COMMISSION IMPLEMENTING REGULATION (EU) 2023/1756

of 11 September 2023

renewing the approval of the low-risk active substance *Cydia pomonella* granulovirus (CpGV) 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) in conjunction with Article 22(1) thereof,

Whereas:

(1) Commission Directive 2008/113/EC ([2]) included *Cydia pomonella* granulovirus (CpGV) as an active substance in Annex I to Council Directive 91/414/EEC ([3]).

(2) 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 *Cydia pomonella* granulovirus (CpGV), as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 15 August 2024.

(4) An application for the renewal of the approval of the active substance *Cydia pomonella* granulovirus (CpGV) was submitted to Germany, the rapporteur Member State, and the Netherlands, the co-rapporteur Member State, in accordance with Article 1 of Commission Implementing Regulation (EU) No 844/2012 ([5]) and within the time period provided for in that Article.

(5) The applicant submitted the supplementary dossiers required to the rapporteur Member State, the co-rapporteur Member State, the Commission and the European Food Safety Authority ('the Authority') in accordance with Article 6 of Implementing Regulation (EU) No 844/2012. 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 16 October 2020. In its draft renewal assessment report the rapporteur Member State proposed to renew the approval of *Cydia pomonella* granulovirus (CpGV).

(7) The Authority made the supplementary summary dossier available to the public. The Authority also circulated the draft renewal assessment report to the applicant and to the Member States for comments and launched a public consultation on it. The Authority forwarded the comments received to the Commission.

([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).

(8) On 4 October 2022, the Authority communicated to the Commission its conclusion ([6]) which indicated *Cydia pomonella* granulovirus (CpGV) 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 and a draft of this Regulation regarding *Cydia pomonella* granulovirus (CpGV) to the Standing Committee on Plants, Animals, Food and Feed on 22 March 2023 and on 24 May 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, on the renewal report. The applicant submitted its comments, which have been carefully examined and taken into consideration.

(11) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance *Cydia pomonella* granulovirus (CpGV) that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied.

(12) The Commission further considers that *Cydia pomonella* granulovirus (CpGV) is a low-risk active substance pursuant to Article 22 of Regulation (EC) No 1107/2009. *Cydia pomonella* granulovirus (CpGV) fulfils the conditions set out in point 5 of Annex II to Regulation (EC) No 1107/2009 as it belongs to the *Baculoviridae* family and has not demonstrated adverse effects on any non-target insects.

(13) It is therefore appropriate to renew the approval of *Cydia pomonella* granulovirus (CpGV) as a low-risk substance.

(14) In accordance with Article 14(1) of Regulation (EC) No 1107/2009 in conjunction with Article 6 thereof, and in the light of current scientific and technical knowledge and the outcome of the risk assessment, it is, however, necessary to provide for certain conditions in order to ensure the fulfilment of the limits on relevant microbiological contamination and the protection of operators and workers, taking into account that microorganisms are *per se* considered as potential sensitizers.

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

(16) Commission Implementing Regulation (EU) 2023/689 ([7]) extended the approval period of *Cydia pomonella* granulovirus (CpGV) 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.

(17) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

([6]) EFSA (European Food Safety Authority), 2022. Peer review of the pesticide risk assessment of the active substance *Cydia pomonella* granulovirus (CpGV), *EFSA Journal* 2022;20(11):7630. Available online: www.efsa.europa.eu.

([7]) 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 a*troviride (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).

HAS ADOPTED THIS REGULATION:

Article 1

Renewal of the approval of the active substance

The approval of the active substance *Cydia pomonella* granulovirus (CpGV), 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 November 2023.

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

Done at Brussels, 11 September 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
Cydia pomonella granulovirus (CpGV)	Not applicable	*Bacillus cereus*: < 1×10^7 CFU/g in the formulated products.	1 November 2023	31 October 2038	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 *Cydia pomonella* granulovirus (CpGV), and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the strict maintenance of environmental conditions and quality control analysis during the manufacturing process to be assured by the producer, 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 operators and workers, taking into account that micro-organisms are per se considered as potential sensitizers, ensuring that adequate personal protective equipment is included as a condition of use. Conditions of use shall include risk mitigation measures, where appropriate.

(1) Further details on identity and specification of active substance are provided in the Review Report PLAN/2023/240.
(2) https://ec.europa.eu/food/system/files/2016-10/pesticides_ppp_app-proc_guide_phys-chem-ana_microbial-contaminant-limits.pdf.

ANNEX II

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

(1) in Part A, entry 198 on *Cydia pomonella* granulovirus (CpGV) is deleted;

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

No	Common Name, Identification Numbers	IUPAC Name	Purity [1]	Date of approval	Expiration of approval	Specific provisions
'45	*Cydia pomonella* granulovirus (CpGV)	Not applicable	*Bacillus cereus*: < 1×10^7 CFU/g in the formulated products.	1 November 2023	31 October 2038	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 *Cydia pomonella* granulovirus (CpGV), and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the strict maintenance of environmental conditions and quality control analysis during the manufacturing process to be assured by the producer, 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 operators and workers, taking into account that microorganisms are per se considered as potential sensitizers, ensuring that adequate personal protective equipment is included as a condition of use. Conditions of use shall include risk mitigation measures, where appropriate.

[1] Further details on identity and specification of active substance are provided in the Review Report PLAN/2023/240.

[2] https://ec.europa.eu/food/system/files/2016-10/pesticides_ppp_app-proc_guide_phys-chem-ana_microbial-contaminant-limits.pdf'.