Review report for the active substance *emamectin*

Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 16 July 2013

in view of the approval of *emamectin* as active substance in accordance with Regulation (EC) No 1107/2009

1. **Procedure followed for the evaluation process**

This review report has been established as a result of the evaluation of the new active substance *emamectin*, made in the context of the work provided for in Articles 5 and 6 of Directive 91/414/EEC\(^1\) concerning the placing of plant protection products on the market, to be read in conjunction with Regulation (EU) No 188/2011\(^2\), laying down detailed rules for the assessment of new active substances and the transitional provisions foreseen in Article 80(1)(a) of Regulation (EC) No 1107/2009, repealing Directive 91/414/EEC, with a view to the possible approval of this substance for the use in plant protection products.

In accordance with the provisions of Article 6(2) of Directive 91/414/EEC, the authorities of the Netherlands received on 23 June 2006 an application from Syngenta Crop Protection AG, hereafter referred to as the applicant, for the inclusion of the active substance *emamectin* in Annex I to the Directive. The authorities of the Netherlands indicated to the Commission on 29 January 2007 the results of a first examination of the completeness of the dossier, with regard to the data and information requirements provided for in Annex II and, for at least one plant protection product containing the active substance concerned, in Annex III to the Directive. Subsequently, and in accordance with the requirements of Article 6(2), a dossier on *emamectin*\(^3\) was distributed to the Member States and the Commission.

The Commission referred the dossier to the Standing Committee on the Food Chain and Animal Health on 13 July 2007, during which the Member States confirmed the receipt of the dossier.

---

\(^2\) OJ L 53, 26.2.2011, p. 51
\(^3\) Data mostly related to the variant *emamectin benzoate*
In accordance with the provisions of Article 6(3), which requires the confirmation at Community level that the dossier is to be considered as satisfying, in principle, the data and information requirements provided for in Annex II and, for at least one plant protection product containing the active substance concerned, in Annex III to the Directive and in accordance with the procedure laid down in Article 20 of the Directive, the Commission confirmed in its Decision 2007/669/EC\(^4\) of 15 October 2007 that these requirements were satisfied.

Within the framework of that decision and with a view to the further organisation of the works related to the detailed examination of the dossier provided for in Article 6(2) and (4) of Directive 91/414/EEC, it was agreed between the Member States and the Commission that the Netherlands would, as rapporteur Member State, carry out the detailed examination of the dossier and report the conclusions of its examination accompanied by any recommendations on the inclusion or non-inclusion and any conditions relating thereto, to EFSA as soon as possible and at the latest within a period of one year.

Following an agreement between the Commission and the European Food Safety Authority (EFSA), the latter organises a peer review for those active substances for which the decision on completeness has been published after June 2002.

In analogy with the provisions of Article 8(1) of Regulation (EC) No 451/2000\(^5\) for existing active substances, the Netherlands submitted on 6 March 2008 to EFSA the report of their examination, hereafter referred to as the draft assessment report, including, as required, a recommendation concerning the possible inclusion of emamectin in Annex I to the Directive.

In analogy with the provisions of Article 8 of Regulation (EC) No 451/2000 for existing active substances and, where applicable, according to the provisions of Article 7 of Regulation (EU) No 188/2011, EFSA organised the consultation on the draft assessment report by all the Member States as well as by Syngenta Crop Protection AG, being the main data submitters, on 5 October 2008 by making it available.

EFSA organised an intensive consultation of technical experts from a certain number of Member States, to review the draft assessment report and the comments received thereon (peer review).

According to the provisions of Article 8(1) of Regulation (EU) No 188/2011, EFSA sent to the Commission its conclusion on the risk assessment [Conclusion regarding the peer review of the pesticide risk assessment of the active substance emamectin (approved: 13 November 2012)\(^6\)]. This conclusion refers to background document A (draft assessment report) and background document B (EFSA peer review report).

According to the provisions of Article 9 of that Regulation, the Commission produced a draft review report on emamectin. The Commission referred this draft referred to the applicant for commenting on 22 March 2013 and on 16 May 2013 to the Standing Committee on the Food Chain and Animal Health, for final examination. The draft review report was finalised in the meeting of the Standing Committee on 16 July 2013.

The present review report contains the conclusions of the final examination by the Standing Committee. Given the importance of the conclusion of EFSA, and the comments and clarifications

---

\(^4\) OJ L 274, 10.10.2007, p. 15.
\(^5\) OJ L 55, 29.2.2000, p. 25
submitted after the conclusion of EFSA (background document C), these documents are also considered to be part of this review report.

2. Purposes of this review report

This review report, including the background documents and appendices hereto, has been developed and finalised in support of Commission Implementing Regulation (EU) No 828/2013\(^7\) concerning the approval of emamectin as active substance under Regulation (EC) No 1107/2009, and to assist the Member States in decisions on individual plant protection products containing emamectin they have to take in accordance with the provisions of that Regulation, and in particular the provisions of Article 29(1) of Regulation (EC) No 1107/2009 and the uniform principles laid down in Regulation (EU) No 546/2011.

This review report provides also for the evaluation required under part I, Section A.2(b) of the above mentioned uniform principles, as well as under several specific sections of chapter B of these principles. In these sections it is provided that Member States, in evaluating applications and granting authorisations, shall take into account the information concerning the requirements of Regulation (EU) No 544/2011, submitted for the purpose of approval of the active substances, as well as the result of the evaluation of those data.

In accordance with the provisions of Article 10 of Regulation (EU) No 188/2011, this review report will be made available to the public.

The information in this review report is, at least partly, based on information which is confidential and/or protected under the provisions of Regulation (EC) No 1107/2009. It is therefore recommended that this review report would not be accepted to support any registration outside the context of that Regulation, e.g. in third countries, for which the applicant has not demonstrated to have regulatory access to the information on which this review report is based.


The overall conclusion from the evaluation is that it may be expected that plant protection products containing emamectin will fulfil the safety requirements laid down in Article 4(1) – (3)\(^8\) of Regulation (EC) No 1107/2009. This conclusion is however subject to compliance with the particular requirements in sections 4, 5, 6 and 7 of this report, as well as to the implementation of the provisions of Article 29(1) of Regulation (EC) No 1107/2009 and the uniform principles laid down in Regulation (EU) No 546/2011, for each emamectin containing plant protection product for which Member States will grant or review the authorisation.

Furthermore, these conclusions were reached within the framework of the uses which were proposed and supported by the data submitter and mentioned in the list of uses supported by available data (attached as Appendix II to this review report).

Extension of the use pattern beyond those described above will require an evaluation at Member State level in order to establish whether the proposed extensions of use can satisfy the requirements

---

\(^7\) OJ L 232, 30.8.2013, p. 23.

\(^8\) read in conjunction with articles 78(3) and 80(1).

The following reference values have been finalised as part of this evaluation:

- **ADI**: 0.0005 mg/kg bw per day
- **ARfD**: 0.01 mg/kg bw
- **AOEL**: 0.0003 mg/kg bw per day

With particular regard to residues, the review has established that the residues arising from the proposed uses (excluding lettuce⁹), consequent on application consistent with good plant protection practice, have no harmful effects on human or animal health. The highest Theoretical Maximum Daily Intake (TMDI) for all considered consumer groups is 34% of the Acceptable Daily Intake (ADI), and the highest International Estimated Short-Term Intake (IESTI) is 5% of the Acute Reference Dose (ARfD), based on EFSA PRIMo Model rev.2 and not taking into account uses in lettuce.

The review has identified several acceptable exposure scenarios for operators, workers and bystanders, which require however to be confirmed for each plant protection product in accordance with the relevant sections of the above mentioned uniform principles.

The review has also concluded that under the proposed and supported conditions of use there are no unacceptable effects on the environment, as provided for in Article 4(3)(e) of Regulation (EC) No 1107/2009, provided that certain conditions are taken into account as detailed in section 6 of this report.

### 4. Identity and Physical/chemical properties

The main identity of emamectin is given in Appendix I.

At the time of evaluation no FAO specification was allocated.

The active substance shall have a minimum purity of 950 g/kg, expressed as emamectin benzoate anhydrous (a mixture of min. 920 g/kg emamectin B1a benzoate and max. 50 g/kg emamectin B1b benzoate).

The review has established that for the active substance notified by the applicant Syngenta Crop Protection AG there are no relevant impurities which are of toxicological, ecotoxicological and/or environmental concern.

### 5. Endpoints and related information

In order to facilitate Member States, in granting or reviewing authorisations, to apply adequately the provisions of Article 29(1) of Regulation (EC) No 1107/2009 and the uniform principles laid down in Regulation (EU) No 546/2011, the most important endpoints were identified during the re-

---

⁹ For lettuce, an acute risk to consumers consequent on application of emamectin can currently not be excluded. Therefore, uses in lettuce are not referred to in this review report.
evaluation process. These endpoints are listed in the conclusion of EFSA, and in section 3 of this report.

6. **Particular conditions to be taken into account on short term basis by Member States in relation to the granting of authorisations of plant protection products containing emamectin.**

On the basis of the proposed and supported uses (as listed in Appendix II), the following issue has been identified as requiring particular and short term attention from all Member States, in the framework of any authorisations to be granted, varied or withdrawn, as appropriate:

Member States shall pay particular attention to:

- the protection of workers and operators;
- the risk to non-target invertebrates.

Conditions of use shall include risk mitigation measures, where appropriate.

7. **List of studies to be generated**

Some further studies were identified which were at this stage considered necessary in relation to the approval of emamectin under the current approval conditions. This is the case for information confirming the risk of enantio-selective metabolisation or degradation.

The applicant shall submit to the Commission, Member States and the Authority the relevant information two years after adoption of the pertinent EFSA guidance document on evaluation of isomer mixtures.

Some endpoints however may require the generation or submission of additional studies to be submitted to the Member States in order to ensure authorisations for use under certain conditions. A complete list of studies to be generated, still ongoing or available but not peer reviewed can be found in the relevant part of the EFSA Conclusion (page 16).

8. **Information on studies with claimed data protection**

For information of any interested parties, the rapporteur Member State will keep available a document which gives information about the studies for which the main data submitter has claimed data protection and which during the re-evaluation process were considered as essential with a view to approval under Regulation (EC) No 1107/2009. This information is only given to facilitate the operation of the provisions of Article 62 of Regulation (EC) No 1107/2009 in the Member States. It is based on the best information available but it does not prejudice any rights or obligations of Member States or operators with regard to its uses in the implementation of the provisions of Article 62 of Regulation (EC) No 1107/2009 and neither does it commit the Commission.
9. Updating of this review report

The information in this report may require to be updated from time to time in order to take account of technical and scientific developments as well as of the results of the examination of any information referred to the Commission in the framework of Articles 13, 21, 38, 44, 56 of Regulation (EC) No 1107/2009. Any such adaptation will be finalised in the Standing Committee on the Food Chain and Animal Health, in connection with any amendment of the approval conditions for emamectin.
### APPENDIX I

**Main identity**

**EMAMECTIN**

<table>
<thead>
<tr>
<th>Chemical name (IUPAC)</th>
<th>Emamectin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Emamectin B&lt;sub&gt;1a&lt;/sub&gt;:</td>
<td>(10E,14E,16E)-(R,4S,5'S,6'S,6'R,8'R,12S,13S,20R,21R,24S)-6''-[(S)-sec-butyl]-21,24-dihydroxy-5'',11,13,22-tetramethyl-2-oxo-(3,7,19-trioxatetracyclo[15.6.1.1&lt;sup&gt;4,8&lt;/sup&gt;.0&lt;sup&gt;20,24&lt;/sup&gt;]pentacos-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-arabinino-hexopyranoside) of emamectin</td>
</tr>
</tbody>
</table>

### Chemical name (ISO)

<table>
<thead>
<tr>
<th>Common name (ISO)</th>
<th>Emamectin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Emamectin is a mixture of ≥ 90% emamectin B&lt;sub&gt;1a&lt;/sub&gt; and ≤10% emamectin B&lt;sub&gt;1b&lt;/sub&gt;</td>
<td>Emamectin</td>
</tr>
<tr>
<td>Unless stated otherwise, the following data relate to the variant emamectin benzoate</td>
<td>Emamectin</td>
</tr>
</tbody>
</table>

### Chemical name (CA)

<p>| Emamectin: (4''R)-4''-deoxy-4''-(methylamino) avermectin B&lt;sub&gt;1&lt;/sub&gt; or 4''-deoxy-4''-(methylamino)-(4''R)-avermectin B&lt;sub&gt;1&lt;/sub&gt; |
| Emamectin B&lt;sub&gt;1a&lt;/sub&gt;: (4''R)-5-O-demethyl-4''-deoxy-4''-(methylamino)avermectin A&lt;sub&gt;1a&lt;/sub&gt; or 5-O-demethyl-4''-deoxy-4''-(methylamino)-(4''R)-avermectin A&lt;sub&gt;1a&lt;/sub&gt; |
| Emamectin B&lt;sub&gt;10&lt;/sub&gt;: (4''R)-5-O-demethyl-25-de(1-methylethyl)-4''-deoxy-4''-(methylamino)-25-(1-methylethyl)-avermectin A&lt;sub&gt;10&lt;/sub&gt; |</p>
<table>
<thead>
<tr>
<th>CIPAC No</th>
<th>emamectin: 791</th>
<th>emamectin benzoate: 791.412</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAS No</td>
<td>emamectin: 119791-41-2 (formally 137335-79-6) and 123997-28-4</td>
<td>emamectin benzoate: 155569-91-8 (formerly 137512-74-4 and 179607-18-2)</td>
</tr>
<tr>
<td>EC No (EINECS or ELINCS) ‡</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>FAO SPECIFICATION</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>Minimum purity</td>
<td>min 950 g/kg as emamectin benzoate anhydrous (a mixture of min. 920 g/kg emamectin B1a benzoate and max. 50 g/kg emamectin B1b benzoate)</td>
<td></td>
</tr>
<tr>
<td>Molecular formula</td>
<td>Emamectin B1a: C49H75NO13</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Emamectin B1b: C48H73NO13</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Emamectin B1a benzoate: C56H81NO15 or C49H75NO13.C7H6O2</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Emamectin B1b benzoate: C55H79NO15 or C48H73NO13.C7H6O2</td>
<td></td>
</tr>
<tr>
<td>Emamectin benzoate exists as the anhydrous and various hydrated forms having different crystal morphologies. The amount of water is non-stoichiometric, however in the hemihydrate the amount of water is more or less fixed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Molecular mass</td>
<td>emamectin B1a: 886.1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>emamectin B1b: 872.1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>emamectin B1a benzoate: 1008.3</td>
<td></td>
</tr>
<tr>
<td></td>
<td>emamectin B1b benzoate: 994.2</td>
<td></td>
</tr>
<tr>
<td></td>
<td>emamectin benzoate hemihydrate: 1016</td>
<td></td>
</tr>
</tbody>
</table>
Emamectin

Appendix I
Main identity

Structural formula

emamectin B1a
(major component)

emamectin B1b
(minor component)

R = CH2CH3 for emamectin B1a benzoate
R = CH3 for emamectin B1b benzoate
### APPENDIX II

List of uses supported by available data

**EMAMECTIN**

<table>
<thead>
<tr>
<th>Crop and/or situation (a)</th>
<th>Member State or Country (b)</th>
<th>Product name</th>
<th>F G or I (c)</th>
<th>Pests or Group of pests controlled (d)</th>
<th>Formulation (e)</th>
<th>Application (f)</th>
<th>Application rate per treatment (g)</th>
<th>PHI (days) (h)</th>
<th>Remarks (i)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peppers</td>
<td>S-EU</td>
<td>AFFRM 095 SG</td>
<td>F</td>
<td><em>Heliothis armigera</em> <em>Spodoptera exigua</em> <em>Spodoptera littoralis</em> <em>Ostrinia nubilalis</em></td>
<td>SG 9.5 g ai/kg</td>
<td>foliar spray</td>
<td>BBCH 11-89</td>
<td>7 days</td>
<td>0.0013-0.0025</td>
</tr>
<tr>
<td>EU</td>
<td>AFFIRM 095 SG</td>
<td>I</td>
<td>SG 9.5 g ai/kg</td>
<td>foliar spray</td>
<td>BBCH 11-89</td>
<td>7 days</td>
<td>0.0013-0.0025</td>
<td>800-1500</td>
<td>0.020</td>
</tr>
<tr>
<td>Cucumbers</td>
<td>EU</td>
<td>AFFIRM 095 SG</td>
<td>I</td>
<td>not stated</td>
<td>SG 9.5 g ai/kg</td>
<td>foliar spray</td>
<td>BBCH 11-89</td>
<td>7 days</td>
<td>0.0013-0.0040</td>
</tr>
<tr>
<td>Melons</td>
<td>S-EU</td>
<td>AFFIRM 095 SG</td>
<td>F</td>
<td>not stated</td>
<td>SG 9.5 g ai/kg</td>
<td>foliar spray</td>
<td>BBCH 11-89</td>
<td>7 days</td>
<td>0.0013-0.0025</td>
</tr>
<tr>
<td>EU</td>
<td>AFFIRM 095 SG</td>
<td>I</td>
<td>SG 9.5 g ai/kg</td>
<td>foliar spray</td>
<td>BBCH 11-89</td>
<td>7 days</td>
<td>0.0013-0.0025</td>
<td>800-1500</td>
<td>0.020</td>
</tr>
</tbody>
</table>
Emamectin

APPENDIX II

List of uses supported by available data

[1] No PHI stated. Last application determined by growth stage.

Remarks
(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated

Footnote: EC = Emulsifiable Concentrate

(i) g/kg or g/l. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for the same active substance used in different variants (e.g. fluroxypyr). In certain cases, where only one variant is synthetized, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).
(j) Growth stage at 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
(k) The minimum and maximum number of application possible under practical conditions of use must be provided
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions