Modification of the existing maximum residue level for abamectin in citrus fruits

European Food Safety Authority (EFSA),
Alba Brancato, Daniela Brocca, Luis Carrasco Cabrera, Chloe De Lentdecker, Lucien Ferreira, Luna Greco, Samira Jarrah, Dimitra Kardassi, Renata Leuschner, Christopher Lythgo, Paula Medina, Ileana Miron, Tunde Molnar, Alexandre Nougadere, Ragnor Pedersen, Hermine Reich, Angela Sacchi, Miguel Santos, Alois Stanek, Juergen Sturma, Jose Tarazona, Anne Theobald, Benedicte Vagenende and Laura Villamar-Bouza

Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the ‘Task Force Abamectin’, as applicant, submitted a request to the competent national authority in Spain to modify the existing maximum residue level (MRL) for the active substance abamectin in citrus fruits. The data submitted in support of the request were found to be sufficient to derive a MRL proposal of 0.04 mg/kg. Adequate analytical methods for enforcement are available to control the residues of abamectin in the crop 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 reliable end points, appropriate for use in regulatory risk assessment are presented.

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Keywords: abamectin, citrus fruits, pesticide, MRL, consumer risk assessment

Requestor: European Commission
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Correspondence: pesticides.mrl@efsa.europa.eu
Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, the Task Force Abamectin submitted an application to the competent national authority in Spain (evaluating Member State (EMS)) to modify the existing maximum residue level (MRL) for the active substance abamectin in citrus fruits. 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). EFSA identified data gaps and points that needed further clarifications, which were addressed by the EMS in a revised evaluation report. To accommodate for the intended use of abamectin, the EMS proposed to raise the existing MRL to 0.04 mg/kg.

EFSA based its assessment on the revised evaluation report submitted by the EMS, the draft assessment report (DAR) prepared under Directive 91/414/EEC, the Commission review report and its addendum, the conclusions 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 was investigated in primary crops belonging to the group of fruit crops, leafy crops and pulses/oilseeds following foliar applications and in rotational crops in root/tuber crops, leafy crops and cereals (small grain) following soil application during the European Union (EU) pesticides peer review. Studies investigating the effect of processing on the nature of abamectin showed limited degradation under standard processing conditions.

Based on the metabolic pattern identified in metabolism studies, hydrolysis studies and the toxicological significance of metabolites, the capabilities of the analytical methods, the residue definition for enforcement and risk assessment was proposed as ‘abamectin (sum of avermectin B\textsubscript{1a}, avermectin B\textsubscript{1b} and delta-8,9-isomer of avermectin B\textsubscript{1a}, expressed as avermectin B\textsubscript{1a})’. The residue definition is applicable to primary crops, including the crops under assessment, rotational crops and processed products.

The available residue trials were sufficient to derive a MRL proposal of 0.04 mg/kg for citrus fruits. The additional validation data in high acid content matrices assessed under the current application demonstrated that the enforcement methods are suitable to control residues of abamectin in citrus fruits. The methods determine residues at or above the limit of quantification (LOQ) of 0.002 mg/kg (combined LOQ of 0.006 mg/kg). The new data provided addressed the data gap identified for high acid content matrices in the MRL review.

As citrus dried pulp may be used as a feed product, a potential carry-over of residues into food of animal origin was assessed. The residue levels in citrus by-products resulting from the intended use did not require a modification of the existing MRLs for animal products.

The toxicological profile of abamectin was assessed in the framework of the EU pesticides peer review 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 metabolite included in the residue definition was considered to be of the same toxicity as the parent active substance.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). The chronic consumer risk assessment performed in the framework of previous MRL assessments was updated, including the supervised trials median residue (STMR) derived for citrus fruits. The short-term exposure assessment was performed only with regard to the commodities under consideration.

Based on the available information, EFSA concluded that the proposed use of abamectin on citrus fruits 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\textsuperscript{(a)} | Commodity       | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification                |
|----------------|----------------|------------------------|------------------------|--------------------------------------|
| 0110000        | Citrus fruits  | 0.015                  | 0.04                   | SEU use supported by extrapolation from residue data on oranges and mandarins. Risk for consumers unlikely |

MRL: maximum residue level; SEU: southern Europe.

\textsuperscript{(a)}: Commodity code number according to Annex I of Regulation (EC) No 396/2005.

\textsuperscript{(F)}: Fat soluble.

\textsuperscript{(R)}: Code 1000000 except 1040000: avermectin B\textsubscript{1a}.
In the framework of the MRL review under Article 12 of Regulation (EC) No 396/2005, a data gap was identified (validation of the analytical methods for crop matrices with high acid). Since the information submitted within the current application was considered sufficient to address the open questions, the footnote on missing confirmatory data for commodities classified as high-acid content commodities can be deleted in the MRL legislation.
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Background

Regulation (EC) No 396/2005\(^1\) (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 Directive 91/414/EEC\(^2\), repealed by Regulation (EC) No 1107/2009\(^3\), 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 'Task Force Abamectin' submitted an application to the competent national authority in Spain, hereafter referred to as the evaluating Member State (EMS), to modify the existing MRL for the active substance abamectin in citrus fruits. 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. The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2015-00809 and the following subject:

*Abamectin – Setting of new MRLs in citrus.*

Spain proposed to raise the existing MRL of abamectin in citrus fruits from the value of 0.015 to 0.04 mg/kg. EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified data gaps and points that needed further clarifications, which were addressed by the EMS in a revised evaluation report. The last revision of the evaluation report (Spain, 2018) replaced the previously submitted versions.

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 limit of quantification (LOQ) for the pesticide/product combination;
- an assessment of the risks of the acceptable daily intake and acute reference dose 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 revised evaluation report submitted by the EMS (Spain, 2018) 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.

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 avermectin B\(_{1a}\) (\(\geq 80\%\)) and avermectin B\(_{1b}\) (\(\leq 20\%\)).

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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.
The IUPAC names for the two components of abamectin are:

**Avermectin B1a:**

$$(2\alpha,4\alpha,8\alpha)-[(S\alpha,S\alpha,6\alpha,7\alpha,11\alpha,15\alpha,17\alpha,20\alpha,20b\alpha)-(2,6\text{-dideoxy}-3\alpha\text{-methyl}-\alpha\text{-L-arabino-hexopyranosyl})-3\alpha\text{-methyl-}\alpha\text{-L-arabino-hexopyranosyl}]-2,6\text{-dideoxy-4-O-(2,6\text{-dideoxy-3-O-methyl-}\alpha\text{-L-arabino-hexopyranosyl})-3\alpha\text{-methyl-}\alpha\text{-L-arabino-hexopyranosyl}}$$

**Avermectin B1b:**

$$(2\alpha,4\alpha,8\alpha)-[(S\alpha,S\alpha,6\alpha,7\alpha,11\alpha,15\alpha,17\alpha,20\alpha,20b\alpha)-(2,6\text{-dideoxy}-3\alpha\text{-methyl}-\alpha\text{-L-arabino-hexopyranosyl})-3\alpha\text{-methyl-}\alpha\text{-L-arabino-hexopyranosyl}]-2,6\text{-dideoxy-4-O-(2,6\text{-dideoxy-3-O-methyl-}\alpha\text{-L-arabino-hexopyranosyl})-3\alpha\text{-methyl-}\alpha\text{-L-arabino-hexopyranosyl}}$$

The chemical structures of the active substance, its main components and major metabolite are reported in Appendix D.

Abamectin was approved on 1 May 2009 for the use as insecticide and acaricide and on 3 April 2017 the use was extended to nematicide. 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 two reasoned opinions on the modification of MRLs for abamectin (EFSA, 2015, 2017). The MRL proposals on from these reasoned opinions have been implemented in an MRL regulation or were voted at the SCOPAFF meeting (the regulation implementing the MRL proposal on bananas has not yet been published). Abamectin is authorised for use in veterinary medicine; the MRLs set in Regulation (EU) No 37/2010 have been taken over in the EU pesticide legislation.

**Assessment**

EFSA has based its assessment on the revised evaluation report submitted by the EMS (Spain, 2018), the DAR and its addendum prepared under Directive 91/414/EEC (Netherlands, 2005, 2008), the European Commission review report on abamectin and its addendum (European Commission, 2008, 2017a), 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, 2015) as well as the conclusions from previous EFSA opinions on abamectin (EFSA, 2010, 2014, 2015, 2017).

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, 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.

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 previous and current MRL applications, are presented in Appendix B.
1. **Residues in plants**

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

1.1.1. **Nature of residues in primary crops**

The metabolism of abamectin following foliar applications was investigated in primary crops belonging to the fruit crops, leafy crops and pulses/oilseeds groups using avermectin B1a in the framework of the EU pesticides peer review and the MRL review (EFSA, 2008, 2014). Avermectin B1a was largely metabolised but represented still the predominant compound in almost all plant parts (4–23% total radioactive residue (TRR) at preharvest interval (PHI) of 8 days). The photolysis product delta-8,9-isomer of avermectin B1a (also referred to as (Z)-8,9-isomer) was found in concentrations not exceeding 10% TRR, but considered of the same toxicity as B1a. Details of the metabolism studies are presented in Appendix B.

1.1.2. **Nature of residues in rotational crops**

Abamectin is proposed for use on permanent crops and investigations of residues in rotational crops are not required. Although accumulation is not expected (DT$_{90}$ < 1 day), confined rotational crop studies were assessed in the EU pesticides peer review (EFSA, 2008). Details of the studies are presented in Appendix B.

1.1.3. **Nature of residues in processed commodities**

The effect of processing on the nature of abamectin was investigated using avermectin B1a in the framework of the EU pesticides peer review (EFSA, 2008). Some degradation of abamectin was observed. The major degradation product was considered of the same toxicity as the parent. Therefore, no reduction factor related to processing should be used in risk assessment. 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.

1.1.4. **Methods of analysis in plants**

Analytical methods using liquid chromatography with tandem mass spectrometry (LC–MS/MS) were validated for one ion transition in high water, high acid and high oil content commodities. According to the previous EFSA reasoned opinions, confirmatory methods with an additional ion transition and independent laboratory validation (ILV) are missing for high acid and high oil content commodities (EFSA, 2014, 2017). Further validation data for the LC–MS/MS method in high acid content matrices (strawberry) and the ILV were assessed in the framework of the current MRL application (Spain, 2018). The methods are able to quantify avermectin B$_{1a}$r, avermectin B$_{1b}$ and the delta-8,9-isomer of B$_{1a}$ at or above the LOQ of 0.002 mg/kg for each analyte (combined LOQ of 0.006 mg/kg). The new data provided addressed the data gap identified for high acid content matrices in the MRL review.

1.1.5. **Stability of residues in plants**

The storage stability of avermectin B$_{1a}$r, avermectin B$_{1b}$ and the delta-8,9-isomer of avermectin B$_{1a}$ in plants stored under deep freeze conditions was investigated in the framework of the EU pesticides peer review (EFSA, 2008). It was demonstrated that in the group to which the crops assessed in this application belong, residues were stable during frozen storage for up to 14 months. Additional storage stability data provided in the current MRL application showed stability in orange peel and pulp for at least 12 months under deep-freeze conditions (Spain, 2018).

1.1.6. **Proposed residue definitions**

Based on the metabolic pattern identified in metabolism studies, the results of hydrolysis studies, the toxicological significance of metabolites, the capabilities of analytical methods, the residue definition for enforcement and risk assessment proposed in the EU pesticides peer review in 2008 and confirmed during the MRL review is:

‘abamectin (sum of avermectin B$_{1a}$r, avermectin B$_{1b}$ and delta-8,9-isomer of avermectin B$_{1a}$r, expressed as avermectin B$_{1a}$)’
The same residue definition is currently set in Regulation (EC) No 396/2005. The residue definition applies to primary crops, rotational crops and processed products. Taking into account the proposed use assessed in this application, EFSA concluded that this residue definition is appropriate for the crop under assessment.

EFSA emphasised that the above studies do not investigate the possible impact of plant metabolism on the isomer ratio of abamectin and further investigation on this matter would in principle be required. Since guidance on the consideration of isomer ratios in the consumer risk assessment is not yet implemented, EFSA recommends that this issue is reconsidered after implementation.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

Residue trials conducted with abamectin on oranges and mandarins over two seasons in southern Europe were submitted. Although few single applications slightly exceeded the acceptable tolerance of +25% in rate, the trials were considered acceptable since the deviation was no more than 32%. Extrapolation from oranges and mandarins is possible (European Commission, 2017b). The residue data supported a MRL proposal for the group of citrus fruits.

According to the EMS, the samples were analysed for avermectin B$_{1a}$, avermectin B$_{1b}$ and delta-8,9-isomer of avermectin B$_{1a}$ with a sufficiently validated analytical method and were stored for up to 12 months under conditions for which integrity was demonstrated.

1.2.2. Magnitude of residues in rotational crops

Not required (intended use is on permanent crops).

1.2.3. Magnitude of residues in processed commodities

Specific studies to assess the magnitude of abamectin residues in processed commodities are not required, because the residue concentration in the raw agricultural commodity were low (< 0.1 mg/kg) (European Commission, 1997d). The distribution of residues between peel and pulp was determined and a tentative peeling factor was derived from the two trials with quantifiable residues in the whole fruit.

1.2.4. Proposed MRLs

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

2. Residues in livestock

Citrus dried pulp may be used for feed purposes. Livestock dietary burdens were calculated for different groups of livestock according to OECD guidance (OECD, 2013). The input values are summarised in Appendix D.1. The results of the calculations are presented in Appendix B.3.

The dietary burdens derived did not exceed the trigger value of 0.1 mg/kg dry matter (DM) for all relevant groups of livestock. The existing MRLs in edible tissues of bovine and ovine are the legal limits resulting from the use in veterinary medicine. The residue levels in citrus by-products resulting from the intended use do not require a modification of the existing MRLs for animal products.

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 sub-groups 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 complete list of input values can be found in Appendix D.2.

The toxicological reference values for abamectin used in the risk assessment (i.e. acceptable daily intake (ADI) and acute reference dose (ARfD) values) were derived in the framework of the EU pesticides peer review (European Commission, 2008). The metabolite included in the residue definition was considered to be of the same toxicity as the parent active substance.
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 the edible portion of citrus fruits (pulp, excluding peel) derived from supervised field trials. As worst case, the EMS used the HR derived for the whole fruit in the risk assessment (Spain, 2018). The short-term exposure did not exceed the ARfD for the crops assessed in this MRL application (see Appendix B.4).

3.2. **Long-term (chronic) dietary risk assessment**

The chronic consumer risk assessment performed in the framework of the MRL review was already revised twice to include median residue levels (STMRs) assessed in EFSA reasoned opinions issued after the MRL review (EFSA, 2015, 2017). The calculation was revised further with the STMR derived for peeled citrus fruits.

The estimated long-term dietary intake was in the range of 2–10% 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.4.

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.

**Conclusions and recommendations**

The data submitted in support of this MRL application were found to be sufficient to derive MRL proposals for citrus fruits. Adequate analytical methods for enforcement are available to control the residues of abamectin in the commodity under consideration. Based on the available information, 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.

EFSA emphasised that the above assessment did 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 on how to address the dietary risk assessment of isomer mixture is not yet implemented, EFSA recommended that the issue is reconsider after implementation. The lack of information on the isomer composition in plants is a source of uncertainty in the consumer risk assessment, which was 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.

The MRL recommendations were 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

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CF conversion factor for enforcement to risk assessment residue definition
CV coefficient of variation (relative standard deviation)
DALA days after last application
DAR draft assessment report
DAT days after treatment
DM dry matter
DT₉₀ period required for 90% dissipation (define method of estimation)
EC emulsifiable Concentrate
EMS evaluating Member State
FAO Food and Agriculture Organization of the United Nations
GAP Good Agricultural Practice
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
LOD limit of detection
LOQ limit of quantification
MRL maximum residue level
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
PRIMo (EFSA) Pesticide Residues Intake Model
RA risk assessment
RAC raw agricultural commodity
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
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 or G or I<sup>(a)</sup> | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)<sup>(d)</sup> | Remarks |
|----------------------|-------------------------|------------------------|---------------------------------|-------------|------------------|-------------------------------|-----------------|---------|
| Citrus fruits        | SEU                     | F                      | *Phylloncistis citrella,* *Tetranychus urticae,* *Panonychus citri,* *Acera Sheldoni* | EC          | 18 g/L           | Tractor mounted sprayer (atomisers) | BBCH 31–32 BBCH 71–74 | 1–3     | 7 days | 0.54–0.72 | 1,000–2,000 | 5.4–14.4 | g/ha 10 |

*NEU: northern European Union; SEU: southern European Union; MS: Member State; GAP: Good Agricultural Practice; MRL: maximum residue level; EC: emulsifiable concentrate.*

<sup>(a):</sup> Outdoor or field use (F), greenhouse application (G) or indoor application (I).

<sup>(b):</sup> CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide formulation types and international coding system.

<sup>(c):</sup> 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.

<sup>(d):</sup> PHI: minimum preharvest interval.
Appendix B – List of end points

B.1. Residues in plants

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

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

| Primary crops (available studies) | Crop groups | Crop(s) | Application(s) | Sampling | 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 | 14C-avermectin B1a (EFSA, 2008) |
| Tomatoes                         | Foliar (F, G), 5 × 0.026 kg/ha | 0, 3, 7, 14, 28 DALA | 14C-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 | 14C-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 | 3H-avermectin B1a (EFSA, 2008) |
|                                 | Foliar (F) to mature plants, 10 × 0.017 kg/ha | 0, 7 DALA | 14C-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 | 3H-avermectin B1a (EFSA, 2008) |
| Pulses/oilseeds                  | Cotton      | Onto leaf, 1 × 200 μL/leaf | 0, 1, 2, 4, 8 DAT | 14C-avermectin B1a (EFSA, 2008) |
|                                 | Foliar (F), 2 × 0.02 kg/ha | 60 DALA | 14C-avermectin B1a (EFSA, 2008) |
|                                 | Foliar (F), 3 × 0.022 and 3 × 0.22 kg/ha | 21 DALA | 14C-avermectin B1a (EFSA, 2008) |

| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s) | PBI (DAT) | Comment/source |
|--------------------------------------|-------------|---------|----------------|-----------|---------------|
| Root/tuber crops                     | Carrots     | Soil application, 3 × 0.029 and 12 × 0.034 kg/ha | 14–31, 120–123, 365 | 14C-avermectin B1a (EFSA, 2008) |
|                                     | Turnips     |                     |               | 14C-avermectin B1a (EFSA, 2008) |
| Leafy crops                         | Lettuce     |                     |               | Studies provided although not triggered (DT90 avermectin B1a < 1 day) |
| Cereal (small grain) other           | Sorghum     |                     |               |               |
### Processed Commodities (hydrolysis study)

| Conditions                                      | Stable? | Comment/source                                                                 |
|------------------------------------------------|---------|-------------------------------------------------------------------------------|
| Pasteurisation (20 min, 90°C, pH 4)             | Yes     | Study performed with $^{14}$C-avermectin B$_{1a}$                              |
| Baking, brewing and boiling (60 min, 100°C, pH 5) | Yes     | Avermectin B$_{1a}$ degraded (30–40\% AR) forming mainly its monosaccharide (10–20\% AR) (EFSA, 2008) |
| Sterilisation (20 min, 120°C, pH 6)             | Yes     |                                                                               |

**F:** field application; **G:** glasshouse application; **DAT:** days after treatment; **DALA:** days after last application; **PBI:** plant-back interval.

### Rotational Crop and Primary Crop Metabolism Similar?

- Yes [EFSA (2008, 2016)]

### Residue Pattern in Processed Commodities Similar to Residue Pattern in Raw Commodities?

- Yes [Not exactly the same from a chemical point of view. The same from a toxicological point of view (EFSA, 2008)]

### Plant Residue Definition for Monitoring (RD-Mo)

- Abamectin (sum of avermectin B$_{1a}$, avermectin B$_{1b}$, and delta-8,9-isomer of avermectin B$_{1a}$, expressed as avermectin B$_{1a}$)

### Plant Residue Definition for Risk Assessment (RD-RA)

- Abamectin (sum of avermectin B$_{1a}$, avermectin B$_{1b}$, and delta-8,9-isomer of avermectin B$_{1a}$, expressed as avermectin B$_{1a}$)

### Methods of Analysis for Monitoring of Residues (Analytical Technique, Crop Groups, LOQs)

- Matrices with high oil content: HPLC–MS/MS, LOQ 0.002 mg/kg for each analyte (combined 0.006 mg/kg). Confirmatory method and ILV missing (EFSA, 2014)
- Matrices with high water content (bananas), HPLC–MS/MS, LOQ 0.002 mg/kg for each analyte. Confirmatory method and ILV available (EFSA, 2017)
- Matrices with high acid content (strawberries): HPLC–MS/MS, LOQ 0.002 mg/kg for each analyte. Confirmatory method and ILV available (Spain, 2018)
### B.1.1.2. Stability of residues in plants

| Category             | Commodity       | T (°C)    | Stability (months/years) |
|----------------------|-----------------|-----------|--------------------------|
| High water content   | Not specified   | Deep freeze | 3 years                 |
| High oil content     | Not specified   | Deep freeze | 2 years                 |
| Dry/High starch      | –               | –         | –                        |
| High acid content    | Not specified   | Deep freeze | 14 months               |
| Oranges              | Deep freeze     | –         | 12 months                |

Comments: Orange peel and pulp (Spain, 2018)
Reference: 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(b)                                                                 | Calculated MRL (mg/kg) | HR(c) (mg/kg) | STMR(d) (mg/kg) | CF(e) |
|------------------|------------------|---------------------------------------------------------------|----------------------------------------------------------------------------------|------------------------|--------------|----------------|-------|
| Citrus fruits    | SEU              | 16 × < 0.01; 0.021; 0.029 Pulp: 18 × < 0.01                  | Residue trials on oranges (8) and mandarins (8) compliant with the GAP (within 25% accepted deviation range, except in two last (ca. + 28%) and three-first (ca. + 32%) single applications) Pulp: < LOD, except in one sample (< LOQ) MRL(OECD): 0.032 (unrounded) Extrapolation to whole group of citrus fruits | 0.04                   | 0.029        | 0.01           | N/A   |

MRL: maximum residue level; GAP: Good Agricultural Practice; LOD: limit of detection; LOQ: limit of quantification; OECD: Organisation for Economic Co-operation and Development.  
(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): Individual residue values were reported as sum of avermectin B1a, avermectin B1b and delta-8,9 isomer of avermectin B1a, expressed as avermectin B1a (combined LOQ 0.01 mg/kg).  
(c): Highest residue refers to the whole commodity and not to the edible portion of the fruit (pulp).  
(d): Supervised trials median residue refers to the whole commodity and not to the edible portion (pulp).  
(e): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment. N/A not applicable.
B.1.2.2. Residues in succeeding crops

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

|             | Not triggered | Not relevant, permanent crops |
|-------------|---------------|------------------------------|

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

|             | Not triggered | Not relevant, permanent crops |
|-------------|---------------|------------------------------|

B.1.2.3. Processing factors

| Processed commodity | Number of valid studies | Processing factor (PF) | CF\(_p\)\(^{(b)}\) | Comment/ source |
|---------------------|-------------------------|------------------------|-----------------|-----------------|
| Citrus, peeled       | 2                       | < 0.14; < 0.19         | < 0.17          | N/A             | Tentative only  |

(a): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur).
(b): Conversion factor for risk assessment in the processed commodity; median of the individual conversion factors for each processing residue trial. For the residues of abamectin in the pulp, the limit of detection of 0.004 mg/kg was used in the calculation.

B.2. Residues in livestock

| Relevant groups (subgroups) | Dietary burden expressed in | Most critical subgroup\(^{(a)}\) | Most critical commodity | Trigger exceeded (Y/N) |
|-----------------------------|-----------------------------|---------------------------------|-------------------------|------------------------|
|                             | mg/kg bw per day            | mg/kg DM                        |                         |                        |
|                             | Median | Maximum        | Median | Maximum        | Cattle (all)       | Citrus, dried pulp | No        |
| Cattle (all)                | 0.0010 | 0.0011         | 0.0250 | 0.0295         | Dairy cattle       | Citrus, dried pulp | No        |
| Cattle (dairy only)         | 0.0010 | 0.0011         | 0.0250 | 0.0295         | Dairy cattle       | Citrus, dried pulp | No        |
| Sheep (all)                 | 0.0005 | 0.0006         | 0.0130 | 0.0175         | Lamb               | Apple, pomace     | No        |
| Sheep (ewe only)            | 0.0004 | 0.0006         | 0.0130 | 0.0175         | Ram/Ewe            | Apple, pomace     | No        |
| Swine (all)                 | 0.0005 | 0.0007         | 0.0215 | 0.0290         | Swine (breeding)   | Citrus, dried pulp | No        |
| Poultry (all)               | 0.0001 | 0.0004         | 0.0020 | 0.0050         | Turkey             | Potato culls      | No        |
| Poultry (layer only)        | 0.0001 | 0.0002         | 0.0013 | 0.0028         | Poultry layer      | Potato culls      | No        |
| Fish                        | N/A                          |                                  |                         |                        |

bw: body weight; DM: dry matter.
(a): When one group of livestock includes several subgroups (e.g. poultry ‘all’ including broiler, layer and turkey), the result of the most critical subgroup is identified from the maximum dietary burdens expressed as ‘mg/kg bw per day’.

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**

Not required.

### B.3. Consumer risk assessment

| ARFD | 0.005 mg/kg bw (European Commission, 2008) |
|------|------------------------------------------|
| Highest IESTI, according to EFSA PRIMo | Oranges: 26.5% of ARFD  
Grapefruits: 17.8% of ARFD  
Mandarins: 11.1% of ARFD  
Lemons: 6.9% of ARFD  
Limes: 4.0% of ARFD  
Other citrus fruits: 0.1% of ARFD |

**Assumptions made for the calculations**
The calculation was based on the highest residue level expected in the edible part of citrus fruits (pulp).

| ADI | 0.0025 mg/kg bw per day (European Commission, 2008) |
|-----|---------------------------------------------------|
| Highest IEDI, according to EFSA PRIMo | 10% ADI (DE child)  
Contribution of crops assessed:  
Oranges: 1.52% of ADI  
Mandarins: 0.30% of ADI  
Grapefruits: 0.28% of ADI  
Lemons: 0.13% of ADI  
Limes: 0.05% 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). The conversion factor for risk assessment of 1.25 was used for the (veterinary) MRLs. The contribution of commodities where no GAP was reported in the framework of the MRL review and subsequent EFSA reasoned opinions was not included in the calculation.

### B.4. Recommended MRLs

| Code(a) | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|---------|-----------|------------------------|-------------------------|-----------------------|
| 0110000 | Citrus fruits | 0.015 | 0.04 | SEU use supported by extrapolation from residue data on oranges and mandarins. Risk for consumers unlikely |

**Enforcement residue definition:** Abamectin (sum of avermectin B1a, avermectin B1b and delta-8,9-isomer of avermectin B1a, expressed as avermectin B1a).

MRL: maximum residue level; SEU: southern Europe.  
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
Appendix C – Pesticide Residue Intake Model (PRIMo)

### Abamectin

| Status of the active substance: | Approved |
|--------------------------------|----------|
| Code no. | LOQ (mg/kg bw) | Proposed LOQ (mg/kg bw) |
| ADI (mg/kg bw per day) | 0.0025 | 0.005 |
| Source of ADI | COM | Source of ADI | COM |
| Year of evaluation | 2008 | Year of evaluation | 2008 |

#### Toxicological end points

| Highest calculated TMDI values in % of ADI | Commodity/ group of commodities | TMDI (range) in % of ADI | minimum – maximum |
|-------------------------------------------|---------------------------------|--------------------------|-------------------|
| 9.9 | DE child | Tomato | 1.9 | Oranges | 1.2 | Tomatoes | 1.0 |
| 9.7 | NL child | Tomato | 2.0 | Oranges | 1.2 | Tomatoes | 1.2 |
| 8.2 | FR toddler | Tomato | 0.5 | Sheep meat | 0.8 | Oranges | 0.9 |
| 8.0 | ES child | Tomato | 0.9 | Oranges | 0.7 | Bovine: Meat | 0.5 |
| 7.6 | WHO regional European diet | Tomato | 1.3 | Oranges | 0.5 | Sheep meat | 0.6 |
| 7.4 | WHO cluster diet D | Tomato | 1.2 | Oranges | 0.3 | Potatoes | 0.7 |
| 7.3 | SE general population 90th percentile | Tomato | 0.9 | Oranges | 0.3 | Apples | 0.6 |
| 7.2 | WHO cluster diet E | Tomato | 0.6 | Oranges | 0.4 | Bovine: Meat | 0.9 |
| 7.1 | FR infant | Apple | 0.5 | Oranges | 0.4 | Bovine: Meat | 0.3 |
| 7.0 | ES adult | Tomato | 1.0 | Oranges | 0.5 | Apples | 0.3 |
| 6.8 | IT kids/toddler | Tomato | 0.3 | Apples | 0.2 | Oranges | 0.3 |
| 6.7 | PT General population | Tomato | 1.1 | Oranges | 0.6 | Bovine: Meat | 0.3 |
| 6.5 | UK Toddler | Orange | 0.8 | Oranges | 0.7 | Apples | 0.7 |
| 6.4 | DK child | Tomato | 0.7 | Oranges | 0.5 | Cucumbers | 0.6 |
| 6.3 | WHO Cluster diet F | Tomato | 0.5 | Oranges | 0.3 | Bovine: Meat | 0.3 |
| 6.2 | NL general | Orange | 0.6 | Oranges | 0.5 | Tomatoes | 0.6 |
| 6.1 | IT adult | Tomato | 1.4 | Oranges | 0.3 | Apples | 0.6 |
| 6.0 | FR all population | Tomato | 1.0 | Oranges | 0.5 | Tomatoes | 0.6 |
| 5.9 | UK infant | Orange | 0.5 | Oranges | 0.4 | Apples | 0.6 |
| 5.8 | PL general population | Tomato | 1.1 | Oranges | 0.7 | Apples | 0.5 |
| 5.7 | UK vegetarian | Tomato | 0.8 | Oranges | 0.3 | Bovine: Meat | 0.5 |
| 5.6 | DK adult | Tomato | 0.5 | Oranges | 0.3 | Potatoes | 0.6 |
| 5.5 | LT adult | Tomato | 0.6 | Oranges | 0.3 | Potatoes | 0.3 |
| 5.4 | UK Adult | Tomato | 0.5 | Oranges | 0.3 | Apples | 0.5 |
| 5.3 | PT adult | Tomato | 0.5 | Oranges | 0.4 | Apples | 0.3 |

#### Chronic risk assessment – refined calculations

| No of diets exceeding ADI | 2 | 10 |
|---------------------------|---|----|

### 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.
### Acute risk assessment/children – refined calculations

The acute risk assessment is based on the ARfD.

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

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

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

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

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

| Commodity          | pTMRL (mg/kg) | ARfD/ADI Exceeded |
|--------------------|---------------|-------------------|
| Oranges            | 0.01/-        | Yes               |
| Grapefruit         | 0.01/-        | Yes               |
| Mandarins          | 0.01/-        | Yes               |
| Lemons             | 0.01/-        | Yes               |
| Limes              | 0.01/-        | Yes               |
| Other citrus fruit | 0.01/-        | Yes               |

### No of critical MRLs (IESTI 1):

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.

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

The acute risk assessment adultes/general population is based on the ADI.

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 ADI.

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

| Commodity          | pTMRL (mg/kg) | ARfD/ADI Exceeded |
|--------------------|---------------|-------------------|
| Apple juice        | 0.0123/-      | Yes               |
| Orange juice       | 0.01/-        | Yes               |
| Raspberries juice  | 0.033/-       | Yes               |
| Pear juice         | 0.0123/-      | Yes               |

### No of critical MRLs (IESTI 2):

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.

### 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.

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.

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

| Commodity          | pTMRL (mg/kg) | ARfD/ADI Exceeded |
|--------------------|---------------|-------------------|
| Oranges            | 0.01/-        | Yes               |
| Grapefruit         | 0.01/-        | Yes               |
| Mandarins          | 0.01/-        | Yes               |
| Lemons             | 0.01/-        | Yes               |
| Limes              | 0.01/-        | Yes               |
| Other citrus fruit | 0.01/-        | Yes               |

### No of critical MRLs (IESTI 1):

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.

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

| Commodity          | pTMRL (mg/kg) | ARfD/ADI Exceeded |
|--------------------|---------------|-------------------|
| Apple juice        | 0.0123/-      | Yes               |
| Orange juice       | 0.01/-        | Yes               |
| Raspberries juice  | 0.033/-       | Yes               |
| Pear juice         | 0.0123/-      | Yes               |

**Note:** 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 for unprocessed commodity.

**pTMRL:** Provisional temporary MRL for processed commodity.
Appendix D – Input values for the exposure calculations

D.1. Livestock dietary burden calculations

| Feed commodity          | Median dietary burden | Maximum dietary burden |
|-------------------------|-----------------------|------------------------|
|                         | Input value (mg/kg)   | Comment                | Input value (mg/kg) | Comment |
| Risk assessment residue definition: Sum of avermectin B$_{1a}$, avermectin B$_{1b}$ and delta-8,9-isomer of avermectin B$_{1a}$, expressed as avermectin B$_{1a}$ |
| Apple pomace, wet       | 0.040                 | STMR (EFSA, 2014) $\times$ PF(a) | 0.040 | STMR (EFSA, 2014) $\times$ PF(a) |
| Citrus, dried pulp      | 0.100                 | STMR $\times$ PF(a)    | –      | – |
| Potato, culls           | 0.002                 | STMR (EFSA, 2014) $\times$ PF(a) | 0.005 | HR $\times$ PF(a) (EFSA, 2014) |
| Potato, process waste   | 0.002                 | STMR (EFSA, 2014) $\times$ PF(a) | –      | – |
| Potato, dried pulp      | 0.002                 | STMR (EFSA, 2014) $\times$ PF(a) | –      | – |

STMR: supervised trials median residue; HR: highest residue; PF: processing factor.
(a): For fruit by-products, in the absence of processing factors supported by data, default processing factors (PF) of 5 (apple wet pomace) and 10 (citrus dried pulp) were included in the calculation. For potato processed waste and dried pulp a PF of 1 was applied. Assuming a zero-residue in potatoes, concentration of residues is not expected in these feed items.

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: Sum of avermectin B$_{1a}$, avermectin B$_{1b}$ and delta-8,9 isomer of avermectin B$_{1a}$, expressed as avermectin B$_{1a}$ |
| Citrus fruits  | 0.010                   | STMR-Peeled (LOQ)     | 0.010 | HR-Peeled (LOQ) |
| Tree nuts      | 0.013                   | STMR (EFSA, 2014)     | –      | – |
| Pome fruits    | 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   | 0.030                   | STMR (EFSA, 2014)     | –      | – |
| Blackberries   | 0.023                   | STMR (EFSA, 2014)     | –      | – |
| Raspberries    | 0.023                   | STMR (EFSA, 2014)     | –      | – |
| Currants (red, black, white) | 0.006 | STMR (EFSA, 2014) | – | – |
| Gooseberries   | 0.006                   | STMR (EFSA, 2014)     | –      | – |
| Bananas        | 0.006                   | STMR-Peeled (EFSA, 2017) | – | – |
| Papayas        | 0.008                   | STMR (EFSA, 2014)     | –      | – |
| 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)     | –      | – |
| 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) | – | – |

Acute risk assessment performed only for the crops under assessment.
### Table: Risk assessment residue values for abamectin

| Commodity                      | Chronic risk assessment | Acute risk assessment |
|--------------------------------|-------------------------|-----------------------|
|                                | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment               |
| Lamb’s lettuces                | 0.055                   | STMR (EFSA, 2014)     |                     |                       |
| Lettuces                       | 0.010                   | STMR (EFSA, 2014)     |                     |                       |
| Scarole (broad-leaf endive)    | 0.020                   | STMR (EFSA, 2014)     |                     |                       |
| Rocket, Rucola                 | 0.005                   | STMR (EFSA, 2014)     |                     |                       |
| Baby leaf crops (including brassica species) | 0.055 | STMR (EFSA, 2014) | |                       |
| Witloofs                       | 0.006                   | STMR (EFSA, 2014)     |                     |                       |
| Herbs, except celery leaves    | 0.127                   | STMR (EFSA, 2014)     |                     |                       |
| Celery leaves                  | 0.010                   | STMR (EFSA, 2014)     |                     |                       |
| Beans (with pods)              | 0.007                   | STMR (EFSA, 2015)     |                     |                       |
| Peas (with pods)               | 0.007                   | STMR (EFSA, 2015)     |                     |                       |
| Celeries                       | 0.015                   | STMR (EFSA, 2015)     |                     |                       |
| Leeks                          | 0.006                   | STMR (EFSA, 2014)     |                     |                       |
| Hops (dried)                   | 0.016                   | STMR (EFSA, 2014)     |                     |                       |

Risk assessment residue definition: Sum of avermectin B<sub>1a</sub> and B<sub>1b</sub>, expressed as avermectin B<sub>1a</sub>

- Bovine, Meat: 0.013<sup>(a)</sup> V-MRL × CF (EFSA, 2014)
- Bovine, Fat: 0.013 V-MRL × CF (EFSA, 2014)
- Bovine, Liver: 0.025 V-MRL × CF (EFSA, 2014)
- Bovine, Kidney: 0.010 V-LOQ (EFSA, 2014)
- Bovine, Edible offal: 0.025 V-MRL × CF (EFSA, 2014)
- Sheep, Meat: 0.033<sup>(a)</sup> V-MRL × CF (EFSA, 2014)
- Sheep, Fat: 0.063 V-MRL × CF (EFSA, 2014)
- Sheep; Liver: 0.031 V-MRL × CF (EFSA, 2014)
- Sheep; Kidney: 0.025 V-MRL × CF (EFSA, 2014)
- Sheep, Edible offal: 0.063 V-MRL × CF (EFSA, 2014)

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

(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% muscle and 20% fat content for mammal meat (FAO, 2016).

(b): MRL resulting from the veterinary use of abamectin (V-MRL) are derived for avermectin B<sub>1a</sub>. A conversion factor (CF) of 1.25 was used to take into account the consumer exposure to avermectin B<sub>1</sub>.
## Appendix E – Used compound codes

| Code/trivial name     | Chemical name/SMILES notation(a)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Structural formula(a) |
|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|
| Avermectin B<sub>1a</sub> | (2aE,4E,8E)-7′-5′,6′,6′-([5]-sec-butyl)-5′,6′,6′,7,10,11,14,15,17a,20a,20b-dodecahydro-20,20b-dihydroxy-5′,6,8,19-tetramethyl-17-oxospiro[11,15-methano-2H,13H,17H-furo[4,3-2pq][2,6]benzodioxacyclotadecin-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 B<sub>1a</sub>](image) |
| Avermectin B<sub>1b</sub> | (2aE,4E,8E)-7′-5′,6′,6′-([5]-sec-butyl)-5′,6′,6′,7,10,11,14,15,17a,20a,20b-dodecahydro-20,20b-dihydroxy-5′,6,8,19-tetramethyl-17-oxospiro[11,15-methano-2H,13H,17H-furo[4,3-2pq][2,6]benzodioxacyclotadecin-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 B<sub>1b</sub>](image) |
| δ-8,9-isomer of avermectin B<sub>1a</sub> or [8,9-Z]-isomer of avermectin B<sub>1a</sub> (NOA 427011) | (2aZ,4E,8E)-7′-5′,6′,6′-([5]-sec-butyl)-5′,6′,6′,7,10,11,14,15,17a,20a,20b-dodecahydro-20,20b-dihydroxy-5′,6,8,19-tetramethyl-17-oxospiro[11,15-methano-2H,13H,17H-furo[4,3-2pq][2,6]benzodioxacyclotadecin-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 | ![δ-8,9-isomer of avermectin B<sub>1a</sub> or [8,9-Z]-isomer of avermectin B<sub>1a</sub>](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 November 2008).