



## Food, Beverage & Cosmetics ADVISORY ■

**JANUARY 29, 2019**

### Take a Bite of the New Mandatory National Bioengineered Food Disclosure Standard

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On December 20, 2018, the Agricultural Marketing Service (AMS) of the U.S. Department of Agriculture (USDA) announced its final rule on the mandatory disclosure standard for bioengineered foods. That rule, the National Bioengineered Food Disclosure Standard (NBFDS), follows the National Bioengineered Food Disclosure Law (NBFDL) passed by Congress in 2016 which, among other things, expressly preempts inconsistent state requirements, like the law passed by Vermont requiring labeling of food produced with genetic engineering (colloquially referred to as Vermont’s “GMO labeling law”).

The NBFDS, published at [83 Fed. Reg. 65814–65876](#), requires that, subject to certain limitations and exemptions, foods must bear a specified disclosure by January 2022 if they contain ingredients on the USDA’s list of bioengineered foods or are otherwise known to be bioengineered.

#### **Who Must Comply?**

The NBFDS applies to food manufacturers and importers, and also retailers who package and label food for retail sale or sell bulk food items. The NBFDS does not apply to restaurants, restaurant-like retail food establishments (e.g., those that provide prepared foods such as cafeterias, food trucks, and airplanes), or very small food manufacturers that have annual receipts of less than \$2.5 million.

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## What Bioengineered Foods Are Subject to the Disclosure Requirements?

### **What are “foods” under the NBFDS?**

The NBFDS applies to (1) all foods subject to Federal Food, Drug, and Cosmetic Act (FDCA) labeling requirements (including raw produce, seafood, dietary supplements, most prepared foods, snacks, desserts, chewing gum, and drinks); or (2) products subject to the labeling requirements of the Federal Meat Inspection Act, Poultry Products Inspection Act, or Egg Products Inspection Act if the most predominant ingredient of the food would independently be subject to the labeling requirements under the FDCA, or if the most predominant ingredient of the food is broth, stock, water, or a similar product and the second-most predominant ingredient would be subject to the FDCA labeling requirements (e.g., soups, stews).

Alcoholic beverages that are not subject to the Federal Alcohol Administration Act (e.g., wines with less than 7% alcohol by volume and beers brewed without malted barley and hops) are subject to the NBFDS. Otherwise, alcoholic beverages are not “foods” under the NBFDS.

### **What does “bioengineered” mean?**

Bioengineered (BE) foods are those foods “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.”

### **Why not just call it the GMO rule?**

Colloquially, some refer to organisms that are the result of bioengineering as genetically modified organisms (GMOs), food derived from bioengineering as GMO food, and the NBFDS as the GMO labeling rule. However, bioengineering is only one method that can be used to accomplish genetic modification; other methods include selection, hybridization, and induced mutation. Most importantly, “bioengineered” is the term used and defined in the NBFDS.

### **What about refined foods?**

Critically, the NBFDS does not apply to most highly refined foods. Highly refined foods that are derived from BE crops that do not contain detectable modified genetic material are not BE foods and do not need to be disclosed. The USDA expects that high fructose corn syrup, vegetable oils, and various other refined ingredients are unlikely to require BE food disclosure.

The AMS intends to provide guidance on testing and validated refining processes that make modified genetic material undetectable.

***What about incidental additives?***

The NBFDS does not apply to incidental additives (defined in 21 C.F.R. 101.100(a)(3)) because they are not BE foods under the NBFDS.

***What about pet food or animal feed?***

The NBFDS does not apply. The NBFDS expressly applies to food for human consumption only.

***Other Exemptions*****Do dairy or meat products have to be labeled BE if the animal ate BE feed?**

The NBFDL prohibits a food derived from an animal from being considered a BE food solely because the animal consumed feed produced from, containing, or consisting of a BE substance. Consistent with this prohibition, the NBFDS exempts such products from bearing a BE disclosure.

**Can organic foods be considered BE foods?**

Food certified under the National Organic Program (NOP), i.e., foods that are certified as “100% organic,” “organic,” or “made with organic [specified ingredients or food(s)],” are expressly exempted from disclosure because NOP regulations already do not allow BE ingredients in these products. Products made with less than 70% organically produced ingredients must disclose any BE food ingredients, however.

**Is there a de minimis threshold?**

Foods in which no ingredient intentionally contains a BE substance may inadvertently or unavoidably contain up to 5% of BE substance in each ingredient without requiring disclosure. This threshold is designed to recognize that trace amounts of BE substance may remain on shared equipment with non-BE harvested foods.

***What is the List of BE Foods?***

The USDA provided a non-exhaustive List of BE Foods, including alfalfa, apple (Arctic™ varieties), canola, corn, cotton, eggplant (certain varieties), papaya (certain varieties), pineapple (certain varieties), potato, salmon (AquAdvantage®), soybean, summer squash, and sugar beet.

The USDA will update the List of BE Foods as needed and conduct annual reviews of the list, which means that compliance with the NBFDS must be evaluated periodically through a product's life because increasingly more foods are derived from BE ingredients. The USDA also invites public input on the list.

Companies should not rely solely on the list, however, and should conduct their own reviews to determine if disclosure is required. The USDA specifically states that a regulated entity must disclose a food as BE when it has records showing the food is BE, even if the food is not on the list.

***What if a company uses an ingredient that is on the List of BE Foods that is not derived from BE ingredients?***

The company must maintain records sufficient to verify the food is sourced from a non-BE source, such as organic certification, records showing a non-BE source was used, or geographic records showing the food originated from an area where no BE source is available.



## **How Must BE Foods Be Disclosed?**

The NBFDS provides multiple ways to disclose the presence of BE foods.

1. A text disclosure stating the food is “bioengineered food” or “contains bioengineered food ingredients.” Note that “may be bioengineered,” which was a disclosure statement previously under consideration, is not permitted.
2. The BE symbol.
3. An electronic or digital disclosure accompanied on the packaging by the statement “Scan here for more information” and the statement “Call [INSERT PHONE NUMBER] for more food information.” The first screen of the digital disclosure must include the BE symbol.
4. A text message disclosure stating “Text [command word] to [number] for bioengineered food information.” The manufacturer cannot use any of the consumer’s personally identifiable information if this disclosure method is selected.

There are specific placement requirements for the disclosure. Also, small and very small packages may include a shortened statement accompanying text and electronic or digital disclosures.

## **Voluntary Disclosure**

Companies may make a voluntary disclosure of foods derived from BE sources that do not contain detectable modified genetic materials using modified versions of the above disclosures. The voluntary disclosure should state “derived from bioengineering” or “ingredient(s) derived from a bioengineered source” or should use the voluntary disclosure symbol.

## Compliance Deadline

Compliance with the NBFDS is mandatory as of **January 1, 2022**.

## Enforcement

The USDA does not have authority to issue a recall or impose civil penalties for violation of the NBFDS. That said, there is a mechanism in the NBFDS for filing a written complaint with the AMS for suspected violations. Following investigation and an opportunity for hearing, the AMS will make a public summary of any finalized findings.

Many expect states to adopt identical NBFDS standards, imposing a private right of action directly or through their state consumer statutes.

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If you have any questions or would like additional information, please contact your Alston & Bird attorney or any of the following:

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