

COMMISSION IMPLEMENTING REGULATION (EU) 2021/81**of 27 January 2021****approving the basic substance *Allium cepa* L. bulb extract 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 23(5) in conjunction with Article 13(2) thereof,

Whereas:

- (1) On 4 September 2018, the Commission received an application from l'Institut de l'agriculture et de l'alimentation Biologique (ITAB), for the approval of *Allium cepa* L. bulb extract as a basic substance. That application was accompanied by the information required by the second subparagraph of Article 23(3) of Regulation (EC) No 1107/2009.
- (2) The Commission asked the European Food Safety Authority ('the Authority') for scientific assistance. The Authority provided the Commission with a technical report on *Allium cepa* L. bulb extract on 12 December 2019 ⁽²⁾. The Commission presented the review report ⁽³⁾ and a draft of this Regulation to the Standing Committee on Plants, Animals, Food and Feed on 18 May 2020.
- (3) The information provided by the applicant shows that the *Allium cepa* L. bulb extract fulfils the criteria of a foodstuff as defined in Article 2 of Regulation (EC) No 178/2002 of the European Parliament and of the Council ⁽⁴⁾. Moreover, it is not predominantly used for plant protection purposes but the extract can be useful in plant protection in a product consisting of the substance. Consequently, it is to be considered as a basic substance.
- (4) After examination of the application and all related documents, it may be expected that the *Allium cepa* L. bulb extract satisfies, in general, the requirements laid down in Article 23 of Regulation (EC) No 1107/2009, in particular with regard to the uses which were examined and detailed in the Commission review report. It is therefore appropriate to approve the *Allium cepa* L. bulb extract as a basic substance.
- (5) 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 for the approval.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²⁾ EFSA (European Food Safety Authority), 2019. Technical report on the outcome of the consultation with Member States and EFSA on the basic substance application for *Allium cepa* bulb extract for use in plant protection as a fungicide in potatoes, tomatoes and cucumbers. EFSA supporting publication 2019:EN-1767. doi:10.2903/sp.efsa.2019.EN-1767.

⁽³⁾ Final Review report for the basic substance *Allium cepa* L. bulb extract finalised in the Standing Committee on Plants, Animals, Food and Feed at its meeting on 22 October 2020 in view of the approval of *Allium cepa* L. bulb extract as basic substance in accordance with Regulation (EC) No 1107/2009 (SANTE/10842/2020 Rev2).

⁽⁴⁾ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

- (6) In accordance with Article 13(4) of Regulation (EC) No 1107/2009, the Annex to Commission Implementing Regulation (EU) No 540/2011 ⁽³⁾ should be amended accordingly.
- (7) 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 a basic substance

The substance *Allium cepa* L. bulb extract as specified in Annex I is approved as a basic substance subject to the conditions as 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, 27 January 2021.

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	Specific provisions
<i>Allium cepa</i> L. bulb extract CAS No: not allocated CIPAC No: not allocated	Not applicable	The onion bulbs used to prepare the extracts shall be of food grade quality meeting the requirements of WHO monographs on selected medicinal plants (Volume 1, Geneva, 1999) on <i>Bulbus Allii Cepae</i>	17.2.2021	<i>Allium cepa</i> L. bulb extract shall be used in accordance with the specific conditions included in the conclusions of the review report on <i>Allium cepa</i> L. bulb extract (SANTE/10842/2020 Rev2) and in particular Appendices I and II thereof.

⁽¹⁾ Further details on identity, specification and manner of use of the basic substance are provided in the review report.

ANNEX II

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

Number	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Specific provisions
'23	<i>Allium cepa</i> L. bulb extract CAS No: not allocated CIPAC No: not allocated	Not applicable	The onion bulbs used to prepare the extracts shall be of food grade quality meeting the requirements of WHO monographs on selected medicinal plants (Volume 1, Geneva, 1999) on <i>Bulbus Allii Cepae</i>	17.2.2021	<i>Allium cepa</i> L. bulb extract shall be used in accordance with the specific conditions included in the conclusions of the review report on <i>Allium cepa</i> L. bulb extract (SANTE/10842/2020 Rev2) and in particular Appendices I and II thereof.'

⁽¹⁾ Further details on identity, specification and manner of use of basic substance are provided in the review report.