

17 June 2021

Original: English

(21-4971) Page: 1/2

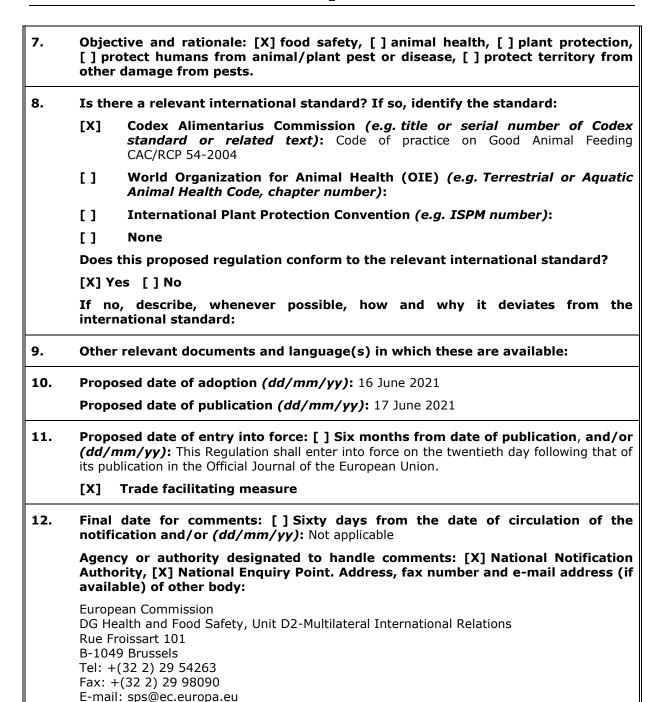
Committee on Sanitary and Phytosanitary Measures

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): 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:
 - [X] All trading partners
 - [] Specific regions or countries:
- 5. Title of the notified document: Commission Implementing Regulation (EU) 2021/967 concerning the renewal of the authorisation of manganese chelate of hydroxy analogue of methionine as a feed additive for all animal species, and repealing Regulation (EU) No 350/2010 (Text with EEA relevance). Language(s): English, French and Spanish. Number of pages: 4

https://members.wto.org/crnattachments/2021/SPS/EEC/21 4207 00 e.pdf https://members.wto.org/crnattachments/2021/SPS/EEC/21 4207 00 f.pdf https://members.wto.org/crnattachments/2021/SPS/EEC/21 4207 00 s.pdf

Description of content: Regulation (EC) No 1831/2003 provides for the authorisation of 6. additives for use in animal nutrition and for the grounds and procedures for granting and renewing such authorisation. Manganese chelate of hydroxy analogue of methionine was authorised for 10 years as a feed additive for all animal species by Commission Regulation (EU) No 350/2010. In accordance with Article 14(1) of Regulation (EC) No 1831/2003, an application was submitted for the renewal of the authorisation of manganese chelate of hydroxy analogue of methionine as feed additive for all animal species in the additive category 'nutritional additives'. That application was accompanied by the particulars and documents required under Article 14(2) of Regulation (EC) No 1831/2003. It results from the opinion of the European Food Safety Authority ('the Authority') of 30 September 2020 that, under the proposed conditions of use, manganese chelate of hydroxy analogue of methionine does not have an adverse effect on animal health, consumer safety or the environment. The Authority also concluded for the additive a risk for the user by inhalation and that it is a skin sensitizer. 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 proof of the efficacy of the additive, on which the initial authorisation was based, withstands in a renewal procedure. The Authority also verified the report 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 manganese chelate of hydroxy analogue of methionine shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the authorisation of this additive should be renewed. As a consequence of the renewal of the authorisation of manganese chelate of hydroxy analogue of methionine as feed additive, Regulation (EU) No 350/2010 should be repealed.



13. Text(s) available from: [X] National Notification Authority, [X] National Enquiry Point. Address, fax number and e-mail address (if available) of other body:

European Commission DG Health and Food Safety, Unit D2-Multilateral International Relations

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