



1 December 2021

(21-9061)

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Committee on Sanitary and Phytosanitary Measures

Original: English

**NOTIFICATION**

<b>1. Notifying Member:</b> <u>EUROPEAN UNION</u> <b>If applicable, name of local government involved:</b>
<b>2. Agency responsible:</b> European Commission, Health and Food Safety Directorate-General
<b>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):</b> Preparation of a kind used in animal nutrition (HS Code: 2309)
<b>4. Regions or countries likely to be affected, to the extent relevant or practicable:</b> <input checked="" type="checkbox"/> <b>All trading partners</b> <input type="checkbox"/> <b>Specific regions or countries:</b>
<b>5. Title of the notified document:</b> Commission Implementing Regulation (EU) 2021/2090 of 25 November 2021 concerning the denial of authorisation of titanium dioxide as a feed additive for all animal species (Text with EEA relevance). <b>Language(s):</b> English, French and Spanish. <b>Number of pages:</b> 2 <a href="https://members.wto.org/crnattachments/2021/SPS/EEC/21_7419_00_e.pdf">https://members.wto.org/crnattachments/2021/SPS/EEC/21_7419_00_e.pdf</a> <a href="https://members.wto.org/crnattachments/2021/SPS/EEC/21_7419_00_f.pdf">https://members.wto.org/crnattachments/2021/SPS/EEC/21_7419_00_f.pdf</a> <a href="https://members.wto.org/crnattachments/2021/SPS/EEC/21_7419_00_s.pdf">https://members.wto.org/crnattachments/2021/SPS/EEC/21_7419_00_s.pdf</a>
<b>6. Description of content:</b> Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting or denying such authorisation. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC. Titanium dioxide was authorised without a time limit by Directive 70/524/EEC as a colourant additive (colouring agents authorised for colouring foodstuffs by Community rules) for cats and dogs. It was also authorised without a time limit for all animal species, with the exception of cats and dogs, for animal feedingstuffs under certain conditions. That product was subsequently entered in the Register of feed additives as an existing product, in accordance with Article 10(1) of Regulation (EC) No 1831/2003. In accordance with Article 10(2) of Regulation (EC) No 1831/2003, in conjunction with Article 7 thereof, an application was submitted for the re-evaluation of titanium dioxide as a feed additive for all animal species. The applicant requested the additive to be classified in the additive category 'sensory additives' and the functional group 'colourants: substances that add or restore colour in feedingstuffs'. The application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003. The European Food Safety Authority ('the Authority') noted in its opinion of 5 May 2021 that it could not conclude on the safety of titanium dioxide for the target species, consumers and environment, given the absence of specific data related to its use as a feed additive and considering that the genotoxicity of particles of titanium dioxide could not be ruled out, raising potential concerns on the safety of the additive for the target species (especially for long-living animals and reproductive animals), consumers and users. In the absence of studies with titanium dioxide, the Authority could not conclude on the assessment of the effects of the additive on eyes and skin. The Authority further noted that titanium dioxide is potentially carcinogenic to workers if inhaled and that, as the genotoxicity of particles of

	titanium dioxide cannot be ruled out, it should be considered as an additional potential concern to users handling 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.
7.	<b>Objective and rationale:</b> <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><b>Is there a relevant international standard? If so, identify the standard:</b></p> <p><input checked="" type="checkbox"/> <b>Codex Alimentarius Commission (e.g. title or serial number of Codex standard or related text):</b> Code of practice on Good Animal Feeding CAC/RCP 54-2004</p> <p><input type="checkbox"/> <b>World Organization for Animal Health (OIE) (e.g. Terrestrial or Aquatic Animal Health Code, chapter number):</b></p> <p><input type="checkbox"/> <b>International Plant Protection Convention (e.g. ISPM number):</b></p> <p><input type="checkbox"/> <b>None</b></p> <p><b>Does this proposed regulation conform to the relevant international standard?</b></p> <p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><b>If no, describe, whenever possible, how and why it deviates from the international standard:</b></p>
9.	<b>Other relevant documents and language(s) in which these are available:</b>
10.	<p><b>Proposed date of adoption (dd/mm/yy):</b> 25 November 2021</p> <p><b>Proposed date of publication (dd/mm/yy):</b> 30 November 2021</p>
11.	<p><b>Proposed date of entry into force:</b> <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 its publication in the Official Journal of the European Union.</p> <p><input type="checkbox"/> <b>Trade facilitating measure</b></p>
12.	<p><b>Final date for comments:</b> <input type="checkbox"/> Sixty days from the date of circulation of the notification and/or (dd/mm/yy): Not applicable</p> <p><b>Agency or authority designated to handle comments:</b> <input checked="" type="checkbox"/> National Notification Authority, <input checked="" type="checkbox"/> National Enquiry Point. <b>Address, fax number and e-mail address (if available) of other body:</b></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><b>Text(s) available from:</b> <input checked="" type="checkbox"/> National Notification Authority, <input checked="" type="checkbox"/> National Enquiry Point. <b>Address, fax number and e-mail address (if available) of other body:</b></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>