

COMMISSION IMPLEMENTING REGULATION (EU) 2022/456
of 21 March 2022

approving the basic substance chitosan 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 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 19 December 2018, the Commission received an application from KitoZyme for the extension of use of chitosan hydrochloride, approved by Commission Implementing Regulation (EU) No 563/2014 ⁽²⁾ as a basic substance. As that application was not complete, on 28 November 2019, KitoZyme submitted a revised application 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 8 July 2020 ⁽³⁾ with the summary of the outcome of the consultation with Member States on the basic substance application for an extension of use of chitosan hydrochloride and presenting EFSA's scientific views on the individual comments received. Based on that technical report and the documentation provided by the applicant, it is appropriate to define the scope of the application as covering the active substance 'chitosan'. The Commission presented its review report ⁽⁴⁾ on the substance chitosan to the Standing Committee on Plants, Animals, Food and Feed on 19 May 2021.
- (3) The information provided by the applicant shows that chitosan 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 ⁽⁵⁾. Moreover, it is not predominantly used for plant protection purposes but nevertheless it can be useful in plant protection, in a product consisting of the substance and water. Consequently, it is to be considered as a basic substance pursuant to Art 23 of Regulation (EC) No 1107/2009.
- (4) After examination of the application and all related documents, it has been established that chitosan 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 chitosan as a basic substance.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²⁾ Commission Implementing Regulation (EU) No 563/2014 of 23 May 2014 approving the basic substance chitosan hydrochloride 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 (OJ L 156, 24.5.2014, p. 5).

⁽³⁾ EFSA (European Food Safety Authority), 2020. Technical report on the outcome of the consultation with Member States and EFSA on the basic substance application for approval of chitosan hydrochloride for an extension of use in plant protection as an elicitor in horticulture, olive trees, grapes, grass and post-harvest fruit treatment. EFSA supporting publication 2020:EN-1900. 53 pp. doi:10.2903/sp.efsa.2020.EN-1900.

⁽⁴⁾ Final review report for the basic substance chitosan finalised in the Standing Committee on Plants, Animals, Food and Feed at its meeting on 28 January 2022 in view of the approval of chitosan as basic substance in accordance with Regulation (EC) No 1107/2009 (SANTE/10594/2021).

⁽⁵⁾ 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).

- (5) In accordance with Article 13(2) of Regulation (EC) No 1107/2009 in conjunction with Article 6(a)(b)(d)(j) thereof and in the light of current scientific and technical knowledge, it is, however, necessary to include certain conditions for the approval.
- (6) In accordance with Article 13(4) of Regulation (EC) No 1107/2009, the Annex to Commission Implementing Regulation (EU) No 540/2011 ⁽⁶⁾ 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 chitosan as specified in Annex I is approved, and subject to the conditions as laid down in that Annex, as a basic substance.

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, 21 March 2022.

For the Commission
The President
Ursula VON DER LEYEN

⁽⁶⁾ 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 |
|---|--|--|------------------|--|
| Chitosan CAS No: 9012-76-4 EC No: 618-480-0 | Chemical name (not IUPAC): poly [4-O-(2-acetamido-2-deoxy- β -D-glucopyranosyl)-2-amino-2-deoxy- β -D-glucopyranose] | \geq 85 % chitosan heavy metals: max. 20 mg/kg Food grade, meeting the specifications for 'chitosan extract from fungi' as set out in Commission Implementing Regulation (EU) 2017/2470 ⁽²⁾ . | 11 April 2022 | Chitosan shall be used in accordance with the specific conditions included in the conclusions of the review report on chitosan (SANTE/10594/2021) and in particular Appendices I and II thereto. |

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

⁽²⁾ Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods (OJ L 351, 30.12.2017, p. 72).

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 |
|--------|---|--|---|------------------|---|
| '24 | Chitosan CAS No: 9012-76-4 EC No: 618-480-0 | Chemical name (not IUPAC): poly[4-O-(2-acetamido-2-deoxy-β-D-glucopyranosyl)-2-amino-2-deoxy-β-D-glucopyranose] | ≥ 85 % chitosan heavy metals: max. 20 mg/kg Food grade, meeting the specifications for "chitosan extract from fungi" as set out in Commission Implementing Regulation (EU) 2017/2470 ⁽²⁾ | 11 April 2022 | Chitosan shall be used in accordance with the specific conditions included in the conclusions of the review report on chitosan (SANTE/10594/2021) and in particular Appendices I and II thereto.' |

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

⁽²⁾ Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods (OJ L 351, 30.12.2017, p. 72).