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COMMISSION IMPLEMENTING REGULATION (EU) 2025/2316

of 17 November 2025

amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances aluminium silicate, difenoconazole, diflufenican, disodium phosphonate, extract from tea tree, flurochloridone, indolylbutyric acid, maltodextrin, phosphane, plant oils/clove oil, plant oils/spear mint oil, potassium phosphonates and triclopyr

(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) Commission Directive 2006/74/EC ([2]) included triclopyr as an active substance in Annex I to Council Directive 91/414/EEC ([3]) until 31 May 2017.

(2) Commission Directive 2008/66/EC ([4]) included diflufenican as an active substance in Annex I to Directive 91/414/EEC until 31 December 2018.

(3) Commission Directive 2008/69/EC ([5]) included difenoconazole as an active substance in Annex I to Directive 91/414/EEC until 31 December 2018.

(4) Commission Directive 2008/127/EC ([6]) included aluminium silicate, extract from tea tree, plant oils/clove oil and plant oils/spear mint oil as active substances in Annex I to Directive 91/414/EEC until 31 August 2019.

(5) Commission Directive 2011/28/EU ([7]) included indolylbutyric acid as an active substance in Annex I to Directive 91/414/EEC until 31 May 2021.

(6) Commission Directive 2011/34/EU ([8]) included flurochloridone as an active substance in Annex I to Directive 91/414/EEC until 31 May 2021.

([1]) OJ L 309, 24.11.2009, p. 1, ELI: http://data.europa.eu/eli/reg/2009/1107/oj.
([2]) Commission Directive 2006/74/EC of 21 August 2006 amending Council Directive 91/414/EEC to include dichlorprop-P, metconazole, pyrimethanil and triclopyr as active substances (OJ L 235, 30.8.2006, p. 17, ELI: http://data.europa.eu/eli/dir/2006/74/oj).
([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, ELI: http://data.europa.eu/eli/dir/1991/414/oj).
([4]) Commission Directive 2008/66/EC of 30 June 2008 amending Council Directive 91/414/EEC to include bifenox, diflufenican, fenoxaprop-P, fenpropidin and quinoclamine as active substances (OJ L 171, 1.7.2008, p. 9, ELI: http://data.europa.eu/eli/dir/2008/66/oj).
([5]) Commission Directive 2008/69/EC of 1 July 2008 amending Council Directive 91/414/EEC to include clofentezine, dicamba, difenoconazole, diflubenzuron, imazaquin, lenacil, oxadiazon, picloram and pyriproxyfen as active substances (OJ L 172, 2.7.2008, p. 9, ELI: http://data.europa.eu/eli/dir/2008/69/oj).
([6]) Commission Directive 2008/127/EC of 18 December 2008 amending Council Directive 91/414/EEC to include several active substances (OJ L 344, 20.12.2008, p. 89, ELI: http://data.europa.eu/eli/dir/2008/127/oj).
([7]) Commission Directive 2011/28/EU of 4 March 2011 amending Council Directive 91/414/EEC to include indolylbutyric acid as active substance and amending Commission Decision 2008/941/EC (OJ L 60, 5.3.2011, p. 17, ELI: http://data.europa.eu/eli/dir/2011/28/oj).
([8]) Commission Directive 2011/34/EU of 8 March 2011 amending Council Directive 91/414/EEC to include flurochloridone as active substance and amending Commission Decision 2008/934/EC (OJ L 62, 9.3.2011, p. 27, ELI: http://data.europa.eu/eli/dir/2011/34/oj).

(7) Commission Implementing Regulation (EU) No 1043/2012 ([9]) approved the active substance phosphane until 31 March 2023.

(8) Commission Implementing Regulation (EU) No 355/2013 ([10]) approved the active substance maltodextrin until 30 September 2023.

(9) Commission Implementing Regulation (EU) No 369/2013 ([11]) approved the active substance potassium phosphonates until 30 September 2023.

(10) Commission Implementing Regulation (EU) No 832/2013 ([12]) approved the active substance disodium phosphonate until 31 January 2024.

(11) The active substances aluminium silicate, difenoconazole, diflufenican, extract from tea tree, flurochloridone, indolylbutyric acid, plant oils/clove oil, plant oils/spear mint oil and triclopyr were included in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011 ([13]). The active substances disodium phosphonate, maltodextrin, phosphane and potassium phosphonates were included in Part B of the Annex to that Regulation.

(12) Commission Implementing Regulation (EU) 2020/2007 ([14]) extended the approval periods of the active substances disodium phosphonate and potassium phosphonates until 31 January 2026.

([9]) Commission Implementing Regulation (EU) No 1043/2012 of 8 November 2012 approving the active substance phosphane, 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 310, 9.11.2012, p. 24, ELI: http://data.europa.eu/eli/reg_impl/2012/1043/oj).

([10]) 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, ELI: http://data.europa.eu/eli/reg_impl/2013/355/oj).

([11]) Commission Implementing Regulation (EU) No 369/2013 of 22 April 2013 approving the active substance potassium phosphonates, 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 111, 23.4.2013, p. 39, ELI: http://data.europa.eu/eli/reg_impl/2013/369/oj).

([12]) Commission Implementing Regulation (EU) No 832/2013 of 30 August 2013 approving the active substance disodium phosphonate, 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 233, 31.8.2013, p. 3, ELI: http://data.europa.eu/eli/reg_impl/2013/832/oj).

([13]) 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).

([14]) 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).

(13) Commission Implementing Regulation (EU) 2023/918 ([15]) extended the approval periods of the active substances flurochloridone and indolylbutyric acid until 15 March 2026.

(14) Commission Implementing Regulation (EU) 2023/1446 ([16]) extended the approval periods of the active substances extract from tea tree, plant oils/clove oil and plant oils/spear mint oil until 31 January 2026, and the approval period of the active substance maltodextrin until 28 February 2026.

(15) Commission Implementing Regulation (EU) 2023/2592 ([17]) extended the approval period of the active substance difenoconazole until 15 March 2026, and the approval period of the active substance diflufenican until 15 January 2026.

(16) Commission Implementing Regulation (EU) 2024/324 ([18]) extended the approval period of the active substance phosphane until 15 March 2026.

(17) Commission Implementing Regulation (EU) 2024/2221 ([19]) extended the approval periods of the active substances aluminium silicate and triclopyr until 31 March 2026.

(18) Applications for the respective renewals of the approval of the active substances aluminium silicate, difenoconazole, diflufenican, extract from tea tree, flurochloridone, indolylbutyric acid, maltodextrin, phosphane, plant oils/clove oil, plant oils/spear mint oil and triclopyr were submitted in accordance with Commission Implementing Regulation (EU) No 844/2012 ([20]).

(19) On 6 December 2016, 19 January 2016, 5 April 2016, 20 January 2017, 18 July 2018, 28 June 2018, 17 December 2020, 15 September 2020, 19 September 2016, 26 September 2016 and 4 September 2014, the rapporteur Member States, respectively, for the active substances aluminium silicate, difenoconazole, diflufenican, extract from tea tree, flurochloridone, indolylbutyric acid, maltodextrin, phosphane, plant oils/clove oil, plant oils/spear mint oil and

([15]) Commission Implementing Regulation (EU) 2023/918 of 4 May 2023 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances aclonifen, ametoctradin, beflubutamid, benthiavalicarb, boscalid, captan, clethodim, cycloxydim, cyflumetofen, dazomet, diclofop, dimethomorph, ethephon, fenazaquin, fluopicolide, fluoxastrobin, flurochloridone, folpet, formetanate, *Helicoverpa armigera nucleopolyhedrovirus*, hymexazol, indolylbutyric acid, mandipropamid, metalaxyl, metaldehyde, metam, metazachlor, metribuzin, milbemectin, paclobutrazol, penoxsulam, phenmedipham, pirimiphos-methyl, propamocarb, proquinazid, prothioconazole, S-metolachlor, *Spodoptera littoralis nucleopolyhedrovirus*, *Trichoderma asperellum* strain T34 and Trichoderma atroviride strain I-1237 (OJ L 119, 5.5.2023, p. 160, ELI: http://data.europa.eu/eli/reg_impl/2023/918/oj).

([16]) 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 (OJ L 178, 13.7.2023, p. 1, ELI: http://data.europa.eu/eli/reg_impl/2023/1446/oj).

([17]) 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 (OJ L, 2023/2592, 22.11.2023, ELI: http://data.europa.eu/eli/reg_impl/2023/2592/oj).

([18]) 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 (OJ L, 2024/324, 22.1.2024, ELI: http://data.europa.eu/eli/reg_impl/2024/324/oj).

([19]) Commission Implementing Regulation (EU) 2024/2221 of 6 September 2024 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances acequinocyl, aluminium silicate, emamectin, fatty acids C7 to C20, pendimethalin, plant oils / rape seed oil and triclopyr (OJ L, 2024/2221, 9.9.2024, ELI: http://data.europa.eu/eli/reg_impl/2024/2221/oj).

([20]) 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).

triclopyr informed the co-rapporteur Member States, the Commission and the European Food Safety Authority (the 'Authority') that they had assessed the admissibility of the applications pursuant to Article 3 of Implementing Regulation (EU) No 844/2012, and in particular the completeness and the timeliness, of each of the applications for renewal of the approval of each of those active substances and concluded that they were admissible. Those applications have been made public by the Authority pursuant to Article 5 of Implementing Regulation (EU) No 844/2012.

(20) On 11 May 2020, 11 January 2019, 20 July 2018, 2 March 2022, 7 August 2022, 14 June 2022, 8 June 2023, 23 December 2021, 29 September 2021, 29 September 2023 and 10 October 2018, the rapporteur Member States, respectively, for the active substances aluminium silicate, difenoconazole, diflufenican, extract from tea tree, flurochloridone, indolylbutyric acid, maltodextrin, phosphane, plant oils/clove oil, plant oils/spear mint oil and triclopyr submitted the draft renewal assessment reports to the Authority. The Authority, pursuant to Article 12 of Implementing Regulation (EU) No 844/2012, concluded that the reports for all those active substances contained all the relevant information in the agreed format, circulated them to the applicants and to the other Member States and made them available to the public for written comments.

(21) For the active substances plant oils/clove oil and plant oils/spear mint oil, additional information for the purposes of the renewal assessment was requested by the Authority pursuant to Article 13(3) of Implementing Regulation (EU) No 844/2012 and was submitted by the applicants within the deadline given. The rapporteur Member State submitted the revised draft renewal assessment report for plant oils/spear mint oil to the Authority and the public consultation on it finished on 5 September 2025. However, additional time is needed for the Authority to complete the evaluations and to finalise its conclusions for plant oils/clove oil and plant oils/spear mint oil, as well as for the Commission to adopt the ensuing risk management decisions.

(22) For the active substances difenoconazole, diflufenican, extract from tea tree, flurochloridone and indolylbutyric acid, on 22 July 2021, 5 May 2021, 20 June 2024, 28 October 2024 and 3 April 2024, respectively, additional information for the purposes of assessment of the approval criteria concerning endocrine disrupting properties set out in points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605 ([21]), was requested by the Authority in consultation with the Member States pursuant to Article 13(3a) of Implementing Regulation (EU) No 844/2012. The additional information for difenoconazole, diflufenican and flurochloridone was submitted by the applicants within the deadline given, and for extract from tea tree and indolylbutyric acid the submission is pending. The rapporteur Member States submitted the revised draft renewal assessment reports for diflufenican and flurochloridone to the Authority and the public consultations on them finished on 18 June 2024 and 3 June 2025, respectively. However, additional time is needed for the Authority to complete the evaluation and to finalise its conclusion for difenoconazole, diflufenican, extract from tea tree, flurochloridone and indolylbutyric acid, as well as for the Commission to adopt the ensuing risk management decision.

(23) For the active substances aluminium silicate, maltodextrin, phosphane and triclopyr, the Authority adopted its conclusions on 14 October 2022, 15 February 2024, 9 December 2024, and 17 July 2024, respectively, and communicated them to the applicants, the Member States and the Commission. The Commission has initiated discussions on the renewal of the approvals of those active substances in the Standing Committee on Plants, Animals, Food and Feed. Additional time is necessary for the delivery of the opinion of that Committee and for the Commission to adopt the ensuing risk management decisions.

(24) Applications for the respective renewal of the approvals of the active substances disodium phosphonate and potassium phosphonates were submitted in accordance with Commission Implementing Regulation (EU) 2020/1740 ([22]).

([21]) Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties (OJ L 101, 20.4.2018, p. 33, ELI: http://data.europa.eu/eli/reg/2018/605/oj).

([22]) 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).

(25) On 19 November 2024 and 8 January 2025, the rapporteur Member State for the active substances disodium phosphonate and potassium phosphonates informed the co-rapporteur Member State, the Commission and the Authority that it had assessed the admissibility pursuant to Article 8 of Implementing Regulation (EU) 2020/1740, and in particular the completeness and the timeliness, of each of the applications for renewal of the approval of each of those active substances and concluded that they were admissible. Those applications have been made public by the Authority pursuant to Article 10 of Implementing Regulation (EU) 2020/1740.

(26) The risk assessments pursuant to Article 11 of Implementing Regulation (EU) 2020/1740 for disodium phosphonate and potassium phosphonates have not yet been finalised by the rapporteur Member State and additional time is required to complete the remaining steps in each renewal procedure.

(27) It is therefore likely for all of the active substances covered by this Regulation that no decision on the renewal of the approval can be taken before the expiry of their respective approval periods, between 15 January and 31 March 2026. Furthermore, the reasons for the delays in these renewal procedures are beyond the control of the respective applicants. Therefore, the approval periods of those active substances should be extended to enable the completion of the assessments required and to finalise the respective procedures on the renewal of the approvals.

(28) For the active substances disodium phosphonate and potassium phosphonates, the risk assessment has not been finalised yet by the rapporteur Member State. Taking into account the subsequent steps to be completed in each renewal procedure, the duration of the extension of the approval periods of these active substances should be set at 42 months.

(29) For the active substances difenoconazole, diflufenican, extract from tea tree, flurochloridone, indolylbutyric acid, plant oils/clove oil and plant oils/spear mint oil, the Authority needs additional time to reach a conclusion on the risk assessment. Taking into account the subsequent steps to be completed in each renewal procedure, the duration of the extension of the approval periods of these active substances should be set at 19 months and 15 days for diflufenican and flurochloridone, at 22 months and 15 days for difenoconazole, extract from tea tree and indolylbutyric acid, at 23 months and 15 days for plant oils/spear mint oil, and at 29 months for plant oils/clove oil.

(30) For the active substances aluminium silicate, maltodextrin, phosphane and triclopyr, as the delivery of an opinion of the Standing Committee on Plants, Animals, Food and Feed is pending, and in light of the remaining steps to be completed in these renewal procedures, the duration of the extension of the approval period should be set at 12 months.

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

(32) 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 for the approval of this active substance 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, as appropriate under the circumstances, the earliest possible application date.

(33) 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, 17 November 2025.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

1. Part A of the Annex to Implementing Regulation (EU) No 540/2011 is amended as follows:
   (1) in the sixth column, expiration of approval, of row 136, Triclopyr, the date is replaced by '31 March 2027';
   (2) in the sixth column, expiration of approval, of row 173, Difenoconazole, the date is replaced by '31 January 2028';
   (3) in the sixth column, expiration of approval, of row 181, Diflufenican, the date is replaced by '31 August 2027';
   (4) in the sixth column, expiration of approval, of row 220, Aluminium silicate, the date is replaced by '31 March 2027';
   (5) in the sixth column, expiration of approval, of row 228, Extract from tea tree, the date is replaced by '15 December 2027';
   (6) in the sixth column, expiration of approval, of row 241, Plant oils/clove oil, the date is replaced by '30 June 2028';
   (7) in the sixth column, expiration of approval, of row 243, Plant oils/spear mint oil, the date is replaced by '15 January 2028';
   (8) in the sixth column, expiration of approval, of row 326, Indolylbutyric acid, the date is replaced by '31 January 2028';
   (9) in the sixth column, expiration of approval, of row 354, Flurochloridone, the date is replaced by '31 October 2027'.

2. 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 28, Phosphane, the date is replaced by '15 March 2027';
   (2) in the sixth column, expiration of approval, of row 40, Potassium phosphonates, the date is replaced by '31 July 2029';
   (3) in the sixth column, expiration of approval, of row 44, Maltodextrin, the date is replaced by '28 February 2027';
   (4) in the sixth column, expiration of approval, of row 54, Disodium phosphonate, the date is replaced by '31 July 2029'.