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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 66

[Document No. AMS-FTPP-19-0104]

National Bioengineered Food Disclosure Standard; Validation of Refining Processes

ACTION: Request for comments.

SUMMARY: The Agricultural Marketing Service (AMS) of the Department of Agriculture (USDA) is soliciting comments and feedback on draft instructions for validation of refining processes as it pertains to the National Bioengineered Food Disclosure Standard (Standard).

DATES: Comments are due by **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: We invite you to submit written comments via the internet at <http://www.regulations.gov>. All comments should refer to the date and page number of this issue of the **Federal Register**. All comments submitted in response to this notice, including the identity of individuals or entities submitting comments, will be made available to the public on the internet via <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Trevor Findley, Deputy Director, Food Disclosure and Labeling Division, Fair Trade Practices Program, Agricultural Marketing Service, U.S. Department of Agriculture, telephone (202) 690-3460, email trevor.findley@usda.gov.

SUPPLEMENTARY INFORMATION:

Background

On July 29, 2016, Public Law 114-216 amended the Agricultural Marketing Act of 1946 (7 U.S.C. 1621 *et. seq.*) (amended Act) to require USDA to establish a national, mandatory standard for disclosing any food that is or may be bioengineered. In accordance with the amended Act, USDA published final regulations to implement the Standard on December 21, 2018 (83 FR 65843). The regulations became effective on February 19, 2019, with a mandatory compliance date of January 1, 2022.

Foods that do not contain detectable modified genetic material are not bioengineered foods and do not require disclosure under the Standard. Under the definition of *bioengineered food* at 7 CFR 66.1, food does not contain modified genetic material if the genetic material is not detectable pursuant to § 66.9. The recordkeeping requirements for detectability at 7 CFR 66.9 specify the requirements for validating that a refining process renders modified genetic material in a food undetectable. A refining process is validated through analytical testing that meets the standards described in paragraph (c) of 7 CFR 66.9. Paragraph (c) requires that analytical testing meet the following standard: (1) laboratory quality assurance must ensure the validity and reliability of test results; (2) analytical method selection, validation, and verification must ensure that the testing method used is appropriate (fit for purpose) and that the laboratory can successfully perform the testing; (3) the demonstration of testing validity must ensure consistent accurate analytical performance; and (4) method performance specifications must ensure analytical tests are sufficiently sensitive for the purposes of the detectability requirements of this part.

In the preamble to the final regulations, USDA indicated it would provide instructions to the industry to explain how they can ensure acceptable validation of

refining processes in accordance with AMS standards (83 FR 65843). A draft of those instructions is now available on the AMS bioengineered food disclosure website at <https://www.ams.usda.gov/rules-regulations/be>. With this notice, AMS is seeking comments on these draft instructions. USDA will provide further instructions on testing method selection at a later date. At this time, we are only seeking feedback on the validation instructions referenced in this notice. Any comments not directly related to these draft instructions will not be considered.

After reviewing the comments on these draft instructions, AMS will publish final instructions on its website. The final instructions will be maintained and available on the AMS web site. These final instructions pertain to the requirements of the existing regulations, which can be found at

<https://www.federalregister.gov/documents/2018/12/21/2018-27283/national-bioengineered-food-disclosure-standard>.

(Authority: 7 U.S.C. 1639)

Dated: December 10, 2019.

Bruce Summers,

Administrator,

Agricultural Marketing Service.

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