Agricultural Marketing Service

Overview of the National Bioengineered Food Disclosure Standard

July 2021

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?

Email questions to: befooddisclosure@usda.gov

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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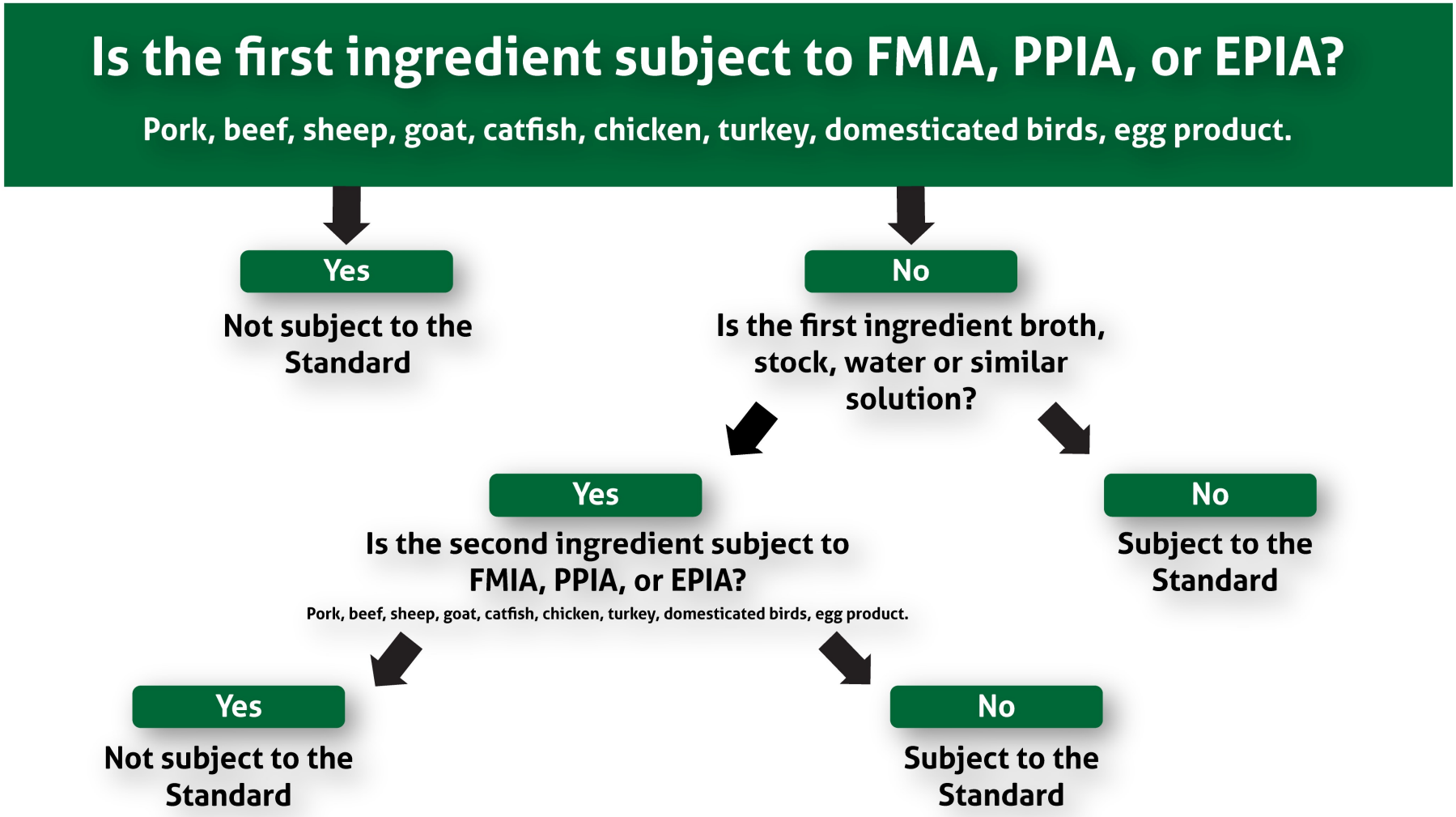

Is this food subject to disclosure?

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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).

Slide 12

CDE3 Per Rupa's edit to the script, delete "the crux of" in the first sentence.
Courtney D Enlow, 11/25/2020

CR-OWD1 Made the change
Chilukuri, Rupa - OGC, Washington, DC, 11/27/2020

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

Slide 14

CDE2 Per Rupa's edit to the script, the last line of the notes should read: If a regulated entity is using a food that is not on this list but they have actual knowledge that the food they are using is a bioengineered food, then they must make a bioengineered food disclosure.
Courtney D Enlow, 11/25/2020

CR-OWD2 Revised
Chilukuri, Rupa - OGC, Washington, DC, 11/27/2020

Annual Updates to the Bioengineered Foods List

- 2020 Bioengineered Food List Update
  - Proposed Rule Stage
  - Listed on the Spring 2021 Unified Agenda of Regulatory and Deregulatory Actions under RIN **0581-AD95**
- Research for the 2021 Update to the Bioengineered Food List is underway

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.

Guidance to Ensure Acceptable Validation of a Refining Process

- AMS published final guidance on refining process method validation on July 7, 2020
- The guidance includes 8 General Steps to Validate a Refinement Process

Key Steps to Validate a Refinement Process

1. Identify raw materials, ingredients, and product-contact materials
2. Define characteristics and intended use of end product
3. Define the sequence and interaction of all processing steps used to arrive at the end product
4. Identify key step or steps in the refinement process that may influence the end product's characteristics and its ability to meet specified requirements

Key Steps to Validate a Refinement Process

5. Assemble relevant validation information that demonstrates the refinement process operates as intended to meet specified requirements (end product characteristics), conducting studies as needed
6. Continually verify the refinement process is operating as validated
7. Revalidate the refinement process, as applicable, if significant changes are made to the process
8. Maintain record(s) of the validation and ongoing verification

Detectability (testing)

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

Guidance on Testing Methods

- AMS published final guidance on testing methods on July 7, 2020
- The guidance includes 5 Key Concepts

Key Steps in Selecting a Test Method

1. General considerations in selecting a test method
2. DNA-based test methods
3. Emerging technologies and other methods
4. General consideration in selecting a laboratory
5. Recordkeeping requirements

Slide 25

CDE4 Please delete the sentence in the notes beginning with "As new and emerging technologies..." and replace with Rupa's edit to the script: "Technology, such as DNA sequencing, continually progresses and may become more commercially and economically accessible. If these emerging technologies meet the requirements of 7 CFR 66.9(c), they would be sufficient to comply with the Standard."
Courtney D Enlow, 11/25/2020

CR-OWD9 Made this change.
Chilukuri, Rupa - OGC, Washington, DC, 11/27/2020

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Guidance Documents available at:

https://www.ams.usda.gov/rules-regulations/be/validation-process

The regulations implementing the National Bioengineered Food Disclosure Standard (the Standard) identify the requirements for detecting modified genetic material at 7 CFR 66.9. In the final rule, AMS indicated it would provide industry stakeholders further instructions regarding (1) acceptable testing methodology used to satisfy that a food does not contain detectable modified genetic material and (2) validating a refining process. Instructions and FAQs can be found at the links below.

Resources

- Guidance on Testing Methods (pdf)
- FAQs on Testing Methods (pdf)
- Guidance on Validation (pdf)
- FAQs on Refining Process Validation (pdf)

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**

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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 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**

Slide 42

CR-OWD4 Revised the slide heading to "Voluntary Disclosure Under the Standard"
Chilukuri, Rupa - OGC, Washington, DC, 11/27/2020

Voluntary Disclosure for exempt entities

- 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.

Slide 43

CR-OWD6 Revised the slide heading to read "Voluntary Disclosure for exempt entities"
Chilukuri, Rupa - OGC, Washington, DC, 11/27/2020

Voluntary Disclosure for foods "derived from bioengineering"

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. corn syrup originating from BE corn, soybean oil)
- Is not allowed for any other foods or ingredients
  - Examples that <u>cannot</u> be voluntarily disclosed: food produced from animals fed bioengineered feed; soups where the first ingredient is meat; incidental additives

Slide 44

CDE5 Can we leave out the example of "sugar derived from a sugar beet"? A group representing the sugar beet industry is currently asking the court to let them be a part of this case, so I'd rather not mention anything to do with sugar beets.
Courtney D Enlow, 11/25/2020

CR-OWD7 Agreed and replaced with "corn syrup originating from BE corn". Also revised heading to read "Voluntary disclosure for foods ”derived from bioengineering”
Chilukuri, Rupa - OGC, Washington, DC, 11/27/2020

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:

Slide 45

CDE6 This slide is vague. I recommend making it clear that this slide only applies to the second type of voluntary disclosure. Please make similar edits to the notes below (as provided in the script).
Courtney D Enlow, 11/25/2020

CR-OWD8 Made changes to the slide heading -added for foods "derived from bioengineering"
Chilukuri, Rupa - OGC, Washington, DC, 11/27/2020

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

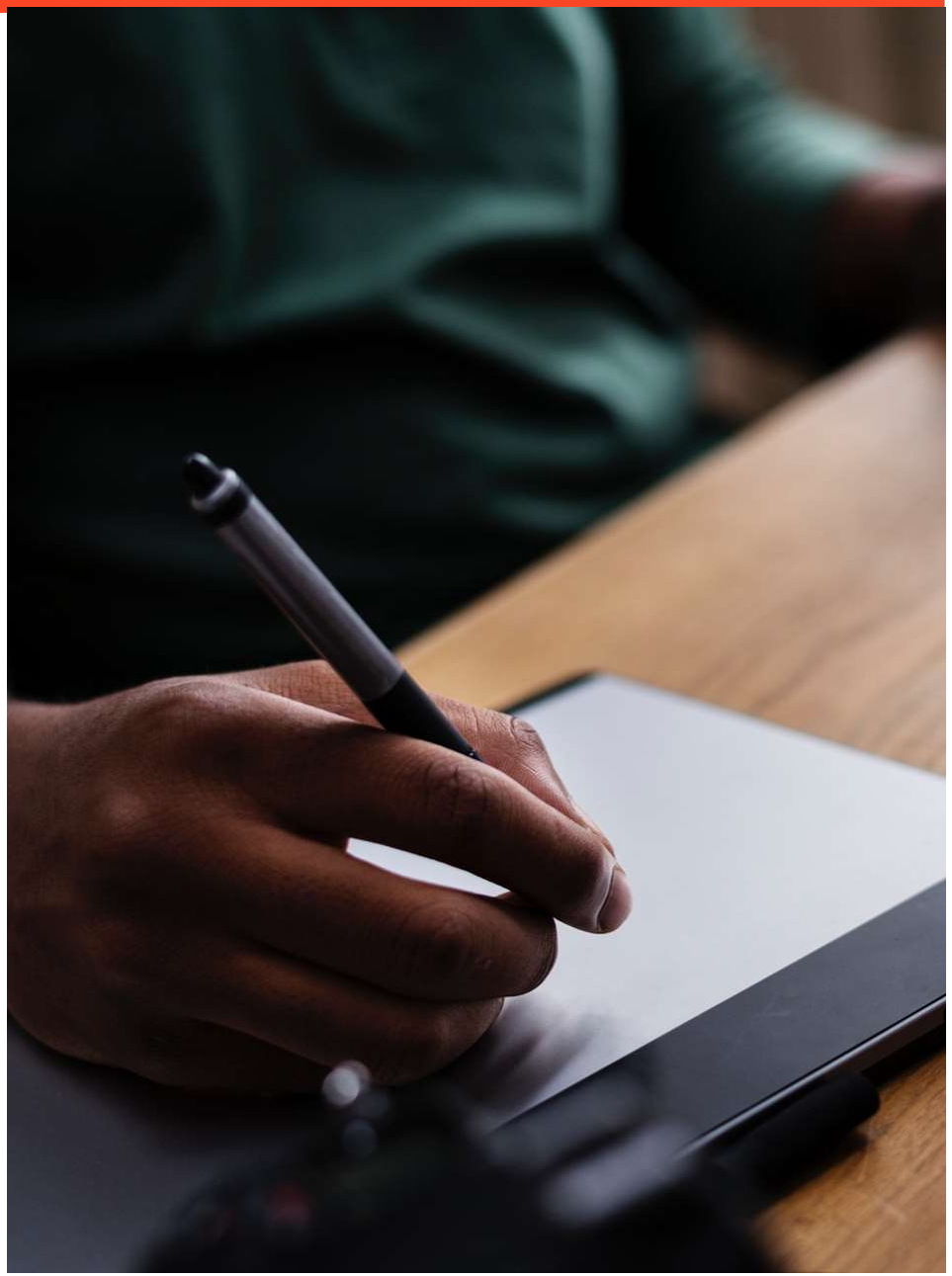
Regulated entities are able to determine what business records to maintain, provided that they demonstrate compliance with the disclosure standard. Examples of possible records include:

- **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.**

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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

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