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BIOENGINEERED FOOD DISCLOSURE RULES FINALIZED, REQUIRE DISCLOSURE OF "DETECTABLE" GMOS

Feb 07, 2019

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) signed into law by President Obama in 2016. 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 rule takes effect on February 19, 2019, and implementation will be phased in over the next three years.

The NBDS requires food manufacturers, 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. The final rule defines "bioengineered food" as any 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," and excludes any genetically modified material that is "not detectable." Non-detectable amounts of modified genetic material do not require BE labeling

Disclosure can be through text, a symbol, electronic or digital link, or text message, as follows:

- **Text:** Entities can state "bioengineered food" or "contains a bioengineered food ingredient" for multi-ingredient food.
- Symbol: Entities can use a variation of the following symbol, which incorporates the word "bioengineered" and can be used in either color or black and white:



- Electronic or digital link: An electronic or digital link must be accompanied by the statement "Scan here for more food information" or equivalent language, and the BE disclosure must be provided on the first page accessed through the link, without any marketing or promotional material. A telephone number that provides access to the BE food disclosure must be provided near the link, along with the statement "Call [number] for more food information."
- Text Message: If utilizing the text message option, the entity must not charge the consumer a
 fee to access the disclosure, and the text must include the statement, "text [command word] to
 [number] for bioengineered food information."

There are additional disclosure options for small food manufacturers (use of a telephone number, internet website), and modified disclosure options for small and very small packages. For foods sold in bulk containers, retailers are responsible for providing signage on or near the bulk item.

WHAT FOODS DOES NBDS APPLY TO?

According to the final rule, "food" requiring disclosure of BE material includes all of the following:

- Raw produce;
- Processed food and their ingredients, including processing aids and enzymes;
- Meat and egg-containing products, if the most predominant ingredient of the food would independently be subject to labeling requirements under the Food, Drug & Cosmetic Act (FDCA), or 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; and

Dietary supplements.

LIST OF BIOENGINEERED FOODS

The final rule adopts a single List of Bioengineered Foods to identify the BE 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. The list consists of the following crops/foods:

- Alfalfa
- Apple (Artie[™] 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

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. If 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. The list is not exhaustive, and may be incomplete. Therefore, businesses that 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. AMS will consider revisions to the list on an annual basis, including foods resulting from new technologies, and entities will have 18 months to update their labels to reflect any revisions.

Refined ingredients, such as refined sugar, high fructose corn syrup, and refined vegetable oils, 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." 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.

EXEMPTIONS

The final rule provides for several exemptions from the disclosure requirement:

- Foods served in a restaurant or similar retail food establishment are exempt, as are ready-toeat items prepared by grocery stores.
- Very small food manufacturers (with annual receipts of less than \$2.5 million) are exempt.
- 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. Verification of compliance with the threshold will be done through records, not prescriptive tests or methodologies.
- 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.
- Foods certified under AMS' National Organic Program (NOP) are exempt. This exemption covers all NOP certified label categories ("100% Organic," "Organic" and "Made with Organic").

IMPLEMENTATION DATES

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.
- January 1, 2022 as the mandatory compliance date. By that date, all regulated entities must comply with the requirements of the NBFDS.

For more information on bioengineered food disclosure obligations, contact Merrit Jones.

RELATED PRACTICE AREAS

Food & Agribusiness

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