

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

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

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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,20 R,21R,24S)-6'-[(S)-sec-butyl]-21,24-dihydroxy-5',11,13,22-tetramethyl-2-oxo-(3,7,19-trioxatetracyclo[15.6.1.14,8.020,2 4]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,20 R,21R,24S)-21,24-dihydroxy-6'-isopropyl-5',11,13,22-tetramethyl-2-oxo-(3,7,19-trioxatetracyclo[15.6.1.14,8.020,2 4]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-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.

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,2 4S)-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]penta cosa-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,2 4S)-21,24-dihydroxy-6'-isopropyl-5',11,13,22-tetramethyl-2-oxo-(3,7,19-trioxatetracyclo[15.6.1.14,8.020,24]penta cosa-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.'

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