II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2021/1455

of 6 September 2021

approving the low-risk active substance *Bacillus amyloliquefaciens* strain AH2 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, Probelte S.A. submitted to the Netherlands, on 1 June 2015, an application for the approval of the active substance *Bacillus amyloliquefaciens* strain AH2.

(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') on 25 October 2015 of the admissibility of the application.

(3) On 21 December 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 Regulation (EC) No 1107/2009, it requested the applicant to supply additional information to the Member States, the Commission and the Authority. The rapporteur Member State submitted its assessment of the additional information to the Authority in an updated draft assessment report in December 2018.

(5) On 26 May 2020, the Authority communicated to the applicant, the Member States and the Commission its conclusion ([2]) on whether the active substance *Bacillus amyloliquefaciens* strain AH2 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]) 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 AH2. EFSA Journal 2020;18(7):6156. Doi: https://doi.org/10.2903/j.efsa.2020.6156.

(6) On 22 October 2020, the Commission presented to the Standing Committee on Plants, Animals, Food and Feed a review report and a draft Regulation regarding *Bacillus amyloliquefaciens* strain AH2.

(7) The applicant was 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, 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 amyloliquefaciens* strain AH2 is a low-risk active substance pursuant to Article 22 of Regulation (EC) No 1107/2009. *Bacillus amyloliquefaciens* strain AH2 is a microorganism, which fulfils the conditions set in point 5.2. of Annex II to Regulation (EC) No 1107/2009. No critical area of concerns were identified for humans, animals and the environment.

(10) It is therefore appropriate to approve *Bacillus amyloliquefaciens* strain AH2 as a low-risk 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.

(12) In accordance with Article 13(4) of Regulation (EC) No 1107/2009, Commission 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 amyloliquefaciens* strain AH2, 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*.

([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).

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

Done at Brussels, 6 September 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity [1]	Date of approval	Expiration of approval	Specific provisions
Bacillus amyloliquefaciens AH2	n.a.	The nominal content of *Bacillus amyloliquefaciens* AH2 in the technical product and formulation is $1{,}0 \times 10^{11}$ CFU/L (range $7x10^{10} - 7x10^{11}$). No relevant impurities	27 September 2021	27 September 2036	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on *Bacillus amyloliquefaciens* AH2 and in particular Appendices I and II thereof, shall be taken into account.

[1] Further details on the identity and the specification of the active substance are provided in the renewal 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
'33	*Bacillus amyloliquefaciens* AH2	n.a.	The nominal content of *Bacillus amyloliquefaciens* AH2 in the technical product and formulation is $1{,}0 \times 10^{11}$ CFU/L (range $7x10^{10}$ – $7x10^{11}$). No relevant impurities	27 September 2021	27 September 2036	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on *Bacillus amyloliquefaciens* AH2 and in particular Appendices I and II thereof, shall be taken into account.

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