



Agricultural Marketing Service  
U.S. DEPARTMENT OF AGRICULTURE



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

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**Fair Trade Practices Program**



# 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. Recordkeeping Requirements
- VI. Compliance & Enforcement



# 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.





# 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





# **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).

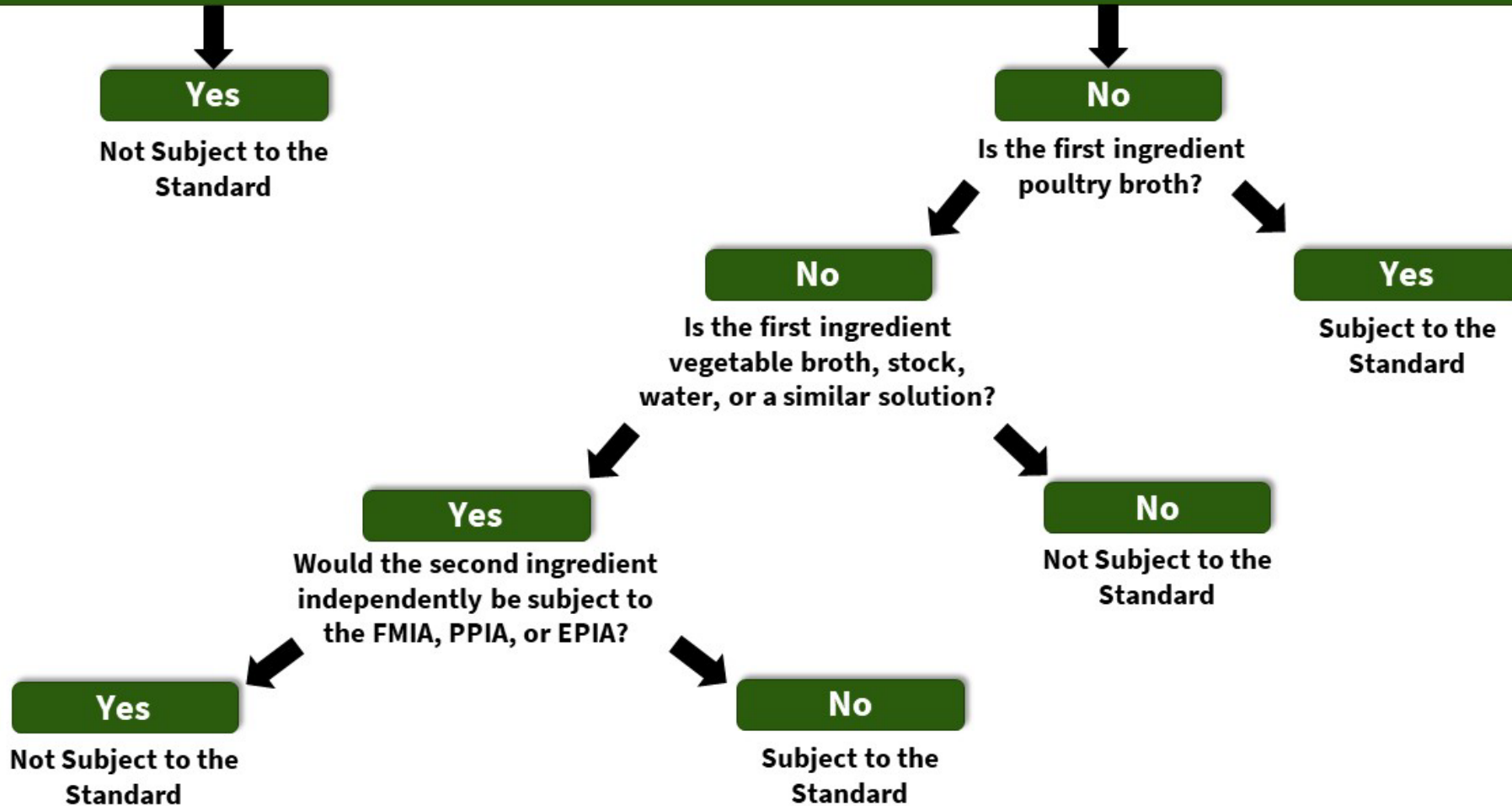






# Is the first ingredient subject to the FMIA, PPIA, or EPIA?

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

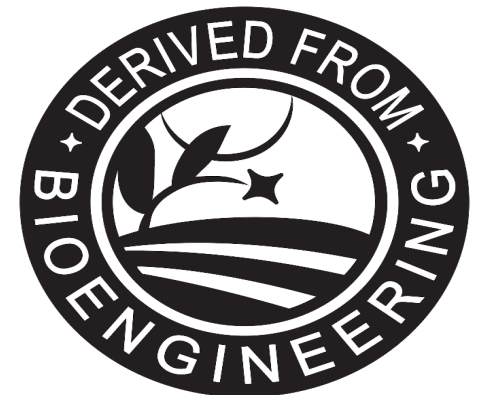




# Voluntary Disclosure under the Standard

**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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# Recordkeeping Requirements





# Recordkeeping Requirements at 7 CFR 66.9

1. A record that indicates the food is produced from a non-bioengineered crop.
2. A record that indicates the food has been subjected to a refinement process validated to render modified genetic material undetectable.
3. A record such as a certificate of analysis or other testing record appropriate to a specific food that confirm the absence of detectable modified genetic material. These would be batch-by-batch testing records to confirm each batch does not contain detectable modified genetic material.

# Examples of Records to Justify Non-Disclosure

- Organic certifications
- Documentation that ingredient is sourced from a country that does not allow production of that specific ingredient in a bioengineered form
- Laboratory test results
- Process verifications



# Recordkeeping

- Regulated entities subject to mandatory bioengineered food disclosure are required to keep sufficient records to establish compliance with the standard
- Must keep customary or reasonable records that would be generated in the normal course of business
- Regulated entities may determine which records to maintain, provided they are sufficient to demonstrate compliance
- Records may be in any format (hard copy or electronic)
- Records may be stored at any business location



# Recordkeeping

Regulated entities may determine the types of business records to maintain, provided that the records demonstrate compliance with the disclosure standard. Examples of possible records include:

- Ingredient List
- Invoices
- Bills of lading
- Inventory records
- Supply chain records



# Recordkeeping

- Records must be maintained for two years after the food is sold or distributed for retail sale
- Some records, such as those verifying a certain manufacturing process or testing, may be necessary to retain for longer periods
- When requested by USDA, records need to be produced within five business days, unless USDA grants an extension
- If on-site access is necessary, USDA will provide notice at least three business days in advance
- Suppliers are not required to maintain records



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# Compliance & Enforcement



# Compliance and Enforcement

- The BE Standard is enforced at the retail level, where consumers make decisions about their food.
- Failure to make a bioengineered food disclosure as required by the BE Standard is prohibited.
- Complaints about possible violations of the BE Standard will be made to AMS through the BE complaint Portal on the AMS website.

# 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:**  
Street Address  Apartment/Unit   
City  State  Zip Code  Country

**Contact Information:**  
Phone Number  Email

## Part 2: Who is your complaint against?

Please enter as much contact information as possible for the business you are complaining about.

**Information:**  
\* Store/Business Name

**Location:**  
Street Address (or shopping center name, close intersection, cross streets, etc.)  Apartment/Unit   
City  State  Zip Code  Country

Online submission: [BE Complaints Portal \[https://fdld-complaint-be.ams.usda.gov/\]](https://fdld-complaint-be.ams.usda.gov/)



# Compliance and Enforcement

- AMS will determine whether further investigation is warranted.
- AMS will conduct a records audit, if appropriate.
- The regulated entity 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.



# **BE Complaint Cases**

17 - Complaint Cases filed January 1 through April 10, 2023

14 - Closed Complaint Cases – No reasonable Grounds

2 - Investigated Complaint Cases - Closed

1 - Open Complaint Case (current investigation case)



# 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)