



The USDA's Proposed National Bioengineered Food Disclosure Standard

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On May 3, 2018, the U.S. Department of Agriculture ("USDA") released its much-anticipated proposed rule to establish a national standard for the disclosure of bioengineered ingredients in certain food products. The public comment period on the proposal has begun and runs through July 3, 2018. The proposed rule sheds light on certain aspects of the disclosures that food manufacturers and others will be required eventually to provide. But the USDA's proposal leaves significant questions unanswered, providing an opportunity for the public to shape the final rule in critical ways.

Background

The USDA's rule is promulgated under the 2016 National Bioengineered Food Disclosure Standard Act. It preempts the GMO labeling regimes of several states, including Vermont, and requires the USDA to issue a final rule on the disclosure of bioengineered ingredients in food products by July 29, 2018. You can read more about the background of the Act and the actions undertaken by the USDA prior to the release of its proposed rule <a href="https://example.com/here-

Definition of "Bioengineered" Ingredients

The proposed rule requires disclosure of "bioengineered" ingredients. Under the Act, "bioengineered" (or "BE") means food "(A) that contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques; and (B) for which the modification could not otherwise be obtained through conventional breeding or found in nature."

The proposed rule is silent as to whether ingredients that are genetically modified through other techniques, such as gene editing, are covered. But the USDA does provide some clarifying guidance on what constitutes a "bioengineered" food or ingredient. Its proposed rule offers a list of "Commercially Available BE Foods" that have been "highly adopted" in the food industry, and a list of "Commercially Available BE Foods" that are "not highly adopted." Only food products containing ingredients on these lists will be subject to the anticipated disclosure rules.

Foods are "highly adopted" where 85% or more of the crop produced in the U.S. is "bioengineered"—including canola, field corn, and soybeans. Foods are "not highly adopted" where less than 85% of the U.S. crop is bioengineered—including apples with non-browning cultivars, sweet corn, papaya, potato, and summer varieties of squash. The proposed rule provides a process by which the lists can be updated depending on changes in technology and food cultivation.

Disclosure Options

Except for certain exemptions (more on that below), if a food product appears on, or contains an ingredient on, either the "highly adopted" or "not highly adopted" list, regulated entities will be required to make a disclosure on the label of that food product or not make a disclosure if they have documented verification that the food is not a bioengineered food or that it does not contain a bioengineered food ingredient.

The proposed rule allows regulated entities to choose from at least three disclosure options for non-exempt foods: a text disclosure on a food label, a symbol disclosure, or an electronic link disclosure. The USDA is considering a text message disclosure option as well. Under this proposed option, the company would be required to include a statement on the food label directing the consumer to a number to text for more information about the food. The number must provide an immediate response with only the required text disclosure.

If a regulated entity uses a text disclosure on a food label, the disclosure requirement would vary depending on which list the food or food ingredient appear. For food products made from ingredients on the "highly adopted" list, the regulated entity would disclose that the food product "Contains a bioengineered food ingredient." For food products made with ingredients on the "not highly adopted list," USDA proposes to give regulated entities the discretion to use the disclosure "May contain a bioengineered food ingredient" instead.

For the symbol disclosure option, the USDA proposes <u>three symbols</u> for public comment (along with black-and-white versions of each).

For the electronic link disclosure option, the USDA proposes to allow regulated entities to include a link on food packaging that can be scanned by a smartphone, at which point the user's smartphone will open a website containing the required disclosures. The USDA seeks comments on text statements that would accompany the digital link—for example, "Scan icon for food information." Regulated entities that use digital link disclosures would also be required to include a telephone number on the food label that would allow consumers to call at any time of day and receive the required disclosure.

The possible text message disclosure option would allow regulated entities to provide a number on food packaging and an instruction to send a text message to that number "for more food information." After sending a text message to that number, the consumer would receive a text message in response containing the required disclosure for that food product.

Entities responsible for disclosure would be required to maintain records necessary to substantiate compliance with the standards for individual disclosure options, including the type and wording of the disclosure used, and to substantiate the claim included in the disclosure or implied by the absence of a disclosure statement.

Exemptions from the Labeling Requirements

The proposed rule exempts a number of foods and food manufacturers from the labeling requirements. Exempted foods include animal products (e.g., meat or eggs) from animals that consume feed containing bioengineered ingredients; food certified as organic under the USDA's national organic program; and food served in restaurants or similar retail food establishments, including cafeterias, food stands, and bars.

The USDA is weighing different options for two categories of additional exemptions: an exemption based on the relatively low level of bioengineered ingredients in a food product, and an exemption for small food manufacturers based on the manufacturers' annual receipts. The USDA seeks public comment on the appropriate thresholds for these exemptions, and proposes several different options for consideration.

Proposed Compliance Dates

The USDA proposes a compliance deadline of January 1, 2020, with a delayed compliance date of January 1, 2021 for small food manufacturers. The USDA's proposed deadlines for bioengineered food disclosures are intended to align with the Food & Drug Administration's extension of the deadlines to comply with updated Nutrition Facts, Supplement Facts and Serving Size labeling requirements to the same dates.

Final Thoughts

The USDA's statutory deadline to issue a final rule, July 29, 2018, is fast approaching. But it likely will not meet it because the proposed rule contains a number of unanswered questions, many relating to critical issues such as how the presence of "bioengineered" ingredients will be disclosed and which foods and food manufacturers will be exempted from the labeling requirements.

These unanswered questions also mean that the final rule is likely to be influenced significantly by public comments. Food manufacturers, retailers, consumers, industry groups, and other interested parties have an important opportunity to shape the final contours of the USDA's bioengineered food labeling rules.

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