REASONED OPINION

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

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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.

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

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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_{1a}, avermectin B_{1b} and delta-8,9-isomer of avermectin B_{1a}, expressed as avermectin B_{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[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Abamectin (sum of avermectin B_{1a}, avermectin B_{1b} and delta-8,9-isomer of avermectin B_{1a}, expressed as avermectin B_{1a})[(F),(R)]				
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.
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(F): Fat soluble.
(R): Code 1000000 except 1040000: avermectin B_{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%).

[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:

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

Avermectin B1b:

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

The chemical structures of the active substance, 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[4] and on 3 April 2017 the use was extended to nematicide.[5] 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.[6] 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[7] 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[8] 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[9] and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 1997a–g, 2000, 2010a,b, 2017b; OECD, 2011). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011[10].

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.

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

[5] 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.

[6] 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 phenmedipham in or on certain products. OJ L 302, 19.11.2015, p. 15–50.

[7] 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, benzovindiflupyr, bromoxynil, fludioxonil, fluopicolide, fosetyl, mepiquat, proquinazid, propamocarb, prohexadione and tebuconazole in or on certain products. OJ L 167, 24.6.2016, p. 46–103.

[8] 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.

[9] 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.

[10] 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 following foliar applications was investigated in primary crops belonging to the fruit crops, leafy crops and pulses/oilseeds groups using avermectin B_{1a} in the framework of the EU pesticides peer review and the MRL review (EFSA, 2008, 2014). Avermectin B_{1a} 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 B_{1a} (also referred to as (*Z*)-8,9-isomer) was found in concentrations not exceeding 10% TRR, but considered of the same toxicity as B_{1a}. 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 B_{1a} 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}, 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}, 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}, avermectin B_{1b} and delta-8,9-isomer of avermectin B_{1a}, 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 reside (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

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
DT_{90}	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 G or I[a]	Pests or group of pests controlled	Preparation		Application				Application rate per treatment				PHI (days)[d]	Remarks
				Type[b]	Conc. a.s.	Method kind	Range of growth stages and season[c]	Number min–max	Interval between application (min)	g a.s./hL min–max	Water L/ha min–max	Rate	Unit		
Citrus fruits	SEU	F	*Phyllocnistis citrella, Tetranychus urticae, Panonychus citri, Aceria 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.
(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)	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	^{14}C-avermectin B_{1a} (EFSA, 2008)
		Tomatoes	Foliar (F, G), 5 × 0.026 kg/ha	0, 3, 7, 14, 28 DALA	^{14}C-avermectin B_{1a} (EFSA, 2008)
			Foliar (G), 3 × 0.28 kg/ha		
			Foliar (F), 3 × 0.25 kg/ha		
	Leafy crops	Celery	Foliar (F) to immature plants, 4 × 0.017 kg/ha	0, 14 DALA	^{14}C-avermectin B_{1a} (EFSA, 2008)
			Foliar (F) to immature plants, 4 × 0.011 kg/ha and 4 × 0.110 kg/ha	0, 7, 14, 29, 43 DALA	^{3}H-avermectin B_{1a} (EFSA, 2008)
			Foliar (F) to mature plants, 10 × 0.017 kg/ha	0, 7 DALA	^{14}C-avermectin B_{1a} (EFSA, 2008)
			Foliar (F) to mature plants, 10 × 0.011 kg/ha and 10 × 0.110 kg/ha	0, 1, 3, 7, 15, 22 DALA	^{3}H-avermectin B_{1a} (EFSA, 2008)
	Pulses/oilseeds	Cotton	Onto leaf, 1 × 200 μL/leaf	0, 1, 2, 4, 8 DAT	^{14}C- avermectin B^{1a} (EFSA, 2008)
			Foliar (F), 2 × 0.02 kg/ha	60 DALA	^{14}C- avermectin B_{1a} (EFSA, 2008)
			Foliar (F), 3 × 0.022 and 3 × 0.22 kg/ha	21 DALA	^{14}C- avermectin B_{1a} (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	^{14}C-avermectin B_{1a} (EFSA, 2008) Studies provided although not triggered (DT_{90} avermectin B_{1a} < 1 day)
		Turnips			
	Leafy crops	Lettuce			
	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} Avermectin B_{1a} degraded (30–40% AR) forming mainly its monosaccharide (10–20% AR) (EFSA, 2008)
	Baking, brewing and boiling (60 min, 100°C, pH 5)	Yes	
	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

Plant products (available studies)	**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 B_{1a}, avermectin B_{1b} and delta-8,9 isomer of avermectin B_{1a}, expressed as avermectin B_{1a} (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[a]	Processing factor (PF)		CF_P[b]	Comment/ source
		Individual values	Median PF		
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)	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
Enforcement residue definition: Abamectin (sum of avermectin B_{1a}, avermectin B_{1b} and delta-8,9-isomer of avermectin B_{1a}, expressed as avermectin B_{1a})				
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.
(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):	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:	**COM**	Source of ARfD:	**COM**
Year of evaluation:	**2008**	Year of evaluation:	**2008**

MRLs according to Reg. (EU) 2016/1003 and SANTE/11743/2017(banana) except for citrus.

Chronic risk assessment – refined calculations

TMDI (range) in % of ADI minimum – maximum	
2	10
No of diets exceeding ADI:	---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	pTMRLs at LOQ (in % of ADI)
9.9	DE child	3.9	Apples	1.5	Oranges	1.2	Tomatoes	1.0
9.2	WHO Cluster diet B	3.8	Tomatoes	0.4	Wine grapes	0.4	Bovine: Meat	1.2
7.7	NL child	2.0	Apples	1.2	Oranges	0.8	Tomatoes	1.2
6.2	IE adult	0.5	Tomatoes	0.5	Sheep: Meat	0.4	Oranges	1.1
5.9	FR toddler	0.9	Tomatoes	0.8	Apples	0.8	Oranges	0.9
4.8	ES child	1.2	Tomatoes	0.9	Oranges	0.7	Bovine: Meat	0.5
4.7	WHO regional European diet	1.3	Tomatoes	0.5	Bovine: Meat	0.3	Potatoes	0.7
4.1	WHO cluster diet D	1.2	Tomatoes	0.3	Herbs	0.3	Potatoes	0.7
3.9	SE general population 90th percentile	0.9	Tomatoes	0.4	Bananas	0.3	Apples	0.8
3.9	WHO cluster diet E	0.6	Tomatoes	0.4	Wine grapes	0.4	Bovine: Meat	0.9
3.6	FR infant	0.8	Apples	0.6	Strawberries	0.4	Oranges	0.7
3.6	ES adult	1.0	Tomatoes	0.5	Oranges	0.4	Bovine: Meat	0.3
3.6	IT kids/toddler	1.7	Tomatoes	0.3	Apples	0.2	Oranges	0.3
3.6	PT General population	1.1	Tomatoes	0.6	Wine grapes	0.4	Potatoes	1.2
3.5	UK Toddler	0.8	Oranges	0.7	Tomatoes	0.5	Apples	0.7
3.4	DK child	0.7	Apples	0.6	Tomatoes	0.5	Cucumbers	0.6
3.4	WHO Cluster diet F	0.8	Tomatoes	0.5	Bovine: Meat	0.3	Oranges	0.6
3.3	NL general	0.6	Oranges	0.5	Tomatoes	0.4	Apples	0.6
3.1	IT adult	1.4	Tomatoes	0.3	Apples	0.2	Lettuce	0.2
3.1	FR all population	1.0	Wine grapes	0.5	Tomatoes	0.3	Bovine: Meat	1.3
2.7	UK Infant	0.5	Oranges	0.5	Apples	0.4	Tomatoes	0.6
2.7	PL general population	1.1	Tomatoes	0.7	Apples	0.3	Potatoes	0.5
2.3	UK vegetarian	0.8	Tomatoes	0.3	Oranges	0.2	Wine grapes	0.5
2.2	DK adult	0.5	Tomatoes	0.3	Wine grapes	0.3	Bovine: Meat	0.6
2.1	LT adult	0.8	Tomatoes	0.6	Apples	0.3	Potatoes	0.3
1.8	UK Adult	0.5	Tomatoes	0.3	Wine grapes	0.2	Oranges	0.5
1.7	FI adult	0.5	Tomatoes	0.4	Oranges	0.1	Apples	0.3

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						Acute risk assessment/adults/general population – refined calculations					
Unprocessed commodities											
No of commodities for which ARfD/ADI is exceeded (IESTI 1):			**---**			**No of commodities for which ARfD/ADI is exceeded (IESTI 1):**			**---**		
IESTI 1		***)**	****)**			**IESTI 2**		***)**	****)**		
Highest % of ARfD/ADI	Commodities		pTMRL/ threshold MRL (mg/kg)			Highest % of ARfD/ADI	Commodities		pTMRL/ threshold MRL (mg/kg)		
26.5	Oranges		0.01/-			19.2	Oranges		0.01/-		
17.8	Grapefruit		0.01/-			17.8	Grapefruit		0.01/-		
11.1	Mandarins		0.01/-			8.4	Mandarins		0.01/-		
6.9	Lemons		0.01/-			5.1	Lemons		0.01/-		
4.0	Limes		0.01/-			2.9	Limes		0.01/-		
0.1	Other citrus fruit		0.01/-			0.1	Other citrus fruit		0.01/-		
No of critical MRLs (IESTI 1)			---			**No of critical MRLs (IESTI 2)**			---		

Acute risk assessment/adults/general population – refined calculations					
No of commodities for which ARfD/ADI is exceeded (IESTI 1):			**---**		
IESTI 1		***)**	****)**		
Highest % of ARfD/ADI	Commodities		pTMRL/ threshold MRL (mg/kg)		
5.1	Oranges		0.01/-		
4.0	Grapefruit		0.01/-		
2.7	Mandarins		0.01/-		
1.4	Lemons		0.01/-		
1.3	Limes		0.01/-		

Acute risk assessment/adults/general population – refined calculations					
No of commodities for which ARfD/ADI is exceeded (IESTI 2):			**---**		
IESTI 2		***)**	****)**		
Highest % of ARfD/ADI	Commodities		pTMRL/ threshold MRL (mg/kg)		
4.2	Oranges		0.01/-		
3.0	Grapefruit		0.01/-		
2.1	Mandarins		0.01/-		
1.0	Lemons		0.01/-		
0.9	Limes		0.01/-		

Acute risk assessment/children – refined calculations						Acute risk assessment/adults/general population – refined calculations					
Processed commodities											
No of commodities for which ARfD/ADI is exceeded:			**---**			**No of commodities for which ARfD/ADI is exceeded:**			**---**		
		*****)**						*****)**			
Highest % of ARfD/ADI	Processed commodities		pTMRL/ threshold MRL (mg/kg)			Highest % of ARfD/ADI	Processed commodities		pTMRL/ threshold MRL (mg/kg)		
12.5	Apple juice		0.0123/-			1.6	Apple juice		0.0123/-		
11.2	Tomato juice		0.032/-			1.6	Orange juice		0.008/-		
9.9	Orange juice		0.01/-			1.2	Tomato (preserved-		0.032/-		
7.9	Raspberries juice		0.033/-			0.5	Wine		0.006/-		
4.3	Pear juice		0.0123/-			0.4	Peach preserved with		0.01/-		

*) 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.

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 variabilty factor of 3.
Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100% of the ARfD.

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

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) × PF[(a)]	0.040	STMR (EFSA, 2014) × PF[(a)]
Citrus, dried pulp	0.100	STMR × PF[(a)]	–	–
Potato, culls	0.002	STMR (EFSA, 2014) × PF[(a)]	0.005	HR × PF[(a)] (EFSA, 2014)
Potato, process waste	0.002	STMR (EFSA, 2014) × PF[(a)]	–	–
Potato, dried pulp	0.002	STMR (EFSA, 2014) × 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)	Acute risk assessment performed only for the crops under assessment.	
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)		

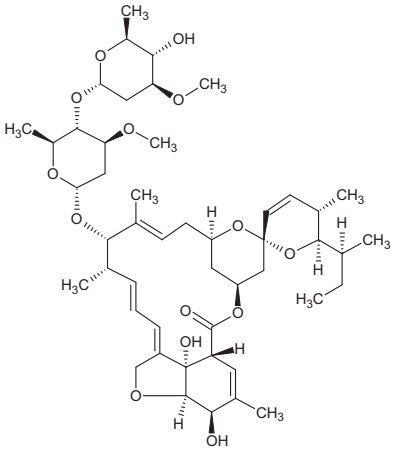
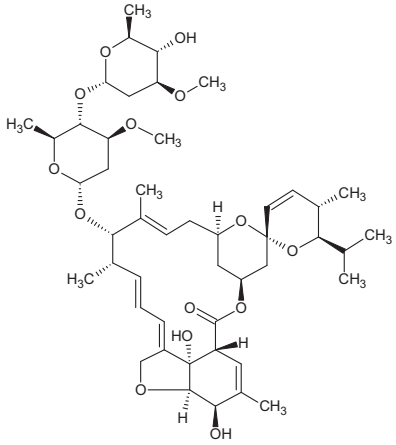
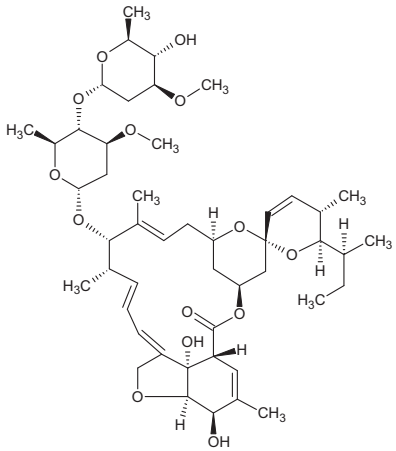
Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Lamb's lettuces	0.055	STMR (EFSA, 2014)		
Lettuces	0.010	STMR (EFSA, 2014)		
Scarole (broad-leaf endive)	0.020	STMR (EFSA, 2014)		
Rocket, Rucola	0.005	STMR (EFSA, 2014)		
Baby leaf crops (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_{1a} and B_{1b}, expressed as avermectin B_{1a}				
Bovine, Meat	0.013[(a)]	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[(a)]	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_{1a}. A conversion factor (CF) of 1.25 was used to take into account the consumer exposure to avermectin B_1.

Appendix E – Used compound codes

Code/trivial name	Chemical name/SMILES notation[(a)]	Structural formula[(a)]
Avermectin B_{1a}	(2a*E*,4*E*,8*E*)-(5′*S*,6*S*,6′*R*,7*S*,11*R*,13*S*,15*S*,17a*R*,20*R*,20a*R*,20b*S*)-6′-[(*S*)-*sec*-butyl]-5′,6,6′,7,10,11,14,15,17a,20,20a,20b-dodecahydro-20,20b-dihydroxy-5′,6,8,19-tetramethyl-17-oxospiro[11,15-methano-2*H*,13*H*,17*H*-furo[4,3,2-*pq*][2,6]benzodioxacyclooctadecin-13,2′-[2*H*]pyran]-7-yl 2,6-dideoxy-4-*O*-(2,6-dideoxy-3-*O*-methyl-α-L-arabino-hexopyranosyl)-3-*O*-methyl-α-L-arabino-hexopyranoside CO[C@H]1C[C@@H](O[C@@H](C)[C@@H]1O)O[C@@H]2[C@@H](OC)C[C@@H](O[C@H]2C)O[C@@H]3C(C)=CC[C@@H]6C[C@H](OC(=O)[C@@H]4C=C(C)[C@@H](O)[C@H]5OCC(=CC=C[C@@H]3C)[C@@]45O)C[C@@]7(O6)C=C[C@H](C)[C@H](O7)[C@@H](C)CC	
Avermectin B_{1b}	(2a*E*,4*E*,8*E*)-(5′*S*,6*S*,6′*R*,7*S*,11*R*,13*S*,15*S*,17a*R*,20*R*,20a*R*,20b*S*)-5′,6,6′,7,10,11,14,15,17a,20,20a,20b-dodecahydro-20,20b-dihydroxy-6′-isopropyl-5′,6,8,19-tetramethyl-17-oxospiro[11,15-methano-2*H*,13*H*,17*H*-furo[4,3,2-*pq*][2,6]benzodioxacyclooctadecin-13,2′-[2*H*]pyran]-7-yl 2,6-dideoxy-4-*O*-(2,6-dideoxy-3-*O*-methyl-α-L-arabino-hexopyranosyl)-3-*O*-methyl-α-L-arabino-hexopyranoside CO[C@H]1C[C@@H](O[C@@H](C)[C@@H]1O)O[C@@H]2[C@@H](OC)C[C@@H](O[C@H]2C)O[C@@H]3C(C)=CC[C@@H]6C[C@H](OC(=O)[C@@H]4C=C(C)[C@@H](O)[C@H]5OCC(=CC=C[C@@H]3C)[C@@]45O)C[C@@]7(O6)C=C[C@H](C)[C@H](O7)C(C)C	
δ-8,9-isomer of avermectin B_{1a} or [8,9-*Z*]-isomer of avermectin B_{1a} (NOA 427011)	(2a*Z*,4*E*,8*E*)-(5′*S*,6*S*,6′*R*,7*S*,11*R*,13*S*,15*S*,17a*R*,20*R*,20a*R*,20b*S*)-6′-[(*S*)-*sec*-butyl]-5′,6,6′,7,10,11,14,15,17a,20,20a,20b-dodecahydro-20,20b-dihydroxy-5′,6,8,19-tetramethyl-17-oxospiro[11,15-methano-2*H*,13*H*,17*H*-furo[4,3,2-*pq*][2,6]benzodioxacyclooctadecin-13,2′-[2*H*]pyran]-7-yl 2,6-dideoxy-4-*O*-(2,6-dideoxy-3-*O*-methyl-α-L-arabino-hexopyranosyl)-3-*O*-methyl-α-L-*arabino*-hexopyranoside CO[C@H]1C[C@@H](O[C@@H](C)[C@@H]1O)O[C@@H]2[C@@H](OC)C[C@@H](O[C@H]2C)O[C@@H]3C(C)=CC[C@@H]6C[C@H](OC(=O)[C@@H]4C=C(C)[C@@H](O)[C@H]5OCC(=CC=C[C@@H]3C)[C@@]45O)C[C@@]7(O6)C=C[C@H](C)[C@H](O7)[C@@H](C)CC	

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).