COMMISSION IMPLEMENTING REGULATION (EU) 2024/777

of 5 March 2024

concerning the authorisation of L-lysine base, liquid, L-lysine monohydrochloride, liquid, and L-lysine monohydrochloride produced by *Escherichia coli* NITE BP-02917 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, an application was submitted for the authorisation of concentrated liquid L-lysine, concentrated liquid L-lysine monohydrochloride and L-lysine monohydrochloride produced by *Escherichia coli* NITE BP-02917. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) The application concerns the authorisation of concentrated liquid L-lysine, concentrated liquid L-lysine monohydrochloride and L-lysine monohydrochloride, produced by *Escherichia coli* NITE BP-02917 as feed additives for all animal species, requesting those additives to be classified in the category 'nutritional additives', functional group 'amino acids, their salts and analogues' and in the category 'sensory additives', functional group 'flavouring compounds'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinions of 27 September 2022 ([2]) and of 11 May 2023 ([3]) that, under the proposed conditions of use, concentrated liquid L-lysine, concentrated liquid L-lysine monohydrochloride and L-lysine monohydrochloride, produced by *Escherichia coli* NITE BP-02917 are safe for the target species, consumers and the environment when used both as amino acids and as flavouring compounds. The Authority expressed concerns on the simultaneous oral administration of these additives as amino acids in feed and in water for drinking. It also concluded that concentrated liquid L-lysine, concentrated liquid L-lysine monohydrochloride and L-lysine monohydrochloride are not considered to have the potential to cause respiratory toxicity, or skin sensitisation. Concentrated liquid L-lysine monohydrochloride and L-lysine monohydrochloride are not considered skin and eye irritants while concentrated liquid L-lysine, due to its high pH may be corrosive for skin and eyes. The Authority further concluded that concentrated liquid L-lysine, concentrated liquid L-lysine monohydrochloride and L-lysine monohydrochloride produced by *Escherichia coli* NITE BP-02917 are an efficacious source of the essential amino acid L-lysine for non-ruminant animal species. For the supplemental L-lysine to be as efficacious in ruminants as in non-ruminant species, it would require protection against degradation in the rumen. The three forms of the additive were also considered efficacious as feed flavouring compounds under the proposed conditions of use. The Authority did not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

([1]) OJ L 268, 18.10.2003, p. 29, ELI: http://data.europa.eu/eli/reg/2003/1831/oj
([2]) *EFSA Journal* 2022;20(10):7612.
([3]) *EFSA Journal* 2023;21(6):8048.

(5) The names ‘concentrated liquid L-lysine’ 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 22,4 % respectively.

(6) In view of the above, the Commission considers that L-lysine base, liquid, L-lysine monohydrochloride, liquid, and L-lysine monohydrochloride, produced by *Escherichia coli* NITE BP-02917 satisfy the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of those additives should be authorised. The Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of L-lysine base, liquid.

(7) The Commission considers that, when the additives are used as amino acids, and in particular in the case of supplementation via water for drinking, it is appropriate to alert the user to take into account the dietary supply with all the essential and conditionally essential amino acids.

(8) The Commission considers that the physical characteristics of the powder of L-lysine monohydrochloride in relation to the particle size distribution and the dusting potential entails a risk of endotoxin exposure for users, therefore, a limitation on the maximum endotoxin exposure should be set up.

(9) The Commission considers that for the use of L-lysine base, liquid, L-lysine monohydrochloride, liquid, and L-lysine monohydrochloride, produced by *Escherichia coli* NITE BP-02917 as flavouring compounds, safety reasons do not require the setting of maximum contents. In order to allow better control, the recommended maximum content should be indicated on the label of the feed additives. Where such contents are exceeded, certain information should be indicated on the label of the premixtures concerned.

(10) 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, belonging to the category ‘nutritional additives’, functional group ‘amino acids, their salts and analogues’ and to the category ‘sensory additives’, functional group ‘flavouring compounds’, 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, 5 March 2024.

For the Commission
The President
Ursula VON DER LEYEN

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/kg of complete feed with a moisture content of 12 %			
Category of nutritional additives. Functional group: amino acids, their salts and analogues.									
3c320i	—	L-Lysine base, liquid	*Additive composition* Aqueous solution of L-lysine with a minimum content of 50 % L-lysine Liquid form *Characterisation of the active substance* L-lysine produced by *Escherichia coli* NITE BP-02917 Chemical formula: NH_2-$(CH_2)_4$-$CH(NH_2)$-COOH CAS number: 56-87-1 *Analytical method* (1) For the quantification of lysine in premixtures and compound feed: — ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS), Commission Regulation (EC) No 152/2009 (2) (Annex III, F) 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	All species	—	—	—	1. The lysine content shall be indicated on the labelling of the additive. 2. The additive may be used via water for drinking. 3. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment and the stability in water for drinking shall be indicated. 4. The label of the additive and premixture shall indicate the following: '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.'	26 March 2034

			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)					5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal skin and eye protective equipment.	

(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) Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed (OJ L 54, 26.2.2009, p. 1; ELI: http://data.europa.eu/eli/reg/2009/152/oj).

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/kg of complete feed with a moisture content of 12 %			
Category of nutritional additives. Functional group: amino acids, their salts and analogues.									
3c321i	—	L-lysine monohydrochloride, liquid	*Additive composition* Aqueous solution of L-lysine monohydrochloride with a minimum content of 22,4 % of L-Lysine and a maximum moisture content of 65 % Liquid form *Characterisation of the active substance* L-lysine monohydrochloride, produced by *Escherichia coli* NITE BP-02917 Chemical formula: NH_2-$(CH_2)_4$-CH(NH_2)-COOH-HCl CAS number: 657–27-2 *Analytical method* (1) For the identification of L-lysine monohydrochloride in the feed additive: — Food Chemical Codex 'L-lysine monohydrochloride monograph'	All animal species	—	—	—	1. The lysine content shall be indicated on the labelling of the additive. 2. The additive may be used via water for drinking. 3. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment and the stability in water for drinking shall be indicated. 4. The label of the additive and premixture shall indicate the following:	26 March 2034

			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 and compound feed: — ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS), 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).					'The supplementation with L-lysine monohydrochloride, in particular via water for drinking, 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://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en

ELI: http://data.europa.eu/eli/reg_impl/2024/777/oj

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/kg of complete feed with a moisture content of 12 %			
Category of nutritional additives. Functional group: amino acids, their salts and analogues.									
3c322v	—	L-lysine monohydrochloride	*Additive composition* Powder of L-lysine monohydrochloride with a minimum content of 78 % of L-Lysine and a maximum moisture content of 1,5 % Solid form *Characterisation of the active substance* L-lysine monohydrochloride, produced by *Escherichia coli* NITE BP-02917 Chemical formula: NH_2-$(CH_2)_4$-$CH(NH_2)$-COOH-HCl CAS number: 657–27-2 *Analytical method* (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	All animal species	—	—	—	1. The lysine content shall be indicated on the labelling of the additive. 2. The additive may be used via water for drinking. 3. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment and the stability in water for drinking shall be indicated. 4. The label of the additive and premixture shall indicate the following: 'The supplementation with L-lysine monohydrochloride, in particular via water for drinking, should take into account all essential and conditional essential amino acids in order to avoid imbalances.'	26 March 2034

			For the quantification of lysine in premixtures and compound feed: — ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS), 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)					5. The endotoxin content of the additive and its dusting potential shall ensure a maximal endotoxin exposure of 1 600 IU endotoxins/m³ air (2).	

(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).

ELI: http://data.europa.eu/eli/reg_impl/2024/777/oj

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/kg of complete feed with a moisture content of 12 %			
Category: sensory additives. Functional group: flavouring compounds									
3c320i	—	L-Lysine base, liquid	*Additive composition* Aqueous solution of L-lysine with a minimum content of 50 % L-lysine Liquid form *Characterisation of the active substance* L-lysine, produced by *Escherichia coli* NITE BP-02917 Chemical formula: NH_2-$(CH_2)_4$-CH(NH_2)-COOH CAS number: 56-87-1 *Analytical method* (1) For the quantification of lysine in premixtures: — ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS), Regulation (EC) No 152/2009 (Annex III, F) 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	All animal species	—	—	—	1. The additive shall be incorporated into the feed in the form of a premixture. 2. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 3. On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 25 mg/kg.' 4. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixture where the use level on the label of the premixture would result in exceeding the content referred to in point 3.	26 March 2034

								5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal skin and eye protective equipment.	

(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

ELI: http://data.europa.eu/eli/reg_impl/2024/777/oj

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/kg of complete feed with a moisture content of 12 %			
Category: sensory additives. Functional group: flavouring compounds									
3c321i	—	L-lysine monohydrochloride, liquid	*Additive composition* Aqueous solution of L-lysine monohydrochloride with a minimum content of 22,4 % of L-Lysine and a maximum moisture content of 65 % Liquid form *Characterisation of the active substance* L-lysine monohydrochloride, produced by *Escherichia coli* NITE BP-02917 Chemical formula: NH_2-$(CH_2)_4$-CH(NH_2)-COOH-HCl CAS number: 657–27-2 *Analytical method* (1) For the identification of L-lysine monohydrochloride in the feed additive: — Food Chemical Codex 'L-lysine monohydrochloride monograph'	All animal species	—	—	—	1. The additive shall be incorporated into the feed in the form of a premixture. 2. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 3. On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 25 mg/kg.'	26 March 2034

			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: — ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS), Regulation (EC) No 152/2009 (Annex III, F)					4. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixture where the use level on the label of the premixture would result in exceeding the content referred to in point 3.	

(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

ELI: http://data.europa.eu/eli/reg_impl/2024/777/oj

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/kg of complete feed with a moisture content of 12 %			
Category: sensory additives. Functional group: flavouring compounds									
3c322v	—	L-lysine monohydrochloride	*Additive composition* Powder of L-lysine monohydrochloride with a minimum content of 78 % of L-Lysine and a maximum moisture content of 1,5 % Solid form *Characterisation of the active substance* L-lysine monohydrochloride, produced by *Escherichia coli* NITE BP-02917 Chemical formula: NH_2-$(CH_2)_4$-CH(NH_2)-COOH-HCl CAS number: 657–27-2 *Analytical method* (1) For the identification of L-lysine monohydrochloride in the feed additive: — Food Chemical Codex 'L-lysine monohydrochloride monograph'	All animal species	—	—	—	1. The additive shall be incorporated into the feed in the form of a premixture. 2. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 3. On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 25 mg/kg.'	26 March 2034

			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: — ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS), Regulation (EC) No 152/2009 (Annex III, F)					4. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixture where the use level on the label of the premixture would result in exceeding the content referred to in point 3. 5. The endotoxin content of the additive and its dusting potential shall ensure a maximal endotoxin exposure of 1 600 IU endotoxins/m³ air (²).	

(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).

ELI: http://data.europa.eu/eli/reg_impl/2024/777/oj