U.S. Department of Agriculture National Bioengineered Food Disclosure Standard

Frequently Asked Questions

General

Q: What is the National Bioengineered Food Disclosure Standard?

- The National Bioengineered Food Disclosure Standard (NBFDS or Standard) requires food manufacturers, importers, and certain retailers to disclose information about whether food offered for retail sale is bioengineered (BE) or uses BE food ingredients. The Standard is designed to provide consumers more information about their food.
- The Standard defines bioengineered foods as those that contain detectable genetic material that has been modified through *in vitro* recombinant deoxyribonucleic acid (rDNA) techniques and for which the modification could not otherwise be obtained through conventional breeding or found in nature.

Q: Who must comply with the disclosure requirements of the Standard? What is a regulated entity?

- Regulated entities must comply with the Standard. The Standard defines regulated entities as food manufacturers, importers, and certain retailers who label food for retail sale.
- The law does not apply to restaurants and similar retail food establishments (e.g. cafeterias, food trucks, airplanes, etc.) or very small food manufacturers, which are food manufacturers with annual receipts of less than \$2,500,000.
- The law does include dietary supplements in the definition of food covered under the standard, so manufacturers and importers of dietary supplements must comply with the disclosure requirements of the Standard.

Q: What products must comply with the NBFDS disclosure requirements?

- Bioengineered foods or foods that contain bioengineered food ingredients must be labeled with the bioengineered food disclosure.
- The Standard defines bioengineered foods as those that contain detectable genetic material that has been modified through *in vitro* recombinant deoxyribonucleic acid (rDNA) techniques and for which the modification could not otherwise be obtained through conventional breeding or found in nature.
- Highly refined foods or ingredients that do not contain detectable modified genetic material are not bioengineered foods.

Q. What is the List of Bioengineered Foods?

- The List of Bioengineered Foods (List) identifies bioengineered foods that are authorized for commercial production (by the country in which it is produced) and in legal production somewhere in the world. The List tells regulated entities which foods they must keep records for and which foods may require BE disclosures.
- The List includes: alfalfa, apple (ArcticTM varieties), canola, corn, cotton, eggplant (BARI Bt Begun varieties), papaya (ringspot virus-resistant varieties), pineapple (pink

- fleshed varieties), potato, salmon (AquAdvantage®), soybean, summer squash and sugarbeet.
- When only one company produces a bioengineered food, such as ArcticTM Apples or AquAdvantage[®] salmon, AMS will include the trade name on the List to simplify compliance for regulated entities.
- Regulated entities whose records show that a food they are selling or using is bioengineered must make appropriate disclosure of that food, even if that food is not on the List.
- Additional information about the crops and foods on the List is available on the AMS website. The information will be maintained and updated.
- The online information will include details about specific varieties of crops and foods that have been bioengineered, to help regulated entities more easily identify foods for which disclosure may be necessary.

Q. How will the List be updated?

- USDA will update the List when necessary to reflect the current availability of bioengineered foods.
- Before updating the List, USDA will coordinate with other Federal regulatory agencies who regulate biotechnology.
- USDA will conduct annual reviews of the List and, as necessary, conduct rulemaking to amend the List. Public input into the List's composition is invited on an ongoing basis.
- The Standard also outlines a rulemaking process to help determine whether there are certain "factors and conditions" that may exclude certain foods from being considered a bioengineered food.

Q. How can I tell if my food has detectable modified genetic material?

• The Standard identifies three different ways that a regulated entity can determine that modified genetic material is not detectable: (1) by using records to verify that a food is sourced from a non-bioengineered crop, (2) by using records to verify that a food has been subjected to a refinement process that has been validated to render modified genetic material undetectable, or (3) by maintaining certificates of analysis or other testing records appropriate to a specific food that confirm the absence of detectable modified genetic material.

Q. Will the Standard have an impact on foreign trade?

- The Standard is not intended to, or expected to, disrupt trade. The Standard places the same requirements on domestic and foreign entities.
- During the rulemaking process, USDA sought comment from all stakeholders regarding any unique issues associated with bioengineered food disclosure for imports.
- The proposed rule was notified to the World Trade Organization and open for comments from our trading partners.
- USDA's Foreign Agricultural Service is prepared to work closely with countries who
 import food into the United States to help them understand the requirements of the
 Standard.

For Manufacturers

Q. What records are sufficient to verify that a food is sourced from a non-bioengineered crop?

• A variety of records may be sufficient to verify a food is sourced from a non-bioengineered crop. A non-exhaustive list includes: organic certification, records that show a non-BE crop variety was used, and records that show a food originated in an area where that specific BE food is not produced.

Q. What is a validated refining process?

- A validated refining process is one that has been demonstrated to make modified genetic material undetectable when followed. Validation is confirmed through testing and through maintenance of processing records.
- AMS will provide guidance related to the use of validated refining processes.

Q. Once I have validated that a refining process makes modified genetic material undetectable, do I need to continue to test that process?

• No, once a process has been validated through testing and a regulated entity maintains records showing the validated process is followed, the process does not need to be tested again unless significant changes are made to that refining process.

Q. What kind of testing is required to confirm the presence or absence of modified genetic material?

- AMS does not specify which tests must be used, but we provide standards of performance regarding detectability testing methodology.
- In general, the testing laboratory is expected to employ quality assurance standards common to the industry to ensure the validity and reliability of test results.
- Specific standards of performance are described in § 66.9(c) of the NBFDS, and AMS will provide additional guidance regarding those standards in the future.

Q. What is the threshold for bioengineered substance, and how is it measured?

- The threshold is designed to recognize the realities of the supply chain and acknowledge that BE and non-BE food and ingredients are often grown, harvested, transported, and processed in close proximity to one another. Because of this reality, even when a non-BE ingredient is used, there may be a trace amount of a BE substance that remains on shared equipment.
- The threshold exempts food in which no ingredient intentionally contains a bioengineered substance and allows for the inadvertent or technically unavoidable presence of a BE substance, of up to five percent, in each ingredient.

Q. What is inadvertent or technically unavoidable?

• The inadvertent or technically unavoidable presence of a BE substance is that which occurs unintentionally when reasonable and customary practices are implemented to separate BE and non-BE ingredients. A small amount of BE corn that remained in a combine after a reasonable effort to remove all BE corn before harvesting non-BE corn would be considered inadvertent or technically unavoidable if present in an amount less

than five percent. Conversely, if a food manufacturer was producing a non-BE cracker, ran out of one non-BE ingredient, and decided to use a BE version of that ingredient, that would be considered an intentional use and would require a BE food disclosure.

Q. If I am a food manufacturer, importer, or retailer and I don't use a food, or an ingredient produced from a food, on the List of Bioengineered Foods, am I subject to the Standard?

• Regulated entities are those responsible for making bioengineered food disclosures on retail food packages. Regardless of a food's inclusion on the List, the entity responsible for labeling the food for retail sale must comply with the Standard if they have actual knowledge that the food or ingredient is bioengineered.

Q: What are the recordkeeping requirements for regulated entities?

- Regulated entities must keep records that are customary and reasonable to demonstrate
 compliance with the Standard. Examples of such records include, among other things,
 supply chain documents, bills of lading, invoices, supplier attestations, labels, contracts,
 brokers' statements, third-party certifications, laboratory testing results, validated process
 verifications, and other records generated and maintained in the normal course of
 business.
- If a regulated entity uses a food, or an ingredient produced from a food, on the List of Bioengineered Foods, the entity must maintain records regarding that food or ingredient.
- If a regulated entity uses a food, or an ingredient produced from a food, that is not on the List of Bioengineered Foods, but the regulated entity has actual knowledge that the food or ingredient is bioengineered, the entity must maintain records for that food or ingredient.

Q: How long are regulated entities required to retain records that verify compliance with NBFDS?

• Records can be kept in electronic or paper form and must be kept for two years beyond the date a food is sold or distributed for retail sale.

Q. When am I required to notify USDA of a new BE product being developed?

- There is no requirement to notify USDA AMS of a new BE product being developed.
- When conducting annual List reviews, AMS will rely on a variety of resources and public input to determine what foods should be added to the List. Updates to the List will be completed using notice and comment rulemaking.

Disclosure

Q: If I am a regulated entity, how must I make the disclosure to show that my food is bioengineered or includes bioengineered food ingredients?

- The disclosure may be made using one of four different methods: (1) text, (2) symbol, (3) electronic or digital link, or (4) text message.
- The text disclosure is: "bioengineered food" or "contains bioengineered food ingredients."
- The symbol disclosure is:



- The electronic or digital disclosure must include a statement such as "Scan here for more food information" and must be accompanied by a telephone number and the statement "Call [1-000-000-0000] for more food information." When accessed, the electronic or digital link must include the bioengineered food disclosure (text or symbol) on the first screen a consumer sees on the electronic or digital device.
- The text message disclosure must include the statement "Text [command word] to [number] for bioengineered food information." When used, the number must immediately send a response to the consumer's mobile device with the bioengineered food disclosure.
- Small food manufacturers (< \$10,000,000 annual receipts) may make the disclosure using a telephone number or URL and the statement "Call/visit [phone number/website] for more food information."
- The Standard includes reasonable accommodations for disclosure on foods in small and very small packages, including a shortened statement accompanying disclosures made by text message and electronic or digital disclosure.

Q: Where must the bioengineered food disclosure be placed?

- The Standard prescribes three different locations for the disclosure. First, the disclosure can be placed on the information panel directly adjacent to the statement identifying the name and location of the distributor (or similar information). This will frequently be directly below the nutrition fact panel. Second, the disclosure can be placed on the principal display panel, which is typically the front of the package and the panel that consumers will see first when shopping. If there is not enough space on the information panel or the principal display panel, then the disclosure may be made on an alternative panel likely to be seen by the consumer under ordinary shopping conditions.
- Consumers should look in these places for the bioengineered food disclosure, which may be made using (1) text disclosure, (2) symbol disclosure, (3) electronic or digital disclosure, or (4) text message disclosure.

Q: Is there a specific size requirement for the disclosure?

• The Standard does not prescribe a specific size for the disclosure. Regardless of the disclosure option a regulated entity chooses to use, the Standard requires that the disclosure be of sufficient size and clarity to appear prominently and conspicuously on the label, making it likely to be read and understood by the consumer under ordinary shopping conditions.

Voluntary Disclosure

Q: Can an entity voluntarily make disclosures for foods that are derived from bioengineered crops, but do not contain detectable modified genetic material?

• Yes. The Standard acknowledges that consumers want additional information about their food and how it was produced, and that some regulated entities want to provide consumers with this information. To provide consumers with more information, the Standard allows regulated entities to voluntarily disclose the presence of ingredients

derived from bioengineering when the modified genetic material is no longer detectable. This voluntary disclosure can be made using any of the disclosure methods available for mandatory disclosures, and by using the phrase "derived from bioengineering" or "ingredient(s) derived from a bioengineered source," or the symbol:



• Entities electing to make voluntary disclosures must comply with all requirements of the Standard.

Q: Can an entity that is otherwise exempt from disclosure, such as a very small food manufacturer or a restaurant, voluntarily comply with the Standard?

- Yes, exempt entities such as very small food manufacturers, and restaurants or similar retail food establishments who are labeling bioengineered foods for retail sale may voluntarily comply with NBFDS in the same manner as regulated entities including using one of the disclosure methods set forth in the Standard.
- Exempt entities may voluntarily disclose foods that are derived from bioengineered crops, but do not contain detectable modified genetic material, in accordance with the Standard.

Compliance and Enforcement

Q: What is the compliance date, or when must bioengineered foods be disclosed?

- The mandatory compliance date is January 1, 2022. Foods entering commerce after this date must be labeled in compliance with the Standard.
- Regulated entities may voluntarily comply with the NBFDS until December 31, 2021.
- Consumers may begin to see disclosures as early as February 2019.

Q: Can companies continue using existing labels or packaging that do not include NBFDS information?

• The Standard gives regulated entities until January 1, 2022, to comply with the Standard. Until that time, regulated entities can use labels that may not include a bioengineered food disclosure or labels that include a disclosure made in conformance with preempted state labeling requirements.

Q: What happens if a regulated entity does not comply with the Standard?

- It is a violation of the Standard for a regulated entity to knowingly fail to make a bioengineered food disclosure in accordance with the requirements of the Standard.
- If anybody suspects a violation may have occurred, they can file a written complaint with the AMS Administrator by mail or on the AMS website. The Administrator will determine whether reasonable grounds exist for an investigation of the complaint, and if so, request records from the entity responsible for disclosure. Based on those records, AMS will make its findings available to the regulated entity and provide them with an opportunity for a hearing. After the hearing, and once AMS has finalized its findings, AMS will make public a summary of the results of the investigation.

- USDA does not have the authority to issue a recall or impose civil penalties for violations of the Standard.
- After the Standard is implemented, States may adopt identical requirements and States may impose remedies for violations of their standards, such as monetary damages and injunctive relief.

Requirements for Retailers and Importers

Q: What are a retailer's responsibilities under the Standard?

• Retailers are responsible for ensuring that (1) foods packaged by the retailer and (2) foods sold in bulk containers or bulk displays comply with the Standard. For these foods, retailers have the same recordkeeping requirement as all other regulated entities under the Standard.

Q: Are foods prepared by a retailer subject to the Standard (i.e. baked goods, grab-n-go items, hot bar items, etc.)?

• A retailer that prepares and sells restaurant-type foods—which are those usually eaten on the premises, while walking away, or soon after arriving at another location—do not need to make a bioengineered food disclosure on restaurant-type foods. A retailer that prepares all other types of foods is subject to the requirements of the Standard and must make appropriate bioengineered food disclosures. For example, individual bagels prepared and sold by a retailer would not be subject to the Standard, but a package of six bagels prepared and sold by a retailer would be subject to the Standard.

Q: Are bulk foods subject to the Standard?

• Yes, bulk foods are subject to the Standard and must be disclosed using one of the four disclosure methods (text, symbol, electronic or digital, text message). The disclosure must be placed on signage or other materials on or adjacent to the bulk container.

Q: Are places such as fish markets, farmers markets and butcher shops subject to the NBFDS?

• If a fish market, a farmers market, or a butcher shop sells a bioengineered food that is not otherwise exempt, then the food must be labeled according to the Standard. If one of these entities operates in a manner that would make it a restaurant or similar retail food establishment, then the entity would be exempt.

Q: What are an importer's responsibilities under the Standard?

• Importers are responsible for ensuring that all imported bioengineered foods comply with the Standard. For imported foods, importers have the same recordkeeping requirements as all other regulated entities under the Standard.

Resources

Q. What is the information that AMS has on its website for each of the items on the List of Bioengineered Foods?

• The information on the website is designed to help regulated entities understand which varieties of foods on the List of Bioengineered Foods may be bioengineered. The website will include specific information about traits, varieties, and production information (i.e. location) that will help regulated entities determine whether they need to make a BE disclosure.

Q: If I think there is a food that is bioengineered, but it does not include a bioengineered food disclosure, how do I report that?

• Anybody who suspects a violation may have occurred can file a written complaint with the AMS Administrator by mail or on the AMS website. More detailed instructions will be posted to the AMS website closer to the compliance date.

Q: If I have further questions or want more specific information pertaining to the Standard, who do I contact?

• Please e-mail befooddisclosure@ams.usda.gov