New Food and Dietary Supplement Labels in 2020: USDA Proposes GMO Labeling Rule to Coincide with FDA's Implementation of the Nutrition Labeling Final Rules

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On May 4, 2018, the Food and Drug Administration (FDA) published a final rule[1] officially extending the compliance dates for the final rules providing updated nutrition information on the label of food, including dietary supplements. The extension is to **January 1, 2020** for manufacturers with $10 million or more in annual sales and to **January 1, 2021** for manufacturers with less than $10 million dollars in annual food sales.

Also on May 4th, the U.S. Department of Agriculture's (USDA or agency) Agricultural Marketing Service (AMS) published its long awaited proposed rule[2] that will require food manufacturers and other entities labelling foods for retail sale to disclose information about bioengineered (BE) food--commonly known as genetically modified organisms (GMO)--food and BE food ingredient content. As expected, the proposed compliance dates for the BE Rule are the same as those for the FDA's labeling changes **(January 1, 2020 for large manufacturers and January 1, 2021 for small manufacturers)** to minimize the amount of changes that the industry will be required to make to its product labels.

Comments on the proposed rule should be submitted by **July 3, 2018** at www.regulations.gov. Due to the mandate that a final rule be published by July 29, 2018, AMS noted in a press release that it will not provide an extension of time to submit comments on the Proposed Rule. Interested parties are encouraged to submit their comments by the deadline to ensure the comments are considered before a final rule is published. We provide a summary of the key provisions of the proposed rule below.

Background

Public Law 114-216, enacted on July 29, 2016, amended the Agricultural Marketing Act of 1946 (the amended Act) and charged USDA with developing a national mandatory system for disclosing the presence of bioengineered material in foods. The law also preempted future and existing state laws attempting to establish GMO labeling requirements for foods containing bioengineered materials. As a result, it invalidated Vermont's GMO Labeling Law, which went into effect just a few weeks before the National Bioengineered Food Disclosure Standard (NBFDS) was enacted and prevented other states from issuing their own laws. Because of the urgency of the issues surrounding GMO labeling, the law mandated AMS to publish a final rule by July 2018.

On June 28, 2017, AMS posted a list of 30 questions for consideration by stakeholders to assist the agency in developing a Proposed Rule setting national standards and procedures for the labeling of bioengineered foods (i.e., GMO labeling). The

questions covered an array of topics from the terms that AMS should consider as interchangeable with "bioengineering," to the text that a manufacturer should be required to use when it chooses to use text to disclose a bioengineered food. AMS received over 112,000 responses to its request and conducted a mandated study to identify potential technological challenges that may impact whether consumers would have access to the BE disclosure through electronic or digital disclosure methods. Following review of all information, AMS drafted the proposed rule with the intent to "provide for disclosure of foods that are or may be bioengineered in the interest of consumers, but also to minimize implementation and compliance costs for the food industry . . . ."

Applicability

The proposed rule applies to foods for human consumption subject to the labeling requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act), including but not limited to "raw produce, seafood, dietary supplements, and most prepared foods, such as breads, cereals, non-meat canned and frozen foods, snacks, deserts, and drinks.[3] " The disclosure requirements, however, will not apply to pet foods or feed, even though they are also foods under the FD&C Act.

Bioengineering and Bioengineered Food

In the proposed rule, AMS proposes to directly incorporate the statutory definition of "bioengineering" into the definition of "bioengineered food" without any further interpretation of what "bioengineering" means. The amended Act defines bioengineering as a 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[4]. 7 U.S.C. 1639(1).

Despite deciding to incorporate the definition without further interpretation in the proposed rule, AMS welcomes comments on what could be considered to constitute "bioengineering." While it received comments in response to its 30 questions, AMS acknowledged that there was a wide difference in public opinion about how the statutory definition of bioengineering should be interpreted and applied to the definition of "bioengineered food."

Lists of Bioengineered Foods

Due to the complexity of the definition of "bioengineering," USDA intends to create food lists in "an attempt to make it easier and less burdensome for consumers and regulated entities alike to understand what products may need to be disclosed under the NBFDS . . . .":

(1) a proposed list of BE foods that are commercially available in the United States with a high adoption rate, and (2) a proposed list of BE foods that are commercially available in the United States that are not highly adopted.

AMS used the term "adoption" to refer to the prevalence with which BE cultivars of a food crop are planted or produced in the United States, relative to the number of BE cultivars of the same crop in production. The agency is proposing the following foods to be considered as highly adopted: **Canola – 90%, Corn, Field – 92%, Cotton – 93%, Soybean – 94%, and Sugar Beet – 100%**. This list would only include commercially available BE foods that have an adoption rate of 85% or more in the US.

AMS is proposing the following foods to be considered as not highly adopted (less than 85%): **Apple, Non-browning cultivars, Corn, Sweet, Papaya, Potato, and Squash, Summer varieties**.

According to the preamble "**only foods or products on either of those lists or made from food on either of the lists would be subject to the disclosure [requirements] under the NBFDS**." (Emphasis added). Therefore, the industry would only

need to determine whether the consumer-facing end product is on either of the lists or is produced using foods on either of the lists.

Disclosure Threshold

AMS is considering three alternative proposals regarding the amount of a BE substance that may be present in a food in order for the food to be a BE food. The agency is seeking comments on which proposal to adopt in the final rule.

1. The first proposed alternative would establish that a food in which an ingredient contains a BE substance that is **inadvertently or technically unavailable and accounts for no more than five percent (5%) of the specific ingredient by weight**, would not be subject to the disclosure requirements. However, any other use of a food or food ingredient that contained a BE substance would be subject to disclosure.

2. The second proposed alternative would establish that a food in which an ingredient contains a BE substance that is **inadvertently or technically unavailable and accounts for no more than nine-tenths of a percent (0.9%) of the specific ingredient by weight**, would not be subject to the disclosure requirements.

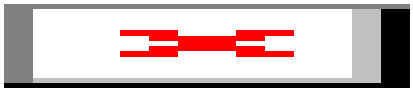
3. The third proposal is for AMS to allow regulated entities to use a small amount of BE ingredients up to a certain threshold, **such as 5% of the total weight of the product**, before being required to label a product with the BE disclosure on the product label.

Disclosure Methods

The proposed rule outlines several choices for BE disclosure:

(1) Text disclosure - AMS is proposing using the terms "bioengineered food" or "contains a bioengineered food ingredient." For foods that are in the non-high adoption list, AMS is proposing the following terms: "bioengineered food," "May be bioengineered food," "Contains a bioengineered food ingredient," or "may contain a bioengineered food ingredient."

(2) Symbol Disclosure - AMS is proposing 3 alternative symbols with variations of the symbols and is inviting comments on the variations:



The use of other symbols that use the acronym GMO would not be permitted.

(3) Electronic or digital link disclosure – If using an electronic or digital link, the label must include the language "Scan here for more food information," or similar language.

(4) AMS is also proposing the use of text messages to accommodate people that may not have access to the internet. If using a text message disclosure, the packaging would be required to say "Text [number] for more food information."

Compliance Dates

As noted above, the compliance date for the proposed rule is January 1, 2020, with a delayed compliance date of January 1, 2021 for small food manufacturers. However, AMS will allow regulated entities to use labels printed by the initial

compliance date (January 1, 2020) regardless of whether they comply with the NBFDS, "until the regulated entity uses up remaining label inventory or until January 1, 2022, whichever date comes first." For example:

If a food manufacturer used the last of its existing labels on December 1, 2021, and the product entered the stream of commerce the following week, the food manufacturer would not have to change the labels on the food products if those products remain on the store self after January 1, 2022.

According to AMS, this approach should help reduce costs and burdens on regulated entities. The agency is seeking comments on this approach, as well as the other requirements listed above.

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[1] 83 Fed. Reg. 19,619 (May 4, 2018), available at https://www.federalregister.gov/documents/2018/05/04/2018-09476/food-labeling-revision-of-the-nutrition-and-supplement-facts-labels-and-serving-sizes-of-foods-that

[2] 83 Fed. Reg. 19,860 (May 4, 2018), available at https://www.regulations.gov/document?D=AMS-TM-17-0050-0004.

[3] It also applies to foods that are subject to the labeling requirements of the Federal Meat Inspection Act, or the Egg Products Inspection Act , "if the most predominant ingredient of the food would independently be subject to the labeling requirements" under the FD&C Act; or "if 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" of the FD&C Act.

[4] AMS is seeking comments as to whether it should include a definition for "conventional breeding" and/or "found in nature" in a final version of the rule.