Genetically Engineered Microbes in the Bioengineered Food Disclosure Standard

The Future of Microbial Biotechnology Workshop 2022

www.ams.usda.gov/be

Presentation Overview

1. Who is regulated?
2. What foods are considered bioengineered foods?
3. How are Genetically Engineered Microbes (GEMs) regulated under the Standard?
4. How must bioengineered foods be labeled?
5. What are the recordkeeping requirements?
6. Q&A

Email questions to: befooddisclosure@usda.gov

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?

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

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).

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

Genetically Engineered and Bioengineered are not the same

- “Bioengineered food” is a term defined in the Standard.
  - 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.
- GEMs is a standard term that includes enzymes, yeasts, microbes, etc., made in a controlled environment

GEMs are not on the List

- AMS did not include enzymes, yeasts, and other similar foods produced in controlled environments on the list.
- GEMs do not categorically meet the definition of a "bioengineered food" because they may be:
  - May qualify as incidental additives, and/or
  - May not contain detectible modified genetic material
- Regulated entities must determine whether recordkeeping and, ultimately, disclosure of those substances are required on a case-by-case basis.

Incidental Additives

- The definition of bioengineered food also excludes foods subject to certain factors or conditions. The Standard currently includes one factor or condition, which is incidental additives.

- 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.

GEMs and the Standard

- For foods not on the AMS List of Bioengineered Foods, like enzymes, yeasts, and other micro-organisms:
  - If a regulated entity's records demonstrate they have actual knowledge that they are using a bioengineered version of these foods, then they must make a disclosure.
- Actual Knowledge - that a food is bioengineered means that you have knowledge that there is detectable modified genetic material

Detectability

- 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; or
  - Testing records for the specific food confirm the absence of detectable modified genetic material.
  - AMS has released guidance on testing methods and process validation and it available on the AMS website.

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

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

How must bioengineered foods be labeled?

Disclosure Format

1. On-package text

   "Bioengineered food" or "Bioengineered foods" 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. Disclosures for entities that are exempt.
2. Foods that do not contain detectable modified genetic material but are derived from bioengineering.

Voluntary Disclosure for foods "Derived from Bioengineering"

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

Recordkeeping

Regulated entities may determine the types of 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

Compliance Dates

- The mandatory compliance date for all regulated entities is January 1, 2022.
- Food entering commerce after the mandatory compliance date must comply with the Standard
- Food is considered to have entered commerce the day on which it is labeled for retail sale
- Stamps, stickers, or inkjets that use one of the allowed disclosure options, are acceptable

Questions & Answers

Is documentation required to verify the BE status of enzymes, yeasts, and other micro-organisms?

- As required by 7 CFR 66.109, if a regulated entity has actual knowledge that a food is a bioengineered food a disclosure is required.

- For foods not on the AMS List of Bioengineered Foods, like enzymes, yeasts, and other micro-organisms, if records demonstrate actual knowledge that the food they are using is bioengineered, then they must make a disclosure.

I'm using a Genetically Engineered Microbe in my food product and have not included the GEM on the ingredient list, do I need to label my product BE?

- The definition of bioengineered food, at 7 CFR 66.1, excludes incidental additives as described in 21 CFR 101.100(a)(3).
- Incidental additives, when used in accordance with this definition, are not required to be included on the ingredient list.
- If the ingredient you are using is considered an incidental additive, then mandatory and voluntary disclosure based solely on the presence of the incidental additive is not permitted.

Our product is made from a recombinant enzyme and there is a less than 5% of DNA left in the final product, do we need to label our product as bioengineered?

- The threshold exemption at 7 CFR 66.5(c) only applies when the presence of a bioengineered substance is **inadvertent** or **technically unavoidable**, and below five percent for each ingredient.
- Any intentional use of a BE substance requires a disclosure, regardless of the percentage that food or ingredient represents in the finished food product.
- Given the proprietary nature of food production, companies are in the best position to determine on a case-by-case basis whether their products are subject to labeling under the Standard.

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 an email to

befooddisclosure@usda.gov

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