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

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Abstract

According to Article 12 of Regulation (EC) No 396/2005, EFSA has reviewed the maximum residue levels (MRLs) currently established at European level for the pesticide active substance emamectin. To assess the occurrence of emamectin residues in plants, processed commodities, rotational crops and livestock, EFSA considered the conclusions derived in the framework of Regulation (EC) No 1107/2009, the MRLs established by the Codex Alimentarius Commission as well as the European authorisations reported by Member States (including 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: emamectin, MRL review, Regulation (EC) No 396/2005, consumer risk assessment, insecticide

Requestor: European Commission

Question number: EFSA-Q-2013-00777

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Acknowledgement: EFSA wishes to thank the rapporteur Member State the Netherlands for the preparatory work on this scientific output.

Suggested citation: EFSA (European Food Safety Authority), Anastassiadou M, Brancato A, Carrasco Cabrera L, Ferreira L, Greco L, Jarrah S, Kazocina A, Leuschner R, Magrans JO, Miron I, Nave S, Pedersen R, Raczyk M, Reich H, Rojas A, Ruocco S, Sacchi A, Santos M, Stanek A, Theobald A, Vagenende B and Verani A, 2019. Reasoned opinion on the review of the existing maximum residue levels for emamectin according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2019;17(8):5803, 81 pp. https://doi.org/10.2903/j.efsa.2019.5803

ISSN: 1831-4732

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Summary

Emamectin was approved on 1 May 2014 by means of Commission Implementing Regulation (EU) No 828/2013 in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011.

As the active substance was approved after the entry into force of Regulation (EC) No 396/2005 on 2 September 2008, the European Food Safety Authority (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.

As the basis for the MRL review, on 15 December 2017 EFSA initiated the collection of data for this active substance. In a first step, Member States were invited to submit by 15 January 2018 their national Good Agricultural Practices (GAPs) in a standardised way, in the format of specific GAP forms, allowing the designated rapporteur Member State (RMS) the Netherlands to identify the critical GAPs in the format of a specific GAP overview file. Subsequently, Member States were requested to provide residue data supporting the critical GAPs, within a period of 1 month, by 8 March 2018. On the basis of all the data submitted by Member States and by the EU Reference Laboratories for Pesticides Residues (EURLs), EFSA asked the RMS to complete the Pesticide Residues Overview File (PROFile) and to prepare a supporting evaluation report. The PROFile and evaluation report, together with Pesticide Residues Intake Model (PRIMO) calculations were provided by the RMS to EFSA on 15 June 2018. Subsequently, EFSA performed the completeness check of these documents with the RMS. The outcome of this exercise including the clarifications provided by the RMS, if any, was compiled in the completeness check report.

Based on the information provided by the RMS, Member States and the EURL, and taking into account the conclusions derived by EFSA in the framework of Commission Regulation (EU) No 188/2011 and the MRLs established by the Codex Alimentarius Commission, EFSA prepared in February 2019 a draft reasoned opinion, which was circulated to Member States for consultation via a written procedure. Comments received by 22 March 2019 were considered during the finalisation of this reasoned opinion. The following conclusions are derived.

The metabolism of emamectin in plant was investigated in primary and rotational crops. According to the results of the metabolism studies, the residue definition for enforcement can be proposed as emamectin B1a and its salts, expressed as emamectin B1a (free base). This residue definition is applicable to all plant and processed commodities. For the risk assessment purpose, the residue definition is proposed as sum of emamectin B1a, emamectin B1b, 8,9-Z-MAB1a, plus 3 times AB1a, plus 3 times MFB1a and 3 times FAB1a, expressed as emamectin B1a (free base). This residue definition applies to all plant commodities (raw and processed). Although not sufficiently validated for all matrices, analytical methods are available for the enforcement of the proposed residue definition in the four main plant matrices. According to the EURLs, the limit of quantification (LOQ) of 0.002 mg/kg in high water and high acid content commodities and 0.005 mg/kg in high oil content and dry commodities are achievable in routine analyses.

Available residue trials data were considered sufficient to derive (tentative) MRL proposals as well as risk assessment values for all commodities under evaluation, except for kohlrabi and cotton seeds, for which no data were available. Robust and tentative peeling factors could be derived for melons and citrus fruits, respectively.

Emamectin is authorised for use on crops that might be fed to livestock. Livestock dietary burden calculations were therefore performed for different groups of livestock according to OECD guidance. 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 was in principle unnecessary. However, in this particular case, given the high chronic toxicity of emamectin and its fat solubility, EFSA assessed the nature and magnitude of residues in ruminants and swine.

The metabolism of emamectin residues in livestock was investigated in lactating goats at dose rate covering the maximum dietary burdens calculated in this review (700–940N). According to the results of these studies, the residue definition for enforcement and risk assessment in ruminants and swine was proposed as emamectin B1a and its salts, expressed as emamectin B1a (free base). A sufficiently validated analytical method for the enforcement of the proposed residue definition in livestock matrices is not available and it is required (data gap). According to the EURLs, the LOQ of 0.01 mg/kg is achievable by using a single residue method in routine analyses.
A livestock feeding study on dairy cows was used to derive MRL and risk assessment values in milk and tissues of ruminants. Since extrapolation from ruminants to pigs is acceptable, results of the livestock feeding study on ruminants were relied upon to derive the MRL and risk assessment values in pigs. In view of the data gaps identified for the analytical methods and storage stability of residues in livestock, all MRLs are tentative.

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 those commodities where data were insufficient to derive an MRL, EFSA considered the existing EU MRL, multiplied by the corresponding conversion factor, as an indicative calculation. The highest chronic exposure was calculated for the Spanish adult, representing 28% of the acceptable daily intake (ADI). However, an exceedance of the acute reference dose (ARfD) was identified for lettuces and escaroles (broad-leaved endives) representing 218% and 102% of the ARfD, respectively. Considering fall-back GAPs for these crops, the highest chronic exposure represented 17% of the ADI (DE child) and the highest acute exposure amounted to 40% of the ARfD (lettuce).

Apart from the MRLs evaluated in the framework of this review, internationally recommended codex maximum residue limits (CXLs) have also been established for emamectin. Additional calculations of the consumer exposure, considering these CXLs, were therefore carried out and an exceedance of the ARfD was identified for the existing CXL in lettuce (117%). Excluding this CXL from the calculation, the highest chronic exposure represented 19% of the ADI (DE child) and the highest acute exposure amounted to 54% of the ARfD (Chinese cabbage).
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Background

Regulation (EC) No 396/20051 (hereinafter referred to as ‘the Regulation’) 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 the European Food Safety Authority (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.

As emamectin was approved on 1 May 2014 by means of Commission Implementing Regulation (EU) No 828/20133 in accordance with Regulation (EC) No 1107/20094 and amending the Annex to Commission Implementing Regulation (EU) No 540/20115, EFSA initiated the review of all existing MRLs for that active substance.

By way of background information, in the framework of Commission Regulation (EU) No 188/20116 emamectin was evaluated by the Netherlands, designated as rapporteur Member State (RMS). Subsequently, a peer review on the initial evaluation of the RMS was conducted by EFSA, leading to the conclusions as set out in the EFSA conclusion (EFSA, 2012). The representative uses evaluated in the peer review were field and glasshouse foliar spray applications on grapes, tomatoes, peppers, cucumbers, melons and lettuce. Emamectin has been approved for use as an insecticide. Furthermore, according to the provisions of the approval regulation, confirmatory information was requested, as regards the risk of enantioselective metabolisation or degradation. The applicant shall submit to the Commission, Member States and the Authority the relevant information 2 years after adoption of the pertinent guidance document on evaluation of isomer mixtures, however, since the guidance document has not been adopted this information is pending.

According to the legal provisions, EFSA shall base its reasoned opinion in particular on the relevant assessment report prepared under Directive 91/414/EEC repealed by Regulation (EC) No 1107/2009. It should be noted, however, that, in the framework of Regulation (EC) No 1107/2009, only a few representative uses are evaluated, whereas MRLs set out in Regulation (EC) No 396/2005 should accommodate all uses authorised within the European Union (EU), and uses authorised in third countries that have a significant impact on international trade. The information included in the assessment report prepared under Regulation (EC) No 1107/2009 is therefore insufficient for the assessment of all existing MRLs for a given active substance.

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;
- the analytical methods for enforcement of the proposed MRLs.

As the basis for the MRL review, on 15 December 2017 EFSA initiated the collection of data for this active substance. In a first step, Member States were invited to submit by 15 January 2018 their Good Agricultural Practices (GAPs) that are authorised nationally, in a standardised way, in the format of specific GAP forms. In the framework of this consultation, 15 Member States provided feedback on

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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 Implementing Regulation (EU) No 823/2013/EC of 29 August 2013 approving the active substance emamectin, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. OJ No L 232, 30.8.2013, p. 23-28.
4 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.
5 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.
6 Commission Regulation (EU) No 188/2011 of 25 February 2011 laying down detailed rules for the implementation of Council Directive 91/414/EEC as regards the procedure for the assessment of active substances which were not on the market 2 years after the date of notification of that Directive. OJ No L 53, 26.2.2011, p. 51-55.
their national authorisations of emamectin. Based on the GAP data submitted, the designated RMS the Netherlands was asked to identify the critical GAPs (cGAPs) to be further considered in the assessment, in the format of a specific GAP overview file. Subsequently, in a second step, Member States were requested to provide residue data supporting the cGAPs by 8 March 2018.

On the basis of all the data submitted by Member States and the EU Reference Laboratories for Pesticides Residues (EURL), EFSA asked the Netherlands to complete the PROFile and to prepare a supporting evaluation report. The PROFile and the supporting evaluation report, together with the Pesticide Residues Intake Model (PRIMo) calculations, were submitted to EFSA on 15 June 2018. Subsequently, EFSA performed the completeness check of these documents with the RMS. The outcome of this exercise including the clarifications provided by the RMS, if any, was compiled in the completeness check report.

Considering all the available information, and taking into account the MRLs established by the Codex Alimentarius Commission (CAC) (i.e. codex maximum residue limits (CXLs)), EFSA prepared in February 2019 a draft reasoned opinion, which was circulated to Member States for commenting via a written procedure. All comments received by 22 March 2019 were considered by EFSA during the finalisation of the reasoned opinion.

The evaluation report submitted by the RMS (Netherlands, 2018), taking into account also the information provided by Member States during the collection of data (Austria, 2018; France, 2018; Greece, 2018; Hungary, 2018; Italy, 2018) and the EURL report on analytical methods (EURL, 2018) are considered as main supporting documents to this reasoned opinion and, thus, made publicly available.

In addition, further supporting documents to this reasoned opinion are the completeness check report (EFSA, 2019a) and the Member States consultation report (EFSA, 2019c). These reports are developed to address all issues raised in the course of the review, from the initial completeness check to the reasoned opinion. Furthermore, the exposure calculations for all crops reported in the GAP overview file listing all authorised uses are key supporting documents and made publicly available as background documents to this reasoned opinion. A screenshot of the report sheet of the PRIMo is presented in Appendix C.

### 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

Emamectin is the ISO common name for a mixture of emamectin B$_{1a}$ (≥ 90%) and emamectin B$_{1b}$ (≤ 10%): (10E,14E,16E,22Z)-(1R,4S,5'S,6'S,8'R,12S,13S,20R,21R,24S)-6'-[(S)-sec-butyl]-21,24-dihydroxy-5',11,13,22-tetramethyl-2-oxo-[3,7,19-trioxatetryclo[15.6.6.1,8,9,10,24]pentacosao-10,14,16,22-tetraene]-6-spiro-2'-((5',6'-dihydro-2'H-pyrane)-12-yl,6-dideoxy-3'-O-methyl-4-O-(2,4,6-trideoxy-3-O-methyl-4-methylamino-α-L-lyxo-hexopyranosyl)-α-L-arabino-hexopyranoside; and (10E,14E,16E,22Z)-(1R,4S,5'S,6'S,8'R,12S,13S,20R,21R,24S)-21,24-dihydroxy-6'-isopropyl-5',11,13,22-tetramethyl-2-oxo-[3,7,19trioxatetryclo[15.6.1,14,8,20,24]pentacosao-10,14,16,22-tetraene]-6-spiro-2'-((5',6'-dihydro-2'H-pyrane)-12-yl,6-dideoxy-3'-O-methyl-4-O-(2,4,6-trideoxy-3-O-methyl-4-methylamino-α-L-lyxo-hexopyranosyl)-α-L-arabino-hexopyranoside(E,Z)-3-(2-chloro-thiazol-5-ylmethyl)-5-methyl-[1,3,5]oxadiazinan-4-ylidene-N-nitroamine; respectively (IUPAC).

The chemical structure of the active substance and its main metabolites are reported in Appendix F. The EU MRLs for emamectin are established in Annex IIIA of Regulation (EC) No 396/2005. CXLs for emamectin were also established by the CAC. An overview of the MRL changes that occurred since the entry into force of the Regulation mentioned above is provided below (Table 1).
Review of the existing MRLs for emamectin

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

| Procedure             | Legal implementation                        | Remarks                                      |
|-----------------------|---------------------------------------------|----------------------------------------------|
| MRL application       | Commission Regulation (EC) No 1050/2009(a)  | Various crops (EFSA, 2009).                 |
| MRL application       | Commission Regulation (EU) No 813/2011(b)   | Plums, apricots and citrus fruit (EFSA, 2011) |
| Implementation of CAC 2012 | Regulation (EU) No 293/2013(c)     | Implementation of CXL (EFSA, 2015).          |
| MRL application       | Commission Regulation (EU 2018/1514(d))    | Leafy brassica and beans and peas with pods (EFSA, 2018) |
| MRL application       | Not yet legally implemented                | Kiwi (EFSA, 2019b)                          |

MRL: maximum residue level; CAC: codex maximum residue limit; CXL: codex maximum residue limit.

(a): Commission Regulation (EC) No 1050/2009 of 28 October 2009 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for azoxystrobin, acetamiprid, clomazone, cyflufenamid, emamectin benzoate, famoxadone, fenbutatin oxide, flufenoxuron, fluopicolide, indoxacarb, ipoxynil, mepanipyrim, prothiocionazole, pyridalyl, thiacloprid and trifloxystrobin in or on certain products. OJ L 290, 6.11.2009, p. 7–55.

(b): Commission Regulation (EC) No 813/2011 of 11 August 2011 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acequinocyl, emamectin benzoate, ethametsulfuron-methyl, flubendiamide, fludioxonil, kresoxim-methyl, methoxyfenozide, novaluron, thiacloprid and trifloxystrobin in or on certain products. OJ L 208, 13.8.2011, p. 23–79.

(c): Commission Regulation (EU) No 293/2013 of 20 March 2013 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for emamectin benzoate, etofenprox, etoxazole, flutriafol, glyphosate, phosmet, pyraclostrobin, spinosad and spirotetramat in or on certain products. OJ L 96, 5.4.2013, p. 1–30.

(d): Commission Regulation (EU) 2018/1514 of 10 October 2018 amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for abamectin, acibenzolar-S-methyl, clopyralid, emamectin, fenhexamid, fenpyrazamine, fluazifop-P, isofetamid, Pasteuria nishizawae Pn1, talc E553B and tebuconazole in or on certain products. OJ L 256, 12.10.2018, p. 8–32.

For the purpose of this MRL review, all the uses of emamectin currently authorised within the European Union (EU) as submitted by the Member States during the GAP collection, have been reported by the RMS in the GAP overview file. The cGAPS identified in the GAP overview file were then summarised in the PROFile and considered in the assessment. The details of the authorised cGAP for emamectin are given in Appendix A. The RMS 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 following documents:

- the PROFile submitted by the RMS;
- the evaluation report accompanying the PROFile (Netherlands, 2018);
- the draft assessment report (DAR) and the final addendum to draft assessment report on emamectin benzoate prepared under Council Directive 91/414/EEC (Netherlands, 2008, 2012);
- the conclusion on the peer review of the pesticide risk assessment of the active substance emamectin (EFSA, 2012);
- the Joint Meeting on Pesticide residues (JMPR) Evaluation report (FAO, 2009, 2011, 2014),
- the previous reasoned opinions on emamectin (EFSA, 2009, 2011, 2015, 2018).

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 546/2011 and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (European Commission, 1997a–g, 2000, 2010a,b, 2017; OECD, 2011, 2013).

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.

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7 Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.
1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

The metabolism of emamectin was investigated after foliar treatment in fruits (pears), leafy vegetables (lettuce and head cabbage) and cereals (sweet corn) using emamectin B$_{1a}$ benzoate only, labelled as [3, 7, 11, 13, 23-$^{14}$C]-emamectin B$_{1a}$ or as [23-$^{14}$C]-emamectin B$_{1a}$ in the pear study (Netherlands, 2008). All four studies were assessed in the framework of the peer-review (EFSA, 2012).

After eight foliar applications of 16.8 or 84 g a.s./ha on lettuce and head cabbage, the major component identified was parent emamectin B$_{1a}$, representing 7–34% TRR (0.01–0.1 mg eq/kg, low dose; 0.09–1.0 mg eq/kg, high dose) of the total radioactive residues (TRR) within 3 days after application, and typically less than 5% TRR, after 7 days. The remaining radioactivity was resolved into six degradation compounds structurally related to emamectin B$_{1a}$, out of which four were photometabolites (8,9-Z-MAB$_{1a}$, FAB$_{1a}$, MFB$_{1a}$, AB$_{1a}$), each occurring mostly at less than 5% TRR. However, when considered altogether, the photometabolites represented up to 20% TRR (0.07 mg eq/kg low dose; 0.6 mg eq/kg high dose). A similar metabolic pathway was observed in sweet corn, for which the parent and photometabolites were observed. Emamectin B$_{1a}$ was the major component identified in both leaves and husk, accounting for up to 14% (0.1 mg eq/kg) and 23% TRR (0.06 mg eq/kg), respectively.

After three foliar applications of 16.8 or 168 g a.s./ha on pears, only the parent was identified, being the photometabolites totally absent. Initially, a different metabolic profile was suggested in fruit crops. However, such a specific metabolism was not confirmed by the supervised residue trials conducted on apple and peach (reported in a previous reasoned opinion, EFSA, 2009), melons (assessed in the peer-review, EFSA, 2012) and strawberries (submitted in the framework of this MRL review, Italy, 2018), where the photometabolites were quantified (see also Section 1.2.1). According to the EFSA conclusion, the differences observed in the pear metabolism study should thus be considered as a result from different experimental patterns (characterisation of the residues after 14 and 28 days in pear, while after 0–7 days in the other crops), rather than from a particular metabolism in fruit crops.

The metabolic pathway of emamectin was similar in fruits, leafy vegetables and cereals, exhibiting an extensive photodegradation of emamectin B$_{1a}$ benzoate in the surface of the crops.

1.1.2. Nature of residues in rotational crops

Emamectin is authorised on crops that may be grown in rotation. The field DT$_{90}$ reported in the soil degradation studies evaluated in the framework of the peer review was 53 days (Netherlands, 2008), indicating that there is no potential for residues to be present in soil at the time rotational crops would be planted. Although not required, confined rotational crop studies with radiolabelled [3, 7, 11, 13, 23-$^{14}$C] emamectin B$_{1a}$ benzoate were submitted and assessed in the framework of the peer review (EFSA, 2012).

Emamectin B$_{1a}$ benzoate was applied at a rate of 100.8 g a.s./ha (covering the most cGAP evaluated in this review) onto bare soil. Crops were planted at nominal plant-back intervals (PBI) of 30, 120/141 and 365 days after treatment (DAT). Crops planted at each interval consisted of leafy vegetable (lettuce), roots (carrots) and cereals (barley). Total radioactive residues were below 0.01 mg eq/kg in all plant matrices, except in barley straw (0.03 mg eq/kg at 141 DAT). Further characterisation of the TRRs was not performed and it is not needed.

1.1.3. Nature of residues in processed commodities

Studies investigating the nature of residues in processed commodities were assessed in the peer-review (Netherlands, 2008; EFSA, 2012). Studies were conducted with radiolabelled [23-$^{14}$C]-emamectin B$_{1a}$ benzoate 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).

The studies demonstrated that emamectin undergoes limited hydrolysis (ca. 15–20%). The level of degradation increases with temperature/pH: 15% degradation under pasteurisation, 14% degradation under boiling/brewing/baking and 20% degradation under sterilisation. The monosaccharide MSB$_{1a}$...
(4.8% of the total applied radioactivity (TAR) under boiling/brewing/baking; 7.2% TAR under sterilisation), AB1a (1.8% TAR under sterilisation) and aglycone milbemectin B (1.4% under boiling/brewing/baking) were the metabolites identified. Further minor unknown degradation products could not be identified. All the breakdown products were below 10% of TAR. The toxicological properties of the metabolite MSB1a were not discussed in the peer review. These studies are considered sufficient to assess the nature of parent emamectin B1a in processed commodities. Concerning the photometabolites, having regard to the low residue levels observed in the raw commodities (maximum residue observed 0.04 mg/kg), their similar chemical structure to the parent and the safety margin of the risk assessment (19% acceptable daily intake (ADI)), EFSA is of the opinion that additional processing studies conducted with all the species included in the plant RA RD are not needed. Overall, the processing of emamectin is not expected to modify the nature of the residues.

1.1.4. Methods of analysis in plants

The EU pesticide peer review concluded that a single residue method using liquid chromatography/liquid chromatography (LC/LC) coupled to tandem mass spectrometry (MS/MS) was sufficiently validated for emamectin B1a, with one ion transition on high water, high acid and high oil content commodities, as well as dry commodities and wheat straw. The limit of quantification (LOQ) was reported to be 0.001 mg/kg. Validation results for emamectin B1b and the 4 photometabolites (8,9-Z-MAB1a, FAB1a, MFB1a, AB1a) also exist at the same LOQ. Confirmatory methods were missing and an independent laboratory validation (ILV) was provided only for high water content commodities (Netherlands, 2008; EFSA, 2012). A confirmatory method for the four main matrices was evaluated in the frame of a previous MRL application (EFSA, 2018). An ILV for at least one of the other two matrix group (high acid or high oil content commodities) relevant for this MRL review is still required (data gap).

During the completeness check, EURs provided validation results on QuEChERS and QuOil multiresidue methods using LC–MS/MS with a LOQ of 0.01 mg/kg in high water and high acid content commodities, dry commodities and high oil content commodities for the enforcement of emamectin B1a benzoate (detected as free base) in routine analysis (EUR, 2018). During the MSC report, EURs provided additional information on the enforcement LOQ achieved in routine analysis. The new reported values are 0.002 mg/kg for high water and high acid content commodities, and 0.005 mg/kg in dry commodities and high oil content commodities (EFSA, 2019b).

1.1.5. Stability of residues in plants

The storage stability of emamectin B1a and B1b benzoate, and the four photometabolites (each compound individually) was investigated in the framework of the peer review (EFSA, 2012) in high water (tomato, beans with pod) and high starch (potato) content commodities (Netherlands, 2008; EFSA, 2012). The available studies demonstrated storage stability for all the six compounds, individually, for a period of 18 months when stored at -20°C.

In the framework of an MRL application (Italy, 2015), a new storage stability study was conducted with oranges (whole fruit), representing the high acid content commodities group. The storage stability of emamectin B1a was demonstrated for a period of 24 months when stored at -18°C. Alike, the photometabolites were found to be stable for the same storage period and temperature as parent; however, emamectin B1b was slightly degraded (64%) at 24 months. Emamectin B1b is thus considered to be stable for a period of 18 months when stored at -18°C.

As regards the storage stability of emamectin and the photometabolites in high oil content matrices, no studies are available, resulting in a data gap.

1.1.6. Proposed residue definitions

The metabolic pathway of emamectin was similar in all crops investigated and a different metabolic pathway is not expected in rotational crops.

Based on the metabolism studies and considering that emamectin B1a was the only compound detected at significant levels in most of the plant parts investigated, as well as the fact that most of the trials and end points were expressed as benzoate, the residue definition for enforcement was proposed as "emamectin B1a, expressed as emamectin B1a benzoate", during the peer review (EFSA, 2012). However, it is noted that the residue definition for enforcement considered in the current MRL Regulation is "Emamectin benzoate B1a, expressed as emamectin". Bearing in mind that different toxicological reference values were derived for emamectin benzoate and emamectin free base, to
harmonise how the residue definition is expressed becomes of utmost importance. Considering that the analytical methods validated to be used in the residue trials as well as the analytical methods for enforcement reported by EURLs and JMPR (FAO, 2011; EURL, 2018) measure individual emamectin components as free bases, EFSA suggests the following residue definition for enforcement: emamectin B$_{1a}$ and its salts, expressed as emamectin B$_{1a}$ (free base).

For processed commodities, emamectin B$_{1a}$ was found to be degraded up to 20%, mostly under sterilisation. Emamectin B$_{1a}$ is considered as sufficient marker for enforcement in processed commodities and thus, the residue definition for enforcement as derived above also applies to processed commodities.

An analytical method for the enforcement of the proposed residue definition at the LOQ of 0.001 mg/kg in the four main plant matrices is available, but it should be noted that an ILV only exists for the high water content commodities (see Section 1.1.4). According to the EURLs, the LOQ of 0.002 mg/kg in high water and high acid content commodities and 0.005 mg/kg in high oil content and dry commodities are achievable in routine analyses (EFSA, 2019b).

In the peer review, the photometabolites (8,9-Z-MAB$_{1a}$, FAB$_{1a}$, MFB$_{1a}$, AB$_{1a}$) were provisionally included in the residue definition for risk assessment (EFSA, 2012). New toxicological studies on these metabolites were assessed in a previous MRL application (EFSA, 2018), and their inclusion in the residue definition for risk assessment was confirmed. These compounds share a common toxicological mode of action with parent compound but with different potencies. Therefore, the residue definition for risk assessment is proposed as sum of emamectin B$_{1a}$, emamectin B$_{1b}$, 8,9-Z-MAB$_{1a}$, plus 3 times AB$_{1a}$, plus 3 times MFB$_{1a}$ and 3 times FAB$_{1a}$, expressed as emamectin B$_{1a}$ (free base). It is noted that the sum is expressed as free base in order to be consistent with the proposed residue definition for enforcement. This residue definition applies to all plant and processed commodities.

In addition, EFSA emphasises that the above studies do not investigate the possible impact of plant metabolism on the isomer ratio of emamectin and further investigation on this matter would in principle be required. Since guidance on the consideration of isomer ratios in the consumer risk assessment is not yet available, EFSA recommends that this issue is reconsidered when such guidance is available.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

To assess the magnitude of emamectin residues resulting from the reported GAPs, EFSA considered all residue trials reported by the RMS in its evaluation report (Netherlands, 2018) as well as the residue trials evaluated in the framework of the peer review (EFSA, 2012), the supporting trials submitted by Member States (Austria, 2018; France, 2018; Greece, 2018; Hungary, 2018; Italy, 2018) or in the framework of a previous MRL application (EFSA, 2009, 2011, 2015, 2018). All residue trial samples belonging to the high water and high acid content commodities were stored in compliance with the conditions for which storage stability of residues was demonstrated. Decline of residues during storage of the trial samples is therefore not expected for commodities belonging to these categories. Nonetheless, since no storage stability studies were submitted for high oil content commodities, decline of residues during the storage conditions for the residue trials on walnuts and cotton seeds cannot be excluded. A data gap has been identified (see Section 1.1.5).

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, 2017).

MRL and risk assessment values could not be derived for kohlrabies and cotton seeds and the following data gaps were identified:

- **Kohlrabies:** no trials are available to support the southern outdoor GAP. Therefore, four trials compliant with the southern outdoor GAP are required.
- **Cotton seeds:** two trials are available and show residues below the LOQ. However, in the absence of a metabolism study on a representative crop of the oilseeds group and considering the data gap as regards the storage stability in high oil content commodities (see above), two additional trials on cotton seeds compliant with the southern outdoor GAP are required to eventually conclude on a no residue situation. Furthermore, trials analysing simultaneously for enforcement and risk assessment residue definitions are required.
For all other crops, available residue trials are sufficient to derive (tentative) MRL and risk assessment values, taking note of the following considerations:

- Quinces, medlars and loquats: tentative MRL and risk assessment values can be derived from the northern and southern trials, performed according to a more cGAP. However, four trials compliant with the northern GAP and four compliant with the southern GAP are still required.
- Apricots: tentative MRL and risk assessment values can be derived from trials performed with peaches according to the southern cGAP on apricots. However, a minimum of four trials performed on apricots compliant with the southern GAP of apricots are required.
- Plums: MRL and risk assessment values can be derived from four GAP-compliant and eight overdosed northern trials. As residues in the overdosed trials were within the same range as in the GAP-compliant ones or even below the LOQ, the whole data set is deemed acceptable, and the MRL is not expected to be overestimated. However, four northern and eight southern trials analysing simultaneously for enforcement and risk assessment residue definitions are still desirable.
- Strawberries: MRL and risk assessment values can be derived from the indoor overdosed residue trials scaled down to the GAP target application. Further residue trials are therefore not required.
- Potatoes: The number of residue trials supporting the southern outdoor GAP is not compliant with the data requirements for this crop. However, the reduced number of residue trials is considered acceptable in this case because all results were below the LOQ and a no residues situation is expected. Further residue trials are therefore not required.
- Tomatoes and sweet peppers: as MRL and risk assessment values can be derived from the indoor data and the limited number of residue trials (four) supporting the outdoor GAPs confirms that the outdoor uses are less critical, additional trials compliant with the outdoor GAPs are not required.
- Cucurbits with edible peel: MRL and risk assessment values can be derived from the indoor residue trials on cucumbers, as the limited data set supporting the northern use exhibited residues below the LOQ. MRL and risk assessment values can be derived from the indoor use on courgettes (extrapolated from cucumbers); however, for sake of completeness, four additional trials compliant with the southern GAP on courgettes are still required. Tentative MRL and risk assessment values can be derived for gherkins from the indoor data performed on cucumbers according to a more cGAP. Four trials compliant with the indoor GAP on gherkins are still required.
- Melons: although MRL and risk assessment values can be derived from the indoor use, four trials compliant with the northern GAP and four additional trials compliant with the southern one of melons are still required.
- Watermelons: MRL and risk assessment values can be derived from extrapolation of the indoor use of melons; however, eight trials compliant with the southern GAP of watermelons are still required.
- Pumpkins: only tentative MRL and risk assessment values can be derived from the southern and indoor trials of melons, performed according to a more cGAP. Four trials compliant with the southern GAP and Four compliant with the indoor one of pumpkins are still required.
- Salad plants (except lettuce) and fresh herbs: although MRL and risk assessment values can be derived for these crops, three additional trials compliant with the northern GAP of the group of salad plants (except lettuce) and fresh herbs are required.
- Oranges, mandarins and lemons, table and wine grapes (southern European Union (SEU)), broccoli and cauliflower: although conversion factors (CFs) for risk assessment can be derived for each metabolism group of commodities, eight trials analysing simultaneously for enforcement and risk assessment values are still desirable. Alike, four trials analysing simultaneously for enforcement and risk assessment values are still desirable for head cabbage and beans (without pods) (northern European Union (NEU)).

1.2.2. Magnitude of residues in rotational crops

There were no studies investigating the magnitude of residues in rotational crops available for this review.

Considering the cGAPs reported in this review, the maximum concentration of emamectin expected to reach the soil is 0.011 mg/kg (immediately after application), 0.0093 mg/kg (after 4 days) and
0.0082 mg/kg (after 7 days), assuming a soil mixing depth of 20 cm and soil bulk density of 1.5 g/cm³. This value is based on the critical indoor GAP authorised on lettuce (3 × 19 g a.s./ha at BBCH 89) for which 25% crop interception is expected. Therefore, it is estimated that the confined rotational crop study is overdosed by a factor of 2.4N.

In the light of this, and based on the results of the confined rotational crop study (see Section 1.1.2), significant residue levels of emamectin are not expected in succeeding crops, provided that emamectin benzoate is applied in compliance with the GAPs reported in Appendix A.

1.2.3. Magnitude of residues in processed commodities

The effect of peeling was assessed with data available from the trials conducted with melons (Netherlands, 2008) and citrus fruits (oranges and mandarins) (EFSA, 2011). An overview of all available peeling studies is available in Appendix B.1.2.3. Robust (fully supported by data) and tentative (not fully supported) peeling factors could be derived for melons and citrus fruits, respectively.

Further processing studies are not required as they are not expected to affect the outcome of the risk assessment.

1.2.4. Proposed MRLs

The available data are considered sufficient to derive (tentative) MRL proposals as well as risk assessment values for all commodities under evaluation, except for kohlrabi and cotton seeds, for which no data are available to derive MRL and risk assessment values. Considering the data gaps (see Sections 1.1.4 and 1.1.5) identified for high oil (analytical methods not sufficiently validated and absence of storage stability studies), high acid content commodities (analytical methods not sufficiently validated), MRLs for all commodities belonging to these categories are tentative.

Regarding the risk assessment values, residue trials analysing simultaneously for enforcement and risk assessment residue definitions were available for most of the crops, which allowed EFSA to derive CFs for risk assessment applying the following principles: residue trials in which both parent (emamectin B₁a) and metabolites were below the LOQ were not considered for the calculation of the median CF; when residues were above or at the LOQ for parent and below for all the metabolites (emamectin B₁b, 8,9-Z-MAB₁a, FAB₁a, MFB₁a, AB₁a), a CF of 1 was derived and considered in the calculation of the median CF. In trials where residues were above or at the LOQ for parent and, at least, one metabolite, the experimental values were included in the calculation of the CF.

For those commodities where a CF could not be directly calculated from the supporting residue data, the highest CF derived for each metabolism group was applied for risk assessment, namely 1.1 for fruits and fruiting vegetables (as derived from strawberries), 1.5 for leafy vegetables (as derived from lettuce) and 1.0 for pulses and oilseeds (as derived from beans with pods).

2. Residues in livestock

Emamectin is authorised for use on citrus and pomace fruits, potato, head cabbage, kale and cotton seeds that might be fed to livestock. Livestock dietary burden calculations were therefore performed for different groups of livestock according to OECD guidance (OECD, 2013), which has now also been agreed upon at European level. The input values for all relevant commodities are summarised in Appendix D.1. 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 in principle unnecessary. However, in this particular case, given the high chronic toxicity of emamectin (ADI = 0.0005 mg/kg body weight (bw) per day) and its potential fat solubility (see Section 2.2), it is necessary to assess the nature and magnitude of residues in animal products. It is highlighted that for feed items coming from cotton seeds, insufficient data were available. The animal intake of emamectin residues via these commodities has therefore not been assessed and may have been underestimated, but it is not expected to change the dietary burden calculation.

2.1. Nature of residues and methods of analysis in livestock

A new metabolism study in livestock has been submitted in the framework of this review (Netherlands, 2018). The study has not been peer reviewed. The metabolism of emamectin residues was investigated in lactating goats at dose rate (0.50–0.66 mg/kg bw per day) covering the maximum...
dietary burdens calculated in this review (700-940N). [5-3H]-emamectin and [5-3H]/[25-14C]-emamectin were used in the study. It is noted that this metabolism study in livestock does not investigate the nature of residues of all the components included in the RA RD of plant commodities; however, the highest contributor to the maximum dietary burden in ruminants was found to be kale, for which trials analysing for RA RD are available, and they show that only one photometabolite, FAB1a, was found at the LOQ level (0.001 mg/kg). In view of this, EFSA considers this metabolism study as sufficient to depict the metabolism in ruminants. It should be stressed nonetheless that if new uses on crops that might be fed to livestock are authorised in the future, the suitability of this metabolism study might need to be reconsidered.

Total radioactive residues in milk ranged from 0.012 mg eq/kg to 0.043 mg eq/kg. The levels exhibited a considerable variation between the different days, and thus a plateau was not reached. In tissues, TRRs presented the following order: liver (1.002 mg eq/kg), kidney (0.449 mg eq/kg), fat (0.283 mg eq/kg) and muscle (0.100 mg eq/kg). There was no significant difference in tissue residue levels between [5-3H]-emamectin and [5-3H]/[25-14C]-emamectin treated goats. The major component in milk and tissues was parent emamectin B1a. In milk, it accounted for 44-93% (0.017–0.040 mg eq/kg), while in tissues, it accounted for 58–89% with no major divergences among the different tissues. The lowest residues of emamectin B1a were found in muscle (0.051 mg eq/kg) and the highest in liver (0.984 mg eq/kg). The metabolite AB1a was also systematically present in milk and tissues (<8%), accounting for a maximum of 0.053 mg eq/kg in liver.

The RMS suggested to include the metabolite AB1a in the RA RD. However, considering the predominant presence of parent emamectin B1a in milk and tissues, the low residue levels of metabolite AB1a found in this overdosed study (700-940N) and the maximum dietary burden calculated for the current supported uses (<0.001 mg/kg bw per day), EFSA suggests expressing the residue definition for enforcement and risk assessment in livestock as emamectin B1a and its salts, expressed as emamectin B1a (free base). The suggested residue definitions are restricted to ruminants and swine. If in the future, new uses are authorised leading to a significant increase in the maximum dietary burden, the inclusion of the photometabolite AB1a in the RA RD might be reconsidered.

A single residue method based on LC/LC-MS/MS for parent emamectin B1a was reported during the peer review (Netherlands 2008, 2012). Since residue definitions for livestock were not required at that time, the method was not peer reviewed. Validation results were submitted for emamectin B1a in milk, muscle, liver, kidney and fat with a LOQ of 0.001 mg/kg. However, the method is not considered sufficiently validated as quantitative confirmatory validation data and ILV were missing, what constitutes data gaps. Moreover, validation results for eggs were not summarised and they would be needed if additional uses involving feed items are proposed in the future. According to EURLs, emamectin B1a (determined as free base) can be enforced in milk in routine analysis with a LOQ of 0.01 mg/kg by an analytical method based on liquid chromatography–atomic fluorescence spectrometry (LC–AFS) (EURL, 2018).

2.2. Magnitude of residues in livestock

A feeding study with dairy cows has been submitted under this MRL review and included in the ER prepared by the RMS (Netherlands, 2018). Three groups of lactating cows, each consisting of three animals were dosed for 28 consecutive days with encapsulated emamectin benzoate at levels of 0.03, 0.09 and 0.30 mg/kg in the diet (equivalent to 0.0012, 0.0035 and 0.0115 mg/kg bw per day). Samples of tissues and milk were analysed for emamectin B1a and B1b residues. Samples were stored between sacrifice and analysis for 3–4 months, but the storage stability of residues was not demonstrated for this period in animal matrices (data gap).

The residues do not accumulate in milk, but they reach a plateau level after 7 consecutive days of dosing. Residue levels in cream were generally 3–10 times higher than in whole milk samples. Residue levels in whole milk increased with the dosing levels.

In tissues, residue levels followed the order: liver > kidney > fat > muscle and they increased with the dosing level. Since residue levels in cream were up to 10 times higher than in whole milk, they were higher in fat than in muscle (about twofold higher in the highest feeding level group) and log Kow = 5.0 (23°C, pH 7), EFSA considers the residue in animal commodities as fat soluble. It is noted that this is not in line with the approach of JMPR.

Based on the above studies, MRL and risk assessment values could be derived for all commodities of ruminants. Since extrapolation from ruminants to pigs is acceptable, results of the livestock feeding study on ruminants were relied upon to derive MRL and risk assessment values in pigs. MRL and risk assessment values were derived in compliance with the latest recommendations on this matter (FAO,
2009). It is noted that significant levels of emamectin B₁₉ are only expected in liver and kidney, while for the rest, MRLs are proposed at the LOQ. Considering the data gaps identified for the analytical methods and storage stability for livestock commodities, these MRLs are considered tentative.

### 3. Consumer risk assessment

In the framework of this review, only the uses of emamectin reported by the RMS in Appendix A were considered; however, the use of emamectin was previously also assessed by the JMPR (FAO, 2011, 2014). 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. 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 PRIMo (EFSA, 2007). Input values for the exposure calculations were derived in compliance with the decision tree reported in Appendix E. Hence, for those commodities where a (tentative) MRL could be derived by EFSA in the framework of this review, input values were derived according to the internationally agreed methodologies (FAO, 2009). For kohlrabies and cotton seed where data were insufficient to derive an MRL (see Section 1, EFSA considered the existing EU MRL multiplied by the relevant CF as an indicative calculation. For kohlrabies, the CF of 1.5, as derived for leafy vegetables (see Section 1.2.4), was applied, while for cotton seed, the CF of 1 (derived for pulses and oilseeds) was applied. For citrus fruits and cucurbits with inedible peel, EFSA also considered the peeling factors derived in Section 1.2.3. All input values included in the exposure calculations are summarised in Appendix D.2.

The exposure values calculated were compared with the toxicological reference values of emamectin, derived by EFSA (2012). The highest chronic exposure was calculated for Spanish adult, representing 28% of the ADI. With regard to the acute exposure, however, an exceedance of the acute reference dose (ARfD) was identified for lettuces and escaroles representing 218% and 102% of the ARfD, respectively. A second exposure calculation (scenario EU2) was therefore performed, considering fall-back GAPs for these crops. According to the results of this second calculation, the highest chronic exposure declined to 17% of the ADI (DE child), while the highest acute exposure was calculated for lettuce, representing 40% of the ARfD.

Based on these calculations, a risk to consumers was identified for the most cGAPs of emamectin on lettuces (indoor) and escaroles (broad-leaved endives) (SEU outdoor). However, fall-back GAPs-SEU outdoor and -NEU outdoor, were identified for lettuces and escaroles, respectively. For this fall-back GAPs, the risk assessment did not indicate risk to consumers. For the remaining commodities, although some major uncertainties remain due to the data gaps identified in the previous sections, the indicative exposure calculation did not indicate a risk to consumers.

EFSA emphasises that the above assessment does not consider the possible impact of plant and livestock metabolism on the isomer ratio of emamectin and further investigation on this matter would in principle be required. Since guidance on the consideration of isomer ratios in the consumer risk assessment is not yet available, EFSA recommends that this issue is reconsidered when such guidance is available.

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

To include the CXLs in the calculations of the consumer exposure, CXLs were compared with the EU MRL proposals in compliance with Appendix E and all data relevant to the consumer exposure assessment have been collected from JMPR evaluations. As CXLs are currently expressed as emamectin B₁₉ benzoate, they were expressed as emamectin B₁₉ free base applying the molecular factor of 0.88. Therefore, comparisons of CXLs with the MRLs derived in the present review are based on the converted values. Furthermore, the CFs derived by EFSA were applied to the risk assessment values derived by JMPR. For those commodities having a CXL higher than the EU MRL proposal, risk assessment values applied in the second EU scenario were replaced by the risk assessment values derived by JMPR. For each commodity for which the CXL was assessed, EFSA applied the CFs derived for the corresponding metabolism group (see Section 1.2.4). Since the CXLs reported for tree nuts...
correspond to the LOQ, a CF of 1 was applied to the risk assessment values derived from JMPR for all tree nuts commodities. The highest residue (HR) and supervised trials median residue (STMR) values for muscle and fat derived by JMPR were used to calculate the input values for meat to be included in the risk assessment, considering that emamectin is fat soluble. The data gaps identified in the EU assessment regarding the analytical methods for enforcement for high acid, high oil content commodities and dry commodities, as well as for livestock commodities also apply to CXLs input values; therefore, these CXLs are deemed tentative. An overview of the input values used for this exposure calculation is also provided in Appendix D.3.

Chronic and acute exposure calculations were also performed using revision 2 of the EFSA PRIMo and the exposure values calculated were compared with the toxicological reference values derived for emamectin. The highest chronic exposure was calculated for German children, representing 19% of the ADI. With regard to the acute exposure, however, an exceedance of the ARfD was identified for lettuce, representing 117% of the ARfD. A second exposure calculation was therefore performed, excluding the CXLs for this crop. According to the results of this second calculation, the highest chronic exposure remained at 19% of the ADI for German children, while the highest acute exposure was then calculated for Chinese cabbage, representing 54% of the ARfD.

Based on these calculations, a potential risk to consumers was identified for the CXLs of emamectin on lettuces and no further refinements of the risk assessment were possible. For the remaining CXLs, although 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 emamectin in plant was investigated in primary and rotational crops. According to the results of the metabolism studies, the residue definition for enforcement can be proposed as emamectin B1a and its salts, expressed as emamectin B1a (free base). This residue definition is applicable to all plant and processed commodities. For the risk assessment purpose, the residue definition is proposed as sum of emamectin B1a, emamectin B1b, 8,9-Z-MAB1a, plus 3 times AB1a, plus 3 times MF81a and 3 times FAB1a, expressed as emamectin B1a (free base). This residue definition applies to all plant commodities (raw and processed). Although not sufficiently validated for all matrices, analytical methods are available for the enforcement of the proposed residue definition in the four main plant matrices. According to the EURLs, the LOQ of 0.002 mg/kg in high water and high acid content commodities and 0.005 mg/kg in high oil content and dry commodities are achievable in routine analyses (EFSA, 2019b).

Available residue trials data were considered sufficient to derive (tentative) MRL proposals as well as risk assessment values for all commodities under evaluation, except for kohlrabi and cotton seeds, for which no data were available. Robust and tentative peeling factors could be derived for melons and citrus fruits, respectively.

Emamectin is authorised for use on crops that might be fed to livestock. Livestock dietary burden calculations were therefore performed for different groups of livestock according to OECD guidance. Since the calculated dietary burdens for all groups of livestock were found to be below the trigger value of 0.1 mg/kg DM, further investigation of residues as well as the setting of MRLs in commodities of animal origin was in principle unnecessary. However, in this particular case, given the high chronic toxicity of emamectin and its fat solubility, EFSA assessed the nature and magnitude of residues in ruminants and swine.

The metabolism of emamectin residues in livestock was investigated in lactating goats at dose rate covering the maximum dietary burdens calculated in this review (700–940N). According to the results of these studies, the residue definition for enforcement and risk assessment in ruminants and swine was proposed as emamectin B1a and its salts, expressed as emamectin B1a (free base). A sufficiently validated analytical method for the enforcement of the proposed residue definition in livestock matrices is not available and it is required (data gap). According to the EURLs, the LOQ of 0.01 mg/kg is achievable by using a single residue method in routine analyses.

A livestock feeding study on dairy cows was used to derive MRL and risk assessment values in milk and tissues of ruminants. Since extrapolation from ruminants to pigs is acceptable, results of the livestock feeding study on ruminants were relied upon to derive the MRL and risk assessment values in pigs. In view of the data gaps identified for the analytical methods and storage stability of residues in livestock, all MRLs are tentative.
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 those commodities where data were insufficient to derive an MRL, EFSA considered the existing EU MRL, multiplied by the corresponding conversion factor, as an indicative calculation. The highest chronic exposure was calculated for the Spanish adult, representing 28% of the ADI. However, an exceedance of the ARfD was identified for lettuces and escaroles (broad-leaved endives) representing 218% and 102% of the ARfD, respectively. Considering fall-back GAPs for these crops, the highest chronic exposure represented 17% of the ADI (DE child) and the highest acute exposure amounted to 40% of the ARfD (lettuce).

Apart from the MRLs evaluated in the framework of this review, internationally recommended CXLs have also been established for emamectin. Additional calculations of the consumer exposure, considering these CXLs, were therefore carried out and exceedance of the ARfD was identified for the existing CXL in lettuce (117%). Excluding this CXL from the calculation, the highest chronic exposure represented 19% of the ADI (DE child) and the highest acute exposure amounted to 54% of the ARfD (Chinese cabbage).

Recommendations

MRL recommendations were derived in compliance with the decision tree reported in Appendix E of the reasoned opinion (see Table 2). 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 Table 2 footnotes for details). In particular, some tentative MRLs and existing EU MRLs need to be confirmed by the following data:

- ILV for high acid or high oil content commodities.
- Storage stability studies for high oil content commodities.
- Confirmatory method (or to monitor a second transition in Multiple Reaction Monitoring mode (MRM)) and ILV for milk, muscle, liver, kidney and fat.
- Storage stability studies of residues in all bovine tissues and milk.
- Four residue trials supporting the authorised southern use on kohlrabies.
- Two additional residue trials supporting the authorised southern use on cotton seeds.
- A minimum of four residue trials performed on apricots supporting the authorised southern use.
- One additional trial compliant with the northern outdoor GAP supporting the fall-back MRL for escaroles.

It is highlighted, however, that some of the MRLs derived result from a CXL of from a GAP in one climatic zone only, whereas other GAPs reported by some Member States were not fully supported by data. EFSA therefore identified the following data gap which is not expected to impact on the validity of the MRLs derived but which might have an impact on national authorisations:

- Additional residue trials supporting the GAPs on quinces, medlars and loquats (NEU and SEU), courgettes (SEU), gherkins (indoor), melons (NEU and SEU), watermelons (SEU), pumpkins (SEU and indoor), salad plants and fresh herbs (NEU).

If the above-reported data gap is not addressed in the future, Member States are recommended to withdraw or modify the relevant authorisations at national level.

Furthermore, the cGAPs reported for lettuces (indoor) and escaroles (broad-leaved endives) (SEU outdoor) were found to lead to an exceedance of the ARfD. As a result, the MRLs derived for those crops are based on fall-back GAPs (SEU outdoor for lettuces and NEU outdoor for escaroles). Member States are therefore recommended to reconsider or withdraw their national authorisations on lettuces and escaroles (broad-leaved endives) to ensure that the fall-back MRLs derived for emamectin in these crops are not exceeded.

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

- Residue trials analysing simultaneously for enforcement and risk assessment values for oranges, mandarins and lemons, plums, table and wine grapes (southern use), broccoli, cauliflower and head cabbage, as well as beans (without pods) (northern use).
### Table 2: Summary table

| Code number | Commodity | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review | Comment |
|-------------|-----------|-------------------------|----------------------|-----------------------|---------|
|             |           |                         |                      | MRL (mg/kg)           |         |
|             |           |                         |                      | Comment              |         |
| **Enforcement residue definition (existing):** Emamectin benzoate B1a, expressed as emamectin | | | | | |
| **Enforcement residue definition (proposed):** Emamectin B1a and its salts, expressed as emamectin B1a (free base) (F) | | | | | |
| 110020      | Oranges   | 0.01*                   | –                    | 0.003                 | Further consideration needed<sup>(a)</sup> |
| 110030      | Lemons    | 0.01*                   | –                    | 0.003                 | Further consideration needed<sup>(a)</sup> |
| 110050      | Mandarin  s | 0.01*               | –                    | 0.003                 | Further consideration needed<sup>(a)</sup> |
| 120010      | Almonds   | 0.01*                   | 0.001*               | 0.001*                | Further consideration needed<sup>(a)</sup> |
| 120020      | Brazil nuts | 0.01*                | 0.001*               | 0.001*                | Further consideration needed<sup>(a)</sup> |
| 120030      | Cashew nuts | 0.01*                | 0.001*               | 0.001*                | Further consideration needed<sup>(a)</sup> |
| 120040      | Chestnuts | 0.01*                   | 0.001*               | 0.001*                | Further consideration needed<sup>(a)</sup> |
| 120050      | Coconuts  | 0.01*                   | 0.001*               | 0.001*                | Further consideration needed<sup>(a)</sup> |
| 120060      | Hazelnuts | 0.01*                   | 0.001*               | 0.001*                | Further consideration needed<sup>(a)</sup> |
| 120070      | Macadamia | 0.01*                   | 0.001*               | 0.001*                | Further consideration needed<sup>(a)</sup> |
| 120080      | Pecans    | 0.01*                   | 0.001*               | 0.001*                | Further consideration needed<sup>(a)</sup> |
| 120090      | Pine nuts | 0.01*                   | 0.001*               | 0.001*                | Further consideration needed<sup>(a)</sup> |
| 120100      | Pistachios | 0.01*                 | 0.001*               | 0.001*                | Further consideration needed<sup>(a)</sup> |
| 120110      | Walnuts   | 0.01*                   | 0.001*               | 0.001*                | Further consideration needed<sup>(a)</sup> |
| 130010      | Apples    | 0.02                    | 0.02                 | 0.02                  | Recommended<sup>(d)</sup> |
| 130020      | Pears     | 0.02                    | 0.02                 | 0.02                  | Recommended<sup>(d)</sup> |
| 130030      | Quinces   | 0.02                    | 0.02                 | 0.02                  | Recommended<sup>(e)</sup> |
| 130040      | Medlars   | 0.02                    | 0.02                 | 0.02                  | Recommended<sup>(e)</sup> |
| 130050      | Loquats/Japanese medlars | 0.02 | 0.02                 | 0.02                  | Recommended<sup>(e)</sup> |
| 140010      | Apricots  | 0.02                    | –                    | 0.006                 | Further consideration needed<sup>(a)</sup> |
| 140030      | Peaches   | 0.03                    | 0.03                 | 0.03                  | Recommended<sup>(d)</sup> |
| 140040      | Plums     | 0.02                    | –                    | 0.015                 | Recommended<sup>(f)</sup> |
| 151010      | Table grapes | 0.05                 | 0.03                 | 0.04                  | Further consideration needed<sup>(c)</sup> |
| 151020      | Wine grapes | 0.05                 | 0.03                 | 0.04                  | Further consideration needed<sup>(c)</sup> |
| 152000      | Strawberries | 0.05                 | –                    | 0.05                  | Further consideration needed<sup>(a)</sup> |
| 211000      | Potatoes  | 0.01*                   | –                    | 0.001*                | Recommended<sup>(f)</sup> |
| 231010      | Tomatoes  | 0.02                    | 0.02                 | 0.02                  | Recommended<sup>(d)</sup> |
| 231020      | Sweet peppers/bell peppers | 0.02 | 0.02                 | 0.02                  | Recommended<sup>(g)</sup> |
| 231030      | Aubergines/eggplants | 0.02 | 0.02                 | 0.02                  | Recommended<sup>(d)</sup> |
| 231040      | Okra, lady’s fingers | 0.02 | 0.02                 | 0.02                  | Recommended<sup>(h)</sup> |
| 232010      | Cucumbers | 0.01*                   | 0.007                | 0.007                 | Recommended<sup>(d)</sup> |
| 232020      | Gherkins  | 0.01*                   | 0.007                | 0.007                 | Recommended<sup>(d)</sup> |
| 232030      | Courgettes | 0.01*                 | 0.007                | 0.007                 | Recommended<sup>(d)</sup> |
| 233010      | Melons    | 0.01*                   | 0.007                | 0.008                 | Recommended<sup>(g)</sup> |
| 233020      | Pumpkins  | 0.01*                   | 0.007                | 0.008                 | Further consideration needed<sup>(c)</sup> |
| 233030      | Watermelons | 0.01*                | 0.007                | 0.008                 | Recommended<sup>(g)</sup> |
| 241010      | Broccoli  | 0.01*                   | –                    | 0.003                 | Recommended<sup>(f)</sup> |
| 241020      | Cauliflowers | 0.01*                | –                    | 0.003                 | Recommended<sup>(f)</sup> |
| 242010      | Brussels sprouts | 0.01*               | –                    | 0.004                 | Recommended<sup>(f)</sup> |
| 242020      | Head cabbages | 0.01*                | –                    | 0.004                 | Recommended<sup>(f)</sup> |
| 243010      | Chinese cabbages/pe-tsai | 0.03       | 0.2                 | 0.2                   | Recommended<sup>(d)</sup> |
| Code number | Commodity                                      | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review | Comment  |
|-------------|------------------------------------------------|-------------------------|---------------------|-----------------------|----------|
| 243020      | Kales                                          | 0.03                    | –                   | 0.03                  | Recommended (f) |
| 244000      | Kohlrabies                                     | 0.01*                   | –                   | 0.01                  | Further consideration needed (i) |
| 251010      | Lamb’s lettuces/com salads                     | 1                       | –                   | 0.6                   | Recommended (f) |
| 251020      | Lettuces                                       | 1                       | 0.7                 | 0.2                   | Recommended (f) |
| 251030      | Scarole (broad-leaf endive)                    | 0.2                     | –                   | 0.15                  | Further consideration needed (a) |
| 251040      | Cresses and other sprouts and shoots           | 1                       | –                   | 0.6                   | Recommended (f) |
| 251050      | Land cresses                                    | 1                       | –                   | 0.6                   | Recommended (f) |
| 251060      | Roman rocket/rucola                            | 1                       | –                   | 0.6                   | Recommended (f) |
| 251070      | Red mustards                                    | 1                       | –                   | 0.6                   | Recommended (f) |
| 251080      | Baby leaf crops (including brassica species)   | 1                       | –                   | 0.6                   | Recommended (f) |
| 254000      | Watercresses                                    | 0.01*                   | –                   | 0.6                   | Recommended (f) |
| 256010      | Chervil                                         | 1                       | –                   | 0.2                   | Recommended (f) |
| 256020      | Chives                                          | 1                       | –                   | 0.2                   | Recommended (f) |
| 256030      | Celery leaves                                   | 1                       | –                   | 0.2                   | Recommended (f) |
| 256040      | Parsley                                         | 1                       | –                   | 0.2                   | Recommended (f) |
| 256050      | Sage                                            | 1                       | –                   | 0.6                   | Recommended (f) |
| 256060      | Rosemary                                        | 1                       | –                   | 0.2                   | Recommended (f) |
| 256070      | Thyme                                           | 1                       | –                   | 0.2                   | Recommended (f) |
| 256080      | Basil and edible flowers                        | 1                       | –                   | 0.2                   | Recommended (f) |
| 256090      | Laurel/bay leave                                | 1                       | –                   | 0.2                   | Recommended (f) |
| 256100      | Tarragon                                        | 1                       | –                   | 0.2                   | Recommended (f) |
| 260010      | Beans (with pods)                               | 0.03                    | 0.015               | 0.03                  | Recommended (g) |
| 260020      | Beans (without pods)                            | 0.01*                   | 0.015               | 0.015                 | Recommended (g) |
| 260030      | Peas (with pods)                                | 0.03                    | –                   | 0.03                  | Recommended (f) |
| 260040      | Peas (without pods)                             | 0.01*                   | –                   | 0.001*                | Recommended (f) |
| 270050      | Globe artichokes                                | 0.1                     | –                   | 0.09                  | Recommended (f) |
| 401060      | Rape seed                                       | 0.01*                   | 0.005*              | 0.005*                | Further consideration needed (k) |
| 401090      | Cotton seeds                                    | 0.01*                   | 0.002*              | 0.01                  | Further consideration needed (i) |
| 1011010     | Swine muscle                                    | 0.01*                   | 0.004               | 0.004                 | Further consideration needed (m) |
| 1011020     | Swine fat tissue                                | 0.02                    | 0.02                | 0.02                  | Further consideration needed (m) |
| 1011030     | Swine liver                                     | 0.08                    | 0.08                | 0.08                  | Further consideration needed (m) |
| 1011040     | Swine kidney                                    | 0.08                    | 0.08                | 0.08                  | Further consideration needed (m) |
| 1012010     | Bovine muscle                                   | 0.01*                   | 0.004               | 0.004                 | Further consideration needed (m) |
| 1012020     | Bovine fat tissue                               | 0.02                    | 0.02                | 0.02                  | Further consideration needed (m) |
| 1012030     | Bovine liver                                    | 0.08                    | 0.08                | 0.08                  | Further consideration needed (m) |
| 1012040     | Bovine kidney                                   | 0.08                    | 0.08                | 0.08                  | Further consideration needed (m) |
| 1013010     | Sheep muscle                                    | 0.01*                   | 0.004               | 0.004                 | Further consideration needed (m) |
| 1013020     | Sheep fat tissue                                | 0.02                    | 0.02                | 0.02                  | Further consideration needed (m) |
| 1013030     | Sheep liver                                     | 0.08                    | 0.08                | 0.08                  | Further consideration needed (m) |
| 1013040     | Sheep kidney                                    | 0.08                    | 0.08                | 0.08                  | Further consideration needed (m) |
| 1014010     | Goat muscle                                     | 0.01*                   | 0.004               | 0.004                 | Further consideration needed (m) |
### Table: Outcome of the review

| Code number | Commodity               | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | MRL (mg/kg) | Comment                  |
|-------------|-------------------------|-------------------------|----------------------|-------------|--------------------------|
| 1014020     | Goat fat tissue         | 0.02                    | 0.02                 | 0.02        | Further consideration needed (m) |
| 1014030     | Goat liver              | 0.08                    | 0.08                 | 0.08        | Further consideration needed (m) |
| 1014040     | Goat kidney             | 0.08                    | 0.08                 | 0.08        | Further consideration needed (m) |
| 1015010     | Equine muscle           | 0.01*                   | 0.004                | 0.004       | Further consideration needed (m) |
| 1015020     | Equine fat tissue       | 0.02                    | 0.02                 | 0.02        | Further consideration needed (m) |
| 1015030     | Equine liver            | 0.08                    | 0.08                 | 0.08        | Further consideration needed (m) |
| 1015040     | Equine kidney           | 0.08                    | 0.08                 | 0.08        | Further consideration needed (m) |
| 1020010     | Cattle milk             | 0.01*                   | 0.002                | 0.002       | Further consideration needed (m) |
| 1020020     | Sheep milk              | 0.01*                   | 0.002                | 0.002       | Further consideration needed (m) |
| 1020030     | Goat milk               | 0.01*                   | 0.002                | 0.002       | Further consideration needed (m) |
| 1020040     | Horse milk              | 0.01*                   | 0.002                | 0.002       | Further consideration needed (m) |
|             | Other commodities       | See Reg. 2018/1514      | –                    | –           | Further consideration needed (m) |
|             | of plant and/or         |                         |                      |             |                          |
|             | animal origin           |                         |                      |             |                          |

**MRL**: maximum residue level; **CXL**: codex maximum residue limit.

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

(F): The residue definition is fat soluble.

(a): 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 existing residue definition); no CXL is available (combination F-I in Appendix E).

(b): 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 existing residue definition); there are no relevant authorisations or import tolerances reported at EU level (combination A-V in Appendix E).

(c): 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 existing residue definition); existing CXL is covered by the tentative MRL (combination F-III in Appendix E).

(d): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level, which is also fully supported by data, leads to a lower tentative MRL (combination A-V in Appendix E).

(e): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level, which is not fully supported by data, leads to a lower tentative MRL (combination F-V in Appendix E).

(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 H-I in Appendix E).

(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; existing CXL is covered by the recommended MRL (combination H-III in Appendix E).

(h): 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 E).

(i): GAP evaluated at EU level is not supported by data but no risk to consumers was identified for the existing EU MRL (also assuming the existing residue definition); no CXL is available (combination D-I in Appendix E).

(j): 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 H-VI in Appendix E).

(k): 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 existing residue definition); there are no relevant authorisations or import tolerances reported at EU level (combination A-V in Appendix E).

(l): GAP evaluated at EU level is not supported by data but no risk to consumers was identified for the existing EU MRL (also assuming the existing residue definition); existing CXL is covered by the existing EU MRL (combination D-III in Appendix E).

(m): 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 existing residue definition); GAP evaluated at EU level, which is also not fully supported by data, would lead to a lower tentative MRL (combination F-V in Appendix E).

(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 E).

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Abbreviations

a.i. active ingredient
a.s. active substance
ADI acceptable daily intake
AR applied radioactivity
ARfD acute reference dose
BBCH growth stages of mono- and dicotyledonous plants
bw body weight
CAC Codex Alimentarius Commission
CCPR Codex Committee on Pesticide Residues
CF conversion factor for enforcement residue definition to risk assessment residue definition
cGAP critical GAP
cXL codex maximum residue limit
DAR draft assessment report
DAT days after treatment
DB dietary burden
DM dry matter
DT$_{90}$ period required for 90% dissipation (define method of estimation)
eq residue expressed as a.s. equivalent
EUROs European Union Reference Laboratories for Pesticide Residues (former CRLs)
FAO Food and Agriculture Organization of the United Nations
GAP Good Agricultural Practice
HR highest residue
IEI international estimated daily intake
IESTI international estimated short-term intake
ILV independent laboratory validation
InChIKey International Chemical Identifier Key
ISO International Organisation for Standardization
IUPAC International Union of Pure and Applied Chemistry
JMPR Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
K$_{ow}$ $n$-octanol/water partition coefficient
LC liquid chromatography
LC-AFS liquid chromatography–atomic fluorescence spectrometry
LOQ limit of quantification
LWA Leaf Wall Area
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Mo monitoring
MRL maximum residue level
MRM Multiple Reaction Monitoring mode
MS/MS tandem mass spectrometry detector
MW molecular weight
NEDI national estimated daily intake
NESTI national estimated short-term intake
NEU northern European Union
NTMDI national theoretical maximum daily intake.
OECD Organisation for Economic Co-operation and Development
PBI plant-back interval
PF processing factor
PHI preharvest interval
PRIMo (EFSA) Pesticide Residues Intake Model
PROFile (EFSA) Pesticide Residues Overview File
QuEChERS Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
RA risk assessment
RAC raw agricultural commodity
RD residue definition
RMS rapporteur Member State
SANCO Directorate-General for Health and Consumers
SEU southern European Union
SMILES simplified molecular-input line-entry system
SG water-soluble granule
STMR supervised trials median residue
TAR total applied radioactivity
TMDI theoretical maximum daily intake
TRR total radioactive residue
WG water-dispersible granule
WHO World Health Organization
### Appendix A – Summary of authorised uses considered for the review of MRLs

#### A.1. Authorised outdoor uses in northern EU

| Crop and/or situation | MS or country | F G or I(1) | Pests or Group of pests controlled | Preparation | Method kind | Range of growth stages & season(2) | Number min–max | Interval between application (min) | a.s./hl min–max | Water L/ha min–max | Rate and unit | PHI (days) | Remarks |
|-----------------------|---------------|-------------|------------------------------------|-------------|-------------|-----------------------------------|----------------|-----------------------------------|----------------|-------------------|--------------|-----------|---------|
| **Apples** BE F       | F Codling moth | SG 1% (w/w) | Foliar treatment – general (see also comment field) | 1–3         | 7           | 32 g a.i./ha                        | 3              | After flowering except from mid-May to end-June. Max 3 applic./12 months. 2,85 kg F/ha soil (std orchard) or 1,9 kg/ha soil × 1,7 ha LWA/ha LWA |
| **Pears** BE F        | F Codling moth | SG 1% (w/w) | Foliar treatment – general (see also comment field) | 1–3         | 14          | 32 g a.i./ha                        | 3              | After flowering except from mid-May to end-June. Max 3 applic./12 months. 2,85 kg F/ha soil (std orchard) or 1,9 kg/ha soil × 1,7 ha LWA/ha LWA |
| **Quinces** FR F      | F Cydia pomonella, Cydia molesta, Eulia, Capua reticulana, Pandemis heparana, Podana | SG 9.5 g/kg | Foliar treatment – spraying | 70–89       | 3           | 19 g a.i./ha                        | 3              | After flowering except from mid-May to end-June. Max 3 applic./12 months. 2,85 kg F/ha soil (std orchard) or 1,9 kg/ha soil × 1,7 ha LWA/ha LWA |
| Crop and/or situation | MS or country | F, G or T | Type | Conc. a.s. | Method kind | Range of growth stages & season | Number min-max | Interval between application (min) | Application rate per treatment a.s./hl | PHI (days) | Remarks |
|-----------------------|--------------|-----------|------|-----------|------------|--------------------------------|----------------|-------------------------------|----------------------------------|-----------|---------|
| Medlars               | FR           | F         | SG   | 9.5 g/kg  | Foliar treatment – spraying | 70–89            | 3                            | 7                  | –                               | 19 g a.i./ha | 3       |
| Loquats               | FR           | F         | SG   | 9.5 g/kg  | Foliar treatment – spraying | 70–89            | 3                            | 7                  | –                               | 19 g a.i./ha | 3       |
| Plums                 | AT           | F         | WG   | 9.5 g/kg  | Foliar treatment – general (see also comment field) | 71–89            | 3                            | –                  | –                               | 23.75 g a.i./ha | 7       |
| Table grapes          | HU           | F         | SG   | 9.5 g/kg  | Foliar treatment – spraying | 81               | 3                            | 10                 | –                               | 14.25 g a.i./ha | 7       |
| Wine grapes           | HU           | F         | SG   | 9.5 g/kg  | Foliar treatment – spraying | 81               | 3                            | 10                 | –                               | 14.25 g a.i./ha | 7       |
| Tomatoes              | HU           | F         | SG   | 9.5 g/kg  | Foliar treatment – spraying | 89               | 3                            | 7                  | –                               | 19 g a.i./ha | 3       |
| Crop and/or situation | MS or country | F G I (a) | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) (d) | Remarks |
|-----------------------|---------------|-----------|-------------------------------------|-------------|-------------|-------------------------------|----------------|---------|
| Sweet peppers         | HU            | F         | Helicoverpa armigera                | SG 9.5 g/kg | Foliar treatment – spraying | 89 3 7           | 19 g a.i./ha | 3       |
| Cucumbers             | HU            | F         | Helicoverpa armigera                | SG 9.5 g/kg | Foliar treatment – spraying | 89 3 7           | 19 g a.i./ha | 3       |
| Courgettes            | HU            | F         | Helicoverpa armigera                | SG 9.5 g/kg | Foliar treatment – spraying | 89 3 7           | 19 g a.i./ha | 3       |
| Melons                | HU            | F         | Helicoverpa armigera                | SG 9.5 g/kg | Foliar treatment – spraying | 89 3 7           | 19 g a.i./ha | 3       |
| Pumpkins              | HU            | F         | Helicoverpa armigera                | SG 9.5 g/kg | Foliar treatment – spraying | 89 3 7           | 19 g a.i./ha | 3       |
| Watermelons           | HU            | F         | Helicoverpa armigera                | SG 9.5 g/kg | Foliar treatment – spraying | 89 3 7           | 19 g a.i./ha | 3       |
| Chinese cabbages      | BE, DE, HU, NL, PL, SI | F   | Pieris spp., Plutella spp., Plusia spp., Heliothis spp. | SG 9.5 g/kg | Foliar treatment – spraying | 39–49 3 7 | 15 g a.i./ha | 3       |
| Kales                 | BE, DE, HU, NL, PL, SI | F   | Pieris spp., Plutella spp., Plusia spp., Heliothis spp. | SG 9.5 g/kg | Foliar treatment – spraying | 39–49 3 7 | 15 g a.i./ha | 3       |
| Lamb's lettuces       | BE, FR        | F         | Leaf noctuid caterpillars           | 0.95% (w/w) | Foliar treatment – spraying | 1–3 7            | 14.25 g a.i./ha | 3       |
| Crop and/or situation | MS or country | F or G | Pests or Group of pests controlled | Preparation Type(b) | Conc. conc. a.s. | Application Method kind | Range of growth stages & season(c) | Number min–max | Interval between application (min) | a.s./hL min-max | Water L/ha min-max | Rate and unit | PHI (days) (d) | Remarks |
|-----------------------|---------------|--------|----------------------------------|---------------------|-----------------|------------------------|-------------------------------|----------------|-------------------------------|----------------|----------------|---------------|----------------|---------|
| Lettuces              | HU            | F      | *Helicoverpa armigera*           | SG                  | 9.5 g/kg        | Foliar treatment – spraying | 89                       | 3              | 7                             | –              | –              | 19 g a.i./ha | 3              |         |
| Escaroles             | FR            | F      | Lepidoptera                      | SG                  | 9.5 g/kg        | Foliar treatment – spraying | 16–49                    | 3              | 7                             | –              | –              | 14.25 g a.i./ha | 3              |         |
| Cresses               | BE, FR        | F      | Leaf noctuid caterpillars        | SG                  | 0.95% (w/w)     | Foliar treatment – spraying | 1–3                      | 7              | –                             | –              | –              | 14.25 g a.i./ha | 3              |         |
| Land cresses          | FR            | F      | Lepidoptera                      | SG                  | 9.5 g/kg        | Foliar treatment – spraying | 16–49                    | 3              | 7                             | –              | –              | 14.25 g a.i./ha | 3              |         |
| Roman rocket          | BE, FR        | F      | Leaf noctuid caterpillars        | SG                  | 0.95% (w/w)     | Foliar treatment – spraying | 1–3                      | 7              | –                             | –              | –              | 14.25 g a.i./ha | 3              |         |
| Red mustards          | FR            | F      | Lepidoptera                      | SG                  | 9.5 g/kg        | Foliar treatment – spraying | 16–49                    | 3              | 7                             | –              | –              | 14.25 g a.i./ha | 3              |         |
| Baby leaf crops       | BE, FR        | F      | Leaf noctuid caterpillars        | SG                  | 0.95% (w/w)     | Foliar treatment – spraying | 1–3                      | 7              | –                             | –              | –              | 14.25 g a.i./ha | 3              |         |
| Chervil               | BE, FR        | F      | Leaf noctuid caterpillars        | SG                  | 0.95% (w/w)     | Foliar treatment – spraying | 1–3                      | 7              | –                             | –              | –              | 14.25 g a.i./ha | 3              |         |
| Chives                | BE, FR        | F      | Leaf noctuid caterpillars        | SG                  | 0.95% (w/w)     | Foliar treatment – spraying | 1–3                      | 7              | –                             | –              | –              | 14.25 g a.i./ha | 3              |         |
| Celery leaves         | BE, FR        | F      | Leaf noctuid caterpillars        | SG                  | 0.95% (w/w)     | Foliar treatment – spraying | 1–3                      | 7              | –                             | –              | –              | 14.25 g a.i./ha | 3              |         |
| Crop and/or situation | MS or country | F G or t | Pests or Group of pests controlled | Preparation | Type(b) | Conc. a.s. | Method kind | Application | Range of growth stages & season(c) | Number min–max | Interval between application (min) | Application rate per treatment | PHI (days) (d) | Remarks |
|-----------------------|--------------|----------|-----------------------------------|-------------|---------|----------|------------|------------|----------------------------------|----------------|-----------------------------|-------------------------------|----------------|--------|
| Parsley BE, FR F      |              |          | Leaf noctuid caterpillars         | SG          | 0.95% (w/w) | Foliar treatment – spraying | 1–3        | 7          | –                               | –              | –                          | 14.25 g a.i./ha               | 3              |        |
| Sage BE, FR F         |              |          | Leaf noctuid caterpillars         | SG          | 0.95% (w/w) | Foliar treatment – spraying | 1–3        | 7          | –                               | –              | –                          | 14.25 g a.i./ha               | 3              |        |
| Rosemary BE, FR F     |              |          | Leaf noctuid caterpillars         | SG          | 0.95% (w/w) | Foliar treatment – spraying | 1–3        | 7          | –                               | –              | –                          | 14.25 g a.i./ha               | 3              |        |
| Thyme BE, FR F        |              |          | Leaf noctuid caterpillars         | SG          | 0.95% (w/w) | Foliar treatment – spraying | 1–3        | 7          | –                               | –              | –                          | 14.25 g a.i./ha               | 3              |        |
| Basil BE, FR F        |              |          | Leaf noctuid caterpillars         | SG          | 0.95% (w/w) | Foliar treatment – spraying | 1–3        | 7          | –                               | –              | –                          | 14.25 g a.i./ha               | 3              |        |
| Laurel BE, FR F       |              |          | Leaf noctuid caterpillars         | SG          | 0.95% (w/w) | Foliar treatment – spraying | 1–3        | 7          | –                               | –              | –                          | 14.25 g a.i./ha               | 3              |        |
| Tarragon BE, FR F     |              |          | Leaf noctuid caterpillars         | SG          | 0.95% (w/w) | Foliar treatment – spraying | 1–3        | 7          | –                               | –              | –                          | 14.25 g a.i./ha               | 3              |        |
| Beans (with pods) HU  |              | F        | Helicoverpa armigera              | SG          | 9.5 g/kg   | Foliar treatment – spraying | 79         | 3          | 7                               | –              | –                          | 19 g a.i./ha                 | 3              |        |
| Beans (without pods)  | FR           | F        | Lepidoptera                       | SG          | 9.5 g/kg   | Foliar treatment – spraying | 16–79      | 3          | 7                               | –              | –                          | 14.25 g a.i./ha               | 3              |        |
| Peas (with pods) BE, HU, NL, PL, SI |  | F | Heliolthys spp., Ostrinia nubilalis | SG | 9.5 g/kg | Foliar treatment – spraying | 71–89      | 3          | 7                               | –              | –                          | 20 g a.i./ha                 | 3              |        |
### A.2. Authorised outdoor uses in southern EU

| Crop and/or situation | MS or country | F G or T(a) | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) (d) | Remarks |
|-----------------------|---------------|-------------|-----------------------------------|-------------|-------------|--------------------------------|----------------|---------|
|                       |               |             |                                   |             |             |                                |                |         |
| Globe artichokes      | FR            | F           | Lepidoptera                       | SG          | 9.5 g/kg    | Foliar treatment – spraying    | 16–59          | 3       | 7       | –      | –      | 14.25 g a.i./ha | 3      |

### A.2. Authorised outdoor uses in southern EU

| Crop and/or situation | MS or country | F G or T(a) | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) (d) | Remarks |
|-----------------------|---------------|-------------|-----------------------------------|-------------|-------------|--------------------------------|----------------|---------|
|                       |               |             |                                   |             |             |                                |                |         |
| Oranges               | IT            | F           | Phyllocnistis citrella            | SG          | 0.95% (w/w) | Foliar treatment – spraying    | 71–89          | 2       | 10      | –      | –      | 19 g a.i./ha | 7      |
| Lemons                | IT            | F           | Phyllocnistis citrella            | SG          | 0.95% (w/w) | Foliar treatment – spraying    | 71–89          | 2       | 10      | –      | –      | 19 g a.i./ha | 7      |
| Mandarins             | IT            | F           | Phyllocnistis citrella            | SG          | 0.95% (w/w) | Foliar treatment – spraying    | 71–89          | 2       | 10      | –      | –      | 19 g a.i./ha | 7      |
| Walnuts               | IT            | F           | Cydia pomonella; Cydia sp.        | SG          | 0.95% (w/w) | Foliar treatment – spraying    | 71–89          | 3       | 7       | –      | –      | 38 g a.i./ha | 3      |
| Apples                | HR            | F           | Cydia pomonella                   | SG          | 9.5 g/kg    | Foliar treatment – spraying    | 67–85          | 3       | 7       | –      | –      | 38 g a.i./ha | 7      |
| Crop and/or situation | MS or country | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|---------------|-----------------------------------|-------------|-------------|-------------------------------|------------|---------|
|                       |               |                                   | Type(b)    | Conc. a.s.  | Method Kind                   | Number min-max | Interval between application (min) | a.s./hL min-max | Water L/ha min-max | Rate and unit |         |
| Pears                 | HR            | Cydia pomonella                   | SG         | 9.5 g/kg   | Foliar treatment – spraying   | 67–85       | 3                                 | –                   | –                                      | 38 g a.i./ha | 7       |
| Quinces               | FR            | Cydia pomonella, Cydia molest, Eulia, Capua reticulana, Pandemis heparana, Podana | SG         | 9.5 g/kg   | Foliar treatment – spraying   | 70–89       | 3                                 | –                   | –                                      | 19 g a.i./ha | 3       |
| Medlars               | FR            | Cydia pomonella, Cydia molest, Eulia, Capua reticulana, Pandemis heparana, Podana | SG         | 9.5 g/kg   | Foliar treatment – spraying   | 70–89       | 3                                 | –                   | –                                      | 19 g a.i./ha | 3       |
| Loquats               | FR            | Cydia pomonella, Cydia molest, Eulia, Capua reticulana, Pandemis heparana, Podana | SG         | 9.5 g/kg   | Foliar treatment – spraying   | 70–89       | 3                                 | –                   | –                                      | 19 g a.i./ha | 3       |
| Crop and/or situation | MS or country | G or F | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|------------------------|--------------|--------|-----------------------------------|-------------|------------|-------------------------------|-----------|---------|
|                        |              |        |                                   |             |            |                               |           |         |
| Apricots               | IT           | F      | Grapholita molesta, Anarsia lineatella, Lithocolletis spp. | SG 0.95% (w/w) | Foliar treatment – spraying | 71–89 | 3 7 | – – | 38 g a.i./ha | 14 |
| Peaches                | IT           | F      | Grapholita molesta, Anarsia lineatella, Lithocolletis spp. | SG 0.95% (w/w) | Foliar treatment – spraying | 71–89 | 3 7 | – – | 38 g a.i./ha | 7 |
| Plums                  | IT           | F      | Cydia funebrana                   | SG 0.95% (w/w) | Foliar treatment – spraying | 71–89 | 3 7 | – – | 38 g a.i./ha | 7 |
| Table grapes           | PT           | F      | Lobesia botrana, Eupoecillia anbiguela | SG 8.5 g/kg | Foliar treatment – spraying | 71–85 | 4 10 | – – | 12.75 g a.i./ha | 7 |
| Wine grapes            | PT           | F      | Lobesia botrana, Eupoecillia anbiguela | SG 8.5 g/kg | Foliar treatment – spraying | 71–85 | 4 10 | – – | 12.75 g a.i./ha | 7 |
| Strawberries           | IT           | F      | Lobesia botrana, Eupoecillia anbiguela | SG 0.95% (w/w) | Foliar treatment – spraying | 11–89 | 3 7 | – – | 15 g a.i./ha | 1 |
| Potatoes               | IT           | F      | Phtorimaea operculella            | SG 0.95% (w/w) | Foliar treatment – spraying | 11–41 | 3 7 | – – | 14.25 g a.i./ha | 3 |

Review of the existing MRLs for emamectin

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| Crop and/or situation | MS or country | FG or \( x^{(a)} \) | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|----------------------|--------------|----------------|----------------------------------|-------------|----------------|-----------------------------|-----------|--------|
| Tomatoes             | HR           | F              | *Heliothis armigera, Spodoptera exigua, Spodoptera littoralis* | SG          | 9.5 g/kg | Foliar treatment – spraying | 12–89     | 3      | 7      | 19 g a.i./ha | 3 | Fall-back GAP from HR |
| Sweet peppers        | EL           | F              |                                     | SG          | 0.95%   | Foliar treatment – spraying | 1–3       | 7      | –      | –             | 3 |                     |
| Aubergines           | EL           | F              |                                     | SG          | 0.95%   | Foliar treatment – spraying | 1–3       | 7      | –      | –             | 3 |                     |
| Cucumbers            | IT           | F              | *Heliothis armigera, Spodoptera spp., Ostrinia nubilalis, Plusia gamma, Pieris brassicae, Plutella xylostella, Depressaria Erinacea, Tuta absoluta* | SG          | 0.95% (w/w) | Foliar treatment – spraying | 11–89     | 3      | 7      | 14.25 g a.i./ha | 3 | Fall-back GAP from IT |
| Crop and/or situation | MS or country | F or G | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|---------------|--------|------------------------------------|-------------|------------|------------------------------|-----------|---------|
| Gherkins              | IT            | F      | *Heliothis armigera, Spodoptera spp., Ostrinia nubilalis, Plusia gamma, Pieris brassicae, Plutella xylostella, Depressaria erinaceella, Tuta absoluta* | SG          | Foliar treatment – spraying | 11–89 | 3 | 7 | – | – | 14.25 g a.i./ha | 3 |
| Courgettes            | IT            | F      | *Heliothis armigera, Spodoptera spp., Ostrinia nubilalis, Plusia gamma, Pieris brassicae, Plutella xylostella, Depressaria erinaceella, Tuta absoluta* | SG          | Foliar treatment – spraying | 11–89 | 3 | 7 | – | – | 14.25 g a.i./ha | 3 |
| Melons                | EL            | F      | *SG 0.95% (w/w)* | Foliar treatment – spraying | 1–3 | 7 | – | – | 21.375 g a.i./ha | 3 |

Review of the existing MRLs for emamectin
| Crop and/or situation | MS or country | F G or x₁ | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|---------------|------------|----------------------------------|-------------|-------------|-----------------------------|------------|---------|
|                        |               |            |                                  |             |             |                             |            |         |
| **Pumpkins**           | IT            | F          | Heliothis armigera, Spodoptera spp., Ostrinia nubilalis, Plusia gamma, Pieris brassicae, Plutella xylostella, Depressaria erinaceaella, Tuta absoluta | SG 0.95% (w/w) | Foliar treatment – spraying | 11–89 | 3 | 7 | – | 14.25 g a.i./ha | 3 |
| **Watermelons**        | EL            | F          | SG 0.95% | Foliar treatment – spraying | 1–3 | 7 | – | – | 14.25 g a.i./ha | 3 |
| **Broccoli**           | EL            | F          | SG 0.95% | Foliar treatment – spraying | 1–3 | 7 | – | – | 14.25 g a.i./ha | 3 |
| **Cauliflower**        | EL            | F          | SG 0.95% | Foliar treatment – spraying | 1–3 | 7 | – | – | 14.25 g a.i./ha | 3 |
| Crop and/or situation | MS or country | FG or t(a) | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|--------------|------------|-----------------------------------|-------------|------------|-------------------------------|------------|---------|
| Brussels sprouts      | IT F         |            | Heliolthis armigera, Spodoptera spp., Ostrinia nubilalis, Plusia gamma, Pieris brassicae, Plutelia xylostella, Depressaria erinaceella, Tuta absoluta | SG 0.95% (w/w) | Foliar treatment – spraying | 14.25 g a.i./ha | 3 |
| Head cabbages         | EL F         |            | Spodoptera spp.; Ostrinia nubilalis | SG 0.95% (w/w) | Foliar treatment – spraying | 14.25 g a.i./ha | 3 |
| Kohlrabies             | ES F         |            | Caterpillars | SG 8.55 g/kg | Foliar treatment – general (see also comment field) | 12.8 g a.i./ha | 3 |
| Lamb’s lettuces       | IT F         |            | Spodoptera spp.; Ostrinia nubilalis | SG 0.95% (w/w) | Foliar treatment – spraying | 14.25 g a.i./ha | 3 |
| Lettuces              | EL F         |            | Spodoptera spp.; Ostrinia nubilalis | SG 0.95% (w/w) | Foliar treatment – spraying | 14.25 g a.i./ha | 3 |
| Escaroles             | IT F         |            | Spodoptera spp.; Ostrinia nubilalis | SG 0.95% (w/w) | Foliar treatment – spraying | 14.25 g a.i./ha | 3 |
### Crop and/or situation
- **MS or country**
- **FG or X**
- **Pests or Group of pests controlled**
- **Preparation**
  - **Type**
  - **Conc. a.s.**
  - **Method**
  - **Range of growth stages & season**
  - **Number min-max**
  - **Interval between application (min)**
  - **Application rate per treatment**
    - **a.s./hl min-max**
    - **Water L/ha min-max**
    - **Rate and unit**
- **Remarks**

| Crop and/or situation | MS or country | FG or X | Pests or Group of pests controlled | Preparation | Type | Conc. a.s. | Method | Range of growth stages & season | Number min-max | Interval between application (min) | Application rate per treatment | Rate and unit | Remarks |
|-----------------------|---------------|---------|------------------------------------|-------------|-------|-----------|--------|-------------------------------|----------------|-----------------------------|-------------------------------|--------------|---------|
| Cresses               | IT            | F       | Spodoptera spp.; Ostrinia nubilalis | SG          | 0.95% (w/w) | Foliar treatment – spraying | 11–49 | 3 | 7 | – | – | 14.25 g a.i./ha | 3 | |
| Land cresses          | IT            | F       | Spodoptera spp.; Ostrinia nubilalis | SG          | 0.95% (w/w) | Foliar treatment – spraying | 11–49 | 3 | 7 | – | – | 14.25 g a.i./ha | 3 | |
| Roman rocket          | IT            | F       | Spodoptera spp.; Ostrinia nubilalis | SG          | 0.95% (w/w) | Foliar treatment – spraying | 11–49 | 3 | 7 | – | – | 14.25 g a.i./ha | 3 | |
| Red mustards          | IT            | F       | Spodoptera spp.; Ostrinia nubilalis | SG          | 0.95% (w/w) | Foliar treatment – spraying | 11–49 | 3 | 7 | – | – | 14.25 g a.i./ha | 3 | |
| Baby leaf crops       | IT            | F       | Spodoptera spp.; Ostrinia nubilalis | SG          | 0.95% (w/w) | Foliar treatment – spraying | 11–49 | 3 | 7 | – | – | 14.25 g a.i./ha | 3 | |
| Chervil               | FR            | F       | Lepidoptera                         | SG          | 9.5 g/kg   | Foliar treatment – spraying | 16–49 | 3 | 7 | – | – | 14.25 g a.i./ha | 3 | |
| Chives                | FR            | F       | Lepidoptera                         | SG          | 9.5 g/kg   | Foliar treatment – spraying | 16–49 | 3 | 7 | – | – | 14.25 g a.i./ha | 3 | |
| Celery leaves         | FR            | F       | Lepidoptera                         | SG          | 9.5 g/kg   | Foliar treatment – spraying | 16–49 | 3 | 7 | – | – | 14.25 g a.i./ha | 3 | |
| Parsley               | FR            | F       | Lepidoptera                         | SG          | 9.5 g/kg   | Foliar treatment – spraying | 16–49 | 3 | 7 | – | – | 14.25 g a.i./ha | 3 | |
| Sage                  | FR            | F       | Lepidoptera                         | SG          | 9.5 g/kg   | Foliar treatment – spraying | 16–49 | 3 | 7 | – | – | 14.25 g a.i./ha | 3 | |
| Crop and/or situation | MS or country | F G or t | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|--------------|----------|-----------------------------------|-------------|------------|--------------------------------|------------|---------|
| Rosemary              | FR           | F        | Lepidoptera                       | SG 9.5 g/kg | Foliar treatment – spraying | 16–49        | 3 | 7     | – | – | 14.25 g a.i./ha | 3 |
| Thyme                 | FR           | F        | Lepidoptera                       | SG 9.5 g/kg | Foliar treatment – spraying | 16–49        | 3 | 7     | – | – | 14.25 g a.i./ha | 3 |
| Basil                 | FR           | F        | Lepidoptera                       | SG 9.5 g/kg | Foliar treatment – spraying | 16–49        | 3 | 7     | – | – | 14.25 g a.i./ha | 3 |
| Laurel                | FR           | F        | Lepidoptera                       | SG 9.5 g/kg | Foliar treatment – spraying | 16–49        | 3 | 7     | – | – | 14.25 g a.i./ha | 3 |
| Tarragon              | FR           | F        | Lepidoptera                       | SG 9.5 g/kg | Foliar treatment – spraying | 16–49        | 3 | 7     | – | – | 14.25 g a.i./ha | 3 |
| Beans (with pods)     | CY, GR, PT   | F        |                                    | SG 9.5 g/kg | Foliar treatment – spraying | 71–89        | 1 to 3 | 7 | – | – | 20 g a.i./ha | 3 |
| Beans (without pods)  | IT           | F        | Heliothis armigera, Spodoptera spp., Ostrinia nubilalis, Plusia gamma, Pieris brassicae, Plutella xylostella, Depressaria erinaceella, Tuta absoluta | SG 0.95% (w/w) | Foliar treatment – spraying | 71–89        | 3 | 7 | – | – | 14.25 g a.i./ha | 3 |
| Crop and/or situation | MS or country | F G or T | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|---------------|----------|-----------------------------------|-------------|------------|--------------------------------|-------------|---------|
| Peas (with pods)      | CY, GR, PT, FR | F        | Heliothis spp., Ostrinia nubilalis | SG 9.5 g/kg | Foliar treatment – spraying | 71–89  3  7 | –  20 g a.i./ha | 3        |
| Peas (without pods)   | IT F          |          | Heliothis armigera, Spodoptera spp., Ostrinia nubilalis, Plusia gamma, Pieris brassicae, Plutella xylostella, Depressaria erinaceella, Tuta absoluta | SG 0.95% (w/w) | Foliar treatment – spraying | 71–89  3  7 | –  14.25 g a.i./ha | 3        |
| Globe artichokes      | EL F          |          | SG 0.95% | Foliar treatment – spraying | 1–3  7 | –  14.25 g a.i./ha | 1        |
| Cotton seeds          | EL F          |          | SG 0.95% | Foliar treatment – spraying | 1–3  7 | –  14.25 g a.i./ha | 28       |
### A.3. Authorised indoor uses in EU

| Crop and/or situation | MS or country | FG or xf | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|--------------|----------|-----------------------------------|-------------|-------------|--------------------------------|------------|---------|
| Strawberries          | IT I         |          | Heliotis armigera, Spodoptera spp., Ostrinia nubilalis, Plusia gamma, Pieris brassicae, Plutella xylostella, Depressaria erinacea, Tuta absoluta | SG 0.95% (w/w) Foliar treatment – spraying | 11–89 3 7 | – – | 14.25 g a.i./ha 3 |
| Tomatoes              | HR, HU I     |          | Heliotis armigera, Spodoptera exigua, Spodoptera littoralis | SG 9.5 g/kg Foliar treatment – spraying | 12–89 3 7 | – – | 19 g a.i./ha 3 |
| Sweet peppers        | HU I         |          | Helicoverpa armigera               | SG 9.5 g/kg Foliar treatment – spraying | 89 3 7 | – – | 19 g a.i./ha 3 |
| Aubergines           | HR I         |          | Heliotis armigera, Spodoptera exigua, Spodoptera littoralis, Tuta absoluta | SG 9.5 g/kg Foliar treatment – spraying | 12–89 3 7 | – – | 14.25 g a.i./ha 3 |
| Crop and/or situation | MS or country | FG or Gt | Pests or Group of pests controlled | Preparation | Type | Conc. | Method kind | Range of growth stages & season | Number min-max | Interval between application (min) | Application rate per treatment | PHI (days) | Remarks |
|----------------------|---------------|----------|-----------------------------------|-------------|------|-------|-------------|--------------------------------|----------------|-------------------------------|-------------------------------|------------|---------|
| Cucumbers            | HU I          |          | Helicoverpa armigera              | SG          | 9.5  | g/kg  | Foliar treatment – spraying | 89                  | 3                             | 7                            | –           | –       |
|                      |               |          |                                   |             |      |       |                          |                    |                               | 19 g a.i./ha            | 3          |         |
| Gherkins             | IT I          |          | Heliothis armigera, Spodoptera spp., Ostrinia nubilalis, Plusia gamma, Pieris brassicae, Plutella xylostella, Depressaria erineaceella, Tuta absoluta | SG          | 0.95% (w/w) | Foliar treatment – spraying | 11–89             | 3                             | 7                            | –           | –       |
|                      |               |          |                                   |             |      |       |                          |                    |                               | 14.25 g a.i./ha          | 3          |         |
| Courgettes           | HU I          |          | Helicoverpa armigera              | SG          | 9.5  | g/kg  | Foliar treatment – spraying | 89                  | 3                             | 7                            | –           | –       |
|                      |               |          |                                   |             |      |       |                          |                    |                               | 19 g a.i./ha            | 3          |         |
| Melons               | HU I          |          | Helicoverpa armigera              | SG          | 9.5  | g/kg  | Foliar treatment – spraying | 89                  | 3                             | 7                            | –           | –       |
|                      |               |          |                                   |             |      |       |                          |                    |                               | 19 g a.i./ha            | 3          |         |
| Crop and/or situation | MS or country | FG or G | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment |
|-----------------------|---------------|---------|-----------------------------------|-------------|------------|-------------------------------|
|                        |               |         |                                   | Type(a)     | Concentration | PHI (days) | Remarks |
|                        |               |         |                                   | Conc. a.s.  | Method-kind | Water L/ha | Rate and unit |
|                        |               |         |                                   | Range of growth stages & season(c) | Number min-max | Interval between application (min) |
|                        |               |         |                                   | a.s./hl min-max | Water L/ha min-max |

| Pumpkins               | IT I          | H. armigera, S. spp., O. nubilalis, P. brassicae, P. xylostella, D. erinaceella, T. absoluta | SG 0.95% (w/w) | Foliar treatment – spraying | 11–89 | 3 | 7 | 14.25 g a.i./ha | 3 |
| Watermelons            | HU I          | H. armigera | SG 9.5 g/kg | Foliar treatment – spraying | 89 | 3 | 7 | 19 g a.i./ha | 3 |
| Lamb’s lettuces        | IT, FR I      | S. spp.; O. nubilalis | SG 0.95% (w/w) | Foliar treatment – spraying | 11–49 | 3 | 7 | 14.25 g a.i./ha | 3 |
| Lettuces               | HU I          | H. armigera | SG 9.5 g/kg | Foliar treatment – spraying | 89 | 3 | 7 | 19 g a.i./ha | 3 |
| Cresses                | FR I          | L. | SG 9.5 g/kg | Foliar treatment – spraying | 16–49 | 3 | 7 | 14.25 g a.i./ha | 3 |
| Land cresses           | IT I          | S. spp.; O. nubilalis | SG 0.95% (w/w) | Foliar treatment – spraying | 11–49 | 3 | 7 | 14.25 g a.i./ha | 3 |
| Crop and/or situation | MS or country | FG or I(a) | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|--------------|------------|-----------------------------------|-------------|------------|-------------------------------|----------|---------|
| Roman rocket          | IT           | I          | Spodoptera spp.; Ostrinia nubilalis | SG          | Foliar treatment – spraying   | 11–49 3 7 | – – | 14.25 g a.i./ha | 3 |
| Red mustards          | IT           | I          | Spodoptera spp.; Ostrinia nubilalis | SG          | Foliar treatment – spraying   | 11–49 3 7 | – – | 14.25 g a.i./ha | 3 |
| Baby leaf crops       | IT           | I          | Spodoptera spp.; Ostrinia nubilalis | SG          | Foliar treatment – spraying   | 11–49 3 7 | – – | 14.25 g a.i./ha | 3 |
| Watercresses          | BE           | I          | Leaf noctuid caterpillars          | SG          | Foliar treatment – spraying   | 1–3 7 | – – | 14 g a.i./ha | 3 |
| Sage                  | PT           | I          | Helicoverpa armigera               | SG          | Foliar treatment – spraying   | 15–47 3 7 | – – | 12.75 g a.i./ha | 3 |
| Beans (with pods)     | HU           | I          | Helicoverpa armigera               | SG          | Foliar treatment – spraying   | 79 3 7 | – – | 19 g a.i./ha | 3 |
| Peas (with pods)      | EU           | I          | Heliothis spp., Ostrinia nubilalis | SG          | Foliar treatment – spraying   | 71–89 3 7 | – – | 15 g a.i./ha | 3 |

MRL: maximum residue level; MS: Member State; a.s.: active substance; SG: water-soluble granule; a.i.: active ingredient; GAP: Good Agricultural Practice; WG: water-dispersible granule; LWA: Leaf Wall Area.

(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide.
(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.
(d): PHI: minimum preharvest interval.
### 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) | Comment/Source |
|-----------------------------------|-------------|---------|----------------|----------------|----------------|
| Fruit crops                       | Pears       | Foliar: 3 × 16.8 or 168 g a.s./ha, 7 days interval | 2 DAT<sub>1</sub>, 14, 28 DAT<sub>3</sub> | [23<sup>14</sup>C]-emamectin B<sub>1a</sub> benzoate (EFSA, 2012) |
| Leafy crops                       | Lettuce     | Foliar: 8 × 16.8 or 84 g a.s./ha, 7 days interval | 0, 1, 3, 7, 10 DAT<sub>8</sub> | [3, 7, 11, 13, 23-14C]-emamectin B<sub>1a</sub> benzoate (EFSA, 2012) |
|                                  | Head cabbage| Foliar: 8 × 16.8 or 84 g a.s./ha, 7 days interval | 0, 1, 3, 7, 10 DAT<sub>8</sub> | [3, 7, 11, 13, 23-14C]-emamectin B<sub>1a</sub> benzoate (EFSA, 2012) |
| Cereals/grass                     | Sweet corn  | Foliar: 6 × 16.8 or 84 g a.s./ha, 3-5 days interval | 0, 1, 3, 7 DAT<sub>6</sub> | [3, 7, 11, 13, 23-14C]-emamectin B<sub>1a</sub> benzoate (EFSA, 2012) |

| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s) | PBI (DAT) | Comment/Source |
|--------------------------------------|-------------|---------|----------------|-----------|----------------|
| Root/tuber crops                     | Carrots     | Bare soil application: 6 × 16.8 g a.s./ha (total 100.8 g a.s./ha), 7 days interval | 30, 141, 365 | [3, 7, 11, 13, 23-14C]-emamectin B<sub>1a</sub> benzoate (EFSA, 2012) |
| Leafy crops                          | Lettuce     | Bare soil application: 6 × 16.8 g a.s./ha (total 100.8 g a.s./ha), 7 days interval | 30, 120, 365 | [3, 7, 11, 13, 23-14C]-emamectin B<sub>1a</sub> benzoate (EFSA, 2012) |
| Cereal (small grain)                 | Barley      | Bare soil application: 6 × 16.8 g a.s./ha (total 100.8 g a.s./ha), 7 days interval | 30, 141, 365 | [3, 7, 11, 13, 23-14C]-emamectin B<sub>1a</sub> benzoate (EFSA, 2012) |

| Processed commodities (hydrolysis study) | Conditions | Stable? | Comment/Source |
|------------------------------------------|------------|---------|----------------|
| Pasteurisation (20 min, 90°C, pH 4)      | Yes        | Emamectin B<sub>1a</sub> benzoate (parent) 84.4% TAR. Degradation products (15.7% TAR) not identified (Netherlands, 2008) |
| Baking, brewing and boiling (60 min, 100°C, pH 5) | Yes | Emamectin B<sub>1a</sub> benzoate 85.9% TAR. Milbemectin B (1.4% TAR) and MSB1a (4.8% TAR) were the metabolites identified (Netherlands, 2008) |
| Sterilisation (20 min, 120°C, pH 6)      | Yes        | Emamectin B<sub>1a</sub> benzoate 79.8% TAR. MSB<sub>1a</sub> (7.2% TAR) and AB<sub>1a</sub> (1.8% TAR) were the metabolites identified (Netherlands, 2008). Remaining TAR was not identified |
Can a general residue definition be proposed for primary crops? | Yes | -
---|---|---
Rotational crop and primary crop metabolism similar? | Yes | Degradation products in rotational crops were characterised as natural products only: parent or 'mectin-like' degradates were not detected
Residue pattern in processed commodities similar to residue pattern in raw commodities? | Yes | Slightly different degradation profile (parent degraded up to 20%. Metabolite MSB1a, AB1a, and milbemectin formed), which is not expected to modify the nature of residues in processed commodities

**Plant residue definition for monitoring (RD-Mo)**

| All plant commodities (raw and processed): | Emamectin B1a and its salts, expressed as emamectin B1a (free base) |

**Plant residue definition for risk assessment (RD-RA)**

| All plant commodities (raw and processed): | Sum of emamectin B1a, emamectin B1b, 8,9-Z-MAB1a, plus 3 times AB1a, plus 3 times MFB1a and 3 times FAB1a, expressed as emamectin B1a (free base) |

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

- High water, high acid, high oil content commodities and dry commodities (EFSA 2012):
  - Single residue method LC/LC–MS/MS
  - LOQ 0.001 mg/kg for emamectin B1a benzoate (determined as free base)
  - Confirmation method for the four main matrices (EFSA, 2018)
  - ILV (LC/LC–MS/MS) available for high water content commodities only (EFSA, 2012). ILV for at least one of the other two matrices is required (data gap)
  - QuEChERS (LC–MS/MS) for enforcement emamectin B1a benzoate (determined as free base) in routine analysis, LOQ 0.002 mg/kg in high water and high acid content commodities, 0.005 mg/kg in high oil content and dry commodities (EFSA, 2019)

a.s.: active substance; DAT: days after treatment; PBI: plant-back interval; LC/LC–MS/MS: liquid chromatography/liquid chromatography with tandem mass spectrometry; LC–MS/MS: liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; ILV: independent laboratory validation; TAR: total applied radioactivity; QuEChERS: Quick, Easy, Cheap, Effective, Rugged, and Safe
### B.1.1.2. Stability of residues in plants

| Plant products (available studies) | Category          | Commodity     | T (°C) | Stability period | Compounds covered | Comment/Source |
|------------------------------------|-------------------|---------------|--------|------------------|-------------------|---------------|
|                                    |                   |               | Value  | Unit             |                   |               |
| High water content                 | Tomato            | –20           | 18     | Months           | RD-Mo             | EFSA (2012)   |
|                                    | Beans with pods   | –20           | 18     | Months           | RD-RA             |               |
|                                    | Potato            | –20           | 18     | Months           | RD-Mo             |               |
|                                    |                   | –20           | 18     | Months           | RD-RRA            |               |
|                                    | High oil content  | –              |        |                  | Not available     |               |
|                                    | High acid content | Orange        | –18    | 24 Months        | RD-Mo             |               |
|                                    |                   | –18           | 18     | Months           | RD-RA             | Italy (2015)  |

RD: residue definition; Mo: monitoring; RA: risk assessment.

### B.1.2. Magnitude of residues in plants

#### B.1.2.1. Summary of residues data from the supervised residue trials – Primary crops

| Commodity                        | Region/Indoor(a) | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source                                                                 | Calculated MRL (mg/kg) | HR(b) (mg/kg) | STMR(c) (mg/kg) | CF(d) |
|----------------------------------|------------------|------------------------------------------------------------------|--------------------------------------------------------------------------------|------------------------|---------------|-----------------|-------|
| Oranges, mandarins and lemons    | SEU              | Mo: 12 × < 0.001; 2 × 0.001; 0.0018; 0.0026 RA: –                  | Combined data set on oranges (8) and mandarins (8) without adjuvant. Application rate within 25% deviation. Residues in samples were analysed for emamectin B1a only (EFSA, 2011). Extrapolation to lemons is applicable MRL\_OECD = 0.003 | 0.003*©(e)            | 0.003         | 0.001           | 1.10(f) |
| Walnuts                          | SEU              | Mo: 4 × < 0.001 RA: 4 × < 0.012                                   | Trials on walnuts without adjuvant were selected. Application rate within 25% deviation (Italy, 2018) | 0.001*(g) (tentative) | < 0.001       | < 0.001         | 1.00   |
| Pome fruits                      | NEU              | Mo: 0.0018; < 0.001; < 0.001; < 0.001; 0.0004; 0.0026; 0.001; 0.0026; < 0.001; < 0.001 RA: 0.0128; < 0.012; 0.0119; < 0.012; 0.0154; 0.0136; 0.012; 0.0136; – RA: – | Combined data set on apples (8) and pears (2) without adjuvant. Residues in pears trials were analysed for emamectin B1a only (Netherlands, 2008; France, 2018). Tentative extrapolation to quinces, medlars and loquats (less critical GAP) is proposed MRL\_OECD = 0.006 | 0.007*(h) (tentative for quinces, medlars and loquats) | 0.004         | 0.001           | 1.00   |
| Commodity                  | Region/Indoor(a) | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source                                                                                                                                                                                                 | Calculated MRL (mg/kg) | HR(b) (mg/kg) | STMR(c) (mg/kg) | CF(d) |
|----------------------------|------------------|---------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|---------------|-----------------|-------|
| SEU                        | Mo: 0.0026; 0.007; 0.0044; 0.0044; 0.0026; 0.001; < 0.001; 0.0026; 0.0026; 0.0026; < 0.001; 0.007; 0.0044 RA: 0.0136; 0.018; 0.0154; 0.0154; 0.0136; 0.012; < 0.012; 0.0136; 0.0136; < 0.012; < 0.012; < 0.012; < 0.012; < 0.012; < 0.012; < 0.012; RA: 0.0136; 0.018; 0.0154; 0.0154; 0.0136; 0.012; < 0.012; 0.0136; 0.0136; < 0.012; < 0.012; < 0.012; < 0.012; < 0.012; < 0.012; | Combined data set on apples (11) and pears (2) without adjuvant. Residues in pears trials were analysed for emamectin B1a only (Netherlands, 2008; France, 2018; Italy, 2018). Tentative extrapolation to quinces, medlars and loquats (less critical GAP) is proposed MRL_{OECD} = 0.01 | 0.015(h) (tentative for quinces, medlars and loquats) | 0.007 | 0.003 | 1.0 |
| Apricots                   | Mo: 2 x < 0.001; 2 x 0.001; 0.0018; 0.0035; 0.0018; 0.0026 RA: 2 x < 0.012; 2 x 0.012; 0.0128; 0.0145; 0.0128; 0.0136 | Trials on peaches compliant with GAP on apricots. Residue trials without adjuvant selected (Netherlands, 2008) MRL_{OECD} = 0.005 | 0.006(h) (tentative) | 0.004 | 0.001 | 1.00 |
| Peaches                    | Mo: 0.0035(0); 0.0018; 0.001; 0.0018; 0.0007; 0.0035; 0.0035; 0.0044 RA: 0.0145; 0.0128; 0.012; 0.0128; 0.018; 0.0145; 0.0145; 0.0154 | Trials on peaches compliant with GAP. First value (0.0035) corresponds to a higher residue level observed at a longer PHI (10). Residue trials without adjuvant selected (Netherlands, 2008) MRL_{OECD} = 0.01 | 0.015 | 0.007 | 0.004 | 1.00 |
| Plums                      | Mo: 0.001; 0.0018; 0.0062; 0.0088; 5 x < 0.001(0); 0.001(0); 2 x 0.0018(0) RA: 0.012; 0.0128; 0.0172; 0.0198; < 0.001; < 0.001; < 0.001; < 0.001; | Four GAP-compliant trials on plums (first 4 values) analysed for enforcement and risk assessment, and eight overdosed trials with 1.6N rate, deemed acceptable since residues are in the same range or < LOQ. Trials without adjuvant were selected (Austria, 2018; Hungary, 2018) MRL_{OECD} = 0.01 | 0.015 | 0.009 | 0.001 | 1.00 |
|                          | Mo: 3 x < 0.001; 3 x 0.0018; 2 x 0.0026 RA: – | Residues trials on plums performed with app. Rate within 25% deviation. Trials without adjuvant were selected. Residues in samples were analysed for emamectin B1a only (EFSA, 2011). MRL_{OECD} = 0.004 | 0.005 | 0.003 | 0.002 | 1.10(f) |
| Table and wine grapes      | Mo: 4 x < 0.001; 0.001; 2 x 0.0026; 0.0044 RA: 4 x < 0.012; 0.012; 2 x 0.0136; 0.0154 | Trials on wine grapes performed with application rates within 25% deviation (Hungary, 2018). Extrapolation to table grapes is applicable. MRL_{OECD} = 0.007 | 0.007(e) | 0.004 | 0.001 | 1.00 |
| Commodity | Region/Indoor(a) | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source | Calculated MRL (mg/kg) | HR(b) (mg/kg) | STMR(c) (mg/kg) | CF(d) |
|-----------|-----------------|---------------------------------------------------------------|----------------|------------------------|--------------|----------------|--------|
| SEU       | Mo: 3 × < 0.001; 0.0026; 0.0079; 0.0194; 0.0018; 0.0123 RA: – | Trials on wine grapes performed with application rates within 25% deviation. The first two values correspond to higher residues observed at longer PHI. Residues in samples were analysed for emamectin B1a and B1b only (EFSA, 2012). Extrapolation to table grapes is applicable MRL<sub>OECD</sub> = 0.03 | 0.04<sup>(e)</sup> | 0.019 | 0.002 | 1.10<sup>(f)</sup> |
| Strawberries | Unscaled Mo: 0.0106; 0.0026; 0.0018; 0.0053; 0.0044; 0.007; 0.0053; 0.0088 Unscaled RA: 0.0244; 0.0136; 0.0128; 0.0163; 0.0154; 0.018; 0.0163; 0.0226 Scaling factors: 1.33; 1.50; 2.0; 1.5; 1.25; 1.33; 1.2; 1.25 Scaled Mo: 0.0079; 0.0018; 0.001; 0.0035; 0.0075; 0.0044; 0.007 Scaled RA: 0.0203; 0.0128; 0.0119; 0.0145; 0.0163; 0.0154; 0.0197 | Overdosed trials on strawberries performed at 1.3N rate. Trials results scaled to the GAP (Italy, 2018) MRL<sub>OECD</sub> = 0.01 | 0.015 | 0.008 | 0.004 | 1.00 |
| EU | Unscaled Mo: 0.0097; 0.0044; 0.0405; 0.0026; 0.0062; 0.007; 0.0255; 0.0088 Unscaled RA: 0.0207; 0.0154; 0.056; 0.0136; 0.0172; 0.018; 0.0459; 0.0198 Scaling factors: 1.38; 1.25; 1.31; 1.5; 1.4; 1.33; 1.38; 1.25 Scaled Mo: 0.007; 0.0035; 0.0308; 0.0018; 0.0044; 0.0053; 0.0185; 0.007 Scaled RA: 0.018; 0.0145; 0.0442; 0.0128; 0.0154; 0.0163; 0.0353; 0.018 | Overdosed trials on strawberries performed at 1.4N rate. Trials results scaled to the GAP (Italy, 2018) MRL<sub>OECD</sub> = 0.05 | 0.05 | 0.031 | 0.006 | 1.10 |
| Commodity    | Region/ Indoor | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source                                                                                     | Calculated MRL (mg/kg) | HR(b) (mg/kg) | STMR(c) (mg/kg) | CF(d) |
|-------------|---------------|----------------------------------------------------------------|---------------------------------------------------------------------------------------------------|------------------------|--------------|----------------|-------|
| Potatoes SEU | Mo: 4 x < 0.001; RA: 4 x < 0.012 | Reduced data set on potatoes, deemed acceptable as no residues are expected (Italy, 2018) |                                                                                                   | 0.001*                 | < 0.001      | < 0.001        | 1.00  |
| Tomatoes NEU | Mo: 3 x < 0.001; RA: 3 x < 0.012; 0.0128 | Trials on tomatoes performed with application rates within 25% variation. No decline PHI trials conducted (Netherlands, 2008; EFSA, 2012). Reduced data set deemed acceptable as it is covered by the indoor use MRL_{OECD} = 0.003 |                                                                                                   | 0.004                  | 0.002        | 0.001          | 1.00  |
| SEU          | Mo: 4 x < 0.001; 3 x 0.001; 0.0018; RA: 4 x < 0.012; 3 x 0.0119; 0.0128 | Trials on tomatoes performed with application rates within 25% variation (Netherlands 2008; EFSA, 2012) MRL_{OECD} = 0.002 |                                                                                                   | 0.003                  | 0.002        | 0.001          | 1.00  |
| EU          | Mo: 0.0035; 0.0018; 0.0001; 0.0026; 0.0018; 0.0035; 0.001; 0.001; 0.0007; 0.0062; 0.00355; 0.0053; 0.0007; 0.0026; 0.00885; 0.0035 RA: 0.0145; 0.0128; < 0.012; 0.0136; 0.0128; 0.0145; 0.012; 0.018; 0.0172; 0.0145; 0.0163; 0.018; 0.0136; 0.0198; 0.0145 | Combined data set on normal sized tomato (8) and cherry tomato (8) compliant with GAP. Values 1, 11 and 15 correspond to higher residues observed at longer PHI (Netherlands 2008; EFSA 2012) MRL_{OECD} = 0.01 | 0.015                  | 0.009        | 0.004          | 1.00  |
| Aubergines/ eggplants SEU | Mo: 2 x < 0.001; 2 x 0.001; RA: 2 x < 0.012; 2 x 0.012 | Trials on tomatoes performed according to the cGAP on aubergines. No decline PHI trials were conducted (Netherlands, 2008; EFSA, 2012) MRL_{OECD} = 0.002 |                                                                                                   | 0.002                  | 0.001        | 0.001          | 1.00  |
| EU          | Mo: 0.0035; 0.0018; < 0.001; 0.0026; 0.0018; 0.0035; 0.001; 0.001; RA: 0.0145; 0.0128; < 0.012; 0.0136; 0.0128; 0.0145; 0.012 | Trials on normal sized tomatoes performed with application rates within 25%. Extrapolation to aubergines is acceptable (Netherlands, 2008; EFSA 2012) MRL_{OECD} = 0.006 |                                                                                                   | 0.007                  | 0.004        | 0.002          | 1.00  |
| Commodity | Region/Indoor<sup>(a)</sup> | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source | Calculated MRL (mg/kg) | HR<sup>(b)</sup> (mg/kg) | STMR<sup>(c)</sup> (mg/kg) | CF<sup>(d)</sup> |
|-----------|-----------------------------|---------------------------------------------------------------|-----------------|------------------------|----------------|----------------|--------|
| Sweet peppers/bell peppers | NEU | Mo: 3 × < 0.001; 0.0053<sup>(i)</sup> RA: 3 × < 0.012; 0.0163 | Trials on peppers performed with application rate within 25%. Last value corresponds to a higher residue observed at longer PHI (Netherlands, 2008; EFSA 2012; Hungary, 2018). Reduced data set deemed acceptable as it is covered by the indoor use MRL<sub>OECD</sub> = 0.01 | 0.015 | 0.005 | 0.001 | 1.00 |
| | SEU | Mo: 2 × < 0.001; 0.001; 0.0018 RA: 2 × < 0.012; 0.012; 0.0128 | Trials on peppers performed with application rates within 25% (Netherlands, 2008; EFSA, 2012; Hungary, 2018). Reduced data set deemed acceptable as it is covered by the indoor use MRL<sub>OECD</sub> = 0.003 | 0.004 | 0.002 | 0.001 | 1.00 |
| Cucumbers, gherkins and courgettes | NEU | Mo: 4 × < 0.001 RA: 4 × < 0.012 | Trials on cucumbers performed with application rates within 25% (Hungary, 2018). Reduced data set deemed acceptable as all residues < LOQ. Extrapolation to courgettes is applicable (no NEU authorised uses on gherkins) | 0.001* | < 0.001 | < 0.001 | 1.00 |
| | SEU | Mo: 2 × < 0.001; 2 × 0.001 RA: 2 × < 0.012; 2 × 0.012 | Trials on cucumbers performed with application rates within 25% (Italy, 2018). Extrapolation to gherkins is applicable and to courgettes tentative MRL<sub>OECD</sub> = 0.002 | 0.002<sup>(h)</sup> (tentative for courgettes) | 0.001 | 0.001 | 1.00 |
| | EU | Mo: 3 × < 0.001; 3 × 0.001; 2 × 0.0018 RA: 3 × < 0.012; 3 × 0.012; 2 × 0.0128 | Trials on cucumbers performed with application rates within 25% (Netherlands, 2008). Extrapolation to courgettes is applicable and to gherkins tentative (less critical GAP) MRL<sub>OECD</sub> = 0.003 | 0.004<sup>(h)</sup> (tentative for gherkins) | 0.002 | 0.001 | 1.00 |
| Commodity                  | Region/Indoor<sup>(a)</sup> | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source                                                                 | Calculated MRL<sup>(b)</sup> (mg/kg) | HR<sup>(b)</sup> (mg/kg) | STMR<sup>(c)</sup> (mg/kg) | CF<sup>(d)</sup> |
|----------------------------|-----------------------------|-----------------------------------------------------------------|--------------------------------------------------------------------------------|--------------------------------------|-------------------------|--------------------------|----------------|
| Melons, pumpkins and watermelons | NEU                         | --                                                              | No trials available compliant with the NEU GAP on melons                      | --                                   | --                      | --                       | --            |
|                            | SEU                         | Mo: $2 \times < 0.001; 2 \times 0.001$                          | Trials on melons performed with application rate within 25% (EFSA, 2012). Extrapolation to pumpkins and watermelons is tentative MRL<sub>OECD</sub> = 0.003 Yes | 0.003<sup>(h)</sup> (tentative)    | 0.001                   | 0.001                    | 1.00          |
|                            |                             | RA: $2 \times < 0.012; 2 \times 0.012$                          |                                                                              |                                      |                         |                          |               |
|                            | EU                          | Mo: $< 0.001; 2 \times 0.001; 2 \times 0.0018; 0.0026; 0.0035; 0.0044$ RA: $< 0.012; 2 \times 0.012; 2 \times 0.0128; 0.0136; 0.0145; 0.0182$ | Trials on melons performed with application rates within 25% (EFSA, 2012). Extrapolation to watermelons is applicable and to pumpkins tentative (less cGAP) MRL<sub>OECD</sub> = 0.007 Yes | 0.008<sup>(h)</sup> (tentative for pumpkins) | 0.004                   | 0.002                    | 1.00          |
| Broccoli, cauliflower      | SEU                         | Mo: $4 \times < 0.001; 3 \times 0.001; 0.0018$ RA: --            | Combined data set on broccoli (4 trials) and cauliflower (4 trials) compliant with GAP Residues in samples were analysed for emamectin B1a only (Greece, 2018) MRL<sub>OECD</sub> = 0.002 Yes | 0.003                   | 0.002                   | 0.001                    | 1.50<sup>(k)</sup> |
| Brussels sprouts           | SEU                         | Mo: $3 \times < 0.001; 0.0018$ RA: $3 \times < 0.012; 0.0128$  | Trials on brussels sprouts performed with application rates within 25% (Italy, 2018) MRL<sub>OECD</sub> = 0.003 Yes | 0.004                   | 0.002                   | 0.001                    | 1.00          |
| Head cabbages              | SEU                         | Mo: $3 \times < 0.001; 0.0018$ RA: --                            | Trials on head cabbage compliant with GAP. Residues in samples were analysed for emamectin B1a only (Greece, 2018) MRL<sub>OECD</sub> = 0.003 Yes | 0.004                   | 0.002                   | 0.001                    | 1.50<sup>(k)</sup> |
| Kales, Chinese cabbage/pe-tsai | NEU                        | Mo: 0.0035; 0.0097; 0.0018; 0.0079 RA: 0.0145; 0.0207; 0.0128; 0.0189 | Trials con Kale performed with application rate within 25% (EFSA, 2018). Extrapolation to Chinese cabbages/pe-tsai is applicable MRL<sub>OECD</sub> = 0.02 Yes | 0.03                   | 0.01                    | 0.006                    | 1.00          |

<sup>(a)</sup> Indoor

<sup>(b)</sup> HR = calculated residue/MDAR (mg/kg)

<sup>(c)</sup> STMR = calculated residue/OECD MRL (mg/kg)

<sup>(d)</sup> CF = calculated residue/MRL of the least restrictive MRL (EC or national)

<sup>(h)</sup> Tentative

<sup>(k)</sup> Applicable
| Commodity | Region/ Indoor<sup>(a)</sup> | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source | Calculated MRL (mg/kg) | HR<sup>(b)</sup> (mg/kg) | STMR<sup>(c)</sup> (mg/kg) | CF<sup>(d)</sup> |
|-----------|-----------------------------|---------------------------------------------------------------|-----------------|----------------------|----------------------|----------------------|------------|
| Kohlrabies | SEU                         | –                                                             | No trials available compliant with the SEU GAP on kohlrabies | –                    | –                     | –                     | –          |
| Lettuces  | NEU                         | Mo: 0.0044; 0.0141; 0.0035; 0.0062; 0.0317; 0.0238; 0.0317; 0.0106; RA: 0.0154; 0.0251; 0.0145; 0.0172; 0.0427; 0.0348; 0.0484; 0.0244 | Residue trials on lettuces (open and closed varieties, or unknown) performed with application rates within 25% (Hungary, 2018) MRL<sub>OECD</sub> = 0.06 Yes | 0.07 | 0.032 | 0.012 | 1.10 |
|           | SEU                         | Mo: 0.0264; 0.037; 0.088; 0.0968; 0.0062; 0.0035; 0.0053; 0.029; RA: 0.0382; 0.0497; 0.1102; 0.119; 0.0172; 0.0145; 0.0163; 0.0436 | Residue trials on lettuces (open and closed varieties) compliant with GAP (Netherlands, 2008) MRL<sub>OECD</sub> = 0.18 Yes | 0.2 | 0.1 | 0.028 | 1.20 |
|           | EU                          | Mo: 0.0766; 0.1082; 0.2077; 0.1558; 0.0528; 0.0634; 0.088; 0.0458; 0.264; 0.2904; 0.352; 0.2288; 0.1346; 0.1716; 0.5412; 0.1417; RA: 0.1292; 0.1562; 0.3068; 0.2253; 0.0773; 0.0838; 0.1509; 0.0793; 0.322; 0.3923; 0.5138; 0.364; 0.2208; 0.2649; 0.6587; 0.2569 | Residue trials on lettuces (open and closed varieties, or unknown) performed with application rates within 25%. First value corresponds to a shorter PHI (Netherlands, 2008; Hungary, 2018) MRL<sub>OECD</sub> = 0.71 Yes | 0.7 | 0.54 | 0.15 | 1.50 |
| Salad plants (except lettuces and escaroles), watercresses and sage | NEU                         | Mo: 0.0035; 0.0317; 0.0238; RA: 0.0145; 0.0427; 0.0348 | Residue trials on open leaf lettuce variety performed with application rates within 25% (Hungary, 2018). Extrapolation to the whole subgroup of salad plants and sage is acceptable MRL<sub>OECD</sub> = 0.08 Yes | 0.15<sup>(h)</sup> (tentative) | 0.032 | 0.024 | 1.10 |
|           | SEU                         | Mo: 0.0264; 0.037; 0.088; 0.0968; 0.0062; 0.029; RA: 0.0382; 0.0497; 0.1102; 0.119; 0.0172; 0.0436 | Residue trials on open leaf lettuce variety compliant with GAP (Netherlands, 2008). Extrapolation to the whole subgroup of salad plants and sage is applicable MRL<sub>OECD</sub> = 0.19 Yes | 0.2 | 0.097 | 0.033 | 1.20 |
| Commodity | Region/ Indoor(a) | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source | Calculated MRL (mg/kg) | HR(b) (mg/kg) | STMR(c) (mg/kg) | CF(d) |
|-----------|------------------|---------------------------------------------------------------|----------------|------------------------|-------------|---------------|-------|
| EU        |                  | **Mo:** 0.0766(0); 0.1082; 0.2077; 0.1558; 0.0634; 0.0458; 0.264; 0.2904 **RA:** 0.1292; 0.1562; 0.3068; 0.2253; 0.0838; 0.0793; 0.322; 0.3923 | Residue trials on open leaf lettuce variety compliant with GAP. First value corresponds to a shorter PHI (Netherlands, 2008; Hungary, 2018). Extrapolation to the whole subgroup of salad plants (no indoor use for escaroles), watercresses and sage is applicable **MRL_{OECD} = 0.53  Yes** | 0.6 | 0.290 | 0.132 | 1.40 |
| Escaroles and fresh herbs (except sage) | NEU | **Mo:** 0.0035; 0.0317; 0.0238 **RA:** 0.0145; 0.0427; 0.0348 | Residue trials on open leaf lettuce variety performed with application rates within 25% (Hungary, 2018). Extrapolation to escaroles and the whole subgroup of fresh herbs is acceptable **MRL_{OECD} = 0.08  Yes** | 0.15(h) (tentative) | 0.032 | 0.024 | 1.10 |
| SEU |                  | **Mo:** 0.0264; 0.037; 0.088; 0.0968; 0.0062; 0.029 **RA:** 0.0382; 0.0497; 0.1102; 0.119; 0.0172; 0.0436 | Residue trials on open leaf lettuce variety compliant with GAP (Netherlands, 2008). Extrapolation to escaroles and the whole subgroup of fresh herbs is applicable **MRL_{OECD} = 0.19  Yes** | 0.2 | 0.097 | 0.033 | 1.20 |
| Beans and peas (with pods) | NEU | **Mo:** 4 × < 0.001; 3 × 0.001; 0.0079 **RA:** 4 × < 0.012; 3 × 0.012; 0.0189 | Trials on beans with pods performed with application rates within the 25% deviation (EFSA, 2018). Extrapolation to peas (with pods) is applicable **MRL_{OECD} = 0.01** | 0.015 | 0.008 | 0.001 | 1.00 |
| SEU |                  | **Mo:** 5 × < 0.001; 2 × 0.001; 0.0018 **RA:** 5 × < 0.012; 2 × 0.012; 0.0128 | Trials on beans with pods compliant with the GAP (EFSA, 2018). Extrapolation to peas (with pods) is applicable **MRL_{OECD} = 0.002** | 0.003 | 0.002 | 0.001 | 1.00 |
| EU |                  | **Mo:** < 0.001; 0.0053; 0.0106; 0.0026; 0.0167; 0.007; 0.0044; 0.0062 **RA:** < 0.012; 0.0163; 0.0216; 0.0136; 0.0277; 0.018; 0.0154; 0.0172 | Trials on beans with pods compliant with the GAP, performed at application rates within 25% deviation (EFSA 2018). Extrapolation to peas (with pods) is applicable **MRL_{OECD} = 0.03** | 0.03 | 0.017 | 0.006 | 1.00 |
## Commodity Region/Indoor(a) Residue levels observed in the supervised residue trials (mg/kg) Comments/Source Calculated MRL (mg/kg) HR(b) (mg/kg) STMR(c) (mg/kg) CF(d)

### Beans (without pods)
- **NEU**
  - Mo: 4 × < 0.001
  - RA: –
  - Trials on beans without pods compliant with GAP. Residues in samples were analysed for emamectin only (France, 2018)
  - 0.001*< 0.001 < 0.001 1.00(m)
- **SEU**
  - Mo: 4 × < 0.001
  - RA: 4 × < 0.012
  - Trials on beans without pods compliant with the GAP (Italy, 2018)
  - 0.001*< 0.001 < 0.001 1.00

### Peas (without pods)
- **SEU**
  - Mo: 8 × < 0.001
  - RA: 8 × < 0.012
  - Combined data set on 4 trials on beans without pods and 4 on peas without pods, compliant with the GAP (Italy, 2018)
  - 0.001*< 0.001 < 0.001 1.00

### Globe artichokes
- **NEU**
  - Mo: 3 × 0.001; 0.0044
  - RA: 3 × 0.012; 0.0154
  - Trials on globe artichokes compliant with GAP (Netherlands, 2008)
    MRL\textsubscript{OECD} = 0.01
  - 0.015 0.004 0.001 1.00

### Cotton seeds
- **SEU**
  - Mo: 2 × < 0.01
  - RA: –
  - Reduced data set (n = 2) on cotton seeds compliant with GAP (Greece, 2018); not sufficient to derive MRL
  - – – – –

---

**GAP:** Good Agricultural Practice; **OECD:** Organisation for Economic Co-operation and Development; **MRL:** maximum residue level; **LOQ:** limit of quantification; **PHI:** preharvest interval; **cGAP:** critical Good Agricultural Practice.

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

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

(b): Highest residue. The highest residue for risk assessment (RA) refers to the whole commodity and not to the edible portion.

(c): Supervised trials median residue. The median residue for risk assessment (RA) refers to the whole commodity and not to the edible portion.

(d): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.

(e): Tentative MRL in the absence of sufficiently validated analytical methods.

(f): In the absence of residue data for metabolites included in the RD-RA, a CF of 1.1 was applied for fruit crops as derived from residue trials on strawberries.

(g): Tentative MRL in the absence of storage stability.

(h): Tentative MRL in the absence of GAP-compliant trials.

(i): Selected value corresponds to higher residue levels observed at a longer PHI.

(j): Residue values coming from overdosed trials.

(k): In the absence of residue data for metabolites included in the RD-RA, a CF of 1.5 was applied for leafy vegetables as derived from residue trials on lettuces.

(l): Selected value corresponds to a residue level selected at shorter PHI.

(m): In the absence of residue data for metabolites included in the RD-RA, a CF of 1.0 was applied for legume vegetables (fresh) as derived from residue trials on beans with pods.
B.1.2.2. Residues in rotational crops

(a) Overall summary

Residues in rotational and succeeding crops expected based on confined rotational crop study?

|                  | No                                                                 |
|------------------|--------------------------------------------------------------------|
| Based on the rotational confined crop study and considering the critical GAPs reported in this review and that emamectin is not persistent in the soil, significant residue levels of emamectin are not expected in succeeding crops, provided that emamectin benzoate is applied in compliance with the GAPs reported in Appendix A |
| Residues in rotational and succeeding crops expected based on field rotational crop study? |
| Not triggered | No study available and not required |

GAP: Good Agricultural Practice.

B.1.2.3. Processing factors

| Processed commodity | Number of valid studies(a) | Processing Factor (PF) | Median PF | CF_p(b) | Comment/Source |
|---------------------|---------------------------|------------------------|-----------|---------|----------------|
| Citrus fruits, peeled | 2                         | Oranges: < 0.3         | < 0.25    | 1.1     | Tentative(c) (EFSA, 2011) In the absence of trials analysing for RD-RA in processed commodities, CF of RAC was applied |
|                      |                           | Mandarins: < 0.2       |           |         |                 |
| Melons, peeled       | 11                        | < 0.2; < 0.25; < 0.3; 2 × < 0.5; 5 × < 1; 1; | < 1.0     | 1       | Netherlands (2008, 2012) |

PF: Processing factor (=Residue level in processed commodity expressed according to RD-Mo/Residue level in raw commodity expressed according to RD-Mo);
CF_p: Conversion factor for risk assessment in processed commodity (=Residue level in processed commodity expressed according to RD-RA/Residue level in processed commodity expressed according to RD-Mo).

(a): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur).
(b): Median of the individual conversion factors for each processing residues trial.
(c): A tentative PF is derived based on a limited data set.
### B.2. Residues in livestock

| Relevant groups (subgroups) | Dietary burden expressed in | Most critical subgroup<sup>a</sup> | Most critical commodity<sup>b</sup> | Trigger exceeded (Y/N) | Comments |
|-----------------------------|-----------------------------|-----------------------------------|-----------------------------------|------------------------|----------|
|                             | mg/kg bw per day            | mg/kg DM                          |                                   |                        |          |
|                             | Median | Maximum | Median | Maximum |                                   |          |
| Cattle (all)                | 0.0005 | 0.0007   | 0.02   | 0.02     | Cattle (dairy)                   | Kale, leaves | No        | Given the high chronic toxicity of emamectin (ADI = 0.0005 mg/kg bw per day), MRLs in livestock are proposed although the dietary burden is not triggered |
| Cattle (dairy only)         | 0.0005 | 0.0007   | 0.01   | 0.02     | Cattle (dairy)                   | Kale, leaves | No        | Given the high chronic toxicity of emamectin (ADI = 0.0005 mg/kg bw per day), MRLs in livestock are proposed although the dietary burden is not triggered |
| Sheep (all)                 | 0.0003 | 0.0005   | 0.01   | 0.01     | Sheep (lamb)                     | Kale, leaves | No        | Given the high chronic toxicity of emamectin (ADI = 0.0005 mg/kg bw per day), MRLs in livestock are proposed although the dietary burden is not triggered |
| Sheep (ewe only)            | 0.0003 | 0.0004   | 0.01   | 0.01     | Sheep (ram/ewe)                  | Kale, leaves | No        | Given the high chronic toxicity of emamectin (ADI = 0.0005 mg/kg bw per day), MRLs in livestock are proposed although the dietary burden is not triggered |
| Swine (all)                 | 0.0002 | 0.0002   | 0.01   | 0.01     | Swine (breeding)                 | Kale, leaves | No        | Given the high chronic toxicity of emamectin (ADI = 0.0005 mg/kg bw per day), MRLs in livestock are proposed although the dietary burden is not triggered |
| Poultry (all)               | 0.0002 | 0.0002   | 0.00   | 0.00     | Poultry (turkey)                 | Cotton, meal | No        | Given the high chronic toxicity of emamectin (ADI = 0.0005 mg/kg bw per day), MRLs in livestock are proposed although the dietary burden is not triggered |
| Poultry (layer only)        | 0.0001 | 0.0001   | 0.00   | 0.00     | Poultry (layer)                  | Cabbage, heads, leaves | No        | Given the high chronic toxicity of emamectin (ADI = 0.0005 mg/kg bw per day), MRLs in livestock are proposed although the dietary burden is not triggered |

bw: body weight; DM: dry matter; ADI: acceptable daily intake; MRL: maximum residue level.

<sup>a</sup> When one group of livestock includes several subgroups (e.g. poultry 'all' including broiler, layer and turkey), the result of the most critical subgroup is identified from the maximum dietary burdens expressed as 'mg/kg bw per day'.

<sup>b</sup> The most critical commodity is the major contributor identified from the maximum dietary burden expressed as 'mg/kg bw per day'.
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 bw per day) | Duration (days) | Comment/Source                                                                                                                                 |
|-------------------------------|-------------------------|--------------------------|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------|
|                               | Lactating goat          | 0.5                      | 7               | 700N compared to the maximum dietary burden calculated for cattle (dairy and all diets). [5-3H]-emamectin (Netherlands, 2018)          |
|                               |                         | 0.66                     | 7               | 940N compared to the maximum dietary burden calculated for cattle (dairy and all diets). [5-3H]/[25-14C]-emamectin (Netherlands, 2018) |

Time needed to reach a plateau concentration in milk and eggs (days)
Metabolism in rat and ruminant similar

Can a general residue definition be proposed for animals?

Animal residue definition for monitoring (RD-Mo):
Ruminants and swine: emamectin B1a and its salts, expressed as emamectin B1a (free base)

Animal residue definition for risk assessment (RD-RA):
Ruminants and swine: emamectin B1a and its salts, expressed as emamectin B1a (free base)

Fat soluble residues

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

| Method                                      | Matrix groups                          | LOQ (mg/kg)            | Comment/Source                                                                 |
|---------------------------------------------|----------------------------------------|-------------------------|------------------------------------------------------------------------------|
| Single Residue Method LC/LC–MS/MS           |                                        | 0.001                   | Feeding study with dairy cows (Netherlands, 2018)                             |
| Confirmatory method (or to monitor a second transition in MRM), and ILV missing (data gap) |                                        |                         |                                                                               |
| LC-AFS for enforcement emamectin B1a benzoate (determined as free base) in muscle in routine analysis, LOQ 0.01 mg/kg (EURL, 2018) |                                        |                         |                                                                               |

bw: body weight; LC/LC - MS/MS: liquid chromatography/liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; ILV: independent laboratory validation.
## B.2.1.2. Stability of residues in livestock

| Animal products (available studies) | Animal | Commodity | T (°C) | Stability period Value | Stability period Unit | Compounds covered | Comment/Source |
|-------------------------------------|--------|-----------|--------|------------------------|-----------------------|------------------|----------------|
| Bovine All tissues                  | Bovine | All tissues |       |                        |                       |                  | Not available (data gap) |
| Bovine Milk                         | Bovine | Milk       |       |                        |                       |                  | Not available (data gap) |
| Poultry Eggs                        | Poultry| Eggs       |       |                        |                       |                  | Not available and not required |

## B.2.2. Magnitude of residues in livestock

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

| Animal commodity | Residues at the closest feeding level (mg/kg) | Estimated value at 1N MRL proposal (mg/kg) |
|------------------|----------------------------------------------|------------------------------------------|
|                  | Mean  | Highest | STMR<sub>M0</sub><sup>(a)</sup> (mg/kg) | HRMO<sub>M0</sub><sup>(b)</sup> (mg/kg) |
| Cattle (all) – Closest feeding level (0.0012 mg/kg bw; 1.7 N rate)<sup>(c)</sup> | | | |
| Muscle           | < 0.001 | < 0.002 | 0.001 | 0.001 | 0.001* (tentative)<sup>(f)</sup> |
| Fat              | < 0.002 | 0.002  | 0.001 | 0.001 | 0.001* (tentative)<sup>(f)</sup> |
| Liver            | 0.009  | 0.010  | 0.004 | 0.006 | 0.006 (tentative)<sup>(f)</sup> |
| Kidney           | 0.004  | 0.004  | 0.002 | 0.002 | 0.002 (tentative)<sup>(f)</sup> |
| Cattle (dairy only) – Closest feeding level (0.0012 mg/kg bw; 1.7 N rate)<sup>(c)</sup> | | | |
| Milk<sup>(d)</sup> | 0.0005 | n.a.   | 0.001 | 0.001 | 0.001* (tentative)<sup>(f)</sup> |
| Sheep (all)<sup>(e)</sup> – Closest feeding level (0.0012 mg/kg bw; 2.4 N rate)<sup>(c)</sup> | | | |
| Muscle           | < 0.001 | < 0.002 | 0.001 | 0.001 | 0.001* (tentative)<sup>(f)</sup> |
| Fat              | < 0.002 | 0.002  | 0.001 | 0.001 | 0.001* (tentative)<sup>(f)</sup> |
| Liver            | 0.009  | 0.010  | 0.002 | 0.004 | 0.004 (tentative)<sup>(f)</sup> |
| Kidney           | 0.004  | 0.004  | 0.001 | 0.002 | 0.002 (tentative)<sup>(f)</sup> |
| Sheep (ewe only)<sup>(e)</sup> – Closest feeding level (0.0012 mg/kg bw; 3 N rate)<sup>(c)</sup> | | | |
| Milk<sup>(e)</sup> | 0.0005 | n.a.   | 0.001 | 0.001 | 0.001* (tentative)<sup>(f)</sup> |
| Swine (all)<sup>(e)</sup> – Closest feeding level (0.0012 mg/kg bw; 6 N rate)<sup>(c)</sup> | | | |
| Muscle           | < 0.001 | < 0.002 | 0.001 | 0.001 | 0.001* (tentative)<sup>(f)</sup> |
| Fat              | < 0.002 | 0.002  | 0.001 | 0.001 | 0.001* (tentative)<sup>(f)</sup> |
| Liver            | 0.009  | 0.010  | 0.001 | 0.002 | 0.002 (tentative)<sup>(f)</sup> |
| Kidney           | 0.004  | 0.004  | 0.001 | 0.001 | 0.001* (tentative)<sup>(f)</sup> |
| Poultry (all) – No study available and not required | | | |
| Muscle           | –     | –      | –     | –     | – |
| Fat              | –     | –      | –     | –     | – |
| Liver            | –     | –      | –     | –     | – |
| Poultry (layer only) – No study available and not required | | | |
| Eggs             | –     | –      | –     | –     | – |

n.a.: not applicable; MRL: maximum residue level; bw: body weight.

(a): Median residues expressed according to the residue definition for monitoring, recalculated at the 1N rate for the median dietary burden.

(b): Highest residues expressed according to the residue definition for monitoring, recalculated at the 1N rate for the maximum dietary burden.

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

(d): For milk, mean was derived from samplings performed from day 10 to day 27 (daily mean of 3 cows).

(e): Since extrapolation from cattle to other ruminants and swine is acceptable, results of the livestock feeding study on ruminants were relied upon to derive the MRL and risk assessment values in sheep and swine.

(f): Tentative MRL in the absence of sufficiently validated analytical method and storage stability studies.
B.3. Consumer risk assessment

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

| ARfD                  | 0.01 mg/kg bw (EFSA, 2012) |
|-----------------------|---------------------------|
| Highest IESTI, according to EFSA PRIMo (rev.2) | **Scenario EU1 (without risk mitigation measures):** Lettuce: 218% of ARfD Escarole (broad-leaved endives): 102% of ARfD **Scenario EU2 (with risk mitigation measures):** lettuce: 40% of ARfD |
| NESTI (% ARfD)        | Not assessed in this review |
| Assumptions made for the calculations | **Scenario EU1 (without risk mitigation measures):** The calculation is based on the highest residue levels expected in raw agricultural commodities, except for citrus fruits and cucurbits with inedible peel for which a peeling factor was applied, multiplied by the conversion factors for risk assessment For those commodities where data were insufficient to derive an MRL, EFSA considered the existing EU MRL multiplied by the highest CF of the corresponding metabolism group, for an indicative calculation **Scenario EU2 (with risk mitigation measures):** Fall back GAPs were considered for lettuces and escaroles. Consideration of these less critical GAPs does not impact on the residue levels in livestock commodities. Therefore, all other input values remain unchanged |
| ADI                   | 0.0005 mg/kg bw per day (EFSA, 2012) |
| TMDI according to EFSA PRIMo | Not assessed in this review |
| NTMDI, according to (to be specified) | Not assessed in this review |
| Highest IEDI, according to EFSA PRIMo (rev.2) | **Scenario EU1 (without risk mitigation measures):** 28% ADI (ES adult) **Scenario EU2 (with risk mitigation measures):** 17% ADI (DE child) |
| NEDI (% ADI)          | Not assessed in this review |
| Assumptions made for the calculations | **Scenario EU1 (without risk mitigation measures):** The calculation is based on the median residue levels derived for raw agricultural commodities, multiplied by the conversion factors for risk assessment, except for citrus fruits and cucurbits with inedible peel for which a peeling factor was applied For those commodities where data were insufficient to derive an MRL, EFSA considered the existing EU MRL multiplied by the highest CF of the corresponding metabolism group, for an indicative calculation The contributions of commodities where no GAP was reported in the framework of the MRL review were not included in the calculation **Scenario EU2 (with risk mitigation measures):** Fall back GAPs were considered for lettuces and escaroles. Consideration of these less critical GAPs does not impact on the residue levels in livestock commodities. Therefore, all other input values remain unchanged |
Consumer exposure assessment through drinking water resulting from groundwater metabolite(s) according to SANCO/221/2000 rev.10 Final (25/02/2003)

| Metabolite(s) | Not assessed in this review |
|---------------|----------------------------|
| ADI (mg/kg bw per day) | Not assessed in this review |
| Intake of groundwater metabolites (% ADI) | Not assessed in this review |

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

| ARfD | 0.01 mg/kg bw (EFSA, 2012) |
|------|----------------------------|
| Highest IESTI, according to EFSA PRIMo (rev.2) |
| Scenario CX1: lettuce: 117% of ARfD |
| Scenario CX2: Chinese cabbage: 54% of ARfD |
| NESTI (% ARfD) | Not assessed in this review |
| Assumptions made for the calculations |
| Scenario CX1: For those commodities having a CXL higher than the EU MRL proposal, highest residue levels applied in the second EU scenario were replaced by the highest residue levels derived by JMPR, multiplied by the conversion factors for risk assessment. The HR values for muscle and derived by JMPR were used to calculate the input values for meat considering that emamectin is fat soluble. |
| Scenario CX2: CXLs that may pose an acute risk to European consumers (lettuce) were disregarded from the assessment and, where available, the input values according to the second EU scenario were applied (see Scenario EU2) |

ADfD: acute reference dose; bw: body weight; NESTI: national estimated short-term intake; PRIMo: (EFSA) Pesticide Residues Intake Model; WHO: World Health Organization; IESTI: international estimated short-term intake; CXL: codex maximum residue limit; MRL: maximum residue level; HR: highest residue.

| ADI | 0.0005 mg/kg bw per day (EFSA, 2012) |
|-----|-------------------------------------|
| TMDI according to EFSA PRIMo | Not assessed in this review |
| NTMDI, according to (to be specified) | Not assessed in this review |
| Highest IEDI, according to EFSA PRIMo (rev.2) |
| Scenario CX1: 19% ADI (DE child) |
| Scenario CX2: 19% ADI (DE child) |
| NEDI (% ADI) | Not assessed in this review |
| Assumptions made for the calculations |
| Scenario CX1: 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, multiplied by the conversion factors for risk assessment. The STMR values for muscle and derived by JMPR were used to calculate the input values for meat considering that emamectin is fat soluble. |
| Scenario CX2: CXLs that may pose an acute risk to European consumers (lettuce) were disregarded from the assessment and, where available, the input values according to the second EU scenario were applied (see above) |

ADI: acceptable daily intake; bw: body weight; NEDI: national estimated daily intake; PRIMo: (EFSA) Pesticide Residues Intake Model; WHO: World Health Organization; TMDI: theoretical intake; CXL: codex maximum residue limit; MRL: maximum residue level; STMR: supervised trials median residue.
### B.4. Proposed MRLs

Table B.1: Summary table

| Code number | Commodity             | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review MRL (mg/kg) | Comment                                      |
|-------------|-----------------------|-------------------------|----------------------|-----------------------------------|---------------------------------------------|
| 110020      | Oranges               | 0.01*                   | –                    | 0.003                             | Further consideration needed<sup>(b)</sup>  |
| 110030      | Lemons                | 0.01*                   | –                    | 0.003                             | Further consideration needed<sup>(b)</sup>  |
| 110050      | Mandarins             | 0.01*                   | –                    | 0.003                             | Further consideration needed<sup>(b)</sup>  |
| 120010      | Almonds               | 0.01*                   | 0.001*               | 0.001*                            | Further consideration needed<sup>(b)</sup>  |
| 120020      | Brazil nuts           | 0.01*                   | 0.001*               | 0.001*                            | Further consideration needed<sup>(b)</sup>  |
| 120040      | Chestnuts             | 0.01*                   | 0.001*               | 0.001*                            | Further consideration needed<sup>(b)</sup>  |
| 120050      | Coconuts              | 0.01*                   | 0.001*               | 0.001*                            | Further consideration needed<sup>(b)</sup>  |
| 120060      | Hazelnuts             | 0.01*                   | 0.001*               | 0.001*                            | Further consideration needed<sup>(b)</sup>  |
| 120070      | Macadamia             | 0.01*                   | 0.001*               | 0.001*                            | Further consideration needed<sup>(b)</sup>  |
| 120080      | Pecans                | 0.01*                   | 0.001*               | 0.001*                            | Further consideration needed<sup>(b)</sup>  |
| 120090      | Pine nuts             | 0.01*                   | 0.001*               | 0.001*                            | Further consideration needed<sup>(b)</sup>  |
| 120100      | Pistachios            | 0.01*                   | 0.001*               | 0.001*                            | Further consideration needed<sup>(b)</sup>  |
| 120110      | Walnuts               | 0.01*                   | 0.001*               | 0.001*                            | Further consideration needed<sup>(b)</sup>  |
| 130010      | Apples                | 0.02                    | 0.02                 | 0.02                              | Recommended<sup>(d)</sup>                    |
| 130020      | Pears                 | 0.02                    | 0.02                 | 0.02                              | Recommended<sup>(d)</sup>                    |
| 130030      | Quinces               | 0.02                    | 0.02                 | 0.02                              | Recommended<sup>(e)</sup>                    |
| 130040      | Medlars               | 0.02                    | 0.02                 | 0.02                              | Recommended<sup>(e)</sup>                    |
| 130050      | Loquats/Japanese medlars | 0.02                 | 0.02                 | 0.02                              | Recommended<sup>(e)</sup>                    |
| 140010      | Apricots              | 0.02                    | –                    | 0.06                              | Further consideration needed<sup>(b)</sup>  |
| 140030      | Peaches               | 0.03                    | 0.03                 | 0.03                              | Recommended<sup>(d)</sup>                    |
| 140040      | Plums                 | 0.02                    | –                    | 0.015                             | Recommended<sup>(f)</sup>                    |
| 151010      | Table grapes          | 0.05                    | 0.03                 | 0.04                              | Further consideration needed<sup>(c)</sup>  |
| 151020      | Wine grapes           | 0.05                    | 0.03                 | 0.04                              | Further consideration needed<sup>(c)</sup>  |
| 152000      | Strawberries          | 0.05                    | –                    | 0.05                              | Further consideration needed<sup>(c)</sup>  |
| 211000      | Potatoes              | 0.01*                   | –                    | 0.001*                            | Recommended<sup>(f)</sup>                    |
| 231010      | Tomatoes              | 0.02                    | 0.02                 | 0.02                              | Recommended<sup>(d)</sup>                    |
| 231020      | Sweet peppers/bell peppers | 0.02                | 0.02                 | 0.02                              | Recommended<sup>(g)</sup>                    |
| 231030      | Aubergines/eggplants  | 0.02                    | 0.02                 | 0.02                              | Recommended<sup>(g)</sup>                    |
| 231040      | Okra, lady's fingers  | 0.02                    | 0.02                 | 0.02                              | Recommended<sup>(h)</sup>                    |
| 232010      | Cucumbers             | 0.01*                   | 0.007                | 0.007                             | Recommended<sup>(d)</sup>                    |
| 232020      | Gherkins              | 0.01*                   | 0.007                | 0.007                             | Recommended<sup>(d)</sup>                    |
| 232030      | Courgettes            | 0.01*                   | 0.007                | 0.007                             | Recommended<sup>(d)</sup>                    |
| 233010      | Melons                | 0.01*                   | 0.007                | 0.008                             | Recommended<sup>(g)</sup>                    |
| 233020      | Pumpkins              | 0.01*                   | 0.007                | 0.008                             | Further consideration needed<sup>(c)</sup>  |
| 233030      | Watermelons           | 0.01*                   | 0.007                | 0.008                             | Recommended<sup>(g)</sup>                    |
| 241010      | Broccoli              | 0.01*                   | –                    | 0.003                             | Recommended<sup>(f)</sup>                    |
| 241020      | Cauliflowers          | 0.01*                   | –                    | 0.003                             | Recommended<sup>(f)</sup>                    |
| 242010      | Brussels sprouts      | 0.01*                   | –                    | 0.004                             | Recommended<sup>(f)</sup>                    |
| 242020      | Head cabbages         | 0.01*                   | –                    | 0.004                             | Recommended<sup>(f)</sup>                    |
| 243010      | Chinese cabbages/pe-tsai | 0.03                 | 0.2                  | 0.2                               | Recommended<sup>(d)</sup>                    |
| 243020      | Kales                 | 0.03                    | –                    | 0.03                              | Recommended<sup>(f)</sup>                    |
## Review of the existing MRLs for emamectin

| Code number | Commodity                                      | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review | Comment |
|-------------|------------------------------------------------|-------------------------|----------------------|-----------------------|---------|
| 244000      | Kohlrabies                                      | 0.01*                   | –                    | 0.01                  | Further consideration needed<sup>(i)</sup> |
| 251010      | Lamb's lettuces/corn salads                     | 1                       | –                    | 0.6                   | Recommended<sup>(f)</sup>             |
| 251020      | Lettuces                                        | 1                       | 0.7                  | 0.2                   | Recommended<sup>(i)</sup>             |
| 251030      | Scarole (broad-leaf endive)                     | 0.2                     | –                    | 0.15                  | Further consideration needed<sup>(a)</sup> |
| 251040      | Cresses and other sprouts and shoots            | 1                       | –                    | 0.6                   | Recommended<sup>(f)</sup>             |
| 251050      | Land cresses                                    | 1                       | –                    | 0.6                   | Recommended<sup>(f)</sup>             |
| 251060      | Roman rocket/rucola                             | 1                       | –                    | 0.6                   | Recommended<sup>(f)</sup>             |
| 251070      | Red mustards                                    | 1                       | –                    | 0.6                   | Recommended<sup>(f)</sup>             |
| 251080      | Baby leaf crops (including brassica species)    | 1                       | –                    | 0.6                   | Recommended<sup>(f)</sup>             |
| 254000      | Watercresses                                    | 0.01*                   | –                    | 0.6                   | Recommended<sup>(f)</sup>             |
| 256010      | Chervil                                         | 1                       | –                    | 0.2                   | Recommended<sup>(f)</sup>             |
| 256020      | Chives                                          | 1                       | –                    | 0.2                   | Recommended<sup>(f)</sup>             |
| 256030      | Celery leaves                                   | 1                       | –                    | 0.2                   | Recommended<sup>(f)</sup>             |
| 256040      | Parsley                                         | 1                       | –                    | 0.2                   | Recommended<sup>(f)</sup>             |
| 256050      | Sage                                            | 1                       | –                    | 0.6                   | Recommended<sup>(f)</sup>             |
| 256060      | Rosemary                                        | 1                       | –                    | 0.2                   | Recommended<sup>(f)</sup>             |
| 256070      | Thyme                                           | 1                       | –                    | 0.2                   | Recommended<sup>(f)</sup>             |
| 256080      | Basil and edible flowers                        | 1                       | –                    | 0.2                   | Recommended<sup>(f)</sup>             |
| 256090      | Laurel/bay leave                                | 1                       | –                    | 0.2                   | Recommended<sup>(f)</sup>             |
| 256100      | Tarragon                                        | 1                       | –                    | 0.2                   | Recommended<sup>(f)</sup>             |
| 260010      | Beans (with pods)                               | 0.03                    | 0.015                | 0.03                  | Recommended<sup>(g)</sup>             |
| 260020      | Beans (without pods)                            | 0.01*                   | 0.015                | 0.015                | Recommended<sup>(g)</sup>             |
| 260030      | Peas (with pods)                                | 0.03                    | –                    | 0.03                  | Recommended<sup>(f)</sup>             |
| 260040      | Peas (without pods)                             | 0.01*                   | –                    | 0.001*               | Recommended<sup>(f)</sup>             |
| 270050      | Globe artichokes                                | 0.1                     | –                    | 0.09                  | Recommended<sup>(f)</sup>             |
| 401060      | Rape seed                                       | 0.01*                   | 0.005*               | 0.005*               | Further consideration needed<sup>(k)</sup> |
| 401090      | Cotton seeds                                    | 0.01*                   | 0.002*               | 0.01                 | Further consideration needed<sup>(l)</sup> |
| 1011101     | Swine muscle                                    | 0.01*                   | 0.004                | 0.004                | Further consideration needed<sup>(m)</sup> |
| 1011102     | Swine fat tissue                                | 0.02                    | 0.02                 | 0.02                 | Further consideration needed<sup>(m)</sup> |
| 1011103     | Swine liver                                     | 0.08                    | 0.08                 | 0.08                 | Further consideration needed<sup>(m)</sup> |
| 1011104     | Swine kidney                                    | 0.08                    | 0.08                 | 0.08                 | Further consideration needed<sup>(m)</sup> |
| 1012010     | Bovine muscle                                   | 0.01*                   | 0.004                | 0.004                | Further consideration needed<sup>(m)</sup> |
| 1012020     | Bovine fat tissue                               | 0.02                    | 0.02                 | 0.02                 | Further consideration needed<sup>(m)</sup> |
| 1012030     | Bovine liver                                    | 0.08                    | 0.08                 | 0.08                 | Further consideration needed<sup>(m)</sup> |
| 1012040     | Bovine kidney                                   | 0.08                    | 0.08                 | 0.08                 | Further consideration needed<sup>(m)</sup> |
| 1013010     | Sheep muscle                                    | 0.01*                   | 0.004                | 0.004                | Further consideration needed<sup>(m)</sup> |
| 1013020     | Sheep fat tissue                                | 0.02                    | 0.02                 | 0.02                 | Further consideration needed<sup>(m)</sup> |
| 1013030     | Sheep liver                                     | 0.08                    | 0.08                 | 0.08                 | Further consideration needed<sup>(m)</sup> |
| 1013040     | Sheep kidney                                    | 0.08                    | 0.08                 | 0.08                 | Further consideration needed<sup>(m)</sup> |
| 1014010     | Goat muscle                                     | 0.01*                   | 0.004                | 0.004                | Further consideration needed<sup>(m)</sup> |
| 1014020     | Goat fat tissue                                 | 0.02                    | 0.02                 | 0.02                 | Further consideration needed<sup>(m)</sup> |
| 1014030     | Goat liver                                      | 0.08                    | 0.08                 | 0.08                 | Further consideration needed<sup>(m)</sup> |
| 1014040     | Goat kidney                                     | 0.08                    | 0.08                 | 0.08                 | Further consideration needed<sup>(m)</sup> |
| 1015010     | Equine muscle                                   | 0.01*                   | 0.004                | 0.004                | Further consideration needed<sup>(m)</sup> |
| 1015020     | Equine fat tissue                               | 0.02                    | 0.02                 | 0.02                 | Further consideration needed<sup>(m)</sup> |
| 1015030     | Equine liver                                    | 0.08                    | 0.08                 | 0.08                 | Further consideration needed<sup>(m)</sup> |
| Code number | Commodity            | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review                                                                 |
|------------|----------------------|-------------------------|----------------------|---------------------------------------------------------------------------------------|
| 1015040    | Equine kidney        | 0.08                    | 0.08                 | Further consideration needed(m)                                                       |
| 1020010    | Cattle milk          | 0.01*                   | 0.002                | Further consideration needed(m)                                                       |
| 1020020    | Sheep milk           | 0.01*                   | 0.002                | Further consideration needed(m)                                                       |
| 1020030    | Goat milk            | 0.01*                   | 0.002                | Further consideration needed(m)                                                       |
| 1020040    | Horse milk           | 0.01*                   | 0.002                | Further consideration needed(m)                                                       |
| –          | Other commodities of plant and/or animal origin | See Reg. 2018/1514 | –                    | Further consideration needed(n)                                                       |

MRL: maximum residue level; CXL: codex maximum residue limit.
*: Indicates that the MRL is set at the limit of quantification.

(F): The residue definition is fat soluble.
(a): 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 existing residue definition); no CXL is available (combination F-I in Appendix E).
(b): 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 existing residue definition); there are no relevant authorisations or import tolerances reported at EU level (combination A-V in Appendix E).
(c): 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 existing residue definition); existing CXL is covered by the tentative MRL (combination F-III in Appendix E).
(d): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level, which is also fully supported by data, leads to a lower MRL (combination H-VII in Appendix E).
(e): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level, which is not fully supported by data, leads to a lower tentative MRL (combination F-VII in Appendix E).
(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 H-I in Appendix E).
(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; existing CXL is covered by the recommended MRL (combination H-III in Appendix E).
(h): 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 E).
(i): GAP evaluated at EU level is not supported by data but no risk to consumers was identified for the existing EU MRL (also assuming the existing residue definition); no CXL is available (combination D-I in Appendix E).
(j): 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 H-VI in Appendix E).
(k): 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 existing residue definition); there are no relevant authorisations or import tolerances reported at EU level (combination A-V in Appendix E).
(l): GAP evaluated at EU level is not supported by data but no risk to consumers was identified for the existing EU MRL (also assuming the existing residue definition); existing CXL is covered by the existing EU MRL (combination D-III in Appendix E).
(m): 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 existing residue definition); GAP evaluated at EU level, which is also not fully supported by data, would lead to a lower tentative MRL (combination F-V in Appendix E).
(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 E).
Appendix C – Pesticide Residue Intake Model (PRiMo)

- PRiMo(EU1)

| Emamectin |
|-----------------|-----------------|-----------------|
| Status of the active substance: | Approved | Code no. |
| LOQ (mg/kg bw): | Proposed LOQ: | |
| Toxicological end points |
| ADI (mg/kg bw per day): | 0.0005 | ARfD (mg/kg bw): |
| Source of ADI: | EFSA | Source of ARfD: |
| Year of evaluation: | 2012 | Year of evaluation: |

### Chronic risk assessment – refined calculations

| Commodity/group of commodities | 1st contributor to MS diet | 2nd contributor to MS diet | 3rd contributor to MS diet | Commodity/group of commodities | pTMRLs at LOQ (in % of ADI) |
|--------------------------------|---------------------------|---------------------------|---------------------------|--------------------------------|---------------------------|
| Tomatoes                        | 0.5                       | 0.7                       | 1.0                       | Milk and cream                 |                           |
| Herbs                          | 1.7                       | 1.0                       | 0.8                       |                                |                           |
| Lettuce                        | 0.8                       | 0.9                       | 0.8                       | Milk and cream                 |                           |
| Milk and cream                 | 1.0                       | 1.2                       | 1.3                       |                                |                           |
| Apples                         | 3.3                       | 1.3                       | 1.2                       |                                |                           |
| Beer (w/ pods)                 | 0.8                       | 0.8                       | 0.8                       |                                |                           |
| Wine grapes                    | 0.9                       | 0.9                       | 0.9                       |                                |                           |
| Scarelle (bread-leaf endive)   | 0.7                       | 0.7                       | 0.7                       |                                |                           |
| Potatoes                       | 1.0                       | 1.0                       | 1.0                       |                                |                           |
| Beans (with pods)              | 1.2                       | 1.2                       | 1.2                       |                                |                           |
| Water cress                    | 0.6                       | 0.6                       | 0.6                       |                                |                           |

### Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI. A long-term intake of residues of emamectin is unlikely to present a public health concern.

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The acute risk assessment is based on the ARfD.

For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS, an average unit weight was used for the IESTI calculation.

In the IESTI 1 calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002); for lettuce, a variability factor of 5 was used.

In the IESTI 2 calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variability factor of 3.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

| Commodities                  | pTMRL/Threshold MRL (mg/kg) | Highest % of ARfD/ADI | Commodity |
|------------------------------|-----------------------------|-----------------------|-----------|
| Lettuce                      | 0.8118/0.37                 | 218.4                 | Lettuce   |
| Scarole (broad-leaf)         | 0.11616/0.11                | 101.6                 | Scarole   |
| Table grapes                 | 0.002134/-                  | 14.0                  | Table    |
| Rocket, Rucola               | 0.40656/-                   | 12.6                  | Rocket,  Rucola |
| Lamb's lettuce               | 0.40656/-                   | 11.4                  | Lamb's lettuce |
| Grape juice                  | 0.02134/-                   | 7.0                   | Grape    |
| Apple juice                  | 0.007/-                     | 3.6                   | Apple    |
| Tomato juice                 | 0.0086/-                    | 1.5                   | Tomato   |
| Orange juice                 | 0.00286/-                   | 1.4                   | Orange   |
| Peach juice                  | 0.007/-                     | 1.3                   | Peach    |
| Wine                         | 0.02134/-                   | 0.8                   | Wine     |
| Apple juice                  | 0.007/-                     | 0.5                   | Apple    |
| Orange juice                 | 0.00286/-                   | 0.3                   | Orange   |
| Peach preserved with         | 0.007/-                     | 0.1                   | Peach    |

No of critical MRLs (IESTI 1): 2

No of critical MRLs (IESTI 2): 2

No of commodities for which ARfD/ADI is exceeded: --

No of commodities for which ARfD/ADI is exceeded (IESTI 1): --

No of commodities for which ARfD/ADI is exceeded (IESTI 2): --

Conclusion:

For emamectin, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.

The estimated short-term intake (ESTI 1) exceeded the ARfD/ADI for 2 commodities. Also, the IESTI 2 calculation, using less conservative variability factors, resulted in exceedances of the ARfD/ADI for 2 commodities.

No exceedance of the ARfD/ADI was identified for processed commodities.
### Emamectin

**Status of the active substance:**
- Approved
- Code no.

**LOQ (mg/kg bw):**
- Proposed LOQ: 0.0005

**ADI (mg/kg bw per day):**
- 0.0005

**ARfD (mg/kg bw):**
- 0.01

**Source of ADI:**
- EFSA

**Source of ARfD:**
- EFSA

**Year of evaluation:**
- 2012

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### Chronic risk assessment – refined calculations

#### TMDI (range) in % of ADI

| Commodity/group of commodities | Minimum – Maximum |
|--------------------------------|-------------------|
| Herbs                         | 0.6               |
| Tomatoes                      | 0.6               |
| Wine grapes                   | 0.6               |
| Water cress                   | 1.0               |
| Potatoes                      | 0.6               |
| Milk and cream                | 0.6               |
| Burgundy raisins              | 0.6               |
| Tomatoes                      | 0.6               |
| Milk and cream                | 0.6               |
| Milk and cream                | 0.6               |
| Tomatoes                      | 0.6               |
| Potatoes                      | 0.6               |
| Milk and cream                | 0.6               |
| Milk and cream                | 0.6               |
| Tomatoes                      | 0.6               |
| Potatoes                      | 0.6               |
| Milk and cream                | 0.6               |
| Milk and cream                | 0.6               |
| Tomatoes                      | 0.6               |
| Potatoes                      | 0.6               |
| Milk and cream                | 0.6               |
| Milk and cream                | 0.6               |
| Tomatoes                      | 0.6               |
| Potatoes                      | 0.6               |
| Milk and cream                | 0.6               |
| Milk and cream                | 0.6               |
| Tomatoes                      | 0.6               |
| Potatoes                      | 0.6               |
| Milk and cream                | 0.6               |
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| Tomatoes                      | 0.6               |
| Potatoes                      | 0.6               |
| Milk and cream                | 0.6               |
| Milk and cream                | 0.6               |
| Tomatoes                      | 0.6               |
| Potatoes                      | 0.6               |
| Milk and cream                | 0.6               |
| Milk and cream                | 0.6               |
| Tomatoes                      | 0.6               |
| Potatoes                      | 0.6               |
| Milk and cream                | 0.6               |
| Milk and cream                | 0.6               |
| Tomatoes                      | 0.6               |
| Potatoes                      | 0.6               |
| Milk and cream                | 0.6               |
| Milk and cream                | 0.6               |
| Tomatoes                      | 0.6               |
| Potatoes                      | 0.6               |
| Milk and cream                | 0.6               |
| Milk and cream                | 0.6               |
| Tomatoes                      | 0.6               |
| Potatoes                      | 0.6               |
| Milk and cream                | 0.6               |
| Milk and cream                | 0.6               |
| Tomatoes                      | 0.6               |
| Potatoes                      | 0.6               |
| Milk and cream                | 0.6               |

#### Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI. A long-term intake of residues of emamectin is unlikely to present a public health concern.
The acute risk assessment is based on the ARfD. For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS, an average European unit weight was used for the IESTI calculation.

In the IESTI 1 calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002); for lettuce, a variability factor of 5 was used.

In the IESTI 2 calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variability factor of 3.

Threshold MRLs are the calculated residue levels which would lead to an exposure equivalent to 100% of the ARfD.

| No of commodities for which ARfD/ADI is exceeded (IESTI 1): | --- | No of commodities for which ARfD/ADI is exceeded (IESTI 2): | --- |
| --- | --- | --- | --- |
| IESTI 1 | IESTI 2 | IESTI 1 | IESTI 2 |

| Highest % of ARfD/ADI | Commodities | pTMRL/ threshold MRL (mg/kg) | Highest % of ARfD/ADI | Commodities | pTMRL/ threshold MRL (mg/kg) | Highest % of ARfD/ADI | Commodities | pTMRL/ threshold MRL (mg/kg) | Highest % of ARfD/ADI | Commodities | pTMRL/ threshold MRL (mg/kg) |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 14.0 | Table grapes | 0.02134/- | 14.0 | Table grapes | 0.02134/- | 7.8 | Lamb’s lettuce | 0.04065/- | 7.8 | Lamb’s lettuce | 0.04065/- |
| 12.6 | Rocket, Rucola | 0.04065/- | 12.6 | Rocket, Rucola | 0.04065/- | 6.8 | Table grapes | 0.02134/- | 6.8 | Table grapes | 0.02134/- |
| 11.4 | Lamb’s lettuce | 0.04065/- | 11.4 | Lamb’s lettuce | 0.04065/- | 5.1 | Wine grapes | 0.02134/- | 5.1 | Wine grapes | 0.02134/- |
| 8.5 | Globe artichokes | 0.04238/- | 7.5 | Kohlrabi | 0.015/- | 4.5 | Globe artichokes | 0.04238/- | 4.4 | Water cress | 0.04065/- |
| 7.5 | Kohlrabi | 0.015/- | 6.9 | Strawberries | 0.04455/- | 3.5 | Chinese cabbage | 0.0007/- |

No of critical MRLs (IESTI 1): --- No of critical MRLs (IESTI 2): ---

Acute risk assessment/children – refined calculations

Review of the existing MRLs for emamectin

For emamectin, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.

No exceedance of the ARfD was identified for any unprocessed commodity.

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

Conclusion:

For emamectin, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.

No exceedance of the ARfD was identified for any unprocessed commodity.

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

No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

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

| Status of the active substance: | Approved |
|------------------------------|----------|
| Code no.                     |          |

| LOQ (mg/kg bw) | Proposed LOQ |
|----------------|--------------|
| 0.0005         | 0.01         |

| Source of ADI: | EFSA |
|----------------|------|
| Source of ARfD:| EFSA |

| Year of evaluation: | 2012 |
|---------------------|------|
| Year of evaluation: | 2012 |

### Chronic risk assessment – refined calculations

#### TMDI (range) in % of ADI

| Commodity/group of commodities | Maximum | Minimum |
|--------------------------------|---------|---------|
| Apples                         | 1.6     | 1.4     |
| Lettuce                        | 2.0     | 1.7     |
| Milk and cream                 | 2.9     | 2.2     |
| Milk and cream                 | 2.3     | 1.3     |
| Apples                         | 0.7     | 0.5     |
| Herbs                          | 1.3     | 0.8     |
| Apples                         | 0.9     | 0.8     |
| Apples                         | 2.3     | 1.3     |
| Apples                         | 0.7     | 0.6     |
| Milk and cream                 | 0.9     | 0.8     |
| Herbs                          | 1.6     | 1.1     |
| Carnotrol                     | 1.8     | 0.8     |
| Milk and cream                 | 1.3     | 0.8     |
| Herbs                          | 1.6     | 0.8     |
| Apples                         | 1.2     | 0.8     |
| Apples                         | 0.9     | 0.4     |
| Milk and cream                 | 1.4     | 0.7     |
| Apples                         | 1.0     | 0.7     |
| Mice and cream                 | 1.7     | 0.8     |
| Herbs                          | 1.3     | 0.8     |
| Apples                         | 1.2     | 0.8     |
| Apples                         | 1.3     | 0.8     |
| Milk and cream                 | 1.0     | 0.7     |
| Apples                         | 0.7     | 0.5     |
| Mice and cream                 | 0.9     | 0.4     |
| Apples                         | 0.5     | 0.4     |
| Milk and cream                 | 0.6     | 0.4     |
| Apples                         | 0.7     | 0.5     |

#### No of diets exceeding ADI:

- 4

#### Highest TMDI values in % of ADI

| Commodity/group of commodities | MS Diet | TMDI values in % of ADI |
|--------------------------------|---------|-------------------------|
| Apples                         | DE child| 22.1                    |
| Lettuce                        | WHO Cluster diet B | 8.2 |
| Milk and cream                 | ES adult | 12.2 |
| Lettuce                        | WHO regional European diet | 8.6 |
| Lettuce                        | ES child | 9.5 |
| Lettuce                        | IT adult | 8.6 |
| Milk and cream                 | FR toddler | 4.0 |
| Lettuce                        | WHO Cluster diet F | 6.8 |
| Lettuce                        | IT kids/toddler | 6.6 |
| Lettuce                        | IE adult | 1.9 |
| Milk and cream                 | WHO Cluster diet E | 2.1 |
| Lettuce                        | DK child | 3.2 |
| Milk and cream                 | WHO Cluster diet D | 2.5 |
| Herbs                          | FR infant | 2.6 |
| Lettuce                        | NL infant | 2.7 |
| Milk and cream                 | UK Infant | 3.9 |
| Milk and cream                 | SE general population 90th percentile | 1.2 |
| Milk and cream                 | FR all population | 2.1 |
| Milk and cream                 | UK Toddler | 2.1 |
| Milk and cream                 | UK vegetarian | 3.2 |
| Wine grapes                    | PT General population | 1.2 |
| Lettuce                        | LT adult | 1.6 |
| Milk and cream                 | UK Adult | 2.7 |
| Lettuce                        | PL general population | 1.8 |
| Milk and cream                 | FL adult | 1.8 |
| Lettuce                        | DK adult | 0.7 |

#### Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI. A long-term intake of residuals of emamectin is unlikely to present a public health concern.
### Acute risk assessment/children – refined calculations

The acute risk assessment is based on the ARfD.

For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS, an average European unit weight was used for the IESTI calculation.

In the IESTI 1 calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002); for lettuce, a variability factor of 5 was used.

In the IESTI 2 calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variability factor of 3.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

| Commodity               | pTMRL/ADI | Highest % of ARfD/ADI | pTMRL/MRL | Consumed p/kg bw | Unit weight kg | IESTI 1 | IESTI 2 |
|-------------------------|-----------|-----------------------|-----------|-----------------|---------------|---------|---------|
| Lettuce                 | 0.495/0.37| 79.9                  | 0.495     |                |               | 1       |         |
| Chinese cabbage         | 0.165/-   | 59.9                  | 0.165     |                |               | 1       |         |
| Table grapes            | 0.02134/- | 61.3                  | 0.02134   |                |               |         |         |
| Chinese cabbage         | 0.165/-   | 32.6                  | 0.165     |                |               |         |         |
| Rocket, Rucola          | 0.40656/- | 12.6                  | 0.40656   |                |               |         |         |
| Lamb’s lettuce          | 0.40656   | 5.1                   | 0.40656   |                |               |         |         |
| Table grapes            | 0.22134   | 6.2                   | 0.22134   |                |               |         |         |
| Table grapes            | 0.02134/- | 6.8                   | 0.02134   |                |               |         |         |
| Wine                     | 0.02134   | 5.1                   | 0.02134   |                |               |         |         |

### Acute risk assessment/adults/general population – refined calculations

| Processed commodities   | pTMRL/ADI | Highest % of ARfD/ADI | pTMRL/MRL | Consumed p/kg bw | Unit weight kg | IESTI 1 | IESTI 2 |
|-------------------------|-----------|-----------------------|-----------|-----------------|---------------|---------|---------|
| Grape juice             | 0.02134   | 0.8                   | 0.02134   |                |               |         |         |
| Apple juice             | 0.0121    | 0.8                   | 0.0121    |                |               |         |         |
| Peach juice             | 0.0154    | 0.3 Peach preserved   | 0.0154    |                |               |         |         |
| Tomato juice            | 0.0143    | 0.3 Orange juice      | 0.0121    |                |               |         |         |
| Pear juice              | 0.0121    | 0.3 Tomato (preserved)| 0.0143    |                |               |         |         |

Conclusion:

For emamectin, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.

The estimated short-term intake (ESTI 1) exceeded the ARfD for 1 commodities.

Also, the IESTI 2 calculation, using less conservative variability factors, resulted in exceedances of the ARfD for 0 commodities.

For processed commodities, no exceedance of the ARfD was identified.
### Emamectin

**Status of the active substance:** Approved  
**Code no.:**  
**LOQ (mg/kg bw):**  
**Proposed LOQ:**  
**ADI (mg/kg bw per day):** 0.0005  
**ARfD (mg/kg bw):** 0.01  
**Source of ADI:** EFSA  
**Source of ARfD:** EFSA  
**Year of evaluation:** 2012  

### Toxicological end points

| LOQ (mg/kg bw) | Proposed LOQ | ADI (mg/kg bw per day) | ARfD (mg/kg bw) | Source of ADI | Source of ARfD | Year of evaluation |
|----------------|--------------|------------------------|-----------------|---------------|---------------|-------------------|
| 0.0005         |              | 0.01                   |                 | EFSA          | EFSA          | 2012              |

### Chronic risk assessment – refined calculations

| Commodity/group of commodities | Highest calculated TMDI values in % of ADI | No of diets exceeding ADI |
|--------------------------------|-------------------------------------------|---------------------------|
|                                | Minimum – Maximum                         | 2 - 21                    |

| Commodity/group of commodities | 2nd contributor to MS diet | 3rd contributor to MS diet | pTMRLs at LOQ |
|--------------------------------|---------------------------|---------------------------|---------------|
|                                | in % of ADI                | in % of ADI                | in % of ADI    |

| Commodity/group of commodities | 2nd contributor to MS diet | 3rd contributor to MS diet | pTMRLs at LOQ |
|--------------------------------|---------------------------|---------------------------|---------------|
|                                | in % of ADI                | in % of ADI                | in % of ADI    |

**Conclusion:**  
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI. A long-term intake of residues of emamectin is unlikely to present a public health concern.
### Acute risk assessment/children – refined calculations

The acute risk assessment is based on the ARfD.

For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS, an average European unit weight was used for the IESTI calculation.

In the IESTI 1 calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002); for lettuce, a variability factor of 5 was used.

In the IESTI 2 calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variability factor of 3.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

For emamectin, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.

In the IESTI 1 calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002); for lettuce, a variability factor of 5 was used.

In the IESTI 2 calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variability factor of 3.

### Acute risk assessment/adults/general population – refined calculations

| IESTI 1 | IESTI 2 |
|---------|---------|
| No of commodities for which ARfD/ADI is exceeded | No of commodities for which ARfD/ADI is exceeded |
| commodities | commodities |
| ARfD/ADI | ARfD/ADI |
| pTMRL/ | pTMRL/ |
| threshold MRL | threshold MRL |
| (mg/kg) | (mg/kg) |
| --- | --- |
| 0.0121/- | 0.0121/- |
| 0.02134/- | 0.02134/- |
| 0.04065/- | 0.04065/- |
| 0.0143/- | 0.0143/- |
| 0.04065/- | 0.04065/- |
| 0.0154/- | 0.0154/- |
| 0.02134/- | 0.02134/- |
| 0.04065/- | 0.04065/- |
| 0.0154/- | 0.0154/- |
| 0.04065/- | 0.04065/- |
| 0.0154/- | 0.0154/- |
| 0.04065/- | 0.04065/- |

**No exceedance of the ARfD/ADI was identified for any unprocessed commodity.**

### No of critical MRLs (estic 1)

| IESTI 1 | IESTI 2 |
|---------|---------|
| No of commodities for which ARfD/ADI is exceeded | No of commodities for which ARfD/ADI is exceeded |
| pTMRL/ | pTMRL/ |
| threshold MRL | threshold MRL |
| (mg/kg) | (mg/kg) |
| --- | --- |
| 0.0121/- | 0.0121/- |
| 0.02134/- | 0.02134/- |
| 0.04065/- | 0.04065/- |
| 0.0143/- | 0.0143/- |
| 0.04065/- | 0.04065/- |
| 0.0154/- | 0.0154/- |
| 0.02134/- | 0.02134/- |
| 0.04065/- | 0.04065/- |
| 0.0154/- | 0.0154/- |
| 0.04065/- | 0.04065/- |
| 0.0154/- | 0.0154/- |
| 0.04065/- | 0.04065/- |

**No exceedance of the ARfD/ADI was identified for any unprocessed commodity.**

### No of critical MRLs (estic 2)

| IESTI 1 | IESTI 2 |
|---------|---------|
| No of commodities for which ARfD/ADI is exceeded | No of commodities for which ARfD/ADI is exceeded |
| pTMRL/ | pTMRL/ |
| threshold MRL | threshold MRL |
| (mg/kg) | (mg/kg) |
| --- | --- |
| 0.0121/- | 0.0121/- |
| 0.02134/- | 0.02134/- |
| 0.04065/- | 0.04065/- |
| 0.0143/- | 0.0143/- |
| 0.04065/- | 0.04065/- |
| 0.0154/- | 0.0154/- |
| 0.02134/- | 0.02134/- |
| 0.04065/- | 0.04065/- |
| 0.0154/- | 0.0154/- |
| 0.04065/- | 0.04065/- |
| 0.0154/- | 0.0154/- |
| 0.04065/- | 0.04065/- |

**No exceedance of the ARfD/ADI was identified for any unprocessed commodity.**

### Conclusion:

For emamectin, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.

No exceedance of the ARfD was identified for any unprocessed commodity.

For processed commodities, no exceedance of the ARfD was identified.
**Appendix D – Input values for the exposure calculations**

### D.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** | Sum of emamectin B1a, emamectin B1b, 8,9-Z-MAB1a plus 3 times AB1a plus 3 times MFB1a and 3 times FAB1a, expressed as emamectin B1a (free base) |
| Oranges, dried pulp          | 0.011                 | STMR<sub>Mo</sub> x default PF (10)<sup>(a)</sup> x CF (1.1) | 0.011 | STMR<sub>Mo</sub> x default PF (10)<sup>(a)</sup> x CF (1.1) |
| Lemons, dried pulp           | 0.011                 | STMR<sub>Mo</sub> x default PF (10)<sup>(a)</sup> x CF (1.1) | 0.011 | STMR<sub>Mo</sub> x default PF (10)<sup>(a)</sup> x CF (1.1) |
| Mandarins, dried pulp        | 0.011                 | STMR<sub>Mo</sub> x default PF (10)<sup>(a)</sup> x CF (1.1) | 0.011 | STMR<sub>Mo</sub> x default PF (10)<sup>(a)</sup> x CF (1.1) |
| Apple, pomace, wet           | 0.013                 | STMR<sub>Mo</sub> x default PF (5)<sup>(b)</sup> x CF (1) | 0.013 | STMR<sub>Mo</sub> x default PF (5)<sup>(b)</sup> x CF (1) |
| Potato, culls                | 0.001*                | STMR<sub>Mo</sub> x CF (1) | 0.001* | HR<sub>Mo</sub> x CF (1) |
| Potato, process waste        | 0.001*                | STMR<sub>Mo</sub> (b) x CF (1) | 0.001* | STMR<sub>Mo</sub> (b) x CF (1) |
| Potato, dried pulp           | 0.001*                | STMR<sub>Mo</sub> (b) x CF (1) | 0.001* | STMR<sub>Mo</sub> (b) x CF (1) |
| Cabbage, heads, leaves       | 0.002                 | STMR<sub>Mo</sub> x CF (1.5) | 0.003 | HR<sub>Mo</sub> x CF (1.5) |
| Kale, leaves (forage)        | 0.006                 | STMR<sub>Mo</sub> x CF (1) | 0.010 | HR<sub>Mo</sub> x CF (1) |

STMR: supervised trials median residue; HR: highest residue; PF: processing factor; CF: conversion factor; Mo: monitoring.

*(a): In the absence of processing factors supported by data, default the processing factor of was included in the calculation to consider the potential concentration of residues in these commodities.

*(b): For processed commodities of potatoes no default processing factor was applied because residues are expected to be below the LOQ in potato tubers. Concentration of residues in these commodities is therefore not expected.

### D.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 for plant commodities:** | Sum of emamectin B1a, emamectin B1b, 8,9-Z-MAB1a plus 3 times AB1a plus 3 times MFB1a and 3 times FAB1a, expressed as emamectin B1a (free base) |
| Oranges, mandarins and lemons| 0.0007                  | STMR<sub>Mo</sub> x CF (1.10) x PF (0.25) (tentative) | 0.001 | HR<sub>Mo</sub> x CF (1.10) x PF (0.25) (tentative) |
| Walnuts                      | 0.001*                  | STMR<sub>Mo</sub> x CF (1.00) (tentative) | 0.001* | HR<sub>Mo</sub> x CF (1.00) (tentative) |
| Apples and pears             | 0.003                   | STMR<sub>Mo</sub> x CF (1.00) (tentative) | 0.007 | HR<sub>Mo</sub> x CF (1.00) (tentative) |
| Quinces, medlars and loquats | 0.003                   | STMR<sub>Mo</sub> x CF (1.00) (tentative) | 0.007 | HR<sub>Mo</sub> x CF (1.00) (tentative) |
| Apricots                     | 0.001                   | STMR<sub>Mo</sub> x CF (1.00) (tentative) | 0.004 | HR<sub>Mo</sub> x CF (1.00) (tentative) |
| Peaches                      | 0.004                   | STMR<sub>Mo</sub> x CF (1.00) (tentative) | 0.007 | HR<sub>Mo</sub> x CF (1.00) (tentative) |
| Plums                        | 0.002                   | STMR<sub>Mo</sub> x CF (1.10) | 0.010 | HR<sub>Mo</sub> x CF (1.10) |
| Table and wine grapes        | 0.002                   | STMR<sub>Mo</sub> x CF (1.10) (tentative) | 0.021 | HR<sub>Mo</sub> x CF (1.10) (tentative) |
| Strawberries                 | 0.007                   | STMR<sub>Mo</sub> x CF (1.10) (tentative) | 0.034 | HR<sub>Mo</sub> x CF (1.10) (tentative) |
| Potatoes                     | 0.001*                  | STMR<sub>Mo</sub> x CF (1.00) (tentative) | 0.001* | HR<sub>Mo</sub> x CF (1.00) |
| Tomatoes                     | 0.004                   | STMR<sub>Mo</sub> x CF (1.00) | 0.009 | HR<sub>Mo</sub> x CF (1.00) |
| Commodity                        | Chronic risk assessment | Acute risk assessment                                 |
|---------------------------------|-------------------------|-------------------------------------------------------|
|                                 | Input value (mg/kg)      | Comment                                              |
|                                 |                         | Input value (mg/kg)                                  |
|                                 |                         | Comment                                              |
| Sweet peppers/bell peppers      | 0.003                   | STMR$_{Hr}$ × CF (1.00)                              |
|                                 |                         | 0.011                   | HR$_{Hr}$ × CF (1.00)                             |
| Aubergines/eggplants            | 0.002                   | STMR$_{Hr}$ × CF (1.00)                              |
|                                 |                         | 0.004                   | HR$_{Hr}$ × CF (1.00)                             |
| Cucumbers and courgettes        | 0.001                   | STMR$_{Hr}$ × CF (1.00)                              |
|                                 |                         | 0.002                   | HR$_{Hr}$ × CF (1.00)                             |
| Gherkins                        | 0.001                   | STMR$_{Hr}$ × CF (1.00) (tentative)                  |
|                                 |                         | 0.002                   | HR$_{Hr}$ × CF (1.00) (tentative)                |
| Melons and watermelons          | 0.002                   | STMR$_{Hr}$ × CF (1.00) × PF (1.00)                  |
|                                 |                         | 0.004                   | HR$_{Hr}$ × CF (1.00) × PF (1.00)                |
| Pumpkins                        | 0.002                   | STMR$_{Hr}$ × CF (1.00) (tentative)                  |
|                                 |                         | 0.004                   | HR$_{Hr}$ × CF (1.00) (tentative)                |
| Broccoli, cauliflowers          | 0.002                   | STMR$_{Hr}$ × CF (1.50)                              |
|                                 |                         | 0.003                   | HR$_{Hr}$ × CF (1.50)                             |
| Brussels sprouts                | 0.001                   | STMR$_{Hr}$ × CF (1.00)                              |
|                                 |                         | 0.002                   | HR$_{Hr}$ × CF (1.00)                             |
| Head cabbages                   | 0.002                   | STMR$_{Hr}$ × CF (1.50)                              |
|                                 |                         | 0.003                   | HR$_{Hr}$ × CF (1.50)                             |
| Kales, Chinese cabbage/pe-tsai  | 0.006                   | STMR$_{Hr}$ × CF (1.00)                              |
|                                 |                         | 0.010                   | HR$_{Hr}$ × CF (1.00)                             |
| Kohlrabies                      | 0.015                   | EU MRL × CF (1.50)                                     |
|                                 |                         | 0.015                   | EU MRL × CF (1.50)                                 |
| Lettuces                        | 0.223                   | Scenario EU1: STMR$_{Hr}$ × CF (1.50)                |
|                                 |                         | 0.812                   | Scenario EU1: HR$_{Hr}$ × CF (1.50)               |
|                                 | 0.042                   | Scenario EU2: STMR$_{Hr}$ × CF (1.50) (a)           |
|                                 |                         | 0.150                   | Scenario EU2: HR$_{Hr}$ × CF (1.50) (a)           |
| Escaroles/broad-leaved endives  | 0.040                   | Scenario EU1: STMR$_{Hr}$ × CF (1.20)                |
|                                 |                         | 0.116                   | Scenario EU1: HR$_{Hr}$ × CF (1.20)               |
|                                 | 0.030                   | Scenario EU2: STMR$_{Hr}$ × CF (1.20) (a) (tentative) |
|                                 |                         | 0.040                   | Scenario EU2: HR$_{Hr}$ × CF (1.20) (a) (tentative) |
| Lambs lettuce/corn salads       | 0.185                   | STMR$_{Hr}$ × CF (1.40)                              |
|                                 |                         | 0.407                   | HR$_{Hr}$ × CF (1.40)                             |
| Cresses and other sprouts and shoots | 0.185                   | STMR$_{Hr}$ × CF (1.40)                              |
|                                 |                         | 0.407                   | HR$_{Hr}$ × CF (1.40)                             |
| Land cresses                    | 0.185                   | STMR$_{Hr}$ × CF (1.40)                              |
|                                 |                         | 0.407                   | HR$_{Hr}$ × CF (1.40)                             |
| Roman rocket/rucola             | 0.185                   | STMR$_{Hr}$ × CF (1.40)                              |
|                                 |                         | 0.407                   | HR$_{Hr}$ × CF (1.40)                             |
| Red mustards                    | 0.185                   | STMR$_{Hr}$ × CF (1.40)                              |
|                                 |                         | 0.407                   | HR$_{Hr}$ × CF (1.40)                             |
| Baby leaf crops (including brassica species) | 0.185                   | STMR$_{Hr}$ × CF (1.40)                              |
|                                 |                         | 0.407                   | HR$_{Hr}$ × CF (1.40)                             |
| Watercresses                    | 0.185                   | STMR$_{Hr}$ × CF (1.40)                              |
|                                 |                         | 0.407                   | HR$_{Hr}$ × CF (1.40)                             |
| Chervil                         | 0.040                   | STMR$_{Hr}$ × CF (1.20)                              |
|                                 |                         | 0.116                   | HR$_{Hr}$ × CF (1.20)                             |
| Chives                          | 0.040                   | STMR$_{Hr}$ × CF (1.20)                              |
|                                 |                         | 0.116                   | HR$_{Hr}$ × CF (1.20)                             |
| Celery leaves                   | 0.040                   | STMR$_{Hr}$ × CF (1.20)                              |
|                                 |                         | 0.116                   | HR$_{Hr}$ × CF (1.20)                             |
| Parsley                         | 0.040                   | STMR$_{Hr}$ × CF (1.20)                              |
|                                 |                         | 0.116                   | HR$_{Hr}$ × CF (1.20)                             |
| Sage                            | 0.185                   | STMR$_{Hr}$ × CF (1.40)                              |
|                                 |                         | 0.407                   | HR$_{Hr}$ × CF (1.40)                             |
| Rosemary                        | 0.040                   | STMR$_{Hr}$ × CF (1.20)                              |
|                                 |                         | 0.116                   | HR$_{Hr}$ × CF (1.20)                             |
| Thyme                           | 0.040                   | STMR$_{Hr}$ × CF (1.20)                              |
|                                 |                         | 0.116                   | HR$_{Hr}$ × CF (1.20)                             |
| Basil and edible flowers        | 0.040                   | STMR$_{Hr}$ × CF (1.20)                              |
|                                 |                         | 0.116                   | HR$_{Hr}$ × CF (1.20)                             |
| Laurel/bay leave                | 0.040                   | STMR$_{Hr}$ × CF (1.20)                              |
|                                 |                         | 0.116                   | HR$_{Hr}$ × CF (1.20)                             |
| Tarragon                        | 0.040                   | STMR$_{Hr}$ × CF (1.20)                              |
|                                 |                         | 0.116                   | HR$_{Hr}$ × CF (1.20)                             |
| Beans and peas (with pods)      | 0.006                   | STMR$_{Hr}$ × CF (1.00)                              |
|                                 |                         | 0.017                   | HR$_{Hr}$ × CF (1.00)                             |
| Beans (without pods)            | 0.001*                  | STMR$_{Hr}$ × CF (1.00)                              |
|                                 |                         | 0.001*                  | HR$_{Hr}$ × CF (1.00)                             |
| Peas (without pods)             | 0.001*                  | STMR$_{Hr}$ × CF (1.00)                              |
|                                 |                         | 0.001*                  | HR$_{Hr}$ × CF (1.00)                             |
| Globe artichokes                | 0.021                   | STMR$_{Hr}$ × CF (1.30)                              |
|                                 |                         | 0.042                   | HR$_{Hr}$ × CF (1.30)                             |
### Risk assessment residue definition for animal commodities:

Ruminants and swine: emamectin B1a and its salts, expressed as emamectin B1a (free base).

### Commodity Risk Assessment

| Commodity           | Chronic risk assessment | Acute risk assessment |
|---------------------|-------------------------|-----------------------|
| Cotton seeds        |                         |                       |
| Input value (mg/kg) | Comment                 | Input value (mg/kg)   |
| 0.01                | EU MRL x CF (1.00)      | 0.01                  |
| Comment             |                         | Comment               |
|                     | EU MRL x CF (1.00)      |                       |

### Risk assessment residue definition for plant commodities:

Sum of emamectin B1a, emamectin B1b, 8,9-Z-MAB1a, plus 3 times AB1a, plus 3 times MFB1a and 3 times FAB1a, expressed as emamectin B1a (free base).

| Commodity           | Chronic risk assessment | Acute risk assessment |
|---------------------|-------------------------|-----------------------|
|                      |                         |                       |
|                      |                         |                       |
|                      |                         |                       |
|                      |                         |                       |

### Commodity Risk Assessment

| Commodity           | Chronic risk assessment | Acute risk assessment |
|---------------------|-------------------------|-----------------------|
|                      |                         |                       |
|                      |                         |                       |
|                      |                         |                       |
|                      |                         |                       |

### Consumer risk assessment with consideration of the existing CXLs

| Commodity           | Chronic risk assessment | Acute risk assessment |
|---------------------|-------------------------|-----------------------|
|                      |                         |                       |
|                      |                         |                       |
|                      |                         |                       |
|                      |                         |                       |

### Consumer risk assessment with consideration of the existing CXLs

| Commodity           | Chronic risk assessment | Acute risk assessment |
|---------------------|-------------------------|-----------------------|
|                      |                         |                       |
|                      |                         |                       |
|                      |                         |                       |
|                      |                         |                       |

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STMR: supervised trials median residue; HR: highest residue; CF: conversion factor; Mo: monitoring; PF: processing factor; MRL: maximum residue level; CXL: codex maximum residue limit.

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

(a): The consumer risk assessment performed with the RA values derived from EU cGAP (EU1) indicates exceedance of the ARfD. Fall back GAPs were identified. Therefore, a second scenario (EU2) was performed considering the fall-back GAP on this crop.
| Commodity               | Chronic risk assessment | Acute risk assessment |
|-------------------------|-------------------------|-----------------------|
|                         | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment               |
| Hazelnuts               | 0.001* STMR<sub>Mo</sub> (CXL) × CF (1.00) (tentative) | 0.001* HR<sub>Mo</sub> (CXL) × CF (1.00) (tentative) |
| Macadamia              | 0.001* STMR<sub>Mo</sub> (CXL) × CF (1.00) (tentative) | 0.001* HR<sub>Mo</sub> (CXL) × CF (1.00) (tentative) |
| Pecans                 | 0.001* STMR<sub>Mo</sub> (CXL) × CF (1.00) (tentative) | 0.001* HR<sub>Mo</sub> (CXL) × CF (1.00) (tentative) |
| Pine nuts              | 0.001* STMR<sub>Mo</sub> (CXL) × CF (1.00) (tentative) | 0.001* HR<sub>Mo</sub> (CXL) × CF (1.00) (tentative) |
| Pistachios             | 0.001* STMR<sub>Mo</sub> (CXL) × CF (1.00) (tentative) | 0.001* HR<sub>Mo</sub> (CXL) × CF (1.00) (tentative) |
| Pome fruits            | 0.004 STMR<sub>Mo</sub> (CXL) × CF (1.10) | 0.011 HR<sub>Mo</sub> (CXL) × CF (1.10) |
| Apricots               | 0.001 STMR<sub>Mo</sub> × CF (1.00) (tentative) | 0.004 HR<sub>Mo</sub> × CF (1.00) (tentative) |
| Peaches                | 0.009 STMR<sub>Mo</sub> (CXL) × CF (1.10) | 0.014 HR<sub>Mo</sub> (CXL) × CF (1.10) |
| Plums                  | 0.002 STMR<sub>Mo</sub> × CF (1.10) | 0.010 HR<sub>Mo</sub> × CF (1.10) |
| Table and wine grapes  | 0.002 STMR<sub>Mo</sub> × CF (1.10) (tentative) | 0.021 HR<sub>Mo</sub> × CF (1.10) (tentative) |
| Strawberries           | 0.007 STMR<sub>Mo</sub> × CF (1.10) (tentative) | 0.034 HR<sub>Mo</sub> × CF (1.10) (tentative) |
| Potatoes               | 0.001* STMR<sub>Mo</sub> × CF (1.00) | 0.001* HR<sub>Mo</sub> × CF (1.00) |
| Tomatoes               | 0.003 STMR<sub>Mo</sub> (CXL) × CF (1.10) | 0.013 HR<sub>Mo</sub> (CXL) × CF (1.10) |
| Sweet peppers/bell peppers | 0.003 STMR<sub>Mo</sub> × CF (1.00) | 0.011 HR<sub>Mo</sub> × CF (1.00) |
| Okra, lady's fingers   | 0.003 STMR<sub>Mo</sub> (CXL) × CF (1.10) | 0.013 HR<sub>Mo</sub> (CXL) × CF (1.10) |
| Aubergines/eggplants   | 0.003 STMR<sub>Mo</sub> (CXL) × CF (1.10) | 0.013 HR<sub>Mo</sub> (CXL) × CF (1.10) |
| Cucumbers, gherkins and courgettes | 0.001 STMR<sub>Mo</sub> (CXL) × CF (1.10) | 0.002 HR<sub>Mo</sub> (CXL) × CF (1.10) |
| Melons and watermelons | 0.002 STMR<sub>Mo</sub> × CF (1.00) × PF (1.00) | 0.004 HR<sub>Mo</sub> × CF (1.00) × PF (1.00) |
| Pumpkins               | 0.002 STMR<sub>Mo</sub> × CF (1.00) × PF (1.00) (tentative) | 0.004 HR<sub>Mo</sub> × CF (1.00) × PF (1.00) (tentative) |
| Broccoli, cauliflowers | 0.002 STMR<sub>Mo</sub> × CF (1.50) | 0.003 HR<sub>Mo</sub> × CF (1.50) |
| Brussels sprouts       | 0.001 STMR<sub>Mo</sub> × CF (1.00) | 0.002 HR<sub>Mo</sub> × CF (1.00) |
| Head cabbages          | 0.002 STMR<sub>Mo</sub> × CF (1.50) | 0.003 HR<sub>Mo</sub> × CF (1.50) |
| Chinese cabbage/pet- tsa | 0.013 STMR<sub>Mo</sub> (CXL) × CF (1.50) | 0.145 HR<sub>Mo</sub> (CXL) × CF (1.50) |
| Kales                  | 0.006 STMR<sub>Mo</sub> × CF (1.00) | 0.010 HR<sub>Mo</sub> × CF (1.00) |
| Kohlrabies             | 0.015 EU MRL × CF (1.50) | 0.015 EU MRL × CF (1.50) |
| Lettuces               | 0.100 Scenario CX1: STMR<sub>Mo</sub> (CXL) × CF (1.50) | 0.435 Scenario CX1: HR<sub>Mo</sub> (CXL) × CF (1.50) |
|                        | 0.042 Scenario CX2: STMR<sub>Mo</sub> × CF (1.50) (a) | 0.150 Scenario CX2: HR<sub>Mo</sub> × CF (1.50) (a) |
| Escaroles/broad-leaved endives | 0.030 STMR<sub>Mo</sub> × CF (1.20) (tentative) | 0.040 HR<sub>Mo</sub> × CF (1.20) (tentative) |
| Lambs lettuce/corn salads | 0.185 STMR<sub>Mo</sub> × CF (1.40) | 0.407 HR<sub>Mo</sub> × CF (1.40) |
| Cresses and other sprouts and shoots | 0.185 STMR<sub>Mo</sub> × CF (1.40) | 0.407 HR<sub>Mo</sub> × CF (1.40) |
| Land cresses           | 0.185 STMR<sub>Mo</sub> × CF (1.40) | 0.407 HR<sub>Mo</sub> × CF (1.40) |
| Roman rocket/rucola    | 0.185 STMR<sub>Mo</sub> × CF (1.40) | 0.407 HR<sub>Mo</sub> × CF (1.40) |
| Red mustards           | 0.185 STMR<sub>Mo</sub> × CF (1.40) | 0.407 HR<sub>Mo</sub> × CF (1.40) |
### Commodity

| Commodity                          | Input value (mg/kg) | Comment                                      | Input value (mg/kg) | Comment                                      |
|------------------------------------|---------------------|----------------------------------------------|---------------------|----------------------------------------------|
| Baby leaf crops (including brassica species) | 0.185               | STMR_{Mo} × CF (1.40)                         | 0.407               | HR_{Mo} × CF (1.40)                          |
| Watercresses                        | 0.185               | STMR_{Mo} × CF (1.40)                         | 0.407               | HR_{Mo} × CF (1.40)                          |
| Chervil                             | 0.040               | STMR_{Mo} × CF (1.20)                         | 0.116               | HR_{Mo} × CF (1.20)                          |
| Parsley                             | 0.040               | STMR_{Mo} × CF (1.20)                         | 0.116               | HR_{Mo} × CF (1.20)                          |
| Sage                                | 0.185               | STMR_{Mo} × CF (1.40)                         | 0.407               | HR_{Mo} × CF (1.40)                          |
| Rosemary                            | 0.040               | STMR_{Mo} × CF (1.20)                         | 0.116               | HR_{Mo} × CF (1.20)                          |
| Basil and edible flowers            | 0.040               | STMR_{Mo} × CF (1.20)                         | 0.116               | HR_{Mo} × CF (1.20)                          |
| Laurel/bay leaves                   | 0.040               | STMR_{Mo} × CF (1.20)                         | 0.116               | HR_{Mo} × CF (1.20)                          |
| Tarragon                            | 0.040               | STMR_{Mo} × CF (1.20)                         | 0.116               | HR_{Mo} × CF (1.20)                          |
| Beans and peas (with pods)          | 0.006               | STMR_{Mo} × CF (1.00)                         | 0.017               | HR_{Mo} × CF (1.00)                          |
| Beans (without pods)                | 0.001               | STMR_{Mo} (CXL) × CF (1.00)                   | 0.008               | HR_{Mo} (CXL) × CF (1.00)                    |
| Peas (without pods)                 | 0.001               | STMR_{Mo} × CF (1.00)                         | 0.001               | HR_{Mo} × CF (1.00)                          |
| Globe artichokes                    | 0.021               | STMR_{Mo} × CF (1.30)                         | 0.042               | HR_{Mo} × CF (1.30)                          |
| Rape seed                           | 0.004               | STMR_{Mo} (CXL) × CF (1.00)                   | 0.004               | HR_{Mo} (CXL) × CF (1.00)                    |
| Cotton seeds                        | 0.01*               | EU MRL × CF (1.00)                            | 0.01                | EU MRL × CF (1.00)                           |

**Risk assessment residue definition for animal commodities:** Ruminants and swine: emamectin B_{1a} and its salts, expressed as emamectin B_{1a} (free base)

| Commodity          | Input value (mg/kg) | Comment                                      |
|--------------------|---------------------|----------------------------------------------|
| Swine meat         | 0.002               | 0.8 × STMR (CXL) muscle + 0.2 STMR (CXL) fat (tentative) |
| Swine fat          | 0.002               | STMR (CXL) (tentative)                       |
| Swine liver        | 0.005               | STMR (CXL) (tentative)                       |
| Swine kidney       | 0.005               | STMR (CXL) (tentative)                       |
| Bovine and equine meat | 0.002         | 0.8 × STMR (CXL) muscle + 0.2 STMR (CXL) fat (tentative) |
| Bovine and equine fat | 0.002          | STMR (CXL) (tentative)                       |
| Bovine and equine liver | 0.005          | STMR (CXL) (tentative)                       |
| Bovine and equine kidney | 0.005         | STMR (CXL) (tentative)                       |
| Sheep and goat meat | 0.002              | 0.8 × STMR (CXL) muscle + 0.2 STMR (CXL) fat (tentative) |
| Sheep and goat fat | 0.002               | STMR (CXL) (tentative)                       |
| Sheep and goat liver | 0.005             | STMR (CXL) (tentative)                       |
| Sheep and goat kidney | 0.005             | STMR (CXL) (tentative)                       |
| Cattle and horse milk | 0.001*            | STMR (CXL) (tentative)                       |
| Sheep and goat milk | 0.001*              | STMR (CXL) (tentative)                       |

STMR: supervised trials median residue; HR: highest residue; CF: conversion factor; Mo: monitoring; CXL: codex maximum residue limit; MRL: maximum residue level.

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

(a): The consumer risk assessment performed with the RA values derived from JMPR (CX1) indicates exceedance of the ARfD. Therefore, a second scenario (CX2) was performed disregarding the CXL, and considering the fall back GAP identified for the crop, according to the second EU scenario.
Appendix E – Decision tree for deriving MRL recommendations

Evaluation of the GAPs and available residues data at EU level

- GAP or DB > 0.1 mg/kg
- DM in EU?
  - Yes
  - Is RD-RA derived for this commodity?
    - No
    - MRL And RA derived in Section 3?
      - No
      - MRL fully supported by data?
        - No
        - No
        - Not considered for the RA.
        - No
        - Not considered for the RA.
      - Yes
      - Risk identified?
        - No
        - No
        - No
        - No
        - Not considered for the RA.
        - No
        - Not considered for the RA.
      - Yes
      - Risk identified?
        - No
        - No
        - No
        - No
        - Not considered for the RA.
        - No
        - Not considered for the RA.
      - Yes
      - Risk identified?
        - No
        - No
        - No
        - No
        - Not considered for the RA.
        - No
        - Not considered for the RA.
      - Yes
      - Risk identified?
        - No
        - No
        - No
        - No
        - Not considered for the RA.
        - No
        - Not considered for the RA.
      - Yes
      - Risk identified?
        - No
        - No
        - No
        - No
        - Not considered for the RA.
        - No
        - Not considered for the RA.
      - Yes
      - Risk identified?
        - No
        - No
        - No
        - No
        - Not considered for the RA.
        - No
        - Not considered for the RA.
      - Yes
      - Risk identified?
        - No
        - No
        - No
        - No
        - Not considered for the RA.
        - No
        - Not considered for the RA.
      - Yes
      - Risk identified?
        - No
        - No
        - No
        - No
        - Not considered for the RA.
        - No
        - Not considered for the RA.
      - Yes
      - Risk identified?
        - No
        - No
        - No
        - No
        - Not considered for the RA.
        - No
        - Not considered for the RA.
      - Yes
      - Risk identified?
        - No
        - No
        - No
        - No
        - Not considered for the RA.
        - No
        - Not considered for the RA.
      - Yes
      - Risk identified?
        - No
        - No
        - No
        - No
        - Not considered for the RA.
        - No
        - Not considered for the RA.
      - Yes
      - Risk identified?
        - No
        - No
        - No
        - No
        - Not considered for the RA.
        - No
        - Not considered for the RA.
      - Yes
      - Risk identified?
        - No
        - No
        - No
        - No
        - Not considered for the RA.
        - No
        - Not considered for the RA.
      - Yes
      - Risk identified?
        - No
        - No
        - No
        - No
        - Not considered for the RA.
        - No
        - Not considered for the RA.
      - Yes
      - Risk identified?
        - No
        - No
        - No
        - No
        - Not considered for the RA.
        - No
        - Not considered for the RA.
      - Yes
      - Risk identified?
        - No
        - No
        - No
        - No
        - Not considered for the RA.
        - No
        - Not considered for the RA.
Comparison of the EU recommendation with the existing CXL

1. CXL available?
   - Yes
     - RD comparable?
       - Yes
         - CXL higher?
           - Yes
             - Maintain EU recommendation; higher CXL is not safe for consumer.
           - No
             - Maintain current CXL or EU recommendation; higher CXL is not safe for consumer.
       - No
         - Maintain EU recommendation indicating that no CXL is available.
   - No
     - RD comparable?
       - Yes
         - CXL higher?
           - Yes
             - Maintain EU recommendation; higher CXL is not safe for consumer.
           - No
             - Maintain current CXL or EU recommendation; higher CXL is not safe for consumer.
       - No
         - Maintain EU recommendation indicating that CXL is covered.

Consumer risk assessment with consideration of the existing CXL

1. CXL supported by data?
   - Yes
     - CXL is included in the RA.
     - Risk identified?
       - Yes
         - Maintain EU recommendation; higher CXL is not safe for consumer.
       - No
         - Maintain current CXL or EU recommendation; higher CXL is not safe for consumer.
   - No
     - Input values for the RA remain unchanged.
     - Risk identified?
       - Yes
         - Maintain EU recommendation; higher CXL is not safe for consumer.
       - No
         - Maintain current CXL or EU recommendation; higher CXL is not safe for consumer.

Recommendations with consideration of the existing CXL

1. (I) Maintain EU recommendation indicating that no CXL is available.
2. (II) Maintain EU recommendation indicating CXL is not compatible.
3. (III) Maintain EU recommendation indicating that CXL is covered.
4. (IV) Maintain current CXL or EU recommendation; higher CXL is not safe for consumer.
5. (V) Maintain EU recommendation indicating that CXL is not compatible.
6. (VI) Maintain current CXL or EU recommendation; higher CXL is not safe for consumer.
7. (VII) CXL is recommended; EU recommendation is covered as well.

Result EU assessment

- Yes
- No
### Appendix F – Used compound codes

| Code/trivial name(a) | IUPAC name/SMILES notation/InChiKey(b) | Structural formula(c) |
|----------------------|---------------------------------------|-----------------------|
| emamectin B1a        | \((10E,14E,16E)-1(1,4,5,5'6,6',8R,12S,20R,21R,24S)-6'-(5)-sec-butyl)-21,24-dihydroxy-5',11,13,22-tetramethyl-2-oxo-(3,7,19-trioxatetracyclo [15.6.1.1(4,8,020,24)pentacosa-10,14,16,22-tetraene)-6-spiro-2'-5',6'-dihydro-2'H-pyran)-12-yl 2,6-dideoxy-3-O-methyl-4-O-(2,4,6-trideoxy-3-O-methyl-4-methyleno-\(\alpha\)-lyxo-hexopyranosyl)-\(\alpha\)-arabino-hexopyranoside\) | \(\text{CXEGAUXYQAKHK3-COFQVFHOSAN}\) |
| emamectin B1b        | \((10E,14E,16E)-1(1,4,5,5'6,6',8R,12S,20R,21R,24S)-21,24-dihydroxy-6'-isopropyl-5',11,13,22-tetramethyl-2-oxo-(3,7,19-trioxatetracyclo [15.6.1.1(4,8,020,24)pentacosa-10,14,16,22-tetraene)-6-spiro-2'-5',6'-dihydro-2'H-pyran)-12-yl 2,6-dideoxy-3-O-methyl-4-O-(2,4,6-trideoxy-3-O-methyl-4-methyleno-\(\alpha\)-lyxo-hexopyranosyl)-\(\alpha\)-arabino-hexopyranoside\) | \(\text{DXIOOXFZLKCVKHK-VAUHGISISN}\) |
| emamectin B1a benzoate| \((10E,14E,16E)-1(1,4,5,5'6,6',8R,12S,20R,21R,24S)-6'-(5)-sec-butyl)-21,24-dihydroxy-5',11,13,22-tetramethyl-2-oxo-(3,7,19-trioxatetracyclo [15.6.1.1(4,8,020,24)pentacosa-10,14,16,22-tetraene)-6-spiro-2'-5',6'-dihydro-2'H-pyran)-12-yl 2,6-dideoxy-3-O-methyl-4-O-(2,4,6-trideoxy-3-O-methyl-4-methyleno-\(\alpha\)-lyxo-hexopyranosyl)-\(\alpha\)-arabino-hexopyranosidebenzoate\) | \(\text{GCKZANITMOIAR-PEHUFCNHN}\) |
| Code/trivial name(a) | IUPAC name/SMILES notation/InChIKey(b) | Structural formula(c) |
|---------------------|--------------------------------------|----------------------|
| emamectin B₁b benzoate | (10E,14E,16E)-1(R,4S,5'S,6'S,6'R,8R,12S,13S,20R,21R,24S)-21,24-dihydroxy-6'-isopropyl-5,11,13,22-tetramethyl-2-oxo-(3,7,19-trioxatetracyclo[15.6.1.1\(4\),0\(0\),20,24\)]pentacosa-10,14,16,22-tetraene)-6-spiro-2'-\(5\)'-dihydro-2'-H-pyran)-12-yl 2,6-dideoxy-3-O-methyl-4-O-(2,4,6-trideoxy-3-O-methyl-4-methylamino-\(\alpha\)-lyxo-hexapyranosyl)-\(\alpha\)-arabino-hexapyranoside benzoate | O-C(O)1cccc1.C@H1C[C@H1]@C@H1O[C@H1]O[C@H1]1[C@H1]O[C@H1]2[C@H1]OC[C@H1]1H[C@H1]2C0[C@H1]3C0[C@H1]6C[C@H1]OC(=-O)[C@H1]4C-C(C)O[C@H1]O[C@H1][O][C@H1]5OCC(-CC-C[C@H1]3C[C@H1]45O)C[C@H1]7(06)C-C[C@H1]C[C@H1](07)C(O)C ISGYOHXFFCGHKT-WVYDVEQSA-N |
| 8,9-Z-MAB₁a NOA 438376 | (1'R,2'S,4'S,5'S,6'R,8'R,10'E,12'S,13'R,14'E,16'Z,20'R,21'R,24'S)-6-\{(2S)-butan-2-yl\}-21',24'-dihydroxy-5,11,13,22-tetramethyl-2'-oxo-5,6-dihydrospiro[pyran-2,6'-\{3,7,19\}trioxatetracyclo[15.6.1.1\(4\),0\(0\),20,24\)]pentacosa\{10,14,16,22\}tetraen]-12'-yl 2,6-dideoxy-3-O-methyl-4-O-[2,4,6-trideoxy-3-O-methyl-4-(methylamino)-\(\alpha\)-lyxo-hexapyranosyl]-\(\alpha\)-arabino-hexapyranoside | CO[C@H1]1C[C@H1]@C@H1O[C@H1][C@H1][C@H1]1O[C@H1]2[C@H1]OC[C@H1]1H[C@H1]2C0[C@H1]3C0[C@H1]6C[C@H1]OC(=-O)O[C@H1]4C-C(C)C[C@H1]O[C@H1]5OCC(-CC-C[C@H1]3C[C@H1]45O)C[C@H1]7(06)C-C[C@H1]C[C@H1](07)C(O)C CXEGAVXQQAKH3-ITVRGHKNSA-N |
| FAB₁a NOA 415693 | (1'R,2'S,4'S,5'S,6'R,8'R,10'E,12'S,13'S,14'E,16'E,20'R,21'R,24'S)-6-\{(2S)-butan-2-yl\}-21',24'-dihydroxy-5,11,13,22-tetramethyl-2'-oxo-5,6-dihydrospiro[pyran-2,6'-\{3,7,19\}trioxatetracyclo[15.6.1.1\(4\),0\(0\),20,24\)]pentacosa\{10,14,16,22\}tetraen]-12'-yl 2,6-dideoxy-3-O-methyl-4-O-[2,4,6-trideoxy-4-formamido-3-O-methyl-\(\alpha\)-lyxo-hexapyranosyl]-\(\alpha\)-arabino-hexapyranoside | CO[C@H1]1C[C@H1]@C@H1O[C@H1][C@H1][C@H1]1O[C@H1]2[C@H1]OC[C@H1]1H[C@H1]2C0[C@H1]3C0[C@H1]6C[C@H1]OC(=-O)O[C@H1]4C-C(C)C[C@H1]O[C@H1]5OCC(-CC-C[C@H1]3C[C@H1]45O)C[C@H1]7(06)C-C[C@H1]C[C@H1](07)C(O)C CTOLTUCXVWGDP-RTHKKNZFHSAN-
| Code/trivial name(a) | IUPAC name/SMILES notation/InChiKey(b) | Structural formula(c) |
|---------------------|--------------------------------------|----------------------|
| MFB1a NOA 415692   | (1'R, 2S, 4'S, 5'S, 6'R, 8'R, 10'E, 12'S, 13'S, 14'E, 16'E, 20'R, 21'R, 24'S)-6-[(2S)-butan-2-yl]-21', 24'-dihydroxy-5,11', 13', 22'-tetramethyl-2'-oxo-5,6-dihydrospiro[pyran-2, 6-'-[3, 7, 19]triotacetacryclo [15.6.1.1^{4, 8, 0}_{20, 24}^{20, 24}][pentacosa][10, 14, 16, 22] tetraen]-12'-yl 2, 6-dideoxy-3-O-methyl-4-O-[(2, 4, 6-trideoxy-4-[formyl(methyl)amino]-3-O-methyl-a-l-fu-lyxo-hexopyranosyl)-a-L-arabino-hexopyranoside | ![Structure](image1) |
| AB1a NOA 438309    | (1'R, 2S, 4'S, 5'S, 6'R, 8'R, 10'E, 12'S, 13'S, 14'E, 16'E, 20'R, 21'R, 24'S)-6-[(2S)-butan-2-yl]-21', 24'-dihydroxy-5,11', 13', 22'-tetramethyl-2'-oxo-5,6-dihydrospiro[pyran-2, 6-'-[3, 7, 19]triotacetacryclo [15.6.1.1^{4, 8, 0}_{20, 24}^{20, 24}][pentacosa][10, 14, 16, 22] tetraen]-12'-yl 4-O-(4-amino-2, 4, 6-trideoxy-3-O-methyl-a-L-fu-lyxo-hexopyranosyl)-2, 6-dideoxy-3-O-methyl-a-L-arabino-hexopyranoside | ![Structure](image2) |
| MSB1a NOA 419150   | (1'R, 2S, 4'S, 5'S, 6'R, 8'R, 10'E, 12'S, 13'S, 14'E, 16'E, 20'R, 21'R, 24'S)-6-[(2S)-butan-2-yl]-21', 24'-dihydroxy-5,11', 13', 22'-tetramethyl-2'-oxo-5,6-dihydrospiro[pyran-2, 6-'-[3, 7, 19]triotacetacryclo [15.6.1.1^{4, 8, 0}_{20, 24}^{20, 24}][pentacosa][10, 14, 16, 22] tetraen]-12'-yl 2, 6-dideoxy-3-O-methyl-a-L-arabino-hexopyranoside | ![Structure](image3) |

(a) NOA: Notice Of Assessment; MSB: mitoxantrone salmon bile; MFB: mitoxantrone fish bile; AB: abamectin
(b) IUPAC name: International Union of Pure and Applied Chemistry name; SMILES notation: Simplified Molecular Input Line Entry System; InChiKey: International Chemical Identifier
(c) Structural formula: Chemical structure representation

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| Code/trivial name(a) | IUPAC name/SMILES notation/InChiKey(b) | Structural formula(c) |
|---------------------|----------------------------------------|----------------------|
| Aglycone milbemectin B NOA 419153 | (1'R,2S,4'S,5'S,6R,8'R,10'E,12'S,13'S,14'E,16'E, 20'R,21'R,24'S)-6-[(2S)-butan-2-yl]-12,21,24'- trihydroxy-5,11',13',22'-tetramethyl-5,6-dihydro- 2'/H-spiro[pyran-2,6'-[3,7,19]trioxatetracyclo [15.6.1.14,8.020,24]pentacosa[10,14,16,22] tetraen]-2'-one | ![Structural formula](image) |

IUPAC: International Union of Pure and Applied Chemistry; SMILES: simplified molecular-input line-entry system; InChiKey: International Chemical Identifier Key.

(a): The metabolite name in bold is the name used in the conclusion.
(b): ACD/Name 2015 ACD/Labs 2015 Release (File version N20E41, Build 75170, 19 December 2014).
(c): ACD/ChemSketch 2015 ACD/Labs 2015 Release (File version C10H41, Build 75059, 17 December 2014).