



COMMISSION IMPLEMENTING REGULATION (EU) 2026/402

of 24 February 2026

concerning the authorisation of L-cystine produced with *Escherichia coli* DSM 34232 as a feed additive for all animal species

(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 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ⁽¹⁾, and in particular Article 9(2) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of L-cystine produced with *Escherichia coli* DSM 34232. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) That application concerns the authorisation of L-cystine produced with *Escherichia coli* DSM 34232 as a feed additive for all animal species, requesting that additive to be classified in the additive category 'nutritional additives' and in the functional group 'amino acids, their salts and analogues'; and in the additive category 'sensory additives' and in the functional group 'flavouring compounds'. The applicant requested the additive to be authorised for use also in water for drinking. However, Regulation (EC) No 1831/2003 does not allow the authorisation of flavouring compounds for use in water for drinking. Therefore, the use of this additive in water for drinking should not be allowed. In addition, the applicant later withdrew the application for the authorisation of L-cystine produced with *Escherichia coli* DSM 34232 in the category 'nutritional additives' and the functional group 'amino acids, their salts and analogues'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 17 September 2025 ⁽²⁾ that, under the proposed conditions of use, L-cystine produced with *Escherichia coli* DSM 34232 is safe for all animal species as well as for consumers and the environment. The Authority also concluded that L-cystine produced with *Escherichia coli* DSM 34232 is not considered a skin and eye irritant, nor a skin sensitiser. The Authority further concluded that, as L-cystine produced with *Escherichia coli* DSM 34232 is used in food as flavouring compound, it is expected that it can provide a similar function in feed and no further demonstration of efficacy is necessary. It did not consider that there is a need for specific requirements of post-market monitoring. The Authority also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (5) In view of the above, the Commission considers that, L-cystine produced with *Escherichia coli* DSM 34232 satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that substance should be authorised for all animal species. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive.
- (6) The Commission considers that safety reasons do not require the setting of maximum contents for L-cystine produced with *Escherichia coli* DSM 34232. In order to allow better control, the recommended maximum content should be indicated on the label of the additive. Where the recommended maximum content is exceeded, certain information should be indicated on the label of the premixtures concerned.
- (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 268, 18.10.2003, p. 29, ELI: <http://data.europa.eu/eli/reg/2003/1831/oj>.

⁽²⁾ EFSA Journal 2025;23:e9688 <https://doi.org/10.2903/j.efsa.2025.9688>.

HAS ADOPTED THIS REGULATION:

Article 1

Authorisation

The substance specified in the Annex, belonging to the additive category 'sensory additives' and to the functional group 'flavouring compounds', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

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, 24 February 2026.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the additive	Name of the additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					mg/kg of complete feed with a moisture content of 12 %			
Category: Sensory additives. Functional group: Flavouring compounds								
2b392	L-cystine	<i>Additive composition</i> L-cystine Solid form ----- <i>Characterisation of the active substance</i> L-cystine produced with <i>Escherichia coli</i> DSM 34232 IUPAC name: (2R)-2-Amino-3-[[[(2R)-2-amino-2-carboxyethyl]disulfanyl]propanoic acid Chemical formula: C₆H₁₂N₂O₄S₂ CAS number: 56-89-3 FLAVIS number: 17.006 Purity: minimum 98,5 % on a dry matter basis. <i>Analytical methods</i> ⁽¹⁾ For the identification of L-cystine in the feed additive: — Food Chemical Codex “L-cystine monograph” For the determination of cystine in the feed additive: — Ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD). For the determination of cystine in premixtures: — Ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS).	All animal species	-	-	-	1. The additive shall be incorporated into the feed in the form of a premixture. 2. In the directions for use of the additive and premixtures, the storage conditions and the stability to heat treatment shall be indicated. 3. On the label of the additive the following shall be indicated: “Recommended maximum content of the active substance per kg of complete feedingstuff with a moisture content of 12 %: 25 mg”. 4. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixture where the use level on the label of the premixture would result in exceeding the recommended maximum content referred to in point 3.	17 March 2036

Identification number of the additive	Name of the additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					mg/kg of complete feed with a moisture content of 12 %			
		— Commission Regulation (EC) No 152/2009 ⁽²⁾, or — Ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD).						

⁽¹⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en.

⁽²⁾ Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed (OJ L 54, 26.2.2009, p. 1, ELI: <http://data.europa.eu/eli/reg/2009/152/oj>).