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Food & Beverage ADVISORY ■

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USDA AMS Issues Bioengineered Food Disclosure Testing and Validation Guidance

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As mandated by Congress in 2016, the U.S. Department of Agriculture's (USDA) Agricultural Marketing Service (AMS) published its final rule in December 2018 establishing the National Bioengineered Food Disclosure Standard (NBFDS). The regulations can be found at 7 C.F.R. Part 66. The NBFDS requires manufacturers, importers, and certain retailers to disclose the presence of bioengineered (BE) food or food that contains BE food ingredients on products labeled for U.S. retail sale. All foods entering commerce after January 1, 2022 must be labeled in compliance with the NBFDS.

The mandatory disclosure requirement applies to both human food subject to the labeling requirements under the Federal Food, Drug, and Cosmetic Act and some products under the jurisdiction of the USDA's Food Safety and Inspection Service. There are express exemptions to the disclosure requirement in the regulations, including: (1) food served in a restaurant or similar retail food establishment; (2) very small food manufacturers; (3) a threshold for inadvertent or technically unavoidable presence of BE substances of up to 5% for each ingredient; and (4) food certified under AMS's National Organic Program. Also, under the regulations, food derived from an animal cannot be considered a BE food solely because the animal consumed feed produced from, containing, or consisting of a BE substance.

What Is Bioengineered Food?

AMS's regulations define "bioengineered food," in part, 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." In addition to removing incidental additives from the definition of BE food, AMS has also excluded food that "does not contain modified genetic material if the genetic material is not detectable pursuant to [specific standards]" from the definition of BE food, and therefore from the scope of the NBFDS. The steps for demonstrating that a food or ingredient does not contain detectable modified genetic material is the subject of AMS's guidance documents.

To aid regulated entities considering whether they need to make a BE food disclosure, AMS has developed a List of Bioengineered Foods. If a regulated entity uses a food or an ingredient produced from food that is on the List of Bioengineered Foods, the entity's records will determine whether the food must bear a BE food disclosure. The list is not exhaustive, so entities are still required to disclose BE foods if they have actual knowledge that the food is BE.

AMS's Final Guidance on Validation of a Refining Process and Detectability Testing

If the genetic material in a food or ingredient is not detectable, under AMS's regulations, the food is not BE and therefore disclosure is not required. This concept may be especially important in determining whether some refined ingredients produced from those on the List of Bioengineered Food (e.g., high fructose corn syrup, canola oil) are exempt from the disclosure requirement. There are three ways under the regulations to demonstrate modified genetic material is not detectable: (1) records verify the food is sourced from a non-BE crop or source; (2) records verify food has been subjected to a refinement process "validated" to make modified genetic material undetectable; or (3) testing records confirm the absence of modified genetic material. The regulations also set out general standards of performance that must be followed if using analytical testing, including that the testing method used is fit for the purpose and testing validity ensures consistent accurate analytical performance.

On July 2, 2020, AMS released final guidance documents and associated FAQs on both validation of a refinement process and testing methods, Guidance to Ensure Acceptable Validation of a Refining Process and Guidance on Testing Methods.

Validation of a refining process

The 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. AMS's guidance on validation includes the following general steps to validate a refinement process: (1) identify raw materials, ingredients, and product-contact materials; (2) define characteristics and the intended use of the end product; (3) define the sequence and interaction of all processing steps used to arrive at the end product; (4) identify key steps in the refinement process that may influence the end product's characteristics and its ability to meet specified requirements; (5) assemble validation information that demonstrates the refinement process operates as intended to meet specific requirements (end-product characteristics), conducting studies as needed; (6) continually verify the refinement process is operating as validated; (7) revalidate the refinement process, as applicable, if significant changes are made to the process; and (8) maintain records of the validation and ongoing verification.

Key takeaways:

- The identification of the key steps in the refinement process, which may include the entire process, is crucial. This is the step in the process that renders modified genetic material undetectable. Also important is determining what parameters (e.g., time, temperature) and decision criteria (e.g., limits) make it a key step.

- While end-product testing is one way to validate that a refining process used to create an ingredient renders any modified genetic material undetectable, AMS does not establish a specific threshold of minimal detection for rDNA.
- Validation refers to the process, not the facility where the process occurs. Therefore, once a process has been validated, another manufacturer does not need to revalidate that process if completed in a different facility.
- Continued verification that the refinement process is operating as validated is required.
- Significant changes to the validated refinement process that could impact the process's ability to meet the specified requirements will need to be revalidated.

Detectability testing

The 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 certificates of analysis or other records of testing appropriate to the specific food that confirm the absence of modified genetic material. AMS's guidance on testing methodology provides basic instructions that address: (1) selecting a test method; (2) DNA-based methods; (3) emerging technologies and other methods; (4) general considerations in selecting a laboratory; and (5) recordkeeping requirements.

Key takeaways:

- When considering a test method, AMS has deemed it critical that the method be appropriate (validated) for the product/commodity being tested. Therefore, if a test method does not already exist to detect modified DNA in a particular ingredient or food, developing and validating a new method for that ingredient or commodity will likely be required.
- AMS indicates that broad-spectrum tests may not be sufficient to detect genetic modifications, and industry may consider event-specific testing in some instances. Event-specific polymerase chain reaction (PCR) testing could be burdensome for industry since some commodities, like soy and corn, have multiple commercialized events.
- AMS does not identify a sample size requirement for testing and instead defers to a Codex Alimentarius guideline on validation criteria. In addition to determining an appropriate sample size, it will also be important to consider how often testing should be conducted for a given ingredient or food.
- If there is a complaint that a BE food was not properly disclosed, AMS indicates that it will not be testing foods to determine compliance. Rather, the regulated entity's ingredient-specific records will be the focus of its inquiry.

Next Steps for Regulated Entities

As the January 1, 2022 mandatory compliance date approaches, manufacturers, importers, and retailers should work to develop a compliance strategy, taking into account both the flexibilities provided under the NBFDS and the potential enforcement and litigation risk that lies ahead.

An effort to evaluate each product's BE status is a good starting point. Are existing records sufficient, or is additional information needed from your suppliers to make this determination? If you are relying on testing records or records involving a validated refinement process to demonstrate that a product is not required to bear a BE food disclosure, what testing or validation is complete, and was it performed in accordance with AMS guidance? If not, is any additional testing or validation needed? Once a determination is made that a food requires a BE food disclosure, what disclosure option (text, symbol, electronic/digital link, or text) will be used? If mandatory disclosure is not required, is the "derived from bioengineering" voluntary disclosure applicable? And ultimately, is a recordkeeping system in place to ensure continued compliance with the NBFDS?

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