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MEMORANDUM

From: Martin J. Hahn
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Re: **AMS Releases Draft Instructions on Testing Methods for the National Bioengineered Food Disclosure Standard**

The U.S. Department of Agriculture's (USDA's) Agricultural Marketing Service (AMS) has released Draft Instructions on Testing Methods (Draft Instructions) for use in compliance with the National Bioengineered Food Disclosure Standard (NBFDS). 1/ The document provides guidance on the selection of a test method that may be used to ascertain that a highly refined food or ingredient does not contain detectable modified genetic material and therefore does not require disclosure that the food is bioengineered. The Draft Instructions address selecting a test method that is "fit for purpose"; current DNA-based test methods; emerging technology; selection of a test laboratory; and recordkeeping requirements. Comments on the Draft instructions are due by March 4, 2020 and must be submitted to Docket Number AMS-FTPP-19-0112.

Background

On July 29, 2016, Congress established the National Bioengineered Food Disclosure Act, establishing a national standard for disclosing that a food is or may be bioengineered (BE disclosure). In its regulations implementing the new law, AMS defined a "bioengineered food" as "A food that contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (rDNA) techniques and for which the modification could not otherwise be obtained through conventional breeding or found in nature; Provided that such a food does not contain modified genetic material if the genetic material is not detectable pursuant to § 66.9." In other words, a food is not a bioengineered food and does not require a BE disclosure if it does not contain detectable amounts of modified genetic material.

AMS's NBFDS regulations provide that modified genetic material is not detectable if the entity that would be responsible for making the BE disclosure for a food maintains records showing the food has been subjected to a refinement process validated to make the modified genetic material in the food undetectable. The regulations at 7 C.F.R. § 66.9(c) require that analytical testing that meets

1/ National Bioengineered Food Disclosure Standard: Draft Instructions on Testing Methods, 85 Fed. Reg. 5927 (Feb. 3, 2020).

the following standards must be used to validate that a refining process renders modified genetic material in a food undetectable:

1. Laboratory quality assurance must ensure the validity and reliability of the test results;
2. Analytical method selection, validation, and verification must ensure that the testing method used is appropriate and that the laboratory can successfully perform the testing;
3. The demonstration of testing validity must ensure consistent accurate analytical performance; and
4. Method of performance specifications must ensure analytical tests are sufficiently sensitive for the purposes of the detectability requirements of the regulations.

AMS's Draft Instructions are intended to assist entities in selecting a test methodology that satisfies these criteria.

AMS Instructions for Testing Methods

The Draft Instructions provide the following guidance concerning detectability testing.

- **Selecting a "Fit for Purpose" Test Method:** AMS advises that entities should ensure a test method is "fit for purpose," meaning it is suitable to provide an answer as to whether a food contains modified genetic material. AMS identifies the following factors as critical for ensuring a method is fit for purpose:
    - The method's appropriateness for the analyte of interest;
    - Whether the method is validated for the product or commodity being tested;
    - The accuracy, precision, robustness, reliability, and reproducibility of the method;
    - Whether the value of measurement falls within the method's accurate range (i.e., an appropriate Limit of Detection and Limit of Quantitation); and
    - The method's accessibility and practicality.

  AMS also advises that entities should either use methods validated by accepted international bodies or validate their own methods to detect modified genetic material, and the agency provides resources for developing an analytical scheme to determine the presence and nature of rDNA in a food or ingredient.

- **DNA-Based Test Methods:** AMS acknowledges that at this time, polymerase chain reaction (PCR) is the most widely used and commercially accepted test method for determining whether modified genetic material is detectable in a food or ingredient. The guidance states that quantitative PCR, which identifies how much modified DNA is detectable, is preferred. However, either quantitative or qualitative PCR, which verifies the presence or absence of modified genetic material, is acceptable. AMS notes that for some matrices, broad-spectrum PCR may not be capable of detecting all single or multiple-genetic modification events, and in such circumstances event-specific or construct-specific PCR tests may be necessary. Notably, AMS states that in some instances, PCR may not be fit for purpose to test for detectable modified genetic material in a highly processed food product that consists almost exclusively of lipids or sugars that can inhibit the PCR reaction.

- **Emerging Technologies and Other Technologies:** While PCR is used most commonly, AMS states that any other DNA-based method or emerging that meets the criteria in 7 C.F.R. § 66.9(c) and is fit for purpose for detecting modified genetic material may be used.

- **Laboratory Selection:** AMS encourages selection of a laboratory that adheres to the ISO 17025 standard, along with the requirements in 7 C.F.R. § 66.9(c).

- **Recordkeeping Requirements:** AMS identifies the following as examples of customary or reasonable records that entities could use to demonstrate compliance with the disclosure requirements as they relate to detectability testing: supply chain records, supplier attestations, third-party certifications, laboratory testing results, validated process verifications, and other records generated in the normal course of business. Entities also may maintain certificates of analysis or other records of testing that confirm the absence of modified genetic material. AMS notes that records should include details corresponding with the factors for assessing whether a test method is fit for purpose. The guidance explains that if AMS conducts an audit or examination under 7 C.F.R. § 66.402, the agency does not intend to conduct independent testing of food products, but will look at a regulated entity's ingredient-specific records.

We encourage companies to review the AMS guidance and submit comments on the document. The Draft Instructions are notable in that they could be interpreted as suggesting that if a validated test method does not already exist to detect modified genetic material in a food, such as for foods for which PCR is not an appropriate test method, then regulated entities are responsible for developing and validating a new method. Such an interpretation would impose a new burden on entities not established in the NBFDS regulations.

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We will continue to monitor AMS's implementation of the NBFDS. Should you have any questions or require assistance validating a refining process, please do not hesitate to contact us.