



5 September 2025

(25-5566)

Page: 1/2

Committee on Sanitary and Phytosanitary Measures

Original: English

NOTIFICATION

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| 1. | Notifying Member: <u>UNITED STATES OF AMERICA</u> If applicable, name of local government involved: |
| 2. | Agency responsible: Food and Drug Administration (FDA) |
| 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): Preparations of a kind used in animal feeding (HS code(s): 2309); Food technology (ICS code(s): 67) |
| 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: Biomin GmbH; Filing of Food Additive Petition (Animal Use); Notification of Petition. Language(s): English. Number of pages: 2 https://www.federalregister.gov/d/2025-16859 https://members.wto.org/crnattachments/2025/SPS/USA/25_05865_00_e.pdf |
| 6. | Description of content: The Food and Drug Administration (FDA or we) is announcing that we have filed a food additive petition, submitted by Biomin GmbH, proposing that we amend our food additive regulations to provide for the safe use of zearalenone hydrolase to degrade zearalenone in swine food at no less than 10 U/kg complete feed (U = the five-fold enzymatic activity that hydrolyzes 1 mmol zearalenone per minute in a solution of 5 mg/L zearalenone). The food additive petition was filed on 6 August 2025. |
| 7. | Objective and rationale: <input checked="" type="checkbox"/> food safety, <input checked="" 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. | Is there a relevant international standard? If so, identify the standard: <input type="checkbox"/> Codex Alimentarius Commission (e.g. title or serial number of Codex standard or related text): <input type="checkbox"/> World Organization for Animal Health (OIE) (e.g. Terrestrial or Aquatic Animal Health Code, chapter number): <input type="checkbox"/> International Plant Protection Convention (e.g. ISPM number): <input checked="" type="checkbox"/> None Does this proposed regulation conform to the relevant international standard? <input type="checkbox"/> Yes <input type="checkbox"/> No If no, describe, whenever possible, how and why it deviates from the international standard: |

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| 9. | Other relevant documents and language(s) in which these are available: |
| 10. | Proposed date of adoption (dd/mm/yy): Not applicable Proposed date of publication (dd/mm/yy): Not applicable |
| 11. | Proposed date of entry into force: [] Six months from date of publication, and/or (dd/mm/yy): Not applicable [X] Trade facilitating measure |
| 12. | Final date for comments: [] Sixty days from the date of circulation of the notification and/or (dd/mm/yy): Not applicable Agency or authority designated to handle comments: [X] National Notification Authority, [] National Enquiry Point. Address, fax number and e-mail address (if available) of other body: <p>For access to the docket to read background documents or comments received, go to https://www.regulations.gov and insert the docket number found in brackets in the heading of this document into the "Search" box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.</p> <p>For further information contact: Lauren Howell, Center for Veterinary Medicine, Food and Drug Administration, 5001 Campus Drive, College Park, MD 20740, +(240) 402 8012, E-mail: Lauren.Howell@fda.hhs.gov</p> |
| 13. | Text(s) available from: [] National Notification Authority, [] National Enquiry Point. Address, fax number and e-mail address (if available) of other body: <p>Text can be found in the Federal Register, Vol. 90, No. 168, Page 42550 or on the Internet at: https://www.federalregister.gov/d/2025-16859</p> |