



9 March 2021

(21-1965)

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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): Preparation of a kind use 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) 2021/363 of 26 February 2021 concerning the authorisation of a preparation of fumonisin esterase produced by <i>Komagataella phaffii</i> DSM 32159 as a feed additive for all animal species (Text with EEA relevance). Language(s): English, French and Spanish. Number of pages: 3 https://members.wto.org/crnattachments/2021/SPS/EEC/21_1737_00_e.pdf https://members.wto.org/crnattachments/2021/SPS/EEC/21_1737_00_f.pdf https://members.wto.org/crnattachments/2021/SPS/EEC/21_1737_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 such authorisation. In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of a preparation of fumonisin esterase produced by <i>Komagataella phaffii</i> DSM 32159. That application was accompanied by the particulars and documents required under Article 7 of Regulation (EC) No 1831/2003. The application concerns the authorisation of a preparation of fumonisin esterase produced by <i>Komagataella phaffii</i> DSM 32159 as a feed additive for all animal species, to be classified in the additive category "technological additives". The European Food Safety Authority ("the Authority") concluded in its opinion of 1 July 2020 that, under the proposed conditions of use, the preparation of fumonisin esterase produced by <i>Komagataella phaffii</i> DSM 32159 does not have an adverse effect on animal health, consumer safety or the environment. It also concluded that the additive is not toxic by inhalation and the respiratory exposure is likely to be low but a risk of sensitisation via the respiratory route could not be excluded. The additive is non-irritant to skin and eyes and is not considered as a dermal sensitiser. 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 Authority also concluded that the preparation concerned has the capability to degrade fumonisins in fermenting feed (with a fumonisin content within the limits operating in the Union) but only in silages, not in other fermenting feeds. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the methods of analysis of the feed additive in feed submitted by the Reference Laboratory

<p>set up by Regulation (EC) No 1831/2003. The assessment of the preparation of fumonisin esterase produced by <i>Komagataella phaffii</i> DSM 32159 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that preparation should be authorised.</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): 26 February 2021</p> <p>Proposed date of publication (dd/mm/yy): 1 March 2021</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>
<p>13. 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>