# 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)

## 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'.

(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.

*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.

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2019/1964. (See end of Document for details)*

*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

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2019/1964. (See end of Document for details)*

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 | All species | | | | 1. The lysine content shall be indicated on the labelling of the additive.<br>2. L-lysine base, liquid, may be placed on the market and used as an additive consisting of a preparation.<br>3. For users of the additive | 18.12.2029 |

**a** 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

**b** 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).