

USDA Issues Final Rule on National Bioengineered Food Disclosure Standard

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Food, Drugs, and Devices

Today, USDA published its long-awaited [final rule](#) that establishes the requirements for disclosing bioengineered (BE) foods.¹ This alert briefly summarizes the final definition of BE food, the foods that are subject to the BE disclosure, the required BE disclosures, the recordkeeping requirements, and the rule's implementation and compliance dates.

Under the final rule, the label of a BE food must include a disclosure indicating that the food is a BE food or contains a BE food ingredient. Failure to provide a BE disclosure when one is required is a prohibited act.

The definition of “BE food” excludes certain highly refined ingredients

The final rule defines “BE food” to mean a “food that contains 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 breed found in nature.”² The definition of BE food excludes “incidental additives,” as described in 21 C.F.R. 101.100(a)(3). Notably, the definition of BE food does *not* encompass certain highly refined products, such as oil and sugar, if modified genetic material cannot be detected through a validated testing process.

Certain food is exempt or excluded from the mandatory BE disclosure

Food that is expressly exempt from bearing a mandatory BE disclosure includes:

- food served in a restaurant or similar retail food establishment;
- food produced by a very small food manufacturer (annual receipts less than \$2.5 million);

¹ For information about the May 2018 proposed rule, see our previous client alert, available [here](#).

² “Food” is defined to mean “a food (as defined in section 201 of the Federal Food, Drug, and Cosmetic Act . . .) that is intended for human consumption.”

- food in which no ingredient intentionally contains a BE substance, with an allowance for inadvertent or technically unavoidable BE presence of up to 5% for each ingredient;
- food derived from an animal based solely on the fact that the animal has consumed feed produced from, containing, or consisting of a BE substance; and
- food certified under the National Organic Program.

The final definition of “food” also expressly applies only to food intended for human consumption (including dietary supplements), thereby excluding animal food from the mandatory BE disclosure requirement. Additionally, the mandatory BE disclosure is only required on food that is subject to:

- (1) The labeling requirements under the Federal Food, Drug, and Cosmetic Act (FDCA); or
- (2) The labeling requirements under the Federal Meat Inspection Act, the Poultry Products Inspection Act, or the Egg Products Inspection Act only if:
 - a. The most predominant ingredient of the food would independently be subject to the labeling requirements under the FDCA; or
 - b. 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 the FDCA.

USDA’s list of bioengineered foods

A BE food is only subject to the disclosure standard if the food, or an ingredient used in the food, is on USDA’s final [list of BE foods](#), which consists of the following: alfalfa, apple (Arctic™ varieties), canola, corn, cotton, eggplant (BARI Bt Begun varieties), papaya (ringspot virus-resistant varieties), pineapple (pink flesh varieties), potato, salmon (AquAdvantage®), soybean, squash (summer), and sugarbeet.

USDA intends to review and consider updates to the list of BE foods on an annual basis and will solicit recommendations through notification in the Federal Register and on its website.

Responsible party

The entity responsible for the BE disclosure depends on who packages the food. Food manufacturers or importers who package food prior to it arriving at the retailer are responsible for complying with the BE disclosure standard for those foods. Retailers are responsible for complying with the BE disclosure standard for any food they package or sell in bulk.

Mandatory BE disclosure options

Consistent with the statutory requirement, the final rule requires the BE disclosure to be made through a text statement, a symbol, an electronic or digital link, or a text message.

- The text statement must be “bioengineered food” if the food itself is BE or contains only BE ingredients. The text statement must be “contains a bioengineered food ingredient” if not all ingredients are BE.

- The symbol disclosure must be:



- The electronic or digital link disclosure must be a link, which must be accompanied by: (1) a label statement that says, “Scan here for more food information” or equivalent language that only reflects technological changes; and (2) a telephone number that will provide the BE disclosure to the consumer any time of the day, which must be accompanied by the statement “Call [number] for more food information.”
- The text message disclosure must be identified with the label statement “Text [command word] to [number] for bioengineered food information.” The text message response must be the text disclosure statement described above, without any additional marketing or promotional material.

Modified requirements apply to small and very small packages, food sold in bulk containers, and small food manufacturers.

Recordkeeping requirements

The final rule's recordkeeping requirements only apply to: (1) foods that are on the rule's list of BE foods; and (2) foods that have a BE disclosure because the responsible entity has actual knowledge that the food is BE or contains a BE ingredient. If a food is on the BE food list, or contains an ingredient on the list, but does not have a BE disclosure, the responsible entity must maintain records demonstrating that the food is not, or does not contain, a BE food. Such records must either:

- Verify that the food is sourced from a non-BE crop or source;
- Verify that the food has been subjected to a refinement process validated to make modified genetic material in the food undetectable; or
- Confirm the absence of modified genetic material through appropriate testing.

USDA can request access to records to evaluate compliance. Interested parties can file a complaint with USDA about potential violations of the disclosure requirements, which could trigger record review.

Implementation, voluntary, and mandatory compliance dates

The final rule establishes two “implementation dates” by which companies “should begin implementing” the rule's requirements “by identifying the foods that will need to bear a BE disclosure.” The implementation date is January 1, 2020 for companies with \$10 million or more in annual receipts. Companies with less than \$10 million in annual receipts have an additional year to begin implementing the rule's requirements. Additionally, USDA is providing a “voluntary” compliance period through December 31, 2021, during which companies can use BE disclosures, such as the preempted Vermont disclosure or USDA's BE disclosure through

stickers or ink stamps on existing packaging, All companies, regardless of size, must comply with the mandatory BE disclosure requirements by January 1, 2022.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our Food, Drugs, and Devices practice:

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