II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1446

of 12 July 2023

amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 2,5-dichlorobenzoic acid methylester, acetic acid, aluminium ammonium sulphate, aluminium phosphide, aluminium silicate, calcium carbide, cymoxanil, dodemorph, ethylene, extract from tea tree, fat distillation residues, fatty acids C7-C20, flonicamid (IKI-220), gibberellic acid, gibberellins, halosulfuron-methyl, hydrolysed proteins, iron sulphate, magnesium phosphide, maltodextrin, metamitron, plant oils/clove oil, plant oils/rape seed oil, plant oils/spear mint oil, pyrethrins, sulcotrione, tebuconazole and urea

(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) The active substances 2,5-dichlorobenzoic acid methylester, acetic acid, aluminium ammonium sulphate, aluminium phosphide, aluminium silicate, calcium carbide, cymoxanil, dodemorph, ethylene, extract from tea tree, fat distillation residues, fatty acids C7-C20, flonicamid (IKI-220), gibberellic acid, gibberellins, halosulfuron-methyl, hydrolysed proteins, iron sulphate, magnesium phosphide, maltodextrin, metamitron, plant oils/clove oil, plant oils/rape seed oil, plant oils/spear mint oil, pyrethrins, sulcotrione, tebuconazole and urea are listed in the Annex to Commission Implementing Regulation (EU) No 540/2011 ([2]).

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

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

([2]) 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).

([3]) 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) 2022/708 ([4]) extends the approval period of the active substances 2,5-dichlorobenzoic acid methylester, acetic acid, aluminium ammonium sulphate, aluminium phosphide, aluminium silicate, calcium carbide, cymoxanil, dodemorph, ethylene, extract from tea tree, fat distillation residues, fatty acids C7-C20, gibberellic acid, gibberellins, hydrolysed proteins, iron sulphate, magnesium phosphide, metamitron, plant oils/clove oil, plant oils/rape seed oil, plant oils/spear mint oil, pyrethrins, sulcotrione, tebuconazole and urea until 31 August 2023.

(4) Commission Implementing Regulation (EU) 2017/2069 ([5]) extends the approval period of the active substance flonicamid (IKI-220) until 31 August 2023.

(5) The approval of the active substance halosulfuron-methyl is set to expire on 30 September 2023 in accordance with Commission Implementing Regulation (EU) No 356/2013 ([6]).

(6) The approval of the active substance maltodextrin is set to expire on 30 September 2023 in accordance with Commission Implementing Regulation (EU) No 355/2013 ([7]).

(7) Applications and supplementary dossiers for the renewal of the approval of those active substances were submitted in accordance with Commission Implementing Regulation (EU) No 844/2012 ([8]), which continues to apply to these active substances pursuant to Article 17 of Commission Implementing Regulation (EU) 2020/1740 ([9]). They were declared admissible by the respective rapporteur Member States.

(8) For the active substances 2,5-dichlorobenzoic acid methylester, acetic acid, aluminium phosphide, calcium carbide, dodemorph, ethylene, extract from tea tree, flonicamid (IKI-220), iron sulphate, magnesium phosphide, maltodextrin, metamitron, plant oils/clove oil, plant oils/spear mint oil, sulcotrione, tebuconazole and urea, 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.

(9) For the active substances halosulfuron-methyl, hydrolysed proteins and pyrethrins, the European Food Safety Authority ('the Authority') will need additional time to adopt a conclusion and, where appropriate, to organise a consultation of experts. Furthermore, additional time is needed to adopt the ensuing risk management decision.

([4]) Commission Implementing Regulation (EU) 2022/708 of 5 May 2022 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 2,5-dichlorobenzoic acid methylester, acetic acid, aclonifen, aluminium ammonium sulphate, aluminium phosphide, aluminium silicate, beflubutamid, benthiavalicarb, boscalid, calcium carbide, captan, cymoxanil, dimethomorph, dodemorph, ethephon, ethylene, extract from tea tree, fat distilation residues, fatty acids C7 to C20, fluoxastrobin, flurochloridone, folpet, formetanate, gibberellic acid, gibberellins, hydrolysed proteins, iron sulphate, magnesium phosphide, metam, metamitron, metazachlor, metribuzin, milbemectin, phenmedipham, pirimiphos-methyl, plant oils/clove oil, plant oils/rape seed oil, plant oils/spear mint oil, propamocarb, proquinazid, prothioconazole, pyrethrins, quartz sand, fish oil, repellents by smell of animal or plant origin/sheep fat, S-metolachlor, Straight Chain Lepidopteran Pheromones, sulcotrione, tebuconazole and urea (OJ L 133, 10.5.2022, p. 1).

([5]) Commission Implementing Regulation (EU) 2017/2069 of 13 November 2017 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances flonicamid (IKI-220), metalaxyl, penoxsulam and proquinazid (OJ L 295, 14.11.2017, p. 51).

([6]) Commission Implementing Regulation (EU) No 356/2013 of 18 April 2013 approving the active substance halosulfuron-methyl, 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 109, 19.4.2013, p. 18).

([7]) Commission Implementing Regulation (EU) No 355/2013 of 18 April 2013 approving the active substance maltodextrin, 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 109, 19.4.2013, p. 14).

([8]) 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).

([9]) 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).

(10) For the active substance cymoxanil, 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) of Implementing Regulation (EU) No 844/2012, with a deadline of 17 June 2024.

(11) For the active substances gibberellic acid and gibberellins, 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) of Implementing Regulation (EU) No 844/2012 and was submitted by the applicants within the deadline given. However, additional time is needed for its evaluation and to adopt the related conclusion as well as the ensuing risk management decision.

(12) For the active substances aluminium ammonium sulphate, aluminium silicate and fat distillation residues, the Authority has submitted its conclusion. The Commission has initiated discussions on those active substances in the Standing Committee on Plants, Animals, Food and Feed.

(13) As regards the approval of the active substances fatty acids C7-C20 (in particular, pelargonic acid) and plant oils/rape seed oil, the Commission has presented the renewal report and a draft Regulation renewing their approval to the Standing Committee on Plants, Animals, Food and Feed. Pending the delivery of an opinion of this Committee on the draft Regulations, additional time is needed to adopt the ensuing risk management decision.

(14) 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 August 2023 and 30 September 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.

(15) As the risk assessment has not yet been finalised by the respective rapporteur Member States, and in light of the remaining time required to complete each respective renewal procedure, the duration of the extension for the active substances 2,5-dichlorobenzoic acid methylester, acetic acid, aluminium phosphide, calcium carbide, dodemorph, ethylene, flonicamid (IKI-220), iron sulphate, magnesium phosphide, metamitron, sulcotrione and urea should be set at thirty-nine months, for the active substances extract from tea tree, maltodextrin, plant oils/clove oil and plant oils/spear mint oil should be set at twenty-nine months, and for the active substance tebuconazole should be set at thirty-five months and a half.

(16) As the Authority needs additional time to adopt a conclusion and, where appropriate, to organise a consultation of experts, the duration of the extension for the active substances hydrolysed proteins and pyrethrins should be set at nineteen months and a half and thirty-three months and a half, respectively. In particular, when 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, the duration of the extension for the active substance cymoxanil is set at thirty-five months and a half, and considering additional time is needed for its evaluation, the duration of the extension for the active substances gibberellic acid and gibberellins should be set at twenty-two months and a half.

(17) 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 ([10]), 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 Delegated Regulation (EU) 2020/217 ([11]), amending Annex VI to Regulation (EC) No 1272/2008, classifying halosulfuron-methyl as toxic for reproduction category 1B, the duration of the extension for the active substance should be set at eighteen months.

([10]) 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).

([11]) Commission Delegated Regulation (EU) 2020/217 of 4 October 2019 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 and correcting that Regulation (OJ L 44, 18.2.2020, p. 1).

(18) As the delivery of an opinion of the Standing Committee on Plants, Animals, Food and Feed is pending, the duration of the extension for the active substances aluminium ammonium sulphate, aluminium silicate, fat distillation residues, fatty acids C7-C20 and plant oils/rape seed oil should be set at fifteen months and a half.

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

(20) In case the Commission is to adopt a Regulation providing that the approval of an active substance referred to in the Annex to this Regulation is not renewed because the approval criteria are not satisfied, the Commission will set the expiry date at the same date as before 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 endeavour to set, as appropriate under the circumstances, the earliest possible application date.

(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, 12 July 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 218, Acetic acid, the date is replaced by '30 November 2026';

(2) in the sixth column, expiration of approval, of row 219, Aluminium ammonium sulphate, the date is replaced by '15 December 2024';

(3) in the sixth column, expiration of approval, of row 220, Aluminium silicate, the date is replaced by '15 December 2024';

(4) in the sixth column, expiration of approval, of row 223, Calcium carbide, the date is replaced by '30 November 2026';

(5) in the sixth column, expiration of approval, of row 227, Ethylene, the date is replaced by '30 November 2026';

(6) in the sixth column, expiration of approval, of row 228, Extract from tea tree, the date is replaced by '31 January 2026';

(7) in the sixth column, expiration of approval, of row 229, Fat distillation residues, the date is replaced by '15 December 2024';

(8) in the sixth column, expiration of approval, of row 230, Fatty acids C7 to C20, the date is replaced by '15 December 2024';

(9) in the sixth column, expiration of approval, of row 232, Gibberellic acid, the date is replaced by '15 July 2025';

(10) in the sixth column, expiration of approval, of row 233, Gibberellins, the date is replaced by '15 July 2025';

(11) in the sixth column, expiration of approval, of row 234, Hydrolysed proteins, the date is replaced by '15 April 2025';

(12) in the sixth column, expiration of approval, of row 235, Iron sulphate, the date is replaced by '30 November 2026';

(13) in the sixth column, expiration of approval, of row 241, Plant oils/clove oil, the date is replaced by '31 January 2026';

(14) in the sixth column, expiration of approval, of row 242, Plant oils/rape seed oil, the date is replaced by '15 December 2024';

(15) in the sixth column, expiration of approval, of row 243, Plant oils/spear mint oil, the date is replaced by '31 January 2026';

(16) in the sixth column, expiration of approval, of row 246, Pyrethrins, the date is replaced by '15 June 2026';

(17) in the sixth column, expiration of approval, of row 257, Urea, the date is replaced by '30 November 2026';

(18) in the sixth column, expiration of approval, of row 260, Aluminium phosphide, the date is replaced by '30 November 2026';

(19) in the sixth column, expiration of approval, of row 262, Magnesium phosphide, the date is replaced by '30 November 2026';

(20) in the sixth column, expiration of approval, of row 263, Cymoxanil, the date is replaced by '15 August 2026';

(21) in the sixth column, expiration of approval, of row 264, Dodemorph, the date is replaced by '30 November 2026';

(22) in the sixth column, expiration of approval, of row 265, 2,5-Dichlorobenzoic acid methylester, the date is replaced by '30 November 2026';

(23) in the sixth column, expiration of approval, of row 266, Metamitron, the date is replaced by '30 November 2026';

(24) in the sixth column, expiration of approval, of row 267, Sulcotrione, the date is replaced by '30 November 2026';

(25) in the sixth column, expiration of approval, of row 268, Tebuconazole, the date is replaced by '15 August 2026';

(26) in the sixth column, expiration of approval, of row 305, Flonicamid (IKI-220), the date is replaced by '30 November 2026';

2. Part B is amended as follows:

(1) in the sixth column, expiration of approval, of row 35, Halosulfuron-methyl, the date is replaced by '31 March 2025';

(2) in the sixth column, expiration of approval, of row 44, Maltodextrin, the date is replaced by '28 February 2026'.