II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2016/1429

of 26 August 2016

approving the active substance *Bacillus amyloliquefaciens* strain MBI 600, 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) thereof,

Whereas:

(1) In accordance with Article 7(1) of Regulation (EC) No 1107/2009 France received on 28 June 2013 an application from BASF Agricultural Specialities Ltd for the approval of the active substance *Bacillus amyloliquefaciens* strain MBI 600.

(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 (hereinafter 'the Authority') on 4 September 2013 of the admissibility of the application.

(3) On 5 January 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 21 September 2015.

(5) On 4 December 2015 the Authority communicated to the applicant, the Member States and the Commission its conclusion ([2]) on whether the active substance *Bacillus amyloliquefaciens* strain MBI 600 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.

([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 MBI 600. *EFSA Journal* 2016;14(1):4359, 37 pp. doi:10.2903/j.efsa.2016.4359.

(6) On 8 March 2016 the Commission presented to the Standing Committee on Plants, Animals, Food and Feed the review report for *Bacillus amyloliquefaciens* strain MBI 600 and the draft of this Regulation providing that *Bacillus amyloliquefaciens* strain MBI 600 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 amyloliquefaciens* strain MBI 600.

(10) 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 and restrictions.

(11) 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.

(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 active substance

The active substance *Bacillus amyloliquefaciens* strain MBI 600, 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*.

([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).

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

Done at Brussels, 26 August 2016.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity [1]	Date of approval	Expiration of approval	Specific provisions
Bacillus amyloliquefaciens strain MBI 600. Accession number in the National Collection of Industrial, Marine and Food Bacteria Ltd (NCIMB), Scotland: NCIMB 12376 Deposit number in the American Type Culture Collection (ATCC): SD-1414	Not applicable	Minimum concentration: $5{,}0 \times 10^{14}$ CFU/kg	16 September 2016	16 September 2026	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 MBI 600, and in particular Appendices I and II thereto, 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, including full characterisation of impurities and metabolites; (b) the protection of operators and workers, taking into account that *Bacillus amyloliquefaciens* strain MBI 600 is to be considered as a potential sensitiser. Conditions of use shall include risk mitigation measures, where appropriate. Strict maintenance of environmental conditions and quality control analysis during the manufacturing process shall be assured by the producer.

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

ANNEX II

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

	Common Name, Identification Numbers	IUPAC Name	Purity (*)	Date of approval	Expiration of approval	Specific provisions
'101	*Bacillus amyloliquefaciens* strain MBI 600. Accession number in the National Collection of Industrial, Marine and Food Bacteria Ltd (NCIMB), Scotland: NCIMB 12376 Deposit number in the American Type Culture Collection (ATCC): SD-1414	Not applicable	Minimum concentration: $5{,}0 \times 10^{14}$ CFU/kg	16 September 2016	16 September 2026	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 MBI 600, and in particular Appendices I and II thereto, 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, including full characterisation of impurities and metabolites; (b) the protection of operators and workers, taking into account that *Bacillus amyloliquefaciens* strain MBI 600 is to be considered as a potential sensitiser. Conditions of use shall include risk mitigation measures, where appropriate. Strict maintenance of environmental conditions and quality control analysis during the manufacturing process shall be assured by the producer.'

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