EUROPEAN
COMMISSION

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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the authorisation of L-arginine produced with *Corynebacterium glutamicum* KCCM 80393 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 80393 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) 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 80393. 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 80393 as a feed additive for use in feed and in water for drinking for all animal species, requesting that additive to be classified in the additive 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 opinion of 18 March 2025[2] that L-arginine produced with *Corynebacterium glutamicum* KCCM 80393 is safe for the target species when supplemented in appropriate amounts to the diet according to their nutritional needs. However, due to the risk of nutritional imbalances and hygienic reasons, the Authority has concerns on the of use l-arginine in water for drinking. The Authority concluded that the use of L-arginine produced with *Corynebacterium glutamicum* KCCM 80393 in animal nutrition is safe for the consumers and the environment. In the absence of data, it could not conclude on the potential of the substance to be an irritant to skin and/or eyes, or to be a dermal or respiratory sensitiser. The Authority further concluded that the substance is regarded as an efficacious source of the amino acid L-arginine for non-ruminant nutrition. For the supplemental L-arginine to be as efficacious in ruminants as in non-ruminant species, it requires protection against degradation in the rumen. The Authority did not consider that there is a need for specific requirements of post-market monitoring. It

[1] OJ L 268, 18.10.2003, p. 29, ELI: http://data.europa.eu/eli/reg/2003/1831/oj.
[2] EFSA Journal, 23(5), e9453. https:// doi.org/10.2903/j.efsa.2025.9453.

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 80393 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. The Commission considers that the safe use of this amino acid in water for drinking, with regard to possible hygiene risks, is to be considered within the scope of Regulation (EC) No 183/2005 laying down requirements for feed hygiene[3]. When fed to ruminants, L-arginine produced with *Corynebacterium glutamicum* KCCM 80393 should be protected 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 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

[3] Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene, OJ L 35, 8.2.2005, p. 1, ELI: https://eur-lex.europa.eu/eli/reg/2005/183/oj.