Modification of the existing maximum residue level for abamectin in bananas

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Cheminova Agro Italia Srl submitted a request to the competent national authority in Italy to modify the existing maximum residue level (MRL) for the active substance abamectin in bananas. The data submitted in support of the request were found to be sufficient to derive MRL proposals for all crops under consideration. Adequate analytical methods for enforcement are available to control the residues of abamectin in the plant matrix 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 practice is unlikely to present a risk to consumer health.

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Keywords: abamectin, bananas, pesticide, MRL, consumer risk assessment

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The EFSA Journal is a publication of the European Food Safety Authority, an agency of the European Union.
In accordance with Article 6 of Regulation (EC) No 396/2005, Cheminova Agro Italia Srl submitted an application to the competent national authority in Italy (evaluating Member State, EMS) to modify the existing maximum residue level (MRL) for the active substance abamectin in bananas. 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 3 October 2016. To accommodate for the intended use of abamectin, the EMS proposed to raise the existing MRL from the limit of quantification (LOQ) of 0.01 to 0.02 mg/kg.

EFSA based its assessment on the evaluation report submitted by the EMS, the draft assessment report (DAR) prepared under Council Directive 91/414/EEC, the revised Commission review report on abamectin, the conclusion on the peer review of the pesticide risk assessment of the active substance abamectin, the Joint Meeting on Pesticide Residues (JMPR) evaluation reports, as well as the conclusions from previous EFSA opinions on abamectin.

The metabolism of abamectin for foliar applications in primary crops belonging to the fruit (citrus, tomato), leafy (celery) and pulses/oilseeds (cotton) groups using avermectin B1a has been investigated in the framework of the EU pesticides peer review.

The effect of processing on the nature of avermectin B1a was investigated in the framework of the EU pesticides peer review and these studies showed that degradation of avermectin B1a was observed (30–40% of the initial radioactivity) under standard processing conditions.

As the proposed use of abamectin is on permanent crops, investigations of residues in rotational crops are not required.

Based on the metabolic pattern identified in metabolism studies, hydrolysis studies and the toxicological significance of metabolites, the residue definitions for plant products were proposed as ‘abamectin (sum of avermectin B1a, avermectin B1b and delta-8,9 isomer of avermectin B1a, expressed as avermectin B1a)’ for enforcement and risk assessment. These residue definitions are applicable to primary crops, rotational crops and processed products.

EFSA concluded that for the crops assessed in this application, the metabolism of abamectin in primary and in rotational crops, and the possible degradation in processed products have been sufficiently addressed and that the previously derived residue definitions are applicable.

Sufficiently validated analytical methods based on liquid chromatography with tandem mass spectrometry (LC-MS/MS) are available to quantify residues in the crops assessed in this application according to the enforcement residue definition. The methods allow quantifying residues at or above the LOQ of 0.002 mg/kg for each analyte (overall LOQ of 0.006 mg/kg). The new data provided in the current MRL application are expected to fulfil the data gap for enforcement analytical methods for high water content matrices that was identified in the Article 12 MRL review.

The available residue trials are sufficient to derive a MRL proposal of 0.02 mg/kg for bananas.

Specific studies to assess the magnitude of abamectin residues in processed commodities are not necessary as banana is a crop that is mostly eaten raw. Residues of abamectin in commodities of animal origin were not assessed since the crop under consideration in this MRL application is normally not fed to livestock.

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 metabolites included in the residue definition are of similar toxicity as the parent active substance.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). The short-term exposure assessment was performed for the commodities assessed in this application in accordance with the internationally agreed methodology and the calculations were based on the highest residue (HR) derived from supervised field trials. The short-term exposure did not exceed the ARfD for the crop assessed in this application.

In the framework of the MRL review, a comprehensive long-term exposure assessment was performed, taking into account the existing uses at European Union (EU) level. EFSA updated the calculation with the relevant supervised trials median residue (STMR) values derived from the residue trials submitted in support of this MRL application for bananas; and in addition, the STMRs derived in EFSA opinions published after the MRL review. The estimated long-term dietary intake was in the range of 2–9% of the ADI.
EFSA concluded that the proposed use of abamectin on bananas will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers’ health.

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

| Code\(^{(a)}\) | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/Justification |
|--------------|-----------|-------------------------|-------------------------|------------------------|
| 0163020      | Bananas   | 0.01*                   | 0.02                    | The submitted data are sufficient to derive a MRL proposal for SEU use. No consumer health concern was identified |

MRL: maximum residue level; SEU: southern Europe.
*\(^{a}\): Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(F): Fat soluble.

**Enforcement residue definition:** Abamectin (sum of avermectin B1a, avermectin B1b and delta-8,9 isomer of avermectin B1a, expressed as avermectin B1a)\(^{(F)}\)
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Background

Regulation (EC) No 396/20051 (hereinafter referred to as ‘the MRL regulation’) establishes the rules governing the setting of pesticide maximum residue levels (MRLs) at European Union (EU) level. Article 6 of the MRL regulation lays down that any party having a legitimate interest or requesting an authorisation for the use of a plant protection product in accordance with Council Directive 91/414/EEC, repealed by Regulation (EC) No 1107/20093, shall submit an application to a Member State to modify a MRL in accordance with the provisions of Article 7 of the MRL regulation.

The applicant Cheminova Agro Italia Srl4 submitted an application to the competent national authority in Italy, hereafter referred to as the evaluating Member State (EMS), to modify the existing MRL for the active substance abamectin in bananas. This application was notified to the European Commission and the European Food Safety Authority (EFSA) and was subsequently evaluated by the EMS in accordance with Article 8 of the MRL regulation.

The EMS summarised the data provided by the applicant in an evaluation report which was submitted to the European Commission and forwarded to EFSA on 3 October 2016. The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2016-00630 and the following subject:

Abamectin – MRLs in banana.

Italy proposed to raise the existing MRL of abamectin in bananas from the limit of quantification (LOQ) to 0.02 mg/kg.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation.

Terms of Reference

In accordance with Article 10 of Regulation (EC) No 396/2005, EFSA shall assess the application and the evaluation report and give a reasoned opinion on the risks to the consumer and where relevant to animals associated with the setting of the requested MRLs. The opinion shall include:

- an assessment of whether the analytical method for routine monitoring proposed in the application is appropriate for the intended control purposes;
- the anticipated LOQ for the pesticide/product combination;
- an assessment of the risks of the acceptable daily intake (ADI) and acute reference dose (ARfD) being exceeded as a result of the modification of the MRL;
- the contribution to the intake due to the residues in the product for which the MRLs was requested;
- any other element relevant to the risk assessment.

In accordance with Article 11 of the MRL regulation, EFSA shall give its reasoned opinion as soon as possible and at the latest within three months from the date of receipt of the application.

The evaluation report submitted by the EMS (Italy, 2016) 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. Furthermore, a screenshot of the Report sheet of the PRIMo is presented in Appendix C.

The active substance and its use pattern

The detailed description of the intended use of abamectin which is the basis for the current MRL application is reported in Appendix A.

Abamectin is the ISO common name for the mixture of at least 80% of avermectin B1a and no more than 20% of avermectin B1b. The IUPAC names for the two components of abamectin are:

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1 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.
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.
3 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.
4 Cheminova Agro Italia Srl, Via Fratelli Bronzetti 32/28, 24124, Bergamo, Italy.
Avermectin B1a:
\[(2\alpha, 4\alpha, 8\alpha, E)-[5\alpha, 6\alpha, 6\beta, R, 7\alpha, 11\alpha, 13\alpha, 15\alpha, 17\alpha R, 20\alpha R, 20\alpha S]-6\{[(S)-sec-butyl]-5\alpha, 6\alpha, 7\beta, 10\alpha, 11\alpha, 14\alpha, 15\alpha, 17\alpha R, 20\alpha R, 20\beta S]-20, 20\text{b-dodecahydro-20, 20b-dihydroxy-5, 6, 8, 9-tetramethyl-17 oxospiro[11, 15-methano}2H, 13H, 17H-furo[4, 3, 2-pq][2, 6]benzodioxacyclooctadecin-13, 2\{[2H]pyran\}-7-\text{yl} 2, 6\text{dideoxy 4-O-[2, 6-dideoxy-3-O-methyl-\alpha-L-arabino-hexopyranosyl]-3-O-methyl-\alpha-L-arabino-hexopyranoside.}\]

Avermectin B1b:
\[(2\alpha, 4\alpha, 8\alpha, E)-[5\alpha, 6\alpha, 6\beta, R, 7\alpha, 11\alpha, 13\alpha, 15\alpha, 17\alpha R, 20\alpha R, 20\alpha S]-5\alpha, 6\alpha, 7\gamma, 10\alpha, 11\alpha, 14\alpha, 15\alpha, 17\alpha R, 20\alpha R, 20\beta S]-20, 20\text{b-dodecahydro-20, 20b-dihydroxy-6'-isopropyl-5, 6, 8, 9-tetramethyl-17 oxospiro[11, 15-methano}2H, 13H, 17H-furo[4, 3, 2-pq][2, 6]benzodioxacyclooctadecin 13, 2\{[2H]pyran\}-7-\text{yl} 2, 6\text{dideoxy-4-O (2, 6-dideoxy-3-O-methyl-\alpha-L-arabino-hexopyranosyl)-3-O-methyl-\alpha-L-arabino-hexopyranoside.}\]

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

Abamectin was approved for the uses as acaricide and insecticide on 1 May 2009 and then also as nematicide (EFSA, 2016; European Commission, 2017).

The EU MRLs for abamectin are established in Annexes II of Regulation (EC) No 396/2005. 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 EU MRL legislation. After completion of the MRL review, EFSA has issued one reasoned opinion on the modification of MRLs for abamectin (EFSA, 2015). The proposals from this reasoned opinion have been considered in recent regulation and for EU MRL legislation.

Abamectin is a pharmacologically active substance approved for veterinary use, for which maximum residue limits in foodstuffs of animal origin were set out for bovine and ovine species in the Annex to Commission Regulation (EU) No 37/2010.

Assessment

EFSA has based its assessment on the evaluation report submitted by the EMS (Italy, 2016), the DAR and its addendum prepared under Directive 91/414/EEC (Netherlands 2005, 2008), the revised European Commission review report on abamectin (European Commission, 2017), the conclusion on the peer review of the pesticide risk assessment of the active substance abamectin (EFSA, 2008, 2016), the JMPR Evaluation reports (FAO, 1992, 1997), as well as the conclusions from previous EFSA opinions on abamectin (EFSA, 2010, 2014, 2015).

For this application, the data requirements established in Regulation (EU) No 544/2011 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, 2016; 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.

A selected list of end points of the studies assessed by EFSA in the framework of the MRL review, including the end points of studies submitted in support of the current MRL application, are presented in Appendix B.

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5 Commission Directive 2008/107/EC of 25 November 2008 amending Council Directive 91/414/EEC to include abamectin, epoxiconazole, fenpropimorph, fenpropathrin and tralkoxydim as active substances. OJ L 316, 26.11.2008, p. 4–11.
6 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.
7 Commission Regulation (EU) 2015/2075 of 18 November 2015 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 abamectin, desmedipham, dichlorprop-P, haloxyfop-P, oryzalin and phemedeflam in or on certain products. OJ L 302, 19.11.2015, p. 15–50.
8 Commission Regulation (EU) 2016/1003 of 17 June 2016 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 abamectin, acequinocyl, acetamiprid, benzovindiflurpyr, bromoxynil, fluodioxonil, fluopicolide, fosetyl, mepipquat, proquinazid, propamocarb, prohexadione and tebuconazole in or on certain products. OJ L 167, 24.6.2016, p. 46–103.
9 Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin. OJ L 15, 20.1.2010, p. 1–72.
10 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.
11 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 abamectin for foliar applications in primary crops belonging to the fruit (citrus, tomato), leafy (celery) and pulses/oilseeds (cotton) groups using avermectin B1a has been investigated in the framework of the EU pesticides peer review (EFSA, 2008).

The metabolism of abamectin following foliar application was investigated using avermectin B1a only. No data is available on the plant metabolism of avermectin B1b which may account for up to 20% of technical abamectin. Nevertheless due to the close structural similarity of both compounds and considering also the results of supervised residue trials, this was considered not of concern (EFSA, 2008).

Following foliar application, avermectin B1a was identified as the major compound in almost all plant parts and was extensively degraded. Avermectin B1a levels were ranging from 4% to 23% total radioactive residue (TRR) 8 days after the last application. In the tested crops, at least one non-polar metabolite was identified, the delta-8,9 isomer of avermectin B1a. Its concentration did not exceed 8% of the TRR. The major part of the extracted radioactivity, ranging from 30% to 82% of the TRR, was characterised as polar or moderately polar radioactivity, but not further identified. Comparing the chromatographic profile of these unidentiﬁed fractions, to the degradation proﬁle of avermectin B1a in photolytic systems, it could be concluded that the plant metabolic pattern essentially results from photoysis. The details of the available metabolism studies are reported in the EFSA reasoned opinion according to Article 12 of Regulation (EC) No 396/2005 (EFSA, 2014).

For the intended use, the metabolic behaviour in primary crops is sufﬁciently addressed.

1.1.2. Nature of residues in rotational crops

As the proposed use of abamectin is on permanent crops, investigations of residues in rotational crops are not required.

1.1.3. Nature of residues in processed commodities

The effect of processing on the nature of avermectin B1a was investigated in the framework of the EU pesticides peer review (EFSA, 2008). These studies showed that 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. Further minor unknown degradation products could not be identiﬁed.

The MRL review conﬁrmed the conclusion of the EU pesticides peer review that the residue deﬁnition for enforcement and risk assessment proposed for plant commodities is applicable to processed commodities (EFSA, 2014).

Studies on the nature or magnitude of residues in processing were not provided in the current application and are not required as residues at harvest in the crop under consideration were less than 0.01 mg/kg (based on the residue deﬁnition for risk assessment for the raw commodity).

1.1.4. Methods of analysis in plants

Analytical enforcement methods for the determination of abamectin residues in plant commodities were assessed during the peer review under Council Directive 91/414/EEC (EFSA, 2008) and under the Article 12 MRL review (EFSA, 2014). The method, based on liquid chromatography with tandem mass spectrometric (LC-MS/MS) quantification of avermectin B1a, avermectin B1b and the delta-8,9 isomer of avermectin B1a, was partially validated in high water content, high acid content and high oil content commodities at the LOQ of 0.002 mg/kg for each individual component (combined LOQ of 0.006 mg/kg) (EFSA, 2014). The Article 12 MRL review identiﬁed a data gap for an independent laboratory validation (ILV) and validation of an additional mass transition for the analytical method proposed for enforcement of avermectin B1a, avermectin B1b and delta-8,9 isomer avermectin B1a, achieving an LOQ of 0.002 mg/kg for each compound in acidic, high water content and high oil content matrices (EFSA, 2014).
Analytical methods for the determination of abamectin residues as avermectin B1a, avermectin B1b and the delta-8,9 isomer of avermectin B1a were submitted with the current MRL application (Italy, 2016). The analytical method derived from the QuEChERS multiresidue method with LC-MS/MS detection was validated in banana (high water content matrix) with an LOQ of 0.002 mg/kg for each analyte. An ILV was performed for the determination of abamectin in banana. The methods are sufficiently validated for residues of avermectin B1a, avermectin B1b and the delta-8,9 isomer of avermectin B1a in the crops under consideration. The methods allow quantifying residues at or above the LOQ of 0.002 mg/kg for each analyte (overall LOQ of 0.006 mg/kg). The new data provided in the current MRL application are expected to fulfill the data gap for enforcement analytical methods for high water content matrices that was identified in the Article 12 MRL review.

1.1.5. Stability of residues in plants

The storage stability of avermectin B1a, avermectin B1b and the [8,9-Z]-isomer of avermectin B1a in plants stored under deep freeze conditions was investigated in the framework of the EU pesticides peer review; storage stability was demonstrated for a period of 35, 24 and 14 months in high water content, high oil content and high acid content commodities, respectively, when stored under deep freeze conditions (temperature not specified; EFSA, 2008).

1.1.6. Proposed residue definitions

Based on the metabolic pattern identified in metabolism studies (primary and rotational crops), the results of hydrolysis studies, the toxicological significance of metabolites and/or degradation products, the capabilities of enforcement analytical methods, the following general residue definitions were proposed in the framework of the EU pesticides peer review (EFSA, 2008) and confirmed during the MRL review (EFSA, 2014):

- residue for risk assessment: abamectin (sum of avermectin B1a, its [8,9-Z]-isomer and avermectin B1b, expressed as avermectin B1a);
- residue definition for enforcement: abamectin (sum of avermectin B1a, its [8,9-Z]-isomer and avermectin B1b, expressed as avermectin B1a).

The same residue definitions are applicable to rotational crops and processed products.

In accordance with Commission Regulation (EU) No 2016/1003, the residue definition for enforcement in plants is defined in Regulation (EC) No 396/2005 as: abamectin (sum of avermectin B1a, avermectin B1b and delta-8,9 isomer of avermectin B1a, expressed as avermectin B1a).

Taking into account the proposed use assessed in this application, EFSA concluded that these residue definitions are appropriate for the crop under assessment and no further information is required.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

In support of the MRL application, the applicant submitted four Good Agricultural Practice (GAP) compliant residue trials on banana. The trials were conducted at four locations in Santa Cruz de Tenerife, Spain in February 2015. Two foliar spray applications were performed in the treated plot at an interval of 7 days; the last application was performed 7 days before harvest. In general, trials should be carried out over a minimum of two growing seasons (European Commission, 1997b); however, taking into account that translocation of residues into banana pulp was below the LOQ, and taking into account that seasonal variations in the subtropical zone is limited and the moderate variety of climatic conditions in crop production areas, residue trials data from only one season is a minor deviation and the data may be considered sufficiently representative to support the present application.

Samples of banana pulp (flesh) and peel were analysed for the parent compound and the metabolites included in the residue definitions for enforcement and risk assessment. According to the assessment of the EMS, the methods used were sufficiently validated and fit for purpose. The samples of these residue trials were stored under conditions for which integrity of the samples has been demonstrated.

The number and quality of the trials is sufficient to derive a MRL of 0.02 mg/kg for banana.
1.2.2. Magnitude of residues in rotational crops

As the proposed use of abamectin is on a permanent crop, investigations of residues in rotational crops are not required.

1.2.3. Magnitude of residues in processed commodities

Specific studies to assess the magnitude of abamectin residues in processed commodities are not necessary as residue levels in banana pulp and whole fruit were at or below the limit of quantification. Bananas are consumed peeled; however, a reliable peeling factor could not be derived from the available data because residue levels in banana pulp and whole fruit were at or below the level of quantification.

1.2.4. Proposed MRLs

The available data are considered sufficient to derive MRL proposals as well as risk assessment values for the commodity under evaluation (see Appendix B.1.2.1). In Section 3, EFSA assessed whether residues on these crops resulting from the intended uses are likely to pose a consumer health risk.

2. Residues in livestock

Not relevant as banana is not used for feed purposes in the EU.

3. Consumer risk assessment

EFSA performed a dietary risk assessment using revision 2 of the EFSA PRIMo (EFSA, 2007). 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 toxicological reference values for abamectin used in the risk assessment (i.e. ADI and ARfD values) were derived in the framework of the EU pesticides peer review under Directive 91/414/EEC (EFSA, 2008).

The active substance is specified as ≥ 80%/≤ 20% and the toxicological studies were carried out according to these specifications (EFSA, 2008). The possible impact of plant metabolism on the isomer ratio of the active substance was not assessed and further investigation on this matter would in principle be required.

Under the peer review, the delta-8,9 isomer of avermectin B1a, which is a photolytic degradation product that forms part of the residue definition in plant commodities, was assessed as having the same toxicological profile as abamectin (EFSA, 2008).

3.1. Short-term (acute) dietary risk assessment

The short-term exposure assessment was performed for the commodities assessed in this application in accordance with the internationally agreed methodology (FAO, 2016). The calculations were based on the highest residue (HR) in banana pulp (flesh only, excluding peel) derived from supervised field trials and the complete list of input values can be found in Appendix D.2.

The short-term exposure did not exceed the ARfD for the crop assessed in this application (international estimated short-term intake (IESTI) is 10% of the ARfD; see Appendix C).

3.2. Long-term (chronic) dietary risk assessment

In the framework of the MRL review a comprehensive long-term exposure assessment was performed, taking into account the existing uses at EU level (EFSA, 2014). EFSA updated the calculation with the relevant supervised trials median residue (STMR) values for banana pulp derived from the residue trials submitted in support of this MRL application for bananas; and in addition, the STMR values derived in EFSA opinions published after the MRL review (EFSA, 2015). The uses reported in the MRL review for cherries, avocados, cress, peas (fresh, without pods), globe artichokes and cotton seed were not supported by data and subsequently, following the MRL review, the EU MRLs for these commodities were lowered to the specific LOQ and were therefore not further considered in the risk assessment.
After publication of the EFSA reasoned opinion on the MRL review, additional information on the GAP on apricots not covered by the MRL review but already evaluated by EFSA in a previous reasoned opinion (EFSA, 2010) were provided by France to the Commission; and consequently, EFSA updated the calculation including also the relevant STMR values derived from the residue trials submitted in support of this MRL (EFSA, 2010).

The input values used in the exposure calculations are summarised in Appendix D.2.

The estimated long-term dietary intake was in the range of 2–9% 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 C.

EFSA concluded that the long-term intake of residues of abamectin resulting from the existing and the intended uses is unlikely to present a risk to consumer health.

It should be highlighted that the above assessment does not consider the possible impact of plant metabolism on the isomer ratio of the active substance and further investigation on this matter would in principle be required. Since guidance is not yet available on the consideration of isomer ratios in the consumer risk assessment, EFSA recommends that this issue is reconsidered when such guidance is available. The lack of information on the isomer composition in plants is a source of uncertainty in the consumer risk assessment, which is estimated to be of limited or no material impact considering that the wide margin of exposure is expected to offset the overall uncertainty within the risk assessment.

Conclusions and recommendations

The data submitted in support of this MRL application were found to be sufficient to derive MRL proposals for all crops under consideration.

Adequate analytical methods for enforcement are available to control the residues of abamectin in plant matrices 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 practice is unlikely to present a risk to consumer health.

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  
CF      conversion factor for enforcement to risk assessment residue definition  
DAR     draft assessment report  
DAT     days after treatment  
EMS     evaluating Member State  
EW      emulsion in water  
FAO     Food and Agriculture Organization of the United Nations  
GAP     Good Agricultural Practice  
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/MS   tandem mass spectrometry detector  
NEU     northern Europe
| Abbreviation | Description |
|--------------|-------------|
| OECD         | Organisation for Economic Co-operation and Development |
| PBI          | plant back interval |
| PHI          | preharvest interval |
| PRIMo        | (EFSA) Pesticide Residues Intake Model |
| QuEChERS     | Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method) |
| RA           | risk assessment |
| RD           | residue definition |
| SANCO        | Directorate-General for Health and Consumers |
| SEU          | southern Europe |
| SMILES       | simplified molecular-input line-entry system |
| STMR         | supervised trials median residue |
| TRR          | total radioactive residue |
| UV           | ultraviolet (detector) |
| WHO          | World Health Organization |
### Appendix A – Summary of intended 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 | PHI (days) (d) | Remarks |
|-----------------------|-------------------------|-------------|------------------------------------|-------------|-------------|---------------------------------|----------------|---------|
|                       |                         | FG or I     |                                    | Type (b)    | Conc. a.s. | Method kind                      | Number min-max | gh a.s./hl min-max | Water L/ha min-max | gh a.s./ha min-max |  |
| Banana Spain F        | FG or I                 | Mites       | EW                                 | Handheld sprayer. Foliar spraying | All stage, up to PHI. At first larvae apparition in 1st generation | 1–2          | 7                  | 0.9              | 2,000             | 18       | 7       | Formulated product: 50 mL/hL (1,000 mL/ha) |

NEU: northern European Union; SEU: southern European Union; MS: Member State; EW: emulsion in water; a.s.: active substance.

(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 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 | Crop(s) | Label position | Application(s) (No of applications and rate kg a.s./ha) | Sampling |
|----------------------------------|-------------|---------|----------------|-----------------------------------------------------|----------|
| Fruit and fruiting vegetables   | Citrus fruits | $^{14}$C-Avermectin B1a | 1x 4 and 40 μg/fruit | 1, 2, 4, 8 and 12 weeks |
|                                  | Tomatoes    | $^{23}$-$^{14}$C-Avermectin B1a | Foliar (G): 5x 0.026 | 0, 3, 7, 14 and 28 DAT |
|                                  |             |         | Foliar (G): 3x 0.28 | 0, 3, 7, 14 and 28 DAT |
|                                  |             |         | Foliar (F): 5x 0.026 | 0, 3, 7, 14 and 28 DAT |
|                                  |             |         | Foliar (F): 5x 0.25 | 0, 3, 7, 14 and 28 DAT |

| Leafy crops | Celery | $^{14}$C-Avermectin B1a and $^{3}$H-avermectin B1a | Foliar (F): immature plant 4x 0.017, 0.011 and 0.11 | 0, 2 weeks (14 C-label) and 0, 1, 2, 4, 6 weeks (3 H-label) |
|             |        |         | Foliar (F): mature plant 10x 0.017, 0.011 and 0.11 | 0, 7 DAT (14 C-label) and 0, 1, 3, 7, 15, 22 DAT (3 H-label) |

| Pulses/oilseeds | Cotton | $^{14}$C-Avermectin B1a | Foliar (F): 1x 200 μL/leaf | 0, 1, 2, 4, 8 DAT |
|                 |        |                     | Foliar (F): 2x 0.02 | 2 months (at maturity) |
|                 |        |                     | Foliar (F): 3x 0.022 and 3x 0.22 | 21 DAT |

Reference: EFSA (2014)

| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s) (No of applications and rate kg a.s./ha) | PBI (DAT) |
|-------------------------------------|-------------|---------|-----------------------------------------------------|----------|
| Root/tuber crops                    | Carrots     | Soil application 3x 0.029 and 12x 0.034 | Sowing intervals: 14–31, 120–123 and 365 |
|                                    | Turnips     |         |                                                     |          |
| Leafy crops                         | Lettuce     |         |                                                     |          |
| Cereal (small grain)                | Sorghum     |         |                                                     |          |

Comments: $^{14}$C-avermectin B1a
Reference: EFSA (2014)

| Processed commodities (hydrolysis study) | Conditions                         | Investigated? |
|-----------------------------------------|-----------------------------------|---------------|
|                                        | Pasteurisation (20 min, 90°C, pH 4) | Yes           |
|                                        | Baking, brewing and boiling (60 min, 100°C, pH 5) | Yes |
|                                        | Sterilisation (20 min, 120°C, pH 6) | Yes |

Comment: The residue definition for enforcement and risk assessment in processed commodities is expected to be the same as for primary crops
Reference: EFSA (2014)

F: field application; G: glasshouse application; DAT: days after treatment; a.s.: active substance; PBI: plant back interval.

Reference: EFSA (2014)
Can a general residue definition be proposed for primary crops? Yes
Rotational crop and primary crop metabolism similar? Yes
Residue pattern in processed commodities similar to residue pattern in raw commodities? Yes

| 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) |

Conversion factor (monitoring to risk assessment) –

Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)
Matrices with high water content (banana): LC–MS/MS, LOQ 0.002 mg/kg for each analyte (Italy, 2016)
Confirmatory method available
ILV available

| B.1.1.2. Stability of residues in plants |
|----------------------------------------|

| Category | Commodity | T (°C)       | Stability (months/years) |
|----------|-----------|--------------|--------------------------|
| High water content | – | Deep freeze | 3 years |
| High oil content | – | Deep freeze | 2 years |
| Dry/high starch | – | – | – |
| High acid content | – | Deep freeze | 14 months |

Comment: Reference: EFSA (2008)
**B.1.2. Magnitude of residues in plants**

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

| Crop       | Region/indoor(a) | Residue levels observed in the supervised residue trials (mg/kg) | Comments (OECD calculations) | MRL proposals (mg/kg) | HR(b) (mg/kg) | STMR(c) (mg/kg) | CF(d) |
|------------|------------------|---------------------------------------------------------------|-------------------------------|-----------------------|--------------|----------------|-------|
| Bananas    | SEU              | Whole fruit: < 0.006; < 0.006; 0.007; 0.009 Pulp: < 0.006; < 0.006; < 0.006; < 0.006 | Trials on banana; compliant with GAP | 0.02 | 0.009 (whole fruit) 0.006 (pulp) | 0.0065 (whole fruit) 0.006 (pulp) | -     |

MRL: maximum residue level; GAP: 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 according to the residue definition for monitoring.
(c): Supervised trials median residue according to the residue definition for monitoring.
(d): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.
B.1.2.2. Conversion factors for risk assessment in plant products
Not required.

B.1.2.3. Residues in succeeding crops
Not relevant for permanent crops.

B.1.2.4. Processing factors
Specific studies to assess the magnitude of abamectin residues in processed commodities are not necessary as residue levels in banana pulp and whole fruit were at or below the limit of quantification. Bananas are consumed peeled; however, a reliable peeling factor could not be derived from the available data because residue levels in banana pulp and whole fruit were at or below the level of quantification.

B.2. Residues in livestock
Not relevant since the crop under consideration is not fed to livestock.

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
Not required.

B.2.1.2. Stability of residues in livestock
Not required.

B.2.2. Magnitude of residues in livestock

B.2.2.1. Summary of the residue data from livestock feeding studies
Not required.

B.2.2.2. Conversion factors for risk assessment in animal
Not relevant.

B.3. Consumer risk assessment

| ARFD | 0.005 mg/kg bw (EFSA, 2008) |
|------|-----------------------------|
| Highest IESTI, according to EFSA PRIMo | Bananas: 10% of ARFD |
| Assumptions made for the calculations | The calculation is based on the highest residue levels expected in banana pulp (flesh) |
| ADI | 0.0025 mg/kg bw per day (EFSA, 2008) |
| Highest IEDI, according to EFSA PRIMo | 9.1% ADI (DE child) Contribution of crops assessed: Banana: 0.4% of ADI |
| Assumptions made for the calculations | The calculation is based on the median residue levels derived for raw agricultural commodities. For the crop under consideration, the median residue level expected in banana pulp was considered |
| | The contributions of commodities where no GAP was reported in the framework of the MRL review were not included in the calculation |
B.4. **Recommended MRLs**

| Code<sup>(a)</sup> | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|-------------------|-----------|-------------------------|-------------------------|------------------------|
| 0163020           | Bananas   | 0.01*                   | 0.02                    | The submitted data are sufficient to derive a MRL proposal for SEU use. No consumer health concern was identified |

**Enforcement residue definition:** Abamectin (sum of avermectin B1a, avermectin B1b and delta-8,9 isomer of avermectin B1a, expressed as avermectin B1a)<sup>(F)</sup>

MRL: maximum residue level; SEU: southern Europe.

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

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

<sup>(F)</sup>: Fat soluble.
Appendix C – Pesticide Residue Intake Model (PRIMo)

Abamectin

Status of the active substance: Approved

Code no. LOQ (mg/kg bw): 0.006

Proposed LOQ: 0.006

Toxicological end points

ADI (mg/kg bw per day): 0.0025

ARfD (mg/kg bw): 0.005

Source of ADI: EFSA

Source of ARfD: EFSA

Year of evaluation: 2008

No of diets exceeding ADI: ---

Highest calculated TMDI values in % of ADI

| Commodity/group of commodities | MS Diet |
|--------------------------------|---------|
| 9.1 DE child                   | Tomatoes 0.9 |
| 8.5 WHO Cluster diet B        | Tomatoes 0.4 |
| 6.6 NL child                  | Tomatoes 0.8 |
| 5.4 IE adult                  | Tomatoes 0.8 |
| 5.1 FR toddler                | Tomatoes 0.8 |
| 4.1 WHO regional European diet| Tomatoes 0.3 |
| 4.0 ES child                  | Tomatoes 0.5 |
| 3.7 WHO cluster diet D        | Tomatoes 0.3 |
| 3.6 SE general population 90th percentile | Tomatoes 0.4 |
| 3.5 WHO cluster diet E        | Tomatoes 0.4 |
| 3.4 PT General population     | Tomatoes 0.6 |
| 3.3 DK child                  | Tomatoes 0.6 |
| 3.3 FR infant                 | Tomatoes 0.6 |
| 3.1 ES adult                  | Tomatoes 0.3 |
| 3.1 UK Toddler                | Tomatoes 0.5 |
| 3.0 IT adult                  | Tomatoes 0.3 |
| 2.9 WHO Cluster diet F        | Tomatoes 0.3 |
| 2.8 FR all population         | Tomatoes 0.5 |
| 2.7 PL general population     | Tomatoes 0.7 |
| 2.5 UK infant                 | Tomatoes 0.4 |
| 2.2 UK vegetarian             | Tomatoes 0.2 |
| 2.0 LT adult                  | Tomatoes 0.2 |
| 2.0 DK adult                  | Tomatoes 0.3 |
| 1.6 UK adult                  | Tomatoes 0.3 |
| 1.5 FI adult                  | Tomatoes 0.2 |

Highest contributor to MS diet (in % of ADI)

| Commodity/group of commodities | MS Diet |
|--------------------------------|---------|
| 9.1 DE child                   | Tomatoes 1.2 |
| 8.5 WHO Cluster diet B        | Tomatoes 0.8 |
| 6.6 NL child                  | Tomatoes 0.8 |
| 5.4 IE adult                  | Tomatoes 0.8 |
| 5.1 FR toddler                | Tomatoes 0.8 |
| 4.1 WHO regional European diet| Tomatoes 0.3 |
| 4.0 ES child                  | Tomatoes 0.5 |
| 3.7 WHO cluster diet D        | Tomatoes 0.3 |
| 3.6 SE general population 90th percentile | Tomatoes 0.4 |
| 3.5 WHO cluster diet E        | Tomatoes 0.4 |
| 3.4 PT General population     | Tomatoes 0.6 |
| 3.3 DK child                  | Tomatoes 0.6 |
| 3.3 FR infant                 | Tomatoes 0.6 |
| 3.1 ES adult                  | Tomatoes 0.3 |
| 3.1 UK Toddler                | Tomatoes 0.5 |
| 3.0 IT adult                  | Tomatoes 0.3 |
| 2.9 WHO Cluster diet F        | Tomatoes 0.3 |
| 2.8 FR all population         | Tomatoes 0.5 |
| 2.7 PL general population     | Tomatoes 0.7 |
| 2.5 UK infant                 | Tomatoes 0.4 |
| 2.2 UK vegetarian             | Tomatoes 0.2 |
| 2.0 LT adult                  | Tomatoes 0.2 |
| 2.0 DK adult                  | Tomatoes 0.3 |
| 1.6 UK adult                  | Tomatoes 0.3 |
| 1.5 FI adult                  | Tomatoes 0.2 |

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI) based on pTMRLs were below the ADI. A long-term intake of residues of Abamectin 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 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 Abamectin, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.

For processed commodities, 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.

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.

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

**pTMRL: provisional temporary MRL for unprocessed commodity.

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

### Conclusion:

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

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

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

D.1. Livestock dietary burden calculations

Not required.

D.2. Consumer risk assessment

| Commodity                        | Chronic risk assessment | Acute risk assessment |
|----------------------------------|-------------------------|-----------------------|
|                                  | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment |
| **Risk assessment residue definition:** abamectin (sum of avermectin B1a, avermectin B1b and delta-8,9 isomer of avermectin B1a, expressed as avermectin B1a) |
| Citrus fruit                     | 0.006                   | STMR (EFSA, 2014)     |                      |
| Tree nuts (shelled or unshelled) | 0.013                   | STMR (EFSA, 2014)     |                      |
| Pome fruit                       | 0.008                   | STMR (EFSA, 2015)     |                      |
| Apricots                         | 0.009                   | STMR (EFSA, 2010)     |                      |
| Peaches                          | 0.009                   | STMR (EFSA, 2014)     |                      |
| Plums                            | 0.006                   | STMR (EFSA, 2014)     |                      |
| Table grapes                     | 0.006                   | STMR (EFSA, 2014)     |                      |
| Wine grapes                      | 0.006                   | STMR (EFSA, 2014)     |                      |
| Strawberries                     | 0.03                    | STMR (EFSA, 2014)     |                      |
| Blackberries                     | 0.023                   | STMR (EFSA, 2014)     |                      |
| Raspberries                      | 0.023                   | STMR (EFSA, 2014)     |                      |
| Currants (red, black and white)  | 0.006                   | STMR (EFSA, 2014)     |                      |
| Gooseberries                     | 0.006                   | STMR (EFSA, 2014)     |                      |
| Bananas                          | 0.006                   | STMR pulp             | 0.006                | HR pulp |
| Papaya                           | 0.008                   | STMR (EFSA, 2014)     |                      |
| Potatoes                         | 0.002                   | STMR (EFSA, 2014)     |                      |
| Radishes                         | 0.004                   | STMR (EFSA, 2014)     |                      |
| Spring onions                    | 0.006                   | STMR (EFSA, 2014)     |                      |
| Tomatoes                         | 0.031                   | STMR (EFSA, 2014)     |                      |
| Peppers                          | 0.012                   | STMR (EFSA, 2014)     |                      |
| Aubergines (egg plants)          | 0.031                   | STMR (EFSA, 2014)     |                      |
| Cucumbers                        | 0.007                   | STMR (EFSA, 2015)     |                      |
| Gherkins                         | 0.007                   | STMR (EFSA, 2015)     |                      |
| Courgettes                       | 0.007                   | STMR (EFSA, 2015)     |                      |
| Other cucubits – edible peel     | 0.007                   | STMR (EFSA, 2015)     |                      |
| Melons                           | 0.006                   | STMR (EFSA, 2014)     |                      |
| Pumpkins                         | 0.006                   | STMR (EFSA, 2014)     |                      |
| Watermelons                      | 0.006                   | STMR (EFSA, 2014)     |                      |
| Other cucubits – inedible peel   | 0.006                   | STMR (EFSA, 2014)     |                      |
| Chinese cabbage                  | 0.009                   | STMR (EFSA, 2015)     |                      |
| Lamb’s lettuce                   | 0.055                   | STMR (EFSA, 2014)     |                      |
| Lettuce                          | 0.01                    | STMR (EFSA, 2014)     |                      |
| Commodity                          | Chronic risk assessment | Acute risk assessment |
|-----------------------------------|-------------------------|-----------------------|
|                                   | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment |
| Scarole (broad-leaf endive)       | 0.02                    | STMR (EFSA, 2014)     |                      |         |
| Rocket, rucola                    | 0.005                   | STMR (EFSA, 2014)     |                      |         |
| Leaves and sprouts of *Brassica* spp. | 0.055            | STMR (EFSA, 2014)     |                      |         |
| Witloof                           | 0.006                   | STMR (EFSA, 2014)     |                      |         |
| Herbs                             | 0.127                   | STMR (EFSA, 2014)     |                      |         |
| Celery leaves                     | 0.01                    | STMR (EFSA, 2014)     |                      |         |
| Beans (with pods)                 | 0.007                   | STMR (EFSA, 2014, 2015) |                |         |
| Peas (with pods)                  | 0.007                   | STMR (EFSA, 2014, 2015) |                |         |
| Celery                            | 0.015                   | STMR (EFSA, 2015)     |                      |         |
| Leek                              | 0.006                   | STMR (EFSA, 2014)     |                      |         |
| Hops (dried)                      | 0.016                   | STMR (EFSA, 2014)     |                      |         |

**Risk assessment residue definition:** abamectin (sum of avermectin B1a and B1b, expressed as avermectin B1a)

| Commodity | Input value (mg/kg) | Comment               |           |           |
|-----------|---------------------|-----------------------|-----------|-----------|
| Bovine: Meat | 0.007\(^{(a)}\)    | Vet MRL×CF (EFSA, 2014) |          |           |
| Bovine: Fat     | 0.013                | Vet MRL×CF (EFSA, 2014) |          |           |
| Bovine: Liver    | 0.025                | Vet MRL×CF (EFSA, 2014) |          |           |
| Bovine: Kidney   | 0.01*                | Vet MRL (EFSA, 2014)   |          |           |
| Sheep: Meat      | 0.033\(^{(a)}\)      | Vet MRL×CF (EFSA, 2014) |          |           |
| Sheep: Fat       | 0.063                | Vet MRL×CF (EFSA, 2014) |          |           |
| Sheep: Liver     | 0.031                | Vet MRL×CF (EFSA, 2014) |          |           |
| Sheep: Kidney    | 0.025                | Vet MRL×CF (EFSA, 2014) | Acute risk assessment only for the crops under consideration |

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

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

\(^{(a)}\): Consumption figures in the EFSA PRIMo are expressed as meat. Since the active substance is fat-soluble, STMR and HR residue values were calculated considering a 80%/90% muscle and 20%/10% fat content for mammal/poultry meat respectively (FAO, 2016).
### Appendix E – Used compound codes

| Code/trivial name | Chemical name/SMILES notation(a) | Structural formula(a) |
|------------------|----------------------------------|-----------------------|
| **Avermectin B1a** | (2aE,4E,8E)- (5’S,6S,6’R,7S,11R,13S,15S,17aR,20R,20aR,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-methano-2H,13H,17H-furo[4,3,2-pq][2,6]benzodioxyoctadecin-13,2’-[2H]pyran]-7-yl 2,6-dideoxy-4-O-(2,6-dideoxy-3-O-methyl-D-arabinofuranosyl)-3-O-methyl-D-arabinohexopyranoside | ![Structural formula](image) |
| **Avermectin B1b** | (2aE,4E,8E)- (5’S,6S,6’R,7S,11R,13S,15S,17aR,20R,20aR,20bS)-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-2H,13H,17H-furo[4,3,2-pq][2,6]benzodioxyoctadecin-13,2’-[2H]pyran]-7-yl 2,6-dideoxy-4-O-(2,6-dideoxy-3-O-methyl-D-arabinofuranosyl)-3-O-methyl-D-arabinohexopyranoside | ![Structural formula](image) |
|delta-8,9-Isomer of avermectin B1a | (2aZ,4E,8E)- (5’S,6S,6’R,7S,11R,13S,15S,17aR,20R,20aR,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-methano-2H,13H,17H-furo[4,3,2-pq][2,6]benzodioxyoctadecin-13,2’-[2H]pyran]-7-yl 2,6-dideoxy-4-O-(2,6-ddeoxy-3-O-methyl-D-arabinofuranosyl)-3-O-methyl-D-arabinohexopyranoside | ![Structural formula](image) |
| **[8,9-Z]-Isomer of avermectin B1a NOA 427011** | ![Structural formula](image) |

**SMILES:** simplified molecular-input line-entry system.  
(a): (ACD/ChemSketch, Advanced Chemistry Development, Inc., ACD/Labs Release: 12.00 Product version: 12.00 (Build 29305, 25 Nov 2008).