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# MEMORANDUM

**From**: Martin J. Hahn
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**Re**: **AMS Releases Draft Instructions on Validating a Refining Process for National Bioengineered Food Disclosure Standard**

The U.S. Department of Agriculture's (USDA's) Agricultural Marketing Service (AMS) is seeking public comment on draft instructions to validate a refining process under the National Bioengineered Food Disclosure Standard (NBFDS). 1/ Validated refining processes can be used to demonstrate a food does not contain detectable modified genetic material and therefore does not require a disclosure under the NBFDS. We apologize for the delay in issuing this summary. AMS released the document prior to the holidays and only provided a 30 day comment period. Comments on the draft instructions are due by January 16, 2020.

## 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. Once a refining process has been validated, additional testing (e.g., regular certificates of analysis) would not be necessary to confirm the absence of detectable modified genetic material in the food, provided no significant changes are made to the validated process and

1/ National Bioengineered Food Disclosure Standard: Validation of Refining Processes, 84 Fed. Reg. 68816 (Dec. 17, 2019).

provided records are maintained to demonstrate the refining process has been validated and that the validated refining process is followed.

To validate that a refining process renders modified genetic material in a food undetectable, the AMS regulations require that detectability testing satisfying the following standards:

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 also stated in the preamble to the final rule that it would provide additional instructions industry can use to ensure acceptable validation of refining processes in compliance with the regulations.

**AMS Instructions for Validating Refining Processes**

The draft instructions lay out the following general steps to validate a refining process:

1. Identify raw materials, ingredients, and product-contact materials.

2. Define characteristics and intended end use of the product (i.e., that genetic material is not detectable).

3. Define the sequence and interaction of all processing steps used to arrive at the end product.

4. Identify all control measures (i.e., critical process steps) that may influence the end product's characteristics and its ability to meet specified requirements. AMS states that these include any action or activity that could prevent, reduce, or eliminate the ability to meet specified requirements.

5. Select measurable critical control points (CCPs) where control measures can be evaluated for meeting the specified requirements. It should be determined when and how CCPs will be measured to validate genetic material is rendered undetectable.

6. Assemble relevant information to determine if control measures operate as intended to meet specified requirements, conducting studies as needed.

    6a. Validation. Collect evidence or data to demonstrate that defined operational activities consistently and effectively meet specified requirements. AMS explains that this can be done through a variety of approaches, including reference to scientific or technical literature or previous validation studies; experimental data applicable to in-plant operations; applied data obtained during operational conditions; mathematical modelling; and surveys.

    6b. Verification. Confirm, through objective evidence, that the validated process meets or continues to meet the specified requirements. This means applying tests or other evaluations, in addition to monitoring, to determine whether a control measure is or has been operating as intended. AMS explains that verification occurs at initial validation and

on an ongoing basis as a process check. AMS identified analytical testing as an initial verification method. The agency notes that laboratory methods of analysis for ultra-refined processed foods such as oils and sugars need to be carefully considered. AMS cautions that genetic material could be removed (absent) or difficult to detect and the chemical and physical characteristics of the matrix may cause interferences, potentially rendering classical polymerase chain reaction (PCR) techniques inappropriate, in which case indirect measurement may be more appropriate. AMS, however, does not define what it means by an indirect measure. The agency identifies observation of monitoring activities, review of records, and potentially ongoing analytical tests as examples of ongoing verification tools.

6c. Monitoring. Planned observations or measurements should be conducted to continually assess whether control measures are operating as intended and validated. AMS explains that for ongoing monitoring, measurements will need to be continually recorded to demonstrate the control measures occurred as validated.

6d. Re-validation. Re-validation would be necessary if significant changes are made to the validated process or process deviations occur.

7. Document and analyze the validation data to determine if the process will produce an end product that consistently meets specified requirements and maintain records of the validation.

AMS also notes in the draft instructions that once a refining process has been validated, that specific process does not require re-validation by others, so long as the specific process is followed and appropriate records are maintained. In other words, validated processes are not unique to specific manufacturers.

We would encourage companies to review the AMS document closely and submit comments on the document. Notably, AMS drafted the document in a way that would suggest there is a single step in a refining process that could be responsible for eliminating rDNA and would require companies to treat such a process as a CCP. Because CCPs are reserved for food safety, it would seem appropriate to use different terminology. More importantly, we question the advisability of requiring the entity to identify the specific step or steps in the process that are responsible for eliminating the rDNA, because rDNA could be removed at multiple steps in the process. If the process has been validated to remove rDNA—by data showing no detectable levels of rDNA—the final regulation presumably would deem the process validated.

Moreover, AMS introduces the concept of verification testing, which could be viewed as suggesting AMS believes continued testing is necessary to verify the refining method continues to produce non-detectable levels of rDNA. Such a position is seemingly at odds with the final regulation and the statement in the preamble that once a process has been validated to result in non-detectable levels of rDNA, no further analysis should be necessary.

Another potentially confusing aspect of the guidance involves the statement that PCR testing may be inappropriate in some instances and that “indirect measures” may be more appropriate. It is unclear what types of “indirect measures” are being contemplated by AMS. Because the final regulation requires a food to contain detectable levels of rDNA to fall within the definition of a BE Food, it would seem a food only can be deemed BE if there is a method of analysis that can detect and confirm the presence of rDNA in the product. It is unclear how an indirect method could be used to document detectable levels of rDNA.

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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.