



# **Overview of the National Bioengineered Food Disclosure Standard**

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# 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.**





# Presentation Outline

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



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# 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.

# 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



# 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.

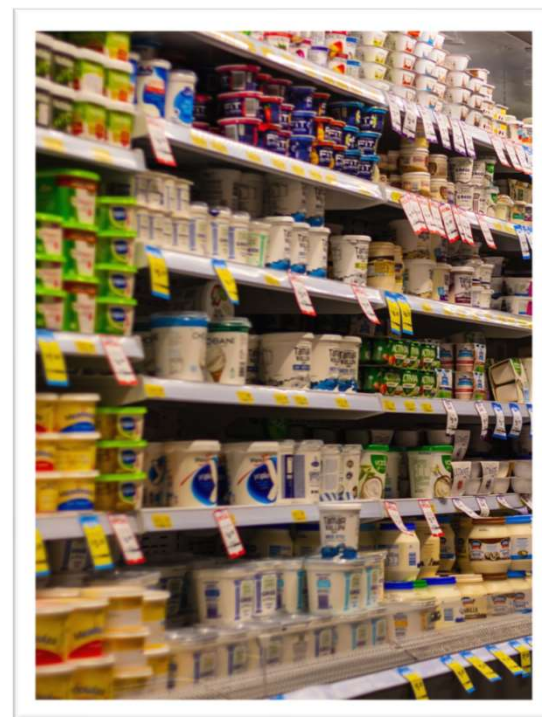


# **Foods Subject to the Standard**

# 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).

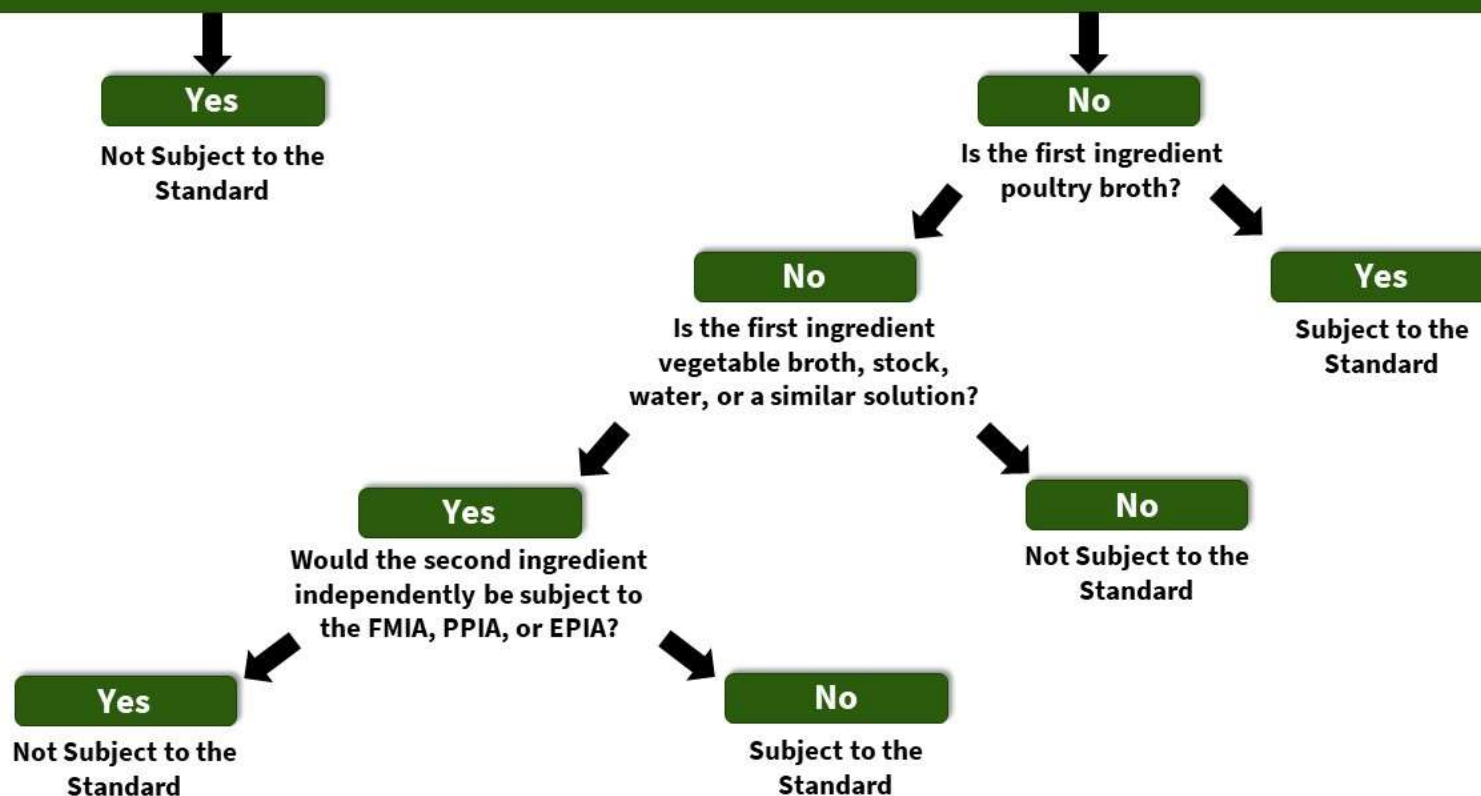






## Is the first ingredient subject to the FMIA, PPIA, or EPIA?

Pork, beef, 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



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# Disclosure Options



# Disclosure Options

1. On-package text
  - Should read “**Bioengineered food**” or “**Contains a bioengineered food ingredient**” or “**Contains bioengineered food ingredients**”
2. Symbol
3. Electronic or digital disclosure
4. Text message



# Voluntary Disclosure under the Standard

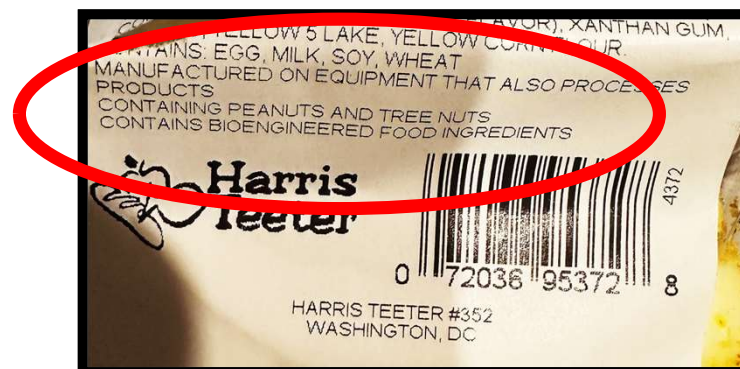
**Two types of voluntary disclosures may be made:**

1. Entities that are exempt
2. Foods that do not contain detectable modified genetic material but are derived from bioengineering



# 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







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# Compliance & Enforcement

# Compliance and Enforcement



**The National Bioengineered Food Disclosure Standard (BE 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 BE 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](mailto: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](mailto: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](http://www.ams.usda.gov/be)

or send your questions by email to

[befooddisclosure@usda.gov](mailto:befooddisclosure@usda.gov)

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