COMMISSION IMPLEMENTING REGULATION (EU) 2020/1175

of 7 August 2020

concerning the authorisation of L-cysteine hydrochloride monohydrate produced by fermentation with *Escherichia coli* KCCM 80180 *and Escherichia coli* KCCM 80181 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-cysteine hydrochloride monohydrate produced by fermentation with *Escherichia coli* KCCM 80180 and *Escherichia coli* KCCM 80181. This application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) This application concerns the authorisation of L-cysteine hydrochloride monohydrate produced by fermentation with *Escherichia coli* KCCM 80180 and *Escherichia coli* KCCM 80181 as a feed additive for all animal species. The applicant requested this additive to be classified in the additive category 'sensory additives'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 10 January 2020 ([2]) that, under the proposed conditions of use in feed L-cysteine hydrochloride monohydrate produced by fermentation with *Escherichia coli* KCCM 80180 and *Escherichia coli* KCCM 80181 does not have adverse effects on animal health, consumer safety or the environment. In its conclusions it also considered that the applicant proposes to label the additive with the hazard statement H335 (may cause respiratory irritation) under the Regulation (EC) No 1272/2008 ([3]). Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular, as regards the users of the additive. The Authority further concluded that since the substance is used in food and its function in feed is the same as that in food, no further demonstration of efficacy in feed is necessary.

(5) Restrictions and conditions should be provided for to allow for a better control. For L-cysteine hydrochloride monohydrate, recommended contents should be indicated on the label of the additive. Where such contents are exceeded, certain information should be indicated on the label of premixtures.

(6) 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.

(7) The assessment of L-cysteine hydrochloride monohydrate produced by fermentation with *Escherichia coli* KCCM 80180 and *Escherichia coli* KCCM 80181 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of this substance should be authorised as specified in the Annex to this Regulation.

(8) The fact that L-cysteine hydrochloride monohydrate produced by fermentation with *Escherichia coli* KCCM 80180 and *Escherichia coli* KCCM 80181 is not authorised for use as a flavouring in water for drinking, does not preclude its use in compound feed, which is administered via water.

([1]) OJ L 268, 18.10.2003, p. 29..
([2]) EFSA Journal 2020;18(2):6003.
([3]) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

(9) 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

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

Article 2

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, 7 August 2020.

For the Commission
The President
Ursula VON DER LEYEN

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									
2b920i	-	L-cysteine hydrochloride monohydrate	*Additive composition:* L-cysteine hydrochloride monohydrate *Characterisation of the active substance:* L-cysteine hydrochloride monohydrate Produced by fermentation with *Escherichia coli* KCCM 80180 and *Escherichia coli* KCCM 80181 Purity: min. 98,5 % Chemical formula: $C_3H_7NO_2S \cdot HClH_2O$. CAS number 7048-04-6 FLAVIS 17.032 *Method of analysis* ([1]): For the identification of L-cysteine hydrochloride monohydrate in the feed additive: — ion-exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS), Ph.Eur. 6.6-2.2.56-Method 1 For the quantification of L-cysteine hydrochloride monohydrate in the feed additive: — ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FD) For the quantification of L-cysteine hydrochloride monohydrate in premixtures:	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 premixture, 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 of complete feedingstuff with a moisture content of 12 %: 25 mg/kg'. 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 premixtures, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 25 mg/kg. 5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation. Where those risks cannot be eliminated or reduced to a minimum by such procedures	30.9.2030

			— ion-exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS), Commission Regulation (EC) No 152/2009 (Annex III, F)					and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection.	

([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