Modification of the existing maximum residue levels for emamectin in various crops

EFSA (European Food Safety Authority), Giulia Bellisai, Giovanni Bernasconi, Alba Brancato, Luis Carrasco Cabrera, Lucien Ferreira, German Giner, Luna Greco, Samira Jarrah, Aija Kazocina, Renata Leuschner, Jose Oriol Magrans, Ileana Miron, Stefanie Nave, Ragnor Pedersen, Hermine Reich, Silvia Ruocco, Miguel Santos, Alessia Pia Scarlato, Anne Theobald, Benedicte Vagenende and Alessia Verani

Abstract
In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Syngenta France S.A.S. submitted a request to the competent national authority in France to modify the existing maximum residue levels (MRLs) for emamectin. The data submitted in support of the request were found to be sufficient to derive MRL proposals for apricots, cherries, spinaches and similar leaves and herbal infusions from leaves and herbs, whereas a change of the existing MRL is not necessary for pome fruits. Adequate analytical methods for enforcement are available to control the residues of emamectin B1a on the commodities under consideration. Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of residues resulting from the uses of emamectin benzoate according to the intended agricultural practices are unlikely to present a risk to consumer health. The consumer risk assessment shall be regarded as indicative since affected by uncertainty related to the data gaps identified in the MRL review.

© 2021 European Food Safety Authority. EFSA Journal published by John Wiley and Sons Ltd on behalf of European Food Safety Authority.

Keywords: Emamectin, various commodities, insecticide, MRL, consumer risk assessment

Requestor: European Commission
Question number: EFSA-Q-2020-00659
Correspondence: pesticides.mrl@efsa.europa.eu
Declarations of interest: The declarations of interest of all scientific experts active in EFSA's work are available at https://ess.efsa.europa.eu/doi/doiweb/doisearch.

Acknowledgements: EFSA wishes to thank Stathis Anagnos, Laszlo Bura, Andrea Mioc, Marta Szot, Aikaterini Vlachou for the support provided to this scientific output.

Suggested citation: EFSA (European Food Safety Authority), Bellisai G, Bernasconi G, Brancato A, Carrasco Cabrera L, Ferreira L, Giner G, Greco L, Jarrah S, Kazocina A, Leuschner R, Magrans JO, Miron I, Nave S, Pedersen R, Reich H, Ruocco S, Santos M, Scarlato AP, Theobald A, Vagenende B and Verani A, 2021. Reasoned Opinion on the modification of the existing maximum residue levels for emamectin in various crops. EFSA Journal 2021;16(8):6824, 40 pp. https://doi.org/10.2903/j.efsa.2021.6824

ISSN: 1831-4732

© 2021 European Food Safety Authority. EFSA Journal published by John Wiley and Sons Ltd on behalf of European Food Safety Authority.

This is an open access article under the terms of the Creative Commons Attribution-NoDerivs License, which permits use and distribution in any medium, provided the original work is properly cited and no modifications or adaptations are made.

The EFSA Journal is a publication of the European Food Safety Authority, a European agency funded by the European Union.
Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, Syngenta France S.A.S. submitted an application to the competent national authority in France (evaluating Member State, EMS) to modify the existing MRLs for the active substance emamectin in pome fruits, apricots, cherries, spinach and similar leaves and herbal infusions from flowers, leaves and herbs. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 7 October 2020. To accommodate for the intended uses of emamectin, the EMS proposed to raise the existing MRLs for apricots from 0.02 to 0.05 mg/kg, for cherries from the limit of quantification (LOQ) of 0.01 to 0.03 mg/kg, for spinach and similar leaves from the LOQ of 0.01 to 0.15 mg/kg and for herbal infusions from leaves and herbs from the LOQ of 0.02 to 1.5 mg/kg, whereas no change of the existing MRL of 0.02 mg/kg was proposed for pome fruits. The MRL proposals were derived by the EMS according to the residue definition for enforcement ‘emamectin B1a benzoate expressed as emamectin (free base)’.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified data requirements and points which needed further clarification, which were requested from the EMS. On 21 May 2021, the EMS submitted the requested information and a revised evaluation report, which replaced the previously submitted evaluation report. Subsequent to the data requirements set by EFSA, the intended use on herbal infusions from flowers was withdrawn by the applicant.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC (EU pesticides peer review), the data evaluated under previous MRL assessments, including review of the existing EU MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review), and the additional data provided by the EMS in the framework of this application, the following conclusions are derived.

The metabolism of emamectin in plants was investigated in primary and rotational crops. Studies investigating the effect of processing on the nature of emamectin (hydrolysis studies) showed the active substance degrades under standard hydrolysis condition (ca. 20%), but overall, this is not expected to modify the nature of residues in processed products. Based on the metabolic pattern identified in metabolism studies, the results of hydrolysis studies, the toxicological significance of photo-metabolites, the capabilities of enforcement analytical methods, the residue definition for enforcement was proposed by the MRL review as ‘emamectin B1a and its salts, expressed as emamectin B1a (free base)’. This residue definition has not been implemented yet. The residue definition for enforcement set in Regulation (EC) No 396/2005 is ‘emamectin benzoate B1ar, expressed as emamectin’. For the risk assessment purpose, the residue definition was proposed as ‘sum of emamectin B1a, emamectin B1b, 8,9-MAB1a, plus three times AB1a, plus three times AB1b, plus three times MFB1a and three times FAB1a, expressed as emamectin B1a (free base)’. These residue definitions apply to all plant commodities (raw and processed). EFSA concluded that for the crops assessed in this application, metabolism of emamectin in plants, and the possible degradation in processed products has been sufficiently addressed and that the previously derived residue definitions are applicable.

Sufficiently validated analytical methods are available to quantify residues in the crops assessed in this application according to the enforcement residue definition. The methods enable quantification of residues at or above 0.001 mg/kg (LOQ) in all four main matrix crop groups. Taking into account that successfully validated analytical enforcement methods are available for the main four plant matrices and considering the low relevance of herbal infusions in the consumer diet, the analytical method using LC-MS/MS is assumed to be capable to determine residues of emamectin B1a also in the herbal infusions at the LOQ of 0.001 mg/kg. For routine analysis and the crops under assessment, the MRL review reported that the LOQ of 0.002 mg/kg in high water content commodities and 0.005 mg/kg in dry commodities is achievable.

Available residue data were sufficient to derive MRL proposals for the commodities under evaluation; but for pome fruits, there was no need to modify the existing EU MRL. MRL proposals were derived according to the existing enforcement residue definition and the residue definition proposed during the MRL review (as emamectin B1ar free base). Specific studies investigating the magnitude of emamectin residues in processed commodities were not provided and are not required, as significant residues are not expected in raw agricultural commodities (RAC). Nevertheless, considering the high acute toxicity and the low acceptable daily intake (ADI) of emamectin further information to refine consumer intake assessments for processed commodities would be desirable.
The occurrence of emamectin residues in rotational crops was investigated in the framework of the EU pesticides peer review and the MRL review. Based on the available information, it was concluded that significant residue levels are unlikely to occur in rotational crops, provided that the active substance is used according to the proposed good agricultural practice (GAP).

Residues of emamectin in commodities of animal origin were not assessed since the intended use on apples (relevant for the feed commodity wet apple pomace) assessed in this MRL application is covered by the existing authorised use on apples and the conclusions reached in the framework of the MRL review are still valid.

The toxicological profile of emamectin was assessed in the framework of the EU pesticides peer review and the data were sufficient to derive an acceptable daily intake (ADI) of 0.0005 mg/kg body weight (bw) per day and an acute reference dose (ARfD) of 0.01 mg/kg bw. The metabolites included in the residue definition were considered to have comparable or higher toxicity than the parent active substance and therefore potency factors were derived.

The consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo). The short-term exposure did not exceed the ARfD for the crops assessed in this application. In the framework of the review of the existing MRLs for emamectin according to Article 12 of Regulation (EC) No 396/2005, a comprehensive long-term exposure assessment was performed taking into account the existing uses at the EU level and Codex MRLs. EFSA updated this risk assessment with median residue values for the crops under assessment in this application and in a previous MRL application that was conducted right before the MRL review finalisation. Under the assumption that for the existing uses of emamectin benzoate the MRLs will be amended as proposed in the MRL review, the estimated long-term dietary intake accounted for a maximum of 50% of the ADI.

EFSA concluded that the proposed uses of emamectin benzoate on pome fruits, apricots, cherries, spinaches and similar leaves and herbal infusion from leaves and herbs will not result in a consumer exposure exceeding the toxicological reference values and therefore are unlikely to pose a risk to consumers’ health. However, the consumer risk assessment shall be regarded as indicative and affected by uncertainty due to the data gaps identified in the MRL review.

EFSA proposes to amend the existing MRLs as reported in the summary table below. Full details of all end points and the consumer risk assessment can be found in Appendices B–D.

| Code\(^{(a)}\) | Commodity       | Existing EU MRL/ (proposed in MRL review)\(^{(b)}\) (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|----------------|-----------------|----------------------------------------------------------|-------------------------|-----------------------|
| **Existing enforcement residue definition (1):** Emamectin benzoate B\(_{1a}\), expressed as emamectin (F) (Regulation (EC) No 396/2005) | | | | |
| **Proposed enforcement residue definition (2):** Emamectin B\(_{1a}\) and its salts, expressed as emamectin B\(_{1a}\) (free base) (F) (MRL review) | | | | |
| 0130000    | Pome fruits    | 0.02 (0.02)\(^{(b)}\) (1) No change (2) No change | | The submitted data do not provide evidence that the existing MRL has to be modified. Risk for consumers unlikely. |
| 0140010    | Apricots       | 0.02 (0.006)\(^{(b)}\) (1) 0.05 (2) 0.05 | | The submitted data are sufficient to derive an MRL proposal for the intended SEU use. Risk for consumers unlikely. |
| 0140020    | Cherries (sweet) | 0.01* (–)\(^{(b)}\) (1) 0.04 (2) 0.04 | | The submitted data are sufficient to derive an MRL proposal for the intended NEU/SEU use. The MRL value derived on the basis of combined NEU and SEU data sets. Risk for consumer unlikely. |
| Code\(^{(a)}\) | Commodity | Existing EU MRL/ (proposed in MRL review)\(^{(b)}\) (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|---|---|---|---|---|
| 0252000 | Spinaches and similar leaves | 0.01\(^{*}\) \((-)^{(a)}\) | Further risk management considerations required | The submitted data are sufficient to derive an MRL proposal of 0.2 mg/kg for the intended SEU use by extrapolation from residues in open leaf lettuces. Based on the applicable (‘old’) data requirements for the assessment of this MRL application, the residue data submitted for the intended NEU use (4 trials) were not sufficient to support this intended use and 2 additional trials would be required. The EMS proposed to apply (‘new’) data requirements under Regulation (EU) No 283/2013 for the number of trials necessary to support the use on a crop group consisting only of minor crops (3 NEU and 3 SEU trials), since the NEU and SEU GAPs are the same. The MRL proposal of 0.15 mg/kg was thus derived from merged NEU and SEU data sets. Risk for consumer unlikely. |
| 0632000 | Herbal infusions from leaves and herbs | 0.02\(^{*}\) \((-)^{(a)}\) | Further risk management considerations required | See comments above. The MRL proposals are derived by extrapolation from trials on open leaf lettuces applying a generic dehydration factor of 10. Risk for consumer unlikely |

MRL: maximum residue level; NEU: northern Europe; SEU: southern Europe; GAP: Good Agricultural Practice. 
*\(^{*}\): Indicates that the MRL is set at the limit of analytical quantification (LOQ). 
\(^{(a)}\): Commodity code number according to Annex I of Regulation (EC) No 396/2005. 
\(^{(b)}\): MRL as proposed in the framework of the MRL review under art 12 of Regulation (EC) No 396/2005. 
\(^{(F)}\): Fat soluble.
# Table of contents

Abstract................................................................................................................................................... 1  
Summary................................................................................................................................................. 3  
Assessment.............................................................................................................................................. 7  
1. Residues in plants .......................................................................................................................... 8  
   1.1. Nature of residues and methods of analysis in plants ................................................................. 8  
      1.1.1. Nature of residues in primary crops ......................................................................................... 8  
      1.1.2. Nature of residues in rotational crops ...................................................................................... 8  
      1.1.3. Nature of residues in processed commodities ........................................................................... 9  
      1.1.4. Methods of analysis in plants ................................................................................................... 9  
      1.1.5. Storage stability of residues in plants ....................................................................................... 9  
      1.1.6. Proposed residue definitions .................................................................................................... 9  
   1.2. Magnitude of residues in plants ............................................................................................... 10  
      1.2.1. Magnitude of residues in primary crops .................................................................................... 10  
      1.2.2. Magnitude of residues in rotational crops ................................................................................. 12  
      1.2.3. Magnitude of residues in processed commodities ....................................................................... 12  
      1.2.4. Proposed MRLs ........................................................................................................................ 12  
2. Residues in livestock ....................................................................................................................... 13  
3. Consumer risk assessment .............................................................................................................. 13  
4. Conclusion and Recommendations ................................................................................................... 14  
References............................................................................................................................................... 14  
Abbreviations ........................................................................................................................................... 15  
Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs ............... 17  
Appendix B – List of end points ......................................................................................................... 20  
Appendix C – Pesticide Residue Intake Model (PRIMo) .................................................................. 28  
Appendix D – Input values for the exposure calculations .................................................................... 30  
Appendix E – Used compound codes.................................................................................................. 36
Assessment

The European Food Safety Authority (EFSA) received an application to modify the existing maximum residue levels (MRLs) for emamectin in fruit pome, apricots, cherries, spinaches and similar leaves and herbal infusions from leaves and herbs. The detailed description of the intended uses of emamectin in pome fruits, apricots, cherries, spinaches and similar leaves and herbal infusion from leaves and herbs, which are the basis for the current MRL application, is reported in Appendix A.

Emamectin is the ISO common name for a mixture of emamectin B$_{1a}$ (≥ 90%) and emamectin B$_{1b}$ (≤ 10%): (10E,14E,16E,22Z)-(1R,4S,5’S,6’S,6’R,8R,12S,13S,20R,21R,24S)-6-[(S)-sec-butyl]-21,24-dihydroxy-5’,11,13,22-tetramethyl-2-oxo-(3,7,19-trioxatetracyclo[15.6.1.14,8.0.20,24]pentacosa-10,14,16,22-tetraene)-6-spiro-2’-(5’,6’-dihydro-2’-H-pyran)-12-y12,6-dideoxy-3-O-methyl-4-O-(2,4,6-trideoxy-3-O-methyl-4-methylamino-α-L-lyxo-hexopyranosyl)-α-L-arabinino-hexopyranoside; and (10E,14E,16E,22Z)-(1R,4S,5’S,6’S,6’R,8R,12S,13S,20R,21R,24S)-21,24-dihydroxy-6’-isopropyl-5’,11,13,22-tetramethyl-2-oxo-(3,7,19-trioxatetracyclo[15.6.1.14,8.0.20,24]pentacosa-10,14,16,22-tetraene)-6-spiro-2’-(5’,6’-dihydro-2’-H-pyran)-12-y12,6-dideoxy-3-O-methyl-4-O-(2,4,6-trideoxy-3-O-methyl-4-methylamino-α-L-lyxo-hexopyranosyl)-α-L-arabinino-hexopyranoside (E,Z)-3-(2-chloro-thiazol-5-ylmethyl)-5-methyl-1,3,5] oxadiazinane-4-ylidene-N-nitroamine, respectively (IUPAC). The chemical structures of the active substance and its main metabolites are reported in Appendix E.

Emamectin was evaluated in the framework of Directive 91/414/EEC$^1$ and according to Commission Regulation (EU) No 188/2011$^2$, with the Netherlands designated as rapporteur Member State (RMS) for the representative use as field and glasshouse foliar spray applications on grapes, tomatoes, peppers, cucumbers, melons and lettuce. The draft assessment report (DAR) prepared by the RMS (Netherlands, 2008, 2012) has been peer reviewed by EFSA (EFSA, 2012). Emamectin was approved$^3$ for the use as insecticide on 1 May 2014.

The EU MRLs for emamectin are established in Annex III of Regulation (EC) No 396/2005$^4$. The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has been performed (EFSA, 2019c) but the proposed modifications have not yet been implemented in the EU MRL legislation. Right before completion of the MRL review, EFSA has issued one reasoned opinion on the modification of MRLs for emamectin. The proposals from this reasoned opinion have been considered yet in MRL regulations.$^5$ In addition, certain Codex maximum residue limits (CXLs) have been taken over in the EU MRL legislation.$^6$

In accordance with Article 6 of Regulation (EC) No 396/2005, Syngenta France S.A.S. submitted an application to the competent national authority in France (evaluating Member State, EMS) to modify the existing MRLs for the active substance emamectin in pome fruits, apricots, cherries, spinaches and similar leaves and herbal infusion from flowers, leaves and herbs. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 7 October 2020. To accommodate for the intended uses of emamectin, the EMS proposed to raise the existing MRLs for apricots from 0.02 to 0.05 mg/kg, for cherries from the limit of quantitation (LOQ) of 0.01 to 0.03 mg/kg, for spinnaches and similar leaves from the LOQ of 0.01 to 0.15 mg/kg and for herbal infusions from leaves and herbs from the LOQ of 0.02 to 1.5 mg/kg, whereas no change of the existing MRL of 0.02 mg/kg was proposed for pome fruits.

---

1. Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1-32.
2. Commission Regulation (EU) No 188/2011 of 25 February 2011 laying down detailed rules for the implementation of Council Directive 91/414/EEC as regards the procedure for the assessment of active substances which were not on the market 2 years after the date of notification of that Directive. OJ No L 53, 26.2.2011, p. 51-55.
3. Commission Implementing Regulation (EU) No 828/2013 of 29 August 2013 approving the active substance emamectin, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. OJ L 232, 30.8.2013, p. 23-28.
4. Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1–16.
5. For an overview of all MRL Regulations on this active substance, please consult: https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/active-substances/?event=search.as
6. Commission Regulation EU) No 293/2013 of 20 March 2013 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for emamectin benzoate, etofenprox, etoxazole, flutriafol, glyphosate, phosmet, pyraclostrobin, spinosad and spirotetramat in or on certain products. OJ L 96, 5.4.2013, p. 1–30.
EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified data requirements and points which needed further clarification, which were requested from the EMS. On 21 May 2021, the EMS submitted the requested information and a revised evaluation report (France, 2020), which replaced the previously submitted evaluation report. Subsequent to the data requirements set by EFSA, the applicant withdrew the intended use on flowers for herbal infusions as not sufficiently supported by data; a change of the existing MRL in pome fruits was no longer required.

EFSA based its assessment on the evaluation report submitted by the EMS (France, 2020), the draft assessment report (DAR) and its addendum (Netherlands, 2008, 2012) prepared under Directive 91/414/EEC, the Commission review report on emamectin (European Commission, 2013), the conclusion on the peer review of the pesticide risk assessment of the active substance emamectin (EFSA, 2012), as well as the reasoned opinion on the MRL review according to Article 12 of Regulation No 396/2005 (EFSA, 2019c) and another opinion on emamectin (EFSA, 2019b).

For this application, the data requirements established in Regulation (EU) No 544/2011 and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 1997a–g, 2000, 2010a,b, 2017; 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 546/20117.

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

The evaluation report submitted by the EMS (France, 2020) and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available as background documents to this reasoned opinion.

1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

The metabolism of emamectin in primary crops belonging to the group of fruit crops, leafy crops and cereals/grass has been investigated in the framework of the EU pesticides peer review and the MRL review (EFSA, 2012, 2019c). All studies were conducted using emamectin B1a benzoate.

In the crops tested, emamectin B1a was extensively metabolised, forming a number of photodegradation products which were mainly observed in leafy crops (lettuces and cabbages). Emamectin B1a was the predominant compound (3–34% of total radioactive residues, TRR) within 3 days after last application. The different photodegradation products (also referred to as photometabolites, consisting of 8,9-Z-MAB1a,F A B1a, MFB1a,A B1a) individually were present at low levels (less than 5% TRR), but together represented a significant amount (up to 20%) of the TRR.

In the framework of the peer review and MRL review, it was highlighted that the available studies did not investigate the possible impact of plant metabolism on the isomer ratio of emamectin (EFSA, 2012, 2019c). It is noted that the approval regulation3 requested confirmatory information as regards the risk of enantioselective metabolisation or degradation. Specifically, the applicant shall submit to the Commission, Member States and the Authority the relevant information 2 years after adoption of the pertinent guidance document on evaluation of isomer mixtures. Since the EFSA guidance on the risk assessment of compounds that may have stereoisomers has been issued (EFSA, 2019d) and endorsed by European Commission and Member States in December 2020, EFSA would therefore recommend reconsidering this point in the framework of the peer review of the active substance.

For the intended uses, the metabolite behaviour in primary crops is sufficiently addressed.

1.1.2. Nature of residues in rotational crops

Field DT50 of emamectin B1a benzoate was reported to be 414 days and confined rotational crop studies with emamectin B1a benzoate were submitted and assessed (EFSA, 2012, 2019c). Total

---

7 Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.
radioactive residues were below 0.01 mg eq/kg in all plant matrices, except in barley straw (0.03 mg eq/kg at 141 DAT). Experimental findings confirmed no potential for emamectin residues to be present in rotational crops.

For the proposed uses assessed in this application, no further information is required.

1.1.3. Nature of residues in processed commodities

The effect of processing on the nature of emamectin B1a was investigated in the framework of the EU pesticides peer review and the MRL review (EFSA, 2012, 2019c). These studies showed a degradation (ca. 15–20% of total applied radioactivity, AR) of emamectin B1a under standard hydrolysis condition to aglycone milbemectin B, MSB1ar, AB1a and several unknown compounds, which could not be identified. All breakdown products were individually below 10% of AR.

For the photo-metabolites included in the residue definition for risk assessment, the conclusion of the MRL review was that additional standard hydrolysis studies conducted with 8,9-Z-MAB1ar, FAB1ar, MFB1ar, AB1ar were not needed, considering low residue levels of emamectin in raw commodities and a similar chemical structure of these degradation products to the structure of the parent (EFSA, 2019c).

1.1.4. Methods of analysis in plants

Analytical methods for the determination of emamectin residues were assessed during the EU pesticides peer review and the MRL review (EFSA, 2012, 2019c). The residue methods allow distinguishing between emamectin B1a and emamectin B1b and are sufficiently validated for the determination of residues of emamectin B1a in the crops under evaluation which belong to the group of matrices with high water content (pome fruits, apricots, cherries, spinaches and similar leaves). These methods enable quantification of residues of emamectin B1a at or above the LOQ of 0.001 mg/kg.

Validation data specific for herbal infusions were not provided. Herbal infusions are usually considered ‘difficult’ matrix for which separate validation data would be required to demonstrate the applicability of the analytical method (European Commission, 2010b). Taking into account that successfully validated analytical enforcement methods are available for the main four plant matrices and considering the low relevance of herbal infusions in the consumer diet, the analytical method using LC-MS/MS is assumed to be capable to determine residues of emamectin B1a also in the herbal infusions at the LOQ of 0.001 mg/kg. However, confirmation would be desirable.

Additionally, according to the EURs, the LOQ of 0.002 mg/kg in high water content commodities and 0.005 mg/kg in dry commodities is achievable in routine analyses; the QuEChERS and QuOil multi-residue methods using LC-MS/MS are validated with an LOQ of 0.01 mg/kg in high water and dry commodities (EFSA, 2019c).

1.1.5. Storage stability of residues in plants

The storage stability of emamectin B1ar, emamectin B1b, and the four photo-metabolites 8,9-Z-MAB1ar, FAB1ar, MFB1ar, AB1a (each compound individually) in plants stored under frozen conditions was investigated in the framework of the EU pesticides peer review and the MRL review (EFSA, 2012, 2019c).

Storage stability of all investigated compounds was demonstrated for a period of 18 months when stored at −20°C in the high-water content group, representative for the crops on which residue field trials were submitted (see Section 1.2.1).

1.1.6. Proposed residue definitions

Based on the metabolic pattern identified in metabolism studies, the results of hydrolysis studies, the toxicological significance of the relevant compounds and the capabilities of enforcement analytical methods, the following residue definitions were proposed during the MRL review (EFSA, 2019c):

- Residue definition for enforcement: Emamectin B1a and its salts, expressed as emamectin B1a (free base).

The residue definition for enforcement set in Regulation (EC) No 396/2005 is ‘Emamectin benzoate B1a, expressed as emamectin’. Thus, residues are expressed as emamectin (sum of isomers) rather than the B1a component.
Since the photo-metabolites (8,9-Z-MAB1a, FAB1a, MFB1a, AB1a) share a common toxicological mode of action with parent compound but with different potencies, their potency has to be considered for the consumer exposure and the risk assessment residue definition was proposed by the MRL review as follows:

- Residue definition for risk assessment: Sum of emamectin B1a, emamectin B1b, 8,9-Z-MAB1a, plus three times AB1a, plus three times MFB1a and three times FAB1a, expressed as emamectin B1a (free base).

Overall, processing conditions are not expected to modify the nature of emamectin residues, and the residue definitions as derived for primary crops also apply to processed commodities (EFSA, 2019c).

EFSA concluded that these residue definitions are applicable to the crops under assessment.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

In support of the MRL application, the applicant submitted residue trials performed on apples, pears, apricots, peaches, cherries and lettuces. In case different formulation products were tested, EFSA agreed with the EMS and selected results from the trials where the formulation indicated in the intended GAP was applied. The applied product was also mixed with an adjuvant in side-by-side trials. Since the intended uses do not foresee the inclusion of an adjuvant, the results from trials carried out using an adjuvant were disregarded.

All samples were analysed for emamectin B1a benzoate, emamectin B1b benzoate and the photodegradation products included in the residue definition for risk assessment. Conversion factors based on molecular weight were used to express the residue levels above the LOQ as emamectin B1a benzoate and emamectin B1b benzoate to emamectin B1a. With the exception of FAB1a, the photometabolites were present at quantifiable levels in some samples of lettuces (leafy crop), thus confirming the observations from the metabolism studies (see Section 1.1.1). Since molecular weight conversion factors to express residues of photodegradation products as emamectin B1a are around 1 and their magnitude in crops was low (max 0.004 mg/kg for MFB1a), residue levels above the LOQ of the metabolites 8,9-ZB1a, AB1a and MFB1a were not adjusted to emamectin B1a equivalents. According to the assessment of the EMS, the samples of the residue trials were stored under conditions for which sample integrity has been demonstrated and samples have been analysed with methods sufficiently validated and fit for purpose (France, 2020).

Pome fruits

NEU: The results of 10 residue trials (8 on apples and 2 on pears) compliant with the GAP (± 25% tolerance) were provided. Trials were conducted over 3 years in different NEU locations in France and Switzerland.

The proposed extrapolation from apples and pears to the whole group of pome fruits is acceptable since the number of independent trials submitted is sufficient and a minimum of four trials on apples have been provided (European Commission, 2017). The data package is sufficient to derive an MRL proposal of 0.01 mg/kg by extrapolation for the whole group of pome fruits in the NEU.

SEU: The results of 12 residue trials (10 on apples and 2 on pears) compliant with the GAP (± 25% tolerance) were provided. The data package, which includes a minimum of four trials on apples, is sufficient to derive an MRL proposal of 0.02 mg/kg by extrapolation for the whole group of pome fruits in the SEU.

It is noted that the EMS derived the same MRL proposal of 0.02 mg/kg proportionally scaling up the residue data from trials conducted at lower application rate (ca. 30 g/ha) than the intended nominal application rate of 37.5 g/ha of the GAP (France, 2020). Since the individual application rate was always within the 25% of the acceptable tolerance and considering that upsampling by the several individual components of the residue definitions having residues below the LOQ (EFSA, 2018c), EFSA does not consider suitable to use the proportionality approach.

Even though the intended NEU and SEU GAPs are identical, the NEU and SEU residue data sets were not combined since, when tested statistically, showed to belong to different populations (U-Test, 5%). The MRL proposal of 0.02 mg/kg is based on the more critical situation for residues observed in
the SEU. It is, however, noted that the existing EU MRL for pome fruit is currently set at an identical level of 0.02 mg/kg, and thus, there is no change needed.

**Apricots**

SEU: The results of eight trials, four on apricots and four on peaches, compliant with the GAP (± 25% tolerance) on apricots were provided.

The proposed extrapolation from peaches and apricots to apricots is acceptable since the number of independent trials submitted is sufficient for a major crop and 50% of the trials have been performed on apricots (European Commission, 2017). The data package is sufficient to derive an MRL proposal of 0.05 mg/kg for apricots in the SEU.

**Cherries**

NEU: The results of eight residue trials on cherries are available. All trials were overdosed compared to the nominal application rate, and in five trials, the first application rate exceeded the 25% tolerance. However, in only two of the trials, the third and the last application were still deviating by 30% and 34%, respectively, from the intended nominal application rate.

SEU: The results of four residue trials on cherries are available. All trials were overdosed compared to the nominal application rate of the intended GAP, and in two trials, the second application exceeded the 25% tolerance, but in none of the trials, the third and last application were outside the tolerance range.

Since the application rates deviated for more than 25% in a number of trials, the EMS applied the proportionality approach to scale down the levels of emamectin B1a which in few trials were quantified above the LOQ. Taking into account that the scaling principle has a limited use in case of multiple applications (EFSA, 2018c) and that in the trial conducted with the widest range of deviation (up to 34%) all individual components of the residue definitions were below the LOQ, EFSA did not consider appropriate to use the proportionality.

Since the intended NEU and SEU GAPs are identical, the two data sets were merged to derive a more robust MRL proposal of 0.04 mg/kg for the intended field use on cherries.

**Spinaches and similar leaves**

NEU: Four residue trials on open-leaf lettuces compliant with the intended use on spinaches and similar leaves are available.

SEU: Eight residue trials on open-leaf lettuces compliant with the intended use on spinaches and similar leaves are available.

The proposed extrapolation from open-leaf lettuces to spinaches and similar leaves is possible and the intended SEU use is fully supported by data. The SEU use would need an MRL of 0.2 mg/kg.

However, for the intended NEU use, the number of trials available (four) is sufficient to derive an MRL proposal for spinaches but not to derive an MRL proposal for the whole group. According to the data requirements applicable for the assessment of this MRL application (i.e. ‘old’ data requirements under Regulation (EU) No 544/2011), two additional trials on open leaf lettuces would be required to get the minimum number of six trials required to extrapolate results to a group of all minor crops such as spinaches and similar leaves (European Commission, 2017).

In order to derive an MRL for the whole group of spinaches on the basis of available data, the EMS proposed to apply the requirements applicable under Regulation (EU) No 283/20138 introduced with the guidance document SANTE/2019/12752 (European, Commission, 2020) (‘new’ data requirements) for the number of residue trials necessary to support the intended use on the group of only minor crops if the GAP is the same in both geographical zones (minimum three NEU and three SEU trials). The EMS derived an MRL proposal of 0.15 mg/kg from the merged data sets (tested statistically as similar, Mann–Whitney U-test, 5%).

EFSA agreed to put forward for risk management decision the possible anticipation of the applicability of the regulatory framework of the new data requirement.

---

8 Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market. OJ L 93, 3.4.2013, p. 1–84.
Herbal infusions from leaves and herbs

The applicant submitted four residue trials on open-leaf lettuces in support of the intended NEU use and eight residues trials on open-leaf lettuces in support of the intended SEU use of emamectin on leaves and herbs of crops used for herbal infusions. Residue trials were compliant with the intended GAPs. Extrapolation from open leaf lettuces is possible and the SEU use is fully supported. Regarding the minimum number of trials required to support the NEU use by extrapolation, the situation is comparable to that for spinaches and similar leaves. The EMS proposed to derive the MRL from the combined data set of NEU and SEU residue trials, taking into account a default dehydration factor of 10.

1.2.2. Magnitude of residues in rotational crops

Certain crops under consideration in the framework of this application (i.e. spinaches and similar leaves and crops intended for herbal infusions) can be grown in rotation; therefore, the possible transfer of emamectin residues to crops that are grown in crop rotation shall be assessed.

There are no studies available investigating the magnitude of residues in rotational crops. However, based on the results of confined rotational crop studies (see Section 1.1.2), the MRL review concluded that significant residue levels of emamectin are not expected in succeeding crops when the active substance is applied in compliance with the authorised critical GAPs (EFSA, 2019c).

Since the maximum application rate for the crops that can be grown in rotation which are under assessment (3 × 15 g/ha) is lower than the application rate of the critical indoor GAP on lettuces assessed in the MRL review (3 × 19 g/ha), EFSA confirmed the previous conclusion that no residues are expected in rotational crops, provided that the active substance is applied according to the intended GAPs.

1.2.3. Magnitude of residues in processed commodities

Due to low residue levels (< 0.1 mg/kg) observed in the residue trials on the crops under assessment, no processing studies were provided (European Commission, 1997d). Nevertheless, considering the high acute toxicity and the low acceptable daily intake (ADI) of emamectin, further information to refine consumer intake assessments by consideration of processed commodities would be desirable.

1.2.4. Proposed MRLs

The available data are considered sufficient to derive MRL proposals as well as risk assessment values for the commodities under evaluation (see Appendix B).

To derive MRL proposals based on the residue definition for enforcement as proposed during the MRL review but not implemented yet in the MRL legislation, the individual residue levels above the LOQ of 0.001 mg/kg determined as emamectin B1a benzoate were recalculated to emamectin B1a (free base) using a molecular weight (MW) conversion factor (CF) of 0.889 derived from the active substance and its benzoate salt (EFSA, 2019c).

To comply with the existing residue definition for enforcement reported in Regulation (EC) No 396/2005, the individual residue levels above the LOQ of 0.001 mg/kg calculated as emamectin B1a were recalculated to emamectin by a default CF of 1.1 which takes into account that the active substance is a mixture of ≥ 90% emamectin B1a and ≥ 10% emamectin B1b (EFSA, 2012).

 Conversion factors (CF) from enforcement to risk assessment were calculated applying the criteria adopted in the MRL review (EFSA, 2019c). When residues of the compounds included in the residue definition for risk assessment (emamectin B1a, 8,9-Z-MAB1a, FAB1a, MFB1a, AB1a) were individually all below or at the LOQ, the CF was indicated as 1, whereas when residues were above the LOQ in at least one component, the experimental value was calculated from the results of the residue trials submitted.

Prior to be summed up for the risk assessment purpose, the four individual residue values above the LOQ of 0.001 mg/kg determined as emamectin B1b benzoate in lettuce trials were recalculated to emamectin B1a (free base) using an MW CF of 1.12. Since only occasionally quantified and considering that the MW CF is close to 1, residue levels above the LOQ of 0.001 mg/kg determined as 8,9-Z-MAB1a, MFB1a and AB1a were summed as such without recalculation to emamectin B1a. Residues of 9 MW 886.1 emamectin B1a/MW 1008.3 emamectin B1a benzoate.

9 MW 886.1 emamectin B1a/MW 1008.3 emamectin B1a benzoate.
FAB\textsubscript{1a} above the LOQ were never observed in the samples from the residue trials submitted. The experimental CFs took into account the individual relative potency factors (RPF) of the photo-metabolites.

It shall be noted that the EMS derived all set of MRL proposals according to the residue definition for enforcement of ‘emamectin B1a benzoate expressed as emamectin (free basis)’ and used the proportionality approach to scale residues in pome fruits and cherries. For risk assessment, the EMS recalculated the values of each photo-metabolite to emamectin free base using MW CFs prior to apply the RPFs. This shall explain the slightly different residues figures and MRL proposals reported in the evaluation report (France, 2020).

In Section 3, EFSA assessed whether residues on these crops resulting from the intended uses are likely to pose a consumer health risk.

2. Residues in livestock

Residues of emamectin in commodities of animal origin were not assessed in the framework of this MRL application. Although the by-product of one of the crops under assessment – apple wet pomace – is used as feed item, it was not necessary to update the previous dietary burden calculation for livestock as the intended use on apples assessed in this MRL application is covered by the existing authorised use\textsuperscript{10} on apples and the conclusions reached in the framework of the MRL review are still valid (EFSA, 2019c).

3. Consumer risk assessment

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

The toxicological reference values used in the risk assessment (i.e. ADI and ARfD values) were derived in the framework of the EU pesticides peer review (European Commission, 2013). The photo-metabolites included in the residue definition for risk assessment MFB\textsubscript{1a}, FAB\textsubscript{1a}, AB\textsubscript{1a} and 8,9-Z MAB\textsubscript{1a} were considered to be of the same or higher potency in comparison to the parent (EFSA, 2018b). EFSA established a relative potency factor (RPF) of approximately 3 for the metabolites MFB\textsubscript{1a}, FAB\textsubscript{1a} and AB\textsubscript{1a} and a RPF of 1 for the metabolite 8,9-Z MAB\textsubscript{1a} in comparison to the parent. The RPFs are used for both the acute and chronic risk assessment.

Short-term (acute) risk assessment

The short-term exposure assessment was performed for the commodities assessed in this MRL application in accordance with the internationally agreed methodology (FAO, 2016). The calculations were based on the highest residue derived from supervised field trials. For pome fruits, the highest residue selected was the one corresponding to the Codex MRL (CXL) assessed in the MRL review (EFSA, 2019c). The complete list of input values can be found in Appendix D.1.

The short-term exposure did not exceed the ARfD for any of the crops assessed in this application (see Appendix B.3).

Long-term (chronic) risk assessment

In the framework of the review of the existing MRLs for emamectin according to Article 12 of Regulation (EC) No 396/2005, a comprehensive long-term exposure assessment was performed taking into account the existing uses at EU level and the acceptable CXLs (EFSA, 2019c). Conversion factors for risk assessment were used to estimate the contribution of emamectin B\textsubscript{1h} and the photo-metabolites included in the EU residue definition for risk assessment of plants and animal products. For several commodities, the residue data were insufficient and only tentative MRLs and tentative input values for risk assessment were derived (EFSA, 2019c). EFSA updated the calculation with the STMR values derived from the residue trials conducted on pome fruits, apricots, cherries, spinach and similar leaves, herbal infusions from leaves and herbs. In addition, the STMR derived for peaches and

\textsuperscript{10} The input value reported to be used for apple wet pomace in the animal burden calculations conducted in the framework of the MRL review (EFSA, 2019) is higher (0.013 mg/kg) than the input value derived according to the proposed use under assessment (0.005, derived multiplying the STMR of 0.001 mg/kg per the default processing factor of 5 and using the conversion factor for risk assessment of 1).
kiwi fruits in another EFSA opinion were considered (EFSA, 2019b). The crops for which no uses were reported in the framework of the MRL review, were excluded from the exposure calculation, assuming that there is no use of emamectin on these crops. The input values used in the exposure calculations are summarised in Appendix D.1.

Under the assumption that the MRLs will be amended as proposed in the MRL review, the total calculated intake accounted for 50% of the ADI (NL toddler diet). The contribution of residues on the crops under consideration to the total consumer exposure was accounting, with respect to the ADI, for a maximum of 13% for apples, 7% for spinaches and less for the remaining crops under assessment.

Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of residues resulting from the existing and the intended uses of emamectin benzoate is unlikely to present a risk to consumer health. The consumer risk assessment shall be regarded as indicative and affected by uncertainty due to the data gaps identified in the MRL review.

For further details on the exposure calculations, a screenshot of the Report sheet of the PRIMo is presented in Appendix C.

4. Conclusion and Recommendations

The data submitted in support of this MRL application were found to be sufficient to derive an MRL proposal for apricots, cherries, spinaches and similar leaves and herbal infusions from leaves and herbs, whereas a change of the existing MRL is not necessary for pome fruits.

EFSA concluded that the proposed uses of emamectin on apricots, cherries, spinaches and similar leaves and herbal infusions from leaves and herbs will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers’ health. The consumer risk assessment shall be regarded as indicative since affected by uncertainty related to the data gaps identified in the MRL review.

The MRL recommendations are summarised in Appendix C.

References

EFSA (European Food Safety Authority), 2012. Conclusion on the peer review of the pesticide risk assessment of the active substance emamectin. EFSA Journal 2012;10(11):2955, 89 pp. https://doi.org/10.2903/j.efsa.2012.2955

EFSA (European Food Safety Authority), Brancato A, Brocca D, Ferreira L, Greco L, Jarrah S, Leuschner R, Medina P, Miron I, Nougadere A, Pedersen R, Reich H, Santos M, Stanek A, Tarazona J, Theobald A and Villamar-Bouza L, 2018a. Guidance on use of EFSA Pesticide Residue Intake Model (EFSA PRIMo revision 3). EFSA Journal 2018;16(1):5147, 43 pp. https://doi.org/10.2903/j.efsa.2018.5147

EFSA (European Food Safety Authority), Brancato A, Brocca D, Cabrera LC, De Lentdecker C, Erdos Z, Ferreira L, Greco L, Jarrah S, Kardassi D, Leuschner R, Lythgo C, Medina P, Miron I, Molnar T, Pedersen R, Reich H, Riemschneider C, Sacchi A, Santos M, Stanek A, Sturma J, Tarazona J, Theobald A, Vagenende B and Villamar-Bouza L, 2018b. Reasoned opinion on the modification of the existing maximum residue levels for emamectin in leafy brassica and beans and peas with pods. EFSA Journal 2018;16(4):5255, 27 pp. https://doi.org/10.2903/j.efsa.2018.5255

EFSA (European Food Safety Authority), 2018c. Recommendations on the use of the proportionality approach in the framework of risk assessment for pesticide residues. EFSA supporting publication 2017;EN-1503, 18 pp. https://doi.org/10.2903/sp.efsa.2017.EN-150. EFSA Online Library. https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2018.EN-1503

EFSA (European Food Safety Authority), Anastassiadou M, Brancato A, Carrasco Cabrera L, Ferreira L, Greco L, Jarrah S, Kazocina A, Leuschner R, Magrans JO, Miron I, Pedersen R, Raczyk M, Reich H, Ruocco S, Sacchi A, Santos M, Stanek A, Tarazona J, Theobald A and Verani A, 2019a. Pesticide Residue Intake Model - EFSA PRIMo revision 3.1 (update of EFSA PRIMo revision 3). EFSA supporting publication 2019;EN-1605, 15 pp. https://doi.org/10.2903/sp.efsa.2019.en-1605

EFSA (European Food Safety Authority), 2019b. Reasoned Opinion on the modification of the existing maximum residue levels for emamectin in kiwi and peaches. EFSA Journal 2019;17(5):5710, 26 pp. https://doi.org/10.2903/j.efsa.2019.5710

EFSA (European Food Safety Authority), 2019c. Reasoned Opinion on the review of the existing maximum residue levels for emamectin according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2019;17(8):5803, 81 pp. https://doi.org/10.2903/j.efsa.2019.5803

EFSA (European Food Safety Authority), Bura L, Friel A, Magrans JO, Parra-Morte JM and Szentes C, 2019d. Guidance of EFSA on risk assessments for active substances of plant protection products that have stereoisomers as components or impurities and for transformation products of active substances that may have stereoisomers. EFSA Journal 2019;17(8):5804, 33 pp. https://doi.org/10.2903/j.efsa.2019.5804

European Commission, 1996. Appendix G. Livestock feeding studies. 7031/VI/95-rev 4, 22 July 1996.
DS powder for dry seed treatment
EDI estimated daily intake
EMS evaluating Member State
eq residue expressed as a.s. equivalent
FAO Food and Agriculture Organization of the United Nations
FID flame ionisation detector
GAP Good Agricultural Practice
GC gas chromatography
GC-FID gas chromatography with flame ionisation detector
GC-MS gas chromatography with mass spectrometry
GC-MS/MS gas chromatography with tandem mass spectrometry
GS growth stage
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
LC liquid chromatography
LOQ limit of quantification
MRL maximum residue level
MS Member States
MS mass spectrometry detector
MS/MS tandem mass spectrometry detector
MW molecular weight
NEU northern Europe
OECD Organisation for Economic Co-operation and Development
PBI plant back interval
PF processing factor
PHI preharvest interval
PRIMo (EFSA) Pesticide Residues Intake Model
QuEChERS Quick, Easy, Cheap, Effective, Rugged and Safe (analytical method)
RA risk assessment
RAC raw agricultural commodity
RD residue definition
RMS rapporteur Member State
RPF relative potency factor
SANCO Directorate-General for Health and Consumers
SC suspension concentrate
SEU southern Europe
SG water-soluble granule
SL soluble concentrate
SP water-soluble powder
STMR supervised trials median residue
TAR total applied radioactivity
TRR total radioactive residue
UV ultraviolet (detector)
WHO World Health Organization
Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs

| Crop and/or situation | NEU, SEU, MS or country | F G or 1<sup>a</sup> | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)<sup>d</sup> | Remarks |
|----------------------|-------------------------|---------------------|------------------------------------|-------------|-----------------------------|-------------------------|---------|
| **Apples** | NEU | F | Insect pests | SG | 9.5 | Foliar application | BBCH 71–89 | 3 | 7 days | 1,000–1,500 | 37.5 g a.i./ha | 3 |
| **Apples** | SEU | F | Insect pests | SG | 9.5 | Foliar application | BBCH 71–89 | 3 | 7 days | 1,000–1,500 | 37.5 g a.i./ha | 3 |
| **Pears** | NEU | F | Insect pests | SG | 9.5 | Foliar application | BBCH 71–89 | 3 | 7 days | 1,000–1,500 | 37.5 g a.i./ha | 3 |
| **Pears** | SEU | F | Insect pests | SG | 9.5 | Foliar application | BBCH 71–89 | 3 | 7 days | 1,000–1,500 | 37.5 g a.i./ha | 3 |
| **Quinces** | NEU | F | Insect pests | SG | 9.5 | Foliar application | BBCH 71–89 | 3 | 7 days | 1,000–1,500 | 37.5 g a.i./ha | 3 |
| **Quinces** | SEU | F | Insect pests | SG | 9.5 | Foliar application | BBCH 71–89 | 3 | 7 days | 1,000–1,500 | 37.5 g a.i./ha | 3 |
| **Medlar** | NEU | F | Insect pests | SG | 9.5 | Foliar application | BBCH 71–89 | 3 | 7 days | 1,000–1,500 | 37.5 g a.i./ha | 3 |
| **Medlar** | SEU | F | Insect pests | SG | 9.5 | Foliar application | BBCH 71–89 | 3 | 7 days | 1,000–1,500 | 37.5 g a.i./ha | 3 |
| **Loquats/ Japanese medlars** | NEU | F | Insect pests | SG | 9.5 | Foliar application | BBCH 71–89 | 3 | 7 days | 1,000–1,500 | 37.5 g a.i./ha | 3 |
| **Loquats/ Japanese medlars** | SEU | F | Insect pests | SG | 9.5 | Foliar application | BBCH 71–89 | 3 | 7 days | 1,000–1,500 | 37.5 g a.i./ha | 3 |
| **Other pome fruits** | NEU | F | Insect pests | SG | 9.5 | Foliar application | BBCH 71–89 | 3 | 7 days | 1,000–1,500 | 37.5 g a.i./ha | 3 |
| **Other pome fruits** | SEU | F | Insect pests | SG | 9.5 | Foliar application | BBCH 71–89 | 3 | 7 days | 1,000–1,500 | 37.5 g a.i./ha | 3 |
| **Apricots** | NEU | F | Insect pests | SG | 9.5 | Foliar application | BBCH 71–89 | 3 | 7 days | 500–1,500 | 23.75 g a.i./ha | 7 |
## Crop and/or situation
### Type (b)
- NEU
- SEU
- MS
- F
- G
- or I

### Conc. a.s. (g/kg)
- 9.5

### Method kind
- Foliar application

### Preparation
- SG

### Application
### Range of growth stages and season (c)
- BBCH 71–89

### Interval between application (d)
- 3

### Application rate per treatment
### Water (L/ha) min–max
- 500–1,500

### PHI (days)(e)
- 3

### Remarks

#### Apricots
- Insect pests
- SEU
- F
- SG 9.5
- Foliar application
- BBCH 71–89
- 3
- 7 days
- 500–1,500
- 23.75
- g a.i./ha
- 7

#### Cherries (sweet)
- Insect pests
- NEU
- F
- SG 9.5
- Foliar application
- BBCH 71–89
- 3
- 7 days
- 500–1,500
- 19
- g a.i./ha
- 7

#### Cherries (sweet)
- Insect pests
- SEU
- F
- SG 9.5
- Foliar application
- BBCH 71–89
- 3
- 7 days
- 500–1,500
- 19
- g a.i./ha
- 7

#### Spinaches
- Insect pests
- NEU
- F
- SG 9.5
- Foliar application
- BBCH 11–49
- 3
- 7 days
- 200–1,000
- 15
- g a.i./ha
- 3

#### Spinaches
- Insect pests
- SEU
- F
- SG 9.5
- Foliar application
- BBCH 11–49
- 3
- 7 days
- 200–1,000
- 15
- g a.i./ha
- 3

#### Purslanes
- Insect pests
- NEU
- F
- SG 9.5
- Foliar application
- BBCH 11–49
- 3
- 7 days
- 200–1,000
- 15
- g a.i./ha
- 3

#### Purslanes
- Insect pests
- SEU
- F
- SG 9.5
- Foliar application
- BBCH 11–49
- 3
- 7 days
- 200–1,000
- 15
- g a.i./ha
- 3

#### Chards/beet leaves
- Insect pests
- NEU
- F
- SG 9.5
- Foliar application
- BBCH 11–49
- 3
- 7 days
- 200–1,000
- 15
- g a.i./ha
- 3

#### Chards/beet leaves
- Insect pests
- SEU
- F
- SG 9.5
- Foliar application
- BBCH 11–49
- 3
- 7 days
- 200–1,000
- 15
- g a.i./ha
- 3

#### Other spinach leaves and similar leaves
- Insect pests
- NEU
- F
- SG 9.5
- Foliar application
- BBCH 11–49
- 3
- 7 days
- 200–1,000
- 15
- g a.i./ha
- 3

#### Other spinach leaves and similar leaves
- Insect pests
- SEU
- F
- SG 9.5
- Foliar application
- BBCH 11–49
- 3
- 7 days
- 200–1,000
- 15
- g a.i./ha
- 3

#### Strawberry leaves
- Insect pests
- NEU
- F
- SG 9.5
- Foliar application
- BBCH 11–49
- 3
- 7 days
- 200–1,000
- 15
- g a.i./ha
- 3

#### Strawberry leaves
- Insect pests
- SEU
- F
- SG 9.5
- Foliar application
- BBCH 11–49
- 3
- 7 days
- 200–1,000
- 15
- g a.i./ha
- 3
| Crop and/or situation | NEU, SEU, MS or country | F G or I<sup>(a)</sup> | Pests or group of pests controlled | Preparation | Type<sup>(b)</sup> | Conc. a.s. (g/kg) | Method kind | Range of growth stages and season<sup>(c)</sup> | Number | Interval between application | g a.s./hl min-max | PHI (days)<sup>(d)</sup> | Water (L/ha) min-max | Rate Unit | Remarks |
|-----------------------|-------------------------|------------------------|-----------------------------------|-------------|----------------|-----------------|-------------|--------------------------------|--------|-----------------------------|-----------------|----------------|-------------------|-----------|---------|
| Rooibos               | NEU                     | F                      | Insect pests                      | SG          | 9.5            | Foliar application | BBCH 11–49 | 3                               | 7 days | 200–1,000                   | 15 g a.i./ha    | 3               |                   |           |         |
| Rooibos               | SEU                     | F                      | Insect pests                      | SG          | 9.5            | Foliar application | BBCH 11–49 | 3                               | 7 days | 200–1,000                   | 15 g a.i./ha    | 3               |                   |           |         |
| Mate/maté             | NEU                     | F                      | Insect pests                      | SG          | 9.5            | Foliar application | BBCH 11–49 | 3                               | 7 days | 200–1,000                   | 15 g a.i./ha    | 3               |                   |           |         |
| Mate/maté             | SEU                     | F                      | Insect pests                      | SG          | 9.5            | Foliar application | BBCH 11–49 | 3                               | 7 days | 200–1,000                   | 15 g a.i./ha    | 3               |                   |           |         |
| Other leaves and herbs| NEU                     | F                      | Insect pests                      | SG          | 9.5            | Foliar application | BBCH 11–49 | 3                               | 7 days | 200–1,000                   | 15 g a.i./ha    | 3               |                   |           |         |
| Other leaves and herbs| SEU                     | F                      | Insect pests                      | SG          | 9.5            | Foliar application | BBCH 11–49 | 3                               | 7 days | 200–1,000                   | 15 g a.i./ha    | 3               |                   |           |         |

MRL: maximum residue level; GAP: Good Agricultural Practice; NEU: northern European Union; SEU: southern European Union; MS: Member State; a.s.: active substance; SG: water-soluble granule.

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

<sup>(b)</sup>: CropLife International Technical Monograph no 2, 7th Edition. Revised March 2017. 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 | Crops | Applications | Sampling (DAT) | Comment/Source |
|-----------------------------------|-------------|-------|--------------|----------------|---------------|
| Fruit crops                       | Pears       | Foliar: 3 × 16.8 or 168 g/ha, 7 days interval | 2 DAT, 14, 28 DAT₂ | [23-14C]-emamectin B₁₆₂ benzoate (EFSA, 2012) |
|                                  | Lettuces    | Foliar: 8 × 16.8 or 84 g/ha, 7 days interval | 0, 1, 3, 7, 10 DAT₀ | [3, 7, 11, 13, 23-14C]-emamectin B₁₆₂ benzoate (EFSA, 2012) |
|                                  | Head cabbages | Foliar: 8 × 16.8 or 84 g/ha, 7 days interval | 0, 1, 3, 7, 10 DAT₀ | [3, 7, 11, 13, 23-14C]-emamectin B₁₆₂ benzoate (EFSA, 2012) |
|                                  | Sweet corn  | Foliar: 6 × 16.8 or 84 g/ha, 3-5 days interval | 0, 1, 3, 7 DAT₀ | [3, 7, 11, 13, 23-14C]-emamectin B₁₆₂ benzoate (EFSA, 2012) |

| Rotational crops (available studies) | Crop groups | Crops | Applications | PBI (DAT) | Comment/Source |
|--------------------------------------|-------------|-------|--------------|-----------|---------------|
| Root/tuber crops                     | Carrot      | Bare soil, 6 × 16.8 g/ha, 7 days interval (total 100.8 g/ha) | 30, 141, 365 | [3, 7, 11, 13, 23-14C]-emamectin B₁₆₂ benzoate (EFSA, 2012) |
| Leafy crops                          | Lettuce     | Bare soil, 6 × 16.8 g/ha, 7 days interval (total 100.8 g/ha) | 30, 120, 365 | [3, 7, 11, 13, 23-14C]-emamectin B₁₆₂ benzoate (EFSA, 2012) |
| Cereal (small grain)                 | Barley      | Bare soil, 6 × 16.8 g/ha, 7 days interval (total 100.8 g/ha) | 30, 141, 365 | [3, 7, 11, 13, 23-14C]-emamectin B₁₆₂ benzoate (EFSA, 2012) |

| Processed commodities (hydrolysis study) | Conditions | Stable? | Comment/Source |
|------------------------------------------|------------|---------|----------------|
| Pasteurisation (20 min, 90°C, pH 4)      | Yes        | [23-14C]-emamectin B₁₆₂ benzoate (EFSA, 2012). Emamectin B₁₆₂ (84.4% TAR); degradation products (15.7% TAR) not identified. |
| Baking, brewing and boiling (60 min, 100°C, pH 5) | Yes        | [23-14C]-emamectin B₁₆₂ benzoate (EFSA, 2012). Emamectin B₁₆₂ (85.9% TAR); Milbemectin B (1.4% TAR); MSB₁₆₂ (4.8% TAR) |
| Sterilisation (20 min, 120°C, pH 6)      | Yes        | [23-14C]-emamectin B₁₆₂ benzoate (EFSA, 2012). Emamectin B₁₆₂ (79.8% TAR), MSB₁₆₂ (7.2% TAR); AB₁₆₂ (1.8% TAR) |
Can a general residue definition be proposed for primary crops?  

| Yes |

Rotational crop and primary crop metabolism similar?

| Not triggered |

Residue pattern in processed commodities similar to residue pattern in raw commodities?

| Yes |

Parent or "mectin-like" compounds were not detected (EFSA, 2012).

Yes | Slightly different  
Under hydrolysis conditions emamectin B₁₃a benzoate degraded up to 20% AR. Metabolites formed are not expected to modify the nature of residues in processed commodities (EFSA, 2012).

Plant residue definition for monitoring (RD-Mo)

All plant commodities (raw and processed):  
Regulation (EU) No 396/2005: Emamectin benzoate B₁₃a, expressed as emamectin  
EFSA, 2019c: Emamectin B₁₃a and its salts, expressed as emamectin B₁₃a (free base)

Plant residue definition for risk assessment (RD-RA)

All plant commodities (raw and processed):  
Sum of emamectin B₁₃a, emamectin B₁₃b, 8,9-Z-MAB₁₃a, plus 3 times AB₁₃a, plus 3 times MFB₁₃a and 3 times FAB₁₃a, expressed as emamectin B₁₃a (EFSA, 2019c)

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

Matrices with high water content, high oil content, high acid content and dry matrices.  
- Single Residue Method, LC–MS/MS (EFSA 2012)  
  LOQ 0.001 mg/kg for emamectin B₁₃a benzoate (determined as free base)  
  Confirmatory method available for the four matrices; ILV (LC–MS/MS) available for high water content matrix (EFSA, 2012). ILV missing for high acid or high oil content matrix (EFSA, 2019c)  
- Multi residue method QuEChERS (LC–MS/MS) (EFSA, 2019c)  
  LOQ 0.002 mg/kg in high water and high acid content matrices; 0.005 mg/kg in high oil content and dry matrices for emamectin B₁₃a benzoate (determined as free base) in routine analysis

DAT₁, DATₙ: days after the first, the n treatment; PBI: plant-back interval; LC–MS/MS: liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; ILV: independent laboratory validation; QuEChERS: Quick, Easy, Cheap, Effective, Rugged, and Safe.

### B.1.1.2. Stability of residues in plants

| Plant products (available studies) | Category | Commodity | T (°C) | Stability period | Compounds covered | Comment/Source |
|-----------------------------------|----------|-----------|--------|-----------------|-------------------|----------------|
| High water content               | Tomatoes | -20       | 18     | Months          | Emamectin B₁₃a, Emamectin B₁₃b, 8,9-Z-MAB₁₃a, AB₁₃a, MFB₁₃a, FAB₁₃a | EFSA (2012) |
|                                  | Beans with pod | -20 | 18 Days |                |                   | EFSA (2012) |
|                                  | Potatoes | -20       | 18     | Months          |                   | EFSA (2012) |
| High oil content                 | –        | –         | –      | –               | Not available (data gap) | EFSA (2019c) |
| High acid content                | Oranges  | -18       | 24     | Months          | Emamectin B₁₃a, Emamectin B₁₃b, 8,9-Z-MAB₁₃a, AB₁₃a, MFB₁₃a, FAB₁₃a | EFSA (2019b) |
## B.1.2. Magnitude of residues in plants

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

| Commodity | Region | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source | Calculated MRL (mg/kg) | HR(b) (mg/kg) | STMR(c) (mg/kg) | CF(d) |
|-----------|--------|---------------------------------------------------------------|----------------|------------------------|--------------|----------------|-------|
| **Pome fruits** | NEU | Mo: 6 × < 0.001; 0.002; 2 × 0.003; 0.004 | Residue trials on apples (8) and pears (2) compliant with GAP (25% tolerance in application rate). Extrapolation to pome fruits possible. Emamectin B₁₈ benzoate, AB₁₈, MFB₁₈, FAB₁₈ (individually): 10 × < 0.001 mg/kg 8,9-Z-MAB₁₈: 9 × < 0.001; 0.001 mg/kg | 0.01 | 0.004 | 0.001 | 1.00 |
| | SEU | Mo: 2 × < 0.001; 0.003; 2 × 0.004; 2 × 0.005; 2 × 0.007; 0.009; 2 × 0.010 | Residue trials on apples (10) and pears (2) compliant with GAP (25% tolerance in application rate). Extrapolation to pome fruits possible. EMA B₁b benzoate, AB₁a, FAB₁a, 8,9-Z-MAB₁a (individually): 12 × < 0.001 mg/kg MFB₁a: 11 × < 0.001; 0.001 mg/kg | 0.02 | 0.010 | 0.005 | 1.00 |
| **Apricots** | SEU | Mo: 0.001; 0.005; 0.011; 0.014 0.018; 2 × 0.019; 0.021 RA: < 0.012; 0.016; 0.022; 0.025; 2 × 0.030; 0.032; 0.035 | Residue trials on peaches (4) and apricots (4) compliant (25% tolerance in application rate) with GAP and combined to derive the MRL proposal in apricots. EMA B₁b benzoate, AB₁a, FAB₁a, 8,9-Z-MAB₁a (individually): 8 × < 0.001 mg/kg MFB₁a: 6 × < 0.001; 2 × 0.002 mg/kg Individual CFs: 1.00; 2 × 1.57; 1.66; 1.76; 1.78; 2.04; 3.08 | 0.05 | Mo: 0.021 RA: 0.035 | Mo: 0.017 RA: 0.028 | 1.71 |
| **Cherries** | NEU | Mo: < 0.001; 4 × < 0.001; 0.002; 0.009; 0.017 RA: 4 × < 0.012; < 0.012; 0.013; 0.020; 0.028 | Combined NEU (8) and SEU (4) residue trials on cherries compliant with GAP (25% tolerance) and slightly overdosed (underlined values, total of 5 NEU and 2 SEU trials, but only in 2 NEU trials the 3rd and last application still exceeded the 25% tolerance). Emamectin B₁₈ benzoate, 8,9-Z-MAB₁₈, AB₁₈, MFB₁₈, FAB₁₈ (individually): 16 × < 0.001 mg/kg MRL<sub>NEU</sub>: 0.03 mg/kg MRL<sub>SEU</sub>: 0.05 mg/kg | 0.04 | 0.022 | 0.002 | 1.00 |
| | SEU | Mo: < 0.001; 0.009; 0.010; 0.022 RA: < 0.012; 0.020; 0.021; 0.033 | | | | | |

**Residue definition for enforcement**: Emamectin B₁₈ and its salts, expressed as emamectin B₁₈ (free base)

**Residue definition for risk assessment**: Sum of emamectin B₁₈, emamectin B₁b, 8,9-Z-MAB₁₈, plus 3 times AB₁₈, plus 3 times MFB₁₈ and 3 times FAB₁₈, expressed as emamectin B₁₈
| Commodity                          | Region | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source                                                                                                                                                                                                 | Calculated MRL (mg/kg) | HR(b) (mg/kg) | STMR(c) (mg/kg) | CF(d) |
|-----------------------------------|--------|---------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------|----------------|-------|
| Spinaches and similar leaves      | NEU    | **Mo**: 0.004; 0.024; 2 × 0.032                                | Residue trials on open leaf lettuces compliant with GAP on spinaches and similar leaves. Extrapolation to the whole group of spinaches and similar leaves possible but number of trials not sufficient (minimum 6 trials per zone would be required) according to SANCO 7525/VI/95 (European Commission, 2017). Emamectin B₁₅, benzoate, FAB₁₅ (individually): 4 × < 0.001 mg/kg 8,9-Z-MAB₁₅: 2 × < 0.001; 2 × 0.001 mg/kg AB₁₅: < 0.001; 2 × 0.001; 0.002 mg/kg MFB₁₅: 3 × < 0.001; 0.002 mg/kg Individual CFs: 1.35; 1.46; 1.54; 4.13 | –                      | Mo: 0.032     | RA: 0.049       |       |
|                                   | RA:    | **0.015; 0.035; 0.043; 0.049**                                  |                                                                                                                                                                                                             |                        |              |                |       |
|                                   |        | **NEU/SEU**                                                   | Combined data set of NEU and SEU residue trials on open leaf lettuce compliant with GAP on spinaches and similar leaves. According to SANTE/2019/12752, extrapolation to the whole group of spinaches and similar leaves possible based on a minimum of 6 residue trials equally distributed across both zones for applications under Regulation (EU) No 283/2013. Since this proposal deviates from the data requirements applicable for the assessment of this MRL application, EFSA proposes a risk management decision for this MRL proposal. | 0.15                   | Mo: 0.096     | RA: 0.119       |       |
|                                   |        |                                                                 |                                                                                                                                                                                                             |                        | Mo: 0.033     | RA: 0.047       | 1.41  |
|                                   |        |                                                                 |                                                                                                                                                                                                             |                        |              |                |       |
|                                   |        | **SEU**                                                       |                                                                                                                                                                                                             | 0.2                    | Mo: 0.096     | RA: 0.119       |       |
|                                   |        | **Mo**: 0.006; 0.025; 0.026; 0.029; 0.037; 0.051; 0.092; 0.096 |                                                                                                                                                                                                             |                        | Mo: 0.033     | RA: 0.047       | 1.41  |
|                                   |        | RA: 0.017; 0.035; 0.040; 0.044; 0.050; 0.069; 0.115; 0.119     |                                                                                                                                                                                                             |                        |              |                |       |
|                                   |        | **NEU**                                                       |                                                                                                                                                                                                             | 0.15                   | Mo: 0.096     | RA: 0.119       |       |
|                                   |        | **Mo**: 0.004; 0.006; 2 × 0.024; 0.026; 0.029; 2 × 0.032; 0.037; 0.051; 0.092; 0.096 RA: 0.015; 0.017; 2 × 0.035; 0.040; 0.043; 0.044; 0.049; 0.050; 0.069; 0.115; 0.119 | Combined data set of NEU and SEU residue trials on open leaf lettuce compliant with GAP on spinaches and similar leaves. According to SANTE/2019/12752, extrapolation to the whole group of spinaches and similar leaves possible based on a minimum of 6 residue trials equally distributed across both zones for applications under Regulation (EU) No 283/2013. Since this proposal deviates from the data requirements applicable for the assessment of this MRL application, EFSA proposes a risk management decision for this MRL proposal. | 0.15                   | Mo: 0.096     | RA: 0.119       |       |
## Commodity Region

| Commodity                              | Region/(a)         | Residue levels observed in the supervised residue trials (mg/kg)                                                                 | Comments/Source                                                                                     | Calculated MRL (mg/kg) | HR(b) (mg/kg) | STMR(c) (mg/kg) | CF(d) |
|----------------------------------------|--------------------|-----------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------|------------------------|--------------|----------------|-------|
| Herbal infusions from leaves and herbs | NEU                | Mo: see individual levels for spinaches and similar leaves Residue trials on open leaf lettuces compliant with GAP on leaves and herbs used for herbal infusions. Extrapolation possible but number of trials may not be sufficient depending on the legislative framework (see individual comments for spinaches and similar leaves). A dehydration factor of 10 is applied as MRL refers to dried products. | – 2 1.5 | Mo: 0.32 RA: 0.49 Mo: 0.28 RA: 0.39 | Mo: 0.96 RA: 1.19 Mo: 0.33 RA: 0.47 | Mo: 0.96 RA: 1.19 Mo: 0.30 RA: 0.44 | 1.50 1.41 1.46 |
|                                        | SEU                | RA: see individual levels for spinaches and similar leaves 3 Residue trials on open leaf lettuces compliant with GAP on leaves and herbs used for herbal infusions. Extrapolation possible but number of trials may not be sufficient depending on the legislative framework (see individual comments for spinaches and similar leaves). A dehydration factor of 10 is applied as MRL refers to dried products. | – | Mo: 0.96 RA: 1.19 | Mo: 0.96 RA: 1.19 | Mo: 0.96 RA: 1.19 | Mo: 0.96 RA: 1.19 | 1.50 1.41 1.46 |
|                                        | NEU/SEU            | Mo: see individual levels for spinaches and similar leaves Residue trials on open leaf lettuces compliant with GAP on leaves and herbs used for herbal infusions. Extrapolation possible but number of trials may not be sufficient depending on the legislative framework (see individual comments for spinaches and similar leaves). A dehydration factor of 10 is applied as MRL refers to dried products. | – | Mo: 0.96 RA: 1.19 | Mo: 0.96 RA: 1.19 | Mo: 0.96 RA: 1.19 | Mo: 0.96 RA: 1.19 | 1.50 1.41 1.46 |

MRL: maximum residue level; GAP: Good Agricultural Practice; Mo: monitoring; RA: risk assessment; EMA: emamectin.

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

(b): Highest residue. The highest residue for risk assessment refers to the whole commodity and not to the edible portion. Each individual value is paired to the value for enforcement which is reported in ascendent order.

(c): Supervised trials median residue. The median residue for risk assessment refers to the whole commodity and not to the edible portion. Each individual value is paired to the value for enforcement which is reported in ascendent order.

(d): Conversion factor (CF) to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment. The individual CFs were calculated applying the criteria adopted in the MRL review (EFSA, 2019c): when residues of the compounds included in the residue definition for risk assessment (emamectin B1b, 8,9-Z-MAB1a, FAB1a, MFB1a, AB1a) were all ≤ LOQ the CF was indicated as 1, whereas when residues were above the LOQ in at least one component, the experimental value was calculated from the results of the residue trial submitted. The mean CF is reported.

**Note:**

Mo: individual residue values above the LOQ determined as emamectin (EMA) B1a benzoate in the residue trials (France, 2020) and calculated as EMA B1a free base by applying a molecular weight (MW) conversion factor of 0.88.

RA: Individual residues of EMA B1a benzoate and EMA B1b benzoate above the LOQ were calculated as free base using a MW CF of 0.88 and 1.12, respectively; Since the individual values of the photodegradation products were below the LOQ (FAB1a) and only occasionally above the LOQ (8,9-ZB1a AB1a and MFB1a) in the samples from the residue trials submitted and considering that for the latter three compounds the MW CFs are close to 1, the individual levels above the LOQ were not calculated as emamectin B1a equivalents prior to be summed up. Ultimately, the risk assessment (RA) individual residue level took not account the individual Relative Potency Factor (RPF) of 3.
B.1.2.2. Residues in rotational crops

| Question                                                                 | Answer                                                                                           |
|--------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------|
| Residues in rotational and succeeding crops expected based on confined rotational crop study? | No                                                                                               |
|                                                                                             | In rotational crop matrices (barley, lettuces, carrots) and at plant back intervals of 30, 120, 141 and 365 days, TRRs ranged from < 0.003 mg eq/kg to 0.030 mg eq/kg. No parent compound (emamectin B₁a benzoate) and no “mectin-like” metabolites could be detected (EFSA, 2012) |
| Residues in rotational and succeeding crops expected based on field rotational crop study?  | Not triggered                                                                                   |
|                                                                                             | No studies available and not required (EFSA, 2019c)                                              |

B.1.2.3. Processing factors

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

B.2. Residues in livestock

Not necessary. Intended use on apples is covered by the authorised use assessed in the MRL review.

B.3. Consumer risk assessment

| ARfD       | 0.01 mg/kg bw (European Commission, 2013) |
|------------|------------------------------------------|
| Highest IESTI, according to EFSA PRIMo | Spinaches: 26.9% of ARfD                     |
|            | Chards/beet leaves: 22.5% of ARfD              |
|            | Other spinach and similar leaves: 18.6% of ARfD |
|            | Apricots: 17.1% of ARfD child                  |
|            | Strawberry leaves: 7.1% of ARfD                 |
|            | Rooibos: 4.8% of ARfD                          |
|            | Mate/mate: 4.8% of ARfD                        |
|            | Strawberries (sweet): 2.7% of ARfD              |
|            | Purslanes: 2.3% of ARfD                        |

Assumptions made for the calculations

The calculation is based on the highest residue levels (HR) expected in raw agricultural commodities under assessment, except pome fruits (the HR derived under the MRL review was higher, thus previous acute risk assessment still valid).

Calculations were performed with PRIMo revision 3.1

| ADI       | 0.0005 mg/kg bw per day (European Commission, 2013) |
|-----------|----------------------------------------------------------|
| Highest IEDI, according to EFSA PRIMo | 50.47% ADI (NL toddler)                                      |
|           | Contribution of crops assessed:                           |
|           | Apples: 12.48% of ADI                                      |
|           | Spinaches: 6.75% of ADI                                   |
|           | Pears: 4.34% of ADI                                       |
|           | Apricots: 2.96% of ADI                                    |
|           | Mate/mate: 0.94% of ADI                                   |
|           | Chards/beet leaves: 0.75% of ADI                          |
|           | Other spinach and similar leaves: 0.60% of ADI            |
|           | Rooibos: 0.41% of ADI                                     |
|           | Strawberries (sweet): 0.15% of ADI                        |
Assumptions made for the calculations

The calculation is based on the median residue levels (STMR) derived for the crops under assessment, including pome fruits (the STMR derived under this assessment is higher than the STMR derived in the MRL review, EFSA, 2019c) and for peaches and kiwi fruits (EFSA, 2019b).

The STMRs derived in the framework of the MRL review according to the enforcement residue definition were multiplied by the conversion factors (CFa) for risk assessment, directly calculated from the supporting residue data or from metabolism studies. For citrus fruits and cucurbits with inedible peel, a peeling factor was applied. The STMR for mammalian products corresponding to the Codex MRLs were multiplied by a molecular weight CF of 0.88 (EFSA, 2019c).

The contributions of commodities where no GAP or no safe CXL was reported in the framework of the MRL review and in subsequent EFSA outputs, were not considered in the calculation.

The chronic risk assessment calculation is based on the assumption that MRLs for existing uses of emamectin benzoate will be amended as recommended in the MRL review and it is affected by the uncertainty related to the data gaps identified during the review (EFSA, 2019c).

Calculations were performed with PRIMo revision 3.1.

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

B.4. Recommended MRLs

| Code(a) | Commodity       | Existing EU MRL/ (proposed in MRL review)(b) (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|---------|-----------------|-----------------------------------------------------|-------------------------|-----------------------|
|         |                 |                                                     |                         |                       |
|         |                 | Existing enforcement residue definition (1): Emamectin benzoate B₁₁₁, expressed as emamectin (F) (Regulation (EC) No 396/2005) Proposed enforcement residue definition (2): Emamectin B₁₁₁ and its salts, expressed as emamectin B₁₁₁ (free base) (F) (MRL review) |
| 0130000 | Pome fruits     | 0.02 (0.02)b                                       | (1) No change           | The submitted data do not provide evidence that the existing MRL has to be modified. Risk for consumers unlikely. |
|         |                 |                                                     | (2) No change           |                       |
| 0140010 | Apricots        | 0.02 (0.006)b                                      | (1) 0.05                | The submitted data are sufficient to derive an MRL proposal for the intended SEU use. Risk for consumers unlikely. |
|         |                 |                                                     | (2) 0.05                |                       |
| Code<sup>(a)</sup> | Commodity | Existing EU MRL/ (proposed in MRL review)<sup>(b)</sup> (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|----------------|-----------|----------------------------------------------------------|--------------------------|------------------------|
| 0140020 Cherries (sweet) | 0.01* (<) <sup>(b)</sup> | (1) 0.04 (2) 0.04 | The submitted data are sufficient to derive an MRL proposal for the intended NEU/SEU use. The MRL value derived on the basis of combined NEU and SEU data sets. Risk for consumer unlikely. |
| 0252000 Spinaches and similar leaves | 0.01* (<) <sup>(b)</sup> | Further risk management considerations required ‘Old’ data requirements: (1) 0.2 (2) 0.2 (based on SEU data set) ‘New’ data requirements (1) 0.2 (2) 0.15 (merged SEU/NEU data set) | The submitted data are sufficient to derive an MRL proposal of 0.2 mg/kg for the intended SEU use by extrapolation from residues in open leaf lettuces. Based on the applicable ‘old’ data requirements for the assessment of this MRL application, the residue data submitted for the intended NEU use (4 trials) were not sufficient to support this intended use and 2 additional trials would be required. The EMS proposed to apply more favourable (‘new’) data requirements under Regulation (EU) No 283/2013 for the number of trials necessary to support the use on a crop group consisting only of minor crops (3 NEU and 3 SEU trials), since the NEU and SEU GAPs are the same. The MRL proposal of 0.15 mg/kg was thus derived from merged NEU and SEU data sets. Risk for consumer unlikely. |
| 0632000 Herbal infusions from leaves and herbs | 0.02* (<) <sup>(b)</sup> | Further risk management considerations required ‘Old’ data requirements: (1) 0.2 (2) 0.2 (based on SEU data set) ‘New’ data requirements (1) 0.2 (2) 0.15 (merged SEU/NEU data set) | See comments above. The MRL proposals are derived by extrapolation from trials on open leaf lettuces applying a generic dehydration factor of 10. Risk for consumer unlikely |

MRL: maximum residue level; NEU: northern Europe; SEU: southern Europe; GAP: Good Agricultural Practice.

*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(b): MRL as proposed in the framework of the MRL review under art 12 of Regulation (EC) No 396/2005.
(F): Fat soluble.
Appendix C – Pesticide Residue Intake Model (PRIMo)

Emamectin

### Toxicological reference values

| LOQs (mg/kg) | 0.01 | 0.05 |
|-------------|------|------|
| ADI (mg/kg bw per day) | 0.0005 |
| ARfD (mg/kg bw) | 0.01 |

Source of ADI: Source of ARfD: EFSA PRIMo revision 3.1; 2021/01/06

Year of evaluation: No of diets exceeding the ADI : ---

#### Calculated exposure (% of ADI)

| MS Diet | Exposure (µg/kg bw per day) | Highest contributor to MS diet (in % of ADI) | 2nd contributor to MS diet (in % of ADI) | 3rd contributor to MS diet (in % of ADI) |
|---------|-----------------------------|---------------------------------------------|------------------------------------------|------------------------------------------|
| ...     | ...                         | ...                                         | ...                                      | ...                                      |

#### Commodity/group of commodities

| Commodity/group of commodities | MRLs set at the LOQ (in % of ADI) | Commodities not under assessment (in % of ADI) |
|-------------------------------|-----------------------------------|-----------------------------------------------|
| ...                           | ...                               | ...                                           |

#### Chronic risk assessment: JMPR methodology (EDTI/TMDI)

Conclusion: FI 6 yr LT adult UK vegetarian

#### Supplementary results - chronic risk assessment

- Input values
- Supplementary results - chronic risk assessment
- Details - acute risk assessment/children
- Details - acute risk assessment/adults

DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.
### Acute risk assessment/children

#### Details - acute risk assessment/children

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

A short-term intake of residues of Emamectin is unlikely to present a public health risk.

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

**Conclusion:**

### Acute risk assessment/adults/general population

#### Details - acute risk assessment/adults/general population

The acute risk assessment is based on the ARD. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

The calculation is based on the large portion of the most critical consumer group.

### Show results for all crops

#### Results for children

| Commodity | MRL/input (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI | Commodity | MRL/input (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI |
|-----------|-------------------|---------------------|-----------------------|-----------|-------------------|---------------------|-----------------------|
| Chinese cabbages/pe-tsai | 0.03/0.15 | 3.7 | 25% | Chards/beet leaves | 0.02/0.01 | 0.16 | 0.6% |
| Bovine: Liver | 0.08/0.06 | 0.51 | 3% | Pears | 0.02/0.01 | 0.34 | 2% |
| Roman rocket/rucola | 1/0.41 | 1.1 | 5% | Apricots | 0.05/0.05 | 0.53 | 5% |
| 0.2/0.04 | 2.3 | 10% | Spinaches/frozen; boiled | #VALUE! | 0.98 | 0% |
| Kohlrabies/boiled | 0.01/0.02 | 0.32 | 3% | Apples/juice | 0.02/0.01 | 0.17 | 0% |
| Watermelons | 0.01/0  | 0.49 | 3% | Strawberries | 0.05/0.03 | 0.32 | 2% |
| Sweet peppers/bell peppers | 0.02/0.01 | 0.65 | 5% | Spinaches | #VALUE! | 0.48 | 0% |
| Cherries (sweet) | 0.04/0.02 | 0.27 | 2% | Bovine: Edible offals (other than liver and kidney) | 0.08/0.06 | 0.21 | 2% |
| Plums | 0.02/0.01 | 0.42 | 2% | Kohlrabies | 0.01/0.02 | 0.21 | 3% |
| 0.05/0 | 0.10 | 0.5% | Courgettes/boiled | 0.01/0  | 0.05 | 2% |
| Details - acute risk assessment/adults | — | — | — | Details - acute risk assessment/adults | — | — | — |

#### Results for adults

| Commodity | MRL/input (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI | Commodity | MRL/input (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI |
|-----------|-------------------|---------------------|-----------------------|-----------|-------------------|---------------------|-----------------------|
| Chinese cabbages/pe-tsai | 0.03/0.15 | 3.7 | 25% | Chards/beet leaves | 0.02/0.01 | 0.16 | 0.6% |
| Bovine: Liver | 0.08/0.06 | 0.51 | 3% | Pears | 0.02/0.01 | 0.34 | 2% |
| Roman rocket/rucola | 1/0.41 | 1.1 | 5% | Apricots | 0.05/0.05 | 0.53 | 5% |
| 0.2/0.04 | 2.3 | 10% | Spinaches/frozen; boiled | #VALUE! | 0.98 | 0% |
| Kohlrabies/boiled | 0.01/0.02 | 0.32 | 3% | Apples/juice | 0.02/0.01 | 0.17 | 0% |
| Watermelons | 0.01/0  | 0.49 | 3% | Strawberries | 0.05/0.03 | 0.32 | 2% |
| Sweet peppers/bell peppers | 0.02/0.01 | 0.65 | 5% | Spinaches | #VALUE! | 0.48 | 0% |
| Cherries (sweet) | 0.04/0.02 | 0.27 | 2% | Bovine: Edible offals (other than liver and kidney) | 0.08/0.06 | 0.21 | 2% |
| Plums | 0.02/0.01 | 0.42 | 2% | Kohlrabies | 0.01/0.02 | 0.21 | 3% |
| 0.05/0 | 0.10 | 0.5% | Courgettes/boiled | 0.01/0  | 0.05 | 2% |
| Details - acute risk assessment/adults | — | — | — | Details - acute risk assessment/adults | — | — | — |

#### Total number of commodities exceeding the ARfD/ADI in children and adult diets

- **Children:** 34 commodities
- **Adults:** 34 commodities

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

### Conclusion:

The calculation is based on the large portion of the most critical consumer group.

www.efsa.europa.eu/efsajournal 29 EFSA Journal 2021;19(8):6824
## Appendix D – Input values for the exposure calculations

### D.1. Consumer risk assessment

| Commodity          | Existing MRL- (MRL review)/ proposed MRL | Source/ type of MRL | Chronic risk assessment | Acute risk assessment<sup>(a)</sup> |
|--------------------|----------------------------------------|---------------------|-------------------------|--------------------------------------|
|                    |                                        |                     | Input value (mg/kg)      | Comment                              |
|                    |                                        |                     | Comment                  |                                      |
| Oranges            | 0.01 (0.003)                            | EFSA (2019c)        | 0.0003                   | STMR Mo-RAC*CF (1.1)*PeF (0.25)      |
|                    |                                        |                     |                         |                                      |
| Lemons             | 0.01 (0.003)                            | EFSA (2019c)        | 0.0003                   | STMR Mo-RAC*CF (1.1)*PeF (0.25)      |
| Mandarins          | 0.01 (0.003)                            | EFSA (2019c)        | 0.0003                   | STMR Mo-RAC*CF (1.1)*PeF (0.25)      |
| Almonds            | 0.01* (0.001*)                          | EFSA (2019c)        | 0.0010                   | LOQ (CXL)                            |
| Brazil nuts        | 0.01* (0.001*)                          | EFSA (2019c)        | 0.0010                   | LOQ (CXL)                            |
| Cashew nuts        | 0.01* (0.001*)                          | EFSA (2019c)        | 0.0010                   | LOQ (CXL)                            |
| Chestnuts          | 0.01* (0.001*)                          | EFSA (2019c)        | 0.0010                   | LOQ (CXL)                            |
| Coconuts           | 0.01* (0.001*)                          | EFSA (2019c)        | 0.0010                   | LOQ (CXL)                            |
| Hazelnuts/cobnuts  | 0.01* (0.001*)                          | EFSA (2019c)        | 0.0010                   | LOQ (CXL)                            |
| Macadamia          | 0.01* (0.001*)                          | EFSA (2019c)        | 0.0010                   | LOQ (CXL)                            |
| Pecans             | 0.01* (0.001*)                          | EFSA (2019c)        | 0.0010                   | LOQ (CXL)                            |
| Pine nut kernels   | 0.01* (0.001*)                          | EFSA (2019c)        | 0.0010                   | LOQ (CXL)                            |
| Pistachios         | 0.01* (0.001*)                          | EFSA (2019c)        | 0.0010                   | LOQ (CXL)                            |
| Walnuts            | 0.01* (0.001*)                          | EFSA (2019c)        | 0.0010                   | STMR-Mo-RAC*CF (1)                   |
| Other tree nuts    | 0.01* (0.001*)                          | EFSA (2019c)        | 0.0010                   | LOQ (CXL)                            |
| Apples             | 0.02 (0.02)                             | Intended/ EFSA (2019c) | 0.0050                   | STMR-Mo-RAC (SEU)*CF (1)             |
|                    |                                        |                     |                         |                                      |
| Pears              | 0.02 (0.02)                             | Intended/ EFSA (2019c) | 0.0050                   | STMR-Mo-RAC (SEU)*CF (1)             |
| Quinces            | 0.02 (0.02)                             | Intended/ EFSA (2019c) | 0.0050                   | STMR-Mo-RAC (SEU)*CF (1)             |
| Medlar             | 0.02 (0.02)                             | Intended/ EFSA (2019c) | 0.0050                   | STMR-Mo-RAC (SEU)*CF (1)             |
| Loquats/ Japanese medlars | 0.02 (0.02) | Intended/ EFSA (2019c) | 0.0050                   | STMR-Mo-RAC (SEU)*CF (1)             |
| Other pome fruit   | 0.02 (0.02)                             | Intended/ EFSA (2019c) | 0.0050                   | STMR-Mo-RAC (SEU)*CF (1)             |
| Apricots           | 0.05                                   | Intended use        | 0.0390                   | STMR-RA-RAC                          |
| Cherries (sweet)   | 0.04                                   | Intended use        | 0.0020                   | STMR-Mo-RAC*CF (1)                   |
| Peaches            | 0.15                                   | EFSA (2019b)        | 0.0340                   | STMR-RA-RAC                          |
| Plums              | 0.02 (0.015)                            | EFSA (2019c)        | 0.0022                   | STMR-Mo-RAC*CF (1.1)                 |
| Table grapes       | 0.05 (0.04)                             | EFSA (2019c)        | 0.0022                   | STMR-Mo-RAC*CF (1.1)                 |

**Risk assessment residue definition:** Sum of emamectin B₁₆, emamectin B₁₈, 8,9-Z-MAB₁₆, plus 3 times AB₁₆, and 3 times MFB₁₆ and 3 times FAB₁₆, expressed as emamectin B₁₆.

<sup>(a)</sup> MFB₁₆ and 3 times FAB₁₆ are included in the calculation of residues for the risk assessment but are not included in the residue definition to avoid double counting.
| Commodity                     | Existing MRL- (MRL review)/ proposed MRL | Source/ type of MRL | Chronic risk assessment Input value (mg/kg) | Comment | Acute risk assessment(a) Input value (mg/kg) | Comment |
|-------------------------------|------------------------------------------|---------------------|--------------------------------------------|---------|--------------------------------------------|---------|
| Wine grapes                   | 0.05 (0.04) EFSA (2019c)                 |                    | 0.0022 STMR-Mo-RAC*CF (1.1)                |         | 0.0210 HR-Mo-RAC*CF                        |         |
| Strawberries                  | 0.05 (0.05) EFSA (2019c)                 |                    | 0.0066 STMR-Mo-RAC*CF (1.1)                |         | 0.0340 HR-Mo-RAC*CF                        |         |
| Kiwi fruits (green, red, yellow) | 0.15 EFSA (2019b)                     |                    | 0.0340 STMR-RA-RAC                        |         | 0.0840 HR-RA-RAC                           |         |
| Potatoes                      | 0.01* (0.001*) EFSA (2019c)             |                    | 0.0011 STMR-Mo-RAC*CF (1.1)               |         | 0.0110 HR-Mo-RAC*CF                        |         |
| Tomatoes                      | 0.02 (0.02) EFSA (2019c)                |                    | 0.0044 STMR-Mo-RAC (EU)*CF (1.1)          |         | 0.0140 HR-Mo-RAC (CXL)*CF                 |         |
| Sweet/bell peppers            | 0.02 (0.02) EFSA (2019c)                |                    | 0.0030 STMR-RAC*CF (1)                    |         | 0.0110 HR-RAC*CF                           |         |
| Aubergines/egg plants         | 0.02 (0.02) EFSA (2019c)                |                    | 0.0044 STMR-Mo-RAC (EU)*CF (1.1)          |         | 0.0140 HR-Mo-RAC (CXL)*CF                 |         |
| Okra/lady's fingers           | 0.02 (0.02) EFSA (2019c)                |                    | 0.0044 STMR-Mo-RAC (EU)*CF (1.1)          |         | 0.0140 HR-Mo-RAC (CXL)*CF                 |         |
| Other solanacea               | 0.02 (0.02) EFSA (2019c)                |                    | 0.0044 STMR-Mo-RAC (EU)*CF (1.1)          |         | 0.0140 HR-Mo-RAC (CXL)*CF                 |         |
| Cucumbers                     | 0.01 (0.007) EFSA (2019c)               |                    | 0.0011 STMR-Mo-RAC (CXL)*CF (1.1)         |         | 0.0022 HR-Mo-RAC (CXL)*CF                 |         |
| Gherkins                      | 0.01 (0.007) EFSA (2019c)               |                    | 0.0011 STMR-Mo-RAC (CXL)*CF (1.1)         |         | 0.0022 HR-Mo-RAC (CXL)*CF                 |         |
| Courgettes                    | 0.01 (0.007) EFSA (2019c)               |                    | 0.0011 STMR-Mo-RAC (CXL)*CF (1.1)         |         | 0.0022 HR-Mo-RAC (CXL)*CF                 |         |
| Other cucurbits - edible peel | 0.01 (0.007) EFSA (2019c)               |                    | 0.0011 STMR-Mo-RAC (CXL)*CF (1.1)         |         | 0.0022 HR-Mo-RAC (CXL)*CF                 |         |
| Melons                        | 0.01 (0.008) EFSA (2019c)               |                    | 0.0020 STMR-Mo-RAC*CF (1)*PeF (1)         |         | 0.0040 HR-Mo-RAC*CF*PeF                   |         |
| Pumpkins                      | 0.01 (0.008) EFSA (2019c)               |                    | 0.0020 STMR-Mo-RAC*CF (1)*PeF (1)         |         | 0.0040 HR-Mo-RAC*CF*PeF                   |         |
| Watermelons                   | 0.01 (0.008) EFSA (2019c)               |                    | 0.0020 STMR-Mo-RAC*CF (1)*PeF (1)         |         | 0.0040 HR-Mo-RAC*CF*PeF                   |         |
| Other cucurbits - inedible peel | 0.01 (0.008) EFSA (2019c)             |                    | 0.0020 STMR-Mo-RAC*CF (1)*PeF (1)         |         | 0.0040 HR-Mo-RAC*CF*PeF                   |         |
| Broccoli                      | 0.01 (0.003) EFSA (2019c)               |                    | 0.0015 STMR-Mo-RAC*CF (1.5)               |         | 0.0030 HR-Mo-RAC*CF                        |         |
| Cauliflowers                  | 0.01 (0.003) EFSA (2019c)               |                    | 0.0015 STMR-Mo-RAC*CF (1.5)               |         | 0.0030 HR-Mo-RAC*CF                        |         |
| Brussels sprouts              | 0.01* (0.004) EFSA (2019c)              |                    | 0.0010 STMR-Mo-RAC*CF (1)                 |         | 0.0020 HR-Mo-RAC*CF                        |         |
| Head cabbages                 | 0.01* (0.004) EFSA (2019c)              |                    | 0.0015 STMR-Mo-RAC*CF (1.5)               |         | 0.0030 HR-Mo-RAC*CF                        |         |
| Chinese cabbages/pe-tsai      | 0.03 (0.2) EFSA (2019c)                 |                    | 0.00135 STMR-Mo-RAC (CXL)*CF (1.5)        | 0.1455  | HR-Mo-RAC (CXL)*CF                        |         |
| Kales                         | 0.03 (0.03) EFSA (2019c)                |                    | 0.0060 STMR-Mo-RAC*CF (1)                 |         | 0.0100 HR-Mo-RAC*CF                        |         |
| Commodity                        | Existing MRL-(MRL review)/proposed MRL | Source/type of MRL | Chronic risk assessment | Acute risk assessment(a) |
|---------------------------------|----------------------------------------|-------------------|-------------------------|-------------------------|
|                                 |                                        |                   | Input value (mg/kg)     | Comment                 | Input value (mg/kg)     | Comment                 |
| Kohlrabies                      | 0.01* (0.01)                           | EFSA (2019c)      | 0.0150                  | LOQ*CF (1.5)            | 0.0150                  | LOQ*CF (1.5)            |
| Lamb's lettuce/corn salads      | 1 (0.6)                                | EFSA (2019c)      | 0.1848                  | STMR-Mo-RAC*CF (1.4)    | 0.406                   | HR-Mo-RAC*CF            |
| Lettuces                        | 1 (0.2)                                | EFSA (2019c)      | 0.0336                  | STMR-Mo-RAC*CF (1.2)    | 0.1200                  | HR-Mo-RAC*CF            |
| Escaroles/broad-leaved endives  | 0.2 (0.15)                             | EFSA (2019c)      | 0.0264                  | STMR-Mo-RAC*CF (1.1)    | 0.035                   | HR-Mo-RAC*CF            |
| Cress and other sprouts, shoots | 1 (0.6)                                | EFSA (2019c)      | 0.1848                  | STMR-Mo-RAC*CF (1.4)    | 0.406                   | HR-Mo-RAC*CF            |
| Land cress                      | 1 (0.6)                                | EFSA (2019c)      | 0.1848                  | STMR-Mo-RAC*CF (1.4)    | 0.406                   | HR-Mo-RAC*CF            |
| Roman rocket/ruccola            | 1 (0.6)                                | EFSA (2019c)      | 0.1848                  | STMR-Mo-RAC*CF (1.4)    | 0.406                   | HR-Mo-RAC*CF            |
| Red mustards                    | 1 (0.6)                                | EFSA (2019c)      | 0.1848                  | STMR-Mo-RAC*CF (1.4)    | 0.406                   | HR-Mo-RAC*CF            |
| Spinaches                       | 0.2 or 0.15                            | Intended use      | 0.0470                  | STMR-RA-RAC             | 0.119                   | HR-RA-RAC               |
| Purslanes                       | 0.2 or 0.15                            | Intended use      | 0.0470                  | STMR-RA-RAC             | 0.119                   | HR-RA-RAC               |
| Chards/beet leaves              | 0.2 or 0.15                            | Intended use      | 0.0470                  | STMR-RA-RAC             | 0.119                   | HR-RA-RAC               |
| Other spinach and similar leaves| 0.2 or 0.15                            | Intended use      | 0.0470                  | STMR-RA-RAC             | 0.119                   | HR-RA-RAC               |
| Watercress                      | 0.01 (0.6)                             | EFSA (2019c)      | 0.1848                  | STMR-Mo-RAC*CF (1.4)    | 0.406                   | HR-Mo-RAC*CF            |
| Chervil                         | 1 (0.2)                                | EFSA (2019c)      | 0.0396                  | STMR-Mo-RAC*CF (1.2)    | 0.116                   | HR-Mo-RAC*CF            |
| Chives                          | 1 (0.2)                                | EFSA (2019c)      | 0.0396                  | STMR-Mo-RAC*CF (1.2)    | 0.116                   | HR-Mo-RAC*CF            |
| Celery leaves                   | 1 (0.2)                                | EFSA (2019c)      | 0.0396                  | STMR-Mo-RAC*CF (1.2)    | 0.116                   | HR-Mo-RAC*CF            |
| Parsley                         | 1 (0.2)                                | EFSA (2019c)      | 0.0396                  | STMR-Mo-RAC*CF (1.2)    | 0.116                   | HR-Mo-RAC*CF            |
| Sage                            | 1 (0.6)                                | EFSA (2019c)      | 0.1848                  | STMR-Mo-RAC*CF (1.4)    | 0.406                   | HR-Mo-RAC*CF            |
| Rosemary                        | 1 (0.2)                                | EFSA (2019c)      | 0.0396                  | STMR-Mo-RAC*CF (1.2)    | 0.116                   | HR-Mo-RAC*CF            |
| Thyme                           | 1 (0.2)                                | EFSA (2019c)      | 0.0396                  | STMR-Mo-RAC*CF (1.2)    | 0.116                   | HR-Mo-RAC*CF            |
| Basil and edible flowers        | 1 (0.2)                                | EFSA (2019c)      | 0.0396                  | STMR-Mo-RAC*CF (1.2)    | 0.116                   | HR-Mo-RAC*CF            |
| Laurel/bay leaves               | 1 (0.2)                                | EFSA (2019c)      | 0.0396                  | STMR-Mo-RAC*CF (1.2)    | 0.116                   | HR-Mo-RAC*CF            |
| Tarragon                        | 1 (0.2)                                | EFSA (2019c)      | 0.0396                  | STMR-Mo-RAC*CF (1.2)    | 0.116                   | HR-Mo-RAC*CF            |
| Other herbs                     | 1 (0.2)                                | EFSA (2019c)      | 0.0396                  | STMR-Mo-RAC*CF (1.2)    | 0.116                   | HR-Mo-RAC*CF            |
| Beans (with pods)               | 0.03 (0.03)                            | EFSA (2019c)      | 0.0060                  | STMR-Mo-RAC*CF (1)      | 0.0170                  | HR-Mo-RAC*CF            |
| Beans (without pods)            | 0.01* (0.15)                           | EFSA (2019c)      | 0.0010                  | STMR-RAC (CXL)*CF (1)   | 0.0080                  | HR-RAC (CXL)*CF         |
| Commodity                                | Existing MRL-(MRL review)/proposed MRL | Source/type of MRL | Chronic risk assessment | Acute risk assessment<sup>(a)</sup> |
|------------------------------------------|----------------------------------------|--------------------|-------------------------|-------------------------------------|
|                                          |                                       |                    | Input value (mg/kg)      | Input value (mg/kg)                  | Comment               |
| Peas (with pods)                         | 0.03 (0.03)                            | EFSA (2019c)       | 0.0060                  | 0.0170                              | HR-Mo-RAC*CF          |
| Peas (without pods)                      | 0.01* (0.001*)                         | EFSA (2019c)       | 0.0010                  | 0.0010                              | HR-Mo-RAC*CF          |
| Globe artichokes                         | 0.1 (0.09)                             | EFSA (2019c)       | 0.0208                  | 0.0429                              | HR-Mo-RAC*CF          |
| Rapeseeds/canola seeds                   | 0.01* (0.005*)                         | EFSA (2019c)       | 0.0050                  | 0.0050                              | LOQ(CXL)*CF           |
| Cotton seeds                             | 0.01 (0.01)                            | EFSA (2019c)       | 0.0100                  | 0.010                               | STMR-RAC*CF           |
| Strawberry leaves                        | 2 or 1.5                               | Intended use       | 0.4700                  | 1.1900                              | HR-RA-RAC            |
| Rooibos                                  | 2 or 1.5                               | Intended use       | 0.4700                  | 1.1900                              | HR-RA-RAC            |
| Mate/mate                                | 2 or 1.5                               | Intended use       | 0.4700                  | 1.1900                              | HR-RA-RAC            |
| Other herbal infusions (dried leaves)    | 2 or 1.5                               | Intended use       | 0.4700                  | 1.1900                              | HR-RA-RAC            |

**Risk assessment residue definition:** Emamectin B<sub>1a</sub> and its salts, expressed as emamectin B<sub>1a</sub><sup>(c)</sup>.
| Commodity                              | Existing MRL-(MRL review)/proposed MRL | Source/type of MRL | Chronic risk assessment | Acute risk assessment<sup>(a)</sup> |
|---------------------------------------|----------------------------------------|-------------------|-------------------------|----------------------------------|
| **Commodity**                         | **Input value (mg/kg)** | **Comment** | **Input value (mg/kg)** | **Comment** |
| Sheep: Fat tissue                     | 0.02 (0.02)                       | Reg 2018/1514    | 0.0018 STMR-RAC (CXL)*MW CF (0.88) | 0.010 HR-RAC (CXL)*MWCF          |
| Sheep: Liver                          | 0.08 (0.08)                       | Reg 2018/1514    | 0.0053 STMR-RAC (CXL)*MW CF (0.88) | 0.063 HR-RAC (CXL)*MWCF          |
| Sheep: Kidney                         | 0.08 (0.08)                       | Reg 2018/1514    | 0.0053 STMR-RAC (CXL)*MW CF (0.88) | 0.063 HR-RAC (CXL)*MWCF          |
| Sheep: Edible offal (other than liver and kidney) | 0.08 (0.08)                       | Reg 2018/1514    | 0.0053 STMR-RAC (CXL)*MW CF (0.88) | 0.063 HR-RAC (CXL)*MWCF          |
| Goat: Muscle/meat<sup>(b)</sup>       | 0.01 (0.004)                      | Reg 2018/1514    | 0.0018 STMR-RAC (CXL)*MW CF (0.88) | 0.005 HR-RAC (CXL)*MWCF          |
| Goat: Fat tissue                      | 0.02 (0.02)                       | Reg 2018/1514    | 0.0018 STMR-RAC (CXL)*MW CF (0.88) | 0.010 HR-RAC (CXL)*MWCF          |
| Goat: Liver                           | 0.08 (0.08)                       | Reg 2018/1514    | 0.0053 STMR-RAC (CXL)*MW CF (0.88) | 0.063 HR-RAC (CXL)*MWCF          |
| Goat: Kidney                          | 0.08 (0.08)                       | Reg 2018/1514    | 0.0053 STMR-RAC (CXL)*MW CF (0.88) | 0.063 HR-RAC (CXL)*MWCF          |
| Goat: Edible offal (other than liver and kidney) | 0.08 (0.08)                       | Reg 2018/1514    | 0.0053 STMR-RAC (CXL)*MW CF (0.88) | 0.063 HR-RAC (CXL)*MWCF          |
| Equine: Muscle/meat<sup>(b)</sup>    | 0.01 (0.004)                      | Reg 2018/1514    | 0.0018 STMR-RAC (CXL)*MW CF (0.88) | 0.005 HR-RAC (CXL)*MWCF          |
| Equine: Fat tissue                    | 0.02 (0.02)                       | Reg 2018/1514    | 0.0018 STMR-RAC (CXL)*MW CF (0.88) | 0.010 HR-RAC (CXL)*MWCF          |
| Equine: Liver                         | 0.08 (0.08)                       | Reg 2018/1514    | 0.0053 STMR-RAC (CXL)*MW CF (0.88) | 0.063 HR-RAC (CXL)*MWCF          |
| Equine: Kidney                        | 0.08 (0.08)                       | Reg 2018/1514    | 0.0053 STMR-RAC (CXL)*MW CF (0.88) | 0.063 HR-RAC (CXL)*MWCF          |
| Equine: Edible offal (other than liver and kidney) | 0.08 (0.08)                       | Reg 2018/1514    | 0.0053 STMR-RAC (CXL)*MW CF (0.88) | 0.063 HR-RAC (CXL)*MWCF          |
| Milk: Cattle                          | 0.01 (0.002)                      | Reg 2018/1514    | 0.0010 STMR-RAC (CXL)*MW CF (0.88) | 0.001 STMR-RAC (CXL)*MWCF        |
| Milk: Sheep                           | 0.01 (0.002)                      | Reg 2018/1514    | 0.0010 STMR-RAC (CXL)*MW CF (0.88) | 0.001 STMR-RAC (CXL)*MWCF        |
| Milk: Goat                            | 0.01 (0.002)                      | Reg 2018/1514    | 0.0010 STMR-RAC (CXL)*MW CF (0.88) | 0.001 STMR-RAC (CXL)*MWCF        |
| Commodity   | Existing MRL- (MRL review)/ proposed MRL | Source/ type of MRL | Chronic risk assessment | Acute risk assessment<sup>(a)</sup> |
|-------------|------------------------------------------|---------------------|-------------------------|----------------------------------|
| Milk: Horse | 0.01 (0.002) | Reg 2018/1514 | 0.0010 STMR-RAC (CXL)*MW CF (0.88) | 0.001 STMR-RAC (CXL)*MWCF |

STMR-RAC: supervised trials median residue in raw agricultural commodity; HR-RAC: highest residue in raw agricultural commodity; PeF: Peeling factor.

(a): Input values for the commodities which are not under consideration for the acute risk assessment are reported in grey.
(b): Consumption figures in the EFSA PRIMo are expressed as meat. Since the a.s. is a fat-soluble pesticide, STMR and HR residue values were calculated considering an 80%/20% muscle and fat content for mammal meat (FAO, 2016).
(c): Codex input values for animal products are expressed as emamectin B1a benzoate and were converted to emamectin B1a to reflect the risk assessment residue definition by a molecular weight (MW) conversion factor (CF) of 0.88.
## Appendix E – Used compound codes

| Code/trivial name(a) | IUPAC name/SMILES notation/InChiKey(b) | Structural formula(c) |
|----------------------|----------------------------------------|-----------------------|
| emamectin B1a        | (10E,14E,16E)- (1R,4S,5’S,6S,6’R,8R,12S,13S,20R, 21R,24S)-6’-{(5)-sec-butyl}-21,24-dihydroxy-5’,11,13,22-tetramethyl-2-oxo-(3,7,19-trioxatetracyclo [15.6.1.13,0.02,0,24]pentacosa-10,14,16,22-tetraene)-6-spiro-2’-(5’,6’-dihydro-2’H-pyran)-12-yl 2,6-dideoxy-3-O-methyl-4-O-(2,4,6-trideoxy-3-O-methyl-4-methylamino-α-L-lyxo-hexopyranosyl)-α-L-arabinohexopyranoside | ![emamectin B1a structural formula](image1) |
|                      | CO[O[C@@H]1C[C@@H](O [O[C@@H]1C[C@@H]1NC]O[C@H]2O[C@H]2)C][O[C@@H]2][C[C@@H](OC)C[C@@H](O[C@H]2C)O[C@@H]3]C(C) = C(C[C@@H](OC(=O[C@@H]4C=C(C[C@@H]6C[C@H](OC(=O[C@@H]4C=C(C[C@@H]3C)[C@@H]4)5O)C[C@@H](O6)C[C@H](C)[C@H]7)[C@H]1CC) | |
|                      | DXEGAUYYQAKHKJ-COFQVFHO-SA-N          | ![emamectin B1a structural formula](image2) |
| emamectin B1b        | (10E,14E,16E)- (1R,4S,5’S,6S,6’R,8R,12S,13S, 20R,21R,24S)-21,24-dihydroxy-6’-isopropyl-5’,11,13,22-tetramethyl-2-oxo-(3,7,19-trioxatetracyclo [15.6.1.13,0.02,0,24]pentacosa-10,14,16,22-tetraene)-6-spiro-2’-(5’,6’-dihydro-2’H-pyran)-12-yl 2,6-dideoxy-3-O-methyl-4-O-(2,4,6-trideoxy-3-O-methyl-4-methylamino-α-L-lyxo-hexopyranosyl)-α-L-arabinohexopyranoside | ![emamectin B1b structural formula](image3) |
|                      | CO[C@H]1C[C@@H](O [C@H]1NC][O[C@@H]2O[C@H]2)[C[C@@H](OC)C[C@@H](O[C@H]2C)O[C@@H]3][C[C@@H](OC(=O[C@@H]4C=C(C[C@@H]6C[C@H](OC(=O[C@@H]4C=C(C[C@@H]3C)[C@@H]4)45O)C[C@H]7)[C@H]1C[C@@H](O6)C[C@H](C)[C@H]7)[C@H]1CC) | |
|                      | DXIOOXFZLCKVHK-VAUHGIGSYA-N           | |

---

(a) Code/trivial name

(b) IUPAC name/SMILES notation/InChiKey

(c) Structural formula
| Code/trivial name\(^{(a)}\) | IUPAC name/SMILES notation/InChIKey\(^{(b)}\) | Structural formula\(^{(c)}\) |
|-----------------------------|----------------------------------|----------------------------------|
| emamectin B\(_{1a}\) benzoate | (10\(E\),14\(E\),16\(E\))- (1\(R\),4\(S\),5\(S\),6\(S\),R,8\(R\),12\(S\),13\(S\), 20\(R\),21\(R\),24\(S\))-6-[(5)-sec-butyl]-21,24- dihydroxy-5',11,13,22-tetramethyl-2- oxo-(3,7,19-trioxatetracyclo [15.6.1.1\(4\),8.0\(20\),24\]pentacosa-10,14,16,22-tetraene)-6-spiro-2'-[(5',6'- dihydro-2'H-pyran)-12-yl 2,6-dideoxy-3-O-methyl-4-O-(2,4,6-trideoxy-3-O- methyl-4-methylamino-\(\alpha\)-L-lyxo-hexopyranosyl)-\(\alpha\)-L-arabinohexopyranoside benzoate | ![Structural formula for emamectin B\(_{1a}\) benzoate]() |
| emamectin B\(_{1b}\) benzoate | (10\(E\),14\(E\),16\(E\))- (1\(R\),4\(S\),5\(S\),6\(S\),R,8\(R\),12\(S\),13\(S\), 20\(R\),21\(R\),24\(S\))-21,24-dihydroxy-5'- isopropyl-5',11,13,22-tetramethyl-2-oxo- (3,7,19-trioxatetracyclo [15.6.1.1\(4\),8.0\(20\),24\]pentacosa-10,14,16,22-tetraene)-6-spiro-2'-[(5',6'- dihydro-2'H-pyran)-12-yl 2,6-dideoxy-3-O-methyl-4-O-(2,4,6-trideoxy-3-O- methyl-4-methylamino-\(\alpha\)-L-lyxo-hexopyranosyl)-\(\alpha\)-L-arabinohexopyranoside benzoate | ![Structural formula for emamectin B\(_{1b}\) benzoate]() |
| Code/trivial name<sup>(a)</sup> | IUPAC name/SMILES notation/InChIKey<sup>(b)</sup> | Structural formula<sup>(c)</sup> |
|-------------------------------|-------------------------------------------------|----------------------------------|
| 8,9-Z-MAB<sub>1α</sub> NOA 438376 | (1'R,2S,4'S,5S,6R,8'R,10'E, 12'S,13'R,14'E,16'Z,20'R,21'R,24'S)-6-[(25)-butan-2-yl]-21',24'-dihydroxy-5,11',13',22'-tetramethyl-2'-oxo-5,6-dihydrospiro[pyran-2,6'-[3,7,19]trioxatetracyclo[15.6.1.1<sub>4,8</sub>.0<sub>20,24</sub>]pentacosa[10,14,16,22]tetraen]-12'-yl 2,6-dideoxy-3-O-methyl-4-O-[2,4,6-trideoxy-3-O-methyl-4-(methylamino)-a-L-lyxo-hexopyranosyl]-a-L-arabinohexopyranoside | ![Structural formula for 8,9-Z-MAB<sub>1α</sub> NOA 438376](image) |
| FAB<sub>1α</sub> NOA 415693 | (1'R,2S,4'S,5S,6R,8'R, 10'E,12'S,13'S,14'E,16'E, 20'R,21'R,24'S)-6-[(25)-butan-2-yl]-21',24'-dihydroxy-5,11',13',22'-tetramethyl-2'-oxo-5,6-dihydrospiro[pyran-2,6'-[3,7,19]trioxatetracyclo[15.6.1.1<sub>4,8</sub>.0<sub>20,24</sub>]pentacosa[10,14,16,22]tetraen]-12'-yl 2,6-dideoxy-3-O-methyl-4-O-(2,4,6-trideoxy-4-formamido-3-O-methyl-a-L-lyxo-hexopyranosyl)-a-L-arabinohexopyranoside | ![Structural formula for FAB<sub>1α</sub> NOA 415693](image) |
| Code/trivial name<sup>(a)</sup> | IUPAC name/SMILES notation/InChiKey<sup>(b)</sup> | Structural formula<sup>(c)</sup> |
|-------------------------------|---------------------------------------------|----------------------------------|
| MFB<sub>1a</sub> NOA 415692   | (1'R,2S,4'S,5'S,6'R,8'R,10'E,12'S,13'S,14'E,16'E,20'R,21'R,24'S)-6-[(2S)-butan-2-yl]-21',24'-dihydroxy-5,11',13',22'-tetramethyl-2'-oxo-5,6-dihydrospiro[pyran-2,6'-[3,7,19]trioxatetracyclo[15.6.1.1<sup>4</sup>,8.0<sup>20</sup>,24]<sup>pentacosa</sup>[10,14,16,22]<sup>tetraen</sup>-12'-yl-2,6-dideoxy-3-O-methyl-4-O-[(2,4,6-trideoxy-4-[formyl(methyl)amino]-3-O-methyl-α-L-lyxo-hexopyranosyl]-α-L-arabino-hexopyranoside <br> O=CN<sup>(C</sup>[C@H]1[C@@H](OC)[C@@H](O[C@H]1C[C@@H](O[C@@H][O[C@@H]2][C@@H][O[C@@H]3][C@@H]4)[C@H]6[C@H](O[C=O][C@@H]5)[C@@H]450)[C@@H]7')(O6)C=C[C@H]4'[C@H](O7)[C@@H]5CC | ![Structural formula](image) |
| AB<sub>1a</sub> NOA 438309   | (1'R,2S,4'S,5'S,6'R,8'R,10'E,12'S,13'S,14'E,16'E,20'R,21'R,24'S)-6-[(2S)-butan-2-yl]-21',24'-dihydroxy-5,11',13',22'-tetramethyl-2'-oxo-5,6-dihydrospiro[pyran-2,6'-[3,7,19]trioxatetracyclo[15.6.1.1<sup>4</sup>,8.0<sup>20</sup>,24]<sup>pentacosa</sup>[10,14,16,22]<sup>tetraen</sup>-12'-yl-4-O-[(4-amino-2,4,6-trIDEOXY-3-O-METHYL-α-L-lyxo-hexopyranosyl)-2,6-dIDEOXY-3-O-METHYL-α-L-arabino-hexopyranoside <br> CO[C@H]1[C@@H](O[C@H]1N)[C@H]2OC[C@@H](O[C@H]2C)[C@@H]3[C@@H]4[C@H](O[C@H]3)[C@H]450)[C@@H]5CC | ![Structural formula](image) |
| Code/trivial name<sup>(a)</sup> | IUPAC name/SMILES notation/InChiKey<sup>(b)</sup> | Structural formula<sup>(c)</sup> |
|-------------------------------|-------------------------------------------------|---------------------------------|
| MSB<sub>1</sub>a <br> NOA 419150 | \((1'R,25,4'S,5'S,6'R,8'R,10'E,12'S,13'S,14'E,16'E,20'R,21'R,24'S)-6-[(25)-butan-2-yl]-21',24'-dihydroxy-5,11',13',22'-tetramethyl-2'-oxo-5,6-dihydrospir[pyran-2,6'-]3,7,19\]trioxatetracyclo[15.6.1.1<sup>4,8</sup>,0<sup>20,24</sup>]pentacosa[10,14,16,22][tetraen]-12'-yl\)2,6-dideoxy-3-O-methyl-a-L-arabinohexopyranoside<sup>(a)</sup> | ![ Structural formula image ]<sup>(c)</sup> |
| Aglycone milbemectin B <br> NOA 419153 | \((1'R,25,4'S,5'S,6'R,8'R,10'E,12'S,13'S,14'E,16'E,20'R,21'R,24'S)-6-[(25)-butan-2-yl]-12',21',24'-trihydroxy-5,11',13',22'-tetramethyl-5,6-dihydro-2'H-spiro[pyran-2,6'-]3,7,19\]trioxatetracyclo[15.6.1.1<sup>4,8</sup>,0<sup>20,24</sup>]pentacosa [10,14,16,22][tetraen]-2'-one<sup>(a)</sup> | ![ Structural formula image ]<sup>(c)</sup> |

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

<sup>(a)</sup> The metabolite name in bold is the name used in the conclusion.
<sup>(b)</sup> ACD/Name 2020.2.1 ACD/Labs 2020 Release (File version N15E41, Build 116563, 15 June 2020).
<sup>(c)</sup> ACD/ChemSketch 2020.2.1 ACD/Labs 2020 Release (File version C25H41, Build 121153, 22 March 2021).