USDA AMS Publishes Bioengineered (BE) Labeling Proposed Rule

On May 4, 2018, the U.S. Department of Agriculture ("USDA") published the highly-anticipated proposed regulation implementing the National Bioengineered Food Disclosure Standard ("NBDFS") (Public Law 114-216) mandated by Congress in 2016, which amended the Agricultural Marketing Act of 1946 (the "Act"). See 83 Fed. Reg. 19860. The NBDFS charged the USDA's Agricultural Marketing Service ("AMS") with developing a national mandatory system for disclosing the presence of bioengineered ("BE") material in food.

Proposed Rule Overview

The proposed rule would require food manufacturers and other entities that label foods for retail sale to disclose BE food or food ingredients. The rule also preempts any state or local law that directly or indirectly establishes BE labeling or disclosure requirements. Disclosure must be made available through one of three options: (1) on-package text disclosure, (2) symbol disclosure, or (3) an electronic or digital link disclosure. Regulated entities would be required to retain records about a BE food or food ingredients and be able to make them available to USDA's AMS within 5 business days of a request for production.

The proposed rule lists several exemptions from disclosure. For example, food products produced from an animal that ate BE feed do not require disclosure. Food service establishments and very small food manufacturers are also exempt. Foods certified under USDA's National Organic Program ("NOP") are not subject to BE disclosure, and non-genetically modified organism ("GMO") labeling is outside the scope of this rulemaking.

USDA proposed a compliance date of January 1, 2020, with a delayed compliance date of January 1, 2021 for small food manufacturers. The proposed rule is open for comment until July 3, 2018, and due to the Congressionally mandated timeline, the comment period is unlikely to be extended.

Definition of "Bioengineering"

Prior to this rulemaking, USDA released a list of 30 questions for stakeholder input. One of the most controversial items is the definition of "bioengineering". USDA intends to define "bioengineering" with respect to a food, as 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." 7 U.S.C. 1639(1). USDA received wide differences in public opinion about how the statutory definition of "bioengineering" should be interpreted and applied. Specifically, stakeholders offered conflicting views on highly refined foods and ingredients, and whether they should fall within the proposed definition. AMS seeks comment on the proposed definition of "bioengineering" and its applicability to all foods produced from bioengineering, including highly refined products.

Disclosure of Highly Refined Products

The proposed rule discusses two positions regarding the applicability of a BE disclosure to highly refined products.
Position 1 states that highly refined products do not “contain genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques.” The reasoning is based on the fact that the products have undergone processes that have removed genetic material and thus cannot be detected using common testing methods. Therefore, highly refined products would not fall within the definition of “bioengineering” and would be exempt from disclosure. Additionally, it is argued that by nature of the intended food product, the highly refined foods generally either do not contain nucleic acids or contain minute amounts of foreign material, which could result in incidental detection of DNA due to inadvertent transfer during the refinement process. Position 1 also holds that highly refined products made from BE crops, such as sucrose or dextrose, are chemically identical to those made from non-BE crops.

Position 2 states the definition of “bioengineering” includes all foods produced from bioengineering, such as highly refined products. The reasoning behind Position 2 is that a highly refined product, such as the sugar beet, contains BE material before it is processed; therefore, the resulting product (e.g., sugar) may contain at least trace amounts of genetic material from the BE sugar beet. And although detectability of genetic material may depend on the characteristics of the refinement process, proponents of Position 2 state that a food may still have modified genetic material, even if none was detected. Thus, Position 2 proponents believe there should be a presumption that highly refined products meet the definition of “bioengineering” and require BE disclosure.

Proposed Lists of BE Foods

In an attempt to make it easier and less burdensome for consumers and regulated entities to understand what products may need to be disclosed under the NBFDS, AMS developed (1) a proposed list of bioengineered foods that are commercially available in the United States with a high adoption rate and (2) a proposed list of bioengineered foods that are commercially available in the United States that are not highly adopted. AMS proposed that only foods on either of those lists or made from foods on either of those lists would require disclosure. Thus, regulated entities would only need to determine whether the finished product, or an ingredient, is on either of the lists or is produced using foods on either of the lists. AMS would maintain the lists on its website and review and revise on an annual basis. The two proposed lists are as follows:

Commercially Available BE Foods - Highly Adopted

- Canola
- Corn, Field
- Cotton
- Soybean
- Sugar Beet

It is important to note that AMS intends that this particular list identifies crops and foods in general, and, foods containing derivatives of the crops would be subject to the same disclosure requirement as foods on the list.
Commercially Available BE Foods - Not Highly Adopted

- Apple, Non-browning cultivars
- Corn, Sweet
- Papaya
- Potato
- Squash, Summer varieties

Disclosure Exemptions under the NFBDS

The NFBDS includes two express exemptions to the disclosure requirement: (1) food served in a restaurant or similar retail food establishment, and (2) very small food manufacturers. 7 U.S.C. 1639b(b)(2)(G). “Similar retail food establishments” are to include “a cafeteria, lunch room, food stand, saloon, tavern, bar, lounge, other similar establishment operated as an enterprise engaged in the business of selling prepared food to the public, or salad bars, delicatessens, and other food enterprises located within retail establishments that provide ready-to-eat foods that are consumed either on or outside of the retailer’s premises.” A “very small food manufacturer” is “any food manufacturer with annual receipts less than $2,500,000”.

The NFBDS also prohibits a food derived from an animal to be considered a BE food solely because the animal consumed feed produced from, containing, or consisting of a bioengineered substance. 7 U.S.C. 1639b(b)(2)(A). Foods certified under the USDA’s NOP (7 CFR part 205) will also be exempt.

Threshold Exemption Subject to Comment

Foods with amounts of BE substances below an established threshold level would also be exempt from disclosure. USDA AMS is seeking comment on three different alternative thresholds:

- Alternative 1-A: Foods with an ingredient that contains a BE substance that is inadvertent or technically unavoidable, and accounts for no more than 5% of the specific ingredient by weight, would not be subject to the disclosure because of that one ingredient. Any other use of a food or food ingredient that contained a BE substance would be subject to disclosure.

- Alternative 1-B: Foods with an ingredient that contains a BE substance that is inadvertent or technically unavoidable, and accounts for no more than 0.9% of the specific ingredient by weight, would not be subject to the disclosure because of that one ingredient.

- Alternative 1-C: Foods may contain a small amount of BE ingredients, up to 5% of the total weight of the product and would not be subject to the disclosure requirements. Under this approach, a regulated entity could use ingredients it knew were bioengineered, and would not have to disclose, if the total amount of all BE ingredients used in the product were no greater than 5% of the total weight of the product.
Incidental Additives, Enzymes, and Yeasts

Commenters in response to AMS’ 30 questions requested that incidental additives not be subject to disclosure. As described in 21 CFR § 101.100(a)(3), incidental additives that are present in food at an insignificant level and do not have any technical or functional effect in the food are exempt from ingredient listing. USDA AMS has exempted incidental additives from BE disclosure requirements in the proposed rule.

Some foods produced through bioengineering may not be produced as crops in the same manner that foods currently on the two above-mentioned proposed lists are produced. For example, enzymes and yeast may be produced with bioengineering. AMS seeks comments on whether such foods should be included on the proposed lists, and how they should be described. Additionally, should AMS choose to exclude incidental additives from the definition of a “bioengineered food,” a number of enzymes that are currently used in food production but not listed in the ingredient statement may be exempt from disclosure. However, some enzymes may also be used in a manner that requires ingredient listing. Thus, AMS seeks comment on whether, more generally, enzymes present in food should be considered “bioengineered.”

Disclosure Options

The NFBDS provides three disclosure options for all food subject to the mandatory BE food disclosure. USDA AMS must also provide reasonable disclosure alternatives for small and very small packages. 7 U.S.C. 1639b(b)(2)(D), 1639b(b)(F), and 1639b(b)(E). Food manufacturers, importers, and certain retailers would be responsible for the disclosure. If a food is packaged prior to receipt by a retailer, either the food manufacturer or the importer would be responsible for ensuring that the food label bears a BE disclosure. If a retailer packages a food, then the retailer would be responsible for the BE disclosure.

The disclosure is required to appear prominently and conspicuously on the label, so it is easy to be read and understood by the consumer. The disclosure should be placed in one of the following places:

- the information panel adjacent to the statement identifying the name and location of the manufacturer/distributor or similar information (also known as the “signature line”);
- anywhere on the principal display panel; or
- an alternative panel if there is insufficient space on the information panel or the principal display panel.

Disclosure may be made through a text disclosure, a symbol disclosure, or an electronic or digital link disclosure. For a text disclosure, a regulated entity may place “bioengineered food,” “bioengineered food ingredient,” or a similar alternative on the package. For the symbol disclosure, AMS proposed three alternative symbols. The three symbols are designed to communicate the bioengineered status of a food in a way that would not disparage biotechnology or suggest BE food is more or less safe than non-BE food. The three symbol alternatives are provided below:

The third disclosure option available is to use an electronic or digital link disclosure. 7 U.S.C. 1639b(b)(2)(D), 1639b(d). The use of an electronic or digital link to disclose BE food must be accompanied by the statement “Scan
here for more food information” or equivalent language. 7 U.S.C. 1639b(d)(1). A telephone number that provides access to the BE food disclosure would be required, along with the statement “Call for more food information,” and must be near the electronic or digital link. Additionally, the electronic or digital link must provide the bioengineering disclosure on the first product information page accessed through the link, without any marketing or promotional material. 7 U.S.C. 1639b(d)(2).

USDA AMS conducted a study to identify potential technological challenges that may impact whether consumers would have access to the bioengineering disclosure through electronic or digital disclosure methods. The study considered five factors: (1) the availability of wireless Internet or cellular networks; (2) the availability of landline telephones in stores; (3) challenges facing small retailers and rural retailers; (4) the efforts that retailers and other entities have taken to address potential technology and infrastructure challenges; and (5) the cost and benefits of installing in retail stores electronic or digital scanners or other evolving technologies that provide bioengineering disclosure information. 7 U.S.C. 1639b(c)(3). Should consumers not have sufficient access, USDA shall provide additional disclosure options. 7 U.S.C. 1639b(c)(4).

On September 6, 2017, USDA made the results of the study public and identified meaningful steps that can be made to improve access for consumers facing challenges:

- Education for consumers and retailers around electronic and digital disclosure links and BE foods.
- Offline options, such as those that provide the bioengineering disclosure through phone or text message, to increase access for consumers who lack smartphones or broadband access.
- Developing or endorsing user-friendly scanner apps to ease the consumer experience.

Initial Compliance Dates

As previously mentioned, the proposed compliance date is January 1, 2020, with a delayed compliance date of January 1, 2021 for small food manufacturers. The proposed compliance date is intended to align with the Food and Drug Administration’s nutrition labeling compliance date.

Request for Comments

USDA AMS seeks comments on the proposed rule implementing the National Bioengineered Food Disclosure Standard. As previously mentioned, the comment period is open until July 3, 2018. Comments may be submitted online through the Federal eRulemaking portal www.regulations.gov, or may be filed with the Docket Clerk at 1400 Independence Ave., SW, Room 4543-South, Washington, DC 20250.

Please contact us if you have any questions regarding the USDA AMS proposed rule regarding BE labeling or for assistance drafting comments. For more information on our Food Law Practice in general, visit www.khlaw.com/Food-and-Drug.

[1] Adoption refers to the prevalence with which bioengineered cultivars of a food crop are planted or produced in the United States, relative to the number of non-bioengineered cultivars of the same crop in production. 83 Fed.
Reg. 19860, 19864.