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COMMISSION IMPLEMENTING REGULATION (EU) 2024/1206

of 29 April 2024

amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 1-decanol, 6-benzyladenine, aluminium sulfate, azadirachtin, bupirimate, dithianon, dodine, fluometuron, hexythiazox, isoxaben, lime sulphur, orange oil, prosulfuron, quinmerac, sintofen, sodium silver thiosulfate, tau-fluvalinate, tebufenozide, tembotrione and zinc phosphide

(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 17, first subparagraph, thereof,

Whereas:

(1) According to Article 78(3) of Regulation (EC) No 1107/2009, active substances included in Annex I to Council Directive 91/414/EEC ([2]) are deemed to have been approved under Regulation (EC) No 1107/2009. Those substances are listed in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011 ([3]) and active substances approved under Regulation (EC) No 1107/2009 are listed in Part B of that Annex, while active substances approved under Regulation (EC) No 1107/2009 as candidates for substitution are listed in Part E of that Annex.

(2) The active substances 1-decanol, 6-benzyladenine, aluminium sulfate, azadirachtin, bupirimate, dithianon, dodine, fluometuron, hexythiazox, isoxaben, lime sulphur, quinmerac, sintofen, tau-fluvalinate, tebufenozide and zinc phosphide are listed in Part A of the Annex to Implementing Regulation (EU) No 540/2011. The active substances orange oil, sodium silver thiosulfate and tembotrione are listed in Part B of that Annex and the active substance prosulfuron is listed in Part E of that Annex.

(3) Commission Implementing Regulation (EU) 2020/2007 ([4]) extended the approval period of the active substances orange oil, prosulfuron, quinmerac, sodium silver thiosulfate, tembotrione and zinc phosphide until 31 July 2024 and of the active substances 1-decanol, 6-benzyladenine, aluminium sulfate, azadirachtin, bupirimate, dithianon, dodine, fluometuron, hexythiazox, isoxaben, lime sulphur, sintofen, tau-fluvalinate and tebufenozide until 31 August 2024.

([1]) OJ L 309, 24.11.2009, p. 1, ELI: http://data.europa.eu/eli/reg/2009/1107/oj.

([2]) 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, ELI: http://data.europa.eu/eli/dir/1991/414/oj).

([3]) 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, ELI: http://data.europa.eu/eli/reg_impl/2011/540/oj).

([4]) Commission Implementing Regulation (EU) 2020/2007 of 8 December 2020 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 1-decanol, 1,4-dimethylnaphthalene, 6-benzyladenine, acequinocyl, Adoxophyes orana granulovirus, aluminium sulfate, amisulbrom, Aureobasidium pullulans (strains DSM 14940 and DSM 14941), azadirachtin, Bacillus pumilus QST 2808, benalaxyl-M, bixafen, bupirimate, Candida oleophila strain O, chlorantraniliprole, disodium phosphonate, dithianon, dodine, emamectin, flubendiamide, fluometuron, fluxapyroxad, flutriafol, hexythiazox, imazamox, ipconazole, isoxaben, L-ascorbic acid, lime sulphur, orange oil, Paecilomyces fumosoroseus strain FE 9901, pendimethalin, penflufen, penthiopyrad, potassium phosphonates, prosulfuron, Pseudomonas sp. strain DSMZ 13134, pyridalyl, pyriofenone, pyroxsulam, quinmerac, S-abscisic acid, sedaxane, sintofen, sodium silver thiosulfate, spinetoram, spirotetramat, Streptomyces lydicus strain WYEC 108, tau-fluvalinate, tebufenozide, tembotrione, thiencarbazone, valifenalate, zinc phosphide (OJ L 414, 9.12.2020, p. 10, ELI: http://data.europa.eu/eli/reg_impl/2020/2007/oj).

(4) Applications and supplementary dossiers for the renewal of the approvals of each of those active substances were submitted in accordance with Commission Implementing Regulations (EU) No 844/2012 ([5]) and (EU) 2020/1740 ([6]), respectively.

(5) For the active substances azadirachtin, bupirimate, dithianon, hexythiazox, isoxaben, lime sulphur, orange oil, quinmerac, sodium silver thiosulfate, tau-fluvalinate, tebufenozide, tembotrione and zinc phosphide, the risk assessment pursuant to Article 11 of Implementing Regulation (EU) No 844/2012 has not yet been finalised by the respective rapporteur Member States.

(6) For the active substances 1-decanol, 6-benzyladenine, aluminium sulfate, dodine, fluometuron, prosulfuron and sintofen, the European Food Safety Authority (the 'Authority') needs additional time to reach a conclusion requiring, where appropriate, a consultation of experts. Further time is needed for the Commission to adopt the ensuing risk management decision.

(7) Given that it is likely that no decision on the renewal of the approval of these active substances can be taken before the expiry of their respective approval periods on 31 July 2024 and 31 August 2024, and that the reasons for the delays in the renewal procedures are beyond the control of the respective applicants, the approval periods of those active substances should be extended in order to enable the completion of the assessments required and to finalise the respective procedures on renewal of approval.

(8) For the active substances azadirachtin, bupirimate, dithianon, hexythiazox, isoxaben, lime sulphur, orange oil, quinmerac, sodium silver thiosulfate, tau-fluvalinate, tebufenozide, tembotrione and zinc phosphide, as the risk assessment has not yet been finalised by the rapporteur Member States and in light of the time required to complete the remaining steps in each renewal procedure, the duration of the extension of the approval periods should be set at 29 months.

(9) For the active substances 1-decanol, 6-benzyladenine, aluminium sulfate, dodine, fluometuron, prosulfuron and sintofen, as the Authority needs additional time to reach a conclusion on their risk assessment, the duration of the extension of the approval period for these active substances should be set at 23 months and 2 weeks.

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

(11) In case the Commission adopts a Regulation providing that the approval of an active substance referred to in the Annex to this Regulation is not renewed, the Commission will set the expiry date at the date of entry into force of that Regulation or at the same date as it stood before the adoption of this Regulation, whichever date is later. In case the Commission adopts a Regulation providing for the renewal of the approval of an active substance referred to in the Annex to this Regulation, the Commission will set the earliest possible application date, as appropriate under the circumstances.

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

([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, ELI: http://data.europa.eu/eli/reg_impl/2012/844/oj).

([6]) Commission Implementing Regulation (EU) 2020/1740 of 20 November 2020 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, and repealing Commission Implementing Regulation (EU) No 844/2012 (OJ L 392, 23.11.2020, p. 20, ELI: http://data.europa.eu/eli/reg_impl/2020/1740/oj).

HAS ADOPTED THIS REGULATION:

Article 1

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

Article 2

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

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

Done at Brussels, 29 April 2024.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

I. Part A of the Annex to Implementing Regulation (EU) No 540/2011 is amended as follows:

(1) in the sixth column, expiration of approval, of row 311, quinmerac, the date is replaced by '31 December 2026';

(2) in the sixth column, expiration of approval, of row 314, zinc phosphide, the date is replaced by '31 December 2026';

(3) in the sixth column, expiration of approval, of row 317, 6-benzyladenine, the date is replaced by '15 July 2026';

(4) in the sixth column, expiration of approval, of row 323, dodine, the date is replaced by '15 July 2026';

(5) in the sixth column, expiration of approval, of row 328, tau-fluvalinate, the date is replaced by '31 January 2027';

(6) in the sixth column, expiration of approval, of row 330, bupirimate, the date is replaced by '31 January 2027';

(7) in the sixth column, expiration of approval, of row 333, 1-decanol, the date is replaced by '15 July 2026';

(8) in the sixth column, expiration of approval, of row 334, isoxaben, the date is replaced by '31 January 2027';

(9) in the sixth column, expiration of approval, of row 335, fluometuron, the date is replaced by '15 July 2026';

(10) in the sixth column, expiration of approval, of row 341, sintofen, the date is replaced by '15 July 2026';

(11) in the sixth column, expiration of approval, of row 343, azadirachtin, the date is replaced by '31 January 2027';

(12) in the sixth column, expiration of approval, of row 345, lime sulphur, the date is replaced by '31 January 2027';

(13) in the sixth column, expiration of approval, of row 346, aluminium sulfate, the date is replaced by '15 July 2026';

(14) in the sixth column, expiration of approval, of row 350, tebufenozide, the date is replaced by '31 January 2027';

(15) in the sixth column, expiration of approval, of row 351, dithianon, the date is replaced by '31 January 2027';

(16) in the sixth column, expiration of approval, of row 352, hexythiazox, the date is replaced by '31 January 2027'.

II. In Part B of the Annex to Implementing Regulation (EU) No 540/2011, in the sixth column, expiration of approval, of row 56, orange oil, row 59, tembotrione and row 63, sodium silver thiosulfate, the date is replaced by '31 December 2026'.

III. In Part E of the Annex to Implementing Regulation (EU) No 540/2011, in the sixth column, expiration of approval, of row 6, prosulfuron, the date is replaced by '15 June 2026'.