



12 January 2021

(21-0397)

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Committee on Sanitary and Phytosanitary Measures

Original: English

**NOTIFICATION**

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| <b>1. Notifying Member:</b> <u>EUROPEAN UNION</u><br><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> HS Code 2309 - Preparation of a kind used in animal nutrition  |
| <b>4. Regions or countries likely to be affected, to the extent relevant or practicable:</b><br><input checked="" type="checkbox"/> <b>All trading partners</b><br><input type="checkbox"/> <b>Specific regions or countries:</b>  |
| <b>5. Title of the notified document:</b> Commission Implementing Regulation (EU) 2020/2120 of 16 December 2020 amending Implementing Regulation (EU) 2016/1964 as regards the authorisation of a preparation of montmorillonite-illite as feed additive for all animal species (Text with EEA relevance). <b>Language(s):</b> English, French and Spanish. <b>Number of pages:</b> 6<br><a href="https://members.wto.org/crnattachments/2021/SPS/EEC/21_0376_00_e.pdf">https://members.wto.org/crnattachments/2021/SPS/EEC/21_0376_00_e.pdf</a><br><a href="https://members.wto.org/crnattachments/2021/SPS/EEC/21_0376_00_f.pdf">https://members.wto.org/crnattachments/2021/SPS/EEC/21_0376_00_f.pdf</a><br><a href="https://members.wto.org/crnattachments/2021/SPS/EEC/21_0376_00_s.pdf">https://members.wto.org/crnattachments/2021/SPS/EEC/21_0376_00_s.pdf</a>   |
| <b>6. Description of content:</b> The use of a preparation of montmorillonite-illite as a feed additive was authorised for all animal species by Commission Implementing Regulation (EU) 2016/1964. In accordance with Article 13 of Regulation (EC) No 1831/2003, the Commission requested the European Food Safety Authority ('the Authority') to issue an opinion on whether the authorisation of a preparation of montmorillonite-illite as a feed additive would still meet the conditions laid down in Article 5 of Regulation (EC) No 1831/2003, considering a modification of the terms of that authorisation. The modification relates to the current authorisation for the use of the additive as anticaking agent in complementary feedingstuffs. The request was accompanied by the relevant supporting data. The Authority concluded in its opinions of 30 October 2014, 10 September 2015 and 20 March 2020 that the proposed modification to the terms of authorisation of the preparation of montmorillonite-illite does not modify the previous conclusions that the additive does not have an adverse effect on animal health, consumer safety or the environment. It also concluded that dust generated during normal handling of the additive has the potential to expose the whole of the respiratory tract of users to harmful substances (crystalline silica) for which no safe levels of exposure have been identified and that in the absence of data on the effects on skin and eyes, must be considered as irritant to skin and eyes and as a potential 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 has also concluded that the additive is efficacious as an anti-caking agent. 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 |

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| <p>additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003. The assessment of the proposed modification to the authorisation shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Implementing Regulation (EU) 2016/1964 should therefore be amended accordingly.</p> |   |
| <b>7.</b>   | <p><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.</p>  |
| <b>8.</b>   | <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> |
| <b>9.</b>   | <p><b>Other relevant documents and language(s) in which these are available:</b></p>  |
| <b>10.</b>  | <p><b>Proposed date of adoption (dd/mm/yy):</b> 16 December 2020</p> <p><b>Proposed date of publication (dd/mm/yy):</b> 17 December 2020</p>  |
| <b>11.</b>  | <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 that of its publication in the Official Journal of the European Union.</p> <p><input checked="" type="checkbox"/> <b>Trade facilitating measure</b></p>   |
| <b>12.</b>  | <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<br/>         DG Health and Food Safety, Unit D2-Multilateral International Relations<br/>         Rue Froissart 101<br/>         B-1049 Brussels<br/>         Tel: +(32 2) 29 54263<br/>         Fax: +(32 2) 29 98090<br/>         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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