

31 March 2021

Original: English

(21-2630) Page: 1/2

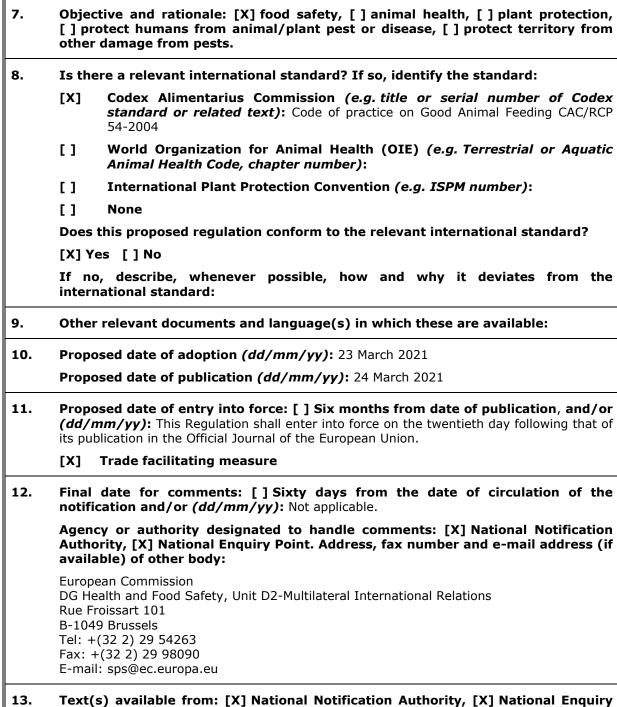
Committee on Sanitary and Phytosanitary Measures

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:
 - [X] All trading partners
 - [] 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 sensitiser 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.



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