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COMMISSION IMPLEMENTING REGULATION (EU) 2024/1892

of 10 July 2024

amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances amisulbrom, S-abscisic acid, thiencarbazone and valifenalate

(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) Commission Implementing Regulation (EU) No 193/2014 ([2]) approved the active substance amisulbrom until 30 June 2024. Commission Implementing Regulation (EU) No 151/2014 ([3]) approved the active substance S-abscisic acid until 30 June 2024. Commission Implementing Regulation (EU) No 145/2014 ([4]) approved the active substance thiencarbazone until 30 June 2024. Commission Implementing Regulation (EU) No 144/2014 approved the active substance valifenalate until 30 June 2024 ([5]).

(2) The active substances amisulbrom, S-abscisic acid, thiencarbazone and valifenalate are listed in Part B of the Annex of Commission Implementing Regulation (EU) No 540/2011 ([6]).

(3) Commission Implementing Regulation (EU) 2020/2007 ([7]) extends the approval period of the active substances amisulbrom, S-abscisic acid, thiencarbazone and valifenalate until 30 September 2024.

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

([2]) Commission Implementing Regulation (EU) No 193/2014 of 27 February 2014 approving the active substance amisulbrom, 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 59, 28.2.2014, p. 25, ELI: http://data.europa.eu/eli/reg_impl/2014/193/oj).

([3]) Commission Implementing Regulation (EU) No 151/2014 of 18 February 2014 approving the active substance S-abscisic acid, 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 48, 19.2.2014, p. 1, ELI: http://data.europa.eu/eli/reg_impl/2014/151/oj).

([4]) Commission Implementing Regulation (EU) No 145/2014 of 14 February 2014 approving the active substance thiencarbazone, 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 45, 15.2.2014, p. 12, ELI: http://data.europa.eu/eli/reg_impl/2014/145/oj).

([5]) Commission Implementing Regulation (EU) No 144/2014 of 14 February 2014 approving the active substance valifenalate, 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 45, 15.2.2014, p. 7, ELI: http://data.europa.eu/eli/reg_impl/2014/144/oj).

([6]) 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).

([7]) 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 Regulation (EU) 2020/1740 ([8]) three years before the extended expiry date of the active substances. On 3 May 2023, 11 April 2022, 28 June 2022 and 4 July 2022 the rapporteur Member States of amisulbrom, S-abscisic acid, thiencarbazone and valifenalate respectively informed the Commission that they had checked the admissibility, in particular the completeness and the timeliness, of each of these applications, and concluded that they were admissible.

(5) For the active substances thiencarbazone and valifenalate, the risk assessment pursuant to Article 11 of Implementing Regulation (EU) 2020/1740 has not yet been finalised by the respective rapporteur Member States.

(6) For the active substances amisulbrom and S-abscisic acid, the European Food Safety Authority (the 'Authority') needs additional time to reach a conclusion requiring, where appropriate, a consultation of experts. Additional time is needed for the Commission to adopt the ensuing risk management decision.

(7) It is therefore 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 30 September 2024, and given 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 thiencarbazone and valifenalate, as the risk assessment has not yet been finalised by the respective 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 amisulbrom and S-abscisic acid, 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,

([8]) 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, 10 July 2024.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

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

(1) in the sixth column, expiration of approval, of row 65, S-abscisic acid, the date is replaced by ‘15 September 2026’;

(2) in the sixth column, expiration of approval, of row 69, amisulbrom, the date is replaced by ‘15 September 2026’;

(3) in the sixth column, expiration of approval, of row 70, valifenalate, the date is replaced by ‘1 March 2027’;

(4) in the sixth column, expiration of approval, of row 71, thiencarbazone, the date is replaced by ‘1 March 2027’.