



31 March 2021

(21-2630)

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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): HS Code 2309 Preparation of a kind used in animal nutrition
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) 2021/507 concerning the renewal of the authorization of pyridoxine hydrochloride (vitamin B6) as a feed additive for all animal species and repealing Implementing Regulation (EU) No 515/2011 (Text with EEA relevance). Language(s): English, Spanish, French. Number of pages: 3 https://members.wto.org/crnattachments/2021/SPS/EEC/21_2177_00_e.pdf https://members.wto.org/crnattachments/2021/SPS/EEC/21_2177_00_f.pdf https://members.wto.org/crnattachments/2021/SPS/EEC/21_2177_00_s.pdf
6. Description of content: Regulation (EC) No 1831/2003 provides for the authorization of additives for use in animal nutrition and for the grounds and procedures for granting and renewing such authorization. Pyridoxine hydrochloride (vitamin B6) was authorized for 10 years as a feed additive for all animal species by Commission Implementing Regulation (EU) No 515/2011(2). In accordance with Article 14 of Regulation (EC) No 1831/2003, an application was submitted for the renewal of the authorization of pyridoxine hydrochloride as a feed additive for all animal species, requesting the additive to be classified in the additive category "nutritional additives". That application was accompanied by the particulars and documents required under Article 14(2) of that Regulation. The European Food Safety Authority ("the Authority") concluded in its opinion of 30 September 2020(3) that the applicant has provided evidence that the additive complies with the existing conditions of authorization. The Authority concluded that pyridoxine hydrochloride under the current authorized conditions of use does not have an adverse effect on animal health, consumer safety or the environment. It also concluded that the additive is non-irritant to skin and eyes and is not a skin sensitizer but it may cause photosensitisation and in the absence of inhalation toxicity studies, adverse effects in the respiratory tract could not be fully excluded. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards to the users of the additive. The Authority also concluded that there is no need for assessing the efficacy of the additive in the context of the renewal of the authorization. The assessment of pyridoxine hydrochloride shows that the conditions for authorization, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the authorization of that additive should be renewed.

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): 23 March 2021</p> <p>Proposed date of publication (dd/mm/yy): 24 March 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 that of 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>