



2026/353

19.2.2026

COMMISSION IMPLEMENTING REGULATION (EU) 2026/353

of 18 February 2026

**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 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-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 2025 ⁽²⁾ 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-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 sensitisers. 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.

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

⁽²⁾ EFSA Journal 2025, 23(7), e9535, <https://doi.org/10.2903/j.efsa.2025.9535>.

- (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 1831/2003 of the European Parliament and of the Council⁽³⁾ 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.
- (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 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, 18 February 2026.

For the Commission
The President
Ursula VON DER LEYEN

⁽³⁾ Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 12 January 2003 laying down requirements for feed hygiene (OJ L 35, 8.2.2003, p. 1, ELI: <http://data.europa.eu/eli/reg/2003/183/oj>).

ANNEX

Identification number of the additive	Name of the additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					mg/kg of complete feed with 12 % moisture content			
Category: nutritional additives. Functional group: amino acids, their salts and analogues								
3c353	L-histidine	<i>Additive composition</i> L-histidine Solid form <i>Characterisation of the active substance</i> L-histidine ≥ 90 % (on a dry matter basis) produced with <i>Corynebacterium glutamicum</i> KCCM 80389 Histamine ≤ 100 ppm IUPAC name: (2S)-2-amino-3-(1H-imidazol-5-yl) propanoic acid Chemical formula: C ₆ H ₉ N ₃ O ₂ CAS number: 71-00-1 <i>Analytical method</i> ⁽¹⁾ For the determination of histidine in the feed additive: — Ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS or IEC-VIS/FLD), or — High performance liquid chromatography coupled with spectrophotometric detection (HPLC-UV)	All animal species	—	—	—	1. In the directions for use of the additive and premixtures, the storage conditions, the stability to heat treatment and in water for drinking shall be indicated. 2. The additive may be used via water for drinking. 3. Feed business operators shall ensure that L-histidine is rumen protected, when fed to ruminants. 4. The moisture content shall be indicated on the label of the additive. 5. The label of the additive and premixtures shall indicate the following: ‘The supplementation with L-histidine, in particular via water for drinking, shall take into account all essential and conditionally essential amino acids in order to avoid nutritional imbalances.’	11 March 2036

Identification number of the additive	Name of the additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					mg/kg of complete feed with 12 % moisture content			
		For the determination of histidine in premixtures and compound feed: — Ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS) – Commission Regulation (EC) No 152/2009 ⁽²⁾ For the determination of histidine in water for drinking: — Ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS) For the determination of histamine in the feed additive: — High performance liquid chromatography coupled with spectrophotometric detection (HPLC-UV)						
3c354	L-histidine monohydrochloride monohydrate	<i>Additive composition</i> L-histidine monohydrochloride monohydrate Solid form <i>Characterisation of the active substance</i> L-histidine monohydrochloride monohydrate ≥ 98 % with a minimum content of 72 % histidine (on a dry matter basis), produced with <i>Corynebacterium glutamicum</i> KCCM 80389 Histamine ≤ 100 ppm	All animal species	—	—	—	1. In the directions for use of the additive and premixtures, the storage conditions, the stability to heat treatment and in water for drinking shall be indicated. 2. The additive may be used via water for drinking. 3. Feed business operators shall ensure that L-histidine monohydrochloride monohydrate is rumen protected, when fed to ruminants.	11 March 2036

Identification number of the additive	Name of the additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					mg/kg of complete feed with 12 % moisture content			
		IUPAC name: (2S)-2-amino-3-(1H-imidazol-5-yl) propanoic acid hydrate hydrochloride Chemical formula: $C_6H_9N_3O_2 \cdot HCl \cdot H_2O$ CAS number: 5934-29-2 <i>Analytical method ⁽¹⁾</i> For the determination of histidine in the feed additive: — Ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS or IEC-VIS/FLD), or — High performance liquid chromatography coupled with spectrophotometric detection (HPLC-UV) For the determination of histidine in premixtures and compound feed: — Ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS) – Regulation (EC) No 152/2009 For the determination of histidine in water for drinking: — Ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS)					4. The moisture content shall be indicated on the label of the additive. 5. The label of the additive and premixtures shall indicate the following: 'The supplementation with L-histidine monohydrochloride monohydrate, in particular via water for drinking, shall take into account all essential and conditionally essential amino acids in order to avoid nutritional imbalances.'	

Identification number of the additive	Name of the additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					mg/kg of complete feed with 12 % moisture content			
		For the determination of histamine in the feed additive: — High performance liquid chromatography coupled with spectrophotometric detection (HPLC-UV)						

Category: Sensory additives. Functional group: Flavouring compounds

3c353	L-histidine	<i>Additive composition</i> L-histidine Solid form <i>Characterisation of the active substance</i> L-histidine ≥ 90 % (on a dry matter basis) produced with <i>Corynebacterium glutamicum</i> KCCM 80389 Histamine ≤ 100 ppm IUPAC name: (2S)-2-amino-3-(1H-imidazol-5-yl) propanoic acid Chemical formula: C₆H₉N₃O₂ CAS number: 71-00-1 <i>Analytical method ⁽¹⁾</i> For the determination of histidine in the feed additive: — Ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS or IEC-VIS/FLD) or — High performance liquid chromatography coupled with spectrophotometric detection (HPLC-UV)	All animal species	—	—	—	- The additive shall be incorporated into the feed in the form of a premixture. - In the directions for use of the additive and premixtures, the storage conditions and the stability to heat treatment shall be indicated. - On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance in complete feedingstuff with a moisture content of 12 %: 25 mg/kg.' - The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixture where the use level on the label of the premixture would result in exceeding the content referred to in point 3.	11 March 2036
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Identification number of the additive	Name of the additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					mg/kg of complete feed with 12 % moisture content			
		For the determination of histidine in premixtures: — Ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS) – Regulation (EC) No 152/2009 For the determination of histamine in the feed additive: — High performance liquid chromatography coupled with spectrophotometric detection (HPLC-UV)					5. The moisture content shall be indicated on the label of the additive.	
3c354	L-histidine monohydrochloride monohydrate	<i>Additive composition</i> L-histidine monohydrochloride monohydrate Solid form <i>Characterisation of the active substance</i> L-histidine monohydrochloride monohydrate ≥ 98 % with a minimum content of 72 % histidine (on a dry matter basis), produced with <i>Corynebacterium glutamicum</i> KCCM 80389 Histamine ≤ 100 ppm IUPAC name: (2S)-2-amino-3-(1H-imidazol-5-yl) propanoic acid hydrate hydrochloride Chemical formula: C ₆ H ₉ N ₃ O ₂ ·HCl·H ₂ O CAS number: 5934-29-2	All animal species	—	—	—	1. The additive shall be incorporated into the feed in the form of a premixture. 2. In the directions for use of the additive and premixtures, the storage conditions and the stability to heat treatment shall be indicated. 3. On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance in complete feedingstuff with a moisture content of 12 %: 25 mg/kg.'	11 March 2036

Identification number of the additive	Name of the additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					mg/kg of complete feed with 12 % moisture content			
		<i>Analytical method ⁽¹⁾</i> For the determination of histidine in the feed additive: — Ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS or IEC-VIS/FLD), or — High performance liquid chromatography coupled with spectrophotometric detection (HPLC-UV) For the determination of histidine in premixtures: — Ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS) – Regulation (EC) No 152/2009 For the determination of histamine in the feed additive: — High performance liquid chromatography coupled with spectrophotometric detection (HPLC-UV)					4. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixture where the use level on the label of the premixture would result in exceeding the content referred to in point 3. 5. The moisture content shall be indicated on the label of the additive.	

⁽¹⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en.

⁽²⁾ 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>).