REGULATIONS


(*) Text with EEA relevance.

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.
The titles of all other acts are printed in bold type and preceded by an asterisk.
REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2021/1455

of 6 September 2021


(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,


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.


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.

The applicant was given the possibility to submit comments on the review report.

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.

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.

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

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.


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*.

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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

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<table>
<thead>
<tr>
<th>Common Name, Identification Numbers</th>
<th>IUPAC Name</th>
<th>Purity (1)</th>
<th>Date of approval</th>
<th>Expiration of approval</th>
<th>Specific provisions</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Bacillus amyloliquefaciens</em> AH2</td>
<td>n.a.</td>
<td>The nominal content of <em>Bacillus amyloliquefaciens</em> AH2 in the technical product and formulation is $1.0 \times 10^{11}$ CFU/L (range $7 \times 10^{10} - 7 \times 10^{11}$). No relevant impurities</td>
<td>27 September 2021</td>
<td>27 September 2036</td>
<td>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 <em>Bacillus amyloliquefaciens</em> AH2 and in particular Appendices I and II thereof, shall be taken into account.</td>
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</tbody>
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(1) Further details on the identity and the specification of the active substance are provided in the renewal report.
In Part D of the Annex to Implementing Regulation (EU) No 540/2011, the following entry is added:

<table>
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