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

(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) Pursuant to Article 78(3) of Regulation (EC) No 1107/2009, active substances included in Annex I to 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 Commission Implementing Regulation (EU) No 540/2011 ([3]). Active substances approved under Regulation (EC) No 1107/2009 are listed in Part B of that Annex.

(2) Commission Implementing Regulation (EU) 2022/708 ([4]) extends the approval period of the active substance flurochloridone until 31 May 2023. That Regulation also extends the approval period of the active substance metam until 30 June 2023 and of the active substances aclonifen, beflubutamid, benthiavalicarb, boscalid, captan, dimethomorph, ethephon, fluoxastrobin, folpet, formetanate, metazachlor, metribuzin, milbemectin, phenmedipham, pirimiphos-methyl, propamocarb, proquinazid, prothioconazole and S-metolachlor until 31 July 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) 2022/708 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).

(3) Commission Implementing Regulation (EU) 2018/1266 ([5]) extends the approval period of the active substances clethodim, cycloxydim, dazomet, diclofop, fenazaquin, hymexazol, indolylbutyric acid, metaldehyde and paclobutrazol until 31 May 2023.

(4) Commission Implementing Regulation (EU) 2017/1527 ([6]) extends the approval period of the active substance fluopicolide until 31 May 2023.

(5) Commission Implementing Regulation (EU) 2017/2069 ([7]) extends the approval period of the active substance metalaxyl until 30 June 2023, and of the active substance penoxsulam until 31 July 2023.

(6) The approval of the active substance ametoctradin is set to expire on 31 July 2023 in accordance with Commission Implementing Regulation (EU) No 200/2013 ([8]).

(7) The approval of the active substance cyflumetofen is set to expire on 31 May 2023 in accordance with Commission Implementing Regulation (EU) No 22/2013 ([9]).

(8) The approval of the active substance *Helicoverpa armigera nucleopolyhedrovirus* is set to expire on 31 May 2023 in accordance with Commission Implementing Regulation (EU) No 368/2013 ([10]).

(9) The approval of the active substance mandipropamid is set to expire on 31 July 2023 in accordance with Commission Implementing Regulation (EU) No 188/2013 ([11]).

(10) The approval of the active substance *Spodoptera littoralis nucleopolyhedrovirus* is set to expire on 31 May 2023 in accordance with Commission Implementing Regulation (EU) No 367/2013 ([12]).

([5]) Commission Implementing Regulation (EU) 2018/1266 of 20 September 2018 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 1-decanol, 6-benzyladenine, aluminium sulfate, azadirachtin, bupirimate, carboxin, clethodim, cycloxydim, dazomet, diclofop, dithianon, dodine, fenazaquin, fluometuron, flutriafol, hexythiazox, hymexazol, indolylbutyric acid, isoxaben, lime sulphur, metaldehyde, paclobutrazol, pencycuron, sintofen, tau-fluvalinate and tebufenozide (OJ L 238, 21.9.2018, p. 81).

([6]) Commission Implementing Regulation (EU) 2017/1527 of 6 September 2017 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances cyflufenamid, fluopicolide, heptamaloxyloglucan and malathion (OJ L 231, 7.9.2017, p. 3).

([7]) 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).

([8]) Commission Implementing Regulation (EU) No 200/2013 of 8 March 2013 approving the active substance ametoctradin, 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 67, 9.3.2013, p. 1).

([9]) Commission Implementing Regulation (EU) No 22/2013 of 15 January 2013 approving the active substance cyflumetofen, 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 11, 16.1.2013, p. 8).

([10]) Commission Implementing Regulation (EU) No 368/2013 of 22 April 2013 approving the active substance *Helicoverpa armigera nucleopolyhedrovirus*, 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. 36).

([11]) Commission Implementing Regulation (EU) No 188/2013 of 5 March 2013 approving the active substance mandipropamid, 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 62, 6.3.2013, p. 13).

([12]) Commission Implementing Regulation (EU) No 367/2013 of 22 April 2013 approving the active substance *Spodoptera littoralis nucleopolyhedrovirus*, 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. 33).

(11) The approval of the active substance *Trichoderma asperellum* strain T34 is set to expire on 31 May 2023 in accordance with Commission Implementing Regulation (EU) No 1238/2012 ([13]).

(12) The approval of the active substance *Trichoderma atroviride* strain I-1237 is set to expire on 31 May 2023 in accordance with Commission Implementing Regulation (EU) No 17/2013 ([14]).

(13) 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 ([15]), which continues to apply to these active substances pursuant to Article 17 of Commission Implementing Regulation (EU) 2020/1740 ([16]). They were declared admissible by the respective rapporteur Member States.

(14) For the active substances aclonifen, ametoctradin, beflubutamid, clethodim, cycloxydim, cyflumetofen, dazomet, diclofop, fenazaquin, fluopicolide, *Helicoverpa armigera nucleopolyhedrovirus*, hymexazol, mandipropamid, metalaxyl, metaldehyde, metam, metazachlor, paclobutrazol, *Spodoptera littoralis nucleopolyhedrovirus*, *Trichoderma asperellum* strain T34 and *Trichoderma atroviride* strain I-1237, 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.

(15) For the active substances boscalid, flurochloridone, indolylbutyric acid, penoxsulam, and proquinazid, the European Food Safety Authority ('the Authority') will need additional time, in accordance with Article 13 of Implementing Regulation (EU) No 844/2012, to adopt a conclusion and where appropriate to organise a consultation of experts. Furthermore, additional time is needed for the ensuing risk management decision in accordance with Article 14 of Implementing Regulation (EU) No 844/2012.

(16) For the active substance prothioconazole, 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 15 April 2023. For the active substances dimethomorph, fluoxastrobin, folpet, formetanate, metribuzin, milbemectin, paclobutrazol, penoxsulam, phenmedipham, pirimiphos-methyl and propamocarb, 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 for the related conclusion as well as for the ensuing risk management decision in accordance with Articles 13 and 14 of Implementing Regulation (EU) No 844/2012.

(17) For the active substances benthiavalicarb and captan, the Authority has submitted its conclusion in accordance with Article 13 of Implementing Regulation (EU) No 844/2012. The Commission has initiated discussions on those active substances in the Standing Committee on Plants, Animals, Food and Feed pursuant to Article 14 of Implementing Regulation (EU) No 844/2012 and as regards captan, it has presented the renewal report and the draft Regulation renewing its approval. Pending the opinion of this Committee on that draft Regulation, additional time is needed for the ensuing risk management decision in accordance with Article 14 of Implementing Regulation (EU) No 844/2012.

([13]) Commission Implementing Regulation (EU) No 1238/2012 of 19 December 2012 approving the active substance *Trichoderma asperellum* (strain T34), 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 350, 20.12.2012, p. 59).

([14]) Commission Implementing Regulation (EU) No 17/2013 of 14 January 2013 approving the active substance *Trichoderma atroviride* strain I-1237, 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 9, 15.1.2013, p. 5).

([15]) 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).

([16]) 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).

(18) For the active substance S-metolachlor, on 3 February 2023, the Authority has submitted to the Commission and Member States its conclusion in accordance with Article 13 of Implementing Regulation (EU) No 844/2012, excluding the assessment of the endocrine disrupting properties. However, additional time is needed for adopting a risk management decision in accordance with Article 14 of Implementing Regulation (EU) No 844/2012.

(19) It is therefore 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 May 2023, 30 June 2023 and 31 July 2023. The reasons for the delay in the renewal procedures are also beyond the control of the respective applicants.

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

(21) 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 is to 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.

(22) Taking into account that the current approval of clethodim, cycloxydim, cyflumetofen, dazomet, diclofop, fenazaquin, fluopicolide, flurochloridone, *Helicoverpa armigera nucleopolyhedrovirus*, hymexazol, indolylbutyric acid, metaldehyde, paclobutrazol, *Spodoptera littoralis nucleopolyhedrovirus, Trichoderma asperellum* strain T34 and *Trichoderma atroviride* strain I-1237 expires on 31 May 2023, this Regulation should enter into force as soon as possible.

(23) 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, 4 May 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 88, Phenmedipham, the date is replaced by '15 February 2025';

(2) in the sixth column, expiration of approval, of row 97, S-metolachlor, the date is replaced by '15 November 2024';

(3) in the sixth column, expiration of approval, of row 110, Milbemectin, the date is replaced by '15 February 2025';

(4) in the sixth column, expiration of approval, of row 142, Ethephon, the date is replaced by '15 November 2024';

(5) in the sixth column, expiration of approval, of row 145, Captan, the date is replaced by '15 November 2024';

(6) in the sixth column, expiration of approval, of row 146, Folpet, the date is replaced by '15 February 2025';

(7) in the sixth column, expiration of approval, of row 147, Formetanate, the date is replaced by '15 February 2025';

(8) in the sixth column, expiration of approval, of row 150, Dimethomorph, the date is replaced by '15 February 2025';

(9) in the sixth column, expiration of approval, of row 152, Metribuzin, the date is replaced by '15 February 2025';

(10) in the sixth column, expiration of approval, of row 154, Propamocarb, the date is replaced by '15 June 2025';

(11) in the sixth column, expiration of approval, of row 156, Pirimiphos-methyl, the date is replaced by '15 June 2025';

(12) in the sixth column, expiration of approval, of row 158, Beflubutamid, the date is replaced by '31 October 2026';

(13) in the sixth column, expiration of approval, of row 163, Benthiavalicarb, the date is replaced by '15 November 2024';

(14) in the sixth column, expiration of approval, of row 164, Boscalid, the date is replaced by '15 April 2026';

(15) in the sixth column, expiration of approval, of row 166, Fluoxastrobin, the date is replaced by '15 June 2025';

(16) in the sixth column, expiration of approval, of row 168, Prothioconazole, the date is replaced by '15 August 2025';

(17) in the sixth column, expiration of approval, of row 215, Aclonifen, the date is replaced by '31 October 2026';

(18) in the sixth column, expiration of approval, of row 217, Metazachlor, the date is replaced by '31 October 2026';

(19) in the sixth column, expiration of approval, of row 297, Fluopicolide, the date is replaced by '31 August 2026';

(20) in the sixth column, expiration of approval, of row 301, Penoxsulam, the date is replaced by '15 May 2026';

(21) in the sixth column, expiration of approval, of row 302, Proquinazid, the date is replaced by '15 May 2026';

(22) in the sixth column, expiration of approval, of row 304, Metalaxyl, the date is replaced by '30 September 2026';

(23) in the sixth column, expiration of approval, of row 316, Cycloxydim, the date is replaced by '31 August 2026';

(24) in the sixth column, expiration of approval, of row 322, Hymexazol, the date is replaced by '31 August 2026';

(25) in the sixth column, expiration of approval, of row 326, Indolylbutyric acid, the date is replaced by '15 March 2026';

(26) in the sixth column, expiration of approval, of row 329, Clethodim, the date is replaced by '31 August 2026';

(27) in the sixth column, expiration of approval, of row 339, Dazomet, the date is replaced by '31 August 2026';

(28) in the sixth column, expiration of approval, of row 340, Metaldehyde, the date is replaced by '31 August 2026';

(29) in the sixth column, expiration of approval, of row 342, Fenazaquin, the date is replaced by '31 August 2026';

(30) in the sixth column, expiration of approval, of row 344, Diclofop, the date is replaced by '31 August 2026';

(31) in the sixth column, expiration of approval, of row 348, Paclobutrazol, the date is replaced by '31 August 2026';

(32) in the sixth column, expiration of approval, of row 354, Flurochloridone, the date is replaced by '15 March 2026'.

2. Part B is amended as follows:

(1) in the sixth column, expiration of approval, of row 22, Metam, the date is replaced by '30 November 2025';

(2) in the sixth column, expiration of approval, of row 29, *Trichoderma asperellum* strain T34, the date is replaced by '31 October 2025';

(3) in the sixth column, expiration of approval, of row 31, Cyflumetofen, the date is replaced by '31 October 2025';

(4) in the sixth column, expiration of approval, of row 32, *Trichoderma atroviride* strain I-1237, the date is replaced by '31 October 2025';

(5) in the sixth column, expiration of approval, of row 33, Ametoctradin, the date is replaced by '31 December 2025';

(6) in the sixth column, expiration of approval, of row 34, Mandipropamid, the date is replaced by '31 December 2025';

(7) in the sixth column, expiration of approval, of row 38, *Helicoverpa armigera nucleopolyhedrovirus*, the date is replaced by '31 October 2025';

(8) in the sixth column, expiration of approval, of row 42, *Spodoptera littoralis nucleopolyhedrovirus*, the date is replaced by '31 October 2025'.