Overview of the National Bioengineered Food Disclosure Standard Guidance Documents

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Presentation Outline

- Bioengineered food definition
- Detectability
- Guidance to Ensure Acceptable Validation of a Refining Process
- Guidance on Testing Methods

Definition of Bioengineered Food

- A food that contains genetic material that has been modified through *in vitro* rDNA techniques and for which the modification could not otherwise be obtained through conventional breeding or found in nature.

What is **not** a bioengineered food?

- Foods in which the modified genetic material is not detectable are not bioengineered foods.

- Food subject to certain factors and conditions are not bioengineered foods (*i.e.*, incidental additives).

Detectability

- Modified genetic material is not detectable if:
  1. Records verify the food is made from a non-bioengineered food; or
  2. **Records verify that the food has been refined using a process validated to render the modified genetic material undetectable; or**
  3. **Testing records for the specific food confirm the absence of detectable modified genetic material.**

Guidance to Ensure Acceptable Validation of a Refining Process

- AMS published final guidance on refining process method validation on July 7, 2020
- The guidance includes 8 General Steps to Validate a Refinement Process

Key Steps to Validate a Refinement Process

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 or steps in the refinement process that may influence the end product’s characteristics and its ability to meet specified requirements

Key Steps to Validate a Refinement Process

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
8. Maintain record(s) of the validation and ongoing verification

Guidance on Testing Methods

- AMS published final guidance on testing methods on July 7, 2020
- The guidance includes 5 Key Concepts

Key Steps in Selecting a Test Method

1. General considerations in selecting a test method
2. DNA-based test methods
3. Emerging technologies and other methods
4. General consideration in selecting a laboratory
5. Recordkeeping requirements

Useful Resources

ISO 16393. (2019). Molecular biomarker analysis – Determination of the performance characteristics of qualitative measurement methods and validation of methods.

ISO 17025. (2017). General requirements for the complete testing and calibration laboratories.

ISO 24276 (2006). Foodstuffs- Method of analysis for the detection of genetically modified organisms and derived products-General requirements and definitions.

ISO 21568 (2005). Foodstuffs- Method of analysis for the detection of genetically modified organisms and derived products-Sampling.

ISO 21569 (2005). Foodstuffs- Method of analysis for the detection of genetically modified organisms and derived products-Qualitative nucleic acid based methods.

ISO 21570 (2005). Foodstuffs- Method of analysis for the detection of genetically modified organisms and derived products-Quantitative nucleic acid based methods.

ISO 21571 (2005). Foodstuffs- Method of analysis for the detection of genetically modified organisms and derived products-Nucleic acid extraction.

Codex Alimentarius Commission. (2009). Guidelines on analytical terminology, CAC/GL 72-2009.

Codex Alimentarius Commission. (2010). Guidelines on performance and validation of methods for detection, identification and quantification of specific DNA sequences and specific proteins in foods. CAC/GL 74-2010

Thank You!

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