



Government Affairs Extra

Bioengineered Food Disclosures

BY
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Earlier this year, the U.S. Department of Agriculture (USDA) proposed a new regulation that would require food manufacturers to disclose information about bioengineered (BE) food and BE food ingredients. The proposed rule is the result of a 2016 law that required the USDA to establish a National Bioengineered Food Disclosure Standard for all food. For purposes of the BE disclosure law, "food" includes alcohol beverages intended for human consumption as well as non-alcohol beverages.

The law and the proposed rule state that the BE disclosure standard shall apply only to foods subject to labeling requirements under the Federal Food, Drug, and Cosmetic Act (FDCA) or, in certain circumstances, meat, poultry, or egg laws. Therefore, the law arguably applies only to non-malt beverages below 7 percent alcohol by volume (ABV), such as hard seltzers, hard ciders, and low-alcohol wines. The legislative history of the law supports this view. A 2016 Senate committee report states: "It is the intent of Congress that the disclosure requirement applies only to those foods subject solely to the labeling requirements under the [FDCA] and excludes from its scope alcoholic beverage products over which the Tax & Trade Bureau [TTB] has labeling authority pursuant to Section 205 of the Federal Alcohol Administration Act [FAA Act]." The law also preserves the TTB's rights and obligations under the FAA Act. Nevertheless, neither the law nor the proposed rule explicitly excludes alcohol beverages subject to TTB's labeling authority.

As a result, there is some debate about whether alcohol beverages will be included in the final rule. On the one hand, the beer industry has interpreted the law and the proposed rule to apply only to alcohol beverages that are labeled under the FAA Act. There are also Memoranda of Understanding between the TTB's predecessor agency and the Food and Drug Administration (FDA), which state that the

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FDA defers to the TTB for primary regulation of the labeling of alcohol beverages. On the other hand, these memoranda also mention the FDCA labeling requirements, and the proposed rule's exemptions do not explicitly exclude beverages subject to TTB labeling regulations for malt beverages, distilled spirits, and wine containing 7 percent ABV or greater.

The proposed rule indicates that it will apply to breweries, wineries, and distilleries. Table Two of the proposed rule lists the number of small firms directly affected by the proposed rule by North American Industry Classification System (NAICS) code. The table includes the

industry classification codes for breweries, wineries, and distilleries, as well as beer, wine, and liquor stores. A star designation in Table Two indicates sectors of the industry that are less likely to be required to disclose pursuant to the BE food disclosure standard. None of the alcohol beverage-related industry codes have a star. The proposed rule discusses only express exemptions to the disclosure requirement for very small food manufacturers and food served in a restaurant or similar retail food establishments such as saloons, taverns, or bars. Finally, the same Senate committee report states that the federal requirements for label

changes "will impact virtually every food and beverage product on the market."

BIOENGINEERING

Turning to the proposed rule, the law defines bioengineered food products broadly as foods that contain 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. The proposed rule would establish an additional type of BE food: incidental additives present in the food at insignificant levels that do not have any technical or functional effect. A USDA chart listing the top 50 ingredients that would trigger disclosure for food products under one scope outlined in the proposed rule includes yeast, yeast extract, artificial flavor, natural flavor, spice, and flavor.

To ensure that manufacturers can easily determine which products must have disclosures under the proposed rule, the USDA would create lists of BE foods that are commercially available in the United States with a high adoption rate (e.g., soybeans and field corn) and commercially available BE foods that are not highly adopted (e.g., sweet corn). The USDA would update the lists annually. Regardless of the list on which the BE food appears, a manufacturer must disclose a BE food unless it qualifies as a very small food manufacturer or qualifies for another exemption from the proposed rule.

The law mandates that BE disclosures occur via (1) text, (2) symbols, or (3) digital links. The USDA proposed using text to indicate a food is bioengineered or contains a "bioengineered food ingredient." The rule also proposed three different symbols containing the letters BE. The three symbols were a leaf with a starburst attached next to a hill; a smiling green sun with rays; and a smiling white sun with a leaf. Since the proposed rule's publication, the USDA appears to have abandoned the two smiley face sun logos. In August, the USDA filed patents for six new logos that contain the words "Bioengineered," "Made with Bioengineering," or "May Be Bioengineered Food" as white text on a black background in a circle. The words surround the leaf with a starburst, which are imposed over a sun and a hill that is strikingly similar to President Obama's 2008 campaign logo. The Department is also proposing a digital link (e.g., a QR code) accompanied by text inviting the consumer to "scan here for more food information."

The proposed rule exempts food served in restaurants or similar retail food establishments, very small food manufacturers with annual revenues under \$2.5 million, and food certified under the National Organic Program. The proposed rule would require BE disclosures from food manufacturers, importers, and

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retailers who package and label foods for retail sale and display, and who sell bulk food items. Small food manufacturers with annual receipts of \$2.5 million to \$10 million would have additional flexibility with respect to disclosures, as would small and very small food packages with less than 40 and 12 square inches of surface area, respectively. The proposed rule would permit manufacturers exempt from the BE disclosure requirements to make voluntary disclosures regarding BE food.

The FDA has also taken steps to guide manufacturers who wish to voluntarily label their foods as made with or without BE or the use of BE ingredients. In August, the FDA issued a call for comment on documentation that manufacturers should maintain to substantiate any voluntary claims that a food was not developed using genetic engineering. FDA advises manufacturers to obtain certifications or affidavits from farmers, processors, and others in the food production and distribution chain. The agency notes that such recordkeeping requirements would not apply to organic products because foods labeled "organic" are not permitted to contain genetically engineered materials. The comment period for the request closed in October.

The USDA's proposed BE rule received more than 14,000 comments from individuals and entities as diverse as the Beer Institute, Organic Trade Association, Academy of Nutrition and Dietetics, Illinois Farm Bureau, and National Fisheries Institute. On August 31, the USDA submitted its proposed version of the final BE rule to the executive branch agency that reviews final rules. As the law required the USDA to establish a BE standard by July 2018, the Center for Food Safety recently filed a complaint arguing that the USDA failed to comply with mandatory deadlines. Once finalized, the rule would be phased in over two years, with delayed compliance dates for small food manufacturers and entities with existing inventories of food with pre-BE disclosure labels.

We recommend reviewing the final rule and the lists of ingredients, once published, to determine any applicable changes to the rule's scope that may impact brewers.

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