



12 January 2021

(21-0390)

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Committee on Sanitary and Phytosanitary Measures

Original: English

**NOTIFICATION**

<b>1. Notifying Member:</b> <u>EUROPEAN UNION</u> <b>If applicable, name of local government involved:</b>
<b>2. Agency responsible:</b> European Commission, Health and Food Safety Directorate-General
<b>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):</b> HS Code 2309 - Preparation of a kind used in animal nutrition
<b>4. Regions or countries likely to be affected, to the extent relevant or practicable:</b> <input checked="" type="checkbox"/> <b>All trading partners</b> <input type="checkbox"/> <b>Specific regions or countries:</b>
<b>5. Title of the notified document:</b> Commission Implementing Regulation (EU) 2020/2116 of 16 December 2020 concerning the renewal of the authorisation of L-histidine monohydrochloride monohydrate produced by <i>Escherichia coli</i> 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). <b>Language(s):</b> English, French and Spanish. <b>Number of pages:</b> 4  <a href="https://members.wto.org/crnattachments/2021/SPS/EEC/21_0373_00_e.pdf">https://members.wto.org/crnattachments/2021/SPS/EEC/21_0373_00_e.pdf</a> <a href="https://members.wto.org/crnattachments/2021/SPS/EEC/21_0373_00_f.pdf">https://members.wto.org/crnattachments/2021/SPS/EEC/21_0373_00_f.pdf</a> <a href="https://members.wto.org/crnattachments/2021/SPS/EEC/21_0373_00_s.pdf">https://members.wto.org/crnattachments/2021/SPS/EEC/21_0373_00_s.pdf</a>
<b>6. Description of content:</b> L-histidine monohydrochloride monohydrate produced by <i>Escherichia coli</i> ATCC 9637 was authorised for 10 years as a feed additive for salmonids by Commission Regulation (EC) No 244/2007. In accordance with Article 14 of Regulation (EC) No 1831/2003, an application was submitted for the renewal of the authorisation of L-histidine monohydrochloride monohydrate produced by <i>Escherichia coli</i> ATCC 9637 as a feed additive for salmonids. The application included a request to change the strain designation to <i>Escherichia coli</i> NITE SD 00268 and was accompanied by the particulars and documents required under Article 14 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 of Regulation (EC) No 1831/2003. The European Food Safety Authority ('the Authority') concluded in its opinion of 18 March 2020 that, under the proposed conditions of use, L-histidine monohydrochloride monohydrate produced by <i>Escherichia coli</i> 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-

<p>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. The assessment of L-histidine monohydrochloride monohydrate produced by <i>Escherichia coli</i> 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. As a consequence of the renewal of the authorisation of L-histidine monohydrochloride monohydrate produced by <i>Escherichia coli</i> 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.</p>
<p><b>7. Objective and rationale:</b> <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.</p>
<p><b>8. Is there a relevant international standard? If so, identify the standard:</b></p> <p><input checked="" type="checkbox"/> <b>Codex Alimentarius Commission (e.g. title or serial number of Codex standard or related text):</b> Code of practice on Good Animal Feeding CAC/RCP 54-2004</p> <p><input type="checkbox"/> <b>World Organization for Animal Health (OIE) (e.g. Terrestrial or Aquatic Animal Health Code, chapter number):</b></p> <p><input type="checkbox"/> <b>International Plant Protection Convention (e.g. ISPM number):</b></p> <p><input type="checkbox"/> <b>None</b></p> <p><b>Does this proposed regulation conform to the relevant international standard?</b></p> <p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><b>If no, describe, whenever possible, how and why it deviates from the international standard:</b></p>
<p><b>9. Other relevant documents and language(s) in which these are available:</b></p>
<p><b>10. Proposed date of adoption (dd/mm/yy):</b> 16 December 2020</p> <p><b>Proposed date of publication (dd/mm/yy):</b> 17 December 2020</p>
<p><b>11. Proposed date of entry into force:</b> <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 that of its publication in the Official Journal of the European Union.</p> <p><input checked="" type="checkbox"/> <b>Trade facilitating measure</b></p>
<p><b>12. Final date for comments:</b> <input type="checkbox"/> Sixty days from the date of circulation of the notification and/or (dd/mm/yy): Not applicable</p> <p><b>Agency or authority designated to handle comments:</b> <input checked="" type="checkbox"/> National Notification Authority, <input checked="" type="checkbox"/> National Enquiry Point. <b>Address, fax number and e-mail address (if available) of other body:</b></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. Text(s) available from:  National Notification Authority,  National Enquiry Point. Address, fax number and e-mail address (if available) of other body:**

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