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[...](2025) **XXX** draft

COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

**concerning the authorisation of L-cystine produced with *Escherichia coli* K12 DSM
34232 as a feed additive for all animal species**

(Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

concerning the authorisation of L-cystine produced with *Escherichia coli* K12 DSM 34232 as a feed additive for all animal species

(Text with EEA relevance)

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.

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 nutrition¹, 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* K12 DSM 34232. The 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* K12 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 withdrew the application for the authorisation L-cystine produced with *Escherichia coli* K12 DSM 34232 in the category ‘nutritional additives’ and in the functional group ‘amino acids, their salts and analogues’.
- (4) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 17 September 2025² that, under the proposed conditions of use, L-cystine produced with

¹ Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (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>.

Escherichia coli K12 DSM 34232 is safe for all animal species as well as for the consumers and the environment. The Authority also concluded that L-cystine produced with *Escherichia coli* K12 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* K12 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* K12 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* K12 DSM 34232. In order to allow better control, the recommended maximum content should be indicated on the label of the additives. 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,

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,

For the Commission
The President
Ursula VON DER LEYEN