COMMISSION IMPLEMENTING REGULATION (EU) 2020/1761

of 25 November 2020

concerning the authorisation of L-cysteine hydrochloride monohydrate produced by fermentation with *Escherichia coli* KCCM 80109 and KCCM 80197 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 80109 and KCCM 80197. 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 80109 and KCCM 80197 as a feed additive for all animal species. The applicant requested this additive to be classified in the additive category 'sensory additives'.

(4) The applicant requested the feed 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 L-cysteine hydrochloride monohydrate produced by fermentation with *Escherichia coli* KCCM 80109 and KCCM 80197 in water for drinking should not be allowed. The fact that of L-cysteine hydrochloride monohydrate produced by fermentation with Escherichia coli KCCM 80109 and KCCM 80197 is not authorised for use as a flavouring in water for drinking does not preclude its use in compound feed administered via water.

(5) The European Food Safety Authority ('the Authority') concluded in its opinion of 19 March 2020 ([2]) that, under the proposed conditions of use L-cysteine hydrochloride monohydrate produced by fermentation with *Escherichia coli* KCCM 80109 and KCCM 80197 do not have adverse effects on animal health, consumer health or the environment. The Authority concluded for L-cysteine hydrochloride monohydrate produced by fermentation with *Escherichia coli* KCCM 80109 and KCCM 80197 that although users' exposure via inhalation is unlikely due to the low dusting potential, the product is proposed to be classified as respiratory irritant due to its low pH when in solution. In addition, based on the results of the studies provided, it should be classified as skin irritant and that it can cause serious eye damage. L-cysteine hydrochloride monohydrate is not a dermal sensitiser. The Authority also concluded, that since L-cysteine hydrochloride monohydrate produced by fermentation with *Escherichia coli* KCCM 80109 and KCCM 80197 is used in food as flavouring, it is to be expected that it can provide a similar function in feed and no further demonstration of efficacy is necessary when used in feed. 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 produced by fermentation with *Escherichia coli* KCCM 80109 and KCCM 80197 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 produced by fermentation with *Escherichia coli* KCCM 80109 and KCCM 80197 should be authorised as specified in the Annex to this Regulation.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) *EFSA Journal* 2020;18(4):6101.

(7) Restrictions and conditions should be provided for to allow better control. In particular, a recommended content should be indicated on the label of the feed additive. Where such content is exceeded, certain information should be indicated on the label of premixtures.

(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

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

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, 25 November 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 80109 and KCCM 80197 Purity: ≥ 98,5 % assay Chemical formula: $C_3H_7NO_2S \bullet HClH_2O$ CAS number: 7048-04-6. FLAVIS number: 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: ion-exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS), Commission Regulation (EC) No 152/2009 ([2])Annex III, F)	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, dermal contact or eyes contact. Where those	16.12.2030

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						mg of active substance/kg of complete feedingstuff with a moisture content of 12 %			
								risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection, safety glasses and gloves	

([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).