

Inside The New GMO Labeling Disclosure Proposal

By **Robert Hibbert** and **Ryan Fournier** (May 7, 2018, 11:48 AM EDT)

On May 4, 2018, the U.S. Department of Agriculture, through its Agricultural Marketing Service, released its highly anticipated rule proposing a nationwide labeling requirement for foods containing bioengineered ingredients, also known as genetically modified organisms or “GMO” ingredients. The proposed rule offers a sweeping national disclosure requirement, with public comment available until July 3, 2018.

Applicability

The proposed rule by the U.S. Department of Agriculture was issued in response to the National Bioengineered Food Disclosure Law, which Congress passed and President Barack Obama signed into law in the summer of 2016, mandating that the USDA set a national standard for a bioengineered disclosure on food.[1] The USDA’s proposed rule reaches far and wide, impacting labeling obligations for a substantial percentage of food products offered for sale in the United States.

The proposed rule applies to foods that are subject to the labeling requirements of the Federal Food, Drug And Cosmetic Act.[2] This includes, but is not limited to, “raw produce, seafood, dietary supplements, and most prepared foods, such as breads, cereals, non-meat canned and frozen foods, snacks, desserts, and drinks.”[3] While pet food and animal feed are “food” under the FFDC, the proposed rule does not extend to these articles.[4] As explained in greater detail in the preamble, it also applies to some of the meat, poultry and egg products independently regulated by the USDA, but only if an ingredient regulated by the U.S. Food and Drug Administration predominates.[5]

The USDA’s proposed rule would require a relevant food label to display a bioengineered disclosure indicating to consumers that it is a “bioengineered food,” absent certain exemptions.[6] It defines a “bioengineered food” to mean “... a 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 found in nature.”[7]

Exemptions



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The proposed rule exempts certain bioengineered foods from requiring a disclosure. For example, the proposed rule exempts foods served in restaurants and similar retail food establishments.[8] It also exempts foods certified under the USDA's National Organic Program.[9]

Additionally, the USDA clarified a hotly debated (and often litigated) issue surrounding whether foods derived from animals would need to include a bioengineered disclosure if the animal consumed a bioengineered food (e.g., if a bioengineered disclosure would be required on milk sourced from a cow that ate bioengineered feed). The agency has clearly stated that food from animals would not require a bioengineered disclosure simply because the animal consumed feed "produced from, containing, or consisting of a bioengineered substance." [10]

Finally, there will be much debate surrounding an exemption for foods that contain only a small amount of bioengineered ingredients. The proposed rule outlines three regulations for consideration. The agency proposes to exempt foods from disclosure requirements if "an ingredient contains a bioengineered substance that is inadvertent or technically unavoidable, and accounts for no more than five percent (5%) by weight of the specific ingredient." [11] The alternative is 0.9 percent by weight of the specific ingredient. [12] What is considered "inadvertent or technically unavoidable" will likely need to be debated further. However, this would allow for some bioengineered material to be present in the product due to unavoidable issues such as bioengineered crops grown in close proximity to non-bioengineered crops, or where bioengineered food would be handled by the same machinery as non-bioengineered food. The third alternative seems to offer the most straight forward approach, which would exempt foods "in which the ingredient or ingredients that contain a bioengineered ingredient that accounts for no more than 5% of the total weight of the food in final form." [13] We note that this definition removes the "inadvertent or technically unavoidable" requirement, therefore allowing certain entities to use a small amount of bioengineered ingredients up to the proposed threshold.

The agency is seeking comment on which of these three proposals to adopt.

Bioengineered List

The USDA intends to create two bioengineered foods "lists" to assist consumers and regulated entities in determining whether a food item requires the bioengineered disclosure.

The first list is for "highly adopted commercially available bioengineered foods," such as canola, corn (field) and soybean. When the proposed rule uses the term "adoption," it refers to the prevalence with which the bioengineered food is cultivated compared to the non-bioengineered version. The USDA proposes to consider "highly adopted" to mean those bioengineered foods with an adoption rate of 85 percent or more in the United States. [14] The second list will include foods that are "not highly adopted commercially available bioengineered foods" (under 85 percent), such as apple, corn (sweet), or papaya. [15]

Importantly, regardless of which list a bioengineered food appears, "only foods or products on either of those lists or made from food on either of the lists would be subject to [the bioengineered] disclosure ..." [16] "Regulated entities would only need to determine whether the end product or an ingredient used in the end product, is on either of the lists or is produced using foods on either of the lists." [17]

While these lists are not yet finalized, we expect much debate and input from those industry groups representing commodities identified on these lists. Currently, the proposed rule identifies canola, corn (field), cotton, soybean and sugar beet as highly adopted commercially available bioengineered

foods.[18] The proposed rule identifies apple, corn (sweet), papaya, potato and certain varieties of squash as not highly adopted commercially available bioengineered foods.[19]

Disclosure Methods

The proposed rule allows for any one of the following label disclosure methods: (1) written text disclosure, (2) symbol disclosure, (3) electronic or digital link disclosure or (4) a text-message disclosure. We note that the National Bioengineered Food Disclosure Law gave the USDA three options to consider for such a disclosure, including a (1) written text, (2) symbol or (3) electronic or digital disclosure method printed directly on a food label. The proposed rule offers all three options.

For text disclosures, the proposed rule bases the language on whether the food article is on the highly adopted commercially available bioengineered foods or not highly adopted commercially bioengineered foods lists as discussed above. For example, if a food is considered highly adopted, then the written text disclosure must state that it is a “bioengineered food” or “contains a bioengineered food ingredient.”[20] If a food is considered not highly adopted, then the text disclosure can use “may” statements, such as “may contain a bioengineered food ingredient” or “may be a bioengineered food.”[21] Notably, the written text disclosures offered in the proposed rule only refer to “bioengineered foods.”[22] There are no acronym options, including the much used “GMO” term.

Additionally, the proposed rule offers different symbol varieties as a disclosure option. Again, the symbols abandon the acronym “GMO,” and instead, the USDA proposes symbols using the acronym “BE.” The agency has presented symbol options for public comment.[23] Given that the USDA has publicly stated it does not want the bioengineered disclosure to be perceived as a “warning” to consumers, it is not surprising that two of these symbols resemble a “smiley face” or that the symbol uses a new acronym (i.e., “BE”), most likely to move away from any stigma associated with the term “GMO”:



We expect much comment and debate on these symbols given the variety of consumer perceptions as it relates to bioengineered foods.

Finally, the proposed rule recognizes technical changes occurring in the marketplace, and it is the first time the USDA has codified regulatory allowance of an electronic or a text-message disclosure. Importantly, the electronic or text-message disclosures allow companies to comply with bioengineered disclosure requirements without noting the presence of bioengineered foods directly on the product label. For example, if using an electronic or digital link disclosure, the label statement only has to say, “Scan here for more food information,” or something similar.[24] For a text-message disclosure, the label statement only has to say, “Text [number] for more food information.”[25] One question that arises is how many consumers would actually go through the extra step of scanning a digital link or texting a number listed on a label solely for the purposes of determining if it is a bioengineered food or contains bioengineered ingredients. Ultimately, these two alternatives do not require the use of any term or phrase expressly referencing bioengineered foods on the label.

Compliance Date Requirements

Compliance with the proposed rule is set for Jan. 1, 2020, and Jan. 1, 2021, for small food manufacturers.[26] However, we note that the proposed rule allows food manufacturers and labelers to use their existing inventory of food labels entered into commerce prior to Jan. 1, 2022, or until regulated entities use up their remaining inventories, whichever comes first.[27] Further, it is possible for the agency to extend these deadlines with future rulemaking provisions.

60-Day Comment Period

The USDA provided the public 60 days to comment on the proposed rule. Anyone can submit their comments online. We expect the agency to receive substantial comments based on its prior receipt of over 112,000 responses it received last summer.[28]

The agency stated in a press release that the comment period will not be extended given that there is a congressionally mandated timeline to finalize the proposed rule by July 29, 2018.[29]

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[1] The National Bioengineered Food Disclosure Standard, S. 764, 114th Congress (2016) (enacted). A full text of the bill can be found [here](#).

[2] 7 CFR § 66.3(b)(1).

[3] 83 FR 19860, 19862.

[4] 83 FR 19860, 19861.

[5] 7 CFR § 66.3(b)(2)(i)-(ii).

[6] 7 CFR § 66.3(a).

[7] 7 CFR § 66.1 “Bioengineered Food.”

[8] 7 CFR § 66.5(a) and (b). The proposed definition of “similar retail food establishments” means “a cafeteria, lunch room, food stand, saloon, tavern, bar, lounge, other similar establishment operated as an enterprise engaged in the business of selling prepared food to the public, or salad bars, delicatessens, and other food enterprises located within retail establishments that provide ready-to-eat foods that are consumed either on or outside of the retailer’s premises.” 83 FR 19860, 19867.

[9] 7 CFR § 66.5(e).

[10] 7 CFR § 66.5(d).

[11] 7 CFR § 66.5(c).

[12] Id.

[13] Id.

[14] See 83 FR 19860, 19864.

[15] Id.

[16] Id.

[17] Id.

[18] Id.

[19] Id.

[20] 7 CFR § 66.102(a)(1)-(2).

[21] 7 CFR § 66.102(b).

[22] 7 CFR § 66.102.

[23] 7 CFR § 66.104.

[24] 7 CFR § 66.106(a).

[25] 7 CFR § 66.108(a).

[26] 7 CFR § 66.1 “Small Food Manufacturer” means “any food manufacturer with less than \$10 million in annual receipts but \$2,500,000 or more in annual receipts.”

[27] 7 CFR § 66.120.

[28] You can read more about the questions the USDA had to consider in promulgating the proposed rules [here](#).

[29] You can find the press release [here](#).