COMMISSION IMPLEMENTING REGULATION (EU) 2022/1469

of 5 September 2022

concerning the authorisation of L-lysine sulphate produced by *Escherichia coli* CGMCC 7.398 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 an authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of L-lysine sulphate produced by *Escherichia coli* CGMCC 7.398. The application was accompanied by the particulars and documents required under Article 7(3) of that Regulation.

(3) The application concerns the authorisation of L-lysine sulphate produced by *Escherichia coli* CGMCC 7.398 as a feed additive 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 23 March 2022 ([2]) that, under the proposed conditions of use L-lysine sulphate produced by *Escherichia coli* CGMCC 7.398, when supplemented to diets in appropriate amounts, does not have an adverse effect on animal health, consumer safety or the environment. With respect to the safety of the user of that additive, the Authority could not conclude on the potential of L-lysine sulphate to be irritant to skin or eyes, or on its potential to be a dermal sensitiser. The endotoxin activity of the additive represents a risk of exposure by inhalation to endotoxins for persons handling the additive. 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. Further, the Authority concluded that the additive is considered an efficacious source of the essential amino acid L-lysine for animal nutrition and that in order to be efficacious in ruminants, it 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 sulphate produced by *Escherichia coli* CGMCC 7.398 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.

(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* 2022;20(4):7246.

HAS ADOPTED THIS REGULATION:

Article 1

The substance specified in the Annex, belonging to the additive category 'nutritional additives' and to the functional group 'amino acids, their salts and analogues', 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, 5 September 2022.

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 additive/kg of complete feed with a moisture content of 12 %			
Category: nutritional additives. Functional group: amino acids, their salts and analogues.									
3c323i		L-lysine sulphate	*Additive composition* Preparation of L-lysine with a content of: — lysine ≥ 55,0 % — sulphate ≥ 18,0 % Solid form *Characterisation of the active substance* L-lysine sulphate produced by fermentation with *Escherichia coli* CGMCC 7.398 Chemical formula: $C_{12}H_{28}N_4O_4$-O_4S 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 optical detection (IEC-VIS/FLD) – EN ISO 17180 For the identification of sulphate in the feed additive: — European Pharmacopoeia Monograph 20301	All species	-	-	10 000	1. The L-lysine content shall be indicated on the labelling of the additive. 2. 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.' 3. The endotoxin content of the additive and its dusting potential shall ensure a maximal endotoxin exposure of 1 600 IU endotoxins/m^3 air (2). 4. 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 level by such procedures and measures, the addi-	26.9.2032

			For the quantification of lysine in premixtures, compound feed and feed materials: — ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS) – Commission Regulation (EC) No 152/2009 (Annex III, F).					tive and premixtures shall be used with personal protective equipment, including skin, eyes and breathing protection.	

(1) Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en

(2) Exposure calculated based on the endotoxin level and the dusting potential of the additive according to the method used by EFSA (*EFSA Journal* 2018;16(10):5458); analytical method: European Pharmacopoeia 2.6.14. (bacterial endotoxins).