



17 June 2021

(21-4971)

Page: 1/2

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) 2021/967 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
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 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.

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): 16 June 2021</p> <p>Proposed date of publication (dd/mm/yy): 17 June 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>