COMMISSION IMPLEMENTING REGULATION (EU) 2020/1798

of 30 November 2020

concerning the authorisation of L-lysine monohydrochloride produced by *Corynebacterium glutamicum* DSM 32932 and L-lysine sulphate produced by *Corynebacterium glutamicum* KFCC 11043 as feed additives 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 applications were submitted for the authorisation of L-lysine monohydrochloride produced by *Corynebacterium glutamicum* DSM 32932 and L-lysine sulphate produced by *Corynebacterium glutamicum* KFCC 11043. The applications were accompanied by the particulars and documents required under Article 7(3) of that Regulation.

(3) The applications concern the authorisation of L-lysine monohydrochloride produced by *Corynebacterium glutamicum* DSM 32932 and L-lysine sulphate produced by *Corynebacterium glutamicum* KFCC 11043 as feed additives for all animal species, to be classified in the additive category 'nutritional additives', functional group 'amino acids, their salts and analogues'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 19 March 2020 ([2]) that, under the proposed conditions of use, L-lysine monohydrochloride produced by *Corynebacterium glutamicum* DSM 32932 does not have an adverse effect on animal health, consumer safety or the environment. The Authority stated a risk for the users as it should be considered as an eye irritant. 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. In its opinion of 1 July 2020 ([3]), the Authority concluded that, under the proposed conditions of use, L-lysine sulphate produced by *Corynebacterium glutamicum* KFCC 11043 does not have an adverse effect on animal health, human health or the environment. The Authority also concluded that both additives are efficacious sources of the amino acid L-lysine for all animal species and that in order to be as efficacious in ruminants as in non-ruminant species, the additives should be protected against degradation in the rumen. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the reports 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) The assessment of L-lysine monohydrochloride produced by *Corynebacterium glutamicum* DSM 32932 and of L-lysine sulphate produced by *Corynebacterium glutamicum* KFCC 11043 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of these substances should be authorised as specified in the Annex to this Regulation.

(6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) *EFSA Journal* 2020;18(4):6078.
([3]) *EFSA Journal* 2020;18(7):6203.

HAS ADOPTED THIS REGULATION:

Article 1

The substances specified in the Annex, belonging to the additive category 'nutritional additives' and to the functional group 'amino acids, their salts and analogues', are authorised as 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, 30 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/kg of complete feed with a moisture content of 12 %			
Category of nutritional additives. Functional group: amino acids, their salts and analogues									
3c322i		L-lysine monohydrochloride, technically pure	*Additive composition* Powder of L-lysine monohydrochloride with a minimum of 78 % L-lysine and a maximum moisture content of 1,5 %. *Characterisation of the active substance* L-lysine monohydrochloride produced by fermentation with *Corynebacterium glutamicum* DSM 32932. Chemical formula: $C_6H_{15}ClN_2O_2$ CAS Number: 657-27-2 *Analytical methods* (1) For the identification of L-lysine monohydrochloride in the feed additive: — Food Chemical Codex 'L-lysine monohydrochloride monograph' For the quantification of lysine in the feed additive and premixtures containing more than 10 % lysine: — ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS/FLD) – EN ISO 17180. For the quantification of lysine in premixtures, compound feed and feed materials: — ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS), Commission Regulation (EC) No 152/2009 (2) (Annex III, F).	All species	-	-	-	1. The lysine content shall be indicated on the labelling of the additive. 2. L-lysine monohydrochloride, technically pure, may be placed on the market and used as an additive consisting of a preparation. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks for the eyes. Where those 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. 4. Declarations to be made on the labelling of the additive and premixtures: 'The supplementation with L-lysine should take into account all essential and conditional essential amino acids in order to avoid imbalances.'	21.12.2030

3c323		L-lysine sulphate	*Additive composition* Granulate with a minimum L-lysine content of 55 % and a maximum content of 22 % sulphate and 4 % moisture *Characterisation of the active substance* L-lysine sulphate produced by fermentation with *Corynebacterium glutamicum* KFCC 11043 Chemical formula: $C_{12}H_{30}N_4O_8S$ CAS number: 60343-69-3 *Analytical methods* (1) For the quantification of lysine in the feed additive and premixtures containing more than 10 % lysine: — ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS/FLD) – EN ISO 17180 For the identification of sulphate in the feed additive: — European Pharmacopoeia Monograph 20301 For the quantification of lysine in premixtures, compound feed and feed materials: — ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS), Regulation (EC) No 152/2009 (Annex III, F).	All species	-	-	10 000	1. The L-lysine content shall be indicated on the labelling of the additive. 2. L-lysine sulphate may be placed on the market and used as an additive consisting of a preparation. 3. Declarations to be made on the labelling of the additive and premixtures: 'The supplementation with L-lysine should take into account all essential and conditional essential amino acids in order to avoid imbalances.'	21.12.2030

(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).