

CONSUMER'S GUIDE TO BIOENGINEERED FOOD DISCLOSURES

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INTRODUCTION

Over the last decade consumers have become increasingly aware of the food science that brings food from farm to shelf. Many consumers are concerned about the recent increase of genetic modification through modern technologies like gene editing, CRISPR, and genetic engineering. Specifically, consumers wonder how these technologies may affect food quality and safety. In response to these concerns, Congress passed the National Bioengineered Food Disclosure Standard

(NBFDS).¹ In short, the NBFDS is a federal law that will require most food manufacturers and retailers to disclose whether certain foods are bioengineered (BE). BE foods covered by the NBFDS will designate on their labels that they are bioengineered. Those designations may take the form of text disclosures, symbols, or digital links.² This issue brief explains the new regulation and what consumers can expect when the NBFDS becomes mandatory on January 1, 2022.³

WHAT IS BIOENGINEERING?

Under the law, “bioengineering” with respect to food means: A Food: (A) that contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques; and (B) for which the modification could not otherwise be obtained through conventional breeding or found in nature.⁴

In other words, a bioengineered food has had its DNA modified in ways that are not possible through traditional plant breeding methods like selective breeding. Bioengineering uses DNA editing, which requires a human to physically modify or add specific genes to a plant’s DNA. This technology then yields specific plant traits like pesticide tolerance, different coloration, or virus resistance.

Diagram of Traditional Plant Breeding Through Selective Breeding⁵

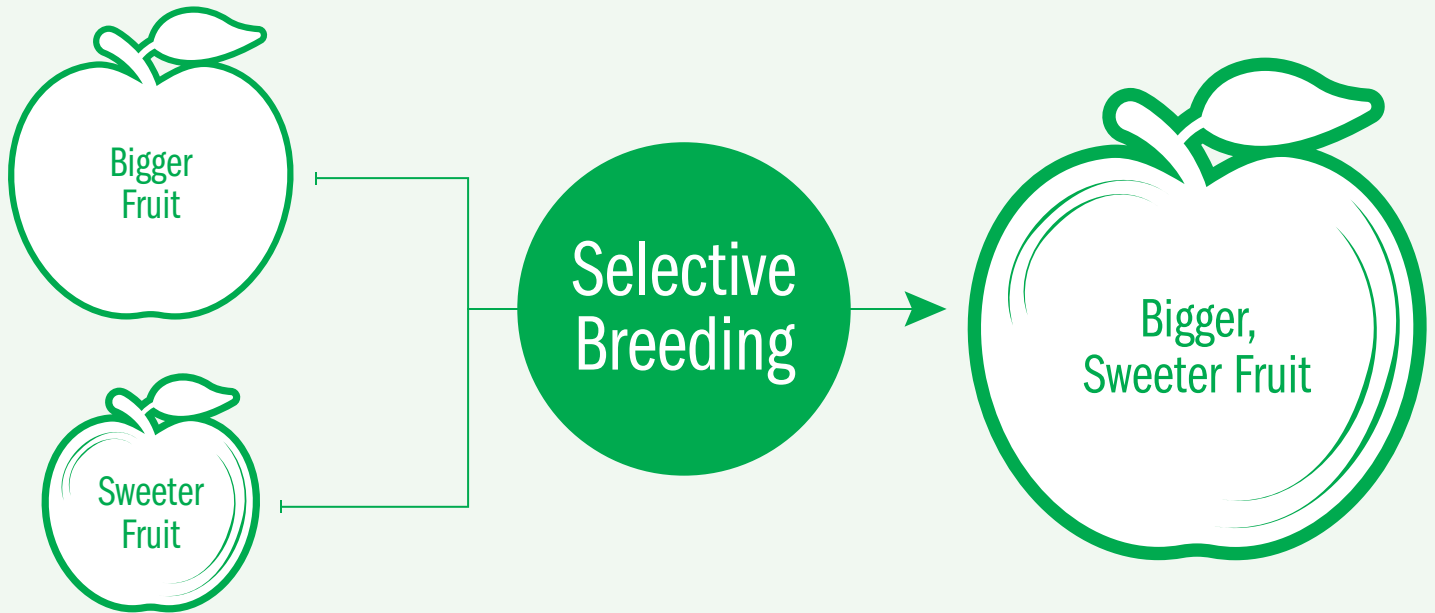
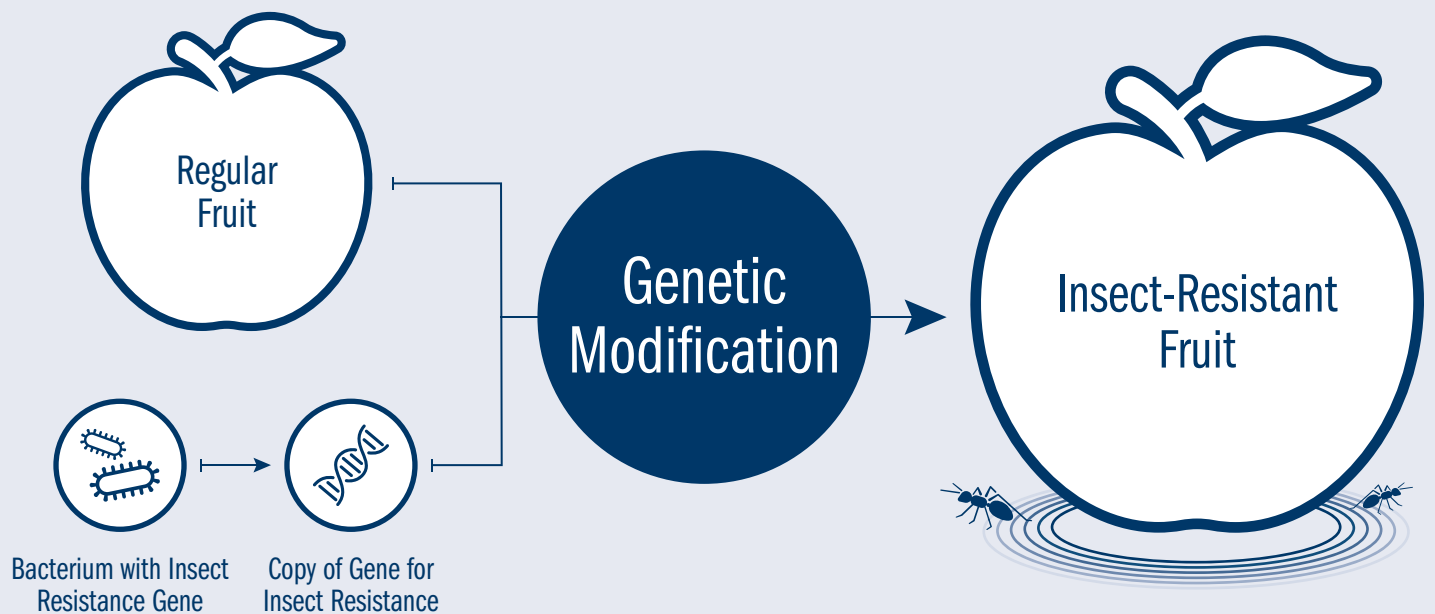


Diagram of Modern Genetic Engineering Through Genetic Modification⁶



WHAT FOODS ARE COVERED UNDER THE STANDARD?

The NBFDS only requires disclosure if the food or ingredient is on the list of bioengineered foods (or if the manufacturer actually knows it is using other BE food ingredients not on the list). USDA's Agricultural Marketing Service (AMS) develops the BE food list and updates it annually.⁷

The current list of bioengineered foods includes:

- | | |
|--|--|
| <ul style="list-style-type: none">○ Alfalfa○ Apple (Arctic™ Varieties)○ Canola○ Corn○ Eggplant (BARI Bt Begun Varieties)○ Papaya (Ringspot Virus-Resistant Varieties) | <ul style="list-style-type: none">○ Pineapple (Pink Flesh Varieties)○ Potato○ Salmon (AquAdvantage®)○ Soybean○ Squash (Summer)○ Sugarbeet⁸ |
|--|--|

Therefore, foods requiring disclosure under the NBFDS include: (1) foods or ingredients on the BE food list; (2) foods that the manufacturer has actual knowledge are bioengineered, whether included on the list or not;⁹ or (3) foods where a manufacturer's records do "not indicate whether or not the food is bioengineered."¹⁰

Disclosure is **not** required for foods where an ingredient contains less than 5 percent bioengineered substances, if those substances are present incidentally or unintentionally.¹¹ "Bioengineered substances" are any substances that contain "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."¹²

Even though a food may not be bioengineered itself, producers may voluntarily label the food as "derived from bioengineering."¹³ These foods are the products of foods on the BE food list. Specifically, the food is a highly refined product that no longer contains any detectable DNA from the original bioengineered food.¹⁴ For example, a canola oil manufacturer may voluntarily disclose that the canola oil is "derived from bioengineering" because canola is on the BE food list, even though the highly

refined canola oil does not have any detectable DNA from BE canola. However, in this case the canola oil manufacturer is **not required** to disclose that information.

Generally, the NBFDS only applies in a limited capacity to foods regulated by the Federal Meat Inspection Act, Poultry Products Inspection Act, or Egg Products Inspection Act (collectively, FSIS statutes).¹⁵ These laws apply to most meat, egg, and poultry products like beef, pork, goat, lamb, eggs, turkey, and chicken. Specifically, the NBFDS does not apply to foods where the most predominant or sole ingredient is already regulated by the FSIS statutes.¹⁶ So, a multi-ingredient food product with a meat, egg, or poultry product as the first listed ingredient (the most predominant ingredient by weight) is exempt. Additionally, if the food's first ingredient is broth, stock, or water, and the second ingredient is a meat, egg, or poultry product (like chicken soup), the food is exempt.¹⁷ So, a can of beef stew will not require BE disclosure where the first ingredient is beef, but the stew also contains BE corn.

Consumers should note that 95 percent of animals used for food are fed bioengineered animal feed.¹⁸ However, manufacturers and retailers are not required to disclose that the animals that produced the meat, eggs, or milk consumed bioengineered feed.¹⁹ Products from animals consuming BE feed do not need the disclosure because the NBFDS only applies to food that "has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques."²⁰ Using BE animal feed does not change the animal's DNA. The only exception to this is the AquAdvantage® salmon because the salmon's DNA has been genetically engineered.²¹

With the exception of products under the FSIS statutes, the NBFDS applies only to foods subject to the Federal Food, Drug, and Cosmetic Act's (FFDCA) labeling requirements.²² Therefore, any foods that are not covered by the FFDCA labeling requirements are also not required to have a BE disclosure. This is an important distinction because it means the NBFDS does not apply to some incidental additives or alcoholic beverages.²³ In short, incidental additives are substances that "are present in a food at insignificant levels and do not have any



technical or functional effect in that food.”²⁴ This includes substances that migrate from equipment or packaging onto food and substances that are added to food during manufacturing, but removed prior to packaging.²⁵ As to alcohol, only wines with less than 7 percent alcohol by volume and beers brewed without malted barley and hops are covered by the NBFDS.²⁶

Finally, though not technically excluded, any food that is Certified Organic under USDA’s National Organic Program is “considered sufficient to make claims about the **absence** of bioengineering in the food.”²⁷ This means that any USDA Certified Organic food may claim that it is **not** made with bioengineering or genetic modification.²⁸ However, this does not apply to foods with less than 70 percent organic ingredients “because those products may include bioengineered ingredients along with organic ingredients.”²⁹

In sum, most manufacturers need to include a disclosure where:

1. The food contains an ingredient from the BE food list
2. The first or sole ingredient is not meat, eggs, or poultry (or second ingredient for soups)
3. The ingredient contains 5 percent or more BE food by weight

Manufacturers that know the food contains BE ingredients or cannot establish whether the food contains BE ingredients must also include a disclosure. However, manufacturers do not need to include a disclosure if the food is derived from a BE food but does not contain a detectable amount of BE DNA.

HOW WILL I KNOW WHAT FOODS ARE BIOENGINEERED?

The BE disclosure will generally appear in one of four forms: text; symbolic, electronic, digital, or through an SMS text message.³⁰ The disclosure, regardless of form, must be prominent such that consumers will see it in normal shopping conditions.³¹

For foods on the BE food list or foods made entirely of ingredients on the BE food list, a text disclosure will state, “Bioengineered food.”³² For foods that contain at least one ingredient on the BE list, a text disclosure will state, “Contains a bioengineered food ingredient.”³³ For symbolic disclosures, a food made from ingredients on the BE list will have a specific circular symbol in color or black and white:³⁴

Example of the symbolic disclosure:



Manufacturers may also use an electronic or digital link disclosure.³⁵ The statement, “Scan here for more information” or a similar statement that directs the consumer where to scan³⁶ will appear next to the link.³⁷ The link must take the consumer directly to an informational page that contains a BE disclosure through either text or symbol.³⁸ This page cannot contain advertisements and may not collect personally identifying information except as necessary to actually display the page; any information collected must be deleted immediately and cannot be used for any other purpose.³⁹ Electronic or digital links must also provide a phone number consumers may call at any time for more information.⁴⁰

An SMS text message disclosure will appear as, “Text [command word] to [number] for bioengineered food information.”⁴¹ The manufacturer cannot charge any fees for this service, include any advertisements, collect or sell any personally identifiable information, or use any information for marketing purposes.⁴²

Small food manufacturers also have the option to disclose through a 24-hour phone number or provide a URL for a website containing a proper disclosure.⁴³ Even if a food would otherwise need to bear a disclosure, very small manufacturers,



restaurants, and similar establishments are exempt from providing BE disclosures.⁴⁴ Restaurants and similar establishments include food trucks, “a cafeteria, lunch room, food stand, saloon, tavern, bar, lounge, [. . .] salad bars, delicatessens, and other food enterprises located within retail establishments that provide ready-to-eat foods that are consumed either on or outside the retailer’s premises.”⁴⁵ A very small food manufacturer is “a food manufacturer with annual receipts of less than \$2.5 million.”⁴⁶ This threshold exempts “about 74 percent of food manufacturers [. . .] from mandatory disclosure, but 96 percent of products will still be subject to disclosure.”⁴⁷

For more information on NBFDS, see:

[National Bioengineered Food Disclosure Standard Statute Text](#)

[Regulation Text](#)

[Federal Register Notice](#)

[Agricultural Marketing Service: BE Disclosure](#)

[FDA: Agricultural Biotechnology](#)

[Congressional Research Service: The National Bioengineered Food Disclosure Standard: Overview and Select Considerations](#)

WHAT’S THE DIFFERENCE BETWEEN GMOs AND BIOENGINEERED FOODS?

Many consumers are more familiar with the term “genetically modified organism,” or “GMO,” than the term “bioengineered.” Both USDA and FDA hope to clear up some of this confusion and encourage use of more precise terminology. It is unclear whether FDA or the AMS treat the term “bioengineered” as synonymous with “genetically modified” as in the case of “GMO” labeling.

The AMS’s response to comments asking for clarification does not definitively answer this question one way or another, but states that it retains the authority to “determine other terms that are similar to ‘bioengineering.’” But, for purposes of ensuring disclosure consistency and minimizing marketplace confusion, the AMS has chosen not to adopt other similar terms and to require the use of the term ‘bioengineered.’⁴⁸ Further, the AMS states that manufacturers may still use the term “GMO” in label claims because “nothing in the final rule prohibits regulated entities from providing additional statements or other claims [. . .], so long as such statements are consistent with all other applicable laws and regulations.”⁴⁹ However, the NBFDS expressly preempts state “GMO” labeling laws.⁵⁰ So, it seems that the AMS takes the position that the definition of a “GMO” is similar to the term “bioengineered,” but not necessarily identical, and the AMS may choose to further regulate the term “GMO” at a later date. Further, manufacturers may continue using the term “GMO” on labels if the use complies with existing federal law but will not need to comply with any state-level genetic modification disclosure

laws once the NBFDS becomes effective.⁵¹ Finally, USDA informally defines “genetic modification” as including both genetic engineering and traditional methods for gene selection, such as hybridization.⁵²

Prior to the NBFDS, “FDA’s longstanding position has been that the term [“GMO”] has traditionally been used broadly to signify the alteration of the genotype of a plant using any technique, new or traditional.”⁵³ However, it is unclear whether this is still FDA’s policy or whether that policy would be enforceable under the NBFDS. In guidance on the issue, FDA states that the NBFDS only grants the agency authority over statements about the absence of genetically engineered foods.⁵⁴ Possibly because of this confusion, FDA claimed it would not object to the term “non-GMO” or similar terms appearing on labels if the claim is otherwise not false or misleading.⁵⁵ Beyond this guidance, FDA appears to consider the terms “GMO” and “bioengineered” as sharing considerable overlap. In its description of the NBFDS, FDA states that “certain types of GMOs will require a disclosure that lets you know if the food you are eating (or ingredients in the food you are eating) is a bioengineered food.”⁵⁶ FDA also refers to foods on the BE food list as “GMOs.”⁵⁷ In considering recent guidance and both agencies’ informal use of the terms, it appears that the position of USDA and FDA is that all bioengineered foods are genetically modified, but not all foods derived from genetic modification (GMOs) are bioengineered. However, USDA may invoke its authority to conclusively define “GMO” in the future.



CONCLUSION

Beginning in January 2022, consumers will start seeing the new BE disclosures, either through text, symbol, link, or possibly through an SMS text message. A BE disclosure means that the food likely contains ingredients produced using genetic engineering. However, not all foods containing BE ingredients will necessarily be labeled accordingly, like beef stew or food purchased at a restaurant. It is important to understand what the new BE disclosure means in order to make the most informed food choices.

About the Center for Agriculture and Food Systems at Vermont Law School

Vermont Law School's [Center for Agriculture and Food Systems](#) (CAFS) uses law and policy to build a more sustainable and just food system. In partnership with local, regional, national, and international partners, CAFS addresses food system challenges related to food justice, food security, farmland access, animal welfare, worker protections, the environment, and public health, among others. CAFS works closely with its partners to provide legal services that respond to their needs and develop resources that empower the communities they serve. Through CAFS' Food and Agriculture Clinic and Research Assistant program, students work directly on projects alongside partners nationwide, engaging in innovative work that spans the food system.



For more information visit the Labels Unwrapped website at <http://labelsunwrapped.org/>



ENDNOTES

- 1 7 U.S.C. § 6524.
- 2 See Agric. Marketing Serv., *BE Symbols*, USDA, <https://www.ams.usda.gov/rules-regulations/be/symbols>.
- 3 7 C.F.R. § 66.13.
- 4 7 U.S.C. § 1639(1).
- 5 Image, Emma Berthold, *What Is genetic modification?*, AUSTRALIAN ACADEMY OF SCIENCE, <https://www.science.org.au/curious/earth-environment/what-genetic-modification>.
- 6 *Id.*
- 7 7 C.F.R. § 66.7.
- 8 7 C.F.R. § 66.6.
- 9 National Bioengineered Food Disclosure Standard, 83 Fed. Reg. 65814, 65826 (Dec. 21, 2018), <https://www.federalregister.gov/d/2018-27283/p-204>.
- 10 *Id.*; see also, 7 C.F.R. § 66.104.
- 11 7 C.F.R. § 66.5(c).
- 12 7 C.F.R. § 66.1.
- 13 7 C.F.R. § 66.116(b).
- 14 7 C.F.R. § 66.9(a)(2).
- 15 7 C.F.R. § 66.3(b)(2).
- 16 7 CFR § 66.3(b)(2)(i).
- 17 7 CFR § 66.3(b)(2)(ii).
- 18 *GMO Crops, Animal Food, and Beyond*, FDA (Sept. 28, 2020), <https://www.fda.gov/food/agricultural-biotechnology/gmo-crops-animal-food-and-beyond>.
- 19 Nat'l. Bioengineered Food Disclosure Standard, 83 Fed. Reg. at 65824.
- 20 7 U.S.C. § 1639(1).
- 21 7 C.F.R. § 66.6.
- 22 7 C.F.R. § 66.3(b)(1).
- 23 Nat'l. Bioengineered Food Disclosure Standard, 83 Fed. Reg. at 65815.
- 24 21 C.F.R. § 101.100(a)(3).
- 25 *Id.*
- 26 Nat'l. Bioengineered Food Disclosure Standard, 83 Fed. Reg. at 65815.
- 27 7 U.S.C. § 6524 (emphasis added).
- 28 7 U.S.C. § 6524.
- 29 Nat'l. Bioengineered Food Disclosure Standard, 83 Fed. Reg. at 65825.
- 30 7 C.F.R. § 66.100(2)(b).
- 31 § 66.100(2)(d).
- 32 § 66.102(a)(1).
- 33 § 66.102(a)(2).
- 34 § 66.104.
- 35 § 66.106.
- 36 E.g. “Scan anywhere on package for more food information” or “Scan icon for more food information.” § 66.106(a).
- 37 § 66.106(a).
- 38 § 66.106(b).
- 39 § 66.106(b)(3)-(4).
- 40 § 66.106(a)(2) (“Call [1-000-000-0000] for more food information.”).
- 41 § 66.108(a).
- 42 § 66.108(d).
- 43 § 66.110.
- 44 § 66.5(a).
- 45 § 66.5(a).
- 46 § 66.1.
- 47 Nat'l. Bioengineered Food Disclosure Standard, 83 Fed. Reg. at 65846.
- 48 Nat'l. Bioengineered Food Disclosure Standard, 83 Fed. Reg. at 65851.
- 49 Nat'l. Bioengineered Food Disclosure Standard, 83 Fed. Reg. at 65852.
- 50 See e.g. Nat'l. Bioengineered Food Disclosure Standard, 83 Fed. Reg. at 65832, 65861.
- 51 Nat'l. Bioengineered Food Disclosure Standard, 83 Fed. Reg. at 65832.
- 52 *Agricultural Biotechnology Glossary*, U.S. DEP'T OF AGRIC. (defining “genetic engineering” as “[t]he production of heritable improvements in plants or animals for specific uses, via either genetic engineering or other more traditional methods.”), <https://www.usda.gov/topics/biotechnology/biotechnology-glossary#:~:text=Genetic%20modification%3A%20The%20production%20of,or%20other%20more%20traditional%20methods>.
- 53 CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, U.S. FOOD & DRUG ADMIN., VOLUNTARY LABELING INDICATING WHETHER FOODS HAVE OR HAVE NOT BEEN DERIVED FROM GENETICALLY ENGINEERED PLANTS: GUIDANCE FOR INDUSTRY 7 (2015) (revised March 2019).
- 54 *Id.* at fn. 2.
- 55 *Id.* at 7.
- 56 U.S. Food & Drug Admin., *How GMOs Are Regulated for Food and Plant Safety in the United States* (Apr. 22, 2020), <https://www.fda.gov/food/agricultural-biotechnology/how-gmos-are-regulated-food-and-plant-safety-united-states>.
- 57 U.S. Food & Drug Admin, *GMO Crops, Animal Food, and Beyond* (Sept. 28, 2020) (“To make it easier for consumers to know if the foods they eat contain GMO ingredients, the U.S. Department of Agriculture maintains a list of bioengineered foods available throughout the world.”), <https://www.fda.gov/food/agricultural-biotechnology/gmo-crops-animal-food-and-beyond>.

