COMMISSION IMPLEMENTING REGULATION (EU) 2023/1757

of 11 September 2023

amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances bensulfuron, chlormequat, chlorotoluron, clomazone, daminozide, deltamethrin, eugenol, fludioxonil, flufenacet, flumetralin, fosthiazate, geraniol, MCPA, MCPB, propaquizafop, prosulfocarb, quizalofop-P-ethyl, quizalofop-P-tefuryl, sodium 5-nitroguaiacolate, sodium o-nitrophenolate, sodium p-nitrophenolate, sulfuryl fluoride, tebufenpyrad, thymol, and tritosulfuron

(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 paragraph, 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 and are listed in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011 ([3]). Active substances approved under Regulation (EC) No 1107/2009 are listed in Part B of the Annex to Implementing Regulation (EU) No 540/2011, and 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 bensulfuron, chlormequat, chlorotoluron, clomazone, daminozide, deltamethrin, fludioxonil, flufenacet, fosthiazate, MCPA, MCPB, propaquizafop, prosulfocarb, quizalofop-P-ethyl, quizalofop-P-tefuryl, sodium 5-nitroguaiacolate, sodium o-nitrophenolate, sodium p-nitrophenolate, sulfuryl fluoride, tebufenpyrad and tritosulfuron are listed in Part A of the Annex to Implementing Regulation (EU) No 540/2011. The active substances eugenol, geraniol and thymol are listed in Part B and the active substance flumetralin in Part E of that Annex.

(3) Commission Implementing Regulation (EU) 2022/1480 ([4]) extended the approval period of the active substances bensulfuron, chlorotoluron, clomazone, daminozide, deltamethrin, fludioxonil, flufenacet, fosthiazate, MCPA, MCPB, prosulfocarb, sodium 5-nitroguaiacolate, sodium o-nitrophenolate, sodium p-nitrophenolate, and tebufenpyrad until 31 October 2023, of the active substances chlormequat, propaquizafop, quizalofop-P-ethyl, quizalofop-P-tefuryl and tritosulfuron until 30 November 2023 and of the active substance flumetralin until 11 December 2023.

([1]) OJ L 309, 24.11.2009, p. 1.

([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).

([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).

([4]) Commission Implementing Regulation (EU) 2022/1480 of 7 September 2022 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 2-phenylphenol (including its salts such as the sodium salt), 8-hydroxyquinoline, amidosulfuron, bensulfuron, bifenox, chlormequat, chlorotoluron, clofentezine, clomazone, daminozide, deltamethrin, dicamba, difenoconazole, diflufenican, dimethachlor, esfenvalerate, etofenprox, fenoxaprop-P, fenpropidin, fenpyrazamine, fludioxonil, flufenacet, flumetralin, fosthiazate, lenacil, MCPA, MCPB, nicosulfuron, paraffin oils, paraffin oil, penconazole, picloram, prohexadione, propaquizafop, prosulfocarb, quizalofop-P-ethyl, quizalofop-P-tefuryl, sodium 5-nitroguaiacolate, sodium o-nitrophenolate, sodium p-nitrophenolate, sulphur, tebufenpyrad, tetraconazole, tri-allate, triflusulfuron and tritosulfuron (OJ L 233, 8.9.2022, p. 43).

(4) Commission Implementing Regulation (EU) 2018/184 ([5]) extended the approval period of the active substance sulfuryl fluoride until 31 October 2023.

(5) The approval of the active substance eugenol is set to expire on 30 November 2023 in accordance with Commission Implementing Regulation (EU) No 546/2013 ([6]).

(6) The approval of the active substance geraniol is set to expire on 30 November 2023 in accordance with Commission Implementing Regulation (EU) No 570/2013 ([7]).

(7) The approval of the active substance thymol is set to expire on 30 November 2023 in accordance with Commission Implementing Regulation (EU) No 568/2013 ([8]).

(8) Applications and supplementary dossiers for the renewal of the approval of each of those active substances were submitted in accordance with Commission Implementing Regulation (EU) No 844/2012 ([9]). All of these applications were declared admissible by the respective rapporteur Member States.

(9) For the active substances chlormequat, eugenol, flumetralin, fosthiazate, geraniol, propaquizafop, prosulfocarb, quizalofop-P-ethyl, quizalofop-P-tefuryl, sodium 5-nitroguaiacolate, sodium o-nitrophenolate, sodium p-nitrophenolate, sulfuryl fluoride, tebufenpyrad and thymol, 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.

(10) For the active substances bensulfuron, chlorotoluron, deltamethrin, MCPA and MCPB, the European Food Safety Authority ('the Authority') needs additional time to reach a conclusion requiring, where appropriate, a consultation of experts. Furthermore, additional time is needed for the Commission to adopt the ensuing risk management decision.

(11) For the active substances clomazone, daminozide, fludioxonil, flufenacet and tritosulfuron, additional information for the purposes of assessment of the approval criteria set out in point 3.6.5 and point 3.8.2 of Annex II to Regulation (EC) No 1107/2009, was requested by the Authority pursuant to Article 13(3a), first subparagraph, of Implementing Regulation (EU) No 844/2012 and was submitted by the applicants within the period set by the Authority. However, additional time is needed for the Authority to evaluate the information received and adopt a conclusion on whether the active substances can be expected to meet the approval criteria and for the Commission to adopt the ensuing risk management decision.

([5]) Commission Implementing Regulation (EU) 2018/184 of 7 February 2018 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances FEN 560 (also called fenugreek or fenugreek seed powder) and sulfuryl fluoride (OJ L 34, 8.2.2018, p. 10).

([6]) Commission Implementing Regulation (EU) No 546/2013 of 14 June 2013 approving the active substance eugenol, 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 163, 15.6.2013, p. 17).

([7]) Commission Implementing Regulation (EU) No 570/2013 of 17 June 2013 approving the active substance geraniol, 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 Implementing Regulation (EU) No 540/2011 (OJ L 168, 20.6.2013, p. 18).

([8]) Commission Implementing Regulation (EU) No 568/2013 of 18 June 2013 approving the active substance thymol, 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 167, 19.6.2013, p. 33).

([9]) 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), which continues to apply to the procedure for the renewal of the approval of those active substances pursuant to Article 17 of 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).

(12) 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 October 2023, 30 November 2023 and 11 December 2023, and that the reasons for the delays in the renewal procedures are beyond the control of the respective applicants, the approval periods of the active substances should be extended in order to enable the completion of the assessments required and finalise the regulatory decision-making procedures on the respective applications for renewal of approval.

(13) 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 for the active substances chlormequat, fosthiazate, propaquizafop, prosulfocarb, quizalofop-P-ethyl, quizalofop-P-tefuryl, sodium 5-nitroguaiacolate, sodium o-nitrophenolate, sodium p-nitrophenolate, sulfuryl fluoride and tebufenpyrad should be set at thirty-nine months and for the active substances eugenol, flumetralin, geraniol and thymol should be set at twenty-nine months.

(14) As the Authority needs additional time to reach a conclusion on the risk assessment for the active substances bensulfuron, chlorotoluron, deltamethrin, MCPA and MCPB requiring, where appropriate, a consultation of experts, the duration of the extension for those active substances should be set at thirty-three months and a half.

(15) As the Authority requested additional information for the purposes of assessment of the approval criteria set out in point 3.6.5 and point 3.8.2 of Annex II to Regulation (EC) No 1107/2009, the duration of the extension for the active substance daminozide should be set at twenty-two months and a half and, as additional time is needed for its evaluation, the duration of the extension for the active substances clomazone, fludioxonil, flufenacet and tritosulfuron should be set at nineteen months and a half.

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

(17) 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 same date as it stood before the adoption of this Regulation or at the date of the entry into force of the Regulation providing that the approval of the active substance is not renewed, whichever date is later. As regards cases where the Commission is to adopt 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, as appropriate under the circumstances, the earliest possible application date.

(18) 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

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, 11 September 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

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

1. Part A is amended as follows:

(1) in the sixth column, expiration of approval, of row 40, Deltamethrin, the date is replaced by '15 August 2026';

(2) in the sixth column, expiration of approval, of row 65, Flufenacet, the date is replaced by '15 June 2025';

(3) in the sixth column, expiration of approval, of row 69, Fosthiazate, the date is replaced by '31 January 2027';

(4) in the sixth column, expiration of approval, of row 102, Chlorotoluron, the date is replaced by '15 August 2026';

(5) in the sixth column, expiration of approval, of row 104, Daminozide, the date is replaced by '15 September 2025';

(6) in the sixth column, expiration of approval, of row 107, MCPA, the date is replaced by '15 August 2026';

(7) in the sixth column, expiration of approval, of row 108, MCPB, the date is replaced by '15 August 2026';

(8) in the sixth column, expiration of approval, of row 160, Prosulfocarb, the date is replaced by '31 January 2027';

(9) in the sixth column, expiration of approval, of row 161, Fludioxonil, the date is replaced by '15 June 2025';

(10) in the sixth column, expiration of approval, of row 162, Clomazone, the date is replaced by '15 June 2025';

(11) in the sixth column, expiration of approval, of row 186, Tritosulfuron, the date is replaced by '15 July 2025';

(12) in the sixth column, expiration of approval, of row 271, Bensulfuron, the date is replaced by '15 August 2026';

(13) in the sixth column, expiration of approval, of row 272, Sodium 5-nitroguaiacolate, the date is replaced by '31 January 2027';

(14) in the sixth column, expiration of approval, of row 273, Sodium o-nitrophenolate, the date is replaced by '31 January 2027';

(15) in the sixth column, expiration of approval, of row 274, Sodium p-nitrophenolate, the date is replaced by '31 January 2027';

(16) in the sixth column, expiration of approval, of row 275, Tebufenpyrad, the date is replaced by '31 January 2027';

(17) in the sixth column, expiration of approval, of row 276, Chlormequat, the date is replaced by '28 February 2027';

(18) in the sixth column, expiration of approval, of row 278, Propaquizafop, the date is replaced by '28 February 2027';

(19) in the sixth column, expiration of approval, of row 279, Quizalofop-P-ethyl and Quizalofop-P-tefuryl, the date is replaced by '28 February 2027';

(20) in the sixth column, expiration of approval, of row 307, Sulfuryl fluoride, the date is replaced by '31 January 2027'.

2. Part B is amended as follows:

(1) in the sixth column, expiration of approval, of row 45, Eugenol, the date is replaced by '30 April 2026';

(2) in the sixth column, expiration of approval, of row 46, Geraniol, the date is replaced by '30 April 2026';

(3) in the sixth column, expiration of approval, of row 47, Thymol, the date is replaced by '30 April 2026';

3. Part E is amended as follows:

in the sixth column, expiration of approval, of row 1, Flumetralin, the date is replaced by '11 May 2026'.