EUROPEAN
COMMISSION

Brussels, XXX
SANTE/12066/2020
[…](2021) XXX draft

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

renewing the approval of the active substance abamectin 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

(Text with EEA relevance)

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(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC[1], and in particular Article 20(1) thereof,

Whereas:

(1) Commission Directive 2008/107/EC[2] included abamectin as an active substance in Annex I to Council Directive 91/414/EEC[3].

(2) Active substances included in Annex I to Directive 91/414/EEC are deemed to have been approved under Regulation (EC) No 1107/2009 and are listed in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011[4].

(3) The approval of the active substance abamectin, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 30 April 2022.

(4) An application for the renewal of the approval of the active substance abamectin was submitted in accordance with Article 1 of Commission Implementing Regulation (EU) No 844/2012[5] within the time period provided for in that Article.

(5) The applicant submitted the supplementary dossiers required in accordance with Article 6 of Implementing Regulation (EU) No 844/2012. The application was found to be complete by the rapporteur Member State.

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1 OJ L 309, 24.11.2009, p. 1.

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

3 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).

4 Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).

5 Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in 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 252, 19.9.2012, p. 26).

(6) The rapporteur Member State prepared a draft renewal assessment report in consultation with the co-rapporteur Member State and submitted it to the European Food Safety Authority ('the Authority') and the Commission on 17 April 2019.

(7) The Authority made the supplementary summary dossier available to the public. The Authority also circulated the draft renewal assessment report to the applicant and to the Member States for comments and launched a public consultation on it. The Authority forwarded the comments received to the Commission.

(8) On 15 July 2020, the Authority communicated to the Commission its conclusion[6] on whether abamectin can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Commission presented a renewal report and the draft Regulation for abamectin to the Standing Committee on Plants, Animals, Food and Feed, on 25 March 2021.

(9) As regards the criteria to identify endocrine disrupting properties introduced by Commission Regulation (EU) 2018/605[7], the conclusion of the Authority indicates that, based on the scientific evidence, it is highly unlikely that abamectin is an endocrine disrupter via the estrogenic, androgenic and thyroidogenic modalities. Furthermore, the available evidence indicates that abamectin is unlikely to be an endocrine disruptor via the steroidogenic modality. Thus, the Commission concludes that abamectin is not to be considered as having endocrine disrupting properties.

(10) The Commission invited the applicant to submit its comments on the conclusion of the Authority and, in accordance with the third paragraph of Article 14(1) of Implementing Regulation (EU) No 844/2012, on the renewal report. The applicant submitted its comments on both versions of the renewal report, which have been carefully examined.

(11) It has been established with respect to one or more representative uses of at least one plant protection product containing abamectin that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied.

(12) The risk assessment for the renewal of the approval of the active substance abamectin is based on representative uses as insecticide and acaricide in protected crops. While it is not necessary, in the light of this risk assessment, to maintain the restriction to use only as insecticide and acaricide, it is necessary to provide, in accordance with Article 14(1) of Regulation (EC) No 1107/2009 in conjunction with Article 6 thereof and in the light of current scientific and technical knowledge, for certain conditions and restrictions. It is, in particular, appropriate to restrict the use of plant protection products containing abamectin to use in permanent greenhouses, as defined in Article 3(27) of Regulation (EC) No 1107/2009, in order to mitigate the high risk identified to aquatic organisms and wild terrestrial non-target organisms.

(13) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.

(14) Implementing Regulation (EU) 2021/XXX[8] extended the approval period of abamectin to 30 April 2022 in order to allow the renewal process to be completed before the expiry of the approval period of that active substance. However, given that

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6 EFSA Journal 2020;18(8):6227. Available online: www.efsa.europa.eu.

7 Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties (OJ L 101, 20.4.2018, p. 33).

8 OJ L XX.XX.X.XXXX. p.).

a decision on renewal has been taken ahead of that extended expiry date, this Regulation shall apply from 1 July 2021.

(15) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Renewal of the approval of the active substance

The approval of the active substance abamectin is renewed as set out in Annex I.

Article 2

Amendments to Implementing Regulation (EU) No 540/2011

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with Annex II to this Regulation.

Article 3

Entry into force and date of application

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 July 2021.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN

EUROPEAN
COMMISSION

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ANNEXES 1 to 2

ANNEXES

to the

COMMISSION IMPLEMENTING REGULATION (EU) .../...

renewing the approval of the active substance abamectin 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

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity[1]	Date of approval	Expiration of approval	Specific provisions
Abamectin CAS No 71751-41-2 Avermectin B1a CAS No 65195-55-3 Avermectin B1b CAS No 65195-56-4 Abamectin CIPAC No 495	Avermectin B1a (10E,14E,16E)-(1R,4S,5′S,6S,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[15.6.1.14,8.020,24]pentacosa-10,14,16,22-tetraene)-6-spiro-2′-(5′,6′-dihydro-2′H-pyran)-12-yl 2,6-dideoxy-4-O-(2,6-dideoxy-3-O-methyl-α-L-arabino-hexopyranosyl)-3-O-methyl-α-L-arabino-hexopyranoside Avermectin B1b (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[15.6.1.14,8.020,24]pentacosa-10,14,16,22-tetraene)-6-spiro-2′-(5′,6′-dihydro-2′H-pyran)-12-yl 2,6-dideoxy-4-O-(2,6-dideoxy-3-O-methyl-α-L-arabino-hexopyranosyl)-3-O-methyl-α-L-arabino-hexopyranoside	≥ 850 g/kg abamectin (sum of avermectin B1a and avermectin B1b), min. 800 g/kg avermectin B1a and max. 200 g/kg avermectin B1b	1 July 2021	31 May 2036	Only uses in permanent greenhouses shall be authorised. For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on Abamectin, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: - the protection of operators and workers, ensuring that conditions of use include the application of adequate personal protective equipment - the significant effect of photolysis on the residue levels. Where appropriate, seasonal restrictions for the application/growing/harvest should be considered (cf. representative uses excluded application from November till February) and particular attention is required to ensure that available residue trials reflect the most critical residue situation of the envisaged uses, even under protected crop conditions.

[1] Further details on the identity and the specification of the active substance are provided in the renewal report.

ANNEX II

The Annex to Commission Implementing Regulation (EU) No 540/2011 is amended as follows:

(1) in Part A, entry 99 on Abamectin is deleted;

(2) in Part B, the following entry is added:

No.	Common Name, Identification Numbers	IUPAC Name	Purity[2]	Date of approval	Expiration of approval	Specific provisions
'XX	Abamectin CAS No 71751-41-2 Avermectin B1a CAS No 65195-55-3 Avermectin B1b CAS No 65195-56-4 Abamectin CIPAC No 495	Avermectin B1a (10E,14E,16E)-(1R,4S,5′S,6S,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[15.6.1.14,8.020,24]pentacosa-10,14,16,22-tetraene)-6-spiro-2′-(5′,6′-dihydro-2′H-pyran)-12-yl 2,6-dideoxy-4-O-(2,6-dideoxy-3-O-methyl-α-L-arabino-hexopyranosyl)-3-O-methyl-α-L-arabino-hexopyranoside Avermectin B1b (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[15.6.1.14,8.020,24]pentacosa-10,14,16,22-tetraene)-6-spiro-2′-(5′,6′-dihydro-2′H-pyran)-12-yl 2,6-dideoxy-4-O-(2,6-dideoxy-3-O-methyl-α-L-arabino-hexopyranosyl)-3-O-methyl-α-L-arabino-hexopyranoside	≥ 850 g/kg abamectin (sum of avermectin B1a and avermectin B1b), min. 800 g/kg avermectin B1a and max. 200 g/kg avermectin B1b	1 July 2021	31 May 2036	Only uses in permanent greenhouses shall be authorised. For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on Abamectin, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: - the protection of operators and workers, ensuring that conditions of use include the application of adequate personal protective equipment. - the significant effect of photolysis on the residue levels. Where appropriate, seasonal restrictions for the application/growing/harvest should be considered (cf. representative uses excluded application from November till February) and particular attention is required to ensure that available residue trials reflect the most critical residue situation of the envisaged uses, even under protected crop conditions.'

[2] Further details on the identity and the specification of the active substance are provided in the renewal report.