



2024/2221

9.9.2024

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

(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 subparagraph, thereof,

Whereas:

- (1) Commission Directive 2006/74/EC ⁽²⁾ approved the active substance triclopyr until 31 May 2017. Commission Directive 2008/127/EC ⁽³⁾ approved the active substances aluminium silicate, fatty acids and plant oils / rape seed oil until 31 August 2019.
- (2) According to Article 78(3) of Regulation (EC) No 1107/2009, active substances included in Annex I to Council Directive 91/414/EEC ⁽⁴⁾ are deemed to have been approved under Regulation (EC) No 1107/2009.
- (3) Commission Implementing Regulation (EU) No 828/2013 ⁽⁵⁾ approved the active substance emamectin until 30 April 2024. Commission Implementing Regulation (EU) No 496/2014 ⁽⁶⁾ approved the active substance acequinocyl, until 31 August 2024. Commission Implementing Regulation (EU) 2017/1114 ⁽⁷⁾ renewed the approval of the active substance pendimethalin until 31 August 2024.

⁽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⁾ 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>).

⁽⁴⁾ 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>).

⁽⁵⁾ Commission Implementing Regulation (EU) No 828/2013 of 29 August 2013 approving the active substance emamectin, 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 232, 30.8.2013, p. 23, ELI: http://data.europa.eu/eli/reg_impl/2013/828/oj).

⁽⁶⁾ Commission Implementing Regulation (EU) No 496/2014 of 14 May 2014 approving the active substance acequinocyl, 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 143, 15.5.2014, p. 1, ELI: http://data.europa.eu/eli/reg_impl/2014/496/oj).

⁽⁷⁾ Commission Implementing Regulation (EU) 2017/1114 of 22 June 2017 renewing the approval of the active substance pendimethalin, as a candidate for substitution, 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 162, 23.6.2017, p. 32, ELI: http://data.europa.eu/eli/reg_impl/2017/1114/oj).

- (4) The approvals of the active substances aluminium silicate, fatty acids, plant oils / rape seed oil and triclopyr, respectively, are listed in Part A of the Annex to Implementing Regulation (EU) No 540/2011 ⁽⁸⁾. The approvals of the active substances acequinocyl and emamectin, respectively, are listed in Part B of the Annex to Implementing Regulation (EU) No 540/2011. The approval of the active substance pendimethalin is listed in Part E of the Annex of Implementing Regulation (EU) No 540/2011.
- (5) Commission Implementing Regulation (EU) 2020/2007 ⁽⁹⁾ extends the respective approval periods of the active substances acequinocyl, emamectin and pendimethalin until 30 November 2024 .
- (6) Commission Implementing Regulation (EU) 2023/1446 ⁽¹⁰⁾ extends the respective approval periods of the active substances aluminium silicate, fatty acids, plant oils / rape seed oil until 15 December 2024.
- (7) Commission Implementing Regulation (EU) 2023/689 ⁽¹¹⁾ extends the approval period of the active substance triclopyr until 15 December 2024.
- (8) Applications and supplementary dossiers for the renewal of the approvals of each of these active substances were submitted, in accordance with Commission Implementing Regulation (EU) 2020/1740 ⁽¹²⁾, 3 years before the extended expiry date of the active substances. On 23 May 2023, 6 December 2016, 29 February 2016, 23 August 8, 4 June 2018, 9 December 2015, 1 February 2022, 29 September 2016 and 4 September 2014 respectively, the rapporteur Member States for acequinocyl, aluminium silicate, emamectin, fatty acids C7 to C20, pendimethalin,

⁽⁸⁾ 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).

⁽⁹⁾ 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, penflupyrad, potassium phosphonates, prosulfuron, Pseudomonas sp. strain DSMZ 13134, pyridalyl, pyriofenone, pyroxusulam, quinmerac, S-abcisic acid, sedaxane, sintofen, sodium silver thiosulfate, spinetoram, spirotetramat, Streptomyces lydicus strain WYEC 108, tau-fluvalinate, tebufenozide, tembotrione, thiencazabone, valifenalate, zinc phosphide (OJ L 414, 9.12.2020, p. 10, ELI: http://data.europa.eu/eli/reg_impl/2020/2007/oj).

⁽¹⁰⁾ 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).

⁽¹¹⁾ Commission Implementing Regulation (EU) 2023/689 of 20 March 2023 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances Bacillus subtilis (Cohn 1872) strain QST 713, Bacillus thuringiensis subsp. Aizawai strains ABTS-1857 and GC-91, Bacillus thuringiensis subsp. Israeliensis (serotype H-14) strain AM65-52, Bacillus thuringiensis subsp. Kurstaki strains ABTS 351, PB 54, SA 11, SA12 and EG 2348, Beauveria bassiana strains ATCC 74040 and GHA, clodinafop, Cydia pomonella Granulovirus (CpGV), cyprodinil, dichlorprop-P, fenpyroximate, fosetyl, malathion, mepanipyrim, metconazole, metrafenone, pirimicarb, pyridaben, pyrimethanil, rimsulfuron, spinosad, Trichoderma asperellum (formerly T. harzianum) strains ICC012, T25 and TV1, Trichoderma atroviride (formerly T. harzianum) strain T11, Trichoderma gamsii (formerly T. viride) strain ICC080, Trichoderma harzianum strains T-22 and ITEM 908, triclopyr, trinexapac, triticonazole and ziram (OJ L 91, 29.3.2023, p. 1, ELI: http://data.europa.eu/eli/reg_impl/2023/689/oj).

⁽¹²⁾ 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).

plant oils / rape seed oil and triclopyr, respectively informed the co-rapporteur Member State, the Commission and the European Food Safety Authority (the 'Authority') that they had assessed the admissibility, in particular the completeness and the timeliness, of each of these applications, and concluded that they were admissible.

- (9) With regard to the renewal of the approvals of the active substances acequinocyl, emamectin, fatty acids C7 to C20 and pendimethalin, respectively, the Authority needs additional time to conclude the risk assessment carried out for these substances, including, where appropriate, a public consultation and a consultation of experts. Additional time is necessary for the Commission to adopt the ensuing risk management decision.
- (10) For the active substances aluminium silicate, plant oils / rape seed oil and triclopyr, the Authority has submitted its conclusion to the applicant, the Member States and the Commission. The Commission has presented a renewal report and a draft Regulation on the renewal of these active substances' approvals to the Standing Committee on Plants, Animals, Food and Feed.
- (11) Given that it is therefore 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 15 November 2024, 30 November 2024 and 15 December 2024, and that the reasons for the delays in the renewal procedures are beyond the control of the respective applicants, the approval periods of those active substances should be extended in order to enable the completion of the assessments required and to finalise the respective procedures on renewal of approval.
- (12) As the Authority needs additional time to reach a conclusion on the risk assessment of the active substances acequinocyl, emamectin and fatty acids C7 to C20, the duration of the extension of the approval period for these active substances should be set at 23 months and 2 weeks. For the active substance pendimethalin, 2 additional months are necessary to finalise the public consultation pursuant to Article 12 of Implementing Regulation (EU) 2020/1740, therefore the extension of the approval period for this active substance should be set at 25 months and 2 weeks.
- (13) As for the active substances aluminium silicate, plant oils / rape seed oil and triclopyr, 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 those active substances should be set at 15 months and 2 weeks and Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.
- (14) 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 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 the earliest possible application date, as appropriate under the circumstances.
- (15) 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, 6 September 2024.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

1. Part A is amended as follows:
 - (1) in the sixth column, expiration of approval, of row 136, triclopyr, the date is replaced by ‘31 March 2026’;
 - (2) in the sixth column, expiration of approval, of row 220, aluminium silicate, the date is replaced by ‘31 March 2026’;
 - (3) in the sixth column, expiration of approval, of row 242, plant oils / rape seed oil, the date is replaced by ‘31 March 2026’;
 - (4) row 230, Fatty acids C7 to C20, is replaced by the following:

No.	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
230	Fatty acids C7 to C20					
	CAS No 112-05-0 (Pelargonic Acid) 67701-09-1 (Fatty acids C7-C18 and C18 unsaturated potassium salts) 124-07-2 (Caprylic Acid) 334-48-5 (Capric Acid)	Nonanoic acid Caprylic Acid, Pelargonic Acid, Capric Acid, Lauric Acid, Oleic Acid (ISO in each case) Octanoic Acid, Nonanoic Acid, Decanoic Acid, Dodecanoic Acid, cis-9-Octadecenoic Acid (IUPAC in each case) Fatty acids, C7-C10, Me esters	≥ 889 g/kg (Pelargonic Acid) ≥ 838 g/kg fatty acids ≥ 99 % fatty acid methyl esters	1 September 2009	1 December 2026	PART A Only uses as insecticide, acaricide, and herbicide and plant growth regulator may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on fatty acids (SANCO/2610/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account. Conditions of use shall include, where appropriate, risk mitigation measures.’
	143-07-7 (Lauric Acid) 112-80-1 (Oleic Acid) 85566-26-3 (Fatty acids C8-C10 Me esters) 111-11-5 (Methyl octanoate) 110-42-9 (Methyl decanoate) CIPAC No not allocated	Nonanoic acid Caprylic Acid, Pelargonic Acid, Capric Acid, Lauric Acid, Oleic Acid (ISO in each case) Octanoic Acid, Nonanoic Acid, Decanoic Acid, Dodecanoic Acid, cis-9-Octadecenoic Acid	≥ 889 g/kg (Pelargonic Acid) ≥ 838 g/kg fatty acids ≥ 99 % fatty acid methyl esters	1 September 2009	31 August 2024	

		(IUPAC in each case) Fatty acids, C7-C10, Me esters				
--	--	---	--	--	--	--

(¹) Further details on the identity and specification of the active substance are provided in the renewal report.

2. Part B is amended as follows:
- (1) in the sixth column, expiration of approval, of row 49, emamectin, the date is replaced by ‘15 November 2026’;

(2) in the sixth column, expiration of approval, of row 72, acequinocyl, the date is replaced by ‘15 November 2026’;
3. Part E, in the sixth column, expiration of approval, of row 7, pendimethalin, the date is replaced by ‘15 January 2027’.
