II

(Non-legislative acts)

REGULATIONS

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

(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) 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]).

(2) Commission Implementing Regulation (EU) 2022/378 ([4]) extends the approval period 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

([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) 2022/378 of 4 March 2022 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances abamectin, 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, Pseudomonas chlororaphis strain MA342, pyrimethanil, Pythium oligandrum M1, 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 72, 7.3.2022, p. 2).

pomonella *Granulovirus* (CpGV), cyprodinil, dichlorprop-P, fenpyroximate, fosetyl, malathion, mepanipyrim, metconazole, metrafenone, pirimicarb, 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 until 30 April 2023.

(3) Commission Implementing Regulation (EU) 2018/1260 ([5]) extends the approval period of the active substance pyridaben until 30 April 2023.

(4) 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 ([6]), which continues to apply to these active substances pursuant to Article 17 of Commission Implementing Regulation (EU) 2020/1740 ([7]), and were declared admissible by the respective rapporteur Member State.

(5) For the active substances *Beauveria bassiana* strains ATCC 74040 and GHA, malathion and pyridaben the risk assessment pursuant to Article 11 of Implementing Regulation (EU) No 844/2012 by the respective rapporteur Member States has not yet been finalised.

(6) For the active substances *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, the European Food Safety Authority ('the Authority') requested additional information in accordance with Article 13(3) of Implementing Regulation (EU) No 844/2012. It was submitted by the given deadline of 14 July 2022 and additional time will be needed for its evaluation and for the related conclusion by risk assessors as well as the ensuing risk management decision in accordance with Articles 13 and 14 of Implementing Regulation (EU) No 844/2012.

(7) For the active substance rimsulfuron, 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 as amended by Commission Regulation (EU) 2018/605 ([8]), and in accordance with Article 14(1a) of Implementing Regulation (EU) No 844/2012, EFSA in consultation with the Member States has to determine if additional information is required. For the active substances clodinafop and fenpyroximate, the deadline for the submission of 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 as amended by Regulation (EU) 2018/605, and in accordance with Article 13(3a) Implementing Regulation (EU) No 844/2012 has been set on 17 November 2023 and 4 May 2024 respectively. For the active

([5]) Commission Implementing Regulation (EU) 2018/1260 of 20 September 2018 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances pyridaben, quinmerac and zinc phosphide (OJ L 238, 21.9.2018, p. 30).

([6]) 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).

([7]) 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).

([8]) 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).

substances cyprodinil, dichlorprop-P, fosetyl, mepanipyrim, metconazole, metrafenone, pirimicarb, pyrimethanil, spinosad, triclopyr, trinexapac, triticonazole and ziram, 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 as amended by Regulation (EU) 2018/605, was requested by the Authority pursuant 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 by risk assessors as well as the ensuing risk management decision in accordance with Articles 13 and 14 of Implementing Regulation (EU) No 844/2012.

(8) For 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 and Cydia pomonella *Granulovirus* (CpGV), the Authority has submitted its conclusion in accordance with Article 13(1) of Implementing Regulation (EU) No 844/2012 and the Commission has presented the respective renewal reports as well as draft Regulations renewing the approval of these active substances to the Standing Committee on Plants, Animals, Food and Feed pursuant to Article 14 of Implementing Regulation (EU) No 844/2012. However, the Standing Committee on Plants, Animals, Food and Feed has not yet been able to deliver its opinion on any of the draft Regulations renewing the approvals of the above mentioned active substances.

(9) 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 approvals on 30 April 2023, and the reasons for the delay in the renewal procedures cannot be attributed to the respective applicants.

(10) Given 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 to finalise the regulatory decision-making procedures on the respective applications for renewal of approval. Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.

(11) 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.

(12) 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, 20 March 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

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 74, Ziram, the date is replaced by '15 March 2025';

(2) in the sixth column, expiration of approval, of row 90, Mepanipyrim, the date is replaced by '15 March 2025';

(3) in the sixth column, expiration of approval, of row 123, Clodinafop, the date is replaced '15 December 2025';

(4) in the sixth column, expiration of approval, of row 124, Pirimicarb, the date is replaced by '15 March 2025';

(5) in the sixth column, expiration of approval, of row 125, Rimsulfuron, the date is replaced by '15 August 2025';

(6) in the sixth column, expiration of approval, of row 127, Triticonazole, the date is replaced by '15 March 2025';

(7) in the sixth column, expiration of approval, of row 130, Cyprodinil, the date is replaced by '15 March 2025';

(8) in the sixth column, expiration of approval, of row 131, Fosetyl, the date is replaced by '15 March 2025';

(9) in the sixth column, expiration of approval, of row 132, Trinexapac, the date is replaced by '15 December 2024';

(10) in the sixth column, expiration of approval, of row 133, Dichlorprop-P, the date is replaced by '15 March 2025';

(11) in the sixth column, expiration of approval, of row 134, Metconazole, the date is replaced by '15 March 2025';

(12) in the sixth column, expiration of approval, of row 135, Pyrimethanil, the date is replaced by '15 March 2025';

(13) in the sixth column, expiration of approval, of row 136, Triclopyr, the date is replaced by '15 December 2024';

(14) in the sixth column, expiration of approval, of row 137, Metrafenone, the date is replaced by '15 December 2024';

(15) in the sixth column, expiration of approval, of row 138, *Bacillus subtilis* (Cohn 1872) strain QST 713, the date is replaced by '15 August 2024';

(16) in the sixth column, expiration of approval, of row 139, Spinosad, the date is replaced by '15 March 2025';

(17) in the sixth column, expiration of approval, of row 193, *Bacillus thuringiensis* subsp. aizawai strain ABTS-1857 and strain GC-91, the date is replaced by '15 August 2024';

(18) in the sixth column, expiration of approval, of row 194, *Bacillus thuringiensis* subsp. israeliensis (serotype H-14) strain AM65-52, the date is replaced by '15 August 2024';

(19) in the sixth column, expiration of approval, of row 195, *Bacillus thuringiensis* subsp. kurstaki strain ABTS 351, strain PB 54, strain SA 11, strain SA 12, strain EG 2348, the date is replaced by '15 August 2024';

(20) in the sixth column, expiration of approval, of row 197, *Beauveria bassiana* strain ATCC 74040, strain GHA, the date is replaced by '30 September 2025';

(21) in the sixth column, expiration of approval, of row 198, *Cydia pomonella* Granulovirus (CpGV), the date is replaced by '15 August 2024';

(22) in the sixth column, expiration of approval, of row 204, *Trichoderma atroviride* (formerly *T. harzianum*) strain T11, the date is replaced by '15 April 2025';

(23) in the sixth column, expiration of approval, of row 206, *Trichoderma harzianum* strain T-22, strain ITEM 908, the date is replaced by '15 April 2025';

(24) in the sixth column, expiration of approval, of row 207, *Trichoderma asperellum* (formerly *T. harzianum*) strain ICC012, strain T25, strain TV1, the date is replaced by '15 April 2025';

(25) in the sixth column, expiration of approval, of row 208, *Trichoderma gamsii* (formerly *T. viride*) strain ICC080, the date is replaced by '15 April 2025';

(26) in the sixth column, expiration of approval, of row 213, Fenpyroximate, the date is replaced by '15 June 2026';

(27) in the sixth column, expiration of approval, of row 300, Malathion, the date is replaced by '31 July 2026';

(28) in the sixth column, expiration of approval, of row 313, Pyridaben, the date is replaced by '31 July 2026'.