Modification of the existing maximum residue levels for emamectin in kiwi and peaches

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Syngenta (France SAS) submitted a request to the competent national authority in France to modify the existing maximum residue level (MRL) for the active substance emamectin in peaches. A second request was submitted by Syngenta Italia S.p.a to the competent national authority in Italy to modify the MRL emamectin in kiwi. The data submitted in support of the request were found to be sufficient to derive MRL proposals for kiwi and peaches. Adequate analytical methods for enforcement are available to enforce the residues resulting from the use of emamectin benzoate on the commodities under consideration at the validated limit of quantification (LOQ) of 0.001 mg/kg. Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of residues resulting from the use of emamectin benzoate according to the reported agricultural practices is unlikely to present a risk to consumer health.

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Keywords: emamectin, emamectin benzoate, peaches, kiwi, pesticide, MRL, consumer risk assessment

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, Syngenta submitted an application to the competent national authority in France (evaluating Member State, EMS) to modify the existing maximum residue level (MRL) for the active substance emamectin benzoate in peaches. The EMS-FR 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 5 March 2015. To accommodate for the intended use of emamectin benzoate, the EMS-FR proposed to raise the existing MRL from 0.03 mg/kg to 0.09 mg/kg. A second request was submitted by Syngenta to the competent national authority in Italy to modify the MRL emamectin benzoate in kiwi. The EMS-IT 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 EFSA on 9 November 2015. To accommodate for the intended use of emamectin benzoate, the EMS-IT proposed to raise the existing MRL of emamectin benzoate in kiwi from the limit of quantification (LOQ) of 0.01 mg/kg to 0.15 mg/kg.

EFSA assessed the applications and the evaluation reports as required by Article 10 of the MRL regulation. EFSA identified data gaps, which were requested from both the EMSs France and Italy. On 11 December 2018 and 1 March 2019, France and Italy respectively, submitted the requested information in the form of an evaluation report, which replaced the previously submitted versions.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC, the data evaluated under previous MRL assessments and the additional data provided by the EMS in the framework of this application, the following conclusions are derived.

The metabolism of emamectin benzoate following foliar application was investigated in crops belonging to the groups of fruit crops, leafy crops and cereals.

Studies investigating the effect of processing on the nature of emamectin benzoate (hydrolysis studies) demonstrated that the active substance significantly degrades under standard hydrolysis condition (ca. 20%) to MSB1a, AB1a and several unknown compounds.

As the proposed uses of emamectin benzoate are on permanent crops, investigations of residues in rotational crops are not required.

Based on the metabolic pattern identified in metabolism studies, hydrolysis studies, the toxicological significance of metabolites and degradation products, the residue definition for enforcement for plant products was set as emamectin benzoate B1a, expressed as emamectin (Regulation (EU) No 396/2005); for risk assessment recently EFSA proposed the following residue definition: Sum of emamectin B1a, emamectin B1b, 8,9-Z-MAB1a, plus 3 times AB1a, plus 3 times MFB1a and 3 times FAB1a, expressed as emamectin (ongoing MRL review).

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

Sufficiently validated analytical methods based on liquid chromatography with tandem mass spectrometry (LC–MS/MS) are available to quantify residues in the crops assessed in this application according to the enforcement residue definition. The methods enable quantification of residues at or above 0.001 mg/kg in the crops assessed (LOQ).

The available residue trials are sufficient to derive MRL proposal of 0.15 mg/kg for kiwi and peaches.

Residues of emamectin benzoate in commodities of animal origin were not assessed since the crops under consideration in this MRL application are normally not fed to livestock.

The toxicological profile of emamectin benzoate was assessed in the framework of the EU pesticides peer review under Directive 91/414/EEC (EFSA, 2012) 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 are of similar toxicity as the parent active substance.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). The short-term exposure did not exceed the ARfD for the crops assessed in this application. The estimated long-term dietary intake was in the range of 15.2–93.9% of the ADI.

EFSA concluded that the proposed use of emamectin benzoate on kiwi and peaches will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers’ health.

EFSA proposes to amend the existing 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.
### Enforcement residue definition:

Emamectin B1a benzoate, expressed as emamectin (Regulation (EU) No 396/2005)

| Code^{(a)} | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|------------|-----------|------------------------|-------------------------|------------------------|
| 0162010    | Kiwi      | 0.01*                  | 0.15                    | The submitted data are sufficient to derive a MRL proposal for the SEU use. Risk for consumers unlikely |
| 0140030    | Peaches   | 0.03                   | 0.15                    | The submitted data are sufficient to derive a MRL proposal which is based on the more critical residue trials from NEU. Risk for consumers unlikely |

MRL: maximum residue level; SEU: southern Europe; NEU: northern Europe.

*: 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.
Assessment

The detailed description of the intended uses of emamectin benzoate in peaches and kiwi, which are the basis for the current maximum residue level (MRL) application, is reported in Appendix A.

Emamectin is the ISO common name for a mixture of emamectin B₁₉ (≥90%) and emamectin B₁₆ (<10%): (10E,14E,16E,22Z)-(1R,4S,5S,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[15.6.1.14,8.020,24]pentacosa-10,14,16,22-tetraene)-6-spiro-2'-(5',6'-dihydro-2'H-pyran)-12-yl2,6-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,5S,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[15.6.1.14,8.020,24]pentacosa-10,14,16,22-tetraene)-6-spiro-2'-(5',6'-dihydro-2'H-pyran)-12-yl2,6-dideoxy-3-O-methyl-4-O-(2,4,6-trideoxy-3-O-methyl-4-methylamino-α-L-lyxo-hexopyranosyl)-α-L-arabinino-hexopyranoside(ETH)-3-(2-chlorothiazol-5-ylmethyl)-5-methyl-[1,3,5]oxadiazinan-4-ylidene-N-nitroamine; respectively (IUPAC).

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

Emamectin benzoate was evaluated in the framework of Directive 91/414/EEC in accordance with Commission Regulation (EU) No 188/2011 with the Netherlands designated as rapporteur Member State (RMS) for the representative use as an insecticide after foliar applications on grapes, tomatoes, peppers, cucurbits and lettuces, outdoor and/or indoor, depending on the vegetable. The draft assessment report (DAR) prepared by the RMS (Netherlands, 2008, 2012) has been peer reviewed by European Food Safety Authority (EFSA, 2012). Emamectin benzoate was approved for the use as insecticide on 1 May 2014.

The EU MRLs for emamectin benzoate are established in Annex IIIA of Regulation (EC) No 396/2005. The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) is currently ongoing. EFSA has previously issued reasoned opinions on the modification of MRLs for emamectin benzoate (EFSA 2009, 2011, 2018). The proposals from these reasoned opinions have been considered by the European Commission and forwarded to EFSA on 9 November 2015. To accommodate for the intended use of emamectin benzoate, the EMS-FR proposed to raise the existing MRL from 0.03 mg/kg to 0.09 mg/kg.

A second request was submitted by Syngenta to the competent national authority in Italy (EMS-IT) to modify the MRL emamectin benzoate in kiwi. The EMS-IT drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005 (France, 2015), which was submitted to the European Commission and forwarded to EFSA on 5 March 2015. To accommodate for the intended use of emamectin benzoate, the EMS-IT proposed to raise the existing MRL from 0.03 mg/kg to 0.09 mg/kg.

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

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 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: http://ec.europa.eu/food/plant/pesticides/pesticides-database/public/?event=pesticide.residue.selection&language=EN
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 spirotetratrom in or on certain products. OJ L 96, 5.4.2013, p. 1–30.
EFSA assessed the application and the evaluation reports as required by Article 10 of the MRL regulation. EFSA identified data gaps, which were requested from both the EMSs France and Italy. On 11 December 2018 and 1 March 2019, France and Italy, respectively, submitted the requested information in revised evaluation reports, which replaced the previous versions.

EFSA based its assessment on the revised evaluation reports submitted by the EMS-FR and the EMS-IT (France, 2015; Italy, 2015), the DAR and its final addendum prepared under Directive 91/414/EEC (Netherlands, 2008, 2012), the conclusion on the peer review of the pesticide risk assessment of the active substance emamectin (EFSA, 2012), the European Commission review report on emamectin (European Commission, 2013), the JMPR Evaluation report (FAO, 2011), EFSA scientific reports and reasoned opinions (EFSA, 2009, 2011, 2018).

For this application, the data requirements established in Regulation (EU) No 544/20117 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, 2013). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011.8

As the review of the existing MRLs under Article 12 of Regulation 396/2005 is not yet finalised, the conclusions reported in this reasoned opinion may need to be reconsidered in the light of the outcome of the MRL review.

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

The evaluation reports submitted by the EMS-FR and EMS-IT (France, 2015; Italy, 2015) 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 B1a benzoate following foliar application was investigated in crops belonging to the groups of fruit crops, leafy crops and cereals/grass in the framework of the EU pesticides peer review (EFSA, 2012). Emamectin B1a benzoate was extensively metabolised, forming a number of photodegradation products which were mainly observed in leafy crops (lettuce and cabbages). Emamectin B1a was the predominant compound (3–22% of total radioactive residue (TRR), at preharvest interval (PHI) ≤ 1 day). The different photodegradation products (also referred to as ‘mectin-like’ fraction or photodegradation metabolites, consisting of e.g. 8,9-Z-MAB1a, FAB1a, MF1a, AB1a) individually were present in low levels, but together represented significant amount (up to 20% of TRR). In fruit crops (pears), emamectin B1a was the only compound identified; photodegradation metabolites were not identified in the fruits (EFSA, 2012).

For the intended use in kiwi and peaches, plant metabolism is considered to be sufficiently addressed.

1.1.2. Nature of residues in rotational crops

Since kiwi and peaches are permanent crops, the assessment of the nature of residues in rotational crops was not required.

1.1.3. Nature of residues in processed commodities

Standard hydrolysis studies simulating processing conditions representative of pasteurisation, boiling and sterilisation were assessed in the framework of the EU pesticides peer review (EFSA,

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7 Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances. OJ L 155, 11.6.2011, p. 1–66.
8 Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.
The compound was found to degrade significantly under standard hydrolysis condition (ca. 20%) to MSB1a, AB1a and several unknown compounds.

### 1.1.4. Methods of analysis in plants

The EU pesticide peer review concluded that an analytical method using liquid chromatography with tandem mass spectrometry (LC–MS/MS) was sufficiently validated for one ion transition on high water, high acid and high oil content matrices, dry commodities and wheat straw with individual LOQ of 0.001 mg/kg for all components of the residue definition for monitoring and risk assessment (EFSA, 2012). Independent laboratory validation (ILV) was provided only for high water content commodities (EFSA, 2012). Confirmatory methods are available for all the above mentioned four groups of commodities (EFSA, 2018).

Thus, for kiwi and peaches, crops belonging to the crop group characterised as matrices with high acid and high water content, sufficiently validated analytical methods are available for enforcing the proposed MRL for emamectin.

### 1.1.5. Stability of residues in plants

The storage stability of emamectin (B1a and B1b) and its relevant photodegradation metabolites under frozen conditions (−20°C) was demonstrated for at least 18 months in high water- and dry/high starch content commodities (EFSA, 2012).

In the context of current application, the applicant submitted a new storage stability study in orange which is relevant for the setting of MRL in kiwi (Italy, 2015). This new study demonstrated that emamectin (B1a and B1b) and its relevant photodegradation metabolites were stable at −18°C for at least 18 months in high acid content commodities.

### 1.1.6. Proposed residue definitions

Based on the metabolism studies submitted in primary crops, rotational crops and the studies addressing the nature of residues in processed commodities, the following residue definitions have been used for the current MRL proposals:

- **Residue definition for enforcement:**
  Emamectin benzoate B1a, expressed as emamectin (Regulation (EU) No 396/2005)

- **Residue definition for risk assessment:**
  Sum of emamectin B1a, emamectin B1b, 8,9-Z-MAB1a, plus 3 times AB1a, plus 3 times MFB1a and 3 times FAB1a, expressed as emamectin (EFSA, 2018).

The risk assessment residue definition was derived on a provisional basis, pending the finalisation of the MRL review. It is noted that the residue definitions (enforcement and risk assessment) will be revised following the MRL review under Article 12 of Regulation (EC) No 396/2005.

The MRL proposals derived in the framework of the current assessment (which are derived based on the existing residue definitions) may need to be reviewed, in case the residue definitions will be revised following the MRL review under Article 12 of Regulation (EC) No 396/2005.

### 1.2. Magnitude of residues in plants

#### 1.2.1. Magnitude of residues in primary crops

In support of the MRL applications, the applicants submitted residue trials performed in kiwi and peaches. All samples were analysed for all the components included in the residue definition for enforcement and risk assessment. According to the assessment of the EMS-FR and EMS-IT, the analytical methods used to analyse the residue trial samples were sufficiently validated and fit for purpose (France, 2015; Italy, 2015).

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9 In the Member States consultation on the draft Art 12 Reasoned Opinion the following new residue definitions were agreed:

- **Enforcement:** Emamectin B1a and its salts, expressed as emamectin B1a (free base);
- **Risk assessment:** Sum of emamectin B1a, emamectin B1b, 8,9-Z-MAB1a, plus 3 times AB1a, plus 3 times MFB1a and 3 times FAB1a, expressed as emamectin B1a (free base).
The samples of these residue trials were stored under conditions for which integrity of the samples has been demonstrated.

The available studies are sufficient to derive a MRL proposal for the crops under consideration.

**Kiwi**

(Southern Europe (SEU) Good Agricultural Practice (GAP): 3 × 19 g/ha (expressed as emamectin benzoate) at 7 days interval, PHI 7 days)

The applicant submitted eight SEU residue trials. All trials are decline studies which were performed with and without oil (0.25%) on the same plot. In each sample the residue concentration of each component of the residue definition for enforcement and risk assessment were measured at PHI 3, 7 and 14 days in each of the following portions: whole-fruit, peel and flesh. In almost all portions, the residue levels of emamectin B₁b and photodegradation metabolites were below the LOQ.

Since the residue levels of trials treated with and without oil are comparable, the values from trials without oil were used for calculating MRL proposal and risk assessment values. Furthermore, EFSA followed the EMS approach selecting, when relevant, the highest residue level in the whole fruit even when the value was related to longer PHI than the one defined in the GAP.

**Peaches**

(SEU and northern Europe (NEU) GAP: 3 × 38 g/ha (expressed as emamectin benzoate) at 7 days interval, PHI 3 days)

The applicant submitted 12 residue trials (8 SEU and 4 NEU). For each trial, two different formulations were used: a soluble granule formulation containing 9.5 g/kg emamectin benzoate and another formulation containing in addition 0.25% w/v Heliosol as an adjuvant. The results indicate that the adjuvant does not have an effect on the residues levels. All trials are decline studies where the levels of each chemical part of the residue definition for enforcement and risk assessments were measured at PHI 1, 3, 7 and 14 days in the whole fruit. In most samples, the residue levels of emamectin B₁b and photodegradation metabolites were below the LOQ. The residue levels of trials treated without oil were higher than those with oil, particularly for NEU use. The values from trials without oil were used for calculating MRL proposal and risk assessment values.

The EMS (France, 2015) stated that the SEU and NEU data sets are statistically comparable and consequently the MRL proposal was derived from the pooled data set. However, EFSA calculated separate MRL proposals for SEU and NEU uses since different light exposures may impact the levels of photodegradation metabolites formed.

1.2.2. **Magnitude of residues in rotational crops**

Kiwi and peaches are permanent crops and therefore studies on rotational crops are not required.

1.2.3. **Magnitude of residues in processed commodities**

The residue trials in kiwi allowed deriving peeling factors (Italy, 2015) which provide evidence that the residues in the peeled fruit are lower than the residues in the unpeeled fruit.

1.2.4. **Proposed MRLs**

The available residue trials are sufficient to derive MRL proposals for kiwi and peaches (Appendix B.4). In Section 3, EFSA assessed whether residues on this crop resulting from the intended use are likely to pose a consumer health risk.

2. **Residues in livestock**

Not relevant as crops under consideration are not used for feed purposes.

3. **Consumer risk assessment**

EFSA performed a dietary risk assessment using revision 2 of the EFSA PRIMo.

For further details on the exposure calculations, a screenshot of the Report sheet of the PRIMo is presented in Appendix C.
Short-term (acute) dietary risk assessment

The short-term exposure assessment for emamectin was performed in accordance with the internationally agreed methodology. The calculation was based on the highest residue (HR) derived from supervised field trials submitted in the current application reflecting the residue definition for risk assessment (Appendix D.1).

The short-term exposure did not exceed the ARfD for any of the crops assessed in this application (the estimated exposure for peaches and kiwis amounted to 47.5% and 32.2% of the ARfD, respectively).

Long-term (chronic) dietary risk assessment

The calculation was based on the median residue concentration (STMR) derived from supervised field trials submitted in the current application, reflecting the residue definition for risk assessment. In addition, STMR values from previous published EFSA opinions (EFSA, 2009, 2011, 2018) and from FAO (2011) were included in the dietary exposure assessment. Furthermore, for other food commodities of plant and animal origin the MRL currently implemented in EU Regulation 2018/1514 were also used. The MRL values were used considering that the MRL review for emamectin is ongoing and therefore to cover potential uses that are currently not considered. The complete list of input values used in the exposure calculations is presented Appendix D.1.

The estimated long-term dietary intake was in the range of 15.2–93.9% of the ADI. Peaches and kiwis contributed to a maximum of 3.4% and 1.6% of the ADI, respectively.

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

4. Conclusion and Recommendations

The data submitted in support of this MRL application were found to be sufficient to derive an MRL proposal for kiwi and peaches.

EFSA concluded that the proposed use of emamectin benzoate will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers’ health.

The MRL recommendations are summarised in Appendix B.4.

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Abbreviations

a.s. active substance
ADI acceptable daily intake
ARfd acute reference dose
BBCH growth stages of mono- and dicotyledonous plants
bw body weight
CAC Codex Alimentarius Commission
CF conversion factor for enforcement to risk assessment residue definition
cGAP critical GAP
CXL Codex maximum residue limit
DAR draft assessment report
DAT days after treatment
EC emulsiifiable concentrate
EMS evaluating Member State
eq residue expressed as a.s. equivalent
FAO Food and Agriculture Organization of the United Nations
GAP Good Agricultural Practice
HR highest residue
IEDI international estimated daily intake
IESTI international estimated short-term intake
ILV independent laboratory validation
InChiKey International Chemical Identifier Key
ISO International Organisation for Standardisation
IUPAC International Union of Pure and Applied Chemistry
| Acronym | Description |
|---------|-------------|
| JMPR | Joint FAO/WHO Meeting on Pesticide Residues |
| LC | liquid chromatography |
| LOQ | limit of quantification |
| MRL | maximum residue level |
| MS/MS | tandem mass spectrometry detector |
| MW | molecular weight |
| NEU | northern Europe |
| OECD | Organisation for Economic Co-operation and Development |
| PBI | plant-back interval |
| PF | processing factor |
| PHI | pre-harvest interval |
| PRIMo | (EFSA) Pesticide Residues Intake Model |
| 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 |
| SEU | southern Europe |
| SG | water-soluble granule |
| SMILES | simplified molecular-input line-entry system |
| STMR | supervised trials median residue |
| TRR | total radioactive residue |
| WG | water-dispersible granule |
| 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 | Pest or Group of pests controlled | Preparation | Application | Application rate per treatment | Remarks |
|-----------------------|--------------------------|----------------------------------|-------------|-------------|-------------------------------|---------|
|                       |                          |                                  | Type (b)    | Conc. a.s. (g/kg) | Method kind | Range of growth stages & season (c) | Number min–max | Interval between application (min) | g a.s./hL min–max | Water L/ha min–max | Rate | Unit | PHI (days) (d) | |
| Peaches               | NEU and SEU (NEU-EU: SI, HU SEU-EU: IT, GR) | Laspeyresia molesta, Cydia molesta, Anarsia lineatella | Foliar spray | 9.5 | BBCH 69–89 | 3 | 7 | – | 500–1,500 | 38 | g a.s/ha | 3 | Application rate expressed as emamectin benzoate with and without oil (0.25%) |
| Kiwi                  | SEU                      | Leafroller Argyrotaenia jungiana | Foliar spray | 9.5 | BBCH 71–89 | a) 3 | 7 | – | 500–1,500 | 19 | g a.s/ha | 7 | Application rate expressed as emamectin benzoate max. total rate per crop/season: 19 g/ha with and without oil (0.25%) |

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

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

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

(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.

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

B.1. Residues in plants

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

| Metabolism studies, methods of analysis and residue definitions in plants |
| Primary crops (available studies) | Crop groups | Crops | Applications | Sampling |
|----------------------------------|-------------|-------|--------------|---------|
| Fruit crops | Pears | Foliar, 3 × 16.8 or 168 g/ha, interval 7 days | 2 DAT_1; 14, 28 DAT_3 |
| Leafy crops | Lettuce | Foliar, 8 × 16.8 or 84 g/ha, interval 7 days | 2 DAT_1; 1, 3, 7, 10 DAT_8 |
| | Head cabbage | Foliar, 8 × 16.8 or 84 g/ha, interval 7 days | 2 DAT_1; 1, 3, 7, 10 DAT_8 |
| Cereals/grass | Maize | Foliar, 6 × 16.8 or 84 g/ha, interval 3-5 days | 2 DAT_1; 1, 3, 7 DAT_6 |

Comments: [3, 7, 11, 13, 23-14C]-emamectin B_1a benzoate or [23-14C]-emamectin B_1a benzoate (pear study) variant. Reference: EFSA (2012)

| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s) | PBI (DAT) |
|-------------------------------------|-------------|---------|----------------|-----------|
| Root/tuber crops | Carrots | Bare soil, 6 × 168 g/ha, interval 7 days | 30, 141, 365 |
| Leafy crops | Lettuce | Bare soil, 6 × 168 g/ha, interval 7 days | 30, 120, 365 |
| Cereal (small grain) | Barley | Bare soil, 6 × 168 g/ha, interval 7 days | 30, 141, 365 |

Comments: [3, 7, 11, 13, 23-14C]-emamectin B_1a benzoate variant. Reference: EFSA (2012)

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

Comment: [23-14C]-emamectin B_1a benzoate variant. Reference: EFSA (2012) Emamectin B_1a benzoate underwent hydrolysis (ca 20%) forming the monosaccharide MSB_1a (pH 5, 100°C and pH 6, 120°C), aglycone milbemectin B (pH 6, 120°C) and AB_1a (pH 6, 120°C). All degradation products were individually < 10% of applied radioactivity.

DAT_1, DAT_n days after the first, days after nth treatment; PHI, plant-back interval.
Can a general residue definition be proposed for primary crops? | Yes | EFSA (2012)
---|---|---
Rotational crop and primary crop metabolism similar? | No | Degradation products in rotational crops were characterised as natural products only: Parent or ‘mectin-like’ degradates were not detected EFSA (2012)
Residue pattern in processed commodities similar to residue pattern in raw commodities? | No | Different degradation profile EFSA (2012)
Plant residue definition for monitoring (RD-Mo) | | Emamectin benzoate B1a, expressed as emamectin (Regulation (EU) No 396/2005)
Plant residue definition for risk assessment (RD-RA) | | Sum of emamectin B1a, emamectin B1b, 8,9-Z-MAB1a, plus 3 times AB1a, plus 3 times MFB1a and 3 times FAB1a, expressed as emamectin (EFSA, 2018)
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs) | | Matrices with high water, high oil and high acid content and dry matrices: LC–MS/MS, LOQ of 0.001 mg/kg for all components of the residue definition for monitoring and risk assessment (EFSA, 2012) ILV available for high water content matrices (EFSA, 2012) Confirmatory method available for all the above four groups of commodities.

LC–MS/MS: liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; ILV: independent laboratory validation.

### 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 | Tomato, Beans with pod | –20 | 18 Months | Emamectin B1a benzoate, Emamectin B1b benzoate, 8,9-Z MAB1a, AB1a, MFB1a, and FAB1a | EFSA (2012) |
| | Dry/High starch | Potato | –20 | 18 Months | | |
| | High acid content | Whole orange | –18 | 18 Months | | Italy (2015) |
| Processed products | – | – | – | – | – |
| Others | – | – | – | – | – |
## B.1.2. Magnitude of residues in plants

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

| Commodity | Region/Indoor(a) | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source | Calculated MRL (mg/kg) | HR(b) (mg/kg) | STMR(c) (mg/kg) | CF(d) |
|-----------|-----------------|---------------------------------------------------------------|----------------|------------------------|--------------|----------------|-------|
| Kiwi      | SEU (outdoor without oil) | **Mo**: 0.006, 0.010, 0.010, 0.020, 0.022, 0.036, 0.045, 0.067 **RA**: 0.016, 0.020, 0.020, 0.030, 0.032, 0.046, 0.055, 0.077 | Residue trials on kiwi compliant with SEU GAP. Values underlined refer to a PHI of 14 days and they were used since they were higher than values measured at PHI of 7 days (which represent the cGAP). Trials performed with oil (0.25%) do not have impact neither on MRL nor on risk assessment. Therefore, residue values from trials without oil were used for calculating MRL proposal and risk assessment values | **0.15** | **Mo**: 0.07 **RA**: 0.08 | **Mo**: 0.02 **RA**: 0.03 | – |
|           | SEU (outdoor with oil) | **Mo**: 0.010, 0.011, 0.011, 0.024, 0.026, 0.048, 0.055, 0.074 **RA**: 0.020, 0.021, 0.021, 0.034, 0.036, 0.058, 0.065, 0.084 | | | | | |

**Residue definition for enforcement:**
Emamectin benzoate B1a, expressed as emamectin (Regulation (EU) No 396/2005) (residue definition may change in the light of the outcome of the MRL review)

**Residue definition for risk assessment:**
Sum of emamectin B1a, emamectin B1b, 8,9-Z-MAB1a, plus 3 times AB1a, plus 3 times MFB1a and 3 times FAB1a, expressed as emamectin (France, 2015; EFSA, 2018) (provisionally, residue definition to be reconsidered in the light of the outcome of the MRL review)

**Note:**
For monitoring, the individual residue values of emamectin B1a benzoate was recalculated to the emamectin B1a free base by adjusting for the molecular weight. In addition, the residue level of Emamectin B1b (expressed as free base) was summed up.
For risk assessment, same as for monitoring and in addition the photodegradation metabolites were expressed as emamectin by using the following procedure: 8,9-Z-MBA1 was adjusted using a MW conversion factor (CF) of 1; MFB1a was first adjusted with a MW CF of 0.97 and then by a relative potency factor (RPF) of 3; FAB1a was first adjusted with a MW CF of 0.98 and then by a RPF of 3; AB1a was first adjusted with a MW CF of 1.02 and then by a RPF of 3. Ultimately, all the calculated values, described as above, were summed up.

**Note 1:** The corresponding MRL proposals for the residue definition agreed in the draft Art 12 Reasoned Opinion are identical to the ones presented in the table below.
| Commodity   | Region/Indoor\(^{(a)}\) | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source                                                                 | Calculated MRL (mg/kg) | HR\(^{(b)}\) (mg/kg) | STMR\(^{(c)}\) (mg/kg) | CF\(^{(d)}\) |
|-------------|--------------------------|---------------------------------------------------------------|--------------------------------------------------------------------------------|------------------------|-----------------------|------------------------|----------|
| Peaches     | SEU (outdoor without oil)| Mo: 0.003, 0.004, 0.006, 0.011, 0.013, 0.022, 0.026 RA: 0.013, 0.013, 0.016, 0.020, 0.023, 0.034, 0.039 | Residue trials on peaches compliant with SEU GAP The use of oil (0.25%) has limited impact on MRL and on risk assessment. Therefore, residue values from trials without oil were used for calculating MRL proposal and risk assessment values | 0.05                   | Mo: 0.03 RA: 0.04     | Mo: 0.01 RA: 0.02     | –        |
|             | SEU (outdoor with oil)   | Mo: 0.004, 0.007, 0.010, 0.013, 0.014, 0.022, 0.022 RA: 0.013, 0.017, 0.017, 0.024, 0.025, 0.035, 0.039, 0.044 |                                                                                   | 0.04                   | Mo: 0.02 RA: 0.04     | Mo: 0.01 RA: 0.02     | –        |
|             | NEU (outdoor without oil)| Mo: 0.014, 0.017, 0.021, 0.071 RA: 0.030, 0.033, 0.034, 0.081 | Residue trials on peaches compliant with NEU GAP                                                                 | 0.15                   | Mo: 0.07 RA: 0.08     | Mo: 0.02 RA: 0.03     | –        |
|             | NEU (outdoor with oil)   | Mo: 0.004, 0.006, 0.011, 0.012 RA: 0.016, 0.016, 0.022, 0.044 | The use of oil (0.25%) leads to lower MRLs and risk assessment values. Therefore, residue values from trials without oil were used for calculating MRL proposal and risk assessment values | 0.03                   | Mo: 0.01 RA: 0.04     | Mo: 0.01 RA: 0.02     | –        |

MRL: maximum residue level; GAP: Good Agricultural Practice; cGAP: critical GAP.
*a*: Indicates that the MRL is proposed at the limit of quantification.
(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Indoor: indoor EU trials or Country code: if non-EU trials.
(b): Highest residue. The highest residue for risk assessment refers to the whole commodity and not to the edible portion.
(c): Supervised trials median residue. The median residue for risk assessment refers to the whole commodity and not to the edible portion.
(d): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.
B.1.2.2. Residues in rotational crops

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

No

Rotational crop matrices (barley, lettuce, carrot) at plant-back intervals of 30, 120–141 and 365 days, total radioactivity ranged from < 0.003 to 0.030 mg eq/kg. No parent compound (emamectin B1a benzoate) and no ‘mectin-like’ degradates could be detected. (EFSA, 2012)

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

Not triggered

EFSA (2012)

B.1.2.3. Processing factors

| Processed commodity | Number of valid studies\(^{(a)}\) | Processing Factor (PF) | Median PF | Comment/Source |
|---------------------|----------------------------------|------------------------|-----------|----------------|
| Kiwi, pulp          | 8                                | 0.03, 0.09, 0.07, 0.18, 0.04, 0.08, 0.18, 0.29 | 0.08      | 14.3 Italy (2015) |

\(^{(a)}\): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur).

\(^{(b)}\): Conversion factor for risk assessment in the processed commodity; median of the individual conversion factors for each processing residues trial.

B.2. Residues in livestock

Not relevant

B.3. Consumer risk assessment

ARfD

0.01 mg/kg bw (European Commission, 2013)

Highest IESTI, according to EFSA PRIMo

Peaches: 47.5% of ARfD
Kiwi: 32.2% of ARfD

Assumptions made for the calculations

The calculation is performed only for the crops under assessment, considering the highest residue levels from the supervised field trials on kiwi and peaches, reflecting the residue definition for risk assessment
ADIs

Highest IEDI, according to EFSA PRIMO

Assumptions made for the calculations

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; WHO: World Health Organization; STMR: supervised trials median residue; MRL: maximum residue level.

B.4. Recommended MRLs

| Code(a) | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|---------|-----------|------------------------|-------------------------|-----------------------|
| 0162010 | Kiwi      | 0.01*                  | 0.15                    | The submitted data are sufficient to derive a MRL proposal for the SEU use. Risk for consumers unlikely |
| 0140030 | Peaches   | 0.03                   | 0.15                    | The submitted data are sufficient to derive a MRL proposal which is based on the more critical residue trials from NEU. Risk for consumers unlikely |

MRL: maximum residue level; SEU: southern Europe; NEU: northern Europe.

*: 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.
Appendix C – Pesticide Residue Intake Model (PRIMo)

Emamectin

| Status of the active substance | Code no. |
|--------------------------------|----------|
|                               | LOQ (mg/kg bw) | Proposed LOQ |
| Toxicological end points      | ADI (mg/kg bw per day) | ARfD (mg/kg bw) |
| Source of ADI:                | COM       | Source of ARfD: | COM       |
| Year of evaluation:           | 2013      | Year of evaluation: | 2013      |
| ADI (mg/kg bw per day):       | 0.0005    | ARfD (mg/kg bw):  | 0.01      |
| Source of ADI:                | COM       | Source of ARfD: | COM       |
| Year of evaluation:           | 2013      | Year of evaluation: | 2013      |

The risk assessment has been performed on the basis of the MRLs collected from Member States in April 2006. For each pesticide/commodity the highest national MRL was identified (proposed temporary MRL = pTMRL).

The pTMRLs have been submitted to EFSA in September 2006.

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs, were below the ADI. A long-term intake of residues of Emamectin is unlikely to present a public health concern.

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Modification of existing MRLs for emamectin in peaches and kiwi
The acute risk assessment is based on the ARfD. For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS, an average European unit weight was used for the IESTI calculation.

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

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

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

| Highest % of ARfD/ADI | Commodities | pTMRL/threshold MRL (mg/kg) | Highest % of ARfD/ADI | Commodities | pTMRL/threshold MRL (mg/kg) | Highest % of ARfD/ADI | Commodities | pTMRL/threshold MRL (mg/kg) | Highest % of ARfD/ADI | Commodities | pTMRL/threshold MRL (mg/kg) |
|-----------------------|-------------|-----------------------------|-----------------------|-------------|-----------------------------|-----------------------|-------------|-----------------------------|-----------------------|-------------|-----------------------------|
| 47.5                  | Peaches     | 0.06 -                      | 34.8                  | Peaches     | 0.06 -                      | 14.0                  | Peaches     | 0.06 -                      | 10.8                  | Peaches     | 0.06 -                      |
| 32.2                  | Kiwi        | 0.06 -                      | 24.8                  | Kiwi        | 0.06 -                      | 7.7                   | Kiwi        | 0.06 -                      | 6.0                   | Kiwi        | 0.06 -                      |

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

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

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

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

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

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

### D.1. Consumer risk assessment

| Commodity                  | Chronic risk assessment | Acute risk assessment |
|---------------------------|-------------------------|-----------------------|
|                           | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment               |
| Kiwi                      | 0.03 STMR<sub>RA</sub>  |                       | 0.08 HR<sub>RA</sub> |                       |
| Peaches                   | 0.03 STMR<sub>RA</sub> (NEU use) |           | 0.08 HR<sub>RA</sub> (NEU use) | Acute risk assessment is performed only for the crops under assessment |
| Citrus fruit              | 0.003 STMR<sub>RA</sub> (EFSA, 2011)<sup>(a)</sup> |           |                       |                       |
| Pome fruit                | 0.005 STMR<sub>RA</sub> (EFSA, 2009)<sup>(a)</sup> |           |                       |                       |
| Apricots                  | 0.008 STMR<sub>RA</sub> (EFSA, 2011)<sup>(a)</sup> |           |                       |                       |
| Plums                     | 0.003 STMR<sub>RA</sub> (EFSA, 2011)<sup>(a)</sup> |           |                       |                       |
| Table grapes              | 0.0025 STMR<sub>RA</sub> (FAO, 2011)<sup>(b)</sup> |           |                       |                       |
| Wine grapes               | 0.0025 STMR<sub>RA</sub> (FAO, 2011)<sup>(b)</sup> |           |                       |                       |
| Strawberries              | 0.009 STMR<sub>RA</sub> (EFSA, 2009)<sup>(a)</sup> |           |                       |                       |
| Tomatoes                  | 0.006 STMR<sub>RA</sub> (EFSA, 2009)<sup>(a)</sup> |           |                       |                       |
| Peppers                   | 0.003 STMR<sub>RA</sub> (EFSA, 2009)<sup>(a)</sup> |           |                       |                       |
| Aubergines                | 0.002 STMR<sub>RA</sub> (EFSA, 2009)<sup>(a)</sup> |           |                       |                       |
| Cucurbits-edible peel     | 0.001 STMR<sub>RA</sub> (EFSA, 2009)<sup>(a)</sup> |           |                       |                       |
| Cucurbits-inedible peel   | 0.002 STMR<sub>RA</sub> (EFSA, 2009)<sup>(a)</sup> |           |                       |                       |
| Broccoli                  | 0.001 STMR<sub>RA</sub> (EFSA, 2009)<sup>(a)</sup> |           |                       |                       |
| Cauliflower               | 0.001 STMR<sub>RA</sub> (EFSA, 2009)<sup>(a)</sup> |           |                       |                       |
| Head cabbage              | 0.001 STMR<sub>RA</sub> (EFSA, 2009)<sup>(a)</sup> |           |                       |                       |
| Chinese cabbage           | 0.017 STMR<sub>RA</sub> (EFSA, 2018)<sup>(c)</sup> |           |                       |                       |
| Kale                      | 0.017 STMR<sub>RA</sub> (EFSA, 2018)<sup>(c)</sup> |           |                       |                       |
| Other leafy brassica      | 0.017 STMR<sub>RA</sub> (EFSA, 2018)<sup>(c)</sup> |           |                       |                       |
| Lettuces and other salad plantsexcept scarole | 0.272 STMR<sub>RA</sub> (EFSA, 2009)<sup>(a)</sup> |           |                       |                       |
| Scarole                   | 0.03 STMR<sub>RA</sub> (EFSA, 2009)<sup>(a)</sup> |           |                       |                       |
| Herbs and edible flowers  | 0.272 STMR<sub>RA</sub> (EFSA, 2009)<sup>(a)</sup> |           |                       |                       |
| Beans (with pods)         | 0.017 STMR<sub>RA</sub> (EFSA, 2018)<sup>(c)</sup> |           |                       |                       |
| Peas (with pods)          | 0.017 STMR<sub>RA</sub> (EFSA, 2018)<sup>(c)</sup> |           |                       |                       |
| Globe artichokes          | 0.027 STMR<sub>RA</sub> (EFSA, 2009)<sup>(a)</sup> |           |                       |                       |
| Mammalian meat<sup>(d)</sup> | 0.002 STMR<sub>RA</sub> (FAO, 2011)<sup>(b)</sup> |           |                       |                       |
| Mammalian fat<sup>(d)</sup> | 0.002 STMR<sub>RA</sub> (FAO, 2011)<sup>(b)</sup> |           |                       |                       |
| Mammalian liver<sup>(d)</sup> | 0.006 STMR<sub>RA</sub> (FAO, 2011)<sup>(b)</sup> |           |                       |                       |
| Mammalian kidney<sup>(d)</sup> | 0.006 STMR<sub>RA</sub> (FAO, 2011)<sup>(b)</sup> |           |                       |                       |
| Mammalian edible offal<sup>(d)</sup> | 0.006 STMR<sub>RA</sub> (FAO, 2011)<sup>(b)</sup> |           |                       |                       |
| Milk and cream products    | 0.0005 STMR<sub>RA</sub> (FAO, 2011)<sup>(b)</sup> |           |                       |                       |
| Other food commodities of plant and animal origin | MRL Regulation (EU) No 2018/1514 |               |                       |                       |

**Notes:**

- **STMR:** supervised trials median residue; **HR:** highest residue; **Mo:** monitoring; **RA:** risk assessment; **NEU:** northern Europe; **MRL:** maximum residue level.
- **(a):** The median residues (STMR<sub>RA</sub>) refer to emamectin free base. The contribution of the photodegradation metabolites was not considered in the chronic risk assessment as residue data were not available. For monitoring, individual residue values of emamectin B1a benzoate were recalculated to emamectin (free base) using a conversion factor (CF) of 0.97 (EFSA, 2009).
- **(b):** The median residues (STMR<sub>RA</sub>) refer to emamectin B1a benzoate.
- **(c):** For risk assessment, individual residue values of emamectin B1a benzoate were recalculated to emamectin B1a using a molecular weight (MW) CF of 0.88. Since the MW CF for EMA B1b is 0.88 and for the photodegradation metabolites ranged from 0.95 to 1, the individual residues (all < LOQ) of EMA B1b benzoate, 8,9-Z-MBA1a, AB1a, MFB1a, FaB1a were not adjusted to express them as emamectin equivalents prior to be summed up (EFSA, 2018).
- **(d):** Mammalians: swine, bovine, sheep, goats, equine, other farmed animals.
### Appendix E – Used compound codes

| Code/trivial name | IUPAC name/SMILES notation/InChIKey<sup>(a)</sup> | Structural formula<sup>(b)</sup> |
|-------------------|-------------------------------------------------|----------------------------------|
| **emamectin B<sub>1a</sub>**<br> (10E,14E,16E)-<br> (1R,4S,5'S,6S,6'R,8R,12S,13S,20R,21R,24S)-6'-<br> [(5)-sec-butyl]-21,24-dihydroxy-5',11,13,22-<br> tetramethyl-2-oxo-(3,7,19-trioctatetraacyclo<br> [15.6.1.1<sup>4,6</sup>,0<sup>20,24</sup>]<br> pentacosa-10,14,16,22-<br> tetraene)-6-spiro-2'-<br> (5',6'-diydro-2'H-pyran)-<br> 12-yl 2,6-dideoxy-3-O-methyl-4-O-(2,4,6-<br> trideoxy-3-O-methyl-4-methylamino-<br> α-L-arabinohexopyranosyl)-α-L-arabinohexopyranoside | ![Structural formula](image.png) |
| **emamectin B<sub>1b</sub>**<br> (10E,14E,16E)-<br> (1R,4S,5'S,6S,6'R,8R,12S,13S,20R,21R,24S)-21,24-dihydroxy-6'-<br> isopropyl-5',11,13,22-<br> tetramethyl-2-oxo-(3,7,19-trioctatetraacyclo<br> [15.6.1.1<sup>4,6</sup>,0<sup>20,24</sup>]<br> pentacosa-10,14,16,22-<br> tetraene)-6-spiro-2'-<br> (5',6'-diydro-2'H-pyran)-<br> 12-yl 2,6-dideoxy-3-O-methyl-4-O-(2,4,6-<br> trideoxy-3-O-methyl-4-methylamino-<br> α-L-arabinohexopyranosyl)-α-L-arabinohexopyranoside | ![Structural formula](image.png) |
| **emamectin B<sub>1a</sub> benzoate**<br> (10E,14E,16E)-<br> (1R,4S,5'S,6S,6'R,8R,12S,13S,20R,21R,24S)-6'-<br> [(5)-sec-butyl]-21,24-dihydroxy-5',11,13,22-<br> tetramethyl-2-oxo-(3,7,19-trioctatetraacyclo<br> [15.6.1.1<sup>4,6</sup>,0<sup>20,24</sup>]<br> pentacosa-10,14,16,22-<br> tetraene)-6-spiro-2'-<br> (5',6'-diydro-2'H-pyran)-<br> 12-yl 2,6-dideoxy-3-O-methyl-4-O-(2,4,6-<br> trideoxy-3-O-methyl-4-methylamino-<br> α-L-arabinohexopyranosyl)-α-L-arabinohexopyranosidebenzoate | ![Structural formula](image.png) |
| Code/trivial name | IUPAC name/SMILES notation/InChIKey\(^{(a)}\) | Structural formula\(^{(b)}\) |
|------------------|-----------------------------------------------|----------------------------------|
| emamectin \(B_{1b}\) benzoate | \((10E,14E,16E)-\) \((1R,4'S,5'S,6'R,8'R,12S,13S,20R,21R,24S)-21,24\)-dihydroxy-6'-isopropyl-5',11,13,22-tetramethyl-2-oxo-[3,7,19-tri]oxatetraacyclo[15.6.1.1\(^{2,6}\),\(^{10,20,24}\)pentacosan-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-a-\(\alpha\)-lyxo-hexopyranosyl)-a-\(\alpha\)-arabinino-hexopyranoside benzoate | ![EMAMECTIN](image) |
| 8,9-Z-MAB\(_{1a}\) NOA 438376 | \((1'R,25'S,3'S,5'R,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',13,12'-tetramethyl-2'-oxo-5,6-dihydrospiro[pyran-2,6'-[3,7,19]tri]oxatetraacyclo[15.6.1.1\(^{2,6}\),\(^{10,20,24}\)pentacosan-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-\(\alpha\)-lyxo-hexopyranosyl)-a-\(\alpha\)-arabinino-hexopyranoside | ![8,9-Z-MAB](image) |
| FAB\(_{1a}\) NOA 415693 | \((1'R,25'S,3'S,5'R,8'R,10'E,12'S,13'S,14'E,16'Z,20'R,21'R,24'S)-6'-(25)-butan-2-yl-21',24'-dihydroxy-5,11',13,12'-tetramethyl-2'-oxo-5,6-dihydrospiro[pyran-2,6'-[3,7,19]tri]oxatetraacyclo[15.6.1.1\(^{2,6}\),\(^{10,20,24}\)pentacosan-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-\(\alpha\)-lyxo-hexopyranosyl)-a-\(\alpha\)-arabinino-hexopyranoside | ![FAB](image) |
| Code/trivial name | IUPAC name/SMILES notation/InChIKey(a) | Structural formula(b) |
|------------------|-------------------------------------|-----------------------|
| **MFB1a** NOA 415692 | (1'R, 2S, 4'R, 5S, 6R, 8'R, 10'E, 12'S, 13'S, 14'E, 16'E, 20'R, 21'R, 24'S)-6-[[25S]-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^{4,8},9{0',24}]pentacosao[10,14,16,22]tetraen]-12'-yl 2,6-dideoxy-3-O-methyl-4-O-[(2,4,6-trideoxy-4-[formyl(methyl)amino]-3-O-methyl-a-L-lyxo-hexopyranosyl]-a-L-arabinohexopyranoside | ![Structural formula](image1) |
| **AB1a** NOA 438309 | (1'R, 2S, 4'R, 5S, 6R, 8'R, 10'E, 12'S, 13'S, 14'E, 16'E, 20'R, 21'R, 24'S)-6-[[25S]-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^{4,8},9{0',24}]pentacosao[10,14,16,22]tetraen]-12'-yl 4-O-(4-amino-2,4,6-trideoxy-3-O-methyl-a-L-lyxo-hexopyranosyl)-2,6-dideoxy-3-O-methyl-a-L-arabinohexopyranoside | ![Structural formula](image2) |
| **MSB1a** NOA 419150 | (1'R, 2S, 4'R, 5S, 6R, 8'R, 10'E, 12'S, 13'S, 14'E, 16'E, 20'R, 21'R, 24'S)-6-[[25S]-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^{4,8},9{0',24}]pentacosao[10,14,16,22]tetraen]-12'-yl 2,6-dideoxy-3-O-methyl-a-L-arabinohexopyranoside | ![Structural formula](image3) |
| Code/trivial name | IUPAC name/SMILES notation/InChiKey<sup>(a)</sup> | Structural formula<sup>(b)</sup> |
|------------------|-----------------------------------------------|----------------------------------|
| Aglycone milbemectin B NOA 419153 | (1'R,2S,4'S,5S,6'R,8'S,10'E,12'S,13'S,14'E,16'E,20'R,21'R,24'S)-6'-(2S)-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 | ![Structural formula](image) |

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

(a): ACD/Name 2015 ACD/Labs 2015 Release (File version N20E41, Build 75170, 19 December 2014).
(b): ACD/ChemSketch 2015 ACD/Labs 2015 Release (File version C10H41, Build 75059, 17 December 2014).