



12 January 2021

(21-0394)

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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) 2020/2117 of 16 December 2020 concerning the renewal of the authorisation of selenomethionine produced by <i>Saccharomyces cerevisiae</i> CNCM I-3399 with the new name 'selenised yeast <i>Saccharomyces cerevisiae</i> CNCM I-3399' as a feed additive for all animal species, and repealing Regulation (EC) No 900/2009 (Text with EEA relevance). Language(s): English, French and Spanish. Number of pages: 4 https://members.wto.org/crnattachments/2021/SPS/EEC/21_0374_00_e.pdf https://members.wto.org/crnattachments/2021/SPS/EEC/21_0374_00_f.pdf https://members.wto.org/crnattachments/2021/SPS/EEC/21_0374_00_s.pdf
6. Description of content: Selenomethionine produced by <i>Saccharomyces cerevisiae</i> CNCM I-3399 was authorised for 10 years as a feed additive for all animal species by Commission Regulation (EC) No 900/2009. In accordance with Article 14 of Regulation (EC) No 1831/2003, an application was submitted for the renewal of the authorisation of selenomethionine produced by <i>Saccharomyces cerevisiae</i> CNCM I-3399 as feed additive for all animal species in the additive category 'nutritional additives'. The application was accompanied by the particulars and documents required under Article 14 of Regulation (EC) No 1831/2003. It results from the opinion of the European Food Safety Authority ('the Authority') of 7 May 2020 that, under the proposed conditions of use, selenomethionine produced by <i>Saccharomyces cerevisiae</i> CNCM I-3399 does not have an adverse effect on animal health, consumer safety or the environment. The Authority also concluded that the additive is a potential dermal and respiratory 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. Finally, the Authority recommended changing the denomination of the additive. 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 selenomethionine produced by <i>Saccharomyces cerevisiae</i> CNCM I-3399 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

<p>the authorisation of selenomethionine produced by <i>Saccharomyces cerevisiae</i> CNCM I-3399 as feed additive, Regulation (EC) No 900/2009 should be repealed. Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation for selenomethionine produced by <i>Saccharomyces cerevisiae</i> CNCM I-3399, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the renewal of the authorisation.</p>
<p>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.</p>
<p>8. 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>
<p>9. Other relevant documents and language(s) in which these are available:</p>
<p>10. Proposed date of adoption (dd/mm/yy): 16 December 2020</p> <p>Proposed date of publication (dd/mm/yy): 17 December 2020</p>
<p>11. 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>
<p>12. 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. 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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