COMMISSION IMPLEMENTING REGULATION (EU) 2020/997

of 9 July 2020

concerning the authorisation of L-lysine base, liquid, L-lysine sulphate and L-lysine monohydrochloride, technically pure, 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(1) of Regulation (EC) No 1831/2003, applications were submitted for the authorisation of L-lysine base, liquid, and L-lysine monohydrochloride, technically pure, produced by *Corynebacterium glutamicum* NRRL-B-67439 or *Corynebacterium glutamicum* NRRL B-67535 and L-lysine sulphate and L-lysine monohydrochloride, technically pure, produced by *Corynebacterium glutamicum* CGMCC 7.266 as nutritional feed additives for use in feed and in water for drinking for all animal species. These applications were accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) These applications concern the authorisation of L-lysine base, liquid, and L-lysine monohydrochloride, technically pure, produced by *Corynebacterium glutamicum* NRRL-B-67439 or *Corynebacterium glutamicum* NRRL B-67535 and L-lysine sulphate and L-lysine monohydrochloride, technically pure, produced by *Corynebacterium glutamicum* CGMCC 7.266 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 opinions of 7 October 2019 ([2]) and 28 January 2020 ([3]) that, under the proposed conditions of use, L-lysine base, liquid, and L-lysine monohydrochloride, technically pure, produced by *Corynebacterium glutamicum* NRRL-B-67439 or *Corynebacterium glutamicum* NRRL B-67535 and L-lysine sulphate and L-lysine monohydrochloride, technically pure, produced by *Corynebacterium glutamicum* CGMCC 7.266 do not have an adverse effect on animal health, consumer health or the environment. It could not conclude on the potential toxicity by inhalation of L-lysine monohydrochloride, technically pure, produced by *Corynebacterium glutamicum* NRRL-B-67439 or *Corynebacterium glutamicum* NRRL B-67535 and anticipated that L-lysine base, liquid, produced by *Corynebacterium glutamicum* NRRL-B-67439 or *Corynebacterium glutamicum* NRRL B-67535 is corrosive to skin and eyes and poses an inhalation risk. For L-lysine sulphate and L-lysine monohydrochloride, technically pure, produced by *Corynebacterium glutamicum* CGMCC 7.266, the Authority could not exclude that the additives are toxic by inhalation, irritant to skin or eyes, or on their potential to be a dermal sensitiser. Therefore, appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive. The Authority concluded that L-lysine base, liquid, and L-lysine monohydrochloride, technically pure, produced by *Corynebacterium glutamicum* NRRL-B-67439 or *Corynebacterium glutamicum* NRRL B-67535 and L-lysine sulphate and L-lysine monohydrochloride, technically pure, produced by *Corynebacterium glutamicum* CGMCC 7.266 are effective sources of the essential amino acid L-lysine for all animal species. For the supplemental L-lysine to be fully efficacious in ruminants, it should be protected against degradation in the rumen. In its opinions mentioned above, the Authority referred to a previous statement concerning potential nutritional imbalances for amino acids, when they are administered via water for drinking. However, the Authority did not propose a maximum content for the supplementation with L-lysine. Thus, it is appropriate to indicate on the label of the additive, and premixtures containing it, an alert to take into account the dietary supply with all the essential and conditionally essential amino acids, particularly in the case of supplementation with L-lysine as amino acid via water for drinking.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) *EFSA Journal* 2019;17(10):5886.
([3]) EFSA Journal 2020;18(2): 6019.

(5) 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.

(6) The assessment of L-lysine base, liquid, and L-lysine monohydrochloride, technically pure, produced by *Corynebacterium glutamicum* NRRL-B-67439 or *Corynebacterium glutamicum* NRRL B-67535 and of L-lysine sulphate and L-lysine monohydrochloride, technically pure, produced by *Corynebacterium glutamicum* CGMCC 7.266 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 additive should be authorised as specified in the Annex to this Regulation.

(7) 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 are authorised as feed additives in animal nutrition in the additive category 'nutritional additives', functional group 'amino acids, their salts and analogues', 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, 9 July 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 additive/kg of complete feed with a moisture content of 12 %			
Category of nutritional additives. Functional group: amino acids, their salts and analogues.									
3c320	-	L-lysine base, liquid	**Additive composition:** Aqueous solution of L-lysine with a minimum of 50 % L-lysine **Characterisation of the active substance:** L-lysine produced by fermentation with *Corynebacterium glutamicum* NRRL-B-67439 or *Corynebacterium glutamicum* NRRL B-67535. Chemical formula: NH_2-$(CH_2)_4$-CH(NH_2)-COOH CAS Number: 56-87-1 **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	All species	-	-	-	1. The lysine content shall be indicated on the labelling of the additive. 2. L-lysine base, liquid, 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 by inhalation and for the skin and 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, including breathing, skin and eye protection. 4. The additive may be also used via water for drinking.	30.7.2030

(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

			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 (Annex III, F) For the quantification of lysine in water: — ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD)					5. Declarations to be made on the labelling of the additive and premixtures: 'The supplementation with L-lysine, in particular via water for drinking, should take into account all essential and conditional essential amino acids in order to avoid imbalances.'	
3c322		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* NRRL-B-67439 or *Corynebacterium glutamicum* NRRL B-67535 or *Corynebacterium glutamicum* CGMCC 7.266. Chemical formula: NH_2-$(CH_2)_4$-CH(NH_2)-COOH 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:	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 by inhalation. 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, including breathing protection.	30.7.2030

			— 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 (Annex III, F). For the quantification of lysine in water: — ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD); or — ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS).					4. The additive may be also used via water for drinking. 5. Declarations to be made on the labelling of the additive and premixtures: 'The supplementation with L-lysine, in particular via water for drinking, should take into account all essential and conditional essential amino acids in order to avoid imbalances.'	
3c325		L-lysine sulphate	**Additive composition:** Granulate with a minimum L-lysine content of 52 % and a maximum content of 24 % sulphate. **Characterisation of the active substance:** L-lysine sulphate produced by fermentation with *Corynebacterium glutamicum* CGMCC 7.266 Chemical formula: $C_{12}H_{28}N_4O_4 \bullet H_2SO_4$/ $[NH_2\text{-}(CH_2)_4\text{-}CH(NH_2)\text{-}COOH]_2SO_4$ CAS number: 60343-69-3 **Analytical methods[1]:** For the quantification of lysine in the feed additive and premixtures containing more than 10 % lysine:	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. 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 additive and premixtures shall be used with personal protective equipment, including breathing protection.	30.7.2030

			— 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) – Commission Regulation (EC) No 152/2009 (Annex III, F) For the quantification of lysine in water: — ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD)					4. The additive may be also used via water for drinking. 5. Declarations to be made on the labelling of the additive and premixtures: 'The supplementation with L-lysine, in particular via water for drinking, should take into account all essential and conditional essential amino acids in order to avoid imbalances.'	