



2025/2566

19.12.2025

COMMISSION IMPLEMENTING REGULATION (EU) 2025/2566

of 18 December 2025

concerning the authorisation of L-lysine sulphate and L-lysine monohydrochloride produced with *Corynebacterium glutamicum* CGMCC 7.453 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, two applications were submitted for the authorisation of L-lysine sulphate and L-lysine monohydrochloride produced with *Corynebacterium glutamicum* CGMCC 7.453 respectively. Those applications were accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) The applications concern the authorisation of L-lysine sulphate and L-lysine monohydrochloride produced with *Corynebacterium glutamicum* CGMCC 7.453 as feed additives for use in feed and in water for drinking for all animal species, requesting those additives to be classified in the category 'nutritional additives' and in the functional group 'amino acids, their salts and analogues'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinions of 18 March 2025 ⁽²⁾ that L-lysine sulphate and L-lysine monohydrochloride produced with *Corynebacterium glutamicum* CGMCC 7.453 are safe for the target species when administered via feed. The use of lysine 'per se' will not raise safety concerns for the target animals provided it is supplemented in appropriate amounts to the diets. The Authority has concerns on the use of L-lysine sulphate and L-lysine monohydrochloride in water for drinking. With regard to the high intrinsic content of sulphate in L-lysine sulphate, the Authority considers that, when using the additive, the formulation of the complete feed should carefully take into account the maximum tolerable level of total sulphur. The contribution of sulphur/sulphate present in water for drinking to the total sulphur intake should also be considered. The Authority concluded that the use of L-lysine sulphate and L-lysine monohydrochloride produced with *Corynebacterium glutamicum* CGMCC 7.453 in animal nutrition is safe for the consumers and for the environment. It also concluded that the additives should be considered as irritants to skin, eyes and the respiratory tract. The Authority further concluded that the substances are regarded as an efficacious source of the essential amino acid L-lysine for non-ruminant animal species and that 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. It also verified the report 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, ELI: <http://data.europa.eu/eli/reg/2003/1831/oj>.

⁽²⁾ EFSA Journal, 23(4), e9343. <https://doi.org/10.2903/j.efsa.2025.9343>.
EFSA Journal, 23(4), e9345. <https://doi.org/10.2903/j.efsa.2025.9345>.

- (5) In view of the above, the Commission considers that L-lysine sulphate and L-lysine monohydrochloride produced with *Corynebacterium glutamicum* CGMCC 7.453 satisfy the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of those substances as feed additives should be authorised. The Commission considers that the safe use of these amino acids in water for drinking, with regard to possible hygiene risks, is to be considered within the scope of Regulation (EC) No 1831/2003 of the European Parliament and of the Council⁽³⁾ laying down requirements for feed hygiene. It is appropriate to alert the user to take into account the dietary supply with all the essential and conditionally essential amino acids, in particular in the case of supplementation with L-lysine sulphate and L-lysine monohydrochloride via water for drinking. When fed to ruminants, L-lysine sulphate and L-lysine monohydrochloride produced with *Corynebacterium glutamicum* CGMCC 7.453 need to be protected against degradation in the rumen. Also, the Commission considers that a maximum level should be set up for L-lysine sulphate due to the potential adverse effects from the intrinsic high sulphate content in the additive. The level of 10 000 mg/kg of complete feed was regarded as safe according to the Authority's opinion of 16 June 2015⁽⁴⁾ issued for another L-lysine sulphate. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive.
- (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

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 additives in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

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, 18 December 2025.

For the Commission
The President
Ursula VON DER LEYEN

⁽³⁾ Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 12 January 2003 laying down requirements for feed hygiene (OJ L 35, 8.2.2003, p. 1, ELI: <https://data.europa.eu/eli/reg/2003/183/oj>).

⁽⁴⁾ EFSA Journal 2015; 13(7):4155. <https://doi.org/10.2903/j.efsa.2015.4155>.

ANNEX

Identification number of the feed additive	Name of the 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: nutritional additives. Functional group: amino acids, their salts and analogues								
3c330	L-lysine sulphate	<i>Additive composition</i> L-lysine sulphate with a minimum L-lysine content of 55 % and a maximum content of 21 % sulphate Solid form _____ <i>Characterisation of the active substance</i> L-lysine sulphate produced with <i>Corynebacterium glutamicum</i> CGMCC 7.453 Chemical formula: C ₁₂ H ₂₈ N ₄ O ₄ ·O ₄ S CAS number: 60343-69-3 _____ <i>Analytical methods ⁽¹⁾</i> For the identification of sulphate in the feed additive (L-lysine sulphate): — European Pharmacopoeia monograph 20301 For the determination of lysine in the feed additive: — Ion-exchange chromatography coupled to post-column derivatisation and optical detection (IEC-VIS/FLD), EN ISO 17180	All species	-	-	10 000	1. In the directions for use of the additive and premixtures, the storage conditions, the stability to heat treatment and the stability in water for drinking shall be indicated. 2. The additive may be used in water for drinking. 3. Feed business operators shall ensure that L-lysine sulphate is rumen protected, when fed to ruminants. 4. The moisture content shall be indicated on the labelling of the additive. 5. The label of the additive and premixtures shall indicate the following: 'The supplementation with L-lysine sulphate, in particular via water for drinking, shall take into account all essential and conditionally essential amino acids in order to avoid nutritional imbalances.'	8 January 2036

Identification number of the feed additive	Name of the 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 determination of lysine in premixtures: — Ion-exchange chromatography coupled to post-column derivatisation and optical detection (IEC-VIS/FLD), EN ISO 17180 or — Ion-exchange chromatography coupled to post-column derivatisation and optical detection (IEC-VIS), Commission Regulation (EC) 152/2009 ⁽²⁾ For the determination of lysine in compound feed: — Ion-exchange chromatography coupled to post-column derivatisation and optical detection (IEC-VIS), Regulation (EC) 152/2009 For the determination of lysine in water for drinking: — Ion-exchange chromatography coupled to post-column derivatisation and optical detection (IEC-VIS)					6. 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 skin, eyes and breathing protection.	

(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>).

⁽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 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 additive/kg of complete feed with a moisture content of 12 %			
Category: nutritional additives. Functional group: amino acids, their salts and analogues								
3c331	L-lysine monohydrochloride	<i>Additive composition</i> L-lysine monohydrochloride with a minimum content of 78 % of L-Lysine on a dry matter basis Solid form <i>Characterisation of the active substance</i> L-lysine monohydrochloride produced with <i>Corynebacterium glutamicum</i> CGMCC 7.453 Chemical formula: C₆H₁₄ N₂O₂ CAS number: 657-27-2 <i>Analytical methods</i> ⁽¹⁾ For the identification of L-lysine monohydrochloride in the feed additive: — Food Chemical Codex ‘L-lysine monohydrochloride monograph’ For the determination of lysine in the feed additive: — Ion-exchange chromatography coupled to post-column derivatisation and optical detection (IEC-VIS/FLD), EN ISO 17180	All species	-	-	-	1. In the directions for use of the additive and premixtures, the storage conditions, the stability to heat treatment and the stability in water for drinking shall be indicated. 2. The additive may be used via water for drinking. 3. Feed business operators shall ensure that L-lysine monohydrochloride is rumen protected, when fed to ruminants. 4. The moisture content shall be indicated on the label of the additive. 5. The label of the additive and premixtures shall indicate the following: ‘The supplementation with L-lysine monohydrochloride, in particular via water for drinking, shall take into account all essential and conditionally essential amino acids in order to avoid nutritional imbalances.’	8 January 2036

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 additive/kg of complete feed with a moisture content of 12 %			
		For the determination of lysine in premixtures: — Ion-exchange chromatography coupled to post-column derivatisation and optical detection (IEC-VIS/FLD), EN ISO 17180 or — Ion-exchange chromatography coupled to post-column derivatisation and optical detection (IEC-VIS), Commission Regulation (EC) No 152/2009 For the determination of lysine in compound feed: — Ion-exchange chromatography coupled to post-column derivatisation and optical detection (IEC-VIS), Commission Regulation (EC) No 152/2009 For the determination of lysine in water for drinking: — Ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS)					6. 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 skin, eyes and breathing protection.	

(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