EUROPEAN
COMMISSION

Brussels, XXX
SANTE/13933245/2025 CIS
(POOL/G5/2025/13933245/13933245-EN CIS.docx)
[…](2026) XXX draft

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the authorisation of L-valine produced from *Corynebacterium glutamicum* KCCM 80366, in the form of an inactivated fermentation product, as a feed additive for all animal species

(Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the authorisation of L-valine produced from *Corynebacterium glutamicum* KCCM 80366, in the form of an inactivated fermentation product, 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-valine produced from *Corynebacterium glutamicum* KCCM 80366, in the form of an inactivated fermentation product. 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-valine produced from *Corynebacterium glutamicum* KCCM 80366, in the form of an inactivated fermentation product, as a feed additive 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 November 2025[2] that L-valine produced using *Corynebacterium glutamicum* KCCM 80366 is safe for all animal species when supplemented in appropriate amounts to the diet according to their nutritional needs. The Authority also concluded that the use of L-valine produced using *Corynebacterium glutamicum* KCCM 80366 in animal nutrition is safe for the consumers and the environment. It further concluded that the additive should not be considered a skin irritant but should be considered a skin and respiratory sensitiser. It could not make any conclusions regarding the eye irritancy potential of the additive. The Authority further concluded that the substance is regarded as an efficacious source of the essential amino acid L-valine for all animal species but, in order to be as efficacious in ruminants as in non-ruminants, it should be protected from ruminal degradation. The Authority did not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on

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

[2] *EFSA Journal*, *23*(12), e9782. https://doi.org/10.2903/j.efsa.2025.9782.

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-valine produced from *Corynebacterium glutamicum* KCCM 80366, in the form of an inactivated fermentation product, 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, L-valine produced from *Corynebacterium glutamicum* KCCM 80366, in the form of an inactivated fermentation product, 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 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