



Overview of USDA's National Bioengineered Food Disclosure Standard

**Dr. Sonja Jones, Food Technologist
Food Disclosure and Labeling Division
USDA-AMS**



Presentation Outline

- I. Regulated Entities
- II. Bioengineered Foods
- III. Foods Subject to the Standard
- IV. Disclosure Options
- V. Compliance & Enforcement



Public Law 114-216



The law amended the Agricultural Marketing Act of 1946 and was signed on July 29, 2016.

The Law directs the Secretary to establish the National Bioengineered Food Disclosure Standard for disclosing bioengineered food and food that may be bioengineered.



Regulated Entities

Regulated Entities

1. Food Manufacturers
2. Importers
3. Retailers who:
 - Package and label food for retail sale or
 - Sell bulk food items

Does not include:

- Restaurants and similar retail food establishments
- Very small food manufacturers (< \$2,500,000 annual receipts)

Suppliers' Role

Suppliers are not a regulated entity

- The regulated entities (i.e., retailers, manufacturers) that suppliers ship ingredients to may request records from suppliers so that they can comply with the law

Any requirements or requests from a regulated entity to their supplier are governed by private contracts and relationships that are not regulated by the Standard



Bioengineered Foods

Bioengineered Food Definition

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.

- Food subject to certain factors and conditions are not bioengineered foods (i.e., incidental additives).
- Foods in which the modified genetic material is not detectable are not bioengineered foods.

Factors or Conditions

USDA adopted incidental additives as a factor or condition.

- Incidental additives, when used in accordance with 21 CFR 101.100(a)(3), are not bioengineered foods or ingredients and do not trigger the need for disclosure.

Detectability

Modified genetic material is not detectable if:

- 1) Records verify the food is made from a non-bioengineered food;
- 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.

Highly Refined Ingredients

Ingredients derived from a food on the List

- An ingredient that is derived from a food on the List is a bioengineered food if the ingredient contains detectable modified genetic material.
 - If the highly refined ingredient (canola oil, soybean oil, etc.) contains detectable modified genetic material, then it is considered a bioengineered food ingredient and does require a BE disclosure.
 - If records show that the highly refined ingredient does not contain detectable modified genetic material, then a BE disclosure is not required.



What is the difference between BE and GMO?

Genetically modified foods and bioengineered foods are not the same.

- “Bioengineered food” is a term defined in the Standard at 7 CFR 66.1
 - Among other things, the phrase “bioengineered food” describes food that contains genetic material that has been modified through certain plant breeding techniques and that could not otherwise be obtained through conventional breeding or found in nature.
- Genetically modified food is a phrase that is not well-defined, but may be used by the general public, food manufacturers, retailers, third-party certifiers, and others, to describe foods produced through certain types of plant breeding techniques.



List of Bioengineered Foods

- Alfalfa
- Apple (Arctic™ varieties)
- Canola
- Corn
- Cotton
- Eggplant (BARI Bt Begun varieties)
- Papaya (ringspot virus-resistant varieties)
- Pineapple (Pink flesh varieties)
- Potato
- Salmon (AquAdvantage®)
- Soybean
- Squash (summer)
- Sugarbeet

Updating the List

Foods that meet the definition of a bioengineered food are added to this List through the Notice and Comment Rulemaking Process, if they meet the following criteria:

1. The food is approved for commercial production **and**
2. The food is currently in legal production somewhere in the world

AMS discovers new BE crops/animals to add to the List through a variety of sources

- Interagency communications/reports (FAS, FDA, APHIS, etc.)
- News articles
- International Government agricultural websites
- Requests for Information
- BE Inbox

Does the USDA certify food to be bioengineered, or non-bioengineered?

- No, USDA does not certify foods to be bioengineered or non-bioengineered.
- The Standard requires disclosure for foods that are or may be bioengineered and does not require any claims to be made about the absence of bioengineered food ingredients.
- The Standard, at 7 CFR 66.118, does allow other claims to be made about bioengineered foods, provided that such claims are consistent with applicable Federal law.

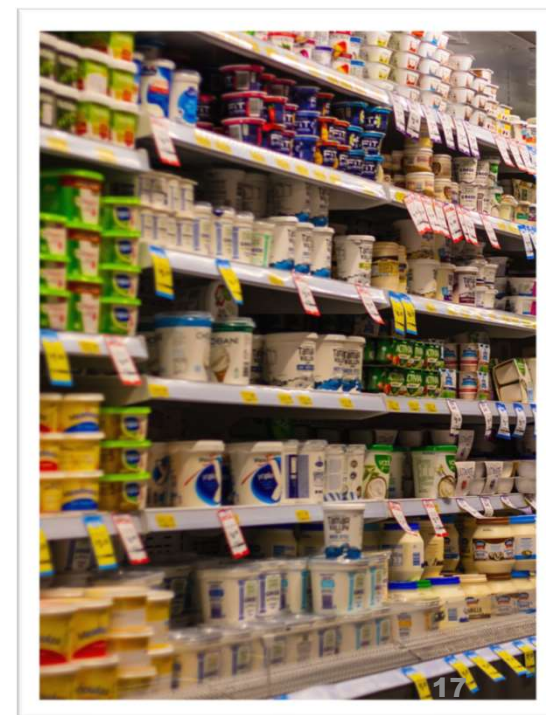


Foods Subject to the Standard

Foods Subject to the Standard

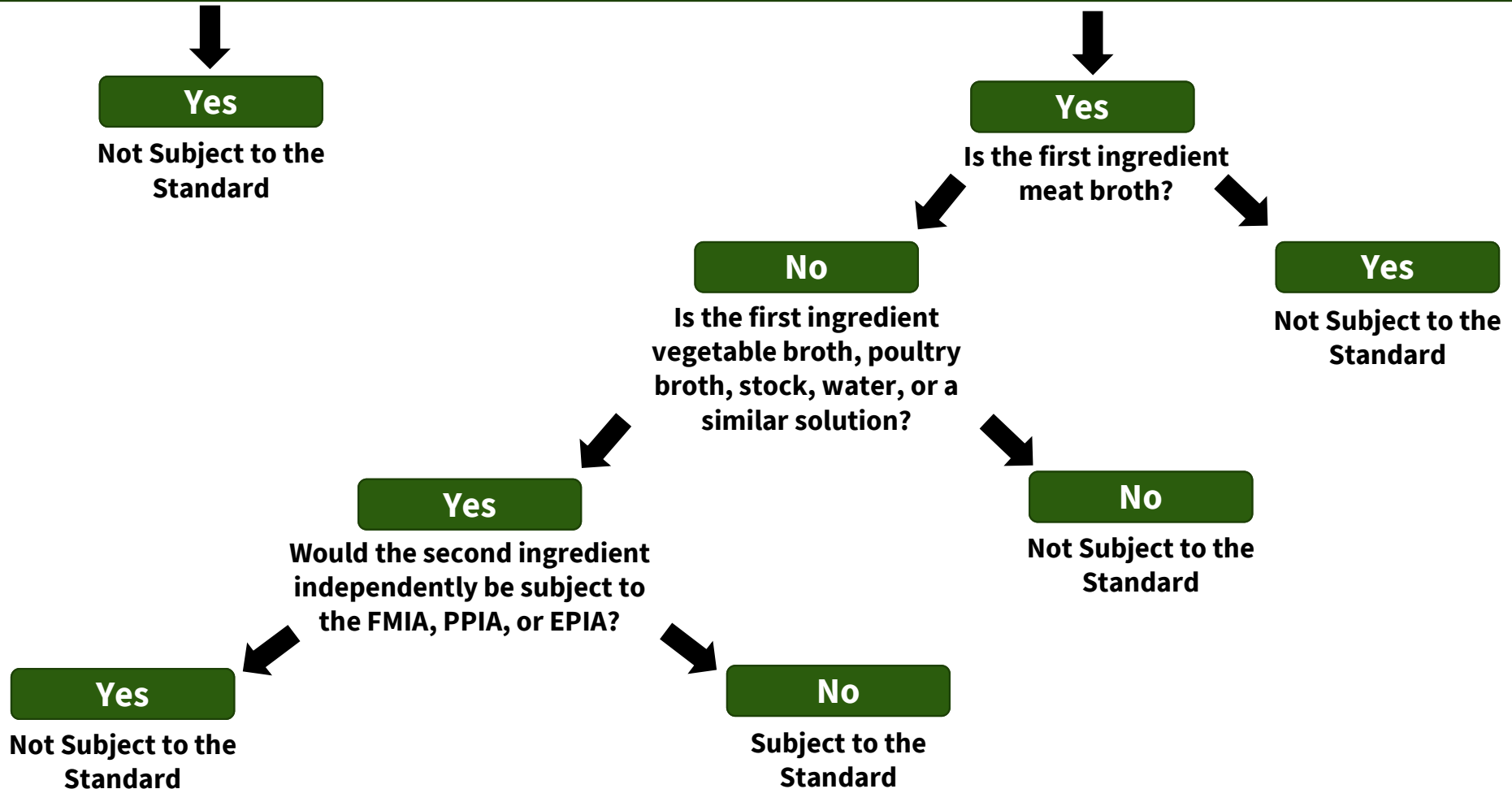
The Standard applies to food subject to:

- 1) The labeling requirements of the Federal Food, Drug, and Cosmetic Act (FDCA) or;
- 2) Certain foods subject to the labeling requirements under the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), or the Egg Products Inspection Act (EPIA).



Is the first ingredient subject to the FMIA, PPIA, or EPIA?

Pork, beef, catfish, sheep, goat, chicken, turkey, domesticated birds, egg product



Exemptions

Exempt Entities

- Restaurants and similar retail food establishments
- Very small food manufacturers (< \$2,500,000 annual receipts)



Exempt Products

- Threshold: Allows each ingredient to contain up to five percent of a BE substance, as long as it is inadvertent or technically unavoidable
- Animals fed bioengineered feed
- Food certified under the National Organic Program



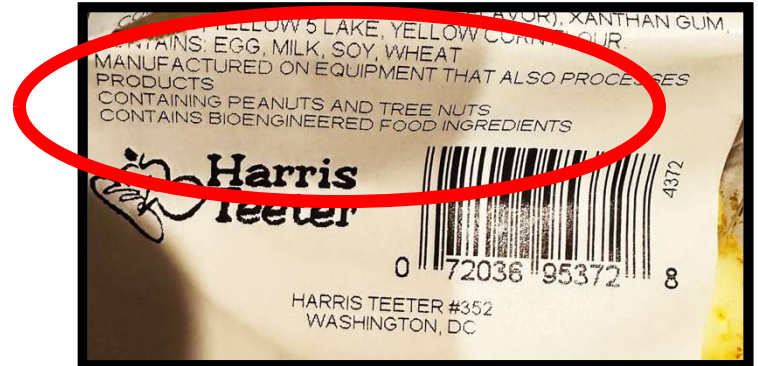
Disclosure Options

Disclosure Options

Disclosure Option	Mandatory Disclosure	Voluntary Disclosure
On Package Text	“Bioengineered” “Contains a Bioengineered Ingredient” “Contains Bioengineered Ingredients”	“Derived From Bioengineering”
Symbol		
Electronic or Digital Link	“Scan here for more food information” / “Call [1-000-000-0000] for more food information”	
Text Message	“Text [command word] to [number] for bioengineered food information”	

Disclosure Format

1. Information panel adjacent to the manufacturer/distributor information
2. Principal display panel
3. If there is insufficient space on either the information panel or the principal display panel, then disclosure may be made on any other panel likely to be seen by a consumer under ordinary shopping conditions



Disclosure Format

Foods Sold in Bulk Containers

1. Retailers are responsible for disclosure
2. Disclosure can be made using any of the four standard options
3. Disclosure must be placed on signage or other materials on or near the bulk food items





Compliance & Enforcement

Compliance and Enforcement



The National Bioengineered Food Disclosure Standard (the Standard) is enforced at the retail level, where consumers make decisions about their food.



Enforcement of the Standard is complaint-driven, and compliance is based on records.



Complaints about possible violations of the Standard will be made to AMS' Food Disclosure and Labeling Division (FDLD).

How to File a Complaint

Anyone can submit a BE complaint:

- Through the BE Complaint Portal (Preferred): <https://www.ams.usda.gov/rules-regulations/be/file-complaint>
- Or by Mail: U.S. Department of Agriculture
Food Disclosure & Labeling Division
1400 Independence Avenue, S.W.,
Room 2069-S, Stop 0216
Washington, DC 20250
- Or by Phone: 202-720-4486
- Or by Email: befodddisclosure@usda.gov

Bioengineered (BE) Foods Complaint Submission Form

Please use this form to report possible violations of the National Bioengineered (BE) Foods Disclosure Standard. For general BE inquiries and questions, please call (202) 720-4486 or email BEfooddisclosure@usda.gov.

Clear Submit

Part 1: Your Information

Please include your name and contact information. Disclaimer: The identities of the complainants will be considered confidential and will be protected to the greatest extent permissible by law.

Name:

*First Name *Last Name

Location:

Compliance and Enforcement

- AMS will determine whether further investigation is warranted.
- AMS will conduct a records audit, if appropriate.
- The regulated entity and complainant will be notified about the results of the audit or investigation.
- AMS does not have the authority to recall any foods that have not properly disclosed BE ingredients or levy any fines.

Thank You!

For additional information, including [fact sheets](#), [FAQs](#), a [disclosure determination tool](#), and more please visit the AMS webpage at

www.ams.usda.gov/be

or send your questions by email to

befooddisclosure@usda.gov

Please note: All presentation photos are intended for visual interest only and may not represent actual BE products.