CENTER FOR
Science IN THE
Public Interest
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Nutrition Action Healthletter

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By Electronic Submission
Docket No. AM-TM-17-0050
U.S. Department of Agriculture
1400 Independence Ave. SW,
Room 4543-South,
Washington, DC 20250

Re: Comments to Docket No. AMS-TM-17-0050 Regarding the Regulations for the National Bioengineered Food Disclosure Law

The Center for Science in the Public Interest (CSPI)[1] appreciates the opportunity to submit comments on the United States Department of Agriculture's (USDA) proposed regulations that implement the National Bioengineered Food Disclosure Law (NBFDL)[2]. CSPI supports the NBFDL and wants to ensure that it is implemented in a manner that provides useful and scientifically accurate information to consumers about bioengineered foods in a uniform and neutral manner. While the proposed rule is a first step in implementing the NBFDL, it is lacking much of the detail needed for (1) consumers to understand what is and is not covered by the law, and (2) food manufacturers to know exactly what is required. Therefore, USDA should address each of the issues set forth below before the National Bioengineered Food Disclosure Standard (NBFDS) is finalized.

I. The National Bioengineered Disclosure Standard21 Should Allow Substitution of the Term "Genetically Engineered" for the Term "Bioengineered."

In the proposed rule, the USDA states that it considered alternative phrases to the term "bioengineered" for the disclosure text, but determined that "bioengineered" "adequately describes food products of the technology that Congress intended to be within the scope of the NBFDS."[3] Regardless of whether the term "bioengineered" is

[1] CSPI is a nonprofit education and advocacy organization that focuses on improving the safety and nutritional quality of our food supply. CSPI seeks to promote health through educating the public about nutrition; it represents citizens' interests before legislative, regulatory, and judicial bodies; and it works to ensure advances in science are used for the public good. CSPI is supported by the 500,000 member-subscribers to its *Nutrition Action Healthletter* and by foundation grants. CSPI receives no funding from industry and no grants from the federal government.
[2] Public Law 114-216, which amended the Agricultural Marketing Act of 1946 (7 U.S.C. 1621 *et. Seq.*).
[3] Agricultural Marketing Service and U.S. Department of Agriculture. (2018). National Bioengineered Food Disclosure Standard. 7 CFR 66, page 19871.

adequate, CSPI believes that USDA should allow entities disclosing pursuant to the NBFDL to substitute the term "genetically engineered" if they prefer that term.

Under the NBFDL, Congress gave the Secretary of Agriculture the discretion to allow the disclosure to use other terms "similar" to "bioengineered." 7 U.S.C. 1621 *et seq*. The term "genetically engineered" is similar to "bioengineered" and is a scientifically accurate description of what Congress intended to be covered by the NBFDL. As evidence, in its November 2015 "Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants," the Food and Drug Administration (FDA) uses the terms "genetically engineered" and "bioengineered" interchangeably throughout the guidance and allows both options for voluntary disclosure.[4] In addition, many food manufacturers may also prefer the term "genetically engineered," as they may believe it is more informative or familiar to some consumers than is "bioengineered." Therefore, USDA should allow food manufacturers an option to substitute the term "genetically engineered" for the term "bioengineered" when making a disclosure under the NBFDL. If USDA only allows the term "bioengineered," there may be confusion from consumers about what the disclosure refers to.[5]

II. The NBFDS Should Include Highly Processed Ingredients, but USDA Should Develop Specific Disclosure Language Involving those Ingredients that Is Scientifically Accurate.

Highly refined ingredients, such as sugar or corn oil, can be derived from a genetically engineered (GE) crop. However, during the refinement process, all the organism's DNA and protein (including the DNA engineered into the crop and the protein produced by the gene) are removed. Importantly, those refined ingredients are biologically and chemically indistinguishable from the same ingredient that is derived from a non-GE crop and to label them differently could be misleading. Similarly, to label highly refined products as bioengineered in the same way as an ear of GE corn or a GE apple is labeled—which both have bioengineered content—would also be misleading. For these reasons, some countries with mandatory labeling (such as Japan, Australia, and New Zealand), exempt highly refined ingredients from disclosure.

USDA should read the NBFDL broadly and provide consumers with as much information as possible about which ingredients originated from a bioengineered crop or animal so long as the disclosure is scientifically accurate. However, the USDA's proposed disclosure options fail to make a distinction between food products or ingredients that contain bioengineered material and those derived from bioengineered crops but are free from any bioengineered material – i.e. only content identical to the

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[4] U.S. Food and Drug Administration. (2015). Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants. Available at https://www.fda.gov/RegulatoryInformation/Guidances/ucm059098.htm.

[5] Whether the final rule only allows "bioengineered" or adds additional terms, there will need to be an education campaign to explain the information provided by the disclosure.

non-engineered form. Therefore, USDA should develop disclosure language for highly refined ingredients that conveys this difference to the consumer. For example, food manufacturers could state that "The sugar [or corn syrup or soybean oil] in this product came from bioengineered crops, but it is identical to sugar [or corn syrup or soybean oil] produced from non-bioengineered crops. Alternatively, the disclosure could say "produced from bioengineered crops but does not contain any bioengineered material." Whatever wording is chosen, it must convey accurate information to consumers.

III. USDA Should Require Ingredient-Specific Disclosure for Multi-Ingredient Processed Foods.

The disclosure required under the proposed NBFDS provides consumers with only limited information. If a multi-ingredient product contains one or more ingredients made from a bioengineered crop or animal, a food manufacturer must disclose that the whole food product is bioengineered rather than identifying the bioengineered ingredients. The result is that the consumer does not know which ingredient(s) led to the disclosure, nor do they know whether that ingredient(s) is a major or minor portion of a food.

For example, a food product that is made of 70 percent bioengineered corn would have the same disclosure as a food product that contains 3 percent cornstarch. Another issue is that a consumer might think that a multi-ingredient food product, such as a frozen pizza, displays a mandatory disclosure because it has bioengineered tomatoes or because the flour is from bioengineered wheat (which are two of the major ingredients in a frozen pizza). When in fact, the presence of one or two minor ingredients, such as corn oil or sugar (making up a small percentage of the product by weight), would necessitate the disclosure. Thus, the proposed disclosure could lead to consumer misunderstanding about why a product has a bioengineered label, as well as the extent to which bioengineered foods and ingredients are in the food supply.

Campbell Soup Company publicly provided the results of its interactions with consumers about disclosing bioengineered content. Those results indicate that consumers found a disclosure that included information on which ingredients came from GE crops (e.g., "the corn, soy, and sugar in this product came from genetically modified crops") most valuable. Disclosure of the specific ingredient is needed because in a multi-ingredient product, consumers may not know the different ingredients in a food product that were derived from bioengineered crop such as corn (*e.g.*, maltodextrin, malic acid, citric acid, caramel, dextrin, etc.).

For these reasons, USDA should require that the disclosure identify which ingredients in the ingredient list are a bioengineered food using a symbol, such as an asterisk. In practice, this would mean that if a product included several ingredients derived from bioengineered corn, each of those ingredients would have an asterisk next to it, and the text or symbol disclosure would provide a declarative statement that the asterisk designates bioengineered ingredients. For an electronic disclosure, a food manufacturer could list the ingredients that are bioengineered in the multi-

ingredient food using parentheticals. Providing such detail will also encourage consumers to think more carefully about the nature of biotechnology, the contents of the food and how biotechnology relates to each specific ingredient, rather than requiring a disclosure that encompasses the whole multi-ingredient product.

IV. The NBFDS Should Include Definitions for "Conventional Breeding" and "Found in Nature."

The NBFDL sets forth a definition of "bioengineered" that includes an exemption for foods modified through *in vitro* rDNA techniques if the modifications could also be obtained through "conventional breeding" or could be "found in nature." Currently, neither term has a commonly understood scientific definition that the food industry can apply in a uniform manner. Congress did not define those terms when it defined "bioengineered." Nonetheless, USDA should define them so that food manufacturers know which foods to disclosure and consumers will understand the foods that will, and will not, be disclosed. Without such definitions in the regulations, food manufacturers will have too much discretion to determine which foods require disclosure, leading to consumer confusion.

USDA should not choose any of the proposed definitions for "conventional breeding," set forth in the proposed rule. Instead, it should provide an inclusive list of the breeding techniques that do not involve changing of the DNA of a food organism with rDNA techniques. This would include traditional breeding methods, such as pollination, hybridization, wide crosses, vegetative propagation, and cloning. The definition should also include other methods, such as marker-assisted selection, chemical mutagenesis, and radiation-based mutagenesis. USDA could set forth a definition that encompasses all the different breeding techniques provided in the proposed rule's sample definitions. USDA should also set up a mechanism to amend the definition to include additional breeding techniques considered "conventional" by the scientific community. USDA could keep the list on its website and publish additions on an annual basis.

USDA should create a definition of "found in nature," that identifies different criteria that can be utilized to determine if a particular modification from an rDNA technique could be "found in nature." The criteria could include whether the modification adds a gene, promoter, or other type of DNA sequence derived from a different organism, as well as whether the existence of the modification (the altered DNA sequence) has been documented to exist in another variety of that organism. USDA could also require food manufacturers to analyze the extent of the changes made in the organism's genome; a small change to a single gene is more likely to be found in nature and be exempt from disclosure, while the probability of finding multiple changes within a genome in nature is very small. Finally, the criteria could include whether the variety is subject to intellectual property protection. If it is subject to protection, that should be considered *prima facie* evidence that it cannot be "found in nature" and required human intervention.

V. USDA Should Provide Additional Standards Concerning the Text Disclosure.

Under the proposed rule, USDA provides little or no details the size, positioning, and formatting of the text disclosure on the label of a food product. Section 66.100 (c) requires only that the disclosure "must be of sufficient size and clarity to appear prominently and conspicuously on the label, making it likely to be read and understood by the buyer under ordinary shopping conditions." This leaves it to the discretion of the food manufacturer to determine the size of the letters of the text, the font for the text, the color of the text, whether the text is highlighted in any manner, and any other details about the text disclosure. This would lead to a lack of uniformity that would likely make information hard to find, resulting in consumer frustration. USDA should replace the general obligation language in 66.100 (c) with details identifying exactly how the disclosure should appear uniformly for all bioengineered foods.

As rationale, the USDA states that the rule would "align with other mandatory food labeling requirements," citing FDA and Food Safety and Inspection Service's general regulations requiring federally mandated information to be prominently placed and conspicuous.[6] Yet, other food labeling requirements provide precise detail on the formatting, position, and/or text size (either in absolute or relative terms), including the Nutrition Facts panel,[7] ingredients list,[8] information panel,[9] statement or standard of identity,[10] the percent and "from concentrate" declarations on juice (FDA only),[11] net quantity of contents statement,[12] safe handling instructions (USDA only),[13] and nutrient content disclosures.[14] This ensures that the information provided to the consumer is uniform and that food manufacturers are not the ones to determine the format, positioning, and text size.

Moreover, even if the proposed Section 66.100 (c) were adequate with respect to the food label declaration, the rule provides no guidance for the online bioengineering disclosure. Both Section 66.100 (c), and existing regulations (21 CFR 101.15(FDA) and 9 CFR 317.2(b)) expressly cover only the food "label." It is not clear if they could be applied to cover the format of information posted on a website. This leaves a food manufacturer with enormous discretion.

We urge the USDA to revise its proposed rule to substitute details on the form of the disclosure for the term "prominence" in Section 66.100 (c), so that all text

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[6] 21 CFR 101.15(FDA) and 9 CFR 317.2(b)(USDA).
[7] 9 C.F.R. § 317.309(d)(USDA: meat); 9 C.F.R. § 381.409(d)(USDA: poultry); 21 CFR 101.2(c) (FDA); 21 CFR 101.9 and 21 CFR 101.9 (FDA).
[8] 9 C.F.R. § 317.2(h)(6)(USDA); 21 CFR 101.2(c)(FDA).
[9] 9 C.F.R. § 317.2(h)(6)(USDA); 21 CFR 101.2(c)(FDA).
[10] 9 C.F.R. § 317.2(h)(6)(USDA); 21 CFR 101.2(c)(FDA); 21 CFR 101.3(d)(FDA).
[11] 21 CFR 101.30(e)(FDA); 21 CFR 101.30(g)(FDA); 21 CFR 102.33 (FDA).
[12] 9 C.F.R. § 317.2(h)(USDA: meat); 9 C.F.R. § 381.121(c) (USDA: poultry).
[13] 9 C.F.R. § 317.2(l) (USDA: meat); 9 C.F.R. § 381.125(b) (USDA: poultry).
[14] 9 C.F.R. § 317.313(f)(g) (USDA: meat); 9 C.F.R. § 381.413(f)(g) (USDA: poultry); 21 CFR 101.13(h)(FDA).

disclosures are consistently formatted, both on the product label and on any website used to comply with the rule. Because this is the first rule providing for online disclosure of food information, USDA should put careful thought into its design and ensure that competing text (regardless of font size and contrast) does not obscure the disclosure.

VI. The USDA Should Allow Compliance with the Electronic Disclosure Through an Access Link on the First Screen.

While consumers should never be required to access digital information in order to accurately understand or interpret claims on a product label, a growing subset of consumers do rely on such technology, and the NBFDL permits its use as one option for the bioengineering disclosure. The NBFDL requires that "the electronic or digital link will *provide access* to the bioengineering disclosure located, in a consistent and conspicuous manner, on the first product information page that appears for the product on a mobile device, Internet website, or other landing page, which shall exclude marketing and promotional information."[15] The USDA has applied this provision to require placement of the bioengineering disclosure on the first page that appears when consumers scan or enter the url posted on the product label. However, the law could also allow for placement of an access link (i.e. "access… on the first product information page,") to the bioengineered disclosure in a consistent location on the first page to appear for the product.

Such an approach would allow product information to be prioritized to public health importance. The bioengineering disclosure is not the most important information for every consumer. Nor does it have public health relevance, as the currently bioengineered crops and ingredients made from those crops are safe. By contrast, nutrition information and ingredients both convey information about food that has strongly-supported relevance to public health. Therefore, this information should appear before the details of the bioengineering disclosure.

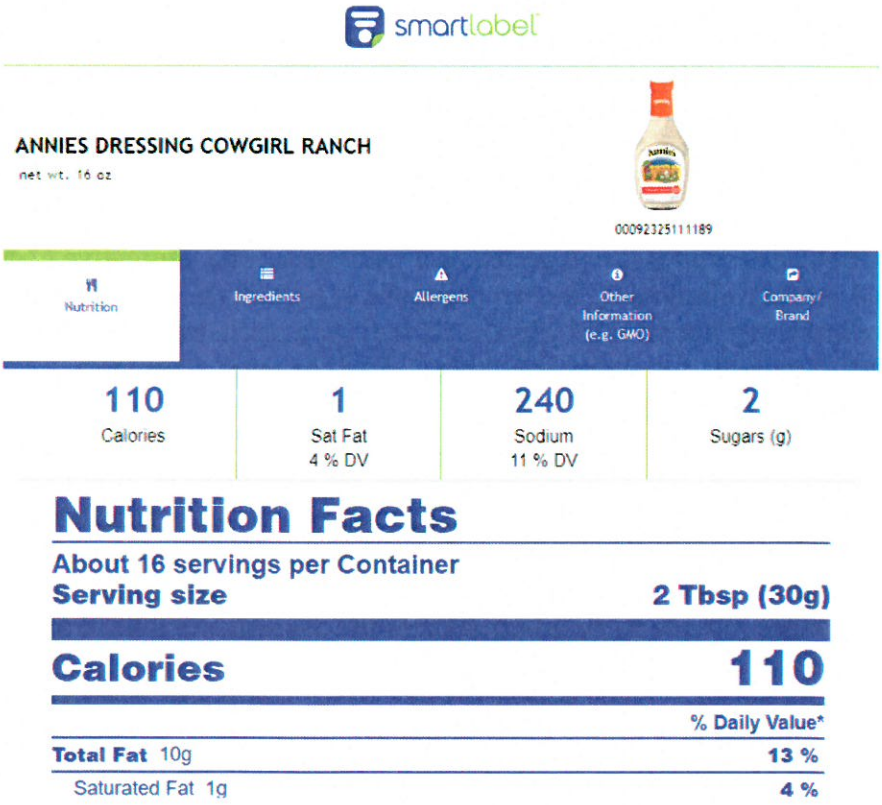
An approach that allows product information to be prioritized according to public health importance better serves these consumers so that they can instantly access other types of information related to food, including nutrition information, ingredients, additives, allergen/gluten information, and information related to environmental, labor, or animal welfare practices. So too, food recall information should be prioritized. Technology allows consumers to scan the label of a recalled food and be redirected to a webpage with relevant information, including warnings and instructions for medical action (*e.g.*, prophylactic vaccination against Hepatitis A).[16] Indeed, food recall notices should appear on the first page, and should not be required to include a bioengineering disclosure. (Beyond the public health benefit, this approach would reduce confusion as some consumers may wrongly infer that

[15] Public Law 114-214 §293(d)(2) July 29, 2016 (emphasis added).
[16] See http://www.foodsafetynews.com/2015/11/food-traceability-tool-developed-in-new-zealand-uses-qr-codes/#.Wzt8dPZFyUm.

bioengineered ingredients are the source of recalls linked to *Salmonella*, undeclared allergens, or any number of unrelated issues.)

The above can be accomplished by providing a clearly identifiable access link to the bioengineering disclosure. The link should be clearly labeled with the words "bioengineering information" (or another standardized term). As noted above, the rules should specify the size, positioning, and formatting of the access link. The rule could also require the bioengineering disclosure to be available in a specific size, positioning, and format immediately following this link (with one additional link permitted in the case of an intervening recall notice).

Such a format would be compatible to the approach currently employed by General Mills through the SmartLabel program, which offers separate tabs for "nutrition," "ingredients," "allergens," and "Other Information (*e.g.*, GMO)," with the Nutrition Facts page displayed prominently on the first page.



VII. The NBFDS Should Allow Food Manufacturers to Provide Consumers with Additional Information about the Bioengineering Disclosure.

The proposed disclosure provides only limited information to the consumer. For example, it does not tell the consumer which GE crop or animal was used in producing the food, why a GE crop was developed, and the benefits or any other impacts that may occur from the utilization of that GE crop or animal. The GE crop

or animal used in the food product, the trait bioengineered into that organism, and the benefits of the bioengineered crop to farmers, the environment, or the consumer, may be information that a consumer finds important when deciding whether to purchase or consume a food product with the required disclosure. Food manufacturers should be allowed to provide that type of additional information to the consumer in a location close to the mandatory disclosure (i.e., near, but separate from, the symbol or the text disclosure on the food package, and on the same webpage as the electronic disclosure). Consumers need information about both potential benefits and impacts if they are to make informed choices, one of the stated purposes of the law.

VIII. USDA Should Choose Alternative 2-A of the Three Alternatives Presented for the Symbol Disclosure.

The symbol disclosure under the NBFDL should be neutral, noticeable to the consumer, and provide the required information. Of the three proposed symbols, the first alternative comes the closest to meeting those objectives. That alternative is described by the NBFDS as a circle with a green circumference with the capital letters "BE" in white. It has two filled arches that look like rounded hills and a stem ending with a four-pointed starburst. While this alternative is not as neutral as a single circle with the letters "BE" inside, it is more neutral than the other two options, (which look like either a smiling sun or a smiling face).

If the USDA determines it will go forward with the second alternative (2-B), CSPI would propose eliminating the ten triangular leaves on the perimeter of the circle and eliminating the inverted white arch, leaving a circle with the letters BE in the middle.[17] Similarly, for alternative three (2-C) to be more acceptable, USDA should eliminate the inverted green arch.

For all three alternatives, USDA should allow the food manufacturer to substitute "GE" for "BE" if they wish, as well as have the discretion to incorporate the words "bioengineered" or "genetically engineered" and "may be."[18] Food manufacturers should be allowed to make these minor text modifications to the symbol if they believe the changes provide more information to the consumer in a form that is better understood.

IX. The Definition of a "Very Small Food Manufacturer" Should Be Identical to the FDA's Definition for its Labeling Requirements.

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[17] As stated in the NBFDS, the second alternative symbol "is a filled, green circle with the lower-case letters 'be' in white type, slightly above the center of the circle. Just below the letters is an inverted, white arch, beginning jut below the middle of the 'b' and ending just below the middle of the 'e.' Around the outside of the circle are ten triangular leaves spread equally around the perimeter of the circle."

[18] As stated in the NBFDS, the third alternative symbol "is a circle with a circumference made up of 12 separate, equally-spaced segments.... The interior of the circle is a white background with the lowercase letters "be" in green type, located slightly above the center of the circle. Below the letters is an inverted, green arch, beginning below the center of the 'b' and ending below the center of the 'e'."

Section 66.1 of the proposed rule defines "very small food manufacturer" to mean "any food manufacturer with annual receipts of less than $2,500,000" and exempts them from the disclosure requirement. The Federal Register notice announcing the proposed rule states that the decision to choose $2,500,000 was done in part to give regulatory relief to manufacturers whose products make up a very small percentage of national food sales. However, FDA exempts only persons or businesses with sales of not more than $500,000 from certain food labeling requirements.[19] The NBFDL's disclosure requirement applies to food subject to the labeling requirements under the Federal Food, Drug, and Cosmetic Act (Section 66.3 (b)). Therefore, USDA should adopt the FDA's definition, so consumers receive consistent information on food products that have labeling requirements from USDA and FDA. Applying the same definition will also simplify compliance for food manufacturers.

X. The Text Message Disclosure Label Statement Should Identify that the Information Provided is the Bioengineered Disclosure Statement.

Section 66.108 of the proposed rule provides for the disclosure through a text message in which a consumer will text a number and receive the bioengineered disclosure statement in a return text message. To accomplish this, the food manufacturer is required to include on the product label the statement "Text [number] for more food information."[20] However, this statement is misleading because it suggests a consumer may receive general food information potentially covering nutrition, additives, allergen/gluten information, or even information related to environmental, labor, or animal welfare practices. Instead, the consumer may only receive information about whether the food contains bioengineered foods. The USDA should change the language required on the label to accurately reflect what food information the consumer will receive. Section 66.108 (a) should therefore require the that the label state: "Text [number] for bioengineered food information."

CSPI appreciates the opportunity to provide this comment to the USDA. CSPI would welcome the opportunity to meet with the staff at USDA's Agricultural Marketing Service to discuss the issues addressed in this letter in more detail if that would be helpful.

Sincerely,

Gregory Jaffe
Director, Biotechnology Project
gjaffe@cspinet.org
(202)777-8369

[19] 21 CFR 101.9(j)(1)(i).
[20] Section 66.108 (a).