



EUROPEAN
COMMISSION

Brussels, **XXX**
SANTE/8493684/2025 CIS
(POOL/G5/2025/8493684/8493684-EN
CIS.docx)
[...](2025) **XXX** draft

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

of **XXX**

concerning the authorisation of L-histidine and L-histidine monohydrochloride monohydrate, produced with *Corynebacterium glutamicum* KCCM 80389, as feed additives for all animal species

(Text with EEA relevance)

EN

EN

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

of XXX

concerning the authorisation of L-histidine and L-histidine monohydrochloride monohydrate, produced with *Corynebacterium glutamicum* KCCM 80389, as feed additives 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-histidine and L-histidine monohydrochloride monohydrate, produced with *Corynebacterium glutamicum* KCCM 80389. 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-histidine and L-histidine monohydrochloride monohydrate, produced with *Corynebacterium glutamicum* KCCM 80389, as feed additives for all animal species, requesting those additives 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 as regards the functional group 'flavouring compounds'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 24 June 2025² that, under the proposed conditions of use, L-histidine and L-histidine monohydrochloride monohydrate, produced by fermentation with *Corynebacterium glutamicum* KCCM 80389, in feed are safe for the target species when supplemented in appropriate amounts to the diet according to the nutritional needs of the target species. However, due to the risk of nutritional imbalances and hygienic reasons, the Authority has concerns on the use of L-histidine and L-histidine monohydrochloride monohydrate in water for drinking. The Authority concluded that the use of L-

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

² EFSA Journal, 23(7), e9535. <https://doi.org/10.2903/j.efsa.2025.9535>.

histidine and L-histidine monohydrochloride monohydrate, produced with *Corynebacterium glutamicum* KCCM 80389, in animal nutrition is safe for the consumers and the environment. It also concluded that L-histidine and L-histidine monohydrochloride monohydrate, produced with *Corynebacterium glutamicum* KCCM 80389, are not irritant to skin or eyes and are not skin sensitizers. The Authority further concluded that the substances are regarded as an efficacious source of the amino acid L-histidine for all non-ruminant species, but for the substances to be fully efficacious in ruminants they should be protected from ruminal degradation, and that they are considered 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 additives 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-histidine and L-histidine monohydrochloride monohydrate, produced with *Corynebacterium glutamicum* KCCM 80389, satisfy the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of those substances as feed additives should be authorised. The Commission considers that the safe use of those additives in water for drinking, with regard to possible hygiene risks, is to be considered within the scope of Regulation (EC) No 183/2005 of the European Parliament and of the Council³ laying down requirements for feed hygiene. When fed to ruminants for the use under the functional group 'amino acids, their salts and analogues', L-histidine and L-histidine monohydrochloride monohydrate, produced with *Corynebacterium glutamicum* KCCM 80389, need protection against degradation in the rumen. It is also 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-histidine and L-histidine monohydrochloride monohydrate 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-histidine and L-histidine monohydrochloride monohydrate, produced with *Corynebacterium glutamicum* KCCM 80389, 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 the recommended maximum 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 substances specified in the Annex, belonging to the category 'nutritional additives' and functional group 'amino acids, their salts and analogues', and to the category 'sensory

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>.

additives' and functional group 'flavouring compounds', are authorised as additives 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