COMMISSION IMPLEMENTING REGULATION (EU) 2020/2116

of 16 December 2020

concerning the renewal of the authorisation of L-histidine monohydrochloride monohydrate produced by *Escherichia coli* ATCC 9637 as a feed additive for salmonids and its extension of use to other finfish, and repealing Regulation (EC) No 244/2007

(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 and renewing such authorisation.

(2) L-histidine monohydrochloride monohydrate produced by *Escherichia coli* ATCC 9637 was authorised for 10 years as a feed additive for salmonids by Commission Regulation (EC) No 244/2007 ([2]).

(3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, an application was submitted for the renewal of the authorisation of L-histidine monohydrochloride monohydrate produced by *Escherichia coli* ATCC 9637 as a feed additive for salmonids. The application included a request to change the strain designation to *Escherichia coli* NITE SD 00268 and was accompanied by the particulars and documents required under Article 14(2) of that Regulation. In addition, in accordance with Article 7 of that Regulation, the application requested an extension of use to other finfish. The application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 18 March 2020 ([3]) that, under the proposed conditions of use, L-histidine monohydrochloride monohydrate produced by *Escherichia coli* NITE SD 00268, when supplemented at levels appropriate to the requirements of the target species, does not have an adverse effect on animal health, consumer health or the environment. The Authority also concluded that while the additive in question is not a skin irritant, 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 amino acid histidine for fish species. 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.

(5) The assessment of L-histidine monohydrochloride monohydrate produced by *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.

(6) As a consequence of the renewal of the authorisation of L-histidine monohydrochloride monohydrate produced by *Escherichia coli* ATCC 9637 as a feed additive under the conditions laid down in the Annex to this Regulation, Regulation (EC) No 244/2007 should be repealed.

([1]) OJ L 268, 18.10.2003, p. 29.

([2]) Commission Regulation (EC) No 244/2007 of 7 March 2007 concerning the authorisation of L-histidine monohydrochloride monohydrate as feed additive (OJ L 73, 13.3.2007, p. 6.).

([3]) *EFSA Journal* 2020;18(4):6072.

(7) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation for L-histidine monohydrochloride monohydrate produced by *Escherichia coli* ATCC 9637, it is appropriate to provide for a transitional period to allow interested parties to prepare to meet the new requirements resulting from the renewal of the authorisation.

(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

The authorisation of L-histidine monohydrochloride monohydrate produced by *Escherichia coli* ATCC 9637, belonging to the additive category 'nutritional additives' and to the functional group 'amino acids, their salts and analogues', is renewed subject to the conditions laid down in the Annex.

Article 2

1. L-histidine monohydrochloride monohydrate produced by *Escherichia coli* ATCC 9637 and premixtures containing it, which are produced and labelled before 6 July 2021 in accordance with the rules applicable before 6 January 2021 may continue to be placed on the market and used until the existing stocks are exhausted.

2. Feed materials and compound feed containing the substances referred to in point 1, which are produced and labelled before 6 January 2022 in accordance with the rules applicable before 6 January 2021 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for salmonids.

Article 3

Regulation (EC) No 244/2007 is repealed.

Article 4

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, 16 December 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.									
3c351	-	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 photometric detection (HPLC-UV) — 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:	Finfish	-	-	-	1. L-histidine monohydrochloride monohydrate may be placed on the market and used as an additive consisting of a preparation. 2. In the directions for use of the additive and premixture, the storage conditions and the stability to heat treatment shall be indicated. 3. 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 essential trace elements such as copper and zinc.' — Histidine content.	6 January 2031

			— 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 histamine in the feed additive: — high performance liquid chromatography coupled to a spectrophotometric detection (HPLC-UV)					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 premixtures shall be used with personal protective equipment.	

(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