Official Journal
of the European Union

EN
L series

2024/324

22.1.2024

COMMISSION IMPLEMENTING REGULATION (EU) 2024/324

of 19 January 2024

amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances benzovindiflupyr, bromuconazole, buprofezin, cyflufenamid, fluazinam, fluopyram, flutolanil, lambda-cyhalothrin, mecoprop-P, mepiquat, metsulfuron-methyl, phosphane and pyraclostrobin

(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 bromuconazole, buprofezin, cyflufenamid, fluazinam, flutolanil, mecoprop-P, mepiquat and pyraclostrobin are listed in Part A of the Annex to Implementing Regulation (EU) No 540/2011. The active substances fluopyram and phosphane are listed in Part B of that Annex and the active substances benzovindiflupyr, lambda-cyhalothrin and metsulfuron-methyl are listed in Part E of that Annex.

(3) Commission Implementing Regulation (EU) 2023/114 ([4]) extended the approval period of the active substances buprofezin, mecoprop-P and pyraclostrobin until 31 January 2024, of the active substances fluazinam, flutolanil and mepiquat until 29 February 2024, of the active substance benzovindiflupyr until 2 March 2024 and of the active substances cyflufenamid, lambda-cyhalothrin, metsulfuron-methyl and phosphane until 31 March 2024.

(4) Commission Implementing Regulation (EU) 2018/670 ([5]) extended the approval period of the active substance bromuconazole until 31 January 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) 2023/114 of 16 January 2023 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances benzovindiflupyr, buprofezin, cyflufenamid, fluazinam, flutolanil, lambda-cyhalothrin, mecoprop-P, mepiquat, metiram, metsulfuron-methyl, phosphane and pyraclostrobin (OJ L 15, 17.1.2023, p. 9, ELI: http://data.europa.eu/eli/reg_impl/2023/114/oj).

([5]) 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, ELI: http://data.europa.eu/eli/reg_impl/2018/670/oj).

(5) The approval of the active substance fluopyram is set to expire on 31 January 2024 in accordance with Commission Implementing Regulation (EU) No 802/2013 ([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 these applications were declared admissible by the respective rapporteur Member States.

(7) For the active substances benzovindiflupyr, bromuconazole, cyflufenamid, fluopyram, lambda-cyhalothrin and metsulfuron-methyl, 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 substance phosphane, 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 substance fluazinam, the Authority requested the submission of additional information for the purposes of assessment of the approval criteria set out in points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, pursuant to Article 13(3a), first subparagraph, of Implementing Regulation (EU) No 844/2012, with a deadline of 17 December 2023.

(10) For the active substances buprofezin, mepiquat and pyraclostrobin, the Authority requested the submission of additional information for the purposes of assessment of the approval criteria set out in points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, pursuant to Article 13(3a), first subparagraph, of Implementing Regulation (EU) No 844/2012. This information 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 substances flutolanil and mecoprop-P, the Authority has submitted its conclusion to the applicant, the Member States and the Commission. The Commission has initiated discussions on these active substances 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 these active substances can be taken before the expiry of their respective approval periods on 31 January 2024, 29 February 2024, 2 March 2024 and 31 March 2024, and that the reasons for the delays in the renewal procedures are beyond the control of the respective applicants, the approval periods of these 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 of the approval periods for the active substances bromuconazole and cyflufenamid should be set at 39 months and for the active substances benzovindiflupyr, fluopyram, lambda-cyhalothrin and metsulfuron-methyl should be set at 29 months.

([6]) Commission Implementing Regulation (EU) No 802/2013 of 22 August 2013 approving the active substance fluopyram, 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 225, 23.8.2013, p. 13, ELI: http://data.europa.eu/eli/reg_impl/2013/802/oj).

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

(14) As the Authority needs additional time to reach a conclusion on the risk assessment for the active substance phosphane requiring, where appropriate, a consultation of experts, the duration of the extension of the approval period for this active substance should be set at 23 months and 2 weeks.

(15) As the Authority requested additional information for the purposes of assessment of the approval criteria set out in points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009 for the active substance fluazinam, and in light of the time required to complete the remaining steps in the renewal procedure, the duration of the extension of the approval period for this active substance should be set at 25 months and 2 weeks.

(16) 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 points 3.6.5 and 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 of the approval period for the active substance buprofezin should be set at 22 months and 2 weeks, and for the active substances mepiquat and pyraclostrobin should be set at 19 months and 2 weeks.

(17) 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 accomplish each renewal procedure, the duration of the extension of the approval periods for the active substances flutolanil and mecoprop-p should be set at 15 months and 2 weeks.

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

(19) 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.

(20) 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 third 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, 19 January 2024.

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 57, Mecoprop-P, the date is replaced by '15 May 2025';
   (2) in the sixth column, expiration of approval, of row 81, Pyraclostrobin, the date is replaced by '15 September 2025';
   (3) in the sixth column, expiration of approval, of row 187, Flutolanil, the date is replaced by '15 June 2025';
   (4) in the sixth column, expiration of approval, of row 189, Fluazinam, the date is replaced by '15 April 2026';
   (5) in the sixth column, expiration of approval, of row 191, Mepiquat, the date is replaced by '15 October 2025';
   (6) in the sixth column, expiration of approval, of row 296, Cyflufenamid, the date is replaced by '30 June 2027';
   (7) in the sixth column, expiration of approval, of row 318, Bromuconazole, the date is replaced by '30 April 2027';
   (8) in the sixth column, expiration of approval, of row 320, Buprofezin, the date is replaced by '15 December 2025'.
2. Part B is amended as follows:
   (1) in the sixth column, expiration of approval, of row 28, Phosphane, the date is replaced by '15 March 2026';
   (2) in the sixth column, expiration of approval, of row 51, Fluopyram, the date is replaced by '30 June 2026'.
3. Part E is amended as follows:
   (1) in the sixth column, expiration of approval, of row 3, Metsulfuron-methyl, the date is replaced by '31 August 2026';
   (2) in the sixth column, expiration of approval, of row 4, Benzovindiflupyr, the date is replaced by '2 August 2026';
   (3) in the sixth column, expiration of approval, of row 5, Lambda-cyhalothrin, the date is replaced by '31 August 2026'.