

COMMISSION IMPLEMENTING REGULATION (EU) 2020/642**of 12 May 2020****approving the basic substance L-cysteine 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 9 February 2018 the Commission received an application from Soleo-EcoSolutions, for the approval of L-cysteine as a basic substance. That application was accompanied by the information required by the second subparagraph of Article 23(3).
- (2) The Commission asked the European Food Safety Authority ('the Authority') for scientific assistance. The Authority provided the Commission with a technical report on L-cysteine on 29 January 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 17 July 2019.
- (3) The information provided by the applicant shows that L-cysteine 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 nevertheless is useful in plant protection in a product consisting of the substance. Consequently, it is to be considered as a basic substance.
- (4) It has appeared from the examinations made that L-cysteine may be expected to satisfy, 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 L-cysteine 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 which are detailed in Annex I to this Regulation.
- (6) In accordance with Article 13(4) of Regulation (EC) No 1107/2009, the Annex to Commission Implementing Regulation (EU) No 540/2011 ⁽⁵⁾ 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,

⁽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 L-cysteine for use in plant protection as insecticide. EFSA supporting publication 2019: EN-1562. 46 pp. doi:10.2903/sp.efsa.2019.EN-1562.

⁽³⁾ Final Review report for the basic substance L-cysteine finalised in the Standing Committee on Plants, Animals, Food and Feed at its meeting on 24 March 2020 in view of the approval of L-cysteine as basic substance in accordance with Regulation (EC) No 1107/2009 (SANTE/11056/2019).

⁽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).

⁽⁵⁾ 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).

HAS ADOPTED THIS REGULATION:

Article 1

Approval of a basic substance

The substance L-cysteine is approved as a basic substance as laid down in Annex I.

Article 2

Amendments to Implementing Regulation (EU) No 540/2011

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, 12 May 2020.

For the Commission
The President
Ursula VON DER LEYEN

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ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Specific provisions
L-cysteine (E 920) CAS No: 52-89-1 EINECS: 200-157-7 (L-cysteine hydrochloride) CAS No: 7048-04-6 EINECS: 615-117-8 (L-cysteine hydrochloride monohydrate)	L-cysteine hydrochloride (1:1)	Min. 98,0 % L-cysteine hydrochloride (on anhydrous basis) Food grade in conformity with Commission Regulation (EU) No 231/2012 ⁽²⁾ . max. 1,5 mg/kg As max. 5 mg/kg Pb	2.6.2020	L-cysteine (E 920) shall be used as a mixture with matrix (flour, food grade) at a concentration of maximum 8% (of L-cysteine hydrochloride, on anhydrous basis) in accordance with the specific conditions included in the conclusions of the review report on L-cysteine (SANTE/11056/2019) 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 Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).

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
'21	L-cysteine (E 920) CAS No: 52-89-1 EINECS: 200-157-7 (L-cysteine hydrochloride) CAS No: 7048-04-6 EINECS: 615-117-8 (L-cysteine hydrochloride monohydrate)	L-cysteine hydrochloride (1:1)	Min. 98,0 % L-cysteine hydrochloride (on anhydrous basis) Food grade in conformity with Commission Regulation (EU) No 231/2012. max. 1,5 mg/kg As max. 5 mg/kg Pb	2.6.2020	L-cysteine (E 920) shall be used as a mixture with matrix (flour, food grade) at a concentration of maximum 8% (of L-cysteine hydrochloride, on anhydrous basis) in accordance with the specific conditions included in the conclusions of the review report on L-cysteine (SANTE/11056/2019) 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.