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

of **XXX**

**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)

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

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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 nutrition¹, 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) 2020/997².
- (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 2024³ 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

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>.

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.
- (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 152/2009⁴. 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 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,

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>.

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 [6 months from the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication] in accordance with the rules applicable before [the date of entry into force of this Regulation - Date to be inserted by the Service responsible for the publication] 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 is produced and labelled before [12 months from the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication] in accordance with the rules applicable before [the date of entry into force of this Regulation - Date to be inserted by the Service responsible for the publication] 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 is produced and labelled before [24 months from the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication] in accordance with the rules applicable before [the date of entry into force of this Regulation - Date to be inserted by the Service responsible for the publication] 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.

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,

For the Commission

The President

Ursula VON DER LEYEN