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Setting of import tolerances for abamectin in various crops

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Syngenta Crop Protection AG submitted a request to the competent national authority in the Netherlands to set an import tolerance for the active substance abamectin in various commodities imported from the United States of America. The data submitted in support of the request were found to be sufficient to derive MRL proposals for tree nuts, peaches, avocados, lettuces and salad plants, spinaches and similar leaves, Florence fennels and cotton seed. Adequate analytical methods for enforcement are available to control the residues of abamectin on the commodities under consideration. Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of residues resulting from the use of abamectin according to the reported agricultural practices is unlikely to present a risk to consumer health.

Keywords: abamectin, various crops, import tolerance, pesticide, MRL, consumer risk assessment

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, Syngenta Crop Protection AG submitted an application to the competent national authority in the Netherlands (evaluating Member State, EMS) to set import tolerances for the active substance abamectin in various plant commodities. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 24 May 2019. The EMS proposed to establish maximum residue levels (MRLs) for various plant commodities (citrus fruits, tree nuts, pome fruits, peaches, strawberries, avocados, tomatoes, peppers, aubergines, cucurbits with edible peel, lettuces and salad plants, spinaches and similar leaves, herbs and edible flowers, celeries, Florence fennels and cotton seed). EFSA focused the assessment on residue data on those crops for which the EMS proposed to increase the EU MRL or for which the risk management decision requested in the framework of the recent MRL assessment is pending.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified the need for further clarification, which was requested from the EMS. On 31 January 2020, the requested information was submitted in a revised evaluation report, which replaced the previously submitted evaluation report.

Based on the conclusions derived by EFSA on the peer review of the pesticide risk assessment in the framework of Directive 91/414/EEC and the conclusions derived by EFSA on the peer review of the pesticide risk assessment for amendment of the conditions of approval, the MRL review, the data evaluated under previous MRL assessments and the additional data provided by the EMS in the framework of the MRL application, the following conclusions are derived.

The metabolism of abamectin in primary and rotational crops, and the possible degradation in processed products has been sufficiently addressed. The residue definition for enforcement established in Regulation (EC) No 396/2005 for plant products is 'Abamectin (sum of avermectin B1a, avermectin B1b, delta-8,9 isomer of avermectin B1a, expressed as avermectin B1a)'. The residue definition covers primary crops, rotational crops and processed products and the risk assessment in plants. For the crops assessed in this application, EFSA concluded that the metabolism of abamectin in plants and the possible degradation in processed products has been sufficiently addressed and that the previously derived residue definition is applicable. Sufficiently validated analytical methods are available to quantify residues in the crops assessed according to the enforcement residue definition. The methods allow quantification of residues at or above 0.002 mg (limit of quantification (LOQ)) for each individual analyte.

The available residue trials are sufficient to derive MRL proposals for tree nuts, peaches, avocados, lettuces and salad plants with the exclusion of red mustards (not applied for), spinaches and similar leaves, Florence fennels and cotton seeds.

Specific studies investigating the magnitude of residues of abamectin in processed commodities were not provided. Considering the low chronic dietary exposure of each individual commodity under assessment, further data are not essential.

As the uses of abamectin are on imported crops, investigations of residues in rotational crops are not required. Investigation of the possible occurrence of abamectin residues in commodities of animal origin is also not necessary.

The toxicological profile of abamectin was assessed in the framework of the EU pesticides peer review under Directive 91/414/EEC and the data were sufficient to derive an acceptable daily intake (ADI) of 0.0025 mg/kg body weight (bw) per day and an acute reference dose (ARfD) of 0.005 mg/kg bw.

The consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo). A long-term consumer risk was not identified for any of the European diets incorporated in the EFSA PRIMo. The highest chronic intake was calculated to account for 12% of the ADI.

According to the internationally agreed methodology, an acute consumer risk was not identified in relation to the uses assessed. EFSA concluded that the reported uses of abamectin on the crops under assessment will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers' health. It is highlighted that for some of the commodities assessed in the current application, MRL proposals were previously derived by EFSA in the framework of the assessment of confirmatory data following the MRL review; hence, when

modifying the EU MRLs for these commodities, risk managers should take into account the current and the previous recommendations of EFSA on the MRL modifications.

The process of renewal of the approval of the active substance abamectin in accordance with Regulation (EC) No 1107/2009 is not yet finalised, and therefore, the conclusions reported in this reasoned opinion may need to be reconsidered in the light of the outcome of the peer review of the pesticide risk assessment of the active substance abamectin.

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

Full details of all endpoints and the consumer risk assessment can be found in Appendices B–D.

Code[a]	Commodity	Existing EU MRL/ MRL proposals derived in a recent assessment of EFSA (not yet implemented)[b] (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Abamectin (sum of avermectin B1a, avermectin B1b and delta-8,9 isomer of avermectin B1a, expressed as avermectin B1a)[F]				
0120010	Almonds	0.02 (ft 1)/(0.01* or 0.006*)[c]	0.01*	The submitted data are sufficient to derive an import tolerance at the LOQ of 0.01 mg/kg for the whole group of tree nuts US tolerance: 0.01 mg/kg Risk for consumers unlikely
0120020	Brazil nuts	0.01*	No change	
0120030	Cashew nuts	0.01*	No change	
0120040	Chestnuts	0.01*	No change	
0120050	Coconuts	0.01*	No change	
0120060	Hazelnuts/ cobnuts	0.02 (ft 1)/(0.01* or 0.006*)[c]	0.01*	
0120070	Macadamias	0.01*	No change	
0120080	Pecans	0.01*	No change	
0120090	Pine nut kernels	0.01*	No change	
0120100	Pistachios	0.01*	No change	
0120110	Walnuts	0.02 (ft 1)/(0.01* or 0.006*)[c]	0.01*	
0140030	Peaches	0.02	0.04	The submitted data are sufficient to derive an import tolerance (US GAP). US tolerance: 0.09 mg/kg. Risk for consumers unlikely
0163010	Avocados	0.01*	0.02	The submitted data are sufficient to derive an import tolerance (US GAP). US tolerance: 0.02 mg/kg. Risk for consumers unlikely
0251010	Lamb's lettuces/ corn salads	2 (ft 2)/3	Further risk management considerations required	The submitted data on open leaf lettuces are sufficient to derive an import tolerance (US GAP) of 0.08 mg/kg by extrapolation. US tolerance: 0.1 mg/kg. Risk for consumers unlikely The proposed import tolerance is lower than the MRL proposal derived by EFSA in the assessment of MRL review confirmatory data. Hence, the previously derived MRL proposal of 3 mg/kg is still valid

Code[a]	Commodity	Existing EU MRL/ MRL proposals derived in a recent assessment of EFSA (not yet implemented)[b] (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
0251020	Lettuces	0.09 (ft 2)/0.01* or 0.006* or 0.09[c]	Further risk management considerations required	The submitted data are sufficient to derive an import tolerance (US GAP) of 0.08 mg/kg based on data set of residue trials in open leaf lettuces only; combining the residue trials on open leaf varieties and head forming varieties a slightly lower MRL proposal of 0.07 mg/kg is derived US tolerance: 0.1 mg/kg. Risk for consumers unlikely Risk managers need to decide whether the proposed import tolerance of 0.07 or 0.08 mg/kg or the previously presented option of 0.09 mg/kg should be implemented in the EU legislation
0251030	Escaroles/ broadleaved endives	0.1 (ft 2)/0.03	0.08	The submitted data on open leaf lettuces are sufficient to derive an import tolerance (US GAP) by extrapolation US tolerance: 0.1 mg/kg. Risk for consumers unlikely
0251040	Cresses & other sprouts and shoots	0.01*/0.03	0.08	
0251050	Land cresses	0.01*	0.08	
0251060	Roman rocket/ rucola	0.015/0.03	0.08	
0251990	Baby leaf crops (incl. brassica species)	2 (ft 2)/3	Further risk management considerations required	The submitted data on open leaf lettuces are sufficient to derive an import tolerance (US GAP) of 0.08 mg/kg by extrapolation. US tolerance: 0.1 mg/kg. Risk for consumers unlikely The proposed import tolerance is lower than the MRL proposal derived by EFSA in the assessment of confirmatory data. Hence, the previously derived MRL proposal of 3 mg/kg is still valid
0251990	Others (lettuces and salad plants)	0.01*	0.08	The submitted data on open leaf lettuces are sufficient to derive an import tolerance (US GAP) by extrapolation. US tolerance: 0.1 mg/kg. Risk for consumers unlikely
0252010	Spinaches	0.01*/0.03	0.1 or 0.15 Further risk management considerations required	The import tolerance request is sufficiently supported by data. Using the OECD MRL calculator, an MRL proposal of 0.15 mg/kg is derived which is higher than the MRL in place in the USA (US tolerance: 0.1 mg/kg). Risk for consumers unlikely Further risk management considerations are recommended to decide on the most appropriate MRL

Code[a]	Commodity	Existing EU MRL/ MRL proposals derived in a recent assessment of EFSA (not yet implemented)[b] (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
0252020	Purslanes	0.01*/0.03	0.1 or 0.15 Further risk management considerations required	The import tolerance request is sufficiently supported by data (extrapolation from spinaches). Using the OECD MRL calculator, an MRL proposal of 0.15 mg/kg is derived which is higher than the MRL in place in the USA (US tolerance: 0.1 mg/kg). Risk for consumers unlikely Further risk management considerations are recommended to decide on the most appropriate MRL
0252030	Chards/beet leaves	0.01*/0.03		
0252990	Others (spinaches and similar leaves	0.01*/0.03		
0270040	Florence fennels	0.01*	0.03	The submitted data are sufficient to derive an import tolerance (US GAP) by extrapolation from celery. US tolerance: 0.1 mg/kg. Risk for consumers unlikely
0401090	Cotton seeds	0.01*	0.02	The submitted data are sufficient to derive an import tolerance (US GAP). US tolerance: 0.02 mg/kg Risk for consumers unlikely

*: Indicates that the MRL is set at the limit of analytical quantification (LOQ). MRL: maximum residue level.
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(b): The MRL proposals which were derived in the framework of the assessment of confirmatory data requested in the framework of the MRL review under Article 12 of Regulation (EC) No 396/2005, have not yet been implemented in the EU MRL legislation (EFSA, 2020).
(c): More than one MRL proposal was derived by EFSA for further risk management considerations (EFSA, 2020).
(ft 1): The European Food Safety Authority identified some information on analytical methods and residue trials as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 19 November 2017, or if that information is not submitted by that date, the lack of it.
(ft 2): The European Food Safety Authority identified some information on residue trials as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 19 November 2017, or if that information is not submitted by that date, the lack of it.
(F): Fat soluble.

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Assessment

The European Food Safety Authority (EFSA) received an application to modify the existing maximum residue level (MRL) for abamectin in various crops. The detailed description of the uses of abamectin notified to be authorised in the Unites States of America (USA), which are the basis for the current MRL application, is reported in Appendix A.

Abamectin is the ISO common name for the mixture of avermectin B1a (≥ 80%) and avermectin B1b (≤ 20%). The IUPAC names for the two components of abamectin are:

Avermectin B1a:

(2a*E*,4*E*,8*E*)-(5′*S*,6*S*,6′*R*,7*S*,11*R*,13*S*,15*S*,17a*R*,20*R*,20a*R*,20bS)-6′-[(*S*)-sec-butyl] 5′,6,6′,7,10,11,14,15,17a,20,20a,20b-dodecahydro-20,20b-dihydroxy-5′,6,8,19-tetramethyl-17 oxospiro[11,15 methano2*H*,13*H*,17*H*-furo[4,3,2-pq][2,6]benzodioxacyclooctadecin-13,2′-[2H]pyran]-7-yl 2,6-dideoxy 4-*O*(2,6-dideoxy-3-*O*-methyl-α-L-arabino-hexopyranosyl)-3-*O*-methyl-α-L-arabino-hexopyranoside.

Avermectin B1b:

(2a*E*,4*E*,8*E*)-(5′*S*,6*S*,6′*R*,7*S*,11*R*,13*S*,15*S*,17a*R*,20*R*,20a*R*,20b*S*) 5′,6,6′,7,10,11,14,15,17a,20,20a,20 bdodecahydro-20,20b-dihydroxy-6′-isopropyl-5′,6,8,19 tetramethyl-17-oxospiro[11,15-methano 2*H*,,13 *H*17*H*-furo[4,3,2-pq][2,6]benzodioxacyclooctadecin 13,2′-[2*H*]pyran]-7-yl 2,6-dideoxy-4-*O*(2,6-dideoxy-3-*O*-methyl-α-L-arabino-hexopyranosyl)-3-O-methyl-α-L-arabino-hexopyranoside.

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

Abamectin was evaluated in the framework of Directive 91/414/EEC[1] with the Netherlands designated as rapporteur Member State (RMS) for the representative uses as a foliar treatment on citrus. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by EFSA (EFSA, 2008). Following the initial peer review, abamectin was approved[2] for the use as an insecticide and acaricide on 1 May 2009. On 3 April 2017, the conditions of approval were amended to allow for use as a nematicide to be authorised.[3] The process of renewal of the first approval is currently ongoing.

The EU MRLs for abamectin are established in Annexes II of Regulation (EC) No 396/2005.[4] The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has been performed (EFSA, 2014) and the proposed modifications have been implemented in the MRL legislation. After completion of the MRL review, EFSA has issued several reasoned opinions on the modification of MRLs for abamectin, which were taken over in the MRL legislation.[5] In 2019, EFSA assessed confirmatory data which were requested in the framework of the MRL review (EFSA, 2020); the proposals from this reasoned opinion have not yet been considered for implementation in the MRL legislation.

In accordance with Article 6 of Regulation (EC) No 396/2005, Syngenta Crop Protection AG submitted an application to the competent national authority in the Netherlands (evaluating Member State, EMS) to set import tolerances for the active substance abamectin in various plant commodities. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the EFSA on 24 May 2019. The EMS proposed to establish MRLs for various plant commodities (citrus fruits, tree nuts, pome fruits, peaches, strawberries, avocados, tomatoes, peppers, aubergines, cucurbits with edible peel, lettuces and salad plants, spinaches and similar leaves, herbs and edible flowers, celeries, Florence fennels and cotton seed).

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified the need for further clarification, which was requested from the EMS. On 31

[1] 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.

[2] Commission Directive 2008/107/EC of 25 November 2008 amending Council Directive 91/414/EEC to include abamectin, epoxiconazole, fenpropimorph, fenpyroximate and tralkoxydim as active substances. OJ L 316, 26.11.2008, p. 4–11.

[3] Commission Implementing Regulation (EU) 2017/438 of 13 March 2017 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance abamectin. OJ L 67, 14.3.2017, p. 67–69.

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

[5] For an overview of all MRL Regulations on this active substance, please consult: http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=pesticide.residue.selection&language=EN

January 2020, the requested information was submitted in a revised evaluation report (Netherlands, 2019), which replaced the previously submitted evaluation report.

It is noted that in the original submission, the applicant also notified an use on papaya in Brazil which was not sufficiently supported by data. After request of additional information from EFSA, the applicant withdrew the application for papaya within the current MRL application.

For several crops for which residue data were submitted in the import tolerance application (i.e. citrus fruit, pome fruit, strawberries, tomatoes, aubergines, peppers, cucurbits with edible peel and celery), the MRL proposals derived by the EMS were equal to or lower than the existing or recently recommended MRLs (EFSA, 2020) which are not yet implemented in the EU MRL legislation. For herbs and edible flowers (except celery leaves), the EMS did not propose to modify the existing MRL.[6] EFSA focussed the assessment on residue data on those crops for which the EMS proposed to increase the EU MRL or for which the risk management decision requested in the framework of the recent MRL assessment is pending (EFSA, 2020).

EFSA based its assessment on the revised evaluation report submitted by the EMS (Netherlands, 2019), the draft assessment report (DAR) and its addendum (Netherlands, 2005, 2008) prepared under Regulation (EC) 1107/2009, the European Commission review reports on abamectin (European Commission, 2008, 2012), the European Commission Draft addendum to the review report on abamectin (European Commission, 2017a). The conclusion on the peer review of the pesticide risk assessment of the active substance abamectin (EFSA, 2008), as well as the conclusions from previous EFSA opinions on abamectin including the Article 12 MRL review (EFSA, 2014, 2015, 2017, 2018b, 2020).

For this application, the data requirements established in Regulation (EU) No 544/2011[7] and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 1997a–g, 2000, 2010a,b, 2017b; OECD, 2011). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011.[8]

A selected list of end points of the studies assessed by EFSA in the framework of this MRL application including the end points of relevant studies assessed previously, are presented in Appendix B.

The evaluation report submitted by the EMS (Netherlands, 2019) and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available as background documents to this reasoned opinion.

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 abamectin was investigated in primary crops belonging to the fruit crops, leafy crops and pulses/oilseeds groups following foliar applications and using avermectin B1a (EFSA, 2008, 2014). Although largely degraded by photodegradation, avermectin B1a represented still the predominant compound in almost all plant parts (4–23% of total radioactive residue at preharvest interval of 8 days). The photodegradation product delta-8,9 isomer of avermectin B1a (also referred to as (Z)-8,9-isomer) was found in concentrations not exceeding 10% total radioactive residue (TRR) but considered of the same toxicity as avermectin B1a.

For the reported US uses, the metabolic behaviour in primary crops is sufficiently addressed.

[6] The US tolerance for fresh herbs is 0.03 mg/kg; the residue trials submitted in support of the application lead to a considerably higher MRL (0.15 mg/kg). Considering that EU MRLs should not be set at a higher level than the MRL in the country of origin, the EMS did not suggest to implement the US tolerance.

[7] Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances. OJ L 155, 11.6.2011, p. 1–66.

[8] 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.

1.1.2. Nature of residues in rotational crops

Investigations of residues in rotational crops are not required for imported crops.

1.1.3. Nature of residues in processed commodities

The effect of processing on the nature of abamectin (using avermectin B1a) was investigated in the framework of the EU pesticides peer review (EFSA, 2008). Degradation of avermectin B1a was observed (30–40% of the initial radioactivity) under standard processing conditions. The major resulting degradation product was the monosaccharide of avermectin B1a, accounting for 10–20% of the initial radioactivity.

1.1.4. Methods of analysis in plants

Analytical methods for the determination of abamectin residues in plants were assessed during the EU pesticides peer review, the MRL review and the evaluation of confirmatory data (EFSA, 2008, 2014, 2020). The methods, which are based on liquid chromatography tandem mass spectrometry (LC-MS/MS), are sufficiently validated to quantify residues of avermectin B1a, avermectin B1b and the delta-8,9 isomer of avermectin B1a at or above the limit of quantification (LOQ) of 0.002 mg/kg for each analyte (total residues as sum of LOQs of 0.006 mg/kg) in high water content, high acid content, high oil content matrices and in dry commodities (high protein/high starch content).

1.1.5. Storage stability of residues in plants

The storage stability of avermectin B1a, avermectin B1b and the delta-8,9 isomer of avermectin B1a in plants under deep-freeze conditions was investigated in the framework of the EU pesticides peer review (EFSA, 2008). Storage stability was demonstrated for a period of 36, 24 and 14 months in high water content, high oil content and high acid content commodities, respectively. Additional data showed stability in orange peel and pulp for at least 12 months under deep-freeze conditions.

1.1.6. Proposed residue definitions

Based on the metabolic pattern identified in metabolism studies, the results of the hydrolysis studies, the toxicological significance of metabolites, the capabilities of the analytical methods, the following residue definitions proposed in the EU pesticides peer review in 2008 were confirmed during the MRL review (EFSA, 2014):

- Residue definition for enforcement and risk assessment: sum of avermectin B1a, avermectin B1b and delta-8,9 isomer of avermectin B1a, expressed as avermectin B1a.

The same residue definitions apply to primary crops, rotational crops and processed products.

The residue definition for enforcement set in Regulation (EC) No 396/2005 is equivalent to the above-mentioned residue definition, and is defined as:

- Abamectin (sum of avermectin B1a, avermectin B1b and delta-8,9 isomer of avermectin B1a, expressed as avermectin B1a)

EFSA concluded that these residue definitions are appropriate and no further information is required.

The US tolerance definition for plants includes avermectin B1a, avermectin B1b and the 8,9-Z isomer of avermectin B1a (US EPA, 2019), and therefore, the US and EU residue definitions for monitoring are comparable.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

In support of the import tolerance application for setting MRLs for abamectin in various commodities imported from the United States, the applicant submitted residue trials performed in various crops.

The residue trial samples were analysed using methods (HPLC-FLD or HPLC-MS/MS) that measured 'avermectin B1a + its delta 8,9 isomer'[9] and 'avermectin B1b + its delta 8,9- isomer'. The analysis was therefore not fully in compliance with the residue definition established at EU level (i.e. sum of avermectin B1a, avermectin B1b and delta-8,9 isomer of avermectin B1a, expressed as avermectin B1a). Since no quantifiable residues of avermectin B1b and its 8,9-delta isomer were found in any of the trials submitted, the inclusion of the 8,9-delta isomer of avermectin B1b in the analysis has no significant impact on the final residues and the deviation is acceptable.

According to the assessment of the EMS, the methods used were sufficiently validated and fit for the purpose, despite the deviation from the residue definition (Netherlands, 2019). The samples of these trials were stored under conditions for which their integrity has been demonstrated.

1.2.1.1. Tree nuts

The results of independent residue trials on walnut (5), almond (3) and pecan (7) were provided. All trials were carried out in the USA over two seasons with three or five instead of two applications. Except in two trials on almond, samples were collected at a shorter PHI of 14 days. Since no quantifiable residues (< LOQ) were found under these least favourable conditions, EFSA concluded that no further trials are required to support the less critical US GAP (2 × 26 g/ha, PHI 21 days).

The proposed extrapolation from the residue data on walnuts, almonds and pecans to the whole group of tree nuts is acceptable (European Commission, 2017b).

1.2.1.2. Peaches

The results of 13 residue trials on peaches carried out in the USA over two seasons and compliant with the reported US GAP support the proposed MRL.

1.2.1.3. Avocados

The results of five residue trials on avocados carried out in the USA during 1999 and compliant with the reported US GAP support the proposed MRL.

1.2.1.4. Salad plants (lamb's lettuces, escarole, cresses & other sprouts and shoots, land cresses, Roman rocket/rucola, baby leaf crops)

The results of six residue trials on open leaf lettuces carried out in the USA over two seasons and fully compliant with the US GAP were provided. To complete the data set, the applicant proposed to consider the results of additional six residue trials on open leaf varieties which were performed with five or six instead of three applications. The residue behaviour observed in the decline trials shows that the higher number of applications did not had a significant impact on residues at harvest. Additionally, the two sets of residue data obtained with three applications or with five/six applications showed to statistically belong to similar populations (U-test, 5%). Therefore, EFSA agreed to combine the two sets of data in order to derive an MRL proposal.

The proposed extrapolation from open leaf variety lettuces to the commodities listed in the group of salad plants is acceptable (European Commission, 2017b) and sufficiently supported by data. It is noted that the setting of an MRL for red mustards was not requested.[10]

1.2.1.5. Lettuces

The results of residue trials on open leaf lettuces (12 trials; see Section 1.2.1.4) and head-forming lettuce varieties (six trials) carried out in the USA support an MRL proposal of 0.07 mg/kg, which is slightly lower than the MRL of 0.08 mg/kg based on the data set on open leaf lettuces used for the extrapolation to the other salad plants proposed by the EMS.

1.2.1.6. Spinaches and similar leaves

The results of five residue trials on spinaches carried out in the USA over two seasons and fully compliant with the US GAP were provided. To complete the data set, the applicant proposed to consider the results of six residue trials on spinaches performed with six instead of three applications. The two sets of residue data obtained with three or six applications showed to statistically belong to similar populations (U-test, 5%) and were combined in order to derive an MRL proposal for spinaches.

[9] The method used did not allow a chromatographic separation of avermectin B1b and its delta 8,9 isomer.
[10] The applicant confirmed that no MRL is requested for red mustards (Netherlands, 2019).

The proposed extrapolation from spinaches to the group of spinaches and similar leaves is acceptable (European Commission, 2017b) and sufficiently supported by data.

1.2.1.7. Florence fennels

The results of six residue trials on celery carried out in the USA during 2008 and compliant with the reported US GAP for Florence fennels support the proposed MRL by extrapolation.

1.2.1.8. Cotton seed

The results of 11 residue trials on cotton carried out in the USA over two seasons and compliant with the reported US GAP support the proposed MRL.

1.2.2. Magnitude of residues in rotational crops

As the uses of abamectin are on crops to be imported, investigations of residues in rotational crops are not required.

1.2.3. Magnitude of residues in processed commodities

Specific studies investigating the magnitude of abamectin residues in processed commodities were not provided. Processing studies on cotton meal and refined oil were assessed by JMPR and showed a reduction of residues (FAO, 2015). Considering the low dietary exposure to each individual commodity, specific studies investigating the magnitude of residues after processing of peaches and cooking of vegetables are not required according to current guidance (European Commission, 1997d), but would be desirable.

1.2.4. Proposed MRLs

The available residue trials are sufficient to derive MRL proposals for the commodities under assessment, i.e. tree nuts, peaches, avocados, lettuces and salad plants with the exclusion of red mustards (not applied for), spinaches and similar leaves, Florence fennels and cotton seed (see Appendix B.4).

In Section 3 EFSA assessed whether residues on these crops resulting from the uses reported to be authorised in the USA are likely to pose a consumer health risk.

2. Residues in livestock

Cotton seed and cotton meal may be used for feed purposes. However, abamectin residues expected in cotton seed following the use notified to be authorised in the USA are covered in the most recent livestock dietary burden calculations performed by EFSA[11] (EFSA, 2018b). An update of the livestock dietary burden calculation was not required and further investigation on the nature and magnitude of residues in products of animal origin was not necessary.

3. Consumer risk assessment

EFSA performed a dietary risk assessment using revision 3.1 of the EFSA PRIMo (EFSA, 2018a, 2019a). This exposure assessment model contains food consumption data for different subgroups of the EU population and allows the acute and chronic exposure assessment to be performed in accordance with the internationally agreed methodology for pesticide residues (FAO, 2016).

The estimated exposure was then compared with the toxicological reference values (i.e. ADI and ARfD values) derived for abamectin during the EU pesticides peer review (European Commission, 2008). The complete list of input values can be found in Appendix D.1. For further details on the exposure calculations, a screenshot of the Report sheet of the PRIMo is presented in Appendix C.

3.1. Short-term (acute) dietary risk assessment

The short-term exposure assessment was performed only with regard to the uses of abamectin under consideration in accordance with the internationally agreed methodology (FAO, 2016). The calculations were based on the highest residue (HR) or the median residues (STMR) for cotton seeds, derived from supervised field trials.

[11] The same input value of 0.004 mg/kg for cotton seeds was used in the dietary burden calculation (EFSA, 2018b).

The short-term exposure did not exceed the ARfD for any of the crops assessed in this application (see Appendix C).

3.2. Long-term (chronic) dietary risk assessment

The most recent risk assessment performed by EFSA (EFSA, 2020) was updated to include the STMR values derived from the residue trials submitted in support of this MRL application where a higher STMR was derived.

The estimated long-term dietary intake was in the range of 0.5–12% of the ADI. The contribution of residues expected in the commodities assessed in this application to the overall long-term exposure is presented in more detail in Appendix B.3.

EFSA concluded that the long-term intake of residues of abamectin resulting from the existing and the notified US uses assessed in the present reasoned opinion is unlikely to present a risk to consumer health.

4. Conclusion and Recommendations

The available residue trials are sufficient to derive MRL proposals for tree nuts, peaches, avocados, lettuces and other salad plants, with the exclusion of red mustards (not applied for), spinaches and similar leaves, Florence fennels and cotton seeds.

EFSA concluded that the notified uses of abamectin on various crops assessed in the present reasoned opinion will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers' health.

It is highlighted that for some of the commodities assessed in the current application, MRL proposals were previously derived by EFSA in the framework of the assessment of confirmatory data following the MRL review (EFSA, 2020); hence, when modifying the EU MRLs for these commodities, risk managers should take into account the current and the previous recommendations of EFSA on the MRL modifications.

The process of renewal of the approval of the active substance abamectin in accordance with Regulation (EC) No 1107/2009 is not yet finalised, and therefore, the conclusions reported in this reasoned opinion may need to be reconsidered in the light of the outcome of the peer review of the pesticide risk assessment of the active substance abamectin.

The MRL recommendations are summarised in Appendix B.4.

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Abbreviations

a.s.	active substance
ADI	acceptable daily intake
AR	applied radioactivity
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CAC	Codex Alimentarius Commission
CAS	Chemical Abstract Service
CF	conversion factor for enforcement to risk assessment residue definition
cGAP	critical GAP
CIRCA	(EU) Communication & Information Resource Centre Administrator
CS	capsule suspension
CV	coefficient of variation (relative standard deviation)
CXL	Codex maximum residue limit
DALA	days after last application
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
DP	dustable powder
DS	powder for dry seed treatment
DT_{90}	period required for 90% dissipation (define method of estimation)
EC	emulsifiable concentrate
EDI	estimated daily intake
EMS	evaluating Member State
eq	residue expressed as a.s. equivalent
FAO	Food and Agriculture Organization of the United Nations
FID	flame ionisation detector
FLD	fluorescence detector
GAP	Good Agricultural Practice
GC	gas chromatography
GC-FID	gas chromatography with flame ionisation detector
GC-MS	gas chromatography with mass spectrometry
GC-MS/MS	gas chromatography with tandem mass spectrometry
GS	growth stage
HPLC	high-performance liquid chromatography
HPLC-MS	high-performance liquid chromatography with mass spectrometry
HPLC-MS/MS	high-performance liquid chromatography with tandem mass spectrometry
HR	highest residue
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ILV	independent laboratory validation
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LC	liquid chromatography
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
MS	mass spectrometry detector
MS/MS	tandem mass spectrometry detector
MW	molecular weight
NEU	northern Europe
OECD	Organisation for Economic Co-operation and Development
PBI	plant back interval
PF	processing factor
PHI	preharvest interval

P_{ow}	partition coefficient between n-octanol and water
PRIMo	(EFSA) Pesticide Residues Intake Model
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
RA	risk assessment
RD	residue definition
RMS	rapporteur Member State
SANCO	Directorate-General for Health and Consumers
SC	suspension concentrate
SEU	southern Europe
SL	soluble concentrate
SP	water-soluble powder
STMR	supervised trials median residue
TRR	total radioactive residue
UV	ultraviolet (detector)
WHO	World Health Organization

Appendix A – Summary of notified GAP triggering the amendment of existing EU MRLs

Crop and/or situation	NEU, SEU, MS or country	F G or I[a]	Pests or group of pests controlled	Preparation		Application				Application rate per treatment			Unit	PHI (days)[d]	Remarks
				Type[b]	Conc. a.s.	Method kind	Range of growth stages & season[c]	Number min–max	Interval between application (min)	g a.s./hL min–max	Water L/ha min–max	Rate			
Grapefruit, orange, lemon, lime, mandarin, other citrus fruit	US	F	Asian citrus psyllid, Broad mite, Citrus bud mite, Citrus leaf miner, Citrus rust mite, Citrus thrips, Two spotted spider, mite	EC	18.0	Foliar treatment – broadcast spraying		2	30		935–4,677	26.00	g a.i./ha	7	Max total per season = 52 g/ha Since the requested import tolerance was lower than the existing EU MRL, an evaluation of the submitted data was considered not necessary
Almond, brazil nut, cashew nut, chestnut, hazelnut, macadamia, pecan, pine nut, pistachio, walnut, other tree nuts	US	F	European red mite, Pacific spider mite, Strawberry spider mite, Two spotted spider mite	EC	18.0	Foliar treatment – broadcast spraying		2	21		374	26.00	g a.i./ha	21	Max total per season = 52 g/ha

Crop and/or situation	NEU, SEU, MS or country	F G or I[a]	Pests or group of pests controlled	Preparation		Application				Application rate per treatment			Unit	PHI (days)[d]	Remarks
				Type[b]	Conc. a.s.	Method kind	Range of growth stages & season[c]	Number min–max	Interval between application (min)	g a.s./hL min–max	Water L/ha min–max	Rate			
Apple, pear, quince, medlar, loquats/ Japanese medlar, other pome fruit	US	F	European red mite, McDaniel spider mite, Tentiform leaf miner, Two spotted spider mite, White apple leafhopper, Pear psylla, Pear rust mite, Yellow mite	SC	84.0	Foliar treatment – broadcast spraying		2	21		374	26.00	g a.i./ha	28	Max total per season = 52 g/ha Since the requested import tolerance was lower than the recently proposed MRL (EFSA, 2020), an evaluation of the submitted data was considered not necessary
Peach	US	F	European red mite, Pacific spider mite, Two spotted spider mite	SC	84.0	Foliar treatment – broadcast spraying		2	21		374	26.00	g a.i./ha	21	Max total per season = 52 g/ha
Strawberry	US	F	Carmine spider mite, Strawberry spider mite, Two spotted spider mite	SC	84.0	Foliar treatment – broadcast spraying		4	7		468	26.00	g a.i./ha	3	Since the requested import tolerance was lower than the existing EU MRL, an evaluation of the submitted data was considered not necessary

Crop and/or situation	NEU, SEU, MS or country	F G or I[a]	Pests or group of pests controlled	Preparation		Application				Application rate per treatment			Unit	PHI (days)[d]	Remarks
				Type[b]	Conc. a.s.	Method kind	Range of growth stages & season[c]	Number min–max	Interval between application (min)	g a.s./hL min–max	Water L/ha min–max	Rate			
Avocado	US	F	Scirtothrips, perseae	EC	18.0	Foliar treatment – broadcast spraying		2	30		935	26.00	g a.i./ha	14	Max total per season = 52 g/ha
Tomato, aubergine/egg plant, sweet pepper/bell pepper	US	F	Broad mite, Colorado potato beetle, Liriomyza leaf miners, Spider mites, Thrips palmi, Tomato psyllid, Tomato russet mite, Tomato pinworm	SC	84.0	Foliar treatment – broadcast spraying		3	7		187	21.00	g a.i./ha	7	Max total per season = 63 g/ha Since the requested import tolerances were lower than the existing/recently proposed MRL (EFSA, 2020), an evaluation of the submitted data was considered not necessary
Cucumber, gherkin, courgette, other cucurbits – edible peel	US	F	Leaf miners, Spider mites	SC	84.0	Foliar treatment – broadcast spraying		3	7		187	21.00	g a.i./ha	7	Max total per season = 63 g/ha Since the requested import tolerance was lower than the existing EU MRL, an evaluation of the submitted data was considered not necessary

Crop and/or situation	NEU, SEU, MS or country	F G or I[a]	Pests or group of pests controlled	Preparation		Application				Application rate per treatment			Unit	PHI (days)[d]	Remarks
				Type[b]	Conc. a.s.	Method kind	Range of growth stages & season[c]	Number min–max	Interval between application (min)	g a.s./hL min–max	Water L/ha min–max	Rate			
Lamb's lettuce/corn salad, lettuce, escarole/broadleaved endive, cress and other sprouts and shoots, land cress, roman rocket/rucola, baby leaf crops (including brassica species)	US	F	Carmine spider mite, Liriomyza leaf miners, Two spotted spider mite	SC	84.0	Foliar treatment – broadcast spraying		3	7		187	21.00	g a.i./ha	7	Max total per season = 63 g/ha
Spinach, purslane, chard/beet leaves,	US	F	Carmine spider mite, Liriomyza leaf miners, Two spotted spider mite	SC	84.0	Foliar treatment – broadcast spraying		3	7		187	21.00	g a.i./ha	7	Max total per season = 63 g/ha
Chervil, chive, parsley, sage, rosemary, thyme, basil and edible flowers, laurel/bay, tarragon, other herbs	US	F	Carmine spider mite, Liriomyza leaf miners, Two spotted spider mite	SC	84.0	Foliar treatment – broadcast spraying		3	7		187	21.00	g a.i./ha	7	Max total per season = 63 g/ha Not assessed, since EMS did not derive a MRL proposal.

Crop and/or situation	NEU, SEU, MS or country	F G or I[a]	Pests or group of pests controlled	Preparation		Application				Application rate per treatment			Unit	PHI (days)[d]	Remarks
				Type[b]	Conc. a.s.	Method kind	Range of growth stages & season[c]	Number min–max	Interval between application (min)	g a.s./hL min–max	Water L/ha min–max	Rate			
Celery leaves	US	F	Carmine spider mite, Liriomyza leaf miners, Two spotted spider mite	SC	84.0	Foliar treatment – broadcast spraying		3	7		187	21.00	g a.i./ha	7	Max total per season= 63 g/ha Since the requested import tolerance was lower than the recently proposed MRL (EFSA, 2020), an evaluation of the submitted data was considered not necessary.
Celery	US	F	Carmine spider mite, Liriomyza leaf miners, Two spotted spider mite	SC	84.0	Foliar treatment – broadcast spraying		3	7		187	21.00	g a.i./ha	7	Max total per season = 63 g/ha Since the requested import tolerance was lower than the existing EU MRL, an evaluation of the submitted data was considered not necessary
Florence fennel	US	F	Carmine spider mite, Liriomyza leaf miners, Two spotted spider mite	SC	84.0	Foliar treatment – broadcast spraying		3	7		187	21.00	g a.i./ha	7	Max total per season = 63 g/ha

Crop and/or situation	NEU, SEU, MS or country	F G or I[a]	Pests or group of pests controlled	Preparation		Application				Application rate per treatment			Unit	PHI (days)[d]	Remarks
				Type[b]	Conc. a.s.	Method kind	Range of growth stages & season[c]	Number min–max	Interval between application (min)	g a.s./hL min–max	Water L/ha min–max	Rate			
Cotton	US	F	Carmine spider mite, Pacific spider mite, Strawberry spider, mite, Two spotted spider, mite	EC	18.0	Foliar treatment – broadcast spraying		2	21			21.00	g a.i./ha	20	Max total per season = 42 g/ha

NEU: northern European Union; SEU: southern European Union; MS: Member State; MRL: maximum residue level; a.s.: active substance; SC: suspension concentrate; EC: emulsifiable concentrate.
(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 7th Edition. Revised March 2017. Catalogue of pesticide formulation types and international coding system.
(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**	**Crops**	**Applications**	**Sampling**	**Comment/Source**
	Fruit crops	Citrus fruits	Onto fruit, 1 × 4 μg/fruit and 1 × 40 μg/fruit	1, 2, 4, 8, 12 weeks post application	^{14}C-avermectin B1a (EFSA, 2008)
		Tomato	Foliar (F, G), 5 × 0.026 kg/ha	0, 3, 7, 14, 28 DALA	^{14}C-avermectin B1a (EFSA, 2008)
			Foliar (G), 3 × 0.28 kg/ha		
			Foliar (F), 3 × 0.25 kg/ha		
	Leafy crops	Celery	Foliar (F) to immature plants, 4 × 0.017 kg/ha	0, 14 DALA	^{14}C-avermectin B1a (EFSA, 2008)
			Foliar (F) to immature plants, 4 × 0.011 kg/ha and 4 × 0.110 kg/ha	0, 7, 14, 29, 43 DALA	^{3}H-avermectin B1a (EFSA, 2008)
			Foliar (F) to mature plants, 10 × 0.017 kg/ha	0, 7 DALA	^{14}C-avermectin B1a (EFSA, 2008)
			Foliar (F) to mature plants, 10 × 0.011 kg/ha and 10 × 0.110 kg/ha	0, 1, 3, 7, 15, 22 DALA	^{3}H-avermectin B1a (EFSA, 2008)
	Pulses/ oilseeds	Cotton	Onto leaf, 1 × 200 μL/leaf Onto leaf, 1 9 200 μL/leaf	0, 1, 2, 4, 8 DAT	^{14}C-avermectin B1a (EFSA, 2008)
			Foliar (F), 2 × 0.02 kg/ha	60 DALA	^{14}C-avermectin B1a (EFSA, 2008)
			Foliar (F), 3 × 0.022 and 3 × 0.22 kg/ha	21 DALA	^{14}C-avermectin B1a (EFSA, 2008)
Rotational crops (available studies)	**Crop groups**	**Crops**	**Applications)**	**PBI (DAT)**	**Comment/Source**
	Root/tuber crops	Carrot	Soil application, 3 × 0.029 and 12 × 0.034 kg/ha	14–31, 120–123, 365	^{14}C-avermectin B1a (EFSA, 2008) Studies provided although not triggered (DT_{90} avermectin B1a < 1 day)
		Turnip			
	Leafy crops	Lettuce			
	Cereal (small grain)	Sorghum			

Processed commodities (hydrolysis study)	**Conditions**	**Stable?**	**Comment/Source**
	Pasteurisation (20 min, 90°C, pH 4)	yes	^{14}C-avermectin B1a (EFSA, 2008) Avermectin B1a degraded (30–40% AR) forming mainly its monosaccharide (10–20% applied radioactivity (AR)). The major degradation product was considered of the same toxicity as the parent
	Baking, brewing and boiling (60 min, 100°C, pH 5)	Yes	
	Sterilisation (20 min, 120°C, pH 6)	Yes	
	Other processing conditions	–	–

Can a general residue definition be proposed for primary crops?	Yes	EFSA (2008)
Rotational crop and primary crop metabolism similar?	Yes	EFSA (2008)
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes	EFSA (2008)
Plant residue definition for monitoring (RD-Mo)	Abamectin (Sum of avermectin B1a, avermectin B1b and delta-8,9 isomer of avermectin B1a, expressed as avermectin B1a)	
Plant residue definition for risk assessment (RD-RA)	Abamectin (Sum of avermectin B1a, avermectin B1b and delta-8,9 isomer of avermectin B1a, expressed as avermectin B1a)	
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)	Matrices with high water content (bananas, lettuces) HPLC–MS/MS (QuEChERS), LOQ 0.002 mg/kg per each analyte ILV available (EFSA, 2017, 2020) Matric with high acid content (strawberries, oranges) HPLC–MS/MS (QuEChERS), LOQ 0.002 mg/kg per each analyte ILV available (EFSA, 2018b, 2020) Matrices with high oil content (sunflower seeds): HPLC–MS/MS (QuEChERS), LOQ 0.002 mg/kg per each analyte ILV available (EFSA, 2020) Matrices with high protein content/dry commodity (dried beans) HPLC–MS/MS (QuEChERS), LOQ 0.002 mg/kg per each analyte ILV available (EFSA, 2020) Matrices with high starch content/dry commodity (wheat grain) HPLC–MS/MS (QuEChERS), LOQ 0.002 mg/kg per each analyte ILV not available (EFSA, 2020) and not required	

DAT: days after treatment; DALA: days after last application; PBI: plant-back interval; HPLC–MS/MS: high-performance liquid chromatography with tandem mass spectrometry; QuEChERS: Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method); ILV: independent laboratory validation; LOQ: limit of quantification.

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	Not specified	−18	36	Months	AVM B1a, AVM B1b, 8,9-delta isomer AVM B1a	EFSA (2008)
	High oil content	Not specified	−18	24	Months	AVM B1a, AVM B1b, 8,9-delta isomer AVM B1a	EFSA (2008)
	High acid content	Not specified	−18	14	Months	AVM B1a, AVM B1b, 8,9-delta isomer AVM B1a	EFSA (2008)
	Processed products	Orange peel, orange pulp	−18	12	sMonths	AVM B1a, AVM B1b, 8,9-delta isomer AVM B1a	EFSA (2008)

B.1.2. Magnitude of residues in plants

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

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)
Tree nuts	US	15 × < 0.01	Residue trials on walnuts, almonds and pecans conducted at a more cGAP (3 or 5 × 28 g/ha, PHI 14 days except 2 trials with PHI 21 days) A no residue situation is expected also at the US GAP (2 × 26 g/ha, PHI 21 days) Extrapolation to tree nuts possible US tolerance: 0.01 mg/kg	0.01*	0.010	0.010
Peaches	US	3 × < 0.004; 3 × 0.004; 0.005; 0.006; 0.007; 2 × 0.008; 0.010; 0.026	Residue trials compliant with the US GAP US tolerance: 0.09 mg/kg	0.04	0.026	0.005
Avocados	US	< 0.004; 0.005; 0.006; 0.007; 0.009	Residue trials compliant with the US GAP US tolerance: 0.02 mg/kg	0.02	0.009	0.006
Lamb's lettuces, Escarole, Cresses & other sprouts and shoots, Land cresses, Roman rocket/rucola, baby leaf crops	US	Residue trials with 3 applications: 0.007; 0.008; 0.015; 2 × 0.022; 0.032 Residue trials with 5–6 applications: 0.010; 0.018; 0.019; 0.020; 0.025; 0.054	Combined data set of residue trials on open leaf lettuces with 3 applications (fully US GAP-compliant) or 5–6 applications (statistically similar, U-test, 5%) Extrapolation to the group of salad plants possible US tolerance: 0.1 mg/kg	0.08	0.054	0.020
Lettuces	US	Residue trials in open leaf varieties, *3 applications*: 0.007; 0.008; 0.015; 2 × 0.022; 0.032 *5-6 applications*: 0.010; 0.018; 0.019; 0.020; 0.025; 0.054 Residue trials in head forming varieties (3 applications): 3 × < 0.004; 0.007; 2 × 0.008	Combined data set of residue trials on open leaf lettuces with 3 applications (fully US GAP-compliant) or 5–6 applications (statistically similar, U-test, 5%) and on closed leaf lettuces (fully US GAP-compliant) MRL of 0.08 mg/kg for lettuces is derived if the results on closed leaf lettuces are disregarded US tolerance: 0.1 mg/kg	(Open leaf varieties and head-forming varieties: 0.07) Open leaf varieties only: 0.08	0.054	(Open leaf varieties and head-forming varieties: 0.013) Open leaf varieties only: 0.020

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)
Spinaches and similar leaves	Us	Residue trials with 3 applications: 2 × < 0.004; 0.017; 0.023; 0.052 Residue trials with 6 applications: 0.022; 0.026; 0.031; 0.047; 0.048; 0.093	Combined data set of residue trials on spinaches with 3 applications (fully US GAP-compliant) or 6 applications (statistically similar, U-test, 5%) Extrapolation to the group of spinaches and similar leaves possible US tolerance: 0.1 mg/kg	0.15	0.093	0.026
Florence fennels	US	0.005; 2 × 0.007; 0.009; 0.012; 0.018	Residue trials on celery compliant with the US GAP on Florence fennels Extrapolation to Florence fennels possible US tolerance: 0.1 mg/kg	0.03	0.018	0.008
Cotton seeds	US	10 × < 0.004; 0.013	Residue trials compliant with the US GAP US tolerance: 0.02 mg/kg	0.02	0.013	0.004

*: Indicates that the MRL is proposed at the limit of quantification; GAP: Good Agricultural Practice; cGAP: critical GAP; MRL: maximum residue level.
(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 refers to the whole commodity and not to the edible portion.
(c): Supervised trials median residue. The median residue for risk assessment refers to the whole commodity and not to the edible portion.

B.1.2.2. Residues in rotational crops

Residues in rotational and succeeding crops expected based on confined rotational crop study?	Not triggered	The present MRL application is an import tolerance request and residues in rotational crops were not investigated
Residues in rotational and succeeding crops expected based on field rotational crop study?	Not triggered	The present MRL application is an import tolerance request and residues in rotational crops were not investigated

MRL: maximum residue level.

B.1.2.3. Processing factors

No processing studies were submitted in the framework of the present MRL application.

B.2. Residues in livestock

Not relevant

B.3. Consumer risk assessment

ARfD	0.005 mg/kg bw (European Commission, 2008)
Highest IESTI, according to EFSA PRIMo	Lamb's lettuces: 73% of ARfD Peaches: 49% of ARfD Escaroles/broad-leaved endives: 43% of ARfD Spinaches: 42% of ARfD Lettuces: 41% of ARfD Chards/beet leaves: 35% of ARfD Avocados: 9% of ARfD Florence fennels: 5% of ARfD Roman rocket/rucola: 3% of ARfD Tree nuts: ≤1% of ARfD Cress and other sprouts and shoots: 0.04% of ARfD
Assumptions made for the calculations	The calculation was based on the highest residue levels or the median residue for cotton seeds, derived for raw agricultural commodities for the crops under consideration. For Lamb's lettuces and baby leaf crops (including brassica species), the highest residue derived in the MRL review of confirmatory data was applied Calculations performed with PRIMo revision 3.1

ADI	0.0025 mg/kg bw per day (European Commission, 2008)
Highest IEDI, according to EFSA PRIMo	12% of ADI (NL toddler) Contribution of crops assessed: Spinaches: 0.007% of ADI Lettuces: 0.004% of ADI Escaroles/broad-leaved endives: 0.002% of ADI Peaches: 0.001% of ADI Cotton seeds: 0.001% of ADI Remaining commodities: <0.001% of ADI
Assumptions made for the calculations	The calculation was based on the median residue levels derived for raw agricultural commodities and the existing MRLs for bovine and sheep tissues (derived from the use in veterinary medicine). For citrus fruits and bananas, the median residue refers to the edible portion (pulp) Pending risk management decision on whether to confirm or lower the existing MRLs for pome fruits, tomatoes and beans with pods, EFSA used the input values applied in the framework of the MRL review The conversion factor for risk assessment of 1.25 was used for the MRLs of bovine and sheep products. The contribution of commodities where no GAP was reported during the MRL review or supported in the framework of the evaluation of its confirmatory data as well as in EFSA reasoned opinions issued after the MRL review, was not included in the calculation Calculations performed with PRIMo revision 3.1

ARfD: acute reference dose; bw: body weight; IESTI: international estimated short-term intake; PRIMo: (EFSA) Pesticide Residues Intake Model; ADI: acceptable daily intake; IEDI: international estimated daily intake; MRL: maximum residue level.

B.4. Recommended MRLs

Code[a]	Commodity	Existing EU MRL/MRL proposals derived in a recent assessment of EFSA (not yet implemented)[b] (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Abamectin (sum of avermectin B1a, avermectin B1b and delta-8,9 isomer of avermectin B1a, expressed as avermectin B1a)[F]				
0120010	Almonds	0.02 (ft 1)/(0.01* or 0.006*)[c]	0.01*	The submitted data are sufficient to derive an import tolerance at the LOQ of 0.01 mg/kg for the whole group of tree nuts US tolerance: 0.01 mg/kg Risk for consumers unlikely
0120020	Brazil nuts	0.01*	No change	
0120030	Cashew nuts	0.01*	No change	
0120040	Chestnuts	0.01*	No change	
0120050	Coconuts	0.01*	No change	
0120060	Hazelnuts/ cobnuts	0.02 (ft 1)/(0.01* or 0.006*)[c]	0.01*	
0120070	Macadamias	0.01*	No change	
0120080	Pecans	0.01*	No change	
0120090	Pine nut kernels	0.01*	No change	
0120100	Pistachios	0.01*	No change	
0120110	Walnuts	0.02 (ft 1)/(0.01* or 0.006*)[c]	0.01*	

Code[a]	Commodity	Existing EU MRL/MRL proposals derived in a recent assessment of EFSA (not yet implemented)[b] (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
0140030	Peaches	0.02	0.04	The submitted data are sufficient to derive an import tolerance (US GAP). US tolerance: 0.09 mg/kg. Risk for consumers unlikely
0163010	Avocados	0.01*	0.02	The submitted data are sufficient to derive an import tolerance (US GAP). US tolerance: 0.02 mg/kg. Risk for consumers unlikely
0251010	Lamb's lettuces/corn salads	2 (ft 2)/3	Further risk management considerations required	The submitted data on open leaf lettuces are sufficient to derive an import tolerance (US GAP) of 0.08 mg/kg by extrapolation. US tolerance: 0.1 mg/kg. Risk for consumers unlikely The proposed import tolerance is lower than the MRL proposal derived by EFSA in the assessment of MRL review confirmatory data. Hence, the previously derived MRL proposal of 3 mg/kg is still valid
0251020	Lettuces	0.09 (ft 2)/0.01* or 0.006* or 0.09[c]	Further risk management considerations required	The submitted data are sufficient to derive an import tolerance (US GAP) of 0.08 mg/kg based on data set of residue trials in open leaf lettuces only; combining the residue trials on open leaf varieties and head-forming varieties a slightly lower MRL proposal of 0.07 mg/kg is derived US tolerance: 0.1 mg/kg. Risk for consumers unlikely Risk managers need to decide whether the proposed import tolerance of 0.07 or 0.08 mg/kg or the previously presented option of 0.09 mg/kg should be implemented in the EU legislation
0251030	Escaroles/ broad leaved endives	0.1 (ft 2)/0.03	0.08	The submitted data on open leaf lettuces are sufficient to derive an import tolerance (US GAP) by extrapolation US tolerance: 0.1 mg/kg. Risk for consumers unlikely
0251040	Cresses & other sprouts and shoots	0.01*/0.03	0.08	
0251050	Land cresses	0.01*	0.08	
0251060	Roman rocket/rucola	0.015/0.03	0.08	
0251990	Baby leaf crops (incl. brassica species)	2 (ft 2)/3	Further risk management considerations required	The submitted data on open leaf lettuces are sufficient to derive an import tolerance (US GAP) of 0.08 mg/kg by extrapolation. US tolerance: 0.1 mg/kg. Risk for consumers unlikely The proposed import tolerance is lower than the MRL proposal derived by EFSA in the assessment of confirmatory data. Hence, the previously derived MRL proposal of 3 mg/kg is still valid

Code[(a)]	Commodity	Existing EU MRL/MRL proposals derived in a recent assessment of EFSA (not yet implemented)[(b)] (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
0251990	Others (lettuces and salad plants)	0.01*	0.08	The submitted data on open leaf lettuces are sufficient to derive an import tolerance (US GAP) by extrapolation. US tolerance: 0.1 mg/kg. Risk for consumers unlikely
0252010	Spinaches	0.01*/0.03	0.1 or 0.15 Further risk management considerations required	The import tolerance request is sufficiently supported by data. Using the OECD MRL calculator, an MRL proposal of 0.15 mg/kg is derived which is higher than the MRL in place in the USA (US tolerance: 0.1 mg/kg). Risk for consumers unlikely Further risk management considerations are recommended to decide on the most appropriate MRL
0252020	Purslanes	0.01*/0.03	0.1 or 0.15 Further risk management considerations required	The import tolerance request is sufficiently supported by data (extrapolation from spinaches). Using the OECD MRL calculator, an MRL proposal of 0.15 mg/kg is derived which is higher than the MRL in place in the USA (US tolerance: 0.1 mg/kg). Risk for consumers unlikely Further risk management considerations are recommended to decide on the most appropriate MRL
0252030	Chards/beet leaves	0.01*/0.03		
0252990	Others (spinaches and similar leaves	0.01*/0.03		
0270040	Florence fennels	0.01*	0.03	The submitted data are sufficient to derive an import tolerance (US GAP) by extrapolation from celery. US tolerance: 0.1 mg/kg. Risk for consumers unlikely
0401090	Cotton seeds	0.01*	0.02	The submitted data are sufficient to derive an import tolerance (US GAP). US tolerance: 0.02 mg/kg Risk for consumers unlikely

*: Indicates that the MRL is set at the limit of analytical quantification (LOQ). MRL: maximum residue level.
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(b): The MRL proposals which were derived in the framework of the assessment of confirmatory data requested in the framework of the MRL review under Article 12 of Regulation (EC) No 396/2005 have not yet been implemented in the EU MRL legislation (EFSA, 2020).
(c): More than one MRL proposal was derived by EFSA for further risk management considerations (EFSA, 2020).
(ft 1): The European Food Safety Authority identified some information on analytical methods and residue trials as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 19 November 2017, or, if that information is not submitted by that date, the lack of it.
(ft 2): The European Food Safety Authority identified some information on residue trials as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 19 November 2017, or, if that information is not submitted by that date, the lack of it.
(F): Fat soluble.

Appendix C – Pesticide Residue Intake Model (PRIMo)

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Abamectin (sum of avermectin B1a, avermectin B1b and delta-8,9 isomer of avermectin B1a, expressed as avermectin B1a) (R) (F)

LOQs (mg/kg) range from:	0.01	to:	0.05

Toxicological reference values

ADI (mg/kg bw per day):	0.0025	ARfD (mg/kg bw):	0.005
Source of ADI:	COM	Source of ARfD:	COM
Year of evaluation:	2008	Year of evaluation:	2008

Input values

Details – chronic risk assessment | Supplementary results – chronic risk assessment

Details – acute risk assessment/children | Details – acute risk assessment/adults

Comments:

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	12%	NL toddler	0.31	3%	Apples	1%	Pears	1%	Bananas		12%
	11%	DE child	0.28	4%	Apples	2%	Oranges	1%	Tomatoes		11%
	9%	GEMS/Food G06	0.23	4%	Tomatoes	0.6%	Lamb's lettuce/corn salads	0.4%	Aubergines/egg plants		9%
	8%	GEMS/Food G11	0.21	4%	Lamb's lettuce/corn salads	1%	Tomatoes	0.5%	Apples		8%
	8%	GEMS/Food G08	0.19	3%	Lamb's lettuce/corn salads	1%	Tomatoes	0.4%	Apples		8%
	7%	NL child	0.18	2%	Apples	0.7%	Tomatoes	0.6%	Oranges		7%
	7%	GEMS/Food G07	0.16	1%	Tomatoes	1.0%	Lamb's lettuce/corn salads	0.6%	Oranges		7%
	7%	SE general	0.16	2%	Bovine: Muscle/meat	0.9%	Tomatoes	0.4%	Bananas		7%
	6%	FR child 3 15 yr	0.15	1%	Oranges	1%	Tomatoes	0.7%	Bovine: Muscle/meat		6%
	6%	IE adult	0.15	0.5%	Tomatoes	0.4%	Oranges	0.4%	Sheep: Muscle/meat		6%
	6%	GEMS/Food G10	0.14	2%	Tomatoes	0.5%	Bovine: Muscle/meat	0.5%	Oranges		6%
	5%	RO general	0.13	2%	Tomatoes	0.5%	Apples	0.4%	Wine grapes		5%
	5%	FR toddler 2 3 yr	0.13	1%	Apples	0.6%	Bovine: Muscle/meat	0.6%	Tomatoes		5%
	5%	ES child	0.13	1%	Tomatoes	0.9%	Oranges	0.7%	Bovine: Muscle/meat		5%
	5%	DE women 14-50 yr	0.13	0.9%	Tomatoes	0.9%	Lamb's lettuce/corn salads	0.8%	Apples		5%
	5%	GEMS/Food G15	0.12	1%	Tomatoes	0.4%	Apples	0.3%	Potatoes		5%
	5%	DE general	0.11	0.8%	Tomatoes	0.8%	Apples	0.8%	Lamb's lettuce/corn salads		5%
	4%	UK toddler	0.11	0.8%	Oranges	0.7%	Tomatoes	0.6%	Bovine: Muscle/meat		4%
	4%	DK child	0.10	0.7%	Apples	0.7%	Tomatoes	0.7%	Bovine: Muscle/meat		4%
	4%	ES adult	0.10	1.0%	Tomatoes	0.5%	Oranges	0.4%	Lettuces		4%
	4%	IT toddler	0.10	2%	Tomatoes	0.3%	Apples	0.2%	Lettuces	0.0%	4%
	4%	FR adult	0.09	0.8%	Lamb's lettuce/corn salads	0.6%	Tomatoes	0.6%	Wine grapes		4%
	4%	PT general	0.09	1%	Tomatoes	0.6%	Wine grapes	0.4%	Potatoes		4%
	4%	IT adult	0.09	1%	Tomatoes	0.3%	Lettuces	0.3%	Apples	0.0%	4%
	4%	UK infant	0.09	0.6%	Bovine: Muscle/meat	0.5%	Oranges	0.5%	Apples		4%
	3%	NL general	0.09	0.5%	Tomatoes	0.5%	Apples	0.4%	Oranges		3%
	3%	FI 3 yr	0.08	0.7%	Tomatoes	0.4%	Strawberries	0.4%	Potatoes		3%
	3%	PL general	0.07	1%	Tomatoes	0.7%	Apples	0.3%	Potatoes	0.0%	3%
	3%	FI 6 yr	0.07	0.5%	Tomatoes	0.3%	Strawberries	0.3%	Potatoes		3%
	2%	DK adult	0.06	0.6%	Tomatoes	0.3%	Apples	0.3%	Bovine: Muscle/meat		2%
	2%	FR infant	0.06	0.5%	Apples	0.3%	Spinaches	0.2%	Beans (with pods)		2%
	2%	UK vegetarian	0.06	0.8%	Tomatoes	0.3%	Oranges	0.2%	Wine grapes		2%
	2%	UK adult	0.05	0.5%	Tomatoes	0.3%	Bovine: Muscle/meat	0.3%	Wine grapes		2%
	2%	LT adult	0.05	0.8%	Tomatoes	0.6%	Apples	0.3%	Potatoes	0.0%	2%
	2%	FI adult	0.05	0.7%	Tomatoes	0.2%	Apples	0.2%	Strawberries		2%
	0.5%	IE child	0.01	0.1%	Apples	0.1%	Tomatoes	0.0%	Potatoes		0.5%

Conclusion:

The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.

The long-term intake of residues of Abamectin (sum of avermectin B1a, avermectin B1b and delta-8,9 isomer of avermectin B1a, expressed as avermectin B1a) (R) (F) is unlikely to present a public health concern.

Acute risk assessment /children	Acute risk assessment / adults / general population
Details - acute risk assessment /children	Details - acute risk assessment/adults

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
73%	Lamb's lettuce/corn salads	2 / 1.3	3.7
67%	Sweet peppers/bell peppers	0.07 / 0.06	3.3
49%	Peaches	0.02 / 0.03	2.5
45%	Cucumbers	0.04 / 0.03	2.2
43%	Escaroles/broad-leaved	0.1 / 0.05	2.2
42%	Spinaches	0.1 / 0.09	2.1
41%	Lettuces	0.09 / 0.05	2.1
37%	Tomatoes	0.09 / 0.03	1.9
33%	Pears	0.03 / 0.01	1.7
32%	Courgettes	0.04 / 0.03	1.6
29%	Chards/beet leaves	0.1 / 0.09	1.5
28%	Chervil	2 / 1.07	1.4
27%	Oranges	0.04 / 0.01	1.3
26%	Apples	0.03 / 0.01	1.3
24%	Strawberries	0.15 / 0.07	1.2
23%	Parsley	2 / 1.07	1.2
21%	Melons	0.01 / 0.01	1.1
17%	Chives	2 / 1.07	0.87
17%	Watermelons	0.01 / 0.01	0.86
16%	Celeries	0.05 / 0.02	0.82
16%	Sage	2 / 1.07	0.81
16%	Aubergines/egg plants	0.09 / 0.03	0.80
16%	Grapefruits	0.04 / 0.01	0.79
16%	Basil and edible flowers	2 / 1.07	0.78
15%	Chinese cabbages/pe-tsai	0.05 / 0.02	0.77
15%	Potatoes	0.01 / 0.01	0.77
12%	Beans (with pods)	0.03 / 0.05	0.61
12%	Mandarins	0.04 / 0.01	0.59
12%	Bananas	0.02 / 0.01	0.58
9%	Avocados	0.01 / 0.01	0.45
9%	Table grapes	0.01 / 0.01	0.44
9%	Peas (with pods)	0.03 / 0.05	0.43
8%	Leeks	0.01 / 0.01	0.41
7%	Blackberries	0.08 / 0.03	0.35
7%	Apricots	0.02 / 0.01	0.35
7%	Lemons	0.04 / 0.01	0.34
6%	Raspberries (red and yellow)	0.08 / 0.03	0.30
6%	Quinces	0.03 / 0.01	0.30
6%	Florence fennels	0.03 / 0.02	0.29
5%	Plums	0.01 / 0.01	0.25
5%	Onions	0.01 / 0.01	0.23
4%	Bovine: Liver	0.02 / 0.03	0.20
4%	Limes	0.04 / 0.01	0.20
4%	Pumpkins	0.01 / 0.01	0.19
4%	Bovine: Edible offals (other	0.02 / 0.03	0.18
3%	Medlar	0.03 / 0.01	0.17
3%	Roman rocket/rucola	0.02 / 0.05	0.15
3%	Coconuts	0.01 / 0.01	0.14
3%	Sheep: Muscle/meat	0.02 / 0.03	0.14
2%	Radishes	0.01 / 0	0.10
2%	Gherkins	0.04 / 0.03	0.10
2%	Spring onions/green onions	0.01 / 0.01	0.09
2%	Bovine: Muscle/meat	0.01 / 0.01	0.09
1%	Thyme	2 / 1.07	0.06
1%	Pistachios	0.01 / 0.01	0.06
1%	Wine grapes	0.01 / 0.01	0.06
0.8%	Chestnuts	0.01 / 0.01	0.04
0.8%	Bovine: Kidney	0.01 / 0.01	0.04

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
49%	Lamb's lettuce/corn salads	2 / 1.3	2.4
35%	Chards/beet leaves	0.1 / 0.09	1.8
26%	Parsley	2 / 1.07	1.3
22%	Escaroles/broad-leaved	0.1 / 0.05	1.1
19%	Cucumbers	0.04 / 0.03	0.95
18%	Sweet peppers/bell peppers	0.07 / 0.06	0.91
17%	Aubergines/egg plants	0.09 / 0.03	0.87
16%	Courgettes	0.04 / 0.03	0.79
14%	Strawberries	0.15 / 0.07	0.69
13%	Lettuces	0.09 / 0.05	0.66
12%	Chinese cabbages/pe-tsai	0.05 / 0.02	0.61
10%	Tomatoes	0.09 / 0.03	0.51
10%	Peaches	0.02 / 0.03	0.49
8%	Beans (with pods)	0.03 / 0.05	0.41
7%	Spinaches	0.1 / 0.09	0.37
7%	Pears	0.03 / 0.01	0.37
7%	Celeries	0.05 / 0.02	0.35
7%	Apples	0.03 / 0.01	0.34
7%	Florence fennels	0.03 / 0.02	0.34
6%	Oranges	0.04 / 0.01	0.31
6%	Watermelons	0.01 / 0.01	0.28
5%	Melons	0.01 / 0.01	0.27
5%	Blackberries	0.08 / 0.03	0.27
4%	Sage	2 / 1.07	0.21
4%	Gherkins	0.04 / 0.03	0.21
4%	Table grapes	0.01 / 0.01	0.20
4%	Quinces	0.03 / 0.01	0.18
4%	Chives	2 / 1.07	0.18
4%	Peas (with pods)	0.03 / 0.05	0.18
4%	Mandarins	0.04 / 0.01	0.18
4%	Grapefruits	0.04 / 0.01	0.18
4%	Raspberries (red and yellow)	0.08 / 0.03	0.18
4%	Purslanes	0.1 / 0.09	0.18
3%	Potatoes	0.01 / 0.01	0.15
3%	Onions	0.01 / 0.01	0.15
3%	Wine grapes	0.01 / 0.01	0.14
3%	Avocados	0.01 / 0.01	0.14
3%	Basil and edible flowers	2 / 1.07	0.13
3%	Bananas	0.02 / 0.01	0.13
2%	Sheep: Muscle/meat	0.02 / 0.03	0.12
2%	Apricots	0.02 / 0.01	0.11
2%	Plums	0.01 / 0.01	0.11
2%	Rosemary	2 / 1.07	0.11
2%	Rosemary	2 / 1.07	0.11
2%	Rosemary	2 / 1.07	0.11
2%	Tarragon	2 / 1.07	0.11
2%	Pumpkins	0.01 / 0.01	0.10
2%	Bovine: Liver	0.02 / 0.03	0.10
2%	Leeks	0.01 / 0.01	0.09
2%	Lemons	0.04 / 0.01	0.09
2%	Sheep: Liver	0.03 / 0.03	0.09
2%	Coconuts	0.01 / 0.01	0.09
2%	Chervil	2 / 1.07	0.09
2%	Bovine: Edible offals (other	0.02 / 0.03	0.08
2%	Medlar	0.03 / 0.01	0.08
1%	Bovine: Muscle	0.01 / 0.01	0.07
1%	Limes	0.04 / 0.01	0.07
1%	Roman rocket/rucola	0.02 / 0.05	0.06

0.7%	Garlic	0.01 / 0.01	0.04	0.9%	Chestnuts	0.01 / 0.01	0.05
0.7%	Walnuts	0.02 / 0.01	0.03	0.9%	Sheep: Edible offals (other	0.05 / 0.06	0.04
0.7%	Hazelnuts/cobnuts	0.02 / 0.01	0.03	0.8%	Radishes	0.01 / 0	0.04
0.6%	Rosemary	2 / 1.07	0.03	0.5%	Spring onions/green onions	0.01 / 0.01	0.03
0.6%	Almonds	0.02 / 0.01	0.03	0.5%	Pistachios	0.01 / 0.01	0.03
0.6%	Pecans	0.01 / 0.01	0.03	0.5%	Shallots	0.01 / 0.01	0.03
0.5%	Bovine: Fat tissue	0.01 / 0.01	0.03	0.5%	Pecans	0.01 / 0.01	0.02
0.5%	Cashew nuts	0.01 / 0.01	0.03	0.4%	Walnuts	0.02 / 0.01	0.02
0.3%	Cress and other sprouts and	0.01 / 0.05	0.02	0.4%	Bovine: Kidney	0.01 / 0.01	0.02
0.2%	Laurel/bay leaves	2 / 1.07	0.01	0.4%	Macadamia	0.01 / 0.01	0.02
0.2%	Brazil nuts	0.01 / 0.01	0.01	0.4%	Cress and other sprouts and	0.01 / 0.05	0.02
0.1%	Celery leaves	0.09 / 0.01	0.01	0.3%	Cashew nuts	0.01 / 0.01	0.02
0.1%	Macadamia	0.01 / 0.01	0.01	0.3%	HOPS (dried)	0.1 / 0.09	0.02
0.07%	HOPS (dried)	0.1 / 0.09	0.00	0.3%	Almonds	0.02 / 0.01	0.01
0.07%	Pine nut kernels	0.01 / 0.01	0.00	0.2%	Bovine: Fat tissue	0.01 / 0.01	0.01
0.06%	Shallots	0.01 / 0.01	0.00	0.2%	Hazelnuts/cobnuts	0.02 / 0.01	0.01
				0.2%	Pine nut kernels	0.01 / 0.01	0.01
				0.1%	Brazil nuts	0.01 / 0.01	0.01
				0.1%	Garlic	0.01 / 0.01	0.01
				0.08%	Celery leaves	0.09 / 0.01	0.00
				0.05%	Sheep: Kidney	0.02 / 0.03	0.00

Expand/collapse list

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)

Processed commodities

Results for children

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
72%	Escaroles/broad-leaved endives / boiled	0.1 / 0.05	3.6
58%	Chards/beet leaves / boiled	0.1 / 0.09	2.9
26%	Spinaches / frozen; boiled	0.1 / 0.09	1.3
24%	Courgettes / boiled	0.04 / 0.03	1.2
16%	Florence fennels / boiled	0.03 / 0.02	0.82
16%	Gherkins / pickled	0.04 / 0.03	0.78
14%	Peaches / canned	0.02 / 0.03	0.68
13%	Beans (with pods) / boiled	0.03 / 0.05	0.66
12%	Pumpkins / boiled	0.01 / 0.01	0.62
12%	Tomatoes / juice	0.09 / 0.03	0.59
11%	Oranges / juice	0.04 / 0.01	0.53
9%	Potatoes / fried	0.01 / 0.01	0.47
9%	Apples / juice	0.03 / 0.01	0.43
8%	Leeks / boiled	0.01 / 0.01	0.40
6%	Tomatoes / sauce/puree	0.09 / 0.03	0.30

Expand/collapse list

Results for adults

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
23%	Chards/beet leaves / boiled	0.1 / 0.09	1.2
22%	Escaroles/broad-leaved	0.1 / 0.05	1.1
16%	Courgettes / boiled	0.04 / 0.03	0.78
15%	Spinaches / frozen; boiled	0.1 / 0.09	0.77
15%	Celeries / boiled	0.05 / 0.02	0.74
8%	Pumpkins / boiled	0.01 / 0.01	0.39
8%	Purslanes / boiled	0.1 / 0.09	0.38
7%	Florence fennels / boiled	0.03 / 0.02	0.35
5%	Apples / juice	0.03 / 0.01	0.27
5%	Tomatoes / sauce/puree	0.09 / 0.03	0.25
4%	Peaches / canned	0.02 / 0.03	0.21
4%	Peas (with pods) / boiled	0.03 / 0.05	0.18
3%	Oranges / juice	0.04 / 0.01	0.15
2%	Wine grapes / juice	0.01 / 0.01	0.12
2%	Leeks / boiled	0.01 / 0.01	0.12

Conclusion:

No exceedance of the toxicological reference value was identified for any unprocessed commodity.

A short term intake of residues of Abamectin (sum of avermectin B1a, avermectin B1b and delta-8,9 isomer of avermectin B1a, expressed as avermectin B1a) (R) (F) is

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

Appendix D – Input values for the exposure calculations

D.1. Consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment[a]
Risk assessment residue definition for plant products: Sum of avermectin B1a, avermectin B1b and delta-8,9 isomer of avermectin B1a, expressed as avermectin B1a				
Citrus fruits	0.010	STMR-Pulp (EFSA, 2018b)		–
Tree nuts	0.010	STMR (Import tolerance application, US)	0.010	HR (Import tolerance application, US)
Pome fruits	0.008	STMR (EFSA, 2014)[b]		–
Apricots	0.009	STMR (EFSA, 2010)		
Peaches	0.009	STMR (EFSA, 2014)	0.026	HR (Import tolerance application, US)
Plums	0.006	STMR (EFSA, 2014)		–
Table grapes	0.006	STMR (EFSA, 2014)		
Wine grapes	0.006	STMR (EFSA, 2014)		
Strawberries	0.030	STMR (EFSA, 2014)		
Blackberries	0.023	STMR (EFSA, 2014)		
Raspberries	0.023	STMR (EFSA, 2014)		
Avocados	0.006	STMR (Import tolerance application, US)	0.009	HR (Import tolerance application, US)
Bananas	0.006	STMR-Pulp (EFSA, 2017)		–
Potatoes	0.002	STMR (EFSA, 2014)		
Radishes	0.004	STMR (EFSA, 2014)		
Garlic, Onions, Shallots	0.010	STMR (EFSA, 2014)		
Spring onions	0.006	STMR (EFSA, 2014)		
Tomatoes	0.031	STMR (EFSA, 2014)[b]		
Peppers	0.012	STMR (EFSA, 2014)		
Aubergines (egg plants)	0.031	STMR (EFSA, 2014)		
Cucurbits, edible peel	0.007	STMR (EFSA, 2015)		
Cucurbits, inedible peel	0.006	STMR (EFSA, 2014)		
Chinese cabbages	0.009	STMR (EFSA, 2015)		
Lamb's lettuces	1.03	STMR (EFSA, 2020)	1.30	HR (EFSA, 2020)
Lettuces	0.020	STMR (Open leaf data set, Import tolerance application, US)	0.054	HR (Open leaf data set, Import tolerance application, US)
Escarole (broadleaf endive)	0.020	STMR (Import tolerance application, US)	0.054	HR (Import tolerance application, US)
Rocket, Rucola	0.020	STMR (Import tolerance application, US)	0.054	HR (Import tolerance application, US)
Cresses & other sprouts/shoots	0.020	STMR (Import tolerance application, US)	0.054	HR (Import tolerance application, US)
Baby leaf crops (including brassica species)	1.03	STMR (EFSA et al., 2020)	1.30	HR (EFSA et al., 2020)
Spinaches & similar leaves	0.026	STMR (Import tolerance application, US)	0.093	HR (Import tolerance application, US)

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment[a]
Herbs, except celery leaves	0.127	STMR (EFSA, 2014)	–	
Celery leaves	0.009	STMR (EFSA et al., 2020)		
Beans (with pods)	0.011	STMR (EFSA et al., 2020)[b]		
Peas (with pods)	0.020	STMR (EFSA et al., 2020)		
Celeries	0.015	STMR (EFSA, 2015)		
Florence fennel	0.008	STMR (Import tolerance application, US)	0.018	HR (Import tolerance application, US)
Leeks	0.006	STMR (EFSA, 2014)		
Cotton seeds	0.010	STMR (CXL) (EFSA, 2014)	0.013	STMR (Import tolerance application, US)
Hops (dried)	0.016	STMR (CXL) (EFSA, 2014)	–	
Risk assessment residue definition for animal products: Sum of avermectin B1a and B1b, expressed as avermectin B1a[c]				
Bovine, Meat	0.013[d]	LOQ × CF (EFSA, 2014)	–	
Bovine, Fat	0.013	MRL × CF (EFSA, 2014)		
Bovine, Liver	0.025	MRL × CF (EFSA, 2014)		
Bovine, Kidney	0.010	LOQ (EFSA, 2014)		
Bovine, Edible offal	0.025	MRL × CF (EFSA, 2014)		
Sheep, Meat	0.033[d]	MRL × CF (EFSA, 2014)		
Sheep, Fat	0.063	MRL × CF (EFSA, 2014)		
Sheep, Liver	0.031	MRL × CF (EFSA, 2014)		
Sheep, Kidney	0.025	MRL × CF (EFSA, 2014)		
Sheep, Edible offal	0.063	MRL × CF (EFSA, 2014)		

STMR: supervised trials median residue; HR: highest residue; MRL: maximum residue level; CF: conversion factor for enforcement to risk assessment residue definition.

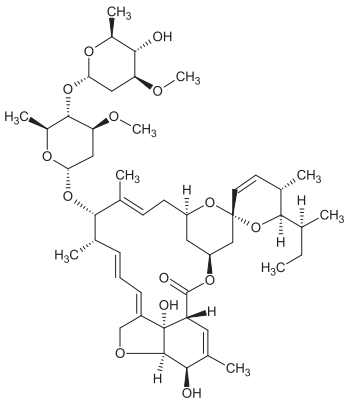
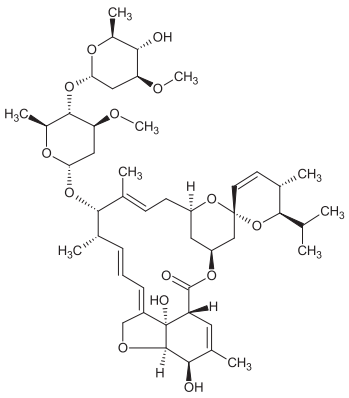
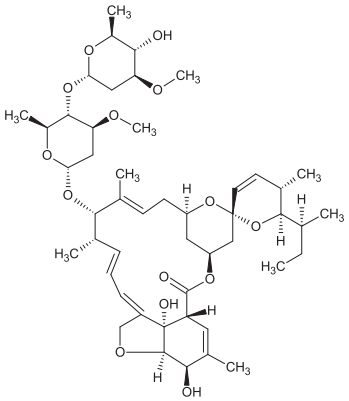
(a): Acute risk assessment performed only for the crops under assessment.

(b): EFSA included the input values tentatively derived in the framework of the MRL review. Thus, regardless to the final decision on whether to confirm or lower the existing MRL, which is pending risk management decision.

(c): MRL resulting from the veterinary use of abamectin is derived for avermectin B_{1a}. A conversion factor (CF) of 1.25 was used to take into account the consumers' exposure to avermectin B_{1b}.

(d): Consumption figures in the EFSA PRIMo are expressed as meat. Since the active substance is fat-soluble, residue values were calculated considering an 80% muscle and 20% fat content for mammalian meat (FAO, 2016).

Appendix E – Used compound codes

Code/trivial name[a]	Chemical name/SMILES notation/InChiKey[b]	Structural formula[c]
Avermectin B1a (AVM B1a)	(2a*E*,4*E*,8*E*)-(5′*S*,6*S*,6′*R*,7*S*,11*R*,13*S*,15*S*,17a*R*,20*R*,20a*R*,20b*S*)-6′-[(*S*)-*sec*-butyl]-5′,6,6′,7,10,11,14,15,17a,20,20a,20b-dodecahydro-20,20b-dihydroxy-5′,6,8,19-tetramethyl-17-oxospiro[11,15-methano-2*H*,13*H*,17*H*-furo[4,3,2-*pq*][2,6]benzodioxacyclooctadecin-13,2′-[2*H*]pyran]-7-yl 2,6-dideoxy-4-*O*-(2,6-dideoxy-3-*O*-methyl-α-L-*arabino*-hexopyranosyl)-3-*O*-methyl-α-L-*arabino*-hexopyranosid CO[C@H]1C[C@@H](O[C@@H](C)[C@@H]1O)O[C@@H]1[C@@H](OC)C[C@@H](O[C@H]1C)O[C@@H]1C(C)=CC[C@@H]2C[C@H](OC(=O)[C@@H]3C=C(C)[C@@H](O)[C@H]4OCC(=CC=C[C@@H]1C)[C@@]34O)C[C@@]1(O2)C=C[C@H](C)[C@H](O1)[C@@H](C)CC RRZXIRBKKLTSOM-XPNPUAGNNA-N	
Avermectin B1b(AVM B1b)	(2a*E*,4*E*,8*E*)-(5′*S*,6*S*,6′*R*,7*S*,11*R*,13*S*,15*S*,17a*R*,20*R*,20a*R*,20b*S*)-5′,6,6′,7,10,11,14,15,17a,20,20a,20b-dodecahydro-20,20b-dihydroxy-6′-isopropyl-5′,6,8,19-tetramethyl-17-oxospiro[11,15-methano-2*H*,13*H*,17*H*-furo[4,3,2-*pq*][2,6]benzodioxacyclooctadecin-13,2′-[2*H*]pyran]-7-yl 2,6-dideoxy-4-*O*-(2,6-dideoxy-3-*O*-methyl-α-L-*arabino*-hexopyranosyl)-3-*O*-methyl-α-L-*arabino*-hexopyranoside CO[C@H]1C[C@@H](O[C@@H](C)[C@@H]1O)O[C@@H]1[C@@H](OC)C[C@@H](O[C@H]1C)O[C@@H]1C(C)=CC[C@@H]2C[C@H](OC(=O)[C@@H]3C=C(C)[C@@H](O)[C@H]4OCC(=CC=C[C@@H]1C)[C@@]34O)C[C@@]1(O2)C=C[C@H](C)[C@H](O1)C(C)C ZFUKERYTFURFGA-PVVXTEPVNA-N	
[8,9-Z]-isomer of avermectin B1a (NOA 427011)	(2a*Z*,4*E*,8*E*)-(5′*S*,6*S*,6′*R*,7*S*,11*R*,13*S*,15*S*,17a*R*,20*R*,20a*R*,20b*S*)-6′-[(*S*)-*sec*-butyl]-5′,6,6′,7,10,11,14,15,17a,20,20a,20b-dodecahydro-20,20b-dihydroxy-5′,6,8,19-tetramethyl-17-oxospiro[11,15-methano-2*H*,13*H*,17*H*-furo[4,3,2-*pq*][2,6]benzodioxacyclooctadecin-13,2′-[2*H*]pyran]-7-yl 2,6-dideoxy-4-*O*-(2,6-dideoxy-3-*O*-methyl-α-L-*arabino*-hexopyranosyl)-3-*O*-methyl-α-L-*arabino*-hexopyranoside CO[C@H]1C[C@@H](O[C@@H](C)[C@@H]1O)O[C@@H]2[C@@H](OC)C[C@@H](O[C@H]2C)O[C@@H]3C(C)=CC[C@@H]6C[C@H](OC(=O)[C@@H]4C=C(C)[C@@H](O)[C@H]5OCC(=CC=C[C@@H]3C)[C@@]45O)C[C@@]7(O6)C=C[C@H](C)[C@H](O7)[C@@H](C)CC RRZXIRBKKLTSOM-XKKMCYFKNA-N	

(a): The metabolite name in bold is the name used in the conclusion.
(b): ACD/Name 2019.1.1 ACD/Labs 2019 Release (File version N05E41, Build 110555, 18 July 2019).
(c): ACD/ChemSketch 2019.1.1 ACD/Labs 2019 Release (File version C05H41, Build 110712, 24 July 2019).