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

of **XXX**

**concerning the authorisation of L-arginine produced with *Corynebacterium glutamicum*
KCCM 80387 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-arginine produced with *Corynebacterium glutamicum* KCCM 80387 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) 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 L-arginine produced with *Corynebacterium glutamicum* KCCM 80387. 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 L-arginine produced with *Corynebacterium glutamicum* KCCM 80387 as a feed additive for all animal species, requesting that additive 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'. The applicant requested the additives to be authorised for use also in water for drinking. However, Regulation (EC) No 1831/2003 does not allow the authorisation of 'flavouring compounds' for use in water for drinking. Therefore, the applicant withdrew the application for water for drinking for the functional group 'flavouring compounds'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 28 January 2025² that, under the proposed conditions of use, L-arginine produced with *Corynebacterium glutamicum* KCCM 80387 does not pose any safety concerns regarding the production strain and that the additive is safe for the target species, the consumers and the environment. The Authority has concerns on the use of L-arginine in water for drinking. It also concluded that L-arginine produced with *Corynebacterium glutamicum* KCCM 80387 is not irritant to skin, and not a dermal sensitiser but is irritant to the eyes and respiratory tract. The Authority further concluded that the substance is regarded as an efficacious source of the amino acid L-arginine for all non-ruminant species, but for the substance to be fully efficacious in ruminants, it should be protected from ruminal degradation and that it is considered

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

² EFSA Journal, 23(2), e9258. <https://doi.org/10.2903/j.efsa.2025.9258>.

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efficacious when used as a flavouring compound in animal nutrition. The Authority did not consider that there is a need for specific requirements of post-market monitoring. The 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-arginine produced with *Corynebacterium glutamicum* KCCM 80387 satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that substance as a feed additive should be authorised. When fed to ruminants for the use under the functional group ‘amino acids, their salts and analogues’, L-arginine produced with *Corynebacterium glutamicum* KCCM 80387 needs protection against degradation in the rumen. 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-arginine 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 Commission considers that for the use of L-arginine produced with *Corynebacterium glutamicum* KCCM 80387 as flavouring compounds, safety reasons do not require the setting of maximum contents. In order to allow for 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.
- (7) 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 category ‘nutritional additives’, functional group ‘amino acids, their salts and analogues’ and to the category ‘sensory additives’, functional group ‘flavouring compounds’, 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