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COMMISSION

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**COMMISSION IMPLEMENTING REGULATION (EU) .../...**

**of **XXX****

**concerning the authorisation of L-lysine produced with *Corynebacterium glutamicum*  
NRRL B-68248 as a feed additive for all animal species**

(Text with EEA relevance)

# COMMISSION IMPLEMENTING REGULATION (EU) .../...

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**concerning the authorisation of L-lysine produced with *Corynebacterium glutamicum* NRRL B-68248 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<sup>1</sup>, 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) An application was submitted for the modification of the terms of an authorisation of L-lysine base, liquid, which was authorised as an additive in animal nutrition by Commission Implementing Regulation (EU) 2020/997<sup>2</sup>. That modification concerned the inclusion of *Corynebacterium glutamicum* NRRL B-68248 as a production strain. The application was accompanied by the relevant data supporting the request for the modification.
- (3) However, the Commission considers that this application actually concerns a new additive, which is produced with a new production strain.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 4 July 2024<sup>3</sup> 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 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. The

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

<sup>2</sup> 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](http://data.europa.eu/eli/reg_impl/2020/997/oj).

<sup>3</sup> EFSA Journal, 22(7), e8950.

Authority 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.

- (5) In view of the above, the Commission considers that L-lysine produced with *Corynebacterium glutamicum* NRRL B-68248 satisfies the conditions, as provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that substance as a feed additive should be authorised. 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-threonine via water for drinking. 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 substance specified in the Annex, belonging to the additive category ‘nutritional additives’ and to the functional group ‘amino acids, their salts and analogues’, is authorised as an additive 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,

*For the Commission*  
*The President*  
*Ursula VON DER LEYEN*