II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1090

of 24 July 2020

concerning the authorisation of L-histidine monohydrochloride monohydrate 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 authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003 three applications were submitted for the authorisation of L-histidine monohydrochloride monohydrate. The applications were accompanied by the particulars and documents required under Article 7(3) of that Regulation.

(3) The applications concern the authorisation of L-histidine monohydrochloride monohydrate produced by *Escherichia coli* NITE BP-02526, *Corynebacterium glutamicum* KCCM 80172 or *Corynebacterium glutamicum* KCCM 80179 as a feed additive for all animal species, to be classified in the additive category 'nutritional additives'. L-histidine monohydrochloride monohydrate produced by *Escherichia coli* NITE BP-02526 and *Corynebacterium glutamicum* KCCM 80179 are also applied for the additive category 'sensory additives'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinions of 2 July 2019 ([2]), ([3]), ([4]) that, under the proposed conditions of use, L-histidine monohydrochloride monohydrate produced by *Escherichia coli* NITE BP-02526, *Corynebacterium glutamicum* KCCM 80172 or *Corynebacterium glutamicum* KCCM 80179, when supplemented at levels appropriate to the requirements of the target species, does not have an adverse effect on animal health, consumer safety or the environment. This conclusion covers also the use of L-histidine monohydrochloride monohydrate produced by *Escherichia coli* NITE BP-02526 or *Corynebacterium glutamicum* KCCM 80179 as sensory additive at the intended use level. With respect to the safety of the user of the additive, the Authority stated only a mild irritation risk to the eyes for L-histidine monohydrochloride monohydrate produced by *Corynebacterium glutamicum* KCCM 80172 or *Corynebacterium glutamicum* KCCM 80179. For L-histidine monohydrochloride monohydrate produced by fermentation with *Escherichia coli* NITE BP-02526, the Authority stated a risk by inhalation. Therefore, appropriate protective measures should be taken for this additive to prevent adverse effects on human health, in particular as regards the users of the additive. Further, the Authority concluded that L-histidine

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) *EFSA Journal* 2019; 17(7):5783.
([3]) *EFSA Journal* 2019; 17(7):5784.
([4]) *EFSA Journal* 2019; 17(8):5785.

monohydrochloride monohydrate produced by *Escherichia coli* NITE BP-02526, *Corynebacterium glutamicum* KCCM 80172 or *Corynebacterium glutamicum* KCCM 80179 is an efficacious source of the essential amino acid L-histidine for animal nutrition and that in order to be efficacious in ruminants, the additive should be protected against degradation in the rumen. Moreover, the Authority concluded that L-histidine monohydrochloride monohydrate produced by *Escherichia coli* NITE BP-02526 or *Corynebacterium glutamicum* KCCM 80179 is efficacious as feed flavouring compound.

(5) The Authority does not consider that there is a need for specific requirements of post-market monitoring. It 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.

(6) Restrictions and conditions should be provided for to allow for a better control for those additives when used as flavourings. For these additives used as flavourings recommended contents should be indicated on the label. Where such contents are exceeded, certain information should be indicated on the label of premixtures. The use of L-histidine monohydrochloride monohydrate as a flavouring compound is not authorised in water for drinking. The fact that L-histidine monohydrochloride monohydrate is not authorised for use as a flavouring in water for drinking, does not preclude its use in compound feed, which is administered via water.

(7) The assessment of that substance shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that substance should be authorised as specified in the Annex to this Regulation.

(8) 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

1. L-histidine monohydrochloride monohydrate produced by *Escherichia coli* NITE BP-02526, *Corynebacterium glutamicum* KCCM 80172 or *Corynebacterium glutamicum* KCCM 80179 specified in the Annex, belonging to the additive category 'nutritional additives' and to the functional group 'amino acids, their salts and analogues' are authorised as feed additives in animal nutrition subject to the conditions laid down in that Annex.

2. L-histidine monohydrochloride monohydrate produced by *Escherichia coli* NITE BP-02526 or *Corynebacterium glutamicum* KCCM 80179 specified in the Annex, belonging to the additive category 'sensory additives' and to the functional group 'flavouring compounds' is authorised as a feed additive in animal nutrition subject to the conditions laid down in that Annex.

Article 2

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, 24 July 2020.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the additive	Name of the holder of authorisation	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 a moisture content of 12 %			
Category of nutritional additives. Functional group: amino acids, their salts and analogues									
3c352	-	L-histidine monohydrochloride monohydrate	**Additive composition:** Powder with a minimum content of 98 % L-histidine monohydrochloride monohydrate and 72 % histidine and a maximum content of 100 ppm histamine **Characterisation of the active substance:** L-histidine monohydrochloride monohydrate produced by fermentation with *Corynebacterium glutamicum* KCCM 80172 or *Corynebacterium glutamicum* KCCM 80179 or *Escherichia coli* NITE BP-02526 Chemical formula: $C_3H_3N_2$-CH_2-CH(NH_2)-COOH· HCl· H_2O CAS number: 5934-29-2 **Analytical method** (1): For the quantification of histidine in the feed additive: — high performance liquid chromatography coupled with photometric detection (HPLC-UV) — ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD)	All animal species	-	-	-	1. L-histidine monohydrochloride monohydrate may be placed on the market and used as an additive consisting of a preparation. 2. The additive can be also used via water for drinking. 3. The endotoxin content of the additive and its dusting potential shall ensure a maximal endotoxin exposure of 1 600 IU endotoxins/m^3 air (2). 4. For users of the additive and premixture, feed business operators shall establish operational procedures and organisational measures to address potential risks for the eyes and skin and by inhalation. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixture shall be used with personal protective equipment. 5. In the directions for use of the additive and premixture, the storage conditions, the stability to heat treatment and the stability in water for drinking shall be indicated.	16.8.2030

			For the quantification of histidine in premixtures, feed materials and compound feed: — ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS), Commission Regulation (EC) No 152/2009 (Annex III, F) For the quantification of histidine in water: — ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS/FLD)					6. Declaration to be made on the label of the additive and premixture: 'The supplementation with L-histidine monohydrochloride monohydrate, in particular via water for drinking, should take into account all essential and conditional essential amino acids in order to avoid imbalances.' — Histidine content.	

Category: Sensory additives. Functional group: Flavouring compounds

3c352	-	L-histidine monohydrochloride monohydrate	**Additive composition:** Powder with a minimum content of 98 % L-histidine monohydrochloride monohydrate and 72 % histidine and a maximum content of 100 ppm histamine **Characterisation of the active substance:** L-histidine monohydrochloride monohydrate produced by fermentation with *Corynebacterium glutamicum* KCCM 80179 or *Escherichia coli* NITE BP-02526. Chemical formula: $C_3H_3N_2$-CH_2-CH (NH_2-COOH· HCl· H_2O CAS number: 5934-29-2 **Analytical method** (1): For the quantification of histidine in the feed additive: — high performance liquid chromatography coupled with photometric detection (HPLC-UV)	All animal species	-	-	-	1. L-histidine monohydrochloride monohydrate may be placed on the market and used as an additive consisting of a preparation. 2. The additive shall be incorporated into the feed in the form of a premixture. 3. The endotoxin content of the additive and its dusting potential shall ensure a maximal endotoxin exposure of 1 600 IU endotoxins/m^3 air (3). 4. For users of the additive and premixture, feed business operators shall establish operational procedures and organisational measures to address potential risks for the eyes and skin and by inhalation. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixture shall be used with personal protective equipment.	16.8.2030

			— ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) For the quantification of histidine in premixtures: — ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) or — ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS), Commission Regulation (EC) No 152/2009 (Annex III, F) For the quantification of histidine in feed materials and compound feed: — ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS), Commission Regulation (EC) No 152/2009 (Annex III, F)					5. In the directions for use of the additive and premixture, the storage conditions and the stability to heat treatment shall be indicated. 6. On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 25 mg/kg ' — The histidine content. 7. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixtures, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 25 mg/kg.	

(1) Details of the analytical methods are available at the following address of the Reference Laboratory: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports

(2) Exposure calculated based on the endotoxin level and the dusting potential of the additive according to the method used by EFSA (EFSA Journal 2017;15(3):4705); analytical method: European Pharmacopoeia 2.6.14. (bacterial endotoxins).

(3) Exposure calculated based on the endotoxin level and the dusting potential of the additive according to the method used by EFSA (EFSA Journal 2017;15(3):4705); analytical method: European Pharmacopoeia 2.6.14. (bacterial endotoxins).