted to fruit crops only. For leafy crops and pulses and oilseeds, appropriate metabolism studies are missing to cover the nature of residues in lettuce, spinach, beans (fresh with pods), peas (fresh with pods) and cotton seed. Meanwhile, the residue definition consisting in methomyl only is applied to these commodities on a tentative basis. A validated analytical method is available for the enforcement of the proposed residue definition in commodities of plant origin.

Studies on the nature of the residues in succeeding crops show that methomyl residues either did not translocate to succeeding crops in significant amount, either were extensively degraded into carbon fragments before being incorporated into natural plant constituents. In any case, levels of methomyl and its immediate metabolites always remain below or equal to 0.01 mg/kg. Therefore a specific residue definition for rotational crops is not needed and significant residues are not expected in crops grown in rotation.

The available residue trials allowed EFSA assessing the magnitude of residues resulting from the authorised GAPs reported in this review. MRL proposals as well as risk assessment values were derived for all commodities under evaluation. For peppers, cucurbits with inedible peel, beans (fresh, with pods), peas (fresh, with pods) where residue trials were missing, MRL proposals were derived on a tentative basis only. For lettuce, spinach and cotton seed, MRL and risk assessment values remain tentative because a metabolism study is still required.

Hydrolysis studies demonstrated that degradation of methomyl can occur, depending on the pH and temperature conditions but methomyl remains the major compound. Methomyl oxime was significantly present after sterilisation but this compound does not share the mode of action of methomyl and was considered of no toxicological relevance. Moreover, since methomyl is only present in a specific group of food items, an assessment for this compound would never be more critical than for the parent

compound. Consequently, a separate residue definition for methomyl-oxime was not deemed necessary and a specific residue definition for processed commodities is not needed. Studies on the magnitude of residues in processed commodities related to the authorised uses are not available. EFSA was not able to propose peeling factor for melons because information regarding the peel/pulp ratio was missing from the available residues trials. It is highlighted that this information might allow a significant refinement for the acute exposure calculations for melons and watermelons.

The calculated dietary burdens for all groups of livestock were found to be below the trigger value of 0.1 mg/kg DM. Therefore, further investigation of residues as well as the setting of MRLs in commodities of animal origin is unnecessary. Available metabolism studies in lactating goats and laying hens indicated that methomyl the parent compound or structurally related metabolites were totally absent in tissues and products. Considering that the dietary burden is not significant, EFSA did not propose a residue definition for animal products. It was noted that the JMPR proposed a residue definition for animal product, as the sum of thiodicarb and methomyl, expressed as methomyl. This residue definition takes also into account the use of thiodicarb, which is readily degraded to methomyl into plant and animal commodities. However, considering that the use of thiodicarb is not authorised in Europe and that methomyl is not a good marker for animal commodities, this residue definition was not approved by EFSA.

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 melons and watermelons, an exceedance of the ARfD was identified representing 182% and 147% of the ARfD, respectively. Considering fall-back MRLs for these crops, the highest chronic exposure represented 2.3% of the ADI (Who Cluster diet B) and the highest acute exposure amounted to 54.6% of the ARfD (melons).

Apart from the MRLs evaluated in the framework of this review, internationally recommended CXLs have also been established for methomyl. Although CXLs were defined for the sum of thiodicarb and methomyl, expressed as methomyl, thiodicarb and methomyl do not have the same toxicological reference values. A combined residue definition was therefore not considered appropriate by EFSA, and only the CXLs based on the methomyl uses were assessed. Additional calculations of the consumer exposure, considering these CXLs, were carried out and exceedances of the ARfD were identified for the existing CXLs in peppers (1108%), oranges (944%), wheat (751%), plums (671%), apples (666%), pears (656%), grapefruits (635%), peas with pods (553%), melons (425%), mandarins (396%), barley (376%), watermelons (342%), beans with pods (309%), lemons (245%), peaches (237%), onions (223%), table grapes (210%), asparagus (200%), beans without pods (189%), wine grapes (189%), cucumbers (164%), pumpkins (148%), limes (143%), courgettes (130%), potatoes (123%). Excluding these CXLs from the calculation, the highest chronic exposure represented 5% of the ADI (DE child) and the highest acute exposure amounted to 75.3% of the ARfD (lettuce).

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Background

Regulation (EC) No 396/2005¹ establishes the rules governing the setting and the review of pesticide maximum residue levels (MRLs) at European level. Article 12(1) of that regulation stipulates that EFSA shall provide, within 12 months from the date of the inclusion or non-inclusion of an active substance in Annex I to Directive 91/414/EEC² a reasoned opinion on the review of the existing MRLs for that active substance. Methomyl was initially not included in Annex I to Directive 91/414/EEC by means of Commission Directive 2007/628/EC,³ which entered into force on 19 March 2008 with a period of grace until 19 March 2009. methomyl was included in Annex I to Council Directive 91/414/EEC on 1 September 2009 by means of Commission Directive 2009/115/EC,⁴ following re-submission for inclusion according to Commission Regulation (EC) No 33/2008,⁵ and has been deemed to be approved under Regulation (EC) No 1107/2009,⁶ in accordance with Commission Implementing Regulation (EU) No 540/2011.⁷ Therefore, as amended by Commission Implementing Regulation (EU) No 541/2011,⁸ EFSA initiated the review of all existing MRLs for that active substance.

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.

The United Kingdom, the designated rapporteur Member State (RMS) in the framework of Directive 91/414/EEC, was asked to complete the PROFile for methomyl and to prepare a supporting evaluation report. However, as neither registered GAPS nor import tolerances from any Member State had been provided, the RMS was not able to submit these documents. Nevertheless, a PROFile was prepared by

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

² Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1–32. Repealed by Regulation (EC) No 1107/2009.

³ Commission Directive 2007/628/EC of 19 September 2007 concerning the non-inclusion of methomyl in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance. OJ L 255, 29.9.2007, p. 40–41.

⁴ Commission Directive 2009/115/EC of 31 August 2009 amending Council Directive 91/414/EEC to include methomyl as active substance. OJ L 228, 1.9.2009, p. 17–19.

⁵ Commission Regulation (EC) No 33/2008 of 17 January 2008 laying down detailed rules for the application of Council Directive 91/414/EEC as regards a regular and an accelerated procedure for the assessment of active substances which were part of the programme of work referred to in Article 8(2) of that Directive but have not been included into its Annex I. OJ L 15, 18.9.2008, p. 5–12.

⁶ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.

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

⁸ Commission Implementing Regulation (EU) No 541/2011 of 1 June 2011 amending Implementing Regulation (EU) No 540/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p.187–188.

EFSA in order to compile all the information relative to methomyl, by default including the representative uses evaluated during the peer review.

A request for additional information was addressed to the Member States in the framework of a completeness check period which was initiated by EFSA on 6 March 2015 and finalised on 6 May 2015. Evaluation reports on additional GAPs were submitted by Greece and Italy (Greece, 2015; Italy, 2015) and after having considered all the information provided by RMS and Member States, EFSA prepared a completeness check report which was made available to all Member States on 11 June 2015. Further clarifications were sought from Member States via a written procedure in June–July 2015.

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 Member States, EFSA prepared in August 2015 a draft reasoned opinion, which was submitted to Member States for commenting via a written procedure. All comments received by 11 September 2015 were considered by EFSA during the finalisation of the reasoned opinion.

The evaluation reports submitted by Member States Greece, Italy (Greece, 2015; Italy, 2015) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available.

In addition, key supporting documents to this reasoned opinion are the completeness check report (EFSA, 2015a) and the Member States consultation report (EFSA, 2015b). These reports are developed to address all issues raised in the course of the review, from the initial completeness check to the reasoned opinion.

Considering the importance of the completeness check and consultation report, all documents are considered as background documents to this reasoned opinion and, thus, are made publicly available.

For the sake of transparency also the chronic and acute exposure calculations for all crops reported in the framework of this review performed using the EFSA Pesticide Residues Intake Model (PRIMO) are made publicly available.

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

Methomyl is the ISO common name for *S*-methyl (*EZ*)-*N*-(methylcarbamoyloxy)thioacetimidate (IUPAC). It should be noted that neither the ISO common name nor the IUPAC identify the configuration but the *Z*- or *cis*-isomer is so strongly favoured thermodynamically that the *E*- or *trans*-isomer is not detectable in practice.

Methomyl belongs to the group of oxime carbamate compounds which are used as insecticides. Methomyl is taken up via the cuticle (contact) or by ingestion and acts by inhibition of the enzyme acetylcholinesterase.

The chemical structure of the active substance and its main metabolites are reported in Appendix E.

Methomyl was evaluated in the framework of Directive 91/414/EEC in the second stage with the United Kingdom designated as rapporteur Member State (RMS). The representative uses supported for the peer review process comprised foliar applications on cucumbers, courgettes, tomatoes, eggplants and table and wine grapes. Following the first peer review, which was carried out by EFSA (2006), a decision on non-inclusion of the active substance in Annex I to Directive 91/414/EEC was published by means of Commission Directive 2007/628/EC, which entered into force on 19 March 2008 with a period of grace until 19 March 2009. After this first conclusion, additional data for

methomyl had been submitted in the framework of Directive 91/414/EEC and an additional report was issued by the United Kingdom in May 2008 (United Kingdom, 2008). Following this second peer review also carried out by EFSA (2008b), a decision on inclusion of the active substance in Annex I to Directive 91/414/EEC was published by means of Commission Directive 2009/115/EC, which entered into force on 1 September 2009.

According to Regulation (EU) No 540/2011, methomyl is deemed to have been approved under Regulation (EC) No 1107/2009. This approval is restricted to uses as insecticide on vegetables only; uses may be authorised at rates not exceeding 0.25 kg of methomyl per hectare per application and for a maximum of 2 applications per season. In addition, authorisations shall be limited to professional users only.

The EU MRLs for methomyl are established in Annexes II and IIIB of Regulation (EC) No 396/2005 and CXLs for this active substance were also established by the Codex Alimentarius Commission (CAC). It is noted that these CXLs were derived for the sum of methomyl and thiodicarb, expressed as methomyl because the assessment made by the JMPR also includes the methomyl levels arising from thiodicarb. An overview of the MRL changes that occurred since the entry into force of the regulation mentioned above is provided below.

Table 1: Overview of the MRL changes since the entry into force of Regulation (EC) No 396/2005

Procedure	Legal implementation	Remarks
Article 43: MRL of concern for the active substances methomyl and thiodicarb	Regulation (EC) No 1097/2009	MRLs lowered for bananas, carrots, peppers, cucumbers, melons, head cabbage, and sugar beet due to a risk that the Acceptable Daily Intake and the Acute Reference Dose (ARfD) for one or more consumer groups may be exceeded (EFSA, 2008a).

For the purpose of this MRL review, the critical uses of methomyl currently authorised within the EU, have been reported by Member States during the completeness check and were reported in the PROFile. The details of the authorised GAPs for methomyl are given in Appendix A. The Member States did not report any use authorised in third countries that might have a significant impact on international trade.

Assessment

EFSA has based its assessment on, the draft assessment report (DAR) and its addenda prepared under Council Directive 91/414/EEC (United Kingdom, 2004), the conclusion on the second peer review of the pesticide risk assessment of the active substance methomyl (EFSA, 2008b), the JMPR Evaluation reports (FAO, 2001a, 2001b, 2004, 2008), the previous reasoned opinions on methomyl (EFSA, 2008a) as well as the evaluation reports submitted during the completeness check (Greece, 2015; Italy, 2015). The assessment is performed in accordance with the legal provisions of the uniform principles for evaluation and authorisation of plant protection products as set out in Commission Regulation (EU) No 546/2011⁹ and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (European Commission, 1996, 1997a, 1997b, 1997c, 1997d, 1997e, 1997f, 1997g, 2000, 2010a, 2010b, 2011 and OECD, 2011).

More detailed information on the available data and on the conclusions derived by EFSA can be retrieved from the list of end points reported in Appendix B.

1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

A study investigating the metabolism of methomyl in grapes was evaluated and validated during the peer review (EFSA, 2008b). The metabolism of methomyl was also investigated in cabbage, tobacco and maize (United Kingdom, 2004) but, as these studies were not performed according to the modern standards, they do not provide useful information to assess the metabolic pathway in these crops. In addition, a study performed on cotton leaves was reported in the JMPR evaluation (FAO, 2001b) but does not contain analysis in cotton seeds. Therefore, the only relevant study which can be considered in this review is the grape study.

After foliar application on grapes, methomyl remains the major component of the residue in fruits (51–97% TRR). Three metabolites, resulting from three different metabolic pathways, were identified but no one exceeded 10% of the TRR: methomyl-oxime (7.2% TRR),¹⁰ IN-HUZ57 (5.6% TRR)¹¹ and IN-G6520 (1.2% TRR).¹² During the peer review, the experts concluded that methomyl-oxime was less toxic than the parent compound (not contributing to the inhibition of cholinesterase) and that metabolites IN-HUZ57 and IN-G6520 were at least as toxic as the parent compound. Therefore, due to their low amounts in grapes, these three metabolites are not expected to significantly contribute to the global toxicological burden (EFSA, 2008b).

Indicative analysis were also performed in grape leaves where metabolites IN-HUZ57 and IN-G6520 were also found, but in higher amounts (up to 16.4% of the TRR) compared to the parent compound (3.6% of the TRR after 14 days). In addition, another degradation product (metabolite IN-NR282¹³), resulting from a fourth degradation pathway, was also found in grape leaves in higher amount than methomyl (8.1% TRR); this compound was considered as non-toxicologically relevant (EFSA, 2008b). Therefore, the metabolic pattern in fruits and leaves were found to be significantly different. This highlights the need for additional validated metabolism studies in leafy crops and in pulses and oilseeds in order to cover all the authorised uses which are evaluated in this review.

⁹ Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.06.2011, p. 127–175.

¹⁰ Methomyl-oxime (code IN-X1177) results from the hydrolysis of the carbamate ester of methomyl (see Appendix E).

¹¹ Metabolite IN-HUZ57 results from the displacement of the S-methyl moiety by glutathione, catabolised or its cysteine derivative, followed by further hydroxylation (see Appendix E).

¹² Metabolite IN-G6520 results from the oxidation of the methylamino substituent (see Appendix E).

¹³ Metabolite IN-NR282 results from the isomerisation of methomyl to its E-isomer, followed by hydrolysis of the carbamate ester (see Appendix E).

1.1.2. Nature of residues in rotational crops

According to the soil degradation studies evaluated in the framework of the peer review, DT_{90} value of methomyl is 43 days, which is lower than the trigger value of 100 days (EFSA, 2008b). According to the European guidelines on rotational crops (European Commission, 1997c), further investigation of residues in rotational crops is not required and relevant residues in rotational crops are not expected. Therefore, studies investigating the nature of residues in rotational crops were not reported nor required during the peer review (EFSA, 2008b).

Nevertheless, a confined rotational crops study conducted at 9N rate compared to the current authorisations is available in the JMPR evaluation (FAO, 2001b). This study was performed with cabbage, red beet and sunflower and investigated plant back intervals (PBI) of 30 and 120 days. Total radioactivity analysis showed low residues uptakes (0.04-0.2 mg eq/kg) in red beets and cabbage planted 30 and 120 days after treatment (DAT). Higher total residues levels were observed in mature sunflower seeds (2 mg eq/kg at 30 DAT; 1.5 mg eq/kg at 120 DAT). The residues pattern in the sunflower seeds was not further analysed but it was concluded that the important radioactivity levels in this matrix may be due to the incorporation of carbon fragments (resulting from the extensive degradation of methomyl in soil) into natural plant constituents. For all crops investigated, levels of methomyl and its immediate metabolites always remain below or equal to 0.01 mg/kg at all investigated plant back intervals. Therefore a specific residue definition for rotational crops is not needed and significant residues are not expected in crops grown in rotation.

1.1.3. Nature of residues in processed commodities

The effect of processing on the nature of residues was investigated in the framework of the peer review (EFSA, 2008b). Studies were conducted with methomyl, simulating representative hydrolytic conditions for pasteurisation (20 minutes at 90°C, pH 4), boiling/brewing/baking (60 minutes at 100°C, pH 5) and sterilisation (20 minutes at 120°C, pH 6). These studies showed that methomyl can degrade to methomyl-oxime, depending on the pH and temperature conditions. Indeed, the degradation is low under pasteurisation (93.7% methomyl/ 4.3% methomyl-oxime) but is higher under baking/boiling/cooking (86% methomyl/ 13.5% methomyl-oxime) and even more important under sterilisation (58.2% methomyl/ 39.5% methomyl-oxime).

Methomyl-oxime does not share the mode of action of the parent compound because it does not induce acetyl-cholinesterase inhibition. It has also been demonstrated that this metabolite has no toxicological relevance (EFSA, 2008b).

1.1.4. Methods of analysis in plants

During the peer review, an analytical method using HPLC with post column derivation and fluorescence detection (HPLC-FLD) was validated for the determination of methomyl in the four main crop groups with a limit of quantification (LOQ) of 0.01 mg/kg (EFSA, 2008b). This method was confirmed by reversed-phase HPLC-MS with single ion monitoring and an independent laboratory validation (ILV) is available for three different matrices (United Kingdom, 2004). Furthermore, the multi-residue QuEChERS method is also applicable for the determination of methomyl. The LC-MS/MS analyses methomyl residues in high water, high acid content and dry commodities, with an LOQ of 0.01 mg/kg (CEN, 2008).

Hence, it is concluded that methomyl can be enforced with an LOQ of 0.01 mg/kg in the four main crop groups.

1.1.5. Stability of residues in plants

In the framework of the peer review, storage stability of methomyl was demonstrated for a period of 26 months at -20 °C in commodities with high water content and for a period of 27 months at -20 °C in acidic commodities (EFSA, 2008b). Further storage stability studies were evaluated by the JMPR (FAO, 2001b). In this framework, the storage stability of methomyl was also demonstrated in commodities with high oil content (peanuts) and dry commodities (maize) for a period of 24 months at -20°C.

1.1.6. Proposed residue definitions

A residue definition for monitoring and risk assessment including methomyl only was agreed during the peer review. This proposal is still relevant in the present review, also considering that it is restricted to fruit crops only. For leafy crops and pulses and oilseeds, appropriate metabolism studies are therefore required to cover the nature of residues in lettuce, spinach, beans (fresh with pods), peas (fresh with pods) and cotton seed. Meanwhile, the residue definition consisting in methomyl only is applied to these commodities on a tentative basis. A validated analytical method is available for the enforcement of the proposed residue definition in commodities of plant origin.

Methomy-oxime is a minor metabolite in primary crops but may be present in significant amounts in certain processed commodities, in particular in sterilised products. During the peer review, it has been demonstrated that methomyl-oxime does not share the mode of action of the parent compound because it does not induce acetyl-cholinesterase inhibition. Hence, methomyl-oxime should in principle be assessed separately from the parent compound, and since it is only present in a specific group of food items, the consumer exposure to this metabolite is expected to be lower than for methomyl. Therefore, an assessment for methomyl-oxime would never be more critical than for the parent compound, and a separate residue definition for methomyl-oxime or a specific residue definition for processed commodities are not deemed necessary. During the peer review, it was also concluded that methomyl-oxime was of no toxicological relevance (EFSA, 2008b)

It is noted that the proposed residue definition (methomyl only) deviates from the current Regulation where residues of methomyl and thiodicarb are considered together in a common residue definition being the sum of thiodicarb and methomyl, expressed as methomyl. This residue definition, also adopted by Codex, was proposed to cover the fact that thiodicarb is readily degraded to methomyl in plant commodities. However, as thiodicarb and methomyl do not have the same toxicological reference values, a combined residue definition is not appropriate in this case and EFSA is in favour to maintain its initial proposal with a separate residue definition for methomyl only. Since the MRL review for thiodicarb is not foreseen under Article 12 of Regulation 396/2005, this substance could not be addressed by EFSA in the present reasoned opinion, but as the use of thiodicarb is no longer authorised within the EU, this change of residue definition will only have consequences for food products treated with thiodicarb that may be imported from third countries. Hence, if no need to establish import tolerances for thiodicarb is identified by risk managers, MRLs for thiodicarb may be established at a specific LOQ or at the default MRL of 0.01 mg/kg. However, if the need to establish import tolerances is identified, a specific assessment for thiodicarb may be required prior to the legal implementation of the current MRL review.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

To assess the magnitude of methomyl residues resulting from the reported GAPs, EFSA considered all residue trials evaluated in the framework of the peer review (United Kingdom, 2004) and the additional data submitted during the completeness check (Greece, 2015; Italy, 2015). All residue trial samples considered in this framework were stored in compliance with the demonstrated storage conditions (see section 1.1.5). Decline of residues during storage of the trial samples is therefore not expected.

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 (European Commission, 2011).

For peppers, the number of residue trials reported is not compliant with the data requirements. Therefore, only tentative MRL and risk assessment values could be derived by EFSA and the following data gap was identified:

- Peppers: 3 additional trials on peppers compliant with the southern outdoor GAP are required.

For cucurbits with inedible peel as well as for fresh legumes (with pods), the available residue trials were performed at a more critical GAP compared to the current authorisations. Since significant residues were quantified in these crops, only tentative MRL and risk assessment values could be

derived by EFSA. Moreover, the mass ratio peel/pulp was not reported in the available studies performed on melons. Therefore, residues data are only available for peel and pulp separately. EFSA made a conservative calculation of the residues concentration in whole melons, assuming a mass ratio peel/pulp of 40%/60%. Nevertheless, this calculation remains tentative and the mass ratio peel/pulp is still needed in order to properly recalculate the residue concentration in melons. The following data gaps were identified:

- Cucurbits with inedible peel: 8 residue trials compliant with the southern outdoor GAP and 8 residue trials compliant with the indoor GAP are required;
- Beans (fresh with pods) and peas (fresh with pods): 8 residue trials compliant with the southern outdoor GAP are required (these trials should be performed once the residue definition in pulses and oilseeds is confirmed – see also section 1.1.6).

For all other crops, available residue trials are sufficient to derive MRL and risk assessment values, taking note of the following considerations:

- Tomatoes, aubergines, cucumbers, gherkins and courgettes: the available residue trials were performed at a more critical GAP compared to the current authorisations (3 applications instead of 2 and overdosed application rate of 1.2N to 2N). Since all results (n=34) were below the LOQ of the method of analysis used in the trials (0.02 mg/kg), EFSA considered that significant residues are not expected in these crops and proposed to derive appropriate MRL and risk assessment values at the monitoring LOQ of 0.01* mg/kg. Further residue trials are not required.
- Cotton seed: the number of residue trials supporting the southern outdoor GAP is not compliant with the data requirements for this crop (4 trials instead of 8). Moreover, the available residue trials were performed at a more critical GAP compared to the current authorisation (overdosed application rate of 1.8N). Since the results were below the LOQ of the method of analysis used in the trials (0.005 mg/kg), EFSA considered that significant residues levels of methomyl are not expected in this crop and proposed to derive MRL and risk assessment values at the monitoring LOQ of 0.01* mg/kg. Further residue trials are not required for the time being. However, considering that the residue definition in pulses and oilseeds still need to be confirmed (see section 1.1.6), this proposal remains tentative only and further data might be required in the future, depending on the outcome of the metabolism study.

1.2.2. Magnitude of residues in rotational crops

Based on the confined rotational crop study evaluated by the JMPR (see also section 1.1.2.), levels of methomyl and its related metabolites remained below 0.01 mg/kg. Rotational crop field trials are therefore not required.

1.2.3. Magnitude of residues in processed commodities

Residue transfer from raw grape to different processed commodities (wine, juice and raisins) has been investigated in the framework of the peer review. Nevertheless, as the use on wine and table grapes is no longer authorised within Europe, these studies were not considered in the present review. Due to the missing information regarding the peel/pulp ratio in the trials performed on melons (see section 1.2.1), EFSA was not able to propose peeling factor for this crop. However, it is highlighted that this information might allow a significant refinement for the acute exposure calculations for melons and watermelons.

Apart from the peeling data on melons, further processing studies are not required as they are not expected to affect the outcome of the risk assessment. However, if processing factors were to be required by risk managers, in particular for enforcement purposes, additional processing studies would be needed.

1.2.4. Proposed MRLs

Consequently, the available data are considered sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation. Nevertheless, for peppers, cucurbits with

inedible peel, beans (fresh, with pods) and peas (fresh, with pods) where residue trials were missing, MRL proposals are derived on a tentative basis only. For lettuce, spinach and cotton seed, the residue trials were deemed appropriate but MRL and risk assessment values remain tentative because a metabolism study is still required.

2. Residues in livestock

Methomyl is authorised for use on cotton seed that might be fed to livestock. Livestock dietary burdens were therefore calculated for different groups of livestock using the agreed European methodology (European Commission, 1996). The input values for all relevant commodities have been selected according to the recommendations of JMPR (FAO, 2009) and are summarised in Appendix B. Since the calculated dietary burdens for all groups of livestock were found to be below the trigger value of 0.1 mg/kg dry matter (DM), further investigation of residues as well as the setting of MRLs in commodities of animal origin is unnecessary.

Metabolism studies in lactating goats and laying hens were however submitted during the peer review. These studies indicated that methomyl is extensively degraded when fed to livestock. The parent compound or structurally related metabolites are totally absent in tissues and products. Acetonitrile, thiocyanate and acetamide were detected as ultimate degradation products, before incorporation of the administered radioactivity in natural molecular constituents or elimination through expired volatile compounds. Based on these findings, and also considering that the dietary burden is not significant, EFSA did not propose a residue definition for animal products (EFSA, 2008b).

It is noted that the JMPR proposed a residue definition for animal product, as the sum of thiodicarb and methomyl, expressed as methomyl. However, this residue definition takes also into account the use of thiodicarb, which is readily degraded to methomyl into plant and animal commodities. However, considering that the use of thiodicarb is not authorised in Europe and that methomyl is not a good marker for animal commodities, this residue definition is not supported by EFSA.

3. Consumer risk assessment

In the framework of this review, only the uses of methomyl reported by the Member States (see Appendix A) were considered, however the use of methomyl was previously also assessed by the JMPR (FAO, 2001a, 2004, 2008). The CXLs, resulting from these assessments 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.

3.1. 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 the decision tree reported in Appendix D. Hence, for those commodities where a (tentative) MRL could be derived by EFSA in the framework of this review, input values were median and highest residue values derived according to the internationally agreed methodologies (FAO, 2009). All input values included in the exposure calculations are summarised in Appendix C2.

The exposures calculated were compared with the toxicological reference values for methomyl, derived by EFSA (2008b) under Directive 91/414/EEC. The highest chronic exposure was calculated for WHO Cluster diet B, representing 2.8% of the ADI. With regard to the acute exposure, however, an exceedance of the ARfD was identified for melons and watermelons, representing 182% and 147% of the ARfD, respectively. EFSA acknowledges that this assessment is based on overdosed residues trials (see section 1.2.1). Nevertheless, in the absence of GAP compliant trials, EFSA is not able to refine it. Moreover, as it was highlighted in section 1.2.3, data to derive processing factors for peeling of cucurbits with inedible peel are missing and might be useful to refine the calculation. In the absence of such data, EFSA attempted to identify fall-back GAPs for these crops. A second exposure calculation was therefore performed considering the southern GAPs on melons and watermelons. According to the results of this second calculation, the highest chronic exposure remained unchanged;

the highest acute exposure is still calculated for melons, but then representing 54.6% of the ARfD; the acute exposure calculated for watermelons declined to 44% of the ARfD.

Based on these calculations, EFSA concludes that all uses of methomyl are acceptable with regard to consumer exposure, except for the indoor uses on melons and watermelons where a potential risk to consumers was identified and no further refinements of the risk assessment were possible. For the other commodities, many uncertainties remain due to the major data gaps identified in the previous sections but the indicative exposure calculations did not indicate a risk to consumers.

3.2. Consumer risk assessment with consideration of the existing CXLs

In order to include the CXLs in the calculations of the consumer exposure, CXLs were compared with the EU MRL proposals in compliance with Appendix D and all data relevant to the consumer exposure assessment have been collected from JMPR evaluations.

It is noted that the residue definition for CXLs (sum of thiodicarb and methomyl, expressed as methomyl) is different than the EU proposal (methomyl only). This is due to the fact that the JMPR intended to simultaneously assess the residues of thiodicarb, another active substance which is readily degraded to methomyl into plant commodities. However, considering that thiodicarb and methomyl do not have the same toxicological reference values, a combined residue definition was not considered appropriate by EFSA. Therefore, only the CXLs based on the methomyl uses were assessed by EFSA. Based on the available JMPR reports (FAO, 2001a, 2004, 2008), EFSA was able to identify that CXLs for tomatoes, rape seed and spices (fruits and berries) were directly linked to thiodicarb uses. It is assumed that all the other CXLs for plant commodities correspond to methomyl residues levels arising from methomyl uses. EFSA also noticed that CXLs were derived for livestock commodities but these CXLs were not derived from methomyl uses only as they also include the intake of thiodicarb residues. Moreover, the JMPR came to the conclusion that MRLs for the sum of thiodicarb and methomyl should be set at the LOQ (0.02* mg/kg) and proposed risk assessment values equal to 0.00 mg/kg (FAO, 2001a). For these reasons, EFSA remains on the opinion that MRLs in livestock commodities are not required and disregarded the CXLs for livestock commodities (see also section 2). An overview of the input values used for this exposure calculation is also provided in Appendix C3.

Chronic and acute exposure calculations were also performed using revision 2 of the EFSA PRIMo and the exposures calculated were compared with the toxicological reference values derived for methomyl. While the chronic exposure remained below the ADI, an exceedance of the ARfD was identified for citrus fruits, apples, pears, peaches, plums, table grapes, wine grapes, potatoes, onions, peppers, cucumbers, courgettes, melons, pumpkins, watermelons, beans (fresh with pods), beans (fresh without pods), peas (fresh, with pods), asparagus, barley grain and wheat grain. The highest IESTI according to EFSA PRIMo were between 123% of the ARfD (potatoes) and 1108% of the ARfD (peppers). All details are reported in Appendix B.3.2. A second exposure calculation was therefore performed, excluding the CXLs for all these crops. According to this second calculation, the highest acute exposure is calculated for lettuce, representing 75.3% of the ARfD; the chronic exposure declined to 5% of the ADI (DE child).

Based on these calculations, a potential risk to consumers was identified for the CXLs of methomyl on citrus fruits, apples, pears, peaches, plums, table grapes, wine grapes, potatoes, onions, peppers, cucumbers, courgettes, melons, pumpkins, watermelons, beans (fresh with pods), beans (fresh without pods), peas (fresh, with pods), asparagus, barley grain and wheat grain. No further refinements of the risk assessment were possible. For the remaining CXLs, although major uncertainties remain due to the data gaps identified for some of them, the indicative exposure calculation did not indicate a risk to consumers.

Conclusions

The metabolism of methomyl has been properly investigated in grapes. The other submitted metabolism studies were not deemed acceptable. Methomyl remained the major component of the residue in grapes and the three identified metabolites are not expected to significantly contribute to the global toxicological burden. Consequently, a residue definition for monitoring and risk assessment including methomyl only can be proposed but is restricted to fruit crops only. For leafy crops and pulses and oilseeds, appropriate metabolism studies are missing to cover the nature of residues in

lettuce, spinach, beans (fresh with pods), peas (fresh with pods) and cotton seed. Meanwhile, the residue definition consisting in methomyl only is applied to these commodities on a tentative basis. A validated analytical method is available for the enforcement of the proposed residue definition in commodities of plant origin.

Studies on the nature of the residues in succeeding crops show that methomyl residues either did not translocate to succeeding crops in significant amount, either were extensively degraded into carbon fragments before being incorporated into natural plant constituents. In any case, levels of methomyl and its immediate metabolites always remain below or equal to 0.01 mg/kg. Therefore a specific residue definition for rotational crops is not needed and significant residues are not expected in crops grown in rotation.

The available residue trials allowed EFSA assessing the magnitude of residues resulting from the authorised GAPs reported in this review. MRL proposals as well as risk assessment values were derived for all commodities under evaluation. For peppers, cucurbits with inedible peel, beans (fresh, with pods), peas (fresh, with pods) where residue trials were missing, MRL proposals were derived on a tentative basis only. For lettuce, spinach and cotton seed, MRL and risk assessment values remain tentative because a metabolism study is still required.

Hydrolysis studies demonstrated that degradation of methomyl can occur, depending on the pH and temperature conditions but methomyl remains the major compound. Methomyl oxime was significantly present after sterilisation but this compound does not share the mode of action of methomyl and was considered of no toxicological relevance. Moreover, since methomyl is only present in a specific group of food items, an assessment for this compound would never be more critical than for the parent compound. Consequently, a separate residue definition for methomyl-oxime was not deemed necessary and a specific residue definition for processed commodities is not needed. Studies on the magnitude of residues in processed commodities related to the authorised uses are not available. EFSA was not able to propose peeling factor for melons because information regarding the peel/pulp ratio was missing from the available residues trials. It is highlighted that this information might allow a significant refinement for the acute exposure calculations for melons and watermelons.

The calculated dietary burdens for all groups of livestock were found to be below the trigger value of 0.1 mg/kg DM. Therefore, further investigation of residues as well as the setting of MRLs in commodities of animal origin is unnecessary. Available metabolism studies in lactating goats and laying hens indicated that methomyl the parent compound or structurally related metabolites were totally absent in tissues and products. Considering that the dietary burden is not significant, EFSA did not propose a residue definition for animal products. It was noted that the JMPR proposed a residue definition for animal product, as the sum of thiodicarb and methomyl, expressed as methomyl. This residue definition takes also into account the use of thiodicarb, which is readily degraded to methomyl into plant and animal commodities. However, considering that the use of thiodicarb is not authorised in Europe and that methomyl is not a good marker for animal commodities, this residue definition was not supported by EFSA.

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 melons and watermelons, an exceedance of the ARfD was identified representing 182% and 147% of the ARfD, respectively. Considering fall-back MRLs for these crops, the highest chronic exposure represented 2.3% of the ADI (Who Cluster diet B) and the highest acute exposure amounted to 54.6% of the ARfD (melons).

Apart from the MRLs evaluated in the framework of this review, internationally recommended CXLs have also been established for methomyl. Although CXLs were defined for the sum of thiodicarb and methomyl, expressed as methomyl, thiodicarb and methomyl do not have the same toxicological reference values. A combined residue definition was therefore not considered appropriate by EFSA, and only the CXLs based on the methomyl uses were assessed by EFSA. Additional calculations of the consumer exposure, considering these CXLs, were therefore carried out and exceedances of the ARfD were identified for the existing CXLs in peppers (1108%), oranges (944%), wheat (751%), plums (671%), apples (666%), pears (656%), grapefruits (635%), peas with pods (553%), melons (425%), mandarins (396%), barley (376%), watermelons (342%), beans with pods (309%), lemons (245%), peaches (237%), onions (223%), table grapes (210%), asparagus (200%), beans without pods (189%), wine grapes (189%), cucumbers (164%), pumpkins (148%), limes (143%), courgettes (130%), potatoes (123%). Excluding these CXLs from the calculation, the highest chronic exposure

represented 5% of the ADI (DE child) and the highest acute exposure amounted to 75.3% of the ARfD (lettuce).

Recommendations

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 representative study investigating primary crop metabolism in leafy crops;
- a representative study investigating primary crop metabolism in pulses and oilseeds;
- three additional trials on peppers compliant with the southern outdoor GAP are required;
- six additional residue trials supporting the southern outdoor GAP on table and wine grapes;
- eight residue trials compliant with the southern outdoor GAP on cucurbits with inedible peel;
- eight residue trials compliant with the indoor GAP on cucurbits with inedible peel;
- eight residue trials compliant with the southern outdoor GAP on beans (fresh with pods) and peas (fresh with pods) (these trials should be performed once the residue definition in pulses and oilseeds is confirmed – see also data requirement for a metabolism study).

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.

Furthermore it is highlighted that a possible risk to consumer was identified for the most critical GAP (indoor GAP) that is currently authorised for melons and watermelons. EFSA acknowledges that the submission of GAP compliant trials supporting these GAPs (together with robust processing factor for peeling in cucurbits with inedible peel) would allow refining this assessment. Meanwhile, Member States are anyhow recommended to modify their national authorisations in order to comply with the fall-back MRL derived by EFSA.

It is noted that the proposed residue definition (methomyl only) is different than the existing one defined in the Regulation. The existing residue definition is common to methomyl and thiodicarb (sum of thiodicarb and methomyl, expressed as methomyl) and was set as such in order to take into account the fact that methomyl is also a metabolite of thiodicarb. However, as both compounds have different toxicological reference values, this combined residue definition was not deemed appropriate by EFSA and it was proposed to proceed with a separate residue definition for methomyl only. Since the MRL review for thiodicarb is not foreseen under Article 12 of Regulation 396/2005, this substance could not be addressed by EFSA in the present reasoned opinion, but as the use of thiodicarb is no longer authorised within the EU, this change of residue definition will only have consequences for food products treated with thiodicarb that may be imported from third countries. Hence, if no need to establish import tolerances for thiodicarb is identified by risk managers, MRLs for thiodicarb may be established at a specific LOQ or at the default MRL of 0.01 mg/kg. However, if the need to establish import tolerances is identified, a specific assessment for thiodicarb residues may be required prior to the legal implementation of the current MRL review.

Table 2: 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 (existing): sum of methomyl and thiodicarb expressed as methomyl					
Enforcement residue definition (proposed): methomyl					
110010	Grapefruit	0.02*	1	-	Further consideration needed ^(a)
110020	Oranges	0.02*	1	-	Further consideration needed ^(a)
110030	Lemons	0.02*	1	-	Further consideration needed ^(a)
110040	Limes	0.02*	1	-	Further consideration needed ^(a)
110050	Mandarins	0.02*	1	-	Further consideration needed ^(a)
130010	Apples	0.02*	0.3	-	Further consideration needed ^(a)
130020	Pears	0.02*	0.3	-	Further consideration needed ^(a)
140030	Peaches	0.02*	0.2	-	Further consideration needed ^(a)
140040	Plums	0.02*	1	-	Further consideration needed ^(a)
151010	Table grapes	0.02*	0.3	-	Further consideration needed ^(a)
151020	Wine grapes	0.5	0.3	-	Further consideration needed ^(a)
161040	Kumquats	0.02*	1	1	Recommended ^(b)
211000	Potatoes	0.02*	0.02*	-	Further consideration needed ^(c)
220020	Onions	0.02*	0.2	-	Further consideration needed ^(c)
231010	Tomatoes	0.02*	1	0.01*	Recommended ^(d)
231020	Peppers	0.02*	0.7	0.04	Further consideration needed ^(e)
231030	Aubergines (egg plants)	0.02*	-	0.01*	Recommended ^(f)
232010	Cucumbers	0.1	0.1	0.01*	Recommended ^(g)
232020	Gherkins	0.1	0.1	0.1	Recommended ^(h)
232030	Courgettes	0.1	0.1	0.01*	Recommended ^(g)
233010	Melons	0.1	0.1	0.015	Further consideration needed ^(e)
233020	Pumpkins	0.1	0.1	0.05	Further consideration needed ^(e)
233030	Watermelons	0.1	0.1	0.015	Further consideration needed ^(e)
251020	Lettuce	0.2	0.2	0.2	Further consideration needed ⁽ⁱ⁾
252010	Spinach	0.05	-	0.01*	Further consideration needed ^(j)
260010	Beans (fresh, with pods)	0.02*	1	0.1	Further consideration needed ^(k)
260020	Beans (fresh, without pods)	0.02*	1	-	Further consideration needed ^(c)
260030	Peas (fresh, with pods)	0.02*	5	0.1	Further consideration needed ^(k)
270010	Asparagus	0.02*	2	-	Further consideration needed ^(c)
300010	Beans (dry)	0.02*	0.05	0.05	Further consideration needed ^(l)
401060	Rape seed	0.05*	0.05	-	Further consideration needed ^(m)
401070	Soya bean	0.1	0.2	0.2	Further consideration needed ^(l)
401090	Cotton seed	0.1	0.2	0.2	Further consideration needed ⁽ⁱ⁾
500010	Barley grain	0.02*	2	-	Further consideration needed ^(c)
500030	Maize grain	0.02*	0.02*	0.02	Further consideration needed ^(l)
500050	Oats grain	0.02*	0.02*	0.02	Further consideration needed ^(l)
500090	Wheat grain	0.02*	2	-	Further consideration needed ^(c)
820000	Spices (fruits, berries)	0.1*	0.07	-	Further consideration needed ^(m)
1011010	Swine meat	0.02*	0.02*	-	Further consideration needed ^(m)
1011030	Swine liver	0.02*	0.02*	-	Further consideration needed ^(m)
1011040	Swine kidney	0.02*	0.02*	-	Further consideration needed ^(m)
1011050	Swine edible offal	0.02*	0.02*	-	Further consideration needed ^(m)
1012010	Bovine meat	0.02*	0.02*	-	Further consideration needed ^(m)
1012030	Bovine liver	0.02*	0.02*	-	Further consideration needed ^(m)
1012040	Bovine kidney	0.02*	0.02*	-	Further consideration needed ^(m)
1012050	Bovine edible offal	0.02*	0.02*	-	Further consideration needed ^(m)
1016010	Poultry meat	0.02*	0.02*	-	Further consideration needed ^(m)
1016030	Poultry liver	0.02*	0.02*	-	Further consideration needed ^(m)
1016040	Poultry kidney	0.02*	0.02*	-	Further consideration needed ^(m)
1016050	Poultry edible offal	0.02*	0.02*	-	Further consideration needed ^(m)
1020010	Cattle milk	0.02*	0.02*	-	Further consideration needed ^(m)
1020020	Sheep milk	0.02*	0.02*	-	Further consideration needed ^(m)
1020030	Goat milk	0.02*	0.02*	-	Further consideration needed ^(m)

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
1020040	Horse milk	0.02*	0.02*	-	Further consideration needed ^(m)
1030000	Birds' eggs	0.02*	0.02*	-	Further consideration needed ^(m)
-	Other commodities of plant and animal origin	See regulation	-	-	Further consideration needed ⁽ⁿ⁾

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

- (a): There are no relevant authorisations or import tolerances reported at EU level; CXL is supported by data but a risk to consumers cannot be excluded. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-VI in Appendix D).
- (b): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; there are no relevant authorisations or import tolerances reported at EU level (combination A-VII in Appendix D).
- (c): There are no relevant authorisations or import tolerances reported at EU level; CXL is not sufficiently supported by data and a risk to consumers cannot be excluded. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-IV in Appendix D).
- (d): 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 not compatible with EU residue definitions (combination G-II 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; CXL is higher, supported by data but a risk to consumers cannot be excluded (combination E-VI in Appendix D).
- (f): 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).
- (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): 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).
- (i): MRL is derived from the existing CXL, which is not sufficiently supported by data but for which no risk to consumers is identified (assuming the tentative residue definition); GAP evaluated at EU level, which is also not fully supported by data, would lead to a lower tentative MRL (combination E-V 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 (assuming the tentative residue definition); no CXL is available (combination E-I in Appendix D).
- (k): 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 (assuming the tentative residue definition); CXL is higher but it is also not sufficiently supported by data and a risk to consumers cannot be excluded (combination E-IV in Appendix D).
- (l): MRL is derived from the existing CXL, which is not sufficiently supported by data but for which no risk to consumers is identified (assuming the tentative residue definition); there are no relevant authorisations or import tolerances reported at EU level (combination A-V in Appendix D).
- (m): There are no relevant authorisations or import tolerances reported at EU level; CXL is not compatible with EU residue definitions. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-II in Appendix D).
- (n): 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).

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Abbreviations

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CAC	Codex Alimentarius Commission
CCPR	Codex Committee on Pesticide Residues
CEN	European Committee for Standardization (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
DB	dietary burden
DM	dry matter
DT ₉₀	period required for 90% dissipation (define method of estimation)
EC	European Commission
eq	residue expressed as a.s. equivalent
FAO	Food and Agriculture Organization of the United Nations
GAP	good agricultural practice
HPLC-FLD	high performance liquid chromatography with postcolumn fluorescence derivatization
HPLC-MS	high performance liquid chromatography with mass spectrometry
ILV	independent laboratory validation
ISO	International Organisation for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
NEU	northern European Union
OECD	Organisation for Economic Co-operation and Development
PF	processing factor
PHI	pre-harvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model

PROFile	(EFSA) Pesticide Residues Overview File
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
RAC	raw agricultural commodity
RD	residue definition
RMS	rapporteur Member State
SEU	southern European Union
TRR	total radioactive residue
WHO	World Health Organization

Appendix A – Summary of authorised uses considered for the review of MRLs

Critical outdoor GAPs for Southern Europe																				
Crop		Region	Outdoor/ Indoor	Member state or country	Pest controlled	Formulation			Application								PHI or waiting period (days)	Comments (max. 250 characters)		
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Rate				
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.	Min.			Max.	Unit
Tomatoes	<i>Lycopersicon esculentum</i>	SEU	Outdoor	EL, IT	Biting and sucking insects	SL	200.0	g/L	Foliar treatment - spraying	20	89	1	2	14			0.25	kg a.i./ha	7	
Peppers	<i>Capsicum annuum, var. grossum and var. longum</i>	SEU	Outdoor	IT	Biting and sucking insects	SL	200.0	g/L	Foliar treatment - spraying	20	89	1	2	14			0.25	kg a.i./ha	14	
Aubergines (egg plants)	<i>Solanum melongena</i>	SEU	Outdoor	EL, IT	Biting and sucking insects	SL	200.0	g/L	Foliar treatment - spraying	20	89	1	2	14			0.25	kg a.i./ha	7	
Cucumbers	<i>Cucumis sativus</i>	SEU	Outdoor	EL, IT	Biting and sucking insects	SL	200.0	g/L	Foliar treatment - spraying	20		1	2	14			0.25	kg a.i./ha	7	
Gherkins	<i>Cucumis sativus</i>	SEU	Outdoor	IT	Biting and sucking insects	SL	200.0	g/L	Foliar treatment - spraying	20		1	2	14			0.25	kg a.i./ha	7	
Courgettes	<i>Cucurbita pepo var. melopepo</i>	SEU	Outdoor	EL, IT	Biting and sucking insects	SL	200.0	g/L	Foliar treatment - spraying	20		1	2	14			0.25	kg a.i./ha	7	
Melons	<i>Cucumis melo</i>	SEU	Outdoor	IT	Biting and sucking insects	SL	200.0	g/L	Foliar treatment - spraying	20		1	2	14			0.25	kg a.i./ha	14	
Pumpkins	<i>Cucurbita maxima</i>	SEU	Outdoor	IT	Biting and sucking insects	SL	200.0	g/L	Foliar treatment - spraying	20		1	2	14			0.25	kg a.i./ha	14	
Watermelons	<i>Citrullus lanatus</i>	SEU	Outdoor	IT	Biting and sucking insects	SL	200.0	g/L	Foliar treatment - spraying	20		1	2	14			0.25	kg a.i./ha	14	
Lettuce	<i>Lactuca sativa</i>	SEU	Outdoor	IT	Biting and sucking insects	SL	200.0	g/L	Foliar treatment - spraying	20	41	1	2	14			0.25	kg a.i./ha	21	
Spinach	<i>Spinacia oleracea</i>	SEU	Outdoor	IT	Biting and sucking insects	SL	200.0	g/L	Foliar treatment - spraying	20	41	1	2	14			0.25	kg a.i./ha	21	
Beans (with pods)	<i>Phaseolus vulgaris,</i>	SEU	Outdoor	IT	Biting and sucking insects	SL	200.0	g/L	Foliar treatment - spraying	51	79	1	2	14			0.25	kg a.i./ha	10	
Peas (with pods)	<i>Pisum sativum</i>	SEU	Outdoor	IT	Biting and sucking insects	SL	200.0	g/L	Foliar treatment - spraying	51	79	1	2	14			0.25	kg a.i./ha	10	
Cotton seed	<i>Gossypium spp.</i>	SEU	Outdoor	EL	Biting and sucking insects	SL	200.0	g/L	Foliar treatment - spraying	51	79	1	2	14			0.25	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	Pest controlled	Formulation			Application								PHI or waiting period (days)	Comments (max. 250 characters)		
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Rate				
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.	Min.			Max.	Unit
Tomatoes	<i>Lycopersicon esculentum</i>	NEU/SEU	Indoor	IT	Biting and sucking insects	SL	200.0	g/L	Foliar treatment - spraying	20	89	1	2	14			0.25	kg a.i./ha	7	
Peppers	<i>Capsicum annuum, var. grossum and var. longum</i>	NEU/SEU	Indoor	IT	Biting and sucking insects	SL	200.0	g/L	Foliar treatment - spraying	20	89	1	2	14			0.25	kg a.i./ha	21	
Aubergines (egg plants)	<i>Solanum melongena</i>	NEU/SEU	Indoor	IT	Biting and sucking insects	SL	200.0	g/L	Foliar treatment - spraying	20	89	1	2	14			0.25	kg a.i./ha	7	
Cucumbers	<i>Cucumis sativus</i>	NEU/SEU	Indoor	IT	Biting and sucking insects	SL	200.0	g/L	Foliar treatment - spraying	20		1	2	14			0.25	kg a.i./ha	7	
Gherkins	<i>Cucumis sativus</i>	NEU/SEU	Indoor	IT	Biting and sucking insects	SL	200.0	g/L	Foliar treatment - spraying	20		1	2	14			0.25	kg a.i./ha	7	
Courgettes	<i>Cucurbita pepo var. melopepo</i>	NEU/SEU	Indoor	IT	Biting and sucking insects	SL	200.0	g/L	Foliar treatment - spraying	20		1	2	14			0.25	kg a.i./ha	7	
Melons	<i>Cucumis melo</i>	NEU/SEU	Indoor	IT	Biting and sucking insects	SL	200.0	g/L	Foliar treatment - spraying	20		1	2	14			0.25	kg a.i./ha	21	
Pumpkins	<i>Cucurbita maxima</i>	NEU/SEU	Indoor	IT	Biting and sucking insects	SL	200.0	g/L	Foliar treatment - spraying	20		1	2	14			0.25	kg a.i./ha	21	
Watermelons	<i>Citrullus lanatus</i>	NEU/SEU	Indoor	IT	Biting and sucking insects	SL	200.0	g/L	Foliar treatment - spraying	20		1	2	14			0.25	kg a.i./ha	21	

Appendix B – List of end points

B.1. Residues in plants

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

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

Primary crops (available studies)	Crop groups	Crop(s)	Application(s)	Sampling (DAT)
	Fruit crops	Grapes	Foliar, 1 x 0.99 kg a.s./ha	2, 7, 14 ^(a)
	Leafy crops	Tobacco ^(b) cabbage ^(b)	Not relevant	Not relevant
	Cereals/grass crops	Maize ^(b)	Not relevant	Not relevant
	Pulses/Oilseeds	Cotton ^(c)	Local, 50 µg per leaf	8
<p><u>Source, United Kingdom, 2004:</u> (a): Samples of grapes and leaves were collected. (b): Studies on tobacco, cabbage and maize were disregarded during the peer review because not compliant with the modern standards; these studies do not provide qualitative and quantitative information on the metabolic pathway. <u>Source, FAO, 2001b:</u> (c): In the study on cotton, only leafy parts were sampled and analysed; this study is not sufficient to elucidate the metabolism in pulses and oilseeds.</p>				
Rotational crops (available studies)	Crop groups	Crop(s)	Application(s)	PBI (DAT)
	Leafy crops	Cabbage	4.48 kg a.i./ha	30, 120
	Root crops	Red beets	4.48 kg a.i./ha	30, 120
	Pulses/oilseeds	Sunflower	4.48 kg a.i./ha	30, 120
Source: FAO, 2001b				
Processed commodities (hydrolysis study)	Conditions		Investigated?	
	Pasteurisation (20 min, 90°C, pH 4)		Yes	
	Baking, brewing and boiling (60 min, 100°C, pH 5)		Yes	
	Sterilisation (20 min, 120°C, pH 6)		Yes	
Source: EFSA, 2008b				

Can a general residue definition be proposed for primary crops?

No
Rotational crop and primary crop metabolism similar?
Not relevant (significant residues in succeeding crops unlikely due to behaviour of methomyl in soil).
Residue pattern in processed commodities similar to residue pattern in raw commodities?
Yes
Plant residue definition for monitoring (RD-Mo)
Methomyl (for fruit crops only)
Plant residue definition for risk assessment (RD-RA)
Methomyl (for fruit crops only)
Conversion factor (monitoring to risk assessment)
Not relevant

Methods of analysis for monitoring of residues
(analytical technique, crop groups, LOQs)

High water content, high oil content, acidic and dry
commodities: HPLC-FLD, LOQ 0.01 mg/kg (EFSA, 2008b).

B.1.1.2. Stability of residues in plants

Plant products (available studies)	Category	Commodity	T (°C)	Stability (Months/years)
	High water content ^(a)	Potatoes	-20	26 months
	High acid content ^(a)	Grapes	-20	27 months
	High oil content ^(b)	Peanuts	-20	24 months
	Dry commodities ^(b)	Maize	-20	24 months
(a): Source, EFSA, 2008b				
(b): Source, FAO, 2001b				

B.1.2. Magnitude of residues in plants

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

Crop	Region/ Indoor (a)	Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg)	Recommendations/comments (OECD calculations)	MRL proposals (mg/kg)	HR (mg/kg) (b)	STMR (mg/kg) (c)
Tomatoes Aubergines (egg plants)	SEU	8x<0.02	Trials performed on tomatoes at a more critical GAP (3 x 0.30-0.5 kg a.s./ha) (United Kingdom, 2004). Deemed acceptable because no residue above LOQ are quantified. Possible extrapolation to aubergines.	0.01*	0.01	0.01
	Indoor	5x<0.005; 5x<0.02	Trials performed on tomatoes at a more critical GAP (3 x 0.46-0.6 kg a.s./ha) (Italy, 2015). Deemed acceptable because no residue above LOQ are quantified. Possible extrapolation to aubergines.	0.01*	0.01	0.01
Peppers	SEU	2x<0.005; 0.006; 0.01; 0.021	Trials compliant with GAP (Italy, 2015). Rber = 0.03 Rmax = 0.04 MRL _{OECD} = 0.04	0.04 ^(d) (tentative)	0.02	0.01
	Indoor	7x<0.005; 0.014	Trials compliant with GAP (Italy, 2015). Rber = 0.01 Rmax = 0.02 MRL _{OECD} = 0.02	0.02	0.01	0.01
Cucumbers Gherkins Courgettes	SEU	8x<0.02	Combined dataset of trials performed with cucumbers (5) and courgettes (3) at a more critical GAP (3 x 0.3-0.5 kg a.s./ha) (United Kingdom, 2004). Deemed acceptable because no residue above LOQ are quantified.	0.01*	0.01	0.01
	Indoor	8x<0.02	Combined dataset of trials performed with cucumbers (5) and courgettes (3) at a more critical GAP (3 x 0.3-0.5 kg a.s./ha) (Italy, 2015). Deemed acceptable because no residue above LOQ are quantified.	0.01*	0.01	0.01

Crop	Region/ Indoor (a)	Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg)	Recommendations/comments (OECD calculations)	MRL proposals (mg/kg)	HR (mg/kg) (b)	STMR (mg/kg) (c)
Melons Pumpkins Watermelons	SEU	3x<0.005; 2x0.006; 2x0.007; 0.009	Trials performed on melons at a more critical GAP (2 x 0.45-0.47 kg a.s./ha) (Italy, 2015) used on a tentative basis, assuming a theoretical ratio peel/pulp of 40%/60%. Possible extrapolation to pumpkins and watermelons. Rber = 0.01 Rmax = 0.01 MRL _{OECD} = 0.01	0.015 ^(d) (tentative)	0.01	0.01
	Indoor	4x<0.005; 0.005; 0.009; 0.013; 0.03	Trials performed on melons at a more critical GAP (2 x 0.45 kg a.s./ha) (Italy, 2015) used on a tentative basis, assuming a theoretical ratio peel/pulp of 40%/60%. Possible extrapolation to pumpkins and watermelons. Rber = 0.02 Rmax = 0.04 MRL _{OECD} = 0.04	0.05 ^(d) (tentative)	0.03	0.01
Lettuce Spinach	SEU	8x<0.003	Trials on lettuce compliant with GAP (Italy, 2015). In 5 trials, the lettuce variety was identified as an open-leaf; extrapolation to spinach is therefore acceptable.	0.01 ^{*(e)} (tentative)	0.003	0.003
Beans (fresh, with pods) Peas (fresh, with pods)	SEU	2x<0.005; <0.01; 2x<0.025; 2x<0.05; 0.01	Trials performed on fresh beans with pods at more critical GAP (2 x 0.2-0.46 kg a.s./ha) (Italy, 2015) used on a tentative basis. MRL is not proposed at the LOQ since residues were quantified in 1 trial. Extrapolation to fresh peas with pods is possible. Rber = 0.09 Rmax = 0.08 MRL _{OECD} = 0.10	0.10 ^(d, e) (tentative)	0.05	0.02
Cotton seed	SEU	4x<0.005	Trials performed at a more critical GAP (2 x 0.44-0.46 kg a.s./ha) considered acceptable because residues levels of methomyl were not detected (Greece, 2015).	0.01 ^{*(e)} (tentative)	0.01	0.01

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

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

(b): Highest residue.

(c): Supervised trials median residue.

(d): Available residue trials are not sufficient or used on a tentative basis because not compliant with GAP.

(e): In the absence of metabolism studies covering leafy crops and pulse/oilseeds, only tentative MRL and risk assessment values can be derived for these crops.

B.1.2.2. Residues in succeeding crops

Confined rotational crop study
(quantitative aspect)

Not relevant (significant residues in succeeding crops unlikely due to behaviour of methomyl in soil)

Field rotational crop study

-

B.1.2.3. Processing factors

Processed commodity	Number of studies	Processing Factor (PF)	
		Individual values	Median PF
Robust processing factors (sufficiently supported by data)			
-	-	-	-

B.2. Residues in livestock

	Median dietary burden (mg/kg bw per d)	Maximum dietary burden (mg/kg bw per d)	Highest contributing commodity ^(a)	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Dairy ruminants	0.0001	0.0001	Cotton seed meal	0.0023	N
Meat ruminants	0.0001	0.0001	Cotton seed meal	0.0023	N
Poultry	0.00005	0.00005	Cotton seed meal	0.0008	N
Pigs	0.0001	0.0001	Cotton seed meal	0.0015	N

(a): Calculated for the maximum dietary burden

B.2.1. Nature of residues and methods of analysis in livestock

B.2.1.1. Metabolism studies, methods of analysis and residue definitions in livestock

Livestock (available studies)	Animal	Dose (mg/kg diet)	Duration (days)	N rate/comment
	Laying hen	45	3	Not relevant
	Lactating Goat	162	3	Not relevant
	Pig	-	-	-
Source, United Kingdom, 2004.				

Time needed to reach a plateau concentration in milk and eggs (days)

> 3 days

Metabolism in rat and ruminant similar (Yes/No)

Yes

Animal residue definition for monitoring (RD-Mo)

No proposal (exposure of livestock is insignificant)

Animal residue definition for risk assessment (RD-RA)

No proposal (exposure of livestock is insignificant)

Conversion factor (monitoring to risk assessment)	Not relevant
Fat soluble residues (Yes/No)	Not relevant
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)	-

B.2.1.2. Stability of residues in livestock

Animal products (available studies)	Animal	Commodity	T (°C)	Stability (Months/years)
-	-	Muscle	-70	6 months
-	-	Liver	-70	5 months
-	-	Kidney	-	-
-	-	Milk	-70	6 months
-	-	Egg	-	-
Source: EFSA, 2008b				

B.2.2. Magnitude of residues in livestock

B.2.2.1. Summary of the residue data from livestock feeding studies

A feeding study performed with cows was evaluated during the peer review (Germany, 2004) but is not reported in this review since the dietary burden is not significant and because residue definition for livestock commodities was not derived. A poultry feeding study was not submitted and is not required.

Ruminants	Commodity	Residues at closest feeding level		Estimated value at 1N		MRL (mg/kg)
		Mean (mg/kg)	Highest (mg/kg)	STMR (mg/kg) ^(b)	HR (mg/kg) ^(c)	
	Muscle	-	-	-	-	-
	Fat	-	-	-	-	-
	Liver	-	-	-	-	-
	Kidney	-	-	-	-	-
	Milk	-	-	-	-	-
Poultry	Commodity	Residues at closest feeding level		Estimated value at 1N		MRL (mg/kg)
		Mean (mg/kg)	Highest (mg/kg)	STMR (mg/kg) ^(b)	HR (mg/kg) ^(c)	
	Muscle	-	-	-	-	-
	Fat	-	-	-	-	-
	Liver	-	-	-	-	-
	Kidney	-	-	-	-	-
	Eggs	-	-	-	-	-

Pig	Commodity	Residues at closest feeding level		Estimated value at 1N		MRL (mg/kg)
		Mean (mg/kg)	Highest (mg/kg)	STMR (mg/kg) ^(b)	HR (mg/kg) ^(c)	
	Muscle	-	-	-	-	-
	Fat	-	-	-	-	-
	Liver	-	-	-	-	-
	Kidney	-	-	-	-	-

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

(a): Closest feeding level and N dose rate related to the maximum dietary burden.

(b): Mean residue level recalculated at the 1N rate for the median dietary burden.

(c): Highest residue level for tissues and eggs and mean residue level for milk recalculated at the 1N rate for the maximum dietary burden.

B.3. Consumer risk assessment

B.3.1. Consumer risk assessment without consideration of the existing CXLs

ADI	0.0025 mg/kg bw per day (EFSA, 2008b)
Highest IEDI, according to EFSA PRIMo	<p>Scenario 1: without risk mitigation measures 2.3% ADI (WHO Cluster diet B)</p> <p>Scenario 2: with risk mitigation measures 2.3% ADI (WHO Cluster diet B)</p>
Assumptions made for the calculations	<p>Scenario 1: without risk mitigation measures The calculation is based on the median residue levels in the raw agricultural commodities. Peeling factor are not available for cucurbits with inedible applied. The contributions of commodities where no GAP was reported in the framework of this review were not included in the calculation.</p> <p>Scenario 2: with risk mitigation measures The median residue levels for melons and watermelons resulting from the GAPs of concern are replaced by the median residue levels resulting from the fall-back GAPs (assuming that the GAPs of concern will be withdrawn for these crops).</p>
ARfD	0.0025 mg/kg bw (EFSA, 2008b)
Highest IESTI, according to EFSA PRIMo	<p>Scenario 1: without risk mitigation measures 182% ARfD (Melons) 147% ARfD (Watermelons)</p> <p>Scenario 2: with risk mitigation measures 54.6% ARfD (Melons)</p>
Assumptions made for the calculations	<p>Scenario 1: without risk mitigation measures The calculation is based on the highest residue levels in the raw agricultural commodities. Peeling factor are not available for cucurbits with inedible applied.</p> <p>Scenario 2: with risk mitigation measures The highest residue levels for melons and watermelons resulting from the GAPs of concern are replaced by the highest residue levels resulting from the fall-back GAPs (assuming that the GAPs of concern will be withdrawn for these crops).</p>

B.3.2. Consumer risk assessment with consideration of the existing CXLs

<p>ADI</p> <p>Highest IEDI, according to EFSA PRIMo</p>	<p>0.0025 mg/kg bw per day (EFSA, 2008b)</p> <p>Scenario 1: implementing all CXLs 82.2% ADI (DE child)</p> <p>Scenario 2: implementing CXLs partially 5% ADI (WHO Cluster diet B)</p>
<p>Assumptions made for the calculations</p>	<p>Scenario 1: implementing all CXLs For those commodities having a CXL higher than the EU MRL proposal, median residue levels applied in the second EU scenario were replaced by the median residue levels derived by JMPR. CXLs for tomatoes, rape seed and spices were not considered because the residue definition for these CXLs is not comparable with the EU proposals (CXLs were probably derived from thiodicarb uses). For the same reason, CXLs for livestock commodities were also disregarded.</p> <p>Scenario 2: implementing CXLs partially CXLs that may pose an acute risk to European consumers (see below) were disregarded from the assessment and, where available, the input values according to the second EU scenario were applied (see above).</p>
<p>ARfD</p> <p>Highest IESTI, according to EFSA PRIMo</p>	<p>0.0025 mg/kg bw (EFSA, 2008b)</p> <p>Scenario 1: implementing all CXLs 1108% ARfD (Peppers) 944% ARfD (Oranges) 751% ARfD (Wheat) 671% ARfD (Plums) 666% ARfD (Apples) 656% ARfD (Pears) 635% ARfD (Grapefruits) 553% ARfD (Peas with pods) 425% ARfD (Melons) 396% ARfD (Mandarins) 376% ARfD (Barley, adult) 342% ARfD (Watermelons) 309% ARfD (Beans with pods) 245% ARfD (Lemons) 237% ARfD (Peaches) 223% ARfD (Onions) 210% ARfD (Table grapes) 200% ARfD (Asparagus) 189% ARfD (Beans without pods) 189% ARfD (Wine grapes, adult) 164% ARfD (Cucumbers) 148% ARfD (Pumpkins, adult) 143% ARfD (Limes) 130% ARfD (Courgettes) 123% ARfD (Potatoes)</p> <p>Scenario 2: implementing CXLs partially 75.3% ARfD (lettuce)</p>
<p>Assumptions made for the calculations</p>	<p>Scenario 1: implementing all CXLs For those commodities having a CXL higher than the EU MRL proposal, highest residue levels applied in the second</p>

EU scenario were replaced by the highest residue levels derived by JMPR. CXLs for tomatoes, rape seed and spices were not considered because the residue definition for these CXLs is not comparable with the EU proposals (CXLs were probably derived from thiodicarb uses). For the same reason, CXLs for livestock commodities were also disregarded.

Scenario 2: implementing CXLs partially

CXLs that may pose an acute risk to European consumers were disregarded from the assessment and, where available, the input values according to the second EU scenario were applied (see above).

B.4. Proposed MRLs

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
Enforcement residue definition (existing): sum of methomyl and thiodicarb expressed as methomyl					
Enforcement residue definition (proposed): methomyl					
110010	Grapefruit	0.02*	1	-	Further consideration needed ^(a)
110020	Oranges	0.02*	1	-	Further consideration needed ^(a)
110030	Lemons	0.02*	1	-	Further consideration needed ^(a)
110040	Limes	0.02*	1	-	Further consideration needed ^(a)
110050	Mandarins	0.02*	1	-	Further consideration needed ^(a)
130010	Apples	0.02*	0.3	-	Further consideration needed ^(a)
130020	Pears	0.02*	0.3	-	Further consideration needed ^(a)
140030	Peaches	0.02*	0.2	-	Further consideration needed ^(a)
140040	Plums	0.02*	1	-	Further consideration needed ^(a)
151010	Table grapes	0.02*	0.3	-	Further consideration needed ^(a)
151020	Wine grapes	0.5	0.3	-	Further consideration needed ^(a)
161040	Kumquats	0.02*	1	1	Recommended ^(b)
211000	Potatoes	0.02*	0.02*	-	Further consideration needed ^(c)
220020	Onions	0.02*	0.2	-	Further consideration needed ^(c)
231010	Tomatoes	0.02*	1	0.01*	Recommended ^(d)
231020	Peppers	0.02*	0.7	0.04	Further consideration needed ^(e)
231030	Aubergines (egg plants)	0.02*	-	0.01*	Recommended ^(f)
232010	Cucumbers	0.1	0.1	0.01*	Recommended ^(g)
232020	Gherkins	0.1	0.1	0.1	Recommended ^(h)
232030	Courgettes	0.1	0.1	0.01*	Recommended ^(g)
233010	Melons	0.1	0.1	0.015	Further consideration needed ^(e)
233020	Pumpkins	0.1	0.1	0.05	Further consideration needed ^(e)
233030	Watermelons	0.1	0.1	0.015	Further consideration needed ^(e)
251020	Lettuce	0.2	0.2	0.2	Further consideration needed ⁽ⁱ⁾
252010	Spinach	0.05	-	0.01*	Further consideration needed ^(j)
260010	Beans (fresh, with pods)	0.02*	1	0.1	Further consideration needed ^(k)
260020	Beans (fresh, without pods)	0.02*	1	-	Further consideration needed ^(c)
260030	Peas (fresh, with pods)	0.02*	5	0.1	Further consideration needed ^(k)
270010	Asparagus	0.02*	2	-	Further consideration needed ^(c)
300010	Beans (dry)	0.02*	0.05	0.05	Further consideration needed ^(l)
401060	Rape seed	0.05*	0.05	-	Further consideration needed ^(m)
401070	Soya bean	0.1	0.2	0.2	Further consideration needed ^(l)
401090	Cotton seed	0.1	0.2	0.2	Further consideration needed ⁽ⁱ⁾
500010	Barley grain	0.02*	2	-	Further consideration needed ^(c)
500030	Maize grain	0.02*	0.02*	0.02	Further consideration needed ^(l)
500050	Oats grain	0.02*	0.02*	0.02	Further consideration needed ^(l)
500090	Wheat grain	0.02*	2	-	Further consideration needed ^(c)
820000	Spices (fruits, berries)	0.1*	0.07	-	Further consideration needed ^(m)
1011010	Swine meat	0.02*	0.02*	-	Further consideration needed ^(m)

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
1011030	Swine liver	0.02*	0.02*	-	Further consideration needed ^(m)
1011040	Swine kidney	0.02*	0.02*	-	Further consideration needed ^(m)
1011050	Swine edible offal	0.02*	0.02*	-	Further consideration needed ^(m)
1012010	Bovine meat	0.02*	0.02*	-	Further consideration needed ^(m)
1012030	Bovine liver	0.02*	0.02*	-	Further consideration needed ^(m)
1012040	Bovine kidney	0.02*	0.02*	-	Further consideration needed ^(m)
1012050	Bovine edible offal	0.02*	0.02*	-	Further consideration needed ^(m)
1016010	Poultry meat	0.02*	0.02*	-	Further consideration needed ^(m)
1016030	Poultry liver	0.02*	0.02*	-	Further consideration needed ^(m)
1016040	Poultry kidney	0.02*	0.02*	-	Further consideration needed ^(m)
1016050	Poultry edible offal	0.02*	0.02*	-	Further consideration needed ^(m)
1020010	Cattle milk	0.02*	0.02*	-	Further consideration needed ^(m)
1020020	Sheep milk	0.02*	0.02*	-	Further consideration needed ^(m)
1020030	Goat milk	0.02*	0.02*	-	Further consideration needed ^(m)
1020040	Horse milk	0.02*	0.02*	-	Further consideration needed ^(m)
1030000	Birds' eggs	0.02*	0.02*	-	Further consideration needed ^(m)
-	Other commodities of plant and animal origin	See regulation	-	-	Further consideration needed ⁽ⁿ⁾

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

- (a): There are no relevant authorisations or import tolerances reported at EU level; CXL is supported by data but a risk to consumers cannot be excluded. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-VI in Appendix D).
- (b): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; there are no relevant authorisations or import tolerances reported at EU level (combination A-VII in Appendix D).
- (c): There are no relevant authorisations or import tolerances reported at EU level; CXL is not sufficiently supported by data and a risk to consumers cannot be excluded. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-IV in Appendix D).
- (d): 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 not compatible with EU residue definitions (combination G-II 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; CXL is higher, supported by data but a risk to consumers cannot be excluded (combination E-VI in Appendix D).
- (f): 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).
- (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): 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).
- (i): MRL is derived from the existing CXL, which is not sufficiently supported by data but for which no risk to consumers is identified (assuming the tentative residue definition); GAP evaluated at EU level, which is also not fully supported by data, would lead to a lower tentative MRL (combination E-V 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 (assuming the tentative residue definition); no CXL is available (combination E-I in Appendix D).
- (k): 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 (assuming the tentative residue definition); CXL is higher but it is also not sufficiently supported by data and a risk to consumers cannot be excluded (combination E-IV in Appendix D).
- (l): MRL is derived from the existing CXL, which is not sufficiently supported by data but for which no risk to consumers is identified (assuming the tentative residue definition); there are no relevant authorisations or import tolerances reported at EU level (combination A-V in Appendix D).
- (m): There are no relevant authorisations or import tolerances reported at EU level; CXL is not compatible with EU residue definitions. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-II in Appendix D).
- (n): 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).

Appendix C – Input values for the exposure calculations

C.1. Livestock dietary burden calculations

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: methomyl				
Cotton seed	0.005	STMR	0.005	STMR
Cotton seed meal	0.007	STMR x 1.3 ^(a)	0.007	STMR x 1.3 ^(a)

* Indicates that the input value is proposed at the limit of quantification.

(a) In the absence of processing factors supported by data for cotton seed meal (20% oil content), a default processing factors of 1.3 was included in the calculation in order to consider the potential concentration of residues in this commodity. STMR: supervised trials median residue

C.2. Consumer risk assessment without consideration of the existing CXLs

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: methomyl				
Tomatoes	0.01*	STMR	0.01*	HR
Peppers	0.006	STMR (tentative)	0.02	HR (tentative)
Aubergines (egg plants)	0.01*	STMR	0.01*	HR
Cucumbers	0.01*	STMR	0.01*	HR
Gherkins	0.01*	STMR	0.01*	HR
Courgettes	0.01*	STMR	0.01*	HR
Melons/ Watermelons	0.006	STMR (tentative)	0.03	HR (tentative)
	0.006	STMR (fall-back, tentative)	0.009	HR (fall back, tentative)
Pumpkins	0.006	STMR (tentative)	0.03	HR (tentative)
Lettuce	0.003	STMR (tentative)	0.003	HR (tentative)
Spinach	0.003	STMR (tentative)	0.003	HR (tentative)
Beans (fresh, with pods)	0.02	STMR (tentative)	0.05	HR (tentative)
Peas (fresh, with pods)	0.02	STMR (tentative)	0.05	HR (tentative)
Cotton seed	0.005	STMR (tentative)	0.005	HR (tentative)

* Indicates that the input value is proposed at the limit of quantification.

C.3. Consumer risk assessment with consideration of the existing CXLs

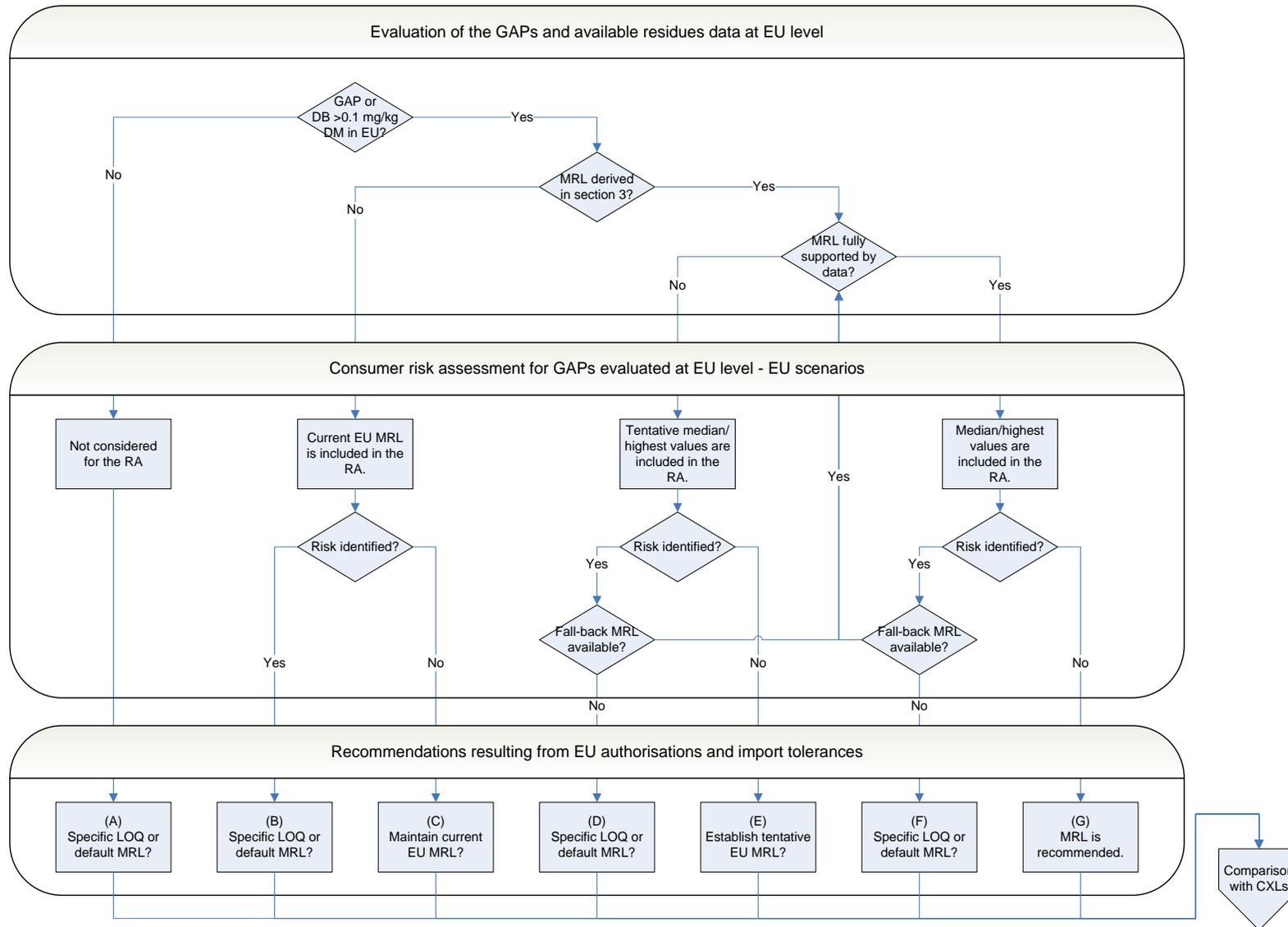
Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: methomyl				
Grapefruit	0.03	STMR x 0.2 ^(a) (CXL)	0.18	HR x 0.2 ^(a) (CXL)
Oranges	0.03	STMR x 0.2 ^(a) (CXL)	0.18	HR x 0.2 ^(a) (CXL)
Lemons	0.03	STMR x 0.2 ^(a) (CXL)	0.18	HR x 0.2 ^(a) (CXL)
Limes	0.03	STMR x 0.2 ^(a) (CXL)	0.18	HR x 0.2 ^(a) (CXL)
Mandarins	0.03	STMR x 0.2 ^(a) (CXL)	0.18	HR x 0.2 ^(a) (CXL)
Apples	0.09	STMR (CXL)	0.17	HR (CXL)
Pears	0.09	STMR (CXL)	0.18	HR (CXL)
Peaches	0.05	STMR (CXL)	0.10	HR (CXL)
Plums	0.08	STMR (CXL)	0.51	HR (CXL)
Table grapes	0.01	STMR (CXL)	0.08	HR (CXL)
Wine grapes	0.09	STMR (CXL)	0.20	HR (CXL)
Kumquats	0.17	STMR (CXL)	0.89	HR (CXL)
Potatoes	0.02	STMR (CXL, tentative)	0.02	HR (CXL, tentative)
Onions	0.07	STMR (CXL, tentative)	0.14	HR (CXL, tentative)
Tomatoes	0.01*	STMR ^(b)	0.01*	HR ^(b)
Peppers	0.11	STMR (CXL)	0.44	HR (CXL)
Aubergines (egg plants)	0.01*	STMR	0.01*	HR
Cucumbers	0.02	STMR (CXL)	0.07	HR (CXL)
Gherkins	0.02	STMR (CXL)	0.07	HR (CXL)
Courgettes	0.02	STMR (CXL)	0.07	HR (CXL)
Melons	0.02	STMR (CXL)	0.07	HR (CXL)
Pumpkins	0.02	STMR (CXL)	0.07	HR (CXL)
Watermelons	0.02	STMR (CXL)	0.07	HR (CXL)
Lettuce	0.01	STMR (CXL, tentative)	0.07	HR (CXL)
Spinach	0.003	STMR (tentative)	0.003	HR (tentative)
Beans (fresh, with pods)	0.06	STMR (CXL, tentative)	0.68	HR (CXL, tentative)
Beans (fresh, without pods)	0.06	STMR (CXL, tentative)	0.68	HR (CXL, tentative)
Peas (fresh, with pods)	0.46	STMR (CXL, tentative)	4	HR (CXL, tentative)
Asparagus	0.33	STMR (CXL, tentative)	1.1	HR (CXL, tentative)
Beans (dry)	0.02	STMR (CXL, tentative)	0.02	HR (CXL, tentative)
Soya bean	0.02	STMR (CXL, tentative)	0.02	HR (CXL, tentative)
Cotton seed	0.04	STMR (CXL, tentative)	0.10	HR (CXL, tentative)
Barley grain	0.14	STMR (CXL, tentative)	1.30	HR (CXL, tentative)
Maize grain	0.02	STMR (CXL, tentative)	0.02	HR (CXL, tentative)
Oats grain	0.02	STMR (CXL, tentative)	0.02	HR (CXL, tentative)
Wheat grain	0.14	STMR (CXL, tentative)	1.30	HR (CXL, tentative)

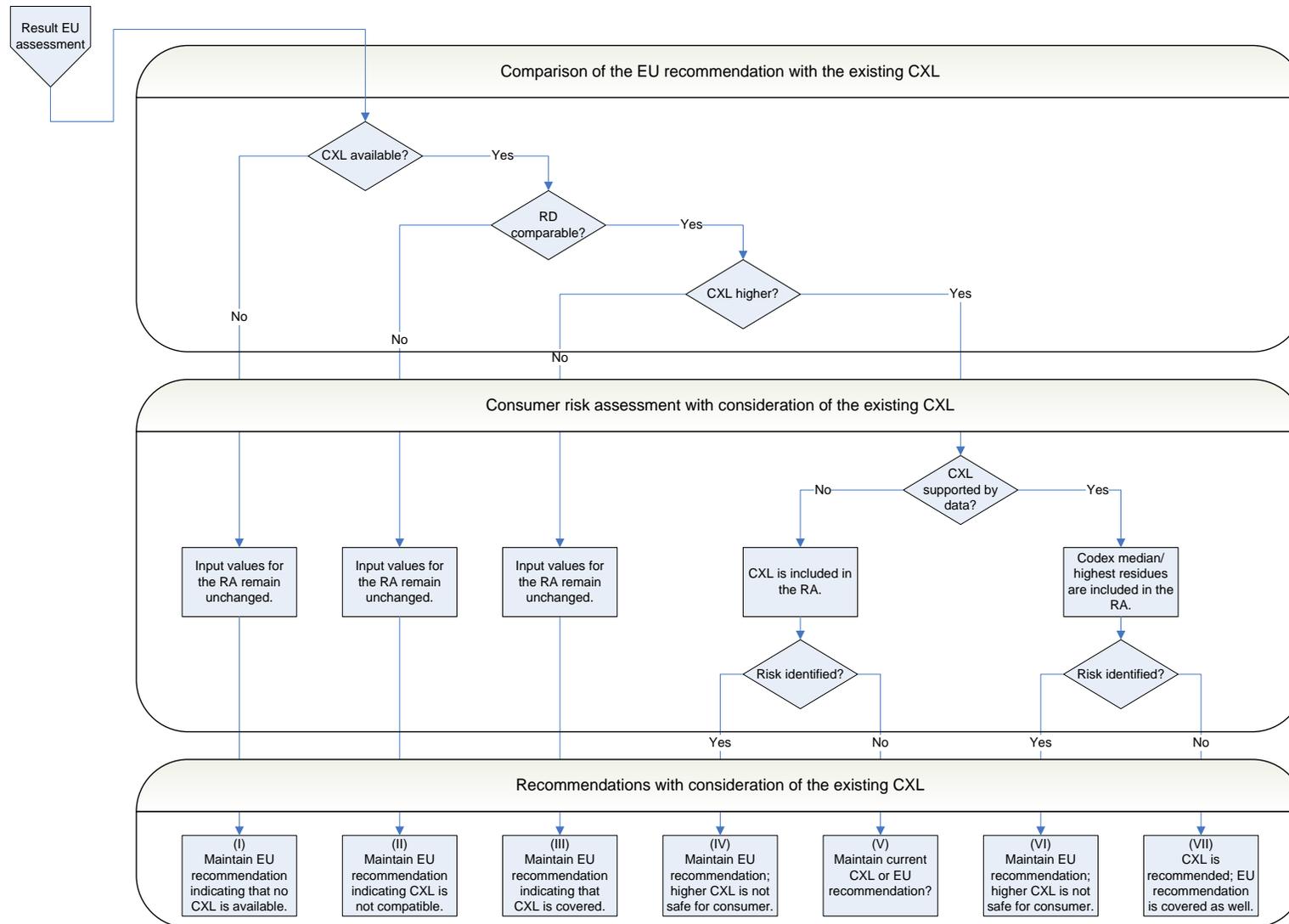
* Indicates that the input value is proposed at the limit of quantification.

(a): Processing factor for citrus peeling of 0.2 derived by JMPR (FAO, 2001b) was taken into account.

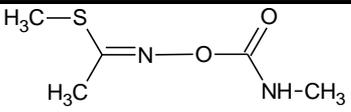
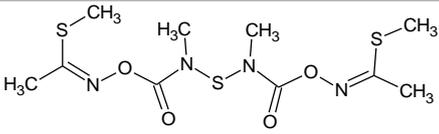
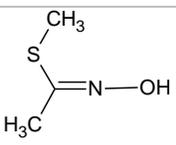
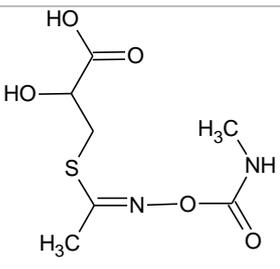
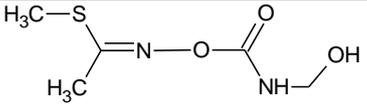
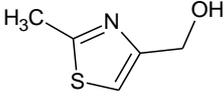
(b): CXL for tomatoes was not considered because the residue definition for this CXL is not comparable with the EU proposal (CXLs were probably derived from thiodicarb uses). For the same reason, CXLs for rape seed, spices and livestock commodities were also disregarded.

Appendix D – Decision tree for deriving MRL recommendations





Appendix E – Used compound codes

Code/trivial name	Chemical name/SMILES notation ^(a)	Structural formula ^(a)
Methomyl	<i>S</i> -methyl (<i>EZ</i>)- <i>N</i> -(methylcarbamoyloxy)thioacetimidate C\C(=N\OC(=O)NC)SC	
Thiodicarb	(3 <i>EZ</i> ,12 <i>EZ</i>)-3,7,9,13-tetramethyl-5,11-dioxa-2,8,14-trithia-4,7,9,12-tetraazapentadeca-3,12-diene-6,10-dione CN(SN(C)C(=O)O\N=C(\C)SC)C(=O)O\N=C(\C)SC	
IN-X1177/ Methomyl-oxime	methyl (1 <i>EZ</i>)- <i>N</i> -hydroxyethanimidothioate C\C(=N\O)SC	
IN-HUZ57/ Hydroxyl cysteine derivative of methomyl	(5 <i>EZ</i>)-9-hydroxy-6-methyl-3-oxo-4-oxa-7-thia-2,5-diazadec-5-en-10-oic acid O=C(O\N=C(\C)SCC(O)C(=O)O)N C	
IN-G6520/ Hydroxymethyl methomyl	methyl (1 <i>EZ</i>)- <i>N</i> -{[(hydroxymethyl)carbamoyl]oxy}ethanimidothioate C\C(=N\OC(=O)NCO)SC	
IN-NR282	(2-methyl-1,3-thiazol-4-yl)methanol OCC1csc(C)n1	

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