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COMMISSION IMPLEMENTING REGULATION (EU) 2023/2592

of 21 November 2023

amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 1-naphthylacetamide, 1-naphthylacetic acid, 2-phenylphenol (incl. its salts such as sodium salt), 8-hydroxyquinoline, amidosulfuron, bifenox, dicamba, difenoconazole, diflufenican, dimethachlor, esfenvalerate, etofenprox, fenoxaprop-P, fenpropidin, fenpyrazamine, fluazifop P, lenacil, napropamide, nicosulfuron, paraffin oils, paraffin oil, penconazole, picloram, prohexadione, spiroxamine, sulphur, tetraconazole and tri-allate

(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 2-phenylphenol (incl. its salts such as sodium salt), amidosulfuron, bifenox, dicamba, difenoconazole, diflufenican, dimethachlor, etofenprox, fenoxaprop-P, fenpropidin, lenacil, napropamide, nicosulfuron, paraffin oils, paraffin oil, penconazole, picloram, sulphur, tetraconazole and tri-allate are listed in Part A of the Annex to Implementing Regulation (EU) No 540/2011. The active substances 1-naphthylacetamide, 1-naphthylacetic acid, 8-hydroxyquinoline, fenpyrazamine, fluazifop P, prohexadione and spiroxamine are listed in Part B and the active substance esfenvalerate is listed in Part E of that Annex.

(3) Commission Implementing Regulation (EU) 2022/1480 ([4]) extended the approval period of the active substances 2-phenylphenol, 8-hydroxyquinoline, amidosulfuron, bifenox, dicamba, difenoconazole, diflufenican, dimethachlor, esfenvalerate, etofenprox, fenoxaprop-P, fenpropidin, fenpyrazamine, lenacil, nicosulfuron, paraffin oils, paraffin oil, penconazole, picloram, prohexadione, sulphur, tetraconazole and tri-allate until 31 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) 2019/291 ([5]) extended the approval period of the active substances 1-naphthylacetamide, 1-naphthylacetic acid, fluazifop P and spiroxamine until 31 December 2023.

(5) The approval of the active substance napropamide is set to expire on 31 December 2023 in accordance with Commission Implementing Regulation (EU) 2018/670 ([6]).

(6) 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 ([7]). All of those applications were declared admissible by the respective rapporteur Member States.

(7) For the active substances 1-naphthylacetamide, 1-naphthylacetic acid, bifenox, esfenvalerate, etofenprox, fenpyrazamine, fluazifop P, napropamide, paraffin oils, prohexadione, spiroxamine, tetraconazole and tri-allate, 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.

(8) For the active substances 8-hydroxyquinoline, dicamba, dimethachlor, nicosulfuron, and penconazole, 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.

(9) For the active substances 2-phenylphenol, difenoconazole, diflufenican, fenpropidin and picloram, 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, with a deadline of 20 September 2025 for 2-phenylphenol, of 22 January 2024 for difenoconazole, of 5 November 2023 for diflufenican, of 10 March 2025 for fenpropidin and of 1 December 2025 for picloram.

(10) For the active substances amidosulfuron, fenoxaprop-P, lenacil and paraffin oil additional information for the purposes of the 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.

(11) For the active substance sulphur, the Authority has submitted its conclusion to the applicant, the Member States and the Commission. The Commission has initiated discussions on this active substance in the Standing Committee on Plants, Animals, Food and Feed.

(12) Given that it is likely that no decision on the renewal of the approval of those active substances can be taken before the expiry of their respective approval periods on 31 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.

([5]) Commission Implementing Regulation (EU) 2019/291 of 19 February 2019 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 1-naphthylacetamide, 1-naphthylacetic acid, acrinathrin, azoxystrobin, fluazifop p, fluroxypyr, imazalil, kresoxim-methyl, oxyfluorfen, prochloraz, prohexadione, spiroxamine, tefluthrin and terbuthylazine (OJ L 48, 20.2.2019, p. 17).

([6]) Commission Implementing Regulation (EU) 2018/670 of 30 April 2018 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances bromuconazole, buprofezin, haloxyfop-P and napropamide (OJ L 113, 3.5.2018, p. 1).

([7]) 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).

(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 bifenox, etofenprox, napropamide, paraffin oils, tetraconazole and tri-allate should be set at thirty-nine months and for the active substances 1-naphthylacetamide, 1-naphthylacetic acid, esfenvalerate, fenpyrazamine, fluazifop P, prohexadione and spiroxamine should be set at twenty-nine months.

(14) As the Authority needs additional time to open a public consultation for the active substances dicamba and nicosulfuron, and in light of the time required to complete the remaining steps in each renewal procedure, the duration of the extension for those active substances should be set at thirty-nine months.

(15) As the Authority needs to reach a conclusion on the risk assessment for the active substances dimethachlor and penconazole requiring, where appropriate, a consultation of experts, and in light of the time required to complete the remaining steps in each renewal procedure, the duration of the extension for those active substances should be set at thirty-three months and a half.

(16) 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 for the active substances 2-phenylphenol, difenoconazole, diflufenican, fenpropidin and picloram, and in light of the time required to complete the remaining steps in each renewal procedure, the duration of the extension for 2-phenylphenol should be set at forty-six months and a half, for difenoconazole should be set at twenty-six months and a half, for diflufenican should be set at twenty-four months and a half, for fenpropidin should be set at forty months and a half, and for picloram should be set at forty-nine months and a half.

(17) As the Authority needs additional time for the evaluation of the additional information received for the purposes of the 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, 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 amidosulfuron, fenoxaprop-P, lenacil and paraffin oil, should be set at nineteen months and a half.

(18) Under point 3.6.4 of Annex II to Regulation (EC) No 1107/2009 an active substance shall only be approved if it is not or has not to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([8]), as toxic for reproduction category 1B, unless the exposure of humans to that substance in a plant protection product under realistic proposed conditions of use is negligible. As provided by Article 4(1) of Regulation (EC) No 1107/2009, the assessment of the active substance shall first establish whether the approval criteria set out in points 3.6.2 to 3.6.4 and 3.7 of Annex II are satisfied. In view of Commission Regulation (EU) 2017/776 ([9]), amending Annex VI to Regulation (EC) No 1272/2008, classifying 8-hydroxyquinoline as toxic for reproduction category 1B, the duration of the extension for the active substance should be set at 12 months.

(19) As the delivery of an opinion of the Standing Committee on Plants, Animals, Food and Feed is pending, and in light of the time required to complete the remaining steps in each renewal procedure, the duration of the extension for the active substance sulphur should be set at 15 months and a half. Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.

(20) 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.

([8]) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

([9]) Commission Regulation (EU) 2017/776 of 4 May 2017 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (OJ L 116, 5.5.2017, p. 1).

(21) 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, 21 November 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 169, Amidosulfuron, the date is replaced by '15 August 2025';

(2) in the sixth column, expiration of approval, of row 170, Nicosulfuron, the date is replaced by '31 March 2027';

(3) in the sixth column, expiration of approval, of row 172, Dicamba, the date is replaced by '31 March 2027';

(4) in the sixth column, expiration of approval, of row 173, Difenoconazole, the date is replaced by '15 March 2026';

(5) in the sixth column, expiration of approval, of row 176, Lenacil, the date is replaced by '15 August 2025';

(6) in the sixth column, expiration of approval, of row 178, Picloram, the date is replaced by '15 February 2028';

(7) in the sixth column, expiration of approval, of row 180, Bifenox, the date is replaced by '31 March 2027';

(8) in the sixth column, expiration of approval, of row 181, Diflufenican, the date is replaced by '15 January 2026';

(9) in the sixth column, expiration of approval, of row 182, Fenoxaprop-P, the date is replaced by '15 August 2025';

(10) in the sixth column, expiration of approval, of row 183, Fenpropidin, the date is replaced by '15 May 2027';

(11) in the sixth column, expiration of approval, of row 284, Dimethachlor, the date is replaced by '15 October 2026';

(12) in the sixth column, expiration of approval, of row 285, Etofenprox, the date is replaced by '31 March 2027';

(13) in the sixth column, expiration of approval, of row 287, Penconazole, the date is replaced by '15 October 2026';

(14) in the sixth column, expiration of approval, of row 288, Tri-allate, the date is replaced by '31 March 2027';

(15) in the sixth column, expiration of approval, of row 292, Sulphur, the date is replaced by '15 April 2025';

(16) in the sixth column, expiration of approval, of row 293, Tetraconazole, the date is replaced by '31 March 2027';

(17) in the sixth column, expiration of approval, of row 294, Paraffin oils, the date is replaced by '31 March 2027';

(18) in the sixth column, expiration of approval, of row 295, Paraffin oil, the date is replaced by '15 August 2025';

(19) in the sixth column, expiration of approval, of row 299, 2-phenylphenol (incl. its salts such as sodium salt), the date is replaced by '15 November 2027';

(20) in the sixth column, expiration of approval, of row 310, Napropamide, the date is replaced by '31 March 2027'.

2. Part B is amended as follows:

(1) in the sixth column, expiration of approval, of row 6, Prohexadione, the date is replaced by '31 May 2026';

(2) in the sixth column, expiration of approval, of row 7, Spiroxamine, the date is replaced by '31 May 2026';

(3) in the sixth column, expiration of approval, of row 12, 1-naphthylacetamide, the date is replaced by '31 May 2026';

(4) in the sixth column, expiration of approval, of row 13, 1-naphthylacetic acid, the date is replaced by '31 May 2026';

(5) in the sixth column, expiration of approval, of row 15, Fluazifop P, the date is replaced by '31 May 2026';

(6) in the sixth column, expiration of approval, of row 18, 8-hydroxyquinoline, the date is replaced by '31 December 2024';

(7) in the sixth column, expiration of approval, of row 25, Fenpyrazamine, the date is replaced by '31 May 2026'.

3. In Part E:

in the sixth column, expiration of approval, of row 2, Esfenvalerate, the date is replaced by '31 May 2026'.