

Overview of the National Bioengineered Food Disclosure Standard

February 2019

www.ams.usda.gov/be

Presentation Overview

- 1. Who is regulated?**
- 2. What foods are considered bioengineered foods?**
- 3. How must bioengineered foods be labeled?**
- 4. What are the recordkeeping requirements?**
- 5. What does enforcement look like?**

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.

Who is regulated?

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



Regulated Entity

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)**

What foods are considered bioengineered foods?

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

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



Yes

Not subject to the Standard



No

Is the first ingredient broth, stock, water or similar solution?



Yes

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

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



Yes

Not subject to the Standard



No

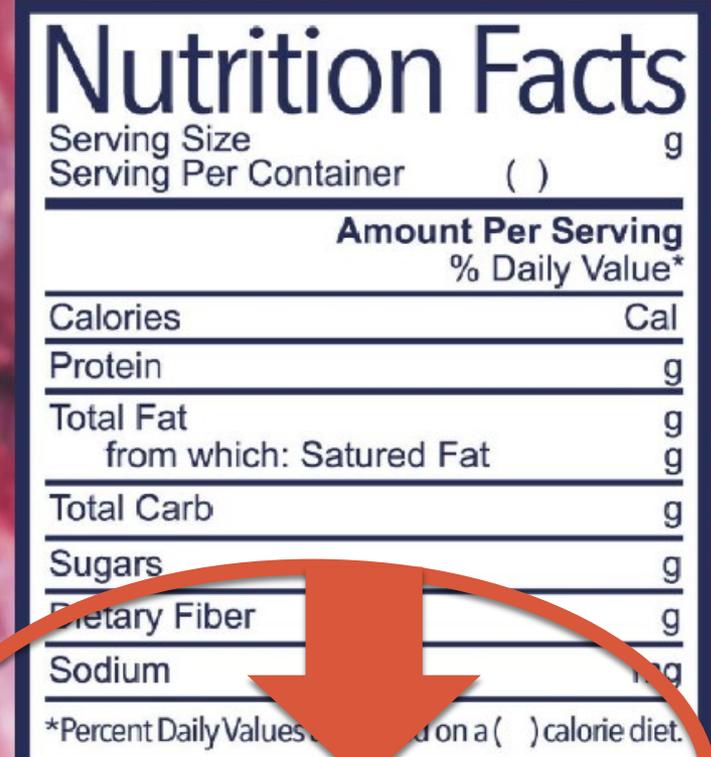
Subject to the Standard



No

Subject to the Standard

Is this food subject to disclosure?



Nutrition Facts	
Serving Size	() g
Serving Per Container	()
Amount Per Serving	
% Daily Value*	
Calories	Cal
Protein	g
Total Fat	g
from which: Saturated Fat	g
Total Carb	g
Sugars	g
Dietary Fiber	g
Sodium	mg
*Percent Daily Values are based on a diet of () calories.	

Ingredients: Pork, salt, water, modified food starch, sugar.

Is this food subject to disclosure?

Nutrition Facts	
Serving Size	g
Serving Per Container	()
Amount Per Serving	
% Daily Value*	
Calories	Cal
Protein	g
Total Fat	g
from which: Saturated Fat	g
Total Carb	g
Sugars	g
Dietary Fiber	g
Sodium	mg
*Percent Daily Values are based on a diet of () calorie diet.	

Ingredients: Vegetable broth, potatoes, chicken, peas, carrots, corn, modified food starch, chicken fat, soybean oil.

Is this food subject to disclosure?



Nutrition Facts	
Serving Size	g
Serving Per Container	()
Amount Per Serving	
% Daily Value*	
Calories	Cal
Protein	g
Total Fat	g
from which: Saturated Fat	g
Total Carb	g
Sugars	g
Dietary Fiber	g
Sodium	mg

*Percent Daily Values are based on a () calorie diet.

Ingredients: Vegetable broth, turkey, egg noodles, water, corn, peas, carrots, salt, soybean oil.

Is this food subject to disclosure?

Nutrition Facts

Serving Size () g
Serving Per Container ()

Amount Per Serving
% Daily Value*

Calories	Cal
Protein	g
Total Fat	g
from which: Saturated Fat	g
Total Carb	g
Sugars	g
Dietary Fiber	g
Sodium	mg

*Percent Daily Values are based on a () calorie diet.

Ingredients: Freeze dried egg, freeze dried egg yolk, nonfat dry milk, corn starch, salt, smoke flavor, xanthan gum.

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.
- 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).

Found in Nature and Conventional Breeding

- **USDA did not define either of the terms “found in nature” or “conventional breeding.”**
- **USDA intends to make determinations about whether a specific modifications would be considered “found in nature” or obtained through “conventional breeding” on a case-by-case basis.**

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:**
 - **Records verify the food is made from a non-bioengineered food;**
 - **Records verify that the food has been refined using a process validated to render the modified genetic material undetectable; or**
 - **Testing records for the specific food confirm the absence of detectable modified genetic material.**

Detectability

(non-bioengineered food)

- **Modified genetic material is not detectable if:**
 - **Records verify the food is made from a non-bioengineered food.**
- **Such records may include:**
 - **Organic certification**
 - **Documentation that ingredient is sourced from a country that does not allow production of that specific ingredient in a bioengineered form**

Detectability (refined food)

- **Modified genetic material is not detectable if:**
 - **Records verify that the food has been refined using a process validated to render the modified genetic material undetectable.**
- **Such records may include:**
 - **Documentation that a specific process is used to refine an ingredient and that process has been shown, using the analytical testing that meets the NBFDS's performance standards, to render any modified genetic material undetectable.**

Detectability (refined food)



- **Once a process has been shown to render modified genetic material in a specific ingredient undetectable, no additional testing of that ingredient is necessary unless changes are made to the refining process.**

Detectability (testing)



- **Modified genetic material is not detectable if:**
 - **Testing records for the specific food confirm the absence of detectable modified genetic material.**

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.**

Exemptions



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

**How must
bioengineered
foods be
labeled?**



Disclosure Options

- 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 Accessibility

- 1. On-package text**
- 2. Symbol**
- 3. Electronic or digital disclosure**
- 4. Text message**

Disclosure for small manufacturers/packages

For small food manufacturers (\$2,500,000 - \$10,000,000 in annual receipts)

- **Telephone or website**

For small and very small packages

- **Shortened statements for electronic or digital, text message, and phone number disclosures**
- **Very small packages may use existing URL or phone no.**

On-Package Text Disclosure

- **“Bioengineered food”**
- **“Contains a bioengineered food ingredient” or “Contains bioengineered food ingredients”**

Disclosure Symbol



Electronic/Digital Disclosure

- **Must include the instructions to “Scan here for more food information” or similar language that reflects a change in technology, such as “Scan anywhere on package for more food information”**
- **When accessed, the electronic or digital link must go directly to the product information page. The product information page must:**
 - Be the first screen to appear on an electronic or digital device
 - Include the bioengineered food disclosure in text or symbol form
 - Must not collect information about the consumer or their devices

Electronic/Digital Disclosure

- **The electronic or digital disclosure must also be accompanied by a telephone number, in close proximity, that includes the statement “Call [1-000-000-0000] for more food information.”**
- **The phone number must provide the BE food disclosure, regardless of time of day**
- **The BE food disclosure may be a recorded message.**

Text Message Disclosure



- “Text [command word] to [number] for bioengineered food information.”
- The number must be a number, including a short code, that sends an immediate response to the consumer’s mobile device.

Disclosure Options for Small Food Manufacturers

- **Any of the four disclosure options available to all regulated entities.**
- **Using the statement “Call for more food information,” accompanied by a telephone number that will provide the disclosure to the consumer, regardless of the time of day.**
- **Using the statement “Visit [URL of the website] for more food information” and a website that is consistent with the requirements of electronic or digital disclosure.**

Disclosure for Small Packages

Small Packages (less than 40 square inches)

- **Using a shortened version of the required on-package statements, including “Scan for info,” “Text for info,” or “Call for info.”**

Disclosure for Very Small Packages

Very Small Packages (less than 12 square in)

- **If the label includes a preexisting Uniform Resource Locator for a website or a telephone number that a consumer can use to get more food information, then the URL or number may be used for the required disclosure**

Foods Sold in Bulk Containers



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

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Voluntary Disclosure

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**

Voluntary Disclosure

- **For entities that would otherwise be exempt**
- **May voluntarily disclose using any of the disclosure options available to regulated entities**
- **May include very small food manufacturers, restaurants, bars, food trucks, etc.**

Voluntary Disclosure

For foods that do not contain detectable modified genetic material but are derived from bioengineering

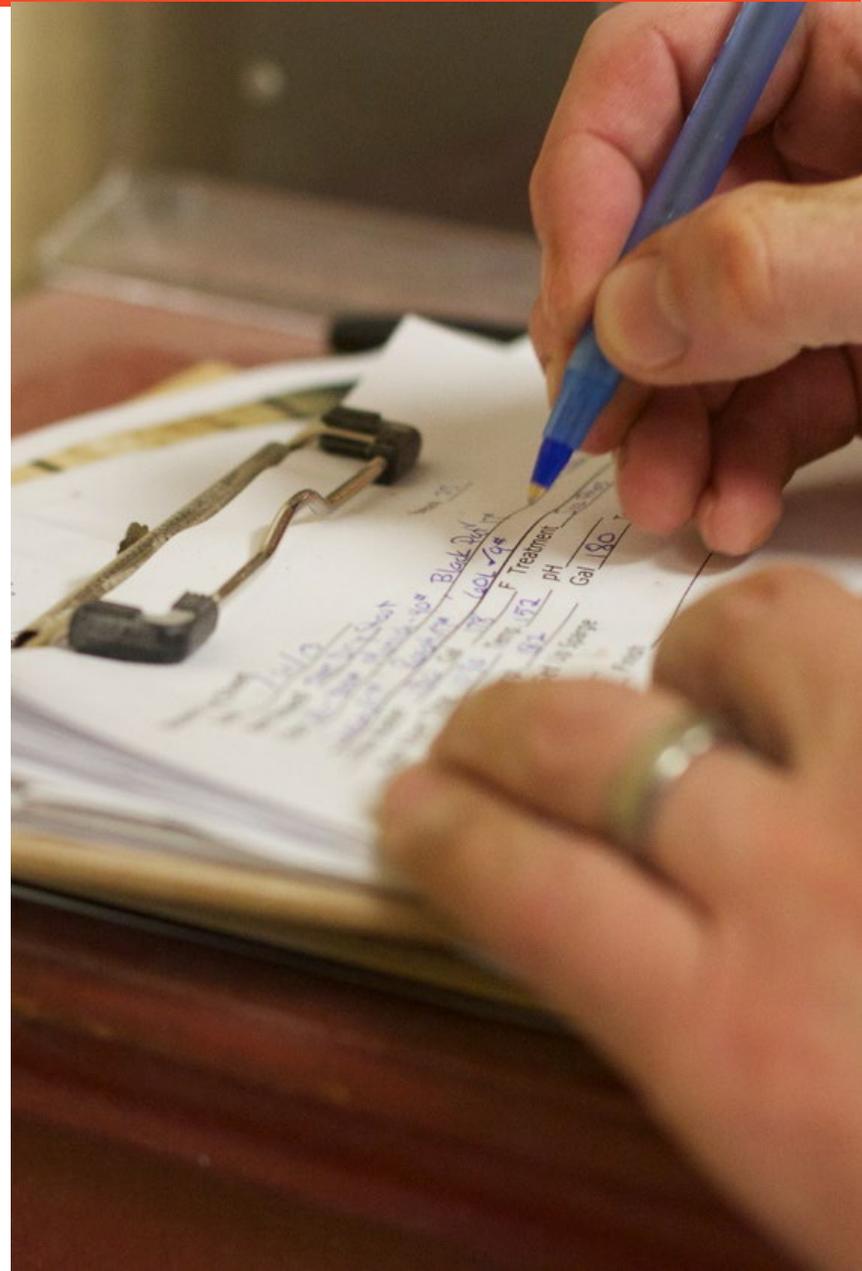
- Only applies to highly refined ingredients in which the modified genetic material is no longer detectable (e.g. sugar derived from a sugar beet, soybean oil)
- Is not allowed for any other foods or ingredients
 - Examples that cannot be voluntarily disclosed: food produced from animals fed bioengineered feed; soups where the first ingredient is meat; incidental additives

Voluntary Disclosure

- May use any of the available disclosure options, however, text must be “derived from bioengineering” or “ingredients derived from a bioengineered source,” or if a symbol is used, it must be this symbol:



What are the recordkeeping requirements?



How Recordkeeping Applies to Disclosure

- **For non-disclosure of foods on the List of Bioengineered Foods, records need to validate that the food is not bioengineered or no longer contains detectable modified genetic material pursuant to § 66.9**
- **For positive disclosure of foods on the List of Bioengineered Foods, records would simply identify the food or ingredient (e.g. “Canola”)**

Recordkeeping

- **Everyone subject to mandatory bioengineered food disclosure is required to keep sufficient records to establish compliance with the standard**
- **Must keep customary or reasonable records that would be generated in the course of normal business – no new records or forms are required**
- **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 are able to determine what business records to maintain, provided that they demonstrate compliance with the disclosure standard. Examples of possible records include:



- **Invoices**
- **Bills of lading**
- **Inventory records**
- **Supply chain records**
- **Country of origin records**
- **Process verifications**
- **Organic certifications**
- **Laboratory test results**

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**

How is the Standard enforced?



Enforcement

- **Failure to make a bioengineered food disclosure as required by the NBFDS is prohibited**
- **Complaints about possible violations of the NBFDS will be made to AMS**
- **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**

Enforcement

- **Regulated entities 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**
- **The summary of the results of the audit or investigation will be posted to AMS's website**

Compliance Dates

Implementation Date

- **January 1, 2020**
- **Small Food Manufacturers: January 1, 2021**

Compliance Date

- **The mandatory compliance date for all regulated entities is January 1, 2022.**
- **Regulated entities may voluntarily comply before that time and may use existing labels.**

Thank You!

**For additional information,
please visit the AMS webpage at**

www.ams.usda.gov/be

or send an email to

befooddisclosure@usda.gov

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