

USDA Publishes Final BE Guidance Documents On Validation and Detectability Testing

Article By:

Food and Drug Law at Keller and Heckman

The USDA's Agricultural Marketing Service (AMS) [issued](#) final guidance to assist regulated entities in complying with the National Bioengineered Food Disclosure Standard (NBFDS). By the mandatory compliance date of January 1, 2022, regulated entities will need to disclose whether food offered for retail sale is bioengineered (BE) or contains BE ingredients. The final guidance discusses two possible ways entities can show their products do not contain BE material and thus avoid disclosure: (1) verifying that the food has been subjected to a refinement process validated to make the modified genetic material in the food undetectable (7 CFR 66.9(b)), and (2) utilizing acceptable testing methods to confirm the absence of modified genetic material (7 CFR 66.9(c)).

The [Guidance to Ensure Acceptable Validation of a Refining Process](#) outlines eight general steps: (1) identify raw materials, ingredients, and product-contact materials; (2) define characteristics and intended use of end product; (3) define the sequence and interaction of all processing steps used to arrive at the end product; (4) identify key step(s) in the refinement process that may influence the end product's characteristics and its ability to meet specified requirements; (5) assemble relevant validation information that demonstrates the refinement process operates as intended to meet specified 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 record(s) of the validation and ongoing verification.

As our readers may [recall](#), we previously covered the draft instructions for acceptable testing methods to confirm the absence of detectable modified genetic material. The final [Guidance on Testing Methods](#) is largely similar, and addresses five main topics: (1) general considerations in 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.

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[validation-and-detectability-testing](#)