



1 December 2021

(21-9063)

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Committee on Sanitary and Phytosanitary Measures

Original: English

NOTIFICATION

1. Notifying Member: <u>EUROPEAN UNION</u> If applicable, name of local government involved:
2. Agency responsible: European Commission, Health and Food Safety Directorate-General
3. Products covered (provide tariff item number(s) as specified in national schedules deposited with the WTO; ICS numbers should be provided in addition, where applicable): Preparation of a kind used in animal nutrition (HS Code: 2309)
4. Regions or countries likely to be affected, to the extent relevant or practicable: <input checked="" type="checkbox"/> All trading partners <input type="checkbox"/> Specific regions or countries:
5. Title of the notified document: Commission Implementing Regulation (EU) 2021/2080 of 26 November 2021 concerning the authorisation of L-histidine monohydrochloride monohydrate produced by fermentation with <i>Escherichia coli</i> NITE SD 00268 as a feed additive for all animal species except finfish (Text with EEA relevance). Language(s): English, French and Spanish. Number of pages: 5 https://members.wto.org/crnattachments/2021/SPS/EEC/21_7475_00_e.pdf https://members.wto.org/crnattachments/2021/SPS/EEC/21_7475_00_f.pdf https://members.wto.org/crnattachments/2021/SPS/EEC/21_7475_00_s.pdf
6. Description of content: 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. 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 <i>Escherichia coli</i> 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. The application concerns the authorisation of the extension of use of L-histidine monohydrochloride monohydrate produced by fermentation with <i>Escherichia coli</i> 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'. The European Food Safety Authority ('the Authority') concluded in its opinion of 5 May 2021 that, under the proposed conditions of use, L-histidine monohydrochloride monohydrate produced by fermentation with <i>Escherichia coli</i> 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.

7.	Objective and rationale: <input checked="" type="checkbox"/> food safety, <input type="checkbox"/> animal health, <input type="checkbox"/> plant protection, <input type="checkbox"/> protect humans from animal/plant pest or disease, <input type="checkbox"/> protect territory from other damage from pests.
8.	<p>Is there a relevant international standard? If so, identify the standard:</p> <p><input checked="" type="checkbox"/> Codex Alimentarius Commission (e.g. title or serial number of Codex standard or related text): Code of practice on Good Animal Feeding CAC/RCP 54-2004</p> <p><input type="checkbox"/> World Organization for Animal Health (OIE) (e.g. Terrestrial or Aquatic Animal Health Code, chapter number):</p> <p><input type="checkbox"/> International Plant Protection Convention (e.g. ISPM number):</p> <p><input type="checkbox"/> None</p> <p>Does this proposed regulation conform to the relevant international standard?</p> <p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If no, describe, whenever possible, how and why it deviates from the international standard:</p>
9.	Other relevant documents and language(s) in which these are available:
10.	<p>Proposed date of adoption (dd/mm/yy): 26 November 2021</p> <p>Proposed date of publication (dd/mm/yy): 29 November 2021</p>
11.	<p>Proposed date of entry into force: <input type="checkbox"/> Six months from date of publication, and/or (dd/mm/yy): This Regulation shall enter into force on the twentieth day following its publication in the Official Journal of the European Union.</p> <p><input checked="" type="checkbox"/> Trade facilitating measure</p>
12.	<p>Final date for comments: <input type="checkbox"/> Sixty days from the date of circulation of the notification and/or (dd/mm/yy): Not applicable</p> <p>Agency or authority designated to handle comments: <input checked="" type="checkbox"/> National Notification Authority, <input checked="" type="checkbox"/> National Enquiry Point. Address, fax number and e-mail address (if available) of other body:</p> <p>European Commission DG Health and Food Safety, Unit D2-Multilateral International Relations Rue Froissart 101 B-1049 Brussels Tel: +(32 2) 29 54263 Fax: +(32 2) 29 98090 E-mail: sps@ec.europa.eu</p>
13.	<p>Text(s) available from: <input checked="" type="checkbox"/> National Notification Authority, <input checked="" type="checkbox"/> National Enquiry Point. Address, fax number and e-mail address (if available) of other body:</p> <p>European Commission DG Health and Food Safety, Unit D2-Multilateral International Relations Rue Froissart 101 B-1049 Brussels Tel: +(32 2) 29 54263 Fax: +(32 2) 29 98090 E-mail: sps@ec.europa.eu</p>