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The Bioengineered Food Disclosure Standard

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Background & Introduction

On July 29, 2016, President Obama signed the National Bioengineered (BE) Food Disclosure Law (Law).[1] This law required the Secretary of Agriculture to create regulations establishing the National BE Food Disclosure Standard (Standard). The Secretary of Agriculture delegated this task to the Agriculture Marketing Service (AMS), an agency housed within the United States Department of Agriculture (USDA).
On December 21, 2018, AMS published a final rule formally creating the Standard.[2] The Standard requires food manufactures, importers, and retailers to include a disclosure on certain food labels when the food is BE or contains BE ingredients. The Standard addresses whether a food contains BE ingredients, and does not address the safety of BE foods. This fact sheet explains which products require disclosures, how "regulated entities" should make those disclosures, what records regulated entities should keep, and how AMS will enforce the Standard. The last section of this factsheet lists links to resources published by AMS.

[1] 7 U.C.S. § 1639-1639c.
[2] 83 Fed. Reg. 65814, 7 C.F.R. § 66.

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Definitions

Both the Law and the Standard use certain terms that have a specific meaning.

First and foremost, the Standard defines BE food as "food that contains 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".[3] AMS has not defined either "conventional breeding" or "found in nature". Instead, AMS has stated that it "intends to make determinations about whether a specific modification [is] considered 'found in nature' or obtained through 'conventional breeding' on a case-by-case basis."[4] For example, if a food manufacturer uses a tool such as CRISPR/Cas9, which cuts or removes a portion of the genetic code, AMS will examine the manufacturer's records and determine whether that genetic deletion would have been achievable through conventional plant breeding techniques. The Standard clarifies that a food does not contain modified genetic material if such material is not detectable in the food.[5]

The Standard uses the term "regulated entity", and explains that a regulated entity is "the food manufacturer, importer, or retailer that is responsible for making [BE] food disclosures".[6] Simply put, the term regulated entity refers to the party responsible for putting the label on the product. If the retailer receives the food already labeled, then the food manufacturer or importer is the regulated entity. If the retailer labels the product, the retailer is the regulated entity.[7]

Finally, the Standard defines small food manufacturers as those "with annual receipts of at least $2,500,000, but less than $10,000,000."[8] This is important because when Congress drafted the Law, it required USDA to set two implementation dates. One date for small food manufacturers and one for all other food manufacturers. The Standard set the implementation date for small food manufacturers as January 1, 2021. The Standard set the implementation date for all other food manufacturers as January 1, 2020. AMS explains that these implementation dates are when regulated entities should prepare to fully comply with the Standard. According to AMS that includes identifying foods that may require a BE disclosure, collecting the necessary records to

[3] 7 C.F.R. § 66.1.
[4] U.S. Dep't of Argic., *Webinar: Overview of the National Bioengineered Food Disclosure Standard December 2020*, YouTube (Dec. 10, 2020), https://www.youtube.com/watch?v=rxE2FgrZPVs.
[5] 7 C.F.R. § 66.9.
[6] 7 C.F.R. § 66.1.
[7] 7 C.F.R. § 66.100(a).
[8] 7 U.S.C. § 66.1.

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meet the Standard's recordkeeping requirements, and choosing the type of BE disclosures that the regulated entity plans to use.[9]

Although the Law only required USDA to set implementation dates, the Standard also set a mandatory compliance date. That date, January 1, 2022 is "when foods entering commerce must be labeled in accordance with the Standard".[10] The mandatory compliance date is when USDA will begin enforcing the Standard's provisions.

Which Food Labels Require Disclosures?

Both the Law and Standard explain which foods the Standard applies to. The Standard applies to foods that fall under the food labeling jurisdiction of the Food and Drug Administration (FDA) and some of the food that falls under the labeling jurisdiction of the Food Safety Inspection Service (FSIS).[11]

However, both the Law and Standard state the following:

> This subchapter shall apply only to a food subject to—
> (1) the labeling requirements under the Federal Food, Drug, and Cosmetic Act (FFDCA); or
> (2) the labeling requirements under the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), or the Egg Products Inspection Act (EPIA) only if—
> (A) the most predominant ingredient of the food would independently be subject to the labeling requirements under the FFDCA; or
> (B)(i) the most predominant ingredient of the food is broth, stock, water, or a similar solution; and (ii) the second-most predominant ingredient of the food would independently be subject to the labeling requirements under the FFDCA.[12]

To help explain this complicated regulatory scope, AMS created the following flow chart[13]:

[9] U.S. Dep't of Agric., *BE Frequently Asked Questions-General*, https://www.ams.usda.gov/rules-regulations/be/faq/general (last visited December 20, 2021).
[10] U.S. Dep't of Agric., *BE Frequently Asked Questions-General*, https://www.ams.usda.gov/rules-regulations/be/faq/general (last visited December 20, 2021).
[11] 7 U.S.C. § 1639a(c); 7 C.F.R. § 66.3(b).
[12] 7 U.S.C. § 1639a(c); 7 C.F.R. § 66.3(b).
[13] U.S. Dep't of Agric., *Webinar: Overview of the National Bioengineered Food Disclosure Standard December 2020*, YouTube (Dec. 10, 2020), https://www.youtube.com/watch?v=rxE2FgrZPVs.

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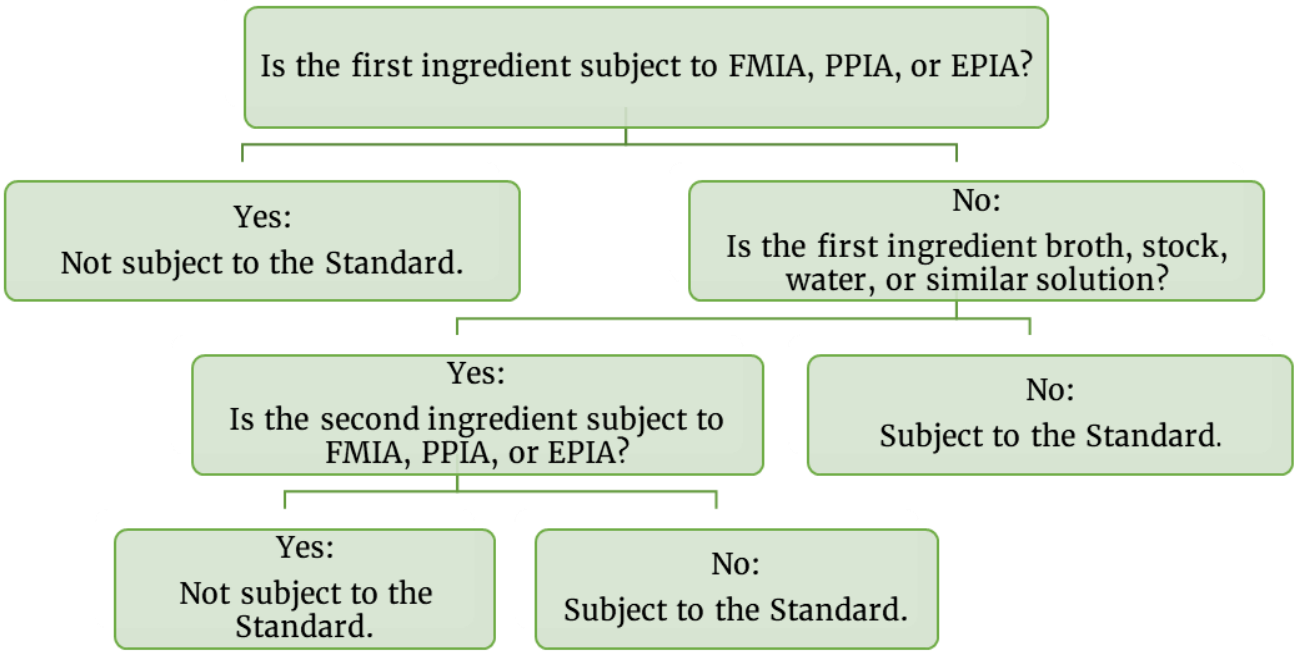

To help regulated entities determine which foods require a BE food disclosure, AMS keeps a list of BE crops and foods that are legally produced anywhere in the world. AMS updates the list annually. However, if a regulated entity has actual knowledge that its product is a BE food or contains BE ingredients and the food or ingredient is not listed, then the regulated entity must keep record of such and must include a disclosure on the label.[14] As of January 1, 2022, the list includes the following foods:

1. Alfalfa
2. Artic™ apple varieties
3. Canola
4. Corn
5. Cotton
6. BARI Bt Begun eggplant varieties
7. Ringspot virus-resistant papaya varieties
8. Pink flesh pineapple varieties
9. Potato
10. AquAdvantage® Salmon
11. Soybean
12. Summer squash
13. Sugarbeet

If a food contains a listed crop or food, the Standard requires the label of the final food product to include a BE disclosure. However, if a food contains a processed form of a listed crop or food, the labeling requirements will differ depending on whether the BE material is detectable. If the BE material is detectable, then a disclosure is required.

[14] 7 C.F.R. § 66.109.

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However, if the BE material is undetectable then no disclosure is required.[15] If a regulated entity is using a non-BE version of a listed food, or is using a highly refined version of a listed food (meaning that there is no detectable genetic modification), the regulated entity must keep accurate records indicating such.[16]

Additionally, the Standard explicitly exempts certain foods from disclosures. These exemptions include food served in restaurants or food retail establishments and food made by very small food manufacturers (those with annual receipts of less than $2.5 million[17]). Although exempt, restaurants, retail food establishments, and very small food manufacturers may voluntarily disclose that the food they produce or serve is BE.

Food certified under the National Organic Program (NOP) is also exempt.[18] The NOP already prohibits foods carrying the NOP seal to be BE or contain BE ingredients, so purchasers are aware of the content without adding additional notifications.

Further, food derived from an animal that ate BE feed is exempt.[19] It is important to note that most animal feed—including that fed to meat, poultry and dairy animals—is BE or has BE ingredients. However, the Standard does not require disclosure on products made from animals who consumed BE animal feed.

Finally, while meat, poultry, or egg products do not typically require disclosure, if a manufacturer includes an ingredient with detectable BE material, and that BE material accounts for more than 5% of the ingredient, then the food label must include a disclosure.[20]
For example, beef jerky would likely not be subject to the Standard even if it contains sugar from sugarbeets, a listed BE food.[21] However, if sugar from sugarbeets was unavoidable and the BE material in the sugar makes up more than 5% of the sugar, then the beef jerky label must include a BE disclosure. Similarly, chicken soup, where the first ingredient is broth and the second ingredient is chicken, would likely not be subject to the Standard as long as the soup contains no ingredients with more than 5% BE material.

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[15] *See* 7 C.F.R. § 66.1 (explaining under the definition of BE food at (1)(ii) that "food does not contain modified genetic material if the genetic material is not detectable pursuant to § 66.9").
[16] 7 C.F.R. § 66.9.
[17] *Id*.
[18] 7 C.F.R. § 66.5.
[19] 7 C.F.R. § 66.5(d).
[20] 7 C.F.R. §66.5; U.S. Dep't of Agric., *Disclosure Determination Tool*, https://www.ams.usda.gov/rules-regulations/be/zingtree (last visited December 22, 2021).
[21] *See* U.S. Dep't of Agric., *Webinar: Overview of the National Bioengineered Food Disclosure Standard December 2020*, YouTube (Dec. 10, 2020), https://www.youtube.com/watch?v=rxE2FgrZPVs (explaining that a product with a first ingredient of freeze dried egg "is not a [BE] food, regardless of whether any of the remaining ingredients would on their own, be considered a [BE] food").

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Disclosures

If a food is required to have a BE disclosure, the regulated entity must make the disclosure so it can be read and understood by consumers under ordinary shopping conditions.[22] This includes considerations of size, clarity, and placement. For example, regulated entities can either place the disclosure on the side information panel near the manufacturer or distributor name or address, or on the principal display panel (PDP).[23] The PDP is typically the front of a package label. If the disclosure does not fit on either the side information panel or the PDP, the regulated entity can put the disclosure anywhere a consumer will likely see it under ordinary shopping conditions.[24] The Standard offers all regulated entities four ways to make disclosures: text, symbol, electronic or digital link, or text message.

As a first option, the Standard allows regulated entities to print on the food label that the food contains BE food.[25] If the food product contains more than one BE ingredient, regulated entities should use either "bioengineered foods" or "bioengineered food ingredients" on the label.[26] Regulated entities are to use "bioengineered food" if the BE food is a raw agricultural commodity or all the ingredients are BE.[27] If the food product contains one or more BE food ingredients, then regulated entities should use the phrase "contains a bioengineered food".[28] If an exempt entity wishes to voluntarily include a text disclosure, then the exempt entity should include the statement "derived from bioengineering" or "ingredient(s) derived from bioengineered source".[29]

The second disclosure option available to regulated entities is to place the BE symbol on the food product label.[30] The symbol is available for download on AMS's website for use either in color or black and white. The symbol for mandatory disclosures differs from the symbol allowed for voluntary disclosures. If a food is required to have a label, then the regulated entity should use the symbol that reads "Bioengineered".[31] If a very small food manufacturer, restaurant, or similar retail food establishment wishes to voluntarily disclose that a food product is BE, then it should use the symbol that reads "Derived from Bioengineering".[32] The color version of these symbols are as follows:

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[22] 7 C.F.R. § 66.100(c)-(d).
[23] 7 C.F.R. § 66.100(d).
[24] 7 C.F.R. § 66.100(d)(3).
[25] 7 C.F.R. § 66.102.
[26] *Id.*
[27] 7 C.F.R. § 66.102(a)(1).
[28] 7 C.F.R. § 66.102(a)(2).
[29] 7 C.F.R. § 66.116(b)(1).
[30] 7 C.F.R. § 66.104.
[31] 7 C.F.R. § 66.104(a).
[32] 7 C.F.R. § 66.116(b)(2).

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As a third disclosure option, the Standard allows regulated entities to place an electronic or digital link on the food product label.[33] If a regulated entity chooses this option, it must include the statement "scan here for more information" directly above or below where the consumer should scan.[34] However, similar statements that allow for advances in technology are allowed. For example, the statement "scan anywhere on package for more information" is allowed if true.[35] When a consumer scans the link, the consumer should be taken directly to the "product information page" which must include only the BE disclosure.[36] The product information page must not include any marketing or promotional information. When consumers access the product information page, the regulated entity must not collect, analyze, or sell any personal information about consumers or their devices.[37] If a regulated entity chooses the digital or electronic link option, it must also include a telephone number near the digital link with the statement "Call [1-000-000-0000] for more information".[38] When a consumer calls this telephone number, they should receive the BE disclosure.

For the third option, slightly different regulations apply to small and very small food packages as well as small food manufacturers. If the food package is small or very small (defined as less than 40 sq. in. and less than 12 sq. in., respectively)[39], the regulated entity may replace the statement and phone number with the statement "scan for info".[40] If the regulated entity is a small food manufacturer, it may include the statement "call for more food information" along with a telephone number without also including a digital link.[41] Similarly, a small food manufacturer may include the statement "visit [URL of website] for more information" without also including a

[33] 7 C.F.R. § 66.106.
[34] 7 C.F.R. § 66.106(a)(1).
[35] *Id.*
[36] 7 C.F.R. § 66.106(b).
[37] 7 C.R.R. § 66.106(b)(4).
[38] 7 C.F.R. § 66.106(a)(2).
[39] 7 C.F.R. § 66.1.
[40] 7 C.F.R. § 66.112(a).
[41] 7 C.F.R. § 66.110(a).

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phone number.[42] If a small food manufacturer has a BE food product with a small or very small label, then it may include only the statement "call for info" along with a phone number.[43]

If an exempt entity wishes to include an electronic or digital voluntary disclosure, all of the above applies, but the disclosure must make clear that the food product is "derived from" BE ingredients.[44]

The fourth option is a text message disclosure. If a regulated entity chooses this option, it must include the phrase "Text [command word] to [number] for bioengineered food information."[45] The text message the consumer receives in return must only include the BE disclosure without any marketing or promotional information.[46] Like with the digital or electronic link option, the regulated entity must not collect, analyze, or sell consumers' personal information or information about their devices.[47] Additionally, the regulated entity must not use any information obtained from consumers as a result of the text message for marketing purposes.[48] If the food package is small or very small, the regulated entity may instead include a phone number and short code along with the statement "Text for info".[49] If an exempt entity wishes to make a voluntary text message disclosure, then the exempt entity should explain the food product is "derived from" BE ingredients.[50]

If food is sold in bulk, there are additional regulations that apply. BE food sold in bulk containers (such as in a display case, bin, carton, or barrel) or food used at the retail level to present the product to consumers (such as at a seafood counter) must use one of the four required disclosure options.[51] However, the disclosure must appear on signage, a placard, a label, a sticker, a twist tie, or other similar format so that consumers can easily identify and understand the food is BE.[52]

Record Keeping

According to the Standard, regulated entities "must maintain records that are customary and reasonable to demonstrate compliance" with the Standard.[53] The

[42] 7 C.F.R. § 66.110(b).
[43] 7 C.F.R. § 66.112(c).
[44] 7 C.F.R. § 66.116(b)(3).
[45] 7 C.F.R. § 66.108(a).
[46] 7 C.F.R. § 66.108(b)-(c).
[47] 7 C.F.R. § 66.108(d)(1).
[48] 7 C.F.R. § 66.108(d)(2).
[49] 7 C.F.R. § 66.112(b).
[50] 7 C.F.R. § 66.116(b)(4).
[51] 7 C.F.R. § 66.114(a).
[52] 7 C.F.R. § 66.114(b).
[53] 7 C.F.R. § 66.302(a)(1).

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Standard offers a few examples of what AMS considers customary and reasonable as follows: supply chain records, bills of lading, invoices, supplier attestations, labels, contracts, brokers' statements, third party certifications, laboratory testing results, validated process verifications, and other records generated or maintained in regular course of business.[54] AMS has explained that "it is up to each regulated entity to determine which records to maintain to demonstrate they are in compliance. These records can be kept in any format, including hard copy or electronic copy and may be stored at any business location".[55] Regulated entities must maintain records for at least two years after the BE food is sold or distributed for retail sale.[56]

If a regulated entity uses an ingredient on the list of BE foods, then it must keep records of how that ingredient was used in the final food product.[57] If a regulated entity has actual knowledge that its food product contains BE ingredients, but the BE ingredients are not on the list of BE foods, the regulated entity must maintain those records as well.[58]

When AMS requests records from a regulated entity, the regulated entity typically has five days to produce the requested records to AMS. However, AMS may specify a different timeframe.[59] If AMS requests to inspect records at the regulated entity's place of business, AMS will give the regulated entity three business days' notice.[60] The Standard also requires AMS to conduct the inspection during normal business hours. If a regulated entity does not comply with AMS's request to inspect records, then AMS may take enforcement action.

Enforcement

According to AMS, "enforcement of the Standard is complaint driven and compliance is based on records".[61] Additionally, AMS "does not intend to test individual foods or ingredients to ensure they are properly labeled. When AMS receives a compliant, it will determine if a further investigation is warranted. If appropriate, AMS will conduct an audit of the regulated entity's records and notify the entity of its findings".[62]

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[54] 7 C.F.R. § 66.302(a)(4).
[55] U.S. Dep't of Agric., *Webinar: Overview of the National Bioengineered Food Disclosure Standard December 2020*, YouTube (Dec. 10, 2020), https://www.youtube.com/watch?v=rxE2FgrZPVs.
[56] 7 C.F.R. § 66.302(a)(3).
[57] 7 C.F.R. § 66.302(b)(1).
[58] 7 C.F.R. § 66.302(b)(2).
[59] 7 C.F.R. § 66.304(a).
[60] 7 C.F.R. § 66.304(b).
[61] U.S. Dep't of Agric., *Webinar: Overview of the National Bioengineered Food Disclosure Standard December 2020*, YouTube (Dec. 10, 2020), https://www.youtube.com/watch?v=rxE2FgrZPVs.
[62] *Id.*

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If after an audit and investigation AMS finds that a regulated entity was not in compliance with the Standard, then the regulated entity can appeal the finding. In which case there will be a hearing. Appealing entities have 30 days after receiving results of an audit to request a hearing and can submit a response and supporting documents.[63]

After the final agency action, which may be either the investigation or hearing, AMS will make the findings public.[64] However, if the regulated entity requested a hearing and wishes to appeal the findings of the hearing, it can seek judicial review. This means that the regulated entity can appeal its case to the federal court system.

Conclusion

The National BE Food Disclosure Standard requires regulated entities to first determine whether their food product falls under the Standard. If their food product is subject to the Standard, the regulated entity must include a BE disclosure in one of four formats. Additionally, the Standard requires regulated entities to keep records which AMS will use if it ever has reason to conduct an audit and investigation. If consumers become familiar with the four disclosure types, consumers will be able to spot many BE foods on grocery store shelves.

Linked References & Resources

AMS's webpage on BE Disclosures

AMS's Disclosure Determination Tool

AMS's What is a Bioengineered Food? Factsheet

AMS's December 10, 2020, NBFDS Webinar

[63] 7 C.F.R. § 66.404(a).
[64] 7 C.F.R. § 66.406.

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