COMMISSION IMPLEMENTING REGULATION (EU) 2017/806

of 11 May 2017

approving the low-risk active substance *Bacillus amyloliquefaciens* strain FZB24, 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 22(1) in conjunction with Article 13(2) thereof,

Whereas:

(1) In accordance with Article 7(1) of Regulation (EC) No 1107/2009 France received on 19 June 2013 an application from Novozymes Biologicals France for the approval of the active substance *Bacillus amyloliquefaciens* strain FZB24.

(2) In accordance with Article 9(3) of that Regulation, France, 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 4 September 2013.

(3) On 13 April 2015, 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 Regulation (EC) No 1107/2009, 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 22 February 2016.

(5) On 10 May 2016, the Authority communicated to the applicant, the Member States and the Commission its conclusion [2] on whether the active substance *Bacillus amyloliquefaciens* strain FZB24 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 6 October 2016, the Commission presented to the Standing Committee on Plants, Animals, Food and Feed the review report for *Bacillus amyloliquefaciens* strain FZB24 and a draft Regulation providing that *Bacillus amyloliquefaciens* strain FZB24 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. Those approval criteria are therefore deemed to be satisfied. It is therefore appropriate to approve *Bacillus amyloliquefaciens* strain FZB24.

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

[2] EFSA (European Food Safety Authority), 2016. Conclusion on the peer review of the pesticide risk assessment of the active substance *Bacillus amyloliquefaciens* strain FZB24. EFSA Journal 2016;14(6):4494, 18 pp. doi:10.2903/j.efsa.2016.4494.

(9) The Commission further considers that *Bacillus amyloliquefaciens* strain FZB24 is a low-risk active substance pursuant to Article 22 of Regulation (EC) No 1107/2009. *Bacillus amyloliquefaciens* strain FZB24 is not a substance of concern and fulfils the conditions set in point 5 of Annex II to Regulation (EC) No 1107/2009. *Bacillus amyloliquefaciens* strain FZB24 is a wild-type strain naturally occurring in the environment. It is not pathogenic to humans or animals. The additional exposure of humans, animals and the environment by the uses approved under Regulation (EC) No 1107/2009 is expected to be negligible compared to exposure expected through realistic natural situations.

(10) It is therefore appropriate to approve *Bacillus amyloliquefaciens* strain FZB24 substance for a period of 15 years.

(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, however, necessary to include certain conditions.

(12) In accordance with Article 13(4) of Regulation (EC) No 1107/2009, the Annex to Commission Implementing Regulation (EU) No 540/2011 [1] 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 active substance

The active substance *Bacillus amyloliquefaciens* strain FZB24, 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.

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, 11 May 2017.

For the Commission
The President
Jean-Claude JUNCKER

[1] 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 strain FZB24. Accession number in the culture collection of the 'Deutsche Sammlung von Mikroorganismen' (DSM), Germany: 10271 Accession number at the Agricultural Research Service Culture Collection (NRRL), USA: B-50304	Not applicable	Minimum concentration: 2×10^{14} CFU/kg	1 June 2017	1 June 2032	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* strain FZB24, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — specification of the technical material as commercially manufactured, including full characterisation of impurities and metabolites; — the protection of operators and workers, taking into account that microorganisms are considered as potential sensitizers. Strict maintenance of environmental conditions and quality control analysis during the manufacturing process shall be assured by the producer. 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.

ANNEX II

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

	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
'10	*Bacillus amyloliquefaciens* strain FZB24. Accession number in the culture collection of the 'Deutsche Sammlung von Mikroorganismen' (DSM), Germany: 10271 Accession number at the Agricultural Research Service Culture Collection (NRRL), USA: B-50304	Not applicable	Minimum concentration: 2×10^{14} CFU/kg	1 June 2017	1 June 2032	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* strain FZB24, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — specification of the technical material as commercially manufactured, including full characterisation of impurities and metabolites; — the protection of operators and workers, taking into account that microorganisms are considered as potential sensitizers. Strict maintenance of environmental conditions and quality control analysis during the manufacturing process shall be assured by the producer. 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.