COMMISSION IMPLEMENTING REGULATION (EU) 2022/159

of 4 February 2022

approving the low-risk active substance *Bacillus amyloliquefaciens* strain IT-45 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 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) In accordance with Article 7(1) of Regulation (EC) No 1107/2009, Danstar Ferment AG and Comercial Quimica Masso submitted to France, on 26 June 2017, an application for the approval of the active substance *Bacillus amyloliquefaciens* strain IT-45.

(2) In accordance with Article 9(3) of that Regulation, France, as rapporteur Member State, notified the applicants, the other Member States, the Commission and the European Food Safety Authority ('the Authority') on 1 December 2017 of the admissibility of the application.

(3) On 15 May 2019, the rapporteur Member State submitted a draft assessment report to the Commission with a copy to the Authority, concluding that the active substance *Bacillus amyloliquefaciens* strain IT-45 could be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

(4) In accordance with Article 12(3) of Regulation (EC) No 1107/2009, the Authority also set a time limit for the applicants to supply additional information to the Member States, the Commission and the Authority

(5) In its Conclusion, communicated to the applicants, the Member States and the Commission, following a peer review of the pesticide risk assessment pursuant to Article 12 (2) of Regulation (EC) No 1107/2009, the Authority held that the active substance *Bacillus amyloliquefaciens* strain IT-45 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 ([2]).

(6) On 21-22 October 2021, the Commission presented to the Standing Committee on Plants, Animals, Food and Feed its review report on the active substance *Bacillus amyloliquefaciens* strain IT-45 and a draft of this Regulation regarding *Bacillus amyloliquefaciens* strain IT-45.

(7) The applicants were given the possibility to submit comments on the review report.

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

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

([2]) Conclusion on the Peer review of the pesticide risk assessment of the active substance *Bacillus amyloliquefaciens* strain IT-45. EFSA Journal 2021;19(5):6594 https://doi.org/10.2903/j.efsa.2021.6594.

(9) Since the Commission considers that *Bacillus amyloliquefaciens* strain IT-45 is a low-risk active substance, pursuant to Article 22 of Regulation (EC) No 1107/2009, and since plant protection products containing that substance may be expected to pose only a low risk to human and animal health and the environment, it may be approved for up to 15 years. No critical area of concerns were identified for humans, animals and the environment.

(10) *Bacillus amyloliquefaciens* strain IT-45 is a microorganism, which also fulfils the conditions established by Article 22 (2) of Regulation (EC) No 1107/2009, in conjunction with point 5.2. of Annex II to that Regulation. It is therefore appropriate to approve *Bacillus amyloliquefaciens* strain IT-45 as a low-risk substance.

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

(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

Approval of the active substance

The active substance *Bacillus amyloliquefaciens* strain IT-45, as specified in Annex I, is approved

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

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, 4 February 2022.

For the Commission
The President
Ursula VON DER LEYEN

([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 amyloliquefaciens IT-45	n.a.	The nominal content of *Bacillus amyloliquefaciens* IT-45 in the technical product and formulation is: minimum: 2×10^{13} CFU/kg, maximum: 6×10^{14} CFU/kg. No relevant impurities	27 February 2022	27 February 2037	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 amyloliquefaciens* IT-45 shall be taken into account.

(1) Further details on the identity and the specification of the active substance are provided in the review report.

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
'35	*Bacillus amyloliquefaciens* IT-45	n.a.	The nominal content of *Bacillus amyloliquefaciens* IT-45 in the technical product and formulation is: minimum: 2 x 10^{13} CFU/kg, maximum: 6 x 10^{14} CFU/kg. No relevant impurities	27 February 2022	27 February 2037	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 amyloliquefaciens* IT-45 shall be taken into account.

(1) Further details on the identity and the specification of the active substance are provided in the review report.'