



**US Department of Agriculture**

# Bioengineered Food Labeling

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# COI Disclosure Information

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**I have the following financial relationships to disclose.**

**I have accepted an unsolicited offer of hotel accommodations and meals for this workshop from ILSI Japan (a non-federal source) in compliance with applicable US Federal Government ethical rules and statutes. Acceptance of this offer was approved by the designated US government official in advance of my travel.**



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# The National Bioengineered Food Disclosure Standard

- The National Bioengineered Food Disclosure Standard was passed by the US Congress in July of 2016.
- It directed the United States Department of Agriculture (USDA) to establish a national mandatory standard for disclosing foods that are or may be bioengineered.
- A team of dedicated individuals from the USDA, Agricultural Marketing Service (AMS) worked over two years to produce final regulations.





# The National Bioengineered Food Disclosure Standard

- AMS relied heavily on information and input from stakeholders across the agricultural landscape, including producers, food processors, food manufacturers, retailers and consumers.
- This information included over 112,000 responses to questions AMS posted on its website and more than 14,000 comments after AMS published the proposed rule in 2018.
- The final rule was published December 20, 2018.
- The mandatory compliance date for the standard is January 1, 2022.





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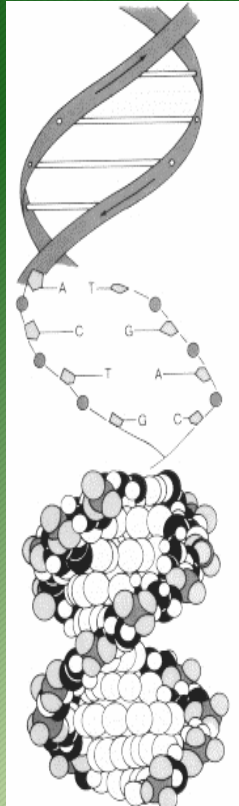
# The National Bioengineered Food Disclosure Standard

- The NBFDS provides a uniform, national standard for labeling bioengineered foods, increases transparency for the US food system and give consumers information about the bioengineered status of their foods.
- The National Bioengineered Food Disclosure Standard avoids a potentially expensive and confusing patchwork of state labeling regulations.



# The Context for Bioengineered Crops in the US

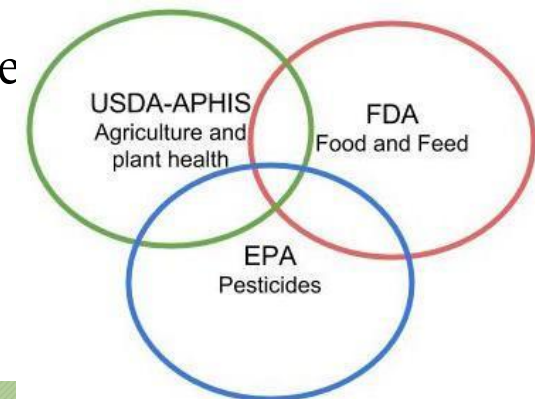
- The term “bioengineering” describes the use of modern biotechnology, genetic engineering or recombinant DNA technology.
- Bioengineering is the application of *in vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombinant barriers and that are not techniques used in traditional breeding and selection of plants.
- **Genetically modified (GMO):** can encompass any alteration to the genetic composition of a plant, including traditional hybridization or breeding techniques. This term could apply to most cultivated food crops since most food crops are the product of selective breeding.





# The Context for Bioengineered Crops in the US: Safety and Environment

- The US government has a coordinated, risk-based system to ensure that new biotechnology products are safe for the environment and human and animal health.
- The Coordinated Framework is based upon existing US laws designed to protect public health and the environment.
- The U.S. government has also written new regulations, policies, and guidance to apply these laws to biotechnology-derived products.
- The U.S. Government agencies responsible for oversight of the products of agricultural modern biotechnology are:
  - The US Department of Agriculture, Animal and Plant Health Inspection Service (USDA)
  - The U.S. Environmental Protection Agency (EPA)
  - The Department of Health and Human Services' Food and Drug Administration (FDA).





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# The Context for Bioengineered Crops in the US

- Within USDA, the Animal and Plant Health Inspection Service (APHIS) is responsible for protecting agriculture from pests and diseases.
- Under the Plant Protection Act, USDA-APHIS has regulatory oversight over products of modern biotechnology that could pose such a risk.
- USDA-APHIS regulates organisms and products that are known or suspected to be plant pests or to pose a plant pest risk, including those that have been altered or produced through genetic engineering.







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# The Context for Bioengineered Crops in the US

- The EPA through a registration process regulates the sale, distribution and use of pesticides in order to protect health, and the environment, regardless of how the pesticide was made or its mode of action.
- This includes regulation of those pesticides that are produced by an organism through techniques of modern biotechnology.
- The Biopesticides and Pollution Prevention Division of the Office of Pesticide Programs, under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), regulates the distribution, sale, use and testing of pesticidal substances produced in plants and microbes.





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# The Context for Bioengineered Crops in the US

- The FDA is responsible for ensuring the safety and proper labeling of all plant-derived food and feed, including those developed through genetic engineering.
- All food and feed, whether imported or domestic and whether derived from crops modified by conventional breeding techniques or bioengineering techniques, must meet the same rigorous safety standards.
- Under the Federal Food, Drug, and Cosmetic Act (FDCA), it is the responsibility of food and feed manufacturers to ensure that the products they market are safe and properly labeled.



FDA U.S. FOOD & DRUG  
ADMINISTRATION

# Labelling foods not derived from bioengineered plants\*

- The US Food and Drug Administration (FDA) permits voluntary labelling of non-bioengineered food only to the extent that the labelling is truthful and not misleading, e.g. :
  - “Not bioengineered.”
  - “Not genetically engineered.”
  - “Not genetically modified through the use of modern biotechnology.”
  - “We do not use ingredients that were produced using modern biotechnology.”
  - “This oil is made from soybeans that were not genetically engineered.”
  - “Our corn growers do not plant bioengineered seeds.”



\*The FDA does not enforce labelling or mislabeling using the term GMO or GM.



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# Labelling foods not derived from bioengineered plants

- As a result of the National Bioengineered Food Disclosure Standard, The US Food and Drug Administration (FDA) no longer has authority over voluntary labeling to indicate the presence of GE content in human foods, including salmon.
- FDA retains jurisdiction over labeling statements to indicate the absence of GE content in human food.
- The NBFDS does not apply to animal food or feed.





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# Labeling foods derived from Bioengineering

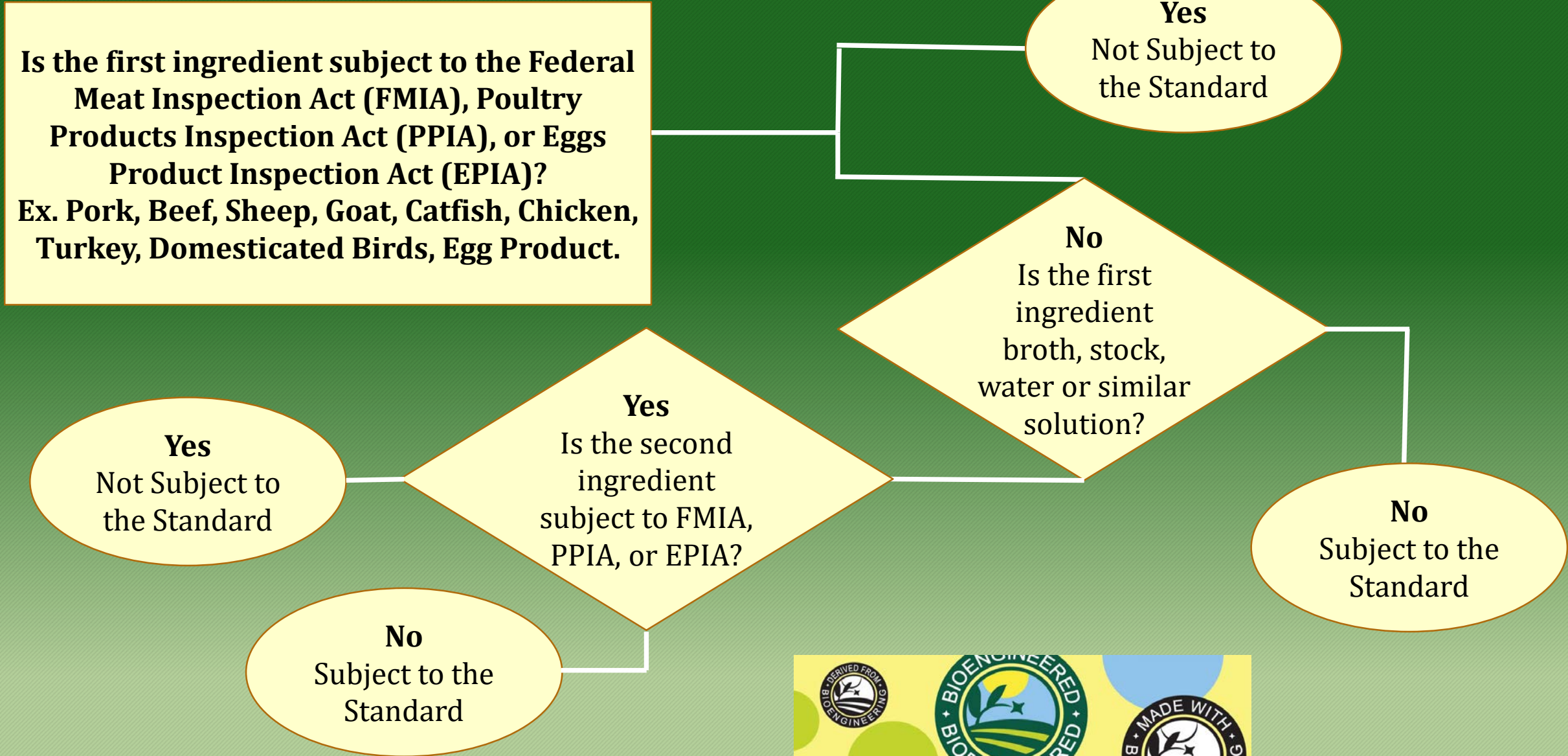
- Foods that require bioengineering disclosure:
  - Foods that are subject to the Federal Food, Drug and Cosmetic Act (FDCA).
  - Foods that are subject to the labeling requirements under the Federal Meat Inspection Act, the Poultry Products Inspection Act, or the Egg Products Inspection Act, only if:
    - the predominant ingredient\* would be independently subject to labeling under the FDCA, or
    - The predominant ingredient is broth, stock, water or similar solution and the second most predominant ingredient would independently be subject to labeling under the FDCA.

\*Ingredients required to be declared on the label or labeling of a food are listed by common or usual name in descending order of predominance by weight.





# Is Your Food Subject To Disclosure?





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### IRL/GB Salad dressing.

**Ingredients:** water, vegetable oils (contains genetically modified soyabeanoil), sugar, vinegar, modified starch, wheat starch, salt, mustard (water, mustard seed, vinegar, salt, spices, herbs), egg yolk, thickener (E412), acids (E330), preservatives (E202), colours (E160a), antioxidant (E385).  
**Produced in:** The Netherlands. Store in a cool, dry place. Shake before use.

### Grass Fed Ribeye Steaks

#### Nutrition Facts

Serving Size: 4 oz. (112g)  
Servings Per Container: 2

#### Amount Per Serving

**Calories** 320 Calories from Fat 240

**% Daily Value\***

**Total Fat** 27g **41%**

Saturated Fat 11g **55%**

Trans Fat 0g

**Cholesterol** 80mg **26%**

**Sodium** 60mg **3%**

**Total Carbohydrate** 0g **0%**

**Protein** 19g

**Iron** 10%

Not a significant source of trans fat, dietary fiber, sugars, vitamin A, vitamin C, and calcium.

\*Percent Daily Values (DV) are based on a 2,000 calorie diet.

**INGREDIENTS:** 100% GRASS FED BEEF.

### Soup A

Number of ingredients: 41

#### Nutrition Facts

Serving Size 1 cup (243g)  
Servings Per Container 1

Water, Pasta (Flour, Water, Egg), Chicken, Carrots, Celery, Onions, Chicken Base (Chicken, Salt, Chicken Fat, Dextrose, Sugar, Natural Flavor, Roasted Chicken Flavor, Chicken Broth, Turmeric, Hydrolyzed Corn Gluten, Lactose, Onion Powder, Disodium Inosinate, Disodium Guanylate, Autolyzed Yeast Extract and Spices), Modified Food Starch, Vegetable Base (Salt, Hydrolyzed Corn Gluten, Lactose, Sugar, Onion Powder, Disodium Inosinate, Disodium Guanylate, Autolyzed Yeast Extract, Turmeric, Natural Flavorings, Spices) Canola/Olive Oil Blend, Garlic, Spices

### Soup B

Number of ingredients: 18

#### Nutrition Facts

Serving Size 1 cup (243g)  
Servings Per Container 1

Chicken Broth, Onions, Carrots, Celery, Cooked Chicken (Chicken Meat, Water, Corn Starch), Brown Rice, Wild Rice, Cornstarch, Roasted Chicken Skin, Chicken Fat, Sea Salt, Onion Powder, Garlic Powder, Spices, Paprika, Turmeric, Rosemary Extract

**INGREDIENTS:** CHICKEN STOCK, CHICKEN FAT, MODIFIED FOOD STARCH, WHEAT FLOUR, COOKED CHICKEN MEAT, CREAM (MILK), WATER, SALT, COOKED MECHANICALLY SEPARATED CHICKEN, MARGARINE (CORN COTTONSEED, CANOLA AND/OR SOYBEAN OIL, WATER, BETA CAROTENE FOR COLOR), CONTAINS LESS THAN 1% OF: DRIED WHEY (MILK), SOY PROTEIN CONCENTRATE, MONOSODIUM GLUTAMATE, YEAST EXTRACT, FLAVORING, VEGETABLE OIL, SOY PROTEIN ISOLATE, SODIUM PHOSPHATES, AUTOLYZED YEAST EXTRACT, CHICKEN FLAVOR (CONTAINS CHICKEN STOCK, CHICKEN POWDER, CHICKEN FAT), CHICKEN FLAVOR, SPICE EXTRACT, PARTIALLY HYDROGENATED SOYBEAN

**INGREDIENTS:** MILLED CORN, SUGAR, CORN SYRUP, MOLASSES, SALT, PARTIALLY HYDROGENATED VEGETABLE OIL (ONE OR MORE OF: COCONUT, COTTONSEED, AND SOYBEAN)\*\*†, SODIUM ASCORBATE AND ASCORBIC ACID (VITAMIN C), NIACINAMIDE, ZINC OXIDE, REDUCED IRON, WHEAT STARCH, PYRIDOXINE HYDROCHLORIDE (VITAMIN B6), RIBOFLAVIN (VITAMIN B2), THIAMIN HYDROCHLORIDE (VITAMIN B1), VITAMIN A PALMITATE, BHT (PRESERVATIVE), ANNATTO COLOR, FOLIC ACID, VITAMIN D AND VITAMIN B12.  
\*\*\* ADDS A NEGLIGIBLE AMOUNT OF FAT.  
† LESS THAN 0.5g TRANS FAT PER SERVING.



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## The National Bioengineered Food Disclosure Standard: Regulated Entities

- The standard identifies three groups as regulated entities
  - Food manufacturer
    - Packages food for human consumption and retail sale
  - Importer
    - Imports food for retail sale
  - Retailers
    - Packages and labels food for retail sale
    - Sells bulk food items







## The National Bioengineered Food Disclosure Standard: Exempt businesses

- Restaurants or a similar retail food establishments
  - full service and fast food restaurants, cafeterias, lunch rooms, food stands, food trucks, trains and airplanes, bars, taverns and lounges
  - ready-to-eat foods sold in a grocery store deli, salad bar, or hot bar
- Very small manufacturers (annual receipts < 2.5 million US Dollars)



# How to disclose bioengineered food: package location

- There are three options\*:
  - 1) on the information panel next to the manufacturer of distributor information
  - 2) on the principal panel display
  - 3) if there is not enough space on the package, on an alternate panel likely to be seen by the consumer
- Note: the disclosure should not interfere with the interpretation of disclosures required by the FDA or USDA-FSIS.



# How to disclose bioengineered food: Label

- There are four options\*:
  1. On-package Text
  2. Symbol
  3. Electronic or digital
  4. Text message
- Small manufacturers (\$2.5-10 million annual receipts) also can use a telephone number or website.



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## How to disclose bioengineered food: Approved Mandatory Symbols\*



\*A bioengineered food disclosure is a marketing label, and does not convey any information about the health, safety, or environmental attributes of bioengineered food as compared to non-bioengineered counterparts.



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## How to disclose bioengineered food: Approved Voluntary Symbols\*



\*Foods that carry a symbol that states “Derived from Bioengineering,” or that otherwise disclose the product contains ingredients “derived from bioengineering” are not bioengineered foods. Such labeled foods do not contain detectable modified genetic material. As a result, entities can make these specific voluntary disclosures for these types of products.



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# How is bioengineered food defined in the National Bioengineered Food Disclosure Standard?

- Bioengineered Food

- Human food containing detectable genetic material that has been modified through *in vitro* recombinant DNA techniques and for which the modification could not otherwise be obtained through conventional breeding or found in nature.
  - Note: The terms "found in nature" and "conventional breeding" have not been defined in the standard. USDA-AMS has decided that it will make determinations about whether a specific modification would be considered "found in nature" or obtained through "conventional breeding" on a case-by-case basis. Modifications that could be found in nature or obtained through conventional breeding are not considered bioengineered foods.





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USDA-AMS collected the legally produced bioengineered foods and compiled them in an annually reviewed list\*



\*Even if a food is not included on the List, regulated entities whose records show that a food they are selling is bioengineered must make appropriate disclosure of that food.

<u>Name of BE Food</u>	<u>Number of Varieties</u>
Alfalfa	3
Apple (Arctic™ varieties)	3
Canola	19
Corn	47
Cotton	34
Eggplant (BARI Bt Begun varieties)	1
Papaya (rsv resistant varieties)	4
Pineapple (pink flesh varieties)	1
Potato	37
Salmon (AquAdvantage®)	1
Soybean	20
Squash (summer)	2
Sugarbeet	3



# Foods that are excluded from Mandatory NBFDS Labeling

- The Standard does not apply to:
  - foods that are primarily meat, catfish, poultry, or egg products.
    - Meat and catfish are subject to the Federal Meat Inspection Act
    - Poultry is subject to the Poultry Production Inspection Act
    - Eggs are subject to the Egg Products Inspection Act
  - incidental additives that are present in a food at insignificant levels; do not have any technical or functional effect in that food or are removed in processing before packaging.
  - foods where modified genetic material cannot be detected, e.g. purified vegetable oil and refined sugar.
  - foods that contain less than 5% inadvertent or technically unavoidable BE content by weight for each ingredient.
  - foods certified by the USDA AMS National Organic Program.





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# Voluntary Disclosure



- The Standard allows for two types of Voluntary Disclosure:
- Entities that are exempt, such as very small food manufacturers and restaurants, may voluntarily make bioengineered food disclosures.
- Regulated entities may make voluntary disclosures for foods that are derived from foods produced through bioengineering but do not contain detectable modified genetic material.
  - This is only available for foods that are derived from foods produced using bioengineering, but do not contain detectable modified genetic material, e.g. highly refined ingredients like sugar derived from a sugar beet or a soybean oil derived from soybeans.
  - Voluntary disclosure for highly refined ingredients must be made using this symbol or the text "derived from bioengineering" or "ingredients derived from a bioengineered source."



# Recordkeeping

- The disclosure provisions of the Standard are driven by recordkeeping.
- All entities subject to the Standard must keep sufficient records to show that they are in compliance with the disclosure requirement.
- Records must be kept for two years.
- When a regulated entity uses a food on the List of Bioengineered Foods, and decides not to make a bioengineered food disclosure, the records must verify that the food is not bioengineered or does not contain detectable modified genetic material.
- When a regulated entity makes a disclosure of foods on the List, records would simply identify the food.





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# Enforcement



- Failure to make a bioengineered food disclosure as required by the Standard is prohibited.
- Enforcement of the Standard is complaint-driven and compliance is based on records.
- USDA does not intend to test individual foods or ingredients to ensure they are properly labeled.
- When AMS receives a complaint, it will determine if a further investigation is warranted. If necessary, AMS will conduct an audit of the regulated entity's records and notify the entity of its findings.
- A regulated entity will be able to appeal the results of an audit or investigation.
- Following an appeals hearing, AMS will notify the regulated entity of its final determination in the matter.
- A summary of the results of the audit or investigation will then be posted to the AMS website.

# Performance Criteria for Bioengineered Food Testing

1. Quality assurance ensures validity and reliability of test results;
2. Analytical method selection, validation, and verification ensures that the testing method used is appropriate (fit for purpose) and that the laboratory can successfully perform the testing;
3. The demonstration of testing validity must ensure consistent accurate analytical performance
4. Method performance specifications must ensure analytical tests are sufficiently sensitive for the purposes of the detectability requirements of this part.

# Disclaimer

- “The material provided in this presentation is not specific to the National Bioengineered Food Disclosure Standard. The Standard does not require the use of any specific test or method. The only requirement is that any test must meet the performance criteria shown on the previous slide. AMS will be issuing additional guidance on testing.”
- For questions or more information call 202-720-4486 or email [befooddisclosure@ams.usda.gov](mailto:befooddisclosure@ams.usda.gov)

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