COMMISSION IMPLEMENTING REGULATION (EU) 2023/1000

of 23 May 2023

renewing the approval of the active substance *Bacillus thuringiensis* subsp. *aizawai* GC-91 in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) No 540/2011

(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 20(1) thereof,

Whereas:

(1) Commission Directive 2008/113/EC ([2]) included a reference to the approval of *Bacillus thuringiensis* subsp. *aizawai* strain GC-91 as an active substance in Annex I to Council Directive 91/414/EEC ([3]).

(2) According to Article 78(3) of Regulation (EC) No 1107/2009, active substances included in Annex I to Directive 91/414/EEC 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 ([4]).

(3) The approval of the active substance *Bacillus thuringiensis* subsp. *aizawai* strain GC-91, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011 expires on 15 August 2024.

(4) On 29 April 2016 an application for the renewal of the approval of the active substance *Bacillus thuringiensis* subsp. *aizawai* strain GC-91 was submitted to the Netherlands, the rapporteur Member State and to Germany, the co-rapporteur Member State in accordance with Article 1 of Commission Implementing Regulation (EU) No 844/2012 ([5]) within the time period provided for in that Article.

(5) The applicant also submitted the supplementary dossiers required by Article 6 of Implementing Regulation (EU) No 844/2012 to the rapporteur Member State, the co-rapporteur Member State, the Commission and the European Food Safety Authority ('the Authority'). The application was found to be admissible by the rapporteur Member State.

(6) The rapporteur Member State prepared a draft renewal assessment report in consultation with the co-rapporteur Member State and submitted it to the Authority and the Commission on 31 July 2018. In its draft renewal assessment report the rapporteur Member State proposes to renew the approval of *Bacillus thuringiensis* subsp. *aizawai* strain GC-91.

([1]) OJ L 309, 24.11.2009, p. 1.

([2]) Commission Directive 2008/113/EC of 8 December 2008 amending Council Directive 91/414/EEC to include several micro-organisms as active substances (OJ L 330, 9.12.2008, p. 6).

([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).

([4]) 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).

([5]) 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) The Authority communicated the draft renewal assessment report to the applicant and to the Member States for comments, launched a public consultation and forwarded the comments received to the Commission. The Authority also made the supplementary summary dossier available to the public.

(8) On 30 September 2020, the Authority communicated to the Commission its conclusion ([6]) which indicates that *Bacillus thuringiensis* subsp. *aizawai* strain GC-91 can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

(9) The Commission presented a renewal report regarding *Bacillus thuringiensis* subsp. *aizawai* strain GC-91 and a draft of this Regulation to the Standing Committee on Plants, Animals, Food and Feed on 19 May 2021 and on 25 January 2023, respectively.

(10) The Commission invited the applicant to submit its comments on the conclusion of the Authority and, in accordance with Article 14(1), third subparagraph, of Implementing Regulation (EU) No 844/2012 ([7]), on the renewal report. The applicant submitted its comments, which have been carefully examined.

(11) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance *Bacillus thuringiensis* subsp. *aizawai* strain GC-91 that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied.

(12) It is therefore appropriate to renew the approval of *Bacillus thuringiensis* subsp. *aizawai* strain GC-91.

(13) It is, however, necessary to provide for certain conditions pursuant to Article 14(1), read in conjuction with Article 6, of Regulation (EC) No 1107/2009. It is, in particular, appropriate as a precautionary approach for consumer dietary protection to include a minimum time period between the application of plant protection products containing *Bacillus thuringiensis* subsp. *aizawai* strain GC-91 and the harvest of edible crops used for fresh consumption, unless residues data show levels of *Bacillus thuringiensis* subsp. *aizawai* strain GC-91 below 10^5 CFU/g at harvest.

(14) In addition, in order to increase the confidence in the conclusion that *Bacillus thuringiensis* subsp *aizawai* strain GC-91 does not affect human health, the applicant should provide further data regarding the density decline of viable spores of *Bacillus thuringiensis* subsp. *aizawai* strain GC-91 on edible plant parts from the time of application of a plant protection product containing this active substance until the time of harvest or until levels found are below 10^5 CFU/g.

(15) Furthermore, it is also appropriate to require that Member States, when assessing applications for authorisations of plant protection products containing *Bacillus thuringiensis* subsp. *aizawai* strain GC-91, pay particular attention to the protection of operators and workers, and to the protection of wild pollinators.

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

([6]) EFSA (European Food Safety Authority). Conclusion on the peer review of the pesticide risk assessment of the active substance *B. thuringiensis* subsp. *aizawai* strain GC-91. *EFSA Journal*, 2020, DOI: 10.2903/j.efsa.2020.6293.

([7]) This Regulation was replaced by Regulation (EU) 2020/1740, however, it continues to apply to the procedure for the renewal of the approval of active substances: (1) whose approval period ends before 27 March 2024; (2) for which a Regulation, adopted in accordance with Article 17 of Regulation (EC) No 1107/2009 on or after 27 March 2021, extends the approval period to 27 March 2024 or a later date.

(17) Commission Implementing Regulation (EU) 2023/689 ([8]) extended the approval period of *Bacillus thuringiensis* subsp. *aizawai* strain GC-91 to 15 August 2024 in order to allow the renewal process to be completed before the expiry of the approval period of that active substance. However, given that a decision on renewal has been taken ahead of that extended expiry date, this Regulation should apply earlier than that date.

(18) 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

Renewal of the approval of the active substance

The approval of the active substance *Bacillus thuringiensis* subsp. *aizawai* strain GC-91, as specified in Annex I, is renewed subject to the conditions laid down in that Annex.

Article 2

Amendments to Implementing Regulation (EU) No 540/2011

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with Annex II to this Regulation.

Article 3

Entry into force and application

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 July 2023.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 23 May 2023.

For the Commission
The President
Ursula VON DER LEYEN

([8]) 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).

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
Bacillus thuringiensis subsp. *aizawai* GC-91	n.a.	No relevant impurities	1 July 2023	30 June 2038	The implementation of the uniform principles, as provided for in Article 29(6) of Regulation (EC) No 1107/2009, requires that the conclusions of the review report on *Bacillus thuringiensis* subsp. *aizawai* GC-91 and in particular Appendices I and II thereto, are taken into account. In this overall assessment the Member States shall pay particular attention to: — the protection of operators and workers, taking into account that micro-organisms are *per se* considered as potential sensitisers, ensuring that adequate personal protective equipment is included as a condition of use; — the assurance by the producer of strict maintenance of environmental conditions and quality control analysis during the manufacturing process, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in the Working Document SANCO/12116/2012 (2); — the protection of wild pollinators (in particular honey bee larvae and bumble bees). Conditions of use shall include specific risk mitigation measures, where appropriate. Conditions of use shall include the following risk mitigation measures: — a minimum time period of 2 days shall be kept between the application of plant protection products containing *Bacillus thuringiensis* subsp *aizawai* GC-91 and the harvest of edible crops used for fresh consumption, unless available measured or estimated residues data show levels of *Bacillus thuringiensis* subsp. *aizawai* GC-91 below 10^5 CFU/g at harvest.

Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
					The applicant shall submit to the Commission, the Member States and the Authority additional information as regards: — data in at least one representative edible crop (i.e. pome fruits, grapes and tomatoes) regarding the density decline of viable spores of *Bacillus thuringiensis* subsp. *aizawai* GC-91 on edible plant parts from the time of application of a plant protection product containing this active substance until the time of harvest or until levels found are below 10^5 CFU/g, including storage stability data of the micro-organisms between the sampling and the spore counting analysis. The relevant methods and protocols to be employed shall be agreed between the applicant and the Rapporteur Member State. The applicant shall submit the requested information by 13 December 2025.

(1) Further details on the identity and the specification of the active substance are provided in the renewal report.
(2) pesticides_ppp_app-proc_guide_phys-chem-ana_microbial-contaminant-limits.pdf (europa.eu).

ANNEX II

The Annex to Implementing Regulation (EU) No 540/2011 is amended as follows:

(1) in Part A, entry 193 is deleted,

(2) in Part B, the following entry is added:

No.	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
'160	*Bacillus thuringiensis* subsp. *aizawai* GC-91	n.a.	No relevant impurities	1 July 2023	30 June 2038	The implementation of the uniform principles, as provided for in Article 29(6) of Regulation (EC) No 1107/2009, requires that the conclusions of the review report on *Bacillus thuringiensis* subsp. *aizawai* GC-91 and in particular Appendices I and II thereto, are taken into account. In this overall assessment the Member States shall pay particular attention to: — the protection of operators and workers, taking into account that micro-organisms are *per se* considered as potential sensitisers, ensuring that adequate personal protective equipment is included as a condition of use; — the assurance by the producer of strict maintenance of environmental conditions and quality control analysis during the manufacturing process, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in the Working Document SANCO/12116/2012 (2); — the protection of wild pollinators (in particular honey bee larvae and bumble bees). Conditions of use shall include specific risk mitigation measures, where appropriate. Conditions of use shall include the following risk mitigation measures: — a minimum time period of 2 days shall be kept between the application of plant protection products containing *Bacillus thuringiensis* subsp *aizawai* GC-91 and the harvest of edible crops used for fresh consumption, unless available measured or estimated residues data show levels of *Bacillus thuringiensis* subsp. *aizawai* GC-91 below 10^5 CFU/g at harvest.

No.	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
						The applicant shall submit to the Commission, the Member States and the Authority additional information as regards: — data in at least one representative edible crop (i.e. pome fruits, grapes and tomatoes) regarding the density decline of viable spores of *Bacillus thuringiensis* subsp. *aizawai* GC-91 on edible plant parts from the time of application of a plant protection product containing this active substance until the time of harvest or until levels found are below 10^5 CFU/g, including storage stability data of the micro-organisms between the sampling and the spore counting analysis. The relevant methods and protocols to be employed shall be agreed between the applicant and the Rapporteur Member State. The applicant shall submit the requested information by 13 December 2025.'

(1) Further details on the identity and the specification of the active substance are provided in the renewal report.
(2) pesticides_ppp_app-proc_guide_phys-chem-ana_microbial-contaminant-limits.pdf (europa.eu).