COMMISSION IMPLEMENTING REGULATION (EU) 2015/2306

of 10 December 2015

concerning the authorisation of L-cysteine hydrochloride monohydrate as a feed additive for cats and dogs

(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. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ([2]).

(2) L-cysteine hydrochloride monohydrate was authorised without a time limit in accordance with Directive 70/524/EEC as a feed additive for all animal species. This product was subsequently entered in the Register of feed additives as existing product, in accordance with Article 10(1) of Regulation (EC) No 1831/2003.

(3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, an application was submitted for the re-evaluation of L-cysteine hydrochloride monohydrate as a feed additive for cats and dogs. The applicant requested that additive be classified in the additive category 'sensory additives'. This application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 10 October 2013 ([3]) that, under the proposed conditions of use in feed, L-cysteine hydrochloride monohydrate does not have adverse effects on animal health, human health or the environment. The Authority further stated that L-cystine and L-cysteine hydrochloride are flavouring agents authorised in food for which the efficacy is demonstrated although it is not clear that L-cysteine hydrochloride monohydrate is used as a flavouring in pet food in the same way as it is used in food. Considering the evidence provided by the applicant, the Authority also concluded that the efficacy of L-cysteine hydrochloride monohydrate with respect to the final concentration in feed cannot be assessed. However, the Authority also stated that this additive is authorised in food and, where the function for feed is essentially the same as that for food, no further demonstration of efficacy is necessary. Considering further evidence provided by the applicant the Commission concluded that, although L-cysteine hydrochloride monohydrate relates to a different chemical structure with respect to L-cystine and L-cysteine hydrochloride, the fact that the additive is monohydrated does not change its efficacy. The Commission also concluded that use levels for this additive are higher to the normal and maximum use levels reported in food for different types of products, therefore, there is sufficient evidence of the efficacy of this substance.

(5) The Authority concluded that no safety concerns would arise for users provided that appropriate protective measures are taken. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(6) The assessment of L-cysteine hydrochloride monohydrate shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of L-cysteine hydrochloride monohydrate should be authorised as specified in the Annex to this Regulation.

(7) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation for L-cysteine hydrochloride monohydrate it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1).
([3]) EFSA Journal 2013;11(10):3437

(8) 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 a feed additive in animal nutrition subject to the conditions laid down in that Annex.

Article 2

Transitional Measures

1. The substance specified in the Annex and premixtures containing this substance, which are produced and labelled before 30 June 2016 in accordance with the rules applicable before 31 December 2015 may continue to be placed on the market and used until the existing stocks are exhausted.

2. Compound feed and feed materials containing the substance specified in the Annex which are produced and labelled before 31 December 2017 in accordance with the rules applicable before 31 December 2015 may continue to be placed on the market and used until the existing stocks are exhausted.

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, 10 December 2015.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Identification number of the additive	Name of the holder of authorisation	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 of active substance/kg of complete feedingstuff with a moisture content of 12 %.			
Category: Sensory additives. Functional group: Flavouring compounds.									
2b920	—	L-cysteine hydrochloride monohydrate	*Additive composition* L-cysteine hydrochloride monohydrate. *Characterisation of the active substance* L-cysteine hydrochloride monohydrate $C_3H_7NO_2S{\cdot}HClH_2O$ CAS No: 7048-04-6 L-cysteine hydrochloride monohydrate solid form, produced by hydrolysis of keratin from avian feathers. Purity: min. 98,5 % assay. *Method of analysis* (1) For the quantification of L-cysteine hydrochloride monohydrate in feed additive: titrimetry, European Pharmacopoeia (Ph. Eur. 6,0, method 01/2008:0895). For the quantification of Cyst(e)ine (including L-cysteine hydrochloride monohydrate) in premixtures and feedingstuffs: ion exchange chromatography method with post-column derivatisation and photometric detection: Commission Regulation (EC) No 152/2009 (2) (Annex III, F).	Cats and dogs	—	—	—	1. Indicate in the directions for use of the additive and premixture: — the storage conditions; — supplementation with L-cysteine hydrochloride monohydrate shall depend on the requirements of cats and dogs for sulphur-containing amino acids and the level of other sulphur-containing amino acids in the ration. 2. For safety: breathing protection, safety glasses and gloves shall be worn during handling.	31 December 2025

(1) Details of the analytical methods are available at the following address of the Reference Laboratory: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports
(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).