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COMMISSION IMPLEMENTING REGULATION (EU) 2025/106

of 22 January 2025

approving the active substance *Bacillus subtilis* strain RTI477 as a low-risk active substance 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 13(2) in conjunction with Article 22(1) thereof,

Whereas:

(1) On 1 April 2019, the Netherlands received an application pursuant to Article 7(1) of Regulation (EC) No 1107/2009 from FMC Agricultural Solutions A/S for the approval of the active substance *Bacillus subtilis* strain RTI477.

(2) On 17 May 2019, in accordance with Article 9(3) of Regulation (EC) No 1107/2009, 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.

(3) On 3 August 2022, 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 circulated the draft assessment report received from the rapporteur Member State to the applicant and the other Member States. In accordance with Article 12(3) of Regulation (EC) No 1107/2009, the Authority 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 form of an updated draft assessment report in March 2024.

(5) On 31 July 2024, the Authority communicated to the applicant, the Member States and the Commission its conclusion ([2]) on whether the active substance *Bacillus subtilis* strain RTI477 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) The Commission presented a review report and a draft Regulation regarding *Bacillus subtilis* strain RTI477 to the Standing Committee on Plants, Animals, Food and Feed on 2 October 2024 and on 5 December 2024, respectively.

([1]) OJ L 309, 24.11.2009, p. 1, ELI: http://data.europa.eu/eli/reg/2009/1107/oj.
([2]) Conclusion on the peer review of the pesticide risk assessment of the active substance *Bacillus subtilis* strain RTI477. *EFSA Journal*, 2024;22:e8989 https://doi.org/10.2903/j.efsa.2024.8989.

(7) The Commission invited the applicant to submit its comments on the conclusion of the Authority and, in accordance with Article 13(1) of Regulation (EC) No 1107/2009, on the review report. The applicant submitted its comments, which have been carefully examined.

(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) The Commission further considers that *Bacillus subtilis* strain RTI477 is a low-risk active substance pursuant to Article 22 of Regulation (EC) No 1107/2009. *Bacillus subtilis* strain RTI477 fulfils the conditions set in point 5.2.1 of Annex II to Regulation (EC) No 1107/2009 in the version thereof applicable to the procedure for the approval of *Bacillus subtilis* strain RTI477, because at strain level *Bacillus subtilis* strain RTI477 has not demonstrated multiple resistance to anti-microbials used in human or veterinary medicine.

(10) It is therefore appropriate to approve *Bacillus subtilis* strain RTI477 as a low-risk active substance.

(11) 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 include 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 per se are considered as potential sensitisers.

(12) In accordance with Article 13(4) of Regulation (EC) No 1107/2009 in conjunction with Article 22(2) thereof, Implementing Regulation (EU) No 540/2011 ([3]) should be amended accordingly.

(13) 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 RTI477, 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

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

([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, ELI: http://data.europa.eu/eli/reg_impl/2011/540/oj).

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, 22 January 2025.

For the Commission
The President
Ursula VON DER LEYEN

Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
Bacillus subtilis RTI477	Not applicable	No relevant impurities	12 February 2025	12 February 2040	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* RTI477, 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 protection of operators and workers, taking into account that microorganisms per se are considered as potential sensitisers, ensuring that adequate personal protective equipment is included as a condition of use, — the strict maintenance by the producer of environmental conditions and quality control analysis during the manufacturing process, in order to ensure the adherence to the limits on microbiological contamination as set in the OECD Issue Paper on Microbial Contaminants Limits for Microbial Pest Control Products No 65 (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) Organisation for Economic Cooperation and Development (OECD): https://doi.org/10.1787/9789264221642-en.

ELI: http://data.europa.eu/eli/reg_impl/2025/106/oj

ANNEX II

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

No	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
'50	*Bacillus subtilis* RTI477	Not applicable	No relevant impurities	12 February 2025	12 February 2040	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* RTI477, 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 protection of operators and workers, taking into account that microorganisms per se are considered as potential sensitisers, ensuring that adequate personal protective equipment is included as a condition of use, — the strict maintenance by the producer of environmental conditions and quality control analysis during the manufacturing process, in order to ensure the adherence to the limits on microbiological contamination as set in the OECD Issue Paper on Microbial Contaminants Limits for Microbial Pest Control Products No 65 (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) Organisation for Economic Cooperation and Development (OECD): https://doi.org/10.1787/9789264221642-en.'.