EUROPEAN
COMMISSION

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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the renewal of the authorisation of L-cysteine hydrochloride monohydrate as a feed additive for cats and dogs and repealing Implementing Regulation (EU) 2015/2306

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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 and renewing such an authorisation.

(2) L-cysteine hydrochloride monohydrate was authorised for 10 years as feed additive for cats and dogs by Commission Implementing Regulation (EU) 2015/2306[2] .

(3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, an application was submitted for the renewal of the authorisation of L-cysteine hydrochloride monohydrate for cats and dogs, requesting the additive to be classified in the additive category 'sensory additives' and in the functional group 'flavouring compounds'. That application was accompanied by the particulars and documents required under Article 14(2) of Regulation (EC) No 1831/2003.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 18 November 2025[3] that the applicant has provided evidence that L-cysteine hydrochloride monohydrate remains safe for cats and dogs as well as for the users and the environment under the conditions of use currently authorised. The Authority further concluded that L-cysteine hydrochloride monohydrate should be considered an irritant to skin, eyes and mucous membranes. Any exposure is considered a risk. The Authority stated that the application for renewal of the authorisation does not include a proposal for amending or supplementing the conditions of the original authorisation that would have an impact on the efficacy of the additive. Therefore, it concluded that there is no need for assessing the efficacy of the additive in the context of the renewal of the authorisation. The Authority considered that there is no need for specific requirements of post-market monitoring.

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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 Commission Implementing Regulation (EU) 2015/2306 of 10 December concerning the authorisation of L-cysteine hydrochloride monohydrate as a feed additive for cats and dogs. (OJ L 326, 11.12.2015, p. 46, ELI: http://data.europa.eu/eli/reg_impl/2015/2306/oj).

3 EFSA Journal. 2025;23:e9783, https://doi.org/10.2903/j.efsa.2025.9783.

(5) The Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in the assessment carried out regarding the method of analysis of L-cysteine hydrochloride monohydrate as a feed additive in the context of the previous authorisation are valid and applicable for the current application. In accordance with Article 5(4), point (c), of Commission Regulation (EC) No 378/2005[4], an evaluation report of the Reference Laboratory is therefore not required.

(6) In view of the above, the Commission considers that L-cysteine hydrochloride monohydrate satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the authorisation of that additive should be renewed. 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. Those protective measures should be without prejudice to other workers' safety requirements under Union law.

(7) The Commission considers that safety reasons do not require the setting of maximum content for L-cysteine hydrochloride monohydrate. 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.

(8) As a consequence of the renewal of the authorisation of L-cysteine hydrochloride monohydrate, Implementing Regulation (EU) 2015/2306 should be repealed.

(9) Since a new requirement for the labelling of the additive is introduced by this Implementing Regulation, it is appropriate to provide for a transitional period for interested parties to prepare themselves to meet that new requirements resulting from the renewal of the authorisation.

(10) 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
Renewal of the authorisation

The authorisation of the substance specified in the Annex, belonging to the additive category 'sensory additives' and to the functional group 'flavouring compounds', is renewed subject to the conditions laid down in that Annex.

Article 2
Repeal

Implementing Regulation (EU) 2015/2306 is repealed.

[4] Commission Regulation (EC) No 378/2005 of 4 March 2005 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the duties and tasks of the Community Reference Laboratory concerning applications for authorisations of feed additive (OJ L 59, 5.3.2005, p. 8, ELI: http://data.europa.eu/eli/reg/2005/378/oj).

Article 3

Transitional measures

1. The feed additive L-cysteine hydrochloride monohydrate as authorised by Implementing Regulation (EU) 2015/2306 and premixtures containing that additive which are intended for cats and dogs, and which are produced and labelled before [*6 months after the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication]* in accordance with the rules applicable before *[the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*] may continue to be placed on the market and used until the stocks concerned are exhausted.

2. Compound feed and feed materials containing the feed additive referred to in paragraph 1, which are intended for cats and dogs and which are produced and labelled before [*24 months after the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*] in accordance with the rules applicable before [*the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*] may continue to be placed on the market and used until the stocks concerned are exhausted if they are intended for non-food producing animals.

Article 4

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