Rules and Regulations

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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; Guidance on Validation of a Refining Process and Selecting a Testing Method

ACTION: Notification of guidance.

SUMMARY: The Agricultural Marketing Service (AMS) of the Department of Agriculture (USDA) posts final guidance to validate a refining process and selects a testing method as it pertains to the National Bioengineered Food Disclosure Standard (Standard).

DATES: The guidance documents are available and effective July 7, 2020.

ADDRESSES: The final guidance and accompanying question and answer documents can be found at *https:// www.ams.usda.gov/rules-regulations/be.*

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 65814). 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, among other things, (1) the requirements to validate that a refining process renders modified genetic material in a food undetectable and (2) standards of performance for detectability testing.

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 Part 66.

In the preamble to the final regulations, USDA indicated that it would provide instructions to the industry to explain how they can ensure (1) acceptable validation of refining processes in accordance with AMS standards and (2) acceptable testing methodology used to satisfy that a food does not contain detectable modified genetic material (83 FR 65843).

On December 17, 2019, AMS published a document in the **Federal Register** announcing the publication of a draft Instruction to Ensure Acceptable Validation of Refining Processes (84 FR 68816), with a comment period that closed on January 16, 2020. On January 23, 2020, in response to multiple requests for an extension of the comment period, AMS extended the comment period another 15 days (85 FR 3860). The new comment period closed on February 7, 2020.

On February 3, 2020, AMS published a document in the **Federal Register** announcing publication of Draft Instructions on Testing Methods (85 FR 5927), with a comment period that closed on March 4, 2020.

This document announces the publication of the final guidance to validate a refining process and to select an acceptable testing method. In addition to these two guidance documents, AMS is publishing two corresponding question and answer documents that respond to a number of questions and comments it received during the public comment periods. These four documents are available on the AMS bioengineered food disclosure website at *https://www.ams.usda.gov/ rules-regulations/be.* 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.

Bruce Summers,
Administrator, Agricultural Marketing Service.

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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 930

[Doc. No. AMS–SC–19–0100; SC–20–930–1 FR]

Tart Cherries Grown in the States of Michigan, et al.; Free and Restricted Percentages for the 2019–20 Crop Year

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This rule implements a recommendation from the Cherry Industry Administrative Board (Board) to establish free and restricted percentages for the 2019–20 crop year pursuant to the marketing order for tart cherries grown in the states of Michigan, New York, Pennsylvania, Oregon, Utah, Washington, and Wisconsin. This action establishes the proportion of tart cherries from the 2019–20 crop that may be handled in commercial outlets. This action should stabilize marketing conditions by adjusting supply to meet market demand and help improve grower returns. Also, a correction is made to section 930.151 to reflect the correct desirable carry-out inventory not