REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2019/1964

of 26 November 2019

concerning the authorisation of L-lysine base, liquid, L-lysine monohydrochloride, liquid, L-lysine monohydrochloride, technically pure, 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 authorisation. Article 10(2) of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 82/471/EEC ([2]).

(2) Concentrated liquid L-lysine (base), concentrated liquid L-lysine monohydrochloride, L-lysine monohydrochloride, technically pure, and L-lysine sulphate produced by fermentation with *Corynebacterium glutamicum* were authorised without a time limit pursuant to Directive 82/471/EEC by Commission Directive 88/485/EEC ([3]). These feed additives were subsequently entered in the Register of feed additives as existing products, in accordance with Article 10(1) of Regulation (EC) No 1831/2003.

(3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, applications were submitted for the re-evaluation of concentrated liquid L-lysine (base), concentrated liquid L-lysine monohydrochloride, L-lysine monohydrochloride, technically pure, and L-lysine sulphate produced by fermentation with *Corynebacterium glutamicum* as feed additives for all animal species. Applications were also submitted for the authorisation of concentrated liquid L-lysine (base), concentrated liquid L-lysine monohydrochloride, L-lysine monohydrochloride, technically pure, and L-lysine sulphate for all animal species in accordance with Article 7 of Regulation (EC) No 1831/2003. The applications were accompanied by the particulars and documents required under Article 7(3) of that Regulation.

(4) The applications concern the authorisation of concentrated liquid L-lysine (base), concentrated liquid L-lysine monohydrochloride, L-lysine monohydrochloride, technically pure, and L-lysine sulphate as feed additives for all animal species, to be classified in the additive category 'nutritional additives'.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition (OJ L 213, 21.7.1982, p. 8).
([3]) Commission Directive 88/485/EEC of 26 July 1988 amending the Annex to Council Directive 82/471/EEC concerning certain products used in animal nutrition (OJ L 239, 30.8.1988, p. 36).

(5) The European Food Safety Authority ('the Authority') concluded in its opinions of 11 September 2013 ([4]), 28 October 2014 ([5]), 10 March 2015 ([6]), 16 June 2015 ([7]), 2 December 2015 ([8]), 19 April 2016 ([9]), 28 November 2018 ([10]), ([11]) and 3 April 2019 ([12]) that, under the proposed conditions of use, concentrated liquid L-lysine (base) produced by *Escherichia coli* FERM BP-10941, *Escherichia coli* FERM BP-11355, *Corynebacterium glutamicum* KCCM 11117P, *Corynebacterium glutamicum* NRRL B-50547, *Corynebacterium glutamicum* NRRL B-50775 and *Corynebacterium glutamicum* KCCM 10227, concentrated liquid L-lysine monohydrochloride produced by *Escherichia coli* FERM BP-10941 and *Escherichia coli* FERM BP-11355, L-lysine monohydrochloride, technically pure, produced by *Escherichia coli* FERM BP-10941, *Escherichia coli* FERM BP-11355, *Escherichia coli* CGMCC 3705, *Escherichia coli* CGMCC 7.57, *Corynebacterium glutamicum* NRRL B-50547, *Corynebacterium glutamicum* NRRL B-50775, *Corynebacterium glutamicum* KCCM 11117P and *Corynebacterium glutamicum* KCCM 10227 and L-lysine sulphate produced by *Corynebacterium glutamicum* KCCM 10227 and *Corynebacterium glutamicum* DSM 24990 do not have an adverse effect on animal health, consumer safety or the environment. The safety of the additives produced by genetically modified microorganism, in particular by *Corynebacterium glutamicum* NRRL B-50547, is subject to the condition that the manufacturing process is performed ensuring that no recombinant DNA of the production strain is present in the final product. The Authority also stated that the four forms of L-lysine should be considered hazardous for the users of the additives, in particular upon inhalation. Some of the forms should also be considered to be mildly irritant to eyes or corrosive to skin and eyes. 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 additives. The Authority also concluded that the additives are an efficacious source 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 report on the methods of analysis of the feed additives in feed and water submitted by the Reference Laboratory set up by Article 21 of Regulation (EC) No 1831/2003.

(6) The names 'concentrated liquid L-lysine (base)' and 'concentrated liquid L-lysine monohydrochloride' should be changed to 'L-lysine base, liquid' and 'L-lysine monohydrochloride, liquid' as the minimum content of L-lysine of those additives is only 50 % and 22 % respectively.

(7) The assessment of concentrated liquid L-lysine (base), concentrated liquid L-lysine monohydrochloride, L-lysine monohydrochloride, technically pure, and L-lysine sulphate produced by fermentation with *Corynebacterium glutamicum* spp or *Escherichia coli* spp as mentioned in recital (5) 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.

(8) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation for concentrated liquid L-lysine (base), concentrated liquid L-lysine monohydrochloride, L-lysine monohydrochloride, technically pure, and L-lysine sulphate produced by fermentation with *Corynebacterium glutamicum*, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.

(9) 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

Authorisation

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 an additive in animal nutrition subject to the conditions laid down in that Annex.

([4]) EFSA Journal 2013;11(10):3365.
([5]) EFSA Journal 2014;12(11):3895.
([6]) EFSA Journal 2015;13(3):4052.
([7]) EFSA Journal 2015;13(7):4156.
([8]) EFSA Journal 2016;14(3):4346.
([9]) EFSA Journal 2016;14(5):4471.
([10]) EFSA Journal 2019;17(1):5532.
([11]) EFSA Journal 2019;17(1):5537.
([12]) EFSA Journal 2019;17(5):5697.

Article 2

Transitional measures

1. Concentrated liquid L-lysine (base), concentrated liquid L-lysine monohydrochloride, L-lysine monohydrochloride, technically pure, and L-lysine sulphate produced by fermentation with *Corynebacterium glutamicum* authorised by Commission Directive 88/485/EEC and premixtures containing them may be placed on the market until 18 June 2020 in accordance with the rules applicable before 18 December 2019 and used until the existing stocks are exhausted.

2. Feed materials and compound feed containing the substances referred to in paragraph 1 which are produced and labelled before 18 December 2020 in accordance with the rules applicable before 18 December 2019 may be placed on the market and used until the existing stocks are exhausted if they are intended for food producing animals.

3. Feed materials and compound feed containing the substances referred to in paragraph 1 which are produced and labelled before 18 December 2021 in accordance with the rules applicable before 18 December 2019 may be placed on the market and used until the existing stocks are exhausted if they are intended for non-food producing animals.

Article 3

Entry into force

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, 26 November 2019.

For the Commission
The President
Jean-Claude JUNCKER

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 *Escherichia coli* FERM BP-10941 or *Escherichia coli* FERM BP-11355 or *Corynebacterium glutamicum* KCCM 11117P or *Corynebacterium glutamicum* NRRL B-50547 or *Corynebacterium glutamicum* NRRL B-50775 or *Corynebacterium glutamicum* KCCM 10227. 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 can 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.'	18.12.2029

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 %			
			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).						
3c321	-	L-lysine monohydrochloride, liquid	*Additive composition:* Aqueous solution of L-lysine monohydrochloride with a minimum of 22 % L-lysine and a maximum moisture content of 66 % (minimum of 58 % L-lysine in the dry matter). *Characterisation of the active substance:* L-lysine monohydrochloride produced by fermentation with *Escherichia coli* FERM BP-10941 or *Escherichia coli* FERM BP-11355. Chemical formula: NH_2-$(CH_2)_4$-CH(NH_2)-COOH CAS Number: 657-27-2 *Analytical methods* [1]*:*	All species	-	-	-	1. The lysine content shall be indicated on the labelling of the additive. 2. L-lysine monohydrochloride, 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 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 and eye protection.	18.12.2029

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 %			
			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 (Annex III, F).					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.'	

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 %			
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 *Escherichia coli* FERM BP-10941 or *Escherichia coli* FERM BP-11355 or *Escherichia coli* CGMCC 3705 or *Escherichia coli* CGMCC 7.57 or *Corynebacterium glutamicum* NRRL B-50547 or *Corynebacterium glutamicum* NRRL B-50775 or *Corynebacterium glutamicum* KCCM 11117P or *Corynebacterium glutamicum* KCCM 10227. 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: — 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 monohydrochloride, technically pure, may be placed on the market and used as an additive consisting of a preparation. 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 by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection. 5. The additive can be also used via water for drinking. 6. 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.'	18.12.2029

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 %			
			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).						
3c324		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* KCCM 10227 or *Corynebacterium glutamicum* DSM 24990. 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.	18.12.2029

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 %			
			— 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-UV) – Commission Regulation (EC) No 152/2009.					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.'	

(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) 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).