



2025/1395

16.7.2025

COMMISSION IMPLEMENTING REGULATION (EU) 2025/1395

of 15 July 2025

**correcting and amending Implementing Regulation (EU) 2020/997 as regards the terms of the
authorisation of L-lysine base, liquid, as a feed additive 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) and Article 13(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 and modifying such authorisation.
- (2) L-lysine base, liquid was authorised for 10 years as a feed additive for all animal species by Commission Implementing Regulation (EU) 2020/997 ⁽²⁾.
- (3) In accordance with Article 13(1) of Regulation (EC) No 1831/2003, the Commission requested the European Food Safety Authority ('the Authority') to issue an opinion on whether the authorisation of L-lysine base, liquid, as a feed additive would still meet the conditions laid down in Article 5 of Regulation (EC) No 1831/2003 if the terms of that authorisation were modified. The modification consists of the addition of a new production strain, *Corynebacterium glutamicum* NRRL B-68248. Unlike provided for in the current authorisation, the additive produced with that new production strain is not intended to be used in water for drinking. The request was accompanied by the relevant supporting data.
- (4) The Authority concluded in its opinion of 4 July 2024 ⁽³⁾ that the genetic modification in the production strain *Corynebacterium glutamicum* NRRL B-68248 raises no safety concerns. No viable cells or DNA of the production strain were detected in the final product. Therefore, the final product does not pose any safety concern in regard to the production strain. L-Lysine base produced with *Corynebacterium glutamicum* NRRL B-68248 does not represent a risk for the target species, consumers or the environment. The Authority considered the additive to be neither irritant to skin or the eyes, nor a dermal sensitiser. L-Lysine base, liquid, produced with *Corynebacterium glutamicum* NRRL B-68248 is considered to be 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 Authority did not consider that there is a need for specific requirements of post-market monitoring.
- (5) In view of the above, the Commission considers that L-lysine base, liquid, still meets the conditions provided for in Article 5 of Regulation (EC) No 1831/2003 when modifying the terms of the authorisation with the addition of the new production strain *Corynebacterium glutamicum* NRRL B-68248. In addition, it is not necessary to provide for protective measures to prevent adverse effects on the health of the users of the additive produced with *Corynebacterium glutamicum* NRRL B-68248, taking account of the Authority's opinion of 4 July 2024.
- (6) In order to allow better control, a new identification number should be granted to L-lysine base, liquid, produced with *Corynebacterium glutamicum* NRRL B-68248, as it is not authorised to be used in water for drinking, unlike provided for in the current authorisation of the additive.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29, ELI: <http://data.europa.eu/eli/reg/2003/1831/oj>.

⁽²⁾ 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 (OJ L 221, 10.7.2020, p. 90), ELI: http://data.europa.eu/eli/reg_impl/2020/997/oj.

⁽³⁾ EFSA Journal, 22(7), e8950. <https://doi.org/10.2903/j.efsa.2024.8950>.

- (7) The additive L-lysine base, liquid, consists of a preparation in the form of an aqueous solution containing a minimum of 50 % L-lysine as active substance. The authorisation of the additive should therefore explicitly specify that it concerns a preparation. In this regard, Implementing Regulation (EU) 2020/997 provides that L-lysine base, liquid, is allowed to be placed on the market and used as an additive consisting of a preparation, but this has erroneously not been properly reflected in the terms of the authorisation, in particular regarding the additive composition. Implementing Regulation (EU) 2020/997 should therefore be corrected accordingly.
- (8) In order to preserve the legitimate expectations of the feed business operators created by the erroneous lack of description of the additive L-lysine base, liquid, as a preparation, a transitional period should be provided to allow those operators to adapt to the correction introduced by this Regulation.
- (9) The analytical method laid down in Implementing Regulation (EU) 2020/997 concerning the quantification of L-lysine, base, liquid, in premixtures, compound feed and feed materials refers to the provisions of an annex to Commission Regulation (EC) No 152/2009 ⁽⁴⁾. However, as a result of amendments brought to Regulation (EC) No 152/2009, reference to such specific provisions is no longer appropriate. Taking into account that Regulation (EC) No 152/2009 may still be the subject of future amendments based on scientific and technological developments, the relevant analytical method should only refer to Regulation (EC) No 152/2009 as a whole. For the same reason, the reference to Regulation (EC) No 152/2009 should be adapted similarly as regards the analytical method for the additive L-lysine monohydrochloride, technically pure and the additive L-lysine sulphate, which are also included in the Annex to Implementing Regulation (EU) 2020/997.
- (10) Implementing Regulation (EU) 2020/997 should therefore be amended accordingly.
- (11) 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

Correction and amendment to Implementing Regulation (EU) 2020/997

The Annex to Implementing Regulation (EU) 2020/997 is replaced by the Annex to this Regulation.

Article 2

Transitional measures

1. The feed additive L-lysine base, liquid, with identification number 3c320, produced with *Corynebacterium glutamicum* NRRL B-67439 or with *Corynebacterium glutamicum* NRRL B-67535, as authorised by Implementing Regulation (EU) 2020/997, and premixtures containing this additive, which is produced and labelled before 5 February 2026 in accordance with the rules applicable before 5 August 2025 may continue to be placed on the market and used until the stocks concerned are exhausted.
2. Compound feed and feed materials containing the feed additive referred to in paragraph 1, which are produced and labelled before 5 August 2026 in accordance with the rules applicable before 5 August 2025 may continue to be placed on the market and used until the stocks concerned are exhausted if they are intended for food-producing animals.
3. Compound feed and feed materials containing the feed additive referred to in paragraph 1, which are produced and labelled before 5 August 2027 in accordance with the rules applicable before 5 August 2025 may continue to be placed on the market and used until the stocks concerned are exhausted if they are intended for non-food-producing animals.

⁽⁴⁾ 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>).

*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, 15 July 2025.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the feed additive	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 12 % moisture content			
Category: nutritional additives. Functional group: amino acids, their salts and analogues								
3c320	L-Lysine base, liquid	<i>Additive composition:</i> Preparation of L-lysine with a minimum content of 50 % L-lysine – Aqueous solution <i>Characterisation of the active substance:</i> L-lysine produced by fermentation with <i>Corynebacterium glutamicum</i> NRRL B-67439 or <i>Corynebacterium glutamicum</i> NRRL B-67535 Chemical formula: NH₂-(CH₂)₄-CH(NH₂)-COOH CAS number: 56-87-1 <i>Analytical methods (1):</i> 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. 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. 3. The additive may be also used via water for drinking.	30.7.2030

Identification number of the feed additive	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 12 % moisture content			
Category: nutritional additives. Functional group: amino acids, their salts and analogues								
		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 For the quantification of lysine in water: — ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD)					4. 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.’	
3c320ii	L-Lysine base, liquid	<i>Additive composition:</i> Preparation of L-lysine with a minimum content of 50 % L-lysine – Aqueous solution _____ <i>Characterisation of the active substance:</i> L-lysine produced by fermentation with <i>Corynebacterium glutamicum</i> NRRL B-68248 Chemical formula: NH₂-(CH₂)₄-CH(NH₂)-COOH CAS number: 56-87-1 _____	All species	-	-	-	1. The lysine content shall be indicated on the labelling of the additive.	30.7.2030
							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.’	

Identification number of the feed additive	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 12 % moisture content			
Category: nutritional additives. Functional group: amino acids, their salts and analogues								
		<i>Analytical methods ⁽¹⁾:</i> 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						
3c322	L-lysine monohydrochloride, technically pure	<i>Additive composition:</i> Powder of L-lysine monohydrochloride with a minimum of 78 % L-lysine and a maximum moisture content of 1,5 %. ————— <i>Characterisation of the active substance:</i> L-lysine monohydrochloride produced by fermentation with	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.	30.7.2030

Identification number of the feed additive	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 12 % moisture content			
Category: nutritional additives. Functional group: amino acids, their salts and analogues								
		<i>Corynebacterium glutamicum</i> NRRL-B-67439 or <i>Corynebacterium glutamicum</i> NRRL B-67535 or <i>Corynebacterium glutamicum</i> CGMCC 7.266. Chemical formula: NH₂-(CH₂)₄-CH(NH₂)-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.					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. 4. The additive may be also used via water for drinking.	

Identification number of the feed additive	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 12 % moisture content			
Category: nutritional additives. Functional group: amino acids, their salts and analogues								
		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 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).					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	<i>Additive composition:</i> Granulate with a minimum L-lysine content of 52 % and a maximum content of 24 % sulphate. ————— <i>Characterisation of the active substance:</i> L-lysine sulphate produced by fermentation with <i>Corynebacterium glutamicum</i> CGMCC 7.266	All species	-	-	10 000	1. The 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.	30.7.2030

Identification number of the feed additive	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 12 % moisture content			
Category: nutritional additives. Functional group: amino acids, their salts and analogues								
		Chemical formula: C₁₂H₂₈N₄O₄•H₂SO₄/[NH₂-(CH₂)₄-CH(NH₂)-COOH]₂SO₄ CAS number: 60343-69-3 <i>Analytical methods</i> ⁽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 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 For the quantification of lysine in water: — ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD)					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. 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.’	

⁽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.