



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

[Docket No. FDA-2020-F-1275]

Food Additives Permitted in Feed and Drinking Water of Animals; Fumonisin Esterase

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, we, or the Agency) is amending the regulations for food additives permitted in feed and drinking water of animals to provide for the safe use of fumonisin esterase to degrade fumonisins present in swine feed. This action is in response to a food additive petition filed by Biomin GmbH.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. See section V of this document for further information on the filing of objections. Either electronic or written objections and requests for a hearing on the final rule must be submitted by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit objections and requests for a hearing as follows. Please note that late, untimely filed objections will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Objections received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic objections in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting objections. Objections submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your objection will be made public, you are solely responsible for ensuring that your objection does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your objection, that information will be posted on <https://www.regulations.gov>.
- If you want to submit an objection with confidential information that you do not wish to be made available to the public, submit the objection as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper objections submitted to the Dockets Management Staff, FDA will post your objection, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2020-F-1275 for "Food Additives Permitted in Feed and Drinking Water of Animals; Fumonisin Esterase." Received objections, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at

<https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit an objection with confidential information that you do not wish to be made publicly available, submit your objections only as a written/paper submission. You should submit two copies in total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of objections. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your objections and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper objections 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, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Wasima Wahid, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl. (HFV-221), Rockville, MD 20855, 240-402-5857, wasima.wahid@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In a document published in the *Federal Register* of May 6, 2020 (85 FR 26902), FDA announced that we had filed a food additive petition (animal use) (FAP 2311) submitted by Biomin GmbH, Erber Campus 1, 3131 Getzersdorf, Austria. The petition proposed that the regulations for food additives permitted in feed and drinking water of animals be amended to provide for the safe use of fumonisin esterase to degrade fumonisins present in swine feed.

II. Conclusion

FDA concludes that the data establish the safety and utility of fumonisin esterase to degrade fumonisins in swine feed, and that the food additive regulations should be amended as set forth in this document.

III. Public Disclosure

In accordance with § 571.1(h) (21 CFR 571.1(h)), the petition and documents we considered and relied upon in reaching our decision to approve the petition will be made available for public disclosure (see FOR FURTHER INFORMATION CONTACT). As provided in § 571.1(h), we will delete from the documents any materials that are not available for public disclosure.

IV. Analysis of Environmental Impact

We have determined under 21 CFR 25.32(r) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Objections and Hearing Requests

Any person who will be adversely affected by this regulation may file with the Dockets Management Staff (see ADDRESSES) either electronic or written objections. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provision of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection.

List of Subjects in 21 CFR Part 573

Animal feeds, Food additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 573 is amended as follows:

PART 573--FOOD ADDITIVES PERMITTED IN FEED AND DRINKING WATER OF ANIMALS

1. The authority citation for part 573 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348.

2. Add § 573.485 to subpart B to read as follows:

§ 573.485 Fumonisin esterase.

The food additive fumonisin esterase may be safely used to degrade fumonisins in swine feed in accordance with the following prescribed conditions:

(a) Fumonisin esterase, a carboxylesterase, is produced by a nontoxigenic and nonpathogenic yeast, *Komagataella phaffii*, genetically engineered to express the fumonisin esterase gene from the bacterium *Sphingopyxis* sp. Hydrolyzed fumonisin and two tricarballic

acid molecules are the reaction products of fumonisin hydrolysis by this 493 amino acid fumonisin esterase enzyme.

(b) The additive shall meet the following specifications:

(1) The fermentation media for the *Komagataella phaffii* shall not contain methanol.

(2) Viable genetically engineered *Komagataella phaffii* shall not be present.

(3) One unit of fumonisin esterase activity is defined as the amount of enzymatic activity required to release one micromole of tricarballic acid (CAS 99-14-9) per minute from 100 micromolar fumonisin B1 in 20 millimolar Tris-hydrochloride buffer (pH 8.0) containing 0.1 milligram per milliliter of bovine serum albumin at 30 °C.

(c) The additive is incorporated at a minimum of 15 units of fumonisin esterase activity per kilogram of complete swine feed that cannot contain more than 10 parts per million of total fumonisins.

(d) To assure safe use of the additive, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act:

(1) The label and labeling of the additive, any feed premix, and complete feed shall contain the common or usual name of the additive's source, dried *Komagataella phaffii* fermentation product.

(2) The label and labeling of the additive and any feed premix shall also contain:

(i) Adequate directions for use including a statement that the additive must be uniformly applied and thoroughly mixed into complete feeds;

(ii) A guarantee for the minimum amount of fumonisin esterase activity, expressed in accordance with paragraph (b)(3) of this section, and the unit of weight being consistent with the inclusion rate stated in the directions for use;

(iii) Appropriate warning and safety precaution statements concerning the additive as a respiratory sensitizer;

(iv) A cautionary statement concerning the maximum fumonisin content as established in paragraph (c) of this section.

Dated: July 29, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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