COMMISSION IMPLEMENTING REGULATION (EU) 2021/2080

of 26 November 2021

concerning the authorisation of L-histidine monohydrochloride monohydrate produced by fermentation with *Escherichia coli* NITE SD 00268 as a feed additive for all animal species except finfish

(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 the extension of use of L-histidine monohydrochloride monohydrate produced by fermentation with *Escherichia coli* NITE SD 00268 as a feed additive from finfish to all animal species. 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 the extension of use of L-histidine monohydrochloride monohydrate produced by fermentation with *Escherichia coli* NITE SD 00268 as a feed additive from finfish to all animal species to be classified in the additive category 'nutritional additives', functional group 'amino acids, their salts and analogues', and in the additive category 'sensory additives', functional group 'flavouring compounds'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 5 May 2021 ([2]) that, under the proposed conditions of use, L-histidine monohydrochloride monohydrate produced by fermentation with *Escherichia co*li NITE SD 00268 does not have an adverse effect on animal health, consumers safety or the environment. The Authority also concluded for the additive in question that it was not possible to conclude on the potential for the additive to be toxic if inhaled, an irritant to eyes or a skin sensitiser. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive. The Authority also concluded that the additive is an efficacious source of the essential amino acid histidine and efficacious as a flavouring compound.

(5) The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the reports 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) The assessment of L-histidine monohydrochloride monohydrate produced by fermentation with *Escherichia coli* NITE SD 00268 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of this additive should be authorised as specified in the Annex to this Regulation.

(7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) *EFSA Journal* 2021; 19(5):6622.

HAS ADOPTED THIS REGULATION:

Article 1

1. The substance L-histidine monohydrochloride monohydrate produced by fermentation with *Escherichia coli* NITE SD 00268 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 a feed additive in animal nutrition subject to the conditions laid down in that Annex.

2. The substance L-histidine monohydrochloride monohydrate produced by fermentation with *Escherichia coli* NITE SD 00268 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, 26 November 2021.

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: nutritional additives									
Functional group: amino acids, their salts and analogues									
3c351i	-	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 *Escherichia coli* NITE SD 00268 Chemical formula: $C_3H_3N_2$-CH_2-CH(NH_2)-COOH·HCl·H_2O CAS number: 5934-29-2 Einecs number 211-438-9 *Analytical method* (1) For the quantification of histidine in the feed additive: — high performance liquid chromatography coupled with spectrophotometric detection (HPLC-UV),	All animal species except finfish	-	-	-	1. In the directions for use of the additive and premixture, the storage conditions and the stability to heat treatment shall be indicated. 2. Declaration to be made on the label of the additive and premixture: — 'The supplementation with L-histidine monohydrochloride monohydrate shall be limited to the nutritional requirements of the target animal, which depend on the species, the physiological state of the animal, the performance level, the environmental conditions, the level of other amino acids in the diet and the level of essential trace elements, such as copper and zinc.' — 'Histidine content'. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address the potential risks by inhalation or dermal contact. Where those risks cannot be eliminated or reduced to a minimum by such procedures and	19 December 2031

			— ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD). For the quantification of histidine in premixtures, feed materials and compound feed: — ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS), Commission Regulation (EC) No 152/2009 (Annex III, F). For the quantification of histamine in the feed additive: — high performance liquid chromatography coupled to a spectrophotometric detection (HPLC-UV).					measures, the additive and premixtures shall be used with appropriate personal protective equipment, including eyes, skin and breathing protection.	
Category: Sensory additives									
Functional group: Flavouring compounds									
3c351i	-	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 *Escherichia coli* NITE SD 00268	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 premixture, 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 of complete feed with a moisture content of 12 %: 25 mg/kg.	19 December 2031

			Chemical formula: $C_3H_3N_2$-CH_2-CH(NH_2)-COOH·HCl·H_2O CAS number: 5934-29-2 Einecs number 211-438-9 *Analytical method* (1) For the quantification of histidine in the feed additive: — performance liquid chromatography coupled with spectrophotometric detection (HPLC-UV), — 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), Commission Regulation (EC) No 152/2009 (Annex III, F). For the quantification of histamine in the feed additive: — high performance liquid chromatography coupled to a 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 level of active substance in complete feed referred to in point 3. 5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address the potential risks by inhalation or dermal contact. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment, including eyes, skin and breathing protection.	

(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