COMMISSION IMPLEMENTING REGULATION (EU) 2019/1605

of 27 September 2019

approving the low-risk active substance *Bacillus subtilis* strain IAB/BS03, 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

(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 13(2) in conjunction with Article 22 thereof,

Whereas:

(1) In accordance with Article 7(1) of Regulation (EC) No 1107/2009, Investigaciones y Aplicaciones Biotecnológicas S.L. submitted to the Netherlands on 16 December 2014 an application for the approval of the active substance *Bacillus subtilis* strain IAB/BS03.

(2) In accordance with Article 9(3) of that Regulation, the Netherlands, as rapporteur Member State, notified the applicant, the other Member States, the Commission and the European Food Safety Authority ('the Authority') of the admissibility of the application on 23 June 2015.

(3) On 24 February 2017, the rapporteur Member State submitted a draft assessment report to the Commission with a copy to the Authority, assessing whether that active substance can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

(4) The Authority complied with Article 12(1) of Regulation (EC) No 1107/2009. In accordance with Article 12(3) of that Regulation, it requested that the applicant supply additional information to the Member States, the Commission and the Authority. The assessment of the additional information by the rapporteur Member State was submitted to the Authority in the format of an updated draft assessment report on 14 December 2017.

(5) On 18 April 2018, the Authority communicated to the applicant, the Member States and the Commission its conclusion [2] on whether the active substance *Bacillus subtilis* strain IAB/BS03 can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Authority made its conclusion available to the public.

(6) On 12 December 2018, the Commission presented to the Standing Committee on Plants, Animals, Food and Feed the review report for *Bacillus subtilis* strain IAB/BS03 and a draft Regulation providing that *Bacillus subtilis* strain IAB/BS03 is approved.

(7) The applicant was given the possibility to submit comments on the review report.

(8) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance, and in particular the uses which were examined and detailed in the review report, that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied.

(9) It is therefore appropriate to approve *Bacillus subtilis* strain IAB/BS03.

(10) The Commission considers that *Bacillus subtilis* strain IAB/BS03 is a low-risk active substance pursuant to Article 22 of Regulation (EC) No 1107/2009. *Bacillus subtilis* strain IAB/BS03 is not a substance of concern and fulfils the conditions set in point 5 of Annex II to Regulation (EC) No 1107/2009.

---

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

[2] EFSA (European Food Safety Authority), 2018. Conclusion on the peer review of the pesticide risk assessment of the active substance *Bacillus subtilis* strain IAB/BS03. EFSA Journal 2018;16(6):5261. DOI:10.2903/j.efsa.2018.5261.

(11) It is therefore appropriate to approve *Bacillus subtilis* strain IAB/BS03 as a low-risk substance for a period of 15 years.

(12) In accordance with Article 13(2) of Regulation (EC) No 1107/2009 in conjunction with Article 6 thereof and in the light of current scientific and technical knowledge, it is necessary to provide for certain conditions.

(13) In accordance with Article 13(4) of Regulation (EC) No 1107/2009, Commission Implementing Regulation (EU) No 540/2011 ([3]) should be amended accordingly.

(14) 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

Approval of the active substance

The active substance *Bacillus subtilis* strain IAB/BS03, as specified in Annex I, is approved subject to the conditions laid down in that Annex.

Article 2

Amendments to Implementing Regulation (EU) No 540/2011

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

Article 3

Entry into force

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, 27 September 2019.

For the Commission
The President
Jean-Claude JUNCKER

([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).

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
Bacillus subtilis strain IAB/BS03 Accession number in the Spanish Type Culture Collection (CECT), Spain: CECT 7254 Accession number in the German Type Culture Collection (DSMZ), Germany: DSM 24682	Not applicable	Minimum concentration: 1×10^{13} CFU/kg Maximum concentration: 5×10^{13} CFU/kg	20 October 2019	20 October 2034	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 *Bacillus subtilis* strain IAB/BS03, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: a) the specification of the technical material as commercially manufactured used in plant protection products, including full characterisation of relevant secondary metabolites; b) the protection of operators and workers, taking into account that microorganisms are per se considered as potential sensitisers, and ensuring that adequate personal protective equipment is included as a condition of use. Strict maintenance of environmental conditions and quality control analysis during the manufacturing process shall be assured by the producer, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in OECD Issue Paper on Microbial Contaminant Limits for Microbial Pest Control Products, contained in the Working Document SANCO/12116/2012 (2). 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.
(2) https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_phys-chem-ana_microbial-contaminant-limits.pdf

ANNEX II

In Part D of the Annex to Implementing Regulation (EU) No 540/2011, the following entry is added:

'17	*Bacillus subtilis* strain IAB/BS03 Accession number in the Spanish Type Culture Collection (CECT), Spain: CECT 7254 Accession number in the German Type Culture Collection (DSMZ), Germany: DSM 24682	Not applicable	Minimum concentration: 1×10^{13} CFU/kg Maximum concentration: 5×10^{13} CFU/kg	20 October 2019	20 October 2034	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 *Bacillus subtilis* strain IAB/BS03, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: a) the specification of the technical material as commercially manufactured used in plant protection products, including full characterisation of relevant secondary metabolites; b) the protection of operators and workers, taking into account that microorganisms are per se considered as potential sensitisers, and ensuring that adequate personal protective equipment is included as a condition of use. Strict maintenance of environmental conditions and quality control analysis during the manufacturing process shall be assured by the producer, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in OECD Issue Paper on Microbial Contaminant Limits for Microbial Pest Control Products, contained in the Working Document SANCO/12116/2012 [1]. Conditions of use shall include risk mitigation measures, where appropriate.

[1] https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_phys-chem-ana_microbial-contaminant-limits.pdf'