THE
NATIONAL LAW REVIEW

USDA AMS National Bioengineered (BE) Food Disclosure Standard Final Rule

Friday, December 28, 2018

On December 21, 2018, the U.S. Department of Agriculture's (USDA) Agricultural Marketing Service (AMS) published its final rule implementing the National Bioengineered Food Disclosure Standard (NBFDS) (Public Law 114-216) mandated by Congress in 2016, which amended the Agricultural Marketing Act of 1946. See 83 Fed. Reg. 65814. This final rule follows AMS' proposed rule, which was published on May 4, 2018. See 83 Fed. Reg. 19860. The NBFDS preempted State and local genetic engineering labeling requirements and charged AMS with developing a national mandatory standard for disclosing the presence of bioengineered (BE) food. The final rule is codified at 7 C.F.R. Part 66.

This alert provides an overview of the final rule and is divided into four parts: (1) Applicability; (2) Disclosure; (3) Administrative Provisions; and (4) Compliance Dates.

KELLER AND HECKMAN LLP

Article By Evangelia C. Pelonis
Melvin S. Drozen Samuel D. Jockel
Keller and Heckman LLP Publications

Biotech, Food, Drug
Administrative & Regulatory
All Federal

I. Applicability

In addition to food manufacturers, the final rule requires importers of food labeled for retail sale in the U.S. and some U.S. retailers to disclose foods and ingredients produced from foods that are or may be bioengineered. Under 7 C.F.R. § 66.100(a), if a retailer packages a food or sells food in a bulk container and/or display, then the retailer is responsible for ensuring that the food bears a BE food disclosure if necessary.

A. "Food"

> Under the NBFDS, "food," as defined by the Federal Food, Drug, and Cosmetic Act (FDCA), is subject to the disclosure requirements if it is intended for human consumption. Therefore, "food," for purposes of the NBFDS, does not include articles used for animals, such as pet food and animal feed. The preamble to the final rule notes that both raw agricultural commodities (e.g. apples) and processed items, such as soup (and each of the soup's ingredients), are "food." Dietary supplements, processing aids, and enzymes also fall within the definition of "food.

"Food" not subject to the labeling requirements of the FDCA is not subject to the NBFDS, i.e., distilled spirits, wine or malt beverages, which fall under the labeling provisions of the Federal Alcohol Administration Act. Please note that alcoholic beverages under FDA's labeling jurisdiction (e.g., wine products with less than 7% alcohol by volume and beers that do not meet the definition of a malt beverage) are subject to BE labeling.

Meat and Egg-Containing Products

As set out in the NBFDS, and adopted in the final rule, food subject to the labeling requirements of the Federal Meat Inspection Act, the Poultry Products Inspection Act, or the Egg Products Inspection Act is subject to BE disclosure if:

1. The most predominant ingredient of the food would independently be subject to labeling requirements under FDCA or

2. The most predominant ingredient of the food is broth, stock, water, or a similar solution AND the second-most predominant ingredient of the food would independently be subject to the labeling requirements under FDCA

Therefore, while a canned stew with pork as its primary ingredient would not be subject to the NBFDS, a soup, containing broth, carrots and chicken (in descending order of predominance) would be subject to BE disclosure.

B. "Bioengineered Food" and Detectability

In its proposed rule, given the statutory definition of "bioengineering," which in part, refers to a food that "contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques," AMS invited comment on whether refined foods and ingredients should be subject to disclosure. The final rule directly incorporates the statutory definition of "bioengineering" into the definition of "bioengineered food," with a modification:

> "a food that contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques and for which the modification could not otherwise be obtained through conventional breeding or found in nature; *provided that* such a food does not contain modified genetic material if the genetic material is not detectable pursuant to § 66.9."

Consequently, the definition above excludes foods where modified genetic material is not detectable. AMS adopted the position that if the genetic material is not detectable, the food does not contain modified genetic material and is therefore not subject to BE labeling. Under 7 C.F.R. § 66.9(a), to demonstrate that a food's genetic material is not detectable, the entity must maintain records that either:

1. Verify that the food is sourced from a non-BE crop or source;
2. Verify that the food has been subjected to a refinement process validated to make the modified genetic material in the food undetectable (a "validated refining process" is defined further in the regulations under 7 C.F.R. § 66.9(b)); or
3. Provide for testing records appropriate to the specific food that confirm the absence of modified genetic material.

Highly Refined Ingredients With No Detectable Modified DNA Exempt

Despite the detectability standards outlined above, in the preamble, AMS concedes that refined ingredients are unlikely to require BE food disclosure:

> "...based on the available scientific evidence, refined beet and cane sugar, high fructose corn syrup, degummed refined vegetable oils and various other refined ingredients are unlikely to require BE food disclosure because the conditions of processing serve effectively to degrade or eliminate the DNA that was initially present in the raw agricultural commodity." 83 Fed. Reg. 65814, 65834.

Given the detectability standards, adequate sourcing or detection testing records are required to substantiate non-disclosure of these ingredients and foods. However, if an entity wishes to disclose a food made with ingredients derived from a BE source, where the genetic material is not necessarily detectable, the final rule allows for voluntary disclosure under 7 C.F.R. § 66.116(b). (*See* Voluntary Disclosure section below).

C. List of Bioengineered Foods

The final rule adopts a single List of Bioengineered Foods (List), under 7 C.F.R. § 66.6, to identify the crops or foods that are both (1) authorized for commercial production somewhere in the world and (2) reported to be in legal commercial production for human food somewhere in the world. While the proposed rule contained two separate BE food lists, AMS consolidated the lists for simplicity. The List consists of the following crops/foods:

- Alfalfa
- Apple (Artic™ varieties)
- Canola
- Corn
- Cotton

- Eggplant (BARBI Bt Begun varieties)
- Papaya (ringspot virus-resistant varieties)
- Pineapple (pink flesh varieties)
- Potato
- Salmon (AquAdvantage®)
- Soybean
- Squash (summer)
- Sugarbeet

The List provides a tool to determine whether a food must bear a BE disclosure. If an entity uses a food or ingredient on the list above, or its ingredient utilizes (or is sourced from) a food/crop from the List, that entity must maintain records regarding that food or ingredient. (*See* Recordkeeping section below). That entity's records drive the disclosure determination. For example, if a food or food ingredient is on the List and the entity's records show that the food is a BE food (or does not indicate whether or not the food is BE), the food must bear a BE disclosure if no exemptions otherwise apply. *(See* Disclosure and Recordkeeping sections below.) AMS plans to maintain additional information on its website associated with the bioengineered status of the foods and crops on the List.

The List is not exhaustive, and AMS acknowledges that the List may not be complete. Therefore, regulated entities knowingly using a BE food, even if that food is not on the List, are required to make disclosures (and maintain records) for that food. 7 C.F.R. § 66.109.

Through a Federal Register notice announcement, AMS will consider revisions to the List on an annual basis, soliciting recommendations regarding updates to the List and will consider supporting information and input from other agencies. Following a review, AMS will determine whether to initiate rulemaking to amend the List, and if the List is revised, regulated entities will have 18 months to make updates to their labels as needed. 7 C.F.R. § 66.7.

D. Evolving Technologies, Gene Editing

The final rule does not explicitly address whether new technologies, such as gene editing techniques, would result in disclosure under the NBFDS. The preamble to the final rule notes that determinations about what constitutes BE food focus on whether the products of technology (the food) meet the definition of "bioengineered food," rather than the technology itself. Foods resulting from new technologies will be considered during reviews and updates to the List of Bioengineered Foods.

E. Yeast, Enzymes and Other Organisms

While AMS sought comment on whether enzymes and yeast should be considered "bioengineered food," in its final rule, AMS declined to make a categorical exclusion for such substances. For BE yeasts, enzymes and other organisms that do not qualify as incidental additives (*see* Factors and Conditions above), they may require disclosure as BE foods unless they meet the requirements of another provision to exempt them from disclosure. For example, if a BE enzyme, which does not qualify as an incidental additive, does not have detectable modified genetic material, that enzyme would not be subject to disclosure.

F. Factors and Conditions: Refining the Scope of Disclosure

The final rule adopts a process to consider exclusions of certain foods under the Secretary of Agriculture's authority to consider "other factors and conditions under which a food is considered a BE food." 7 U.S.C. 1639b(b)(2)(C). The regulatory definition of "bioengineered food" is subject to "factors and conditions," one of which AMS has adopted in the final rule: a food is not a BE food if it is an incidental additive, pursuant to FDA's regulations at 21 C.F.R. § 101.100(a)(3). Thus, an incidental additive is not considered a BE food and therefore does not require disclosure.

Under 7 C.F.R. §§ 66.200, 66.202, and 66.204, AMS' process for considering other factors and conditions include consideration of requests or petitions in light of specific "standards for consideration." If the agency determines that the request satisfies the standards for consideration, AMS will initiate a rulemaking to amend the definition of "bioengineered food." Ultimately, as was done with incidental additives in the final rule, this process is an avenue to potentially limit the scope of the definition of "bioengineered food" and exclude certain products from

disclosure.

G. Exemptions

The final rule provides for several exemptions from the disclosure requirement under 7 C.F.R. § 66.5:

1. Food served in a restaurant or similar retail food establishment. AMS modified the proposed definition of "similar retail food establishment" to include examples, such as a food truck and transportation carrier. In the preamble to the final rule, AMS clarified that salads, soups and other ready-to-eat items prepared by grocery stores are exempt from the disclosure requirements.

2. Very small food manufacturers (with annual receipts of less than $2.5 million).

3. Threshold for inadvertent or technically unavoidable presence of bioengineered substances of up to 5% for each ingredient, with no allowance for any BE presence that is intentional. Therefore, food in which any single ingredient contains more than 5% of a bioengineered substance cannot use this threshold exemption. In the preamble to the final rule, AMS acknowledges the sufficiency of the existing industry standards, which typically calculate threshold amounts as the BE content of an ingredient relative to the non-BE content of that same item or ingredient. Verification of compliance with the threshold will be done through records, not prescriptive tests or methodologies.

4. Food derived from an animal is prohibited from being considered a BE food solely because the animal consumed feed produced from, containing, or consisting of a BE substance.

5. Food certified under AMS' National Organic Program (NOP) are exempt. This exemption covers all NOP certified label categories ("100% Organic," "Organic" and "Made with Organic").

II. Disclosure

Under 7 C.F.R. § 66.100, disclosure under the NBFDS is the responsibility of food manufacturers, importers and certain retailers. In the preamble, AMS explains that the focus of the NBFDS is on affirmative BE claims and not on absence claims, deferring to FDA and USDA's Food Safety and Inspection Service (FSIS) to regulate absence claims.

Disclosure is required to appear prominently and conspicuously on the label and must be easy to be read and understood by the consumer. The disclosure must be made in one of the following manners:

- on the information panel (IP) directly adjacent to the statement identifying the name and location of the handler, distributor, packer, manufacturer, importer or any statement disclosing similar information (also known as the "signature line");

- anywhere on the principal display panel (PDP); or

- an alternative panel if there is insufficient space on the IP or PDP.

For multi-unit packages, where individual units are not labeled for retail sale and are enclosed within and not intended to be separated from the multi-unit package, the preamble to the final rule states that disclosure is only required on the outer packaging.

A. Form of Disclosure

An entity can choose one of four options for disclosure: (1) text disclosure (7 C.F.R. § 66.102); (2) symbol disclosure (7 C.F.R. § 66.104); (3) electronic or digital link (7 C.F.R. § 66.106); or (4) text message disclosure (7 C.F.R. § 66.108). AMS has chosen to use the term "bioengineered," instead of adopting other similar terms. Further, the final rule does not adopt any "may" disclosure option. The mandatory disclosure options are as follows:

1. **Text:** The text disclosure option allows entities to use "bioengineered food" and "contains a bioengineered food ingredient" for multi-ingredient food.

2. **Symbol:** While the proposed rule sought comment on three alternative symbols, the final rule uses a variation of one of the proposed symbols, which incorporates the word "bioengineered" and can be used in either color or black and white:

3. **Electronic of Digital Link**: 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. A telephone number that provides access to the BE food disclosure is required, along with the statement "Call [number] 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. The disclose must confirm with either the text disclosure or symbol disclosure.
4. **Text Message**: As required under the NBFDS, 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. Ultimately, the Secretary concluded that consumers would not have sufficient access to the BE disclosure through electronic or digital means under ordinary shopping conditions, and as a result, the final rule provides for a text message disclosure option. If utilizing the text message option, the entity must not charge the consumer a fee to access the disclosure by text message, and the requirements involve including a statement, "text [command word] to [number] for bioengineered food information."

The final rule provides additional disclosure options for small food manufacturers (use of a telephone number; internet website) under 7 C.F.R. § 66.110 and modified disclosure options for small and very small packages under 7 C.F.R. § 66.112. For foods sold in bulk containers, retailers will be responsible to comply with the BE disclosure; the disclosure is to appear on signage on or near the bulk item. 7 C.F.R. § 66.114.

B. Voluntary Disclosure

Under 7 C.F.R. § 66.116, the final rule allows entities to voluntarily disclose the presence of BE foods under two circumstances: (1) if a food is on the List, entities that are otherwise exempt from the requirements of the NBFDS (e.g. very small food manufacturers, and restaurants and similar retail food establishments) can voluntarily disclose; or (2) for certain foods that do not meet the definition of "bioengineered food" but are derived from BE crops or food on the List.

Under the "derived" voluntary disclosure scenario, the text disclosure option reflects that the product is derived from bioengineering (i.e. "derived from bioengineering" or "ingredients derived from a bioengineered source"). An entity that chooses to voluntarily disclose may replace the word "ingredient" in the above text disclosure option with the name of the specific crops or ingredients that are being disclosed. Moreover, the final rule creates a specific symbol for the "derived" voluntary disclosure option, which can be used in either color or black and white:

Under the "derived" category, for foods that do not meet paragraph (1) of the regulatory definition of BE food (*e.g.* that do not contain modified genetic material), and that are derived from a food on the List of Bioengineered Foods, to qualify for voluntary disclosure, the food cannot be an incidental additive nor can it qualify for the other exemptions under 7 C.F.R. § 66.5 (*i.e.* the food cannot be below the established threshold, the food cannot be certified under the National Organic Program, etc.). For example, if a beverage company makes a soda containing corn syrup originating from BE corn, and the corn syrup does not have detectable modified genetic material, the corn syrup alone does not trigger mandatory disclosure, and the entity may be able to voluntarily disclose.

III. <u>Administrative Provisions</u>

A. Recordkeeping

Under 7 C.F.R. § 66.302, entities (both those subject to mandatory disclosure and those voluntarily disclosing) must maintain records for a least two years beyond the date the food or food product is sold or distributed for retail sale. As it relates to the List, if an entity's food or ingredient is on the List, the regulated entity must maintain records. If a food ultimately has a BE food disclosure based on actual knowledge, even if the food is not on the List, the entity must disclose and maintain records. 7 C.F.R. § 66.109. For food not on the List and where the entity does not have actual knowledge that the food is BE, that product is not subject to the disclosure

requirements and thus does not have to maintain records.

The final rule does not prescribe what records are required; while the rule provides examples (bills of lading, invoices, etc.), the preamble to the final rule states that regulated entities are free to determine for themselves which of their customary business records will demonstrate compliance and should be maintained.

Food Sourced Abroad: The preamble notes that if records demonstrate that a product originates from a country where BE food is not commercially grown, those records would be sufficient to justify non-disclosure and compliance with the NBFDS.

Access to Records: The final rule includes provisions that require entities to provide records to AMS within five business days (or upon an extension) upon request. Other provisions detail on-site access (7 C.F.R. § 66.404(b)) and the consequences of a failure to provide access (7 C.F.R. § 66.404(c)).

B. Enforcement

Failure to make a BE food disclosure as required by the NBFDS is a prohibited Act under the NBFDS. 7 C.F.R. § 66.400. The enforcement provisions of the final rule (7 C.F.R. §§ 66.402, 404, and 406) allow for the filing of written complaints with the Administrator of AMS, further investigation by the agency, and an auditing of an entity's records. If an entity, subject to an audit, requests a hearing on the results of the audit, the final rule includes procedures for how the hearing can be requested and AMS' role in reviewing the findings and potentially revising the findings. Ultimately, the summary of the results of an audit or the summary of the final results of an investigation at the conclusion of the hearing will be made public.

IV. Effective, Implementation and Compliance Dates (66.13)

The final rule creates a phased system for compliance. The final rule becomes effective on February 19, 2019. The implementation dates are as follows:

- January 1, 2020 for regulated entities other than small food manufacturers
- January 1, 2021 for small food manufacturers ("any food manufacturer with annual receipts of at least $2,500,000, but less than $10,000,000")

AMS expects that entities should begin implementing the NBFDS no later than those dates. The final rule also establishes:

- January 1, 2022 as the mandatory compliance date. By that date, all regulated entities must comply with the requirements of the NBFDS.
- December 31, 2021 as the last day for the voluntary compliance period. The voluntary compliance date allows entities to use labels that are compliant with preempted State labeling laws during the compliance period, or they can apply stickers or ink stamp disclosures to existing labels.

© 2019 Keller and Heckman LLP

Source URL: https://www.natlawreview.com/article/usda-ams-national-bioengineered-be-food-disclosure-standard-final-rule