COVINGTON

USDA Issues Proposed Rule on National Bioengineered Food Disclosure Standard; FDA Extends Compliance Date for Nutrition Facts Label Final Rule

May 4, 2018

Food, Beverage, and Dietary Supplements

Yesterday, USDA and FDA each issued a long-awaited rulemaking document affecting food labeling.

FDA issued a final rule extending the compliance date for the Nutrition Facts Label (NFL) Final Rule and the Serving Size Final Rule. For manufacturers with $10 million or more in annual food sales, FDA extended the compliance date for these rules from July 26, 2018 to January 1, 2020; for manufacturers with less than $10 million in annual food sales, FDA extended the compliance date for these rules from July 26, 2019 to January 1, 2021.

Separately, the Agricultural Marketing Service (AMS), the component of USDA tasked with implementing the National Bioengineered Food Disclosure Standard (BE disclosure standard), issued a proposed rule that sets forth the requirements and procedures for disclosing bioengineered (BE) foods (BE Proposed Rule). In line with numerous stakeholder requests, the proposed compliance date for the BE disclosure standard is aligned with FDA's NFL compliance date--January 1, 2020 for all but small manufacturers (who have until January 1, 2021). The proposed compliance date also provides additional time for entities to use up existing label stock, if necessary. The comment period closes July 3, 2018 (60 days from today), and AMS stated it will not extend the comment period; the statutory deadline for AMS to issue a final rule is July 29, 2018. The remainder of this alert will address the BE proposed rule.

Scope of the BE Proposed Rule

The BE disclosure standard applies to food subject to the labeling requirements of the Federal Food, Drug, and Cosmetic Act (FDCA), or the labeling requirements of the Federal Meat Inspection Act, the Poultry Products Inspection Act, or the Egg Products Inspection Act, so long as the most predominant ingredient in the food would independently be subject to the labeling requirements of the FDCA or the most predominant ingredient in the food is broth, stock, water, or a similar solution and the second most predominant ingredient would independently be subject to the labeling requirements of the FDCA. This means that a food where meat is the primary ingredient, such as canned ham, would *not* be subject to the BE disclosure standard, while food that contains meat as a non-predominant ingredient, such as barley soup with beef, *would* be subject to the BE disclosure standard.

The BE Proposed Rule would also expressly exempt a few discrete categories of food from the BE disclosure standard requirements:

- food served in a restaurant or retail food establishment;
- food produced by a very small food manufacturer (annual receipts less than $2.5 million);
- food derived from an animal based soley on the fact that the animal has consumed feed produced from, containing, or consisting of a BE substance;
- food certified organic under the National Organic Program; and
- food that contains a BE substance below a certain "threshold," for which AMS requests comments on three alternatives:
  - food in which an ingredient contains a BE substance that is inadvertent or technically unavoidable and accounts for 5% or less, by weight, of the ingredient;
  - food in which an ingredient contains a BE substance that is inadvertent or technically unavoidable and accounts for 0.9% or less, by weight, of the ingredient; or
  - food in which the ingredient or ingredients that contain a BE substance account for no more than 5% of the total weight of the food in final form.

Basic Requirements of the BE Proposed Rule

Under the BE Proposed 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. AMS proposes to define "BE food" to mean "a food that contains genetic material that has been modified through *in vitro* recombinant DNA techniques and for which the modification could not otherwise be obtained through conventional breeding or found in nature." The proposed definition of BE food exempts "incidental additives," as described in 21 C.F.R. 101.100(a)(3). AMS also specifically requests comment on whether the proposed definition of BE food should exempt food, such as certain highly refined products, where modified genetic material cannot be detected through a validated testing process.

The BE Proposed Rule includes two proposed lists of BE foods that are commercially available in the United States - those with a "high adoption rate" and those with a "low adoption rate." AMS explained that "adoption" refers to the prevalence with which BE cultivars of a food crop are planted or produced in the U.S. relative to the number of non-BE cultivars of the same crop. The goal of these lists would be to "serve as the linchpin in determining whether a regulated entity would need to disclose a BE food under the NBFDS." Only if a food, or an ingredient used in the food, is on either list or is produced using foods on either list would it be subject to the BE disclosure standard. The proposed list of commercially available BE foods that are highly adopted (with an adoption rate of 85 percent or more) is: canola, corn (field), cotton, soybean, and sugar beet. The proposed list of commercially available BE foods that are not highly adopted is: apple (non-browning cultivars), corn (sweet), papaya, potato, and squash (summer varieties). AMS proposes to review and revise these lists on an annual basis.

AMS also identified three entities that it proposes would be responsible for the BE disclosure: food manufacturers, importers, and certain retailers. Food manufacturers or importers who package food prior to it arriving at the retailer would be responsible for complying with the BE

disclosure standard for those foods, and a retailer would be responsible for complying with the BE disclosure standard for any food it packages.

Format and Placement of the BE Disclosure

AMS proposes that the BE disclosure could be made through a text statement, a symbol, an electronic or digital link, or a text message.

- The text statement for high adoption BE foods would be "bioengineered food" if the food itself is BE or contains entirely BE ingredients, and would be "contains a bioengineered food ingredient" if only certain ingredients are BE. For non-high adoption BE foods, the text statement could also be "may be a bioengineered food" or "may contain a bioengineered food ingredient."
- The symbol disclosure could be through one of a few circular logos that AMS designed and included in the BE Proposed Rule:

- The electronic or digital link disclosure could be a link, which must be accompanied by a label statement that states "Scan here for more food information" or equivalent language that only reflects technological changes, and also by 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 for more food information."
- The text message disclosure option must be identified with the label statement "Text [XX] for more food information," and the text message response must be the text disclosure statement described above, without any additional marketing or promotional material.

The BE Proposed Rule includes modified requirements for small and very small packages and for foods sold in bulk containers, and also allows for voluntary disclosures consistent with the content and format requirements above on the labels of BE foods that are not subject to mandatory disclosure.

Recordkeeping Requirements and Compliance

The BE Proposed Rule would only impose recordkeeping requirements relating to food that is on one of the two lists of BE foods that are commercially available in the United States. If a food itself is or contains an ingredient that is on one of the lists, and the food does not bear the BE

disclosure, then the responsible entity must maintain records demonstrating that the food is not, or does not contain, a BE food.

AMS can request access to such records to evaluate compliance, and interested parties can also file a complaint with AMS about potential violations of the disclosure requirements that could trigger record review. Failure to provide a BE disclosure when such disclosure is required is a prohibited act.

Key Issues for Stakeholders to Consider

AMS has provided 60 days for comment from May 4, 2018, i.e., until July 3, 2018. AMS also advised that it intends to conduct a webinar on the BE disclosure standard rulemaking. In the BE Proposed Rule, AMS specifically requests comment on two issues that are critical to how AMS will ultimately implement the BE disclosure standard.

First, AMS is evaluating whether highly refined foods and ingredients should fall within the definition of BE food, and explains that comments identified two primary approaches to this issue: (1) highly refined products are not bioengineered because they do not *contain* modified genetic material, even if they have been derived from GE plants, and therefore are not BE food as defined in the BE Proposed Rule; or (2) highly refined products are BE food if they are produced from bioengineering, as they would be presumed to contain modified genetic material, but testing could be used to rebut this presumption and show that certain of these products are not BE food as defined in the BE Proposed Rule. AMS seeks comment on these two approaches and how the agency should define BE food in the final rule, including how the final rule should allow for the use of testing to demonstrate that modified genetic material is not present in a food or ingredient.

AMS also requests comment on different options for determining, as directed by the statute, threshold levels of BE material in a food, below which the food would be exempt from the BE disclosure requirement. The BE Proposed Rule identifies two potential threshold levels (0.9 and 5 percent) and two different ways of calculating the threshold (by ingredient or by total weight).

Covington & Burling LLP continues to monitor developments in food labeling requirements. If you have any questions concerning the rules discussed in this alert or other food regulatory matters, or would like assistance in preparing comments to USDA on the BE Proposed Rule, please contact any of the following attorneys in our Food & Drug Practice group or visit our food, beverage and dietary supplements practice website:

Miriam Guggenheim	+1 202 662 5235	mguggenheim@cov.com
Jeannie Perron	+1 202 662 5687	jperron@cov.com
Jessica O'Connell	+1 202 662 5180	jpoconnell@cov.com
MaryJoy Ballantyne	+1 202 662 5933	mballantyne@cov.com

our clients and other interested colleagues. Please send an email to unsubscribe@cov.com if you do not wish to receive future emails or electronic alerts.