COMMISSION IMPLEMENTING REGULATION (EU) 2021/2095

of 29 November 2021

concerning the authorisation of L-lysine base, L-lysine monohydrochloride and L-lysine sulphate 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 an authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003, applications were submitted for the authorisation of L-lysine base, L-lysine monohydrochloride and L-lysine sulphate. 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 base and L-lysine monohydrochloride produced by *Corynebacterium glutamicum* KCCM 80183, L-lysine monohydrochloride and L-lysine sulphate produced by *Corynebacterium glutamicum* CCTCC M 2015595 and L-lysine sulphate produced by *Corynebacterium glutamicum* KCCM 80227 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 17 March 2021 ([2]), ([3]) and 23 June 2021 ([4]) that, under the proposed conditions of use, L-lysine base and L-lysine monohydrochloride produced by *Corynebacterium glutamicum* KCCM 80183, L-lysine monohydrochloride and L-lysine sulphate produced by *Corynebacterium glutamicum* CCTCC M 2015595 and L-lysine sulphate produced by *Corynebacterium glutamicum* KCCM 80227 do not have an adverse effect on animal health, consumer safety or the environment. For L-lysine sulphate produced by *Corynebacterium glutamicum* KCCM 80227, the Authority concluded that that active substance is not toxic by inhalation, not irritant to skin or eyes, and not a skin sensitiser. With respect to the safety of the user of L-lysine monohydrochloride and L-lysine sulphate produced by *Corynebacterium glutamicum* CCTCC M 2015595, the Authority could neither exclude a risk by inhalation, nor that the active substance might be irritant to skin or eyes, or a dermal sensitiser. Further, the Authority stated L-lysine base produced by *Corynebacterium glutamicum* KCCM 80183 to be hazardous by inhalation and L-Lysine monohydrochloride produced by *Corynebacterium glutamicum* KCCM 80183 to be hazardous by inhalation and mildly irritant to eyes. Therefore, the Commission considers that for the lysine forms produced by *Corynebacterium glutamicum* CCTCC M 2015595 and *Corynebacterium glutamicum* KCCM 80183, appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive. The Authority also concluded that all 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.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) *EFSA Journal* 2021;19(4):6520.
([3]) *EFSA Journal* 2021;19(4):6537.
([4]) *EFSA Journal* 2021;19(7):6706.

(5) The assessments of L-lysine base and L-lysine monohydrochloride produced by *Corynebacterium glutamicum* KCCM 80183, L-lysine monohydrochloride and L-lysine sulphate produced by *Corynebacterium glutamicum* CCTCC M 2015595 and L-lysine sulphate produced by *Corynebacterium glutamicum* KCCM 80227 show 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,

HAS ADOPTED THIS REGULATION:

Article 1

The substances and preparations 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, 29 November 2021.

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:** Preparation (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* KCCM 80183 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 optical detection (IEC-VIS/FLD) – EN ISO 17180. For the quantification of lysine in premixtures, compound feed and feed materials:	All species	-	-	-	1. The lysine content shall be indicated on the labelling of the additive. 2. The additive can be also used via water for drinking. 3. 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.' 4. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address the potential risks by inhalation, eye or dermal contact. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment, including eyes, skin and breathing protection.	20.12.2031

			— ion exchange chromatography coupled with post-column derivatisation and optical 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 optical detection (IEC-VIS).						
3c322ii		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* KCCM 80183 or *Corynebacterium glutamicum* CCTCC M 2015595 Chemical formula: NH_2-$(CH_2)_4$-CH(NH_2)-COOH CAS Number: 657-27-2	All species	-	-	-	1. The lysine content shall be indicated on the labelling of the additive. 2. The additive can be also used via water for drinking. 3. 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.' 4. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address the potential risks by inhalation, eye or dermal contact. Where those risks cannot be eliminated or reduced	20.12.2031

			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 optical 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 optical 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 optical detection (IEC-VIS).					to a minimum by such procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment, including eyes, skin and breathing protection.	

3c325i	-	L-lysine sulphate	**Additive composition:** Granulated preparation of L-lysine sulphate with a minimum L-lysine content of 52 %, a maximum content of 24 % sulphate and a maximum content of 4 % moisture. **Characterisation of the active substance:** L-lysine sulphate produced by fermentation with *Corynebacterium glutamicum* CCTCCM 2015595 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: — 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. For the quantification of lysine in premixtures, compound feed and feed materials:	All species	-	-	10 000	1. The L-lysine content shall be indicated on the labelling of the additive. 2. The additive may be also used via water for drinking. 3. 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.' 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 additive and premixtures shall be used with personal protective equipment, including breathing protection.	20.12.2031

			— ion exchange chromatography coupled with post-column derivatisation and optical 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).						
3c324i	-	L-lysine sulphate	**Additive composition:** Granulated preparation of L-lysine sulphate with a minimum L-lysine content of 52 %, a maximum content of 24 % sulphate and a maximum content of 4 % moisture. **Characterisation of the active substance:** L-lysine sulphate produced by fermentation with *Corynebacterium glutamicum* KCCM 80227 Chemical formula: C_{12} H_{28} $N_4O_4 \bullet H_2SO_4/[NH_2\text{-}(C\ H_2)_4\text{-}CH\ (NH_2)\text{-}COOH]_2SO_4$ 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. 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.'	20.12.2031

			— 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. 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). For the quantification of lysine in water: — ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD).						

(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